IAEA-TECDOC-1641

Patient Dose Optimization in Fluoroscopically Guided Interventional Procedures

Final report of a coordinated research project

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PATIENT DOSE OPTIMIZATION IN FLUOROSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES

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INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2010

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PATIENT DOSE OPTIMIZATION IN
FLUOROSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES
IAEA, VIENNA, 2010
IAEA-TECDOC-1641
ISBN 978-92-0-100510-6
ISSN 1011-4289

Printed by the IAEA in Austria
January 2010

FOREWORD

In recent years, many surgical procedures have increasingly been replaced by interventional procedures that guide catheters into the arteries under X ray fluoroscopic guidance to perform a variety of operations such as ballooning, embolization, implantation of stents etc. The radiation exposure to patients and staff in such procedures is much higher than in simple radiographic examinations like X ray of chest or abdomen such that radiation induced skin injuries to patients and eye lens opacities among workers have been reported in the 1990's and after. Interventional procedures have grown both in frequency and importance during the last decade.

This Coordinated Research Project (CRP) and TECDOC were developed within the International Atomic Energy Agency's (IAEA) framework of statutory responsibility to provide for the worldwide application of the standards for the protection of people against exposure to ionizing radiation. The CRP took place between 2003 and 2005 in six countries, with a view of optimizing the radiation protection of patients undergoing interventional procedures.

The Fundamental Safety Principles and the International Basic Safety Standards for Protection against Ionizing Radiation (BSS) issued by the IAEA and co-sponsored by the Food and Agriculture Organization of the United Nations (FAO), the International Labour Organization (ILO), the World Health Organization (WHO), the Pan American Health Organization (PAHO) and the Nuclear Energy Agency (NEA), among others, require the radiation protection of patients undergoing medical exposures through justification of the procedures involved and through optimization. In keeping with its responsibility on the application of standards, the IAEA programme on Radiological Protection of Patients encourages the reduction of patient doses. To facilitate this, it has issued specific advice on the application of the BSS in the field of radiology in Safety Reports Series No. 39 and the three volumes on Radiation Protection with Newer Imaging Techniques recently produced. In addition it has embarked on a series of CRPs, of which this is one, and which add to those already available in radiology, mammography and computed tomography (CT). This series of TECDOCs is a further contribution to the resources provided by the IAEA in support of implementation of the BSS.

The International Action Plan for the Radiological Protection of Patients, approved by the General Conference of the IAEA in September 2002, requires that: "The practice-specific documents under preparation should be finalized as guidance rather than regulations, and they should include input from professional bodies, from international organizations and from authorities with responsibility for radiation protection and medical care."

This TECDOC is prepared and issued in this spirit. It provides useful advice for those involved in one of the more dose intensive areas developing in radiology today. The present publication is based on the results of the groups who participated in the coordinated research project.

The IAEA officer responsible for this publication was M.M. Rehani of the Division of Radiation, Transport and Waste Safety.

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1. INTRODUCTION

1.1. BACKGROUND: THE UPSURGE OF INTERVENTIONAL PROCEDURES

The Fundamental Safety Principles [1] and the International Basic Safety Standards for Protection against Ionizing Radiation (BSS) [2] issued by the International Atomic Energy Agency (IAEA) and co-sponsored by the Food and Agriculture Organization of the United Nations (FAO), the International Labour Organization (ILO), the World Health Organization (WHO), the Pan American Health Organization (PAHO) and the Nuclear Energy Agency (NEA), among others, require the radiation protection of patients undergoing medical exposures through justification of the procedures involved and through optimization. In keeping with its responsibility on the application of standards, the IAEA programme on Radiological Protection of Patients encourages the reduction of patient doses. To facilitate this, it has issued specific advice on the application of the BSS in the field of radiology in Safety Report Series No. 39 [3] and three volumes on Radiation Protection with Newer Computed Tomography (CT) Imaging Techniques are being processed. In addition it has embarked on a series of CRPs, of which this is one, and which add to those already available in radiology, CT [4] and mammography [5]. This series of TECDOCs is a further contribution to the resources provided by the IAEA in support of implementation of the BSS.

The BSS [2] and International Commission on Radiological Protection (ICRP) publication 73 [6] promote the application of the basic principles of radiation protection, among which, the need to perform radiological examinations with a minimal dose to the patient, while maintaining adequate image quality. From 2002 to 2006 six countries participated in a research project initiated by the IAEA to study radiation absorbed dose to the skin of patients from fluoroscopic procedures. The initiative for this study stemmed from reports of occasional but severe radiation skin injury in patients undergoing complex fluoroscopically guided interventions [7-9]. Skin injury is recognized as a potential complication to the rapidly proliferating complex fluoroscopically guided procedures that are known to involve long fluoroscopy times and sometimes multiple runs of serial imaging, considerably in excess of standard diagnostic procedures. Even so, many interventionalists still do not acknowledge that skin injuries have occurred or could occur. Such denial has lead, in many cases, to uncertain and ill-directed care for some patients.

As the popularity of these procedures increases, several concerns should be addressed. The first is that the number of incidences of severe skin injury will increase unless proactive efforts are introduced to identify the root causes of the injuries and to curb their occurrence. The second is that more complex procedures will be developed and this could lead to a greater proportion of procedures resulting in severe injury. Thirdly, it is also expected that such procedures will continue to expand not only in number but also in localities where they are performed, introducing the probability that these procedures will be attempted with equipment not well designed for dose conservation.

In light of the above concerns, it was deemed important to assess the potential for unusually high skin doses in a variety of countries in an effort to understand the potential causes and factors behind radiation skin injury and provide lessons so as to avoid them. The purpose is to provide data that will assist physicians in identifying

the factors that increase the risk for skin injury. The goal is to reduce risk by offering advice on awareness and on actions that can be taken to reduce the likelihood of such complications.

1.2. RISKS ASSOCIATED WITH PATIENT DOSE

The use of ionizing radiation for fluoroscopically guided interventions introduces two principal types of known additional risks during medical care. The first is the stochastic risk of induced neoplasia. The second is deterministic risks for effects in superficial tissues such as the skin or the lens of the eye. Another kind of stochastic risk associated with ionizing radiation is that of heritable genetic risks passed on to descendants. This risk applies only to patients who will parent future offspring. Common sense would suggest that reproduction within the population of interventional patients is far lower that that of the general population by virtue of the age and health status of many interventional patients.

Risks associated with the use of ionizing radiation to treat patients with exigent medical needs deserve considerations that are quite different from the risks associated with exposure to a population of healthy individuals. For example, when a patient is in near-term peril of death due to his condition, the long term risks associated with exposure to radiation pale against the immediate benefit of the procedure. This is the case, for example, with a 65-year-old patient with severe coronary stenosis. On the other hand, a population of healthy patients undergoing a screening examination to search for non-symptomatic incipient disease, as with screening mammography, deserves a different consideration because the majority of the screened population has a long term healthy life ahead of them. In other words, to decide on the beneficial effectiveness related to the use of ionizing radiation, it is necessary to obtain a realistic assessment of the risk in relation to the health status of the individual who is undergoing the procedure and in relation to the anticipated benefits of that procedure for that individual. This assessment includes the age, sex, health status, and life expectancy, taking into account the medical condition and treatment. The triple aspect of 1) assessing risk of ionizing radiation in relation to the specific medical status of an individual patient, 2) assessing the prognosis of the patient in the absence of its use, and 3) placing all risks in perspective against the anticipated benefits of the medical procedure are often omitted when discussing the benefits versus risks of medical ionizing radiation.

1.2.1. The impact of stochastic risks on medical care

A typical kerma-area-product (KAP) of 80 Gy.cm^2 for a percutaneous transluminal coronary angioplasty translates into an associated effective dose of about 20 mSv [10]. Using some of the most recent risk assessments [11] for a 60-year-old patient, the risk of developing cancer from that procedure is about 0.1 %. In other words, given 1000 patients who undergo this procedure, one patient might develop cancer from it many years later, whereas 999 are likely to experience no carcinogenic effect. In all 1000 patients the benefits depend on the success of the procedure in improving the quality of their lives and in prolonging their lives, but these benefits are expected in the near term. For younger patients the risk for the same KAP is greater and about 4 times greater for a child of age 10 years. Limiting radiation dose from interventional procedures is therefore an important goal to improve the near- and the long term benefits for the individual patient. The goal of radiation management in relation to

stochastic effects is therefore to improve the overall medical care for the entire population of patients, but it has a reduced impact on the care of any one patient, due primarily to the temporal patterns of near- and long term benefits versus long term risks from the radiation.

1.2.2. The impact of deterministic effects on medical care

The primary deterministic risk from fluoroscopically guided interventional procedures is injury to the skin. While severe skin injury is rare, the near-term impact on the patient and the patient's family, as well as on the medical profession, can be very severe. For the patient, the consequences can include relatively prompt onset (a few days to a few weeks) of long term pain and suffering with loss of mobility and income, leading to severe depression in some cases. Some patients have developed a dependency on their medications. For the family, there is a loss of resources to assist them as their energies become focused on wound care. The long term conditions have lead to clinical depression for some family members. Inevitably, these events have lead to law suits seeking financial damages as a result of the injury. Not only are physicians and health care facilities at risk for financial losses, the reputations of physicians and facilities are also at risk. The actual percentage of cases that result in mild to severe skin injury is not known and is thought to be very low. Some have estimated less than one case in 10,000 procedures. Hundreds of cases have been reported in professional journals or in public legal documents. Because injury can occur soon after a procedure and can have a severe detrimental impact on quality of life, limiting radiation to prevent injury for individual patients is an important near-term consideration in the benefit/risk assessment for that patient.

1.2.3. Practical aspects of limiting radiation delivery to the patient

For complex fluoroscopically guided interventional procedures, the management of procedures to conserve the application of radiation is essential to minimize the risk of injury. This concept takes on a wide variety of perspectives because it must be adapted to the wide variety of equipment and environments that might be employed for these procedures. Understanding the limitations of equipment while limiting radiation delivery from the specific equipment used in the procedure is an important goal to keep risk low. Additionally, understanding the characteristics of the patient and of the procedure that can lead to injury is another essential factor in assisting the physician in radiation management.

While some machines might be equipped with dose monitoring devices, many are not. To assist physicians in dose management, monitoring dose to the patient is essential. Understanding the advantages and limitations of dose measuring features as available in the machine is critical to dose optimization. Understanding how to monitor dose in the absence of integral devices is another important challenge.

Finally, the training of the individual in the performance of a procedure is an essential factor in optimization. Experience contributes to the efficient completion of a procedure and is important in the optimization of the benefit-risk ratio.

1.3. THE EVOLUTION OF REGULATION, TECHNOLOGY, AND MEDICAL PROCEDURES

In the early part of the 20th century, injury from fluoroscopy occurred in patients initially as a result of ignorance about the effects of radiation and as a result of the primitive devices used after the discovery of X rays in 1895. In the 1930s through the 1950s, fluoroscopically guided intervention of pulmonary tuberculosis was a popular treatment. The idea was to collapse the infected lung and essentially starve the disease of oxygen. To do this, the artificially induced pneumothorax was monitored to ensure that the collapsed lung remained so. This involved frequent and numerous fluoroscopic studies of the lungs of the same patient that extended over a period of many days to weeks, and sometimes to months. Typically, the fluoroscopic beam entered the patient's chest anteriorly and the image was viewed on a flat fluorescent screen located posteriorly [12]. Since absorbed doses to patients' chests accumulated with each procedure, some patients had a sufficiently high skin dose to cause radiation skin damage. Many women later developed breast cancer from the breast doses [13].

These events led to demands for improved radiation management through better equipment. Regulatory agencies were authorized to oversee the manufacture of equipment with the intent of improving the safe use of medical radiation, including fluoroscopy. Improvements in technology and the introduction of regulation lead to a marked decrease in the occurrence of skin injury from fluoroscopy. By the 1970's, reports on radiation-induced skin injury in patients had disappeared except for circumstances where the machine was modified to eliminate safety features which then lead to injury [14] and in one instance of an interventional procedure in the hand that lead to skin sloughing and bone necrosis [15].

In subsequent decades, after new treatments using antibiotics eliminated the demand for artificially induced pneumothorax procedures, the lessons learned about radiation injury were largely forgotten. The rarity of the occurrence of injury from properly operating machines subsequently lead to a false impression that medical fluoroscopy was safe from any threat of injury. The safety of fluoroscopy was actually due to two important facts. First, the machines were designed by regulation to limit radiation output. Second, the procedures for which fluoroscopy was used were limited to short diagnostic studies.

With the introduction of transcatheter therapeutic procedures that can require extended durations of fluoroscopy and serial imaging over the same area of patient anatomy, the potential for radiation absorbed skin doses to exceed thresholds for serious injury became possible. Research and development of fluoroscopically guided interventional procedures initially focused on the development of therapeutic devices that were deployable through a strategically placed catheter. Thus, fluoroscopy was a tool used to guide the deployment of the therapeutic devices but played no direct role in the therapy. As such, other than for the need to provide an adequate image quality for guidance, little attention was paid to the development of fluoroscopic units for these purposes. Although the fluoroscopy-on times were increasing, there was no warning about the potential for injury until the first documented case of induced necrosis occurred in 1990 [16, 17].

1.4. TYPE AND MAGNITUDE OF THE PROBLEM OF PATIENT DOSE

Since 1990, hundreds of radiation skin injuries from fluoroscopic interventions have been reported in the scientific literature and in legal proceedings [8, 9, 16, 18-49]**.** The extent of the problem is unknown because no systematic method of collecting data on unreported injuries exists. Further, it is a commonly noted problem that in some reported injuries the identification of the etiology was undetermined for a considerable period of time because the medical community was unfamiliar with such injuries. It is impossible to assess the number of injuries that might have occurred but for which the cause was mistakenly identified as due to other factors. Based on this experience, it can only be stated that the occurrence of such injuries likely exceeds that which is reported.

To reduce the likelihood of adverse radiation effects, physicians must be well trained in methods to conserve radiation use and the fluoroscopic equipment must be appropriately designed and maintained for high quality imaging at low radiation output. One purpose of this project is to assess the potential for conserving radiation use by studying how procedures are performed in a selection of countries representative of the global situation.

2. FOUNDATION OF THE CRP

2.1. BASIC PRINCIPLES OF RADIATION PROTECTION

The primary principle of radiation protection, as established by the ICRP [6] and converted into mandatory requirements of international safety standards [1], are that while avoiding radiation injuries, there is a necessity to reduce the probability of cancer development by maintaining ‘‘the minimum patient exposure to achieve the required diagnostic [and therapeutic] objective, taking into account norms of acceptable image quality established by appropriate professional bodies . . .’’. This latter principle is commonly referred to as optimization of protection. International Basic Safety Standard (BSS) requires that “the medical practitioner, the technologist or other imaging staff select the following parameters, as relevant, such that their combination produces the minimum patient exposure consistent with acceptable image quality and the clinical purpose of the examination, paying particular attention to this selection for paediatric radiology and interventional radiology…”

Thus optimization and prevention of accidental exposure are crucial to the application of Standards. IAEA, in the discharge of its responsibility of application of safety standards, launched a coordinated research project (CRP) covering both these aspects in the case of interventional radiological procedures. It is based on the experience that was available from the literature that most radiation induced injuries can be prevented and also that there is an opportunity for optimization to lower doses to patients in such procedures.

2.2. SCOPE AND OBJECTIVES OF THE RESEARCH

2.2.1. Scope of the CRP

In many Member States, equipment is rapidly being upgraded to include advanced dose conservation and imaging technology. However, it is expected that complex fluoroscopically guided interventional procedures will proliferate among other Member States ahead of the ability to replace existing fluoroscopic equipment. This implies that in many States extended procedures will be performed using equipment lacking advanced dose conservation technology such as pulsed fluoroscopy, adjustable filters, or a built-in system to measure patient dose such as dose area product (DAP). In light of this expectation, it was felt appropriate to focus on operational optimization to manage radiation exposure to patients. Therefore the project was designed to include a wide range of equipment, a wide range of interventional procedures (cardiac and non-cardiac), to assess differences in practices, and to utilize the modern dosimetry techniques to assess patient doses. The ultimate goal is to evaluate the role of different factors in patient dose management.

2.2.2. Specific objectives

The specific objectives were:

1. Identify potential high-dose interventional procedures from participating countries

2. Evaluate image quality and dose output characteristics of equipment used for each procedure

3. Measure and record dose and dose-related quantities for each procedure and each patient

4. Correlate skin dose with other dose-related quantities, e.g., body mass index, fluoroscopy time, complexity of procedure or doctors' training

5. Assess results and give advice for dose optimization while maintaining diagnostic accuracy and/or treatment efficacy.

3. REVIEW OF LITERATURE

3.1. SKIN INJURY

The first known case of radiation-induced dermal necrosis from a transcatheter intervention occurred in 1990, but it did not appear in the literature until 1996 [16]. In 1992, a conference jointly sponsored by the American College of Radiology and the United States Food and Drug Administration was held in Reston, Virginia in the United States to address the changing uses of fluoroscopy [17]. In 1994, the first published report on the potential for injury to patients appeared in the medical literature [18]. That article identified suspected thresholds for a wide range of skin injuries which were subsequently updated (Table 1).

TABLE 1. POTENTIAL EFFECTS IN SKIN FROM FLUOROSCOPY

Effect	Single-dose threshold (Gy)	Onset
Early transient erythema	2	~2 – 24 h
Main erythema	6	~10 d
Temporary epilation	3	~3 wk
Permanent epilation	7	~3 wk
Dry desquamation	14	~4 wk
Moist desquamation	18	~4 wk
Secondary ulceration	24	>6 wk
Late erythema	15	8-10 wk
Ischemic dermal necrosis	18	>10 wk
Dermal atrophy (1st phase)	10	>12 wk
Dermal atrophy (2nd phase)	10	>1y
Induration (invasive fibrosis)	10	
Telangiectasia	10	>1y
Dermal necrosis (late phase)	>12?	>1y
Skin cancer	None known	>5y

(Adapted from Ref. 18 and revised according to information provided in private communication with J. W. Hopewell, 1999).

As a result of reports on radiation injuries in patients, the United States Food and Drug Administration issued an advisory and warning to health care personnel about the potential for injury [7]. That advisory identified procedures that could potentially result in very high skin doses. It also delineated some recommendations on how to avoid skin injury. Following that report, many reports on injuries started to appear in European and American journals [8, 9, 16, 19-49]. The reported injuries ranged from depilation to necrosis. A review of injuries was provided in 2001 that identified the progression of injuries and the radiological factors that contributed to the injuries [8, 9]. That review was confined mostly to reports in the western hemisphere. Reports on injury were also starting to appear in Asia [40-49]. During the investigations of this report, one participant reviewed the literature for injuries in Japanese patients and found over 30 reports on injuries ranging from depilation to necrosis during the time span of 1995 to 2004 (Figures 1, 2). The procedures included cardiac and hepatic interventions, including coronary angioplasty and transarterial chemoembolization (TACE). In a review of 10 cases [50] the injuries resulted from multiple procedures (ranging from 3 to 13) on the same patient. The total absorbed dose to the skin of these patients was estimated in the range of 10.95 Gy to 58.5 Gy. The extreme case involved a patient who underwent 3 cardiac angiographies and percutaneous transluminal coronary angioplasties in a period of 2 months with a 4^{th} procedure after another 7 months. The total dose was estimated at 58.5 Gy. The main area of injury in most cases was the right side of the back. The nature of injury varied from skin ulcer in 8 cases and induration in 2 cases. Skin grafting was required in 4 of the ten cases reviewed. Complicating factors included diabetes in 6 cases, renal failure in 2 cases, hyperlipoidemia in 3 cases and chronic hepatitis C in one case. As a consequence of this report, The Japanese Cardiologists Association announced that young cardiologists should be trained in radiation protection.

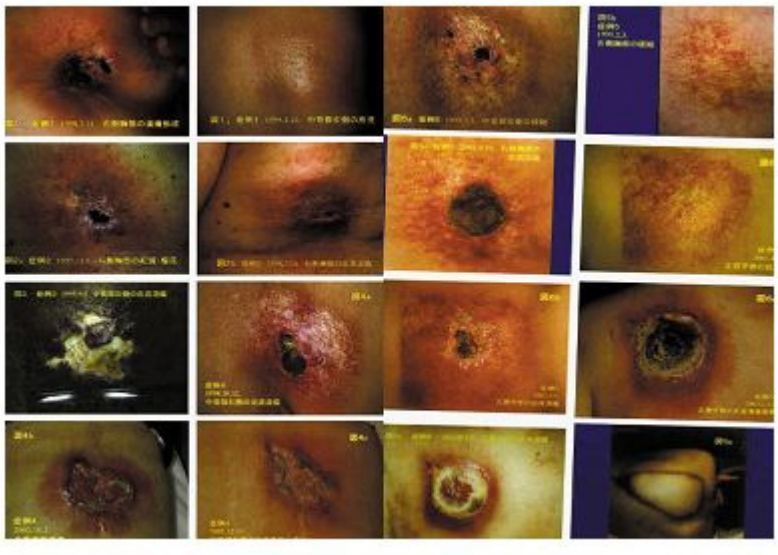


FIG. 1. Cases of radiologically induced skin injury.

Reports indicate that certain medical conditions such as diabetes, connective tissue diseases or hyperthyroidism may increase sensitivity to radiation injury. Other tentative risk factors are advanced age, previous exposure to radiation or presence of malignant disease [9].

Injuries are still occurring. In the USA, a very recent report tells of a 154 kg patient who underwent a 6 hour-long cardiac procedure one month before a rash appeared on his back. The patient complained of the skin lesion for more than six months before obtaining a correct diagnosis [51].

The important findings of the published reports are as follows:

- The nature of radiation injury is not like that of a thermal injury and its progression is quite different;
- The patient has no sensation that an injury is occurring until the radiation insult is past the point of serious harm;
- That an injury has occurred is usually not apparent until days to weeks after the procedure when an erythema develops;
- The progression of the injury after the initial erythema depends on the dose and the fractionation of the dose delivered. The injury might completely heal, heal with permanently altered skin structure, or might progress into ulceration and necrosis. Progression may take months to years;
- Treatment is prophylactic to prevent infection and to control pain but is essentially ineffective at reversing the progression of tissue breakdown;
- Injuries are rare in relationship to the total number of procedures performed each year.

- Injury is associated with:
- Difficult and lengthy procedures with the beam oriented for prolonged periods over the same skin area;
- Prolonged use of high-dose modes of operation;
- Unnecessary body parts in the field of the X ray beam;
- Large patients or steep beam angles requiring transmission through thick body mass;
- Patients with health conditions that predispose them to radiation injury;
- Multiple procedures in the same patient over short periods of time;
- Lack of dose monitoring to warn physicians that high doses are accumulating;
- Inexperienced physicians.

