RADIOLOGICAL PROTECTION OF PATIENTS IN GENERAL DIAGNOSTIC RADIOLOGY (RADIOGRAPHY) (Topical Session 1a)

Swiss nation-wide survey on radiation doses in diagnostic radiology (IAEA-CN-85-82)
A. Aroua, J.F. Valley, J.-P. Vader, B. Burnand

Evaluation of patient skin dose equivalent due to diagnostic procedures with x-rays in Lagos State, Nigeria (IAEA-CN-85-149)
M.A. Aweda

Entrance surface dose measurement for some of the radiological patients in Bangladesh (IAEA-CN-85-193)
Z. Begum

The first trial patient dose survey in diagnostic radiology in Viet Nam (IAEA-CN-85-206)
Dang Thanh Luong, Duong van Vinh, Ha Ngoc Thach, Phan Tuong Van, Nguyen Phuong Dung, Pham Quang Dien, Nguyen Manh Phuc, Nguyen Manh Truong

Radiation doses to patients in diagnostic radiology in Romania; comparison with guidance levels and possibilities of reduction (IAEA-CN-85-5)
C. Milu, A. Dumitrescu, R. Marin, F.S. Popescu

Patient's dose assessment during sinus X-rays radiography at "Hopital du Point G" (IAEA-CN-85-14)
S. Sidibe, B.Y. Sacko, M. Doucoure, B. Traore, I. Traore

Trends and the determination of effective doses for standard x-ray procedures (IAEA-CN-85-29)
H.M. Johnson, C. Neduzak, J. Gallet, J. Sandeman

A project: "Radiological protection in radiology", IAEA–Universidad Central de Venezuela (IAEA-CN-85-33)
A.R. Díaz, G. Salazar, R. Fermín, M. González

Ionizing radiation used in medical diagnostics as a sourse of a radiation exposure of the patient with occupational diseases. Analysis and problems (IAEA-CN-85-42)
D.B. Apostolova, Z.D. Paskalev

Patient's and occupational dose exposure in roentgen examinations (IAEA-CN-85-47)
L. Qafmolla, G. Shehi

Indonesia's experience on IAEA-CRP on radiation protection in diagnostic radiology (IAEA-CN-85-81)
Nasukha

Radiation protection of patients in general diagnostic radiology in Lithuania (IAEA-CN-85-99)
G. Morkunas, J. Ziliukas

Doses to patients from diagnostic radiology in Romania (IAEA-CN-85-105)
O. Iacob, C. Diaconescu

Some experiences from radiation protection of patients undergoing X-ray examinations in Tanzania (IAEA-CN-85-113)
J.E. Ngaile, W.E. Muhogora, A.M. Nyanda

Medical exposure in Russia (IAEA-CN-85-136)
S.A. Kalnitsky, A.B. Bazukin, M.M. Vlasova, S.I. Ivanov, E.V. Ivanov, Y.O. Jakubovskiy-Lipsky, A.A. Gontsov

Radiation dose in radiography and methods for dose reduction (IAEA-CN-85-142)
B. Yue, K. Wei, Q. Zhou, Y. Cheng, C. Hou, L. Ge, X .Qi

Estimation of patient radiation doses during radiologic examinations in the Republic of Haiti (IAEA-CN-85-151)
G. Massillon J., C. Borrás

Medical radiation exposure and usage for diagnostic radiology in Malaysia (IAEA-CN-85-209)
Kwan-Hoong Ng, Premavathy Rassiah, Hwee-Beng Wang, Ahmad Shariff Hambali, Pirunthavany Muthuvelu, B.J.J. Abdullah, S. Sivalingam

Patient dose surveys for radiological examinations in Dutch hospitals between 1993 and 2000 (IAEA-CN-85-217)
F.M. Spoelstra, J. Geleijns, J.J. Broerse, W.M. Teeuwisse, D. Zweers

Patient doses and examination frequency for diagnostic radiology in Iceland 1993–1998 (IAEA-CN-85-263)
G. Einarsson, S.M. Magnusson

Can patient positioning using an ultrashort fluoroscopic pulse be justified? (IAEA-CN-85-91)
T. Deprez, L. Schrijvers, H. Pauwels, H. Bosmans, G. Marchal

Development of an international code of practice for dosimetry in x-ray diagnostic radiology (IAEA-CN-85-269)
F. Pernicka, G.A. Carlsson, D.R. Dance, L.A. DeWerd, H.M. Kramer, K.-H. Ng

Quality control and patient doses for x-ray examinations in some hospitals in Thailand (IAEA-CN-85-288)
P. Plainoi, W. Diswath, N. Manatrakul

Quality control of diagnostic x-ray units (IAEA-CN-85-205)
O.T. Marinkovic, S. Milacic, D. Jovicic, I. Tanaskovic

Digital technology influence on patient dose in radiological examination of the upper digestive apparatus (IAEA-CN-85-107)
E. Núñez, X. Pifarré, J. Ruiz, C. Escalada, M.C. Paredes

Radiation protection and quality assurance in dental radiology: I. Intraoral radiography (IAEA-CN-85-257)
Y. Martinez-Beneyto, M. Alcaraz, S. Jódar-Pórlan, A.M. Saura-Iniesta, E. Velasco-Hidalgo

Radiation protection and quality assurance in dental radiology: II. Panoramic radiology (IAEA-CN-85-258)
S. Jódar-Pórlan, M. Alcaraz, Y. Martinez-Beneyto, A.M. Saura-Iniesta, E. Velasco-Hidalgo

Study on patient dose in diagnostic radiolgy in Japan: Investigation of entrance surface dose of patient using direct measurement by TLD (IAEA-CN-85-301)
S. Iwanami, T. Ishiguchi, T. Ishigaki, S. Koga

RADIOLOGICAL PROTECTION OF PATIENTS IN GENERAL DIAGNOSTIC RADIOLOGY (FLUOROSCOPY) (Topical Session 1b)

Fluoroscopy without image intensifier (IAEA-CN-85-152)
L.V. Canevaro, G. Drexler

Evaluation of the dosimetric performance characteristic of fluoroscopy system used in medicine (IAEA-CN-85-157)
Qi Xuesong, Wei Kedao, Cheng Yuxi, Zhou Qifu, Ge Lijuan, Hou Changsong

Patient dose measurements in fluoroscopic examinations, aiming to the establishment of reference levels in Brazil (IAEA-CN-85-93)
L.V. Canevaro, G. Drexler

Patient and staff dose during hysterosalpingography (IAEA-CN-85-73)
N. Buls, M. Osteaux

Patient dosimetry in histerosalpingography (IAEA-CN-85-94)
H.J. Khoury, A. Maia, M. Oliveira, R. Kramer, G. Drexler

Dosimetric assessment of swallowing examinations with videofluoroscopy (IAEA-CN-85-67)
M.M.B. Costa, L.V. Canevaro, A.C.P. Azevedo

RADIOLOGICAL PROTECTION ISSUES IN SPECIFIC USES OF DIAGNOSTIC RADIOLOGY, SUCH AS MAMMOGRAPHY AND COMPUTED TOMOGRAPHY (WITH SPECIAL CONSIDERATION OF THE IMPACT OF DIGITAL TECHNIQUES) (Topical Session 2)

Evaluation of diagnostic radiology services in five Latin American countries: Results for mammography (IAEA-CN-85-103)
M.E. Brandan, C.E.M. Caspani, R. de la Mora, A.A. Miranda, M.-C. Plazas, C. Borrás

Study about diagnostic quality in a public-center of mammography of Santa Fe – Argentina (IAEA-CN-85-144)
R. Lescano, J. Kiguen, L. Gaitán, C. Caspani

Benefit and risk in breast screening (IAEA-CN-85-166)
J. Law, K. Faulkner, F. Neilson

Quality assurance programme in mammography of the Sociedad Española de Diagnósticos por Imagen de la Mama (SEDIM) (IAEA-CN-85-235)
B. Fernández, C. González, I. Hernando, M. Iríbar, J. A. López, R Salvador, A. Vega, I. Vizcaíno

Image quality and patient dose optimization in mammography in Hungary (IAEA-CN-85-108)
S. Pellet, A. Motoc, F. Giczi, E. Vano, C. Maccia, M. Gödény, B. Kovács, G. Forray

A review of the role of radiation metrology in the safety of diagnostic radiology patients (IAEA-CN-85-305)
J.G.P. Peixoto, C.E. de Almeida

Image quality and dose in mammographic images obtained in Mexico City hospitals (IAEA-CN-85-210)
C. Ruiz-Trejo, M.-E. Brandan, M. Verdejo, A. Flores, M. Guevara, J. Martín, L. Madero-Preciado

A comparison of two different processing chemicals for mammography: Repercussion on dose to patients (IAEA-CN-85-171)
F. Sendra-Portero, E. Ristori-Bogajo, P. Buch-Tomé, M. Martínez-Morillo, E. Nava-Baro

Study of radiological risk in breast cancer screening programme at Comunidad Valenciana (IAEA-CN-85-234)
J.I. Villaescosa, A. León, G. Verdú, M.D. Cuevas, M.D. Salas

Mammography quality assurance in Morocco (IAEA-CN-85-128)
F. Zaoui, K. Talsmat, K. Lalaoui

Organ doses in CT of thorax: Sequential slices versus helical slices (IAEA-CN-85-201)
C. Bodineau Gil, J. Macías Jaén, I. Tort Ausina, R. Ruiz-Cruces, P. Galán Montenegro, A. Díez de los Ríos

How will the introduction of multi-slice CT affect patient doses? (IAEA-CN-85-63)
W. Huda, P.J. Mergo

Dual-slice spiral scanner: doses delivered during thoracic and abdominal examinations (IAEA-CN-85-174)
G. Marinello, M.C. Besse, N. Vasile, M.C. Anglade

Patient doses for computed tomography in Hungary (IAEA-CN-85-39)
S. Pellet, L. Ballay, A. Motoc, D. Heissler, A. Temesi, F. Giczi

Radiation dose and quality control in fluoroscopy and computed tomography scanning (IAEA-CN-85-141)
K. Wei, B. Yue, Q. Zhou, Y. Cheng, C. Hou, L. Ge, X. Qi

Patient doses from computed tomography in northeast region of Ukraine (IAEA-CN-85-116)
N. Pylypenko, V. Kornyeyeva, H. Gur

Use of the EC quality criteria as a common method of inspecting CT laboratories — A pilot project by the Nordic radiation protection authorities (IAEA-CN-85-175)
C.G. Torp, H.M. Olerud, G. Einarsson, P. Grøn, W. Leitz, A. Servomaa

Establishment of computed tomography reference dose levels in Onassis Cardiac Surgery Center (IAEA-CN-85-203)
V. Tsapaki, E. Kyrozi, T. Syrigou, I. Mastorakou, S. Kottou

Radiation protection of patients during CT fluoroscopy (IAEA-CN-85-10)
J.E. Aldrich, B.B. Forster

RADIOLOGICAL PROTECTION IN INTERVENTIONAL RADIOLOGY, INCLUDING FLUOROSCOPY NOT CARRIED OUT BY RADIOLOGISTS (Topical Session 3)

Patient dose in interventional radiology (IAEA-CN-85-85-190)
M. Fernández Bordes, R. Berenguer, P. Gómez, M.J. Béjar, S. González

Patient doses in interventional cardiology (IAEA-CN-85-200)
F. Carrera, C. Ojeda, A. Sánchez, I. Tort, R. Ruiz-Cruces, J. Francisco Díaz

Radiation risk evaluation and reference doses in interventional radiology (IAEA-CN-85-76)
K. Faulkner, E. Vano, R. Padovani, J. Zoetelief

An assessment of methods for monitoring entrance surface dose in fluoroscopically guided interventional procedures (IAEA-CN-85-61)
J.C. Waite, M. Fitzgerald

Radiation dose during angiographic procedures (IAEA-CN-85-85-69)
Ch. Lavoie, P. Rasuli

Radiological protection in interventional cardiology in Chile (IAEA-CN-85-80)
A. Ramírez, E. Vañó, F.A. Leyton, C. Oyarzún, J. Gamarra, E. Farias, A.M. Silva, P. Ortiz

Absorbed doses to patients from angioradiology (IAEA-CN-85-111)
R. Rodríguez-Romero, F. Díaz-Romero, J. Hernández-Armas

Investigation of radiation skin dose in interventional cardiology (IAEA-CN-85-71)
C.M. Webster, D. Hayes, J. Horrocks

Patient doses in digital cardiac imaging (IAEA-CN-85-64)
W. Huda, K. Phadke, K. M. Ogden, M.L. Roskopf

Radiation doses to patients in haemodynamic procedures (IAEA-CN-85-110)
B. Cañadillas-Perdomo, C. Pérez-Martín, A. Catalán-Acosta, D. de Armas-Trujillo, J. Hernández-Armas

Comparison between thermoluminiscence dosimetry and transmission ionization chamber measurements (IAEA-CN-85-177)
I. Hernando, R. Torres

Radiofrequency catheter ablation: relationship between fluoroscopic time and skin doses according to diagnoses. Basis to establish a quality assurance programme (IAEA-CN-85-168)
E. Cotelo, J. Pouso, W. Reyes

Estimation of skin dose in interventional neuro and cardiac procedures (IAEA-CN-85-62)
P.J. Marsden, Y. Washington, J. Diskin

Patient radiation doses from neuroradiology procedures (IAEA-CN-85-112)
M.J. García-Román, E. Prada-Martínez, J. Abreu-Luis, J. Hernández-Armas

Radiation doses in interventional neuroradiology (IAEA-CN-85-68)
C. Theodorakou, P. Butler, J.A. Horrocks

Radiation injury of the skin following diagnostic and interventional fluoroscopic procedures (IAEA-CN-85-38)
T.R. Koenig, L.K. Wagner, F.A. Mettler

Iodine visibility in coronary angiography using copper filtration (IAEA-CN-85-78)
A.T. Rogers, M.E. Holloway

The use of constancy checks to optimise patient dose in interventional radiology systems (IAEA-CN-85-196)
E. Vaño, J.M. Fernandez, L. Lopez, J.I. Ten, L. Gonzalez, E. Guibelalde

Organ doses in interventional radiology procedures: Evaluation of software (IAEA-CN-85-226)
I. Tort, R. Ruiz-Cruces, M. Pérez-Martínez, F. Carrera, C. Ojeda, A. Díez de los Ríos

Occupational hand doses in interventional radiology (IAEA-CN-85-253)
V. Spasic Jokic, B. Djurovic, S. Lukac

Doses to patients and staff from endovascular treatment of abdominal aortic aneurysms – preliminary results (IAEA-CN-85-129)
E.G. Bjørklund, A. Widmark, T. Gjølberg, D. Bay, J.J. Jørgensen , L.E. Staxrud

Optimisation of patient and staff exposure in interventional cardiology (IAEA-CN-85-147)
R. Padovani, M.R. Malisan, G. Bernardi, E. Vaño, V. Neofotistou

Occupational exposures from selected interventional radiological procedures (IAEA-CN-85-51)
J. Janeczek, A. Beal, D. James

A study on the annual equivalent doses received by cardiologists in a UK hospital (IAEA-CN-85-72)
R.Y.L. Fong, E. Ryan, S. Alonso-Arrizabalaga

Staff dosimetry and risk assessment during digestive and angiographic examinations (IAEA-CN-85-49)
J. Pages, M. Osteaux

RADIOLOGICAL PROTECTION OF PATIENTS IN NUCLEAR MEDICINE (Topical Session 4)

Doses of ionising radiation received by patients diagnosed at the Nuclear Medicine Department in Warsaw from 1985 to 1999 (IAEA-CN-85-86)
J.Chaæ, M. Marciniak, E. Dziuk, M.K. Janiak

Doses from nuclear medicine examinations: A 25-year follow-up study (IAEA-CN-85-114)
K.J.A. Kairemo, H. Korpela

General comments on radiological patient protection in nuclear medicine (IAEA-CN-85-183)
M. Téllez de Cepeda, R. Plaza, E. Corredoira, L.M. Martín Curto

Patient dose assessment in different diagnostic procedures in nuclear medicine (IAEA-CN-85-192)
E. de Sena, M.J. Béjar, R. Ruano, R. Berenguer, P. Tamayo

Radiation protection of thyroid cancer patients receiving I-131 therapy: Some considerations (IAEA-CN-85-202)
S. Kottou, D. Papadimitriou, M. Molfetas, A. Samartzis, P. Mavrokephalos, A. Perris, C.C. Alevizaki

Current trends on internal dosimetry for patient protection in nuclear medicine (IAEA-CN-85-219)
A.M. Rojo, P.A. Gisone, J.J. Kunst

Internal radiation dosimetry, pharmacokinetics and biodistribution of the ^{99m}Tc labeled IOR egf/r3 monoclonal antibody (IAEA-CN-85-254)
L.A. Torres, A. Perera, M. Ramos, A. Hernández, N. Iznaga, M.E. Solano, I. Alvarez, J.L. Rodríguez

A protocol to determinate the situation of nuclear medicine in Venezuela, 1999–2000 (IAEA-CN-85-267)
L. Carrizales, G. Leandro

Parameter estimation and compartmental modelling for individualization of therapeutic dosage of radiopharmaceuticals (IAEA-CN-85-164)
A. Giussani, C. Cantone

DEVELOPING AND USING DOSE GUIDANCE (REFERENCE) LEVELS IN RADIOLOGY AND NUCLEAR MEDICINE EXAMINATIONS (Topical Session 5)

Practical implementation of the medical exposure directive (97/43) in Luxembourg with special reference to diagnostic reference levels (IAEA-CN-85-53)
A. Schreiner-Karoussou, C. Back, N. Harpes, F. Shannoun

A proposal to prove compliance of ESD with EU-guidelines (IAEA-CN-85-189)
M. Tschurlovits

Diagnostic radiography dose and guidance levels (IAEA-CN-85-176)
M. Cuadros, A. Augusto

Results of the study of entrance surface dose from conventional examinations in diagnostic radiology (IAEA-CN-85-281)
A. Martínez, L. Jova, R. de la Mora, C. Guevara, I. Fleitas, J. Carrazana, E. Díaz

A trial to establish diagnostic reference levels for radiological examinations in Greece (IAEA-CN-85-95)
E. Papageorgiou, P. Dimitriou, E. Vardalaki, C.J. Hourdakis, L. Vlahos

Patient exposures from diagnostic radiological procedures in India (IAEA-CN-85-21)
J.B. Sasane, S.G. Sawant, V.K. Shirva, P.K. Dash Sharma, K. Chhokra, V. Jayalakshmi, K.N. Govindarajan, R.N. Kulkarni, K.S. Parthasarathy , A.S. Pradhan, B.C. Bhatt

Need for harmonisation in the establishment and use of reference dose levels in radiology (IAEA-CN-85-15)
J. Zoetelief

Patient dose surveys and the use of local and national diagnostic reference levels (IAEA-CN-85-248)
M.L. Ramsdale, D. Peet, P. Hollaway, A. Rust

An approach to local diagnostic reference levels (DRL's) in the context of national and international DRL's (IAEA-CN-85-77)
A.T. Rogers

Dimond: A European approach to establish and use reference levels in fluoroscopy guided procedures (IAEA-CN-85-194)
E. Vano, K. Faulkner, R. Padovani, J. Zoetelief, M. Toivonen, V. Neofotistou

Reference dosimetry for CT in the UK (IAEA-CN-85-57)
P.C. Shrimpton, B.F. Wall

The establishment and use of dose reference levels in general paediatric radiology (IAEA-CN-85-59)
P.J. Marsden, J. Hardwick, C. Mencik, C. McLaren, C. Young, P. Mashford

Introduction of guidance dose levels in paediatrics CT (IAEA-CN-85-139)
F.R. Verdun, M. Bernasconi, P. Schnyder, J.F. Valley, F. Gudinchet

Implementation of diagnostic reference levels for X-ray examinations in the UK (IAEA-CN-85-55)
B.F. Wall

Diagnostic reference activities for nuclear medicine in Australia and New Zealand (IAEA-CN-85-259)
J.E. Towson, R.C. Smart

Nuclear medicine and its radiological protection in China (IAEA-CN-85-28)
J. Wu

Preliminary results of the analysis of the administered activities in diagnostic studies of nuclear medicine (IAEA-CN-85-280)
G. López Bejerano, L.J. Sed

Administered activity and estimated radiation doses from nuclear medicine diagnostic procedures to the Israeli population (IAEA-CN-85-65)
J. Weininger, A.B. Shlomo, J.K.Y. Shamai, T. Schlesinger

Development of diagnostic reference levels in paediatric radiology (IAEA-CN-85-56)
D. Hart, B.F. Wall

RADIOLOGICAL PROTECTION OF THE EMBRYO AND FOETUS IN PREGNANT PATIENTS (Topical Session 6)

Ten years investigation on radiological exposures to the embryo and fetus in pregnant women of Iran (IAEA-CN-85-66)
A. Arbabi

Diagnostic radiation of potentially reproductive females (IAEA-CN-85-01)
M.E. Abd El-Bagi, M.S. Al-Mutairi, M.A. Al-Thagafi, N.M. Al-Masri, O. Al-Sasi

Programme for reducing the risk factors due to prenatal exposure (IAEA-CN-85-182)
L. Arranz, N. Ferrer, J.M. Sastre

Unjustified prenatal radiation exposure in medical applications (IAEA-CN-85-121)
J. Cárdenas Herrera, G. López Bejerano, A.I. Lamadrid, O. García Lima, E. Díaz Bernal, V. Freixas, R. Sánchez

Radiation during pregnancy (IAEA-CN-85-75)
K. Faulkner, J.F. Malone, R.H. Corbett, P. Craven, E.K. Osei

Experimental determination of fetal doses received during conventional X rays explorations of Troncus. Influence of the lead apron (IAEA-CN-85-236)
X. Pifarré, L. Brualla, J. Ruiz, C. Escalada, D. Planes, M.C. Paredes

The software program *Peridose* to calculate the fetal dose or dose to other critical structures outside the target area in radiation therapy (IAEA-CN-85-9)
P.H. van der Giessen

Dose to the uterus from radiotherapy procedures for breast carcinoma (IAEA-CN-85-232)
C. Martín Rincón, I. Jerez Sainz, I. Modolell Farré, M.L. España López, P. López Franco

Patient and fetal dose in diagnostic x-rays and radiotherapy in Bangkok, Thailand (IAEA-CN-85-26)
J. Pataramontree, S. Wangsuphachar, J. Apaiphonlacharn, P. Chaichan, S. Sompradit, K. Suteerakul, W. Thamwerawong

RADIOLOGICAL PROTECTION OF PAEDIATRIC PATIENTS (Topical Session 7)

The development of standard operating protocols for paediatric radiology (IAEA-CN-85-58)
P.J. Marsden, C. Mencik, C. McLaren, C. Young, S. Scadden, P. Mashford, K. McHugh, M. Beckett, M Calvert, J. Hardwick

Radiation doses to neonates and issues of radiation protection in a special care baby unit (IAEA-CN-85-52)
C.I. Armpilia, I.A.J. Fife, P.L. Croasdale

Evaluation of the radiation dose in a paediatric x-ray department (IAEA-CN-85-41)
P.A. Kaplanis , S. Christofides, G. Christodoulides, K. Aristidou

Radiation exposure of children during radiodiagnostic examinations of chest in Slovakia (IAEA-CN-85-207)
M. Horváthová, D. Nikodemová

Radiation detriment ascribable to infants and children undergoing micturating cystourethrograms — A review of studies in Spain, Britain, New Zealand and Venezuela (IAEA-CN-85-172)
D.L. Evans, M.C. Canete

RADIOLOGICAL PROTECTION OF PATIENTS IN RADIOTHERAPY: EXTERNAL BEAM
(Topical Session 8a)

Radiological protection of the radiotherapy patient? (IAEA-CN-85-153)
M.P.R. Waligórski, J. Lesiak

High dose and low dose radiation exposure in the induction of breast cancer (IAEA-CN-85-17)
E. Fernandez-Vicioso, R. Ruiz-Cruces, J.M. Pastor Vega

A computer tool for daily application of the linear quadratic model (IAEA-CN-85-181)
J. Macías Jaén, P. Galán Montenegro, C. Bodineau Gil, A. Wals Zurita, A. M. Serradilla Gil

Tolerance of the different structures of the eye to therapeutic ionizing radiation (IAEA-CN-85-197)
E. Fernandez-Vicioso, R. Ruiz-Cruces, K. Faulkner

Influence of dose per fraction on 7 days per week fractionation in radiotherapy (IAEA-CN-85-18)
M. Vilches, D. Guirado

Palliative radiation therapy for overloading radiotherapy centre, especially for developing country (IAEA-CN-85-46)
M. Myo, Susworo, T. San

Dose distribution over the radiation field and organs of the body during radiotherapy procedures (IAEA-CN-85-36)
S. Roy, A.S.M. Ambia, S. Akhter, H. Banu, M. Begum

Peripheral dose in photon beams from a linear accelerator with a multileaf collimator (IAEA-CN-85-97)
R. Lope Lope, F.Lozano Flores, J. Gracia Sorrosal, J.A. Font Gómez, A. Hernández Vitoria

Patient dose from photoneutrons in a 18 MV linac (IAEA-CN-85-251)
R. Barquero, R. Méndez, M.P. Iñiguez

Shielding for radiation scattered dose distribution to the outside fields in patients treated with high energy radiotherapy beams (IAEA-CN-85-70)
Sung Sil Chu

Neutron dose to patients treated with high-energy medical accelerators (IAEA-CN-85-8)
P.H. McGinley

Radiological protection considerations during the treatment of glioblastoma patients by boron neutron capture therapy at the high flux reactor in Petten, the Netherlands (IAEA-CN-85-298)
R.L. Moss, J.Rassow, E. Finke, F. Stecher-Rasmussen, W. Sauerwein

Quality control in radiotherapy treatment: Radiation induced myelopathy (IAEA-CN-85-255)
E. Fernández-Vicioso, R. Ruiz-Cruces

Quality assurance in radiotherapy (IAEA-CN-85-223)
S. Groth, A. Meghzifene, H. Tatsuzaki, V. Levin, J. Izewska

The estro-equal results for photon and electron beams checks in European radiotherapy beams (IAEA-CN-85-48)
H. Ferreira, A. Dutreix, A. Bridier, D. Marre, J. Chavaudra, H. Svensson

Standard operating procedures for quality audits of ^{60}Co external beam radiotherapy facilities (IAEA-CN-85-120)
E.F. Larrinaga Cortina, L. Domínguez Hung, R. Campa Menéndez

Preliminary results of a national quality audit programme in radiotherapy services in Cuba (IAEA-CN-85-247)
L. Domínguez Hung, E.F. Larrinaga Cortina, R. Campa Menéndez, J.L. Morales López, A.F. García Yip

Error prevention in radiotherapy treatments using a record and verify system (IAEA-CN-85-170)
S. Navarrete Campos, A. Hernández Vitoria, M. Canellas Anoz, E. Millán Cebrián, A. García Romero

Manual cross check of computed dose times for motorised wedged fields (IAEA-CN-85-79)
J. Porte

Quality assurance of the treatments performed with a linear accelerator by means of in vivo dosimetry (IAEA-CN-85-239)
N. Jornet, M. Ribas, T. Eudaldo, P. Carrasco

IAEA Radiation Events Database (RADEV) (IAEA-CN-85-268)
J. Wheatley, P. Ortiz-Lopez

Methodology for the application of probabilistic safety assessment techniques (PSA) to the cobalt-therapy units in Cuba (IAEA-CN-85-165)
J.J. Vilaragut Llanes, R. Ferro Fernández, M. Troncoso Fleitas, B. Lozano Lima, A. De la Fuente Puch, Y. Pérez Reyes, C. Duménigo González

Normal tissue damage in radiotherapy development of a clinical audit tool (IAEA-CN-85-265)
A. Barrett

RADIOLOGICAL PROTECTION OF PATIENTS IN RADIOTHERAPY: BRACHYTHERAPY (Topical Session 8b)

Accurate assessment of the distortions produced by the transit dose in HDR brachytherapy (IAEA-CN-85-6)
E.K. Nani, A.W.K. Kyere, K. Tetteh

Methodology for comprehensive patient, worker and public radiation protection considerations while introducing new medical procedures (IAEA-CN-85-22)
E. Neeman, M. Keren

Radiation safety program in a high dose rate brachytherapy facility (IAEA-CN-85-12)
L.V. Rodriguez, R.C. Solis, T.M. Hermoso

Radiation protection of patients in epiescleral brachytherapy (IAEA-CN-85-180)
J.M. de Frutos, G. Sánchez, J.R. Sendón, A. del Castillo, I. Hernando

Estimation of the transit dose component in high dose rate brachytherapy (IAEA-CN-85-173)
A. García Romero, E. Millán Cebrián, F.J. Lozano Flores, R. Lope Lope, M. Canellas Anoz

Patient dosimetry in intravascular radiation therapy (IAEA-CN-85-85)
S. Van de Putte, Y Taeymans, H. Thierens

Design and implementation of an intravascular brachytherapy installation in cardiology (IAEA-CN-85-195)
C. Prieto, E. Vano, M. Sabate, J.M. Fernandez, Y.C. Galvan

Radiation risk to patient from intracoronary brachytherapy (IAEA-CN-85-127)
A Hefner, C Kirisits, D. Georg, R Pötter

RADIOLOGICAL PROTECTION OF PATIENTS IN BIOMEDICAL RESEARCH (Topical Session 9)

No contributed papers have been received for this session

INFLUENCE OF STANDARDIZATION IN THE DESIGN AND DEVELOPMENT OF MEDICAL RADIOLOGICAL EQUIPMENT ON THE RADIOLOGICAL PROTECTION OF PATIENTS (Topical Session 10)

Initial evaluation of a full breast digital system (IAEA-CN-85-233)
E. Vañó, M. Chevalier, P. Morán, J.M. Fernández, T. Cepeda, A. Fabra, C.S. Alvarez Pedrosa

Experimental determination of blurring in x-ray fluoroscopy last image hold due to patient movement and its repercussion to patient doses (IAEA-CN-85-167)
E. Guibelalde, E.Vañó, J.M. Fernández, L. González, J. Alberdi, A. Molinero

The Danube hospital project for automated transcription of X ray dose data from radiography, fluoroscopy and computed tomography (CT) into the electronic patient record (IAEA-CN-85-246)
G. Pärtan, R. Mayrhofer, H. Mosser, A. Maltsidis, Th. Dechant, W. Honsal, W. Hruby

Dimond II: Measures for optimising radiological information content and dose in digital imaging (IAEA-CN-85-261)
A. Dowling, J. Malone, D. Marsh

Implementation of "early alert system" area detector at patient from entrance in afterloading brachytherapy (IAEA-CN-85-237)
R. Videla Valdebenito

EDUCATION, TRAINING AND CONTINUOUS PROFESSIONAL DEVELOPMENT IN THE RADIOLOGICAL PROTECTION OF PATIENTS (Topical Session 11)

The new system of education and training of medical staff in radiation protection in Albania (IAEA-CN-85-92)
B. Grillo, K. Preza, V. Titka, G. Shehi

Education and training of the radiation protection in the Spanish schools of medicine (IAEA-CN-85-198)
R. Ruiz-Cruces, M.T. Delgado Macias, J.H. Armas, E. Vañó Carruana, A. Diez de los Ríos, M. Martínez Morillo

The changing role of the radiographer under IR(ME)R 2000 (IAEA-CN-85-50)
S. Barlow

The education and training of professionals. The perspective of the Spanish Society of Medical Physics (SEFM) (IAEA-CN-85-214)
T. Eudaldo, E. Millán, M.C. Paredes, E. Vañó, F. Peinado, C. Nuñez de Villavicencio, J.C. Mateos, J.J. Peña

Medical Radiation Physics Training Emerald (IAEA-CN-85-146)
S. Tabakov, C. Roberts, I.L. Lamm, F. Milano, C. Lewis, D. Smith, A. Litchev, B.A. Jonsson, M. Ljungberg, S.E. Strand, L. Jonsson, L. Riccardi, A. Benini, G. da Silva, N. Teixeira, A. Pascoal, A. Noel, P. Smith, L. Musilek, N. Sheahan

Education, training and continuing professional development for the medical physicist — The EFOMP view in relation to EC Council directives (IAEA-CN-85-178)
I.L. Lamm

An interactive Web-based radiation protection course in fluoroscopy (IAEA-CN-85-11)
J. Aldrich

Patient dose optimisation in cardiology during fluoroscopy examinations (IAEA-CN-85-138)
F.R. Verdun, S. Wicky, M. Narbel, P. Schnyder, J.F. Valley

CD-ROM training course in quality assurance in diagnostic imaging (IAEA-CN-85-156)
H.J. Khoury, P. Machado, G. Drexler

The reduction in DAP values possible with operator education and additional filtration in a cardiac catheterisation laboratory (IAEA-CN-85-98)
H.M. Warren-Forward, L. Duggan

Education for radiological protection in radiotherapy. ESTRO recommendations for EU Euratom guidelines (IAEA-CN-85-266)
A. McKenzie, A. Barrett

How changes in a radiologist's technique can reduce patient dose in barium enema studies (IAEA-CN-85-34)
R.H. Corbett

Using the BERT concept to promote public understanding of radiation (IAEA-CN-85-2)
Kwan-Hoong Ng, J.R. Cameron

Communicating risks and benefits of medical exposures to patients (IAEA-CN-85-54)
B.F. Wall

TOPICS FOR RESEARCH AND DEVELOPMENT IN THE RADIOLOGICAL PROTECTION OF PATIENTS (Topical Session 12)

Drug interaction with radiopharmaceuticals and the importance for the radiation dose to the patient (IAEA-CN-85-130)
D.M.M. Mattos, M.L. Gomes, R.S. Freitas, V.N. Cardoso, M. Bernardo-Filho

Protective effects of several plant polyphenols against chromosomal damage induced in vivo by X-rays. Comparative study versus diosmin and rutin (IAEA-CN-85-154)
M. Alcaraz, B. Rosa, J. Castillo, O. Benavente-García, J. Lorente, V. Vicente, M. Canteras

Cytokinesis block micronucleus in human lymphocytes: Effect of low dose radiation in vascular radiology (IAEA-CN-85-256)
M. Alcaraz, B. Rosa, J.L. Navarro, M.J. Dato, C. Acevedo, M. Canteras

IMPLEMENTATION OF REGULATIONS ON THE RADIOLOGICAL PROTECTION OF PATIENTS (Topical Session 13)

Radiation protection in hospitals of Ecuatorial Guinea (IAEA-CN-85-25)
P. Rabat Macambo

Strategic management of radiation protection programme in the Ministry of Health Malaysia — An approach based on MS ISO 9000 quality management system (IAEA-CN-85-124)
H.B. Wang

New perspective for radiation protection in diagnostic procedure in Paraguay (IAEA-CN-85-90)
R.A. Sosky, M. Gamarra

Radiation protection infrastructure in the Republic of Croatia (IAEA-CN-85-44)
S. Grgic

Medical management of radiation safety and radiological protection of patients in Armenia (IAEA-CN-85-40)
N.M. Hovhannisyan

Contribution of the ARCAL XX/IAEA project to improvement of radiation safety in medical practices (IAEA-CN-85-148)
E. Medina Gironzini

Implementation of ICRP-60, BBS-115 and the patient directives in radiation safety regulations of Taek (IAEA-CN-85-83)
H.B. Okyar, M. Vural

Protection of patients in the first radiotherapy standard in Peru (IAEA-CN-85-250)
R. Ramírez Quijada

The justification of a medical exposure — Who does it? (IAEA-CN-85-60)
P.J. Marsden, J. Hardwick, K. McHugh

The patient's radiological protection in medical practices: Legal support in the Cuban legislation (IAEA-CN-85-306)
I.A. González, M. Durán Delgado

Radiation protection of patients in diagnostic radiology in Estonia (IAEA-CN-85-74)
I. Filippova

Radiological procedures: Quality criteria and dose optimisation: French status (IAEA-CN-85-211)
Ph. Grenier, M. Bourguignon, E. Marshall-Depommier, H. Beauvais-March, M. Valero, J.F. Lacronique, G. Frijal

Ethical and legal aspects of medical exposure to ionizing radiation in the Netherlands in the year 2000 (IAEA-CN-85-218)
J. Rijlaarsdam

Consequences and problems which arose from the application of the Spanish laws about quality criteria in radiodiagnostic, nuclear medicine and radiotherapy from the point of view of radiophysicists (IAEA-CN-85-117)
A. Hernández Vitoria, B. Fernández González, J. Martí Climent, J. Pérez Calatayud

Evaluation of the radiological protection in several departments of nuclear medicine (IAEA-CN-85-279)
G. López Bejerano, L. Jova Sed

Radiotherapy practice in an unregulated environment: Call for joint action (IAEA-CN-85-283)
Sh. Elegba

Quality systems for radiotherapy: Impact by a central authority for improved accuracy, safety and accident prevention (IAEA-CN-85-115)
H. Järvinen, P. Sipilä, R. Parkkinen, A. Kosunen, I. Jokelainen

Guidelines for the design of the working rules of the guarantee and quality control in radiotherapy commission (IAEA-CN-85-272)
J. Pardo, M.A. Galmés, J. Font, J. Caro, J. Serra, F. Mata, S. Bertán, A. Biete, J.A. Carceller, R. Escó, A. Palacios, C. Veiras, M.G. Vazquez

Radiological protection of patients in general diagnostic radiology (IAEA-CN-85-89)
A.W. Karigi

Radiotherapy procedures quality control program: Guidelines established by the Spanish Society of Radiotherapy and Oncology (IAEA-CN-85-273)
A. Palacios, J. Pardo, A. Valls, I. Petschen, A. Castell, A. Villar, B.A. Pedro Olivé, V. Muñoz, J. Fernández, R. Rodríguez, C. Otón

Final report from the Spanish Society of Radiotherapy and Oncology Infrastructures Commission about department standards recommendable in radiation oncology (IAEA-CN-85-274)
R. Escó, J. Pardo, A. Palacios, A. Biete, J. Fernández, A. Valls, L. Herrazquin, P. Román, R. Magallón

Health regulations about radiation oncology in Spain: The legislative dilemma between radiation protection and treatment of cancer (IAEA-CN-85-275)
R. Escó, A. Biete, J. Pardo, J.A. Carceller, C. Veiras, A. Palacios, M.G. Vazquez

Radiation protection problems in the practice of radiotherapy in Nigeria (IAEA-CN-85-284)
K.K. Ketiku, O.T. Oladeji

Radiological protection in medicine: Current problems in Indonesia (IAEA-CN-85-45)
E. Hiswara

Topical Session 1a

RADIOLOGICAL PROTECTION OF PATIENTS IN GENERAL DIAGNOSTIC RADIOLOGY (RADIOGRAPHY)

SWISS NATION-WIDE SURVEY ON RADIATION DOSES IN DIAGNOSTIC RADIOLOGY

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Abstract

A nation-wide survey on radiation doses in diagnostic radiology was conducted in Switzerland in 1998-1999. More than 250 types of examinations were considered, covering conventional and interventional radiology, angiography, CT, mammography, osteodensitometry, conventional tomography and dental radiology. This survey aimed at establishing the collective radiological impact of radiodiagnostics on the Swiss population. The methodology of the survey is described. The examnination frequencies and integral dosimetric results associated with diagnostic radiology in Switzerland are presented.

1. Introduction

At the international level there is a great interest for establishing the radiation doses due to medical exposure. This is due to the fact that medical exposure is the highest source of artificial irradiation. During the last two decades many national surveys of the frequencies and doses associated with medical examinations have been reported in the litterature. A comparative work regarding these surveys is published regularly by UNSCEAR (1).

Switzerland has a long tradition in surveying the medical exposure that started in the late 50s (2-5); the present work being the continuation of the previous studies. The aim of this work is to determine the collective radiological impact of radiodiagnostics on the Swiss population, to gather enough data in order to issue recommendations aiming at patient dose reduction and to set a comprehensive framework for future studies.

2. Material and methods

The methodology of the study is outlined in the diagram shown in figure 1. The frequential and dosimetric aspects were handled separately.

Concerning the dosimetric issue no measurements were performed. Rather, a standard technique was established for each type of examination (technical parameters, projections considered, number of films or CT slices, duration of fluoroscopy, etc.). After the validation of the technique, the dose indices (ESD, DAP) were modelled based on the conditions of the examination. The organ and tissue equivalent doses were then established using appropriate conversion factors. To this purpose, the programs ODS60 (6) and CTDOSE (7) were used for radiography/fluoroscopy and CT examinations respectively.

The second part of the study consisted in surveying the frequency of examinations in all the establishments who prescribe and perform radiological examinations in Switzerland: hospitals, practitioners and other institutions (school, penitentiary and military medicine, etc.). An information on the patient's age and gender and on the indication of the examination (affection of the patient, aim of the examination, sevrity of the case) was collected, whenever possible.

A convolution of the frequency and the dosimetric results was then performed, taking into account for each examination the patient's age and gender profiles, the film-screen sensitivity profiles and the corpulence profiles. For the age correction different models were used.

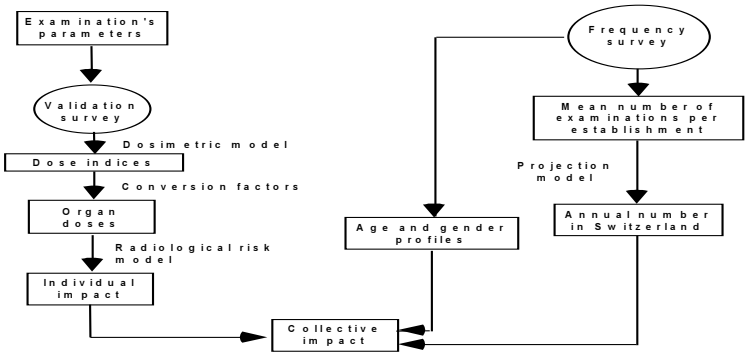

Figure 1 Methodology of the study

3. Results

The survey revealed that the total annual number of examinations (all types together) in Switzerland is about 9.5 millions (1.34 per inhabitant) and that the collective dose is 7100 Sv, corresponding to a mean annual effective dose of 1.0 mSv per inhabitant.

Table 1 presents the distribution of the annual number of examinations and the collective dose with the different categories of examinations. In terms of the number of examinations, the radiography and dental radiology have the highest contributions to the total number (47% and 42% respectively). The other modalities represent together 11% of the total. In terms of dose, radiography, tomodensitometry and conventional fluoroscopy have the highest contribution to the collective dose (42%, 28% and 17% respectively). The other modalities represent 13% of the collective dose.

Table 1. Annual number of examinations and collective dose in mSv (rounded values) per category of examinations

Category	*Annual number*	*Fraction (%)*	*Collective dose*	*Fraction (%)*
Radiography	4'500'000	47	3'000'000	42.2
Dental radiology	4'000'000	42	70'000	1.0
CT (tomodensitometry)	300'000	3.2	2'000'000	28.1
Mammography	200'000	2.1	40'000	0.6
Radiography and fluoroscopy : non-angio	150'000	1.6	1'200'000	16.9
Radiography and fluoroscopy : angiography	70'000	0.7	500'000	7.0
Radiography and fluoroscopy : interventional	30'000	0.3	250'000	3.5
Osteodensitometry	30'000	0.3	40	0.0
Conventional tomography	10'000	0.1	50'000	0.7
Total	9'500'000	100	7'100'000	100

Table 2 presents the distribution of the annual number of examinations and the collective dose with the different categories of establishments. In terms of the annual number of examinations, the dentists are on top position with 42% of the total, followed by the hospitals with 31% and the general practitioners with 16%. The other categories contribute together for 11%. In terms of the collective dose, the hospitals alone contribute for about 73%. The general practitioners contribute for almost 10% and the radiologists for almost 7%. The contribution of the other categories all together is about 10%.

Table 2. Annual number of examinations and collective dose in mSv (rounded values) per category of establishments

Category	*Annual number*	*Fraction (%)*	*Collective dose*	*Fraction (%)*
General and internal medicine	1'500'000	15.8	670'000	9.4
Radiology	250'000	2.6	480'000	6.7
Small hospitals (< 500 beds)	2'000'000	21.1	3'300'000	46.2
Large hospitals (> 500 beds)	950'000	10.0	1'900'000	26.6
Dental medicine	4'000'000	42.1	70'000	1.0
Chiropractic	60'000	0.6	140'000	2.0
Others	700'000	7.4	580'000	8.1
Total	9'500'000	100	7'100'000	100

The distribution of the collective dose with the age of the patient is given in figure 2. The distribution peaks at age 65. If a correction for the age of the patient is performed according to an appropriate risk model we obtain a reduced mean annual effective dose of about 0.6 mSv per inhabitant.

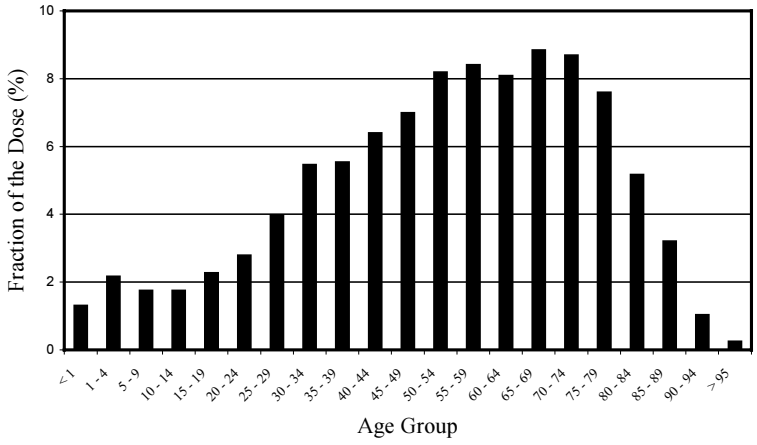

Figure 2 Distribution of the collective dose with the age of the patient

4. Conclusion

The present survey allowed the establishment of an accurate picture regarding the exposure of the Swiss population by diagnostic radiology. Both the frequencies and the doses associated with the different types of examinations were investigated. The results of the study will be used to elaborate recommendations in order to reduce the patient doses involved in diagnostic radiology.

Acknowledgements

The authors are grateful to the Swiss Federal Office of Public Health who financed this survey under contract Nr. 316.96.0576.

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EVALUATION OF PATIENT SKIN DOSE EQUIVALENT DUE TO DIAGNOSTIC PROCEDURES WITH X-RAYS IN LAGOS STATE NIGERIA

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Abstract

This paper reports the study of Patient Skin Dose Equivalents in Lagos State, Nigeria, as one of the strategies of patient protection and x-ray procedure quality assessment. 13 most frequent x-ray diagnostic procedures were studied. These were chest, skull, cervical spine, lumbosacral spine, sinusis, pelvis, plain abdomen, shoulder, foot, hysterosalpingography, intravenous urography, barium meal and barium enema. 1977 procedures were monitored for a period of 12 months in both private and public hospitals carefully selected from all over the state. The results obtained compared favorably well with those from similar studies reported in the literature. The slight differences observed have been ascribed to variations in the patient anatomy, exposure conditions and choice of radiographic parameters.

1. Introduction

The main radiation protection problem in the diagnostic applications of x-rays is the unnecessary irradiation of patients and staff. Exposures to ionizing radiation and the associated health hazards necessitate the need for justification, optimization and respect of norms as recommended by the relevant international organizations [1]. Patient exposures in most cases are justified having taken account of alternative diagnostic methods using non-ionizing radiation [2]. Optimization implies reduction of patient dose to minimum possible while still obtaining all the necessary diagnostic information according to the ALARA principle.

Evaluation of Patient Skin Dose Equivalent (PSDE) is an optimization process intended for monitoring and assessment of performance within a department as part of dose reduction and patient protection strategies. PSDE is useful in the assessment of the potential harms from a particular procedure and for intercomparison of quality and standards between departments at national and international levels. The various direct and indirect methods of patient dosimetry exist in the literature [3,4,5]. PSDE monitoring is of particular importance in third world countries where the larger percentage of the radiation facilities are old, many of them not regularly serviced and the quality control and recalibration of the electric, mechanical and dosimetric performance parameters are almost non existent as in the developed countries.

This paper reports the PSDE from 13 most frequent x-ray diagnostic procedures in Lagos state, Nigeria. Lagos, being the economic and the industrial nerve center of the country, is the most densely populated city in the West African subregion. The number of private hospitals in the state is far greater than public and they are of varying sizes and standards. Some of the public and private hospitals have been selected for this study. The results obtained were compared with similar studies reported in the literature. The goal is to improve the quality of radiodiagnostic procedures, the quality being defined in terms of qualitative image vis-à-vis the dose to patient.

2. Materials and methods

PSDE were monitored for a period of 12 months in 10 different public and private hospitals distributed all over Lagos state. The criteria for selection of hospital included good representation of type of diagnostic procedures studied, the geographical location, how busy the hospital is and the facilities available. The 13 procedures studied were chest, skull,

cervical spine, lumbosacral spine (LSS), sinusis, pelvis, plain abdomen, shoulder, foot, hysterosalpingography (HSG), Intravenous Urography (IVU), Barium Meal (BM) and Barium Enema (BE). 1977 procedures were monitored out of which 1485 were common and 492 were special procedures.

Thermoluminescence Dosemeter (TLD) LiF chips were placed one on each side and one at the central axis of the rectangular x-ray beam on the patient skin. From reading the chips the average PSDE for each exposure was determined. The TLD reader was Tolede 654 from Vinten U.K. at the Federal Radiation Protection Service. The system had been pre-calibrated at the dosimetry laboratory of IAEA in Seibersdorf, Austria. A patient radiological examination conditions and radiological parameters.

3. Results and discussions

The number of exposures, the range of the PSDE and the mean values for the various procedures monitored are summarized in table 1 below.(Table not provided). The ranges of the PSDE from the literature are contained in the last column for comparison. The PSDE recorded cover a wide range and vary with patients. This observation is expected because each patient is unique in anatomy, age, weight, illness and exposure conditions. Patient dose depends on type of procedure, beam size or the volume of tissue in the beam, patient positioning as well as radiological parameters such as KV, mAs, type and speed of film, use of intensifier and grid, age, type and the output of the x-ray facility. These technical and patient anatomical difference have been identified to account for the wide PSDE ranges. Some procedures such as LSS, HSG, IVU, BM and BE gave PSDE values which are multiples of the means annual background dose limit. The range of the PSDE obtained compared with those by Roger R.T. [6] and the means PSDE values by Shrimpton et al.[7] show a good agreement. The slight differences could be attributed to the patient anatomical and exposure parameter differences.

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ENTRANCE SURFACE DOSE MEASUREMENT FOR SOME OF THE RADIOLOGICAL PATIENTS IN BANGLADESH

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Abstract

ESD values were measured for the most common types of X-ray procedures in four of the main hospitals of Dhaka the Capital City of Bangladesh. Patients undergoing a variety of examination protocols such as Chest PA, Lumber Spine AP and Lateral, Skull AP and Lateral, Pelvis AP were studied in the four hospitals numbered as 1, 2, 3 and 4.Diagnostic Radiology is the largest contributor to the artificial sources of ionizing radiation. Since X-ray is a powerful technique of diagnostic imaging, a large number of patient's (a part of total population) are availing this technique every day in all countries of the world including Bangladesh. But so far no attempt has been made in Bangladesh to find out the doses delivered to the patient undergoing different X-ray procedures. So. in this study Entrance Surface Dose (ESD) values have been measured for about 196 patients undergoing different X-ray procedures. The observed ESD values in the different local hospitals were compared with the values within the hospitals and also with the International Reference ESD Values.

1. Introduction

Though a net benefit to health may be achieved by all increase in the provision of radiation services in medical fields yet it carries some risk. International Atomic Energy Agency has imposed no limit on medical exposures, the aim is to ensure that the doses are not only low enough to justify the particular diagnostic examination but are kept even lower when the objective is reasonably achievable.

Entrance Surface Dose is one of the basic dosimetric quantities for measuring the patient dose. In connection with optimizing patient dose it is also the basic quantity for comparing with the International Reference Values which is also important from the point of view of radiation protection of the patients. Though ESD value measurement for the patient is an essential component of Quality Control programme for individual X-ray radiology departments but comparison of ESD values between different hospitals, showing the variation of ESD values and the ratio of maximum and minimum ESD values can picture out the overall situation of the radiology departments of the country and can help to take protective measures where necessary. So, such an attempt has been undertaken in the present study. The results of the patient dose measurement, presented here are the first reported works that have been done in Bangladesh.

2. Experimental procedure

Since Chest PA patients were easily available in the hospitals, 10 patients for this projection in all the hospitals were taken but the patient sample size had to be lowered because of lower availability of the patients for some of the other procedures. In order to obtain representative values of ESDs for each X-ray procedure at least five patients per type of radiograph has been studied to provide a good indication of typical clinical practice. Only adult patients are included in the sample for the assessment of general diagnostic radiology procedures. Both sexes have been included as long as extremes in physique are avoided. Patients with weight 60 ±10 kg. were considered in this study [1]. Since effects of field size on radiation output in air has been found to be small and in fact negligible for field sizes used in radiograph [2}, the effect of field size has been neglected in this study.

For each diagnostic procedure a batch of three TLD chips were attached to the skin as close as possible to the point where the central axis of the X-ray beam enters the patient. The exposure parameters of the patients such as kVp, mAs, time, FFD etc. were noted down. Following the X-ray procedure the chips were read by the Harshaw 3500 TLD Reader. The average of three chips was taken as the ESD value received by the patient for that particular procedure. For background one batch of chips was kept without exposure every time when the other chips were exposed.

3. Results and discussion

Patient data and exposure parameters are shown in Table I. The mean ESD values in different hospitals together with the reference ESD values and also the range factors (ratio between maximum and minimum ESD values) is shown in Table II.

Table I. Patient Data and Exposure Parameters for ESD Measurement

Serial No. of the hospitals	Type of X-ray Procedure	Range of Age of Patient	Range of Wt. Of Patient	Range of kVp	Range of FFD (cm)
1.	Chest PA	18-36	56-68	50-55	114-138
2.		22-60	55-75	65-80	150-150
3		24-78	54-65	55-70	150-150
4.		28-65	50-69	55-73	200-200
1.	Lumber	21-60	52-71	70-81	90-103
2.	Spine AP	20-55	52-68	70-85	90-90
3.		31-70	50-74	70-90	105-110
4.		20-70	50-70	60-77	90-110
1.	Lumber Spine	21-60	52-71	77-85	90-110
2.	Lateral	22-55	52-68	80-90	90-90
3.		31-70	54-65	70-95	105-110
4.		23-70	50-70	73-85	90-110
1.	Skull AP	20-50	53-73	57-70	80-100
2.		22-50	50-65	70-80	90-100
3.		18-68	52-80	75-85	105-110
4.		24-45	50-67	60-75	100-100
1.	Skull Lateral	20-50	53-59	57-81	80-103
2.		34-50	50-65	70-80	90-100
3.		18-68	52-74	65-80	105-110
4.		24-45	50-67	55-70	100-100
1.	Pelvis AP	18-65	50-58	65-77	90-112
2.		32-48	50-66	70-80	90-105
3.		19-75	50-80	65-80	105-110
4.		27-70	52-77	66-73	97-113

A large variation of ESD values for the same type of X-ray procedure even in the same hospital has been observed. The mean ESD values for each procedure was compared with the Internationally Accepted Reference Values. It is observed that in most of the cases the local hospitals delivered ESD values lower than the corresponding Reference Value. In case of Chest PA, the variation between kVp used among the hospitals was large (50-80 kVp), also variation between used FFD was large (114-200), so a large variation of the ratio of 35.9 in the max/min ESD values was observed. This abnormally high variation in the ratio of ESD values indicates wide variation in the dose, delivered to the patient for the same type of examination. Hospitals 1, 3, and 4 delivered ESD values for Chest PA nearly equal to the Reference Value

Table II. Mean and Range of ESD Values for different types of X-ray examinations in different hospitals together with the Reference Value and Range factor

Name of Hospital	Type of Exam.	No. of Patients	Maximum ESD (mGy)	Minimum ESD (mGy)	Mean ESD (mGy)	Reference Value (mGy)	ESD Range Factor Max/ Min
1. 2. 3. 4.	Chest PA	10 10 10 10	0.49±0.17 4.67±0.22 0.73±0.21 0.74±0.10	0.14±0.01 0.28±0.04 0.19±0.03 0.13±0.03	0.33±0.07 1.58±0.16 0.44±0.14 0.44±0.13	0.4	35.9
1. 2. 3. 4.	Lumber Spine AP	10 10 9 10	5.67±0.65 25.54±3.66 10.28±0.40 6.22±1.07	2.54±0.15 4.52±0.36 3.51±0.06 1.36±0.09	4.01±0.67 9.71±0.57 7.07±0.55 3.48±0.64	10	18.8
1. 2. 3. 4.	Lumber Spine LAT	10 9 10 10	8.28±0.40 33.68±1.32 23.25±0.41 12.46±0.63	5.89±0.48 7.31±1.00 9.08±0.02 3.03±0.29	7.20±0.66 12.66±1.20 13.82±0.76 6.6±0.69	30	11.12
1. 2. 3. 4.	Skull AP	7 7 10 5	2.58±0.13 15.40±1.5 3.51±0.86 1.64±0.17	1.19±0.28 2.40±0.18 1.34±0.14 0.86±0.10	1.17±0.24 8.6±0.95 2.4±0.45 1.21±0.15	5	17.9
1. 2. 3. 4.	Skull LAT	5 5 10 5	0.93±0.11 10.09±0.8 3.66±0.33 1.56±0.14	1.46±0.08 3.78±0.24 1.52±0.07 0.49±0.02	1.16±0.12 6.96±0.44 2.44±0.34 0.92±0.14	3	20.59
1. 2. 3. 4.	Pelvis AP	5 5 8 6	4.83±0.64 8.04±0.28 9.24±0.52 3.28±0.13	2.07±0.27 4.00±0.15 2.73±0.56 1.91±0.10	3.34±0.55 6.20±0.30 5.15±0.46 2.63±0.66	10	4.8

but hospital 2 delivered higher than Reference Value. In case of Lumber Spine AP hospital 1 delivered dose nearly equal to the Reference Value but all other hospitals delivered lower doses. In case of Skull AP all the four hospitals delivered lower doses than the Reference Value except hospital 1 which delivered higher value. In case of Skull Lateral hospital 3 delivered ESD value nearly equal to the Reference Value. The other two hospitals delivered lower values except hospital 1 which again delivered about 2 times higher value than the Reference Value. In the case of Pelvis, all the hospitals delivered lower mean ESD values than the Reference Value.

From the present study though it is observed that in many cases the mean ESD values are below the Internationally accepted Reference Values, in most of the cases the fluctuation of the ESD values was too large, even in the same type of X-ray examination and same X-ray facility. It was found that the ratio of maximum and minimum ESD values for different X-ray procedures ranged from 2.62 to 77.8, the Chest PA has showed the largest variation. Higher ESD than the Reference ESD values for a particular type of X-ray procedure in general represent an unnecessary over exposure to the patient whereas low ESD values may lead to poor diagnosis and unnecessary repetition of the X-ray procedure. In both cases the chance of

increasing radiation exposure to the patient increases. Also a considerable spread of patient doses between hospitals for similar types of X-ray procedure reflects the need for dose optimization maintaining the relevant appropriate parameters for the radiological X-ray procedures in Bangladesh

Acknowledgements

I express my heart-felt gratitude to Mr. Fazle Karim Miah, Chief Scientific Officer, Bangladesh Atomic Energy Commission for his constant guidance throughout the course of the whole work. I am also thankful to all my colleagues of HPRML, Bangladesh Atomic Energy Commission who extended their help and cooperation during the work.

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THE FIRST TRIAL PATIENT DOSE SURVEY IN DIAGNOSTIC RADIOLOGY IN VIET NAM

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Abstract

This paper presents the results of the patient dose survey in some hospitals in Hanoi City from 1995 to 1997 under IAEA CRP "Radiation Protection in Diagnostic Radiology in Asia and Far East". The main investigated types of the X-ray examination were: Chest PA,LAT; Skull PA/AP,LAT; Lumbar spine AP,LAT; and Pelvis AP and in barium meal as well. The fluctuation of the entrance surface doses (ESD) was too large, even in the same type of X-ray examination and X-ray facility. It was found that the ratio of maximum and minimum ESD ranged from 1.5 to 18. The mean values of ESD for chest and skull were higher than the CEC recommended guidance values, while the mean values of lumbar spine and pelvis were smaller than that of CEC recommended guidance values. The result of dose intercomparison was also reported. Some methods of dose reduction were applied for improving the patient dose in X-ray departments such as a high kV technique, high sensitive screen-film combination.

1. Introduction

The World Health Organization (WHO) has defined quality assurance in medical X-ray diagnosis as:
"... An organized effort by the staff operating a facility, to ensure that the diagnostic images produced by the facility are of sufficiently high quality so that they consistently provide adequate diagnostic information at the lowest possible cost and with the least possible exposure of the patient to radiation"

It was clear that the patient dose monitoring should be an essential component of quality control programme in diagnostic radiology . In Vietnam there are more than two thousands X-ray machines being used in diagnostic radiology. These x-ray machines are very different in types and models. Most of them are very old and have been working for a long time without quality control. This paper presented the first results of the patient dose survey conducted in 1995-1997 period in Hanoi City according to CEC recommended conditions. Selected types of X-ray examination for investigation were lung PA,LAT; skull AP/PA, LAT; lumbar spine AP, LAT; pelvis AP and in barium meal as well. The results of thermoluminescent dosimeter system intercomparison were also reported.

2. Experiment and discussion

1. Thermoluminescent dosimeter system and result of dose intercomparison:

1-1/ Thermoluminescent system
TLD-100 was chosen for measuring the ESD per radiograph. TLDs have an advantage of being physically small, enabling them to be stuck directly to the patient's skin. They will fully measure the radiation backscattered from the patient's body. Universal ToLeDo Reader 654D was used for reading the thermoluminescent signals from TLDs. The measuring regime was setup as following:

- Preheating temperature: 130^{o} C time: 16 seconds
- Reading temperature : 260^{o} C time: 16 seconds
- Annealing temperature : 300^{o}C time: 25 seconds
- Heating rate : 16^{o}C/sec.

TLDs were individually calibrated against OB/6 Buchler reference source: Cs-137 20Ci.

1-2/ Calibration and Intercomparison of Dosimetric System

55 TLDs were divided into 11 sets of 5 dosimeters and have been sent to the Primary Standard Dosimetry Laboratory at National Radiation Laboratory (NRL) in New Zealand.

The Table 1 presented the result of dose intercomparison. It was shown that the absorbed doses in air of the dosimeter sets TLD7, TLD8 and TLD9 were in a good agreement with reference values. The deviations in % (Δ = (Ref.-meas.)/Ref. x 100%) of sets TLD7, TLD8 and TLD9 were of 0.2%, -1.4% and 2.2%, respectively.

Table 1. Result of Dose Measurement for Intercomparison of TLD Systems

Code	Eff.energy keV	Mean cal. dose, mGy	Sdev mGy	Ref. Dose mGy	Deviation %	corrected meas. values
TLD7	26.9	4.22	0.09	4.23	0.2	4.28mGy
TLD8	33	25.97	1.07	25.6	-1.4	26.63mGy
TLD9	41.1	2.21	0.06	2.26	2.2	2.26mGy

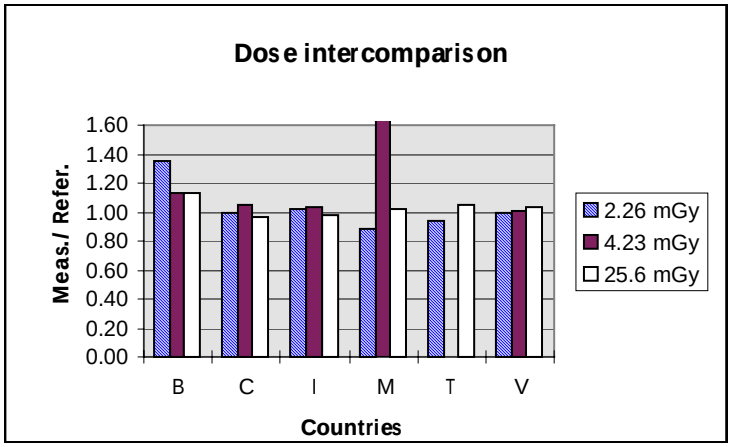

Figure 1 Results of dose intercomparison in Asia-Pacific Region.

The result of the dose intercomparison showed that the TLD system was adequate for monitoring the patient dose.

2. Patient dose survey

2-1/ Entrance Surface Dose (ESD)

Here, the patient dose can be understood as the entrance surface dose, that can be defined as the absorbed dose to air at the point of intersection of X-ray beam axis with the entrance surface of patient, including backscattered radiation. The entrance surface dose is to be expressed in term of *mGy.*

2-2/ Selection of measurement samples

For the dose measurements to be indicative of routine practice and to be comparable, the careful selection of measurement samples is required. Adult patients of both of sexes were selected for assessment of general diagnostic radiology procedures. At least 10 patients were selected for each type of examination for one x-tube. The mass of patient should be in the range of 65±10 kg.

2-3/ The patient dose

3. Patient doses in radiography

Table 2. The results of ESD survey before QC

	Lung PA	Lung LAT	L.spine AP	L.spine LAT	Skull AP/PA	Skull LAT	Skull Hertz	Pelvis AP
Hospital 1	0.7	1.83	5.06	10.25	9.05		30.65	2.89
Hospital 2	1.47	3.71	6.3	10.91	6.7	4.66		5.28
Hospital 3	0.98	7.8	7.47	20.2	7.52	7.67		6.04

The patient dose survey was conducted in 7 X -ray rooms of three hospitals [2]. The result of dose monitoring before carrying out QC is presented in the table 2. It was found that except for the lung PA examination, the ESDs of the different types of x-ray examination in hospital 3 were higher than that in other hospitals, particularly in lung LAT, lumbar spine AP/PA, LAT and pelvis AP examinations. One of reasons related to these high values of ESD may be that the X-ray machines of this hospital were too old and functioning not properly. Some times, it is necessary to repeat exposure at least two times for getting one radiograph because the power of radiation exposure is not enough for the fat patient. The ESD of the skull in the Hertz position in hospital 1 was very high (> 30mGy).

Table 3. CEC values [1] and the ratio of the measured ESD and CEC

	Ratio of the measured ESD and CEC recommended values						
	Lung PA	Lung LAT	L.spine AP	L.spine LAT	Skull PA/AP	Skull LAT	Pelvis AP
CEC values	0.3 mGy	1.5 mGy	10 mGy	30 mGy	5 mGy	3 mGy	10 mGy
Hospital 1	2.3	1.22	0.5	0.34	1.81	-	0.29
Hospital 2	4.9	2.47	0.63	0.36	1.34	1.55	0.53
Hospital 3	3.26	5.2	0.74	0.67	1.50	2.55	0.64

The table 3 showed that ESDs of the lumbar spine (AP, LAT) and pelvis (LAT) examination were less than that of CEC recommended values. In the mean time, for the lung and skull examinations the obtained ESDs were higher then CEC values. The ratios of the measured ESD and CEC recommended values for lung examination were ranged from1.2 to 5.2. From the practice, it was learn that, except for lung examination, radiographic technical data for the other types of studied x-ray examination in the investigated hospitals was similar to the CEC suggested technical data, particularly in kVp, mAs and FFD specification. The low voltage technique was still widely used in the practice for the lung examination. That may be one of the main reasons to get a high value of ESD for the lung examination in all most hospitals. Another reason is that the deferent screen-film combination was popularly accepted to be used in hospitals for the economical causes. ESD varied in the very large scale for any given X-ray examination. The ratios of max/min of ESD values were varied from 1.5 upto 16. The largest variations were observed for the chest LAT in the hospital 3 and skull AP/PA in the hospital 1.

4. Patient doses in fluoroscopy

The patient doses (DAP) in the barium meal examination were performed on 7 units(4 U arm intensifier fluoroscopy units, 3 direct fluoroscopy units). The average values of DAP were quite different from hospital to hospital (see the table 4). The maximum attitude of discrepancy is of 14.2 factor for the fluoroscopy intensifier units

Table 4. The patient doses (DAP) in the barium meal examination

	TUR-D351 (Direct)	Picker (Direct)	Trophy	Shimazu1	Shimazu2	Elemma (Direct)	GE TFX15
Exposure time, sec.	91	50	121	22	42	16.2	109
DAP, $mGycm^2$	1241	5373	5054	351	355	763	1067
$mGycm^2$/sec.	13.6	107.5	41.8	16.0	8.5	47.1	9.8

The figures in the above table showed that the patient doses in barium meal strongly depend on the skills of radiologist. It may also mean that the reduction of patient dose depends on carefulness and experiences of radiologists.

2-*4/Dose Reduction*
It was shown that ESD of lung examination were high. So we have tried to apply two methods for reducing the patient dose for PA lung x-ray examination. The increased kV and screen - film combination with higher sensitivity methods were used in three hospitals. The patient dose reduction varied from 40 % to 80% for the Chest PA and from 10% to 80% for Chest LAT. for other types o examinations the general patient dose reducion was found in the interval of 15% to 45%. It was found that by using the high kV technique or high sensitive screen-film combination the ESDs of patient under chest examination were reduced very much.

4. Conclusion

The paper presented the first patient dose survey in diagnostic radiology in Vietnam according to CEC condition. The ESDs of chest and skull examination were higher than that of CEC recommended values. The necessary measures should be taken so that the QA and QC programme in diagnostic radiology in Vietnam will be established and implemented regularly. The high kV and high sensitive film screen methods should be applied in the x-ray departments for reducing the medical exposure to collective public dose.

Acknowledgements

We would like to acknowledge to IAEA for supporting this study in the framework of the IAEA's RC 8415/RB under CRP "Radiation Protection in Diagnostic Radiology in Asia and Far East". We also express our thanks to all staff of Centre of Radiation Protection and Nuclear Physics, X-ray departments of hospitals K, Viet Duc, Tran Hung Dao, Bach Mai and Hospital Traditional Medicine, Hospital Central Ophthaimic for their cooperation and assistance in carrying out this survey.

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RADIATION DOSES TO PATIENTS IN DIAGNOSTIC RADIOLOGY IN ROMANIA; COMPARISON WITH GUIDANCE LEVELS AND POSSIBILITIES OF REDUCTION

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Abstract

During 1990-2000 the Institute of Public Health-Bucharest participated to two research programmes, co-ordinated by International Atomic Energy Agency, in co-operation with European Commission. Patient dose measurements were performed in 10 X-ray units from 5 big hospitals from Romania, for the main X-ray diagnostic procedures using thermoluminescent dosemeters (TLDs). The obtained values were compared with the internationally recommended guidance levels. The highest ratio patient surface entrance dose/ guidance level was determined for chest radiography due to the routine practice of using low "kV" technique.
A special attention was given also to conventional fluoroscopy (direct viewing), still in use in about 20% of the total X-ray examinations in Romania.

1. Introduction

According to the definition, in X-ray diagnostic radiology, a Guidance Level (GL) is a dose level set for standard procedures and for groups of standard-sized patients or a standard phantom:

- entrance surface dose per radiograph, for diagnostic radiography;
- entrance surface dose rate, for fluoroscopy;
- average glandular dose per cranio-caudal projection, for mammography;
- multiple scan average dose, for computed tomography.

Consistent guidance levels are given by International Atomic Energy Agency in Basic Safety Standards from 1996 [1] and by European Commission in its guidances from 1996 and 1999 [2,3].

The GLs practically should assist in the optimisation of the patient protection, by helping to avoid unnecessarily high doses to the patient. The system for using GLs includes:

- estimation of patient doses, as part of a regular quality assurance programme;
- comparison of obtained doses with the internationally recommended guidance levels;
- corrective actions whenever guidance levels are consistently exceeded.

Since the beginnings of 1990, the Institute of Public Health-Bucharest participated to the co-ordinated research programmes (CRPs) on "Radiation Doses in Diagnostic Radiology and Methods for Dose Reduction" [4] and on "Technologies for Dose Reduction in Diagnostic Radiology for Eastern European Countries", initiated by the International Atomic Energy Agency, in co-operation with European Commission.

2. Method

The investigations were performed in 5 main hospitals from Bucharest, Cluj-Napoca and Iassy, during several X-ray examinations (conventional fluoroscopy and standard radiography)

and consisted in patient dose measurements and in comparisons with internationally recommended guidance levels.

The entrance surface dose on patient in medical radiography was directly measured by means of TL dosemeters, after an intercalibration of all participating laboratories to the CRP. A set of dosemeters from each participant was exposed in the same laboratory to different beams (25, 60, 80 and 120 kV and ^{137}Cs) and to different doses (0, 1, 5 and 50 mGy).

The dose-area product and dose rate in fluoroscopy were determined using appropriate calibrated ion chambers type PTW-Freiburg.

When performing measurements on the patient, several relevant data were collected: equipment generator and X-ray tubes imaging system and processing, patient data and technical factors (settings, distances, exposure time) for each examinations.

After a comparison with guidance levels, an analysis of the results was performed, in order to identify the causes which contribute most to the dose and, if appropriate, dose reduction methods were applied, keeping the image quality [3].

3. Results

In Table 1 are presented the measured entrance doses to patient for the main radiographic examinations and projections. The mean value ranged from 45.3 mGy for thoracic spine (LAT) to 1.1 mGy for chest (PA). The ratio between the measured (mean) dose and guidance level [1] varies from 1.0 for cholecystography (AP) to max. 2.8 for chest (PA).

Table 1. Patient doses (adults) for diagnostic radiography

Type of examination and projection		Measured entrance dose (mGy)		Guidance Level	Ratio (M/G)
		Range	Mean value		
SKULL	AP	4.7 – 19.0	9.1	5	1.8
	LAT	4.4 – 14.5	6.9	3	2.3
CHEST	PA	0.5 – 1.5	1.1	0.4	2.8
	LAT	1.0 – 3.1	1.8	1.5	1.2
THORACIC SPINE	AP	6.5 – 20.6	12.0	7	1.7
	LAT	19.2 – 55.0	35.6	20	1.8
LUMBAR SPINE	AP	7.4 – 25.8	16.8	10	1.7
	LAT	26.0 – 72.8	45.3	30	1.5
ABDOMEN	AP	10.7 – 21.3	14.2	10	1.4
PELVIS	AP	9.6 – 24.4	16.6	10	1.7
CHOLECYSTOGRAPHY	AP	7.8 – 15.8	10.1	10	1.0

The calculated effective doses are given in Table 2.

Table 2. Effective dose per radiographic procedure

Procedure	Effective dose per radiographic procedure/(mSv)
SKULL	0.17 (± 0.09)
CHEST	0.25 (± 0.11)
THORACIC SPINE	2.00 (± 1.20)
LUMBAR SPINE	2.93 (± 1.40)
ABDOMEN	1.90 (± 1.10)
PELVIS	2.60 (± 1.30)
CHOLECYSTOGRAPHY	1.60 (± 0.90)

In Table 3 are shown the dose-area product values obtained for fluoroscopic procedures (the barium examinations include also the radiographic images) and the calculated effective doses.

Table 3. Patient doses in fluoroscopic procedures

Procedure	Dose – Area Product (Gy . cm^2)		Effective Dose (mSv)
	Range	Mean value	
Chest fluoroscopy	4.3 – 10.7	7.5	0.95
Barium meal	11.0 – 30.0	20.5	4.10
Barium enema	18.5 – 45.7	32.1	9.10

The Table 4 presents the range of measured entrance surface dose rates for conventional fluoroscopic installations (direct viewing) and the comparison with guidance value.

Table 4. Entrance surface dose rates (mGy/ min)

Settings for chest fluoroscopy			Dose rate	
kV range	mA range	total filtration mm Al	Measured	Guidance
70 - 85	2.5 – 3.0	2.5	22 – 49.5	25

4. Dose reduction

For the very frequent chest radiography, the analysis of physical parameters used (Table 5) shown that a low “kV” technique is generally preferred, explained by the care to protect X-ray tube.

Table 5. Physical parameters used and comparison with recommended values for chest radiography

Parameter	Used	Guidance
FFD (cm)	160 (150-170)	180 (140-200)
kV	75 (70-80)	125
Speed of film/ screen combination	200	400

By increasing of kV and reduction of both mA.s and field size a dose reduction up to 30 % was obtained, keeping the quality of image.

An increase of screen-film sensitivity determined a dose reduction up to 40 %.

Important possibilities for dose reduction are available in fluoroscopy. In Romania 20 % of the total X-ray examinations are fluoroscopies and 80 % of fluoroscopies are for chest, most of them still using conventional (direct viewing) fluoroscopy. According to Art. 8 of Conncil Directive 97/ 43/ EURATOM of 30 June 1997 [5], such techniques are considered unjustified and should be prohibited in the future.

Important practical possibilities for dose reduction are available in fluoroscopy: use of as low mA and kV factors as possible, attention to a good collimation, short duration of investigation, dispense with antiscatter grids and others well known good practices.

5. Conclusions

By comparing local practice against guidance levels of dose for patients, it was demonstrated that guidance levels are important quantitative guides for the optimisation of patient protection in diagnostic radiology.

As the guidance levels from basic safety standards are based on investigations in some developed countries, they are too restrictive for some other countries.

The guidance levels should be understood as guidelines, rather than standards in medical diagnostic radiology, and they should be evaluated in relation with quality assurances programmes in each country, by professionals from both medical and physics communities.

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PATIENT'S DOSE ASSESSMENT DURING SINUS X-RAYS RADIOGRAPHY AT « HOPITAL DU POINT G »

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Abstract

OBJECTIVE
- To evaluate the patients X-rays dose during head radiography for sinusitis
- To precise the influence of source-image distance on the patient's dose.

MATERIAL AND METHOD
From may 1997 to january 1999, 83 patients with clinical suspicious sinusitis have been included in this study. Skull radiography in 3 positions (posterior, lateral and Blondeau view) have been achieved for each patient on 24x30 centimeters size films. These radiography were realised on a Diagnost 7 Masio Philip X-rays machine. Three TLD dosimeters were pasted against every patient target organs (thyroid, rigth and left eyes). The source-image distance (SID) was 100 centimeters for the first group (35 patients) and 125 centimeters for the second group (48 patients). The selected parameters (high voltage and charge) were as follow:
Skull postero-anterior view: 65 to 85 kV, 80 mAs
Skull lateral view: 60 to 75 kV, 80 mAs
Blondeau view (paranasal sinuses): 90 to 95 kV, 100 mAs.

RESULTS

All the radiographies were analysed by the same radiologist who didn't know the SID. All the films were of good quality. The patient's dose in millisievert for each target organ were:

	Left eye	Right eye	Thyroid
Group I (SID = 100 cm)	3,2 (+ ou – 0,66)	3, 0 (+ ou – 0,82)	0,62 (+ ou – 0,09)
Group II (SID = 125 cm)	1,9 (+ ou – 0,48)	1, 86 (+ ou – 0,50)	0,39 (+ ou – 0,08)

In conclusion, the increase of SID from 100 to 125 centimeters allows patient's dose reduction by a factor of 1.6 without the alteration of the films quality, hence the reliability of the diagnosis.

1. Introduction

Radiation doses from radiodiagnostic radiology are the largest contribution to the collective dose from all man-made sources of radiations. In Mali (west africa), where the radiation protection law instead International Atomic Energy Agency (IAEA) effort is still on draft form, the number of X-rays diagnostic installations grows year by year. If 86% of these installations are a second-hand machines, most of them are at least 20 years old (Sidibé *et al*., 1995). Also any project on dose assessment and developping dose reference levels and image quality criteria for common diagnostic examination have been running. In « hôpital du Point G », skull radiography is the second largest examination just after chest radiography, and sinusitis is the mainly reason of such radiography. If it is well recognised that the over-zealous reductions in patient doses can have deleterious effects on the diagnostic information of the image, in some cases, doses reduction can even be obtained together with an improvement of the image. In this fact our present study have been done with following purposes:

- To evaluate the patients X-rays dose during head radiography for sinusitis;
- To precise the influence of source-image distance on the patient's dose.

2. Material and methods

From May 1997 to January 1999, 83 patients with a clinical suspicious sinusitis were included in this study. These patients included 36 males and 47 females. The mean age of our study population was 28 years (average: 5 to 67 years). All the radiographic examiantions were realised according to the physician recommendation through following projections: skull postero-anterior, lateral and Blondeau views. Radiography were realised on a Diagnost 7 Massio Philip X-rays machine with a 24x30 centimeters size films (Kodak X-Omat K film). Patients were divided in two groups according to the Source – Image – Distance (SID) which was 100 centimeters for group I (35 patients) and 125 centimeters for group II (48 patients). For patient doses evaluation we used 3 previous calibrated thermoluminescent dosimeters (TLD). These TLD were pasted for each patient on thyroid, right and left eyes. These organs were selected because they are target organs for each view. The selected constant parameter (high voltage and charge) for X-rays radiography were as follow:

- Skull postero-anterior view: 65 to 85 kV, 80 mAs
- Skull lateral view: 60 to 75 kV, 80 mAs
- Blondeau view: 90 to 95 kV, 100 mAs.

All the films were transported through the same processing sequence (developing, fixing, washing and drying) of an automated processor. Each picture was closly identified and evaluation of all pictures have been done by the same radiographer without information on the SID parameter. For image quality assessment we used a qualitative rating with 3 scales (Poor, Satisfactory, Good) for each picture.

3. Results

The criteria for image quality assessment were:

Skull postero-anterior view:

- symetrical reproduction of the skull;
- symetrical reproduction of rock face on the lower part of the orbits;
- repoduction of spongiosa and corticalis;
- visualization of the skull sutures.

Skull lateral view:

- visualization of the skull sutures;
- superimposition (left-right) of the orbits roof;
- visualization of the skull and neck junction.
-

Blodeau view:

- symetrical reproduction of face;
- visualization of maxillary sinus;
- visualization of the rock under maxillary sinus.
-

Table I, II, and III represented the summary of these criteria, and table IV represented patient's doses in millisivert.

Table I. Image quality assessment according to a qualitative 3 scales (skull postero-anterior view)

	Poor	Satisfactory	Good
Group I (SID = 100 cm)	0	9	26
Group II (SID = 125 cm)	0	12	36

Table II. Image quality assessment according to a qualitative 3 scales (skull lateral view)

	Poor	Satisfactory	Good
Group I (SID = 100 cm)	1	15	19
Group II (SID = 125 cm)	0	21	27

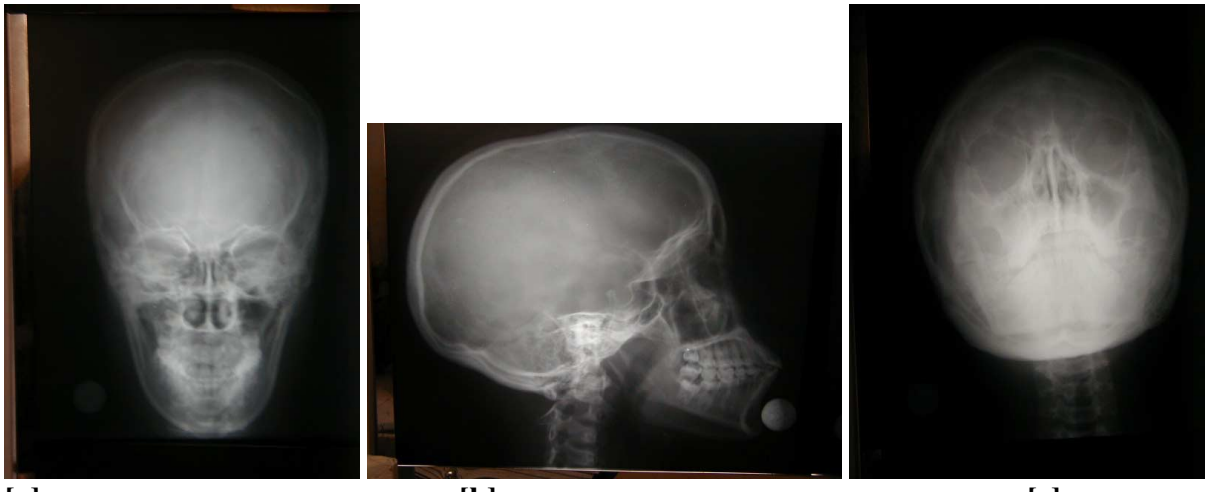
Table III. Image quality assessment according to a qualitative 3 scales (Blondeau view)

	Poor	Satisfactory	Good
Group I (SID = 100 cm)	3	11	21
Group II (SID = 125 cm)	4	18	26

Table IV. The patient's dose in millisievert for each target organ were

	Left eye	Right eye	Thyroid
Group I (SID = 100 cm)	3,2 (+ ou – 0,66)	3, 0 (+ ou – 0,82)	0,62 (+ ou – 0,09)
Group II (SID = 125 cm)	1,9 (+ ou – 0,48)	1, 86 (+ ou – 0,50)	0,39 (+ ou – 0,08)

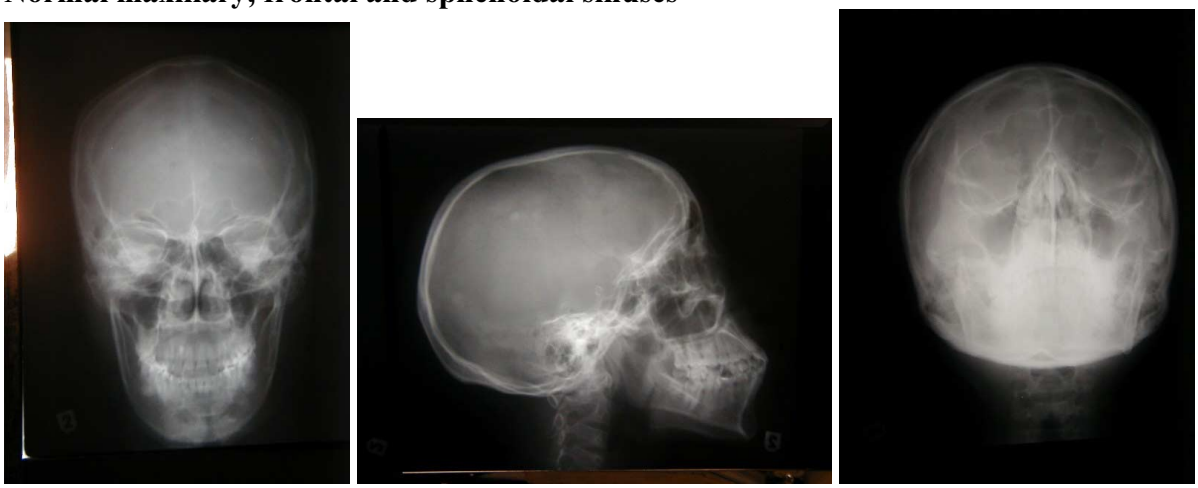
Right maxillary sinusitis



[a] [b] [c]

Figure 1. X-ray radiography at SID 100 centimeters: [a] skull postero-anterior view; [b] skull lateral view; [c] Paranasal sinuses (Blondeau view)

Normal maxillary, frontal and sphenoidal sinuses



[a] **[b]** **[c]**

Figure 2. X-ray radiography at SID 125 centimeters: [a] skull postero-anterior view; [b] skull lateral view; [c] Paranasal sinuses (Blondeau view).

In conclusion, the increase of SID from 100 to 125 centimeters allows patient's dose reduction by a factor of 1.6 without the alteration of the films quality, hence the reliability of the diagnosis.

According to the situation of the situation of X-rays equipment in Mali, a national project of dose assessment and developping dose reference levels and image quality is necessary.

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TRENDS AND THE DETERMINATION OF EFFECTIVE DOSES FOR STANDARD X-RAY PROCEDURES

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Abstract

Trends in the entrance skin exposures (air kerma) for standard x-ray imaging procedures are reported for the Province of Manitoba, Canada. Average annual data per procedure using standard phantoms and standard ion chambers have been recorded since 1981. For example, chest air kerma (backscatter included) has decreased from 0.14 to 0.09 mGy. Confounding factors may negate the gains unless facility quality control programs are maintained. The data were obtained for a quality assurance and regulatory compliance program. Quoting such data for risk evaluation purposes lacks rigor hence a compartment model for organ apportioning, using organ absorbed doses and weighting factors, has been applied to determine effective dose per procedure. The effective doses for the standard procedures are presented, including the value of 0.027 mSv (1999) calculated for the effective dose in PA chest imaging.

1. Introduction

The Canadian province of Manitoba lies in mid continent with a population of 1.2 million persons. Health care facilities are distributed throughout the province with tertiary care concentrated in the provincial capital of Winnipeg. Radiation Protection Services is mandated by the Province to provide x-ray regulatory services for the health care facilities. An inspectorate group operating from the Medical Physics Department of CancerCare Manitoba surveys medical x-ray facilities annually. A compliance review is conducted during each survey and guidance is provided (and demonstrated) for changes in techniques that will maintain film density and image quality as well as controlling patient dose.

Legislation does not specify dose limits for entrance skin exposures in specified procedures. Rather the province-wide averages of the previous year's surveys are used to benchmark the entrance skin exposures for the current year's surveys. Entrance skin exposures are measured with selected phantoms in place, the thickness of the phantom being varied according to the procedure in order to simulate the patient. The year-by-year entrance skin exposure data for standard procedures have been tabulated to assess the trends. These data are reported here.

While entrance skin exposure data are an appropriate quality control tool, the data are erroneously used as the measure of patient dose. To address this concern, a means of calculating the effective dose has been implemented. The average effective doses for the standard procedures tested in the compliance program have been determined for the 1999 data.

2. Methodology

In performing the compliance tests, x-ray machines were set up in an identical manner to the technique used by the facility's technologists. The tube was set at a height of 100 cm (focal spot to film), the appropriate phantom was positioned as if it was the patient and imaging parameters (tube voltage, current and time) were obtained from the technologist. Phantom thickness was constant for a specific procedure but varied according to the procedure (see Table I). Entrance skin exposure data were consistently measured with a 6 cc ion chamber (Radcal Corporation) and an MDH meter (1015 and 1515). The ion chamber was inserted in a

machined receptacle at the top of the phantom block. Phantoms of various thickness were constructed from pressed wood having a specific gravity of 1.00.

Entrance skin exposure data were collected with the instrumentation in milliroentgen (mR) and were subsequently converted to air kerma in milligray (mGy): 1.00 mR = 0.00873 mGy.

3. Results

The average annual air kerma data for three x-ray imaging views are shown in Figures 1 and 2. These data are the average of each annual set of compliance measurements for these procedures measured on medical x-ray machines in the province of Manitoba during the period 1981 – 1999. Data concerning the phantom thickness used to obtain the respective views are provided in Table I. Figures 1 and 2 demonstrate the gradual decrease in average air kerma for certain views as a result of the compliance review program, while maintaining film density and image quality.

Entrance skin exposure data obtained in the 1999 survey year are reported as air kerma in Table I. The standard procedures measured in our program are listed. Air kerma data include backscatter from the phantom. The tube voltage and phantom thickness and average film density are shown according to the procedure. Film speed is “400” throughout the provincial system.

Table I. Average air kerma data for standard procedures in Manitoba, 1999. Data shown are from x-ray machines with manual timing, anti-scatter grids and were obtained with phantom thickness as shown for the procedures. Tube voltages are nominal averages

Imaging Procedure	X-Ray Tube Voltage (kVp)	Phantom Thickness (cm)	Average Air Kerma (mGy)	Average Film Optical Density
PA Chest	110	10	0.091 +/-.03	1.6
AP Abdomen	85	18	1.36 +/-.47	1.6
AP Cervical Spine	70	13	0.41 +/-.17	1.4
AP Thoracic Spine	75	18	1.15 +/-.42	1.3
AP Lumbar Spine	85	23	2.47 +/-.95	1.2
Lateral Skull	80	15	0.52 +/-.14	1.2

4. Discussion

The regular program of compliance inspection and the interactions with x-ray technologists to assess the techniques and the doses resulted in the gradual decline in average air kerma and hence in patient doses. The introduction of 400-speed film has assisted in this reduction process. Nevertheless, confounding factors may be a potential source of further dose reduction on the one hand and may threaten the trend on the other. These confounding factors include:

(a) Reduced attention to quality control by the technologists may fail to observe changes in x-ray unit calibration or phototimer tracking.

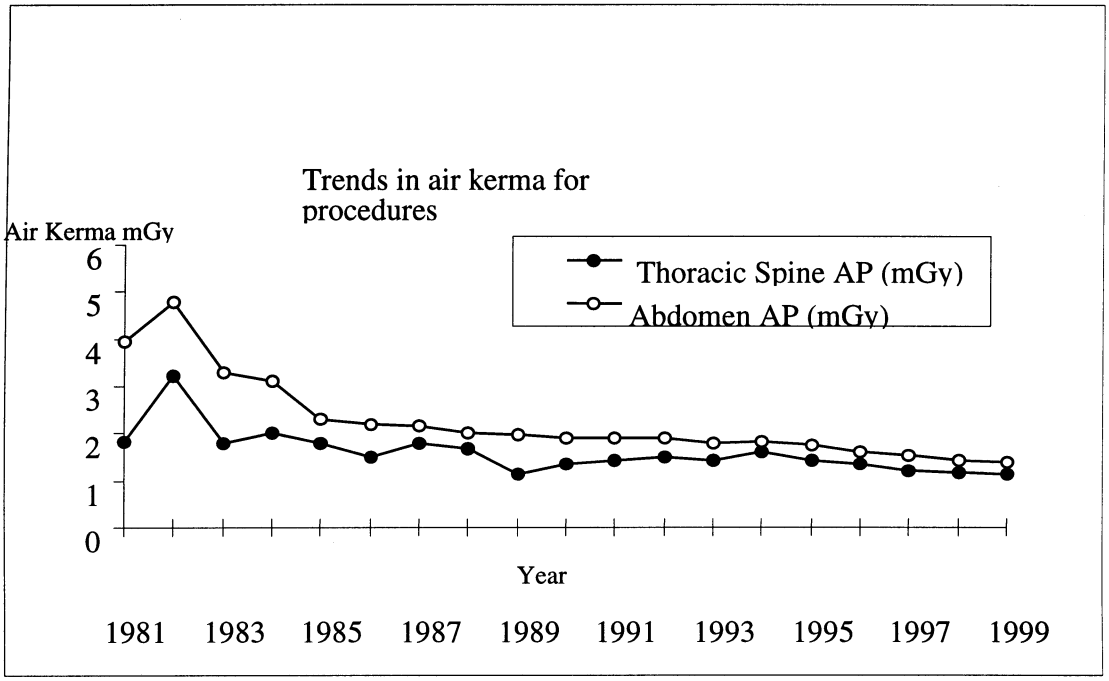

Figure 1. Air Kerma trends in the period 1981 - 1999, inclusive, for selected procedures.

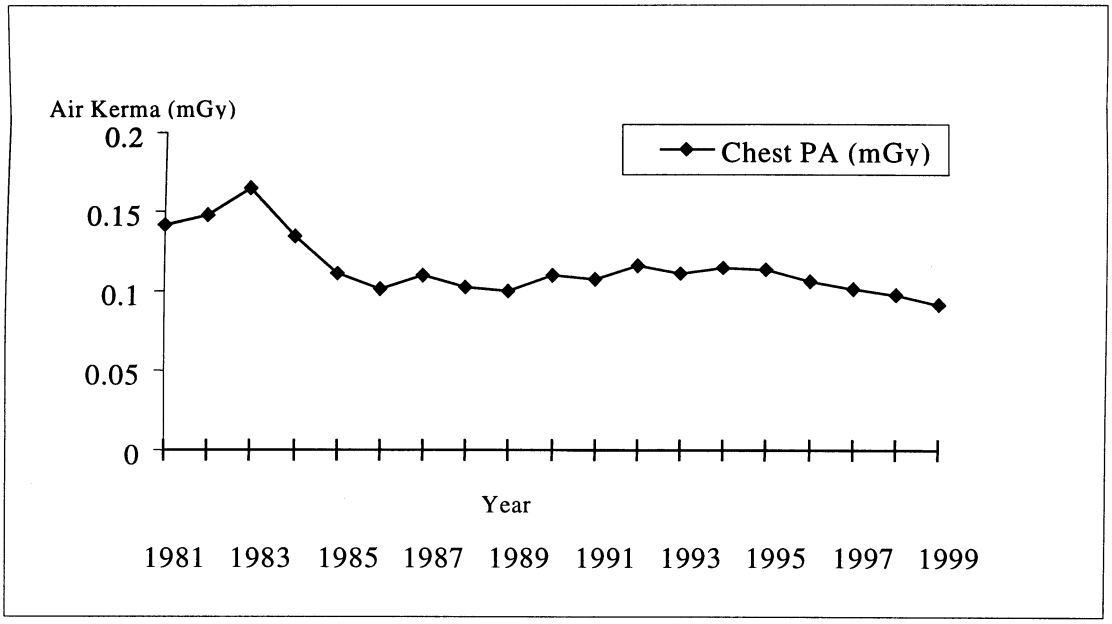

Figure 2. Annual average air kerma, 1981-1999, imaged on medical x-ray equipment in in Manitoba for PA Chest procedures with 10-cm phantom. Data include backscatter from the phantom.

(b) Cost-driven film changes and/or chemistry changes without testing.
(c) Radiologists reading different film densities from different facilities without feedback; different radiologists preferring films of different densities from the same facility.
(d) Failure to track repeat and reject analyses and evaluate factors contributing to spoiled films.

The confounding factors will be addressed through communication among radiologists and technologists and through adherence to the facility's quality control program.
Data include backscatter from the phantom.

5. Effective dose determination

We used a compartment model derived from a Health Physics Society standard (1) to calculate effective dose from the standard procedures in our compliance program. Tissue weighting factors in Reference 1 were converted to those of ICRP 60 (2) and the "remainder" organs were adjusted. Body compartments were defined for the major procedures: head and neck, thorax, abdomen and extremities. The models for the first three compartments were applied to convert entrance skin exposure (air kerma) data to effective doses (see Table II). The application of this method was as follows:

- account for backscatter (taken to be 30% for this application);
- convert exposure data to air kerma "free in air" in SI units;
- determine the absorbed dose at depth for each critical organ in the respective compartment using the orientation-specific information in Reference 3 (assuming average photon energy equals 50% of kVp);
- apportion the organ masses to the imaging field of view as necessary and calculate the resultant tissue weighting factor for the organ in the compartment;
- the radiation weighting factor was unity; multiply the resultant tissue weighting factor by the absorbed dose to the organ (tissue) to obtain the organ effective dose;
- sum the effective organ doses for the diagnostic image to determine effective dose.

Table II. Effective doses for standard procedures using the compartment model

Imaging Procedure	Imaging Compartment	Ave. Photon Energy (keV)	Air Kerma 1999 (mGy)	Effective Dose (mSv)
PA Chest	Thorax	55	0.091 +/-.03	0.027
AP Abdomen	Abdomen	42.5	1.36 +/-.47	0.525
AP Cervical Spine	Head and Neck	35	0.41 +/-.17	0.023
AP Thoracic Spine	Thorax	37.5	1.15 +/-.42	0.217
AP Lumbar Spine	Abdomen	42.5	2.47 +/-.95	0.953
LAT Skull	Head and Neck	40	0.52 +/-.14	0.018

6. Conclusion

Compliance surveys of diagnostic x-ray equipment in Manitoba indicate a downward trend in entrance skin exposures for standard imaging procedures. The trend requires vigilance and maintenance of quality control activities to avoid negating the gains. The data were converted to effective doses using a compartment model. While approximations exist in the effective dose calculations, the results are useful indicators of the potential risks from imaging.

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IAEA-CN-85-33

A PROJECT: "RADIOLOGICAL PROTECTION IN RADIOLOGY", IAEA–UNIVERSIDAD CENTRAL DE VENEZUELA

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Abstract

For several years a reference center of the UCV has been working in the project VEN/9/007 on dose reduction in diagnostic radiology sponsored by the IAEA.
The dose and quality image was evaluated for different types of radiological study (conventional radiology, CT, mammography, interventional radiology) in different facilities at Caracas and others regions of the Venezuela. TL dosimeters were used to assess dose and reduction in dose. Based on the recommendations given by CEC documents on diagnostic quality criteria, a quality control program in radiological protection of patients and staff have been developed, for example: Pilot study by using TLD in personnel radiation monitoring. Comparative study between high and low kVp in chest. Evaluation and dose reduction in chest pediatric. Reduction of radiation dose in studies of billiards via. Quality Image and reduction of the dose in studies of colon by enema. Radiation dose of staff in fluoroscopy procedures. Evaluation and dose reduction in dental radiography in public Institutions. A mammography accreditation program for Venezuela, applied to public hospitals.

1. Introducción

En el área de medicina hay un importante porcentaje de enfermedades diagnosticadas con el uso los rayos X. Por lo tanto, cualquier país que aspire mejorar los programas de cuidados de salud de su población debe garantizar su uso adecuado y seguro. En tal sentido, el Organismo Internacional de Energía Atómica (OIEA) ha publicado las Normas Básicas para la protección contra la radiación ionizante, donde se dedica un apéndice para la exposición médica y particularmente a la protección radiológica del paciente [1].

Pero en el área de radiodiagnóstico, además de la protección radiológica del paciente, es fundamental la calidad de la imagen obtenida, para garantizar un diagnóstico adecuado. La Comisión de las Comunidades Europeas (CEC) ha elaborado un documento sobre criterios de calidad para diferentes estudios radiológicos [2].

Pero una buena calidad de imagen con dosis bajas al paciente depende de diversos factores, entre ellos, el funcionamiento de la unidad, las condiciones de las instalaciones y de los equipos; los insumos; las técnicas para la obtención de la imagen; la calidad del servicio de mantenimiento.

En esta dirección, a comienzo de los años noventa, el OIEA patrocinó un estudio piloto en algunos países, para reducir dosis en pacientes y al mismo tiempo evaluar la calidad de imagen obtenida en diferentes tipos de estudios radiológicos [3].

En la misma dirección de ese estudio, el centro de Física Médica y Dosimetría (CFMD) de la Universidad Central de Venezuela (UCV) ha desarrollado el proyecto VEN 9/007 "Protección Radiológica en Radiología", subvencionado por el OIEA. En el presente trabajo se muestran algunos resultados relacionados con la medición y reducción de dosis en pacientes y el monitoreo de la calidad de la imagen.

2. Materiales y metodos

Las evaluaciones se realizaron en los servicios radiológicos del Hospital Universitario de Caracas (HUC) y la Facultad de Odontología de la UCV, y en servicios de radiología de otras instituciones médica u odontológica de Caracas y del interior del país. Para ello se tomó como patrón de trabajo, la metodología desarrollada en el estudio piloto del OIEA y otras experiencias en esta área [4][5].

El procedimiento se realizó en tres fases. La primera se utilizó para obtener información básica sobre el servicio de radiología por medio de un cuestionario**.** En este se indagó sobre la calificación del personal, el equipamiento, insumos, técnicas radiográficas, y las prácticas de control de calidad y mantenimiento.

En la segunda, por una parte, se efectuó una evaluación física de la cadena para la toma radiográfica, para ello se siguió el protocolo español de control de calidad en radiodiagnóstico [6] Por otra, se tomaron las radiografías de pacientes (o de maniquíes) y se midió la dosis de entrada, sin modificar ningún parámetro de la cadena. Para la evaluación de la calidad de la imagen clínica se siguieron los criterios propuesto por la CEC y para medir la dosis de entrada se utilizaron dosímetros termoluminiscentes (TLD-100).

En la tercera fase, previa a la toma radiográfica, se modifica(n) el (o los) parámetro(s) de la cadena que pueda(n) – de acuerdo a los resultados obtenidos en la segunda fase – estar influyendo en un aumento de la dosis de radiación que está recibiendo el paciente (o el maniquí) En estas nuevas condiciones se mide la dosis y se evalúa la imagen clínica obtenida.

3. Resultados

Los trabajos se desarrollaron con la colaboración de estudiantes de pregrado u postgrado de la UCV que hicieron su tesis en el CFMD, o profesores que realizaron su trabajo de investigación en el Centro. A continuación se presentan – en forma resumida – algunos de los 53 trabajos realizados entre 1995 y 1999.

I. Evaluación y reducción de los rangos exposición en radiología odontológica en el área metropolitana de Caracas [7]

En radiología odontológica, probablemente una de las causas por la que los pacientes están expuesto a recibir mayor dosis, se debe a que se aumenta el tiempo de exposición al paciente en función de disminuir el tiempo de revelado de la película y no siguen las especificaciones para el revelado de la película dadas por el fabricante. Esto, además, puede influir en la calidad de la imagen obtenida.

Para evaluar esta situación la investigación en servicios odontológicos públicos de Caracas se midió la dosis de entrada y se evalúo la calidad de imagen con un maniquí odontológico. Se utilizaron, para ello, los parámetros de exposición y el proceso de revelado que usa el servicio visitado habitualmente. Posteriormente, en una nueva visita, se evaluaron los mismos parámetros, pero siguiendo las condiciones de preparación de químicos y procesamiento recomendado para las películas por el fabricante, y la técnica de exposición ajustada a las nuevas condiciones.

Resultados: Disminución – en algunos caso –- hasta de un 80 % de la dosis de radiación medida en los consultorios visitados y una mejora significativa de la calidad de imagen.

II. En los cinco trabajos citados se evaluó la calidad de imagen y la dosis para técnicas de bajo y alto Kvp

1. Estudio comparativo entre el alto y bajo Kvp en patología del mediastino en el servicio de Cardiología del HUC [8].
2. Calidad de la imagen y dosis en tórax en el servicio de radiología general del HUC [9].
3. Evaluación y reducción de dosis en tórax pediátrico en el Hospital Julio Criollo Rivas de Caracas [10].
4. Determinación y disminución de la dosis a pacientes sometidos a estudios de vías biliares del servicio de Gastroenterología del HUC [11].
5. Reducción de dosis en radiografías de tórax del examen preventivo del Hospital Industrial de San Tome, Estado Anzoátegui [12].
6. Resultado. Con la técnica de alto Kvp se obtuvo adecuada calidad de la imagen y la disminución de la dosis recibida por el paciente.

III. Calculo y reducción de la dosis en estudios simples de tórax, columna lumbar, y pelvis en la clínica industrial CORPOVEN-Anaco-Anzoátegui [13]

Parte de los estudios radiológicos realizados en tórax, columna y pelvis en esta clínica se utilizan con fines de contratación laborales. En este sentido, el trabajo de investigación, por una parte, evalúa el hecho de someter a las personas que solicitan empleo a una evaluación radiológica y por otra, para reducir la dosis de radiación, se cambio el tipo de películas y chasis convencionales por pantallas de tierras raras y películas adecuadas.

Resultados: Se logró disminuir la dosis y se mejora la calidad de la imagen. Asimismo se hizo una revisión de los archivos radiológicos de la clínica – para el caso de las radiografías de tórax - en lo que se refiere al valor de estos estudios para el caso de las personas que solicitan empleo, más del 90 % de las personas evaluadas presentaron una imagen de tórax normal.

IV. Elaboración de un programa de acreditación para unidades de mamografía en Venezuela y su aplicación a las unidades de hospitales públicos de Caracas [14]

En 1994 se realizó, en Venezuela, un primer trabajo en esta área, donde se evaluó la calidad de la imagen y la dosis de radiación en los mamógrafos de Caracas [15] Como continuación de ese trabajo, en el presente se elabora un programa de acreditación para unidades de mamografía en Venezuela. Asimismo, el programa de acreditación propuesto se utilizó para evaluar las unidades de mamografía de los hospitales públicos de Caracas.

Resultados: Con relación a las **características de funcionamiento y normativa que rigen el tipo de servicio médico asistencial,** no existe una normativa común, ni criterios ni parámetros de selección específicos. Con relación a la **evaluación de la calidad de la imagen del maniquí**, solo un centro está dentro de los límites de tolerancia para la prueba. En cuanto a la **calidad de la imagen clínica,** el 70 % de los centros no cumplieron criterios de colocación adecuada. Con respecto a la **exposición**, las fallas en la técnica de exposición estuvieron presentes en el 57% de las imágenes obtenidas. **La presencia de múltiples artefactos**, fue considerada como una fuente en la reducción de la calidad de la imagen. Con

relación a la **medición de la dosis de entrada**, solo una de las unidades estuvo dentro de los límites de tolerancia permitidos.

V. Dosis al personal que labora en procedimientos radiológicos con fluoroscopia en el Hospital Universitario de Caracas [16]

En radiodiagnóstico, uno de los procedimientos donde el personal recibe mayor dosis de radiación es en los estudios angliográficos. En este trabajo se evalúan los procedimientos de protección radiológica seguidas y la dosis recibida por el personal. Se le mide la dosis con dosímetros TL a nivel del cristalino, tiroides, tórax, mamas, y gónadas.

Resultados: Se determinó que el médico intervensionista recibe una dosis alta cuando no se siguen procedimientos de protección radiológica.

6. Conclusiones

Con el desarrollo del Proyecto VEN/9/007 se pone en práctica una metodología para el uso eficiente y seguro de las fuentes de radiación ionizantes en radiodiagnóstico. Sumado a esto, la incorporación de alumnos y profesores al proyecto, a través de la realización de tesis y otros trabajos de investigación, no solo da importantes aportes para el caso de Venezuela, sino que en su desarrollo están explícitos los conocimientos adquiridos por este personal y que pueden poner en práctica en su trabajo en los centros de atención médica donde laboran, lo cual contribuye a obtener imágenes de buena calidad y con dosis baja de radiación.

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IONIZING RADIATION USED IN MEDICAL DIAGNOSTICS AS A SOURCE OF RADIATION EXPOSURE OF THE PATIENT WITH OCCUPATIONAL DISEASES. ANALYSIS AND PROBLEMS

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Abstract

X-rays in medical diagnostic are the major source of bulgarian population exposure to ionizing radiations. Diagnostic X-ray is the most diagnostic application and is used in wide variety of examination. The modern concept for radiation protection of patients in diagnostic radiology is based on two main principles: justification of the examinations and radiation protection optimization. It is pointed out that the collective effective dose of radiation may be considerably reduced by decreasing the number of clinically unwarranted X-ray examination of storage and delivery of diagnostic information and adopting a system for physical and technical quality control of the X-ray equipment.
The aim of this investigation is assessment the collective effective doses for the patients with occupational diseases, exposed to ionizing radiation by radiological diagnostics.
The study covers the period of 1990 through 1999. A total of 3293 patients, treated in Department of occupational toxicology, Clinic of occupational diseases, Medical University- Sofia were examined with X-ray and KT (cervical and lumbar spine, chest, skull, stomach, extremities, pelvis, brain). The most of the observed patient were with heavy metals poisonings predominantly and a little with other chemical agents poisonings. Number of patients with radiological examinations was 1938, number of examination per capita was 0,59 and the total number of radiological examinations was 2536. The average number of radiological examination for one patient was 1,36, the most number of radiological examination for one patient was 4. The collective effective dose for an examined patient was 1803 man.mSv. Our results shown the essential of the raising ensure that the medical exposure of patients be the minimum necessary to achieve the required diagnostic objective.

1. Introduction

In many branches of medicine, ionizing radiation is a powerful tool both as an aid to diagnosis and a means of therapy. Diagnostic X-ray is the most familiar application and is used in wide variety of examination. X-rays in medical diagnostic are the major source of bulgarian population exposure to ionizing radiations. It has been estimated that over 90% of the total exposure of the bulgarian population from uses of radiation comes from the diagnostic use of X-rays [1,2,3].

There are two categories of biological effects of ionizing radiation: deterministic and stochastic effects. For stochastic effects no threshold dose is assumed and the probability of their occurrence is believed to the proportional to the dose (linear dose-effect relationship in the low dose, low dose-rate range). The probability of a fatal radiation induced cancer has been estimated at approximately 5 per cent per Sievert effective dose for the low dose, low dose-rate and 1% for serious genetic diseases, for the whole population with is normal age distribution. Many organs are believed to be sensitive to stochastic effects, notably the gonads, female breast, bone marrow, lung, thyroid and bone surfaces [4,5,6].

The modern concept for radiation protection of patients in diagnostic radiology is based on two main principles: justification of the examinations and radiation protection optimization. It is pointed out that the collective effective dose of radiation may be considerably reduced by decreasing the number of clinically unwarranted X-ray examination of storage and delivery of diagnostic information and adopting a system for physical and technical quality control of the X-ray equipment [7,9].

The aim of this investigation is assessment the collective effective doses for the patients with occupational diseases, exposed to ionizing radiation by radiological diagnostics.

2. Materials and methods

The study covers the period of 1990 through 1999. A total of 3293 patients, treated in Department of occupational toxicology, Clinic of occupational diseases, Medical University-Sofia were examined with X-ray and CT. The examination considered: chest PA (posterior-anterior) and LAT (lateral) projections, cervical spine AP (anterior-posterior) and LAT projection, lumbar spine AP, LAT and LSJ (lumbo-sacral-joint) projection, skull- PA and LAT, hand and wrist AP, pelvis AP, Ro-contrast stomach, CT brain. The most of the observed patient were with heavy metals poisonings predominantly and a little with other chemical agents poisonings.

For an assessment of the collective effective dose, the radiological examined patients were distributed by age, number of radiological examinations, and structure of radiological diagnosis.

Number of patients with radiological examinations was 1938, number of examination per capita was 0,59 and the total number of radiological examinations was 2536.

3. Results and discussion

The number of treated patients, the number of patients with radiological examinations, the total number of conducted radiological examinations, and the number of radiological examinations for one patient, distributed by the observed years are shown in Table I.

Table I. Number of treated patients, patients with radiological examinations, total number of conducted radiological examinations, and radiological examinations for one examined patient

Year	Number of treated patients	Number of examination patients	Number of radiological examinations	Number of examinations for one examined patient
1990	331	195	265	1,35
1991	342	202	273	1,35
1992	347	204	255	1,25
1993	335	189	246	1,30
1994	342	201	281	1,40
1995	348	202	272	1,35
1996	342	202	282	1,40
1997	338	201	251	1,25
1998	328	198	257	1,29
1999	246	153	214	1,39
Total	3299	1938	2596	

The results in the Table I shows the average number of radiological examinations for one examined patient was 1,36, the most number of radiological examinations for one patient was 4. The ratio (number of radiological examinations) / (number of treated patients) is 0,79.

The distribution of the treated patients by the age and sex for 1998 is presented in Table II. The number of radiological examinations included in Table II consists only X-ray graphy as

there is unclear patient dose in X-Ray scopy because different time examinations. The structure of radiological diagnosis, effective dose per one radiological examination – patient dose H_{eff} (mSv) and collective effective doses are presented in Table III.

Table II. Distribution of the number of treated patients by the age and sex for 1998

Age of patients	Number of patients attending hospital		Total	Number of radiological examinations (X-ray graph)		Total	Number of examinations for one patient
	man	woman		man	woman		
18-25	8	3	11	2	-	2	0,18
26-45	105	43	148	51	34	85	0,58
46-55	100	38	138	42	51	93	0,67
56-60	16	6	22	6	3	9	0,41
>60	6	4	10	1	-	1	0,10
Total	235	94	328	102	88	190	0,58

Table III. Structure of radiological diagnosis, effective dose per one radiological examination – patient dose H_{eff} (mSv) and collective effective doses for 1998

Structure of radiological diagnosis	Number of radiological examinations	H_{eff} (mSv)	Collective effective doses (man.mSv/y)
Ro-graphy: Chest- PA, LAT	48 15 -total 63	0,08mSv	5,04
Cervical spine- AP, LAT	48 12 -total 60	0,7mSv	42
Lumbar spine- AP, LAT, LSJ	19 2 2 -total 23	1,3mSv	29,9
Scull- PA, LAT	20 9 -total 29	0,7mSv	20,3
Hand and wrist - AP	15	0,7mSv	10,5
Pelvis- AP	5	0,7mSv	3,5
Ro-contrast stomach	13	3,0mSv	39
CT brain	6	5,0mSv	30
Total	214		180,24

The data in Table II show the most number of the patients treated in clinical conditions are between age range 26-45 and 46-55. The number of radiological examinations per capita varied from 0,10 to 0,67, and the mean value was 0,58. The results in Table III for the structure of radiological diagnosis show the most number of radiological examinations are for the chest and cervical spine- 63 and 60 respectively.

For the investigation period (1990-1999) diagnostic medical exposure provides 0,54 mSv/y average dose per patient.

4. Conclusions

The Bulgarian population exposure, presented as a mean annual effective collective doses, amounts to: 20240 mSv/y from natural background, 6400 mSv/y from X-ray diagnostics; the average effective dose from X-ray diagnostics- 0,34 mSv/y. Number of examination per capita for Bulgarian population (period 1990-1995y) is 0,59 [8]. Worldwide, diagnostic medical exposures provide 0,3 mSv/y average dose per capita [9].

The received doses from the patients with occupational pathology are more high than the doses mentioned above. Our results shown the essential of the raising ensure that the medical exposure of patients be the minimum necessary to achieve the required diagnostic objective.

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PATIENT'S AND OCCUPATIONAL DOSE EXPOSURE IN ROENTGEN EXAMINATIONS

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Abstract

The study of roentgen exposure in diagnostics, is a constant obligation everywhere because: (a) the higher number of people undergoing roentgen examination and (b) relative high exposure doses during examinations. We are interested about exposure doses for patients and occupational staff only. Nevertheless, being linked with the main goal of our paper: **"exposure dose**" we would give below the figures of frequencies for widely performed examinations, just to calculate such parameters like mean exposure dose and collective effective dose.

The use of ionizing radiation in Albania is as follow: about 70% belong to the medical application and 30% to the others, research, agriculture and industrial applications.
From the medicine uses 80% belong to the X-ray and 20% radioactive sources. The use of X-ray procedure in medicine is 85% in diagnostic and 15% in radiotherapy.
In this way, the main field, which contribute of exposure doses for both, population and occupational staff in Albania, is X-ray diagnostic irradiation. The amount of exposure dose as well as the collective dose coming up from X-ray in diagnostic is about 75-80% of total value for above-mentioned parameter.

1. Introduction

The evaluations of exposure dose are given separately, for patients and occupational staff. From these values of exposure dose, we tried an approach, through extrapolation for total exposure dose coming up from all X-ray diagnostic examinations. For such evaluations (of patient doses) we use the data carried out during 80-th in vitro and vivo with TLD, furnish by IAEA and EC, as well as the data performed with PMX-meter.

We have discussed about most widely used examinations as: chest and stomach fluoroscopic procedures, skeleton and head & neck radiographs, which have the frequencies of 307,20,140 and 50 exposure/year/100 inhabitants respectively.

The justification and optimization principles as the main principles in radiation protection field have been in our consideration during X-ray examination [1]. The number of diagnostic X-ray examinations in Albania has not increased significantly in recent years.

UNSCEAR (United Nations Scientific Committee on the Effects of Atomic Radiation) recommends regular surveys of the number of X-ray examinations in order to study the trends and differences in the use of radiation between different countries. Changes in the distribution of X-ray examinations contribute to changes in the collective dose of the population [1, 2].

2. Material and methods

Actually, the individual monitoring (workers+patients) has been performed, during our study with TLD-100 cards, given by IAEA, which control was established already.

Every month, the Personal Dosimetry Division in Institute of Nuclear Physics (INP) distributes about 300 pieces of TLD-100 cards to measure the effective dose of employees at the nuclear facilities in Tirana city. We tried to extents the personnel, patients and population control by

TLD-s cards in some other cities of Albania, for instance in Durres, Korça, Shkodra cities, we have three months control only.

Table la. Frequency / 1000 inhabitants / year in vitro examinations

GRAPHIES					FLUOROSCOPIES	
Head & Neck	**Chest**	**Abdomen**	**Pelvis**	**Extremities**	**Chest**	**Stomach**
50	60	10	20	50	307	20

For these measurements we have used the Harshaw TLD-s. For each type of examination we performed at least 8 sets of measurements, and for each set we have used10-15TLD-s.

Table lb. Frequency / 1000 inhabitants / year in vivo examinations

GRAPHIES					FLUOROSCOPIES	
Head & Neck	**Chest**	**Abdomen**	**Pelvis**	**Extremities**	**Chest**	**Stomach**
42	45	10	17	52	280	15

The most significant contribution to the radiation dose to population is mainly due to **in vivo** examinations. While results in table lc shown the figure of the mean annual effective dose for occupational staff of Tirana City during 1997,1998, 1999 years [3].

Table lc. Mean Annual Effective Dose of occupational Staff in Tirana city

No		Mean Annual Effective Doses **(mSv)**		
	Occupational Practices	**1997**	**1998**	**1999**
1	HOSPITAL No. 1	3.45	3.50	2.95
2	Ptisio-Pneumology Hospital	3.40	3.90	4.30
3	Dispensary anti TBS	4.60	4.55	4.45
4	Nuclear Medicine	3.39	4.65	4.20
5	Regional Polyclinic No. 2	4.65	4.80	4.85

So, for instance to keep the exposure dose for chest fluoroscopy, we have measured 10 different patients, and to each patient we put on the skin surface of chest size 15 TLD-s, as well as about 10 TLD-s in other points outside of chest size, like gonads, eyes, etc.

A set of output X-ray beam's tube, without patient, at the same conditions (RV; mAs; source-skin-distance; beam aperture) were performed with ionizing chamber to verify the values of exposure doses measured by TLD-s.

The last one were carried out with universal dosimeter+ionizing chamber of appropriate volume, HVL etc. [2, 4].

In table 2a is show an example of output verification for beam used in chest fluoroscopy (85 Rv; 1.3 mA).

Table 2a. Output verification for beam in chest fluoroscopy (85 RV; 1.3 mA)

Exposure time (sec).	15	10	18	30	20	24	30	20
Measure by TLD (mGy)	9.5	8	10	17.2	15	19.3	22.1	14
Tubeo output values mAs	0.48	0.61	0.42	0.44	0.58	0.61	0.54	0.52
Measure by ionizing chamber mGy	11.5	9.4	14.2	23.7	15.7	18.9	23.2	15.7
Tube output measured ionizing chamber mAs	0.59	0.72	0.61	0.61	0.60	0.60	0.62	0.61

The figure in third and fifth rows represents the tube output values (mAs), while in the last column is shown the mean values of each one set. The difference of those in percentage is about 11%; which is a good agreement between two sets.

The exposure doses, in average values, calculated for 8-15 examinations of each type are shown in table 2b.

Table 2b. The values of exposure doses for different examinations (mRem)

Methods	GRAPHIES					FLUOROSCOPIES	
	Head & Neck	**Chest**	**Abdomen**	**Pelvis**	**Extremities**	**Chest**	**Stomach**
TLD-s	140 (15)	50 (15)	650 (10)	820 (12)	20 (15)	112 (20)	200 (9)
Ionizing **Chamber**	60 (15)	52 (12)	500 (10)	900 (12)	30 (15)	136 (20)	300 (9)

The values in brackets showed the number of measurements for a given type of examinations. The set b **(in vivo)** of measurements was carried out for different examinations with Harshaw TLD-s with parallel with TLD furnish by EC. Furthermore were done directly the measurements of different beam's output with PMX-meter.

The agreement between both sets a (in vitro) and b (in vivo) of measurements is quite good within the limits of fluctuation down by the differences of parameters used for the same type of examinations in different X-ray machines. In table 2c are shown the average values of beam output per 1 mAs for different X-ray machines and different types of examinations.

Table 2c. Average values of beam output in mRem / 1 mAs

Methods	GRAPHIES			FLUOROSCOPIES	
	Chest + Abdomen	Abdomen + Pelvis	Head + Neck	Chest	Stomach
TLD-s	60	100	80	65	95
Beam output	70	105	77	75	100

3. Results

The main goal of our study is to calculate the mean exposure dose per capita-year of population. Our results are extrapolate to whole population because:

- The frequency of X-ray diagnostic exposure for above-mentioned examinations is high (the average value of la and lb figures is about 500 examinations / 1000 inhabitants/Year and adding to this value those of other types of examinations, not included in our paper, the frequency will be more than 750 for patient examination. It means that the **"Patient Group"** is almost equal with **"Whole Population Group".**
- Taking into account, X-ray biologic damages, we need to have common average level of irradiation for whole population, where in this case are included and occupational staff, who are working in ionizing radiation field too.

So, from the point of view of common average level in table 3, represents the average values for each type of examination carried out from tables 2a; 2b as well as from all TLD-s measurements.

Table 3. The average values of exposure dose for different examination (mRem)

	GRAPHIES				FLUOROSCOPIES	
	Head + Neck	**Chest**	**Abdomen**	**Pelvis**	**Chest**	**Stomach**
Average values of exposure dose	193	53	612	800	227	464
Frequency	51	46	53	10	294	18
Exposure dose/capita	3.8	1.15	11.55	80	0.8	25.8

The annual exposure dose per capita, given from patient's examinations is about 62.64 mRem (0.6264 mGy) and about 0.5123 for occupational staff.

4. Discussions

The examination groups, patients and occupational staff, studied in our paper, excluding the pelvic and abdominal part of skeleton, have a limited contribution to the annual exposure dose.

The above-mentioned values (0.6264 mGy) for patients and (0.6123 mGy) for occupational staff, have represented about 45-50% of total exposure dose coming up from X-ray diagnostic examinations.

Our results are in a good agreement with those of our European colleagues, in which for groups of examinations like: the CT, Barium Enema, and Double Contrast, Lumper Spine, Carotit Angiography and Intestinal Transit, the contribute to the annual exposure dose per capita, is greater (about 66%) than our case [1, 2].

Consequently the annual exposure dose in Albania, result more than 1.2 mGy/year per capita.

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IAEA-CN-85-81

INDONESIA'S EXPERIENCE WITH IAEA-CRP* ON RADIATION PROTECTION IN DIAGNOSTIC RADIOLOGY

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Abstract

IAEA-CRP on Radiation Doses in Diagnostic Radiology and Methods for Dose Reduction has been participated by some Asian and East European countries. Indonesia is one of participants that followed the IAEA program. This paper is not disscuss of CRP-results since it will be published on TECDOC soon. But the work on evaluation of examination frequencies, film reject rate analysis, patient dose measurements, image quality before and after Quality Control (QC) and QC itself gave some experiences to investigator to be explored and presented. Experiences could be in form of problems, how to solve problems and some suggestions. Started from no QC up to complicated QC to be face on conventional radiography to CT-scan and fluoroscopy units. These valuable experiences of Indonesia are proven exercise of IAEA-CRP as a good start for next CRP or national projects in diagnostic radiology.

1. Introduction

The Indonesia as a developing country with population of more than 200 million people have many problems on radiology diagnostic services. It is not only facilities, but also human resources to serve of about 100 million people if approximately 50 percent of population occupy this health service. The number of x-ray diagnostic machines nationally is only about 1197 units that spread to the whole country which have of about 5000 islands. Quality of services is very important one to success the aim of diagnoses.

Two well known International agencies that concern radiological health care all over the world are World Health Organization (WHO) and International Atomic Energy Agency (IAEA). WHO activities on radiological health care for Member states assist in developing a policy of services through publication, experts adviser and training for increase knowledge and skill human resources [1]. On the other hand, IAEA seek to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity through the world [2]. Indonesia as a Member of both WHO and IAEA, is always participated their activities.

The International Commission on Radiological Protection (ICRP) published recommendation concerning the radiation protection in diagnostic radiology is an ideal concept that it is not a simply practical implementation. Optimization needs more efforts to success radiation protection in diagnostic radiology that is more attention on daily practices.

A Coordinated Research Program (CRP) on assessment of radiation doses in diagnostic radiology and studying methods for reduction was firstly started in IAEA Member States in cooperation with the Commission of the European Communities (CEC) [3]. A second CRP-IAEA that Indonesia is one of the nine Asian country regionally participated on Radiation Doses in Diagnostic Radiology and Methods for Dose Reduction Project. There were two phases to complete the project, which were Conventional radiography for the first phase and Flouroscopy and CT-scan for the second.

* IAEA-CRP is International Atomic Energy Agency-Coordinated Research Project.

The Technical Assistance (TA) has been planned to develop quality assurance program on medical application of ionizing radiation nationally, especially in diagnostic radiology. A scenario has planned on 1993 to develop a quality assurance program as required for radiodiagnostic examination in Indonesia for some hospitals. The action plan of the idea was performed through technical cooperation of International Atomic Energy Agency (IAEA). The National Workshop on Quality Assurance and Radiation Protection in Diagnostic Radiology was dedicated to radiologist, radiographers and medical phycisists on 1994. The workshop was organized by our institution joint with Radiologist's society and one of the hospitals that participated on the project. Introducing and understanding of radiation protection optimization in diagnostic radiology has been given on lectures by some international experts. Practical sessions were also organized on the last day of five day's workshop.

2. Basic understanding of the project

It is necessary to participants of the CRP's to understand the main objective of project, especially for investigators. Fundamental basis of radiation protection in diagnostic radiology on The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Sources (BSS) needs more elaborations. Optimization of radiation protection by means a quality assurance program and dose reduction methods is also necessary to elaborate practically for them. Thinking separately of dose reduction to patients without inherently improvement of image quality is not satisfactory for optimization in protection radiation. However, this is not simple to be implemented on daily practices.

3. Selection of hospitals

The project should participate one major hospital and three satellite hospitals. Before choosing hospitals that participated the project, investigators should have data for number of patients, type of examination - projection and facilities those hospitals. Unless the project will not complete as the schedule time.

- **Number of patients and type of examinations**

Eight x-ray projections that selected on the project were chest PA and lateral, LS-AP, LSJ (L5-S1) lateral, pelvis AP, skull Pa and lateral. Problems arrive from number of patients. Each hospital has own number of patients, as an example the major hospital recorded daily minimum and maximum patients for chest PA respectively were 34 and 71 patients. While the satellite hospital, 10 and 30 patients for daily minimum and maximum patients respectively. It was seen that the daily maximum number of patients at satellite hospital to be the daily minimum number of patients of the major hospital. This number affects to percentage of reject film statistically. Next experience was founded when evaluation to be done for limited (less) - not many patients (examination) such as skull PA on the satellite hospital and LS lateral for the other satellite hospital.

The above problems were not only for film reject analysis, but also for patient dosimetry measurements. To complete 10 patients of weight 65± 10 kg to 8 type examination may be require more than scheduled time. So that, some satellite hospitals could not complete and continued for patient dose measurements, moreover it will be automatically a evaluation of image quality problem.

It seems that the number of patients and type of examination (8 x-ray projections) for he first phase of IAEA-CRP could not perfectly be completed on the schedule time as it was planned before. Three satellite hospitals were targeted to participate and complete the IAEA-CRP, two hospitals were dropped. It was just because of limited the number of patients for some type examinations. Solution could be done by choosing satellite hospitals on the other city to get enough number of patients of some type examinations, like Bandung, Semarang or Surabaya cities. However, the other problems will occur from transportation and coordination when the action plan to be implementation.

Next experiences happened when second phase project started. Selection of hospitals on the first phase based on feasibility study of conventional radiography. The hospitals that participated on first phase, it would be possible to continue their participation on second phase. Actually, fluoroscopy units on the hospitals that participated on first phase were not as many as required. Alternative hospital should be participated to fulfil the second phase of project. Since difficulties on the target of patient weight on the first phase, so the second phase patient weight was lowered to be 60± 10 kg. Due to limited patients on CT chest examination and standard QC CT-phantom, Indonesia could not complete this part.

- **Facilities and equipment used**

Number of patient consideration when choosing hospitals is not enough without take account facilities - equipment used on hospitals. Minimum performance criteria of the facilities and equipment should be have to success the IAEA-CRP. Choosing facilities - equipment to be used for IAEA-CRP will affect to daily schedule hospitals if unusual facilities alter their functions, such as a x-ray unit used to LS examination than change of function to chest examinations.

Problems come out after the units were evaluated for QC. The condition of unit is less possible to get good image and low doses, such as not possible to reach high kVp and the stability of unit. This is happened at major hospital. By this experience, minimum requirement of facilities and equipment should be identified before IAEA-CRP to be done. These are not only performances of facilities and equipment, but also the possibility to increase image quality and to minimize doses.

TLD reader as a basic equipment of patient dose measurements could not work perfectly. Unfortunately, it could not be repaired soon. That was happened for 4 months. New reader was prepared to solve this problem. Meaning that on this IAEA-CRP, two TLD readers were used. Another experience according to TLD was loss TLD materials, since it were brought by patients. Two problems come out for dose patient measurement of fluoroscopy examination, one from limited of patient number then second from dosemeter. Patient dose measurement of fluoroscopy examinations is dependent on Dose Area Product (DAP) dosemeter.

4. Conclusion

IAEA-CRP need more efforts, such as understanding of concept as the whole, feasibility study of condition participants (number of patients, type of examinations, facilities and equipment used) that carry the project. Project like IAEA-CRP on Radiation Protection in Diagnostic Radiology practically is not simple to be implemented to whole hospitals nationally. This experience might be useful for institutions or organizations that offers grants. Support from government or such international organizations is very helpful to run quality control program.

Acknowledgements

The author is grateful to all hospitals involved and for help and assistance from the staffs. The author also wishes to thank to IAEA that allowed Indonesia to participate on CRP on Radiation Protection in Diagnostic Radiology.

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IAEA-CN-85-99

RADIATION PROTECTION OF PATIENTS IN GENERAL DIAGNOSTIC RADIOLOGY IN LITHUANIA

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Abstract

The situation in control of exposure due to general diagnostic radiological examinations in Lithuania is described. Experience in creation of legal basis for radiation protection, results of measurements of patients' doses and quality control tests of x-ray units are given. The main problems encountered in implementation of international recommendations and requirements of European Medical Exposure Directive are discussed.

1. Introduction

Lithuania with 3.7 million of population has more than 1100 diagnostic x-ray machines. According to the UNSCEAR classification Lithuania is in the group of states of health care level I. More than 2 million of x-ray examinations are being performed each year. It indicates that medical exposure due to diagnostic radiology is the important source among all the other sources. Individual doses to patients in some cases may be rather high, because units older that 20 years are still in operation. It is evident that control of doses to patients and their radiation protection are very important.

2. National requirements for radiation protection in medicine

Development of the legal system was started in 1996 with adoption of the Lithuanian Hygienic Norm HN 73-1997 *Basic Standards of Radiation Protection.* Three international documents [1-3] were taken for a basis of this Hygienic Norm. Specific hygiene norms on radiation protection in x-ray radiology, nuclear medicine and radiation protection have been adopted later.

General principles of radiation protection of patients (justification of medical exposure, optimization of radiation protection) are to be followed in all the fields of medical applications of radiation including diagnostic radiology. Medical exposure may be applied only in case the patient has a prescription for this procedure. Medical practitioner is responsible for radiation protection of individual patient. Special measures shall be taken to protect the pregnant women.

Guidance levels of dose for diagnostic radiography are established. The levels recommended in the BSS [1] are taken as a basis for the guidance levels. Some modifications of these levels are based on results of measurements of patients' doses. These modifications recommend higher entrance surface doses than doses, given in [1].

Criteria of acceptability of performance of diagnostic x-ray units as established by EC [4 were taken. Results of pilot tests of quality control of x-ray units were used for establishment of these criteria. These results showed that the significant part of old x-ray units can not meet some of the recommended criteria. For this reason exceptions are applied to units which are manufactured before January 1st of 1997. The exceptions are for such parameters as the maximum dose rate at the entrance screen of conventional image intensifier (1.6 μGy/s. instead of recommended 0.8 μGy/s.), minimum operating tube voltage of dental units (45 kV

instead of 50 kV), deviation of exposure time from set values, some features of automatic exposure control. Such approach allows use of available x-ray units without major reconstruction of them. In many cases this reconstruction is not possible nor feasible.

Two particular problems should be mentioned. One of them is connected with the requirement of the BSS [3] on not to use fluoroscopy units without image intensifier. There are such units still available in Lithuania. Lithuanian Hygiene Norm on radiation protection in x-ray radiology does not allow use of such units after the January 1st of 2002. This deadline is 2 years later than the deadline determined by the Medical Exposure Directive. It is connected with the restricted financial possibilities of the state.

Photofluorography units are still used in Lithuania, mainly for screening purposes. More than 100 examinations are being performed each year per 1000 population. Higher doses and poorer image quality are the reason for abandoning of this type of procedure in many countries. The complicated tuberculosis situation in Lithuania requires chest examinations, and not always conventional x-ray units are available. Investigation of justification of this type of examinations has been started. It will be basis for taking decision about expedience of photofluorography.

The experience from creation of legal basis shows that close co-operation between regulatory authority and interested health care institutions and availability of results of actual investigations of patients' doses, quality control of radiological equipment may be helpful in creation of effective legislation.

3. Doses to patients

RADOS TLD system is used for measurements of patients' doses. Measurements are performed in randomly selected x-ray departments all around Lithuania. LiF pellets without slide holders in black bags are taped on the skin of the patient in the centre of x-ray field in the direction to the x-ray tube. Sex of patient, his/her weight, height and thickness in the centre of x-ray field, exposure parameters such as kVp, mA or mAs, size of x-ray field, focus-film distance, total filtration are written down in the special protocols. Since there is a shortage of standard size patients, doses to all the patients available during period of measurements are recorded. The average weight of patients in different departments was (66±12) to (77±18) kg (95% of confidence). It indicates that if a number of patients is not large enough, differences in their weights are not essential.

The results of measurements are presented in Fig. These results show that in some hospitals the reference levels, established by the Lithuanian *Basic Safety Standards* are exceeded more than 2 times. It indicates that these levels should be reviewed. New reference levels at the 75^{th} percentile of measured doses should established [5]. For this reason the trial which includes larger number of hospitals of different level is about to started.

The effective doses due to the chest (PA) examinations have been calculated using [6]. The distribution of doses is log normal, with the maximum at 0.2 mSv. The average of effective dose received during chest PA examinations is (0.06±0.02) mSv.

The average effective dose received during photofluorography in two hospitals was (0.32±0.10) mSv per image. It should be pointed out that averages of effective doses in these

hospitals are rather different - (0.46±0.14) and (0.14±0.03) mSv per image. These results show, that the risk/benefit analysis of such type of examinations shall be performed though not only doses but quality of image should be taken into account.

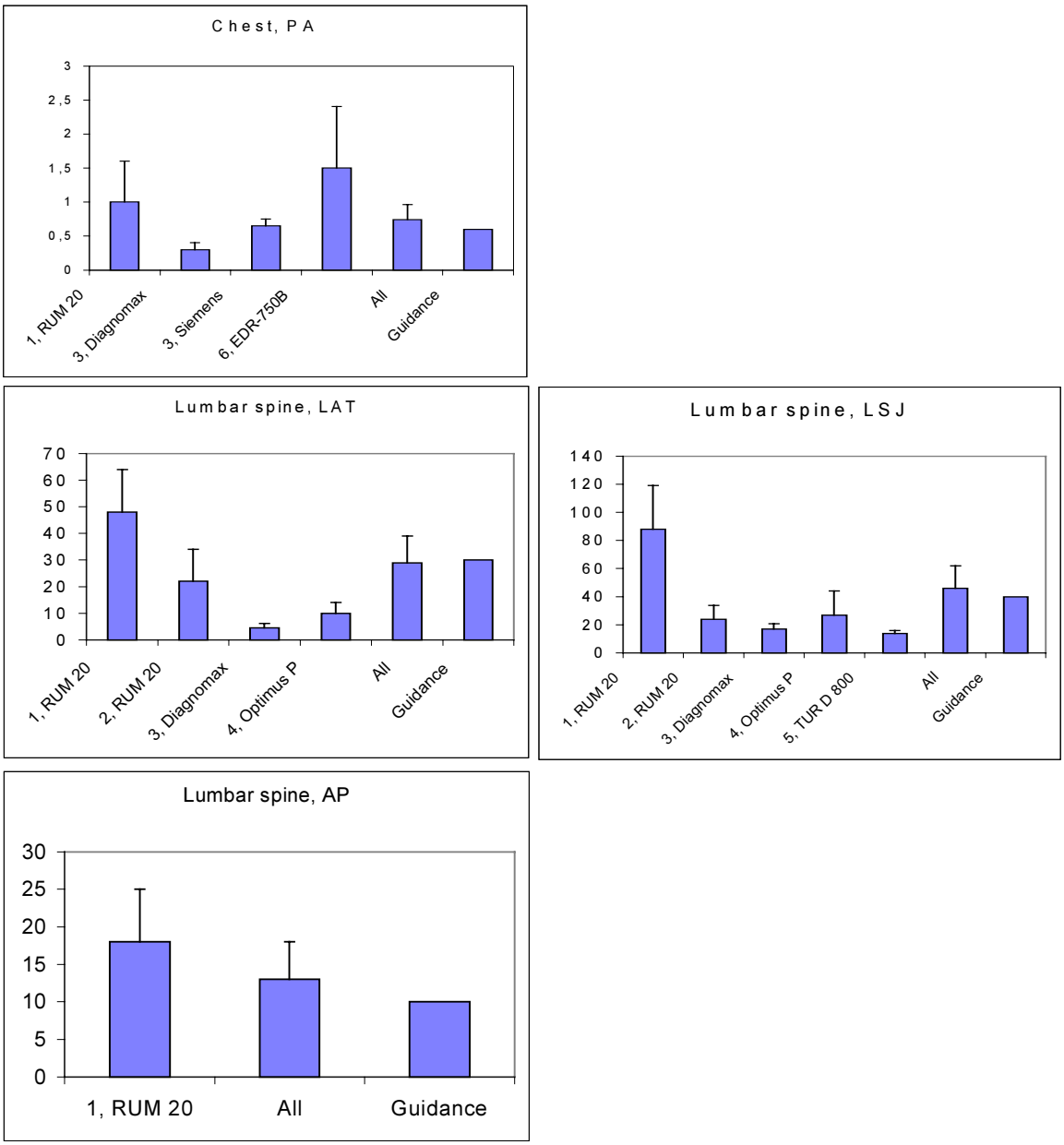

Fig. Results of measurements of patients' entrance surface doses (in mGy) in different departments using different x-ray equipment (indicated). Error bars are for 95% of confidence

4. Performance of x-ray units

Quality control of x-ray machines is performed with the help of PMXIII by RTI Electronics. 143 units were checked in 1998, 150 - in 1999. In 2000 this number increased because quality control became a condition for licensing. The results of these tests are presented in the Table.

Table. Results of quality control of diagnostic x-ray units

	Checked	Did not pass	Fixed	Not fixed
Dental units	142	4	3	1
Portable units	59	5	3	2
Conventional units	85	25	24	1
Mammography units	7	0	0	0
Photofluorography units	28	5	5	0
Angiography units	2	0	0	0
Total	323	39	35	4

Most frequently x-ray units do not pass tests because of problems with high voltage generator (poor waveform), too low x-ray tube voltage, dose linearity and timer accuracy. Dose repeatability and too low voltage are the main problems in dental x-ray units during acceptance testing.

It is seen that quality control is the powerful tool in improving of performance of x-ray units. Nearly 90% of units were successfully repaired. On the other hand, even new dental units do not pass testing. It shows the importance of acceptance testing.

5. Conclusions

During the last 5 years Lithuania is making intensive efforts in improving of radiation protection of patients. International recommendations and requirements of European Directives is the powerful moving force. However, many radiologists are used to very prescriptive system, which was in force until the beginning of 90s. The lack of qualified experts is to be mentioned on this occasion. It results in very heavy workload of regulatory authority, which should perform calculations of shielding thickness, quality control tests, measurements of dose rate in workplaces.

On the other hand, the Radiation Protection Centre shall collect the most recent information on operational radiation protection in order to prepare the effective standards, rules and recommendations. These documents shall be drafted in close co-operation with radiologists, radiation protection advisers, hospital physicists. However, it remains the problem. Hospital radiation workers are not motivated to take part in drafting of these documents, even in discussions of drafts.

Quality assurance remains the very sensitive point in the whole system of the patient radiation protection. Hospitals are trying to rely on results of annual quality control checks, performed by the Radiation Protection Centre and other organizations. Everyday control of developing process, analysis of image quality should be introduced.

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DOSES TO PATIENTS FROM DIAGNOSTIC RADIOLOGY IN ROMANIA

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Abstract

Effective doses to over 2400 patients undergoing 20 most important types of X-ray examinations have been estimated from entrance surface doses or dose-area products, measured in 27 X-ray departments, and the appropriate conversion coefficients calculated by the NRPB for six mathematical phantoms representing 0, 1, 5, 10, 15 year old children and the adult. The patient-weighted mean effective dose from X-ray examinations performed annually in Romania is 1.32 mSv, with 1.40 mSv for the average adult patient and 0,59 mSv for the average paediatric patient. The corresponding annual collective effective dose is about 13,430 manSv, with the main contribution belonging to adult patients (95%), the remainder of 5 percent – to paediatric patients.

1. Introduction

Diagnostic radiology represents throughout the world the largest manmade source of public exposure to ionising radiation. In Romania, on our last estimate, its contribution to the annual collective effective dose from artificial radiation sources is about 90 percent [1].

The present work intended to update the magnitude of patient exposure (children and adults) during conventional diagnostic X-ray examinations performed annually in Romania.

2. Methods

Individual effective doses to over 2400 patients undergoing 20 most frequently performed types of X-ray examinations at 27 diagnostic X-ray departments have been derived from entrance surface dose (ESD) measured with TLD-100 thermoluminiscent dosemeters directly stuck to the patient's skin or dose-area product(DAP) measured by a Diamentor transmission ionisation chamber attached to the diaphragm housing of the X-ray set [2]. Appropriate conversion coefficients, calculated by the NRPB using Monte-Carlo techniques on a series of 6 mathematical phantoms representing 0, 1, 5, 10, 15 year old children as well as the adult, have been applied [3, 4].The age-dependent frequencies of X-ray examinations necessary for the annual collective effective dose and the average patient effective dose calculation are those reported by our last national study on medical exposures, published in the UNSCEAR-2000 Report [5].Measurements have been carried out from July 1997 to July 2000 and all dosemeters have been calibrated at WHO Regional Reference Centre for Secondary Standard Dosimetry, Bucharest, Romania.

3. Results

Tables I–VI summarise the results of our survey on patient exposure during X- ray examinations in terms of Dose-Area Product (DAP), Entrance Surface Dose (ESD) and effective dose per examination.

Table VII presents the patient-weighted effective doses per examination and the annual collective effective doses received by patients as a result of one year of diagnostic conventional X-ray examinations in Romania. The values are of 1.32 mSv from all medical exams and 13,432 manSv for collective dose.

Table I. Individual and annual collective effective doses to 0 year old patients

Examinations	Annual number of patients	DAP (Gy cm^2)	Effective dose (mSv)	Annual collective effective dose (man Sv)
Chest radiography	35,998	0.11 ± 0.05	0.18 ± 0.08	6.5
Full spine	1,103	2.2 ± 1.3	3.5 ± 2.4	3.9
Pelvis, hip	8,761	1.7 ± 1.4	3.1 ± 0.8	27.2
Head	8,395	0.80 ± 0.10	0.32 ± 0.07	2.7
Abdomen	3,215	1.2 ± 0.8	2.0 ± 1.3	6.4
Cystourethrography	2,246	2.4 ± 1.0	5.6 ± 2.2	12.6
Urography	473	5.4 ± 2.8	8.6 ± 4.5	4.1
Limbs, joints	3,065		0.08	0.2
All medical examinations	63,256		1.0	63.6

Table II. Individual and annual collective effective doses to 1 year old patients

Examinations	Annual number of patients	Dose Area Product (DAP) (Gy cm^2)	Effective dose (mSv)	Annual collective effective dose (man Sv)
Chest radiography	63,334	0.17 ± 0.09	0.11 ± 0.07	7.0
Chest fluoroscopy	12,882	0.80 ± 0.45	0.53 ± 0.30	6.8
Full spine	2,190	4.6 ± 3.9	3.2 ± 2.7	7.0
Pelvis, hip	23,280	3.8 ± 1.4	3.5 ± 1.3	81.5
Head	5,025	2.0 ± 0.9	0.28 ± 0.11	1.4
Abdomen	12,860	0.46 ± 0.20	0.20 ± 0.10	2.6
Cystourethrography	3,546	1.8 ± 0.8	2.9 ± 1.1	10.3
Urography	709	10.8 ± 4.7	6.1 ± 2.7	4.3
Limbs, joints	60,872		0.08	4.9
All medical exams	184,698		0.68	125.8

Table III. Individual and annual collective effective doses to 5 year old patients

Examinations	Annual number of patients	DAP (Gy cm^2)	Effective dose (mSv)	Annual collective effective dose (man Sv)
Chest radiography	65,770	0.31 ± 0.12	0.10 ± 0.04	6.6
Chest fluoroscopy	86,061	0.76 ± 0.42	0.38 ± 0.21	32.7
Full spine	1,314	7.2 ± 4.4	4.0 ± 2.1	5.3
Pelvis, hip	10,200	5.1 ± 2.5	3.0 ± 1.6	30.6
Head	12,530	5.3 ± 2.8	0.30 ± 0.16	3.8
Abdomen	4,296	1.3 ± 0.7	0.8 ± 0.3	3.4
Cystourethrography	2,492	4.6 ± 1.4	2.4 ± 0.7	6.0
Urography	945	6.2 ± 3.3	3.8 ± 1.6	3.6
Barium meal	9,252	1.6 ± 0.8	1.0 ± 0.5	9.3
Limbs, joints	51,676		0.08	4.1
All medical exams	244,536		0.43	104.4

Table IV. Individual and annual collective effective doses to 10 year old patients

Examinations	Annual number of patients	DAP (Gy cm^2)	Effective dose (mSv)	Annual collective effective dose (man Sv)
Chest radiography	58,192	0.57 ± 0.20	0.12 ± 0.04	7.0
Chestphotofluorography	12,442	1.1 ± 0.4	0.26 ± 0.10	3.2
Chest fluoroscopy	77,565	1.2 ± 0.80	0.38 ± 0.25	29.5
Full spine	2,628	13.5 ± 5.3	5.3 ± 1.8	13.9
Pelvis, hip	13,080	22.0 ± 7.0	3.6 ± 1.2	47.1
Head	11,702	6.8 ± 2.2	0.34 ± 0.12	4.0
Abdomen	3,190	3.9 ± 2.2	1.2 ± 0.7	3.8
Cystourethrography	516	14.5 ± 5.3	2.5 ± 0.9	1.3
Urography	1182	14.1 ± 9.0	4.2 ± 2.7	5.0
Barium meal	10,453	3.8 ± 1.9	1.6 ± 1.0	16.7
Limbs, joints	54,741		0.08	4.4
All medical exams	245,691		0.55	135.9

Table V. Individual and annual collective effective doses to 15 year old patients

Examination	Annual number of patients	DAP (Gy cm^2)	Effective dose (mSv)	Annual collective effective dose (man Sv)
Chest radiography	47,365	0.73 ± 0.21	0.13 ± 0.04	6.2
Chest photofluorography	49,769	2.9 ± 0.6	0.40 ± 0.10	19.9
Chest fluoroscopy	97,572	1.8 ± 1.1	0.33 ± 0.25	32.2
Spine - lumbar - cervical	10,283 11,437	18.8 ± 7.1 2.4 ± 1.3	4.5 ± 1.9 0.57 ± 0.32	46.3 6.5
Pelvis, hip	7,260	23.5 ± 10.3	3.4 ± 1.5	24.7
Head	25,950	6.1 ± 2.7	0.21 ± 0.11	5.4
Abdomen	2,161	3.8 ± 1.2	0.85 ± 0.27	1.8
Cystography	194	20.4 ± 6.4	2.2 ± 0.7	1.4
Urography	1418	21.4 ± 11.5	4.8 ± 2.6	6.8
Barium meal	20,346	8.4 ± 5.1	2.1 ± 1.1	42.7
Limbs, joints	48,610		0.08	3.9
All medical examinations	322,365		0.61	196.8

Table VI. Annual individual and collective effective doses to adult patients undergoing some conventional X-ray examinations

Examination	Annual number of patients	ESD (mGy)	Effective dose (mSv)	Annual collective effective dose (manSv)
Chest radiography	943,059	2.4 ± 1.0	0.25 ± 0.11	235.8
Chest photofluorography	2, 330,493	5.9 ± 2.8	0.63 ± 0.30	1468.2
Chest fluoroscopy	2, 263,700	13.4 ± 5.6	0.95 ± 0.40	2150.5
Spine - lumbar - thoracic - cervical	224,849 75,151 196,513	51.3 ± 24.0 29.5 ± 14.1 10.3 ± 4.9	3.0 ± 1.4 2.1 ± 1.2 0.21 ± 0.1	674.5 157.8 41.1
Pelvis	195,708	17.1 ± 9.4	2.9 ± 1.6	567.6
Hip	69,761	19.2 ± 5.6	1.7 ± 0.5	118.6
Head	390,695	20.0 ± 14.1	0.17 ± 0.12	66.4
Abdomen	312,728	19.3 ± 10.3	1.9 ± 1.0	594.1
Barium meal	986,902	55.2 ± 25.6	4.1 ± 1.9	4046.2
Barium enema	221,378	83.0 ± 35.0	9.0 ± 3.8	1992.4
Cholecistography	60,199	39.8 ± 22.4	1.6 ± 0.9	96.3
Urography	62,787	48.2 ± 24.0	5.8 ± 2.9	364.2
Mamography	39,973	31.7 ± 15.3	0.62 ± 0.3	24.8
Angiography	14,206	21.3 ± 7.7	0.22 ± 0.08	3.1
Hysterosalpingography	1,050	57.4 ± 23.5	6.6 ± 2.7	6.9
Lung tomography	52,804	18.0 ± 9.6	2.8 ± 1.5	147.8
Limbs, joints	693,390	6.6 ± 2.5	0.08 ± 0.03	55.5
All medical examinations	9,135,346		1.40	12.812

Table VII. Exposure from diagnostic radiology in Romania

Examinations	Annual number of examinations (1995)	%	Effective dose* (mSv)	Annual collective effective dose (manSv)	%
Chest radiography	1,213,718	11.90	0.22	269.1	2.0
Chest photofluorography	2,392,704	23.46	0.62	1491.3	11.10
Chest fluoroscopy	2,537,780	24.89	0.89	2251.7	16.76
Spine - lumbar	236,186	2.32	3.02	714.0	5.32
- thoracic	81,332	0.80	2.35	190.9	1.42
- cervical	207,950	2.04	0.21	44.6	0.33
Pelvis	253,837	2.49	2.66	675.4	5.03
Hip (both)	74,213	0.73	2.99	221.9	1.65
Head	454,297	4.45	0.18	83.7	0.62
Abdomen	338,450	3.32	1.81	612.1	4.56
Barium meal	1,026,953	10.0	4.0	4114.8	30.63
Barium enema	221,378	2.17	9.0	1992.4	14.83
Cholecistography	61,428	0.60	1.57	96.3	0.72
Urography	67,513	0.66	5.75	388.0	2.89
Mammography	40,336	0.40	0.61	24.8	0.18
Angiography	14,206	0.14	0.22	3.1	0.02
Hysterosalpingography	1,050	0.01	6.57	6.9	0.05
Lung tomography	52,804	0.52	2.79	147.8	1.10
Limbs, joints	912,335	8.95	0.08	72.5	0.54
Cystourethrography	8,984	0.09	3.4	30.6	0.23
All medical examinations	10,197,474	100	**1.32**	13,432	100
Per capita			**0.59**		

4. Conclusions

The new value of the annual collective effective dose resulting from diagnostic X-ray conventional examinations performed in Romania is of about 13,430 manSv with the main contribution of 95 per cent belonging to adult patients and the remainder of 5 per cent - to paediatric patients.

Unfortunately, fluoroscopic examinations have had a contribution of more than 60 per cent to this annual collective effective dose and barium enema was associated with the highest effective dose - 9 mSv.

The patient - weighted mean effective dose from X-ray examinations performed annually in Romania is 1.32 mSV with 1.40 mSv for the average adult patient and 0.59 mSv for the average paediatric patient. The annual per caput effective dose due to diagnostic radiology in Romania is 0.59 mSv.

The knowledge of the real level of patient dose is an essential component of quality assurance programs in diagnostic radiology.

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IAEA-CN-85-113

SOME EXPERIENCES FROM RADIATION PROTECTION OF PATIENTS UNDERGOING X-RAY EXAMINATIONS IN TANZANIA

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Abstract

A study of patient entrance surface dose (ESD) received by adult patients was undertaken in five major diagnostic facilities in Tanzania. Five selected X-ray projections for chest PA; Abdomen AP; lumbar spine AP; lumbar spine LAT and pelvis AP were done in the study. The mean ESDs after introduction of dose reduction methods were 0.34 mGy, 5.41 mGy, 3.7 mGy, 4.8 mGy and 8.8 mGy for chest PA; abdomen AP; pelvis AP; lumbar spine AP and lumbar spine LAT respectively. The variations of doses observed in the study were influenced by performance characteristic of X-ray equipment, patient shape and size, type of image receptor, radiographic techniques as well as skills employed. The results show that increasing the tube voltage reduced the ESD by 35.5%, while lowering of mAs reduced ESD in the range from 15% to 60%. The reduction of ESD by increasing the filtration ranged from 11% to 58% while increasing of speed class of film-screen combination reduced the ESD in the range from 33% to 57%. The corresponding results of image quality show that out of 1064 scores of image criteria 298,481 and 285 were rated for good, satisfactory and poor respectively. The results of this study provide an evidence of existing potential for dose reduction in the diagnostic radiology facilities and the most important factor for improvement is to increase awareness, both from reality of harm from unnecessary radiation exposure and with relative ease doses can be reduced. The study should therefore be implemented on the national scale as an approach to establish guidance levels of patient entrance surface dose for good medical practice and regular monitoring purposes.

1. Introduction

In diagnostic radiology, measurements of radiation doses to the patients provide means for setting and checking standards of good practices as an aid to the optimization of patient protection. It is difficult for an X-ray facility to be aware of its performance without some form of patient dose monitoring. In Tanzania, the medical use of X-rays for diagnosis of diseases and injury started as early as 1938 and as technology and health care improved there has been an increase in the usage of radiation. To date the country has more than 300 diagnostic X-ray units and it is estimated that about 1,000,000 X-ray examinations are carried out annually in the country [2]. Despite such extensive use, there was no radiation protection until the Protection from Radiation Act, 1983 came into force. The Act established the National Radiation Commission (NRC), as the Competent Authority responsible for all matters relating to radiation protection [1]. The increasing trend of the number of X-ray examinations in absence of guidance levels prompted the NRC, to carry out a pilot study to investigate the factors that influence patient dose from diagnostic radiology. The patient dose assessment based on such pilot study would be a precursor of establishing the National guidance levels of patient entrance surface dose for regular monitoring purposes. The range of doses associated with the same procedures that were found in the study which have shown huge potential for dose reduction were due to the diversity of diagnostic factors like, the difference in patient size and shape, the variety of available imaging systems, processing chemicals, skills employed and the range of technical parameters that were used, such as tube potential, current, exposure time, filtration, field size, and distance. The study revealed that different techniques and clinical factors that influenced the doses to patients from diagnostic radiology, might give added knowledge for use in the optimization of diagnostic radiology procedures. This paper presents and discusses some experiences from radiation protection of patients undergoing X-ray examinations from five major diagnostic radiology facilities in Tanzania.

2. Materials and methods

The Entrance Surface Dose (ESD) study involved a total of ten X-ray rooms at four referral hospitals and one regional hospital. The hospitals were the Muhimbili Medical Centre (MMC), Kilimajaro Christian Medical Centre (KCMC), Bugando Medical Centre (BMC), Mbeya Consultant Hospital (MCH) and Arusha Regional Hospital (ARH) which collectively attend nearly 50% of patients undergoing X-ray examination in the country annually [2,7]. Five selected X-ray projections for chest PA; abdomen AP; lumbar spine AP; lumbar spine LAT and pelvis AP were used in the study as recommended [3]. Ten adult patients whose individual weights and thickness were close to 70 kg and 20 cm respectively had their ESD measured. The ESD were determined using the LiF thermoluminescent dosemeter (TLD) chips, which were calibrated at the National Calibration Laboratory (NCL) for ionizing radiation, Arusha, Tanzania. A Harshaw TLD system model 4000B (No.3190) was used to evaluate the TLDs. Two calibrated TL chips enclosed in a labelled 30 x 30 x 0.01 mm^3 polythene sachet were used to determine the ESD by attaching the dosemeters at the middle of the light field on the patient for each radiographic exposure. The quality assurance program (QA) on x-ray equipment was undertaken before the introduction of the dose reduction methods. The quality control (QC) tests on the X-ray equipment were undertaken by using a non-invasive X-ray test device, Victoreen model 4000M+. The leakage measurements were measured using a calibrated Radiation Alert Monitor 4. The beam alignment and the beam perpendicularity were determined by using RMI test tools. During the X ray examination, requirements and technical parameters of good imaging were closely followed. The quality of the obtained radiographs per X-ray projection was tested for compliance with the European guidelines on quality criteria for radiographic images [8] by five experienced radiologists. The observers evaluated the image quality of all ten radiographs of each X ray projections and scores good for feature detected and fully reproduced, detail visible clearly defined; satisfactory for feature just visible, detail just visible but not clearly defined and poor for feature invisible, detail invisible or not clear.

3. Results and discussions

3.1. Quality assurance program on X-ray equipment

The results of quality control (QC) checks done on X-ray equipment are given in table 1. By comparing these results with the recommended tolerances [3,6], it can be seen that all the X-ray machines under study, passed all QC tests done. However, in clinical situations where diagnostic conditions for which equipment and technique related factors are variable, the use of these X-ray machines may still lead to un –optimized diagnostic procedures. Therefore the QC results provide guidance on the choice of exposure techniques and hence suggest the need for optimized dose reduction methods. The lowering of mAs was found to be effective for X-ray equipment with higher timer reproducibility than lower timer reproducibility. The increasing of filtration was found to be effective for an X-ray machine of lower half value layer. Likewise, the increasing of tube potential reduced the patient dose [4] more efficiently for the X-ray machines that possessed better tube voltage consistency and higher accuracy.

3.2. Entrance surface dose measurement on patient

The mean ESD per examination before the introduction of dose reduction methods was found to be in the range from 0.1 to 0.9 mGy for chest, 3.5 to 13.9 mGy for abdomen AP and 1.6 to 13.1 mGy for pelvis AP X-ray examinations. For Lumbar spine, AP and Lumbar spine, LAT

the dose ranges were 3.6-12.7 mGy and 10.0-29.6 mGy respectively. It can be seen that about 70% of the mean doses are below the recommended ESD guidance levels [3, 5]. Indeed, the dose results compare well with the results from similar studies [3]. Despite the fact that majority of ESD values are below the Internationally recommended ESD guidance levels, the corresponding ESD variations may not be fully justified.

Table 1. Results of QC checks on X-ray equipment at the five hospitals (maximum value of performance indicated)

Parameters	KCMC		MMC		BMC	ARH		MCH
	R1	R4	R4A	R4B	R203	R207	R1	R1
kV accuracy (10%)*	4.1	8.0	5.3	7.2	4.1	7.5	5.4	5.6
kV reproducibility(4%)*	1.0	0.5	0.5	0.5	1.1	0.5	1.0	0.3
kV consistency (10%)*	6.0	2.1	4.2	3.8	7.8	4.3	6.6	2.1
HVL,mmAL (at 80kVp)*	4.1	4.0**	3.4	3.1	3.7	2.8	3.7	2.1
Timer accuracy(10%)*	0.4	1.5	1.6	1.0	1.5	1.0	6.1	0.8
Timer reproducibility(5%)*	1.0	0.3	0.9	0.3	0.5	0.2	0.1	0.1
Output linearity mGy/mAs(5%)*	3.9	1.0	1.1	2.9	3.9	1.8	5.0	4.6
Leakage radiation at 1 m (1000 μSv/h)*	9.5	20.0	10.3	15.0	20.8	350	12.0	400
Light –radiation Beam alignment (Deviation at 1 m) (+2%)*	A	A	A	A	A	A	A	A
Beam perpendicularly(1.5°)*	A	A	A	A	A	A	A	A

*Tolerance ** at 120 kVp A; Acceptable R: Room

Factors that influences ESD are comprehensively discussed elsewhere [3,4]. The choice of film-screen combination influences the patient entrance surface dose [4]. A sensitive screen-film combination requires much less exposure than a low sensitivity non-screen film system, although shows less detail. Two types of speed classes of film-screen combination such as 200 and 400 were employed although majority of hospitals use the '200' type, as they are relatively cheaper than the other class. The alternative use of high kV technique for chest X-ray examination reduced the patient dose, as high energy X-rays are more penetrating than low-energy X-rays [4]. The influence of filtration reduces the intensity of the beam. Filters selectively remove many more low-energy X-ray than high –energy X-rays [3,4]. The observed high mAs variation in a majority of X-ray examinations for patients of similar size, also suggested that the reduction of mAs could be effective in reducing patient dose.

Irrespective of the type of X-ray examination, the results show that increasing the tube voltage reduced ESD by 35.5% while lowering of mAs reduced ESD in the range from 15% to 60%. The reduction of ESD by increasing the filtration ranged from 11% to 58% while increasing of speed class of film –screen combination reduced ESD in the range from 33% to 57%. These include film –developing conditions, speed class of film combinations, filtration and exposure factors such as kVp and mAs. Large variation of distance from the x-ray tube has also been found to influence the ESD on patients [3].

After introduction of the dose reduction methods the change of the ESD median from second round ESD measurement was 0.41 mGy to 0.36 mGy for chest PA, 8.9 mGy to 6.4 mGy for

abdomen AP and 5.21 mGy to 3.3 mGy for pelvis AP. For Lumbar spine AP, the ESD changed from 6.7 mGy to 4.94 while for lumbar spine LAT, it changed from 15.6 mGy to 6.2 mGy. The changes corresponded to about 12%, 28%. 37%, 26% and 60% for chest respectively. Table 2 gives the summary of ESD measurements before and after the undertaking of quality control checks. The mean ESD values for second round were 0.34 mGy, 5.41 mGy, and 3.7 mGy for chest, A, abdomen, AP and pelvis respectively. For lumber spine AP and lumbar spine LAT the mean ESD were 4.8 mGy and 8.8 mGy respectively. Assuming the mean ESD, it can be seen that about 56%, 50%, 75%, 43% and 57% of measurements respectively for chest PA, abdomen AP, pelvis AP, lumbar spine AP and lumber spine LAT X-ray projections, achieved the mean ESD level of dose reduction.

Table 2. Summary of the measurements of patient entrance surface doses

Examination	dose range prior to QC (mGy)	dose range after QC (mGy)	dose reduction (%)	corrective measures
Chest PA	0.2- 1.1	0.13-0.6	17-50	Lowering of mAs
Chest PA	0.3- 0.72	0.20-0.31	33-57	Increase of speed class of film- screen combinations
Chest PA	0.93	0.60	35.5	Increase of kVp
Chest PA	0.15	0.10	33.0	Lowering mAs and increase filtration
Chest PA	0.4-0.60	0.30-0.39	25-58	Increase of filtration
Abdomen AP	3.5-12.6	2.8 -9.6	20-30	Lowering of mAs
Abdomen AP	3.0	2.3	23	Lowering mAs and Increase filtration.
Abdomen AP	9.8	5.53	44	Increase speed class of film-screen combination.
Abdomen AP	9,8-10.0	4.8-7.54	25-51	Lowering of mAs, increase of speed class of film-screen combination.
Pelvis AP	5.1-13.9	3.9-5.5	24-60	Lowering of mAs
Pelvis AP	4.94-5.7	2.9-3.1	41-46	Increase speed class film-screen combinations
Pelvis AP	4.03	3.07	24	Lowering of mAs, increase of speed class of film-screen combinations
Pelvis AP	5.7	3.0	47	Increase of filtration
L/spine AP	4.0-9.7	3.3-7.1	27-48	Lowering of mAs
L/spine AP	7.3-9.47	4.4-5.78	39-40	Increase speed class film-screen combinations.
L/spine AP	3.5	3.1	11	Increase filtration
L/spine AP	7.4	4.3	42	Lowering mAs and increase filtration
L/spine AP	7.3	3.6	51	Lowering mAs and Increase speed class of film screen combinations
L/spine LAT	8.4-18.3	5.9-12.50	15-49	Lowering of mAs
L/spine LAT	20.4	11.8	42	Increase speed class film-screen combinations.
L/spine LAT	8.51	4.5	47	Lowering of mAs and increase of speed of film -screen combinations
L/spine LAT	6.7	4.4	34	Increase of filtration

Other factors observed to influence patient doses were unnecessary exposure due to improper film development as previously presented [7]. Retaking of X-rays was also a common cause of unnecessary radiation and was done for several reasons such as unqualified X-ray operator

and loss of the original films and chemicals. This leads to the conclusion that lack of necessary attention or awareness about the levels of doses and risk associated with particular procedures and particular techniques may also contribute to patient dose.

In a rapidly changing field of modern x-ray diagnostics, the referring physician and the radiologist/radiographer who are responsible for clinically directing the examination must build their decision upon a correct assessment of the indications for X-ray examination and the way the results are likely to influence diagnosis and subsequent patient dose. The above facts should take into consideration the physical properties and biological effects of ionizing radiation and the concepts of benefits and risks in radiological protection. Generally, the effectiveness of dose reduction was observed to be independent of the type of x-ray examination and X-ray equipment type. This suggests that the influence of the technique used and skill employed may be significant to the ESD reductions.

3.3. Image quality assessment

The results of image quality assessment based on the European guidelines show that out of 1064 scores of image criteria 298 (28%), 481(45%) and 285 (27%) were rated for good, satisfactory and poor respectively. Majority of observers noted the detailed nature of the quality criteria and were of opinion that slight variations in film processing conditions could be a source of significant number of radiographs rated satisfactory otherwise could be good radiographs. Despite that the guidelines were less familiar to some observers, they have been found useful and their adoption in the country is recommended. The need to provide relevant education and training to staff in the radiology department has been seen.

4. Conclusions

Some experiences from radiation protection of patients undergoing X-ray examinations in Tanzania have been presented. The results of the study provide evidence of the existing potential for dose reduction in the country's hospitals and the most important factor for improvement is to increase safety culture, both from reality of harm from unnecessary radiation exposure and of the relative ease with which doses can be reduced. This requires familiarity with the levels of doses connected with the various X-ray projections and with techniques of quality control. The study should therefore be implemented on the national scale as an approach to establish national guidance levels of patient entrance surface dose associated with particular procedures for good medical practice and regular monitoring purposes.

Acknowledgement

The work was supported by the International Atomic Energy Agency through the research project number 9336/RO which the authors of this paper gratefully acknowledge.

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IAEA-CN-85-136

MEDICAL EXPOSURE IN RUSSIA

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Abstract

Recently there have been considerable changes in radiology, which is because of coming to a new form of property, reforms of health services and crisis in the society. Big area, bad means of communication and low density of population in most regions of the country should be also mentioned among the factors, influencing the level of both health protection and radiology services. Al this factors don't allow to create an effective radiology system in a short time. Meanwhile the main nearest task of radiology is the integration and optimization of all means of visualization on the base of solving fundamental problems of health protection according to the Federal program, normative acts and decrees of the government. In this connection it seemed to be an urgent task to estimate various aspects of radiology activity of Russian Health in the dynamics for the recent period of time. The data of the state statistics are to be used to cope with this task. These data on the base of the computer program "Region", the quantity indices of various visualization methods used in Russia and the doses of exposure of the population have been estimated and the reference book "Medical irradiation of the population in Russia.1980-1997 years" has been published.

It turned out that the average annual number of X-ray examinations per thousand population in Russia before 1988 year was constantly up to 1600. And only then because of Chernobyl accident its increase stopped and its gradual decline began (table 1). Such high frequency of the examinations was caused mainly by the large scales of mass preventive photofluorography (more than 40%), held for early tuberculosis exposure.

It was as a result of reorganization of fluorographic examination system started in the late 80-s and early 90-s that this pernicious tendency was overcome and the number of fluorography was reduced almost twice from 90 to 56 millions a year, which considerably contributed to reducing the exposure. Unfortunately as a result of it, the rate of tuberculosis has increased, which led to the recommencement of mass fluorographic screening in former or ever larger scales.

Recently the number examinations per 1000 population has reduced to 1200. The specific feature of modern X-ray diagnostic is its competing with new non-radiation examinations, in particular with ultrasound and endoscopic ones. These methods are very efficient and recently have been developing very actively. Nevertheless, the classical radiology is not going to surrender and in spite of some reduction in examinations it is still the leader among all ways of visualization. The structure of X-ray examinations has changed considerably during the last decades: the number of the most dose-making examinations has become 8 times less, the number of the most informative and the least dose-making radiography examinations has twice, and only the amount of photofluorography examinations , including screening, has declined inconsiderably.

Among all X-ray examinations the maximum quantity is still that of chest and skeleton. The amount of X-ray examinations is equal for male and female parts of population, 53,7% and 46,3% accordingly. Speaking of the age of the examined , it should be noted that the most part of X-ray examinations is held among middle-aged and especially elderly people. Children's contribution is inconsiderable. This correlation has been stable for the recent period of time.

A detailed study of X-ray examinations shows that the main contribution to it is made by diagnostics and screening of lung, stomach examinations as well as examinations of skull and extremity. Recently there has increased the number of special X-ray examinations among

which are angiography and intervention methods. They are the most informative, but at the same time they are accompanied by very high dose, including the influence on skin.

Table 1. The dynamics of medical radiation exposure in Russia

Index	Years						
	1965	1970	1975	1980	1985	1990	1997
X-Ray Examinations							
Number examinations per 1000 population	1120	1204	1332	1488	1682	1177	1230
Contribution, %							
Fluoroscopy	47	40	27	13	7	5,5	5
Radiography	27	27	36	49	43	54	54
Photofluorography	26	33	37	38	50	41	39
Dental	*	*	*	*	4,7	7,0	7,8
Mammography	*	*	*	0,6	0,4	0,3	0,4
CT	*	*	*	*	*	*	0,5
Chest	81	76	71	64	62	51	45
Digestive organs	6	8	10	13	14	12	6
Skeleton	10	12	14	18	19	24	36
Other	3	4	5	5	7	13	13
Nuclear medicine							
Number examinations per 1000 population	*	*	*	9,0	10,5	15,3	12,6
Ultrasound diagnostic							
Number examinations per 1000 population	*	*	*	*	*	80	270
Radiation therapy							
Number examinations per 1000 population	*	*	*	0,98	0,99	1,57	1,66

* the data are not provided by statistical form.

Considerably yielding to traditional X-ray examinations are dental and mammography. Their contribution to the general number of X-ray examinations is inconsiderably, in spite of their importance and significance. However the speed of the development of this methods is rather high. The most rapid is the development of ultrasound diagnostic and computed tomography. Presently magnetic-resonance tomography (MRT) has joined them, positron-emission tomography (PET) is coming up and the future radiology belongs to these new methods.

There are 4150 physicians, 103 radiologist and 235 X-ray unit for 1 million population in Russia. On one equipment 5260 examinations a year are held. An average X-ray examinations for 1 radiologist is 12385 a year. Recently an average effective dose from X-ray examinations has had a 20% decline from 1,0 to 0,8 mSv which is caused by change in the structure of X-ray examinations (table 2).

Table 2. Average effective individual and collective dose in radiology

Index	Year			
	1980	1985	1990	1997
X-ray examinations				
Individual effective dose, mSv per:				
procedur	*	*	0.79	0,65
patient	*	*	1,20	1,10
Annual effective dose per caput, mSv	1,26	1,32	1,00	0,80
Including, mSv:				
Screening	*	*	191,1	189,0
Mammography	*	*	1,26	2,05
Dental	*	*	2,5	3,0
Collective dose, thousand.man-Sv	175	189	148	117
Contribution dose, %				
Fluoroscopy	45,8	37,5	33,1	25,4
Radiography	26,1	29,7	38,3	39,5
Fotofluorography	26,0	31,3	28,6	35,1
Screening	19,9	23,1	19,2	23,8
Dental	*	*	*	0,4
Mammography	*	*	*	0,3
Localization dose, %				
Chest	31	33,5	31,2	37,4
Including screening	21	22,9	20,4	29,4
Digestive	58	52	41	29
Skeleton	6,4	9,4	13,8	16,2
Other	4,6	5,0	12,7	11,4
Nuclear medicine				
Annual effective dose per caput ,mkSv	45,0	52,2	76,7	62,8
Collective dose, thousand man-Sv	6,23	7,47	11,35	9,19

Further reduction of medical exposure is possible on the base of optimization of equipment and personnel usage, integration level, single information space on the base of computer, the priority of primary radiology help to the population as well as centralization, concentration and unification of various radiation methods, submission of radiology activity to economic advisability. It's also necessary to provide high-quality training of wide-profile specialists in the radiology. For this purpose all educational and post-educational cycle should be reformed.

The problem of complex education and complex diagnostics should be provided with complex equipment of radiology. To gain this, big medical institutions should firstly the whole range of equipment for full-scale examinations, including angiographic, CT, MRT, PET etc., and secondary to introduce new methods of radiology, including intervention ones.

The exceptional significance of medical exposure is detriment not only by the level of its contribution to a population dose, but also by possessing the most considerable, economically not burdensome reserves to reduce this contribution and consequently to provide a considerable decline of the whole dose on population from all the sources of radiation.

RADIATION DOSE IN RADIOGRAPHY AND METHODS FOR DOSE REDUCTION

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Abstract

The research contract between the International Atomic Energy Agency (IAEA) and laboratory of Industrial Hygiene(LIH), China, was conducted from 1994 to 1998 and entitled "Radiation Dose in Diagnostic Radiology and Methods for Dose Reduction", involving some of Asia and Far East countries. The results of the research have demonstrated significant dose reduction has been achieved without any loss of diagnostic information. The CEC diagnostic reference dose values can be valid for conventional radiography examinations in China.

1. Introduction

A Coordinated research programme of IAEA in cooperation with 9 countries in Asia and the Far East has been launched since 1994 [1].

The programme of four years was instituted in two phases. Phases 1 of the CRP dealed with conventional radiographic units and phases 2 with fluoroscopy and computed tomography units. The report is the results obtained in the phase 1.

The scope of the phase was the participant to be asked to assess the radiation dose reduction due to implementation of QC procedures in the sample of hospitals. This assessment involved: classification by type and frequency of X-ray examinations; Analysis of film-reject rate; Measurement of patient dose in radiography pre and post-QC implementation of each selected examination; QC measurements of X-ray performance; Dissemination of Information and training of the hospitals and image quality evaluation of using image quality criteria in the CEC working document [2].

2. Materials and methods

Four hospitals were selected as the co-ordinator on implementing the project. In each hospital two X-ray conventional radiography rooms were chosen to collect information of eight X-ray projections which should estimate the frequency of examinations and the film reject rate during a period of two weeks for pre- and post –QC implementation.

In order to obtain entrance surface dose (ESD) values for each projection performed in each hospital, measurements should be carried out on a sample of 10 adult normal sized patients (65Kg5) using sets of 4 chips of LiF TLD to the patient's skin in the center of the beam for pre- and post-QC implementation. The organ dose and effective dose were calculated using software programmes provided by IAEA from NRPB in English and NRL in New Zealand. The TLD systems were sent to the NRL to perform calibration and intercomparison exercise.

QC tests for each X-ray unit were made with RMI QC kit (USA) according to the technical prerequisites of the CRP. Once the QC tests are finished, the results were analyzed in order to identify possible improvement and to implement corrective actions with the relevant parameters which may influence the ESD.

Table I. The results of measured ESD (mean ±SD, mGy)

Hospital	Projection Types					
	Chest	Skull		Lumber Spine		Pelvis
	PA	PA	LAT	AP	LAT	AP
pre-QC						
A	0.27±0.04	3.81±0.66	3.53±0.87	12.36±1.30*	14.88±3.30*	11.70±2.60*5.
B	0.45±0.13	3.23±0.57	2.24±0.40	8.24±2.20	19.06±2.54	07±1.26
C	0.28±0.05	5.05±1.47	4.02±0.91	7.00±1.00	15.70±1.80	2.60±1.20
D	0.38±0.06	***	***	6.54±1.40	13.50±2.90	7.16±0.87
post-QC						
A	0.29±0.05	5.88±1.09	4.84±0.77	8.39±0.68	8.03±0.62	1.74±0.49
B	0.33±0.03	3.70±1.00	2.97±0.64	5.35±0.94	15.2±1.39	4.60±0.70
C**	0.09±0.02	4.70±2.10	***	3.90±1.40	8.40±1.20	1.20±0.30
D	0.24±0.05	***	***	7.78±2.07	16.26±5.43	6.42±1.94

*: Tube potential is incorrect. **: Adopted high speed class of screen film combination.
***: Patient number is less than 10.

Table II. The results of E (mean ±SD,mSv)

Hospital	Projection Types					
	Chest	Skull		Lumber Spine		Pelvis
	PA	PA	LAT	AP	LAT	AP
pre-QC						
A	0.04±0.008	0.02±0.06	0.03±0.005	1.13±0.14	0.24±0.06	1.67±0.42
B	0.07±0.02	0.03±0.01	0.02±0.01	0.76±0.21	0.30±0.04	0.69±0.17
C	0.06±0.04	0.04±0.01	0.03±0.01	0.76±0.14	0.29±0.04	0.39±0.19
D	0.06±0.01	*	*	0.67±0.17	0.24±0.06	1.07±0.16
post-QC						
A	0.05±0.01	0.04±0.007	0.03±0.006	0.93±0.09	0.16±01	0.27±09
B	0.05±0.003	0.03±0.01	0.02±0.06	0.48±09	0.22±0.03	0.62±0.12
C	0.01±0.004	0.03±0.02	*	0.41±0.15	0.14±0.02	0.19±0.05
D	0.04±0.01	*	*	0.82±0.24	0.29±0.11	1.11±0.52

*: Patient number is less than 10.

Table III. Results of Different dose reduction actions

Dose Reduction Action	Hospital/ Room	Projection	Average Dose Reduction(%)
Increased Tuble Potential	A/2	Lumber Spine (AP)	32
	A/2	Lumber Spine (LAT)	45
Increased Screen Film Sensitivity	C/1	Chest (PA)	67
	C/2	Lumber Spine (AP)	44
	C/2	Lumber Spine (LAT)	46
	C/2	Pelvis (AP)	54
Increased Filtration	B/1	Chest (PA)	27
Increased Tube Potential & Increased Screen Film Sensitivity	A/2	Pelvis (AP)	85

Table IV. Examination frequencies by hospital (%)

Hospital	Total Patients Number	Projection Types						
		Chest		Skull		Lumber Spine		Pelvis
		PA	LAT	PA	LAT	AP	LAT	AP
Pre-QC								
A	908	37.7	10.6	0.7	0.8	24.9	23.7	3.0
B	1269	55.7	17.3	2.1	2.0	10.3	9.9	2.7
C	1091	53.8	10.4	0.01	0.01	17.4	16.0	2.4
D	766	41.8	11.0	0.0	0.0	23.0	21.4	2.8
post-QC								
A	929	37.2	12.9	0.01	0.01	27.1	22.8	0.02
C	522	35.6	14.8	0.02	0.02	27.8	21.8	0.02

Table V. Film reject rate by hospital and by case

Hospital	Films No.	Rejected Films No.	Rejected Rate(%)	Cases			
				Too Dark	Too Light	Position	Others
Pre-QC							
A	908	34	3.7	12	18	1	3
B	1269	72	5.6	28	36	3	5
C	1091	39	3.6	14	15	3	7
D	766	25	3.3	11	9	2	3
Post-QC							
A	929	12	1.3	5	6	1	0
C	522	4	0.8	3	0	1	0

3. Results

Table I presents the results of measured ESD by projection type and by hospital. Table II shows the results of calculated effective doses E(ICRP 60). Table III shows the percentage of average dose reduction where different kinds of technical actions were adopted. Table IV presents the examination frequencies of each hospital during 2 weeks for pre-and post-QC implementation. Table V presents the film reject rate of each hospital during 2 weeks for pre- and post-QC implementation.

4. Conclusions

1. The High chest (PA) frequency projection is 50% and the Low skull frequency projections (AP and LAT) are less than 1% because of the use of CT scanner.

2. The film reject rate varied from 3.3% to 5.6% in these four hospitals pre-QC due to the inappropriate set of the parameters. After the corrective actions for post-QC the reject rate reduced to less than 1.3%.
3. Most of the measured ESD for the projections is lower than the CEC reference values.
4. Four kinds of dose reduction methods used in different X-ray rooms, the dose reduction varied from 27% to 85%.

Acknowledgements

This work was supported in part by the IAEA under contract number 8221/R1, We would like to thank Ms. Modupe Oresegun and Mr. P. Ortiz-lopez for their assistance.

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ESTIMATION OF PATIENT RADIATION DOSES DURING RADIOLOGIC EXAMINATIONS IN THE REPUBLIC OF HAITI

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Abstract

The International Commission on Radiological Protection and the international organizations that co-sponsored *the International Basic Safety Standards for the Protection against Ionization Radiation and for the Safety of Radiation Sources* (BSS) –among them PAHO and WHO– recommended the use of investigation levels to provide guidance for medical exposures. In this work, entrance surface doses for several common diagnostic radiology procedure have been determined from exposure rate measurements and patient technique factors in seven "World Health Imaging System – Radiography" (WHIS-RAD) units, installed in public health services facilities of the Republic of Haiti. The results show the entrance surface doses below the guidance levels published in the BSS. Concomitant image quality measurements performed, however, indicate serious artifacts in the film processing, calling for the need of additional training of the technologists.

1. Introducción

Haití tiene una población de alrededor de 8 millones de habitantes. En los servicios públicos, se estima hay unos 20 equipos de rayos X. Entre 1993 y 1996 la Organización Panamericana de la Salud / Organización Mundial de la Salud (OPS/OMS), dotó al país de 11 equipos de radiografía del tipo "WHIS-RAD" –World Health Imaging System– Radiography, 7 de la firma Philips y 4 de la firma Bennett. Este equipo se caracteriza por tener un sistema de soporte en arco C que mantiene el receptor de imagen siempre alineado con el tubo de rayos X a una distancia fija de 1,4m, con una mesa flotante. El tubo de rayos X tiene un punto focal de menos de 1mm y una potencia de 24 a 30kWs. El generador es de alta frecuencia y funciona con baterías [1].

2. Objetivo

El objetivo de este trabajo, es hacer una estimación de la dosis de entrada en la superficie del paciente (*DES*), utilizando las técnicas radiológicas recomendadas por la OMS (kVp y mAs) [2] y las tasas de exposición en aire medidas en 7 de estas unidades, para compararlas con los niveles orientativos de dosis publicados en las *Normas básicas internacionales para la protección contra la radiación ionizante y para la seguridad de las fuentes de radiación,* (NBS) [3] copatrocinadas por seis organismos internacionales –entre ellos la OPS y la OMS– y publicadas (en castellano) por el Organismo Internacional de Energía Atómica (OIEA) en 1997. De acuerdo con los criterios de las NBS, se evaluó también la calidad de la imagen radiológica.

3. Métodos

Durante las pruebas de aceptación de los equipos se verificó que todos cumplían con las especificaciones de la OMS.[1] Se midieron: el tamaño del punto focal, la exactitud del potencial, la congruencia del campo luminoso y el de radiación, la calidad de la imagen, la capa hemirreductora (CHR), la reproducibilidad y linealidad del generador, y la tasa de exposición en aire. Para las cuatro últimas medidas se usó un monitor de rayos-X (MDH

Radcal-1015) y filtros de aluminio. De los valores de CHR medidos, se determinó que la filtración total de los equipos era de 3 mm de aluminio, de acuerdo con las especificaciones de la OMS. La calidad de la imagen se determinó radiografiando dos patrones de resolución espacial de pares de líneas, uno de alto contraste y otro de bajo contraste.

Se determinaron las *DES* para cada una de las técnicas recomendadas [2] por la OMS, utilizando un factor de conversión de 0.00877 para convertir de mR a mGy y corrigiendo por la geometría de medición.

4. Resultados

En la figura-1 se presentan la tasa de exposición y la CHR en función del potencial del tubo, medidas en cada una de las unidades. Las variaciones mínima y máxima de los valores obtenidos para la tasa de exposición son del orden de 5 y 19% a 70 y 53 kVp respectivamente y hay una variación de 5% para las CHR, independientemente de la energía del haz.

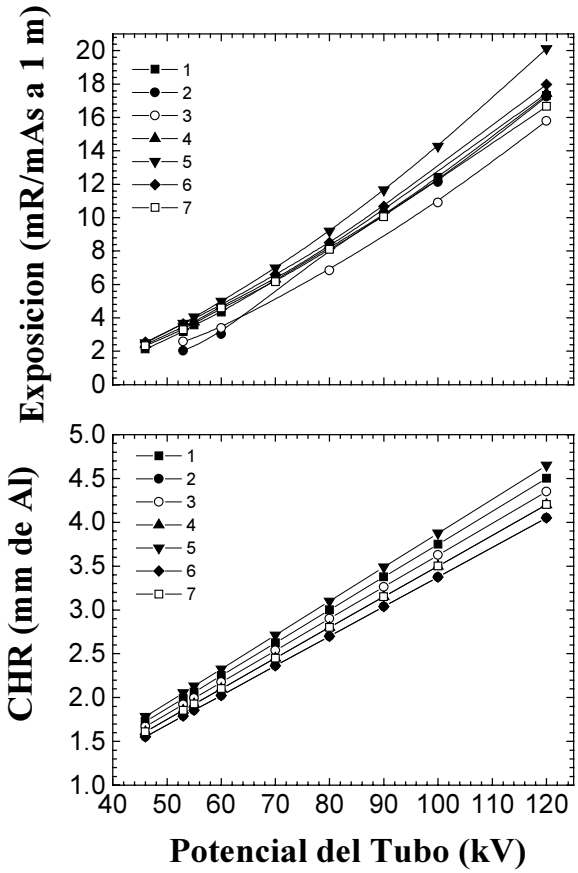

Figura-1. Tasa de exposición y CHR en función del potencial del tubo medidas en las 7 unidades WHIS-RAD

En la figura-2 se presenta la variación de las DES promedio en función del espesor del paciente para 6 proyecciones radiográficas. Las desviaciones estándar varían entre 8 y 12%, independientemente de la técnica.

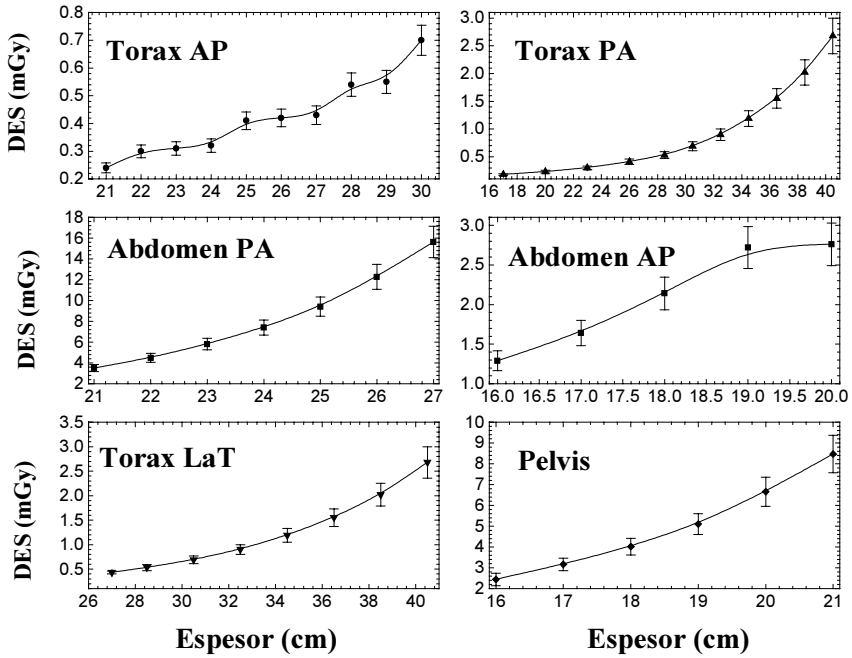

Figura-2 Dosis de entrada en la superficie del paciente en función del espesor del paciente para diferentes proyecciones radiográficas

Tabla-1 Comparación de los valores de *DES* determinados en este trabajo, asumiendo un espesor del paciente de 20 cm y una anchura de 34.4 cm, con los reportados en las NBS

Examen		*DES (mGy)*	
		NBS	HAITI
Tórax	PA	0.4	0.23 ± 11%
	AP		0.24 ± 7.7%
	LAT	1.5	1.19 ± 12%
Abdomen	AP	10	2.76 ± 9.7%
	PA		3.51 ± 9.7%
Cráneo	PA	5	3.01 ± 10.6%
	LAT	3	1.33 ± 10.6%
Pelvis		10	6.66 ± 10.6%

Tabla-2. Evaluación de la calidad de imagen en las unidades WHIS-RAD [Patrones de barras sobre el receptor de imagen: 0.1 mm Pb (AC) y 0.001 mm Pb (BC); 70 kV, 3.2 mAs]

Unidad	*Contraste**	*Resolución (pl/mm)*		*Revelado*
		AC	***BC***	
1	1.27	3.1	2	OK
3	0.71	4.0	2.2	OK
4	0.37	3.1	2.2	Artefactos
5	1.04	3.4	2.2	Artefactos
6	0.47	3.7	2.5	Artefactos
7	0.41	3.1	2.8	Artefactos

*Diferencia en la densidad óptica entre las áreas opaca y transparente en el patrón de barras de Pb.

En la tabla-1 se presentan los valores de DES, con sus desviaciones estándar, obtenidos en este trabajo y los publicados en la literatura para un adulto típico

Los resultados de la evaluación de la calidad de imagen se presentan en la tabla-2.

3. Conclusiones

Los valores presentados en la tabla-1 muestran que la dosis que recibe un paciente durante los exámenes radiológicos estudiados es más baja que los niveles orientativos publicados en las NBS. Sin embargo, los resultados de la tabla-2 indican que sólo dos instituciones producían placas radiográficas sin artefactos serios, factor que afecta significativamente la calidad de la imagen, y como consecuencia en las otras instituciones, la probabilidad de que el médico no haga una interpretación radiológica adecuada, lo cual implica la posible necesidad de repetir la radiografía y por tanto duplicar la dosis al paciente. Ello muestra la importancia de entrenar bien a los técnicos en los procesos de revelado como parte integral de un servicio de radiología.

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MEDICAL RADIATION EXPOSURE AND USAGE FOR DIAGNOSTIC RADIOLOGY IN MALAYSIA

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Abstract

A national dose survey of routine X-ray examinations in Malaysia (a Level II country) from 1993 to 95 had established baseline data for seven common types of x-ray examinations. A total of 12 randomly selected public hospitals and 867 patients were included in this survey. Survey results are generally comparable with those reported in the UK, USA and IAEA. The findings support the importance of the on-going national quality assurance programme to ensure doses are kept to a level consistent with optimum image quality. The data was useful in the formulation of national guidance levels as recommended by the IAEA. The medical radiation exposure and usage for diagnostic radiology (1990-1994) enabled a comparison to be made for the first time with the UNSCEAR 2000 Report. In 1994, the number of physicians, radiologists, x-ray units and x-ray examinations per 1000 population was 0.45, 0.005, 0.065 and 183 respectively; 3.6 million x-ray examinations were performed; the annual effective dose per capita was 0.05 mSv and collective dose was 1000 person-Sv. Chest examinations contributed 63% of the total. Almost all examinations experienced increasing frequency except for barium studies, cholecystography, and intravenous urography (-23%, -36%, -51%). Notable increases were observed in computed tomography (161%), cardiac procedures (190%), and mammography (240%).

1. Introduction

There is a continuing need to analyze the frequencies, doses and trends of medical radiation procedures to permit comparison with medical radiation usage in other parts of the world, comparisons with other sources of radiation, and identification of areas of concern. It also helps to assess how the introduction of new techniques, radiation protection actions or quality assurance programs affect the trends. Exposures from medical radiation world-wide have been assessed by the United Nations Scientific Committee on the Effects of Atomic Radiation [1]. Worldwide interest in patient doses has been stimulated by a report of the National Radiological Protection Board (NRPB) [2].

2. National Dose Survey of Routine X-ray Examinations

Malaysia with 2216 persons per physician in 1994 belongs to health care Level II according to UNSCEAR [3]. A national survey initiated by the University of Malaya and the Ministry of Health has been conducted from 1993 to 95 to establish baseline data on patient doses from 7 routine types of x-ray examinations (12 projections) in 12 public hospitals following the protocols of NRPB [4]. For each x-ray room machine specific data such as type, model, waveform, filtration, film-screen combination, and output were recorded. Basic equipment quality control including the processor had been implemented in these hospitals since 1992 [5]. 867 patients with a mean weight around 60 kg (45-75kg) were included in this study. For each patient and x-ray unit the following parameters were recorded: sex, ethnic origin, age, weight, height, body mass index, focus-skin distance, focus-film distance, field size, kVp, and mAs. Entrance skin dose (ESD) was measured using LiF TLD chips (TL-100, Harshaw) calibrated by the Primary Standard Dosimetry Laboratory at the National Radiation Laboratory, New Zealand and the Secondary Standard Dosimetry Laboratory at the Malaysian

Institute for Nuclear Technology Research (MINT) within the recommended precision and accuracy levels [4].

Table 1 compares the ESD values [6] of this survey with established reference dose values from other countries. The reference dose values recommended by the IAEA Basic Safety Standard [9] are based on the Commission of the European Communities (CEC) [10].

Table 1. Comparison of ESD (mGy) with international established reference dose values [6]

Radiograph	Projec-tion	Malaysia (1996) [6] Median Values	USA (1992) CRCPD/CDRH [7] Median values	NRPB (1986) [8] Median values	NRPB (1992) [4]	IAEA Basic Safety Standard (1996) [9]
Chest	PA	0.3	0.17	0.18	0.3	0.4
	LAT	1.2	Not given	0.99	1.5	1.5
Abdomen	AP	9.2	5.6	6.68	10	10
Pelvis/ Hip	AP	5.3	Not given	5.67	10	10
Skull	AP/PA	4.7	Not given	4.20	5	5
	LAT	3.0	1.6	2.19	3	3
Cervical Spine	AP	0.7	1.5	-	-	-
	LAT	1.5	Not given	-	-	-
Thoracic Spine	AP	6.4	Not given	-	7	7
	LAT	15.9	Not given	-	20	20
Lumbar Spine	AP	9.1	6.4	7.68	10	10
	LAT	14.0	Not given	19.7	30	30

3. Medical Radiation Usage and Exposure in Diagnostic Radiology

The medical radiation usage for diagnostic radiology (1990-1994) [11] enabled a comparison to be made for the first time with the UNSCEAR Report 2000 [12]. In 1994, the number of physicians, radiologists, x-ray units and x-ray examinations per 1000 population was 0.45, 0.005, 0.065 and 183 respectively. The increase from 1990 to 1994 for population, number of physicians and radiologists was 10%, 26%, 47% respectively. The total number of x-ray units increased from 889 in 1990 to 1270 in 1994 (43%), with an increase in the number of examinations from 2.88 million to 3.58 million (24%). The average number was estimated to increase from 162 to 183 per 1000 persons (13%). Almost all examinations experienced increasing frequency except for barium studies, cholecystography, and intravenous urography (-23%, -36%, -51%). Notable increases were observed in computed tomography (161%), cardiac procedures (190%), and mammography (240%).

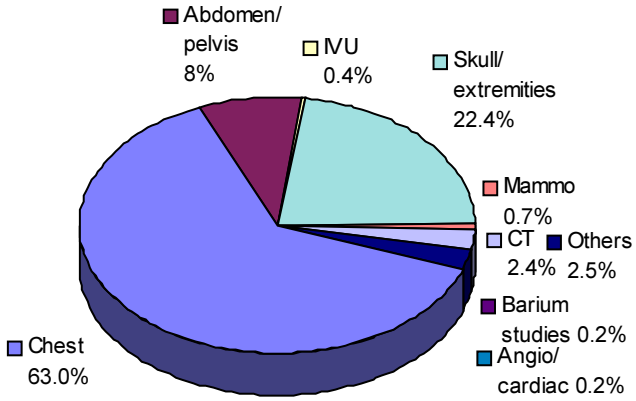

Fig. 1 Frequency of x-ray examinations in Malaysia,1994 [11]

The distribution of the types of x-ray examinations for 1994 [11] is shown in Fig 1. A total of 3.6 million x-ray examinations were performed. Chest radiography was the most frequent examination (63%); followed by skull and extremities (22.4%). On the whole plain radiography accounted for 93.4% of radiological procedures with the others e.g. CT, mammography, making up the remainder.

Table 2 shows the annual examination per capita, effective dose per examination and annual effective dose per capita for various types of x-ray examinations in 1994. The annual effective dose per capita to the population was estimated as 0.05 mSv per person and the collective dose, 1000 person-Sv [13].

Table 2. Exposure from diagnostic medical x-ray examinations in Malaysia (1994) [13]

Examination	Annual exams per capita	Effective dose per exam (mSv)	Annual effective dose per capita (mSv)
Chest	0.115 (63%)	0.03	0.0035
Skull/ extremities	0.041 (22.4%)	0.04	0.0016
Abdomen/ pelvis	0.015 (8.3%)	1.05	0.0159
Barium studies	0.0003 (0.2%)	6.0	0.002
Cholecystography	(0.01%)	1.5	0.000037
Hysterosalpingography	(0.02%)	1.36	0.00007
Angiography	(0.03%)	6.8	0.0004
Cardiac procedures	(0.13%)	6.8	0.002
Intraven. Urography	0.0006 (0.4%)	2.4	0.002
Mammography	0.001 (0.7%)	0.1	0.0001
Computed Tomography	0.004 (2.4%)	4.85	0.021
Others	0.005 (2.5%)	0.1	0.0023
Total	0.183 (100%)	0.275*	0.0503

* value is a weighted average

4. Discussion

The results of this survey provide valuable baseline data for Malaysian patient doses. Survey results arte generally compatible with those reported in the UK, USA and IAEA. Wide variations of typically range over factors between 5 and 30 for individual patient dose suggested that significant dose reductions is possible without adversely affecting image quality [6]. This survey has also led to an increased awareness amongst professionals in

diagnostic radiology in Malaysia of the need for dose management. Since the survey, faster film-screen combinations have been introduced and greater emphasis placed on quality assurance. Furthermore the data would be useful for the formulation of a national guidance dose level for incorporation in the amendments of the 1988 Malaysia Radiation Protection Regulations (Basic Safety Standard). We have also participated in an IAEA coordinated research project on 'Radiation protection and quality assurance in diagnostic radiology'. Information on medical radiation exposure and usage in Malaysia allows appropriate radiation protection measures to be implemented and diagnostic radiology standard to be improved.

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PATIENT DOSE SURVEYS FOR RADIOLOGICAL EXAMINATIONS IN DUTCH HOSPITALS BETWEEN 1993 AND 2000

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Abstract

Our inventory studies on radiation dose to patients in Dutch hospitals are reviewed and compared with current European guidelines on patient dose and reference dose values of the NRPB. Between the years 1993 and 2000 doses were measured and effective dose was assessed at 14 hospitals for paediatric radiography, at 18 hospitals for PA chest radiography, at 10 respectively 9 hospitals for barium meal and barium enema examinations and at 18 hospitals for CT scans of the brain, chest (including high resolution CT of the chest), abdomen and lumbar spine in The Netherlands.
Effective doses varied from 1 μSv (AP chest radiograph premature) to 26 mSv (CT abdomen scan). Doses were in general well below the reference dose values, with the exception of CT where the dose length product often exceeded reference levels. Interhospital variations were considerable, the largest range was observed for PA chest examinations, i.e. a ratio of 27 between maximum and minimum effective dose.

1. Introduction

It is recommended that periodic dose measurements are performed to evaluate the optimisation of patient dose, as well as to test compliance with guidelines and regulations. Quality control, including patient dosimetry, has even become a legal requirement under the new European legislation [1]. This paper is a review of dose assessment studies in several hospitals in the Netherlands concerning paediatric radiography, chest radiography, barium meal and barium enema examinations and CT scans. For all examinations the operational dosimetric quantities as well as the effective dose are presented. The following operational quantities have been measured: the entrance skin dose (including backscatter) for paediatric radiographs, the entrance air kerma free-in-air for PA chest radiographs of adults, the dose area product for barium contrast examinations and the weighted CTDI for computed tomography. For adult chest X-rays, multiplication of the measured air kerma free-in-air with backscatter factors resulted in entrance skin doses (including backscatter). For computed tomography, the weighted CTDI and dose-length product were derived.

2. Dose surveys

Paediatric radiography

Special attention for patient dose in paediatric radiology is indicated since it is generally assumed that children are a factor 2 to 3 more sensitive to radiation than adults. The entrance dose and effective dose for 6 frequently applied projections in paediatric radiology, i.e. pelvis, abdomen and chest radiographs in infants and for children aged 5 years were established at 14 hospitals [2]. PMMA phantoms of different thicknesses were used to simulate the attenuation of the infants and the 5-year-old children. Entrance skin dose was measured on these phantoms with an ionisation chamber. Effective doses (E) were calculated using the NRPB effective dose conversion factors for paediatric X-ray examinations [3]. The dosimetric findings of the paediatric X-ray projections (Table I) can be compared to the European Commission (EC) guidelines [4]. Effective dose ranged from 1 to 70 μSv per radiograph. The highest values were found for radiographs of the abdomen of 5 year old children. Entrance skin dose varied between 6 and 417 μGy. Not a single hospital exceeded the entrance skin dose values as recommended in the EC guidelines. However, the interhospital variation was

large and due to large differences in applied tube voltage, additional filtration and film-screen combination speed class. In half of the hospitals tube voltages were outside the range suggested in the EC guidelines. Low tube voltage, lack of copper filtration, low speed class film-screen combination and high ratio anti-scatter grids lead to relatively high effective doses.

Table I. Effective dose, entrance skin dose and EC reference dose values for paediatric radiography (AP projections except for (PA) chest radiographs of 5 year old children). Doses are presented as mean values, minimum and maximum values appear between brackets.

Region	Effective dose (μSv)				Entrance skin dose (μGy)					
	Infant*		5 year old child		Infant*		EC	5 year old child		EC
Pelvis	9	[5-14]	26	[8-55]	48	[23-83]	200	202	[53-417]	900
Abdomen	10	[3-21]	43	[20-70]	37	[10-75]	1000	239	[116-391]	1000
Chest	5	[1-15]	7	[2-14]	28	[6-66]	80	41	[14-90]	100

EC = dosimetric guidelines of the European Commission
* for pelvis projection the patient age is 5 months, chest and abdomen projections apply to premature children.

PA chest radiography

Chest radiography yields relatively low doses to the adult patient but is the most frequently performed X-ray examination. At 18 hospitals, air kerma free-in-air was measured with an ionisation chamber whilst simulating the exposure during routine PA chest X-ray radiographs at each of these hospitals with a LucAl chest phantom [5]. Tube voltage, filtration and film-screen combination were noted. Effective dose was subsequently calculated using conversion factors from Schultz et al [6]. These conversion factors were derived by means of Monte Carlo calculations for the computational phantoms Adam and Eva representing standard male and female patients. Entrance skin dose for patients was assessed from air kerma free-in-air using backscatter factors published by Petoussi-Henss et al [8]. Mean effective dose and entrance skin dose are shown in Table II, as well as the recommended values from the EC guidelines [7]. Only one hospital did not comply with the EC guidelines for patient dose due to a low (i.e. 100) speed class film-screen combination. The interhospital variation in effective dose of a factor 34 is, compared to the other examinations, the largest observed during the Dutch field surveys.

Table II. Effective dose, entrance skin dose and EC reference dose values for PA chest radiography in adult patients. Doses are presented as mean values, minimum and maximum values appear between brackets.

Region	Effective dose (μSv)	Entrance skin dose (μGy)	EC Entrance skin dose (μGy)
PA chest	22 [5-137]	107 [30-390]	300

3. Gastrointestinal examinations

Barium meal examinations for exploration of the upper gastrointestinal tract and barium enema for assessment of the colon lead to a relatively high radiation burden and they are estimated to contribute about 13% to the collective dose due to diagnostic radiology. Barium

meal examinations include visualisation of the oesophagus, stomach and duodenal bulb. In both barium meal and barium enema examinations a large number of different projections is used during fluoroscopy and radiography. For assessment of the dose area product (DAP) during 2323 procedures (590 barium meal, 1733 barium enema) flat ionisation chambers were installed in 10 hospitals [9,10]. Furthermore, parameters such as tube voltage, focus skin distance, projection angle, field size and filtration were registered. Effective dose was calculated from the measured DAP values by multiplication with effective-dose-conversion factors [11]. Three hospitals had higher DAP values for barium meal examinations than recommended, but all hospitals complied with NRPB guidelines for barium enema examination (Table III). Differences between hospitals were due to e.g. differences in fluoroscopy times (meal: 1.7-7.0 minutes, enema 2.8-8.8), the number of exposures (meal: 9-28, enema: 7-27), the tube voltage (meal: 72-117 kV, enema: 72-126), the application of copper filtration, the entrance image intensifier dose rates (meal: 0.16-1.27 μGy/s, enema: 0.19-1.30), different protocols as well as over- or undertable tube position.

Table III. Dose area product (DAP), effective dose (E) and NRPB reference values [12] for gastrointestinal radiology. Doses are presented as mean values, minimum and maximum values appear between brackets.

Examination	Region	DAP ($Gy.cm^2$)	NRPB DAP ($Gy.cm^2$)	E (mSv)	NRPB E (mSv)
Barium meal	Upper GI	21 [7-56]	25	7 [3-19]	3
Barium enema	Colon	29 [18-53]	60	5 [3-8]	7

The NRPB effective dose is a typical value from a recent dose review [13]

4. Computed tomography

Computed tomography (CT) has become a frequently used X-ray examination for visualisation of transsections in different parts of the body. It is also a technique that is associated with a relatively high radiation dose to the patient, the contribution of CT to the collective dose due diagnostic radiology is estimated to be in the range of 40 to 50%. Different scan protocols at various hospitals can cause large variations in patient dose. An effective method for CT dosimetry is assessment of the weighted computed tomography dose index ($CTDI_w$) which reflects the average absorbed dose within a single slice. Multiplication of the weighted CTDI with the product of slice thickness and number of slices yielded the dose-length product. This quantity is indicative for the exposure of the entire CT examination. $CTDI_w$ was assessed at 18 hospitals for different scan parameters. Scan parameters such as tube voltage and current, thickness and spacing of slides, patient variables and use of contrast were collected for about 3000 clinical CT examinations. Patient effective dose was assessed for these examinations using effective dose conversion factors published by Jones and Shrimpton [14] and by Jansen et al [15]. Five CT examinations were considered: brain, chest, abdomen, lumbar spine and HRCT (high resolution computed tomography) chest [16]. A summary of the results is shown in Table IV. Dose values are compared to values recommended by the European Commission [17] and the NRPB [12]. CT examinations of the chest and abdomen gave the highest effective dose. Interhospital variations in the number of slices, slice thickness, and tube current contribute most to the large ranges in patient dose.

Table IV. $CTDI_w$, dose length product and EC reference values, effective dose and typical values for effective dose from the NRPB. Doses are presented as mean values, minimum and maximum values appear between brackets.

Region	$CTDI_w$ (mGy)	EC $CTDI_w$ (mGy)	DLP (mGy.cm)	EC DLP (mGy.cm)	E (mSv)	NRPB E (mSv)
Brain	71 [23-159]	60	702 [315-1537]	1050	3 [1-5]	2
Chest	22 [10-38]	30	593 [269-1168]	650	10 [4-19]	8
Abdomen	27 [10-50]	35	950 [396-1551]	780	17 [7-26]	10
Lumbar spine		n.a.		570	5 [2-12]	10*
HRCT chest		35		280	2 [1-7]	

n.a.= not available, * CT pelvis

4. Conclusion

Patient dosimetry is often applied as an instrument for optimisation of radiological techniques. Interhospital, interregional and international comparisons provide insight in the radiation exposure of patients. Comparison of the survey results with European guidelines shows that the entrance skin doses for paediatric and adult radiographs are well below the European reference values, with only one exception, i.e. at one hospital the measured entrance skin dose was slightly higher than the reference value. The considerable variations between hospitals suggest that there is still an opportunity for further optimisation of radiographic techniques. Reference dose levels in The Netherlands could be more restrictive than the European values. There are no European criteria for patient dose of barium contrast examinations. Comparison with reference values of dose-area-product published by NRPB showed that in The Netherlands the mean barium meal values are high and the mean barium enema values are below the reference values. For computed tomography, all reference doses were exceeded at one or more hospitals. For a CT abdomen examination even 13 out of 18 hospitals exceeded the dose-length-product reference value.

Assessment of image quality has hardly ever been realised satisfactory in dosimetric field studies. Current guidelines and reference values on patient dose are generally derived from a percentile (often the 75-percentile) of the observed distribution. Future reference doses should be related to the radiographic technique that yields a good diagnostic sensitivity at a dose that is ‘as low as reasonably achievable’.

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IAEA-CN-85-263

PATIENT DOSES AND EXAMINATION FREQUENCY FOR DIAGNOSTIC RADIOLOGY IN ICELAND 1993-1998

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Abstract

Presented are data on the frequency of x-ray examinations that have been gathered in two surways with a five year interval. There is a 17% increase in the number of x-ray examinations from 1993 to 1998. At the same time computed tomography examinations are nearly doubled. Patient dose data for the different types of examinations are also presented and an assessment is made of the contribution of these examinations to the Collective Effective Dose. The number of CT examinations has increased from 8,3% of all x-ray examinations in 1993 to 13,6% in 1998 and contributes more the 50% of the CED in 1998.

1. Introduction

The Icelandic Radiation Protection Institute (IRPI) performed two surveys on the frequency of diagnostic x-ray examinations in Iceland in 1993 and 1998. Measurement of patient doses for over 4500 conventional x-ray examinations have been performed at 14 x-ray departments all over the country, in more than 28 x-ray rooms. These measurements were made with Dose Area Product meters (DAP). Dose evaluation for CT examination have been made for all the CT units in the country. Patients doses for breast examinations have also been evaluated.

This paper will present results of these efforts, revealing trends in the frequency of radiological examinations and patient doses and an assessment of the collective effective dose (CED)[1] contributed by diagnostic radiology examinations. Of particular interest are trends in patient doses and examination frequency in computed tomography and its contribution to the CED.

2. Material and Methods

Examination frequency

Data on examination frequency was collected by IRPI on two separate occasions, in 1994 (for examinations made in 1993) and again in 1999 (for examinations made in 1998). Earlier data collections have been made in Iceland, but not in the detail necessary for comparison with the this data. Data was collected from all x-ray departments in the country, covering more than 95% of the medical diagnostic imaging examinations done in Iceland in these years. About 80% of the data was detailed with information on examination types, age and sex of the patient.

Patient doses

In 1994 IRPI started a program to evaluate patient doses by using dose measurement systems consisting of DAP meters connected to PC-computers. A software was developed, that made it easy for the radiographers to collect data about all x-ray examinations made with the x-ray equipment. This includes information such as examination type, age, weight and sex of the patient, the high tension (kV) used, number of films used and the film-screen combination used. The software collected data from the DAP meters during the x-ray procedure and could separate DAP for fluoroscopy and radiographs. It could also calculate the fluoroscopy time. From this data the effective dose [1] for the different x-ray examinations could be calculated using appropriate conversion coefficients from the literature [2].

All Mammography examinations are performed at the Icelandic Cancer Societies Breast Screening Center in Reykjavik and with mobile equipment around the country. Patient doses for breast imaging is based on data collected by a computer program on the PC-computers which are connected to the x-ray equipment that are used in the screening program. This program collects information about exposure factors for each image made, such as kV, mA, exposuretime, thickness of the compressed breast and other information. The mean glandular tissue dose is calculated and stored for each exposure. The effective dose was calculated by using the ICRP weight factor for breast [1], multiplied with the mean glandular dose and the mean numer of projections used.

For CT examinations, patient doses were assessed by dose measurements in 4 of the 5 CT units used in Iceland. Free in air and phantom doses were measured with a pencil shaped ionization chamber connected to an electrometer (Radcal Corp. USA). The CTDIw [3] for each unit was calculated and with information from examination protocols at each location the DLP [3] for the most common examinations was calculated. The effective dose for CT examinations was calculated by using normalized values of effective dose per DLP for different body regions [3].

3. Results

Examination frequency

The national survey in 1993 shows that 160.710 x-ray examinations were made that year and this number has increased to 188.740 in 1998 (+ 17,4%). The most striking increase is in CT examinations, which went from 13.370 to 25.760, which is an increase of 93%. The results are shown in table 1.

Table 1. Frequency of x-ray examinations 1993 and 1998

	1993	1998	Change %
Number of all x-ray examination (incl. CT and Mammography)	160.711	188.739	+17.4
Computed Tomography	13.368	25.841	+93.3
CT ex. as a fraction of all x-ray examinations	8.3%	13.6%	
Mammography	13.155	14.872	+13.1
Number of x-ray examinations per 1000 inhabitants	609	685	+12.5

There are good data available about the number of CT examinations since they began in 1981. Today there are 5 CT-units in use in the country and the majority of the examinations are made with 4 of these units (1 is an old unit that only contributes less then 1% of the examinations). In figure 1, the examination frequency for CT examinations are shown, from 1981 and on the

figure are indicators for the number of CT units that are in use at each time. In 1993 the first spiral CT unit was introduced and today there are 2 spiral units and one multi-slice unit.

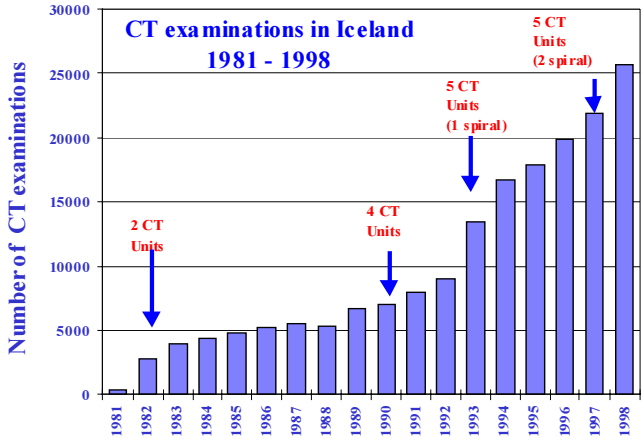

Figure 1 Frequency of CT examinations in Iceland 1981 - 1998

The increase in Mammography examination are mainly due to different coverage of the country in the screening program for these years. The average number of Mammography examinations per year from 1989-1998 is 14100.

Patient doses

Patient mean effective dose for the most common conventional x-ray examinations, based on DAP measurements are shown in table 2. The table also shows information on mean high tension (kV) used, the mean number of films, and mean DAP values (in $Gycm^2$) and measurement range. There is a very wide range in DAP measurements for most of these examinations.

Table 2. Mean effective doses for some common conventional x-examinations, with information about used kVp, number of used, mean measured DAP and measurement

Examination type	Mean kVp	Mean number of films	Mean DAP $Gycm^2$	Range $Gycm^2$		Mean effective dose mSv
				Min	Max	
Barium Enema	99	15,4	56,6	1,5	204,7	***11,9***
MUCG	74	11,0	34,5	2,3	51,9	***10,7***
ERCP	80	7,5	22,1	0,1	100,6	***4,4***
Urography	72	11,2	18,2	0,8	64,8	***3,5***
Lumbal Spine	73	4,6	12,9	0,2	97,6	***2,0***
Abdomen	76	3,2	6,1	0,2	40,1	***1,4***
Pelvis	74	1,4	3,4	0,1	24,6	***0,7***
Thoracal Spine	71	2,9	5,2	0,3	18,5	***0,7***
Cervical Spine	69	5,8	1,0	0,05	3,6	***0,2***
Lung	122	2,2	0,6	0,01	5,4	***0,1***
Skull	72	3,8	2,0	0,02	4,3	***0,05***

The mean effective dose for Mammography is 0,36 mSv and contribute 5,4 manSv to the CED. The method of data collection and dose measurements in CT, only gives average doses for the different examinations, with no indication of range. The mean effective dose for the most common CT examinations are shown in table 3 with assessment of their contribution to the CED. The contribution of the different x-ray examinations to the Collective Effective Dose are shown in figure 2.

Table 3. Number of CT examinations in 1998, mean effective dose and contribution to CED

Examination Type	*Number of examin. 1998*	*Mean Effective Dose mSv*	*Collective Effective Dose manSv*
Head	10.888	1,3	14,6
Lung/Chest	4.186	8,5	35,5
Neck	437	4,0	1,7
Spine	3.309	3,3	10,8
Kidneys	435	5,3	2,3
Abdomen	3.154	13,2	41,6
Liver/Spleen	2.046	5,8	11,9
Pelvis	775	6,1	4,7
Other	532	4,5	6,8
Total:	**25.762**		**129,9**

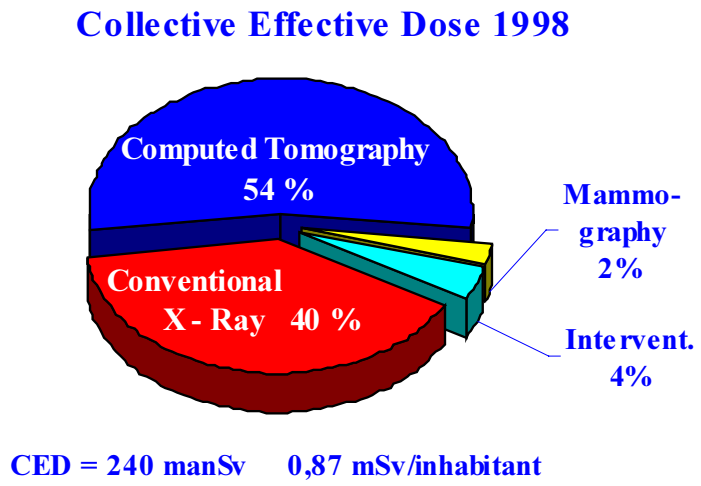

Figure 2 Collective effective dose for x -ray examinations in Iceland

4. Discussion and conclusion

Examination frequency is increasing in Iceland but the number of examinations per thousand inhabitants is very similar in Iceland (689) as in the neighbouring countries, such as Norway (708), Sweden (568) and Finland (704) [4]. But lower then the average number for Level I countries according to the latest UNSCEAR report (920) [4]. The most pronounced trend in examination frequency is the increase in CT examinations which has nearly doubled.

CT examinations now contributes more than 50% of the total CED from all x-ray examinations, similar to trends in other countires[5]. The highest doses arise from CT examination of the abdomen, chest and pelvis. On average CT examinations are high dose examinations which have a great effect on CED. Patient dose measurements for conventional examinations show a wide range, which indicates a potential for optimization in performance. Advances in CT technology are opening new diagnostic possabilities for the benefit of the patient and CT examinations are becoming the examination of chocie for more and more indications. Even though new CT equipment can achieve examinations with lower patient doses compared to older CT units, changes in examination protocolls can include larger parts of the patient being irradiated and higher doses. The CED is increasing rapidly due to both higher number of CT examinations performed and increasing doses per examination. Efforts to reduce doses should inlude optimisation of both how CT examinations are performed and the criteria for requesting them.

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CAN PATIENT POSITIONING USING AN ULTRASHORT FLUOROSCOPIC PULSE BE JUSTIFIED?

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Abstract

A study was performed to find out if a new fluorography procedure, a so-called pre-shot technique, could be justified as a tool for patient positioning to reduce patient dose and/or the amount of retakes with conventional X-ray examinations. The ratio of fluorography (S) and radiography (G) for two tissue types was obtained from dose measurements (PMX-III; RTI Electronics) by performing a simulation on a RANDO skull (0.69% S/G) and an abdomen (2.49% S/G) phantom. During 8 weeks, the radiographic technique (type of examination, incidence, number of necessary pre-shots and the number of radiographs per imaging session) was recorded from musculoskeletal examinations performed on a modified X-ray system (Siemens, Seregraph CF fluorospot). Analyses of the data shows that in up to 40% of the cases more than one shot has been used. This increases the relative amount of patient entrance dose up to respectively 1.31% (skull) and 3.0% (abdomen). Taking into account the retake rates with blind positioning (from literature: 3,2%-10%) and high patient dose with fluoroscopically guided positioning, we may justify the use of this alternative technique for X-ray departments with high retake rates and/or fluoroscopically guided positioning. The use of the proposed technique will reduce the retake rate to a minimum or zero and/or the overall patient dose. Several advantages are gained when combining this technique with storage phosphor plates: increase of patient throughput, decrease or removal of the clear room functionality.

1. Introduction

The use of fluorography to position the patients for conventional X ray examinations is forbidden in many European countries. In other countries, however, this is common practice. Whether this procedure necessarily leads to higher averaged patient dose depends on the retake rate of radiographs due to wrong positioning when fluorography is not applied. With a retake rate because of wrong positioning of n%, the use of fluorography is acceptable if the associated extra dose for the patient is less than n% of the dose for the radiographs. A few dose measurements have shown that in most cases the use of fluorography cannot be justified.

Recently, we have modified a digital X-ray system such that pressing the fluorography button results in a fixed fluorography time of 0.5s only. We have studied the doses necessary for positioning with this fluorography mode and we investigated whether this practice could be justified.

2. Material and methods

The study was performed in an X-ray room in which radiographs of thorax and skeleton are acquired.

The equipment consisted of a Seregraph CF fluorospot (Siemens, Erlangen) and storage phosphor plates of Agfa (Mortsel, Belgium). The newly developed so-called pré shot technique restricted the fluoroscopy time to a maximum of 0.5s per shot. As the digital system was foreseen of an image hold option, the fluoroscopic image remained visible and allowed for further improvement of the positioning. Occasionally, this position adjustment could be verified with an extra fluoroscopy shot.

The doses caused by this new procedure for patient positioning evaluations were measured. Two parts of a RANDO phantom were used for this purpose: the skull to simulate an exposure with a lot of bony structures and the abdomen mainly consisting of soft tissue. An experienced radiographer was asked to position the phantoms 5 successive times using the pré shot

fluoroscopy mode with the same characteristic curve and mA as had been used before. Doses were measured with a PMX-III solid state dosimeter (Mölndal; Sweden). This device measures the entrance dose without taking into account the back scatter fraction.

During a period of 8 weeks, the following data were recorded for all examinations: the type of examination, the incidence, the number of necessary pre-shots and the number of radiographs per imaging session. For each examination, the radiographers indicated also how the positioning was performed: (1) without fluorography, (2) using 1 scopy pulse without any further need for correction, (3) using 1 scopy pulse and correction of positioning, however without any further fluorographic control, and (4) using more than 1 scopy pulse. In total, 2363 examinations were performed. Only examinations with a high occurrence rate were further evaluated in the study.

3. Results

The comparative dose studies for fluoroscopy versus radiography in the phantom studies are summarized in Table 1. For the examination of the skull, the averaged entrance dose for fluoroscopy was 27.4 μGy (st dev 4.5 μGy). The entrance dose for the radiography of the skull phantom was 3998 μGy (stdev 0.7 μGy). The dose associated with the pre-shot fluoroscopy technique was therefore 0.69% of the dose for the corresponding radiograph. For the abdomen, the dose from fluoroscopy was 17.6 μGy (st dev 3.6 μGy) and the radiography gave a dose of 704.5 μGy (stdev 2.5 μGy). The dose ratio in this case was higher: 2.49%.

The number of pre-shots for the whole series of examinations is summarized in Table 2. In up to 40% of the cases more than 1 shot has been used. In Fig. 1 we show the average number of pre-shot fluoroscopy pulses for the 20 most frequently performed small musculoskeletal examinations in the X-ray room. Fig. 2 represents the frequency of necessary adjustments to the patient positioning after a first fluoroscopic pre-shot pulse. In our radiological practice, an average of 1.4 pre-shots is necessary. The number of shots for the skull examination is up to 1.9. The abdominal examinations require only 1.2.

4. Discussion

From the dose investigations, it is clear that the dose associated with a single pre-shot exposure is very low as compared to the dose from radiography. For the skull, we note a dose ratio between fluoroscopy and radiography of 0.69% and for the abdomen 2.49%. Taking into account the number of fluoroscopic pulses for these examinations, the relative amount of patient entrance dose increases up to respectively 1.31 % and 3.0 %. This dose ratio has to be compared with the retake rate due to false positioning.

This parameter is, however, not always known. From a literature search we retrieved a few retake rates for centers using blind positioning. Arvanitis [1] reported an overall retake rate of 3.2%. Lewentat [2] reports up to 7.6%. After improving the working procedure, it went down to 5.0%. These values represent an upper limit of the real retake rates due to wrong positioning. Hence, when using conventional cassettes, a major source of retakes is caused by over or under exposure. Hill [3] summarizes his literature review with the indication of a 10% retake rate, of which 19% is due to wrong positioning. Highest retakes are observed for skull (18.9%) and abdomen (19.2%) and lowest for IVU (5.3%) and chest (6.3%). Retake rates due to wrong positioning for skull and abdomen are thus about 3.6 %. It is obvious that for these type of examinations, patient doses would be reduced if the pre-shot fluoroscopic technique would be used for positioning instead of blind positioning. This situation may be different for other types of examinations.

In centers in which positioning is usually performed by means of fluoroscopy, the dose reduction is guaranteed. For departments that use fluoroscopically guided positioning, the results of this study may be important. Indeed, the use of fluoroscopy as it is today is usually not justified. This new option justifies the use of fluoroscopically guided positioning, as long as the number of pre-shots is limited. There are multiple other advantages of the technique when used in combination with storage phosphor plates. First, the patient can leave the radiology department immediately after the X-ray is taken. Hence, both problems due to positioning or wrong exposure are eliminated. This leads to a significant increase in through put. Second, there is no need anymore for a clear room. Third, the total patient dose can be lower, especially for departments with high retake rates.

A surprising result from this study is that in more than 40% of the cases repositioning of the patient was performed after the fluoroscopy pulse. This may be due to several reasons: (1) only a few radiographers are expert in blind positioning; (2) requirements on image quality are very high; (3) radiographers want to reach perfection. In the frame of the European directive 97/43 and the ALARA principle, it may be necessary to reduce the image quality requirements in a controlled manner. Finally, the teaching about how to position the patient in a blind way remains important since doses can then be reduced even when the pre shot technique is available.

5. Conclusion

This study shows that the use of ultrashort fluoroscopic pulses for patient positioning may be justified for a large number of X-ray departments.

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Table I. Comparative dose evaluation of pre-shot fluoroscopy versus radiography

Phantom:	**SKULL**			**ABDOMEN**		
	Scopy [S]	***Graphy [G]***	**ratio**	***Scopy [S]***	***Graphy [G]***	**ratio**
Settings:	dose [uGy]	dose [uGy]		dose [uGy]	dose [uGy]	
	87 kV 2,2 mA	*73 kV 70,1 mAs*		*87 kV 2,2 mA*	*73 kV 12,7 mAs*	
Measurement:		*AEC 0*	S/G		*progr. AE*	S/G
1	31,33	3999	0,78%	15,54	703,2	2,21%
2	31,93	3998	0,80%	20,91	704,2	2,97%
3	29,20	3998	0,73%	21,61	705,1	3,06%
4	21,74	3998	0,54%	16,64	701,6	2,37%
5	24,14	3997	0,60%	13,10	708,3	1,85%
Average:			0,69%			2,49%

Table II. Overview of the use of fluoroscopy for conventional X-ray examinations: skeletal and abdominal radiography

Overview of fluoroscopy	n	
No scopy used	213	8,45%
One scopy without correction	482	19,12%
One scopy with correction	657	26,06%
More than one scopy	1011	40,10%
Total examinations	2363	

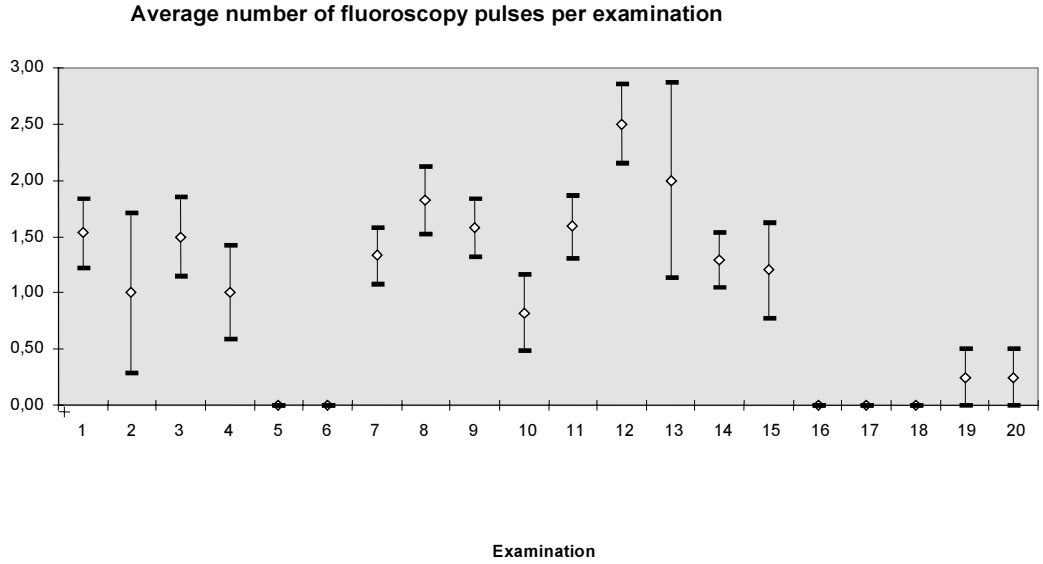

Figure 1 Average number of fluoroscopy pulses for musculoskeletal examinations

(1: upper arm, 2: ankle P, 3: femur ¾, 4: femur F/P, 5: hand ¾, 6: hand F, 7: knee ¾, 8: knee ax, 9: knee condyl, 10: knee F, 11: knee P, 12: nose F, 13: nose P, 14: lower leg F, 15: lower leg P, 16: wrist ¾, 17: wrist F, 18: wrist P, 19: foot ¾, 20: wrist P)

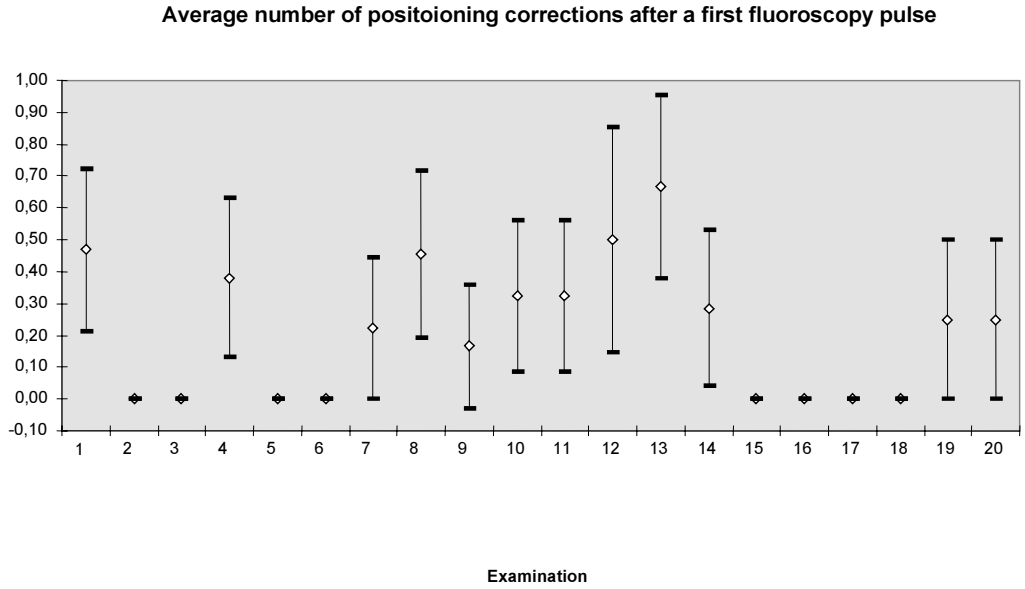

Figure 2 Average number of corrections to the position of the patient. Same examinations as in Fig. 1

DEVELOPMENT OF AN INTERNATIONAL CODE OF PRACTICE FOR DOSIMETRY IN X-RAY DIAGNOSTIC RADIOLOGY

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Abstract

Medical x-ray examinations contribute greatly to the population dose from man-made radiation sources. There is a need to control this dose and therefore to optimise the design and use of x-ray imaging systems. A key stage in this process is the standardisation of the procedures for dose measurement in the clinic. The Dosimetry and Medical Radiation Physics section of the IAEA has a number of activities to further advance the standards for x-ray diagnostics. One of these activities is the coordination of a working group to develop a code of practice, which will facilitate the IAEA calibration activities, TLD intercomparisons and audits, educational activities, and a technical assistance to Member States. The code of practice will aid in the standardisation of various dosimetric techniques in x-ray diagnostic radiology. The CoP working group has had an initial meeting to review the current status of dosimetry for conventional radiology, fluoroscopy, mammography, computed tomography and dental radiology. The CoP will include the establishment of standards and calibrations at the SSDLs, phantom and patient measurements and procedures for dosimetry in the clinic.

1. Introduction

A key stage in controlling x-ray irradiation of patients is the standardisation of the procedures for dose measurement in the clinic. In many situations, it is of interest to make measurements directly on the patient. However, for the control of technical parameters, for the comparison of different systems and for optimisation of the systems, it is preferable to make measurements using a standard phantom to simulate the patient. With the exception of mammography, there is hardly any international advice available for the performance of such measurements or the selection of phantoms for use in different situations.

Approximately 40% of Secondary Standard Dosimetry Laboratories (SSDLs) are currently involved with calibration of diagnostic ionization chambers. At present, the manner in which calibrations at diagnostic radiation qualities are performed at SSDLs is not co-ordinated. Many use different radiation qualities and standards, some of which may be unsuitable. Quality control can only work satisfactorily if correct measurements are made. A large number of SSDLs are requesting guidance on establishing calibration facilities.

The objective of the Dosimetry and Medical Radiation Physics (DMRP) section of the IAEA is to enhance the capacity of Member States to achieve and maintain a high level of quality in dosimetry and medical radiation physics, to improve the implementation of traceable standards at the national level and to ensure control of radiation dose in the Member States. This goal has as its precedent the prior work in radiation therapy. A series of

recommendations for dosimetry have been published with the latest dosimetry protocol "Absorbed Dose Determination in External Beam Radiotherapy: An International Code of Practice for Dosimetry based on Standards of Absorbed Dose to Water", published in 2000 [1]. The increased need to standardize dosimetric measurements in x-ray diagnostic radiology led the DMRP to establish a working group with the aim of preparing the new Code of Practice (CoP) that will review the current status of dosimetric measurements in conventional radiology[1], fluoroscopy, mammography, computerized tomography and dental radiology and give recommendations on selection of the instruments, their calibration and procedures for clinical dosimetry.

2. Background of X-ray diagnostic dosimetry

In developed countries about 90% of medical radiation dose is due to x-ray diagnostics and 10% to nuclear medicine [2]. Since the risk for stochastic effects (induction of cancer and genetic disorders) is believed to be without a threshold, the detriment to the population increases with increasing population dose. An increasing part of this dose from diagnostic x-rays is due to the use of procedures such as fluoroscopy in interventional radiology and computed tomography (CT). Patient dose measurements are therefore becoming increasingly important. For example, in the International Basic Safety Standards [3] it is stated that representative dose values shall be determined in radiological examinations. The European Union has adopted a directive towards "health protection of individuals against the dangers of ionising radiation in relation to medical exposures" which requires extensive dose measurements [4]. This translates into a need to optimise the design and use of x-ray imaging systems. It is generally recognized that even a 10% reduction in patient dose is a worthwhile objective for optimisation. In this context it is important to note that the image quality should always be sufficient for the clinical need.

Due to the increased need for quality assurance in diagnostic radiology, it has become important to provide traceability of measurements in this field. The Standing Advisory Committee "SSDL Scientific Committee" recommended in 1996 that the experience of the IAEA in the field of standardization at radiotherapy and radiation protection levels for the IAEA/WHO Network of SSDLs be extended to the field of x-ray diagnostics. This recommendation has led DMRP to start the development of the necessary facilities and procedures for the calibration of ionization chambers [5].

Various examination techniques are used in x-ray diagnostics. They include conventional radiography, fluoroscopy and other interventional radiological procedures, mammography, CT and dental. In some cases specialised dosimeters are required, whose design and performance must be matched to the needs of the clinical measurement. The use of such dosimeters and/or the interpretation of the results obtained may require specialised techniques and knowledge. In addition there are special requirements for the calibration of such instruments at the SSDLs. Methods to perform such calibrations are not yet completely developed. The most common type of radiation detector for diagnostic radiological dose measurement is a parallel plate ionization chamber. There may be special requirements for the calibration and use of each type of chamber. All ionization chambers should have a sufficiently flat energy response over the range of the relevant radiation qualities. Mammographic ionization chambers generally require a thin entrance window and a construction using low atomic number materials, e.g. air equivalent or plastic materials. A CT-chamber, often called a pencil chamber, has an active

[1] In this paper the term conventional radiology is used to cover all x-ray imaging modalities other than dental radiography, fluoroscopy, mammography and CT.

volume in the form of a thin cylinder about 100 mm in length. Its response should be uniform along its entire axial length. In fluoroscopy there is a need to measure the input air kerma rate to the image intensifier and the patient dose. The chambers used for each aspect need to be of adequate design and size. Air Kerma Area Product (KAP) meters are also used in fluoroscopy. They are mounted on the x-ray housing and their sensitive area extends over the entire cross-section of the beam. The signal from a KAP meter is proportional to the product of air-kerma and field size at any plane perpendicular to the beam axis. For the measurement of panoramic dental examinations, ionisation chambers need to be cylindrical.

Although ionization chambers are the main devices used for dosimetric measurements, other devices with special properties are frequently used. Important examples are semiconductor diodes and thermoluminescent dosimeters (TLDs). Because of the inherent problems involved in the use of these two devices, they should not be used for calibrations at SSDLs. They are used for quality control and in clinical dosimetry.

The contrast in a radiographic image is mainly determined by the x-ray tube voltage. It is standard practice, therefore, to measure this voltage as part of quality control. Non-invasive instruments are mostly used for this purpose. Such instruments require special calibration consideration [6].

It is obvious, that standardisation of procedures for measurements in the clinic and the SSDLs is of great importance. The CoP will address both of these areas to bring coordination to them.

3. Present status of the code of practice

The working group established to prepare the CoP has met in November 2000 to review the current status of dosimetry in diagnostic radiology and prepare an initial draft of the document. Its basic concepts are briefly outlined below.

Requirements for calibrations at SSDLs

The chamber and electrometer (or charge-measuring device) both need to be calibrated at an SSDL, either separately or as a system. The quality for which the calibration was performed must be stated, since past work has indicated a significant energy dependence of response of some chambers. For this reason, the SSDLs need to establish radiation qualities suitable for each application. Radiation qualities as given in IEC 61267 [7] provide some guidance but these are in the process of revision. Where such radiation qualities do not exist, appropriate beams must be identified. Each SSDL must have chambers calibrated at the reference radiation qualities. For a chamber with sufficiently flat energy dependence, interpolation can be done for any intermediate point. Sufficiently flat energy response depends on the application, e.g. for conventional x-rays this is a maximum variation within +3% across the energy range. An application of this response is in the measurements of HVL with ionization chambers. These measurements can be affected by the energy dependence of response [8], and by the beam diameter used.

When choosing an instrument for dosimetry in diagnostic radiology, it is important to match the instrument to the task. This will include the size and sensitivity of the instrument and its response to different radiation qualities. The use of an appropriate instrument is essential. In some cases, the commercially available instrumentation marketed for general or particular applications does not meet these requirements [9] and there may be no internationally agreed specification. This can create difficulties, particularly where there is no local expertise available. Specific devices are designed for use in the clinic. For example, the KAP meter is a very useful instrument for dosimetry in diagnostic radiology as ‘kerma-area product’ is more

directly related to radiation risk than dose itself. Opinion is divided about the calibration of KAP meters, whether they should be calibrated at the SSDL or in situ. Examples of calibration procedures are given by IPEM [10] and by Larsson et al. [11]. Semi-conductor devices can be as small as TLDs and have the advantage that they allow real time measurement. A problem is that the inherent response of semi-conductor devices is not sufficiently flat. This problem is sometimes compensated for by the software corrections in the instrument.

Clinical measurements

Many times it is preferable to make dose measurements using a phantom to simulate the patient. When a phantom is used, the measured dose will depend upon the phantom shape and size and it is essential that the phantom is standardised so that such variations are avoided. Ideally, standard phantoms should be designed to offer the same primary attenuation and scatter production as a representative patient. The phantom only needs to be representative of average or mean values of a typical patient. It is not the intention that the result of dose measurements with phantoms should equal that from measurements with patients. When a phantom is used to simulate the patient, the x-ray equipment should be set up in the same way as for the real examination. Dose measurements made at the surface of the phantom include backscatter whereas those made free in-air do not. It is desirable to standardise the dose specification to avoid ambiguity. In this regard, standardized worksheets will be provided for each application. These worksheets will facilitate the international intercomparison of results. Two applications are discussed below as representative of the needs suggested by the CoP.

Mammography

During the past few decades there have been significant advances in the equipment used for mammography. Even when the latest equipment is used, there is considerable variation from centre-to-centre in the choice of imaging parameters and techniques. Thus, there may be quite large differences in breast dose. A review of the development and current status of dosimetry for mammography is given in Dance et al. [12].

The most practical dose measurement for mammography is an estimate of the incident air kerma at the surface of the breast (with or without backscatter). Since a low energy x-ray spectrum is used for the examination, the dose decreases rapidly with increasing depth in the breast. More appropriate quantities for specifying breast dose have therefore been suggested. The use of the mean dose to the glandular tissues within the breast (MGD) has been generally adopted. Direct measurement of MGD is not possible. Instead, use is made of conversion factors that relate measurements of entrance air kerma to MGD. Several countries have introduced protocols for dosimetry in mammography but there is wide variation in the methodology suggested.

CT

CT examinations constitute about 4% of all radiographic examinations but can contribute 40% of collective dose [13]. It is therefore of considerable importance to monitor the dose for such examinations. In conventional CT scanning, the patient dose is built up from that received from each individual CT slice. In-phantom measurements are more representative of the patient dose. Standard phantoms are available for both body and head examinations [14] and are in common use. Within the last decade helical CT scanning has been introduced. Care must be taken to ensure that the guidance is appropriate for this imaging technique.

4. Conclusion

The need for standardization of dosimetry measurements in diagnostic radiology and for calibrations of the measurement equipment is obvious. A limited international guidance is available for the performance of measurements in the hospital. A few SSDL laboratories offer a calibration service for diagnostic radiology instruments but a greater uniformity amongst the SSDLs is needed. Methods to perform such calibrations are not yet completely developed. The CoP should identify separately the requirements for conventional radiology, fluoroscopy, mammography, CT and dental radiography. It is expected that the document will be published in the beginning of 2003.