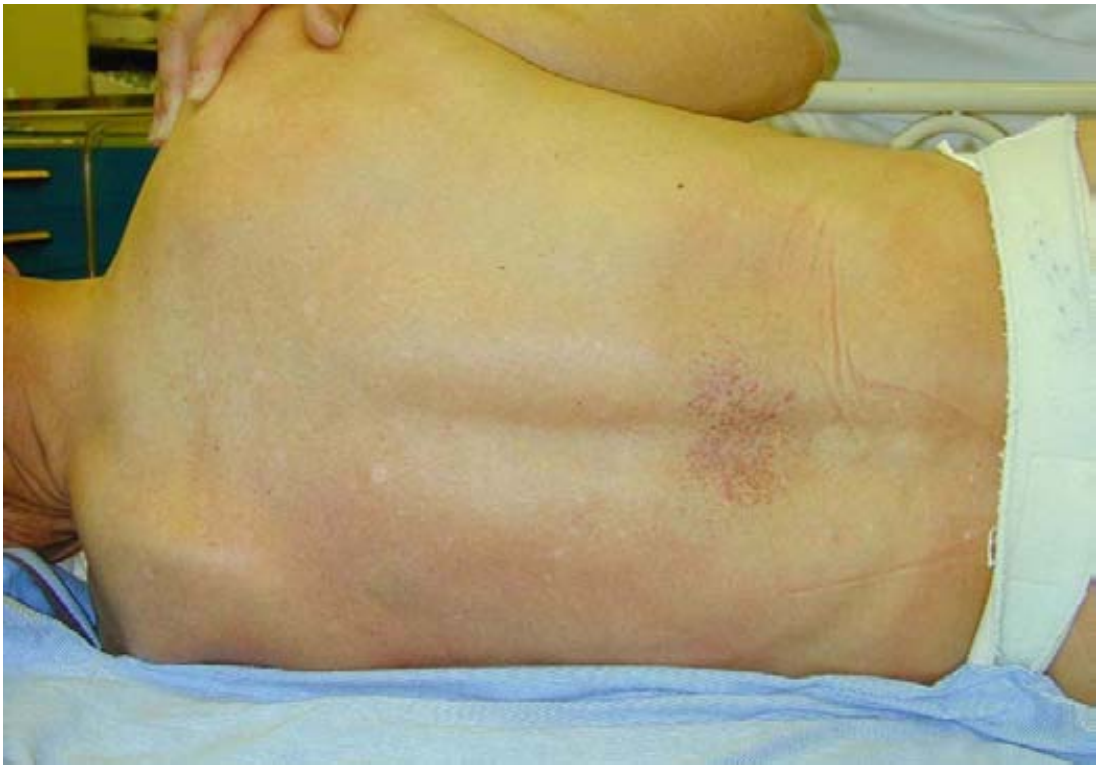


FIG. 2. Radiation injury after repeated embolization.

It is important to emphasize that these injuries are rare. However, they can be very severe, are characteristically delayed but occur in the near term, are often discovered by dermatologists due to lack of follow-up by interventionalists and they can result in serious disfigurement with very profound changes in quality of life. It is therefore very important to recognize the risk posed by extensive use of radiation and to develop strategies to prevent the proliferation of the occurrence of injuries while trying to reduce their frequency to levels that are necessary only in extreme life-threatening situations where dose-limiting options have been exhausted.

3.2. DOSE MONITORING

Many researchers have reported on methods used to quantify radiation delivery to patients and these have been reviewed by Padovani [52]. Methods proposed fall into one of several categories. These can be classified as:

- Realtime or post-procedure readout devices;
- Skin surface or machine output devices;
- Local small area monitors or wide-area monitors;
- Direct or indirect monitors.

Realtime means that the accumulating dose can be quantitatively reviewed at any time during a procedure. Some dosimeters cannot be read out until after their use because they must undergo a time-consuming processing for readout. While useful as a quality control measure, the latter dosimeters cannot be employed for readout during a procedure to assess the potential radiation risk to a patient. Such post-procedural readout devices include standard radiography or radiotherapy film and luminescent devices that require special readout equipment, like thermoluminescent and photostimulable luminescent devices. Realtime devices made of other materials, including an X ray sensitive "film" that self-darkens rapidly after exposure to X rays (International Specialty Products, Wayne, New Jersey, USA), can be examined relatively easily during a procedure to assess any developing risk.

Skin surface monitors are devices that are placed very close to the patient's skin to monitor dose at the surface. Machine-output monitors provide information on the cumulated output of the machine, but not on the dose to the skin surface.

Local area monitors are essentially monitors designed to measure dose at a point. The sensitive material of these types of monitors is typically small, not much larger than a few millimeters. Some are intended to be used as skin surface monitors. This requires accurate a-priori placement of the device on the most irradiated skin site of the patient, which is not always an easy thing to accomplish. Others recommend they be used as output monitors and be placed on the port of the X ray tube to monitor the radiation output. The reading can then be used to estimate by calculation the dose at the patient's skin surface. Both techniques have the disadvantage that the monitor cannot account for changes in the irradiated skin site due to the movement of the X ray source. It has the further disadvantage that the distance to the skin surface can change during the procedure, further complicating dose assessment. It can be used as an estimate of the skin dose in order to roughly inform a physician on the potential risk during a procedure.

Wide area monitors measure the radiation delivery over a broad area, reducing the problem of assuring that the monitor actually measures the dose to the irradiated skin site. Dosimetry film is a wide area monitor but standard type film requires processing and can only be used as a post-procedure dosimeter. The film does provide a picture of how the dose is distributed over a wide area of skin. A different type of "film" is Gafchromic media. This material is flat like film and can be placed on the table under the patient (Figure. 3 and [53]). It responds rapidly to X ray exposure, darkens quickly without special processing and can be viewed in normal lighting conditions. If

concern is raised over skin dose during a procedure, it can be removed from under the patient and examined promptly for dose assessment.

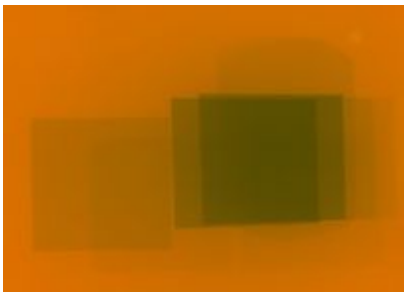


FIG. 3. Gafchromic film.

Kerma-area-product (KAP) meters are wide-area output detectors that can only assess the average dose over the radiation beam area. Readout is provided in units of $Gy.cm^2$, or some variation thereof. These devices provide no assessment of dose to the skin. To obtain an estimate of skin dose, the area of the beam at the skin surface must be known. This should be useful for procedures in which the beam seldom changes either in size or in angulation.

A direct monitor detects radiation output and provides a signal from which the dose can be assessed. Sensor materials used to detect radiation for direct monitors are available in a wide variety, including X ray sensitive film or film-like material, thermoluminescent or photostimulable luminescent devices, scintillation and solid state detectors, or ionization chambers. An indirect monitor examines and records the operating parameters of the machine and calculates the dose based on those operating conditions. The accuracy of the dose estimate depends on an extensive calibration technique.

This investigation utilizes many of the above methods to estimate skin dose or some analog of skin dose, as, for example, cumulated dose to a reference point.

Many researchers have investigated means by which some of these devices might be used in conjunction with other data to assess skin dose. Almost all such techniques are conditional on certain assumptions about the circumstances of dose delivery and do not apply to all situations.

One technique deserves comment. Based on the kerma-area product, one manufacturer produced a method of monitoring the collimation and the position of the X ray beam relative to the patient's skin surface in order to assess dose to the skin of the patient [54, 55]. The device also provided a real-time map of the dose that displayed a picture of how dose changed across the skin surface. The physician could see where dose was building. This proved to be a very useful device to some investigators, but the demand for the device was so low among users that the manufacturer ceased offering it as an option on their equipment.

4. MATERIALS AND METHODS

4.1. SELECTION OF SITES (HOSPITALS)

Table 2 lists the hospitals or departments participating in this project. Each facility is identified throughout the remainder of this document by the letter corresponding to this table.

TABLE 2. FACILITIES PARTICIPATING IN PROJECT

A	All India Institute of Medical Sciences Hospital, New Delhi, India
B	Santa Maria Hospital, Udine, Italy
C	Aichi Medical University Hospital, Aichi, Japan
D	University of Malaya Medical Center, Kuala Lumpur, Malaysia
E	King Chulalongkorn Memorial Hospital, Bangkok, Thailand
F	University of Ankara, Faculty of Engineering, Department of Engineering Physics, Turkey

4.2. SELECTION OF PROCEDURES

Procedures monitored for patient dose were selected on the basis of the following criteria:

1. The procedure must be known to potentially involve long fluoroscopy exposures over a stationary site,
2. The procedure must be performed sufficiently often at the participating facility to accumulate an adequate sample number for analysis,
3. The procedure must involve the abdomen, thorax or head.

On the basis of the above criteria the following procedures were selected for study:

1) Cardiac procedures:
   a. Coronary angiography and interventions
   b. Electrophysiologic and ablation procedures
2) Head and abdomen procedures:
   a. Neurovascular interventional procedures
   b. Hepatic interventions (Transarterial Chemoembolization, Transarterial Oily Chemoembolization (TOCE))
   c. Endoscopic Retrograde Cholangiopancreatography (ERCP)
   d. Percutaneous Transhepatic Biliary Drainage (PTBD).

4.3. FACILITIES AND PERSONNEL

4.3.1. X ray systems

Table 3 lists the fluoroscopic systems available for specific procedures at the facilities of each participant. Each participant collected data regarding their equipment, some details of which are provided in Appendix A.

TABLE 3. FLUOROSCOPY SYSTEMS (YEAR OF INSTALLATION IF KNOWN) BY PARTICIPANT AND PROCEDURE

Participant	Hepatic	Neuro	Biliary/ERCP	Cardiac
A	Philips X-Radfluoro (2001)		Siemens Polystar(1995)	Siemens Polystar (1995) Philips X-Radfluoro (2001)
B		GE Advantx LCA		GE Innova 2000 (2003) Philips Integris 3000
C	Toshiba Angiorex-US031A/J1 (2000)	Toshiba Angiorex-US031a/J1 (2000)		Siemens HICOR
D	GE Advantx LCA (1995)	GE Advantx LCA (1995)	GE Advantx LCA (1995)	Philips Integris BH 3000 (1995) Siemens Angiostar Plus (2000)
E	Siemens Polystar (1996)	Siemens Neurostar Biplane (2000)	GE Advantx AFM (1992) Siemens Polystar (1996)	Siemens Coroscop HS (1994 to 2003) Siemens Axiom Sensis Biplane (2004) GE Advantx LC DC (1994)
F	Siemens Multistar Plus/TOP (1998)	Siemens Neurostar Biplane		2*GE Advantx LC+DLX (2000) Siemens Bicor Plus/TOP (1998) Philips Integris H3000[1] (1997)

[1] Used only for ablation procedures.

4.3.2. Physicians: Training in interventional cardiology

Current guidelines of professional societies state that fellows in cardiology must undergo practical training in invasive cardiology. They specify the duration of training and how many procedures are required, depending on whether training is at the beginning of a career in interventional cardiology or just a part of the basic knowledge [56].

In order to evaluate the impact of training on radiation exposure of patients, data of 3,606 diagnostic cardiac procedures performed at Udine between 01/01/2000 and 31/12/2002 were retrieved from a data-base that was prospectively generated. Missing data on exposure parameters were found in 187. In the remaining 3.401 (94%) the following exposure parameters were examined: fluoroscopy time, number of cine-frames, air kerma area product (KAP) during fluoroscopy, cineangiography and the combined total.

During the period considered, five cardiology fellows attended the catheterization laboratory for periods of five to six months and they participated in 819 diagnostic procedures (mean 168 ± 76, minimum 88, maximum 276). These procedures (F group) were compared with 2,582 performed by three staff members alone (S group): in addition to exposure parameters, we also considered age, sex, body surface area, ejection fraction (EF), mean angina class (according to Canadian Cardiovascular Society-CCS), previous coronary by-pass operation (CABG), acute myocardial infarction (AMI) as the indication to undergo examination and the type of procedure performed other than left heart catheterization (left ventriculography, aortography, and right heart catheterization).

Cardiac catheterization was performed with Judkins technique in 90% of cases in both groups and in 10% by radial or brachial approach. At the beginning, participation of fellows was limited to venous and arterial site puncture and manipulation of catheters at the right site of the cardiovascular system. As their experience grew, the fellows were allowed to perform left heart catheterization first and eventually to engage the coronary ostia. A staff member was beside them, scrubbed in the majority of cases, but in the last part of the training (typically the last two months) they were allowed to work with supervision only, in selected patients.

Patients examined by fellows and staff were comparable for sex (69 vs 70%), age (66±11 vs 66±10) and body mass index (26.7±3.8 vs 26.4±4.2), but were different regarding some clinical aspects: patients in S group were examined more often for ongoing AMI (11% vs 3,4%, $P<0.001$) and had a lower EF (56%±15 vs 59%±14. $P<0.001$), whereas CCS class was similar (2.8±0.7 vs 2.9±0.8, P=ns), as well as history of previous CABG (8.9% vs 7.5%, P=ns). Patients in F group were more likely to undergo right heart catheterization (27% vs 17%, $p\leq0.001$) and left ventriculography (78% vs 73%, $p\leq0.01$), but not aortography, (18% vs 16%, P=ns).

4.4. PATIENT DOSIMETRY

4.4.1. Description of the dosimetry procedures

For the measurement of patient doses, kerma-area product (KAP) [also called dose-area product (DAP)] and maximum air kerma at skin surface (abbreviated as maximum skin dose or MSD) were selected as the main dosimetric quantities. Slightly different instrumentation was used by each center for these purposes due to their different resources. Additionally, gafchromic dosimetric media (self-developing "film") were distributed to each center by the IAEA to be used only in selected procedures. Dosimetric techniques employed for the examinations by the centers are given in Table 4.

TABLE 4. DOSIMETRIC TECHNIQUES USED BY CENTERS

Site		Hepatic	Neuro	Biliary/ERCP	Cardiac
A	KAP (DAP)	Add-on (1998)		Add-on (1998)	
	Skin Dose	Estimated[1]		Estimated[1]	Gafchromic
B	KAP (DAP)		Built-in		Built-in
	Skin Dose		Gafchromic		Gafchromic
C	KAP (DAP)				
	Skin Dose	SDM	SDM	SDM	SDM+ Gafchromic
D	KAP (DAP)	Add-on	Add-on	Add-on	Built-in
	Skin Dose	Gafchromic	Gafchromic	Gafchromic	Gafchromic
E	KAP (DAP)	Built-in	Built-in	Built-in	Built-in
	Skin Dose	Estimated[1]	Gafchromic	Estimated[1] (TOCE)	Gafchromic
F	KAP (DAP)	Built-in	Built-in	Built-in	Built-in
	Skin Dose	Portal ion chamber	Portal ion chamber	Output at tube port	
	Skin Dose	TLD	TLD	TLD, Estimated[1]	TLD, Gafchromic

[1] Estimated means determined from the area of the beam and the KAP.

4.4.1.1. Kerma Area Product

A KAP (DAP) meter was the most commonly used dosimeter (Table 4). KAP was typically measured with a transmission chamber fitted in the angiographic system or temporary added externally to the collimator assembly. On some equipment KAP was calculated, not measured, by the system from the machine parameter data. Cumulative KAP (DAP) values for each examination were recorded. Some centers downloaded the KAP (DAP) readings to a computer for analysis with the help of special software.

Kerma-area product (KAP) is a dose quantity useful for the estimation of patient effective dose. KAP is also known as dose-area product (DAP). Both terms apply to the integral over the beam area of the free-in-air air kerma and are commonly measured in units of $Gy.cm^2$, or some standard derivative thereof.

Proper calibration of KAP meters was assured by an intercomparison exercise performed at the beginning of the study by all participants. Correction factors for patient table attenuation were measured by each participant for the proper correction of displayed KAP. On one system for participant A the table attenuation factor was not determined and the KAP was reported uncorrected for table attenuation.

KAP is of limited usefulness as a skin dose monitor because the area of the beam at the skin surface must be known to estimate entrance air kerma averaged over the X rayfield. (Only the entrance air kerma averaged over the area of the beam is estimable. In-field variations in beam intensity, due for example to the heel effect, are not taken into account.) And, since KAP is a cumulative quantity, the measurement applies to all beam angles employed during a procedure unless someone notes down the KAPs for all the different series. Further, if a bi-plane system is employed, the KAP for both X ray tubes is sometimes summed and recorded as a single KAP value. So, even if area at the skin is known, there is no possibility to determine the average entrance air kerma at a single site on the skin surface.

By combining KAP with beam area results obtained from film located next to the patient's entrance-skin surface, an estimate of the entrance air kerma is possible for single planes. The entrance area of the beam can be ascertained from the film but some accounting for beam reorientation during the procedure is necessary.

Once the entrance air kerma averaged over the X rayfield (ESAK or $K_{e,a}$) is evaluated, the entrance skin absorbed dose (ESD) can be calculated from the following equation:

$$ESD = f(E) \times B(A,E) \times K_{e,a} \quad (1)$$

In the above equation, f(E) is the energy-dependent f-factor that converts air kerma into absorbed skin dose. Since the X ray beam is mainly bremsstrahlung, only an estimate of this factor is possible. We choose to use a factor of 1.06 mGy tissue absorbed dose per mGy air kerma [57]. The factor B(A,E) is the backscatter factor that takes into account the added dose to the skin area from radiation scattered backward from the patient's body backward toward the entrance skin surface. This factor depends on the area of the beam and the quality of the bremsstrahlung radiation. Only an estimate of this factor is possible and it typically ranges from 1.2 – 1.4 for diagnostic X ray beams [58]. We will use a factor of 1.3 for this report. Therefore, the ESD in this report, as derived from KAP and portal film beam area is:

$$ESD = 1.4 \times K_{e,a} \quad (2)$$

We have rounded off the estimate to two significant figures.

4.4.1.2. Portal measurements

A slow radiographic portal film (such as Kodak X-Omat V) was used to estimate the KAP (DAP) by some centers where the KAP (DAP) meter was not available or when it was not possible to mount the existing meter to the X ray tube housing. This method was used for neuroradiological, biliary and hepatic examinations by some centers. The film was placed on the table underneath the patient and centered as closely as possible to the area of the skin expected to receive the highest dose.

Portal film has the advantage that the readout is directly related to the radiation that enters locally on the skin, it includes backscatter, and it is independent of beam reorientation. Said another way, error in skin dose estimate due to beam reorientation and back scatter radiation is eliminated for this dosimetry medium, except in cases where the film does not intercept the beam, such as with a lateral beam. The disadvantage is that the film must be processed for readout and provides no readout during the procedure. Calibration and quality control to assure a stable readout are also time-consuming.

One center used a small ion chamber to measure radiation output at the port of the X raytube. This allows for an estimate of skin dose if the distance from the chamber to the skin is accurately recorded.

4.4.1.3. Radiochromic media

Radiochromic dosimetry media (commonly referred to as "films") can be handled in normal lighting conditions, respond nearly immediately to exposure to radiation, and they require no chemical processing since they are self-developing. They are used to measure absorbed dose and to map radiation fields produced by X ray beams in a manner similar to that of portal film. As such, radiochromic media have the same advantage of locally specific dose monitoring without error resulting from beam reorientation or backscatter. Radiochromic film can be examined during a procedure if there is a need to obtain an estimate of skin dose. Exposure to ionizing radiation causes radiochromic film to immediately darken. The degree of darkening is proportional to exposure and can be quantitatively measured with a reflectance densitometer. There does exist a gradual darkening of the film with time and darkening is usually maximum within 24 hours. However, the amount of darkening within the period immediately following the initial exposure is not large and does not interfere with the ability to use it for skin dose guidance during a procedure as long as this phenomenon is understood and taken into account.

A limited quantity of radiochromic films was distributed to the centers to be used nearly exclusively for cardiac examinations. Some centers had their own films and used them for additional studies. For cardiac work, films were placed on the table under the patient pad in such a way that the most heavily exposed parts of the body were covered by the film. Necessary data, such as the beam orientation (superior, inferior etc.), patient ID, date and type of examination, were recorded on the film.

When used in the manner described, the film darkening includes backscatter, and beam reorientation and field non-uniformities are recorded. The only correction factor necessary is the conversion from entrance air kerma at the skin to absorbed dose in the skin. The recorded entrance air kerma at the skin multiplied by an f(E) of 1.06 gives the estimated absorbed skin dose.

4.4.1.4. Thermoluminescent dosimetry (TLD)

Use of thermoluminescent dosimeters (TLDs) is a well established technique of dosimetry. They have excellent dosimetric characteristics and are reliable for skin dose measurements as long as the irradiation geometry remains fixed over the TLD during the course of the examination. Lithium Fluoride TLD chips (3.7 x 3.7 x 0.9 mm) in plastic pockets were attached to the patient's skin where the exposure was expected to be at its highest level. The limitation of this technique is that the highest-dose area of the skin must be known *a priori*. If the site is ill chosen, the reading will underestimate the true skin dose. To overcome this limitation, especially in the case of multi-projection examinations, it becomes necessary to use large numbers of TLD in an array over the exposed portion of the body. Managing a large number of TLD becomes problematic, rendering this technique difficult to implement for routine work.

Because the TLD are placed on the skin, the reading includes backscatter radiation. Since calibration is usually in terms of air kerma, the usual correction factor of 1.06 must be applied to convert the reading to absorbed dose.

4.4.1.5. Skin dose monitor

Skin dose monitors (SDMs) are ZnCd scintillation dosimeters (McMahon, Inc., San Diego, California, USA). The scintillator has a dimension on the order of a millimeter and is bonded to the tip of a fiber optic cable. The other end of the cable is connected to a light sensitive meter that cumulatively records the light output and converts the light signal into an electronic signal which is calibrated for display in units of mGy. Like TLDs, these devices must be placed on the skin surface at the point where the skin dose is likely to be greatest. Unlike TLDs, the readout is in real-time and requires no processing. An additional disadvantage is that the fiber optic cable must be strategically positioned during the procedure in order to avoid interference with the rotating gantry of a c-arm fluoroscope. Use of multiple sensors is cumbersome or impossible. Further, the monitor base is not well shielded and must be kept away from the radiation area to avoid a false readout.

4.4.2. Measured and collected items

4.4.2.1. Calibration of KAP meters

In order to verify and compare the calibration of the reference chambers used to calibrate the KAP meters, individually calibrated thermoluminescent dosimeters (TLD 100) were sent from the central processing center in Vienna (Peter Homolka, Center for Biomedical Engineering and Physics, Medical University of Vienna) to the participating centers. Calibration was performed by irradiation of the TLDs with a clinical X ray system (Siemens Polydoros 50S with Biangulux 150/12/50 tube) and a reference class dosimeter (PTW Unidos chamber Type M77334 1cc calibrated by PTB, Braunschweig, Germany, U=+/- 5%, coverage factor k=2). At the participants' facilities, TLDs were exposed by placing them close to the center of the beam on the top of a reference chamber. The exposure was corrected for the effect of the distance between the position of the TLDs and the reference point in the chamber. Every center reported the dose as measured with their locally used reference dosimeter. After returning the TLDs to the central center the batches were read out using a Harshaw TLD 4000 system. Background radiation associated with each center was assessed using one TLD set dedicated for this purpose. This value was subtracted from the exposed TLDs.

4.4.2.2. Intercomparison of radiochromic film dosimetry

To provide consistency in interpretation of the radiochromic data, all exposed radiochromic dosimetry films (RDF) were processed for dosimetry readout by a centralized laboratory located in Udine, Italy (Participant B). In order to assure agreement on the processed doses among the participants, an intercomparison of the calibration of the radiochromic film was performed. At each participant's facility, an unexposed radiochromic film (RDF) film was cut in square pieces of 3x3 cm^2. These pieces were irradiated by X rays in steps of about 100-200 mGy covering an interval between 0 and 5 Gy. Air kerma was assessed with a calibrated dosimeter. Before and after irradiating the film, the incoming air kerma was measured with an ion chamber

or a semiconductor photodiode in order to ensure that no variation took place during the exposure. The film was placed 15 cm above the table to reduce the dose contribution of backscattered radiation from patient table. The exposed pieces of radiochromic detector, including a non-irradiated piece for the zero-level evaluation, were put together in order of ascending dose value, forming a "calibration strip". These calibration strips were forwarded to the central Udine facility for scanning.

Scanning of each film-strip piece was performed with a reflective flatbed scanner (Epson Expression 1680Pro (A4 format) and Microtek TMA1600 (A3 format)), whose 48-bit colour-scale mode response as a function of film position and orientation on the scanner bed was previously investigated. The RDF was placed with its coloured side downward, in contact with the scanner's glass bed, and it was covered by a black background in order to eliminate undesired reflected light. Since there is some residual long term darkening of the film that takes place slowly after exposure, all films were processed after a waiting period of at least 48 hours. In addition, two reference steps, a black and a white, are added to the "calibration film" providing a normalization reference for the scanner's software. The automatic optimization of the acquisition parameters (such as contrast, brightness, etc.) is recorded and then used for all the subsequent acquisitions of exposed films (the automatic control of parameters has to be turned off for all the acquisitions except for the "calibration film"). Although the acquisitions are performed in RGB mode, the film response is read in its red component, since the latter showed a higher sensitivity in the dose interval of interest. The resulting values on the red channel vs. air kerma values are interpolated with a square function using a proprietary software package (PicoDose programme from TA, Torino, Participant B and Systat10, SPSS Inc, USA) or with a home made Matlab routine. A separate calibration has been obtained with a reflective densitometer (XRite Spectrodensitometer) that can read only the red part of the reflected light.

Images are acquired with Adobe Photoshop software at 16 bit red color, converted to 16 bit gray and stored in tiff format. PicoDose software reads tiff images, applies calibration curve and displays the dose distribution. The area of maximum dose is detected and the maximum dose value and area are registered. A Matlab routine developed in house was used to write dose distributions into a numerical matrix file for subsequent and separate processing.

4.4.2.3. Patient dosimetry and procedure data

Patient dosimetry acquisition

Each country collected data for patients undergoing the different procedures selected for investigation at their site. For each patient and type of procedure, relevant technical and dosimetric data were registered: age, sex, weight and height, and procedure type. An example form for this exercise is provided in the Appendix B. Some facilities collected data on machine parameters (kVp, mA, FOV, beam orientation, and other factors) to allow recreation of the procedure for accurate dosimetry estimations.

Patient dosimetry processing

The "maximum skin dose" (MSD) estimates or other dose analogues were determined according to the methodologies and technologies employed by the different

participants: thermoluminescent dosimeters (TLD), skin dose monitor (SDM), slow radiographic films (EDR2, X-Omat V, Kodak), radiochromic film (Gafchromic, ISP), KAP, etc.

Data analysis

Once data were acquired and properly processed, the results were compared to several other data acquisitions to determine whether the various dose analogues were sufficiently consistent to suggest that they would be useful for dose monitoring at facilities with otherwise limited resources. In most cases the data were plotted as maximum skin dose versus a dose-related quantity such as body mass index, fluoroscopy time, or kerma-area product. Linear regression was performed and the correlation coefficients were derived. These correlation coefficients were then tested for significance to determine how reliable the correlation was between maximum skin dose and the dose analog.

4.4.2.4. Image quality and dose for non-cardiologic procedures

Ninety-two cases were evaluated for image quality during hepatic artery embolization, neurointervention, and biliary intervention. The numbers of cases for each procedure are listed in Table 5. The images were evaluated following the *Description of Terms for Image Criteria* shown below.

TABLE 5. NON-CARDIOLOGIC CASES EVALUATED FOR IMAGE QUALITY

Procedure	Participant A	Participant C	Participant E	Total
Hepatic artery embolization	16	19	7	42
Neurointervention	-	2	14	16
Biliary intervention	34	-	-	34

Description criteria

Visualization: characteristic features are detectable but details are not fully reproduced (features just visible)

Reproduction: details of anatomical structures are visible, but not necessarily clearly defined (details emerging)

Visually sharp reproduction: anatomical details are clearly defined (details clear).

5. RESULTS

5.1. INTERCOMPARISON OF REFERENCE CHAMBERS

The dose values reported by the participants for the intercomparison tests and the doses actually deposited on the TLDs are shown in Table 6.

Participant A

Doses measured locally with a Radcal 10X5-3CT were substantially lower than doses on the TLDs (by approx. a factor of 2.3 for data from the first trial). Thus, Participant A was notified about this discrepancy and asked to repeat the intercomparison exercise. The second set of TLDs yielded an agreement to within 10 per cent.

Participant B

Doses measured locally with an RTI PMX III Diode R100 corresponds within approx. 10 per cent maximum deviation (2^{nd} batch) to the TLD doses. The local dosimeter readings were corrected for calibration by -6.5 per cent prior to reporting.

Participant C

Doses measured locally (Radcal MDH 1015C/10X5-6) corresponded with the doses on the TLDs (deviation smaller than calibration uncertainty of the reference dosimeter,ε).

Participant D

Doses measured locally with the Radcal 9010 were substantially higher than doses measured using the TLDs. The deviations were different for the measurements undertaken on the three systems reported.

Participant E

Doses measured locally using a Victoreen 4000 M+ correspond within deviations smaller than the calibration uncertainty of the reference dosimeter (ε) with the TLD measurement.

Participant F

Doses measured locally with the Radcal MDH 10x5-6 were slightly lower than doses on the TLDs. Three measurements were reported using the same setting giving practically identical results.

Measurements reported by most of the participants (Participant A, second run, Participants B, C, E, F) are in good agreement with the TLD reference (within 10 per cent). The data from Participant D indicated that the doses measured locally may be too high (deviation to dose on TLDs ranged from plus 25 to plus 56 per cent).

TABLE 6. INTERCOMPARISON OF REFERENCE CHAMBERS

Participant	Room/Device	kV	Dose reported (mGy)	Dose on TLDs (U) (mGy, mGy) coverage factor k=2
Participant A 1st Trial		73	30.64	69 ± 14
		73	58.68	135 ± 8
		73	27.87	65 ± 2
Participant A 2nd Trial	Fluoro mode with AEC ON	78	10.11	9 ± 3
	Acquisition mode manual	81	10.03	9 ± 1
	Acquisition mode manual	81	10.07	9 ± 1
Participant B		74	10.32	11 ± 0.5
		73	9.85	11 ± 2
		73	10.4	10 ± 6
Participant C		80	10.1	10 ± 5
		80	10.1	10 ± 0.4
		80	10.2	10 ± 2
Participant D	Siemens Angiostar Plus	73	10.13	8 ± 0.4
	Philips Intergris BH 3000	83	10.52	8 ± 1
	GE Advantx LCA	80	10.12	7 ± 0.8
Participant E	Siemens Neurostar	81	2.623	3 ± 0.8
	Siemens Neurostar	81	2.161	2 ± 1.3
Participant F	Philips-1	81	10.06	11 ± 3.5
	Philips-1	81	10.27	11 ± 1.1
	Philips-1	81	10.7	12 ± 2.6

Note: Dose on TLD data are subject to calibration uncertainty of laboratory standard (reference dosimeter). Dose on TLDs also shows standard deviation of the TLDs in the batches, respectively. Reported doses are also subject to uncertainty.

5.2. INTERCOMPARISON OF RADIOCHROMIC CALIBRATIONS

The participants A, B, C, D, E, and F provided to the Udine laboratory a set of GAFchromic strips exposed to known air kerma values. Figures 4 A and 4 B report the calibration results for the different sets. Participant B, Participant C and Participant D demonstrate similar calibration curves. Participant F's data is consistently lower than that of the previous participant's and these are consistent with the differences reported in the TLD intercomparison exercise. Participant E's data demonstrates aberrant performance that is likely due to incorrect methodology, as opposed to malfunctioning equipment.

Participant B's calibration curve was used in all the evaluations of field film submitted from the different countries.

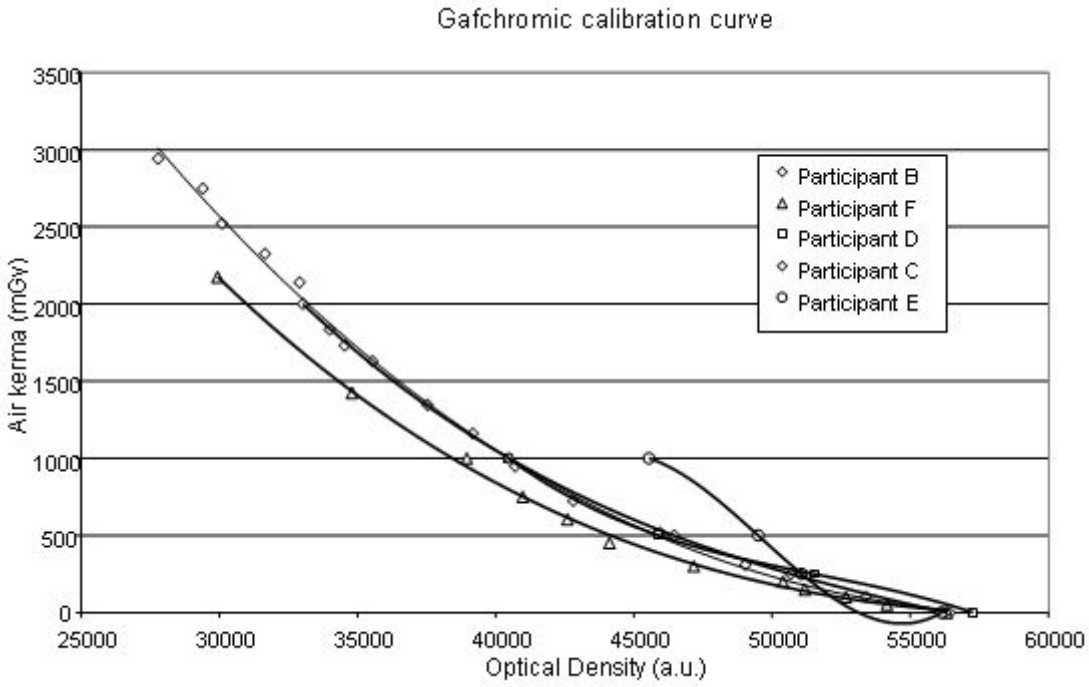


FIG.4 A. Calibration of Gafchromic film by various centers using flatbed scanner.

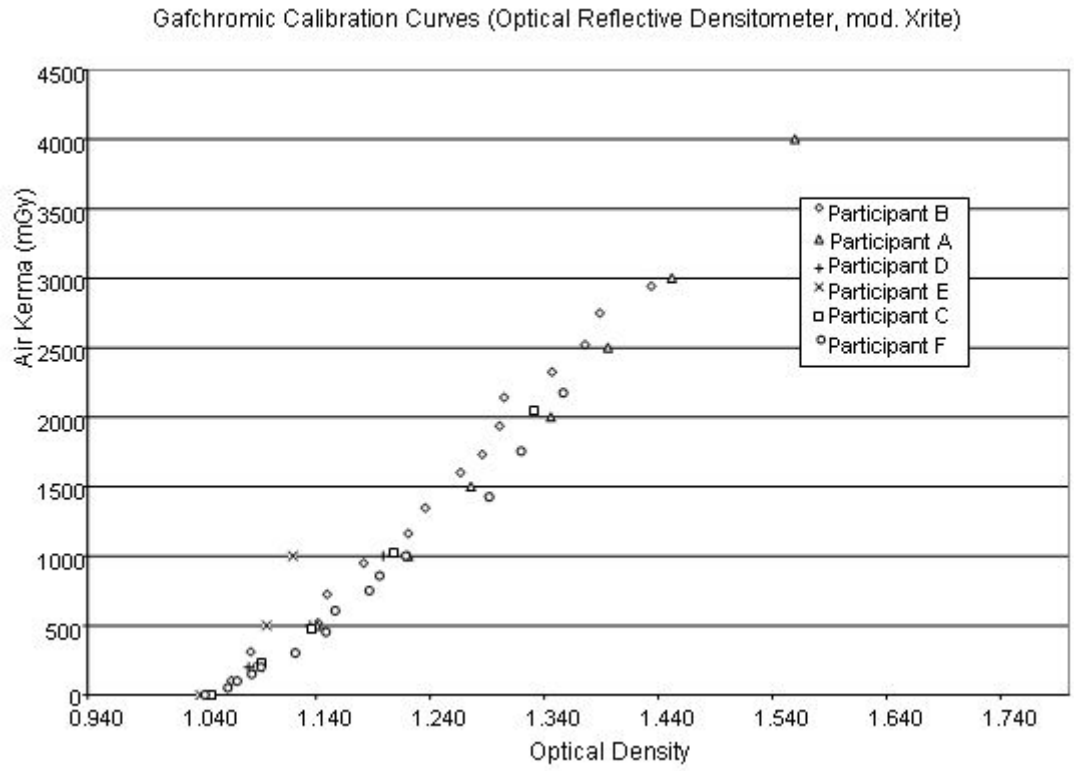


FIG.4 B. Calibration of Gafchromic film by various centers using a reflective densitometer.

5.3. CARDIAC INVESTIGATIONS

5.3.1. Patient characteristics

Table 7 lists the patient population of the cardiac procedures investigated in this study.

TABLE 7. NUMBERS OF CARDIAC PROCEDURES FOR EACH PARTICIPANT

Country	Cardiac				Total
	CA	PTCA	CA-PTCA	RF ablation	
Participant A	-	52	-	-	52
	36	31	-	53	
Participant B	22	10		7	120
Participant C	26	7	23	-	39
Participant D	19	15	15	15	56
Participant E	28	7	32	11	64
Participant F	131	122	70	86	78
Total					409

Patients' ages and body mass indices (BMI in units of kg/m^2) for all samples are reported in Table 8. Body mass index is the mass of an individual in kilograms divided by the square of the individual's height in meters.

TABLE 8. PATIENTS' AGES AND BODY MASS INDICES BY PROCEDURE AND PARTICIPANT

Country	CA		CA-PTCA	
	Age (range, median, mean)	BMI (range, median, mean)	Age (range, median, mean)	BMI (range, median, mean)
Participant A	-	-	-	-
Participant B	44-103, 66, 70	17.6-40.9, 25.2, 26.2	-	-
Participant C	53-88, 64, 65	17.3-28.8, 23.4, 23.7	-	-
Participant D	41-71, 56.5, 56.1	14.7-32.4, 23.3, 23.2	44-75, 63, 62.1	18.0-30.1, 24.8, 24.5
Participant E	51-79, 71.0, 66	18.9-28.6, 24.2, 23.7	42-79, 64, 63.1	19.1-40.2, 25.3, 27.5
Participant F	41-84, 59.5, 59.2	18.2-35.7, 26.8, 26.8	45-80, 56, 60.5	20.7-34.6, 25.8, 26.4

Country	PTCA		RF ablation	
	Age (range, median, mean)	BMI (range, median, mean)	Age (range, median, mean)	BMI (range, median, mean)
Participant A	34-67, 51, 51.9	17.9-32.3, 24.8, 25.0	-	-
Participant B	38-103, 71, 70.1	21.9-32.4, 26.6, 26.9	16-81, 60, 58	19-38.9, 26, 26.1
Participant C	42-75, 67.5,64.5	14.5-27.3, 23.0,22.6	17-69,65,52.9	17.5-33.0,22.8,23.8
Participant D	42-60, 54.0, 50.9	20.1-25.0, 23.1, 23.0	-	-
Participant E	49-84, 63, 64.3	18.8-33.3, 24.6, 27.3	22-75, 46,47.2	18.6-27, 24, 23.3
Participant F	35-78, 65, 60.4	23.2-42.2, 26.1, 28.4	16-70, 39.0, 38.5	18.3-42.1, 24.1, 25.5

5.3.2. Dosimetric results for cardiac procedures

In Table 9 and Figures 5 A through H, dosimetric results for cardiac procedures are summarized for each participant. In Figures 5 A-H, the box represents the range between the mean and median values. Thicker boxes represent situations where the data is skewed by outlying data points.

TABLE 9. FLUOROSCOPY TIME, KAP AND MAXIMUM SKIN DOSE FOR CARDIAC PROCEDURES

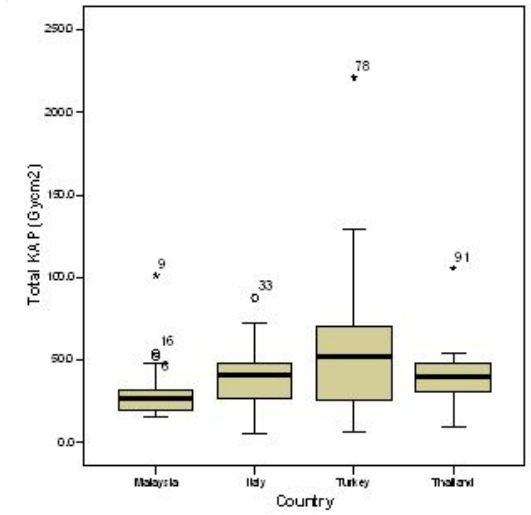
Participant	CA			
	N	Fluoroscopy time (min) (range, median, mean)	KAP ($Gy.cm^2$) (range, median, mean)	MSD (Gy) (range, median, mean)
A	-			
B	36	2-21.9, 5.5, 6.3	5.1-87.6, 40.7, 38.4	0.07-0.59, 0.19, 0.24
C	20	3.8-38.7, 10.0, 11.7	-	0.07-1.21, 0.25, 0.33
D	26	1.8-25, 7.2, 9.9	15.5-101, 27.2, 30.7	0.11-0.82, 0.26, 0.31
E	19	2.6-18.1, 6, 8.7	9.9-106, 40.1, 42.9	0.07-0.31, 0.08, 0.14
F	28	0.7-33, 3.1, 6.0	6.4-221, 52.5, 57.6	0.09-2.11, 0.48, 0.59

Participant	PTCA			
	N	Fluoroscopy time (min) (range, median, mean)	KAP ($Gy.cm^2$) (range, median, mean)	MSD (Gy) (range, median, mean)
A	52	2.3-85.2, 14.9, 19.4	-	0.35-6.94, 1.80, 2.27
B	31	1.9-41, 12.3, 13.9	3.7-205, 74.9, 72.5	0.07-3.60, 0.79, 0.96
C	10	10.3-56.6, 15.1, 19.9	-	0.29-5.05, 0.73, 1.23
D	7	13.3-57.3, 25.1, 27.8	40-113, 82.3, 79.5	0.32-2.32, 0.57, 0.99
E	15	0.9-82.7, 9.8, 15.9	1.36-112, 30, 31.1	0.07-1.1, 0.1, 0.22
F	7	2.3-32.5, 6.2, 10.3	12.7-109, 46.9, 57.4	0.11-2.09, 1.17, 1.08

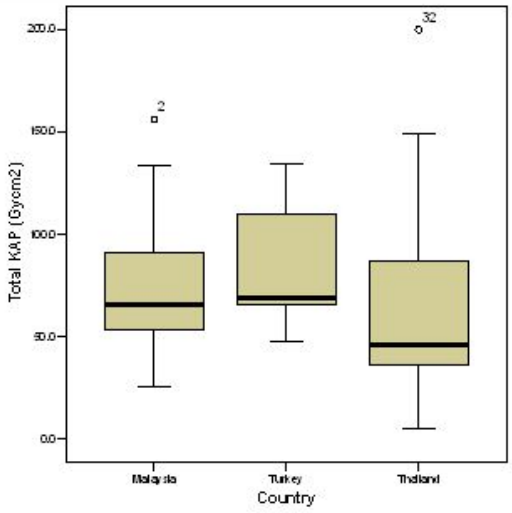
Participant	CA-PTCA			
	N	Fluoroscopy time (min) (range, median, mean)	KAP (Gy.cm2) (range, median, mean)	MSD (Gy) (range, median, mean)
A	-			
B	-			
C	-			
D	23	13.3-57.3, 25, 27.8	40.3-113, 82.3, 79.5	0.32-2.32, 0.57, 0.99
E	15	0.9-21.8, 7, 8.8	5-200, 46.5, 66.6	0.08-2.94, 0.25, 0.55
F	32	4.1-42.2, 11.4, 15.6	33.8-281.4, 88.4, 109	0.51-5.83, 1.69, 2.04

Participant	RF Ablation			
	N	Fluoroscopy time (min) (range, median, mean)	KAP ($Gy.cm^2$) (range, median, mean)	MSD (Gy) (range, median, mean)
A	-			
B	53	1.9-33.8, 12.2, 12.2	0.4-31.9, 8.3, 9.4	0.02-0.52, 0.18, 0.18
C	7	5.2-79.8, 23.1, 27.8	-	0.13-1.3, 0.34, 0.47
D	-			
E	15	7-96.7, 15.2, 23.1	17.7-447, 73.2, 103	0.13-2.22, 0.58, 0.69
F	11	14.7-70.7, 22.9, 31.4	30.9-285, 95.2, 126	0.67-5.52, 2.33, 2.78