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QUALITY CONTROL AND PATIENT DOSES FROM X-RAY EXAMINATIONS IN SOME HOSPITALS IN THAILAND

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Abstract

Quality control measurements on 203 diagnostic X-ray units were carried out in 126 hospitals in the central region of Thailand during 1998-2000. The measurements consisted of tube voltage, half-value layer (HVL), exposure time, radiation output, beam alignment, light beam diaphragm and entrance surface dose (ESD) in four common radiographic procedures namely adult chest PA, adult mass chest PA in mobile bus unit, abdomen AP and mammography (cephalo caudal view). ESD measurements of 320 examinations were performed using parallel plate ionization chamber and Keithley model 35050A Dosimeter on 192 X-ray units (conventional and mobile) and 11 mammography units.
The analysis of test results showed that:

1. 92% had X-ray tube voltage within the tolerance limit of 10% and HVL 3.03 mmAl ± 0.55 SD at 80 kVp measured
2. 90% had exposure time within tolerance limit of 10%
3. 86% and 98% had acceptable beam alignment and light beam diaphragm
4. 95% had radiation output > 25 μGy at 1 m. for true 80 KVp
5. It was found that the ESD values were
    - adult chest (PA) varied from 0.18 mGy to 1.17 mGy (mean 0.2021 ± 0.2218 SD)
    - adult mass chest (PA) varied from 0.043 mGy to 1.03 mGy (mean 0.2935 ± 0.2195 SD)
    - abdomen (AP) varied from 0.302 mGy to 6.30 mGy (mean 2.177 ± 1.4818 SD)
    - mammography (cephalo caudal view) varied from 3.49 mGy to 12.21 mGy (mean 7.788 ± 2.9896 SD)

Further surveys are necessary and are being done to include measurements of image quality and for propagation of quality assurance activities in Thailand so as to reduce patient doses while maintaining the image quality.

1. Introduction

Diagnostic radiology is the main contributor to the man-made exposure of general population. Since Quality Assurance (QA) programmes ensure high quality diagnostic images with the least possible radiation dose to the patient, all countries have been recommended to introduce programmes for their radiological facilities. In Thailand periodic quality control of all X ray equipment in use is required by legislation. For monitoring purposes radiation leakage, total beam filtration, exposure time, tube voltage (kVp), radiation output, accuracy of beam limiting devices and adequacy of room shielding design were measured. Where available, tolerance limits established by FDA, NCRP, AAPM and ACR were used as a reference [1-4].

According to a programme of patient dose measurements was introduced as part of the quality assurance service already provided for X-ray departments throughout many countries. The emphasis that each patient exposure should be as low as reasonably practicable and encouragement to X ray departments to formulate a strategy for dose reduction [5]. We, therefore, initiated to add the patient dose measurement of entrance surface dose in four common radiographic procedures into our routine protocol as a pilot study. The performance characteristics of 203 diagnostic X-ray units were carried out in 126 hospitals during 1998-2000. These diagnostic units were located in the central region of Thailand in government and private hospitals; they covered the whole range of commercial equipment in Thailand. They represent 8% of the total diagnostic units of central region and 3% of the country.

2. Materials and methods

The quality control measurements were carried out on 203 X ray units. The measured units consisted of conventional and mammographic X ray units. Performance measurements were focused on tube voltage, beam quality (half - value layer), exposure time, radiation output, beam alignment and accuracy of beam limiting devices, and entrance surface dose (ESD) in four common radiographic procedures namely adult chest PA, adult mass chest PA in mobile bus unit, abdomen AP and mammography (cephalo caudal view).

The parameters which were measured are listed in Table 1 and Table 2 for conventional and mammography X ray units respectively, as well as the acceptability criteria [1-4]. The X ray tube potential and exposure time were measured at 60, 70, 80, 90 and 100 kV using Keithley dosimeter/kVp readout model 35050A and kVp divider model 35080A at 56 cm. X ray source to table top.

The X ray beam quality, radiation output and radiation output reproducibility were performed at 80 kV actual beam for 20 mAs at 40 cm. from the X ray tube focus to chamber using Keithley dosimeter/kVp readout model 35050A, ionization chamber model 96035 B and 100 cm. aluminuim sheets (No.1100) were insert between the tube and ionization chamber in case of beam quality measurement. The linearity of the radiation output (variation of the output as a function of mAs) was checked between 5 mAs and 64 mAs.

The correspondance between the light beam and the actual X ray beam, and X ray beam alignment were tested using the collimator and beam alignment test tools by RMI at 100 cm. from the X ray tube focus to the test tool which was placed on the table.

The patient doses for conventional X ray units, were calculated measuring the X ray output and using the tabulated exposure parameters of each X ray examination used in the hospital in question. While the surface dose of the mammographic X ray units were measured on RMI acryric phantom as required by the American College of Radiology (ACR) with the Keithley dosimeter/kVp readout model 35050A, ionization chamber model 96035 B using the local examination technique in each place.

Table 1. Acceptability criteria of the measured parameters for conventional X ray units

kV accuracy	±10%
kV reproducibility	5%
Filtration at 80 kV actual beam	≥ 2.3 mmAl
Tube output (80 kV at 1 m from the focus)	>25 μGy(mA.s) $^{-1}$
Reproducibility of the tube output	5%
Linearity of the tube output	±10%
Exposure time	
• Accuracy	±10%
• Reproducibility	5%
Correspondance light beam and actual X ray beam	≤ 2% of FID
Leakeage radation at 1m from the focus in any direction	<1 μGy.s $^{-1}$

Table 2. Acceptability criteria of the measured parameters for mammography X ray units. Results

kV accuracy	±5%
kV reproducibility	2%
Filtration at 30 kV actual beam	≥ 0.3 mmAl
Reproducibility of the tube output	5%
Linearity of the tube output	±10%
Automatic exposure cells reproducibility	5%
Correspondance light beam and actual X ray beam	≤ 1% of FID
Leakage radiation at 1 m from the focus in any direction	<1 $\mu Gy.s^{-1}$

The analysis of X ray units test results showed that 92% had acceptable deviation between nominal and measured values of X ray tube voltage with in the tolerance limit of 10% and HVL 3.03 mm.Al ± 0.55 SD at 80 kVp actual beam whereas 90% of the X ray units meet the recommended limits of exposure time (deviation ≤ 10%). Of the X ray generators assessed, 84% had tolerable (μGy/mAs) linearity. For the light beam and actual X ray beam 2% of the X ray units showed a difference of more than 2% of FID (focus to image distance). Moreover, in 86% of the X ray tubes, the beam was properly aligned. Measurements on the X ray tubes showed that 96% had adequate beam filtration (HVL ≥ 2.3 mm.Al, 80 kVp) and 95% had radiation output less than 25 μGy at 1 m. for true 80 kVp whereas in 98% exposure reproducibility had acceptable variation within the tolerance limit of 5%.

The entrance surface doses for three main types of examinations (some variety of chest such as adult chest PA nonbucky, adult chest PA with bucky and adult mass chest PA in mobile bus units, abdomen, and mammogram) which were measured during the years 1998-2000, are presented in Table 3.

Figures 1 to 5 show the entrance surface dose of three categories of chest techniques, abdomen and mammogram respectively in term of mode (frequency of data) and median values for entrance surface dose of each technique.

Table 3. Entrance surface dose for three main types of examinations in different years

Examination	mean ESD (mGy)		
	1998	1999	2000
Adult Chest PA (without bucky)	0.25	0.31	0.22
Adult chest PA (with bucky)	0.25	0.22	0.30
Adult mass chest PA (mobile bus unit)	0.31	0.47	0.30
Abdomen	2.79	2.84	1.96
Mammogram	8.81	11.07	7.65

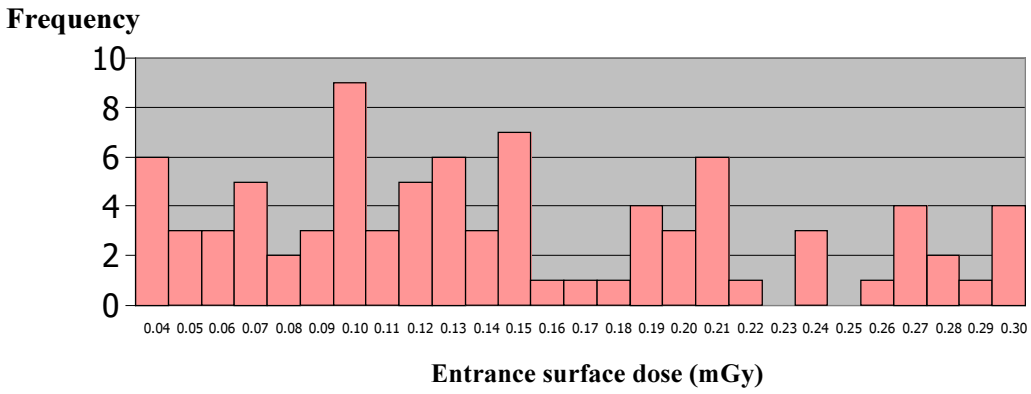

Figure 1. Entrance surface dose of adult chest PA nonbucky

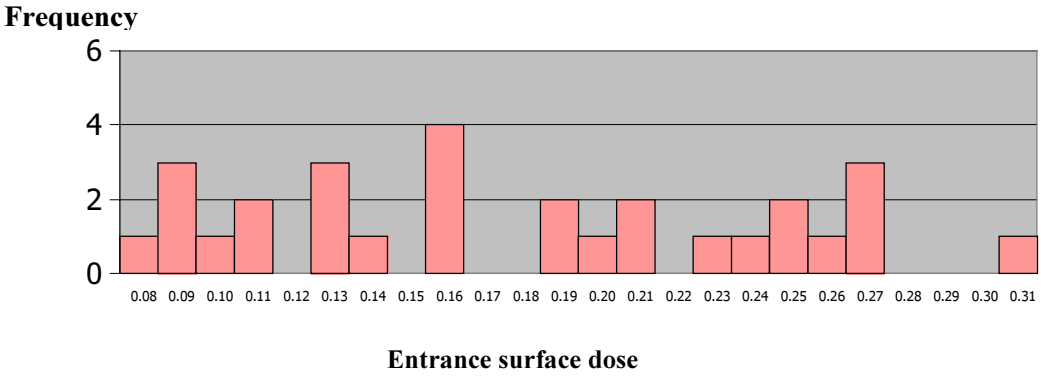

Figure 2. Entrance surface dose of chest PA with bucky stand

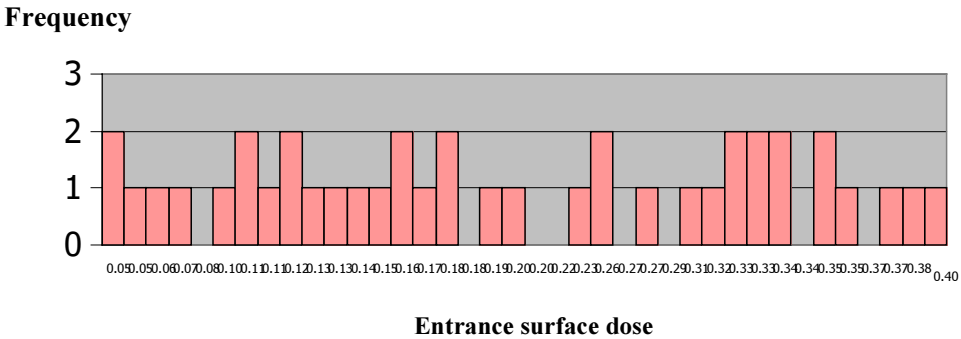

Figure 3. Entrance surface dose of adult mass chest PA in mobile bus units

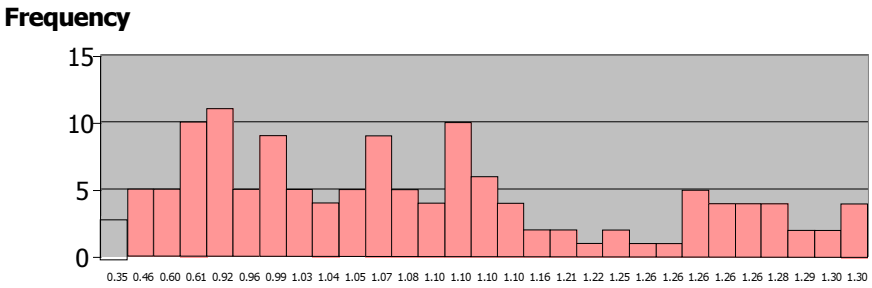

Figure 4. Entrance surface dose of abdomen

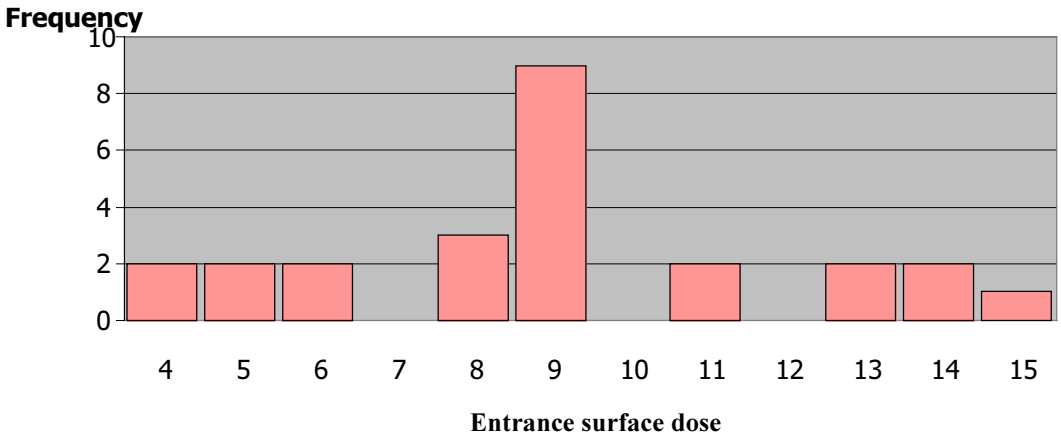

Figure 5. Entrance surface dose of MAMMOGRAM

3. Discussion

The results presented here confirm that the acceptable level of the quality control in diagnostic X ray equipment have led to the improvement and reduction in patient doses. In addition, the procedure which was adopted has been well received by the radiologists, commercial firms and public services. This encouraged us to extend the inspection to technical parameters such as focus, image quality, image recording system, television monitors, film storage conditions, and film development methods. The implemention of Quality Assurance in Thailand may take time. Staff training and administrative actions of the radiation protection authorities will improve the existing situation for the benefit of patients and staff.

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IAEA-CN-85-205

QUALITY CONTROL OF DIAGNOSTIC X-RAY UNITS

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Abstract

The quality control program for diagnostic x-ray units has started at the Institute of Occupational and Radiological Health during 1990. It includes, among other measurements, reproducibility of dose, high voltage and exposure time. Dose reproducibility was less than 5% for 70% of tested x-ray units. The exposure time and high voltage reproducibility were less than 5% in 60% cases. The cassettes with amplifying foils made from components of rare earth are used in 10% of all x-ray departments. It is very important to work as much as it is possible to modernize general infrastructure as the radiological protection of patients would be better.

1. Introduction

All ionizing irradiation sources in FR Yugoslavia are constantly subjected to the regular dosimetric control performed by specialized institutions authorized by Federal legal regulations.

The medical radiological equipment is of the special importance as includes radiological protection of patient, besides public (and/or environment) and occupational protection. The radiological protection of patient has specific characteristics in diagnostic radiology, radiotherapy or nuclear medicine.

In the diagnostic radiology if the image is not of adequate quality it may lead radiologist to an incorrect diagnosis. If the quality of the radiograph is so poor that it cannot be used, than the patient will be exposed again. That cause an unjustified increase in patient dose and increase in the cost of diagnosis.

The most objective evaluation of image quality is the physical measurement of X-ray unit parameters. The quality control program for diagnostic X-ray units has started at the Institute of Occupational and Radiological Health during 1990. The certain results of generator investigations to date are present in this paper.

2. Instruments and methods

The kVp applied to the X-ray tube should be checked to ensure that it is in reasonable agreement with the kVp indicated on the control panel. The direct measurement of kVp is not practicable as a routine test. The most common indirect method is to determine the peak voltage from measurements of radiation quality. We have used digital kVp meter, Victoreen, Model 07-473 or Victoreen, NERO, Model 6000M. The measurements were done in the interval from 60 to 100 kVp in steps of 10 kV.

The radiation output was measured for dose reproducibility testing by Victoreen RAD CHECK Plus, Model 06-526 or Victoreen, NERO, Model 6000M, with parameters: 100 kVp, 320 mAs and distance 1m from focus.

And, for the exposure time reproducibility testing we have used instruments Victoreen, Model 07-457 or Victoreen, NERO, Model 6000M. The duration of scannings was selected at the control panel as 1 s, 0.5 s or 0.32 s.

3. Results

During last ten years about 250 X-ray tubes have been tested annually. But, 318 X-ray tubes have been tested from January, 1999 to September, 2000.These results are presented in this paper as they represent the quality level of X-ray units.

A patient can receive widely different exposure depending on the facility. In the Table I are given doses per mAs for different X-ray generators at the patient position.

Table I. The dose in mGy/mAs

The type of X-ray unit	$\bar{D}$	σ	D_{min}	D_{max}
half-wave	1.3	0.500	0.054	2.807
6,12- rectifiers	0.117	0.060	0.015	0.352

$\bar{D}$ – mean value; σ - standard deviation; D_{min} , D_{max} - extreme value

The results of dose, high voltage and exposure time reproducibility are shown according strong criteria (less than 5%), and following the accepted criterion by our legal regulations (less than 10%). They are given in the Table II.

Table II. The reproducibility for various type of X-ray units

Reproducibility	Number of tested units	Measured deviations		
		< 5 %	> 5% and <10%	> 10 %
DOSE	318	72.54%	10.96%	16.50%
kVp (for 80 kV)	249	59.73%	35.71%	4.56%
TIME	318	63.28%	15.44%	21.28%

4. Discusion

Although the majority of analyzed generators (83.5%) showed satisfied reproducibility of dose (less than 10%), the mean values of measured quantity ranged over two orders of magnitude due interaction of numerous factors.

There have been 79 dental X-ray tubes tested. About 30% units have had inaccurate timer, and were repaired after control.

The cassettes with amplifying foils made from components of rare earth are used in 10% of all x-ray departments.

It is very important to work as much as it is possible to modernize general infrastructure as the radiological protection of patients would be better.

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IAEA-CN-85-107

DIGITAL TECHNOLOGY INFLUENCE ON PATIENT DOSE IN THE RADIOLOGICAL EXAMINATION OF THE UPPER DIGESTIVE APPARATUS

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Abstract

The radiological study of the superior digestive apparatus (oesophagus, stomach and duodenum) throughout the barium contrast is a kind of exploration which provides medium-high dosage levels for patients. In these studies the fluoroscopy and the acquisition of images for the diagnosis are shared. The acquisition of images, up until a few years ago, was accomplished through radiographic film and chemical processing; nowadays, the new generation of image-intensifier tube incorporates a new utility to digitally capture the images.

This new capturing method, with higher sensitivity, allows us to obtain images with a mAs 5 times smaller than the classical system of radiological film (reduction of the dosage up to 80%). This leads us to expect very important reductions in dosage in the studies conducted with this new technology. Nonetheless, these expectations haven't been reflected in the dosimetric samples that our work team has conducted in several centers of the community of Madrid these past years. In this work, the reasons of this phenomenum are analyzed.

1. Introducción

El estudio radiológico del aparato digestivo superior (esófago, estómago y duodeno) mediante contraste de bario es un tipo de exploración que conlleva niveles de dosis medios-altos para los pacientes. La bibliografía cita valores de alrededor de 8 mSv de dosis efectiva [1]. En estos estudios se simultanea el uso de escopia y la adquisición de imágenes para el diagnóstico. Suelen usarse equipos telemandados con intensificador de imagen.

La adquisición de las imágenes, hasta hace unos años, se llevaba a cabo mediante películas en chasis con pantallas de refuerzo y procesado químico de las mismas; en la actualidad, las nuevas generaciones de telemandos implementan una utilidad de captura digital de las imágenes a través del intensificador. Este nuevo modo de captura, de mayor sensibilidad, permite conseguir imágenes, a igualdad de kilovoltajes, con un mAs cinco veces menor que el sistema clásico de película+pantalla de refuerzo (reducción de dosis de hasta un 80%). Esto hace esperar unos niveles de reducción de dosis muy importantes en los estudios realizados con esta nueva tecnología.

Sin embargo, estas expectativas no se han reflejado en los muestreos dosimétricos que nuestro grupo de trabajo ha llevado a cabo en los últimos años en varios centros sanitarios públicos de la Comunidad de Madrid. En este trabajo se analizan las razones de este fenómeno.

2. Objetivos

El objetivo del presente trabajo es analizar la influencia de los sistemas digitales de adquisición de imagen en las dosis a pacientes en los estudios del aparato digestivo superior (esófago-estómago-duodeno).

3. Material y método

El estudio se basa en la recogida de datos dosimétricos en muestras suficientes de pacientes y en su posterior análisis estadístico. Las medidas se han realizado en cinco equipos distintos ubicados en cuatro centros de la red pública sanitaria española. Los cuatro centros se encuentran en la Comunidad Autónoma de Madrid y se trata de dos Hospitales grandes y dos

Centros de Especialidades. Dos de los equipos incorporan sistemas digitales de adquisición a través de intensificador y los otros tres funcionan con película y pantallas de refuerzo (tabla I). En estos tres casos la sensibilidad de las cadenas de imagen es similar, con una velocidad relativa de 400.

Tabla I. descripción de los equipos en los que se ha medido

Equipo	Marca	Modelo	Ubicación	Adquisición	Línea de imagen
A	General Electric	Prestilix 1600 X	Hospital 1	Digital	-
B	Philips	Multidiagnost 3	Hospital 2	Digital	-
C	General Electric	Telegem II	Hospital 2	Película	Agfa Ortho Regular/ Agfa ST-G2
D	General Electric	Prestilix 1600 X	Centro Especialid. 1	Película	Agfa Ortho Regular/ Agfa ST-G2
E	General Electric	Telegem II	Centro Especialid. 2	Película	Kodak Lanex Regular/ Kodak PDS

Se han medido exclusivamente estudios gastrointestinales realizados mediante ingestión de contraste (papilla de bario), también llamados EED's (Esófagos-Estómagos-Duodenos). Para cada paciente se han registrado los siguientes datos de interés:

1. Número de adquisiciones de imagen
2. Tiempo total de escopia (en minutos)
3. Producto dosis x área (en cGy x cm^2)
4. Técnica media de la escopia (kV y mA)
5. Técnica de cada adquisición (kV y mAs)

Las medidas del producto dosis x área se llevaron a cabo con una cámara de transmisión Diamentor de PTW-Freiburg que, en todos los casos, se instaló en el colimador de los equipos. Dicha cámara estaba convenientemente calibrada y sus lecturas eran corregidas por los factores ambientales de Presión y Temperatura. El resto de datos son proporcionados por los mismos equipos de Rayos-X en sus consolas de control.

Paralelamente se ha medido el rendimiento de los cinco equipos para aquellos kilovoltajes de interés (kV's promedios en escopia y adquisición); estas medidas se han realizado con un analizador de haces PMX-III de RTI Electronics.

Las medidas presentadas en este trabajo han sido recogidas durante el periodo 1997-1999 por este Servicio de Radiofísica, dentro del proceso de registro de datos dosimétricos obligatorio por ley en España en todas las instalaciones de Radiodiagnóstico médico desde 1996 [2], [3]. Se han rechazado medidas sobre pacientes de complexiones extremas (delgados y/o gruesos).

4. Resultados

En la tabla II se presentan los resultados obtenidos. La tabla contiene el tamaño de la muestra en cada caso, los productos dosis x área, datos radiológicos correspondientes a la escopia (kV medios, mA·min promedio por estudio y tiempos medios de escopia) y datos radiológicos correspondientes a adquisición de imagen (kV medios, mA·min promedio por estudio y número medio de adquisiciones por estudio).

Tabla II. registro de datos dosimétricos y técnicas radiológicas según centros

Equipo	Tamaño muestra	Producto dosis x área (cGy x cm^2)	Datos de escopia			Datos adquisición		
			kV medio	mA·min promedio debido a escopia	Tiempo medio de escopia (minutos)	kV medio	mA·min promedio debido a adquisición	Número medio de adquisiciones
A (digital)	54	2796	101	10.0	4.0	123	0.7	17.8
B (digital)	30	2384	81	18.7	5.5	134	1.0	21.3
C (película)	13	3569	119	14.0	4.5	116	3.2	18.1
D (película)	41	1530	111	5.5	2.0	110	4.1	16.6
E (película)	47	1696	111	2.0	1.4	111	2.0	14.2

Lo que se quiere determinar es qué proporción de la dosis-paciente es atribuible a la escopia y cuál lo es a la adquisición de imagen. Para ello no basta con comparar los mA·min promedios para cada uno de los dos conceptos, ya que los kV's promedios de escopia y adquisición pueden ser distintos. Como ejemplo, cabe señalar el equipo B: un mA·min de escopia (a 81 kV) producirá una dosis menor que un mA·min de adquisición (a 134 kV).

Lo que se ha hecho es medir para cada equipo y cada kilovoltaje de interés los rendimientos a 1 metro (Tabla III). Estos rendimientos permitirán ponderar los mA·min de escopia y los de adquisición para hacerlos comparables, aún a pesar de haber sido generados a distintas energías.

Tabla III. Rendimientos a 1 metro (X), en μGy/mAs, para cada equipo y para cada kV de interés

Modo trabajo	Equipo A		Equipo B		Equipo C		Equipo D		Equipo E	
	KV	X (μGy/mAs)	kV	X (μGy/mAs)	kV	X (μGy/mAs)	kV	X (μGy/mAs)	KV	X (μGy/mAs)
Escopia	101	90.0	81	57.5	119	107.5	111	137.5	111	107.8
Adquis.	123	130.0	134	153.8	116	102.5	110	136.3	111	107.8

Con estos rendimientos se puede determinar la relación entre la dosis recibida por el paciente procedente de la escopia y la dosis recibida procedente de la adquisición de imágenes. A esta relación la llamamos r y la calculamos mediante la siguiente relación:

$$r = (mA{\cdot}min_{\text{escopia}} \cdot X_{\text{kV medio escopia}}) / (mA{\cdot}min_{\text{adquisición}} \cdot X_{\text{kV medio adquisición}})$$

donde X es el rendimiento para cada uno de los kV's indicados en los subíndices y mA·min es el mA·min medio por estudio imputable a escopia y a adquisición respectivamente.

La tabla IV contiene los resultados obtenidos para el parámetror.

Tabla IV. relación entre las dosis imputables a los tiempos de escopia y las imputables a la adquisición de imagen

Equipo	Datos de escopia		Datos de adquisición		Dosis debido a escopia / dosis debido a adquisición (r)
	kV medio	mA·min medio por estudio	kV medio	mA·min medio por estudio	
A	101	10.0	123	0.7	9.9
B	81	18.7	134	1.0	7.0
C	119	14.0	116	3.2	4.6
D	111	5.5	110	4.1	1.3
E	111	2.0	111	2.0	1.0

5. Conclusiones

La primera conclusión es que la mayor reducción de dosis en este tipo de estudios se consigue al disminuir los tiempos de escopia; los equipos D y E, aún con un sistema de adquisición convencional, son los que menores productos dosis x área han proporcionado a los pacientes debido a sus reducidos tiempos medios de escopia.

No parece que la introducción de sistemas digitales de adquisición influya tanto en la reducción de dosis. Así, en el equipo C, con adquisición convencional y tiempos altos de escopia, la introducción de un sistema digital de captura de imagen podría reducir los 3.2 mA·min que se dedican actualmente a adquisición hasta un 0.7 mA·min (equivalente al de la sala A). No obstante, si se mantienen los 14.0 mA·min usados en escopia, la reducción final de la dosis (de 17.2 mA·min a 14.7 mA·min) no representará más que una reducción del 15%, lejos de aquel 80% que habíamos previsto. (1)

Este factor de disminución será más importante en equipos en los que se trabaja con bajos tiempos de escopia. Así, las salas D y E, de seguir trabajando en las actuales condiciones, conseguirían reducir sus dosis en un 35% y un 40% respectivamente, al implementar un sistema de captura digital de imágenes.

Por otra parte existe la sospecha de que la operativa de un sistema digital, mucho más simple que la de un sistema convencional de chasis con película, puede conllevar la captura de un número mayor de imágenes. En los equipos A y B, la media de adquisiciones por estudio es de 19.1, mientras que en los tres restantes este valor es de 15.7. Hay que tener en cuenta que en un sistema digital se capturan imágenes sin más que pulsar un botón; el sistema clásico supone la colocación de chasis en la bandeja, retirada del mismo y procesado en reveladora luz-día o cuarto oscuro.

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IAEA-CN-85-257

RADIATION PROTECTION AND QUALITY ASSURANCE IN DENTAL RADIOLOGY: I. INTRAORAL RADIOGRAPHY

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Abstract

This paper studies 2524 official reports on quality assurance in dental radiography, made in the context of the three first revisions of these dental clinics as a result of the entry into force of the regulations establishing the duties for this type of facilities. In the results section we present a quantitative analysis of the facilities equipped with an intraoral device, making a especial reference to the brands they have available, as well as their physical features (KV, mAs, filtration, length of cone) and the deviations detected in their operation. Some of the features in the process of obtaining radiological images at those facilities (Film control, development time, liquid renewal) are determined, and the average dose of ionizing radiation used in order to obtain the radiological image of the same tooth is presented. This paper shows, in a quantitative way, the characteristic features of intraoral dental radiology in our medium. The study is intended to be continues during the next years, what would allow the assessment of the prospective improvement in dental radiological performances as a result of the newly established regulations.

1. Introducción

La radiología dental es la exploración de diagnóstico radiológico más frecuente del mundo industrializado y representa casi el 25% de todos los exámenes radiológicos realizados en la Unión Europea.

En 1996 se instauró una nueva normativa en la que, con carácter de norma básica sanitaria, se establecen los criterios de calidad en radiodiagnóstico para mejorar el acto radiológico médico y evitar exposiciones inadecuadas o excesivas. Como consecuencia de su entrada en vigor, las clínicas odontológicas que utilizan este tipo de aparataje radiológico dental, se han ido sumando al proceso de control de calidad realizado por unidades técnicas, instituciones u organismos previamente homologados por el Consejo de Seguridad Nuclear.

En este trabajo se presenta el primer análisis cuantitativo de los parámetros controlados en estos informes preceptivos de control de calidad y supone una revisión del proceso de obtención de imagen radiológica en estas clínicas odontológicas. Esto podría representar la situación actual de la radiología dental intraoral en nuestro país.

2. Material y método

Se estudian 2524 informes oficiales de control de calidad en radiodiagnóstico de clínicas odontológicas en las dos primeras revisiones de la instalación radiológica como consecuencia de la entrada en vigor del Real Decreto 2071/1995, por el que se establecen los criterios de calidad en radiodiagnóstico. Los informes se han realizado desde la segunda mitad del año 1996 hasta diciembre de 1998, por la U:T:P:R Asigma S:A., y corresponden fundamentalmente a instalaciones de carácter privado. Todas las clínicas habían sido previamente verificadas por diversas Unidades Técnicas de Protección Radiológica homologadas por el Consejo de Seguridad Nuclear. Todas las clínicas se encontraban legalmente autorizadas como instalaciones de rayos X con fines de diagnóstico dental en el momento de la realización de los informes.

3. Resultados

Las clínicas estudiadas poseen algún tipo de aparatos de radiodiagnóstico para radiografía intraoral y se encuentran ubicadas en territorio español, fundamentalmente en tres comunidades autónomas españolas: Andalucía (1105/2524), Murcia (383/2524) y Comunidad Valenciana (361/2524).

Los resultados obtenidos contabilizan 52 modelos de aparatos de rayos X para radiografía intraoral, correspondientes a 22 fabricantes diferentes, y en donde estaca la casa Trophy con cerca del 59.74% (1524/2551) de todos los aparatos intraorales descritos. Estos aparatos funcionan con valores de kilovoltaje que oscilan entre los 50 kV y los 70 kV como valores mínimo y máximo respectivamente, funcionando el 71.36% (1563/2190) de los equipos con valores de 70 kV; la filtración del haz primario de radiación ha variado entre los 0.4 mm y los 3.4 mm de Al como valores extremos, observándose que el 98.85 % (2495/2524) de los equipos incorpora valores de filtración superior a 1.5 mm de Al, valor recomendado actualmente por la Unión Europea para la utilización de aparatos que funcionen a menos de 70 kV. Los equipos incorporan valores de miliamperaje que oscilan entre los 7-11 mA, siendo el 75.78% (1912/2523) de estos aparatos los que funcionan con 8 mA. La longitud del colimador que se utiliza para establecer la distancia recomendada entre el foco y la piel del paciente ha variado desde la inexistencia del mismo en algún caso hasta los 40 cms, según modelos descritos; el 87.47% de los equipos utiliza colimadores de 20 cm de longitud.

Los parámetros obtenidos sobre el funcionamiento del aparato estudiado en cada una de las clínicas dentales han puesto de manifiesto que el 10.61 % (268/2524) de los aparatos presentaban alteraciones superiores al 20 % en alcanzar el kV que venía descrito por el fabricante del aparato, un 7.05% (178/2524) de los equipos presentaban alteraciones en el tiempo de exposición marcado por el cronómetro del aparato y un 9.23% (223/2524) de las instalaciones presentaban desviaciones superiores al 20% en el rendimiento del tubo de rayos X (dosis de radiación por unidad de tiempo, mAs). Otras alteraciones importantes se han detectado con una frecuencia mucho menor; desviaciones en la reproducibilidad de la linealidad (no hay aumento de la dosis proporcional al tiempo de exposición) en un 4.36%, pero durante las dos primeras revisiones se observó además desviaciones en la reproducibilidad de la dosis (una misma técnica de exposición produce diferente dosis de radiación)(3/1370) y reproducibilidad del tiempo (una misma técnica de exposición se realiza con diferente tiempo de exposición) (3/1370).

Sólo el 16.14% (388/2404) de las instalaciones dispone de un disparador fijo instalado fuera de la sala de exploración, aunque un 82.53% (1984/2404) de las instalaciones dispone de un cable alargador de una longitud mayor de 2 metros. Se ha puesto de manifiesto que durante la segunda revisión se produce un aumento significativo de las instalaciones las que ubicaron disparadores fijos situados fuera de la sala de exposición (5.54% anual). Además se ha constatado la utilización de cables disparadores de menos de 1 metro de longitud, e incluso la instalación de un dispositivo de exposición fijo dentro de la sala de exploración. Respecto a la señal acústica-luminosa de exposición a la radiación cabe reseñar que en el 4.86 % (122/2508) de los informes revisados esta señal no funciona.

Las películas radiográficas intraorales más utilizadas en la clínica diaria dental ha sido la fabricada por la casa Kodak, siendo el modelo Ultraspeed, de sensibilidad D, la utilizada por el 75.77% (1561/2060) de las clínicas; observándose un aumento significativo del 10.94% en la utilización de este tipo de película durante la segunda revisión (1998) con respecto de la primera (1996-1997). Solamente el 16.31% (336/2060) de las instalaciones utiliza películas de sensibilidad E, tipo Ektaspeed de Kodak, películas que disminuyen un 50% la dosis de

radiación a la que se expone el paciente. El sistema digital de obtención de imagen, se utiliza en cerca del 5.3% (115/2166) de las instalaciones revisadas, aumentando esta cifra en un 2.55% durante la segunda revisión efectuada en el año 1998. Las películas radiográficas intraorales se almacenan dentro de la sala de exploración en el 38.67% (741/1916) de las salas dentales, mostrándose una disminución significativa (23.66%) de las instalaciones que seguían almacenándolas dentro de la sala durante la segunda revisión. Generalmente se controla la fecha de caducidad de las películas (96.9%:1814/1872) por el personal que trabaja en la instalación.

El revelado radiográfico mayoritariamente es un revelado manual (88.20% (1824/2066), que suele realizarse a temperatura ambiente en el 99.9% de las instalaciones en donde se realiza de esta forma. Una parte importante de las instalaciones estudiadas (77.25% (1389/1798)) admite no mantener un tiempo de revelado o procesado radiográfico fijo, la renovación de los líquidos es semanal en el 73.42% (1293/1761) de las instalaciones.

La dosis de radiación estimada en dichas instalaciones odontológicas para la exposición de un molar superior en las condiciones habituales de cada sala ha puesto de manifiesto que una dosis inferior a 5 mGy es la empleada en el 83.35% (2083/2499) de las instalaciones odontológicas, que alcanzaría hasta el 98.2% (2454/2499) si se establece en 10 mGy la dosis máxima empleada para obtener dicha imagen radiológica. La dosis media empleada en dicha exploración atendiendo a todos los informes que recogen este dato es el 4.14 mGy, observándose una disminución de un 30 % en la dosis media de radiación empleada durante el años 1998 con respecto a los años 1996-1997. El 93.5% de las instalaciones cumpliría con las recomendaciones oficiales actuales de utilizar dosis de radiación inferiores a 7 mGy en esta exposición. En la actualidad se esta llevando a cabo el estudio de los informes correspondientes a la tercera revisión (1999), y se han obtenido datos de dosis medias para dicha exploración de 3.18 mGy , que supone una dosis inferiores a la empleada en la primera revisión (1996-19979) de 4.87 mGy, y a los 3.41 mGy empleados durante la segunda revisión efectuada en 1998.

4. Discusión

En términos generales, los equipos para radiología intraoral que se han encontrado en las clínicas odontológicas son de características físicas habituales en el entorno del medio de desarrollo en el que nos encontramos [1,2]. Si las alteraciones de los parámetros físicos se hubiesen producido siempre en aparatos diferentes, podría decirse que aproximadamente un tercio de los equipos revisados (28%) pueden presentar alteraciones significativas (kV, mA, filtración, señal acústica, disparador) en el momento de las revisiones de control de calidad.

Las actuales recomendaciones oficiales de utilizar un aparato que funcione a 70 kV, 8 mA, 20 cms de distancia foco-piel y una filtración del haz superior a 1.5 mm de Al se cumplirían como máximo en el 71.36% de las instalaciones radiológicas dentales revisadas (2524). Gracias a este procedimiento obligatorio de control de calidad que deben cumplir todas las clínicas odontológicas con aparatos de radiología intraoral, se ha podido aumentar en casi un 14.5% el número de clínicas que durante la segunda revisión cumplirían con las recomendaciones oficiales de la Unión Europea con respecto a los años anteriores.

Se ha observado una ausencia completa en la utilización de un colimador rectangular adaptado al tamaño de la película radiológica en los informes (2524) de las clínicas estudiadas, frente al 5-7.33% con el que se emplea en Estados Unidos [3,4], o frente al 29-36% que se describe en instalaciones con aparatos intraorales en Suecia [6,7].

Por otro lado, otros parámetros fundamentales han quedado excluidos de los requisitos controlables en los informes de garantía y/o control de calidad y que pueden ser las causas del incremento considerable de las dosis de radiación administradas en las exploraciones radiológicas: el revelado de la película fotográfica [7]. En este sentido, destaca que el 88.20% del revelado de la película radiográfica en nuestro medio es manual y sólo un 6´3% de las instalaciones realiza un procesado radiográfico automático. Estos resultados son significativamente inferiores al 50% de procesado automático en Dinamarca [1,2], el 88% en Suecia [5], o el 93% en Canadá [8].

La dosis de radiación de calidad suficiente de un molar superior en nuestro estudio es inferior a 7 mGy en el 93.5 % de los casos, en donde se ha puesto de manifiesto una dosis media de 4.14 mGy, disminuyendo este valor a 3.18 mGy durante la tercera revisión correspondiente a 1999.

En general, numerosos autores ponen de manifiesto un grado significativo de insatisfacción en incumplimiento de las recomendaciones oficiales para la reducción de la dosis de radiación en las instalaciones radiológicas odontológicas tanto en Europa [2,5], como en Estados Unidos [9]. Los resultados obtenidos del presente estudio han puesto de manifiesto, que en España y tras la instauración obligatoria de la normativa mediante la cual todas las clínicas odontológicas con aparatos de radiología intraoral deben de someterse a estudios de control de calidad efectuados por empresas externas homologadas, se ha reducido las dosis de radiación en un 30% y se ha conseguido aumentar en un 14.5% el número de instalaciones que cumpliría las Recomendaciones Oficiales de Protección Radiológica; todo ello en sólo dos años de evolución tras el citado requisito legal.

Se pretende continuar con este estudio durante los próximos años, lo que permitiría evaluar una posible mejoría en las actuaciones radiológicas dentales de nuestros profesionales y personal auxiliar como consecuencia de la nueva normativa instaurada.

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IAEA-CN-85-258

RADIATION PROTECTION AND QUALITY ASSURANCE IN DENTAL RADIOLOGY: II. PANORAMIC RADIOLOGY

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Abstract

This paper studies 278 official reports on quality assurance in dental radiology in the context of the first revision of these dental clinics, as a result of the entry into force of the regulations establishisng the duties for this type of facilities. In the results section we present a quantitative analysis of the facilities equipped with an panoramic radiology apparatus, making a special reference to the brands they have available, as well as their physical features (kV, mA, filtration) and the deviations detected in their operation. Some of their features in the process of obtaining radiological images at those facilities (film control, development time, liquid renewal) are determined, an the average dose of ionising radiation used in order to obtain the same tooth radiological image is presented. This paper shows, in a quantitative way, the characteristic features of panoramic radiology in our medium. The study is intended to be continued during the next years, what would allow the assessment of the prospective improvement in dental radiological performances as a result of the newly established regulations.

1. Introducción

La exploración radiológica en Odontología representa aproximadamente el 25% de todas las exploraciones radiológicas con fines de diagnostico medico que se realizan anualmente en al Unión Europea [1,2]. La radiología intraoral constituye casi el 90% de todas las exploraciones realizadas en odontología [1], campo en donde la radiología panorámica constituye también un elemento esencial en la radiología oral actual, constituyendo la segunda exploración odontológica por su número de exploraciones realizas [3]. Sin embargo, recientes estudios ponen de manifiesto, tanto en Europa como en Estados Unidos, que muchas exploraciones radiológicas son de escasa calidad o representan imágenes sin calidad diagnóstica, bien porque se ha realizado una mala técnica radiológica o bien porque se ha realizado un inadecuado procesamiento de la película radiográfica [1,4]. En este trabajo se presenta el primer análisis cuantitativo de los parámetros controlados en los informes oficiales de control de calidad y supone una revisión del proceso de obtención de la imagen radiológica en las clínicas odontológicas que realizan radiografías panorámicas. Por ello, podría ayudar a reflejar la situación de desarrollo en la que se encuentra la radiología dental de nuestro país.

2. Material y método

Se estudian 278 informes oficiales de control de calidad en radiodiagnóstico de clínicas odontológicas que emplean radiología panorámica, generalmente desde la primera revisión de la instalación radiológica y hasta la tercera revisión, como consecuencia de la entrada en vigor del Real Decreto 2071/1995 de 22/12/95, en el que se establecen los criterios de control de calidad en radiodiagnóstico. Los informes se han realizado desde la segunda mitad del año 1996 hasta final de 1999, por la U.T.P.R. Asigma S.A.L. y corresponden fundamentalmente a instalaciones de carácter privado. Todas las clínicas han sido previamente verificadas por diversas Unidades Técnicas de Protección Radiológica homologadas por el Consejo de Seguridad Nuclear. En el momento de la primera revisión, todas las clínicas odontológicas analizadas ya se encontraban legalmente autorizadas como Instalaciones de Rayos X con fines de diagnostico dental.

3. Resultados

Los informes de control de calidad estudiados corresponden a clínicas odontológicas que poseen algún tipo de aparato de radiodiagnóstico para la realización de radiografía panorámica/ortopantomografia y se encuentran ubicadas en territorio español, fundamentalmente en tres comunidades autónomas: Murcia (82/278), Andalucía (79/278) y Comunidad Valenciana (63/278).

Los resultados obtenidos contabilizan más de 49 modelos de aparatos de rayos X para radiografía panorámica, correspondientes a 19 fabricantes diferentes, y en donde destaca la casa Trophy con cerca del 32% (90/278) de todos los equipos de radiología descritos. Estos aparatos funcionan con kilovoltajes variables que oscilan entre los 50 kV y los 130 kV como valores mínimo y máximo respectivamente, miliamperaje entre los 5 y los 400 mA, y una filtración del haz primario de radiación que ha variado entre los 2 mm y los 3.2 mm de Al como valores extremos, utilizando siempre filtración de Aluminio.

Los parámetros obtenidos sobre el funcionamiento del aparato estudiado en cada una de las clínicas dentales han puesto de manifiesto que el 4.18% (10/259) de los aparatos presentaban alteraciones superiores al 10% en alcanzar el kV que venia descrito por el fabricante del aparato y que por ello se han considerado fuera de tolerancia; un 2.1% de los equipos (5/237) han presentado alteraciones respecto al tiempo de exposición marcado por el cronómetro del aparato y un 4.8% (8/173) presentaban desviaciones superiores al 20% en el rendimiento del tubo de rayos X (dosis de radiación por unidad de tiempo).

El revelado radiográfico de la radiografía panorámica se realiza en procesadora automática mayoritariamente (63.92%:163/255), y en donde la renovación de los líquidos de revelado se hace mensualmente en el 61.5% (147/239) de las clínicas odontológicas analizadas en las que se ha recogido este dato.

El tipo de película más frecuentemente utilizada para la realización de la radiología panorámica es la Kodak T-MAT en sus diferentes modalidades con el 53.78% (142/264) de todas las instalaciones dentales verificadas en el control de calidad, en donde destaca la utilización de las pantallas de refuerzo Kodak Lanex en sus diferentes modalidades en el 89.71% (192/214) de todas las instalaciones revisadas.

En los informes de Control de Calidad que se han analizado se han descrito otras irregularidades en algunos parámetros sometidos a estudio: a) se pone de manifiesto que en el 5.43% (13/239) se realiza un almacenamiento incorrecto de la película radiográfica, ya que se mantiene dentro de la sala de exposición, expuesta a la radiación dispersa producida durante la exploración, con el consiguiente aumento del velo por la radiación de la película radiográfica; b) en el 6.43% (11/171) se encuentran entradas de luz en el cuarto oscuro que aumentarían el velo por luz de las películas radiográficas durante su manipulación; y c) se describe una ausencia completa de control en el tiempo de revelado de la película radiográfica en el 75% (33/44) de las instalaciones dentales en las que se ha recogido este dato.

En el 11.87% de los informes (33/278) se reflejan recomendaciones de carácter imperativo que exigen una corrección inmediata: en 25 instalaciones se exige revisión/reparación de los equipos (8.99%: 25/278); en otras 2 se recomienda la revisión de la instalación eléctrica (0.71%:2/278) por alterar el funcionamiento del equipo; en otra (0.35%: 1/278) se recomienda

el cambio del tipo de líquidos empleados por ser completamente inadecuados para el procesado de la película radiográfica empleada.

La dosis de radiación de radiación se ha determinado con un detector de semiconductor (PMX III) en la posición de telerradiografia del aparato de radiodiagnóstico estudiado y en las condiciones habituales en al que se realizan en la exploración de cada sala. La determinación de la dosis de radiación ha puesto de manifiesto un descenso significativo de las dosis empleadas durante los últimos años. La dosis media de radiación ha disminuido desde 1.473 mGy en 1996, 1.16 mGy en 1997, 0.37 mGy en 1998, hasta 0.21 mGy en 1999. Ello pone de manifiesto que desde la entrada en vigor de la reglamentación de control de calidad las dosis empleadas se han reducido hasta casi 8 veces respecto de las empleadas en 1996. La dosis media empleada en el conjunto global de todos los años analizados es de 0.80 mGy, siendo como valores máximos extremos alguna instalación que llegaron a emplear 18 mGy (en 1996), 28 mGy (en 1997) , o 12.75 mGy (en 1998). En 1999 ninguna instalación ha superado 1 mGy como nivel máximo de radiación administrada para dicha exploración. La determinación de la dosis de radiación ha puesto de manifiesto un significativo descenso de las dosis empleadas durante los últimos años.

4. Discusión

Recientemente se ha publicado que el 95% de las clínicas odontológicas en la Comunidad de Murcia utilizan habitualmente un aparato de radiología intraoral, y que, además, durante 1996 un 2.8% de las mismas dispone de un aparato para radiología intraoral [5]. Esta situación refleja la segunda plaza que ocupa la práctica de la radiología panorámica en el diagnostico odontológico en nuestro medio. Según nuestros resultados al menos un 4.5% de las clínicas odontológicas poseen un aparato para radiología panorámica actualmente en esta misma comunidad; resultado todavía muy distante al descrito en otros países en donde casi el 22% de las clínicas odontológicas [6] disponía de un aparato de estas características.

Los equipos de radiología panorámica que se han encontrado en las clínicas odontológicas son de características físicas (kV, mA, filtración) habituales en el entorno del medio desarrollado en el que nos encontramos [3]. Si las alteraciones de los parámetros físicos se hubiesen producido siempre en aparatos diferentes, podría decirse que más del 16% de los equipos revisados pueden presentar alteraciones significativas en el momento de las revisiones de control de calidad, y de los casi el 13% ha debido necesariamente solucionar algún tipo de problema antes de volver a trabajar.

Cabe destacar que el 63.92% del revelado de la película de la radiografía panorámica en nuestro medio es automático, y solo un 30% de las instalaciones realizada un procesado manual.. Se asume que el procesado radiográfico automático permite administrar menos dosis de radiación aumentando la calidad de la imagen radiológica [7]; siempre que se realiza el revelado de forma manual, todos los autores describen resultados similares a los nuestros en cuanto a una gran variedad de tiempos de revelado, tiempos de cambio de líquidos y temperaturas empleadas, actuaciones que pueden suponer un incremento de la dosis de radiación administradas y del número de exploraciones innecesarias que se realizan [2,3].

Igualmente se admite que entre el 26 y el 33% de las radiografías panorámicas que se realizan son inaceptables y carecen de suficiente calidad para la interpretación diagnostica [1,8], atribuyéndose al inadecuado procesamiento y /o movimientos del paciente y al escaso

contraste o ennegrecimiento los defectos más frecuentes que las producen [9]. Otros estudios han descrito que hasta el 40% de los equipos de rayos X para radiología dental sobrepasan los valores óptimos recomendados. Si a ello se suma que algunos autores han asociado las exposiciones múltiples en exámenes radiológicos dentales con mayor incidencia de cáncer de glándulas salivales y tumores cerebrales [1] parece evidente la necesidad de optimizar las dosis de radiación empleadas en Odontología.

A pesar de lo anterior, las dosis de radiación empleadas en la radiología panorámica han ido disminuyendo significativamente durante los años sometidos al estudio. La técnica empleada para la determinación de la dosis de radiación no es la más recomendable y se han descrito en los informes las dificultades para obtener un valor de dosis aceptable en aparatos que no disponían de telerradiografía, por lo que algunos de los valores más altos pueden deberse a medidas realizadas en la posición de realización de la radiografía panorámica y que no se han eliminado hasta la última revisión realizada en el año 1999. Aunque existen instalaciones que han empleado 151 veces más dosis de radiación que la media obtenida para 1999 en la realización de una misma exploración radiológica, la dosis actual ha disminuido el 14% de la dosis de 1996. La dosis media en nuestro estudio es de 0.80 mGy y se encontraría en la misma línea de las descritas por otros autores para la misma exploración radiológica.

En general, numerosos autores ponen de manifiesto un grado significativo de insatisfacción en el cumplimiento de las recomendaciones oficiales para la reducción de dosis de radiación en las instalaciones odontológicas tanto en Europa [10,11] como en Estados Unidos [12]. Dado que en nuestro estudio alguno de los parámetros analizados se alejan significativamente de las recomendaciones generales de protección radiológica resulta comprensible que se pretenda aunar esfuerzos para disminuir o eludir algunos de los factores que más influyen en el incremento de la dosis de radiación administrada o en la perdida de la calidad diagnostica de la imagen radiológica. Pretendemos continuar este estudio durante los próximos años, lo que permitiría evaluar la posible mejoría que puede experimentar la practica de la radiología panorámica en nuestro país, como consecuencia de la normativa instaurada.

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Study on patient dose in diagnostic radiology in Japan: Investigation of entrance surface dose of patient using direct measurement by TLD

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Abstract

This study was conducted to research radiation exposures by routine X-ray examinations in the hospitals to establish the guidance level in Japan. So a multicenter study was carried out to evaluate radiation doses in routine radiographic examinations. In this study, we investigated entrance surface doses of patients using direct measurement by TLD for various 5 types of radiography; Chest PA, Abdomen AP, Lumber spine AP, Lumber spine LAT and Pelvis AP. From the results, we examines the (a) need for introducing the guidance level in Japan, (b) controversial points in the calculation method for patient dose evaluation, (c) evaluation accuracy required for introducing the guidance level, and (d) necessity for a standardized method for patient dose evaluation.

Introduction

X-ray examinations are commonly used in health care and become the largest man-made source of exposure for the population. The need for standardization of medical exposure has been suggested and the guidance levels has been proposed for various radiographic examinations by IAEA(1). Problems in introducing the guidance level should be researched before the appropriate guidance level is established(2). One of the problems is an evaluation of patient doses(3). To date, patient doses have been evaluated by calculations based on radiographic conditions, or model experiments using phantoms. The patient doses are then evaluated based on several assumptions. Direct measurement of patient dose is difficult to perform in many patients due to its time requirement, level of expertise required and difficulty in providing an explanation of the procedure to the patient. However, such direct measurement is essential since it incorporates all

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This paper belongs to Topical Session 1a. For technical reasons, it could not be included with the other papers of that session.

aspects of radiography from the radiographic equipment used, to the actual conditions of each patient without assumption. In this study, we investigated entrance surface doses of patients using direct measurement by TLD for various types of radiography. From the results, we examines the (a) need for introducing the guidance level in Japan, (b) controversial points in the calculation method for patient dose evaluation, (c) evaluation accuracy required for introducing the guidance level, and (d) necessity for a standardized method for patient dose evaluation.

Materials and Methods

The research method matched the English protocol(4) as much as possible while considering differences at Japanese medical treatment sites. Five types of simple radiography were selected on the basis of their prevalence in the clinical practice; the posteroanterior (PA) chest, anteroposteterior (AP) abdomen, AP pelvis, and AP and lateral (LAT) lumber spine.

Direct measurement of the patient's entrance surface dose was performed using thermoluminesent dosimeters (MSO-TLD) for the 5 types of radiographic examination at 18 university hospitals. TLDs were mailed to the hospitals and each TLD was placed on the patient's skin at the center of the radiation field when the radiography was taken. Then the TLDs were returned by mail for read out. All preprocessing, calibration and reading of TLD were undergone by one of the authors to eliminate variations between measurement facilities.

Results

Figs.1 show distributions of entrance surface doses per radiograph for all adult patients at 13 institutions for 5 types of radiographies. Table 1 summarizes the results for 5 types of radiography. Fig.2 shows distribution of average entrance surface doses for 5 types of radiography at each institute. Fig.3 shows average entrance surface doses of each institution, in order to smallest to largest.

Results are compared with patient doses calculated by radiographic conditions such as a tube voltage, a tube current and an exposure time.

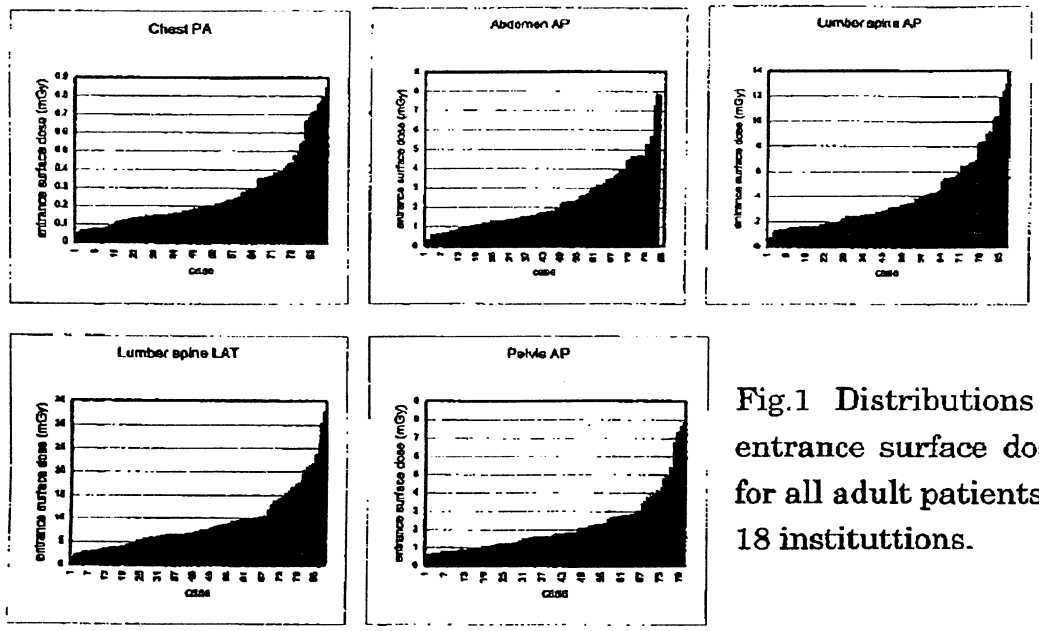
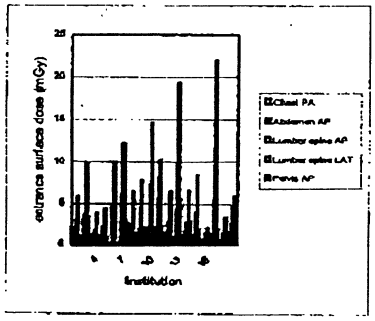


Fig.1 Distributions of entrance surface doses for all adult patients at 18 instituttions.



Fig,2 Distribution of average entrance doses for 5 types of radiograph at each institute.

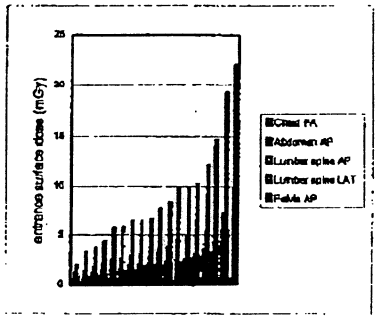


Fig.3 Average entrance surface doses of each institute , in order of smallest to largest.

Table 1 Minimum, median, mean and maximum values of entrance surface doses (mGy) for all adult patients at 18 institutions.

Radiograph	Minimum	Median	Mean	Third quartile	Maximum
Chest PA	0.04	0.19	0.26	0.35	0.84
Abdomen AP	0.2	1.6	2.2	3.1	7.8
Lumber spine AP	0.5	2.8	3.9	5.3	13
Lumber spine LAT	1.2	7.1	8.9	10	33
Pelvis AP	0.5	1.6	2.1	2.6	7.8

Discussions and Conclusions

Results are discussed according to the 4 points described in Introduction and the following 4 points are concluded.

(a) The guidance level is needed also in Japan. (b) Calculation methods are not effective for patient dose evaluation whenever the quality assurance (AC) is performed for X-ray equipments. (c) Evaluation accuracy in patient dose is required within 25% for introducing the guidance level. (d) A protocol on patient dose evaluation is necessity for introducing the guidance level also in Japan.

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Acknowledgement

This paper is based on the Research for Application of the ICRP Recommendations to Japanese People (1988-1999) supported by Japan Science and Technology Agency and conducted by Commission on Radiological Protection of the Japan Radiological Society (Commission Chairman: S.Koga).

Topical Session 1b

RADIOLOGICAL PROTECTION OF PATIENTS IN GENERAL DIAGNOSTIC RADIOLOGY (FLUOROSCOPY)

FLUOROSCOPY WITHOUT IMAGE INTENSIFIER

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Abstract

The objective of the present work was to evaluate the doses received by patients during fluoroscopy procedures carried out with an equipment without image intensifier. This evaluation is providing dose levels that our patients are presently exposed, as gives the data for epidemiological studies on risk estimate of cancer induction in patients exposed earlier when no image intensifiers existed. Diamentor M4 and E meters were used to measure the product dose-area (DAP). The data were acquired during barium enema, barium meal, barium swallow and histerosalpingographies. The measured values of DAP are considered high. This work intends to call the attention toward the optimization of the radiological protection in facilities that still use equipment without image intensifiers. While these equipment cannot be disabled, the patient exposure monitoring should be incentivated, and the application of radiological protection practices and programs of quality assurance should be of priority.

1. Introducción

En la actualidad, siguiendo las recomendaciones de la ICRP [1][2] y las directivas sobre protección radiológica del paciente [3], la preocupación por los métodos de optimización de la calidad de la información diagnóstica, el establecimiento de niveles de referencia y la reducción de dosis, tiene caracter prioritario. Esto sucede hoy, en tiempos en que equipos de rayos X sin intensificador de imagen ya fueron desactivados en paises desarrollados, pero continuan siendo usados en paises en desarrollo.

En los últimos años ha surgido gran interés por las exposiciones de pacientes en procedimientos fluoroscópicos diagnósticos e intervencionistas. Se trabaja intensamente en investigaciones sobre protección radiológica, niveles de exposición y recomendaciones al respecto [4][5][6][7][8] debido, en parte, a que la tecnología de los equipos es cada vez mas sofisticada. Por otro lado, al igual que en muchos países en desarrollo, en Brasil existen pocos estudios dosimétricos sobre fluoroscopía [9][10] y pocas recomendaciones y reglamentaciones sobre el asunto. Recién en junio de 1998 fue publicado el Reglamento Técnico "Portaria 453/98" del Ministerio de Salud de Brasil [11], que establece la obligatoriedad de la aplicación de programas de garantía de calidad, el uso de intensificadores de imagen en equipos fluoroscópicos, y la sustitución hasta 2003 de los actuales existentes sin este dispositivo.

Tanto en Europa como en Estados Unidos ya no es posible la dosimetria en fluoroscopía realizada con equipos sin intensificador de imagen, porque éstos fueron desactivados hace varias décadas. Sin embargo, en Brasil y otros países, todavía se puede medir exposiciones a pacientes en estos equipos. La evaluación de las exposiciones a pacientes irradiados de esta manera, proporcionará los niveles de dosis a los que nuestra población está actualmente expuesta, así como datos que permitan estimar dosis recibidas en el pasado en países donde equipos sin intensificador no existen mas, y datos para estudios epidemiológicos sobre estimativas de riesgos de inducción de cancer en los pacientes expuestos.

El presente trabajo forma parte de un proyecto de optimización de la protección radiológica en fluoroscopía, apoyado por la IAEA [12] aplicado en instituciones médicas de Rio de Janeiro,

siendo uno de los objetivos la evaluación de dosis recibidas por pacientes en procedimientos fluoroscópicos realizados con y sin intensificador de imagen. Se presentan aqui algunos resultados parciales de esta investigación en un hospital.

2. Materiales y métodos

Los exámenes fueron realizados con un equipo (Philips Müller Technique) con 30 años de uso, generador trifásico Müller-Medio 50, pantalla intensificadora, tubo de raios X bajo la mesa, diafragma regulable, focos fino y grueso de 1,2 e 2,0 mm, respectivamente, usandose normalmente el foco grueso. Todos los controles son manuales. Para escopía, la corriente puede variarse entre 0 y 6 mA y la tensión del tubo entre 40 y 110 kVp, y dispone de un indicador de tiempo de escopia con alarma sonora a los 5 minutos. El seriógrafo se acciona manualmente para obtener radiografías desplazando el chasis a una posición debajo de la pantalla, lo que acciona un disparador para exponer la película con la técnica radiográfica seleccionada. La película puede ser dividida para obtener dos imágenes radiográficas en la misma, desplazando manualmente una lámina de plomo debajo de la pantalla fluorescente, antes de la exposición. Existe una rejilla antidifusora sostenida por resortes para permitir su movimiento en el momento de la exposición.

Se utilizaron medidores Diamentor M4 y E (PTW, Freiburg, Alemania) para medir el producto dosis-área (DAP). La calibración de los instrumentos fue realizada *in situ*, considerando la atenuación de la mesa de exámen. El fabricante garantiza una incertidumbre de ±1% en la medida del DAP [13]. Se aplicó un único factor de calibración: el promedio de los obtenidos para los diferentes kVp utilizados, porque esto no introdujo errores significativos.

Se adquirieron datos en 23 exámenes de enema de bario con doble medio de contraste (clisteropaco), 13 seriografías gastroduodenales, 3 esofagografías y 13 histerosalpingografías, realizados según los protocolos médicos de la institución. Los exámenes fueron conducidos por médicos del primer año de la residencia en radiología. Los datos registrados en cada examen fueron: técnica fluoroscópica (kVp, mA), tiempo de exposición, técnica radiográfica (kVp, mAs), número total de imágenes, tamaño de campo fluoroscópico y radiográfico y DAP total. En los exámenes de enemas de bario y de histerosalpingografía fue posible registrar el DAP de la parte fluoroscópica y el DAP de la parte radiográfica del examen y estimar la dosis por imagen y la tasa de dosis en fluoroscopía.

3. Resultados y discusión

En las tablas I y II se presentan los resultados obtenidos en los exámenes evaluados. De la tabla I, es posible observar que los valores de DAP total resultaron extremamente elevados al compararlos con los niveles de referencia para fluoroscopía actualmente disponibles [4][5][14][15][16] (entre paréntesis y en negrito en la tabla I). La comparación directa de nuestros resultados con estos valores derivados de dosimetría en equipos con intensificador de imagen no es rigurosamente procedente pero sí válida a fin de tener una referencia en relación a los valores típicos actuales para los procedimientos evaluados.

En histerosalpingografías, Fernández et al [16] midieron en España valores de DAP total entre 2,5 y 16 $Gycm^2$, con una media de 7,5 imágenes y tiempos de exposición entre 0,1 e 1 minuto. Los DAPs totales (3er. cuartil) obtenidos en nuestro estudio fueron alrededor de 15 veces mayores, a pesar de que el número promedio de imágenes es el mismo. Esto evidencia, al

igual que para enemas de bario, la contribución al DAP total de la parte fluoroscópica del examen, mostrada en la tabla II. Para seriografías, las medidas resultaron de 3 a 6 veces mayores que los valores de referencia, y para enemas de bario, superiores por un factor de 3 a 5. Estos hechos sugieren que los protocolos médicos sean revistos, además de evaluar el desempeño del equipo.

Algunos problemas detectados em relación a la ausencia total o parcial de procedimientos de optimización se deben, en general, a la falta de recursos financieros y otras dificultades (como la falta de físicos médicos y la escasa formación en protección radiológica de los radiólogos) que la mayoría de las instituciones de salud pública tienen que enfrentar en muchos países en desarrollo. Los exámenes tienen que ser realizados por los profesionales con los equipos y herramientas disponibles.

En los casos evaluados, las dosis/imagen fueron relativamente bajas, aunque no se evaluó la calidad de imagen (combinación película-pantalla verde). Las tasas de dosis son consideradas elevadas, en función de las recomendaciones actuales [11].

Tabla I. Resultados de las medidas realizadas en la evaluación de procedimientos fluoroscópicos realizados con el equipo de rayos X sin intensificador de imagen. n: número de exámenes evaluados. Los valores de los niveles de referencia actualmente disponibles están indicados entre paréntesis y en negrito en la tercera columna

	Tiempo [min]	N°. Imágenes	DAP total [Gycm^2]	Dosis por imagen [mGy]	Tasa de dosis escopía [mGy/min]
ENEMA DE BARIO (n = 23)			**(37-62)**		
Rango	3,8-21,7	5-14	85-316		50
Media	8,8	9,7	159	4	16
Desviación Estandar	4,2	1,8	63	4	56
3er Cuartil	11,2	10,0	190	1	
SERIOGRAFIA (n = 13)			**(25-53)**		
Rango	3,4-16,1	8-17	62-345		
Media	8,0	13,8	136		
Desviación Estandar	3,1	3,2	74		
3er Cuartil	9,3	17,0	164		
HISTEROSALPINGOGRAFIA (n = 13)					
Rango	1,2-7,2	5-10	25-118		
Media	3,9	7,3	107	3	24
Desviación Estandar	1,6	1,4	51	2	3
3er Cuartil	4,5	8,0	136	4	26
ESOFAGOGRAFIA (n = 3)			**(10)**		
Rango	3-7,3	6-10	40-106		
Media	5,1	8,7	105		
Desviación Estandar	2,2	2,3	44		

Tabla II Estimativas de las contribuciones radiográfica y fluoroscópica en exámenes de enema de bario e histerosalpingografía

	Tiempo [min]	Nº. Imág.	DAP total [Gycm^2]	DAP grafía [Gycm^2]	% Grafía	DAP escopía [Gycm^2]	% Escopía
ENEMA DE BARIO (n = 23)							
Rango	3,8-21,7	5-14	85-316	1073-3437	6-25	76-288	75-95
Media	8,8	9,7	159	2056	13	147	87
Desviación Estandar	4,2	1,8	63	717	6	67	6
3er Cuartil	11,2	10,0	190	2594	17	179	92
HISTEROSALPINGOGRAFIA (n = 13)							
Rango	1,2-7,2	5-10	25-118	504-1109	13,5-15,2	32-62	85-87
Media	3,9	7,3	107	807	14,4	47	86
Desviación Estandar	1,6	1,4	51	428	1,2	21	1
3er Cuartil	4,5	8,0	136	958	14,8	54	86

4. Conclusiones

Hoy en dia se dedica mucha atención a la dosimetría en equipos modernos y sofisticados, pero en algunos países, la población continúa siendo irradiada con equipos fluoroscópicos sin intensificador de imagen. Este trabajo pretende llamar la atención hacia la optimización de la protección radiológica en instalaciones que todavía usan equipos sin intensificadores. Aún cuando su uso esté "justificado" en ciertas situaciones, es posible aplicar medidas de protección radiológica a pacientes que inevitablemente serán expuestos. Mientras estos equipos no puedan ser desactivados, debería incentivarse la dosimetría a pacientes, la aplicación de conductas de protección radiológica y de programas de garantía de calidad.

Estos resultados preliminares muestran que aún existen muchos problemas que deben ser resueltos en nuestro país. El hecho de disponer de valores numéricos para los parámetros evaluados constituye un paso importante que servirá para tomar acciones a ser implementadas en fluoroscopia. En Brasil estos equipos serán desactivados hasta 2003, las mejorías se hacen de forma gradual y las disposiciones legales ayudan a corregir los desvíos. Sin embargo, en otros países que no disponen de esta posibilidad, probablemente estos equipos seguirán siendo utilizados, con la consiguiente exposición a los pacientes.

Agradecimientos: Los autores agradecen a los Dres. J.E. Peixoto e H.A. Koch, a los médicos residentes R1 E.P. Dias, F.P. Nobre, A.R. Vianna, L.T. Ramos, L. Risk, M.V. Esquivel, P.V. Madeira, F. Lima, N. S. S. Louzada y C.F.Costa, a los físicos A. de Amorim e M. Balthar y a los tecnólogos R. Silva y J. Portela. Este trabajo fue realizado con el apoyo de CNPq (Brasil), GSF (Alemanha) e IAEA (Contract BRA 11061).

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IAEA-CN-85-157

EVALUATION OF THE DOSIMETRIC PERFORMANCE CHARACTERISTIC OF FLUOROSCOPY SYSTEM USED IN MEDICINE

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Abstract

Objective: To discuss establishment of diagnostic reference dose value in fluoroscopic examinations, for survey of 16 different types of fluoroscopy systems.
Methods: Choosing dosimetric characteristic parameters including: IIESDR, ESDR(typical value) and ESDRmax (ESDR maximum), DAP which was calibrated in situ on the X-ray unit.
Results: Results of dose survey are summarized in three tables, from these we could get wide changes in accordance with those in many other countries were resulting from maximum and minimum of IIESDR, ESDR and ESDRmax when measurements were performed at same entrance field size on I.I. Image Intensifier of the 15 fluoroscopy systems and under conditions of ABC. And also we could get less changes of DAP mean values, though differences for patient weight, technological parameters of fluoroscopic exam setting, fluoroscopic time and number of film were more remarkable.
Conclusions: Measurements on IIESDR, ESDR(typical value) and ESDRmax (ESDR maximum) are not satisfied as diagnostic reference level. But it is suggested that DAP values, in fluoroscopic exam, are used as a tool to achieve this.

1. Introduction

Recently, medical diagnostic X-ray fluoroscopy systems with Image Intensifier (I.I.) have been used extensively in complex X-ray examination. They have occupied 25-40% of all the diagnostic X-ray exams for collective effective dose, which cause people's attention. This paper discusses the establishment of diagnostic reference dose value in fluoroscopic exams by dosimetric characteristic measurements for 16 different types of fluoroscopy systems.[1,2,3]

2. Material and methods

16 types of fluoroscopy systems from 4 hospitals, three dosimetric characteristic parameters were chosen: (1) Entrance Surface Dose Rate of Image Intensifier (IIESDR), (2) Entrance Surface Dose Rate of phantom (typical ESDR and maximum $ESDR_{max}$), (3) Dose Area Product (DAP) in upper gastrointestinal (GI) Barium meal exam of patient.

The measure equipment often used includes: (1) a DIADOS dosemeter of PTW made in Germany, (2) a Solidose 400 dosemeter of RTI made in Sweden, (3) a DOSEGUARD-100 dose area product dosemeter of RTI made in Sweden. Moreover, using two pieces of 20 mm Al plates and a piece of 2 mm Pb plate simulated typical adult patient and a fat adult patient. The three dosemeter were calibrated by the Secondary Standard Dosimetry Laboratory (SSDL) of LIH.

For twenty patients of Barium meal exam four fluoroscopy systems which were undertable were chosen, each patient (male or female) weight was 60 +/- 10kg . The DAP meter was calibrated in situ on X-ray unit to which was attached, then put the Solidose 400 dosemeter on 10 cm x 10 cm field and measured dose, put the film in a magazine with screen to measure the true size of exposure field, made the product of acquired dose and true area of exposure field calibrate to reading of DAP meter, and got a calibrating factor of DAP meter in situ for every fluoroscopy system, then we could calculate each patient DAP value($Gycm^2$) and DAP mean values of five patients in Barium meal exam for every fluoroscopy system.

3. Results

Table I gives main characteristics of 16 fluoroscopy systems. Table II gives dosimetric performance characteristic of IIESDR, ESDR and $ESDR_{max}$ for 16 fluoroscopy systems. Table III gives DAP measurements of twenty upper GI Barium meal exam for 4 fluoroscopy systems.

Table I. Characteristics of 16 fluoroscopy systems investigated in several hospitals

Hospitals/Room Number	X-ray System				
	Type	Total filtration mmAl	Focus spot size mm	Size of II cm	Using Time of I.I. year
A/1	RCT	-	0.6 0.2	23 30	6
A/2	RCT	-	-	23	14
A/3	RCT	-	-	23	4
A/4	C-arm	-	-	13 17 30	3
A/5	RCT	-	0.6 0.2	23	8
A/6	RCT	-	0.6 0.2	23	4
A/7	RCT	5.2	-	23	13
B/1	RCT	4.8	0.6 0.2	23	7
B/2	RCT	-	-	23 30	2
B/3	C-arm	-	-	17 25 38	1
B/4	RCT	-	0.6 0.2	23	2
B/5	RCT	3.5	0.6 0.2	23	13
C/1	RCT	4.0	-	23	2
C/2	C-arm	3.8	-	15 23 30	2
C/3*	W II	-	-	-	-
D/1	RCT	3.5	0.6 0.2	23	3

* Indicate W II =without image intensifier RCT= Remote control table

4. Discussion

From table II it can be seen that 15 fluoroscopy systems were performed at same entrance field size on I.I. and measured under conditions of ABC, though changes of their maximum and minimum values of IIESDR, ESDR and $ESDR_{max}$ are in accordance with those in many other countries.

From table III it can be seen 20 patient weight and technical parameters of fluoroscopic exam setting (such as kV, mA, size of exposure field, fluoroscopic time and number of film) were more different, but the maximum of DAP mean value was 2.1 times more than the minimum. The change of DAP was less than that of three dosimetric performance parameters by far, because many factors affecting patient dose in fluoroscopic exam changed dynamicly, and their overlapping became the total exposure effects of patients.

In respect of establishment to diagnostic reference dose value of fluoroscopic exam many authors have discussed it further since ICRP publication 73 and IAEA Safety Series No. 115 were published [2,3,4]. They give respectively diagnostic reference dose value to different types of fluoroscopy systems, for example, guide level in IAEA Safety Series No. 115 is 25 mGy/min to typical ESDR and 100 mGy/min to $ESDR_{max}$ for fluoroscopic exam. Britain gave 25Gycm^2 as DAP reference value for fluoroscopic exam in 1992, revised 7.6Gycm^2 for digital fluoroscopy system and 15.5 Gycm^2 for none-digital fluoroscopy system in 1998. Countries in North Europe believe that 25 Gycm^2 is valid as reference dose value (DAP) in Barium meal exam.

Table II. Measurements of three dosimetric characteristic parameters (IIESDR, ESDR and $ESDR_{max}$) for 16 fluoroscopy systems normal mode of fluoroscopic grid in, field size of 23 cm, with ABC

Hospitals/Room Number	IIESDR Gy/min			ESDR mGy/min			$ESDR_{max}$* mGy/min		
	kV	mA	Measurement	kV	mA	Measurement	kV	mA	Measurement
A/1	85	1.7	108	90	1.7	16.1	124	2.4	36.9
A/2	79	2.0	40	77	2.0	23.5	112	4.0	99.1
A/3	85	1.4	20	79	1.4	7.9	95	1.4	11.4
A/4	76	6.3	27	73	6.8	5.7	125	16	60.8
A/5	88	1.4	44	89	1.4	10.7	121	2.6	33.34
A/6	76	1.6	58	77	1.6	11.4	124	2.4	40.0
A/7	78	0.2	9.0	70	2.0	6.83	100	4.0	26.7
B/1	76	1.3	33	76	1.2	6.5	120	3.0	41.2
B/2	75	2.1	68	78	1.6	9.9	114	2.4	29.4
B/3	71	3.2	36	71	3.0	11.5	111	6.0	58.6
B/4	80	1.5	72	83	1.7	12.0	115	2.3	27.9
B/5	85	0.5	33	80	1.0	3.9	120	1.0	8.2
C/1	70	1.0	21.4	74	1.1	5.5	120	1.9	24.0
C/2	88	2.1	67.8	89	2.1	13.9	125	4.0	55.7
C/3				70	2.0	46.8			
D/1	88	2.0	44.9	74	1.3	5.6	123	2.5	29.4
	Mean value		45.5			10.1			38.8

Table III. Value of 20 patient measurements in Barium meal (upper GI) examination

Hospitals/Room Number	Patients number	Patient weight Kg		Fluoroscopic time min		Number of images (films)		DAP value $Gycm^2$	
		Range	Mean value	Range	Mean value	Range	Mean value	Range	Mean value
A/1	5	57-67	47.4	0.57-8.7	4.8	5-12	9.0	8.16-47.89	27.9
B/2	5	54-65	54.6	3.32-6.92	6.1	8-12	9.2	9.84-15.38	13.6
C/1	5	63-70	56.3	3.1-8.7	6.1	3-9	5.2	10.37-35.50	18.8
D/1	5	59-68	51.0	3.2-6.1	4.4	6	6	15.49-31.24	22.0

There are many complicated factors affecting the patient dose in the same exam, such as difference of fluoroscopic time, the number of film and patient size [5]. The author thinks DAP is better than IIESDR and ESDR (or $ESDR_{max}$) for evaluating patient stochastic effects. But in interventional radiological exam, $ESDR_{max}$ of skin for evaluating deterministic effect of skin is better than the other parameters.

5. Conclusions

First, according to IAEA Safety Series No 115, 16 fluoroscopy systems investigated (except traditional fluoroscopy system C/3) satisfy the guide level. But IAEA Safety Series No 115 just gives typical ESDR (mGy/min) and $ESDR_{max}$, they can not be satisfied with requirements of all kinds of fluoroscopic exam .we should stipulate diagnostic dose guide level (also called diagnostic reference dose level) for every item of fluoroscopic exam.

Secondly, Britain and countries in North Europe make DAP value 25$Gycm^2$ as diagnostic reference dose level. According to the stipulation, we chose 4 fluoroscopy systems to measure the DAP mean values in Barium meal exam for 20 patients, DAP mean value of one fluoroscopy system (A/1) is 27.9 $Gycm^2$ more than 25 $Gycm^2$, but ESDR and $ESDR_{max}$ of this fluoroscopy system are all under the guide level limits of IAEA Safety Series No. 115. Thus it can be seen that ESDR and $ESDR_{max}$ reflected the characteristics of equipment, but to evaluate the dose which is accepted by patient in fluoroscopic exam, we still should consider many subjective and objective factors, such as patients'size, fluoroscopic time, the number of films, operator technical skill and so on. It is DAP that synthesized all kinds of affecting factors for patients and got DAP mean value. The author thought DAP value is fit for the diagnostic reference level of patient dose in fluoroscopic exam.

Acknowledgement

This work was supported in part by IAEA under the contract number 8221/R2. We would like to thank Ms. Modupe Oresegun for her assistance.

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IAEA-CN-85-93

PATIENT DOSE MEASUREMENTS IN FLUOROSCOPIC EXAMINATIONS, AIMING TO THE ESTABLISHMENT OF REFERENCE LEVELS IN BRAZIL

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Abstract

This work was performed to investigate the actual exposure levels of the patients submitted to fluoroscopic procedures in diagnostic radiology. The data will be useful for a baseline in the establishment of local reference levels for fluoroscopic procedures, as recommended by the European Commission and IAEA. At present time there are not internationally accepted definitions for references levels for fluoroscopic complex procedures. Dose-area product (DAP) meters were employed in a pilot survey expressing the radiation exposures in terms of this quantity. This class of instrumentation has not been employed in Brazil yet. Parameters recorded were radiographic technique, fluoroscopy time, number of images, fluoroscopic and radiographic field sizes and DAPs. For fluoroscopy practice, a reference parameters set is recommended, instead of one diagnostic reference level. High patient exposures were found, calling for joined actions of health authorities, physicians, medical physicists, technicians and manufacturers. Monitoring of patient exposure, optimizing the radiation protection and establishing quantitative assessments of the exposition to the population in Brazil in this kind of procedure is important.

1. Introducción

Las Normas Básicas Internacionales para Protección Contra las Radiaciones Ionizantes (BSS) [1], recomiendan el uso de niveles orientativos para fluoroscopía en téminos de tasas de dosis de entrada en la superficie de la piel. En 1999 la Comisión Europea publicó un documento con orientaciones relacionadas a los niveles de referencia de diagnóstico [2], teniendo en cuenta que la directiva 97/43/Euratom [3] exige que los Estados-Miembros promuevan la fijación y uso de niveles de referencia. Este documento presenta valores de referencia propuestos para fluoroscopía, expresados en la magnitud producto dosis-área (DAP), y reconoce que aun no se han resuelto todas las cuestiones en relación a esta práctica.

En Brasil, el Reglamento Técnico del Ministerio de Salud, Portaria 453/98 [4], establece niveles de referencia para algunos procedimientos radiográficos. Para fluoroscopía exige el registro de la tasa de dosis al paciente y del tiempo de examen o del producto dosis-área, y una tasa de kerma menor que 50 mGy/min en la entrada de la piel. Esta reglamentación fue establecida siguiendo las orientaciones de las BSS [1]. Sin embargo, en procedimientos fluoroscópicos los estudios dosimétricos a pacientes son relativamente recientes, existen pocos datos disponibles [5][6][7][8], los medidores del producto dosis-área han sido usados apenas en forma experimental [9] y aún no está definida la metodología que debe aplicarse para determinar niveles de referencia de diagnóstico locales. El presente trabajo forma parte de un proyecto de optimización de la protección radiológica en fluoroscopía, apoyado por la IAEA [10] aplicado en instituciones médicas de Rio de Janeiro, siendo uno de los objetivos la evaluación de las dosis recibidas por pacientes, a fin de conocer los niveles de exposición y servir de punto de partida para el establecimiento de niveles de referencia. Se presentan aqui algunos resultados preliminares de esta investigación en un departamento de radiodiagnóstico.

2. Materiales y métodos

Los exámenes fluoroscópicos evaluados fueron realizados en un equipo de rayos X telecomandado marca GE, con generador de alta frecuencia MPG 50 e intensificador de imagen de 23 cm de diámetro, debajo de la mesa de exámenes. La técnica fluoroscópica es determinada por el control automático de brillo. En el panel de comando, se puede seleccionar la tensión del tubo, el producto mAs y el tiempo de exposición para grafía, presentando también opciones para dividir automaticamente la película. El foco grueso (2 mm) es utilizado para grafía y el foco fino (1,2 mm) para escopía. Dispone también de un indicador de tiempo de escopia con alarma sonora a los 5 minutos.

Se utilizaron medidores Diamentor M4 y E (PTW, Freiburg, Alemania) para medir el producto dosis-área (DAP). La calibración de los instrumentos fue realizada *in situ*. El fabricante garantiza una incertidumbre de ±1% en la medida del DAP [11]. Se aplicó un único factor de calibración: el promedio de los obtenidos para los diferentes kVp utilizados, porque esto no introdujo errores significativos.

La dosimetría a pacientes fue realizada en 60 procedimientos: 9 enemas de bario con duplo medio de contraste (clisteropaco), 39 esofagografías, 5 seriografías gastroduodenales, 4 uretrocistografías y 3 urografías intravenosas, siguiendo los protocolos médicos de la institución. Los exámenes fueron conducidos por médicos del primer año de la residencia en radiología.

Los datos registrados en cada examen fueron: técnica fluoroscópica (kVp, mA), tiempo de exposición, técnica radiográfica (kVp, mAs), número total de imágenes, tamaño de campo fluoroscópico y radiográfico, distancia foco-piel, distancia foco-receptor de imagen, DAP de la parte fluoroscópica del examen, DAP de la parte radiográfica del examen, DAP por imagen y DAP total. Se calculó la tasa de dosis de entrada en la superficie de la piel en fluoroscopía de la siguiente manera:

$$Tasa = \frac{DAP_{escopia}}{tiempo_{total}} \cdot \frac{\mathrm{BSF}}{Área_{fluoro}} \cdot 10$$

Donde $DAP_{escopia}$ es el DAP medido correspondiente a la parte fluoroscópica del examen, en $cGycm^2$. El $Área_{fluoro}$ fue calculada en la superficie de entrada del paciente, a partir de las distancias foco-receptor de imagen y foco-piel y del área del intensificador de imagen. BSF es el factor de retro-dispersión, adoptado como 1,35, y el factor 10 es un factor de conversión de cGy para mGy.

3. Resultados y discusión

En la tabla I se presentan los resultados obtenidos en los exámenes evaluados. Los valores de DAP totales son muy elevados si se comparan con los propuestos en la literatura [12][13][14][15] como niveles de referencia para fluoroscopía (entre parentesis y en negrito en la tabla I).

Las grandes desviaciones estandar obtenidas en el número de imágenes y en el tiempo total de examen sugieren la necesidad de una revisión de los protocolos médicos de los exámenes por

parte de los médicos radiólogos, a fin de establecer procedimientos estandarizados para cada tipo de examen.

Las tasas de dosis variaron entre 46 y 77 mGy/min (tercer cuartil), con valores promedios entre (42 ± 20) y (65 ± 21) mGy/min, superiores a los recomendados por la Portaria 453/98 [4] (50 mGy/min) y por las BSS [1] (25 mGy/min, bajo nivel), lo que sugiere que debería realizarse una revisión del equipo.

La parte fluoroscópica del examen osciló entre 40 y 76% del DAP total, dependiendo del tipo de procedimiento: para esofagografías fue de (58 ± 15)%, para enemas de bario de (66 ± 13)%, para seriografías de (76 ± 16)%, para uretrocistografías de (61 ± 10)% y para urografías intravenosas de (40 ± 7)%.

En la tabla II se muestra un resumen de los parámetros ("valores típicos") considerados importantes para caracterizar cada tipo de examen. En todos los casos, el criterio usado para establecer los valores típicos fue el de adoptar el tercer cuartil de la distribución del parámetro correspondiente, considerando que estos datos fueron adquiridos por primera vez.

En el presente trabajo se propone la caracterización de los exámenes complejos mediante un conjunto de "parámetros de referencia". Debido a los diversos factores que intervienen en los procedimientos fluoroscópicos, un único parámetro de referencia no posibilita la identificación de los posibles motivos de exposiciones elevadas o alejadas de los valores típicos, si es que esto sucede. En un primer nivel de información, consideramos fundamental cuantificar tres "parámetros de referencia": DAP total, tiempo de irradiación del paciente y número de imágenes. Un analisis mas profundo debería considerar las contribuciones fluoroscópica y radiográfica al DAP total, aspectos mas relacionados con el protocolo médico. Esto permite una revisión del procedimiento de realización del examen. Un conjunto completo de "parámetros de referencia" debería incluir también la tasa de dosis de entrada en la superficie de la piel y el tamaño de campo (área irradiada).

4. Conclusiones

Este trabajo proporciona los primeros valores locales de DAP para los tipos de exámenes fluoroscópicos evaluados, con la intención de servir de punto de partida para, que una vez evaluados otros equipos y prácticas, se pueda llegar a proponer valores provisionales de referencia en fluoroscopía en Brasil. Los elevados valores de DAP medidos en todos los casos, sugieren la necesidad de implementar una metodología padronizada para definir niveles de referência regionales en fluoroscopía y su posterior optimización, mediante el analisis de las causas que originan estos resultados. Es imprescindible la monitoración de las exposiciones a pacientes durante los procedimientos, mediante la instalación de medidores del producto dosis-área en los equipos fluoroscópicos y del registro dosimétrico del paciente, aspectos ya obligatorios en otros países [16].

Los niveles de referencia para fluoroscopía deberían establecerse midiendo un conjunto de parámetros, en vez de un único indicador. Tiempo de exposición, número de imágenes y DAP total constituyen la base de este conjunto. Un conjunto mas completo incluye el DAP de la parte radiográfica y el DAP de la parte fluoroscópica del examen, separadamente.

En función de los resultados, medidas inmediatas deben ser tomadas. Acciones conjuntas entre autoridades sanitarias, médicos, físicos médicos, técnicos y fabricantes deben ser

establecidas. Una revisión cuidadosa de los protocolos médicos de los exámenes podría permitir, en ciertas situaciones, la diminución de las dosis. Por lo tanto, los radiólogos deben ser concientizados sobre la importancia de esta cuestión e involucrados en la problemática de la determinación de niveles de exposición de pacientes.

Tabla I. Resultados de las medidas realizadas. n: número de exámenes evaluados. Los valores de los niveles de referencia disponibles internacionalmente [12][13][14][15] están indicados entre paréntesis y en negrito en la tercera columna

	Tiempo [min]	No. Imágenes	DAPtotal [Gycm^2]	Tasa Dosis escopia[mGy/min]
ESOFAGOGRAFIA (n = 39)			**(10)**	
Rango	0,7-6,4	2-27	4-33	
Media ± Desv. Estandar	2,7 ± 1,5	11,2 ± 5,5	13 ± 7	46 ± 15
3er Cuartil	3,6	14,0	17	56
ENEMA DE BARIO (n = 9)			**(37-62)**	
Rango	3,8-23	7-24	37-324	
Media ± Desv. Estandar	10,1 ± 6,6	13,8 ± 5,8	118 ± 81	65 ± 21
3er Cuartil	12,1	19,0	108	77
SERIOGRAFIA (n = 5)			**(25-53)**	
Rango	5,8-17,9	15-24	26-140	
Media ± Desv. Estandar	12,4 ± 4,4	20,0 ± 3,3	84 ± 41	42 ± 20
3er Cuartil	13,6	21,0	93	46
URETROCISTOGRAFIA (n = 4)			**-**	
Rango	2,8-5,8	9-10	38-46	
Media ± Desv. Estandar	4,3 ± 1,5	9,3 ± 0,6	43 ± 4	51 ± 10
3er Cuartil	4,5	10,0	44	48
UROGRAFIA INTRAVENOSA (n = 3)			**(20-40)**	
Rango	1,5-3,5	6-11	23-59	
Media ± Desv. Estandar	2,4 ± 1,0	8,7 ± 2,5	42 ± 18	56 ± 14
3er Cuartil	2,9	10,0	52	64

Tabla II. "Valores típicos" obtenidos para los diferentes exámenes evaluados

Examen	Tiempo total [min]	No. de imágenes	DAP total [Gycm^2]	Tasa de dosis [mGy/min]
Enema de bário	12	20	108	77
Seriografia	14	21	93	46
Esofagografia	4	14	17	56
Uretrocistografia	5	10	44	48
Urografia intravenosa	3	10	52	64

Agradecimientos: Los autores agradecen a la Dra. Denise Madeira Moreira, a los médicos residentes R1: LC. Campos, HC. Marques y AA. Salomão F., a las enfermeras VL. de Oliveira, AC. de Oliveira y RN. Eiras, a los físicos A. de Amorim y M. Balthar y a los tecnólogos R. Silva y J. Portela. Este trabajo fue realizado con el apoyo de CNPq (Brasil), GSF (Alemanha) e IAEA (Contract BRA11061).

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PATIENT AND STAFF DOSE DURING HYSTEROSALPINGOGRAPHY

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Abstract

Hysterosalpingography (HSG) is a useful and widely employed technique which uses X-ray fluoroscopy to investigate the female genital tract. Fluoroscopy is assessed by a gynaecologist, a physician who is not always trained to work with ionising radiation. Dose-area product measurements in a group of 34 patients allowed an estimation of the median effective dose (0,83 mSv) and the median dose to the ovaries (1,63 mGy) of the patient per procedure. The dose to the staff was estimated using thermoluminescent dosimetry. The following median entrance surface doses were estimated per procedure: 0,22 mGy to the lens of the eye, 0,15 mGy to the neck at thyroid level and 0,19 mGy to the back of the hand. The annual eye dose limit could be exceeded if the gynaecologist is a member of the public.

1. Introduction

Hysterosalpingography (HSG) with water-soluble contrast media is a useful and widely employed method of investigating the female genital tract. The most common indication to perform an HSG is infertility. During an HSG, X-ray fluoroscopy is carried out by a gynaecologist to visualise the genital tract (uterus and Fallopian tubes). Since most patients (age between 20-40) desire pregnancy and the X-rays are targeted at the gonadal region, optimisation in terms of dose reduction and image quality is essential. A gynaecologist is a physician who is generally speaking not trained and used to work with ionising radiation as a radiologist and therefore not always familiar of the harmful effects to himself and his patient. Often he is not an occupational exposed worker but a member of the public. This clinical study is undertaken to estimate the effective dose and organ doses to the patient with respect to articles 4 and 9 the Euratom 97/43 directive [1] which imposes the European member states the promotion of the establishment and use of diagnostic reference levels. The doses to the eye, neck and hands of the staff (gynaecologist) were also estimated by using thermoluminescent dosimetry.

Several international papers have already been published regarding the patient dose in HSG [2-6], but no recent papers, to our knowledge, could be found regarding the dose to the staff.

2. Material and Methods

A total of 34 patients were evaluated on a over-couch General Electric Prestilix 1600 DRS radiographic unit. The input air kerma rate for the smallest field size (12.5 cm) in high dose rate selection measured on top of the image intensifier with a 15 cm^3 ionisation chamber and 2 mm additional copper filtration is 0.68 $\mu Gy.s^{-1}$. Digital acquisition is used during the examinations.

The dose area product (DAP) as a measure of radiation dose was determined for each radiographic and fluoroscopic exposure to each patient. Accordingly, the kilovoltage and view/projection for each single exposure were documented. The effective dose and doses to the ovaries and uterus were estimated using the recorded DAP value in combination with effective dose conversion factors derived from Monte Carlo computer calculations for a

female mathematical anthropomorphic phantom [7]. These factors are expressed in function of beam quality, applied kilovoltage and anatomical projection.

For the staff dosimetry, entrance surface doses (ESD) were measured by using thermoluminescent dosimeters TLD-100H (LiF: Mg, Cu, P) at different positions on the body of the gynaecologist. Three TLD chips were attached to the skin between the eyes, three to the skin of the neck at the level of the thyroid and three to the skin of the back of the hands for each examination. The ESD at one position (eye, thyroid or hand) was calculated as the average of the three readings. The TLD's were calibrated in air at 96 kVp (= energy used during ERCP) on the same X-ray unit. They were processed with a Harshaw-Bicron 5500 TLD reader and annealed in a PTW-TLDO oven. The gynaecologist wears a wrap around apron with 0,25 mm lead equivalence as personal protection.

3. Results and discussion

3.1. Dose to the patient

An overview of the patient exposure data per HSG procedure in terms of dose area product (DAP), fluoroscopy screening time, ovarian dose, uterus dose and effective dose is presented in table 1. 80 % of the dose to the patient is due to the contribution of fluoroscopy. Since the data presents not a normal distribution, the 1st quartile, median, 3rd quartile and maximum values are provided besides the mean.

Table 1. Patient exposure data evaluated for 34 examinations

Exposure indicator	Hysterosalpingography (34 studies evaluated)				
	Mean	1st quartile	Median	3rd quartile	Maximum
Dose Area Product (Gy cm²)	5,62	3,54	4,30	6,38	23,2
Fluoroscopy screening time (s)	58	34	43	66	210
Ovarian dose (mGy)	2,70	1,36	1,63	2,82	15,5
Uterus dose (mGy)	4,06	1,81	2,15	4,32	27,8
Effective dose (mGy)	1,39	0,70	0,83	1,44	8,53

From the data in table 1 can be seen that the exposure to the patient shows a large variation. This can easily be understood considering the influence of the patient size on the tube load and the variation in the assessed screening time according to the conduct of the procedure and the patient condition. The effective dose of the HSG patient is comparable to the dose resulting from other conventional radiological examinations. Table 2 compares our data to this from other studies previously published in literature.

All the values presented are median values recorded on digital units unless stated different. The data shows a large variation due to the difference in radiographic equipment, applied clinical technique and statistical analysis.

Table 2. Comparison of HSG dosimetric data published in literature

Study	Sample size	Fluoroscopy screening time (s)	DAP (Gy.cm²)	Ovarian dose (mGy)	Effective dose (mSv)
This study	34	43	4,30	1,6	0,83
[2]	21[b]	15		3,1	
	24	12	0,22	0,5	
[4][a]	40	40		2,8	
[6][a]	16[b]		4,42		
	16		2,07		
[5][a]	35			4,5	1,95
[3]	41		7,13	4,6	3,10

[a] mean values
[b] analogue unit

3.2. Dose to the staff

Table 3 shows an overview of the entrance surface doses to the forehead, neck and hand of the gynaecologist. A comparison is made to staff doses from other interventional radiological (IR) procedures previously published in literature. Due to the lack of HSG staff dose data in literature, no comparison could be made for this procedure. The data shows that staff doses in HSG are rather low compared to those from more complex IR procedures. In HSG, the staff is located at a very short distance to the area of exposure but the beamload and fluoroscopy screening times are low compared to more complex IR procedures where screening times are often between several minutes up to a half hour.

Table 3. Entrance Surface Dose (ESD) per HSG procedure for the eye, neck and hand of the staff, compared to other dosimetric data previously published in literature

Study	Procedure	Sample size		ESD (mGy) per procedure		
				Eye	Thyroid	Hand
Present	HSG	34	Median	0,22	0,15	0,19
			3rd quart.	0,26	0,19	0,25
			Maximum	0,28	0,21	0,29
[8]	Cardiac IR	5	Maximum	0,15	0,34	0,65
[9]	Cardiac IR		Median	0,24	0,10	0,30
[10]	Percutaneous renal surgery	8	Median	0,19		0,23
[11]	Various IR	30	Mean			1,5

4. Conclusions

This study investigated the patient and staff doses during hysterosalpingography (HSG) The third quartile values of the ovarian dose and the effective dose for a group of 34 patients were 2,82 mGy and 1,44 mSv respectively. The measurements show that the dose-area product (DAP) is an easy tool to guard the patient dose during the examination. This is strongly

advised since the gonadal region is exposed and all patients are young women who desire pregnancy.

Considering an average of 85 annually performed HSG examinations and the data (third quartile values) presented in table 3, the gynaecologist would receive an annual ESD of 22 mGy at eye level, 16 mGy at thyroid level and 21 mGy to the skin of the hand. This is, in general, lower than doses to staff-members who perform more complex IR procedures (angiography and cardiology) but the gynaecologist is often a member of the public who is not trained to work with ionising radiation. Moreover, the annual dose limit of 15 mSv to the lens of the eye could be exceeded. From the view of patient protection, it is clear that gynaecologists who perform HSG should be properly trained to use ionising radiation and especially in limiting the fluoroscopy screening time. He should also be a member of the occupational exposed workers.

It is advised that HSG should be included in future clinical multi-center patient and staff dose surveys at national and international level.

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PATIENT DOSIMETRY IN HISTEROSALPINGOGRAPHY

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Abstract

The objectives of this study were to determine the entrance surface dose to the patient and to estimate the dose to the uterus and ovaries due to hysterosalpingography (HSG) diagnostic examinations performed in Recife-Pe, Brazil. The entrance doses were measured using four thermoluminescent dosimeters per patient, attached to anatomical landmarks on the patient's skin. The study was carried out on 25 patients between 21 and 45 years of age who underwent the HSG examinations in two training hospitals and one private radiodiagnostic institute. The number of exposures performed ranged from 4 to 15 radiographs per patient measured. Entrance surface doses varied between 4.99 and 36.6 mGy, with an average of 12.6mGy. The doses to the ovaries and uterus ranged from 0.80 mGy to 5.8 mGy and 1.10mGy to 8.05 mGy, respectively.

1. Introduction

Hysterosalpingography (HSG) is a radiological procedure which is performed on young women to investigate the causes of infertility and sterility or to check the patency of the tubes following reversal of sterilization. Many patients undergoing HSG are between 20 to 40 years old and desire pregnancy. The average patient age according to Tyrell et.al is 31 years [1]. During this diagnostic examination many different radiographic projections and fluoroscopies are made resulting in a high patient dose. The uterus and the ovaries are the main irradiated organs [2,3]. For this reason, this examination requires rigorous optimization of the procedures in order to have the image quality required for the diagnosis with the lowest patient dose possible.

There are only few publications on patient dosimetry in HSG in Brazil, one of which is the study made by Canevaro in Rio de Janeiro [4].

The current study was undertaken to evaluate the dose received by the patients during the HSG examination performed in Recife, the Capital of the State of Pernambuco, located in the Brazilian northeastern region. Its aim was to obtain dose values for the same procedure performed in different hospitals in order to help to estabilish a reference dose level for this radiodiagnostic procedures in Pernambuco.

2. Material and methods

This study was performed in two hospitals (A and B) and one radiodiagnostic private institute (C). Both hospitals are educational institutions were radiologist residents performed specialized training. At A and C HSG was performed by series of exposures and the tube potential (kV) and mA were set manually by the radiographer. The X-ray equipment used are, respectively, Siemens Polimat B and EMIC. Hard copy images were obtained on 24 x 30 cm film using standard film screen radiography only. In hospital B a fluoroscopic technique irradiation was used to position the patient adequately for the radiography. The equipment is

the Phillips Super 80CP. On this unit both kV and mA are controlled automatically following operating algorithms programmed into the x-ray generator.

The measurements were made with in a total of 25 patients with ages ranging from 27 to 42 years and abdomen thickness ranging from 16 to 20 cm. The examinations were performed with 100 to 110cm focus-film distance and the field size, determined by the radiographer, varied between 19 cm x 15cm and 30cm x 24cm on the patient's surface. Table I shows some of the exposure parameters.

Table I. Values of The Main Technical Parameters for the institutions A,B and C

Parameter	Mean Value			Min Max		
	A	B	C	A	B	C
Tube potential (kV)	70.8	73.0	69.9	66-77	71-75	64-77
No. of films	5.9	6.8	4.7	4-15	5-7	4-5

The dosimetric evaluation was performed with LiF TLDs (TLD-100) calibrated with radiation energies similar to the ones used in clinical setting. The results were corrected to take into account backscattering. Two dosimeters were packaged in a polyethylene case and heat sealed. Two bags were placed on the surface of each patient, one on the right and the other on the left side of the abdomen, 3 cm from the field center. The TLDs were processed on a Victoreen readout system model 2800M and the average of their readings corresponds to the entrance surface dose.

In order to obtain reasonable estimates for the dose to the uterus and to the ovaries, the HSG was simulated with the Monte Carlo program EVA [5]. This program determines among other doses quantities also conversion coefficients between organ doses and entrance surface dose. A simple multiplication of the measured entrance surface doses (Table II) with the appropriate conversion coefficient leads to the organ doses shown in Table III.

3. Results

Figure 1 shows the distribution of entrance surface doses. Table II on the other hand shows the mean values obtained for the three institutions. In spite of having more experience physicians in the institution C, the entrance dose received by the patients during the exams were higher than those observed in the other two (A and B). Probably this is due to the fact that the value of the total filtration of the x-ray equipment used in institution B (2.5mm of Al) is lower than the ones used in the other two institutions (3.5mm of Al).

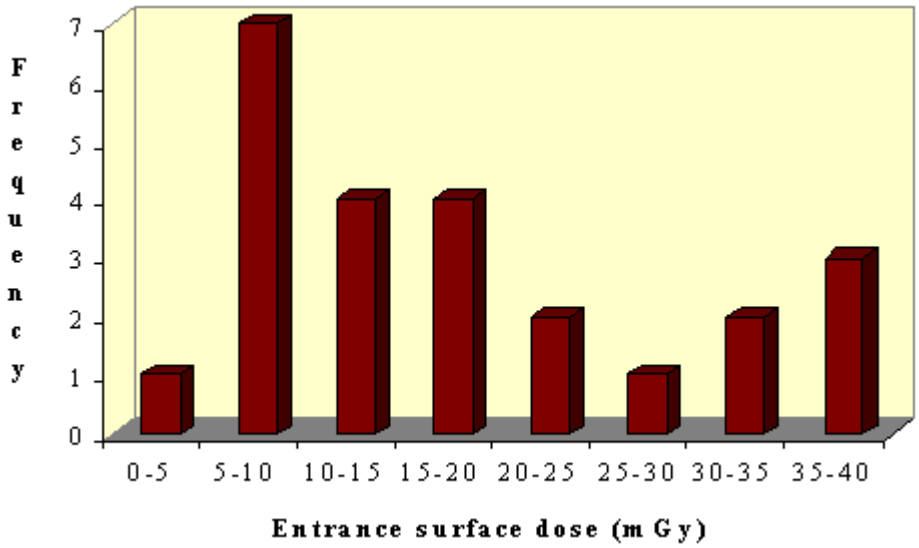

Figure 1: Frequency distribution of entrance surface doses for HSG Examinations

Table II. Entrance surface doses in mGy obtained at institutions A,B and C, for HSG examinations

Institution	Entrance Surface Dose (mGy)	
	Mean	Min-Max
A	8.44	4.99 - 14.28
B	17.36	6.08- 36.40
C	31.74	26.41- 36.60

Table III shows the doses to the uterus and to the ovaries determined as the mean absorbed dose to each organ. The results are similar to the other found in the literature.

Table III. Mean ovaries and uterus doses obtained at institutions A,B and C for HSG examinations

Institution	Ovaries dose (mGy)	Uterus dose (mGy)
A	1.18	1.71
B	5.27	6.97
C	2.38	3.42
Mean Dose (mGy)	2.94	4.03

4. Conclusion

The large range of entrance surface doses found is due to several factors like variation in patient thickness, field size, potential x-ray tube, etc. Different procedures for the examination generate different doses to the ovaries and what seems to improve positioning (case B) needs the major number of radiographs. The results obtained provide useful guidance on dose levels and optimization strategies.

Acknowledgements

The authors would like to thank the radiologists and radiographers that contributes to this study, for the institutions that allowed us to use their installation and to the CNPq for the financial support.

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DOSIMETRIC ASSESSMENT OF SWALLOWING EXAMINATIONS WITH VIDEOFLUOROSCOPY

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Abstract

Dosimetric analysis measurements of the Dose-area-product (DAP) of 7 individuals were estimated for the deglutition dynamic using the videofluoroscopic method. The aim of this study is to establish in a preliminary way, typical DAP values, for this kind of study. The DAP values were obtained attaching to the X ray tube exit, an ionization chamber from PTW and a Diamentor M4 meter. The typical DAP values obtained during the videofluoroscopic evaluation of the deglutition dynamic including its three phases was 4101 +/- 881 cGy.cm^2 and the typical DAP rate was 577 +/- 94 cGy.cm^2/min. These values refer to a standard patient (1.57 cm height, 56 kg. weight) and a protocol that can be performed in about 7 minutes. The values, defined herein as typical refer to the used protocol. To our knowledge, the mean DAP rate is a good parameter to estimate radiation exposure from videofluoroscopic study of swallowing process.

1. Introduction

The efficiency and the quality of a semiotic method is represented by its ability of solving questions and indicating solutions. Videofluoroscopy has been accepted as the “gold standard” for the evaluation of the oral and pharigeal phases of the swallowing process. Its efficiency is unquestionable for the study of the esophageal phase, as well.

To study swallowing in its three phases, including the esophageal one in the disphagia protocol evaluation, in spite of increasing the examination time, is indeed an important decision. Not seldom, oro-pharingeal disphagias are associated with some morfological or functional involvement of the esophagus. Besides this, low tract disphagias of esophageal origin are commonly refered to, by the patient, as high disphagia due to upper transmission. These facts are more than adequate justifiactions to the inclusion of the esophageal evaluation in the protocol for disphagia studies, by the videofluoroscopic method.

However, in radiological examinations, exposure time to radiation must be taken into account in the cost-benefit analysis. Therefore it is important to evaluate the radiation doses to which the patients will be exposed when evaluated by a protocol that includes swallowing in its three phases. On the other hand, medical procedures are the most important causes of human exposure to artificial radiation sources.

The Committee of Radiological Protection from the Pan American Health Organization [1], points out that a radiological examination, clinically justified, generally causes a benefit to the patient and compensates the associated radiation exposure risk. The fact of recognizing the possibility of harmful effects, is the resposible for safety in radiodiagnostic methods nowadays.

Radiation interacts with the body determining the energy absorption by mass unit in a given tissue or organ, characterizing the absorbed dose. The dose received in a given kind of

examination is distributed in a variable mode in the body being maximun at the skin surface. Dose in tissues greatly depend on the radiographic technique. The unit of absorbed dose is the Gray (J/kg).

Costa et al [2,3,4] have evaluated patient doses using TLD's the videofluoroscopic method and compared the results with the deglutogram which uses radiograpic film, and concluded positively, with respect to the videofluoroscopy.

The low radiation in videofluroscopy was shown more evident when compared to classical radioscopy, the method where the images in the fluorescent screen were directly observed in dark room. It was observed [2] that the method that uses fluoroscopy with image intensifier causes an exposure around 13 times lower than the classical radioscopy.

The overall radiation emitted during an examination can be measured with a "dose x area meter", an equipment that registers in $cGy.cm^2$ the radiation quantity that may reach the patient during an examination. The DAP (Dose Area Product) is a dosimetric quantity specifically related to patient exposure. It reflects the greater or smaller exposure determined by the procedure. Therefore, not only the radiation dose but also the field size in cm^2, are important in the evaluation of radiation exposure produced by a given examination.

The most appropriate parameter to evaluate patient exposure in fluoroscopic examinations is the DAP, that registers the absorbed dose in the air multiplied by the total irradiated area during the examination. The DAP, generally expressed in $cGy.cm^2$, must not be mistaken with the concept of radiation dose per area expressed in cGy/cm^2, that is the dose per unit area where each cm^2 receives the dose. The DAP does not measure the dose in a particular body region, the expressed value is proportional to the total energy imparted to the patient during the whole procedure.

In this regard, we have tried to adopt, for patient radiological protection the reference doses, and standardize the radiation that is needed to correctly perform a given type of examination [5,6].

Dosimetric data depend on the kind of radiological equipment, the degree of patient cooperation, the radiologist ability and the exposure time. Preliminary results [3,10], coincide with data from the European Comunity are of the order of 1100 $cGy.cm^2$ for an esophagography, of 4000 $cGy.cm^2$ for barium meal and 6000 $cGy.cm^2$ for barium enema. In these examinations, radiographies represent 20-50 % of DAP [7,8].

In a dynamic examination, different regions with distinct densities are exposed to radiation. Therefore, different DAP are to be expected. Different registred DAP are summed up by the DAP meter allowing the quantification of the total overall radiation produced during a videofluoroscopic examination. This characteristic of summing up in the examination time the DAP variations, makes the videofluoroscopic method an excelent standard to study deglutition dynamic. For these reasons, the present study can offer in preliminary values of typical DAP which could represent this type of examination.

2. Materials and methods

The videofluoroscopic examinations were performed using an X ray equipment from Medicor model UV 56M, type FR2 with undercouch tube model D19-12/50-150. The tv system is

Vidiomed 2, with image intensifier type RBV 23/13. It uses a Vidicon tube with 525 lines, 60 Hz, interlacing 2:1. The images were registered in the VHS format with a video/monitor Samsung high speed mechanism model-CXE 1331. The DAP values were obtained attaching to the X ray tube exit a Diamentor model M4 from PTW.

Radiation exposure of 7 persons were analyzed during the videofluorsocopic examination, two men and 5 women, with ages between 21 and 72. The individuals were evaluated for the three phases of swallowing (oral, pharingeal and esophageal). One woman, a volunteer, had no complain and the remaining 6, refered to disphagia related to Parkinson disease.

The oral, pharingeal and esophageal phases were examined with a previously defined protocol [9] which includes observation during deep nasal inspiration and expiration and deglutition of saliva, water and contrasted home made test bolus (moisturized and homogenized bread with powder barium sulfate in soft consistency) from 0.5 to 2,5 cm diameter as well as barium sulfate solution.

The radiation doses to which the patients were exposed were calculated using the relation : ($DAP = DAP_m \times 0{,}97 \times 1{,}14$) where DAP represents the actual value, DAP_m is the measured value without correction. Correction factors are 0,97 determined by the manufacturer for undercouch tubes and 1,14 is the ionization chamber calibration factor.

3. Results and discussion

To our knowledge, there is no similar protocol for the evaluation of either DAP of swallowing, radiographic nor videofluoroscopic methods. For this reason, results obtained here can serve as a reference and a basis for future evaluations. It is necessary to take into account, the kind of protocol employed in the evaluation of swallowing when comparing DAP. Does the protocol include the three phases of swallowing? What kind of equipment is used for registering the events?

Protocols that do not include the three phases of swallowing can present lower values of DAP, limiting information that could be obtained in exchange of a shorter examination time. Observation with fluoroscopy first and then registration in a radiographic film causes a loss of dynamic information and the use of a higher dose rate to sensitize the radiographic film that, depending on the used protocol, can cause in a higher DAP.

Aiming the reduction of this possible discrepancy we have considered DAP rate ($cGy.cm^2/min$). Therefore, the exclusion of one examination phase would generate reduced DAP but similar values of DAP rate.

An analysis of table 1 allows the evaluation of sample quality, radiological technique, time variations necessary for fulfilling the proposed protocol and data registred by the Diamentor for each one of the individuals in $cGy.cm^2$. This table also shows the DAP rate in $cGy.cm^2/min$. Table 1 shows also the normalized values obtained by the product of examination time multiplied by the mean DAP rate. Results show new values for DAP comparable to the measured in each examination.This table, points out to the fact that, in the evaluation of swallowing which occurs in head, neck and mediastinum regions, where the contrasted esophagus is visualized in its cranio-caudal transit, the mean DAP does not change much with individual physical completion. Its variation depends on a larger scale on the changes of employed technique. Therefore, even a small sample was representative of

exposure to radiation in this protocol that can be verifyed by the small variance of the results. Consequently, a larger sample, that could present a greater dispersion depending on physical completion is out of procedure control. Dose control can and must be performed according to the protocol and in the proposed time.

Table 1. Data

	Hight (cm)	Weight (kg)	mA (aver.)	kV	Total time (min)	DAP_m ($cGy.cm^2$)	DAP ($cGy.cm^2$)	DAP rate ($cGy.cm^2$/min)	DAP rate normalized ($cGy.cm^2$/min)
CMF	1.48	42	1.0	65	7.1	3061	3385	477	4096
SIF	1.65	60	1.6	70	7.5	4777	5282	704	4327
MLO	1.49	59	1.0	64	7.7	4107	4541	590	4442
JM	1.60	63	1.2	65	6.7	4125	4561	680	3865
AFS	1.60	60	1.6	70	7.8	4257	4707	603	4500
PFMC	1.65	54	1.1	65	5.9	2694	2979	505	3404
CDP	1.55	52	1.1	60	6.8	2941	3252	478	3923
St.dev.							881.5		387

In table 2, the descriptive statistics is discussed and allows the evaluation of the influence of the different variables in DAP values. Age, sex and physical complexion, represented by height and weight are determining factors in density variations and consequently in final DAP. These parameters, inherent to the patient, do not change, nevertheless its observation will help the interpretation of the DAP found for each individual. The location of a determined DAP in one or other end of the gaussian distribution can point out towards a better or worse performance of the applied methodology or radiological equipment. When patient who were expected to be located in the lower part of the curve appear in the upper part, it can be an indicative of careless examination, lack of examinator expertise or deficient equipment. Another important factor to be considered is collimation. As the measurement is done after the collimator, to colimate a field, whenever possible, reduces exposure area and consequently the DAP.

The DAP obtained in our study can be related to other studies of dose-area of digestive system [7,8]. Our results are distributed in the lower dose level obtained up to date in radiological procedures of this system. The examination time is the parameter that can be easily manipulated to reduce DAP together with an optimized technique. For this reason, we define exposure by an examination per unit time (minutes). This exposure was obtained for each examination dividing total DAP by the time required for that specific examination. Examination time is clearly dependent on the protocol and depends on the examinator's expertise and the degree of difficulty presented to perform the examination. However, it is here that the efforts to reduce DAP must be directed. This reduction can be achieved improving the examinator's performance, specially through the elaboration of protocols which clearly define the sequence of events to be observed. However, to reduce DAP, the examination quality can not be degraded.

The DAP rates served as a basis to obtain a mean value of what exposure during the evaluation of swallowing. We believe that it is the best parameter to represent exposure. This resource allows the reduction of several variables interfeering in the generarion of DAPs. If we compare standard deviation which covers 68% of mean dispersion, we can see that it from

about 21% of total exposure to around 16% in exposure per minute, showing less disperssion in the average when considering exposure/minute.

Table 2. Descriptive Statistics

	Age (y)	High t (m)	Weigh t (kg)	KV	mA	Total time (min)	DAP_m ($cGy.cm^2$)	DAP ($cGy.cm^2$)	DAP rate ($cGy.cm^2$/min)
Average	53,57	1,57	55,71	65,57	1,23	7,07	3709	4101	577
Standard error	7,79	0,03	2,7	1,32	0,1	0,25	301	333	35
Standard deviation	20,61	0,07	7,13	3,51	0,26	0,67	797	881	94
Minimum	21	1,48	42	60	1	5,9	2694	2979	477
Maximum	72	1,65	63	70	1,6	7,8	4777	5282	704
Sum	375	11,01	390	459	8,6	49,5	25962	28709	4038
Counts	7	7	7	7	7	7	7	7	7

Conclusion

Typical value of DAP obtained during the videofluoroscopic analysis of swallowing with analysis of its three phases is 4101 +/- 881 $cGy.cm^2$ and the typical DAP rate was 577 +/- 94 $cGy.cm^2$/min for individuals 1,57 cm height, 56 kg weight, examined with protocols which can be performed in around 7 minutes. The values defined here as typical refer to the used protocol. To our knowledge, the mean DAP rate is a good parameter to estimate radiation exposure due to videofluoroscopic study of swallowing.

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Topical Session 2

RADIOLOGICAL PROTECTION ISSUES IN SPECIFIC USES OF DIAGNOSTIC RADIOLOGY, SUCH AS MAMMOGRAPHY AND COMPUTED TOMOGRAPHY (WITH SPECIAL CONSIDERATION OF THE IMPACT OF DIGITAL TECHNIQUES)

EVALUATION OF DIAGNOSTIC RADIOLOGY SERVICES IN FIVE LATIN AMERICAN COUNTRIES: RESULTS FOR MAMMOGRAPHY

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Abstract

Under the auspices of PAHO/WHO, a multicentric investigation is carried out in five Latin American countries. Its aim is to correlate quality indicators of radiology services with the accuracy of the radiological interpretation as determined by a panel of experts. We present preliminary results from mammographic imaging facilities, which indicate that the failure to comply with the international standards of quality control produces images of unacceptable quality, as measured either by using a phantom or by an independent evaluation of the clinical images.

1. Introduction

Quality assurance programs in health services, in particular in radiology services are slowly being implemented in Latin America and the Caribbean some under Government Regulations. They will require the conjunction of strong political will, financial support and professional training to become a relevant factor in the routine service offered by radiological facilities. The Pan American Health Organization/World Health Organization, (PAHO/WHO) coordinates and partially funds an investigation aimed at *correlating quality indicators of radiology services with the accuracy of the radiological interpretation.* Grants have been awarded to government, academic and/or professional multidisciplinary teams in Argentina, Bolivia, Colombia, Cuba and Mexico to pursue these studies following common procedures based on internationally accepted protocols. The project should be completed after 12 months of work, and here we present preliminary results obtained during the first half of the grant duration.

2. Experimental procedure

2.1. Selection

The selected pathologies (and their associated radiological technologies) are: breast lumps (screening and diagnostic mammography), gastrointestinal ailments (radiography and fluoroscopy), back pain (computed tomography) and tuberculosis (radiography). The selected services belong to the medium complexity classification and are located in urban areas. The common quality control protocols are based on those endorsed by the American College of Radiology (ACR) [1], the American Association of Physicists in Medicine (AAPM) [2], the European Community (EC) [3], etc. The panels of radiology experts in charge of evaluating the accuracy of the radiological interpretation are endorsed by the national radiological societies.

2.2. Documentation

Records are collected in relation to the population covered by the services (public vs. private), the type of facility, the patient workload, the radiological, imaging and processing equipment and supplies, the staff education and training, the quality assurance and maintenance programs and the radiation safety standards.

2.3. Measurements

The measurements performed include the evaluation of devices (X-ray units, image receptors, and image processors), darkroom and viewing conditions, patient dose, and image quality. The clinical film evaluation by the expert panels considers imaging aspects (view and labeling, patient positioning, contrast and latitude, and artifacts) as well as the radiological interpretation report performed at the radiological service by the local physicians.

3. Results for mammography

Results from the study of mammography services are available from the five teams. The IFUNAM group evaluated a total of 31 parameters in three mammo units [4] functioning in two Mexico City public hospitals. The out-of-compliance results corresponded to beam collimation and alignment (in the three units), viewbox illuminance and homogeneity (in the three units), and darkroom conditions. One of the units, "Number 1", operated at an X-ray tube potential 10% higher than the nominal value and the cleanliness of the intensifying screens was considered totally unacceptable. In this unit "Number 1", chemicals' temperature in the two film processors was monitored during one month, finding unacceptable results (discrepancy larger than 2^{o} C between the unit temperature reading and that given by the control thermometer). Image quality was evaluated using the ACR accreditation phantom under five technical factors, as indicated by the ACR protocol [1]. Unit Number 1 failed the criterion for acceptable contrast, optical density and resolution at all five tube factors. The other two systems passed the test in either one or two, out of the five technical modalities. Mean glandular doses were calculated out of kerma in air measurements performed according to the ACR manual; the obtained values are 1.4, 1.6 and 1.0 mGy respectively.

The RFSF group studied four mamography units, each at a different hospital in the city of Santa Fé. All systems passed the 8 tests performed on the equipment performance (focal spot size, beam alignment, tube potential accuracy and reproducibility, timer accuracy, HVL, air kerma rate, SID, leakage radiation). However, all of the viewboxes were out-of-compliance due to their poor illuminance homogeneity. The radiological interpretation study was performed with 25, 20 and 16 clinical images obtained in three of the hospitals. The image quality was evaluated by a Panel that gave qualifications equal to 2.9, 3.2 and 4.2, over a maximum of 5. The lowest grade was due to finding 24/25 films dirty, 17/25 scratched and 12/25 with artifacts which simulated microcalcifications. The positioning was evaluated by the Panel with grades equal to 3.3, 4.3 and 3.6 over a maximum of 5. The diagnosis by the Panel coincided with that by the hospital facility in 60/61 cases.

The CCEEM group evaluated 255 clinical films corresponding to 80 patients in 2 hospitals. Positioning problems were detected and correlated with technologist training. The radiological interpretation by the Expert Panel coincided with that by the institution in 68/80 patients. Of the 80 patients, 27 received fine needle aspiration biopsy, as part of their clinical management. In 21 of them, the biopsy was done in patients where the panel and the facility physician

concurred in the radiological interpretation. 2 biopsies confirmed the institution's assessment, and 4 concurred with the Panel.

The IBTEN group evaluated 64 clinical films from 28 patients obtained at 2 hospitals and one clinic. The Panel detected positioning problems as well as inadequate film labeling for 27/28 patients.

The INCAN group performed quality control measurements on 3 units belonging to 2 hospitals in Bogota. 24 tests on equipment performance were used. The units were out-of-compliance in 4%, 4% and 30% of these tests, respectively. The system which presented the most serious problems, "Hospital 2", lacks a maintenance program and the radiation safety conditions were considered inadequate. The mammo Expert Panel analyzed 20 films obtained with this same system. The results showed that none of the films had a label recording the technical parameters. Furthermore, 28% of the oblique and 18% of the craneocaudal views were considered non acceptable in terms of technical quality, and 45% of the films were considered to present a non acceptable optical density.

4. Conclusions

We have presented partial results for the evaluation of mammographic equipment performance, image quality, dose and radiological interpretation corresponding to 14 systems in five Latin American countries. Even though the study is still in progress, some general results seem to appear already. The UNAM and INCAN results indicate a correlation between the failure to pass the equipment quality control tests and the poor quality of the image;, this one assessed either using the accreditation phantom or as determined by the panel of radiology experts. Concerning the dose to the patient, the only calculations to date (UNAM) indicate values well below the guidance levels published in the BSS [5], but similar to those published by the FDA in their MQSA program [6]. Since the ultimate goal is an image of sufficient diagnostic quality to produce an accurate radiological interpretation, the possibility that low values indicate insufficient film exposure needs to be explored. The completion of the tests, and a careful statistical analysis of the results, as well as the study of other radiological techniques, should help better understand the intricate relation among the various equipment parameters and the final image quality in radiological procedures. The knowledge and experience gained by the participants of these five research teams should promote better conditions for radiological services in Latin America and the Caribbean.

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IAEA-CN-85-144

STUDY ABOUT DIAGNOSTIC QUALITY IN A PUBLIC-CENTER OF MAMMOGRAPHY OF SANTA FE, ARGENTINA

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Abstract

The objective is to apply a method that allows us to evaluate the diagnostic quality of a public-center of mammography and to validate it.

The representative centers of a social class were grouped; this one is evaluated measuring the mechanics, electrics, dosimetrics and personal parameters of the process to get the mammography diagnostic. The original study and the respective report, was submitted to the valuation of a panel of experts, who evaluated image, technique and diagnostic. The equipment and techniques used are described in this case.

The judgment of the ACR and the Argentine legislation are applied. The dosimetric results of the mammography practice, serve to determine the local reference levels. The whole people who has intervened in the diagnosis is evaluated, and the services that can influence it. Seeking the parametric sensibility in relationship with the succeeded and precocious diagnosis, the success of it is confirmed by the panel of experts.

We concluded indicating that the success percentage in the diagnosis is about 98,36%, that there is 100% of coincidence among the perception and the value of the study quality. The valuation of the image reaches 69,2% of the maximum score, and the placement technique, 73,9%. The parametric sensibilities of the principal variables are discussed.

1. Objetivo

El objetivo es evaluar la calidad que tiene el centro para emitir un diagnostico precoz y certero sobre mastología y relacionarlo con los diferentes parámetros que intervienen en el proceso de obtención de dicho diagnostico.

2. Metodo y equipos

Se seleccionó un centro al azar que representara al acceso que tienen un determinada clase social y se evaluaron cada uno de los parámetros cuya nomina se puede apreciar en la tabla de resultados que se informa como N° 1.

Con la aceptación de las pacientes, el centro y el médico que diagnosticó originalmente los estudios, se realizó la copia del diagnostico y de las placas y se hacen todos anónimos para someterlos a la evaluación de un panel de expertos, reconocidos por la sociedad profesional, que evalúa la calidad de la imagen (Blanda / Normal / Quemada – Sobrexpuesta / Normal / Subexpuesta); la técnica utilizada para el posicionamiento y proceso de obtención de la imagen (Identificación – Artefactos – Sucia - Mal comprimida – Movida - Vista del músculo pectoral – Pliegues - Nariz de camello - Pezón incluido – Axila – imagen cortada); el Diagnóstico (Coincidencia total / parcial / no hay coincidencia – informe inespecífico – sugerencias explicitadas correctas / incorrecta) y por último se considera la evaluación general de la placa con su capacidad para emitir el diagnostico y si ha lugar, se explicite un comentario general de la mismas.

Para la evaluación de los parámetros mecánicos, eléctricos y dosimétricos del centro se aplicaron los criterios de la ACR (1) y de la legislación Argentina (2) además de las recomendaciones que se explicitan en el material no impreso (3) y la tesina (4).

Los equipos y herramientas utilizadas fueron: Densitómetro Digital Tobias Associates Modelo TBX, Sensitómetro Nuclear Ass., Precision Photometer Nuclear Ass., Thermometer Digital RMI, HVL of Al and CU, Mamographic Resolution Estándar, Star X-Ray Test Patterns 0,50° y 1°, Slit Cameras, Mamographic Step Wedge 18-239 Nuclear Ass., Control Tools Screen Film, duplicator AGFA, mAmeter UNFOR y Dosimeter PTW DI4/DL4 con camera PTW Modelo 3223, para baja energía.

3. Resultados

El equipo evaluado es un GE Senographic 600T- Senix HF, la maquina reveladora automática es AGFA y se usa compartida con el servicio de Radiología general, las pantallas reforzadoras y las películas usadas son KODAK. La carga de trabajo es de 200 estudios por mes.

Table 1. Los parámetros evaluados y su resultados se explicitan en la tabla N° 1

Tamaño de la mancha focal	Nominal: 0,3 Medido:Ô 0,34 - 0,39	Tol = 0,45	Pass
kVp – Reproducibilidad	R = 0	Tol = 2%	Pass
kVp – Precisión	P = 1,9%	Tol = 4%	Pass
Tiempo de exposición	A 24 kVp, R = 0,7	Tol = 10%	Pass
HVL	A 24 kVp, <0,3 mm de Al		Pass
Rendimiento	a 24 kVp, 9,8 mR/mAs	Tol = 8	Pass
Distancia foco imagen	Nominal 65cm Medido 63 cm Ä1,8%	Tol = 2%	Pass
Fuga	< de 1mGy a 1 m		Pass
Campo de luz / de radiación	1,5 mm en la peor condición	< ± 5	Pass
Dosis Kerma en aire	18,7 mGy		
Dosis Glandular Media	3,12 mGy	Tol=4mGy	Pass
Revelado Temp.. y tiempo	Revel 34,8ºC/Fija 34,1ºC Total 210s		
Sensitometria	v+b=0,19 IV=1,2 paso 15 IC=2,69-0,54=2,15 P 17- P 14		
Cuarto oscuro	Hermeticidad = Buena, Luz de seg.= no usa, Frecuencia de limpieza y cambio = 15 días		
Negatoscopio, luminancia	Centro 2012 nit		Fail
Negatoscopio, homogenidad	31%		Fail
Lectura Iluminación ambient	25 lux	< 50 lux	Pass

El médico informante es uno (1)(por lo que no se realizan la doble lectura del film) y su especialidad es en mastología, no es radiólogo tiene entre 15 a 20 años de experiencia y ha asistido a 37 cursos, conferencias, talleres y congresos en los últimos 5 años.

Las técnicas de mamografía son dos ambas con titulo terciario, especialización no estructurada en mamografía y con asistencia a conferencias y congresos en los últimos 5 años.

Tabla 2. La evaluación de la calidad diagnóstica de la placa se usó dos grupos diferentes de evaluadores, arrojando el resultado que se muestra

Nº	IMAGEN					TECNICA					DIAG.					EV. GRAL					TOTAL	OBSERVACIONES
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5		
1			X					X						X				X			13	Sucio,Rayas,Falta pectoral, Falla revelado
2			X					X						X				X			13	Sucio,Rayas,Pezón incluido
3		X						X						X					X		13	Sucio,Rayas
4			X					X						X				X			13	Sucio,Rayas,Pliegues, Pezón incluido,Artef Cal
5			X						X				X					X			13	Sucio,Rayas,Imagen cortada,Blanda, Artef Cal
6			X							X				X					X		16	Sucio,Rayas,Quemada
7			X					X					X					X			12	Sucio,Rayas,Pezón incluido, Falta desc Cal vasc
8			X					X							X			X			14	Sucio,Rayas, Falta pectoral, Artef Cal
9		X						X					X					X			11	Sucio,Rayas,Falta pectoral, Artef,Diag Bien/Mal descri
10				X					X						X				X		17	Sucio,Rayas,Pezón incluido,Pliegues, Artef Cal
11			X					X						X				X			13	Sucio,Rayas,Pezón incluido,Pliegues
12			X					X							X			X			14	Sucio,Rayas,Blanda,Imagen cortada
13		X						X							X				X		14	Sucio,Rayas,Blanda, Falta compresión
14			X					X						X				X			13	Sucio,Rayas,
15				X					X						X				X		17	Sucio
16		X							X						X			X			14	Sucio,Pliegues, Pezón incluido
17		X								X				X				X			14	Sucio,Rayas, Artef, Imagen cortada
18				X					X					X					X		16	Sucio,Blanda,Pezón inclui, Artfac,Falta descr Cal benig
19			X					X						X				X			13	Sucio,Pezón incluido,Artef
20			X				X								X			X			13	Sucio,Pezón incluido,Artef
21		X							X						X			X			14	Sucio,Rayas,Artef
22		X					X								X			X			12	Sucio,Rayas,Pezón incluido, Artef
23				X					X						X				X		17	Pezón incluido
24			X					X				X						X			11	Sucio, Imagen cortada Diagnós observado
25			X					X				X					X				10	Sucio,Pezón incluido,Artef, Error Diagnóstico

El centro tiene servicio de mantenimiento interno de malas condiciones de prestación, no tiene servicio de física médica y el oficial de protección radiológica es el medico con reciente autorización individual para el manejo de equipos Rayos-X.

Para la evaluación de la calidad diagnóstica de la placa se usó dos grupos diferentes de evaluadores, arrojando el resultado que se muestra en la tabla N° 2

En el 92% de las placas, la calidad diagnóstica fue evaluada como Regular o Buena, (58% Regular y 42% Buena), solo dos estudios resultaron con una valoración por debajo de regular. La evaluación total fue el 82,4% del valor máximo.

El diagnóstico fue coincidente en 24/25 de los casos, solo se observó en 1 caso que faltaba la descripción de microcalcificaciones agrupadas, en 1 faltaba describir microcalcificaciones vasculares, en 1 falta descripción de microcalcificaciones benignas y 2 se observaron por informe escueto.

La imagen fue calificada con un promedio de 2,88/5, porque el 96% de las placas se encontró que estaban sucias, en el 68% rayadas, en el 48% con artefactos que simulaban microcalcificaciones y/o masa y 16% estaban blandas o quemadas. Se llegó a la conclusión que existen severos inconvenientes antes y durante el procesado de la película.

La técnica se evaluó en promedio con 3,28/5, por el posicionamiento y la compresión de la mama, (se encontró que en el 50% de los estudios tenían alguna placa con pezón incluido, en el 16% de los estudios alguna placa con pliegues, en alguna placa del 10% no se tomaba el pectoral y solo en el 16% de los estudios alguna placa estaba recortada y en 1 le faltaba compresión.

La evaluación por item de las placas arrojó que la Imagen se valuaba con 2,88/5, La técnica con 3,28/5, el diagnóstico con 4,12/5 y en Percepción general 3,25/5. Arrojando la Evaluación general del Servicio 10,28/15.

4. Conclusiones

Los parámetros del equipo dan en todos los casos como cumpliendo con las tolerancias establecidas, excepto los negastoscopios que dan francamente mal.

Se destaca primero la validez del método elegido ya que la Percepción de la calidad del Servicio para emitir un diagnóstico certero (0,66), coincide con la valoración que se desprende de cada uno de sus ítems (0,68).

La otra cosa importante es la relación encontrada entre la evaluación de los expertos y las causas de esa valoración, así mencionamos cuatro:

1º) La falta de un revelador cautivo, la mezcla de marcas, así como el descuido en la limpieza de los chasis, pantallas y películas traen como consecuencia la suciedad, rayas, artefactos, placas blandas y duras, que encontraron los evaluadores y que hacen perder calidad diagnóstica a la placa.

2º) Por otro lado la falta de posibilidad de contar con un chasis de mayor tamaño (24 x 30) y las películas correspondientes (a pesar de contar la máquina con la platina compatible), traen

como consecuencia directa las Imágenes cortadas en las placas de mamas grandes y concurren con otras causas que también influencian, a encontrar pliegues, pezón incluido y falta del músculo pectoral.

3º) La alta carga de trabajo, junto con la expertice de las dos técnicas radiólogas y los detalles enunciados en el ítems anterior tienen que ver con la la falta de compresión y problemas de posicionamiento como pezón incluido y pliegues.

4º) Las imágenes sucias y rayadas sumada a los artefactos y a la muy mala calidad de los negatoscopios, agravado por la imposibilidad de doble lectura, son la consecuencia de los inconvenientes detectados en el diagnóstico.

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BENEFIT AND RISK IN BREAST SCREENING

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Abstract

Justification of breast screening in radiation protection terms both for the screened population and on an individual basis is necessary. In this paper the number of cancers detected, and the number of cancers potentially induced by radiation, in the UK National Health Service Breast Screening Programme (NHS BSP) are compared. Detection rates reported up to 1998 are used, with x-ray doses for 1997 and 1998 and breast cancer induction risk factors, stratified by age, recommended by the National Radiological Protection Board in 1994. Cancers detected exceed those potentially induced at all ages from 50 – 64. The relationship between these cancer numbers and the associated benefit and risk, in terms of breast cancer deaths avoided and induced, is then investigated. Improved values of the Nottingham Prognostic Indicator (NPI) attributed to screening provide one means of doing this. Using this strict criterion the breast-screening programme is also justified in radiation protection terms.

1. Introduction

It is widely considered that breast cancer can be induced by high doses of ionising radiation, such as X rays. The probability or risk of induction is believed to be dependent on dose. The time lapse between exposure to ionising radiation and development of breast cancer is generally agreed to be at least 10 years for women in the screening age group. Breast cancer induction decreases with increasing age at exposure [1]. In a breast-screening programme, the benefits achieved in the form of lives saved or prolonged should clearly exceed the risks arising from any breast cancers that may be induced from the associated radiation exposure. In this context both benefit and risk can only be estimated statistically, so that it is the probability of each which must be compared. Many attempts to consider the balance between radiation risk and benefit have been published. Most have considered only the numbers of cancers detected and induced, both of which can be estimated with relative confidence (e.g. [2]). Assessing benefit from treatment outcome is a much harder task. Treatment outcome is statistically more difficult to predict, especially in breast cancer, for which 5-year survival is a less reliable indication of "cure" or final outcome than in many other cancers [3].

This paper will consider the latest cancer detection rates and dose estimates, and hence the relative numbers of cancers detected and induced. It will then use treatment outcome data in an attempt to relate those numbers to the balance of benefits and risks.

2. Breast doses in the NHS BSP

The mean dose to breast glandular tissue (MGD) is generally considered to be the dose quantity most relevant to the risk of radiation induction of breast cancer. Average values of MGD for the NHS BSP have recently been reported by Young and Burch [4], who have found mean dose levels *per film* of 2.03 ± 0.02 mGy for lateral oblique views and 1.65 ± 0.02 mGy for craniocaudal (CC) views. The mean dose *per woman* is slightly higher because a small minority of women have more than one film per view, especially where the larger film size of 24 x 30cm is not available. The corresponding mean doses per woman for single view and two-view screening are 2.14 ± 0.04 and 3.65 ± 0.07 mGy respectively.

Current routine practice in the NHS BSP is to perform two view screening on the first round (ages 50 – 52) and single view screening on subsequent rounds. In the calculations that follow later in this paper, the dose levels for both single and two-view screening will be used for the 50 – 64 year age band.

The highest doses are likely to be received by women with the thickest breasts (around 10cm). These women also require more than one film per view, possibly up to four such films. However, the number of women in this subgroup is extremely small and difficult to predict. Young and Burch [4] report that for oblique films only, one film per thousand exceeded 8.6mGy, and they describe this as the maximum dose per film that may normally be expected. The corresponding dose level for CC films was 7.1mGy, giving a combined normal maximum dose for two-view screening of 15.7mGy at one film per view. Even for the 0.1% of the screened population receiving the highest doses (mainly those having the thickest breasts), the dose should not exceed 20 mGy.

3. Radiation risk factors for breast cancer induction

The risk of radiation induction of breast cancer decreases with increasing age of the woman at time of exposure (e.g. [1]). Numerical values for the magnitude of this risk factor are based on work by the National Radiological Protection Board (NRPB), with further subdivision from 10 to 5 year age bands following discussion with NRPB [2]. Although this data is 5 years old, these estimates of the risk factors are considered to remain the best available for the UK population. They refer to all breast cancers in a female population, not fatal cancers in a mixed population as in some earlier studies, and are given in Table I.

Table I. Radiation Risk Factors For Breast Cancer Induction – UK Female Population

Age Band	Breast Cancers Induced per Million women per mGy
50-54	13.2
55-59	11.5
60-64	9.4

Screening detection rates in the NHS BSP are reported at annual intervals. Those for the last four years for which figures are available are given in Table II and refer to England rather than the UK [5].

Table II. Cancer Detection Rates in the English Breast Screening Programme (/1,000) [5]

Age Band	1994-95	1995-96	1996-97	1997-98	Mean
50-54	4.3	4.6	5.0	5.4	4.8
55-59	4.7	4.7	5.0	5.3	4.9
60-64	6.3	5.9	6.0	6.0	6.1
Mean 50-64	5.1	5.1	5.3	5.6	5.3

4. Cancers detected and cancers induced

Table III gives the ratios of cancers detected/induced, using the data from Table II, for three 5-year age bands of the NHS BSP, and for the various dose levels discussed earlier. These

ratios are all in double figures, i.e. the cancers detected exceed the numbers induced even for almost all the women in the highest dose subgroup.

Table III. Ratio of Cancers Detected to Cancers Induced at Various Dose Levels

Age Band	Radiation Dose Levels (mGy)			
	2.14	3.65	11	20
50-54	170	100	33	18
55-59	199	117	39	21
60-64	303	178	59	32

5. Breast cancer treatment outcomes

In many types of cancer, 5-year survival is used as an indicator of outcome because, beyond this interval after initial treatment, life expectancy is restored to that of a normal population of the same age. With breast cancer, however, long-term recurrence is such that this position may not be achieved until 20 years after treatment or even longer.

To relate cancer detection and induction to benefit and risk, it is necessary to consider outcomes both with and without screening. Thus the benefit of screening is not the proportion of those with screen detected cancers who survive a given period, but the difference between that proportion and the corresponding proportion who would have been predicted to survive if they had been in a comparable unscreened population.

Thus one possible measurement of Benefit/Risk may be taken to be:

$$\text{Benefit/Risk} = \frac{\text{Detections x } (A - B)}{\text{Inductions x } M}$$

Where: A = % survival of screen detected cases, B = % survival of symptomatically detected cases and M = % mortality of symptomatically detected cases. M is defined here in terms of symptomatic detection because it must be assumed at present that the majority of induced cancers will appear in women over the age of 64 who do not refer themselves for screening. If screening of older age groups in future years could be assumed, the mortality of screen-detected cancers would replace that for cancers detected symptomatically.

5.1. Nottingham prognostic indicator (NPI)

Of the various sources of data to be considered, that based on the NPI appears to be the most firmly based, and the easiest to interpret and apply. The NPI is calculated as (0.2 x size in cm) + Stage + Grade. The lower the NPI, the better the prognosis. It was first derived empirically from observation and case records, and subsequently verified in a study of 1662 further cases.

The introduction of breast screening leads to the detection of smaller cancers which have a lower NPI value and hence a better chance of long-term survival. Table IV summarises the 15-year survival for different groups of women. The proportion of women presenting in each group before screening is taken from a symptomatic clinic, where as the screening data is based upon a large-scale survey of screen-detected cancers in the Northern and Yorkshire Region of England. (The 15-year survival of an age-matched population of women without breast cancer was 83%.)

Table IV. Nottingham Prognostic Indicator Data

NPI	15-Year Survival (%)		Proportion of Women Presenting	
	Actual	Age Corrected	Before Screening	After Screening
<3.4	80	96	29	76
3.4-5.4	42	51	54	20
>5.4	13	16	17	4

5.2. Benefit/risk ratio

The benefit risk ratio may be calculated using the above equation. Table V is a summary of the ratio of lives saved to the possible fatal cancers induced.

Table V. Benefit/Risk Ratio (Lives Saved/Possible Fatal Cancers Induced)

Age Band	Single View	Two Views	Highest Dose
50-54	105	62	11
55-59	123	73	13
60-64	188	110	20

6. Discussion

Justification is a fundamental concept in radiation protection legislation and in radiology. A practice is justified when it is beneficial and the benefit can be shown to exceed the associated radiation risk. Justification for a medical radiation procedure can properly be considered in terms of the average dose to all patients, without the need to allow for higher doses that may be received by sub-groups. Nevertheless it would provide added reassurance if it could be shown that benefit exceeded risk for all sub-groups or even for all individuals in a screening programme

In attempting to convert from detection/induction to benefit/risk, data from a variety of sources may be used. Of these data sources, those based upon the NPI may be the best for this purpose. The NPI is derived from parameters that are relatively easy to determine, and its relationship to survival has been established. Survival at 15 years is a much better basis than the 5 years survival widely used for other cancers.

7. Conclusions

For the NHS BSP as it is at present, there appears to be an ample margin of benefit over risk. This statement applies on the basis of the average MGD per woman, i.e. on a population dose basis. Radiological Justification can properly be based on this. At a dose level exceeded by only 0.1% of women screened this remains true. Newer designs of X-ray equipment should lead to further improvements in this position.

Thus, despite all the uncertainties and shortcomings of present information, it does appear that in the NHS BSP radiation hazards if they exist are quite small compared to the benefits. In these terms, the NHS BSP achieves radiological justification. Nevertheless, it remains essential that radiographic image quality, with its implications for cancer detection rates, and radiation dose levels continue to be closely monitored in the NHS BSP and in other breast screening programmes.

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IAEA-CN-85-235

QUALITY ASSURANCE PROGRAMME IN MAMMOGRAPHY OF THE SOCIEDAD ESPAÑOLA DE DIAGNÓSTICOS POR IMAGEN DE LA MAMA (SEDIM)

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Abstract

The European Union Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure has been partially transposed to the Spanish national law by the Real Decreto 1976/1999, which establishes the quality criteria in Diagnostic Radiology. A key instrument in this legal regulation is the so-called Quality Assurance Program (QAP) which has to be implemented in each Diagnostic Radiology unit.

The Spanish Breast Imaging Diagnostic Society (Sociedad Española de Diagnóstico por Imagen de la Mama, SEDIM) has proposed a reference QAP to be used as a guide in all the mammography units in the country. Its main issues are displayed in the present paper. The SEDIM QAP includes some items related to justification and optimization of mammography exams as well as a proposal for the assignment of functions and responsibilities. A guide for the image and technical parameters quality evaluation is also included. Some keys on equipment acquisition, maintenance and on continuing education and information management can also be found in that document.

1. Introduction

El 29 de Diciembre de 1.999 se publicó en España el Real Decreto 1976/1999 [1], por el que se establecen los criterios de calidad en radiodiagnóstico. Dicho Real Decreto, que tiene carácter de norma básica sanitaria, persigue, entre otros fines, incorporar a la legislación española los preceptos de la Directiva 97/43/EURATOM [2] en lo que al diagnóstico médico con rayos X se refiere. Para ello, y como instrumento clave, exige la confección e implantación de un Programa de Garantía de Calidad (PCG) en todas las unidades asistenciales de radiodiagnóstico.

Por un lado, la norma legal citada presta atención particular y establece requisitos especiales para las instalaciones y los equipos de mamografía. Por otro, puntualiza que el PGC ha de elaborarse de acuerdo con protocolos nacionales o internacionales. Por estas razones, la Sociedad Española de Diagnóstico por Imagen de la Mama (SEDIM) decidió preparar un documento [3] que contuviera las bases para la elaboración, con arreglo a criterios unificados, de los programas de garantía de calidad en mamografía. El documento, del que se hace una breve presentación en este trabajo, pretende facilitar a profesionales y titulares de unidades de diagnóstico mamográfico la confección de sus propios programas.

El Programa de Garantía de Calidad de la SEDIM es el punto de partida de una serie de iniciativas y recomendaciones que esta Sociedad tiene intención de acometer para contribuir a optimizar adecuadamente la práctica del diagnóstico por imagen de la mama en España, de una forma similar a la que ya existe en otros países tanto de Europa como de América.

2. Contenido del programa de garantia de calidad

El Programa de Garantía de Calidad de la SEDIM contempla un conjunto de aspectos que pretenden cubrir todos los requisitos de la normativa española antes citada, a la vez que

resulten de aplicación práctica y directa en las instalaciones concretas. El índice del documento, es el siguiente:

- Datos identificativos de la unidad asistencial
- Justificación: Indicaciones, protocolos y requisitos técnicos de los estudios mamográficos
- Descripción y ubicación de los recursos técnicos y clínicos
- Descripción de los recursos humanos: Cualificación profesional. Distribución de responsabilidades y funciones
- Catálogo y protocolos de estudios mamográficos
- Evaluación de la calidad
- Adquisición de equipamiento
- Control del mantenimiento de los equipos
- Plan de formación continuada del personal.
- Metodología de los informes radiológicos y custodia de la Información
- Registro de incidentes y accidentes.

El documento se completa con dos anexos:

- Anexo I Protocolo de control de calidad de parámetros técnicos
- Anexo II. Protocolo de control de calidad para el screening.

2.1 Desarrollo de los criterios de protección radiológica. Justificación y optimización. Indicación de las exploraciones

El Programa de Garantía de Calidad de la SEDIM desarrolla los criterios básicos de justificación y optimización. La justificación de un estudio radiológico está esencialmente asociada a la existencia de una indicación clínica correctamente establecida. Por ello, el PGC da una relación de los casos en que, en el estado actual de los conocimientos, está indicada, y por tanto justificada, la exploración mamográfica. Se transcriben a continuación:

- Mamografía en mujer asintomática (chequeo/"screening"):

  - Mujeres a partir de los 40 años (inclusive) hasta los 75 años, con periodicidad anual.
  - Mujeres con antecedentes familiares directos de carcinoma de mama: madre, hermana o hija, a partir de los 35 años (inclusive), con periodicidad anual.
  - Mujeres con factores considerados de riesgo para cáncer de mama.
  - Mujeres sometidas a tratamiento hormonal sustitutorio, de cualquier edad.
  - Mujeres candidatas a transplante de algún órgano.
  - Mujeres que van a someterse a mamoplastia de reducción o aumento.

- Mamografía en mujer sintomática ("diagnóstica"):

  - Pacientes a partir de los 30 años (inclusive) con sintomatología mamaria no aclarada con la valoración clínica.
  - Pacientes menores de 30 años, con sintomatología mamaria no aclarada con la valoración clínica y ecográfica (mamografía del lado afecto).

- Pacientes de cualquier edad, a las que se ha diagnosticado un cáncer mamario por otros métodos diagnósticos, y no dispongan de Mamografía, como estudio basal de referencia.
- Pacientes de cualquier edad, con enfermedad metastásica demostrada, sin tumor primario conocido.
- Pacientes con antecedentes personales de cáncer mamario, con periodicidad anual.

- Mamografía en varones sintomáticos

- Controles mamográficos "cortos"

  - Cuadros probablemente inflamatorios/infecciosos, o postraumáticos, con traducción exclusivamente mamográfica, para evaluar curso, tras oportuno tratamiento.
  - Imágenes múltiples, probablemente benignas (BIRADS-3), con traducción exclusivamente mamográfica.
  - Imagen probablemente benigna (BIRADS-3), cuyas características (tipo, ubicación y tamaño) y/o no disponibilidad de medios impiden aplicar estudios complementarios.

- Magnificación / Compresión localizada.

  - Imágenes mamográficas de existencia dudosa, para confirmar o descartar su presencia.
  - Imágenes mamográficas de presencia real, para una mejor evaluación de su semiología.

- Otras proyecciones mamográficas complementarias.

  - Visualización y localización de lesiones no aclaradas en proyecciones estándar

- Neumoquistografía:

  - Por motivos diagnósticos, ante formaciones quísticas con criterios ecográficos de dudosa “habitación” o sin claros criterios semiológicos de quiste simple.
  - Por motivos terapéuticos, ante formaciones quísticas simples que causen síntomas o angustia a la paciente.

- Galactografía:

  - Secreción mamaria uniorificial espontánea.

- Punción percutánea bajo control estereotáxico:

  - Lesiones no palpables, o palpables sin adecuada precisión, sólo visibles en mamografía. Se preferirá la monitorización ecográfica cuando sea posible.

- Marcaje prequirúrgico de lesión no palpable mediante métodos mamográficos:

    - Lesiones no palpables, o palpables sin adecuada precisión, sólo visibles en mamografía.

En cuanto al criterio de optimización, se entiende centrado en el objetivo de una calidad de imagen idónea obtenida con la menor dosis compatible. La consecución de ese objetivo está relacionada con las características del equipo disponible y con el uso que de él se hace. Se establecen en el PGC pautas para las características técnicas exigibles en el equipamiento (mamógrafos y sistema de imagen), y también, en otro capítulo, se indican los controles de calidad periódicos a los que debe someterse. Pero igualmente se presta atención a los requisitos a considerar en la realización de mamografías. Se incluyen recomendaciones concretas en lo relativo a posición, compresión, contraste, exposición, ruido, definición de imagen, artefactos, colimación y marcado de películas, que se relacionan en cada caso con sus efectos sobre las características de la imagen. Se discuten en el mismo apartado los requisitos, las posibilidades y las limitaciones de las más importantes proyecciones mamográficas.

2.2. Descripción de los recursos técnicos y humanos

El PGC de la Sociedad Española de Diagnóstico por Imagen de la Mama propone unos formularios para el registro de las características técnicas del equipamiento, básicos para un adecuado control de calidad posterior.

Además presenta un modelo de distribución de responsabilidades y funciones entre los diferentes profesionales que trabajan en una unidad asistencial. En esa asignación de funciones y responsabilidades se atiende de manera muy particular a aquellos aspectos que tienen que ver con el control y con la garantía de calidad.

2.3. Evaluación de la calidad

La evaluación de la calidad se articula en dos apartados:

- Determinación del estado de referencia inicial
- Verificación periódica y evaluación continua de sistemas y componentes

El PGC da una relación de los parámetros que deben incluirse en los controles de calidad, tanto para los sistemas de registro y visualización de imágenes como para el mamógrafo. La periodicidad recomendada para estos controles varía en función del tipo de control y también en función de que la unidad se destine a mamografía diagnóstica o de cribado (screening). En cualquier caso, se entiende obligado un control de todos los parámetros y dispositivos en el momento de la instalación del equipo, con carácter previo a su puesta en funcionamiento, que sirva de referencia para sucesivos controles.

En sendos anexos, se recogen formularios y tablas para la toma de datos en las operaciones de control de calidad típicas. Cubren diversos aspectos, desde la identificación y descripción de los componentes y de la propia sala de exploración, hasta la verificación de los parámetros técnicos fundamentales: indicadores de funcionamiento, características del haz de radiación, características del compresor, respuesta del sistema de exposimetría automática, estado de chasis y pantallas, calidad objetiva sobre maniquí de la imagen, etc.

En cuanto a la evaluación de dosis, se recomienda realizar estimaciones tanto de la dosis de entrada como de la dosis glandular promedio. En cuanto a la calidad de imagen, se recomienda valorarla sobre imágenes reales tanto como sobre objetos de test.

3. Adquisición de equipo. Mantenimiento

Dentro del programa de calidad se reconoce que toda instalación, modificación o ampliación que suponga la adquisición de equipo ha de efectuarse conforme a especificaciones en cuya elaboración intervendrán el radiólogo y el radiofísico responsables. Se indican los elementos mínimos de dichas especificaciones. Además, de acuerdo con lo establecido en la normativa española, se indica que la instalación de un nuevo equipo llevará aparejada una prueba de aceptación, previa al uso clínico, realizada por el suministrador en presencia de un representante del titular. Se recomienda que este representante sea, siempre que resulte posible, un especialista en radiofísica hospitalaria.

4. Otros aspectos

El PGC propuesto se completa con otros aspectos como los relativos a la formación continuada del personal, para la que se sugieren pautas iniciales así como periodicidades y contenidos concretos. Un sistema de acreditación a desarrollar por la propia SEDIM completa el cuadro de recomendaciones.

En el texto se ofrece también una relación de criterios para la elaboración y custodia de los informes radiológicos, así como para la identificación y registro de posibles accidentes o incidentes.

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IMAGE QUALITY AND PATIENT DOSE OPTIMIZATION IN MAMMOGRAPHY IN HUNGARY

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Abstract

In 1999 the International Atomic Energy Agency initiated a coordinated research program (CRP) of the aims to define a methodology for the implementation of the European QA/QC protocol for mammography in the Eastern European countries. In Hungary three mammography centers with dedicated mammography devices and film-screen systems have been selected for participation in the program. The outcome of mammography can be predicted by image quality evaluation on clinical and test phantom images and the patient doses. The improvement of these performance indicators after QA/QC program implementation should be an outcome of the project. The authors summarize the program of work, the activities and their preliminary results.

1. Introduction

It is scientifically justified that acceptable performance of mammography can only be achievable through rigorous and consistent Quality Assurance and Quality Control activity. QC helps us to ascertain a constant high quality level of mammography equipment's and auxiliary devices' performance. In 1999 the International Atomic Energy Agency initiated a coordinated research program (CRP) of the aims to define a methodology for the implementation of the European QA/QC protocol for mammography in the Eastern European countries.

Experience shows that the outcome of mammography can be predicted by image quality evaluation on clinical and test phantom images and the patient doses. The improvement of these performance indicators after QA/QC program implementation should be an outcome of the project.

2. Preconditions

A research group for participation in the CRP has been organized. The chief scientific investigator has been a health physicist and the co-investigator has been a radiologist, an expert of mammography. The coordinator of the National Patient Dose Evaluation Program (NPDEP) and 3 competent radiologists of participating mammography centers have also become the members of the research group.

Three mammography centers with dedicated mammography devices and film-screen systems have been selected for participation in the program. The mammography centers of National Institute for Oncology, Budapest (OOI) and the "Haynal Imre" Medical University, Budapest (HIE) are only involved in diagnostic mammography, but the mammography center of the County Hospital of Vas, Szombathely (VAS) is also involved in mammography screening.

The most important dosimetry and QC devices were available, but the PMMA plates, the image phantom for constancy tests and the film-screen contact test tool were required from the Agency.

3. Program of work

A Research Coordination Meeting was organized in Prague, 3-6 November, 1999, when details of work plan and timetable were discussed and accepted:

- Evaluation of the image quality of a set of 120 clinical images using the European image quality criteria [1],
- Evaluation of the image quality using mammography test phantom images,
- Film reject analysis using a sample of a minimum 1000 images per mammography centers,
- Intercomparison of TLD systems,
- Assessment of first set of patient entrance doses and glandular doses with their respective radiographic techniques, breast thickness and comparison with reference/guidance levels,
- Implementation of QC program to the mammography units, processors and viewing boxes,
- Corrective actions if necessary,
- Repetition of the above activities (evaluation of image quality and patient doses, QC program).

4. Activities and results

Total of 120 clinical images (10 patients per center, 4 images per patient) have been evaluated by the field radiologists according to the EC criteria using the forms supplied. The clinical images and the evaluations were sent to Spain and France for independent assessment. All the films were accepted by the field radiologists for diagnostic purposes. However only 63% of images were considered by the French specialist who evaluated the films as accepted.

The image qualities in the mammography centers were evaluated using the RMI 156 mammography accreditation phantom according to the phantom instructions. The phantom images and the evaluations were also sent to Spain for independent assessment. The results of the parallel assessments are correlate and each of our mammography systems could fulfill the accreditation level of the American Mammography Accreditation Program.

For film reject analysis for at minimum 1000 films the rejected films were collected. The rejecter (radiologist or radiographer) and cause of rejection were registered. The results have been analyzed and the rejected films were sent to the Agency. Reject rates by causes of rejection can be seen in Table 1.

Table 1. Reject Rates by Causes of Rejection

Causes	Reject Rate (%)		
	VAS	OOI	HIE
Too light	34,5	13,9	21,0
Too dark	20,4	2,3	11,9
Positioning	32,1	61,9	14,0
Motion	3,8	2,4	1,4
Technical	9,8	12,5	37,6

In cooperation with the Dosimetry and Medical Radiation Physics Section of NAHU, IAEA we participated in an intercomparison of the TL systems. The "European Protocol for Dosimetry in Mammography" requires that the accuracy and precision of the dosimetric results are both to be better than ± 10 % [2]. Our results were outside of these limits (up to 17%) for all 3 beam qualities.

Patient dose measurements were made with TLDs on 10 patients per mammography center for CC projections. The results of dose measurements were sent to the Agency. The mean ESD were 2.73, 14.3 and 15.8 mGy, respectively.

Overall QC measurement were performed based on the European Protocol for the Quality Control of the Physical and Technical Aspects of Mammography Screening [3]. Summary of the QC activity is presented in Table 2.

Table 2. Summary of the QC Measurements of the Physical and Technical Aspects of Mammography

Mammography center	VAS	OOI	HIE
X-RAY SOURCE			
Focal spot size: star pattern method	X	A	X
Source-to-image distance	A	A	A
Alignment of field/image rec. (chest wall side)	A	X	N
Alignment of field/image rec. (short edges)	A	X	A
Radiation leakage	X	X	X
Specific tube output at 1 m	D	D	D
Tube output rate at FFD	D	D	D
TUBE VOLTAGE			
Reproducibility	A	A	A
Accuracy	N	N	N
Half Value Layer	A	A	A
AEC-SYSTEM			
Optical density control setting: central value	A	N	A
Optical density control setting: range	A	A	A
Opt. dens. control setting: difference per step	A	A	N
Guard timer	X	X	X
Short term reproducibility	A	A	D
Long term reproducibility	N	N	N
Object thickness compensation	N	N	N
Tube voltage compensation	D	A	N
COMPRESSION			
Compression force	A	A	A
Compression plate alignment	X	N	A
BUCKY			
Grid system factor	A	A	A
Grid imaging	A	A	A
SCREEN-FILM			
Inter cassette sensitivity: mAs variation	A	N	N
Inter cassette sensitivity OD variation	D	A	N
Screen-film contact	N	A	A

FILM PROCESSING			
Temperature	N/A	N/A	N/A
Processing time	N/A	N/A	N/A

FILM AND PROCESSOR			
Sensitometry	N	N	N
Artefacts	A	A	N
DARKROOM			
Light leakage	N	A	A
Safelights	N	N	N
Film hopper	X	X	X
Cassettes	A	A	A
VIEWING BOX			
Luminance	A	A	A
Homogeneity	A	A	A
AMBIENT LIGHT LEVEL	**A**	**N**	**A**
SYSTEM PROPERTIES			
Entrance surface air kerma	A	A	
Image Quality	A	N	N

X: The parameter is not measured
A: The measured value is better than the acceptable level
D: The measured value is better than the desirable value
N: The measured value is not acceptable
N/A: The parameter is measured but there is no limiting value

5. Conclusions

The Directive 97/43 EURATOM of European Council regulates the health protection of individuals against the dangers of ionizing radiation in relation to medical examination or treatment. According to the Directive all doses due to medical exposure for radiological purposes shall be kept as low as reasonably achievable consistent with obtaining the required diagnostic information. This optimization process shall include the consistent production of adequate diagnostic information as well as the QA/QC activity.

In Hungary about 70 mammography equipment are in operation and 12 mammography centers are involved in mammography screening. A significant factor is that there are no any compulsory regulations for the quality assurance activity currently in place in Hungary to ensure optimal exposures and film processing. However, meeting the requirements of harmonization of legislation derived from our partnership with the EU, we also have to complete the regulations of the medical exposures. The present coordinated research program is an outstandingly valuable help of the International Atomic Energy Agency in this process.

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IAEA-CN-85-305

A REVIEW OF THE ROLE OF RADIATION METROLOGY IN THE SAFETY OF DIAGNOSTIC RADIOLOGY PATIENTS

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Abstract

A discussion is conducted on the parameters associated with the radiation metrology in the mammography range and the uncertainties involved in all steps of the calibration chain as contained in the ISO recommendations. It is recognized by the international guidelines that there is a need to offer calibration for the mammography beam qualities by the radiation metrology network in order to improve the quality of the clinical diagnostic procedures and enhance the safety aspects of the medical practice. Major efforts have been made by several laboratories to establish appropriate and traceable calibration infra-structure to provide the basis for a quality control program in mammography in order to reduce the unnecessary patient exposure.

1. Introduction

During the past few decades significant technological advances has been observed concerning the equipment specifications used for mammography. Nowadays, there is wide variety of choices of anode, filter materials and potential voltage applied as produced by the most modern high frequency generators. As result of the technical developments on the equipment as well as on the film-screen characteristics, the breast doses are now much lower than the ones delivered by the first mammography units.

The range of tube voltages used in clinical mammography x-ray varies from 22 to 50 kV depending on anode-filter materials. According to the National Council on Radiation Protection and Measurement – NCRP [1] the combination of a Mo anode and filter is stated as the best technical option for clinical purpose. These combination of filtration and anode has been the one selected for the European intercomparison of diagnostic dosimeters [2]. Peixoto and de Almeida describes in details the implementation using different anode such tungsten - W, Molybdenum - Mo, and rhodium – Rh and its filtration combination with Mo and Rh [3].

2. The main physical factors and its associated uncertainties in performing mammography calibrations

The Secondary Standard Dosimetry Laboratories– SSDL main responsibility is to establish the metrological link between the Primary Standard Dosimetry Laboratory – PSDL and the hospital users as well as to provide calibration data and technical advice to guaranty the basis for a quality control program for clinical mammography units.

The evaluation of the experimental uncertainties is indeed an important step to define the limitations and applicability of a particular method and its assessment should follow the recommendations given by ISO [4], where the uncertainties are expressed as relative standard uncertainties whose evaluation are classified as type A and type B. The method of evaluation of type A standard uncertainty is by statistical analysis of a series of observations, whereas the method for evaluation of type B standard uncertainty is based on means other than statistical analysis. The classification rests exclusively on the procedure used to evaluate the uncertainty, and does not relate to the origin of the uncertainty. Type A and type B uncertainties may be combined in quadrature to yield the *combined standard uncertainty*, u_c, and an *expanded*

uncertainty (previously called overall uncertainty) can be built by multiplying u_c by a factor, which must always be stated. This factor is chosen on the basis of the desired level of confidence to be associate with the uncertainty.

The associated type B uncertainty used in this work and given below, consider *a* as the half-width of the extreme values interval:

$$u_B = a/\sqrt{3} \text{ , Assuming a uniform rectangular distribution} \quad (1)$$

$$u_B = a/\sqrt{6} \text{ , Assuming a uniform triangular distribution} \quad (2)$$

2.1. Main Factors Influencing the Ionometric Standards

2.1.1. Current measurements

The estimated standard uncertainty associated with the ionization current measurements or scale reading may be divided in two situations. Firstly, when the calibration of an ionization chamber is performed with the associated electrometer, the type A uncertainty on the scale reading is estimated from the measurements with the system (chamber plus electrometer), whose values are typically about 0.3 %.The type B uncertainty is included in the calibration factor provided by the standard laboratory [5]. Secondly, when the calibration of an ionization chamber is done alone in other words, separately from the electrometer (in terms of mGy/nC). In this case, the current I is integrated by an external capacitor until a specified voltage V is reached, for a specified time interval t being determined according to the basic relation $I=C\ V/t$. The typical values for the standard uncertainties for voltage are 0.01 % and 0.02 %, and for capacitance 0.04 % type A and type B respectively, and for the time base is of the order of 0.01 % for type B.

2.1.2. Recombination Loss

The absorbed dose deposited in the chamber gas volume as result of the ionization produced is proportional to the charge Q produced. The collected charge Q' trough may be less than Q, because of ion recombination in the gas. An ion chamber is said to be completely saturated when the ionic recombination is minimum [6].

Assuming a uniform rectangular distribution for the extreme values in the applied potential range between –100 and –300 V, the typical values for the uncertainty due to the ion recombination loss is 0.08 %.

2.1.3. Current Leakage

The leakage current measurement in the absence of radiation is obtained during a set of measurement, for a secondary standard class instrument. The estimated uncertainty for current leakage has to be negligible otherwise it will require a correction [6].

2.1.4. Energy dependence

Assuming a uniform triangular distribution for the extreme values of the PTB calibrations factors for non-attenuated and attenuated qualities, combined standard uncertainty in the energy dependence is 0.03 %.

2.1.5. Long term stability of the secondary standard

The reproducibility of a set of measurements is defined as the agreement between the results of measurements of the one parameter carried out under somewhat different conditions [4].

The coefficient of exposure reproducibility represents the degree of stability of the response of the system. Assuming a uniform rectangular distribution the u_c is 0.23%.

2.1.6. Focus-to-chamber distance

The variations of focus-to-chamber distances are not expected to deviate from the well known inverse of the square of the distance relation. The uncertainty estimation assumes a uniform rectangular distribution is of the order of 0.03% for the extreme values obtained in all beam quality measurements [6].

2.2. Factors Influencing only the Calibration of the user's Chamber

2.2.1. Current measurements or scale reading. See section 2.1.1.

2.2.2. Recombination loss. See section 2.1.2.

2.2.3. Leakage. See section 2.1.3.

2.3. Factors influencing both types of instruments

2.3.1. Chamber Positioning

The estimated chamber positioning uncertainty must be considered when the substitution method is used free in air at 100 cm of distance from the x-ray target. Assuming a uniform rectangular distribution the u_b is 0.02 %.

2.3.2. Effect of the exposure repeatability

The repeatability of the measurements values is defined as the agreement between the results successive readings of the same parameter carried out under the same conditions of measurement[4]. Assuming a uniform rectangular distribution the u_b is 0.09%.

2.3.3. Air density ($k_{t,p}$)

The pressure and temperature measured values during the experimental procedure are normalized for the reference value of 20°C and 101,325 kPa. Assuming a uniform rectangular distribution the u_b is 0.06 % [6].

2.3.4. Field homogeneity

The uncertainty estimation assuming a uniform rectangular distribution is typically 0.01 % for the extreme values obtained in the 6 cm field homogeneity. This interval is sufficient to satisfy all the mammography chambers in all beam quality measurements obtained from constant potential with different anode filter combinations.

2.3.5. Radiation background

The estimated standard uncertainty for radiation background is negligible.

2.3.6. Humidity

The relative humidity shall be kept between 30 and 70% during the measurements and in this case the associated uncertainty is negligible.

2.3.7. Difference in x-ray spectra

The uncertainty due to effect of different x-ray spectra is estimated assuming a uniform rectangular distribution smaller than 0.46 %.

2.3.8. Air Kerma rate

The typical results obtained for all qualities shows a linear relationship for tube loading for the interval from 10 and 200 mAs. Assuming a uniform rectangular distribution u_b is 0.13 %.

3. Conclusions

The SSDL's main responsibility is to provide instrument calibration with appropriate radiation beam qualities and its energy dependence as well as, to give technical advice to the users on how to develop quality control for diagnostic radiology procedures traceable to the metrological network.

It is very important to state that one should not need to carry out uncertainty calculations for each instrument to be calibrated although, representative calculations must be performed for typical calibration procedures. In order to clarify the recommended method of uncertainty estimation, and to show the typical values for each parameter, Table 1 presents the overall values for the calibration of a typical mammography ionization chamber.

Table 1. Typical estimated uncertainty analysis for calibration of mammography chambers.

Source of uncertainty	Type A (%)	Type B (%)
a. Factors influencing only the secondary standard:		
a.1. Current measurements		
a.1.1. Voltage	0.01	0.02
a.1.2. Capacitance	0.04	0.04
a.1.3. Time base		0.01
a.2.Recombination loss	0.0	0.08
a.3.Leakage		
a.4. Energy dependence		0.03
a.5. Long term stability of the secondary standard		0.23
a.6. Focus-to-chamber distance		0.03
b. Factors influencing only the instrument to be calibrated:		
b.1. Current measurements or scale reading		
b.1.1. Voltage	0.01	0.02
b.1.2. Capacitance	0.04	0.04
b.1.3. Time base		0.01
b.2. Recombination loss		0.08
b.3. Leakage	0.0	
c. Factors influencing both instruments:		
c.1. Chamber Positioning		0.02
c.2. Exposure reproducibility		0.09
c.3. Air density ($k_{T,P}$)	0.04	0.06
c.4. Field homogeneity		0.01
c.5.Radiation background	0.0	
c.6. Humidity		0.0
c.7. Difference in x-ray spectra		0.46
c.8. Air Kerma rate		0.13
Combined standard uncertainty (quadratic sum)	0.56 %	
Combined standard uncertainty, PSDL (expanded ÷ by k)	0.7 %	
Combined standard uncertainty, PSDL + SSDL	**1.8 % (k = 2)**[a]	

[a] if the SSDL uses the same x-ray spectra, air kerma rate and focus-to-chamber distance as the PSDL the combined uncertainty is 1,5 % (k=2).

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IMAGE QUALITY AND DOSE IN MAMMOGRAPHIC IMAGES OBTAINED IN MEXICO CITY HOSPITALS

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Abstract

The performance of three mammographic systems in large mexican hospitals has been evaluated, as well as the image quality and associated dose. Quality control tests include examination of X-ray equipment, darkroom conditions, film processor, and viewboxes. Systems referred to as "1", "2", and "3" passed 50%, 75% and 75% of these tests, respectively. Quality image is assessed using five images obtained under similar nominal conditions in each X-ray equipment. System 1 generates no image of acceptable quality, while equipments 2 and 3 produce one and two, respectively. The mean glandular dose for the best images obtained in each service with an accreditation phantom has been measured, and the values are 1.4 mGy, 1.6 mGy, and 1.0 mGy, respectively.

1. Introducción

En 1997 la Secretaría de Salud (SSA) emite cuatro Normas Oficiales Mexicanas (NOM), donde se regula en materia de protección radiológica el uso adecuado de los equipos de rayos X con fines de diagnóstico médico. Al poner en práctica lo exigido por las NOM para los sistemas de mamografía, se detectan una serie de carencias, entre otras, la falta de aplicación de programas de garantía de calidad en esta área, lo que ocasiona: a) falta de equipo apropiado para realizar pruebas de control de calidad en los equipos de rayos X, b) falta de conocimientos para realizar una correcta evaluación de la calidad de la imagen, y c) necesidad de capacitar recursos humanos en esta área a todos niveles (técnicos y médicos radiólogos, físicos médicos e ingenieros de servicio).

A inicios del año 2000, contando con el apoyo de la Secretaría de Salud, el Instituto de Física de la Universidad Nacional Autónoma de México (IFUNAM) y la Organización Panamericana de la Salud (OPS), inician el proyecto de investigación: "Calidad de Imagen y Dosis en Estudios Mamográficos Realizados en México" [1]. En este trabajo se presentan los resultados, a la fecha, de este proyecto de investigación.

2. Objetivos

- Verificar las condiciones de operación de tres sistemas de mamografía, situados en dos hospitales públicos de alto impacto, en México, D.F.
- Relacionar estas condiciones de operación con la dosis glandular promedio impartida a las pacientes y con la calidad de la imagen de un maniquí de acreditación reconocido por el Colegio Estadounidense de Radiología (ACR).

3. Equipo

Para realizar este trabajo se utilizó el equipo recomendado por el ACR [2] y por la Comunidad Europea (EC) [3].

4. Procedimiento

Todas las pruebas se realizaron de acuerdo a lo estipulado por el ACR[2]. Las pruebas no contempladas dentro de estos procedimientos, se realizaron de acuerdo a la EC [3].

Las 31 pruebas realizadas, agrupadas en 7 rubros generales, son: *Equipo de mamografía*: Estabilidad mecánica, distancia foco - imagen, tamaño de punto focal, tensión en el tubo, tiempo de exposición, capa hemirreductora, rendimiento, coincidencia del campo luminoso con el receptor de imagen, alineación del campo de radiación con el receptor de imagen, alineación de la placa de compresión con el receptor de imagen, reproducibilidad del control automático de exposición (CAE), capacidad de desempeño del CAE, control de densidad del CAE, fuerza de compresión, deformación de la placa de compresión, factor de rejilla. *Receptor de imagen:* Contacto pantalla–película, uniformidad de la velocidad de las pantallas. *Equipo de revelado:* Temperatura del revelador, tiempo de revelado, sensitometría, artefactos. *Cuarto oscuro:* Fugas de luz, luces de seguridad. *Negatoscopios:* Brillantez, homogeneidad. *Dosis:* Exposición de entrada, dosis glandular promedio. *Calidad de imagen:* Densidad óptica al centro del maniquí, resolución, contraste.

En particular, la prueba de calidad de imagen se realizó haciendo 5 exposiciones en modo semiautomático sobre el maniquí de acreditación, para un valor de la tensión nominal en todos los casos igual a 28 kV, y para valores del control de densidad iguales a -4, -2, 0, +2 y +4.

El interés por la dosis entregada a la paciente, llevó a que se le midiera durante exposiciones en modo manual, seleccionando el técnico radiólogo, de acuerdo a su criterio, los factores técnicos adecuados para obtener la mejor imagen del maniquí de acreditación.

5. Resultados

Entre las pruebas de control de calidad relativas al funcionamiento del equipo, la mayor deficiencia con respecto a lo establecido en las NOM, se refiere a la exactitud en la tensión de operación. La Figura 1 muestra los resultados de esta prueba realizada en los tres equipos. Las discrepancias entre los valores medidos del sistema 1, superan de manera consistente y reproducible lo permitido por las normas.

Los resultados del control de calidad realizado se resumen en la Tabla I.

La Figura 2 resume los resultados de la calidad de la imagen para los tres sistemas. El número indica cuantas imágenes, de las cinco estudiadas, cumplen con el criterio de aceptación del ACR. Se puede concluir que solamente los sistemas 2 y 3 producen imágenes (1y 2, respectivamente) con la calidad requerida de acuerdo al criterio del ACR.

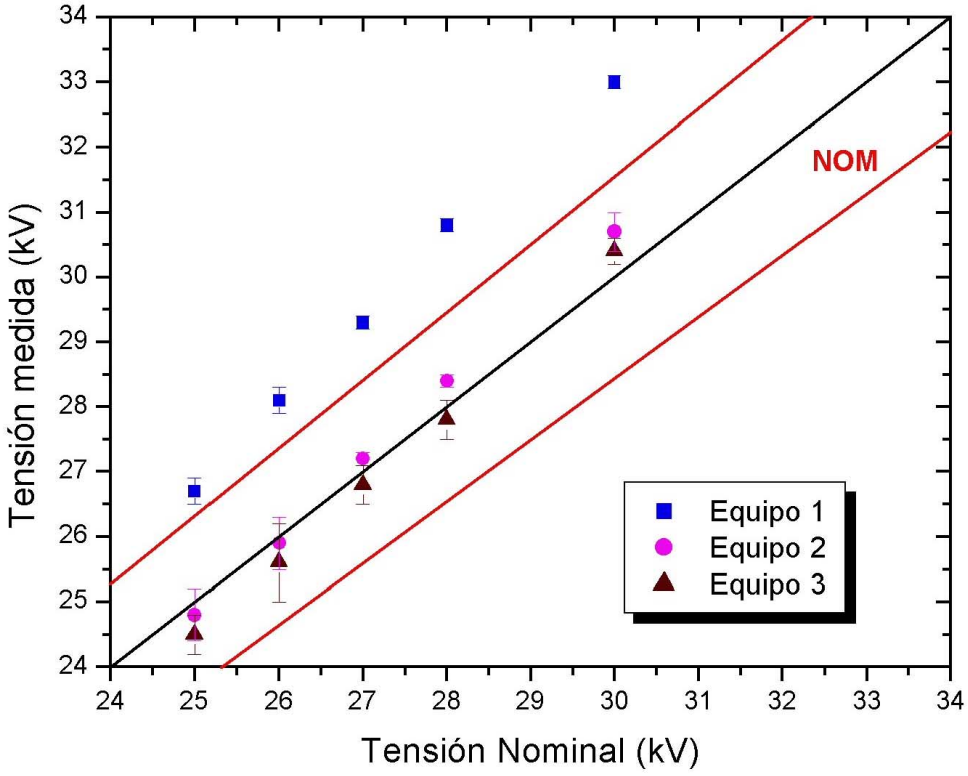

Figura 1: Tensión medida en los equipos de rayos X. La línea continua muestra la identidad, las líneas punteadas muestran las tolerancias aceptadas por la NOM.

Tabla I: Control de calidad

	Sistema 1	Sistema 2	Sistema 3
Funcionamiento general	Aprueba	Aprueba	Aprueba
Generación de rayos X	No	Aprueba	Aprueba
Colimación	No	No	No
Compresión	No	No	No
Control automático de exposición	Aprueba	Aprueba	Aprueba
Rejilla antidispersora	Aprueba	Aprueba	Aprueba
Receptor de imagen	No	Aprueba	Aprueba
Equipo de revelado	No	No	No
Cuarto oscuro	No	No	No
Negatoscopios	No	No	No

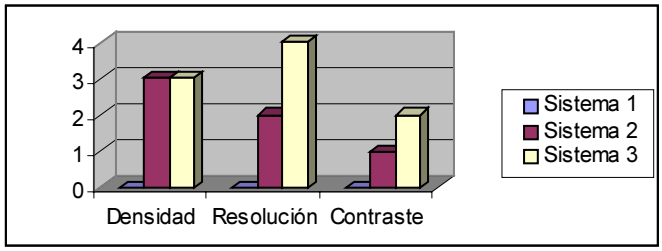

Figura 2: Calidad de la imagen

La Tabla II muestra los resultados de la dosis. Los valores listados son el promedio (y su desviación estándar) de tres exposiciones realizadas con los factores técnicos escogidos por el técnico radiólogo. Los tres sistemas imparten a la paciente dosis inferiores a los 3 mGy establecidos en la NOM. En particular, para el sistema 1, los factores técnicos usados para la medida de dosis no corresponden a ninguna de las cinco medidas de calidad de la imagen.

Tabla II: Dosis glandular promedio

Sistema 1	1.4 ± 0.1 mGy	Aprueba
Sistema 2	1.6 ± 0.1 mGy	Aprueba
Sistema 3	1.0 ± 0.1 mGy	Aprueba

6. Conclusiones

- Los sistemas estudiados no cumplen con las Normas Oficiales Mexicanas. Esto es comprensible ya que no existe todavía un programa de garantía de calidad asociado a ellos.
- En términos generales, el funcionamiento apropiado del sistema, de acuerdo a los criterios de la garantía de calidad se ve reflejado en la calidad de la imagen evaluada con el maniquí aceptado por el ACR.
- Las dosis bajas no garantizan que se estén obteniendo imágenes de calidad adecuada.
- A pesar de no cumplir con las especificaciones de calidad exigidas por la NOM, los sistemas estudiados producen imágenes aceptadas por la plantilla de profesionales asociados. Esto se debe a la pericia y experiencia de los técnicos radiólogos que operan los equipos. Sin embargo, debe recordarse de que esta experiencia fue adquirida a costa de exposiciones innecesarias a las pacientes.
- En hospitales de alto impacto, la gran cantidad de pruebas requeridas al establecer un programa de garantía de calidad, hace imprescindible que su realización sea vigilada por un físico médico de tiempo completo.
- Los resultados de este trabajo deberán ser de utilidad para hacer ajustes a las Normas Oficiales Mexicanas, en lo referente a mamografía, cuando la Secretaría de Salud considere conveniente su revisión.

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A COMPARISON OF TWO DIFFERENT PROCESSING CHEMICALS FOR MAMMOGRAPHY: REPERCUSSION ON DOSE TO PATIENTS

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Abstract

The main technical objective of screen-film mammography is to reach the best image quality with the lowest dose to the breast. Sensitometric gradient and speed are factors related with both subjects respectively. For a given choice of film, these factors are affected by processing variables. By this reason, manufacturers have developed diferent types of films that are recommended for particular processing conditions.
The purpose of this work is to compare the variations of both sensitometric characteristics of mammographic screen and film systems induced by two different manufactured chemicals: RPX-Omat EX/LO (Kodak) and G139/G334 (Agfa). A comparison of thirteen mammographic films by means of light sensitometry was performed at different processing conditions: 90s/Kodak, 120s/Kodak, 180s/Kodak, 90s/Agfa, 120s/Agfa and 180s/Agfa. Secondly, 99 combinations of screens and films were evaluated by X-ray sensitometry at 120s/Kodak and 120s/Agfa processing. At light sensitometry, variations in processing time led to different modifications in film speed, depending on the chemicals used. At X-Ray sensitometry, Agfa chemicals induced higher values of sensitivity for almost all combinations, while Kodak chemicals gave higher gradient/speed quotient. The results show that dose to patients in mammography and image contrast are highly dependent on the chemicals selected at medium cycle (120s) processing.

1. Introducción

La mamografía es un procedimiento radiológico cuyo uso ha tenido un importante incremento en los últimos 15 años, debido a su demostrada rentabilidad en la detección precoz del cáncer de mama, pues contribuye a reducir la mortalidad e incrementar el número de tratamientos conservadores. Diversos estudios han demostrado la utilidad de realizar mamografías a mujeres asintomáticas en las edades de mayor riesgo, en la cuarta, quinta y sexta décadas de la vida [1].

Técnicamente, la mamografía se realiza mediante películas radiográficas de una sola emulsión y una pantalla de refuerzo, con un sistema de procesado automático dedicado. Utilizar una emulsión simple en lugar de doble permite conseguir mayor resolución espacial a costa de disminuir la sensibilidad del sistema. Para la obtención de imágenes de calidad diagnóstica en una zona anatómica con bajo contraste de objeto como es la mama, es preciso que el receptor de imagen ofrezca suficiente contraste intrínseco.

Uno de los elementos clave en la calidad de imagen mamográfica y la dosis suministrada por exploración es el sistema pantalla-película empleado. En tal sentido, el contraste y la sensibilidad de dicho sistema, que pueden determinarse mediante técnicas de sensitometría, son parámetros técnicos que deben evaluarse como un estándar de calidad. Parámetros sensitométricos como el gradiente o la velocidad están relacionados con el contraste y la sensibilidad del sistema, es decir, con la calidad de imagen y la dosis empleada respectivamente.

El procesado afecta tanto al gradiente como a la velocidad. Los principales factores que afectan ambos parámetros son: el tiempo de inmersión en el baño de revelado, la temperatura de revelado y el grado de reciclado de los líquidos. Los fabricantes han desarrollado diferentes tipos de películas y pantallas de refuerzo, recomendándolas para ciclo estándar (90s), extendido (180s) o ambos. El objetivo de este trabajo es comparar las variaciones de gradiente y velocidad inducidas por dos tipos de productos químicos de procesado, mediante sensitometría de luz y de rayos X.

2. Material y método

En el presente trabajo se ha realizado un estudio comparativo incluyendo 13 películas y 9 pantallas de refuerzo para mamografía, comercializadas por seis fabricantes diferentes.

2.1. Sensitometría de luz

Se han utilizado trece películas comercializadas por 6 fabricantes: Trimax FM, Trimax HM y Trimax HM2 (Imation); MR3-II, MR5-II y MR6 (Agfa); UM-MA HC (Fuji); Min-R MA, Min-R E y Min-R 2000 (Kodak); CM-New y CM-H (Konika), y Microvision-C (Sterling).

Las películas se expusieron con un sensitómetro de luz verde (07-456 Victoreen), que proporciona una tira de 21 escalones de diferente exposición (E), que aumenta 0,15 LogE en cada escalón, desde 0,05 hasta 3,05. Una vez expuestas, las películas se procesaron en 6 condiciones de procesado diferentes (Tiempo de procesado/Líquidos/temperatura del revelador): 90s/Kodak/37.6°C, 120s/Kodak/34.3°C, 180s/Kodak/34.7°C, 90s/Agfa/34.0°C, 120s/Agfa/34.0°C y 180s/Agfa/34.7°C.

Los líquidos(revelador/fijador) Kodak fueron RP X-Omat EX/LO, y los Agfa fueron G139/G334. El tiempo de procesado se midió desde la entrada en el baño de revelado hasta la salida eal exterior (tiempo seco-seco).

La densidad óptica de la tira sensitométrica se leyó mediante un densitómetro digital (07-424 Victoreen). Se obtuvieron las curvas características de logE frente a densidad óptica (DO) y se calculó la velocidad como el inverso del LogE necesario para alcanzar una DO de 1+velo+base (1+VB), siendo VB la densidad óptica obtenida sin exposición. El gradiente medio se calculo como la pendiente entre DO iguales a 0,25+VB y 2+VB. El procedimiento concreto se repitió cuatro veces. Los resultados se presentan en términos de la media de las cuatro series.

2.2. Sensitometría de rayos X

Para este estudio, se realizó sensitometría de rayos X, mediante una cuña escalonada de aluminio, a 99 combinaciones pantalla/película (11 películas combinadas con 9 pantallas de refuerzo) en dos unidades mamográficas diferentes (UC Mammo Diagnostic y Senograph 800T), con procesados de 120s, y líquidos Kodak y Agfa respectivamente. La cuña de aluminio se calibró para cada unidad empleando dosímetros de termoluminescencia. La velocidad se calculó como el inverso de la exposición necesaria para obtener una DO de 1+VB y el gradiente medio como se ha descrito en la sensitometría de luz. El procedimiento se repitió con las 99 combinaciones tres veces, en días diferentes y los resultados se presentan en términos de media y desviación estándar.

3. Resultados y conclusiones

En la sensitometría de luz, el incremento del tiempo de procesado repercute en un aumento de la sensibilidad o el gradiente más marcado, según se empleen líquidos Agfa o Kodak, respectivamente (Figura 1).

Los resultados de la sensitometría de luz han sido presentados con detalle anteriormente [2]. Sería deseable haber utilizado una procesadora única, pero es una tarea cara y difícil de conseguir. Desafortunadamente la temperatura de revelado de la procesadora a 90s/Kodak excedió en 3 ºC a las restantes, lo cual debe tenerse en cuenta.

Todas las películas alcanzaron la mayor velocidad, en términos absolutos con procesado Kodak/118s. La desviación estándar de las cuatro series varió entre 0,00 y 0,03. Al evaluar los resultados entre 90s y 120s asi como 120s y 180s, puede verse que la relación entre velocidad y tiempo de procesado es muy diferente según el tipo de químicos empleado. Con líquidos Kodak, la velocidad aumentó siempre según se incrementó el tiempo de procesado, pero con líquidos Agfa no varió o incluso disminuyó en un 84% de los casos.

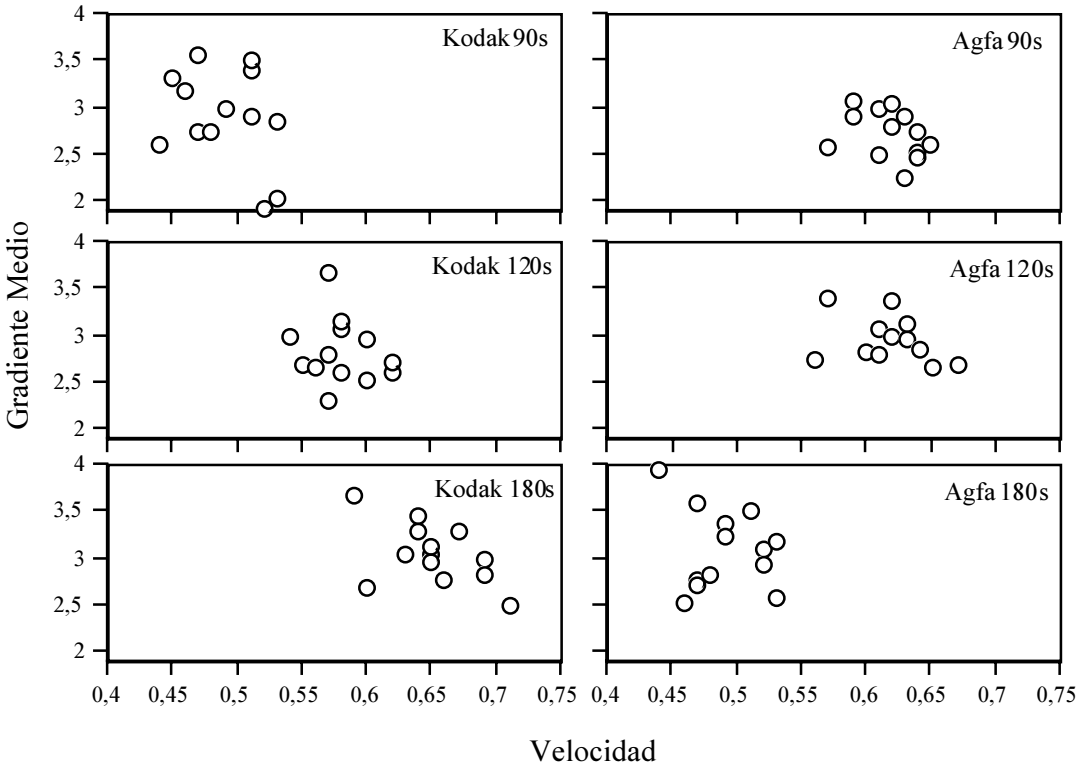

Figura 1. Sensitometría de luz. Se presenta el gradiente medio de las 13 películas estudiadas frente a la velocidad empleado diferentes tipos de procesado: químicos Kodak y Agfa a ciclos (seco-seco) de 90, 60 y 120 s

Los resultados de la sensitometría de rayos X (ciclo 120 s) mostraron una mayor velocidad del sistema pantalla película cuando se emplearon líquidos Agfa (Figura 2). Estos resultados coinciden con lo encontrado en la sensitometría de luz para un ciclo de 120 s (figura1). La utilización de químicos Kodak, en cambio, muestran un cociente gradiente velocidad mayor que con procesado Agfa (figura 3). Esta tendencia a favorecer velocidad o contraste según los químicos de procesado empleados no ha sido descrita anteriormente en nuestro conocimiento.

Utilizar películas mamográficas con un contraste intrínseco elevado es uno de los objetivos a conseguir en mamografía de pantalla-película [3], debido a que el contraste que se presenta al radiólogo es el resultado del contraste de objeto a los rayos X y el gradiente del receptor de imagen.

Nuestros resultados muestran que las variaciones de tiempo de procesado influyen de manera muy distinta en velocidad y gradiente, dependiendo de los químicos de revelado empleados. Esto ha sido corroborado al emplear combinaciones pantalla-película, exposición a rayos X en dos mamógrafos calibrados y procesado a 120 s. En estas condiciones la dosis a pacientes y el contraste de imagen son altamente dependientes de los químicos de revelado empleados para un gran rango de combinaciones pantalla-película. Sería interesante comprobar la sensibilidad y contraste a los rayos X con ciclo corto y extendido, así como con otros tiempos de revelado.

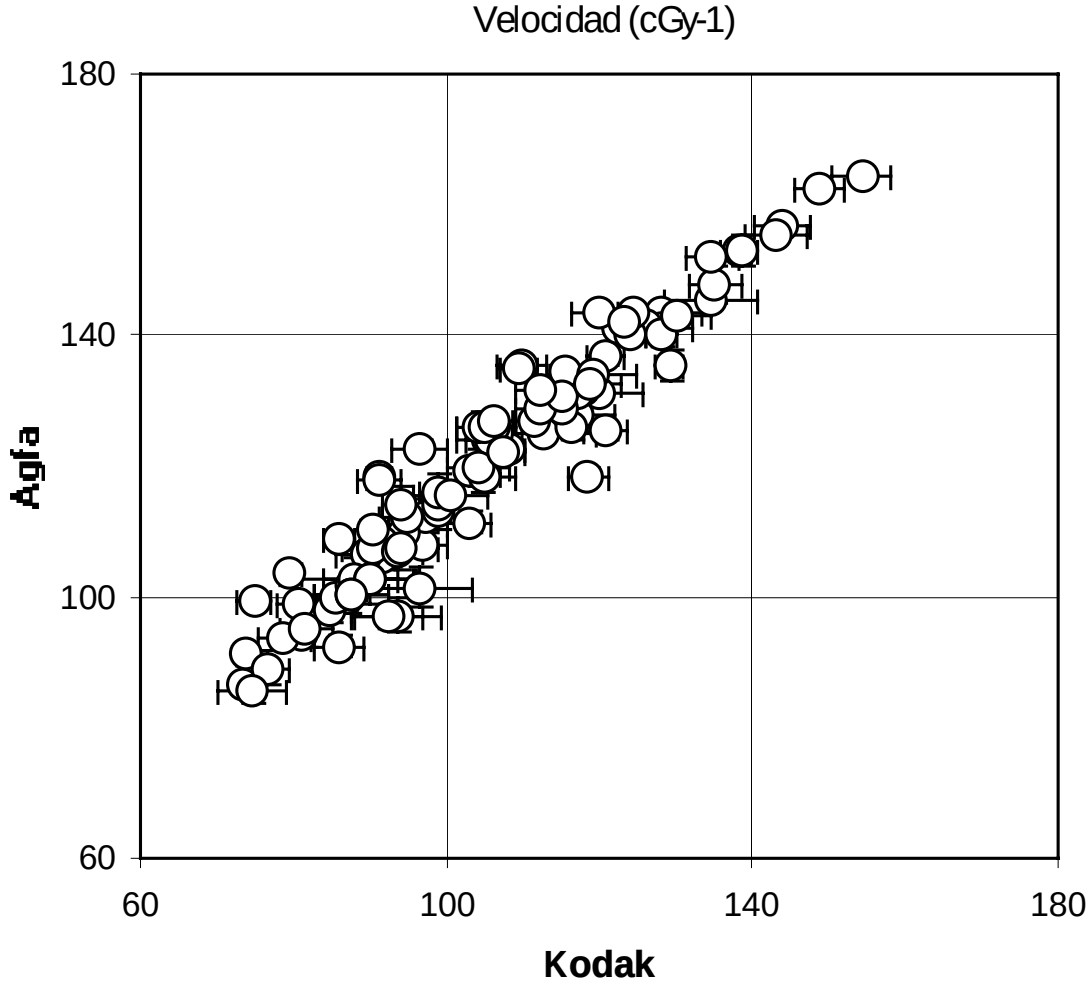

Figura 2. Sensitometría de rayos X. Velocidad obtenida por cada una de las 99 combinaciones pantalla película según los químicos empleados (120 s seco-seco). Se presenta la media de tres observaciones. Las barras de error corresponden a la desviación estándar.

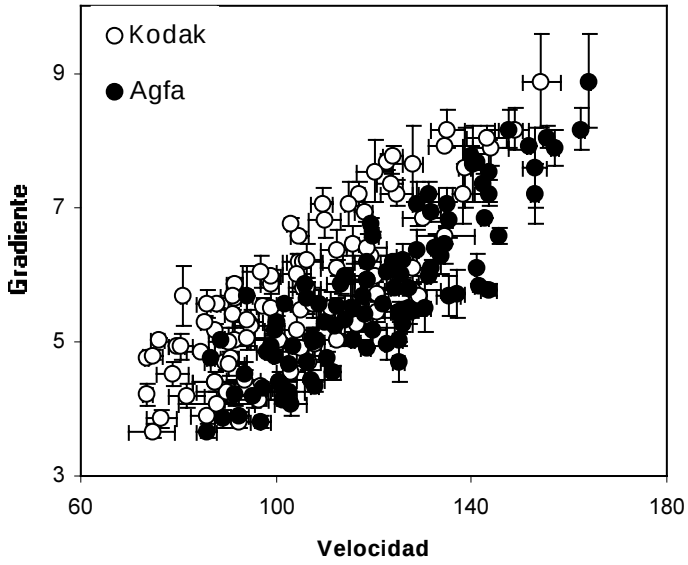

Figura 3. Sensitometría de rayos X. Representación gráfica de velocidad frente a gradiente para las 99 combinaciones pantalla película, con procesado AGFA (puntos negros) y Kodak (puntos blancos).

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IAEA-CN-85-234

STUDY OF RADIOLOGICAL RISK IN BREAST CANCER SCREENING PROGRAMME AT COMUNIDAD VALENCIANA

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Abstract

It is demostrated that screening mammography¨s programmes reduces breast cancer mortality considerably. Nevertheless, radiology techniques have an intrinsic risk being the most important late somatic effect the induction of cancer. This study is made in order to evaluate the risk produced into the population by the Comunidad Valenciana Breast Sceening Programme. All The calculations are carried out for two risk models, UNSCEAR 94 and NRPB 93. On the one hand, screening series detriment are investigated as a function of doses delivered and other parameters related to population structure and X-ray equipment. And on the other hand radiation induced cancer probability for a woman who starts at 45 years and remains into the programme until 65 years old is calculated as a function of mammography unit¨s doses and average compression breast thickness.

1. Introducción

El estudio cuyos resultados se exponen en este trabajo surgió como respuesta a las inquietudes de la sociedad que demandan una sanidad de mayor calidad con los mínimos riesgos posibles. En el caso de los programas de detección precoz del cáncer de mama basados en exploraciones de Rayos-X, pese al beneficio intrínseco que la experiencia ha demostrado, no deja de ser una práctica con una serie de riesgos asociados. Entre ellos se encuentra la posibilidad de inducir un cáncer al paciente debido a la radiación recibida durante la exploración, con una probabilidad muy baja pero no nula. El grupo de investigación formado por miembros del Departamento de Ingeniería Química y Nuclear de la U.P.V, la Unidad de Prevención del Cáncer de la Consellería de Sanidad de Valencia y el Servicio de Protección Radiológica del hospital La Fe decidió emprender un estudio que incluye la dosimetría y cuantificación del detriemento radiológico implícito en el **Programa de Detección Precoz del Cáncer de Mama de la Comunidad Valenciana**.

2. Metodología

2.1. La dosimetría

El detrimento radiológico, entendido como el número de cánceres inducidos por la radiación, depende de la dosis impartida en el órgano. Así, el primer paso fue el cálculo de este parámetro.

La dosimetría empleada se basó en técnicas de simulación por métodos de Monte Carlo empleando el código MCNP-4B (Monte Carlo Neutron Particle). Se trata de un software público de gran aceptación desarrollado en Los Alamos Laboratory.

Para abarcar la diversidad de casos posibles se utilizó un modelo de la mama análogo al empleado por *Dance* [1], un semicilindro de radio 8 cm y altura variable entre 3 y 9 cm con incrementos de 0,5 cm. Se supuso que dicho órgano está compuesto por un recubrimiento de tejido adiposo de 0,5 cm de espesor y una parte interior formada por una mezcla del 50% de tejido adiposo y 50% de tejido glandular, con las composiciones de *Hammerstein et al* [2]. Se pueden consultar más detalles en el artículo *"Mammographic Dosimetry Using MCNP-4B"* [3] publicado por este grupo.

En la modelización se empleó un espectro teórico del catálogo de *Birch and Marshall*[4] de características acordes con las de los equipos habituales en mamografía y que opera a 30 kV, tiene ánodo de molibdeno, filtro de 1 mm de berilio y HVL comprendidos entre 0,31 y 0,49 mm de aluminio.

Los resultados de las simulaciones suministraron valores de dosis en función del espesor de la mama y por mAs aplicado. Para completar el estudio era necesario conocer los mAs.

2.2. Toma de datos de las exploraciones

Aprovechando el control de calidad anual de los equipos realizado a finales de 1998, se tomó una muestra de exploraciones correspondientes a 100 mujeres por cada unidad (en ese momento existían 11) y se registraron los valores de espesor de compresión y a los mAs aplicados, así como las condiciones de irradiación. Con ellos se determinó una correlación estadística entre los mAs y el espesor de la mama propia de cada equipo cuyos resultados completaron el cálculo de la dosis recibidas en cada caso.

2.3. Estructura de la población por edad

La dosis no es el único factor que afecta al riesgo intrínseco a la radiación. También influye la edad del paciente en el momento de la exposición. Para emprender el estudio del detrimento radiológico se hizo un análisis de las mujeres que se habían sometido al programa desde su inicio y se determinó su edad. Con ello se podía deducir el número de mujeres de cada edad que había sido irradiada por cada equipo.

2.4. El cálculo del detrimento radiológico

Este apartado se llevó a cabo con el software ASQRAD (Assesment System for the Quantification of Radiation Detriment) que es una herramienta aplicable en los cálculos del detrimento radiológico (forma cuantitativa de expresar la combinación de probabilidad de que ocurra un efecto contra la salud y la gravedad de tal efecto) desarrollada conjuntamente por el CEPN (Centre d'Etude sur l'Evaluation de la Protection dans le Domaine Nucléaire) en Francia y la NRPB (National Radiological Protection Board) en el Reino Unido.

Con él se determinaron los efectos somáticos, expresados como la probabilidad de aparición de un cáncer de mama inducido por la radiación. De los múltiples modelos de riesgo que contiene el programa se emplearon los dos más recientes, el UNSCEAR 94 y el NRPB 93.

El ASQRAD permite introducir los datos demográficos de una población determinada. Como el estudio se basó en el Programa de la Comunidad Valenciana, se elaboró una tabla específica de esta población con datos suministrados por la *Unidad de Prevención del Cáncer* y el *Instituto Nacional de Estadística.*

Los datos de partida son la dosis recibida, el órgano irradiado, la edad y sexo del paciente. Se observó una variación lineal del detrimento con la dosis en el intervalo de valores propios de la mamografía, así que se calculó un detrimento por unidad de dosis para todas las edades incluidas en el intervalo de estudio. Seguidamente se multiplicaron por la dosis real y el número de mujeres irradiadas a esa dosis. El resultado fue el detrimento global de la población.

3. Resultados

El estudio tuvo en cuenta la metodología del programa valenciano en el que las series de cribado son bienales, con doble proyección en la primera serie y proyecciones simples en series sucesivas. Desde su inicio hasta el momento del estudio se habían completado tan solo 3 series. El número de cánceres totales inducidos por la radiación en cada una de las series, por cada unidad mamográfica y cada uno de los modelos de riesgo empleados se refleja en las siguientes las tablas 1,2 y 3.Los resultados globales se muestran en la tabla 4.

Datos por unidades

Tabla 1. Cánceres totales inducidos en la primera serie

Unidad	Población	Cánceres Mortales		Cánceres Mortales por 100000		Exceso de Cánceres		Exceso of Cánceres por 100000	
		Unscear 94	NRPB 93	Unscear 94	NRPB 93	Unscear 94	NRPB 93	Unscear 94	NRPB 93
Unidad1	16525	0,47	0,91	2,8	5,5	0,94	1,817	5,7	11
Unidad2	12438	0,19	0,36	1,5	2,9	0,38	0,72	3,1	5,8
Unidad3	13780	0,15	0,29	1,1	2,1	0,29	0,58	2,1	4,2
Unidad4	15764	0,32	0,63	2	4	0,65	1,25	4,1	7,9
Unidad5	14713	0,28	0,56	1,9	3,8	0,56	1,12	3,8	7,6
Unidad6	17509	0,23	0,44	1,3	2,5	0,46	0,88	2,6	5
Unidad7	18755	0,27	0,52	1,4	2,8	0,65	1,05	3,5	5,6
Unidad8	13245	0,16	0,33	1,2	2,5	0,28	0,66	2,1	5
Unidad9	3225	0,06	0,14	2	4,2	0,11	0,26	3,4	8,1
Unidad10	16937	0,13	0,28	0,8	1,6	0,25	0,51	1,5	3
Unidad11	18696	0,32	0,61	1,7	3,3	0,64	0,61	3,4	3,3

Tabla 2. Cánceres totales inducidos en la segunda serie

Unidad	Población	Cánceres Mortales		Cánceres Mortales por 100000		Excesos de Cánceres		Excesos de Cánceres por 100000	
		Unscear 94	NRPB 93	Unscear 94	NRPB 93	Unscear 94	NRPB 93	Unscear 94	NRPB 93
Unidad1	17324	0,33	0,62	1,9	3,6	0,65	1,16	3,7	6,7
Unidad3	14877	0,10	0,18	0,6	1,2	0,19	0,34	1,3	2,3
Unidad6	19577	0,22	0,39	1,1	2	0,43	0,73	2,2	3,7
Unidad7	20755	0,17	0,32	0,8	1,5	0,34	0,60	1,6	2,9
Unidad8	15784	0,15	0,34	1	2,2	0,30	0,72	1,9	4,6
Unidad9	3528	0,04	0,08	1,1	2,3	0,08	0,16	2,3	4,5
Unidad10	18292	0,13	0,28	0,7	1,5	0,25	0,56	1,4	3,1

Tabla 3. Cánceres totales inducidos en la tercera serie

Unidad	Población	Cánceres Mortales		Cánceres Mortales per 100000		Excesos de Cánceres		Excesos de Cánceres por 100000	
		Unscear 94	NRPB 93	Unscear 94	NRPB 93	Unscear 94	NRPB 93	Unscear 94	NRPB 93
Unidad1	16409	0,30	0,54	1,8	3,3	0,605	1,015	3,7	6,2
Unidad3	14877	0,10	0,16	0,6	1,1	0,18	0,32	1,2	2,2
Unidad6	19577	0,13	0,25	0,7	1,3	0,27	0,47	1,4	2,4
Unidad8	15784	0,10	0,19	0,6	1,2	0,208	0,36	1,3	2,3

Resultados globales

Tabla 4. Número de cánceres totales inducidos por la radiación en toda la población examinada durante las tres series primeras.

	UNSCEAR 94	NRPB 93
Primera Serie	3.22	6.04
Segunda Serie	2.06	4
Tercera Serie	1.9	3.27

4. Conclusiones

Como conclusión global se observa que los mayores detrimentos los da el modelo NRPB 93 en todos casos [5].

En cuanto a la evolución del detrimento dependiendo de la serie del programa, ambos modelos predicen resultados mayores en la primera serie, fenómeno que responde a dos causas: en ella se realiza doble proyección en cada seno y el factor de proyecciones adicionales es mayor en esta serie que en las restantes, lo que hace que la dosis promedio por individuo sea mucho mayor.

Los resultados por unidades son bastante diferentes debido fundamentalmente a la diferencia de dosis impartidas.

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MAMMOGRAPHY QUALITY ASSURANCE IN MOROCCO

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Abstract

The "Centre National de l'Energie, des Sciences et des Techniques Nucléaires" (CNESTEN) realised, from February 1999 to March 2000, a quality control of 41 mammography facilities in Morocco. The protocol and standards adopted for achieving the control of elements constituting the mammography chain are those elaborated by GIM and Qualix association. Statistics and conformities results are presented. The program was performed in order to demonstrate to the practitioners in mammography field, the utility and necessity to have a national quality assurance policy. The main objective of CNESTEN is to be accredited by the Moroccan government as a reference laboratory in quality control and dose evaluation in medical imaging and radiotherapy. To achieve this goal the CNESTEN has set up Medical Physic Unit well trained and equipped with the necessary instruments.

1. Introduction

The mammography is considered as an important tool for the early detection of the breast cancer. However the value and the diagnostic performance depend closely on the performance of elements constituting the mammography chain.

The institution of procedures of quality control and assurance quality program, specific to the mammography, is considered as factor permitting to get the maximum diagnostic information with minimizing the dose delivered to the patient and the medical personal. The cost of the exam is also reduced. Several procedures of quality control, aiming to improve and to assure quality of the images, have been developed and adopted in several countries: USA, Canada, European Union, etc.

In Morocco, the quality assurance in medical imaging is not regulated, and is therefore not adopted and performed by the different centres of medical imaging. Rare are practitioners who judge usefulness to adopt procedures of quality control for monitoring the performance of theirs facilities.

The CNESTEN, national institute, is considered as the main promoter of the use of nuclear techniques in the different socio-economic sectors in Morocco. The Department of the Medical and Biological Applications of CNESTEN via the Medical Physics Unit has start work in order to institute a national mammography assurance quality program. With the collaboration of the National Federation of Radiologists (FNR) and the Moroccan Society of Radiology(SMR), the CNESTEN undertook the realisation, free of charge, of quality control of mammography facilities. The goal is to demonstrate the interest to adopt a quality assurance program for improving the quality of images and reducing the cost of exams.

2. Technical procedures

The number of mammography facilities in Morocco is 80 distributed mainly between cities of Casablanca and Rabat. For reasons of logistical order we were not able to achieve the control of all facilities. Only 41 facilities benefited from this program: Casablanca: 20, Rabat: 12, Fez: 4 and Tangier: 5 facilities. A detailed information letter concerning the progress and the

objective of the program was sent to responsible person in all facilities before the realisation of installation check.

The tests were done according to the French protocol, elaborated by the interdisciplinary grouping of mammography (GIM)[1] and the European committee [2]. Several parameters are concerned [3]: Storage film local, Dark room, Processor film, Screens–films systems, Mammography unit and the viewing conditions, as well as a global evaluation of the image quality with MTM 100 French phantom breast in the usual clinical conditions exposition.

After control, the results have been analysed [4-5] and have been interpreted [6-7] in accordance with French Standard Qualix Association [8]. A final report regrouping the results, noted irregularities as well as recommendations have been sent to the responsible of the installation concerned under confidential letter.

3. Statistics and conformities results

3.1. Storage film local and dark room

In the storage local, The visual inspection of films storage conditions revealed that: The storage was vertical in 22 facilities (53%) while it was horizontal in 6 facilities (15%). 13 facilities (32%) have not storage local. The temperature measured inside the local was in accordance with French standards (21°C). However the temperature inside the dark room was higher than the standards in 25 facilities (61%), while it was from 17°c to 21 °C in 18 facilities (39%).

For the darkroom fog check, a film was half covered in the room for two minutes and then processed. The difference of optical density between the two areas (covered and not covered) should be inferior to 0.20 OD according to the French standards. In 31 facilities (75%) the darkroom fog was correct. In 2 facilities (5%) the power lamp was superior to 25 KW. The others facilities (20%) were not equipped with lamp.

3.2. Processing film

It is demonstrated that conditions of processing film have a big influence on the contrast and level of dose irradiation. The timing processing and developer temperature should be adjusted to obtain high quality mammography images. Only 4 facilities (9.7%) are equipped with the processing film machine dedicated only to the mammography exams.

3.2.1. Sensitometric film

The parameters measured are base fog density and film's speed and contrast. The methodology consisted of sensitising a strip film by the sensitometer, running it through the processor, and measuring, by the densitometer the optical density in different steps.

- **Base fog density:** In 34 facilities (83%) the base fog density was lower than 0.2 OD while it was higher than 0.2 OD in the others facilities (17%).
- **Sensitivity screen-film:**In almost facilities visited we noted that the reference conditions processor were not respected. In 15 facilities (37 %) the sensitivity film-screen was inside the range: from steps 10 to 11, and in 26 facilities (63%) the sensitivity was from steps 12 to 14.

- **Film Contrast:** this parameter is considered as the difference value of the optical densities between the interest and surrounded regions. In 24 facilities (58%), the contrast values was from 0.40 to 1. In 13 facilities (32%), the contrast value was within 1.1 and 1.40 and in 4 facilities (10%) it was within 1.41 to 1.60.

3.2.2. The processing time

The processing time was measured by the chronometer. It's the time taking by the film from his entrance and exit through the processor. In 10 facilities (24%) the time of processing was from 75 to 90 s. In 20 facilities (49%), it was from 100 to 120 s, in 8 facilities (20%) from 130 to 150 s and finally, it was from 160 to 180 s in 3 facilities (7 %).

3.2.3 Cassettes - screen – film contact

In all facilities visited we noted only one contact screens- film problem.Two cassettes had a bad closing in 2 facilities but tracks of dust were present on the screens in 38 facilities.

4. Mammography units statement

The mammography unit mechanical state was controlled by checking the: rotator and translator movements, compression breast (force, thickness), paddle, grid etc…

4.1. X-ray field congruence

According to the Qualix standards, we fixed the acceptability margin at ± 5 mm between the X-ray limit and the external board of the breast table. In 35 facilities (85%) the difference was within the margin fixed. In 6 facilities (15%) the difference was superior to ± 5 mm.

4.2. kVp accuracy and reproducibility

This test consist of checking out the accuracy and the reproducibility of kVp. We compared the kVp delivered by the X-ray generator and those measured by the kVp Divider. The range of kVp checked was from 25 to 30 kVp and the difference acceptability was fixed to ± 1.5 kVp. In 22 facilities(54%), the difference was ≤ 1.5 kVp wile it was ≥ 1.5 kVp in 9 facilities (22%). In 10 facilities (24%) equipped with the SIEMENS Mammomat B mammography unit, the test was not achieved because of the no compatibility of the kVp Divider's operative mode with the specified mammography unit.

4.3. Automatic exposure control AEC

To check out the AEC set-up and performance, we selected several cassettes which had very close speed. when it was not possible we used only one cassette. We realized several expositions, from 25 to 31 kVp, using a Plexiglas phantom of 4 cm thickness. The kVp were increased by step of one kVp. Then we varied progressively the thickness of the Plexiglas phantom: 2, 3, 4, 5 and 6 cm while keeping the same kVp.

The optical density was measured in all films.The optical density should be between 1.45 to 1.60 OD and the variation densities should be from 1.20 to 1.30. In 17 facilities (41%), the automatic exposure was efficient when in 20 facilities (49%) failures or problems in AEC density tracking or density calibration were noted. The test was not performed in 4 facilities because they are not equipped with an automatic exposure.

4.4. Image quality evaluation

For image quality evaluation, we used the MTM 100 French phantom breast. Its semicircular shape, 4 cm thickness, made with PMMA material and contained some inclusions like aspects of human equivalence (fibber, masses, microcalcifications). The phantom was positioned on the breast table with its longest edge centrally with the chest wall edge of the table. We exposed the phantom in the same conditions as used clinically for a standard sized breast. The film density in the reference zone should be inside the range of 1.30 to 1.6 OD. If The film density is outside the range we made an other exposure in order to have the density in the specified range: 1.3 to 1.6 OD.

A score number was calculated, it's relating to the visualisation (partially or totally) of inclusions. A total score which is the summary of score's number inclusions, was attributed for each facility. A minimum score of 24 points is required for accrediting the facility. In 14 facilities (34%) the score was lower than 24. In 16 facilities (34%) the score number was from 24 to 38 and in 11 facilities (27%) it was from 40 to 56.

Some artifacts were observed on the phantom image. This was attributed to the dust and the mod processing (roller, developer was mixed with the fixer, concentration of the developer, chemistry replenishment..). In one facility we noted a grid artifact.

5. Viewing conditions

We tested the luminance of the monitors brightness using a photometer. Five measurements in the coins and in the middle for each monitor were performed. The luminance should be superior to 1700 Candela/m2. In 15 facilities (37%), the luminance was superior to the standard fixed. In 18 facilities (43%), the brightness was insufficient and in the others facilities (20%), the test was not performed because the photometer was not available at that time.

We point out that others tests like; the humidity, focal spot performance, breast exposure entrance and dose and beam quality (half-value layer) were also not performed because of the late purchase of the material.

6. Conclusion

This study which concerned 41 facilities of mammography permitted to reach a certain number of main objectives. Although the majority of mammography facilities are recent, some abnormalities degrading the quality of the images and therefore decreasing the diagnostic value of the exam were discovered. The detailed reports sent to practitioners convinced them of the necessity and the utility to institute a quality assurance program of their installation. Some radiologists follow our suggestions and recommendations and corrected the abnormalities noted. A final report including all results of this study will be presented to the Ministry of Health, Moroccan Federation of Radiologists and the Moroccan Society of Radiology, during special seminar dedicated to the quality assurance in mammography. We hope to arrive at the mechanism to regulate the quality assurance in mammography.

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IAEA-CN-85-201

ORGAN DOSES IN CT OF THORAX: SEQUENTIAL SLICES VERSUS HELICAL SLICES

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Abstract

Helical scanning introduces additional choices in technical parameters and has an impact on how much radiation dose a patient receives. Helical scanning allows the entire thorax to be scanned within a single breathold, reducing slice registration due to breathing artifacts. Organ doses from thoracic computed tomography have been estimated in an anthropomorphic phantom using thermoluminescence dosimeters. With a very similar radiological techniques in helical and axial scanning the absorbed organ dose measured were more relevant in lung 12,0 ± 2,0 mGy and 11,0 ± 2,0 mGy respectively; and in heart 9,0 ± 4,0 mGy and 9,0 ± 5,0 mGy. Our results show that contiguous helical CT scans acquired with the same technical factors as contiguous axial scans, imply approximately the same radiation dose.

1. Introduction

Helical computed tomography

Helical Computed Tomography (CT), involves simultaneous transport of a patient at a constant speed through the gantry while helical CT data are continuously acquired over multiple gantry rotation, instead of stationary gantry when the table was moving in the conventional CT. In our days the new CT equipment are helical, so CT is synonymous of helical CT or volumetric reconstruction [1].

Successful application of CT in medical diagnosis is given by the volume coverage speed of a scanner, which refers to its capability to scan rapidly a large volume of interest.

To receive images of high quality it is important that the patient does not move during the data acquisition process, in order to avoid:

1. loss of sharpness of the image (as happens in classical radiography), and
2. motion artifacts (inherent to image reconstruction in computed tomography when inconsistent data are received).

Short scan times are desirable to limit such motion effects in single scans. Short total examination times are also desirable to limit motion between scans, since it can cause omission of anatomical levels.

Helical CT does a volumetric exploration simultaneously with the acquisition by means of rotations of the tube, with the patient over a table, that moves at the same time than the tube over the gantry. The acquisition does not stop, while the system tube-detector spins around the patient.

The selection of basic scan parameters for spiral CT is the same as in conventional CT. The parameter value may differ slightly, with any possible limitation for spiral mode.

The principal advantages of this technique are:

- the elimination of motion artifacts,
- the use of less contrast media,
- the shortened examinations times,
- the new reconstructions and data presentations available through workstation technologies.

The applications of thoracic helical CT [2]. Helical CT depicts small pulmonary nodules not seen at conventional CT by elimination of respiratory loss of registration. Pulmonary lesions can be analysed in detail using retrospective reconstruction of the data volume. Multiplanar and three-dimensional images of lung mass and arteriovenous malformations are free of motion artifacts. In comparison to conventional CT, helical CT provides a more consistent level of vascular enhancement because of the shortened acquisition time.

2. Materials and methods

Thermoluminescence dosimetry

To measure organ doses, we have used thermoluminescence dosimeters, and the material employed is available as TLD-100 (FLi:Mg,Ti with 7,5% of ^{6}Li and 92,5% of ^{7}Li). The selected form of TLD is a small cylindrical rod (1mm diameter y 6 mm high), the most appropriate geometry to CT dosimetry.

Dosimeters calibration was made at the Centro Nacional de Dosimetría (National Dosimetry Center) in Valencia, Spain. The dosimeters were irradiated with photons generated by x-ray equipment with the code D-120: x-ray tube potential of 120 kVp, the mean photon energy is 54 keV, the first half value lawyer is 4,33 mm of Al and the second one is 6,84 mm of Al. Kerma in air and air as medium was 10,14 ± 0,36 mGy over the surface of phantom with dimensions 295 x 295 x 153 mm^3, but without phantom.

The thermoluminescence dosimeter reader is the a Harshaw 5500 (Bicron-Harshaw, USA), including user interface, acquisition, storage and retrieval of TLD data and application software are performed in a separate computer.
The TLDO (PTW- Freiburg, Germany) Annealing Oven is controlled by a programmable microprocessor with profiles for annealing and preheating cycles.

In this study, we have used 243 TLD dosimeters in each thoracic CT examinations.

The Rando phantom

The Rando phantom (New York Laboratory), is one of the most used physical phantom simulating the head and trunk of an average male adult.

The most realistic tissue substitutes for use in phantom construction are probably those based on epoxy resins, which effective atomic number is 7.30 and density 0,985 g cm^{-3}. Its weight is 73,5 kg and its height 175 cm.

The Rando phantom consists of 25 mm thick transverse slices containing each of theme rectangular grid of plugs which can be replaced by capsules containing TLDs.

In conventional and helical CT, TLD were located on the surface of the patient, in the slice at the Rando phantom, in the middle of the longitudinal dimension of the irradiated volume.

Examinations: sequential and helical CTs.

This study presents the dosimetric results obtained during computed tomography thorax examinations, carried out using two different techniques, sequential and helical CT with a helical CT scanner (Tomoscan AV, Philips).

Table 1. Sequential technique in thoracic examinations

Parameters	Reference
Number of scans	20
Slice collimation	10 mm
Scan increment	10 mm
Voltage	120 kVp
Tube current*scan time (one rotation)	280 mAs

The performance of helical CT requires several user-defined parameters that exceed the requirements of conventional CT. One needs to carefully selects the collimation, table increments and reconstruction interval. The miliampere-second is for the whole examination. Pitch (dimensionless) is the table feed per 360° rotation divided by the slice thickness.

Table 2. Helical technique in thoracic examinations

Parameters	Reference
Scan range	20 cm
Slice collimation	10 mm
Pitch	1
Voltage	120 kVp
Tube current*scan time (spiral)	5600 mAs

3. Results and discussion

Table 3 shows the organ doses with two different techniques: sequential and helical.

Table 3. Absorbed Doses in organs (mGy)*

Organs	Sequential	Helical
Thyroid	2,4 ± 0,7	2,5 ± 0,6
Oesophagus	5,8 ± 0,5	7,4 ± 0,6
Red bone marrow	7,0 ± 4,0	7,0 ± 5,0
Breastbone	14,2 ± 1,3	14,6 ± 1,1
Ribbons	12,0 ± 2,0	11,0 ± 2,0
Heart	9,0 ± 4,0	9,0 ± 5,0
Center of patient	14,0 ± 5,0	14,0 ± 5,0
Lungs	11,0 ± 2,0	12,0 ± 2,0
Surface (skin)	23,0 ± 3,0	21,0 ± 2,0

*Mean ± Standard deviation

Our results are in agreement with McNitt-Gray et al [3].

The comparison of the dosimetric data obtained using the two different techniques shows that there is not any relevant difference between them as far as the surface dose and the doses received by the organs of interest.

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IAEA-CN-85-63

HOW WILL THE INTRODUCTION OF MULTI-SLICE CT AFFECT PATIENT DOSES?

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Abstract

Imaging protocols for patients undergoing CT examinations on a conventional single section scanner (GE CT/i) were compared with those developed after a multi-slice scanner (GE LightSpeed) was introduced into clinical practice. For multi-slice CT, the reduction in patient scan time was a more than a factor of two for head scans, and approximately 25% for body scans. The number of images available for review on the multi-slice CT system increased by approximately 40%. Use of this multi-slice CT scanner resulted in an effective dose of 1.2 mSv for head examinations and 9.1 mSv for body examinations. The increase in patient effective dose after the introduction of multi-slice CT was approximately 30% for head CT examinations and 150% for body examinations. Higher patient doses were due to a shorter CT geometry, x-ray beam profiles that are greater than the detector width, and the use of a pitch ratio of only 0.75. Since multi-slice CT offers major reductions in scan time as well as improved image quality, it is anticipated that both individual and collective doses from CT will continue to increase for the foreseeable future.

1. Introduction

Multi-slice CT systems, which were introduced into routine clinical work in 1999 [1], significantly improve utilization of the x-ray tube output. These multi-slice systems typically use *multiple detectors* that can cover between 20 mm and 40 mm of axial distance, and can acquire four simultaneous sections for each 360° revolution of the x-ray tube. In this study, we investigated the how the introduction of multi-slice CT affected radiation doses to patients undergoing head and body CT examinations.

2. Method

2.1. CT scanners. We compared the protocols used for patients undergoing CT examinations on a conventional single section scanner (GE CT/i) with those introduced after a multi-slice scanner (GE[1] LightSpeed) was installed at the University of Florida. The single section scanner generated axial sections for head CT scans, whereas spiral CT was used for chest and abdomen examinations. The LightSpeed was operated in axial mode for head imaging, and in helical mode with a pitch ratio of 0.75 for body imaging (i.e., collimator is 20 mm & table increment of 15 mm per 360° x-ray tube rotation).

Computed Tomography Dose Index (CTDI) data are shown in summary form in Table 1. The CT/i dose data are for a section thickness of 10 mm, and the LightSpeed data are for four 5 mm sections (≡ 20 collimator thickness). These data show that for the same techniques (kVp/mAs), the LightSpeed has a 20% higher head dose and 40% higher body dose.

[1] General Electric Medical Systems, Milwaukee, WI.

Table 1. CTDI doses for the CT/i and LightSpeed scanners (@ 120 kVp and 340 mAs)

Phantom size	Location	CTDI for CT/i	CTDI for LightSpeed
Head	Periphery	40 mGy	48 mGy
Head	Center	40 mGy	48 mGy
Body	Periphery	20 mGy	32 mGy
Body	Center	11 mGy	14 mGy

2.2. Spiral/Axial protocols. Head CT scans were performed at 120 kVp using axial scans. In the posterior fossa, 15 sections (3 mm thick) were obtained with a table increment distance of 5 mm, a tube current of 200 mA and a scan time of 2 seconds. The rest of the brain was covered using 8 sections (10 mm thick) with a table increment of 10 mm, a tube current of 140 mA and a scan time of 2 seconds.

Chest CT scans were performed at 120 kVp in helical mode with a pitch ratio of 1.5. In the shoulder region, approximately 10 x 7 mm sections were acquired using 400 mA and in the lung region, 50 x 7 mm sections were acquired using 230 mA. The scan time was 1 second, and the total coverage length (420 mm) required 41 rotations of the x-ray tube. Abdominal CT scans were performed at 120 kVp in helical mode with a pitch ratio of 1.5. A total of 36 x 7 mm sections were acquired using 320 mA and a scan time of 1-second which required 25 x-ray tube rotations.

2.3. Multi-slice protocols. With the introduction of multi-slice, CT imaging typically uses 4 x 5 mm thick detector which acquire data for four images in one rotation of the x-ray tube (1 second). Total z-axis coverage distance remained the same as for single slice CT, with all scans performed at 120 kVp. Head CT scans used 140 mA and 2 seconds and contiguous sections. Total axial distance covered (155 mm) requires 8 rotations of the x-ray tube. Chest CT scans have a 1-second scan time with the shoulder region using 400 mA and the lung region using 220 mA. The scan length of 420 mm requires a total of 29 rotations at a pitch of 0.75. Abdomen CT scans are performed using 240 mA and a 1-second scan time, and require 18 rotations of the x-ray tube.

2.4. Patient doses. Patients undergoing CT examinations were modeled as uniform cylinders of water with a diameter of 17.6 cm for the head [2], 21 cm for the chest [3] and 27.7 cm for the abdomen [4]. The mean dose for a single section for the CT/i was obtained using published Monte Carlo dosimetry data [5]. CT/i mean section dose data were scaled for the LightSpeed using a factor of 1.2 for head CT scans, and 1.4 for body CT scans.

Mean section dose data were used to compute the energy imparted for a single section [6] using CTDI data given in Table 1. The total energy imparted to a patient was obtained by taking into account the mAs, scanned section thickness and total number of rotations of the x-ray tube. Energy imparted was converted into the corresponding values of effective dose using conversion factors of 9.1 mSv/J for a head CT examination and 18 mSv/J for a body CT examination [7].

3. Results

3.1. Scan times/images. Table 2 shows the scan times and total number of images generated for the conventional and multi-slice CT scanners. For multi-slice CT, the reduction in patient

scan time was a more than a factor of two for head scans, and 25% for body scans. The average number of images from the multi-slice CT system increased by approximately 40%.

Table 2. Scan times and # of images for spiral/axial and multi-slice CT

Examination type	Spiral/Axial	Multi-slice
Head	~70 seconds/23 images	~30 seconds/32 images
Chest	~40 seconds/60 images	~30 seconds/84 images
Abdomen	~25 seconds/36 images	~20 seconds/50 images

3.2. Effective doses. Table 3 provides a summary of the effective doses for the three types of CT examination for the conventional and multi-slice CT scanners. Current multi-slice CT scanners result in average effective dose of 1.2 mSv for head examinations and 9.1 mSv for body examinations. The average increase in patient effective dose from the introduction of multi-slice CT was approximately 30% for head CT examinations and 150% for body examinations.

Table 3. Radiation dose summary for spiral/axial and multi-slice CT.

Examination type	Spiral/Axial	Multi-slice
Head	0.9 mSv	1.2 mSv
Chest	3.9 mSv	10.5 mSv
Abdomen	3.5 mSv	7.7 mSv

4. Discussion

Published CTDI doses for the LightSpeed are between 20% and 40% higher, which is partly due to a shorter geometry. The increased CTDI value is also due to the use of wide x-ray beam profiles which are needed to maintain a constant radiation dose for an irradiated section whilst the focal spot moves during the rotation of the x-ray tube [1, 8]. In the future, it can be expected that the multi-slice CT systems will be designed to have collimation systems that move with the focal spot size [8], which will help ensure that no unnecessary radiation is incident on the patient.

Another important reason for higher patient doses on the LightSpeed system is because of the use of a low pitch ratio in helical scanning (i.e., 0.75). The LightSpeed system offers a pitch ratio of 1.5, and use of this scanning mode would reduce patient effective doses by a factor of two! In the future, it is likely that pitch ratios ≥ 1.0 will be used, which will help to reduce patient doses. Nonetheless, patient doses for multi-slice CT will still likely be larger than for single slice CT systems. Multi-slice systems have thinner sections, and the mAs will need to be increased to maintain a constant level of quantum mottle. In addition, the increased utilization of the x-ray tube output results in shorter scan times allowing higher tube currents to be used.

In the United Kingdom, CT examinations have been reported to account for 4% of all radiographic examinations, yet account for up to 40% of the collective dose from medical exposure [9]. It is notable that multi-slice CT reduces scan times, improves z-axis resolution and provides the radiologists with more images. In the future, CT scans performed on a given patient are therefore likely to use more radiation (e.g., multi-phase liver scans or general body surveys). In addition, the improved imaging performance will also serve to have CT replace

conventional radiographic examinations [10, 11]. The data presented here indicate that individual and collective patient effective doses from CT examinations are likely to continue to increase for the foreseeable future. It is therefore important that the radiology profession reviews patient scanning protocols to ensure that patient exposures are justified by the diagnostic information that is obtained during CT examinations, and that all radiation doses are kept as low as reasonably achievable (ALARA).

Acknowledgements

The authors are grateful to Dr. Neil Bromberg for supplying the CTDI data. Robert Rothermel RT and William Garrisi RT are thanked for their technical assistance with CT protoocls.

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DUAL-SLICE SPIRAL SCANNER: DOSES DELIVERED DURING THORACIC AND ABDOMINAL EXAMINATIONS

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Abstract

A new dual-slice spiral scanner (PICKER-ELSCINT CT-Twin) dedicated to thoracic and abdominal examinations being implanted in our hospital, a dosimetric study was performed in order to evaluate the dose delivered to different body parts (skin, mid-thickness, lungs, etc) as a function of the CT parameters used for the most current protocols (determined by a statistical study including 250 patients). The aim was to establish a simple method allowing a quick estimation of the dose delivered to the patients knowing CT parameters used (kV, mAs/slice, pitch, slice thickness).

Dosimetric measurements were performed using an Alderson anthropomorphic phantom and $Li_2B_4O_7$:Cu TL powder (chosen because of its flat energy response in the studied energy range). Results obtained (precision: ± 5%) have shown that doses are dependent on the number of scans, mAs/slice and kV but very little dependent on slice thicknesses. For instance, doses at the abdomen center of patients irradiated at 120 kV vary from 0.7 to 1.7 cGy for mAs varying from 133 to 333 with a variation less than 10% when one passes from "pitch 0.7- thickness 8 mm" to "pitch 2- thickness 13 mm". Other charts and tables deduced from experimental results will be presented. They show that doses delivered by helical computed tomography being relatively high, the number of procedures and section per procedures should be carefully adapted to the age of patients and the underlying pathology.

1. Introduction

The knowledge of the absorbed dose delivered during radiological procedures is an indispensable step to estimate the radiation risks associated with a given procedure and therefore to optimize it with respect to the radiation risk and the risk-benefit analysis (underlying pathology, patient's age, etc). As it is a long and cumbersome work to evaluate it for each patient and the different radiological procedures in use, we prefer to undertake a dosimetric study every time a new radiological equipment or a new procedure is implanted in a department of radiology, following the method shown in Figure 1.

The evaluation of the doses delivered during thoracic and abdominal examinations performed with a dual slice spiral scanner will be presented as an illustration of the method.

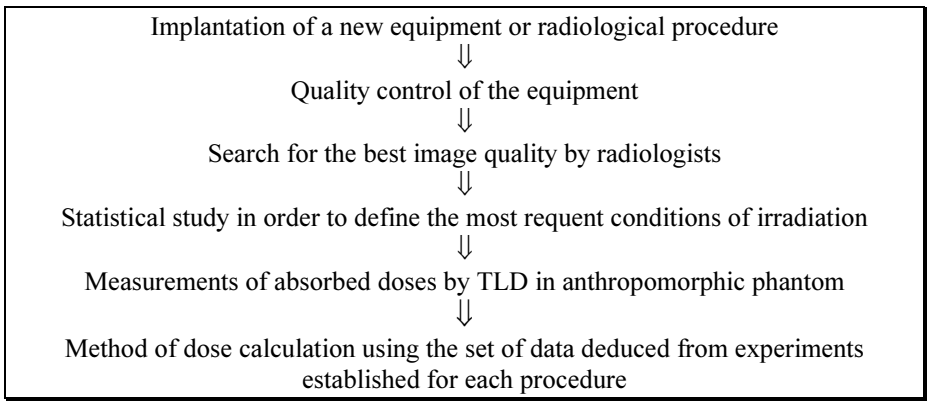

Figure 1: General method followed at Hosp. Henri Mondor for evaluation of the patient's dose

2. Materials and method

2.1. CT equipment

A whole body dual-slice spiral computed tomography (CT) CT-Twin PICKER-ELSCINT was used. It permits rapid scanning of a large volume of tissue, the X-ray tube rotating continuously in a circular motion while the patient is transported on a table at a constant velocity through the center of the circle, so that the X-ray beam describes a spiral path through the patient [1]. Moreover the CT-Twin offers the particularity to have a wide fan beam of X-rays striking two side-by-side parallel arcs of detectors, producing a double spiral of spatial information. Data are interpolated from the raw data collected with the two detectors arrays. Such CT permitting to achieve faster scanning compared single-slice spiral ones [2] are relatively new so that only a few dosimetric data are available for them.

Irradiation parameters used for the present study were:

- Helix mode, i.e. dual-slice spiral mode
- Scan diameter 430 mm
- Voltages: 120 and 140 kV
- Number of mAs/slice varying from 100 to 333
- Pitch values (defined as the table feed distance per 360° rotation divided by the nominal section thickness): 0.75, 1 and 2
- Slice thickness varying from 8.8 to 13 mm.

They cover all the range of irradiation parameters noted in the files of 250 patients submitted to thoracic and abdominal examinations.

2.2. Phantom

Experiments have been performed by simulating patients of average size with an anthropomorphic phantom type ALDERSON and irradiating it in the different conditions used for patients (see §2.1). In order to improve the accuracy, multiple scans on the same area have sometimes been made, and the dose obtained divided by the number of scans.

2.3. Thermoluminescent dosimetry (TLD)

Experiments were performed using $Li_2B_4O_7$:Cu TL powder [3] chosen because of its energy response better than LiF in the energy range of diagnostic radiology [4, 5]. As an indication, the mass energy absorption ratio of $Li_2B_4O_7$:Cu and Lif to tissue in the energy range 20 to 200 keV, vary of 11% and 43%, respectively.

TL powder was spread out in very thin envelops made of black paper and stuck at the entrance and exit surface of the Alderson phantom (for evaluation of the skin doses), or contained in opaque cylindrical containers which were inserted in the holes of the phantom for evaluation of the dose at mid-thickness or within the organs). Previously to experiments a direct calibration of the powder under both the presentations have been carried out by comparing its response to the response of a calibrated ionization chamber specially dedicated to low-energy X-rays.

After irradiation, TL powder was read out on an automatic FIMEL-PCL 3 reader [6] (preheating temperature: 178°C, heating temperature : 403°C, no annealing of TLD after readout) and results obtained with an intrinsic precision of ± 5%.

3. Results

An example of the results obtained for a slice of the Alderson phantom situated close to the center of the explored region and irradiated at 120 kV –266 mAs (pitch 0.75, slice thickness 8.8 mm, length of the scanned volume 320 mm) are shown in Figure 2-A. Results obtained for other conditions of irradiation and other scanned volume have shown that the delivered doses are essentially dependent on the number of scans, voltage and mAs/slice [Figure 2-B] but very little dependent on the cut thickness. For instance, doses at the abdomen center irradiated at 120 kV (currently used for patients of average size) vary from 7 to 17 mGy for mAs varying from 133 to 333 and can reach 28 mGy for 340 mAs at 140 kV (often used for thick patients). Skin abdominal doses are higher than dose at the abdomen center, varying from 10 to 26 mGy at 120 kV, and reaching 37 mGy at 140 kV. Similar measurements performed at the thorax level have shown comparable skin doses but higher doses at the lung centers, the dose variation being from 10 to 24 mGy at 120 kV for mAs varying from 133 to 333.

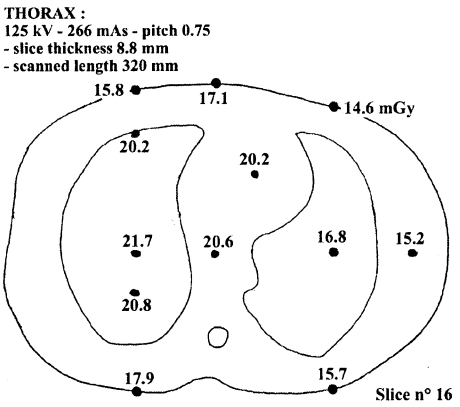

Figure 2 [A] Example of results obtained by TL measurements at different points of a slice of an Alderson phantom irradiated in patient conditions.

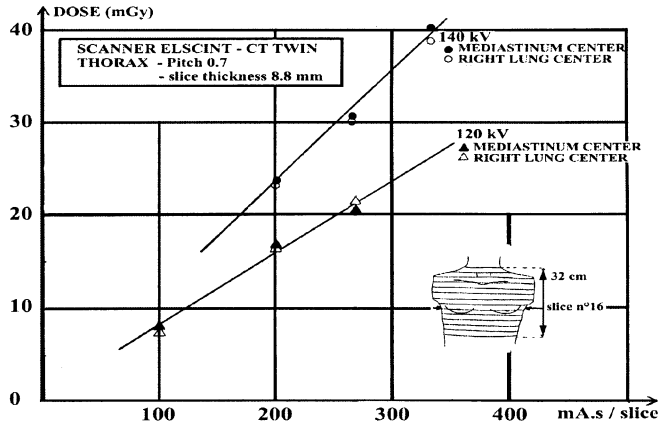

Figure 2 [B] Graphic data which can be deduced from numerous measurements [B].

From all the experimental results obtained we have established a set of simple charts and tables giving the doses for 100 mAs/slice for different values of voltage, pitch and slice thickness (see one example shown in Table 1). The dose delivered to a patient can be deduced from them knowing the actual number of mAs used for the patient examination (easily readout on the CT computer control console), and of course using the chart or table corresponding to the other irradiation parameters used.

The data obtained have been established using the Alderson phantom representing a standard patient of average size (thickness at the level of measurement equal to 22 cm). For patients slimest or thickest, the delivered dose can be obtained using the standard data and a correction factor, $F_{thickness}$, deduced from a depth dose curve corresponding to the energy used:

$$\text{Dose} = D_o \times \frac{mAs}{100} \times F_{thickness}$$

Table 1. ELSCINT – CT_{TWIN} (Helix mode)

Doses (mGy) for 100 mAs/slice

(Pitch = 0.75 – slice thickness = 8.8 mm

and length scanned = 320 mm)

Voltage	THORAX *			
kV	Skin	Mediastinum	Lung Center	
			Right	Left
120	6.1	8.1	8.1	6.7
140	9.1	11.9	11.9	10.2

** Measurements performed with slice n°16 (Alderson phantom)*

Validity of results obtained using the above formula has been checked experimentally using TLD method.

4. Conclusion

When the radiological procedures are clearly defined and currently practiced in a department of radiology, it is possible to establish a set of simple charts and tables allowing a quick and fairly accurate estimation of the dose delivered to each patient. TLD has been shown a good tool to obtain such data which must be available for the different anatomical sites explored. The work could be considered as cumbersome but data are determined just once for a given protocol and then used for a great number of patients as long as the radiological protocol remains unchanged.

Experimental results obtained have also shown that doses delivered by helical computed tomography using dual-slice helix mode were comparable to doses delivered at the thorax level by other type of CT scanners [1, 7]. As they are relatively high, the number of procedures must not be increased even though the helix mode has improved the image quality and made CT faster. The length of the examined volume should be also carefully adapted to the underlying pathology.

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IAEA-CN-85-39

PATIENT DOSES FOR COMPUTED TOMOGRAPHY IN HUNGARY

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Abstract

The latest initiative of the National Patient Dose Evaluation Program was an overall evaluation of patient doses for computed tomography. The aim of the survey was to collect data from which the patient doses of the CT examination of different body parts can be estimated and the most important technical parameters affecting on the patient exposures can be evaluated. The 54 CT scanners in clinical use in Hungary can be categorized into 31 different models from 8 manufacturers. Per caput frequency for CT is about 62.3 examinations per 1000 inhabitants. 59% of all examinations are connected to the head imaging. The highest mean effective dose arising from the chest and pelvis examinations, 6.98 mSv and 6.64 mSv, respectively. The yearly collective effective dose has been estimated at about 1700 manSv. This total dose is as much as the figure of 1785 manSv previously assessed for photofluorography applied in mass chest screening in Hungary.

1. Introduction

The results of surveys from the most developed countries show that the frequency of CT examinations and consequently the collective dose are increasing steadily, constituting a significant part of the collective dose of the population arising from the medical applications of ionizing radiation [1-3].

Diagnostic importance of CT examinations is outstanding, so the increase of examination frequency is justified. According to the International Commission on Radiological Protection (ICRP) dose limits should not be applied for medical exposures either diagnostic or therapy, because patients have direct benefit from the exposure. However according to the basic principles of radiation protection the medical diagnostic procedures should be optimized and unjustified exposures should be minimized [4,5].

Since the beginning of the eighties computed tomography (CT) plays a significant role in medical diagnostics in Hungary too. According to the records there are 54 CT scanners in clinical use in Hungary which can be categorized into 31 different models from 8 manufacturers.

2. Methods

In the two stages of the survey program scanner specific dosimetric data and examination specific data were collected. Free-in-air and phantom doses were measured by a special pencil-shaped ionization chamber coupled to the electrometer (type 1015 10.3CT, Radcal Corp., California, USA). The phantom measurements were made in PMMA head and body phantoms - 16 cm and 32 cm diameter, respectively - at the center of the phantom and at 10 mm beneath the surface. In addition to the phantom measurements, free-in-air measurements in the rotation center were made.

According to the minimum survey program, the dose measurements were made on the two most frequently used tube voltages, at the minimal, the maximal and 2 mm slice thickness. At

workplaces where we had more time this dose collection program were extended to additional slice thickness.

The clinical performance was investigated by monitoring all CT examinations during one week, comprising all relevant technical and clinical data. The collected data were partly patient related: sex, year of birth, body height and weight of the patient, diagnostic purpose of the examination, body region examined and use of contrast agent. The exposure related data were as follows: scan mode (axial or spiral), gantry tilt angle, tube voltage and loading, slice thickness, table movement increment or pitch factor, number of scans and the start position of the scans.