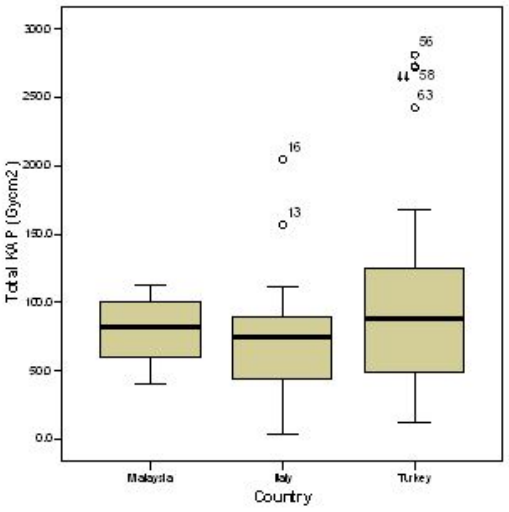
CA (FIG. 5A)



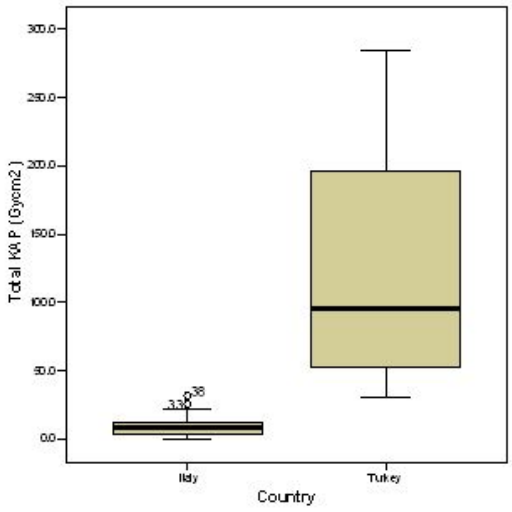
CA-PTCA (FIG. 5B)



PTCA (FIG. 5C)



RF ablation (FIG. 5D)



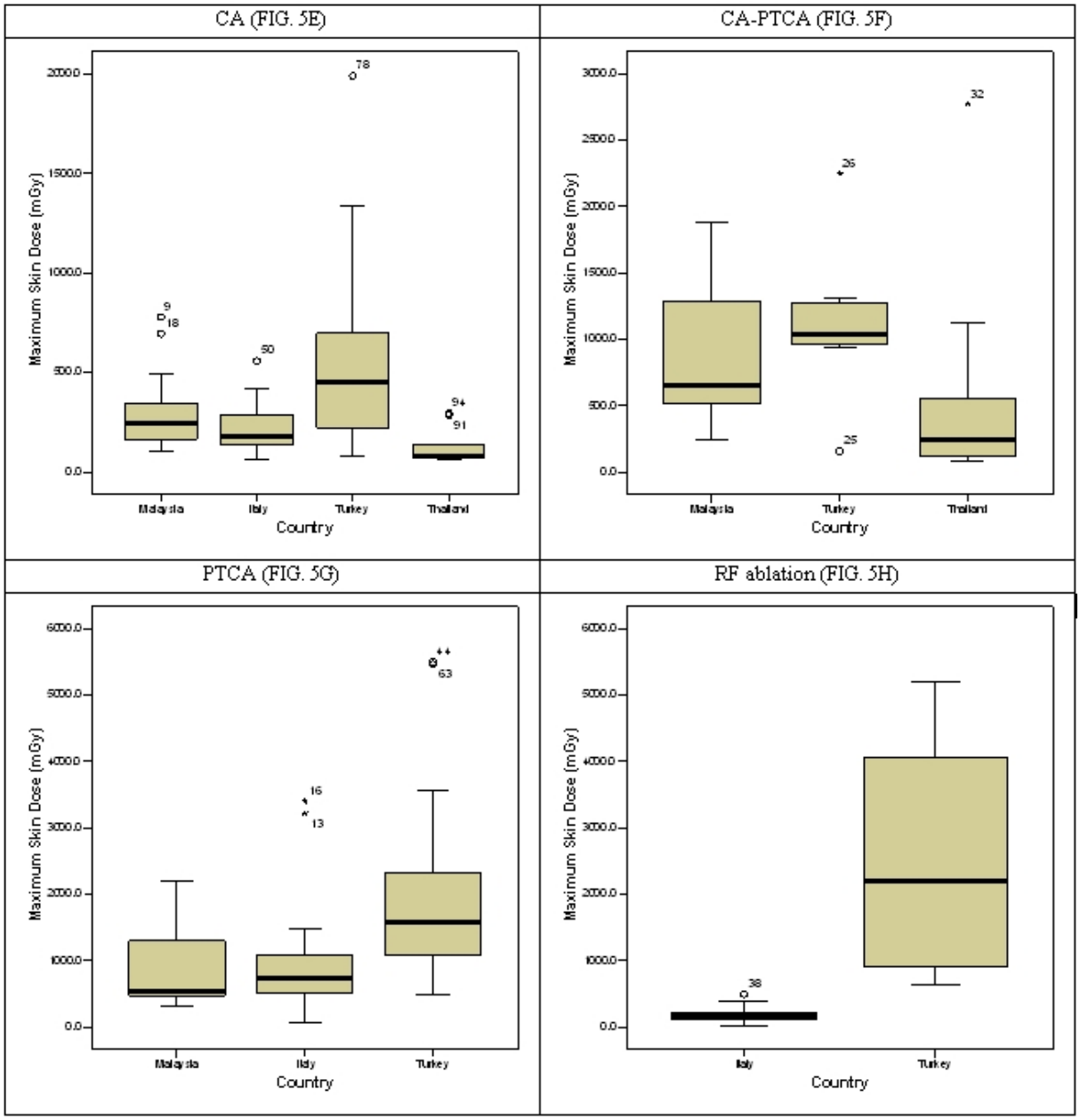


FIG. 5. Box plots of KAP (A-D) and MSD (E-H) values for the four cardiac procedures (CA, CA-PTCA, PTCA and RF ablation) in the different countries.

Table 10 reports cumulative results of our study for cardiac procedures compared with reported literature values. Our data are in the range of reported values for each type of procedure [10, 59-81].

TABLE 10. COMPARISON OF THE KAP VALUES OBTAINED IN THIS STUDY WITH OTHER PUBLISHED DATA

Procedure	Study	Number of patients	KAP (Gy cm2)			
			Mean	Median	3rd quartile	Range or maximum
Coronorary Angiography	Karambatsakidou et al [81]	20	49.0			18-107
	Sapiin et al [83]	176	48.6	37.0	59.6	6.3-453
	Vano, E. [59]	288	66.5	45.75	69.28	11.6-482
	Leung, K.C. [63]	90	13.97			
	Broadhead, D.A [64]	2174	57.8			
	Broadhead, D.A. [64]	126	23.40			
	Zorzetto, M. [72]	79	55.9			146
	Padovani, R. [67]	13	39.3			84
	Padovani, R. [72]	76	56			201
	Padovani, R. [72]	49	74.6			180
	Maccia, C. [73]	130	72			
	Betsou, S. [74]	29	30.4			
	Neofotistou, V. [61]	198	72			27-79
	Williams, J.R. [82]	100	67.3			290
	Cusma, J.T. [68]	597	74.4			
	Hansson, B. [69]	78	73			
	Van de Putte, S. [70]	62	60.6	56.82	80.58	144
	Van de Putte, S. [70]	100	110			171
	Clark, A.L. [77]	117	14.2			1.1-11.3
	Clark, A. [77]	944	20.3			1.0-19.3
	Lobotessi, H. [79]	18	58.3			26.3-125
	This study, 2006 (Part. B,D,F)	90	42.2	44.8	53.1	5.1-221
Coronorary Arteriography/Coronorary Angioplasty	Sapiin et al [83]	70	153.0	103.0	190	18.8-655.0
	Van de Putte et al [70]	10	166	132	185.83	2.0-345.72
	This study, 2006 (Part. D,F)	55	95.5	70.0	125	26-281
Percutaneous	Karambatsakidou	10	35.0			16-115

Procedure		Study	Number of patients	KAP (Gy cm2)			
				Mean	Median	3rd quartile	Range or maximum
Transluminal Angioplasty	Coronary	et al [81]					
		Sapiin et al [83]	32	111	111	180	22.4-477
		Karpinen et al [80]					40-113
		Broadhead, D.A. [64]	214	78			
		Broadhead, D.A. [64]	11	51.6			
		Donovan, M.B. [65]	225	141			
		Donovan, M.B. [65]	218	138			
		Donovan, M.B. [65]	119	176			
		Zorzetto, M. [72]	31	91.8			275
		Padovani, R. [67]	54	102			394
		Maccia, C. [73]	30	93			
		Vano, E. [60]	45	87.5			
		Betsou, S. [74]	12	37.6			
		Betsou, S. [74]	7	70.7			
		Neofotistou, V. [61]	122				27-205
		Cusma, J.T. [68]	200	358			
		Hansson, B. [69]	33	120			
		Van de Putte, S. [70]	15	170			
		Van de Putte, S. [70]	100	115			235
		Van de Putte, S. [70]		166			345
		Vano et al. [59]	45	66.8			12.8-345
		Webster, C.M. [66]	33	32			8-76
		MacFadden, S.L. [62]	15	122			10-357
		Delichas, M.G. [71]	55	106			19.3-403
		Delichas, M.G. [71]	47	63			13-122
		Efstathopoulos, E.P. [75]	30	75			
		Sandborg, M. [76]	66	61			
		This study, 2006	45	71.3	74.9	92.1	3.7-205

Procedure	Study	Number of patients	KAP (Gy cm2)			
			Mean	Median	3rd quartile	Range or maximum
	(Part. B,D,F)					
Radiofrequency Ablation	Broadhead, D.A. [64]	81	95			
	Neofotistou, V. [61]	21			2.9-134	
	Webster, C.M. [66]	23	105		14-341	
	McFadden, S.L. [62]	50	123		21-430	
	This study, 2006 (Part. B,F)	64	33.4		0.6-285	

5.3.3. Relationship between MSD and KAP for cardiac procedures

Several authors have reported that MSD/KAP is a potentially useful parameter to crudely estimate MSD when this dose quantity is not measured directly. When there is good correlation between MSD and KAP, then it is possible to establish a trigger KAP value, corresponding to e.g. 4-6 Gy of MSD, to inform the operator that the skin of the patient is at risk for surpassing the threshold for delayed erythema. Although MSD/KAP is potentially a useful parameter, operators must understand that it is very dependent on techniques, irradiation geometry and operator [81]. Table 11 compares the MSD/KAP obtained in different centers participating in the study for 3 cardiac procedures, CA, PCTA and RF ablation. Table 12 compares the mean values of MSD.KAP obtained in this study with published results for 2 cardiac procedures, CA and PCTA.

TABLE 11. MSD/KAP EVALUATED FOR CARDIAC PROCEDURES IN DIFFERENT CARDIAC CENTERS IN THE STUDY

Country	MSD/KAP (mGy/(Gy.cm^2))		
	CA	PTCA	RF ablation
Participant A			
Participant B	5.8	10.9	13.8
Participant D	8.85	8.20	
Participant E	3.06		
Participant F	9.01	10.9	21.2

TABLE 12. COMPARISON OF THE MEAN VALUES OF MSD/KAP OBTAINED IN THIS STUDY, WITH PREVIOUSLY PUBLISHED RESULTS

Reference	MSD/KAP for CA (mGy/(Gy.cm^2))	MSD/KAP for PTCA (mGy/(Gy.cm^2))
Hansson et al (2000)	3.8	8.1
Quai et al (2003)	4.3	8.7
Vano et al (2001) p1023	4.5-4.9*	4.5-4.9*
Karambatsakidou et al (2005)	3.9	9.7
This study for Part B,D,F (2006)	9.6	14.9

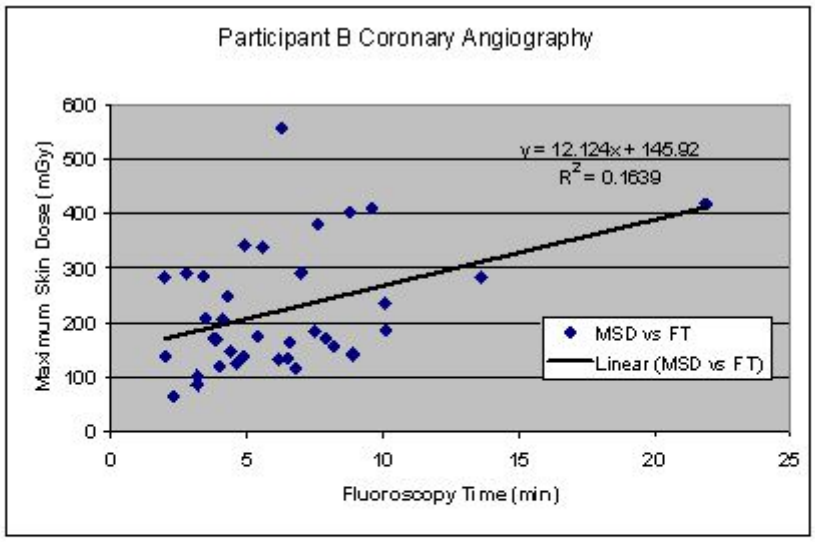
* includes both CA and PTCA procedures.

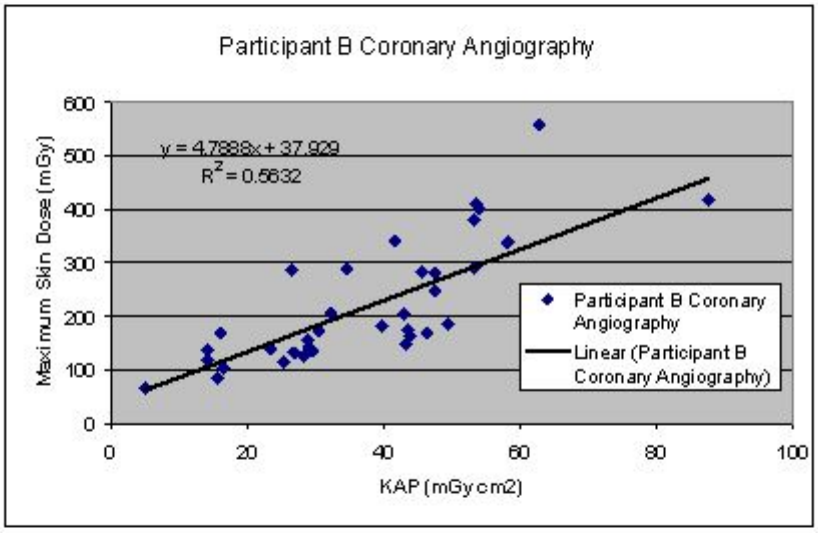
5.3.4. Relationships of MSD to dose analogs

In figures 6 to 9, the MSD is examined as a function of other dose analogues by procedure and country. The linear correlation value of r^2 is specified on each figure.

5.3.5. Portal dose measurements

Too few results were obtained with the slow radiographic films or the output ion chamber to be interpreted.





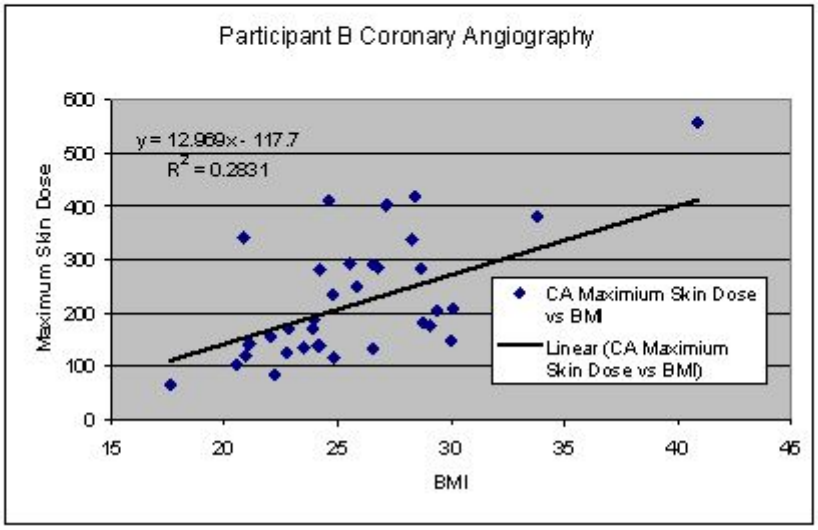
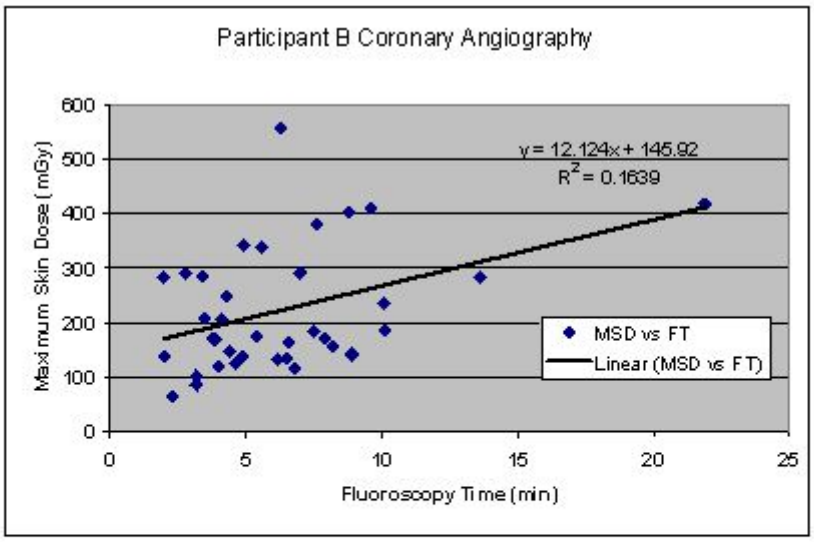
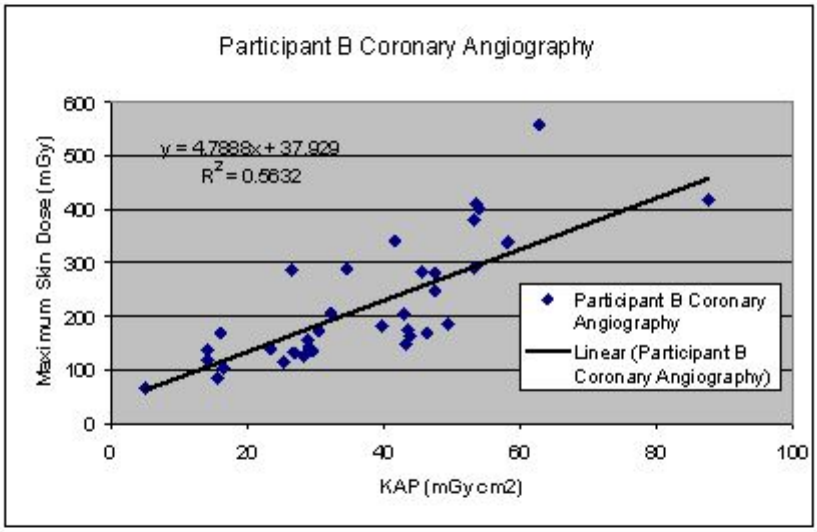
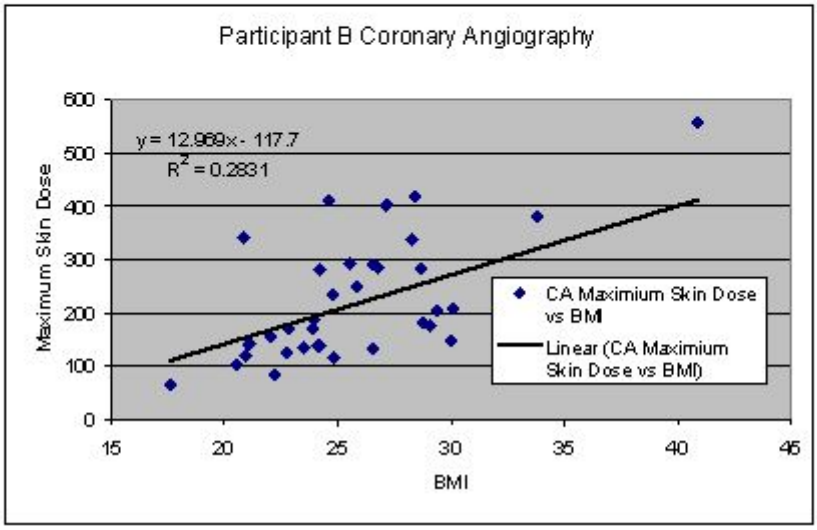
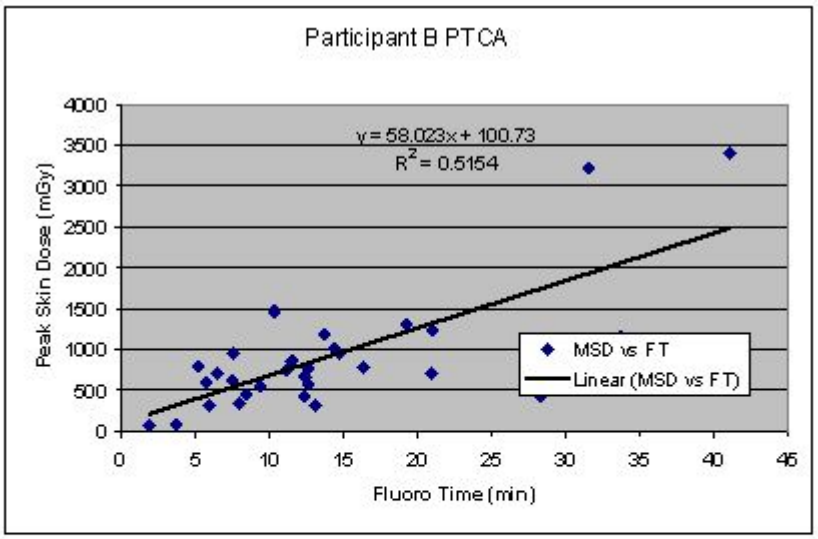


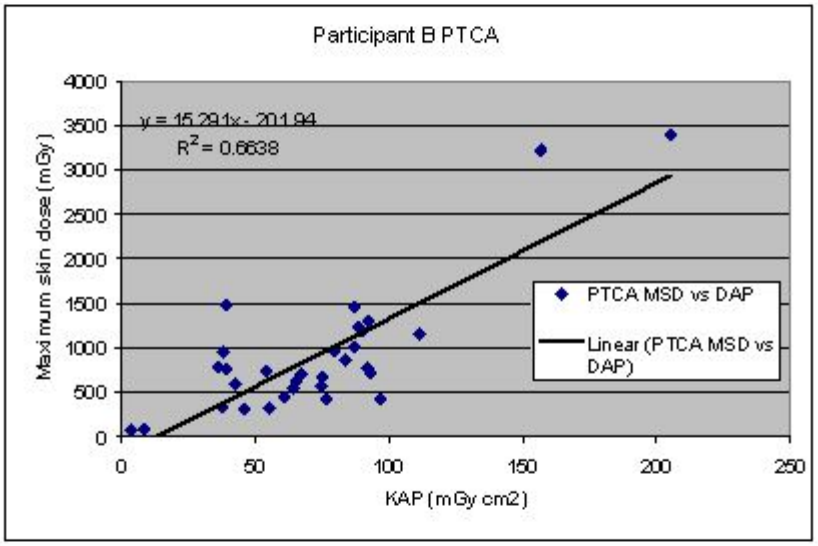
Fig. 6 A-C. Cardiology data for participant A.

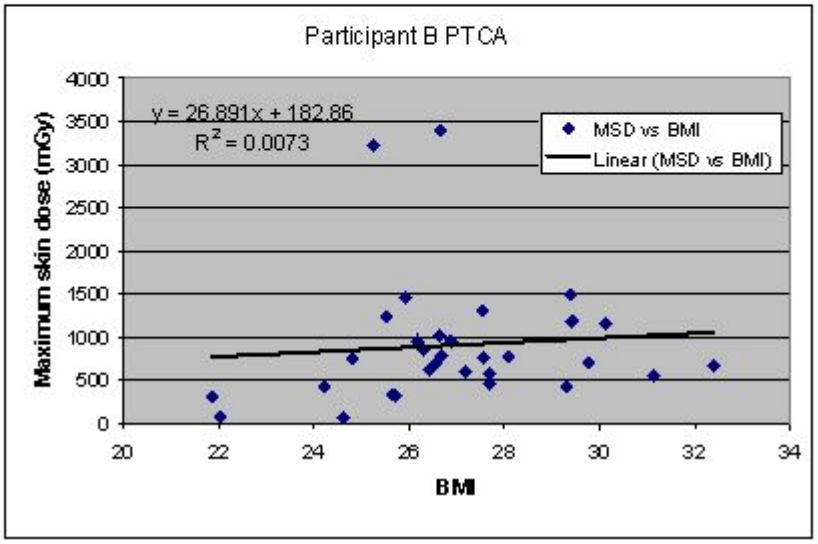

Participant B Coronary Angiography
y = 12.124x + 145.92
R² = 0.1639
Maximum Skin Dose (mGy)
Fluoroscopy Time (min)
MSD vs FT
Linear (MSD vs FT)
0
100
200
300
400
500
600
0
5
10
15
20
25

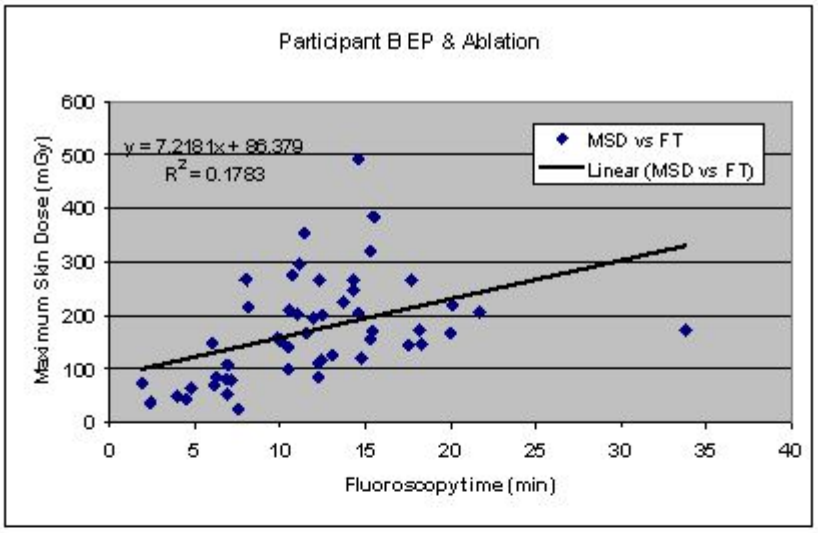

Participant B Coronary Angiography
y = 4.7888x + 37.929
R² = 0.5632
Maximum Skin Dose (mGy)
KAP (mGy cm2)
Participant B Coronary Angiography
Linear (Participant B Coronary Angiography)
0
100
200
300
400
500
600
0
20
40
60
80
100

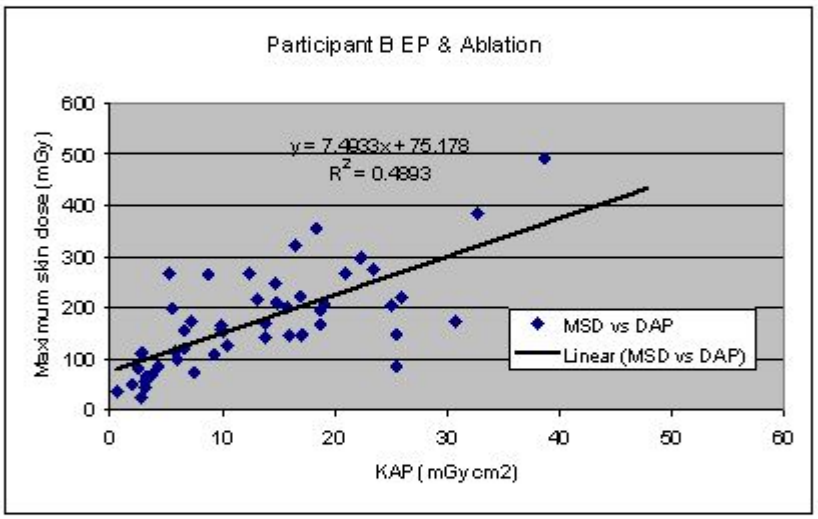

Participant B Coronary Angiography
y = 12.969x - 117.7
R² = 0.2831
Maximum Skin Dose
BMI
CA Maximium Skin Dose vs BMI
Linear (CA Maximium Skin Dose vs BMI)
0
100
200
300
400
500
600
15
20
25
30
35
40
45


Participant B PTCA
y = 58.023x + 100.73
R² = 0.5154
Peak Skin Dose (mGy)
Fluoro Time (min)
MSD vs FT
Linear (MSD vs FT)
0
500
1000
1500
2000
2500
3000
3500
4000
0
5
10
15
20
25
30
35
40
45


Participant B PTCA
y = 15.291x - 201.94
R² = 0.6638
Maximum skin dose (mGy)
KAP (mGy cm2)
PTCA MSD vs DAP
Linear (PTCA MSD vs DAP)
0
500
1000
1500
2000
2500
3000
3500
4000
0
50
100
150
200
250


Participant B PTCA
y = 26.891x + 182.86
R² = 0.0073
Maximum skin dose (mGy)
BMI
MSD vs BMI
Linear (MSD vs BMI)
0
500
1000
1500
2000
2500
3000
3500
4000
20
22
24
26
28
30
32
34





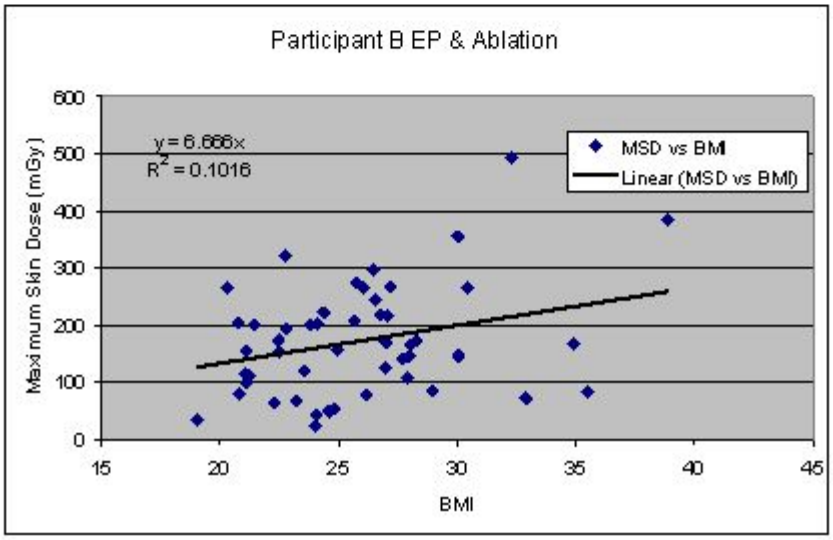
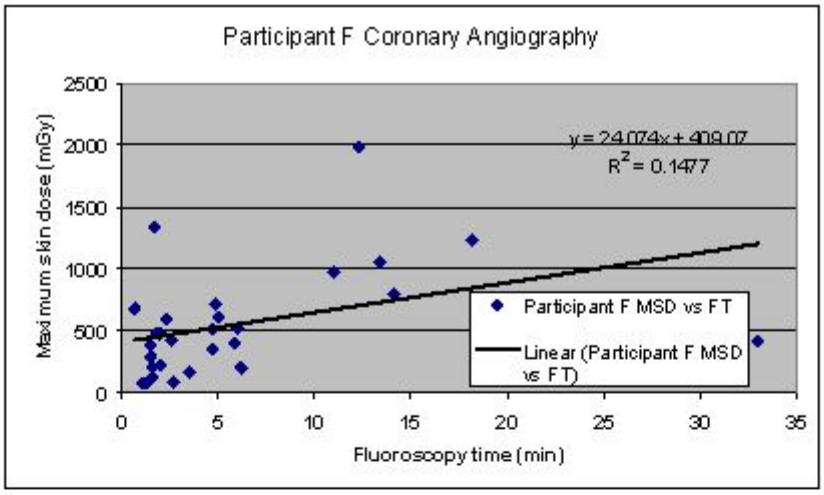
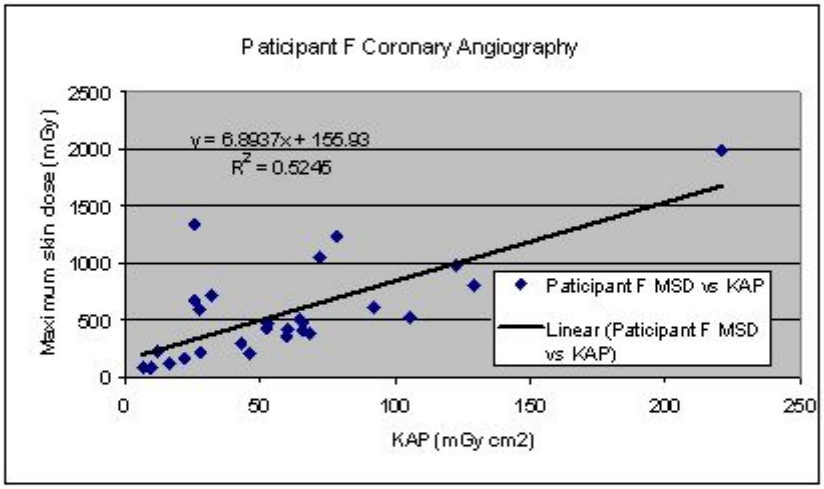
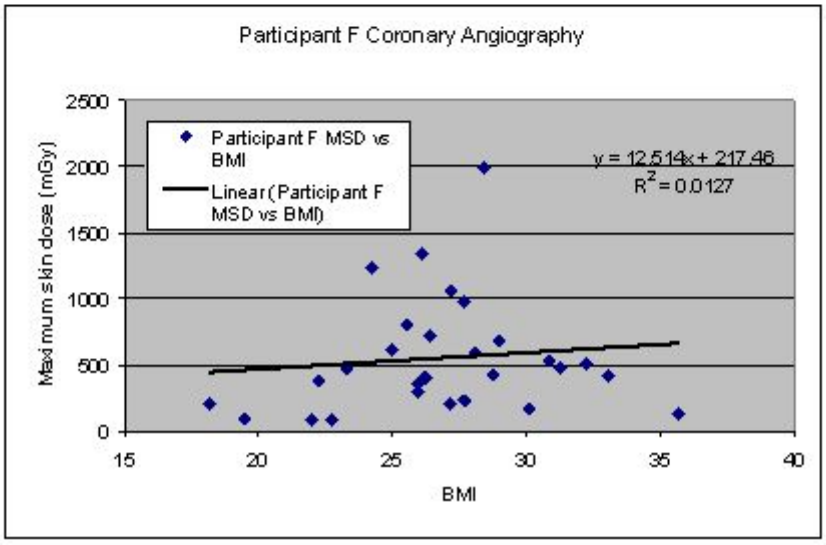
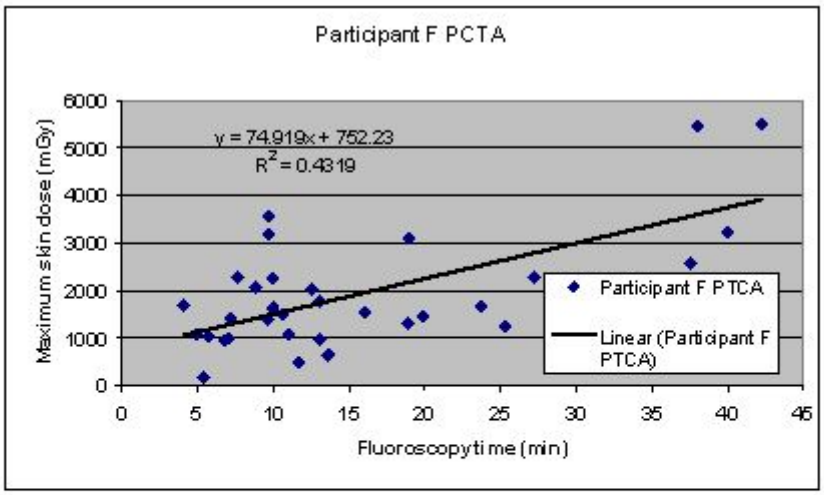


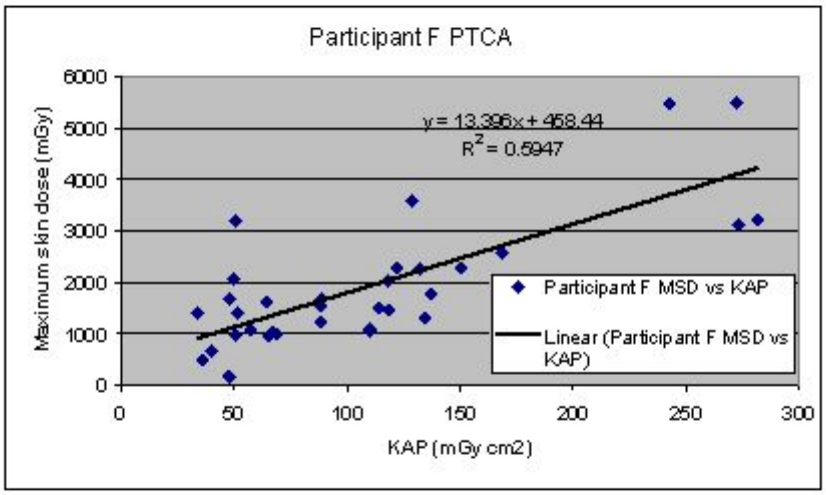
FIG. 7 A-I. Results on dosimetry participant B for coronary angiography, PTCA, and electrophysiological and ablation studies.

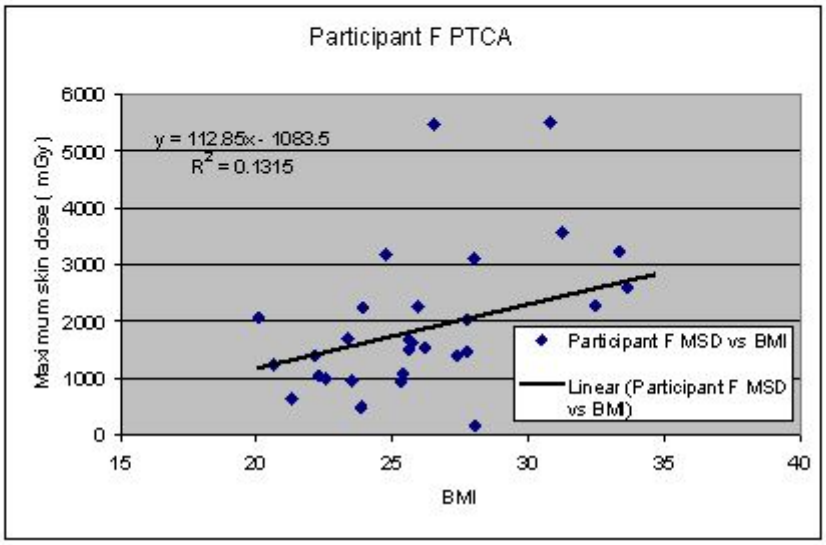

Participant F Coronary Angiography
Maximum skin dose (mGy)
Fluoroscopy time (min)
y = 24.074x + 409.07
R² = 0.1477
Participant F MSD vs FT
Linear (Participant F MSD vs FT)
0
500
1000
1500
2000
2500
0
5
10
15
20
25
30
35

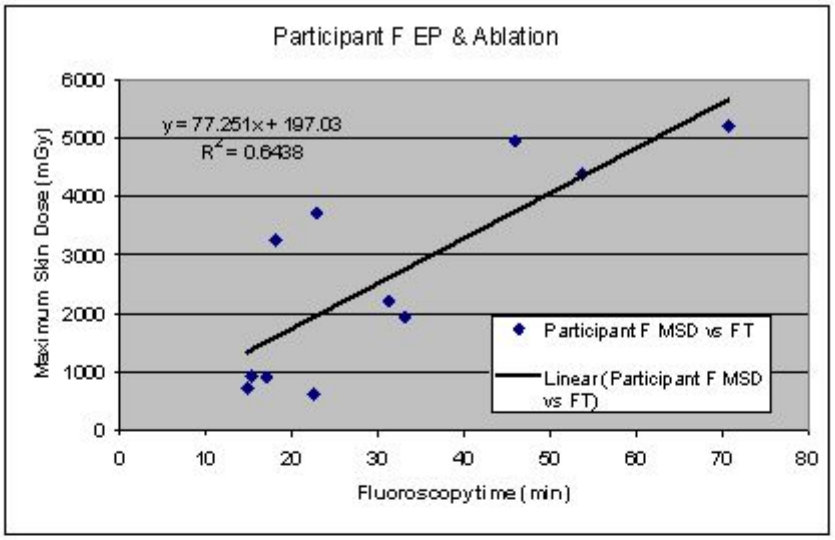

Paticipant F Coronary Angiography
Maximum skin dose (mGy)
KAP (mGy cm2)
y = 6.8937x + 155.93
R² = 0.5245
Paticipant F MSD vs KAP
Linear (Paticipant F MSD vs KAP)
0
500
1000
1500
2000
2500
0
50
100
150
200
250

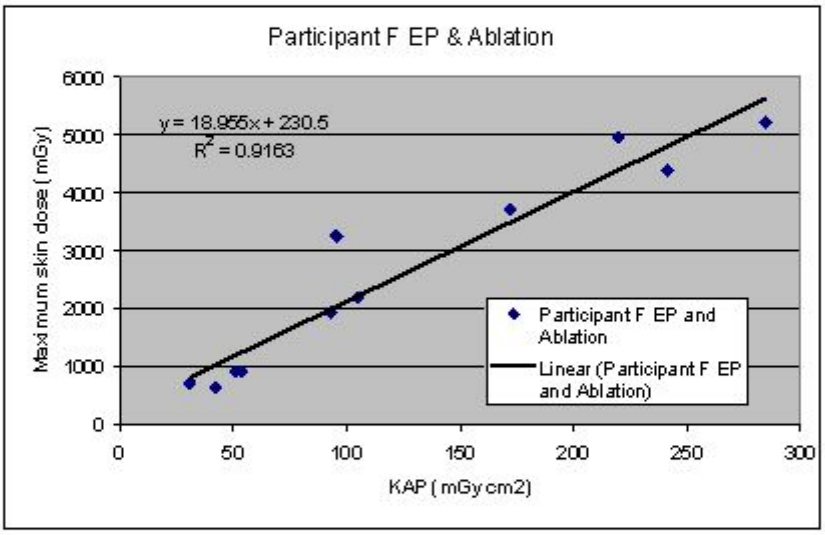

Participant F Coronary Angiography
Maximum skin dose (mGy)
BMI
y = 12.514x + 217.46
R² = 0.0127
Participant F MSD vs BMI
Linear (Participant F MSD vs BMI)
0
500
1000
1500
2000
2500
15
20
25
30
35
40


Participant F PCTA
y = 74.919x + 752.23
R2 = 0.4319
Maximum skin dose (mGy)
Fluoroscopy time (min)
Participant F PTCA
Linear (Participant F PTCA)


Participant F PTCA
y = 13.396x + 458.44
R2 = 0.5947
Maximum skin dose (mGy)
KAP (mGy cm2)
Participant F MSD vs KAP
Linear (Participant F MSD vs KAP)


Participant F PTCA
y = 112.85x - 1083.5
R2 = 0.1315
Maximum skin dose (mGy)
BMI
Participant F MSD vs BMI
Linear (Participant F MSD vs BMI)





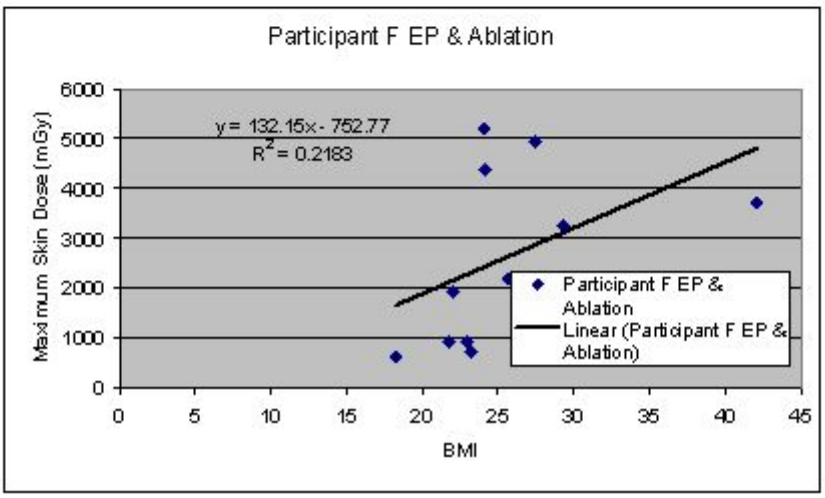


FIG. 8 A-I. Maximum skin dose data for participant F cardiac procedures.