From the measured dosimetric data the Computed Tomography Dose Indexes, $_{n}CTDI_{air}$ and the $_{n}CTDI_{w,body}$ were calculated on each relevant tube voltage and slice thickness.

The CTDI for each patient examination was calculated from the relevant value of $_{n}CTDI_{w,body}$ data multiplied it by the tube loading C used in the patient examination. The CTDI gives the average dose per slice to the patient. The dose-length product (DLP) was calculated from the CTDI multiplied it by the slice thickness and the number of slices [6,7].

The effective dose of patient exposure was calculated applying the normalized values of effective dose per dose-length product over various body regions.

3. Results

Typical patient attendance for individual scanners varied in a wide range with a mean for the sample of around 110 patients per week. These data indicate an annual total of 623000 CT examinations in 1999 from the 54 scanners in operation, involving 303000 patient attendance. It is an important fact that in our survey a CT examination means a sequence of scans with identical technical parameters of tube voltage, tube loading, slice thickness, etc. The corresponding per caput frequency for CT is about 62.3 examinations per 1000 inhabitants.

Frequency data for different types of examination shows that 59% of all examinations are connected to the head imaging (see Figure 1.). The next most important region of the body in terms of examination frequency is the abdomen, which represents 23% of all examinations, with smaller contributions from the chest (12%), and pelvis (4%).

Representative information on the age and sex of patients undergoing CT has been obtained from a sample of 2052 patient records. The shapes of general distribution for patients undergoing CT indicate a bias towards relatively elderly persons compared with the general population. The average age of CT patients and the general population of Hungary is 54 and 39 years, respectively. The percentages of CT patients aged over 43 years and over 64 years are 75% and 25%, respectively. The significant number of older CT patients has important implications for the expression of delayed radiation effects. The 49% of CT patients were male and 51% of them were female.

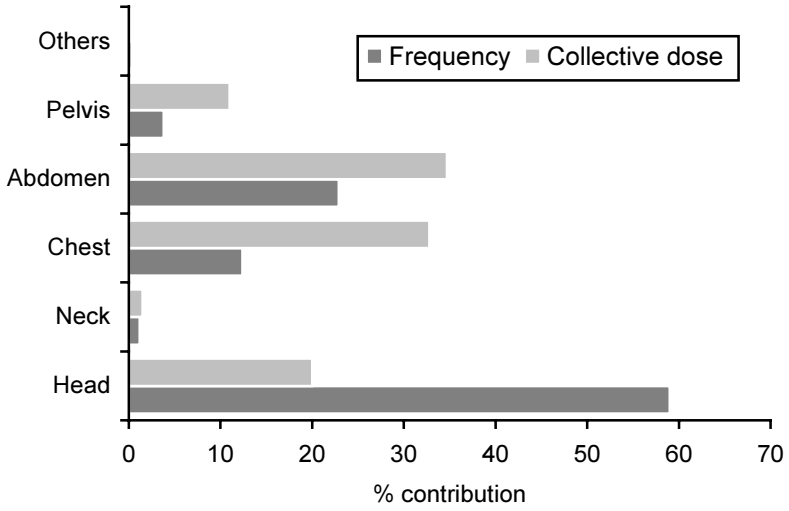

Figure 1. Contribution to CT practice by examination type

Effective dose from CT by examination type can be seen in Figure 2. The highest mean effective dose arising from the chest and pelvis examinations was and 6.64 mSv and 6.98 mSv respectively. There is no significant difference between these figures. The CT examinations of the abdominal region cause about 3.7 mSv mean effective dose. The CT examinations of the head performed with the highest frequency account for only 0,83 mSv mean effective dose.

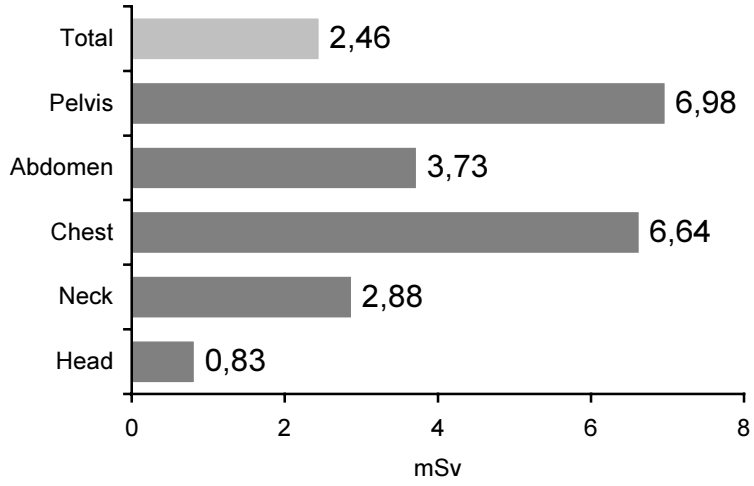

Figure 2. Effective dose from CT by examination type

A relatively wide variation can be observed in mean effective doses for examinations between workplaces, which can be explained by the variations in inherent parameters of scanners, the technical parameters and the frequency distribution of different type of examinations.

The collective effective dose from the 54 scanners operating in Hungary in 1999 has been estimated at about 1700 man Sv. This total dose is as much as the figure of 1785 man Sv

previously assessed for photofluorography applied in mass chest screening in Hungary [8]. The consequent average effective dose per CT examination of about 2.5 mSv was estimated (see Figure 2). Consequently, each scanner gives rise to a collective dose of about 32 man Sv a year.

Contributions to the collective effective dose from CT by examination type can be seen in Figure 1. Whereas examinations of the head represent nearly 60% of all CT examinations, they account for only 20% of the collective dose, which is dominated by examinations of the abdomen and the chest.

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IAEA-CN-85-141

RADIATION DOSE AND QUALITY CONTROL IN FLUOROSCOPY AND COMPUTED TOMOGRAPHY SCANNING

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Abstract

The total of 16 fluoroscopic units were selected in this study. Basic QC tests were performed on all the units with RMI QC kit and a TRI SOLIDOSE 400 dosimeter. 20 patients for 4 fluoroscopic units were selected for barium meal (upper GI) and the doses were measured using two calibrated DAP meters (a RTI DOSEGUARE 100 and a FJ 2020). 3 CT scanner were selected in this study. The QC tests were made with VICTOREEN CT performance phantoms. The doses were measured with pencil ionization chamber and standard head/body phantoms. The dose profile and CTDI in free air were measured using a set of 36 LiF chips inside a specific holder. The results of QC tests for 16 fluoroscopic and 3 CT units reveal that most performance parameters are satisfactory. The DAP values varied from 8 to 48 $Gycm^2$ with an average value of 21 $Gycm^2$. According to chest examination procedure used and CT characteristics, weighted $CTDI_w$, Dose-Length product (DLP) and effective dose (E) for 15 patients were estimated. The average values of them were 29mGy, 612mGycm and 10 mSv respectively. The conclusion from this study was drawen that possible to choose dose reference level can be valid worldwide for all X-ray examinations.

1. Introduction

A co-ordinated research programme (CRP) in 9 countries of Asia and Far East with IAEA, entitled “Radiation Dose in Diagnostic Radiology and Methods for Dose Reduction”, has been launched since 1994. The aim of the project was to explore the potential for dose reduction for some types of X-ray examination [1], to assess whether available dose reference values could be applied in Asia region [2]. The programme of four years has been instituted in two phases. The first phase of the CRP dealed with conventional radiographic units and the second phase with fluoroscopy and computed tomography. This paper reports work on second phase of the CRP.

2. Materials and methods

The fluoroscopic systems selected in the programme included: 3 mobile C-arm systems, 12 remote control tables, and 1 system without image intensifier. The total 16 units were selected from 4 hospitals.

The service lives of CT scanners selected in the programme are: 2 years for 1 CT, 4 years for 1CT and 5 years for 1 CT.

The 2nd round of intercomparison and calibration of TLD systems was finished in January 1998. 50 chips of China-made LiF-TLD were sent to National Radiation Laboratory (NRL) in New Zealand which was responsible for the TLD intercomparison and calibration [3].

The quality control(QC) tests for fluoroscopic units were made with RMI QC kit. The dose and dose rate for the fluoroscopic units were measured with the PTW DIADOS and TRI Solidose 400 dosimeters.

Five patients per hospital(room) were selected for barium meal(upper GI) fluoroscopic examinations and the dose was measured using a calibrated DAP meter consisting of made Sweden RTI DOSEGUARD 100, or China made FJ2020.

Table I. Quality control measurements on fluoroscopic units

Parameters (tolerances indicated with *)	**A/1**	**A/2**	**A/3**	**A/4**	**A/5**	**A/6**	**A/7**	**B/1**	**B/2**	**B/3**	**B/4**	**B/5**	**C/1**	**C/2**	**C/3***	**D/1**
kV Accuracy(10%)*	NM	A	NM	NM	A	A	A	A	A	NM	A	A	A	A	NA	A
HVL, mm of Al,(measure at 80 kV)	NM	NM	NM	NM	NM	A	A	A	NM	NM	NM	A	A	A	NM	A
Timer Accuracy (10%)*	NM	NM	NM	NM	NM	A	A	NM	NM	NM	NM	NM	NM	NM	NM	A
mAs linearity (10%)*	NM	NM	NM	NM	NM	A	A	A	NM	NM	NM	NM	A	A	NM	A
Output (mGy/mAs) at 80 kV, at 50 cm	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Light/Radiation Beam Alignment (deviation at 1m)(±2%)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
High contrast resolution (field size of 23 cm or nearest, normal mode of fluoro):																
—at the centre (lp/mm)	1.2	1.4	0.6	1.6	1.2	1.0	0.6	0.8	1.4	2.4	1.2	0.6	1.2	2.4	0.9	1.2
—in the peripheral (lp/mm)	1.0	1.2	0.6	1.6	1.2	0.8	0.6	0.8	1.4	2.4	1.2	0.6	1.2	2.4	0.9	1.2
Dose rate at the entrance of I.I (field size of 23 cm of nearest, normal mode of fluoro):																
—Grid (Y/N)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	None	Y
—ABC (Y/N)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	None	Y
—kV,_mA	85 1.7	79 2.0	85 1.4	76 6.3	88 1.4	76 1.6	78 0.2	76 1.3	75 2.1	71 3.2	80 1.5	85 0.5	70 1.0	88 2.1	-	88 2.0
—Dose rate (µGy/min)	108	40	20	27	44	58	9.0	33	68	36	72	33	21.4	67.8	-	44.9
Entrance dose rate to the patient (field size of 23 cm or nearest, normal mode of fluoro grid in):																
—kV, mA	90 1.7	77 2.0	79 1.4	73 6.8	89 1.4	77 1.6	70 2.0	76 1.2	78 1.6	70 3.0	83 1.7	80 1.0	74 1.1	89 2.1	70 2.0	74 1.3
—Dose (mGy/min)	16.1	23.5	7.9	5.7	10.7	11.4	6.83	6.5	9.9	11.5	12.0	3.9	5.5	13.9	46.8	5.6
Maximum entrance dose rate to the patient (highest image quality, boost mode):																
—Lowest field size/cm	23	23	23	13	23	23	23	23	23	17	23	23	23	15	-	23
—kV, mA	124 2.4	112 4.0	95 1.4	125 16	121 2.6	124 2.4	100 4.0	120 3.0	114 2.4	111 6.0	115 2.3	120 1.0	120 1.9	125 4.0	-	123 2.5
—Dose rate at 30 cm (mGy/min)	36.9	99.1	11.4	60.8	33.34	40.0	26.7	41.2	29.4	58.6	27.9	8.2	24.0	55.7	-	29.4

NM = Not Measured A= Acceptable * without image intensifier

Table II. Quality control of CT units; summary of QC results for a 10 mm slice thickness.*

Hospital/Room	E/1	F/1	G/1
kV	120	125	130
mAs	320	455	210
Scan time (s)	4	7	3
FOV (cm)	25	24	24
Matrix	512 × 512	512 x 512	512 x 512
Algorithm(soft tissue)	standard	standard	standard
High contrast resolution	1.0	1.0	1.0
CT number calibration:			
— air	-976.0±1.0	-999±2.2	-1000.7±2.5
—polye	-71.8±3.1	-101±4.8	-81.3±3.0
—polys	-35.2±3.4	-51±3.3	-23.6±2.8
—water	1.1.±3.0	-28±4.6	1.6±3.0
—nylon	85.9±3.5	74±4.1	100.5±3.9
—polyc	93.3±3.1	91±6.1	104.0±3.2
—acrylic	116.0±3.6	95±2.7	127.1±3.2
CT# contrast scale CS = 1/ (Ctair—CTwater)	-1/977	-1/971	-1/1002
Low contrast delectability (mm)	3.0	3.0	3.0
Noise: SD of water SD*100*CS(%)	0.30	0.44	0.42
Uniformity(min-max)	3.0	5.0	2.0
nCTDI10cm air (mGy/mAs)	0.334	0.215	0.302

* Standard head techniques for the CT units.

Table III. Patient dose measurement; barium meal(upper GI, not follow through) examination*

Parameters tolerances indicated with)	A/1	B/2	C/1	D/1
Patient data:				
- Average age(year±sd)	52±6	51±4	39±19	40±19
- Average weight(kg±sd)	57.2±9.8	59.8±5.2	63±6.7	59.4±8.4
Mean number of images(n±sd)	9±2.9	9.2±1.6	5.2±2.4	6±0
Mean fluoroscopy time (minutes±sd)	4.8±3.0	6.1±2.3	6.1±2.6	4.4±1.2
Dose Area Product($Gy.cm^2$±sd)	27.9±14.3	13.6±2.5	18.8±9.7	22.0±6.8
	(27.9-47.89) **	(9.84-15.38)**	(10.37-35.50)**	(15.49-31.24)**

* The data for 5 patients per room has been recorded and the patient weight 60± 10kg has been selected.

** Range in parentheses.

The QC tests for CT scanners were made with VICTOREEN 76-410-4130 and 76-421 phantoms. The dose for CT scanner was measured with VICTOREEN Model 660, 660-6 CT probes and the head/body dose phantoms.

In order to use the Monte Carlo data to calculate effective dose to patients for a CT examination, it is necessary to know the absorbed dose free-in-air on the axis of rotation of the CT scanner [2]. This can be determined using a set of 36 LiF-TLD chips stacked together inside a specific holder which can be aligned along the axis of rotation of the CT scanner using simple support jig. The TLD were calibrated in air kerma with calibration factor from NRL, New Zealand.

Table IV. patient dose evaluation in CT; chest, general examination *

Hospital Room	E/1	F/1	G/1
Average age (year±sd)	66±5.3	55±4.6	58±6.0
Average weight (kg±sd)	57±2.7	60±1.5	55±3.5
Technical parameters:			
Average kV	120	130	125
Average mAs (C)	300	455	150
Scan time(s)	3.0	7	3.0
Slice thickness(mm) (T)	10	10	10
Average no. of slices (N)	22±4	20±3	22±2
Average couch increment (mm)	10	10	10
Examination performed: without(N), with(Y) or without and with contrast media(NY)	None	None	None
Dose evaluation:			
Average CTDIw = nCTDIw.C (mGy)	27.1	43.0	17.2
Average DLP = nCTDIw.C.T.N(mGy.cm)	596.2	860.0	378.4
Average Effective Dose (mSv)	9.8	10.4	8.2

* The data for 5 patients per room has been recorded and the patient weight 55±10kg has been selected.

The dose descriptor relating to a single CT slice is expressed as the CTDI. A weighted CTDI(CTDIw) and the Dose –Length Product(DLP) in the head or body CT dosimetry phantoms were derived from the measured $CTDI_{air\ 10}$. [2] The organ doses and effective dose(E) to patients in the study may be derived from kVp, mAs, slice thickness, number of slices, couch increment, start and finish positions and the CTDI/mAs measured free-in-air on axis for the CT scanner, using CTDOSE programme supplied by New Zealand and NRPB250 data base by UK. The patient weight of 55+/-10kg was selected for the chest CT examination.

3. Results and discussion

From results of TLD calibration a precision of 5% or better at 0.1 mGy could be achieved. This fact makes the system attractive for low dose measurements in diagnostic radiology with satisfactory accuracy and precision.

The results of QC tests for 16 fluoroscopic units are summarized in Table I and for 3 CT scanners in Table II. A large majority of the units is satisfactory.

Table III summarizes all mean values of the radiological factors and the DAP for barium meal examination.

Assessing dose to patients from fluoroscopic examinations was always difficult, mainly due to the dynamic nature of the investigation: many parameters (kVp, mA, field position and size) were variable during the same examination and others (number of exposures, fluoroscopy

time) from patient to patient. From Table III it can be seen that the range of mean DAP values (13.6 - 27.9 $Gycm^2$) as encountered in clinical practice at 4 fluoroscopic units for the upper GI studies is relatively small, especially when it is taken into account that large variation existed in numerous aspects of each examination, all were closely related to patient dose. This involves, for example, the variations in the fluoroscopy time (0.57–8.7 minutes), in the dose rate at the entrance surface of image intensifier (9.0–108μGy/min), in the entrance dose at the surface of phantom (3.9–23.5mGy/min) and in number of exposures(3 – 12 images).The highest Dose-Area Product was measured at fluoroscopic unit A/1 which can be explained by the combination of high required entrance dose at the surface of the image intensifier during fluoroscopy and radiography, long fluoroscopy time and great number of exposures.

The results of patient dose evaluation in CT chest examination are summarized in Table IV. The table shows the average weighted CTDI for a single slice in the patient chest examination, the Dose-Length Product for the complete examination and the average effective dose. These average dose values in hospitals E/1 and G/1 compare rather well with the CEC reference dose values for the chest CT examination, the average in hospital F/1 is higher than the reference value.

4. Conclusions

Quality assurance programme for X-ray diagnosis were begun in China in the mid 1980s and became firmly established in early 1990s, when the national regulations and standards were made. This kind of CRP is considered a good and cost effective start for national projects on radiation protection and quality assurance in diagnostic radiology in developing countries.

It was noted in the studies that the traditional fluoroscopy (without II), upper GI with barium meal for fluoroscopy, and the CT examinations often caused higher absorbed doses to patients than these of conventional radiography [4]. It seems possible to choose reference levels of dose indicator that are valid worldwide for all X-ray examinations, including radiography, fluoroscopy and CT scanning [5].

Acknowledgement

This work was supported in part by IAEA under the contract number 8221/R2. We would like to thank Ms. Modupe Oresegun for her assistance.

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PATIENT DOSES FROM COMPUTED TOMOGRAPHY IN THE NORTH-EAST REGION OF UKRAINE

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Abstract

Survey of CT-examinations, including the measurements of a computed tomography dose index (CTDI) and patient dose assessment was implemented in CT departments of north-east region of Ukraine. The value of CTDI differs by factor 1.3 – 2 for the different units of one type of CT scanner. Total number of CT examinations has increased from 19,717 in 1997 to 46,374 in 1998. The number of CT examinations of children is about 7.6% of total number of examinations. The collective effective dose to the patients due to CT examinations was 160.7 man.-Sv in 1998. The comparison of number and collective effective doses for different kind of CT examinations shows that although only 21.6% of the CT examinations concern to abdomen, the contribution of this kind of CT examination to collective effective dose is the highest and makes about 50%. Whereas CT examinations of head represent 65.4% of the all examinations in 1998, its contribution to the collective dose is only 15%.

1. Introduction

In accordance with the state documents, accepted recently in Ukraine in the field of nuclear regulation, a problem of the population exposure control at medical use of ionising radiation sources is very actual now. A realisation of such monitoring is in need of the implementation of both organisational and practical measures.

Computed tomography takes the special position among other methods of receiving the diagnostic information and finds more and more broad use in practice of medical establishments. At the same time doses of patients undergoing the CT examinations are much higher, than ones from the conventional radiography. It caused an increase in the contribution of CT-examinations to a collective dose from a medical exposure.

The purpose of this study was to survey the state of computed tomography in the four regions of the north-east area of Ukraine and assess the collective dose from this X-ray diagnostic method.

2. Material and methods

Dosimetry measurements and patient dose assessment at the CT-examinations were carried out in 11 hospitals of the north-east area of Ukraine, including the Dnepropetrovsk, Donetsk, Poltava and Kharkov regions.

The quantity computed tomography dose index (CTDI) was measured free-in-air at each operating CT scanner by means of a specially designed dosimeter with thermoluminescent detectors (TLD). The dosimeter consists of the PMMA capsule with the outer and inner diameter equal 8 and 5 mm, accordingly. Inside the capsule the LiF:Mg,Ti thermoluminescent pellets with a diameter of 4,5 mm and thickness of 0,8 mm (type MTS-N, Krakow Institute of Nuclear Physics) are placed. Length of an accommodation area of the detectors was selected to be sufficient to enclose the full dose profile at free-in-air measurements. The dosimeters were placed along a rotation axis of the scanner so that a single slice scanning plane crosses the centre of the dosimeter. The exposure of the dosimeters were performed at the

combinations of scan parameters, such as tube voltage, current-time product and slice thickness that are most frequently used in routine practice of the CT department.

The measured CTDI were used for the calculation of effective doses apply to average sized adult patient for the routine CT-examination of head, chest, abdomen and pelvis. For an evaluation of doses from CT examinations carried out on the scanners type CT-1010 (Ukraine) and GE CT-MAX the effective dose conversion factors were obtained using the heterogeneous anthropomorphic phantoms (Riga, Latvia) and thermoluminescent detectors based on LiF type MTS-N and MCP-N (Krakow Institute of Nuclear Physics). For the calculation of effective doses from CT-examinations performed on other types of CT scanners the effective dose conversion factors readily available in publications [1,3] were used.

The data about the number and the structure of CT-examinations carried out in 11 hospitals in 1997-1999 were obtained from the special questionnaires sent to every CT department. The information received has provided the age distribution of CT-examinations and taken into consideration a scanning of the following body sections: head, chest, abdomen and pelvis.

3. Results

The measurements of CTDI were performed on 6 types of CT scanners. The results have shown that the value of computed tomography dose index measured for the relevant combinations of scan parameters differs by factor 1.3 – 2 for the same type of CT scanner.

The age distribution of CT-examinations performed during 1997-1999 is presented on Figure 1. It can be seen that the number of child examinations is rather small, being about 7.6% of all patients.

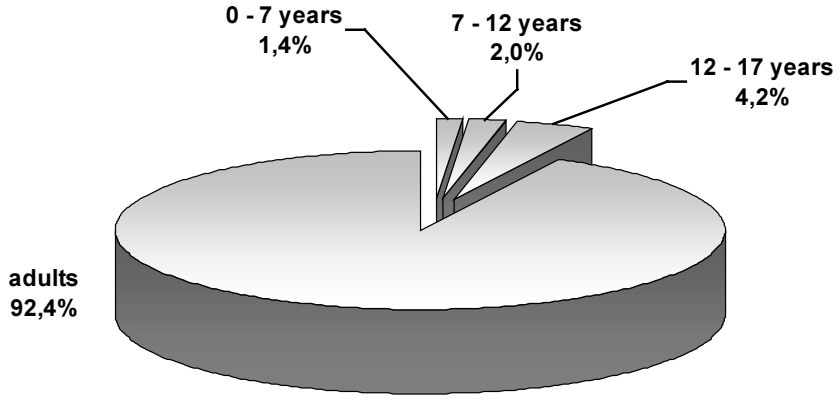

Figure 1. Age distribution of CT-examinations in north-east region of Ukraine in 1997-1999

Figure 2 shows the data about the number and structure of CT examinations of adults carried out in north-east region of Ukraine. As it follows from Figure 2, the total number of CT examinations is gradually increased from 19,717 in 1997 to 46,374 in 1998. The structure of the examinations in 1997-1998 was as follows: head - 65.2%, abdomen -19.5%, chest –

10.0%, pelvis – 5.3%. One of the reason the substantial contribution of the head examination is the relatively large number of CPT–1010 type scanners which are constructed specially for the head scanning.

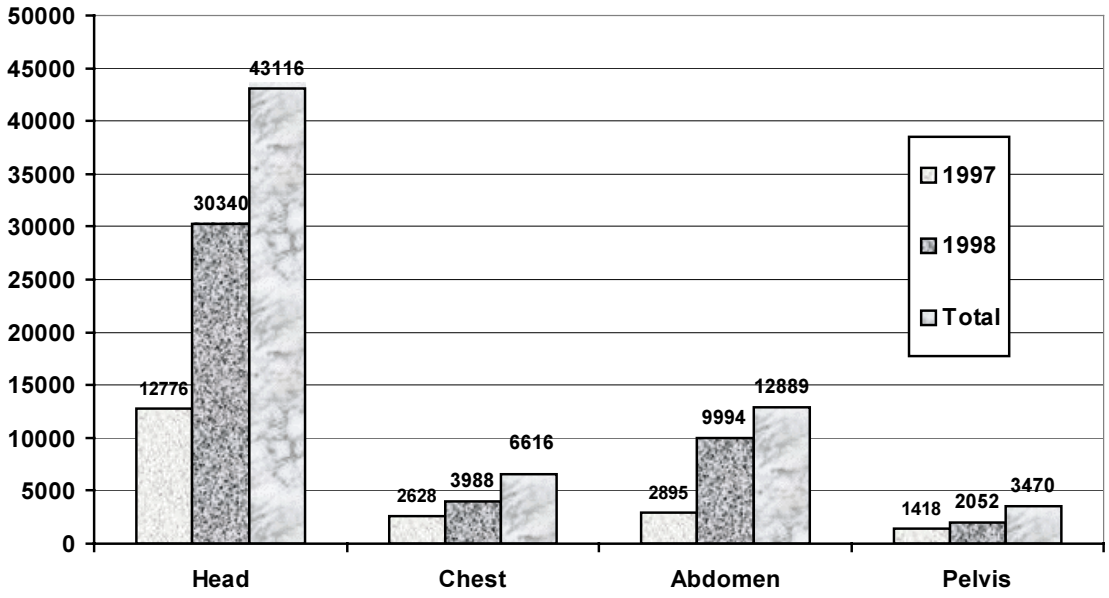

Figure 2. Number and structure of CT examinations in north-east region of Ukraine in 1997-1998

The results of determination of effective doses apply to average sized adult patient for the routine CT-examination of head, chest, abdomen and pelvis obtained using the heterogeneous anthropomorphic phantoms are given in the Table 1. The data are expressed in the terms of an effective dose conversion factor - effective dose normalized to CTDIn.

Table 1. Effective dose conversion factors for different kinds of CT examinations

Type of scanner	Examination	Effective dose conversion factors E/CTDIn, (mSv/mGy/mAs))	
		female phantom	male phantom
CPT-1010	Head	11.3	14.0
GE CT-MAX	Head	6.6	6.4
	Chest	19.5	19.9
	Abdomen	18.7	17.4
	Pelvis	13.8	9.6

The patient effective doses received during CT-examinations were assessed from CTDI measured of each CT scanner and changed for head from 0.3 up to 3.0 mSv, for chest from 2.6 to 12.4 mSv, for abdomen from 3.5 to 26.5 mSv, for pelvis from 2.0 to 18.5 mSv.

The derived collective doses from CT examinations performed in 1998 for adult patients are show on Figure 3. In addition, the comparison of number and collective effective doses for different kind of CT examinations is given on this Figure. The conclusion may be done that although only 21.6% of the CT examinations concern to abdomen, the contribution of this kind of CT examination to collective effective dose is the highest and makes about 50%. Whereas CT examinations of head represent 65.4% of the all examinations in 1998, its contribution to the collective dose is only 15%.

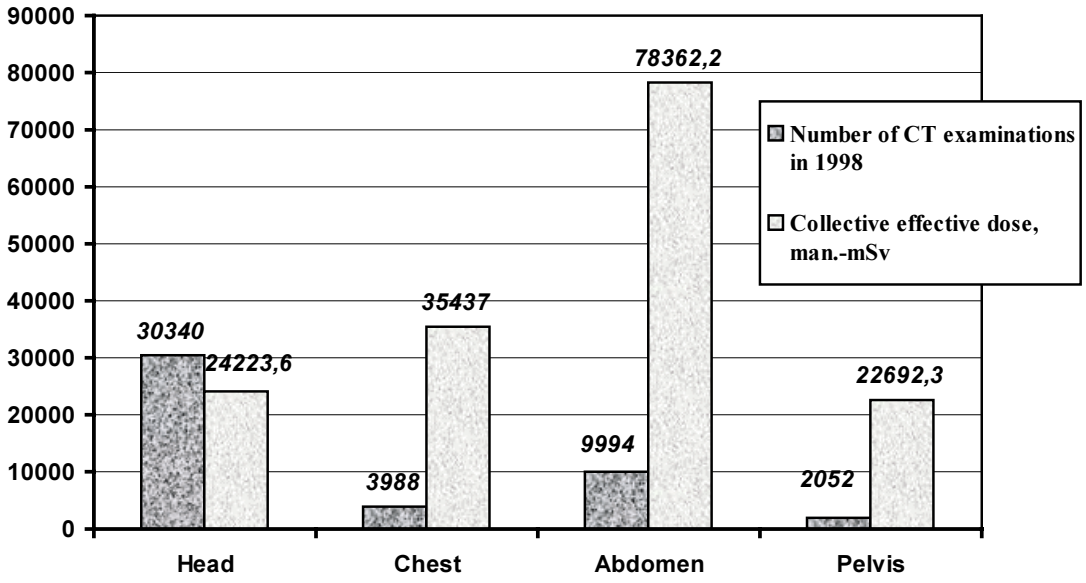

Figure 3. Number of CT examinations and collective effective dose (adults) in 1998

4. Conclusion

Realisation of regular CTDI measurements in CT departments is necessary for the evaluations of patient doses and for the estimations of the relative contribution of different kinds of CT examinations to collective effective dose.

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USE OF THE EC QUALITY CRITERIA AS A COMMON METHOD OF INSPECTING CT LABORATORIES– A PILOT PROJECT BY THE NORDIC RADIATION PROTECTION AUTHORITIES

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Abstract

In the frame of Nordic radiation protection co-operation quality criteria for computed tomography (CT) as published by the European Commission were used for the evaluation of selected CT laboratories in each of the Nordic countries. The mean values for all five countries of the weighted CT dose index ($CTDI_w$) and dose length product (DLP) were 60 mGy and 740 mGy·cm for CT of the brain, 11 mGy and 420 mGy·cm for CT of the chest, and 40 mGy and 420 mGy·cm for CT of the lumbar spine, respectively. A comparison with the reference levels set in the above mentioned publication gives a diversified result: compliance for the DLP-values is generally achieved with good margins whereas the $CTDI_w$–values were frequently larger for brain and lumbar spine examinations. The radiographic technique was generally also within the recommendations from the EC. Generally most of the image quality criteria were fulfilled, but it must be born in mind that the study was biased in the way that two local radiologists in consensus evaluated their own images. Image material from only three patients was selected for each of the clinical indications, that means the project was not designed for ranking laboratories, but it is a way of making the departments aware of the need for optimisation regarding image quality and patient dose, and also on the problems associated with this task. During the study suggestions were brought forward concerning amendments of the quality criteria: some need a better definition, some are not relevant for the diagnostic task in question, some could be added. Instead of "yes" and "no" a range of maybe 5 levels of visualisation should be introduced in order to better characterize the level of diagnostic performance.

1. Introduction

The radiological community has for long been aware of the increasing contribution from computed tomography (CT) to the collective effective dose. The reduction of exposures by optimisation of CT procedures is therefore of principal concern in radiological protection. The concept of "diagnostic reference levels" was promoted by the International Committee on Radiological Protection (ICRP) in 1996 [1], and adopted in the Medical Exposure Directive [2] by the European Commission, which also recently provided a set of image quality criteria for various CT procedures [3]. The radiation protection authorities in the five Nordic countries have for long been co-operating on surveys of patient doses in diagnostic radiology [4, 5], and also on legislation and inspection strategies. Within the frame of Nordic radiation protection co-operation a pilot project was initiated. The goal was to try whether the EC quality criteria for CT can be used as an inspection tool, and as a way of getting in touch with the local clinical practice.

2. Materials and methods

Data from five hospitals in each of the Nordic countries were collected. The image quality was evaluated according to the EC quality criteria for three examination types, with suggested specific clinical indications (to ensure that the patient group is homogenous): (a) Brain,

general (differential diagnosis of haemorrhage versus thrombosis/emboli) (b) Chest, general (suspected lung metastasis), and (c) CT of Lumbar Spine, discal herniation (sciatica/disc diagnosis, uncertain which root affected). Each of the hospitals was asked to select three representative patients for each indication (9 patients in total), to perform the examinations according to normal practice, and to present the images from the examinations on film. Staff from the radiation protection authority met at the hospital with two experienced CT radiologists and one CT radiographer (and a hospital physicist if present). The *two* local radiologists were evaluating the images in consensus, following the schemes in EUR 16262EN Appendix II [3]. The various criteria for visualisation and critical reproduction of anatomical details in the images should be answered with either "yes" or "no". If a criterion could not be evaluated it was marked by "NA" in the "yes" box. The radiographic technique for each of the patients was recorded with assistance of the CT radiographer (EUR 16262EN Appendix I). The $CTDI_w$, corrected for the pitch, and the DLP values were calculated from the exposure parameters using the nominal CTDI values for the respective scanners, using information from http://www.sghphy.demon.co.uk/index.htm (Impact, St. Georges' Hospital, London). If $CTDI_w$ and DLP values were provided on the CT monitor, compliance was checked by comparison with the calculated values. From EUR 16262EN Table 2 (page 67) the effective dose from the examination was assessed. In Norway the conversion factors provided by the National Radiological Protection Board (NRPB) in UK [6] were used additionally. The software called CTDOSE (Heron Le JC, National Radiation Laboratory, Christchurch, New Zealand), and the scanner matching data from the Impact group, were then used to calculate the effective dose and some organ doses (lenses, gonads).

3. Results

There were totally twenty-five laboratories included in the survey. The distribution of CT scanners is given in Table I. All except two were helical scanners, illustrating the development of technology during the past decade [7, 8].

Table I. The manufacturers of CT scanners in the survey

Manufacturer	Number of various CT scanner models
Elscint, Picker	1
General Electric	7
Picker	3
Toshiba	4
Philips	3
Siemens	6
Hitachi	1

Image criteria

The fulfilment of the EC quality criteria is shown in Table II, as the percentage of "yes" answers (that means the rest is the sum "No" or "NA" answers). The criteria for visualisation and critical reproduction of anatomical details are presented separately. In brain examinations, the percentage of "NA" answers approached 35 %, while the corresponding figure for lumbar spine examinations was 57 %. In both cases this was due to criteria connected to contrast administration, but the clinical indication did not require use of contrast. That means the number of not fulfilled criteria was actually rather small.

Table II. Total percentage fulfilled of the entire EC image quality criteria in each of the Nordic countries for CT examinations of brain, chest and lumbar spine

		# Criteria	Denmark	Finland	Iceland	Norway	Sweden
Brain	Visualisation	4	75 %	85 %	60 %	47 %	82 %
	Critical rep.	6	89 %	93 %	86 %	63 %	73 %
Chest	Visualisation	5	91 %	98 %	88 %	98 %	95 %
	Critical rep.	10	95 %	97 %	93 %	90 %	87 %
LS	Visualisation	3	40 %	53 %	33 %	43 %	33 %
	Critical rep.	8	85 %	87 %	82 %	76 %	53 %

Radiation dose to the patient

The mean values for each country of weighted CT dose index, dose length product and effective dose for all examinations of the brain, chest and lumbar spine are given in Table III, IV and V respectively. The number of examinations included in each country is given in parenthesis (the number of patients multiplied with the number of hospitals). The mean values for all five countries are also given in each table to be compared with the EC reference values.

Table III. Dose figures CT of the brain

	Denmark (15)	Finland (12)	Iceland (12)	Norway (18)	Sweden (15)	Mean value	EC reference value
$CTDI_w$ (mGy)	53	60	64	56	67	60	60
DLP(mGy·cm)	600	740	700	640	1030	740	1050
E (mSv)	1.4	1.7	1.6	1.5	2.4	1.7	–

Table IV. Dose figures CT of the chest

	Denmark (15)	Finland (12)	Iceland (12)	Norway (17)	Sweden (15)	Mean value	EC reference value
$CTDI_w$ (mGy)	10.6	10.6	11.7	10.5	10.9	10.8	30
DLP(mGy·cm)	420	530	440	350	350	420	650
E (mSv)	7.2	9.0	7.5	6.0	6.0	7.1	–

Table V. Dose figures CT of the lumbar spine

	Denmark (15)	Finland (12)	Iceland (12)	Norway (18)	Sweden (12)	Mean value	EC* reference value
$CTDI_w$ (mGy)	40	40	45	32	40	40	35
DLP(mGy·cm)	430	460	450	250	500	420	800
E (mSv)	8.2	8.6	8.6	4.8	9.5	7.9	–

* no specific values provided, the values are for routine abdomen

The effective dose calculated from the DLP values compared with the effective dose based on the NRPB method was within 2% for the brain, 15% lower for the chest, and 22% higher for the LS columna. For brain examinations in Norway the lens doses ranged from 4.8–56.3 mGy depending on whether the lenses were included in the primary scan volume or not. The uterus

doses ranged from 4.5–10.9 mGy for lumbar spine examinations, while the uterus dose for chest examinations generally were below 0.1 mGy.

Imaging technique
The radiographic technique was generally in accordance with the European guidelines [3]. However, it was some variance in window width and window level settings, and some laboratories used pitch higher than one for the brain examinations. Most brain and lumbar spine examinations were done using axial scan technique, while helical technique with pitch around 1.5 was used for chest examinations.

For the chest examinations it varied between the laboratories whether the upper abdomen was included or not. It also varied whether a separate series was done before the contrast administration or not. The total scan length calculated as the sum of the scan lengths for all series therefore ranged from 160–780 mm, with a mean of 370 mm.

4. Discussion and conclusion

The dose results
$CTDI_w$ as defined in the EC guidelines is not corrected for the pitch. The lower $CTDI_w$ values for chest examinations in the Nordic countries compared to the reference value is partly explained by this fact. Otherwise, the mean $CTDI_w$ values from this survey are equal to or higher than the EC reference values. The DLP values were considerably lower than the EC reference values, probably because of shorter total scan lengths, for example, the higher DLP value in the Swedish brain examinations is explained by procedures including both series with and without contrast. The effective doses in the present survey are in the same range as previously published Nordic results [8, 9].

The image evaluation
- The noise, spatial resolution and diagnostic acceptability were generally valued as good.
- A low percentage “yes” in the image evaluation schemes did not necessarily indicate poor quality. Patient age and pathology was certainly also an explanation for both “NA” and “no” answers, in addition to the various use of pre-contrast series.
- The image evaluation was film based, while now it is more common to use a workstation for diagnostics. This may have affected the choice of window settings, and the selection of images recorded on film, which in some respect differed from the EC recommendations.

The inspection strategy
This Nordic pilot project shows that the EC quality criteria can be used as a collaborative inspection tool. The main benefit from the method was to get in touch with the hospitals and introduce the EC quality criteria to the local staff. This may have encouraged discussion about local techniques, image quality and optimisation of the CT procedures. However, the radiologists work within their own reference frames. That introduces a bias, and the survey design is not suitable for ranking. For that purpose it would be better using an independent panel of radiologist evaluating the images, and a grading system for image evaluation.

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IAEA-CN-85-203

ESTABLISHMENT OF COMPUTED TOMOGRAPHY REFERENCE DOSE LEVELS IN ONASSIS CARDIAC SURGERY CENTER

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Abstract

The purpose of the study was to apply European Commission (EC) Reference Dose Levels (RDL) in Computed Tomography (CT) examinations at Onassis Cardiac Surgery Center (OCSC). These are weighted CT Dose Index ($CTDI_w$) for a single slice and Dose-Length Product (DLP) for a complete examination. During the period 1998-1999, the total number of CT examinations, every type of CT examination, patient related data and technical parameters of the examinations were recorded. The most frequent examinations were chosen for investigation which were the head, chest, abdomen and pelvis. CTDI measurements were performed and $CTDI_w$ and DLP were calculated. Third Quartile values of $CTDI_w$ were chosen to be 43mGy for head, 8mGy for chest, and 22mGy for abdomen and pelvis examinations. Third Quartile values of DLP were chosen to be 740mGycm for head, 370mGycm for chest, 490mGycm for abdomen and 420mGycm for pelvis examination. Results confirm that OCSC follows successfully the proposed RDL for the head, chest, abdomen and pelvis examinations in terms of radiation dose.

1. Introduction

The development of Computed Tomography (CT) scanners has been one of the most explosive phenomena in modern medicine. They were introduced in clinical practice in 1972[1]. CT provides high quality cross-sectional images and increasing application of this modality has made a substantial impact on both patient care and population exposure from medical X-rays. Conditions of exposure during CT examinations differ from those in conventional X-ray procedures. National surveys on CT practice have established the increasing importance of CT as significant source of medical exposure to X-rays [2]. The growth of CT technology and its widespread use make CT scanners to account for around 40% of medical exposure to X-rays for the general population, while representing only 4% of the total number of such procedures [3]. The European Council Directive 97/43/Euratom [4] suggests that an examination should only be carried out on the basis of a justifiable clinical indication, and exposure of the patient should always be limited to the minimum necessary to meet clinical objectives. The optimal use of ionizing radiation involves the interaction of three important aspects of imaging process. These are the image quality, radiation dose to the patient, and choice of examination technique. One of the basic principles of radiation protection is to try and keep the dose to the patient As Low As Reasonably Achievable (ALARA) consistent with the clinical requirements. The European Commission (EC) recently proposed certain guidelines in order to optimize the protection of patients [5]. These guidelines suggest quality criteria in order to define a level of performance considered necessary to produce images of standard quality for a particular anatomical region. Quality criteria are presented for several CT examinations and apply to standard adult patients undergoing usual application of the technique for the type of examination under consideration. These are divided into four parts which are diagnostic requirements, criteria for radiation dose to the patient, example of good imaging technique and clinical conditions with impact on imaging performance.

The guidelines also introduce the concept of Diagnostic Reference Levels (RDL). These are defined in order to facilitate optimization of protection in medical exposure and to allow

comparison of performance. The quantities suggested by the EC are the weighted CT dose index ($CTDI_w$) and the dose-length product (DLP). A summary of the RDL proposed can be seen in Table I.

Table I. Proposed European Commission (EC) Reference Dose Levels (RDL) for routine Computed Tomography (CT) examinations

Procedure	Weighted CT Dose Index $CTDI_w$ (mGy)	Dose-Length Product DLP (mGycm)
Head	60	1050
Chest	30	650
Abdomen	35	800
Pelvis	35	600

$CTDI_w$ is an estimate of the average dose over a single slice (or per rotation for helical scanning) in a CT dosimetry phantom and is given by the equation:

$$CTDI_w = (1/3)CTDI_{100c} + (2/3)CTDI_{100p} \quad \text{(mGy)} \qquad (1)$$

$CTDI_{100c}$ and $CTDI_{100p}$ represent dose measurements made with a 100mm pencil ionization chamber at the center (c) and periphery (p) of a standard head or body polymethylmethacrylate (PMMA) phantom [5].

DLP includes the volume of the patient irradiated in the course of a complete examination. It is given by the equation:

$$DLP = \sum_i CTDIw \bullet TNC \qquad \text{mGycm} \qquad (2) \quad \text{and}$$

$$DLP = \sum_i CTDIw \bullet TAt \qquad \text{mGycm} \qquad (3)$$

for serial and spiral scanning respectively. In equation (2) *i* represents each scan sequence forming part of the examination and N is the number of slices of thickness T in cm. In equation (3) *i* represents each helical scan sequence forming part of the examination, T is the nominal irradiated slice thickness in cm, A is the tube current in mA, and *t* is the total acquisition time in sec.

2. Methods

The present methods are based upon those proposed by the EC guidelines. Assessment of image quality is not included in this work, which was focused on implementing the quality criteria for radiation dose to the patient.

The CT scanner installed at the Onassis Cardiac Surgery Center (OCSC) is a Picker PQ 5000V. Spiral scanning is performed for all procedures apart from the head and face & sinuses examinations. Every type of CT examination which was performed at OCSC during the period 1998-1999 was recorded and categorized following EC guidelines. The total number of procedures of each type of examination was then calculated so as to decide which of them

should be initially investigated. Then, a random sample of 10 standard-sized patients was taken for each chosen procedure using established techniques.

Dosimetry measurements were carried out using a pencil-shaped ionization chamber (Radcal, Model 20x5-10.3CT) connected to a radiation measuring device (Model 2025AC). $CTDI_c$ and $CTDI_p$ were measured by placing the ionization chamber in the center and the periphery of a head phantom for head examination and in a body phantom for body examinations. $CTDI_w$ and DLP were then calculated according to EC guidelines, in order to check compliance with dose criteria.

Finally third quartile values of the above quantities were calculated for every examination in investigation and a comparison was made with the proposed RDL.

3. Results

The results of the survey revealed that the examinations that accounted for 92% of the total procedures performed at OCSC for the period 1998-1999 were the head, chest, abdomen and pelvis. Chest examination was found to be the most frequent type with a percentage of 34%. This is easily explained by the fact that our hospital is a dedicated cardiac surgery center dealing almost exclusively with patients having cardiological problems. The next most frequent procedures were head and abdomen having a percentage of 23% each, followed by the pelvis examination having a percentage of 12%. Table II presents the protocols used for each type of examination.

Table II. Routine CT examinations protocols in Onassis Cardiac Surgery Center (OCSC)

Procedure	*kV*	*mA*	*mAs*	*T (mm)*
Head	130	250	394	4, 8
Chest	120	225	144	8
Abdomen	120	250	394	10
Pelvis	120	250	394	10

The protocols are fixed for every standard-sized patient and are altered only for very thin or obese patients. Therefore, $CTDI_w$ has a certain constant value for every type of examination (Table III). The table includes also the proposed RDL so as a direct comparison can be done. Our results are well below the proposed values and what is really encouraging is that the chest examination which is the most frequent in our center has a $CTDI_w$ of 8.3mGy which is 3.6 times less than the EC value. The low $CTDI_w$ value of the chest examination is probably due to the low value of mAs-product (144mAs) used, compared to the values presented by other authors such as Clarke [6] whose mAs-product values ranged from 145mAs to 330mAs, or Hidajat [7] who presented a value of 180 mAs.

Table III. Weighted CT Dose Index ($CTDI_w$) values for routine examinations at OCSC compared to EC $CTDI_w$

Procedure	$CTDI_w$ (mGy)	EC $CTDI_w$ (mGy)
Head	43.5	60
Chest	8.3	30
Abdomen	22.5	35
Pelvis	22.5	35

DLP was then calculated and the results are found in Table IV together with the proposed EC values. The third quartile values which were found at OCSR are almost half the proposed EC RDL for the body examinations. It should be noted that all these examinations are performed using spiral scanning and that in most cases no additional scanning is performed since the software of the scanner is able of reconstructing images at every direction inside the body of the patient.

Table IV. Third quartile values of Dose-Length Product (DLP) for routine examinations at OCSC compared to EC DLP

Procedure	DLP (mGy cm)	EC DLP (mGy cm)
Head	740	1050
Chest	374	650
Abdomen	491	800
Pelvis	424	600

Taking into consideration all the above results, it was decided that the RDL at OCSC will be the ones found in Table V.

Table V. Reference Dose Levels for routine CT examinations at Onassis Cardiac Surgery Center

Procedure	$CTDI_w$ (mGy)	DLP (mGy cm)
Head	43	740
Chest	8	370
Abdomen	22	490
Pelvis	22	420

4. Conclusion

The initial investigation of the state of the art of CT examinations in terms of radiation dose revealed that OCSC CT scanner has a satisfactory dosimetric performance as far as the most frequent protocols are used. However, it should be noted that the setting and review of RDL should be a continuing process in order to promote continuous improvement over time. This means that they should always be pursued to achieve further dose reduction without compromising the diagnostic value of an individual examination.

Therefore, our study should extend to the other parts of the EC quality criteria so as to investigate the suitability of the proposed diagnostic requirements and the imaging techniques and if yes to ensure that they are also fulfilled.

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RADIATION PROTECTION OF PATIENTS DURING CT FLUOROSCOPY

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Abstract

CT fluoroscopy provides pseudo real-time cross sectional imaging and has been used in our clinic for biopsies, drainage and pain control. In the fluoroscopic configuration the radiologist stands in the room adjacent to the table as in conventional angiography. Because of concerns regarding patient doses, measurements were made to estimate doses.

Effective doses were calculated using the method of Huda and the data of NRPB. It was found that as far as the patient is concerned, two minutes of CT Fluoroscopy gave a similar effective dose as a standard abdomen CT exam. As in other CT scanners, the scattered dose decreases rapidly away from the radiation plane and is 1 mGy per minute at 10 from the image plane.

1. CT Fluoroscopy/Background

Our existing CT Scanner (Toshiba Express SX) can be used for fluoroscopic CT. In this pseudo real-time mode eight 512x512 frames are displayed per second. For each progressive frame only one eighth of the data (or 45^0) is changed. All the other back projections remain the same facilitating fast computation. The scanner can operate up to 50 mA for a fluoroscopy time of 120 seconds. The fluoroscopy system appears just as a normal angiography suite with a footswitch and video monitor in the room. When the scanner was first installed we carried out some measurements to look at staff and patient doses. Only patient doses are reported here.

2. Methods

Measurements were performed with the standard 32 cm diameter cylindrical acrylic dosimetry phantom, using a Radcal model 9010 dosimeter with a uniform response 10 cm CT chamber (model 20X5-10.3CT). Scatter measurements were made with a Keithley 36150 radiation survey meter. Because the surface dose changes in the phantom on a cyclic basis because of tube rotation, most measurements were made in the integral mode of operation.

3. Calculation of effective dose

There are two basic ways to approach the calculation of effective dose in CT. One is to estimate from actual CT scans the percentage volume of an organ irradiated to give average organ doses, and using doses from phantom measurements and tissue weighting factors arrive at E. This is extremely time consuming, so most efforts have been directed at computational methods using Monte Carlo techniques. Here average organ doses are estimated using a mathematical model of the body. The NRPB(National Radiological Protection Board, Oxford, UK) have been one of the groups involved in this and have published their data [1,2].

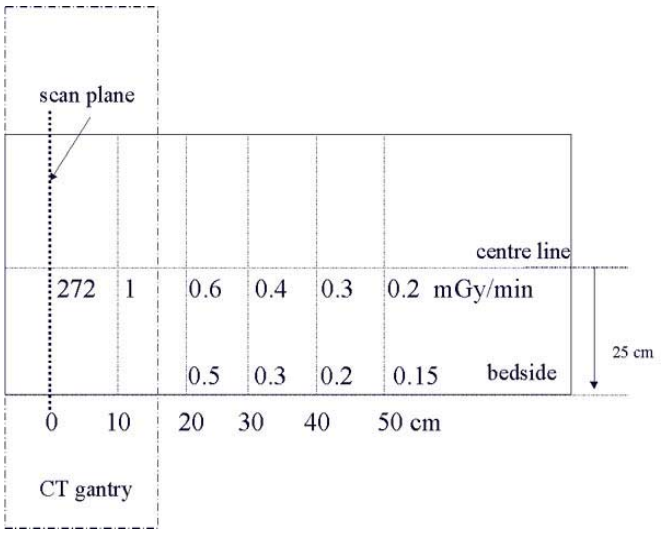
Dr Walter Huda and his colleagues at New York State University have built upon the work of NRPB to provide conversion factors from CTDI measurements [3-6], which are more commonly used by manufacturers to describe scanner performance. Over the thorax and abdomen the conversion factor from imparted energy to effective dose varies from about 15 to

23 mSv per J[5](The author suggest an average value of about 18). Because of this relatively small variation, given the many assumptions we make to calculate any human effective dose, it is straightforward to pro rate the effective dose for different slice sequences.

4. Patient dose

Measurements made in the acrylic phantom were converted to patient effective dose by calculation of energy imparted to the phantom. For normal single slice operation of the CT scanner for the abdomen at 120 kVp and 200 mAs and the effective dose was 0.24 mSv per cm slice. For fluoroscopic operation of the CT scanner for the abdomen at 120 kVp and 50 mA and 1 cm slice thickness the effective dose was 3.56 mSv per minute. Two minutes of CT fluoroscopy therefore gives an effective dose similar to a standard abdomen CT exam.

5. Radiation scatter



The radiation scatter was measured under the same scan conditions as for fluoroscopic CT described above. Because of the highly collimated narrow x-ray beam, the scattered radiation decreases rapidly outside the actual beam. At 10 cm from the beam plane on the surface of the phantom the air kerma dose rate has dropped to 1 mGy per minute(272 mGy per minute in the beam).

6. Clinical uses

For us the major uses so far for CT fluoroscopy have been 1.Biopsies: probably the most commonly used application 2. Drainage: Abscesses mostly, and again main advantage over US is visualizing the fluid collection deep in abdomen/pelvis, and ensuring safe pathway to access collection via percutaneous route (avoiding bowel, major vessels etc.), and 3. Much less commonly, injection of structures such as celiac plexus for pain control.

7. Future fluoroscopic CT

Several manufacturers have shown prototype multislice scanners which are capable of fluoroscopic use [7], and which we be available in the next 24 months. In general these are multislice scanners with slice thicknesses of less than 1 cm. As the effective dose increases as

the slice thickness decreases in order to counteract the reduction in data, procedural doses are likely to be in excess of current CT doses.

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Topical Session 3

RADIOLOGICAL PROTECTION IN INTERVENTIONAL RADIOLOGY, INCLUDING FLUOROSCOPY NOT CARRIED OUT BY RADIOLOGISTS

PATIENT DOSE IN INTERVENTIONAL RADIOLOGY

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Abstract

This paper presents the estimation of dose-area product (DAP) received by 128 patients during different interventional radiological procedures in the Hospital Universitario de Salamanca, analyzing the differences between procedures classified as either vascular, non vascular, diagnostic or therapeutic. These differences can be assessed and reference dose levels can be established as a function of the variation of those parameters.
Comparisons between dose-area product values obtained from this study are made with the data from nine other patient dose surveys, although explanations for some of the differences could not be obtained in some cases.
The reference values in these procedures in our centre are very high due to a great number of images, so the clinical protocol should be changed to avoid this problem.

1. Material y método

Todos los procedimientos han sido realizados en un equipo Philips Integris V-3000 Sincraboost T que lleva incorporada una cámara de transmisión PTW Diamentor que presenta un grado de incertidumbre menor al 10% tal y como demuestra el último control de calidad a la que fue sometida.

Para cada exploración radiológica se recogen datos que permitan realizar la estimación de la dosis de entrada en superficie (DES) en cada una de las localizaciones exploradas por el radiólogo. Los métodos de trabajo incluyendo las tablas de recogida de datos están explicados en la referencia [1]. En el caso de arteriografías cerebrales, adicionalmente se ha empleado TLD-100 con el fin de poder estimar los valores de dosis piel en el paciente tal y como se detalla en [1].

2. Resultados

En la tabla 1 se ofrecen los datos clasificados según sea el tipo de procedimiento: vascular o visceral, diagnóstico o terapéutico con datos del valor de PDA y su distribución porcentual y parámetros relevantes de la técnica empleada. Además se citan una serie de porcentajes, a saber:

% magnificación es el porcentaje del tiempo de escopia en el que se magnifica la imagen.

% cateterización muestra el porcentaje de tiempo de escopia empleado para el posicionamiento del catéter o para la colocación del stent.

% colimación expresa el porcentaje de pacientes en los que se ha empleado la colimación.

Los niveles de dosis obtenidos en arteriografía y flebografía son semejantes si bien el porcentaje de dosis debido a la escopia es mayor en el segundo caso y el número de imágenes es menor.

En el caso de procedimientos vasculares no se encuentran diferencias apreciables de niveles de PDA entre los diagnósticos y los terapéuticos. Cabe destacar que la edad media de los pacientes sometidos a embolización de varicocele es de 21 años y son irradiados en la zona

pélvica. Con respecto a otros procesos terapéuticos vasculares, en los que se cuenta con pocos estudios, sí hemos encontrado unos valores algo superiores como en el caso de embolización de shunt portacava percutáneo, en la embolización de hemorragias digestivas y en las angioplastias.

En el caso de procedimientos viscerales, hemos encontrado valores reducidos de PDA como en la dilatación esofágica (terapéutico). El valor de PDA está por debajo de 50 Gy*cm^2 con un número de imágenes reducido debido a que la finalidad es corroborar el procedimiento.

En la tabla 2, se muestran los valores de dosis piel medidos con TLD-100 en arteriografías cerebrales. El valor medio obtenido es de 338,9 mGy, siendo el máximo 1135 mGy, valor próximo al umbral de dosis única para el efecto en piel de eritema temporal (2 Gy).

La tabla 3 muestra los resultados obtenidos de PDA (Gy*cm^2) así como de tiempo de escopia y número de imágenes de los trabajos analizados en la bibliografía. Como se puede apreciar no es posible la comparación de todos los datos que este trabajo propone en ninguno de ellos.

3. Conclusiones

Los valores de referencia de nuestro centro, aunque en algún caso con un número de pacientes muy reducido, presentan unos valores muy elevados debido fundamentalmente al gran número de imágenes. Por lo tanto, el protocolo médico de este centro que exige un gran número de imágenes, redunda en un PDA muy alto.

La variabilidad de los resultados que se observa en la bibliografía presentada corrobora la dependencia de éstos con los distintos procedimientos clínicos y con el equipo usado en cada caso. Por lo tanto, el establecimiento de valores de dosis de referencia en radiología intervencionista debe tener en cuenta las variaciones intrínsecas debidas a estos efectos.

Un número de imágenes elevado, como el que se presenta, condiciona el resultado de PDA obtenido y en los casos en los que se puede comparar, existe correlación entre el valor de la estimación dosimétrica y el número de aquellas.

El porcentaje de magnificación en la mayoría de los procedimientos es bastante bajo salvo en arteriografías cerebrales en los que se emplean tamaños de intensificador más pequeños. Con respecto al porcentaje de cateterización se observa que es muy alto en los procedimientos diagnósticos, como se esperaba, pero no lo es tanto en los terapéuticos ya que en este caso el tiempo de escopia dedicado a la colocación del stent o del balloon es pequeño frente al tiempo que se dedica a la aplicación del mismo.

Finalmente, el tipo de resolución empleado ha sido siempre el medio y creemos que en algún caso se podría haber optado por el bajo con la consiguiente optimización de la dosis obtenida.

TABLA 1	Producto Dosis por Área (Gy. Cm^2)					Técnica			%		
Procedimiento (Nº)	**Medio**	**Mediana**	**Rango**	**Grafía**	**Escopia**	**T.e (m)**	**Series**	**Imágenes**	**Magnificación**	**Cateterización**	**Colimación**
Procedimientos DIAGNÓSTICOS VASCULARES – ARTERIOGRAFÍAS **											
Cerebral (48)	182.4	153.6	[491.3 - 19.5]	150.4	32	10.6	9	239	39.7%	58.7%	0%
Troncos sup.(21)	113.3	105.5	[184 – 51.6]	94.6	18.6	6	6.3	187	0%	76.6%	100%
M.inferiores (20)	129.6	104.3	[327.5 - 54.3]	118.9	10.7	2.6	5.2	120	0%	71,1%	42%
Via venosa (3)*	115.9	116.1	[118.5 - 113.2]	110.2	5.8	1.7	3.7	90.3	0%	80.8%	0%
Abdominal (3)*	99.5	93.4	[179.2 -26]	90.8	8.7	1.8	2.3	84.7	0%	85.3%	33%
Renal (5)	300.9	273.6	[530.1 - 63]	213.7	87.3	14.1	6.8	177.6	11.8%	89.7%	33%
Pulmonar (4)	138.3	151.1	[172.5 – 78.3]	90.8	47.5	12.8	5	20.7	0%	95.8%	0%
Procedimientos DIAGNÓSTICOS VASCULARES – FLEBOGRAFÍAS**											
Espermática (3)*	225.8	194.1	[407.1 – 76.2]	120.4	105.4	23.9	3.7	138.3	8.6%	90.3%	67%
Ovárica (3)*	198.5	216.7	[254.0 - 124.7]	125.6	72.9	16.3	6.3	185.7	0%	66.4%	0%
Fistulografía (5)	25.8	36.6	[39.7 – 4.5]	24.6	1.2	1.5	4.4	8.2	0%	79.6%	20%
Procedimientos TERAPÉUTICOS VASCULARES – EMBOLIZACIÓN **											
Em.varicocele (10)	153.5	130	[324.6 – 60]	79.2	74.3	17.3	4.3	108.9	21.9%	65.9%	20%
Procedimientos TERAPEÚTICOS VISCERALES – APARATO DIGESTIVO**											
Dil. Esofágica (3)*	42	41.4	[55.2 – 29.5]	1.2	40.8	12	4	7.3	0%	33.6%	0%

* Datos Preliminares.
** Resolución de la imagen utilizada: MEDIA.
(Nº): representa el número de procedimientos.

*TABLA 2 **	*MEDIA*	*MEDIANA*	*1º PERCENTIL*	*3º PERCENTIL*	*MÁXIMO*	*MÍNIMO*
Dosis piel máximo en Art. Cerebral (37)	338.9 mGy	250.2 mGy	93.5 mGy	527.9 mGy	1135 mGy	12 mGy

El valor de dosis en piel ha sido asignado al valor de dosis en piel máximo de entre 5 TLDs colocados en la cabeza del paciente [1]. () indica número de estudios

.**TABLA 3** (*) indica valores preliminares

Procedimiento	[autor] (nº proc)	PDA medio	PDA mediana	PDA rango	PDA grafía	PDA escopia	T.esc. (min)	Nº de imágenes
Art. Cerebral	Este trabajo (48)	182.4	153.6	20-491	150.4	32	10.6	239
	[3] (28)	74.1	69.6	21-196	45.8	28.2	12.1	-
	[4] (90)	45.8	-	-	-	-	-	-
	[8.a] (-)	67	-	-	-	-	-	-
	[8.b] (-)	23	-	-	-	-	-	-
	[8.c] (-)	82	-	-	-	-	-	-
	[9.a] (9)	50.53	53.6	21-79	-	-	16	172
	[9.b] (9)	82.83	74.8	39-131	-	-	18	81
	[10] (40)	66.63	51.8	15-232	-	-	-	-
Art. Miembros inferiores	Este trabajo (20)	129.6	104.3	54-328	118.9	10.7	2.6	120
	[2] (35)	61	33	9-77	19	11	4	37
	[3] (15)	79.8	61.7	8.5-187	51.9	28	7.5	-
	[7] (323)	77.9	68.6	<306	-	-	-	-
	[8.a] (-)	66	-	-	-	-	-	-
	[8.b] (-)	30	-	-	-	-	-	-
	[8.c] (-)	58	-	-	-	-	-	-
	[9.a] (18)	28	16	11-81	-	-	5	92
	[9.b] (12)	58.2	52	39-90	-	-	6	43
	[10] (40)	66.63	51.8	15-232	-	-	-	-
Aortografía abdominal	Este trabajo (3)	99.5	93.4	26-179	90.8	8.7	1.8	84.7
	[2] (16)	61	33	8-192	25	36	7	37
	[3] (21)	118	102	22-301	72.1	46.1	8	-
	[10] (-)	24.7	-	-	-	-	-	-
Art. Renal	Este trabajo (5)	300.9	273.6	63-560	213.7	87.3	14.1	177.6
	[3] (6)	39.8	36.5	17-72	22.1	17.7	5.1	-
	[5] (8)	95	-	41-186	-	-	12.1	-
	[6] (36)	77	75.3	<170	-	-	-	-
	[8.a] (-)	92	-	-	-	-	-	-
	[8.c] (-)	75	-	-	-	-	-	-
	[9.a] (9)	81.6	78.1	62-108	-	-	11	92
	[9.b] (10)	74.6	81	31-106	-	-	7	43
	[10] (14)	92.9	82.7	32-186	-	-	-	-
Art. Pulmonar	Este trabajo (4)	138.3	151.1	78-173	90.8	47.5	12.8	207.3
	[3] (7)	85.2	39	14-185	36.2	49	22.1	-
TIPS (vascular terapéutico)	Este trabajo (*)	444.8	-	-	382.4	62.4	12	82
	[3] (4)	524	347	<1131	125	400	48.4	-

	[7] (56)	182	158	<470	-	-	-	-
	[8.a] (-)	354	-	-	-	-	-	-
	[8.b] (-)	457	-	-	-	-	-	-
	[8.c] (-)	310	-	-	-	-	-	-
Embolización varicocele (vascular terapéutico)	Este trabajo (10)	153.5	130	60-325	79.2	74.3	17.3	108.9
	[2] (20)	75	62	7-260	2	73	13	3
	[8.b] (-)	75	-	-	-	-	-	-
	[8.c] (-)	106	-	-	-	-	-	-
	[9.a] (10)	80.4	79.1	37-135	-	-	20	38
	[9.b] (10)	106.3	101.8	43-180	-	-	30	2.2

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IAEA-CN-85-200

PATIENT DOSES IN INTERVENTIONAL CARDIOLOGY

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Abstract

Cardiovascular diseases are the first cause of dead in Spain. The most usual procedures in interventional cardiology are coronariography and PTCA. The first is a diagnostic technique, and the second one is interventional. Our goal has been to study procedures made during the first six months in the Interventional Cardiology Unit of the Juan Ramón Jimenez Hospital (Huelva-Spain), having in account radiation protection issues.
We have studied 178 patients; 145 of them were underwent coronariography, and 33 of the patients had PTCA too. Every case was analyzed having in account technical and dosimetric parameters.
We show parameters values gathered: Diagnostic techniques (valvular and non-valvular patients), and interventional techniques (coronariography and PTCA in different or in the same intervention.
Higher doses were obtained with valvular patients, although the number of frames was similar. Attending to therapeutic procedures, the highest values were got with the "double" interventions. Interventional procedures exceed in 60% doses got in diagnostic studies; this is because of the number of series and number of frames per series. Similar values obtained by other authors have been got.

1. Introducción

Las enfermedades cardiovasculares son la primera causa de muerte en España (un 38 por ciento del total de los decesos: 44,4 por ciento mujeres y 32,5 por ciento hombres) [1]. Estas enfermedades se agrupan en tres grandes bloques: patología coronaria (angina de pecho, infarto de miocardio y muerte súbita), valvulopatías (procesos que afectan a las cuatro válvulas cardiacas: aórtica, pulmonar, mitral y tricúspide) y dolencias congénitas. Los procedimientos más habituales en un laboratorio de hemodinámica y cardiología intervencionista de pacientes adultos son: coronariografías, estudios de pacientes valvulares en los que se incluye casi siempre la coronariografía de forma asociada y finalmente los procedimientos intervencionistas de dilatación coronaria (angioplastia).

La coronariografía o estudio del árbol coronario con la ayuda de la radioscopia sigue constituyendo el patrón de referencia para estudiar la presencia y extensión de la enfermedad coronaria. Su realización estará indicada si la presencia de enfermedad coronaria va a determinar de manera significativa el manejo del paciente, cuando se quiera valorar las posibilidades de revascularización coronaria o identificar a aquellos pacientes que presentan alto riesgo de complicaciones isquémicas. El procedimiento de coronariografía diagnóstica implica la canulación selectiva de la coronaria derecha y de la coronaria izquierda y la inyección de contraste yodado con filmación en diversas proyecciones. Finalmente, con otro catéter, se opacifica con 40 cc de contraste el ventrículo izquierdo y se filma en proyección OAD. El procedimiento valvular suele incluir la coronariografía anterior y manipulaciones adicionales con monitorización en radioscopia para mediciones fisiológicas. A veces se realiza además opacificación de la aorta ascendente con 60 cc de contraste.

La angioplastia coronaria transluminal percutánea (ACTP) se ha convertido desde 1992 en la técnica de revascularización miocárdica más frecuentemente utilizada en España[2,3]. Consiste en la dilatación de una o varias estenosis dentro de una o varias arterias coronarias.

Según la complejidad se necesitan periodos variables de radioscopia y filmación coronariográfica. Habitualmente, la angioplastia precisa de un estudio coronariográfico previo completo que puede hacerse en una sesión aparte o bien en inmediata continuidad con la angioplastia.

La proliferación de ACTP es creciente[4], y ha venido acompañada de la descripción de casos de efectos deterministas, fundamentalmente en piel, debidos a las altas dosis de radiación involucradas en los procedimientos tanto diagnósticos [5] como terapéuticos [6].

En nuestro trabajo hemos pretendido caracterizar desde el punto de vista de la protección radiológica las intervenciones realizadas durante el primer semestre de funcionamiento del Laboratorio de hemodinámica del Área Hospitalaria Juan Ramón Jiménez de Huelva.

2. Material y métodos

Hemos analizado los datos de los procedimientos realizados sobre 178 pacientes, en el periodo comprendido entre el 22 de junio y el 29 de septiembre de 2000. De esos pacientes, 133 (74.7%) sufrieron únicamente coronariografía diagnóstica (identificados como "CORO"), 12 (6.7%) eran pacientes valvulares que sufrieron coronariografía (identificados como "VAL-CORO"), 20 (11.2%) fueron citados tras una coronariografía para una ACTP (identificados como "ACTP"), y 13 (7.3%) sufrieron la coronariografía y la angioplastia en la misma sesión (identificados como "CORO-ACTP").

De cada paciente se dispuso de los siguientes datos: Producto dosis-área (PDA) por radioscopia, por grafía y total; nº de series de grafía realizadas, y para cada serie, nº de imágenes, velocidad de adquisición, identificada por el protocolo de adquisición empleado ("ventrículo" con 25 imágenes por segundo, y coronario, con 12.5), kVp, mA y tiempo de exposición, ángulos cráneo-caudal y lateral del arco, distancia foco-receptor de imagen y tamaño de campo empleado.

3. Resultados

Se muestran, para cada uno de los cuatro grupos, los valores promedio, intervalos de incertidumbre al 90% de confianza, de acuerdo a una distribución t de Student salvo para el grupo "CORO" que suponemos se ajusta bien a una distribución normal, valores máximo y mínimo de todos los parámetros disponibles para cada estudio.

Se agrupan en coronariografías generales y de pacientes valvulares (CORO Y VAL-CORO) en la Tabla I, y pacientes coronariográficos que sufrieron posteriormente (ACTP) o en el mismo acto (CORO-ACTP) una angioplastia, en la Tabla II.

4. Discusión

Para procedimientos exclusivamente diagnósticos, en pacientes valvulares se ha obtenido una dosis a paciente similar por radioscopia que por grafía, con un PDA total de 41.3 $Gy \cdot cm^2$. Para pacientes no valvulares, el tiempo y la dosis por radioscopia es aproximadamente la mitad, con la consiguiente reducción en el PDA (27.8 $Gy \cdot cm^2$). El número de series y el número de imágenes por serie, en promedio, son prácticamente iguales en ambos tipos de pacientes.

Tabla I. Coronariografías generales y de pacientes valvulares (CORO Y VAL-CORO)

ESTUDIO	VAL-COROS				COROS			
	12 Pacientes				133 Pacientes			
	Med.	Inc.	Máx.	Min.	Med.	Inc.	Máx.	Min.
PDA Radioscopia	20.0	21.2	45.5	3.6	8.2	6.1	31.7	0.6
PDA Radiografía	21.3	29.4	50.8	4.9	19.6	9.9	66.6	0.3
PDA Total	41.3	48.5	96.3	8.5	27.8	15.9	98.3	0.9
t Radioscopia.(min.)	10.7	8.2	22.3	4.5	4.4	2.8	18.4	1.5
Nº Series	12	9.0	28	7	11	4	36	1
Nº Imágenes	723	517.3	1551	276	758	325	2114	32
kVp	73.8	10.0	89.0	64.8	72.7	4.0	86.9	60.0
mA	621.8	151.4	752.3	433.4	620.2	77.6	789.9	315.0
Edad	68.9	129.8	84.6	42.3	62.0	90.3	99.9	38.8
Uso APR "Ventrículo"	1.1	1.8	4.0	0.0	0.9	0.8	7.0	0.0
Uso APR "Coronario"	11.3	10.0	28.0	3.0	10.3	4.3	36.0	0.0
Distancia FR	105.1	5.2	110.7	99.7	103.7	2.5	115.4	98.1
Uso lupa 17	7.1	10.3	28.0	0.0	8.1	4.4	19.0	0.0
Uso lupa 23	5.3	5.6	13.0	0.0	3.2	3.9	29.0	0.0

Med. Media; Inc. Incertidumbre; Máx. Máximo; Min. Mínimo; PDA.- Producto de la dosis por el área irradiada.

Tabla II. Pacientes coronariográficos más angioplastia posterior (ACTP) o en el mismo acto (CORO-ACTP) una angioplastia

ESTUDIO	ACTP-H				CORO-ACTP			
	13 Pacientes				20 Pacientes			
	Med.	Inc.	Máx.	Min.	Med.	Inc.	Máx.	Min.
PDA Radioscopia	22.8	29.9	53.3	3.9	19.1	30.8	84.3	6.6
PDA Radiografía	28.2	35.8	59.3	8.2	48.1	45.2	126.2	15.6
PDA Total	51.0	60.6	112.6	12.1	67.2	74.0	210.5	26.1
t Radioscopia.(min.)	11.1	10.7	27.6	3.4	7.5	6.7	14.9	3.2
Nº Series	28	21.5	51	9	20.9	11.5	38.1	12.2
Nº Imágenes	923	795.1	2304	366	1191.3	787.9	2183.8	478.7
kVp	76.2	8.3	87.2	69.4	60.2	5.8	68.6	55.0
mA	703.1	113.8	815.8	576.5	539.5	102.2	632.2	423.0
Edad	61.9	126.1	89.0	43.7	47.7	118.2	61.4	0.1
Uso APR "Ventrículo"	0.1	0.4	1.0	0.0	1.3	3.9	7.3	0.0
Uso APR "Coronario"	27.8	21.6	51.0	8.0	19.7	14.3	37.3	6.5
Distancia FR	105.3	6.6	113.6	97.2	84.8	3.0	88.7	82.4
Uso lupa 17	26.0	24.5	51.0	0.0	18.1	12.8	37.3	5.7
Uso lupa 23	1.9	8.7	22.0	0.0	2.9	4.1	8.9	0.0

Med. Media; Inc. Incertidumbre; Máx. Máximo; Min. Mínimo; PDA.- Producto de la dosis por el área irradiada.

Para pacientes que sufren angioplastia, se observan valores superiores de PDA por grafía en aquellos en los que se realiza la misma a continuación del estudio diagnóstico, como es de esperar al tratarse de un estudio “doble”. Los valores de radioscopia son similares, e incluso los de número de series, pero no así el de imágenes por serie, que es casi de 300 imágenes superior, en promedio, para el procedimiento extendido.

Comparando procedimientos terapéuticos frente a diagnósticos, se evidencia una mayor dosis a paciente en los primeros, de casi un 60% superior en promedio, debido fundamentalmente a que se duplican las series por paciente, y el número de imágenes por serie, que es superior en promedio en unas 300 imágenes.

En todos los procedimientos son mayoritarios el uso de tamaño de campo de 17 cm. y velocidad de adquisición de 12.5 imágenes por segundo.

En la Tabla III comparamos nuestros valores (en cursiva) con valores de otros autores, encontrando buena correspondencia.

Tabla III. Análisis comparativo de nuestros resultados con los obtenidos por otros autores

Tiempo de radioscopia (min.) media (min.-máx.)		PDA (Gy·cm^2)		Nº de imágenes	
Coronariografía	ACTP	Coronariografía	ACTP	Coronariografía	ACTP
4.4 (1.5-18.4)	**11.2 (3.4-27.6)**	**27.8 (0.9-98.3)**	**51 (60.6-112.6)**	**758 (32-2114)**	**923 (366-2304)**
0.35 [7]	12 (7-35) [8]	72.18 [7]	100 [8]	1550 [7]	450 [7]
3.55 [9]	12.8 (0.1-180) [10]	39.3 [9]	81.68 [11]		1434 [9]
	15.5 (2.63-61.1) [7]		93 (33-402) [12]		
	18.6 [9]		28.5 (20-50.5) [13]		
			110 (40-340) [16]		
			87.5 (67-122) [15]		
			58 (0.5-810) [10]		
			101.9 [9]		
			93.3 [7]		
			91.8 [17]		
			42.0 [14]		
			60.0 [18-19]		

Entre paréntesis el rango.

Es oportuno destacar, como queda de manifiesto en este trabajo, las cada vez mayores posibilidades que ofrecen los equipos dedicados a estudios hemodinámicos, a la hora de caracterizar de forma precisa la dosis efectiva al paciente, como resultado de la identificación exhaustiva de las proyecciones y tamaños de campo empleados, como de los PDA obtenidos.

Queda, para completar un nivel superior de información del detrimento radiológico al paciente, de acuerdo a la clasificación del grupo de expertos del Artículo 31 de la Directiva MED [20], la implementación de métodos asumibles [21] para la determinación de la dosis a órganos y dosis efectiva, que, en cardiología intervencionista, es especialmente complicado por la profusión de proyecciones no coplanares.

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IAEA-CN-85-76

RADIATION RISK EVALUATION AND REFERENCE DOSES IN INTERVENTIONAL RADIOLOGY

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Abstract

In interventional radiology, there are two potential hazards to the patient. These are somatic risks and, for certain procedures, deterministic injuries. The task of radiation protection in interventional radiology is to minimise somatic risks and avoid deterministic injuries. Radiation protection tools and protocols must be developed to achieve these two objectives. Reference doses have been proposed as a method of identifying high dose centres and equipment. The role of reference doses in interventional radiology will be discussed. There are two approaches to reference doses in interventional radiology. These are the measurement of patient entrance skin dose or skin dose rate, or image intensifier input dose rate. Alternatively, dose area product or effective dose to the patient may be monitored. These two main approaches have their advantages and disadvantages.

1. Introduction

The International Commission on Radiological Protection first introduced the concept of reference doses in Publication 60 [1]. The use of reference doses has been expanded in Report 73 [2]. In paragraph 100 '*the commission now recommends the use of diagnostic reference levels for patients. These levels which are a form of investigation level apply to an easily measured quantity, usually the absorbed dose in air or in a tissue equivalent material at the surface of a simple standard phantom or representative patient'.* ICRP introduced the concept of reference doses as a means of identifying centres, equipment or procedures that consistently exceeded the appropriate reference dose level. If these reference dose levels were exceeded, then it was intended that there would be a local review of practice and procedures within the centre and that optimisation studies would be concentrated on high dose equipment as a consequence.

Reference levels were intended to apply to medical exposures and not to occupational or public exposures and are therefore entirely different in nature from dose limits and dose constraints. In practice, reference doses may be regarded as an optimisation tool for the reduction of patient doses in radiology. It was intended by ICRP that the reference dose levels would be selected by professional medical bodies and reviewed as they regarded reference doses as an evolving concept that would continually drive down radiation dose levels to patients.

2. Interventional radiology

Interventional radiology procedures almost invariably involve the use of fluoroscopy using image intensification. There has been a number of reports of deterministic injuries occurring in patients undergoing certain types of interventional radiology procedures that have long fluoroscopy times. Thus, the purpose of applying reference doses in interventional radiology is to minimise the risk of somatic effects and to avoid the occurrence of deterministic injuries for certain types of procedure.

Deterministic injuries in interventional radiology can occur as a result of a combination of factors. The main contributing factor found in an analysis of previous incidences was found to be the use of high dose rate equipment [3]. Another factor was the lack of training and education of the practitioner performing interventional procedures. Moreover the type of protocol used to perform an interventional procedure will have a dramatic influence on the absorbed dose received by patients during that particular procedure.

As the potential for deterministic injuries in interventional radiology could be the result of many different underlying reasons, it is necessary to develop a sophisticated approach to the application of reference doses in interventional radiology procedures. For example, simplistic approaches based upon the measurement of equipment based parameters such as image intensifier input dose rate or entrance dose rate at the patients skin will serve to only identify those centres where the equipment is either incorrectly set up and at the high dose end of the spectrum of equipment used. This approach will not pick up deterministic injuries that occur as a consequence of poor clinical protocols. The alternative approach of establishing reference doses on the basis of patient dose measurements involving either dose area product or effective dose has the advantage of being able to assess whether the clinical examination protocol has contributed to the occurrence of deterministic injuries, but it is difficult to establish whether this is alone the cause on the basis of a single measurement. This paper will describe the two approaches to assessing reference doses in interventional radiology and present a set of reference doses for both equipment related and patient related dose quantities. Furthermore, the advantages and disadvantages of these approaches will be compared and contrasted.

3. Approaches to establishing reference doses

The problem with the use of fluoroscopy equipment for interventional radiology is that the procedures are almost invariably performed under a variety of forms of automated control. As a consequence, the technique factors continually vary during the examination that makes the calculation of patient doses extremely difficult for interventional radiology. Consequently, for this type of examination it is common practice to measure either the dose area product or air-kerma area product by using a large area ionisation chamber attached to the output port of the x-ray tube. The ionisation chamber intercepts the entire radiation beam and the reading is a combination of the area of the patient irradiated and the absorbed dose across the beam. The quantity dose area product has the advantage of being independent of the plane of measurement away from the source of the x-rays. It is possible to convert a dose area product or air-kerma area product reading to the quantities energy imparted and effective dose. This involves the simulation of the procedure and the measurement of radiation dose in a phantom using thermoluminescent dosimeters. Alternatively, radiation transport calculations can be made in mathematical models. Conversion factors are examination specific and depend, for example, upon the area of the patient irradiated and the projection directions used.

Many international bodies and regulatory authorities have specified reference dose in terms of the maximum entrance dose rate at the patient's surface during fluoroscopy. However, none of the regulatory bodies have specified a measurement protocol to assess this quantity. In addition, there is no established international consensus upon the reference value that should be applied as may be deduced from Table I [4]. An alternative quantity, which can be used and easily measured, as part of a quality control programme for fluoroscopy equipment is a measurement of dose rate or air-kerma rate at the image intensifier, input surface. This measurement is usually performed as part of a protocol for the assessment of image quality. A

1 or 1.5 mm copper filter is placed at the x-ray tube housing and an ionisation chamber is placed as close as possible to the input surface of the image intensifier. Measurements are performed at typical technique factors selected by the automatic control system.

Table I. References Dose Rates Recommended by National and International Bodies

Organisation	Fluoroscopy Mode	Dose-rate (mGy/min)
IAEA	Normal	25
IAEA	High level	100
UK	Any	100+
FDA	Normal	50
AAPM	Normal	65

+should not exceed 50 mGy/min.

4. Results

Table II presents a series of reference doses for a number of interventional procedures [5]. These reference doses have been deduced from a large-scale patient dose survey in the North of England performed in a number of x-ray departments in hospitals. The reference dose value is taken to be the 75^{th} percentile of the dose distribution.

Table II. Reference Values for Interventional Procedures. Size Corrected Dose-Area Product ($Gy.cm^2$)

Examination	Reference Value
ERCP	19.39
Angiogram	24.26
Venogram	3.61
Hysterosalpingogram	4.12
Angioplasty	16.92
T-tube cholangiogram	9.70

5. Discussion

Measurement of image intensifier input dose rate is relatively easily made. It will be performed as part of a quality control programme for fluoroscopy equipment. It will identify equipment which has been poorly set up or calibrated or where the performance of the image intensifier has deteriorated over a period of time. It will not, however, be appropriate to use this to assess all centres where deterministic injuries may occur, as the injuries could be the result of use of inappropriate patient protocols.

An alternative approach, that of measuring the patient entrance surface dose rate which may be performed using phantoms, has the advantage that it will measure a quantity from which it is possible to deduce the maximum entrance dose from a knowledge of the total elapsed fluoroscopy time. This requires centres to record examination details such as total fluoroscopy time and number of acquired images. Its disadvantage is that it will overestimate maximum skin entrance dose unless an examination specific reduction factor is applied to take into account the fact that the irradiated area changes throughout interventional procedures. It will, however, detect equipment that is poorly calibrated or set up but once again it's main failing lies with the lack of its sensitivity to assessing problems with patient protocols.

The assessment of dose area product or effective dose using a dose area product meter has the advantage of producing a quantity that is closely related to the somatic risk of the procedure. For this reason, it is recommended for use, as it will give an indication of those centres where the somatic risks are going to be the greatest. Unfortunately, its relationship to maximum skin entrance dose is somewhat tenuous. For example, examinations that have a high dose area product will not necessarily result in a high risk of deterministic injuries to the patient because the irradiated area may change during the examination. It is therefore recommended that a combined approach to the application of reference doses in interventional radiology be adopted. This would involve the measurement of phantom related dose quantities such as image intensifier, input dose rate or maximum skin entrance dose rate at the surface of a patient equivalent phantom, as well as the assessment of effective dose using dose-area for procedures actually performed on patients.

One problem with the use of effective dose measured on patients could be the difficulty of measuring the quantity on a group of patients whose size and build correspond to that of reference man or woman. Interventional radiology is a type of procedure that is performed on relatively sick patients who may not have the same size and composition as reference man. As a result, it may be difficult to determine the reference dose for a group of patients whose size corresponds to that of reference man. In these circumstances it is probably best to perform the series of measurements on all patients who attend the clinic for a specific interventional procedure and apply a height and weight conversion factor to allow for any deviation in size and composition from that of reference man [6]. This technique was first proposed by Linskoug [6] and has been further developed by Chapple et al [7]. It enables reference doses to be obtained from large-scale patient dose surveys by correcting each individual dose quantity into that which it would have been if the individual corresponded to the size and composition of reference man. Thus, there will be a greater statistical certainty are put on the dose quantity derived in this manner.

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AN ASSESSMENT OF METHODS FOR MONITORING ENTRANCE SURFACE DOSE IN FLUOROSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES*

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Abstract

In the light of a growing awareness of the risks of inducing skin injuries as a consequence of fluoroscopically guided interventional procedures (FGIPs), this paper compares three methods of monitoring entrance surface dose (ESD) It also reports measurements of ESDs made during the period August 1998 to June 1999 on 137 patients undergoing cardiac, neurological and general FGIPs. Although the sample is small, the results reinforce the need for routine assessments to be made of ESDs in FGIPs. At present, the most reliable and accurate form of ESD measurement would seem to be arrays of TLDs. However, transducer based methods, although likely to be less accurate, have considerable advantages in relation to a continuous monitoring programme. It is also suggested that there may be the potential locally for threshold dose area product (DAP) values to be set for specific procedures. These could be used to provide early warning of the potential for skin injuries.

1. Introduction

In fluoroscopically guided interventional procedures, patients are being exposed to highly localised X-ray sources for extended periods of time long enough to cause possible skin injuries. A number of cases of severe skin injuries have been reported, which illustrate the importance of dose saving techniques and monitoring procedures [1, 2]. The severity of deterministic skin injuries increases with increasing absorbed dose and has a threshold level under which no noticeable effects occur. Above a dose of 2 Gy, a transient erythema can develop within hours of the procedure. This erythema is temporary and will fade within a week or two. Skin injuries such as dermal necrosis and talangiectasis occur at much higher doses of between 12 Gy and 20 Gy [3] and although cases have been reported of patients receiving serious skin injuries suggestive of such high doses [4], most patients receive ESDs, which are significantly below this level. A dosimetry study was undertaken comparing several methods of monitoring patient dose with a view to identifying the most reliable and 'user-friendly' method for routine use in a clinical environment.

2. Methods and materials

Doses were measured in one of three ways.

1. Thermoluminescent Dosemeters (TLD)

Lithium Fluoride (LiF) dosemeter chips were arranged in arrays of up to 35 chips. The number of TLDs in each array and the position on the patient was optimised for each procedure, based on a number of previous experimental trials. Patient details and exposure factors were noted together with DAP meter readings. The maximum TLD reading was used for comparison with the other measurement methods.

* Project partly funded by the Department of Health, United Kingdom.

2. McMahon Medical 'Skin Dose Monitor' (SDM) Model 104-101

The sensor contains a small scintillator in a reflective plastic housing, linked by a fibre optic to a meter. The sensor is placed at the centre of the field on the skin using a disposable pad. The energy range of the sensor is given by the manufacturer as being between 50 and 150 kVp with a dose-rate range between 0.1 $mGymin^{-1}$ and 3 $Gymin^{-1}$. Calibration of the SDM was carried out using a calibrated ionisation chamber. The SDM was used in conjunction with a TLD array on each patient for direct comparison.

3. PTW M4-KDK Dose Area Product (DAP) Meter

The M4-KDK consists of two parallel plates, separated by a non-sensitive region. The plates each have two chambers, connected to an electrometer. The central chamber is entirely within the x-ray beam and measures the air kerma at the output face of the x-ray tube; an inverse square calculation is performed to calculate ESD.

3. Results

1. ESD Measurements

ESD measured for cardiac, neurological and general procedures are shown in Tables I-III. Results shown were obtained using the TLD arrays. Most ESD values are below 1 Gy.

Table I. ESDs measured during cardiac procedures

Procedure	RF Ablation	Angioplasty	PTCA	Diagnostic LHC	EPS	Diagnostic LHC & Grafts
Range (Gy)	0.03 – 1.01	0.38 – 1.10	0.02 – 0.94	0.06 – 0.33	0.37 – 0.42	0.24 – 0.34
Mean ESD (Gy)	0.13	0.73	0.31	0.18	0.40	0.29
Sample Size	6	3	19	9	2	2

Table II. ESDs measured during neurological procedures

Procedure	Angiogram	Embolisation	GDC Coiling
Range (Gy)	0.02 – 0.36	0.08 – 1.28	0.62 – 1.65
Mean ESD (Gy)	0.14	0.72	1.20
Sample Size	19	3	4

Table III. ESDs obtained for two types of general interventional procedures

Procedure	Aortic Stent Graft	PTA Iliac Artery
Range (Gy)	0.37 – 3.34	0.23 – 0.97
Mean ESD (Gy)	3.09	0.42
Sample Size	3	4

Some monitored procedures do not appear in the above tables as insufficient numbers of patients have been monitored. The highest ESD recorded (4Gy) was for a patient undergoing a Renal PTA and Aortic Stent Graft.

A more simple method of monitoring ESD would be to establish a relationship between measured ESD and DAP reading or fluoroscopy time. Correlation was determined through an ordinary least squares regression model. No correlation between ESD and DAP data was obtained for cardiac PTCA procedures. Some degree of correlation between ESD and fluoroscopy time for general interventional procedures was found ($R^2 = 0.75$, 16 patients) and between DAP and ESD readings for neurological procedures using a 20cm field of view ($R^2 = 0.87$, 10 patients).

4. Assessment of monitoring equipment

1. Thermoluminescent Dosemeters (TLD)

Each TLD was measured to be within 6% of the mean for each batch. TLD arrays were considered the most consistent and accurate means of measuring ESDs. Consequently, the SDM was compared against them. In addition, TLD arrays were the method of choice by clinical staff. However, TLD arrays suffer from the substantial drawback of requiring labour intensive post-exposure processing. Obviously, this will lead to delays before ESDs are available for assessment.

2. McMahon Medical 'Skin Dose Monitor' (SDM) Model 104-101

The SDM was placed on a phantom at the centre of the field together with a calibrated ionisation chamber and readings were compared. The SDM and chamber response agreed at ≥ 90 kV but deviated at lower kVs. Monitor reproducibility was within ± 1% over a five-hour period. Stability was also tested and was found to agree with specifications. In the clinical environment, the SDM was simple to operate. However, the fixing bracket designed to allow the electrometer to be attached to the table rail was inconvenient and not used. Instead, clinical staff tended to position the meter on the table.

3. PTW M4-KDK DAP Meter

The M4-KDK was found to have a similar uncertainty in its response to that of conventional DAP meters. There was a slightly greater dependence of response with field area at field sizes less than 200 cm^2.

5. Discussion

During cardiac procedures, the majority of patients received skin doses below the level of 1 Gy. Results for neurological procedures show that monitoring every patient may not be necessary for angiograms but routine monitoring of GDC coilings and embolisations should be carried out. ESD values show the highest skin doses occurring during general interventional procedures with most readings either approaching or exceeding 1 Gy. Although routine monitoring is carried out by a DAP meter, the ESD is not usually known. The results show that routine ESD monitoring should be considered, particularly for patients undergoing multiple procedures. Although the threshold for transient erythema is recognised to be 2 Gy, individual sensitivities may vary [5]. Therefore ESDs greater than 1 Gy should be recorded.

Correlation between ESD and DAP or fluoroscopy time could not be established for certain. The best correlation between DAP and ESD seemed to be for neurological examinations. This is not surprising since these examinations are unlikely to have large variations in field size. On the whole, the correlation of DAP and measured ESD seems relatively poor. Therefore, monitoring ESD, in addition to DAP and fluoroscopy time is necessary for interventional procedures where there is a risk of high skin doses. However, the use of DAP to monitor threshold values should not be discounted, especially if threshold values can be set for individual centres and for specific examinations. The validity of this approach will probably need to be established locally.

The most reliable method for monitoring skin dose was the use of TLDs. This was the most popular method with clinical staff, although the slowest method, perhaps best suited to ‘sample monitoring’.

The SDM compared favourably with a calibrated ionisation chamber in the laboratory. It was easy to use and produced a real time running total of the ESD. However, there were a number of significant issues surrounding its design. The sensor had a small surface area and therefore monitored a limited area of the skin. The success of the result was highly dependent upon the skill of the radiographer in positioning the monitor correctly. This was not always possible. The bracket supplied with the SDM was too bulky and was not used by any of the departments. The fibre optic cables are fragile and in practice, should be replaced more often than recommended. Cables were crushed underfoot or were coiled too tightly by staff. In some procedures, the weight of the patient reduced the life of the cable significantly due to crushing. Many procedures produced zero readings, attributable to cable damage.

The PTW M4-KDK proved difficult to place since most fluoroscopy units had an integral DAP meter and did not have the required rails at the output face of the tube. Consequently, this method will be unsuitable for some departments. Laboratory results show that corrections may be required at field sizes less than 200cm^2.

6. Conclusion

The periodic assessment of ESD is strongly encouraged. The most suitable method for this would seem to be TLD arrays. This method also seems to be favoured by clinical staff. However, TLD arrays are not suitable for continuous monitoring of, for example, general FGIPs. Instruments such as a twin chamber DAP meter or a SDM, design and positioning considerations apart, should be more suitable for this application especially if used only to provide an early warning of potential skin injury. In addition, it may be possible to set

threshold DAP readings locally for specific examinations to alert clinical staff of the potential for a skin injury.

Acknowledgements

The authors are grateful to Wardray Premise (UK) and to PTW (Freiberg) for the loan of the equipment, to the radiographers who assisted in data collection and to Tony Cotterill, Jane Utting, Abrar Qureshi and Angela Pettett for their input during this study.

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RADIATION DOSE DURING ANGIOGRAPHIC PROCEDURES

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Abstract

The use of angiographic procedures is becoming more prevalent as new techniques and equipment are developed. There have been concerns in the scientific community about the level of radiation doses received by patients, and indirectly by staff, during some of these radiological procedures. The purpose of this study was to assess the level of radiation dose from angiographic procedures to patient at the Ottawa Hospital, General Campus. Radiation dose measurements, using Thermo-Luminescent Dosimeters (TLDs), were performed on more than 100 patients on various procedures. The results show that while the patient dose from the great majority of angiographic procedures is less than 2 Gy, a significant number of procedures, especially interventional procedures may have doses greater than 2 Gy and may lead to deterministic effects.

1. Introduction

In the last few years, the number, the type and complexity of interventional radiological procedures has dramatically increased. These changes were driven by improvements in equipment design, the need for improved patient prognoses and the necessity for more cost effective treatments. With the increased complexity of these procedures, the irradiation time has also increased, giving rise to concern about patient doses. There have been a few reports of deterministic effects from angiographic procedures, especially interventional procedures. For instances, Carstens et al have reported a case of radiation dermatitis after embolization [1], Freedman et al reported radiation burns during a transjugular intrahepatic portosystemic shunt (TIPS) procedure [2], Huda et al reported cases of temporary epilation after an neurological procedure [3], and Shope reported a few cases of radiation induced skin injuries from interventional procedures [4].

Following the reported cases of radiation damage from interventional procedures, the United States Food and Drug Administration had issued a bulletin to health care professional on the potential for radiation injuries from angiographic procedures [5]. This bulletin requests that the absorbed dose to the irradiated areas, likely to approach the threshold for radiation injury, be estimated for angiographic procedures, including interventional procedures. The area of interest when performing these evaluations for angiographic procedures is the skin area closest to the entrance X-ray beam since it will receive the largest amount of radiation.

2. Equipment and method

All procedures were done by the same team of radiologists using an Omnicon L Digital Subtraction Angiography (DSA) unit (Picker, Cleveland OH), utilizing 15 pulse/s fluoroscopy. The entrance doses were measured by placing several equally spaced packets of three thermo-luminescent dosimeters (TLDs) on the table under the patient's pelvis to cover the area exposed to radiation during the procedure. Three TLDs were used per packet to provide confidence for each measurement point. The TLDs used were TLD-100 (LiF) (Harshaw, Cleveland, OH). TLD-100 (LiF) has been shown to be appropriate for the measurements of both skin entrance and organ doses in diagnostic radiology [6]. Each TLD measures approximately 3 x 3 x 1 mm^3. The separation between the packets used was 10 cm

at first and was subsequently decreased to 3 cm. This change in the packet separation was made to increase the number of measurement points to confirm the radiation pattern of entrance dose. The TLDs were calibrated for the energies used during the procedures and were processed at Health Canada laboratories on a Harshaw Nuclear Systems Model 2000D TLD reader (Harshaw, Cleveland, OH). Technical data, such as the tube voltage, current, fluoroscopy time, the number of DSA images and the tube position were recorded for each procedure.

3. Results

The skin entrance doses and pertinent information for angiographic procedures are presented in Table 1. The values presented are the average for all patients undergoing the specific procedure. The numbers in parentheses show the range of values measured for each category.

Table 1. Results of the radiation dose measurement for diagnostic angiographic procedures

Procedure	# of proc.	Patient weights (kg)	Irradiation time (min.)	# images	Dose (mGy)
Aorta/Iliac Arteries					
Translumbar aortogram	3	99 (70-136)	3.5 (2.3-5.2)	88 (76-104)	162 (45-299)
Iliac artery angioplasty & stenting	3	71 (68-84)	20.5 (3.8-43.1)	88 (43-190)	1,028 (161-2,560)
Carotid Artery					
Carotid artery angiogram	1	64	3.3	97	80
Carotid artery angioplasty & stenting	1	74	27.3	93	188
Embolization					
Embolization of liver tumours	8	78.5 (48-117)	20.2 (12.7-43.5)	144 (56-473)	2,062 (137-9,329)
Uterine Artery Embolization	28	73 (53-120)	29.2 (13.3-54.1)	124 (66-241)	1,289 (383-3,363)
Abdomen					
Inferior Vena Cava filter placement	2	66 (64-68)	3.0 (2.9-3.1)	25 (22-27)	44 (41-47)
Abdominal angiogram	3	79 (50-114)	6.8 (4.8-8.1)	243 (163-311)	935 (138-2,450)

One of the major problems in assessing the patient dose is that the range of doses for a specific procedure can be quite considerable. Table 2 shows the individual patient skin entrance dose for embolization of liver tumours. The entrance skin dose values presented are the maximum measured doses for each patient.

Table 2. Results of the radiation dose measurement for embolization of liver tumours

Patient	Age/sex	Weight (kg)	Irradiation	# images	Dose (mGy)
17	47 / M	84	13.1	69	1,032
22	56 / M	97	20.2	162	999
30	71 / F	50	23.2	95	222
35	59 / M	86	18.1	114	573
49	71 / F	48	18.0	108	137
51	68 / M	82	43.5	473	9,329
61	64 / F	117	12.7	74	3,273
63	40 / M	64	13.1	56	930
Average		*78.5*	*20.2*	*144*	*2,062*

4. Discussion

The measurement of patient doses is not an easy task. If properly handled, TLDs can provide an accurate value of skin doses. Unfortunately, TLDs are complicated to use and have limited usage in a clinical setting. Another method of measurement is the use of a detector to measure the dose-area product. The major drawback of the use of dose-area product measurement during angiographic procedures is that it is often difficult to relate the result to the skin dose or to a specific organ dose. This is especially true with angiographic procedures where patients are being irradiated at different angles and skin surface locations for various irradiation times.

In general, patient doses are greater in interventional procedures than in diagnostic angiographic procedures. Not all interventional procedures generate large skin doses. For example, the skin dose produced during the placement of an inferior vena cava filter is small. One of the most difficult problems in assessing the risk from an angiographic procedure is the large variability of skin doses for different patients. For each procedure, it is important to know the range of skin doses that can be attained since this range can be very wide. For example, the embolization of liver tumours, as demonstrated in Table 2, the range of skin doses is from 137 mGy to 9,329 mGy. Two of the eight patients received skin doses greater than the threshold level of 2 Gy. Other procedures show the same characteristics; for iliac angioplasty and stenting, the range of doses is from 161 mGy to 2,560 mGy, for uterine artery embolization, the range is from 383 mGy to 3,363 mGy, and for abdominal angiogram, the range is from 138 mGy to 2,450 mGy. The most important factors responsible for such large variations of skin doses are the size of the patient, the expertise of the operator, and the difficulty in performing the procedure.

Skin doses can be greater than 2 Gy for many interventional procedures. A complete assessment of the range of skin doses should be done to evaluate the risk of deterministic effects for specific procedures.

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RADIOLOGICAL PROTECTION IN INTERVENTIONAL CARDIOLOGY IN CHILE

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Abstract

In September 2000, an expert mission was assigned to Chile, under the regional project named "International BBS in Medical Practices Radiation Protection and Quality Assurance In Interventional Radiology" (ARCAL XLIX). The objectives of the mission were to evaluate the level of radiation protection (RP) and safety in interventional cardiology (IC) installations.
A team of local cardiologists, medical physicists and technologists was created for this purpose and during one week, several cardiology laboratories were evaluated and some basic quality controls (QC) were carried out. A basic pilot training course in radiation protection was imparted at the Hospital of the University of Chile in Santiago de Chile and some of the key objectives for a future national quality assurance programme were presented during the national congress of IC. In addition, a national survey on radiation protection aspects was circulated and its results evaluated. These activities enabled the local team to become familiar with the methodology of assessment of the level of protection and the organization of a programme, which was illustrated with the examples of similar European programmes.
As result of these actions, several proposals were made to both the local authorities and the IAEA. The most important were: a) to initiate a basic QC programme, b) to organize a training in RP for cardiologists in order to formalize their accreditation, c) to improve personal occupational dosimetry, d) to initiate a programme of patient dosimetry, e) to optimize the technical and clinical protocols, f) to create a national registry of incidents with skin injuries.

1. Introduction

In Chile there are 48 specialists in interventioal cardiology (IC) training in renowed European and North American centers. They perform nearly 1,500 therapeutic and 6,000 diagnostic procedures in a year. Facilities and procedures for cardiac electro-physiology are not included in these figures. For comparison, in Spain (data from 1999), there are 110 hemo-dynamic rooms (in 83 hospitals) where 575 therapeutic procedures (22% of the total) per million of population are performed and 2,070 diagnostic procedures per million of population (78% of the total) [1]. These numbers are 50 % of the procedures in other European countries, such as Austria, Switzerland and Germany [2].

Considering the rate of development in Chile, it can be assumed that in a medium term it will reach the current levels of Spain.

There is no specific programme for training cardiologists in radiation protection. There are, however, protective elements in most of the facilities, such as couch- supported articulated shielded screens and personal shielded garment (aprons and thyroid shielding). Personal monitoring does not seem to be used systematically and the dosemeter reading are made by institutions not dependent on the "Comisión Chilena de Energía Nuclear" and with unknown quality control and no systematic participation in intercomparative round . Personal exposure monitoring is done using one single dosimeter which may be insufficient for IC. [3].

With regard to the RP of patients, there is neither a general culture and awareness of cardiologist nor of suppliers of x-ray equipment. The current organization of the IC is structured around the Chilean Society of Cardiology and Cardiovascular Surgery. The interest by its members in achieving a qualitative and quantitative change towards a culture of patient protection and towards implementation of a QA programme in a short time, provides ideal conditions for moving in this direction.

2. Material and methods

In September 2000, an expert mission was assigned to Chile, under the regional project named "International BBS in Medical Practices Radiation Protection and Quality Assurance In Interventional Radiology" (ARCAL XLIX). The objectives of the mission were to evaluate the level of RP and safety in IC . In addition a basic training action in RP and a pilot QA programme should be initiated.

A team of local cardiologists, medical physicists and technologists was created for this purpose and during one week, several cardiology laboratories were evaluated and some basic QC were carried out. A basic pilot training course in RP was imparted at the Hospital of the University in Santiago de Chile and some of the key objectives for a future national quality assurance programme were presented during the national congress of IC. In addition, a national trial on RP aspects was circulated and its results evaluated.

Previous contact with the local delegations of the main industry supplying X ray systems in Chile (Philips, General Electric, Siemens and Toshiba) was established in order to obtain support for these evaluations.

The basic QC carried out, during the mission, in several installations was a reduced version of the European DIMOND (Digital Imaging: Measures for Optimizing Radiological Information Content and Dose) protocol [4] .. In addition, the maximum patient entrance dose rate and the image quality obtained with a test object (TOR 18-FG, from the Leeds University) was measured. In the cardiology lab of the Hospital Clinico of the University of Chile, some patient doses were measured with a transmission chamber together with skin dose evaluation using slow radiotherapy films [5].

A basic pilot training course in RP was imparted at the Hospital of the Chile University in Santiago and during the National Congress of IC held in Antofagasta.

A national survey on radiation protection and collateral aspects was prepared similar to one used in Spain by the Spanish Section of IC to be answered by the medical specialists in Chile.

3. Results

Survey

A survey on RP aspects was made on a personal and anonymous basis. It was distributed to 16 of the 19 existing centers in the country and reply was obtained from 13 of them. Of the 46 professionals involved in IC 39 responded, which gives the survey a valuable indicator of the activity at national level. 56% of those polled consider that their knowledge of RP are adequate for their professional activity, however 97% considers appropriate to perform

continuous training in radiation protection as well as in QC in order to optimize the use of their equipment.

Equipment
Equipment in Chile is uneven. Three of units are of a design of the 1977, 1979 and 1986 all of them had to be adapted for IC. 71% of the equipment used in Chile includes digital image acquisition. 53% of those polled in the survey consider that their facilities are adequate and 38% consider that they should be renewed as RP is concerned. Half of those polled feel acquainted with the features and capabilities of their equipment, while the other half mean to have incomplete knowledge of the use of the equipment; 80% would like to have more detailed information on the capabilities of the equipment.

Occupational dose assessment
Dose monitoring is available to 67 % of the interventional cardiologists but only 61% of those polled use it on a regular basis and 33% lack dosimetric control. In none of the centers are TLD dosimeters available. 54% of the cardiologists are aware of their occupational dose values and pay attention to them and 33% are not aware of them. However, 92% indicate that no professional advice is available on radiological protection; this advice is wanted by 90% of those polled and all participants in the survey consider that effort and investments should be made to improve the level of protection to the professionals involved in IC. The average team for an IC unit in Chile consists of four interventionists, two to three nurses, one to two technologist, two to four nursing assistants. There is only one center with a medical physicist. 92% of those polled declare to have quality control and maintenance for the equipment, and 48% of them indicate that this is performed on scheduled basis. 61% report to be aware of the results of maintenance activities.

Patient dose assessment
All participants in the survey consider that patient dose assessment is of prime importance and 97% agree to participate in comparative studies with other countries, although when interrogated about a possibly excessive exposure, 84% declare that this never occurred and 90% state that never know about of any skin injuries related to the area of incidence of the radiation beam on patients who underwent IC procedure.

4. Conclusions

1. Interventional cardiology in Chile is well organized and a programme of QC and RP could be easily implemented. Cardiologists performing interventional procedures show a great interest in radiation protection and demand a training programme in order to achieve the necessary knowledge to adequately protect their patients and to obtain an accreditation in radiation protection from the Chilean health authority.
2. A pilot training course in radiation protection has been designed for interventional cardiologists (20-30 hours following the European approach on protection in medical exposure).
3. Occupational protection conditions are in general adequate but personal monitoring should be improved by recommending the use of two TLD dosimeters by professionals with a significant workload in IC.
4. Equipment assessed is in good condition in general although there is not yet a culture of radiation protection of patient, which must be implemented in a near future.

5. It is advisable to initiate a programme of patient dose monitoring, to optimize the technical and clinical protocols and to initiate a national registry of incidents with skin injuries.

Acknowledgements

This paper is the result of the work started with an IAEA mission under the Project No. C3-RLA/9/035-0101.

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ABSORBED DOSES TO PATIENTS FROM ANGIORADIOLOGY

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Abstract

The aim of study was to know patients doses exposes when three different procedures of angioradiology were carried out. The explorations considered were drainage biliary, varicocele embolization and dacriocistography made in the Radiodiagnostic Service at the University Hospital of Canary Islands, Tenerife (Spain). In total 14 patients were studies. The measurements were made using large area transmission ionisation chamber which gives the values of Dose Area Product (DAP). In adition, thermoluminiscent dosimeters type TLD-100 were used in anthropomorphic phantom in order to obtain values of organ doses when the phantom was submitted to the same procedures than the actual patients. Furthermore, the Effdose program was used to estimate the effective doses in the procedures conditions. The values for DAP were in the range of 70 – 300 for drainage biliary, 43 – 180 for varicocele embolization and 1.4 – 9 for dacriocistography. The organ doses measured with TLD-100 were higher than the corresponding values estimated by Effdose program. The results for varicocele embolization were higher than other published data. In the case of drainage biliary procedure, the values were closed to other published results. It was not possible to find data for dacriocistography from other authors.

1. Introducción

Los valores de las dosis de radiación a pacientes debidas a diversos procedimientos de Radiología Vascular e Intervencionista han sido determinados por diversos autores [1-5] en los últimos años. En general, las dosis medidas o estimadas son altas debido a las características propias de estos procedimientos radiológicos: grandes tiempos de escopia y alto número de imágenes. Al mismo tiempo se ha constatado la gran dependencia de las dosis con las características técnicas y con la experiencia del personal médico que la realiza. Por todo ello, la comparación entre resultados de diversos autores puede ser complicada y también la comparación entre medidas directas de dosis y estimaciones de las mismas haciendo uso de diversos procedimientos de cálculo.

El procedimiento más frecuentemente usado para la caracterización dosimétrica de los procedimientos de Radiología Vascular e Intervencionista es la medida de la magnitud Producto Dosis Área (P.D.A.). También se han llevado a cabo medidas de dosis, aplicables a los pacientes, usando dosímetros termoluminiscentes en maniquíes.

En este trabajo, se han realizado ambos tipos de medidas en 3 procedimientos propios de Angiorradiología: drenaje biliar, embolización de varicocele masculino (en adelante varicocele) y dacriocistografía (en adelante dacrio). Las dos primeras corresponden a procedimientos de Radiología Intervencionista, mientras que la tercera de la exploraciones sirve para diagnosticar el estado del conducto lacrimal.

En los tres procedimientos hemos planteado el objetivo de conocer el nivel de riesgo estocástico y determinístico en los pacientes, como también han hecho otros autores [6]. Asimismo, se realiza un estudio comparativo de los valores de dosis obtenidos utilizando un programa de cálculo (con los parámetros radiológicos de la exploración y el P.D.A.), con los resultados de las medidas con dosímetros termoluminiscentes colocados en un maniquí antropomórfico (RANDO).

2. Material y método

Se tomaron datos referidos a 14 pacientes (6 mujeres y 8 hombres). A 5 de ellos se les realizó drenaje biliar; a otros 5 pacientes, con edades comprendidas entre 16 y 27 años, la intervención fue por varicocele masculino. A los 4 pacientes restantes se les hizo un estudio diagnóstico de dacriocistografía.

En todos los casos, se registraron los siguientes parámetros radiológicos: kV, mA, tamaño de campo, tiempo de escopia, número de disparos en grafía, y proyección utilizada. Todas las exploraciones se realizaron en un equipo de rayos X marca Philips, modelo Integris V3000. En todos los casos, se midió el P.D.A. (escopia y grafía) con una cámara de ionización DIAMENTOR M2 suministrada y calibrada por PTW – Freiburg (Alemania).

Posteriormente, se hizo uso de un maniquí antropomórfico Rando y de dosímetros termoluminiscentes marca Harshaw tipo TLD – 100 para realizar medidas de dosis en el maniquí. Los dosímetros empleados fueron calibrados para las energías de Rayos X diagnósticos (50 – 120 kV) en el Centro Nacional de Dosimetría (Valencia) . También se verificaron frente a una cámara de ionización PTW calibrada (conectado a un electrómetro PTW DL4-DI4) utilizando Rayos X de 80 kV proporcionados por un equipo radiológico que cumplía las especificaciones del Protocolo Español de Control de Calidad en Radiodiagnóstico.

Los tratamientos térmicos de los TLD (previo lectura, borrado + restaurado) se llevaron a cabo con una estufa PTW THELDO siguiendo los procedimientos estándares de nuestro laboratorio y se realizaron las lecturas de los dosímetros utilizando el Lector termoluminiscente HARSHAW 4000.

Las medidas del PDA, dadas en $Gy \cdot cm^2$, para cada exploración y paciente, se realizaron distinguiendo entre el modo escopia y el modo grafía en las distintas proyecciones utilizadas.

Se utilizaron los valores medios de los parámetros radiológicos de cada exploración y los datos de PDA promedios registrados en los pacientes para reproducir cada uno de los 3 procedimientos sobre el maniquí Rando en el que se colocaron los dosímetros TLD-100.

Por otra parte, se utilizó el programa de cálculo de dosis efectiva EFFDOSE, que utiliza los factores de ponderación tisulares propuestos en las recomendaciones ICRP-60 [1] y que permite también estimar las dosis en órganos en cada una de las exploraciones teniendo en cuenta todas las características de las mismas.

3. Resultados y discusión

Los rangos de los valores de los parámetros medidos en cada una de las exploraciones se presentan en la Tabla I.

Las diferencias entre las características de las exploraciones debidas, sobre todo, a las diferencias anatómicas entre pacientes, quedan reflejadas en esta tabla. Así, el diferente grado de dificultad entre pacientes justifica las importantes variaciones observadas entre los tiempos de escopia para la realización del drenaje biliar que se refleja en el amplio rango de valores de P.D.A. Asimismo, los distintos datos en el modo grafía, para esta exploración, ocasionan una gran variabilidad en los valores de P.D.A. totales. Es de señalar que estos resultados hacen

Tabla I. Resultados obtenidos con pacientes

Exploración	Diámetro Campo (cm)	ESCOPIA				GRAFÍA				P.D.A. TOTAL
		kV	mA	t (min)	P.D.A.	kV	mA	Nº imágenes	P.D.A.	
Drenaje biliar	31-38	81-110	5 - 6	10-34	68-273	70-110	310-425	1-2	1-28	70-300
Varicocele	20-25	68-80	4 - 5	14-61	42-180	70-76	386-486	1-5	0,28-7	43-180
Dacrio	17	73-77	3 - 5	0,1-0,3	0,44-1	70-75	120-585	12-15	1-7,6	1,4-9

Los rangos de valores de P.D.A. se expresan en $Gy \cdot cm^2$.

poco representativo un valor medio de P.D.A. como característico de esta exploración. Estascircunstancias se repiten, como puede observarse en la Tabla I, en el caso de varicocele y también para la dacriocistografía.

Después de la reproducción de las condiciones de irradiación para cada una de las exploraciones, utilizando un maniquí antropomórfico Rando, se midió las dosis en los "órganos" del mismo mediante la colocación en ellos de un conjunto de dosímetros termoluminiscentes en número y distribución variable según las características de la exploración y los órganos considerados. En total se usaron 40 dosímetros TLD-100 colocados en los órganos indicados en la Tabla II en el caso de la reproducción del estudio de drenaje biliar,, mientras que se utilizaron 38 dosímetros para las medidas en los órganos correspondientes al estudio de varicocele. En la exploración diagnóstica de dacriocistografía fueron 17 los dosímetros utilizados.

También en esta Tabla II se muestran los valores de dosis estimadas en los mismo órganos mediante la aplicación del programa Effdose para cuyo uso se utilizaron los datos promedios para cada exploración de kV, filtración, P.D.A. y la proyección más similar a la exploración real de entre las propuestas por NRPB [8]

Se observa que, en general, las dosis estimadas con el programa Effdose en cada órgano son inferiores a los valores promedios medidos con dosímetros termoluminiscentes. Puede deberse esta circunstancia al hecho de que los valores promedios utilizados para estimar las dosis usando el programa informático, tienen una gran desviación estándar consecuencia del amplio rango de valores que se indicaron en la Tabla I. Por tanto, para disminuir esta causa de incertidumbre se requiere incrementar el número de pacientes analizados o bien analizar poblaciones homogéneas de pacientes, próximos a las dimensiones del hombre estándar representado con el maniquí antropomórfico.

Por otra parte, la reproducción precisa del estudio con el maniquí es compleja debido a la diversidad de proyecciones utilizadas y al tiempo de radiación correspondiente a cada una de ellas, así como a los cambios de tamaño de campo que tienen lugar durante el estudio. Por todo ello, se considera conveniente que los sistemas de medida y registro de dosis que han de colocarse obligatoriamente en estos equipos en España desde hace unos meses, incorporasen el registro de dichos parámetros para una mejor estimación de la dosis a pacientes.

Tabla II. Dosis en órganos (medidas y estimadas) para las 3 exploraciones

	DOSIS (mGy)					
Órgano	***Drenaje biliar***		***Varicocele***		***Dacrio***	
	Medida	estimada	Medida	estimada	medida	estimada
Tiroides	0,35	0,09	0,12	0,00	0,15	0,30
Estómago	29,18	38,03	1,71	2,39	0,07	0,00
Esófago	6,00	8,72	0,66	0,08	0,10	0,06
Hígado	116,31	59,76	2,85	1,99	0,06	0,00
Mama	2,92	1,07	0,26	0,02	0,07	0,00
Vejiga	8,02	0,79	8,02	14,80	0,05	0,00
Pulmón	24,44	7,71	1,50	0,08	0,11	0,01
Colón	28,92	4,96	43,61	24,45	-	-
Testículos	0,17	0,06	1,30	8,08	-	-
Ovarios	1,48	4,02	-	-	-	-
Vesícula biliar	-	45,89	-	-	-	-
Cristalino	-	-	-	-	0,82	2,03
Parótidas	-	-	-	-	1,33	-

El cómputo de la dosis efectiva a los pacientes realizada mediante el programa Effdose, proporcionó los valores siguientes: 19 mSv para el drenaje biliar; 9 mSv para el varicocele y 0.13 mSv para dacriocistografía. Como ya se observaba en la Tabla II, las características de la exploración lacrimal (campo pequeño centrado en los ojos durante toda la exploración) justifican tanto los bajos valores de dosis en órganos como el pequeño valor de dosis efectiva.

Aunque no se colocaron suficientes dosímetros para poder medir todos los datos necesarios para la obtención de la dosis efectiva, la aproximación que puede darse con los valores medidos es de: 17 mSv para el drenaje biliar, 7 mSv para el varicocele y 0.04 mSv para dacriocistografía. Considerando únicamente los mismos órganos con sus correspondientes dosis medidas y estimadas, las diferencias entre ambos métodos son grandes. Este resultado parece indicar una cierta tendencia del programa Effdose a repartir la dosis total entre los diversos órganos estrictamente determinado por las características geométricas de la exploración establecidas matemáticamente.

Por tanto, hay que usar con precaución la asimilación de exploraciones a la hora de comparar exploraciones intervencionistas reales con proyecciones normalizadas de exploraciones radiológicas sencillas.

4. Conclusiones

1.- Los valores de dosis medidos con dosímetros termoluminiscentes y los estimados a partir de la medida de los productos dosis-área para las exploraciones Drenaje Biliar, Varicocele y Dacriocistografía, son indicativos de un bajo riesgo de efectos estocásticos debidos a la radiación X usada. La incidencia negativa de la radiación como inductora de enfermedades malignas hereditarias graves es baja, incluso en la intervención de Varicocele masculino que, a priori, era susceptible de ocasionar mayor riesgo.
2.- No se alcanzan, en ningún caso, valores de dosis superiores a los umbrales de efectos determinísticos.

3.- La discordancia entre los valores de dosis estimados y medidos pueden ser debidos a la extrema variabilidad de los parámetros radiológicos usados en las exploraciones. Para intentar conocer la relación entre ambos conjuntos de valores se requiere incrementar el número de pacientes estudiados y asegurar la homogeneidad de características anatómicas entre ellos, al objeto de disminuir la incertidumbre en los resultados.

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IAEA-CN-85-71

INVESTIGATION OF RADIATION SKIN DOSE IN INTERVENTIONAL CARDIOLOGY

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Abstract

Background - The study investigated the radiation skin doses for interventional patients in cardiology; two procedures which have the highest radiation dose are Radiofrequency Catheter Ablation (RFCA) and Percutaneous Transluminal Coronary Angioplasty (PTCA).

Methods and Results - 56 patients were randomly selected and investigated; 23 patients in the RFCA group and 33 in the PTCA group. Skin and effective dose were calculated from Dose Area Product (DAP). Thermoluminescent Dosimetry was the second method of dose measurement used. Patients were followed-up for a three month period to check for possible skin reactions resulting from the radiation dose during the procedure.

Radiation skin doses in 14 patients were calculated to be more than 1 Gy, including three patients who received more than 2 Gy, the threshold dose for deterministic effects of radiation. 7 patients (12.5%) reported skin reactions as a result of the radiation received to their backs during the procedure. Mean DAP and estimated effective doses were 105 Gycm^2 and 22.5 mSv for RFCA, and 32 Gycm^2 and 6.2 mSv for PTCA procedures respectively.

Conclusion - Complex procedures in Interventional Cardiology can exceed the threshold level for deterministic effects in the skin.

1. Introduction

Patients undergoing Percutaneous Transluminal Coronary Angioplasty (PTCA) and Radiofrequency Catheter Ablation (RFCA) may receive considerable doses of X-radiation during the procedure. These two procedures are both complex and lengthy to achieve the desired result; both treat cardiological medical conditions. Unlike PTCA most RFCA procedures involve the investigative test for diagnosis followed by the treatment.

1. The aims of the study were:

a) to evaluate the magnitude and range of radiation skin doses received by patients during PTCA and RFCA procedures,
b) to find if there were any deterministic effects of radiation manifested by the patient such as skin reddening (erythema) with a follow-up for a three month period.

2. Background

Several incidents of radiation induced skin problems have been reported in the USA as a result of high dose examinations (Shope, 1996) [1]. Shope stated that 26 injuries had been reported to the Food and Drug Administration (FDA) between 1992 and 1995; 12 of the patients underwent RFCA procedures and 4 received PTCA examinations. The FDA issued a health warning in 1994, that patients undergoing interventional procedures, could suffer from late radiation skin injury and that it would not be sufficient for clinicians to check patients before they were discharged from hospital (FDA, 1994) [2]. The FDA recognised that a threshold dose of 2 Gy would cause deterministic effects of radiation but recommended that a safety margin of 1 Gy should be observed. The advent of digital equipment with

microprocessor controlled X-ray generators allow higher outputs and X-ray tubes with better cooling capabilities have enabled longer fluoroscopy times and uninterrupted acquisitions of images (Philips, 1995) [3]. A paper written by Park et al, (1996) [4] studied 500 RFCA patients with 5.6% of patients exceeding threshold doses for signs of early transient erythema.

2. Methods

Symptomatic patients were enrolled into PTCA and RFCA groups, monitored for radiation skin dose and followed up for possible deterministic effects of radiation. The investigation took place over 4.5 months between 24th September 1998 and 5th February 1999. 56 patients were studied, 23 patients in the RFCA group and 33 patients in the PTCA group. Patients of both sexes aged between 18 and 75 years were randomised into the study.

1. Radiation skin dose was estimated by two methods; via dose-area product meter (DAP meter) and radiation field area measurement and via Thermoluminescent Dosimetry (TLD). The DAP meter was already installed as an integral part of the equipment. The DAP method gives an average value and does not take account of the distribution of the skin dose due to movements of the x-ray tube. The TLD method allowed point measurements. During the procedure projection, field size, focus skin distance, fluoroscopy time, DAP, kV and mA per 5 minutes RFCA fluoroscopy time and PTCA acquisition.
2. TLDs were placed directly on the patient's back to measure entrance surface dose (ESD) including backscatter. TLDs were placed in the following places: bilaterally midway between the spine and the lateral chest wall at the level of the lower end of the scapula in the region of the ninth thoracic vertebra (T9), one placed over the spine, one placed bilaterally on the lateral chest wall at the same level and one placed half way between the lower costal margin and the axilla on both sides of the patient giving a total of 7 TLDs per patient in the RFCA patients. A further two TLDs were placed in the PTCA group at the level of the lower costal margin.
3. The patients' backs were checked by a nurse for any skin condition prior to the patient leaving hospital within 24 hours of the procedure and by the patients' husband, wife, partner or friend on six dates over a three month period. A form was provided to assist in providing information of any skin condition that may have occurred at that time. The patient was phoned by the researcher after three months to enquire if any skin problems had occurred.
4. The skin dose for each projection was calculated by dividing the DAP by the field size at the patient's skin. Field sizes were estimated from an acquisition taken from rulers placed on the table top in identical projections that the equipment was in when the original acquisition was taken; the same table height and source image distance was used. The estimated skin dose from DAP was multiplied by the backscatter factor. A backscatter correction was used so that results could be compared to TLD measurements which included backscatter. However this method does not take the movement of the tube within a projection into account and therefore would tend to overestimate skin dose in a given projection.
5. Skin dose for each of the three main projections of the C-arm; left and right anterior oblique (LAO & RAO) and postero anterior (PA), were summated and compared.
6. Effective dose was calculated by multiplying the DAP by a conversion factor taken from NRPB-R262[5]. The factors depend on projection, kV and filtration.

3. Results and discussion

Table 1. RFCA & PTCA DAP, Fluoroscopy Time and Images

RFCA	DAP ($Gycm^2$)	FLUORO (minutes)	IMAGES	PTCA	DAP ($Gycm^2$)	FLUORO (minutes)	IMAGES (number)
MIN	14	7	0	**MIN**	8	5	236
MAX	341	117	1806	**MAX**	76	54	1854
MEAN	105	37	144	**MEAN**	32	12	733
ST DEV	85	27	78	**ST DEV**	18	9	392

Table 1 shows the minimum, maximum, mean and standard deviation of both groups studied.

Table 2. Comparison of RFCA & PTCA skin doses from DAP/ field size in LAO, RAO and PA projections

RFCA SKIN DOSE (mGy)	LAO (mGy)	RAO (mGy)	PA (mGy)	PTCA SKIN DOSE (mGy)	LAO (mGy)	RAO (mGy)	PA (mGy)
MIN	54	89	100	**MIN**	42	6	4
MAX	2422	1939	791	**MAX**	1470	1018	306
MEAN	777	403	284	**MEAN**	409	258	70
ST DEV	648	445	223	**ST DEV**	366	268	87

1. Skin dose calculated from DAP was recorded for each patient and compared to the maximum TLD reading for each patient.

The RFCA mean for skin dose from DAP = 777 mGy and mean for TLD dose = 531 mGy. A correlation but not significant could be made between the two sets of measurements. (Correlation = 0.76261 p = 0.08 ns).

The PTCA mean for skin dose from DAP = 522 mGy and mean for TLD dose = 135 mGy. No significant correlation could be found comparing the two doses. (Correlation = 0.15 p = ns). There was a wider difference between the two measurements in the PTCA group as it could not be predicted which projections would be used prior to the procedure and many more views were generally taken than in the RFCA group.

Table 3. Characteristics and doses of patients with skin reactions

No	Exam	Age	Sex	Fluoro time (minutes)	Equipment DAP ($Gycm^2$)	TLD Max Dose (mGy)	Skin Dose (mGy) from DAP	Effective Dose (mSv) from DAP
1	RFCA	66	F	18.9	38.9	147.8	264	5.16
2*	RFCA	63	M	50.3	288.2	1346.59	1880	47.0
3*	RFCA	58	M	117.3	195.6	236.0	1386	25.2
4	PTCA	59	M	6.6	15.5	12.52	187	1.7
5*	PTCA	55	M	53.5	103.8	237.4	1516	13.1
6	PTCA	72	F	8.9	22.4	316.48	289	3.3
7	PTCA	45	M	15.8	30.4	18.29	394	3.4

* denotes patients receiving a skin dose of more than 1 Gy.

Table 3 summarises the seven patients suffering from skin reactions indicating fluoroscopy time, DAP, maximum TLD dose, skin and effective doses. Most of the patients experienced itching prior to redness appearing in the subscapular region on their backs and the time of

onset varied between 24 hours and twelve weeks. None of the estimated doses for these 7 patients exceeded 2 Gy.

2. *Threshold doses***.** 9 of 23 RFCA patients received a total skin dose calculated from DAP of more than 1 Gy. Three of these patients received more than 2 Gy but reported no reaction. 5 patients received skin doses in excess of 1 Gy when the C-arm was angled to the LAO. 2 of the 9 patients received skin doses in excess of 1 Gy when the angulation of the C-arm was in the RAO projection and one of these patients received almost a deterministic level of 1939 mGy. 2 of the 9 patients reported skin injury.

5 PTCA patients received a total skin dose measured from DAP in excess of 1 Gy. Two of these patients received more than 1 Gy to the right side of the back in the direction of the X-ray tube in the LAO angulation. One patient reported a skin reaction.

3. *Effective dose.* Total body effective dose E was calculated from the DAP using conversion factors from NRPB-R262 [5].

Table 4. Effective dose from the two procedures

Procedure	Mean DAP ($Gycm^2$)	Mean E ± SD	Min E (mSv)	Max E (mSv)
RFCA	105	22.5 ± 20	2.8	79.6
PTCA	32	6.2 ± 4.0	1.2	16.8

4. *The risk factor* coefficient for cancer for the adult working population = 0.037 per Sv or 1 in 27,027 per mSv. Younger patients who are exposed to radiation have a greater risk of fatal malignancy than older patients. Lindsay et al, (1992) [6] stated that there is also a higher risk of fatal malignancy in females for increasing lengths of fluoroscopy time. The likelihood of cancer increases with increased radiation doses but not the severity Wagner et al. (1994) [7].

If patients returned with a late skin injury following a procedure with prolonged fluoroscopy time, Nahass (1995) [8] indicated that they should be diagnosed as having radiodermatitis and that they should be followed-up at regular intervals as this condition could later develop into a carcinoma.

4. Actions taken at the time of the procedure and future recommendations were made:

(a) More explanation given to patients as to the amount of radiation they may be receiving. The researcher noticed on consenting patients for the procedures that many patients were unaware of any X-radiation involved.
(b) Patients should be informed of the potential radiation risks involved with RFCA or PTCA procedures.
(c) Patients should be checked regularly for skin reactions for deterministic effects of radiation if a certain dose has been exceeded and asked to report if any should arise.
(d) Collimation should be used wherever possible to reduce field size to observe only the area in question.
(e) Ensure that the table height is at least 60 cms from the tube focus to reduce ESD.
(f) Magnification for RFCA procedures should be used as little as possible.

(g) The angulation of the C-arm should be changed to prevent over exposure in one area remembering that the LAO position produces the most radiation dose. The lateral projection should not be liberally used as the focus to skin distance is minimal.
(h) Use appropriate equipment to deliver the lowest overall exposure dose required for the procedures.
(i) Protocols should be observed and updated regularly with time limits set for lengthy fluoroscopy procedures.

5. Conclusion

It can be seen from the results that very high radiation skin doses were received by several patients in the RFCA and PTCA groups of patients. Seven of these patients have reported skin injury and three of these patients received doses more than 1 Gy. However the remaining four received estimated doses of less than 400 mGy.

Unlike other studies, the researcher followed the patients for a three month period and the skin reactions would have been unnoticed if the follow-up had not taken place.

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PATIENT DOSES IN DIGITAL CARDIAC IMAGING

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Abstract

In this pilot study, we obtained estimates of entrance skin doses and the corresponding effective doses to patients undergoing *digital* cardiac imaging procedures on a GE Advantx LC/LP Plus system. Data were obtained for six patients undergoing diagnostic examinations and six patients who had interventional procedures. For each patient examination, radiographic techniques for fluoroscopic and digital cine imaging were recorded, together with the irradiation geometry. The projection with the *highest* exposure resulted in an average skin dose of 0.64 ± 0.41 Gy (maximum of 1.6 Gy). The average patient skin doses taking into account overlapping projections was 1.1 ± 0.8 Gy (maximum of 3.0 Gy). The exposure area product (EAP) incident on the patient was converted into the energy imparted to the patient and the corresponding effective dose. The average patient effective dose was 28 ± 14 mSv (maximum 62 mSv), with the resultant average fatal cancer risk estimated to be of the order of 8×10^{-3}. Average doses for interventional procedures in cardiac imaging are higher than those associated with diagnostic examinations by approximately 50%.

1. Introduction

Cardiac imaging is recognized as a procedure that results in relatively high patient doses [1]. Cine film is currently being replaced by *digital* x-ray imaging equipment, and the resultant images are increasingly being viewed using (soft copy) display stations. It is therefore of interest to obtain doses to patients who undergo *digital* cardiac imaging procedures, and to produce quantitative estimates of the corresponding patient radiation risks.

In this pilot study, we quantified the entrance skin doses that predict the possibility of inducing a deterministic effect to the skin, as well as patient effective doses that quantify the stochastic risk of inducing cancer and genetic effects. Cardiac imaging may be performed for obtaining a diagnostic information (i.e., diagnostic) or during procedures that attempt to treat the patient (i.e., interventional), and data were obtained for both types of examination.

2. Method

1. Cardiac imaging workload

Each year, about 860 diagnostic examinations and 160 angioplasty examinations are performed in the catheterization suite at University Hospital, Upstate Medical University, Syracuse NY. The imaging is performed on a GE Advantx LC/LP Plus[1] system that was installed in 1999. In this pilot study, data was collected on twelve randomly selected patients undergoing digital cardiac imaging. Six patients underwent diagnostic examinations and the other six patients underwent interventional procedures (e.g., angioplasty).

X-ray beam characteristics were measured at the x-ray tube potential used clinically. The x-ray output was determined in terms of air kerma (μGy) per unit mAs, where an exposure of 1 R (2.58×10^{-4} C kg^{-1}) corresponds to an air kerma of 8.73 mGy. For the frontal plane operated at 80 kVp, the measured output at 60 cm was 130 μGy/mAs at a distance of 60 cm, and the corresponding Half Value Layer was 3.4 mm Al.

[1] General Electric Medical Systems, Milwaukee WI, United States of America.

2. Skin doses
In fluoroscopy, information was recorded for the selected x-ray tube potential (i.e., kVp), tube current (mA) and total fluoroscopy time. In digital imaging, information was recorded for the average x-ray tube potential (kVp), tube current (mA), exposure time per frame (s), and the total number of image frames acquired.

The source to patient skin distance was determined from the source to image receptor distance (SID), together with the air gap between the patient and the image intensifier. Patients were modeled as elliptical cylinders with dimensions of 27 cm (Anterior-Posterior) and 40 cm (Lateral).

Data were recorded for each separate projection. For any patient, the projection with the maximum skin dose was termed projection 1, the second highest skin dose was projection 2 and so forth. Since it is inappropriate to arithmetically sum all entrance skin doses [2], we explicitly estimated the *maximum* skin dose by taking into account any overlap of the x-ray projections used for each patient [3].

3. Effective doses
Data on the image receptor size and x-ray tube output permitted the exposure-area product (EAP) incident on the patient to be determined. The EAP was converted into the corresponding value of energy imparted taking into account both the x-ray beam quality (HVL) and the patient thickness [4], with the effective density in the cardiac region taken to be 800 kg m^{-3}. Values of energy imparted were converted into effective doses using a conversion factor of 19 mSv J^{-1}, which is a representative value of the effective dose per unit energy imparted in cardiac imaging [5].

3. Results & discussion

1. Skin doses.
Table 1 summarizes the entrance skin doses for the twelve patients included in this study. Data in Table 1 show that the entrance skin doses falls off rapidly with projection number. For example, the mean dose for the fifth projection was <20% of the value of the average dose for projection 1.

Table 1. Entrance skin dose (Gy) summary for twelve patients, when *no* account is taken of any overlap of different projections

Projection	# of patients	Mean ± σ	Minimum	Maximum
1	12	0.64 ± 0.41	0.28	1.6
2	12	0.48 ± 0.35	0.12	1.4
3	12	0.23 ± 0.11	0.07	0.47
4	7	0.21 ± 0.14	0.03	0.44
5	5	0.11 ± 0.08	0.02	0.21

For most patients, there was some overlap of entrance skin doses between adjacent projections (e.g., PA & RAO 45° or LAO 45° & LAO 25°). Taking into account projection overlap, the average *maximum* skin doses was 1.1 ± 0.8 Gy. The highest *maximum* skin dose was 3.0 Gy, and the lowest *maximum* skin dose was 0.38 Gy.

2. Effective doses.
The average effective dose for digital cardiac imaging was 28 ± 14 mSv. The minimum patient effective dose was 7.8 mSv and the maximum patient effective dose was 62 mSv. The nominal radiation risk coefficient for an adult working population is taken to be 4% per Sv[6]. Taking into account the demographic data for patients undergoing medical examinations would likely reduce the radiation risk. In this study, we used a risk reduction factor of ~0.34 as a representative value for a population undergoing x-ray studies [7]. The average stochastic risk of inducing fatal cancer for patients undergoing digital cardiac imaging is therefore of the order of 8×10^{-3}.

3 Diagnostic examinations vs Interventional procedures.
The data in Table 2 show average dose parameters for patients undergoing diagnostic examinations and interventional procedures. Average doses for interventional procedures are higher than those associated with diagnostic examinations by approximately 50%. It is also notable that the variability in patient doses is considerably higher for interventional procedures than for diagnostic procedures.

Table 2. Comparison of patient doses between diagnostic and interventional procedures

Dose parameter	Diagnostic procedures	Interventional procedures
Effective dose	23 ± 4 mSv	33 ± 19 mSv
Projection 1 skin dose	0.54 ± 0.20 Gy	0.74 ± 0.56 Gy
Maximum skin dose	0.84 ± 0.20 Gy	1.3 ±1.0 Gy

4. Conclusions

Digital cardiac imaging results in relatively high skin doses and effective doses. The highest skin doses observed in this study are comparable to threshold doses for the induction of deterministic effects such as skin erythema [8]. Effective doses in cardiac imaging are much higher than those encountered in most areas of diagnostic radiology and nuclear medicine [1, 9].

Acknowledgements

The authors gratefully acknowledge the financial and technical support of General Electric. Maryana Kushnir RT provided valuable assistance in helping to collect radiation technique data on patients undergoing cardiac catheterization.

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RADIATION DOSES TO PATIENTS IN HAEMODYNAMIC PROCEDURES

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Abstract

Interventional radio-cardiology gives high doses to patients due to high values of flouroscopy times and large series of radiographic images.
The main objective of the present work is the determination of de dose-area product (DAP) in patients of three different types of cardiology procedures with X-rays.
The efective doses were estimated trough the organ doses values measured with thermoluminescent dosimeters (TLDs-100), suitable calibrated, placed in a phamton type Rando which was submitted to the same radiological conditions corresponding to the procedures made on patients.
The values for the effective doses in the procedures CAD Seldinger was 6.20 mSv on average and 1.85mSv for pacemaker implants.

1. Introducción

La cardiología intervencionista es una especialidad médica en la que se utilizan los Rayos X como guía para la realización de diversas acciones médicas cardíacas. Se han publicado estudios dosimétricos en diferentes lugares [1], [2], [3] que indican que las dosis a los pacientes son suficientemente altas para que se hayan dado casos incluso de efectos determinísticos. Aunque los beneficios para el paciente pueden ser evidentes es necesario evaluar las dosis recibidas por paciente para poder asegurar el cumplimiento de los principios de justificación y optimización que exige el sistema de limitación de dosis en que se basa la protección radiológica en general y la del paciente en particular.

Los largos tiempos de escopia habituales en estos estudios de Hemodinámica [4-6] ocasionan altas dosis en la zona irradiada que, en estos casos, suele estar limitada a pequeñas áreas del tórax del paciente. Asimismo, el frecuente gran número de imágenes obtenidas ocasionan también valores importantes de dosis. Esta situación, conocida desde hace años [7], se mantiene a pesar de los continuos avances en la mejora de los equipos radiológicos diseñados para realizar estas actividades.

En el momento presente, en España ha entrado en vigor, hace unos meses, una normativa por la que estos equipos han de funcionar dotados de un sistema de medida y registro de la dosis a los pacientes. Sin embargo, todavía la mayoría de los equipos radiológicos dedicados a cardiología radiológica funcionan sin contar con ese equipamiento, por lo que las determinaciones de dosis han de realizarse mediante el uso de equipamiento adecuado y mediante la colaboración de diversos profesionales: cardiólogos, técnicos, radiofísicos y personal sanitario.

El propósito de este trabajo es realizar la caracterización dosimétrica de diversos procedimientos de radio-cardiología intervencionista y diagnóstica midiendo el producto dosis área correspondiente a cada procedimiento realizado sobre pacientes reales. Además se han

medido las dosis equivalentes necesarias para el calculo de la dosis efectiva al paciente a partir de la simulación de los procedimientos en un maniquí antropomórfico tipo Rando, en el que se colocaron dosímetros termoluminiscentes.

2. Material y método

El estudio se ha realizado en la Unidad de Hemodinámica del Servicio de Cardiología del Hospital Universitario de Canarias (HUC). Está compuesto de dos salas:

- Sala 1: donde se realizan todos los procedimientos relacionados con marcapasos cardíacos.
- Sala 2: donde se realiza estudios de angiografía coronaria diagnóstica (CAD) tipo Seldinger y tipo Sones ,y estudios de angioplastia coronaria transluminal percutánea (PTCA).

En la sala 1 el equipo usado fue también de la marca Siemens con un tubo Megalix 125/20/82 y generador Polydoros 80.

Todos los estudios realizados en la sala 2 se hicieron con un equipo de la marca Siemens, con generador Polydoros IS-C y con adquisición digital de imágenes. En ambas salas se da escopia pulsada.

Estos equipos cumplieron, durante la realización del estudio, las especificaciones fijadas en el Protocolo Español de Control de Calidad en Radiodiagnóstico [8].

La medida del producto dosis–área se hizo con una cámara de transmisión PTW modelo Diamentor M2, la cual se adosaba al diafragma del tubo de rayos X y cuyo sistema de registro se situaba en la consola de control del equipo radiológico.

En cada uno de los procedimientos se tomaron los siguientes datos:

a) Datos del paciente: edad, sexo, peso, talla, diámetro anteroposterior (AP), y diámetro lateral o transverso. Los diámetros se tomaron a la altura del tórax.
b) Datos del procedimiento:
    - Cinegrafia: kV , mA, distancia foco-intensificaddor (SID), tiempo de grafía, nº fotogramas, todo esto para cada serie.
    - Fluoroscopia: kV, mA, tiempo escopia.
    - El tamaño del campo usado en grafía fue siempre de 17 cm de diámetro, y en escopia de 23cm, para las exploraciones realizadas en la sala 2. Para los estudios relacionados con marcapasos cardíacos (sala 1) el tamaño del campo usado fue de 27cm.

El número de fotogramas por segundo usado en grafía fue siempre de 12,5 excepto para el ventrículograma (que es normalmente la última serie de cine) que fue de 50.

Las proyecciones usadas durante los procedimientos, fueron:
Posteroanterior, posteroanterior-caudal, posteroanterior-craneal, derecha anterior oblicua, derecha anterior oblicua - caudal, derecha anterior oblicua - craneal, izquierda anterior oblicua, izquierda anterior oblicua - craneal, izquierda anterior oblicua - caudal.

Se han realizado medidas en 62 pacientes. En 38 de ellos se hicieron CAD tipo Seldinger (18 mujeres y 20 hombres),. En 7 pacientes los CAD fueron tipo Sones En 6 pacientes se

realizaron PTCA. En 11 pacientes se realizaron implantes de marcapasos tipo DDD bicameral (colocación de dos cables, uno en aurícula y otro en ventrículo).
Todos los pacientes que fueron incluidos en este estudio tuvieron un peso comprendido entre 50 kg y 90 kg.

Se ha usado un maniquí Rando para estimar las dosis en órganos, mediante la utilización de dosímetros termoluminiscentes Harshaw tipo TLD-100 que se distribuyeron por todo el maniquí en posiciones correspondientes a los órganos y tejidos establecidos en las recomendaciones ICPR-60 para el cálculo de dosis efectiva.

La dosis asignada a cada órgano fue determinada haciendo un promedio de todos los resultados proporcionados por los TLDs colocados en el mismo,como es habitual [9]
La dosis de cada TLDs fue medida usando un lector Harshaw 4000, siguiendo para ello el procedimiento habitual en nuestro laboratorio.

La reproducción de los datos en el maniquí se hicieron para dos exploraciones: CAD tipo Seldinger y DDD.

En total fueron usados 65 TLD en la reproducción de el CAD tipo Seldinger y 55 TLDs para los implantes DDD de marcapasos.

3. Resultados

Las medidas realizadas de los parámetros representativos de cada tipo de exploración han dado lugar a los valores medios y desviaciones estándar (SD) que se presentan en la Tabla I.
La complejidad de las exploraciones PTCA se refleja en el alto valor promedio del producto dosis área.

En las exploraciones CAD tipo Seldinger cuyos resultados se presentan en esta Tabla I, sólo se han considerado las exploraciones “típicas”: coronariografia y ventriculografia.

Puede observarse en la tabla como en el cateterismo tipo Sones el valor del PDA es un algo más elevado que en el tipo Seldinger. Probablemente se debe a la mayor dificultad de realización del primer tipo.

La contribución de fluoroscopia y cinefluorografía al PDA en cada exploración, está representada en la figura 1. Se puede observar que en CAD (tipo Seldinger y tipo Sones) se da más cineflourografía que flouroescopia al contrario que en PTCA. En la sala 1, de los marcapasos sólo usa escopia.

Para reproducir las exploraciones cuando se usó el maniquí se utilizaron los valores medios de los parámetros medidos sobre los pacientes reales. En particular, se tenía muy en cuenta la máxima similitud entre el valor medio de PDA en los pacientes y el valor alcanzado en la irradiación del maniquí.

En la Tabla II se presentan los valores de las dosis medidas en “órganos” [10] del maniquí antropomórfico utilizando dosímetros termoluminiscentes TLD-100, que habían sido calibrados en el Centro Nacional de Dosimetría. Los datos corresponden a las dos exploraciones anteriormente indicadas. Es de señalar que estas dosis corresponden a los valores medios obtenidos a partir del conjunto de dosímetros colocados en cada órgano.

Tabla I. Parámetros radiológicos y dosimétricos de las tres exploraciones

		Cine			Escopia			
Tipo de exploración	**Nº pacientes**	**kV (SD)**	**mAs (SD)**	**Nº FOTOGRAMA (SD)**	**SERIES CINE (SD)**	**KVp (SD)**	**mAs (SD)**	**DAP cGy*cm^2 (SD)**
CAD (Seldinger)	38	70,5 (3,7)	3050,2 (231,1)	85,9 (9,5)	8,4 (2,0)	78,8 (7,2)	2271 (2653,3)	1907,5 (1171,1)
CAD (Sones)	8	75,5 (5,1)	3764,7 (511,4)	89,5 (8,1)	9,75 (2,1)	79,4 (1,7)	2567,1 (913,2)	2817 (1092,7)
PTCA	6	90,6(10,5)	2749 (5075)	95,2 (15,6)	9 (3,2)	98,3 (9)	10334.4 (2869)	4115 (4669.3)

Tipo de exploración	**Nº pacientes**	**kV**	**mA**	**DAP (cGy*cm^2) (SD)**
Marcapaso tipo DDD	11	77	4.6	1495 (632.7)

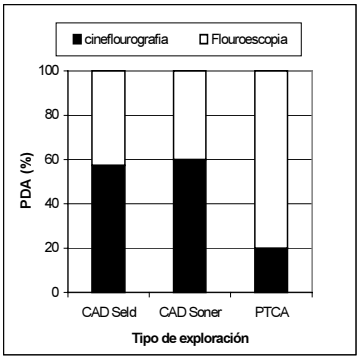

Figure 1. Contribución de la escopia y cine al producto dosis área para los tres tipos de exámenes

Tabla II. Dosis tejido/órgano

CAD tipo Seldinger Marcapasos tipo DDD

Órgano / tejido		**Nº de TLDs**	**Dosis (mGy)**	**Nº de TLDs**	**Dosis (mGy)**
Gónadas	Testículos	1	0.18	1	0.06
	Ovarios	2	0.28	2	0.40
Colon		7	0.64	4	0.09
Pulmón		25	15.37	18	2.07
Estómago		1	15.76	1	6.84
Vejiga		1	1.90	2	1.68
Esófago		6	6.90	6	2.80
Hígado		6	9.58	1	0.63
Tiroides		2	0.92	1	0.65
Corazón		3	12.82	3	3.70
Mama		2	2.25	2	2.25
Cristalino		2	0.25	2	0.10
Superficie ósea		1	28.60		
Piel		9	1.48	11	7.43
Total TLDs		**68**		**55**	

4. Conclusiones

1. La dosis efectiva (considerando solamente los órganos para los que ICRP-60 establece un factor de ponderación) para los dos tipos de exploraciones de cardiología intervencionista, estimada a partir de las medidas de dosis en órganos con dosímetros TLD en maniquí Rando son:
    - CAD tipo Seldinger : 6.2 mSv
    - Implante de marcapasos tipo DDD: 1.85 mSv
2. En los cateterismos, el 60% del PAD total fue impartido en cine-radiografía, este datos es similar al de otros autores (6). En el caso de los procedimientos PTCA el valor impartido en cine-radiografía fue de un 20% del total, este valor es inferior al porcentaje aparecido en la bibliografía.

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IAEA-CN-85-177

COMPARISON BETWEEN THERMOLUMINISCENCE DOSIMETRY AND TRANSMISSION IONIZATION CHAMBER MEASUREMENTS

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Abstract

Radiofrequency catheter ablation is an effective option to treat life-threatening arrhytmias. Among the risks of this type of procedures are the high radiation doses to patients. The major concern for monitoring of doses has been related to skin damage. Skin dose can be measured directly with thermoluminiscence dosimeters (TLDs) or can be determined from the dose-area product (DAP). In this work these two different methods are discussed. The radiation doses have been estimated in more than 20 patients with the two types of monitoring. In order to find the location of the maximum dose from the procedure with TLDs, dosimeter arrays can be placed on the patient. Unfortunately TLDs do not allow immediate feedback to the fluoroscopist. They require a fair amount of handling, calibrating, processing and annealing. On the other hand, the DAP provides immediate feedback of the cumulative dose. To obtain the skin dose from DAP the area of the radiation field on the skin must be determined, and it is necessary to correct the result by a factor that includes the variation of geometry during the procedure. Nevertheless these and other factors can lead to significant errors in dose estimation.

1. Introduccion

La ablación con radiofrecuencia es una alternativa efectiva a la terapia médica para pacientes con arritmias [1]. A pesar de ello es una técnica que presenta sus riesgos entre los que se encuentran las altas dosis de radiación recibidas por el paciente, que pueden alcanzar el umbral de los efectos deterministas y producir eritema e incluso radiodermitis en la zona del paciente directamente expuesta al haz de radiación [2]. Este es un aspecto que exige atención desde el punto de vista de protección radiológica y que tiene obvias implicaciones clínicas.

Para prever el alcance del posible daño producido por la radiación es necesario medir las dosis recibidas por los pacientes. Uno de los métodos más simples consiste en calcularlas a partir de medidas de rendimiento o de la tasa de dosis del equipo de rayos X, teniendo en cuenta el tiempo total de fluoroscopia utilizada. Sin embargo este método está sujeto a fuentes de error considerables, ya que tanto la geometría como los valores de tensión y corriente varían considerablemente durante la exploración. Entre los métodos alternativos se pueden destacar la medida de dosis mediante dosímetros de termoluminiscencia y la medida del producto dosis*área mediante cámaras de transmisión. El objeto de este trabajo es intentar comparar estos dos últimos métodos para desarrollar procedimientos razonablemente sencillos y fiables de estimación de la dosis que reciben los pacientes.

2. Material y metodos

Se han realizado medidas sobre un grupo de más de 20 pacientes que han sido sometidos a procedimientos terapéuticos de ablación en el laboratorio de electrofisiología cardiaca del Hospital Universitario de Valladolid (España) [3]. Para estimar las dosis recibidas por los pacientes se han utilizado simultáneamente dosímetros TLD-100 y las lecturas recibidas por una cámara de transmisión. Para intentar obtener el punto en la piel que recibe mayor cantidad de dosis se ha colocado en la espalda de cada paciente dos filas de 10 dosímetros cada una, con una separación de 2 cm entre ellas. Dentro de cada tira la distancia entre dosímetros

también es de 2 cm. Los dosímetros se leyeron en un equipo Victoreen 2800M siguiendo los procedimientos descritos en la referencia [4].

Como cámara de transmisión se ha utilizado una cámara PTW Diamentor M2 colocada a la salida del tubo de rayos X. Por último y para obtener una idea de los campos de radiación utilizados a lo largo del procedimiento se ha colocado para cada paciente una placa radiográfica lenta (Kodak X-Omat V) en la superficie de la mesa de intervención.

3. Resultados

En función de las características de cada procedimiento se han obtenido valores distintos de tiempo de fluoroscopia, tensión y corriente. Los tiempos son habitualmente grandes y pueden llegar a superar de manera no demasiado infrecuente las 2 horas, con un valor medio superior a la hora de fluoroscopia. Además cuando se trata de pacientes gruesos el sistema de imagen requiere un haz de radiación con tensiones superiores a 90 kV y corrientes de más de 3 mA.

1. DOSIMETRIA DE TERMOLUMINISCENCIA

En la figura 1 se muestran los valores máximos de dosis registrados en los dosímetros colocados en la espalda del paciente y los tiempos de fluoroscopia para la misma muestra de pacientes. Los valores de dosis son siempre altos (en ocasiones y en puntos concretos de la piel han superado 4 Gy), aunque variables entre pacientes debido a la particularidad de cada exploración, y dentro de la tira entre dosímetros debido a que cada uno de ellos está un tiempo distinto dentro del haz directo de radiación. Para ilustrar este último comentario en la figura 2 se muestran los resultados típicos de una tira de 20 dosímetros. A pesar de las precauciones tomadas, no puede garantizarse que el punto de la piel del paciente que ha recibido la máxima dosis haya quedado registrado dentro la lectura de los veinte dosímetros.

2. CAMARA DE TRANSMISION

La cámara de transmisión presenta los resultados en forma de producto dosis*área. Para el cálculo de la dosis en la espalda del paciente a partir de dicho valor puede utilizarse la siguiente expresión:

$$D_{in} = \frac{F(p,T) * F_r * F_t}{S} * L$$

donde D_{in} es la dosis a la entrada de la superficie del paciente, $F(p,T)$ es el factor de corrección por presión y temperatura, F_r es el factor de retrodispersión, F_t es el factor de transmisión de la mesa radiológica, S es el área irradiada en la espalda del paciente y L es la lectura de la cámara. Todos los factores pueden ser evaluados con lo que en definitiva D_{in} puede ser calculada como el producto de un factor por la medida de la cámara. En la tabla 1 se resumen los resultados obtenidos. La variabilidad en los mismos puede explicarse en función de los distintos tiempos de fluoroscopia utilizados, de los parámetros geométricos y de las características de espesor de los pacientes.

	Mínimo	Mediana	Media	Máximo
Parámetros haz radiación				
Tensión (kV)	64	73	76	96
Intensidad (mA)	1.6	2.0	2.2	3.4
Tiempo escopia (min)	20	63.3	73.2	139.1
Medida con TLD				
Máximo de dosis (Gy)	0.3	0.9	1.5	4.7
Abdomen (mGy)	0.5	1.5	1.9	4.5
Frente (mGy)	< 0.01	0.15	0.25	0.76
Medida con Diamentor				
Dosis*àrea (cGy/cm2)	5600	23400	25700	77000
Dosis máxima calculada (Gy)	0.41	1.25	1.8	5.61

Figure 1 Datos estadísticos correspondientes al haz de rayos X y a las medidas con TLD y cámara de transmisión

En condiciones ideales, si la geometría no se hubiera modificado durante un procedimiento, la lectura proporcionada por la cámara debería coincidir con la dosis máxima de la tira de dosímetros. Sin embargo dada la variabilidad de la misma no es el mismo punto de la espalda del paciente el que recibe la máxima dosis por lo que la medida del Diamentor tiende a sobrestimarla en un valor próximo, según estos cálculos, al 30%, aunque en algunos casos han llegado a ser del 50%. Estas variaciones pueden ser debidas a que no se ha conseguido registrar el punto de mayor dosis en el paciente dentro de la superficie registrada por la tira de dosímetros.

4. Discusion

Aunque la radiación puede producir efectos estocásticos y deterministas, en este caso son estos últimos los que adquieren una gran importancia debido por una parte a las altas dosis de radiación recibidas por los pacientes y por otra a que el grupo de población que es sometido a este tipo de procedimientos es relativamente pequeño si se compara con otro tipo de exploraciones de radiodiagnóstico. Aunque pueda haber órganos que tengan riesgo de alcanzar los efectos deterministas, la mayor preocupación a la hora de evaluar las dosis está en el daño sufrido por la piel [5]. Más aún, una vez que se conoce la dosis a la entrada hay distintos métodos para determinar la dosis a órganos internos [6]. En este trabajo se han utilizado dos métodos distintos de obtener la dosis máxima en la piel de los pacientes sometidos a ablación por radiofrecuencia.

La mayor dificultad en la dosimetría con TLD's está en garantizar una correcta colocación de los mismos en la espalda del paciente para asegurar que el punto de la piel que recibe mayor dosis puede quedar registrado con la lectura de los dosímetros irradiados. Obviamente para soslayar esta dificultad puede recurrirse a una matriz más compacta (con menos distancia entre dosímetros) y bidimensional [7]. Con todo uno de los mayores problemas del método es su laboriosidad que lo puede hacer poco recomendable para un uso sistemático. Además los valores obtenidos no pueden verse durante el desarrollo de la exploración, sino que requiere una lectura y limpieza en un laboratorio. Los dosímetros utilizados habitualmente para dosimetría de pacientes son los de fluoruro de litio que presentan una variación en su respuesta con la energía de un 30% - 40% desde 30 keV hasta 100 keV. Además las dosis en estos procedimientos pueden alcanzar el rango en el que la respuesta del TLD se convierte en supralineal (en torno a 6 Gy), lo que obligaría a utilizar necesariamente factores de corrección. La utilización de una cámara de transmisión tiene inicialmente la ventaja de que los valores medidos se presentan en tiempo real en pantalla con lo que el cardiólogo puede tener una idea de la cantidad de dosis que está recibiendo el paciente. Sin embargo a diferencia de los TLD la medida de dosis en la piel se convierte en indirecta y es necesario estimar el área del haz de radiación. Una incertidumbre de un 5% en la medida de las distancias se traduce en una

incertidumbre del 10% en el valor del área. Además no debe olvidarse que dicho área cambia con la orientación de la geometría, con el modo de magnificación usado y con el ajuste de los colimadores. Por otra parte debe aceptarse la inclusión de un factor de corrección que tenga en cuenta la variación del campo de entrada a lo largo del procedimiento.

También el resto de factores presentes en el cálculo presentan una incertidumbre. El factor de retrodispersión depende del tamaño de campo del haz de radiación y de la energía pero su variación puede estar acotada en un 10% de su valor medio para el intervalo de campos y energías utilizados en este tipo de exploraciones [8]. El factor de transmisión de la mesa radiológica depende de la energía pero también del ángulo de incidencia del haz de radiación. Por último si el colimador dispone de filtros compensadores, la utilización de los mismos subestimará la medida de la dosis en las zonas no atenuadas por los mismos mediante el método de cámara de transmisión.

5. Conclusion

Los dos métodos estudiados de estimación de dosis a pacientes en procedimientos de ablación por radiofrecuencia presentan ventajas e inconvenientes que los pueden hacer más o menos recomendables en función del objetivo que se tenga en mente. En este tipo de procedimientos con tan altas dosis puede ser necesario un conocimiento más preciso de las mismas para establecer criterios de vigilancia y actuación específicas para aquellos casos en que se superen determinados niveles. La medida directa con una matriz bidimensional de TLD's suficientemente compacta parece ser la respuesta a esta necesidad ya que es el método que presenta menor grado de error, aunque sea poco práctico. Sin embargo también puede ser muy interesante para el cardiólogo tener en tiempo real la dosis recibida por el paciente durante una intervención para poder determinar si debe ser modificado el procedimiento para proteger la piel del paciente de daños debidos a la radiación. La medida de tiempos de fluoroscopia y parámetros del haz de rayos X (tensión y corriente) puede dar aproximaciones adecuadas, aunque con un margen de error que puede ser muy importante.

Si se está dispuesto a asumir un cierto grado de incertidumbre (que puede ser superior al 30% en determinados casos) en la medida de la dosis para así poder obtener las lecturas durante la intervención, el modo más simple y práctico parece la medida sistemática del producto dosis*área con una cámara de transmisión, con la inclusión de un factor de corrección que tenga en cuenta la variación del campo de entrada a lo largo del procedimiento.

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RADIOFREQUENCY CATHETER ABLATION: RELATIONSHIP BETWEEN FLUOROSCOPIC TIME AND SKIN DOSES ACCORDIND TO DIAGNOSES. BASIS TO ESTABLISH A QUALITY ASSURANCE PROGRAMME

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Abstract

Radiofrequency Cardiac Catheter Ablation is an Interventional Radiology procedure of great complexity because of the cardiologist needs of a simultaneous evaluation of fluoroscopic images and electrophysiologic information.. Therefore, the procedure typically involves extended fluoroscopic time that may cause radiation-skin injures to patients. Skin doses depend on many factors: equipment design features and its proper use, cardiologist practice, fluoroscopic time, irradiated areas, application of radiation protection recommendations, etc. We evaluate fluoroscopic time in relation to pathology and we estimate skin doses on 233 procedures at the Electrophysiology Laboratory in Casa de Galicia, Montevideo, Uruguay. Significant differences among the medians of fluoroscopic time were found in those procedures depending on diagnoses and results. Higher fluoroscopic time was found in flutter and auricular tachycardia (median was 83 minutes, p=0.0001). In successful procedures (almost 90%), median skin doses was 2.0 Grays(p=0.0001). On the basis of records information, the standard operating procedure and the clinical protocol, expanding close cooperation between the cardiologists and the experts in Radiation Protection will secure the establishment of an Assurance Quality Program.

1. Introduccion

La ablación por catéter utilizando radiofrecuencia(AC) es la primera opción terapéutica para un numeroso grupo de pacientes con taquiarritmias. La mayoría de las taquicardias de significación clínica se deben al mecanismo de reentrada, es decir, a la existencia en el corazón de un circuito anatómica y electrofisiológicamente definido que depende para su funcionamiento de una zona crítica. Identificando el circuito mediante un estudio electrofisiológico(EEF) y aplicando radiofrecuencia(AC) en su zona crítica, puede eliminarse la arritmia y curar al paciente. La ubicación de los catéteres se realiza a partir de imágenes fluoroscópicas. La complejidad del procedimiento hace que, en algunos casos, las dosis recibidas por los pacientes pueden producir efectos determinísticos en su piel[1].Uruguay no tiene un Programa Nacional de Protección Radiológica(PR) y el currículum de la especialidad Cardiología no tiene horas asignadas a la formación en PR. Esto motivó el inicio a partir de agosto del año 2000, de un Programa de Educación en PR en Cardiología Intervencionista. Al iniciarse la etapa de evaluación de los procedimientos, los profesionales del Laboratorio de Electrofisiología Cardíaca de Casa de Galicia son ampliamente receptivos a la implementación de un Programa de Garantía de Calidad [2].

Con el fin de evaluar indicadores de posibles efectos determinísticos en la piel de los pacientes sometidos a AC, el presente trabajo tiene como objetivo determinar los tiempos de fluoroscopía (*t*)y estimar las dosis en piel de pacientes(D)en función del diagnóstico que justifica el procedimiento.

2. Material y metodos

El trabajo se realizó en el Laboratorio de Electrofisiología de Casa de Galicia sobre un total de 383 procedimientos en el período diciembre de 1992 a octubre de 2000.Se consideraron únicamente aquellos procedimientos realizados una única vez por sesión (n = 283) en los que se aplicaron los siguientes criterios de exclusión: carencia o dudas en los datos de *t* (n = 22), diagnósticos poco concluyentes (n = 10) o más de uno (n = 17) en el EEF, con lo que la población definitiva queda reducida a 233 AC en 218 pacientes, de las cuales 12 (5.2%) son reintervenciones en procedimientos independientes. Los diagnósticos del EEF fueron clasificados en 4 grupos (Tabla I).

Tabla I. Agrupación de Diagnósticos en el EEF

Diagnóstico	N (%)
Reentrada Nodal (RN)	103 (44.2)
Vías Accesorias (VA)	66 (28.3)
Flutter y Taquicardias Auriculares (FT)	37 (15.9)
Otros diagnósticos (*)	27 (11.6)

(*) Fibrilación auricular crónica(n=17), Fibrilación auricular paroxística (n = 7)yTaquicardias ventriculares (n=3).

Los tiempos de fluoroscopía fueron registrados sistemáticamente en el período junto a características básicas de los pacientes de interés para este estudio registradas en las historias clínicas y en la base de datos del Servicio de Electrofisiología (Tabla II).

Tabla II. Características básicas de los pacientes sometidos a AC

Diagnóstico	RN	VA	FT	Otros
N	103	66	37	27
Hombres (%)	23 (22.3)	37 (56.1)	20 (54.1)	22 (81.5)
Edad +/- 1ds (años)	49.7 +/- 18	37.1 +/- 18	56.7 +/- 14	58.8 +/- 10
Talla +/- 1ds (cm)	164 +/- 8	168 +/- 13	169 +/- 10	173 +/- 11
Peso +/- 1ds (Kg)	67 +/- 16	75 +/- 18	78 +/- 12	86 +/- 21

El equipo de fluoroscopía utilizado en todas las AC fue Siemens Elema modelo Angioskop D (año 1991), no tiene radioscopía pulsada ni mantiene la última imagen y careció de controles de calidad.

Todas las AC fueron realizadas por el mismo equipo de médicos electrofisiólogos, y se utilizaron los siguientes protocolos estandarizados: a) clínico, que comprende la inserción como mínimo de 4 catéteres: uno en seno coronario por vía subclavia y los restantes en aurícula y ventrículo derechos por vía femoral. El catéter de ablación siempre dispuso de un electrodo distal de 4 mm de superficie, con y sin control de temperatura, conectado a un generador de radiofrecuencia Medtronic-Cardiorrythm modelo Atakr. b)radiológico, inserción del catéter en seno coronario con proyecciones AP y OAI en un *t* promedio de un minuto. Inserción del resto de los catéteres, procedimientos diagnósticos y terapéuticos con proyecciones OAD (60% de *t*) y OAI (40% de *t)*. Durante toda la práctica: diámetro de entrada del II es 23 cm, máxima distancia foco-piel y mínima distancia intensificador-piel. Debido a que, *no se dispone de instrumental,* se optó por el método que sigue para estimar D. Las constantes para la estimación de D fueron proporcionadas por la empresa CONATEL, que

realiza el Servicio Técnico del equipo radiológico. De acuerdo al equipo radiológico utilizado y los protocolos arriba señalados, se aplicó la siguiente:

D (Gy) = 1.35x(Rendimiento)x (m A)x tiempo de Fluoroscopía

Donde: 1.35 es el factor de retrodispersión, m A es el promedio estimado a partir del equipo y del protocolo practicado[3][4]. Se aplican los factores de equivalencia entre unidades de medida y se realiza la corrección de la distancia para obtener el rendimiento a la entrada de la piel. Este método sobrestima la dosis en piel [3][4].

Se consideraron finalmente los resultados de la AC de acuerdo a los siguientes criterios clínicos:

a) Éxito. Eliminación de la taquicardia por modificación o eliminación de la conducción en la vía lenta(en RN), por eliminación del o las VA, y en el flutter auricular la demostración de bloqueo bidireccional a nivel del istmo cavo-tricuspídeo.
b) Éxito Parcial. No se cumplen totalmente los criterios de éxito aunque los circuitos de taquicardia son modificados. Solamente la evolución clínica podrá definir el éxito total.
c) Falla. El procedimiento no cumple con ninguno de los objetivos.

3. Metodos estadisticos

Las variables centrales del estudio son estimadores de la radiación recibida por los pacientes sometidos a AC: los *t* registrados y una estimación de D durante las AC a través de la ecuación lineal descrita en métodos. Las variables de agrupamiento y comparación son los diagnósticos establecidos en el EEF y los resultados de la AC. Las distribuciones de ambos estimadores según diagnósticos difirieron significativamente de la normalidad según el test de Shapiro-Wilk, solamente se comportaron como normales las pequeñas distribuciones (éxito parcial y falla) por lo cual las comparaciones de *t* y de D se realizan a través de las pruebas no paramétricas de Kruskall-Wallis y Mann-Whitney. Las comparaciones de proporciones de éxito según los diagnósticos se establecieron por medio de chi cuadrado, 1 grado de libertad. En todos los casos alfa = 0.05. Los datos fueron procesados en EPI INFO 6.04 B y Prophet V5.0.

4. Resultados

Las medianas de *t* (83 min) y D estimada (5.0 Gy) para el diagnóstico FT fueron significativamente mayores que para los otros diagnósticos, los que no mostraron diferencias significativas entre sí (Tabla III y Figura 1).

Tabla III. Tiempos de Fluoroscopia (*t* en minutos) y Dosis (D en Gy) según diagnósticos

Diagnóstico	RN	VA	FT	Otros
t Media +/- 1ds	36 +/- 25	52 +/- 43	91 +/- 50	42 +/- 35
t Mediana	28	42	83	36
D Media +/- 1ds	2.1 +/- 1.5	3.1 +/-2.6	5.5 +/- 2.9	2.5 +/- 2.1
D Mediana	1.7	2.5	5.0	2.2

Las medianas de *t* (33 min) y D estimada (2.0 Gy) para el resultado éxito fueron significativamente menores que para los otros resultados, los que tampoco mostraron diferencias significativas entre sí (Tabla IV y Figura 2)

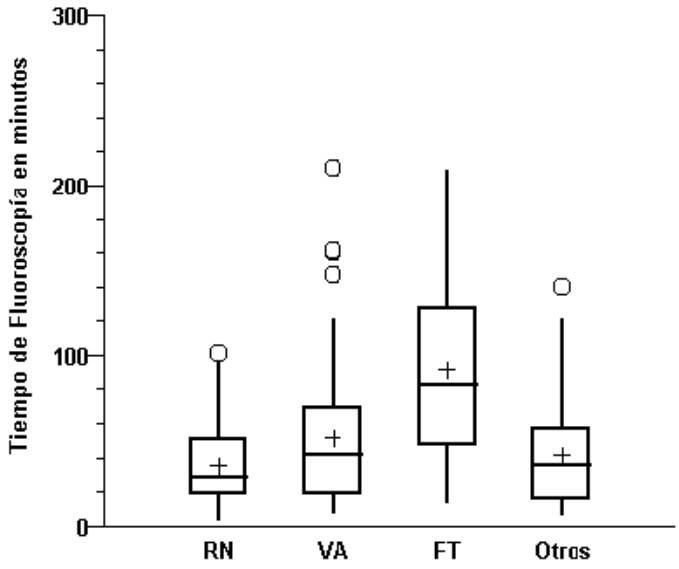
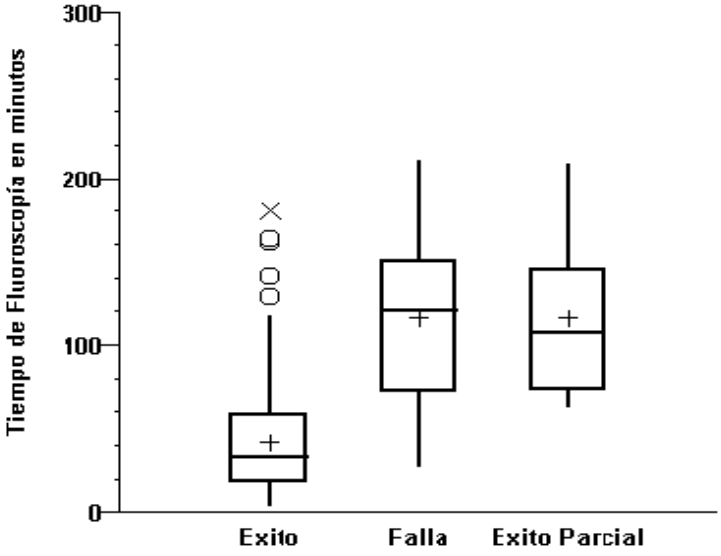


Figura 1. Comparaciones de tiempos de fluoroscopia en 233 ablaciones por catéter de radiofrecuencia según diagnósticos en un servicio de Electrofisiología de Montevideo, Uruguay, entre 1992 y 2000.
El tiempo de FT es significativamente mayor que el del resto de los diagnósticos (kruskall-wallis, p = 0.0001) quienes no mostraron diferencias significativas entre sí.



RN : reentrada nodal (n = 103), VA: vías accesorias (n = 66), FT: flutter y taquicardias auriculares (n = 37) y Otros (n = 27.
Figura 2. Comparaciones de tiempos de fluoroscopia en 233 ablaciones por catéter de radiofrecuencia según resultados obtenidos en un servicio de Electrofisiología de Montevideo, Uruguay, entre 1992 y 2000. El tiempo de éxito es significativamente menor que el de los otros resultados (kruskall-wallis, p = 0.0001) quienes no mostraron diferencias significativas entre sí.
Éxito (n= 207), éxito parcial (n = 8) y falla (n = 18).

Tabla IV. Tiempos de Fluoroscopia (*t* en minutos) y Dosis (D en Gy) según resultados de AC

Resultado	Exito	Éxito Parcial	Fallo
N (%)	207 (88.8)	8 (3.4)	18 (7.7)
t Media +/- 1ds	42 +/- 31	107 +/- 48	116 +/- 51
t Mediana(min)	33	107.5	120
D Media +/- 1ds(Gy)	2.5 +/-1.9	6.9 +/- 2.9	6.9 +/-3.0
D Mediana(Gy)	2.0	6.4	7.2

La proporción de éxitos en FT, 24/37 (64.9%) es significativamente menor que RN(97.1%), p = 0.00001 y que VA(90.9%), p = 0.001, pero no con otros, 23/27 (85.2%), p = 0.07.

5. Discusion

Si bien existe bibliografía de D en AC, no es habitual vincular D y *t* a los diagnósticos que justifican los procedimientos y sus resultados. Al tratarse de los mismos médicos electrofisiólogos, equipos de fluoroscopia y de radiofrecuencia, catéteres de ablación y protocolos clínicos y radiológicos, los diagnósticos y resultados de las AC determinan *t* y D, aunque nuestro cálculo de D está sujeto a error y tiende a la sobreestimación. En FT, *t* y D son elevados porque es una patología compleja, los catéteres tienen una superficie pequeña y el número de casos(15.9%) es bajo para modificar la curva de aprendizaje. La mediana de *t* en los procedimientos exitosos(casi 90%) es 33 minutos y aceptable para nuestras condiciones. Al considerar FT, el éxito es significativamente menor, lo que explica que sea el diagnóstico con mayor *t* y D. Clínicamente, *t* podría optimizarse utilizando catéter de superficie mayor a 4 mm; físicamente, *t* puede disminuirse con equipo de fluoroscopía pulsada, que sostenga la última imagen y con equipo biplano. D puede disminuirse aplicando un Programa de Garantía de Calidad y con un equipo de RX con otras características técnicas. Pese al error de nuestro cálculo de D, los pacientes sometidos a AC por FT, pueden alcanzar fácilmente el umbral de dosis para efectos determinísticos en piel [5].Es necesario medir D con protocolos establecidos e instrumental, para evaluar estos efectos y probabilidades de estocásticos. Dada la curva de aprendizaje de los médicos electrofisiólogos es difícil que cambie la diferencia de *t* entre FT y los demás diagnósticos.

6. Conclusiones

El tiempo de fluoroscopía y las dosis están determinados por el diagnóstico. Al evaluarse los elementos clínicos y físicos de este Laboratorio, se fundamenta el establecimiento de un Programa de Garantía de Calidad que será referencia en nuestro medio.

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ESTIMATION OF SKIN DOSE IN INTERVENTIONAL NEURO AND CARDIAC PROCEDURES

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Abstract

The dose thresholds for inducing deterministic effects such as erythema and epilation are now within the range of some interventional radiology procedures. It is important to identify those procedures where such dose levels are possible so that more detailed dosimetry and dose reduction can be introduced to minimise the risk of such effects. This paper presents results of work on anthropomorphic phantoms to establish a link between a commonly measured dose indicator (dose-area product) and skin dose, for equipment and geometries commonly used for cardiac and neurological interventional radiology procedures. The results indicate that a conversion to skin dose is equipment specific and furthermore depends on field size and projection. By auditing a sample set of patient data, however, it is possible to identify potentially high dose procedures.

1. Introduction

The increased use of radiology for the guidance of interventional procedures, and the increase in complexity of such use, has led to higher patient doses in recent years, with reported cases of deterministic effects in patients [1,2]. The US Food and Drug Administration (FDA) have issued guidance for those procedures where there is a likelihood of significant skin doses [3]. Implementation of the Medical Exposures Directive [4] in member states of the European Union requires us to define standard operating protocols and to apply reference doses to diagnostic (including interventional) procedures.

This paper presents measurements made on anthropomorphic phantoms which can be used to link dose area product (DAP) values to skin dose for situations typically encountered in both interventional neuroradiology and cardiac procedures.

2. Method

For both cardiac and neurological procedures typical exposure conditions were set up by experienced operators on dedicated radiology equipment. In each case the patient was represented by an appropriate Temex anatomical phantom comprising a skeleton encased in rubber. For the chest phantom there were appropriate air cavities to represent the lungs. Skin doses were measured directly using a Skin Dose Monitor (SDM supplied by McMahon Medical) placed on the entrance surface at the centre of the field of view. DAP readings were obtained simultaneously from pre-installed meters (Diamentor, PTW).

Cardiac measurements were performed on an Advantx LC+ (General Electric Medical Systems). Neurological measurements were performed on an angiographic biplanar system (Toshiba Medical Systems) and on an Advantx single plane system (General Electric Medical Systems). Measurements were taken for various geometric configurations and at all field sizes and dose and fluoroscopy pulse rates in normal clinical use.

3. Results

The skin dose measurements from the cardiac system are presented in Table I, and from the neuro systems in Tables II (single plane) and III (biplane).

Table I. Entrance Surface Dose Rates in Cardiac Fluoroscopy

Projection	mGy/min for field size of diameter:		
	23cm	**15cm**	**11cm[a]**
PA	2.4	4.2	18.4
RAO 30^0 + 25^0 CAU	3.0	3.6	10.0
RAO 10^0 + 10^0 CAU	2.0	3.4	13.8
Lateral	18.8	23.0	56.0
LAO 45^0	3.2	4.4	10.8
LAO 45^0 + 25^0 CAU	6.2	9.2	27.2
RAO 30^0	2.4	3.2	9.4

[a] All fluoroscopy on the 11cm diameter field is performed using high detail mode, which was measured in separate tests to be 66% higher than the standard medium detail fluoroscopy mode.

Table II. Entrance Surface Dose Rates in Neurological Fluoroscopy Procedures (Single Plane System)

Projection	mGy/min for field size of diameter:		
	30cm	**23cm**	**15cm**
Lateral	3.0	6.0	15.4
PA (Townes)	-	4.4	11.6

Table III. Entrance Surface Dose Rates in Neurological Fluoroscopy Procedures (Biplane System)

Projection	mGy/min for field size of diameter:			
	30	**23cm**	**15cm**	**13cm**
PA (Townes)	3.2	6.4	10.8	17.8
OM	4.2	8.6	12.6	19.0
Obliques	2.0	3.6	7.2	13.6
Lateral	5.6	10.0	11.2	19.0
Lateral 11^0 CRA/CAU	-	8.6	9.6	-

In all cases the dose rate is seen to rise as the field size is reduced, and is higher for lateral projections, particularly of the thorax.

The biplane system used for neuro-angiography has the facility for dose reduction via pulsed fluoroscopy, with selectable pulse rates of 30, 15, and 7.5 pulses per second. The data presented in Table III above relates to continuous fluoroscopy. It was confirmed by separate measurements on a water phantom that the dose varies in direct proportion to pulse rate, with 30 pulses per second giving an entrance surface dose rate equivalent to that obtained with continuous fluoroscopy.

Simultaneous recording of Dose-Area Product or Dose-Area Product rate, enabled a conversion factor to be calculated from DAP to skin dose for each of the projections given above. These conversion factors are given in Tables IV, V and VI for cardiac, neuro (single plane) and neuro (biplane).

Table IV. DAP to Skin Dose Conversion Factors in Cardiac Fluoroscopy

Projection	mGy per Gycm^2 for field size of diameter:		
	23cm	**15cm**	**11cm**
PA	4.67	7.63	10.93
RAO 30^0 + 25^0 CAU	4.11	6.64	9.33
RAO 10^0 + 10^0 CAU	4.13	6.37	9.53
Lateral	7.64	12.43	17.39
LAO 45^0	3.56	5.73	7.86
LAO 45^0 + 25^0 CAU	3.55	6.08	8.27
RAO 30^0	3.02	5.00	7.21

Table V. DAP to Skin Dose Conversion Factors in Neurological Fluoroscopy Procedures (Single Plane System)

Projection	mGy per Gycm^2 for field size of diameter:		
	30cm	**23cm**	**15cm**
Lateral	5.06	4.48	10.91
PA (Townes)	-	3.23	5.15

Table VI. DAP to Skin Dose Conversion Factors in Neurological Fluoroscopy Procedures (Biplane System)

Projection	mGy per Gycm^2 for field size of diameter:			
	30	**23cm**	**15cm**	**13cm**
PA (Townes)	2.47	4.13	7.62	12.29
OM	3.03	5.19	9.09	15.22
Obliques	1.71	3.03	5.60	9.54
Lateral	3.91	5.57	9.33	16.07
Lateral 11^0 CRA/CAU	-	5.33	8.47	-

Similar data was accumulated for angiographic runs with acquisitions at frame rates used commonly in clinical practice. DAP to skin dose conversion factors were found to be similar to those established for fluoroscopy with the same geometry.

Measurements confirmed that the conversion factors were independent of fluoroscopy dose rate and of acquisition frame rate.

4. Conclusions

The results presented above illustrate the variation that can occur in both skin dose rate and in the relationship between DAP and skin dose between equipment of different types and between different geometries on the same piece of equipment. In order to derive a reasonable estimate of skin dose based on DAP readings, it will be necessary to have details of the equipment used and

of the proportion of total DAP at a given field size and projection. The ease with which such data could be recorded for a limited number of cases will depend on the complexity of the radiological technique. It would clearly be more difficult to achieve for a cardiac procedure than for neuro-embolisation where there is a more limited number of projections and field sizes used. Our results indicate that knowledge of dose rates or frame rates or of the fluoroscopy:acquisition ratio is not as significant. The values presented are for a typical adult sized patient and the variation with patient size or exposure parameter (kV or mA) has not been included.

These measurements were performed as part of an extended quality assurance programme focussing on equipment and procedures with the potential to deliver high dose rates to the skin of patients. In such cases it would be ideal to measure skin dose directly, but this can be expensive, labour intensive, and inconvenient, particularly for complex cardiac procedures where the angulation of the X-ray beam, and thus the site of skin exposure, varies considerably. A large number of hospitals have adopted DAP as the unit for their dose reference levels in fluoroscopic procedures, making DAP data readily available. By the process of establishing conversion factors as described in this paper it is possible to identify those procedures which may result in high skin doses such that efforts at more detailed dosimetry and dose reduction can be targeted effectively. It is not intended that the derivation of skin dose from DAP values be used as an alternative to more direct methods of skin dose measurement.

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PATIENT RADIATION DOSES FROM NEURORADIOLOGY PROCEDURES

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Abstract

Following the presentation of radiation-induced deterministic effects by some patients undergone neuroradiological procedures during successive sesions, like temporary epilation, in the 'Hospital Universitario de Canarias', measurements were made of dose to patients. The maximum dose-area product measured by ionization chamber during these procedures was 39617 cGy·cm^2 in a diagnostic of aneurysm and the maximun dose to the skin measured by thermoluminescent dosemeters (TLDs) was 462.53 mGy. This can to justify certain deterministic effects but it is unlikely that the patients will suffer serious effects from this skin dose. Also measurements were made of effective dose about two usual procedures, embolisation of tumour und embolisation of aneurysm. These procedures were reproduce with a anthropomorphic phantom Rando and doses were measure with TLDs. Effective doses obtained were 3.79 mSv and 4.11 mSv, respectivily. The effective dose valued by the program EFFDOSE was lesser than values measure with TLDs.

1. Introducción

Las determinaciones de los niveles de dosis a pacientes en exploraciones de Neuro-radiología, constituyen un factor clave para el subsiguiente establecimiento de medidas de protección radiológica. Se han realizado algunas determinaciones de estas dosis [1-4] y puede concluirse que, en general, se suministran dosis relativamente altas en la cabeza de los pacientes, que pueden, incluso ocasionar efectos determinísticos tales como depilación temporal y eritemas. Los valores publicados de dosis a pacientes no son coincidentes incluso entre exploraciones similares, debido a las profundas diferencias que pueden darse entre los pacientes, a la diversa instrumentación utilizada y al grado variable de preparación y experiencia entre el personal que realiza estos procedimientos.

Para establecer los riesgos asociados con la exposición de los pacientes a radiaciones en neuro-radiología se ha recomendado la utilización de la magnitud dosis equivalente [5], aunque también se ha indicado la conveniencia de usar la magnitud dosis efectiva [6], cuya evaluación puede ser problemática [7]. En Europa está muy extendido el uso de la magnitud Producto Dosis Área (PDA) para la caracterización dosimétrica de procedimientos radiológicos. El objetivo de este trabajo es determinar los valores de magnitudes dosimétricas características de 3 tipos de exploraciones neuro-radiológicas realizadas en el Hospital Universitario de Canarias (Tenerife - España) y estimar el nivel de riesgos estocásticos y determinísticos de los pacientes sometidos a las mismas.

2. Material y método

Se analizaron 25 casos en procedimientos de neuro-radiología diagnóstica o intervencionista realizados durante el año 2000. Todos los estudios fueron realizados por el mismo neuro-radiólogo utilizando un equipo de angiografía por substracción digital marca Philips modelo Integris 3000, con el generador e intensificador de imágenes propios del equipo y con capacidad para proporcionar campos circulares. El tubo de rayos X y el intensificador de imágenes está dispuesto en un arco tipo C. El haz de rayos X tiene una filtración equivalente a

3.5 mm de aluminio. El equipo ajusta automáticamente el potencial y la corriente del tubo, si bien puede conocerse el rango de kV usado, que varió entre 62 y 97.

La técnica angiográfica empleada en todos los procedimientos de neuro-radiología realizados en el Hospital Universitario de Canarias, implica la inyección automática de un agente de contraste yodado por arteria femoral.

Para la medida del PDA se utilizó, en todos los estudios, una cámara de ionización de transmisión marca PTW modelo Diamentor M2, que permite obtener directamente el valor del PDA en $cGy \cdot cm^2$. La cámara se adosó al diafragma del tubo de rayos X, tras el filtro de aluminio y su sistema de registro se situó en la zona protegida. Los datos correspondientes a cada estudio se recogían mediante un seguimiento permanente del desarrollo del procedimiento que, en algunas ocasiones, podía prolongarse durante varias horas. Se obtuvieron, separadamente, los valores del PDA debidos al uso de rayos X en modo escopia y en modo grafía, así como las distintas proyecciones utilizadas en cada momento.

Adicionalmente, en 6 de los pacientes, se colocaron 4 dosímetros termoliminiscentes de LiF (TLD modelo 100 Harshaw Chemical), adosados a la piel del paciente en aquellas zonas donde se consideraba más probable que se alcanzaran los mayores valores de irradiación: huesos fronto-temporoparietales izquierdo y derecho, frontal a la altura de las cejas y sobre la región nasal. Siempre se midieron las dosis registradas por los dosímetros antes de que transcurrieran 24 horas después de su irradiación con un lector Harshaw 4000. Los resultados se muestran en la *Tabla II*.

La irradiación controlada de los dosímetros utilizados, realizada por un laboratorio oficial de calibración, puso de manifiesto que la respuesta de los mismos era lineal en las diversas energías de rayos X utilizadas.

Una vez finalizada la recogida de los datos en los pacientes reales, se llevó a cabo una medida de dosis en un maniquí antropomórfico tipo Rando con el que se reprodujeron, en el mismo equipo radiológico y por el mismo neuro-radiólogo, las exploraciones realizadas con los valores medios de los datos medidos sobre los pacientes. El proceso se llevó a cabo para dos de las exploraciones estudiadas, colocando un total de 59 dosímetros termoluminiscentes en el maniquí, situando en su superficie y en 'órganos' o 'tejidos' interiores de forma que proporcionaran datos que permitieran calcular la dosis efectiva.

3. Resultados y discusión

En la *Tabla I* se presentan datos de las exploraciones realizadas y los valores de PDA en cada una de ellas.

Destaca la gran variación de tiempos de escopia y valores del PDA, incluso tratándose del mismo estudio, debido, básicamente, al distinto grado de complejidad del caso de cada paciente.

En la *Tabla II* se muestran los resultados de las dosis medidas con dosímetros termoluminiscentes. Se observa que los dosímetros colocados en uno de los lados de la cabeza dan valores de dosis superiores debido a que la exploración se realizó con predominio de la irradiación de uno de los lados, según donde estuviera localizada la lesión.

Tabla I. Producto dosis área medido en los distintos procedimientos

Tipo de estudio	Campo de radiación (cm)	FLUOROSCOPIA				GRAFÍA		PDA Total cGy·cm^2
		kV	mA	Tiempo (s)	PDA cGy.cm^2	Nº exposiciones	PDA cGy·cm^2	
1. D.A.	20	78 – 90	4.3 – 6	112	387	58	2887	3274
2. D.A.	17	74 – 91	4.6 – 6	205	662	132	7490	8152
3. D.A.	20	73 – 97	2.5 – 2.8	4904	20462	317	19155	39617
4. D.A.	17, 20	73 – 96	3.9 – 5.8	2835	8549	131	9956	18508
5. D.A.	17, 20	67 – 77	3.8 – 4.9	162	626	120	7315	7941
6. D.A.	17, 20	67 – 80	3.7 – 5.9	246	1279	138	11214	12493
7. D.A.	17, 20	67 – 84	3.1 – 5.8	264	900	136	7239	8139
1. E.A.	20	62 – 87	2.4 – 5.9	2717	13315	135	8717	22032
2. E.A.	20	67 – 73	3.9 – 5	2640	5588	374	22548	28136
3. E.A.	20	67 – 72	3.8 – 5.6	264	665	176	866	9325
4. E.A.	20	67 – 72	2.4 – 5.6	42	126	60	3259	3385
5. E.A.	20	71 – 83	3.8 – 4.8	1051	2755	180	8411	11166
6. E.A.	17, 20	73 – 76	3.8 – 4.9	143	544	58	3134	3678
7. E.A.	17, 20	71 – 78	3.1 – 5.3	1337	5514	143	8510	14024
8. E.A.	20, 25	67 – 74	2.4 – 4.2	2708	4767	358	8279	13046
9. E.A.	20	70 – 86	3.9 – 4.8	2766	987	268	11637	12624
10. E.A.	20	71 – 77	3.4 – 3.9	153	429	72	4086	4515
11. E.A.	20	75 – 92	4.4 – 5.9	3684	20837	249	15253	36090
12. E.A.	17	67 – 87	4.7 – 6.0	1500	11436	151	12286	23722
13. E.A.	17, 20	66 – 83	2.5 – 5.8	1686	11775	194	14021	25796
1. E.T.	20	73 – 82	3.5 – 5.9	232	828	140	8782	9610
2. E.T.	17, 20	70 – 87	3.2 – 6	247	803	98	5071	5874
3. E.T.	20	71 – 78	4.9 - 5.8	823	3627	177	10401	14028
4. E.T.	20	77 – 91	4.3 – 5.8	1854	5065	209	9601	14666
5. E.T.	17, 20	62 – 81	2.2 – 5.7	996	5664	243	20135	25799

D.A= Diagnóstico de Aneurisma; E.A.= Embolización de Aneurisma; E.T.= Embolización de Tumor.

En la *Tabla III* se presentan los valores medios de dosis medidos en órganos del maniquí antropomórfico Rando, así como los resultados de las dosis medidas con dosímetros superficiales.

Aplicando los factores de ponderación propios de cada tejido u órgano propuestos en las Recomendaciones ICRP 60[8], puede calcularse la dosis efectiva recibida por el fantoma RANDO, ($E = \Sigma w_T H_T$). Obteniendo las contribuciones $H_{\text{médula ósea roja}}$ y $H_{\text{superficie ósea}}$ mediante simulación con el programa Effdose, se llegó a una dosis efectiva, con los órganos que se había medido, de 3.79 mSv para embolización de tumor y 4.11 mSv para embolización de aneurisma.

Tabla II. Dosis en distintos puntos de la cabeza de los pacientes

Paciente	Tiempo escopia, s	Nº exposiciones	Posición	Dosis (mGy)
5. D.A.	162	120	Frontal	3.99
			Región nasal	3.84
			Temporoparietal dcho.	162.50
			Temporoparietal izdo.	107.55
6. D.A.	246	152	Frontal	9.02
			Región nasal	4.58
			Temporoparietal dcho.	63.37
			Temporoparietal izdo.	281.14
7. D.A.	264	136	Frontal	3.40
			Región nasal	3.05
			Temporoparietal dcho.	0.03
			Temporoparietal izdo.	90.86
12. E.A.	1500	151	Frontal	8.81
			Región nasal	6.31
			Temporoparietal dcho.	0.55
			Temporoparietal izdo.	16.89
13. E.A.	1686	194	Frontal	13.97
			Región nasal	7.65
			Temporoparietal dcho.	68.79
			Temporoparietal izdo.	15.24
5. E.T.	996	243	Frontal	7.09
			Región nasal	0.01
			Temporoparietal dcho.	86.49
			Temporoparietal izdo.	462.53

Dcho.= derecho, Izdo.=izquierdo

Tabla III. Dosis en piel y órganos en reproducción de procedimientos con fantoma Rando

Órgano/Tejido	Nº _TLDs Colocados	Dosis en Procedimiento (mGy)	
		E.T.	E.A.
Ovarios	2	0.12	0.10
Testículos	1	0.13	0.05
Colon	8	0.17	0.19
Pulmón	16	0.78	1.26
Estómago	1	0.22	0.35
Vejiga	1	0.09	0.12
Mama	2	0.61	1.85
Hígado	5	0.18	5.16
Esófago	3	1.46	7.02
Tiroides	1	2.24	7.7
Superficie cabeza	13	206.35	36.37
Cristalino	2	11.83	396.61
Glándulas parótidas	2	14.28	13.61
Oído medio	2	202.77	206.12

4. Conclusión

Comparando con otros datos publicados [2], podemos ver como los valores de PDA con los que se trabaja en el Hospital Universitario de Canarias son del orden que los impartidos en otros lugares. Se pudo ver como cada proyección tiene una contribución diferente al DAP por lo que la dosis recibida por el paciente puede ser reducida minimizando el uso de aquellas proyecciones específicas. Otros factores para la reducción de la dosis pueden ser alternar la entrada del haz de radiación entre caras opuestas, reducir el campo a la región de interés o hacer uso de filtración adicional.

Los procedimientos de neuro-radiología pueden causar dosis de radiación relativamente altas en la región craneofacial, pero en los casos estudiados, la máxima dosis en piel (462.53 mGy en el caso 5 E.T.) está muy por debajo de la dosis conocida que causa depilación temporal (3 Gy) o eritema local (6 Gy). Asimismo, para el valor más alto de dosis efectiva, 4.11 mSv, y usando el coeficiente de cáncer mortal publicado por la International Commision on Radiological Protection [5], $5 \cdot 10^{-5}$ mSv^{-1}, con este valor de dosis se provocaría un cáncer mortal por cada 4886 estudios. Este riesgo es bastante menor que el asociado a la enfermedad por la cual el paciente se somete a un procedimiento de neuro-radiología.

Los valores de dosis efectiva medidos con la reproducción de los procedimientos con el fantoma supera en la mayoría de los órganos a la obtenida con el programa de simulación Effdose y esto se refleja en la dosis efectiva que para el último de los métodos fue 2.02 mSv (E.T.) y 1.77 mSv (E.A.).

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IAEA-CN-85/68

RADIATION DOSES IN INTERVENTIONAL NEURORADIOLOGY

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Abstract

Patient radiation doses during interventional radiology (IR) procedures may reach the thresholds for radiation-induced skin and eye lens injuries. This study investigates the radiation doses received by patients undergoing cerebral embolization. Measurements were conducted using thermoluminescent dosimeters. Radiotherapy verification films were used in order to visualise the radiation field. For each procedure the fluoroscopic and digital dose-area product, the fluoroscopic time, the total number of acquired images and entrance-skin dose calculated by the angiographic unit were recorded. In this paper, the skin, eye and thyroid glands doses on a sample of patients are presented. From a preliminary study of 13 patients having undergone cerebral embolization, it was deduced that six of them have received a dose above 1 Gy. Detailed dose data from patients undergoing IR procedures will be collected in the future with the aim of developing a model to allow estimation of the dose prior to the procedure as well as to look at techniques of dose reduction.

1. Introduction

In 1994 the Food and Drug Administration (FDA) [1] reported a number of severe radiation-induced skin injuries to patients resulting from interventional radiology (IR) procedures. Since then numerous reports have been published on patient and staff radiation doses in IR procedures [2,3,4]. Cerebral embolization (CE) is a neuroradiological procedure and it is considered to be a high dose IR procedure. It is used for treatment of life-threatening diseases such as aneurysms and/or arteriovenous malformations (AVMs). Alternative treatments are surgery and radiosurgery. Embolization results in the occlusion of aneurysms and/or AVMs from the blood supply. The efficacy of the procedure is monitored by injection of contrast media in the vessels in conjunction with fluoroscopy and digital subtraction angiography (DSA). Materials that are used for the occlusion of the vessels are metal coils (platinum) in the case of aneurysms and chemical agents (superglue) in the case of AVMs. The metal coil is supplied in a cartridge which allows it to be fed into the catheter and then into position in the area of interest. Superglue has a liquid form and it solidifies as soon as it comes in contact with blood and it reaches the area of interest via a catheter. In most of the cases, the AVM embolization is likely to be repeated in a short period of time and it is followed by radiosurgery at which the dose to the target volume (AVM) may reach levels as high as 25 Gy. Thus, the cumulative dose resulting from embolization and radiosurgery may reach high levels. Many authors have reported doses in CE varying from few hundreds of mGy up to few Gy [2,3,4]. This study investigates the entrance-skin doses (ESD), the dose-area product (DAP) and organ doses to thirteen patients undergoing CE and the radiation doses to the physician performing the CE. Also, the dose distribution over the patient's skin area has been obtained by means of thermoluminescent dosimeters (TLDs) and it is compared with that obtained from films placed at the irradiated area. The relationship of the dose with some technical parameters such as fluoroscopy time, number of acquired images and with the ESD which is calculated by the unit is investigated.

2. Methods and materials

Measurements were made on a Siemens biplane X-ray system consisting of a lateral (LAT) and a posterior-anterior (PA) Megalix X-ray tube and a Polydoros IS-Ax2 (Neurostar) pulse generator. Tube settings are controlled by the automated exposure control (AEC). The X-ray

unit is equipped with a DAP-meter which provides the user with the cumulative DAP for each plane and for each mode (fluoroscopy-DSA) separately. The ESD and the ESD rate are calculated by the unit at a focus skin distance (FSD) of 55 cm giving an estimation of the ESD during the procedure in each plane. It also provides the user with useful technical parameters such as tube voltage, tube current and exposure time, magnification, frames/sec, number of acquired images for each DSA run. During the fluoroscopy mode the ESD and the ESD rate as well as the tube voltage, mA, pulses/sec and the DAP are provided. Three different protocols for DSA mode can be used when CE is performed. The user has the option to change the settings of the program and the most frequently changed parameters are the frame rate, scene duration and pulses/sec (fluoroscopy). In the following table (I) the parameters for the three different protocols are shown.

Table I. DSA protocols

Protocols	kVp	ms[1]	Scene(sec)[2]	dose[3]	Frame rate	Pulses/sec
AngioDSA Carotids	73	160	80	4.8	2	7.5
Angio DSA AVM Glue	70	125	20	4.8	3	7.5
Angio DSA Vertebral	70	64	40	4.8	2	7.5

[1]maximum pulse width in milliseconds
[2]maximum duration of a scene in seconds
[3]input dose per frame in μGy, measured at the following nominal conditions: 70kV, 2.5 mm Copper filter and 17cm Image Internsifier

Lithium fluoride TLDs (TLD-100) were used to measure the ESD for the PA and for the LAT plane. The TLDs were arranged in a grid form as shown in figure 1 to measure the dose distribution. The TLDs were placed on two exposed films. One of the two films was placed on the back side of the patient's head to measure the dose from the PA plane and the second one on the right side of the patient's head in order to measure the dose from the lateral plane. The grid was square with dimensions (15x15)cm^2 and every three cm for both vertical and horizontal dimension (bullets in the figure) a TLD was placed, giving 36 TLDs for each plane. The dose to the eyes and to the thyroid glands of the patient and the doses to the physician's eye were measured with TLD-100H which are suitable for measuring low doses due to their high sensitivity.

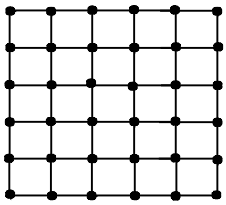


Figure 1

For doses above 1 Gy, correction factors have been applied to TLD-100 doses in order to account for supralinearity.

Kodak X-OMAT V radiotherapy verification film has been used to visualise the radiation field for two patients and for both planes.

Dose rates have been measured using a tissue equivalent phantom (15x15x15) cm^3 for both fluoroscopy and DSA. Different field sizes, pulses/sec, frames/sec have been used.

3. Results and discussion

In figures 2 and 3 the isodose curves obtained from the TLD grids for PA plane and LAT plane for respectively are superimposed onto the images taken from the films. Figures 2 and 3 correspond to two different patients. Starting from the edges of the grid the first isodose curve is that of the lowest dose range. The dose scales shown in the figures are in mGy.

From figure 2 it may be seen that an area of (8x7) cm^2 receives a dose above 400mGy and from figure 3 an area of (6x6)cm^2 receives a dose above 1750mGy. By not using TLDs arranged in a grid form the irradiated area cannot be estimated and from those two examples it may be seen that a large area of the patient's head has received the highest dose. In both figures the x-ray tube has been moved throughout the procedure. Due to the movement of the X-ray tube during the procedure there is a risk of placing the TLDs outside the field size or outside the area of the highest dose unless a large TLD grid is used. Although the grids are (15x15) cm^2, it may be seen that they are not large enough to cover the whole radiation field since the isodose curves for the low doses are interrupted.

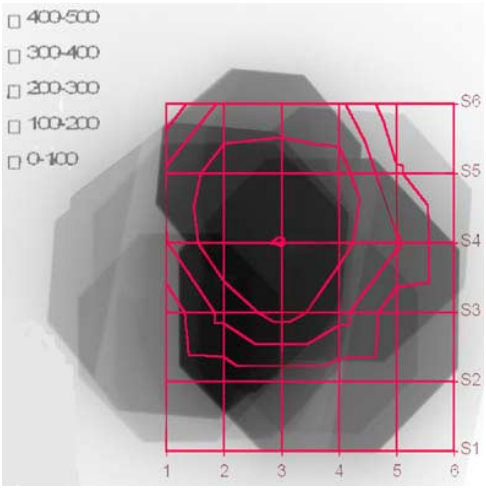


Figure 2. Patient A

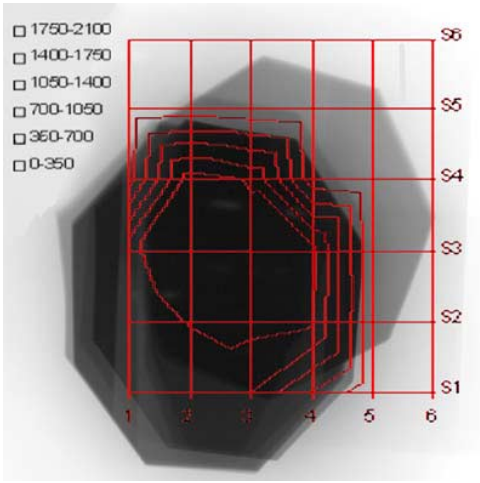


Figure 3. Patient B

In table II the results for both PA and LAT plane for the thirteen patients are shown.

It may be seen from the ESD_{TLD} that for the PA plane 4 patients have received a dose above 1 Gy and 2 of these have exceeded the threshold of 2 Gy for transient erythema [5] while for the LAT plane 6 patients have exceeded 1 Gy and one has exceeded the threshold of 3 Gy for temporary epilation [5]. Comparing the ESD_{DAP} and the ESD_{TLD} for both PA and LAT plane it may be seen that the ESD in most of the cases is higher than the ESD TLD. Thus, the ESD calculated by the x-ray unit tends to overestimate the actual dose since the actual FSD is always higher than 55cm typically between (70-80) cm and since the tube is moving during the procedure spreading the dose over the patient's head.

Table II. Patients' results

Patient	Fluoroscopy Time (min)		Number of images		DAP ($Gycm^2$)		ESD_{DAP}[1] (Gy)		ESD_{TLD}[2] (Gy)	
	PA	LAT	PA	LAT	PA	LAT	PA	LAT	PA	LAT
1	4.9	22.0	73	156	52.7	61.9	0.52	0.69	0.24	0.59
2	4.6	11.0	127	316	49.5	106.7	0.53	2.00	1.20	1.44
3	8.9	2.0	52	28	30.5	6.1	0.64	0.15	0.26	0.09
4	26.3	8.0	123	118	62.1	22.9	1.48	0.61	0.90	0.38
5	1.9	18.0	90	272	72.6	76.7	0.79	2.20	0.40	1.40
6	2.5	22.0	55	725	38.3	365.2	0.27	4.44	2.44	3.2
7	9.9	16.0	229	425	92.9	127.0	2.12	2.86	1.14	1.78
8	3.9	4.0	139	159	55.1	34.6	1.09	0.96	0.63	0.63
9	1.8	31.0	59	227	25.2	129.6	0.23	1.63	0.88	1.21
10	2.0	22.0	54	87	15.1	24.6	0.37	0.63	0.18	0.52
11	6.5	14.3	216	344	52.1	43.2	0.68	0.12	0.40	0.55
12	0.9	17.2	58	137	14.1	14.8	0.21	0.32	0.10	0.18
13	2.9	10.9	767	975	218.6	231.0	5.01	2.63	2.61	1.94

[1] ESD_{DAP}: the ESD calculated by the x-ray unit at 55cm FSD
[2] ESD_{TLD}: the maximum TLD dose

In table III the dose for the eyes and thyroid glands of the patient, as well as the doctor's left eye dose who performs the CE, are shown. It may be seen that the patient's right eye and right thyroid gland receives a higher dose than the left eye does and this is because the lateral x-ray tube is always on the right side of the patient's head. The eye doses are high in some patients but are below the threshold for formation of detectable opacities[6]. The doctor's eye receives a low dose and only in three cases the dose reaches the 3/10 of the annual dose limit (i.e classified worker) if one case per day (250 each year) with such a dose is performed.

Table III. Organ doses

Patient	Right eye dose (mGy)	Left eye dose (mGy)	Right thyroid dose (mGy)	Left thyroid dose (mGy)	Doctor's eye dose (mGy)
1	38.1	5.2	50.5	8.0	0.069
2	16.1	13.1	21.3	7.5	0.120
3	3.2	3.3	2.4	2.3	0.038
4	16.1	13.1	21.3	7.5	0.078
5	16.1	13.1	21.3	7.5	0.078
6	71.8	10.9	36.2	9.2	0.471
7	64.1	22.1	11.3	4.9	0.218
8	8.5	5.5	6.8	4.0	0.018
9	13.7	6.6	16.4	2.2	0.218
10	14.1	5.2	5.2	3.1	0.061
11	44.0	30.0	6.7	2.6	0.110
12	12.7	5.1	180.4	7.2	0.018
13	69.2	27.5	36.1	18.4	-

In figure 4 the relationship between the doctor's eye dose, the total DAP and the LAT DAP is shown. It may be seen that the doctor's eye dose is correlated better with the LAT DAP than with the total DAP since the LAT X-ray tube is always on the left side of the doctor. It may be seen that as the LAT DAP increases the doctor's eye dose increases linearly.

Figure 4

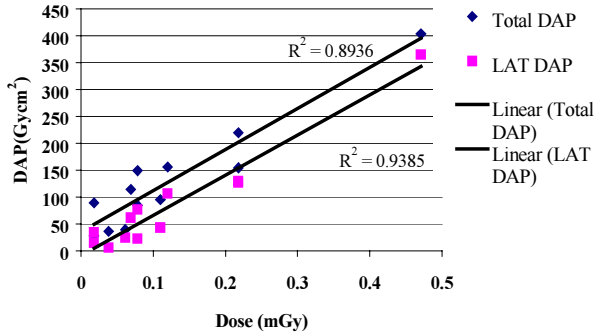
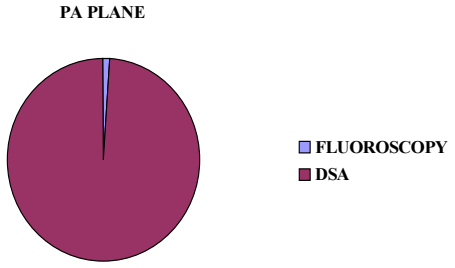


Figure 5



In figure 5 the contribution of DSA and fluoroscopy mode to the total DAP is shown for PA plane for patient 13. It may be seen that the main contribution comes from the DSA mode and not from the fluoroscopy mode. Thus, the use of DSA mode should be limited to the minimum.

From quality assurance measurements it was deduced that the ESD/sec for fluoroscopy mode is within a range of (0.029-0.2) mGy/sec which is equivalent to (1.76-11.9) mGy/min for different technical parameters while for the DSA mode the ESD/sec is in a range of (1.6-6.62) mGy/sec for the same parameters as in fluoroscopy. The ESD/frame for the DSA mode may vary from (0.73-2.65) mGy/frame. Comparing the dose rates for fluoroscopy and DSA it may be seen that the doses from DSA are much higher than that of fluoroscopy. Thus, by limiting the images obtained during a procedure the ESD may be highly reduced.

4. Conclusions

In this paper a new method to obtain dose distribution over the patient's skin area for CE procedures has been introduced. This method gives accurate and reliable results of the ESD by combining a TLD grid for measuring the ESD and films for visualising the field size. The results show that a relatively large skin area may receive a dose that can exceed the thresholds for skin injuries. The patient's eye and thyroid glands may receive a relatively high dose but it is below the threshold for causing any radiation-induced injuries. It has been found that there is a good correlation between the doctor's eye dose and the DAP from the LAT plane. It also has been found that the contribution of the DSA mode to the total DAP is much higher than that from the fluoroscopy mode. Quality assurance results showed that the ESD rate is much higher for the DSA mode than that for the fluoroscopy mode. Thus, the number of images obtained during a procedure should be kept to the minimum. Us eof distance and shielding may also reduce staff doses.

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IAEA-CN-85-38

RADIATION INJURY OF THE SKIN FOLLOWING DIAGNOSTIC AND INTERVENTIONAL FLUOROSCOPIC PROCEDURES

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Abstract

Many radiation injuries to the skin, resulting from diagnostic and interventional fluoroscopic procedures, have been reported in recent years. In some cases skin damage was severe and debilitating. We analyzed 72 reports of skin injuries for progression and location of injury, type and number of procedures, and contributing patient and operator factors. Most cases (46) were related to coronary angiography and percutaneous transluminal coronary angioplasty (PTCA). A smaller number was documented after cardiac radiofrequency catheter ablation (12), transjugular intrahepatic portosystemic shunt (TIPS) placement (7), neuroradiological interventions (3) and other procedures (4). Important factors leading to skin injuries were long exposure times over the same skin area, use of high dose rates, irradiation through thick tissue masses, hypersensitivity to radiation, and positioning of arms or breasts into the radiation entrance beam. Physicians were frequently unaware of the high radiation doses involved and did not recognize the injuries as radiation induced. Based on these findings, recommendations to reduce dose and improve patient care are provided.

1. Introduction

The number of interventional cardiologic and radiologic procedures performed under fluoroscopy has grown markedly worldwide during the last decade [1]. Advances in interventional techniques have made more complex procedures possible. This trend results in increased fluoroscopy use and is accompanied by a sharp increase in the number of reported skin injuries. We reviewed over 70 case reports of skin injuries that resulted from fluoroscopic procedures [See, for example, reference 2]. More than 90% of cases were reported since 1996. Although the absolute number of injuries may appear very small when compared to the more than 700,000 interventional procedures performed annually [1], skin damage is likely to be under-reported. The main reason is widespread unawareness of this radiation effect and consequent inability of physicians to correctly diagnose it. Radiation damage can be serious. Chronic ulceration and tissue necrosis were documented in about half of all cases. The purpose of our review is to describe these injuries and to investigate common factors related to the patients and their procedures that may have led to the injuries.

2. Skin injuries

Radiation induced skin injury is usually not observed immediately after a procedure, but after a characteristic latent period in which the patient can be free of symptoms. The latent period is most often in the range of 2 weeks to 3 months, but varied in the reviewed case material from a few hours to more than 3 years. Skin injury represents a deterministic radiation effect that requires a radiation dose above a certain threshold. The following radiation skin effects were observed and are given in order of their time of onset (threshold doses are given in brackets). Skin erythema can occur within hours (early transient erythema, 2 Gy) or after 10 days (main erythema, 6 Gy). When a single fixed beam orientation is employed, lesions are typically sharply defined and match the entrance port of the radiation beam (Figure 1). Epilation can be

seen after 3 weeks and can be temporary (3 Gy) or permanent (7 Gy). Erythema and epilation are early signs which, when observed, can serve as a warning signal indicating that a certain threshold has been exceeded.

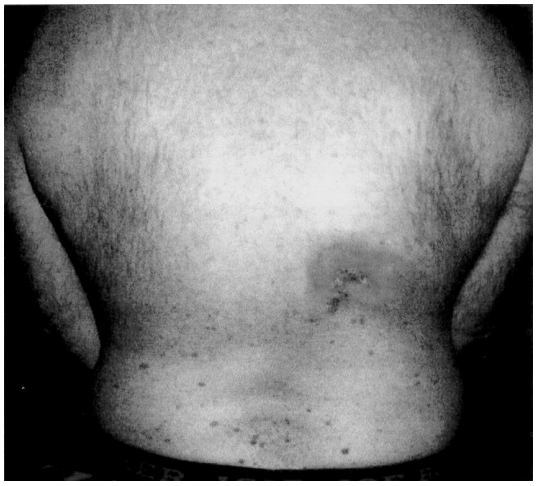

Fig. 1. Well demarcated erythema in large-chested man after PTCA of right coronary artery using stationary left anterior oblique and slightly cranial x-ray beam orientation

After 4 weeks dry or moist desquamation (14 Gy and 18 Gy respectively) can occur. Secondary ulceration (24 Gy) may arise after about 6 weeks, ischemic dermal necrosis (18Gy) after 10 weeks. Prophylaxis against local infection is essential in these cases. Wound healing is typically prolonged and less efficient due to microvascular radiation damage in the dermis, which leads to a relative ischemia. Ulcers which have slowly healed over an extended period of time have a tendency to recur, often provoked by trivial trauma. One of the problems of radiation ulcers is that they can increase in size and depth despite all treatment. Pain control can be a difficult task to achieve. Several cases are known to the authors in which deep tissue necrosis extended to involve muscles and bones. In at least 4 cases deep tissue ulceration was present for more than a year.

In a substantial number of reviewed cases (23%), wound healing could not be achieved despite intensive wound care. Skin grafting finally had to be performed (Figure 2). In a number of cases the initial graft was unsuccessful. Skin grafts are often complicated in these cases by the compromised vascular supply.

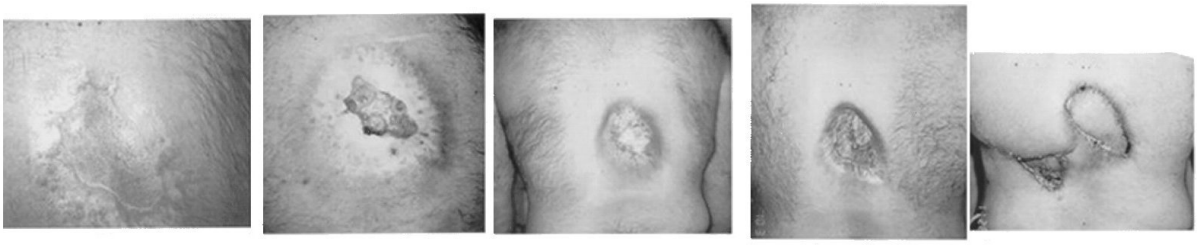

Fig. 2. Progression of injury in heavy-set male following TIPS procedure.
From left to right: injury at 4 months; 7 months; 9 months; 22 months; 23 months.

Late radiation sequela, which can be seen after 3 months to more than a year, are dermal atrophy (10 Gy) and telangiectasia (10 Gy). These, together with areas of hyper- and

hypopigmentation, give the skin a poikilodermic appearance. Subcutaneous induration results from a relative increase in the fibrous component of the tissues and can be painful. It may limit motion of it occurs close to a joint (e.g. at the shoulder in cardiac procedures). We noticed radiation skin injuries at the breast in two female patients after interventional cardiac procedures. One patient was only 17 years old. Breast tissue in the adolescent is among the most sensitive tissues for development of radiation induced malignancies. This will significantly increase the patient's statistical risk for breast cancer in the future.

2.1. Which procedures have a potential of skin injury?

Out of 72 reviewed cases of fluoroscopically induced skin injuries, 46 cases (63%) were related to coronary procedures. The majority of these (43 patients) underwent percutaneous transluminal coronary angioplasty (PTCA). The high proportion of this procedure in the total number of reported cases reflects the high number of annually performed cardiologic interventions that far outweigh other interventional procedures (700,000 coronary procedures versus 30,000 other procedures). In decreasing order of prevalence, the location of the skin injury was: right and left scapular or subscapular area, right lateral chest below axilla, midback, and right anterolateral chest. The site of the injury corresponds to the site of the entrance beam and reflects the beam orientation predominately used during the procedure.
A smaller number of skin injuries was caused by cardiac catheter radiofrequency ablation (12 patients), transjugular intrahepatic portosystemic shunt (TIPS) placement (7 patients) and neuroradiological interventions (3 patients). The skin injury involved the back and arm in patients undergoing ablation and the midback and right subscapular area in patients undergoing TIPS procedures. Four patients had other interventions in the abdomen or chest. However, any fluoroscopic intervention has the potential to cause injury if the radiation dose exceeds the deterministic threshold.

2.2. What factors contribute to the injury?

In many reports, a substantial delay occurred between the initial moment the patient presented skin with changes to a physician and the moment the physician made the correct diagnosis. Physicians did not initially associate the injury with radiation from fluoroscopy. Patients were treated in the interim, without success, for a variety of other suspected causes. Meanwhile, some patients underwent a second fluoroscopically guided intervention with additional exposure to the same area. The correct diagnosis was sometimes delayed by several years, in one case the delay was more than 5 years. The latency period between the last intervention and the first appearance of the skin lesion probably contributes to the delay in diagnosis, as the physician is less likely to consider radiation as the etiology.

Several reports originating from radiation therapy literature indicate a correlation between certain diseases and an exaggerated radiation complication after treatment. These include connective tissue diseases (scleroderma, lupus erythematosus, mixed connective tissue disease), diabetes mellitus, hyperthyroidism and the homozygous form of ataxia telangiectasia [3]. Some chemotherapeutic agents are also known to increase sensitivity to radiation [4, 5]. A few reports from interventional work now cite these as probable sensitizing factors for some observed skin reactions.

Long exposure time to the same skin area was the most prevalent factor among the reviewed cases that resulted in skin injuries. Procedures were often difficult or prolonged due to complications, such as arterial dissection.

Extensive use of high magnification or high detailed-mode led to high dose rates. In some cases of skin injury, the physician used these modes exclusively. Cinefluorography is associated with a 10 times higher dose rate per imaging frame than conventional fluoroscopy. High doses can accumulate within minutes during this imaging mode.

Irradiation through thick masses of tissue increases the skin dose. Large patients, common in our study group, are therefore at higher risk for radiation damage. In a similar way, beam angulation increases the tissue pathlength for the x-rays to penetrate and puts the skin closer to the x-ray source. The skin dose, for example, increases by a factor of 4 when 30° cranial angulation are added to a 40° left-anterior-oblique (LAO) projection in a cardiac procedure [6]. Steep beam angles were frequently employed in the reviewed case material and contributed to the reported injuries.

In three cases of radiofrequency ablation procedures, radiation injuries were observed on the arm. In two cases, involving different procedures, skin lesions appeared on the breast. During the procedures these body parts were in the primary radiation beam in close proximity to the x-ray tube, resulting in very high skin doses.

In three cases equipment malfunction or other deficiencies were causative factors for the injuries.

2.3. What can be done to reduce the risk?

Physicians must be able to identify radiation-induced skin injuries in patients. Prior to performing a procedure, a detailed history of prior fluoroscopic interventions and any observed skin effects is essential. If the patient has had such procedures, a brief inspection of the skin is appropriate. The diagnosis of radiation-induced skin injury can often be made based on history and physical examination. Areas of skin injury are usually well defined and occur in typical locations. A skin biopsy may sometimes be helpful in excluding other causes, but should not be performed as part of “routine work-up” as they may result in a nonhealing ulcer.

Interventionalists must keep fluoroscopic on-times to a minimum. Fluoroscopy times or the actual radiation dose should be monitored. Normal values should be established for each procedure. If a procedure is more complicated than expected, or if the fluoroscopy times or radiation dose exceeds a certain limit, consultation with more experienced staff should be sought.

Pulsed fluoroscopy and heavy beam filtration provides imaging at a significantly reduced radiation dose and its use is highly recommended. The dose can be lowered by 50-70% with no perceivable loss in image quality.

Image magnification, high-resolution settings and cineangiography should be used and judiciously and sparingly.
If a procedure proves to be lengthy, the incident beam angle should be varied in order to expose different areas of skin. This will be effective only if the field of view is minimized by

collimation. Otherwise different projections will lead to overlapping radiation fields. General rules of dose reduction must be followed, e.g. the image intensifier should be kept as close to the patient as possible, the distance between x-ray tube and patient should be kept large. If large air gaps between the patient and image intensifier cannot be avoided, the grid should be removed, if possible, as it only adds to additional radiation without effective function.

Extraneous body parts, such as an arm or a female breast, have to be positioned and secured in a way that they will not be exposed in the primary x-ray beam.

Real-time dose monitoring enables the physician to recognize high dose levels and is recommended. The physician can take action to lessen the dose rate early if the dose monitor indicates high radiation levels. Dose monitors also keep track of doses from fluorography and eliminate the need to monitor fluoroscopy time. Increased output due to equipment malfunction can be recognized.

Patients who receive a high skin dose (e.g., in excess of 3 Gy) should be counseled and advised on examining their skin at the proper location. If any skin changes are observed, the patient should contact the physician who performed the procedure.

A good quality control program should be established to assure high standards in dose reduction and image quality.

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IODINE VISIBILITY IN CORONARY ANGIOGRAPHY USING COPPER FILTRATION

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Abstract

With constantly developing technology and emerging clinical applications, the field of interventional radiology is rapidly expanding. This is bringing enormous benefits to patients in terms of less invasive procedures. However, interventional radiology often involves prolonged fluoroscopy and cine runs which potentially leads to high staff and patient doses. One approach to dose reduction and improved iodine contrast visibility is the use of added copper filtration in conjunction with high heat capacity x-ray tubes which enable the x-ray spectrum to be matched to the k-edge of iodine whilst reducing dose. This paper presents results characterising the iodine imaging performance of a modern vascular x-ray imaging system. The results indicate that skin dose savings of 75% are possible with acceptable iodine contrast loss and that, for iodine sensitive patients, reductions of iodine concentration of about 25% may be achievable.

1. Introduction

With constantly developing technology and emerging clinical applications, the field of interventional radiology is rapidly expanding. This is bringing enormous benefits to patients in terms of less invasive procedures. However, interventional radiology often involves prolonged fluoroscopy and cine runs which potentially leads to high staff and patient doses. Indicative of this growing awareness of safety and protection needs in interventional radiology was the interest shown in the recent workshop on efficacy and safety in interventional radiology [1]. One common approach to patient dose reduction has been the use of additional beam filtration. This is well documented in the fields of paediatric and fluoroscopic imaging [2,3]. Recent technical developments in tube technology have allowed higher copper added filtration to be utilised along with an mA-kVp curve which maintains the beam spectrum at a kVp advantageous to imaging iodine which is used as a contrast medium in angiography. Last year, Nottingham City Hospital installed a new cardiac catheterisation laboratory with the features mentioned above and this paper describes our attempts to characterise its performance in terms of iodine visibility and dose as the extra filtration is applied.

2. Method

The installation was a Philips Integris H5000F C-arm imaging system with an x-ray tube that could run continuously at 30mA enabling high levels of copper filtration to be employed. The x-ray tube has three filter 'modes' for fluoroscopy. Mode 1 has no added filtration (HVL ~3.2 mm Al @ 80 kVp), Mode 2 has added filtration of 1.5 mm Al + 0.1 mm Cu (HVL ~5.3 mm Al @ 80 kVp) and Mode 3 has added filtration of 1.5 mm Al + 0.4 mm Cu (HVL ~ 7.4 mm Al @ 80 kVp). Entrance skin doses were measured using a calibrated ionisation chamber and include backscatter.

Images were obtained of three different sized plastic tubes (1.0 mm, 1.5 mm & 2.5 mm diameter) laid across a 10 cm PMMA phantom. For each Mode of fluoroscopy images were obtained at four iodine concentrations (370 mg/ml, 320 mg/ml, 200 mg/ml & 100 mg/ml I_2) representing concentrations used clinically (370 mg/ml & 320 mg/ml I_2) and less concentrated contrast media. Fluoroscopic images were captured in the unit's 'photofile' and

transferred to a PC workstation for analysis. All imaging was performed using the 23cm field size.

Contrast was defined as the difference in signal level between the maximum iodine signal in the vessel (averaged over four profiles) and the background flat-field signal from the 10 cm PMMA phantom which was obtained from a region-of-interest within the central portion of the image.

3. Results

The measured entrance skin dose rates, with backscatter, are given in Table 1 along with the filter details for each Mode of fluoroscopy.

Table 1. Entrance skin dose rates, with backscatter, for a 10 cm PMMA phantom

FLUOROSCOPY MODE	ADDED FILTER	SKIN DOSERATE (mGy/min)
Mode 1	no added filter	18.1
Mode 2	1.5mm Al + 0.1mm Cu	8.1
Mode 3	1.5mm Al + 0.4mm Cu	4.4

Figures 1 & 2 show how the contrast varies with varying the amount of filtration and the iodine concentration. The contrast values are in arbitrary units and the standard deviation of the contrast values ranges from 5-10%. This level of standard deviation is due to the averaging technique employed across the four profiles of each vessel. Results are only presented for the 2.5mm vessel diameter as the smaller vessels indicated similar trends.

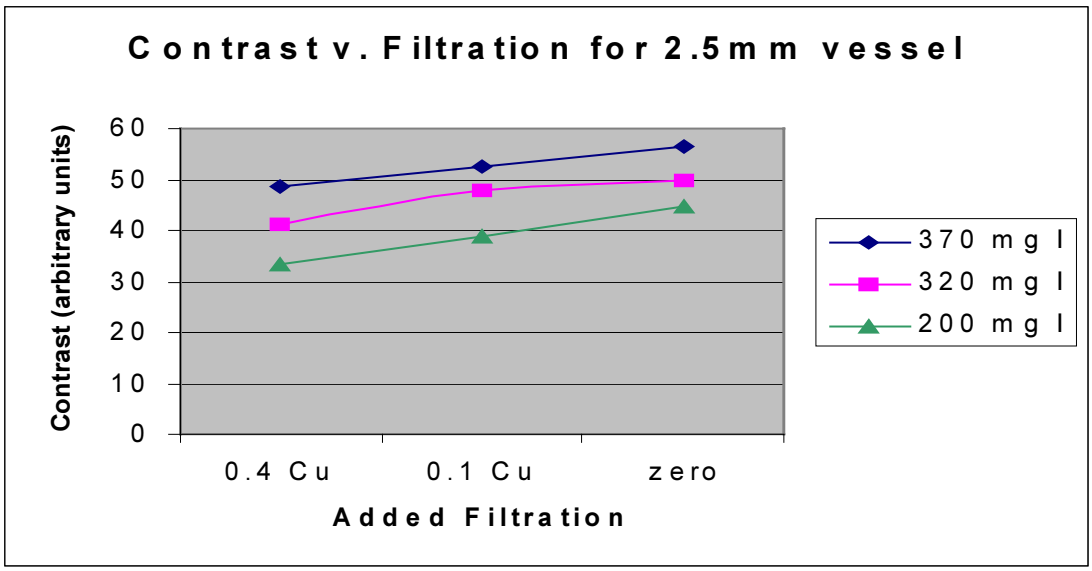

Figure 1 Contrast as a function of added filtration for a 2.5mm vessel imaged on a 10cm PMMA phantom

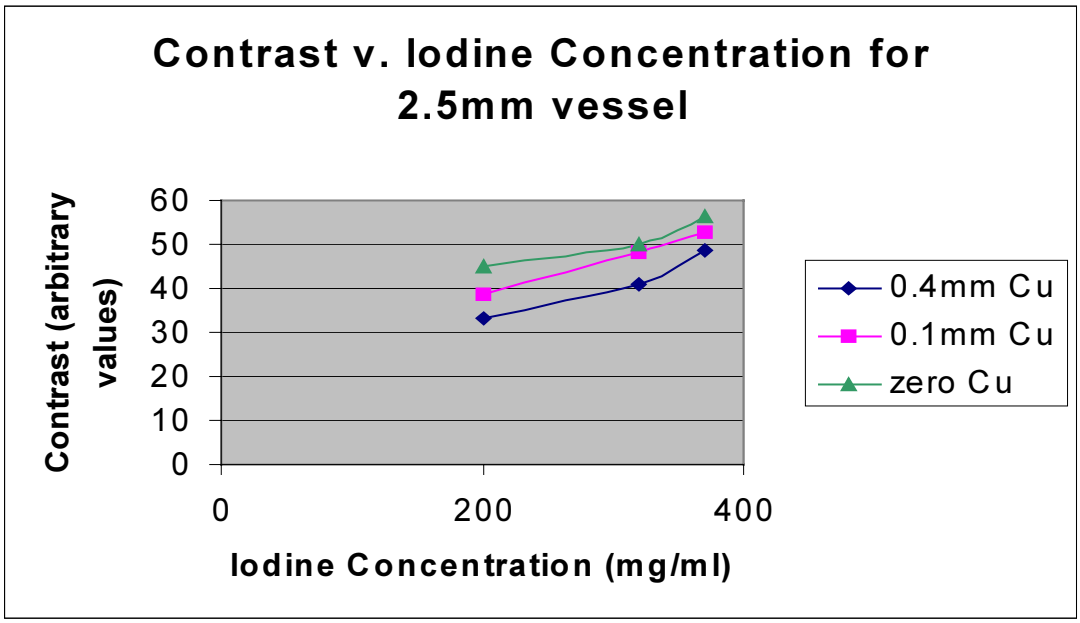

Figure 2 Contrast as a function of iodine concentration (mg/ml I2) for a 2.5mm vessel imaged on a 10cm PMMA phantom

4. Discussion

The results obtained must be seen in the context of a first characterisation of the iodine imaging capability of our new cardiac catheterisation x-ray unit. We have not, as yet, ascertained a threshold value for iodine contrast in terms of clinical acceptability and our arbitrary units. However, it is clear that real differences are achieved by the use of added copper filtration where, clinically, the loss of iodine contrast seems acceptable and results in a skin dose saving of approximately 75%. This is especially important for the more complex angioplasty with stenting examinations where examination skin doses can approach several gray. It is also worth noting that, in the case of no added filter, similar levels of iodine contrast would be achieved, to that of the largest copper filter, with 25% less iodine concentration. This has implications for situations where patient reactions to iodine are important. It is our intention, given our results so far, to work with the manufacturer and the cardiologists to further optimise the iodine imaging performance of the x-ray unit.

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IAEA-CN-85-196

THE USE OF CONSTANCY CHECKS TO OPTIMISE PATIENT DOSE IN INTERVENTIONAL RADIOLOGY SYSTEMS

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Abstract

Results of constancy checks using the European DIMOND protocol are reported for 10 digital fluoroscopy systems. Fluoroscopy dose rates and dose per image at the entrance of the image intensifier and at the entrance of copper filters are obtained together with image quality using Leeds test objects. Dose values for different fluoroscopy modes and different image acquisition modes are presented. Values for several image intensifier formats are also reported. Relations between values obtained with copper filters and polymethyl methacrylate are obtained for different X-ray systems using different beam qualities, and practical recommendations to use the results of constancy checks in the managing of patient dose in interventional radiology systems are given.

1. Introduction

The European DIMOND constancy check protocol (DIMOND = Digital Imaging: Measures for Optimising Radiological Information Content and Dose) has been designed to harmonise the evaluation of complex fluoroscopy systems used in interventional radiology (IR). Simplicity in the required experimental approach and the short time necessary to carry out the test (30-60 minutes) were two objectives in the design of the protocol. The approach requires a calibrated ionisation chamber, copper filters, and an image quality test object. Dose rate and dose per image at the entrance surface of the image intensifier (II) and at the entrance surface of Cu filters are measured. The image quality of the test object is evaluated on the TV monitor and by numerical methods whenever possible.

During the acceptance tests of the new X-ray systems to be used for IR procedures or when establishing the baseline level (status test), dose rate and dose per image for all the fluoroscopy modes, for all the options of image acquisition (in cine mode and in subtraction mode), and for all the image intensifier formats available, are usually measured.

The dose values at the entrance to the copper filter normalised at a focus distance of 50 cm, together with the obtained image quality with a test object permit to follow the performance of the system during the clinical use of the system and to detect any problem in order to suggest corrective action when necessary. In addition, these results provide useful information for the medical specialist to optimise clinical procedures, supplying information about the increase in patient dose when using high dose fluoroscopy modes or low noise imaging modes [1]. The effect of increasing skin dose during magnification is also evaluated with the DIMOND constancy check protocol.

One of the practical problems to take advantage of the results of the constancy checks in the routine clinical work, is to establish the equivalence between a certain thickness of copper with polymethyl methacrylate (PMMA) which is more similar in attenuation and backscatter properties to patients. This equivalence depends on the different X-ray beam qualities and it is usual for IR systems that beam qualities be very different for fluoroscopy modes and imaging

acquisition. Concern about the knowledge of skin dose values has been reported [2] and this basic quality control can help to avoid deterministic effects on patients [3].

2. Material and methods

The constancy check protocol has been applied to the following systems:

- 2 cardiology labs (Philips Optimus-200 and Philips Integris H-3000 with the "spectra beam" option).
- 2 interventional rooms used for cardiology, vascular and neuroradiology procedures (GE Advantx systems).
- 2 mobile C arm systems (Philips BV-300 and BV-300+).
- 1 Toshiba DFP-2000 dedicated to vascular and neuroradiology procedures.
- 1 multipurpose interventional room (Toshiba KXO-80M).
- 1 interventional room for vascular procedures (Siemens Polydoros 1000)
- 1 digital remote control room used provisionally for interventional urology procedures (Philips Omnidiagnost).

Image quality has been evaluated with the Leeds test object TOR-18FG (positioned at the entrance of the image intensifier with the copper filters or PMMA plates placed in the beam). High contrast resolution and low contrast threshold have been evaluated by one or two observers (always the same people) based on the visual perception on the monitor existing inside the interventional room (live image for fluoroscopy). Geometrical circular distortion was also observed with this test object. When storage of the images in CD-ROM or in the PACS was possible, additional numerical evaluation was made (fig. 1).

Doses were measured with a calibrated ionisation chamber RADCAL (Radcal Corporation, Monrovia, USA) model 20x6-60E and several copper filters of 1 mm thickness and 20x20 cm and PMMA plates of 1 cm thickness and 20x20 cm to simulate several patient thicknesses were used. To measure the dose at the entrance of the copper filters (or at the entrance of the PMMA plates), the ionisation chamber was positioned over the patient couch, maintaining the C arm in vertical position with the image intensifier over the couch. The distances during dose measurements were 70 cm focus-chamber and 100 cm focus-image intensifier. The automatic brightness control was activated during the measurements. Dose values were normalised at 50 cm from the focus in order to simulate one of the worst geometries (usual focus-patient skin distance will be somewhat greater). Measurements at the entrance of the image intensifier were also made during this protocol but these results are not reported in this paper.

3. Results and discussion

Tables 1 and 2 present the dose results measured for different X-ray systems. Some of the systems use extra copper filtration for low dose modes (e.g. Philips Integris H-3000). This represents an important change in the X-ray beam quality and this also means a different equivalence between copper and PMMA. Table 3 presents the results of the entrance dose values (dose in air with backscatter) for different copper and PMMA thicknesses, measured for the Philips Integris H-3000.

In general, for cardiology modes, systems select higher kV values in fluoroscopy (70 kV for 2 mm Cu with the Integris system) than in cine (60 kV for 2 mm Cu) to improve contrast. For the Integris system with additional high filtration (0.4 mm Cu + 1.5 mm Al) the entrance dose

rate for 20 cm of PMMA in fluoroscopy (low dose mode) is 20 mGy/min (at 50 cm from the focus), equivalent to the dose rate measured with approximately 3.5 mm Cu. For cine, 0.3 mGy/frame is required and in this case, 20 cm of PMMA are equivalent to approximately to 2 mm Cu. Thicker patients (or cardiology projections with large angulations equivalent to 26 cm PMMA) requires an increase of dose rate in fluoroscopy and dose/frame in a factor near 2. Values of entrance dose rate in fluoroscopy or dose per frame for different PMMA thicknesses, is a useful measure to be taken during the acceptance test of the systems (figure 2).

Table 1. Entrance dose values for 2 mm Cu, normalised at 50 cm focus chamber distance.

X ray system	Image intensifier format (cm)	Fluoroscopy mode	Dose Rate (mGy/min)
Philips Integris H-3000	23	Low	6.7
		Medium	18.8
		High	61.4
Philips BV300+	23	Normal	8.2
		High	19.6
Philips Optimus 200	23	Normal	26.0
Toshiba DFP2000	24.5	Low	9.7
		Medium	11.9
		High	16.9
Siemens Polydoros 100	28	Normal	25.3
Toshiba KXO-80m	24.5	Default	22.5
Philips BV300	23	Normal	8.9
		High	20.4
Philips Omidiagnost	25	Normal	27.2
GE Advantx I	22	Low	10.2
		Medium	21.9
		High	46.6
GE Advantx II	22	Low	4.7
		Medium	10.0
		High	18.4

Table 2. Entrance dose values for 2 mm Cu, normalised at 50 cm focus chamber distance (cine)

Modality	Image intensifier size (cm)	Cine mode	Dose/image (µGy/frame)
Philips Integris	23	Default	280
GE Advantx I	22	A	51
		B	84
		C	155
		D	284
GE Advantx II	22	A	57
		B	96
		C	138
		D	184
Philips Optimus	23	Default	430

Concerning skin dose increase during magnification, it should be stressed that this is also very dependent of the X-ray system. The Philips Integris system evaluated increases dose rate and dose/frame by a factor near 1.25 from the II format of 23 cm to 18 cm. The GE systems

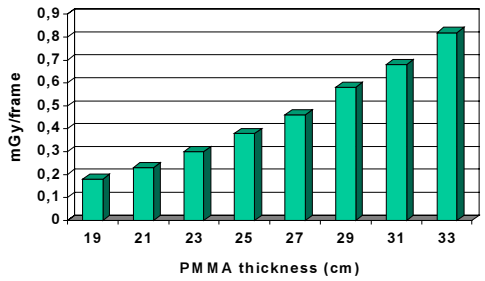
evaluated increase dose rate and dose/frame by a factor near 1.4 from the II format of 23 cm to 18 cm. The Toshiba DFP-2000 maintain the skin dose at a similar value for 23 and 18 cm.

Another important factor to point out is the increasing in dose rate when changing from fluoroscopy low to medium and high modes. These factors for the Philips Integris system evaluated (for 2 mm Cu) are approximately 3, and for the GE systems evaluated are a factor of 2. The different image quality levels of cine imaging for the GE systems requires a dose factor between 1.3 and 1.8 from one mode to the next (for 2 mm Cu).

Table 3: Entrance dose values (normalised at 50 cm focus chamber distance). Fluoroscopy low mode includes the extra filtration: 1.5 mm Al + 0.4 mm Cu). Cine mode has any additional filtration. Philips Integris H3000, 23 cm II format

Attenuation material	Thickness	Fluoroscopy Dose rate (mGy/min)	Cine Dose/image (μGy/fr)
Cu	1 mm	2.6	138
	2 mm	6.7	280
	4 mm	24.4	537
	5 mm	30.9	762
	6 mm	38.2	956
PMMA	14 cm	7.3	152
	20 cm	19.7	280
	26 cm	42.7	559

FIGURE 2: Philips Integris System (Cine mode, II: 23 cm, FID 110 cm, FSD 64,5 cm). San Carlos University Hospital Madrid



4. Conclusions

Values of dose rate and dose per image at the entrance of the patient (simulating different thicknesses and establishing the equivalence with Cu filters), together with image quality, should be determined during acceptance tests for all the fluoroscopy and imaging modes and for all the image intensifier formats in IR systems. During the DIMOND constancy checks, the most usual operation modes should be re-evaluated and the results could be used to estimate patient skin doses. These values will help the medical specialists to optimise clinical protocols managing patient dose in a correct way and also avoiding deterministic risks in prolonged and complicated procedures.

Acknowledgements

This work has been partly supported by the European Commission (DIMOND III contract). One of the authors (LL) would like to express particular gratitude to the IAEA for the grant received for her stay in Madrid. Acknowledgements are also given to the Radiology Department of the San Carlos Hospital and to the Ruber International Hospital and Clinica Ruber for their kind co-operation in the evaluation of their systems.

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ORGAN DOSES IN INTERVENTIONAL RADIOLOGY PROCEDURES: EVALUATION OF SOFTWARE

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Abstract

Interventional Radiology (IR) procedures require large fluoroscopy times and important number of radiological images, so the levels of radiation to patient are high, which leads us to calculate the organ doses. The objective of this work is to estimate and make a comparison of the results given by the different software that we have to do the calculation of organ doses in complex procedures of IR. To do this, 28 patients have been selected, distributed in the 3 procedures with highest doses. The determination of organ doses and effective doses has been made using the projections utilized and different software, based on MonteCarlo Methods: Eff-dose, PCXMC and Diasoft. We have obtained dispersion in the average organ dose between the 3 programs very high. In many cases, it is higher than 25% and in some particular cases, is greater than 100%. Dispersion obtained in effective doses is not so high, being under 20% in all cases. This shows that a better solution is needed to solve the problem of the organ doses calculation, being necessary a more accurate method that brings us to a trustworthy approach to reality, and, by the moment, we do not dispose of it.

1. Introduction and objective

Procedures in Interventional Radiology (IR) require long time of fluoroscopy and an important number of radiological images, being very high the level of radiation doses given to patient. This leads us to determine the dose received in organs, because in some cases can be very high. Although the probability of the stochastic effects to appear always exists, deterministic effects only exist if certain threshold doses are surpassed, that are different for each organ. In the IR procedures, it is interesting to estimate if the doses given are higher than the limits we have for deterministic effects. The objective of this paper is to estimate the organ doses and to analyze the results given by different software available to carry out the calculation of organ doses in complex procedures in IR.

2. Material and methods

To do this study, 28 patients have been selected, distributed in the 3 procedures considered to have the higher risk that are:

1. Abdominal aortic aneurysm endoprothesis treatment (AAA)
2. Transjugular intrahepatic portosystemic shunts (TIPS)
3. Mesenteric arteriography with venous return (AMRT).

Measures have been obtained using a transmission ionization chamber Diamentor M2 (PTW-Freiburg) placed at the exit of the X-ray tube of the IR equipment (Siemens Digitron 3), which has allowed us to obtain the Dose-Area product (DAP) of the irradiated field.
Following data have been collected:

- Total DAP (in fluoroscopy and radiography)
- Characteristics of patient (age, sex, weight, and height)
- Projections utilized, as well as the anode angle
- Radiological technique (kV and mAs)
- Total time of radioscopy
- Total number of images obtained

The posterior determination of organ doses and effective dose has been done knowing in each case the projections applied, and using different software based on Monte Carlo Methods: Eff-dose, PCXMC and Diasoft.

Eff-Dose asks for data on kV, total filtration of the beam, DAP, and projections utilized. In this work, the closer simple projection and similar to the irradiated field in each procedure has been selected, following the methodology described by Ruiz-Cruces et al. [1-3]

PCXMC asks for more information to carry out the dosimetric estimation, requesting the DAP, projections, kV, anode angle, total filtration of beam, age of the patient, source-patient distance, size of the irradiated field by means of coordinates (X, Y, Z), number of energy levels and number of photons in each level (maximum 50000). Moreover, it allows us to adjust the field with rotation degrees, which is an advantage from the previous program. [4]

Diasoft asks for the same parameters than Eff-Dose: kV, total filtration of the beam, DAP, projections utilized, as well as the source-patient distance. [5] This program has the possibility of being executed directly connected to the transmission ionization chamber of PTW Freiburg.

3. Results

Table I shows the organs with doses that have a relative error higher than 25% for each procedure, with its dose value, calculated as the dose obtained with the different programs as well as the average that results. For the AAA and AMRT there are only 2 and 4 organs in each case with this characteristic, meanwhile for the number increases until 19. It is important also that there are 5 organs in this last procedure that have a relative error that surpass 100%. This error appears as a consequence of the disparity of results between those ones given by PCXMC and the other two of them. The values given by Eff-Dose and DiaSoft are almost equal for all the procedures.

Table II shows the effective doses obtained with the three programs, the average value and its standard deviation, expressed also as a relative error. The values given by Eff-Dose and DiaSoft are almost totally equal for all the procedures, but on the other hand, the calculation made by PCXMC is very different from the other ones. The standard deviation between the results of the three programs varies from 6 to 8, and the relative error from 15 to 17%.

Table III shows the standard deviation end the average relative error of the organ doses in each procedure. It stands out the relative error of 56% in the case of TIPS, meanwhile in the other two procedures the relative errors are 16 and 14% in each case. The results given by PCXMC are very different in some particular cases, making that the average relative error to be as high as showed.

Table I. Organ doses with relative error higher than 25% for each procedure

Procedure	Organ	Dose Eff-Dose*	Dose DiaSoft *	Dose PCXMC*	Dose Average*	Relative Error (%)
AAA	Adrenals	106,90	106,90	209,26	141,02	42
	Lung	7,21	7,21	12,09	8,84	32
TIPS	Adrenals	389,36	389,40	142,52	307,09	46
	Breast	3,36	3,36	1,43	2,72	41
	Bladder	129,84	129,80	42,92	100,85	50
	Stomach	107,39	107,40	33,31	87,70	52
	U L I	83,37	83,37	46,12	70,95	30
	L L I	14,37	14,37	57,52	28,75	87
	Heart	18,87	18,87	7,08	14,94	46
	Kidney	606,02	606,00	237,74	483,25	44
	Liver	159,83	159,80	53,53	124,39	49
	Lung	21,63	21,63	7,83	17,03	47
	Ovaries	**12,48**	**12,48**	**68,07**	**31,01**	**103**
	Pancreas	175,21	175,20	53,61	134,67	52
	Spleen	356,39	356,40	117,83	276,87	50
	Testes	**0,20**	**0,19**	**10,09**	**3,49**	**164**
	Thymus	2,39	2,39	0,54	1,77	60
	Thyroid	**0,27**	**0,27**	**0,00**	**0,18**	**140**
	Urinary bladder	**2,55**	**2,55**	**35,28**	**13,64**	**107**
	Uterus	**9,67**	**9,67**	**56,45**	**25,26**	**107**
	Esophagus	25,17	25,17	3,81	18,05	68
AMRT	Adrenals	59,49	59,49	128,45	82,48	48
	Breast	0,64	0,64	1,29	0,86	44
	Heart	3,59	3,59	6,38	4,52	36
	Lung	249,78	249,80	214,28	4,68	44

*Given in **mGy**

Table II. Dispersion obtained in effective dose for each procedure

	Effective Dose (mSv)					
Procedure	**Eff-Dose**	**DiaSoft**	**PCXMC**	**Average**	**Standard Deviation**	**Relative Error (%)**
AAA	75,68	75,68	57,48	69,6	10	15
TIPS	51,18	51,18	37,81	46,7	8	17
AMRT	40,30	40,29	29,91	36,8	6	16

Table III. Standard deviation and average relative error of the entire organ doses in each procedure

Procedure	Standard deviation*	Relative error (%)*
AAA	14	16
TIPS	37	56
AMRT	6	14

*Average for all the organs

4. Discussion and recommendations

To have three different programs to carry out the same calculations should imply first a way to arise a more accurate result. However, as it can be seen in this work, this is not in this way.

The results given by the three programs are very different, so in general, the dispersion error is very high.

First, we have Eff-Dose y DiaSoft that provide values that are practically equal, which implies that two of them can be utilized indiscriminately.

On the other hand, PCXMC, which results are very different from the other two programs, has the advantage of be able to adjust better the angle of the field for each projection.

All we have said shows that a better solution is needed to solve the problem of the calculation of organ doses, being necessary a more accurate method to be closer to reality, and by the moment, we do not have this method.

As a recommendation, we propose as lesser solution to calculate an average using the three programs, obtaining an estimated value with its relative error.

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OCCUPATIONAL HAND DOSES IN INTERVENTIONAL RADIOLOGY

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Abstract

In this paper we present a case of radiologist performing interventional procedures. Radiologist works for number of interventional procedures, but we reported only percutaneous nephrostomy and percutaneous biliary drainage which represent about 30 % of his occupational exposure. Radiologist is occupationally exposed for eighteen years and from 1995 has radiation injuries. From 1999. art. hypertension, cataract complicata incip.ou., onychodystrophia and hyperceratosis mani bill. The most important are hands skin injuries. In ordinary dosimetric control low doses, less than 10 mGy per year, were recorded, so personal dosimetry results and biological results are not in accordance. For that reason we performed additional measurements during many procedures and in this paper we present results for two chosen procedures. Radiation exposure of radiologist hands during 200 percutaneous nephrostomy and 63 percutaneous biliary drainage per year are reported. Exposures were measured with thermoluminescent dosemeters (TLD) type CaF_2:Mn. Hands doses of equivalent of 221 μSv in average per drainage and 31 μSv in average per nephrostomy were recorded.

1. Introduction

Different radiologists at the same procedures show variation in their personal doses, specially the hand and finger dose in interventional radiology. Factors influencing the doses are: factors related to patients (age, sex, weight, etc.), factors related to eqipement and factors related to radiologists (technique, screening time, number of procedures, type of procedures, etc.).

Medical staff radiation exposure is under physical and biomedical monitoring due to radiologist protection. Sometimes, for different reasons, results of these two monitoring techniques are not in accordance.

In this paper we present a case of radiologist performing interventional procedures, as percoutaneus nephrostomy (unilateral, bilateral, change of a nephrostomy catheter), biliary drainage, percutaneous apscess/pseudocyst drainage and placement of an ureteric stent. Percutaneous nephrostomy and percutaneous biliary drainage represent about 30 % of his occupational exposure.

This radiologist is occupationally exposed in interventional radiology for 18 years. According to medical documentation in his family there were no hereditary important diseases. He was healthy and had no visible (or clinical) signs of radiation leasions until 1993. Medical examination from 1993 showed regular biochemical and hematological parameters, exept lower white blood cells (but still in the range of expected values). The same year physician registered dry skin of the hands. From 1995 the radiologist was not answering the calls for medical examinations until 1999. when we found: art. hypertension, cataract complicata incip. ou., onychodystrophia and hyperceratosis mani bill. The most important were skin changes which can be considered as precancerogenes lesions. We tried to re-evaluate this radiologist's occupationally exposure because these changes can be considered as late effects of cumulative occupational doses.

Cytogenetics tests results didn't show unstable chromosomal aberrations as parameter of recent irradiation. Micronucleus test showed significantly high rate - 46/1000. In vitro radio

sensitivity was normal (micronucleus rate was 198/1000). All these results can be considered as late effects of ionising radiation exposure.

Previous whole body exposure mesurements were performed by TLD type CaF_2:Mn worn under the lead apron. Under these circumstances, personal monitor located under the apron on the trunk of the individual indicates the dose equivalent to the shielded trunk of the body. Our measurements included nine dosemeters at unshielded and shielded parts of the body.

2. Materials and methods

All measurements were performed by calibrated TLD type CaF_2:Mn.

Calibration of the intensities of the radiation fields is traceable to the Federal Bureau of Measures and Precious Metals (further: FBMPM). The ionization chambers and electrometer used for field calibration are owned by national metrological institution FBMPM and are traceable to primary Yugoslav standards as well as to international standards. The intensity of the field is assessed in terms of air kerma with the field collimated to minimize unwanted scatter. Conversion coefficients from air-kerma to the dose equivalent vary as a function of photon energy, angle of incidence and size and shape of backscatter medium. Personal monitors are irradiated to a known value of dose equivalent while mounted on 30 x 30 x 15 cm slab (polymethylmethacrylate) PMMA phantom. An anterior to posterior radiation condition is simulated. Multiple personal monitors are irradiated to obtain informations on accuracy and precision. As there are limitations when we use radiation qualities as metrological standards which often differ from the radiation qualities that personal monitors encounter in the working circumstances which often cannot be fully characterized we used users beam for the calibration purposes. We also simulated working conditions from the stand point of distances from the beam focus as well as appropriate holders and all elements which can be found in roentgen room. All dosimeters were put in tissue equivalent folies when we irradiated them in free-air with well known air kerma.

We put personal monitors at seven places where we expected higher doses (right and left eye, thyroide, neck , right shoulder, left and right hand) as well as on two places where ordinary low doses (chest and gonades) were expected. In estimation of effective dose we looked up them as single personal dosimeter at one specific place. We also used direct reading electronic device type PDM -102 Aloka placed on chest under the lead apron.

Medical examinations were performed according to recent regulatory papers for occupational exposure.

All measurements were performed on SHIMADZU X-ray apparatus type IDR-1000, model F-2 with 1mm Al equivalent and maximum tube voltage of 150 kV. In this work X-ray scatter radiation was produced at various X-ray tube potentials in the range of 85 to 90 kVp with X-ray tube in the overtable position. Medical staff were in proximity of patient undergoing a procedure.

In the two chosen procedures duration of the procedure nephrostomy was 15 min in average and drainage 20 min in average.

We used NCRP Rep.122 as well as ICRP Rep.47 for estimating H_E in practice using personal monitors. [1,2]

3. Results

Mean dose in conventional TL dosimetry was 10.52 mGy per year with dosemeter worn under the protective apron.
Electronic device recorded about 9 μSv per procedure also worn under the apron.
Results of individual hand doses are given in table I.

Table I. Radiologists individual hand dose measurements results

procedure	biliary drainage	nephrostomy
mean hand dose per procedure [μSv]	221	31
number of procedures per year	63	200
screening time [min]	20	15
total hand dose per year [mSv]	13.9	6.2

Our measurements results are comparable with other authors results who reported similar cases.[3,4,5]
Estimated cumulative hand dose for eighteen years occupational exposure, based on measurements of these two procedures taking into account that they represent 30 % of total exposure, is about 3.3 Gy. This dose can be reduced by improving tehnique and reducing the number of procedures per radiologist.

4. Conclusion

In interventional radiology total doses at the unprotected parts of the body, especially hands, can exceed the dose limits recommended by ICRP. Our results showed that hand doses for mentioned two procedures did not exceeded recommended dose limits but taking into account cumulative dose effects can cause radiation skin injuries and substantiate the need for both, medical and physical, monitoring in aim to keep doses as low as possible.

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IAEA-CN-85-129

DOSES TO PATIENTS AND STAFF FROM ENDOVASCULAR TREATMENT OF ABDOMINAL AORTIC ANEURYSMS – PRELIMINARY RESULTS

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Abstract

Patient radiation doses received during endovascular treatment of abdominal aortic aneurysms (AAA) can be significant and give rise to both deterministic and stochastic effects. Recording of dose-area product (DAP), fluoroscopy time and number of exposures together with calculations of effective dose were performed for 8 patients. In addition, the entrance surface dose was measured for 3 of the patients. Typically, DAPs of 340 $Gycm^2$, fluoroscopy times of 30 minutes and 310 exposures were obtained together with maximum entrance surface doses of 1,8 Gy and effective doses of 50 mSv. Finger doses to the staff performing the procedure were in the order of a few hundred μSv. Conversion factors (effective dose/DAP) and (maximum entrance surface does/DAP) of $0{,}61 \cdot 10^{-2}$ $Gy/Gycm^2$ and 0,15 $mSv/Gycm^2$, were obtained respectively.

1. Introduction

Endovascular treatment of abdominal aortic aneurysms (AAA) has been carried out since the early 90ies, but is still experimentally. The aim is to increase the survival rate and improve the quality of life for the patients. The procedure reduces the surgical stress and there is minimal need for intensive care. The patient is early mobilised and is discharged from hospital the third day postoperatively. About 30-50% of the patients fulfil the physiological and anatomical criteria necessary to be considered as candidates for this new, minimally invasive treatment modality.

This endovascular procedure may give rise to significant patient doses, due to potentially long fluoroscopy times, frequently use of different magnification modes together with a large number of exposures, and are therefore associated with both deterministic and stochastic risks. High skin doses may result in deterministic effects such as erythema, epilation, desquamation, tissue necrosis or ulceration [1, 2]. Such radiation induced skin injuries have already been reported in the literature following percutaneous transluminal coronary angioplasty (PTCA) [2-4]. The severity of these effects can be quantified by the entrance surface dose (ESD), which can be estimated using, for example, thermoluminescent dosimeters (TLDs) [5]. The stochastic risks of carcinogenesis and genetic effects are quantified by the effective dose (ED), which may be obtained by Monte Carlo simulations on phantoms [6].

The vascular surgeons and interventional radiologists performing the procedure may receive large occupational doses, for instance to their hands, since they are working close to the patient not only during fluoroscopy but also during the exposures.

Because of potential high patient doses associated with endovascular treatment of AAA, dose monitoring is of great importance. The most common way of dose monitoring is the dose-area product (DAP). In this procedure, DAP may be difficult to relate to the maximum entrance surface dose (MESD) and in some extent also to ED, because the irradiated skin area is varying during the procedure. Relationships between the easily measured DAP to both MESD and ED would therefore be of great help in estimating the risks of both deterministic and stochastic effects associated with this treatment.

In the present study, doses to the patients and staff associated with endovascular treatment of AAA were examined as well as conversion factors between DAP to both MESD and ED were carried out.

2. Material and methods

Eight patients (seven men, one woman) having a mean age of 66 years (range 56-79) were treated for AAA (mean 55 mm, range 51-60 mm) with bifurcated stent-grafts (AneuRx, Medtronics, Inc, USA). In some of the cases, stent-graft extensions were used to seal a distal leakage or to secure the limbs near the origin of the internal iliac artery. All patients were included and evaluated according to the Eurostar Protocol[1].

All the stent-graft procedures were performed in a newly designed vascular and endovascular operating theatre having a special designed operating table (Koordinat O.R.) [7]. Beyond that, the theatre was fitted with all the facilities found in an ordinary angio-lab. The X-ray equipment used in this study was a Siemens Multistar Plus equipped with a ceiling mounted C-arm with a four-field (14/20/28/40 cm) image intensifier (Sirecon 40-4 HDR). The X-ray generator used was a Polydoros IS-A.

DAP was measured with a transmission ionisation chamber (DAP meter) (Diamentor, PTW, Freiburg, Germany) permanently attached to the collimator. For each patient the total DAP was separated into contributions from fluoroscopy and exposure. At present time, no information is available of the calibration procedure or the uncertainty in the DAP measurements.

TLDs (LiF:Mg,Ti, Harshaw TLD-100 chips) were used to measure ESD. The TLDs were calibrated free in air using the radiation quality ISO N-60 traceable to the measuring institute in Utrecht, the Netherlands[2] [8]. Background radiation was corrected for by means of 4 non-irradiated TLD controls. Overall uncertainty associated with TLD readings were estimated to be within ± 10%. Patient skin doses were obtained by placing 14 TLDs in the median plane at the patients back. The TLDs were placed with 2 cm spacing and centered at the level of crista. Finger doses to the staff performing the procedure were obtained by placing a sterilised TLD ring dosimeter on the middle phalanx of the middle finger bilaterally under the surgical gloves. All TLDs were read within one day after irradiation.

Rough estimates of the effective dose to the patients were obtained from the total DAP using the NRPB-R186 software [9]. This program uses an average adult patient of 70 kg mass and 174 cm height for its calculations. The abdominal PA projection with field size of 35 x 47 cm^2 were chosen for the effective dose calculations. The use of this projection will introduce an error to the estimated effective dose, since the field size usually used are smaller and the irradiated area of the skin varies during the procedure. The overall error is estimated to be within ±25%.

[1] Data registry center for stent-grafting in Europe. European Society for Vascular Surgery.
[2] TLD ring dosimeters used for measuring finger doses were calibrated free in air on a rod PMMA phantom, 1,9 cm in diameter.

3. Results

The endovascular procedure was completed for all patients and the second limb was attached without any problems. There was no 30-days mortality and no serious complications were observed. The use of one extension in patient 2, 5 and 8 and two extensions in the case of patient 1 and 7, matches the variations observed in DAPs, fluoroscopy times and number of exposures taken (Figure 1). Even though the fluoroscopy times were relatively long, typically 30 minutes, the exposures contributed mainly to the total DAP. A mean total DAP of 340 Gycm^2 and an average number of 310 exposures were obtained for these eight patients.

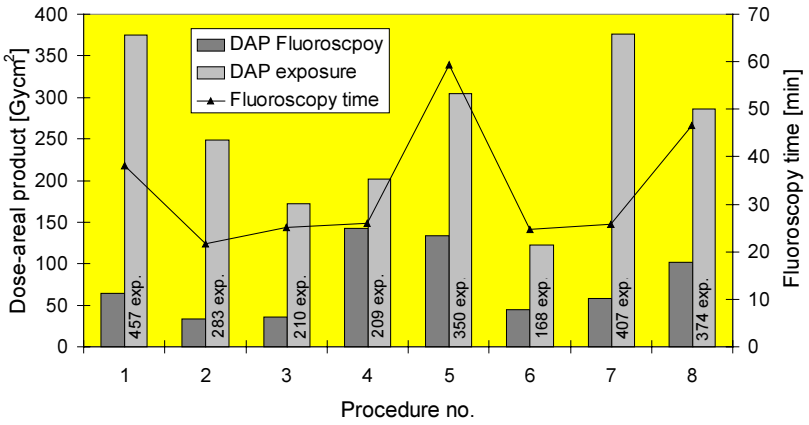

Figure 1. The contributions from fluoroscopy and exposure to the total DAP together with the fluoroscopy time and the number of exposures taken during endovascular treatment of AAA. At the present time, total uncertainty in DAP measurements are unknown

Skin dose distributions measured along the patients' back in the median plane are shown in Figure 2. Maximum skin doses in the range 1,3-2,3 Gy were obtained, matching the threshold dose for transient erythema for one of the patients. Maximum skin dose was generally localised somewhere between 6 cm cranialt and 10 cm caudalt from crista.

ED and MESD together with DAP to ED conversion factor (ED/DAP) and DAP to MESD conversion factor (MESD/DAP) for the procedure are given in Table I. Relatively high effective doses around 50 mSv were obtained. A mean ED/DAP conversion factor of 0,15 mSv/Gycm^2 and a mean MESD/DAP conversion factor of $0{,}61 \cdot 10^{-2}$ Gy/Gycm^2 were obtained for this procedure.

The finger doses to the surgeon and radiologists performing the endovascular procedure are shown in figure 3. The received finger doses, given a normal workload, were below the occupational dose limits of 500 mSv/year proposed by the ICRP [10], indicating a good working practice.

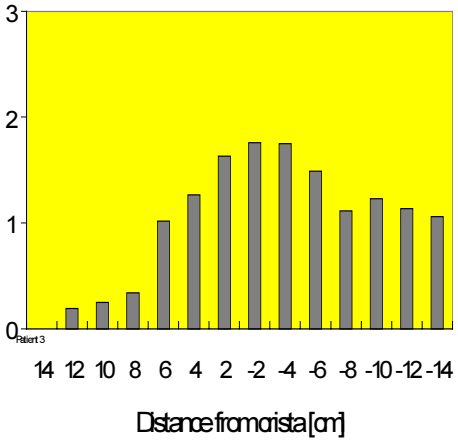

Figure 2. Skin dose distributions along the median plane of the patients back. Distances given in positive numbers and negative numbers are in the cranial and caudal direction from crista, respectively. The mean weight of the 3 patients was 83 kg, varying between 78-92 kg. Total uncertainty in the TLD readings was estimated to be within ± 10%

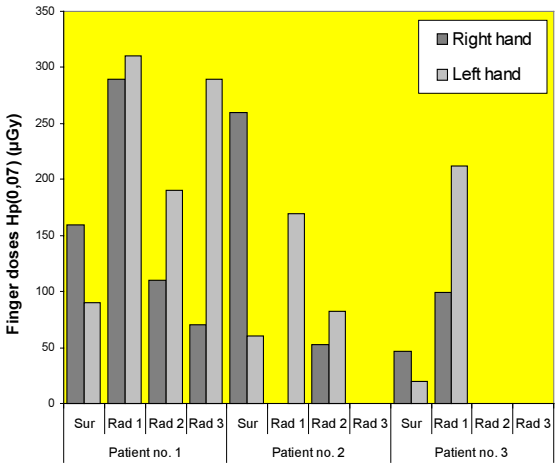

Figure 3. Finger doses received by the staff performing the endovascular treatment of AAA. Sur = surgeon, Rad = radiologist. Total uncertainty in the TLD readings is estimated to be within ± 10%

Table I. Mean values of total DAP, maximum entrance surface dose (MESD) and effective dose (ED) together with DAP to maximum entrance surface dose conversion factor (MESD/DAP) and DAP to effective dose conversion factor (ED/DAP) for the endovascular treatment procedure of AAA. Range is given in brackets

DAP [Gycm^2]	MESD [Gy]	ED [mSv]	MESD/DAP [Gy/Gycm^2]	ED/DAP [mSv/Gycm^2]
338 ± 32% (167-439)	1,79 ± 26% (1,35-2,27)	50 ± 34% (22-64)	$0{,}61 \cdot 10^{-2}$ ± 33% $(0{,}48\text{-}0{,}85) \cdot 10^{-2}$	0,15 ± 7% (0,13-0,17)

4. Discussion

Patients undergoing endovascular treatment of AAA are normally elderly and have as well, often, severe pulmonal and cardiovascular diseases. Total survival rate of these patients vary from 63-74%, depending on different publications [11]. Although the effective dose to the patient from this procedure is relatively high, 50 mSv, life expectancy and age distribution of the patients, indicate that deterministic skin injuries rather than stochastic risk of developing cancer are the effect to be considered. The main purpose with this study was therefore to establish a maximum advisable DAP to prevent skin damage such as transient erythema and temporary epilation, having threshold values of 2 Gy and 3 Gy, respectively. In obtaining a MESD/DAP conversion factor, TLDs were used to map the dose distribution along the patients back (Figure 2). To avoid missing the maximum skin dose it is of great importance to use many TLDs, especially in this procedure where magnification is used in combination with a moving primary beam irradiating different skin areas. Such use may result in an overlapping of exposed skin areas, which again can give high doses to small separated skin areas. By using

the MESD/DAP conversion factor of $0{,}61 \cdot 10^{-2}$ Gy/Gycm^2 (Table I), maximum advisable DAPs to avoid transient erythema and temporary epilation of 330 Gycm^2 and 490 Gycm^2 were obtained, respectively. By having a DAP meter available during the procedure, the operator can prevent skin injuries by not letting the total DAP exceed the limits for skin injuries. If additional exposure is required to finish the procedure, the operator may avoid the appearance of skin damage by changing the projection in such a way that the irradiation is spread over different skin areas. Of the eight patients studied in this work, five of them exceeded the DAP limit for transient erythema. Unfortunately, no follow-ups of these patients were performed to determine if transient erythema really did occur. No complications were associated with these eight procedures, but potentially much higher skin doses are believed to occur if complications had appeared. Therefore, the monitored DAP should always be registered in the patients case records and used in evaluating the need of individual patient follow-ups with respect to skin injuries.

Patients selected for endovascular treatment of AAA will receive additional doses from preoperative evaluations and frequently postoperative follow-up controls. CT-scan and angiography are performed preoperatively. At the ambulatory evaluation, CT-scan and plain X-ray of the stent-graft are performed 1, 3, 6 and 12 months postoperatively and each six months thereafter. In addition, 12 months postoperatively one angiography is performed. The total accumulated skin dose related to endovascular treatment of AAA, although not given as a single exposure, may have the potential for increasing the risk of developing skin injuries. The Norwegian Radiation Protection Authority has, in collaboration with Aker Hospital, University of Oslo, initiated a work where the total accumulated doses to the patiens undergoing this treatment are collected. The work will also include a close follow-up study of patients received doses above 3 Gy, with respect to induced skin injuries.

No dose measurements from endovascular treatment of AAA could be found in the literature, for comparison. It is believed that the variation in DAP values and skin doses are significant from hospital to hospital, since the results are depending on the practice of the persons whom performing the procedure and also of the weight of the treated patients. At this time, only limited data exists and more data should be collected before reference values and conclusions are drawn.

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IAEA-CN-85-147

OPTIMISATION OF PATIENT AND STAFF EXPOSURE IN INTERVENTIONAL CARDIOLOGY

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Abstract

The Council Directive of the European Community 97/43/Euratom (MED) deals with the health protection of individuals against dangers of ionising radiation in relation to medical exposure, and also focuses attention at some special practices (Art. 9), including interventional radiology, a technique involving high doses to the patient. The paper presents the European approach to optimisation of exposure in interventional cardiology. The DIMOND research consortium (DIMOND: Digital Imaging: Measures for Optimising Radiological Information Content and Dose) is working to develop quality criteria for cineangiographic images, to develop procedures for the classification of complexity of therapeutic and diagnostic procedures and to derive reference levels, related also to procedure complexity. DIMOND project includes also aspects of equipment characteristics and performance and content of training in radiation protection of personnel working in interventional radiology field.

1. Introduction

The number and complexity of diagnostic and interventional procedures (IR) done in the medical practice have grown enormously, in particular in the last ten years, due to the availability of more suitable materials necessary to the procedures, and to the availability of the modern diagnostic units, either using X-rays or US, MR. However, the vast majority of these procedures are performed in a radiological room under fluoroscopy, simply because the vascular are the leading indications. Today, interventional radiology reduces the need for many traditional interventions, particularly surgery, therefore reducing the overall discomfort and risks for the patient compared to the traditional methods.

Due to the potential of high patient [1,2] and staff [3-8] doses and to the observed deterministic injures, after long fluoroscopic interventional procedures, the Council Directive 97/43/Euratom of 30 June 1997 includes this practice in the art. 9 of the 'Special practices'.

The paper presents the European approach to optimisation of exposure in interventional cardiology and some of the results obtained by the DIMOND research consortium (DIMOND = Digital Imaging: Measures for Optimising Radiological Information Content and Dose). DIMOND group is working on the development of quality criteria for angiographic images. Also procedures for the classification of complexity of therapeutic and diagnostic procedures are studied together with the proposal of reference levels, also related to procedure complexity. DIMOND project includes also aspects of equipment characteristics and performance, staff and patient dosimetry and content of training [(9)] in radiation protection for personnel working in interventional radiology.

2. Methods and results

2.1. Image quality criteria

An important aspect of optimisation strategy is the definition of methods for image quality assessment. The approach of EC guidelines on 'quality criteria for radiographic images' was

assumed as a model for the implementation of similar methodology for IR images. DIMOND has developed a preliminary set of quality criteria for coronary angiography images (table I) [10]. The quality is assessed as a visibility level of important anatomical and, also, pathological markers. Two pilot trials have been conducted on a set of 15 studies, obtained in 4 centres in Greece, Italy and Spain. Each study has been analysed by 6 independent cardiologists adopting a scoring system for the quantitative assessment of image quality. The preliminary experience indicates that criteria can be translated into a scoring system that yields reproducible data in most instances.

1 Table I. Example of quality criteria for left coronary angiography images based on the visibility of anatomical markers

LEFT CORONARY ANGIOGRAPHY
Image criteria

2	*Performed at full inspiration if necessary to avoid diaphragm superimposition or to change anatomic relationship (in apnoea in any case).*
3	*Arms should be raised clear of the angiographic field and the spine should appear as less as possible.*
4	*Visually sharp reproduction of vessel walls.*
5	*Simultaneous and full opacification of the vessel lumen at least until the first critical lesion (70% by visual estimation).*
6	*Panning should be limited. If necessary, pan in steps rather than continuously, or make subsequent cine runs to record remote structures.*
7	*Visually sharp reproduction of the origin, proximal, mid and distal portion of the Left Anterior Descending and Circumflex arteries, in at least two orthogonal views.*
8	*Visually sharp reproduction of the side branches > 1 mm of the Left Anterior Descending and Circumflex arteries in at least two orthogonal views; the origin should be seen in at least one projection.*
9	*Visually sharp reproduction of the lesions in vessels > 1 in at least two orthogonal views.*
10	*Visualisation of collateral circulation when present.*

When criteria 6-9 have been fulfilled, avoid extra projections (mainly LAO semiaxial).

2. 2. Patient exposure: reference level and complexity index

Reference level (RL) is a powerful instrument for optimisation in diagnostic medical exposures and DIMOND is trying to introduce it for interventional cardiology. But, taking into account that in IR the patient pathology drives the procedure complexity, RL has to take into account some of the complexity factors affecting the procedure.

From a sample of Coronary angiography (CA) and Percutaneous Transluminal Coronary Angiograplasty procedures (PTCA) collected in 4 centres of three European Countries, preliminary reference levels (RL) expressed in term of mean values of DAP, fluoroscopy time and number of frames have been derived (table II). Differences between centres are evident and the evaluation of procedures complexity is necessary in order to explain such differences.

A index of pathology severity allows to derive RL as a function of pathology, helping a better evaluation of the optimisation level of the practice in an installation. As an example, in Udine hospital, a partner of DIMOND consortium, the correlation of severity of cardiovascular pathology with technical parameters adopted for the PTCA procedures was evaluated [11].

Table II. Mean fluoroscopy time, number of frames and dose-are product (DAP) measured in some European centre

Interventional cardiology id centre	Fluoroscopy time (min)	N°. of frames	DAP ($Gycm^2$)
CAD	4.1 ± 3.6	1093 ± 446	45 ± 28
- Greece I	3.6	1596	54.6
- Greece II	9.1	1715	124.2
- Italy	4.1	748	38.0
- Spain	6.7	918	48.6
PTCA	13.8 ± 8.5	1135 ± 545	73 ± 28
- Greece I	11.1	1414	54.6
- Greece II	16.0	1702	124.2
- Italy	15.1	908	73.3
- Spain	19.8	995	64.3

The relationship between clinical and technical factors (CF) vs. fluoroscopy time and dose area product (DAP) was examined for 402 random PTCA procedures. Good correlation was found with: number and type of lesions treated, use of double wire or double balloon technique, ostial stenting and bifurcation stenting techniques, simple stenting , occlusion of vessel for more than 3 months, the presence of moderate vessel tortuosity (one bend > 90°), severe tortuosity (two or more bends > 90°) and IVUS (intravenous ultrasonography) use. Based on the relative weight observed in the multivariate analysis a complexity index (CI) was derived. For a practical application the procedures were divided in three groups according with different grades of complexity taking into account only: vessel occlusion ≥ 3 months, ostial and bifurcation stenting, and severe tortuosity (two or more bends > 90°) factors. Fig 1 shows the mean fluoroscopy time and DAP of the 3 groups of PTCA defined: simple, moderate and complex procedure. Further studies in different centres can demonstrate the applicability of this approach with the purpose to derive reference levels, complexity dependent, for IC and others frequent IR procedures.

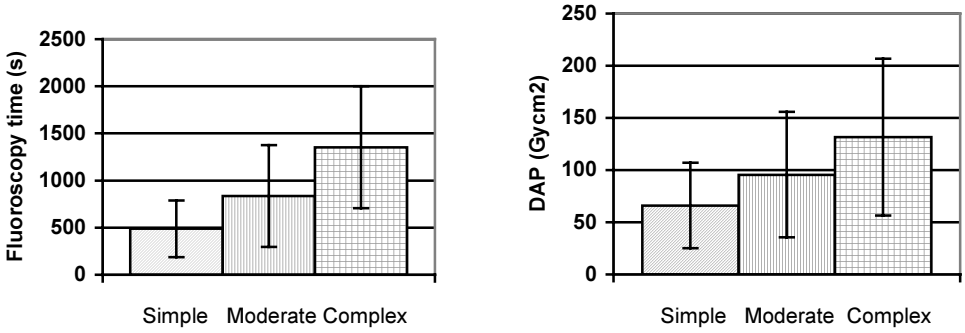

Figure 1. Mean fluoroscopy time and DAP for simple, moderate and complex PTCA procedures

2. 3. Staff exposure

In interventional radiology performed with fluoroscopic systems, where body exposure is not uniform and where part of the body is protected by lead apron or other specific mobile screens, the evaluation of effective dose is difficult and affected by high uncertainties [6]. Published dose data have been analysed and converted in effective dose adopting the dosimetric model proposed by Niklason [6]. The protocol is applicable when two dosimeters

are worn over the apron at the neck level and under the apron at the waist level or when a single dosimeter is worn over the apron at the neck level. Table III reports the effective dose to cardiologist (first operator) and nurse or technician per procedure. When available, dose from diagnostic (CA) and therapeutic (PTCA) procedures are reported. For cardiologist, the effective dose per procedure varies from 0.2 to 18.8, with a mean value of 4.7 μSv. Only Vañó and Steffenino report an effective dose of 18.8 and 15.1 μSv/procedure respectively. In these last two cases, it seems that the presence of cardiologists in training are the main cause of higher doses.

Table III. Effective dose to cardiologist (or first operator) and nurse/technician evaluated in different cardiac centre

Reference	Effective Dose (μSv/procedure)	
	Cardiologist	*Nurse*
Vañó et al., 1998, [8]	18.8	
Padovani et al., 1998, [12]	2.2 (CA) - 8.8 (PTCA)	1.5 (CA) - 3.0 (PTCA)
Folkerts et al., 1997, [3]	2.0	
Li et al., 1995, [4]	8.0	2.0
Watson et al., 1997, [13]	1.8	1.4
Zorzetto et al., 1997, [2]	3.7	
Steffenino et al., 1996, [7]	15.1	3.7
DIMOND, Spain, 1999	2.2 (CA) - 4.4 (PTCA)	0.6 (CA) - 1.1 (PTCA)
DIMOND, Italy, 1999	0.5 (CA) - 1.0 (PTCA)	0.3 (CA) - 0.6 (PTCA)
DIMOND, Greece, 1999	1.0 (CA) - 2.0 (PTCA)	0.6 (CA) - 1.1 (PTCA)

Conclusions

The DIMOND approach to interventional cardiology will be refined in the context of DIMOND III (2000-2003) project and aims to develop a methodology with a set of instruments for the evaluation of the optimisation level in an installation including: quality criteria for images and reference levels as a function of procedure complexity.

From the reported staff dose data the following comments and suggestions can be derived:

(a) many variables affect staff exposure: distance, direction, use of protective screens, procedure, skill, training, equipment performance, etc
(b) the analysis of personal dosimetry data is difficult when: the dosimeters are not worn all the time by operators or the dosimeters are worn in different or wrong positions
(c) the normalisation of the personal dose to workload, expressed in terms of number of procedures or dose-area product, allows a straightforward comparison between facilities and helps to identify those clinicians who are not taking effective radiation safety precautions. In interventional radiology, Dose constraints (ICRP 60 and EC Directive 96/29, art. 7) can be conveniently expressed them in terms of effective dose per procedure or effective dose per unit of dose-area product.

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OCCUPATIONAL EXPOSURES FROM SELECTED INTERVENTIONAL RADIOLOGICAL PROCEDURES

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Abstract

The number of radiology and cardiology interventional procedures has significantly increased in recent years due to better diagnostic equipment resulting in an increase in radiation dose to the staff and patients. The assessment of staff doses was performed for cardiac catheterization and for three other non-cardiac procedures. The scattered radiation distribution resulting from the cardiac catheterization procedure was measured prior to the staff dose measurements. Staff dose measurements included those of the left shoulder, eye, thyroid and hand doses of the cardiologist. In non-cardiac procedures doses to the hands of the radiologist were measured for nephrostomy, fistulogram and percutaneous transluminal angioplasty procedures. Doses to the radiologist or cardiologist were found to be relatively high if correct protection was not observed.

1. Introduction

Providing proper radiation protection to the staff in interventional radiological procedures can pose a real problem. The radiologist and other staff members are usually working close to the area under examination and receive the dose primarily from scattered radiation from the patient. The use of ceiling mounted protection screens is often limited because of their inconvenience. Due to the different nature and complexity of interventional procedures, they were divided between cardiac and non-cardiac groups and were treated separately in this study. The recommendations of Goldstone following the review of occupational exposures in interventional radiology [1] have been taken into account in this study.

2. Cardiac procedures

The equipment used in Tawam Hospital is a Philips digital BV-5000 bi-plane unit. During cardiac catheterization procedures both x-ray tubes situated on C-arms work either simultaneously or separately. The cardiologist is positioned close to both x-ray tubes and the area under investigation as shown in Figure 1. It is apparent that the left hand side of the cardiologist performing the procedure is particularly at risk.

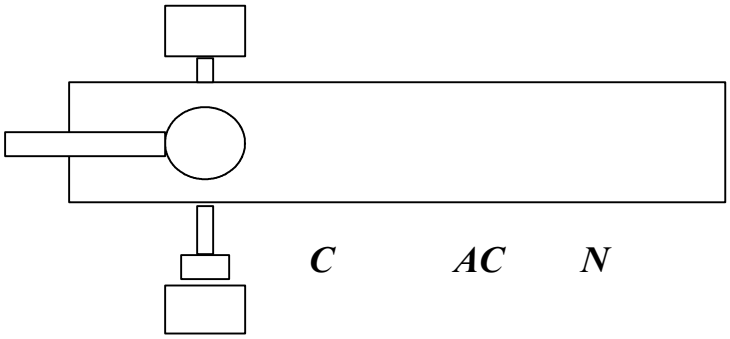

Figure 1. Positions of cardiologist (*C*), assistant cardiologist (*AC*) and nurse (*N*) during cardiac catheterization procedure

3. Non-cardiac procedures

All non-cardiac procedures were performed on the Philips BV-5000 unit, using only single plane. The following typical procedures performed at Tawam Hospital were investigated:

- Upper extremity - fistulogram
- Renal - nephrostomy
- Lower abdomen - percutaneous transluminal angioplasty (PTA) + stenting

For non-cardiac procedures the limiting factor is the hand dose [1]. Radiologists performing them were issued finger dosimeters which were than read after a number of procedures.

4. Method

As a part of our quality assurance and radiation protection program, scattered radiation dose distributions resulting from cardiac catheterization procedures are measured in areas close to the patient [2]. Prior to the measurement, analysis of 10 cardiac procedures involving patients of average size (60 – 80 kg) was performed. The mean dose area product (DAP) resulting from the whole procedure was calculated as 11.8 $Gycm^2$ and used as a reference value in subsequent measurements. The cardiac procedure was recreated using a Rando Alderson phantom as a scattering medium. A 3-D structure containing thermoluminescent detectors (TLD) was positioned close to the phantom where the cardiologist, assistant cardiologist and the nurse would be positioned during the procedure. The present study focuses on the radiation doses received by the cardiologist left arm, eye lens, thyroid and hands resulting from cardiac procedures. TLDs calibrated for skin dose measurements in the diagnostic energy range were attached to the cardiologist left and right arm, close to the eye lens, on the skin above the thyroid and on the fingers of both hands. Doses to eye lens and the thyroid were later calculated. After each procedure DAP values were recorded and TLD readings were corrected for the average procedure. No lead glass protective screens were used in the procedures covered by the study. Radiologists performing non-cardiac procedures were issued finger dosimeters. In these cases TLD readings were also corrected for an average procedure in each group using calculated mean DAP.

5. Result

Sachets containing TLDs were attached to appropriate locations of the cardiologists performing the procedure. Each procedure was closely watched by a monitoring team recording protective measures used and working habits of the staff. In some cases cardiologists did not use protective glasses or thyroid shields due to personal discomfort. A printout indicating fluoroscopy time, number of images acquired and DAP values was obtained at the end of each procedure. The results of the measurements are presented in Table 1 together with explanations.

Table 1. Values of doses per average procedure in cardiac catheterization

TLD location	Calculated dose (mGy)	
	Situation 1	Situation 2
Left shoulder surface	0.86	---
Thyroid	0.054	0.62
Eye lens	0.068	0.65
Right hand	0.36	---
Left hand	0.19	---

Situation 1 – protective glasses with side shield and thyroid shield worn
Situation 2 – no protective glasses and thyroid shield

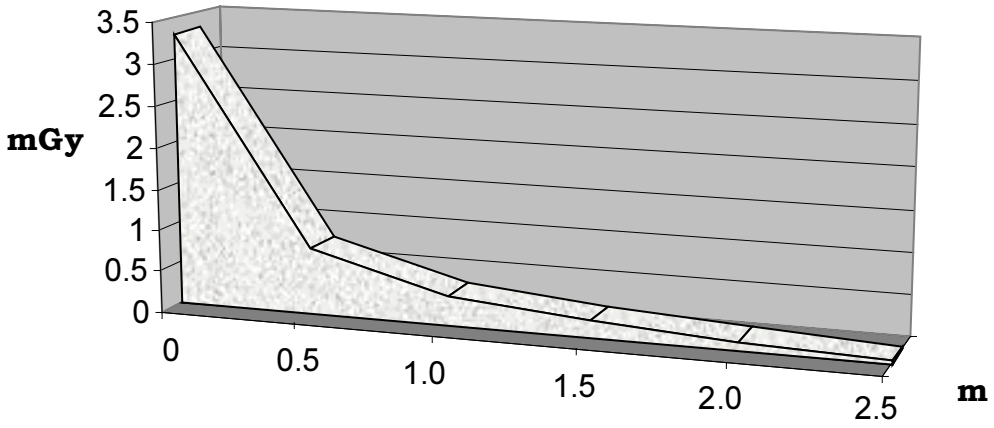

Figure 2. Scattered radiation dose distribution in an area close to the patient

Some cardiologists work closer to the C-arm structure and hence X-ray sources. In those cases the left arm dose was measured as high as 1.85 mGy.

Non-cardiac procedures Hand dose is a limiting factor for non-cardiac procedures [1] as thyroid and eye can be adequately shielded. The hand doses have been measured in our hospital for the most common procedures performed. The radiologists were issued finger dosimeters consisting of a TLD-100 chip sealed in a plastic foil envelope. These were fixed to the index fingers of the radiologist before each procedure. The results presented in Table 2 show the average hand dose per procedure.

Table 2. Values of hand doses per average procedure

Procedure	Personal dose (mGy)	
	Left hand	Right hand
Fistulogram	0.54	0.38
Nephrostomy	0.65	0.39
Percutaneous transluminal angioplasty	0.42	0.22

6. Conclusions

Personal doses measured during our survey generally agree with those reported in the literature [1, 3]. The staff were informed about the results of the survey and the following recommendations concerning radiologists and cardiologists performing interventional procedures were issued:

1. Lead aprons used must be at least 0.35 mm Pb equivalent
2. Thyroid shields and protective glasses with side shields must be used.
3. Radiation resistant gloves must be used.
4. Regular radiation protection training to increase awareness of the staff.
5. Regular radiation protection audits to be performed in order to check the implementation of these recommendations.

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A STUDY ON THE ANNUAL EQUIVALENT DOSES RECEIVED BY CARDIOLOGISTS IN A UK HOSPITAL

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Abstract

A dose assessment study was carried out to determine the likely annual equivalent doses received by various parts of a cardiologist's body. High sensitivity GR-200 thermoluminescent dosemeters were attached to cardiologists' foreheads, little fingers, wrists, elbows, knees and ankles. Three common cardiology procedures were investigated, namely, percutaneous transluminal coronary angioplasty (PTCA), permanent pacemaker insertion (PPM) and left heart catheterisation (LHC). Dose monitoring was done on a case-by-case basis. Data on ten cases of each procedure were gathered. The projected annual equivalent doses were computed by averaging the ten doses measured at each site for each examination type and finding out from the cardiologists how many cases of PTCA, PPM and LHC they do in a year. Results in this study show that for the lens of the eye, the projected annual equivalent dose is below 10 mSv and for the other body parts, it is below 100 mSv per year. The study demonstrated that the methodology used can help to optimise radiation protection in diagnostic radiology.

1. Introduction

For workers who are occupationally exposed to ionising radiations, article 9 of Council Directive 96/29 Euratom [1] states an annual equivalent dose limit of 150 mSv for the lens of the eye and 500 mSv for hands, forearms, feet and ankles. United Kingdom has adopted these values in the Ionising Radiations Regulations 1999 [2]. Paragraph 1(c) of Schedule 4 of Ionising Radiations Regulations 1999 states, "the limit on equivalent dose for the hands, forearms, feet and ankles shall be 500 mSv in a calendar year". For the first time in UK legislation, specific parts of the limbs are subject to a dose limit, hence there is a need to make some dose assessment to these body parts. In diagnostic radiology, the group of workers that is most likely to receive the highest doses are people who are involved in interventional work. Cardiologists are one example.

A study was carried out to (i) assess scattered doses received by different parts of a cardiologist's body, (ii) estimate the likely annual equivalent doses that the various body parts would receive and (iii) establish if additional protective measures are needed.

The dose received by different parts of the cardiologist's body depends on many factors, such as the examination procedure, the patient and complexity of the case, the skill of the cardiologist, the x-ray image intensifier system, the protective equipment used and the position of the cardiologist in relation to the x-ray tube and patient. Due to this interplay of contributing factors and for practical reasons, dose assessment was made per individual case using small, high sensitivity thermoluminescent dosemeters (TLD) that can be attached on or close to the body parts under study. Previous researchers [3] have studied exposure to operating staff in cardiology using thermoluminescence dosimetry but only five cases of cardiac catheterization were investigated. The current study investigated three common cardiology procedures and data from many more cases were collected.

2. Materials and methods

The study was conducted in a well-established cardiology department of a large teaching hospital. Seven cardiologists were involved, comprising one consultant and six specialist registrars in various years of their training. Three common cardiological procedures were

selected for this study: percutaneous transluminal coronary angioplasty (PTCA), permanent pacemaker insertion (PPM) and left heart catheterisation (LHC). Data on ten cases of each of these examinations were collected. Dose monitoring was done on a case-by-case basis. The examinations were carried out in three cardiac laboratories equipped with C-arm x-ray image intensifier units that are less than 5 years old (table 1). Each unit has Diamentor transmission ionisation chamber (Diamentor, PTW, Freiburg, Germany) attached to the head of the x-ray tube.

Table 1. Specification of the x-ray equipment in the three cardiac laboratories

	Laboratory 1	Laboratory 2	Laboratory 3
Manufacturer/ Model	Philips Integris V3000	Siemens Coroskop Classic	Philips Integris H3000
Generator	Optimus CP	Polydoros IS/C	Optimus M2000
Field sizes (cm)	38, 31, 25, 20, 17	23, 17, 13	23, 18, 13
Copper pre-filtration	None	Fluoroscopy and Acquisition*	Fluoroscopy

*No copper filter in acquisition mode if patient size is greater than 25 cm.

Individually calibrated LiF: Cu, Mg, P dosemeters were used to monitor doses at various sites of the cardiologist's body. They were GR-200 chip dosemeters, also called TLD-100H chips (3mm x 3mm x 1mm) from Harshaw Bicron/NE-Technology (BICRON-NE, Solon, OH, USA). These TLDs have high sensitivity and are able to detect doses down to 1μSv above background. They are commonly known as Chinese TLDs. The TLDs were sealed in small black plastic sachets and attached to the forehead, the fifth digit of each hand and the left and right wrists, elbows, knees and ankles. The TLD sachets were taped to the body part using micropore tape except for the forehead where a headband was used and the wrists where wrist bands were used. The TLD at the forehead was aimed at monitoring dose to the eye. The finger TLDs were taped at the distal end of the finger but not at the fingertip so that the dexterity and comfort of the cardiologist were not affected. Two unexposed TLDs were used as control dosemeters. At the end of each examination, all TLDs were removed and read out in a Toledo 654 reader (D. A. Pitman Ltd.). They were annealed in an oven at 240° for 15 minutes followed by rapid cooling to room temperature before re-use.

In addition to the GR-200 dosemeters worn for the purpose of this study, the cardiologists also wore their monthly dosemeters comprising a body film badge, a collar film badge, a headband containing a TLD-100 dosemeter and a wrist band containing a TLD-100 dosemeter. They all wore lead aprons which had 0.5mm lead (Pb) at the front and 0.35mm Pb at the back, a 0.5 mm Pb thyroid shield and no Pb glasses. During PTCA and LH catheterisation procedures, they used a Brompton screen for protection. The screen has a cut-out in the Pb glass and has Pb drapes at the bottom. No protective screen was used for pacemaker insertion procedures. The projected annual equivalent doses were computed by averaging the ten doses measured at each site for each examination type and finding out from the cardiologists how many cases of PTCA, PPM and LHC they do in a year. These three examinations together comprise the majority of their workload. In order to be conservative, data from a cardiologist who had the highest caseload were used.

3. Results and Discussion

The results are presented in figures 1 and 2.

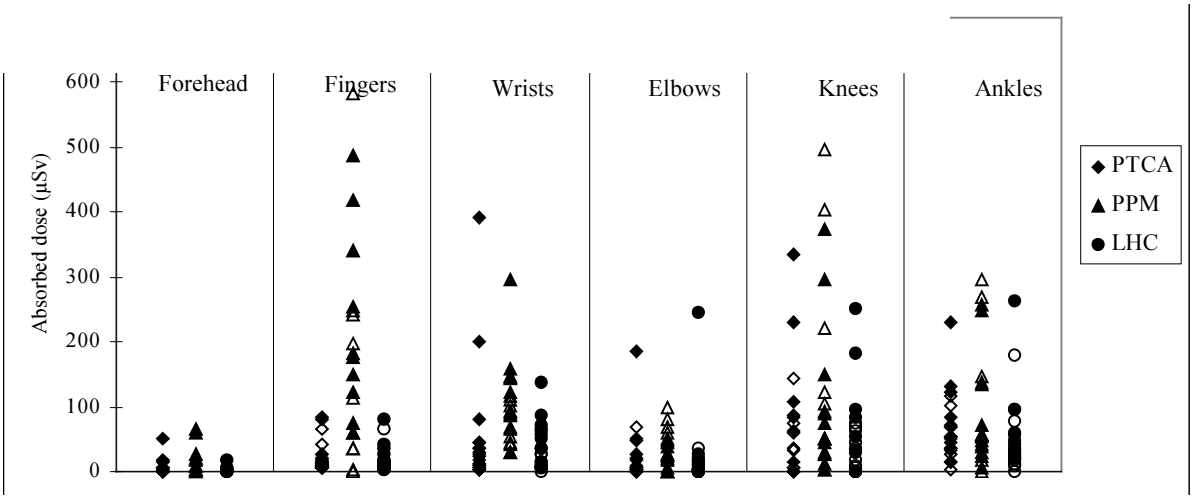

Figure 1. Distribution of individual doses measured in the study. Solid markers are doses measured on the left body part and open markers are doses measured on the right body part

Figure 1 shows all the individual doses measured in the study. For PTCA which is marked by diamond markers, the highest doses are found in the wrists and knees. The left wrist and left knee get a higher dose than the right side. The left is marked by solid diamonds. During PTCA, the cardiologist stands on the right side of the patient and it is the left side of the cardiologist that is closer to the x-ray tube, hence the higher dose. For PPM, the fingers and knees get the highest doses. Many of these doses are also much higher than those received during PTCA and LHC. This is because the cardiologists do not use any protective screen during PPM. In PPM, it is the right side of the cardiologist that gets the higher dose, marked by open triangles. This is because during PPM, the cardiologist stands on the left side of the patient and it is the right side of the cardiologist that is closer to the tube, hence the right side tends to get the higher doses. For LHC, the knees and ankles get the highest doses. Like PTCA, the left side gets a higher dose than the right side. The cardiologist stands on the right side of the patient and it is the left side of the cardiologist that is closer to the tube, hence the higher doses marked by the solid circles. In general, doses received during LHC are lower than those received during PTCA which is a more complicated procedure.

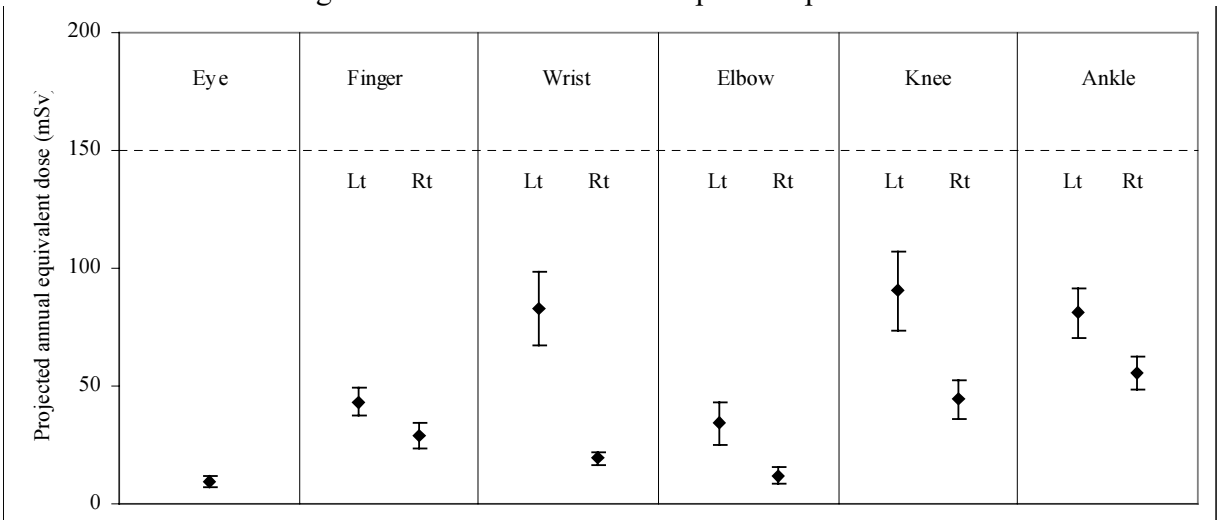

Figure 2. Projected annual equivalent doses for a senior cardiology specialist registrar

Figure 2 shows the projected annual doses and standard error. It also marks the 150 mSv level which is the three-tenths UK annual equivalent dose limit for the various body parts and the full annual dose limit for the lens of the eye. All doses are well below the 150 mSv line. Projected annual equivalent dose to the lens of the eye is below 10mSv and the spread is small. For the other body parts, the projected annual equivalent dose is less than 100 mSv, even taking the spread in dose into account. In each case, the left hand side gets more dose than the right hand side because except for PPMs, it is the left side of the cardiologist's body that is closer to the tube. Left wrist, left knee and left ankle get the highest doses.

4. Conclusions

The use of high sensitivity GR-200 thermoluminescent dosemeters had enabled individual doses at various sites of a cardiologist's body to be measured on a case-by-case basis. Three common cardiology procedures were investigated, namely, PTCA, PPM and LHC. Three conclusions can be drawn from this study.

(1) Overall, doses on the left side of a cardiologist's body are higher than doses on the right. This is due to the fact that for PTCA and LHC procedures, the cardiologist stands on the right side of the patient and it is the left side of the cardiologist's body that is nearer to the x-ray tube.
(2) Results from this study show that the projected annual equivalent doses are well within three-tenths of any UK annual dose limit. Therefore there is no justification for designating cardiologists in the establishment concerned as classified workers on the basis of their equivalent doses. Routine personal monitoring shows that cardiologists' body doses are also well below the three-tenths limit.
(3) Dose monitoring at the additional sites is not routinely required under current circumstances.
(4) From this study, two recommendations are proposed. Firstly from the point of view of radiation protection, routine monitoring of wrist doses should be done on the left wrist. Secondly, the addition of lead curtains to beds in angiography laboratories should be considered. This will greatly reduce doses to knees and ankles. On-going training in radiation protection is necessary in helping radiation workers to keep their doses as low as reasonably achievable.

Acknowledg3ments

I would like to acknowledge the dosimetry and technical work done by physicists Elaine Ryan and Sara Alonso-Arrizabalaga while doing their training at St. Bartholomew's Hospital and the co-operation of the Cardiology Department at St. Bartholomew's Hospital, London, United Kingdom.

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IAEA-CN-85-49

STAFF DOSIMETRY AND RISK ASSESSMENT DURING DIGESTIVE AND ANGIOGRAPHIC EXAMINATIONS

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Abstract

The use of ionizing radiation in medical applications involves not only a risk for the patient, but also for the staff which executed the related examinations. The dose to the forehead, neck, fingers and wrist of a radiologist and an assisting nurse were measured with thermoluminescent dosimeters during angiographic and digestive examinations respectively. Dose to eye lenses and effective dose were estimated for a working period of one year. Effective doses were under the established limit of 20 mSv per year. Nurse eye lens dose was higher than the limit of 150 mSv. Differences of a factor of 3.8 were observed between nurse and radiologist doses. Angiographic procedures are considered as high risk examinations, however, digestive examinations can have a higher risk than interventional procedures.

1. Introduction

The use of ionising radiation in the imaging of body tissues for diagnostic and therapeutic purposes, involves not only a risk for the patient, but also for the staff which executes the related examinations. These risks can be stochastic or deterministic, and may appear minutes or years after the irradiation. Some examples of these radiation-related effects in x-ray workers are: skin cancer, an elevated incidence of leukaemia in radiologists, and radiation cataractogenesis [1]. In the following study, the dose to the forehead, neck, fingers and wrist of both radiologist and assisting nurses have been measured during angiographic and digestive x-ray examinations. From the data collected, the dose to the lens of the eye and the effective dose have been estimated for a working period of one year. Results have been compared with established limits for workers [2]. The related risks have been evaluated in order to establish adequate safety measures.

2. Materials and methods

The angiographic examinations were carried out in a digital x-ray unit Siemens Multiskop equipped with C-arm undercouch tube, high frequency generator, digital processing system and carbon fiber table. No bucky is present in the equipment. All of the examinations but one were executed in the same operation mode: fluoroscopy mode "normal", dose level "normal" (500), 3 frames per second. The dose level "low" (200) was used for the blood sampling of the parathyroid glands.

The digestive examinations were executed in a General Electric Prestilix 1600X DRS unit equipped with overcouch tube and high frequency generator. Both digital and conventional radiographic techniques were used.

The entrance surface dose (ESD) at different positions of the body was measured with thermoluminescent dosimeters TLD 100-H (LiF: Mg, Cu, P; Harshaw Solon). A black polyethylene sachet containing one dosimeter was placed on the forehead and neck (on the thyroid collar, at the external surface) of the radiographer and the assisting nurse. For the assisting nurse the dose to the fingers and the wrist (right hand) was also measured. For the fingers, a plastic ring was used to hold the sachet. The TLD chips were calibrated in-air with

a Siemens x-ray unit equipped with tube and high frequency generator . The tube potentials selected were 70 kVp for the angiographic procedures, and 81 kVp for the digestive examinations. The chips were read in an automatic Harshaw 5500 reader and annealed in a PTW-TLDO oven. The precision of the group of dosimeters was 6% at 11.4 mGy. The individual sensitivities did not differ by more than 17% from the mean sensitivity of the whole group of dosimeters.

The effective dose was estimated conservatively from the measured doses at the forehead and at the neck (over thyroid collar) using conversion coefficients calculated by Faulkner [3]. These coefficients depend on the position of the x-ray tube with respect to the table, the energy of the beam, and the position of the dosimeter in the body.

3. Results and discussion

The mean number of exams per day carried out by both radiologist (4 exams) and assisting nurse (3.5 exams) were determined to estimate effective dose and eye lens dose for a working period of one year (840 exams radiologist, 735 exams nurse).

The measured values of ESD to forehead and neck are given in Table I (radiologist) and Table II (nurse). Fluoroscopy time and number of frames per type of examination are also given. The values of effective dose and dose to the lens of the eye are shown in Figure 1 and 2. The mean values were determined from the mean dose per examination calculated from all of the examinations. Minimum and maximum values were determined from the minimum and maximum doses per type of examination, from the type of examinations with the lowest and highest mean doses.

In Table III the results of the measurements of dose at fingers and wrist levels of the assisting nurse are summarised.

Table I. Doses at forehead and at neck (over thyroid collar) of a radiologist executing interventional procedures. The number of examinations executed is given between brackets

examination type		fluoro time (sec)	# frames	dose forehead (mGy)	dose neck (mGy)
AC-IM (9)	min - max	156 - 288	150 - 459	0.06 – 0.13	0.10 – 0.31
	mean ± stdev	197	262	0.10 ± 0.03	0.19 ± 0.07
AC-HNV (12)		78 - 564	99 - 278	0.03 – 0.09	0.04 – 0.14
	mean ± stdev	314	188	0.06 ± 0.02	0.09 ± 0.03
Angioplasty (2)	min - max	492 - 522	55 - 88	0.04 – 0.05	0.10 – 0.18
	mean ± stdev	507	72	0.04 ± 0.01	0.14 ± 0.05
CT-AMS (3)	min - max	162 - 204	225 - 390	0.11 – 0.15	0.28 – 0.40
	mean ± stdev	183	320	0.12 ± 0.02	0.35 ± 0.06
diverse (11)	min - max	108 - 2286	87 - 508	0.02 – 0.27	0.03 – 0.33
	mean ± stdev	468	257	0.05 ± 0.04	0.11 ± 0.09
total (37)	min - max	78 - 2286	55 - 508	0.02 – 0.27	0.03 – 0.40
	mean ± stdev	407	247	0.08 ± 0.05	0.16 ± 0.1

AC-IM: aortic cross-inferior members; AC-HNV: aortic cross-head and neck vases; CT-ASM: coeliaque trunk- mesantic superior artery, min: minimum; max: maximum; stdev: standard deviation.

Table II. Measured doses at the forehead of an assisting nurse executing digestive examinations. The number of examinations executed is given between brackets

examination type		fluoro time (sec)	# frames	dose forehead (mGy)
barium enema double contrast (14)	min - max	[b]	12 - 15	0.25 - 0.79
	mean ± stdev	403	14	0.50 ± 0.1
barium meal (5)	min - max	[b]	33 - 63	0.24 - 0.85
	mean ± stdev	321	51	0.43 ± 0.3
swallow (4)	min - max	[b]	41 - 66	0.05 - 0.24
	mean ± stdev	46	57	0.15 ± 0.1
small bowel study via	min - max	[b]	37 - 70	0.11 - 0.42
nasoduodenal administration (10)	mean	1045	53	0.25
barium enema single contrast (4)	min - max	[b]	8 - 14	0.15 - 0.23
	mean ± stdev	246	11	0.19 ± 0.04
oesophagus (1)	min - max	[b]	18 - 53	[a]
	mean	134	40	0.15
defaecography (1)	min - max	[b]	30 - 50	[a]
	mean	87	40	0.23
small bowel study via oral	min - max	[b]	19 - 40	[a]
administration (1)	mean	553	36	0.23
fistulography (1)	min - max	[b]	9 - 17	[a]
	mean	113	13	0.11
all examinations (41)	min - max	[b]	8 - 70	0.11 - 0.85
	mean ± stdev	328	35	0.34 ±0.2

[a] not applicable, [b] values not given, min: minimum; max: maximum; stdev: standard deviation.

Table III. Measured values of entrance surface dose (ESD), and calculated values of absorbed dose at fingers and wrist (extrapolated for one year period)of an assisting nurse in digestive examinations

	ESD at fingers mGy	ESD at wrist mGy	absorbed dose fingers (one year period) mSv	absorbed dose wrist (one year period) mSv
minimum	0.07	0.08	55.4	63.3
maximum	0.50	0.68	395.4	537.8
mean ± stdev.	0.26 ± 0.2	0.32 ± 0.2	206.8	255.3

stdev, standard deviation.

4. Summary of conclusions

Differences of a factor of 3.9 for the dose to the lens of the eye, and 3.7 for the effective dose were observed between assisting nurse and radiologist (the latest with the lowest doses). Mean effective dose for both radiologist and nurse was under the limit of 20 mSv per year [4]. Mean and maximum radiologist eye doses were under the limit of 150 mSv per year [4]. However, the nurse eye lens doses were higher than the established limit (Figure 1). The risk involved is the formation of cataracts, which is a late deterministic effect (symptoms appear many years after the irradiation). The mean dose to fingers and wrist estimated for one year were under the limit of 500 mSv for skin.

(a) (b)

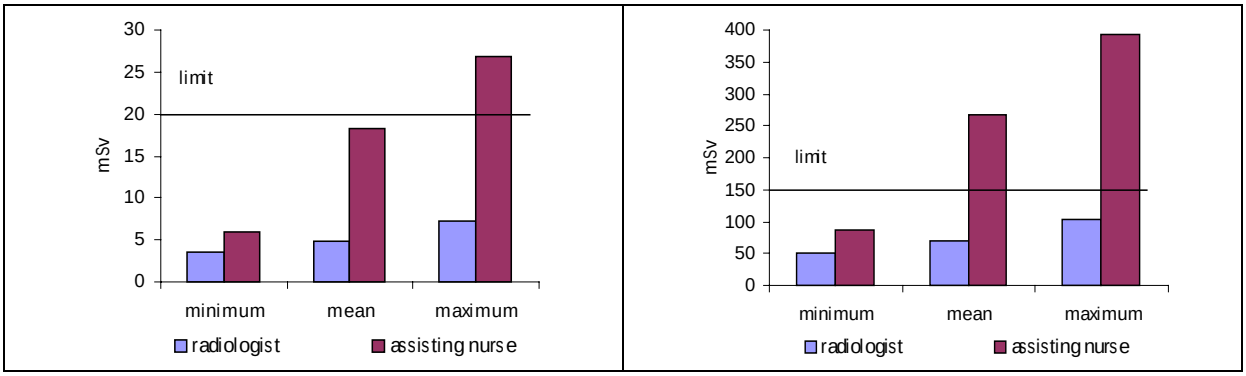

Figure1. Effective dose(a) and dose to the lens of the eye(b) estimated for a period of one year

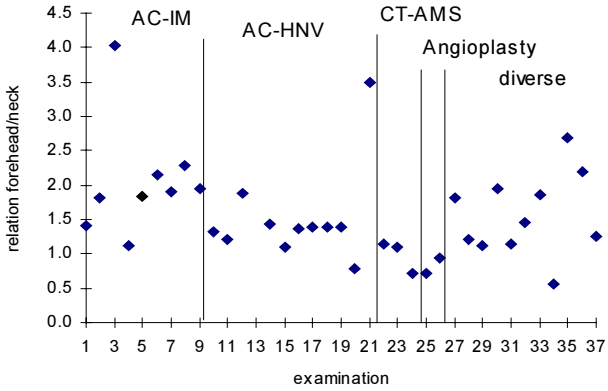

Figure 2. Relation effective dose estimated from dose at forehead/ effective dose estimated from dose at neck level.

To analyse the differences between effective dose estimated from doses at the forehead and at the neck level, the relation between the ED forehead and ED neck was plotted in a graphic (Figure 2). It can be observed that, with the exception of TC-MS and angioplasty procedures, differences up to a factor of 4 exist for the different examinations. This suggests the use of two dosimeters in lieu of one for the estimation of effective dose of personnel executing high-risk examinations [4,5,6]. Both the NCRP and the ICRP recommend the use of two dosimeters for the monitoring of workers wearing a protective apron: one over and one under the apron. The interpretation of the combined results is dependent on the local irradiation conditions and any regulatory requirements [7-8]. They also recommend that if only one dosimeter is used, it should be worn over the apron, high on the trunk. The result will overestimate the effective dose, but will provide information on the dose to the skin, eye, and unshielded parts of the body.

Angiographic procedures are considered a type of radiological examinations with the highest risk for both patient and staff members (especially the radiologist executing the procedures). However, it has been observed that digestive examinations can have a higher risk than interventional examinations, when inadequate equipment and protocols are used (long fluoroscopy times, large number of frames, overcouch tube). It is not customary for the staff

to wear protective lead glasses or thyroid collars. But due to the high-risk the personnel executing these type of examinations are exposed to, the use of extra protective devices have become mandatory in the radiology department where the study was carried out.

Nevertheless, digestive examination protocols should be re-evaluated in order to make the necessary changes to reduce the dose to both patient and staff, specially when it is not possible to make changes in the type of equipment used.

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Topical Session 4

RADIOLOGICAL PROTECTION OF PATIENTS IN NUCLEAR MEDICINE

DOSES OF IONISING RADIATION RECEIVED BY PATIENTS DIAGNOSED AT THE NUCLEAR MEDICINE DEPARTMENT IN WARSAW FROM 1985 TO 1999

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Abstract

In order to evaluate the radiological risk incurred by patients diagnosed at the Department of Nuclear Medicine (DNM), Central Clinical Hospital of the Military University Medical School in Warsaw, the collective committed effective dose equivalents (CCEDE) and the mean personal effective dose equivalents (MPEDE) were calculated for the subsequent years of the period from 1985 to 1999 and compared to the respective values obtained for the mid-1970s. The results indicate that although the number of patients and the total radioactivities used in the diagnostic assays at the DNM increased more than 2.5-fold in the second half of the 1980s and in the 1990s, as compared to the years 1975-1976, the MPEDEs calculated for the periods from 1985 to 1989 and from 1990 to 1994 were similar to and two-fold lower, respectively, than those obtained for the years 1975-1976. However, in the second half of the 1990s, these doses rose again and in 1999 they were almost three times as high as in the mid-1970s. This latter observation results from the increased contribution to CCEDE of the doses from the diagnostic use of I-131 which equalled to 88% in 1975, dropped to 20% in 1994, and again rose to 90% of the total dose in 1999. In fact, beginning from 1995, a new whole-body I-131-based screening procedure was introduced for the detection of the thyroid cancer metastases.

1. Introduction

The constantly increasing numbers of patients diagnosed *in vivo* with use of a variety of radionuclides make it necessary to control and verify the absorbed doses of ionising radiation and to estimate the risk incurred by the exposed persons.

The mean number of patients diagnosed annually at the Department of Nuclear Medicine (DNM), Central Clinical Hospital of the Military University Medical School in Warsaw from 1985 to 1989 and from 1990 to 1999 equalled to 2,661 and 3,111, respectively. The respective annual activities of the radiopharmaceuticals used equalled to 1.02 and 1.27 TBq. For comparison, the mean number of patients diagnosed per year at DNM during the period from 1975 to 1976 equalled to 1,444 and the activities used averaged to 0.06 TBq. The present work was undertaken to compare the exposure to ionising radiation in terms of the collective effective dose equivalent and mean personal effective dose equivalent in patients diagnosed at the DNM in a given year from 1985 to 1999 and, for comparison, in the years 1975 and 1976. The respective dose equivalents were calculated based on the activities of different radionuclides in different organs and tissues and the number of patients diagnosed in each particular year.

2. Material and methods

Calculations of both the collective committed effective dose equivalents (CCEDE) and mean personal effective dose equivalents (MPEDE) were obtained for 2,887 patients diagnosed at the DNM in 1975 and 1976, and for 44,413 patients diagnosed during the period from 1985 to 1999 (Fig.1). The diagnostic tests consisted predominantly of scintigraphies and/or

radioimmunoassays utilising such radionuclides as I-131, Tc-99m, In.113m, Tl-201, Cr-51 and Hg-203. To calculate the doses we used the values of the committed effective dose equivalents $H_T(\tau)$ obtained by a patient after administration of a given radionuclide per unit radioactivity, as indicated by others [1-8]. By multiplying the $H_T(\tau)$ value by the activity of the administered radionuclide and the number of patients in a given year, the CCEDEs were obtained for all the patients diagnosed per year with a particular test. The quotient of the CCEDEs and the number of tests performed in a given year yielded the total CCEDE per year. The MPEDE was obtained by dividing the CCEDE in a given year by the number of patients diagnosed in that year. Contribution of I-131 to the total collective effective dose equivalent was defined as the quotient of the CCEDE from this radionuclide calculated for the thyroid gland and the total CCEDE value.

3. Results and discussion

As shown in Fig. 2, total activities of the radionuclides used annually from 1985 to 1999 generally paralleled the number of patients tested and averaged 1.01 TBq for the period from 1985 to 1989, and 1.27 TBq for the period from 1990 to 1999. In fact, the highest total activity (1.62 TBq) was noted in 1993, when the number of patients was also the greatest (3,599 patients, as shown in Fig. 1). In contrast, although the numbers of patients diagnosed in 1975 or 1976 equalled to more than one-third of the mean number of patients from the period 1985-1996, total activities of the radioisotopes utilised during 1975 and 1976 equalled to only 0.05 and 0.06 TBq, respectively,. These results reflect the quantitative and qualitative changes in both the radionuclides used and the types of tests employed during the 1970s and 1980s. Indeed, in 1975 and 1976 the I-131-labelled sodium iodide, the Hg-203-labelled neohydrine, and the In-113m-labelled compounds were the predominant radiopharmaceuticals used in the radioisotope-based diagnostics. However, labelling of the compounds with In-113m and Hg-203 was abandoned in 1985 and 1986 when, for the first time, most of the *in vivo* tests were done using agents labelled with technetium Tc-99m and other short-lived radionuclides (e.g. Tl-201).[9-13] Moreover, the traditionally I-131-tagged compounds such as NaI, albumins, albumin microspheres and hipuran began to be less and less frequently labelled with this radionuclide. In fact, in 1989 approx. 42,000 diagnostic tests of the thyroid gland in Poland were done using the I-131-labeled compounds and approx. 10,000 tests using the Tc-99m-labeled compounds, while in 1992 the number of tests in which I-131 and Tc-99m were used as the radionuclide tags approximated to 33,000 and 35,000, respectively.[9] During the second half of the 1990s, however, the whole-body scintigraphy with use of I-131-labelled NaI became more and more popular for the detection of thyroid cancer metastases.

For patients diagnosed at DNM the total CCEDE during the period from 1985 to 1989 approximated 30 man-Sv. For comparison, these doses for 1975 and 1976 equalled to 20 and 16 man-Sv, respectively. With regard to the 1990s, this dose reached its nadir (15 man-Sv) in 1992, then began to rise and in 1999 equalled to 89 man-Sv (data not shown). This substantial increase is associated with the dissemination in the mid-1990s of a new diagnostic procedure utilising I-131 for the whole-body screening for metastases of the thyroid cancer. For example, in 1999 as many as 60 patients were diagnosed with this particular method which alone was responsible for 80% of the total CCEDE received by the patients in 1999.

The total CCEDE data were used to obtain the MPEDE values (Fig. 3) and the contribution of I-131 to the total CCEDE (Fig. 4). As shown in Fig. 3, the MPEDEs were the highest during the second half of the 1990s (mean value 19.6 mSv) and rose substantially compared to the second half of the 1980s (mean value 11.7 mSv) Interestingly, the lowest MPEDE values per

patient were noted in 1992 and 1993 (5.0 and 4.9 mSv, respectively). In contrast, in 1975 and 1976, these dose equivalents equalled to 13.4 and 11.4 mSv, respectively, which in view of the low total radioactivities used in those years (Fig. 2) are the relatively very high levels. Nevertheless, these latter values are still below the level received by the total population of patients from the Polish nuclear medicine departments in 1981.[14] However, the values of the MPEDE calculated for each patient diagnosed at the DNM from 1985 to 1995, although generally oscillating around 10 mSv, were still somewhat higher than the respective doses reported for the 1980s from other European countries.[7,8,13,15,16] The reason for this discrepancy is unclear, but it is possible that different types and doses of radionuclides, and/or different diagnostic procedures used in these other countries are responsible.

As shown in Fig. 4, the contribution of I-131 to the total CCEDE indicates that the use of this radionuclide was most responsible for the radiological risk of the patients during the tested period (70-90% CCEDE) except for the first half of 1990s (20-70% CCEDE) when it was often replaced by Tc-99m in the diagnosis of thyroid disorders.

4. Conclusion

The present results indicate that although the number of patients diagnosed at the DNM during the last 15 years almost doubled compared to the mid-1970s the mean MPEDEs obtained *yearly* by the patients from the two periods are similar. However, the lowest MPEDE values were noted in the first half of the 1990s and the highest in 1999. In fact, these values began to rise in 1995 as a result of the markedly increased utilisation of I-131 in the whole-body screening for thyroid-derived metastases, the method rarely used in Poland during the early 1990s. These elevated levels of MPEDE indicate the increased radiological risk for both patients and personnel of the nuclear medicine departments during the last five years, the cost-benefit of which should be carefully re-assessed.

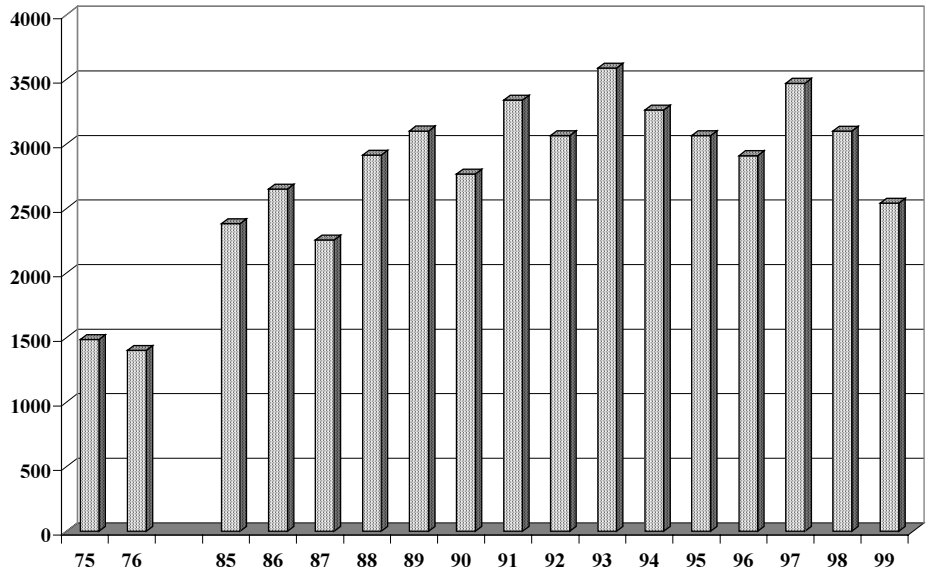

Figure 1 Numbers of patients diagnosed at the DNM per year in 1975 and 1976 and from 1985 to 1999.

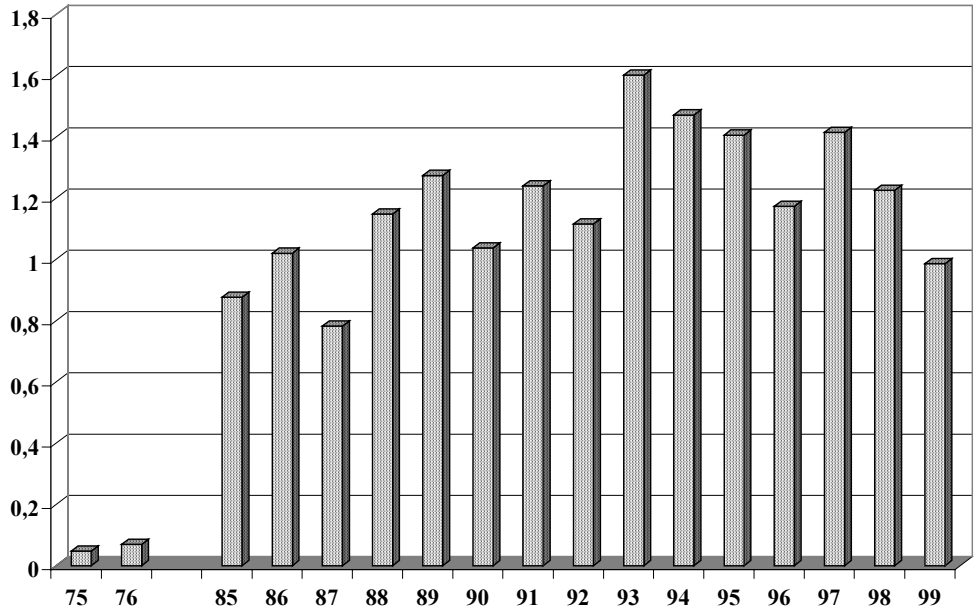

Figure 2 Total activities [TBq] of radionuclides used at the DNM per year in 1975 and 1976 and from 1985 to 1999

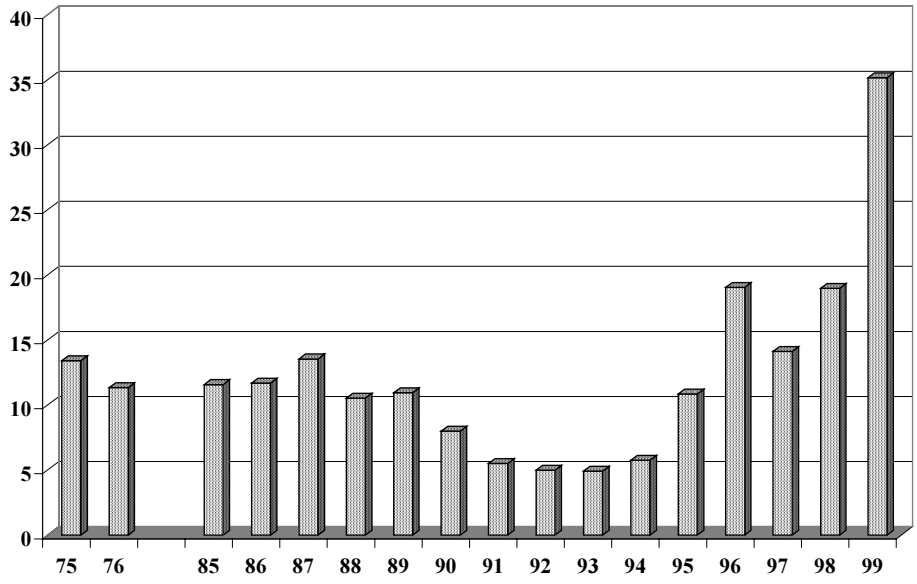

Figure 3 Mean personal effective dose equivalents [mSv] for patients diagnosed at the DNM in 1975 and 1976 and from 1985 to 1999.

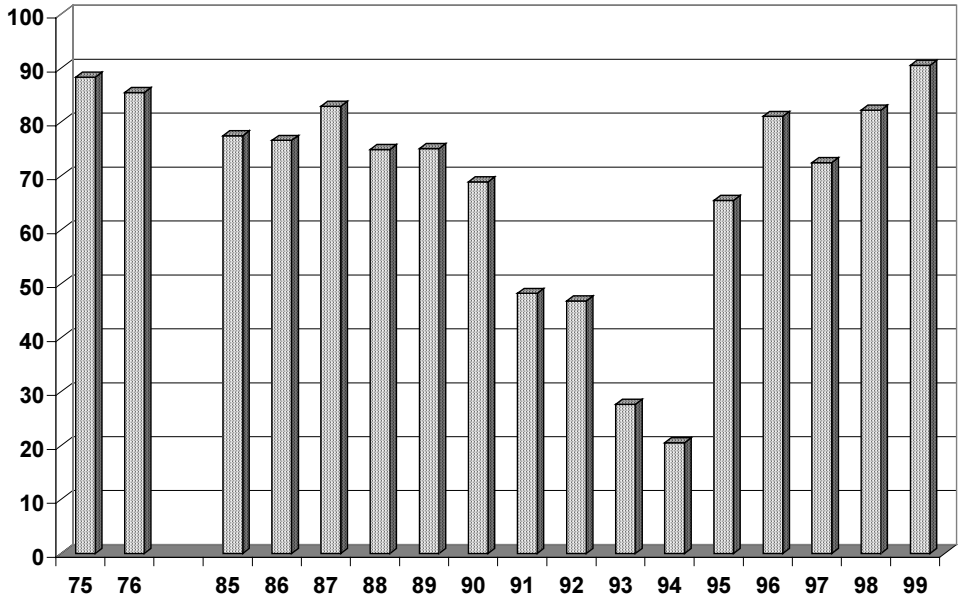

Figure 4 Contribution of I-131 to the total collective effective dose equivalent [%] for patients diagnosed at the DNM in 1975 and 1976 and from 1985 to 1999

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DOSES FROM NUCLEAR MEDICINE EXAMINATIONS: A 25-YEAR FOLLOW-UP STUDY

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Abstract

New radiopharmaceuticals have been introduced in nuclear medicine examinations, and on the other hand, the amount of many routine nuclear medicine procedures have been replaced with clinical methods utilising non-ionisating radiation (ultrasonography, MRI). To clarify the situation in Finland, a country wide survey on the use of radiopharmaceuticals in diagnostics and therapy was made in 1975, 1982, 1989, 1994, 1997 and will be made in 2000. A questionnaire was sent to all hospitals and institutes using unsealed sources in both diagnostic and therapeutic nuclear medicine procedures. For each procedure, the pharmaceutical used, the number of procedures and the typical administered activities were recorded. The collective effective doses from nuclear medicine examinations were calculated according to the ICRP formulae similarly for each survey. In Finland, in each of these years, more than 50 000 procedures in more than 30 different laboratories were performed. Significant changes in collective doses were observed: for example, the collective dose from I-131 was 350 manSv in 1975, and 20 manSv in 1997. In 1975, 68% (n=23967) of collective dose originated from I-131, whereas in 1997 the percentage of I-131 in collective dose was 10 % (n=1118). In 1994 and 1997, the use of the three radionuclides (Tc-99m, I-131 and Tl-201) accounted for 96 % and 95 %, of the collective effective dose.
Our results indicate that the collective effective dose from nuclear medicine examinations has decreased in last 25 years. National surveys form the basis when setting reference levels for typical nuclear medicine examinations. By introducing reference levels based on national practice it is possible to even decrease the collective effective dose.

1. Introduction

Currently more than 50 000 clinical nuclear medicine examinations in more than 30 different laboratories are performed in Finland. Exact data has to be reported regularly to the Radiation and Nuclear Safety Authority based on the implementation of MED-directive. Additionally, data on the frequency and collective effective dose of nuclear medicine examinations in Finland, were available in years 1994 [1] and 1997 [2]. Data was available in years 1975 [3] and 1982 [4] before that. However, the methods for evaluating collective effective dose have been changed. The aim of this study was to calculate collective effective doses from national surveys beginning 1975 in a similar manner, especially for iodine-131. Furthermore we wanted to find out how nuclear medicine procedures have been changed during 1975-2000.

2. Materials and methods

A country wide survey on the use of radiopharmaceuticals in diagnostics and therapy was made concerning the years 1975, 1982, 1989, 1994, 1997 and will be made concerning the year 2000. A questionnaire was sent to all hospitals and institutes using unsealed sources in both diagnostic and therapeutic nuclear medicine procedures. For each procedure, the pharmaceutical used, the number of procedures and the typical administered activitities were recorded. The collective effective doses were calculated according to the ICRP formulae similarly for each survey. The dose factors (mSv/MBq) given in ICRP 62 [5] were used.

3. Results

Information was obtained from all hospitals and institutes. The major component of the collective dose was I-131. Table 1 demonstrates how the collective dose from I-131 has developed between 1975 and 1997.

Table 1. The collective effective doses from the use of I-131 between 1975 and 1997

Year	Total number of nuclear medicine examinations	Collective effective dose from I-131 (manSv)	Collective effective dose from I-131 (%)
1975	59350	350	75,9
1982	85340	303	56,6
1989	55730	124	-
1994	50900	33,0	14,9
1997	51730	19,8	9,6

The collective effective dose from I-131 was 350 manSv in 1975, and 20 manSv in 1997, respectively (Table 1). This means, that in 1975 68% (n=23967) of collective dose originated from I-131, whereas in 1997 the percentage of I-131 in collective dose was 10 % (n=1118). The following radionuclides in descending order, Tc-99m, Tl-201, Cr-51, I-131, In-111, I-123, F-18, O-15, C-11, Se-75, Xe-133, Co-57, were used in more than 100 different investigations in 1997. In 1997, the use of Tc-99m, I-131 and Tl-201 accounted for 95 %, of the effective collective dose.

Table 2 demonstrates how the use of bone scintigraphy using Tc-99m-labelled phosphates or diphosphonates has been changed between 1975 and 1997.

Table 2. The collective doses from the use of Tc-99m-phosphates between 1975 and 1997

Year	Number of bone scintigraphies	Collective effective dose from Tc-99m (manSv)	Collective effective dose from Tc-99m (%)
1975	2761	8,7	1,8
1982	15266	44,6	8,3
1989	19689	62,2	-
1994	20912	62,6	28,5
1997	21845	71,0	34,3

The total amount of nuclear medicine procedures was higher in the 80´s than in the 90´s (Table 1). In 1975 there were 42 laboratories and also 42 different diagnostic procedures and a total of 59350 investigations were performed. Nuclear medicine procedures were carried out in 33 laboratories in 1997, and more than 150 different diagnostic procedures were carried

out, eventhough the total number of investigations was 51730. The amount of bone scintigraphies has stabilized during the last 10 years. The amount of collective effective dose derived from Tc-99m in bone scintigraphy has increased gradually. Figure 1. demonstrates the current practice of bone scintigraphy in different laboratories.

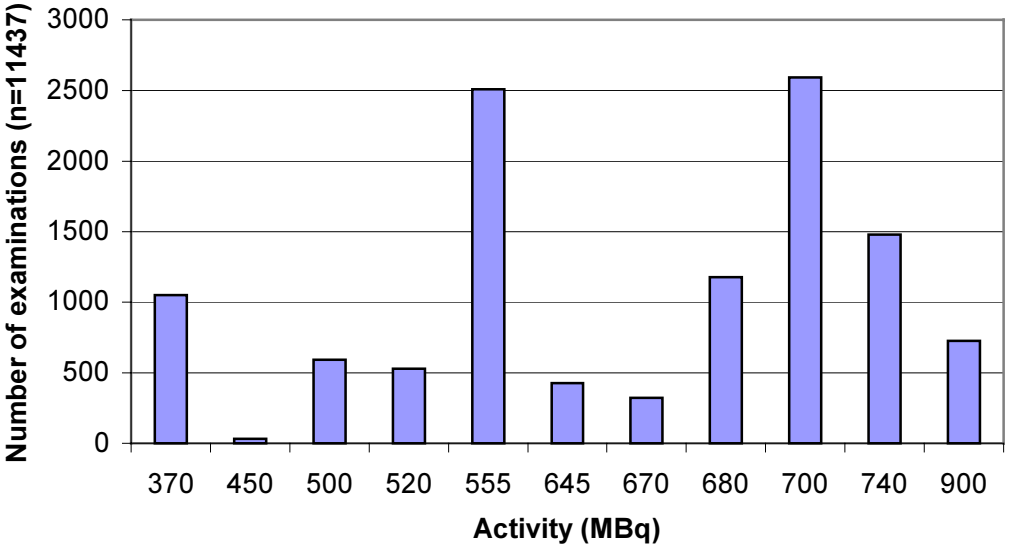

Figure 1. Injected mean activities in bone scintigraphy in Finland in 1997.

4. Discussion

Our results indicate that the collective effective dose from nuclear medicine examinations has decreased in last 25 years. Our results also demonstrate that the total amount of nuclear medicine procedures is nowadays lower than in the 80´s. The major constituent of the collective dose has been I-131 (Table 1). Its use has been decreased in a greater extent than those of other radionuclides in diagnostic nuclear medicine.

The influence of Tc-99m on the collective dose derived from bone scintigraphy has increased (Table 2). There is still a great variability in the administered activities between laboratories (Figure 1). Therefore, reference levels are needed. National surveys form the basis for reference levels for administered activities in nuclear medicine examinations. By introducing reference levels based on national practice make it possible to even decrease the collective dose. The reference level planned for bone scintigraphy is 600 MBq and, if SPECT is performed 800 MBq. For comparison, in German national survey [6], in 1992, the mean effective dose from bone scintigraphy was 4.8 mSv per examination whereas our mean effective dose was 3.2 mSv in 1989 and 3.0 mSv in 1994, respectively. In Germany in 1992 [6], the bone scintigraphy was responsible for 38.8 % of the collective effective dose whereas the collective effective dose was in Finland in 1994 28.5%.

In general, the nuclear medicine has developed into right direction during the last 25 years in Finland, i.e. the collective effective dose has decreased and the diversity of nuclear medicine procedures has increased. Also, most of the collective dose originates nowadays from Tc-99m, which is an optimal solution from the radiation protection point of view.

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GENERAL COMMENTS ON RADIOLOGICAL PATIENT PROTECTION IN NUCLEAR MEDICINE

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Abstract

In this paper an observations series about different aspects of the radiological protection of the patient in Nuclear Medicine is provided. It includes : The specific legislation contribution, the justification and optimization (specially this last one), as a fundamental base of the quality guarantee program, the importance of the fulfillment of the program and the importance of getting done the corresponding internal audits of the pursuit, the communication between the different groups of professionals implicated and between these and the patient, the volunteers who collaborate in the patient's care and the people of the patient's environment, knowing that the patient is a source of external radiation and contamination.

RESUMEN

Se resumen en este trabajo, una serie de observaciones sobre distintos aspectos de la protección radiológica del paciente en Medicina Nuclear que incluyen: El aporte de la legislación específica, los principios de justificación y optimización (en especial éste último) como base fundamental del programa de garantía de calidad así como la importancia de que dicho programa se cumpla y se lleven a cabo las correspondientes auditorias internas de seguimiento, la comunicación tanto entre los diferentes grupos de profesionales implicados como entre éstos y el paciente, los voluntarios que colaboran en su cuidado y las personas de su entorno, teniendo en cuenta que el paciente es una fuente de radiación externa y contaminación.

1. Legislación

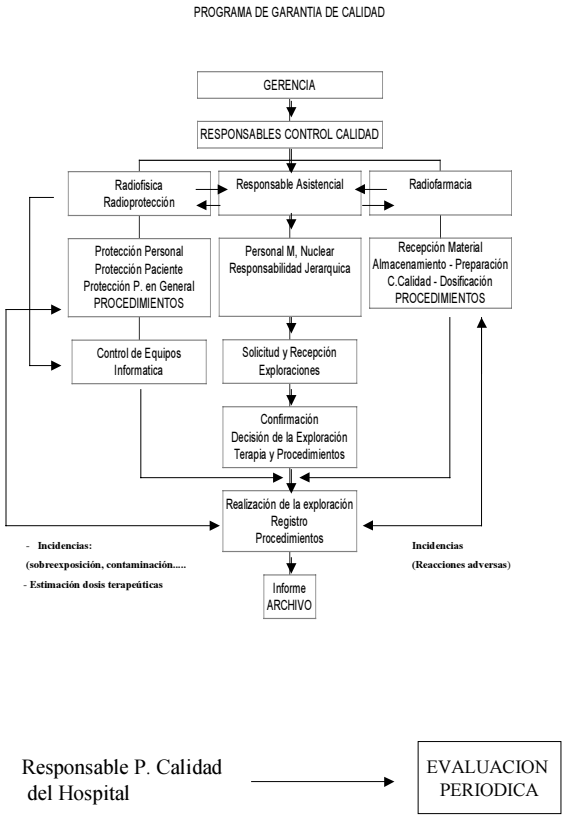
Ante la pregunta legislación si o "demasiado" se puede contestar sin duda que **SI**. Disponer de una legislación específica y viable, ha sido y es fundamental para la mejora o generación, según los casos de los programas de calidad de los servicios implicados.

El Real Decreto 1841/1991 (de 5 de diciembre, por el que se establecen los criterios de calidad en Medicina Nuclear), según indicaciones de la Directiva 97/43 Euratom, está representando un estímulo continuo en la implantación efectiva de los programas de calidad.

El primer paso en este proceso ha sido la necesidad de elaborar un documento propio en cada servicio de Medicina Nuclear, para presentación al correspondiente Sº de Inspección y Acreditación Sanitaria, lo cual lleva implícito que el documento **es de obligado cumplimiento, que ha de ser periódicamente revisado y que puede ser auditado en cualquier momento.**

Implantar dicho programa requiere una conexión permanente de médicos y técnicos especialistas, enfermería al cuidado de pacientes ingresado, empresas de mantenimiento y radiofísicos (que se incluyen formalmente en la legislación, con misiones específicas), todo bajo la responsabilidad final de Dirección.

Este Real Decreto, a diferencia de sus homólogos de Radioterapia y Radiodiagnóstico, no obliga a la constitución de una Comisión de Calidad. Escalada y col. [1] indican su buena experiencia sobre el funcionamiento de una comisión compuesta por miembros de M. Nuclear, Radiofísica y Dirección. En nuestro Hospital se ha optado por el organigrama que aparece en el cuadro I.



Sea cual sea el sistema elegido, lo importante es que funcione y sirva para la **mejora continua.**

La actuación de la Autoridad Competente no es fácil en esta primera fase, ya que se tiene que encontrar el equilibrio entre el papel positivo que una auditoría debe representar en el apoyo a la calidad y la inevitable propuesta de sanciones, en caso de no cumplimiento, que pueden llevar al auditado a concentrarse más en el "papel" y el mínimo registro- con la posibilidad de ocultar o maquillar datos, que en perseguir la auténtica mejora continua.

Finalmente, concluiremos este apartado reseñando la necesidad y por otra parte la facilidad de actualizar los anexos del decreto, especialmente el que se refiere a control de calidad de la instrumentación, dados los constantes avances tecnológicos.

2. El protocolo nacional de control de calidad en la instrumentación

La existencia de un documento nacional de referencia [2], avalado por las sociedades científicas implicadas al respecto y elaborado por un grupo de trabajo mixto, con representantes de cada una de éstas, es una buena opción no sólo a nivel científico sino humano e interprofesional.

No obstante hay que tener claro que, en ningún caso, debe ser un documento estático, dada la velocidad con que avanza la tecnología, como se dijo anteriormente. El documento actual requiere aplicación y crítica basada en la primera, así como la pronta creación de un nuevo grupo de trabajo mixto, para actualización y ampliación.

Escalada y col (1) opinan que la primera aproximación a las pruebas detalladas en el Protocolo Nacional, es difícil. R. Puchal, en su conferencia del VIII Congreso Nacional de Protección Radiológica concluye que el Protocolo es útil. Ambas visiones deben ser consideradas. El documento ha de ser analizado, pero es indiscutible que ha servido claramente de apoyo, desde la publicación del primer borrador, al desarrollo de la sistematización del control de calidad de la instrumentación.

3. Protección del paciente en diagnostico

Se basa en:

Procedimientos detallados que tengan en cuenta la justificación y la optimización de las exploraciones (3).

Detalles tan simples como qué hay que hacer antes de empezar un estudio (4) –prescripción correcta, adecuadamente redactada y legible; paciente, radiofármaco y actividad correspondiente, no portador de atenuadores de radiación ni de actividad o contaminación en lugares no deseados (bolsa de orina, incontinencias u otros); información sobre posibles embarazos y lactancias (5) etc.

Instrumentación en estado correcto. El personal encargado de cada gammacámara o equipo de pruebas “in vivo” ha de ser protagonista de las pruebas diarias (no olvidar centrado de fotopico entre otras), o muy frecuentes, de constancia así como un colaborador imprescindible del radiofísico en general.

En lo que atañe a pruebas de control de calidad en SPECT, se incluyen dos referencias bibliográficas recientes (6) y (7) , que se estiman de interés.

Con respecto a pruebas de aceptación de nuevos equipos, hay que destacar la importancia del papel del radiofísico en aumentar la cultura para la realización de dichas pruebas y la profundidad de las mismas, a través de una buena sincronización con el suministrador.

El trabajo que se viene realizando con equipos recientemente instalados, implica una cada vez mayor aproximación por parte del radiofísico y del suministrador, en la verificación del cumplimiento de las especificaciones de compra y en establecer un nivel de referencia inicial del equipo. Se incluye en la bibliografía el trabajo de R. Barquero y R. Puchal (8) relativo al tema en cuestión.

4. Terapia

Es obvio destacar aquí la importancia de la justificación y la optimización así como la dosimetría del paciente y la información del mismo y de las personas del público próximas, (voluntarios colaboradores, familiares etc), durante la hospitalización y el tiempo posterior al alta en el que deben seguirse normas especiales.

Asegurar que no existen errores en la administración de la dosis prescrita es vital. J. C. Ruiz y col (9) han observado desviaciones frente al valor nominal, al medir las cápsulas de I-131 y concluyen en la necesidad de una verificación sistemática. Más importante aún, a nuestro entender, es la administración de una dosis individualizada tras un estudio de la captación.

En lo que se refiere al alta del paciente también debe individualizarse tanto en lo que se refiere al fin de la hospitalización como al periodo de restricciones (10 y 11).

En nuestro caso, se realiza una encuesta para conocer las condiciones de entorno del paciente una vez dada el alta. Dicha encuesta , así como la entrega y explicación verbal de las normas a seguir en lo que atañe a protección radiológica, es llevado a cabo por el radiofísico, del Sº de Radiofísica y Radioprotección, destinado a Medicina Nuclear, según lo acordado con el Jefe de Medicina Nuclear.

En reseña publicada por Foro Nuclear: "Flash de Isótopos y Protección Radiológica", con fuente : Nuclear News, junio 2000, se indica que la NRC autorizó, en mayo del 2000, la no hospitalización de pacientes, siempre que los miembros de su familia no superen el límite de dosis establecido para el público, autorización que muchos especialistas no ponen en marcha.

En la misma fuente se indica que un estudio publicado en el Journal of Medical Association, sobre dosis de familiares de 30 pacientes a los que se había administrado una dosis de 4,3 GBq de I-131, recibieron una dosis media de 0,24 mSv, siendo el valor máximo de 1.09. Los pacientes tenían instrucciones especiales sobre mantenimiento de distancia, beber líquidos en abundancia y ducharse varias veces al día.

Caldwell y col (12), llegan a la conclusión de que, en determinadas circunstancias, el tratamiento de pacientes con dosis elevadas, puede hacerse sin hospitalización.

En nuestro criterio, parece razonable por diversas razones (recogida de orina entre ellas), ingresar a los pacientes un periodo de tiempo de acuerdo con sus condiciones individuales.

5. Información al paciente

En diagnóstico y mucho más en terapia, es preciso mantener un diálogo con el paciente (riesgos, normas etc). En cualquier caso la información debe ser fácilmente entendible; p. ej si s sobre riesgos en diagnóstico acudir a riesgos comparado con los habituales de la vida diaria o tiempo para recibir la misma dosis por radiación natural (13). Las normas escritas, deben ser, además, atractivas y directas, tal como se indica en "Protección radiológica 97 Euratom". (CE).

Informe quien informe, debe haber unidad de criterio y una forma convenida para informar.
Si se trata de enfermos ingresados el personal de enfermería debe estar preparado para informar, si se requiere. En cualquier caso el personal facultativo debe responsabilizarse de la información al paciente.

6. Conclusion

Como conclusión general se destaca la importancia del programa de Calidad en el que debe entramarse, de forma natural, la protección radiológica del paciente. Todos los implicados en el mismo, deben comunicarse fácilmente entre sí y deben tener formación actualizada. Es importancia que se efectúen auditorias internas con la debida frecuencia.

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IAEA-CN-85-192

PATIENT DOSE ASSESSMENT IN DIFFERENT DIAGNOSTIC PROCEDURES IN NUCLEAR MEDICINE

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Abstract

Effective doses have been estimated for 314 patients under diagnostic procedures in a Nuclear Medicine Department using data reported in ICRP-80 and RIDIC (Radiation Internal Dose Information Center). Data on administered activity, radiopharmaceutical and administration route, age and sex of the patients have been collected. Doses in the most exposed critical organ for every protocol, doses in uterus, dosis in fetus versus the stage of pregnancy (in case the female patient was pregnant) and doses for nursing infants have been also estimated. Ga-67 studies give the highest effective doses per protocol followed by cardiac spect procedures using Tl-201 chloride. Ga-67 studies also give the highest absorbed doses in uterus. Due to not administering different activities depending on height and weight of adults, women receive doses about 20% higher than men. This would be a practice to modify in the future in order to optimise doses.

1. Introducción

Tanto la Directiva Europea relativa a la protección de la salud frente a los riesgos derivados de las radiaciones ionizantes en exposiciones médicas[1] como el Real Decreto de control de calidad en medicina nuclear [2] establecen la obligatoriedad de implantar un programa de garantía de calidad que incluya las medidas de control de calidad y, en particular, las actividades administradas y las estimaciones de las dosis al paciente con objeto de asegurar que la exposición de los mismos a la radiación sea la mínima compatible con el diagnóstico. Especial consideración requieren las mujeres embarazadas o con capacidad de procrear, así como las mujeres que están amamantando [1-8].

La determinación de la actividad óptima de un radiofármaco para una prueba diagnóstica dada es compleja pues depende del tipo de equipamiento utilizado, de la talla y peso del paciente, de sus características metabólicas y de su condición clínica. Su estimación va muy unida al establecimiento de unos criterios de evaluación de las imágenes y estudios realizados por parte del médico especialista. Este punto formará parte del objetivo de un futuro trabajo.

La incertidumbre asociada a la evaluación de las dosis es alta y proviene más de factores fisiológicos que físicos. Los modelos biocinéticos[9-10] que se utilizan son aproximaciones en las que se considera un número limitado de compartimentos con velocidades definidas de captación y eliminación del radiofármaco considerado.

2. Objetivos

1. Calcular una dosis efectiva promedio asociada a cada estudio.
2. Determinar la dosis en determinados órganos de riesgo o grupos de riesgo como pueden ser el útero, el feto o el lactante.

3. Material y métodos

El estudio se ha realizado sobre una muestra de 314 pacientes sometidos a pruebas diagnósticas de medicina nuclear. Se han recogido datos sobre tipo y número de los estudios llevados a cabo en este servicio, edad y sexo de los pacientes, radiofármacos utilizados y vía

de administración de los mismos y actividad administrada a cada paciente como resta entre la actividad antes de la inyección o inhalación y la actividad residual (después de la inyección o inhalación). Las actividades han sido medidas en los activímetros Capintec CRC-30 y PTW-Curiementor 2.

Las dosis absorbidas en útero y en el órgano crítico así como las dosis efectivas se obtuvieron a partir de factores publicados en ICRP-80 [11]. Para aquellos radiofármacos que no aparecían registrados en las tablas de ICRP-80 se utilizaron los factores dados por RIDIC[12] basados en el programa MIRDOSE [10]. La estimación de dosis efectiva para hombres, mujeres, feto en distintas etapas de gestación y para el lactante se ha realizado a partir de distintas publicaciones de RIDIC [6-8].

4. Resultados

En la tabla 1 se muestran las actividades medias administradas, intervalo correspondiente y número de pacientes por radiofármaco y tipo de estudio. Siempre que no se especifique lo contrario el radiofármaco ha sido marcado con Tc-99m y la vía de administración ha sido la intravenosa.

Aproximadamente el 53% de las gammagrafías óseas se realizaron a personas mayores de 64 años y mucho menos frecuentemente (2%) a personas menores de 30 años. La distribución de edades en los estudios de ventilación/perfusión pulmonar fue bastante semejante. En los estudios de tiroides hubo un mayor reparto entre los distintos grupos de edad aunque también se constató un predominio del grupo de mayores de 64 años. Por el contrario el 100% de los estudios de reflujo gastroesofágico se realizaron a personas menores de 15 años y éste fue también el grupo de edad predominante en las gammagrafías renales y renogramas.

Tabla 1. Radiofármaco, actividad administrada y número de pacientes para cada protocolo diagnóstico. (Las actividades del reflujo gastroesofágico (RGE) se refieren a niños)

					$A_{administ\ adultos}$ (MBq)	
Radiofármaco	**Protocolo**	**hombres**	**mujeres**	**niños**	**Intervalo**	**Media**
HMDP	G. Osea	60	122	4	520.5-866.3	717.8
Pertecnectato	G. Tiroidea	7	46	2	121.1-258.6	181.0
DTPA (aerosol)	Ventilación pulm.	7	10	1	564.8-1097.8	763.27
MAA	Perfusión pulm.	7	10	1	167.2-297.4	218.3
Eritrocitos	Ventriculografía	7	6	0	642.7-814.0	735.8
Citrato de Ga-67	Rastreo	5	5	1	239.6-267.6	260.0
DMSA	G. Renal	1	2	5	147.9-226.3	177.3
Sulfuro coloidal (oral)	RGE	0	0	7	5.9-30.0	15.1
DTPA	Renograma	2	0	2	254.3-269.8	262.0
HMPAO	Spect Cerebral	1	3	0	838.4-883.2	864.4
Tetrofosmín (reposo)	Spect cardíaco	1	2	0	673.4-779.9	744.3
Tetrofosmín (esfuerzo)	Spect cardíaco	1	2	0	293.4-338.1	311.4
Cloruro de Tl-201	Spect cardíaco	2	0	0	66.3-70.0	68.2

Las gammagrafías óseas constituyeron el 60% de los estudios con una dosis efectiva promedio en adultos de 5.6 mSv (tabla 2) seguidos por los estudios de tiroides con un 18% y una dosis efectiva de 2.3 mSv y los estudios de ventilación/perfusión pulmonar con un 6% y una dosis

efectiva de 8.5 mSv. La dosis efectiva más alta por estudio se encontró en los rastreos con Ga-67 con un promedio de 26 mSv seguido de los estudios de spect cardíaco con 15.0 mSv y los estudios de ventilación/perfusión pulmonar con 8.5 mSv.

La mayor dosis a un órgano crítico (aquel órgano que recibe más dosis por unidad de actividad administrada) se registró para el citrato de Ga-67 con 163.8 mGy en la superficie de huesos seguido del HMDP con 62.2 mGy en el mismo órgano, como puede verse en la tabla

En la tabla 3 se observa que para el mismo tipo de estudio las dosis efectivas son casi siempre mayores en mujeres que en hombres (a excepción de las gammagrafías renales) en un porcentaje que va del 16% al 29%. Esto es explicable por su menor masa corporal y por la posición de las gónadas dentro del cuerpo y cerca de órganos fuente en dosimetría interna, como vejiga, hígado, riñones o intestinos.

Tabla 2. Dosis en el órgano crítico, dosis en útero y dosis efectiva en adultos (excepto para el sulfuro coloidal que se refieren a niños) para cada radiofármaco

Radiofármaco	**Órgano Crítico (OC)**	**$Dosis_{OC}$ (mGy)**	**$Dosis_{útero}$ (mGy)**	**E (mSv)**
HMDP	Superficie de hueso	62.2	2.4	5.6
Pertecnectato	int. Grueso sup.	10.3	1.5	2.3
DTPA (aerosol)	pared de vejiga	38.2	3.4	6.1
MAA	Pulmones	14.4	0.5	2.4
Eritrocitos	Corazón	16.9	2.9	5.1
Citrato de Ga-67	Superficie de hueso	163.8	19.8	26.0
DMSA	Riñones	31.9	0.8	1.6
Sulfuro coloidal (oral)	pared int. grueso	0.4	0.4	0.4
DTPA	Vejiga	16.2	2.1	1.3
HMPAO	Riñones	29.4	5.7	8.0
Tetrofosmín (reposo)	Vesícula biliar	26.8	5.4	5.7
Tetrofosmín (esfuerzo)	Vesícula biliar	8.4	2.4	2.2
Cloruro de Tl-201	Ovarios	49.8	-	15.0

Tabla 3: Dosis efectiva para niños y adultos en función del sexo para cada radiofármaco (no hay datos disponibles para HMDP ni para

tetrofosmín).	**Dosis efectiva (mSv)**		
Radiofármaco	**Hombres**	**Mujeres**	**Niños**
Pertecnectato	2.1	2.5	2.2
DTPA (aerosol)	4.2	5.9	3.4
MAA	2.6	3.4	2.2
Eritrocitos	4.3	5.7	-
Citrato de Ga-67	25.9	31.3	21.6
DMSA	2.1	1.6	1.3
Sulfuro coloidal	-	-	1.8
DTPA	1.9	-	1.0
HMPAO	9.3	11.2	-
Cloruro de Tl-201	18.7	-	-

Los datos de esta tabla se han obtenido a partir de factores de dosis (mSv/MBq) publicados en ICRP-80 para todos los radiofármacos excepto para el HMDP, DTPA (aerosol) y sulfuro coloidal, para los cuales se han tomado datos publicados por RIDIC. En estos casos no está disponible la dosis en útero sino en ovario.

Las dosis efectivas son de un 4% a un 33% menores en niños con respecto a los adultos debido a que las actividades administradas son menores.

El porcentaje de mujeres en edad de procrear (suponiendo ésta entre 15 y 45 años) fue del 16%. La dosis absorbida mayor en útero y por tanto el mayor riesgo para el niño no nacido, con las actividades utilizadas en nuestro Servicio, se alcanzó con citrato de Ga-67, con 19.8 mGy, seguido del HMPAO con 5.7 mGy (tabla 2). Se han estimado las dosis al feto en el caso de que las mujeres hubieran estado embarazadas (tabla 4). La absorción en función del estadio del embarazo resultó variable según el radiofármaco considerado pero, en general, ésta resultó mayor en los tres primeros meses que en las etapas posteriores. A medida que el feto crece la fracción de energía absorbida por el mismo a partir de órganos maternos aumenta pero, a su vez, el aumento de la masa del feto compensa este efecto.

No existen datos para HMDP ni para tetrofosmín. No se han incluido datos para DTPA, sulfuro coloidal ni Tl-201 puesto que no se dispone de datos de mujeres sometidas a este tipo de estudios.

Tabla 4. Dosis absorbida en el feto en función de la etapa del embarazo

	Dosis absorbida (mGy)			
Radiofármaco	**1ª etapa**	**3 meses**	**6 meses**	**9 meses**
Pertecnectato	2.0	4.0	2.5	1.7
DTPA (aerosol)	4.5	3.4	1.8	2.3
MAA	0.6	0.9	1.1	0.9
Eritrocitos	4.8	3.2	2.5	2.0
Citrato de Ga-67	24.3	52.2	47.0	33.9
DMSA	0.8	0.7	0.6	0.5
HMPAO	7.5	5.8	4.2	3.1

Se estimaron también las dosis al lactante. Por ejemplo, para unas actividades administradas de 181 y 260 MBq de pertecnectato y citrato de Ga-67 respectivamente, tomando como límite de dosis efectiva 1 mSv, y suponiendo los valores más conservadores de concentración en leche y eliminación estaría indicada una interrupción de la lactancia durante 4 días para las pacientes a las que se suministró citrato de Ga-67 y no sería necesaria interrupción para las pacientes a las que se suministró pertecnectato.

Los datos dosimétricos para los fármacos recogidos en este trabajo provienen de ICRP-80 y RIDIC. Las diferencias en dosis efectiva por unidad de actividad administrada a adultos dada en estas dos fuentes así como en ICRP-53 y su apéndice I pueden alcanzar el 82% para algunos radiofármacos. Estas diferencias provienen fundamentalmente de los distintos factores de ponderación para tejidos (a partir del apéndice I de ICRP-53 comienzan a utilizarse los nuevos factores de ponderación publicados en ICRP-60), así como de los distintos modelos biocinéticos utilizados.

4. Conclusiones

1. La dosis efectiva más alta por estudio se encontró en los rastreos con Ga-67 con un promedio de 26 mSv seguido de los estudios de spect cardíaco con 15.0 mSv y los estudios de ventilación/perfusión pulmonar con 8.5 mSv. Las pruebas de mayor riesgo para el feto en el caso de que la paciente se hallara embarazada son el rastreo con Ga-67 y el spect cerebral con HMPAO.
2. El caso de las mujeres merece especial consideración en la evaluación de la dosis en medicina nuclear. Debido a su menor masa corporal y a la posición de las gónadas dentro del cuerpo y cerca de órganos fuente en dosimetría interna como vejiga, hígado, riñones o intestinos, las mujeres tienen una carga de radiación de un 16% a un 29% más alta que los hombres para la misma actividad suministrada por estudio. Si la actividad se administrara en función de la masa corporal individual se eliminarían o reducirían estas diferencias, al menos en dosis efectiva. Esto no se hace de forma rutinaria en nuestro servicio para adultos, aunque sí se varía la actividad que se administra a los niños.
3. En un futuro está proyectado continuar con evaluaciones dosimétricas de este tipo, establecer niveles locales de referencia por prueba diagnóstica y decidir sobre modos de actuación que conduzcan a una optimización de las dosis. En este sentido la administración de actividades personalizadas en función de la talla y peso del paciente sería una buena práctica a llevar a cabo en el futuro.

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RADIATION PROTECTION OF THYROID CANCER PATIENTS RECEIVING I-131 THERAPY: SOME CONSIDERATIONS

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Abstract

As a preliminary step to investigating the potential usefulness of external Thermoluminescence dosimetry (TLD) in estimating parameters of radiation dose to the bladder and the gastric mucosa, 27 inpatients treated with Iodine 131 (60-200 mCi or 2.22-7.4 GBq) for differentiated thyroid carcinoma (19 receiving the iodine in a capsule and 8 in solution form) were studied. Doses and ages were similar in both group as was fluid intake (ad lib but carefully recorded for each case). The TLDs were placed over the urinary bladder and in standard positions in the epigastrium (xiphoid and left subcostal area) and total doses for 22 hours (bladder) as well as total doses and dose rates (epigastrium) at various times from 5 to 90 minutes were recorded.
Both bladder dose and integral dose for 90 minutes over the stomach showed statistically significant positive linear correlation with the administered I-131 activity . No correlation with the amount of fluid intake was found. The 90 minute integral dose at the epigastrium per mCi administered was found to be higher in the capsule group by 70%. Six out of 27 patients reported some discomfort (6/19 and 0/8 for capsule and liquid group respectively, p=0.13). The possible significance of these findings is discussed.

1. Introduction

Iodine 131 is a well established and effective treatment , supplementing surgery, in differentiated thyroid carcinoma. As iodide is also selectively concentrated in salivary glands and gastric mucosa, treatment can result in considerable doses to these organs (as well as to the urinary bladder), which good management should aim to minimize . Furthermore, generalized use of the capsule form for administering I-131 has generated some concern over the high (even if localized) radiation dose to the gastric mucosa. Information concerning these matters is scarce in the literature. [1-3]The aim of this preliminary study was to investigate what information could be obtained by simple external measurements with TLD in easily identifiable anatomical positions on the body surface of patients treated with high doses of I-131. In a second stage there will be an attempt to correlate these findings to actual physiological parameters and absorbed doses, by means of parallel tracer studies.

2. Material and methods

27 patients treated with I-131 for differentiated thyroid carcinoma were studied. The standard procedure in this hospital is by capsule so 19 of the patients were given the iodine in capsule form, while the remaining 8 were given iodine in water solution. All patients were fasting (except for fluids) overnight and for 2 hours after administration of the dose and were encouraged to drink fluids on the first day. Fluid intake was ad lib but was noted for each patient. Any symptoms the patients reported relating to the iodine administration were recorded. TLD dose meters were placed on the xiphoid and on the left subcostal margin (LS) and over the urinary bladder. All patients were hospitalized for 2-3 days till the residual thyroid activity reached levels below those permitted for outpatients. Remaining I-131 activity on the day of discharge was measured with a calibrated G-M monitor. Total dose for 22 hrs over the bladder and dose rates as well as integral dose over the gastric area were measured with TLD dose meters at 5, 10, 20, 30, 45, 60 and 90 min after the dose administration.

The TLD used were LiF:Mg, Ti 3X3X0.9 mm3 in conjunction with a Victoreen 2800 system calibrated against Cs 137 radiation in the 0.2-500 mGy range. The group standard deviation of TLDs was less than 5%. Statistical analysis was by standard techniques using the SPSS statistical package.

3. Results

Both groups were similar in age and treatment parameters as shown below:

	Mean , SD (range)	
	Capsule	Liquid
mCi given	93.7, 39.6 (60-200)	110.0, 52.9 (60-200)
mCi remaining	4.2, 2.0 (1.5-9..2)	5.9, 3.3 (2.6-10.2)
% remaining	4.8, 2.3 (1.8-9.3)	4.9, 3.0 (2.8-10.2)
Age	52.9, 14.4 (23-74)	55.9, 7.9 (43-64)
No of pts reporting gastric discomfort.	6/19	0/8

Six out of the 19 patients receiving capsules reported some gastric discomfort (fullness, mild pain nausea) in the first hour after iodine administration, while none of the 8 patients receiving a liquid dose did so. The difference did not reach statistically significant levels (two-tailed Fisher's exact, P=0.13)

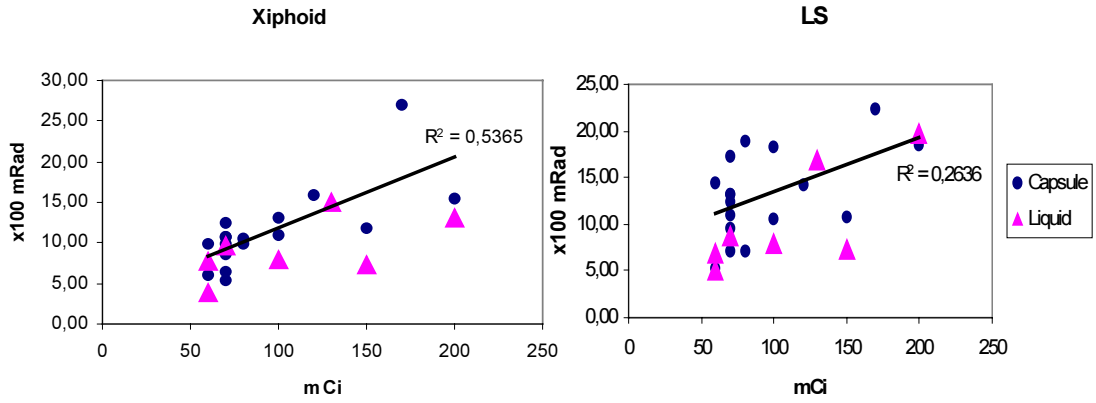
Bladder TLD showed a mean dose of about or 5.5 rad (2.66-12.6) or 55 mGy (26.6-126) . There was a moderate linear correlation ($r=+0.492$ $p<0.05$) with the administered quantity of I-131of the dose accumulated over 22 hours in the bladder area . The quantity of fluids consumed varied from 4 to 21 glasses of water (mean 12.5): no correlation could be found between quantity of fluids and bladder dose measurements. ($r=+0.08$).

Gastric area TLD measurements
In almost all patients receiving capsules the TLD placed in the left subcostal showed maximum count rate in the first five minutes, the count rate curve after that showing decline . The TLD placed on the xiphoid on the other hand, in the majority of patients peaked at 20-30 min , while a few cases had a delayed maximum at 45-60 min. Patients receiving liquid form of I-131 showed an almost uniformly declining dose rate curve at both sites.

The maximal dose rate as well as the dose rate at 90 minutes and the integrated dose for the 90 minutes obtained at each site were selected for further analysis.

Correlation with administered dose
The table below shows correlation coefficients and their statistical significance, between the various TLD measurements and the dose administered. (~, * , **, *** for $0.05<P<0.1$, <0.05, < 0.01 and <0.001 respectively)

	Capsule	Liquid
LS 90 min dose rate	+0.53*	+0.88**
"Maximum dose rate	+0.87***	+0.74*
"Integral dose at 90'	+0.51***	+0.77*
Xiphoid. 90 min dose rate	+0.24 -	+0.75*
"Maximum dose rate	+0. 27 -	+0.69 ~



"Integral dose	+0.73***	+0.61 ~

FIG. 1. Regression line in capsule patients and individual values in both groups for 90 min integral TLD dose at the epigastrium versus quantity of I-131 administered to the patient

As shown in the table , the integral epigastric doses, the maximum observed and the 90 minute dose rates showed a positive linear correlation with the Iodine 131 activity administered to the patient, statistically significant in most cases. .Integral doses plotted against total I-131 administered can also be seen in figure 1 along with the regression line for the capsule group. As it can be seen doses measured in patients receiving the liquid form were well below the regression line for capsules in both locations measured.

As a consequence to the correlation findings, both the observed doses and dose rates were first normalized for administered mCi in all comparisons.
The table below shows comparison of the mean indices between the capsule and liquid groups.

	Capsule	Liquid	
"LS 90 min dose rate index (mrad / mCi . min) "	0.11 ± 0.043	0.069 ± 0.032*	P=0.02
"Maximum dose rate (mrad / mCi . min) "	0.242 ± 0.071	0.223 ± 0.049	P=0.11
"Integral dose at 90 (mrad / mCi) "	15 ± 6	9.7 ± 3**	P=0.007
"Xiph.. 90 min dose rate (mrad / mCi . min) "	0.123 ± 0.077	0.067 ± 0.025*	P=0.016
"Maximum dose rate (mrad / mCi . min) "	0.316 ± 0.18	0.219 ± 0.1	P>0.30
"Integral dose (mrad / mCi) "	12.5 ± 3.2	9.2 ± 3.5*	P=0.05

4. Discussion

Good management of patients receiving Iodine 131 treatment should attempt to maximize thyroiod uptake and minimize dose to salivary glands urinary bladder and intestinal tract. Of these thyroid and salivary glands involve mainly patient preparation but dose to bladder and gastric mucosa are influenced by manner of dose administration and management during the first 24 hours post-treatment. Thus adequate fluid intake will reduce dose to the bladder. In the present study where same quantification of bladder dose was attempted by direct external measurement, no correlation was found between this dose measurement and fluid intake. However, it is probable that this reflects the fact that water intake was already higher than a (probable) plateau point for adequate bladder turnover: as it was not considered ethical to have a control group with restricted fluid intake water intake was ad lib and the study was done during the warm season.

Concerning mode of administration there has been some concern over the dose in the stomach wall when a capsule is administered. There are a few attempts to directly assess the effect of the capsule form on the speed of gastric transit of I-131, [1-3] but none of them in hypothyroid patients , as those receiving I-131 treatment for thyroid carcinoma. In the present study all external measurements in the stomach area showed a dose by nearly 100% higher with capsule administration. In absence of parallel tracer studies (to be carried out in a 2^{nd} stage of the study) one should not attempt to directly relate these results to actual absorbed doses. However, although the difference was not statistically significant (probably because of the small number of patients in the liquid group) it is of interest to note that all six patients who experienced some gastric discomfort following the I-131 dose belonged to the capsule group.

To conclude, should further studies show that this type of external measurement can identify patients likely to have a delayed capsule transit during the pretreatment patient evaluation (eg during a whole body I-131 scan) then it might be worth including measurements in the pretreatment evaluation of patients, so that additional measures can be taken (such as administering multiple capsules and/or digestive preparations) to ensure acceptable doses to the gastric mucosa of these patients.

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CURRENT TRENDS ON INTERNAL DOSIMETRY FOR PATIENT PROTECTION IN NUCLEAR MEDICINE

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Abstract

The associated risk-benefit analyses in nuclear medicine implicitly performed by the clinician have been straightforward. Relatively low administered activity activities yield important diagnostic information, the benefit of which far outweigh any potential risk associated with the attendant normal tissue radiation doses.
Such small risk-to benefit ratios have been very forgiving of possible inaccuracies in dose estimates. With the ongoing development of new radiopharmaceutical and the increasing therapeutic application of internal radionuclides, radiation dosimetry in nuclear medicine continues to evolve from population- and organ-average to patient-specific dose estimation. Patient-specific dosimetry refers to the estimation of radiation dose to tissues of a specific-patients based on theirs individual body and measured biokinetics rather than an average antropomorphic model and hypothetic kinetic. The importance of dosimetry specific-patient considers to avoid the risk of an unsuitable treatment and/or with probability of damage to the patient. This is illustrated by the dosimetric approaches to radioiodine treatment of hyperthyroidism. The most common prescription algorithm to fix the activity administered to a hyperthyroid patient does not consider individual parameters that are highly variable (thyroid uptake, biological half-life, thyroid mass). It arbitrary approach doesn't permit individually optimized therapy and it may be inappropriate and even hazardous.

1. Introduccion

Se plantea la importancia de dosimetría especifica del paciente para evitar el riesgo de un tratamiento inapropiado y/o con probabilidad de daño al paciente. [1] El objetivo es presentar la tendencia y los desafíos actuales en el campo de la dosimetría interna en medicina nuclear, dado que la exactitud en el cálculo de la dosis absorbida en los diferentes tejidos y órganos es la clave para asegurar el beneficio neto en el paciente en especial en la terapia, donde las dosis en órganos que no constituyen el blanco pueden ser significativas. El algoritmo más común para la prescripción de la actividad administrada de I^{131} a un paciente hipertiroideo no tiene en cuenta parámetros individuales que son altamente variables (captación tiroidea, período biológico de semidesintegración, masa de la tiroides). Este protocolo de tratamiento no permite identificar a aquellos pacientes para quienes la terapia con iodo no es la apropiada y puede ser dañina.

2. Dosimetría especifica del paciente

La terapia con radionucleídos basada en la dosimetría específica del paciente apunta a optimizar la dosis. La determinación de la biocinética del radiofármaco en el individuo a partir de mediciones permite calcular la dosis en el órgano blanco o en el tumor para cada paciente. [2]

De esta manera la actividad administrada será la apropiada para alcanzar la dosis terapéutica deseada en el órgano blanco evaluando con mayor exactitud cual es la mayor dosis que puede alcanzarse en el órgano blanco sin pasar el umbral para evitar efectos biológicos en los tejidos sanos.

La utilización de actividades diagnósticas del radiofármaco elegido para la terapia (trazadores), en la etapa previa al tratamiento permite identificar a aquellos pacientes para quienes el tratamiento será más efectivo y a otros para quienes no será efectivo llegando

inclusive a estar contraindicado, por lo tanto en esto último, el esquema de tratamiento con radiofármacos no es el apropiado. Esto es así especialmente en los casos que presentan una relación de uptake baja para blanco /no blanco.

El uso de un protocolo estandarizado para la adquisición de datos farmacocinéticos del paciente para la dosimetría específica permite establecer una correlación entre la dosis estimada y los efectos clínicos observados.

Los objetivos de la planificación del tratamiento utilizando la dosimetría específica del paciente son:

1. Adquir datos cuantitativos secuenciados en el tiempo utilizando actividades bajas o diagnósticas del radiofármaco (o un análogo) para obtener la biodistribución. Con este propósito se utilizan imágenes provenientes de gamma cámara o de sistemas tomográficos tales como SPECT (single photon emission computed tomography) o PET (positron emission tomography).

2. Estimar la dosis en el tumor y otros órganos blanco por unidad de actividad administrada empleando datos biocinéticos específicos del paciente.
   SPECT y PET, aportan datos en tres dimensiones (3D), que podrían usarse directamente con Monte Carlo u otros algoritmos para obtener un mapeo de dosis absorbida en 3D. En estos casos puede ser útil el empleo de tomografía computada con Rx (XCT) o MRI (resonance magnetic imaging) que aportan métodos de corrección por atenuación y las bases anatómicas para el mapeo de la dosis absorbida en 3D.

3. Predecir la dosis entregada en la terapia al paciente por extrapolación a partir de los resultados obtenidos con dosis diagnósticas en función de la actividad administrada. Sin embargo debe reconocerse que la biocinética con actividades diagnósticas no suelen ser idénticas con las utilizadas en terapia. Esto puede suceder cuando al aumentar la actividad administrada se produce el efecto "STUNNING" o de uptake decreciente.
   Este efecto se ha observado en cáncer de tiroides cuando se utilizan actividades diagnósticas altas.

4. Monitorear la biocinética del radiofármaco durante la terapia para comparar las predicciones diagnósticas con los resultados observados que permitirá la verificación de las dosis terapéuticas y la correlación las mismas.

5. Evaluación de la efectividad del tratamiento en la terapia para predecir y en algún caso evitar posibles futuras complicaciones.
   Se consideran histogramas dosis-volumen, probabilidad del control del tumor (TCP) y probabilidad de complicaciones en tejidos normales (NTCP)

2.1. Cálculo de la dosis absorbida

2.1.1. Factores S. El uso de los valores de S del MIRD basados en individuo estándar puede introducir errores en el cálculo aún si se corrigieron usando la masa del órgano específica del paciente. Cuando la distribución de la actividad en los órganos es homogénea, el cálculo de

dosis en diagnóstico y terapia es aceptable. Pero la presencia de inhomogeneidades, cuando los radionucleídos son emisores de baja energía como el Tc^{99m}, [3] puede llevar a errores significativos. Los factores S pueden derivarse de fantomas voxelizados obtenidos a través de tomografías computadas resultando mas realistas que los utilizados por MIRD.[4]

2.1.2. Simulación con Monte Carlo. El método de transporte Monte Carlo es el más exacto, permitiendo modelar la interacción de fotones y electrones con los datos de distribución de actividad específicos del paciente con el mapa de atenuaciones.

3. La dosimetría específica del paciente en la terapia del cáncer tiroideo con I^{131}

Este es un caso donde se pone de manifiesto la relevancia de la dosimetría especifica del paciente para evitar el riesgo de un tratamiento inapropiado y/o con probabilidad de daño al paciente.

El algoritmo general para fijar la actividad administrada de I^{131} a un paciente hipertiroideo no tiene en cuenta parámetros individuales que son altamente variables (captación tiroidea, período biológico de semidesintegración, masa de la tiroides).

Sobre la base de este esquema de tratamiento el 85 % de los pacientes se curan evolucionando a eutiroidismo o a hipotiroidismo, con una sola administración. El 100 % de los pacientes se curan pero con repetidas administraciones.

Este protocolo de tratamiento no permite identificar a aquellos pacientes denominados “small pool” para quienes la terapia con yodo no es la apropiada y puede ser dañina. Estos pacientes (+/-15 %) presentan un período biológico de semi-desintegración de entre 5 y 10 días (en contraste con el 85 % con valores de 20 a 25 días) esto resulta en una dosis en tiroides inferior a la teórica calculada y mayor dosis en sangre por lo tanto si se aumenta la actividad administrada para lograr el efecto sobre la tiroides se dan 28 mCi en lugar de 3.2 mCi típicamente administrados. Esto determina una dosis de 1.5 Gy en sangre que resulta inadmisible para el tratamiento de una enfermedad benigna.

4. Conclusiones

En medicina nuclear son ampliamente utilizados modelos que determinan la dosis promedio en un órgano pero el apartamiento en cuanto a la biocinética y la anatomía en casos particulares determina una inexactitud importante. El incremento de los usos terapéuticos de los radiofármacos junto a la necesidad de cálculos más exactos marcan la tendencia de una medicina nuclear evolucionando desde el cálculo en un paciente promedio a la estimación de la dosis específica de cada paciente. El desarrollo de CT, MRI, SPECT Y PET constituyen herramientas que proporcionan detalles de la anatomía y funcionamiento fisiológico que informan acerca de la distribución de la retención y excreción de los radiofármacos. constituyendo un prometedor avance en la exactitud de la dosimetría interna.

La potencialidad de extender la aplicación de las técnicas de Monte Carlo en la dosimetría interna reemplazando la utilización de modelos matemáticos que limitarían su utilidad a la protección radiológica en el control ocupacional donde es posible aceptar el margen de error que tienen asociado fundamentalmente por los valores de dosis involucrados en ese campo, órdenes de magnitud inferiores respecto de la medicina nuclear.

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INTERNAL RADIATION DOSIMETRY, PHARMACOKINETICS AND BIODISTRIBUTION OF THE ^{99m}TC LABELED IOR egf/r3 MONOCLONAL ANTIBODY

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Abstract

The aim of this work was to assess the internal radiation dosimetry, human pharmacokinetics and biodistribution of the 99mTc-labeled murine monoclonal antibody (MAb) ior egf/r3, used for diagnosis of epithelial tumors. Five patients were included in this study. Multiple blood and urine samples were collected and sequential anterior and posterior whole-body scintigraphies up to 24 hr post-injection were acquired from all patients. The internal radiation dosimetry was estimated using the methods developed by the Medical Internal Radiation Dosimetry (MIRD) committee. Raw data were computed from operations between scintigraphic images and regions of interest (ROI). The residence times of the activity on the source organs were computed to assess the absorbed dose by 24 target organs. The dosimetric results showed that liver, gallbladder and spleen received the higher absorbed dose. The computed mean values were 0.69 mGy/MBq, 0.19mGy/MBq and 0.37 mGy/MBq, respectively. The mean value of effective dose was 1,2E-01 mSv/MBq and the effective equivalent dose was 9,2E-02 mSv/MBq. The Pharmacokinetics and Biodistribution results showed that this compound have a biexponential plasmatic and blood clearance with a rapid biodistribution phase and a slower elimination phase. This compound was excreted by the urinary and hepatobiliary systems. Liver was the principal target organ of this product showing a great retention of the MAb. These dosimetrics results have allowed to use the ior egf/r3 kit in a safe and controlled way.

1. Introduction

Nowadays the cancer of epithelial origin constitutes one of the first causes of death all around the world. That kind of tumors, like cancer of lung, digestive track, breast and others, have a 10-30-fold expression of the epidermal growth factor receptor (EGFr). On the basis of these findings, monoclonal antibodies (MAbs) able to recognize the EGFr and to block its kinase activation, have been developed for the therapy and diagnosis of that kind of tumors [1]. The 99mTc labeled MAb ior egf/r3 developed in the Center of Molecular Immunology have showed potentiality for the diagnosis of tumors from epithelial origin.

To estimate the value of the antibody it is important to consider not only the detection of the tumor but also the radiation exposure of the patients. Methods developed by the Medical Internal Radiation Dose (MIRD) Committee (Loevinger et al, 1988) were used to calculate mean doses to models representing various organs and tissues in order to allow the evaluation of the risks associated to the administration of radiopharmaceuticals for diagnostic purposes. The main aim of this study was to assess the human radiation dosimetry, pharmocokinetics and biodistribution of the ^{99m}Tc- MAb ior egf/r3.

2. Materials and methods

2.1. Patients

The 99mTc-ior egf/r3 was administered to five patients (4 females and 1 male), aged from 58 to 69 years (mean age 63.0±4.2 years). The weight and height mean values were 71.6±14.1 Kg and 161±66cm, respectively. All patients gave informed consent. Three of them had primary tumor without treatment and two were suspected of having recurrences after surgery. All

lesions were confirmed by biopsy (4 adenocarcinomas of rectum and one carcinoma of annal canal).

2.2. Monoclonal Antibody Kit and Radiolabeling

The ior-egf/r3 MAb kit contains a highly specific murine IgG**2**a isotype antibody, which recognizes human epidermal growth factor receptor (h-EGFr). It was produced in the Center of Molecular Immunology (Havana, Cuba) by standard hybridoma techniques as previously described Fernandez et al., 1989 [1]. The freeze dried, sterile and pyrogen free kit was obtained according to the Schwarz's method [2,3]. Each vial contained 3mg of MAb. Kits were labeled with 1.66 GBq of pertechnetate from the $^{99m}Mo/^{99m}Tc$ generator (Amertec II, Amersham, UK) and activity was measured in a dose calibrator (Comp-U-Cal II, Victoreen Inc, USA.)

2.3. Quality Control and Radiopharmaceutical administration

The labeling efficiency was assessed by ascending chromatography. The samples were applied on Whatman 3MM 1x10 strips and immediately placed in development tanks. After that, the strips were dried and the distribution of activity was determined using a ratemeter (SR8, Nuclear Enterprises, UK). The radiopharmaceutical was injected intravenously through an antecubital vein. The administrated dose was 1485.1 ± 86.3 MBq (mean ± SD).

2.4. Pharmacokinetics and excretion analysis

Following intravenous injection, 3-4 ml of blood samples were collected from an antecubital vein opposite to the injection side at different time intervals. A bi-compartmental model was applied in order to perform the pharmacokinetics analysis. Complete urine samples were also collected up to 24 hrs post injection [4]. The radioactivity in blood, plasma and urine (0.3 ml) samples in duplicate was determined using a ratemeter (SR8, Nuclear Enterprises, UK) and expressed as a percentage of administered activity. Appropriate corrections were made for decay with time of injection as reference time.

2.5. Imaging

Whole body images were performed using a Sophy Gamma Camera (Sopha Medical inc., Canada) fitted with a low-energy high-resolution, diverging parallel-hole collimator to increase the lateral viewing aspect. Anterior and posterior whole-body images were acquired using a 20% window centered on the 140 keV emission from ^{99m}Tc at 10 min, 1, 3, 5 and 24 hr post-injection using a gantry speed of 20 cm/min. All whole-body images were stored on the computer in 2048x512 word mode matrix.

2.6. Biodistribution and dosimetry

All images were processed in a SOPHY-20P system. The geometric mean of anterior and posterior images was obtained. Regions of interest (ROI) were drawn over heart, liver, spleen, bladder, upper large intestine (ULI) and low large intestine (LLI), which were considered as the source organs and total counts were computed. Whole body and source organs activity was expressed as percent of the total administered activity remaining in each one at selected time intervals. The MIRD Committee method for determining absorbed dose was used [5,6]. The time-activity curves for each source organ and the remainder of the body tissues were

calculated from the percent of injected dose values and fitted to exponential disappearance curves to estimate initial organ uptakes and clearance half times. Whole-body activity was initially 100 % following an exponential clearance by biological removal and physical decay of activity. Cumulative activities and residence times for each source organ were estimated from the integral under the time-activity curves. ***Absorbed dose***: The absorbed doses to whole body and normal organs were estimated using the computed residence times and the modified S values from MIRD Pamphlet No. 11. The mean absorbed dose per unit of administered activity was computed according to the method described in the MIRD Primer . The effective dose was calculated based on the results of the absorbed dose estimates to various target organs.

2.7. Statistical analysis

Mean and standard deviation (SD) values were calculated. Curves were fitted to a biexponential model by using non-linear regression method. Data were processed using SPSS for Windows and the Microcal Origin software [7].

3. Results

3.1. Pharmacokinetics and excretion

Counts versus time curves from blood and plasma samples were computed and fitted to a biexponential equation ($A*\exp(-\lambda t) + B*\exp(-\lambda t)$). From the rate constants of these curves, the half-life of the fast and slow components, were computed. Fitted curves showed a half-life of the initial fast component (distribution phase) of 9.1 ± 8.4 min (plasma) and 12.2 ± 4.4 min (blood) and a half-life for the predominant late slow component (elimination phase) of 6.6 ± 1.6 hrs (plasma) and 10.8 ± 6.8 hrs (blood). The percent of injected dose excreted by urine under physiological conditions, up to 24 hours post-injection, was 4.7 ± 0.4 %. On the other hand, it was excreted 9.9 ± 1.8 % of the injected dose by the hepatobiliary system.

Table 1. ^{99m}Tc-ior egf/r3 Human biodistribution for the source organs (% of administered activity, mean ± SD)

	Time (Hrs)				
Source Organ	*0*	*1*	*3*	*5*	*24*
Heart	3.5	2.1	1.9	1.7	0.4
Liver	48.8	61.2	58.3	59.3	41.2
Spleen	4.2	4.6	4.2	1.9	0.7
ULI	0	0	0	1.0	4.7
LLI	0	0	0	1.2	5.2
Bladder	0.5	0.5	1.2	1.2	0
Whole body	100	95.2	93.6	88.9	60.2

* There was no statistical difference ($p < 0.05$ paired t-test) between all patients.

3.2. Biodistribution

The biodistribution patterns of the ^{99m}Tc labeled MAb ior egf/r3 in humans is due to a combination of biological behavior of the MAb itself and its target antigen. Quantitative biodistribution data from all patients were very similar for all the source organs. Biodistribution data are presented in Table No.1 (values corrected by decay). The most notable tissue localization occurs in the liver, spleen and heart. Liver uptake was rapid with a peak at

1h post-injection (61.2%) and a great retention (T½ eff = 5.3 hr, T½ Biol.= 45.0 hr) because of the high number of human epidermal growth factor receptors (hEGFr) present in it. The ULI and LlI were found as source organs due to the hepatobiliary system is the most important excretion way of this compound. Approximately 60.2% of the injected MAb remain in the total body at 24 hr postinjection, showing an effective and biological half-life of 5.61 and 84.8 hrs respectively.

3.3. Internal Radiation Dosimetry

The radiation dosimetry calculations were made using the residence times obtained from the biodistribution data. The assessed absorbed dose of 24 target organs and the effective dose after the injection of the Labeled MAb ior egf/r3 are presented in Table 2. The liver (0.69 mGy/MBq), the gallbladder wall (0.19mGy/MBq) and the spleen (0.37 mGy/MBq) received the highest absorbed doses. The effective dose and the equivalent effective dose were of 0.12 and 0.092 mSv/MBq respectively. Liver was the principal contributor organs to the absorbed dose per organ.

Table 2. Normal organ dosimetry for the labeled mAb ^{99m}Tc-ior egf/r3 (mGy/MBq)

TARGET ORGANS	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Average
Adrenals	0,0959	0,1220	0,1230	0,1290	0,0758	0,1100
Gallbladder Wall	0,1780	0,2120	0,1970	0,2380	0,1350	0,1900
LLI Wall	0,1270	0,0475	0,1330	0,0999	0,0452	0,0910
Small Intestine	0,0481	0,0537	0,0751	0,0554	0,0304	0,0530
ULI Wall	0,0967	0,0753	0,2240	0,1040	0,0432	0,1100
Heart Wall	0,0836	0,0964	0,0981	0,0935	0,0739	0,0890
Kidneys	0,0683	0,0897	0,1030	0,0923	0,0556	0,0820
Liver	0,6630	0,7680	0,6550	0,9020	0,4690	0,6900
Red Marrow	0,0270	0,0382	0,0363	0,0328	0,0218	0,0310
Spleen	0,1050	0,2230	1,1100	0,2500	0,1840	0,3700
Urine Bladder Wall	0,0581	0,0883	0,0945	0,0996	0,0516	0,0780
Total Body	0,0434	0,0577	0,0560	0,0560	0,0333	0,0490
EFF DOSE EQ.	0,0943	0,1170	0,1730	0,1270	0,0731	0,1200
EFF DOSE	0,0848	0,0907	0,1280	0,1030	0,0554	0,0920

4. Conclusions

The pharmacokinetics and biodistribution of ^{99m}Tc-labeled Monoclonal Antibody ior egf/r3 have shown that this compound has a biexponential blood and plasmatic clearance with a rapid biodistribution phase and a slower elimination phase. Liver is the target organ of this product and presented an uptake peak at 1hr post-injection with a high retention. The dosimetric results showed that liver, gallbladder and spleen received the higher absorbed doses and it were also reported these values for 24 target organs. These results allow to use this radiopharmaceutical in a safe and controlled way.

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A PROTOCOL TO DETERMINATE THE SITUATION OF NUCLEAR MEDICINE IN VENEZUELA, 1999–2000

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Abstract

This paper present preliminaries results and the methodology followed for the implementation of a Protocol that included -Radiological Protection and -Quality Control at SPECT Systems in two important public hospitals at República Bolivariana de Venezuela. We found in these inspections that the main problems were the lack of medical physicist capacity in nuclear medicine that implemented programs of quality assurance as well as radiation protection in these departments.

1. Introducción

La República Bolivariana de Venezuela recientemente adoptó como Norma el Informe de Colección de Seguridad 115 del OIEA, el cual recomienda que cada país implante Programas de Garantía de Calidad a fin de optimizar la Práctica de la imaginología en general. Dado lo ambicioso, extenso y costoso de esta empresa y que, por otro lado, Venezuela carece de Físicos Médicos especializados en el área de la Medicina Nuclear que impulsen Programas de Control de Calidad para verificar el funcionamiento de los sistemas de imagen, así como también, de la optimización de los procesos de Protección Radiológica en la manipulación de fuentes radiactivas abiertas. Nos hemos dado a la tarea de desarrollar un protocolo de inspección de Seguridad Radiológica y un Protocolo de Control de Calidad de las unidades de medicina nuclear, basados en protocolos y recomendaciones internacionales pero adaptados a nuestra realidad, para poder estimar mediante su aplicación y análisis de los resultados obtenidos, la situación actual de dichas instalaciones en nuestra Nación.

Como primera etapa de este proyecto hemos aplicado dichos protocolos a dos importantes instituciones públicas, como comienzo para que los titulares responsables de las mismas tomen conciencia de la abrumadora necesidad de implantar Programas de Garantía de Calidad en dichos servicios en un futuro inmediato el cual incluya aspectos tales como una capacitación más profunda y rigurosa en lo que a la Práctica con fuentes radiactivas abiertas de actividades bajas y medias se refiere.

2. Metodología

Durante aproximadamente cinco meses se llevó a cabo una exhaustiva revisión bibliográfica la cual involucró la selección de las pruebas que consideramos determinantes para verificar la situación desde el punto de vista de protección radiológica así como para determinar el funcionamiento de las unidades SPECT. Previa la implantación de dichos protocolos se realizaron múltiples ensayos para verificar la exactitud y objetividad de los mismos.

3. Resultados

Tabla I. Aplicación del Protocolo para la Inspección de Seguridad Radiológica. [1-10]

PROTOCOLO DE SEGURIDAD RADIOLÓGICA		
Prueba	**INSTITUCIÓN A**	**INSTITUCIÓN B**
Existencia de detectores de radiación	No cuentan con detectores de contaminación superficial, ni con monitores de radiación. (CI)	No cuentan con detectores de contaminación superficial, monitores de radiación, ni activímetro. (CI).
Activímetro	Aceptable, aún cuando NO se pudo realizar la prueba de linealidad ya que parte del personal del servicio argumentó que el control de calidad no podía ser oneroso.	NA
Sala de espera	No hay un baño exclusivo para los pacientes inyectados con radiofármacos. Utilizan el baño común de la sala de espera (CI) Todos los pacientes y familiares permanecen juntos en la sala de espera, período que puede extenderse hasta dos horas. (CI)	No hay un baño exclusivo para los pacientes inyectados con radiofármacos. Utilizan el baño común de la sala de espera (CI) Todos los pacientes y familiares permanecen juntos en la sala de espera, período que puede extenderse hasta dos horas. (CI)
Radiofármacos Utilizados	^{99M}Tc (10 MBq, administración oral e intravenosa. ^{131}I (20 MBq, administración intravenosa y 200 MBq, por vía oral), ^{67}Ga, ^{153}Sm. Están debidamente identificados y su almacenamiento se realiza en el cuarto caliente pero no hay bitácora de recepción. (CI)	^{99M}Tc (10 MBq, administración oral e intravenosa. ^{131}I (20 MBq, administración intravenosa y 200 MBq, por vía oral), ^{67}Ga, ^{153}Sm. Están debidamente identificados y su almacenamiento se realiza en el cuarto caliente pero no hay bitácora de recepción. (CI)
Inspección general	Se informa al paciente sobre su tratamiento pero los cuidados que debe tener en casa no se le suministran por escrito. (CI)) Llevan registro de las actividades de los radiofármacos utilizados. (C) Están delimitadas y señalizadas las zonas de permanencia para el POE y pacientes. (C) No se admiten embarazadas en el servicio. (C) No hay cuarto habilitado para descontaminación del POE. (CI) No hay lámparas de emergencia, ni extintores de incendio(. (CI) No hay procedimientos de emergencia para contaminación, ni para siniestros (incendios, inundaciones, o terremotos, etc. (CI) No llevan un registro de desechos. Sin embargo, los mismos se almacenan en el cuarto caliente, bajo la campana extractora, clasificándolos según el tipo de radiofármaco, y esperan hasta siete vidas ½ antes de su disposición en la basura común. (A) No se pudo comprobar la integridad de los filtros de la campana. En las áreas de manipulación de material radiactivo no se ingieren alimentos, líquidos, ni se fuma. (C) La Institución no cuenta con tanques de triple decantación para los desechos líquidos producidos en el servicio, ni para las excretas de los pacientes hospitalizados por administración de radiofármacos. (CI)	Se informa al paciente sobre su tratamiento pero los cuidados que debe tener en casa no se le suministran por escrito. (CI)) El registro de las actividades de los radiofármacos utilizados comenzó en Agosto del 2000. (C). Están delimitadas y señalizadas las zonas de permanencia para el POE y pacientes. (C) No se admiten embarazadas en el servicio. (C) No hay cuarto habilitado para descontaminación del POE. (CI) No hay lámparas de emergencia, extintores de incendio, extractor, ni campanas. (CI) No hay procedimientos de emergencia para contaminación, ni para siniestros (incendios, inundaciones, o terremotos, etc. (CI) No llevan un registro de desechos. Tampoco tienen una gestión para los mismos, ya que son dispuestos directamente a la basura común después de cada jornada de trabajo. (CI) En las áreas de manipulación de material radiactivo se ingieren alimentos y líquidos. Se constató la presencia de frutas en el refrigerador del cuarto caliente donde también se almacena ^{131}I. (C) La Institución no cuenta con tanques de triple decantación para los desechos líquidos producidos en el servicio, ni para las excretas de los pacientes hospitalizados por administración de radiofármacos. (CI)

Cuarto caliente	Iluminación aceptable. No tienen lámpara de emergencia. (CI) Paredes pintadas con pintura soluble en agua. (CI) Piso de linóleo, pero sin bordes redondeados, ni sumideros. (CI) Techos de cielo raso. (CI). Sin extractor, pero con campana. (C) Puertas de madera. (CI) Mesón de fórmica, sin bordes redondeados, en su superficie está el generador en uso, y la L plomada de 50 mm de espesor, a menos de medio metro de distancia de éste se encuentra el Activímetro. (CI) Tienen lavamanos de seguridad. (C) Durante la Práctica no siempre usan papel absorbente para cubrir las superficies del mesón y L plomada. (CI) No trabajan con jeringas plomadas ni pipetas automáticas. (CI) Además de la campana extractora tienen una caja de guantes para manipulación de radioisótopos. (C) No hay refrigeradores, ni otros implementos ajenos a la Práctica. (C) No usan jabón de PH neutro. Pero usan sustancias para descontaminar, aunque para el momento de la inspección el personal no estaba al tanto. (CI)	Iluminación aceptable. No tienen lámpara de emergencia. (CI) Paredes pintadas con pintura soluble en agua. (CI) Piso de granito, sin bordes redondeados, ni sumideros. (CI) Techos de cielo raso y sin extractor. (CI) Puertas de madera. (CI) Mesón de cerámica, sin bordes redondeados, en su superficie está el radiofármaco utilizado dentro del castillete plomado, y la L plomada de 50 mm de espesor. (CI) El lavamanos no es de seguridad. (C) Durante la Práctica usan papel absorbente para cubrir las superficies del mesón y L plomada. (CI) Usan jeringas plomadas, algunas estaban contaminadas para el momento de la inspección. No usan pipetas automáticas (CI). Hay múltiples utensilios ajenos a la Práctica tal como una cafetera, la cual se sacó de inmediato de dicho recinto. (CI) Hay un refrigerador dentro del cual se encontraron alimentos, y se almacenaba ^{131}I. (CI) No usan jabón de PH neutro, ni sustancias para descontaminar. (CI)
Metodología de descontaminación de áreas	No tienen ningún manual de procedimientos en caso de contaminación. Para el momento de la inspección se le derramó a una paciente ^{131}I y la única medida que se tomó fue colocar un papel absorbente sobre la contaminación.	No tienen ningún manual de procedimientos en caso de contaminación. Para el momento de la inspección se le derramó a un paciente ^{131}I que contaminó la bata del Dr. Que realizó la administración, y en los frotis tomados en áreas de 10 cm^2, se encontró por ejemplo una contaminación removible de 75875 Bq.
Pacientes hospitalizados	Cuarto señalizado y visitas prohibidas. (A) No hay monitoreo de ropa de cama ni la del paciente, no hay procedimientos de manipulación de excretas. (CI) Dependiendo de la actividad administrada se le da de alta, p ejem si se le administra 200 MBq permanece de 4 a 7 días. (C)	Cuarto señalizado y visitas prohibidas. (A) No hay monitoreo de ropa de cama ni la del paciente, no hay procedimientos de manipulación de excretas. (CI) Dependiendo de la actividad administrada se le da de alta, p ejem. si se le administra 200 MBq permanece de 4 a 7 días. (C)
Personal Ocupacionalmente expuesto	No cuentan con dosimetría personal. (CI) No todos usan guantes durante la manipulación del material radiactivo pues hay alérgicos, y no todos usan batas. (CI)	No cuentan con dosimetría personal. (CI) Todos usan guantes y batas durante la manipulación del material radiactivo. (C)
Control de contaminación radiactiva	Se realizaron múltiples frotis de 10 cm^2 de área con papel de filtro en diversas áreas del cuarto caliente y del Servicio en general, así como también en la ropa del POE. Dichos frotis se analizaron con un espectrómetro de (Na-Tl) al cual se le estableció un límite de detección de 5 Bq, se encontró contaminación radiactiva removible en: -Interior de la L plomada (41 Bq), -Manos y lentes de la Dra (5,8 Bq), -Superficie del mesón (7 Bq). Vale la pena resaltar que estos frotis no fueron tomados el día que ocurrió el derrame de ^{131}I.	El día que ocurrió la contaminación de ^{131}I, se realizaron múltiples frotis de 10 cm^2 de área con papel de filtro en diversas áreas del cuarto caliente y del Servicio en general, así como también en la ropa del POE. Dichos frotis se analizaron con un espectrómetro de (Na-Tl) al cual se le estableció un límite de detección de 5 Bq, se encontró contaminación radiactiva removible en: -Bata del Dr (541 Bq), -Piso y puerta del cuarto caliente (75875 Bq y 6 Bq) respectivamente, -L plomada (31905 Bq), -Navaja (316 Bq), -Asa del refrigerador (11 Bq), -Zapatos del personal que estuvo involucrado (6 y 42 Bq)

Leyenda: (A) Aceptable; (C) Correcto; (CI) Condición Insegura; (POE) Personal Ocupacionalmente Expuesto; (NA) No Aplica

Tabla II. Aplicación del Protocolo para la Inspección de Control de Calidad. [1-10]

PROTOCOLO PARA LA INSPECCIÓN DE CONTROL DE CALIDAD EN DOS SISTEMAS SPECT				
Prueba	**SISTEMA SPECT A**		**SISTEMA SPECT B**	
Inspección mecánica	La salida del aire acondicionado está ubicado sobre la gammacámara. (CI)		La salida del aire acondicionado está ubicado sobre la gammacámara. (CI) El Gantry está desnivelado desde el momento de la instalación. (CI)	
Inspección eléctrica	Correcto		El sistema de rotación de la Gammacámara tiene un micro interruptor invertido que paraliza la máquina en el sentido anti-horario. (CI)	
Inspección colimadores	Desde su instalación la empresa de mantenimiento tiene en su poder el dispositivo que permite operar la máquina sin colimadores, sin ello no se pueden realizar las pruebas intrínsecas del sistema. (CI)		Correcto	
Inspección software	Aleatoriamente las imágenes adquiridas presentan líneas en los ejes X y Y		Correcto	
Sistema de rotación	Valor medio de las desviaciones del centro de rotación: 1,1 cm. (CI) Desviación del centro de rotación estimada en el centro y en el borde del campo de visión: 1,3 cm. (CI) Se corrigió durante la inspección por software		Levemente fuera de tolerancia debido al desnivel de la base de la gammacámara.	
Tolerancia	El valor medio de las desviaciones del centro de rotación deben ser menores de 2 mm La desviación del centro de rotación estimada en el centro y en los bordes del campo de visión no deben diferir entre sí en más de 2 mm			
Uniformidad intrínseca	CTVU	CCVU	CTVU	CCVU
	27.69 % (FT)	9,31 % (FT)	7,55 % (C)	5,57 % (FT)
	21.54 % (FT)	7, 31 % (FT)	4,41 % (C)	2,87 % (C)
Tolerancia	Las uniformidades para el CTVU no deben exceder el 20 % y para el CCVU el 5% intrínseca no debe superar el 5%			
Uniformidad extrínseca	CTVU	CCVU	CTVU	CCVU
	9.96 % (C)	9,83 %	NR	NR
	8.07 % (C)	8,07 %	NR	NR
Tolerancia	La uniformidad extrínseca no debe superar el 5 %			
Tasa Máxima de Conteo	35 kCuentas/s No existen valores de referencia		225 kCuentas/s No existen valores de referencia	
Tolerancia	No permitir una variación máxima de un 10 % respecto a los valores de referencia			
Resolución Temporal	Correcto No existen valores de referencia		Correcto No existen valores de referencia	
Tolerancia	No permitir una variación máxima de un 10 % respecto a los valores de referencia			
Resolución Espacial	Para el momento de la inspección no se pudo acceder al software para el análisis de la imagen obtenida		Correcto No existen valores de referencia	
Tolerancia	Iniciar acciones correctivas cuando el valor de FWMH sea mayor de 20% o más, respecto al valor de referencia			
Linealidad Espacial	Se realizó la prueba y se obtuvieron valores que sugieren comportamientos aceptables pero No existen valores de referencia para hacer la comparación		Se realizó la prueba y se obtuvieron valores que sugieren comportamientos aceptables pero No existen valores de referencia para hacer la comparación	
Tolerancia	Analizar visualmente la imagen obtenida, las mismas deben comparase con las de referencia para determinar si existen desviaciones importantes en las direcciones X y Y.			
Prueba de funcionamiento del SPECT con maniquí JACKSACK	En general en las imágenes obtenidas se observó una buena resolución en los bordes de las esferas. Además, se visualizó claramente la falta de uniformidad del sistema. No existen valores de referencia para hacer la comparación		En las imágenes obtenidas se observó el efecto del desnivel de la base de la Gammacámara que no permite resolver apropiadamente los bordes de las esferas. Por otra parte fue imposible visualizar los objetos pequeños. No existen valores de referencia para hacer la comparación	
Tolerancia	Analizar artefactos circulares que indique problemas de uniformidad, si el sistema presenta problemas de centrado o problemas con la ventana de energía. Las imágenes obtenidas rutinariamente deben compararse con los valores de referencia.			

Leyenda: (A) Aceptable; (C) Correcto; (FT) Fuera de Tolerancia. (NR) No realizado

4. Conclusiones

Si bien hasta los momentos solo se han realizado dos inspecciones completas de las seis que nos tenemos planteadas, los resultados obtenidos de la aplicación de los mencionados Protocolos, en las instituciones inspeccionadas demuestran de una manera clara y contundente

la necesidad de establecer Programas rutinarios de control de calidad tanto en el aspecto de protección radiológica como del equipamiento empleado en los Departamentos de medicina nuclear. Además, demuestran que los mismos representan una fase primordial dentro de un Programa de Garantía de calidad tanto para el paciente como para el personal ocupacionalmente expuesto y permitirán demostrar a las autoridades competentes la urgente necesidad de implantar dichos Programas en el ámbito nacional.

Agradecimientos

.- Hospital Dr. Domingo Luciani en especial a la Dra. Yadelis Aguilar por la importancia que le dio a éste difícil proyecto, por su paciencia y compañía durante la aplicación de los protocolos. Así como por prestarnos los maniquíes para realizar el Protocolo de Control de Calidad en otras Instituciones.
.- Hospital Universitario de Caracas en especial a la Dra. Aixa Manzo y a la TSU Corina Herrera por su invaluable colaboración.
.- Lic. Juan Díaz, Lic. Orlando Cabrera y Lic. Miguel Rodríguez por su asesoría, y por sus valiosos y continuos comentarios para llevar a acabo esta investigación.
.- Dr. Federico Gutt por su apoyo en la logística para poder solventar tantos inconvenientes.
.- Servicio de Radiofísica Sanitaria del IVIC por el prestarnos el detector portátil para contaminación superficial y permitirnos usar el detector de (NaI-Tl) para el análisis de los frotis.
.- Ing. Gustavo Rodríguez de la empresa MEDITRON por su asesoría en la operación de la máquina.

A Todos mil gracias por creer en nosotros y ayudarnos en colocar este granito de arena que poco a poco irá transformando en realidad el sueño que tanto añoramos*:* ***"La optimización de nuestros servicios de imaginología mediante Programas de Garantía de Calidad".***

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PARAMETER ESTIMATION AND COMPARTMENTAL MODELLING FOR INDIVIDUALIZATION OF THERAPEUTIC DOSAGE OF RADIOPHARMACEUTICALS

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Abstract

A successful application of radiopharmaceuticals for therapy requires a patient-specific optimization of the administration activity. Intention of this contribution is to show how this is possible with a relatively limited effort, by combining an optimized experimental schedule for the collection of the anatomic and physiological data of interest and a rigorous mathematical analysis. The benefits of such an optimization will concern not only the success of the therapy, but also the radiological protection of the patients and could even be translated in a more cost-effective usage of the radiopharmaceutical available.

1. Introduction

The therapeutic use of radiopharmaceuticals requires generally the administration of relatively large activities. A realistic dosimetric evaluation is therefore desirable in the effort to optimize the dose to the target organ while sparing the healthy tissues.

The determination of internal dose is however a rather complicated process, which requires the knowledge of several pieces of information: the anatomical features of the irradiated regions, the fractional uptake of the administered substance into these tissues with the characteristic retention times, as well as the kinetics of the excretion process, in order to be able to estimate the dose burden to the organs of the gastroinestinal and of the urinary tracts.

Since the anatomical and biokinetic parameters may differ remarkably between subjects, the evaluation of the correct treatment strategy should be performed on an individual basis. However, the performance of preliminary measurements aimed at the determination of the physiological parameters for each individual undergoing therapy could be a significant complication for the daily routine of an ordinary Nuclear Medicine Service.

It is therefore desirable to devise easy methods for the individualization of the radiometabolic treatment.

2. Patient-specific dose: a case study

Let's consider patients with autonomous thyroid nodule (ATN) being treated with ^{131}I. In these subjects, the uptake of the radiopharmaceutical in extranodular tissue might be relevant, and it is in fact considered responsible of the relatively high prevalence of hypothyroidism occurring after treatment [1]. In this specific case, a correct knowledge of the anatomy of the regions involved, of the fractional uptake into the nodule and into the healthy lobe and of the elimination from these tissues may provide a reliable estimate of the dose received by each of them. On this basis, the activity to administer to each ATN patient may be determined, and the corresponding dose to the extranodular tissue evaluated, thus providing the clinician a patient-specific picture for the evaluation of the possible consequences of the therapy.

Matheoud et al. [2] have studied sixteen patients with ATN, estimating thyroid morphological parameters and iodine kinetics from images of the neck taken at 6 different times between 2 and 120 hours after injection of a tracer activity of ^{123}I. Thyroid uptake in the nodule and in the lobe respectively were obtained by fitting the uptake function

$$U(t)=\frac{U_0\lambda_{in}}{\lambda_{eff}-\lambda_{in}}\left(e^{-\lambda_{in}t}-e^{-\lambda_{eff}t}\right) \quad (1)$$

to the corresponding data set in order to obtain the values of unknown parameters U_0 (the fraction of administered iodine transferred to the nodule and the lobe respectively), λ_{in} (rate of uptake) and λ_{eff} (effective decay constant, which is the sum of the rates of biological decay and of radioactive decay).

Recalling that the dose to the nodule and to the lobe can be estimated using the MIRD formula [3]:

$$\overline{D}=\widetilde{A}S=S\int_0^{\infty}A_0U(t)dt=\frac{A_0U_0S}{\lambda_{eff}} \quad (2)$$

being S the mean absorbed dose per unity cumulated activity $\widetilde{A}$, it was possible from (2) to determine the activity A_0 to be administered in order to release in the nodule the desired dose $\overline{D}$. Consequently, the corresponding radiation dose to the healthy extranodular tissue were evaluated. The parameters, and therefore the optimum dosages required by each subject, showed a great variability, and this fact stresses the importance of tools which enable to individualize the treatment planning.

The possibility of reducing the number of image acquisitions to only 3 was also investigated, in order to make the procedure more easily applicable in the routine. The estimates for the optimum dosage calculated with the 3-point technique deviate in all cases but one less than 5% from those obtained from the 6-point-technique. The deviations of the dose to the lobe are slightly higher, however they never exceed 15%. The ordinary method with only one uptake measurement at 24 hours with a supposedly known dismission rate provides on the contrary estimates differing up to 70% from the more correct ones obtained with the 6-point-method.
The data collected as described above can also be analyzed according to a simple compartment model, like the one shown in Figure 1.

The model tries to give a comprehensive description of the processes involved: the injected activity is distributed between the nodule, the lobe and the rest of the body, and then it is eliminated through the renal pathway. The exchange of material between compartments is considered to be regulated by a first-order kinetics. Under this assumption, this system provides for the compartments nodule and lobe equations which are mathematically equivalent to (1), where now the λ's are combinations of the model parameters k_{ij}. For example, $\lambda_{in} = k_{21}+k_{31}+k_{41}$ for lobe and nodule (and also for compartment 4), that is λ_{in} assumes the same numerical value. Indeed, for each patient, the λ_{in} found with the single fit procedure turned out to assume values which can be considered equivalent within the uncertainties.

The analysis of data with compartmental models is no more complicated than single curve fits. PC-based easy-to-use software packages are available on the market (i.e. SAAM[✦], Modelmaker[§]). They enable to define a model, to associate the experimental data (e.g., the uptake measurements in the nodule and in the lobe) to the corresponding model prediction, to find the best values of the characteristic parameters by means of a least-square fitting procedure of the whole set of data simultaneously, and also to perform calculations (e.g., the cumulated activity) without the need to derive the analytical mathematical expression (which for complex models can be quite difficult to derive). The advantage to use a model is that it provides a physiologically more realistic picture of the distribution of the drug in the organs, and it may enable a more correct evaluation of the dose to other organs which are not directly involved in the therapy.

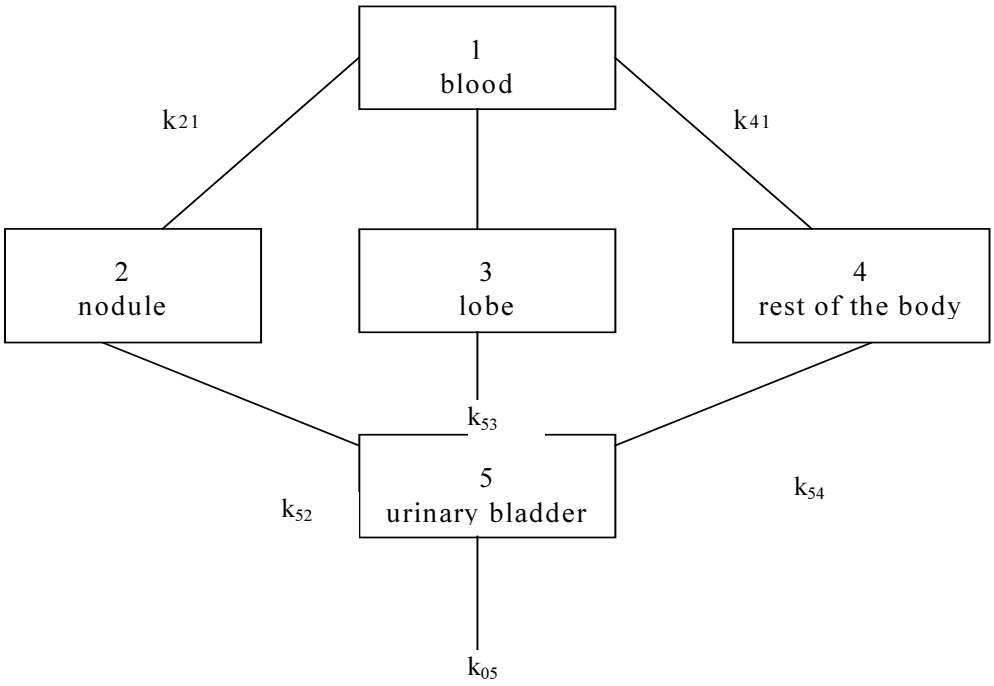

FIG. 1. Model for the kinetics of ^{131}I in ATN patients

For example, the data of the nodule and lobe uptake will enable to derive for each patient the values of the parameters k_{21}, k_{31}, k_{52} and k_{53}. By assuming for the parameter k_{54} (elimination from the compartment "rest of the body") a value of 0.087 h^{-1}, as suggested by ICRP [4], and by taking the process of radioactive decay into consideration, it is then possible to calculate, for each patient, the activity cumulated in the urinary bladder, and thus obtain a more realistic estimate of the dose to this organ and to the sorrounding ones. Even more, as often the urine excreted by the patients in the first hours or day is collected in the hospital for safety reason, it is possible to perform measurements of the amount of drug excreted and use these additional data for the model fitting. Although the dose to the bladder and the sorrounding organs is usually not relevant for the justification and optimization of the therapy, its determination can be in any case of use and also be recorded for any follow-up of the patients.

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[§] Cherwell Scientific, Oxford, UK

3. Conclusions

As this simple example shows, the improvement and individualization of a treatment planning may be obtained with a relatively limited effort combining an optimized experimental schedule and a rigorous although simple mathematical analysis. The advantages of such effort will be reflected not only in the success of the therapy, but also in the radiological protection of the patients and even in a more rational and cost-effective use of the resources (i.e., of the radioactive material) available in a Nuclear Medicine Department.

Acknowledgements

We are grateful to C.Canzi, R.Matheoud and E.Reschini of the Department of Nuclear Medicine of Ospedale Maggiore IRCCS Policlinico, Milano (Italy) for interesting and useful discussions.

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Topical Session 5

DEVELOPING AND USING DOSE GUIDANCE (REFERENCE) LEVELS IN RADIOLOGY AND NUCLEAR MEDICINE EXAMINATIONS

PRACTICAL IMPLEMENTATION OF THE MEDICAL EXPOSURE DIRECTIVE (97/43) IN LUXEMBOURG WITH SPECIAL REFERENCE TO DIAGNOSTIC REFERENCE LEVELS

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Abstract

The Council Directive 97/43 EURATOM of June 30th 1997 requires Member States to promote the establishment and use of diagnostic reference levels for radiodiagnostic examinations. In response to this requirement Luxembourg decided to launch a dose measurement campaign for all hospitals and clinics and to compare the results with the diagnostic reference levels recommended by the European commission. Entrance surface dose measurements were carried out for three common examinations (chest, pelvis and lumbar spine) in five hospitals, using thermoluminescent dosimeters. The results showed that for the examinations of the chest and lumbar spine the European reference dose levels were consistently exceeded in four out of the five hospitals. This was due to: the use of continuous mode fluoroscopy for positioning the patient, the use of film-screen speed classes below the recommended 400 and the use of a kVp lower than that recommended by the European commission. An optimisation process was carried out in one hospital and entrance surface dose measurements were repeated. It was found that the optimisation process led to a dose reduction of 70%.

1. Introduction

The aim of the Council Directive 97/43 EURATOM of June 30th 1997 [1] on health protection of individuals against the dangers of ionising radiation in relation to medical exposure is to *harmonise* the existing legislation in this field within the member states in order to provide a high level of protection to the patient. Article 4, paragraph 2 of the Directive states that Member States shall promote the establishment and use of diagnostic reference levels for radiodiagnostic examinations, and the availability of guidance for this purpose having regard to European diagnostic reference levels where available. Luxembourg decided to adopt these European diagnostic levels [2] in its legislation and to start a dose measurement campaign in every hospital and clinic. This paper presents the first results obtained from this dose measurement campaign.

2. Method

Quality control tests were carried out on the radiological equipment used for conventional radiological examinations in five hospitals. This was done in order to ensure that the equipment functioned correctly and most importantly that the dose delivered by the equipment was within acceptable limits [3].

Entrance surface dose measurements were carried out using thermoluminescent dosimeters (TLDs) which were fixed on the patients skin. The measurements were done for three standard examinations : Thorax, pelvis and lumbar spine, for 25 patients per examination with an average weight of 70 Kg. The method used was based on a document published by the European comission [4].

For each examination the following paremeters were registered:

1. Patient parameters: age, sex, height, weight
2. Technical parameters: sensitivity of intensifying screens, kVp used, mAs, film size, use of automatic exposure control, film to focus distance (FFD), existence of written

protocols, positioning of the patient: use of fluoroscopy instead of light beam diaphragm, number of projections, clinical examination by the practitioner before exposure,

The data obtained was evaluated and compared with the diagnostic reference levels and technical parameters described in the relative European commission document ìEuropean Guidelines on Quality Criteria for Diagnostic Radiographic Imagesî (EUR96) [2].

3. Results

Properly written protocols for each type of examination did not exist in any hospital. Proposed written technical parameters existed but were rarely consulted. Fluroscopy was used in every hospital for the positioning of the patient for the examinations of the pelvis and lumbar spine. For the examination of the thorax only one hospital did not use fluoroscopy for the positioning of the patient and this was due to the fact that the equipment used was a wall stand bucky with no possibility of fluoroscopy. The number of projections demanded for the examination of the lumbar spine was excessive in one hospital i.e. eight projections. In all hospitals no clinical examination was carried out prior to the exposure by the practitioner and in only two out the five hospitals the practitioner saw the patient after the exposure.
Figures 1 to 5 show the results obtained from the entrance surface dose measurements. In four out of the five hospitals the European reference levels were exceeded. The reasons for this are the following:
- systematic use of continuous mode fluoroscopy for the positioning of the patient
- use of a kVp which was too low compared with that recommended [2]
- use of intensifying screens of a lower sensitivity compared to that recommended [2].

Only one hospital had entrance surface dose levels below the recommended European diagnostic reference levels [2] and this was due to two reasons:

- its radiological equipment had the option of pulsed fluoroscopy and this option was used for positioning the patient
- it was equipped with intensifying screens of a much higher sensitivity than that recommended [2].

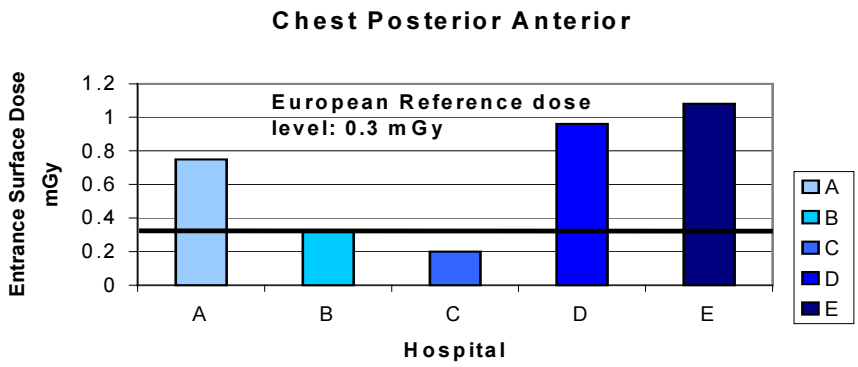

Figure 1

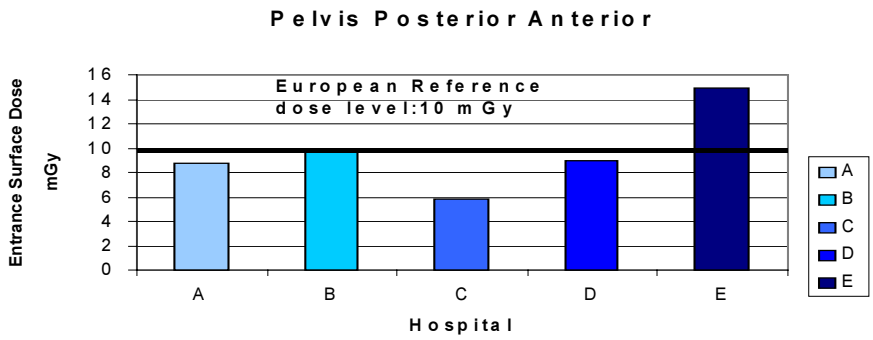

Figure 2

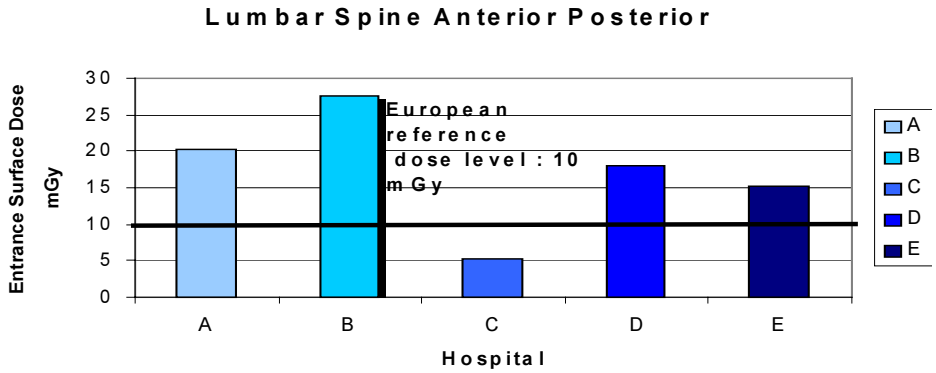

Figure 3

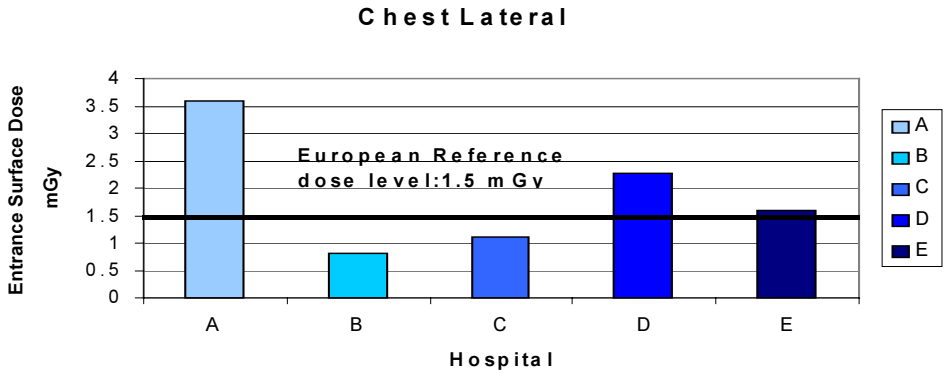

Figure 4

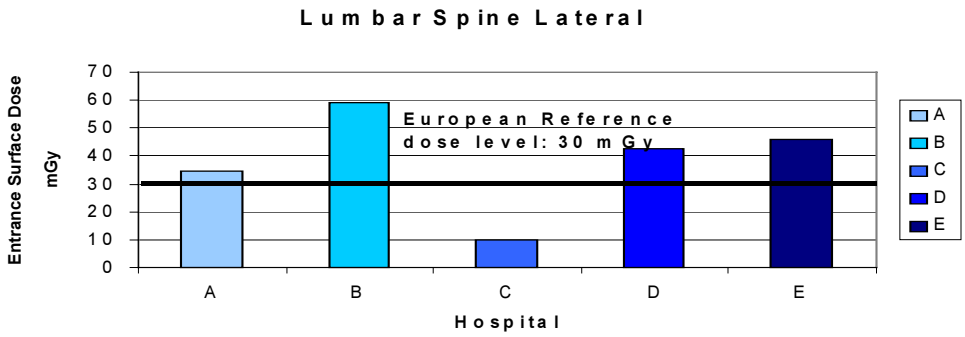

Figure 5

In hospital A (fig. 1-5) the technical parameters were optimised, the use of fluoroscopy for positioning the patient was stopped and written protocols were implemented. The entrance surface dose measurements were repeated and it was found that the entrance surface doses were reduced by 70%.

4. Conclusion

The measurement of entrance surface doses in order to establish diagnostic reference levels is an excellent tool for researching the actual situation in hospitals as far as radiological examinations are concerned. It is perfect as a tool for optimisation purposes i.e. achieve entrance surface doses as low as reasonably possible and for training the personnel involved in the radiology departments.

The use of fluoroscopy for positioning purposes should be put on the European Agenda, as this practice isn't limited to Luxembourg.

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A PROPOSAL TO PROVE COMPLIANCE OF ESD WITH EU-GUIDELINES

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Abstract

The question of compliance with the diagnostic reference levels issued as European Guidelines is discussed based upon measurements of entrance surface dose in four selected projections. The projections were chosen either for the higher dose associated with the investigation or the high frequency of the investigation. The results for the high dose projections lumbar spine and iv pyelography were found to be well below the guidelines. The results for the low dose projections chest pa and chest lat show a mean at about the guidance level. The parameters of the measurements are shown and possible reasons for the scattering of data are discussed. The parameters of the measurements are compared with the proposal of the EU. The main conclusion were a) that even when not all parameters are consistent with EU-guides, the dose is frequently much lower than required. In addition, the ranking in ESD was different for different techniques and different radiologists. Because an approved method to indicate compliance is not yet available, a proposal is given in order to make the guidelines executable.

1. Introduction

"Guidance levels " for entrance surface dose per radiograph in air with backscatter are presented in [1]. Similar data are available in the corresponding EU-guidelines [2]. [1] states:

***guidance levels**: A level of a specified quantity above which appropriate actions should be considered. In some circumstances, actions might needed to be considered when the specified quantity is substantially below the guidance level.*

The EU- directive [3] gives no numbers, but defines in short (Article 2, definitions)

***Diagnostic Reference Levels**: dose levels in medical radiodiagnostic practices or, in the case of radiopharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment. These levels are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied.*

Disregarding the different terminology, the meaning of the term is that a higher dose per radiograph is not necessarily a non-compliance with the directive, but rather a reason for further investigationThe figures set by [1] and [2] are based upon investigations carried out directly at patients. For this reason, the scattering of the data is directed by:

- equipment characteristics
- patient characteristic

2. Measurements

The purpose of the program was:

a) checking compliance with EU- directive for some Austrian radiologists and departments
b) development of a simple procedure to assess ESD without patient dose
c) assessment of input data for estimation of patient dose

The technique to be applied was designed to in order to prove
a) no exposure of the patient

b) simple procedure
c) traceable to standards
d) indicate equipment properties only

Dosimeters: standardized thermoluminescent dosimeters (System Panasonic) as used for individual dosimetry in routine reading were used. The number of exposed dosimeters was between one and five, dependent on the expected dose. The uncertainties of the procedure are reported below.
Assessment of standard exposure conditions: in order to select a phantom corresponding to the conditions (kV, mAs) set by automatic exposure control, data on the variation of the conditions for different patients were recorded for a number of patients.
Phantom: The phantom was a standard acrylic-glass phantom filled with water, as used for assessment of scattered radiation (250 x 250x 150 mm, 10 mm wall thickness). Eventually, the phantom was modified by additional layers of acrylic-glass to prove that the automatic exposure control is adjusted to the mean value as assessed above
Procedure: The measurements were made with dosimeters subject of standardization and the results converted to kerma in air.
Scope: measurements were carried out in 17 wards and radiologists ordinations in Vienna. Four projektions were subject of the investigation, where two low-dose, but frequently applied were chosen as well two medium-dose, but less frequently applied.

The tables shown below present the results of the measurement for some projections, other data can be found in [4]

3. Discussion of the technical parameters and relation to EU-guidelines:

In the following tables, the parameters as required by [3] are shown as applied by the different investigators (indicated by code numbers). Antiscatter grid was always in use.

Table 1. Chest pa

Code Nr	ESD [mGy]	Bias [kV]	mAs	filtration mm Al	FFD [cm]	speed
8	0,61±0,03	133	14	1,3	150	100
5	0,57	125	53	2,5	158	200
1	0,44	90	37	2,5	170	335
16	0,42	115	*	2,0	140	250
2	0,38	125	*	2,0	200	200
17	0,38	125	8,8	2,6	195	300
10	0,39	90	14	2,6	155	280
EU	**0,3**	**125**	**--**	**≥ 3**	**180**$^{++}$	**400**
4	0,28	125	15	2,0	200	250
3	0,26	133	12	2,5	200	300
14	0,23	96	9	2,5	150	280
13	0,22	125	8	2,0	200	(150)*
15	0,20	125	6	2,8	205	400
6	0,18	120	6	3,5	200	250
9	0,18	125	6	2,7	200	400
11	0,18±0,01	121	11	2,5	150	300

bold: EUR 16260 Guideline * unknown ** not confirmed

Table 2. Intravenous Pyelographie

Code Nr	ESD [mGy]	bias [kV]	mAs	filtration mm Al	FFD [cm]	Speed
EU	**10**	**75 - 90**	**--**	**≥ 3**	**115^{++}**	**400**
3	5,67	60	103	2,5	100	400
7	3,76	70	39	4,0	110	280
5	2,94	73	77	2,5	100	200
11	2,55	70	49	2,5	115	280
9	2,24	70	25	2,7	105	400
4	2,21	70	40	2,0	115	210
2	2,17	66	38	2,0	110	400
16	2,12	70	55	2,0	120	250
10	2,08	68	28	2,6	112	250
13	2,04	73	31	2,0	115	200
6	1,50	82	22	4,0	115	250
15	1,49	77	10	2,8	105	400
1	1,29	70	18	2,5	115	600
8	1,02	72	14	1,3	115	400
14	1,01	70	16	2,5	115	400**

bold: EUR 16260 Guideline * unknown ** not confirmed

4. Conclusions

The results include only scattering of data associated with the equipment because of phantom measurements. Phantoms are selected to obtain automatically controlled parameters as potential [kV] and mAs conditions as of an average patient. Regarding projections associated with a higher guidance level as iv Pyelography, the results are well below the guidance level. Projections which require a low ESD lead to results scattered around the guidance level. Figures exceeding the guidance level were partly explained by radiologists by better image quality.

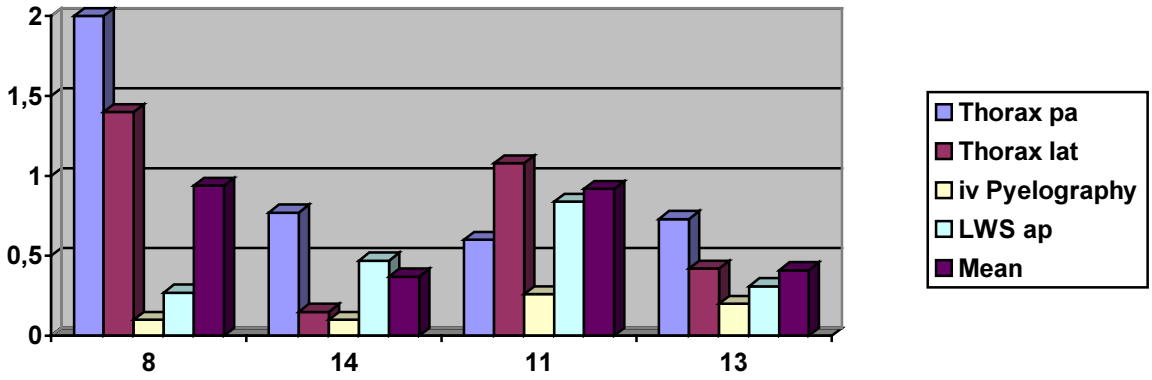
Regarding the relation of the ESD to the guidance level, the different radiologist are in different dose ranking for the different techniques. This implies that a radiologist can be well below the guidance level in one technique and exceeding the guidance level in another technique. Therefore the question arise how to prove compliance with the guideline without measuring all possible projections. The guideline give guidance levels for some projections [2], and to check all even all these projections seems neither practicable nor justified. Therefore, the guideline seems unexecutable at present and very little information how to prove compliance is available at present.

5. Proposal to prove compliance

It is therefore suggested to select a very few representative projections (e.g. those chosen in this project) and to derive an index by the mean of the relation of the ESD in a given projection to the guidance level of this projection fulfilling the condition

$$1 \geq \frac{1}{n}\sum_{n}\frac{ESD_m}{ESD_g}$$

This might be demonstrated by the following example, where the data are plotted for arbitrary chosen radiologist with code numbers 8,14,11,13.



vertical: Ratio of ESD/ guidance level
horizontal: department code

The black area indicates the mean, and all are below 1 and hence in compliance with the guidance level. Although some projections are above the guidance level, the mean is below unity.

This approach seems justified for the following reasons:

- It is not reasonable to check (at least in the present phase where no guidance is available how to prove compliance) in each department each technique for which guidance levels are available for compliance of ESD with the guidelines
- The present approach takes into account high dose and low dose projection and seems representative
- It can be expected that other projection will not depart substantially from these results
- The method seems applicable to routine checks
- The measurements are done without patients because it can not be the purpose of a check of equipment by measuring ESD to determine the BMI

Obviously, when the mean of unity is approached, investigations on the reason are justified. Cases exceeding one have to be investigated.

References

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DIAGNOSTIC RADIOGRAPHY DOSE AND GUIDANCE LEVELS

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Abstract

This work shows a study done on conventional radiodiagnostic equipment. The evaluation was implemented throughout different areas of Bolivia, covering not only single equipment radiographs used in the cities, but also the ones used in rural areas. There have been more than 90 equipment pieces evaluated of which the dose received by a patient for a given exam, has been considered an essential element. For this purpose two types of examinations have been selected, being considered the more frequent. Not only the dose aspect was taken into consideration but the technique used as well. These elements that, that support very important information, have been related to orientative levels..

1. Introduccion

El uso masivo de las radiaciones producidas por los equipos de radiodiagnóstico en el área de salud hace necesario establecer ciertos marcos que vayan a delimitar el trabajo de toma de placas radiográficas. Uno de los elementos que ayudan a establecer estos criterios es la dosis, y lo que representan los niveles orientativos, que es necesario considerarlos pero teniendo presente siempre que ligados a la dosis se encuentran otros elementos tan importantes. Entre estos elementos podemos citar, la técnica empleada para un examen dado, la calidad de la imagen que redundara en un interpretación acertada o no, el equipo radiográfico mismo con una serie de parámetros que deben ser considerados, sistema de revelado, etc. Si tomamos en cuenta todos los aspectos que involucran la obtención de la imagen radiográfica observaremos que la combinación de todos los factores hacen muy difícil establecer metodologías estándares, que permitan obtener una buena calidad radiográfica con dosis bajas.

Por lo anterior en el presente trabajo se ha buscado relacionar dos elementos, como ser la técnica usada y la dosis, y compararlos con los niveles orientativos.

2. Materiales

Para el trabajo se utilizaron los siguientes materiales:

- Medidor de tensión, no invasivo, con el propósito de establecer el valor real del kilovoltaje aplicado en el examen.
- Medidor de tiempo, para establecer el tiempo real de irradiación.
- Cristales de Fli
- Lector de cristales termoluminiscente

3. Metodología

Se han recogido información de 96 equipos de radiodiagnóstico tomando dato s de la técnica empleada, asimismo evaluando los parámetros principales señalados, además de otros como por ejemplo capa hemirreductora, coincidencias de campo y haz luminoso, precisión del medidor de distancia, sistema de revelado, tipo de placas, estado de los chasis, etc.

Además se ha tomado mediante los cristales, las dosis que reciben los pacientes. Existen también otros elementos como ser volumen de pacientes, placas repetidas, y hasta contextura física del paciente que también ha sido recabado como información, pero para efectos del presente trabajo no se considerara.

Con los datos obtenidos y la información proporcionada se han elaborado unos tablas y gráficos que nos permitirán comparar con los niveles orientativos.

4. Resultados

Variación del kilovoltaje

Rango de Variación	**Porcentaje del Total de equipos (%)**
0 kV– 5 kV	46
5 kV – 10 kV	27
10 kV – 20 kV	18
Mayor a 20 kV	9

Variación del tiempo

Diferencia Valor medido y Valor nominal (%)	**Porcentaje del Total de equipos (%)**
Menor al 5 %	31
Entre 5% y 10 %	18
Entre 10% y 20%	23
Mayor a 20%	28

Para comparar con los niveles orientativos se han considerado solo dos exámenes , tórax y abdomen.

Se han considerado los niveles orientativos indicados en las Safety Series 115 " Safety Standars for protection againt ionizing radiation and for the safety of sources" del Organismo Internacional de Energía Atómica, del Anexo II [1].

NIVEL ORIENTATIVO PARA TORAX
(0.4 mGy).

Rango	**Porcentaje de equipos (%)**
Menor o igual a 0.4 mGy	19
Entre 0.4 y 1 mGy	31
Entre 1.0 y 2.0 mGy	21
Mayor a 2 mGy	29

NIVEL ORIENTATIVO PARA ABDOMEN
(10.0 mGy).

Rango	Porcentaje de equipos (%)
Menor o igual a 10.0 mGy	78
Entre 10.0 y 20.0 mGy	13
Mayor a 20.0 mGy	9

5. Conclusiones

- En el estudio solo se han considerado las variables kilovoltaje y tiempo, y no se ha considerado la intensidad de corriente, que es otro elemento que determina la dosis recibida por el paciente en el exámenes. radiográfico.
- Solo considerando el factor tensión tendremos que menos de la mitad de los equipos evaluados se encuentran en buenas condiciones, ya que el kilovoltaje que proporcionan los equipos es similar al que indican el panel.
- En lo que respecta al tiempo, también podemos indicar que casi la mitad de los equipos radiográficos evaluados pueden considerarse en condiciones adecuadas.
- Efectuando la relación de estos parámetros con los niveles orientativos implicaría que la mitad de los equipos dan niveles de radiación similares a los niveles orientativos.
- La anterior conclusión no es cierta ya que con valores muy por debajo de los niveles orientativos, no encontramos con placas subexpuestas, que desde el punto de calidad de imagen, no será el requerido.
- Para efectuar una análisis completo no solo es necesario tener en cuenta la dosis, será preciso considerar como el elemento mas importante la calidad de la imagen.
- Será importante relacionar los parámetros de funcionamiento del equipo, sistema de revelado, técnica usada, con la calidad de imagen y dosis, para así contar con una valoración mas completa.

Referencia

NORMAS BASICAS INTERNACIONALES DE SEGURIDAD PARA LA PROTECCION CONTRA LA RADIACION IONIZANTE Y PARA LA SEGURIDAD DE LAS FUENTES DE RADIACION. Coleccion Seguridad No. 115. OIEA, AEN/OCDE, FAO, OIT, OMS, OPS. Anexo II. 1997

IAEA-CN-85-281

RESULTS OF THE STUDY OF ENTRANCE SURFACE DOSE FROM CONVENTIONAL EXAMINATIONS IN DIAGNOSTIC RADIOLOGY

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Abstracts

The wide diffusion of the X rays diagnostic together to the quick development and expansion that has come experiencing the technology in this practice, have motivated the emission of recommendations, in the Basic Safety Standards of the IAEA, for the establishment of guidance levels for different radiological examinations in each country that allow the optimization of the medical exposure. Considering the above-mentioned and the existence in Cuba of a great number of conventional X ray equipment, with an average over 10 years of use which influences directly on the patient dose, in 1999 began in the country an investigation on the patient exposure in this practice. This work shows the first results of measurements carried out in 9 major hospitals of several provinces of the country. The doses were evaluated in the examinations of lumbar spine AP, lumbar spine LAT, thorax PA, skull AP and skull LAT. The determination of the doses in these examinations was carried out by "in-vivo" measurements on the patients, placing in the center of the irradiation field TLD of LiF. The distributions obtained in the studies are compared with the guidance levels that is shown in the Basic Safety Standards of the IAEA.

1. Introducción

La radiología diagnóstica es la mayor contribuyente a la dosis colectiva de la población mundial entre todas las aplicaciones de las radiaciones ionizantes que el hombre utiliza [1]. Las variaciones en la exposición médica observadas en esta práctica, no solo entre países sino dentro de un mismo país; han motivado la emisión de recomendaciones internacionales, acerca del establecimiento de niveles orientativos de dosis para diferentes exámenes radiológicos, que permitan la optimización de la exposición médica.

Cuba cuenta en la actualidad con más de 1000 equipos de radiografía convencional instalados en el país y una tasa promedio de exámenes de radiodiagnóstico por habitantes comparables con la de los países desarrollados. Sin embargo la tecnología y los años de explotación de este equipamiento sobrepasan los 15 años, lo cual unido a dificultades en la formación en materia de protección radiológica del personal vinculado a esta práctica, hace que revista especial interés el conocimiento de los niveles de exposición recibidos por nuestra población en los exámenes de rayos X convencionales de mayor frecuencia.

El presente trabajo muestra los primeros resultados de un estudio llevado a cabo en el país para evaluar las dosis de entrada en paciente en hospitales cabeceras de diferentes provincias y la comparación de éstos con otros resultados obtenidos y/o recomendados por organizaciones internacionales.

2. Materiales y métodos

Los resultados que se presentan en este trabajo se obtuvieron de las mediciones realizadas en 9 hospitales cabeceras de 3 provincias del país y los equipos en los que se llevaron a cabo las mismas son representativos del 75 % del total de los instalados a nivel nacional. Las evaluaciones fueron realizadas para los estudios de tórax PA, columna lumbar LAT, columna lumbar AP, cráneo LAT y cráneo PA teniendo en cuenta la alta frecuencia de ejecución de los mismos en los servicios radiológicos nacionales. La metodología experimental adoptada, fue

la medición “in vivo” de las Dosis de Entrada (DE), utilizando dosímetros termoluminiscentes (TLD) de fluoruro de Litio (JR1152C) de fabricación china, cuyo tratamiento y calibración se hicieron de acuerdo con lo descrito en la literatura [2]. Los dosímetros se ubicaron dentro de pequeñas bolsas de nylon para facilitar su manipulación y en grupos de tres a fin de obtener una lectura media de las exposiciones. De esta forma fueron colocados sobre la piel del paciente en el centro del campo de radiación. Para cada equipo medido fue seleccionado un mínimo de 10 pacientes por estudio (altura y peso promedio de 1,65 m y 68 kg respectivamente), registrándose en cada caso los datos personales y aquellos relacionados con la exposición radiográfica. A los valores obtenidos de dosis, por estudio, se les realizó tratamiento estadístico para determinar el tercer cuartil y compararlo con los niveles recomendados por las Organizaciones Internacionales.

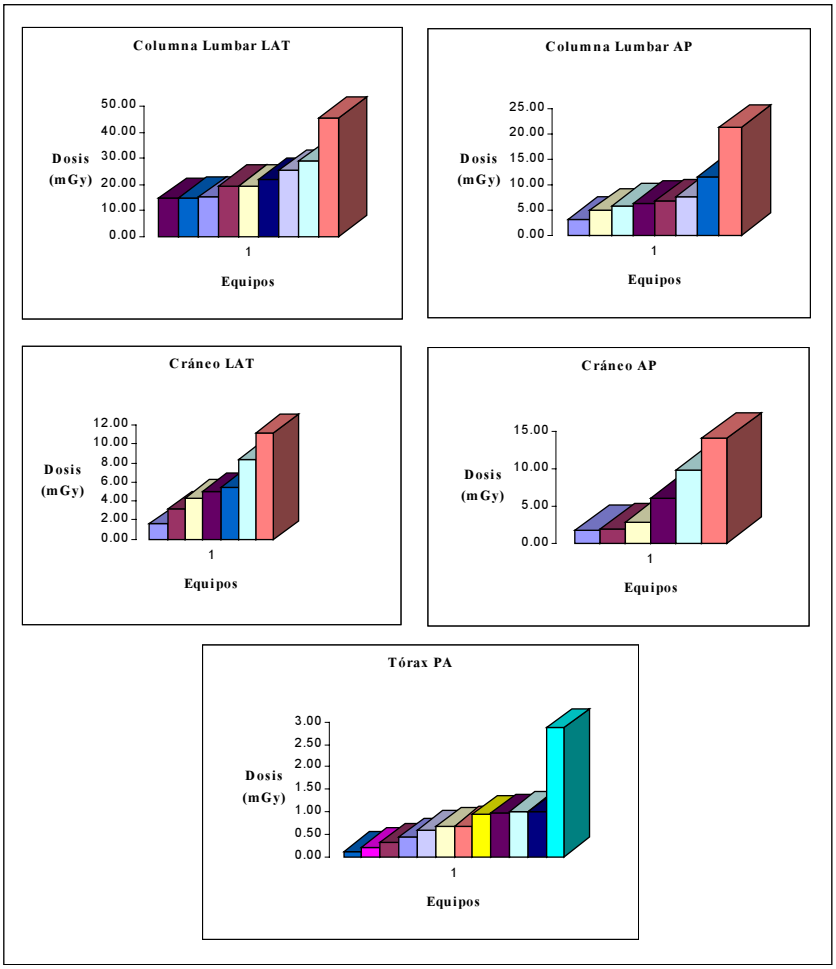

Figura 1. Valores de dosis por equipo para cada estudio

3. Resultados y discusión

Los resultados obtenidos de dosis por estudio para cada equipo, se reflejan en la Figura 1. Las variaciones observadas entre los equipos son debidas a las inconsistencias en la selección de los parámetros de exposición para similares dimensiones de pacientes. Estas inconsistencias pueden estar relacionadas con el nivel de entrenamiento de los técnicos conjuntamente con las condiciones del equipamiento disponible y el procesamiento, que hacen necesaria la selección de parámetros disímiles para lograr una calidad de imagen aceptable.

La Tabla I muestra los valores de dosis obtenidos durante este trabajo conjuntamente con los publicados internacionalmente. Se puede apreciar que en el caso de los estudios de columna lumbar AP y columna lumbar LAT no existen grandes diferencias entre el tercer cuartil obtenido en el presente trabajo con los valores recomendados por las Normas Básicas de Seguridad y los publicados por la Comisión Europea. Sin embargo no ocurre lo mismo con los restantes estudios donde las diferencias son notables. Estas discrepancias pueden estar relacionadas, con las características propias del equipamiento de nuestro país (tecnología y años de explotación superiores a 15 años) y en el caso específico de los exámenes de tórax con la utilización, como promedio, de voltajes inferiores a 90 kV.

Tabla I. Comparación de las dosis obtenidas para cada examen con otros resultados internacionales

Dosis de entrada (mGy)						
Examen	**1er cuartil**	**Media**	**3er cuartil**	**NBS**	**CE**	**EU(1)**
Tórax PA	0.5	1	1	0.4	0.3	0.2
CLS LAT	14	25	36	40	40	-
CLS AP	4	9	10	10	10	5
Cráneo AP	4	7	11	5	5	1.5
Cráneo LAT	3	6	9	3	-	-

* Leyenda:
NBS: Normas Básicas de Seguridad del OIEA
CE: Comisión Europea
EU: Estados Unidos
* (1) Estos valores representan dosis promedios o límites y no incluyen la retrodispersión

Los valores de DE correspondientes al tercer cuartil pueden ser analizados para su utilización en nuestro país como niveles orientativos. A su vez estos resultados demuestran que se requiere una investigación para precisar las causas de los valores de DE superiores a los recomendados internacionalmente en los estudios de tórax y cráneo. En todos los casos se aprecia la necesidad de aplicar técnicas de optimización entre ellas: el control de calidad periódico del equipamiento y elevar la preparación del personal que realiza los exámenes.

Una representación gráfica de la tabla anterior se muestra en la Figura 2.

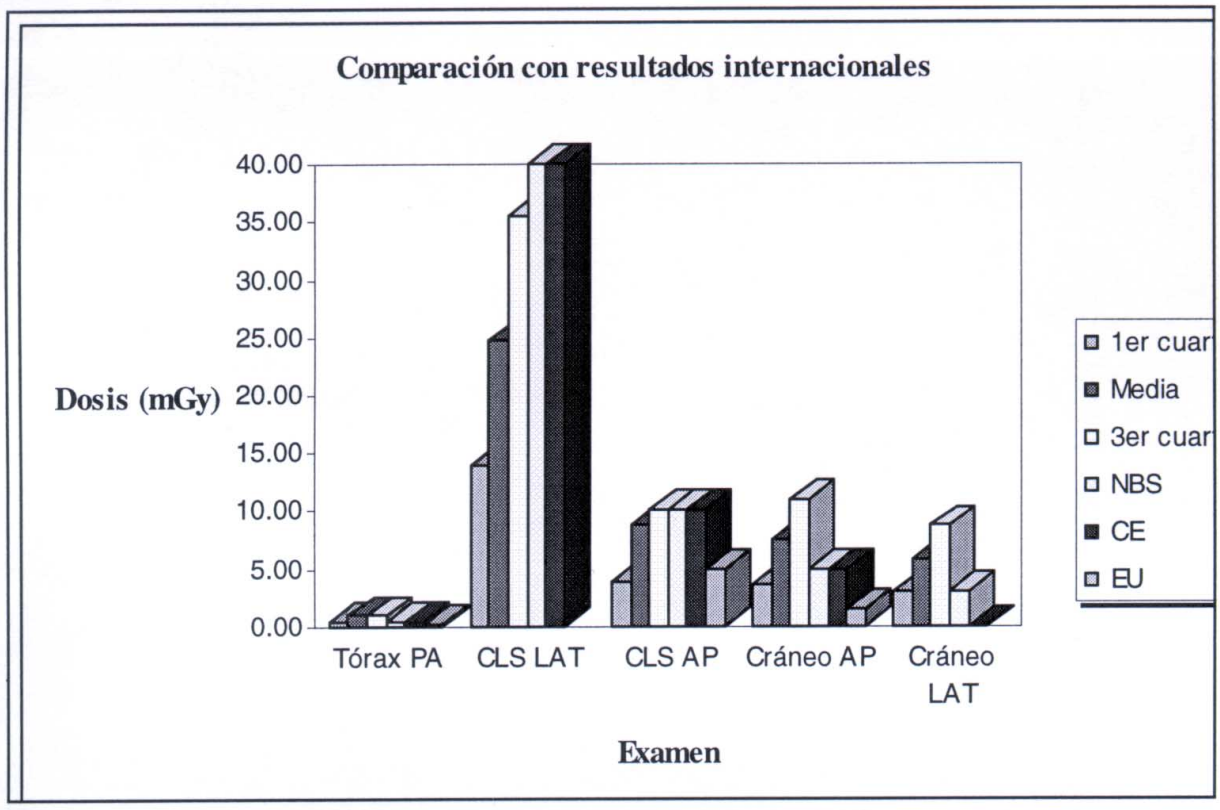

Figura 2. Comparación de las dosis obtenidas para cada examen con otros resultados internacionales

4. Conclusiones

1. Los resultados muestran que en los estudios de columna lumbar las DE que reciben los pacientes se encuentran en correspondencia con las recomendadas internacionalmente.
2. En los estudios de tórax y cráneo se aprecian diferencias con los valores recomendados internacionalmente por lo que se impone la necesidad de establecer niveles de referencia nacionales que se adapten a las condiciones actuales del equipamiento y preparación del personal.
3. El análisis de los valores obtenidos demuestra la existencia de una considerable reserva para la reducción de las dosis que reciben los pacientes mediante la selección apropiada de los factores técnicos (kVp) y del adecuado procesamiento radiográfico.
4. Las variaciones de las dosis observadas entre equipos puso de manifiesto la necesidad de implantar programas nacionales de control de calidad en la práctica de radiodiagnóstico y la importancia de llevar a cabo mediciones periódicas de DE en cada institución.
5. Teniendo en cuenta los resultados se concluye además que es necesario elevar la preparación en protección radiológica del personal involucrado en la práctica, con especial énfasis en el personal técnico que realiza las exploraciones, como eslabón importante en la optimización de la exposición médica.

Referencias

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A TRIAL TO ESTABLISH DIAGNOSTIC REFERENCE LEVELS FOR RADIOLOGICAL EXAMINATIONS IN GREECE

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Abstract

A research for the estimation of doses received by patients undergoing radiological examinations in order to establish diagnostic reference levels (DRLs) was conducted in Greece. A total of 7 big hospitals in Athens were selected and 450 patients consisted the sample. The Entrance Surface Doses (ESDs) to patients undertaking 5 common X-ray examinations (chest, cervical spine, lumbar spine AP & LAT, pelvis) were estimated using both thermoluminescent dosemeters (TLDs) attached to the patient's skin and ionisation chamber for air kerma measurements. Patient's data and exposure settings were recorded. The results from both methods coincided perfectly. The lumbar spine AP & LAT and the pelvis examinations proved to demonstrate lower DRLs than the ones recommended by the E.U. For the cervical spine examination, where there is no E.U. recommendation, the value of 1.0 mGy was established as the national DRL. In the case of the chest examinations the DRL was found to be 0.7 mGy, more than twice the recommended value. Discrepancies in the patient doses and techniques used for the examinations studied were found among the different hospitals. Results concerning the kilovoltage and Focus-to-Film-Distance (FFD) were also analysed and compared to those recommended by the E.U. Correlation between the kilovoltage and milliampere-second product (mAs) settings was found only in the cases where the Automatic Exposure Control was operated.

1. Introduction

Previous studies on radiation exposures during common medical diagnostic procedures have demonstrated that doses may have a range of up to two orders of magnitude, making clear that there is considerable need for dose reduction [1]. The Diagnostic Reference Levels (DRLs), which were set down by the European Community, are dose levels in medical radiodiagnostic practices for typical examinations for groups of standard-sized patients for broadly defined types of equipment. These levels are not expected to exceed for standard procedures when good and normal practice regarding diagnostic and technical performance is applied [2]. This work is a continuation of a previous survey [3] on the estimation of doses received by patients in Greek hospitals.

2. Materials and methods

The following routine examinations were studied: chest PA, cervical spine, lumbar spine AP & LAT and pelvis. Seven big radiology departments belonging to hospitals located in Athens participated. According to the E.U. recommendation [4], the dose measurements should be performed on standard-sized patient with an average weight of 70 ± 3 kg. In this survey the NRPB protocol [5] was followed which has suggested that at least 10 patients for each examination from every X-ray unit should be taken into account for the estimation of ESD, having weights 70 ± 20 Kg.

ESD is defined as the absorbed dose to air at the intersection point of the X-ray beam axis with the entrance surface of the patient, including backscatter radiation and can be determined by two types of dosemeters: TLDs and ionisation chambers [1].
ESD was directly measured using 3 TLDs placed on the patient's skin. The calibration procedure of the TLDs used in this survey (LiF TLD-100) showed: TLDs' batch homogeneity

20%, reproducibility 3%, minimum detectable dose 30μGy [6], energy response curve ±18% for 50-150 kVp, linearity 1%.

Indirect estimation of ESD was obtained by measuring the primary beam air kerma from the X-ray tube. For each X-ray unit a quality control test was performed in respect to kilovoltage & timer accuracy and consistency, tube output measurement (at 75 cm and 20 mA.s), tube linearity and filtration. The tube output measurements were then corrected using the inverse square law, kVp & mA.s values for each patient's examination and appropriate backscatter factors to estimate the ESD using the formula:

$$ESD = K_{air} x \frac{(\mu/\rho)_{muscle}}{(\mu/\rho)_{air}} x \frac{mAs}{20} x \left(\frac{75}{FSD} \right)^2 xBSF$$

where K_{air} is the air kerma measured, (μ/ρ) is the ratio of mass absorption coefficient to density (the ratio of μ/ρ for muscle to that for air can be taken as 1.06 for all typical diagnostic X-ray qualities) [7], FSD is the Focus-to-Skin-Distance (in cm) and BSF is the backscatter factor. The BSFs values depend on beam quality, field size and FSD and were determined from literature [8-11].

The measurements with the TLDs and the calculations with the ionisation chamber for estimating the ESD showed a very high correlation (R=0.97).

For each patient the following data were recorded: hospital, X-ray tube, examination, sex, age, weight, height, kVp and mA.s settings, Automatic Exposure Control (AEC), Focus-to-Film-Distance (FFD), film size and sensitivity of intensifying screen-film.

Table 1: Exposure parameters and ESD values

Examination	Kilovoltage	FFD (cm)	ESD (mGy)
Chest PA	94 (39)	177 (27)	0.7 (0.3)
Cervical spine	75 (43)	144 (23)	1.0 (0.6)
Lumbar spine AP	83 (40)	108 (8)	9 (3)
Lumbar spine LAT	89 (9)	111 (11)	16 (8)
Pelvis	76 (7)	107 (8)	7 (3)

The values in parenthesis represent 1SD value

3. Results

A total number of 450 patients from 7 hospitals and 13 different X-ray units were monitored in this survey. The examination types selected (chest PA, cervical spine, lumbar spine AP & LAT and pelvis) are either the commonest or represent techniques with the highest absorbed dose to the patient. The exposure parameters and the ESD values for each type of examination are presented in Table 1. It should be noted that the ESD values are given as the 3rd quartile of the estimated value, according to the European Commission suggestions [2]. For each type of radiograph included in the CEC Working Document [12] there is "an example of good radiographic technique" in which values are recommended for various parameters, such as kilovoltage and Focus-Film-Distance, which should enable the dose criteria to be met. Table 2 presents the suggested exposure parameters and the percentage of the examinations meeting them. The formula for the ESD values shows the inverse relation between kVp and mA.s. Table 4 presents the findings for such relation for all the X-ray units.

Table 2. Recommended exposure parameters and coincidence in this study

Examination	E.U. kVp Coincidence (%)	E.U. FFD (cm) Coincidence (%)	E.U. DRLs (mGy) Coincidence (%)
Chest PA	125 6%	140-200 90%	0.3 50%
Cervical Spine	60-80** 80%	140-180** 63%	1.0** 75%
Lumbar spine AP	75-90 61%	100-150 100%	10 85%
Lumbar spine LAT	80-95 59%	100-150 100%	30 100%
Pelvis	75-90 46%	100-150 100%	10 100%

*The recommended kVp are taken as 120-130
** These values are considered to be the recommended ones

Table 3. Maximum-to-minimum ratios for ESD values

Examination	Max/Min of ESDs for all patients	Max/Min of mean ESDs between all X-ray units
Chest PA	57	5
Cervical Spine	31	7
Lumbar spine AP	20	6
Lumbar spine LAT	26	8
Pelvis	17	9

Table 4. The kVp-mA.s correlation

X-ray unit	AEC	mA.s v kVp
TUR D703, Siemens Tridoros 5S	No	$mAs \propto kVp^{n}$
Philips Optimus, Siemens Opti 150, Siemens Opti 150	Yes	$mAs \propto kVp^{-n}$
Siemens Gigantos 1012E, Siemens Polyphos 50, CGR Triplunix T	No	mAs constant
CGR Dualix a, CGR Dualix 825, Siemens Tridoros 150,Siemens Tridoros 5S, Siemens Tridoros 5S	No	No correlation

4. Discussion

Table 2 shows that in the case of the chest examinations 90% of them had FFD in the range of 140-200 cm but in less than 10% the 125-kVp setting was used. The ESD value was found to be 0.7 mGy, which is more than twice the recommended value of 0.3 mGy. The non-compliance of the ESD with the E.U. guideline is quite surprising since the latest has been set rather high so as not to discourage users. It is obvious that the “hard setting” technique recommended by the E.U. is not adopted by the radiology labs. 50% of the cases had ESD values exceeding the recommended one. Considering the cases where at least one of the recommended E.U. settings (either kVp or FFD) was followed, the ESD for the chest

examination reaches the value of 0.5 mGy. Only when both the FFD and the kVp recommendations are fulfilled (the kilovoltage taken in the range 120-130) the ESD falls to 0.2 mGy.

As far as the cervical spine examinations is concerned there are no E.U. recommendations. The survey showed that, considering the ESD value of 1.0 mGy as acceptable, the optimal kilovoltage and FFD ranges would be 60-80 kVp and 140-180 cm respectively.

It can be seen that the lumbar spine AP & LAT and the pelvis examinations fulfilled by 100% the recommendations for the 100-150 cm FFD range.

As far as the kilovoltage setting is concerned, the lumbar spine AP & LAT examinations followed by approximately 60% the recommendation for 75-90 kVp and 80-95 kVp range respectively while the pelvis examinations followed by less than 50% the range of 75-90 kVp. Almost 100% of the estimated ESD values for the lumbar spine LAT and pelvis examinations and more that 80% for the lumbar spine AP were below the E.U. DRLs.

Table 3 shows the maximum-to-minimum ratio of ESD values for individual patients and between hospitals. It can be seen that the ESDs for chest examination vary up to 57 times individually but only 5 times between the various hospitals. While each hospital has a wide range of ESD values due to the different radiographic techniques used, the mean ESD for each projection does not vary as greatly from hospital to hospital.

It is obvious from Table 4 that only in the cases where the Automatic Exposure Control was used, the choice of mA.s was inversely proportional to the kVp setting. The findings, surprising enough, make the need for revision of the radiographic techniques used urgent.

It is clear that in the case of the chest examinations immediate measures have to been taken in order to minimise the ESD value. In the other examinations the ESD values proved to be quite satisfactory and below the European guidance dose levels. Differences from the results presented in a previous paper [3] may be attributed to different sample sizes.

5. Conclusion

This study clearly showed that there is a need to harmonise the practices followed by the technologists in order to meet the European criteria for radiographic images and to this direction the establishment of examination protocols provided by the new radiation protection regulations will be of great importance. Additionally, efforts to update the equipment installed in the radiology departments should be made. DRLs can encourage changes in working procedures and equipment by showing what is possible and achieved in other departments.

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IAEA-CN-85-21

PATIENT EXPOSURES FROM DIAGNOSTIC RADIOLOGICAL PROCEDURES IN INDIA

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Abstract

It is very well recognised that the ratio of diagnostic information / patient dose must be optimised in diagnostic radiology for each type of examination. Regulatory authorities in various countries are now engaged in developing dose constraint values for various X-ray examinations. In a co-ordinated research project, Atomic Energy Regulatory Board (AERB) and Bhabha Atomic Research Centre (BARC), India, conducted a nationwide survey to assess the impact of diagnostic radiological practices on population dose in the country. Forms were designed to collect data on :-(i) X-ray examinations, (ii) details of X-ray machines, (iii) type of work and workload in different hospitals, and (iv) X-ray examination techniques and associated technical parameters. Entrance skin doses were estimated by using specially designed and calibrated TLD postal packs. The entrance skin dose was estimated for a particular examination in a hospital on the basis of TL reading of disc under perspex filter, taking into account the focus-to-skin distance, back-scatter factor, the mass energy absorption coefficient and the mAs actually used for the examination. The analysis of entrance skin doses estimated for 12 common X-ray procedures in these 40 hospitals showed that for the most part these doses fall within the reference levels specified in the Basic Safety Standards (BSS).

1. Introduction

In diagnostic radiology, it is prudent to optimise the ratio of diagnostic information/ patient dose for each type of examination. Since the radiation safety standards are not optimised in all the hospitals, there is a wide variation in this ratio. Many countries have introduced comprehensive Quality Assurance programmes for diagnostic procedures, which has led to the gradual reduction in the patient doses, over the years, for the same acceptable quality of the diagnostic images. The dose reductions have now been optimised at levels, which can be, considered minimum for the diagnostic information expected with good quality images. For optimising protection for medical exposures these reference doses should be followed as guidance levels for different procedures. Since the medical procedures are justified because they directly benefit the patients, less attention has been given to the optimisation of protection for medical exposures than for most other applications of radiation sources. As a result, there is considerable scope for dose reduction in diagnostic radiology (ICRP-60). Regulatory authorities in various countries are now engaged in developing dose constraint values for various X-ray examinations.

In a co-ordinated research project, Atomic Energy Regulatory Board (AERB) and Bhabha Atomic Research Centre (BARC), India conducted a nationwide survey to assess the impact of diagnostic radiological practices on population dose in the country. For this purpose, support of Radiological Safety Officers (RSOs), attached to different Radiotherapy centres, in 10 different regions of the country was sought. These RSOs were designated as chief investigators for collection of the data. Forms were designed and were utilised to collect data on :-(i) X-ray examinations including age and sex of patients and projection, (ii) Details of X-ray machines, e.g., Type, make & model, kVp (max), mA (max), total filtration, beam collimation method, lead equivalence of the Pb glass backing of fluoroscopic screen, focus-to-table top distance, availability of radiation safety accessories, etc., (iii) type of work and workload in different

hospitals, and (iv) X-ray examination techniques and associated technical parameters. The data collected from various hospitals were used to estimate the frequency of X-ray examinations as well as the age and sex wise distribution of the patients in the country. The data also helped in assessing radiation safety status of radiology departments and in finding inadequacies in radiation protection features of X-ray units in the country. This data was collated and analysed at BARC. As a part of the project, entrance skin doses for most common X-ray examinations were measured in 40 different hospitals using TLD postal pack developed in the Division [1]. Entrance skin doses were estimated by using TLD postal packs in different hospitals distributed in different regions of the country. RSOs at the participating centres assisted in irradiation of TLD postal packs used for estimation of entrance skin doses during different diagnostic radiological procedures in different hospitals.

2. TLD postal pack

The TLD postal pack consists of $CaSO_4$: Dy teflon TLD discs (0.8 mm x 7 mm ϕ), arranged in 4 rows with 4 TLD discs in each row, covering each row of TLD discs with 4 different filters on front side viz. 0.5 mm perspex, 0.3 mm Cu, 0.5 mm Sn + 0.3 mm Cu and 1.0 mm Cu and a 2.0 mm copper backing plate. The size of the pack is only 6 cm x 6 cm x 0.4 cm. $CaSO_4$: Dy Teflon TLD discs were used because of high sensitivity of $CaSO_4$: Dy phosphor and its nearly flat energy response (within ± 10%) in diagnostic X-ray range of 40 kVp - 125 kVp. The TLD postal pack facilitates simultaneous measurement of output, tube potential (kVp), HVT and total filtration. The output of the X-ray tube is measured by TL readouts of discs under 0.5-mm thick perspex filter. The HVT is estimated by using the ratio of TL readouts under 1 mm thick copper filter to that under 0.5 mm perspex. For the estimation of tube potential ≥ 75 kVp, the ratio of TL readouts under combined 0.5 mm tin + 0.3 mm copper filter to that under 0.3 mm copper filter is used and for tube potentials < 75 kVp, the ratio of TL readouts under 1 mm thick copper filter to that under 0.3 mm copper filter is used. The ratio under 1 mm of copper to that under 0.3 mm copper increases linearly with tube potential up to 80 kVp, beyond which it becomes sub-linear, whereas the ratio under combined 0.5 mm tin + 0.3 mm copper to that under 0.3 mm copper increases linearly up to 125 kVp. For estimation of kVp and HVT from the ratios of TL outputs under various filters, as mentioned above, the ratios given in Table-I are used.

Table I. Ratio of TL outputs under various filters for different Tube Potentials (kVp) and Half Value Thickness (HVT in mm Al) for TLD Postal Pack

Tube Potential (kVp)	HVT (mm Al)	Ratio of TL Outputs		
		1Cu / 0.3 Cu	(0.5 Sn +0.3 Cu) / 0.3 Cu	1 Cu / 0.5 Perspex
60	2.325	0.1161	0.02684	0.01738
70	2.600	0.1743	0.02714	0.03267
81	3.040	0.2202	0.04501	0.04781
90	3.400	0.2497	0.06123	0.06413
102	3.950	0.3011	0.08622	0.08030
117	4.375	0.3114	0.10410	0.09194
125	4.956	0.3532	0.12013	0.11041

The TLD postal pack was found to measure tube potential with an accuracy of ± 5 kVp, in the range of 40 kVp to 130 kVp; the air-kerma output was within ± 5%; and total filtration was within ± 0.5 mm Al equivalence, for X-ray beams with a filtration above 2 mm Al equivalent.

3. Estimation of entrance skin dose

For estimation of entrance skin doses of patients undergoing various radiological examinations following procedure is adopted: - Irradiation of TLD postal packs (without patient) were made at focus-to-TLD pack distance of 50 cm. A range of kVp most commonly used in the hospital was used for irradiation. The mAs used corresponded to the kVp. **(Table-II).** Appropriate calibrations of TLD packs had been first made. The entrance skin dose was then estimated for a particular examination in a hospital on the basis of TL reading of disc under perspex filter, taking into account the focus-to-skin distance, backscatter factor, the mass energy absorption coefficient and the mAs actually used for the examination. Thus,

$$\mathbf{ESD_E=(Air\ Kerma\ /\ mAs)_{50,\ kVp(E)}\ .(50/\ FSD_E)^2.\ (mAs)_E.(BSF)_{HVT\ (E)}.(\mu_{en}/\rho)^{muscle}_{air}}$$

Where,
ESD_E is Entrance skin dose for examination (E),
$(Air\ Kerma\ /\ mAs)_{50,\ kVp\ (E)}$ is the measured Output of X-ray tube per mAs on the central axis of the beam at 50 cm from focus, and tube potential kVp, used for the examination, obtained from TLD postal pack,
$(50/\ FSD_E)^2$ is inverse law correction for the focus-to-skin distance (cm) actually used for the examination (E),
$(mAs)_E$: mAs used for the examination (E),
$(BSF)_{HVT\ (E)}$: Backscatter factor for quality of beam used for the examination (E),
$(\mu_{en}/\rho)^{muscle}_{Air}$: Ratio of mass energy absorption coefficient for energy used for the examination.

Table II. Exposure Chart for TLD postal pack/ (for 20 x 20 cm² field at focus-to-pack distance: 50 cm)

X-ray Tube Potential (kVp)	Exposure (mAs)
40	1000
50	250
60	180
70	120
80	100
90	80
100	60
120	40

On the basis of number of X-ray examinations per 1000 population estimated during a previous survey [2] and increase in the consumption of X-ray films and the population since

then, the number of X-ray examination per 1000 population has been estimated as 150. The number of examinations has been estimated as 140 million per year. Age, sex and examination wise distribution of patients was obtained from the data collected in this survey. The data on details of X-ray equipment provided the status of radiation safety in diagnostic radiology. **Table III** reports on analysis of the entrance skin doses during some common X-ray examinations. The mean, standard deviation, median, the first and third quartiles are shown in **Table-III.**

Table. III: An analysis of skin entrance doses during different examinations, as measured in 40 hospitals during the Co-ordinated research project on patient organ dose measurements during diagnostic radiology

Examination	Skin Entrance Dose (mSv)						
	Mean	SD	Median	First Quartile	Third Quartile	BSS guidance level	No. of values below BSS guidance level
Chest (PA)	0.23	0.10	0.21	0.16	0.29	0.4	37
LS (AP)	7.34	3.41	7.5	4.4	9.4	10	31
LS (LAT)	19.85	8.98	19.2	14.5	22.8	30	34
Pelvis/Hip(AP)	8.31	2.61	7.9	6.7	9.4	10	31
Abdomen (AP)	6.56	2.44	6.2	4.9	7.6	10	36
Skull (AP)	4.56	2.33	4.0	3.0	5.5	5	26
Skull (LAT)	4.37	1.53	4.2	3.1	5.2	3	8
CS(AP/LAT)	1.37	0.74	1.3	0.7	1.8	-	-
Urography	5.81	2.57	5.5	3.7	7.1	10	37
Extremities	0.35	0.25	0.29	0.19	0.39	-	-
TS (AP)	5.14	2.32	4.6	3.2	6.1	7	32
TS (LAT)	12.59	6.34	11.4	5.9	17	20	35

4. Results and discussions

The BSS guidance levels and the number of values below the guidance levels, in the investigated diagnostic examinations, in the 40 Indian hospitals in the present survey, are listed in Table-III. It is obvious from this Table that there is a large variation in entrance skin doses for any particular examination from machine to machine, which is a common observation, in other countries as well. The analysis of entrance skin doses estimated for 12 common X-ray procedures in these 40 hospitals shows that, for the most part, these doses fall within the reference levels specified in the Basic Safety Standards (BSS). Guidance levels for different diagnostic X-ray examinations can be prepared following the method outlined above and these data can be used to obtain diagnostic information commensurate with clinical requirements without undue radiation doses to the patient.

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NEED FOR HARMONISATION IN THE ESTABLISHMENT AND USE OF REFERENCE DOSE LEVELS IN RADIOLOGY

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Abstract

Surveys of patient dose in diagnostic radiology revealed a wide variation in doses to patients for the same types of x-ray examination. The large dose variations found in the surveys focused the attention to possibilities for dose reduction in diagnostic radiology. Reference doses were proposed to foster the elimination of doses at the high end of the distributions. Different proposals concerning the establishment and use of reference dose levels (RDLs) have been made by international organisations involved in radiological protection. In practice the diversity of approaches concerning RDLs is even larger. It is concluded that there is need for harmonisation.

1. Introduction

Surveys of patient dose in diagnostic radiology in the 1950s in the UK [1], in the 1970s in the USA [2], in the 1980s in English hospitals [3] and in 1991 in Europe [4] revealed a wide variation in doses to patients for the same types of x-ray examination. The large dose variations found in the surveys focused the attention to possibilities for dose reduction in diagnostic radiology. Reference doses [4,5] were proposed to foster the elimination of doses at the high end of the distributions.

The International Commission on Radiological Protection (ICRP) [6] recommends the use of diagnostic reference levels (DRLs). For diagnostic radiology, the ICRP states that these levels, which are a form of investigation level, apply to an easily measured quantity, usually the absorbed dose in air or in a tissue-equivalent material at the surface of a simple standard phantom or a representative patient. In practice, DRLs can initially be selected as a percentile point on the observed distribution of doses to patients. Finally, the ICRP [6] recommends that the values should be selected by professional medical bodies, be reviewed at suitable intervals and be specific to a country or region.

The International Atomic Energy Agency (IAEA) [7] introduced the term guidance level as a level of a specified quantity above which appropriate actions should be considered. The guidance levels are intended to be a reasonable indication of doses for average sized patients. They are to be established by relevant professional bodies in consultation with the regulatory authority following the guidance levels given by the IAEA [7]. The levels are intended to provide guidance on what is achievable with current good practice rather than on what should be considered optimum performance. The guidance levels are to be applied with flexibility to allow higher exposures if these are indicated by sound clinical judgement and to be revised as technology and techniques improve.

In the Medical Exposure Directive (MED) [8] it is stated that Member States of the European Union shall promote the establishment and use of DRLs for radiodiagnostic examinations, and the availability of guidance for this purpose having regard to European DRLs where available.

In the present contribution the various approaches followed for the establishment and use of reference dose levels are discussed

2. Dose surveys and the establishment of diagnostic reference levels

Based on the national survey of doses to patients undergoing a selection of routine X-ray examinations in English hospitals [3], national reference dose levels have been established in the UK [5] for standard adult patients. They are obtained as rounded third quartile values of the mean hospital dose distribution, in terms of entrance surface air kerma (including backscatter). Similarly, reference values were established for more complex examinations in terms of air kerma-area product.

In European Guidelines [4,9] reference levels were obtained from European dose surveys for adult and paediatric patients, as rounded third quartile values. Reference dose values for mammography using a 4.5 cm thick polymethylmethacrylate (PMMA) phantom are presented in Ref. [10] as a function of optical density on the mammogram. For CT [11] reference levels are proposed for routine examinations in terms of weighted CT dose index [11] and in terms of dose length product [11]. The reference values again correspond to rounded third quartile values from dose surveys using standard head and body CT dosimetry phantoms.

As the MED [8] has to be implemented in the national legislation of the EU Member States and in practice, various proposals for reference dose levels have been published, (to be) based on dose surveys. A summary of proposals presented during a workshop entitled "Reference Doses and Quality in Medical Imaging" held in Luxembourg in 1997 is given in Table I. In addition, proposals for local reference dose levels were presented during this workshop.

TABLE I. SUMMARY OF PROPOSALS FOR REFERENCE DOSE LEVELS PRESENTED DURING A WORKSHOP HELD IN LUXEMBOURG IN 1997

Country	Reference	Quantities[a]	Concept
Germany	[12]	$K_{a,e}$, $K_{a,i}$, KAP, DLP	Various including, 3rd quartile
Germany	[13]	$K_{a,i}$, $K_{a,A}$,, E_{Fluor}	3rd quartile
Netherlands	[14]	$\underline{K}_{a,e}$ rate (fluoroscopy)	3rd quartile
Netherlands	[15]	E, $K_{a,i}$, KAP	3rd quartile
Sweden	[16]	D_G	Reference (target) levels
Nordic	[17]	$K_{a,e}$, KAP	Guidance levels

[a] $K_{a,e}$ is entrance surface air kerma (including backscatter), $K_{a,i}$ incident air kerma (not including backscatter), KAP air kerma-area product, E_{Fluor} effective dose due to fluoroscopy, E effective dose and D_G mean glandular dose.

2.2. Discussion of various aspects related to reference dose levels

It should be noted that RDLs are not applicable to individual patients due to possible differences in procedures (Section 3.4) and patient dimensions (Section 3.5).

2.3. Dosimetric quantities

The dosimetric quantities indicated in Table I are not all easily measurable, as proposed by the ICRP. In Refs. [13, 15] RDLs are expressed (also) in terms of effective dose and in Ref. [16] target doses for mammography are given in terms of mean glandular dose. Therefore, in this paper the term reference dose level (RDL) is used instead of DRL.

The dosimetric quantities for specification RDLs are usually $K_{a,i}$ $K_{a,e}$ or KAP. The use of these quantities has as a restriction that they are relevant for patient dose only when the techniques (x-ray spectrum, field size etc.) and patient dimensions are approximately constant. Otherwise the use of effective dose will be more appropriate, or RDLs should be established in dependence on the techniques applied and patient dimensions.

2.4. Selection of reference dose level from results of dose surveys

Not all the proposals are following the concept of using third quartile values of widespread surveys as the basis for selection of a reference dose level. The concepts used are not always apparent but some proposals appear to be redefining the purpose of RDLs into a guide to optimum performance or minimum achievable doses compatible with the diagnostic need (guidance levels or target levels in Table I).

2.5. Status of the proposals

According to the ICRP [6] professional medical bodies should select DRLs. According to the IAEA [7] guidance levels are to be established by relevant professional bodies in consultation with the regulatory authority following the guidance levels given by the IAEA. In the MED [8], Member States shall promote the establishment and the use of DRLs, and the availability of guidance for this purpose having regard to European DRLs where available.

In the UK national RDLs are established by relevant professional bodies [5], but not in (formal) consultation with the regulatory authority. The status of the recommendations of the recent proposals (Table I) is less clear and also differ from recommendations in Refs. [6-8]. The German proposal in Ref. [12] has been made by the Federal Office for Radiation Protection in consultation with an expert group of physicians and medical physicists. The recommendations presented in Refs. {13-15} are of scientific value but do not have any official status. The target dose levels for mammography [16] and the Nordic guidance levels [17] are published by national radiation protection authorities.

In practice, it might be preferable to establish national RDLs by professional bodies (national societies of radiologists, medical physics experts and radiographers) jointly with regulatory authorities. Regional or local professionals might establish regional or local RDLs, at lower values than the national levels, if available.

2.6. Differences in procedures

When RDLs are exceeded, it should be noted that the complexity of the procedure might be different from that for which the RDL was established. RDLs could also be exceeded for particularly large patients, unless patient size is taken into account in the RDL. For complex procedures, e.g. in interventional radiology it might be difficult to establish RDLs unless some classification of the complexity of the procedure is provided. Furthermore, it should be stressed that RDLs are aimed at patient dose reduction but the required diagnostic information is also of major importance. This means that in individual cases, the exceeding of RDLs will be justified when the required diagnostic information is essential for patient treatment.

2.7. Measurements with patients or phantoms

The ICRP [6] indicates that a simple standard phantom or a representative patient can be applied to establish or use a DRL. When a phantom is used it should be made sure that it is representative for the average patient. The use of a phantom does not provide information on the influence of variations in patient dimensions on patient dose. The advantage of the use of a phantom is that the number of measurements is smaller than that in the case of measurements with patients.

Measurements with patients have as advantages that the influence of variations in patient dimensions on patient dose are obtained and that there is no need to design and construct representative phantoms. Sometimes only a selection of patients is used for establishing RDLs. This is an approximation of the representative patient mentioned by the ICRP [6]. However, in this way the dose variations will be underestimated. When measurements are made with patients the selection criteria, e.g. size and sex should be specified.

2.8. Corrective actions

The corrective actions to be undertaken when a RDL is systematically exceeded should be specified, including procedures of continuing use under special circumstances.

2.9. Benefits achieved by using national RDLs

Periodic monitoring of patient doses employing the UK national protocol [5] has become widespread in the UK. A review of 1995 [18] showed that by then only about 10 percent of the hospitals exceeded the reference doses for common conventional x-ray examinations. The mean and third quartile values of the dose distributions had dropped by about 30 percent since the national survey in the 1980s [3].

3. Conclusion

RDLs are a valuable tool to achieve patient dose reduction. However, the different approaches met in practice clearly indicate a need for harmonisation.

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IAEA-CN-85-248

PATIENT DOSE SURVEYS AND THE USE OF LOCAL AND NATIONAL DIAGNOSTIC REFERENCE LEVELS

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Abstract

Patient doses have been assessed routinely as part of quality assurance programmes in a group of National Health Service and private hospitals in a southern English health region. Surveys of patient dose have been conducted in plain film radiography, fluoroscopy, computed tomography, mammography and dental radiography. In keeping with national guidance, dose parameters used were entrance skin dose for radiography, dose area product for fluoroscopy, effective dose and dose length product for computed tomography (CT), mean glandular dose for mammography and air kerma and dose width product for dental intra-oral and orthopantomography (OPG) respectively. Comparison of results against recommended standards showed that in plain film radiography and fluoroscopy, doses were well below national reference levels and corresponding local reference levels were adopted at about 75% of the national figures. Elsewhere in CT, mammography and dental radiography, doses were generally in line with national trends. Overall, as an integral part of the QA programme, the dose surveys have contributed greatly to the users understanding of patient dose and in several instances has led to real optimisation.

1. Introduction

As part of the provision of a radiation protection and diagnostic radiology physics service to around 50 hospitals, 30 mammography units and 130 dental practices in the South East of England, sampling of the doses received by patients during common X-ray examinations is undertaken. Results are compared to relevant Diagnostic Reference Levels (DRLs) as an aid to optimisation and in compliance with the EC Directive [1] and UK legislation [2] on the protection of the patient.

2. Methods

Patient dose surveys for plain film radiography and fluoroscopy have been undertaken periodically in accordance with the national dose protocol which recommends that such surveys are carried out at least once every 3 years [3]. Surveys of patient dose have also taken place in computed tomography, mammography and dental X-ray.

For plain film radiography, the patient dosimetry programme started in 1993 and two cycles were completed covering 64 and 77 X-ray departments respectively. In accordance with the recommended protocol, thermoluminescent dosemeters (TLDs) were used to measure entrance skin doses for 5 common examinations; chest, skull, lumbar spine AP, lateral lumbar spine and pelvis. Only standard size patients (60 to 80 kg) were used in the study with generally 10 patients per examination.

Dose area product (DAP) is the recommended dose parameter for complex examinations including fluoroscopy. Since 1995 DAP data have been collected for barium studies, angiography and interventional procedures covering 37 screening rooms in 23 hospitals involving about 10,000 patients.

In CT the effective dose for common examinations has been assessed from knowledge of exposure protocols and measured computed tomography dose index (CTDI) values utilising published CT scanner data [4]. An initial patient dose survey of 8 CT scanners was

undertaken in 1996 and subsequently repeated in 1999/2000 for 7 of the original units plus 3 new scanners. In keeping with the European protocol [5], doses are now also compared to the parameter dose length product (DLP).

The Service undertakes routine performance measurements on 30 mammography units locally including 12 in the national breast screening programme and 18 located in the symptomatic mammography sector. In accordance with the recommended protocol [6] assessment of mean glandular dose is undertaken routinely every 6 months for the 'standard breast' model. Calculation of mean glandular dose using exposure and breast thickness data from samples of patients undergoing mammography is also carried out periodically.

Radiation protection and performance measurements are undertaken on all dental X-ray on a 3-yearly cycle. Since 1997 doses have been assessed on 357 intra-oral and 70 OPG X-ray units using measurements of radiation output. In keeping with national guidance [7] dose parameters used were skin entrance dose for intra-oral and dose width product for OPG.

3. Results

The results of two rounds of patient dose surveys for plain film radiographic examinations carried out over 1992-1995 and 1996-1999 respectively is summarised in table I. The mean values presented across all hospitals for the common examinations studied are compared to the national reference doses published in 1992. The local doses were well below national levels and local reference doses, also shown, were derived from the first round of local dose measurements.

Table 1. Skin entrance dose for plain film radiography

	No of pts	Mean dose (mGy)		% National Reference Dose		Local ref dose (mGy)
		92-95	96-99	92-95	96-99	
Abdo AP	682	5.1	4.8	51	48	7
Chest PA	1601	0.14	0.12	50	40	0.2
L spine AP	866	5.9	5.2	59	52	7
L spine Lat	876	15.3	13.2	51	44	20
Pelvis	638	5.2	4.0	52	40	7

The results of DAP measurements for more than 7500 patients are summarised in table II, highlighting the mean DAP for barium enemas and meals across 30 screening rooms. In the 1992 dose protocol these were the only examinations commonly undertaken in local screening rooms where reference doses were provided. Again, local doses were generally well within national figures and consequently local reference doses based on these values were adopted. The relative impact of local and national reference doses for barium enemas is illustrated in the distribution of doses in Figure 1.

Table 2. Dose area product values for fluoroscopy examinations

Examination	Nos of patients	Mean DAP Gy cm2	% National Ref Level	Local Ref Dose Gy cm2
Ba Enema	3242	31.8	53	40
Ba Meal	1032	11.7	47	15
Ba Swallow	540	7.5	-	10
Ba FT	184	13.7	-	20
Femoral Arteriogram	676	54.6	-	80
Coronary Angiogram	372	35.9	-	50
Coronary Angioplasty	88	34.8	-	35
Venogram	558	4.4	-	5
ERCP	399	11.1	-	12
HSG	216	5.9	-	8
Nephrostomy	92	11.9	-	16
Fibroid embolisation	255	84.0	-	105

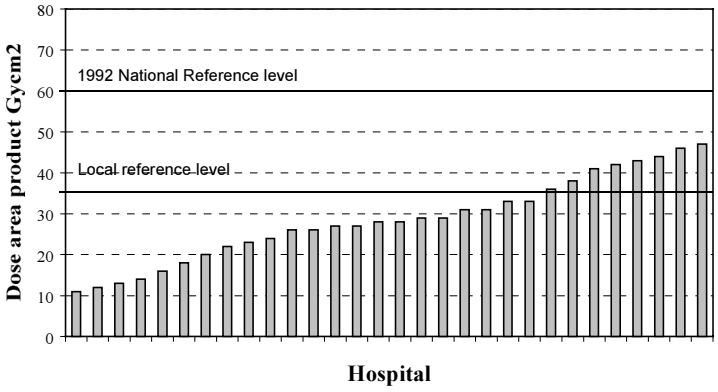

Figure 1. Dose area product for barium enemas

Table 3. Effective and dose length product for computed tomography examinations

Examination	Dose (mSv)		Dose-length Product (mGy cm)			
	Mean	NRPB Mean	Minimum	Maximum	Mean	EC Ref
Brain	2.08	1.78	316	2196	870	600
Neck	2.35	-	143	1107	552	-
Pelvis	6.93	7.12	216	655	423	600
Abdomen	7.01	7.58	469	989	414	800
Chest (normal)	9.04	7.80	162	790	409	650
Liver	6.00	7.17	151	723	364	-
IAM	0.63	0.35	100	641	298	-
L-spine	4.64	3.33	56	450	292	-
Chest (high resolution)	1.34	-	30	104	92	-

The mean effective dose for common CT examinations, based on a standard patient model, is shown in table III. These values are also compared to the means from a national survey conducted by the National Radiological Protection Board (NRPB) [8]. The corresponding range and mean of DLPs is also presented for the same nine examinations.

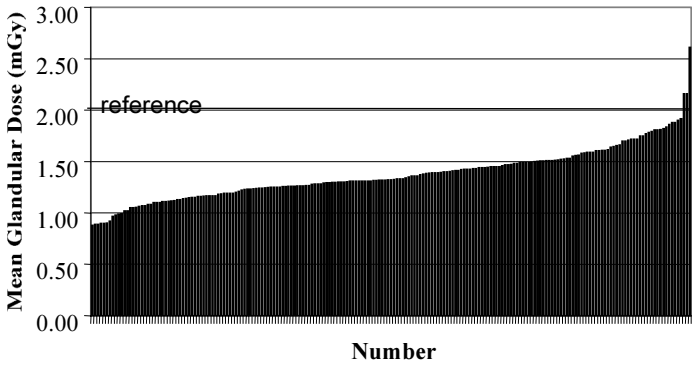

Figure 2. Mammography Dose to the "standard breast

The results for mammography in Figure 2 indicate variation in dose due to equipment factors only as a 'standard breast' is defined. Variations in X-ray equipment design, speed of the film and screen combination and variation in film optical density are the main factors affecting the distribution of patient dose. The reference dose indicated on the graph is used as a maximum recommended level, above which further optimisation of the system is indicated or justification for continued use is required. Surveys of patient dose based upon exposure factor data for real examinations additionally include variations due to the size and composition of the breast and also operation of advanced automatic exposure systems with the capability to modify X-ray beam quality.

Patient doses in dental radiology are illustrated in figs 2 and 3 for mandibular molar intra-oral and OPG examinations respectively.

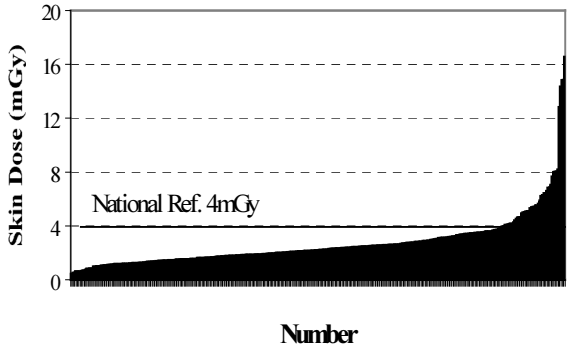

Figure 3. Dental Intra-oral doses (Mandibular Molar) mGy

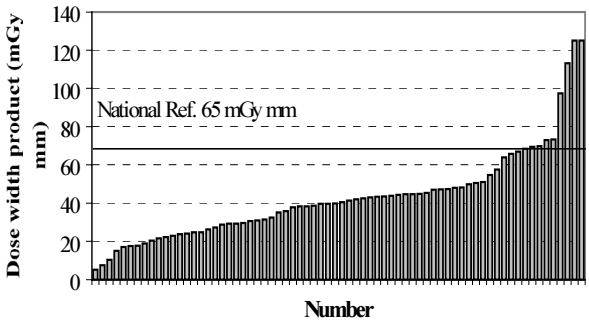

Figure 4. Dental Panoramic doses (mGy mm)

4. Discussion and conclusions

In the UK reference doses for radiography and fluoroscopy, based on dose measurements in the late 1980's and very early 1990's, were published in 1992 as part of the national dose protocol [3] and have remained unchanged. The first round of local dose measurements for radiography confirmed, not unexpectedly regarding the increase in film speed and other dose reduction features introduced since the 1980's, that examinations at all hospitals were generally well within national reference doses. Typically the mean doses for each examination were about 50% of the reference dose. Since the national reference dose no longer impacted on the optimisation process, local reference doses, based on the 75th percentile of the dose distribution from the first round of measurements, were adopted. As shown in table I, the second round of measurements showed slight reductions in mean doses for most examinations.