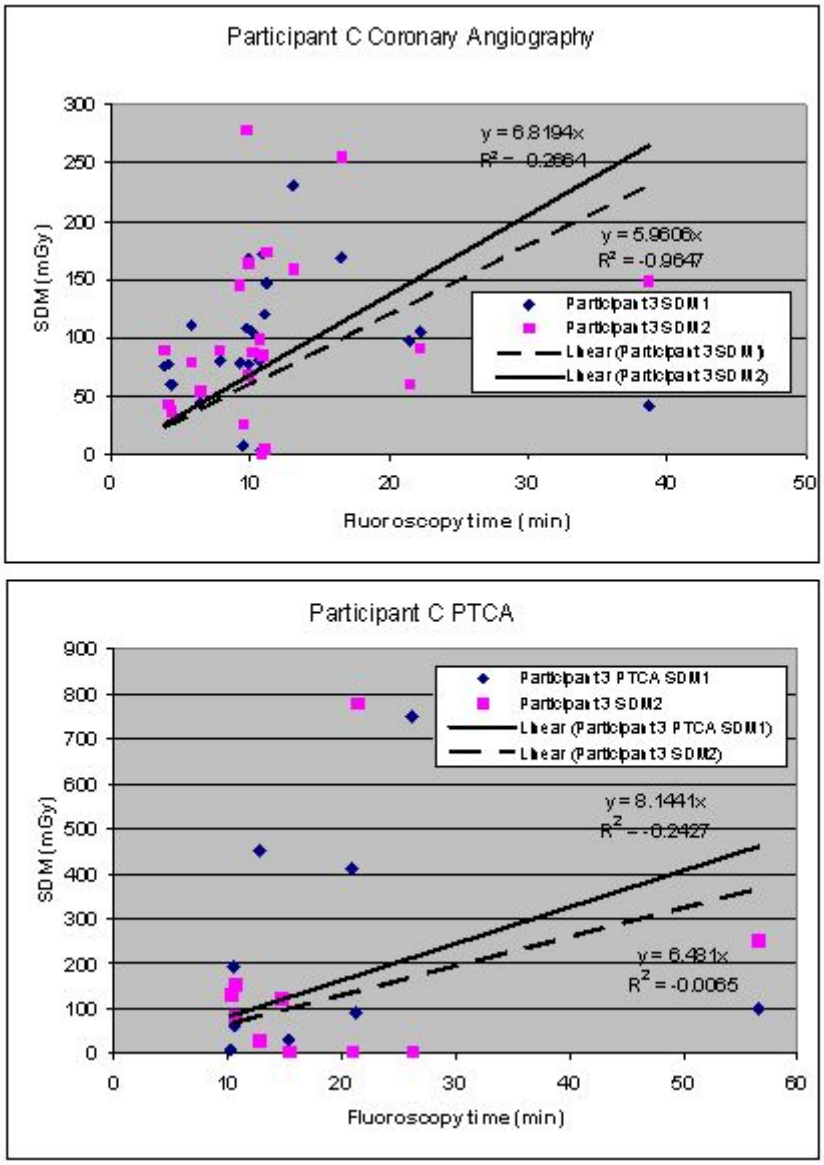


FIG. 9 A-B. Participant C cardiology data with skin dose monitors.

5.4. STATISTICAL ANALYSIS OF CORRELATION

Table 13 provides a summary of the linear regression analysis performed for data from cardiac results. The statistical test is to determine the confidence with which the correlation coefficient of r is different from the value of 0. Specifically, the p-value represents the likelihood of obtaining a value for the correlation coefficient that is greater than the value r. A correlation between, for instance, maximum skin dose and another dose analog like fluoroscopy time was considered significant if p was less than 0.01, moderately significant if p was between 0.01 and 0.05, and not significant if p was greater than 0.05. Grey cells indicate no data available or that the number of data values was less than 10.

TABLE 13. SIGNIFICANCE OF CORRELATION FOR MAXIMUM SKIN DOSE WITH OTHER DOSE ANALOGS IN CARDIAC DOSIMETRY

Dose Analog →			**BMI**						**FT**					**KAP**			**DCS**	**SDM**
Participant →			**A**	**B**	**C**	**D**	**F**	**A**	**B**	**C**	**D**	**F**	**B**	**D**	**F**		A	C
Cardiologic	CA	n		36	27	26	28		36	22	26	28	36	26	28			22
		r		0.53	0.56	0.14	0.10		0.40	0.81	0.55	0.39	0.75	0.75	0.72			0.22
		P(r,n)		**S**	**S**	**N**	**N**		**M**	**S**	**S**	**M**	**S**	**S**	**S**			**N**
	CA+ PTCA	N				23	32				23	32		23	32			
		r				0.33	0.36				0.68	0.66		0.82	0.77			
		P(r,n)				**N**	**M**				**S**	**S**		**S**	**S**			
	PTCA	No.	41	31	10	7	7	52	31	10	7	7	31	7	7		52	10
		r	0.17	0.10	0.28	0.53	0.30	0.85	0.72	0.94	0.76	0.81	0.81	0.32	0.74		0.84	0.04
		P(r,n)	**N**	**N**	**N**	**N**	**N**	**S**	**S**	**S**	**M**	**M**	**S**	**N**	**N**		**S**	**N**
	ABL	No.		50	6		11		50	6		11	53		11			6
		r		0.28	0.00		0.47		0.30	0.95		0.80	0.39		0.96			0.17
		P(r,n)		**M**	**N**		**N**		**M**	**S**		**S**	**S**		**S**			**N**

CA = Coronary Angiography
S = Significant ($p<0.01$)
PTCA = Percutaneous Transluminal Coronary Angioplasty
M = Moderately significant ($0.01<p<0.05$)
ABL = Electrophysiology and Ablation
N = Not significant ($p>0.05$)
BMI = Body Mass Index
n = Number of data points in linear regression
FT = Fluoroscopy Time
r = Linear regression correlation coefficient
KAP = Kerma-Area Product
P(r,n) = Significance of correlation (depends on r and n)
DCS = Dose Calibration Strip
SDM = Skin Dose Monitor

5.5. DATA ANALYSIS OF NON-CARDIAC PROCEDURES

5.5.1. Patient characteristics

Table 14 lists the patient population of the non-cardiac procedures investigated in this study.

TABLE 14. NUMBERS OF NON-CARDIAC PROCEDURES FOR EACH PARTICIPANT

Country	Neuroradiology	Hepatic		Pancreas	Total
	Embolization	Embolization	Biliary (PTBD)	ERCP	
Participant A	-	16 TACE 7 Nuclear Embolization	45	-	68
Participant B	8	-	-	-	8
Participant C	-	19			19
Participant D	12	6	2	-	20
Participant E	12	30 TOCE	11	10	63
Participant F	23	14	-	39	76
Total	55	92	58	49	254

Patients' ages and body mass indices (BMI in units of kg/m^2) for all non-cardiac procedures are reported in Table 15. Body mass index is the mass of an individual in kilograms divided by the square of the individual's height in meters.

TABLE 15. PATIENTS' AGES AND BODY MASS INDICES BY PROCEDURE AND PARTICIPANT

Country	Neuro embolization		Hepatic intervention	
	Age (range, median, mean)	BMI (range, median, mean)	Age (range, median, mean)	BMI (range, median, mean)
Participant A			-	16.6-26.6,20.7,20.7
Participant B	17.2-72.2, 52.0	-	-	-
Participant C	-	-	59-88,71.0,72.1	16.3-27.8, 22.8,22.4
Participant D	25-68, 48.9, 52	17.1-26.7, 23.1, 22.6	62-75, 71.5, 70.0	20.5-261, 24.1, 23.3
Participant E	17-46,30,31	18.5-36.3,22.0,22.9	23-76, 61,59.8	16.8-28.7,22.3,22.4
Participant F	-	19.6-45.0,26.1,26.5	-	20.2-27.9,24.2,24.6

Country	Biliary intervention		ECRP	
	Age (range, median, mean)	BMI (range, median, mean)	Age (range, median, mean)	BMI (range, median, mean)
Participant A	-	15.6-25.0, 19.6, 20.1	-	-
Participant B	-	-	-	-
Participant C	-	-	-	-
Participant D	54-56, 55, 55	24.2-26.7, 25.4, 25.4	-	-
Participant E	17-87, 67,65	16.6-28.5, 20.1, 21.3	39-89, 71.5, 70.2	17-28.7, 21.2, 22.2
Participant F	-	-	-	16.4-35.2, 25.7, 24.7

5.5.2. Dosimetric results for non-cardiac procedures

In Table 16, dosimetric results for non-cardiac procedures are summarized for each participant and in Figures 10 through 12, correlation between the various dose analogs are shown for 3 procedures, neuroembolization, hepatic embolization and ECRP.

TABLE 16. FLUOROSCOPY TIME, KAP AND MAXIMUM SKIN DOSE FOR NON-CARDIAC PROCEDURES

Country	Neuroembolization			
	N	Fluoroscopy time (min) (range, median, mean)	KAP ($Gy.cm^2$) (range, median, mean)	MSD (Gy) (range, median, mean)
Participant A	-	-	-	-
Participant B	8	3.1-46.3, 27.5, 28.2	111-392, 241, 233	0.2-2.2, 0.9,0.9
Participant C	-	-	-	-
Participant D	12	8.3-65.8, 23.1, 18.6	16-302, 9, 120	0.4-1.9, 0.7, 0.8
Participant E	12	14.2-42.2,25.2,28.0	157-582, 235, 267.0	0.4-1.7, 0.9, 0.9
Participant F	23	8.7-140, 44.4, 50.2	100-394, 235, 222	0.5-3.2, 1.95, 1.9

TABLE 16. (con't)

Country	Hepatic embolization			
	N	Fluoroscopy time (min) (range, median, mean)	KAP ($Gy.cm^2$) (range, median, mean)	MSD (Gy) (range, median, mean)
Participant A	16 TACE	2.7-36.5,20.0,18.4	19.4-133,6.6,65.0	0.03-0.7,0.4,0.3
Participant A	7 Nuclear Emb.	1.6-20.1,14.8, 13.0	63.1-166.5,9.3,1	0.15-0.5,0.4,0.4
Participant C	19	3.6-62.9, 24.6, 30.4	-	0.16-2.9, 1.6, 1.5
Participant D	6	15.4-59.9, 42, 38.3	157.1-501.4, 265, 288.1	0.68-3.08, 1.6, 1.8
Participant E	30 TOCE	2.4-48,9.2,14.7	24.3-381.7,184.7,195.2	0.25-2.61,0.9,1.1
Participant F	15	1.8-12.9, 8.7, 7.7	14-204, 48.4, 65.2	0.09–1.25, 0.32 , 0.4

TABLE 16. (con't)

Country	Biliary intervention			
	N	Fluoroscopy time (min) (range, median, mean)	KAP ($Gy.cm^2$) (range, median, mean)	MSD (Gy) (range, median, mean)
Participant A	45	15.6-25.0, 19.6, 20.1	2.7-141, 29.8, 45.1	0.03-0.7, 0.24, 0.25
Participant B	-			
Participant C	-			
Participant D	2	17-25.9, 21.5, 21.5	81.1-147.2, 114.2, 114.2	0.44-0.95, 0.7, 0.7
Participant E	11	0.46-15, 2.4, 5.3	0.28-5.97, 1.3, 1.9	0.004-1.4, 0.2, 0.3
Participant F	-	-	-	-

TABLE 16. (con't)

Country	ECRP			
	N	Fluoroscopy time (min) (range, median, mean)	KAP ($Gy.cm^2$) (range, median, mean)	MSD (Gy) (range, median, mean)
Participant A	-			
Participant B	-			
Participant C	-			
Participant D	-			
Participant E	10	1.8-23, 3.3,6.0	6.3-63.8, 11.1, 20	0.02-0. 4,0.04 ,0.09
Participant F	39	0.15-25.2,1.7,3.7	3.4-423, 23.6, 65.3	0.012-1.14, 0.08.6, 0.2

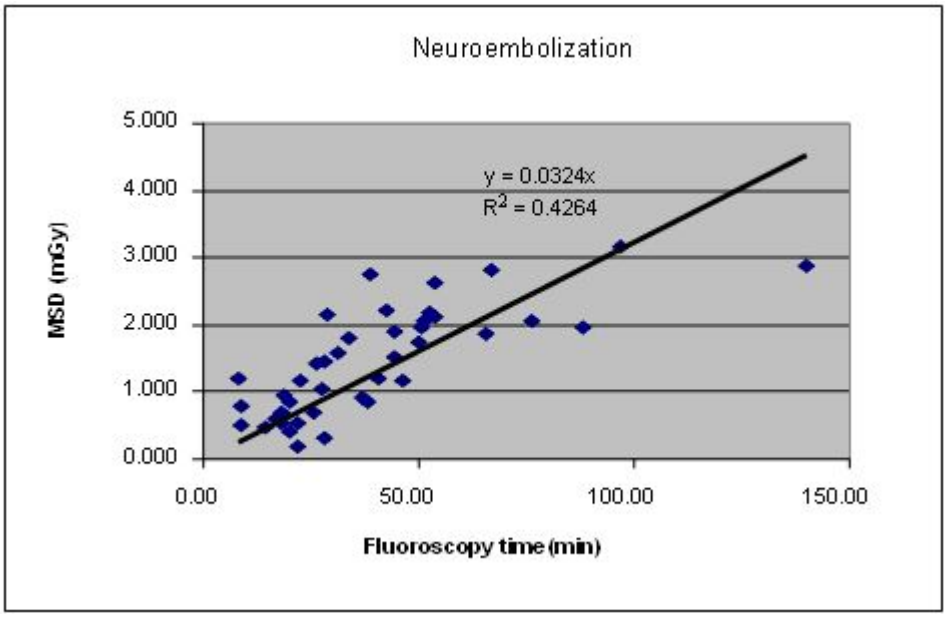


FIG. 10 A. Correlation between MSD and fluoroscopy time in neuroembolization (Participants B and D).

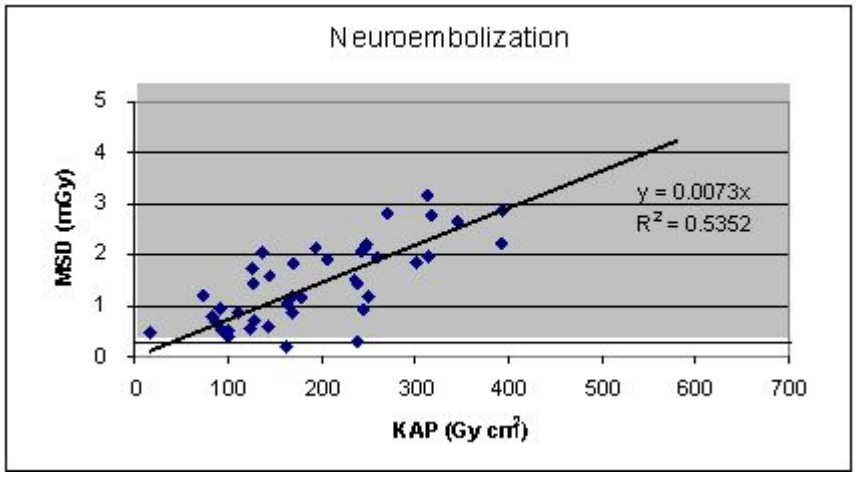


FIG. 10 B. Correlation between MSD and KAP in neuroembolization (Participants B and D).

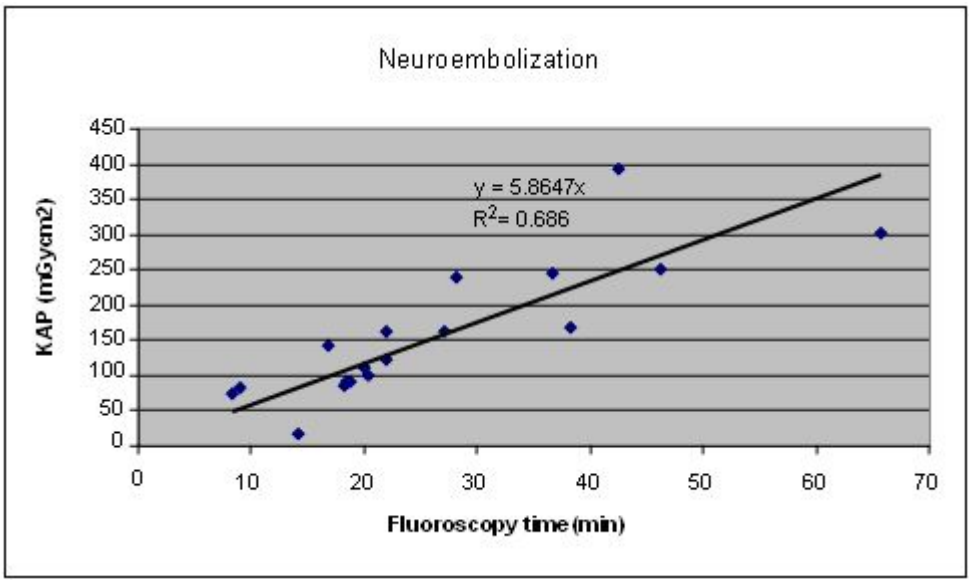


FIG. 10 C. Correlation between KAP and fluoroscopy time in neuroembolization (Participants B and D).

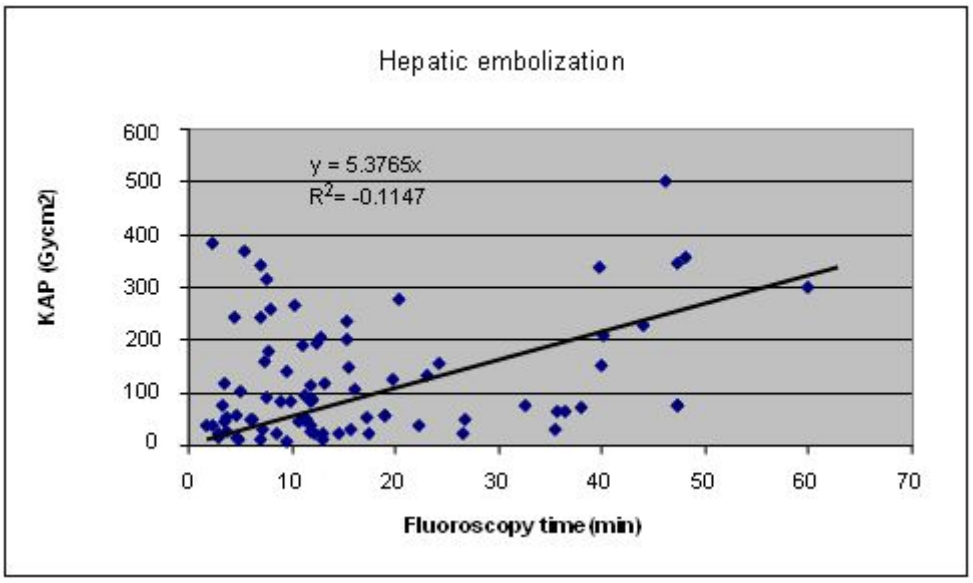


FIG. 11 A. Correlation between KAP and fluoroscopy time in hepatic embolization (Participants A, D, E and F).

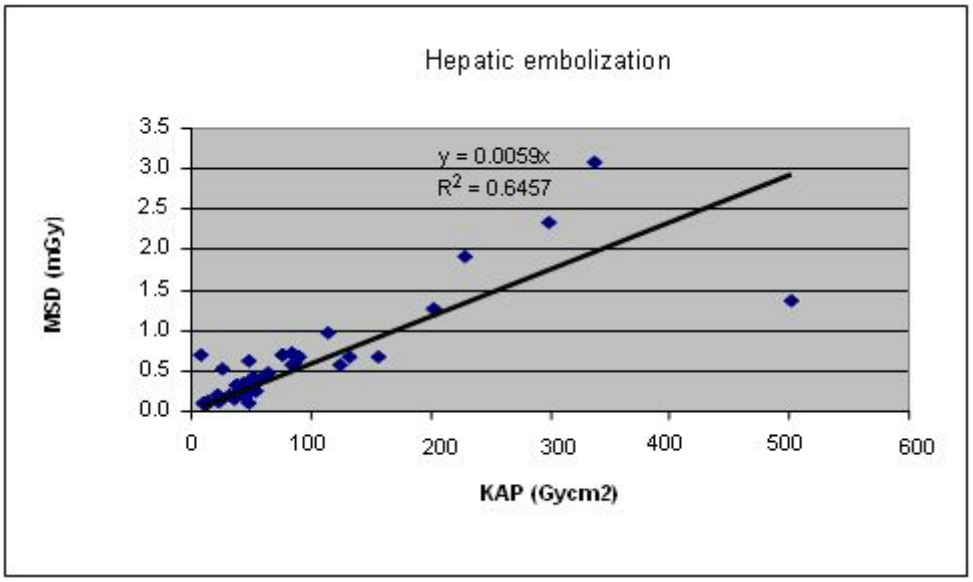


FIG. 11 B. Correlation between MSD and KAP in hepatic embolization (Participants A, C, D and F).

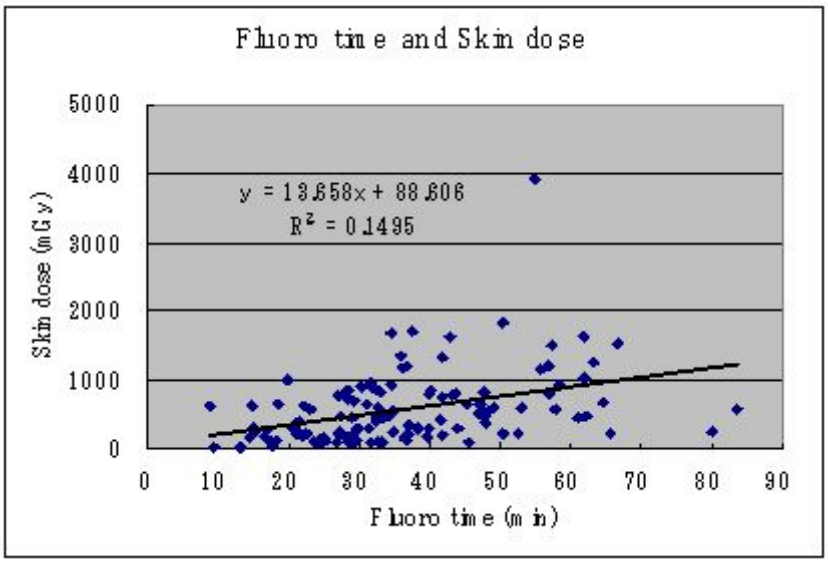


FIG. 11 C. Correlation between MSD and fluoroscopy time in hepatic embolization (Participant C).