A similar picture emerges for the fluoroscopy dose surveys where the measured dose area products for barium enemas and meals were again at about 50% of the national reference dose. Local reference doses were adopted in the same manner for these and ten other examinations.

In CT no formal reference doses have been published in the UK and instead the doses for examinations have been compared to mean dose values published by the NRPB [8] following a survey of CT practice. In a number of cases, by demonstrating that doses at some hospitals exceeded national means, radiologists were persuaded to review examination protocols and optimise exposure factors and technique.

In mammography, the use of a reference dose based on a 'standard breast' has enabled identification of systems where patient dose has not been optimised, or imaging materials and X-ray equipment have been poorly matched. Also, identification of incorrectly adjusted film processors or AEC systems has been possible.

In dental radiography, reference doses have only recently been recommended [7]. As illustrated in figures 2 and 3, small but significant numbers of clinics exceeded the reference doses. Dose reduction strategies were then targeted at these clinics.

Overall, the use of reference doses in all areas of radiology is demonstrated to be beneficial to the optimisation process and even where no formal national figures exist comparison can be

drawn with relevant local dose measurements. Small but significant dose reductions have occurred and the use of local reference dose levels, where the user relates naturally to other local hospitals, has been found to be of particular merit.

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AN APPROACH TO LOCAL DIAGNOSTIC REFERENCE LEVELS (DRL's) IN THE CONTEXT OF NATIONAL AND INTERNATIONAL DRL's

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Abstract

In recent years there has been a greater focus on the management of patient doses. This effort has been driven by the realisation of both the increasing magnitude of patient doses and their variation both intra- and inter-nationally. Legislators and guidance-issuing bodies have developed the idea of 'Diagnostic Reference Levels' (DRL's). In particular, the European Union, in their Council Directive 97/43/Euratom, required Member States to develop DRL's. The UK Government, when consolidating this EU Directive into UK legislation, extended the concept of DRL's from a national to an employer level. However, the methodologies used for development of national and international DRL's do not translate to a local level and hence a new approach is required. This paper describes one particular approach made by a UK hospital to introduce 'Local DRL's' in such a manner as to aid the optimisation process. This approach utilises a dose index, based on the local patient population, which is monitored for trends. Any trend in patient dose triggers an investigation linked to the clinical audit system within the Clinical Radiology Department. It is the audit cycle that ensures a continuing move towards an optimised situation. Additional triggers may be employed such as large patient dose variations.

1. Introduction

In recent years there has been a greater focus on the management of patient doses. This effort has been driven by the realisation of both the increasing magnitude of patient doses [1,2] and their variation both intra- and inter-nationally [3,4]. Legislating and guidance issuing bodies have been active in this area and have developed the idea of 'Diagnostic Reference Levels (DRL's) [5-8]. In the context of the international and national situation the idea of DRL's is reasonably understandable. However, a recent EU directive [5] has led, in the UK, to the introduction of legislation [9] introducing the concept of Local DRL's. The concept has been legislated for without clear guidance to local hospital staff of how it would operate at that level. This paper describes an attempt to bridge the gap of international and national DRL's being set by national authorities and the concept of Local DRL's.

2. International & National Diagnostic Reference Levels

Many bodies have been active in the area of DRL's, including the IAEA [6], European Union [5,8] and various national bodies [eg 7]. When the origin of these DRL's are investigated one discovers similarities in that often a large survey of individual institutions within the geographical boundaries of the authority issuing the DRL's. At each institution mean patient doses for a range of common examinations are determined. These institution mean doses are gathered together into a distribution of means and then an arbitrary level within the distribution is taken as the DRL. This level is typically the 75^{th} percentile. The philosophy of this approach is to provide the 25% of institutions with mean doses above the DRL to work towards dose reduction in that particular examination. The DRL on its own, however, is no incentive to the other 75% of institutions that achieved mean doses below the DRL.

3. Local DRL's in the United Kingdom

Following the EU Council Directive 97/43/Euratom, the UK Government introduced the concept of Local DRL's in legislation promulgated in May 2000 [9]. The definition of DRL's

in the UK legislation is, 'dose levels in radiodiagnostic practices ….. for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment'. This definition of DRL's is similar to that described in the EU Medical Exposures Directive. However, in the UK legislation, it is the local employer, not national authorities that must establish such DRL's. Furthermore, the employer 'must undertake appropriate reviews whenever DRL's are consistently exceeded and ensure that corrective action is taken…' From the employer's perspective they can either implement DRL's using existing national or international guidance or else formulate their own approach. In adopting the former approach of using existing DRL's, the probability is that local dose levels will be lower than published DRL's which suffer from being at the higher end of practice when the relevant survey was undertaken. Therefore there is no downward pressure being exerted by the concept of Local DRL's on locally delivered patient doses. The problem of developing a local approach is that no consensus exists in the UK as to the methodology needed to develop Local DRL's, despite it being a legal requirement. At a local level, the dose distribution in question is one of individual patient doses and is mainly due to patient size variations rather than a distribution of institution mean doses which is the origin of national and international DRL's.

4. The Nottingham approach

The driving force behind the tool of DRL's, whether they be international, national or local, is the concept of optimisation. Therefore, in Nottingham, we looked for ways to link our existing patient dosimetry efforts to a system of quality improvement. Furthermore we required a system that triggered an investigation if 'DRL's are consistently exceeded.' We were aided in this aim by the development at Nottingham of a networked, dose-area product based, patient dose logging system which enables the collection of large numbers of patient doses (> 2000 examination doses per month) [10]. However, the methodology developed does not depend on this patient dose collection system and so is transferable to other institutions.

At Nottingham City Hospital the median dose by examination type is collected from our dose data each month. In our case we can be sure that our median dose reflects the dose to our average patient due to the large number of patient doses measured. Other centres, however, by judicial selection of patients, could achieve the same end. This dose index is then plotted on a control chart that essentially plots the index's time course. During the steady state ie when no changes to practice or equipment occurred, it is possible to calculate a meaningful average median monthly dose. This average median dose (taken over a period of six months in Nottingham) was deemed to be our Local DRL. It was also our target dose in that it was the expected median dose from our local patient population. Any deviations in median dose indicated a sub-optimal radiographic process compared to our baseline practice.

The link to optimisation is achieved by the triggering of a dose and image quality investigation whenever certain criteria are met. These triggers are locally set to reflect local optimisation strategies. In Nottingham our triggers are currently either a downward or upward trend in monthly median dose or else a large standard deviation in the monthly median dose distribution. The number of concurrent investigations and the speed of their completion are entirely resource limited. Resource limitations notwithstanding, the comparison of monthly median dose levels with our Local DRL's linked to an image quality/dose investigation when triggered by preset criteria defines our route from the imposed concept of Local DRL's to that of optimisation. For each examination that is investigated, the outcome ought to be optimised practice within the constraints of current equipment, current good practice guidance and local radiologist preference. Such investigations can also highlight the need for equipment

replacement and produce useful arguments for capital expenditure. Each investigation, if properly disseminated within the organisation, can act as a powerful training resource and often leads to a more harmonised approach, reducing staff-dependent dose variations.

In summary therefore, the methodology described above links the concept of Local DRL's (a legal requirement in the UK) with the process of optimisation. It is the process of optimisation that is the important end point. As stated by the International Commission on Radiological Protection [11], 'The optimisation of protection is the most powerful of the components of the system of radiological protection. It should pervade all stages of the use of radiation in medicine, from the design of premises, equipment, and procedures through to day-to-day applications.' This methodology also fits with the recently proposed National Radiological Protection Board (UK) concept of 'achievable dose' [12]. An achievable dose is one obtained by applying best practice to the radiographic process in terms of, for example, radiographic factors, views required and sensitivity of detector. The outcome of our dose monitoring – audit cycle process, if all best practice guidance is implemented, would be a local achievable dose. This methodology is not the only way to implement Local DRL's but, in Nottingham, we have found it to be a useful mechanism for a planned move towards an optimised practice.

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IAEA-CN-85-194

DIMOND: A EUROPEAN APPROACH TO ESTABLISH AND USE REFERENCE LEVELS IN FLUOROSCOPY GUIDED PROCEDURES

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Abstract

The purpose of this paper is to present a European approach to the establishment of reference levels in fluoroscopy guided procedures agreed between the members of the European DIMOND research consortium. The approach based on determination of dose area product (DAP), fluoroscopy time and number of acquired images is recommended. Three approaches to patient dosimetry have been proposed (from the simplest level to the more complicated). At the first level the fluoroscopy time and number of images are assessed. This information could be upgraded with data on entrance dose rate at the surface of a phantom, supplemented by dose/image for cine or digital imaging, and the irradiated patient area. Additional measurements of DAP and entrance skin dose would complete the third level. Using this information it is possible to optimise procedures and to decide if some corrective action is necessary for the x-ray system or for the technical or clinical protocol. If the number of images or the fluoroscopy time is consistently higher than that corresponding to the reference level, a revision of the clinical protocol should be made. If DAP (or maximum skin dose, if estimated or measured) is consistently higher than the reference DAP level (or maximum skin dose), a revision of the x-ray system (dose rate and dose/image) and the clinical or technical protocol (collimation, magnification, x ray beam orientation, etc) should be made.

1. Introduction

The follow-up of any patient dosimetry programme in diagnostic radiology requires the implicit use of reference levels (RL), to assess the possible application of corrective action. Council Directive 97/43/EURATOM [1] introduces the concept of Diagnostic Reference Levels (DRL). The European Guideline “Radiation Protection 109” [2] states that ‘In principle, DRL are applicable for standard procedures in all areas of diagnostic radiology. They are, however, particularly useful in those areas where a considerable reduction in individual or collective doses may be achieved or where a reduction in absorbed dose means a relatively high reduction in risk’. The document quotes, in particular Interventional Radiology (IR). The International Atomic Energy Agency (IAEA) [3] and the Food and Drug Administration (FDA) in the USA [4] have published reference values for dose rate at the entrance of the patient in fluoroscopy: 25 and 100 mGy/min (in air, including backscatter) for normal and high contrast modes in the IAEA document, and 10 and 20 R/min in the FDA regulation. However no guidance has been given on dose per image or any dosimetric quantity for the full fluoroscopy procedure. Furthermore, the measurement protocol has not been specified.

Cases of skin doses of several Gy, resulting in injuries such as radio-dermatitis and necrosis have been reported in literature [5-7]. Some national bodies have given specific recommendations for conducting these procedures [8]. Also, several international organisations (World Health Organisation, International Commission on Radiological

Protection and the IAEA) are preparing specific documents related with radiation protection (RP) and safety in IR [9, 10].

The purpose of this paper is to present a European approach to RL in fluoroscopy guided procedures agreed among the members of the European research consortium on Digital Imaging: Measures for Optimising Radiological Information Content and Dose (DIMOND).

2. The need for reference levels in fluoroscopy guided procedures

The European document "European Guidelines on Quality Criteria for Diagnostic Radiographic Images" document [11] focuses attention on three aspects of conventional radiographic techniques, namely, diagnostic quality of the radiographic image, radiation dose to the patient and choice of the radiographic technique, as a means to audit the process of diagnostic imaging. The adoption of this approach is also feasible in fluoroscopy and IR, though image quality and patient dose show a strong relationship in fluoroscopy and digital imaging modes. In fluoroscopy guided procedures all aspects of diagnostic information should be considered. This information is obtained both from fluoroscopy and several series of images. Patient doses will be related with the performance of the x-ray system used and the clinical and technical protocol. Thus, RL should be set in relation to both the x-ray system and the procedure protocol.

Concerning the x-ray equipment, there are some features influencing patient dose and image quality:

a) Dose rate in fluoroscopy.
   This depends sometimes of the default setting adjusted by the service engineer. Modern systems usually have three fluoroscopy modes: low, medium and high, and sometimes, for these three modes, there is an extra alternative of standard or high contrast modes. These represent a total of 6 options and the clinician does not always know sufficiently the differences in dose and image quality between them. The application specialist of the x-ray system could recommend some default option but this may not be optimised for the different procedures and personal preferences of the clinicians. Differences in entrance dose rate for a standard patient can range from 15 mGy/min to more than 60 mGy/min. Here some orientation on reference dose rates for some typical procedures can be very useful both for the clinician and for the application specialist. For example, in cardiology procedures, working with image intensifier format of 18-22 cm, and for a standard patient size with AP projection and for a standard size patient, the reference dose rate could be 30 mGy/min. At this dose rate, satisfactory image quality should be obtained.

b) Dose per image (or dose per frame in cine).
   This also depends on the default selected by the service engineer and the x-ray application specialist. Some systems have different image quality (and dose) modes. Modern General Electric systems, for example, offer four modes: A, B, C and D, with better image quality for the option D and dose per image increasing in a factor of approximately 2.2 from one mode to another. Typical entrance dose (in air, including backscatter) for a standard patient and image intensifier format of 22 cm, from 50 μGy/frame until 500 μGy/frame in cine for cardiology, and values from 1 mGy/image until 10 mGy/image for subtraction techniques are usual. Also the clinician must be educated in its use. What criteria should be used to select the level of image quality and what should be the patient dose?. Here, information on reference dose for typical procedures can be useful for the clinician.

c) Other factors such as:
- Image intensifier format (32, 22, 16 or 11 cm) used to improve the resolution also affects (in different way for the different systems) the entrance dose. The change from 22 to 16 cm could imply an increase of a factor of 2 in skin dose for some systems operating under automatic control.
- The use of semitransparent filters may improve image quality and reduce skin dose substantially in some irradiated areas and consequently, reduce DAP.
- Collimation.
- Use of last image hold.
- Experience of the interventionalist using a reasonable fluoroscopy time to perform the procedure.
- Experience of interventionalist to avoid acquiring an excessive number of images.
- An optimised clinical protocol. A good example in cardiology could be the use of cine rates of 25 or 30 frames/s which has been abandoned in a lot of centres working now at 12.5 f/s, thus reducing cine doses by 50%.

All these factors have an important influence on patient dose. To have some reference records of the typical fluoroscopy time, number of images and DAP (and sometimes the skin dose distribution) for the different procedures can be a useful help in the optimisation process. It is permitting to compare the practice in a centre with the "state of the practice" (reference levels) in other centres.

An important aspect to be taken into account is the size of the patient (height and weight) because an increase of 4-5 cm in the thickness of the examined region can mean an increase of a factor of 2 in dose rate or dose/image. The other crucial factor is the complexity of the procedure or the complications during the procedure [12]. The future research on RL for IR should include the standardisation of some levels of complexity justifying the increase in patient dose.

The more practical and useful approach to stablish RL in fluoroscopy guided procedures would be to measure typical values of DAP, fluoroscopy time and number of acquired images. Skin dose distribution with maximum skin dose values should also be sometimes obtained [13]. This is particularly important in procedures using several beam orientations such as in cardiology. It must be noted that a low value of DAP does not guarantee a low skin dose if the entrance radiation fields of different projections overlap significantly. Non optimised protocols will produce DAP readings, fluoroscopy time or image number higher than the reference values.

For fluoroscopy guided procedures, patient dosimetry could be approached from three levels of information [14]:
1) The first level (the most simple but also with the poorest information) would consist only of fluoroscopy time and number of images. These parameters are closely related to the clinical protocol.
2) The second level consists of the data of level one upgraded with information on entrance dose rate at the surface of a phantom, dose/image for cine or digital imaging, and the irradiated patient area. These values are more related to the performance of the x-ray system.
3) Finally, the third level includes measurements of DAP and entrance skin dose in addition to the data of level two. With this information, an orientation about determinist c and stochastic

risks is obtained. This orientation is important because the procedures are complicated and patient doses may be high.

3. Conclusions

For interventional radiology and in general for fluoroscopy guided procedures, reference levels are particularly relevant and can be applied successfully to optimise procedures and to improve patient protection.

Dose area product together with fluoroscopy time and number of images are the preferred quantities to be reported in order to establish and use reference levels for these procedures. These three parameters permit an effective optimisation. Maximum skin dose should be estimated (or measured) for complex or repeated procedures for the same patient.

The level of complexity of the procedures and patient size should be taken into account in order to assign a degree of "tolerance" to the reference levels.

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REFERENCE DOSIMETRY FOR CT IN THE UK

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1. Abstract

Computed tomography is firmly established as a major source of population exposure from diagnostic x-ray examinations and thus a particular focus for radiological protection initiatives. The concept of reference doses is widely recognised as a useful and practical tool for promoting improvements in the optimisation of protection for patients undergoing radiological examinations. National diagnostic reference levels (DRLs) have already been successfully applied in the UK for some conventional x-ray examinations within a framework for advice on patient protection. This approach is being extended to include CT, utilising the robust methodology for reference dosimetry that has been developed by the European Commission (EC) for the particular conditions of exposure in CT. This is based on the dosimetric concepts of weighted computed tomography dose index ($CTDI_w$) per slice in serial scanning or per rotation in helical scanning, and dose-length product (DLP) per complete examination. Notwithstanding some initial values proposed by the EC, specific national DRLs for CT practice in the UK will be established on the basis of widescale national survey data.

1. Introduction

Computed tomography is firmly established as an important tool in diagnostic radiology that provides high quality cross-sectional x-ray images of the body, although the doses to patients are relatively large. Increasing application of this modality has made a substantial impact on both patient care and also population exposure. In developed countries, CT procedures typically represent about 6% of the total number of all medical x-ray examinations, yet provide about 41% of the resultant collective effective dose [1]. Surveys of clinical practice have also demonstrated wide variations in patient dose for a given type of procedure and potential scope for improvement in the optimisation of protection for patients undergoing CT [2].

Whereas it is inappropriate to impose strict limits on the doses received by patients for medical purposes, the concept of reference doses is recognised increasingly as a useful and practical way of promoting the fundamental requirement for optimisation of patient protection, whereby doses are always as low as reasonably practicable in order to meet specific clinical objectives [3, 4]. In essence, reference dosimetry seeks to characterise clinical practice in terms of reference dose quantities that allow simple, yet meaningful comparisons of technique for a given type of procedure. Such dose measurements are intended to facilitate, where needed, improvements in patient protection during the regular process of critical review of equipment and techniques. In particular, diagnostic reference levels can be set for different types of examination on the basis of wide-scale survey data to help identify potentially inadequate performance [5]. This approach has proved effective for reducing unnecessary exposures from conventional x-ray examinations in the UK [6]. A robust methodology for the specific reference dosimetry necessary for CT has already been developed by the European Commission as an integral part of quality criteria for such examinations [7].

2. Reference dose quantities

The principal dosimetric quantity used in CT is the computed tomography dose index (CTDI). This is defined as the integral along a line parallel to the axis of rotation (z) of the dose profile (D(z)) for a single rotation and a fixed table position, divided by the nominal thickness of the x-ray beam. CTDI can be conveniently assessed using a pencil ionisation chamber with an

active length of 100 mm, so as to provide a measurement of $CTDI_{100}$, expressed in terms of absorbed dose to air [8]:

$$CTDI_{100} = \frac{1}{nT}\int_{-50}^{+50} D(z)dz \qquad \text{(mGy)} \qquad (1)$$

where n is the number of tomographic sections, each of nominal thickness T, from a single rotation.

Reference dosimetry for CT is based on such measurements made within standard CT dosimetry phantoms; these presently comprise homogeneous cylinders of polymethylmethacrylate (PMMA), with diameters of 16 cm (head) and 32 cm (body), although phantoms of water-equivalent plastic and with elliptical cross-sections are under development. The combination of measurements made at the centre (c) and 10 mm below the surface (p) of a phantom leads to the following two reference dose quantities [7]:

(a) Weighted CTDI in the standard head or body phantom for a single rotation corresponding to the exposure settings used in clinical practice

$$CTDI_w = \frac{1}{3}CTDI_{100,c} + \frac{2}{3}CTDI_{100,p} \qquad \text{(mGy)} \qquad (2)$$

where $CTDI_{100,p}$ represents an average of measurements at four different locations around the periphery of the phantom.

(b) Dose-length product for a complete examination

$$DLP = \sum_i {}_nCTDI_W * T * N * C \qquad \text{(mGy cm)} \qquad (3)$$

where i is the number of scan sequences in the examination, each with N rotations of collimation T cm and exposure C mAs; ${}_nCTDI_w$ is the normalised weighted CTDI (mGy $mA^{-1}s^{-1}$) appropriate for the applied potential and nominal beam collimation (number and width of slices per rotation).

These quantities can be applied to serial or spiral scanning, for both single- or multi-slice geometry scanners. The dose quantities relate to measurements in the standard head or body dosimetry phantoms, as appropriate to the type of examination, for the exposure conditions used in clinical practice. The concept was initially developed in relation to examinations on adult patients [7], although it has subsequently been extended for application to paediatric CT [9]. Monitoring of $CTDI_w$ per rotation takes account of the exposure settings selected, such as tube current and tube voltage. Monitoring of DLP for a complete examination takes account also of the volume of irradiation, as determined, for example, by the number of slices in serial scanning or the acquisition time in spiral scanning, and the number of such scan sequences conducted during the examination. Such dose data provide useful indications of relative patient exposure for a given type of procedure. Values of DLP may also be used to derive broad estimates of effective dose for CT procedures using region-specific coefficients [7, 9].

3. Diagnostic reference levels

Initial diagnostic reference levels have been published for some common procedures on the basis of surveys of practice for adult [7] and paediatric [9] patients at selected hospitals in seven European countries; these values are shown in Tables I and II.

Table 1. Initial European reference dose values for CT examinations on adult patients [7]

Examination	Diagnostic reference level	
	$CTDI_w$ (mGy)	DLP (mGy cm)
Routine head[a]	60	1050
Face and sinuses[a]	35	360
Vertebral trauma[b]	70	460
Routine chest[b]	30	650
HRCT of lung[b]	35	280
Routine abdomen[b]	35	780
Liver and spleen[b]	35	900
Routine pelvis[b]	35	570
Osseous pelvis[b]	25	520

[a]Data relate to head dosimetry phantom (PMMA, 16 cm diameter).
[b]Data relate to body dosimetry phantom (PMMA, 32 cm diameter).

Table II. Initial European reference dose values for CT examinations on paediatric patients [9]

Examination	Patient age (years)	$CTDI_w$ per slice or rotation[a] (mGy)	DLP per examination[a] (mGy cm)
Brain	< 1 5 10	40 60 70	300[b] 600[b] 750[b]
Chest (general)[c]	< 1 5 10	20 30 30	200 400 600
Chest (HRCT)	< 1 5 10	30 40 50	50 75 100
Upper abdomen[c]	< 1 5 10	20 25 30	330 360 800
Lower abdomen & pelvis[c]	< 1 5 10	20 25 30	170 250 500

[a]Data relate to 16 cm diameter PMMA dosimetry phantom.
[b]DLP values for brain refer to single phase examination (with or without contrast).
[c]Examination mainly conducted using spiral scanning.

Such investigation levels are for comparison locally with the mean values of dose descriptors assessed in a CT facility during examinations on representative groups of patients and should not be applied on an individual patient basis.

Specific national DRLs for CT practice in the UK will be established on the basis of widescale national survey data. The present National Patient Dose Database that is used for setting and reviewing national DRLs for conventional x-ray examinations [6] will be extended to include CT.

Acknowledgement

The initial European reference dose values for CT on adult and paediatric patients were developed as part of EC Contract Nos F14P-CT96-0050 and F14P CT950002, respectively.

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THE ESTABLISHMENT AND USE OF DOSE REFERENCE LEVELS IN GENERAL PAEDIATRIC RADIOLOGY

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Abstract

Diagnostic reference levels for general paediatric radiology have been established in terms of delivered exposure parameters rather than skin dose or dose-area product. With supporting measurements from equipment quality assurance and assumptions of standard patient sizes it was possible to derive reference levels in terms of entrance surface dose. This allowed comparison to be made with other published data. The reference levels for common examinations are presented for different age bands. There is a notable variation with patient age for some examinations which is not apparent in other published data.

1. Introduction

The Medical Exposure Directive of the European Union [1] and the resultant Ionising Radiation (Medical Exposure) Regulations [2] in Great Britain, call for the establishment of diagnostic reference levels for radiodiagnostic practices for typical examinations for groups of standard-sized patients. These reference levels should be interpreted as an expected upper bound on the radiation dose delivered to an exposed individual under normal circumstances. Such a level is not to be taken as a limit, though investigations should be carried out if the levels are consistently exceeded.

In a specialist paediatric hospital, one is faced with the immediate difficulty of not having a standard sized patient, which leads to multiple diagnostic reference levels for each examination. A further problem arises with the selection of dose quantity for the reference level. For some modalities one can use the same quantities as would apply to adults (dose-area product for fluoroscopy, CTDI or total mAs for computed tomography and administered activity for nuclear medicine). However, difficulties arise in general radiography, where for a number of examinations the preferred dose quantity, dose-area product, can not be used as currently available meters are too insensitive. An alternative approach was therefore adopted for all general radiographic examinations, basing the diagnostic reference levels on exposure parameters and using standard protocols and quality assurance results to link these to more universally recognisable dose indicators.

2. Method

It was decided to adopt five commonly used age bands for paediatric dosimetry, namely <1 year, 1 to 5 years, 5 to 10 years, 10 to 15 years and 15+ years. Once reference levels have been determined for each age group and dose data surveyed, it may be possible to refine these age bands and reduce the number of different levels set.
The standard operating protocols for general radiography [3] include guidance on typical exposure parameters to set for the age bands given above. Variation in patient size and clinical requirement calls for flexibility within each band, and so a range of exposure parameters is usually quoted. Table I gives an example of the exposure guidance in the standard operating protocol for routine chests.

Table I. Sample Exposure Chart for PA Chest X-Rays

Age Band	kV	mAs
<1	60 – 65	2.0 – 2.5
1 – 5	65 – 70	2.0 – 3.2
5 – 10	70 – 75	2.5 – 3.2
10 - 15	70 – 75	3.0 – 6.0

The exposure parameters were selected following prolonged assessment of image quality on a recently installed computed radiology imaging system. This assessment is ongoing, and may result in further changes being made in the future.

As a starting point, the diagnostic reference level (DRL) for each examination was set to the maximum kV/mAs combination recommended for each age band. For example, the DRL for a PA Chest on a 7 year old child would be 75kV and 3.2mAs.

There is a requirement in the Directive, and in the national legislation, to have regard to European diagnostic reference levels where available. Such data as there is on paediatric doses tends to quote dose levels (and hence DRLs) as entrance surface dose (ESD). In order to make comparison with this data, and to contribute to the pool of available dose levels, it was therefore necessary to convert from kV/mAs to entrance surface dose. This was achieved using quality assurance measurement to determine the dose in air at the distance equivalent to the entrance surface and to make tissue:air and backscatter corrections in order to arrive at a skin dose at that point [4]. The equation used for this calculation is:

$$D_{surface} = D_{air} \frac{(\mu_{en}/\rho)_{muscle}}{(\mu_{en}/\rho)_{air}} \left(\frac{L}{FSD}\right)^2 BSF$$

where L is the output measurement distance, FSD is the focus skin distance, BSF is the backscatter factor and μ_{en}/ρ is the mass energy absorption coefficient for the given medium.

Routine quality assurance on the general radiology equipment included radiation output measurements at 10kV intervals across the diagnostic range, and at fixed kV for a range of mAs values. The total filtration of the beam is also assessed routinely. Given that the relationship between kV and output is of the form [5]

$$\mu Gy/mAs \propto kV^n$$

the value of n was determined from the gradient of a logarithmic plot and the radiation output calculated for any intermediate kV value.

The standard operating protocol for each examination specifies a focus to image receptor distance. The focus to entrance surface distance was determined from this by subtracting the patient thickness. Direct measurement of this would place a significant burden on the operator, so standard thickness values were taken from published data [6]. Radiation output at this distance was then calculated using an inverse square correction from the standard output measurement distance.

To correct for dose to tissue, the ratio of mass energy absorption coefficients for tissue and air was included. A value of 1.06 was assumed to be valid across the diagnostic energy range [4].

Table II. Calculated Diagnostic Reference Level (DRL) as Entrance Surface Dose (ESD)

Examination	Age Band	DRL kV	DRL mAs	ESD (μGy)	E (μGy)	ESD (μGy) Ref [8]	ESD (μGy) Ref [6]
Skull AP	<1	65	4	266	5.1		800
	1 to 5	65	8	546	6.2	1500	1100
	5 to 10	67	10	728	5.6		1100
	10 to 15	70	13	1051	8.7		1100
Skull LAT	<1	65	3.2	193	4.7		500
	1 to 5	65	7	440	6.0	1000	800
	5 to 10	67	8	532	6.5		800
	10 to 15	70	10	738	7.7		800
Chest PA/AP	<1	65	5	83	8.1		50
	1 to 5	70	3.2	64	6.9	100	70
	5 to 10	75	3.2	77	8.6		120
	10 to 15	75	6	148	10.8		
Chest LAT	<1	65	4	69	7.3		
	1 to 5	75	5	123	11.7	200	
	5 to 10	80	7	209	18.5		
	10 to 15	80	8	256	15.4		
Abdomen AP	<1	63	2	121	21.6		400
	1 to 5	65	4	273	46.9	1000	500
	5 to 10	65	12	868	132.0		800
	10 to 15	75	16	1649	196.2		1200
Pelvis AP	<1	63	2.5	149	18.6	200	500
	1 to 5	65	4	271	37.4	900	600
	5 to 10	65	12	864	76.9		700
	10 to 15	75	16	1646	158.8		2000
C-spine AP	<1						
	1 to 5						
	5 to 10	65	5	323	14.1		
	10 to 15	65	6	442	18.0		
C-spine LAT	<1						
	1 to 5						
	5 to 10	70	8	171	3.9		
	10 to 15	75	12	331	6.9		
T-spine AP	<1						
	1 to 5						
	5 to 10	75	10	913	102.2		
	10 to 15	80	16	1792	401.4		
T-spine LAT	<1						
	1 to 5						
	5 to 10	85	16	2254	209.6		
	10 to 15	85	20	3193	196.4		
L-spine AP	<1						
	1 to 5						
	5 to 10	75	16	1536	146.2		
	10 to 15	70	20	1748	111.7		
L-spine LAT	<1						
	1 to 5						
	5 to 10	75	25	2806	102.7		
	10 to 15	85	25	4102	111.6		

The backscatter factor depends on X-ray beam quality and field and patient size. Backscatter fraction data have been published by the National Radiological Protection Board (NRPB) for typical examinations for children of different ages [7]. Their data is tabulated for different kV and beam filtration values. Values corresponding to the kV and filtration used were derived from this data set by linear interpolation.

Table II presents the results of the calculations based on the current diagnostic reference levels in use at the hospital. The 5th column gives the calculated entrance surface dose. The 7th and 8th columns make comparison with published data from the European Commission [8] and Hart et. al. [6] respectively. In each case the authors quote values for a specific age, rather than age range. To assist with comparison, their quoted values are tabulated to correspond with our upper age range. For example, a DRL for a 5 year old is placed alongside our 1 – 5 year old data. The 6th column presents estimates of effective dose using Monte-Carlo factors published by the NRPB [7].
Cases where DRLs have been exceeded are recorded separately and investigations triggered if the proportion of cases exceeds 25% of the total number performed within the audit period.

3. Conclusions

The diagnostic reference levels established at Great Ormond Street Hospital for general paediatric radiography are easy to use as they are in units which correspond to the exposure chart in each room and do not vary according to the examination. As more sensitive DAP meters become available the hospital may move towards using this quantity for the DRL, but it is unlikely that routine skin doses would be measured.

One of the potential drawbacks to using a kV/mAs combination for a DRL is that it is possible to exceed the DRL whilst giving a lower dose to the patient. For example, giving an exposure of 76kV and 2.5mAs for a PA Chest on a 7 year old child would exceed the DRL (75kV and 3.2mAs) but would result in a lower skin dose. The impact of this will be assessed as cases of DRLs being exceeded are audited in the future.

With regard to age bands, there is scope for reducing the number of bands in examinations where the skin dose derivation of the DRLs varies little. There is, however, clear indication that some examinations have a steep rise in dose with patient age. The European Commission guidelines [8] only quote data for 5 year old children in most circumstances, stating that entrance surface dose values they collated varied little between infants and 5 and 10 year old children. The data from Hart et. al. [6] shows little variation in reference level with age for some examinations (e.g. skull), but quite marked variation in others (in particular for the pelvis). It should also be noted that there are some marked differences in values reported in the two references (e.g. for a 5 year old abdomen).

If the results presented here are of interest to other paediatric centres, it should be emphasised that the exposure parameters are being adapted to a computed radiology (CR) system, which has required considerable changes. In particular, the move to reduce patient dose by increasing kV and reducing mAs leads to poor image quality in paediatric CR as the mAs falls too low to avoid quantum noise. The lower absorption edge of the CR plates compared to intensifying screens in cassettes suggests that image quality is optimised at lower kVs and a new balance must therefore be found between dose and image quality. The parameters quoted here represent the current status in the optimisation process.

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IAEA-CN-85-139

INTRODUCTION OF GUIDANCE DOSE LEVELS IN PAEDIATRICS CT

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Abstract

The purpose of this work is to present a methodology in order to define reference levels for chest or abdominal CT examinations performed on children. For children aged from 0 to 6 the $CTDI_W$ measured in the head test object (i.e. ø 16 cm) should be used as a dose indicator. For children older than 12 years old the $CTDI_W$ measured in the body test object (i.e. 32 cm) should be used as a dose indicator. For children aged between 6 to 12 we propose to use an intermediate $CTDI_W$ in order to avoid an over or underestimation of the dose delivered in the slices. Finally a set of dose length products (DLP) measured in our centre for standard abdominal acquisitions will be given.

1. Introduction

In conventional radiology the use of a screen film system as a detector assures, if the films are correctly processed, that the dose delivered to the patient is within a predictable limit. As a matter of fact, the latitude of exposure available on a screen film system is relatively limited (typically one order of magnitude) and a constant exposure is required to produce a satisfactory film density. On the contrary, digital detectors are characterised by a wide latitude of exposure (typically 3 to 4 orders of magnitude). This property eliminates the typical relationship between the radiation exposure and the image optical density. With digital detectors the only parameter which will be linked to the dose is the image noise. Thus, radiation protection of the patient have to be emphasized with the use of digital detector

CT examinations represent about 5 % of all the radiological examinations performed on adults. However, its contribution to the effective dose delivered in radiology is within 27 to 35 % [1-2]. To avoid an uncontrolled increase of the CT contribution on the effective dose delivered by medical applications a recommendation has been published by the CEC [3]. This recommendation indicates together with a reference dose some image quality requirements for the most common examinations. Manufacturers are now offering on their units the possibility to get a dose indicator corresponding to the examination performed on each patient (i.e. indication of the $CTDI_W$ and the DLP). Thus, it seems now relatively easy for the radiological community to assess the dose delivered to the patient for CT examinations. Those can be compared to the reference levels in order to begin an optimization process.

The use of CT in pediatrics is more limited than for adults and at the present time there is no recommendation to verify if the radiological constants used (kV, mA, pitch …) are adequate. Very often, the mA reduction (if any) performed by radiographers to scan children has no strong scientific background.

For adults, two $CTDI_W$ has been defined : one to be applied for head of neck examinations ($CTDI_W$ head measured with a test object of 16 cm in diameter) and one to be applied to chest or abdominal examinations ($CTDI_W$ body measured with a test object of 32 cm in diameter). In paediatrics it seems that these two quantities are not sufficient to introduce reference levels.

In this paper we will propose an intermediate $CTDI_W$, which can be derived from the standard $CTDI_W$ used for adults. This $CTDI_W$ will be based on the variation of an equivalent abdomen diameter with age. This concept will be used to present the doses delivered for abdominal examinations in our centre. These results will be given for a single-slice CT (SSCT) and a multi-slice CT (MSCT).

2. Material and method

The SSCT used in this study is the HiSpeed CT/i system (GE Medical Systems, Milwaukee, Wis) and the MSCT used in this study is the LightSpeed QX/i (GE Medical Systems, Milwaukee, Wis) which allows the sampling of four slices per tube rotation. The CT units involved in this study calculates and displays the Dose-Length Product (DLP) corresponding to the acquisition protocol used. The indicated $CTDI_W$ and DLP values were verified.

Equivalent abdominal diameters have been estimated by using weight and height tables corresponding to the paediatric population of Switzerland. To begin with, a PA abdominal thickness has been estimated by means of the relationship established for fluoroscopy examination by Leug et al. [4] : PA thickness = 2 [Weight /(1000 x p x Height)]. Since the abdomen section is closer to an ellipse than a circle an equivalent CT diameter has been proposed by simply multiplying the PA thickness described previously by 1.5. Using these data an intermediate $CTDI_W$ has been calculated for children aged between 6 to 12 years.

3. Results and discussion

Figure 1 presents the variation of the proposed equivalent CT diameter in function of age. These data are based on the 3 percentile of the weights and heights distributions mentioned previously. It appears that the use of the $CTDI_W$ measured with the head test object as a dose indicator is adequate for very young children (i.e. 0 to 6 years old). One can notice that a diameter of 32 cm is obtained for the age of 18. Thus, the $CTDI_W$ measured with the body test object appears to be a rather good dose indicator for that particular age. In order to simplify the approach we propose to use this dose indicator for patient older than 12. For children aged between 6 to 12 the use of a $CTDI_W$ measured in a body test object will underestimate the dose delivered in a slice, whereas the use of a $CTDI_W$ measured in a head test object will overestimate that dose. In order to find a compromise we propose to use a mean $CTDI_W$: average of the head and body $CTDI_W$.

The head and body $CTDI_W$'s have been measured and two CT units at different kilovolts. Using these data a mean CTDIw have been calculated for both units. The results are summarised in Table 1.

Using the data presented in Table 1 and the acquisition protocols used in our centre the doses delivered per slice (i.e. $CTDI_W$ divided by the pitch value) have been calculated. For each category of ages an average scan length has been estimated allowing the DLP calculation. These data are summarised in Table 2.

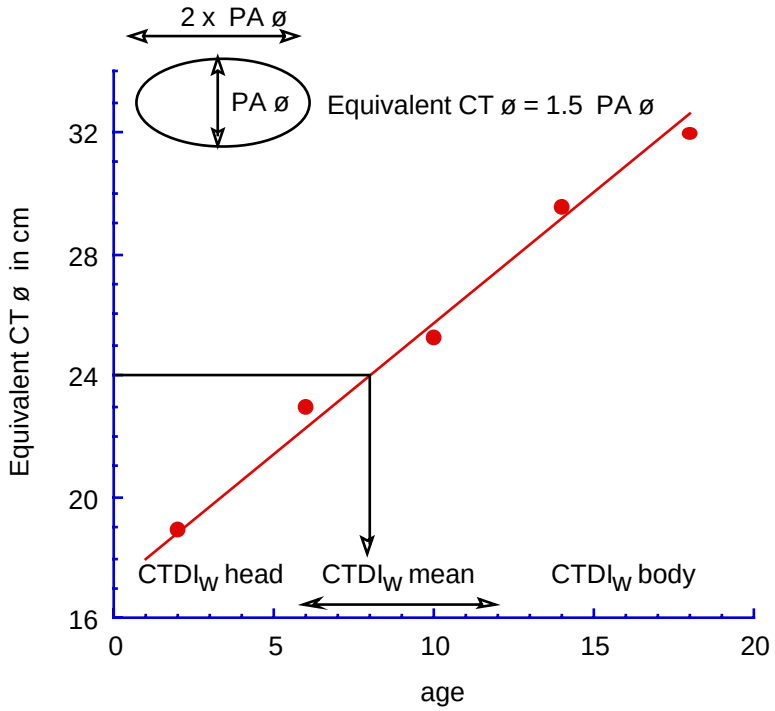

Figure 1 - Equivalent CT diameter versus to age

Table 1. $CTDI_W$ data of the CT used in this study

	$CTDI_W$ (mGy/mAs)	100 kV	120 kV	140 kV
SSCT	head	0.07	0.10	0.14
	mean	0.06	0.08	0.11
	body	0.05	0.06	0.08
MSCT	head	0.17	0.26	0.36
	mean	0.26	0.20	0.27
	body	0.09	0.13	0.19

Table 2. Dose estimators comparison between the two CT used in this study

Unit	Age	Acquisition protocol *	Dose per slice (mGy)	DLP (mGy.cm)
	> 12	120 kV - 290 mA - 1 s - p= 1.2	14.5	32 cm** -> 464
SSCT	6 - 12	120 kV - 230 mA - 1 s - p= 1.2	15.3	22 cm -> 337
	1 - 6	120 kV - 190 mA - 1 s - p= 1.0	19.0	17 cm -> 323
	0 - 1	120 kV - 170 mA - 1 s - p= 1.0	17.0	11 cm -> 187
	> 12	120 kV - 200 mA - 0.8 s - p= 1.5	13.9	32 cm -> 445
SSCT	6 - 12	120 kV - 140 mA - 0.8 s - p= 1.5	14.9	22 cm -> 328
	1 - 6	120 kV - 120 mA - 0.8 s - p= 1.5	16.7	17 cm -> 284
	0 - 1	120 kV - 100 mA - 0.8 s - p= 1.5	13.9	11 cm -> 153

*) the numbers correspond to the tube high voltage, tube current, time of one tube rotation and pitch

**) average scan length

The data presented in this study show that for the standard abdominal acquisition presented here the dose per slice as defined remains almost constant with the age of the patient (i.e. 15 mGy). From our data it appears that the following DLP reference values could be applied : [0 - < 1 year] : 170 mGy.cm ; [1 - < 6 years] : 300 mGy.cm; [6 - < 12 years] : 350 mGy.cm ; and [12 - <18 years] : 450 mGy.cm.

The same methodology was applied to the examinations of the chest. The results show that a significant lower dose delivered in the slice could be used (i.e. 7 mGy). This particular situation is due to the lower X-ray absorption of the tissue.

4. Conclusion

DLP's have been proposed for the standard abdominal examinations in pediatrics CT. The acquisition protocols presented here are considered optimized by our radiographer, since a dose reduction would lead to a drastic image quality reduction. Using these data, the image quality obtained is accepted by our radiologists. It is interesting to notice that the dose per slice remains almost constant for a wide variation of CT equivalent diameter. This result should now be integrated in a simulation in order to verify if a better solution could be reached.

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IMPLEMENTATION OF DIAGNOSTIC REFERENCE LEVELS FOR X-RAY EXAMINATIONS IN THE UK

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Abstract

Since 1992 NRPB has maintained a computer database of the results sent in from x-ray departments throughout the UK that are following the *National Protocol for Patient Dose Measurements in Diagnostic Radiology*. Reviews of the database take place every five years, the first occurring in 1995 and the second due at the end of 2000. As well as providing useful information on trends in patient doses in the UK, the reviews will also be used as the basis for deriving and updating national diagnostic reference levels (DRLs). The new regulations implementing the EC Medical Exposure Directive in the UK require that DRLs and procedures for their use be established in every radiology department. Guidance issued by the Department of Health indicates that DRLs can be based on local dose records, if available, but that national reference levels may be adopted in the first instance. Strict justification will be required for setting locally-derived DRLs which exceed any corresponding national levels. The national DRLs will be of considerable value to the smaller x-ray departments that do not have sufficient resources or patient throughput to establish their own.

1. Introduction

Periodic monitoring of patient doses from diagnostic x-ray examinations following a national protocol [1] is widespread throughout the UK, with hospital physicists sending the results of their local surveys to NRPB for national collation. By the end of 1995 the national patient dose database contained the results of over 50,000 patient dose measurements made at 375 hospitals. A review of these data by NRPB [2] revealed that, by then, only about 10% of hospitals were exceeding the reference doses listed in the protocol for 8 common types of x-ray examination, which had been based on a national patient dose survey in the mid 1980s. The 1995 review revealed that the mean and third quartile values of the dose distributions had dropped by about 30% since the earlier national survey. However, although the distributions of typical doses had shifted downwards, the variability between hospitals remained as high as before, indicating a continuing need for reference doses to help identify and bring more into line those hospitals at the top end of the dose range. By 1997, when the new EC Medical Exposure Directive (MED) [3] was published, many UK X-ray departments were already using the 1995 review data [2] to set lower reference doses for local use. Regulations to implement the MED in the UK came into force in May 2000 [4] and include the requirement for all hospitals, clinics and surgeries engaging in diagnostic medical exposures to establish *Diagnostic Reference Levels* (DRLs) and to produce (and adhere to) written procedures for their use. A Working Party was consequently set up by the Department of Health in January 2000, with representatives from all the professional bodies involved in diagnostic medical exposures in the UK, to provide formal guidance on the establishment and use of DRLs.

2. DRLs at the national level

It was recognised by the Working Party that an urgent first step was to revise the reference doses recommended in the 1992 national protocol [1] to be more representative of current UK practice. Consequently, new national DRLs based on the 1995 review of NRPB's national patient dose database [2] were formally adopted, with the recommendation that they be reviewed every five years. The new set of national DRLs is shown in Table I. It is derived from rounded 3rd quartile values of the distributions of the mean dose on a representative

sample of patients at each hospital in the database, for each of 12 types of radiograph and 3 types of complete examination. In accordance with the national protocol, DRLs are expressed in terms of the entrance surface dose per radiograph (including backscatter from the patient) and the dose–area product per complete examination.

Table I. New national DRLs for some common x-ray examinations

Radiograph/Examination	Diagnostic reference level	
	Entrance surface dose (mGy)	Dose-area product (Gy cm^2)
Skull AP/PA	4	-
Skull LAT	2	-
Chest PA	0.2	-
Chest LAT	0.7	-
Thoracic spine AP	5	-
Thoracic spine LAT	16	-
Lumbar spine AP	7	-
Lumbar spine LAT	19	-
Lumbar spine LSJ	36	-
Abdomen AP	7	-
Pelvis AP	5	-
IVU	-	23
Barium meal	-	17
Barium enema	-	32

Although it is not expected that DRLs will be established for *every* type of x-ray examination, there is a need to extend the list beyond the few common procedures shown in Table I. There is a requirement in the MED to pay special attention to medical exposures of children and to procedures involving high doses. Priority is consequently being given to developing a method for establishing reference doses for common x-ray examinations on children and to extending the national database to cover some of the increasingly practised high-dose procedures using computed tomography (CT) and extensive fluoroscopy (for example in interventional radiology).

A method for establishing reference doses in paediatric radiology which are directly related to the size of the patient is discussed in NRPB-R318 [5] and in a paper by Hart and Wall in these proceedings [6]. Computed tomography (CT) examinations are estimated to be responsible for about 40% of the collective dose from all medical x-ray examinations in the UK, so it is essential that the more common types of CT examination are also included in the national database. A framework for establishing CT DRLs has been developed in European Guidelines on Quality Criteria for Computed Tomography [7], based on the dose quantities, weighted CT dose index ($CTDI_W$) and dose-length product (DLP). This approach to CT dosimetry and its potential use for establishing DRLs at the national level for common CT examinations in the UK, is discussed in a paper by Shrimpton in these proceedings [8].

To extend the range of examinations for which national DRLs can be established, contributors to the national patient dose database have been encouraged to supply data for most of those

procedures which are among the top 25 contributors to the collective dose from all medical x-ray examinations in the UK. In addition, to give special attention to children and high-dose procedures, data is encouraged for six common types of paediatric examination and for some of the more common and standardised types of interventional procedure. Consideration is also being given to deriving national DRLs for mammography and dental radiography from the data available in recent extensive patient dose surveys in the UK. It is hoped that the next review of the database in 2001 will form the basis for a substantially revised and extended list of DRLs for consideration by the Department of Health Working Party.

3. DRLs at the local level

The new medical exposure regulations in the UK [3] require all hospitals to have procedures in place for establishing DRLs, for the regular assessment of patient doses and for checking compliance with DRLs. Periodic measurements for the purpose of assessing representative patient doses are also required by other legislation dealing with quality assurance of medical imaging equipment [9].

There are basically three options available to hospitals for establishing DRLs locally. They can either adopt the national DRLs, use regional patient dose data to derive essentially regional DRLs and adopt them for local use, or use their own hospital dose data to derive reference levels that are specific to their own practice. If sufficient regional dose data are available from enough hospitals on representative groups of patients, regional DRLs can be established in the same way as the national DRLs. They can have the advantage of being more up to date and more relevant to local practice than the national DRLs, but to be as effective in identifying bad practice, they should be no higher than any corresponding national DRLs.

A hospital may specialise in a medical imaging procedure for which no national or regional DRL is available. In this case, dose data from just the one hospital could be used to establish a typical dose to a representative group of patients for that procedure. This could be used as a "reference dose" against which to assess trends in time at that hospital or to compare different sets of imaging equipment or the procedures used by different "operators". When derived in this way from 'very local data', the reference levels are useful tools for local quality assurance and clinical audit programmes, but do not necessarily provide a guide to generally accepted good practice.

Local patient dose monitoring is required to establish whether DRLs are being consistently exceeded and whether corrective action is required. The DH Working Party recognised that practical guidance was needed on effective methods for carrying out this monitoring while also complying with the equipment quality assurance requirements of other regulations [9]. The Institute of Physics and Engineering in Medicine (IPEM) consequently convened a Working Party in October 2000 to provide such guidance. It will essentially be an extension of the 1992 national protocol for patient dose measurements [1] giving practical advice on how to comply with all the new requirements of the recent regulations for patient dose monitoring in diagnostic radiology. An IPEM report containing this guidance is planned to be published at around the time of this conference.

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IAEA-CN-85-259

DIAGNOSTIC REFERENCE ACTIVITIES FOR NUCLEAR MEDICINE IN AUSTRALIA AND NEW ZEALAND

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Abstract

Nuclear medicine centres in Australia and New Zealand were surveyed in 1998 on behalf of the Australian and New Zealand Society of Nuclear Medicine (ANZSNM) and the Australasian Radiation Protection Society (ARPS) in order to establish diagnostic reference levels. A survey form was mailed to all centres, requesting information on the usual radiopharmaceutical activity administered to a standard adult patient and how the activity is calculated for children. The overall response rate was 89.5%. Data was obtained for 80 imaging procedures and 17 non-imaging tracer studies. For the 68 procedures for which data was available from 10 or more centres, the Most Common Activity and the Reference Activity were found from the mode and 75th percentile of the distribution of activities. A follow-up survey of the 8 hospital centres specialising in pediatric nuclear medicine in Australia was conducted in 1999-2000. Data on the maximum and minimum administered activities (A_{max} and A_{min}) was obtained for 43 pediatric imaging procedures. A_{max} values were significantly less than the Reference Activities determined for adults. The median values of A_{max} and A_{min} are recommended as Pediatric Reference Activities. The effective dose from the Reference Activities was calculated for adults (male and female) and children. The survey results are available on the ANZSNM and ARPS websites at http://www.anzsnm.org.au and http://www.arps.org.au .

1. Introduction

The ICRP introduced the term *diagnostic reference levels* (also known as guidance levels) in 1996. In the case of nuclear medicine the quantity of reference is generally taken to be the radiopharmaceutical activity administered to "a typical adult patient". Reference levels are usually set at the 75th percentile (3rd quartile) or within a specified range of the median (2nd quartile) of the values used in routine clinical practice, parameters which are independent of the shape of the distribution of values or the presence of outlying values. The ICRP recommends that reference levels should be established by the appropriate professional organisations.

ANZSNM and ARPS convened a Working Party to survey the radiopharmaceutical activities used routinely in Australia and New Zealand, and to derive diagnostic reference levels from the survey. [1] The initiative was supported by the Australian and New Zealand Association of Physicians in Nuclear Medicine and the Australasian College of Physical Scientists and Engineers in Medicine.

2. Methods

In 1998 a survey form was sent to all nuclear medicine departments and private practices in Australia and New Zealand known to the Working Party, 172 in all. The survey form did not identify the centre (other than whether it was in Australia or New Zealand, and if in a capital city or a regional centre). Information was sought as to whether the centre was a public hospital, private hospital or private practice, and the proportions of inpatients and pediatric patients.

The survey form listed 70 different imaging procedures and 8 non-imaging procedures, with space for the centre to add any further studies. Myocardial perfusion imaging required eight

entries on the form in order to cover all procedural variations (eg 2 day stress/rest with ^{99m}Tc agent, 1 day rest/stress, 1 day stress/rest, etc). For each procedure that it performed, the centre was asked to state the radiopharmaceutical form and activity that it would administer to a standard adult patient for both planar and SPECT studies. The centre was also asked how it determines the activity administered for a lung ventilation study, whether it uses less activity when imaging with a multi-detector system, how it calculates the activity to administer to a pediatric patient and what would be the minimum activity administered to an infant.

Due to the poor quality data for pediatric procedures obtained in this survey, a follow-up survey of the eight specialist pediatric nuclear medicine centres in Australian hospitals was conducted in 1999-2000 to obtain better guidance for pediatric procedures. Each centre stated how it calculates the activity to administer to a pediatric patient, the usual activity it would administer to an adult-sized patient (A_{max}) and the minimum activity (A_{min}) it would administer to an infant.

3. Results

A total of 96 completed survey forms were received from the original survey. It is common for private practices in Australia to be part of a multi-centre group. The 96 returned forms represented a total of 154 centres, an overall response rate of 89.5%. Two-thirds of the responses were from capital cities with the remaining one-third being from regional areas. Fifty seven percent of the responses were from private practices, 29% from public hospitals and the remaining 14% from private hospitals. The high proportion of private practices was also reflected in the proportion of outpatients studied - most centres performing at least 70% of their procedures on outpatients. Paediatric patients most commonly represented 10% or less of the practice workload. Centres do not reduce the administered activities for planar studies compared to SPECT or when using multi-head detectors.

An additional ten imaging procedures and nine non-imaging procedures were identified from the responses, giving a total of 80 imaging procedures and 17 non-imaging procedures. Bone scans are the most common nuclear medicine procedure in Australia and New Zealand, being performed in all centres who responded to the survey. There were wide variations in administered activities, eg. ^{99m}Tc phosphonates for bone scans ranged from 600 MBq to 1500 MBq, ^{99m}Tc-MAG3 for renal scans ranged from 100 MBq to 800 MBq. Five myocardial perfusion protocols were in common use: ^{201}Tl was used by 44% of centres; ^{99m}Tc agents, primarily sestamibi, were used by the remaining 56%. The one-day rest/stress ^{99m}Tc protocol was most commonly used, although it was far from universal. A few centres used a combined ^{201}Tl rest/ ^{99m}Tc stress protocol. Only two centres used ^{133}Xe gas in preference to ^{99m}Tc aerosol or ^{99m}Tc-Technegas. External monitoring of the count rate over the patient's chest during the inhalation procedure was the most common means of estimating when the activity in the patient's lungs was adequate for diagnostic imaging.

For each procedure a frequency distribution of the administered activity was generated. For those procedures with ten or more responses, 68 in all, the mode and the 75th percentile of the distribution were determined as the **Most Common Activity (MCA)** and the **Reference Activity** respectively. For lung ventilation scans, the 75th percentile of the count rate distribution was 2000 c/s, which was assumed to correspond to 40 MBq of ^{99m}Tc administered.

Not all of the imaging procedures in the original survey are applicable to pediatric nuclear medicine. In the follow-up survey of the eight pediatric centres, there were 43 imaging procedures for which information was provided by at least two of the centres. The most commonly performed pediatric procedures were said to be bone, renal (^{99m}Tc-MAG3, ^{99m}Tc-DTPA and ^{99m}Tc-DMSA) and tumor (^{67}Ga citrate, ^{201}Tl chloride and ^{123}I-mIBG), followed by hepatobiliary (^{99m}Tc-IDA derivatives). Data was provided for two pediatric myocardial perfusion protocols: six centres reported ^{201}Tl chloride stress and rest activities, four of the same centres also reported a 1-day rest/stress protocol using ^{99m}Tc-sestamibi. All centres used ^{99m}Tc -Technegas or ^{99m}Tc-DTPA aerosol for lung scans.

The median values of A_{max} and A_{min} were determined for each procedure with two or more responses, being considered a more useful guide than the mode or 75th percentile given the very small sample sizes and obvious 'outlier' values. The pediatric A_{max} median values are similar to the corresponding MCAs and significantly less than the Reference Activities for adults. The variability in A_{min} was less than in the original survey, even though it was more than 5-fold for 8 of the 43 procedures. The median values of A_{max} and A_{min} are recommended as **Pediatric Reference Activities**, with A_{max} capped by the adult Reference Activity.

Three of the pediatric centres calculate the activity to be administered to an individual patient by scaling A_{max} by the ratio of the patient's body weight to 70kg. The other five centres use scaling factors which represent surface area as a function of body weight, obtained from look-up tables or the 'Gilday Chart' which has surface area scaling factors transposed to the x-axis and weight on the y-axis.[2] The surface area factors used are identical to those recommended by the EANM.[3]

The effective doses from the Most Common Activity and the Reference Activity were calculated for each procedure, using 'standard man' dose coefficients preferably from ICRP 80 [4]. Effective dose values for females were calculated by scaling the 'standard man' value by the ratio of effective doses (female/male) given by Stabin. [5] For any radiopharmaceutical not listed by Stabin a ratio of 1.25 was used, being the average of all the ratios determined by Stabin.

Similarly, the effective dose for the 43 pediatric imaging procedures was calculated for the Pediatric Reference Activities and both scaling methods using effective dose coefficients, preferably from ICRP 80, for children aged 0, 1, 5, 10 and 15 years. [4] Scaling factors were applied for 'standard child' weights for these ages. The larger of the A_{min} Reference Activity and the scaled activity was used in the dose calculations. The survey provides a realistic picture of pediatric exposures from nuclear medicine in Australia. Procedures fall into three broad categories:

- high dose, of the order of tens of mSv, for ^{201}Tl-chloride and ^{67}Ga-citrate
- moderate dose, about 10 mSv, for ^{99m}Tc labelled HMPAO, red cells and sestamibi
- low dose, less than 5 mSv, for the remainder.

Table 1. Comparison of survey Reference Activities (MBq) with recommendations from EANM [3] and IAEA Basic Safety Standards (BSS) Schedule 3, Table III-V (*indicates SPECT value)

Procedure	R'pharm	adults		children			
		survey Ref.Act	BSS	survey Amax	EANM Amax	survey Amin	EANM Amin
blood pool	^{99m}Tc rbc	1000	-	770	800	90	80
bone	^{99m}Tc MDP	900	800	750	500	70	40
bone marrow	^{99m}Tc n.colloid	400	400	400	300	80	20
brain	^{99m}Tc HMPAO	800	500	740	740	100	100
cardiac GHPS	^{99m}Tc rbc	1000	800	800	-	80	-
gastric reflux, GIT motility	^{99m}Tc colloid	40	12	40	40	25	10
hepatobiliary	^{99m}Tc HIDA	200	150	170	150	25	20
infection	^{99m}Tc wbc	740	400	400	500	100	40
infection	^{67}Ga citrate	200	-	150	80	20	10
liver/spleen	^{99m}Tc colloid	200	200 *	150	80	20	15
lung perfusion	^{99m}Tc MAA	200	200 *	150	80	20	10
myocard perf	^{99m}Tc mibi 1 d rest+stress	400 +1100	-	300 +1000	-	40 +110	-
myocard perf	^{201}Tl chloride	120	80	100	-	25	-
renal scan	^{99m}Tc DMSA	185	160	130	100	35	15
renal scan	^{99m}Tc DTPA	500	350	370	200	50	20
renal scan	^{99m}Tc MAG3	350	100	180	70	30	15
thyroid	^{99m}Tc pertech	200	80	120	80	20	10
tumor	^{123}I mIBG	370	400	250	200	70	70
tumor	^{131}I mIBG	40	20	40	80	20	35
tumor	^{201}Tl chloride	160	-	120	-	20	-
tumor	^{67}Ga citrate	400	300	300	80	30	10
tumor	^{99m}Tc mibi	800	-	720	-	100	-
met.Ca thyroid	^{131}I iodide	200	400	-	-	-	-

Data for all procedures, including the effective dose estimates for adults and children, are available on http://www.anzsnm.org.au and http://www.arps.org.au .

4. Discussion

Little attention has been directed towards establishing reference levels for nuclear medicine. [6] The IAEA gives no indication as to how the values in the BSS were derived. Currently there are no reference activities recommended by regulatory bodies in Australia. New Zealand has published reference activities, however these were not derived from a survey of current practice. [7]

The Reference Activities from the survey are between a factor of 1.0 and 1.3 higher than those in New Zealand, and up to two times higher than the IAEA values in the BSS. The factor of 2 for the BSS comparison is for a perfusion lung scan, for which the BSS recommends 100 MBq for planar imaging. This activity would be appropriate following a ventilation scan using a gas such as ^{133}Xe or ^{81m}Kr. Following a ventilation scan using ^{99m}Tc-aerosol or Technegas, the larger perfusion activities found in this survey are necessary to mask the ventilation activity.

The effective dose estimates for the Reference Activities and Most Common Activities are for a 'standard' 70 kg man and 57 kg woman. In Australia, the average weights for males and females over 45 years of age are substantially higher. In heavy patients the administered activity is often increased so that the diagnostic information is not compromised. It is not usual practice to administer less activity to lighter adult patients to maintain a constant radiation exposure.

The practical difficulties of achieving adequate image quality in pediatric nuclear medicine are well known. The risk of a non-diagnostic image from too few counts or patient movement, paticularly with dynamic studies and SPECT, has to be weighed against the radiation exposure. The activities administered to adults have generally risen over time which would have a flow-on effect on exposure if used to calculate the activities administered to children. The pediatric centres adopt a conservative approach, eg. the ^{67}Ga-citrate A_{max} medians for infection and tumor imaging are 75% of the MCAs in adults, resulting in a worthwhile reduction in radiation dose.

Surface area scaling boosts the administered activity and hence the information density of images. It results in a fairly uniform variation of effective dose with body size. However the amount of activity administered to infants under 10 kg using surface area scaling is approximately double that with body weight scaling. Similarly, A_{min} values were introduced to compensate for low counts in infants. An unintended consequence of high A_{min} values and surface area scaling is a substantial increase in the effective dose to an infant, eg. brain imaging with ^{99m}Tc-HMPAO, infection imaging with ^{99m}Tc-white cells, lung perfusion imaging with ^{99m}Tc-MAA and renal imaging with ^{99m}Tc-DMSA. Caution is indicated for an A_{min} value exceeding 10% of the corresponding A_{max}, eg. the A_{min} for tumor imaging with ^{123}I-mIBG is considered to be justified.

^{201}Tl-chloride and ^{67}Ga-citrate are associated with a high radiation dose, particularly in the very young. In the context of an infant or child with malignancy who is to receive chemotherapy and possibly radiotherapy, it is justifiable to image with these agents as the information obtained may influence treatment. Of greater concern is the use of ^{201}Tl or ^{67}Ga in infants and children with non-malignant disease, which should only be considered when the radiation dose is justified on very strong clinical grounds. Alternative investigations should be considered.

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IAEA-CN-85-28

NUCLEAR MEDICINE AND ITS RADIOLOGICAL PROTECTION IN CHINA

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Abstract

The China Society of Nuclear Medicine was established in 27 May, 1980. Since then, nuclear medicine in clinical diagnosis and therapy has been developed rapidly in China. So far there are more than 4000 members of the Society, and more than 350 sets of SPECT and 12 sets of PET have been installed and are busily running in clinic nowadays and about 1 million patients with different types of diseases have obtained nuclear medicine imaging examinations per year. Concerning the nuclear medicine therapy, a lot of patients with many types of diseases obtained benefit from radioisotope therapy. Accordingly, several Policies and Regulations have been enacted by the Government for the radiological protection. Furthermore, a special book titled as "Standardization in Diagnostic and Therapeutic Nuclear Medicine" has been promulgated in June, 1997 by the Health Administration of People's Republic of China,and this book is distributed to almost every nuclear medicine physician and technician in China for their reference in routine nuclear medicine work or research. In this book three parts of contents are covered: Policies and Regulations for the radiological protection, basic knowledge and clinical nuclear medicine applications.

1. Nuclear medicine imaging

Radionuclide scintigraphy is a diagnostic method that provides high sensitive and specific images of the distribution of radionuclides in the human body. The radiolabeled compounds used include substrates, ligands, drugs, antibodies, neurotransmitters and other biomolecules that are tracers for specific biological processes. Thus the resulting images can be considered images of these biochemical or physiological processes(often called "functional images"). Accordingly, this imaging technique has been widely used in clinic, especially used in oncology, cardiology, neurology. The China Society of Nuclear Medicine was established in 27 May, 1980. Since then, nuclear medicine has been developed rapidly in China. There are more than 4000 members of the Society so far, and more than 350 sets of SPECT, 12 sets of PET(includes 8 PET centers) up to now are busily running and about 1 million patients per year have received nuclear medicine imaging examinations in China.

2. Radioisotope therapy

Radioisotope therapy, an innovative and promising approach, based on lesion-targeting radiopharmaceuticals, which can potentially be used as powerful carriers of large amounts of radiation for treatment of many types of diseases, such as hyperthyroidism, metastases or recurrence of thyroid cancer, and many other types of cancer. Therefore, this therapeutic methodology nowadays has been widely utilized in clinic in China.

3. Policies and regulations

In the purpose of radiological protection in safe medical application of radioisotope in nuclear medicine, several Policies and Regulations have been enacted by the Government, including:

— Drug Management Policy of People's Republic of China;
— Execution Method of Drug Management Policy of People's Republic of China
— Management Regulation of Radiopharmaceuticals;

— Radiological Protection Byelaw on Radioisotope and Radio-facility;
— Radiological Protection Standards in Clinical Nuclear Medicine;
— Standards on Radiological Protection of Patients in Clinical Nuclear Medicine.

Furthermore, a special book titled as "Standardization in Diagnostic and Therapeutic Nuclear Medicine" has been promulgated in June, 1997 by the Health Administration of People's Republic of China and distributed to almost every nuclear medicine physician and

Table 1. Guidance dose in diagnostic nuclear medicine

Examined organ	Radio-nuclide	Radio-pharmaceutical	Reference dose
bone	Tc-99m	MDP	555-740MBq(15-20mCi)
kidney	I-131	OIH	11.1-18.5MBq(0.3-0.5mCi)
	Tc-99m	DTPA	370-740MBq(10-20mCi)
	Tc-99m	EC	370-740MBq(10-20mCi)
	Tc-99m	DMSA	185-370MBq(5-10mCi)
	Tc-99m	MAG_3	370-740MBq(10-20mCi)
thyroid	Tc-99m	TcO_4	74-185MBq(2-5mCi)
	I-131	NaI-131	1.85-3.7MBq(50-100μCi)
Thyroid cancer metastases	I-131	NaI-131	74-185MBq(2-5mCi)
brain	Tc-99m	ECD	740-1110MBq(20-30mCi)
	Tc-99m	HMPAO	740-1110MBq(20-30mCi)
	F-18	FDG	185-300MBq(5-8mCi)
Lung perfusion	Tc-99m	MAA	111-185MBq(3-5mCi)
Lung ventilation	Tc-99m	DTPA	1110-1480MBq(30-40mCi)
Lung tumor	Tc-99m	MIBI	740-925MBq(20-25mCi)
Lung tumor	Tl-201	$TlCl_3$	101-185MBq(3-5mCi)
Heart function	Tc-99m	RBC	740-925MBq(20-25mCi)
Cardiac perfusion	Tc-99m	MIBI	555-740MBq(15-20mCi)
Cardiac persfusion	Tl-201	$TlCl_3$	74-111MBq(2-3mCi)
infection	Tc-99m	WBC	370MBq(10mCi)
infection	Tc-99m	HigG	370-740MBq(10-20mCi)
infection	Ga-67	Ga-67 Citrate	74-185MBq(2-5mCi)
liver	Tc-99m	Colloid	148-296MBq(4-8mCi)
liver	Tc-99m	EHIDA	185-370MBq(5-10mCi)
Liver blood flow/pool	Tc-99m	RBC	740MBq(20mCi)
lymph	Tc-99m	dextron	74-222MBq(2-6mCi)
Bone marrow	Tc-99m	colloid	555-740MBq(15-20mCi)
tumor	F-18	FDG	259-370MBq(7-10mCi)
tumor	Ga-67	Ga-67 Citrate	74-185MBq(2-5mCi)

Table 2. Guidance dose in therapeutic nuclear medicine

Treated organ	Radionuclide	Radiopharmaceutical	Reference dose
hyperthyrodism	I-131	NaI-131	**
Metastases of thyroid Ca	I-131	NaI-131	2.96-7.4GBq(80-200mCi)
Bone metastases	Sr-89	$SrCl_3$	148MBq(4mCi)
Bone metastases	Sm-153	Sm-153 EDTMP	740-1850MBq(20-50mCi)
Artery intervention of tumor	P-32	P-32 microsphere	1.85-7.4GBq(50-200mCi)
Neuro-endocrine tumor	I-131	I-131-MIBG	3700-7400MBq(100-200mCi)

** Dose=[(70-120μCi/gram of thyroid)×gram of thyroid]/I-131 uptake of thyroid

technician in China for their reference in routine nuclear medicine work or research. Three parts are covered in this book:

— Policies and Regulations which are mentioned above;
— Basic knowledge, including:
  - principle of construction of nuclear medicine department;
  - radiological protection;
  - radiopharmaceuticals;
  - nuclear medicine instrument;
— Clinical Nuclear Medicine application, which mainly includes:
  - routine radionuclide imaging of most organs with the contents of imaging mechanism, clinical indication, radiotracer, imaging protocol, normal and abnormal images, clinical values, and demands of imaging report writing;
— radioisotope therapy with the contents of therapeutic mechanism, clinical indication and taboo, protocol, and therapeutic effective comments;
  - radioimmunoassay.

In the part of clinical nuclear medicine application mentioned above, the guidance radiological dose for each imaging and therapy is recommended, most of which are listed as follows and very beneficial to radiological protection of patients.

PRELIMINARY RESULTS OF THE ANALYSIS OF THE ADMINISTERED ACTIVITIES IN DIAGNOSTIC STUDIES OF NUCLEAR MEDICINE

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Abstract

The world wide use of the Nuclear Medicine diagnostic procedures and the tendency to its increment, infers an important exposure of the population to ionising radiation, it has motivated that the IAEA in the International Basic Safety Standards (BSS), emits recommendations for the establishment of guidance levels of activities administered to the patients in diagnostic procedures. Taking in account the above-mentioned and that in Cuba exist 20 departments of Nuclear Medicine, that possess in their majority equipment with more than 20 years of operation, that influences directly in the medical exposure, a survey was designed and applied in 10 of these departments. The survey evaluates the compliance with the BSS requirements, and in specific, the activities administered to the patients in Nuclear Medicine diagnostic procedures are analysed. In the present work are presented the obtained preliminary results of the statistical analysis carried out to the activity values used in Nuclear Medicine departments, and the comparison among them, making a proposal of guidance levels for the national practice, and they are compared with those recommended internationally.

1. Introducción

Cada día se hace más amplio a nivel mundial el uso diagnóstico de las fuentes no selladas en diferentes ramas de la medicina, unido a un creciente desarrollo del equipamiento y los radiofármacos utilizados, infiriendo a la población una importante dosis de radiación y un potencial impacto medioambiental. Existen indicios de que la exposición de la población por esta vía seguirá incrementándose [1], lo que impone prestar atención a las recomendaciones de Protección Radiológicas emitidas por Organizaciones Internacionales, como es el caso del establecimiento de niveles orientativos para las actividades administradas a los pacientes en estudios diagnósticos de medicina nuclear [2], que sugieren el desarrollo de buenas prácticas y su empleo como herramienta de optimización de la Protección Radiológica a los pacientes.

En la actualidad Cuba cuenta, con unos 20 departamentos de Medicina Nuclear, donde se realiza un elevado número de estudios diagnósticos con el empleo, en su mayoría, de equipamiento con más de 20 años de explotación: captadores de iodo, renógrafos y gammatopógrafos, los cuales han sido desplazados en el mundo, por equipos más modernos y con los que se obtiene una mejor calidad de la imagen: Cámara Gamma, SPECT.

A pesar de que en el país están establecidos los procedimientos para la realización de los estudios, recomendando la actividad a emplear [3], se observa variaciones entre los diferentes departamentos, por lo que en el presente trabajo se hace un análisis de las actividades empleadas por estudio, a partir de las cuales se puede elaborar una propuesta de niveles orientativos, comparándolos con los establecidos internacionalmente.

2. Materiales y métodos

Para conocer las actividades administradas a los pacientes en los principales estudios diagnósticos que se realizan en el país, se aplicó una encuesta en la que participaron 10 departamentos de Medicina Nuclear, de 6 provincias. Para lograr la representatividad de la muestra se seleccionaron los módulos de forma que se incluyera en el estudio todo los tipos de equipos con que se cuenta en el país.

Se tomó la actividad máxima empleada en cada módulo por examen, la que es representativa para estudios en pacientes adultos estándar. Para establecer la propuesta de los niveles orientativos, se realizó el tratamiento estadístico de estos valores, tomando el correspondiente al tercer cuartil [4].

3. Resultados y discusión

Fueron evaluadas las actividades empleadas para los estudios más frecuentes y que en mayor número de entidades se realizan, observándose variaciones entre los valores reportados por éstas para un grupo de estudios. Dichas variaciones se muestran en la Figura 1.

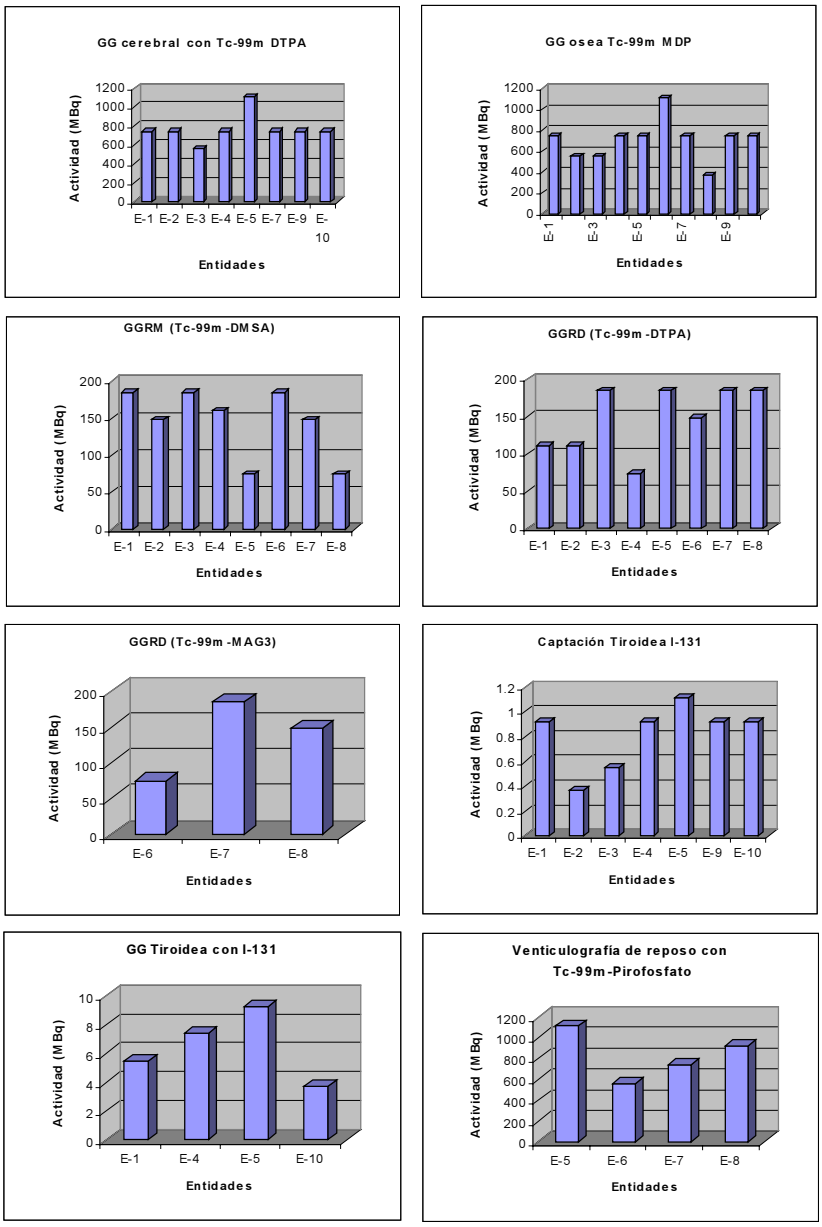


Figura 1. Valores de actividad por estudio en diferentes entidades

En otros estudios como: GG Hepática con Fitato de Sodio, GG Tiroidea con Tc-99m y con I-131 para pacientes operados y en renogramas con Hipurán, no existen diferencias en la actividad suministrada, en cada departamento, a los pacientes, excepto en una de ellas.

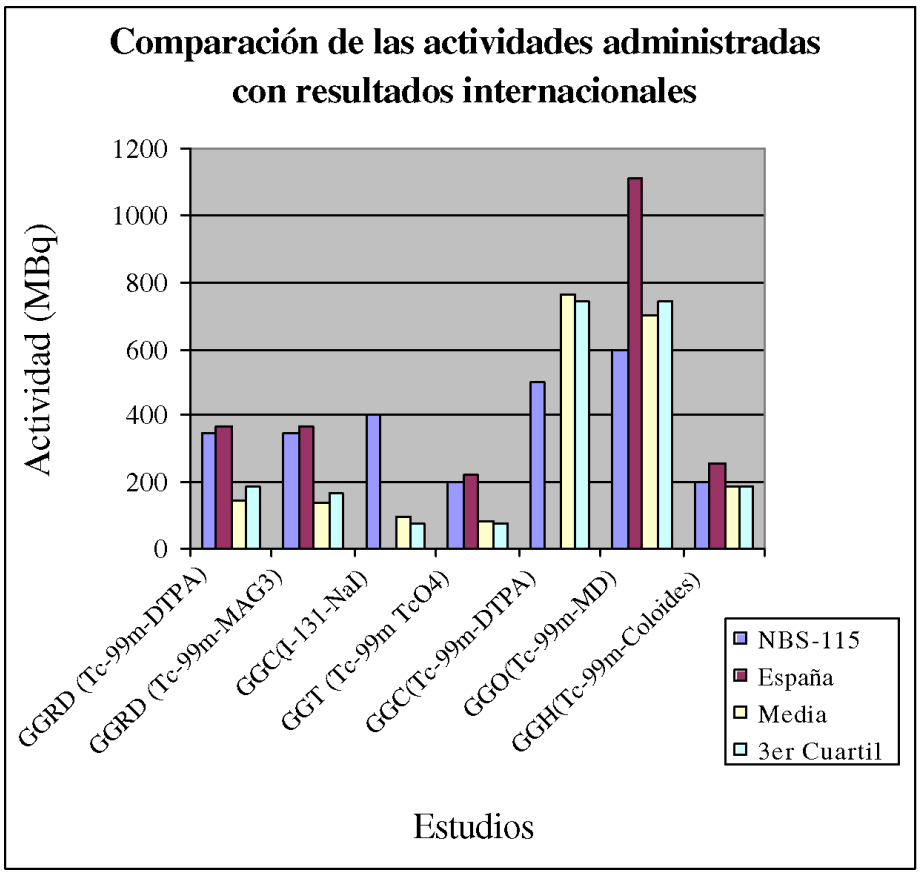
Las variaciones observadas en las actividades empleadas por las entidades están dadas por diferentes causas, entre las que pueden ser señaladas, las condiciones técnicas del equipamiento empleado, las diferentes tecnologías (desde detectores unidimensionales hasta SPECT), la capacitación, grado de asimilación y compromiso del personal, que interviene en la práctica, con las recomendaciones en materia de Protección Radiológica al paciente.

En la Tabla I se muestra un análisis estadístico de los valores de actividad empleada por estudio, en las diferentes entidades del país, observándose que en la mayoría de los casos el valor correspondiente a la media está próximo al del tercer cuartil. Esto puede ser debido a que los departamentos trabajan por protocolos nacionales establecidos donde se recomiendan los valores de actividad a administrar por exámen. Existen tres casos en los que la media supera el valor correspondiente al tercer cuartil, lo cual se debe a que una entidad emplea actividades altas en comparación con el resto, por lo que deben ser determinadas las causas específicas que provocan esta desviación, con relación a las recomendadas en protocolos nacionales.

Tabla 1. Evaluación de los resultados de la encuesta

Nombre del estudio	**Organo de estudio**	**Radio-núclido**	**Fármaco**	**Análisis estadístico de los valores de actividad empleados en los estudios (MBq)**				
				min	**1er Cuartil**	**Media**	**3er Cuartil**	**max**
GG cerebral	Cerebro	Tc-99m	DTPA	555	740	763	740	1110
GG osea	Huesos	Tc-99m	MDP	370	601	703	740	1110
GG Hepática	Hígado	Tc-99m	Fitato de Sodio	148	185	179	185	185
GG Hepática	Hígado	Tc-99m	Coloides	185	185	185	185	185
GG Renal Morfológica	Riñones	Tc-99m	DMSA	74	130	145	185	185
GG Renal Dinámica	Riñones	Tc-99m	DTPA	74	111	148	185	185
GG Renal Dinámica	Riñones	Tc-99m	MAG3	74	111	136	167	185
Renograma	Riñón	I-131	Hipurán	0.74	0.74	0.79	0.79	0.93
GG Tiroidea	Tiroides	I-131	NaI	3.7	4.6	6.15	7.38	9.25
GG Tiroidea	Tiroides	Tc-99m	Pertecnectato	74	74	86	74	148
GG de cuello	Cuello	I-131	NaI	74	74	96	74	185
Captación Tiroidea	Tiroides	I-131	NaI	0.37	0.74	0.82	0.93	1.11
GG de paratiroides	Paratiroides	Tc-99m	MIBI	740	786	832	879	925
GG de mama	Mama	Tc-99m	MIBI	700	756	813	869	925
Venticulografía de reposo	Corazón	Tc-99m	Pirofosfato	555	694	833	971	1110

Los valores de actividad correspondientes al tercer cuartil, los cuales pueden ser propuestos como niveles orientativos en estudios diagnósticos de Medicina Nuclear, han sido comparados con los publicados internacionalmente, obteniéndose que en general los valores propuestos están por debajo de los recomendados. En los casos en que se superan, debe tenerse en cuenta el equipamiento con que son realizados los estudios y la posibilidad de obtener una imagen con calidad diagnóstica a niveles más bajos. No obstante en los estudios GGO(Tc-99m-MDP) y GGH(Tc-99m-Coloides) se deben investigar las causas específicas por las que se sobrepasan estos niveles.



4. Conclusiones

Los valores de actividad propuestos como niveles orientativos para los diferentes estudios diagnósticos que se realizan en el país, están en el rango de los reportados internacionalmente. Se requiere a partir de estos resultados, realizar un análisis en cada entidad, que posibilite su implementación.

Las variaciones de la actividad administrada por estudios, en las entidades encuestadas, es un reflejo de las condiciones técnicas y diferencias tecnológicas del equipamiento empleado y la necesidad de lograr elevar la preparación de todo el personal involucrado en los estudios en aspectos relativos a la Protección Radiológica.

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ADMINISTERED ACTIVITY AND ESTIMATED RADIATION DOSES FROM NUCLEAR MEDICINE DIAGNOSTIC PROCEDURES TO THE ISRAELI POPULATION

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Abstract

The current levels of administered activity of radiopharmaceuticals in several common nuclear medicine diagnostic procedures and their contribution to the radiation doses to the Israeli population in 1998-2000 were analyzed. Diagnostic reference levels and the concept of effective dose per capita are discussed as relevant parameters to optimize patient protection.

1. Introduction

In connection with an IAEA supported project aimed at developing a national program for radiation protection of the patient in diagnostic investigations, we previously reported radiation doses resulting from nuclear medicine imaging in Israel, in 1998 [1]. The contribution of nuclear medicine diagnostic investigations to the radiation doses to the population in Israel was estimated by using the effective dose and effective dose per capita concepts [2]. About 3% of the approximately 6,000,000 Israeli population underwent nuclear medicine diagnostic procedures in 1998, resulting in a contribution of about 1,800 person-Sv to the collective effective dose. Consequently, the effective dose per capita, due to nuclear medicine procedures, was estimated to be 0.3 mSv [1].

As in nuclear medicine procedures the radiation dose to the patient is a function of the amount of the administered radiopharmaceutical and its body distribution, in order to determine the sources for the relatively high effective dose per capita to the Israeli population, and to suggest possible ways to lower it, we analyzed the current levels of administered activity in several common diagnostic procedures.

2. Materials and methods

Thirteen out of more than thirty functioning nuclear medicine and/or nuclear cardiology clinics supplied us with information about the radiopharmaceuticals used, the administered activity (AA) per procedure and the relative number of examinations performed in the period 1998-2000. When relevant, data available about single doses of radiopharmaceuticals purchased in one of the functioning central radiopharmacies, were also analyzed. The distribution of AA per procedure in the clinics surveyed was recorded and averaged, and the resulting effective doses were calculated based on the conversion tables presented in ICRP Publication 80 [2]. Our results were obtained by averaging and extrapolating these data.

3. Results

The eight radiopharmaceuticals we studied cover >90% of all nuclear medicine diagnostic imaging procedures performed in Israel between the years 1998–2000.

Table 1 summarizes the current AA of radiopharmaceuticals per procedure (average, minimum and maximum) in Israeli clinics. In addition it shows the guidance levels (BSS) [3] and the UNSCEAR 2000 [4] data for Health care level I, plus the deviations, in percentages,

Table 1: Current Administered Activity in Common Nuclear Medicine Diagnostic Procedures and the Resulting Effective Doses per Procedure in Israeli Clinics (1998-2000) Compared with the Corresponding BSS Guidance Levels [3] **and to the UNSCEAR 2000 Data for Health Care Level I (1991-1996)** [4]

Radiopharmaceutical	Average Administered Activity (mCi) per procedure			Deviation of the normalized average from BSS	Deviation of the normalized average from UNSCEAR	Effective dose (mSv) per procedure[2]		
	Israel (min – max)	BSS	UNSCEAR			Israel (min – max)	BSS	UNSCEAR
Tc-99m MDP (Bone)	22.9 (20-25)	21.6	19.4	+ 6%	+13%	4.8 (4.2-5.3)	4.6	4.5
Tc-99m CaNaPhytate (liver & spleen)	4.6 (3-5.5)	4.5	3.8	- 14.2%	+23.8%	2.4 (1.6-2.9)	2.3	1.7
Tc-99m RBC (blood pool)	22.5 (15-27.5)	21.6	6.8 – 29.8	+ 4%		5.8 (3.9-7.1)	5.6	2.9 – 8.0
Tc-99m MAA (lungs)	4.0 (2.5-6)	5.4	3.2	- 17.4%	+20.3%	1.6 (1.0-2.4)	2.2	1.5
Tc-99m DTPA (kidneys)	7.6 (2-11.5)	9.5	4.9	- 10.5%	+43%	1.4 (0.4-2.1)	1.7	1.5
Tc-99m Sestamibi (myocardium)	21.3 (10-39)	16.2	16.8	+ 31.5%	+32.8%	6.7 (3.2-9.4)	5.1	7.6 – 10.0
Tl-201 chloride (myocardium)	3.0 (2-4)	2.7	2.7	+11%	+16.8%	24.4 (16.3-32.6)	22.0	6.9 – 20.3
Ga-67 citrate (tumor and inflammation)	7.0 (3.5-10)	8.1		-13.6%		31.1 (15.6-44.4)	36.0	

of the normalized average Israeli data from these values and the resulting calculated effective doses (mSv/procedure).

An uncertainty of up to 25% of all our estimates should be taken into account.

As shown in Table 1, the range of the resulting absorbed doses per procedure in Israel is relatively wide: from less than 1 mSv for some procedures using Tc-99m to more than 30mSv for those using Ga-67 and Tl-201, nevertheless in good agreement with both BSS and UNSCEAR data.

4. Discussion

We compared the results, obtained by us, for nuclear medicine diagnostic imaging procedures performed in Israel between the years 1998–2000 with the guidance levels, i.e. maximum usual activities in nuclear medicine investigations for a typical adult patient, published in the Basic Safety Standards (BSS) [3] in 1996 and also with the most recent data published by UNSCEAR 2000 [4], i.e. the average values for countries of Health care level I (1991-1996).
The Israeli data were rather high: in good agreement with the BSS guidance levels, (the upper limits), however higher than UNSCEAR average values (Table 1).

The average effective dose per capita reported in the UNSCEAR 2000 for countries of health care Level I, was 0.08 mSv. The dose we calculated for the Israeli population for 1998 was 0.3 mSv per capita[1]. In order to determine the sources of the difference between these two values, beside the fact that they do refer to relatively distant periods, we analyzed the contribution of the different diagnostic procedures to the average effective dose per capita.

Bone and cardiovascular imaging were in 1998 the main contributors to the collective radiation dose to the Israeli population from diagnostic nuclear medicine procedures: 19.6 and 62.0 %.

The annual number of Tc-99m MDP and Tl-201 chloride procedures per 1,000 population in Israel significatively exceeded the values reported in UNSCEAR 2000:

12.42 vs. 5.85 for Tc-99m bone imaging and 6.75 vs. 0.007-1.88 for Tl-201 myocardial imaging.

The above mentioned data, in addition to the administered activities which slightly exceeded the UNSCEAR 2000 values (Table 1), make up for the difference in the average effective dose per capita between Israel in 1998 and UNSCEAR 2000, for 1991-1996. As we compared data from relatively distant periods, the significance of the difference we found must be considered with precaution and reconsidered when up dated UNSCEAR values are published.

Aiming to improve the radiation protection of the patient whilst myocardial imaging is the replacement of a procedure requiring administration of 4 mCi Tl-201 chloride, with two studies (one at rest and one under stress) using a total of 30-50 mCi Tc-99m Sestamibi. For a wide range of pathologies, clinical studies proved that these two procedures generally provide similar diagnostic information. The above mentioned administered activities result in an effective dose of 34.1 mSv for Tl-201 and of 9.6-

16 mSv for the Tc-99m Sestamibi procedures. Consequently, by replacing Tl-201 by Tc-99m imaging, the radiation dose to the patient per procedure could drop to 28-47%. The lower effective dose to the patient is also one of the several reasons why more and more myocardial studies using Tc-99m are reported in the literature. In the analyzed frame, i.e. Israel 1998, if all Tl-201 examinations would have been replaced by Tc-99m Sestamibi, the annual collective dose to the population, could have been decreased by at least 730 person-Sv, resulting in an average effective dose per capita of 0.18mSv.

5. Conclusions

- The current level of activity of radiopharmaceuticals administered to the patient per nuclear medicine diagnostic procedure in Israel is in good agreement with the BSS reference levels.
- The average administered activities per nuclear medicine diagnostic procedure in Israel, in 1998-2000, exceed the corresponding values as published in the UNSCEAR 2000 for countries of Health care level I (1991-1996), by 13–43%.
- The effective dose per capita to the Israeli population resulting from nuclear medicine and cardiology diagnostic procedures in 1998 was relatively high, mainly because of the frequent use of high activity Tl-201 procedures.
- By replacing, when possible, myocardial imaging with Tl-201 by Tc-99m agents, the radiation dose per procedure can be significantly reduced.
- The guidance level of activity administered per procedure alone cannot assure the optimization of the radiation dose to a certain population.
- For a comprehensive evaluation of the radiation protection for diagnostic nuclear medicine investigations of a certain population, the effective dose per capita should be considered in addition to the guidance levels of administered activity of radiopharmaceuticals.

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DEVELOPMENT OF DIAGNOSTIC REFERENCE LEVELS IN PAEDIATRIC RADIOLOGY

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Abstract

With a very wide range in patient size from a newborn baby to a 15 year old adolescent, reference doses for paediatric radiology can sensibly be established only for specific sizes of children. Five standard sizes have been chosen representing newborn, 1, 5, 10 and 15 years. A method is described for normalising the dose measured on a child of any size and age to the corresponding dose to the nearest standard sized patient. Normalisation factors for entrance surface dose and dose-area product measurements were calculated based on effective linear attenuation coefficients (μ) measured in phantoms and calculated by Monte Carlo techniques for the typical x-ray spectra and field sizes used in paediatric radiology. These normalisation factors were applied to European paediatric dose survey data to derive some preliminary size/age specific reference doses for some common radiographic projections and for micturating cystourethrography (MCU), the most common fluoroscopic examination performed on children.

1. Introduction

Patient size is an important determinant of the level of dose received by individuals from diagnostic x-ray examinations and is a confounding factor when assessing and comparing radiation doses to patients in x-ray departments. Variations in size are large between paediatric patients (covering the age range from newborn to 15 years) and the use of a single reference size is impractical. Accordingly, it has been common practice to group children by age in order to facilitate meaningful comparison of dose using age-bands such as: 0–1 month, 1–12 months, 1–5 years, 5–10 years and 10–15 years. However, children within the same age band can still be of considerably different sizes, resulting in up to a factor of three difference between the entrance surface doses to obtain the same exit dose and hence the same dose to the image receptor.

This paper discusses methods for deriving factors for normalising doses measured on actual patients to those relating to patients of the nearest standard size representing 0, 1, 5, 10 and 15 year old patients. This procedure will enable the results of local dose surveys to be compared with reference doses for the same standard–sized paediatric patients. The establishment and use of reference doses as a practical way of promoting optimisation of patient protection is required by the EC Medical Exposure Directive [1], where they are referred to as *diagnostic reference levels*. This approach has also been adopted in the dose criteria for radiographic examinations of adult and paediatric patients in European Guidelines [2, 3]. However, in the paediatric guidelines [3], a European–wide paediatric patient dose survey for common types of radiograph, in which the patients were simply divided into a few narrow age bands, failed to demonstrate any clear trends in dose with age. It was possible to provide only tentative reference doses, mainly for five year old patients, in those guidelines. In this paper, the same European survey data have been re–analysed by normalising the measured doses to those for the nearest standard–sized patient and, where there are sufficient data, new reference doses have been derived for each standard size. As patient thickness had not been measured in the European survey, a method was developed for estimating thickness for the various radiographic projections from the available information on patient height and weight.

2. Selection of standard sizes for paediatric patients

The AP and lateral thicknesses of children of various ages for common radiographic projections through the trunk and the head have been published by Bohmann [4]. These data were used to select the required number and dimensions of standard-sized patients so that normalisation factors were unlikely to exceed a factor of two (i.e. differences in thickness between adjacent standard-sized patients were <5 cm). The thicknesses of the five selected standard-sized patients are shown in Table I.

Table I. Standard thicknesses for the trunk and head

Age (y)	Standard thickness by beam projection (cm)				
	Trunk AP	Trunk LAT	Head AP	Head LAT	Trunk average (for multiprojection exams of the trunk)
0	8.5	10	12	9	9
1	12	15	16	12	13
5	14	19	18.5	14.5	15
10	16	23	18.5	14.5	18
15	18	27	18.5	14.5	21

When dose measurements (usually of dose-area product (DAP)) are integrated over a complete examination comprising multiple radiographs and/or fluoroscopy, the projection of the x-ray beam is likely to change and may include AP, PA, lateral and oblique projections. In this case separate AP and lateral standard trunk thicknesses are inappropriate and an "average" trunk thickness would be more useful. A simple estimate of patient average trunk thickness can be made from height and weight data by assuming the patient is a circular cylinder of unit density. The equivalent cylindrical diameter (ECD) is given by:

$$ECD = 2(weight/\pi.height)^{0.5},$$ where ECD and height are in cm and weight is in grams.

3. Derivation of normalisation factors

Assuming exponential attenuation of diagnostic x-ray beams through the patient, the relationship between the entrance surface dose (ESD) and the exit surface dose is given by:

$$\text{Exit dose} = ESD\, e^{-\mu x}$$

where μ is the linear attenuation coefficient for the part of the patient's body being x-rayed, of thickness x, and includes the effect of the inverse square law. For a constant exit dose, the patient entrance surface dose (ESD_x) will vary with patient thickness, x, according to:

$$ESDx = k\, e^{\mu x}$$

Measured values of ESD for a patient of thickness d can, to a first approximation, be normalised to the ESD for a patient of standard thickness, s, which would result in the same exit dose by multiplying by the normalisation factor, F_{ESD} where:

$$F_{ESD} = ESD_s / ESD_d = e^{\mu(s-d)}$$

The factor, F_{DAP}, for normalising DAP measurements for complete examinations involving multiple projections, measured on a patient of known thickness to the nearest standard thickness, is given by:

$$F_{DAP} = e^{\mu(s-d)} . s^2/d^2$$

where there is an additional term to account for the fact that the area component of DAP will increase with patient size roughly as s^2/d^2 (assuming the dimensions of the patient in a plane perpendicular to the axis of the x-ray beam are proportional to the thickness of the patient along the axis of the beam).

Appropriate values of μ for the exposure conditions prevailing in paediatric radiology were obtained from measurements of entrance and exit doses on a soft tissue equivalent phantom (WT1 material) representing paediatric patients of 5, 10, 15, and 20 cm thickness with a number of typical diagnostic x-ray spectra and field sizes. A lung equivalent material phantom (using the lung sections of an Alderson Rando phantom) was also used to simulate chest radiography. Exit doses were measured in front of and behind an antiscatter grid (grid ratio 12:1, 36 lines per cm) since the ratio of primary to scattered radiation in the exiting beam is also a function of patient thickness. As the grid removes most of the scattered radiation, the attenuation coefficient derived from the through-grid exit dose was higher than that measured without a grid. Values of μ were obtained from the slopes of graphs of ln ESD per unit exit dose against phantom thickness.

The phantom measurements were verified and extended to a wider range of exposure conditions by Monte Carlo simulation. Remarkably close agreement was achieved (to within 2% without a grid, and 6% with a grid) between the Monte Carlo calculated μ values and those measured in the soft-tissue equivalent phantom. For the lung equivalent phantom the agreement was not so close, but the discrepancy can be quantitatively explained by small soft-tissue components in the lung sections of the Alderson phantom which were not simulated in the Monte Carlo calculations.

Without a grid, values of μ for soft tissue (WT1) range from 0.20 to 0.25 cm^{-1} for the range of x-ray qualities and beam areas likely to be met in paediatric radiology and with a grid from about 0.25 to 0.30 cm^{-1}. They are more dependent on kV than field size over the ranges studied. The measured values of μ for lung are considerably lower than the values for soft tissue and range from 0.11 to 0.13 cm^{-1}.

Using the appropriate values for μ and the thicknesses of standard patients as discussed above, values of the normalisation factors were calculated for a range of patient thicknesses in 0.5 cm increments from that for a small baby to a large 15 year old. The results are tabulated in NRPB-R318 [6]. All F_{ESD} values were no larger than a factor of two up or down, as were F_{DAP} values apart from some of those for very small babies or very large 15 year olds.

4. Derivation of size/age specific reference doses

The wide-ranging survey data collected for the European paediatric radiology trial [3] were re-analysed to develop size/age specific reference doses for common radiographs. Firstly, to eliminate some unacceptable practices, the data were restricted to those from hospitals that were using the tube voltage, film-screen speed and antiscatter grid technique factors recommended in the European Guidelines [3]. Data for patients of any size were included and the ESDs normalised to those for the nearest standard-sized patient using the F_{ESD} normalisation factors discussed above. The thickness of the radiographed section through the

patient was derived from patient height and weight data using a method developed by the authors [5]. The distribution of the size-normalised doses from the European trial has been used to derive reference doses for standard-sized paediatric patients based on the rounded third quartile values, as shown in Table II. European reference doses for adult patients [2] are also shown for comparison.

By normalising for patient size and rejecting unacceptable practices, the paediatric reference doses now show a reasonable trend with patient age, which was not evident in the original data [3]. The values, even for a 15 year old child, are substantially lower than those shown for an adult, which reflects the expected additional care taken when children are radiographed and the improvements made in patient protection since the adult reference doses were derived over 10 years ago.

DAP data have been collected for micturating cystourethrogram (MCU) examinations at a sample of 12 European hospitals [5]. Between 10 and 30 paediatric patients were included from each hospital with ages ranging between neonate and 15 years old. However, the majority of patients were under 5 years old as is usual for MCU examinations. Information on weight, height and trunk thickness was collected for each patient. The DAP for each patient was normalised to that for the nearest standard trunk thickness for multiprojection examinations as shown in Table I, using appropriate values of F_{DAP}. The rounded third quartiles of the distributions of the mean normalised DAP values were used to derive the provisional reference doses shown in the last row of Table II.

Table II. Size/age specific paediatric radiology reference dose values

	Reference Dose Value					
	Neonate	1 year	5 year	10 year	15 year	Adult
Radiograph	*Entrance surface dose, mGy*					
Chest AP/PA	0.05	0.05	0.07	0.12	-	0.3
Abdomen AP/PA	-	0.4	0.5	0.8	1.2	10
Pelvis AP	-	0.5	0.6	0.7	2	10
Skull AP/PA	-	0.8	1.1	1.1	1.1	5
Skull LAT	-	0.5	0.8	0.8	0.8	3
Examination	*Dose-area product, Gy cm^2*					
MCU	0.6	0.9	1.2	2.4	-	40[a]

[a] Reference dose for IVU examination on adults

Acknowledgements

This project was partly-funded by the European Commission through contract number F14P CT95-0002.

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Topical Session 6

RADIOLOGICAL PROTECTION OF THE EMBRYO AND FOETUS IN PREGNANT PATIENTS

TEN YEARS INVESTIGATION ON RADIOLOGICAL EXPOSURES TO THE EMBRYO AND FETUS IN PREGNANT WOMEN OF IRAN

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Abstract

Over 1340 Iranian pregnant patients, exposed to diagnostic x-rays during 1984 to 1994, referred to me for investigation and estimation of the absorbed dose to their embryo or fetus. They were almost all the patients exposed to x-rays in the whole country in 10 years. Two sets of questioner filed for each patient and all the exposing condition and setting information obtained from the radiology centers concerned. The absorbed dose to embryo or fetus accurately calculated and in some cases measured in a phantom for each patient. The youngest patient at the time of irradiation was 15 and the oldest was 51 with an average of 28.624±5.961 years old. The AP and lateral thickness of patient's abdomen on average were 18.078±0.162 cm and 24.630±8.365 cm respectively. The average weight of patients was 59.285±12.945 kg. ranging from 30 kg to 122 kg. The marriage age of the patients on average was 19.398±4.107 years ranging from 9 to 42 years old. The average age of fetus when exposed to x-rays was 31.22±18.76 days. About %20 of the patients had exposures in 2 to 4 more sessions. The average fetal dose was 0.68± 0.381 cGy with over %37 from 1 to 9 cGy.

1. Introduction

There have been great concern and anxiety amongst many pregnant patients exposed to ionizing radiation on the fate of their fetus over the last century. The sensitivity of the human embryo and fetus to ionizing radiation is an important topic in radiation protection. Observations on patients exposed to ionizing radiation during pregnancy as well as extensive experimental investigations on mammals have greatly increased our understanding of the effects induced when the mammalian embryo and fetus are irradiated. It is evident, in consequence, that ionizing radiation must be considered to be a teratogenetic agent [1, 2, 3, 4 & 5]. The sensitivity of the embryo to ionizing radiation depends on the day of gestation on which it has been exposed [6]. Epidemiological studies have indicated that exposure of pregnant women to diagnostic x-rays can increase the risk of induction of the late effects (cancer) in the children [7]. Besides, exposure of embryo or fetus to moderate doses of ionizing radiation can cause death, malformation, growth retardation and functional impairment. Information from Hiroshima indicates that measurable damage can be produced by doses of 10-19 cGy. [8] . Here I present only a part of a considerable amount of data obtained and filed over a period of 10 years (1984-1994). These data related to almost all pregnant patients in Iran. They were exposed to diagnostic x-rays and referred to me for investigation, measurement and calculation of the absorbed dose to their embryo or fetus. The results reported to the authorities and the referring physician. In very rare cases, when the amount of absorbed dose was considerably high, therapeutic abortion recommended.

2. Materials and methods

During the 10 years the information was obtained from cases exposed in pregnancy:

1. Name, age, education, occupation, address and the telephone number of the patient.
2. Date of the last menstrual period (LMP), pregnancy test, weight and the thickness of the irradiated part of the patient's body.
3. The name of radiology center, the exact date of irradiation and the age of embryo or fetus at the time of irradiation.
4. The date of marriage, blood group, addictions (if any), contraceptives used and other family relation with the spouse.
5. Number of previous pregnancies, number and age of present children, history of any previous abortion and early delivery of any child.
6. History of other previous illnesses of the patient, the spouse and their first grade relatives.
7. Previous treatments and the drugs taken by the patient and her spouse.
8. Age, education, occupation, addiction (if any) and the blood group of the patient's spouse.
9. The total dose absorbed (in cGy) by the embryo or fetus during the radiological procedures.

All the information obtained stored in a database using Fox Pro2 and the statistical analysis of each variable performed by SPSS/PC + vers. 3.0 software.

3. Results

Some of the results, which seems to be useful and relevant to this conference presented as following and the rest to be published in another paper:

Patients Age: Figure 1 shows the age distribution of the pregnant patients at the time of irradiation. The average age is 28.624±5.961. The age of the youngest patient was 15 and the oldest was 51 years.

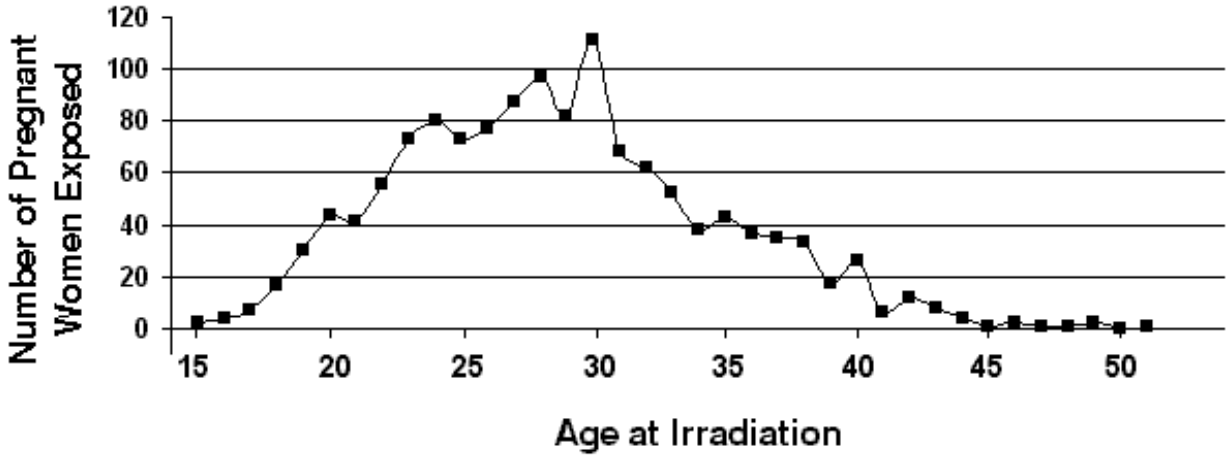

Fig. 1. Distribution of woman exposed and the age at irradiation

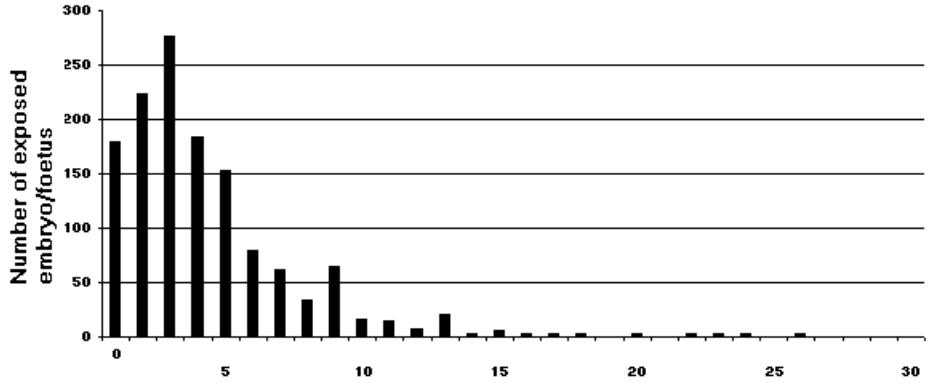

Fig.2. Gestational age in weeks and the corresponding number of exposed fetuses

Embryo or fetus absorbed dose: As shown in Figure 3, the highest occurrence (%37.8) of absorbed dose to fetus is from 1 to 9 cGy and for absorbed dose from 0.1 to 1 cGy is %31.54. The mean fetal absorbed dose was 0.68+0.381 cGy.

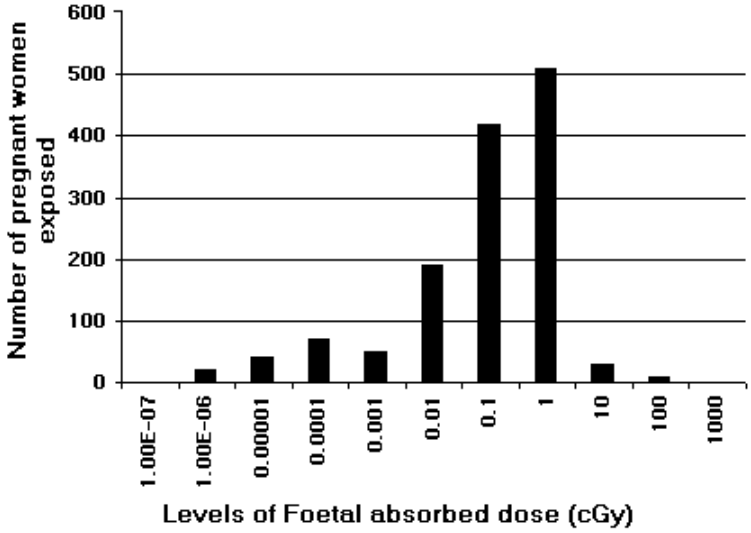

Fig. 3. The absorbed dose by embryo and fetus during the radiological procedures (N =1341).

4. Discussion and conclusions

The main reasons for the patients to undergo radiological examinations were:

1. Non malignant gastrointestinal problems (%32.75), where in most of the cases radiological examinations were not necessary and the cause illness had been the pregnancy itself.
2. Non malignant urologic problems (%19.44). 3) Back pains (%14.31).
3. Orthopedic problems (%11.83). 5) Accidents (%8.07).
4. Non malignant glandular problems except diabetes (%6.97).

The problem of lack of modern radiological systems in developing countries could also lead to higher doses in the patient's investigation.
The majority of the patients were not aware of their pregnancy before undergoing radiological examinations and the most of the radiologists did not consider it seriously. Otherwise in many

of the above cases the radiological examinations could have ruled out or postponed to after the childbirth.
The health effects, if any to be expected from the low levels of exposure prevalent in diagnostic radiology will not be identifiable. Knowing the radiation effects, a great anxiety was observed amongst the majority of the patients and their families for the fate of the child. Many of them decided to commit illegal abortion privately, even if the fetus absorbed dose was negligible.

These facts and the above figures show that we needed and could eliminate or reduce the patients dose and consequently the absorbed dose to the embryo or fetus considerably.

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DIAGNOSTIC RADIATION OF POTENTIALLY REPRODUCTIVE FEMALES

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Abstract

Objectives: To find out how consistent or variable is the understanding and practice of radiation protection procedures for women in the childbearing age at a multispecialty tertiary hospital. **Setting:** Riyadh Military Hospital Study. **Design:** Non-clustered population survey. **Methods:** A questionnaire was distributed during grand rounds, mid-day clinics and a radiology conference. Questions included which radiation protection rule does the respondent use for females, whether he or she is familiar with those rules and what is his or her source of reference. Further questions were about the radiation dangers to the fetus. **Results:** Response was 95 (100%). Fifty-seven (60%) were males and 38 (40%) were females. The majority 50 (53%) were Saudis, 16 (17%) Western and 29 (30%) were other nationals. Sixty-two (65%) followed the old rule "10-day rule"; 17 (18%) followed the new "28-day rule" and 16 (17%) didn't know which rule to follow. None of those who followed the "28-day rule" indicated hospital policy as their reference. **Conclusions:** The understanding and practice of radiation protection guidelines for females is inconsistent. There is significant unfamiliarity with the radiation protection rules among our hospital practitioners.

1. Introduction

There has been significant changes in the guidelines concerning the exposure of women in the child bearing age to diagnostic radiation [1,2,3]. The 10-day rule states that all radiologic examinations of the lower abdomen and pelvis of women of reproductive capacity, that are not of importance in connection with the immediate illness of the patient, be limited in time to the period when pregnancy is improbable, i.e. the 10-day interval following the onset of menstruation. This was replaced by the 28-day rule, which states that the risk of irradiating a fetus is too small in the first month following the start of menstruation and no limitation is necessary unless a period is missed. Lately there has been a recommendation of limited return to the 10-day rule[3] for procedures delivering high radiation dose to the female pelvis, namely pelvic computerized tomography (CT) and barium enemas.

From our own observation, many questions on safety and timing do arise when performing or deciding appointments for radiological procedures in females. The objective of this study is to find out how consistent or variable is the understanding and practice of diagnostic radiation for potentially reproductive females among our hospital practitioners.

2. Methods

A non-clustered population survey. A questionnaire was distributed during grand surgical and medical rounds, a radiology conference and mid-day primary care/dental clinics. Some of the meetings were attended by personnel from other institutions in Riyadh. These were excluded from this study. Demographic information was collected. Respondents were asked whether they followed the 10-day rule or the 28-day rule and whether they were familiar with either of them. They were also asked about their source of information regarding these rules whether it was from the hospital policy, a book, a lecture, course or their own guess. Further questions covered what the respondent would consider is the most dangerous period for fetal exposure to diagnostic radiation and what are the specific dangers. The questionnaire was initially pilot tested. In a study in Britain [4] 20% of hospitals followed the old guidelines. This was used as an acceptable risk with an allowance up to 35% for maximum tolerable prevalence to calculate the sample size for a statistical power of 99.9%. Results were manually checked for

completeness and were subsequently entered on a data base file. Epistat statistical package was used for analysis and chi-square test for cross tabulation.

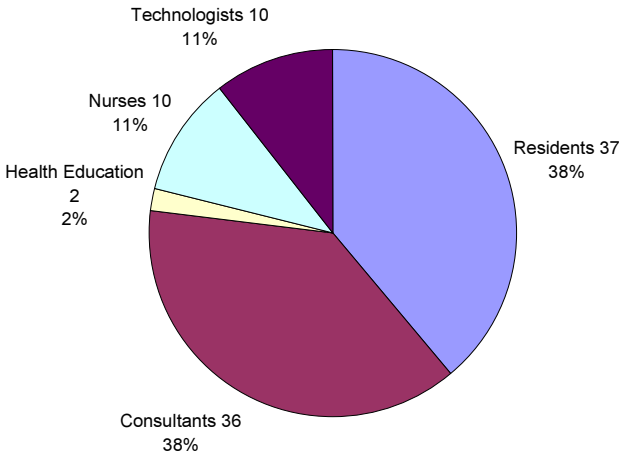

Figure 1a – Actual jobs of respondents

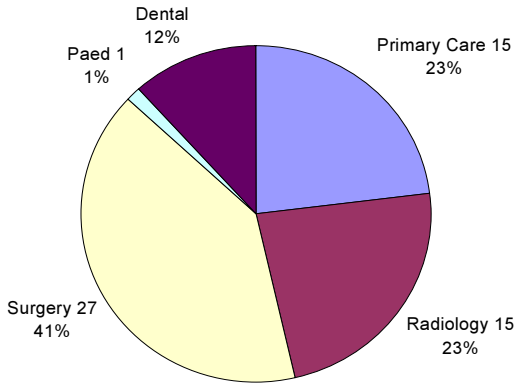

Figure 1b – Departments of respondents 1

3. Results

There were 95 respondents (100% of this cohort. Fifty-seven (60% were males and 38 (40%) were females. The majority 50 (53%) were Saudis, 16 (17%) were Western and 29 (30%) were other nationalities. The actual jobs and departments are shown in Figures 1(a) and 1(b).

Sixty-two (65%) indicated that they follow the 10-day rules; 17 (18%) followed the 28-day rule while 16 (17%) didn't know which rule to follow. Of those who followed the 28-day rule 12 (70%) were Saudis, 2 (12%) were Western and 3 (18%) were other nationals. Thirty-seven (39%) respondents said they were not familiar with the 10-day rule and 66 (69%) were not familiar with the 28-day rule.

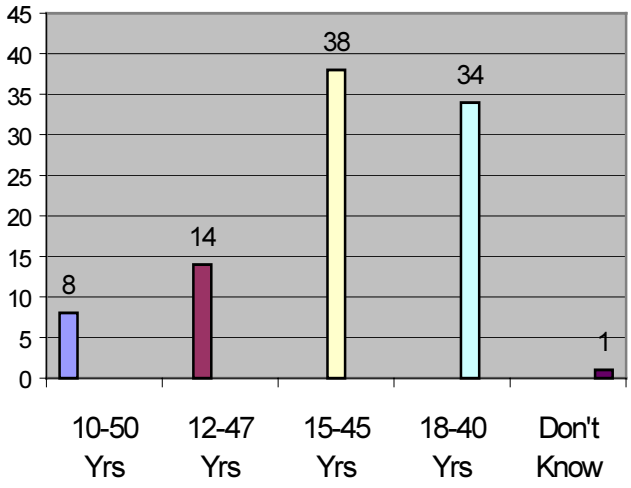

Figure 2. Child bearing age n = 95

None of those who followed the 28-day rule indicated that hospital policy was their source of information. The selected definition for the childbearing age is shown in Figure 2. Only 2 (2%) of the respondents emphasized mental retardation as the potential radiation hazard to the fetus2.

4. Discussion

Radiation protection is an important aspect of patient care. The number of radiological examinations is increasing. As many as 20% of x-rays are not necessary [5]. From our records, females representation (40%) of those undergoing radiological procedures in our department. It is not uncommon that a radiological examination for an adult female may be denied, rescheduled or canceled because or radiation protection guidelines [4]. This may cause frustration.

The majority 62 (65%) of our hospital staff involved in this study followed the old guidelines. This is a very high proportion compared to a study in Britain [4]. However our study was for individuals within one hospital unlike the study which compared policies in different hospital.[4]

Our hospital is multinationally staffed. In absence of strict adherence to hospital policy their response can give reflections of practices abroad or a prejudiced assumption for the practice in Kingdom.

Twenty years ago marital age in Saudi women was low [6]. The rate of first marriage under 15 years of age was 33%. This has dropped to 3.5% but 15.4% of females between 15-19 years are married. About one third of our respondents believed that the child bearing age is only 18-40. This is an underestimate. Only 35 (37%) of respondents correctly identified the period with highest radiation risk to the fetus in utero (8^{th} – 15^{th} week). Accurate identification of this risky period was the main reason which prompted changes of the rules [2]. Only 2 (2%) mentioned mental retardation as a possible risk. In fact this is the main potential danger.

5. Conclusion

The understanding and practice of radiation protection guidelines for women in childbearing age is inconsistent among our practitioners. There is unfamiliarity with the guidelines. Training and education of personnel is necessary. Review and/or circulation of hospital policies is recommended.

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PROGRAMME FOR REDUCING THE RISK FACTORS DUE TO PRENATAL EXPOSURE

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Abstract

When a patient is not aware of her pregnancy, the foetus/embryo may be inadvertently irradiated during a diagnostic exploration or therapeutic intervention. The radiosensitivity of the foetus/embryo changes during the different periods of gestation. For this reason there are different risk factors for each moment at which the patient may suffer irradiation. In the past 7 years, the department of Radiophysics and Radiation Protection has been consulted 75 times for this reason, to evaluate the dose received in the uterus. Since the establishment of a programme to avoid inadvertent irradiation of the foetus/embryo, these consultations have been reduced. This programme is based on informing the patients and on training the medical staff.

1. Introduction

The radiosensitivity of the foetus/embryo changes throughout the various stages of gestation. It is unlikely that exposure of the embryo in the first three weeks after conception would cause deterministic or stochastic effects in the born infant. In this period practically the only risk is radioinduced death (all or nothing law). The risk factor is 1 per Gray (1‰ per mGy).

For the remainder of the organogenesis period, conventionally considered after the third week (until the 8th), malformations may occur in the organ which is developing at the moment of exposure. These effects are of a deterministic nature and a threshold of 100 mSv has been estimated with an associated risk of approximately 0.5 per Gy.

In the period between three weeks after conception and the end of gestation, it is likely that exposure to radiation could cause stochastic effects resulting in an increased probability of cancer in the live born infant. The risk factor is 0.02 per Gy, implying a risk between 2 and 3 times greater than for the general population.

The risk of serious metal retardation or loss in IQ is high between weeks 8 and 15 (0.45 per Gy) and low between weeks 16 and 25 (0.1 per Gy). For purposes of comparison, the ratio of serious mental retardation in born children is 1 in 200. [1 to 3].

2. Estimate of the risk in radiologic and nuclear medicine

In our hospital 75 consultations have been received in the past 7 years to perform a in-uterus dosimetric study to evaluate foetal risk. Of these, 75% correspond to radiological studies and 25% to Nuclear Medicine (68% correspond to diagnostic explorations and 32% to therapeutic treatments with I-131). Patient ages vary from 18 to 42 years and declared gestation weeks vary from 1 to 14 (average of 4 weeks).

The “Effdose” program of the National Institute of Radiation Hygiene of Denmark, the in-uterus dose documentation of NRPB and ICRP-53 and the MIRD method were used for dosimetric studies.

A dose of 10 mGy on the foetus, which may be standard for certain types of abdominal radioexplorations and radionucleide explorations (bone and brain gammagraphs, microcardial

perfusion gammagraphs with Tl 201, with Tc-99m MIBI and with Tc-99m TTF, etc.), will imply an increase in the risk of mental retardation of 4 0/00 when irradiation takes place between weeks 8 and 15 (the period of highest radiosensitivity), which when compared to the natural rate (5 0/00) could be considered as acceptable if the benefits of the exploration are important.

Foetal doses between 10 and 100 mGy or more may occur during complex or simple radioexplorations performed with poorly optimised equipment and protocols, as well as in certain explorations and treatments in nuclear medicine (gammagraphs with Ga-67 or Selenium-75, and therapeutic treatments using I-131, etc.). [3 to 7].

3. Programme for preventing inadvertent irradiation of the foetus/embryo

In view of the results obtained and of interviews performed with several affected patients, it was decided to carry out a program meant to reduce prenatal risks due to irradiation based on:

3.1. Patient information

The prescribing physician should ask the patient if she is pregnant or if she has missed a menstruation. If there are doubts regarding the possibility of a pregnancy, the woman will be considered to be pregnant.

Posters were created with the cooperation of the Ministry of Health and Consumption and the Scientific Societies of Radiological Protection (SEPR), Nuclear Medicine (SEMN) and Radiology (SERAM), with a striking and simple design, encouraging the patient to inform the physician of her situation. These posters were placed next to the appointment windows and in all waiting rooms, in order to inform the patients in both situations: when requesting an appointment and prior to the exploration or treatment. The design of the Nuclear Medicine poster included a request to inform the physician of a lactation situation in order to prevent risk to the lactant.

Additionally, nurses were asked to inquire all women in fertile ages on behalf of the physician responsible for the exploration regarding the possibility of a pregnancy before carrying out the exploration or treatment. In the event of a positive reply the physician was immediately informed.

3.2. Physician training

All prescribing physicians and specialist physicians in radiology and nuclear medicine shall receive information on the justification and optimisation criteria proposed by the ICRP and gathered in our legislation and in Directive 97/43/Euratom. [1,2,8,9].
The criteria indicated are as follows:

- Only when a diagnostic exploration is well justified do the benefits overcome the risks. It should also be kept in mind that the risk of not performing a necessary radiological study may be much greater than the risk caused by the radiation.
- If a pregnancy cannot be ruled out and the radiological study involves the abdominal or pelvis region, particular care shall be paid to the justification, and particularly to the urgency of said study. The ICRP and the EC recommend that diagnostic methods which

involve exposure of the abdomen in possibly pregnant women should be avoided unless there are important clinical indications.
- Once the exploration is justified, the doses shall be kept as low as reasonably possible, in accordance with the diagnostic information required.
- Experience shows that for the same exploration there are great intervals of doses to the uterus depending on the equipment and protocol of exploration used, so that significant dose reductions can be obtained without affecting the quality of the diagnostic image.

If the patient declares a possible pregnant state, the following alternatives are suggested, which shall always be followed under the criteria of the physician responsible for the exploration or treatment:

- Cancel the exploration, considering other available methods (ultrasound or MR) which have the same objective but do not imply exposure to ionising radiation. The patient may also be asked about any similar studies which she has undergone recently.
- Postpone for a later date, if it is not urgent, if the patient is uncertain about her state of pregnancy, until being certain of said state or until after the child is born if the pregnancy is confirmed.
- Modify the exploration, (for radiology) to reduce exposure to radiation, reducing the number of images, selection of projections, reduced radioscopy time and collimation of the radiation beam.
- Carry out the full exploration, in all cases ensuring that technical conditions are optimal, using the minimum mAs, maximum possible collimation in radiology, as well as the available protection means for adjacent areas which do not affect the image, and for Nuclear Medicine performing a careful choice of radio-pharmacology and radionuclides and with the minimum compatible dose administered in order to minimise the dose to the foetus.

In any case, the decision should always be explained to the patient and her consent requested (the patient has a right to know the possible risks). In the case of radiotherapy, before making a decision regarding treatment of the future mother the dose to the foetus shall be carefully calculated. It will normally be high, but treatment of the mother must in general prevail over said dose to the foetus. In discussion and decision regarding treatment the mother's decision will be considered.

4. Conclusion

With the execution of this program the number of cases consulted per year due to inadvertent irradiation of the foetus has been to less than 10%. The cooperation of the medical personnel has been crucial for the success of this experience, so that inclusion of these measures in the continuous training programs has proved its usefulness and effectiveness.

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UNJUSTIFIED PRENATAL RADIATION EXPOSURE IN MEDICAL APPLICATIONS

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Abstract

The exposure to the radiation ionising of pregnant women , frequently constitutes motive of preoccupation for the expectant mother and the medical professionals taken the responsibility with its attention. The protection of the embryo-fetus against the ionising radiation is of singular importance due to its special vulnerability, to this agent. On the other hand the diagnosis or treatment with radiations ionising beneficial for the expectant mother, are only indirectly it for the embryo-fetus that is exposed to a hazard without perceiving anything. The present paper presents the experience obtained in the clinical and dosimetric evaluation from twenty-one patient subjected gestantes to diverse radiodiagnostic procedures or nuclear medicine, during the years 1999 - 2000. The obtained results evidence that 24% of the patients was subjected to procedures of nuclear medicine with diagnostic purposes. While the period of pregnancy of the patients ranged between 4 and 12 weeks. It could be concluded that in all the cases the doses received by the patients in the whole body did not exceed 2 mSv. When conjugating the period of pregnancy of the patients with the doses received there is no have any evidences of significant risks for the embryo-fetus. Paradoxically the physicians of assistance suggested their patients in all the cases to carry out the interruption of the pregnancy., demonstrating with this decision ignorance on the biological effects of the ionizing radiations during the prenatal exposures.

1. Introducción

En los últimos años se ha suscitado en la Comunidad Científica Internacional justificadas preocupaciones por la contribución de las aplicaciones médicas, a la exposición de las radiaciones ionizantes en la población mundial. En tal sentido organizaciones nacionales e internacionales encargadas de la regulación y control en materia de protección radiológica, han adoptado medidas para minimizar los riesgos derivados de las exposiciones médicas, tanto para los pacientes, como para el público en general. [1, 2, 3]. Sin embargo en estas regulaciones no siempre queda claro la especial protección que requiere el embrión-feto y el recién nacido durante los períodos de gestación y lactancia respectivamente.

El embrión-feto y los recién nacidos son muy vulnerables a los riesgos de las radiaciones ionizantes, que pueden llegar a producirles múltiples efectos de severidad variable y por otra parte estos no reciben beneficios directos de la exposición de su progenitora para fines de diagnóstico y tratamiento médico. Estas razones nos motivaron a llamar la atención sobre el comportamiento de las exposiciones médicas, con mujeres gestantes en instituciones hospitalarias.

El trabajo expone los resultados obtenidos en la evaluación clínico-dosimétrica de veintiuna pacientes sometidas a procedimientos médicos de medicina nuclear o radiodiagnóstico, realizados en instituciones hospitalarias de la Ciudad de la Habana, Cuba.

2. Materiales y métodos

Para realizar la evaluación clínico-dosimétrica, a las pacientes que forman parte de esta investigación, estas son sometidas a un interrogatorio detallado, con el objetivo de conocer y precisar las causas y circunstancias de la exposición a que fueron sometidas. Con posterioridad se les realizan exámenes clínicos y de laboratorio y se determina la magnitud de la exposición a las radiaciones ionizantes mediante diversas técnicas de evaluación dosimétrica.

Finalmente, en todos los casos se prestó especial atención a brindarle consejos genéticos a las pacientes con el propósito de reducir su estrés y de facilitar la comprensión real del riesgo al que fueron sometidas.

3. Resultados y discusión

En el interrogatorio a las pacientes gestantes se trató de identificar y precisar los estudios que le fueron practicados y las dosis recibidas o actividades administradas en ellos, edad gestacional en el momento que estos se realizaron; así como factores de riesgos adicionales a esta exposición, como los relacionados con la edad y número de embarazos anteriores. En el gráfico 1 se presenta la distribución de las gestantes incluidas en este trabajo, según su edad y número de embarazos, comprobándose que el 62% de ellas en el momento en que se les realizó el estudio, se encontraban en edad gestacional con bajo riesgo y sólo el 10% se encontraba en edad de mayor riesgo.

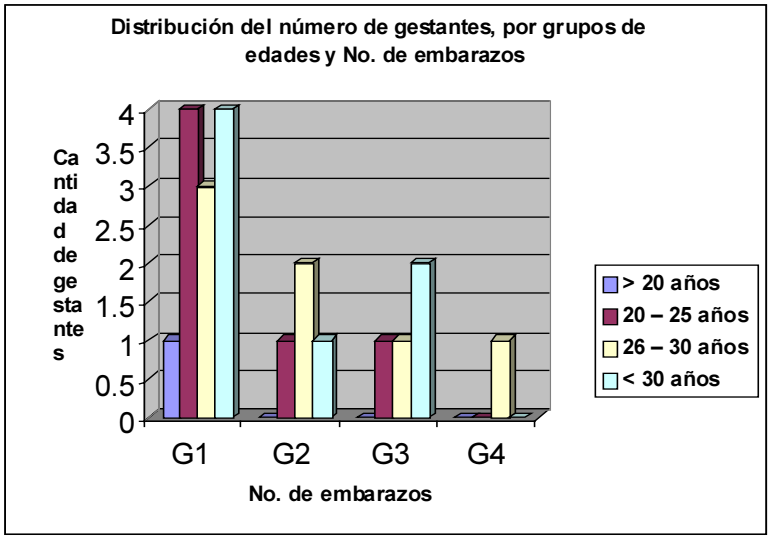

Figure 1. Distribución de las gestantes según edad y número de embarazo

Nota: La G en este gráfico significa el número de embarazos. La distribución de las gestantes según el procedimiento médico y dosis de exposición a que fueron sometidas, se presenta en la tabla No.1. Como se muestra el 76% de las gestantes estuvieron sometidas a procedimientos de radiodiagnóstico, que incluyen desde estudios convencionales hasta estudios de tomografía computarizada, en dos casos. Los procedimientos de medicina nuclear se asociaban a estudios funcionales, especialmente de la glándula tiroidea.

Tabla 1. Distribución de las gestantes según procedimiento médico y dosis de exposición

Procedimientos	Dosis de exposición (mSv)		
	> 1	1-2	hasta 3
Radiodiagnóstico	11 (52%)	5 (24%)	-
Medicina Nuclear	2 (10%)	2 (10%)	1 (5%)

Tanto en los procedimientos de radiodiagnóstico como de medicina nuclear las dosis recibidas por los pacientes en órganos o localizadas, no sobrepasaron los 3 mSv, exponiéndose el 62% de las pacientes a dosis inferiores a 1 mSv.

Aspecto a destacar es, que del interrogatorio realizado a las pacientes, se puso de manifiesto que en una buena parte de los casos, los prescriptores o ejecutores de los procedimientos no adoptaron las medidas elementales para determinar si las pacientes se encontraban embarazadas, violando de tal forma principios establecidos en materia de protección radiológica al paciente. Sólo el 39% de las pacientes fueron interrogadas al respecto, las cuales negaron la posibilidad de encontrarse en la condición antes citada, evidenciando de tal forma el desconocimiento que poseen de que el riesgo de embrión-feto durante la exposición prenatal a las radiaciones ionizantes se encuentra condicionado a la dosis de exposición y a la edad gestacional a la que esta se produce [1, 4, 5].

La tabla No.2 muestra que el 57% de las gestantes estudiadas se expusieron a dosis muy bajas, inferiores a los 3 mSv y en una etapa temprana del embarazo, factores estos, que determinaron la inexistencia de efectos determinísticos y la disminución de los estocásticos [1,4].

Tabla 2. Distribución de las gestantes según edad gestacional y dosis de exposición

Edad gestacional	Dosis de exposición (mSv)		
	> 1	1-2	hasta 3
> 8 semanas	7 (33%)	5 (24%)	-
8-12 semanas	6 (29%)	2 (10)	1(5%)

Sin embargo inexplicablemente los médicos de asistencia de las gestantes indicaron a sus pacientes la interrupción del embarazo. Situación que somete a los pacientes a un riesgo adicional mayor al esperado por las radiaciones y por otra parte manifiesta falta de conocimiento sobre los efectos de las radiaciones ionizantes.

4. Conclusiones

El estudio permitió conocer como con frecuencia, en las instituciones hospitalarias se violan procedimientos usuales y reconocidos en materia de protección radiológica al paciente. Demostrando además, la conveniencia de continuar desarrollando programas de capacitación en esta materia, dirigido esencialmente a los profesionales de la salud encargados de proteger y orientar a sus pacientes. La limitación fundamental del trabajo, es la imposibilidad de darle un sistemático seguimiento epidemiológico a las pacientes expuestas, aspecto para el cual debe trazarse una estrategia.

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RADIATION DURING PREGNANCY

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Abstract

The risks of radiation during pregnancy are well established. There is a risk of somatic effects, genetic effects occurring in subsequent generations and mental retardation if the fetus is irradiated in the critical 8-15 week period when organogenesis occurs. It is imperative that the unintended irradiation of the fetus is avoided. Whilst fetal risks have been appreciated for some time, the International Commission on Radiological Protection has never issued practical guidance. However, many national bodies have developed such guidance. In many centres the 10-day and 28-day rules have been variously applied. The purpose of this paper is to review various sources of advice and to highlight three practical implementation issues. These are:

1. Referral could mean more than one examination is performed.
2. The application of the concept of justification to elective procedures.
3. Practical implementation issues.

1. Introduction

The risks of radiation during pregnancy are well established. The main risks are the possibility of inducing cancer (mainly leukaemia), genetic effects occurring in subsequent generations (as the fetus may be considered as a potential parent), and mental retardation, if the fetus is irradiated during the critical 8-15 week period when organogenesis occurs [1]. It is as a consequence of these potential effects of ionising radiation that operational rules are applied for the diagnostic exposures of women who are or may be pregnant, so that these risks are minimised or are avoided. Over a number of years various advice on avoiding the unintended irradiation of the fetus during pregnancy has been issued by the National Radiological Protection Board (NRPB). This has resulted in what are known as the 10-day and the 28-day rules [2]. As a result of advice from the NRPB [2] the 28-day rule replaced the earlier 10-day rule. At the time it was felt that the risks of radiation to the fetus in the initial period following conception were so low as not to warrant the rescheduling of the mother's examination. This decision arose from a reappraisal of the risks during the first weeks post conception and compares those risks with those of the mother not having the examination. Fundamentally, the basis for the advice on avoiding radiology during pregnancy is a judgement on the risks of performing an examination compared with those of not performing the examination. It is interesting to note that neither the International Commission on Radiological Protection or the International Atomic Energy Agency has issued advice on any rule applying to medical exposure of women who are or may be pregnant. The purpose of this paper is to review the work of international organisations in this area and highlight three practical aspects associated with the implementation of these rules.

1. Referral for a radiological opinion could mean more than one examination is performed.
2. The application of the concept of justification to elective procedures.
3. The implications for practical implementation within a radiology department.

2. National and international advice

Recently two documents have been published which influence the advice on radiation during pregnancy. First is the Medical Exposures Directive of the Commission of the European Communities [3], which places statutory duties on member states. It represents a legal obligation rather than advice on good practice. Article ten of the Directive covers special protection during pregnancy and breast-feeding. This article requires those responsible (i.e. the doctor prescribing the examination and the practitioner performing it) to ask whether a female of child bearing age is or maybe pregnant. If pregnancy cannot be excluded, special attention shall be given to the 'justification' of the procedure. The article requires that the procedures performed on pregnant women are optimised and that the exposure of both the expectant mother and unborn child are considered. In this context the risk/benefit consideration for radiological examinations of women who are pregnant or who may be pregnant is quite demanding and complicated. The risk involves a consideration of the effects of the examination on both the patient and the unborn child. Included in the assessment is the effect of postponing the examination on the mother. The mother mainly derives the benefit of the examination and the embryo/fetus may only benefit indirectly.

The second document is the joint guidance from the National Radiological Protection Board, College of Radiographers and Royal College of Radiologists on exposure to ionising radiation during pregnancy [1]. The objective of the joint advice is to prevent the unnecessary exposure of the fetus during radiological procedures in pregnancy. The advice suggests that when a female of reproductive age is to have an examination in which the pelvis is likely to be irradiated by the main beam emitted by the X-ray set, or during nuclear medicine investigations, she should be asked if she is, or might be pregnant. If there is no possibility of pregnancy then the examination may proceed. If the patient is definitely or probably pregnant then the justification for the examination must be reviewed. In these circumstances, if a procedure is undertaken it is essential that the examination be optimised so that the fetal dose is minimised, consistent with the diagnostic objectives of the examination. If pregnancy cannot be excluded and the radiation dose involved with the examination is considered to be low then the joint advice is to proceed with the examination, provided that the period is not overdue. On the other hand, for 'high dose' procedures, which are considered to be examinations resulting in fetal doses of some tens of mGy, it is suggested that one of the following two courses of action should be adopted.

1. Apply the 10-day rule, in which females of childbearing age are booked for a radiological examination in the first 10 days following the onset of menstruation, or
2. Re-book patients who attend for such examinations and are identified to be in the second half of their cycle and in whom pregnancy cannot be excluded.

3. Practical Implications

There are a number of issues that arise from applying this advice in a practical situation in the context of the operational procedures of a radiological department. Firstly this depends on the definition of a high dose procedure, as a few tens of mGy is an imprecise end point for practical purposes. It could be interpreted usually as applying to all examinations where the

fetal dose could be 20 mGy or more. The joint guidance ignores the issue that women are referred for a radiological opinion. In many instances the radiologist may decide to perform a series of radiological investigations to achieve a diagnosis. Consequently, this could involve the woman having a number of radiological examinations that individually would result in doses below 20 mGy but cumulatively could mean that the fetus receives a dose in excess of 20 mGy. Whilst most departments would be aware that more than one examination may be performed and would be aware that the cumulative dose would be over 20 mGy, some may not recognise that underlying issue. Applying the advice of the NRPB, COR and RCR would not preclude this eventuality. For example, a woman referred for an investigation for lower back pain could have a conventional radiographic examination of the lumbar spine, and intravenous pyelogram followed by a computerised tomography scan of the lumbar spine. Independently, these examinations would each have fetal doses below the 20-mGy value, but collectively the fetal dose would be above this level. This hypothetical example is illustrative of two further issues. Firstly, lower back pain is not considered an emergency or needing urgent investigation. Secondly, conservative treatment, without the need for radiological examinations is usually advocated.

Thus when a request for a radiological opinion is received for lower back pain, or other conditions that could precipitate a series of conventional radiographs of the lower abdomen, then it is recommended that the department develop an operational policy to deal with this situation. It is suggested that the fetal dose is estimated to discover whether the cumulative fetal dose from these examinations is above 20 mGy. It is important to stress the need to estimate the dose to the individual woman, as there is scientific evidence that suggests that women who have x-rays who subsequently discover that they are pregnant would receive a fetal dose higher than that suggested by using the average from a large-scale survey.

In elective investigations, the situation of the embryo/fetus with regard to radiation risks must be respected. Elective in this context means an examination that could be performed straight away or deferred for a period of time without adversely affecting the mother. In many respects, this situation is similar to that of the occupational exposure of a woman who is known to be pregnant as the latter is in effect an elective exposure. For occupational exposures of staff, the fetus is considered to be a member of the public [4]. By implication if one considers occupational exposures to be elective then advice should be consistent in relation to fetal exposure. However, the dose threshold for elective examinations (i.e. a few tens of mGy) is much larger than the dose limit for occupational exposures, which in most circumstances would be regarded as elective exposures. For an elective medical exposure, the benefit of the exposure to the mother and hence the child must be taken into account. In particular, for elective procedures the concept of justification should be adapted to take into account that it may be possible to reschedule the examination and avoid the fetal radiation risk entirely.

Secondly the Medical Exposures Directive is written in terms of the unborn child. In a court of law this could be interpreted as including both the pre- and post-implantation phases of pregnancy. The advice on the development of the 10 and 28-day rules should be viewed in the context. Application of both rules must obviously be adjusted to take account of individual variations of the duration of the menstrual cycle. The impact of changes in the menstrual cycle on the 10 and 28-day rules is explained clearly in the NRPB document [1]. If the woman had a shorter cycle than the normal 28 days, fertilisation could occur before 10 days. For example, a lady with a cycle of 21 days, there would be a possibility of fertilisation occurring at any time after 7 days of the menstrual cycle. Consequently the application of a 10-day rule without

considering the menstrual cycle of the individual concerned could result in the unintended irradiation of the unborn child. This is particularly relevant as many departments use a form that records the date of the last menstrual period and not whether the patient has been asked if she is pregnant.

Applying the 28-day rule also has difficulties. The purpose of asking female patients of childbearing age the date of their last menstrual period is to establish whether the patient is pregnant. This is an inappropriate question if it is the only one that is posed as it has an implicit assumption that the patient has a 28-day menstrual cycle. Thus in a practical situation, it is a waste of time, as is recording the date of the last menstrual period on the request form. Asking the question 'Have you missed a period?' or 'Are you or could you be pregnant?' are to be preferred. For women who state that they have missed a period it is necessary to establish whether they could be pregnant, because not all women in this group will be pregnant. Developing an operational procedure to ask a series of diplomatic and appropriate questions in the light of the above is beset with difficulties.

A fundamental question in formulating advice on irradiation during pregnancy is upon what level of risk should the guidance be based. Implicit in the joint advice is that at 20 mGy the risk is considered not to require the rescheduling of radiological examinations. It is stated in the joint guidance [1] that this level equated to a probability of inducing fatal cancer to age 15 of 1 in 1,650. This compares with a fatal cancer risk to age 15 in the general population of 1 in 1,300. Thus extrapolating from joint advice, 25 mGy doubles the fatal cancer risk to age 15. The choice of a few tens of mGy must be the subject on informed debate and not appear to be a somewhat arbitrary figure. In addition, there is a risk of hereditary effects from fetal irradiation, which at a fetal dose 20 mGy equates to a risk of 1 in 52,000 (extrapolating from reference 1). This is somewhat less than the natural risk of hereditary disease at birth in the human population of 6%, which depends on what is considered to constitute heritable disease. Moreover, there is the unknown risk of the loss of an embryo prior to implantation. One may suspect that many members of the general public would choose, with strictly elective procedures, not to undergo these risks and reschedule their appointments to a time when they are definitely not pregnant.

In addition, most operational procedures for radiological examination of women of childbearing potential will have to be developed at a local level. There is an opportunity for there to be confusion over who has day to day operational responsibility. Is it the referring physician/surgeon, the radiologist identifying the procedures to be performed or the radiographer performing them? This issue has clear medico legal consequences and should be addressed in the implements of the Medical Exposures Directive [3].

In summary, there are a number of practical issues surrounding the implementation of the joint advice in the context of the Medical Exposures Directive of the European Union. These issues have a much wider relevance. We wish to raise these issues in order to stimulate a scientific debate on a basis for the formulation of this advice and how this should be transposed into practical guidelines.

References

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IAEA-CN-85-236

EXPERIMENTAL DETERMINATION OF FOETAL DOSES RECEIVED DURING CONVENTIONAL X RAYS EXPLORATIONS OF TRONCUS. INFLUENCE OF THE LEAD APRON

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Abstract

The aim of this paper is to assess the real doses received by pregnant women during some X rays conventional explorations of torax and abdomen. The procedure that has been used is the measurement of doses by the use of thermoluminiscent dosimeters located on the uterus position of a Random phantom, and simulating different conventional X rays explorations. The results of such measurements are compared with other data published in ICRP 34, which were our reference. We have obtained smaller doses with the measurements than those derived from ICRP 34. The causes of these differences are analysed. The influence of the use of lead apron to protect abdomen during thorax examination, is also analysed, computing the real value of this protection. We conclude that it seems interesting to obtain measurements of theses doses with our own equipment and techniques, because it offers a more realistic approximation to real doses received by patients.

1. Introducción

En los Servicios de Diagnóstico por imagen es frecuente la irradiación de embarazadas como consecuencia de exploraciones de RX a las que se someten, conociendo o no, su estado de gestación. En estos casos es muy importante poder estimar con la mayor precisión posible la dosis de radiación que puede recibir el feto. Como se sabe, los tejidos del feto resultan especialmente radiosensibles, y es fundamental poder ofrecer a la madre los datos mas próximos a la realidad que le ayuden a valorar su situación y a veces a calmar la ansiedad que estas exposiciones pueden producir.

Medir la dosis directamente en útero mediante el uso de un maniquí antropomórfico, pensamos que proporcionaría datos más próximos a la realidad.

2. Objetivos

En este trabajo se pretende hacer una estimación experimental de las dosis recibidas en el útero en las exploraciones radiológicas de tronco más comunes: tórax (PA y lateral), columna dorsal (AP y lateral), columna lumbar (AP y lateral), coxis, sacroilíacas, abdomen y caderas. Esta dosis se considera como la que recibiría el feto en el caso de tratarse de una paciente embarazada. Los resultados obtenidos se comparan con los datos obtenidos a partir de la I.C.R.P. 34 [1], que nos han servido de referencia hasta ahora.

En los estudios de tórax y columna dorsal el útero no se encuentra dentro del haz de rayos y en esos casos se valora la influencia de un delantal de plomo que protege el abdomen durante la exploración.

Las proyecciones de columna dorsal (AP y lateral) y columna lumbar (AP y lateral) han sido efectuadas con técnicas de alto y bajo kilovoltaje con el fin de registrar de qué forma afecta la técnica de exploración a la dosis en útero.

3. Material

Sala convencional de exploraciones radiológicas con un tubo de rayos X MSN 742-240/180 y un generador MPG50 de General Electric. La filtración total del tubo de rayos X es de 3.42 mm de Al.

Sistema de medida basado en dosímetros de termuluminiscencia TLD-100 de dimensiones 3x3x1 mm^3 y un lector Harshaw modelo 4000. Los dosímetros estaban calibrados individualmente frente a una cámara Radcal modelo 20X5-60.

Maniquí antropomórfico Rando formado por 35 discos (34 de 2.5 cm de altura y uno de 10 cm)

4. Metodología

Para la realización de las medidas se reprodujeron las condiciones propias de cada una de las exploraciones radiológicas objeto de estudio usando como paciente al maniqui Rando. En cada medida se colocaron dos dosímetros en el interior del maniquí en la ubicación del útero (parte superior del disco 31, en el 4º orificio de la columna central desde la superficie anterior del maniquí).

En cada estudio se efectuó una serie prolongada de disparos para que la dosis registrada por los dosímetros fuera apreciable. El kilovoltaje seleccionado fué el característico de la exploración; las proyecciones de Columna Dorsal y Lumbar se repitieron para dos valores de kV distintos que se han considerado como los extremos de un intervalo dentro del cual se trabaja habitualmente.

Las exploraciones se simularon con la configuración y la técnica que se indican en la tabla 1.

Tabla 1: Configuración utilizada para la simulación de cada proyección

Exploración	Campo longitudinal	Campo transversal	Placa	dFPelíc. (en cm)	kV
Tórax PA	centro entre discos 15 y 16; límite inferior entre discos 23 y 24	35 cm	35x43 long.	180	120
Tórax lateral	centro mitad disco 15 límite inf. mitad 22	35 cm	35x43 long.	180	120
C. dorsal AP	discos 10 a 20	14 cm	30x40 long.	100	65-80 *
C. dorsal lat.	discos 10 a 20	mitad posterior	30x40 long.	100	65-75 *
C. lumbar AP	discos 21 a 31	14 cm	30x40 long.	100	65-77 *
C. lumbar lat.	discos 21 a 31	rebasa en 1 cm	30x40 long.	100	74-85 *
Abdomen	discos 20 a 32	rebasa en 1 cm	35x43 long.	100	70
Coxis AP	discos 30 a 34	14 cm	24x30 long.	100	70
Coxis lateral	discos 29 a 35	mitad posterior	24x30 long.	100	78
Sacroilíacas	discos 26 a 31	17.5 cm	24x30 trans.	100	70
Pelvis	discos 26 a 35	rebasa en 1 cm	35x43 trans.	100	75

** Exploraciones efectuadas con dos kilovoltajes distintos*

En todos los casos la angulación del tubo es de 0º menos para el coxis AP (15º caudal) y las sacroilícas (10º cefálico). En el caso de las imágenes de tórax y columna dorsal las medidas se efectuaron con y sin delantal para determinar el efecto del mismo.

La reproducibilidad de este sistema se ha puesto a prueba mediante la repetición de las medidas de simulación de tórax en tres ocasiones, obteniéndose una desviación standard media para los 8 dosímetros utilizados del 10% respecto a los valores medios medidos.

5. Resultados

Los resultados de las medidas se muestran en la Tabla 2 y vienen expresados como dosis absorbida en útero por mAs.

Tabla 2. Resultados de dosis absorbida en útero expresados en mGy/mAs

Exploraciones	Kilovoltaje	mGy/mAs
Tórax PA	120	0.30
Tórax lateral	120	0.15
C. dorsal AP	80	<0.06
C. dorsal AP	65	<0.06
C. dorsal lateral	75	<0.06
C. dorsal lateral	65	<0.06
C. lumbar AP	77	7.11
C. lumbar AP	65	4.01
C. lumbar lat.	85	2.56
C. lumbar lat.	74	1.28
Abdomen	70	6.46
Coxis AP	70	10.77
Coxis lateral	78	6.32
Sacroilíacas	70	11.88
Pelvis	75	22.52

NOTA: *Las medidas de Columna Dorsal son inferiores al umbral de sensibilidad del sistema de medida TLD-100 utilizado.*

Como los dosímetros están calibrados para proporcionar valores de exposición, las dosis absorbidas en útero han sido calculadas a partir de

$$D_{medio} = f_{medio} \cdot X \cdot A \qquad \text{donde} \qquad f_{medio} = 0.876 \cdot \frac{(\overline{\mu}_{en} / \rho)_{medio}}{(\overline{\mu}_{en} / \rho)_{aire}},$$

X es la exposición y A es la relación entre la fluencia de energía en el medio y en el aire. Para el rango de energías considerado el valor de A es 1 y el valor de f_{med} se toma como 0.920 [2] y [3].

Para los tórax con delantal se han obtenido los resultados de la Tabla 3. Para las proyecciones de Columna Dorsal no se ha podido establecer la eficacia del delantal por cuanto todas las medidas obtenidas están por debajo del umbral de sensibilidad del sistema de medida de TLD.

Tabla 3. Dosis en útero medidas en exploración de Tórax, con y sin delantal

Exploraciones	Delantal	mGy/mAs
Tórax PA	NO	0.30
Tórax PA	SI	0.28
Tórax Lateral	NO	0.15
Tórax Lateral	SI	0.13

6. Conclusiones

En la tabla 4 se comparan los resultados obtenidos con los que se obtienen a partir de la I.C.R.P. 34.

Tabla 4. Comparación entre las dosis en útero medidas y las calculadas con la ICRP-34

Exploraciones	HVL (mm Al)-kV	I.C.R.P. 34 (mGy/mAs)	Valor medido (mGy/mAs)
Tórax PA	4.9 - 120	0.41	0.30
Tórax lateral	4.9 - 120	0.20	0.15
C. dorsal AP	3.2 - 80	0.11	<0.06
C. dorsal AP	2.6 - 65	0.04	<0.06
C. dorsal lateral	3.0 - 75	0.05	<0.06
C. dorsal lateral	2.6 - 65	0.03	<0.06
C. lumbar AP	3.1 - 77	33.11	7.11
C. lumbar AP	2.6 - 65	18.93	4.01
C. lumbar lat.	3.4 - 85	7.93	2.56
C. lumbar lat.	2.9 - 74	4.46	1.28
Abdomen	2.8 - 70	25.75	6.46
Pelvis	3.0 - 75	38.90	22.52

Se observa cómo en todos los casos presentados los resultados obtenidos son menores que los calculados a partir de la I.C.R.P 34. Este hecho puede ser debido a factores tales como una mayor colimación de los campos, empleo de un generador de alta frecuencia, capa hemirreductora ligeramente menor. Estos resultados aconsejan la medida directa en maniquies o simuladores siempre que sea posible, porque en general puede ofrecer una mejor aproximación a la realidad. Se ha observado que el uso del delantal reduce sólo la dosis en útero entre un 7% y un 13% en las proyecciones de Tórax; esto demuestra que la mayor parte de la radiación que alcanza al feto es transmitida dentro del propio organismo y sólo una pequeña parte procede de dispersión generada en el exterior (colimadores, etc.). No obstante, el hecho de estar considerando efectos estocásticos de las radiaciones nos conduce a recomendar su empleo.

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IAEA-CN-85-9

THE SOFTWARE PROGRAM *PERIDOSE* TO CALCULATE THE FETAL DOSE OR DOSE TO OTHER CRITICAL STRUCTURES OUTSIDE THE TARGET AREA IN RADIATION THERAPY

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Abstract

An accurate estimate of the dose outside the target area is of utmost importance when pregnant patients have to undergo radiotherapy, something that occurs in every radiotherapy department once in a while. Such peripheral doses (PD) are also of interest for late effects risk estimations for doses to specific organs as well as estimations of dose to pacemakers. A software program *Peridose* is described to allow easy calculation of this peripheral dose. The calculation is based on data from many publications on peripheral dose measurements, including those by the author. Clinical measurements have shown that by using data averaged over many measurements and different machine types PDs can be estimated with an accuracy of ± 60% (2 standard deviatons). The program allows easy and fairly accurate estimates of peripheral doses in patients. Further development to overcome some of the constraints and limitations is desirable. The use of average data is to be preferred if general applicability is to be maintained.

1. Background and purpose

The incidence of cancer increases with age and as a consequence most patients entering a radiotherapy department are elderly. Nevertheless, this does not exclude the possibility of cancer occurring in younger people, at an age where they still have the prospect of establishing a family and having children. If young patients are treated with radiation it is essential that the dose to the gonads is kept as low as possible to keep the risks to the offspring at an acceptable level. Should pregnant patients be presented for radiation therapy and this therapy can not be postponed, keeping the dose to the fetus as low as possible is of utmost importance. Furthermore, there are times that conception occurs just prior to or during treatment. Knowledge of this dose at distances larger than a few centimeters outside the primary beam, which is called the peripheral dose (PD), is therefore essential in those cases. Computerised planning systems can accurately calculate the dose inside and at the edges of the primary beams; however, accurate dose calculations are usually limited to a few centimeters outside of the beam edges. Determination of the peripheral dose has been the subject of extensive investigation, the results of which we have published previously [1-3]. In these papers data were presented for photon energies from cobalt-60 gamma radiation to 6, 10, and 23 MV x-rays. These values were derived from measurements of the contributions to the PD from radiation scattered in the patient, leakage radiation, and radiation scattered from the collimator. Our own data were combined with other published data [4] and were used to generate a generalized method to estimate the peripheral dose for any arbitrary field size or shape at different depths. In patients an accuracy of ± 60% (2 standard deviations) could be obtained [5]. In view of the uncertainty of known risk factors, we consider this accuracy acceptable.

On the basis of this generalized method we decided to develop a software program to perform these calculations automatically and to make this program available to the radiotherapy community.

2. Structure of the program

The software is written in Delphi. Minimum system requirements are 4 MB RAM, and requires a 4 MB hard disk. It runs under Windows, version 3.11 and higher.

The data of our paper on a general applicable calculation method [4] form the basis for the calculation algorithm.

All graphical data from that paper are transformed into tabular data and intermediate values are determined by linear interpolation.

In figure 1 the input screen for one beam is presented showing also which input data are required. The maximum number of beams that can be calculated in one run is eight.

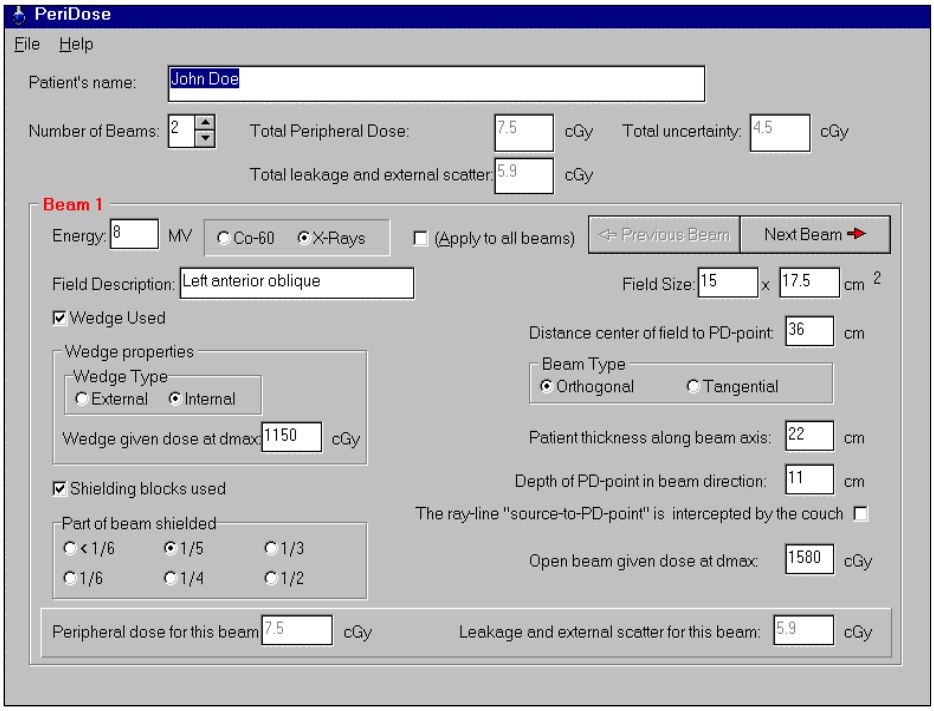

Figure 1. Input screen for beam 1 of two-beam calculation. At the top the total results are shown, at the bottom the results for beam 1

2.1. Orthogonal beams

In *the first step* the peripheral dose is calculated per beam as a percentage of the dose at depth of maximum dose (d_{max}) at a reference depth of 10 cm for a reference thickness of the patient of 20 cm. The equivalent square field size is used. A distinction is made between cobalt-60 gamma radiation and 4 to 25 MV photons.

The small variation of the PD for photon energies between 4 and 25 MV is accounted for by applying a correction factor in *the second step*.

Patient thickness is corrected for in *the third step.* When the primary beam travels through more tissue the contribution from patient scatter to the PD increases. The effect is greatest for

small distances. Variation of the PD with depth is accounted for in *the fourth calculation step.* There are two opposite effects involved. Close to the beam the patient scatter contribution increases with depth as a result of the forward directed Compton scattering. On the other hand the contribution of leakage radiation and scattered radiation from the collimator, referred to as collimator related radiation (CRR), decreases with depth because of attenuation. This decrease roughly follows the percentage depth dose distribution of the primary photon energy. Far away from the beam the CRR is the sole source of radiation so the correction factor follows the primary beam attenuation.

In *step five* a correction is made to the PD if the CRR is intercepted by the couch. This might be the case for posterior-anterior beams for target volumes further away from the PD point, for instance when treating targets in the thorax or head and neck, with the PD point in the pelvic area. The CRR will then be attenuated by the couch.

In our calculation model, distance is defined as the distance of the PD point to the beam central ray, as opposed to some authors who use the distance to the beam edge. Consequently in our model field elongation can have a considerable influence. The PD point is much closer to the edge of an elongated fields with the long axis in the direction of the distance vector than with the long axis perpendicular to that vector. Especially at small distances this can make a considerable difference, again due to foreward directed Compton scattering. This correction is *step six* of the program.
Wedges in the beam have a large effect on the PD by the added amount of scattered radiation emanating from the wedge. This effect is largest for externally mounted wedges and smaller for internally mounted ones. Only few publications [6-8] deal with this issue and based on a combination of our own measurements and the published data, a global correction factor of 4 is used for external wedges and 1.5 for internal wedges in *step seven.*

In step eight the fraction of the PD contributed by the CRR is calculated. Again two sets of data are used, one for cobalt-60 gamma radiation and one for 4 to 25 MV photons, giving the fraction of the CRR as function of the field size and distance. Although this will vary between different collimator designs, it has been shown that this variation is not large [9].

For wedged fields the patient scatter contribution does not change so the increase of the PD is caused entirely by the increase of the scattered radiation from the wedge. This is also accounted for in this calculation step by including this scatter in the CRR fraction.

In *step nine* the influence of blocks is addressed. Published data [2-3,8] have shown that the PD does not change significantly when shielding is introduced in the beam. This can be explained by assuming that the reduction of the patient scatter contribution due to partly shielding the incident beam is counterbalanced by the increased scattered radiation from the shielding blocks and tray.

In the *tenth step* the CRR is corrected for attenuation at other depths, as described in the explanation of step four.

2.2. Tangential beams

The program also offers the option to calculate the PD for tangential (breast) treatment techniques.

In this case the breast is the scattering volume and measurements were made for three breast sizes, which are called small, medium and large with field sizes to match. Interpolation by the program is based on the actual field size as stated by the user.

The program follows the same steps as for orthogonal fields with one exception. Since the patient scatter is determined by the breast size, there is no need for a correction for patient thickness. Furthermore, the depth of the PD point is defined differently. Since PD calculations in patients treated for breast cancer will often concern determination of the fetal dose, depth is now defined as the depth of the PD point (i.e., the fetus) in anterior-posterior direction

3. Results

The results of the calculations are presented in a simple way (Fig. 1). At the bottom of the screen the results per beam are shown, subdivided in the PD and the CRR contribution both in cGy. At the top the combined results for all beams are shown.

The data and results can be saved as a file with default extension *.pdd* and a hard copy of the results can be printed.

3.1. Constraints and limitations

Certain constraints have to be considered. An assumption is that the PD point is located more or less centrally and symmetrically in the body. Differences in the PD for deviations of the central position perpendicular to the plane through the beam axis and the distance vector of up to 5 cm are negligible; variations in distance and depth are accounted for.

The program cannot be used for other treatment modalities than photon beams. For electrons the scarce published data [10] and our own measurements indicate that the PD is roughly a factor of 4 lower, because there is hardly any scatter inside the patient and the CRR is much lower than for photons.

The program was not developed for use in intensity modulated radiation therapy (IMRT). During IMRT the number of monitor units delivered for a given target dose is much greater than in standard techniques. Consequently the contribution of CRR will be much greater but we are not aware of measurements on the exact magnitude of this contribution.

The program does not account for neutron production at higher photon energies. For 25 MV photons this can increase the PD by a factor 2.

3.2. Accuracy

We compared the calculations with clinical measurements and found a mean ratio of measured versus calculated PD of 0.92 with a standard deviation (SD) of 35% for all treatment techiques [5]. For tangential techniques only this was 1.12 and 26% respectively. We find it plausible that the program will be used most frequently for calculations in pregnant patients so the starting point of the program is an SD of 30%. The accuracy of the calculation is given as two SDs. The accuracy of the calculation is largest for open beams with limited shielding. In case of the use of wedges the program uses some average correction factors for internal and external wedges. The accuracy of these factors, however, is estimated to be of the order of ± 30%. When the PD-point is located further away from the central axis of the beam,

it is possible that the collimator-related radiation is intercepted by the treatment couch. In that case an attenuation factor is applied, based on our own measurements for our treatment couch. Data on the attenuation by couches from other manufacturers are not available.

The contribution of collimator-related radiation of linear accelerators to the PD is based on average data. However, some accelerators show higher collimator-related radiation values than others and there is also some dependence on collimator angle. The maximum difference is by a factor 2 [9]. For PD calculations at large distances, where the contribution is predominantly from collimator-related radiation, this can make some difference.

4. Discussion

A software program has been developed which allows the easy calculation of the peripheral dose in patients who are treated with megavoltage photon radiation. Within its constraints and limitations it allows a fairly accurate estimate of the dose at any point in the body outside the treatment area. Knowledge of the peripheral dose can help radiation oncologists in making important decisions in the treatment of cancer patients. Sometimes radiation therapy is the only viable treatment option when pregnant patients have to be treated and then it is of utmost importance to be able to estimate the risk to the fetus and compare this with the risk to the mother of postponing the treatment. Decisions on whether or not abortion should be considered may also depend on this information.

Another area where an estimate of the peripheral dose is of importance is in patients with pacemakers. Damage to pacemakers has been observed above 500 cGy [11] which is only a few percent of common clinical tumor doses. Assessment of doses to specific organs such as the thyroid may also be of interest to determine the possible risk of late effects such as carcinogenesis.

We feel that our program can be of great value for the professionals working in radiotherapy. We also feel that general applicability is desirable and therefore prefer the use of average data to the use of machine specific data, even at the cost of a small loss of accuracy. Situations where the PD has to be estimated are rare and usually occur unexpectedly. A calculation model should then be readily available since there is no time to perform extensive measurements on leakage radiation and collimator scatter.

Note: The program can be obtained from the author, preferably by e-mail request.

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IAEA-CN-85-232

DOSE TO THE UTERUS FROM RADIOTHERAPY PROCEDURES FOR BREAST CARCINOMA

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Abstract

In the early period of the pregnancy, the radiological protection of the unborn child is of particular concern. In several reports dose thresholds for deterministics effects as well as dose values that increase the probability of stocastics effects have been established. The aim of this article was to estimate the peripheral dose (PD) in order to evaluate the absorbed dose in utero for breast carcinoma treatment related to the radiotherapy procedures established in our hospital. The treatment was simulated using an antropomorphic phantom Alderson – Rando, and two similar treatment planning with and without wedges were performed, taken into account the average field parameters used in 300 treatment planning patients. The PD values were determined with a NE 2571 ionization chamber in a General Electric linac, for the treatments considered. Experimental measures provided dose in utero values slightly higher than 5 cGy, dose threshold established in some articles for radioinduced effects in the fetus. The planning system underestimated the PD values and no significant influence with the use of wedges was found.

1. Introducción

La protección radiológica del ser en desarrollo en el caso de mujeres gestantes sometidas a procedimientos de radioterapia externa, es especialmente crítica ya que en muchos casos no se puede posponer el tratamiento hasta el final del embarazo, y es necesario estimar la dosis que va a recibir el embrión o feto, para poder informar a la madre de los riesgos de una forma lo mas relista posible. Diversos estudios establecen los efectos radioinducidos en el ser en desarrollo, a partir de la dosis equivalente en útero como indicador de la dosis recibida por el embrión en los primeros estadios del embarazo. En el primer período de embarazo, dosis del orden de 10 cGy pueden inducir efectos letales en el embrión, mientras que en el periodo que va desde la 3ª a la 8ª semana de embarazo se sugieren umbrales de dosis a partir de 25 cGy para la aparición de malformaciones y otros efectos en el desarrollo [1-3], aunque en algún estudio este umbral disminuye a valores de 5 cGy [4]. Para los posibles efectos estocásticos, no existe un umbral de dosis, pero se estima que a partir de una dosis en útero de 2.5 cGy el riesgo natural de cáncer fatal a la edad de 15 años se duplica, mientras que para el caso de enfermedades genéticas no existe una relación clara con dosis en útero del orden de cGy [1-4]. Es por tanto imprescindible disponer de datos de la dosis periférica (DP), como indicador de la dosis recibida en puntos fuera del campo de tratamiento, particularizados para cada tipo de planificación y equipo de terapia implicado. En uno de los tratamientos más frecuentes en el caso de mujeres en edad de procrear, el relativo al carcinoma de mama, los resultados obtenidos en estudios de DP hablan de valores de dosis en útero del orden de unos pocos cGy [5-6]. El objetivo del presente trabajo es estimar la DP, y en particular la dosis absorbida en útero en un tratamiento estándar de mama de radioterapia externa, tal y como se desarrollan en nuestro hospital. Así mismo se valora la influencia de las cuñas en la DP realizando dos planificaciones similares, una con cuñas y otra sin cuñas.

2. Material y metodos

Para la realización de todas las medidas se ha utilizado un maniquí antropomórfico Alderson – Rando.

2.1. Planificación del tratamiento

El paso previo para la planificación del tratamiento fue la realización de un scanner secuencial al maniquí, tal y como se realiza en la práctica clínica. Se tuvo especial cuidado en la correcta alineación del maniquí y en la unión de las secciones que lo componen, para evitar la existencia de aire entre ellas. Se realizó una adquisición a lo largo del maniquí, con espesores de corte y distancia entre cortes de 5 mm. Tras esto se envío vía red local al planificador Focus 3.0 de Computer Medical Systems para su posterior planificación.

Para la elaboración del plan de tratamiento se realizaron dos planificaciones estándar de mama (arbitrariamente se escogió la mama derecha) con dos campos tangenciales de fotones de 6MV, en una de ellas incluyendo cuñas y en la otra sin cuñas. Se estimó un promedio de los parámetros de los campos utilizados en más de 300 planificaciones de mama realizadas en la práctica clínica, que cumplían los requisitos establecidos para nuestro estudio. Los campos así definidos se ajustaron a la anatomía del maniquí de modo que la zona a tratar quedara cubierta con una dosis del 95% respecto a la dosis prescrita del tratamiento (50 Gy), y no se superase en pulmones el límite de dosis tolerable para estos órganos críticos. Los parámetros de los campos escogidos se presentan en la tabla I.

Se tomaron los valores de dosis suministrados por el planificador para puntos colocados en la línea central a lo largo del maniquí, desde el corte del isocentro hasta el corte donde se estimo anatómicamente la posición del útero (distancia entre ambos cortes = 29.75 cm) y a profundidades de 10 cm y 15 cm desde la superficie, para la posterior comparación con las medidas realizadas con cámara de ionización.

Tabla I. Parámetros de los campos escogidos en la planificación de mama.

CAMPOS	ANCHURA (cm)	ALTURA (cm)	ÁNGULO BRAZO	ÁNGULO COLIMADOR	DISTANCIA FOCO-PIEL (cm)	ÁNGULO CUÑA
Planificación sin cuñas						
Tangencial externo	17.5	10.0	228º	99º	93.3	-
Tangencial interno	17.5	10.0	54º	260º	92.7	-
Planificación con cuñas						
Tangencial externo	17.5	10.0	228º	99º	93.3	15º
Tangencial interno	17.5	10.0	54º	260º	92.7	15º

2.2. Medidas dosimétricas

Las medidas dosimétricas se realizaron con una cámara de ionización cilíndrica NE 2571 de 0.6 cc acoplada a un electrómetro Farmer 2570/1 con un voltaje de polarización de –250 V y

midiendo en rango Low, lo que nos permitía registrar valores desde 0,005 nC. Antes de realizar las medidas, se comprobó el factor unidad de monitor/cGy para verificar que su valor se hallaba dentro de tolerancias y no introducir sesgos en las medidas posteriores.

Los tratamientos planificados se reprodujeron de forma fidedigna en un acelerador Saturno 40 de General Electric-CGR, con energía de fotones de 6 MV (Quality index = 0.679). Se realizaron medidas desde el borde del campo hasta la posición del útero, a lo largo de la línea central del maniquí, aproximadamente cada 2,5 cm, y a una profundidad constante de 15 cm desde la superficie, sustituyendo en cada punto la sección pertinente del maniquí por un bloque de agua sólida RMI, de dimensiones aproximadas a dicha sección, con un alojamiento específicamente diseñado para la cámara. Las lecturas obtenidas para cada campo fueron convenientemente corregidas por presión y temperatura y sumadas, con el objeto de calcular posteriormente la dosis total en cada punto para cada tratamiento.

3. Resultados

La fig. 1 muestra los datos de DP con respecto a la dosis en el isocentro suministrados por el planificador, para el tratamiento con cuña y el tratamiento sin cuña, en función de la distancia en superficie del punto al borde del campo, y para profundidades de 10 y 15 cm desde la superficie. La dosis va disminuyendo exponencialmente según los puntos se va alejando del campo hasta hacerse nula en puntos próximos a nuestra zona de estudio, el útero, que correspondería al punto situado a 25 cm al borde del campo y a 10 cm de profundidad. Así mismo, no se observa en los resultados obtenidos una dependencia significativa de la DP con la cuña a distancias grandes del campo.

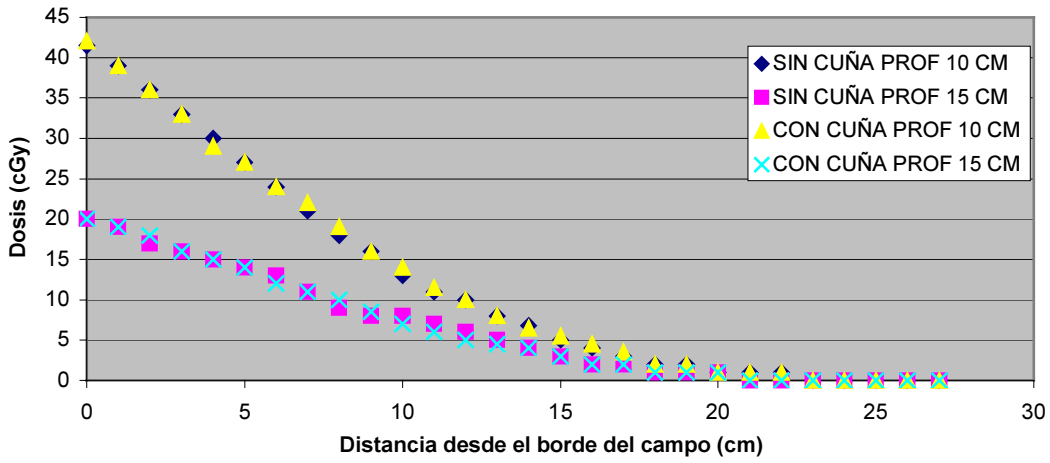

Fig. 1- Datos de DP proporcionados por el planificador.

Las medidas con cámara de ionización fueron realizadas a 15 cm de profundidad, y se utilizaron factores de conversión para determinarlos a 10 cm de profundidad [7]. En este punto hay que decir que la transformación de lecturas a dosis absoluta se realizó de dos maneras diferentes, en una de ellas aplicando los factores de corrección con la razón de poderes de frenado $s_{m,air}$ para la energía de 6 MV de nuestro acelerador, y la otra, considerando que los fotones que colaboran a la radiación dispersa dentro del paciente proceden de interacciones Compton de 90º, por lo que su energía sería aproximadamente de 400 KeV. En

este caso, tal y como publican Andreo y Brahme [8], la razón de poderes de frenado $s_{m,air}$ sería algo mayor, obteniéndose un incremento en la dosis de aproximadamente un 1.5%. Ambos casos se representan en la fig. 2, para una dosis en el isocentro de 50 Gy. Existe una dosis significativa en el útero, de 5.5 cGy para la planificación sin cuña y de 5.4 cGy en la planificación con cuña. Del mismo modo que antes, no se observa una diferencia relevante en el caso de la utilización de cuñas, siendo incluso la dosis un 1.8% mayor en el caso de la planificación sin cuñas.

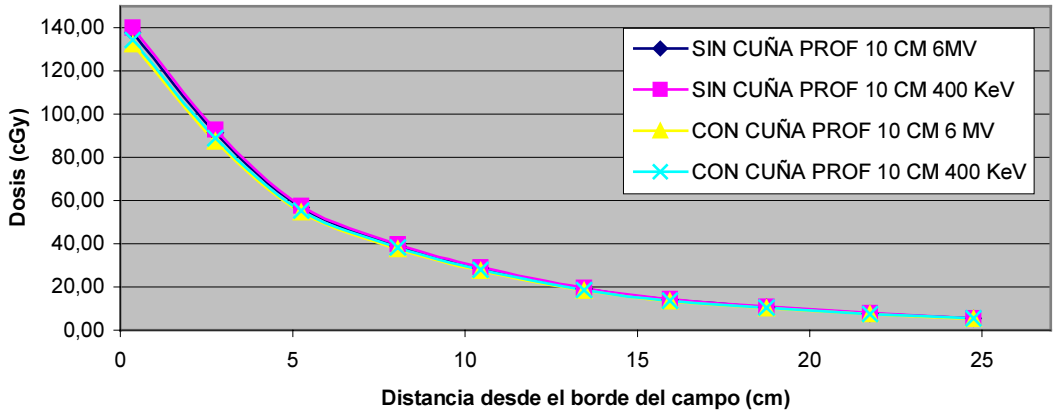

Fig.2- DP medida con cámara de ionización

4. Conclusiones

Los resultados experimentales muestran valores de dosis en útero ligeramente superiores a los umbrales de riesgo de 5 cGy. Considerando las incertidumbres en las medidas (del orden del 10% en conjunto para todo el procedimiento) estos valores pueden ser mayores en la realidad, con lo que es posible que se supere hasta en un 20% el valor umbral establecido por algunos autores, y por tanto es recomendable hacer un estudio particularizado para cada tipo de planificación y unidad de tratamiento en el caso de procedimientos terapéuticos del carcinoma de mama.

El planificador subestima de forma apreciable la dosis en puntos fuera del haz directo de radiación. Esto se debe tanto a las propias limitaciones del algoritmo de cálculo, que no estima de forma precisa la dosis en puntos muy alejados del campo de radiación, así como a que el planificador no contempla la radiación de fuga, que es la contribución más importante a la DP a distancias alejadas del campo. Por tanto, es recomendable que se comprueben de forma experimental los valores de DP aportados por el planificador para estimar la dosis en útero de pacientes embarazadas.

Con respecto a la utilización de cuñas, en nuestras medidas no se ha podido apreciar una diferencia sustancial referente al uso de las mismas en el tratamiento, en contra de lo publicado por algunos autores, que aseguran un aumento de la DP en un factor de 2 o superior [9-10]. Además en la planificación sin cuña se obtienen valores de dosis superiores a los que resultan en la planificación con cuña.

Parece más realista considerar en el cálculo de dosis absorbida los valores de $s_{m,air}$ para fotones procedentes de una dispersión Compton de 90º, pues son estos los que van a contribuir a la DP. Aunque los valores tabulados para energías del orden de cientos de kev no

proceden de espectros continuos, como sería en este caso, sino de fotones monoenergéticos, se puede hacer una estimación con estos valores para no correr el riesgo de hacer un cálculo de la dosis por defecto.

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PATIENT AND FETAL DOSE IN DIAGNOSTIC X-RAYS AND RADIOTHERAPY IN BANGKOK, THAILAND

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Abstract

In 1999 the multicenter study of the patient surface dose has been conducted at Department of Radiology of Chulalongkorn Hospital, another two university hospitals and a hospital in the suburb. Adult female patients were selected to measure the entrance skin dose and accumulated dose by using the thermoluminescent dosimeters and the kerma area product meter respectively. The fetal doses were calculated by Monte Carlo method using the computer program written by Le Heron J.C. The average fetal doses were studied for each diagnostic radiographic procedure. The fetus got 0.29, 0.35, 2.63 mGy when their mothers had radiography of pelvis, lumbosacral spine, excretory urography respectively. The estimated fetal doses for barium meal, barium enema and renal angiography were 1.47, 33.5 and 3.68 mGy respectively. The fetal dose varies so much about 2-3 times of the average fetal dose due to equipments and techniques. The study of lower abdomen by computed tomography gave 48.4 mGy in average to a fetus. The scattered dose level outside radiotherapeutic x-rays at fetal position in Rhando phantom depends on the primary beam area rather than the energy of radiation. If the threshold dose for fetal malformation is 0.1 Gy, the minimum safety distance for him is 22 cm from beam edges for the tumor dose of 60 Gy .

1. Introduction

After three young workmen died within three months after the exposure of the unshielded Co-60 source (560 Ci) at the outskirt of Bangkok, in February 2000. Most Thai people became alert of radiation hazard and protection. The medical physicist was asked to evaluate the conceptus dose more often than before. This report presents data of current levels of radiation dose to patients and fetuses. Most Departments of Radiology in Thailand performed the radiation protection for the patients as follows:

1. Set quality control of the x-ray machines in diagnostic studies, including teletherapeutic machine, the brachytherapy units and those instruments in nuclear medicine. Radiation survey is performed around each machine, under conditions that yield maximum exposure rate.
2. Technologists use proper procedures of radiological technique for small amount of the patients' radiation exposure.
3. Provide the lead apron or gonad protector for the conceptus outside of x-ray beam. An 8 cm of Cerrobend is used to minimize the fetal dose for the pregnant woman during the treatment of tumors.[1]

4. Warning signs of radiation protection for the child bearing age patients are put on the door of entrance as shown in fig.1.
5. Guidelines on safe practice for female patients (~ 12-50 y) who have abdominal or pelvic radiographs, special procedure of lower abdomen and nuclear studies are recommended as followings.
   (a) A brief menstrual history includes age of menarche, regularity or duration of menstrual cycles, the date and duration of the last normal menstrual period.
   (b) When patient data is unclear, the radiologist should question the patient about possible pregnancy. The symptom suggestion of pregnancy should be followed with a urine pregnancy test. The pelvic examination can confirm pregnancy around 8-10 weeks.
6. Dose assessments in diagnostic radiology are listed and conceptus doses are calculated in order to understand the potential detriment of various exposures. Expression of malformation in a conceptus depends on the proportion of differentiating cells and the rate at which cellular injury, while the radiation effects depends on the dose and dose rate of exposure. The ICRP [2] assessed the risk of radiogenic mental deficiency at 0.4%/Gy during the age of 8-15 weeks while the NEA [3,4] stated the proportionality coefficient of 7-13 IQ points decrease per Gray.

Fig.1. Notices in Thai and English for the child bearing age patients before having radiological examination and treatment

3. Aims and objectives

A. To access the current levels of patient surface dose in different diagnostic roentgenological procedures and calculate the fetal dose using Monte Carlo method.
B. To monitor dose outside therapeutic beam at fetus position and normalize to the infield dose for calculation of fetal safety distance.

4. Materials and methods

1. Dose assessment for patients and the conceptus:

1.1. Adult female patients of 50-75 kg in weight, who underwent diagnostic roentgenological examinations in the outpatient department of four hospitals were studied for radiation dose measurement. The study was performed at three university hospitals in Bangkok and one general hospital in suburb. Patient doses were monitored for the examination of lumbosacral spine, pelvis, intravenous urography, barium meal, barium enema, renal angiography, chest and abdominal computed tomography. The accumulated doses were measured using the plane-parallel plate ion chamber and the Diamentor E. The

TLD-100 chips were used for measuring the computed tomography dose index (CTDI) [5].
A.2 Fetal doses were calculated by using the program named XDOSE and CT DOSE which written by Dr. J. Heron, National Radiation laboratory, New Zealand. These programs were a part of a software report NRPB-SR250 and NRPB-SR262, the calculation of organ doses by Monte Carlo calculation. These programs were distributed by the IAEA for the research project on the diagnostic x-rays in Asia.[6]
A.3. Dose measurement outside the 6 and 10 MV x-ray beam were done in Rhando phantom at fetal position using TLD-100 chips and a TLD reader, Harshaw model 5500. [7,8]

5. Results and observations

5.1. Diagnostic x-rays

The primary study of adult female patient surface doses for various types of radiological examination are shown in Table 1 to 3. The number of sample for renal angiography was low because there were few cases/year. The doses depend on the equipment used, the size of patients and the methods used by radiologists in performing the study. The average fetal dose is calculated for x-rays 80 kVp, 3.0 mm.Al HVL. The results show fetal doses from lower abdominal CT and fluoroscopic studies are high. No reference doses for patients in South-East Asia to be compared.

Table 1. Patient surface doses of female adults from four conventional radiological types in Thailand, 1999

X-ray Exam.	No Obser v.	Tube voltag e (kV)	Min	1st quartil e	Media n	Mean	3rd quartil e	Max	av. fetal dose (mGy)
			Absorbed dose (mGy)						
LS AP	23	60–85	0.42	0.76	1.35	1.41	1.83	3.46	0.35
LS R. LAT	27	70–90	1.34	1.76	2.85	4.47	6.03	16.1	0.09
Pelvis AP	22	60–85	0.37	0.54	0.72	1.01	1.18	2.16	0.29
IVU	24	63–73	4.42	6.63	8.97	10.4	13.0	19.7	2.63

Table 2. Patient entrance doses of female adults from fluoroscopic examination

X-ray Exam.	No Obs.	Tube voltag e (kV)	Min	1st quartil e	Media n	Mean	3rd quartil e	Max	av. fetal dose (mGy)
			Absorbed dose (mGy)						
Barium meal*	20	80–100	9.34	38.02	53.87	59.83	82.72	128.5	1.47
Barium enema*	24	80–100	18.74	40.7	79.43	77.42	91.71	196.0	33.5
Renal angio**	6	80–100	38.54	–	130.7	140.4	–	279.9	3.68

* Using Toshiba KXO/80N, Siemens Sireskop,
** Using Siemen Neurostar Plus operated in digital pulsed mode.

Table 3. Patient doses of adults from CT examinations* in Thailand, 1999

CT Exam.	No. Observ.	Tube (kV)	mAs	slice width (mm)	No. of slice	av. fetal dose (mGy)
Chest	15	120	234–340	10	28–57	0.09±0.04
Whole abdomen	15	120	234–340	10	29–103	48.4±16.4

- Using GE Sytec 4000, GE 9800Q, Philips Tomoscan CX/Q

5.2. Radiotherapy

The data presented in Table 4 is the dose outside a beam from Varian Clinac 1800 S/N 237 in the pelvic wall of female Rhando phantom. This data is similar to the total absorbed dose in phantom at 10 cm depth reported by the AAPM [9] in 1995. The safety distance for fetus developing malformation was calculated. If a fetus is too close to a beam edge, the shielding is required. For megavoltage x-rays, the scattered doses depend on the area of primary beam rather than photon energy [7].

Table 4. The average scattered dose to fetus in Rhando phantom normalized to the peak dose at central axis using TLD

Energy (Machine)	Field size	Distance from beam edge			Safety distance for
	(cm)	2.7	5	10 (cm)	malformation*
6–10 MV Clinac 1800	10×10	10%	2%	0.6%	more than 22 cm
	20×20	20%	5%	1.2%	more than 28cm

* The tumor dose is 6000 cGy and the threshold dose for malformation is 10 cGy.[10]

6. Discussion and conclusion

Fetal doses are high in both barium enema study and the whole abdominal CT but it is less than the threshold dose for malformation in the first trimester period. The maximum fetal dose may be 2-3 times of the average fetal dose. The reference doses for patients in South East Asia should be set up. For radiotherapy, scattered doses are similar to those reports by other investigators.[11,12,13]

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Topical Session 7

RADIOLOGICAL PROTECTION OF PAEDIATRIC PATIENTS

THE DEVELOPMENT OF STANDARD OPERATING PROTOCOLS FOR PAEDIATRIC RADIOLOGY

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Abstract

This paper describes how the requirement for operating protocols for standard radiological practice was expanded to provide a comprehensive aide to the operator conducting a medical exposure. The protocols adopted now include justification criteria, patient preparation, radiographic technique, standard exposure charts, diagnostic reference levels and image quality criteria. In total, the protocols have been welcomed as a tool for ensuring that medical exposures are properly optimised.

1. Introduction

Great Ormond Street is a specialist children's hospital in the centre of London. The patients, both inpatient and outpatient, attend from a wide area which includes the whole of the United Kingdom and overseas. Almost 7% of patients come from abroad. The services that are provided by the hospital fall into five broad categories: Medical/Urology, Cardiorespiratory and Critical Care, Host Defence, Surgery, and Neurosciences. Between 40% and 50% of the children treated within the hospital are under the age of 2 years. There is a continuing trend to provide increasingly specialist and complex forms of care.

In order to support the work of the hospital the Radiology Department has found itself at the cutting edge of paediatric radiological practice. The department has a team of radiologists, radiographers and nurses working in a dedicated child-friendly environment. Many of the radiological examinations are performed on patients from one of the Intensive Care Units of which there are five. These examinations include complex interventional procedures such as bronchial stent insertions.

The total annual workload for 1999/2000 was 50,000 + examinations of which 28,000+ were general radiography. The department consists of 2 general x-ray rooms, 1 CT scanner, 2 MRI suites, 1 fluoroscopy unit, 3 angiography suites, 3 nuclear medicine cameras, surface topography, 1 bone densitometer, 1 orthopantomograph(OPT) and 4+ ultrasound machines. Much of the general x-ray work is mobile and is undertaken on one of the large intensive care units. There are also 2 mobile image intensifier which are used for per-operative procedures. The department, with the exception of the OPT, is completely digital and a PACS system is to be installed during 2001. There are 30+ whole time equivalent radiographers.

The European Directive 97/43/Euratom [1] stated aim is "laying down measures for the health protection of individuals against the dangers of radiation". During 1999/2000 standard operating protocols were developed within the Radiology Department at Great Ormond Street Hospital in response to the Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R) [2], the UK implementation of the Directive. The regulations place responsibilities upon employers and employees with regard to the radiation protection of patients, with particular reference to special practices such as the medical exposure of children. Included in

the regulations is the requirement for standard operating protocols for all examinations using ionising radiation. This has been implemented in all sections of the Radiology Department.

2. Method

Developing new protocols at Great Ormond Street Hospital presented an opportunity to review current practices and improve clinical systems and procedures, thereby enhancing the quality of care to patients. This is in line with the requirements for Clinical Governance, which was introduced to ensure that all National Health Service (NHS) organisations have in place proper processes for continuously monitoring and improving quality. One of the key points of Clinical Governance is that all clinicians must understand their individual and collective responsibilities for assuring accountability for the quality of patient care.

All sections of the department had some established protocols but these were disjointed and in many different formats. Most included only basic procedures and detailed the required 'views' that were needed for specific examinations. None incorporated diagnostic reference levels or referral guidelines. The general protocols did attempt to set down quality criteria taken from the European Guidelines on Quality Criteria for Diagnostic Radiographic Images in Paediatrics [3], but this was only for basic examinations such as chest, abdomen, skull and spine. It was decided that a department-wide format had to be adopted for new protocols. This would simplify the use of the protocols for radiographers as many worked in most sections of the department.

The new protocols were to represent a handbook for each examination room in the department. Contained in the protocol files were details of everything required for each radiological exposure that might take place in that room. This included referral guidelines, patient preparation, radiographic technique, exposure factors, diagnostic reference levels, image quality criteria, additional projections and common pathologies. In each section of the department a radiographer was nominated to co-ordinate writing protocols for that section. Most radiographers were involved to some degree in the production of the latest versions of the Great Ormond Street protocols.

The final versions of the protocols were specific to:

- General radiography
- Mobile and theatre radiography
- CT
- Nuclear Medicine (1 for each camera)
- Cardiac and Neuro angiography
- Interventional procedures
- Fluoroscopy
- Bone densitometry
- Dental and maxillo-facial radiography

Identical formats were used throughout. Each had a section preceding the main body of the protocols containing procedures that were common to all areas in which a medical exposure might be made. These were:

- Working in radiation areas including:
    - Local rules
    - Methods of reducing dose

    - The ALARP Principle
    - Names and contact numbers for Radiation Protection Supervisors and the Radiation Protection Adviser
- Methods of ensuring quality control
- Administration, including:
    - Examination requesting
    - Reporting of images
    - Updating of details onto databases and film packet, if appropriate
- Procedures specific to mobile and theatre radiography

The relevance of including these in the protocols was to minimise the number of unnecessary examinations resulting from administrative error, to ensure that the dose was always as low as reasonably practicable for the patient and that staff doses were kept to an absolute minimum.

Following the common section the protocols were written for specific area within the department and each contained:

- Valid reasons for the examination, or justification guidelines. IR(ME)R stated that all medical exposures to ionising radiation must be justified prior to exposure to ensure optimisation of the exposure. Justification of a medical exposure is carried out in most circumstances by the Practitioner, which is usually the radiologist. However there are times when an exposure may be authorised by an Operator (the radiographer), with remote justification by the Practitioner [4]. At such times the radiographer uses his/her training and experience to authorise the exposure, but also has the guidelines written in the protocols to aid the authorisation process. Also included are comments which may help the radiographer when explaining how they have arrived at the justification.
- Patient preparation. This section details steps that should be taken before the exposure is made. Included are:
    - procedures such as patient identification
    - removal of objects that might obscure the image
    - preparation of a carer or person who might be required to assist with holding the patient

  These are all procedures that must be carried out in order to ensure optimisation of the exposure and that patients and carers are not irradiated unnecessarily
- Radiographic technique for standard projections including
    - Positioning of the patient and X-ray tube, together with immobilisation techniques that might be used for avoid having to repeat the exposure
    - Radiographic equipment that should be used, or be available to minimise the exposure
    - Recommended focal spot size
    - Recommended use/absence of an anti-scatter grid
    - Recommended imaging modality e.g. Computed Radiography
    - Recommendations as to whether automatic exposure chambers should be used
    - Radiation protection, including accurate collimation, gonad protection, lead masking and protection for holders hands
    - Correct Focal Film Distance
- Exposure factors for different age/weight ranges. The ranges were chosen as a guide to assist with selection of the relevant exposure factors. The age ranges are 0-1 year, 1-5

years, 5-10 years, and 10-15 years. The ages/weights were then included in tables that easily showed the radiographic exposure factors. An example of the exposure factors used is given in Table I.

Table I. Exposure Factors for an AP/PA Chest beyond the neonatal period

Age	kV	mAs
1 - 5 years	70 - 75	3.2 - 5
5 - 10 years	75 - 80	5 - 7
10 - 15 years	75 - 80	4 - 8

- Image quality criteria. These ensure that operators are aware of the standards expected. Audit of images could then be carried out by comparison with the standard criteria. All images were expected to have correct identification, sidemarkers and correct window levels and shuttering. These assist the radiologist when viewing optimal images to ensure diagnosis .
- Diagnostic reference levels [5]. If these are exceeded they are recorded separately for audit purposes. An example of the diagnostic reference levels used is given in Table II.

Table II. Diagnostic Reference Levels for Chest X-Rays

Age	KV	mAs
1 - 5 years	70	3.2
5 - 10 years	75	3.2
10 - 15 years	75	6

- Additional projections to assist the radiographer in their choice of imaging.
- A list of more common pathologies which might be shown by the selected imaging protocol.

3. Conclusions

The introduction of the new standard operating protocols has been very well received by all members of the radiographic staff working at the hospital. They are of particular value when new staff or agency radiographers are working in the department and also when radiographers work in many different areas. As many of the staff were involved in the production of the protocols the radiographers have ownership of them and are keen to see that they are regularly updated. There is therefore a willingness to contribute to the protocol audit programme. Most importantly they are a guide to best practice and are valuable in the optimisation of all medical exposures.

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RADIATION DOSES TO NEONATES AND ISSUES OF RADIATION PROTECTION IN A SPECIAL CARE BABY UNIT

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Abstract

Radiographs are most commonly taken in the neonatal period to assist in the diagnosis and management of respiratory difficulties. Frequent accurate radiographic assessment is required and a knowledge of the radiation dose is necessary to make the justification of such exposures. A survey of radiation doses to neonates from diagnostic X-ray examinations (chest and abdomen) has been carried out in the special care baby unit (SCBU) of the Royal Free Hospital. Entrance surface dose (ESD) was calculated from Quality Control measurements on the X-ray set itself. Direct measurement of radiation doses was also performed using highly sensitive thermoluminescence dosimeters (LiF:Mg,Cu,P), calibrated and tested for consistency in sensitivity. The mean ESD per radiograph was calculated to be 36μGy (with a standard deviation of 6μGy), averaged over 95 X-ray examinations. The ESD's as derived from the TLD crystals, ranged from 18μGy to 60μGy. The mean energy imparted (EI) and the mean whole body dose per radiograph were estimated to be 14μJ and 10μGy respectively. Assuming that neonates and foetuses are equally susceptible to carcinogenic effects of radiation (it involves an overestimation of risk), the radiation risk of childhood cancer from a single radiograph was estimated to be of the order $(0.3\text{-}1.3)\times10^{-6}$. Radiation doses compared favourably with the reference value of 80μGy ESD published by CEC in 1996.

1. Introduction

Diagnostic radiology plays an important role in the assessment and treatment of neonates requiring intensive care. It is often necessary to perform a large number of X-ray examinations depending upon the infant's birthweight, gestational age and respiratory problems. X-ray examination of children, especially neonates, attracts particular interest because of the increased opportunity for expression of delayed radiogenic cancers as a consequence of relative longer life expectancy. Also, the small sizes of the newborn infants brings all organs within or closer to the useful beam resulting in a relatively higher overall exposure per radiograph than may be the case with adults. It is therefore important to ensure that radiation doses from radiographic examinations carried out in neo-natal units are kept to a minimum while maintaining the quality of radiographic images.

Wide variations have been found in techniques, equipment performance and radiation dose in different hospitals in a European survey of paediatric radiology [1]. The results have highlighted the need to develop dose standards for paediatric and neonatal examinations. The requirement towards dose optimisation, led to the European Commission recommending a standard radiological technique for neonates with the aim of at least achieving a "reference entrance skin dose" of 80μGy [2].

This paper describes a prospective study of radiation dosimetry performed in the SCBU at the Royal Free Hospital. A variety of dosimetric quantities: ESD, EI and whole body dose have been measured and recorded. Finally, an attempt has been made to evaluate the applicability of TLD LiF: Mg,Cu,P as a reliable dosimetry method used in a SCBU.

2. Materials and methods

All radiographic examinations were performed with a capacitor discharge mobile X-ray unit type 38S(GEC) with a single phase generator, total filtration 3.6mm aluminium equivalent thickness, and an X-ray tube target angle of 17^{o}, using Kodak Lanex Regular Screen combination with a 400 relative film-screen combination speed. In most cases the examination was carried out with the baby in the incubator and placed directly on the top of the cassette with the focus-to-film distance (FFD) set at 100cm. Pieces of lead rubber were placed on the perspex top of the incubator in order to reduce the size of the X-ray beam to the area of

interest. More detailed description about the way that the pieces of lead may be placed on the perspex top of incubator can be found in [3].

2.1. Indirect method of measurements

Measurements of tube output were made using a 15cc ionisation chamber with calibration traceable to a national standard. ESD was estimated for each patient and for each exposure from knowledge of the technique factors, X-ray tube output and backscatter factors (BSF), in accordance with the following formula: Entrance surface dose (μGy) = output (μGy mAs^{-1})× mAs×BSF×ISL× $^{L}{}_{F}(\mu_{en}/\rho)_{tis}/(\mu_{en}/\rho)_{air}{}^{V}{}_{T}$A BSF of 1.1±5% was employed, determined by [4] for a neonate with body thickness of 5cm with tube potentials in the range 50-70kVp for a field size of 70-300cm^2 using Monte Carlo techniques. The ISL factor is an inverse square law correction from the chamber calibration distance (100cm from the focus) to the focus-to-skin distance (FSD). The FSD was not measured directly, but approximated by the difference between the known FFD and the neonate equivalent diameter. Because of difficulties in obtaining an accurate measurement of the length or trunk diameter, we used an average equivalent patient diameter of 7.5±1.4cm [5].

The mass energy absorption coefficient ratio averaged over the X-ray energy spectrum was evaluated for muscle as defined by the International Commission on Radiation Units and Measurements (ICRU) and is equal to 1.05 for the range of 50-58kVp used in this study, with an uncertainty of no more than ±1% [6].

The uncertainty in ESD was calculated as the quadrature sum of the estimated uncertainties in output measurement (±3.2%), the use of patient diameter in the ISL correction (±5%) and the BSF evaluation (±5%) to give a value of ±8%.

The EI to the neonate is derived from the ESD integrated over the irradiated area (dose-area product, DAP). The irradiated body area from each radiograph was deduced from measurements made on the film. This area varied widely, owing to different patient sizes but mainly to the varying degrees of collimation employed. The DAP can be approximated by the product of the ESD and the film area demagnified from the FFD to the FSD. This approximation results in a DAP evaluation including backscatter, since the ESD has been calculated after applying the BSF's. The EI is calculated from the estimated DAP using conversion factors for neonates exposed to X-rays with energies between 50 and 70kV_p determined by [4] for a single-phase generator, an anode angle of 17^o and a net filtration of 2.5 mm aluminium equivalent. Estimates of radiation risk can be made from EI, by assuming that all radiosensitive organs are considered uniformly distributed through the irradiated portion of the body [4]. A whole body dose is determined by dividing the imparted energy by the weight of the neonate.

2.2. Direct method of measurements

In this study TLD LiF:Mg,Cu,P (Harshaw TLD-100H) is employed. Only a few reports [7] have studied the performance of LiF:Mg,Cu,P in neonatal X-ray dosimetry. Annealing and read-out of the TLD chips were performed according to the instructions of Qados company [8].

A dedicated calibration employing a perspex jig and tissue substitute phantom, was performed using the X-ray unit on the SCBU. The jig held the TLD chips and calibrated 15cc ionisation chamber. The TLD were individually calibrated and sensitivities established over the exposure range that they would be measuring. The phantom supported the jig and consisted of 1cm slabs of solid water (WT1) which when stacked represented different patient thicknesses.

To ensure that the TLD chips would not actually show up on the films and would not obscure the anatomical and pathological details, the packaged chips were placed on different thicknesses of solid water and irradiated with the X-ray mobile unit. The image quality test showed that the chips are seen in the radiographic image when 4 and 5cm of solid water was used. Consequently, the most appropriate place to put them was considered to be in the X-ray beam, on the shoulder of the baby, if a chest X-ray and on the hip of the baby, if an abdomen X-ray is being performed.

3. Results and Discussion

3.1. Indirect patient dose measurements

A total of 30 neonates were included in this study. The mean number of radiographs received by one neonate was 3.2, which compares with values of 3.8 [9], 5.3 [4] and 4.7 [5] in other studies. Approximately one half of neonates received only one radiograph, but the frequency distribution shows a long tail, with a maximum of 17 radiographs for one neonate. The main influence on the estimated typical total body dose is the number of radiographs taken, which is related to the clinical problems of the neonates. The neonates having a great number of radiographs (above 35 was reported in the studies of [4] and [9]) are of particular concern since they may have an increased probability of further radiography in early childhood. Dosimetry and protection measures will have special benefit for these children.

ESD's ranged from 28μGy to 58μGy. The mean ESD per radiograph was calculated to be 36.3μGy, averaged over the total of 95 X-rays included in the study. The results of our study show that infants did not receive what might be considered 'excessive' radiation from diagnostic modalities. ESD's were found below the EC reference dose for mobile chest X-rays of 80μGy [2]. Although this is encouraging it should not lead to complacency, as being below the reference dose is not an indication of optimum efficiency.

A more significant measure of risk is the EI to the neonate; only a few studies [4,5,9] have considered this quantity in SCBU radiology. The mean EI and the mean whole body dose per radiograph were found to be 14μJ and 10μGy respectively. The mean EI per radiograph is found to be higher (16μJ) for chest and abdomen examinations than for chest X-ray examinations (13μJ). This shows that the total EI depends strongly on the radiation field area and this is the reason why X-ray beam collimation is important in radiographic examinations. Estimates of radiation risk can be made from EI, by assuming that all radiosensitive organs are considered uniformly distributed through the irradiated portion of the body [4]. The problem is what factor is the most appropriate risk factor for the neonates. The alternatives are whether to correlate our data with the studies on foetuses in utero, or to assume that the sensitivity to ionising radiation for the newborn babies is more similar to that ascribed to young children. In practice of radiation protection, since the majority of neonates were pre-term the appropriate risk factor was felt to be that for fetal irradiation. According to the ICRP report 60 [10] the risk of fatal childhood cancer due to prenatal exposure has been estimated to vary from 2.8×10^{-2} Sv^{-1} to 13×10^{-2} Sv^{-1}. The authors stress that the risk in the first trimester appears to be larger than that found in the 2nd and 3rd trimester, but this is not established. If we accept that the cancer risk, meaning leukaemia, is the same for the 2nd and 3rd trimester it should be fairly close for X-rays taken shortly after birth. Therefore, using these factors, the risk of childhood cancer from a single radiograph would be of the order $(0.3\text{-}1.3)\times10^{-6}$. However, the assumption that the newborn and foetus are equally susceptible to carcinogenic effects of radiation involves an overestimation of risk. Firstly, irradiation in utero involves whole body exposure of the foetus, whereas the neonatal radiography involves only partial exposure.

Secondly, it is not known whether babies in a higher oxygen tension than foetuses run a greater risk of carcinogenesis from radiation [11].

The results show the risk from neonatal radiation to be fairly low, and it is considered to be substantially outweighed by the clinical benefit of the radiograph in assessing the progress of a sick baby. This is probably even more marked in the tiny prematures. However, the risk versus benefit of each radiograph is important and must be weighed carefully, especially because radiation effects are cumulative.

3.2. Direct patient dose measurements

Table 1 gives the results from TLD measurements for each examination and gives a comparison between ESD's measured with TLD and ESD's calculated from technique factors.

Table 1: Comparison between ESD measured with TLD and ESD derived from the technique factors

Number of radiographs	Mean ESD measured with TLD (μGy)	Mean ESD calculated from technique factors (μGy)
30	28.9±0.4	31.8±2.5

Comparison between the two measurement techniques shows that dose levels are similar for both techniques. These results indicate that TLD LiF:Mg,Cu,P can be applied as a reliable dosimetry method for effective monitoring of dose levels within a special care baby unit.

Uncertainties in the measurement of doses involve the fact that the TLD chips were not placed on the centre of the radiation beam during the X-ray examination, so as not to affect image quality. Since they were placed on the edge of the beam (shoulder/hip), they measured somewhat lower dose. In fact, a difference of the order of 7% in dose was found. Furthermore, uncertainties in the calculation of ESD's from technique factors involve statistical uncertainties in patient's weight, in equivalent patient diameter and in measurements of kV, mAs and FFD.

3.3. Comparison with previously published results and assessment of dose reduction techniques in a SCBU

Our results may be compared with previously published data to attempt to delineate mechanisms for dose reductions. The mean ESD per radiograph, regarding chest X-rays, found in this study (36μGy), can be compared with the values of 36μGy [9], 44μGy [12], 20μGy [5] and 53μGy [13] given by other studies. The mean ESD per radiograph as far as chest and abdomen examinations are concerned, is found to be 35μGy in this study, whereas values of 70μGy and 58μGy have been reported by [11] and [14] respectively. The comparison shows a range of doses resulting from variations in radiographic techniques used and from differences between irradiated populations included in each site. The use of rare-earth screens enables a great dose reduction and should be a major consideration in sites that still use conventional (fast calcium tungstate) screens. In spite of the recommended high voltage techniques, lower radiographic voltage is still often used in most of the sites. It must be remembered that the effective radiographic voltage depends on the type and age of the generator. Not all the generators allow short exposure times that are required for higher kV technique.

The range of ESD's encountered between different studies demonstrates that the 'as low as reasonably achievable' (ALARA) principle is not being applied. Therefore, investigation into further reduction should be made but without compromising diagnostic information. Probably the most significant factor in radiological technique, regarding radiation protection for both infant and staff, is the careful collimation of the field to the area of interest. Therefore, the risk

of radiation to the newborn is minimized by making sure that only essential radiographs are taken, that careful collimation confines radiation to the relevant part of the infant, that radiation shields over the lower abdomen are used unless this area is to be included on the radiograph. Finally, adequately trained staff perform the radiographs so that the number of repeat radiographs is reduced to the absolute minimum and that the highest standards of radiation protection are achieved.

4. Conclusions

Although the radiation risk of X-ray examinations is found to be low considering the benefit for the infant, radiography of newborns should be performed with full knowledge of the possible harmful effects, considering that infants are particularly susceptible to radiation induced cancer and that prematures may require a large number of X-ray examinations during the early weeks of life.

Comparison between different studies resulting in a large range of doses found in a SCBU shows a continuing need for assessment of radiation dose on neonates together with regular review, and implementation, of dose reduction procedures.

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EVALUATION OF THE RADIATION DOSE IN A PAEDIATRIC X-RAY DEPARTMENT

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Abstract

This is an ongoing study that is conducted for the first time in Cyprus, whose objective is to compare radiation doses received by children during radiological examinations from a dedicated paediatric X-ray unit, with those from other departments around the world and reduce them if needed. Radiation doses were measured simultaneously for comparison purposes, with extremity thermoluminescent dosimeters (TLD) type TLD-100 Lithium Fluoride and with a dose area product meter, (DAP), Gammex-RMI Inc, Model 841-S. Data recorded for each radiological examination are age, sex, weight, height, focal size used (small/large), source image distance, (SID), technique used (manual/automatic), kVp and mAs. The radiation doses received by children, undergoing chest examinations are presented and compared.

1. Introduction

It is generally accepted today, that although dose limits do not apply for patients, dose reference levels should be followed as a guide and an aid to the optimisation of radiation protection in medical exposures. The imaging process must be optimised, once the diagnostic examination has been justified and this involves three aspects :

- the choice of radiographic technique
- the diagnostic quality of the radiographic image
- radiation dose to the patient [1]

If the patient is a child the risk of detrimental effects from ionising radiation, is greater than that of adult patients [2].

Therefore, it is of the utmost importance, that radiation doses, especially paediatric, are kept at a minimum level, without significant deterioration of the image quality and of the diagnostic value of the examination. These are the first results of an ongoing study in which the doses are measured with two methods, TLD dosimeters and DAP meter.

2. Materials and methods

This study is carried out at the Radiology Department of the Makarios III Hospital in Nicosia, Cyprus. This is a Mother-and-Child Hospital with a dedicated paediatric department. The X-ray system used is a paediatric unit, which allows the possibility of beam filtration changes to be done easily, is a high frequency Philips Super 80 CP, with a SRO 33 100 type tube and total filtration 3.3 mm Al. The processor is a Kodak PRX X-OMAT, model M6B set to give a ã of 3.29 and a G of 2.12. The cassettes used are Okamoto type, High Speed 250.

The DAP meter used is the Gammex-RMI Ltd, model 841-S. This is a full field Ion Chamber with a sensitivity of 130 pC/mGycm^2. The dose area product rates are 1 mGycm^{2}s^{-1} to 400.000 mGycm^{2}s^{-1}. The DAP meter with a transparency of greater than 75% was attached to the collimator of the X-ray tube.

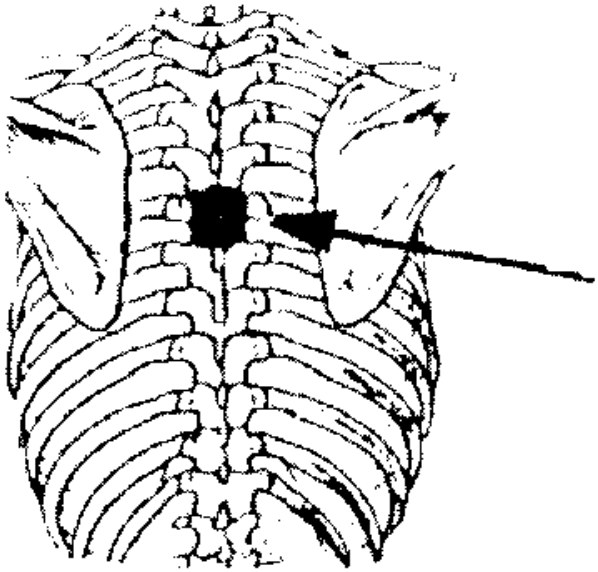

Figure 1. Diagram of TLD placement for Chest PA examinations.

Table 1. Comparison between our examination parameters and patient set-up, with those of the European Guidelines on quality criteria for pediatric chest examinations, for the 5-10 years old, age group

Radiographic Technique	E.C. Guidelines	This Study
Patient position	upright, supine position possible	upright
Radiographic device	table or vertical, depending on age	vertical
Nominal focal spot value	0.6 (less or equal to 1.3)	small focus 0.6 large focus 1.3
Additional filtration	up to 1mm Al +0.1 or 0.2 mm Cu (or equivalent)	2mm Al
Antiscatter grid: r=8; 40/cm	only in special indications and in adolescents	fixed oscillating grid : r=12; 36/cm
Screen film system	nominal speed class 400-800, FFD 100-150 cm	nominal speed class 250, FFD 150cm
Radiographic voltage	100-150 kVp with grid	96-109 kVp with grid
Automatic exposure control	chamber selected-lateral	chamber selected-lateral
Exposure time	< 10 ms	< 10 ms
Protective shielding	lead rubber coverage of the abdomen in immediate proximity of the beam edge	no added protective shielding

The TLD's used are Chipstrate Dosimeters from Harshaw/Bicron. They consist of a $^{1}/_{8}$x$^{1}/_{8}$ inch TLD chip hermetically bonded to a polymide substrate, to which an ID bar code strip is attached. The TLD material is TLD-100 LiF natural, nearly tissue equivalent with a

measurement range 10μGy to 1 Gy. These are placed on the patient as shown in figure 1, according to the European Commission guidelines [1].

The measuring instrument used for the quality control inspections is the Keithley Model 35080A kVp divider, which is compared and calibrated against the secondary standard, at the Nicosia SSDL, which is situated at the Nicosia General Hospital.

The parameters recorded for each examination are : Type of examination, sex, weight, height, age, kVp, mAs and focal size (small or large) used.

The initial examination parameters and patient set-up used, are compared with those recommended by the European Guidelines on Quality Criteria for Diagnostic Radiographic Images in Paediatrics of the European Commission, as shown in Table 1, for the 5-10 years age group for chest examinations.

Our initial Chest Technique set up deviate from the European Guidelines in three parameters :

- Additional Filtration
- Screen Film Combination
- Protective Shielding

The intention of the study was first to measure the doses with the existing set up and then make modifications to the technique in steps. At each modification step to measure the doses, in order to compare the effect of each modification.

3. Results

The results obtained so far are shown in Table 2, which give the mean dose results obtained by the TLD and DAP dosimeters. The results presented are in terms of Entrance Surface Dose ESD_{TLD} and ESD_{DAP}. ESD_{TLD} is expressed in terms of absorbed dose to air which is equivalent to entrance air kerma at diagnostic x-ray energies. The associated uncertainties for chest examinations are 20% and 31% respectively. These results are compared with those of similar studies carried out elsewhere.

The orthochromatic cassettes used in the first modification step are the KB69050-F PTM Kodak, Lanex X-OMATIC with a speed of 400.

The beam filtration used in the second modification step was increased to 0,1 mm Cu + 1,0 mm Al.

4. Discussion of results

The results obtained with the initial set up, show that the radiation doses delivered to children appear to be higher than those in other studies. Nevertheless all our TLD results are however less than the maximum value reported by the National Council on Radiation Protection and Measurements report No 68 [3], which for a 10 year old child, was 0.5 mGy for the same type of examination. The results obtained after the first modification, are substantially improved with the DAP measurements falling within the range of values of the Irish study. The TLD measurements are still higher than the other studies and twice the values of the Irish study.

Table 2. Comparison of doses for chest X-ray examination, between three different studies, for the 5-10 years old age group, in terms of ESD_{TLD} and ESD_{DAP}. Figures in parenthesis give the range of values

Study	Sample Size	Mean ESD_{TLD} (mGy)	Mean ESD_{DAP} (mGy)	Comments
UK	**(N/A)**	**0,06 (N/A)**	**34 (N/A)**	
Ireland	**30**	**0,046 (0,032 – 0,087)**	**23 (10 – 65)**	
Cyprus	**13**	**0,14 (0,09 – 0,23)**	**80 (40 – 218)**	**Original Set Up**
Cyprus	**24**	**0,089 (0,070 – 0,147)**	**24 (18 – 48)**	**With Orthochromatic Cassettes**
Cyprus	**13**	**0,079 (0,058 – 0,119)**	**20 (10 – 58)**	**With Orthochromatic Cassettes and increased beam filtration (0,1 mm Cu+1,0 mm Al)**

The results obtained thus far after the second modification are even better with the DAP measurement being below those of the Irish study and the range of the TLD measurements so far are within the range of the Irish study but the average value is still higher than that of the Irish study. The above modification had no visible effect whatsoever on the quality of the radiograph produced, which has been verified by the Radiologist in charge.

5. Conclusion

The practice as used initially in this study is improved by reducing the radiation dose to be within the European Commission Guidelines. This was achieved by using ultra high speed cassettes and by hardening the radiation beam with increase of the filtration. The doses can further be reduced by using higher kVp techniques and by removing the oscillating grid during paediatric use of the unit, as it is recommended in the European Guidelines.

Acknowledgements

This study is supported by the Biomedical Research Foundation, Nicosia Cyprus. The support and assistance of the personnel of the Radiology Department of the Makarios III Hospital is acknowledged and specially to Radiographers, Vathoulla Ioannou, Stella Komodromou, Stavroulla Karapataki, Eleni Evangelou and Dark Room Technician Nicos Loizou.

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IAEA-CN-85-207

RADIATION EXPOSURE OF CHILDREN DURING RADIODIAGNOSTIC EXAMINATIONS OF CHEST IN SLOVAKIA

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Abstract

Higher individual somatic radiation risk in the younger age groups has been until now inadequately considered in radiation protection. It is therefore essential to develope appropriate radiation protection measures also in the field of diagnostic radiology for paediatric patients. The European Communities elaborated Guidelines on quality criteria for radiodiagnostic radiographic images in paediatrics. Reference dose values for selected types of examinations and for 5 year old child were proposed. In our contribution we have tried to estimate the radiation load of children to 15 years, which undergone chest radiodiagnostic examinations during 1996 in a Slovak district. Our data of entrance surface doses were collected using measurements with TLD for 149 patients divided in 5 age categories at nine radiodiagnostic departments. The calculations of the total absorbed dose were performed using the measured ESD values integrated over the X-ray beam area, the conversion factors between the imparted energy and the dose-area product and the known irradiation parameters (kV, HVL, mass, etc.).
The analysis of the obtained absorbed doses as a function of age for chest PA radiodiagnostic examinations has shown, that the investigated Slovak radiodiagnostic centres use rather lower voltage techniques and the entrance surface doses are much higher than the proposed value of EC.

1. Introduction

Risks to pediatric patients from radiation exposure are aknowledged to be greater than for adults. It is supported by the fact that for certain detrimental effects has the radiation exposure in the first ten years of life, 3 to 4 times greater attributable lifetime risk than exposures between ages of 30 to 40 years, and 5 to 7 time greater when compared to exposures after the age of 50 years. It is therefore essential to develope appropriate radiation protection measures also in the field of diagnostic radiology for paediatric patients. Available data on paediatric doses are limited and comparisons are complicated by range of patient size.

Commision of the European Communities (EC) contributed to this problem giving special attention to the control measures, analysis of patient doses and quality criteria for radiodiagnostic procedures of children.[1] In 1996 EC adopted Guidelines on quality criteria for radiodiagnostic images in paediatrics [2] contain reference entrance surface doses for various diagnostic examinations and for 5 years old children. The patient doses obtained on individual radiodiagnostic departments can be compared with this given standards.

In our paper we surveyed the entrance surface doses, measured during chest examinations of 149 patients (with ages to 15 years) and results of measurements of dose area product for assessment of absorbed doses. The calculations of absorbed doses were performed using the conversion factors between the energy imparted and the dose area product at the known irradiation parameters (kV, HVL, mass of the patients, etc.)

The analysis of the obtained data and their comparison with reference values of EC demonstrate that the entrance surface doses (mainly due to the lower used voltages) are several times higher than recommended.

The results are proposed for application as an indicator of radiation risk for optimisation of diagnostic procedure and hence for reduction of children's radiation load.

2. Materials and methods

Our data were collected for 9 paediatric radiodiagnostic departments in the county of Trnava, where NPP is working . There are 590 996 people living, including 118 974 children, aged to 15 years. Children undergoing radiographic examinations (39 096) in the year 1996 were split into 5 categories: 0-1 year, 1-4 years, 5-9 years, 10-14 years and 15 years old.

Detailed information obtained through questionnaires allowed us to select as the most frequent examination (fig. 1) – the chest PA projection. To provide information on paediatric dose levels during chest examination a combination of direct measurements using LiF-700 Harshaw thermoluminiscent dosemeters (TLD) and indirect measurements using a dose-area product meter was used. TLD?s used to determine the entrance surface dose were calibrated at Slovak Metrological Institute using an X-ray equipment (50 kV, 2mA, 3 mm Al). They were annealed for 60 min at 400°C and by 120 min at 100°C in an automatic TLD oven. All readings were realised with Harshaw 3500 reader, the readout temperature was 300°C. The dose-area product was measured with a Diamentor (PTW Freiburg) type E using a light transparent ionisation chamber (type 57523-B). Conversion factors published by Persliden [3] were used to determine the energy imparted to paediatric patients of different ages from the dose-area product.

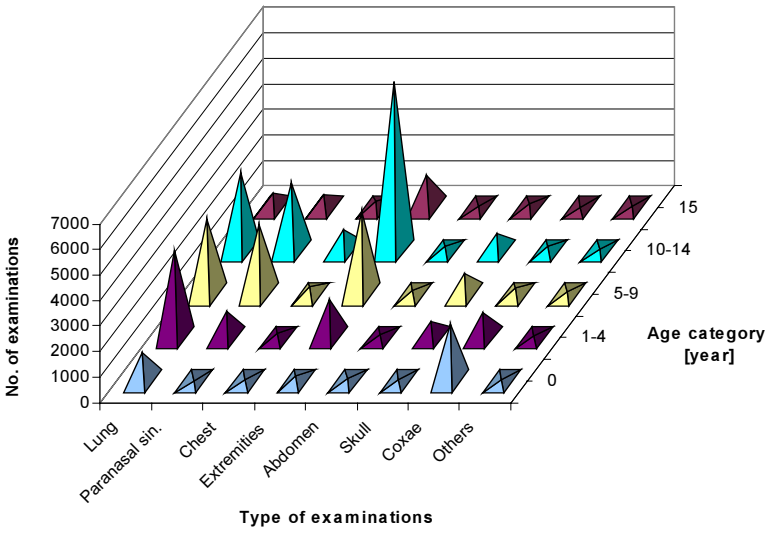

Fig.1. Frequency of radiodiagnostic examinations in paediatric department of Trnava county.

3. Results and discussion

Determination of effective doses for paediatric radiological examinations is difficult, time consuming and due to diferent sizes of patient also uncertain. Therefore we used the procedure proposed by Huda [4] using the energy imparted to the patient for absorbed dose E_a calculation. The values of E_a were calculated by following equation

$$E_a = (ESD \times A \times C_a) / M$$

A = the irradiation beam area in m^2
ESD = the measured entrance surface dose in mGy
C_a = the conversion factor (kg/m^2) of the imparted energy and dose area product [3]
M = the mass of patient in kg

Conversion factors C_a were calculated taking into account the age of patient and the total filtration (HVL in mm of Al), applicated during the examination.

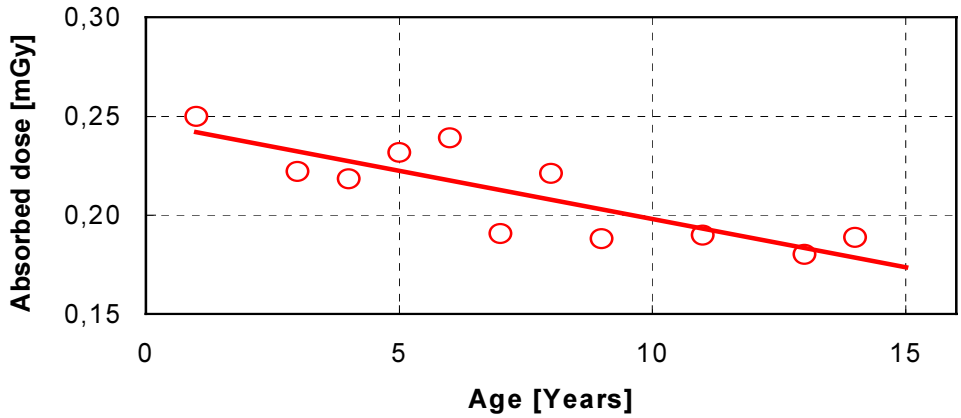

Fig.2. shows the relationship between E_a and the age of patient.

In the table 1 technical parameters and adequate ESD for chest examinations of children are shown.

Table 1. Technical parameters and entrance surface doses for X-ray examinations of chest (children 5-9 ages)

Hospital	Used equipment	Technical parameters		FSD	HVL	ESD
		kV	mA.s	cm	mmAl	μGy
1	chiralux 2	38-46	24-42	100-150	3	586
2	chiralux 2	50-53	18	100-150	2,8	562
3	MP 15-chirana	55-60	4-6	150	2,8	403
4	chiralux 2	50	18	150-200	2,2	431
5	chiralux 2	50	13-18	150	2,85	443
6	durolux	71-73	5-12	150-200	2,6	432
7	chiralux 2	40-44	24	150	2,8	305
8	chirodur 125C	45-47	8-13	150	2,8	488
9	chiralux 2	42-46	18	110-150	2,8	326

Total filtration 3 mmAl

Comparison of our results with reference values published in EC document indicate that in the case of chest PA of 5-9 years old children, the reference value for ESD of 0,1 mGy was defined for “high kV technique” and therefore for penetration of the X-ray beam. As it is shown in the table the radiological departements, investigated in our study, used fot chest examinations rather “low kV technique” leading to several time higher ESD.

Table 2. Entrance surface dose of 5-9 year old children for the chest PA/AP examination

	ESD[μGy]		
	min-max	median	ratio of min:max
departments of Trnava county	253-708	414	1:3
European hospitals	19-1347	67	1:71

The requirements of good radiographic technics given in the EC Guidelines are fulfilled only in 10% of chest examinations. We are following this study in all counties of Slovakia, which should be the basis for establishing reference values of chest examinations in paediatric radiology and implementation of QA programme for children dose reduction.

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IAEA-CN-85-172

RADIATION DETRIMENT ASCRIBABLE TO INFANTS AND CHILDREN UNDERGOING MICTURATING CYSTOURETHROGRAMS — A REVIEW OF STUDIES IN SPAIN, BRITAIN, NEW ZEALAND AND VENEZUELA

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Abstract

The detriment, due to ionizing irradiation, ascribable to infants and children may be as high as three times that to adults. Recent interest in dose reduction, in part associated with the advent of the Diamentor dose-area product meter has led to several studies reporting average dose-area products at a number of centres for micturating cystourethrograms (MCUGS) and other radiological examinations. In this review the data has been further processed to yield the ICRP 60 Equivalent Doses and a detriment factor applied to yield the numbers of infants and children likely to suffer detriment in future life as a result of having undergone the procedure at the centres reviewed.

1. Introduction

The ICRP Publication 60 [1] recognizes that the detriment which people might incur from irradiation needs to be in line with the other risks in life that people are willing to accept. Partly as a result of this and better knowledge concerning the detriment imposed by irradiation the ICRP reduced its recommended limits for exposure to radiation. Amongst other things it re-defines various quantities so as to make predictions of the outcomes of irradiation easier to quantify and understand. An initiative of the Commission of European Communities [2] inspired an interest in the assembling of data on paediatric radiology, there being a paucity of that in the literature.

The use of Monte Carlo methods for studying radiation transport and energy deposition when coupled with mathematical models of the human anatomy has enabled the calculation of tables of organ doses normalized to Entrance Surface Doses and separately to Dose-area Products for a set of standard radiographic projections. Such tables have been published by Hart, Jones & Wall at the NRPB [3] for adult radiology, computed tomography and paediatric radiology. Computer software (CHILDOSE) has been published by J Le Heron ar the NRL [4] which utilizes these tables and specific input parameters such as the filtration, kVp and either entrance surface-dose or dose-area product to make dose calculations. It enables the user to choose the standard examination required and calculates the doses to all organs (of both genders) and the Equivalent Dose (E D) to the child as a whole. In certain instances the actual examination may only be able to be approximated by one of the standard projections or may be somewhere between two of them. When fluoroscopy is involved covering several organs such as the genito-urinary tract practical experience shows that up to three of the standard examinations may have to be calculated to give a good indication of the contributions to the Effective Dose.

The detriment, a human being may suffer as a result of irradiation, may be no harm, the induction of a non fatal cancer, the induction of a fatal cancer and/or gonadal damage resulting in genetically deficient offspring. The susceptibility of adults to suffering such detriment (including the loss of lifestyle effected by cancers and genetic defects) may be broadly desribed by detriment factors of 5%/*Sv* of dose for fatal cancers, 1%/*Sv* of dose for non fatal cancers and 1.3%/*Sv* of dose for genetic effects in offspring. (ICRP 60 Sect 97 [1]).

The susceptibility of children to suffering the detrimental effects of radiation is considerably greater than that for adults, but decreases exponentially into adult-hood. For those aged under 10 years of age the 'multiplicative' model of susceptibility suggests that the susceptibility of children receiving low doses of radiation leading to fatal cancers later in life is approximately 3 times that of adults - that is about 15%/*Sv*. (ICRP 60 [1] Fig. C-5 Annex C.7). Assuming that the same factor of 3 may be applied to the other two much smaller contributions to detriment the factors would be 15%/*Sv* of dose, 3%/*Sv* of dose and 4%/*Sv* of dose for fatal, non-fatal and hereditary effects respectively - a total of 22%/*Sv* of dose. This assumption is probably the most reasonable that can be made at this time as not sufficient time has elapsed for the 'under 10 years of age' Japanese atomic bomb survivors to have completed their life span for the relevant statistics to have been compiled. Those such survivors presently alive would be between 55 and 65 years of age.

The detriment (*D*) is calculated by firstly calculating the Effective Dose (*ED*) and then multiplying that by the detriment factor (*f*) which may be styled

$$D = ED.f$$

The figure of 22%/*Sv* of dose would seem to be a reasonable upper bound in this instance. The 'multiplicative' model is much more conservative than the 'additive' model - predicting higher susceptibilities to radiation detriment for children than the additive model.

2. Method

Review papers from the period 1994 - 1996 were chosen where there was suitable data on micturating cystourethrograms presented. Additional data has been collected in Venezuela during 2000.

The tables of NRPB SR279 and the software published by the New Zealand National Radiation Laboratory (NRL) were used to make a series of calculations of the average Equivalent Doses using the average dose information and radiological settings from the selected studies.

CHILDOSE has options to calculate doses for a child at birth, 1 year, 5, 10 and 15 years of age. As the data reported in the selected literature is given as an average for the periods 0 - 12 months, calculations of the Effective Dose at birth and 1 year may be calculated along with the values of their arithmetic mean (denoted by - 6 m (months)). The filtration in one of the reported studies is 3.1 mm Al. whereas the remainder do not report the filtration used. In such instances 2.5 mm Al is used in the calculations for this report.

An MCUG examination of an individual patient generally comprises two parts - a fluoroscopic part and an X-ray part where 3 - 6 exposures are taken. Quite a variety of diagnostic regimens are followed leading to a range of results varying by an order of magnitude. Generally the kVp is around 65 but in some instances it is around 90. The average dose-area products are generally reported, in the papers, separately for the fluorography and the films (and these may have been made at different kVp's) so the calculations of dose are done separately and the results summed.

Table 1. Effective Doses and Detriment Calculated for a Range of Reported Surveys of Radiological Practice, relating to Abdominal and Pelvic Projections Typical of those for Paediatric MCUG Examinations

Year of Publ.	Author Abbrev	Filtn	kVp	kVp	ESD	ESD	Diam.	Diam.	AP view	CHILDOSE Calculation Effective Dose in mSv				Detriment 0.22/Sv		
		mm Al	Flu.	Film	Flu mGy	Film mGy	Flu cGycm^2	Film cGycm^2		0-1 yrs	2-5 years		6-10 years	11 - 15 years of age		
1993	DLE	3.1	60	60	0.77	1.41			MCUG	0.5	0.13					1per10,000
1994	MFSM	3.0	70	70			17	3.6	Abdomen	0.4						1per10,000
Aberdeen, Scotland							0.12	1	Abdomen		0.8	1	0.12	1	0.13	1per10,000
Aberdeen, Scotland									Pelvis		0.07	1	0.08	1	0.09	1per10,000
Newcastle, England									Abdomen		0.14	1	-	-	0.13	1per10,000
Newcastle, England									Pelvis		0.11	1			0.17	1per10,000
Madrid I									Abdomen		0.21	1	0.29	1	0.23	1per10,000
Madrid I									Pelvis		0.3	1	0.26	1	0.29	1per10,000
Madrid II									Abdomen		0.43	1	0.47	2	0.37	1per10,000

Table 1. (cont.)

Madrid II									Pelvis		0.188	1	0.34	1	-	-
1995	GVR	3.1	85	55			20	238	Abdomen	3.7						9per10,000
Centre I Madrid Comm. Hospital									Pelvis	4.1						9per10,000
									MCUG		2.7	7	3.5	8	4	
Centre II Madrid Paediatric Hospital																10per10,000
1996	***RVFG***	3.1	60	65	116	10			Abdomen	1.9						4per10,000
									Pelvis	2.1						4per10,000
Centre I - Madrid Community Hospital									MCUG		1.4	4	1.95	5	2.74	7per10,000
Centre II		3.1	80	100	117	165			Abdomen	5.4			4.4	10	4.6	12´per10,000
									Pelvis	5.9						14per10,000
Centre II – Madrid Paediatric Hospital									MCUG		6.8	16	4.4	10	4.6	11per10,000
Centre III		3.1	65	70	57	57			Abdomen	1.9						5per10,000
Centre III – Madrid General Hospital									Pelvis	2.0						5per10,000
Centre III – Madrid General Hospital									MCUG		1.2	3	2.1	5	1.9	5per10,000
2000 JM de los Rios Paediatric Hospital Caracas									MCUG	1.3						3 per10,000
2000 JM de los Rios Paediatric Hospital Caracas									MCUG		0.7	2	0.8	2	0.9	2 per 10,000

*Film and fluorographic values are not given separately, just the total is given and that is the value in the Flu column.

Notes to assist in interpreting Table 1

Columns headed Det. Contain the same information as the right0most colmn of the table (the values are rates per 10,000).

For 0-1 years of age the CHILDOSE calculations have been done for both abdominal and pelvic projections. Constraints on the paper length prevent inclusion of the kVp, ESD and/or Dose Area products for the Age ranges 2 - 5, 6 – 10 and 11 – 15.

3. Results and discussion

The radiological parameters and results of the calculations are presented in Table 1. They have been arranged in order of publication.

The Author Abbreviations refer to the publications as follows - DLE- Evans [5], MFSM – Martin, Farquhar, Stockdale & MacDonald [6], GVR – Gonzalez, Vano & Ruiz [7], KFCPB – Kyriou, Fitzgerald, Pettett, Cook & Pablot [8]. RVGF – Ruiz, Vano, Gonzalez & Fernandez [9]. The meanings of the Centre's I, II, and III C1, C2, G3 and G4 are as defined in the papers to which they apply.

The standard radiological examinations dealt with by CHILDOSE do not include the MCUG so calculations have been made of the organs doses for the two projections Abdomen and Pelvis. The Abdomen does not include the testes whereas the Pelvis does. Which is the most realistic representation is hard to decide but the results do not differ greatly. Readers must pass their own judgement on this matter.

The values of the Effective Dose (E D) are those calculated by CHILDOSE using the NPRB tables. Method 1 [4].

The detriment D is calculated as 22%/*Sv*.*ED* where for the purposes of these calculations 1 *mSv* = 1 *mGy* and is expressed in the form *n* per 10,000. This means that *n* infants of every 10,000 undergoing this diagnostic procedure at the relevant institution at the time to which the survey data pertains or having an examination using the same or similar radiological parameters would incur a radiological induced detriment. For 15/22 of those incurring the (non-zero) detriment the detriment would be a fatal cancer some time later in life, for 3/22 of them the detriment would be a non-fatal cancer later in life and for 4/22 of them the detriment would be inheritance of a genetic defect by their offspring.

Examination of Table 1 shows that there are widely varying practices with accompanying disparate detriment.

5. Conclusions

There is significant variation in the detriment being suffered by infants and children having MCUG examinations at different centres around the world. The average Effective Doses calculated corresponding to the average parameters used in the calculations range from 0.5 - 7.1 *mSv*. The range of actual Effective Doses will of course be even wider. If the method were to be compared with some other modality the diagnostic information yield obtainable from each modality would have to be carefully compared particularly in relation to specificity and efficacy. The availability of detriment information certainly makes it easier to quantify the relative risks of various procedures in order to make informed decisions about them.

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Topical Session 8a

RADIOLOGICAL PROTECTION OF PATIENTS IN RADIOTHERAPY: EXTERNAL BEAM

RADIOLOGICAL PROTECTION OF THE RADIOTHERAPY PATIENT?

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Abstract

We propose that the system and concepts of radiation protection should not be used with reference to radiotherapy patients. We justify this on conceptual grounds. The patient undergoing radiotherapy procedures, as prescribed by the medical practicioner, is protected by the quality assurance system legally required for medical exposures.

1. Introduction

The medical exposure of a patient for purposes of radiotherapy is unique in that radiation itself is the healing agent, applied at a dose rate and dose range over three orders of magnitude higher than that occurring naturally. Moreover, unlike at natural dose levels, much is known quantitatively about the dose-effect relationship, both for the curing effect and for the post-irradiation complications, which inevitably accompany radiotherapy. Figuratively speaking, radiation protection is concerned with avoiding the generation of cancer by avoiding exposure, while radiotherapy, in contrast, relies on delivering a dose as high as possible to eradicate the cancer which has already developed. Whether to apply principles of radiation protection to the radiotherapy patient, is a question worth considering. It is the topic of this Conference.

We propose that the system and concepts of radiation protection should not be used with reference to radiotherapy patients. We will justify our view on conceptual grounds, in the context of relevant regulations and recommendations.

2. Radiotherapy

Radiotherapy, for curative or palliative intent, is a well-described sequence of procedures [1-3], the general aim of which is to achieve cytotoxic levels of irradiation to well-defined target volumes of the patient, while as far as possible sparing the exposure of surrounding healthy tissues. Radiotherapy seeks to provide an optimal uniform distribution of dose to the target volume relative to normal tissue, the point of optimisation being to deliver a dose as *high* as possible within the available "therapeutic window". This "window" arises as a range of dose applied to the target volume where the probability of cure exceeds the probability of complications, both probabilities increasing with dose (up to saturation) in a non-linear manner. According to present radiobiological models, the dose-effect relationships used to describe the probability of cure and the probability of complications are mathematical expressions involving exponential or power dependence on dose [4]. A total dose of the order of 60 Gy, or so, to the target volume, delivered in up to about 30 daily fractions of about 2 Gy, is typically applied. It is well recognised that the biological effect is not additive with dose, and depends on the radiosensitivity of the tissue and on the timing of the fractionation scheme. Through careful planning and beam shaping techniques (most frequently, external beams of megavoltage photons and electrons, gamma-rays from sealed sources placed internally, or beta- or gamma- rays from radiopharmacological agents, are used) the dose to the target volume is maximised while sparing the neighbouring healthy tissue or so-called critical volumes. Modern radiotherapy is a complex procedure involving advanced

technology and close co-operation between qualified specialists trained in the areas of medicine, radiation physics and technology. A detailed quality assurance system in radiotherapy is presently required by national and international recommendations [5].

3. Conceptual

Clearly, the governing principles of radiation protection: justification of a practice, dose limitation and optimisation of protection and safety, as stated in the Basic Safety Standards [5], do not apply in the case of radiotherapy. In this context, one may also take issue with the statement concerning the control of medical exposures in the 1990 ICRP Recommendations (S36, p. 74): "*...If the practice is justified and the protection optimised, the dose in the patient will be as low as is compatible with the medical purposes."* Indeed, radiotherapists insist on delivering a dose to the tumour *as high* as is compatible with the probability of occurrence of complications. Radiotherapy is unique in this aspect, unlike, e.g., medical diagnostics. The dose to which the tissue surrounding the target volume is exposed to, as well as the limits of dose applied to critical targets, are governed strictly by medical and *not* by radiation protection considerations. Healthy neighbouring tissues are likely to acquire doses well above levels considered to be of relevance to radiation protection. Disregarding the dispute as to the linearity of dose-effect relationships at low doses, there is unanimous acceptance of the non-linearity of this relationship at dose levels used in radiotherapy. Application of multiplicative dose factors such as those used in defining equivalent dose or effective dose [5,6] is thus inappropriate, even if values of these factors were known at such high dose levels. Therefore, the usage of the Sievert as unit of effective dose equivalent or effective dose, and of collective dose (in units of man Sv), cannot be justified in the case of radiotherapy.

4. Discussion

A case in point is the study of Beentjes [7], quoted in Annex C of UNSCEAR 1993 Report [8]. Here, the collective effective dose from radiotherapy in the Netherlands for 1971 (male and female) radiotherapy patients has been calculated at 18630 man Sv, yielding an average of 9.67 Sv per patient (!). Additional calculations were made using cancer fatality coefficients taken from ICRP-60 [6], presumably valid at low-dose, or the "stochastic" level of radiation hazard. It is difficult to imagine how could meaningful evaluations be made over a wide range of doses, presumably from 60 Gy in the target area to a value orders of magnitude smaller, from scattered radiation, considering, e.g. exponential dose-effect relationships known to be valid at the higher dose levels. The meaning of the collective effective dose, let alone the Sv under such non-uniform irradiation conditions and at such high doses is difficult to understand. In our view, this example illustrates the futility of applying concepts and units of radiation protection in radiotherapy.

5. Quality assurance in radiotherapy

The quality assurance systems in radiotherapy, presently recommended at national and international levels [5], usually pertain to the complete procedure, including calibration of sources, clinical dosimetry, computerised radiotherapy planning systems and recording and reporting all the procedures [9]. Detailed quality assurance tests have been implemented for all radiotherapy equipment, by national and international authorities. It is through strict adherence to such quality assurance systems that patient safety is assured and the possibility of, e.g., accidental overexposure of the patient avoided. Possible stray or scattered radiation related to radiotherapy is of no consequence to the patient's radiation protection, as it is

usually a contribution several orders of magnitude smaller than that relevant to the curative does applied. Thus, in our view, the ultimate safety of the radiotherapy patient results from the correct procedure of applying the medical exposure within the appropriate quality assurance system, and not from protecting him against exposure to radiation. Information, such as that provided in the last UNSCEAR report [10] on, e.g., total dose applied to target volumes in a given number of patients for given types of malignancies is of interest to the specialist but no information concerning population exposure patterns can, or should be derived from such data. Whether any dose-response relationships over a wider range of doses could be extracted from this data in conjunction with additional information on the generation of secondary radiogenic cancers in radiotherapy patients, is a matter for further consideration.

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HIGH DOSE AND LOW DOSE RADIATION EXPOSURE IN THE INDUCTION OF BREAST CANCER

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Abstract

In today's modern practice of Radiation Oncology it is becoming increasingly common to follow many patients with breast cancer. There is a proven association between prior radiation and the development of breast cancer, although in many instances the available sources of data are confusing. Characteristic features of radiation induced breast cancer are the importance of age at first exposure to radiation and the long latency period. The risk of breast cancer is highest in women exposed in the first decade of life and lessens progressively with increased age at exposure. The latency period is typically 10 years or more; a time in which other age dependent factors may influence the expression of the malignant phenotype. Genetic factors may also (in theory) increase a particular patient's susceptibility.

1. Introduction and status of the art

1.1. Low dose radiation and breast cancer

There are many reports in the literature addressing the potential role of mantle irradiation and the development of breast cancer. It has been well established that ionizing radiation can be a carcinogen for breast cancer. The available data demonstrate that this risk decreases with increasing age at exposure. There are several sources of data, but the results of these studies are sometimes contradictory.

1.2. Data on atomic bomb survivors

The sensitivity of the breast tissue to ionizing radiation has been amply demonstrated by epidemiological studies in Japanese Atomic Bomb survivors[1,2]. There are several reports in the literature like the Life Span Study sample demonstrating an increased incidence of breast cancer in this population. There is a strong linear radiation dose response, with the highest dose-specific excess of relative risk among survivors under 20 years at the time of the blast, and much higher for patients exposed during infancy. The cancer excess appears to be confined mainly to the group of women exposed before 40 years of age. A marginally significant trend was seen among women exposed at 40 years or older.

There is a much weaker association between dose and the prevalence of non-proliferative and proliferative breast disease. There are some interesting autopsy studies in survivors of the Atomic Explosions. These studies have been reported by Tokunaga [3] on 225 patients who received low dose radiation (0.2 Gy kerma), and 88 who achieved high dose radiation (1 Gy kerma or more). 81% of the Low dose breasts and 74% of the High dose breasts has one or more non-proliferative lesions, with an statistically significant relationship with dose.

Proliferative disease, and atypical hyperplasia in particular, was also elevated in both groups, (16% Vs 11%), also with a statistically significant relationship with dose.

Evidence for non-proliferative and in particular proliferative disease is strongest for the group of ages 40-49 at the time of the explosion.

1.3. Occupational exposure to ionizing radiation

The risk of breast cancer among female radiological technologists has been studied, in a population of 105,000 female radiation workers between 1926-90, including Radiation therapy technologists, dental X Ray Technologists, fluoroscopy, routine X rays, etc. [4]. The authors used the American Registry of Radiological Technologists, designing a case control study. Breast cancer was not significantly increased with occupational exposure in any of these procedures. there was also no relationship between risk and number of years worked [5-7]. Studies in Denmark yield comparable results [8].

1.4. Diagnostic exposure to ionizing radiation

There is a controversy about the role of mammograms and radiation induced breast cancer. It is important to know that an average woman who is screened with mammograms each year for 30 years, beginning at age 40 will have her breast exposed to a total dose of less than 0.1 Gy. The incidence of breast cancer in female patient with tuberculosis examined with fluoroscopy after therapeutic pneumothorax in Massachusetts among 5000 women between 1925 and 1954 [9]. Average number of examinations was 88. Increased rates of breast cancer were not apparent until about 10-15 years after the initial fluoroscopy examination. The excess risk then remained high trough all intervals of follow up, up to 50 yr. after the first exposure. Age at exposure strongly influenced the risk, with young women, below 40 at highest risk. (RR 1.06), particularly those between 15-24 yr. The estimated mean radiation to the breast was 79 cGy. There was a strong linear relationship between dose and risk of breast cancer. Danish researchers found similar results in a case-control fluoroscopy study [10].