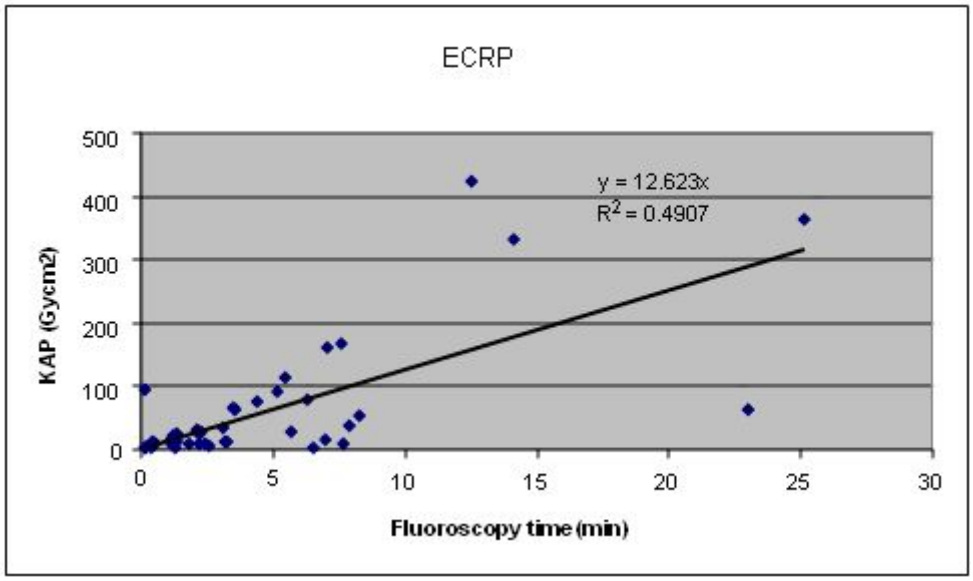


FIG.12 A. Correlation between KAP and fluoroscopy time in ECRP (Participants E and F).

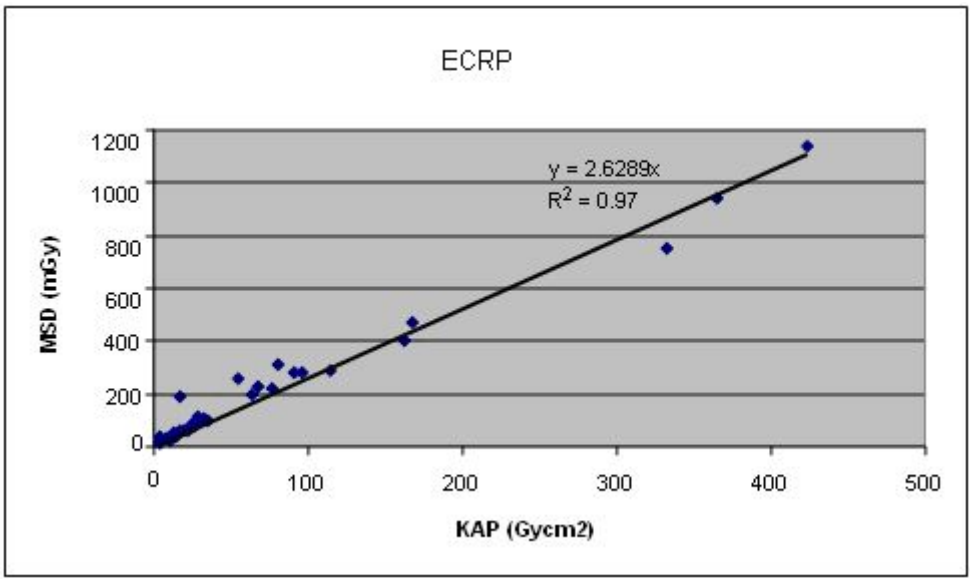


FIG.12 B. Correlation between MSD and KAP in ECRP from Participant E.

5.6. STATISTICAL ANALYSIS OF CORRELATION

Table 17 provides a summary of the linear regression analysis performed for data from non-cardiac results. The statistical test is to determine the confidence with which the correlation coefficient of r is different from the value of 0. Specifically, the p-value represents the likelihood of obtaining a value for the correlation coefficient that is greater than the value r. A correlation between, for instance, maximum skin dose and another dose analog like fluoroscopy time was considered significant if p was less than 0.01, moderately significant if p was between 0.01 and 0.05, and not significant if p was greater than 0.05. Grey cells indicate no data available or that the number of data values was equal or less than 10.

TABLE 17. SIGNIFICANCE OF CORRELATION FOR MAXIMUM SKIN DOSE WITH OTHER DOSE ANALOGS IN NON-CARDIAC DOSIMETRY

Dose analog →			BMI				FT						KAP					TLD
Participant →			A	C	D	E	A	B	C	D	E	F	A	B	D	E	F	F
Hepatic	EMB	n		19	6		7*		19	6		14	7*		6		14	
		r		0.40	0.51		0.41*		0.72	0.57		0.59	0.41*		0.44		0.94	
		P(r,n)		N	N		N*		S	N		M	N*		N		S	
	TACE/ TOCE	n	16			30	16				30		16			30		
		r	0.32			0.37	0.49				0.26		0.00			0.69		
		P(r,n)	N			M	N				N		N			S		
	ERCP	n									10	31				10	31	31
		r									0.95	0.92				0.94	0.98	0.98
		P(r,n)									S	S				S	S	S
	BD	n	34			11	34				11		34			11		
		r	0.14			0.49	0.10				0.93		0.10			0.93		
		P(r,n)	N			N	N				S		N			S		

TABLE 17. (Con't)

Neuro	EMB	n							6		12		33		6	12		23				
		r							0.71		0.69		0.71		0.76	0.73		0.79				
		P(r,n)							N		M		S		N	S		S				

EMB = Embolization
TACE = Transarterial Chemoembolization
TOCE = Transarterial Oily Chemoembolization
ERCP = Endoscopic Retrograde Cholangiopancreatography
BD = Percutaneous Transhepatic Biliary Drainage
BMI = Body Mass Index
FT = Fluoroscopy Time
KAP = Kerma-Area Product
TLD = Thermoluminescent Dosimeter
S = Significant ($p<0.01$)
M = Marginally significant ($0.01<p<0.05$)
N = Not significant ($p>0.05$)
* = Nuclear Embolization
n = Number of data points in regression analysis
r = Correlation coefficient
P(r,n) = Significance of correlation (depends on r and n)

5.7. IMAGE QUALITY CRITERIA FOR NON-CARDIAC PROCEDURES

Table 18 shows that in a total of 92 cases that were evaluated for image criteria, 71 cases (77%) were graded as "**visually sharp reproduction"** and 21 cases (23%) were graded as "**reproduction".** There was no case graded as "**visualization"**. The details of each procedure are also provided. Tables 19 to 21 show the inter-participant variation for hepatic artery embolization, neurointervention and biliary intervention.

TABLE 18. IMAGE QUALITY RESULTS – NON-CARDIAC PROCEDURES

Image criteria	Hepatic artery embolization	Neuro-intervention	Biliary intervention
Visualization	0	0	0
Reproduction	20	1	0
Visually sharp reproduction	22	15	34

TABLE 19. IMAGE QUALITY – HEPATIC ARTERY EMBOLIZATION

Image criteria	Participant A	Participant C	Participant E	Total
Visualization	0	0	0	0
Reproduction	0	19	1	20
Visually sharp reproduction	16	0	6	22

Image criteria in hepatic artery embolization were evaluated as the overall score of serial hepatic angiography including hepatic arteriography and transarterial portal venography in 42 patients. Twenty-two patients (52%) were graded as **visually sharp reproduction** and 20 patients (48%) were graded as **reproduction**. All patients were graded as **visually sharp reproduction** in Participant A, and all patients were graded as **reproduction** in Participant C. In Participant E, only one patient was graded as **reproduction** while the others were graded as **visually sharp reproduction**. The patient graded as **reproduction** by Participant E had enlarged liver due to multiple large hepatic tumors with the maximum diameter of 10cm. The skin dose of that particular patient was 818 mGy, whereas the skin dose of the other 6 patients were 320 to 678 mGy (mean, 482 mGy).

Figure 13 shows the patient's mean of maximum skin doses in hepatic artery embolization in three countries for this image quality portion of this study.

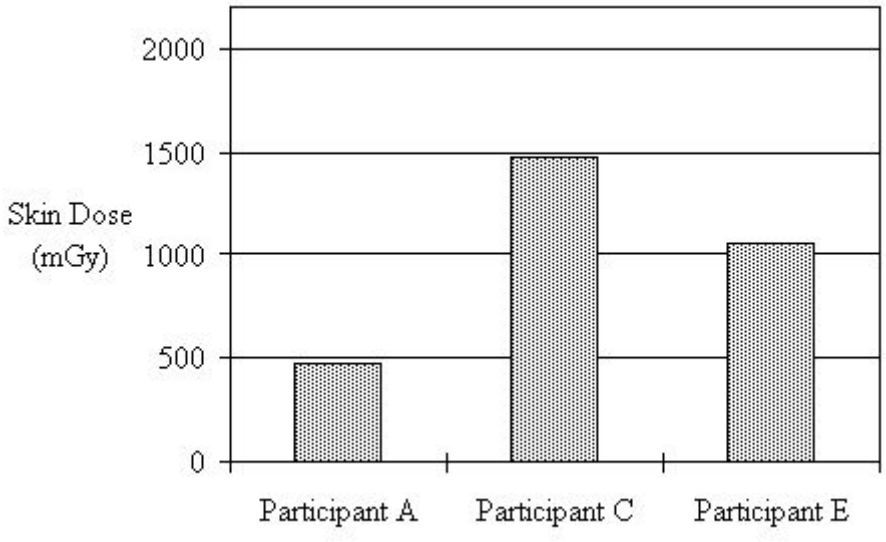


FIG. 13. Patients' mean skin doses in hepatic artery embolization in three countries.

TABLE 20. IMAGE QUALITY – NEUROINTERVENTION

Image criteria	Participant A	Participant C	Participant E	Total
Visualization	-	0	0	0
Reproduction	-	0	1	1
Visually sharp reproduction	-	2	13	15

Image criteria in neurointervention were evaluated as the overall score of serial cerebral angiography in 16 patients. Fifteen patients (94%) were graded as **visually sharp reproduction** and only one patient (6%) was graded as **reproduction**. The patient graded as **reproduction** was treated for traumatic carotid-cavernous fistula. Intracranial vessels were not sharply visualized due to the high-flow arteriovenous communication.

TABLE 21. BILIARY INTERVENTION

Image criteria	Participant A	Participant C	Participant E	Total
Visualization	0	-	-	0
Reproduction	0	-	-	0
Visually sharp reproduction	34	-	-	34

Image criteria in biliary intervention were evaluated as the overall score of serial cholangiography in 34 patients. All patients were graded as **visually sharp reproduction.**

5.8. GROUPING OF PATIENTS WITH HIGH SKIN DOSES

Figure 14 shows the dose distribution for procedures in this study. The large number of skin dose measurements made in the study by different interventional centers of 6 countries for 6 different types of interventional procedures provides the opportunity to discuss single cases of high skin doses and to identify procedures and causes of high doses.

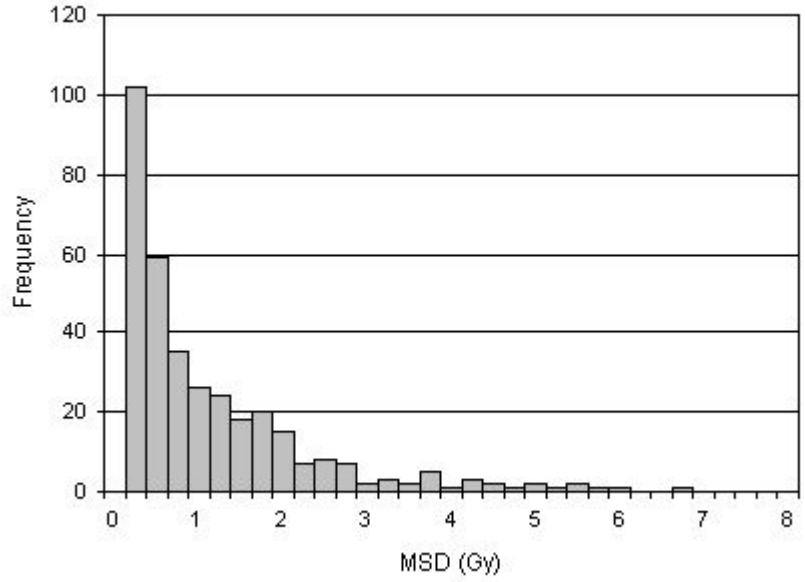


FIG.14. Dose distribution (MSD) from the procedures in this study.

Tables 22 and 23 report on the frequency of procedures with maximum skin dose (MSD) greater than 2 Gy.

TABLE 22. NUMBER OF PATIENTS WITH MSD GREATER THAN 2 GY

Country	Maximum skin dose (Gy)					
	2-3	3-4	4-5	5-6	6-7	7-8
Participant A	12	4	4	2	2	
Participant B		2				
Participant C	3			1		
Participant D	3	1				
Participant E	12	1				
Participant F	18	7	1	4		
Total	48	15	5	7	2	0

TABLE 23. PATIENTS WITH MSD >2 GY BY PARTICIPANT AND PROCEDURE

Country	Maximum skin dose (Gy)				
	PTCA*	RF ablation	Neuro	Hepatic	Biliary
Participant A	24	-	-	0	0
Participant B	2	0		-	-
Participant C	1	-	-	3	0
Participant D	1	-	0	3	0
Participant E	3	1	4	5	0
Participant F	13	7	10	0	0
Total	44	8	14	11	0

*includes PTCA and CA-PTCA.

For cardiac procedures, 12.7% of patients received a skin dose in excess of 2 Gy, for non-cardiac procedures, about 10% of patients received a skin dose in excess of 2 Gy and in the whole cohort of patients, 11.6% received a skin dose in excess of 2 Gy.

Tables 24 through 29 itemize data associated with each case of a skin dose reported to be in excess of 2 Gy.

TABLE 24. FACTORS FOR MSD EXCEEDING 2 GY FOR PARTICIPANT A

Patient	Procedure	Body mass index (kg/m^2)	Fluoro time (min)	No of cine frames	MSD (Gy)	Old/ new equipment
1	PTCA	26.8	30	246	2.7	old
2	PTCA		85	277	5	old
3	PTCA	24.7	12.5		2.1	
4	PTCA		16	704	3.9	old
5	PTCA	26.3	17	426	2.5	old
6	PTCA	28.1	27	267	3.8	old
7	PTCA		21	-	2.2	old
8	PTCA	17.9	39	329	2.7	old
9	PTCA	-	66		6.9	old
10	PTCA	-	44		5.7	old
11	PTCA	-	26		3.6	old
12	PTCA	25.7	16		2.1	
13	PTCA	21.9	31	407	4.3	old
14	PTCA	23.9	11	692	2.9	old
15	PTCA	23.5	30	799	4.5	old
16	PTCA	25.3	26	406	3.1	old
17	PTCA	23	19	733	2.5	old
18	PTCA	27.4	6.3		2.1	
19	PTCA	23.3	27	1140	2.7	old
20	PTCA	25.3	10	535	2.3	old
21	PTCA	32.3	45	318	4.3	old
22	PTCA	25.5	31	-	4.7	old
23	PTCA	23.2	22	-	2.7	old
24	PTCA	28.3	57	-	6.2	old

TABLE 25. FACTORS FOR MSD EXCEEDING 2 GY FOR PARTICIPANT B

Factors responsible for high dose	Patient 1	Patient 2
Procedure	PTCA	PTCA
Body mass index (kg/m^2)	25.2	26.6
Fluoroscopy time (min)	31.5	41.0
DAP (Gy.cm^2)	157	205
MSD (Gy)	3.4	3.6
Old/ new equipment	INOVA 2000	INOVA 2000
Single/Bi-plane	Single	Single

TABLE 26. FACTORS FOR MSD EXCEEDING 2 GY FOR PARTICIPANT C

Factors responsible for high dose	Patient 1	Patient 2	Patient 3	Patient 4
Procedure	PTCA	Hepatic	Hepatic	Hepatic
Body mass index (kg/m^2)	27.3	27.6	22.6	22.9
Fluoroscopy time (min)	56.6	54.9	42.1	35.7
Serial imaging	4899 frames	19 series	16 series	10 series
No of vessels	2	3	2	3
Complexity Angulation, tortuosity		severe	severe	mild
MSD (Gy)	5.1	2.9	2.4	2.4
Equipment (year installed)	Siemens 1998	Toshiba 2000	Toshiba 2000	Toshiba 2000
Single/Bi-plane	Single	Single	Single	Single
Others	>B2 lesion/stenting			

TABLE 27. FACTORS FOR MSD EXCEEDING 2 GY FOR PARTICIPANT D

Factors responsible for high dose	Patient1	Patient 2	Patient 3	Patient 4
Procedure	PTCA	Hepatic	Hepatic	Hepatic
Body mass index (kg/m^2)	25	24.2	24.1	24.3
Fluoroscopy time (min)	57.3	39.8	59.9	44
No of cine frames	887			
DAP ($Gy.cm^2$)	105	338	300	229
MSD (Gy)	2.3	3.3	2.5	2.0
Old/new equipment		1995	1995	1995
Single/Bi-plane	single	single	single	single

TABLE 28. FACTORS FOR MSD EXCEEDING 2 GY FOR PARTICIPANT E

Patient	Procedure	BMI (kg/m^2)	Fluoroscopy time (min)	No. of cine frames	DAP ($Gy.cm^2$)	No of vessels	Difficulty	MSD (Gy) (calculated)	Single/ Bi-plane
1	PTCA	40.2	16.7	12525	200	2	Moderate	3.5	Single
2	PTCA	24.9	7.7	5775	117	1		2.06	Single
3	PTCA	30.7	29.8		212	1	Occlusion	2.31	Biplane
4	RF	27.7	96.7		447	-		2.22	Single
5	Neuro	25.4	32.1	462	210	3	Severe	2.3	Biplane
6	Neuro	19.5	25.2	776	264	2	Moderate	2.3	Biplane
7	Neuro	22.1	14.7	485	205	2	Mild	2.38	Biplane
8	Neuro		38.5		587	3	Severe	2.55	Biplane
9	TOCE	27.6	7.02	84	343	-	Mild	2.11	Single
10	TOCE	22.4	48	184	358	1	Moderate	2.61	Single
11	TOCE	26.1	2.4	228	382	2	Moderate	2.6	Single
12	TOCE	27.1	5.34	170	369	1	Mild	2.07	Single
13	TOCE	22	7.5	905	314	1	Mild	2.15	Single

TABLE 29. FACTORS FOR MSD EXCEEDING 2 GY FOR PARTICIPANT F

Patient	Procedure	Body mass index (kg/m^2)	Fluoro time (min)	No of cine frames	DAP ($Gy.cm^2$)	MSD (Gy) (calculated)	Old/ new equipment	Others
1	RF abl.	27.4	46	0	219.5	5.25	PH_2	Fl.cont.
2	RF abl.	24.2	53.7	0	241.3	4.64	PH_2	Fl.cont.
3	RF abl.	42.1	22.9	51	171.9	3.95	PH_2	Fl.cont.
4	RF abl.	29.3	18.1	54	95.2	3.46	PH_2	Fl.cont.
5	RF abl.	25.6	31.3	86	104.8	2.34	PH_2	Fl.cont.
6	RF abl.	22	33.1		93	2.05	PH_2	
7	RF abl.	24.1	70.7	25	284.5	5.52	PH_2	Fl.cont.
8	PTCA	30.8	42.2	775	272	5.8	PH_1	Puls 25p/s
9	PTCA	26	27.2	2068	150.4	2.4	SM_CV	Fl.cont.
10	PTCA	33.7	37.5	1990	168.4	2.74	SM_CV	Fl.cont.
11	CA+PTCA	24.8	10	976	132.2	3.38	GE_1	St/norm
12	PTCA	33.3	40	1008	281.4	3.41	GE_1	St/norm
13	PTCA	27.8	12.5	742	117.9	2.15	GE_1	St/norm
14	PTCA	28	18.9	1925	273.1	3.29	GE_1	St/norm
15	PTCA	26.5	38	541	242.6	5.79	GE_1	St/norm
16	CA	28.4	12.3	1893	221	2.11	GE_1	St/norm
17	PTCA	20.1	8.8		49.9	2.18		
18	PTCA	23.9	10		132.3	2.39		
19	PTCA	32.5	7.6		121.9	2.41		
20	PTCA	31.3	9.7		128.6	3.79		
21	Neuro	31.8	53.6		246.2	2.13		
22	Neuro	32	66.6		270.1	2.81		
23	Neuro	21.9	76.2		136	2.04		
24	Neuro	29.1	53.8		345.9	2.64		
25	Neuro	24.9	28.7		194.1	2.14		
26	Neuro	24	140		394.3	2.86		

Patient	Procedure	Body mass index (kg/m^2)	Fluoro time (min)	No of cine frames	DAP ($Gy.cm^2$)	MSD (Gy) (calculated)	Old/ new equipment	Others
27	Neuro	27.1	97		313.8	3.16		
28	Neuro	26.6	52.8		248	2.19		
29	Neuro	26.1	51.4		242.4	2.06		
30	Neuro	27.4	38.9		318	2.75		

The greater number of cases with MSD>2 Gy are found in PTCA and RF cardiac ablation procedures. About 11% of all cases in the study received MSD>2 Gy. Two countries reported a higher number of cases with high skin doses.

5.9. FREQUENCY OF REPEATED CARDIAC PROCEDURES

A database for all the procedures performed in the catheterization laboratory at the Udine hospital contains demographic, clinical, technical and dosimetric data for each procedure. In particular, fluoroscopy time, number of acquired images and kerma-area product (KAP) have been registered. It is thus possible to evaluate the frequency of repeated cardiac procedures (Figure 15) and the cumulative KAP (Figure 16). For each patient, the cumulative KAP has been calculated adding the contribution of each procedure performed in the observation period. Patients with a cumulative KAP>300 $Gy.cm^2$ have then been extracted for a follow-up study. This threshold has been selected because it corresponds to approximately 2 Gy of MSD, when a contribution of CA and PTCA procedures together is considered.

For the patients in the follow-up group, MSD was estimated for each procedure and linearly added for all the procedures performed in the observation period with the conservative hypothesis that the same skin area received the maximum doses from each procedure. This assumption, of course, will give an overestimation of the maximum skin dose from all the performed procedures on a patient.

At the time of the study, information on more than 5500 procedures performed between April 1998 and December 2002 was available. The sample includes 3332 patients who underwent a total of 5039 procedures, both diagnostic and therapeutic (Table 30) representing 70% of the total activity performed in the Udine cardiac centre. For each patient, the KAP from each single procedure was added. 78 patients received more than 300 $Gy.cm^2$, 17 female and 61 male with a mean age of 71 years. The mean number of procedures performed on this subgroup of patients was 4.5 (Figure 15). The sample included 4 patients who underwent only an elective PTCA. 39 patients showed a cumulative KAP greater than 350 $Gy.cm^2$ and 18 more than 400 $Gy.cm^2$ with a maximum cumulative KAP of 900 $Gy.cm^2$ (Figure 16).