A scientific publication in 1995 described a family with a cluster of breast cancer cases occurring in a generation, and their relationship with repeated fluoroscopic examination during early childhood and adolescence [11]. The development of breast cancer was correlated with DNA repair proficiency and history of radiation exposure. The authors conclude that the findings suggest that there is a susceptibility factor (deficient repair of radiation-induced DNA damage during G2 phase, like in the cancer prone genetic syndromes) that may interact with exposures to low-levels of ionizing to increase the risk of developing breast cancer.

1.5. Therapeutic exposure of breast tissue to low dose radiation

The best data available come from Sweden, from patients treated with ionizing radiation for benign breast disease, between 1924 and 1954. The results of the study have been published in 1993 and 1995 [12]. The cohort consists in 1216 women treated with radiation therapy (mean dose 5.8 Gy, range 0.003-50.14 Gy), and 1874 patients unexposed to irradiation, who had benign breast disease. Ages at the time of exposure between 8-74 (median 40 yr.). The total number of breast cancer observed was 278, of which 95 were in the unexposed cohort. In the analyses of the dose response relationship, for doses less than 5 Gy there was a clear dose-response linear relationship, with no threshold. This may support the working hypothesis of the mechanisms of carcinogenesis that is that it is a single cell origin [13].

At doses higher than 5 Gy there is an increase also, but with a leveling off in the increase of relative risk, because the cell killing became obvious. This also has been observed in the New York mastitis study for doses greater than 3 Gy, but in many other studies, this trend has not been found, but the information that these studies provide on high doses very limited.

1.6. Scattered irradiation of contralateral breast tissue in radiotherapy for breast cancer

This issue has also been extensively studied. Boice reported data form the Connecticut tumor registry, on 41000 women in a typical case control study [5, 14]. The conclusion was that radiotherapy for breast cancer contributed little to the already high risk for contralateral breast cancer. In their experience less than 3% of second breast cancer in the cohort can be attributed to pervious ionizing radiation treatment. The risk however is significant in women who underwent radiation at a relatively young age (<45 yr.) (RR 1.59). Exposure after the age of 45 entitles a minimal risk of radiation induced breast cancer. Other authors [15,16] have found similar conclusions. In a attempt to reduce the scatter dose to the contralateral site, Macklis has developed a breast shield [17].

2. Results

2.1. Therapeutic doses of radiation and breast cancer

Several studies of patients treated for Hodgkin's disease have shown an increased risk of second breast cancers [18,19]. Problems with these studies include small patient numbers, short follow-up time (less than 15 years), incomplete treatment information and an emphasis in hematological malignancies. Patients treated for Hodgkin's disease (as opposed to other malignancies) are at particular high risk of breast cancer because: a) Excellent prognosis for irradiated patients. b) Young age at exposure that increases the time at risk. c) Exposure at a physiologically vulnerable puberty period. d)-Large amount of breast tissue that receives primary or scatter radiation. Several large retrospective reviews of patients treated for Hodgkin's disease is now available and provides risk estimates for subsequent breast cancer and give suggested follow up guidelines.

One of the first reviews was published by Kaldor [20]. He reported the incidence of second malignancies following treatment of several types of cancer using 11 population-based registries including over 133,000 patients. No information was available on treatment given or other risk factors. Overall, the risk of second cancer at least 5 yr. after treatment for Hodgkin's disease was 90% greater than expected (415 vs. 218). Breast cancers were increased (62 observed vs. 44 expected. RR=1.4). The incidence peaked between 10-15 yr. of follow up.

The data from the British National Lymphoma Investigation on 2846 patients treated for Hodgkin's disease between 1970-1987 was reviewed by Swerdlow [21]. Mean follow up differed by treatment category causing XRT treated patients to have longer follow up. 113 second primaries were recorded for a RR=2.7. Most of these were hematological (only 6 breast primaries: RR=1.2). Patients treated with radiotherapy alone did not have a increased leukemia risk. Yahalom [22], form Memorial Sloan Kettering Cancer Center found similar findings and recommended mastectomy as the treatment of choice for these patients, and suggest screening mammography 8 years following radiation. Radiation induced breast cancers did not differ significantly, form the pathological point of view with a cohort of patients with breast cancers not induced by radiation.

Hancock from Stanford Reviewed records of 885 women treated for HD between 1961-1993 (with a mean follow up of 10 years) [23]. 25 patients developed breast cancer (RR 4.1)

- Age at time of radiation influenced risk. The biggest RR was for patients younger than 15 years (136), versus 19 for patients ages 15–24, 7 for those between 24–29, and 0.7 for those older than 30.

- Length of Follow up also turned out to be an important factor. If less than 15 years, R= 2.0, versus 13.6 for patients with more than 17 years of follow up.

Chemotherapy increased the risk of breast cancer22/26 cancers arose within or at the margin of the radiation field. Majority also arose in full dose area (4 Gy).

Leeuwen has reported several analysis on patients treated for Hodgkin's disease in the Netherlands [18,24], including a 20yr. follow up study of 1939 between 1966-1986. Overall, the RR for second cancer was 3.5. The overall risk of breast cancer was not increased (RR=1.1), but when analyzed by age at irradiation, those with 15 years of follow-up had a RR=4.1 if treated at age 20-29, compared with RR=41.8 for those treated at age less than 20.

Detailed dosimetrical analysis, including 3-D differential dose volume histogram have been developed [19,25,26] to determine doses to various parts of the breast in order to develop a linear model for carcinogenesis. This model attempts to take into account the bimodal dose distribution within the breast and come up with an integral dose to predict for secondary breast cancer.

3. Conclusions

1. The RR for developing breast cancer after irradiation for Hodgkin's disease is somewhere between 4 and 40 depending on age of exposure and length of follow-up.
2. It is unknown whether the increased incidence represents true disease induction or is a mere shift in the age curve
3. Chemotherapy might have an additive role, although lack of chemo only treated patients makes this difficult to assess
4. Vigilant screening is necessary but probably not until 8-10 years following irradiation.
5. There is evidence for non-proliferative and proliferative disease induced by radiation of the breast parenchyma. The correlation is strongest for the group of ages 40-49 at the time of the exposure.
6. The excess of breast cancers appears to be confined mainly to the group of women exposed before 40 years of age.
7. The increased rates of breast cancer are not apparent until about 10-15 years after the initial exposure.
8. Breast cancer is not significantly increased with occupational exposure to ionizing radiation
9. For exposures to doses less than 5 Gy there is a clear dose-response linear relationship, with no threshold
10. At doses higher than 5 Gy there is an increase also, but with a leveling off in the increase of relative risk, because the cell killing is obvious.

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IAEA-CN-85-181

A COMPUTER TOOL FOR DAILY APPLICATION OF THE LINEAR QUADRATIC MODEL

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Abstract

Summary The aim of this paper is to indicate the relevance of the criteria A.S.A.R.A. (As Short As Reasonably Achievable) in the optimization of a fractionated radiotherapy schedule and the presentation of a Windows® computer programm as an easy tool in order to:

- Evaluate the Biological Equivalent Dose (BED) in a fractionated schedule.
- Make comparison between different treatments.
- Compensate a treatment when a delay has been happened.

with a version of the Linear Quadratic model that has into account the factor of accelerated repopulation.
Conclusions Delays in the normal radiotherapy schedule is a item that it has to be controlled as possible because is able to be very important parameter in order to release a good application of treatment, principally when the tumour is fast growing. It is necessary evaluate them. ASARA criteria is useful to indicate the relevance of this aspect. Also computer tools like this one, it could help us in order to make this.

1. Introducción

Según ICRU50 el objetivo de cualquier tratamiento en radioterapia es impartir una determinada dosis en el volumen de planificación para que el volumen tumoral clínico quede englobado por la isodosis del 100%, salvando siempre en la medida de lo posible los tejidos sanos adyacentes al volumen tratado. Este criterio que está directamente relacionado con la calidad de tratamiento en radioterapia, proporciona de forma implícita la adecuada protección radiológica al paciente. A parte de consideraciones tales como la verificación del tratamiento diario para minimizar los errores de las distintas fases que intervienen, así como la elección de un fraccionamiento adecuado. Hay una serie de factores que radiobiológicamente tienen gran trascendencia y que por dificultades propias de la carga de trabajo de un servicio pueden no considerarse como es la tardanza en iniciar un tratamiento, paradas durante el mismo por motivos varios como pueden ser averías, empeoramiento clínico del paciente, etc.

En este trabajo se presenta una discusión sobre la importancia de considerar este punto. Esto nos ha llevado al desarrollo de una herramienta informática en entorno Windows® basado en el modelo lineal cuadrático que permite evaluar equivalencias radiobiológicas entre tratamientos y calcular la compensación por paradas.

El proceso completo (pruebas clínicas y diagnóstico, simulación del tratamiento, dosimetrías clínicas y puesta en tratamiento) para un paciente, se realiza habitualmente con una demora de tiempo entre las distintas fases de que consta. Esto es real y además admisible en muchos casos. No obstante hay situaciones, también reales, no admisibles en las que existe una modificación importante entre los datos tomados en la simulación y los datos reales a la hora de la puesta en tratamiento (adelgazamiento, crecimiento tumoral,...) debido a demoras prolongadas. Este es un aspecto que está al mismo nivel que la elección de dosis y fraccionamiento a la hora de evaluar la optimización del tratamiento. Existen trabajos que abordan el problema de la tardanza inicial y que hablan de efectos deterministas y no

deterministas. Se ha propuesto el criterio A.S.A.R.A. (As Short As Reasonably Achievable) [1].

Los efectos no deterministas se pueden producir por una disminución en la probabilidad del control local de la enfermedad así como desarrollo de metástasis. No presentaría umbral mínimo en la tardanza, la probabilidad de ocurrencia aumenta con el aumento del retraso temporal, aunque no su severidad.

Los efectos deterministas como la ansiedad y empeoramiento general aumenta con el retraso temporal y quizás podríamos hablar de un umbral mínimo de tiempo, aunque esto último es muy discutible y sobre todo cuando hablamos de efectos psicológicos.

El modelo más usado en la actualidad es el modelo lineal cuadrático, que como todos sabemos, tiene una serie de limitaciones que le son inherentes como la incertidumbre de los parámetros radiobiológicos que utiliza, la tasa de radiación, etc. A continuación se expone una de sus versiones donde se define la Dosis Equivalente Radiobiológicamente (D.E.B.) como [2]:

$$DEB = n \cdot d \cdot \left(1 + \frac{d}{\alpha/\beta} \right) - k \cdot \left(T - T_K \right) \qquad [1]$$

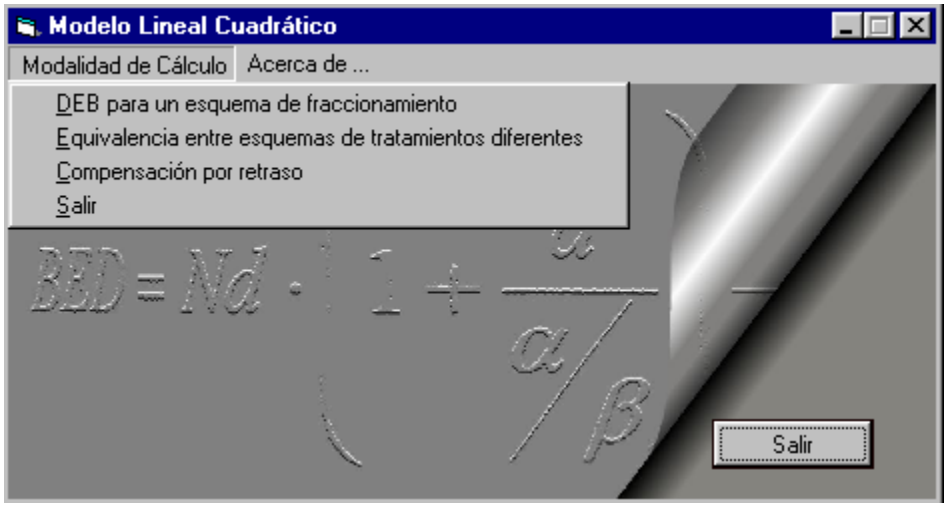
siendo:

- $n \rightarrow$ Número de fracciones totales.
- $d \rightarrow$ la dosis por fracción en (Gy).
- $\alpha/\beta \rightarrow$ el cociente de los parámetros lineal y cuadrático del modelo en (Gy).
- $k \rightarrow$ factor de corrección debido al crecimiento tumoral (Gy/día).
- $T \rightarrow$ Tiempo total del tratamiento en días, (incluyendo festivos).
- $T_k \rightarrow$ Intervalo de tiempo en días a partir del cual se considera repoblación acelerada. Se asume que la repoblación es despreciable antes de T_k, es decir, $k=0$ para $T < T_k$.

Esta versión del modelo radiobiológico no tiene en cuenta el factor de reparación incompleta introducido por Thames y Hendry [3]. Esto tiene principalmente relevancia en tratamientos hiperfraccionados en los que el tiempo de reparación celular sea sensiblemente mayor al espaciado temporal entre fracciones del tratamiento. En este modelo los tratamientos hiperfraccionados sólo son modelados en cuanto a la estimación del tiempo total del tratamiento.

Se ha elaborado un programa para entornos Windows® que permite de forma cómoda y rápida evaluar el factor D.E.B. de un tratamiento radioterápico, evaluar la equivalencia entre dos esquemas distintos de tratamiento y compensar un tratamiento afecto de determinadas interrupciones. En cualquiera de estas tres vertientes optamos por evaluar la Dosis Equivalente Biológica sobre otros conceptos ampliamente usados como la Dosis Estándar Equivalente (D_S) propuesto por Yaes y col [4] ya que D_S es un caso particular de equivalencias entre tratamientos a partir de la D.E.B. para el caso estándar del fraccionamiento diario de 2 Gy y para tejidos donde la proliferación tumoral durante el tratamiento sea despreciable. En el caso de tejidos de respuesta aguda sólo se podría aplicar para tratamientos de igual duración. Es por ello que parece mucho más versátil el uso de la DEB. Cuando calcula la equivalencia entre tratamientos respetando la dosis por fracción y

calculando un nuevo número de sesiones, usa un método de iteración que implica una incertidumbre en la D.E.B. de 0.01 sesiones. Cuando corrige la dosis por fracción debido a un aumento en el tiempo total del tratamiento, el programa estima un factor de penalización en la DBE que resulta de multiplicar el nº de días de parada por el factor de crecimiento tumoral, indicando siempre esta penalización en porcentaje.



La mejor elección de un tratamiento será aquella que logra una mayor DEB en el tumor y al mismo tiempo una DEB menor en el órgano crítico. Hay evidencias en la literatura [5,6,7] de que la probabilidad de control tumoral disminuye con las interrupciones o retrasos en el tratamiento. Esto llega a suponer alrededor de 1.1 % de detrimento en la DEB por día perdido (mejor estudiado en tumores de cabeza y cuello).

La aplicación informática que presentamos nos ayuda, apoyándonos en los métodos de compensación de gap descritos por Hendry et Al [8], a intentar mantener la DEB en el tumor, equilibrándolo con la DEB en los órganos críticos (ventana terapeútica). Estos métodos son:

MÉTODO	VENTAJAS	INCONVENIENTES
Mantener el tiempo total de tratamiento y la dosis por fracción: 1. Tratar los fines de semana. 2. Administrar dos sesiones al día hasta ponerse al día.	Se mantiene el tiempo total , el tamaño de la fracción y el intervalo de 24h entre fracciones. Se mantiene el tiempo total, el tamaño de la fracción.	Aumento de los costes, problemas de ámbito laboral e imposibilidad de realizarlo cuando el gap se produce cerca de la finalización de tratamiento. Pérdida potencial de tolerancia en tejidos de respuesta tardía para intervalos de 6-8h entre fracciones, frente a los de 24h. Problemas de horarios.
Mantener el tiempo total de tratamiento incrementando la dosis por fracción: 1. Aumentar el tamaño de la fracción en tantos días como días de interrupción ha habido: Mantener el isoefecto en el tumor. Mantener el isoefecto en los órganos de riesgo. 2. Aumentar el tamaño de la fracción (todas las fracciones con igual dosis) en los días restantes de tratamiento.	Se mantiene el tiempo total de tratamiento, se administra una fracción al día. Se mantiene el tiempo total de tratamiento.	Imposibilidad de realización en esquemas cortos que usen dosis por fracción elevadas. Mantener el control tumoral se traduce en un aumento de las reacciones tardías. Mantener el control de las reacciones tardías se traduce en una infradosificación del tumor.
Aceptar la prolongación del tratamiento, administrando una (o más) fracción extra hasta compensar el gap.	Se mantiene el control local esperado.	Aumento de las reacciones tardías.

Fuera del rango de dosis/fracción comprendido entre 1 y 4 Gy la utilización del modelo lineal cuadrático puede, de acuerdo con las ideas actuales, conducir a resultados erróneos. Por esta razón, su empleo debe quedar circunscrito a los niveles de dosis descritos.
El programa puede ser bajado de la red en la dirección
http://www.carloshaya.net/servs/fisica/fypri.html.

2. Conclusiones

Normalmente las interrupciones en un tratamiento de radioterapia no es un factor mencionado a la hora de aplicar el tratamiento de la forma más óptima posible. El criterio ASARA recoge este aspecto y, en la medida de lo posible debería ser seguido. Es fundamentalmente útil en el caso de tumores de crecimiento rápido. Podemos hablar de un 1% de detrimento en la D.E.B. por día perdido, por lo que la aplicación de modelos radiobiológicos para optimizar más los tratamientos aplicados es muy importante. En aras de conseguir mejores modelos es necesario también un mayor esfuerzo en el conocimiento de los parámetros que éstos manejan.

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IAEA-CN-85-197

TOLERANCE OF THE DIFFERENT STRUCTURES OF THE EYE TO THERAPEUTIC IONIZING RADIATION

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Abstract

Primary tumours of the visual apparatus are rare, although radiation therapy of tumours near the eye is becoming increasingly more common in daily practice. These tumours often incur the incidental irradiation of eye structures, even when the latter are not clinically involved with the tumour. Depending on the dose and irradiated volume some damage to the different structures of the visual apparatus may occur. In addition, the time to expression and severity of injury are dose-dependent. This review analyses the most recent literature and proposes daily practice guidelines.

1. Eyelashes

The eyelashes serve as end organs of touch; their contact with tiny particles initiates a blink that protects the eye. Irradiation epilates the lash, and thus abolishes this protective reflex. This may led to an increased irritation of the conjunctiva and corneal surfaces. Doses of 28 Gy/2 wk with Ortovoltage (100 kVp) may produce permanent depilation. The eyelash may be spared with megavoltage beams, so the eyelash may be at least partially intact even after 50-60 Gy prescribed to a point deep to the lid. But doses in excess of 50 Gy to the eyelids may produce permanent depilation [1].

Like the hair elsewhere, an epilated lash may regrow a different colour, and the new hair may be sparse and short.

2. Eyelids

The eyelids are the thinnest skin of the body, to allow effortless and rapid motion of the lid. Any inflammatory or fibrosing process will decrease the flexibility of the eyelid.
Radiation induced eyelid changes commonly consist of skin erythema, progressing to pallor and teleangiectasia. Chronic structural changes include ectropion, entropion with trichiasis and closure of the eyelid punctae. It must be remembered that deformity of the eyelid margin may lead to corneal irritation, which over time may produce severe damage. Changes in the upper lid are more serious because of the tarsus.

With regard to dosage, permanent alterations are very rare with doses less than 45-50 Gy with conventional fractionation. In Helium therapy 70% of the tumour dose is given to the eyelid (35-56 Gy) and almost always produces the acute changes [2].

3. Lacrimal Apparatus

Tears are composed of secretions from the following glands: Major lachrymal gland, close to the ocular globe, in the upper outer quadrant of the orbit; Accessory lachrymal glands of

Krause: conjunctival fornices (superior mainly); Accessory lachrymal glands of Wolfring: superior aspect of the tarsal plate; Sebaceous Meibomio glands: in both eyelids, mainly in the superior; Accessory sebaceous glands of Moll and Zeiss, near the eyelid margin, and Goblet Cells mucinous; scattered throughout the conjunctiva.

The tear film consist of three layers: Superficial lipid: from Meibomio and Zeiss; It helps to retard evaporation; Middle aqueous: From the accessory (Wolfring and Krause), and major, and Deep mucinous: to wet the relatively hydrophobic corneal and conjunctival epithelia.

Deficiency of any of the three components leads to a loss of the tear film stability and potentially may lead to the *Dry Eye Syndrome*. In this syndrome, patients develop a red scratchy eye, with foreign body sensation and photophobia. The situation may progress to corneal epithelial breakdown, ulceration with bacterial infection, neovascularization, opacification or perforation. Occasionally, phthisis bulbi (Shrinking of the globe) and symblepharon may be observed.

Most of the patients who develop severe dry eye syndrome, become severely symptomatic within 1 month after completion of irradiation, and corneal neovascularization and opacification are often pronounced within 9-10 months after the completion of the X-ray therapy. In the early stages visual acuity is only slightly impaired. If severe dry-eye syndrome develops, the vision deteriorates rapidly, and the entire eye becomes vulnerable to bacterial infection. The lachrymal gland and tissue have a radiation tolerance very similar to that of the salivary gland tissue. If the fractionated dose to the lachrymal glands and eye is in the range of 32-45 Gy slow changes occur over 4-8 yr, with 25% of patients loosing the eye [3]. Since most of the basal secretion of tears comes from the accessory lachrymal glands, which are most plentiful in the upper lid, efforts should be made to shield some of the upper lid, in addition to the major lachrymal gland (eye retractors).

Although additional information is needed, most patients appear to tolerate doses in the range of 30-40 Gy. Parsons recently did a review of the literature [4,5] and plotted the numbers with his own data form University of Florida, shaping a dose response curve: 0% doses <30 Gy; 20% to 40 Gy. Above 40 Gy there is a very steep shape in the curve (50% to 50 Gy; 100% to 57 Gy). There seems to be a lower incidence of these complications when twice a day fractionation (1.2 Gy twice daily) is used. This phenomenon also decreases side effects in salivary glands [6].

4. Nasolacrimal draining system

Doses in excess of 50 Gy to the nasal portion of the eyelids can, in theory, result in blockage of the nasolacrimal system resulting in epiphora, as a result of desquamation of the epithelium of the ducts, with the subsequent inflammation that may lead to fibrosis and stenosis. The literature is very scanty but some authors [7] have not seen any problems of that sort with doses below 60 Gy. This relative ability to preserve the ductal function is an argument in favour of X-ray therapy for patients with malignant lesions near or involving the tissues around the nasolacrimal duct and sac. It is important to remember that in some of these patients prior surgery may have altered the integrity of the nasolacrimal draining system.

4. Cornea

The cornea is the main refractive element of the eye; a decrease in the corneal clarity, in particular when it involves the central axis, results in diminished vision. Radiation induced changes (excluding those caused by a dry eye) do not depend on vascular damage, but only on disruption of the mitotic activity in the epithelial and connective tissue layers. There are five layers in the cornea: epithelium, Bowman's membrane, corneal storm, Descemet's membrane and endothelium. The anterior epithelium thins with X-ray therapy and may develop tiny ulcers (punctuate keratitis), after a dose of 30-50 Gy. Keratitis may happen by the end of treatment of right after, and lasts 4-6 weeks; patients do have anterior segment triad (increased blinking, lacrimation and photophobia). With appropriate ophthalmologic care usually the tiny ulcers do not coalesce, but it may happen, developing a corneal ulcer. With doses of 60 Gy the risk of corneal ulceration is 15-20%, but this number is increased when chemotherapy is added. Edema of the corneal stroma may appear after dose of 30-50 Gy, but it is transient, and subsides within a month, but with high doses 80 Gy, it may be permanent

A recent work present a clinicopathological correlation between corneal perforation and late radiation therapy-induced corneal necrosis in a male adolescent treated for orbital rhabdomyosarcoma[8].

5. Sclera

The sclera is relatively radioresistant. The main effects of X-ray therapy are related to episcleral plaques used for the treatment of coroidal melanoma. The effects are loss of episcleral vessels, scleral thinning and perforation. Treatment of the scleral thinning is aimed to restore or preserve the integrity of the globe. Loss of 50% of the scleral thickness may require a conjunctival graft to cover the defect [1].

6. Uvea

Irradiation of the iris and uveal structures to cancerous doses may lead to vascular changes such as neovascularization, rubeosis iridis and iridociclitis, resulting in an imbalance between aqueous production and absorption ending in glaucoma. Neovascular glaucoma may result in a rapid loss of vision; sever pain (nailing) and headache. It may progress to blindness.

7. Lens

The lens is a biconvex refractive structure located behind the pupil, 1-1.5 mm anterior to the fleshy cantus. Normal lens epithelial cell lie beneath the anterior capsule and equator only. The germinal layer is located at the equator and is the most sensitive layer to radiation, because these are the cells that have active proliferation, as opposed to the anterior epithelial cells that seldom divide). Radiation damage to the germinative zone of the lens epithelial cell DNA is probably responsible for most post-treatment cataracts. In addition to DNA damage, direct cytoplasmic effects, such as disruption of membrane channels protein cross-linking, and ion pump abnormalities are also important in the post radiation cataract progression. Abnormal epithelial cells, termed Wedl cells, migrate posteriorly and form a posterior subcapsular opacity (due to retaining their nuclear detrie). Older patients may develop cataracts sooner because possible pre-existing DNA damage. The proportion of cell damage necessary to cause a cataract is unknown. In Helium treated patients, exposure of less than 25% of the lens in the field can cause cataract.

In general the latency and frequency of lens opacities are a function of radiation dose. In most human studies, fractionated doses less than 5 Gy have not produced visually significant lens opacities. Does of 3 Gy/1 fraction may cause cataract. With fractionated X-ray therapy (1.5-2.0 Gy/fraction) to a dose of 12-14 Gy (fractionated total body irradiation) the risk is 10%. Due to the technical difficulties associated with electron attenuation, some authors have postulated the use of ortovoltage instead of electrons for patients with cutaneous tumours near of the ocular zone. Although paradoxically, there are very recent works that describe preservation techniques of the crystalline lens in patients with retinobastoma, based on electrons treatment [9].

Cataracts in young children may cause significant ambyopia before surgery can be performed.

There is a second mechanism for cataracts but it is usually not in the therapeutic range. It is related to metabolic damage secondary to X-ray therapy-induced to the anterior epithelium (where all the lens nutrients pass throughout).

8. Retina

The neurosensorial retina consists of an extensive network of neural glial and vascular elements.
Radiation induced retinopathy presents a clinical picture similar to that seen in diabetic retinopathy. Retinal injury after high-dose radiation usually is not expressed clinically for 1.5-3.0 years after irradiation during which time visual acuity often remains normal. Some patients with radiation retinopathy develop vasoproliferation of the anterior surface of the iris, and into the angle of the eye (rubeosis iridis). Anterior segment neovascularization is postulated to have the same cause as posterior segment neovascularization, namely, a vasoproliferative factor [5]. Retinal ischemia and hypoxia result in the development of a diffusible vasoproliferative factor, which is presumed to lead to retinal and optic nerve head neovascularization. The findings in fundoscopic exam are: retinal ischemia, edema, microaneurysm formation, capillary dilatation, haemorrhage, cotton-wool spots, teleangiectasis and retinal or optic nerve head neovascularization.

Acute ultrastructural changes have been studied in Rats irradiated and whose eyes were enucleated 1h to 1 month following X-ray therapy (2-20 Gy X-rays, single dose). Acutely, rod photoreceptors (not Rod Givens) were the most sensitive retinal cells. The outer segments developed small membranous whorls 1 h after receiving 2 Gy. These membrane changes were dose dependent. Photoreceptor death occurred at doses over 10 Gy/1fraction. Retinal pigment epithelium cell damage, manifested by mitochondrial swelling, became apparent after doses over 5 Gy/1fraction. Retinal pigment epithelial cell death did not occur following doses of less than 20 Gy/1fraction. In contrast, the inner retinal neurons and vascular cells showed no ultrastructural changes within the time and doses tested. Repair (evidenced by a decrease in the number of whorls), was noted 1 week following XRT with small doses such as 2 Gy.

The University of Florida recently reported their experience on 64 patients (68 retinas) exposed to therapeutic irradiation by techniques that did not produce severe dry-eye complications. Radiation retinopathy was not seen at doses below 45 Gy but increased steadily in incidence at doses of 45 Gy and above, being very steep above 50 Gy. Between 45 and 55 Gy there was a strong dependency on the dose per fraction (>1.9 Gy) and patients who received chemotherapy. The lowest dose associated with retinopathy was 45 Gy in a diabetic

patient. Fraction sizes of 2.25 Gy or more may lead to earlier and more severe changes (at 45 Gy) [5].

Nakissa et al, reported data on patients who received different doses of X-ray therapy to the retina: All patients who received over 45 Gy to the posterior pole had recognizable changes, but most of these did not affect vision. Decreased visual acuity occurred only in patients receiving over 65 Gy. At 60 Gy 50% of the patients displayed some visual changes, and at 80 Gy 85-90% did [10].

Despite the use of 1.8-2.0 Gy/fractions, dose inhomogeneities can be considerable in orbital treatments (up to 20-25%). This can potentially lead to portions of the retina/globe receiving >2.4 Gy/day) despite the fact that much of the treatment volume receives <2 Gy/day) [11].

Panretinal laser photocoagulation is used to treat severely ischemia, irradiated eyes in an attempt to control neovascular glaucoma, although the precise indications and efficacy of this treatment are uncertain. The identification of a vasoproliferative factor may lead to pharmacological interventions

9. Optic Nerve

Radiation optic neuropathy is mainly a vascular ischemic phenomenon, caused by vascular occlusive disease. Patients with pre-existing small vessel disease are at increased risk for this complication. It presents as painless monocular loss of vision that is usually sudden, although it may follow transient episodes of blurring.

The dose per fraction is a very important determinant in the development of optic neuropathy. In stereotactic radiosurgery it has been proven that the tolerance of the optic nerve is unusually lower than that of the other cranial nerves [12]. A single dose of 7 Gy may lead to blindness. Nevertheless, the dose quoted by Cassady and Loeffler for tolerance of the optic nerve and chiasm is 8 Gy [13].

Several institutions have reported their experience in the case of fractionated radiotherapy; With doses below 50 Gy the only optic neuropathies reported are in patients with pituitary tumours (and probably some pre-existing damage to the optic tract), who have received dose per fraction of 2.25 Gy or higher, or chemotherapy. With doses above 60 Gy there is a steep increase in the incidence of optic neuropathy (at least 15-20% and upwards) [4,14].

10. Orbit

The orbit forms a bony cavity in the skull that houses the globe, extraocular muscles, intraorbital portion of the optic nerve and the orbital fat. Late effects of X-ray therapy on the bony orbit are seen primarily when external beam is applied to the growing facial bones of children, as in the treatment of retinoblastoma or rhabdomyosarcoma. Radiation arrests the bone growth of the orbit, leading to bony hypoplasia and atrophic soft tissue changes. The degree of hypoplasia appears to be inversely related to the patient age at the time of the treatment.

In a typical setting, the mid section of the face and involved orbit are hypoplastic. This is manifest by decreased vertical and horizontal orbital diameters, hypoplasia of the nasal bridge zeugmatic bone, and temporal fossa.

The tip of the nose and nasal alae grow normally, despite the flattened nasal bridge, leading to an increased nasal angle. The frontal bone also grows normally and it appears to be disproportionately prominent. Children older than 3 yr are less severely affected. Midfacial hypoplasia is slightly less common following megavoltage as compared with ortovoltage irradiation.

Fat atrophy and fibrosis may result in enophthalmos. Mucous membrane contracture may lead to forthshortening of the fornices and symblepharon formation. (30% after 60 Gy megavoltage irradiation). In cases of enucleation followed by irradiation, the anophthalmic socket is exacerbated; X-ray therapy induced atrophy and contraction of the soft tissues lead to further volume loss, poor prosthetic fitting, and in some cases complete obliteration of the fornices.

Secondary neoplasms

Children with heritable retinoblastoma secondary to a germline cell mutation, have cancer predisposition due the loss of retinoblastoma tumour suppressor gene in every cell in the body.

Tucker did a dose effect study for second tumours. The relative risk was 1.3 with less than 10 Gy; 12.7 between 10-40 Gy, and 19.4 after doses of more than 40 Gy [1]. These investigators did not found a difference in second tumour development when Ortovoltage or megavoltage were used, and chemotherapy (Cyclophosphamide) exerts an additive effect. New papers exist in the fact that patient with retinoblastoma that they received radiotherapy they didn't develop a second tumour [15,16].

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INFLUENCE OF DOSE PER FRACTION ON 7 DAYS PER WEEK FRACTIONATION IN RADIOTHERAPY

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Abstract

To evaluate the effect of the dose per fraction in a radiotherapy schedule of 7 fractions per week, and compare it with a conventional one of 5fr/w, 2Gy/fr, we use computer simulations methods taking into account the tumor proliferation. We have a significant increase of TCP with regard to te conventional schedule for 7 days per week programmes in which the dose per fraction is =1.7 Gy.

1. Introduction

In the radiotherapy of some tumors, like head and neck cancers, it is a fact that the overall treatment time has a great influence on the local control. Therefore, an increase in the prescribed treatment time produces a significant fall of the tumor control probability. The reason of this is to find in the malignant clonogens proliferation, which can be, in certain cases, very important in the final phase of the treatment, in which the doubling time reaches values of a few days [1,2]. Consequently, it is reasonable to conclude that a shortening of the duration of schedules can increase the effectiveness of the radiotherapy. This is the accelerated fractionation, which, in its pure version, consists in a shortening of the overall treatment time without reducing the fraction size or the total dose. This can be acomplished by delivering more than one daily fraction five days per week or one daily fraction six or seven days per week. However, the concept of accelerated fractionation has been extended to include other fractionated schedules like the continuous hyperfractionated accelerated radiotherapy (CHART), split-courses, concomitant boost and those in which the total dose delivered per week is progressively increased during the course of treatment [3].

The results of randomized clinical trials have been published for complex schedules [4,5], however, we do not have clinical results of more simple ones, like those in which the dose per week is progressively increased. Although the examinated schedules in references [4] and [5] show that the tumor clonogen proliferation is determinant in the therapy effectiveness, these schedules produce a high toxicity, what suggests the need of analyzing other ways of shortening the overall treatment time.

One of the most simple accelerated schedules which can be designed consists in a daily irradiation every day of the week. Using daily fraction of 2 Gy, the high incidence of severe acute reactions and consequential late effects suggests that this schedule gives an unacceptable toxicity [6]. Nevertheless, it is possible to shorten the treatment time decreasing the dose per fraction and maintaing the total dose and the seven days per week programme, for example, reducing from 2 to 1.8 Gy the dose per fraction, although results of this kind of schedule are not available yet [7].

The aim of this study is to evaluate the influence of dose per fraction in 7 days per week fractionated schedules. For that, we will use computer simulation methods based on Monte Carlo techniques.

2. Material and methods

To obtain realist results we will use, there where necessary, the data for multicellular tumor spheroids of the MCF-7 breast cancer which our group has studied for the last years [8].

We make the computer simulation of a fractionated treatment similar to the actual situation in which, after surgery of the tumor, the malignant clonogens cluster in microscopical aggregates before the treatment. Two thousand virtual tumors which contain between 5000 and 50000 clonogens are produced according to a uniform distribution, this implies tumors diameters between 0.5 and 1 mm. This sort of distribution is the best one to reproduce the experimental data obtained for the sizes of the MCF-7 spheroids. This number of tumors guarantees a correct statistical behaviour. The growth is introduced by the exponential model for different values of doubling time (T_D). For each dose per fraction we calculate the mean surviving fraction (SF) by the linear-quadratic model. Possible differences in the response of the tumor clonogens to the radiation for each tumor of the sample have to be considered. These differences can be due to the distinct locations, components and hypoxia in a true situation. In order to take into account this fact, we assign a value of SF to each one of the sample tumors normally distributed around the mean value, and with a standard deviation that implies maximum differences of 10% in relation to the mean. The irradiation programme is simulated by considering that the cell proliferation and cell death are described by binomial statistics. The probability of tumor cure is determined by counting the proportion of tumors containing no surviving clonogens at the end of treatment. In order to make the final analysis of the control data which the simulation provides, and to compare the different fractionated schedules, we will use the logistic model which, although it does not have biological base, fits well the data.

3. Results

Following the described method, we have analyzed a *conventional* schedule, 2 Gy daily irradiation from Monday to Friday, and 7 fractions per week with a daily irradiation between 1-2 Gy.

In all the simulations the parameters values used for the linear-quadratic model are the ones obtained through clonogenic assay for monolayer culture of the MCF-7 cell line, á = 0.32 Gy^{-1} and â = 0.023 Gy^{-2} [9].

The TCP results have been fitted by means of the logistic model. The smallest obtained value for the goodness of these fits is r^2=0.9996. In Figure 1 we can see some cases of the simulation results and their fits by the logistic model for a conventional and accelerated schedule, for T_D = 4 d and T_D = 15 d. The dose per fraction is 2 Gy in the four cases.

By using the fit results for given values of T_D an dose per fraction, we have calculated the TCP for an accelerated programme in which the total dose is the same to the one which produces a TCP = 0.5 according to a conventional schedule of 5 fraction per week of 2 Gy. Figure 2 shows the results of this calculation for several doubling time values and doses per fraction that are between 1 and 2 Gy. Here we represent the level of TCP = 0.5, in order that we can see immediately whether a given schedule of 7 fraction per week is more effective than the corresponding one to the same doubling time for conventional fractionation.

For doubling times between 4 to 30 days, and for the conditions in which the simulation has been carried out, we have a significant increase of TCP with regard to the conventional schedule for schedules of 7 days per week in which the dose per fraction is =1.7 Gy. For a dose per fraction of 1.7 Gy, the TCP increase in relation to TCP = 0.5 of the conventional programme is 2.94% for T_D = 15 d and 22.4% for T_D = 4 d; for a dose per fraction of 2 Gy the increase is 14.36% for T_D = 15 d and 53.48% for T_D = 4 d.

4. Discussion

In the simple case studied in this work, two factors contribute to the loss of tumor control when the dose per fraction is reduced: the first one is the increase of the overall treatment time and, as a result, it is related to the tumoral proliferation; the second one is a value of the â parameter in the linear-quadratic model greater than 0. This second factor produces that the TCP decreases in the 7 fractions per week, in relation to the conventional schedule, for a dose per fraction which in the first one gives rise to an overall treatment time equal to the second one. Thus, the total dose which produces a TCP = 0.5 for the conventional schedule is aprox. 40 Gy (we always suppose that the treatment starts on Mondays); to deliver this same dose in an identic time according to the 7 fractions per week schedule, we have to use a dose per fraction of 1.54 Gy which, if â is equal to 0, would also produce a TCP = 0.5, however, with the á and â values used in this work, the result for TCP is 0.46 (see Figure 2). In conclusion, a â parameter value greater than 0 produces a decrease of the effectiveness of the shortening in the overall treatment time in an accelerated schedule in which the dose per fraction is smaller than 2 Gy.

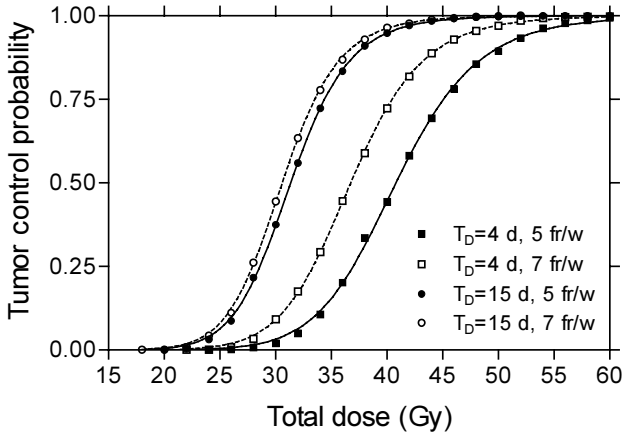

Figure 1: Comparison of TCP's obtained in seven and five fractions per week schedules for T_D equal to 4 and 15 days, such as indicated in the graph. The curves fits the data according to logistic model.

We wonder whether a model like the Poisson model is able to reproduce these results or, more generally, whether we have the need of employing simulation methods in order to estimate the effect of a therapeutic programme. In the case mentioned above, where TCP is 0.34, the predicted value by the Poisson model is 0.30. This result is not surprising because the Poisson model underestimates the cure capacity when proliferation occurs (see Tucker *et al.*[10]). As we see, the TCP variation is of 13%, but this is not the only limitation of Poisson model. The simulation methods, based on Monte Carlo thechniques, let us reproduce true situations where a great statistical variability of the more outstanding parameters is frequent, what cannot be done by means of simple analytical models.

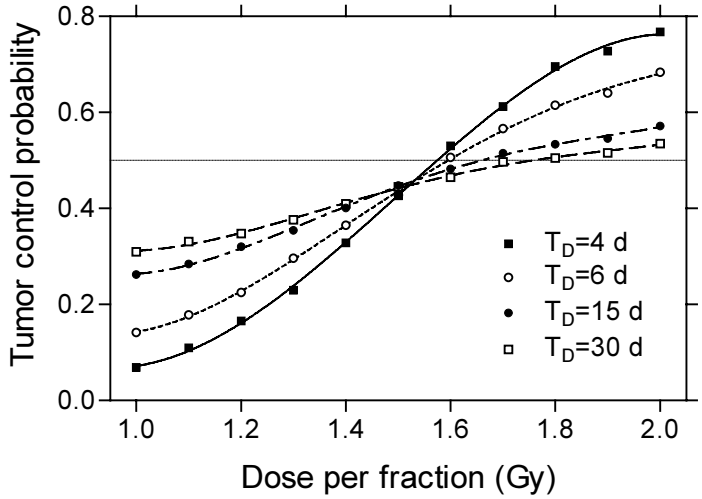

Figure 2: **For a given value of T_D, each point represents the TCP of an accelerated programme with a given dose per fraction if it is reached the same total dose which produces TCP = 0.5 for a conventional schedule, 5fr/w 2Gy/fr. The curves are obtained fitting a polynomial funtion of degree 4. Uncertainties correspond to one standard deviation and are smaller than the symbols which represent points.**

In summary, it is possible to obtain a therapeutical gain using accelerated schedules of 7 fractions per week with dose per fraction under 2 Gy, this can produce a reduction of the complications. Thus, making randomized clinical trials can be considered in order to compare these schedules to the conventional ones. On the other hand, and if we take into account the accelerated repopulation in some tumors like head and neck cancers, it is possible that the use of 7 fractions per week schedule only for the last weeks of treatment increases the tumor control rate. At the moment we are studying this with similar methods to the ones used in this preliminary work.

Acknowledgements

The valuable assistance of Mrs Carmen de Haro in preparation of the manuscript is gratefully acknowledged.

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IAEA-CN-85-46

PALLIATIVE RADIATION THERAPY FOR OVERLOADING RADIOTHERAPY CENTRE, ESPECIALLY FOR DEVELOPING COUNTRY

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Abstract

In developing country, most of the cancer cases are diagnosed in the advanced stages. So, the palliative radiation therapy is the only choice of therapy for these inoperable cases where the chemotherapy is not effective or affordable. In conventional radiation therapy, daily dose of 200 cGy for total 4000 cGy in more than 20 fractions (sometimes, up to 6000 cGy) is used. By using Linear-quadratic model theory of cell killing by radiation, it can be calculated early and late effects by using alpha and beta ratio. This theory is still the best for radiation cell killing until the new detail one is discovered. These data are obtained by experimental as well as clinical results. The effective radiation dose can be calculated by using the data to different organs which if involved in the radiation fields. This can change the daily dose to palliative cases in which the late effect is unnecessary. The daily doses can be 300, 400, 500, and sometimes 1000 cGy per single fraction. These modalities are well documented. It is recommend to change the short term high-dose palliative radiation therapy instead of using conventional palliative radiation therapy in overloading radiotherapy centre, especially for developing country. The reasons are mainly radiation protection aspect, not only for the patients and those who involved with the radiation therapy but also to reduce the unnecessary radiation exposure to the environment.

1. Introduction

Ideally, a teletherapy machine can usually treat about 40 patients a day, each patient taking about 15 minutes [1]. In the developing countries, very few teletherapy machines have to treat a large number of patients. For example, Myanmar has three radiotherapy centres and the largest is Yangon General Hospital (YGH). YGH has two functioning teletherapy machines, both cobalt 60 machines. Each machine must treat 120±20 patients a day, each patient taking less than 11 minutes. As principle, radiotherapy treatments are curative and palliative. Curative radiation treatment is 200 cGy per day for 6000 to 6600 cGy, conventionally. Sometimes, 7000 to 8000 cGy depends on the radiation field size and anatomical location [2]. Palliative radiation treatment is conventionally 200 cGy per day for 4000 cGy. The short term treatment, for example, contains 300 cGy for 10 fractions, 400 cGy for 5 fractions, 500 cGy for 4 fractions or sometime with preradiation medication 1000 cGy for single fraction especially in the pelvic area [3].

By using Linear-quadratic model theory of cell killing by radiation, it can be calculated early and late effects by using alpha and beta ratio [4]. This theory is still the best for radiation cell killing until the new detail one is discovered. These data are obtained by experimental as well as clinical results [5]. The effective radiation dose can be calculated by using the data to different organs which if involved in the radiation fields. This can change the daily dose to palliative cases in which the late effect is unnecessary.

2. Method

Linear-quadratic model theory of radiation cell killing composes surviving fraction radiation dose are related linearly and quadratically [4].

$S = e\ (-aD - bD^2)$

In this equation, S is the fraction of cells surviving a dose D, and a and b are constants.

$aD = bD^2$, or $D = a/b$

There are two components of cell killing: one is proportional to dose (aD), while the other is proportional to the square of the dose (bD^2). The dose at which the linear and quadratic components are equal is the ratio a/b.

The deriving formula is biological effective dose (BED).

BED = D (1+d/(α/b)) dose in Gy.

D is total dose and number of fractions(n) multiples to daily dose (d).

D = nd

Alpha-beta ratio is roughly 10 for acute reaction tissue and tumour tissue, 3 for late responding tissue. The detail data varies with different experiments, different organs and clinical observations. By using this formula, BED is calculated for short term palliation for pelvic diseases. The results are as follow.

3. Results

By using BED formula and alpha-beta ration the following doses obtained,

BED = 40 (1+2/10) = 48 Gy
BED = 30 (1+3/10) = 39 Gy
BED = 20 (1+4/10) = 28 Gy
BED = 20 (1+5/10) = 30 Gy
BED = 10 (1+10/10) = 20 Gy

If 40 Gy with 2 Gy per fraction the BED = 48 Gy is normalised, the total fractions for 3 Gy per fraction with BED 48 Gy can be calculated as following;

D =BED/ (1+d/10) = 48/(1+3/10) = 36.9 Gy, approximately 12 fractions
For 4 Gy per fraction;
D =BED/ (1+d/10) = 48/(1+4/10) = 34.2 Gy, approximately 8 fractions
For 5 Gy per fraction;
D =BED/ (1+d/10) = 48/(1+5/10) = 32 Gy, approximately 6 fractions
For 10 Gy per fraction;,
D =BED/ (1+d/10) = 48/(1+10/10) = 24 Gy, approximately 2 fractions

4. Discussions

By using the linear-quadratic model and BED equation, the total fractions are higher than the conventional fractions. To get the effective palliative to the patients by daily high dose fractionation, it should give more fractions than the conventional fractions with same dose per fraction. On the other hand, the field size, the field site and organs at risk, and interval

between fractions are very important factors to be considered for short term palliative radiation. To give short term high-dose palliative radiation therapy, radiation oncologist should consider not only biological effective dose based on linear-quadratic model but also his cleaver clinical judgement.

5. Conclusion

It is recommend to change the short term high-dose palliative radiation therapy instead of using conventional palliative radiation therapy in overloading radiotherapy centre, especially for developing country. The reasons are mainly radiation protection aspect, not only for the patients and those who involved with the radiation therapy but also to reduce the unnecessary radiation exposure to the environment.

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DOSE DISTRIBUTION OVER THE RADIATION FIELD AND ORGANS OF THE BODY DURING RADIOTHERAPY PROCEDURES

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Abstract

Beam profile of the ^{60}Co teletherapy unit for 10 cm X 10 cm along central axis was measured to study the symmetry of the gamma beam and found that the average dose was 98.44±1.40 mGy. Output dose versus field size was also measured and values were found reasonable. Dose prescription to delivery was measured by placing TLD onto the treatment field for lung and cervix cancer patient which was found to be 39.16±2.98 Gy and 50.48± 3.68 Gy respectively which are within 2 % and 0.17 % of the prescribed dose as 40.00 and 50.40 Gy respectively, reveals good agreement with the treatment planning. Six typical types of patients both male and female with cancers in lung, larynx, breast, cervix, oesophagus and brain treated with ^{60}Co teletherapy were particularly considered for dose assessment at different critical organs of interest. It was observed that the doses to the lens of eye with a maximum value of 460.35+78.87 mGy for a larynx cancer patient to a minimum value of 30.80+4.00 mGy of a cervix cancer patient. Doses to the gonad vary with a maximum value of 3810.80+389.76 mGy for a cervix cancer patient to a minimum value of 8.20+1.00 mGy for a brain cancer patient.

1. Introduction

Ionizing radiation is being used worldwide as essential tools for protecting and improving human health. It is estimated that medical applications of radiation account for about 95% of the exposure to radiation from man-made sources (as reported by UNSEAR). The objective of radiotherapy is to ensure that the target tissue is given the prescribed dose keeping minimum dose to surrounding health tissue. The success or failure of radiotherapy depends upon the accuracy of radiation dose to tumour volume. Radiation dose requires dose optimization to the tumour, as it should not vary within 5% of the prescribed dose. The significant variation in dose, dose distribution or dose fractionation, serious consequences can arise. Applying the well-designed quality assurance programme are necessary in order to ensure the protection of patients. About 60% of all cancer patients will require radiation therapy during some phases of their cancer care. Dose uniformity within the tumour volume and sparing of risk organs are important considerations in judging a treatment plan. The undue radiation to the organs may be one of the reasons for secondary metastasis for long-lived survivors [1].

In this paper, some parameters of quality assurance programme were carried out and radiation dose to the critical organs during the radiotherapy procedures was measured by thermoluminescent dosimeter (TLD). An ALCYON II cobalt-60 teletherapy unit (CGR, MeV, France) of activity 223.6 TBq (09 June 1994) has been installed at the Delta Medical Centre Limited, Dhaka, Bangladesh in August 1994.

2. Material and methods

A phantom made of plexiglass having the dimension of 30 cm × 30 cm × 30 cm have been fabricated by using 0.5 cm thick plexiglass sheet. Beam profile was measured along the axis of the field size 10 cm x cm. Field size, SSD, isocentre were checked before each measurement. Out put dose for different field size were also studied. Lithium Fluoride crystal

in the form of chips (TLD-100) were used as TL dosimeters in this study and those were made grouping and ready for experiment by using TLDSHELL software.

3. Results and discussion

Dose distribution i.e. beam profile of 10 cm X 10 cm field size were measured along the axis of the field at dmax and dose data are presented in the Table 1 with the value of 98.44±1.40 mGy. Dose dependence on field size was measured for 5 X 5 ... and shown in Table 2. An equation obtained by using Excel 97 and the equation is $Y = 27.377\ln(X) + 100.58$ with $R^2 = 0.8452$.

Table 1. Beam Profile along the axis of radiation filed of 10 cm × 10 cm

Distance in cm	Dose (mGy)
-10	1.78
-8	3.38
-6	39.59
-4	96.41
-2	99.52
0	99.19
2	98.63
4	68.35
6	37.82
8	3.17
10	1.11

Table 2. Dose variation with field size

Field Size (cm X cm)	Dose (mGy)
5 X 5	151.57±19.91
10 X 10	154.77±7.61
15 X 15	168.30±8.131
20 X 20	183.63±10.98
25 X 25	196.00±4.44

Organ dose was determined under typical treatment procedures and the dose data are shown in Table 3. It is observed from the Table 3 that the prescribed dose for lung and cervix cancer were 40.00 Gy and 50.40 Gy respectively and the dose measured onto the treatment field area were 39.16±2.98 Gy and 50.48± 3.68 Gy respectively which are within 2 % and 0.17 % of the prescribed dose. These indicate that the study reveals an excellent agreement with the “dose prescription to delivery”.

For laryngeal cancer treatment, the lens of eye receives 0.46±0.079 Gy which is comparable with the dose received by the lens of eye are 639+8, 568+8 and 533+7 mGy as reported by F. K. Miah et al. [2] For the typical brain cancer radiotherapy, gonadal dose found to be 8.2+1.0 mGy considering 45 Gy tumour dose to the brain. M. Mazonakis et. al, [3] determined the conceptus dose during radiotherapy using anthropomorphic phantom delivering 65 Gy to the tumour without using shielding equipment to the conceptus region and dose found to be 17.0, 21.7 and 28.3 mGy at 4, 12, 24 weeks of gestation respectively. It is, therefore, essential to put

necessary shielding to the critical organs, especially gonad during radiotherapy to reduce the potential risk due to the scattered photon.

Table 3. Dose distribution (Gy) over various organs of the patients during typical treatment procedures with the ^{60}Co teletherapy

Cancer site & Sex	Lens of Eye	Neck	Chest	Abdomen	Right Arm	Left Arm	Right Leg	Left Leg	Gonad
Lung (Male)	0.14 ± 0.03	1.04 ± 0.13	39.16 ± 2.98	0.13 ± 0.004	0.20 ± 0.014	0.16 ± 0.03	0.005 ± 0.0005	0.005 ± 0.0002	0.022 ± 0.002
Larynx (Male)	0.46 ± 0.08	3.99 ± 1.28	0.19 ± 0.013	0.043 ± 0.003	0.074 ± 0.005	0.083 ± 0.012	0.011 ± 0.0007	0.012 ± 0.0007	0.023 ± 0.002
Breast (Female)	0.21 ± 0.03	1.99 ± 0.32	6.30 ± 1.70	0.28 ± 0.05	0.15 ± 0.021	0.61 ± 0.02	0.02 ± 0.002	0.016 ± 0.001	0.10 ± 0.008
Cervix (Female)	0.031 ± 0.004	0.088 ± 0.006	0.26 ± 0.024	50.48 ± 3.68	0.44 ± 0.03	0.44 ± 0.041	0.10 ± 0.004	0.15 ± 0.018	3.82 ± 0.39
Oesophagus (Female)	0.02 ± 0.035	2.55 ± 0.72	35.54 ± 2.15	0.52 ± 0.027	0.27 ± 0.035	0.15 ± 0.014	0.007 ± 0.0004	0.008 ± 0.0008	0.009 ± 0.0008
Brain (Male)	0.44 ± 0.06	0.23 ± 0.021	0.04 ± 0.004	0.02 ± 0.0002	0.018 ± 0.0016	0.013 ± 0.001	0.005 ± 0.0004	0.0046 ± 0.0002	0.008 ± 0.0001

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IAEA-CN-85-97

PERIPHERAL DOSE IN PHOTON BEAMS FROM A LINEAR ACCELERATOR WITH A MULTILEAF COLLIMATOR

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Abstract

Radiation doses outside the radiotherapy treatment field are of radiation protection interest when anatomical structures with very low dose tolerances might be involved. One of the major sources of peripheral dose, scatter from secondary collimators, depends on the configuration of the collimator. In this study, peripheral dose was measured at two depths for 6 and 18 MV photons from a linac Primus (Siemens) with a multileaf collimator (MLC). Comparative measurements were made both with leaves and with the upper jaw positioned at the field edge near to the detector. Configuring the MLC leaves at the field edge yielded a reduction in peripheral dose.

1. Introducción

Al realizar un tratamiento radioterápico con haces de fotones, a veces se plantea la necesidad de estimar la dosis que puede llegar a los órganos críticos del cuerpo no contenidos dentro del haz directo. La dosis en zonas fuera del haz primario, conocida como dosis periférica, se debe principalmente a la radiación de fuga, la dispersada por el colimador y modificadores del haz y a la dispersada por el propio paciente. Las dos primeras dependen de cada unidad de radioterapia mientras que la última se puede estimar de modo general en función de la energía de los fotones [1].

Con el fin de reducir la dosis periférica en órganos críticos con una determinada unidad se puede intentar modificar la técnica de tratamiento o bien tratando al paciente de modo que sea el colimador inferior el que defina el borde del campo más cercano al órgano crítico [2].

En este estudio, se presentan los resultados de las estimaciones de la dosis periférica originada en un acelerador lineal con un colimador multiláminas, para dos energías de haces de RX.

2. Material y método

Las medidas de dosis periférica se han hecho con un acelerador Mevatron Primus (Siemens) dotado de un colimador multiláminas (MLC). En este colimador, cuando el ángulo de giro del mismo es de 0ª, la dimensión X del campo viene definida por las láminas y la dimensión Y por dos mandíbulas situadas por encima de las láminas. El acelerador dispone de energías de RX de 6 y 18 MV.

Las medidas relativas de dosis se hicieron con un conjunto de 12 diodos Isorad, situados en un maniquí de agua sólida, y conectados a un electrómetro Multidos (PTW). Para colocarlos dentro del maniquí de agua sólida, previamente se colocaron en sandwich dentro de unas capas de Geliperm (Geistlich).

Los diodos se colocaron a distintas distancias del eje central, que correspondían a distancias desde el borde del haz comprendidas entre 2 y 40 cm. Las medidas se realizaron para cada

energía, para tres tamaños de campo (5 x 5,15 x 15 y 25 x 25 cm^2) y a profundidades de 5 y 10 cm. La distancia fuente –plano de colocación de los diodos fue de 100 cm.

Las medidas se hicieron en primer lugar con el colimador a 0º y luego, sin mover los diodos, se repitieron con el colimador a 90º, con el fin de determinar la dosis periférica cuando eran las multiláminas las que definían el borde del campo situado más próximo al punto de medida y cuando este borde era definido por una de las mandíbulas superiores.

Posteriormente, las dosis periféricas se estimaron como porcentaje respecto a la dosis en el eje central, teniendo en cuenta el factor de calibración de cada diodo.

3. Resultados y discusión

En las figuras 1 a 4 se muestran los resultados de dosis periféricas calculados a partir de las medidas de los diodos, con el colimador a 0º, es decir, con el borde del haz más cercano a los diodos definido por las multiláminas. Se observa que la dosis periférica:

- Aumenta con el tamaño de campo, como era de prever.
- A distancias pequeñas del borde del haz disminuye al crecer la energía a las profundidades seleccionadas. La diferencia encontrada entre las dos energías fue siempre inferior a un 3 % respecto a la dosis en el eje del haz.
- Para cada energía, es mayor a profundidad 10 cm que a 5 cm., siendo este aumento mayor en el caso del haz de 6 MV . La diferencia mayor encontrada entre las dos profundidades fue del orden de 2 % respecto a la dosis en el eje del haz.

Este comportamiento general concuerda con los obtenidos por otros autores [3]. A distancias pequeñas del borde del campo, la mayor contribución a la dosis periférica se debe a la radiación dispersada por el maniquí. Esta contribución aumenta al crecer la profundidad.
Lo mismo ocurre con la dosis periférica medida con el colimador girado 90ª, es decir, con el borde del haz más cercano a los diodos definido por una de las mandíbulas superiores.

Comparando los resultados obtenidos en los casos estudiados de colimador a 0º y 90º, hemos observado que, en todos ellos, la dosis periférica es mayor con el colimador a 90º, siendo esto más notable en el caso del haz de 18 MV. La diferencia obtenida es pequeña en ambos casos (siempre inferior a 1 % respecto a la dosis en el eje del haz). Así pues, la radiación dispersa que llega a los diodos procedente del colimador es siempre menor en el caso del colimador a 0º.

Como ejemplo, en las figuras 5 y 6 se muestran, para cada una de las energías y el mayor tamaño de campo estudiado, los resultados obtenidos con el colimador en cada una de las posiciones y para la profundidad de 10 cm.

Un estudio similar realizado para un haz de 6 MV en un acelerador Mevatron KD2 (Siemens) dotado de un colimador con cuatro mandíbulas, muestra diferencias inferiores entre las dosis periféricas para las dos orientaciones del colimador que las determinadas en el acelerador estudiado en este trabajo[4].

Las dosis periféricas medidas con el acelerador estudiado son inferiores a las publicadas por otros autores [3] para otro acelerador dotado de un colimador multiláminas pero con mandíbulas en las direcciones X e Y.

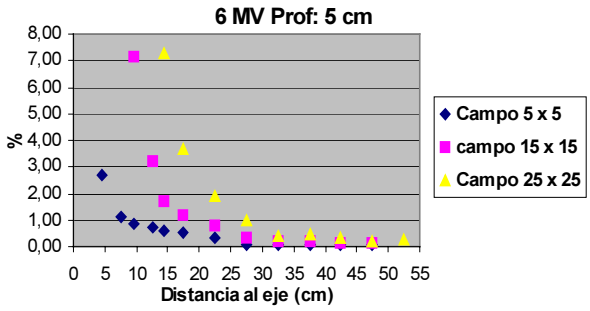

Figura 1
Dosis periférica (% respecto a dosis en el eje del haz). Haz de 6 MV. Profundidad 5 cm.
Borde del haz más próximo a los diodos definido por las láminas.

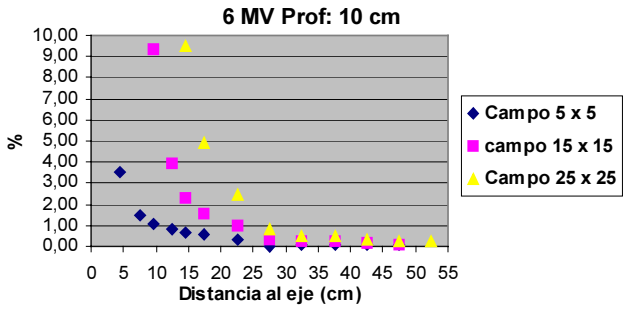

Figura 2
Dosis periférica (% respecto a dosis en el eje del haz). Haz de 6 MV. Profundidad 10 cm.
Borde del haz más próximo a los diodos definido por las láminas.

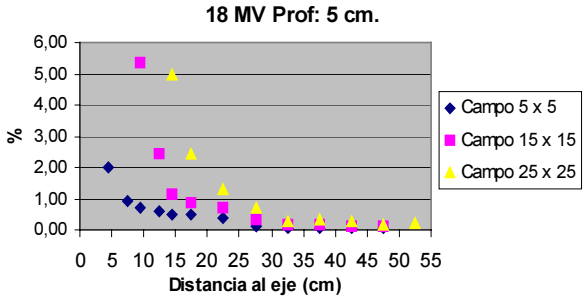

Figura 3
Dosis periférica (% respecto a dosis en el eje del haz). Haz de 18 MV. Profundidad 5 cm.
Borde del haz más próximo a los diodos definido por las láminas.

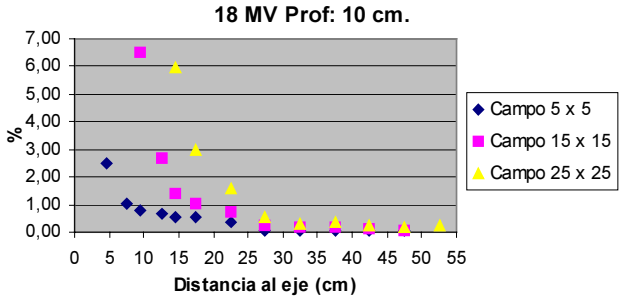

Figura 4
Dosis periférica (% respecto a dosis en el eje del haz). Haz de 18 MV. Profundidad 10 cm.
Borde del haz más próximo a los diodos definido por las láminas.

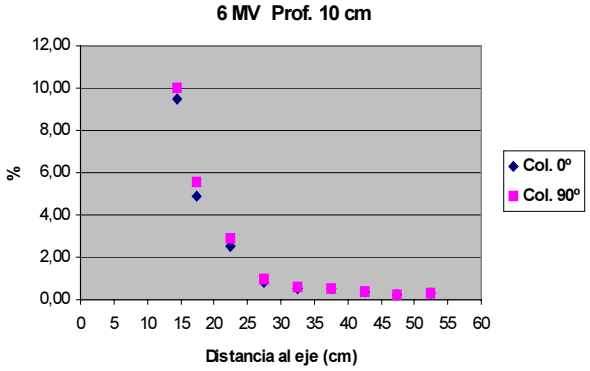

Figura 5
Dosis periférica. Haz de 6 MV. Campo 25x25 cm^2. Profundidad 10 cm. Borde del haz más próximo a los diodos definido por **las multiláminas (Col.0º) y por la mandíbula superior (Col.90º).**

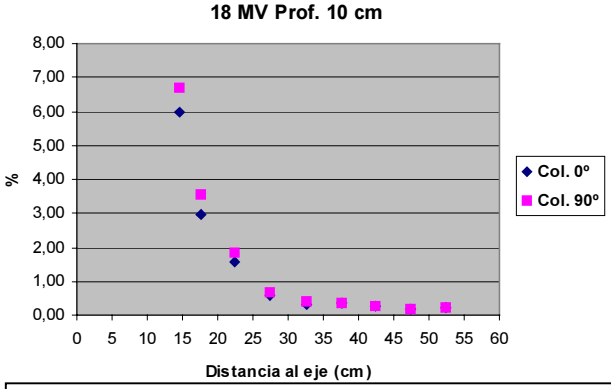

Figura 6
Dosis periférica. Haz de 18 MV. Campo 25x25 cm^2. Profundidad 10 cm. Borde del haz más próximo a los diodos definido por **las multiláminas (Col.0º) y por la mandíbula superior (Col.90º).**

Como aplicación de los resultados obtenidos, en el supuesto de un tratamiento efectuado con un haz de RX de 18 MV y un tamaño de campo de 25 x 25 cm^2, con una dosis de 50 Gy en el eje del haz y a 10 cm de profundidad, la dosis en un órgano situado a la misma profundidad y a 2 cm de distancia del borde del haz sería de un 6 % (borde del campo definido por las multiláminas) frente a un 6.7 % (borde del campo definido por la mordaza superior en función del giro del colimador (0º/90º). Esto supondría una diferencia de dosis de 0.7 %, es decir 35 cGy.

4. Conclusión

En el acelerador estudiado, para disminuir la dosis periférica en aquellos órganos en que la dosis pueda ser clínicamente significativa, es preferible colocar el ángulo del colimador de modo que sean las multiláminas las que definan el borde del haz más cercano al órgano crítico.

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IAEA-CN-85-251

PATIENT DOSE FROM PHOTONEUTRONS IN A 18 MV LINAC

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Abstract

We have estimated by measurements and Monte Carlo simulations, the photoneutron dose equivalent to patients in a Siemens KD-S radiotherapy accelerator operating at 18 MV. The beam was collimated to 40 cm x 40 cm and angles of 0º and 180º for the rotating gantry where considered. The measurements were made with pairs of TLD600-TLD700 thermoluminescent dosemeter chips inside a 25 cm diameter moderating sphere. The calibration of the instrument was performed in a bare Am-Be neutron source. On the other hand the Monte Carlo simulations of the fluence and energy spectra were made by using a simplified model for the neutron source and taking into account neutron scattering from the concrete walls surrounding the room. The agreement between the two approximations was good with a resulting dose to patient of 0.6 mSv per treatment Gy that fits well to reported values in the literature.

1. Introduction

In electron linear accelerators operating at high energies neutrons are produced as a consequence of photonuclear reactions in the target, field-flattening filters and beam collimators. These neutrons deliver an unwanted extra dose to patients, a fact constituting a very active research topic from the 1970's [1,2] which is of special relevance in the case of pregnant patients [3]. Experimental techniques to quantify the neutron dose to patients are limited by many reasons. For example pulse counters are discarded because dead time and pile up effects in the very intense and pulsed radiation field of a linac. On the other hand the high gamma intensity of the therapy beam makes it difficult to extract the relatively small neutron component if detectors sensitive to both radiations are used. Passive neutron activation [4], thermoluminescent TLD [5,6] and superheated drop detectors [7], which have not the pulse counters disadvantages, have been used to measure quantities wich are more or less closely related to the relevant dose equivalent depending on the particular technique.

Monte Carlo simulations can alternatively evaluate the transport of neutrons in the different components of the accelerator and through the room. What has to be calculated is a formidable task with an enormous neutron producing gamma and inversely gamma producing neutrons reactions all of them necesary in principle to correctly describe the resulting mixed neutron-gamma field. However it is much more frecuent to make some simplifications on the neutron source in addition to approximations of the detailed geometry and to neglect nuclear reactions that contribute less to the dose equivalent. In the simulations one obtains the neutron fluence and energy spectra and after that by using the appropriate conversion factor the neutron dose equivalent is estimated.

Some authors [5,6] have obtained the dose equivalent around linacs from the neutron spectrum measured by means of a Bonner spectrometer with TLD´s [8,9]. This system consists of a bare detector and six polyethylene moderating spheres with diameters varying between 5 and 30 cm. Differently, in this work we report on results of TLD dosemeters but only inside a special sized sphere 25 cm diameter whose response versus neutron energy fits the quality factor behaviour [8,9] for the energy range of interest. The results of the

measurements are compared with MonteCarlo calculations in which the source is assumed to be punctual and surrounded by a shielding sphere.

2. Materials and methods

Thermoluminescent LiF:Mg,Ti chips of 3x3x1 mm are located in the paraffine sphere center inside a methacrylate cylindrical box that contains four TLD600 and four TLD700. The responses of the TLD600 are associated to gamma and neutron radiations whereas the corresponding to TLD700 only have gamma contribution. An identical gamma response of TLD600 and TLD700 will be assumed so the neutron contribution follows as a simple sustraction between the responses of the two types of dosemeters. The readout apparatus was a Victoreen 2800M model, and the lectures were obtained in a two steps way, a heating during ten seconds at 160 ºC followed by another ten seconds at 300ºC and taking the intensity emitted in the second time interval. The neutron contribution to the TLD600 reading is converted to dose equivalent by means of a calibration in an Am-Be isotopic neutron source. For this task we proceed to measure the neutron dose equivalent at different distances from the 3Ci bare source (50, 60, 70, 80 and 100 cm) with a scintillation pulse counter LiI (Eu) inside a 30 cm diameter poliethylene sphere [8]. At the same points our TLD-sphere system is irradiated and the neutron contribution of TLD600 is correlated to the LiI (Eu) remmeter response [9]. Then the correlation factor obtained in this way is assumed to be valid for the neutron field existing around the linac. For the irradiations in the accelerator two positions of the rotating gantry where chosen at angles 0º (anteroposterior AP) and 180º (posteroanterior PA) with a field size of 40 * 40 cm delivering 12.5 Gy at the isocenter ic.
The version 4B of the MCNP [10] code was used for the Montecarlo simulations. As the input we have considered an isotropic punctual neutron source with a maxwellian evaporation spectrum

$$p(E) = \frac{E}{T^2} * \exp(-\frac{E}{T}) \qquad (1)$$

and a temperature T = 0.5 MeV corresponding to photoneutron production in the tungsten material of the target. This source is surrounded by a shielding tungsten sphere 10 cm radius as if collimators where closed. The room walls are described as paralelepipedic concrete 2.3 g/cm^3 density with a mass percent composition of 17% hidrogen, 56% oxigen, 20% silicon and smaller proportions of Al, Ca, Mg, K, Fe and C. A number of 50000 neutrons in 12 energy groups, from [0, 4E-7] to [5, 7] MeV are transported up to ring detectors at the experimental positions or up to a punctual detector for the point in the beam. Prompt gamma rays produced in capture reactions were neglected. Since MCNP calculated fluence is normalized per neutron source, it is the neutron yield Q in the accelerator head that is required. We obtain Q in a semiempirical way, by assuming that the thermal fluence Φ_{th} is uniform and proportional to the source strength [11]. The proportionality constant is obtained from the MCNP normalized thermal fluence. Then by an independent measure of the thermal fluence Φ_{th} in the room (with bare and Cadmium shielded TLD) a neutron yield of 2.6 ** 10^{11} neutrons per treatment Gy is obtained, the value of Φ_{th} being 8.1 ** 10^5 n/cm^2 Gy.
The dose equivalent h results multiplying the group fluences Φ_i by the conversion factors $FCONV_i$ in ref. [12] as follows

$$h = \sum_{i=1}^{12} FCONV_i * \Phi_i . \qquad (2)$$

3. Results

The investigated region near the beam is shown in Fig.1, where for completeness a sketch of the accelerator room is also given. The points labelled A, B, C and D are in the patient plane at respectively 30, 25, 25 and 80 cm from the isocenter ic and correspond to AP gantry position. In the measurements the center of the sphere is at those distances whereas in the calculations ring detectors around ic are used. Those same points in the patient plane are calculated for PA gantry position. The point ic is just in the beam center and the points labelled from E to J are in the electron gun plane at distances from ic appearing in Table I bellow. In the last case ring detectors around the source where used to calculate neutron fluence. The point K located at 125 cm from ic is where the thermal fluence Φ_{th} was measured to obtain Q as indicated above.

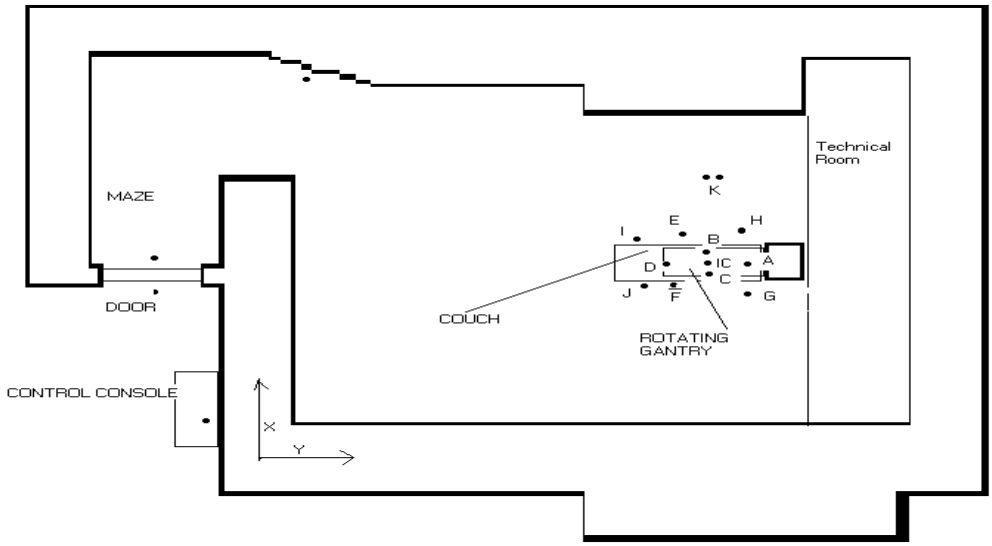

Fig.1 Sketch of the acelerator room with the studied points

The Table below shows the experimental and calculated results in miliSievert per treatment Gray. The calculated values for the points A to D corresponding to patient PA coincide with the values for patient AP and are not given in that Table. This is not extraneous because the room is rather symmetrical and the variation of distances to ceiling and floor does not affect at all. The point ic in the beam is calculated but it is not measured because the strong gamma content of our TLD dosemeters that makes it impossible to induce any value for neutron dose. The mean average among the points located out of the beam is 0.55 mSv/Gy with standard deviations of 40% and 20% for respectively the measured and calculated values.

Our resulting dose equivalent is inside the range of values reported in the literature [4,7] although some differences exist among different accelerator models. The thermal neutron dose represents only a small contribution two orders of magnitude smaller than the total dose. The experimental method we have used here has limitations to measure neutron doses very near to the beam and then as we have shown the Monte Carlo simulations could help in evaluation of doses for those points of interest. Finally we want to note that neutron dose reduction studies by adequate shields for fetus protection, whose importance has been stressed in refs. [3,7] can be accomplished with the methods used in this work.

Plane and position	Point, cm from ic	Measured dose mSv/Gy	Simulated dose mSv/Gy
Patient AP	A 30 B 25 C 25 D 80	0.35 0.86 0.64 0.34	0.60 0.61 0.61 0.44
Patient PA	ic 0		0.63
Electron gun PA	E 104 F 125 G 131 H 131 I 160 J 82	0.44 0.51 0.36 0.69 0.66 0.55	0.62 0.45 0.42 0.42 0.30 0.95

Acknowledgements

We are indebted to Departamento de Ingeniería Nuclear de la ETSII de Madrid, Servicio de Radiofísica y Protección Radiológica del Hospital Universitario Rio Hortega de Valladolid and Servicio de Radioterapia del Hospital Universitario de Valladolid for his valuable support in the calibration of the remmeter, the TLD readings and the irradiations in the linac.

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SHIELDING FOR RADIATION SCATTERED DOSE DISTRIBUTION TO THE OUTSIDE FIELDS IN PATIENTS TREATED WITH HIGH ENERGY RADIOTHERAPY BEAMS

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Abstract

Scattered dose of therapeutic high energy radiation beams are contributed significan t unwanted dose to the patient. Measurement of radiation scattered dose outside fields and critical organs, like fetus position and testicle region, from chest or pelvic irradiation by large field of high energy radiation beam was performed using an ionization chamber and film dosimetry. The scattered doses outside field were measured 5 - 10% of maximum doses in fields and exponentially decrease from field margins. The scattered photon dose received the uterus from thorax field irradiation was measured about 1mGy/Gy of photon treatment dose Shielding construction to reduce this scattered dose was investigated using lead sheet and blocks About 6 cm lead block shield reduced the scatter photon dose under 10mGy for 60Gy on abdomen field and reduced almost electron contamination.

1. Introduction

High energy photon beams from medical linear accelerators produce large scattered radiation by various components of the treatment head, collimator and walls or objects in the treatment room including the patient. These scattered radiation do not provide therapeutic dose and are considered a hazard from the radiation safety perspective. The scattered photon dose received the fetus from thorax field irradiation was measured about 1mGy/Gy of photon treatment dose and typical therapeutic doses of photon radiation lie in the range 40 -70Gy. Thus, without additional shielding, the scattered photon dose received by the fetus might be several hundred mGy. Under conditions of occupational radiation exposure of pregnant women, the NCRP advises that the fetus be regarded as a separate entity distinct from the woman bearing it and that the total dose equivalent limit for the fetus be 5 mSv and no greater than 0.5 mSv in any given month. Similarly the ICRP recommends a dose equivalent limit of 2 mSv once the pregnancy is known. These advisory bodies emphasize that medical exposures are excluded from these occupational exposure dose limits. In addressing medical exposures of benefit to the mother, ICRP take the position that irradiation of the pregnant woman is to be avoided. However it does recognize that there may be exception circumstances in the treatment of a life threatening malignancy of the mother in which therapeutic irradiation is the method of treatment that carries the lowest detrimental risk to the patient and fetus. In such cases it is emphasized by the ICRP that treatment should be planned in a way that minimizes the dose to the fetus by use of all relevant measures including shielding.

There are no internationally recognized guidelines for limiting the dose to the fetus during radiation treatment of the mother for malignancy. However it is known that a dose of 500mGy may cause abortion at any stage of pregnancy and that radiation detriment to the fetus includes risk of mental retardation with a possible threshold in the dose response relationship around 100 mGy for the gestational period of maximum vulnerability

Hammer Jacobson made the controversial recommendation that an abortion be performed whenever an embryo has received a dose above 100mGy during the first 6 weeks following conception to avoid the risk of producing an anomalous child. Irradiation of a fetus also carries the increased risk of childhood cancer and fatal cancer and fatal cancer later in life.

Risk estimates for childhood cancer induction vary but may be as high as 10^{-3} per mSv to the fetus.

The ICRP principle of as low as reasonably achievable (ALARA) was recommended for protection of occupation upon the linear no-threshold dose response hypothesis for cancer induction. We suggest this ALARA principle be applied to the fetus in therapeutic treatment of the mother. Applications of the principle will in many instances reduce the total dose equivalent to the fetus below dose thresholds for nonstochastic radiation effects. Thus effective shielding of the fetus must be introduced when ever possible. In the specific instance considered in this article of a therapeutic high energy photon beam treatment of the mother shielding should be designed to reduce the scattered photon to the normal organs. Radiation dose outside a photon treatment filed is mostly due to scattered photons.

This scattered dose is a function of the distance from the beam edge, treatment geometry, primary photon energy and depth in the patient.

The need for effective shielding of the fetus is reinforced when one considers many pregnant women are treated with external beam radiation therapy every year and then shielding designed to reduce the scattered photon dose to normal organs have to considered.

2. Materials and methods

Irradiation was performed at a gantry angle of 0 degree in phantom using high energy photon beams produced by a Varian 2100C/D medical linear accelerator (Varian Oncology Systems, Palo Alto, CA) located at the Yonsei Cancer Center. The composite phantom used was comprised pf a commercially available anthropomorphic Rando phantom (Phantom Laboratory Inc., Salem, YN) and a rectangular solid polystyrene phantom of dimensions 30 cm x 30 cm x 20 cm. the anthropomorphic Rando phantom represents an average man made from tissue equivalent materials that is transected into transverse slices of 2.5 cm thickness. When assembled the 36 slices, numbered 0-35, Provide a head and torso with skeleton, lungs, and air passages. Slices 20-28 correspond to the abdomen and were removed and replaced by the polystyrene phantom.

Photon dose was measured using a Capintec PR-06C ionization chamber coupled to a Capintec 192 electrometer(Capintec Inc., Ramsey, NJ) and this system had a calibration factor traceable to a standards laboratory and the photon scattered doses were measured by inserting the appropriate dosimeter in the milled a space located in one of the slice of the polystyrene phantom.

In case of fetus, the dosimeter was placed at a depth of 10 cm in this phantom at 100 cm source to axis distance and located centrally 15 cm from the inferior edge of the 30 cm x 30 cm x-ray beam irradiating the Rando phantom chest wall. A fraction of a typical patient treatment dose was delivered during scattered dose measurement.

Of note is that a depth of 10 cm has been previously accepted as the standard depth of a fetus. In our geometric setup the measurement location chosen as representative of the position of the fetus corresponds approximately to an anatomical location that is 10 cm below the umbilicus of the mother, According to the AAPM task group 36 report the mother's umbilicus will be the height of the fundus at 20-22 weeks gestation. Obviously, the fetus occupies a

volume that increases with the period of gestation and the depth of the midline of the fetus will also vary with its position the size of the mother, and other factors.

A wooden bridge of size 40 cm x 40 cm and a clear space of about 21 cm was fabricated and placed on top of the rectangular polystyrene phantom representing the abdomen of the patient. The idea was to simulate the bridge being as close as possible to the patient's body whileensuring the weighty of the bridge and shield rested on the legs of the bridge. Shielding material comprised of 30 cm x 30 cm lead sheets of total thickness 6 cm was placed on the top of the wooden bridge that covered the abdomen.

The scattered photon with and without shielding were measured at the representative position of the fetus. The scattered photon dose was usually made for a 10 Gy primary photon beam treatment, however to obtain good statistics

3. Results

Scattered photon doses of critical organs from various region by 10MV photon beam was measured and presented in table 1.

The scattered photon dose for uterus and testicle can be reduced under 10 mSv when the lead shield was used while the tumor region was irradiation by high energy photon beam and presented in table 2.

Table 1. Scattered photon dose measured at critical organs from 10MV x-ray beam irradiating various regions

unit : mGy/Gy F: in field

Region / Organs	Thorax 12 x12 cm	Abdomen 14 x14 cm	Pelvis 14 x14 cm
Brain	1.8	0.2	0.1
Lens	2.2	0.3	0.2
Thyroid	48.3	1.9	0.8
Lung	F	20.2	1.5
Pancreas	4.8	F	3.7
Kidney	2.5	F	39.8
Uterus	0.9	6.2	F
Testicle	0.7	4.2	58.2

Table 2. Requirement lead thickness to be reduce under 10mGy for 60Gy irradiated on field with 10MV x-ray

unit: cm F: in field

Regio / Organ	Thorax	Abdomen	Pelvis
Uterus	4.5	7.0	F
Testicular	1.2	2.0	6.5

The results indicate that it is possible to improve shielding to reduce scattered photon and side at the position of a fetus when a pregnant women is treated with a high energy photon beam. The AAPM task group report 36 concentrated on shielding of the fetus from scattered photons and recommended that the lead shielding be draped over the edge of the bridge to provide extra shielding of the fetus against collimator scatter. This report also stated that it is prudent to treat with photon beams generated by electrons less than 10 MeV if this modality is adequate to treat the tumor.

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NEUTRON DOSE TO PATIENTS TREATED WITH HIGH-ENERGY MEDICAL ACCELERATORS

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Abstract

The neutron dose equivalent received by patients treated with high energy x-ray beams was measured in this research. A total of 13 different medical accelerators were evaluated in terms of the neutron dose equivalent in the patient plane and at the beam center. The neutron dose equivalent at the beam center was found to ranged from 0.02 to 9.4 mSv per Sv of x-ray dose and values from 0.029 to 2.58 mSv per Sv of x-ray were measured in the patient plane. It was concluded that the neutron levels meet the International Electrotechnical Commission standard for the patient plane. It was also concluded that when intensity modulated radiation treatment is conducted the neutron dose equivalent received by the patient will increase by a factor of 2 to 10.

1. Introduction

Medical accelerators are used routinely to produce high energy x-ray and electron beams for use in the treatment of cancer patients. The radiation beams generated by medical accelerators operated above 8 MeV are contaminated with neutrons as a result of photon reaction with the materials used to fabricate the accelerator structure. The dose equivalent produced by photoneutrons is of importance in assessing the risk to the patient due to stray radiation. In this work the dose equivalent in the patient plane and at the beam center was measured for a number of modern medical accelerators.

2. Materials and methods

Table I list the various accelerators investigated, the beam megavoltage as given by the American Association of Physicist Task Group-21 Protocol [1] and the stated energy indicated by the manufacturer. Moderated activation detectors were used to determine the neutrons in the main beam and at points outside the x-ray beams. A 15.2 cm diameter paraffin moderator equipped with an indium foil at it's center was used to measure the fast neutron fluence at the beam center per unit dose of x-rays. at the isocenter. This dosimeter was utilized due to the relatively small size, which allowed it to be placed within a 20 x 20 cm^2 x-ray beam. The detector also has the desirable feature of having a small sensitivity to photons. The activity of the indium foil after an irradiation has been shown to be directly proportional to the neutron fluence per unit dose of x-ray [2]. Since the detector has a flat energy response in the fast neutron energy region the energy spectrum of the neutrons does not have to be accurately known to determine the fast neutron fluence [2]. The moderator was encased in a cadmium thermal neutron shield to eliminate any response produced by thermal neutrons. The measurements were made at the center of beams of cross sectional area of 20 x 20 cm^2 at 1 m from the target. A ^{252}Cf neutron source was used to calibrate the moderated activation system. Factors [3] to account for neutrons produced in the cadmium thermal neutron shield by photons were applied to the measurements. The foil count rate was evaluated by use of a gas-flow proportional counter. Corrections of the count rate were made for lack of saturation and decay before and during counting. The neutron fluence established by use of the paraffin sphere was converted to neutron dose equivalent based on information given in NCRP Report No. 79 [4].

TABLE I. Accelerators investigated, accelerator parameters, and the fast neutron equivalent per unit dose of x-rays at the beam center.			
Accelerator	Stated energy (MeV)	TG-21 Megavoltage	Neutron dose equivalent per unit dose of x-ray at the isocenter (mSv/Gy x-ray)
1. Siemens KD	20	17.0	4.2
2. Siemens Primus	18	15.3	3.1
3. Siemens MD	15	13.2	1.4
4. Phillips SL25	25	22.0	8.0
5. Phillips SL20	20	17.0	2.3
6. GE Saturne 43	25	18.5	8.5
7. GE Saturne 43	18	14.0	5.1
8. GE Saturne 41	15	12.5	1.7
9. GE Saturne 41	12	11.2	0.8
10. Varian 2300	20	18.5	9.4
11. Varian 2300	18	17.5	8.3
12. Varian 2300	15	13.1	4.0
13. Varian Clinac 18	10	9.2	0.02

Table II. Neutron dose equivalent(mSv) in the patient plane per unit dose (Gy) of x-ray at the isocenter.								
Distance from beam center	30 cm				100 cm			
Accelerator Number	-G	G	Lf	Rt	-G	G	Lf	Rt
1	1.40	1.40	1.60	1.40	1.00	1.10	1.20	1.00
2	0.49	0.47	0.50	0.45	0.45	0.44	0.49	0.44
3	0.31	0.22	0.24	0.25	0.20	0.19	0.21	0.18
4	2.36	2.10	2.40	2.05	1.98	1.97	2.02	2.00
5	0.56	0.53	0.58	0.50	0.41	0.42	0.47	0.47
6	1.83	2.30	2.41	2.58	1.27	1.60	1.29	1.35
7	-	-	-	-	0.59	0.55	0.54	0.51
8	0.46	0.51	0.45	0.41	0.29	0.32	0.31	0.32
9	0.17	0.14	0.16	0.18	0.10	0.08	0.10	0.09
10	1.76	1.81	1.70	1.59	1.22	1.43	1.20	1.15
11	1.67	1.45	1.67	1.57	1.15	1.17	1.17	1.13
12	0.79	0.67	0.72	0.65	0.43	0.45	0.49	0.52
13	0.03	0.08	0.05	0.05	0.03	0.04	0.03	0.05

The neutron dose equivalent outside the beam was determined by use of a 25.4 cm diameter Bonner sphere with an indium foil placed at the center of the sphere. The Bonner sphere was used for these measurements because the neutron energy spectrum was not known for points outside of the beam and the response of 25.4 cm sphere is proportional to the neutron dose equivalent independent of the energy of the neutron field. A second reason the Bonner sphere dosimeter was chosen for measurements in the patient plane was that detailed knowledge of the accelerator head shielding was not required to establish the neutron dose equivalent. On the other hand, if the paraffin moderator had been used for the determination of the dose equivalent the thickness and type of materials in the accelerator head would have been required. The Bonner sphere system was calibrated with the same neutron source used to calibrate the paraffin sphere.

Neutron measurements were made in the patient plane, which is defined as the area formed by a one meter radius circle located one meter from the x-ray target at a right angle to the central axis of the beam. The sphere was positioned at 30 and 100 cm from the central axis of the x-ray beam in order to determine the dose equivalent received by the patient. The collimator of the accelerator was closed to the minimum size when measurements were made in the patient plane in order to maximum neutron production. The location of the points of measurement in the patient plane are indicated by G (toward the gantry), -G (away from the gantry, and left (Lf) and right (Rt) as viewed from the foot of the treatment table looking toward the gantry.

3. Results

Table I summarizes the values found for the fast neutron dose equivalent per unit dose of x-rays at the center of each 20 x 20 cm^2 beam. The values range from 0.024 to 9.4 mSv Gy^{-1} depending on the energy and manufacturer of the accelerator. It should be noted that the neutron contamination at the beam center of the Siemens and Philip accelerators is lower by a factor of at least two as compared to the Varian and GE accelerators with similar Task Group-21 megavoltage values for x-ray beam. In Table II are shown the values of neutron dose equivalent measured in the patient planer per unit dose of x-ray at the isocenter. The Varian and GE patient plane values are a factor of two or more greater than the Siemens and Philips values except for the Siemens KD accelerator which had neutron leakage in the patient plane similar to the Varian 17.5 MV x-ray beam. This comparison of the neutron dose equivalent in the patient plane was based on similar Task Group-21 megavoltage. The overall uncertainty associated with these measurements is of the order of ±20%.

4. Discussion and conclusions

In this work the neutron dose equivalent has been determined at the central axis of the x-ray beam and outside the beam in the patient plane for 13 different medical accelerators. The number of neutrons generated in the paraffin moderator due to photon interactions has been shown to be small [5] and corrections were not made to account for this effect. As a result of the low photon fluence in the patient plane corrections to account for photoneutron produced in the Bonner sphere moderator were not required.

The International Electrotechnical Commission (IEC) has proposed a maximum neutron dose limit in the patient plane of 0.5 mGy of neutrons per Gy of x-ray. This dose limit can be converted to dose equivalent by use of the quality factor for neutrons. The quality factor for neutrons varies from 2 to 10 depending on the neutron energy. Using a quality factor of 10 for fast neutrons yields a value of 5 mSv of neutrons per Gy of x-ray. As can be seen from Table II none of the accelerators exceed the IETC requirement for neutrons.

The neutron dose equivalent received by a 20 cm thick patient treated with parallel opposed 20 x 20 cm^2 beams to a dose of 50 Gy at mid-depth was estimated by use of the depth dose for a fission spectrum, the maximum beam central axis dose and depth dose values for the x-ray beam. A value of 0.30 Sv neutron dose equivalent was found for the GE 25 MeV accelerator based on this technique. Carrying out the calculation using the maximum patient plane dose 30 cm off the central axis one finds a dose equivalent of 0.090 Sv for the GE 25 MeV accelerator.

These dose equivalent levels do not seem excessive. However, there is at present a major interest in using intensity modulated radiation therapy (IMRT). When IMRT is conducted the

dose equivalent outside the beam will be increased by a factor of 2 to 10 depending on the treatment system used. The probability of inducing new cancers when this modality is employed needs to be evaluated. Some possible solutions to this problem would be to add neutron shielding to the accelerator head and the use of lower energy x-ray beams (10-15 MV).

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RADIOLOGICAL PROTECTION CONSIDERATIONS DURING THE TREATMENT OF GLIOBLASTOMA PATIENTS BY BORON NEUTRON CAPTURE THERAPY AT THE HIGH FLUX REACTOR IN PETTEN, THE NETHERLANDS

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Abstract

A clinical trial of Boron Neutron Capture Therapy (BNCT) for glioblastoma patients has been in progress at the High Flux Reactor (HFR) at Petten since October 1997. The JRC (as licence holder of the HFR) must ensure that radiological protection measures are provided. The BNCT trial is a truly European trial, whereby the treatment takes place at a facility in the Netherlands under the responsibility of clinicians from Germany and patients are treated from several European countries. Consequently, radiological protection measures satisfy both German and Dutch laws. To respect both laws, a BNCT radioprotection committee was formed under the chairmanship of an independent radioprotection expert, with members representing all disciplines in the trial. A special nuance of BNCT is that the radiation is provided by a mixed neutron/gamma beam. The radiation dose to the patient is thus a complex mix due to neutrons, gammas and neutron capture in boron, nitrogen and hydrogen, which, amongst others, need to be correctly calculated in non-commercial and validated treatment planning codes. Furthermore, due to neutron activation, measurements on the patient are taken regularly after treatment. Further investigations along these lines, include, dose determination using TLDs and boron distribution measurements using on-line gamma ray spectroscopy.

1. Introduction

The European clinical trial (EORTC 11961) of BNCT for glioblastoma patients started at Petten in October 1997 [1]. The treatment of a patient and the potential exposure of personnel to ionising radiation require by the national Nuclear Energy Law that the JRC (as licence holder of the HFR) must ensure that radiological protection and monitoring of all personnel, including external staff, is provided and that the correct radiation protection measures are taken and followed.

Due to the structure of the European trial, where the treatment takes place at a facility in the Netherlands under the responsibility of clinicians from Germany, it had to be demonstrated that measures taken satisfy both German and Dutch radioprotection laws. To respect both laws, a BNCT radioprotection committee was formed under the chairmanship of an independent radioprotection expert, with members representing all disciplines in the trial. A contractual agreement had to be signed between the German institute (University of Essen) and JRC Petten to guarantee that procedures to be followed complied with German radioprotection regulations (Strahlenschutzordnung §20). During BNCT, both the patient and the supporting treatment tools, such as mask and therapy table, become radioactive. As such, measurements of the patient and surrounds are taken at regular intervals after treatment, checked and an appropriate form completed and reported to the BNCT Radioprotection Committee.

As at the HFR, BNCT worldwide is performed using mixed neutron/gamma beams at nuclear research reactors. The mixed beam must be thoroughly and regularly characterised, using dosimetry techniques in addition to those of conventional radiotherapy. Furthermore, the complex beam and subsequent dose distribution in the patient are modelled using treatment planning codes based on programs developed for nuclear applications, e.g. MCNP [2].

To improve radiological protection of the patient and staff, investigations are continuously in progress to fully characterise the beam (using activation foils, ionisation chambers, TLDs) and to determine the boron distribution in the patient using on-line prompt gamma ray spectroscopy.

2. Radioprotection committee

To conform with the Dutch regulations on radio-protection, a Radio-Protection Committee for BNCT has been formed. The committee has the prime task to review and advise, on a half-yearly basis, the radio-protection methods used for BNCT. If need be, this advice is transmitted to any external authority. The Committee consists of members from each discipline in the BNCT group, and is chaired by an independent expert in radio-protection.

Due to the fact that German staff from Essen University Hospital need to work at Petten, German regulations on radio-protection, especially application of the radio-protection decree: §20 StrSchV (Strahlenschutzverordnung), which regulates the activities of German staff in foreign institutions, had to be contractually agreed. The decree defines regulations on supervision of the staff, personal dosimetry, rules of behaviour, etc.

Radio-protection includes the issuing of personal dosimeters (type: universal dosimeter) to all staff, finger or ring dosimeters to the radiotherapists, and pen dosimeters to participants classified as visitors, eg. nurse(s) and relatives of the patient, [3]. Furthermore it is necessary to measure and record all material in and out of the reactor and perform activation measurements on all material used in patient treatment. The patient is an exceptional case, of course, and it is not required that a personal dosimeter is issued to the patient. However, following treatment, the patient is monitored for radioactivity. So far, the reported radiation doses received by the staff are well below the allowable limits.

3. Treatment planning for BNCT

For BNCT it is necessary to perform a full 3D calculation to predict the dose distributions in the patient's head. Calculations at Petten are performed with the INEEL treatment planning program 'bnct_rtpe/rtt_MC' [4]. This program is based on a Monte Carlo simulation of the particle tracks in a full 3D reconstruction of the head. As part of the overall treatment planning procedure, a quality assurance (QA) system is provided. As part of the QA system, a quality control procedure for the program involves calculations on two standard test cases, i.e. a standard patient and standard phantom, which are calculated to check for possible non-conformance. The cases are chosen in such a way that all the essential parts of the program are used. A control procedure is followed and performed each time a new version of the program is installed.

For the patient plans, each treatment plan is calculated in Petten and presented, discussed and agreed at the radiotherapy department of Essen University during their daily audit on treatment planning.

4. Patients activation measurements

Standard measurements [3]

BNCT of the patient results in neutron activation of a number of naturally occurring elements in the irradiated volume, i.e. the head. As a result, activation measurements of the patient's

head are taken on 3 separate occasions using a standard portable dose ratemeter (Type: NE-PDR1). The first measurement is some 1-2 minutes directly following treatment, the second when the patient leaves the reactor building (5-10 minutes post-BNCT) and lastly, just prior to the patient leaving Petten to return to the hospital in Amsterdam (30-45 minutes post-BNCT). Measurements are taken both at contact and at 30cm distance from the head. The results have been compiled for all patients.

In summary, peak levels, i.e. at contact and directly after radiation, are of the order of 40-50 μSv/h, falling to less than 10 μSv/h some 30-50 minutes after treatment. The remaining activity is predominately due to ^{24}Na only (half-life = 15 h). Activity due to other elements have much shorter half-lives, hence do not contribute or are not additive to the final levels. Measurements, taken at 30cm from the patient's head are an order of magnitude lower. Hence, the dose received by medical staff and relative(s) accompanying the patient is well below recommended limits. Activation measurements using a portable gamma analyser [3]

As one of the many research topics associated with BNCT, gamma-ray spectrometry measurements have been performed on 2 patients. The equipment or counting chain consists of an EG&G HPGe detector (relative efficiency and FWHM at 1.33 MeV of Co-60: 12.7% and 1.71 keV, type : 26N-1602C), an EG&G 459 high voltage power supply, an EG&G 572 amplifier, an ECN portable power supply and a Canberra Accuspec interface, mounted in a Toshiba 3200 SX laptop computer.

Shortly after the treatment, a patient was placed on a chair in the BNCT-Wing, where the portable spectrometer had been set-up. Prior to the arrival of the patient, background measurements were taken. The resulting spectra, with and without the patient, were analysed.

The predominate isotopes were, as expected, identified as ^{38}Cl, ^{49}Ca and ^{24}Na. However, in one patient, the isotopes ^{198}Au and ^{116m}In, were also present. It was concluded that the former isotope was due to (this) patient's gold filling and the latter isotope, assumably, due to the content of one of the drugs taken by the patient. It should be noted that only those radioisotopes which are gamma emitters have been measured.

5. Beam Characterization

Dosimetry guidelines, as followed in conventional treatment centres, apply to photon, electron or fast neutron facilities. For BNCT facilities, where an epithermal neutron beam is used, the beam (in air) includes fast neutrons (>10keV) and gamma rays. The latter comes from both the beam itself (reactor gammas) and from activation of the in-beam material. In human tissue, containing boron-10 compounds, the beam produces effectively four main dose components, all with different biological effectiveness: the boron neutron capture absorbed dose, the nitrogen neutron capture absorbed dose, the fast neutron absorbed dose and the gamma ray absorbed dose.

Furthermore, the neutron beam emanates from a reactor, which in the case of the HFR, has a strict operating schedule, running 24 hours per day for eleven cycles of 4 weeks each, per year. Hence due to burn-up of the reactor fuel, the intensity of the beam over the scheduled 4 weeks cycle reduces by some 4-5%. Also, the intensity of the beam at the start of each cycle may vary by some ±4% per cycle, due to experimental loading changes in the reactor. Hence, quality assurance of the beam during treatment must follow a strictly controlled procedure, which includes the following steps:

- free beam measurements on a monthly basis, using a multi-foil packet consisting of 12 activation foils,
- on the first day of the treatment week (each patient receives a fraction of radiation on four consecutive days), reference phantom measurements are performed using activation foils, twinned ionisation chambers and a pn-diode,
- the measurements are used to calibrate the on-line monitors (see next section),
- on succeeding days of treatment, the reference phantom measurements are repeated using the pn-diode, twinned ionisation chambers and the in-beam monitors, which are all normalised to the first day's measurements.

Following the QA system, as well as Good Clinical Practice (GCP) [5,6], all measurements are written down, controlled and countersigned by the responsible person, documented and later archived. Despite the complexity associated with BNCT dosimetry, QA procedures applied for BNCT infer less radiation and operational procedures than for conventional radiotherapy. Furthermore, reproducibility in BNCT is equivalent with medical accelerators, whilst all safety requirements and equipment functions, including against stray radiation are equivalent. The above philosophy is being developed, along with other European groups, to formulate a European Code of Practice on Dosimetry for BNCT [7].

Additional investigations are underway using thermoluminescence dosimeters (TLDs) which have become the current dosimetric tool in photon, electron and neutron radiation beams for dose determination in "in-vivo" dosimetry, as well as in phantoms simulating patients treatments. The epithermal neutron beam used in BNCT, has gamma and neutron components, which have different relative biological effectiveness (RBE). Hence, knowledge of the separate dose components is required for a safe patient treatment. For reliable and accurate TL dosimetry in BNCT, a study is in progress looking at the detector response to the mixed field in order to determine the sensitivity to each component [8]. The work investigates:-

- Comparative examinations for the selection of TLD's for further application
- Examination of surface properties of TLD 300
- Calibration of the TLD 300

As part of the study, in-vivo measurements have been performed on 4 BNCT patients using TLD 300s. Initial results are related alone to treatment parameters without any patient influence. Simultaneously, measurements were done inside the patient mask at the centre point of the beams on the patient entrance and exit surface for both beams. These results are dependent on treatment parameters of the BNCT facility as well as the patient related parameters.

6. Prompt gamma ray spectroscopy

Application of prompt gamma spectroscopy (PGS) may improve the safety and efficacy of BNCT [9]. PGS holds the potential of in-vivo boron concentration determination at the time of the treatment through the detection of gamma rays promptly emitted in the $^{10}B(n,\alpha)^{7}Li$ and $^{1}H(n,\gamma)^{2}D$ reactions. A series of phantom measurements have been performed, where a tumour within a homogeneously boronated head phantom was simulated [10]. The results indicate that it is possible to determine a boron concentration of 5 μg/g with an accuracy of ± 3 % in a homogeneous boron distribution. Subsequent measurements have been recently performed on patients. The results are pending. Nevertheless, the technique looks very promising and work continues.

Acknowledgements

The clinical trials at Petten are financially supported by the European Commission's "Biomedicine and Health Research" (BIOMED II) Programme, contract no. BMH4-CT96-0325 and the "Quality of Life and Management of Living Resources" Programme, contract no. QLK3-CT-1999-01067

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IAEA-CN-85-255

QUALITY CONTROL IN RADIOTHERAPY TREATMENT: RADIATION INDUCED MYELOPATHY

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Abstract.

Direct injury of the spinal cord has been reported many times, particularly in cases of overexposures with radiotherapy of neoplasm that occurred outside the Central Nervous System. Permanent damage to the spinal cord is the most feared complication of radiation therapy treatments and one of the relatively common causes of litigation for medical malpractice in the context of cancer treatment. We have learned from clinical experience; data from randomized trials and animal experimentation the dose tolerance as well as the interfraction interval for hyperfractionation regimes. We are still lacking precious clinical information, in particular the dose tolerance in combined modality treatments that represent the vast majority of modern treatments.

1. Clinical presentation

The overall functional repercussion of myelopathy depends on the segments of the spinal cord affected. In general, radiation-induced lesions of the spine have a shorter latent period to the clinical manifestation than do similar brain lesions [1]. The spinal cord often is unable to tolerate the absorbed dose levels necessary to eradicate malignant tumors. In many cases, there is a delayed myelitis. The most radiosensitive portion of the CNS appears to be upper thoracic segments and the lower lumbar and sacral segments [2].

Radiation myelopathy presents initially as a subtle unilateral or bilateral sensory deficit, diminished temperature sensation and proprioception, as well as discrete paresis. Pain is not a prominent feature. These signs and symptoms may progress gradually, to overt sensory deficit, paralysis, spasticity and incontinence, or may stabilize at any level of partial neurological deficit. Hyperreflexia, and Babinski, are often found on neurological exam. Often, signs of Brown-Sequard can be found (ipsilateral paralysis and loss of discriminatory and joint sensation, and contralateral loss of pain and temperature sensation).

The diagnosis is generally made by exclusion. First, it is essential to rule out other causes of spinal cord injury like spinal cord compression. Second, the features of neurologic deficit must correlate with the segment of spinal cord irradiated. Finally, time to expression of injury, and the dose received must be consistent with the scientific available data. It is important to keep in mind that there are some predisposing factors that may decrease the latent period and /or increase the incidence of radiation myelopathy. Such factors are previous CNS damage, vascular diseases and concurrent chemotherapy. Diagnostic workup usually yields nonspecific results. MRI may show cord swelling, decrease intensity in T1 and increased in T2, indicative of edema. The CSF is normal, or it has slightly elevated total protein, elevated myelin basic protein, and lymphocytes. The prognosis depends primarily upon the degree and level where the cord is transected. The actuarial mortality from radiation myelopathy at 18 months is 55% for cervical lesions, and 25% for thoracic lesions. Those patients are usually treated with steroids to reduce edema, with some improvement. Supportive care and rehabilitation are also cornerstones.

2. Pathology

Radiation injury to the spinal cord is limited to the white matter. The dominant features, although not pathognomonic are demylination and malacia that are accompanied by a variable degree of gliosis and vascular anomaly. Using morphologic features, the cases of radiation myelopathy can be divided in 3 categories:

- Type I, with predominant white matter demylination and malacia.
- Type II with mainly vascular changes.
- Type III, where there is a combination of both components.

In general latent periods of 17-18 months are associated with Type I or III lesions. Vascular changes encounter in Type III lesions are endothelial alterations, teleangiectasia, hyalinosis, and fibrinoid necrosis. In contrast, longer latencies tend to be associated with the Type II, where the vascular abnormalities are vascular thrombosis, necrosis and hemorrhage. Type III is the most frequent in humans. In addition to architectural changes, there are modifications in the cellular composition within the white matter. Atrocities and microglia are increased in the irradiated segment, instead of the normal nerve fibers surrounded by myelin.

3. Dose-incidence relationship and physical factors

The dose-response relationship is now well established. Schultheiss and Stephens in 1992 [3] reviewed the literature, indicating that a total dose of 45 Gy in 22-25 fractions, results in a myelopathy incidence of 0.3% or less. *A realistic estimate of the Estimated Dose to produce myelitis in 5% of the patients treated with radiation therapy delivered in fractions of 2 Gy is between 57 and 61Gy (ED 5)*.

Moreover, there is a 25-50% incidence of thoracic cord myelopathy at dose levels of 60 Gy with 2 Gy fractions, 40 Gy with 3 Gy fractions and 35 Gy with 4 Gy fractions [1]. In the Costa Rica radiotherapy accident, there were 3 patients who developed spinal cord complications (2 became quadriplegic and one became paraplegic). These patients had received 50 to 57 Gy in 15 to 17 fractions. Also, the major cause of fatality was the myelitis (5 patients) in the Zaragoza radiotherapy accident (Spain) [1].

There are no firm clinical data to support the general belief that the radiation tolerance of the spinal cord of children is much lower than that of adults. However, the few cases of myelitis that have been observed and reported happened in doses of about 40 Gy in fractions of less than 2 Gy. It is reasonable to assume a lower tolerance in clinical practice, so *the dose should be reduced by 5-10% in children.*

The quality control of the radiotherapy treatment is very important in assessing the risk of myelopathy. If a radiation field is very long, this risk is greater, particularly when adjacent field radiotherapy is performed with overlap in the treatment field.

4. Dose fractionation and interfractionation interval

In the linear quadratic model, the endpoint of delayed white matter necrosis has an α/β ratio of 2 Gy. This is typical of a late reacting tissue; it means a strong dependency of radiation

tolerance on fraction size. This fact suggests that hyperfractionation (reduction in the fraction size) would, in theory, reduce the risk of myelopathy [4].

The importance of intervals between fractions is a recent hot issue, since the high incidence of radiation myelopathy in CHART, a regime with three daily doses of radiation, where the time between fractions was kept to a minimum of 6 hr. This was based on the initial results on a rodent study showing a half time of repair of 1.5 hr. There is a study by Ang at al [5] showing that cellular repair of sublethal damage proceeds at slower rate of up to 3.8 hr. so the high incidence of radiation myelopathy in CHART can be attributed to incomplete repair between fractions. To minimize the risk of myelopathy it is prudent to allow an interval of at least 6 hours, preferably 8, when the schedule is two times a day. In treatments delivered three times a day, due to compounding incomplete repair, the dose to the spinal cord must be reduced in 10-15%.

There are some studies in rodents carried out by Van der Kogel [5-7], evaluating the contribution of the overall treatment time in determining the radiation tolerance of the spinal cord. These data suggest that *protracted radiation courses do not appreciably increase the tolerance of the spinal cord*

5. Volume effects

It has been accepted that the dose to the spinal cord should be reduced when the volume (number of cord segments) is large. This tradition evolved based on the belief that radiation volume is a strong determinant of cord tolerance. Clinical data are scarce and inconclusive, but now we have data form large animals (pig, dog, and monkey). Doubling the treatment volume leads to a reduction of 4% of isoeffective dose at a 1-55 incidence level. This means that *in treatment settings, where the probability of myelopathy is less than 1% (the rule), changes in treatment volumes have minimal impact on cord tolerance*.

Kramer et al have indicated the maximum acceptable dose to the cervical and lumbar spinal cord to be 50 Gy in 25 fractions over 5 weeks and, to the thoracic cord 45 Gy delivered over 4½ to 5 weeks [8]. Other works reported tolerance doses range between 35 Gy in 4 weeks and 50 Gy in 5 weeks [9-10]. If these doses are exceeded, transient radiation myelopathy and, perhaps, paralysis may result.

Fitzgerald et al. indicated that 13% of patients who received 40 Gy in an accelerated fractionation scheme and survived 11 months developed progressive myelitis [11].

Diche et al. [12] have examined 754 cases of radiation myelitis post-radiotherapy for lung cancer. They have shown a threshold dose for thoracic radiation myelitis in fractionated radiotherapy of 33.5 Gy. Georgiou et al. indicated [13] a dose to the lumbosacral plexus of 73 Gy and only 4 patients developed plexopathy in this anatomical zone.

6. Reirradiation (recovery form occult radiation injury)

This is an important issue in head and neck patients, who once they are cured, have a chance of 25% of developing a second primary. At the present time most radiation oncologist are reluctant to treat such patients, because of the misconception that previously irradiated tissues cannot be re-treated, particularly the spinal cord. There is experience on retreatment of recurrent brain tumors and nasopharyngeal tumors suggesting the existence of long-term

recovery in the CNS. But in order to developed a rational strategy, and based on previous rodent model by Van der Kogel [5], Ang [6] developed a monkey model, irradiating monkeys at 44 Gy in 20 fractions, with re-irradiation 2 yr. later, with cumulative doses of 83.6, 92.4, 101.2, and 110.0 Gy. Only 2/16 animals developed myelopathy. Asymptomatic animals were observed for at least 2 yr. after the re-treatment. These data indicate that the majority of occult injuries induced by the initial treatment have recovered within 2 years

7. Relation with chemotherapy

There are clinical data indicating that the risk of myelopathy in children is increased when intensive chemotherapy (IV and IT MTX and Ara-C) is administered concurrently with XRT. Quantitative assessment in a rodent model, carried out by Van der Kogel [5], showed that IT Ara-C reduces the radiation tolerance of the spinal cord by about 20%

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QUALITY ASSURANCE IN RADIOTHERAPY

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Abstract

Quality assurance in the management of a patient receiving radiation therapy and the role of the radiation oncologist and medical physicist in this process is described. The constraints on available personnel is recognised and the need for further education resources and IAEA activities in education for both groups described. IAEA activities in the clinical and dosimetric aspects and the resultant publications and education have contributed to a culture of quality assurance.

1. Introduction

Radiotherapy involves the use of ionizing radiation in the treatment of cancer patients. It is a multi-disciplinary speciality involving the use of complex equipment and procedures. It includes many phases, from diagnosis to clinical decision to undertake treatment, treatment delivery and follow-up. A systematic and comprehensive approach to quality assurance (QA), covering all these phases, is of vital importance to ensure optimum treatment of patients. Such QA programmes have been recommended by many professional bodies such as ESTRO [1] and AAPM [2], and should follow the guidelines given in the Basic Safety Standards (BSS) [3] and by WHO [4]

The main rationale and justification for quality assurance in radiotherapy is to ensure that not only does the patient receive good quality treatment but is also protected from accidents and errors (random and systematic). QA aims at minimizing the occurrence of random errors and at eliminating large systematic errors, contributing to the minimization of the morbidity rate and maximization of the cure rate of radiotherapy patients. This concept is emphasized in the BSS [3]. Patient safety is therefore integrated within the overall QA programme of radiotherapy [5].

At the national level, the establishment of a QA programmes should take into account international recommendations and existing national guidelines. To ensure that radiation therapy centres have a common basis for developing and implementing their quality assurance programmes, professional bodies representing radiation oncologists, medical physicists and medical radiation technologists should develop national guidelines or standards for radiation therapy quality assurance and set out a uniform quality assurance program to be adopted by all radiation therapy centres, taking into account the level of practice in the country. Several major issues should be considered before the establishment of a national quality assurance program for radiation therapy, including the licensing and regulation of radiotherapy equipment, the accreditation process, if it exists, the problems with the review process and compliance, the cost-benefit analysis of setting up an independent external quality assurance programme, the need to maintain confidentiality of patient records and the need to respect professional standards.

The IAEA assists its Member States to establish and implement national QA programmes through its programmatic activities and Technical Cooperation projects. The IAEA assistance is directed to national regulatory bodies for the establishment of a regulatory framework, which complies with the BSS, to standards laboratories for metrological traceability, and to end users at hospitals for the development and implementation of QA programmes. Traceability of radiation measurements for radiotherapy dosimetry and quality audit services, run jointly with WHO, such as the IAEA/WHO postal TLD service for the verification of the

clinical beam output, are also offered by the IAEA to the Member States. To coordinate its activities in QA in radiotherapy, close cooperation is maintained with other international organizations and professional bodies such as WHO, ICRU, ESTRO and IOMP.

2. Requirements for QA

QA in radiotherapy encompasses all procedures which aim to ensure a consistent and a safe fulfilment of dose prescription to the target volume while minimizing the dose to normal tissue, minimal exposure to personnel and the public. It involves all clinical, physical and technical, and safety procedures. The QA programme should be established by professionals working in the field of radiotherapy, taking into account the level of practice in the country and following international recommendations and guidelines. Either voluntary quality assurance guidelines or mandatory regulations could be used to achieve national uniformity. In both cases, however, a peer review program to audit the compliance with the national standards, if they exist, or international guidelines, should be established. If necessary, compliance with the national standards can be made as a condition of the licensing process.

The IAEA has established guidelines, taking into account clinical, medical physics, radiation protection and safety considerations, for designing and implementing radiotherapy programmes at the national level [5].

3. Staff requirements

The clinical use of ionizing radiation is a complex process, involving highly trained personnel. It is important that all staff dealing with patients, radiation sources and equipment have the necessary education background, adequate training and recognition of their status. The main categories of staff required and their responsibilities and training requirements are given elsewhere [2, 6, 7].

The shortage of professionals in the field of medical physics in developing countries is fully recognized. In the northern part of Africa, the number of medical physicists in radiotherapy per million population, is less than 0.3 whereas it fluctuates from 2 to 15 in Europe (according to data published by the European Federation of Organizations of Medical Physicists in Europe (EFOMP) [21]). In addition, the competency and qualifications of medical physicists in Europe are wellcontrolled through national regulations and the European Directive [22]. This is not the case in many developing countries where in reality the number of “qualified medical physicists” may be even lower. Consequently, the development and implementation of QA programmes in radiotherapy in many developing countries can be severely hampered by the lack of professionals in the field of medical physics.

A similar situation exists in the clinical field where, in some developing countries, a radiation oncologist may be responsible for upwards of 500 new patients per year in contast to 250 in developed countries.

4. Radiation protection and safety aspects

The general requirements include the review and approval by the regulatory authority aiming at ensuring radiation protection and safety of sources. These requirements cover all aspects described in the BSS and regulatory guidance [19]. In addition to administrative requirements, the control of exposure (occupational, medical and environmental), the safety of sealed radiation sources and equipment, including accessories, require conformity with ISO [10, 11, 12] and IEC standards [8, 9], respectively.

National regulatory bodies should apply the requirements of the BSS, together with national regulations, to review radiotherapy practice.

Radiotherapy centres can use the guidance provided in the BSS or propose alternative measures with an equivalent level of protection and safety [19].

5. Clinical aspects

This process commences with patient registration. Besides the domiciliary and medical records, the pathological diagnosis should be part of a national and institutional cancer registry. Pre-treatment evaluation with combined clinical assessment has a vital role in selecting the optimal management strategy within the limitations of resources. The patients' rights through informed consent must be respected. Psychosocial problems need to be addressed during and after treatment, both for the patients' benefit and to assure their compliance. Treatment planning and daily treatment need to be accurate and to be recorded. During the treatment period, the patient must be examined periodically and the treatment plan modified if required. Finally, an established patient follow-up procedure is required to pre-empt or manage complications and as a long-term assessment of the efficacy of management.

The two major tools to assist in achieving this clinical quality assurance are: firstly an institutional protocol manual clearly identifying the clinical management practice for the institution in all its multidisciplinary aspects, respecting the constraints within an institution, and secondly a departmental procedure manual, covering both clinical (immobilisation, simulation) and physical procedures.

6. Physical and technical aspects

The physical and technical aspects of the QA programme are usually performed under the responsibility of the medical physicist and cover the following areas: quality control of equipment including acceptance testing and commissioning; beam dosimetry including traceability of measurements and use of a code of practice; treatment planning and patient treatment including final verification of the accuracy of the delivered dose. The details of such QA programmes are described extensively by IAEA [5], AAPM [2] and ESTRO [1].

7. Organizational relationship and responsibility for quality

At the institutional level, the organizational structure of a radiotherapy centre should be well defined. An essential element is the establishment of an organizational chart, which should clearly show all hierarchical, functional and operational relationships. All responsibilities, tasks and competencies of each staff member must be clearly defined. For each task, a responsible person must be designated. In particular, the organizational structure should indicate who could stop radiotherapy treatments. It is a general practice to have the medical practitioner (radiation oncologist) be the responsible person for the medical exposure [20], including the protection of the patient. It is also usual practice for the medical practitioner to delegate parts of this responsibility to qualified persons. The medical physicist usually takes responsibility for the physical and technical aspects of QA [2, 5, 7].

At the multi-institutional level, there is a need to coordinate activities related to the external QA programme. It is well established that metrology institutions, such as Secondary Standards Dosimetry Laboratories (SSDLs), are usually competent to check the beam calibrations.

External QA groups which include experts from the metrology institution and radiotherapy centres should be set up at the national level. The IAEA has helped 12 countries to establish External Audit Groups (EAGs) through a Research Coordinated Project [23].

8. IAEA activities in support of QA in radiotherapy

The IAEA activities in support of QA in radiotherapy cover a large spectrum. In particular, the IAEA Division of Human Health provides:

- services to Member States for metrological traceability and external quality audits to radiotherapy centres, in collaboration with the IAEA Laboratories in Seibersdorf,
- research and development to foster exchange of information and help in the transfer of know-how in the field of QA in radiotherapy, covering clinical, physical and technical aspects, and
- support to technical cooperation projects in the field of radiotherapy and medical radiation physics, including training and education of staff.

Through its research and development activities in the clinical aspects of QA, both potentially optimal treatments and resources-sparing treatments are investigated. In the physical and technical aspects of QA, the IAEA Division of Human Health promotes standardization and harmonization of codes of practices and procedures used in QA, in close cooperation with other international organizations and professional bodies.

Education is the foundation for all quality assurance. To this end, the IAEA is in the process of developing a distance-learning programme to assist in the training of the basic sciences of radiation oncology intended primarily for radiation oncologists and therapy technicians.

9. Traceability and quality audit services

In the framework of the international measurement system the IAEA, in collaboration with the Bureau International des Poids et Mesures (BIPM), provides the metrological link through its IAEA/WHO network of Secondary Standard Dosimetry Laboratories (SSDLs) for traceable calibrations needed in radiotherapy. The IAEA's support is accomplished with the transmission of calibration factors for national measurement standards from the BIPM or Primary Standards Dosimetry Laboratories (PSDL) linked to the international measurement system. Each year, the IAEA provides traceability for radiotherapy dosimetry to about 20 Member States, mainly to those countries who are not members of the “meter convention” and do not have access to a PSDL. As a second step, dose quality audits and follow-up programmes are implemented to help the Member States ensure that the standards transmitted to hospitals are kept within the levels required by the international measurement system [14]. These programmes include intercomparisons of ion chamber calibrations made by SSDLs and dose quality audits using mailed Thermo Luminescent Dosimeters (TLDs). The intercomparison programme is available to the member laboratories of the IAEA/WHO SSDL Network, while dose quality audits are provided to radiotherapy centres through the IAEA/WHO TLD postal dose service. Both programmes are essential for assuring high accuracy in clinical dosimetry.

Ionization chambers are used in the intercomparison programme to assess the ability of the SSDLs to calibrate their own as well as hospital’s dosimeters. About 40 SSDLs participated in this programme with 90% of the results within the acceptance level of ±1.5%. The TLD programme for SSDLs annually checks about 80 beam calibrations by 60 laboratories with 95% of the results within the acceptance level of ±3.5%. The TLD programme for hospitals

aims at ensuring proper calibration of radiotherapy beams. The IAEA is responsible for the technical aspects of the service and WHO (or PAHO) takes care of the mailing and distribution of the TLD capsules to radiotherapy hospitals. This service checks approximately 400 clinical beams per year and has checked a total of more than 3500 radiotherapy beams in approximately 1000 centres. At present, about 80% of the results are within the acceptance level of ±5%, compared to 65% in the past. Subsequent follow-up actions in centres with poor results have helped the radiotherapy centres resolve the discrepancies, thus preventing further mistreatment of patients.

10. Codes of Practice

The IAEA has maintained an interest in standardization and development of Codes of Practice (CoP) for radiotherapy dosimetry going as far back as the seventies, resulting in several publications in the field. The IAEA has published the first CoP in 1970 [15], followed by "Absorbed Dose Determination in Photon and Electron Beams" (TRS-277) in 1987 and updated in 1997 [16]. Another Code of Practice (TRS-381) for radiotherapy dosimetry on "the Use of Plane-Parallel Ionization Chambers in High-Energy Electron and Photon Beams" was published in 1997 to update TRS-277 and complement it in the field of parallel-plate ionization chambers [17]. Following the world trend in radiation dosimetry, the IAEA had developed a new Code of Practice, based on absorbed dose to water standards, under the framework of a Co-ordinated Research Project. This CoP has been endorsed by WHO, PAHO, and ESTRO and will be published soon by the IAEA on behalf of these organizations as TRS-398 [18].

The Codes of Practice developed by the IAEA on absorbed dose determination in radiotherapy beams [TRS-277, TRS-381] are presently used by many physicists involved with dosimetry in radiation therapy, and have been adopted by several countries as their national dosimetry protocol.

11. Technical co-operation projects

The IAEA's Technical Co-operation Programme is based on an assessment of the development priorities and conditions in each specific country or region. The programme also includes regional and interregional projects that are developed to improve the efficiency of implementation or to utilize better the collective experience and resources of multiple Member States. During 2000, the IAEA Division of Human Health provided technical assistance to 64 national projects to support the establishment of radiotherapy services or to improve QA of the operational radiotherapy centres in the Member States. In addition, 10 regional projects, aiming at solving common problems in the geographical region mainly through training courses or workshops were also supported. Twelve IAEA Regional Training Courses, covering clinical, physical and technical aspects of QA in radiotherapy, were organized during 2000.

Taking into account the shortage of medical physicists in developing countries, support for the development of university degrees in medical radiation physics has become an important goal. This has been implemented with success, under a technical cooperation project in the Latin American Region and may be extended to East Asia and Africa. In addition, training courses and workshops, covering all aspects of QA, are organized each year by the IAEA. These training courses are directed towards radiotherapy staff, i.e. radiation oncologists, medical radiation physicists, maintenance engineers, and radiographers, including technicians. In addition, attendance at training courses provided by ESTRO is supported by the IAEA.

Through training courses on clinical topics, the IAEA promotes an awareness of the best evidence-based standards of management of clinical problems and encourages subsequent development of the relevant protocol and procedure manual entries. Concerning the physical and technical aspects, the training courses and workshops provide a unique opportunity to physicists to harmonize procedures and for continuous upkeep of knowledge and exchange of experience in QA.

12. Conclusion

There are many indicators that the IAEA through its different activities is assisting the Member Sates in the development and implementation of QA programmes in radiotherapy. These activities also help disseminate not only the technical knowledge but also the basic ingredient of the QA culture. The IAEA maintains close contacts and cooperation with other international organizations and QA networks to coordinate its activities and avoid duplication of efforts.

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THE ESTRO-EQUAL RESULTS FOR PHOTON AND ELECTRON BEAMS CHECKS IN EUROPEAN RADIOTHERAPY BEAMS*

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Abstract

Background and purpose: European Society for Therapeutic Radiology and Oncology (ESTRO) has set up a Quality Assurance network for radiotherapy (EQUAL) carrying out dosimetry audit. Some of the work is done in cooperation with the IAEA. The network deals with measurements performed with mailed TLD irradiated in reference and non-reference conditions, for on-axis points in photons and electrons beams.
Material and methods: The LiF DTL937 (Philitech, France) was used and read with the PCL3 automatic reader (FIMEL-PTW). The participating centres irradiate the TLD capsules to an absorbed dose of 2 Gy determined with the Treatment Planning System used in clinical routine.
Results: Statistical data from the participating centres on their radiotherapy structure such as number of machines and beams qualities available, dosimetry protocols and equipment in use were analysed. 23 European and 2 Mediterranean Basin countries participated.
Photons beam audit: 282 centres and 757 beams have been checked; 11% ^{60}Co beams and 89 % of X-ray beams. Compared to the EQUAL reference dosimetry 1.4 % of the reference beam output dose values and 3% of the percentage depth doses are outside the tolerance level (deviation >±5%). The standard deviation for the reference beam output is 1.8 %. Five percent of the rectangular field dose checks and 4 % the wedge transmission factors had deviations >±5%. The analysis of the global results shows deviations >±5% in at least 1 point for 133 out of the 757 beams, mainly for large and rectangular fields and for wedged beams. At least 45 of these centres had one "real dosimetric" problem in one or more parameters, which corresponds to 7% of the checked beams.
Electron beam audit: 97 centres and 277 beams have been checked. 1.0 % of the reference beam output values (field size 10 cm x 10 cm) and about 2 % of the beam output for the others field sizes (15 cm x 20 cm, and 7 cm x 7 cm) are outside tolerance level (deviation >±5%). The standard deviation for the reference beam output is 2.1% and for other field sizes about 2.4%. There are about three times more deviations outside the optimal level (> 3%) with electron beams than with photon beams. This indicates that improvements on the electron beam calibration and on the TPS algorithms for the electron beams are needed.
Conclusions: The EQUAL programme shows good results for the reference beam output for photon and electron beams, which facilitate exchange of experiences between centres. The largest deviations are for non-reference geometries, which might result in some dose variations between patients in a centre treated with the same prescribed dose but with different set-ups.
Keywords: Radiotherapy, Quality Assurance network, Dosimetry intercomparison, TLD

Introduction

ESTRO (European Society for Therapeutic Radiology and Oncology) has a Quality Assurance network (EQUAL) to check the dose on axis in reference and non-reference conditions for external radiotherapy for photon and electron beams. The external audits covered by the network are based on measurements made with mailed thermoluminescent dosimeters (TLD).
The radiation-induced morbidity is related to the quality of radiotherapy treatment delivered. The EQUAL programme is therefore one of the tasks of the MORQA project funded by a EU contract (Reduction of Radiation *Mor*bidity Through *Q.A.* of Dosimetry and Evaluation of Morbidity). The goal is to improve the radiotherapy in the EU countries and in particular

* Supported by the Europe Against Cancer Programme of the European Union.

reduce unnecessary radiation induced complications. The present paper reports the third year's experience on photon and electron dosimetry checks

Material and methods

From 1998, the EQUAL Network provided dosimetry checks of Co-60 and X-ray beams (Ferreira et al, 2000, Marre et al, 2000) and from December 1999 also of electron beams.

Results

The figure 1 shows the number of participating centres (checked, and scheduled to be checked) and the total number of centres per country. About 50% of the eight hundred European centres have applied showing the great interest for external dosimetry audit. There are in some countries national or international programmes (IAEA/WHO) on dosimetry audit which is the reason for some of the low numbers (Thwaites et al 1992, Nisbet and Thwaites 1997).

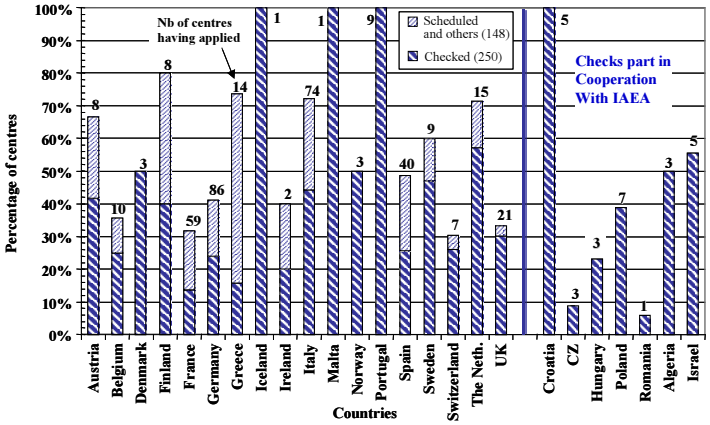

Figure 1: Percentage of centres per country that have applied to participate in EQUAL programme (data in October 2000), compared to the total number of radiotherapy centres in each country.

Dosimetric results and observed deviations: Photon beams

The ratios between the measured dose value Qm and that stated by the participating centre Qs were calculated for all checked parameters: reference beam output (RBO), percentage depth doses (PDD), beam output variation (BOV open and BOV Wedged) and wedge transmission factor (WTF). Definitions are given by Ferreira et al (2000).

The global results for the photon beam checks are shown in the Table 1. The number of beams with deviations in each of the intervals used in the EQUAL protocol (£3%, >3 to £ 5%, >5% to £10% and >10%) are reported for RBO, PDD, BOV and the WTF. A total of 6700 parameters have been checked. The values in standard characters contain all checked beams, including the beams with deviations due to a possible set-up error during the TLD irradiation. The values in ***bold-italic*** characters are the results of checked beams in an interval minus the beams with possible set-up errors in the 1st check. Set-up errors are assumed when the MU (monitor units) has not been modified between the 1st and the 2nd check but the deviation of the recheck measurement is inside the tolerance level (<±5 %).

The global result analysis shows deviations >±5 % in at least 1 point for 133 out of the 757 beams. In these 133 rechecked beams, 88 beams had some deviations >±5 % due to set-up errors and 45 beams had “real dosimetric” problems. The set-up errors are considered as being

due to the incorrect SSD or SDD, an error on the irradiation depth, the wedge orientation or other obvious mistake during the TLD irradiation.

For the reference conditions (RBO), 95 % of the results are in the optimal level of deviations (Qm/Qs ≤ ± 3 %), 4 % are in the level between ± 3 % and ± 5 %, and only 1.4% are outside the tolerance level (Qm/Qs >± 5 %). For the percentage depth doses 90% of the checked beams are in the optimal level, 7 % have deviations between ± 3 % and ± 5 %, and 3% of the checked beams are outside the tolerance level (table 1).

For the beam output variation using open beams 84%, and using wedged beams 87%, are in the optimal level, 4% (open beams) and 3% (wedged beams) are outside the tolerance level (table 1). For wedge transmission factors 81% of the results are in the optimal level and 4% are outside the tolerance level.

The "dosimetric" problems concern 45 beams out of the 133 beams rechecked. A total of 7% (45/669 beams) of the checked photon beams have at least one checked parameter with "dosimetric" problems. The largest number of set-up errors is for wedged beams. Probably, this is so also in clinical practice.

Table 1: Number of photons beams with deviation in different intervals. The values in standard characters contain all checked beams, including the beams with deviations due to a set-up error in the TLD irradiation. The values in ***bold-italic*** characters concern the results of checked beams minus the beams with set-up errors in the 1st check when the MU has not been modified between the 1st and the 2nd checks.

Parameters checked	Deviation Levels (Qm/Qs)				Total of Beams
	≤ 3%	>3 to ≤ 5%	> 5 to ≤ 10%	>10%	
Reference Beam Output	676 (90%)	54 (7%)	17 (2%)	10 (1%)	757
	637 (95%)	***25 (4%)***	***5 (1%)***	***2 (<0.4%)***	***669***
Percentage Depth Dose	603 (87%)	62 (9%)	16 (2%)	11 (2%)	692
	548 (90%)	***45 (7%)***	***11 (2%)***	***4 (1%)***	***608***
Beam Output Variation Open Beams	599 (84%)	82 (11%)	26 (4%)	9 (1%)	716
	529 (84%)	***78 (12%)***	***21 (3%)***	***3 (1%)***	***631***
Beam Output Variation Wedged Beams	558 (85%)	73 (11%)	14 (2%)	15 (2%)	660
	511 (87%)	***60 (10%)***	***11 (2%)***	***3 (1%)***	***585***
Wedge Transmission Factor	520 (78%)	99 (15%)	22 (3%)	24 (4%)	665
	475 (81%)	***85 (15%)***	***19 (3%)***	***5 (1%)***	***480***

Dosimetric results and observed deviations: Electron Beams

Since November 1999 till end of September 2000, 97 centres, out of 267 centres that have applied, and 287 beams qualities have been checked. Table 2 contains all checked electron beams, minus the beams with set-up errors in the 1st check and not yet followed up (287 beams minus 10 beams). As for the photon beam checks, the analyse of the overall results for the electron beams checks is based on the results excluding beams with set-up errors during the TLD irradiation.

86% of the reference beam output values were in the optimal level of deviation (Qm/Qs≤ ± 3 %), 13 % of the beams had a deviations between ± 3 % and ± 5 % and only 1 % were outside the tolerance level (Qm/Qs >± 5 %) .As can be seen from Table 2 the largest deviations were for the largest field size 15 cm x 20 cm.

Table 2: Number of deviations for EQUAL electron beam outputs checks with different field sizes and SSDs. The results concern the electron beams checked minus the beams with set-up errors in the 1st check.

Reference Beam Output	TLD used	Deviation Levels (Qm/Qs)				**Total of beams**
		≤ 3%	>3 to ≤ 5%	> 5 to ≤ 10%	>10%	
10 cm x 10 cm	1 and 2	239 (86%)	35 (13%)	3 (1%)	-	**277**
15 cm x 20 cm	3	212 (81%)	46 (17%)	6 (2%)	-	**264**
7 cm x 7 cm	4	241 (83%)	41 (15%)	4 (2%)	-	**266**
10 cm x 10 cm (SSD ≥ 105 cm)	5	116 (79%)	29 (20%)	1 (1%)	-	**146**
Total	All TLDs	788 (83%)	151 (16%)	14 (1%)	-	**953**

The standard deviation for the beam output values in reference conditions (10 cm x 10 cm, at SSD 100) is 2.1% with a mean value of 1.003 for Qm/Qs. The beam output for the 15 cm x 20 cm and 7 cm x 7 cm field size has a standard deviation of 2.4 % and 2.3 % respectively with a mean value of 1.001.

Conclusion

The EQUAL network has carried out a total of 757 photon and 277 electron beam checks during the last three years. A total of 398 centres have applied to participate in the EQUAL programme (about 50 % of European Radiotherapy centres). The EQUAL programme for electron beams were initiated in November 1999 and 268 centres have already applied to participate.

In the first year of the programme mostly large centres applied. Efforts were therefore made to stimulate small centres. This has resulted in a good participation also of centres with one or two radiation machines.

For the photon beams in reference geometry the mean ratio of measured to stated doses is 0.997 with a SD of 1.8 % and for electrons the mean value is 1.003 with a SD of 2.1 %. About 7 % of the checked beams have dosimetric problems, which could have a real influence on the patient cancer treatment. Beams with dosimetric problems have been followed up and the errors have been corrected and confirmed by the rechecked measurements or on site visit performed by the EQUAL physicists.

The results for the electron beam checks are very good, 98% of the beam outputs are within the tolerance level (Qm/Qs ≤ 5%) .For electron beams the number of deviations outside the optimal level are about three times that for photon beams. This difference can be explained by less accurate TPS algorithms and a larger uncertainty in the ionization chamber dosimetry procedure than for photon beams.

The EQUAL programme shows that a consistent radiotherapy dosimetry for photon and electron beams can be achieved in Europe. However, a number of dosimetric problems in photons beams (7 % of the beams checked) for non-reference conditions have been discovered. Improvements on the Quality Assurance programmes by some of the centres and on the TPS algorithms are measures that could reduce the number of deviations.

Acknowledgements

They are very grateful to the physicists of the European centres for their participation and co-operation to the EQUAL network.
The present work would not have been possible without the strong support of the ESTRO Committee for Quality Assurance and the financial help of the EU Programme "Europe Against Cancer".

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IAEA-CN-85-120

STANDARD OPERATING PROCEDURES FOR QUALITY AUDITS OF ^{60}Co EXTERNAL BEAM RADIOTHERAPY FACILITIES

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Abstract

The use of the radiotherapy implies the necessity of rigorous quality standards in its different components, aimed to provide the best possible treatment and avoid potential patient's risks, that could even causing him the death. Projects of technical cooperation had been developed in Cuba support by the International Atomic Energy Agency addresses to the implementation of Programs of Quality Assurance (PGC) in radiotherapy services. The establishment of the National Quality Audit Program (PNAC) is a superior stage. The National Control Center for Medical Devices as the national regulator entity for the control and supervision of medical devices in the National Health System is the responsible for the making and execution of the PNAC. The audit modality selected was the inspection visit *in situ* due to its intrinsic advantages, our geographical extension and the number of radiotherapy services. This paper presents the methodology for the execution of the PNAC, in form of a Normalized Procedure of Operation (PNO) that defines the objectives, scope, terms and definitions, responsibilities, composition and selection of the auditor team, security's conditions, materials and equipment, steps of the audit execution, results calculation and interpretation, records, etc.

1. Introducción

El cáncer constituye la segunda causa de muerte en nuestro país, representando este indicador el 20.6% de las defunciones ocurridas en 1999 [1]. El empleo de la radioterapia como una de las principales alternativas en la cura y paliación de esta enfermedad, implica el cumplimiento de rigurosos estándares de calidad en las diferentes componentes de su desempeño, con el fin de proporcionar el mejor tratamiento posible y evitar riesgos potenciales al paciente, que incluso pudieran llegar a causarle la muerte. En los últimos años en Cuba se han desarrollado proyectos internacionales de cooperación técnica con el Organismo Internacional de Energía Atómica (OIEA) dirigidos a la implementación de Programas de Garantía de Calidad (PGC) en los servicios de radioterapia y en la elaboración y adecuación a nuestra realidad actual, de protocolos internacionales de garantía de calidad en los aspectos físicos de la radioterapia.

El establecimiento del Programa Nacional de Auditoria de Calidad (PNAC) es una etapa superior en los PGC en los servicios de radioterapia. El Centro de Control Estatal de Equipos Médicos es la entidad reguladora nacional para el control y supervisión de los equipos médicos del Sistema Nacional de Salud (SNS) y el responsable de la confección y ejecución del PNAC; para ello se apoya en un grupo tripartita integrado por el Instituto Nacional de Oncología y Radiobiología-Grupo Nacional de Oncología, responsable del fomento y supervisión de los PGC en los servicios de radioterapia y el Laboratorio Secundario de Calibraciones Dosimétricas del Centro de Protección e Higiene de las Radiaciones (LSCD-CPHR), encargado de garantizar las calibraciones de la instrumentación radiométrica y su traceabilidad como parte integrante de la red internacional de laboratorios patrón secundario OIEA.

Debido a la extensión geográfica de Cuba y al número de servicios de radioterapia (9), se seleccionó como modalidad principal de auditoria la visita de inspección *in situ*, además por las ventajas intrínsecas que esta opción representa, puesto que permite una revisión general de un gran número de aspectos del PGC, de manera directa y en presencia del físico responsable

de su ejecución en el servicio. En el presente trabajo se expone la metodología para la ejecución del PNAC.

2. Desarrollo

La política de calidad del CCEEM define como objetivo principal el cumplimiento de los requisitos de seguridad y de efectividad de todos los equipos médicos, previo a su introducción en el SNS y durante su utilización en el mismo, mediante el desarrollo de los procesos de evaluación de mercado, control regulatorio y vigilancia sanitaria, acorde a las normas nacionales e internacionales vigentes [2,3]. Dentro de dicha política se integra la confección del Procedimiento Normalizado de Operación (PNO) [4] como documento metodológico y normativo de la actividad de auditoria de calidad a estos servicios de radioterapia del PNAC implementado por el CCEEM. Además las instalaciones de radioterapia, como equipos emisores de radiación ionizantes de categoría relevante están sometidos a control regulatorio por el Centro Nacional de Seguridad Radiológica y Nuclear (CNSN), así como las actividades relacionadas con dichas instalaciones [5], auditorias de calidad incluidas, constituyendo este PNO parte de la documentación necesaria para la acreditación de la actividad de auditoria de calidad ante el CNSN.

El PNO describe detalladamente la forma de realizar las operaciones de rutina para garantizar la calidad y uniformidad organizativa del proceso de auditoria de calidad. En su parte inicial se define su objetivo, alcance, términos y definiciones empleadas y las responsabilidades. Como segunda parte se establece la composición del equipo auditor, condiciones de seguridad durante la realización de las visitas y los materiales y equipamiento necesarios a utilizar. Su tercera parte se refiere a las etapas de preparación y ejecución de la auditoria, el cálculo e interpretación de los resultados y la confección de los informes. Por último se definen lo registros de las visitas de auditorias. Además se anexan el protocolo para la recolección de evidencias objetivas y los modelos de recolección de datos. A continuación se explica de manera concisa la estructura antes mencionada.

2.1. Objetivo: su objetivo es establecer la metodología a seguir para la realización de las auditorias de calidad en instalaciones de teleterapia con unidades isotópica de ^{60}Co pertenecientes al SNS. Como objetivo específico documenta y garantiza el cumplimiento de los requisitos regulatorios establecidos por la autoridad competente.

2.2. Alcance: aplicable en el CCEEM, Departamento de Radiofísica, para la ejecución de las auditorias de calidad anuales a las instalaciones de teleterapia con unidades de teleterapia isotópica de ^{60}Co, de las instituciones asistenciales del SNS.

2.3. Términos y definiciones: se especifican conceptos pertenecientes al tema.

2.4. Responsabilidades: se definen las responsabilidades en la planificación, ejecución y control del procedimiento de auditoria de calidad en sí y de las garantía de las condiciones necesarias para lograr los objetivos de la auditoria, así como del entrenamiento y capacitación de los miembros del equipo auditor.

2.5. Condiciones de seguridad: se definen las garantías de la vigilancia radiológica individual del equipo auditor, se aclara la responsabilidad del equipo auditor de informarse acerca del manual de seguridad y el plan de emergencias radiológicas de la institución visitada y seguir las instrucciones y procedimientos en ellos establecidos para la operación

normal o en casos de accidentes radiológicos, además se aclara que la manipulación de la unidad de tratamiento y sus accesorios durante la toma de datos y comprobación del desempeño de los programas de garantía de calidad de radioterapia se harán solamente por el personal de la institución directamente encargado de dichas operaciones. Por último se especifica que los resultados de la auditoria son confidenciales.

2.6. Materiales y equipamiento: se detalla el tipo y estado requerido para el equipo radiométrico, accesorios y materiales necesarios para la recolección de evidencias objetivas.

2.7. Preparación de la visita de auditoria: para cada etapa se definen la responsabilidad de cada integrante del equipo auditor.

- ***a. Selección del equipo auditor:*** Selección de los especialistas que conformarán el equipo auditor de acuerdo a la experiencia teórica-práctica de los mismos, capacitación en el tema de auditorias de calidad y competencia institucional. Designación del auditor principal.
- ***b. Coordinación de la visita:*** Coordinación con el responsable del PGC del servicio a auditar de la fecha de visita. Envío de la comunicación oficial de la auditoria al responsable del servicio de radioterapia especificando: Objetivos, Composición del equipo auditor, Tipos de datos que se requerirán, Medidas a tomar, Tiempo requerido por las visitas, Número de secciones de trabajo, Tiempo por especialistas (físico médicos, oncólogo radioterapeuta, técnico radioterapeuta), Medidas y cálculos que se necesita sean realizados en la institución. Se envía además un modelo de información preliminar que se requiere al servicio sobre el PGC, datos utilizados en la práctica clínica, etc; de manera que se cuente con esa información antes de partir hacia la auditoria.
- ***c. Notificación de la visita:*** Notificación al responsable del servicio de radioterapia la fecha en que se realizará la auditoria, como mínimo una semana antes de la fecha fijada.
- ***d. Revisión preliminar:*** Revisión del modelo de información preliminar y análisis del mismo con vistas a orientar la ejecución de la auditoria a algún punto de interés.
- ***e. Asignación del equipo auditor:*** Asignación de las responsabilidades de cada miembro del equipo auditor en cuanto a las componentes del PGC a auditar.
- ***f. Equipos y accesorios:*** Preparación, gestión y verificación del estado (funcionamiento y aptitud: certificado de calibración, etc) de todo el equipo radiométrico, accesorios y materiales.
- ***g. Documentos de trabajo:*** Preparación de los documentos de trabajo pertinentes (modelos de recolección de datos, formularios, hojas de cálculo, tablas de datos, etc) para facilitar al equipo auditor las investigaciones, documentación e informe de los resultados

2.8. Ejecución de la visita de auditoria: para cada etapa las responsabilidades se delimitan según la asignación realizada a cada miembro del equipo auditor durante la preparación de la visita.

- ***a. Reunión de apertura:*** Presentación de los miembros del equipo auditor al responsable del servicio de radioterapia. Planteamiento del alcance y los objetivos de la auditoria, explicación de los métodos y procedimientos que serán utilizados en la auditoria, designación de un el eslabón de comunicación oficial entre el responsable y el equipo auditor. Se confirma que el equipo auditor tendrá acceso a los recursos y las áreas necesarias; así como la fecha y hora de la reunión de clausura y de cualquier otra reunión conjuntamente con el responsable. Esclarecimiento de cualquier detalle del programa de la auditoria
- ***b. Verificación de la información preliminar:*** Verificación de la información preliminar requerida a la institución en la comunicación oficial de la auditoria, concordancia con los registros presentes en el servicio, disponibilidad y utilización rutinaria de la misma por

personal capacitado (físico médico y técnico radioterapeuta). Se verifican además detalles administrativos del PGC en lo referido a: manual de garantía de calidad y de seguridad, registros de los controles periódicos de calidad, plan de emergencias radiológicas, cadena de mando para reporte de problemas, etc.

c. ***Recolección de evidencias objetivas:*** Realización de la recolección de evidencias objetivas de los aspectos a auditar en lo referente a: Seguridad de la instalación y la unidad de tratamiento, Aspectos mecánicos de la unidad de tratamiento, Aspectos dosimétricos de la unidad de tratamiento y Aspectos clínicos del tratamiento; según la metodología empleada en la puesta en servicio para cada prueba en específico y el protocolo anexado al PNO. Se completan los modelo de recogida de datos correspondientes a cada una de los aspectos por los miembros responsables del equipo auditor, constituyendo esto un registro para su documentación.
d. ***Cálculos e interpretación de los resultados:*** El protocolo de recolección de evidencias objetivas detalla y explica cada una de las pruebas en específico a realizar para cada aspecto a auditar, el procesamiento de los datos adquiridos y la interpretación de sus resultados, definiendo además sus tolerancias.
e. ***Reunión de clausura:*** Realización de la reunión de clausura de la auditoria en presencia del responsable del servicio de radioterapia, una vez concluida la recolección de evidencias objetivas y el esclarecimiento de las posibles no conformidades halladas. Se comentará el cumplimiento de los objetivos de la visita y se expondrán de manera preliminar los resultados hallados en la misma así como de las recomendaciones que el equipo auditor considere pertinentes; destaque que las mismas pueden estar sujetas a cambios debido a análisis *a posteriori*. Se confirma la fecha de entrega del informe final de la auditoria
f. ***Informe de la auditoria:*** Se especifica el formato del informe conteniendo en lo general: Datos de la institución auditada (incluyendo marca y modelo de la unidad de tratamiento), Fecha, Documentos de referencia utilizados (de la institución y del equipo auditor), Resultados de la recolección de evidencias objetivas, Posibles acciones correctivas tomadas en el curso de la visita, Recomendaciones y conclusiones. Se instruye además los medios y plazos para el envío del informe al servicio de radioterapia, las reglas de confidenciabilidad para su distribución y su registro.

2.9. Registros: se definen los registros necesarios para la organización del PNAC, sus procedimientos de archivo y compartimentación pertinentes dentro del Dpto. Radiofísica CCEEM.

2.10. Verificación: se define el responsable de la revisión y conformidad del PNO elaborado, dentro de la política de calidad del CCEEM. Además se aclara que el informe de la auditoria debe ser revisado por una tercera parte independiente del equipo auditor que cumpla con los requisitos exigidos para este.

2.11. Referencias/Documentos aplicables: bibliografía utilizada para la elaboración y ejecución del PNO.

2.12. Anexos: se adjuntan los Registros, Modelos de recogida de datos y el Protocolo para la recolección de evidencias objetivas. En lo referido al protocolo, está basado en lo fundamental, en las recomendaciones de un panel de expertos organizado por el OIEA dentro de las actividades del Programa Regional ARCAL XXX “Mejoramiento de la Garantía de Calidad en Radioterapia” [6].

3. Conclusiones y recomendaciones

El PNO aquí abordado constituye un paso inicial en la conformación del PNAC, como una etapa superior en la ejecución de los PGC en servicios de radioterapia; por resultar novedoso en nuestro contexto necesita de un período de puesta a punto y mejoramiento continuo. El PNO garantiza uniformidad en la estructura organizativa del PNAC, los criterios en cuanto a las tomas de medidas, la interpretación de los resultados y sus tolerancias. El PNO está dirigido únicamente a las instalaciones de teleterapia con unidades de isotópica de ^{60}Co. En lo referente al protocolo para la recolección de evidencias objetivas en los aspectos a auditar, se hace hincapié en los aspectos físicos del PGC, tratándose la parte clínica del tratamiento de manera menos profunda, aunque se comprueban casos típicos en la planificación de los tratamientos y la dosis de tratamiento impartida o unidades monitor (tiempo).

El PNO constituye una parte de la información necesaria para la certificación del PNAC ante las entidades reguladoras competentes en materia de seguridad nuclear.

Se recomienda complementar el PNAC mediante la modalidad de auditoria postal a través de las facilidades que brinda el LSCD-CPHR para mediciones con TLD, validando estos resultados con los registros de las auditorias postales realizadas por el OIEA a distintos servicios de radioterapia del país. Se debe completar y profundizar los aspectos clínicos del tratamiento como son los procedimientos clínicos utilizados, selección de las técnicas de tratamiento, sistemas computarizados de planificación de tratamiento, etc. Por último, el PNAC debe ampliarse a las instalaciones de braquiterapia y unidades de teleterapia de ortovoltaje, elaborándose la documentación metodológica y normativa para estas modalidades de la radioterapia

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PRELIMINARY RESULTS OF A NATIONAL QUALITY AUDIT PROGRAMME IN RADIOTHERAPY SERVICES IN CUBA

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Abstract

The current state of the radiotherapy in Cuba has allowed to pass to a superior stage in the process of the quality assurance, the establishment of a National Quality Audit Program (PNAC). The National Control Center for Medical Devices as national regulator entity for the control and supervision of the medical devices of the National Health System is the responsible for the implementation of this program. This paper presents the preliminary results of the execution of the PNAC in teletherapy services with isotopic units of ^{60}Co. The audits were carried out according to the methodology settled down in the normalized procedure of operation of the PNAC. The physical aspects related with the treatment were audited, such as: the installation and unit's safety, mechanical and dosimetric aspects of the treatment unit and organizational aspects of the institution quality assurance program. Also were carried out, in the clinical aspect, verifications of cases type planned by the qualified personnel of the service. The results corresponding to the determination of the reference dose for each institution were compared with those obtained in a postal audit with the International Atomic Energy Agency. These first audits allowed to evaluate the performance of the institutions' program of quality assurance and a feedback for the setting about to the PNAC.

1. Introduccion

En los últimos años en Cuba se han desarrollado proyectos internacionales de cooperación técnica con el Organismo Internacional de Energía Atómica (OIEA) dirigidos a la implementación de Programas de Garantía de Calidad (PGC) en los servicios de radioterapia y en la elaboración y adecuación a nuestra realidad actual, de protocolos internacionales de garantía de calidad en los aspectos físicos de la radioterapia. Además se ha adquirido nuevo equipamiento (instalaciones de teleterapia con unidades isotópicas de ^{60}Co) para sustituir y modernizar el existente en estos servicios, con muchos años de explotación. El Instituto Nacional de Oncología y Radiobiología-Grupo Nacional de Oncología (INOR) ha sido el responsable del fomento y apoyo a los PGC en los servicios de radioterapia. El establecimiento del Programa Nacional de Auditoria de Calidad (PNAC) es una etapa superior en los PGC en los servicios de radioterapia. El Centro de Control Estatal de Equipos Médicos es responsable de la confección y ejecución del PNAC; para ello se apoya en un grupo tripartita integrado conjuntamente con el INOR y el Laboratorio Secundario de Calibraciones Dosimétricas del Centro de Protección e Higiene de las Radiaciones (LSCD-CPHR), encargado este de garantizar las calibraciones de la instrumentación radiométrica y su traceabilidad como parte integrante de la red internacional de laboratorios patrón secundario OIEA.

En este trabajo presentaremos los resultados preliminares de las auditorias, visitas de inspección *in situ*, realizadas según la metodología establecida en el procedimiento normalizado de operación para la ejecución del PNAC [1]. Se auditaron 3 servicios de radioterapia de un total de 9. Además se comparan los resultados de la comprobación de la tasa de dosis de referencia en cada uno de los servicios auditados y su desempeño en la auditoria postal realizada por el OIEA.

2. Desarrolla

En cada visita de inspección el equipo auditor estuvo integrado por representantes del grupo tripartita. La recolección de evidencias objetivas, en un principio se realizó según las recomendaciones dadas por un panel de expertos en el marco del proyecto ARCAL XXX [2], dirigida fundamentalmente a la verificación de los aspectos físicos de la instalación y la unidad de tratamiento. Además se realizaron comprobaciones en la planificación de casos tipos, en lo referente a los aspectos clínicos del tratamiento, enviados a las instituciones previamente a la realización de la auditoria. El resumen de los principales resultados hallados se presenta para cada uno de los aspectos auditados en forma de tablas. Denotaremos a cada institución auditada por las letras a, b y c.

Tabla I. Aspectos de Seguridad de la Instalación y Unidad de Tratamiento

Resultados hallados y recomendaciones
Monitor estacionario de radiación del local: (a) fuera de servicio (b) sin conectar la indicación sonora (c) verificar si la alimentación externa es confiable
(a) Posición inadecuada de la cámara del circuito cerrado de TV, no permite visualizar el paciente y los indicadores de posición de la fuente ubicados en el cabezal del equipo simultáneamente
(c) Reparar el intercomunicador, para garantizar la necesaria comunicación paciente–operador
(c) Calibrar el monitor ambiental portátil del servicio

Tabla 2. Aspectos Mecánicos y Eléctricos de la Unidad de Tratamiento

Resultados hallados y recomendaciones
(a) Telemando, queda accionado el interruptor tipo “deadman” al accionar el movimiento de la camilla o del brazo de la unidad.
Láseres: (a) La comprobación diaria de los láseres y telémetro, debe ser supervisada por el físico semanalmente. (b) Desajuste frecuente de los láseres laterales (c) Precisar la no alineación de los láseres coronales en el sentido longitudinal de la camilla de tratamiento y corregir la falta de colinealidad entre estos.
Indicadores de distancia: (a) Reemplazar el comprobador de distancia colimador- isocentro de madera, por uno de un material más resistente y colocarlo en el local de los físicos. Emplear el puntero mecánico del fabricante para verificar mensualmente al comprobador de distancia de uso diario. (c) Reparar la falta de nitidez del telémetro
(b) Desajuste de la indicación del tamaño del campo de radiación correspondiente a la apertura de los colimadores en el caso del 10x10 cm^2 en la dirección opuesta al brazo

3. Conclusiones y Recomendaciones

Los tres servicios visitados cuentan con nuevo equipamiento para el tratamiento radiante y están licenciados por el órgano regulador nacional para el uso de la energía nuclear, cumpliendo los requisitos de seguridad y protección, y documentados los procedimientos requeridos legalmente: Manual de seguridad de la instalación y Plan de emergencias radiológicas. La problemática presentada en el aspecto de seguridad, en general, está relacionada con la conexión de los monitores estacionarios de radiación y casuísticamente con la comunicación (visual y oral) técnico- paciente.

Tabla 3. Aspectos Dosimétricos de la Unidad de Tratamiento

Resultados hallados y recomendaciones
Perfiles de los campos de radiación: (b) Realizar los cálculos de la planitud y la simetría, a partir de las mediciones de los perfiles del campo realizadas en la puesta en servicio de la instalación (c) Revisar y normalizar la técnica de procesamiento de las películas de verificación de forma que permita una adecuada interpretación de los parámetros a comprobar con las mismas
(b) Realizar y registrar las mediciones correspondientes al control de la estabilidad de los dosímetros con fuente de control de Sr-90.
(c) Medir los factores de las bandeja existentes en la instalación y compararlos con los instalados en los sistemas computarizados de planificación utilizados en la práctica clínica

Tabla 4. Aspectos Clínicos

Resultados hallados y recomendaciones
(a, b, c) Verificación manual de los cálculos derivados del uso de los sistemas computarizados de planificación de tratamiento.
(b,c) Selección adecuada del sistema computarizado de planificación de tratamiento según la técnica elegida tomando en cuenta las ventajas y limitaciones en la batería de planificación
(c) Se hallaron errores en la utilización de parámetros modificadores del haz durante la realización de los cálculos de comprobación de uno de los casos tipos planificados durante la visita, factor de bandeja y factor de campo incorrecto
(c) Uno de los sistemas computarizados de planificación de tratamiento utilizados, tiene instalado un factor de bandeja lisa, cuando el que se utiliza en la práctica es el de bandeja ranurada.

Tabla 5. Aspectos Organizativos del PGC y Registros

Resultados hallados y recomendaciones
Personal: (a) Se necesita otro físico médico en el servicio de radioterapia por la carga de trabajo de la misma. (b) Adiestramiento de personal técnico en las tareas de planificación, de manera que pueda contarse con una persona independiente en el proceso de verificación de los casos
(a, b, c) Elaborar un registros de incidencias de mal funcionamiento del equipo independiente de los controles de garantía de la calidad
(a, b, c) Disponer de un plan anual de ejecución de las actividades de control de calidad de la instalación, identificando el responsable de cada una y un registro para verificar su ejecución
(a, b, c) Protección Radiológica: debe realizarse un registro de mediciones de tasa de dosis ambientales en las zonas de la instalación y un registro de contaminación y fugas del cabezal
(a, b, c) Programa continuo de educación y entrenamiento con evaluaciones anuales al personal ocupacionalmente expuesto

Tabla 6. Comparación entre los Resultados de la Determinación de Dosis de Referencia y los de la Auditoria Postal OIEA

Institución	% desv. rel. Audit*	Fecha	% desv. rel. OIEA	Fecha
(a)	-1.6	17.11.1999	-1.9	10.12.1999
(b)	-0.1	20.12.1999	0.5	10.12.1999
(c)	-0.5	24.06.2000	-0.8	10.12.1999

*%desv.rel.=$100(D_{med}-D_{ref})/D_{ref}$

D_{med}: Dosis medida por la institución durante la auditoria para condiciones de referencia.

D_{ref}: Dosis de referencia clínica, medida durante la puesta de servicio de la instalación.

En los aspectos mecánicos y eléctricos, las unidades de tratamiento adquiridas han mostrado una excelente estabilidad. Por otra parte, la necesidad del ajuste de los láseres de posicionamiento ha sido la evidencia objetiva recurrente en cada servicio visitado.

La comprobación de la tasa de dosis en los aspectos dosimétricos de la unidad de tratamiento para las tres instalaciones auditadas arrojó la concordancia de las mismas dentro del 2% con respecto al valor clínico establecido durante la puesta de servicio y con los resultados de la auditoria postal OIEA. El temporizador de las unidades de tratamiento es reproducible y el error de entrada-salida de la fuente pequeño y en algunos casos despreciable.

En lo correspondiente a la verificación de las aspectos clínicos del tratamiento se persiguió mediante el envío de casos tipos de referencia para su planificación en el servicio, comprobar la técnica de irradiación elegida, la selección del sistema computarizado de planificación de tratamiento, considerando las ventajas y limitaciones de los disponibles en el servicio, así como las vías de comprobación de los resultados, cálculo manual de las unidades monitor (tiempo). En todos los servicios visitados los físicos-médicos están capacitados para realizar las comprobaciones manuales y es su firma en el expediente clínico la que avala la verificación de la planificación realizada, pero no queda registrada dicha comprobación en el expediente: valor de dosis de referencia utilizados, valores de los distintos modificadores del haz y su descripción, pesos de los campos (si los hubiera), etc. A criterio del equipo auditor esta sería un buena práctica para constatar la realización del cálculo de comprobación y permitir verificaciones posteriores de forma rápidas y diáfana.

En los aspectos organizativos del PGC se manifestó, para las instituciones (a, b), la necesidad de entrenamiento de personal que sustituya y/o apoye al físico-médico en la rutina clínica del servicio. En general se deben implementar registros que permitan documentar mejor el PGC detallando las acciones a ejecutar y que delimiten los responsable de las mismas, para extender la cultura de seguridad y calidad a todos los integrantes del servicio. Se constató una buena preparación, dedicación y compromiso con la calidad de los físicos-médicos en cada una de las instituciones visitadas.

Estas primeras auditorias permitieron poner a punto la metodología del PNAC y los procedimientos de recolección de evidencias objetivas detallados en el procedimiento normalizados de operación. Es evidente la necesidad de profundizar las auditorias en la verificación de los aspectos clínicos del tratamiento y la evaluación de los sistemas computarizados de planificación de tratamientos.

La exposición de los resultados de las auditorias se centró en las instalaciones de teletarapia con unidades isotópicas de ^{60}Co, de los servicios de radioterapia auditados; aunque en el caso de la institución (a) también se auditó un equipo de teleterapia de ortovoltaje.

Se recomienda la ampliación del PNAC a las instalaciones de teleterapia con unidades de ortovoltaje y a las instalaciones de braquiterapia de los servicios de radioterapia del país, confeccionando y validando la documentación necesaria para estos fines.

Es importante además prestar atención a la capacitación y entrenamiento del personal auditor en el desarrollo del PNAC, previendo las perspectivas inmediatas y futuras de este.

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IAEA-CN-85-170

ERROR PREVENTION IN RADIOTHERAPY TREATMENTS USING A RECORD AND VERIFY SYSTEM

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Abstract

Computerized record-and-verify systems (RVS) are being used increasingly to improve the precision of radiotherapy treatments. With the introduction of new treatment devices, such as multileaf or asymmetric collimators and virtual wedges, the responsibility to ensure correct treatment has increased. The purpose of this paper is to present the method that we are following to prevent some potential radiotherapy errors and to point out some errors that can be easily detected using a RVS, through a check of the daily recorded treatment information. We conclude that a RVS prevents the occurrence of many errors, when the settings of the treatment machine do not match the intended parameters within some maximal authorized deviation, and allows to detect easily other potential errors related with a incorrect selection of the treatment patient data. A quality assurance program, including a check of all beam data and a weekly control of the manual and electronic chart, has helped reduce errors.

1. Introducción

En los últimos años se vienen introduciendo en los Servicios de Radioterapia los sistemas de registro y verificación (RVS) que, entre otras cosas, permiten seleccionar datos de irradiación de los pacientes en los modernos aceleradores lineales de electrones (ALE) usados en radioterapia externa [1,4]. Estos sistemas constituyen un medio efectivo de verificar los datos de irradiación programados para el tratamiento de cada paciente, impidiendo aplicarlo si algún dato de la máquina se encuentra fuera de un margen previamente establecido o si no se ha colocado algún accesorio programado (bandeja, cuña, aplicador).

El objetivo de este trabajo es presentar el proceso que seguimos para tratar de evitar errores en los tratamientos radioterápicos, así como llamar la atención sobre algunas dificultades que pueden encontrarse usando los modernos aceleradores dotados de un sistema de colimación que permite definir campos asimétricos y dotados de cuñas virtuales, conectados a un sistema RVS.

2. Material y método

En nuestro hospital se dispone de dos ALE (Mevatron KD2 y Primus de Siemens) que están conectados a un sistema de RVS Lantis de Siemens (Sistema de información para redes locales), que, entre otras cosas, permite:

- seleccionar dentro de una lista el paciente que va a recibir tratamiento
- visualizar los datos clínicos y administrativos del paciente
- visualizar un resumen de las notas de configuración y campos de tratamiento a aplicar
- visualizar los parámetros de los campos de tratamiento
- la configuración automática del ALE: parámetros de consola, parámetros geométricos, accesorios y posiciones del colimador

- comprobar que los parámetros prescritos concuerdan con los reales
- registrar los parámetros dosimétricos de los campos sobre los que se ha administrado tratamiento
- configurar y realizar actividades de película portal.

2. Procedimiento seguido antes de iniciar el tratamiento de un paciente

La dosimetría clínica de cada paciente la realiza un físico o un dosimetrista, y es revisada siempre por un radiofísico.

El radioterapeuta cumplimenta la ficha de cada paciente en presencia del radiofísico y con los datos que éste le suministra relacionados con la colocación y el tratamiento del paciente. El radioterapeuta introduce los datos de la ficha de tratamiento en el sistema Lantis. En caso de que el tratamiento incluya un campo conformado con multiláminas, el físico introduce en el sistema Lantis la forma del campo.

El radioterapeuta autoriza los campos introducidos en el Lantis para el tratamiento de cada paciente.

Previamente a la primera sesión de tratamiento de cada paciente: Los ATS/técnicos de la sala de tratamiento comprueban que los datos de la ficha coinciden con los que muestra la pantalla del ordenador para ese paciente, y, en el caso de campos conformados, comprueban que su forma coincide con la que figura en las placas realizadas en el momento de la localización/simulación del tratamiento, dibujando la forma del campo sobre ellas, para su posterior revisión por el radioterapeuta.

El radioterapeuta y el radiofísico comprueban, a su vez, que los datos dosimétricos y de colocación que figuran en la pantalla coinciden con los usados en los cálculos dosimétricos. Se procede entonces a la colocación del paciente para recibir su primera sesión de tratamiento, en presencia del radioterapeuta y del radiofísico y éstos firman la ficha si todo está conforme.

Semanalmente, el radiofísico y el radioterapeuta, por separado, revisan las fichas de tratamiento y comprueban que coinciden los datos de dosis acumulada en cada campo y número de unidades de monitor para cada campo con los almacenados en el sistema Lantis.

3. Algunos errores que pueden cometerse/evitarse

A lo largo del tiempo de trabajo con los citados ALE, hemos podido ver que pueden surgir inicialmente algunos errores relacionados con la falta de costumbre de uso de las posibilidades que ofrecen (campos asimétricos, cuñas virtuales).

1º) Relacionadas con la tecnología de los nuevos ALE

En el caso de campos asimétricos se puede cometer un error si se traspasan directamente al sistema Lantis las dimensiones de las cuatro mandíbulas (X1,X2, Y1,Y2) utilizadas en el planificador y éste no tiene en cuenta el giro del colimador que se vaya a utilizar en el tratamiento.

Este error, que es fácilmente detectable en el posicionamiento del paciente, puede evitarse si previamente se establece una tabla de correspondencia de la posición de cada mandíbula considerada en el planificador, con la de la unidad de tratamiento, en función del ángulo de colimación utilizado. Al cumplimentar la ficha de tratamiento, resulta muy cómodo usar la citada tabla.

Otro posible error puede venir derivado de no estar familiarizados con las cuñas virtuales que se simulan moviendo una de las mandíbulas del ALE. Es preciso tener establecido claramente el modo de controlar cómo se forman las cuñas virtuales, sabiendo, según la orientación de la cuña que figura en los cálculos dosimétricos, qué posición deben ocupar las mandíbulas que delimitan el campo de tratamiento del paciente para que la cuña virtual se genere en la dirección y sentido debidos.

Este posible fallo puede controlarse de forma sencilla, bien fijando una pegatina en las mandíbulas del ALE que indiquen, según la orientación prevista de la cuña, qué mandíbula corresponde a la parte gruesa de la misma (por ejemplo, orientación 1 mandíbula Y1, orientación 2 mandíbula Y2) y comprobar en la primera colocación del paciente para su tratamiento que la ficha está perfectamente cumplimentada en cuanto a la identificación de la orientación de la cuña y ángulo de colimador para que la cuña se genere según se había previsto.

2º) Relacionadas con posibles confusiones de las personas que aplican los tratamientos a diario.

Además de los posibles errores de posicionamiento que se pueden evitar utilizando un sistema que controle los datos de irradiación del paciente mediante ordenador, hemos podido detectar en algún caso, al verificar semanalmente la coincidencia de las sesiones de tratamiento que figuran en la ficha con las que figuran en el sistema Lantis, que se había olvidado de tratar un campo, en un tratamiento con varios campos, o que se había olvidado de anotar en la ficha un tratamiento que sí se había efectuado.

También pueden producirse errores en la suma de las dosis que se van acumulando al cumplimentar la ficha de modo manual.

Estos raros errores, se pueden detectar fácilmente en las revisiones semanales disponiendo de un sistema RVS, no teniendo mayor transcendencia pero su existencia hace pensar que pueden ocurrir, y no ser detectados, en otras unidades que no dispongan de este tipo de sistemas.

También puede ocurrir que se llame a un paciente para que entre a la sala de tratamiento y que sea seleccionado el nombre de otro paciente en la pantalla del ordenador. Si, casualmente, la localización del tratamiento en ambos pacientes y los tamaños y formas de campo son similares, puede ocurrir que no se detecte la equivocación y se trate al paciente con un número erróneo de unidades de monitor, es decir, con una dosis inadecuada. Este error es más fácil que ocurra cuanto más automatizado sea el tratamiento en cuanto a los posibles accesorios que conlleve (bloques, cuñas). Si, por ejemplo, la cuña es virtual,s e generará según esté programada, pero si la cuña fuera física, debería coincidir para que se pudiera irradiar que la cuña programada para ese paciente coincidiera con la que tenía programada el paciente seleccionado de forma equivocada.

Este error puede verse favorecido por el modo de visualización de los nombres de los pacientes en la pantalla (por ejemplo, tamaño pequeño de las letras) en el momento de seleccionar el paciente, por el hecho de que la persona que aplica el tratamiento rellene la ficha, sin detectar que el número de unidades de monitor de la pantalla no coincide con el que figura en la ficha, ya que no sospecha su confusión.

Este fallo se puede detectar fácilmente porque cuando se selecciona de nuevo el nombre del paciente para su tratamiento, que esta vez sí que corresponde al paciente real, el sistema de RVS avisa de que el paciente ya se ha tratado ese día, pudiéndose entonces realizar las estimaciones de dosis necesarias.

4. Conclusión

El uso de un sistema de registro y verificación permite evitar un número significativo de errores y detectar otros en los tratamientos radioterápicos. También la introducción de aceleradores lineales de electrones con modernos sistemas de colimación permiten tratamientos más precisos, pero es necesario establecer bien la correspondencia entre los datos usados en el planificador y los introducidos en el sistema RVS para controlar la irradiación de cada paciente.

Es preciso establecer un programa eficaz para controlar que los tratamientos se llevan a cabo según lo programado y para detectar posibles errores. A ello contribuyen en gran medida las revisiones previas a la primera sesión de tratamiento de un paciente y la revisión semanal de la ficha. Una estrecha colaboración entre radioterapeutas, físicos y personas que aplican los tratamientos es de gran importancia, de forma que entre ellos se pueda transmitir la información y sistemática de trabajo de forma clara.

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IAEA-CN-85-79

MANUAL CROSS CHECK OF COMPUTED DOSE TIMES FOR MOTORISED WEDGED FIELDS

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Abstract

If a mass of tissue equivalent material is exposed in turn to wedged and open radiation fields of the same size, for equal times, it is incorrect to assume that the resultant isodose pattern will be effectively that of a wedge having half the angle of the wedged field. Computer programs have been written to address the problem of creating an intermediate wedge field, commonly known as a motorized wedge. The total exposure time is apportioned between the open and wedged fields, to produce a beam modification equivalent to that of a wedged field of a given wedge angle.

1. Introduction

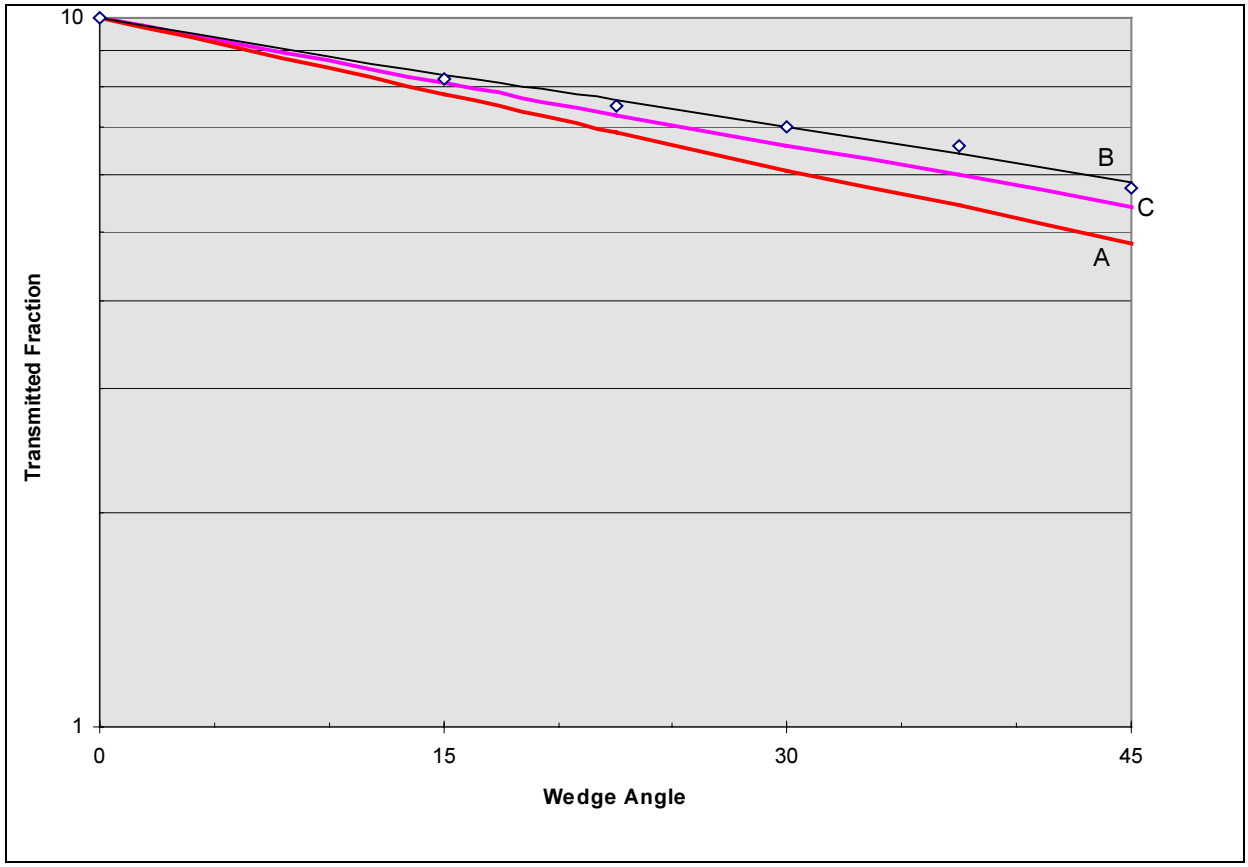
Manual cross check of open field dose calculations follows the usual pattern: -product of relative exposure rate, exposure rate of standard applicator/field, BSF/TAR/%DD gives the output in dose per unit time. Dividing the daily-prescribed dose by this result gives the exposure time. For a wedged field, inclusion of the wedge factor should produce a correct result. Manual planning essentially then, requires the mapping of isodose curves, using accurate depth dose curves supplied, to arrive at a dose maximum normalized to 100% of the prescribed dose, then applying the same calculation methods to arrive at the dose times.

With the advent of computer planning, the curves supplied are only relative and cannot be used for accurate isodose mapping. In the absence of curve mapping, calculations alone can produce acceptable accuracy with open fields and in some cases where identical opposing full-wedged fields are used. However, appreciable discrepancies are seen with non-identical fields and there is no simple way to manually check dose times when motorized wedges are employed. This paper then is an attempt to devise such a method that will give approximately +/-7% error that is accepted for machine output exposure rates.

2. Material and methods

Motorized wedges are routinely used in the tangential fields for treatment of post mastectomy patients. Having created a symmetrical chest wall shape of average size and separation, that would require a full 45-degree wedge, the data is entered and the dose times determined for a given prescribed dose. The 6w x 15 cm wedge field used is generated on the computer at the most accurate calculations matrix. A pair of such fields is then used on the test outline for apping of the isodoses, arriving at the normalization dose and subsequent calculation of dose times in the usual manner, with the inclusion of the given transmission factor for the wedge. Calculation of the dose time by the manual method shows agreement to within +/-3%.

The most logical approach from here was to make a semilog plot of percentage transmission vs. Wedge angle, connecting the two points 100% for the open field and 48.5% for the full wedge, plot A of Fig. 1 this transmission factor was determined practically, by dosemeter measurements in the open and wedged beams. The above exercise was then repeated, this time using an outline appropriate for a half wedge, 22.5 degrees. The corresponding transmission value was taken from the curve and used in the calculation as before. The manually calculated



dose time was 2.24 minutes whereas the computed dose time was 2.2 minutes. There is no way of determining how the time is is apportioned between the wedge and the open fields. This is precisely what the computer does and we are forced to accept it.

An asymmetric shape was now drawn which was typical of the average breast outline and using the same 6w X 15 wedge, 25 and 30 degree wedges were found to be appropriate. The calculation times, manual 2,45 minutes, computed 2.21 minutes. This represents an eleven percent error, which is outside the accepted range. The source of error is apparently the value of the transmission factor used, since the prescribed dose and the field sizes are unchanged. A closer look at the generated fields revealed that the central axis depth doses appeared greater than expected, supporting the reason for not using them in isodose mapping. In order to approach this problem form first principles, an open 6 X 15 filed was constructed from depth dose tables, [1] from which a family of curves of percentage depth dose against field size for fourteen different depths was constructed, and from which depth dose values for 6 x 15 field at the corresponding depths, were taken. A curve of percentage depth dose against depth for the 6 X 15 field of equivalent square 8.5 cm was made, and from which values could be taken for 90% to 35% in increments of ten. These values were then used to draw isodose curves for a 6 x 15 open field. The comparison with the computer-generated field shows that the percentage depth doses of the computed field are approximately 7% greater. If the open field for the 15 x 20 dimension is deduced in a similar manner, the factor is of the same order, being 6.4% since the computer is programmed to use the 15 w x 20 wedge for all breast plan cases, wedge curves of this dimension for 15, 22.5, 30, and 37.5 degrees were generated, each set of curves being normalized 0.5 cm below the surface and 1.0 cm in from the thin end of the wedge. The corresponding open field curves generated were normalized at the same point as the wedged curves.

The open field is superimposed on the wedged fields in turn and a transmission factor for each wedge is determined by using the ratios of the isodose values on the central axis, at equal displacements on both sides and for four successive depths. The mean values of the transmission factors were found to be in excess of those deduced from the graph used for half wedge factor value. The transmission factors were adjusted by the factor in the previous paragraph, 0.936 and then plotted on the semilog curve as Plot B adjacent to Plot A, the line for straight line through the points was drawn and a third line, Plot C was constructed by taking the mean between these two lines. This mean line was then used to determine transmission factors for other wedge combinations and acceptable agreement in the does times was seen for a 25deg / 30deg wedge combination used on the asymmetric outline which is more often the general case. An attempt was made at constructing the equivalent symmetrical outline for which 27.5-degree wedges were used and again acceptable agreement was realized. Unfortunately the results for the full wedge and the 22.5 degree wedge showed a greater deviation than when the lower curve was used.

The prescribed dose in all cases was 4000 CGy in 15 fractions of 267 CGy at 100% for the chosen dose point. The table below shows the results for dose times using transmission factors based on plots A and C compared with the computed dose times. This method, though crude, gives a measure of satisfaction to the physicist who would otherwise be forced to blindly accept the computed calculations.

Table 1: Comparison of results for different wedge combinations

WEDGE COMBINATIONS	DOSE TIMES FOR METHOD PLOT A	COMPUTED	PLOT C
Full 45.0 degrees	3.178	3.13	2.94
Half 22.5 degrees	2.24	2.20	2.07
Symmetric 25 deg	2.374	2.23	2.22
Asymmetric 25/30 deg	2.45	2.23	2.232

Reference

[1] Cohen, M., Jones, D.A.E. and Greece, D. Central Axis Depth Dose Data for Use in Radiotherapy Supplement Number 11. British Journal of Radiologt, British Institute of Radiology, London 1978. P. 59 Table 6.3. PERCENTAGE DEPTH DOSES : 80 cm SSD for Cobalt 60 gamma rays.

QUALITY ASSURANCE OF THE TREATMENTS PERFORMED WITH A LINEAR ACCELERATOR BY MEANS OF IN VIVO DOSIMETRY

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Abstract

In vivo dosimetry by means of diode detectors has been used in routine in our hospital since 1996 to guarantee the dose administrated to patients undergoing a radiotherapy treatment. The aim of this work is to present how in vivo dosimetry was implemented in our centre and which kind of errors have been discovered and corrected. Before the implementation it has to be clear which kind of errors want to be traced, the tolerance and action level and who will perform the measurements and who will evaluate them. Once all these things are clear, the first thing to do is to choose the more appropriate type of diodes and to calibrate them. The lower is the tolerance level the more accurate the calibration has to be. At this point the training and motivation of people who will be involved is very important to succeed implementing in vivo dosimetry in routine. Choosing one treatment unit and one easy and frequent treatment technique is a good way of starting implementation. We started with prostate treatments. In vivo entrance and exit doses were measured and dose to the ICRU point was calculated. Nowadays in vivo dosimetry is performed in the second session of all treatments (X-rays and electrons).

1. Introducción

Aunque actualmente el cálculo de la dosis al paciente en un punto determinado, puede especificarse con precisión suficiente, el problema que se plantea es garantizar que la dosis prescrita por el radioterapeuta y calculada por el radiofísico se corresponda con la recibida realmente por el paciente. Actualmente la única forma de conocerlo es mediante la dosimetria in vivo durante las sesiones de tratamiento.

La utilización de dosimetría in vivo mediante detectores semiconductores (diodos) requiere una elección adecuada del tipo de diodo y una correcta calibración de los mismos, que contemple todos aquellos factores que influyen en la determinación de dosis bien sea a la entrada o a la salida del paciente [1-2].

En este trabajo se presenta la implementación de la dosimetría in vivo en la práctica clínica en este Centro desde 1996 para una unidad de tratamiento.

2. Material

Acelerador lineal Clinac 1800 (Varian) con energías de haces de fotones 6 y 18 MV y haces de electrones de 4, 6, 9, 12 y 16 MeV. Equipo de dosimetría in vivo, DPD-510 con juego de detectores para las diversas energías, EDP-10 (6 MV), EDP-30 (18 MV), QED *negative output* (18 MV) y EDD2 (haces de electrones). Maniquí de láminas de poliestireno o de "plastic water" y cámaras de ionización cilíndrica y plano-paralela para calibración de diodos.

3. Tipo de Detección de Errores

Con las medidas a la "entrada" del haz puede comprobarse la reproducibilidad de las irradiaciones, verificar los parámetros de tratamiento y también determinar indirectamente la dosis al volumen blanco.

La realización de medidas a la "salida" sirven para detectar cambios o errores en el espesor o composición del paciente, y si estas se combinan con las de entrada permiten además comprobar el algoritmo de cálculo de la dosis.

4. Metodología de Implementación

La implementación de la dosimetría in vivo en rutina obliga a definir un procedimiento que abarca diversos aspectos, tales como: quien debe realizar las medidas, cuando, quien las evalúa, que nivel de tolerancia y nivel de acción hay que fijar, saber cada una de las personas envueltas en el proceso como deben actuar en cada momento y considerar el registro y evaluación global de las medidas.

En este Centro la implementación práctica se decidió iniciarla en una técnica de irradiación simple y de uso frecuente. Para ello se eligió la próstata que se trata con una técnica isométrica de 4 campos ortogonales y conformados con haces de fotones 18 MV. Primero se irradia la pelvis con 44 Gy y luego tiene lugar una sobredosis en la glándula prostática hasta 70 Gy.

El Servicio de Radiofísica diseñó una hoja para la recogida de datos del paciente. En ella los/las dosimetristas anotan los datos suministrados por el propio sistema de planificación (profundidad del punto ICRU, espesor del paciente, tamaño del campo, porcentaje de dosis en profundidad en el punto ICRU, en plano medio, a la entrada, a la salida, etc.) [3].

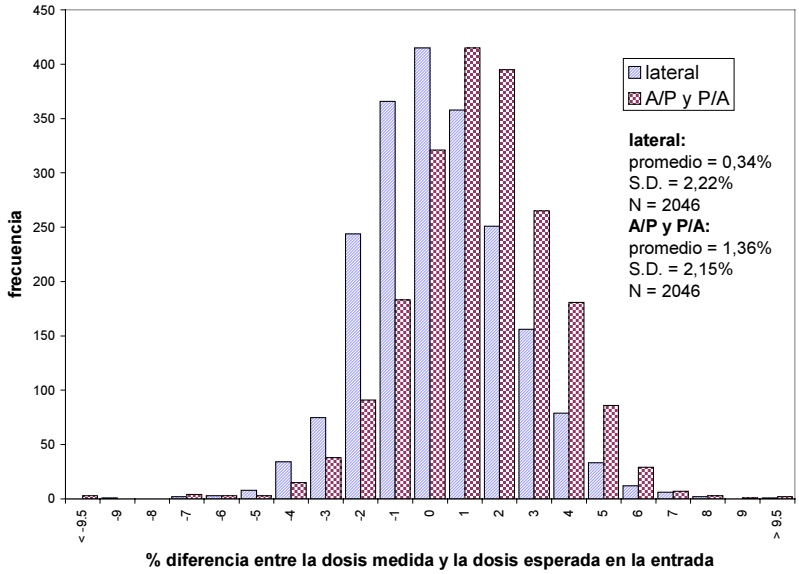
Para contrastar el cálculo de la dosis en el punto ICRU se elaboró un algoritmo de cálculo a partir de las medidas in vivo a la entrada y a la salida.

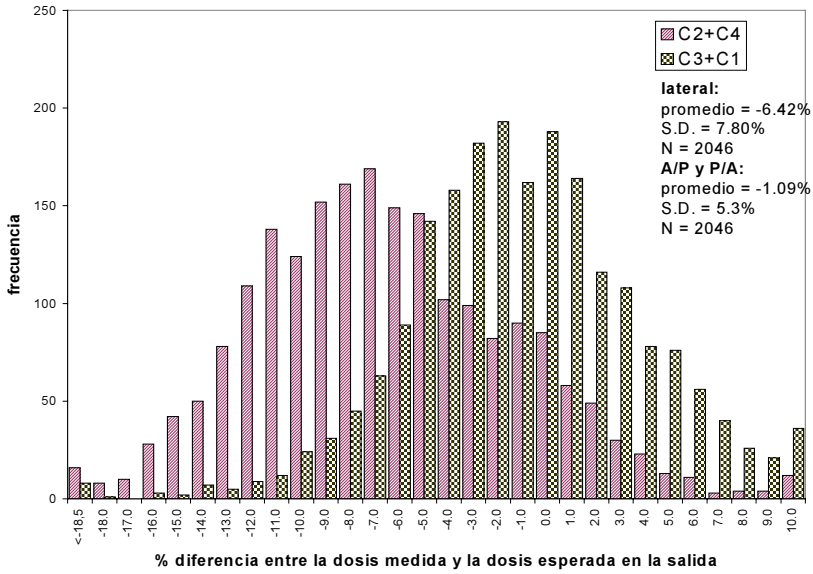
Se establecieron los niveles de tolerancia y de acción en la determinación de la dosis a la entrada y al punto de prescripción de dosis (punto ICRU). En nuestro caso se ha elegido el mismo nivel de tolerancia que de acción en cada caso y se fijó inicialmente en ±5% tanto para la dosis a la entrada como para el punto ICRU.

Tabla I.. Resumen de los promedios de desviaciones entre las dosis esperadas y las dosis obtenidas mediante DIV para tratamientos de prostata. N = 2046 con 1 contorno y N = 532 con CT.

	Campos A/P y P/A				**Campos laterales**			
	1 contorno sin corrección por heterogeneidades		CT con corrección por heterogeneidades		1 contorno sin corrección por heterogeneidades		CT con corrección por heterogeneidades	
	Promedio %	S.D	Promedio %	S.D	Promedio %	S.D	Promedio %	S.D
Entrada	1.36	2.15	1.33	1.90	0.34	2.22	-0.17	1.80
Salida	-1.09	5.30	1.12	4.34	-6.42	7.80	-1.68	5.51
Punto ICRU	0.32	3.14	1.31	2.50	-2.06	4.43	0.57	3.20

La dosimetría in vivo la efectúan los técnicos de la unidad de tratamiento en la segunda sesión de cada una de las partes del tratamiento y cuando se ha modificado algún parámetro en el mismo. Se coloca en el centro de cada campo un diodo a la entrada y otro a la salida del haz, se apuntan las lecturas y se hace la primera revisión sobre la dosis a la entrada. Cuando la dosis a la entrada está fuera del nivel de tolerancia, se tiene que revisar todos los parámetros de tratamiento indicados y señalar cual de ellos no es correcto.





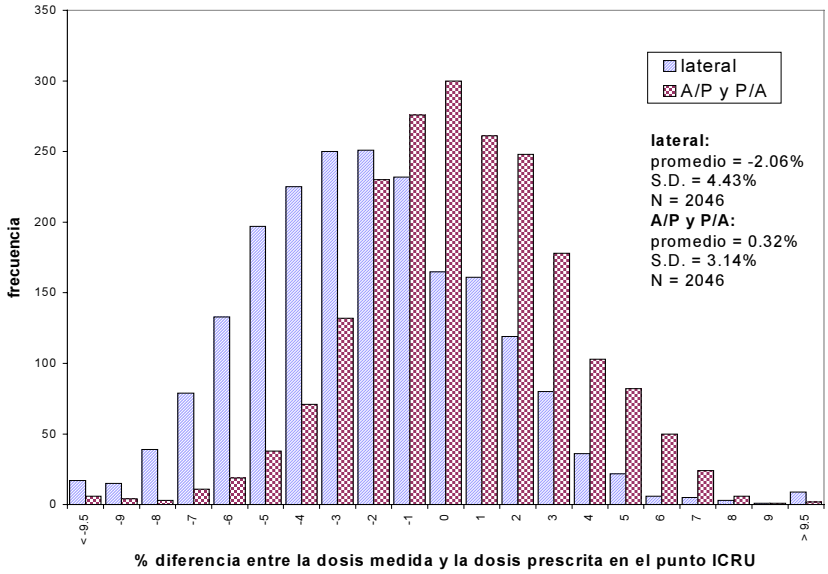


Fig. 1 Histogramas de frecuencia para tratamientos de prostata

Una vez realizada la dosimetría in vivo y cuando las dosis de entrada están dentro de los niveles de tolerancia el radiofísico introduce los datos en la hoja de cálculo y hace la evaluación correspondiente, teniendo en cuenta los factores de corrección. Se compara las dosis a la entrada y a la salida con las dosis medidas y la dosis prescrita con la calculada en el punto ICRU, en este caso haciendo uso del algoritmo de cálculo desarrollado en el propio centro e independiente del sistema de planificación.

5. Resultados

En la figura 1 se muestra el histograma de frecuencias que contiene una serie de 2046 dosimetrias in vivo de próstata. La figura se ha desglosado en tres apartados:

a) % de diferencia entre la dosis calculada y medida a la entrada
b) % de diferencia entre la dosis calculada y medida a la salida
c) % de diferencia entre la dosis calculada a partir de la dosimetría in vivo y la prescrita en el punto ICRU.

Se observa una mayor desviación a la salida que a la entrada, esto obedece a que existe más dificultad de colocación del diodo a la salida.
Posteriormente se introdujo en rutina la planificación 3D que contempla la corrección por heterogeneidades. En la tabla I se indican las diferencias encontradas entre la planifición 2D (sin corrección por heterogeneidades) y 3D.

Las desviaciones superiores al 5% en la dosis de entrada se debían primero a que el diodo se había girado o caído, segundo a algún error en la colocación del paciente como distancia foco-superficie, tamaño de campo o unidades de monitor y finalmente a un error en la introducción de los factores de calibración de los diodos.
Las desviaciones superiores al 5% en la prescripción de la dosis fueron debidas a un cambio en el contorno del paciente entre la planificación y el inicio del tratamiento y a las prótesis incorporadas al paciente y cuya composición no contemplan los sistemas de planificación.

Posteriormente y después de analizar este proceso de implantación, se decidió extender la aplicación de la dosimetría in vivo a otras técnicas de tratamiento, tales como las técnicas isocéntricas con haces de fotones, y también a los tratamientos con haces de electrones. En estos casos sólo se coloca un diodo en la puerta de entrada de cada haz.

Actualmente puede decirse que prácticamente todos los pacientes tratados mediante el acelerador lineal son controlados con dosimetría in vivo.

6. Conclusión

La dosimetría in vivo es un medio de control de calidad relativamente fácil, exacto y que consume poco tiempo en la unidad de tratamiento. Permite comprobar la dosis prescrita durante el tratamiento del paciente y es un control independiente del sistema de cálculo.

Referencias

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[3] JORNET,N., RIBAS, M., EUDALDO T., CARABANTE D., DUCH,M.A., GINJAUME, M., ISERN, J. Quality assurance in radiotherapy by in vivo dosimetry with diodes during prostatic treatments. Med. Biol. Eng. Com. Vol 35, supplement Part 2: 1082 (1997).

IAEA-CN-85-268

IAEA RADIATION EVENTS DATABASE (RADEV)

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Abstract

Whilst the use of ionizing radiation continues to bring benefits to many people throughout the world there is increasing concern at the number of reported accidents involving radiation. Such accidents have had an impact on the lives of patients, workers and members of the public, the consequences of which have ranged from trivial health effects to fatalities. In order to reduce the number of accidents and to mitigate their consequences it is, therefore, necessary to raise awareness of the causes of accidents and to note the lessons that can be learned. The IAEA's database on unusual radiation events (RADEV) is intended to provide a world-wide focal point for such information.

1. Introduction

The use of radiation sources and radioactive material is well established throughout the world and brings substantial benefits to society when used in a safe and controlled manner. The IAEA, in addition to facilitating the transference of technology that utilizes the constructive properties of ionizing radiation, has a statutory function to establish international standards of safety and to provide for their application. The International Basic Safety Standards [1], which were jointly sponsored by FAO, IAEA, ILO, OECD/NEA, PAHO and WHO, establish requirements for protection against the risks associated with exposure to ionizing radiation and include a substantial appendix on Medical Exposure.

Even though many governments have adopted these international standards into their national arrangements, the large number of radiological accidents that have been reported worldwide implies that numerous radiation sources are not managed or regulated appropriately. Indeed, IAEA has, with the cooperation of Member States, already published a number of reports of accidents with significant consequences in order to provide feedback and identify lessons to be learned [2, 3].

Global awareness of the magnitude and seriousness of the problem was raised in September 1998 at the first international conference on the 'Safety of Radiation Sources and the Security of Radioactive Material' held in Dijon, France.

The conclusions of this conference were drawn to the attention of the IAEA Board of Governors at the General Conference. Subsequently, the IAEA Secretariat was requested to prepare and implement an *Action Plan* on the 'Safety of Radiation Sources and the Security of Radioactive Material'. The *Action Plan*, which was endorsed by the Board of Governors and the General Conference in 1999 covers the following seven areas: regulatory infrastructures; management of disused sources; categorization of sources; response to abnormal events; information exchange; education and training; and international undertakings. One of the actions under 'Information Exchange' is for the IAEA secretariat to fully develop and maintain an international database on unusual radiation events (RADEV) and to make it available to Member States.

2. BSS requirements for accidental Medical Exposures

As mentioned above, the BSS [1] includes requirements for Medical Exposures, amongst which are specific requirements relating to accidental medical exposures (as given below). RADEV has been designed to capture the details and lessons to be learned from such accidents.

The following is an extract from Appendix II (Medical Exposures) of the BSS:

II.29. Registrants and licensees shall promptly investigate any of the following incidents:

(a) any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or with a dose or dose fractionation differing substantially from the values prescribed by the medical practitioner or which may lead to undue acute secondary effects;
(b) any diagnostic exposure substantially greater than intended or resulting in doses repeatedly and substantially exceeding the established guidance levels; and
(c) any equipment failure, accident error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.

II.30. Registrants and licensees shall, with respect to any investigation required under para. II.29:

(a) calculate or estimate the doses received and their distribution within the patient;
(b) indicate the corrective measures required to prevent recurrence of such an incident;
(c) implement all the corrective measures that are under their own responsibility;
(d) submit to the Regulatory Authority, as soon as possible after the investigation or as otherwise specified by the Regulatory Authority, a written report which states the cause of the incident and includes the information specified in (a) to (c), as relevant, and any other information required by the Regulatory Authority; and
(e) inform the patient and his or her doctor about the incident.

3. Overall Objectives of RADEV

Capturing information about accidental medical exposures is only part of RADEV's remit. On a broader scale, RADEV includes many different types of events that have occurred outside the nuclear power programme. The overall objectives of RADEV are to:

(a) disseminate information on radiation events and feedback lessons that may help to prevent future accidents, or mitigate their consequences should they occur, and
(b) provide a tool to help Member States, the IAEA and other organizations to identify priorities in their radiation safety programme to facilitate the efficient allocation of resources.

In order to achieve these general objectives a centralized RADEV database is being established at IAEA's headquarters in Vienna to:

(a) provide a repository of information on accidents, near-misses and any other unusual events involving radiation sources not directly involved in the production of nuclear power or its fuel cycle;

(b) categorize events in a standardized manner to facilitate the search for events fitting particular profiles, the identification of causes and the lessons to be learned;
(c) provide a means to analyze trends in radiation events; and
(d) provide summary descriptions of events that can be used directly as training material.

RADEV is designed to capture lessons to be learned from radiation events and is not meant to be a real-time on-line database. A separate IAEA initiative is concerned with developing a 24-hour reporting system for missing and found orphan sources.

4. Events to be included

General Events

- events or potential events involving patients, workers or members of the public;
- events involving radiation sources which have been lost, found, stolen, or subject to unauthorized and inadvertent transfer/sale; and
- events that occurred during the transportation of sources that result or could have resulted in the loss or degradation of control of radiation sources.

Events Involving Patients

Many types of radiation events involving patients have been reported, including:

- Wrong patient exposed
- Wrong tissue exposed (correct patient)
- Wrong radio-pharmaceutical administered
- Wrong activity administered
- Wrong beam settings
- Delivered dose different from intended

The consequences of such events include: ineffective treatment, ineffective diagnosis, severe radiation burns, severe degradation in quality of life and, in some cases death directly attributable to high radiation exposure. Many of these events were caused by deficiencies in, or a lack of: design, testing and calibration of equipment; education, training and qualification of personnel; procedures; defense in depth; quality assurance. In some cases, events involving patients have also resulted in exposures of hospital workers, lost sources and exposures of members of the public.

5. Management and operation

The database has been designed to operate on a personal computer using Microsoft Access 97 or above. Copies of the RADEV software will be provided to selected organizations within Member States for their own use and users will be requested to provide data to IAEA on a regular basis. IAEA will be manage and operate the international RADEV database and will act as the central focal point for all users. IAEA will publish regular summary reports from RADEV and will provide electronic updates of the data to participating organizations. Confidentiality will be maintained by IAEA at all times and details such as names of individuals, hospitals and factories will not be divulged.

6. Implementation

The RADEV project is being implemented in 3 phases:

Phase 1: Establishment of the database. IAEA will collect currently available details of radiation accidents and test the software.

Phase 2 : Limited international trials. IAEA will provide a working version of RADEV to several international and national organizations (including professional organizations in the medical field) for testing and evaluation. Feedback from the trials will be reviewed by IAEA and any necessary changes made to the software.

Phase 3: Distribution of RADEV. IAEA will collect data from participating organizations, compile international statistics and produce summary reports. Electronic copies of the summary reports and the updated database will be available to participating organizations.

The current status at time of the Malaga Conference is that Phase 1 has been successfully completed and international trials are taking place.

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IAEA-CN-85-165

METHODOLOGY FOR THE APPLICATION OF PROBABILISTIC SAFETY ASSESSMENT TECHNIQUES (PSA) TO THE COBALT-THERAPY UNITS IN CUBA

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Abstract

The applications of PSA techniques in the nuclear power plants during the last two decades and the positive results obtained for decision making in relation with safety, as a complement to deterministic methods, have increased their use in the rest of the nuclear applications. At present a wide set of documents from international institutions can be found summarizing the investigations carried out in this field and promoting their use in radioactive facilities. Although still without a mandatory character, the new regulations of radiological safety also promote the complete or partial application of the PSA techniques in the safety assessment of the radiological practices. Also the IAEA, through various programs in which Cuba has been inserted, it is taking a group of actions so that the nuclear community would encourage the application of the probabilistic risk methods for the evaluations and decision making with respect to safety. However, the fact that in any radioactive installation it has not still been carried out a complete PSA study, makes that certain methodological aspects require to be improved and modified for the application of these techniques. This work presents the main elements for the use of PSA in the evaluation of the safety of cobalt-therapy units in Cuba. Also presents, as part of the results of the first stage of the Study, the Guidelines that are being applied in a Research Contract with the Agency by the authors themselves, which belong to the CNSN, together with other specialists from the Cuban Ministry of Public Health.

Resumen

La amplia utilización de las técnicas de APS en el sector nucleoenergético durante las pasadas dos décadas y los positivos resultados obtenidos para la toma de decisiones en materia de seguridad, como complemento de los métodos deterministas, han incentivado su utilización en el resto de las aplicaciones de la esfera nuclear. Son cada vez más frecuentes los documentos de prestigiosas instituciones internacionales que resumen las investigaciones realizadas en este campo y promueven su utilización en instalaciones radiactivas. Aunque aún sin un carácter mandatorio, las nuevas regulaciones de seguridad radiológica también promueven la utilización completa o parcial de las técnicas de APS en la evaluación de seguridad de las diferentes prácticas. Asimismo el OIEA, a través de diversos programas en los que Cuba se ha insertado, está tomando un grupo de acciones para que la comunidad nuclear priorice la aplicación de las técnicas probabilistas de riesgos en la evaluación y toma de decisiones en materia de seguridad. Sin embargo, a pesar de ser una metodología con probada eficacia en el sector nucleoenergético, el hecho de que en ninguna instalación radiactiva se haya realizado aún un estudio completo de APS, hace que existan determinados aspectos metodológicos que requieran profundizarse y adaptarse para la aplicación de dichas técnicas. En el presente trabajo se discuten los principales elementos tenidos en cuenta para la utilización de los APS en la evaluación de la seguridad de las unidades de cobaltoterapia de Cuba y se presenta, como parte de los resultados de la primera etapa del Estudio, la Guía Metodológica que está siendo utilizada en un Contrato de Investigación del OIEA que actualmente realiza el colectivo de autores del CNSN, de conjunto con otros especialistas del Ministerio de Salud Pública (MINSAP).

1. Introducción

La evaluación de la seguridad ha descansado tradicionalmente en el enfoque prescriptivo, es decir, la evaluación del cumplimiento de determinados códigos y normas que resumen los resultados de la evidencia histórica, la investigación y el desarrollo en un momento dado, así como la comprobación mediante análisis deterministas en los que se utilizan las hipótesis más desfavorables para comprobar que ante el peor accidente previsible no ocurren consecuencias radiológicas graves y por tanto se garantiza que los resultados de las evaluaciones queden del lado de la seguridad.

Este enfoque tiene a favor que la demostración de correspondencia es relativamente directa, a la vez que asegura niveles aceptables de seguridad, integridad y fiabilidad. El método determinista es incuestionable, sin embargo posee limitaciones que hacen conveniente el uso de un enfoque complementario para la evaluación. Entre estas limitaciones están:

- Las **regulaciones** descansan en requisitos precisos y detallados, por lo que **tienen una rigidez intrínseca** que puede ser rápidamente rebasada por nuevos desarrollos tecnológicos.
- Los **factores humanos y organizacionales** que influyen en la seguridad **son poco propensos a la evaluación prescriptiva**.
- El enfoque prescriptivo **puede inhibir la innovación** y la búsqueda de soluciones más óptimas para incrementar la seguridad.
- Posee el riesgo de que el diseñador o el operador puede no entender la esencia o razón de ser de las regulaciones, preocupándose simplemente por su cumplimiento. Esto es, este enfoque promueve una ***"cultura de cumplimiento"*** más que la búsqueda de la seguridad máxima factible por los medios mejores posibles.

Existe otro enfoque complementario de evaluación de la seguridad denominado "*Análisis Probabilista de Seguridad (APS)*", que utiliza herramientas conceptuales y matemáticas para realizar una investigación sistemática, exhaustiva y estructurada de los diferentes escenarios de riesgos que pueden conducir a un evento no deseado (*secuencias accidentales*) a partir de la ocurrencia de fallos de equipos o errores humanos (*sucesos iniciadores de accidentes*).

En las últimas dos décadas, el APS ha sido ampliamente utilizado en el sector nucleoenergético, realizándose decenas de estudio en los países con centrales nucleares, y obteniendo positivos resultados para la toma de decisiones en materia de seguridad, como complemento de los métodos deterministas.

El principal objetivo de un APS consiste en proporcionar información cualitativa y cuantitativa acerca de las interioridades del diseño y funcionamiento de una instalación, incluyendo la identificación de los contribuyentes al riesgo y comparación de opciones para incrementar la seguridad.

Es decir, la finalidad de un APS se puede resumir en:

- Determinar y precisar las combinaciones de sucesos que pueden conducir a un accidente o evento no deseado;
- Evaluar la probabilidad de que se produzca cada combinación;
- Evaluar las consecuencias.

Con este fin, la metodología de APS integra información sobre el diseño, practicas de operación y funcionamiento, historial operacional, fiabilidad de equipos y componentes, comportamiento humano, fenómenos favorables a un accidente y efectos potenciales.

Toda esta información es utilizada para lograr que los posibles incidentes, deficiencias, errores y vulnerabilidades de la instalación, proporcionen un panorama equilibrado de su efecto sobre la seguridad, así como la importancia relativa de las contribuciones al riesgo de las secuencias de accidente que podrían iniciarse a causa de fallos en el equipo o las modalidades de operación.

2. Metodología para la ejecución del APS

Para cualquier instalación o práctica, la realización de un Análisis Probabilista de Seguridad comprende las 6 etapas fundamentales que se representan en el diagrama en bloques de la Fig. 1.

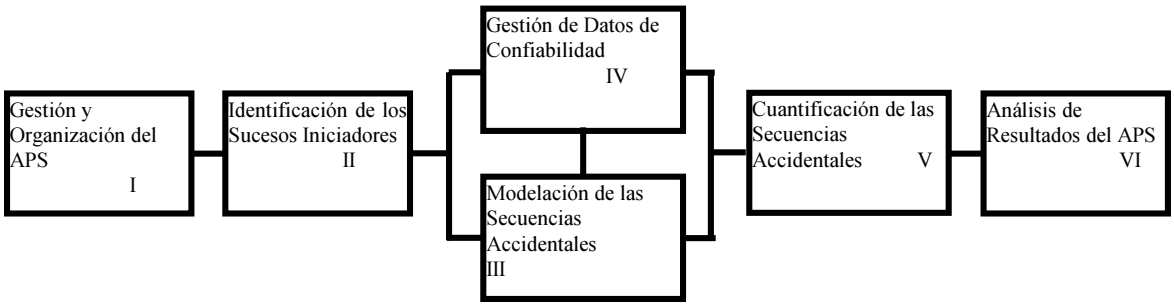

Figura 1. Pasos para la Ejecución del APS

Aunque en principio los métodos de APS pueden ser aplicados a cualquier tipo de instalación, existen un grupo de aspectos que requieren profundizarse para garantizar su plena utilización metodológica, teniendo en cuenta los siguientes elementos:

1. Alcance del estudio
2. Naturaleza y complejidad de la instalación,
3. Grado de introducción del APS en instalaciones similares,
4. Disponibilidad y detalle de los análisis deterministas de seguridad,
5. Idoneidad de los modelos para la instalación
6. Disponibilidad y calidad de los datos de fiabilidad
7. Incidencia e importancia del factor humano en las secuencias accidentales a estudiar.

Especial atención en la aplicación de la filosofía del APS a la práctica de cobaltoterapia, máxime cuando el Estudio está enfocado hacia la seguridad del paciente, debe prestarse a hecho de que muchas de las características de las exposiciones potenciales que se identifiquen serán mayoritariamente generadas por actuaciones humanas, por lo que el APS, en gran medida será un análisis específico y detallado de los factores humanos que intervienen en las secuencias accidentales.

Teniendo en cuenta este aspecto, y las limitaciones que existen para la estimación de las probabilidades de errores humanos; y considerando que es muy elevado el número de posibles actuaciones humanas, el APS deberá utilizar con el mayor nivel de detalle posible las técnicas cualitativas de identificación de peligros y la evaluación de las incertidumbres en las probabilidades asignadas.

Es por esta razón, que a pesar de la existencia de documentos metodológicos para la realización de un APS, y de su utilidad práctica, se han adaptado para la ejecución de los Análisis Probabilista de Seguridad a las prácticas de cobaltoterapia en Cuba las diferentes etapas para la aplicación del Estudio, según se presenta en el diagrama en bloques de la Fig. 2.

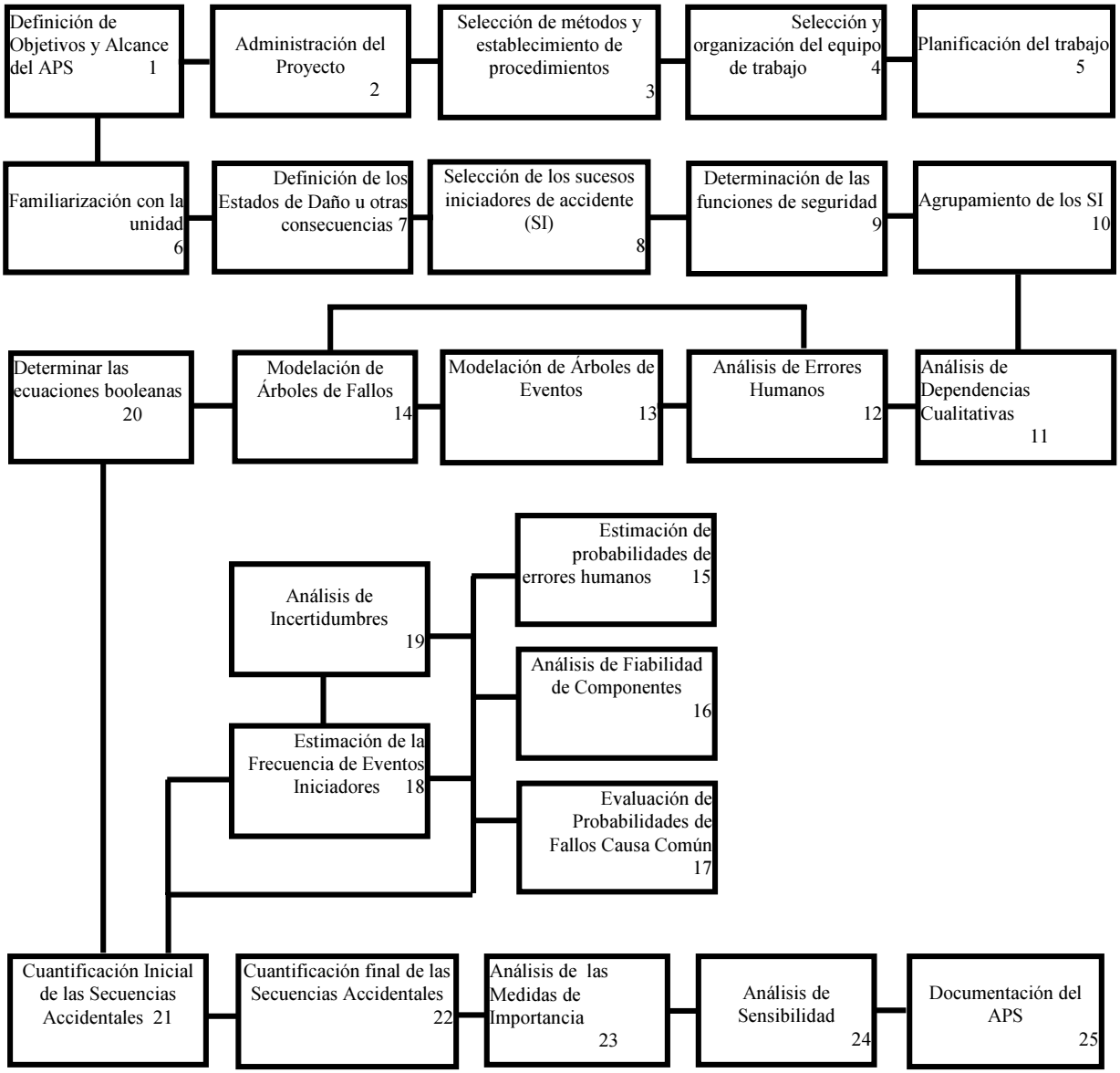

Figura 2. Diagrama en bloques de la Guía Metodológica para la ejecución del APS a la práctica de cobaltoterapia en Cuba

En sentido general, la metodología tiene en cuenta los siguientes puntos:

- Identificación de peligros o accidentes con consecuencias importantes que pueden tener lugar durante el tratamiento con cobaltoterapia *(estado de daño)*
- Identificación de cómo se puede llegar a iniciar las secuencias de sucesos que conlleven a los estados de daño identificados *(sucesos iniciadores de accidente)*. Para ello se combinarán diferentes métodos, que de una forma sistemática y exhaustiva permitan garantizar que la posible ausencia de un suceso iniciador de accidente, no tendrá un aporte relativo significativo, con respecto a todos los considerados en el Estudio.
- Determinación de los efectos sobre el paciente, el trabajador ocupacionalmente expuesto y el público, a partir del análisis de los modos de fallos de los equipos y los posibles errores humanos en las diferentes etapas del tratamiento con cobaltoterapia.

- Desarrollo de los árboles de sucesos que representen las secuencias posibles.
- Análisis, por medio de árboles de fallos de los cabeceros modelados en los árboles de sucesos.
- Cuantificación de las probabilidades asociadas a los sucesos iniciadores y a los sucesos básicos en los árboles de fallos.
- Análisis de la fiabilidad de las acciones humanas que figuren en los sucesos iniciadores, en los árboles de sucesos o en los árboles de fallos
- Cuantificación de las frecuencias anuales de las diversas secuencias y peligros identificados en el primer paso.

Para esta primera etapa del Estudio, no se realizarán de forma *exprofesa* estudios médicos detallados de los accidentes identificados y las secuencias modeladas, así como no se cuantificarán en términos económicos o de daños humanos las consecuencias consideradas en los estados de daño, por lo que no se integrará el riesgo desde el punto de vista cuantitativo, aunque sí será válido desde el punto de vista cualitativo.

Es decir, en esta primera etapa, el estudio solo tendrá un alcance de "*Análisis Probabilista de Seguridad (APS)*" y no de un "*Análisis Probabilista de Riesgo (APR)*"[1].

3. Conclusiones

El trabajo resume los principales elementos tenidos en cuanta durante la realización de la "Guía Metodológica para la aplicación de las técnicas de Análisis Probabilista de Seguridad (APS) a las unidades de cobaltoterapia en Cuba".

Este documento constituye el primer resultado de un proyecto de investigación para la evaluación de la seguridad del paciente durante la práctica de cobaltoterapia en el país.

La metodología incluye la aplicación conjunta de más de 5 técnicas de identificación de riesgos, que posibilitarán el análisis exhaustivo, sistemático y estructurado de la práctica en Cuba.

A su vez, la *Guía* podrá ser utilizada por nuestro órgano regulador como material de referencia durante la evaluación de Estudios similares que se realicen en el país como parte del proceso de licenciamiento de las diferentes instalaciones radiactivas.

[1] En rigor, un Análisis Probabilista de Riesgo se deberá corresponder con la siguiente definición de riesgo:

$$R = \sum_i P_i \cdot \sum_j D_j$$

donde:

P_i: probabilidad de ocurrencia del accidente i

D_j: daño j; consecuencias del accidente, que deberán incluir tanto la salud como las socioeconómicas, y en cuyo cálculo se incluye la magnitud de cada dosis.

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IAEA-CN-85-265

NORMAL TISSUE DAMAGE IN RADIOTHERAPY DEVELOPMENT OF A CLINICAL AUDIT TOOL

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Abstract

Radiotherapy treatments are evaluated by two main outcomes, rates of cure or local tumour control and normal tissue complication rates. Many excellent schemes have been devised for recording the late effects of radiotherapy treatments including the RTOG and LENT SOMA Scales. These have proved invaluable in documenting the outcome of clinical trials, but have proved too complex and time consuming for routine daily use in busy departments. A group in Eindhoven led by Professor Lybeert undertook a pilot study of a potential way of auditing late radiation complications. Using a simplified form derived from the LENT SOMA scales, they collected data on grade 3 and 4 complications in a total of 675 patients and were able to correlate a number of particular complications with specific protocols, ICD codes and physician practice. Further review of the case records made it possible to identify specific factors which may have led to toxicity and could be taken into account to modify treatment protocols. From September 1999 clinicians in participating centres undertaking normal follow-up procedures were asked to identify patients who showed evidence of grade 3 or 4 toxicity as defined in the pro-forma. Date of radiotherapy was recorded so that a temporal correlation of complication with treatment could be made, but this study did not attempt to assess the incidence of complications, but to provide a cross-sectional study of prevalence. Centres participating in the study have been Eindhoven, Köln, Gent, Brussels, Glasgow, Mount Vernon, Madrid, Genova and Lyon. In Eindhoven 651 reports were collected between January 1995 and December 1999. 89 reports had to be discarded because complications were not validated by the reviewing radiotherapists. Dr Lybeert noticed that individual radiotherapists appeared to have different thresholds for reporting specific complications. 13 patients deaths appeared to be related to radiation problems. An overall level of detection of morbidity was approximately 9%. It was possible to link morbidity with specific protocols. Some of these employed large doses per fraction and in some cases these were given in combination with chemotherapy. In the second phase of the study, patients undergoing routine follow-up at the Beatson Oncology Centre were also studied. Forms were completed by the reviewing oncologist and checked and analysed separately by two other radiotherapists. So far a total of 7645 forms have been placed. Of these 4372 have been completed and at routine follow-up 8.9% of these have recorded grade 3 or 4 toxicity. Preliminary analysis of the data suggests again a correlation of large dose per fraction or concomitant chemotherapy with radiotherapy related problems. It is hoped that this study will be completed by December 2000. Comparison of data from different centres will be made. Data from Lyon and Mount Vernon have been extracted from existing databases. It is hoped that there may be some consistency in results which may provide a benchmark for a useful audit tool. This approach will be discussed in relation to the need to develop a simple prospective recording of late morbidity. Keywords: Radiotherapy, Morbidity, QA, Clinical audit** MORQA Project , funded by the “Europe Against Cancer Programme “ of the EU

1. Introduction

Quality assurance programmes in radiotherapy are essential to ensure accuracy in treatment delivery, to optimise local tumour control and survival and to avoid as far as possible any undesirable late consequences.

The European Society of Therapeutic Radiology and Oncology with EU funding set up such programmes in 1998 with two components ;
(1) EQUAL – a European QA network
(2) MORQA – a programme designed to measure the prevalence of complications of treatment in patients who are cured of cancer.

2. Background

Radiotherapy treatments are evaluated by two main outcomes, rate of cure or local tumour control, and normal tissue complication rates. Many schemes have been used for recording late effects of radiotherapy treatments, including the RTOG and Lent-Soma scales. Although these have been used widely in documenting the outcome of clinical trials, they are complex and time consuming to record and therefore have not proved a very practical tool in busy clinical practice. There is still a need for a simple method of assessment. In particular, there would be great value from having a system which enabled the early detection of complications which were associated with a specific protocol or treatment approach, especially when new treatments are being introduced.

3. MORQA – Pilot Study

In 1995, Professor Lybeert set up a programme for registration of late morbidity in his department in Eindhoven. The existing instruments developed by major collaborative groups for measuring toxicity of treatment have proved too complex for routine daily use. He therefore used a simplified form derived from the Lent-Soma scale to collect data on Grade 3 and 4 toxicity in 675 patients over a period of 5 years. His group was able to correlate a number of particular complications with specific protocols, ICD codes and physician practice using cluster analysis techniques and the work led to changes in the patient management within the department. On the basis of his experience, this instrument was adopted as a tool for the main MORQA study.

4. MORQA – Methodology

11 centres in Europe participated in the study after initial site visits to document their structure, function and ability to collect data appropriately.

From September 1999, clinicians in participating centres undertaking routine follow-up care of patients treated with radiotherapy were asked to identify those who showed evidence of Grade 3 or 4 toxicity as defined in the pro forma. Information was sought about the date of radiotherapy (for temporal correlation of complication with treatment) and other treatments given (to assess the effect of treatment interactions). It was recognised that this study could not assess the incidence of complications but only provide a cross-sectional study of prevalence.Completed forms and patient files were assessed by two independent observers. Regular network meetings were held to monitor the progress of the study.

5. Results

A number of different follow-up practices were observed in the participating centres. It was striking that few centres had a fully comprehensive policy of following treated patients, which would be essential for obtaining data on incidence of complications. Because of this variation in practice, the data were collected in several different ways. Data were considered to be complete and representative in 4 of the 11 participating centres. From 1 centre (Mount Vernon), results from a prospectively collected database could be used to determine incidence of complications in patients with two particular types of tumours.

The majority of the effects recorded developed within the first 5 years after treatment although new complications were still recorded at 10-20 years after treatment. Other

treatments given at or near the time of radiotherapy may increase complication rates. We observed that many patients had had surgery or chemotherapy which may have contributed to the outcome. Cluster analysis for the data from Eindhoven has shown correlations with particular schedules of treatment but this could not be confirmed for the overall group of patients where clusters appeared rather to occur in association with the commonest types of tumours. Over and under reporting of side effects was noted. Clinicians unfamiliar with radiotherapy practice often ascribed effects to the treatment which were unconnected (eg. problems with dentition after radiotherapy for carcinoma of the cervix) and doctors with less experience in the specialty might fail to recognise side effects to which radiotherapy may have contributed. There was clear evidence of general lack of knowledge in this area. Review of the endpoints documented showed that some were useful and easily defined (myelitis) whereas others were rarely used (fatigue) or difficult to assess (dyspnoea). It was clear that patient and physician estimates of the severity of a problem could differ.

6. Conclusions and recommendations

1. There is no agreement on how patients who have been treated for cancer should best be followed to determine
(a) local control rates
(b) overall survival
(c) consequences of treatment
These three endpoints are essential for determining whether a new treatment represents a real improvement over an existing one (ie. shows an improvement in therapeutic ratio and not just a higher cure rate at a greater cost).
Recommendation - The development of strategies for patient surveillance is a target for future quality assurance programmes.
2. There is wide-spread ignorance about the consequences of successful treatment for cancer and the interactions of various components of the treatment. An education programme is needed to improve this situation. Collaborations should be set up with other European Cancer groups (ESSO and ESMO through FECS) to study treatment interactions.
Recommendations_- New ESTRO teaching programme on care of the cured patient and consequences of cancer treatments.
Joint initiative with FECS to study treatment outcomes.
3. The established instruments for recording outcomes of treatment are effective within clinical trials settings but too complex for routine practice. Further work is needed to develop a simple tool. This present study shows that it should contain only a small number of items (or it will not be used) and more work is needed to validate these items. Patient's views must contribute to the overall assessment of outcome.
Recommendations - Further discussion to reach a consensus at a European/International level on ways of recording outcomes of treatment.
Development of a way of recording patient's view of treatment outcome.
4. Cluster analysis (used routinely in other branches of science) does not seem to be a sensitive method for use in the study of treatment side effects probably because they are rare and affected by many factors other than radiation alone.
5. It is difficult to show a direct correlation between specific dosimetric estimates (from the EQUAL Study) with particular outcomes because the variation due to errors in radiotherapy delivery is small and co-morbidity and effects of other treatments influence radiotherapy outcomes. Nevertheless dose response curves for complications can be derived and the theoretical improvement to be expected from the QA programme calculated.

Recommendation - Continuation of both aspects of the QA programme is essential to optimise outcomes of treatment.

7. Future programme

The network meetings led to an international meeting MITRE, set up to discuss the issues of identifying, monitoring, recording, eliminating or treating undesired consequences of treatment. This meeting held in Brussels in December 2000 was attended by 160 participants from 29 countries and led to the production of a consensus statement for a strategy for future studies. Application will be made to the Commission of the European Union for funding to continue and develop the programme of quality assurance in cancer treatment

Acknowledgement

This study was made possible thanks to the support of the “Europe Against Cancer “ Programme of the EU.

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Topical Session 8b

RADIOLOGICAL PROTECTION OF PATIENTS IN RADIOTHERAPY: BRACHYTHERAPY

ACCURATE ASSESSMENT OF THE DISTORTIONS PRODUCED BY THE TRANSIT DOSE IN HDR BRACHYTHERAPY

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Abstract

Current polynomial methods used in the modelling of the dose distributions in HDR brachytherapy have been reformulated to improve accuracy. An example is provided to show the effects of the transit dose on the output. The transit dose, which is neglected by current computer software for calculating doses, can result in significant dosimetric errors. These additional unrecognised doses imply over-dosing and distortions in the dose distributions within the irradiated volume. Assessment of dose to critical and radiosensitive organs is therefore inaccurate. These could increase late tissue complications as predicted by the Linear Quadratic Model. Our model works very well for straight catheters and is highly recommended for the evaluation of the transit dose around such catheters.

1. Introduction

Every HDR application results in source dwell and transit doses. Dose calculation formalisms that incorporate the transit dose have been suggested for dose calculations in HDR brachytherapy by Houdek *et al.* [1], Bastin *et al.* [2] and later improved by Cho and Muller-Runkel [3]. Houdek's [1] report on the determination of the transit dose was an oversimplification as it assumed that none other than the inverse square law attenuation was involved. Bastin *et al.* [2] made direct measurements with TLD chips as well as writing an algorithm to represent the transit dose distributions in HDR brachytherapy but observed a startling difference of *18.2 %* (on the average) between their measured values and their own algorithm. This is not surprising, as they assumed isotropic dose distributions, coupled with errors introduced by the finite sizes of the TLD chips. Cho and Muller-Runkel [3] incorporated anisotropy but assumed anisotropy does not depend on radial distance. This could lead to very serious errors as there is, on the average uncertainties of $\pm$*10 %,* from distances within a short range of *1 - 10 cm* from the centre of the source.

In this investigation, current recommended parameters [4,5,6,7] have been used. The anisotropy and the radial dose distribution functions have been hybridised and a model for the calculation of the transit doses, based on the hybridised function, is developed.

2. Method

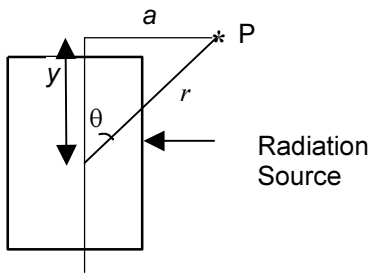

FIG. 1. The geometrical definition of r and θ for a filtered radiation source

The dose rate at a point P above is defined as follows [7,8,9].

$$\dot{D}(r,\theta) = S_k \Lambda_0 \frac{G(r,\theta)}{G(r_0,\theta_0)} F(r,\theta)\, g(r) \quad \ldots\ldots \quad (1)$$

From point – source approximation $G(r,\theta)=1/r^2$ [10] where $r^2 = y^2+a^2$. Now $G(r_0,\theta_0)$ and Λ_0 are constants and the product $g(r)F(r,\theta)$ is a function of the linear displacement y as shown in fig. 1 and so

$$\frac{\Lambda_0 g(r) F(r,\theta)}{G(r_0,\theta_0)} = F(y)\ \{function \quad of \quad y\} \quad \therefore\ d[D(r,\theta)] = S_k \frac{F(y)}{y^2 + a^2} dt\,.$$

Generally $G(r_0,\theta_0) = 1$. From the relationship between y and $F(y)$, we make use of a linear-linear polynomial expressed to the minimum possible degree to represent $F(y)$ hence $F(y) = A + By + Cy^2$ where A, B & C are constants. The source attains a finite velocity V when in motion, resulting in transit dose of magnitude $D(r,\theta)$ deposited at a point P and satisfies

$$V = \frac{dy}{dt} \therefore dt = \frac{dy}{V} \Rightarrow d[D(r,\theta)] = S_k \frac{F(y)}{y^2 + a^2} \frac{dy}{V} \quad \ldots\ldots \quad (2)$$

When the source moves from position y_1 to position y_2 with an average velocity V,

$$D(r,\theta) = \frac{S_k}{V} \int_{y_1}^{y_2} \frac{A + By + Cy^2}{y^2 + a^2} dy = \frac{S_k}{V} \left[Cy + \frac{D}{a} \arctan\left(\frac{y}{a}\right) + \frac{B}{2} \ln(y^2 + a^2) \right]_{y_1}^{y_2} \quad \ldots\ldots\ldots \quad (3)$$

where $D = A - C a^2$.

Assuming none other than the inverse square law attenuation,

$$D(r,\theta) = \frac{S_k \Lambda_0}{aV} \left[\arctan\left(\frac{y}{a}\right) \right]_{y_1}^{y_2} \quad \ldots\ldots \quad (4)$$

When a = 0 eqn. (3) and eqn. (4) become

$$D(r,\theta) = \frac{S_k}{V} \left[\frac{-A}{y} + B \ln y + Cy \right]_{y_1}^{y_2} \quad \ldots\ldots\ldots \quad (5)$$

and $D(r,\theta) = \frac{S_k \Lambda_0}{V} \left[\frac{-1}{y} \right]_{y_1}^{y_2}$ ..... (6) respectively.

2.1. Calculations and results

Figure 2 below simulates a linear implant with (thirteen) 13-dwell positions and an inter-dwell spacing of *0.25 cm*. A,B,C & D are calculation points.

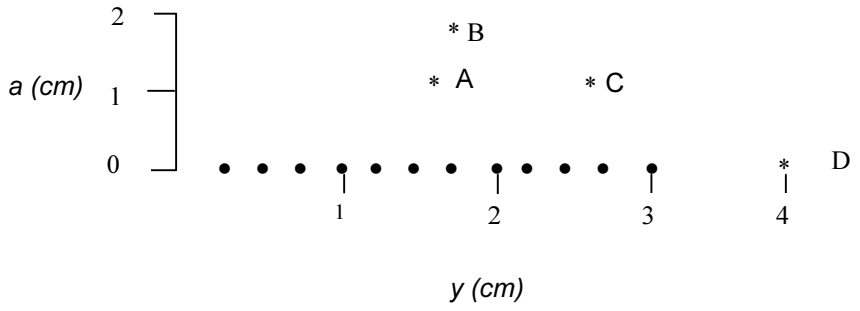

FIG. 2. Illustration of example: •, dwell point; ∗, calculation point

The value of S_k is *11.3056 cGy cm² s⁻¹* [11] and Λ_0 = *1.111* [12] for a *370 GBq* ^{192}Ir source (Mallinckroft Medical B. V.). *V* was obtained from the table provided by Houdek *et al* [1]. The inter-dwell transit doses and the exit doses within the same region, D_T were calculated from eqns. (3) & (5). If the volume of the tissue preceding the proximal dwell site is negligibly small, the entry and exit transit doses D_E, resulting from the travel between the HDR unit and the proximal dwell site could be evaluated from eqns. (4) & (6). The total transit dose is hence $\boldsymbol{D_{ET} = D_E + D_T}$**.** Anisotropy and radial dose profile data generated by Russell *et al* [12] has been used in our dose calculations. The Computer Programme MATTLAB was used to evaluate the constants *A, B & C* in the expression $F(y) = A + By + Cy^2$ for $0 < \theta < \pi/2$ and $\pi/2 < \theta < \pi$ respectively, within the range $0 \leq y \leq 20$ *cm*. Within this range the data was split into two depending on the point at which we observed a discontinuity in the dependence of *F(y)* on *y*. For the special angles $\theta = 0, \pi/2 \& \pi$ the desired accuracy was achieved by using one single equation to parametrize *F(y)*.

TABLE I: Calculated transit doses D_T, D_E & D_{ET} at selected points:

	A	B	C	D
D_T(cGy)	1.918	0.630	1.616	0.489
D_E(cGy)	0.291	0.228	0.186	0.121
D_{ET}(cGy)	2.209	0.858	1.802	0.610

3. Discussion and conclusion

The best results, for example those compatible with the objectives of HDR conformal brachytherapy are obtained by using small inter-dwell distances, that in turn permit fine variation of dwell times. Transit doses are however higher for such distances as the speeds are relatively low. To reduce the risk of late tissue complications, an increased fractionation schedule is applied in HDR relative to LDR brachytherapy. Since source movement is inherent during each HDR treatment cycle, the total transit dose is linearly increased with the number of fractions. Higher transit doses are therefore experienced in order to achieve the best results in HDR brachytherapy. The transit dose is directly proportional to the source strength and smaller catheter diameters will also increase the transit surface doses to proximal tissues. All together, the transit dose has no definite relationship with the static dose but varies widely among patients and different treatment schedules. This leads to over-dosing and more seriously, a distortion of the dose distributions within the irradiated volume.

Consider for example the case of "base of tongue" cancer being treated with interstitial brachytherapy. A common fractionation schedule is to give *3 Gy / fraction / twice / day*. If *3 Gy* is given at a distance of *1 cm* from a straight catheter we observed that the transit dose contributed, on the average up to *0.7 %* of the total dose. For three of such catheters parallel to each other separated by *1.0 cm* the total transit dose at the prescription point "A" (with respect to the central catheter) works out to be *5.3 cGy*. Extending this to two of such planes parallel to each other such that one is exactly above the other and separated by just *0.5 cm*, the transit dose is seen to contribute up to *3.4 %* of the total dose at point "A". So, as the complexity of the implant increases the contribution by the transit dose becomes more significant and can go above *10 %*, in addition to the distortions that may result. From the magnitude of the contributions by the transit dose only, we may be operating outside acceptable limits if the transit dose is neglected and this will go a long way to affect the outcome of treatment.

Our model reproduced the data used [12] within an accuracy of *0.05 %,* which is a marked improvement over the work done by earlier investigators [1,2,3]. On the whole, the physical sizes and shapes of patients as well as heterogeneity effects have not been taken into account. The calculations were based on data from an infinite homogenous phantom [12]. We have started some work on applicators of complex geometry, using Monte Carlo Simulations. Heterogeneity effects from tissues, internal shields and air will be addressed. Scatter integration algorithms will also be written to correct for finite patient sizes and shapes.

Brachytherapy using high dose rate afterloading is increasingly used worldwide for treating interstitial, intracavitary, intraluminal and percutaneous malignancies, owing to its inherent advantages over standard LDR brachytherapy. Current computer software for calculating doses in HDR brachytherapy neglects the transit dose. The contribution of the transit dose to the total dose is however very significant in some cases, especially if we aim at true conformal therapy, in line with the principles of HDR brachytherapy. A failure to account for the transit dose therefore means unreliable output in dosimetry. We strongly advocate for the transit dose to be incorporated into all high dose rate treatment planning systems. This will ensure accuracy in prescription and the assessment of potential risks to patients. Our model works very well for straight catheters and we recommend this very highly for the calculation of doses around such catheters. Apart from the example discussed, our model would work perfectly well, when the transit path preceding the proximal dwell site goes through an appreciable thickness of tissue e.g. in the case of endobronchial brachytherapy. With further development, the methods of calculation could be simplified, whilst not compromising accuracy.

Acknowledgements

We are grateful to Dr. S. Osae, Scientific Officer of the Ghana Atomic Energy Commission for his assistance in preparing this paper.

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IAEA-CN-85-22

METHODOLOGY FOR COMPREHENSIVE PATIENT, WORKER AND PUBLIC RADIATION PROTECTION CONSIDERATIONS WHILE INTRODUCING NEW MEDICAL PROCEDURES

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Abstract

Patient protection is a major consideration while introducing new medical procedure. But protection of the workers and the public should be considered too. A methodology of combining non-patient radiation protection considerations, with the introduction of new medical procedures is described. The new medical procedure was the Intracoronary Gamma Irradiation for the Prevention of Restenosis, by using Iridium 192 gamma radiation sources. The usual authors responsibility is the licensing of the use of radioactive materials while keeping public protection. According to this responsibility, the methodology's original orientation is public protection. As a result of coordination between several competent authorities, managed by the authors, the methodology was adopted for patient and worker protection too. Applicants, actually possible users (hospitals) of the new procedure, were obliged to plan medical procedures and working area according to dose limits and constrains as recommended by the International Atomic Energy Agency and local competent authorities. Exposure calculations had to consider the usual parameters as sources types and activity, dose rate and dose levels, duration and number of treatments. Special attention was given to the presence workers and public by chance presence in or near treatment area. A usual condition to give a license was the installation of continues (during treatment) radiation monitoring systems. But a special attention was given to physical barriers and procedures in order to stop unauthorized personal to arrive near to working area. Satisfactory stuff training for normal operation and emergency situations are essential, including appropriate safety procedures and the presence of safety assistance team while executing treatment

1. Notification and justification

Catheter based intracoronary radiation plus stenting, or after stenting, is quit a new medical procedure [1]. There was a search for means to control restenosis following balloon angioplasty, and Intracoronary Gamma Irradiation is one of the promising of the anti-restenosis strategies [2]. Two types of radiation are used - gamma and beta. In this paper we will discuss only the use of gamma radiation.

One of the first obligations of any potential user of radiation sources is the notification of the competent authority [3]. This was done when a local representative of a producer of gamma-radiation anti-restenosis system, notified us about the wish to introduce the procedure to our country.

First radiation protection requirement is the justification of the practice. In our country different competent authorities has different responsibilities. The duty of justifying medical procedures is Ministry of Health's. A meeting of all parties concerned - Ministry of Health, Ministry of Labor, hospitals representatives was organized under the supervision of The Ministry of The Environment, Radiation Safety Division. All aspects of the new procedures were explained in detail. Applicants had to persuade that the new procedure produce sufficient benefit to the patients and the society to offset the radiation harm that it might cause [3]. Some period later Ministry of Health gave the approval, namely - the justification.

2. Limits, constrains and optimization

Next radiation protection requirement is the optimization of protection and safety. The applicant have to make this optimization, based on guidance provided to him by the competent authority. In this case, the competent authority is Radiation Safety Division of The Ministry of The Environment. Based on BSS-115 standards, our country adopted the maximum dose limit for exposure of individuals of the public of 1 mSv/y [3]. The maximum dose constrain value that is allowed in association with any particular practice is 0.3. For this special and important practice we allowed the maximum constrain value. The meaning is that any applicant had to prove us that maximum public yearly exposure should not exceed 0.3 mSv as a result of using this procedure. Attachment 1 [4] describes the methodology we use to evaluate any application. All four hospitals that asked for such a license, fulfilled this demand. Actually only two hospitals are using this procedure, and dose levels measured in public areas were found smaller then predicted. Since actual procedures rate is less then planned, accumulated public exposure is much smaller then the maximum allowed by the constrain. Measured changes of workers accumulated doses were found negligible.

3. Other requirements, safety and security, intervention

The additional topics of radiation safety are elaborated in the BSS [3]. In order to guide applicants to prepare their requests and actual radiation protection means according to the methodology described in attachment 1, we provide them a general guiding questionnaire[4], based on the BSS and that is valid for all kinds of practices (Attachment.2). This questionnaire is built in a methodological way that leads the applicant step by step through all aspects of radiation protection and license request. It combines professional and administrative demands. Applicants should refer only to relevant topics.

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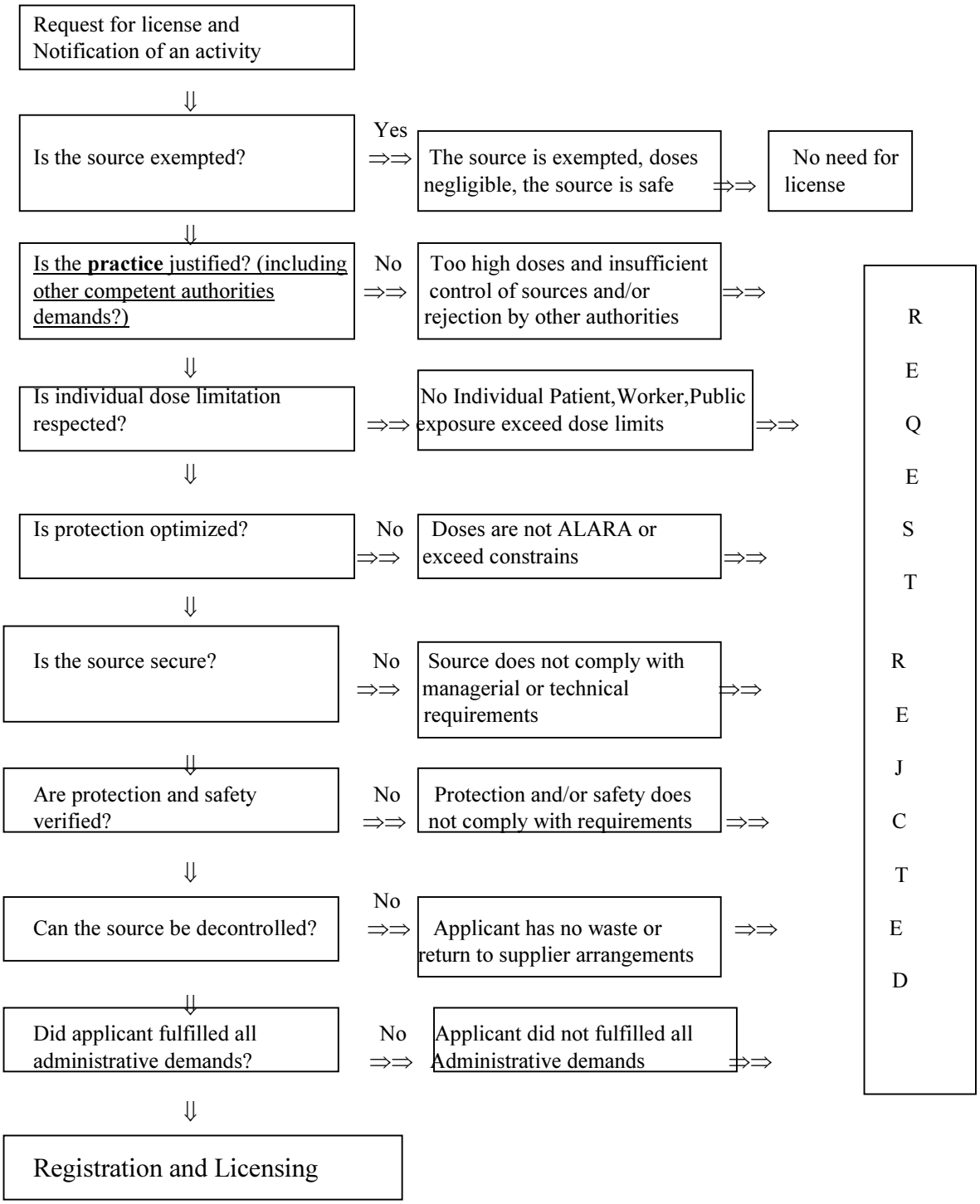
Attachment 1: Processing a license request



Attachment 2: a guiding questionnaire

1. Site Selection - safety and environmental impact assessment, regional mapping;
2. Practice in operation;
3. Reasons for the Practice, Justification;
4. Applicant's Safety and Radiation Protection Organization;
5. Names, position, qualification, responsibility, (curricula vitae for RSO and Operator);
6. Description of the work
7. Project, map, drawing, layout, (adequate drawing and scale) ;
8. Quantification of the radionuclides, types and uses, chemical and physical form;
9. Description of any apparatus containing sealed sources, with copies of any prototype test certificate supplied by the manufacturer demonstrating they met the ISO or equivalent standard, all sealed sources needs the test certification demonstrating that they meet with ISO or equivalent standards, including leakage test, also copy of catalogue or manual containing instruction or procedures for radiation protection and maintenance should be sent;
10. Description of the available instruments, portable and fixed monitor, for measuring dose rates and contamination levels, and its main characteristics, such integrated with access door interlocks, visible and alarm signs;
11. Description of storage facilities, for the radionuclides and the radioactive waste, warning and monitor system and access control, (adequate drawing and scale);
12. Description of the proposed waste management system, including disposal;
13. A formal method of assessment should be used for Safety Analysis for all Fixed Installation. It should be necessary to considered in detail each safety component, and types of failure and repercussion. Points of interest are connected to the viewing system, control room, points of access to exposed room, warning system, safety systems and interlocks, beam stops, radiation level detectors, fire control, ventilation system, including the quality assurance program, materials, shielding thickness, protective barriers, occupancy factors, and calculus, methods and results, as well as reference used by the applicant. The safety assessment should also give confidence that the proposed facility is capable, basically, of meeting the regulatory requirements for the management of waste
Defense in depth are requested for medical radiation beam therapy, accelerators, neutrons generators, industrial and research irradiation facilities and all manufacturing installation, including complex wet operations with risk of spills, labeled compound, and dry and dust operations or others as required by the competent authority;
15. Special design and procedures are requested for uses of unsealed radioactive sources including waste disposal system, decontamination, warning system and access controls;
Manual for Radiation Protection, including an effective occupational and public radiation exposure control; internal dosimetry evaluation; environmental contamination; classification of working places; protective measurements should be elaborated for appreciation and approval by the Competent authority, including optimization or alternatives;
17. Program for training including Initial, On-the-job and refreshment;
18. Administrative Control, records, workers health, source accountability, calibration of survey instruments, calibration and maintenance of devices, leak test program, old sources in use, spent source;
19. Movement of Sources, internal and external of the installation;
20. Physical Security;
21. Emergency Response;
22. Special operational procedures for external uses of radionuclides, sealed or unsealed sources;
23. Consultant Evaluation on Radiation Protection Quality Assurance (In case of any external Consultant on Safety and Radiation Protection)

IAEA-CN-85-12

RADIATION SAFETY PROGRAM IN A HIGH DOSE RATE BRACHYTHERAPY FACILITY

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Abstract

The use of remote afterloading equipment has been developed to improve radiation safety in the delivery of treatment in brachytherapy. Several accidents however, have been reported involving high dose-rate brachytherapy system. These events, together with the desire to address the concerns of radiation workers, and the anticipated adoption of the International Basic Safety Standards for Protection Against Ionizing Radiation (IAEA, 1996), led to the development of the radiation safety program at the Department of Radiotherapy, Jose R. Reyes Memorial Medical Center and at the Division of Radiation Oncology, St. Luke's Medical Center. The radiation safety program covers five major aspects: quality control/quality assurance, radiation monitoring, preventive maintenance, administrative measures and quality audit. Measures for evaluation of effectiveness of the program include decreased unnecessary exposures of patients and staff, improved accuracy in treatment delivery and increased department efficiency due to the development of staff vigilance and decreased anxiety. The success in the implementation required the participation and cooperation of all the personnel involved in the procedures and strong management support. This paper will discuss the radiation safety program for a high dose rate brachytherapy facility developed at these two institutes which may serve as a guideline for other hospitals intending to install a similar facility.

1. Introduction

The use of radiation in treatment of patients involves both benefits and risks. Experiences have shown that patients treated using radiation develop and manifest symptoms of side effects depending on the amount of dose received and target area. Likewise, it has been reported that early radiation workers had developed radiation-induced cancers. These knowledge lead to the continuous work for the improvement of radiation safety of patients and personnel. One of these developments is the use of remote afterloading equipment to improve radiation safety in the delivery of brachytherapy. Several accidents however, have been reported involving high dose-rate brachytherapy system [1].

The Department of Radiotherapy of Jose R. Reyes Memorial Medical Center and the Radiation Oncology Division of St. Luke's Medical Center are two of the hospitals in the Philippines to first acquire remote afterloading systems. The development of a radiation safety program in these hospitals has been started prior to the acquisition of the equipment. The foremost aim of the program is to improve the safety measures in the application of high dose rate brachytherapy, which will be of greatest benefits to patients and staff, and at the same time, satisfy requirements of regulatory agencies.

An effective radiation safety program will produce results such as decreased radiation exposures of patient and staff, improved accuracy in the treatment and increased department efficiency, which will eventually lead to reduced overall operating costs. A well observed radiation safety program develops vigilance of staff as well as decreased personnel and management anxiety.

The guiding document in the preparation of the radiation safety program at the above mentioned hospitals has been the International Basic Safety Standards for Protection Against Ionizing Radiation (IBSS) [2].

This paper will discuss the radiation safety program for a high dose rate brachytherapy facility developed at the Department of Radiotherapy, Jose R. Reyes Memorial Medical Center and at St. Luke's Medical Center which may serve as an example for other hospitals intending to install a similar facility.

2. Radiation safety program

The radiation safety program developed includes the following aspects: quality control and quality assurance, radiation monitoring, preventive maintenance, administrative measures, and quality audit.

2.1. Quality control/quality assurance program

The quality control/quality assurance (QC/QA) program [3] is conducted daily, monthly, and every source exchange. It consists of a set of mandated redundant performance checks, physical measurement, and guidelines for the development of performance procedures that are designed to minimize the frequency of human errors, miscommunication, and equipment malfunction. The quality control program is shown in Table 1.

Table 1. Brachytherapy quality assurance program

Daily	Monthly	Quarterly
Keys/power switch	Source position accuracy	Source calibration
Printer operation	Test run for all channels	Indexer checks
Computer Display (date, time, decay factor)	Source calibration	Dummy and source drive checks
Treatment Indicators	Review of daily checks	Radiation survey
Door Interlocks	Radiation survey	Computer hardware tests
Emergency/Interrupt buttons		Check of safety features
Acoustic and light warning signals		
Stored source position check		
Patient monitoring system		
Survey meters		
Emergency safety containers		

The success of patient treatment in brachytherapy depends on accurate treatment delivery. Accurate delivery means that the intended radiation sources are delivered to their intended positions within the correct applicator and remain there for the correct time. The results of QC/QA tests have shown source position accuracy achievable to within 0.2 mm, and source calibration reproducible to within 3% of specified activity.

The daily quality control includes computer operation checks, date/time and decay factor check, and verification of safety aspects such as warning signs, door interlocks, emergency buttons and patient monitor. These tests ensure that the patient is treated properly and that no person will be unnecessarily exposed to radiation by accident. The monthly checks include source position accuracy, source calibration, and applicator integrity. A graph of the %

difference between the manufacturer-quoted value and the clinically measured source activity for the last four installations is shown in Figure 1.

Quarterly checks are made to coincide with the source change and the preventive maintenance schedule.

Quality control checks are also conducted during treatment delivery process from the entry of the treatment parameters into the remote afterloader to the delivery of treatment. These checks are carried out to validate the entered data, to document the delivered treatment, and to immediately respond to unexpected machine malfunction and emergencies.

2.2. Preventive maintenance program

The preventive maintenance program is based on the checks submitted by the service engineers of the supplier of the company. For every source change, extensive mechanical checks, hardware tests as well as checks on the cycle counter, battery and electronic boards are performed. Values obtained should fall within the specifications and tolerance limits that are followed during the installation and commissioning process.

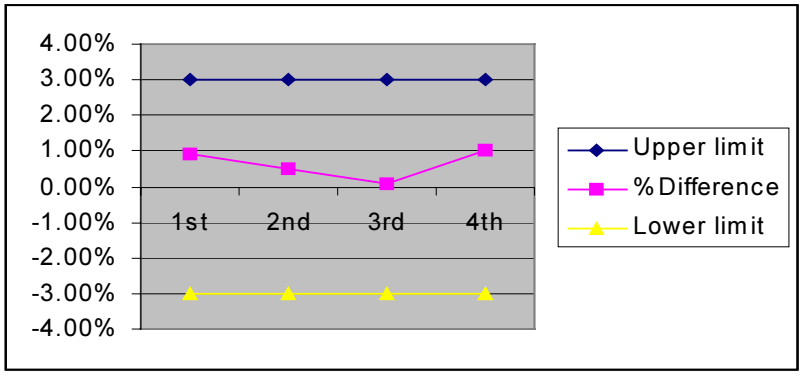

Figure 1. Source calibration accuracy

A list of parts to be replaced on regular basis such as battery and motor drives is provided by the manufacturer and is being followed.

2.3. Administrative measures

The head of the department is responsible for the overall departmental policy relating to quality matters and radiation safety program. He sees to it that his personnel are properly and adequately trained and that the radiation safety program is strictly observed. A medical radiation safety committee, having representatives from the different staff groups aside from the radiation health safety officer and management representative was formed to oversee this task. A forum is held quarterly where members of the committee study and discuss the radiation safety program in the department.

2.4. Radiation monitoring

Radiation monitoring has been used loosely to include activities referring to the source location, survey, and source inventory. Regular area surveys are conducted as part of the radiation monitoring program. Personnel exposures are monitored using film badges and pocket dosimeters.

Calibration of survey instruments is performed is done before first used, semi-annually and following repair [4]. The cylindrical ion chamber, well chamber, together with their respective electrometer are calibrated annually unless repair has been done in which case calibration must be performed prior to operation. Constancy checks is done on the dosemeter every month to confirm that results fall within 2%.

2.5. Quality audit

The quality audit, involves internal and external aspects. The internal aspect includes medical, technical, and procedural checks. The medical audit is performed by one of the consultants of the department through chart rounds, whereby charts of patients being treated are reviewed. The technical checks are conducted by the chief physicist to verify accuracy of source data and treatment plans. Procedural audit is conducted by the supervising radiologic technologist where spot checks are conducted to ensure that the treatment protocol is carried out.

The external audit is conducted by the regulatory agencies and includes checks on the list of qualified users, inventory of sources and records and documentation of procedures.

It is recommended that an IAEA Postal Dose Inter-comparison be performed to be part of an external audit for brachytherapy since it has been shown to be effective in highlighting problem areas and in improving quality for external beam radiotherapy worldwide.

3. Receipt and transport of radioactive source

Brachytherapy sources should be received by trained personnel and should be kept in a controlled and secured area. The type of radioactive source and the strength should agree with what was ordered. When opening the source packaging, it should be determined that there is no contamination present and that proper documents, including return documents, are inside the shipping container. The spent source must be properly secured in the same way that it was received and all documents necessary for its transport back to manufacturer must be complete. The record for receipt and shipping out must be kept and maintained.

4. Records and documentation

Records of the radiation safety procedures and the quality control test results are necessary. Records of equipment performance are kept throughout equipment life to enable reconstruction of events in the future if required.

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IAEA-CN-85-180

RADIATION PROTECTION OF PATIENTS IN EPIESCLERAL BRACHYTHERAPY

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Abstract

Introduction. Choroidal melanoma and other ophthalmic tumors are treated with episcleral plaques. Optimisation and other criteria are necessary to avoid damage in eye and visual function preservation.
Purpose. To study the dosimetric phases to apply radiation protection criteria. To determine procedures for quality assurance of applicators, sources and treatment prescription and planning.
Method. We have revised treatment procedure. First, aspects shared for all the patients. Then treatment planning and applicator assembling. After that, we study insertion and treatment. Finally, we check the chart flow to modify, if necessary. It necessary consider normative and recommendations.
Results and conclusions. Quality assurance of sources (calibration, autoradiography), applicator (effects, dose distribution) and treatment planning are revised. Appropriate patient data acquisition is essential due the special characteristics of tumor and eye. Treatment planning involves optimisation as a factor. Seed selection is very important to avoid misadministration. Next procedure is applicator assembling. We must car to choose the same as dosimetry and to carry out its verification. Sources insertion is a surgical procedure. It is essential an accurate placement. Desinsertion is also surgical, and must be adapted to dosimetry and prescription. Flow chart is modified adding two staff meeting to discuss about patient data and doses.

1. Introducción

La braquiterapia epiescleral es una alternativa a la enucleación o extirpación del ojo afecto en el melanoma uveal, el hemangioma circunscrito de coroides, el retinoblastoma o la degeneración macular asociada a la edad. Como en todo tratamiento radioterápico, los objetivos del tratamiento son suministrar la dosis prescrita minimizando en lo posible los efectos secundarios. En el caso que nos ocupa, al evitar los efectos secundarios podemos preservar el órgano, y más aún preservar la función visual [1, 2, 3].

En el caso de estos tumores, el problema es mayor porque el melanoma es un tumor tradicionalmente considerado como radiorresistente, con lo que las dosis suministradas son mayores que en otros tratamientos, y el angioma es un tumor benigno, por lo que cualquier irradiación debe estar muy justificada. Además, en este caso, el paciente tiene más tiempo de desarrollar efectos secundarios.

Los criterios de protección radiológica en estos tratamientos deben estar encaminados no sólo a tratar de forma eficaz el tumor, sino también a conseguir que el paciente siga conservando la visión.

2. Objetivos

Estudiar las fases de la dosimetría de la braquiterapia epiescleral, para discernir en cuáles de ellas se pueden mejorar nuestros criterios de protección radiológica del paciente. Establecer qué procedimientos son necesarios para asegurar la calidad de las fuentes, aplicadores y sistemas de cálculo empleados. Protocolizar la realización de la dosimetría clínica para conseguir el objetivo de minimar la dosis en los órganos de riesgo. Repasar el diagrama de

flujo de la información y responsabilidad que se había establecido para mejorar la toma de decisiones y la circulación de la documentación.

3. Método

Hemos revisado el procedimiento del tratamiento de braquiterapia epiescleral en nuestro centro. Se estudian por separado parámetros comunes a todos los tratamientos como el aseguramiento de la calidad de fuentes y aplicadores, y del planificador de tratamientos.

Hemos revisado la adquisición de datos para cada paciente. Seguidamente se analiza la preparación del tratamiento, tanto la planificación como la preparación del aplicador. Después, se examina la aplicación del tratamiento tanto en la inserción, en el tiempo que el paciente tiene el aplicador puesto como en la desinserción. Finalmente, se repasa el diagrama de flujo del proceso [4] con la información recopilada anteriormente, por si fuera necesario modificarlo.

Todo el proceso ha sido observado a la luz tanto de la legislación aplicable, como de las recomendaciones nacionales [5] e internacionales [6, 7].

4. Resultados y conclusiones

4.1. Aseguramiento de la calidad de fuentes, aplicadores y planificador

Las acciones en las que se debe incidir son:

Calibración de las fuentes con un detector pozo calibrado para las fuentes de I-125, en vez de la mera verificación de la intensidad en un calibrador de Medicina Nuclear. Progresivo empleo de la tasa de kerma de referencia en aire, TKRA.

La realización de radiografías y autorradiografías de las fuentes, aunque aconsejable, presenta grandes dificultades por las reducidas dimensiones de las fuentes.

Algunos autores recomiendan que, cuando se manipulen las fuentes de I-125 con pinzas u otros medios, se realice una prueba de hermeticidad, debido a su fino encapsulamiento.

El efecto del aplicador sobre la distribución de dosis debe ser incorporado, paulatinamente. Los aspectos que deben investigarse son: atenuación de la TKRA por el alojamiento acrílico de las fuentes y protección a las estructuras extraoculares por la placa metálica. Sobre la distribución de isodosis existen varios trabajos publicados con métodos de Montecarlo, ante la dificultad de realizar una verificación experimental.

4.2. Adquisición de datos del paciente

En braquiterapia epiescleral, este paso es más delicado, si cabe, que en otras aplicaciones. Los tumores son menores que en el resto del organismo y el órgano donde asientan estos tumores, el ojo, es también menor que el resto de los órganos huéspedes de tumores; con lo que la distancia de los órganos críticos, en nuestro caso los más importantes, son la mácula y el nervio óptico, es del orden de unos milímetros.

El melanoma es un tumor, tradicionalmente, considerado como radiorresistente por lo que la dosis suministrada es del orden de 100 Gy, mayor que en resto de los tratamientos y el

angioma es una enfermedad benigna, con lo que el paciente va a tener más tiempo de desarrollar efectos secundarios.

Por estos motivos, es necesario contar con la mayor cantidad de información disponible, proveniente de los medios de imagen como son, ecografía, angiografía, fotografía de fondo de ojo, TAC y RMN.

4.3. Planificación del tratamiento

Se ha descrito [8] cómo aprovechar la baja energía del I-125 para optimar la dosimetría clínica, para que los órganos de riesgo reciban la dosis más baja posible. Como estos autores, podemos aprovechar la anisotropía de las fuentes para disminuir dicha dosis, y evitar poner todas las que permite el alojamiento. No mezclamos intensidades por la forma de suministro de los lotes de fuentes.

Un aspecto importante a tener en cuenta es la edición de los lotes de fuentes, pues es imprescindible que sólo pueda seleccionarse el que está en uso realmente. Si, por error, empleáramos otro la duración del implante no sería correcta.

Hasta ahora, se realizaba un cálculo manual como comprobación del cálculo del planificador. Se diseñará una hoja de cálculo con el que el cálculo será más cómodo, y más preciso al automatizar, por ejemplo, las interpolaciones.

4.4. Preparación del aplicador

En esta parte del proceso hay que vigilar:

Que se emplea el aplicador fijado en la planificación.
Que se emplea el lote de fuentes adecuado.
Realizar una comprobación del aplicador de acuerdo con el procedimiento establecido.

Ensamblar el aplicador, como se ha previsto en la planificación, para preservar los órganos de riesgo. Es especialmente importante cuando algún alojamiento cuando no se han colocado todas las fuentes en el alojamiento.

Además, este proceso se ha de realizar en condiciones de esterilidad como corresponde a un proceso quirúrgico. Este requerimiento puede entorpecer la ejecución del procedimiento. Otra alternativa es esterilizar el aplicador después de su preparación, pero plantea más problemas de protección radiológica.

4.5. Colocación del aplicador

Es una acción que tiene lugar en el quirófano, y que lleva a cabo un oftalmólogo con la información que le suministra el resto del equipo. La colocación tiene lugar, en la mayoría de las ocasiones, mediante transiluminación. En otras ocasiones, cuando la lesión no hace sombra o tiene una localización poco accesible, se puede colocar midiendo la distancia a algunas estructuras.

Los datos del tumor, obtenidos en fases anteriores, son los que van a dar una indicación del tamaño del aplicador. Si estos no son correctos, no podremos dejar margen de seguridad entre

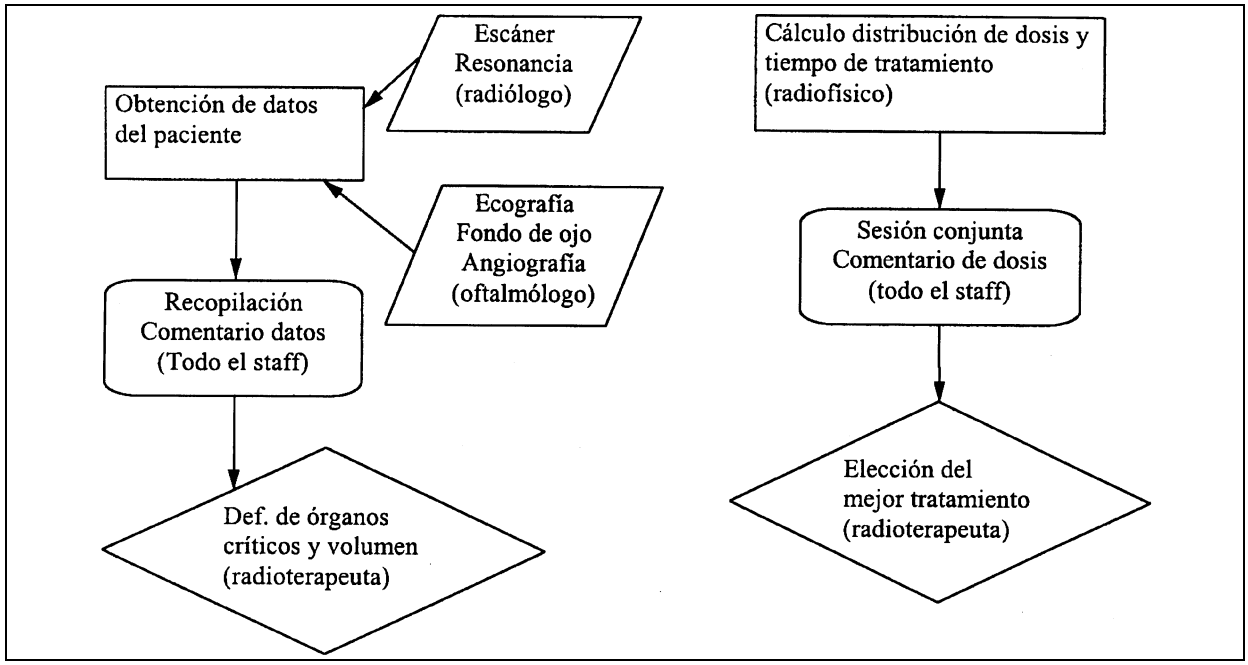
éste y el tumor. Además, se tiene que colocar con la orientación que marca la dosimetría para mantener la posición relativa de las fuentes respectos a los órganos de riesgo y preservar así la optimización de dosis.

4.6. Tratamiento y desinserción

Una vez colocado el aplicador el paciente pasa a una habitación radioprotegida en la que permanece el tiempo fijado en la dosimetría clínica. Una vez transcurrido este tiempo vuelve al quirófano para retirar las fuentes. Este segundo paso por el quirófano es especialmente programado, pues debe respetarse la duración del implante, para suministrar la dosis calculada

4.7. Diagrama de flujo del proceso

Se incluyen dos reuniones de todo es equipo para comentar los datos de los medios de imagen y las dosis que reciben los órganos críticos.



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ESTIMATION OF THE TRANSIT DOSE COMPONENT IN HIGH DOSE RATE BRACHYTHERAPY

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Abstract

Current high dose rate brachytherapy (HDR) treatment planning systems usually calculate dose only from source stopping positions (stationary component), but fails to account for the administered dose when the source is moving (dynamic component or transit dose). Numerical values of this transit dose depends upon the source velocity, implant geometry, source activity and prescribed dose. In some HDR treatments using particular geometry the transit dose cannot be ignored because it increases the dose at the prescriptions points and also could increase potential late tissue complications as predicted by the linear quadratic model. International protocols recommend to verify this parameter [1]. The aim of this paper has been to establish a procedure for the transit dose calculation for the Gammamed 12i equipment at the RT Department in the Clinical University Hospital (Zaragoza-Spain). A numeric algorithm was implemented based on a dynamic point approximation for the moving HDR source and the calculated results for the entrance-exit transit dose was compared with TLD measurements made in some discrete points.

Resumen

Los sistemas de planificación asociados a equipos de alta tasa de dosis (HDR) suelen calcular la dosis suponiendo que la única contribución se debe a cuando la fuente se encuentra en las diferentes posiciones de parada (componente estacionaria), sin tener en cuenta la dosis suministrada cuando la fuente está en movimiento (componente dinámica o de tránsito).

La magnitud de la dosis en tránsito depende fundamentalmente de la velocidad de la fuente, la geometría del implante, la actividad de la fuente y la dosis prescrita, y, en determinadas aplicaciones de Alta Tasa esta dosis puede llegar a ser significativa en cuanto al incremento de potenciales complicaciones tardías en los tejidos sanos, y su estimación está recomendada en los protocolos de verificación [1]. El propósito de este trabajo ha sido establecer una sistemática de cálculo de la componente de tránsito de la dosis, para el equipo Gammamed 12i existente en el Servicio de RT del HCU de Zaragoza. Se ha desarrollado un programa de cálculo y los resultados de dosis entrada-salida calculados se han comparado con medidas hechas con TLD en puntos discretos.

1. Método y resultados

1.1. Teoría general

La dosis total en un punto puede considerarse debida a dos componentes, una depositada cuando la fuente se encuentra en reposo (Ds) y la otra cuando se encuentra en movimiento (Dd), de forma que: $DP = Ds + Dd$.

El cálculo de Ds se lleva a cabo por el algoritmo definido en el Sistema de Planificación. Para la estimación de Dd es preciso tener en cuenta a su vez otras tres contribuciones debidas a la fuente en su recorrido de: entrada al aplicador, entre posiciones de parada y salida del aplicador para recogerse en el equipo [2].
Podemos expresarlo como:

$$Dd = D_{entrada} + D_{entre\ posiciones} + D_{salida}$$

En definitiva, cada componente de Dd depende de la distancia entre el punto considerado para el cálculo y el punto en que se encuentra la fuente en cada momento, así como del tiempo que le cuesta a la fuente recorrer cada intervalo de espacio (velocidad de la fuente).

1.2. Velocidad de la fuente

Puede comprobarse [2,3] que la fuente no se desplaza a velocidad constante en todo su recorrido sino que esa velocidad depende del espacio que recorre. Para el equipo Gammamed 12i no hemos encontrado en la documentación ni en la bibliografía estimación de valores para este parámetro, por lo que ha sido preciso realizar una determinación experimental del mismo.

Mediante un cronómetro se han medido:

- Tiempos de entrada y salida en el recorrido máximo de la fuente que para este equipo es de 1300 mm (utilizando la fuente de simulación para tener una observación más directa). Se obtuvo un valor de 433 mm/seg.

- Tiempos entre paradas, planificando múltiples paradas a intervalo constante, y para diferentes intervalos. En este caso, como ha debido realizarse con la fuente real, se han estimado tiempos totales y se han restado los de entrada y salida así como los de parada seleccionados, para determinar el tiempo empleado en recorrer la totalidad de los espacios inter-parada. Como se conoce el número de espacios y el intervalo entre paradas puede calcularse la velocidad de la fuente en ese recorrido.

Los resultados obtenidos se muestran en la figura 1, y son análogos a los publicados en (2) por otros autores para el equipo Nucletron.

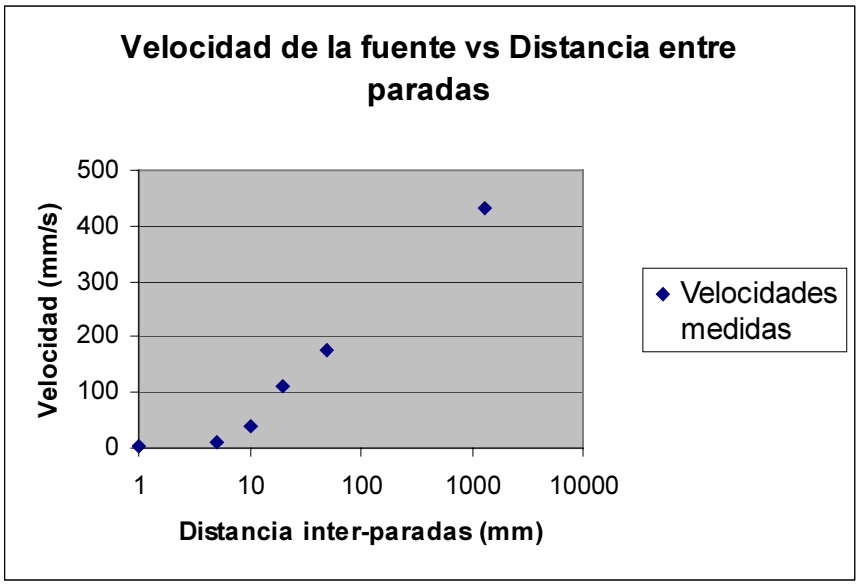

Figura 1. Velocidad de la fuente de Ir-192 del equipo Gammamed 12i de HDR, en función de la distancia entre paradas

1.3. Estimación teórica de Dd

Se ha preparado un programa de ordenador en lenguaje C++ para el cálculo teórico de la dosis dinámica en un aplicador lineal, integrando numéricamente la contribución a la dosis de la fuente a lo largo de todo el recorrido. Una vez introducido el valor de la tasa de kerma en aire

de la fuente es preciso introducir la velocidad estimada para la componente de que se trate. Para las componentes $D_{entrada}$ y D_{salida} el tiempo de irradiación de cada intervalo de integración se calcula suponiendo la velocidad constante e igual a los 370 mm/seg que habíamos determinado.

Para la estimación de $D_{entre\ posiciones}$, es preciso introducir el intervalo entre paradas y el número de paradas, así como la velocidad estimada a partir de la gráfica de la figura 1.

Para el cálculo de dosis se han utilizado los mismos factores que utiliza el sistema de planificación Abacus.

1.4. Verificación del algoritmo

Se han realizado medidas de dosis de entrada y salida con dosímetros TLD 100, calibrados previamente para la energía del Co-60, dispuestos según el esquema de la figura 2.

Los dosímetros son de 3.2x3.2x0.9 mm^3 y se leyeron con un lector 2800M de Victoreen, utilizando un programa de lectura de 10" a 160º y 10" a 300º. El programa de borrado utilizado es de 1h 400º y 8h a 100º.

Se programó una única posición de parada de 1 segundo a una distancia de 29 cm del dosímetro más próximo, de forma que puede considerarse despreciable la contribución estacionaria de dosis.

Los dosímetros se colocaron entre dos láminas de 3.5 cm de PMMA.

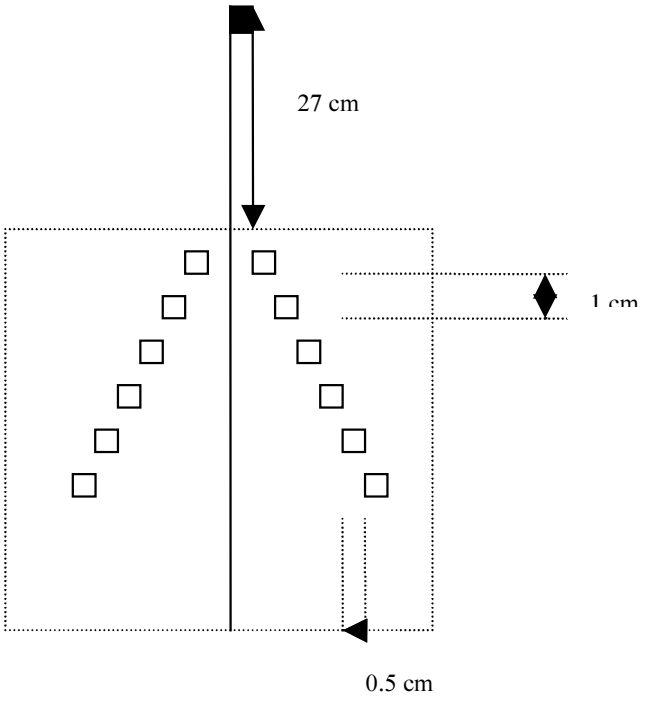

Figura 2. Esquema de colocación de los dosímetros TLD para medida de dosis en tránsito

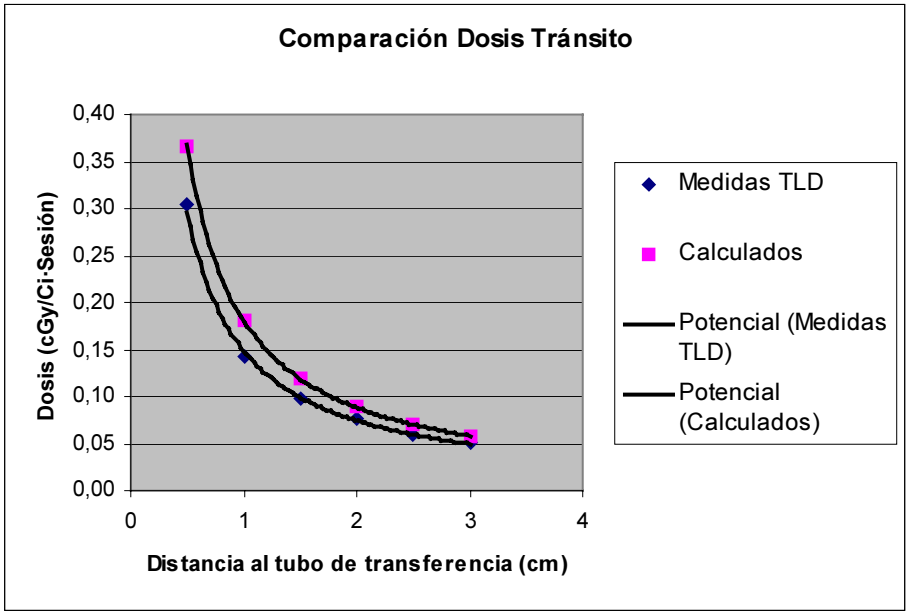

Figura 3. Comparación de valores de dosis de tránsito experimentales y calculadas

La comparación entre los resultados experimentales y los calculados por el algoritmo se muestra en la figura 3. Las diferencias encontradas son del orden de las estimadas en [2].

2. Conclusiones

Dado que la dosis en tránsito es linealmente dependiente de la actividad de la fuente, del número de fracciones y de la velocidad de tránsito, y a la vista de los valores de dosis obtenidos por unidad de actividad y sesión, la contribución de esta componente de dosis en tejidos alrededor de la fuente puede llegar a ser considerable en el caso de que el número de fracciones sea grande y aumente el número de canales utilizados, por lo que en esos casos no debería despreciarse como suele hacerse en los sistemas de planificación asociados a equipos de HDR.
El algoritmo desarrollado resulta práctico para el cálculo de la dosis en tránsito.

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PATIENT DOSIMETRY IN INTRAVASCULAR RADIATION THERAPY

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Abstract

Percutaneous transluminal coronary angioplasty is a well-accepted method for nonsurgical myocardial revascularization. However the long-term success of this method is limited by the occurrence of restenosis. Endovascular brachytherapy has been put forward as means to avoid restenosis. Since this technique involves the placement of a radioactive source in a catheter in the patient's arteries, the possible radiation risk should be considered. In this paper the effective dose of the patient associated with the use of Iridium-192 for IRT treatment has been calculated using Monte Carlo techniques. To put the results into perspective the effective dose form the PTCA procedure was also calculated using the same techniques. Calculations were based on the measurement of DAP(Dose Area Product) for the procedure. We found a mean effective dose of 9 mSv for both the PTCA procedures as for the IRT treatment. Thus leading to the conclusion that, from the perspective of radiation burden, the elimination of one PTCA procedure through the use of IRT is a benefit for the patient.

1. Introduction

Percutaneous transluminal coronary angioplasty is a well-accepted method for nonsurgical myocardial revascularization. However the long-term success of this method is limited by the occurrence of restenosis. Restenosis is seen in approximately 30% of patients undergoing PTCA and usually occurs within 6 months after angioplasty. A number of pharmaceutical approaches have been tested to limit the rate of restenosis, none with sufficient success. Implantation of a stent can only reduce the rate of restenosis for a number of patients. Restenosis can be attributed to three components: recoil of the vessel, late remodelling of the vessel and intimal hyperplasia. The first two components are adequately remedied through the use of stents. The last component however, which is the growth of smooth muscle cells, fibroblasts and intercellular matrix into the lumen of the vessel as a reaction to the injury of the PTCA procedure, is not solved by stent placement. A promising approach is the use of ionising radiation. This can be applied in different ways : implantation of radioactive stents and catheters with gamma or beta sources. This paper focuses on the use of gamma sources, in particular Iridium-192. Data from the SCRIPPS, WRIST and GAMMA I trial suggest that this will be a useful technique to reduce restenosis. The main problem associated with the use of gamma radiation is the range of the photons, which might pose a problem towards staff dosimetry. A second point of interest is the extra dose the patient receives from this IRT treatment. In order to evaluate these risks the RABAS (Radiation Burden Assessment) study has been setup. In this study extensive dosimetry will be done for patients and staff in the treatment of patients with Iridium sources. This paper describes the partial results for the patient radiation burden.

2. Materials and methods

2.1. Catheterisation room and treatment procedure

All patients were treated in the catheterisation room of the University Hospital Ghent, Belgium. The catheterisation room is a bi-plane room and consists of two Philips (Philips, Hamburg, Germany) cardiovascular X-ray units. A DAP meter is attached to the tube housing. These DAP meters are calibrated in situ using a Farmer NE2571 ionisation chamber and Kodak X-Omat V film. The calculation of the calibration factor was done according to the

simplified method described by Shrimpton et al [1]. In this method the calibration factor is taken as the ratio between the actual DAP, calculated as the dose in the centre of the field multiplied with the field size as measured from the film, and the DAP reading. The usefulness of these devices in the calculation of X-ray doses has already been investigated by a number of authors [2-4]. To estimate the additional risk for both patient and staff an IRT-treated and a control group of patients will be studied. Only male patients aged over 40 and satisfying severe inclusion criteria are considered in the study. Prior to the IRT-treatment, the patients in the treatment group are treated with normal PTCA procedures. When the cardiologist is satisfied with the success of the PTCA procedure, the IRT treatment is started. Using fluoroscopy and a dummy ribbon the length of the source is determined. Next the actual source is moved in to the treatment position by a radiation oncologist. At this time only the radiation oncologist is allowed in the room. During the actual treatment time, nobody is allowed in the catheterisation room. After the IRT treatment has ended the cardiologist makes the finals images to ascertain the initial success of the procedure. The patients in the control group are treated with normal PTCA procedures.

2.2. Patient dose study

To calculate patient dose a number of parameters are recorded during the procedures. These include DAP separately for every fluoroscopy and cine run. The position of the X-ray tubes, indicated as a set of two angles: rotation and skew. These angles as well as the tube parameters (tube potential, current, SID, II-field) are registered automatically for every cine run. The values for fluoroscopy are copied from the first cine run following a series of fluoroscopy. In the case of the IRT treated group the DAP and associated tube parameters are divided in two parts. A first part consists of all radiation before the IRT-source placement, the second is everything later on. In this way the additive X-ray patient dose associated with the IRT-treatment can be assessed.

Patient dosimetry is divided in three components. The first component is the entrance skin dose associated with the use of X-rays in interventional radiology. This part was measured with TLD's (LiF, Harshaw TLD-100 chips) attached to the body. A major problem associated with the use of TLD's ,as noted in a previous study [4], is the fact that is difficult to predict the location on the skin where the highest dose will be delivered. The only way to overcome this problem is through the use of an array of TLD chips. For this study 100 TLD's are used per patient. These TLD's are spaced over an array of 95 cm by 20 cm leading to an equal spacing of 5 cm in both the horizontal and vertical direction.

The second and third part are the organ and effective dose from the X-rays and 192-Iridium source respectively. As measurement of these components is difficult or impossible Monte Carlo calculations were done. The effective dose is then calculated using the tissue weighting factors given in ICRP60 [5]. The dose to the bone-marrow is calculated using the method of Rosenstein [6] to divide the energy deposited in the skeleton in two parts. Consequently kerma-to-dose conversion factors calculated by Kerr et al [7] were used to calculate the dose to the marrow. The dose to the bone surface is taken as the dose to the skeleton excluding the marrow.

2.3. Monte Carlo calculations

In the literature different sets of conversion factors relating DAP to effective dose are available. The factors used by most authors are those given in NRPB-R262 [3]. As tabulations

are always limited, we preferred to use our own Monte Carlo calculations. The Monte Carlo code used was MCNP4b2 [8]. The kerma approximation with the following interactions were considered: Rayleigh scattering, Compton Scattering, photoelectric effect and pair production. The patient table is included in the model to compensate for additional attenuation. In the case of X-ray simulation, the source position is calculated from the X-ray tube angles and from the assumption that the iso-center of the bi-plane X-ray set-up is located at the heart for all incidences. For the calculations of IRT doses the source is takes as a curved line source in contact with the heart surface. The position was calculated to closely match the position of the lesion treated in the patient. The IRT sources used in this study (Cordis) have three possible lengths 23 mm, 39 mm and 55 mm. For calculation of the organ dose we used the mathematical phantom developed by Christy and Eckerman [9]. For the calculation of the X-ray dose the phantom has been adjusted for the above head position of the arms during the PTCA procedure. For every patient a Monte Carlo simulation has been done for every tube incidence and field-size used in the PTCA procedure.

2.4. Heart phantom and source position

We used the heart phantom as described in the mathematical phantom [9] which is the model described by Coffey [10]. The surface of the heart is represented by four quarter ellipsoids. Inside the heart a division is made between heart-wall and contents. The heart is described in an auxiliary coordinate system that is related to the phantom coordinate system by a rotation matrix. In this model the groove between atrium and ventricle can be approximated as the YZ-plane, similarly the division between the left and right side of the heart can be approximated as the XY-plane. The cardiovascular blood flow is supplied by two main coronary arteries, the Left and Right coronary artery. Both these arteries have their offspring in the aorta. The RCA (Right coronary artery) runs in the groove between the right atrium and ventricle. The Left coronary artery almost immediately divides into two branches the LAD (left anterior descending) which runs along the division between the left and right ventricle towards the tip of the heart, and the CX (circumflex) that runs along the groove between the left ventricle and atrium. All of these branches are divide in proximal, middle and distal parts.

3. Results and discussion

Table I gives some relevant dose determining parameters for the dose calculations. These include total treatment IRT-dwell time, source activity, source length and source position.

Table 1. Relevant dose determining parameters for IRT procedure

Patient	Dwell time (min)	Activity (MBq)	Source length (mm)	Source Position
A (1)	17.150	10748.5	39	Prox LAD
B (2)	17.150	10748.5	39	Prox CX
C (3)	18.088	6315.90	23	Prox LAD
D (4)	17.450	14737.1	55	Prox LAD
E (10)	15.106	12202.6	39	Prox RCA

Table II gives the dosimetric results for all patients. These include maximum skin dose , effective X-ray dose, effective X-ray dose after IRT treatment, effective dose from IRT treatment.

Table 2. Dosimetric results

Patient	Maximum skin dose (mGy)	Total Effective dose X-ray (mSv)	Effective dose X-ray after IRT (mSv)	Effective dose from IRT (mSv)	Effective dose per disintegration (mSv/dis)	Patient	Maximum skin dose (mGy)	Total Effective dose X-ray (mSv)
A	863	16.0	5.63	7.73	$6.99\ 10^{-13}$	F	241	3.07
B	501	7.13	1.30	9.55	$8.64\ 10^{-13}$	G	818	11.1
C	853	16.9	1.22	4.70	$7.11\ 10^{-13}$	H	753	11.9
D	442	7.73	1.14	10.4	$6.94\ 10^{-13}$	I	352	7.51
E	368	6.09	1.28	6.99	$6.33\ 10^{-13}$	J	473	7.43

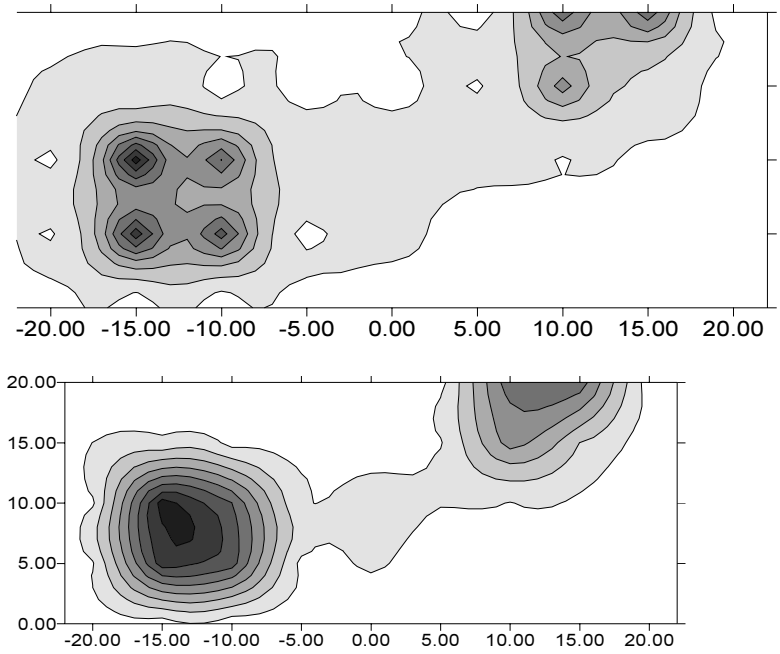

Figure 1: Skin dose distribution for patient C. The horizontal axis indicates the position on the back in cm , 0 is the centre and –20 is the right side. The color bar indicates the skin dose in mSv

3.2. Effective dose

The higher dose found for patient A is due to stent placement. For patient C additional images before the PTCA procedure were needed to determine the exact location of the lesion. It is important to notice the dose after IRT-treatment in Table II, which has a mean value of 1.24 mSv excluding patient A, since a stent was placed after the IRT treatment. The effective dose from the Iridium source itself seems to depend strongly on the source length and hence the total activity. The dose for patient C for whom the longest source was used, is almost twice that of patient B for whom the shortest source was used. This is logical since the total activity on the longer source is also higher. If however we look at the dose per disintegration we find that this value depends on source position and also on source length. Both aspects have the same reason: the proximity to radiosensitive organs. If we compare the dose per disintegration value for a 23 mm source in the prox LAD with that for a 55 mm source in the same position, we find that the dose per disintegration is higher for the shortest source. This can be explained if we look at the orientation of the heart and hence the source in the body.

Because the heart is tilted in the body, the average distance from the source to ,for example, the oesophagus is longer for the longest source. If we compare the values per disintegration with the MIRDOSE 3.0 value of 9.34 10^{-13} mSv/dis we find that this value is 30% higher than the mean (7.2 10^{-13} mSv/dis) of the values given in table II. This can also be explained by the geometrical effect. The calculation in MIRDOSE is based on activity uniformly distributed in the hearth wall. The values in table II are for distinct locations on the hearth surface. If we use our model to calculate the dose per disintegration for a source located posterior we find a value of 10.69 10^{-13} mSv/dis, which is 17% higher than the MIRD value.

4. Conclusions

When considering the use of IRT-treatment in the fight against restenosis, one has to take the potential radiation risk into consideration. To determine this risk Monte Carlo calculations were done to calculate the effective dose associated with these procedures. The mean effective dose found for a PTCA procedure was 9.29 mSv. The mean effective dose found for the IRT-treatment was 9.14 mSv, consisting of 1.24 mSv from the additional X-ray use and 7.90 mSv from the IRT source. It can thus be concluded that the extra radiation burden to the patient from the IRT-treatment is comparable to the PTCA. Thus if one PTCA procedure can be avoided through the use of IRT, then we can conclude that from the perspective of radiation burden, the treatment is justified.

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IAEA-CN-85-195

DESIGN AND IMPLEMENTATION OF AN INTRAVASCULAR BRACHYTHERAPY INSTALLATION IN CARDIOLOGY

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Abstract

Intravascular Brachytherapy (IVB) is a very promising technique for reducing restenosis rates. However, neither the exact absolute dose needed nor the optimal spatial and temporal distribution of dose inside the vessel wall for a successful treatment, nor the physical dosimetry of the various radioactive sources and devices for dose delivery, are well known. In this paper, an overview will be given of the design strategy, the dosimetric and radiation protection-related problems that we have met during the implementation of this technique at San Carlos hospital, adopted or foreseen solutions, and future research fields that we intent to carry out in order to reduce uncertainties and to achieve a deeper knowledge of the parameters that have an influence on the treatment.

1. Introduction

Ionising radiations have been used recently to reduce restenosis rates after percutaneous vascular interventions in technique generically known as Intravascular Brachytherapy. This new technique, consisting of the irradiation with γ or β sources to reduce restenosis rates after angioplasty, is being widely investigated [1].

IVB procedures are radiotherapeutic procedures if we consider them as every process of therapeutic irradiation as stated in the Spanish legislation [2] derived from the European Directive on Medical Exposures [3].

However, there are some aspects different from classic radiotherapy that should be taken into account. The important uncertainties involved in this kind of treatment should not be an excuse to give up this technique as, even taking them into account, the results in patients treated are encouraging. Nevertheless, researching and elaboration of Quality Assurance Programs in this area of Radiotherapy must be encouraged and supported.

2. Objectives

- To list the problems that we have found in the implementation of IVB techniques in the San Carlos University Hospital (SCUH).
- To show the available alternatives and research fields that we have envisaged to solve these problems.

3. Material and methods

The Interventional Cardiology Service of the SCUH is licensed to use one IVB system which consists of a train of Sr-90/Y-90 sealed sources that are hydraulically positioned through a

non-centering catheter[1]. Before long we will be licensed to use another system of afterloading brachytherapy in which a wire with a P-32 source on its tip, advances through a especial balloon[2].

The aim of these IVB systems (and of any other) is to uniformly irradiate the target volume, which is usually very irregular, with the suitable dose. However there are some challenging technical and organisation difficulties that are studied hereafter.

4. Discussion

From the experience obtained in the design and implementation of our IVB installation, we have realised the importance of the following aspects:

1. Coordination between the professional groups involved (cardiologists, radiooncologists, medical physicists). The **creation of multidisciplinary task groups** that work to overcome the problems and uncertainties in IVB is advisable.

2. **Difficulties to gather and bring documentation to the Regulatory Authority** because of the fast introduction of many new and different systems.

3. **Feasible incidents analysis and emergency plans design**. This analysis is specially difficult due to the variety of systems and to the limited experience with them.

4. **Design of operation procedures** that intend to avoid errors and emergency situations.

5. **Redesign needs of cath labs to use γ sources**. The extra necessary shielding weight would lead, in our case, to structural problems. Therefore, we expect the implementation of IVB with γ sources in a properly equipped radiotherapy room.

6. **Evaluation of uncertainties in imparted dose**. These uncertainties are greater than the ones of conventional Radiotherapy and Brachytherapy due to the steepness of the depth dose curve for β radiation, the positioning errors, the movement with heart beat, the asymmetry in the target volume, etc.

7. Even if we have full certainty of the target volume (the latest studies indicate that the target volume should be the adventitia), this is accurately known not before the balloon dilatation and later imaging with IVUS[3], which means that **dosimetry** must usually be **retrospective**. Since a previous dosimetry (before the dilatation) can not be made, we will attempt to make an on-line dosimetry (right after post-dilatation ultrasound imaging) in order to decide the suitable treatment parameters. Afterwards, a more accurate dosimetry will be made retrospectively. The option to make angioplasty and IVUS imaging one day before the brachytherapy treatment, would allow us to make an accurate dosimetry planification in advance. Nevertheless, this would increase the catheterization-related risks, and remodeling in the period from dilatation to treatment would introduce more uncertainties than those that we attempt to avoid with this option.

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[1] (Beta-Cath System. Novoste Corporation. Brussels, Belgium).
[2] (Galileo. Guidant S.A. Diegem, Belgium).
[3] IVUS: Intravascular Ultrasound.

8. **Increasing occupational protection needs**, because the use of some of the systems available requires that the professionals involved stay in the cath lab during the treatment.

9. **Difficulties in the calibration of new sources**. This difficulty worsens because of the important number of different systems available, that are appearing in the market, with different γ and β sources and in very different forms (wires, seeds, radioactive liquids or gas that fills the balloon, radioactive stents, ...).

   In conventional brachytherapy, dose typically stated at 1 cm from the source and the effects of low energy photons and secondary electrons are belittled. However, in IVB the target volume can be 1-3 mm wide, and therefore it is essential to know the distribution dose in the millimetre range in areas of high dose gradient. This is certainly difficult at present and the uncertainties in dose calculations are greater than those usually found in external beam Radiotherapy or conventional brachytherapy. The dosimetry and calibration procedures that we will use will be basically the ones of AAPM TG-60 [4] using radiochromic films [5]. The activity verification for the Galileo system will also be made with a properly calibrated activimeter.

10. **Difficulties in the target volume definition**. We can get detailed images of the lumen from coronariography, but they give us no information of the vessel wall, and therefore this does not allow us to accurately define the target volume. A detailed information of the vessel wall can be obtained through IVUS imaging. These images allow us to accurately define the target volume and constituted a necessary step to get a 3D dosimetry and to the dose-volume histograms calculation.

    Dose volume definition will be made adjusting ICRP-50 [6] definitions to IVB:

    - GTV (Gross tumour volume): Stenosated Area.
    - CTV (Clinical Target Volume): Stenosated Area plus margin injured by the balloon.
    - PTV (Planning Target Volume): Area injured by the balloon plus a certain safety margin to take into account the reduction of dose on the edges, the dosimetric uncertainties, the source movements relative to the vessel wall, etc.

11. **Dose Prescription**. AAPM TG-43 [7] recommends that dose is prescribed at 2 mm from the catheter in water for intracoronary applications. We have assumed this recommendation and we have made a dose prescription form to be filled in by the radiotherapist.

12. **Source localisation into the lumen. Centering effect**. There is an asymmetry in the thickness of the vessel wall in a slice and along the treatment area. Source centering implies an additional technical problem but provides a greater dosimetric precision and a reproducibility not attainable with a non-centering system. As we will have IVUS images, we will be able to compare the dosimetry with both methods (with the “real” position of the catheter and simulating the result that we would get with the catheter centered). In addition, as we will have, at first, two systems with two different radionuclides, we could compare their dosimetric “effectiveness”.

13. The **edge effect** can be defined as the appearance of a higher restenosis rate on the lesion edges. The explanation for this effect can be:

    - On the edges of the treatment area, where dose rates are lower, radiation could stimulate cellular proliferation in areas of subclinical disease.
    - "Geographical Miss" or inadequate positioning related to the lesion, so that the volume treated with a proper dose does not cover the target volume (PTV).

    In order to avoid this problem we have anticipated these measures:

    - Definition of PTV with an adequate safety margin over the stenosated area.
    - Elaboration of an adequate working methodology to position the source properly.
    - Evaluation and documentation of the tridimensional dose distribution in order to assess the coverage of the target volume with the suitable dose.

14. Higher absorption of radiation in **calcifications and stents** than in normal tissue (specially in the case of β radiation). Initially we will suppose that all the tissue that surrounds the source is water. In a following step we will try to enhance the dosimetry taking this effect into account.

15. We have selfimposed making **3D dosimetries** as one of our main goals, that is, to calculate the dose in the whole target volume instead of the calculation in a single point as usually happens in current IVB. We will produce dose-volume histograms (HDV) of the adventitia and the lumen of all the treatments from the target volumes outlined on IVUS images and the determination of the tridimensional dose rate distribution that surrounds the sources employed.

16. **Increase in occupational doses** (mainly in hands and fingers of the specialists) because of the implementation of the technique.

5. Conclusions

1. It is advisable to create multidisciplinary task groups with the three kind of specialists involved in IVB, as well as the design of initial and continuous training programs.
2. The different systems available in the market should be assessed in advance and a polyvalent implementation strategy should be put forward (that could be applicable and valid for several systems), taking into account the limiting factors to use gamma sources.
3. It is advisable to promote more and more efficient patient dosimetry systems. Only by looking for a more accurate dosimetry, could IVB treatment and therefore its results be optimised.
4. More and better occupational dose data should be recorded, mainly in hands and fingers of the specialists.
5. Feasible incidents analysis and emergency plans design should be made.
6. An accurate definition of the target volume and a 3D dosimetry require imaging, and IVUS seems to be the adequate technique.

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RADIATION RISK TO PATIENT FROM INTRACORONARY BRACHYTHERAPY

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Abstract

During the last years coronary endovascular brachytherapy has been extensively explored as a new treatment to prevent restenosis after percutaneous coronary interventions. While clinical and physical aspects of such treatments are addressed in literature, there is little information available on radiation protection and radiation safety aspects. In this paper we estimate the radiation risk for the patient using analytical methods and Monte Carlo calculations for three delivering systems currently used in clinics. Additionally, radiation risk to personnel involved in such treatments is investigated. For gamma emitting sources the radiation exposure to patients is in the order of magnitude of the exposure due to diagnostic angiography. Doses to organs at risk when applying beta emitting sources are significantly lower. Measured doses for the intervention personnel are consistent with the estimated whole body dose. They are smaller than 7,5 µSv per intervention, which is a dose much less than 0,1% of the annual radiation worker`s Maximum Permissible Dose (MPD) recommended by EC regulations, and less than 1% of the general public`s MPD.

1. Introduction

Ischemic heart disease due to narrowing is a significant cause of morbidity and mortality in the Western world. Restenosis is severely limiting the clinical outcome of percutaneous vascular interventions. Clinical studies have shown the possibility to apply endovascular irradiation for the prevention of restenosis [1-5]. Depending on trial protocol and source design, respectively, prescribed doses are between 7 and 20 Gy. The dose specification point, however, differs. For example, a point at 2 mm distance from the source axis has been used in some studies while others used a specified depths (e.g. 1 mm) into the vessel wall.

Detailed knowledge about the dose-distribution around endovascular brachytherapy sources is essential for retrospective analysis of dose-response relationship, to perform accurate treatment planning and to estimate the possible impact on radiation protection for the treated patients. However, since endovascular brachytherapy is a new field in brachytherapy, little information is available on dose distributions for treatment planning and estimations of the dose to organs at risk.

Additionally, detailed knowledge about the magnitude of the whole body dose received by the interventional staff (radiation oncologist, physicist, interventionalist) involved in coronary endovascular brachytherapy is needed in order to limit the dose to staff members according to the ALARA principle.

2. Methods

We studied three different sources designs currently applied for intracoronary brachytherapy treatments: (1) a seed ribbon consisting of six ^{192}Ir seed sources, each 3 mm length, (2) a ^{32}P wire source of 40 mm length, and (3) a ^{90}Sr/^{90}Y seed train of 40 mm total length.

Precision dosimetric studies have been performed for these different source geometries and nuclides using Monte Carlo calculations with EGSnrc [6] code. Beta and gamma emitting

sources were simulated in a plane-cylinder geometry model, using accurate energy emission spectra. We calculated the relative dose at various radial distances from the source center.

For distances beyond 1 cm from a ^{192}Ir source center line it is also possible to calculate the dose following the formalism described in the AAPM TG43 protocol [7]. Using the air kerma rate constant for a Ir-192 seed (0.109 μGy m^2/MBq/h) and the dose rate constant (1.12 cGy/h/U) the dose rate at 1 cm from the source center can be calculated based on a given activity.

The quantity *Total Reference Air Kerma* can be used to specify brachytherapy applications [8]. It is the sum of the products of the *Reference Air Kerma Rate* and the irradiation time for each source, expressed in Gy (or convenient multiples). The TRAK is fast and easy to calculate and should be used in endovascular brachytherapy for the following reasons, (i) doses to all organs and thus to the integral dose to the patient are directly proportional to the TRAK, and (ii) the TRAK provides an estimation of the kerma (dose) rate at one meter from the source which can be useful for radiation protection purposes, and (iii) the inverse square law allows to estimate the dose delivered during the treatment to the organs at a distance from the source(s) down to 10-20 cm.

The dose rate distribution in the standard cardiac catheterization laboratory is measured using suitable dosimeters and survey meters. In order to obtain the dose to individuals the measured dose rate is multiplied by the treatment time, for each relevant location in the catheterization laboratory. The doses to individuals are estimated by applying the inverse square law and taking into account shielding by the human body. Additionally, area monitoring inside and outside the cardiac catheterization laboratory is performed using dosimeters and survey meters [9].

3. Results

Figure 1 presents Relative dose variation in radial direction from the source axis for the three different source design investigated.

In order to further compare the different nuclides concerning radiation exposure a dose prescription of 20Gy is presumed at 2 mm distance from to source axis. Table 1 summarizes the respective dose values at 1cm distance.

Based on a calculation using the TG 43 calculation formalism the dose rate at 1 cm distance from the source is 11.28 Gy/h for a 9250 MBq (250 mCi) ^{192}Ir source. For a typical treatment time of 18 min the resulting dose is 338 cGy at 1cm distance. This value confirms the Monte Carlo result presented in table 1.

Relevant organs, such as bones, lung tissue, spinal cord, thyroid, breast (women) are located at in distances from the source of 10cm and more. Therefore, the doses to these organs at risk can be estimated using the inverse square law and neglecting absorption or scatter. Following this theory, for beta emitting sources the dose to relevant organs at risk at 10cm distance is lower than 0.01cGy, for gamma sources it is lower than 4cGy, respectively.

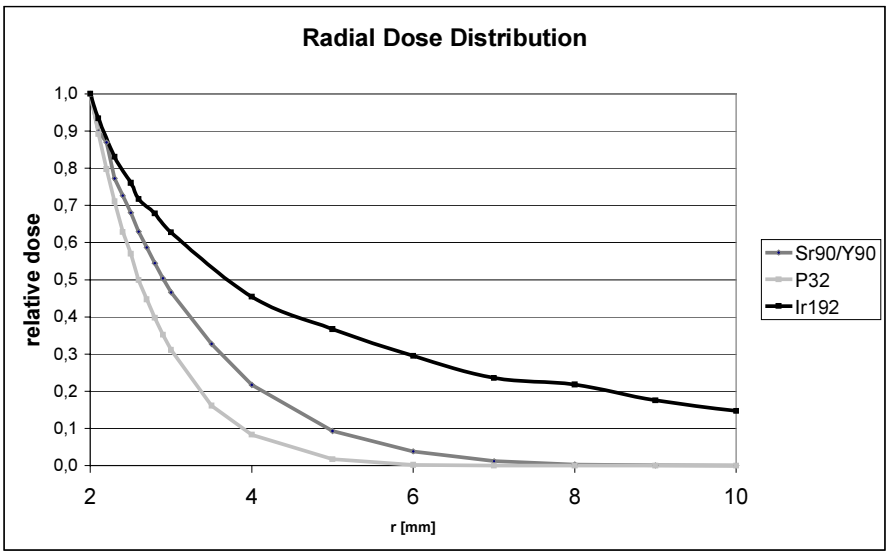

FIG. 1. Relative dose variation in radial direction from the source axis for the three different source design investigated

Table 1. Dose at 1 cm distance from the source axis (dose of 20 Gy at 2 mm) for the three sources types

	Factor	Dose
Ir-192	0,16	320 cGy
Sr-90/Y-90	0,0003	0.6 cGy
P-32	0,0001	0.2 cGy

The Total Reference Air Kerma (TRAK) for the Ir-192 source specified above is 302μGy. Air Kerma Rate for beta sources are only due to Bremsstrahlung and cannot be defined precisely.

The doses measured for the intervention personnel are less than 7,5 μSv per treatment which is a dose less than 0,1% of the annual radiation worker`s Maximum Permissible Dose (MPD) recommended in EC regulations. The measured dose for a single individual of the general public outside is the cardiac catheterization laboratory is less than 1‰ of the general public's MPD.

4. Discussion and conclusion

Pattee et al. [9] estimated the organ dose during an 'average' coronary angioplasty procedure, which are 2.29 cGy for Bone, 9.35 cGy for lung, 0.99 cGy for thyroid and 4.89 cGy for breast (women). According to the results presented above the additional organ doses resulting from endovascular brachytherapy applications are far below this values when using beta emitting sources and in the same order of magnitude for for gamma emitting sources.
The dose at larger distance resulting from a beta emitting nuclei is due to Bremsstrahlung production. Therefore doses to organs at risk are much lower when applying beta emitting sources as compared to gamma sources.

The TRAK value presented for the Ir-192 source applied in intravascular brachytherapy is about one order of magnitude lower than the values reported for 'conventional' brachytherapy applications. It has been shown in several clinical trials that restenosis can be avoided by intracoronary brachytherapy. The possible re-narrowing without brachytherapy have to be treated by another coronary intervention including further angiography exposure. Although there is an additional radiation exposure to patients and personnel by this single treatment the values are much smaller than those caused by a second angiography (ALARA principle).

The personal dose measurements and calculations showed that all principles of ALARA are fulfilled within the clinical trials. Safety and effectiveness is demonstrated for localized radiation therapy with endovascular brachytherapy sources during cardiovascular interventions for the treatment of patients with in-stent restenotic lesions.

Acknowledgements

This work was supported by a grant from the Austrian Research Centers Seibersdorf. We would like to thank our colleagues from the Department of Internal Medicine II, Division of Cardiology, for successful co-operation and fruitful discussions.

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Topical Session 9

RADIOLOGICAL PROTECTION OF PATIENTS IN BIOMEDICAL RESEARCH

No contributed papers have been received for this session.

Topical Session 10

INFLUENCE OF STANDARDIZATION IN THE DESIGN AND DEVELOPMENT OF MEDICAL RADIOLOGICAL EQUIPMENT ON THE RADIOLOGICAL PROTECTION OF PATIENTS

INITIAL EVALUATION OF A FULL BREAST DIGITAL SYSTEM

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Abstract

Full-field digital mammography systems have been developed for overcoming the limitations of the screen-film mammography. This work is focused on the system from GE Medical Systems (Senographe 2000) which has been recently installed in our institution. The imager consists of a thin Ics:Tl scintillator which is in narrow contact with an array of amorphous silicon detectors mounted in a single panel. The flat-panel detector is integrated in a x-ray system with a high-frequency generator Senographe DM and dual track anode of Mo and Rh with Mo and Rh filtration. The aim of this work is to analyse the defaults exposure factors set at the installation of the x-ray unit. The image quality has been evaluated by using one of the two phantoms recommended in the ACR Accreditation Program. Phantom images were obtained at each of the three available imaging modes: contrast (CNT), standard (STD) and DOSE. While maintaining the defaults of kilovoltage and anode/filter combination, phantom images were obtained at lower dose vales. The contrast noise ratio (CNR) was calculated for each of the low contrast objects (masses) of the phantom images and the details visibility was also evaluated. The results obtained for both parameters reveal that similar image quality can be obtained with significant reductions of the average glandular dose.

1. Introduction

The development and application of digital technologies in mammographic x-ray systems has been the subject of many investigations, which have addressed the capability of such systems for overcoming the limitations of screen-film mammography. The first digital mammography systems introduced were for the guidance of stereotactic biopsy procedures [1] but these systems use small-format devices that are not directly applicable to full-breast mammography. To overcome this limitation, four manufacturers have been working in development of prototypes that accomplishes the requirements of full-field digital mammography. Now, the system from GE is commercially available and we present in this work the results obtained in a preliminary evaluation of the Senographe 2000D. This digital mammography system is based on a multipulse high frequency generator (Senographre DMR, GE Medical Systems, Milwaukee, USA). It is equipped with a dual track target (Mo and Rh) with selectable filtration of Mo or Rh and a non-stationary grid. The full breast digital imager is composed of a thallium-doped caesium iodide (CsI:Tl) scintillator in contact with a two dimensional amorphous silicon photodiode array manufactured in a single module. The array is formed by a matrix of 1800x2304 detector elements that are 100 μm in pitch. The electrical signals of each pixel are individually read out and digitised to 16 bits digital values. The important physical properties (dynamic range, presampling modulation transfer function (MTF), noise power spectrum (NPS), detective quantum efficiency (DQE) and noise equivalent quanta (NEQ)) of the flat panel detector were evaluated with a clinical prototype and the results were recently published [2]. These results indicate that the DQE is improved with the flat panel imager (mainly for the frequencies involved in the low-contrast lesions imaging) and the spatial resolution is higher with screen-film systems. The lower spatial resolution can be overcame by contrast enhancement of digital data as it is suggested in some studies [3].

3. Material and methods

The default exposure techniques established by the manufacturer during the installation of the facility have been evaluated in terms of dose and image quality. Tube output at each kVp and anode/filter combination were measured by using an ionisation chamber (4000 M Plus, Victoreen Inc., Cleveland, USA) calibrated and traceable to a secondary standard. The chamber was positioned at 52 cm from the tube focus, and the compression paddle was in place at 10 cm above the chamber. Entrance surface dose (ESD) was calculated from tube output measurements and the current tube time product needed for obtain each phantom image. Image quality was evaluated with the Nuclear Associates model 18-220 phantom (Nuclear Associates, New York, USA) which is one of the two phantoms approved by the ACR Mammography Accreditation Programme [4]. The 18-220 phantom is equivalent to approximately 42 mm compressed average breast (50% adipose/50% glandular composition) and was placed on the breast table with its chest-wall edge aligned with the chest-wall side of the imager. Two phantom images were acquired at the three different automatic imaging modes that are available in the mammographic system: contrast (CNT), standard (STD) and dose (DOSE). The default exposure factors (kVp, mAs, anode/filter combination) together with the ESD and the average glandular dose (DG) displayed at the acquisition workstation monitor were recorded for each image. Subsequently, several images were acquired at the manual mode by reducing to the half the mAs while maintaining the kVp and anode/filter combination. The image quality was estimated in terms of contrast noise ratio (CNR) and detail visibility for the processed phantom images. The CNR was evaluated for the 1ow contrast test objects included in the phantom simulating masses. This parameter was calculated through the following expression [5]:

$$CNR = \frac{\left|\mu_{in} - 1/2(\mu_{out1} + \mu_{out2})\right|}{\sqrt{\sigma^2{}_{in} + 1/2(\sigma^2{}_{out1} + \sigma^2{}_{out2})}}$$

where μ represents the mean and σ the pixel to pixel standard deviation of a region of interest (ROI). The subscript “in” refers data collected from the ROI within the low contrast objets and “out1” and “out2” refers data collected from two ROI adjacent to the test objects. The ROI area was 350 pixel side for the in and out ROIs. An experienced observer evaluated the detail visibility over the processed images displayed in a high-resolution monitor. Window, level and magnification settings were set to maximise visualisation of fibers, specks, and masses. The number of each type of details visualised was compared with the acceptable scores proposed in the Stereotactic Breast Biopsy Accreditation Program (ACR-SBBAP) [6] introduced by the ACR for digital systems.

3. Results

The ESD values estimated from measurements with the ionisation chamber were approximately 10% lower than the values calculated and displayed by the system. This difference is of the same magnitude that the measurement errors.

3.1. Contrast noise ratio (CNR)

The CNR values of the masses calculated according to the above expression are represented in Fig. 1. At Fig. 1(a) each curve corresponds to the default exposure conditions displayed for the three imaging modes (CNT, DOSE and STD). As it can be seen, similar CNR values were

found for the CNT and STD modes while the DG value was 10% lower for the STD mode. CNR values decreased for all the masses when DG values were progressively reduced to the half, excepting in the CNT mode (Fig. 1 (b,c,d)). In this case, the highest CNR values correspond to the lowest DG value.

3.2. Detail visibility

Table I show the scores given to the phantom images together with their corresponding DG values. The images obtained at the default conditions (highest DG values) accomplished the acceptable scores proposed by the ACR-SBBAP [6] (5 for fibers, 4 for specks and 3.5 for masses) excepting the one obtained at the DOSE mode. With this imaging mode, the scores are highest for the image with a half DG value of the default image. This result is in agreement with CNR curves show in Fig. 1(b). The results also demonstrate that images with similar quality can be obtained at lower DG when the system is operating at the CNT mode. At the STD mode, the scores given to the fibers do not meet the acceptable value. However, similar image quality is also obtained with a DG vale half of the default one.

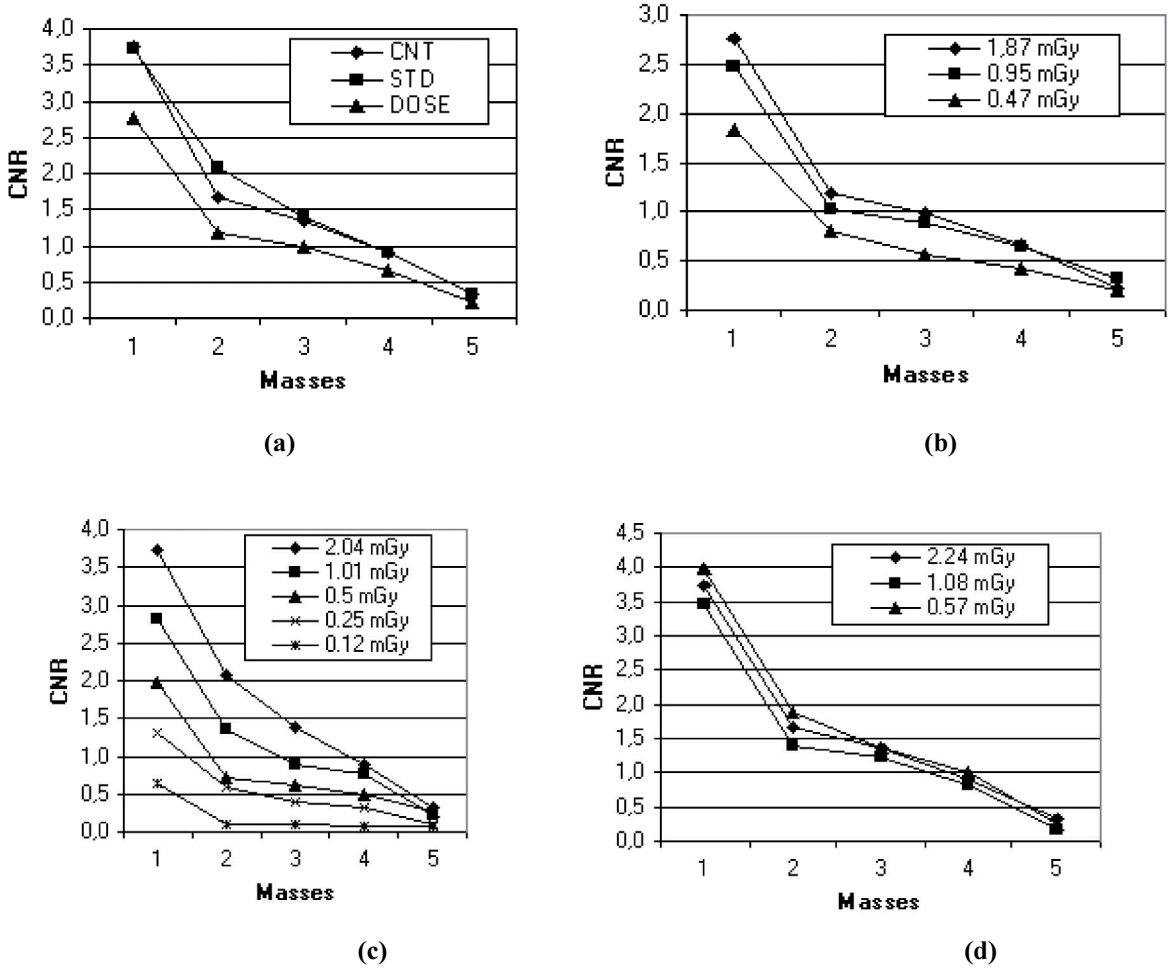

Figure 1. Contrast noise relation (CNR) versus low contrast details (masses) inserted inside the phantom. (a) Comparison of the CNR values obtained at the exposure conditions set at each imaging mode; Effects of reducing the average glandular dose on the CNR values at (b) DOSE mode (Mo/Rh, 31 kV); (c) Standard (STD) mode (Mo/Rh, 28 kV); (d) Contrast (CNT) mode (Mo/Rh, 26 kV)

Correlation between CNR and detail visibility was analysed by considering the CNR values calculated for the last mass detected in most of the phantom images (4th mass). Fig. 2 shows that there exists a positive correlation between CNR and the total score obtained by adding the particular scores given to each type of detail.

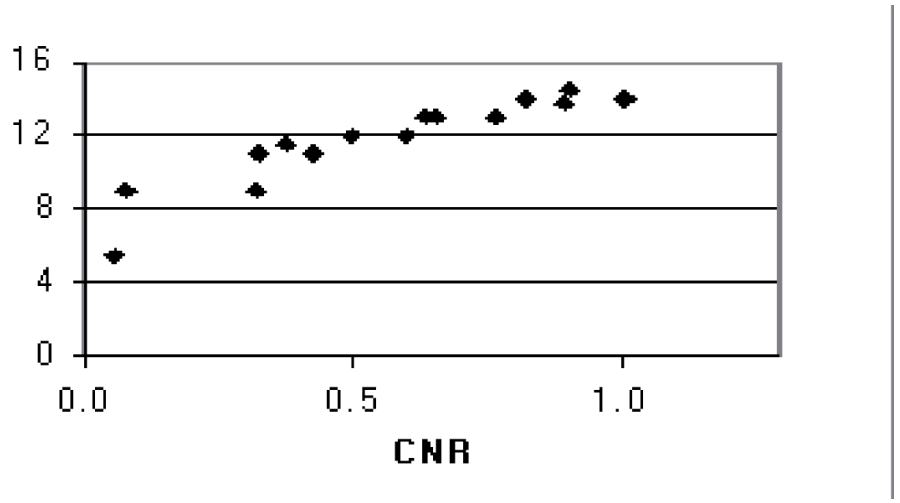

Figure 2. Correlation between total score and contrast noise ratio (CNR)

4. Conclusions

From this initial evaluation could be concluded that enough image quality could be obtained with a dramatic reduction of the DG values associated to the default exposure conditions. The correlation between the total score and CNR show that the latest is a robust parameter for evaluating the image quality in terms of a non-subjective magnitude.

It is also concluded that it is necessary a deeper analysis of the imager behaviour, since the results for the CNT imaging mode are not in agreement with the linearity conditions found for this system in previous studies [3]. Moreover, similar results were obtained with another image quality phantom that are not here presented.

Table I. Effects of decreasing average glandular dose (DG) values (photon fluence) on detail visibility for each imaging mode. The values in the shaded cells correspond to the default exposure conditions.

	CNT Mo/Rh, 26 kVp			STD Mo/Rh, 28kVp					DOSE Mo/Rh, 31 kVp		
DG (mGy)	0.6	1.08	2.24	0.12	0.25	0.5	1.01	2.02	0.5	0.95	1.9
FIBERS	5	5	5.5	3	3	4.5	4.5	4,75	4	5	4.75
SPECKS	4	4	4	2	2	3	4	4	3	4	3.5
MASSES	5	5	5	4	4	4.5	4.5	5	4	4	4.75

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IAEA-CN-85-167

EXPERIMENTAL DETERMINATION OF BLURRING IN X-RAY FLUOROSCOPY LAST IMAGE HOLD DUE TO PATIENT MOVEMENT AND ITS REPERCUSSION TO PATIENT DOSES.

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Abstract

Significant dose reduction can be achieved in fluoroscopy and interventional radiology by using the last image hold (LIH). This feature in modern digital fluoroscopy x-ray units usually works with frame or temporal averaging techniques to reduce noise. This image quality works quite well for objects without motion but it could be a serious limitation in presence of motion blur. With an in-house developed robotic device, authors have experimentally determined the image quality degradation introduced by normal physiological movements (i.e., respiratory and cardiac pulse movements). FAXIL test objects TO.10 and 18FG from Leeds University have been used for spatial resolution limit and threshold contrast detail detectability. Seven X-ray equipments with last image hold features from three different manufacturers were analysed. Although results show that motion blur affects LIH in different extend depending on equipment, magnification, entrance dose and detail size, it can be estimated that, on average for all equipments and analysed conditions, represents 30% degradation in image quality parameters in comparison with static images.

1. Introduction

One of the most effective ways for reducing patient doses in fluoroscopy and in interventional radiology fluoroscopy guide procedures is to minimise fluoroscopy time. For that, Last Image Hold (LIH), is a powerful tool. The last image acquired is presented continuously on the monitor until fluoroscopy is once again activated. Meanwhile, radiologists could decide about the diagnosis and further actions to be taken. In the case of an image sequence, the temporal filtering properties of the human visual system reduces perceived noise. In the case of a single constant image (such as LIH) this mechanism does not work and the image looks noisier and low contrast details disappears [1]. For that reason, it is well known that motion affects LIH and in principle it is contradictory to improve the SNR by summation frames or by temporal filtering and at the same time refrain from motion blurring for the same image. There have been some perception studies [2] on motion blurring in x-ray fluoroscopy, but in our knowledge there is not any experimental publication on motion blurring in LIH fluoroscopy. In addition, there are different possibilities to reduce system noise and manufacturers usually do not provide enough information about their designs, among them, summation of 2 frames accumulated in the digital memory, summation of 4 frames in the same way, use of recursive filters with different k factors (weight factors) or use of movement detection circuits [3].

Authors have developed a computer controlled device able to reproduce patient motions and in which it is possible to insert different types of test objects to evaluate image quality in the presence of motion. In this paper, using this device an experimental determination of the degradation of the spatial resolution and low contrast detail perception caused by patient and organ motion is presented for some X-ray equipment with Last Image Hold fluoroscopy.

2. Material and method.

We have designed and constructed a prototype of 2-D motor controlled phantoms with the preliminary goal of simulating clinical situations in which patient movement could be a cause of

image degradation or rejection. PAtient MOvement Simulation Test Object (PAMOSITO) was constructed with modular parts to use different mobile test objects and static structures (See [4] for a first PAMOSITO design and applications] The system allows programming different cycles of movement along two axes (x and z). PAMOSITO features two step motors for the z axis with a 50 mm range to simulate the patient respiratory movement and small displacements in X-ray oblique projections. The test object can be moved along the x axis by means of a linear motor with a 145 mm range. The linear motor by Linmot© (Sulzer Electronics AG) allows 500 mm/s of maximum velocity (in increments of 190 mm/s) and 1000 mm/s^2 (in increments of 238 mm/s^2) and is a direct linear drive with integrated position sensing. Those excellent dynamic properties make it possible to simulate very close cardiac pulses or quick involuntary movements.

A layer of 2 mm of copper was used to simulate the patient absorption. The test objects employed for the image quality evaluations were TOR(TO.10) and 18FG for fluoroscopy, from FAXIL [University of Leeds, UK]. The evaluation methodology followed the FAXIL recommended viewing protocol [5]. Three observers scored images for low contrast detectable discs and for high contrast spatial resolution limit. Spatial resolution grid was placed 45° respect the x-motion axis.

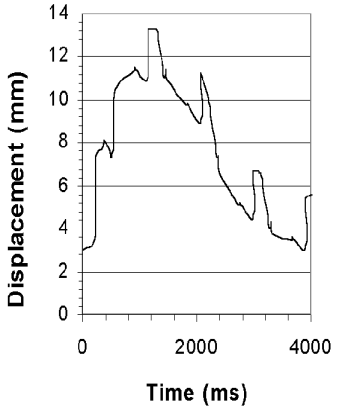

Figure 1: Motion curve loaded into the electronics of PAMOSITO representing a quiet breathing plus a cardiac pulse

PAMOSITO with TO.10 and 18FG test objects was used with the motion curve presented in figure 1, which corresponds to a quiet breathing plus a normal cardiac pulse. This type of motion closely mimic a clinical situation with a sedated patient and it does not affect continuos fluoroscopy. In fact, no significant differences were observed in the fluoroscopy images with this motion curve between the static test object image and the corresponding motion test object images, for all X-ray systems studied. Phantom entrance doses were measured with a RADCAL 2025 external ionising chamber. Doses were normalised at 50 cm phantom entrance surface. Seven different X-ray installations with fluoroscopy and LIH in clinical use for different specialities (vascular, digestive, neurorradiology, and multipurpose systems) were studied. X-ray units were: Toshiba Max1000 (2 units), Toshiba KX080G, Toshiba KXO SDF, Siemens Digitron, Philips BV300 and Philips Omnidiagnost. Image systems admit different magnification, so that images were evaluated for 23 cm, 17 cm and 15 cm fields.

3. Results

Comparative results for high contrast spatial resolution limit in three situations (continuous fluoroscopy with the static phantom, LIH with the static phantom and LIH with the curve motion of figure 1) are shown in Table I for different equipments and for different magnifications. As examples of Contrast Threshold Detail Curve results Figure 2 to 5 are presented for two different equipments and two different magnifications.

TABLE I. Reduction of Spatial resolution limit in lp/mm for Last Image Hold with and without patient motion.

	FIELD 23 cm			FIELD 17 cm			FIELD 15 cm		
X-ray equipment	Fluoro No motion	LIH No motion	LIH Motion	Fluoro No motion	LIH No motion	LIH Motion	Fluoro No motion	LIH No motion	LIH Motion
Toshiba KX080G	2.0	1.8	1.4	2.5	2.5	2.0	3.1	3.1	2.2
Toshiba XKO SDF	1.4	1.4	1.1	1.8	1.8	1.4	2.5	2.5	1.8
Toshiba Max1000 (room1)	1.8	1.8	1.4	2.2	2.0	1.4	2.8	2.5	1.6
Toshiba Max1000 (room 2)	1.4	1.4	0.9	2.0	2.0	1.2	2.8	2.8	2.0
Siemens Digitron	1.0	1.0	0.8	1.2	1.1	0.9	18	1.6	1.1
Philips BV300	1.6	1.4	1.1	2.0	2.0	1.8	--	--	--
Philips Omnidiagnost	1.2	1.2	0.9	2.0	2.0	1.1	2.5	2.5	1.4

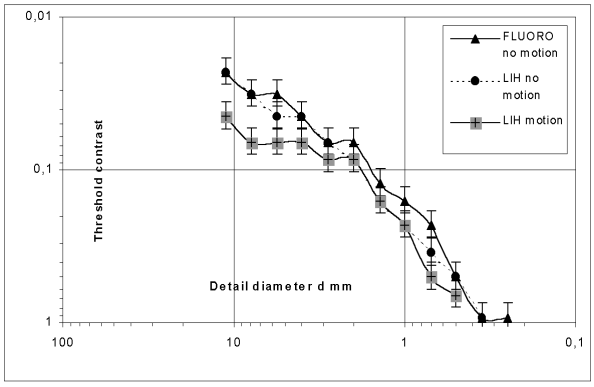

Figure 2: TCDD curve for LIH with and without motion.

Philips Omnidiagnost - Field 23 cm– 71 kV – 14,9 mGy/min

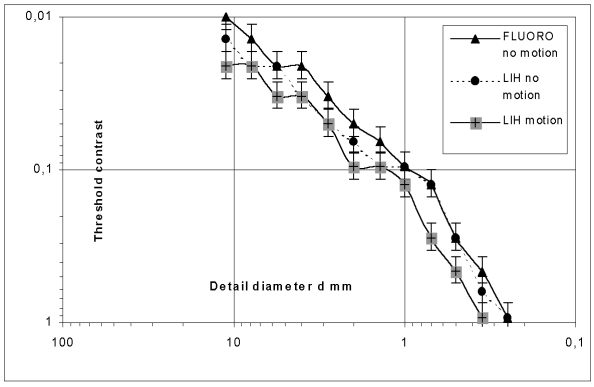

Figure 3: TCDD curve for LIH with and without motion.

Philips Omnidiagnost - Field 17 cm– 74 kV – 25,1 mGy/min

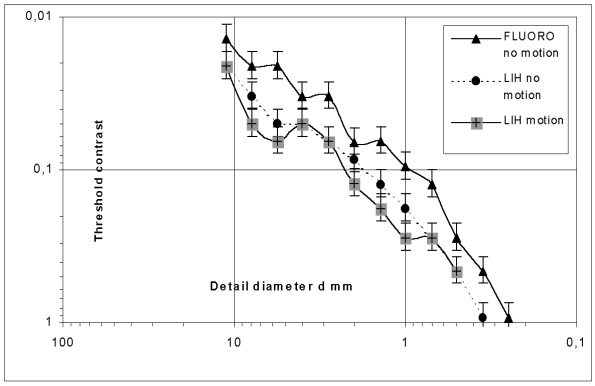

Figure 5: TCDD curve for LIH with and without motion.
Toshiba Max 1000 - Field 17 cm– 75 kV – 16,8 mGy/min

4. Discussion

Note from table I that in the case of no motion spatial resolution is for most situations not affected (on average for all equipments and magnification, the spatial resolution loss can be estimated in 3,5%). This was expected since LIH does not introduce changes in the spatial resolution properties of the system and as mentioned before manufacturers introduce some noise reduction techniques so that noise is not usually a limitation for the spatial resolution limit. However motion blurring affect the LIH significantly and it is more important in magnification modes. On average for all equipments, the loss of spatial resolution is 26,5% (field 23 cm), 28,5% (magnification mode; field 17 cm) and 35% (magnification mode; field 15 cm) respect the corresponding fluoroscopy image. This fact must be known by interventional radiologists since magnification usually requires higher surface entrance patient doses. For example the phantom entrance dose for the Philips Omnidiagnost equipment (last row in table I) was 14,9 mGy/min (field 23 cm), 25,1 mGy/min (field 17 cm) and 39,4 mGy/min (field 15 cm). Note in last row of table I that the improvement of spatial resolution achieved by using the magnification is lost by the LIH with patient motion.

As stated in the introduction more significant losses are observed both for LIH with static objects and LIH with motion objects for Low Contrast Detail sensitivity. Here, we have observed differences depending not only on magnification (compare figure 3 and figure 5 respect figure 2 and figure 4) but on the manufacturer equipment and model (which likely could be explained by use of different temporal filters or number of added frames to built the last image hold). The equipment for figures 2 and 3 shows little degradation when using LIH in static object and an important extra degradation for LIH in moving objects, on the contrary, the equipment for figures 4 and 5 shows an important degradation for LIH and static objects and a little extra degradation for LIH and moving objects. On average for all equipments, magnifications and detail sizes the loss in contrast detail sensitivity for LIH and moving objects is 30% respect to the corresponding fluoroscopy images.

5. Conclusions

Although results show that motion blur affects LIH in different extend depending on equipment, magnification, entrance dose and detail size, it can be estimated that, on average for all equipments and analysed conditions, represents 30% degradation in image quality parameters. Degradation is more important in magnification modes so that radiologists should be known this

fact to optimise their protocols. Manufacturers should be encouraged to improve image quality of LIH both for static and motion structures since it use is essential for patient dose reductions.

Acknowledgements

This project is partially supported by the Spanish CICYT (project n. PM97-0059-C02-01).

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THE DANUBE HOSPITAL PROJECT FOR AUTOMATED TRANSCRIPTION OF X RAY DOSE DATA FROM RADIOGRAPHY, FLUOROSCOPY AND COMPUTED TOMOGRAPHY (CT) INTO THE ELECTRONIC PATIENT RECORD

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Abstract

Introduction Assessment of x-ray exposure data is generally cumbersome, especially because of the lack of a commercially available solution for automatic integration of dose data into an electronic patient record (EPR). Therefore, we constructed a concept for automatically linking x-ray exposure data with a radiology information system (RIS). **Material and Methods:** X-ray modalities are equipped with a Dose-area product (DAP) meter and connected to a RIS PC via a serial RS-232 interface. For computed tomography, dose-length product (DLP) is computed from the normalised CT dose index, number and thickness of slices. Examination details including number of frames, mAs, kV, exposure time etc. are recorded automatically by software polling and added to the examination record in the RIS. **Results:** The system has already been implemented with a digital fluororadiography system, other modalities are continuously being integrated. The time previously necessary for manual dose data transcription and saved now will sum up to about 1000 working hours per year. **Conclusion:** Automatic transfer of exposure parameters from X-ray imaging modalities to the EPR is important for quality assurance and risk assessment. Also, it facilitates compliance with legal requirements and set-up of diagnostic reference levels.

1. Introduction

Increasingly, legislative regulations (e.g. European radiation protection laws, the basis of which is the EURATOM directive 43/97) require routine measurements for quality assurance and radiation protection. According to these laws, dosimetry (and consequences drawn thereof) should be part of everyday radiologic practice. However, dosimetric surveys are cumbersome and complicated and therefore still often seen as scientific undertakings and presented at scientific meetings, rather than taken as a natural part of radiologic practice.

One important reason therefore is that *recording* of X-ray exposure data still has to be done manually and thus causing surplus expenditure of working time. Although some examples of automatic data recording systems exist[1], actually no direct link is available with the electronic patient record (EPR). In order to achieve a future-oriented solution for optimisation of X-ray exposure of its patients, the Danube Hospital management agreed upon financing a development program for the development of a system for automatically recording x-ray exposure data from radiography, fluoroscopy and computed tomography (CT) into the EPR within a commercially available radiology information system (RIS).

2. Material and methods

The Danube Hospital radiology department performs 133 000 radiological examinations per year. All radiologic images are acquired digitally and processed within a hospital wide Picture archiving and Communication System (PACS)(SIENET, Siemens, Erlangen, Germany). Word data (patient identification, examination requests, examination statistics, radiological reports) are connected to the PACS and processed by a commercially available RIS (SAS, Siemens Vienna, Austria).

Dosimetric quantities chosen to be recorded are the dose-area product (DAP)[2,3] for radiographic and fluoroscopic examinations (including angiographic procedures[4]), and the dose-length product (DLP) for CT examinations[5].

Three categories of x-ray producing imaging modalities are available:

1. Exposure parameters are directly contained within the DICOM (Digital Imaging and Communications in medicine) image header. Since PACS and RIS are using a joint data base, interfacing the radiation dose-related data sets is quite simple. This applies to both CT and two recent DSA and DFR units.
2. radiation exposure is measured by a DAP ionisation chamber (Diamentor M4, PTW Freiburg, Germany) already installed on the X-ray unit, however not transmitted to the DICOM image header. Here a RIS PC has to be dedicated to this X-ray unit, both are connected by a data cable via a serial RS232 interface. A background computation process running on the RIS PC polls data from the DAP meter and the X-ray unit (including number of frames, kV, mAs, etc.) and stores them in a data file additively.Following functionalities have to be implemented with RIS softbuttons: DISPLAY values: a message box containing values already stored and the last value actually measured within an examination.ACCEPT values: confirming and/or correcting the values indicated is possible. Thereafter, automatically RESET values (after ending an examination) pops up, which resets the recorded values in the "dosis.ini" file to zero.This solution is possible with three fluoroscopy units (9 and 6 years old).
3. units with no DAP meter installed and no exposure data contained in the DICOM header have to be equipped additionally with a DAP meter, interfacing is achieved like above. This applies to all radiographic units (working with computed radiography digital storage phosphor plates) and a DSA and a cardangiographic unit.

3. Results

Installation of a DAP meter costs approx. ∈ 4720.- per radiographic/fluoroscopic unit (3270.- hardware, approx. 1450.- installation). Costs of interfacing are approx. 1500.- for X-ray units of category 2+3, 4500.- for CT units and approx. 3000.- for the fluoroscopy units of category 1. All this sums up to approx. 89.000.-∈ for the 16 X-ray units of our radiology department. Assuming only 60.000 examinations of which dose values have to be documented within one year, and assuming one minute of additional time required for manual dose data input per examination, this would sum up to 1000 hours of working time per year, i.e. 125 working days, i.e. 0.5 radiographer jobs per year. Thus, the investment for automatic dose transfer will pay itself within a few years. Currently, the most recent of our DFR units (mainly used for gastrointestinal fluororadiography) is interfaced with the RIS. The other X-ray modalities in our radiology department are continuously being integrated as well.

4. Conclusions

Automated transcription of x-ray dose data from radiography, fluoroscopy and CT into the electronic patient report is technically feasible It may be the only economical way to comply with legal requirements of complete documentation of the patients X-ray exposures. This project might serve as an incentive for further similar developments in co-operation between radiologic institutions and manufacturing companies.

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IAEA-CN-85-261

DIMOND II: MEASURES FOR OPTIMISING RADIOLOGICAL INFORMATION CONTENT AND DOSE IN DIGITAL IMAGING

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Abstract

The European Commission concerted action on 'Digital Imaging: Measures for Optimising Radiological Information Content and Dose', DIMOND II, was conducted by 12 European partners over the period January 1997 to June 1999.

The objective of the concerted action was to initiate a project in the area of digital medical imaging where practice was evolving without structured research in radiation protection, optimisation or justification. The main issues addressed were patient and staff dosimetry, image quality, quality criteria and technical issues. The scope included computed radiography (CR), image intensifier radiography and fluoroscopy, cardiology and interventional procedures.

The concerted action was based on the consolidation of work conducted in the partner's institutions together with elective new work. Protocols and approaches to dosimetry, radiological information content/image quality measurement and quality criteria were established and presented at an international workshop held in Dublin in June 1999. Details of the work conducted during the DIMOND II concerted action and a summary of the main findings and conclusions are presented in this contribution.

1. Introduction

The European Commission concerted action on 'Digital Imaging: Measures for Optimising Radiological Information Content and Dose', DIMOND II, was conducted by 12 European partners over the period January 1997 to June 1999.
The partners involved were as follows:

- Department of Medical Physics and Bioengineering, St. James's Hospital, Dublin.
- Regional Medical Physics Department, Newcastle General Hospital, UK.
- Department of Radiology, Krankenhaus der Barmherzigen Bruder, Trier, Germany.
- STUK, Helsinki, Finland.
- Department of Radiology, Leuven, Belgium.
- Department of Radiology, University of Innsbruck, Austria.
- Ministere de la Sante, Division de la Radio Protection, Luxembourg.
- Department of Radiology, Complutense University, Madrid, Spain.
- Medical Physics Department, Regional General Hospital of Athens, Greece.
- TNO Centre for Radiation Protection, Rijswijk, The Netherlands.
- Department of Radiology, Ospedale S. Maria Della Misericordia, Udine, Italy.
- Diakonissenkrankenhaus, Abt. Rontgendiagnostik, Karlsruhe, Germany.

The objective of the concerted action was to initiate project in area of digital medical imaging where practice was evolving without structured research in radiation protection, optimisation or justification [1]. The main issues addressed were patient and staff dosimetry, image quality, quality criteria and technical issues. The scope included computed radiography (CR), image intensifier radiography and fluoroscopy, cardiology and other new interventional procedures [1].

In addition to the formal objective, there was also an informal objective of establishing a cohesive effective group with participants from a range of disciplines and from a wide range of European countries.

The structure of the concerted action consisted of many workpackages and deliverables and was based on the consolidation of work in partners' institutions and elective new work. In practice the work was organised into the following main tasks areas or groups:

- Dosimetry,
- Radiological information content,
- Quality criteria,
- Cardiology,
- Technical parameters and
- Project management,

with input from various other specialised subgroups

2. Objectives and results

Dosimetry

The main objectives of the dosimetry group were to conduct a review of the wide diversity in approaches to patient, staff and equipment dosimetry for different examinations, to conduct a dosimetry intercomparison study between the project partners, to document calibration issues with respect to patient and staff dosimetry, to identify useful trends in published data for interventional and collective dose in Europe and elsewhere and to conduct cardiological patient and staff dosimetry studies [1].

Patient and staff dosimetry protocols have been produced [2,3]. The following approaches to patient dosimetry have been identified: i) patient dose may be established by monitoring the dose area product (DAP) for real or simulated patients, ii) entrance skin dose may be measured using an ionisation chamber for the technique factors used or iii) thermoluminiscent dosimeters (TLDs) may be placed on the patients skin at the centre of the radiation field [2,3]. Patient dose values may be used to develop reference values [3].

Patient examinations have been classified into the following categories: 'simple' (not involving more than four exposures, without the use of fluoroscopy or contrast media), 'complex conventional examinations' and 'interventional examinations' [3].

Staff dosimetry protocols have been established which cover two aspects: personal dosimetry and area dosimetry [2,3]. Area dosimetry involves the assessment of dose at various locations within the X-ray room which enables iso-contour maps to be deducted. Whole body dose should be assessed for all individuals monitored and for high risk individuals, shoulder (eye) and hand doses should also be assessed. A standard protocol has been written [2,3].

An intercomparison of TLD measurements was conducted between the participants as many patient and staff dose measurements utilise TLDs. The results demonstrated a high degree of variability and dispersion values of greater than 25% were found for some systems [3]. This survey demonstrates the importance of intercalibration work. A protocol for image intensifier dosimetry was compiled to be compared with reference values/protocols and to prompt further actions in quality assurance if required [2].

A review of published and partners data on interventional/collective doses has been conducted and the results were presented at the international workshop in Dublin [3]. This review data provides valuable baseline date from which comparisons can be made however factors such as lack of methodological standardisation between European scientists and lack of standardisation between radiographic devices, examinations and techniques contribute significantly to variations observed [3]. Cardiological dosimetry studies were documented for patients & staff [2,3].

3. Radiological information content

The objectives of the Radiological Information Content task group were to conduct a review of objective and semi-subjective methods of measurement of image quality, to review measured image quality and dose issues, to review methods of constancy checking and to relate visualisation criteria and objective / subjective measurements [1].

Methods and protocols were reviewed for quantitative and qualitative measurement of image quality for CR, angiography and digital subtraction angiography (DSA) and related to dose [2,3]. New investigations and reports on measured image quality and dose issues were published [4]. A report on psychophysical aspects of imaging/image quality was produced [3]. Constancy checking protocols have been established among partners and were presented at the international workshop [3]. These protocols highlight the advantages of constancy checking.

4. Quality criteria

One of the objectives of the concerted action was to establish quality criteria guidelines for digital procedures. These guidelines are to be based on the quality criteria guidelines published by the European Commission for diagnostic radiology and CT [5,6] and will include recommendations on clinical and technical parameters, examples of good equipment performance, criteria for patient dose, definition of visualisation criteria and the meaning of linguistic descriptors. The objectives of the quality criteria task group were to select the procedures for the digital quality criteria study, to identify clinical visualisation criteria and technical parameters for these procedure and to conduct a pilot trial of the selected procedures among the partners [1].

The following procedures were identified: CR (chest, skeletal), Image intensifier (small bowel, ascending venography), DSA (pelvis, lower extremities, dilation of iliac arteries) [2]. Clinical visualisation criteria and technical parameters were established and the final draft of the quality criteria document is now in place [7]. An extensive trial of visualisation criteria and technical parameters has been conducted.

5. Cardiology

The need for a multi-centre group specialising in cardiology was identified at the start of the concerted action which lead to the establishment of the cardiology group. Quality criteria were established for angiographic images [2,3] and a scoring system was devised for image quality evaluation [2,3]. A proposal for a complexity index for PTCA procedures was made and radiation protection training objectives for staff were identified and addressed [2].

6. Technical Parameters

Prior to the commencement of the concerted action there was no generic specification for interventional radiology equipment for users or manufacturers, there were no international standards for interventional equipment, there were no technical parameters for digital quality criteria and visualisation studies and there was a lack of technically defined optimisation strategies. The main objectives of the technical parameters task group were to address these issues [1].

The group produced a draft generic specification for interventional radiological equipment for contribution to an IEC standard [8], provided technical parameters for the quality criteria guidelines [7] and identified approaches needed for a definitive study of optimisation strategies.

7. Discussion and conclusions

Considerable progress was achieved in this concerted action in terms of scientific and clinical endeavor, co-ordination and cooperation. Many aspects of diagnostic and interventional radiology, dosimetry protocols, radiological information content and technical parameters were reviewed and have been used as a platform from which protocols, methodologies and quality criteria have been developed and clinical trials conducted. An international workshop was held in Dublin in 1999 and the proceedings are currently in press [3]. The participants of the project extend their thanks to the European Commission for their support in this work and to the co-ordinators of the working groups.

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IAEA-CN-85-237

IMPLEMENTATION OF "EARLY ALERT SYSTEM" AREA DETECTOR AT PATIENT FROM ENTRANCE IN AFTERLOADING BRACHY THERAPY

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Abstract

A system of area monitors to detect the involuntary exit of the radiation sources used in low dose rate deferred braquiteraphy treatment is being implemented in all facilities in Chile. The first implementation of this system, named "Early Alert", was 5 years ago as a in complement to the administrative procedures and verification measures by the medical physics carried out through visual verifications and by means of portable radiation detectors. This detector of the system should be located preferentially at the exit of the treatment room at a height not smaller than two meters. This has resulted in an increase of facilities safety in this practice.

Resumen

En Chile actualmente sé esta implementado en todas las instalaciones que prestan atención de Braquiterapia diferida con bajas tasas de dosis, un sistema de monitores de área los cuales detectan la salida involuntaria de las fuentes de radiación utilizadas. Este sistema denominado "Alerta Temprana" se ha venido implementando favorablemente desde hace 5 años [1] en forma complementaria a los procedimientos administrativos y de verificación por parte de los físicos médicos realizadas a través de verificaciones visuales y mediante detectores portátiles de radiación. Este sistema debe estar ubicado preferentemente en el acceso a la habitación de tratamiento a una altura no menor a dos metros, esto ha permitido aumentar la seguridad en este tipo prestaciones médicas.

1. Introducción

La pérdida de fuentes radiactivas de braquiterapia para baja tasa de dosis es bastante frecuente en Instituciones Públicas, esto ocurre principalmente por lo escaso de los recursos humanos y monetarios asignados para este tipo de procedimientos, que conlleva a por lo general a poseer un solo detector de radiaciones ionizantes para un gran número de procedimientos al año (aproximadamente 300 pacientes al año) y a un bajo número de profesionales especializados. Las instalaciones de Braquiterapia además están asociadas a instalaciones de Teleterapia con ^{60}Co. Se suma a los pocos recursos asignados el nivel social de los pacientes que en muchos casos no logran entender la importancia de mantener en posición los dispositivos de implante dejada por el médico tratante, desde el punto terapéutico como de protección radiológica.

2. Reseña histórica

La implantación de dispositivos con fuentes de braquiterapia se realizaba principalmente en la tarde del día viernes, esto generaba que durante los días sábado y domingo la paciente se encontrara sola la mayor parte del tiempo asistida por personal paramédico de turno, en muchas ocasiones la paciente se retiraba el dispositivo botando las fuentes al piso, posteriormente el aseo del fin de semana era retirado el día lunes en la mañana. El recuento de las fuentes no sé hacia hasta terminado el tratamiento y retiradas los dispositivos del paciente.
El rango de acción para los encargados de protección radiológica se reducía a verificar sala de hospitalización, baños, desagües, pasillos, zona de desechos y finalmente vertedero, en los cuales en algunas oportunidades por lo general se encontraba la última fuente faltante, en otras, nunca más se encontraron.

3. Actualidad

Hoy en día los procedimientos de braquiterapia se realizan en días de semana y en habitaciones habilitadas especialmente, lo que permite una verificación directa de la seguridad del paciente, de los funcionarios y de las demás personas donde se aplican procedimientos establecidos adecuadamente de protección radiológica.

4. Materiales y metodos

Se evaluaron tres instituciones **A** (institucional privada), **B y C** (institucionales del Estado), que poseen sistema de detector de área que es complementario a los procedimientos habituales de protección radiológica, el detector esta ubicado en el acceso a la sala de hospitalización pudiendo estar al interior o exterior a una altura no inferior a 1,5 metros.

Las instalaciones poseen una configuración similar, sin embargo, difieren en la ubicación de sus salas:

Institución A: Cuenta con una sala taller con depósito de almacenamiento incluido y separadamente en otra área de la institución una sala de hospitalización de Braquiterapia. Ver fotografías 1 y 2.

Figure 1 Puerta de ingreso a la sala taller con su dispositivo de alerta temprana ubicado a un costado

Figure 2 Puerta de ingreso a la sala de hospitalización con su dispositivo de alerta temprana ubicado a un costado

Cada sala posee un detector de área, además al interior del taller se ubico un detector de área que alerta la presencia de fuentes radiactivas al manipularlas y colocarlas en los porta-fuentes. Ver Fotografía 3.

Interior de la

Figure 3 Interior de la sala taller con dispositivo de alerta temprana adosado a la pared, al momento de sacar las fuentes este instrumento acusa la presencia de radiación ionizante.

Institución B: Unidad que cuenta con salas de hospitalización para seis pacientes y taller con depósito de almacenamiento de fuentes con solo un acceso principal donde se instaló el detector de área, existe un paramédico de turno día y noche para verificar las condiciones de las pacientes, el movimiento de las fuentes solo se realiza al interior de la unidad. La instrumentación detectaría la salida de fuentes radiactivas desde el taller y de las salas individuales, Fotografía 4.

Figure 4 Sala de hospitalización con capacidad para seis pacientes, existe un paramédico de día y noche para verificar la condición de los pacientes, el movimiento de las fuentes solo se realiza al interior de la unidad.

Institución C: Unidad que cuenta con salas de hospitalización para cuatro pacientes y taller con depósito de almacenamiento de fuentes con solo un acceso principal, donde se instaló el detector de área. (Fotografía 5).

Figure 5 Posición del detector de Alerta temprana en acceso principal a la unidad de Braquiterapia y Medicina Nuclear, ubicación interna, además en la parte superior de la puerta se observa un interruptor magnético que alerta de la salida o entrada de personas.

Figure 6 Las conexiones Eléctricas deficientes o expuestas a la fácil manipulación por personas inexpertas, pueden provocar funcionamiento errado y por ende la interrupción de la detección de las radiaciones ionizantes.

Resultados

La evaluación de la cantidad de situaciones detectadas en las instituciones en la cual se activa la alarma del detector de área, se han enfocado en una o dos de las cuales no se reporta pérdida de material radiactivo (se da a conocer el año y el evento acontecido), estas son:

- En la institución A, en 1999 se activo la alarma del detector de área de la sala de Hospitalización, sin embargo esta alerta fue controlada, debido a que uno de los pacientes tuvo que ser implantado con la fuente radiactiva en quirófano para luego ser derivado a la sala de hospitalización de braquiterapia. Los funcionarios realizan verificaciones del funcionamiento y del estado adecuado de los detectores de área.

- En la Institución B, uno de los problemas que surge en 1999, fue la manipulación de los interruptores por parte de los paramédicos los cuales apagaban el detector por las noches debido a que la señal de funcionamiento no dejaba dormir a las personas de turno, no restableciendo el sistema por las mañanas. El Físico Médico generó una orden para el servicio para que el detector estuviese operativo durante las 24 horas del día. Los funcionarios realizan verificaciones frecuentes del funcionamiento del detector de área.

- En la Institución C, en 1998 una de las pacientes con problemas siquiátricos quiso salir de la unidad, esta paciente sin dispositivos radiactivos implantados, siendo detectada por el sensor activando la alarma en la puerta del único acceso que posee la unidad. Al no tener fuentes de radiación no se activó el detector de área. Los funcionarios no realizan verificaciones frecuentes del funcionamiento y estado del detector de área.

5. Conclusiones y discusion

La implementación de los detectores de área que es parte fundamental el sistema de alerta temprana, este sistema ha demostrado que facilita la detección por salidas involuntarias de material radiactivo, el solo echo que funcione teniendo presencia al interior de las dependencias y que las pruebas que los funcionarios realizan a intervalos regulares

verificando el funcionamiento genera un efecto sicólogo favorable de seguridad y hasta cierto modo de confianza, si bien es cierto por si solo este sistema no es suficiente para llevar un control exhaustivo de la protección radiológica en una instalación, es necesario además capacitar a las personas, paramédicos y otros funcionarios en los aspectos básicos y en algunos casos avanzados de la protección radiológica, además de la utilización rutinaria de los detectores de radiación portátiles.

Es importante destacar la posición del monitor de área y en especial de las conexiones de alimentación eléctrica e interruptores que fijan el umbral de detección del instrumento, este si está en una posición muy cercana a la manipulación por personal ajeno a la unidad, como también la desconexión a la red eléctrica, Fotografía 6, genera situaciones que podrían derivar en la “no-detección” y por lo tanto no alertar la presencia de material radiactivo. Para prevenir estas situaciones es recomendable tapar las conexiones o empotrarlas en la pared.

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Topical Session 11

EDUCATION, TRAINING AND CONTINUOUS PROFESSIONAL DEVELOPMENT IN THE RADIOLOGICAL PROTECTION OF PATIENTS

THE NEW SYSTEM OF EDUCATION AND TRAINING OF MEDICAL STAFF IN RADIATION PROTECTION IN ALBANIA

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Abstract

The present situation as regarding the education and training of medical staff in radiological protection is discussed. In particular the protection of patients, children and pregnant women were the most sensible topics in some courses held in recent years. Emphasis is given in a number of courses and course units dealing with radiation safety problems in the medical field and their content.

1. Introduction

It is the third consecutive year that Albania has begun to implement a national strategy for training of personnel involved in the work with sources of ionising radiation in the medicine. As a matter of fact some 95% of all the applications with radiation sources in the country fall into the medical field, mostly in the diagnostic radiology. We are in backward in other directions with 1 department of radiotherapy and 1 department of Nuclear Medicine both located in the University Hospital Centre "Mother Theresa" in Tirana. But there is a tendency nowadays to open private clinics and in the last year 3 CT scanners, 2 private diagnostic clinics and some 10 clinics in dentistry have been licensed to begin the operation.

There are some 600 professionals working in the medical domain out of 700 radiation workers in the country. This number has pushed the regulatory authority in the field to seek and find a proper way that this big contingent should pass through a process of training in the field of radiation protection. Two other reasons to regulate the training of medical personnel are

- The majority of x -ray machines in the country are old and obsolete and are cause of increase in personal doses the professionals get during their work.
- There is not a safety culture in the country even among the radiation workers. Especially now that the medical system is going to be privatised the radiologists rush to their profit and forget their and the patients safety.

In the frame of the Model Project of IAEA our regulatory authority began to implement a national system of training of all the radiation workers in the medicine. The first national course was held in October 1998 with the financial support received from IAEA. 30 radiologists have participated chosen from some medical institutions in the country where radiation sources are used. The lecturers were local people who had taken part in more than three IAEA courses and seminars on the topics they would present.

The great success of this course and many claims from medical personnel especially in the districts that they were not informed to apply for it, made the authorities to think about setting up a scheme through which all radiation workers in medicine must be trained in some level.

2. Radiation protection courses held by Radiological Protection Act

Under the Model Project we have developed the legislation i.e. the Radiological Protection Act (rpc) of 1995, some regulations and are embarked in preparing the code of practices in the medical uses of radiation. In the regulation "On safe use of ionising radiation" it is stated that :

"All radiation workers should undergo a process of training and retraining. The management of the facility is responsible for training of their employees. It is the duty of the inspectors of RPC (regulatory authority) to ask for certificates of training…". [2]

These regulations require that health physicists acting as radiation protection officers (RPO) should take certified including examinations. A comprehensive knowledge of radiation protection rules and regulations is a prerequisite of appointment as RPO but also for physicians who apply radiological procedures for diagnostic and/or therapeutic purposes.

Continuing in this direction we asked the IAEA and the second training course was planed for October 1999 but organised in February 2000 with the participation of 60 radiologists where two experts sent by IAEA were present. It was well received by radiation workers community and the bulletin of Albanian Radiological Society published many lectures.

Another training course this time in radiotherapy and nuclear medicine was held in October 2000. This time 30 participants from two departments of University Hospital Centre "Mother Theresa" attended. Two foreign lecturers from UK and Sweden together with local lecturers made this course the best organised in last few years. We have got now much experience from this.

3. Radiological protection of the patients

We have set up a general program of training of medical staff with the main topic being:

Lectures given	By
Legislation and regulations	Radiation Protection Office
Code of practice in the particular activity	Expert in the U H Centre
Potential exposures	Expert from scientific society, UHC
Exposure of personnel	RPO of Institute Nuclear Physics
Exposure of patients	Expert from UHC- Tirana
QA and QC	Foreign expert from IAEA

The exposure of the patients is always a subject lengthy treated during the training courses. This is because there has been much interest in reducing the doses received by patients especially during routine diagnostic x-ray investigations.

In the lectures for legislation and regulations always is stated the principles that form the basis of radiation protection system. In the following we want to give some items always the medical staff should bear in mind:

The exposure of patients should always be subject to the normal principles of justification and optimisation.

No patient be administered a diagnostic or therapeutic medical exposure unless the exposure is prescribed by a medical practitioner [2].

For therapeutic uses of radiation (including teletherapy and brachytherapy), the calibration, dosimetry and quality assurance requirements of the Standards be conducted by or under the supervision of a qualified expert in radiotherapy physics.

To optimise the protection for medical exposures the practitioner should ensure the appropriate equipment.

The diagnostic and possibly the therapeutic benefit must exceed the risk of applying ionising radiation.

Radiological examination causing exposure of the abdomen or pelvis of women who are pregnant or likely to be pregnant be avoided unless there are strong clinical reasons for such examination.

Every effort should be made to keep doses to a reasonable minimum because of the higher expected risk of radiation induced effects in children than in adults.

4. Training at organisational level

Numerous opportunities intended to improve radiation use and protection standards are offered every year by various scientific or medical institutions at different levels and times aimed at employees.

For more than 10 year the UHC hold a national 9 months course for technicians working in diagnostic radiology. This certificate has been a necessary document to find a job in medical care system.

Last year University Hospital Centre and Institute of Nuclear Physics has applied to the regulatory authority to get accreditation as organisations which hold one week courses in Radiotherapy and Nuclear Medicine the first and in industrial radiography the second.

Besides these activities different scientific societies often organise specific training on radiation matters. Very active in this regard is Albanian Society of Radiologists (some 200 members). Some time ago it has formed its physics section dealing with doses that patients receive during different examinations.

5. Conclusions

We will continue with organising such training courses in the next two year under IAEA regional project. A scheme is presented in Radiation Protection Commission asking that beginning in 2005 all radiation workers should go through a system of training and retraining every two years and the sum of points they get will influence to the salary.

Education programmes on radiation protection are not yet available in schools and universities. Some efforts are made recently to include lectures of it into the contents of such disciplines as radiological physics, radiation chemistry and radiation biology.

A peer review mission which came in Albania in October 2000 to evaluate achievements under IAEA Model Project has acknowledged progress made in the direction of education and training [3].

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EDUCATION AND TRAINING OF THE RADIATION PROTECTION IN THE SPANISH SCHOOLS OF MEDICINE

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Abstract:

Education in Radiation Protection (RP) should be part of the Medicine curriculum, in accordance with the recommendations of the Directive 97/43/EURATOM and Report 116 of the European Commission. The propose of this paper is to show the current situation of the Radiation Protection teaching at the Schools of Medicine of Spain. 27 Spanish Schools of Medicine have been revised. Only in the Cantabria University, the PR constitutes an obligatory subject. In the other Universities, the PR subject appears as an optional matter with 3 to 5 credits. There is disparity among the educational contents on RP that are imparted in the Medicine Degree of the Spanish Schools. We propose the following recommendations: To define the educational objectives accurately, looking for a real interest for any medical student; to unify the contents and programs in the different study plans, and to elaborate an appropriate educational material, including practical cases that facilitate learning.

1. Introducción

La enseñanza de la Protección Radiológica debe formar parte del curriculum de la Licenciatura de Medicina de acuerdo con la recomendación de la Directiva [1] 97/43/EURATOM sobre exposiciones médicas que, en su artículo 7, indica que los estados miembros "fomentarán que se introduzca un curso de Protección Radiológica en el programa de formación básica de las Facultades de Medicina y Odontología".

En la Guía [2] de la Unión Europea sobre Educación y Formación en Protección Radiológica en Exposiciones Médicas (Report RP116), se recomienda la formación en Protección Radiológica en los estudios de Medicina, indicando incluso una serie de temas específicos. El objetivo de este trabajo consiste en mostrar **la situación actual de la Docencia de la Protección Radiológica en las Facultades de Medicina de España**.

Hay que señalar que, actualmente en España, se han instaurado nuevos planes de estudio de Medicina en numerosas Universidades mientras que, en otras, aún se siguen los planes de estudio que se encontraban en activo desde hace muchos años. Esta situación da lugar a planteamientos dispares en la enseñanza de la Protección Radiológica lo que dificulta un estudio comparativo.

¿Porqué la necesidad de la enseñanza de Protección Radiológica en el PREGRADO?
Todo médico que utilice radiaciones ionizantes debe conocerlas y saber utilizarlas correctamente. No sólo son los que hacen de su utilización la base de su profesión (especialistas en Radiodiagnóstico, Radioterapia y Medicina Nuclear), sino también un gran

número de especialistas médicos en otras áreas. Son precisamente estos últimos profesionales los que mayor necesidad tienen de conocimientos sobre Protección Radiológica ya que los contenidos fundamentales de su especialidad distan mucho de los relacionados con las radiaciones ionizantes. Es necesario tener presente que todos los Licenciados en Medicina pueden prescribir pruebas diagnósticas ó terapéuticas a sus pacientes que impliquen el empleo de este tipo de radiaciones que, como es bien conocido, al tiempo que producen beneficios para los pacientes pueden ocasionar también riesgos derivados de la exposición a las mismas. El médico debe conocer adecuadamente, entendiendo y aceptando las medidas que sea necesario tomar en la práctica para evitar efectos indeseables tanto al personal sanitario como a los pacientes y, por extensión, al público en general.

2. Material y método

Se han revisado los planes de estudio de la licenciatura de Medicina de 27 Facultades españolas. En la Tabla 1 se presentan los datos correspondientes a 21 de ellas, indicando la fecha de resolución para la entrada en vigor de los nuevos planes de estudio así como el Boletín Oficial del Estado (BOE) en que han sido publicados.

Tabla 1. Nuevos Planes de Estudio de las Facultades de Medicina en BOE

Universidad	Resolución	BOE
Alcalá de Henares	9 de Noviembre de 1999	10 diciembre, núm. 23601
Autónoma de Barcelona*	12 de enero de 2000	9 febrero, núm. 2665
Autónoma de Madrid*	1 de septiembre de 1999	16 septiembre, núm. 18871
Barcelona	19 de Septiembre de 1994	1 diciembre, supl. num.287
Cádiz	19 de noviembre de 1992	17 diciembre, num.302
Cantabria	2 de agosto de 1994	7 septiembre, núm. 20034
Castilla La Mancha	18 de septiembre de 1998	6 octubre, núm. 23217
Complutense de Madrid	2 de febrero de 1993	24 febrero, núm. 5270
Córdoba	28 de noviembre de 1995	3 febrero, supl. Núm. 30
Extremadura	11 de enero de 1999	9 febrero, núm. 3361
La Laguna	27 de septiembre de 1995	21 octubre, supl. Núm. 252
Las Palmas de G. Canaria	27 de junio de 1997	23 julio , núm. 16587
Elche	18 de noviembre de 1997	19 diciembre, núm. 27382
Navarra	25 de octubre de 1993	10 enero, núm. 485
Oviedo	10 de marzo de 1994	29 marzo, núm. 7322
P. Vasco	28 de julio de 1993	20 agosto, núm. 21834
Tarragona	14 de junio de 1993	13 julio, núm. 17295
Salamanca	15 de diciembre de 1995	19 enero, supl. Núm. 17
Sevilla	12 de diciembre de 1995	3 febrero, supl. num.30
Valencia	25 de septiembre de 1998	21 octubre, núm. 24310
Valladolid	1 de septiembre de 1994	14 septiembre, núm. 20327

- Ultimas modificaciones al plan de estudios

3. Resultados

En la Tabla 2 se presentan las materias o asignaturas de Protección Radiológica en 10 Facultades, así como la carga lectiva en créditos (1 crédito = 10 horas lectivas) en cada una de ellas. Con el epígrafe “Dedicación” se señala la clasificación de la materia en el correspondiente plan de estudios.

Tabla 2. Facultades de Medicina con asignaturas de Protección Radiológica o relacionadas

Universidad	Asignatura	Créditos	Dedicación
Cantabria	Protección Radiológica	4	Obligatoria
Complutense de Madrid	Protección Radiológica	4,5	Optativa
Córdoba	Protección Radiológica	6	Optativa
Extremadura	Protección Radiológica	3,5	Optativa
La Laguna	Protección Radiológica	3	Optativa
Málaga**	Protección Radiológica	5	Optativa
Murcia**	Protección Radiológica	3	Optativa
Santiago de Compostela**	Radioprotección	3	Optativa
Alcalá	Radiaciones Ionizantes	5	Optativa
Barcelona (Central)	Salud Pública y Ambiental	9	Optativa

** Facultades con planes de estudio antiguos.

Sólo en un caso (Universidad de Cantabria), la Protección Radiológica constituye una asignatura obligatoria de Facultad. En las demás Universidades figura como materia optativa de Facultad con un número de créditos que, como puede observarse, oscila entre 3 y 5. En las Facultades cuyos planes de estudio se analizaron y en cuyos curricula no figura la materia "Protección Radiológica" se dan diversas situaciones:

a) En la Facultad de Medicina de la Universidad de Alcalá, entre las asignaturas optativas en el recientemente publicado plan de estudios, existe una denominada "Radiaciones Ionizantes" de 5 créditos, en cuyos contenidos se encuentran algunos de Radioprotección.

b) En la Universidad Central de Barcelona, en la materia optativa denominada "Salud Pública y Ambiental", de 9 créditos, aparecen como contenidos a impartir dentro de la misma los correspondientes a "Riesgos de las radiaciones ionizantes y Protección Radiológica", a los que se dedica algo menos de la décima parte del tiempo total de la asignatura.

c) En el futuro plan de estudios de la Facultad de Medicina de la Universidad de Zaragoza, está programado dedicar casi 1crédito de los 11 que constituyen la asignatura "Radiología y Medicina Física" de 3º Curso, a la Protección Radiológica.

d) La Facultad de Medicina de Cádiz dedica, aproximadamente 1 crédito a Protección Radiológica repartido, entre la carga lectiva de las asignaturas de Física Médica y de Radiología y Medicina Física que se imparten en 1º y 3º curso respectivamente.

e) En las demás Facultades de Medicina, no indicadas anteriormente, se dedican a los temas correspondientes a Protección Radiológica durante la Licenciatura, una carga lectiva comprendida entre 0 y 0.4 créditos (la mayoría 0.2.

En general, la enseñanza de la Protección Radiológica corre a cargo de profesores bien de Física Médica o bien de Biofísica que, mayoritariamente imparten docencia en Primer Curso. Estos profesores pertenecen en un 60% al área de conocimiento de "Radiología y Medicina Física" y el resto a otras áreas, principalmente "Fisiología" y "Física Aplicada".

4. Discusión y conclusiones

Existe notable disparidad entre los contenidos educativos sobre Protección Radiológica (PR) que se imparten en la Licenciatura de Medicina en las diversas Facultades españolas y también en la carga lectiva de esta disciplina. No existe acuerdo en la inclusión de contenidos dentro del temario sobre Protección Radiológica que versen sobre Física de las Radiaciones Ionizantes, Efectos y Riesgos de las Radiaciones, etc. lo que da lugar a programas muy diferentes.

Actualmente en España existe preocupación en el ámbito oficial para homogeneizar la enseñanza de la Protección Radiológica en los estudios de la licenciatura de Medicina. Parece probable una disposición en que se señale la necesidad de dedicar 3 créditos (30 horas) de formación en esta materia.

Consideramos que la disparidad existente en la Docencia de la PR en España, puede deberse a:

1. la dispersión de sus contenidos en las diversas asignaturas relacionadas con esta disciplina,
2. el número, en general insuficiente, de créditos necesarios para impartir los programas propuestos,
3. la falta de coordinación entre el profesorado responsable de la enseñanza de Física Médica y de Radiología.

Para evitar esta situación se propone el poner en práctica los siguientes puntos:

1. Definir con precisión los objetivos educativos docentes, buscando que sean de interés real para cualquier estudiante de Medicina.
2. Unificar los contenidos y programas en los diferentes planes de estudio.
3. Elaborar un material docente atractivo incluyendo demostraciones o casos prácticos que faciliten el aprendizaje.

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THE CHANGING ROLE OF THE RADIOGRAPHER UNDER IR(ME)R 2000

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Abstract

This paper deals with the way in which the College of Radiographers has used the new Ionising Radiation (Medical Exposure) Regulations 2000 [IR(ME)R] to promote role development among its 17,000 radiographers in the UK. It aims to show that the resultant role development will have a beneficial effect on the radiation protection of the patient in diagnostic radiography.

1. Aim

To keep radiation doses as low as is reasonably achievable whilst maintaining diagnostic efficiency.

The College of Radiographers, which is the professional body of radiography in the UK and boasts over 90% of all state registered radiographers in its membership, has taken the above statement as their theme over the last year in conjunction with the introduction of the new legislation IR(ME)R 2000.

IR(ME)R 2000 is the statutory legislation, which was laid before parliament in April 2000 and is designated as the Ionising Radiation (Medical Exposure) Regulations 2000 which is based on the adopted European Directive 97/43/Euratom.

The objective of the professional body, which in the United Kingdom is the College of Radiographers, has been to reintroduce radiographers to a sense of personal responsibility for radiation exposure, which is, in fact, part of their Code of Professional Conduct. [1] The subject of this paper is the importance of the changing role of the radiographer in diagnostic imaging due to the implementation of IR(ME)R.

The introduction of IR(ME)R legislation in May 2000 has given the College of Radiographers the opportunity to run country wide seminars to introduce members to a new interpretation of their responsibilities.

Under the previous legislation POPUMET (Protection of Persons undergoing Medical Examinations and Treatments Regulations 1988) it seemed possible to defer the responsibilities of physically directing radiation to a third person, the clinically directing radiologist.

The new legislation, IR(ME)R, has a far more robust framework and sets out much more clearly the areas of responsibility for each duty holder post, these being the practitioner, operator and referrer.

These duty holder posts are defined as “a health professional who is entitled in accordance with the employer’s procedures to take responsibility for an individual medical exposure”(practitioner). “Any person who is entitled in accordance with the employer’s procedures to carry out the practical aspects” (operator) and “ a healthcare professional who is entitled in accordance with the employer’s procedures to refer individuals for medical exposure to a practitioner” (referrer) [2].

The policy of the Society and College of Radiographers states [3] “Under these new regulations a radiographer is able to act as a referrer, practitioner, and operator within the field of specialisation defined by his or her expertise, training and continuing professional development. Only these personal attributes and circumstances determine which healthcare professional in any team assumes the role of operator, practitioner or referrer. Profession or discipline alone should not be used to determine duty-holder roles.”

The new legislation has led to an unprecedented level of cooperation between some of the professional bodies associated with healthcare in the UK. The Dept of Health (DOH), Institute of Physics and Engineering in Medicine (IPEM), British Institute of Radiology (BIR), Royal College of Radiologists (RCR), Society and College of Radiographers (SCOR) and the National Radiation Protection Board (NRPB) all worked together in the early stages of consultation of the Draft regulations and suggested a number changes which were indeed incorporated in the final Legislation. Following on from that, implementation of the legislation is being expedited by further collaboration of the same working group to firstly identify any training needs of the post holders and secondly to set national Diagnostic Reference Levels (DRL) for as many examinations as seems practical.

The change of emphasis from POPUMET to IR(ME)R has led to the responsibility for the exposure of the patient to doses of ionising radiation becoming the remit of the Operator (notwithstanding that a Practitioner has already carried out justification).

Radiographers are by definition operators and their appraisal of the relevance of the request to the particular individual patient is probably better than most other healthcare professionals. If the duty of the practitioner in justifying the examination is also carried out by a radiographer, and this is quite likely in some modalities, then the likelihood of patients undergoing an individual exposure to radiation that is unnecessary could be considerably lessened.

Under IR(ME)R the radiographer can take on the role of referrer, practitioner and/or operator and it may well be that, whilst not all radiographers will do all of the above, this reallocation of roles will provide continuity and establish good quality decisions about patient examinations across the board. Ionising radiation is not always the correct diagnostic tool and a referral to, perhaps, Ultrasound or Magnetic Resonance Imaging may be the more suitable course of action.

A radiographer as a practitioner will be named by the employer as such in his or her own field of clinical specialism and would not be expected to perform that role in any other area of work. This will ensure that clinical expertise is used judiciously and in the best interests of the patient. It is acknowledged that even senior experienced radiographers might need a little more clinical training before becoming practitioners and will certainly have to be able to prove ongoing competence with continuing professional development.

The new regulations place a far greater responsibility on the employer to ensure that protocols and standard operating procedures are in place. This will be best achieved by calling in the expertise of the radiographer working in that modality and providing input into the content of these standard operating procedures. The duties of the referrer, operator and practitioner need to be defined, explained and training undertaken locally so as to comply with the local procedures and protocols. These should be written in a way that allows a radiographer to make a professional judgement on supplementary views. The radiographer’s skill and experience in this field is vital in making IR(ME)R workable. Few other clinical staff can make these

judgements safely. The professional judgement used by radiographers as operators must be protected in spite of local “written protocols” if we are to maintain the ethos that “all radiographers are legally accountable for their professional actions and for any negligence by act or omission or injury”(Code of Professional Conduct)[1].

Para 2.7 of the Society and College of Radiographers Guidance for Radiographers [3] states, “ the actions of other professionals do not absolve the radiographer of this responsibility”. This will be achieved by rigorous and regular audit of systems and procedures including looking at the relevance of referral criteria and the right to refuse a request if it is inappropriate or not justified.

From all of the above observations it may be surmised that by compliance with IR(ME)R in the workplace, having due support from the employer down through all the duty holders, then radiation dose to the patient may be consistent with the ALARA (As Low As is Reasonably Achievable) principle. This should result in recordable and hopefully diminishing doses to individual patients.

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IAEA-CN-85-214

THE EDUCATION AND TRAINING OF PROFESSIONALS. THE PESPECTIVE OF THE SPANISH SOCIETY OF MEDICAL PHYSICS (SEFM)

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Abstract

The aim of this paper is twofold. First, to revise some European Societies recommendations regarding qualification, education and training of professionals involved in ionisation radiation practices, to respond to the Directive 97/43 EURATOM. And then, as Medical Physicists are directly concerned in these practices, to describe how the Spanish Society of Medical Physics deals with the challenge of improving the competence of Medical Physicists in order to assure the best patient protection against ionisation radiation. Therefore, to achieve the first aim, the point of view of the European Federation of Organisations on Medical Physics (EFOMP) concerning the introduction of the "Medical Physics Expert" and their guidelines for Continuous Professional Development are reviewed, as well as the point of view of European Society for Therapeutic Radiation Oncology (ESTRO) in professional education matters. Referring to the second aim, after succeeding in the recognition of the Medical Physics Speciality in Spain in 1997, the SEFM is actually promoting the Continuous Education and Training of their specialists through its Education Committee (Comisión de Docencia de la SEFM), so that they can cope with all new professional challenges. Moreover, a number of SEFM members are also involved in education matters to others professionals: Medicine students, nurses, Radiation Technologists, etc. In conclusion, the SEFM has always been aware of the importance of specialisation and continuous education of all professionals involved in radiation ionisation practices, as a way to contribute to guarantee the best radiation protection to the patients.

1. Introducción

La Directiva 97/43 EURATOM [1] relativa a la protección de la salud frente a los riesgos derivados de las radiaciones ionizantes en exposiciones médicas, prevé en su artículo 7 que todos los profesionales implicados en las prácticas radiológicas han de tener una formación teórica y practica adecuada para poder desempeñar su profesión.

Este trabajo pretende dar una visión de la respuesta que dan algunas organizaciones europeas a la Directiva citada [1] y de la implicación de la Sociedad Española de Física Médica (SEFM) en el reto de la formación a los profesionales.

2. El punto de vista europeo: Recomendaciones de los organismos europeos

En el artículo 2 de la Directiva 97/43 EURATOM [1] se define la figura del *experto en física médica*, y en el apartado 3 del artículo 6 se le menciona como directamente implicado en los procedimientos terapéuticos de las áreas de Radioterapia y Medicina Nuclear así como en el área de Radiodiagnóstico, cuando proceda.

La Federación Europea de Organizaciones de Física Médica [EFOMP], en su documento "Policy Statement nº 9" [2], da su respuesta al perfil profesional de la figura del experto en física médica, definiendo la figura del *"Medical Physics Expert"* como el profesional que puede cumplir con las características exigidas en la Directiva [1]. Define sus niveles de competencia en cada una de las áreas donde se manejan radiaciones ionizantes y el desarrollo curricular de formación específica necesaria para desempeñar su cometido en cada una de ellas. Además, recomienda enérgicamente que cada país instaure un Programa de Formación Continuada de los Profesionales [3], con el fin de garantizar en todo momento un alto nivel de competencia profesional de todos los especialistas.

Ya en el año 1994, y con el fin de homogeneizar los contenidos curriculares y potenciar el desarrollo de la Formación Continuada de los Profesionales de cada uno de los paises miembros, la EFOMP propone en su documento "Policy Statement nº 6" [4], la creación de un Registro Nacional de acreditación de los profesionales y potenciar el desarrollo de la Física Médica.

Por su parte, la ESTRO [*European Society for Therapeutic Radiology and Oncology*] en su documento "Quality assurance in Radiotherapy" [5] conviene en la necesidad de que todos los profesionales involucrados en los tratamientos de radioterapia: médicos, físicos, técnicos, dosimetristas, posean una formación especializada y acreditada oficialmente en sus respectivos países.

3. La formación de especialistas en física médica: La radiofísica hospitalaria

Desde 1997 en nuestro país, los profesionales dedicados a la Física Médica en el ámbito hospitalario, tienen el reconocimiento oficial de una Especialidad Sanitaria propia: La Radiofísica Hospitalaria.

El Real Decreto 220/1997 de 14 de Febrero [6], marca el punto de partida para esta nueva especialidad. La formación de especialistas se realiza por el sistema de residencia en unidades acreditadas para la docencia por los Ministerios de Sanidad y Consumo y de Educación y Cultura. Se puede acceder a él con el título universitario de Licenciado en Ciencias Físicas, u otros títulos universitarios superiores en disciplinas científicas y tecnológicas, tras haber superado unas pruebas de selección de carácter nacional. El periodo formativo es de tres años ininterrumpidos, durante los cuales el residente sigue un programa de formación aprobado por los Ministerios de Sanidad y Consumo y de Educación y Cultura, a propuesta de la Comisión Nacional de Radiofísica Hospitalaria. La organización, supervisión, programación anual de actividades formativas y evaluación de los residentes y de las unidades por las que estos hagan su rotación, se rige por la normativa sobre Comisiones de Docencia y sistemas de evaluación, aplicable a los especialistas en formación, según las normativas vigentes.

La SEFM ha tenido un papel destacado en el proceso de reconocimiento de la especialidad. La Radiofísica Hospitalaria representa la culminación de muchos años de trabajo, llevado a cabo principalmente por algunos de sus miembros, que con esfuerzo y tenacidad, han dedicado gran parte de su vida profesional al duro empeño de conseguir una especialidad propia.

El gran interés que la SEFM ha tenido desde siempre por la buena formación de los profesionales dedicados a la Física Médica hospitalaria, queda reflejado, por ejemplo, en los cursos de formación que ha promovido y organizado en los últimos años y que cubren todos los ámbitos de la Radiofísica Hospitalaria.

Actualmente, el esquema formativo de los Especialistas en Radiofísica Hospitalaria de nuestro país esta plenamente adaptado a las recomendaciones de la EFOMP [2] incluyendo el Registro Nacional de especialistas [4].

4. La formación continuada de los profesionales especialistas en radiofísica hospitalaria

A partir del año 2001, la SEFM pone en marcha un Programa de Formación Continuada de los Profesionales (PFCP), para los especialistas en Radiofísica Hospitalaria [8]. Dicho programa sigue las recomendaciones de la EFOMP [3] y [7] y está en la misma línea de otras Sociedades de Física Médica europeas que han implantado programas similares.

Los beneficios de un PFCP en el campo de la Radiofísica Hospitalaria son obvios [3], dado que se trata de una especialidad involucrada en la continua evolución tecnológica de las Especialidades Médicas, y se convierte en una base fundamental para asegurar y mantener un alto grado de competencia profesional que garantice la calidad de los diagnósticos y tratamientos y consecuentemente la protección al paciente, tal y como prevé la Directiva 97/43 EURATOM [1].

El PFCP de la SEFM, se basa en la obtención de una puntuación asignada a cada una de las actividades definidas como de Formación de Continuada, y cada socio adherido al programa, ha de conseguir un número estipulado de puntos al año (promediados en un periodo de cinco años). La SEFM acreditará la formación mediante la puntuación obtenida.

Se consideran actividades de formación continuada: los cursos de formación, seminarios, cursos de refresco, la asistencia a congresos/ jornadas de trabajo, la presentación de trabajos en congreso, la publicación de artículos o libros, la lectura sistemática de revistas, la puesta a punto de nuevas técnicas, etc.

La SEFM contribuye al desarrollo y fomento de las actividades de FCP de diversas maneras:

- Organización del Congreso Nacional de Física Médica (bianual)
- Edición de una publicación periódica: Revista de Física Médica. (ISSN 1576-6632)
- Organización de Cursos de Formación (diez cursos previstos para 2001-2002, con acreditación de Formación Continuada por el Ministerio de Sanidad y Consumo [9])
- Concesión de becas y ayudas para asistir a cursos y/o congresos, tanto nacionales como internacionales.
- Estímulo continuado en la calidad del trabajo del día a día.

5. Formación a otros especialistas

La SEFM está también involucrada en la formación de otros especialistas dentro de las profesiones Sanitarias. Acoge en su seno un buen número de profesionales, Profesores de Universidad, que imparten conocimientos de Física y Protección Radiológica en las facultades de Medicina.

La Unión Europea, siguiendo las recomendaciones de la Directiva 97/43 EURATOM [1] en lo que se refiere a la formación de los especialistas médicos, ha elaborado una guía de formación en protección radiológica [10]. La SEFM cuenta con profesionales plenamente capacitados para llevar a cabo esta formación.

Por otra parte, muchos de los miembros de la SEFM forman parte del profesorado que imparte los cursos relativos a la obtención de la formación necesaria para el Personal Profesionalmente Expuesto, así como los cursos de capacitación necesarios según la legislación vigente.

En los Centros Hospitalarios Universitarios, los radiofísicos hospitalarios son los encargados en muchos casos de la formación en materias de física y protección radiológica de los especialistas médicos en formación en las áreas de Radioterapia y Diagnóstico por la Imagen. También imparten cursos de formación y/o refresco en materia de protección radiológica al personal sanitario de titulación de grado medio de las áreas hospitalarias que manejan radiaciones ionizantes.

6. Conclusiones

La formación de los profesionales implicados en las exposiciones médicas a las radiaciones ionizantes, es de vital importancia para garantizar una correcta protección al paciente frente a los riesgos derivados de estas exposiciones. La SEFM, consciente desde sus inicios de la importancia de la buena formación de los físicos implicados en estos procedimientos radiológicos, ha defendido siempre la especialización de los mismos, hasta conseguir la actual Especialidad de Radiofísica Hospitalaria. En esta misma línea, la SEFM promueve la Formación Continuada, consciente de que es de vital importancia para mantener un óptimo nivel de competencia de los profesionales.

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IAEA-CN-85-146

MEDICAL RADIATION PHYSICS TRAINING EMERALD

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Abstract

Training of young medical physicists is an essential part of the framework of measures for Radiological Protection of Patients. The paper describes the Medical Radiation Physics Training Scheme EMERALD, developed by an European Project Consortium. EMERALD Training covers the Physics of X-ray Diagnostic Radiology, Nuclear Medicine and Radiotherapy. Each of these 3 modules covers 4 months training period. The EMERALD training materials are 3 Workbooks with tasks and a Teachers' Guide (total volume approx 700 pages) and 3 CD-ROMs with image database.

1. Introduction

The increased awareness that medicine delivers about 95% of people's exposure to radiation from man-made sources led to number of measures being taken within the European Community. Subsequent Policy Statements of the European Federation of Organizations for Medical Physics (EFOMP) - the regional chapter of the International Organisation for Medical Physics (IOMP) - specified further measures for radiation protection and requirements for the knowledge and skills of the professionals responsible for the safe and proper use of radiation in medicine. On this basis an EC Leonardo da Vinci pilot project [1] was prepared for developing a Framework of common training modules in Medical Radiation Physics (Physics of X-ray Diagnostic Radiology, Nuclear Medicine, Radiotherapy). These modules are for the training of young graduates and post-graduate students in medical physics or related disciplines, their tutors, as well as other Hospital employees applying radiation to medicine. The partners in the project are a Consortium of Universities and Hospitals from UK, Sweden, Italy and Portugal: King's College London - School of Medicine and Dentistry, University of Lund, University of Florence, King's Healthcare Trust, Lund University Hospital, Florence University Hospital, The Portuguese Oncological Institute, the International Centre for Theoretical Physics in Trieste. The acronym of the project is EMERALD (European Medical Radiation Learning Development). It is Managed and Coordinated by King's College London and is supported by the EFOMP. Special training materials were developed in the framework of EMERALD [2].

2. General structure of EMERALD training modules

The Consortium developed the three Training modules with a common length of 4 months (80 days) each. During this time the trainee will have to acquire most necessary professional skills. This part of the training was called "condensed" and can be performed in most countries, where training conditions are set up. Further the trainee can spend up to 2 months in his own country/state where he/she can additionally study the local Regulations and professional requirements. The paper here describes the "condensed" training EMERALD.
Each of the three Training Modules incorporates:

- List of Competencies (in accord with the UK IPEM Training scheme);
- Student Workbook with tasks (performance of each task leads to certain competency);
- Structured Timetable (describing the approximate time necessary for each task);

Each task in the Workbooks contains explanations and protocols to be followed and requires answers to specific questions and problems. The proper performance of each task should be verified by the Trainer and on this basis the Trainee can continue with other tasks. To help in this process a Teacher's Guide was prepared.

The main types of tasks are:
- Observing real activities and taking notes
- Using existing Regulations, Protocols, Software
- Using various types of measuring equipment
- Understanding the basic characteristics & parameters of equipment
- Performing Measurements (including Dosimetry), Collecting Results, Calculating Parameters and other activities most often related to Quality Control (QC).
- Full Equipment Assessment (as part of the overall Quality Assurance Program)

3. X-ray diagnostic radiology physics module

This module was developed mainly by the UK partners. The training tasks in the X-ray Diagnostic Radiology (DR) Physics Workbook are grouped in the following chapters:
- General principles of DR radiation protection;
- General principles of DR quality control;
- X-ray dosimetry and patient dosimetry;
- Radiological image parameters;
- X-ray tube and generator;
- Radiographic equipment;
- X-ray films/screens and laboratory;
- Fluoroscopic equipment;
- Digital imaging and CT equipment;
- Basis of shielding in DR

4. Nuclear medicine physics module

This module was developed mainly by the Swedish partners. The training tasks in the Nuclear Medicine (NM) Physics Workbook are grouped in the following chapters:
- General principles of Radiation Protection in NM;
- General principles of NM Quality Control organisation and equipment;
- Fundamentals and basic properties of radiopharmaceuticals and radioisotopes;
- Pharmacokinetics and internal dosimetry;
- Single detector systems and survey meters;
- General principles of Scintillation Camera systems;
- Single photon Emmission Tomography – SPECT;
- Positron Emission Tomography with dedicated PET or Dual-Head Coincidence Scintillation Camera;
- Image evaluation and Data analysis;
- Preparation and QC of radiopharmaceuticals;
- QA of equipment and software;
- Radionuclide therapy;
- Radiation Protection of NM staff;
- Radiation Protection of NM patients;
- National and EU legislation in Radiation Protection and Radiopharmacy.

5. Radiotherapy physics module

This module was developed mainly by the Italian and Portuguese partners (with input from Swedish partners). The training tasks in the Radiotherapy Physics (RT) Workbook are grouped in the following chapters:

- Basic methods in Radiotherapy Physics;
- Quality Assurance of a Dosimetric System;
- Calibration of a Kilovoltage x-ray Beam;
- Calibration of a MVXR Beam;
- Calibration of an Electron Beam;
- Calibration of an In-vivo Detector;
- Acquisition of Open Beam Data;
- Acquisition of Dose Distributions and Dose Profiles;
- Acquisition of Wedged Beam Data;
- Manual Monitor Unit and Dose Calculation for Photon and Electron Beams;
- External Beam Treatment Planning using a Computerized System;
- Quality Assurance of an Orthovoltage Unit;
- Quality Assurance of a Teletherapy Unit;
- Quality Assurance of a Linear Accelerator;
- Basic Checks of a Treatment Planning System for external beam therapy;
- Calibration of Brachytherapy Sources;
- Manual Treatment Planning using 192Ir Sources for Interstitial Brachytherapy;
- Manual Treatment Planning for Intracavitary Brachytherapy;
- Surface Moulds in Brachytherapy;
- Computerised Treatment Planning Systems for Brachytherapy;
- Quality Assurance in Brachytherapy.

6. CD-ROM image database EMERALD

Being very expensive contemporary radiological equipment can not be purchased for training purposes. Additionally this equipment is intensively used for diagnostic and treatment purposes. As a result the young medical physicists have extremely limited time for training in the hospitals. The only solution to this problem is to encourage the use of modern educational technology.

In order to provide possibilities for off-site (distance) studying of contemporary radiological equipment the EMERALD Consortium has developed a digital image database (IDB). The volume of the IDB is about 1400 images of Radiological equipment and its components; Block diagrams and performance parameters, graphs, waveforms; QA procedures and measuring equipment; Test objects and image quality examples; Typical images and artefacts, etc. A PC type image browser (ThumbPlus) is used for quick and easy search through the IDB. The browser presents each image as a ~ 128x128 slide, which can be further viewed in its original size (JPEG up to 1024x1024 pixels). Each image is visualised with corresponding caption, on which basis Keyword search of IDB can be performed as well. The IDB is engraved on three CD-ROMs – one for each Training module. The image organisation within each IDB follows the chapters in the Training Workbooks - Fig.1.

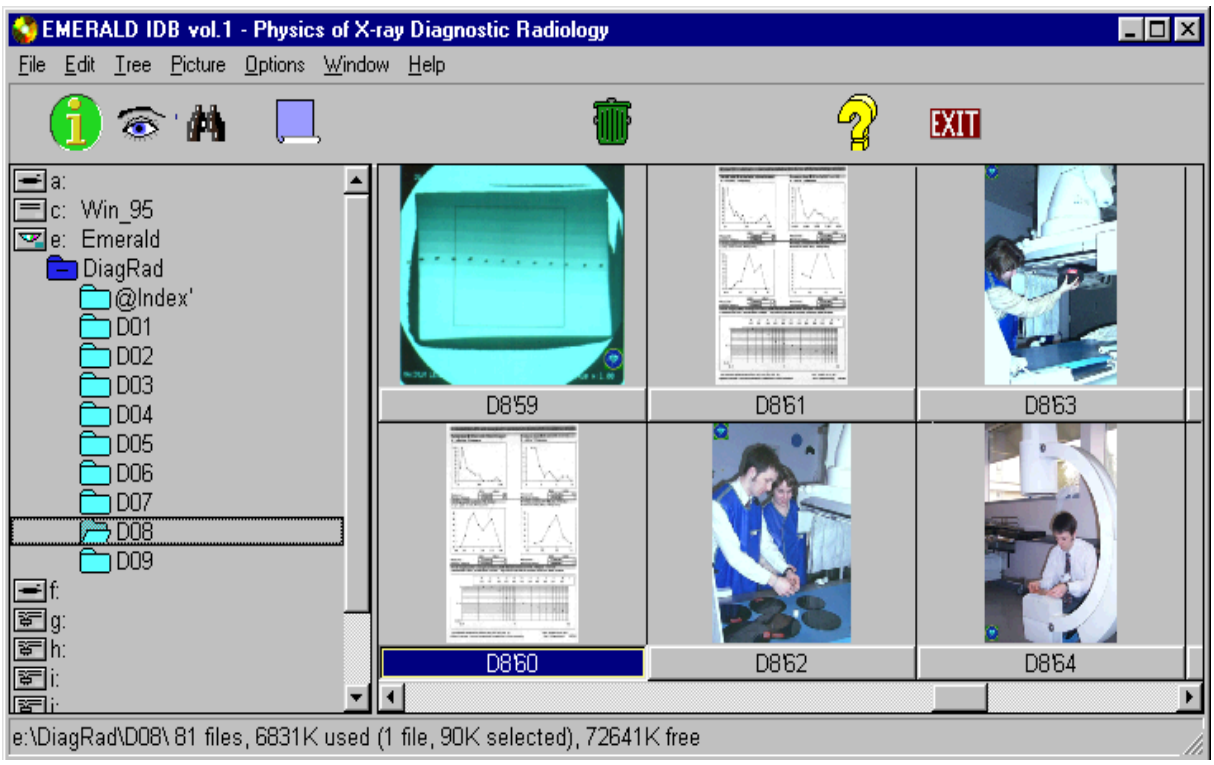

Figure 1. Graphical interface of the EMERALD Image Database with Thumb+Plus browser. An example from Image Directory 8, corresponding to Chapter 8 (Fluoroscopic Equipment - the task on image quality assessment) of the training module on Physics of X-ray Diagnostic Radiology

7. Practical implementation

All teaching materials were tested in practice and refereed. A special European Conference on Medical Physics was organised at ICTP Treiste, on 25-26 September 1998. Senior specialists from 24 countries gathered tt this Conference to discuss the common European approach to Medical Physics Training using EMERALD. The feedback of this Conference was later used during the editing of all EMERALD Training materials. These materials have now been exported in approximately 35 countries.

For the purposes of dissemination a further projects EMERALD II (EMERALD – Internet Issue) was prepared with enlarged Consortium including the old partners and new partners from France, Ireland, Northern Ireland, Czech Republic and Bulgaria [3]. During this second phase of the EMERALD a sequence of international Seminars “Train-the-Trainer” have been organised in Dublin, Lille, Prague, Lisbon, Lund and London . A special session was held also during the Word Congress in Chicago, WC2000. An interactive Training Multimedia is in development at the moment. This new material will be Internet distributable to assist the distance learning on the subject in the world.

Regular information about the development of EMERALD and the Network of specialists who are using this training can be found at the dedicated Web site: http://www.emerald2.net.

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EDUCATION, TRAINING AND CONTINUING PROFESSIONAL DEVELOPMENT FOR THE MEDICAL PHYSICIST — THE EFOMP VIEW IN RELATION TO EC COUNCIL DIRECTIVES

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Abstract

The European Federation of Organisations for Medical Physics, EFOMP, is an umbrella organisation for National Medical Physics Organisations. One of the main objectives of EFOMP is to harmonise and promote the best practice of Medical Physics within Europe. To accomplish this goal, EFOMP has presented various recommendations and guidelines in a number of Policy Statements, unanimously adopted by EFOMP Member Organisations. Policy Statement No 9, "Radiation Protection of the Patient in Europe: The Training of the Medical Physics Expert in Radiation Physics or Radiation Technology", is the EFOMP response to the Medical Exposure Directive, 97/43/Euratom. Here EFOMP presents its recommendations on the role and the competence requirements of the Medical Physics Expert, defined in this Directive, together with recommendations on education, training and Continuing Professional Development. The previous Directive 96/29/Euratom, the Basic Safety Standards Directive, defines a "Qualified Expert" in the radiation protection of workers and the general public. EFOMP has an on-going discussion on the interpretation of the competence requirements of the Qualified Expert in medical practice. The EFOMP approach to achieve harmonisation in the qualification of the Medical Physicist is to encourage the establishment of education and training schemes according to EFOMP recommendations.

1. Introduction

The European Federation of Organisations for Medical Physics was inaugurated in 1980 as an umbrella organisation for National Medical Physics Organisations. Today EFOMP has 32 National Member Organisations (NMOs), representing about 5000 medical physicists working in both clinical and research environments. The federal structure allows EFOMP to represent the medical physics profession, without constraining that diversity of national opinion, which is the essence of Europe.

To harmonise and promote the best practice of medical physics in Europe is one of the main objectives of EFOMP. Some specific aims and purposes include making recommendations on the appropriate general responsibilities and roles of the medical physicists and proposing guidelines for education, training and accreditation programmes in medical physics. EFOMP should also collaborate with international organisations and disseminate professional and scientific information. The EFOMP view on education and training has been presented at several international meetings, one of the latest being the International Conference on "Radiation Protection: What are the future training needs?" [1].

To accomplish its goals, EFOMP has over the years presented a number of policy statements, adopted unanimously by the NMOs, thus expressing the opinion of the medical physics profession in Europe. The first two policy statements, approved in 1983, presented the roles and responsibilities of the clinical medical physicist, discussed the important professional aspects of education and training, and established the basic structure of education and training. "The education of the medical physicist can be divided into three stages. After a first step bringing the physicist up to a basic standard (B.Sc.) in Physics, Mathematics, and other relevant topics in Natural Sciences, the second step is to introduce Medical Physics in postgraduate education. The third step is in-service training in hospitals. After finishing this third step, the physicist can be recognised at an appropriate level. It should also be possible to reach a senior level by further education and training, and to get a higher academic degree, i.e.

M.Sc., Ph.D. or equivalent in Medical Physics." This structure is still relevant and has been developed in several recent policy statements.

The clinically working medical physicist is a member of a team responsible for diagnosis and treatment of patients. The qualified medical physicist has a unique competence and is responsible in his area of competence for equipment, techniques and methods used in the clinical routine, for the introduction and adaptation of new methods, for quality assurance and quality control etc., and often also for research and development. In order to acquire and maintain sufficient knowledge and a certain level of competence, both initial and continuing education and training are necessary.

2. Education and training in medical radiation physics

European legislation has challenged many professional organisations to propose harmonised professional standards of high quality. The European Union's Directives concerning basic safety standards [2] and medical exposures [3] have given impetus to the discussions of education and training requirements in medical physics. From the EFOMP view these Directives primarily deal with medical *radiation* physics, but they also effectively set the standards for the whole medical physics profession.

The EFOMP policy statement No 9, "Radiation Protection of the Patient in Europe: The Training of the Medical Physics Expert in Radiation Physics or Radiation Technology" [4], constitutes the EFOMP response to the Medical Exposure Directive, 97/43/Euratom, [3], the MED. The Medical Physics Expert (MPE) is defined in this Directive as an expert in his own right with a well-defined professional role, requiring him to act as well as give advice on all aspects of radiation protection of the patient. The training of the MPE and his competence to act must be recognised by the competent authorities, and Member States are explicitly required to ensure that medical physicists have access to continuing education and training after qualification in addition to their basic theoretical and practical training.

The EFOMP recommendations on the role and competence requirements of the Medical Physics Expert are presented in policy statement No 9 [4], together with the recommendations on principles of education, training and continuing professional development (CPD). General criteria for structured CPD have been laid down in policy statement No 8, "Continuing Professional Development for the medical Physicist" [5]. CPD is the planned acquisition of knowledge, experience and skills, both technical and personal, required for professional practice throughout one's working life. EFOMP recommends that all medical physicists who have completed their basic education and training should be actively involved in CPD to maintain and increase competence and expertise after qualification.

The EFOMP approach to achieve harmonisation is to encourage the establishment of national education and training schemes at all levels according to EFOMP recommendations. Guidelines for formal EFOMP recognition of National Registration Schemes for Medical Physicists were established in 1995 [6]. EFOMP approval requires inter alia clear statements of theoretical and practical competencies, as well as training programmes consistent with the EFOMP policy on training, and a regular renewal mechanism. CPD is now being recommended as the best way to meet the requirement for a renewal mechanism, and EFOMP is now finalising general guidelines for CPD Schemes [7], recommending NMOs to set up their own detailed CPD Scheme. The concept of CPD is related to the knowledge, skill and experience acquired rather than to the amount of time used to require them. In practice,

however, quantitative and qualitative guidelines cannot be separated. The general and very flexible guidelines proposed for CPD Schemes cover both the scheme itself and the credit point system for assessment of individual CPD activities. EFOMP approval also of the National CPD scheme will thus cover the whole structure of education and training for the medical physicist.

The EFOMP efforts, resulting in recommendations on a structured system for education training, CPD and registration schemes as outlined above, have been recognised by the EC in the recent publication "Guidelines on education and training in radiation protection for medical exposures" [8].

3. Training of the medical physics expert – the specialist medical physicist

The Medical Physics Expert was introduced and defined in the Medical Exposure Directive. The duties of the MPE, specified in the Directive, suggest that the appropriate competence level should correspond to an advanced practical experience. The competence level required to start working independently is the level required to register as a Qualified Medical Physicist, according to the EFOMP recommendations [4, 6]. CPD activities should start immediately after qualification, ensuring increasing competence and leading to a higher level of qualification, e.g. the level where the medical physicist may act as a Medical Physics Expert. The EFOMP approach to structured education, training and CPD, as recommended in the proposed guidelines on CPD schemes [7], is summarised below.

3.1. The qualified medical physicist

- There is a significant divergence across European in the length and style of the academic component of physics qualifications. However, most countries will be able to recognise the Qualified Medical Physicist defined in the guidelines below.
- The entry criterion to Medical Physics education and training is a basic university education in physical sciences, engineering or equivalent.
- Recognition as a Qualified Medical Physicist is achieved by a further 2 to 4 years theoretical education and practical training in Medical Physics (depending on the national education system) under supervision of a Qualified Medical Physicist, preferably a Specialist Medical Physicist. At least half of the time should be spent in a clinical environment. The education and training should follow current EFOMP policies. (The total time for the basic education and the Medical Physics education and training would be around 7 years.)
- The Qualified Medical Physicist is competent to act independently.
- The Qualified Medical Physicist has the minimum qualifications required for enrolment in an EFOMP approved National Register for Medical Physicists.
- The Qualified Medical Physicist should have a formal recognition from a National Competent Authority, and should be enrolled in an EFOMP approved National Register for Medical Physicists [6].
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3.2. The specialist medical physicist, the medical physics expert

- Within the EU, as defined in the Medical Exposure Directive [3] "in relation to medical exposure", the Medical Physics Expert is equivalent to the Specialist Medical Physicist. In other disciplines, the term Medical Physics Expert is not relevant.
- The Qualified Medical Physicist qualifies to become a Specialist Medical Physicist by gaining advanced clinical experience and undergoing specialist training of at least two

further years duration, mostly in one sub-speciality, within the first period of an EFOMP approved National CPD Scheme. (i.e. total education & training at least 9 years)
- The Specialist Medical Physicist is competent to give advice on all professional matters in his sub-speciality.
- The Specialist Medical Physicist may have a formal recognition from a National Competent Authority and should continue to be enrolled in an EFOMP approved National Register for Medical Physicists.

4. The medical physics expert and the qualified expert in medical applications

The MED "supplements Directive 96/29/Euratom and lays down the general principles of the radiation protection of individuals in relation to the exposure referred to in paragraphs 2 and 3." [3, Art 1.1]. The MPE is defined as "an expert in radiation physics acts or gives advice on patient dosimetry, on the development and use of complex techniques and equipment, on optimization, on quality assurance, including quality control, and on other matters relating to radiation protection, concerning exposure within the scope of this Directive" [3, Art 2]. The Basic Safety Standards Directive 96/29/Euratom (BSS) "establishes the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation with the aim of their uniform implementation by Member States" [2, Art 54]. The BSS defines Qualified Experts (QEs), as "Persons having the knowledge and training needed to carry out physical, technical or radiochemical tests enabling doses to be assessed, and to give advice in order to ensure effective protection of individuals and the correct operation of protective equipment, and whose capacity to act as a qualified expert is recognised by the competent authorities" [2, Art 1]. The BSS also states, that Member States shall ensure that training of the QEs is arranged. Both the BSS and the MED should have been transposed into national law no later than 13 May 2000.

The EC "Guidelines on education and training for medical exposures" [8] were written to facilitate implementation of the MED. "Adequate theoretical and practical training for the purpose of radiological practices, as well as relevant competence in radiation protection" is required in the MED, [3, Art 7.1], and the training programmes in the guidelines thus include both general principles of radiation protection and particular staff aspects; "MPEs should know all the training areas at the highest level in addition to physics and all relevant aspects of quality assurance programmes.", according to the Guidelines [8, 1.(24)]. In the "Communication from the Commission concerning the implementation of Council Directive 96/29/Euratom" [9], advice on basic and additional training for QEs is given in Annex I. The requirements on education and training, as well as on the appropriate practical experience, will depend on the complexity of the field of work and on the level and complexity of advice required from the QE; medical applications is one of the five specific areas, where additional topics have been identified. The MPE acts within the scope of the MED, the QE within the scope of the BSS. EFOMP has an on-going discussion on the interpretation of these recommendations relative to medical practice, concerning the role and responsibilities of the MPE. The MPE should be prepared to assume the responsibilities of the QE, but, in health care centres with MPEs available should the MPE and no one else take the responsibilities of the QE, and further, should the QE be required to have the competence of the MPE? The present situation in Europe shows a wide variation in the qualification requirements of the QE in medical practice.

5. Summary

The responsibilities of the Medical Physics Expert defines his competence, and EFOMP wants to emphasise that the term MPE should apply only to suitably experienced medical physicists, with a competence based on a structured education and training programme including CPD. EFOMP has presented policy statements related to all parts of this programme, in order to accomplish one of its main objectives; to harmonise and promote the best practice in medical physics in Europe.

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[4] EFOMP Pol Stat No 9. Radiation Protection of the Patient in Europe: The Training of the Medical Physics Expert in Radiation Physics or Radiation Technology. Physica Medica XV (1999) 149-153

[5] EFOMP Pol Stat No 8. Continuing Professional Development for the Medical Physicist. Physica Medica XIV (1998) 81-83

[6] EFOMP Pol Stat No 6. Recommended guidelines of National Registration Schemes for Medical Physicists. Physica Medica XI (1995) 157-159

[7] EFOMP Pol Stat No 10. Recommended Guidelines on National Schemes for Continuing Professional Development of Medical Physicists. (Draft, 2000), see www.efomp.org

[8] European Commission. Radiation Protection 116. Guidelines on education and training in radiation protection for medical exposures. Directorate General Environment, Nuclear Safety and Civil Protection. Luxembourg, 2000

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IAEA-CN-85-11

AN INTERACTIVE WEB-BASED RADIATION PROTECTION COURSE IN FLUOROSCOPY

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Abstract

The teaching of radiation protection to a large group of physicians, who are separated geographically and have complicated schedules, is a formidable problem. Therefore a web-based solution is attractive, allowing access to the material at any time and place. In this implementation the didactic material is presented in a web-based format. Subsequently, students attend a practical demonstration in one of the departments' fluoroscopy rooms. Because of local experience with distance education, WebCT was chosen to present the material. WebCT(Web Course Tools)was developed by the University of British Columbia(UBC) to allow educators, with or without technical expertise, to create sophisticated web-base. Authors use a standard Web browser to create courses, and students use their browsers to access course material. WebCT provides a wide variety of tools and features that can be added to a course. Among the most useful tools used in this fluoroscopy course are the glossary, multiple-choice questions for each section, and a final test which is scored by the computer. As with all Web-based material the courses can be viewed in the traditional linear fashion or in any random way through the use of linkages.

1. Introduction

The World-Wide-Web Course Tools (WebCT) has been developed by UBC over the last few years and presents an environment that allows educators to create sophisticated web-based courses. These courses can incorporate a large number of tools and features. Furthermore, the interface to WebCT (the interface that is used by the educator to build a course) is entirely web-based. This has many advantages including simplicity and platform-independence. Using Web-CT requires that a course-author connect, using a browser such as Netscape, to a WebCT site. The site is simply an http server that serves the WebCT pages and CGI scripts.

2. What does a WebCT "course" look like?

The content of a course is provided by the course designer. Structure, interactivity, and educational tools are provided by WebCT. WebCT also allows the designer to alter the look of the course by, for example, selecting from existing (or creating custom) colour schemes, choosing between *formal* and *informal* button sets, incorporating custom or WebCT built-in banners, and so on.

3. Main course homepage and tool pages

A course developed using WebCT is organised around one main homepage. This homepage is the entry point for the course (the first page that designers and students see after having logged on to the course). It can contain, among other things, a banner image, a textual message, links to *course content elements* (notes and assignments, for example), and links to *course tools*.

While there is only one main homepage, there can be any number of subsidiary homepages (called *tool* pages). A tool page behaves exactly like the main homepage, except it is not reached immediately on entering the course. Instead, a tool page is reached by clicking an icon on the homepage, or another tool page. Thus the homepage and tool pages can form a hierarchy of pages with the main homepage as the root.

4. Course content

WebCT provides a structure around which one can build a course. If you already have your notes in a word processor it is fairly straightforward to modify the material. The course needs to be broken into short sections, say two screens long, so that the students do not have to scroll too much. Each section is then saved in html format which is required for WebCT. Many word processors also convert images to GIF format. Otherwise the html editor in your word processor should allow you to incorporate links to other types of image format such as JPEG, which is most commonly used for x-ray images.

Once you have your course material in html format you can create a complete interactive course using only the tools provided by WebCT. When you log in to WebCT using a web browser(the system is optimised for Netscape) you can do so as the designer or as a student, naturally with different passwords. As a designer you have access to all designer facilities, such as file management, page design, on-line editing, indexing, glossary definitions, and a whole range of tools for student exams, marking and reporting.

Normally to create a course the files are uploaded using the file management facility, and then arranged in a suitable order or *path*. Each page in the course can then be customised to suit the author. Glossary terms to explain new terms can be useful, and multiple choice questions are easy to add. These MCQs are for self-assessment not final exams which are explained later. On any page an index term can be defined and this will be automatically integrated into the course index. Although this does not seem important initially, as the number of courses and pages grow an index becomes vital.

5. What is a course tool?

A course tool is a feature supplied by WebCT that can be incorporated into any course. Tools can be made accessible (through a clickable icon) from the main course homepage, tool pages, or from content page button bars. Examples of tools include a conferencing system, timed quiz delivery, on-line marking, grade storage and distribution, e-mail between course participants, searchable image archives (both shared and private to a course), student self-evaluation, student presentation areas (both individual and group), student annotation facility, student progress tracking, course glossary and index, and more.

6. Navigation

When students log on to the course, they are presented with the main home page. If they had ever been signed on before, WebCT can take them to the page of content they were at when they ended their previous session (using the "resume session" tool). Otherwise they can click on a path icon (perhaps the main set of notes), a tool page icon, or any other icon available on the homepage.

Once they are on a page of content, included in the button bar are navigation arrows that will take them to the previous or next page of notes in the path. If they ever stray off the path,

perhaps to view an off-site URL, a single click returns them to the point from which they left the path. This avoids the reorientation otherwise necessary after a prolonged foray off the path. The navigation buttons also allow the student to go directly to the homepage, to retrace through the last few accesses, or to view the hierarchy of the current path for direct access to any page on that path. Also, the status bar at the bottom of the browser always displays the name of the path the student is on, and the page number currently being viewed.

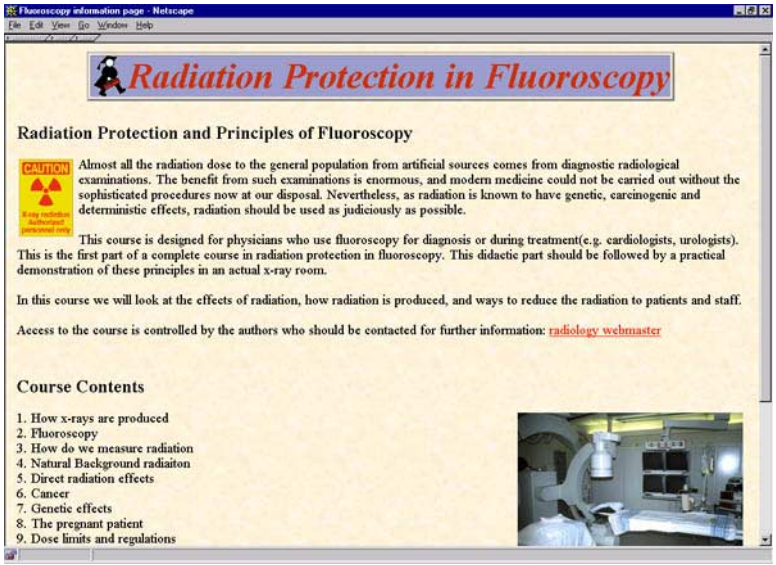
Finally, the button bar on each page of content provides direct access to any course tool that has been included on that page by the designer. These might include links to that page's multiple-choice questions, a link to a conference forum for that page of notes, or a link to reference material for that page.

7. Tests and exams

On each page multiple choice type questions can be added to help the student understand the material. These questions are not used in the assessment of the student. Complete examinations can also be given via WebCT. Examination date, time and length are set on the system. Questions can be of many types. Multiple choice, true-false and simple word answers can be marked on-line. Short answer and essay type questions have to be marked by the examiner. The students can access their marks on-line.

8. Fluoroscopy course

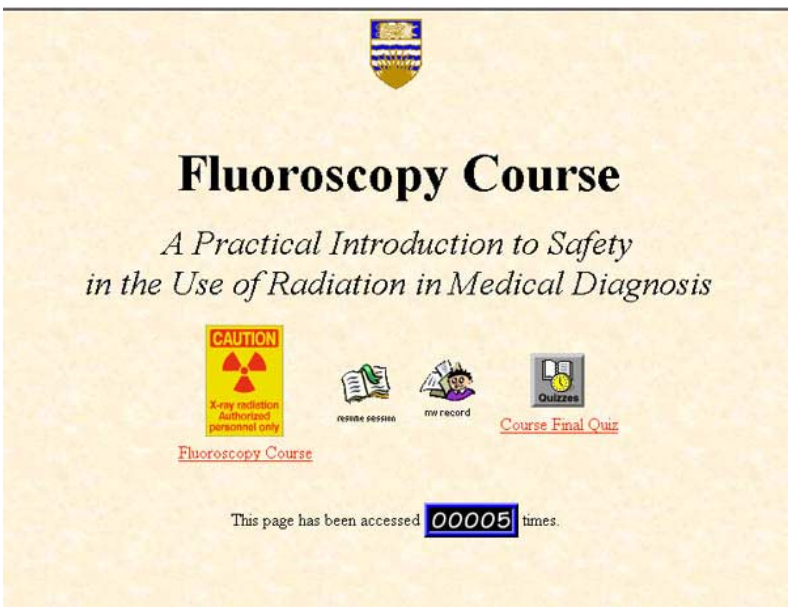
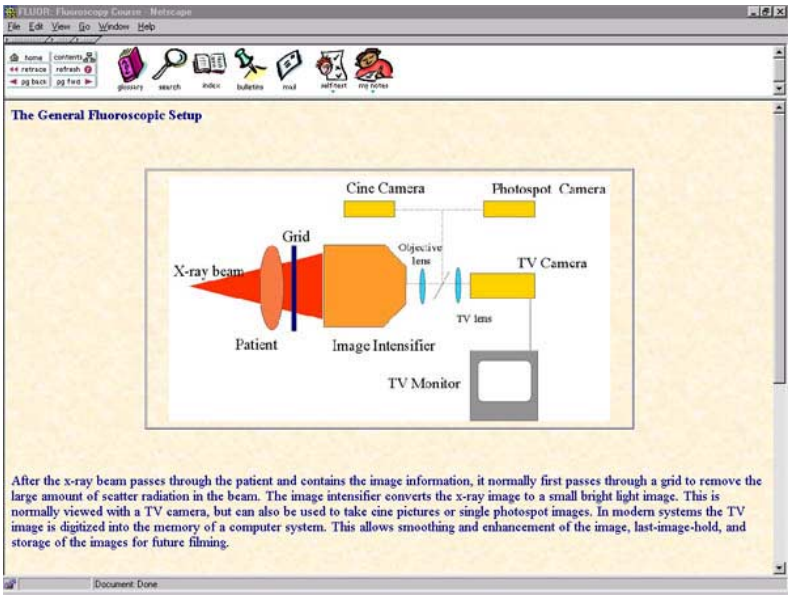
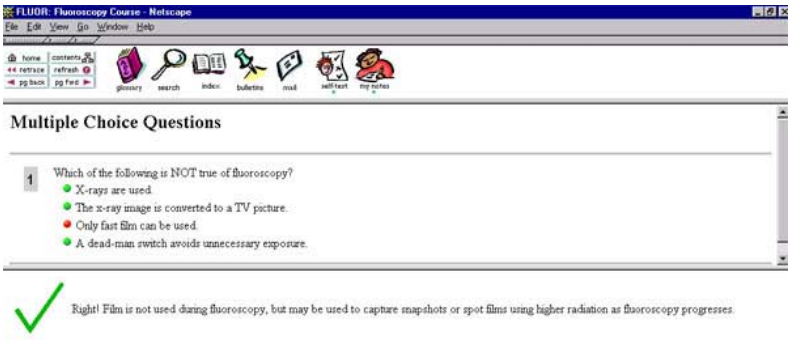
Typical screen captures from our fluoroscopy course are shown below.



The first screen is the page, which anyone can access on the internet, gives information about the course.

To log on students need an ID and password. This enables monitoring of student progress and identifies students who take the final test.

Next is the screen, which a student sees after logging onto the course.

<table>
<tr>
<td> 
</td>
<td>From here the student can start the course or take the final test. At the beginning of each course a list of all the sections is seen as below. The counter can be reset at the start of each course to give an overall picture of student access. For the course instructor much more detailed information on what pages are read and for how long are available if necessary. As well as sometimes verifying that the material is actually read, this information can help to identify difficult sections of the course.</td>
</tr>
<tr>
<td> 
</td>
<td>This shows a typical interactive page. The top bar shows the navigation tools, which enable the student to go through the course page by page or return to the contents page or the home page. Alongside the navigation tools are special tools which enable the student to access the glossary, index, bulletins from the instructor, mail from the instructor or other students, the self-test quiz, and private notes that the student can attach to any page. Terms in the glossary are highlighted in red in the text.</td>
</tr>
<tr>
<td> 
</td>
<td>One of the questions from the self-test quiz for this page is shown at left. This question mode is designed for self-evaluation as the student progresses through the material.

By selecting any answer, correct or incorrect, feedback is given about the reasons for the answer.</td>
</tr>
</table>

We have also used WebCT as the basis of our undergraduate teaching modules in radiology. This is one of the most demanding areas of teaching because of the number and quality of diagnostic images needed. This distance learning package seems well accepted and suitable for instruction where geographic and scheduling constraints would impede normal lectures.

Further information can be found at our website at http://web.ucs.ubc.ca/aldrich/home.htm. and from http://www.webct.com.

IAEA-CN-85-138

PATIENT DOSE OPTIMISATION IN CARDIOLOGY DURING FLUOROSCOPY EXAMINATIONS

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Abstract

Data from 1200 cardiac examinations recorded during the past ten months have been analysed. The DAP's obtained for most of the examinations are comparable to the published data. Moreover, an excellent correlation has been found between the high DAP value and the experience of the operator. DAP measurements for "high dose examinations" are getting mandatory in several countries, and medical physicists should help the physicians to interpret these measurements in order to improve the safety of the ionising radiation use. In our centre it appeared that for their first examinations physicians should be more closely guided by seniors.

1. Introduction

Several studies have shown that during cardiac procedures carried out under fluoroscopy, such as coronary angiography or percutaneous transluminal coronary angioplasty (PTCA), the amount of radiation delivered to the patient could be relatively high. It is therefore important to monitor patient dose so that radiologists or cardiologists can make an objective assessment of the justification of the procedure. The most convenient quantities to monitor patient dose are the fluoroscopy time and the dose-area product (DAP). The main limitation of the DAP quantity is that it cannot give directly a precise information concerning the determinist risk associated with a procedure. However, it can be used to set warning and action levels to avoid skin injuries as demonstrated by Bibbo et al. [1]. The other limitation of the DAP information is that there is a lack of reference or guidance values published in the literature concerning cardiac procedures. Thus, even if the DAP information is recorded in the patient files, it remains very difficult to estimate if a DAP delivered to a patient for a specific procedure was expectable or high.

In such a context it was decided in our hospital to record during almost one year, the total dose area product (DAP), the fluoroscopy time, the examination description and the operator references. The goals of the study were the followings :

- Assess the third quartile of the DAP for the most common examinations and compare them to the available data in order to verify the good practice of operators;
- Verify if a lack of training existed among the operators;
- Give a set of DAP values to the operators to enable them to assess if the DAP they deliver can be justified by the simplicity or complexity of the procedure;
- Propose a warning level to the operators.

2. Material and method

The examinations were performed using two units (advantix LC+ and LCLP, GE Medical Systems, Milwaukee, Wis) of the hospital which are equipped with a DAP-meter (PTW, Freiburg, Germany) traceable to the Swiss Federal Office of Metrology. The total DAP, the

fluoroscopy time, the examination description and the operator references were systematically recorded by the radiographers at the end of each procedure for about 1200 patients.

3. Results and discussion

The number of examinations, the medians, 3rd quartiles and ranges of the DAP values and fluoroscopy times are reported in Table 1. The data have not been corrected according to patient size, since the goal of the study was to define a set of reference DAP values for the operators which could be directly compared with the data available on the DAP-meters at the end of the procedure, without any data processing. The third quartile obtained for the coronary angiographies and angioplasties (PTCA) are comparable to the ones published in the literature.

Table 1. DAP and fluoroscopy times recorded during the survey

procedure	proced. #	DAP_{median}	DAP_{3rd}	range	$time_{median}$	$time_{3rd}$	range
Angiocardiography	25	15.3	22.5	4 - 102	13	17	4 - 23
L and R catheterisms + coronary angiography	95	66	125	13 - 286	10	17	3 - 59
PTCA	210	60	80	10 - 272	9	16	4 - 70
Coronary & Ventriculo. angiography	780	49	84	3 - 702	7	12	1.5 - 65
Left vent. coronary angiography	35	59	66	10 - 203	8	11	1.5 - 40
Coronary angiography	35	40	70	5 - 390	6	22	3 - 50
Cardiac biospsy	20	4.7	7.6	2 - 23	1	1.7	0.5 - 6

The angiocardiography examination is performed most of the time on young patients and the DAP's are generally quite low in spite of relatively long fluoroscopy times. Thus, no correlation between the DAP values and the fluoroscopy times have been evidenced between these two quantities (r=0.08). However, an excellent correlation appeared between the DAP values and the age of the patients (r = 0.88). This result clearly shows that for young patients DAP guidance values should be weighted with the age of the patient.

As opposed to the angiocardiography procedures, an excellent correlation between the DAP and the fluoroscopy times have been systematically obtained for the other procedures which were always performed on adults ($r = 0.88 \pm 0.05$). Thus, for adults it seems that guidance levels can be expressed either in term of fluoroscopy time or DAP value.

Figure 1 present the distribution of the DAP percentiles concerning the coronary-ventriculo angiography examinations per operator. The reference DAP proposed in our centre is also indicated on the figure by a thick line. From this figure it appears clearly that all the operators having more than 5 years of experience, have their DAP third quartile below or close to the proposed reference value, and that even if they often involved with more difficult cases. The data concerning younger cardiologists are presented on the ride side of the figure. All of them are clearly above the proposed reference value.

The DAP data should not only be used to verify if the dose delivered to the patient after a procedure could be expected, but should be also used during the procedure to indicate if one gets close to the deterministic risk associated with fluoroscopy. The difficulties in using DAP to evaluate skin dose is that the irradiated area of the skin change size and location during the procedure. Thus, it is not possible to evaluate a precise entrance dose from a DAP measured during an interventional procedure. Nevertheless, one can adopt a conservative approach in order to define warning and action levels to avoid skin injuries. Taking into account the diameter of the amplifier which is the most frequently used during these procedures (ø 23 cm), and the focal spot to skin of the patient (50 cm when the distance from the focal spot to the amplifier is 90 cm), an averaged area of 130 cm^2 has been obtained. Taking this averaged irradiated area into account and considering that the tube does not move during the procedure, a warning level of 130 $Gy.cm^2$ has been proposed to our staff performing cardiac procedures. This would correspond to an entrance dose of 1 Gy. In spite of being quite conservative, this level is however lower than the DAP's third quartile measured during this survey. Above the warning level proposed here, a senior operator should take over. He should try to work in the lowest dose mode available and distribute the dose by changing the tube angles.

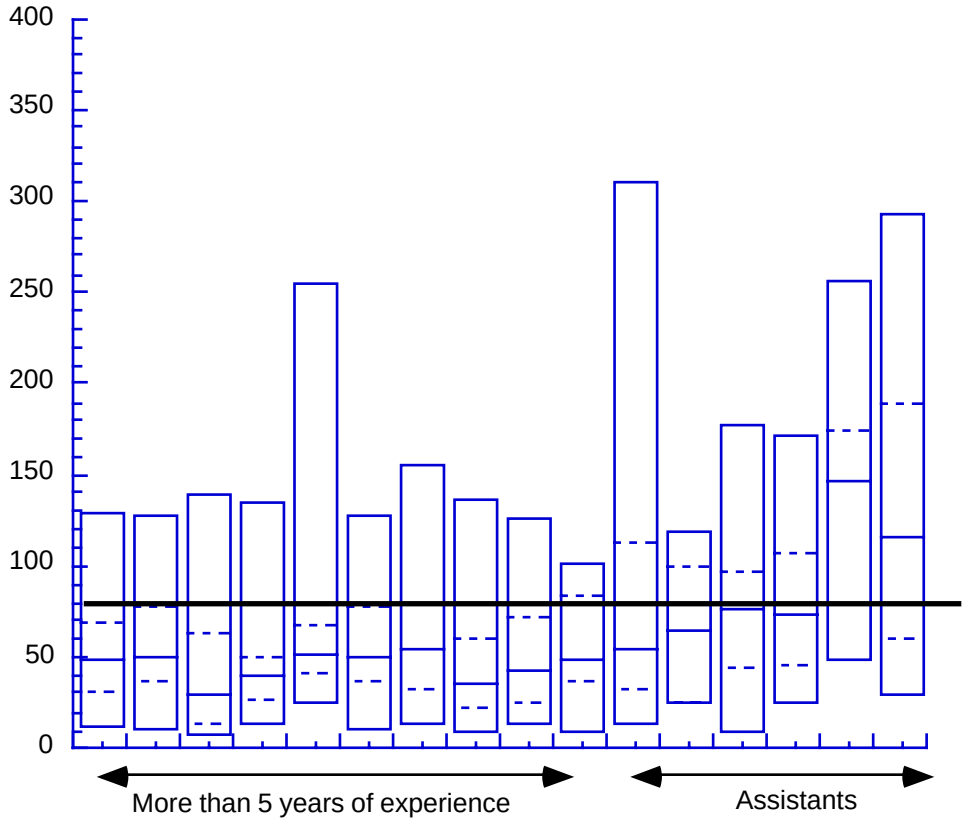

Figure 1. percentiles of the coronaro-ventricolu angiography per operator

4. Conclusion

The systematic recording of the DAP and fluoroscopy times has been integrated in our quality assurance programme. It has enable us to verify if the doses delivered during the most common cardiac examinations were comparable to the data available in the literature. This

study has also enabled our medical staff to take advantage of DAP data displayed during the procedures, in particular to avoid skin burns. Finally, a change in the training of our new medical staff is being implemented with an emphasis on the optimal use of the fluoroscopy units.

Reference

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IAEA-CN-85-156

CD-ROM TRAINING COURSE IN QUALITY ASSURANCE IN DIAGNOSTIC IMAGING

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Abstract

This paper discusses the CD-ROM elaborated to provide a continuous professional formation and a practical guidance on the implementation and operation of routine quality assurance (QA) programme for medical physicists, regulator authorities and for those personnel concerned with the daily provision of diagnostic radiology services. The CD-ROM contains topics on the basic concepts of QA in radiodiagnostic, and it also allows to the user to visualise effects on the variation of technical parameters (tube potential (kV) and current (mA), filtration) in the quality of the image. This possibility will contribute to the better understand of the phenomena associated with the quality of the image. Besides, the program contains the procedures for the execution of the tests of the equipment and the route of implantation of program of quality assurance. It is interactive with the user, it fills out a gap in medical physics area and it allows the student's continuous formation because it assists the beginner, with the basic concepts, and the professional, with the aid in the implantation of the program of QA. The presentation is in portuguese language.

1. Introduction

Use of X-rays for diagnostic examination needs to ensure that the exposure of patients is at the adequate level to achieve an image with quality to allow for the diagnostic [1]. To ensure diagnostic images of optimum quality with low exposures it is necessary to implement a quality assurance program in the institution. To do that it is necessary to have professionals with adequate education and practical training in radiation protection. They do not only require initial training but also continued education throughout their professional lifetime.

Quality assurance programmes and quality control initiatives in general diagnostic radiology has been developed in several European countries in the past 10years [2]. On other hand, in Latin America countries and especially in Brazil theses programs began to be implanted recently. Since in these countries there are a few professionals prepared to implement a QA programme in X-ray departments, a CD-ROM was prepared with the aim to contribute with the professionals' formation. The CD-ROM contains topics on the basic concepts of QA in radiodiagnostic, procedures for the execution of the tests of the equipment and the route of implantation of program of quality assurance. It assists the beginner, with the basic concepts, and the professional, with the aid in the implantation of the program of QA. It is intended to help in the implementation of recently published legal requirements on the use of X-rays in Brazil.

2. Materials and methods

The scope of the CD-ROM was prepared so that the professional that is beginning to work with X-Ray equipment can find information about the legislation, the physical principles of x-ray equipment and of medical imaging. The CD also contribute for training of professionals on the implementation of the quality control tests. The figure 1 shows the main page where is possible to see the main topics of the CD.

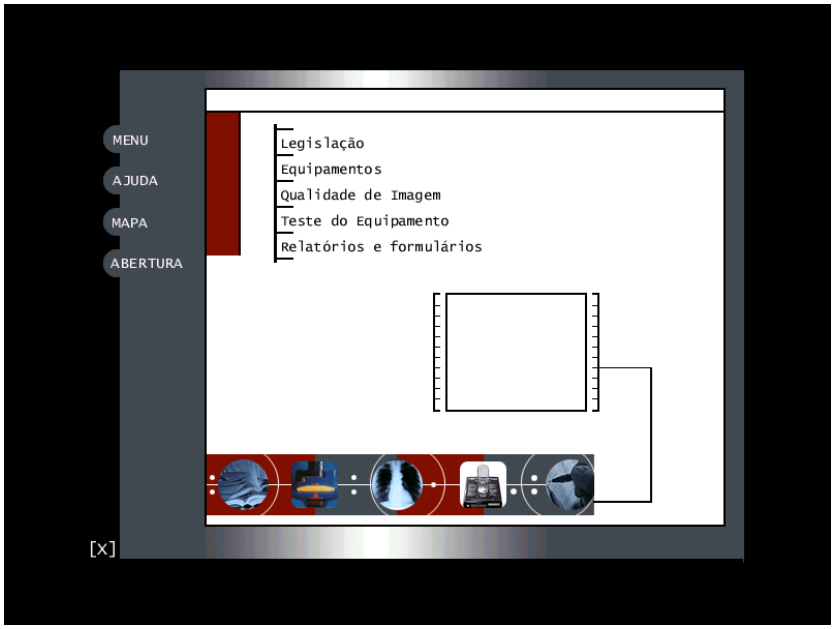

Figure 1. Image of the main page of the CD-ROM

The main menu has the following five topics: Legislation , Equipment, X-ray Quality assurance, Test procedures and Reporting.

In the first item the user will find the information related to brazilian and international legislation and safety standards. In the topic **Equipment** the user will find three items: a) Function of x-ray equipment, b) Type of x-ray equipment, c) Automatic processors. In the first item it is presented an introduction and overview of the x-ray production, the tube x-ray components and its function. Technical aspects of radiation production are discussed. The information are associated with the images of the x-ray components. In the third item automatic film processors are presented and its components and function are discussed.

In the topic **X-ray Quality Assurance** the geometric factors that affect the radiographic image are discussed. The effect of kilovoltage, time and current can be seen in a torax radiography by moving the cursor. The influence of radiographic grids, diaphragms and intensifying screens on the image quality are also described. This topic also present information about the radiographic receptors and the film sensitivity and contrast characteristics. This first part of the CD-ROM give to the user basic information about x-ray equipment and image characteristics and quality. This material will be useful for courses for medical physics, for technicians and radiologists.

The second part of the CD-ROM is for the professionals that have basic knowledge on physicals principles of medical imaging but want to improve their knowledge about specific quality assurance tests. The topic **Test procedures** discuss this subject.

In this topic are presented the general considerations of an X-ray quality assurance program and the procedures to perform collimation and beam alignment test, to check the changes in the performances of the x-ray tube and generator, to estimate the beam filtration and the exposure time. In this topic it is also presented the procedures to check the level of

illumination provided by the viewing boxes and the protocol for a processor quality assurance program. All the description of the tests is associated with images that illustrate each stage of the procedure.

If the user has experience and doesn't need to study how to do the quality assurance tests, but wants to treat the data, he/she can do it with the last topic of the CD-ROM, the **Report**. In this part the program treat the data and compare the results with the tolerance levels and inform if they are adequate or note. It is possible to print the report of the test.

The entire structure is displayed in the Figure 2.

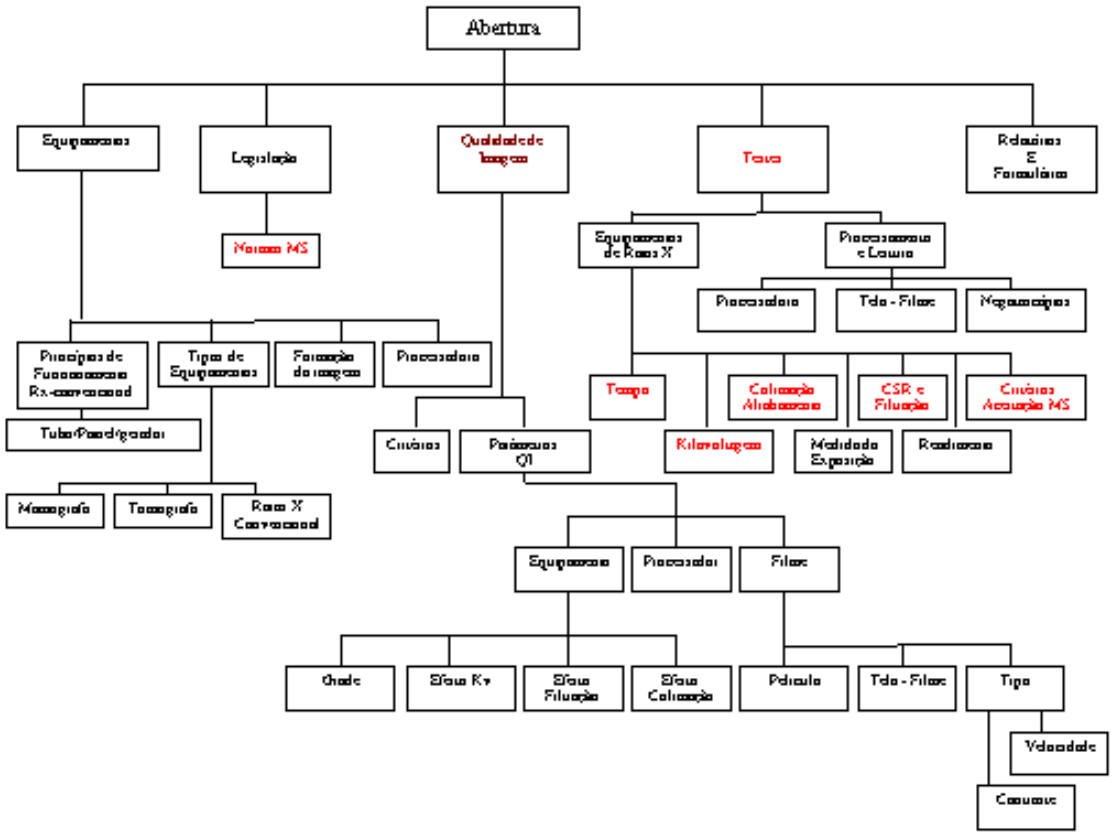

Figure 2. CD-Rom structure

3. Conclusion

The CD-ROM prepared will strongly contribute for the professional's continuous formation and it fills out a gap in medical physics area. It can assists the beginner, with the basic concepts, and the senior professional, with the aid in the implantation of the program of QA. This training material is a practical guide to quality assurance in medical imaging .

References

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THE REDUCTION IN DAP VALUES POSSIBLE WITH OPERATOR EDUCATION AND ADDITIONAL FILTRATION IN A CARDIAC CATHETERISATION LABORATORY

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Abstract:

Radiation doses were recorded for over 1,000 patients undergoing interventional procedures at a cardiac catheterisation laboratory at a local teaching hospital. The laboratory was equipped with two Toshiba DRX C-arms units. The only differing factor between the units was the inclusion of a tantalum rare-earth filter on Unit B. Each unit was fitted with a DAP meter which readily allowed the collection of dose-area product (DAP) readings for all patients. Information was collected over a 12-month period and data analysis showed that the median radiation doses from Unit B was on average 50% lower than those delivered from unit A for the same radiographic procedure and operator. Further analysis also showed that there was a large variation in dose given by the operators and as expected for the type of examination performed.

1. Introduction

A decade ago, deterministic effects were seldom, if at all, associated with the current use of x-rays in diagnostic radiology. This last decade has seen cardiology becoming a highly imaging-dependent specialty, routinely using the greatest variety of imaging in diagnosis and treatment. These developments in cardiac imaging have been associated with a growth in treatment methods, which are moving towards minimally invasive therapy [1]. Most of this change has occurred with the development of sophisticated equipment for coronary angioplasty and stent insertion.

So x-rays are now being used not just to diagnose, but to guide in therapeutic procedures. As a result of these advances, deterministic effects are again becoming associated with diagnostic radiology procedures. While it is recognised that without this range of procedures the life expectancy of many patients would be very low, care must also be taken to reduce the induction of the deterministic effects whilst minimising the occurrence of stochastic effects.

This paper aims to investigate the use of tantalum as an effective filter to reduce radiation dose given to the patients in a cardiac catheterisation laboratory, while at the same time recognising the important role of the operator in this regard.

2. Materials

The cardiac catheterisation suite used in this study comprised two rooms, each containing almost identical Toshiba DRX C-arm units. Each unit was ceiling mounted with a triple mode image intensifier (RTP 9211J) with field sizes 9/7/4.5 inches. For the majority of clinical examination studied pulsed fluoroscopy (15p/s) was used and digital image acquisition was also collected at 15 frames.s^{-1}. The input dose rate to the II for pulsed fluoroscopy and digital image acquisition were 0.34 μGy.s^{-1} and 0.114 μGy.f^{-1} respectively for unit A, 0.28 μGy.s^{-1} and 0.124 μGy.f^{-1} for unit B.

The significant difference between the units was that unit B had been fitted with an additional tantalum filter. Tantalum, is a transition metal obtained from Tantalite has an atomic number of 73 and an atomic mass of 181. Its use as a filter in diagnostic radiology is fairly new, and with its K-edge of 67.5 keV its has potential benefit as a filter in diagnostic radiology, for those techniques employing higher energies.

Exposure parameters such as the applied potential (kVp) and tube current are set by automatic exposure control and can not be chosen manually. Typically the applied potential varied between 80 and 120 kVp, and was dependant on patient habitus and projection of the X-ray beam. Both were installed with a DAP meter (Diamentor from PTW, Germany) which were calibrated according to standard protocol [2].

3. Method

Information was collected on a variety of factors for 1,200 patient over a twelve month period. Patient data included gender, age, height, weight, type of procedure and consultant name. Dose related data consisted of total DAP value, total examination time, number of digital image acquisition, number of frames per run, number of frames per second and projection angles. Information was not specifically collected on mA and kVp for each projection as its variability is thought to even out between operators and more importantly the variability in fluoroscopy time and DAP values is seen to be more important than variations in technical factors.

Information on the number of digital image acquisitions, number of frames per run, number of frames per second and the average length of each frame, allowed the total examination time to be broken down into relative contributions for both digital acquisition (DA) and fluoroscopy modes. This fraction is important, as the dose rate during a DA is far greater than the dose-rate during fluoroscopy. This information together with the projection angle allows a profile to be built of operator technique.

4. Results

The results for some of the most common procedures are summarised in Table I. The median values range from 15.3 $Gy.cm^2$ for an electro-physical simulation (EPS) to as high as 117 $Gy.cm^2$ for an investigation of the left and right arteries. The median examination times varied from 5.6 minutes for a left and coronary angiogram up to 25 minutes for an EPS. Thus an EPS was associated as the lower dose examonation on average but recorded the highest examination time, this is because the examination is primarily carried out under fluoroscopy and with a highly collimated beam giving a small radiation area. Therefore the dose given to a patient is dependent on the complexity and type of procedure and generalities can not be made simply on overall examination time.

Looking at table I in a little more detail shows that unit B delivers slightly lower DAP values than unit A for all examinations and nearly 50% in the case of left and coronaries. These differences are not associated with differences in times between the examinations, as in the C+G procedures, the median examination time for unit B is nearly double that of unit A, but the DAP value is lower. Also for L+C, the median examination times are close, but there are large differences in the median DAP values. The variations observed are related to the

frequency that the operators use each room. Thus differences in operators may not only be indicative of differences in the methodologies adopted but in differences in the pathology severity treated.

In order to better demonstrate the effect of the operator and the additional filtration on the variation in dose, a little more detailed analysis will be given for the most common procedure: the left and coronaries, which represented 77% of all examination studied in this study. The median values for examination times and DAP values for the operators are given in Table II. There are a number of issues to draw from this table, the first is the variation in DAP readings in each room. The median value ranges from 45.6 Gy.cm^2 to 74.4 Gy.cm^2 representing an increase of 63% in DAP values. Comparing the examination time for each operator with their respective DAP values informs us that there is a very small correlation between the two parameters, r = 0.54, p = 0.46 and r = 0.33, p = 0.77 for units A and B respectively. The reason for this can in part be explained by the techniques used by the operators, especially in differences in the proportion of digitally acquired images and fluoroscopy used, figure I. Some examinations were performed with DA representing as low as 5% of the total examination time, while others were using as much as 50%. The median use of DA was approximately 20%.

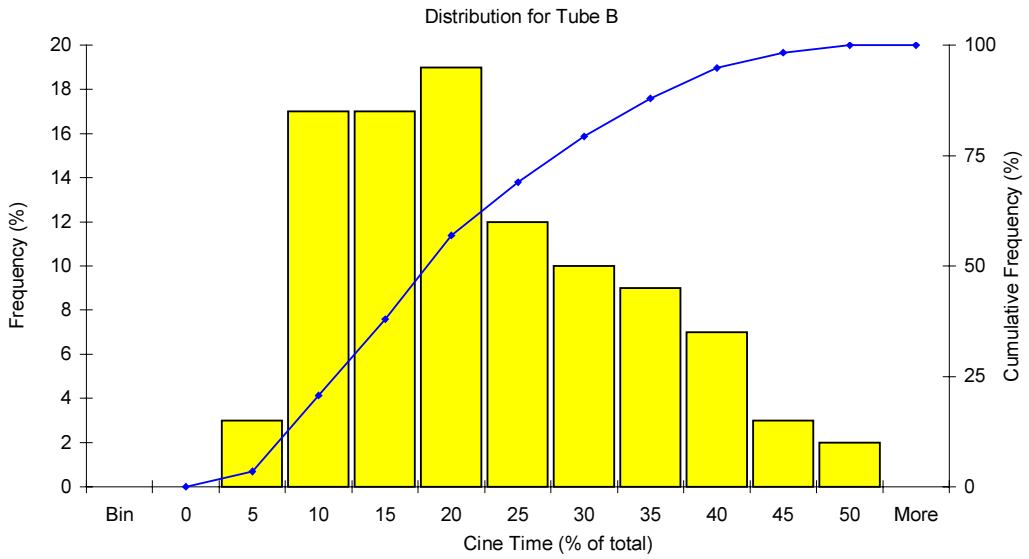

Figure I: Distribution for Cine use for Left Heart Angiography

However, detailed investigations on the use of DA and fluoroscopy did not fully account for the differences in DAP readings. The other reason for the low correlation's seems to be in the differences in radiation field sizes, with some operators collimating down more than others.

The second issue to be seen from Table II is the large differences for the same operator between the two units. The reduction in median dose per operator varies from 41% to 54%. The differences in the examination times are much smaller than the changes in DAP, patient size have been averaged out, and difference in operator have obviously been negated, the differences in DAP values between the two units can be attributed to the filter in unit B.

5. Conclusions

While interventional procedures provide significant advantages over alternative therapies in terms of improved clinical outcomes and reduced overall patient risk, the physicians performing these procedures should be made aware of the potential for injury caused by long periods of fluoroscopy occurring with some of these procedures.

Table 1. Summary Values for the most common procedures

Procedure	Median (St.Dev) Time Minutes		Median (St.Dev) DAP Values Gy.cm^2	
	Unit A	Unit B	Unit A	Unit B
EPS	——	25.2 (17.2)	——	15.3 (19)
Left + Coronaries	6.1 (6.1)	5.5 (4.9)	67 (30.4)	33.5 (18.6)
Coronaries & Graft	9.95 (14.4)	17.5 (17.8)	69.7 (28.5)	68.2 (20.6)
PTCA	13.5 (17.9)	17 (15.6)	82.0 (54)	81.35 (39.2)
Lt & Rt Angio.	19.1 (8.6)	15.9 (4.6)	116.9 (30.9)	113.8 (21.5)

Table 2. Summary values for operator and room for left heart and coronaries

	Summary values per Consultant per room					
	Median Time (sec)			DAP (Gy.cm^2)		
Consultant	Room A	Room B	Diff (%)	Room A	Room B	Diff (%)
A	420	426	+ 1.4%	71.8	42.4	- 41%
B	486	405	- 16%	68.5	31.5	- 54%
C	186	----		57.1	----	
D	300	288	- 4%	45.6	22.8	- 50%
E	300	228	- 31%	74.4	37.7	- 49%
F	246	234	- 5%	53.5	30.9	42%

The study has shown that some operators were giving nearly twice the DAP values as others for the same examination type and unit, with this difference being accounted for by differences in the proportion of fluoroscopy and DA images, and in the extent of collimation used. Therefore, basic instruction to the operators in terms of the significant differences in dose-rates between fluoroscopy and DA images and the importance of collimation is needed.

There was also a reduction of approximately 50% between the two units, with this difference being explained by the tantalum filter in unit B. While image quality has not been assessed, there have been no reports in difference in quality as a result of the filter. In total the variation in DAP readings is nearly a factor of 4 between the operator with the lowest dose using unit B compared to the operator with the highest dose using unit A. Thus there can be a significant reduction in dose at a very low cost to any department.

Regular measurements of patient dose is therefore an essential step to optimising exposure. It makes operators aware of their own performance and allows comparisons with the generally accepted practice. The easiest way for first line assessment is to use Dose-area product meters, which provide continuos guide to the performance of both equipment and operator and should be used as part of quality assurance programme.

However, in the overall framework of assessing the probability of producing a radiation induced deterministic injury, all staff members in a cardiac facility should be aware of the approximate levels of radiation dose resulting from the various radiographic projections that are routinely used. This study has highlighted two cost-effective ways to reduce DAP values, and the next stage will be to use the data collected on projection angles to investigate the potential of estimating radiation skin dose for a range of procedures using thermoluminescent dosimeters, radiographic film and an anthropomorphic phantom.

References

[1] REES, M., Cardiac imaging: present status and future trends, BJR, **70** (1997), S162-S167

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IAEA-CN-85-266

EDUCATION FOR RADIOLOGICAL PROTECTION IN RADIOTHERAPY ESTRO RECOMMENDATIONS FOR EU EURATOM GUIDELINES

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Abstract

The practice of radiation oncology (radiotherapy) encompasses the clinical care of patients as well as the technical aspects of radiotherapy. Benefits to patients accruing from radiotherapy depend upon the accurate delivery of high doses to the tumour with doses to normal tissues being kept to a minimum. In addition to these patient-centred aspects of radiation protection in radiotherapy, appropriate measures must also be taken to reduce the amount of radiation to staff and the general public to as low a level as is reasonably achievable. In order to achieve these aims, a broad basic training is required in all of the disciplines involved in the delivery of ionising radiation. ESTRO has recommendations for core curricula for the disciplines involved, but this annex lists the elements from these curricula which relate specifically to radiation protection. It is important to reiterate that the extent of training required will depend upon the existing levels of knowlege and training of different groups of professionals in physics, radiobiology etc, and this may vary from state to statespecific training objectives for radiation protection in Radiotherapy will cover following subjects: Radiotherapy equipment - safety and accuracy Dosimetric and geometric quantities for accuracy in radiotherapy Radiobiology and radiation risks Radiation treatment planning for optimising delivery of radiation dose Optimal and safe use of radionuclides in radiotherapy Radiation hazards in radiotherapy facilities Keywords: radiotherapy, education, training, continuous professional development in

1. Outline of specific training objectives

Radiotherapy equipment - safety and accuracy

- To show that the principles of operation and details of construction of therapy X-ray generators, including treatment head, are designed for safe and accurate delivery of radiation to the target volume with minimal collateral radiation dose.
- To discuss how filtration and factors affecting output of KV X-ray units determine the radiation dose to skin and target volume.
- To discuss how the construction of cobalt-60 units and methods of safety control minimise the risk of radiation accidents.
- To describe the production of MV X-rays in a linear accelerator, and the arrangements for limiting X-ray head leakage.
- To describe KV X-ray applicators, electron applicators, conventional linear accelerator collimators, multi-leaf collimators, the effect of collimators on penumbra size, shielding materials and dose under shielding materials, and the relevance in restricting radiation dose to the target volume.
- To describe equipment controls and interlocks, and select/confirm systems, and their role in hazard control.
- To explain the role of commissioning measurements and quality control checks in determining the accuracy of radiation dose delivered to the patient.

- To discuss the merits of equipment and limitations of use with respect to the optimal and safe delivery of radiation to the patient.
- To discuss the merits of verification in respect of the information needed to ensure accurate and safe delivery of radiation to the treatment volume.

Dosimetric and geometric quantities for accuracy in radiotherapy

- To discuss the use of percentage depth dose curves, backscatter and peakscatter factors, tissue phantom ratios, tissue standard factors and equivalent squares in determining the radiation dose delivered to a patient.
- To discuss the role of beam geometry, magnification and beam penumbra in determining the extent of the radiation field which treats a patient.
- To explain the definition of field size and its use in ensuring correct coverage of the target volume.
- To explain the variation of depth-dose characteristics with energy and to relate these to the optimum choice of energy in delivering radiation to a patient.
- To explain the general features of isodose charts and their dependence upon FSD and energy with regard to ensuring the adequate and homogeneous irradiation of the target volume.
- To describe the acquisition and use of beam data for radiotherapy treatment planning and to analyse the limitations of the algorithms used.
- To explain calibration protocols and the uncertainties in the calibration process and to relate these to the overall uncertainty of patient radiation dosage.

Radiobiology and radiation risks

- To discuss the justification and use of radiotherapy in malignant and benign disease
- To contrast the use of external beam therapy and brachytherapy in the treatment of disease and to discuss the relative benefits of both modalities to the patient.
- To relate the response to radiation at the molecular and cellular level, including cellular injury and cell survival curves to the macroscopic response of tissue to radiation.
- To discuss the response of tumours and normal tissue to therapeutic levels of radiation including dependence on fractionation, dose rate, radiosensitisation, reoxygenation.
- To consider radiation reactions - early and late.
- To discuss the role of radiobiological modelling including linear-quadratic model in explaining the effects of radiation injury to tissues.
- To discuss therapeutic ratio and its role in optimising dose delivered to patients.
- To discuss the effects of radiation on the embryo and foetus, leukaemogenesis and carcinogenesis, genetic and somatic hazards for exposed individuals and populations.
- To explain the assessment of the efficacy of radiotherapy and its role in the justification of radiation treatment.

Radiation treatment planning for optimising delivery of radiation dose

- To describe the delineation of target volumes including ICRU50 and ICRU62. and its role in optimising radiation treatment.
- To contrast fixed-SSD and isocentric radiotherapy, and to discuss the relative benefits of the two methods.
- To describe beam modification including oblique incidence, inhomogeneities, wedges, compensators and interface effects in the context of achieving accurate, homogeneous irradiation of the target volume.
- To discuss the combination of fields to produce homogeneous irradiation of the target volume.
- To discuss how 3-D treatment planning and optimisation can be used to limit the radiation exposure of normal tissues.
- To discuss how the use of conformal radiotherapy can optimise the irradiation of the target volume with respect to normal tissue.
- To explain how treatment verification and in-vivo dosimetry can enhance the accuracy of the dosage and targeting of the radiation field.
- To explain how Intensity Modulated Radiotherapy (IMRT) can be used to limit the radiation dose delivered to vulnerable organs.
- To explain how stereotactic radiotherapy can limit collateral radiation damage.
- To explain the role of Monte Carlo treatment planning in enhancing the accuracy of dose estimation.
- To discuss the role of different imaging modalities in radiotherapy including CT and MRI in enhancing the accuracy of target volume delineation.
- To describe methods of patient alignment and immobilisation and their role in enhancing the geometric accuracy of dose delivery to the patient.
- To discuss the risks and benefits of special techniques: total-body Irradiation (TBI), intra-operative radiotherapy (IORT) and total-skin electron irradiation (TSEI).

Optimal and safe use of radionuclides in radiotherapy

- To discuss the types of sources used in radiotherapy and their construction, with regard to their efficacy in irradiating target volumes.
- To relate the specification of source strength to the radiation dose delivered to patients.
- To discuss the hazards of specific sources.
- To discuss the principles of clinical use and the associated radiation hazards.
- To discuss the control and testing of sealed sources in relation to the radiation hazard.
- To discuss afterloading including benefits and hazards.
- To discuss the use of unsealed radionuclides for radiotherapy and radiation protection requirements.

- To discuss current national legislation.
- To discuss the design of treatment rooms, including primary and secondary barriers and the effects of leakage and scatter radiation.
- To discuss the design of sealed source storage and dispensing facilities.
- To discuss the measurement of radiation around treatment rooms.

References

[1] Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom

[2] European Commission, Radiation Protection 116, Guidelines on Education and Training in Radiation Protection for Medical Exposures, 2000, Directorate General Environment

IAEA-CN-85-34

HOW CHANGES IN A RADIOLOGIST'S TECHNIQUE CAN REDUCE PATIENT DOSE IN BARIUM ENEMA STUDIES

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Abstract

Changes in a radiologist's technique, especially utilising digital technology, can lead to substantial dose savings in barium enema examinations. Data will be provided showing a 20% saving with only minimal change in technique.

1. Introduction

Since the publication of ICRP60, there has been a considerable amount of work carried out by many to reduce the dose received by patients during common fluoroscopy procedures. This has included equipment improvements, optimisation of equipment, use of fast film/screen combinations, etc. Papers have been published showing large dose savings can be made by attention to equipment [1, 2], but also numbers of papers have been published which have commented that dose can vary considerably depending on the clinical technique [3-11]. These comments do not appear to have been noticed by the radiological community at large, but there are exceptions [12,13]. Many suggest that dose can be reduced by careful clinical radiological technique. This paper follows on from my presentation at IRPA10 [12].

Table 1. Dose results for Barium Enemas.

	Films	Scr.Time	DAP Gycm^2	Films	Scr. Time	DAP Gycm^2
Martin [1] (Range)	12.2 (11.8-12.5)	1.6 (1.5-2.2)	26.1 (11.9-37.6)	12.2 (12-12.4)	3.1 (2.5-3.7)	17.3 (8-26.6)
Hart [7]	10.1	2.9	20	10.7	3.8	16.6
Broadhead [8] (Range)	9.2 (0-30)	2.9 (0.7-38)	21.3 (0.2-1110)	9.7 (0-90)	2.8 (0.5-14)	11.7 (1-399)
Geleijns [9]	28	7.7	21.4	27	7.8	15.3
Warren-Forward [14] (Range)	6.8 (3-11)	2.4 (1.8-3.2)	29.2 (15-47)	8 (3-15)	2 (1.5-2.3)	25 (16-39)
Yakoumakis [2]	7.4	6.2	35			
Lampinen [15] (Range)	11.6 (3-21)	3.2 (1.4-11.9)	35.8 (8-140)			
Ruiz – Cruces[13]		3.8	56.9			
Vaño[16]			49			
Corbett[12] (Range)	12 (9-14)	1.8 (1-3.7)	23.8 (10.1-46.9)	12 (9-14)	3.2 (0.3-9.6)	23.8 (1.4-78)

2. Discussion

Table 1 gives published results for barium enemas from authors from several countries, my results and personal observations from Professor Vaño, Spain [16].
The introduction of Reference Dose Levels in the European Union has spawned a number of publications and conferences [17-20] to highlight their use. These have been well attended by medical physicists. Very few radiologists have attended or shown any interest so far. The purpose of Reference Doses or Levels is to instigate an investigation as to why any examination should give consistently high dose over a period of time. These levels have to be set either EU wide, Country wide or even just within a department. However it is quite clear from the tables that there is a considerable variation between doses in different countries, departments and even equipment. While the equipment variation is well known and has been addressed before, the variation in technique between individual radiologists has not been extensively investigated. I feel this is largely because of that jealously guarded 'right': clinical autonomy. This means that any radiologist feels he or she may use as much radiation as they feel like to get the required clinical information. Each radiologist has his or her own way of doing things. Some take more films, some use extensive screening, and some use video grab. None, or very few, use the same way. From the tables, it can clearly be seen that there must be a major philosophical difference between the way radiologists in the UK, as a whole, work and elsewhere. UK doses are low compared with many other countries. Ruiz-Cruces reports average doses of 56.9 $Gycm^2$, almost 5 times greater than doses from Hairmyres Hospital, described in Table 3. There is even a drive led by the UK National Radiological Protection Board (NRPB) for even lower doses, achievable doses [21]. It will be very difficult to measure the influence of this dose variation, as clinical outcome studies have not to my knowledge been published. Work has been done in Edinburgh, Scotland, on this, which is the subject of a further paper currently in preparation.

Table 2. Dose data from Stonehouse Hospital

Radiologist	Procedure	Films	Screening Time	Dose ($Gycm^2$)
A	Enema	8.7 (4-11)	4.5 (1.1-10.4)	55.1 (30.7-111.5)
B	Enema	8.5 (6-10)	2 (1.4-4.9)	30.1 (13.1-54.2)
C	Enema	11 (9-12)	1.4 (1-2.2)	30.8 (10.8-50)

Table 3. Dose data from Hairmyres Hospital

Radiologist	Procedure	Screening Time	Dose ($Gycm^2$)
C - 1996	Enema	1.8	17.4
C – 1998	Enema	1.5	14.6
D – 1996	Enema	4.3	32.3
D – 1998	Enema	3.7	29.3
E – 1996	Enema	4	29.2
E – 1998	Enema	4.2	30.4
C - 2000	Enema	1.3	11.4

I have mentioned that there can be differences in dose between individual radiologists using the same equipment. Table 2 shows some results by radiologists for an analogue unit in our department. Two radiologists have similar DAP results, though with varying screening times and film numbers. The other radiologist screens nearly three times as much and has doses almost double the Scottish Reference Dose Levels. (32Gycm^2). This was a radiologist of ''the old school'' who has now left our employ.

Some results of doses for enemas made at different years have been obtained following installation of a digital unit. While the doses remain within the Scottish Reference Dose Levels, 2 radiologists show a slight increase in mean dose and screening time with the passage of time, while Radiologist C shows no increase. This may reflect patient mix. The important aspect to note is that the dose levels remain well within the Scottish Reference Dose Levels. Consistently they are between half and a third of the doses reported in other countries.

However complacency is unacceptable. Recently I have introduced a new view into my routine for barium enema studies. This view, a prone shoot through of the rectum, carries a high dose. In order to reduce my dose overall, I now take the filing phase images as 'video grab', not as exposed images. I have found these to be acceptable for diagnostic purposes. This change, including introducing the new view, has led to a 20% reduction in the mean dose received by my patients: 14.6 Gycm^2 to 11.4 Gycm^2. There has also been a slight decrease in my screening time from 1.5 to 1.3 minutes. I am not yet happy to take more views by video grab, but I know others are working on this. It may well be that with even newer digital systems, we may be able to go as far as to obtain all views by video grab, with a major dose saving.

3. Conclusion

It remains unlikely that radiologists will willingly change their techniques to those that use less dose unless they can be shown that such techniques are just as good. This would require a massive re-education and training programme that may just not be cost effective, but perhaps I have shown by example that it is possible. However there remains a major difference between the doses from different countries that will have to be explained further. Analogue v. Digital technology is just not enough.

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USING THE BERT CONCEPT TO PROMOTE PUBLIC UNDERSTANDING OF RADIATION

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Abstract

Radiation phobia can be greatly decreased if the simple BERT (Background Equivalent Radiation Time) concept is used to explain the dose to all diagnostic radiology patients. It converts the radiation dose to an equivalent period of natural background radiation. It is understandable, it does not mention risk, and it educates the patient that human-made radiation is the same as the background radiation which gives them most of their annual dose. Medical physicists should provide each clinical x-ray unit with a table that gives the BERT value for various procedures and patient sizes and educate the radiologists and radiographers how to use the BERT approach for relieving radiation anxiety.

1. Introduction

An occasional patient will ask: "Are x-rays safe?" or "How much radiation did I receive from my chest x-ray?" Medical physicists have a responsibility to instruct radiographers and radiologists how to give a reasonably honest and understandable answer to the patient. They can certainly explain that diagnostic x-rays are safe. There are no data to indicate otherwise. The question about the amount of radiation to the patient is difficult to answer in an understandable way. First, because it is a rare x-ray unit that has a meter to measure the radiation delivered to the patient and second, because scientific units for radiation dose are not understood by the patient.

2. Explain radiation dose to a patient using the BERT concept

Answering the patient's question about the amount of radiation would be easy if you knew the effective dose. However, it is unlikely the patient would be satisfied if your answer is "Your x-ray dose is about 1.1 mSv." The patient would understand and be satisfied if you explained that the dose is about equal to six months of natural background radiation, assuming the average background rate in the UK is about 2.2 mSv per year. Background radiation varies greatly over the earth. The explanation need not use the local background value since there is usually a large uncertainty about the effective dose which depends on biological constants which cannot be determined. The purpose is not to provide high scientific accuracy but to relieve anxiety about radiation by giving an understandable and reasonably correct answer.

This concept of explaining radiation is called the Background Equivalent Radiation Time or BERT. [1,2] The effective dose from an x-ray examination to the patient is converted to the time (in days, weeks, months or years) to obtain the same effective dose from background radiation. This method is also recommended by the U.S. National Council for Radiation Protection and Measurement (NCRP). [3] The BERT method has several advantages: (i). It is understandable to the patient, (ii). It does not mention radiation risk which is unknown, and (iii). It educates the patient that he or she lives in a sea of natural or background radiation.

3. Radiologists and radiographers should educate patients about background radiation

Patients may mistakenly think that human-made radiation is more dangerous than an equal amount of natural radiation. Most patients are unaware that most of their background radiation comes from natural radioactivity in their own body. Radiologists and radiographers should explain to them that we are all radioactive. A typical adult has over 9 kBq of natural radioactivity (i.e. 9 000 radioactive disintegrations in our body each second - over a half million per minute). The resulting radiation strikes billions of our cells each day. In a year, essentially all of the trillions of cells in our body have been hit by background radiation. The idea that radiation to one cell can initiate cancer is illogical - it assumes that the body has no defense or repair mechanisms. The body has several defense mechanisms to protect itself from doses up to about 200 mGy.[4]

Most patients never see the radiologist. Questions about radiation are often asked of the radiographer. Radiographers are generally not prepared to answer a patient's question about radiation dose. However, if tables of effective dose and BERT are available at each x-ray unit, any radiographer can answer the patient's question about radiation dose. (See Table I.) If the patient desires further information the radiographer should recommend a basic book, such as 'Understanding Radiation'. [7]

4. The extent of the usage of BERT concept

The BERT concept is used widely in many countries, including Australia, Ireland, UK and some parts in the USA, to explain and educate doctors, medical students, radiology trainees, residents, radiographers, nurses, and technologists, about radiation doses received by patients. This concept has also been published in several publications. For example, the Royal College of Radiologists (RCR) in the UK has published a guidelines booklet ' Making the Best Use of a Department of Clinical Radiology – Guidelines for Doctors' [5] in which the BERT concept is used to rank radiographic examinations in order of dose level. Similar information was presented in an Australian radiology textbook 'Applied Imaging Technology' [8] and 'Guidelines for Clinical Practice in Radiology' published by the Malaysian Radiological Society [9]. A table listing typical effective doses along with the BERT values is presented in the home page of the National Radiological Protection Board (NRPB) of the UK [6]

Recently we carried out an online survey via the largest medical physics list (medphys@lists.wayne.edu) and received many positive responses. Here are some excerpts of comments and feedback:

- "It empowers patients to make more informed decisions about risk."
- "I think the BERT is a great idea and the relation to natural background is the best thing about it; my guess is most radiation safety people use this approach, but not the specific unit."
- "I do not use it specifically but nearly always explain the dose from any procedure which a patient may receive in terms of a comparison with the ever present background radiation."
- "I've used it when explaining exposure to the families of permanent prostate implant patients. None have ever found it insulting or patronizing, and most are relieved to finally have something familiar to which they can equate their radiation exposure."

- "I have found it to be very useful and very well received and understood. Occupational and non- occupational workers seem to understand very clearly the concept of BERT. I think relating radiation exposure received to background is very wise. Haven't many of us been doing that very thing in an informal way for some time?"

Table I. Typical effective doses and equivalent periods of natural background radiation [5,6]

X-ray examinations	Typical effective dose (mSv)	BERT (Background Equivalent Radiation Time)[1]
Limbs and joints (except hip)	<0.01	<1.5 days
Teeth (single bitewing)	<0.01	<1.5 days
(panoramic)	0.01	1.5 days
Chest (single PA film)	0.02	3 days
Skull	0.07	11 days
Cervical spine (neck)	0.08	2 weeks
Hip	0.3	7 weeks
Thoracic spine	0.7	4 months
Pelvis	0.7	4 months
Abdomen	0.7	4 months
Lumbar spine	1.3	7 months
Barium swallow	1.5	8 months
IVU (kidneys and bladder)	2.5	14 months
Barium meal	3	16 months
Barium follow	3	16 months
Barium enema	7	3.2 years
CT head	2	1 year
CT chest	8	3.6 years
CT abdomen/pelvis	10	4.5 years

[1]Natural background radiation based on UK average = 2.2 mSv per year.

5. Summary and recommendations

Radiation phobia can be greatly reduced by explaining the diagnostic radiation dose to the patient using the BERT concept. Medical physicists have a responsibility to educate radiologists and radiographers how to use the BERT concept and to provide them with tables of BERT values for each clinical x-ray unit. Radiologists and radiographers have a responsibility to educate patients and others who ask them about radiation.. The BERT

concept is understandable, it does not suggest any risk and it educates the patient about background radiation. BERT is not a radiation quantity. It is a method of explaining radiation to the public. The word BERT is never used in the explanation.

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IAEA-CN-85-54

COMMUNICATING RISKS AND BENEFITS OF MEDICAL EXPOSURES TO PATIENTS

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Abstract

An information leaflet for concerned patients is in preparation, which attempts to explain the risks and benefits of diagnostic medical exposures in terms suitable for the layman. In view of the wide variability in patient doses for the same examination and the considerable uncertainties in radiation risk coefficients, x-ray examinations have been divided into just four broad categories each spanning a factor of 10 in risk. The doses are put into perspective by comparison with those from natural background radiation. Sufficient quantitative information on the approximate level of the risks for some common diagnostic procedures is provided to allow patients to make an informed decision on whether the benefits, as described by the referring clinician, outweigh the radiation risks.

1. Introduction

It is not easy for members of the public in the UK to obtain information on the radiation risks associated with diagnostic medical exposures. Doctors who refer patients for medical imaging examinations using ionising radiation are also not always well informed in these matters and concerned patients frequently resort to NRPB for advice. The NRPB website provides answers to a list of 'frequently asked questions' about medical exposures (which are accessed about 40 times a week) and we deal with one or two direct telephone enquiries each day. However, not all concerned patients have internet access or are aware of the existence of NRPB, so there is a need for more readily available information clearly expressed for the layman.

Consequently NRPB, in collaboration with the Royal College of Radiologists (RCR), the College of Radiographers (CoR) and the Royal College of General Practitioners (RCGP), are preparing a special information leaflet for patients. It is primarily intended to meet the following objectives:

- to inform concerned patients about the risks and benefits of medical x-rays
- to allay unfounded fears about the hazards of ionising radiation
- to put the risks and benefits of medical imaging into perspective
- to help GPs reassure anxious patients at time of referral
- to help hospital staff reassure anxious patients at time of examination.

To ensure widespread availability of the leaflet, particularly at time of referral for x-ray examination, it is planned to include electronic copies on appropriate websites so that referring physicians (e.g. general practitioners) can print off copies as required to give to those patients who express concern. Radiographers and radiologists would have similar access to the leaflet on CoR and RCR websites.

2. How to put the dose levels associated with medical exposures into perspective

The dose levels associated with most types of diagnostic x-ray examination are extremely variable from one hospital to another and from one patient to another. NRPB surveys of patient doses in the UK indicate that inter-hospital variations in the mean dose delivered for a particular type of x-ray examination span a factor of 4 to 7 (between the 5^{th} and 95^{th} percentile) [1]. Inter-patient variability due to individual differences in physique and pathology can add a further factor of 2 to 3. It is consequently not warranted to be over-precise in attributing 'typical' doses to x-ray examinations. In the leaflet we have simply divided X-

ray examinations into four broad effective dose categories, each spanning a factor of 10. Estimates of the 'typical' effective dose for each type of examination were derived from information in NRPB's National Patient Dose Database up to the end of 1995 [2].

The public is generally unfamiliar with radiation quantities and units so it is not helpful to express levels of exposure in 'millisieverts' or to try to explain complex concepts like 'effective dose'. An approach that has proved to be very helpful in our experience is to put medical exposures into perspective with everyday exposures by comparing them with the equivalent period of natural background radiation [3, 4, 5]. Admittedly, this uses the concept of effective dose to make the comparison, but the public only needs to appreciate that the dose measure used is roughly related to the total radiation risk from the exposure. In the leaflet, each of the four broad dose categories is related to the equivalent period of natural background radiation, expressed in a similarly imprecise fashion, e.g. 'a few days', 'a few months' or 'a few years' (see table below).

X-ray examination ***(or nuclear medicine isotope scan)***	**Equivalent period of Natural background Radiation**	**Lifetime additional risk of cancer per examination**
Chest Teeth Arms and legs Hands and feet	A few days	***Negligible risk*** Less than 1 in a million
Skull Head Neck	A few weeks	***Minimal risk*** 1 in a million to 1 in 100,000
Breast (mammography) Hip Spine Abdomen Pelvis CT scan of head *(Lung isotope scan)* *(Kidney isotope scan)*	A few months to a year	***Very low risk*** 1 in 100,000 To 1 in 10,000
Kidneys and bladder (IVU) Stomach - barium meal Colon - barium enema CT scan of chest CT scan of abdomen *(Bone isotope scan)*	A few years	***Low risk*** 1 in 10,000 to 1 in 1000

3. How to communicate radiation risks

Feedback on initial drafts of the leaflet from the radiology profession and particularly from members of the public, indicated that there is enormous potential for a leaflet of this sort to appear alarmist, trivialising or patronising, depending on the standpoint of the reader. In an attempt to present a balanced view, we start by explaining clearly what the likely effects of radiation are at the dose levels encountered in diagnostic radiology and, just as importantly, what they are not.

"You will be glad to hear that the radiation doses used for X-ray examinations or isotope scans are many thousands of times too low to produce immediate harmful effects, such as skin burns or radiation sickness. The only effect that is known to be possible at these low doses is a very slight increase in the chance of cancer occurring many years or even decades after the exposure."

The delayed nature of the possible effect is emphasised and very approximate quantitative estimates of the chance of it happening in the remaining lifetime of the patient are indicated in the last column of the Table. Again, in view of the wide variability in the patient doses and the considerable uncertainties in radiation risk coefficients especially when applied to an individual, only broad indications of the risk are justified. The ICRP nominal probability coefficient for all radiation-induced fatal cancers averaged over the whole population (5% per sievert)[6] was used to derive approximate risks for each type of examination. Since each examination category in the Table spans a dose range of a factor of 10, the range in risk indicated for each category also spans a factor of 10. The boundaries of the categories have been chosen to coincide with risk levels that are exact powers of 10.

Having broadly indicated the usually very small chance of delayed radiation–induced cancer following a diagnostic medical exposure, we try to put these levels of risk into perspective. Sir Kenneth Calman, the Chief Medical Officer in the UK at the time of the BSE *(bovine spongiform encephalopathy)* outbreak in British cows, has used the same 'power of 10' classification of risk levels in an attempt to answer the public's questions as to what is meant by "safe" [7]. He suggested using the expressions "negligible", "minimal", "very low" and "low" to describe the level of risk in each category to help individuals to decide whether the risk is acceptable. We have used these same expressions in the leaflet (see Table). An individual's acceptability of any risk depends critically on the perceived personal benefit from the activity giving rise to the risk. So the leaflet emphasises repeatedly that the benefit to the patient from the examination, in terms of making the right diagnosis and consequently giving the right treatment, should always outweigh these relatively small risks.

It is also emphasised in the leaflet that the risks are much lower for older people (who undergo the majority of medical imaging procedures) and a little higher for children and unborn babies (for whom special attention is paid to justifying and optimising medical exposures).

No attempt has been made to compare the risks from diagnostic medical exposures with other risks in daily life, since public perception of both the level and the acceptability of everyday risks is notoriously fickle. For example, we were going to suggest that the 'minimal risk' examinations were as safe as travelling by train (1 in 500,000 risk of death in train accidents per year in UK), until the Paddington train disaster in September 1999. Although this one accident did not substantially increase the risk in the long term, the intense media coverage

that it received meant that most people's perception of rail transport safety underwent rapid re-evaluation.

The leaflet concludes with a summary of the important points to remember -

- in radiology departments, every effort is made to keep radiation doses low and, wherever possible, to use ultrasound or MRI which involve no hazardous radiation
- the radiation doses from X-ray examinations or isotope scans are small in relation to those we receive from natural background radiation, ranging from the equivalent of a few days worth to a few years
- the health risks from these doses are very small but are not entirely negligible for some procedures involving fluoroscopy or computed tomography (CT)
- you should make your doctor aware of any other recent x-rays or scans you may have had, in case they make further examinations unnecessary
- the risks are much lower for older people and a little higher for children and unborn babies, so extra care is taken with young or pregnant patients
- if you are concerned about the possible risks from an investigation using radiation, you should ask your doctor whether the examination is really necessary. If it is, then the risk to your health from **not** having the examination is likely to be very much greater than that from the radiation itself

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Topical Session 12

TOPICS FOR RESEARCH AND DEVELOPMENT IN THE RADIOLOGICAL PROTECTION OF PATIENTS

DRUG INTERACTION WITH RADIOPHARMACEUTICALS AND THE IMPORTANCE FOR THE RADIATION DOSE TO THE PATIENT

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Abstract

A central aspect of the profession of health physics is to establish practical scientifically based radiation protection standards with the worthy aim of minimizing the detriment while at the same time enhancing the benefits derived from sources of ionizing radiation. The biodistribution or pharmacokinetics of radiopharmaceuticals may be altered by drugs and it can lead to misdiagnosis or the necessity to repeat the examination, increasing the dose to the patient. Vincristine (0.03mg/ml) was administered into female mice. One hour after the last dose, ^{99m}Tc-GHA (7.4 MBq) was administered and the animals (n=15) were sacrificed. The organs were isolated and the percentages of radioactivity (%ATI/g) in the organs were calculated. We calculated the Drug Interaction Factor (DIF) and the Effect Mass Factor (EMF). The results were statiscally significant (Wilcoxon test, $p<0.05$) and have shown that the DIF to ^{99m}Tc-GHA was to thymus 1.70, to pancreas 1.68, to uterus 0.42, to spleen 0.78, to lymph node inguinal 0.55, to kidney 0.45, to heart 0.59. The EMF was to ovary 0.28, to uterus 0.64, to thymus 0.17, to spleen 0.45, to lymph node inguinal 0.24, to kidney 0.80, to liver 0.77, to pancreas 0.61. The effects could be explained by the metabolization and/or therapeutic action of these drug.

1. Introduction

The earliest considerations of radiation effects and protection were built on the principles that a certain specific level of radiation can be incurred by various tissues without apparent ill effect. This in turn logically led to concept of a tolerance dose. More completely and precisely, the tolerance dose was considered to be that level of radiation to which an individual could be continuously exposed without demonstrable ill effect [1].

Hence, drug-radiopharmaceutical interaction will be defined as altered biologic behavior due to tissue response of administered drug. When the modified biologic behavior is desired, the alteration is used for diagnostic intervention or drug therapy monitoring; when it is undesired; it may be due to toxicity or direct interaction. If unknown, the drug interaction with radiopharmaceuticals can lead to misdiagnosis or the necessity to repeat the examination, increasing the dose to the patient [2, 3, 4].

More than 80% of all imaging studies (mostly anatomic) currently use technetium-99m (^{99m}Tc), because it has turned out to be the ideal isotope from various considerations [2, 3, 5, 6]. The biological activities of vincristine can be explained by its ability to bind specifically to tubulin and to block the capability of the protein to polymerize into microtubules [7]. The radiopharmaceutical 99mTc-GHA (glucoheptonic acid) is used to renal study [8]. In this paper we are evaluated the effect of vincristine on the biodistribution of the radiopharmaceutical 99mTc-GHA.

2. Material and methods

Vincristine (Oncovin, Eli Lilly, Brazil LTDA) (0.03 mg, 0.3ml) was administered by ocular plexus via into female isogenic Balb/c mice (n=15), in three doses with a total interval of 96 hours. After 96 hours, the animals were sacrificed, the various organs pancreas, lymph nodes (inguinal and mesentheric), thyroid, brain, thymus, ovary, uterus, spleen, kidney, heart,

stomach, lung, liver and bone were isolated and their mass determined in an analytical balance. The mass of the organs of these animals were compared with the control group, without vincristine. The statistical analysis of the results were performed with Wilcoxon test, $p < 0.05$. To study the vincristine effect in the biodistribution of the radiopharmaceutical, one hour after the last dose, 0.3 ml of ^{99m}Tc-GHA (7.4 MBq) was injected by the same via. In the control group (n=15), vincristine was not administered. To prepare the GHA, ^{99m}Tc, as sodium pertechnetate, recently milked from a ^{99}Mo/^{99m}Tc generator (Instituto de Pesquisas Energéticas e Nucleares, Brazil) was added to a kit of DMSA (Laboratório de Radiofarmácia, INCa, Brazil). The radiochemical control was performed by ascendent chromatography, using paper Whatman n^{o} 1 and 0.9% NaCl solution and acetone as mobile phases. The labeling efficiency was > 95% and the percentage of free pertechnetate was < 5%. After 0.5 hour the animals were rapidly sacrificed. The various organs were isolated pancreas, thyroid, brain, thymus, ovary, uterus, spleen, kidney, heart, stomach, lung, liver, bone and lymph nodes (inguinal and mesentheric) and the radioactivity of the ^{99m}Tc-DMSA and ^{99m}Tc-GHA were counted in a well counter NaI(Tl) (Automatic Gamma Counter, 1272 Clinigamma, LKB, Wallac, Finland). The percentages of radioactivity per gram of tissue (% ATI/g) in the organs were calculated dividing the total activity in each organ by the mass of each organ. The percentage of radioactivity in each organ was compared with the control group. Statistical analysis were performed by Wilcoxon test ($p<0.05$). After that, we have calculated the a Drug Interaction Factor (DIF), dividing the %ATI/g in the organs of the treated animals by the %ATI/g in the organs of the control animals and the and the Effect Mass Factor (EMF), dividing the mass of the organs of the treated animals by the mass of the organs of the control animals.

3. Results

Table 1 shows the relationship between the mass of the isolated organs of the group of mice that was treated with vincristine and the control group (no treated) and the values of the EMF.

Table 1. Effect of vincristine on the mass of different organs from female mice

	mass (g)		EMF
Tissue	control	treated	
Lung	0.1446 ± 0.0131	0.1482 ± 0.0167	1.02
Stomach	0.1187 ± 0.0131	0.1223 ± 0.0101	1.03
Heart	0.0858 ± 0.0093	0.0855 ± 0.0119	0.99
Thyroid	0.0135 ± 0.0035	0.0121 ± 0.0035	0.89
Bone	0.0387 ± 0.0082	0.0421 ± 0.0065	1.08
Brain	0.3831± 0.0293	0.3799 ± 0.0162	0.99
Spleen	0.0662 ± 0.0088	0.0300 ± 0.0059	0.45
Thymus	0.0280 ± 0.0055	0.0050 ± 0.0014	0.17
Kidneys	0.1207 ± 0.0122	0.0974 ± 0.0116	0.80
Liver	0.9734 ± 0.0597	0.7545 ± 0.0933	0.77
Ovary	0.0330 ± 0.0087	0.0095 ± 0.0027	0.28
Pancreas	0.0152 ± 0.0022	0.0094 ± 0.0019	0.61
Uterus	0.0453 ± 0.0097	0.0292 ± 0.0069	0.64
Lymph node inguinal	0.0328 ± 0.0062	0.0081 ± 0.0020	0.24
Lymph node mesentheric	0.0312 ± 0.0077	0.0079 ± 0.0023	0.25

The analysis of the results in table 1 shows no significant alteration of the mass of lung, stomach, heart, bone, thyroid and brain and reveals significant ($p < 0.05$) decreasing of the mass of spleen, thymus, kidneys, liver, ovary, pancreas, lymph nodes (inguinal and mesentheric) and uterus. Vincristine was administered into female mice Balb/c (n = 15). The animals were sacrificed, the organs isolated and their mass determined. The results were compared with the control group, without vincristine, and statistical analysis were performed (Wilcoxon test, $p < 0.05$). EMF is the effect mass factor.

Table 2 shows the uptake (%ATI/g) of ^{99m}Tc-GHA in the group of the mice that was treated with vincristine and in the control group. The analysis of the results reveals an increase of the uptake in thymus and pancreas, and decreased the uptake in uterus, spleen, lymph nodes (inguinal and mesentheric), kidney and heart. The analysis of the results reveals no significant reduction of the uptake in lung, liver, ovary, stomach, thyroid, brain and bone and shows results of the DIF.

Table 2. Effect of vincristine on the biodistribution of ^{99m}Tc-GHA in mice

%ATI/g	DIF		
Organs	Control	Treated	
Uterus	2.0455 ± 0.1065	0.8692 ± 0.1387	0.42
Ovary	0.9120 ± 0.0802	1.1052 ± 0.1456	1.21
Spleen	0.9999 ± 0.1749	0.7838 ± 0.0815	0.78
Thymus	1.3154 ± 0.3192	2.2366 ± 0.3924	1.70
Lymph node inguinal	6.2145 ± 0.3363	3.4240 ± 0.7052	0.55
Lymph node mesentheric	2.6655 ± 0.1809	1.3971 ± 0.0799	0.52
Kidney	28.4313 ± 2.5731	12.9191 ± 2.6499	0.45
Lung	2.5168 ± 0.0976	2.3914 ± 0.1338	0.95
Liver	0.5023 ± 0.0376	0.6280 ± 0.0712	1.25
Pancreas	1.1370 ± 0.1535	1.9138 ± 0.3079	1.68
Heart	1.2822 ± 0.0827	0.7666 ± 0.1609	0.59
Thyroid	3.8910 ± 0.7460	4.0743 ± 0.7240	1.04
Brain	0.1261 ± 0.0347	0.1169 ± 0.0101	0.92
Bone	0.8991 ± 0.0860	0.8079 ± 0.0689	0.89
Stomach	3.6938 ± 0.4021	3.5615 ± 0.4080	0.96

Vincristine was administered into mice and after 96h ^{99m}Tc-GHA was injected. The animals, the were sacrificed organs isolated and the activities (%ATI/g) determined. The values are averages (n=15), Wilcoxon test, $p<0.05$. DIF is the drug interaction factor.

4. Discussion

There is considerable evidence that the pharmacokinetics of radiopharmaceuticals may be altered by a variety of drugs, disease states and surgical procedures. If unknown, such factor may lead to poor organ visualization, a requirement to repeat the procedure resulting in unnecessary irradiation of organs of even misdiagnosis [2, 3, 5, 6]. The capability of determined protocols with vincristine to induce long term toxicities, as infertility in males of all ages [7, 9, 10], could also associated with the effect in uterus in our studies to the radiopharmaceutical. As vincristine is a immunosupressive drug [7], this effect could explain

the alteration of the mass of the thymus, spleen and lymph nodes (inguinal and mesentheric), and could explain the alterations in these organs to %ATI/g of the ^{99m}Tc-GHA. This drug can produce hyponatraemia with abnormal water retention due to the non-osmotic rellease of anti-diuretic hormone [7]. This could explain the alterations in uptake in the kidney to the ^{99m}Tc-GHA. Mattos 1999, related the alteration in uptake of ^{99m}Tc-MDP in this organ.

In conclusion, in general, the results could be explained by a direct toxic effect in specific organs, the metabolization and/or therapeutic and immunosupressive action of vincristine. As vincristine is capable to alter, in mice, the mass of many organs, studies are now in progress to evaluate the anatomical characteristics of organs of patients that will be submitted to a protocol with vincristine. Moreover, the fact of the drug interaction can alter the uptake of the radiopharmaceutical in a specific target (organ), unexpected radiation dose in non-target organs is undesired. This is more relevant when this unexpected uptake is in a reproductive organ. Then, we suggest to consider, with special attention, the phenomenon of the drug interaction with the radiopoharmaceutical in the calculation of the radiation dose in organs.

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PROTECTIVE EFFECTS OF SEVERAL PLANT POLYPHENOLS AGAINST CHROMOSOMAL DAMAGE INDUCED IN VIVO BY X-RAYS. COMPARATIVE STUDY VERSUS DIOSMIN AND RUTIN*

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Abstract

Protective effects of grape (Vitis *vinifera*) seed (GSE), *Citrus spp.* fruits (CE) and olive (*Olea europaea* L.) leaf (OL) extracts, the flavonoids diosmin and rutin, widely used as pharmaceuticals, and dimethylsulphoxide (DMSO) against chromosomal damage induced by X-rays were determined by using the micronucleus test for anticlastogenic activity. The reduction of the frequency of micronucleated polychromatic erythrocytes (MnPCEs) in bone marrow of mouse exposed to X-rays was examined. The most effective compounds were, in order: GSE ≈ CE > rutin ≈ DMSO ≈ OL > diosmin. These results suggest a correlation between the antioxidant and anticlastogenic activity of these polyphenolic extracts.

1. Introduction

The micronucleus test "in vivo" is a method devised primarily for screening chemicals for chromosome-breaking effects. The test substances are normally applied sub-acutely to small mammals, and the effect is read in direct smears from bone marrow. The micronucleus assay on mouse bone marrow polychromatic erythrocytes, originally developed by Schmidt (1975) [1], is probably the most frequently used in vivo short-term genotoxicity tests. Bone marrow micronucleated erythrocytes provide a simple and rapid method for detection of chromosomal damage by chemical and physical agents [1-4]. For this reason, micronuclei have been widely used to detect chromosomal breakage and chromosome lagging "in vivo" and "in vitro" [2-4].

2. Materials and methods

Plant Materia: Grape Seeds Extract (GSE) was obtained from four different varieties of *V. vinifera* grapes selected in different areas of the community of Murcia (Spain): "Macabeo" and "Airen" are white grapes and "Tempranillo" and "Monastrel" are red grapes. The grapes were picked at their optimum commercial maturity.

Citrus Fruit Extract (CE) was obtained from immature fruits of several characteristic cultivars from the region of Murcia from three *Citrus* species: *Citrus limonia, Citrus paradisi* and *Citrus aurantium*. The fruits were harvested from the trees by natural abscission during the initial phase of the fruit growth.

Olive Leaf Extract (OL) was obtained from *Olea europaea* L. leaves of five cultivars: Villalonga, Alfafarenca, Picual, Cornicabra and Blanqueta from the regions of Andalucia and Murcia. The leaves were collected when the olive fruits were picked at their usual commercial time.

* This work was supported by a grant from the European Union (grant no. 1FD97-0576).

Chemical Reagents:

Diosmin and rutin were obtained from Extrasynthèse S.A. (Genay, France). DMSO was obtained from Merck (Darmstadt, Germany). Fetal calf serum was obtained from Sigma Chemical Co. (Madrid, Spain).

Extraction and HPLC Analysis of Polyphenolic Compounds from Plant Material

The methods to obtain and quantify the grape seed (GSE), citrus (CE) and olive leaf (OL) extracts have been described previously.

Animals

Adult male Swiss albino mice, 9-12 weeks of age, weighing approximately 25 g were used from our animal colony (license 300030-2A). All mice were acclimatized for at least one week prior to dosing. They were maintained under constant environmental conditions with 12/12 h light/dark cycle. They were fed standard granulated chow (Rodent toxicology diet®, BYK Universal Beekay Feeds, France) and given drinking water ad libitum. Each group consisted of 6 mice.

Chemicals and Treatment

The polyphenolic extracts were administered orally. All solutions were freshly prepared immediately before treatment of the animals. GSE, CE, and OL were dissolved in 0.2 % drinking water and administered during 5 days before the X-irradiation. DMSO was dissolved in water (50 g/100 mL). Diosmin and rutin were dissolved in DMSO (300 mg/mL). DMSO, diosmin and rutin were injected in a single dose of 0.6 mL directly into the gastric lumen 6 h before the X-irradiation.

Exposure to X-rays

The mice were whole-body X-irradiated using CGR apparatus with radioscopy (General Electric, Spain). During exposure to X-rays, the animals were placed in a well-ventilated acrylic box. Irradiation conditions: 120 kV, 1.4 mA, filter 2.5 mm Al, exposure rate of 2cGy/min, FDO 100 cm. The mice were exposed to a single dose of 48 cGy. The X-ray exposure was established by means of thermoluminescent dosimeters (TLDs) (GR-200®, Conqueror Electronics Technology Co. Ltd, China). The TLDs were supplied and measured by CIEMAT (Ministry of Industry and Energy, Spain)

Bone Marrow Preparation and Staining

Two femurs were removed from each mouse 24 h after X-irradiation, and bone marrow samples were taken. The bone marrow cells were dispersed by gently pipetting and then collected by centrifugation at 1,000 rpm for 5 min at 4ºC. Cell pellet was resuspended in one drop of fetal calf serum and bone marrow smears (two slides per mouse) were prepared. The slides were coded to avoid observation bias. After 24 h air-drying, the smears were stained with May-Grünwald/Giemsa[48, 49]. With this method polychromatic erythrocytes (PCEs) stain reddish-blue and normochromatic erythrocytes (NCEs) stain orangey, while nuclear material is a dark purple colour. The number of micronucleated polychromatic erythrocytes (MnPCEs) among 2,000 PCEs per mouse (1,000 PCEs per slide) was determined. The slides were examined at 1,000x magnification using a Zeiss light microscope (Oberkochen, Germany).

Statistical Evaluation

Differences in the frequency per animal of MnPCEs per 1,000 PCEs were tested by analysis of variance and evaluated using Student's t-test.

3. Results

The data presented (Figure 1) show that whole-body exposure to 48 cGy of X-rays results in a substantial increase in the frequency of MnPCEs in comparison with that occurring spontaneously ($p<0.001$). There is a significant reduction of frequency of MnPCEs in all pre-treated, irradiated groups compared with the control and irradiated group.

Figure 1 shows the influence of treatments on the frequencies of MnPCEs in the bone marrow of animals non-irradiated and irradiated, permitting thus to compare the potential toxicity of each treatment vs. their anticlastogenic activity. Diosmin, rutin, GSE, CE and OL show very low levels of MnPCEs generation, similar in respect to non-irradiated control data, while the sulphur-containing compound, DMSO, presents higher genotoxicity levels (>5 MNPCEs/ 1000 PCEs) than the other compounds studied. Also, Figure 1 shows the influence of X-irradiation on the frequencies of MnPCEs in mouse bone marrow. There is a significant reduction of frequency of MnPCEs in the pre-treated groups compared with the irradiated control group. The order of treatments with respect to the minor level of MnPCEs generated after irradiation is: GSE ≈ CE < rutin ≈ DMSO ≈ OL < diosmin (at least $p<0.05$ in each one of the steps represented).

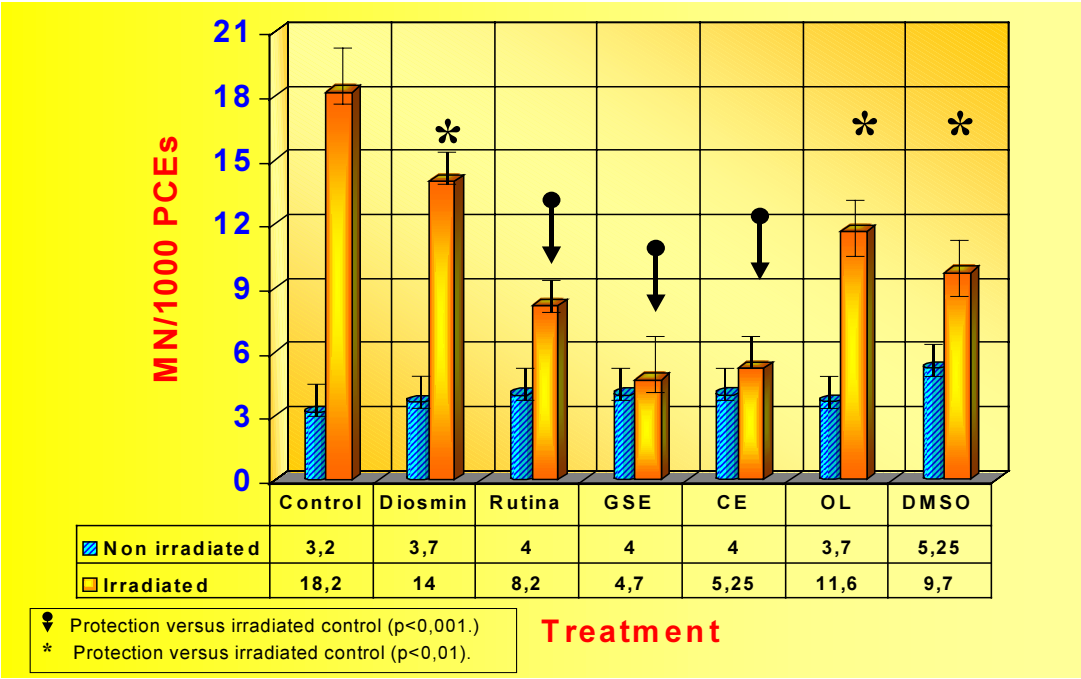

Figure 1. Influence of treatments and X-rays irradiation on the frequencies of MnPCEs in mouse bone marrow (irradiated and non-irradiated)

The radioprotective effects, and consequently the anticlastogenic activity of the different treatments used, were established according to the increase in the MnPCE level in animals after irradiation and their relation with this level in control animals, obtaining a percentage value that shows the level of protection of each treatment. Figure 2 shows the values of these protection capacities, the GSE-pre-treated group being the most effective protection against in vivo chromosomal damage and cytotoxicity induced by X-rays. The order of effectiveness was: GSE ≈ CE > rutin ≈ DMSO ≈ OL > diosmin.

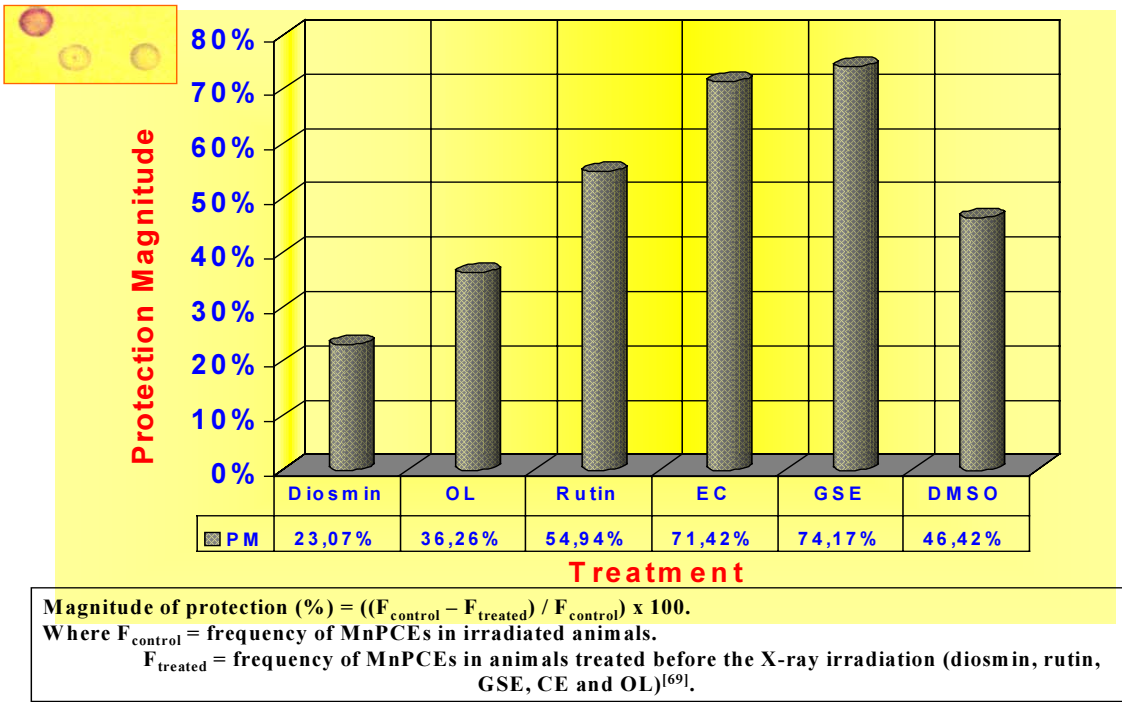

Figure 2. Protection magnitude of different treatments in relation to irradiation with X-rays.

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IAEA-CN-85-256

CYTOKINESIS BLOCK MICRONUCLEUS IN HUMAN LYMPHOCYTES: EFFECT OF LOW DOSE RADIATION IN VASCULAR RADIOLOGY*

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Abstract

This paper studies the frequency of occurrence of micronuclei (MN) in irradiated patients' lymphocytes during medical radiodiagnostic examinations by cytogenetic block (CB) technique. Firstly, dose-response curves have been obtained in order to determine MN occurrence in peripheral blood lymphocytes in nine healthy patients in connection with the radiation doses administered. Subsequently, total blood samples of 25 patients having undergone any complex radiological procedure have been analysed. Four different blood samples have been collected from those patients as follows: **1)** prior to irradiation, corresponding to a non-irradiated control sample; **2)** prior to irradiation, to which the radiological contrast was added at a concentration of 5%; **3)** sample obtained at the beginning of the examination but remaining *in vitro*, exposed to the primary irradiation beam throughout the radiological exploration; **4)** sample obtained from the patient at the end of the radiological procedure. Results show that MN frequency in lymphocytes with cytogenetic block and the ionizing radiation dose administered are interdependent. A significant increase of MN in patients' samples obtained after radiological examinations (irradiated samples) compared to those obtained before examinations (control samples) ($p<0,01$) has been observed. The radiological contrast medium has not produced significant changes in MN induction to the concentration used in this study. The micronucleus assay (CB) is simple and could be applied in situations where physical dosimetry is not possible. It could be used to assess individual sensitivity to radiation and to determine exposures to low doses of irradiation if a previous comparative pattern were available for the exposed worker or patient.

1. Introduction

The cytokinesis blocking method in lymphocytes, described by Fenech and Morley (1985) [1] and based on earlier observations by Carter [2], is now considered to be the best for the micronucleus assay for dosimetry purposes.

In the present work the "in vitro" dose response for X-irradiation, gamma-radiation (Cs-137) and "in vivo" response in patients irradiated during medical radiodiagnostic exploration has been studied.

2. Material and methods

The appearance of micronuclei (MN) in the lymphocytes of patients irradiated during medical radiodiagnostic explorations was studied to establish the existence of a dose-response relationship between irradiation with low doses of X-rays and the frequency of micronucleus appearance and to determine the importance of the Cytogenetic Block test to reveal these exposures.

Firstly, dose-response curves have been obtained in order to determine MN occurrence in peripheral blood lymphocytes in nine healthy patients in connection with the radiation doses administered. Subsequently, total blood samples of 25 patients having undergone any complex radiological procedure have been analysed. Four different blood samples have been

* This work was supported by a grant from the European Union (grant no. 1FD97-0576).

collected from those patients as follows: Four different blood samples have been collected from those patients as follows: **1)** prior to irradiation, corresponding to a non-irradiated control sample; **2)** prior to irradiation, to which the radiological contrast was added at a concentration of 5%; **3)** sample obtained at the beginning of the examination but remaining *in vitro*, exposed to the primary irradiation beam throughout the radiological exploration; **4)** sample obtained from the patient at the end of the radiological procedure.

3. Results

Results show that MN frequency in lymphocytes with cytogenetic block and the ionizing radiation dose administered are interdependent (Fig.1, 2). The results show a dependency relationship between micronucleus frequency and patient age ($r = 0.9237$; $p<0.01$).

The micronucleus assay is simple and could be applied in situations where physical dosimetry is not possible. It could be used to assess individual sensitivity to radiation and to determine exposures to low doses of irradiation if a previous comparative pattern were available for the exposed worker or patient.

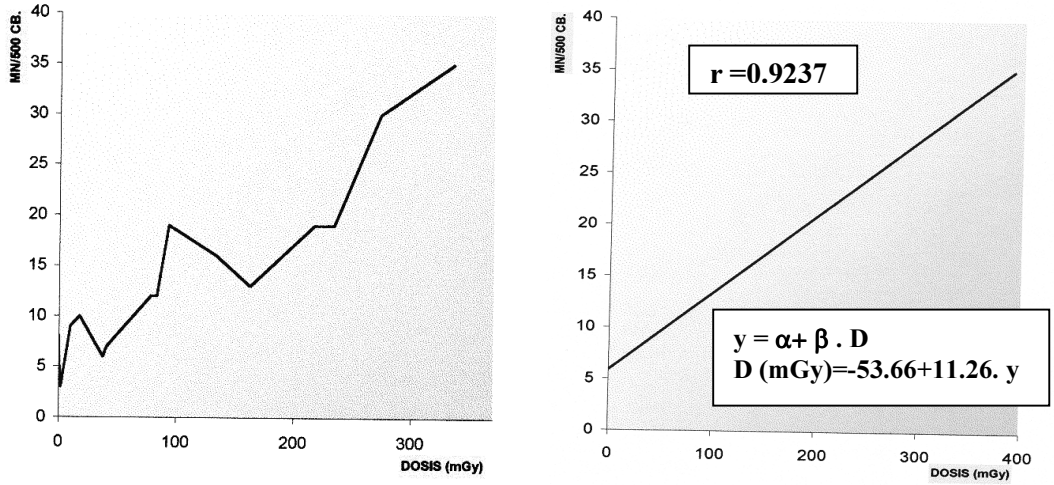

Fig. 1: Dose-effect curves for X-ray induced micronuclei (MN/500 CB) (0-335 mGy).

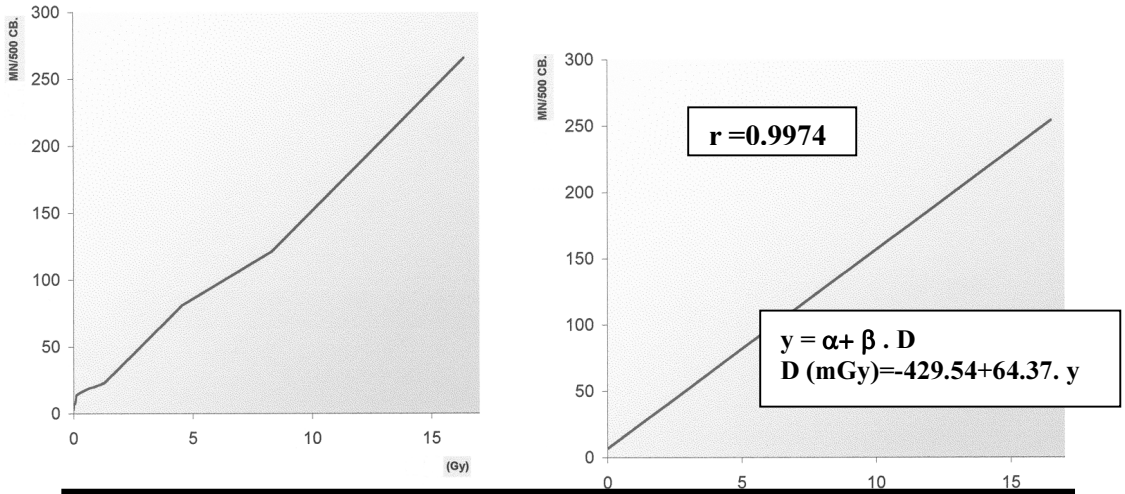

Fig. 2: Dose-effect curves for gamma-irradiation induced micronuclei (MN/500 CB) (0-16'362 Gv).

Likewise, a significant increase of MN in patients' samples obtained after radiological examinations (irradiated samples) compared to those obtained before examinations (control samples) ($p < 0,01$) has been observed. The radiological contrast medium has not produced significant changes in MN induction to the concentration used in this study

Code	Age (years)	EXPLORATION	Cells (CB) scored	Cells without a MN	Cells with MN	Σ MN	Cells (CB) scored	Cells without a MN	Cells with MN	Σ MN	Dose (mGy)
1	21	Arteriography of membrum.	500	497	3	3	500	497	3	3	0.58
2	26	Arteriography of membrum .	500	497	3	3	500	496	4	5	0.38
3	41	Coronary angiography.	500	496	4	4	500	489	11	14	17.32
4	42	Aortography.	500	496	4	4	500	497	3	3	4.24
5	46	Coronary angiography.	500	497	3	3	500	496	4	4	6.45
6	48	Aortography.	500	498	2	2	500	498	2	2	4.77
7	50	Coronary angiography.	500	496	4	4	500	495	5	5	4.28
8	50	Aortoiliac angiography.	500	497	3	3	500	496	4	4	1.21
9	50	Coronary angiography.	500	496	4	4	500	494	6	7	9.45
10	53	Arteriography of membrum	500	495	5	5	500	496	4	9	0.53
11	54	Arteriography of membrum.	500	496	4	4	500	493	7	8	1.51
12	54	Percutaneous cholangiogr..	500	491	9	11	500	493	7	9	4.19
13	54	Coronary angiography.	500	498	2	2	500	495	5	6	4.66
14	60	Coronary angiography.	500	497	3	3	500	493	7	9	4.53
15	60	Coronary angiography.	500	484	6	7	500	490	10	15	3.73
16	62	Coronary angiography.	500	489	11	11	500	491	9	9	2.10
17	64	Excretory urography.	500	489	11	12	500	486	14	20	0.32
18	64	Excretory urography.	500	493	7	7	500	492	8	10	0.25
19	66	Cholangiography transkerh.	500	492	8	10	500	490	10	10	1.97
20	67	Coronary angiography.	500	479	21	23	500	485	15	16	1.88
21	68	Coronary angiography.	500	488	12	12	500	484	16	18	4.07
22	72	Esophagoplasty.	500	490	10	10	500	490	10	13	2.20
23	77	Angioplasty.	500	492	8	10	500	490	10	10	4.10
24	82	Renal arteriography.	500	493	7	7	500	495	5	5	0.71
25	84	Aortography.	500	487	13	13	500	495	5	6	1.072

Fig. 3: Number of micronuclei (MN) in binucleated cells (BN) and distribution of BN presenting one o more micronuclei in the patients irradiated during medical radiodiagnostic exploration (Pre-irradiation: sample I; Post-irradiation: sample IV).

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Topical Session 13

IMPLEMENTATION OF REGULATIONS ON THE RADIOLOGICAL PROTECTION OF PATIENTS

RADIATION PROTECTION IN HOSPITALS OF ECUATORIAL GUINEA*

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Abstract

A population with (400.000) four hundred thousand inhabitant and distributed in territory (28.000) 28 thousand km², the use of ionizing radiations for medical practice in Equatorial Guinea is smallest only decreased and used for diagnostic practices in the main hospitals of the country, where the work burden is not over 20 patients per day. The political, social and economical embryonic development of the country until recent dates it had an negative influence on indicators and health organisations, so that even now the country has not any radiological protection law, this shortness, in addition with the old architectural structure that x ray tools is lodging, as well as dosimetrical lack of employed staff, put this staff under risk of electromagnetic energy. This is to show the present survey of medical activities with ionizing radiation and to request technical support for implement suitably the basic standards of radiation protection which will help us as basis for the elaboration outline law, on radiological protection in accordance with the new guidelines of international organization for Atomic Energy.

1. Introduccion

Guinea Ecuatorial es un país situado en Africa Central y tiene fronteras terrestres con Gabón y Camerún, así como fronteras marítimas al Norte de la Isla de Bioko con Nigeria. Para una superficie total de 28.000 km², este territorio se divide en dos regiones : una continental, de 26.000 km², y otra insular, Bioko, con 2000 km² y en la cual hallamos la ciudad de Malabo, capital política del país. Con una población de poco más de 400.000 habitantes, los principales indicadores de salud de su población en 1999 eran de:

Esperanza de vida al nacer: 49,8%
Tasa de mortalidad infantil: 87 ‰

Tras acceder a la independencia en 1968, el país fue sumido en una de las dictaduras más crueles y sanguinarias del mundo, lo cual trajo consigo la huida de los pocos intelectuales, médicos, políticos, etc. La Administración del Estado y, consigo la Administración de Salud se vieron expuestas a los peores desórdenes burocráticos, y a la desaparición masiva de sus archivos. Esta situación conllevó a que tras la restauración de la democracia once años después, nada se pudo encontrar en los archivos del Ministerio de Sanidad referente a la protección radiológica en el campo de la medicina.

Los Servicios de Radiología que han sido objeto de este estudio han sido nuestra única referencia para iniciar una tímida reglamentación de las normas básicas y prácticas de protección radiológica para los Servicios de Radiología de los hospitales del País. Estos servicios se caracterizaban, en términos generales, por su diseño arquitectónico colonial, pero que se adaptaba perfectamente a las condiciones climatológicas locales y a las condiciones de irradiación, es decir:

Salas amplias y altas : la única sala de rayos X del Hospital General de Malabo tiene 14 x 9 metros, con lo cual el operador se halla a más de 6 metros de la fuente principal de irradiación.

* Sesión técnica : Cuestiones especificas de la protección radiológica ocupacional.

La sala de rayos X del Hospital de Luba, a 56 km de Malabo ; y la de Bata, en la región continental, a 300 km, presentaban similares características.

Estas salas no presentaban suficiente protección de los muros, ventanas y puertas, aunque según recomendaciones de los manuales de la OMS, en países con escasos recursos, es más rentable construir unas salas de dimensiones ligeramente superiores en lugar de comprar material plomado para proteger muros y ventanas[1].

Con esta medida se pretende aplicar el principio de que la irradiación se reduce en función al cuadrado de la distancia[2]. Además, teniendo en cuenta que por lo general cada uno de estos servicios atiende hoy día a menos de veinte (20) pacientes por día, y con radiografías simples de tórax y extremidades; de vez en cuando se realizan pruebas contrastadas gastrointestinales (3-4/semana) y urológicas (2-3/semana), estimamos que los riesgos de una sobreexposición de pacientes y operadores son mínimos.

A pesar de ello, constatamos que nuestros Servicios de Radiología presentan ciertas deficiencias, a veces tan elementales que podemos considerarlas como graves :

Ningún operador del país trabaja con dosímetros personales, porque no los hay.

Los delantales y guantes plomados, o son insuficientes, o son deficientes, o no existen en ciertos Servicios de Radiología.

La extensión de los parabanes con cristal plomado, muchas veces, es deficiente como para proteger a los operadores.

No existe un Departamento que se encargue de evaluar las dosis recibidas por los pacientes y operadores, y por lo tanto, el personal profesionalmente expuesto a las radiaciones ionizantes, así como el público en general, están corriendo los riesgos inherentes a una exposición radiológica no controlada.

La baja cualificación profesional de muchos técnicos y auxiliares de radiología, la negligencia de éstos en la observancia, cuidado y control de las normas de protección radiológicas elementales, ya sea por olvido o por falta de suficiente información actualizada al respecto, les exponen constantemente a los peligros de una sobreexposición a las radiaciones. Téngase en cuenta que la dósis de irradiación recibida por los técnicos y médicos radiólogos varía considerablemente según los reflejos de radioprotección que éstos habrán sabido o no desarrollar (4).

Una de las primeras medidas que tomó el primer grupo de técnicos radiólogos cualificados egresados al país en 1987 y tras verificar que no existía normativa alguna para la protección del personal ocupacionalmente expuesto a las radiaciones ionizantes, así como de los miembros del público, fue elaborar, hacia 1990, un Anteproyecto de Ley sobre Protección Radiológica, que fue propuesto a las Autoridades del Ministerio de Sanidad. Lamentablemente, este Anteproyecto de Ley no siguió su curso ni fue aplicado, y tuvimos que esperar hasta 1993 para ver un primero pero tímido intento de regular, por parte del Ministerio de Sanidad de Guinea Ecuatorial, cierta normativa encaminada a controlar las actividades relacionadas con las radiaciones ionizantes.

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[1] KLECZKOWSKI, B.M ; PIBOULEAU, R. : Planification et conception des équipements de santé dans les régions en développement : approches possibles. OMS, publication offset n° 45. Genève, 1980.

[2] Gárate Rojas, M. : Fundamentos de la Técnica Radiográfica. Ed. AGFA-GEVAERT, Barcelona, 3a ed., 1991.

Dicha normativa, que nunca ha tenido rango de Ley, es la que se viene aplicando hasta hoy y se caracteriza, dada la poca experiencia de los redactores de la misma, por una reglamentación de embrionaria aplicabilidad y que, hoy en día, no se adapta ya a las nuevas directrices de los organismos internacionales de Energía Atómica.

Por todo cuanto antecede, solicitamos de las instancias aquí presentes, un asesoramiento en el aspecto técnico y legislativo encaminado a garantizar las normas de bioseguridad radiológica, introduciendo medidas de seguridad suplementarias en los edificios, instalaciones, uso, reparación y eliminación final del material[3]. Estas medidas coadyuvarían a que se elaborase y se promulgase una Ley de Protección Radiológica de aplicabilidad nacional.

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[4] **Herbelet,** G.: Exemples d'exposition du personnel, in: Rayonnements ionisants et Radioprotection, en la revista " Le Manipulateur" , N° Especial, Ed.: A.F.P.P.E, Paris, Septiembre de 1999.

IAEA-CN-85-124

STRATEGIC MANAGEMENT OF RADIATION PROTECTION PROGRAMME IN THE MINISTRY OF HEALTH MALAYSIA — AN APPROACH BASED ON MS ISO 9000 QUALITY MANAGEMENT SYSTEM

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Abstract

The MS ISO 9000 Quality Management System launched in 1996 was one of the quality improvement efforts introduced by the Ministry of Health Malaysia. The main objective of implementing MS ISO 9000 in the Ministry of Health was to lay the foundation and provide a suitable framework for internalising and institutionalising quality in the health system. This Quality Management System enabled the institutions to systematically document the appropriate work processes in tandem with the requirements of the functional system of the organisation. The Quality Management System allowed the essential activities of the health care delivery to be consistently managed and continually improved upon. This paper discusses the rationale, applicability and approach taken by the Ministry of Health in its efforts to introduce and implement MS ISO 9000 Quality Management System in all its institutions. This paper describe the strategic approach taken by the Radiation Health and Safety Unit, Ministry of Health Malaysia to develop and implement radiation protection activities for the application of radiation in medicine based on the MS ISO 9000 Quality Management System and the achievements of the unit in obtaining the certification.

1. Introduction

The Ministry of Health (MOH) has introduced various quality improvement activities in the delivery of health services. Among these quality initiatives, the Quality Assurance Programme was initiated in 1985, while the Federal Government launched the quality programme for the public services in 1991. These quality initiatives are aimed at enhancing and improving the technical and service quality of health care delivery and various enforcement functions in the MOH.

In the MOH, quality programmes were developed and implemented in parallel, by way of Government of Malaysia Development & Administration Circular (GMDAC) for the administration section, and the Quality Assurance Programme for the technical and professional sections.

In 1996, the Federal Government felt that there was still room for improvement in its service delivery and decided that it was timely for all its agencies to implement a quality management system which was universally and internationally recognised. In this regard, the Government of Malaysia Development & Administration Circular (GMDAC) No. 2/96 for the implementation of MS ISO 9000 in the Malaysian Civil Service was issued. The MOH during the 1996 Directors' Conference had resolved to implement MS ISO 9000 in all its institutions. It was envisaged that the adoption of this standard would complement and further strengthen the various quality improvement activities already existing in the Ministry.

2. Applicability of ms iso 9000 quality management system

For decades, most healthcare service delivery and enforcement functions have structured its organisation according to functions. The functional hierarchy is closely observed with the staff at the bottom of the hierarchy reporting to the immediate superior of the functional area. In the day-to-day tasks, work processes cut across functions. Experience has shown that, in achieving organisational goals, numerous and complex cross-functional work processes are

required. Radiation protection activities involve work processes, which encompass input components, value-added activities and output delivery. Every process is an input and output chain. The strength and applicability of MS ISO 9000 lies in its ability to harmonise the traditional functional system of the organisation with the various interrelated work processes, which are required for the effective and efficient running of the day-to-day tasks. Figure 1 illustrates a conceptual presentation of a generic ISO quality management system demonstrating the interaction between functional system of the organisation and the work processes.

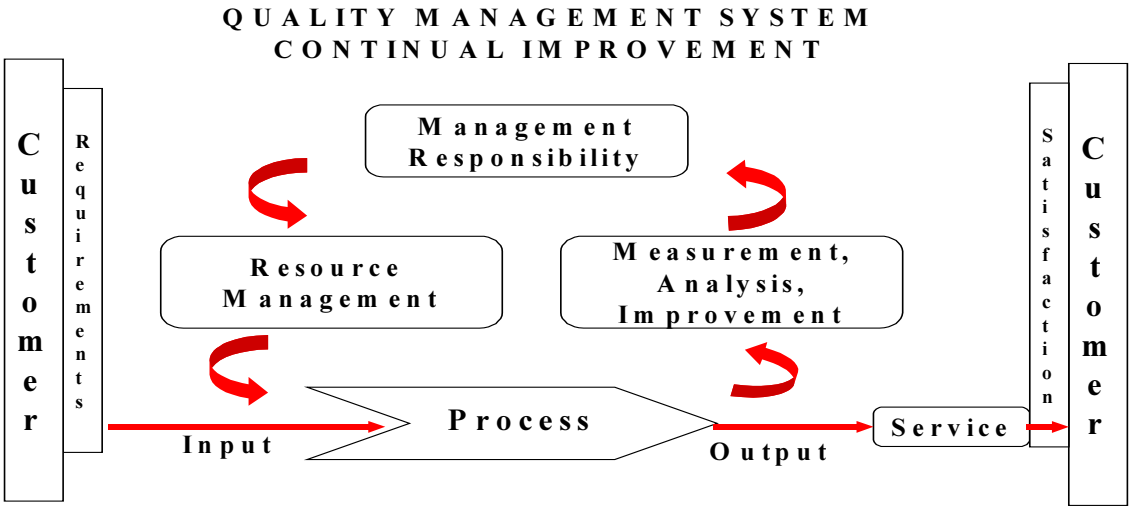

Figure 1: Quality Management Process Model

3. The Ministry of Health approach

The Ministry of Health has established a technical committee to coordinate the overall strategic planning process, scheduling and implementation of MS ISO 9000 Quality Management System. Meanwhile, the Programme Directors are required to facilitate and coordinate the identification of core business processes in their respective programs. They are also required to assist in re-examining selected core business to improve work processes and to possibly effect re-engineering before commencing the documentation process, taking into account international standards where possible and appropriate.

4. Methodology

The methodology for establishing MS ISO 9000 Quality Management System (QMS) consists of steps as illustrated in Figure 2.

The first step involves defining and clarifying organisational mandates and responsibilities. The purpose of this step is to clarify the formal and informal mandate placed on the organisation. Mandates prescribe the right functions to be done by the organisation. It ensures that management responsibilities are clearly identified and defined. In tandem with the mandate and defined management responsibilities, vision describes the organisation's aspiration for the future and mission provides the *raison d'être*. Vision and mission help to identify common goals and direction for the organisation.

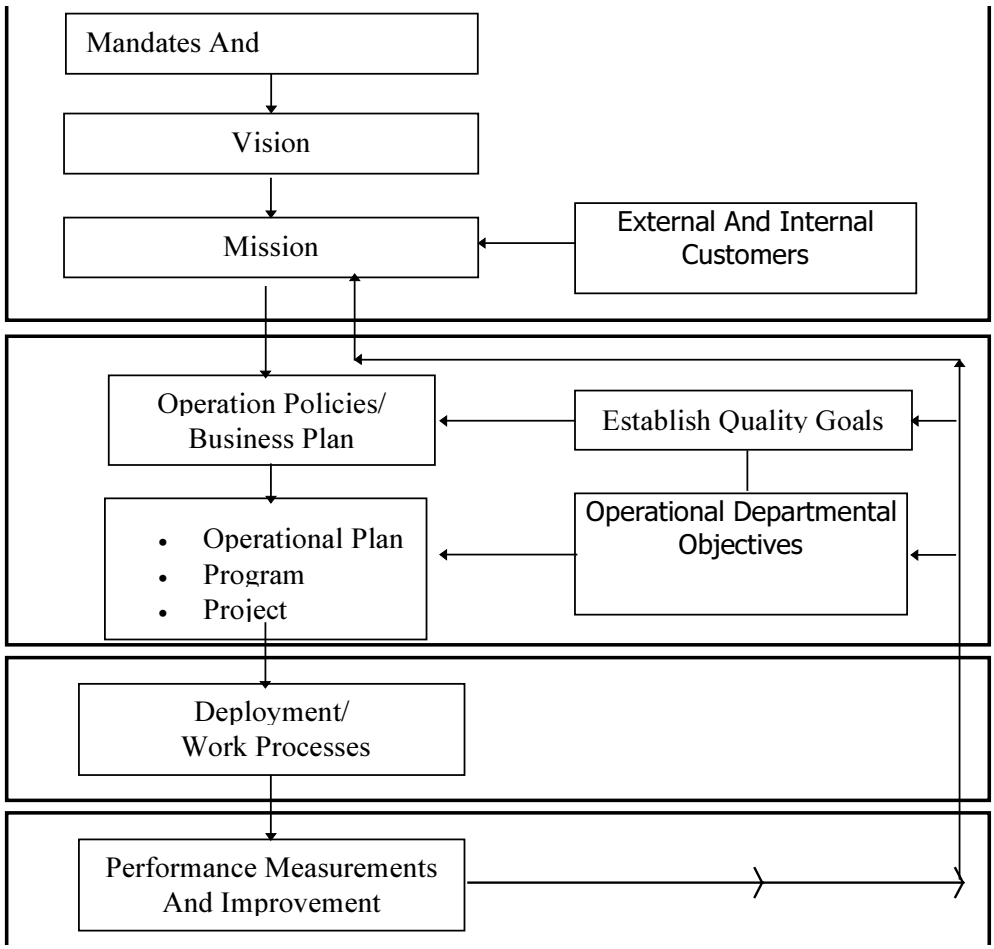

Figure 2: Schematic Approach for Establishing QMS

With this foundation, together with a careful analysis of the customers/patients requirements, quality goals are established. For attaining this goal, necessary strategies, operational plans such as programmes and projects are developed. The purpose of this systematic approach for setting and meeting goals is to integrate quality improvement into the management system thereby attaining the desired quality. In this context, this step enables business plans, hospital and departmental operational policies to be prepared accordingly.

The next step involves deploying and mapping the goals into the operational plans, which are broken down into programmes, or projects of the various functional units, project team or permanent work processes and procedures. For each programme or project, the quality objective, which is specific and achievable within a given time frame, and which is relevant and measurable, is established. The Clients' Charter and the National Indicators of the QAP are good examples of the quality objective. The quality objective lays the foundation for selecting and developing key/core work processes that are essential to produce the necessary output.

These interlinked work processes are defined, designed and documented so that they can be managed and improved upon. The work processes are categorised into:

i) Core process for delivering the services
ii) Support processes
iii) Quality improvement processes

From these work processes, quality management procedures are prepared. These include:
i) Procedures that describe the activities
ii) Procedures that describe the sequential and interactive nature of the process
iii) Instructions that describe the operating practice and control of activities.

The procedures are finally consolidated into a procedure manual of the quality management system.
The last step involves instituting an effective performance measurement system to ensure that service outputs meet both the functional and process objectives and that all patient requirements are satisfied. Objective performance data about important governance, management, clinical and support systems generated through the applications of performance measures or indicators can be used to identify performance variations. Analysis of these variations will consequently lead to identifying opportunities for improvements.

5. Achievements

According to the road map format of the Government of Malaysia Development & Administration Circular (GMDAC) 1/99, the stages for implementing MS 9000 are :
i) Awareness training
ii) Formation of project team
iii) Preparation of action plan
iv) Identification of business core processes
v) Documentation
vi) Implementation
vii) Certification
Since 1996, the Radiation Health and Safety Unit has embarked on an extensive awareness training program for its staff. This has resulted in a high level of awareness amongst the staff regarding MS ISO 9000. Identification and documentation of business core processes for radiation protection activities was completed in mid-1996. In the implementation phase, activities were carried out according to documented procedures. By March 1997, SIRIM the Malaysian certification body for MS ISO 9000 audited the Unit for compliance. The Radiation Health and Safety Unit was subsequently awarded the coveted MS ISO 9002 certificate for the scope; the management of the provision of radiation protection programme for application of radiation in medicine. This makes the Radiation Health and Safety Unit, MOH the first department to be certified in the Malaysian Public Services. For the consecutive years 1998, 1999 and 2000, the Unit was recertified.

6. Conclusion

The standards of the MS ISO 9000 Quality Management System are generic in nature, thus, allowing their use in diverse sectors. It is important to note that these standards apply to an organisation and its operational structure, not the nature of the service, and that the organisation is self-defined. The standards identify requirements relating to the management of processes considered necessary to assure quality. The Quality Management System, while requiring the right and appropriate work processes and activities to be defined, documented and proven, does not necessarily prescribe norms, performance criteria and professional standards. Such standards, including statutory requirements are normally mapped into the system through the establishment of operational policies and business plan. The contention of

the Ministry of Health's quality policy is such that all performance standards relating to the profession, industrial norms and statutory requirements need to be established.

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NEW PERSPECTIVE FOR RADIATION PROTECTION IN DIAGNOSTIC PROCEDURE IN PARAGUAY

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Abstract

The Government in Paraguay approved by Decree Law 10754, dated of October 6, 2000 its National Regulation on Basic Safety Standards for Radiation Protection and the Safety of Radiation Sources, based on the IAEA Safety Standards 115. The primary goal of Patient Protection is to ensure that both, Regulatory Authorities and all Responsible parties in Medical Practices, observe procedural process in conducting their responsibilities on regulatory and administrative affairs. By one side the Government, "Departamento de Protección Radiologica", under the Health Ministry and Comisión Nacional de Energia Atómica and by the other side, the medical practitioner who prescribe or conduct diagnostic or therapeutic treatment, both to ensure that the exposure of patients be the minimum. This document describes how the Regulatory Authorities intend to implement this recent act and by the other hand to take the advantage of this Conference to understand better this subject, especially on the following subjects, essential requirement for licensing, inspection and enforcement programmed in the Country's Capital and in the Interior, where difficulties are higher, also workers and medical training and lessons learned applied to developing countries.

1. Introducción

Desde el año 1990, el Ministerio de Salud Publica y Bienestar Social, a publicado, por Resolución Ministerial las NORMAS BASICAS DE PROTECCIÓN RADIOLÓGICA EN EL AREA DE LA SALUD, las cuales a partir de esa fecha son de observancia obligatoria por parte de todos los Establecimientos de Salud que operan con fuentes ionizantes, en todo el territorio Nacional.

Dicha Resolución fue derogada por Decreto No: 10754, del Poder Ejecutivo, recientemente, de tal forma a tener un Reglamento Único sobre LA PROTECCIÓN CONTRA LAS RADIACIONES IONIZANTES Y PARA LA SEGURIDAD DE LAS FUENTES DE RADIACIÓN. Debido a que en el país existían dos Autoridades, el Ministerio de Salud, por un lado, y la Comisión Nacional de Energía Atómica por el otro, con una superposición de coberturas entre ambas Instituciones, con la promulgación de este decreto se estableció la Autoridad Competente así como, un único Reglamento de Protección contra las Radiaciones Ionizantes, cuyo alcance es en todo el territorio Nacional y fue elaborado por un Comité de Estudio, integrado por varias Instituciones involucradas en el tema.

Esto constituye para el país un avance de gran importancia, porque se cuenta con un Marco Legal acorde a las NORMAS BASICAS DE SEGURIDAD, Colección No: 115, del OIEA.

2. Situacion de la proteccion radiologica en el paraguay en el area de radiodiagnóstico medico – odontológico

El Departamento de Protección Radiológica, en sus funciones de establecer los requisitos necesarios para las instalaciones que conllevan el empleo de radiaciones ionizantes ha tenido la prioridad de evaluar las condiciones que existen de Protección Radiológica en las diferentes instalaciones, previa realización de un Censo Nacional de todos los equipos generadores de radiaciones ionizantes distribuidos en todo el territorio Nacional, teniendo así:

- Instalaciones dependientes del Ministerio de Salud Publica y Bienestar Social (Hosp. Regionales y Centros de Salud).....85
- Instalaciones de Docencia e Investig.....19
- Instalaciones Privadas 183
- Instalaciones del Seguro Social 69
- Instalaciones de las Fuerzas Armadas 32

T O T A L E S **388**

Población nacional 5.123.550.

Región Occidental 97.208 Habitantes
Area 246.925 Km^2

Región Oriental 5.026.342 Habitantes
Area 159.827 Km^2

1.2 AREA del país 406.752 km
1.3 N° estimado de TOE. Total País =550 (Tegnólogo=500 Radiólogo= 50)
1.4 Registro de las Instalaciones de Radiología diagnostica:

3. Protección de los pacientes en radiodiagnostico

En lo que respecta a la forma como se realicen los examenes, esta generalizado el concepto que los Programas de Garantía de Calidad dirigidos al equipo y al funcionamiento del operador pueden contribuir en gran medida a que mejore el contenido de la información de diagnostico, a que se reduzcan la exposición a las radiaciones y a los costos médicos y que se mejore la administración del servicio.

Como respuesta a esta necesidad, muy en especial en lo referente a la protección del paciente el Departamento de Radio protección, puso en practica un programa de evaluación del desempeño de los equipos, exigiendo a cada Instalación tener un programa de Garantía de Calidad en la esfera de la radiología diagnostica.

Paraguay cuenta en la actualidad con mas de 400 equipos de Rx diseminados por todo su territorio, un numero reducido de especialistas dedicados al radiodiagnóstico y un gran numero de tecnólogos en dicha área, sin embargo en lo que se refiere a la implementación de

programas de garantía de calidad, la situación no es la mejor, debido a varios factores que juegan un papel fundamental para la practica de dichos programas:

- Servicios sin equipos de medición, debido al alto costo de los mismos.
- Falta de profesionales con capacidad para llevar a cabo estas tareas.
- Falta de concientización en la cultura de calidad y seguridad radiológica.

4. Implementación del programa de garantia de calidad

Debido a la importancia de la protección radiológica para el paciente, que tienen los programas de Garantía de Calidad en la practica de radiodiagnóstico, el Departamento de Protección Radiológica, lleva adelante la ejecución de programas de Control de Calidad, en las diferentes instalaciones controladas, puesto que las estadísticas señalan que el mal funcionamiento del equipo contribuye en medida considerable a la elevada prevalencia de mala CALIDAD de la imagen, especialmente aquellas tomadas con equipos portátiles, los cuales existen en mayor porcentaje en nuestro país.

El Programa de Garantía de Calidad que aprobamos para su implementación en los diferentes servicios tiene como objetivo vigilar cada una de las fases del funcionamiento de la instalación del equipo de diagnostico por imagen, comenzando por la solicitud de una exploración y terminando por la interpretación del examen y la comunicación de esa interpretación al medico que envía al paciente.

La responsabilidad fundamental del programa de Garantía de Calidad de todo Servicio de Diagnostico por Imágenes recae sobre el medico licenciado para explotar el servicio.

Las autoridades reguladoras cuentan con un programa de inspección para todo el año 2001, que comprenderá a la gran mayoría de los servicios detallados más arriba.

Otra acción es la edición de cuadernos con las recomendaciones básicas para el cuidado de paciente sometido a medicina nuclear, radiodiagnóstico y/o radioterapia que será distribuida en los servicios de diagnostico y tratamiento tanto en el área estatal como en servicios de practica privadas.

Se emitieron precisas instrucciones a los poseedores de licencia para trabajar con radiaciones ionizantes, que deberán tener señalizado con símbolos internacionales los lugares de sus servicios donde se encuentran los equipos o fuentes para que los pacientes que se encuentran en sala de espera se encuentren conciente de que deberían tener el cuidado de no exponerse innecesariamente a los efectos de las radiaciones.

5. Conclusión

1. Se esta implementando el Programa de Control de Calidad en equipos de Rayos X, sobre la base de las recomendaciones Internacionales en este campo. En términos generales podemos afirmar, según las recomendaciones de AGENCIAS INTERNACIONALES que se establecen dos tipos de estudios:

    - **INSPECCIONES BASICAS**: estas se refieren a las que se realizan para la puesta en operación del servicio. Son las mas profundas de las inspecciones y sirven como parámetros de control de las sucesivas, constatando con esto que las características

ofertadas por el fabricante se cumplen en la realidad, y cuando las INSPECCIONES SISTEMATICAS señalen alguna desviación en el funcionamiento.

- **INSPECCIONES SISTEMATICAS**: se realizan comprobaciones sencillas y rápidas dando seguridad de que todo el Servicio sigue funcionando bien.

2. Sé esta diseñando un programa que apunta a diagnosticar la CALIDAD de los **RECURSOS HUMANOS** que se desempeñan en las diferentes instituciones asistenciales, en sus diferentes modalidades de gestión, abarcando al profesional técnico y administrativo, conllevando con esto a la adecuación de dichos recursos con los perfiles organizativos de la institución asistencial y niveles de formación, capacitación, perfeccionamiento y actualización para el desempeño de la tarea, con referencia a patrones establecidos por Asociaciones académico - científica de cada especialidad.

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RADIATION PROTECTION INFRASTRUCTURE IN THE REPUBLIC OFCROATIA

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Ministry of Health of Croatia, Croatia

Abstract

According to present legislation the organization structure of radiation protection in the Republic of Croatia is similar to the organizational structure of radiation protection in the Republic of Croatia is similar to the organizational structure in many countries of the world. Regulator (competent) authority for the safe, traffic, purchase, import and transport of the radioactive sources is the Ministry of Health of the Republic of Croatia. Ministry of Health of the Republic of Croatia is also responsible for the health of workers who work with the radioactive sources in medicine and in industry, as well for the health of patients and members of public. Furthermore, Ministry of health is also responsible for the follow-up of radioactivity in the human environment (air, soil, water - sea, lakes, rivers) and radioactive waste management. To be able to accomplish those tasks, Ministry of Health developed two institutes, Croatian Institute for Radiation Protection and Croatian Institute for Occupational Medicine. For technical assistance and support Ministry of Health authorized three expert institutions.

1. Introduction

According to new legislation of the Republic of Croatia the organizational structure of radiation protection is similar to the organizational structure in many countries of the world. Regulatory (competent) authority for the safe use, traffic, purchase, import and transport of the radioactive sources is the Ministry of Health of the Republic of Croatia.

Ministry of Health of the Republic of Croatia is also responsible for the health of workers who work with radioactive sources in medicine and in industry, aswell for the health of patients and members of public.

Furthermore, Ministry of Health is responsible for the follow-up of radioactivity in the human environment aswell (air, soil, water – sea, lakes, rivers) and, last but not least, radioactive waste management.

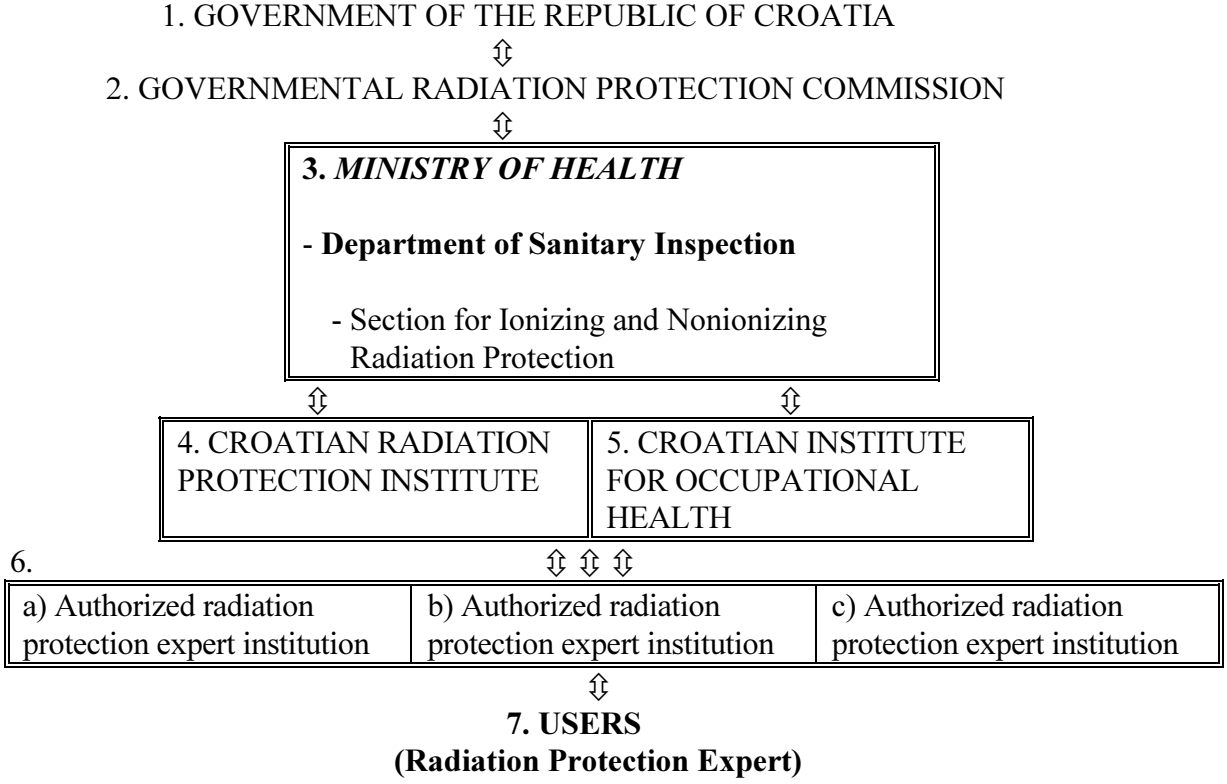
To be able to accomplish those tasks, Ministry of Health developed two institutes, Croatian Institute for Radiation Protection and Croatian Institute for Occupational Medicine. For technical assistance and support Ministry of Health has authorise three expert institutions.

Legislation which covers this field is as follows:

1. Sanitary Inspection Act (“Official Gazette” No. 27/99)
2. The Act on the Organization and Responsibilities of Ministries and other Governmental Bodies (“Official Gazette” No. 55/92 and 92/96)
3. Ionizing Radiation Protection Act (“Official Gazette” No. 27/99).
4. The Act on Health Protection (“Official Gazette” No. 75/93, 1/97).

Like in most countries, with the exception of undeveloped countries, the highest number of sources of ionizing radiation which are being used in Croatia is in medicine, over 70%. Most frequent users of those sources in medicine are X-ray departments. But, I would like to stress here that nuclear medicine is the most specific field of use of open radioactive sources, especially regarding radiation protection and decontamination measures and problems.

2. Organisational infrastructure of radiation protection in the Republic of Croatia



Ad 2. Governmental radiation protection commission was established by the Governmental decision ("Official Gazette" No. 16/95). It's role is to be a link between Government and lower institutions. It has 9 members and it's president is minister of health.

Ad 3. Ionizing radiation protection in the Republic of Croatia which is being performed in *Section for Ionizing and Nonionizing Radiation Protection* of the **Department of Sanitary Inspection** of Ministry of Health relates to following procedures:

1. INSPECTION

2. ADMINISTRATIVE MEASURES

- official decision for improoving measures of radiation protection
- prohibition of work with the radioactive sources to workers whose health surveillance analyses showed abberations
- approvals for trafficking of sources (purchase, use, transport)
- keeping records of all users, sources and workers with radioactive sources

3. ENFORCEMENT (PROSECUTION)

Ad. 4. According to The Act on Health Protection ("Official Gazette" No. 75/93, 1/97) minister of health brought up The decision on establishing Croatian Radiation Protection Institute ("Official Gazette" No. 51/97). This institute is performing all expert works in the field of radiation protection, especially record keeping of all parameters needed to have good radiation protection.

Ad. 5. According to the same Act on Health Protection Government of the Republic of brought up The decision on establishing Croatian Occupational Health Institute ("Official Gazette" No. 10/96). It is not necessary to stress of how big importance for radiation protection is the health protection of workers with radioactive sources.

Health surveillance of workers with radioactive sources is still being performed according to old legislation. Namely, new croatian **Ionizing Radiation Protection Act ("Official Gazette" No. 27/99)** will be in force when it's all regulations will be made and among them is also the one about health surveillance of workers with radioactive sources.

Ministry of Health is improoving every day co-operation with those two institutes. It is of great importance to establish better co-operation of Croatian Occupational Health Institute with the network of 21 authorized units of occupational health throughout Croatia. Next transparency shows those units:

CITY	*OCCUPATIONAL HEALTH UNIT*
1. *ÈAKOVEC*	2 PRIVATE OCCUPATIONAL HEALTH UNITS
2. *DUBROVNIK*	PUBLIC HEALTH SERVICE
3. *KARLOVAC*	PRIVATE OCCUPATIONAL HEALTH UNIT
4. *KOPRIVNICA*	PUBLIC HEALTH SERVICE
5. *LABIN*	PRIVATE OCCUPATIONAL HEALTH UNIT
6. *NAŠICE*	PUBLIC HEALTH SERVICE
7. *OGULIN*	PRIVATE OCCUPATIONAL HEALTH UNIT
8. *OSIJEK*	PRIVATE OCCUPATIONAL HEALTH UNIT
9. *PULA*	PRIVATE OCCUPATIONAL HEALTH UNIT
10. *RIJEKA*	- PUBLIC HEALTH SERVICE - PRIVATE OCCUPATIONAL HEALTH UNIT
11. *SLAVONSKI BROD*	PRIVATE OCCUPATIONAL HEALTH UNIT
12. *SPLIT*	- INSTITUTE FOR PUBLIC HEALTH - PRIVATE OCCUPATIONAL HEALTH UNIT
13. *ŠIBENIK*	PUBLIC HEALTH SERVICE
14. *VALPOVO*	PUBLIC HEALTH SERVICE
15. *VARAŽDIN*	PRIVATE OCCUPATIONAL HEALTH UNIT
16. *VINKOVCI*	PUBLIC HEALTH SERVICE
17. *ZADAR*	PUBLIC HEALTH SERVICE
18. *ZAGREB*	- INSTITUTE FOR MEDICAL RESEARCH AND OCCUPATIONAL HEALTH - INSTITUTE FOR PUBLIC HEALTH OF CITY OF ZAGREB - HEALTH SERVICE OF MINISTRY OF INTERIOR

Ad 6. Authorized radiation protection expert institutions are authorized by special decisions published in "Official Gazette":

1. ***EKOTEH Dosimetry Ltd.*, ("Official Gazette" No. 34/00)**

2. ***INSTITUTE FOR MEDICAL RESEARCH AND OCCUPATIONAL HEALTH*** **("Official Gazette" No. 100/00)**

3. ***"RUÐER BOŠKOVIÆ" INSTITUTE*** **("Official Gazette" No. 10/91)**

They have contracts with users of radioactive sources wich are obligated to perform measures of radiation protection. They make investigations of every source of ionizing radiation in medicine and industry. They also provide dosimetric surveillance of workers with radioactive sources.

Expert institutions must give to the Ministry of Health their report about every investigation of every source they provide and also about their work yearly.

3. An overview of The Ionizing Radiation Protection Law

The Ionizing Radiation Protection Act was adopted by Croatian Parliament in March 1999. It was published in Official Gazzete No. 27/99 on March 19, 1999. and enetred in to force on March 27, 1999. The provisions of the Law were postponed 6 months for preparing 10 regulations with detailed elaboration of some provisions which had to accompany the Law. The Law on september 28, 1999. entered fully into force and regulations which have been prepared are in print and would be issued during 2000.

The Law consists of ten chapters divided into 54 articles with paragraphs: general, provisions, principles of radiation protection, requirements for the practices, exposures, sources, emergencies, radioactive waste, supervision and authorities including the establishment the Croatian Institute for Radiation Protection and the Commission for adiation Protection, penalties for ofences of the provisions, transitional and final provisions.

The basic principles of the Law are the same as in international recommendations (ICRP 60): justification of practices, optimization of protection and safety and limitation of individual doses and are explicitly formulated as the provisions of the Law. According to the Law authorisation for all practices with ionizing radiations is mandatory except for excluded or exempted sources of ionizing radiation. The conditions and procedure for authorization are also formulated in the Law. The principles for exemption are formulated on the basese as defined in the BSS of IAEA.

End user or owner of ionizing radiation sources has primary responsability for implementation of prescribed measures and he has to obtain the authorization for conducting certain practice.

The import of radioactive waste in Republic of Croatia is explicitly forbidden.

Ministry of Health is The Competent Authority for radiation protection in Republic of Croatia. Because of the more effective providing of radiation protection in Croatia pursuant to The Law on Health Care it has been founded The Croatian Institute for Radiation Protection (CRPI) as a medical institute for providing scientific investigations and expertise in the field of radiation protection and for keeping and maintaining records on the sources, users and workers. Also by this Law it is considered that legal persons designated by Minister of Health would perform certain tasks according to special approval if they meet prescribed conditions. These tasks are:

1. monitoring of the level of exposure and radioactivity in environment,
2. personnel dozimetry service, evaluation of patient exposures and exposure of public
3. assessment of compliance with prescribed regulations of the sources of ionizing radiation prior their commissioning for the purpose of granting the authorization for certain practice,

4. surveillance of working conditions and radiation protection measures related to practices involving sources of ionizing radiations as well as surveillance of contamination and levels of exposure to ionizing radiations of workers,
5. the periodic monitoring of exposure levels at approved intervals and contaminations of objects, rooms and atmosphere inside premises where sources of ionizing radiation are being operated
6. radioactive waste management,
7. occasional checking of the suitability of the measuring instruments and protective devices
8. and other tasks according to approval.

Supervision and enforcement of the safety measures provide the sanitary inspection department of Ministry of Health pursuant to The Law on Sanitary Inspection and according to this law.

Minister of Health has to bring 10 regulations for detailed elaborations of the various provisions stipulated by the Law which has to ease the implementations of the Law. These are:

1. Regulations on the exposure limits, on the conditions of exposure for special purposes and on the intervention levels;
2. Regulations on the conditions and measures for the ionizing radiation protection for conducting practices involving x-ray units, accelerators and other devices generating ionizing radiation;
3. Regulations on the conditions and measures for the ionizing radiation protection for conducting practices involving radioactive substances;
4. Regulations on the conditions and ways of obtaining the professional skills as a precondition for work with the sources of ionizing radiation;
5. Regulations on the health conditions, criteria, content, methods and intervals of maintaining of the records about health surveillance of persons who work with sources of ionizing radiation;
6. Regulations on radioactive waste management;
7. Regulations on the conditions, methods, premises and intervals of systematic environmental radiological monitoring;
8. Regulations on the patients ionizing radiation protection in medicine and stomatology;
9. Regulations on the methods and intervals of the surveillance of the sources of ionizing radiations, personnel monitoring, monitoring of exposure of the patients, on maintaining records and registars and on reporting;
10. Regulations on the conditions for authorization of legal persons to provide specific expert duties in the field of ionizing radiation protection.

The Goverment of Republic of Croatia is authorised to bring: "The National Plan and Programme of Ionizing Radiation Protection in the Case of Emergency" which has to elaborate systematically whole infrastructure to meet any accidental case involving radioactive sources and nuclear accident as well.

The nuclear safety issues are out of the scope of this law.

IAEA-CN-85-40

MEDICAL MANAGEMENT OF RADIATION SAFETY AND RADIOLOGICAL PROTECTION OF PATIENTS IN ARMENIA

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Abstract

The events of the last 10 years, Spitak earthquake (1988) and collapse of the Former Soviet Union brought forth the changes of the political situation in Armenia and significant disorder in economy, industry, relations, environmental and public health, including the radiation safety (RS) and control of patients in general diagnostic radiology. In Armenia there are about 750 X-ray rooms, 10 radionuclide diagnostic laboratories, 20 gamma and X-ray units. 95 enterprises in industry, science and technology use the Ionizing Radiation Sources (IRSs) with different purposes; there are 5 electron particle accelerators of different power capacity. About 6,000 individuals have constant contact to IRS: the roentgenologists, radiologists, the staff of Armenian Nuclear Power Plant and that of the accelerators, etc. Besides, more than 3,000 liquidators of the Chernobyl NPP disaster live in Armenia. Nowadays, the precise infrastructure of RS is established in Armenia. The regulating body is the "State Atom Authority", performing the control, coordination and licensing of both enterprises and specialists. Ministry of Health, Ministry of Internal Affairs, and Ministry of Ecology perform the control of IRSs' delivery into the Republic of Armenia and then their proper use and waste disposal in Armenia.

1. Manuscript

In Armenia the integration of radioactive technologies into science, engineering and medicine (for the purposes of diagnostic radiology and radiotherapy) began in 1960s, in parallel to the progress of the above-mentioned branches of the former USSR. The RS, monitoring and control over the works performed with the use of IRSs were exercised and centralized by the bodies of Sanitary Epidemiological Supervision on RS monitoring of the former USSR.

In 1976 the Armenian Nuclear Power Plant (WEP-440 type) was constructed. Reactor I was started up in 1976 and Reactor II - in 1980. In 1989 the NPP was shut down after the disastrous Spitak earthquake. Due to the energy crisis in Armenia it was restarted to supply power in 1994.

There are some 750 X-ray rooms, 10 radionuclide diagnostic laboratories, 20 gamma and X-ray units in Armenia. 95 enterprises of industry, science and technology use the IRSs for various purposes. There are 5 electron particle accelerators of different power capacity. However, during the past few years no radionuclide researches are carried out, the number of X-ray rooms decreased due to the critical economic situation in our country.

In Armenia about 6,000 individuals have constant contact to IRSs: roentgenologists, radiologists, the staff of NPP, the accelerators, etc. Besides, more than 3,000 residents of the Republic responded to the liquidation of Chernobyl NPP disaster and are on a register for prophylactic medical follow-up at the Research Center of Radiation Medicine and Burns (RCRM&B). The entire infrastructure of RS is created in Armenia. The regulation body in this concern is the "State Atom Authority" supervising the execution, coordination and licensing the enterprises and specialists.

Much attention is devoted to radiation safety at Armenian NPP, performed by self dependent department of RS immediately at the NPP.

Much prominence in ensuring the RS belongs to Ministry of Health, the regulating control is provided by its Department of Hygiene and Epidemiological Supervision in concern of radiation situation and licensing of specialists in the system of Public Health. The safety of IRSs at the enterprises, their transportation and wastes disposal, permissions for the receipt, storage and rights to perform activity are conferred and controlled jointly with Ministry of Internal Affairs. All the dosimetric and radiometric researches are carried out by the department of RS of the Center.

Both the Environmental Control and Monitoring of radiation background are performed by the appropriate subdivision in the structure of Ministry of Ecology and Hydrometeorology. The management of medical assistance in a case of radiation emergencies is carried out by RCRM&B.

Nowadays, as a WHO Collaborating Center, RCRM&B performs the following activities:
1. serves as a basic/focal point for medical care in cases of human radiation injuries;
2. carries out training of specialized staff in radiation medicine, radiation hygiene and radiobiology;
3. performs the development and planning of all the measures on medical assistance in the event of radiation accidents;
4. coordinates researches on radiation medicine and radiobiology;
5. develops plans and normative relevant documentation.

In case of an accident the RCRM&B is prepared to:
- promote the team for on-site first aid to the emergency victims;
- promote the dosimeter control group to study the radiation contamination level of the area;
- perform the arrangement ("assortment") and transportation of those injured (radiation contamination accident victims);
- carry out the diagnosis and treatment:
  a) by means of biodosimetry (bioassay),
  b) by means of radiometry with the use of whole body counter;
- render specialized medical aid to wounded and injured persons.

In practice the RCRM&B functions as an All-Armenian Center on diagnostics and treatment of general and local radiation injuries, RS and population protection. The RCRM&B is constantly preoccupied by elaboration and improvement of methods of prophylaxis, diagnostics and therapy of radiation injuries, as well as bioindication. Great importance is given to the studies of the impact of low dose radiation action.

Taking into account all the above-mentioned, in 1995 the Department of burns was created at the RCRM&B, functioning now as a Center of Burns (CB). It would also promote assistance in a case of a radiation accident. Now the CB admits patients not only from all the districts of Armenia, but from other countries of the region as well.

Nowadays, with the assistance of IAEA a number of Projects are performed at the RCRM&B with the assistance of IAEA on RS, radiation medicine and Training Programmes.

IAEA-CN-85-148

CONTRIBUTION OF THE ARCAL XX/IAEA PROJECT TO IMPROVEMENT OF RADIATION SAFETY IN MEDICAL PRACTICES

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Abstract

The objectives of the ARCAL XX Project: "Guidelines on Control of Radiation Sources" (1997-2000) are to promote an effective control of the radiation sources used in medicine, industrial and research applications, harmonising and updating existing procedures within Latin American, adopting the International Basic Safety Standards, in order to avoid unnecessary expositions limiting the probability of accidents occurrence. Nine countries participate with experts in the development of guidelines based in the regional experience. The guidelines content Radiological Safety Requirements, Guide for Authorisation Application and Inspections Procedures. In this moment, there are guidelines in Radiotherapy, Nuclear Medicine and Diagnostic Radiology. The implementation of these guidelines will improve the effectiveness of regulatory control of radiation sources in Latin American and the radiological protection in aspects of occupational, medical, public and potential exposure. This document presents the experience in the development of these guidelines and their contribution for elaborating national regulations in the medical practices.

Resumen

Los objetivos del Proyecto ARCAL XX: "Directrices para el control de Fuentes de Radiación" (1997-2000) son promover un efectivo control de las fuentes de radiación usadas en medicina, industria e investigación, harmonización y actualización de procedimientos existentes dentro de América Latina, adoptando las Normas Básicas Internacionales de Seguridad a fin de evitar exposiciones innecesarias limitando la probabilidad de ocurrencia de accidentes. Nueve países participan con expertos en el desarrollo de directrices basadas en la experiencia regional. Las directrices contienen Requisitos de Seguridad Radiológica, Guía para solicitar Autorizaciones y Procedimientos de Inspección. En este momento hay directrices en Radioterapia, Medicina Nuclear y Radiología Diagnóstica. La implementación de estas directrices mejorará la efectividad del control regulatorio de las fuentes de radiación en América Latina y la protección radiológica en aspectos de exposición ocupacional, médica, pública y potencial. Este documento presenta la experiencia en el desarrollo de estas directrices y su contribución para la elaboración de regulaciones nacionales en las prácticas médicas.

1. Introducción

En 1985, debido a la inquietud de los países del Grupo Andino: Bolivia, Colombia, Ecuador, Perú y Venezuela se da inicio a las actividades de cooperación técnica en materia nuclear en el marco del Programa ARCAL (Acuerdo Regional de Cooperación para la Promoción de la Ciencia y Tecnología Nucleares en América Latina y el Caribe, como se denomina actualmente), con la participación inicial de 10 países de la región.

El Programa ARCAL fue concebido desde sus inicios como un primer paso en el camino de la promoción de la cooperación regional en el uso pacífico de la energía nuclear, en particular de las aplicaciones nucleares, y sobre esta base, lograr una integración regional que permitiese resolver problemas tecnológicos comunes a los países de la región.

Un importante Proyecto fue el de "Protección Radiológica" (ARCAL I), el cual se llevo a cabo entre 1985 y 1993. Aquí se determinaron las necesidades inmediatas de protección radiológica en la región y se mejoró, en parte, las condiciones de protección radiológica existentes en las instalaciones, adicionalmente se desarrollaron actividades regulatorias.

Los Coordinadores del Proyecto ARCAL I diseñaron los siguientes 2 Proyectos que serían una continuación de éste. Tal es así que se desarrolla el Proyecto ARCAL XVII (1994–1996)

denominado “Estructura Normativa y Organización Regulatoria”, con el objetivo de promover la adopción de una norma básica de protección radiológica desarrollada sobre la base de las ultimas recomendaciones internacionales en el tema y promover el desarrollo de estructuras regulatorias que permitan cumplir las funciones esenciales de su misión.

Desde 1997 y por un período de 4 años se desarrolla el Proyecto ARCAL XX: “Directrices para el Control de Fuentes de Radiación” con el objetivo de promover un desarrollo armónico en la región a fin de garantizar un efectivo control de las fuentes de radiación para evitar exposiciones innecesarias y limitar las posibilidades de accidentes, adoptando las nuevas orientaciones de las Normas Básicas Internacionales de Seguridad. [1]

2. El proyecto ARCAL y los resultados esperados

A diferencia de los anteriores Proyectos, en ARCAL XX solamente participan los países que cuentan con la infraestructura básica necesaria para llevar a cabo el control de fuentes de radiación, tal como: Autoridad Competente establecida, Reglamentos y Normativas básicas, Inventario de Fuentes de Radiación, Programa de Licenciamiento e Inspección de instalaciones, Programa de Emergencias Radiológicas, Servicios esenciales en Protección Radiológica (monitoreo ambiental, dosimetría personal y ocupacional, etc.) y Actividades de Capacitación en Seguridad Radiológica. Estos países son: Argentina, Brasil, Chile, Cuba, Ecuador, México, Perú, Uruguay y Venezuela.

Los resultados esperados para el cumplimiento del objetivo principal del Proyecto son:
a) Evaluación de la eficacia de los sistemas regulatorios,
b) Armonización y actualización de criterios de autorización e inspección en aplicaciones médicas, industriales y de investigación,
c) Difusión de información sobre seguridad radiológica.

A partir de ello se obtendrá lo siguiente:

a) Evaluación de los Sistemas de Control de Fuentes de Radiación Ionizante a través de Indicadores de Desempeño,
b) Elaboración de “Guías Reguladoras de Seguridad Radiológica”, las cuales contendrán:
   i) Requisitos de Seguridad Radiológica
   ii) Guía para Solicitar Autorización
   iii) Procedimiento para la Realización de Inspecciones
c) Divulgación en INTERNET de las actividades más importantes realizadas en el marco de ARCAL y del Organismo Internacional de Energía Atómica en el campo de la Protección Radiológica en la región,
d) Publicación del Boletín ARCAL sobre Protección Radiológica.[2]

3. Actividades realizadas

A fin de planificar y evaluar las actividades de ARCAL se establecieron las Reuniones de Coordinadores de Proyecto, las cuales se han llevado a cabo en Caracas, Venezuela (1997), Goiania, Brasil (1997), La Habana, Cuba (1998) y Bariloche, Argentina (1999), hasta el momento.

El mecanismo establecido permitió que cada país se encargue, por lo menos, de coordinar una actividad. Para elaborar los documentos, los expertos de un país elaboraron un primer

borrador tomando en cuenta su experiencia en el tema y los aportes de los demás países. Posteriormente este documento es remitido a todos los países para opinión y en reuniones de expertos del mismo tema se concluye una versión que es nuevamente remitida a los países. Seguidamente un Comité de Revisión se encarga de revisar la redacción de los documentos y homogeneizar el rigor técnico y los términos empleados. Este Comité está integrado por los Coordinadores de Proyecto de Argentina, Cuba, México, Perú y Venezuela. Finalmente el documento es sometido a aprobación en la Reunión de Coordinadores de Proyecto.

De esta forma se han elaborado los siguientes documentos:

I. Instrucciones para la elaboración de documentos
II. Manual del Inspector
III. Evaluación de los Sistemas de Control de Fuentes de Radiación a través de Indicadores de Desempeño
IV. Guía práctica para la rápida identificación de fuentes radiactivas y equipos que las contienen
V. Guías Reguladoras de Seguridad Radiológica para las prácticas de:
   a) Radiografía Industrial
   b) Radioterapia
   c) Medicina Nuclear
   d) Radiodiagnóstico Médico
   e) Irradiación Gamma
   f) Prospección Petrolera
   g) Aplicaciones Industriales de Fuentes no Selladas

Otras actividades desarrolladas son la página Web del Proyecto: www.arcalxx.org.pe y la edición del Boletín ARCAL "Protección Radiológica", el cual se edita desde 1991 y hasta la fecha se han distribuido 61000 ejemplares a mas de 40 países en forma gratuita.

Las referencias [2][3][4] contienen el detalle de las actividades programadas y los expertos y el apoyo logístico interno proporcionado por los países y el OIEA para llevar a cabo dichas actividades.

4. Documentos para las prácticas médicas

Las Guías Reguladoras de Seguridad Radiológica para las prácticas de Radioterapia (Teleterapia y Braquiterapia), Medicina Nuclear y Radiodiagnóstico Médico han sido preparadas por separado. Estas a su vez contienen los siguientes documentos:

I. **Requisitos de Seguridad Radiológica**.- Aquí se establecen los aspectos técnicos que se deben cumplir en cada práctica, como son:
   a) Requisitos Administrativos: Autorización Institucional, Autorizaciones y Acreditaciones Personales, Entidades de Servicio, Renovación de Autorizaciones, Suspensión o revocación de Autorizaciones, Cese en el uso de fuentes de radiación ionizante, Comercialización e importación de fuentes de radiación ionizante.
   b) Requisitos de Protección Radiológica
   c) Requisitos de dirección y organización: Personal y capacitación.
   d) Seguridad radiológica de las instalaciones: Requisitos de diseño de fuentes y/o equipos, Diseño de ambientes del Servicio, Requisitos operacionales.

e) Exposición Ocupacional: Responsabilidades y condiciones de servicio, Clasificación de zonas de trabajo, Dosimetría personal, Vigilancia radiológica de las zonas de trabajo, Dispositivos de protección radiológica, Investigación y seguimiento. Registros.
f) Exposición Médica: Responsabilidades, Justificación, Optimización, Calibración, Dosimetría Clínica y Garantía de Calidad, Investigación en exposiciones médicas accidentales y Registros.
g) Exposición del público: Responsabilidades, Control de visitantes y Vigilancia radiológica de la exposición del público.
h) Exposición potencial.

Adicionalmente se prepararon Anexos sobre: Dotación y Requisitos de personal, Contenido Típico de un Programa del Curso de Seguridad Radiológica, Responsabilidades del Personal, Contenido de un Programa Típico de Seguridad Radiológica y Garantía de Calidad, Comité de Seguridad Radiológica y Garantía de Calidad, Contenido de un Informe de Levantamiento Radiométrico, Niveles Orientativos, Control de Calidad: pruebas mínimas, frecuencia y requisitos de desempeño.

II. **Guía para Solicitar Autorización**.- Aquí se detallan los aspectos técnicos y procedimiento a seguir por los usuarios de radiación ionizante ante la Autoridad Reguladora para obtener las Autorizaciones Personales o Institucionales (construcción u operación). También se establece el procedimiento a seguir por las Entidades de Servicio y cuando cesa la operación de una instalación.

III. **Procedimiento para la realización de Inspecciones**.- Se presentan las listas de chequeo que deben ser utilizada por el Inspector de la Autoridad Reguladora. Hay listas de chequeo para cada práctica y a su vez para las diferentes modalidades, por ejemplo se ha preparado listas de chequeo en Radiodiagnóstico Médico para Radiografía Convencional, Mamografía, Fluoroscopia y Tomografía Computarizada, incluyéndose la Radiología Intervensionista.
Las Guía Reguladoras contienen también: Introducción, Glosario, Referencias y Lista de Participantes. Los demás documentos son también de gran utilidad para estas prácticas. Por ejemplo, la Guía para una rápida identificación de fuentes radiactivas y equipos que las contienen será utilizada cuando se presenten emergencias, ya que mediante este documento se puede identificar de que fuente y/o equipo se trata, y se podrá conocer sus características principales a fin de facilitar la labor de recuperación.

5. Importancia del proyecto

Los documentos elaborados en el Proyecto están permitiendo actualizar los procedimientos y en especial las Normas de las Autoridades Reguladoras ya que éstos son tomados como referencia principal. Adicionalmente se ha tomado en cuenta los documentos que se vienen elaborando en el OIEA e inclusive algunos expertos de la región participan en la elaboración de éstos documentos. Por otra parte, los documentos de ARCAL han sido presentados a otros Proyectos Regionales (AFRA y RCA) como un ejemplo a seguir.

Estos documentos están permitiendo un mejoramiento de las condiciones de seguridad radiológica de las prácticas y en especial se está abordando el tema de las exposiciones médicas con lo cual se logra proteger al paciente adecuadamente. Adicionalmente, se ha tomado en cuenta la experiencia de los países y se está logrando un consenso en su aplicación

debido a las características de la región en donde se comparte, además del idioma, muchas características comunes.
Se espera capacitar a personal de las Autoridades Reguladoras de la región mediante cursos y entrenamientos en otro Proyecto que será consecuencia de ARCAL XX.

Referencias

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IMPLEMENTATION OF ICRP-60, BBS-115 AND THE PATIENT DIRECTIVES IN RADIATION SAFETY REGULATIONS OF TAEK

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Abstract

The use of radiation sources offers a wide range of benefits throughout the world in medicine, research and industry. Precautions are, however, necessary in order to limit the exposure of persons to the radiation that is emitted. The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) were published as IAEA Safety Series No 115 in 1996. This publication marks the culmination of efforts that have continued over the past decades towards harmonization of radiation protection and safety standards internationally. The purpose of the Standards is to establish basic requirements for the protection against the risks associated with exposure to ionizing radiation and for the safety of radiation sources that may deliver such exposure. The Standards are based primarily on the recommendations of the ICRP which is a non-govermantal scientific organization to establish basic principles and recommendations for radiation protection; the most recent recommendations of the ICRP were issued in 1991. In 1997, the Council of the European Union published a new directive laying down the general principles of the radiation protection of individuals undergoing exposures to ionizing radiations related to medical exposures (Directive 97/43 Euratom). Directive 97/43 Euratom is a supplement on Directive 96/29 Euratom on the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiations. The European Directives 96/29-97/43 Euratom and BSS-115 constitute a complete and coherent set of regulatory measures on radiation protection. In Turkey, the infrastructure exists to account for ionizing radiation sources by, for example, a system of licensing, legislative requirements on the user to keep appropriate records and perhaps to report to the TAEK on a periodic basis or, in the case of imported items (including re-export procedures) and customs clearance procedures. The preamble to the Basic Safety Standards states that it is presumed in the Standards that Governments have an adequate national infrastructure in place in order to discharge their responsibilities for radiation protection and safety. In Turkey, the relevant national authority for regulating activities involving radioactive sources is the Turkish Atomic Energy Authority (TAEK). The structure of TAEK and its legislation will be introduced. Radiation Safety Regulation (Official Journal #: 20983) which was issued in 6 September 1991 was revised and issued in 24 March 2000 (Official Journal #: 23999). Revised version of the Radiation Safety Regulation based on BSS-115 and EC Directives include definitions, exemptions, responsibilisation, dose limits (significant decrease in the limits follows the recommendations of ICRP-60), redefinition of controlled and supervised areas, import and re-export procedures of radioactive materials, redefinition of licensing procedures, limitations in import radiation generators used in medicine, quality control, guidance levels of dose, dose rate and activity for medical exposures (including diagnostic radiological prosedures, diagnostic procedures in nuclear medicine), dose levels in interventions and guidelines for intervention levels and action levels in emergency exposure situations.

1. Structure

In Turkey, the authorization to determine the limits of responsibility for the principles and precautions and liability for protection against the hazardous effects of ionizing radiations have been given to Turkish Atomic Energy Authority with the Law numbered as 2690. It has been determined that govermental and private associations, organizations and persons who keep, use, import and export, tarnsport, store, make the commerce of radioactive materials and radiation generators must obtain license from the Authority in accordance with Radiation Safety Decree and Radiation Safety Regulation that have become effective in 1985 and 1991 respectively which have been prepared in accordance with, and with the order of this Law.

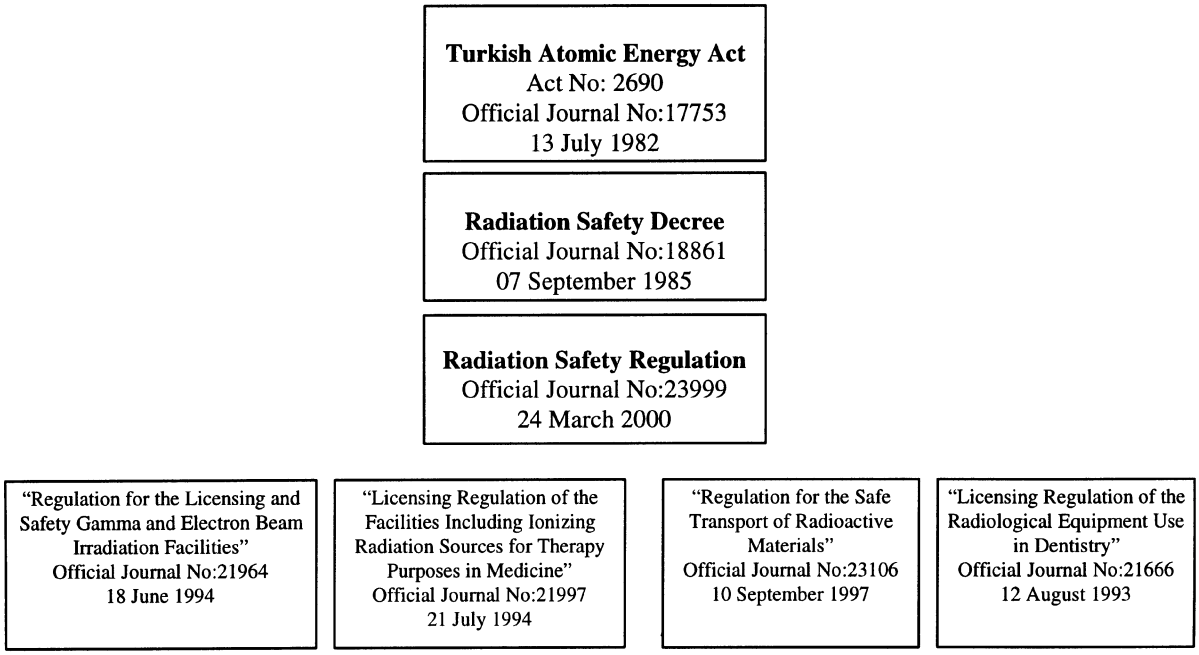
The requirements of license and permission have been described in the Decree and Regulation. In some other specific regulations that have been prepared in accordance with that Decree and Regulation, special conditions related to the area where the radiation sources are

being used are stated. The radiotherapy regulation prepared in this connection has put into force in 1994. This regulation covers the provisions in compliance with Basic Safety Series 115 (BSS 115) [1] criteria.The current legislation related with radiological safety of TAEK are shown below in figure 1.

By the adoption of above mentioned recommendations, procedures followed in the import, export and licensing of sealed radiation sources in accordance with the application of the regulation have been given below.

a) For the realization of the import procedures, it is necessary that the importing company must obtain license from the Authority. For being granted with this license, it is necessary that the responsible persons and the supplier company must be stated, the compliance certificate of those equipment and sources to be imported to ISO, IEC or equivalent national standards, catalogues and other necessary documents related to the company must be submitted. The authorization certificate from the supplier company that this company can perform these are required and in order to obtain the license for the installation, exchange and maintenance and repair of the sources, the information about the tarining and experience of the people that will perform these and their medical reports are also requested.
b) The company that has obtained the license to perform such works is also obliged to apply and get permission for each importation process. The permission is being granted after submission of the proforma invoice of the supplier company, production certificate of the source, serial number of the source, the data including the serial number of the equipment and source head or the container and the name of the custom that importation will be made from.
c) The clearence of the source from the custom is only being made possible after the issuance of transportation permit" which is being prepared as a result of the radiation control of the TAEK experts in the customs. The transport permit is only being granted according to the provisions of "Regulation for the Safe Transport of Radioactive Materials". While this permit is being granted; serial number of the source, emergency case plan, license plate number of the vehicle, name of the driver, personal dosimeter number, the radiation measurement equipment that has to be present in the vehicle is being controlled and the route of the vehicle is being determined.
d) Source exchange procedures is being supervised by the experts after the source reaches its destination.
e) It is necessary that a "LICENSE" must be obtained for the facility where the equipment be put into operation according to the provisions of "Licensing Regulation of the Facilities including Ionizing Radiation Sources for Therapy Purposes in Medicine". For being able to license such facilities; it is necessary that the building in which the source will be present must be granted with civil project approval from the radiation safety view, such facility must employ Radiotherapy Physicists and Radiation Protection Officer and must have all technical equipment that is required. "License" can only be granted to those facilities, after; necessary documents have been submitted the necessary conditions have been complied and quality compliance of the equipment have been approved by the authorized organizations after local measurements and investigations carried out by TAEK experts.
f) For the sending of the used sources to abroad, "Permit for sending abroad" must be obtained by the company licensed for such subject. This permit can only be granted after completion of the inspection at the point where the transportation will start from and following the grant of transportation permit.

FIGURE 1. CURRENT TURKISH ATOMIC ENERGY AUTHORITY LEGISLATION RELATED WITH RADIOLOGICAL SAFETY



In Turkey, a wide range of sources of ionising radiation are used in medicine, research and industry. These include X-ray equipment, sealed gauges containing radioactive materials which are used in industry and liquid radioactive materials used in medicine. While many uses of ionising radiation are clearly beneficial to society, there is an inherent risk associated with any such use.

The primary role TAEK is to ensure that these risks are kept to a minimum through its system of licensing and inspection. Turkish legislation prohibits the use of radioactive substances, irradiating apparatus and other sources of ionising radiation without an appropriate license.

2. Legislation

In general, Turkish legislation governing the use of ionising radiation is derived from European Directives which in turn are based on the recommendations of the International Commission on Radiological Protection (ICRP). The ICRP was established in 1928 and its recommendations, while not mandatory, are highly influential internationally. In 1977 the ICRP published general recommendations on the conceptual framework of radiation protection, based on the following three key principles:

1. **Justification** - the process of showing that a particular use of ionising radiation produces sufficient benefit to the exposed individuals or society to offset the radiation detriment it causes;

2. **Optimisation** - the process of keeping all exposures as low as reasonably achievable, economic and social factors being taken into account; and

3. **Dose limitation** - the process of keeping the sum total of all relevant doses received whether by workers or members of the public within specified limits.

The publication of these general recommendations, commonly referred to as ICRP 26, led directly to the adoption by the European Community in 1980 of **Directive 80/836/Euratom** (subsequently amended by **Directive 84/467/Euratom**). This Directive laid down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation and is commonly known as the Basic Safety Standards (BSS) Directive.

The provisions of the 1980 BSS Directive were implemented into Turkish Law by the **Radiation Safety Decree published in 1985 and Radiation Safety Regulation published in 1991.**

These two statutory instruments provide the framework for the TAEK's licensing system and detail the general radiation protection requirements for all users of ionising radiation. Particular uses of ionising radiation which are covered by additional legislation include dental exposure, radiotherapy regulation and shipment of radioactive substances**.**

As a result of a continual process of reappraisal, ICRP recognized during the 1980's that the risks of exposure to ionising radiation were greater than had previously been thought. ICRP published new general recommendations in 1991, known as **ICRP 60** [2], which updated the standards in ICRP 26 and further developed the conceptual framework.

In particular, ICRP 60 distinguishes between practices (activities that increase human exposure) and intervention (actions taken to decrease human exposure in an actual situation). Practices cover the uses of ionising radiation already referred to such as medical uses etc. An example of intervention is the actions taken to reduce exposure in the aftermath of an accident. The principles which apply to practices, where the risk of exposure can be controlled, are different to those applying to intervention. In the latter case, a balance has to be struck between risks arising from the existing exposure situation and the risks involved in intervention measures taken to reduce that exposure.

In 1996 the European Commission followed up the changed standards in ICRP 60 by adopting a revised BSS directive (**Directive 96/29/Euratom**). In Turkey, the implementation of the BSS Directive to the legislation result in the following changes [3];

- Use of the new ICRP concept of practices and intervention,
- Explicit treatment of natural radiation sources,
- Explicit treatment of “intervention” which includes emergency preparedness.

The revised Radiation Safety Regulation to implement the BSS Directive was published in 2000. Under the EURATOM Treaty, the European Community is required to establish uniform safety standards for radiation protection. This is done by means of the Basic Safety Standards Directives which establish safety standards to protect the health of workers and the general public against the dangers of ionising radiation. These directives form the basis for radiation protection legislation in all Member States.

The Directive does not apply to exposure to radon in homes, to naturally occurring radionuclides in the human body, to above ground exposure to radionuclides in the undisturbed earth’s crust or to cosmic radiation at ground level. A feature of the Directive is the flexibility given to Member States in its implementation. This can be illustrated by a few examples. Firstly, while the Directive includes a list of practices which must be subject to prior authorization, Member States have been given freedom to extend this list. This means

that, in Turkey, no major changes will need to be made to the current licensing system. Secondly, while the Directive lays down a limit on effective dose for exposed workers of 100 millisievert (mSv) over a period of 5 years, subject to a maximum dose of 50 mSv in any single year, Member States may decide on an annual limit. For members of the public, a dose limit of 1 mSv in one year is laid down. However, in special circumstances, a higher dose may be authorized in a single year, provided that the average over five consecutive years dose not exceed 1 mSv per year. This has already been given effect to in Turkish legislation, as annual dose limits of 20 mSv for workers and 1 millisievert (mSv) for members of the public were laid down in the revised Radiation Safety Regulation.

3. Conclusion

Finally, with regarded to work activities involving significant exposure to natural radiation sources, there is a good deal of flexibility but specific to be taken by Member States are laid down. These include the identification of work activities which may be of concern, estimation of exposure, implementation of countermeasures and, if required, the introduction of radiation protection procedures in workplaces.

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IAEA-CN-85-250

PROTECTION OF PATIENTS IN THE FIRST RADIOTHERAPY STANDARD IN PERU

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Abstract

The evolution of control measures on radiotherapy activities between 1980 and 2000 are reviewed. An increasing in the scope toward the patient protection was observed along these years. After approving the last main regulation on radiation safety the issuing of a specific rule for protection and radiation safety in radiotherapy with emphasis on the patient protection was needed. The proposed specific rules on radiotherapy were reviewed and discussed jointly with the radiotherapy users before approving, and modifications were made in order to reach consistency with the national situation. A summary comparison is made between some requisites as proposed at the beginning and as modified after discussions. Modification were made because the current social and economic conditions in the country and taking into consideration another reasons related to the medicine practice. It is suggested to make a revision of the rule and its results after a period of applying it.

1. Introducción

La radioterapia se aplica en el país desde hace más de 30 años, sin embargo el control sobre ella tiene menor tiempo. Las primeras medidas de control se refirieron básicamente a la protección ocupacional y muy poco sobre la protección del paciente, tal como se desprende del análisis de los resultados de entonces, ya que la regulación no copaba todos los aspectos necesarios.

Por ello, en la modificación de la regulación principal en 1997 se incluyó criterios generales en una sección de exposiciones médicas con fines de protección del paciente. El traslado de las disposiciones generales hacia especificaciones más detalladas se convierte en necesaria aunque genera dificultades en su cumplimiento, principalmente cuando estos tienen relación con condiciones sociales y económicas del país, añadido a ello cierta reticencia de los médicos a cumplir con recomendaciones no consideradas fundamentales.

Estos hechos han obligado a establecer una normativa de compromiso entre las partes involucradas en la seguridad de esta práctica, con requisitos ajustados a la realidad actual.

2. Antecedentes y evolucion de las medidas.

El control de fuentes en radioterapia se inició con la simple verificación de algunos sistemas de seguridad y dispositivos para la protección ocupacional, y algunos parámetros de control del haz, ya que las regulaciones vigentes entonces no incluían ninguna obligación sobre la protección del paciente. A pesar de esta deficiencia no se tiene registrado, o no se conoce, ningún evento accidental significativo que haya involucrado exposiciones anormales en pacientes, siendo el único de importancia un incidente de irradiación de un trabajador de mantenimiento.

Se ha realizado un análisis del alcance del control ejercido en las instalaciones de radioterapia existentes – teleterapia y braquiterapia – en los aspectos de protección ocupacional, verificación de equipos e instalaciones, protección del paciente, emergencias y protección del público, y durante los años 1980, 1990 y 2000. Los datos analizados corresponden a 10 unidades de cobaltoterapia, 4 aceleradores lineales, y 10 ambientes de braquiterapia, y se ha

evaluado el alcance de la verificación en cada aspecto seleccionado. Los resultados se muestran en la Tabla 1, observándose que la importancia por la protección del paciente se inició, prácticamente, a partir de 1990.

Tabla 1. Evolucion del control y verificación en radioterapia

ASPECTOS VERIFICADOS	ALCANCE DE LA VERIFICACION		
	1980	**1990**	**2000**
Protección ocupacional			
1. Dosimetría personal	100	100	100
2. Areas de trabajo	100	100	100
3. Niveles de radiación	100	100	100
4. Procedimientos	30	60	100
5. Calificación	10	80	100
Control de equipos, fuentes y ambientes			
6. Sistemas de seguridad	5	100	100
7. Pruebas de hermeticidad	100	100	100
8. Inventario y registro	100	100	100
9. Señales de advertencia y condición	100	100	100
10. Dispositivos mecánicos (colimación, escalas, distanciadores, etc.)	10	100	100
11. Características del haz y modificadores	0	10	100
12. Mantenimiento	0	0	50
Protección del paciente			
13. Calibración formal del haz	100	100	100
14. Dosimetría física	0	10	80
15. Presencia de físico médico	0	10	100
16. Entrenamiento de personal	0	0	50
17. Planificación	0	30	60
18. Chequeos redundantes	0	0	50
19. Procedimientos	0	0	80
20. Registros	0	0	100
21. Transmisión de comunicaciones	0	0	50
22. Investigación de accidentes	0	0	10
Emergencias			
23. Planes disponibles	10	60	100
24. Implementación y conocimiento del plan	0	0	50
Protección del público			
25. Disposición de fuentes en desuso	10	100	100
26. Control de visitantes y otros	10	50	100

3. Especificaciones de las normas

La regulación principal actualmente en vigor prescribe condiciones generales que debe cumplirse en las exposiciones médicas, con miras a proteger al paciente. Aunque estas son aplicables a cualquier práctica médica, no ha particularizado los requisitos aplicables a las diferentes aplicaciones médicas.

La primera estandarización en la práctica de radioterapia se emprendió a través de la preparación de dos normas específicas: una para teleterapia y otra para la braquiterapia.

En la preparación de las mismas se ha considerado la regulación principal, documentos elaborados en radioterapia por el proyecto ARCAL XX (Arreglos Regionales para la Cooperación en América Latina) y recomendaciones de organizaciones internacionales como el Organismo Internacional de Energía Atómica (OIEA), Asociación Americana de Físicos en Medicina (AAPM), Comisión Internacional de Protección Radiológica (CIPR), entre otros. Refs. [1 al 4].

Tabla 2. Comparacion de versiones

VERSIÓN PROPUESTA	VERSIÓN MODIFICADA
1. Equipos con más de 20 años de antigüedad se prohíben.	1. Cada 10 años se deben someter a revisión y examen total, con pruebas de puesta en servicio.
2. Fuentes de ^{226}Ra se retirarán el 31 de Julio del 2001.	2. Fuentes de ^{226}Ra continuarán usándose sujetos a exámenes y verificaciones más frecuentes.
3. Dotación mínima (reporte de Inter-Safety for Radiation Oncology)	3. Flexible para Radioncólogos, pero un mínimo para Físicos Médicos, operadores, oficial de radioprotección y dosimetrista.
4. Sistema de visión alternativo	4. Asegurar que sistema de visión esté siempre operativo en caso contrario no operar.
	5. Prescripción por Radioncólogo.
5. Prescripción por Médico Colegiado	6. Calibración basada en protocolos reconocidos
6. Calibración basada en TRS 277 OIEA.	7. Auditoría dosimétrica obligatoria, de ser posible con red OIEA/OMS
7. Intercomparación dosimétrica mediante red OIEA/OMS	8. Solo describir la relación del equipo de dosimetría clínica
8. Equipo de dosimetría clínica con detalles específicos	9. Solo debe registrarse descripción de volumen blanco, dosis administrada, dosis por fraccionamiento y fechas de administración.
9. Registros describiendo volumen blanco, dosis en el centro de volumen blanco, dosis máximas y mínimas a volumen blanco y otros órganos, fraccionamiento de dosis y tiempo total de tratamiento	

La norma considera requisitos para el diseño de equipos, fuentes e instalaciones, la seguridad operacional, la protección del paciente, el transporte, la gestión de fuentes gastadas, garantía de calidad y las emergencias. El proyecto de la norma inicialmente propuesta fue sometida a consulta entre profesionales involucrados en la práctica de radioterapia con el objetivo de alcanzar disposiciones que puedan aplicarse sin problemas.

Como apreciación general, se consideró necesario establecer disposiciones específicas para mejorar la calidad de la protección y seguridad en la radioterapia, pero también existieron

discrepancias respecto a muchos de los puntos citados en la norma. Una relación de las más significativas puede ser observado en la Tabla 2, en la que se indica la propuesta inicial y la modificación luego de las discusiones.
Las discrepancias se basaron en la dificultad de disponer de recursos para cumplir con todos los requisitos iniciales, ya que existen otras prioridades de atención médica, a considerar ciertos requisitos innecesarios y también que sean más flexibles en el modo de cumplirlas. Un punto importante fue la propuesta de eliminar o retirar fuentes o equipos considerados inseguros, pero que son difíciles de reemplazar en las actuales condiciones, lo cual causaría más daño – por el posible incremento de mortalidad o morbilidad debido a enfermedades no tratadas – en comparación con el riesgo que se evitaría o disminuiría. La solución ha sido establecer medidas compensatorias y de compromisos con los usuarios de las fuentes de radioterapia, consistente con acuerdos anteriormente alcanzados [Ref. 5].

4. Implementacion y recomendación

La norma tendrá un período de adaptación luego del cual se aplicará completamente. Esto significará una mejora en el control de los aspectos de protección al paciente y, por ende, la mejora real de su protección Por parte del ente regulador requerirá de un seguimiento más continuo para verificar su cumplimiento. Al cabo de un período razonable podría revisarse la norma en comparación con los resultados que se obtendrán de su aplicación.

La aprobación de una norma específica en las exposiciones médicas, no solo de radioterapia, debe ser realizada con bastante cuidado dado que se debe obtener una regulación lo suficientemente eficaz para la protección y seguridad pero sin que interfiera con la práctica médica. Se considera adecuado que, al no poder cumplir con aspectos de seguridad que están relacionados a la economía, es factible compensarlas con procedimientos y compromisos del usuario de manera que se logre un nivel apropiado de protección para los pacientes.

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IAEA-CN-85-60

THE JUSTIFICATION OF A MEDICAL EXPOSURE — WHO DOES IT?

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Abstract

It is widely acknowledged that the use of ionising radiation in medical exposures must be justified, but it has often been difficult to determine who makes that justification, and who is responsible for it. New legislation introduced in the UK following the European Union Medical Exposures Directive makes it necessary to ensure that justification takes place and to ensure that the individuals responsible for it are identified and are adequately trained. This paper presents an approach to justification which minimises the need for extra training by focussing responsibility for justification on professionals who have gained sufficient knowledge as part of their specialisation. By acknowledging the role of radiographers in the justification process and allowing them flexibility in their judgement, it is proposed that the justification process will become more robust and should screen out inappropriate referrals more effectively.

1. Introduction

Article 3 of the Medical Exposures Directive [1] requires that all medical exposures should be justified in advance, ensuring that there is sufficient net benefit to the individual to be exposed, or to society, to offset the detriment associated with the use of ionising radiations. Article 5 indicates that the prescriber and the practitioner shall be involved in the justification, with their respective responsibilities left to the member state to determine.

In Great Britain, the Ionising Radiation (Medical Exposure) Regulations 2000 [2] places the responsibility for justification on the practitioner, with the referrer (i.e. prescriber) required to provide relevant medical data. The regulations require the practitioner to be adequately trained, and provide a syllabus of training, but otherwise impose no restriction on the profession of a person entitled to act as a practitioner. In the current climate of skill mixing and role extension there has been considerable local debate on whether the radiographer should be entitled to justify medical exposures or whether this should remain the responsibility of the radiologist. There has also been discussion on the role of medically qualified personnel other than radiologists in the justification process. The syllabus for adequate training is a daunting prospect for some professions, e.g. orthopaedic surgeons, whose use of radiation for medical exposures is well defined and limited.

The approach presented here has been adopted by our respective hospitals, and has been scrutinised by the appropriate regulatory authority in Great Britain.

2. The Practitioner

The Medical Exposures Directive describes the Practitioner as the medical doctor, dentist or other health professional who is entitled to take clinical responsibility for an individual medical exposure in accordance with national requirements. This definition is transferred to the legislation in Great Britain with a regulation that the practitioner is responsible for the justification of a medical exposure.

When implementing the Ionising Radiation (Medical Exposure) Regulations within our hospitals it was necessary to define at an early stage who our practitioners would be. In the UK all qualified radiologists have passed exams for Fellowship of the Royal College of Radiologists and will have received a Certificate of Completion of Specialist Training, also from the Royal College of Radiologists. By this mechanism it is ensured that radiologists have adequate theoretical and practical training to undertake the role of practitioner. Other staff groups require additional training to meet the requirements of the regulations. Guidelines on training issued by the European Commission [3] suggests that interventional cardiology specialists, other medical doctors, and dentists should have between 20 and 30 hours training in "core knowledge", with more detailed training for some groups. It is recommended that such training be delivered via basic residency programmes and specialist courses. Until such training is made available nationally as part of medical or specialist training for medical staff other than radiologists, it was decided that the most pragmatic approach would be to reduce the numbers of persons who would require this level of additional training. Having taken into account the amount of radiation being used by medical staff groups, the complexity of the procedures for which they would need to be responsible, and their degree of autonomy in using radiation, it was decided that the hospital would entitle radiologists, cardiologists and dentists to act as practitioners. Of these, the cardiologists and dentists would, at the moment need additional training before being entitled to justify medical exposures. For staff currently practising in these roles, account would be taken of existing training and experience and any shortfall picked up in a continuing education programme.

Other medical staff groups, such as orthopaedic surgeons, gastroenterologists, endoscopists and urologists would be identified as referrers (prescribers) and not be required to train as practitioners or as operators provided a qualified radiographer acting as operator is present for the exposure. The arrangements for this are described in the following section.

It was also decided that the radiographer effecting the exposure would not be a practitioner.

3. Authorisation of exposures

The Ionising Radiation (Medical Exposure) Regulations require all medical exposures to be justified in advance and authorised. The authorisation would normally be undertaken by the practitioner at the time of justification, most simply by endorsing the proffered referral form. However, the regulations do provide for those situations which may arise when referrals are made out of normal working hours when a practitioner is not available, or in general diagnostic radiology where there may be insufficient radiologist cover to individually authorise every exposure. In such instances it is possible for the operator to authorise the exposure in accordance with guidelines issued by the practitioner. In effect, the practitioner retains the responsibility for justifying the medical exposure, but issues justification criteria to the operator performing the exposure such that the operator can make the authorisation.

4. Authorisation guidelines

As there is no defined content to the guidelines it was possible to adopt an approach which fitted in with the structure adopted by the hospital for the process of a medical exposure and which recognises the professional qualification, experience and training of the radiographer. The general guideline now in place requires radiographers to exercise their judgement within

the bounds of their knowledge and experience, and allows them to authorise exposures with reference to justification criteria. These justification criteria are included in the standard operating protocol for every radiological procedure carried out within the hospital [4]. The text of the current general guidelines is reproduced in Figure 1 below. As an example, the justification criteria for the chest X-ray of a neonate would be:

- Abdominal Pain
- Bowel Obstruction (Erect CXR)
- CCAM
- Chest Pain
- Congenital Cardiac Anomaly
- Cough
- Cyanosis
- Dyspnoea
- Fever
- FTT Neuroenteric Cyst
- Hypoxia
- Haemoptysis
- ICU - Tube Change
- Inhaled Foreign Body
- Lung Abscess
- Tachyphnoea
- Murmur
- Non Accidental Injury (NAI)
- Sequestration Chest Of Abdominal Trauma
- Systemic Disorder Or Skeletal Dysplasia
- VP Shunt Series

Figure 1. Text of Current Authorisation Guidelines

General comments for the procedure would be included, for example it is stated that routine pre-operative chest X-ray in a well child is not indicated, and that mobile x-rays carry a potentially higher radiation dose and should be reserved for children too unwell to come to radiology department.

5. General guidelines for operators authorising exposures

These guidelines apply to medical exposures where it is not practicable for the practitioner to be present to authorise individual exposures. It is expected that practitioners will make themselves available to authorise the following classes of examination:

- CT - all examinations except CT heads
- Cardiology - all procedures
- General fluoroscopy – all procedures
- Vascular (including neuro) - all procedures
- Nuclear Medicine – all procedures.

It follows that operators should not authorise the above classes of examination, but should seek such authorisation from the practitioner on duty in that area according to the local rota.

Provided the operator is a qualified radiographer, registered to practice radiography in the UK, and can demonstrate active participation in continuing professional development, the task of authorising a medical exposure can be delegated to that operator. In so doing it is expected of the operator that they will use their professional knowledge and experience, coupled with an awareness of best practice advocated nationally or locally within the Trust, to determine whether the medical exposure proposed is the most appropriate for the individual presented.

In reaching this decision the operator must take full account of any clinical details accompanying the request, and must refer the request back if it is deemed that there is insufficient detail. They must also take account of all the information given in the Standard Operating Protocol for the exposure proposed.

When authorising an exposure, the operator must consider:

- the objectives of the exposure and the characteristics of the individual involved;
- the potential benefit and detriment to the exposed individual; and
- the efficacy, benefits and risk of alternative techniques involving less or no exposure to ionising radiation.

Special consideration must be given to females where pregnancy cannot be excluded, where potential dose to the unborn child must also be taken into account. Special consideration must also be given to breastfeeding females undergoing nuclear medicine procedures, where dose to the child must also be taken into account. If the operator is unable, due to lack of experience in the area, to decide on an authorisation, the request, and the task of authorisation, may be passed on to a suitably qualified/experienced operator or to the duty practitioner. The operator must never authorise exposures for which they know themselves not to be qualified. From time to time, practitioners within the Trust may issue written supplements to these guidelines which offer advice on specific cases (eg pre-operative chest X-rays). Such supplements will be entitled "Supplementary Guidance on Authorisation of Exposures" and will be endorsed by the Clinical Director of Radiology. These must be adhered to.

6. Summary

Identifying the practitioner who justifies the medical exposure can present difficulties in that considerable extra training may be required and it may result in changing of some traditional professional boundaries. The approach adopted here minimises the need for additional training by placing the burden of justification on those persons best qualified to undertake the task. Development of the authorisation process acknowledges the role of the radiographer and integrates with the operators' use of standard operating protocols.

The justification/authorisation process formalises procedures which have been practised in many hospitals in the UK for many years. As such the transition has been adopted with little difficulty. For the future, however, it is envisaged that the role of the radiographer will gradually extend from one of an operator to encompass the responsibilities of a practitioner in justifying medical exposures. With adequate training this can be achieved without detriment to patient care, but should be planned and audited to ensure that the individual and collective radiation doses are not increased. The National Radiological Protection Board stated in 1990 [5] that the elimination of clinically unhelpful examinations could potentially result in an annual collective dose saving to the UK population of 3200 personSv out of a total of about 16 000 personSv for medical X-ray examinations. This was the most significant way of reducing patient dose identified in the report, and should be one of the easiest to achieve. One of the barriers to this in the past has been the perceived lack of authority of the radiographer to reject referrals. With an acknowledged responsibility in the justification process the radiographer is now best placed to bring patient doses down.

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THE PATIENT'S RADIOLOGICAL PROTECTION IN MEDICAL PRACTICES: LEGAL SUPPORT IN THE CUBAN LEGISLATION

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Abstract

Peaceful applications of nuclear energy have a great importance in medical practice, for their use in diagnosis and therapeutic procedures. The possibility to detect diseases and the use of radiation as a palliative or curative method, enables the use of such polemic energy. Practices associated with the use of ionizing radiation are under regulatory control, and in this regard it becomes necessary to prescribe a series of administrative requirements aimed at granting the corresponding authorization, once it has been demonstrated that the technical requirements that ensure the safe performance of the practice, without undue risk on life, goods and environment are met. This includes the protection of any patient who could be under treatment, who is considered the main user of this application.

1. Antecedents

The use of sources of ionizing radiation in our country goes back to the decade of 40th with the introduction of X-ray therapy devices and then the use of radium needles for the treatment of different kind of skin cancers. Later in the fifties we began the use of radioisotopes for cancer treatment and in 1958 the first teletherapy device with Cobalt-60 sealed source was commissioned in Cuba, making our island one of the first countries in Latin America that used labelled compounds with medical purposes. The absence of a legal framework concerning radiological protection demonstrated the prevailing ignorance concerning the effects of radiation in the human organism. There were neither regulations to control the use of the radioactive sources, nor the protection of the occupationally exposed personnel.

Since 1959 nuclear energy with medical purposes has been continuously employed in our country. In the sixties, with the creation of the necessary infrastructure, began the use of nuclear techniques in biomedicine, radiobiology and investigations of ionizing radiation applications to other sectors. As years went by, it was necessary to develop in great scale activities related with radiopharmacy, and the use of labelled compounds was diversified into Oncology, Cardiology, Nephrology, Orthopaedics services and other medical specialities, in this regard patient radiological protection has been one of the most sensitive issues requiring regulations, directly or indirectly by regulating aspects inherent to the practices' safety.

2. Development

Health in our country being an issue completely run by the State and at the service of the whole society, from the institutional point of view the authorities and responsibilities of the Ministry of Public Health concerning patient's radiological protection are established by Law. To such effects in the Ordinance-Law 207 “On the Use of the Nuclear Energy”, among other aspects, it is prescribed that: **The Ministry of Public Health is the one in charge of ensuring that the use of the nuclear energy in the medical practice is carried out in correspondence with quality assurance systems that ensure patient radiological protection.**

It is also necessary to point out that the medical and paramedic personnel performing tasks inherent to the medical practice functions, are bound to a set of ethical principles establishing, in a generic way, the behavioural rules with patients as well as canons for the moral and social conduct of this personnel. Moreover regarding doctor-patient relationships it is specified, among other aspects, that the personnel of the Cuban Medicine shall propitiate that any patient would be only subjected to the indispensable complementary studies needed to achieve the correct diagnosis, avoiding any tendency to carry out indications departing from this objective and that may cause nuisances and unnecessary dangers to sick persons.

Considering that the holder of the AUTHORIZATION establishes a juridical relationship with the regulatory authority in an effective way, the existence of a group of juridical norms establishing obligations for the holder greatly contributes to the patient's radiological protection, because the requirement of an authorization previous to the conduction of a practice bears also, in an implicit way, a group of technical requirements to be indispensable fulfilled for the safely conduction of the practice.

Regarding that the applicants of authorizations should submit, like part of the required documentation, a sworn declaration manifesting that the doctors and specialists that are related therein are the only ones authorized to prescribe a therapeutic medical exposure using of an authorized source. This lowens the possibility of medical misspractice, but this can not completely avoid the possibility that under certain circumstances a patient may get injured by either technical or human errors.

Basic Safety Standards, for Protection against Ionizing Radiation approved by means of a joined Resolution by the Ministry of Public Health and the Ministry of Science, Technology and Environment, prescribe a group of technical requirements among which we will analyze the following:

With regard to the medical exposure, the holders of authorizations are responsible for ensuring that:

- No patient be administrated a diagnostic or therapeutic medical exposure unless the exposure is prescribed by a medical practitioner.
- medical practitioner be assigned the primary task and primordial obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of, medical exposure;
- medical and paramedic personnel be available as needed, and either be health professionals or have appropriate training adequately to discharge assigned task in the conduct of the diagnostic or therapeutic procedure that the medical practitioner prescribes;
- for therapeutic uses of radiation, the calibration, dosimetry and quality assurance requirements prescribed by this Regulation be conducted by or under the supervision of a qualified expert in radiotherapy physics ;
- training criteria be specified or approved, as proceeds, by the Ministry of Public Health in consultation with the corresponding Regulatory Authority;
- for diagnostic uses of radiation the imaging and quality assurance requirements of the standards be fulfilled with the advice of a qualified expert in either radiodiagnostic physics or nuclear medicine physics, as appropriate.

In all the cases the holder should ensure a set of conditions contributing to practice safety and consequently to the patient's radiological protection, either directly or indirectly. Generally in

the medical practice, mainly in the case of therapeutic applications, various individuals are involved so it is vital the responsible acting and the capacity and preparation of each one of them, like links of a chain allowing the efficient and effective application of the practice and patient safety.

In a more specific way other requirements are established, like that one with regard to the relative the obligation of the holders to maintain for 30 years and make available, a series of records regarding information such as: **in diagnostic radiology**, necessary information to allow retrospective dose assessment, including the number of exposures and the duration of the fluoroscopy examinations; **in nuclear medicine**, types of radio pharmaceuticals administered and their activities; **in radiation therapy**, a description of the planning target volume, the dose to the centre of the planning target volume and the maximum and minimum doses delivered to the planning target volume, the doses to other relevant organs, the dose fractionation and the overall treatment time.

These records are of great importance to the legal effects, since they constitute documentary evidence for any litigation process that might be initiated by any affected patient.

3. Legal actions

Although the goal of the precepts seen above, is in fact to ensure that the use of sources of ionizing radiation is carried out without undue risk for the life, goods and the environment, it is also necessary to foresee enforcement.

The Criminal Law, called in the Doctrine, *the last of the row*, because it acts after the infraction of a group of predetermined norms that when being violated by an illegal act and typified in a criminal type demand criminal liability. Therefore is valid to point out that our criminal legislation in force allows to sanction the responsible one for the occurrence of this sort of infractions, giving the appropriate legal protection to the patient and the Criminal Code establishes as punishable acts, requiring a penalty the constituent of the crime of LESIONS, which may be qualified as *light* or *serious*, according to the law.

In all the suppositions foreseen in the legal body, the precepts are sufficiently ample for typifing events resulting in corporal lesions, either light or serious, intentional or not, therefore in the event that a patient is injured as a result of an inadequate prescription or treatment application by means of the use of ionizant radiation, a law suit may be initiated in a Cuban Court of Law and when it proceeds it may have accessory civil responsibility to the criminal one, implying the compensation of the affected part by the responsible person.

4. Conclusions

We have tried to outline the existent juridical dispositions in the country, relative to patient's radiological protection and the necessity of supervising their fulfilment, because any infringement with the use of nuclear techniques, in such a sensitive sector as it is the Public Health could lead to serious consequences for the exposed patient and severe measures for the medical or responsible paramedic personnel because of the occurrence of any event as a consequence of an act that although unintentional, the existence of inexpertness, negligence or imprudence, demand the intervention of the justice.

The entry into force of the Basic Safety Standards, for Protection against Ionizing a great challenge is imposed to the Ministry of Public Health, from the institutional point of view, and to all the responsible holders for the safe conduction of the medical practice in our country, for the demand of new requirements that they must fulfil; but for the sake of the patient's radiological protection.

6. Recommendations

The necessity to maintain a constant surveillance with regard to the fulfilment and updating of juridical norms related to patient's radiological protection and the obligations of the personnel that work in this sector.

Ensure that the equipment used for the realization of these practices fulfil all the technical requirements that although eventually may lead to financial expenditures, it should be considered that human health is priceless, avoiding events that may result in patient's injury.

Evaluate the possibility to establish at least a simple juridical relationhip among the doctor that prescribes the treatment, or the radiologist, and the patient, by means of a document containing the responsibilities of the medical personnel and the possible effects that may arise in the patient, this would protect both parties legally, because *"The ignorance of the Law doesn't excuse anyone from its fulfilment"*.

RADIATION PROTECTION OF PATIENTS IN DIAGNOSTIC RADIOLOGY IN ESTONIA

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Abstract

The medical use of ionizing radiation started at the beginning of the century. It has always been considered necessery , as well for diagnostic applications where exposure to the patient is the price to pay in order to obtain useful images, as for therapy where the patient is exposed on purpose, in order to kill malignant cells. It is nowadays the major man-made contribution to the population dose . Even with the Developments of substitutive imaging or treatment techniques, there is still an increasing demand and many organizations are joining their efforts to try to keep the dose to the patient " as low as reasonably achievable ".This is particularly the case for the International Commission on Radiological Protection (ICRP) which recommended in publication 26 to follow three main principles: justification, optimisation and limitation. Limitation , however, does not apply to patients since the individuals exposed are expected to benefit from this exposure, but justification and optimization are relevant.

1. Regulatory authority

The national legislation (Radiation Protection Act) nominates a national Regulatory Authority which is given responsibility for regulating any practices involving radiation sources.

Estonian Radiation Protection Centre was established in January 1996. The general functions and responsibilities of Estonian Radiation Protection Centre are following:

- development of regulations, guides and codes
- assessment of applications for permission to conduct practices that entail or could entail exposure to radiation
- authorization of such practices and of the sources associated with them
- conduct of periodic inspections to verify compliance with license conditions
- enforcement of any necessary actions to ensure compliance with the regulations and standards
- keeping records of all sources of ionizing radiation
- keeping records of all radiation doses received by radiation workers and make estimates of doses received by the public
- preparations of plans and procedures for dealing with emergency situations
- advice to other national institutions, users of ionizing radiation and the public on radiation protection and related matters.

2. Legislation

In common with other developing countries, Estonia try to implement all legislative acts in compliance with the Euratom Directive 97/43 of 1997 dealing with the " Basic Standards for the Health Protection of the General Public and Workers against the Dangers of Ionizing Radiation".

2.1. Radiation Protection Act

Radiation Protection Act in Estonia was issued in 23 of April 1997.

Chapter 2 , § 5 :
" A license for activity involving radiation is required for:
1) construction, operation and decommissioning of nuclear facilities
2) handling of nuclear substances or materials or materials containing nuclear substances
3) addition of radioactive substance at production and manufacturing of pharmaceuticals and consumer goods
4) administering of radioactive substance to humans and animals for diagnostic, therapeutic and scientific purposes
5) use of an X-ray apparatus, an accelerator and an irradiator containing radioactive substance in production , medicine and scientific research.

A license for activity involving radiation may be issued if:
1) the licensee for activity involving radiation has a staff of the required professional qualifications;
2) the site for activity , and other conditions guarantee observance of safety requirements".

Chapter 3, § 21 :

"(1) The subject of medical exposure are:
1) the patient at diagnostics and treatment of an ailment;
2) the person nursing the radiation-treated patient if nursing is not his (her) professional occupation and he (she) is aware of the radiation treatment of patient;
3) any person voluntarily having agreed to participate in biological research."

2.2. Regulations of Minister of Social Affairs

The requirements for use of radiation for treatment and diagnostics of ailments was established by ordinance of the Minister of Social Affairs.

The regulation is known as the "The Requirements for Use of Radiation for Therapeutic Purposes and Diagnostics and the Requirements for Radiation Protection of Patients".

Chapter 1. Common requirements.
According this chapter :
- the benefits of the medical procedure must be greater than the detriment it causes;
- phisicians, who give examination or treatment and those who refer patients to it must in every case make sure the exposure to radiation is justified, they both are responsible for this exposure;
- before examination a physician should inform the patient about diagnostic or treatment dose and radiation risks;
- the radiological procedures can to refer only physician, who is sertified in Estonia;
- radiation exposure of test subjects in biological and medical is justified only for very special reasons. It requires a positive opinion from an Radiation Protection Centre;
- in the each user's organization should be established the Quality Assurance system and Quality Assurance Manual;

- before reffering a patient for radiological examination physician have to review results of previous clinical and radiological examinations.

Chapter 2. Requirements to radiological and radiation protection staff.

Chapter 3. Requirements to radiological equipment.
In this chapter:
- difinition " radiological equipment ";
- radiological equipment has to correspond IEC standarts
- in the each user's organization should be established QC programme
- list of quality requirements for X-ray equipment, processing and films.

Chapter 4. Requirements for radiation protection of patients and staff.
In this chapter:
- individual protective shieldings for patients and staff
- working places monitoring
- individual monitoring

2.3. Regulations of Minister of Environment

1. Statute of the National Dose Register of Radiation Workers; Procedure for Certifying Radiation Workers and for Issuing Certificates.

- radiological staff has to be examinated by Commission of Qualified Experts, which was established by Minister of Social Affairs

2. Requirements to rooms and protective shielding in radiological departments.

3. Positives and negatives in radiation protection of patients

3.1. Positives during 1997-2000

- QA system started in Estonia, Qa requirements was included to Estonian legislation
- Authorization system is according IAEA recommendations
- QC requirements was included to Estonian legislation and during 1997-2000 was tested 80% of radiological equipment
- Requirements to radiological and radiation protection staff were included to legislation
- New programme of rezidentship for radiologists? new generation of radiologists
- Special requirements to mammografy
- Profilactic chest examinations only by radiografy
- Developing process only by developing processors (not manually)
- Very good co-operation between Radiation Protection Centre and Radiological Society

3.2. Negatives in radiation protection of patients

- List of " accepted practicies " in radiology not approved yet
- Maximum doses (activities) of radioactive materials which should be administrated to patients are not established yet
- Maximum doses which should be received by patients in diagnostic radiology are not established yet
- Control of patient doses is not established yet

- Clinical audit (internal and external) in hospitals is not established yet
- QC requirements for dental radiografy, nuclear medicine and radiotherapy are not included to national legislation.

4. Plans for 2001-2002 (in co-operation with Finnish STUK)

- Developing the legislation for radiation protection in medical radiology (guides for QA, inspections, patient doses, optimization).
- Preparing the measuring and controll system for radiation protection in medical radiology.
- Training the staff for the new radiation protection tasks required in Medical Directive97/43 Euratom.

RADIOLOGICAL PROCEDURES: QUALITY CRITERIA AND DOSE OPTIMISATION: FRENCH STATUS

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Abstract

The Council Directive 97/43/Euratom of June 30th 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure has come into force on May, 13th 2000. French health directorate has entrusted the "Office de Protection contre les Rayonnements Ionisants (OPRI)" together with the "Société Française de Radiologie" (SFR) to implement the article 6 related to radiological procedures, in order to bring into operation the principle of optimisation. The most frequent diagnostic radiology and interventional procedures (120 protocols) have been standardised in writing. Corresponding patient dosimetry have been determined from measurements on site, calculations and literature review. The criteria for optimisation have been highlighted for each protocols. With the help of the French Society of Medical Physicists (SFPM), measurements are being collected on a large scale in France. Then, knowing more precisely the patient dosimetry of each protocol, referral criteria will be reviewed and prioritised to implement the principle of justification. The authors will present and explain the chosen methodology (methodology of the Accreditation and Evaluation in Health Agency: ANAES) for completing this two years workload program, and will demonstrate clinical examples as well.

1. Introduction

The Council Directive 97/43/Euratom of June 30th, 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure has come into force on May 13th, 2000 date of application of Directive 96/29 Euratom on the basic safety standards to which it is linked.

To implement articles 4 and 6 of the Directive, the French health directorate (Direction Générale de la Santé) entrusted its radiation protection agency (Office de Protection contre les Rayonnements Ionisants – OPRI) with the specific request of working with relevant scientific and professional societies.

For the domain of medical investigations with X rays, the corresponding work has been carried out with the radiologists represented by their national scientific society, i.e., Société Française de Radiologie (SFR).

2. Steering committee

A Steering Committee has been created and brings together SFR members and OPRI specialists in charge of the mission. The Steering Committee established its proper rules of functioning to accomplish the mission:

- To obtain the co-operation and agreement of the accreditation and evaluation in health agency (Agence Nationale d'Accréditation et d'Evaluation en Santé - ANAES) on a proposed method.
- To obtain the co-operation of radiologist experts dedicated to every main radiological specialty (chest, pediatry, neuroradiology...)
- To obtain a broad and representative view of radiological practices in France by selecting contributing experts from university hospitals, general hospitals, private practice with the

advice of the national union of French radiologists (Fédération Nationale des Médecins Radiologistes -FNMR)…

- To obtain the co-operation of experts in medical physics (Société Française de Physique Médicale)
- To use the expertise of radiology technicians (Association Française du Personnel Paramédical d'Electroradiologie)
- To use European guidelines if applicable and to liaise with European experts groups (European Commission MED Working Party)
- To report regularly to the French directorate of health for critical follow up from administrative advisors
- To meet regularly for reviewing and validating all updated documents and to make arbitration when necessary

3. Methods

Since the article 6 of the Directive requires that written procedures have to be established for each type of radiological practice and since such documents are needed for accrediting radiology departments, the Steering Committee has decided to launch a complete standardisation of radiological procedures at the national level with the following steps:

- To identify all diagnostic radiology and interventional protocols starting with those contributing mostly to both individual and collective dose, i.e., the most frequently used protocols and those delivering significant doses.
- To write down radiological procedures for all of the above protocols. So far 120 examinations have been identified and precisely documented along the following lines:
- To define for each radiological examination the quality criteria expected of the outcome, i.e., what is to be seen in images for each clinical situation. Patient dose optimization has to be obtained in a context of sufficient diagnostic information to conclude and answer the clinical question which has priority. The goal is to avoid useless exposures, e.g. exposures with such a reduced dose that medical useful information may be lost, leading subsequently to exposing the patient again to get the needed information. There is no optimisation of the exposure without a good medical outcome.
- To precisely define technical parameters used, e.g. X ray tube voltage, tube current and exposure time product, total filtration, geometric parameters of the examination (distance, exposed area, angle…)
- To discuss and select the dosimetric quantities to be used as National Diagnostic Reference Levels taking into account European choices: - in conventional radiology, the entrance surface dose for single exposure and the dose area product for complete examination, - in computed tomography, the weighted CT Dose Index per slice and the Dose Length Product for a complete CT examination, - in interventional radiology the choice of dosimetric quantities is still subject to discussion. The dosimetric quantities already selected are clearly defined, can be easily measured and consequently can be easily used in all radiology departments.
- To establish for each protocol the corresponding dosimetry according to its physical parameters and to evaluate the influence of each parameter individually and of various combination of parameters on dosimetric values. These evaluations are keystones of the optimisation process.
- To obtain the agreement of the scientific experts on a national basis on all criteria and parameters by using ANAES methodology of experts consensus. The first draft of each

protocol was written by a working party of organ dedicated experts (15 groups) lead by three experts, one being member of the Steering Committee. Each written protocol was then reviewed by groups of 10 to 12 readers carefully chosen by the SFR and FNMR to keep an appropriate balance between all types of practice, and from large cities to country towns. The selection of reviewing groups has been an essential step to ensure the acceptance and the validity of the protocols as truly representing the daily practice.

- To review each protocol with the Steering Committee, the aims of the critical analysis being the validation of each procedure. The Steering Committee has set up an editorial committee in charge of the realization of the reports, with a special task of harmonization of the presentation of the different procedures. Whenever necessary, the protocols have been sent back for further discussion and an iterative method applied.
- To finally establish National Diagnostic Reference Levels in France for all defined protocols, subsequently named "SFR protocols".

Indeed, each expert has contributed primarily in his/her field of expertise (SFR, the radiologists and technicians to the definition and description of the procedures, OPRI and the physicists to all dosimetric issues), with a fruitful interaction between all of them.

4. Current status

Two preliminary reports were published in November 1999 and July 2000 and approved by the French health directorate.

The report is being completed for a publication during the first quarter of 2001. This report will be the first complete set of recommendations for good practice in radiology in France, established and approved by SFR. Validated by more than 150 French radiologist experts, these protocols represent the national current consensus for radiology practice in France. Dosimetric evaluations corresponding to the "SFR protocols" have been obtained by OPRI and SFPM physicists by different means: values calculated from the technical parameters, measurements already available from experiments performed in a number of radiology departments according to the protocols, and values from critical review of literature. All these values indicate that medical exposures to X rays in France for the main diagnostic examinations are in the range of the published European Reference levels. Consequently, these European Reference levels can be adopted as starting points in France.

5. Future developments for assessing French reference levels

Reference Levels in radiology have to be determined in the near future in France with wide scale surveys of typical doses for common procedures, allowing the determination of third quartile values as recommended by the European Commission.

Thus the Steering Committee has decided to launch for 2001 a large campaign of measurements with the following rationale. Methods of measurements are established by the medical physicists of SFPM for the selected protocols and approved by the Steering Committee. Measurements are carried out on a large scale in the country, collecting data for all types of equipment, in departments representative of radiology practice in the country. Since the "SFR protocols" define the new standards of diagnostic radiology practice, it is assumed that the corresponding Reference Levels represent a fair view of the exposures yielding to images fulfilling quality criteria for diagnosis.

The Steering Committee expects that within the year 2001 enough data will be collected allowing to build up French Reference Levels to be subsequently used by all radiologists.

According to the Directive, these Reference Levels will serve for optimization for all radiologists. All practitioners will be encouraged to measure dosimetric quantities corresponding to the "SFR protocols" used on their equipment, to compare the results with the Diagnostic Reference Levels nationally established and to act consequently. In case of discrepancy, investigations will be necessary to fully understand the possible causes. Situations where patient doses are unusually high will lead to review of procedures and equipment if necessary.

6. Perspectives on French medical exposures

The French health directorate and OPRI plan to collect all measured dosimetric values in a national database in order to ensure the perenniality of the national Reference Doses and to facilitate their periodic review in a continuous process of optimization and reduction of unnecessary doses. The French health directorate is currently enforcing quality assurance surveys of radiological equipment which is also a key factor of limitation of medical exposures to ionizing radiation.

It is the intention of the Steering Committee to continue to update the protocols along the lines of the improvement of radiological technology in the future and with the approval of the French health directorate. The annual publication of an updated document is considered. Ultimately, patient dosimetry of each diagnostic radiology protocol will be used to review the referral criteria for imaging to implement the principle of justification of medical exposures to ionising radiation.

ETHICAL AND LEGAL ASPECTS OF MEDICAL EXPOSURE TO IONIZING RADIATION IN THE NETHERLANDS IN THE YEAR 2000

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Abstract

In the ancient time of Greece lived a very wise man. He told physicians; when you treat patients be aware you will 'do good and no harm'. From this specific point of view I kindly ask attention for legal and ethical dimensions of medical exposures of ionizing radiation. This paper gives first a résumé of the basic safety standards for radiation protection. Second it gives the legal instruments a patient, in the Netherlands, has got to exercise his right of self-determination. Third, it pays attention to a basic ethical norm for professional attitude. And finally it brings forward a guideline for self regulation by professionals.

1. Introduction

The merit of the Directive 97/43Euratom dated 30 June 1997 known as 'patient guideline', initiated not only legislation for radiation protection, it creates the necessary platform for further development of a 'radiation protection culture', as well. With respect to the patient rights and ethical dimensions of exposing people to ionizing radiation for medical purposes, those matters have to be taken in further consideration. Because, in recent years, both scientific and technological developments have contributed to an increase in the use of ionizing radiation and radioactive substances. These developments have also contributed to insights regarding the dangers for patients. This has led to calls for more stringent requirements regarding the treatment given by the physician as well as improved patient protection. Therefore, on 30 June 1997 the Counsel of the European Union adopted a new directive[1] The directive in question is based on article 30 of the Treaty Establishing the European Community for Atomic Energy. This article stipulates that member states of the European Union draw up basic safety standards that protect individuals against exposure to ionizing radiation [2]. This directive is concerned mainly with the medical applications of research and therapy and is also referred to as the 'patient directive'. It does not consider the cumulative effects of exposure treatment to radiation that a patient might receive within a given period of treatment

2. Radiation protection

The two most important basic safety standards for protecting the patient, hereinafter referred to as radiation protection, are the justification principle and optimization principle [3]. The first basic safety standard requires that prior to radiological treatment commencing, the physician must consider whether such a course of treatment is on balance beneficial or

[1] Council Directive 97/43/EURATOM of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure and repealing Directive 84/466/Euratom. O.J. L 180.
[2] EURATOM Treaty Establishing the European Community for Atomic Energy. Articles 30,31.
[3] Idem 1 Section 3 paragraph 1 *Justification* Medical exposure referred to in Article 1 (2) shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct health benefits to an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionizing radiation. Idem, Article 4 paragraph 1 subsections a and b *Optimization.* All doses due to medical exposure for radiological purposes except radiotherapeutic procedures referred to in Article 1 (2) shall be kept as low as reasonably achievable consistent with obtaining the required diagnostic information, taking into account economic and social factors. (b) For all medical exposure of individuals for radiotherapeutic purposes, as mentioned in Article 1 (2) (a), exposures of target volumes shall be individually planned; taking into account that doses of non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.

detrimental to the patient's health. Alternative treatments and the benefits to society should be duly considered in reaching this decision. The second basic standard is optimization, a form of quality control. This control relates to both the preparation and use of radiation. Regular evaluations, in which social and economic factors are taken into account, must guarantee that the radiation dose remains as low as possible for the purpose required. Within both the medical purposes as a dosage justification and optimization standards, extra emphasis is placed upon the careful use of radiation because dose limitation for patients does not apply [4]

Despite the fact that positive effects are intended with radiation treatments, certain treatments always carry the risk of deterministic and stochastic effects occurring [5]. This danger can threaten protective measures designed to prevent the violation of the patient's physical and mental integrity. Therefore these basic standards, within the context of radiation protection, require other legal and ethical standards to elaborate this professional guideline. This paper provides an initial step in this direction.

3. Patient rights

International Human Rights Conventions offer citizens protection against a third party violating their life [6]. In line with this the Dutch Constitution grants the right to inviolability of the human body (article 10) and the right to privacy (article 11). Furthermore, this law also stipulates that the quality and accessibility of care must be further regulated (article 22). An elaboration of these constitutional rights took place in the Dutch healthcare legislation. The most important characteristics of this legislation is the strengthening of the patient's legal position. The right to self-determination and informed consent along with an equal relationship with the physician and the right to complain. They are important instruments that enable a patient to independently (autonomously) decide about his health.

In justifying the use of radiation for medical purposes, the physician is legally bound to demonstrate that his determination of the indications and the application of radiation for medical purposes are both correct. Only the physician is qualified to make this justification. This autonomy is limited to the indication for and application of radiation and never replaces the autonomy of patients in their right to decide. In other words, being able to do something is not the same as being allowed to do something. This notion will be dealt with later. Mind you: the "patient directive" does not invoke the terms 'informed consent'.

4. Professionalism

The standard for a physician's professionalism has already been formulated in the Hippocratic oath. In a nutshell this standard is about doing good and not harm. In this context, Hippocrates talked about the 'medicus gratitotus'. By this he meant a serving physician, someone who not only possessed the expertise necessary to carry out his profession but also the skills, moral qualities and values [7]. This standard is still relevant in decisions related to medical treatment and the review thereof.

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[4] International Committee on Radiological Protection; Third principle for development radiation protection: exposure may never exceed prescribed dose limits; except for medical reasons.

[5] Hermans, A.F. Biologische effecten van straling. Stralingshygiëne voor medische toepassingen [Biological effects of radiation. Radiation hygiene for medical applications.] IRS. Leiden. Deterministic effects of radiation in relation to the seriousness of the effect. For example, cataract of the eyes lens, non malignant skin damage, haematological deficiencies, damage to blood vessels and effects on fertility following irradiation of the gametes. Stochastic effects of radiation: concerns the possibility of such effects occurring, for example, the induction of tumours and genetic effects.

[6] Leenen, H.J.J. Prof., Rechten van de mens in de gezondheidszorg [People's rights in healthcare]. Part 1. Third impression, pages 38-44.

[7] Have, ten. H.A.M.J. Prof. e.a. Medische Ethiek [Medical Ethics], page 61 et seq.

5. Additional standards

A medical use of *radiation* can only take place with a patient's permission. Such permission is only of value if the patient has been informed about each stage of the treatment and the physician respects the patient's rights in this case. The golden rule is "no treatment without permission and no permission without information" [8]. Hereby, the physician's duty to care for his patient acquires added value. This also applies when an individual is exposed to radiation for non-medical purposes for which they receive no direct benefit.

Exposing a patient to ionizing radiation for medical purposes also means, at the same time, exposing them to the associated dangers. This is not objectionable if the advantages for the patient's health outweigh the disadvantages. The effectiveness of radiation used for medical purposes can be determined using biological parameters. Such parameters are not available for measuring the radiation load for the patient. Under certain circumstances, this load can harm the patient's quality of life as well as that of his relatives.

The frame of reference available to the physician and patient to determine the effectiveness of the radiation load for the patient differ. This can result in a conflict of interests. A patient's anxiety and uncertainty about his illness and future often result in his unquestionably agreeing to a radiological treatment. The patient finds himself in a vulnerable and dependent position. Such a patient must not only be able to rely upon a physician's 'grace' but also upon a physician who supports him as a 'lawyer' as he practices his right of self determination during the entire course of treatment. Within such a physician – patient relationship based on mutual confidence, requiring the patient to sign a declaration in which he accepts responsibility for the risks associated with the radiological treatment, is inappropriate.

6. Self regulation

The use of radiation for medical purposes is only effective if it is equal to the effectiveness of the provisions for radiation protection. For the professionals concerned, this means that the basic safety standards of justification and optimization are implemented, with due regard to the other legal requirements for the quality of care, by drawing up a guideline.

Such a care guideline concerning the use of radiation for medical purposes and radiation protection has been dawn up by and for professionals and includes the generally accepted indications for all phases of the care [9]. It implements the medical radiological procedure from the justification process prior to the treatment commencing until the intended effect is reached, including the aftercare. The guideline must at the very least comply with the following conditions.

7. Conditions

In general, the guideline's content must be based on the latest scientific knowledge. In particular, it must satisfy the requirements of transparency, recordability, effectiveness and testability. To meet the requirements of a specific situation and the needs of individual patients. And it needs to be applied flexibly. The guideline must be thorough, accessible and authoritative if it is gain general recognition within the profession.

[8] Roscam Abbing, H.D.C. Prof./ de WGBO; van tekst naar toepassing. Het recht op informatie en het toestemmingsvereiste. [The Medical Treatment Agreements Act; from law to implementation. The right to information and the need for consent.] Pages 22-31.

[9] Wijmen van Professor mr. F.C.B. Richtlijnen voor verantwoorde zorg. Preadvies ten behoeve van de jaarvergadering van de vereniging van gezondheidsrecht, [Guidelines for responsible care; Preliminary advice for the annual meeting of the Association of Health Law] 14-04-2000, page 31-81.

8. Recommendations

When the basic safety standards for radiation protection are put into practice, the patient's rights as detailed in the Medical Contract Act must be fully integrated. To this end, the following recommendations are made with respect to:

I. *The Justification principle*.

1a. A physician must provide rational arguments to justify indications which lead to a radiation treatment. These arguments must be based on national and international parameters[12] and the patient's specific characteristics.

1b. The physician needs to inform the patient verbally as well as, in the case of complex treatments, in writing. When the patient is informed, special consideration needs to be given to the radiation load and the effects of this upon the patient's life expectancy and quality of life[13].
The justification and informed consent procedures constitute a continuous and inextricable part of the entire treatment process.

2. During the consultations, the physician should encourage the patient to engage a confidant. Simple diagnostic treatments are not subject to this.

3. The physician registers all the patient's wishes, doubts and decisions in their medical record.

4a. If despite a negative justification the physician still wishes to carry out a radiological treatment, he must first of all consult the medical ethics committee.

4b. Consultation as mentioned under 4a, is also required
Consultation of this committee is also required where the physician in addition to providing the treatment is also the clinical investigator.

II. As regards to the other basic-safety standard; *the optimization principle* the same recommendation could be applied; both now in close connection with quality of care legislation.

1a. The entire process of planning, carrying out the treatment and the aftercare also entails the choice of apparatus and the involvement of other legally required radiation experts. All the information concerning the apparatus, doses received by the patient, effects and agreements are to be recorded in the patient's medical record [14].

1b. Furthermore, all the requirements with respect to the quality of care as decreed in the Quality of Care Institution Act are to be taken into account in the optimization process. detailed under 1a., and are to be recorded in the patient's medical record

2. All diagnostic and therapeutic uses of radiation for medical purposes are to be carried out in accordance with the appropriate protocol. Deviations from such protocols must be recorded in the patient's medical record along with the reasons why [15]. The patient must also be informed as to the consequences of this for his health;

3. Where radiological intervention is used, the planning and implementation of the size and duration of the patient's dose must be accurately recorded in the patient's medical record. The patient shall be fully informed about the size of the dose and the consequences of this for his health;

4. Contrary to what is decreed in the Medical Contact Act [16], the patient's medical records must be retained for thirty years due to the possible emergence of long term effects.

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[12] Radiation Protection Decree of the Nuclear Energy Act. Section 58.
[13] Medical Contract Act. Section 448.
[14] Idem 12. Section 451
[15] Idem 12. Section 454.
[16] Idem 12. Section 454, paragraph 3.

For the guideline to be effected on time, it is recommended that all anonymous data regarding the implementation of the protocol be monitored at a regional level. These data will also be useful for medical auditing purposes.

9. The use of radiation without a medical indication

Another issue is that at present, people are exposed to radiation for non-medical diagnoses. Examples are the taking out of a life insurance, determining the age of a juvenile asylum seeker or obtaining evidence from people suspected of drug smuggling. The physician bears the responsibility for carrying out such procedures [17].

The 'patient directive' compels the member states to pay attention to the justification of the application. This presents a paradoxical situation. The intention of the justification is to determine a sufficient net benefit for the individual. But, what is this benefit for a young asylem seeker? And what means the autonomy of a physisian, in this situation, if he gets an order to make an X-ray for this purpose? Such a request for a diagnostic examination not only calls physician's autonomy into question but also restricts the justification procedure.

10. Conclusion

In conclusion one can say : International Treaties and the Dutch Constitution protect people against physical and mental harm from a third party. This legislative protection is further elaborated on in the Dutch health legislation. Such rights can only be limited by law. By choosing to use radiation for medical purposes, a physician consciously decides to inflict damage due to the positive effects he has in mind. Within certain acceptable boundaries, such an infliction of damage is therefore regarded as a legitimate treatment method. In principle, the patient possesses sufficient legal instruments to practice his right of self-determination. Yet in many cases a patient cannot make decisions regarding his health, as he has insufficient insight with regard to all the consequences that could result from the radiological, high grade medical technology treatment. In such cases a specialized knowledge of high-grade medical is required and only a physician possesses this.

This being the case, the patient's right of self-determination is of course limited. The patient is aware of his inferior position, which limits him in practising his right of self-determination.
Thus: In case of a complex treatment, more garanties must be given to the patient, to enable him to exercise his right for selfdetermination.

Therefore, a careful elaboration of the basic safety standards for radiation protection must take place. This needs to be done in close cooperation with the previously mentioned people and must duly consider patient rights as well as the medical ethics standards of the professional treatment provided by a physician.

The professions who carry out the procedure bear the responsibility of implementing the basic safety standards in a patient oriented manner.

The guideline does not cover how insight is gained into the cumulative dose a patient undergoing medical exposure to ionizing radiation, can receive in a given period. A passport for the medical use might provide a solution to this problem.

[17] Idem 11. Section 58,61.

IAEA-CN-85-117

CONSEQUENCES AND PROBLEMS WHICH AROSE FROM THE APPLICATION OF THE SPANISH LAWS ABOUT QUALITY CRITERIA IN RADIODIAGNOSTIC, NUCLEAR MEDICINE AND RADIOTHERAPY FROM THE POINT OF VIEW OF RADIOPHYSICISTS

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Abstract

New laws about Quality Criteria in Radiodiagnostic, Nuclear medicine and Radiotherapy have been recently issued in Spain, concerning radiological protection to patients in each of those medical specialities. The present work deals briefly with the needs, consequences and problems arose from their putting into effect, in those three fields, from the point of view of radiophysicists. In the diagnostic area the main difficulties arise from organization aspects to carry out the Quality Control programme in a fluid way. In Nuclear Medicine, the most difficult task is related to the dose estimation in each patient treated with radiopharmaceuticals. In radiotherapy, difficulties are connected with the specified tests to establish the initial reference state of the equipment as well as those for the quality control programme. In particular, in brachytherapy the main problem comes from the compulsory calibration in Standard Laboratories of the detectors used to measure the air kerma rate free in air for all types of employed sources. In this paper, these and other difficulties are discussed, as well as some actions taken in order to solve them.

1. Introducción

En los últimos años se han publicado en España los Reales Decretos por los que se establecen los criterios de calidad en Radiodiagnóstico [1], Medicina Nuclear [2] y Radioterapia [3], relacionados con la protección radiológica del paciente en cada uno de esos campos. En los tres decretos se abordan los criterios de calidad en todas las etapas de que consta el diagnóstico/tratamiento del paciente, y que competen a todos los profesionales que intervienen, no limitando el control de calidad al de los equipos que se utilizan. Respecto a este punto, la SEFM ha publicado unas recomendaciones, en colaboración con otras sociedades científicas, para los tres campos de aplicación [4 a 6].

En este trabajo se exponen brevemente las implicaciones, necesidades y problemáticas, emanadas de su aplicación, desde el punto de vista del radiofísico.

2. Criterios de calidad en Radiodiagnóstico (RD)

Las tareas a las que obliga el decreto [1] al radiofísico: control de calidad técnico del equipamiento, estimación de dosis, participación en la elaboración de especificaciones técnicas de compra de equipamiento, asesoramiento en temas de protección radiológica, etc.. no ofrecen en principio dificultades teóricas. Las que pueden surgir están relacionadas principalmente con cuestiones de organización que no dependen directamente de los radiofísicos pero que sí pueden verse afectados por ellas. Por ejemplo, no en todos los hospitales está resultando fácil el funcionamiento de una Comisión de Garantía de Calidad de un modo operativo.

Así, pueden surgir problemas al tratar de llevar a cabo las tareas del radiofísico si fallan los procedimientos establecidos para ello o la cooperación necesaria entre Servicios. Por ejemplo, puede ocurrir que no se le comunique en el momento adecuado la sustitución de una unidad de RX o la instalación de una nueva, o que haya dificultades para establecer las dosis de referencia en exploraciones no comunes si no existe la necesaria colaboración entre los

profesionales que intervienen, o que se incumpla el procedimiento fijado para solicitar un informe de dosis personalizado de un paciente.

En los últimos años se ha avanzado mucho en la optimización de las exploraciones pero tal vez no tanto en el aspecto de la justificación de las mismas.

Otro asunto que puede ofrecer dificultades está ligado con la formación en cuestiones de protección radiológica. Pueden surgir problemas para impartir dicha formación a algunos especialistas o a personas contratadas en sustituciones (vacaciones, bajas laborales). Esto último obliga a programar frecuentemente sesiones de formación a las que deben acudir las personas recién incorporadas pero plantea problemas de organización a veces irresolubles.

3. Criterios de calidad en Medicina Nuclear (MN)

El Real Decreto [2] establece que el programa de garantía de calidad en las unidades asistenciales de Medicina Nuclear debe incluir, entre otros, medidas de control de calidad de la instrumentación y de los sistemas de tratamiento de datos, la relación de dosis efectiva por unidad de actividad administrada de los radiofármacos más utilizados y los parámetros relacionados con la estimación de la dosis absorbida en pacientes. En cuanto al radiofísico, cabe destacar que participa en la estimación de la dosis absorbida por el paciente en una prueba diagnóstica, cuando se requiera, y tras la administración de radiofármacos con fines terapéuticos, en la realización de las pruebas de aceptación del equipamiento y en el control posterior del mismo.

Así pues, la participación del radiofísico en el programa de garantía de calidad en Medicina Nuclear es fundamental en la estimación de las dosis absorbidas por los pacientes y en el control de calidad del equipamiento, para lo cual es importante su integración en la dinámica de funcionamiento de la unidad asistencial de Medicina Nuclear.

En la administración de radiofármacos con fines diagnósticos, la dosis puede estimarse utilizando tablas en distintas publicaciones [7] o información aportada por el fabricante del radiofármaco. Pero en la administración de radiofármacos con fines terapéuticos, la dosis absorbida recibida por los órganos debe ser estimada para cada paciente, precisando de un estudio biocinético para conocer la cinética y biodistribución particular del radiofármaco en cada paciente. Las dificultades técnicas principales de esta evaluación son la no existencia de unos procedimientos consensuados para la estimación dosimétrica y el conocimiento de la cinética y biodistribución de cada paciente concreto. Así, en España se ha creado una comisión, en la que intervienen miembros de las sociedades científicas de Medicina Nuclear, Física Médica y Protección Radiológica, con el fin de redactar un protocolo de procedimientos dosimétricos en la utilización de radiofármacos en Medicina Nuclear.

4. Criterios de calidad en Radioterapia (RT)

A) Braquiterapia (BT)

Aparte de resaltar que el decreto [3] recoge la prohibición explícita de la utilización clínica de las fuentes de Ra-226, que ya estaban prácticamente abandonadas en España, la implicación más destacable de [3] es la obligatoriedad de la verificación de la Tasa de Kerma de Referencia en Aire (TKRA) de todas las fuentes empleadas y que los equipos de referencia para la medida deben estar calibrados en laboratorios de metrología reconocidos. Este hecho, que ya se viene cumpliendo extensamente en RT externa, en braquiterapia significará que para

todas las fuentes de uso clínico deberá existir un calibrador con trazabilidad a un patrón. Por tanto se deberán adquirir en la totalidad de unidades de Radiofísica los calibradores adecuados, con factores de calibración del sistema para todos los modelos de fuentes operativos en el Servicio de RT.

Como se recoge tanto en el Informe del Grupo de BT de la SEFM [8] como extensamente en el Informe sobre necesidades metrológicas en BT [9] este aspecto obligatorio en el decreto es del que mayor problemática y necesidades se derivan para su cumplimiento.

Por diversas razones [8-10], el sistema de referencia para la medida de la TKRA es el detector pozo con los insertos apropiados; la calibración de estos sistemas se debe realizar con un modelo de fuente exacto al que posteriormente se va a utilizar para la medida de su TKRA. El problema es que no existen patrones disponibles en los laboratorios de calibración que cubran la amplia variedad de fuentes en uso en España. Para el caso de fuentes de Tasa Alta (HDR) y Tasa Pulsada (PDR) existe la alternativa del uso de las cámaras cilíndricas típicas para RT Externa [8,9], calibradas para una determinada calidad de RX junto con Cs-137 y/o Co-60.

En el caso de fuentes de Baja Tasa de Cs-137 (LDR) para los que no exista patrón, la solución más viable y práctica [9] para la verificación de su TKRA es mediante el uso de cámaras de gran volumen ($\geq$ 1 litro) calibradas en la energía del Cs-137. Esto requiere la adquisición de la instrumentación adecuada, el desarrollo de procedimientos y metodología de medida y la disponibilidad en los laboratorios para calibrar estas cámaras [9].

Problemas de difícil solución son el caso de fuentes que no se pueden extraer de los aplicadores en sistemas de carga diferida de LDR, caso del Selectron y el caso de conjuntos de fuentes que el fabricante proporciona selladas en sus aplicadores [8]. Es necesario que se desarrollen recomendaciones y procedimientos de verificación dosimétrica para estos casos, de los que hay un buen número operativos en España, para que las unidades de Radiofísica pueda cumplir lo especificado en [3].

B) Radioterapia externa

En radioterapia externa, la publicación del decreto [3], no ha modificado de forma relevante la actuación del radiofísico ya que este campo ha sido tradicionalmente el de su mayor dedicación. Principalmente, las obligaciones que impone respecto a la calibración de equipos no ofrecen problemas particulares a diferencia de lo que ocurre con la braquiterapia. Sin embargo, tras su publicación, han podido surgir algunos cambios en la organización o modo de actuación de los Servicios implicados. Por ejemplo, el decreto impone unas normas de actuación respecto a las averías que se producen en las unidades de terapia, que ha podido alterar las existentes previamente en los Servicios de Radiofísica/Radioterapia. Según el decreto, debe ser el radiofísico el nexo de unión entre el técnico que repara la unidad y el radioterapeuta. El radiofísico debe autorizar al técnico la reparación de la unidad y recibir el informe de la misma. Si la jornada de trabajo del radiofísico no coincide en su totalidad con la de funcionamiento de las unidades de terapia o con el de horario de trabajo de los técnicos, este hecho obliga a tomar decisiones que pueden diferir en cada centro de trabajo (parar tratamientos en caso de avería, prolongación de jornada o guardias de radiofísico, etc..). Hay que resaltar como algo muy positivo que el decreto obligue a que en el parte de reparación el técnico haga constar si, como consecuencia de su reparación, se ha podido alterar alguna característica de los haces. Es posible que, como consecuencia de la publicación del decreto [3], en muchos Servicios de RT se haya tenido que incluir de modo obligatorio un control semanal de la ficha de tratamiento, tanto por parte del radioterapeuta como del radiofísico. La

única dificultad que conllevan estas actuaciones es el tiempo que hay que dedicarles, pero son actuaciones que ayudan a mejorar la calidad de los tratamientos.

5. Dificultades comunes en radioterapia externa y BT

Respecto al contenido y periodicidades de las pruebas para el establecimiento del estado de referencia inicial y del programa de control de calidad en radioterapia externa, braquiterapia y en los equipos de planificación y cálculo, cabe destacar que se entienden sometidas a la flexibilidad que se deriva del artículo 15 en el que se señala que dichas pruebas, tolerancias y periodicidades podrán ajustarse a protocolos de reconocida solvencia pudiendo modificarse además con criterios justificados que tengan en cuenta los objetivos de los tratamientos y tecnología disponible. Esta interpretación parece ser la de más amplia aceptación en la SEFM pero resulta dudosa según lo que literalmente expresa el artículo 12 respecto a las pruebas para fijar el estado de referencia inicial. Si hubiera que hacer rigurosamente lo que figura en el anexo II de [3] se necesitaría una explicación adicional detallada e inclusive una eventual modificación del decreto.

La publicación del decreto [3], pese a implicar un aumento de tiempo de dedicación del radiofísico a tareas como las mencionadas anteriormente, no ha venido emparejada con un aumento de plantilla de los Servicios de Radiofísica, y éstos tienen en general, un déficit de personal [11]. También son necesarios unos medios mínimos instrumentales.

Referencias

[1] REAL DECRETO 2071/1995, de 22 de Diciembre, por el que se establecen los criterios de calidad en Radiodiagnóstico.

[2] REAL DECRETO 1841/1997, de 5 de Diciembre, por el que se establecen los criterios de calidad en Medicina Nuclear.

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[5] TÉLLEZ DE CEPEDA M. y otros. " Protocolo nacional de control de calidad en la instrumentación de Medicina Nuclear". SEFM, SEMN y SEPR, 1999.

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IAEA-CN-85-279

EVALUATION OF THE RADIOLOGICAL PROTECTION IN SEVERAL DEPARTMENTS OF NUCLEAR MEDICINE

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Abstract

For the evaluation of the Radiation Protection in several departments of Nuclear Medicine was elaborated and it applied a survey that includes mainly: aspects of the licence and compliance with the requirements settled down in this, the program of individual radiological surveillance and their evaluation, functions that it completes the Service of Radiation Protection, training program and the personnel's training, equipment and means of Radiation Protection, radiological surveillance program of the work areas, characteristics of the installation, radioactive waste management, quality assurance program, relative aspects to the Radiation Protection in the procedures of diagnoses; as well as to pregnant patients and those related with the investigation of accidental medical exposures. The work makes a systematization and discussion of the state of compliance of the radiation protection requirements reflected in the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) and the main recommendations are exposed to achieve in these departments the optimization of the Radiation Protection.

1. Introducción

Con el propósito de evaluar la situación de la Protección Radiológica (PR) en la práctica nacional de Medicina Nuclear se aplicó una encuesta en 10 módulos de esta práctica en diferentes provincias del país, aportando la información que permite evaluar el grado de cumplimiento de los requisitos básicos, establecidos en las Normas Básicas Internacionales de Protección contra las Radiaciones Ionizantes y de Seguridad de las Fuentes de Radiación (NBIS) [1]. La encuesta consistía en 13 modelos, que recogen los diferentes aspectos relativos a la PR, agrupados de forma tal que facilitan la compilación y análisis posterior de la información. El análisis y conclusiones a que se arribó pueden ser considerados como representativos de la práctica nacional y las valoraciones presentadas en este trabajo, permitirán sentar las bases para realizar un análisis particular en cada entidad de los aspectos, que deben ser tenidos en cuenta para el correcto desempeño de los Servicios de Protección Radiológica (SPR), y como punto de partida para iniciar un proceso de optimización de la PR en ellas [2].

2. Resultados y discusión:

2.1. Información general

Las instituciones estudiadas están licenciadas por el Centro Nacional de Seguridad Nuclear (CNSN), como Autoridad Reguladora se encuentran en período de renovación de dichas licencias y operan según las condiciones previstas en estas.

Desde el punto de vista organizativo, se encuentran nombrados el representante legal autorizado, el Responsable de Protección Radiológica (RPR) y el Facultativo principal; no así

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el Físico dedicado a Medicina Nuclear. No se cumple con la subordinación directa del RPR al Director de la entidad, aunque los aspectos de PR son tratados directamente con este y se les confiere determinada autonomía para cumplir sus funciones. No se encuentra constituido el Comité de Protección Radiológica en la mayoría de las instituciones y en las que existe su funcionamiento es deficiente, por lo que la evaluación de los aspectos relativos a la seguridad radiológica no es sistemática, ni es vista desde un punto de vista integral.

2.2. Programa de vigilancia radiológica individual y su evaluación

Las entidades disponen de un programa de vigilancia radióloga individual, en el que se emplean diferentes métodos. El monitoreo individual de la irradiación externa comprende: cuerpo entero en el que se utilizan dosímetros fílmicos o TLD con una frecuencia trimestral y mensual respectivamente. Sólo cuatro entidades monitorean extremidades con dosímetros TLD con una frecuencia mensual. El monitoreo individual de la contaminación interna por método directo, para el ^{131}Iodo se realiza en dos entidades. Los métodos indirectos no son empleados.

Los resultados del control dosimétrico individual de cada uno de los servicios contratados son registrados, pero es deficiente su: actualización, la información a los TOE, la evaluación y su documentación. Se emplean niveles de registro e investigación, sin embargo la toma de medidas en caso de su superación no esta establecida en todos los servicios o no son documentadas.

Aspecto deficiente en el orden organizativo es la no-disponibilidad en todas las entidades de un lugar que garantice el adecuado almacenamiento de los dosímetros una vez concluido el trabajo y el uso inadecuado y no diario de los dosímetros por parte de algunos TOEs.

2.3. Funciones del Servicio de PR (SPR)

La mayoría de las entidades tienen constituido el SPR por el RPR, lo que se adecua a sus características, pero no todos están certificados. En el aspecto organizativo se establecen las funciones y atribuciones del SPR, pero su cumplimiento y la elaboración de un sistema de registros adecuado de las mismas, con su actualización sistemática, presenta diferentes niveles de implementación. Las causas valoradas que inciden en ello, están dadas por: la ausencia de programas, equipamiento y conocimientos adecuados; así como aspectos propiamente de índole organizativos.

En cuanto a la evaluación por parte del SPR de la situación de la PR ésta se realiza con una frecuencia anual o posterior a las inspecciones realizadas por el CNSN, siendo documentada fundamentalmente para la presentación de la solicitud o renovación de la licencia.

2.4. Capacitación y entrenamiento del personal en materia de PR

La capacitación y entrenamiento del personal en materia de PR aún son deficientes y no se realiza una evaluación periódica de sus resultados, lo cual está dado por la carencia de un programa concebido integralmente en el que se incluyan la capacitación diferenciada a los TOE y la realización de ejercicios prácticos.

El contar con procedimientos e instrucciones debidamente documentados en las entidades, que abarcan los estudios diagnósticos que se ejecutan y algunos aspectos de PR, resulta

valioso para establecer el programa de capacitación y con su evaluación propiciar la revisión y modificación de dichos procedimientos, con el objetivo de ir dando pasos que lleven a optimizar la PR.

2.5. Equipos y medios de PR

La disponibilidad de equipos de PR en los SPR para realizar el monitoreo de áreas presenta serias dificultades y en especial los equipos medidores de contaminación superficial, por su ausencia casi generalizada, o su empleo con un nivel de referencia preestablecido y la carencia de un servicio nacional para su calibración. Sin embargo un mayor número de entidades cuenta con equipos de medición de tasa de dosis, que son regularmente calibrados. Los equipos que miden tasa de dosis o contaminación y cuentan con señalización de sobrepaso de umbral, no están disponibles en todas las entidades o su funcionamiento es defectuoso en parte de estas.

Se cuenta con medios para realizar la descontaminación radiactiva de áreas de trabajo y del personal; pero no siempre son ubicados en las áreas que lo requieren. De igual forma en todas las entidades se encuentran disponibles medios para la protección individual de los trabajadores y se conoce casos como usarlos.

Los aspectos tratados en este tema, requieren que las instituciones realicen inversiones; así como la implementación por parte del SPR de técnicas de medición alternativas que permitan realizar las evaluaciones requeridas.

2.6. Programa de monitoreo de las áreas de trabajo

Las dificultades señaladas con el equipamiento, es la principal causa de que en las entidades exista un deficiente programa de monitoreo de áreas, unido a que no se ha concebido en muchas de ellas de forma integral. Como alternativa para cumplimentar el monitoreo de áreas, las entidades han contratado estos servicios; pero es necesario prestar atención en la necesidad de que este se diseñe respondiendo a las necesidades propias de la entidad y que incluya los diferentes tipos de monitoreo recomendados, estableciéndose niveles de investigación o intervención y procedimientos donde se recojan los pasos a seguir en el caso de su superación.

2.7. Características de los locales

En todas las entidades existen las condiciones constructivas y de ventilación autorizadas en las licencias emitidas por el CNSN, aunque no siempre se cuenta con un registro donde se documenten modificaciones efectuadas.

Las diferentes áreas de trabajo poseen una clasificación adecuada y su disposición en el módulo permiten su correcta separación. Las señalizaciones disponibles en cada local, no reúnen todos los requisitos establecidos estando en algunos casos desactualizada, lo cual conlleva a la existencia de flujo y permanencia de público en áreas controladas.

Aspecto crítico, es la no-disponibilidad de áreas separadas para la permanencia de pacientes a los cuales se les ha suministrado el radionúclido, del resto de los pacientes y acompañantes, igual situación presenta los servicios sanitarios. Ello requiere en algunos casos de inversiones; pero en otros pueden ser tomadas medidas organizativas que posibiliten cumplir con lo establecido.

2.8. Gestión de desechos radiactivos

La gestión de los desechos radiactivos en las entidades se realiza de forma general adecuadamente, aunque aún subsisten problemas organizativos y de sistematicidad. En ellas existe un local para el almacenamiento de los desechos radiactivos, que cumple con los requerimientos establecidos y que permite que estos se encuentren siempre dentro de las condiciones autorizadas. De forma general la segregación se realiza correctamente, no así la señalización de los bultos. Aún debe trabajarse en la optimización de los diferentes procedimientos relativos a la generación de desechos para lograr minimizar su volumen; así como en disponer de un registro que permita contar con un inventario de los desechos hasta su evacuación.

2.9. Programa de Garantía de Calidad (PGC)

El establecimiento de un PGC en las entidades, es uno de los aspectos más novedosos dentro de las funciones del SPR. Las entidades han trabajado en la elaboración del Manual de Seguridad Radiológica, en el que se incluyen procedimientos de trabajo y establecen registros, también se cuenta con procedimientos estándares nacionales e internacionales para la planificación de los estudios diagnósticos o tratamientos y selección del radiofármaco; pero deben ser considerados otros como: Programa de control de calidad (CC) para el equipamiento empleado en los estudios y de PR, a los radiofármacos y a la totalidad del proceso diagnóstico, definición de política, objetivos de calidad y responsabilidades en PR, registros, auditorías internas y externas.

2.10. Aspectos relativos a la PR en procedimientos de diagnóstico, terapia e investigación

Como se ha señalado anteriormente, las entidades disponen de procedimientos para la ejecución de cada tipo de estudio, en los cuales se recomiendan las actividades a emplear en ellos [3], pero se tiene en cuenta adicionalmente las condiciones del equipamiento existente y sus posibilidades para la obtención de resultados con calidad diagnóstica, de ahí las variaciones encontradas. No obstante, debe trabajarse para realizar de forma regular un análisis de estos aspectos y su comparación con los niveles orientativos, con vista a lograr la optimización de la PR e ir incorporando otros aspectos, los cuales como se pudo constatar no son tenidos siempre en cuenta a la hora de realizar un estudio y su aplicabilidad resulta poco práctica, dentro de la organización del servicio de medicina nuclear.

En las entidades se disponen de criterios para la reducción de dosis a infantes y niños y de forma general se dan orientaciones para proteger a los familiares de personas estudiadas o tratadas, pero en este aspecto mucho se debe trabajar, por su implicación en la optimización de la PR.

2.11. Aspectos relativos a la PR de pacientes embarazadas

En las entidades se ha establecido que la realización de estudios a mujeres embarazadas, sólo serán realizados cuando el cuadro clínico así lo requiera y en estos casos se les orienta de forma oportuna. De la misma forma se procede con mujeres en etapa de lactancia materna.

Los SPR deben actuar de forma inmediata en la ubicación de señalizaciones adecuadas en los servicios, que alerten a las mujeres en edad de procreación, o que posean sospecha de un posible embarazo o ya lo estén, de la necesidad de informarle esto a su médico o a los

especialistas y técnicos que realizan las investigaciones, para evitar situaciones de exposiciones no recomendadas o deseadas.

2.12. Investigaciones a exposiciones médicas accidentales

Es necesario trabajar en todas las entidades en la elaboración de procedimientos que establezcan las acciones a seguir en caso de que ocurran exposiciones médicas accidentales y la importancia que reviste desde el punto de vista de la PR, que una vez que estas sucedan sean documentadas y analizadas, lo cual permitirá la corrección de procedimientos y adecuación del programa de PR. Además debe recordarse que sobrepasar sistemáticamente los niveles de referencia es considerado una exposición medica accidental.

3. Conclusiones

La aplicación de la encuesta diseñada, como base para la evaluación de la situación de la PR en la práctica de Medicina Nuclear, resultó adecuada para este fin, permitiendo que en cada entidad se iniciara de inmediato, la toma de medidas y acciones que posibiliten perfilar un programa más abarcador e integral y que permita cumplir con aquellos aspectos que aun no están establecidos de acuerdo a las recomendaciones de las NBIS.

Las consideraciones incluidas en este trabajo servirán de punto de partida y unidas al establecimiento de metodologías, permitirá realizar una optimización adecuada de la PR en la práctica nacional de Medicina Nuclear.

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RADIOTHERAPY PRACTICE IN AN UNREGULATED ENVIRONMENT: CALL FOR JOINT ACTION

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Abstract

There are five radiotherapy centres and thousands of diagnostic x-ray units in Nigeria. There is a five-year old radiation protection decree, which is yet to be implemented. Consequently, radiotherapy and radio-diagnosis are practiced in the country without any form of regulatory guidelines backed by law. This paper is a call for the concerted effort of the WHO and the IAEA to persuade the Nigerian Government to establish the Nigerian Nuclear Regulatory Authority. This will ensure safe applications of atomic energy in the national heath delivery system.

1. Introduction

In the early 1960's, nuclear weapon tests were carried out in the Sahara Desert, which resulted in radiation being drifted into Nigeria with the northeasterly winds. In reaction to this development, the Federal Government in 1964 established the Federal Radiation Protection Service (FRPS) at the Physics Department of the University of Ibadan. The FRPS was established without an Act of Parliament and therefore lacked the powers to regulate and control the use of nuclear radiation. In 1971, a draft decree on Nuclear Safety and Radiation Protection was proposed by the FRPS and sent to the then Federal Military Government for consideration and promulgation. It never went beyond a draft.

On the 24th August 1976, the Federal Military Government enacted Decree No. 46, which established the Nigeria Atomic Energy Commission, (NAEC) [1]. This became the very first by any government in the federation towards the orderly and safe use of nuclear energy. According to this Decree, the Commission was entrusted with the responsibility for the development of atomic energy and all matters relating to its peaceful uses.

The Nigerian Atomic Energy Commission Decree No. 46 (1976) was not intended to regulate the use of nuclear radiation but rather to promote and increase its use. The decree led to the establishment of the two nuclear energy research centres at the Ahmadu Bello University, Zaria and at the Obafemi Awolowo University, Ile-Ife. Over the past 25 years, these two nuclear energy research centres have trained about 250 scientists, engineers and technicians in the various peaceful applications of nuclear energy. Yet there is still no legally constituted body to regulate the activities of these centres. During the same period, the two research centres acquired very sophisticated and powerful nuclear research equipment and machines, including a nuclear reactor, a particle accelerator and neutron generators. They are however not alone in this business of unregulated use of nuclear energy in the country. It is pertinent to know also that the NAEC, which led to the creation of the Research Centres does not exist, yet the decree establishing it has not been repealed!

A similar situation exists in the petroleum industry, which is the mainstay of the Nigerian economy. The petroleum industry is the largest importer and user of radioactive substances in the country. All these applications are neither regulated nor controlled, except for the radiation protection practices imposed by the home countries of the multinational companies. The industry was so concerned about the situation so much that the Department of Petroleum Resources in 1993 organised an International Workshop on Radiation Protection in the

Nigerian Petroleum Industry. This was the first call by a user industry for legislation on radiation protection in Nigeria.

Since the establishment of the FRPS, the number of diagnostic x-ray units in operation nationwide has increased to about two thousand. Similarly, the number of radiotherapy centres in the country also increased from zero to five in the year 2000. By this development, thousands of patients are exposed to radiation annually at the radiotherapy centres in Ibadan, Lagos, Zaria and Abuja. There however, exists a law after all, but it is only not enforceable.

Nigeria and indeed the world do not need a “Koko” before action is taken. Indeed, a pleasant “Koko” incident actually did happen in the Nigerian nuclear energy industry before a regulatory decree was promulgated. Under the auspices of the Energy Commission of Nigeria and the active collaboration of the Ministry of Petroleum Resources and the Ministry of Foreign Affairs, the International Atomic Energy Agency (IAEA), Vienna approved to donate and install a nuclear research reactor in Nigeria. This was based on a Technical Cooperation Project proposal submitted by the Centre for Energy Research and Training, Zaria in 1993. The project commenced in January 1995. The IAEA gave the Nigerian Government some pre-conditions for the implementation of the project, which included promulgation of a decree to regulate the use of ionizing radiation and nuclear materials in Nigeria.

The road to the promulgation of the decree was long and difficult. It was towards this end that the Centre for Energy Research and Training, Zaria held a National Workshop on "Radiation Safety and the Nigerian Legal System" in June 1995. The Energy Commission of Nigeria (ECN) spearheaded the drive to persuade the then Federal Military Government to put in place a law that would regulate all peaceful applications of nuclear energy in the country. As earlier stated above, this struggle started in 1971! The effort this time around yielded the desired result. By August 1995, the Government promptly promulgated the Nuclear Safety and Radiation Protection Decree 19 of 1995[2]. This single act facilitated the supply of the nuclear reactor to Zaria. The installation of the reactor was completed during the first quarter of 1999. It is pertinent to add that the same Federal Government invested a lot of resources to provide the buildings and other infrastructure for the nuclear reactor. The nuclear reactor can however not be commissioned because there is no nuclear regulatory authority on ground. The Nuclear Safety and Radiation Protection Decree 19 of 1995 provides for the establishment of the **Nigerian Nuclear Regulatory Authority**, but none has been set up since 1995. The situation is however different in the case of the radiotherapy facilities. They are being used but in an unregulated manner.

2. Radiotherapy Centres

There are five radiotherapy centres in the country. These are located at the:

i. National Hospital, Abuja
ii. Ahmadu Bello University Teaching Hospital, Zaria
iii. University College Hospital, Ibadan
iv. Lagos University Teaching Hospital, Lagos and
v. EKO Hospitals, Lagos

They all have facilities for external beam radiotherapy and for brachytherapy. The radiotherapy centre at the National Hospital Abuja was fully established and equipped by the Federal Government of Nigeria without any foreign assistance. It is the “flagship of the medical institutions in Nigeria”. Its facilities include a linear accelerator, X-ray generator and

Cesium-137 radioactive sources. There is however only one Medical Physicist, who also doubles as the Radiation Protection Officer for the hospital. The radiotherapy centres at the three university teaching hospitals are to a very large extent equipped and trained under Technical Cooperation programmes with the IAEA. The facilities include Cobalt-60 and Cesium 137 radioactive sources. Here again, there are about 2-3 Medical Physicists. The reason for this is the non-establishment of the NNRA, which is the organ to regulate the number and quality of every cadre of workers in the radiotherapy centres and the procedures of their activities. The radiotherapy centre at the EKO Hospitals in Lagos is a private outfit. It has a Co-60 radioactive source and an X-ray generator. There is also one Medical Physicist. With the existing facilities, it is obvious that there is a lot of room for improvement in terms of training and recruitment of personnel in the areas of radiation protection and dosimetry. The Draft IAEA Regulation Guidelines for Radiotherapy provides a useful resource base and will be very useful to the NNRA whenever it gets established.

3. Decree 19 of 1995

The Nuclear Safety and Radiation Protection Decree of 1995 [2] provides for the establishment of the Nigerian Nuclear Regulatory Authority (NNRA).

It has a Governing Board with the Head of State as its chairman and six Federal ministers as members, amongst others. Under such a tremendous weight of its members, the Board may never be able to meet regularly and consequently render the NNRA weak and effective. This may also partially explain the reason for not constituting the NNRA five years after the law establishing it came into existence.

The NNRA has the responsibility for nuclear safety and radiological protection regulation in the country. The Authority has the powers, amongst others, to:

a. categorize and license all activities involving exposure to ionizing radiation;
b. establish appropriate register for each category of sources (or machines) and practices involving ionizing radiation;
c. license operators of practices;
d. issue codes of practice;
e. review and approve safety standards and documentation;
f. protect the health of all users, handlers and the general public from the harmful effects of ionizing radiation;
g. undertake investigations and research into ionizing radiation sources and practices

In carrying out its functions, the NNRA shall establish the National Institute of Radiation Protection and Research (NIRPR). This is to serve as the technical arm of Authority. Thus the decree can be seen to be broad and adequate in terms of its responsibilities, powers and functions. The structure of the Governing Board can not make the Authority operate effectively.

Five years have lapsed since the enactment of this decree. The national pride of “operating a nuclear reactor in Nigeria before the year 2000” was not a sufficient reason for its implementation! This is the historical task that the nuclear medicine and radiotherapy centres in the country are being faced with. It is noteworthy, that the Ministry of Health (**heath)**started ‘the struggle’ for the Radiation Safety Law in 1971, but the Energy Commission of Nigeria (**research)** succeeded in getting the decree enacted in 1995. For the implementation of the

decree, the Energy Commission of Nigeria started the initiative in 1995 without a breakthrough. It may well now be the turn of '**health'** to get the NNRA established for the benefit of all. History may indeed repeat itself, *albeit* in a spiral. With the joint effort of the IAEA and the WHO, health considerations may provide the sufficient reason for the Nigerian Government to implement Decree 19 of 1995 so that medical applications of ionizing radiation, as well as other peaceful applications of nuclear energy may carried out safely. This will also enhance international confidence on such practices in Nigeria.

4. Draft IAEA TECDOC on Regulatory Guidance for Radiation safety in Radiotherapy

According to this draft IAEA TECDOC [3], the objective is to assist regulatory authorities in preparing regulatory guidance for radiotherapy practice. The document is applicable to all established uses of ionizing radioactive sources and machines radiation-emitting machines employed in radiotherapy practice. It covers occupational, public, medical, potential and emergency exposure situations. The document provides for authorization of practice, procedure and personnel and their cadres. In fact the document is particularization of the BSS[1]. Of all the various cadres listed in the document that are vital to the safe practice of radiotherapy, this paper will dwell on the medical physics and radiation protection cadres. This is in view of the BSS requirement for radiation protection, which demands for justification of the practice, dose limitation and optimization of protection, and dose constraints.

It is conceivable to start a radiotherapy practice with just the Radiation Oncology but without a Medical Physicist and without a Radiation Protection Officer. In fact this is what happened in the case of Nigeria, where five Radiotherapy Centres got established without a regulatory authority. Consequently, there are only about three Medical Physicists superintending the dose limitation and dose constraints in the five hospitals located in four different cities! At other times, these same Medical Physicists perform the duties of the Radiation Protection Officers. The situation is like driving a car without a break. It is just a question of time before the 'unexpected' happens. All these are happening principally because there is no regulatory authority. This is not to say that the Radiotherapy Centres have not been prudent, but that when one person does the work of three, then safety could be compromised. This draft TECDOC, along with others for different specific practices constitute veritable regulatory guidance for the Nigerian Nuclear Regulatory Authority.

5. Recommendations

(a) IAEA and WHO

IAEA should tie future assistance to Nigeria to the establishment of the NNRA. The IAEA has done this before to get the decree implemented, in the first instance. This time around, the IAEA and the WHO should make a joint presentation to the Nigerian Government on the need to establish the NNRA.

(b) ECN and Federal Ministry of Health

Pending the establishment of the NNRA, the ECN should in consultation with the National health Council of Nigeria setup an ad hoc committee to carry out some of the regulatory functions of the NNRA. This should be done with the support and understanding of such international bodies, such as the IAEA and WHO.

(c) Nigerian Government

The Government should establish the NNRA without further delay. The decree should thereafter be amended accordingly to facilitate the operations of the **NNRA** by amending its composition and appointing somebody with less state responsibilities as its chairman.

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IAEA-CN-85-115

QUALITY SYSTEMS FOR RADIOTHERAPY: IMPACT BY A CENTRAL AUTHORITY FOR IMPROVED ACCURACY, SAFETY AND ACCIDENT PREVENTION

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Abstract

High accuracy in radiotherapy is required for the good outcome of the treatments, which in turn implies the need to develop a comprehensive Quality Systems for the operation of the clinic. The legal requirements as well as the recommendation by professional societies support this modern approach for improved accuracy, safety and accident prevention. The actions of a national radiation protection authority can play an important role in this development. In this paper, the actions of the authority in Finland (STUK) for the control of the implementation of the new requirements are reviewed. It is concluded that the role of the authorities should not be limited to simple control actions, but comprehensive practical support for the development of the Quality Systems should be provided.

1. EC directives lay down the legislative basis for quality systems

The EC directive on medical exposure (MED) [1] and the directive on basic safety standards (BSS) [2] lay down the basis for the radiation safety of the patients and the staff and public, respectively. The number of detailed requirements in these directives implies in practice that the user of radiation must establish and maintain a well documented system of organizational and technical arrangements to ensure radiation safety of the operation. In terms of modern quality concepts this is considered equivalent to saying that the user must have a comprehensive Quality System [3] for the operation.

For radiotherapy, the requirements by the EC directives are supported by the recommendations issued by the European Society for Therapeutic Radiology and Oncology (ESTRO) [4,5]. The recommendations by ESTRO on the Quality Systems in radiotherapy combine the general principles of quality standards [3] with practical experiences on quality assurance in radiotherapy procedures [6]. The recommendations provide the general approach of the quality standards but tailored to the concepts and practical needs in the field of radiotherapy.

2. Regulatory actions at a national level

The radiation protection legislation in Finland has established the basis of radiation safety essentially in terms of licensing the use of radiation and setting up a number of requirements on the arrangements for radiation safety by the user. The implementation of the requirements is verified by regular inspections of the operation, including the inspection and acceptance of the local quality assurance programs, by a radiation protection authority (STUK). As a particular detail for radiotherapy, the inspections by the authority incorporate a thorough set of dosimetric measurements to verify the accuracy and correctness of the procedures applied by the user.

The new EC directives (BSS and MED) imposed a number of changes in the basic legislation for radiation protection, while a special degree by the Ministry of Health and Social Affairs was issued to cover the detailed requirements given in the MED directive. Based on the predictions of the practical impact of these changes, as well as on the recommendations

published by the ESTRO, a national working group of radiotherapy experts (physicians, physicists and a nurse) was convened by STUK in order to prepare a national guide on Quality Systems in radiotherapy. The guide, finally issued in autumn 2000, is entirely based on the ESTRO guide [5] but is written in Finnish and supplemented by the national experiences of clinical work. A few meetings with key radiotherapy physicians, physicists and the heads of radiotherapy departments preceded this work in order to provide the necessary support and to direct the effort on the actual needs of the clinics.

Besides the changes of the basic legislation and the above practical guide on Quality Systems, a number of special guides (so called ST-guides) to supplement and detail the legal requirements have been issued by STUK. Some of these pertain to all applications of radiation (e.g, guide on personnel monitoring), but two of these are specific to the radiotherapy applications: "Quality Assurance for Radiotherapy" and "Radiation Safety of Radiotherapy Rooms and Equipment". The former one is the key guide, which details the basic principles and requirements for overall QA in radiotherapy.

3. Regulatory actions versus audits

An important new concept in the requirements for overall QA in radiotherapy is the need for internal and external *audits* of the radiotherapy process. Here a clear distinction has to be made for the following types of audits:

a) Quality Audits for *external certification* that the Quality System operated by the clinic conforms to a given standard.
b) Dosimetry Audits or "Quality Audits" for the verification of the accuracy and correctness of the local dosimetry and quality control procedures.
c) Clinical Audits as introduced in the MED directive, for a comprehensive evaluation of the quality of the clinical practice including the work done by all professionals of the clinic.

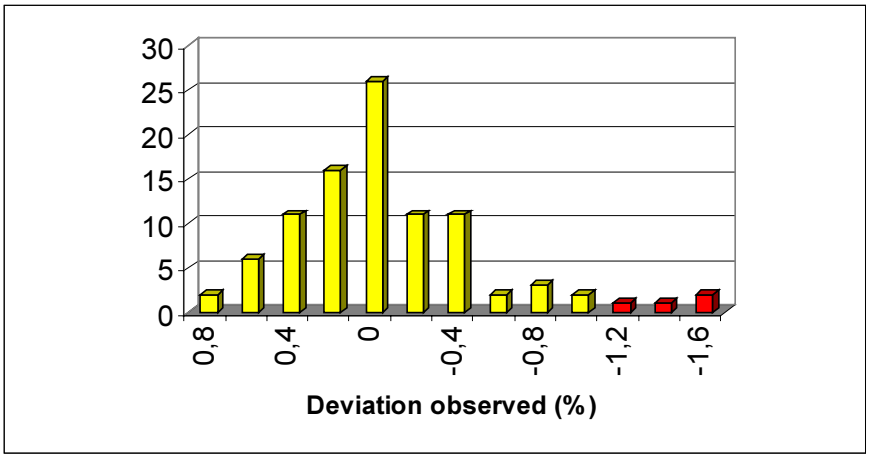

Fig. 1. The distribution of deviations of the absorbed dose to water measured by the hospital at the reference point in high-energy photon beams, from the result of corresponding measurement by STUK.

The last one is the most comprehensive evaluation aiming at comparing the existing clinical practices with "good" practices and introducing improvements when necessary. As such, it should inherently include an element for the verification of the correct dose to the patient; in other words, Dosimetry Audits should be a part of its implementation. For the full implementation of the Clinical Audits, no exact model nor detailed recommendations are

available but the requirement in the MED directive calls for its implementation in accordance with the national arrangements. The objectives of the Clinical Audits are well specified in the new Finnish legislation, while the organization and practical implementation of the Clinical Audits are now under extensive discussion between authorities, professional societies and radiation users.

The extensive comparative measurements by STUK, in connection with the regular inspections of radiotherapy equipment and practices, are considered as a practical means of control. These are aimed at verifying the accuracy and the correctness of methods of Quality Assurance applied by the user, the criteria being set by the action levels defined for the results of the comparative measurements. An example on the distribution of the observed deviations are given in Fig.1.

The system of regular comparative measurements provides STUK with the necessary follow-up and confirmation that the technical conditions for a high-quality radiotherapy are continuously maintained in all clinics. The system of on-site visits enables a much more effective and comprehensive evaluation than a mere postal control of certain parameters with the help of thermoluminescence dosimeters, as widely applied for audits [7]. During the on-site visits, the problems can be immediately identified and further investigations and the necessary remedial actions initialized.

Due to the established system of regular site-visits with comprehensive measurements, in Finland there is no need for postal TL-audits in the same sense as recommended e.g. by the ESTRO. However, an occasional participation of the clinics at other audit programs, such as the ESTRO-EQUAL program [7], is considered to provide a useful external audit of the whole national system of comparative measurements. Further, the TL-audits for the comparative measurements, carried out annually by the IAEA for the laboratories in the SSDL Network, provides another confirmation of the accuracy and quality of the methods applied in the national system.

4. Central register of abnormal incidences

One of the major objectives of the Quality Systems is to provide the organization, the radiotherapy department, with a framework which makes it possible to identify mistakes before they effect the treatment, i.e., to ensure effective methods of accident prevention. Information on such incidences are centrally collected by STUK in order to provide possibilities to learn from the incidences and effectively affect on minimizing their appearance. Whenever necessary, a through investigation of the cases are conducted, the marketing organizations and manufacturers are contacted, and other users of similar equipment or techniques are alerted.

5. Education and training actions

The MED directive imposed more attention to the need of continuous training of the all users of radiation. The authorities, which are responsible for the control of the implementation of these requirements and the acceptance of the training programs, are not expected to provide the training needed for the required competence. However, as the centres of expertness, radiation protection authorities can provide training for the training organizations, and also such practical training which improves the knowledge of the users on safety features. In Finland for radiotherapy, STUK organizes regular annual meetings with the radiotherapy

physicists and targeted training for particular topics in radiation dosimetry and quality assurance. Also, national guides on dosimetry are prepared and issued by STUK, in collaboration with radiotherapy physicists.

6. Quality of radiotherapy metrology

For practical reasons, the maintenance of the national standards for ionizing radiations is also a responsibility of STUK. The standard dosimetry activities are developed to conform to the international requirements, in particular, to the requirements of the Mutual Recognition Arrangement (MRA) [8]. The Quality System of the laboratory has been developed in accordance with the new ISO standard [9], and the data on the calibration and measurement capabilities (cmc) have been prepared for EUROMET database. Research on calibration and measurement techniques are undertaken to maintain the expertness and to develop the methods to cope with the rapid development of radiotherapy techniques. A number of improvements of calibration techniques are being implemented. This includes, among other things, the implementation of the new international code of practice for absorbed dose to water calibrations [10], centralized calibrations of plane parallel ionization chambers in electron beams, new calibration techniques for brachytherapy sources, and new radiation qualities for the calibrations of dosimeters in diagnostic radiology.

7. Conclusions

The EC directives create the regulatory basis for the development of the Quality Systems in radiotherapy, the major efforts which are also recommended by the ESTRO. The radiation protection authorities evidently play an important role for the implementation of the legal requirements. The role of the authorities should not be limited to simple control actions, but the authorities should provide comprehensive practical support for the development of the Quality Systems. This could include preparation of appropriate guidance, arrangements or support of dosimetric comparisons, central collection of data on abnormal incidences, acceptance of training programs with targeted training of trainers and key professionals, maintenance of high quality in radiation metrology and high expert knowledge through appropriate research efforts.

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GUIDELINES FOR THE DESIGN OF THE WORKING RULES OF THE GUARANTEE AND QUALITY CONTROL IN RADIOTHERAPY COMMISSION

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Abstract

The 1566/1988 Royal Decree stated on July 17 th and focused in Quality Criteria in Radiation Therapy was published at the Official Spanish Gazette on August 28 th. Its publication began a self-analysis process in all the Spanish Radiation Oncology Departments due to the fact that it implies the guidelines elaboration of each step of the radiation therapy process, including the patient post-treatment follow up and the equipment quality control.
The Royal Decree orders the Managers of the Hospitals and facilities that have a Radiation Oncology Department to create the Guarantee and Quality Control in Radiotherapy Commission. According to the Spanish law regulations, every single commission must have its own working rules based in the Chapter II, focused in "Organos Colegiados", of the 30/1992 Law stated on November 27 th about Public Administration Legal Rules. The Guidelines for the design of the Guarantee and Quality Control in Radiotherapy Commissión Working Rules here presented, have been done by consensus in Son Dureta University Hospital and afterwards sent to all Radiation Oncology Departments by the Spanish Society for Radiotherapy and Oncology.

1. Introducción

La publicación en el Boletín Oficial del Estado, el 28 de Agosto de 1988, del Real Decreto 1566/1988 de 17 de Julio, por le que se establecen los criterios de calidad en Radioterapia, inició un proceso de reflexión interna en los Servicios de Oncología Radioterápica de toda España debido, entre otras razones, a que implica la realización de protocolos de todas las etapas asistenciales del paciente que va a recibir radioterapia, incluidas las revisiones y controles posteriores al tratamiento.

Lo anterior no afecta solamente a los Servicios de Oncología radioterápica sino que involucra también a los Servicios de Protección radiológica y Física Médica y a las Direcciones y Gerencias de los Centros Asistenciales

Como uno de los primeros pasos para poder iniciar unos procedimientos y planes de trabajo eficientes y efectivos, se contempla en el Real Decreto 1566/1988 la obligatoriedad que tiene el titular del centro sanitario en cuanto a la creación de una Comisión de Garantía y Control de Calidad en Radioterapia.

Esta Comisión debe dotarse obligatoriamente de un reglamento de funcionamiento de acuerdo con lo previsto en el Capítulo II, sobre Organos Colegiados, de la Ley 30/1992 del 26 de Noviembre del Régimen Jurídico de las Administraciones Públicas.

El reglamento que a continuación se expone es fruto de una labor de consenso y se ajusta a las normativas legales vigentes en el Estado Español anteriormente mencionadas. Fue aprobado por la Comisión de Garantía y Control de Calidad en Radioterapia del Hospital Universitario Son Dureta en las Sesiones celebradas los días 03/02/99 y 17/06/99. y posteriormente fue distribuido por la Asociación Española de Radioterapia y Oncología a todos los Servicios de Radioterapia.

2. Reglamento de funcionamiento de la comision de garantia y control de calidad en radioterapia

Introducción*:* La Comisión de Garantía y Control de Calidad en Radioterapia se crea en base al Artículo 3, Apartado 1 a, del Real Decreto 1566/1998 de 17 de Julio por el que se establecen los criterios de calidad en Radioterapia. Su composición se establece en base al Artículo 4. Apartado 1 del antedicho Real Decreto.
El presente Reglamento se establece de acuerdo con el Capítulo II (artículos 22 al 27) de la Ley 30/1992 del 26 de Diciembre del Régimen Jurídico de las Administraciones Públicas.

1. Vigencia y ambito de aplicación: El presente reglamento entrará en vigor a partir del día de su aprobación por los componentes de la Comisión de Garantía y Control de Calidad en Radioterapia y será de aplicación en el Hospital _____ .

2. Composicion de la comisión

2.1. Clases de Miembros: En principio la Comisión estará compuesta por los siguientes:

Miembros Permanentes, aquellos que forman parte de la misma en función del cargo que ocupan:

- Representante/s de la Administración del Centro.
- Responsable de la Unidad Asistencial de Radioterapia.
- Responsable de la Unidad de Radiofísica.
- Responsable de Enfermería de Radioterapia y Radiofísica.

Miembros no Permanentes, aquellos que forman parte de la misma a propuesta de los Responsables de las Unidades Asistenciales a las que pertenecen:

- Un médico especialista en Oncología Radioterápica.
- Un Radiofísico hospitalario.

Si por necesidades de funcionamiento o ampliación de funciones de la Comisión de Garantía y Control de Calidad en Radioterapia es necesario ampliar la representación de los componentes de esta, será necesaria la aprobación de estos por mayoría absoluta de los miembros de la Comisión.

2.2. Designación de los Miembros
El nombramiento de todos los miembros de la Comisión corresponde al Titular del Centro Sanitario (Gerente). En el caso de los miembros no permanentes, el nombramiento se efectuará a propuesta del responsable de la Unidad Asistencial correspondiente.

2.3. Renovación de los Miembros

- Permanentes: Si dejan de desempeñar el Cargo que motiva su designación.
- No permanentes: Deberá efectuarse una renovación anual, pudiendo ser reelegidos. Dejarán de ser miembros:
- Si cesan en su relación laboral con la Unidad Asistencial.
- A petición propia.
- A petición del responsable de su Unidad Asistencial.

2.4. Derechos de los Miembros

- Recibirán, con una antelación mínima de 48 horas, la convocatoria para las Sesiones conteniendo el Orden del Día.
- Participarán en los debates y las votaciones de las Sesiones.
- Podrán formular ruegos, preguntas y su voto particular.
- Podrán obtener información precisa para cumplir las funciones que se les asignen.
- No podrán atribuirse las funciones de la representación de la Comisión que corresponden al Presidente de la misma a no ser que se les haya otorgado por acuerdo.
- Si se realizan votaciones, no podrán abstenerse en las mismas aquellos miembros que formen parte de la Comisión debido al cargo que ocupen.

2.5. Obligaciones de los Miembros

- A asistir a las reuniones de la Comisión a las que sea convocado, salvo por motivos o circunstancias de fuerza mayor.
- A respetar la confidencialidad de la información personal que conozca por su condición de componente de la Comisión, aún con posterioridad a su cese en la misma.

3. Presidente

3.1. Elección del presidente

- Se elegirá entre los miembros permanentes de la Comisión.
- Se elegirá preferentemente por acuerdo o por votación si fuera preciso.
- En caso de votación, todos los votos de los miembros tendrán el mismo valor.

3.2. Renovación del Presidente

- Deberá efectuarse una renovación cada dos años, pudiendo ser reelegido.
- Además, deberá elegirse un nuevo Presidente cuando el actual:
- Cese en el desempeño del cargo que conlleva ser miembro permanente.
- Solicite ser relevado de la presidencia.

3.3. Funciones del Presidente

- Ostentar la representación del órgano.
- Acordar la convocatoria de las Sesiones y fijación del Orden del Día.
- Presidir las Sesiones, moderar los debates y suspenderlos por causas justificadas.
- Dirimir con su voto los empates.
- Asegurar el cumplimiento de las Leyes y lo dispuesto en el presente Reglamento.
- Visar las Actas y certificaciones de los acuerdos de la Comisión.
- Ejercer el resto de funciones que sean inherentes a su condición de Presidente.
- Si la Comisión así lo decidiera, en caso de ausencia o enfermedad, sería sustituido por otro miembro de la misma.
- Responder a las solicitudes o sugerencias realizadas a la Comisión, tras consultar con los componentes de ésta.

4. Secretario

4.1. Elección del Secretario

- Se elegirá preferentemente entre los miembros de la Comisión.
- Se elegirá preferentemente por acuerdo o por votación si fuera preciso.

4.2. Renovación del Secretario

- Deberá efectuarse una renovación cada dos años, pudiendo ser reelegido.
- Además, deberá elegirse un nuevo Secretario si los miembros de la Comisión así lo decidieran por mayoría, o si el actual:
- Deja de formar parte de la Comisión.
- Solicita ser relevado del cargo.

4.3. Funciones del Secretario

- Efectuar la convocatorio de las Sesiones por orden del Presidente.
- Recibirá los actos de comunicación de sus miembros.
- Redactará y autorizará las Actas de las sesiones que deberán ser firmadas por los asistentes a las mismas.
- Si no es miembro de la Comisión asistirá a las reuniones con voz y sin voto.

5. Funciones de la Comisión

Las funciones de la Comisión de Garantía y Control de Calidad en Radioterapia son las previstas a desarrollar conforme a lo dispuesto en el art. 2 "Programa de Garantía de Calidad", art. 4 "Comisión de Garantía y Control de calidad en Radioterapia" y art. 5 "Procedimientos en Radioterapia" del Real Decreto 1566/1998, de 17 de Julio.

6. Convocatorias y sesiones

6.1. La Comisión de garantía y Control de Calidad en Radioterapia se reunirá con carácter ordinario, al menos una vez al trimestre, y con carácter extraordinario siempre que lo solicite alguno de sus miembros.

6.2. Los acuerdos se tomarán preferentemente por consenso. En el caso no deseable que hubiera que recurrir a la votación, el acuerdo será tomado por mayoría de votos. En caso de empate el Presidente de la Comisión tendrá voto de calidad.

6.3. No podrá ser objeto de deliberación o acuerdo ningún tema que no está en el Orden del Día a no ser por acuerdo de la mayoría de asistentes se decida la urgencia del mismo.

6.4. La Comisión podrá convocar a una o varias sesiones, como asesores, a los profesionales que acuerde previamente, en función de su especial conocimiento o dedicación a los temas a tratar.

6.5. De cada Sesión que celebre la Comisión se levantará Acta por el Secretario en la que se especificará los asistentes, el orden del día, los puntos principales de las deliberaciones y el contenido de los acuerdos adoptados.

6.6. Se podrá formular voto particular por escrito en el plazo de 48 horas que se incorporará al texto del Acta.

6.7. En la siguiente reunión que se realice será aprobada o modificada, según proceda, el Acta de la anterior reunión, siendo ello incluido siempre como primer punto del orden del día. El

Secretario podrá emitir certificación sobre los acuerdos que se hayan adoptado sin perjuicio de la aprobación posterior del Acta, debiendo hacerse constar en este caso específicamente en la misma.

7. Norma final

El presente Reglamento estará supeditado a la normativa que, en su caso, se vaya dictando en materia de Control de Calidad en Radioterapia.

IAEA-CN-85-89

RADIOLOGICAL PROTECTION OF PATIENTS IN GENERAL DIAGNOSTIC RADIOLOGY

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Abstract

With medical radiation exposures to mankind ranking the highest among man-made radiation, radiation protection safeguards have to be put in place in all countries. Competent authorities should have the legal legislation and adequate infrastructure to ensure implementation, enforcement and compliance with the radiation protection standards. Justification, optimization, quality assurance and control are to be the guiding ideals for those who prescribe and/or carry out radiographic procedures. Radiation dose limitation in medical practices is to be encouraged so far as it does not compromise image quality and the provision of a direct benefit to the exposed individual.

1. Introduction

Medical exposures contribute the highest man-made doses to the world population. When risk of medical irradiation is compared with the risk from other sources of man-made exposures or from natural background radiation, the doses received in medicine range over four orders of magnitude (1) .Through out the world, there is over use of diagnostic radiology, and in developing countries the economic aspect of unnecessary radiology is significant. Patients have come to believe that no examination by their doctor is complete unless they have been "x-rayed" (2) . The actual procedure is satisfying because it is usually dramatic, yet causes little discomfort or inconvenience. There is, therefore, great need for radiological protection of patients in diagnostic radiology.

1. Justification of medical exposures

Medical exposures should be justified by weighing the diagnostic benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure (7).

The decision as to whether an examination involving a certain radiation dose to patient is justified is the responsibility of the physician requesting the examination or of the practitioner who carries out the procedure.

In all cases, the practitioner shall satisfy himself that the necessary information is not already available from other previous examinations and investigations or that equal information could not be obtained at a lesser risk from investigations using other techniques (8).

There is therefore no need to request for a radiological examination without determining whether a similar examination had been performed. Any previous radiographs are part of the patients' record and are essential when interpreting the new examination. A proper storage and retrieval system is essential for the efficient use of radiology and contributes to the limitation of unproductive examinations (2).

In order to prevent unnecessary exposures, no practice involving exposure to ionizing radiation shall be authorized by the relevant competent authorities unless the introduction of the practice produces a positive net benefit (3).

2. Optimization of protection for medical exposures:

The design, plan, and subsequent use and operation of sources and practices shall be performed in a manner to ensure that exposures are as low as reasonably achievable (3)

2.1. The x-ray equipment should be so designed to ensure that: -

a) failure of a single component of the system is promptly detected to avoid unplanned exposures to patient.
b) there is minimal human error in the delivery of exposures.
c) they conform to the International Electrotechnical Commission (IEC) standards and the ISO standards.
d) operating terminology and values are displayed on operating consoles in a language understood by the user.
e) radiation beam control mechanisms are provided.
f) exposure rates outside examination area are as low as reasonably achievable.
g) the devices automatically terminate irradiation after a preset time (7).

2.2. The medical practitioners who prescribe or conduct radiological diagnostic examinations should ensure: -

a) exposure to the patient be the minimum necessary to achieve the required diagnostic objective.
b) whenever feasible, shielding of radiosensitive organs is provided.
c) highest kV_p that permits good diagnostic image is used.
d) faster intensifying screens are used.
e) use of carbon fiber cassette fronts and table tops. Patients dose is reduced to as much as 50%.
f) Use of tight collimation. This means a smaller irradiated area and less risk to the patient. Good collimation also improves image quality.
g) Proper beam filtration. Addition of a proper amount of filtration to the x-ray tube offers reduced patient exposure.
h) For pregnant patients, any procedure which exposes the foetus to the direct beam is delayed to the third trimester or if possible after completion of pregnancy (8).

3. Quality control and quality assurrance of radiographic equipment:

Quality Assurance (QA) is a program to produce high quality radiographs with minimum cost and minimum patient exposure. Quality Control (QC) is the routine measurement of the physical parameters of the various components of the x-ray imaging system. The major components are the x-ray generator, the x-ray tube and image receptor, the image processor and ancillary equipment (6).

Regulatory Authorities should establish procedures for quality assurance to ensure maximum protection to patient. In Kenya for example, this is carried out by the 'The Radiation Protection Board', the competent authority that keeps a record of all radiation facilities in the country. The program determines when maintenance or repairs are required in order that a facility may continue to produce high quality radiographs with minimum patient exposure.

Various test tools are used to evaluate parameters like Kvp accuracy, mAs reciprocity, focal spot size evaluation, x-ray beam alignment, Half Value layer (HVL).

3.1. The quality assurance programme ensures that:

a) planned and systematic actions aimed at providing adequate confidence that the specified design and operational requirements related to protection and safety of patients are satisfied (7).
b) production of optimum quality radiographs, increasing patient safety (9)
c) accurate and reproducible performance of the x-ray generator_and ancillary equipment ensuring a consistent technique chart thus reducing radiographic errors (9)
d) unnecessary exposures due to improper film development (10) or a faulty x-ray machine are avoided.
e) There is no variation of the machine output, ensuring that the patient is not needlessly overexposed (8)

Quality control tests should be performed periodically to ensure continued good performance, equipment initially installed in good condition and proper calibration can deteriorate over time, and very often this deterioration is so gradual that it is only detected when QC checks are made. [(8)]

4. Qualified radiographic staff

In some hospitals and other institutions, doctors or nurses who have no radiographic qualifications are obliged occasionally to make an x-ray examination. Responsibility for ensuring that this does not happen lies with the competent authorities. In Kenya, for example, this is safeguarded by the establishment of the Radiation Protection Act, 1982. The Act in section (9) states that "No person shall cause ionizing radiation to be applied to any other person for the purpose of diagnosing or treating a disease unless the application is prescribed by a medical or dental practitioner registered under the Medical Practitioners and Dentist Act. No person shall administer ionizing radiation to another person unless he is in possession of a valid licence issued under the Act" (4).

If the x-ray operator is not well trained, he may make a mistake in setting the various controls on the x-ray unit or in positioning the patient, resulting to unnecessary repeat x-ray (10), and even to over exposure of patients.

A properly informed radiographer is able not only to help reduce the radiation risk to the patient, but also help soothe any unnecessary fears that might arise (8)

The practitioner should have adequate training in the field of radiation protection accepted by the competent authority (5).

5. Dose limitation in medical exposures

Medical exposures are usually intended to provide a direct benefit to the exposed individual. If the practice is justified and the protection optimized, the dose in the patient will be as low as is compatible with the medical purposes (11).

When the examination is directly associated with illness, the dose limitation system can be applied, except for the dose limits.

In each individual case of exposure, the individual who is to be exposed to the risk is also the individual who has the benefit of examination. The limit is therefore not required because the outcome of the justification and optimization procedures should always be in the best interest of the individual incurring the risk at any level of dose (3).

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IAEA-CN-85-273

RADIOTHERAPY PROCEDURES QUALITY CONTROL PROGRAM: GUIDELINES ESTABLISHED BY THE SPANISH SOCIETY OF RADIOTHERAPY AND ONCOLOGY

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Abstract

The main purpose of the Royal Decree 1566/1998 of July 17 th, is to establish the quality criteria in radiation therapy in order to assure the optimisation of both radiation oncology treatments and radiation protection of the patients. According to this decree, the implementation of a quality control program in the radiation oncology departments is imperative. This program must be in writing and always available for supervision of health authorities. When necessary, modifications to improve non-optimal procedures or equipment will be made. The Spanish Society of Radiotherapy and Oncology, in order to co-operate and facilitate to all its members, set up a task force focused on elaborate a set of guidelines that every single Radiation Oncology Department could use to develop its own quality control program. No agreements regarding equipment quality control were made by the Commission, in spite they are a part of the quality control program in radiotherapy, because it is considered that correspond to members of other scientific societies.

1. Introduccion

El objetivo del Real Decreto 1566/1988, de 17 de julio, es establecer los criterios de calidad en radioterapia para asegurar la optimización del tratamiento radioterápico y la protección radiológica del paciente.

En esta norma, se exige la implantación de un programa de garantía de calidad en las unidades asistenciales de radioterapia, que constará por escrito y estará siempre a disposición de la autoridad competente, a efectos tanto de auditoria como de vigilancia. Proponiendo si preciso, medidas correctoras para mejorar las características defectuosas o inadecuadas de las practicas clínicas o del equipamiento.

El programa de garantía de calidad, implica de forma directa a diversos profesionales sanitarios, fundamentalmente especialistas en Oncología Radioterápica, Radiofísicos hospitalarios y personal sanitario que administra los tratamientos radioterápicos.

2. Objetivo

La AERO, a efectos de colaborar, coordinar y asesorar a sus miembros, nombró un grupo de trabajo, con el fin de crear un documento base, que sirviera de guión para que cada unidad asistencial de radioterapia, elaborara su propio programa de control de calidad del

procedimiento radioterapeútico, abarcando todas sus etapas clínicas. Igualmente, elaborara un índice general de los apartados recomendados para formar parte del documento en su globalidad.

No se pretendió consensuar otros apartados que deben formar parte del programa de garantía en radioterapia tal como el programa de calidad del equipamiento y programa de mantenimiento, por corresponder fundamentalmente a profesionales representados por otras sociedades científicas.

3. Material y metodo

Se creó un grupo de trabajo constituido por 12 miembros, representantes de todas las autonomías, 11 especialistas en Oncología radioterápica y 1 radiofisico hospitalario. Todos ellos conocedores del estado del arte de la especialidad.

Un miembro ejercía de coordinador y otro de secretario. Se llevaron a cabo 2 reuniones de presencia física, consensuando el resto de opiniones a través de una lista de correo electrónico, mantenida por el secretario de la comisión.

Sirvieron de apoyo básico los siguientes documentos:

- Real decreto 1566/1998, de 17 de julio, por el que se establecen los criterios de calidad en radioterapia.
- Practical guidelines for the implementation of a quality system in radiotherapy. A project of the ESTRO Quality Assurance Committee sponsored by "Europe against Cáncer".
- Normas editadas por el Comité de Expertos en Radioterapia de la "Academia de Ciencias Medicas de Catalunya i Balears".

4. Resultados

En diciembre de 1999, quedo concluido un documento, de 15 paginas, básico y genérico, de forma que pudiese ser guión de todas las unidades asistenciales españolas. Fue remitido por correo a todos los responsables de Servicios de Radioterapia y se encuentra a disposición de la comunidad científica en la secretaria de AERO.

Este documento consta de un *"índice"*, recomendado como guión del programa de garantía y control de calidad en radioterapia en su globalidad y el "*control de calidad de las etapas clínicas".*

4.1. Índice

- Introducción.
- Objetivos Generales.
- Disponibilidades:
    - Descripción del Servicio
    - Personal
    - Organización Jerárquica
    - Utillaje de Radioterapia
    - Utillaje de Radiofísica
- Funcionamiento Asistencial

  - Introducción
  - Descripción del circuito asistencial
  - Carga Asistencial.
- Control de Calidad Radiofisico
  - Aceptación de las Unidades
  - Estado de Referencia
  - Control de Calidad Periódico
- Control de Calidad Clínico

4.2. Control de Calidad de las Etapas clínicas

Quedaron definidas todas ellas, así como su objetivo y el responsable o responsables de cada nivel de actuación. Igualmente aunque sobrepasa el ámbito de esta comunicación, quedaron explicitados los procedimientos a utilizar, los recursos mínimos humanos y materiales necesarios para realizarlos y los programas de control asociados en cada etapa clínica.

5. Etapa clínica nº 1: evaluación inicial

Definición: valoración que realiza el médico especialista en Oncología Radioterápica del estado del paciente, tipo y extensión de la enfermedad y posibilidades terapéuticas aplicables.
Objetivo: obtener los datos que permitan ofrecer la mejor opción terapéutica.
Responsable: médico especialista en Oncología Radioterápica.

6. Etapa clínica nº 2: decisión terapéutica

Definición: etapa clínica en la que el médico especialista en Oncología Radioterápica elige entre las modalidades de tratamiento posibles, aquella cuyos objetivos metodología y desarrollo se adaptan mejor a las necesidades y deseos del paciente.
Objetivo: obtener la opción terapéutica óptima para cada situación clínica y necesidades del paciente con relación a los medios disponibles.
Responsable: médico especialista en Oncología Radioterápica.

7. Etapa clínica nº 3: localización

Definición: etapa clínico-técnica en la que el médico especialista en Oncología Radioterápica delimita los volúmenes blanco y los órganos críticos con sus márgenes correspondientes para la planificación del tratamiento.
Objetivo: definir y delimitar los volúmenes de tejido a irradiar y proteger**.**
Responsable: médico especialista en Oncología Radioterápica.

8. Etapa clínica nº 4: plan de irradiación

Definición: Etapa clínico-técnica en la que se hace la propuesta terapéutica en base a la enfermedad, el estado del paciente, medios disponibles, experiencia y estado del arte de la especialidad. Consta de: Prescripción provisional, calculo, optimización y prescripción definitiva.
Objetivo: Obtener el plan de tratamiento óptimo.
Responsable: médico especialista en Oncología Radioterápica y radiofisico hospitalario.

9. Etapa clínica nº 5: simulación y o verificacion del tratamiento

Definición: reproducción fidedigna y documentada de las condiciones del tratamiento prescrito que se lleva a cabo antes de iniciarlo.
Objetivo: verificar que las características del tratamiento previsto se ajustan a las necesidades del paciente en cuanto a su enfermedad, anatomía y posición en la mesa de la unidad.
Responsable: médico especialista en Oncología Radioterápica.

10. Etapa clínica nº 6: aplicación del tratamiento

1. Irradiación externa o transcutánea o teleterapia

Definición: proceso mediante el cual se lleva a cabo la irradiación terapéutica, reproduciendo en la unidad de tratamiento los parámetros de irradiación y posición del paciente contenidos en el informe dosimétrico y ficha de tratamiento.
Objetivo: reproducir en cada sesión de tratamiento el plan terapéutico previsto y especificado en el informe dosimétrico y ficha de tratamiento.
Responsable: El personal sanitario que administra el tratamiento

2. Braquiterapia.

Definición: Colocación del material radiactivo en el tejido tumoral (Braquiterapia intersticial), en su superficie externa (plesioterapia) o en una cavidad anatómica (endocavitaria), mediante carga inmediata o diferida (manual o mecanizada).
Objetivo: Situar el material radiactivo dentro o lo más cerca posible del tumor, para conseguir una distribución de dosis óptima en relación al tumor y tejidos sanos circundantes.
Responsable: Médico especialista en Oncología Radioterápica.

11. Etapa clínica nº 7: control del tratamiento

1. Radioterapia externa, transcutánea o teleterapia.

Definición: proceso en el que se controla la aplicación del tratamiento, sus características, así como la respuesta de la enfermedad y evolución del enfermo.
Objetivo: controlar la aplicación del tratamiento y la respuesta inmediata del paciente, así como verificar la constancia de los datos anatómicos, para modificar el plan de irradiación cuando se considere preciso.
Responsable: médico especialista en Oncología Radioterápica.

2. Braquiterapia.

Definición: proceso en el que se controla la aplicación del implante, su estabilidad y el correcto funcionamiento del equipo automatizado en cuanto a entrada y salida de las fuentes radiactivas, así como la evolución de la enfermedad y aparición de complicaciones. Al final de la aplicación se retiran las fuentes radiactivas, excepto en los implantes definitivos.
Objetivo: comprobar que el implante se mantiene estable, que no hay averías en los dispositivos de carga diferida que puedan modificar la dosis administrada, así como que no aparecen efectos tóxicos o complicaciones que aconsejen un cambio en la estrategia de tratamiento. Al final del tratamiento, comprobar que el paciente no es portador de fuentes radiactivas no previstas y éstas han sido almacenadas correctamente.
Responsable: Médico especialista en Oncología Radioterápica, Radiofísico hospitalario y operador.

12. Etapa clínica nº 8: evaluación final

Definición: Etapa clínico-técnica en la que se revisan las características de tratamiento administrado y sus efectos sobre la enfermedad, los tejidos sanos y el estado del paciente.
Objetivos: comprobar las eventuales variaciones entre el tratamiento prescrito y el administrado, su justificación, y valorar la respuesta al tratamiento y sus posibles toxicidades.
Responsable: médico especialista en oncología radioterápica.

13. Etapa clínica nº 9: seguimiento del paciente después del tratamiento

Definición: Etapa clínica en la que se valora la evolución de la enfermedad, y los posibles efectos tóxicos agudos, y la eventual aparición de efectos tóxicos tardíos.
Objetivos: Valorar la eficacia del tratamiento administrado.
Responsable: médico especialista en oncología radioterápica.

Este documento, cuyo resumen hemos expuesto, fue remitido a todos los responsables de Servicios de Oncología Radioterápica de la nación y se encuentra a disposición de la comunidad científica en la secretaria de AERO.

FINAL REPORT FROM THE SPANISH SOCIETY OF RADIOTHERAPY AND ONCOLOGY INFRASTRUCTURES COMMISSION ABOUT DEPARTMENT STANDARDS RECOMMENDABLE IN RADIATION ONCOLOGY

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Abstract

The publication of the Royal Decree 1566/1988 of July 17th, about Quality Assurance and Control in Radiation Therapy, mandates the elaboration of protocols in Radiation Therapy. Those protocols must contemplate necessarily the material and human resources necessary to implement a quality practical radiation therapy, that is according to law. In order to establish norms regarding human and material resources, it is necessary to establish beforehand some patient care standards, that serve as a frame of reference to determine the resources needed for each procedure. Furthermore, the necessary coordination of resources, material and human, that has to be present in a correct patient care planning mandates the publication of rules that are easy to interpret and follow up. In this direction, both editions of the "Withe Book of Oncology in Spain", the "GAT Document for Radioterapy", and the rules edited by the Committee of Experts in Radiation Therapy of the Academy of Medical Sciences of Catalunya and Balears, have represented an important advance in the establishment of these criteria in Spain. The Spanish Society of Radiation Therapy and Oncology (AERO), in an attemp to facilitate to all its associates and the health authorities some criteria for planning and implementing resources, requested its Commission of Infrastructures the elaboration of a set of rules to determine the necessary resources in each radiation therapy procedure. The objective of this document is to establish some recommendations about the minimal necessities of treatment units and staff, determining their respective work capabilities, to be able to develop a quality radiation therapy in departments already existing. Summarizing, it is intended that the patient care is limited in a way that quality is not affected by patient overload. Also tries to offer the Public Administration some planning criteria useful to create the necessary services od Radiation Oncology, with the adequate resources, which will bring a suppression of the waiting list in our speciality, in the rational distribution of resources, in the optimization of treatments and in the radiation protection of our patients.

1. Introducción

La publicación del R. D. 1566/1998 de 17 de julio, de Garantía y Control de Calidad en Radioterapia, obliga a la elaboración de unos procedimientos en radioterapia. Estos procedimientos deben contemplar necesariamente los recursos materiales y humanos precisos para la realización de una radioterapia práctica de calidad y ajustada a la legislación.

Para poder marcar unas normas respecto a recursos humanos y materiales es preciso que se establezcan antes unos estándares asistenciales que sirvan de marco referencial para la determinación de los citados recursos, necesarios para la realización de cada procedimiento. Por otra parte, la necesaria ordenación de recursos materiales y humanos que se debe producir en una correcta planificación asistencial obliga a la publicación de unas normas claras. En este sentido, las dos ediciones del "Libro Blanco de la Oncología en España", documento "GAT

para la Radioterapia" y las normas editadas por el Comité de Expertos en Radioterapia de la "Academia de Ciencias Medicas de Catalunya i Balears" han supuesto avances importantes en el establecimiento de estos criterios para España.

La "Sociedad Española de Radioterapia y Oncología (AERO)", en un intento de facilitar, a todos sus asociados y a las autoridades sanitarias unos criterios de planificación y ordenación de recursos, sugiriendo cuales deben ser los límites de cargas de trabajo para desarrollar una radioterapia de calidad, ha solicitado al "Comité de Infraestructura de la AERO" la redacción de unas normas para la determinación de recursos en cada procedimiento en radioterapia, que sirvan de guía en la planificación de servicios de Oncología Radioterapia. Con estas normas se pretende que las cargas asistenciales queden limitadas de manera que la calidad no se vea mermada por la sobrecarga asistencial. Se pretende dar a los poderes públicos unas normas que les sirvan no sólo para la planificación, sino también para la auditoria de servicios, si lo consideraran pertinente.

2. Objetivo

Elaborar unas recomendaciones en cuanto a estándares básicos de capacidades de trabajo de unidades y de personal, que permitan ofrecer una actividad médica de calidad, así como, ofrecer unos criterios de planificación que sirvan para crear los necesarios servicios de Oncología Radioterapia, con la dotación adecuada, lo que redundará en la eliminación de las listas de espera en nuestra especialidad y en la ordenación racional de los recursos.

3. Método

Los miembros del "Comité de Infraestructura de la AERO", en sus reuniones de trabajo han aportado, además de su experiencia, las recomendaciones de organismos internacionales, datos publicados en la literatura internacional, así como, las prácticas habituales de los centros de trabajo en los que desarrollan su función.

De forma explícita, este Comisión no emite recomendaciones respecto a las cargas asistenciales de Físicos y Dosimetristas, por considerar que no son de su competencia.

Las recomendaciones que siguen se basan principalmente en la legislación vigente, en el tiempo que requiere todo el proceso asistencial en radioterapia, desde la primera visita hasta el final del seguimiento y fundamentalmente en el documento redactado por el "Comité de Expertos de la Academia de Ciencias Medicas de Catalunya i Balears", al representar un trabajo reciente y coincidente en los objetivos respecto al encargo de la AERO para todo el territorio nacional.

Al igual que en el documento mencionado, esta Comisión de Infraestructura, recomienda en primer lugar y como base de todo el proceso, un escrupuloso cumplimiento de la normativa existente, en cuanto a la garantía de la calidad recogida en la legislación publicada. Así mismo la Comisión hace un especial énfasis en la correcta información a los pacientes y en la indispensable obtención del consentimiento informado previamente al inicio de los tratamientos.

5. Recomendaciones

Se recomienda que la responsabilidad de todas las unidades funcionales de radioterapia, recaigan sobre un Jefe de Servicio. En este sentido, se aconseja a las autoridades sanitarias la creación de jefaturas de servicio en todos los hospitales en que no exista este cargo.

Las etapas del tratamiento radioterápico, contempladas en el anexo 3, del Real Decreto 1966 son responsabilidad exclusiva del médico radioterapeuta. Estas etapas son: Evaluación inicial, decisión terapéutica, localización, plan de irradiación, simulación del tratamiento, aplicación del tratamiento, control del tratamiento, evaluación final y seguimiento del paciente.

6. Unidades de tratamiento

Tiempos estimados:

Los tiempos medios estimados para la realización de cálculos de cargas de trabajo son:
Para la realización de todas las etapas clínicas se calcula un tiempo de 9 a 10 horas por paciente. En este tiempo se computa la dedicación a labores puramente asistenciales, como puede ser la realización de la historia de primer día, el tiempo dedicado a la asistencia a comités para la toma de decisiones, etc. Creemos que es más razonable planificar en base a tiempos globales, pues la determinación de un tiempo para la realización de una historia, además de ser difícil de cuantificar, por depender de muchas variables individuales del paciente no contempla los tiempos dedicados a labores asistenciales, sin que el paciente esté físicamente presente, pero imprescindibles para una radioterapia de calidad. Por otro lado, el manejar una cifra global elimina la planificación basada en una medida de tiempos, como de sí una cadena de montaje se tratara, sin tener en consideración factores humanos y sociales, siempre presentes en las relaciones médico-enfermo.

Respecto a las unidades de tratamiento se calcula que su capacidad está en 4 pacientes por hora de tiempo efectivo de tratamiento. En este cálculo de tiempos se deben excluir todas las técnicas especiales, tales como radiocirugía, tratamientos esterotáxicos fraccionados, irradiaciones corporales totales e irradiaciones cutáneas totales, en las que no se pueden seguir estos criterios de tiempo, por ser técnicas mucho más laboriosas y requerir mas tiempo de máquina de tratamiento.

Idealmente una unidad de tratamiento debe funcionar entre 10 y 12 horas dedicada a tratar enfermos. Menos puede suponer una infrautilización de los recursos. Dedicar más tiempo supone un envejecimiento prematuro de la unidad con aumento de los tiempos de paradas por averías. A este tiempo de tratamiento siempre se debe añadir 2 horas adicionales para los necesarios controles diarios, pausas para descanso del personal, cambios de turnos y cierre de unidades. Por ello, para 10 horas útiles de trabajo se precisan 12 de funcionamiento real y para 12 horas de tratamiento se precisan 14 de funcionamiento real.

Resultados para unidades de tratamiento:

En base a estas cifras, una unidad de tratamiento con un funcionamiento de 10 horas puede tratar a 40 pacientes diarios y con 12 horas a 48 pacientes.

Considerando que a los días útiles de trabajo se debe descontar el 10 % de tiempo útil por averías y revisiones y que la duración media de un tratamiento de radioterapia es de 22 días,

una unidad puede realizar al año tratamientos entre 409 y 491 pacientes, dependiendo de que se siga el criterio de 10 o de 12 horas de trabajo.

Aplicando los datos de incidencia y prevalencia de cáncer, así como, los de porcentaje de pacientes que requieren radioterapia, perfectamente documentados tanto en el "Informe GAT" como en el "Libro Blanco de la Oncología en España", se calcula que debe de existir una unidad de tratamiento por cada 200 - 250.000 habitantes, debiéndose tender a alcanzar la ratio de una unidad por 200.000 habitantes.

Por otro lado, esta cifra debe depender de criterios geográficos, así en áreas de fuerte dispersión de la población podría ser adecuado disminuir el número de habitantes por máquina para no obligar a los pacientes a desplazamientos prolongados para alcanzar el recurso. No obstante, la "Comisión de Infraestructura de la AERO" considera que estas situaciones deben tratarse de manera individualizada, por depender no sólo de la distancia, sino también de las infraestructuras en comunicaciones y facilidades de acceso.

7. Necesidades de personal:

Un servicio no puede dar adecuada calidad asistencial si tiene carencias de personal, lo que provoca sobrecargas asistenciales en los distintos colectivos implicados en los tratamientos, que siempre redundan en una disminución de la calidad asistencial.

Personal facultativo:

Para el cálculo de las necesidades de personal facultativo se debe considerar que el tiempo total dedicado a todo el proceso radioterápico es de 8 a 9 horas por paciente. Si consideramos que la jornada legal anual es de 1645 horas, cada facultativo puede realizar entre 165 a 185 pacientes completos por año.

Teniendo en cuenta que no todo el tiempo del facultativo puede dedicarse a labores asistenciales y que existe unos tiempos de dedicación a labores de gestión para cada estamento medico. Así se recomienda que a la carga asistencial de un facultativo especialista se debe descontar un 20 % que es el tiempo que debe dedicar a labores de gestión y calidad, para un jefe de sección se estima en un 40 % y para un jefe de servicio en un 80 %. De esta manera la capacidad de un facultativo especialista es de 132 a 148. Para un jefe de sección su capacidad será de 99 a 111 y para un jefe de servicio de 33 a 37 pacientes anuales. Si el servicio dispone de área propia de hospitalización se deba añadir un facultativo dedicado a la asistencia de los pacientes ingresados (igualmente no significa que un medico se dedique exclusivamente a la hospitalización, sin que el tiempo que cada facultativo dedica a este trabajo, se debe compensar con la disminución de la carga asistencial).

En los servicios en los que existan tratamientos de braquiterapia se debe añadir un médico por cada unidad de braquiterapia o lanzador de fuente, para los servicios que dispongan de unidades de carga diferida.

Personal no facultativo:
Respecto a personal no facultativo, esta Comisión hace las siguientes recomendaciones:

- 2 puestos de técnico superior en radioterapia (TERT) por unidad de tratamiento y turno de 7 horas de trabajo.

- 1 enfermero (DUE) por turno de trabajo, por cada 3 unidades de tratamiento radioterápico. Como minimo, independientemente de las unidades debe haber un DUE.
- 1 auxiliar de enfermería por cada 3 unidades de tratamiento. Como mínimo, independientemente de las unidades debe haber un auxiliar de enfermería.
- 1 TERT por cada unidad de simulación y turno.
- 1 TERT para el taller de radioterapia (moldes, bloques conformados, etc.).

Un Servicio de Física de las dimensiones adecuadas a la carga asistencial de radioterapia, que como exponíamos en la introducción debe ser definido por los profesionales responsables.

Para el área de consultas se precisa:
- 1 DUE para el área de consultas.
- 1 Auxiliar de enfermería en cada consulta.
- 1 Celador por turno, que debe atender tanto al área de consulta como al de unidades de tratamiento.
- 1 administrativo por cada 700 pacientes nuevos vistos en el servicio. Como mínimo, independientemente de la cantidad de pacientes vistos, de debe disponer de un administrativo.

Respecto a los criterios de reposición de unidades, la AERO recomienda que las unidades se repongan entre los 10 y 15 años de funcionamiento y que la reposición de las unidades de cobalto se haga por aceleradores multienergéticos. Respecto a la carga de las unidades de Cobalto, se recomienda que sea sustituida cuando la actividad se encuentre por debajo de los 3.000 Curios.

Se recomienda que todos los servicios dispongan de simulador virtual o acceso propio a tiempo de TAC y planificador 3D como herramientas fundamentales para poder brindar a los pacientes unos tratamientos con la calidad que estos merecen y de acuerdo al estado actual de la especialidad.

IAEA-CN-85-275

HEALTH REGULATIONS ABOUT RADIATION ONCOLOGY IN SPAIN: THE LEGISLATIVE DILEMMA BETWEEN RADIATION PROTECTION AND TREATMENT OF CANCER

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Abstract

The Royal Decree 1566/1998 of July 17 th establishes the criteria on quality in radiation therapy and is a cornerstone in Spanish regulation of this medical field. The Royal Decree gives some rules that, from a medical point of view, are considered as a good practice. Radiation protection of patients is necessary to achieve a high quality radiation oncology treatments. That is the reason why Royal decree 1566/1998 is titled "quality criteria in radiation therapy". A quality control program must be tailored to every single radiation oncology department and, by this reason, is difficult its standarization. Nevertheless, some medical procedures are defined by the royal decree and such procedures are the minimum criteria that all the departments must follow in the development of its own quality control program. The authors make some reflections about health regulations about radiation oncology in Spain, pointing out that may occur a legislative dilemma between radiation protection and treatment of cancer due to application of the legislative rules. The social and medical cost of rigid bureaucratic procedures is pointed out. A large amount of equipment controls and measurements takes time that could be used in treating patients. This is more important in an environment of limited technical and human resources.

1. Introduccion

El Real Decreto 1566/1998, de 17 de Julio, por el que se establecen los criterios de calidad en radioterapia, marca un hito importante en la visión legal de la radioterapia en nuestro país.

Este decreto esta basado en la normativa europea 84/466/EURATOM, sobre protección radiológica del paciente.

En él se marcan unas normas, que desde el punto de vista medico pueden ser incluidas en la buena praxis. La protección radiológica al paciente se entiende desde el punto de vista medico como indispensable para una radioterapia de calidad, de ahí que el titulo del Real Decreto sea el de "criterios de calidad en radioterapia".

Este decreto entró en vigor al día siguiente de su publicación y se estableció un plazo que expiró el 13 de mayo de 2000 para completar el establecimiento completo del programa de calidad en cada uno de los centros que contaran con unidades asistenciales de Radioterapia.

Un programa de calidad debe incluir una serie de capítulos entre los que se incluye la definición y objetivos del programa, la justificación y optimización de las exploraciones, el funcionamiento del servicio, control del funcionamiento del equipamiento radiológico, vigilancia de la protección radiológica del personal profesionalmente expuesto y del publico en general, formación del personal, auditorias y sistemas de control y procesos no conformes, acciones correctoras, preventivas y de mejora.

Este programa de calidad debe ser adaptado a cada centro y por tanto difícil de sistematizar, pero en la descripción del programa de calidad, por imperativo legal, deben estar contemplados los procedimientos médicos marcados en el anexo III del citado texto legislativo. Estos procedimientos que marcan las normas y pasos de buen hacer radioterápico, si que pueden adaptarse a criterios nacionales y por ello pueden ser redactados por un organismo nacional que dicte unos criterios mínimos de buen funcionamiento en cada una de las etapas clínicas.

Lo anterior, no obstante, además de mejorar la calidad de un servicio, marca una sistemática de trabajo muy bien definida y que no solo exige rigidez en el trabajo, sino también en los recursos que se manejan para cada procedimiento.

Por ejemplo, si no está regulado el equipamiento necesario para realizar una tarea, esta puede ser puesta en funcionamiento con unos recursos mínimos. Ahora bien, si está regulada, su incumplimiento es fácilmente detectable.

Por lo tanto nos encontramos con unas exigencias no solamente de buena calidad, sino también de adecuación de recursos humanos y materiales a cada tarea.

Lo anterior tal vez no haya sido comprendido por la sociedad, con lo que se nos produce un primer conflicto al ser necesario cumplir una ley de calidad, pero debido a que en bastantes casos no se dispone de los medios adecuados, no es posible hacerlo.

Por otro lado, la Ley general de Sanidad de nuestro país, obliga a prestar atención sanitaria a los ciudadanos, y en el caso de que existan medios, pero no sean los adecuados para el nivel de calidad impuesto, ¿es licito no tratar a un paciente, teniendo los instrumentos para hacerlo, pero incumpliendo normas de calidad?.

A este respecto existen 2 comunicaciones a congresos de Radioterapia en la que se pone de manifiesto este problema. En 1993, Escó y cols. presentaron una comunicación al VII Congreso Nacional de Radioterapia titulado: La seguridad radiológica en un acelerador y los tratamientos ¿son compatibles?.

En esta comunicación los autores demostraron que al aumentar los controles técnicos y dosimétricos en un acelerador (al realizarse estos en horario de trabajo) se originan mayores interrupciones en los tratamientos, de manera que solo el 6´9 % de los pacientes, de una muestra de 318 terminan los tratamientos sin interrupciones, frente a un 34´1 % para una muestra de 401 pacientes en un periodo de tiempo en el que las revisiones no eran tan exhaustivas.

Hay que tener en cuenta que los alargamientos en los tiempos totales de tratamiento, es decir la interrupciones, producen una perdida de control de 1´5 a 1´7 % por cada día de tratamiento perdido. Por todo ello, los autores concluyeron que la seguridad radiológica puede comprometer seriamente la seguridad terapéutica de nuestros tratamientos, con lo que vuelva a plantearse el dilema de seguridad radiológica versus seguridad terapéutica como disyuntiva clave en la legislación.

Además en nuestro país la legislación sanitaria es compleja y no es el decreto de calidad el único que nos regula el trabajo. El Real Decreto 1836/99 sobre instalaciones nucleares y

radiactivas de 3 de diciembre de 1999, marca los requisitos administrativos necesarios para la puesta en marcha de una instalación radiactiva, es decir de una instalación de radioterapia.
Estos requisitos legales, comprensibles para evitar daños a los profesionales, pacientes y publico en general, vuelven a presentar un dilema al retrasar la apertura de instalaciones para tratamiento de pacientes con tumores malignos.

En este sentido, en el X Congreso Nacional de Radioterapia, Esco y Col presentaron un trabajo en el que a partir de sus propios datos y de los publicados en la literatura, un acelerador lineal de electrones, es capaz de tratar cada año de funcionamiento unos 327 pacientes con intención curativa, de los que alrededor del 30 % se curaran, es decir, unos 98 pacientes anuales son curados gracias a la irradiación.

Por lo tanto, todo tramite que retrase la puesta en marcha de un acelerador de manera innecesaria tiene un coste social de 98 fallecimientos anuales, con lo que el dilema sanitario vuelve a presentarse, protección radiológica si, pero meditando el coste social que puede suponer la excesiva burocratización y la lentitud en los trámites.

Actualmente existe un proyecto de Real Decreto sobre justificación del empleo de radiaciones ionizantes en el diagnostico y tratamiento de pacientes, con lo que se pretende reducir al máximo la irradiación de los pacientes y sobre todo eliminar la irradiación innecesaria.

De nuevo vuelve a presentarse el dilema, esta norma es necesaria, pero su aplicación excesiva puede llevar a la no irradiación de pacientes, pues aplicada a sus máximos extremos, ¿cómo podemos justificar una irradiación paliativa en un paciente con dolor si el tratamiento con radioterapia no es curativo y el tratamiento con mórficos, más tóxicos, no precisa justificación?.

Con este análisis de la legislación sanitaria mas importante que afecta a la radioterapia no queremos expresar su falta de acierto, únicamente llamar la atención sobre la necesidad de armonizar la protección radiológica del paciente con la posibilidad de tratar a los pacientes y sobre todo con la posibilidad de realizar un tratamiento que también sea efectivo y seguro desde el punto de vista de la curación del tumor o alivio de sus síntomas.

RADIATION PROTECTION PROBLEMS IN THE PRACTICE OF RADIOTHERAPY IN NIGERIA

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Abstract

Many radiation protection problems have been identified in the practice of radiotherapy in Nigeria. The majority of these arise as a result of non-availability of essential equipment. Others are due to breakdown of equipment as a result of lack of spare parts and necessary expertise for maintenance. Recommendations are made for tackling these problems and these include regional cooperation with exchange of human and material resources between institutions.

1. Introduction

The radiation protection of patients receiving radiotherapy involves the accurate delivery of the prescribed radiation dose to the tumour while avoiding as much as possible the irradiation of healthy tissues [1].

In order to achieve these objectives, there must be proper guidelines with respect to the dosimeter, treatment planning, patient positioning, choice of equipment, equipment design and performance, radiation quality assurance and personnel training and experience. For a period of 20-30 years there have been only two radiotherapy centres in the country (both with Cobalt 60 equipment) serving a population of 100 million people. They have largely operated with equipment installed at the time of establishment. The IAEA has over the last 10 years provided some technical assistance to the country for the improvement of radiotherapy services. Two additional government centres will commence operation soon while a private centre was opened over a year ago.

2. Dosimetry aspect

Radiation delivery must involve accurate knowledge of radiation output characteristics from the therapy unit. Radiation output from the equipment must be calibrated regularly at least annually using a more recent international code of practice for absorbed dose determination and the results cross-checked by taking part in the IAEA/WHO Postal Dose Intercomparison using TLD capsules [2]. In addition, the reference or standard ionization chamber with the electrometer in use must be calibrated against a primary standard for various photon energies available in the centre. This dosimetry equipment should be re-calibrated once every two or three years in a standardizing laboratory for accuracy while a constancy check must be performed occasionally using a suitable radioactive source check.

It is also necessary to have a beam data acquisition system for producing isodose charges and evaluation of dose distribution for each treatment condition required in treatment planning procedures. It will be useful to have the beam data linked to a treatment-planning computer.

Presently, dosimetry equipment are not readily available for calibration of radiotherapy equipment and plotting radiation profiles and isodose curves. Radiation output determination from the Cobalt 60 equipment is based in most cases on decay factors from previous calibration and IAEA TLD intercomparison studies.

3. Quality Assurance

Quality assurance is very essential to the safety and effective treatment of patients in radiotherapy. There should be periodic checks on beam symmetry, uniformity and flatness as recommended in the protocols used for the quality control programme [3] [4].

4. Treatment Planning

This involves a consideration of the beam quality, accurate dose delivery, beam directional and modification devices and patient's positioning. There should be a uniform dose distribution to the target colume within 5% [5] [6] variation while every effort must be made to limit radiation dose to surrounding tissues to the minimum levels using beam shaping devices and making allowance in dosimetry plans for tissues with different densities.

Patient's contour and internal structure information must be accurately determined. These can be achieved using a simulator and a CT scanner linked to a computerised treatment planning system. In centres where these are not available, some gadgets like solder and callipers, multi-pin device or pantograph will help limit errors in obtaining patient's outline compared with the use of lead strips.

Each Radiotherapy Department must have essential accessories and good mould room facilities to aid patient's planning, positioning and protection. These include beam directional and modification devices, like beam direction shells, wedges, lead shields. Mechanical and optical alignment devices should be essential parts of every therapy equipment.

The 2 old radiotherapy centres in Nigeria do not have many of these facilities. Radiation plannings are still manually done. There are very few wedges and isodose curves. Radiation planning is done based on clinical parameters only with the risk of some inaccuracy in the definition of the target organ and unnecessary irradiation of normal structures.

5. Limitations in provision and designs of equipment

(a) ***Superficial Therapy:*** There are no orthovoltage and Linear Accelerator for superficial therapy of skin cancers and especially Keloid lesions, which are very common in Nigerians. Therefore, in many cases Cobalt 60 machines are used with boluses to increase skin dose. This gives unnecessary irradiation to normal deep sealed organs.

(b) ***Cobalt 60 Equipment:*** The only working Cobalt 60 machine in Lagos has a solid couch thus precluding undercouch treatment and accurate replication of parallel A-P opposed fields. This may cause wrong areas to be radiated when patient turns.

(c) ***Brachytherapy:***The department uses a curietron machine for the treatment of cervical cancer, which is the second most common female cancer in Nigeria. There are no rectal dose meters to assess correctly doses received during intracavitary insertion. Radiation doses and distribution are determined using plain radiographs to calculate doses to Points A & B. A computer planning system will give more accurate results.

6. Recommendations

(a) Increased technical assistance to third world countries to help acquire essential equipment.
(b) There should be standardization in the design of radiotherapy equipment to ensure good quality and safety compliance and performance.
(c) Spare parts should be widely and readily available for equipment. This is a major problem in third world countries, which rely on importation of equipment from abroad and technical assistance from donor agencies.
(d) There should be good training of local staff to make them self-reliant in the operation and maintenance of equipment.
(e) There is a need to set up a secondary standard Dosimetry Laboratory in the country to calibrate dosimeter, equipment used for radiotherapy equipment.
(f) Regional cooperation and exchange of facilities, equipment and experts between institutions is recommended.

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IAEA-CN-85-45

RADIOLOGICAL PROTECTION IN MEDICINE: CURRENT PROBLEMS IN INDONESIA

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Abstract

Radiological Protection in Medicine: Current Problems in Indonesia. The medical applications of ionizing radiation in Indonesia have been introduced in the early 20th century. Since then it dominates the application of radiation in various fields. By several regulations, the government has tried to control these applications. However, some problems are still persisting. This paper presents the safety-related regulations that in place in Indonesia, authorization status regarding medical applications, the existing problems and the eforts to tackle them. Eventhough the funds are always the scapegoat, it is believed that the real reason for all problems concerning radiation protection in Indonesia is lack of safety culture among the users.

1. Introduction

A German-born Dutch physician introduced the first use of atomic energy in Indonesia in the early 20th century. During the first five decades, the peaceful uses of atomic energy in this country had been dominated by x-ray radiation for medical purposes, both diagnostic and therapy. In the 1960s, this was followed gradually by the use in research and agriculture. The last two decades saw the rapid growth of these uses, including in industry, research, agriculture, and education, as well as in hospitals.

Despite its rapid growth in various aspects, the potential hazard of the use of atomic energy has also been realized from the very beginning. As a matter of fact, activities in radiation safety in Indonesia have been initiated as early as in the middle of 1950s. In recognizing the need to carry out research on the effect of radiation on man in the light of the bombing of Hiroshima and Nagasaki with atomic weapon, the government at that time established the Committee for Study on Radioactivity.

The highest regulations concerning the execution of the use and control of nuclear energy in Indonesia at present is Act No. 10 Year 1997 on Nuclear Energy. This Act supersedes the Basic Stipulations of Atomic Energy Act of 1964 which was then found to be inappropriate due to the development in times and continuing progress in science and technology in the use of nuclear energy.

Article 16 of the 1997 Act states that any activity related to the utilization of nuclear energy shall maintain the safety, security, peace, health of the workers and the public, and protection of the environment. According to this article, therefore, the safety provisions need to be further regulated, including the provision for radiological protection in medicine.

The new Act also separates the authority in executing and controlling of nuclear energy into two different institutions to avoid the overlapping of activities on the use and control, as well as to optimize the control of nuclear energy in order to improve nuclear safety. The function of execution is given to an executing body, which is called the National Nuclear Energy Agency (BATAN), whereas the function of control is given to a regulatory body called the Nuclear Energy Control Board (BAPETEN).

2. Regulation

In the regulation system in Indonesia, the government regulation has the second power after the Act. To implement article 16 of the 1997 Act No. 10 of Nuclear Energy, Government Regulation No. 63 Year 2000 has been enacted. This regulation, which stipulates the safety and health against the utilization of ionizing radiation, replaces Government Regulation No. 11 Year 1975 on the Working Safety Provisions against Radiation.

The scope of the government regulation No. 63 Year 2000 includes the requirements for dose limitation system, radiation safety management system, calibration, preparedness and countermeasures for radiological accident. In the radiation safety management system, the owner shall apply and establish radiation protection organization, radioactivity and radiation dose monitoring, radiation protection instrument, health examination of workers, document record keeping, quality assurance and education and training.

Concerning the radiological protection for patient, article 6 of the regulation states that "in applying doses for diagnostic and therapeutic medical purposes, the owner shall consider the patient protection against ionizing radiation pursuant to article 3 item (a) and (c)". Article 3 itself states that "(a) any utilisation of nuclear energy shall produces benefit to offset the radiation harm that it might cause, (b) the radiation dose received by workers or member of the public shall not exceed the dose limit specified by the regulatory authority, and (c) any utilisation of nuclear energy shall be designed and radiation sources shall be designed and operated so that the magnitude of radiation exposures be kept as low as reasonably achievable".

Concerning calibration, article 30 clause (1) and (2) of the regulation states that "the owner shall calibrate its radiation survey instrument regularly at least once a year" and "the owner shall calibrate its radiotherapy machine output regularly at least once in two years". Further guidance has been enacted in 1991 by BATAN before BAPETEN was established. Director General of BATAN Decree No. 84 Year 1991 regulates the responsibility of the owner concerning calibration and radionuclide standardization, level and responsibility of calibration facility, and certification and tag of calibration and standardization. This decree will soon be revised by BAPETEN.

3. Authorization status

The authorization system in Indonesia is applying only the licensing scheme. By this scheme, all legal person utilising nuclear energy shall apply for license from the regulatory authority. The license will be granted if the person meet five requirements, mostly related to safety, stipulated in Government Regulation No. 64 Year 2000 on the Licensing for Utilisation of Nuclear Energy. This new regulation replaces the old one stipulated in 1975 (i.e., Government Regulation No. 12 Year 1975 on the Licensing of Radioactive Materials).

In the field of medical, by the end of December 1999 there were 1307 licenses have been granted. These consist of 40 licenses for therapy application (8 linear accelerators, 28 radioisotopes and 14 X-ray machine), 12 for diagnostic application with radioisotopes, 1197 for diagnostic X-rays, and 58 for storage of radioisotopes.

The application of radiation in the field of medical is in fact the highest among other fields. By the end of December 1999, the licenses granted to all other application were 464, consists

of 234 licenses for radiography, 82 for gauging, 21 for logging, 26 for chemical analysis and 101 for various others.

4. The problems

Problems encountered in radiological protection in the medical application of radiation in Indonesia can be categorised as administrative-related and technical-related. From administrative point of view, as much as 905 licenses for hospitals have been expired by the end of January 1999. In the same time, calibration certificates for output of 19 therapy units have also expired and 11 therapy units were operated without license. In addition, calibration certificates for radiation survey instrument in most hospitals were expired as well, and even some hospitals have no instrument at all.

From technical viewpoint, inspection conducted during 1999 to some hospitals in four provinces revealed that most hospitals have no logbook on the therapeutic irradiation for patient. In addition, record keeping of occupational doses was not maintained and there were no health examination carried out for the workers.

5. Efforts to tackle the problems

Before BAPETEN was established, control of utilisation of nuclear energy in Indonesia was carried out by BATAN. BATAN and Department of Health were actually set up a Joint Commission in 1991 to tackle the problems encountered in the medical applications of radiation. Every year this commission gave recommendations to hospitals concerning radiation control. The Directorate General of Medical Services of the Department of Health has regularly also released memorandum to hospitals concerning radiological safety. However, all these recommendations made by the Joint Commission, as well as memorandum from the Department of Health, were ignored by most hospitals. The ignorance was thought to be rooted from behaviour, responsibility, communication and administrative bureaucracy. In order to tackle the above-mentioned problems, several efforts have been conducting by the BAPETEN since the middle of 1999. Persuasive approach was started with the hospitals by letters and dialogue, rather with punishment as stipulated in the 1997 Act. This approach was quite successful, since some the hospitals beginning to realize the importance of license and then extended their licenses.

Recently the controlling part of joint commission of BATAN-Department of Health was updated and become an MoU between BAPETEN and Department of Health on building and controlling nuclear energy in the field of medicine. This new joint commission will focus their tasks on calibration of various radiation instruments used in hospitals and other medical institutions, as well as on other safety-related problems.

BAPETEN is at present also developing some safety-related guidance to various applications. Two of them that related to radiological protection in medicine are guidance on dose levels for diagnostic radiology for patient and guidance on safety standards for the application of radiotherapy instrument. These guidances are still in preparation and planned to be ready by the beginning of next year.
The data from Department of Health also revealed that all over Indonesia there are only five radiophysicists, or medical physicists, in duty in hospitals. These medical physicists were not the real ones, since they are actually radiographers that trained specifically in medical physics after working for more than 10 years.

To cope with the lack of medical physicists, Physics Department of the University of Indonesia, in collaboration with Faculty of Medicine, BATAN and Department of Health, since 1998 have been running interest on medical physics. Students must pass 105 credits on physics before voluntarily choosing medical physics. Number of credits to finish study on physics are 144, so that subjects related to medical physics to be passed are 39.

In spite of several actions carried out by BAPETEN, some problems are still persisting. In the calibration of output therapy machine, for example, the one who pay the cost actually government, not the hospitals themselves. When BAPETEN asked the hospitals why they did not calibrate their output machine, they just simply said that they have no money for it. BAPETEN was then asked for extra budget to the government, which luckily agreed, to perform this calibration. What will happen in two years time, when the hospitals need to recalibrate their output and the government has no more money? Fund is also the reason why radiation workers in some big government hospitals are not personally monitored. To make it worse the situation, facility within the Department of Health that gives personal radiation monitoring services is also facing the same problem, not enough funds to monitor all radiation workers in government hospitals.

A medical physicist is known to be needed by hospitals. However, hospitals in Indonesia are still not interested to recruit medical physicist. The tasks of physicists at present are handled by radiographers. The medical physicist who will soon graduate are still not certain whether they can work at hospitals, since it is still not compulsory for the hospitals to recruit medical physicist to perform the physics-related tasks in hospitals.

6. Concluding remarks

The problems in radiological protection in medicine in Indonesia are quite complicated. Fund is always the scapegoat for the problems, but it is believed that it is not the real reason. The main reason is thought to be caused by the lack of behaviour and responsibility toward safety, or in short safety culture, among the users, as well as communication between parties involved in the radiation safety and the existing administrative bureaucracy. The government, particularly BAPETEN as the regulatory authority, therefore, shall continuously promoting safety culture and communication to achieve the highest standard in safety among the users of radiation in Indonesia.

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