TABLE 30. PROCEDURES PER PATIENT PERFORMED IN CARDIAC CATHETERIZATION LABORATORY OF PARTICIPANT B FROM APRIL 1998 TO DECEMBER 2002

No. of cardiac procedures/patient	Patients	
	Number	(%)
1	1967	59.0
2	940	28.2
3	194	5.8
4	138	4.1
5	41	1.2
6	29	0.9
7	14	0.4
>7	9	0.3

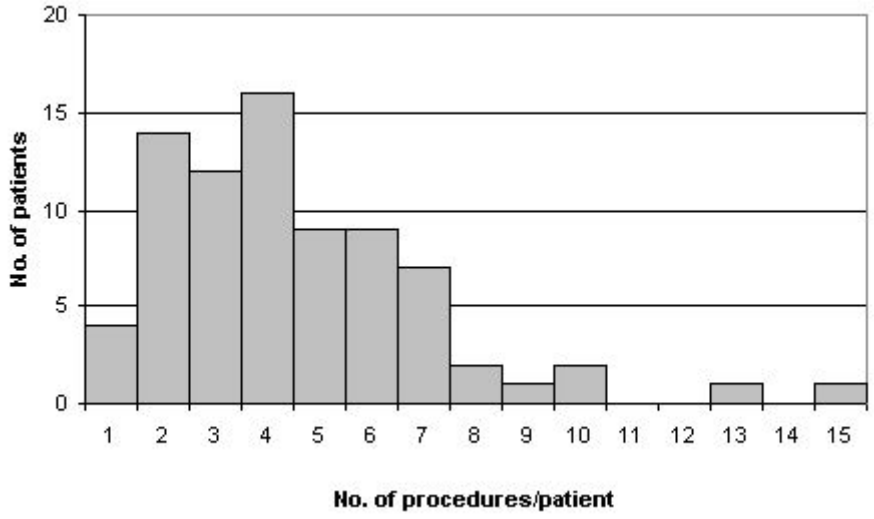


FIG. 15. Distribution of the number of cardiac procedures performed on the sample of 78 patients included in the follow-up study for the detection of skin injuries.

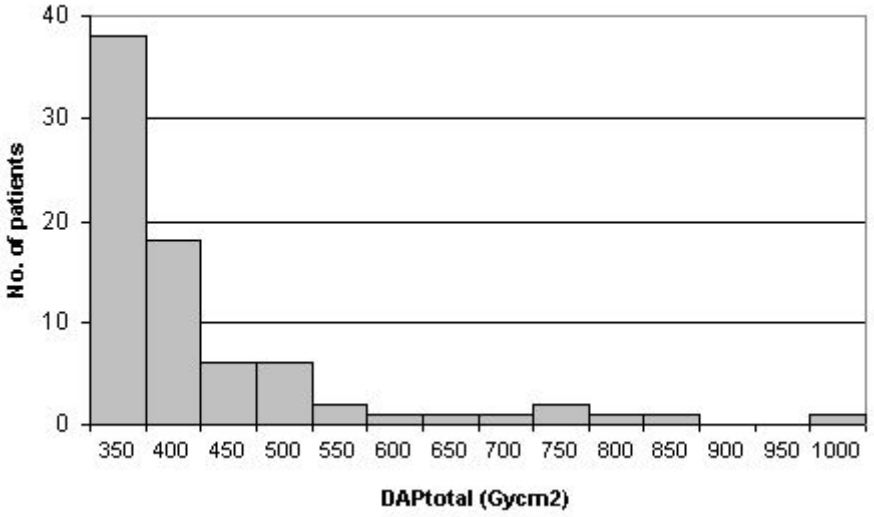


FIG. 16. Distribution of cumulative KAP for the 78 patients included in the follow-up study.

The highest MSD estimated, from the correlations found between MSD and KAP both for CA and PTCA, was 8.4 Gy and only 32 patients (41% of the follow-up group) exceeded a maximum cumulative skin dose of 4 Gy (Figure 17).

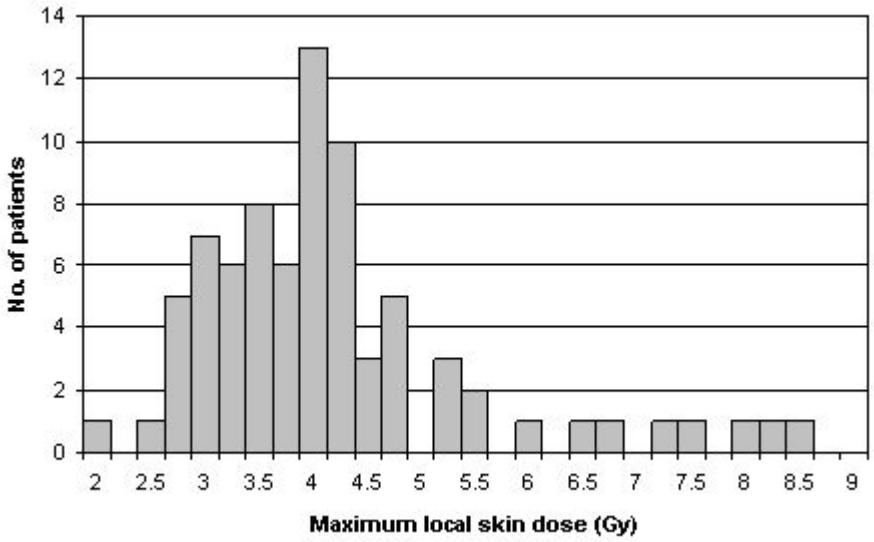


FIG.17. Distribution of estimated maximum skin dose for the 78 patients included in the follow-up study.

5.10. PATIENT DOSE AND CARDIOLOGISTS' EXPERIENCE

For the study on the effects of experience on patient dose in cardiology by Participant B, exposure parameters and data on dye consumption are shown in Table 31. All parameters were increased in diagnostic procedures performed with cardiology fellows in comparison with those of staff members only, in particular fluoroscopy time (+38%) and KAP_{fluoro} (+45%). KAP_{image} and the number of images were

increased to a lesser degree (8% and 9% respectively): as a consequence, the difference in total KAP was less prominent (+21%). Contrast consumption was also increased to a very slight amount (+10 cc, or 7%): this finding, albeit significant from a statistical point of view, is not likely to be relevant from the clinical point of view.

TABLE 31. EXPOSURE PARAMETERS AND EXPERIENCE IN CORONARY ANGIOGRAPHIES (ALL PROCEDURES)

	Fluoroscopy time (min)	No. Images	KAP_{image} ($Gy.cm^2$)	KAP_{fluoro} ($Gy.cm^2$)	KAP ($Gy.cm^2$)	Contrast media (cm^3)
Staff	3.8 ± 4.5	589 ± 282	20.8* ± 14	10.6 ± 14	31.5 ± 28	140 ± 60
Fellows	5.5 ± 5.9	642 ± 260	22.5* ± 12	15.5 ± 16	38.1 ± 28	150 ± 58

*P = 0.0023. Other comparisons P ≤ 0.001

As major differences were noted in the type of procedures performed in the groups, we reassessed exposure parameters after eliminating all procedures with right heart catheterization and without left ventriculography: differences still remained highly significant (Table 32).

TABLE 32. EXPOSURE PARAMETERS AND EXPERIENCE IN CORONARY ANGIOGRAPHIES (MORE UNIFORM PROCEDURE SELECTION)

	Fluoroscopy time (min)	No. Images	KAP_{image} ($Gy.cm^2$)	KAP_{fluoro} ($Gy.cm^2$)	KAP ($Gy.cm^2$)	Contrast media (cm^3)
Staff	3.3 ± 3.8	661 ± 288	22.7 ± 12	9.4 ± 10	32.2 ± 28	147 ± 54
Fellows	4.8 ± 5.3	711 ± 263	24.5 ± 12	13.2 ± 13	37.7 ± 24	151 ± 53
Difference	+36%	+7.6%	7.9%	40%	17%	2.7%

All comparisons P ≤ 0.001.

In order to examine the learning curve of fellows, exposure parameters of the first 50 procedures were compared with the last 50 performed (Table 33). For one fellow performing less than 100 procedures, the last 40 were considered. All parameters were lower at the end of the training, but only KAP_{image} was statistically significant.

TABLE 33. CHANGES IN EXPOSURE ANALOGUES WITH EXPERIENCE

	Fluoroscopy time (min)	No. Images	KAP_{image} ($Gy.cm^2$)	KAP_{fluoro} ($Gy.cm^2$)	KAP ($Gy.cm^2$)	Contrast media (cm^3)
First 50	5.9 ± 6.8	691 ± 289	25.7 ± 14**	16.3 ± 15	42.0 ± 29	149 ± 60
Last 50*	5.2 ± 4.0	647 ± 253	22.2 ± 11**	15.2 ± 14	37.5 ± 24	149 ± 54
Change	-12%	-6.4%	-14%	-6.7%	-10.7%	0%

* For one fellow performing less than 100 procedures, the last 40 were considered.

** P<0.001.

6. DISCUSSION

6.1. INTERCOMPARISONS AND CALIBRATIONS

The results of our intercomparison tests with TLD (Table 6) demonstrate the potential variability of dosimetry measurements at facilities. Some variability can be expected as a result of normal variations in calibrations and in performance of dosimetry devices. Other potential concerns relate to the guidance that might be provided to facilities in the proper measurement of air kerma or absorbed dose. For example, the wide variance in results for the two trials of Participant A indicates the difference that feedback on methods and techniques can make. For any facility, resources must be available to check one's measurements and verify their accuracy. Obtaining agreement to within 10% requires careful attention to details regarding dosimetric measurements.

Our intercomparisons of dosimetry using Gafchromic media (Figures 3, 4 A and 4 B) demonstrate that results among various centers can be consistent, with the usual variations expected due to procedure setup, calibration of electronic dosimeters, and normal variances due to testing conditions (e.g., temperature and pressure). However, results are not guaranteed and those of Participant E demonstrate an unusual variance. Therefore, it is essential that participants in any dosimetry program be provided with resources to verify the accuracy of their measurements.

As a result of our intercomparisons of calibrations, it was decided to make Participant B the repository and standard of this exercise for all Gafchromic media results. This provided a resource of confidence in the consistency of all further patient-oriented dosimetry. It avoided errors that might result from the different methodologies of the participants.

6.2. CARDIAC PROCEDURES

6.2.1. Body mass index and age of patients

In general, the body mass index (BMI) of patients undergoing cardiac procedures in these studies was larger for the European population of participants (generally the median or mean > 25 kg/m^2) than for the Asian participants (generally the median or mean < 25 kg/m^2). One notable exception is the BMI for CA-PTCA and PTCA procedures for Participant E (Asian with average BMI around 27.5).

There is no obvious trend regarding age. For RF ablation procedures, Participant F's average patient age was 38.5 years (11 patients), whereas the average age for the other participants was about 50-55 years (75 patients).

The observed differences in demographics demonstrate how body mass and patient age vary widely among institutions and countries due to many different factors, including genetic heritage, diet, patient selection and more. Considering the fact that body mass plays an important role in fluoroscopic and fluorographic dose rates, it might be predicted that certain countries are at greater risk for high dose delivery to patients than are others. However, this study found a very weak correlation between BMI and MSD as discussed in the last paragraph of 6.2.2.

6.2.2. Body mass index and maximum skin dose

Figures 6B, 7C,F,I and 8C,F,I demonstrate how body mass index is related to the maximum skin dose for all cardiac procedures, where maximum skin dose is defined as that measured with the radiochromic film.

Body mass index (BMI) is not related in any particularly obvious way to maximum skin dose (MSD). The data from each center tend to suggest a positive correlation of MSD with increasing BMI for coronary angiography and percutaneous transluminal coronary angioplasty. The data from some centers (Table 6) suggest this with a relatively strong correlation while most others demonstrate a weak or absent correlation. The positive slope is likely related to the automatic methods of dose and dose rate control by the fluoroscope with increasing body mass. However, the weakness of the correlation suggests that other factors not related to BMI far more strongly influence patient dose. These factors might be location of the diseased vessels, tortuosity of vessels, extent and type of disease, number of involved vessels, etc. The implication is that although greater BMI does tend to increase dose to patients and does influence the ultimate outcome, a large BMI does not *de facto* means that the dose will be high.

For coronary ablation procedures, Figures 7I and 8I suggest diverse relationships. For Participant B body mass index seems to play a minimal role in maximum skin dose. There is a moderate correlation for increasing dose with increasing BMI. On the other hand, the relationship observed between MSD and BMI for Participant F is quite different. The MSD rises moderately as BMI increases and the MSD values are considerably higher than those of Participant B. While the correlation was not found to be significant, a lack of statistical significance does not mean that the trend is not correct. The marked scatter about the regression line for Participant F demonstrates a greater variation in procedures than those for Participant B. Examination in Table 16 of the fluoroscopy-on times shows that the on-times for Participant F are more than twice those of Participant B on the average. This does not explain fully the differences observed. Body mass index for all three participants are comparable. But, there exists a marked difference in the age distribution of ablation patients for Participant F (mean 38.5) compared to Participant B (mean 58). This suggests some form of difference in patient characteristics, but why age would affect MSD when BMI is similar and fluoroscopy times comparable is not evident. The answer to this question might lie in the data of the relationship of MSD to fluoroscopy-on time as discussed in the next sections.

Body mass index is not a strong predictor of high skin dose risk to patients from fluoroscopy. Other factors appear to play a more important role in determining the likely dose delivered to a patient. Caution is advised that this does not mean that BMI plays no role in increasing risk because it is well known that dose output increases with increasing beam attenuation due to increased patient mass. A large patient will exacerbate dose rate delivery when an exceptionally high dose procedure is performed.

6.2.3. Fluoroscopy-on time and maximum skin dose

The influence of fluoroscopy-on time on maximum skin dose (MSD) for cardiac procedures is provided in Figures 6A, 7A,D,G, 8A,D,G and 9C. MSD is moderately

to strongly correlated in a linear manner to fluoroscopy-on time (Table 13), but the relationship varies among centers and for different categories of procedures.

The fact that the data show positive trends with increasing fluoroscopy time is an obviously anticipated result. The widely scattered data within each facility are likely due to variations in body habitus, geometric beam orientations, and varying settings of the fluoroscope for each procedure. But the wide variation in slope of the relationship indicates that some centers are better able to conserve dose with increasing fluoroscopy time. The obvious factors involved would be due to either differences in procedural techniques or due to differences in equipment performance, or both. In fact, Participant F noted that his physicians frequently used high electronic magnification and that this often caused the machine to operate at unusually high dose rates in fluoroscopy. The simple linear regression illustrates that the rate of dose build-up with time at the study centers varies by a factor of about 4, suggesting that considerable dose savings can be achieved through effective operational use and/or design of equipment.

The higher doses for very short fluoroscopy times during coronary angiography Figure 8.A suggests that modes of operation which bypass recording of time during fluoroscopy must have been used by Participant F.

The value of dose monitoring became readily apparent during this investigation. As is obvious from Figures 7A,D,G, 8A,D,G, and 9D, the data for Participant F tend to demonstrate a MSD obviously higher than those of other participants. In researching the causes for this result, Participant F discovered that the magnification modes frequently used by the physicians resulted in much higher skin dose rates than previously identified during routine physics investigations. Other factors found to result in the higher doses were the use of higher pulse-rate fluoroscopy and probable smaller distance between the patient and the X ray tube. Potential factors not thoroughly investigated include potentially different patient populations with different complexities in procedures. The intent of this investigation was not to completely answer all questions regarding the reasons for these differences, but rather to make measurements to determine weather differences exist. Findings might then be investigated for further dose reduction. In this case, it is clear that a situation existed that was unknown to the facility and dose monitoring made the discovery possible.

Figure 6A demonstrates that doses for Participant A also tend to be higher than those of others during PTCA. While difficulty of procedures could potentially explain this result, the use of higher dose rate modes is the more likely explanation.

6.2.4. Air kerma area product and maximum skin dose

The relationship of maximum skin dose (MSD) and air-kerma-area product (KAP) for coronary procedures is provided in Figures 7B,E,H, and 8B,E,H. The linear correlation between air-kerma-area product and maximum skin dose (MSD) is significant for most centers (Table 13) and is consistent among centers, as indicated by the similarities in the linear regression curves. Although this correlation is relatively consistent among centers, the fact that some data points vary widely from the norm and render high doses with low KAP suggest that KAP be used cautiously as an indicator for accumulated dose. Nevertheless, KAP appears to be a useful indicator of skin dose in some circumstances but the relationship would have to be determined

for each individual fluoroscopy unit and physician before it can be used reliably for coronary procedures.

For ablation procedures (Figures 7 G,H,I and 8 G,H,I) the linear correlation between MSD and KAP is statistically significant for Participants B and F. The higher doses for Participant F suggest that higher dose rate modes of operation or higher dose rate geometries must have been employed compared to those used by Participant B. As previously noted, the fluoroscopy-on time alone does not explain the larger doses delivered at site F. The differences in MSD versus kerma-area product as seen in Figures 7I and 8I suggest that the explanation might lie in the field sizes and geometries employed. If Participant F employed greater geometric magnification than those of Participants B, then higher dose rates for similar fluoroscopy times would result as a matter of the inverse-square law. Participant F noted that the physicians did not always move the image receptor toward the patient. The dose would be higher as a result. Also, on one of the fluoroscopy units for Participant F, it was noted that the X ray field was larger than anticipated. The data suggest that this along with differences in fluoroscopic application among users probably accounts for the large differences in dose delivery or KAP values. The fact that this shows more in the ablation procedures than in the other cardiac procedures reflects the fact that less cine-images are acquired and more fluoroscopy is used during the ablation procedures.

6.2.5. Comparison of KAP and MSD/KAP with other reports

Table 10 shows that our data for kerma area product are similar to values reported from other facilities, with our data trending toward the lower tier of what has been previously recorded.

Our values of MSD per KAP as provided in Tables 11 and 12 are generally about twice as high as those reported by others. We speculate this might be due in part to our method of ascertaining maximum skin dose which may be more conservative than some. It might also be due to a more aggressive use of collimation by some of our participants and a higher dose rate employed by others. However, what it clearly demonstrates is that the use of MSD/KAP to assess maximum skin dose from KAP is fraught with qualification and cannot be employed without an investigation into the reliability of such methods for a given combination of physician, machine, and procedure.

6.2.6. Dose calibration strip and maximum skin dose

Data on skin dose as derived by visual inspection from a dose calibration strip might be useful as a real-time device to monitor skin dose during a procedure. The data of Fig. 6C show that use of such a calibration strip is not altogether easy and some considerable error can be expected. When used cautiously for guidance, the strip will be useful in monitoring skin dose in real time for individual patients and should be accurate to within a factor of two. There exist some physical obstacles to correctly using a dose calibration strip, as, for example, the well-known Mach effect. Some research into standardizing the use of this visual estimate of dose is a matter for future investigation.

6.2.7. Skin dose monitor and fluoroscopy time

Figures 9A and 9B show the relationship of both skin dose monitor (SDM1 and SDM2) cardiac data with fluoroscopy time. The lack of correlation of the results suggests strongly that placement of the skin dose monitor *a priori* over the critical skin area is next to impossible and use of a skin dose monitor during cardiac procedures might be more misleading than helpful.

6.2.8. Effect of physician experience

The major emphasis of training programs in invasive cardiology is generally related to the possible increased risk of complications with less attention is devoted to the radiation exposure of patients. Krasuki [83] and co-workers observed fluoroscopy time as high as 12.2 minutes in diagnostic cardiac procedures performed by fellows and 10.2 minutes in that performed by physician assistants. The authors do not comment on this finding and discussion is limited to comparison between fluoroscopy times in the two groups. Also in the present work, the exposure of patients was significantly increased during fellows' training, this increase being mainly due to fluoroscopy, as more time is required for manipulating catheters by a less experienced operator and maybe a less thorough knowledge how to use the equipment. Nevertheless, mean fluoroscopy time was 5.5±5.9 minutes, which is below the preliminary reference levels recently proposed [84] and far better than that reported by Krasuki [83]. Other parameters increased to a lesser extent: this is of note, as cine runs determine 60-70% of exposure in diagnostic examinations. It is likely that the close supervision by staff members made this possible: since the senior cardiologists were almost always scrubbed and beside the fellows, they must have stopped them from manipulating the catheter after an agreed upon time had expired. Moreover, the supervisor prevented the performance of too many or runs that were too long.

Clinical characteristics of patients were different in the F and S groups because the risk profile was worse in the latter: EF was significantly lower and more patients had AMI as the indication to undergo catheterization. This selection bias makes sense, as it is necessary to limit complications or to reduce diagnostic time in acute cases. Other significant differences were seen in the type of procedures being performed by fellows: as right side catheterization was among the initial steps of the training, it was more likely that cases where this procedure had to be performed were actually assigned to fellows. The same observation has to be made for left ventriculography, as this is the next step. Whereas performing more actions might be one of the causes of longer exposures time in patients in F group, this does not seem to be the case: in fact, if procedures with right catheterization and without left ventriculography were excluded, differences still remain significant.

Contrast dye consumption was also increased in the F group, as a likely consequence of longer screening time. Even if this was significant from a statistical point of view, a mean amount of 10 cc more is not likely to harm the patient even if renal function is abnormal. Even if in this study data on renal function were not available, the staff member in charge for the single cases should have properly considered this risk.

In order to better understand the impact of the learning curve, the first and the last part of the training were compared: as fellows gained experience, a trend towards reduction in exposure parameters was seen (only KAP_{image} was significant), whereas

dye consumption remained the same. This reduction was albeit small and the importance of a close supervision is underscored: staff member must have reduced their participation in any given case according to fellows' actual skill. A possible explanation for the significant reduction of KAP_{image} could only be a better use of collimation while filming.

Participation of cardiology fellows in diagnostic cardiac procedures causes a significant increase in patient exposure, especially during fluoroscopy. Nevertheless careful supervision allowed this increase to remain within acceptable limits. Exposure can be further reduced by limiting the number of diagnostic procedures performed with or by cardiology fellows. It would be important to decide whether a cardiology fellow who will eventually become an invasive cardiologist should receive a practical training.

6.2.9. Results of repeated examinations

The data of Participant B on repeated examinations demonstrates the potential for cumulated skin dose from multiple examinations. Conversely it also demonstrates that conservative radiation management is unlikely to result in dangerous cumulative levels of radiation in patients who undergo multiple procedures. The injury of Fig. 2 demonstrates how dose accumulation for multiple procedures must not be overlooked in dose assessment for individual patients. The literature review of section 2 also shows that multiple procedures are implicated in a good number of radiation injuries.

6.3. NON-CARDIAC PROCEDURES

6.3.1. Patient characteristics

A wide range of interventional procedures are represented in the "non-cardiac" procedures (Tables 14, 15, 16). Patients undergoing hepatic procedures tended to be older than those undergoing neuroembolization procedures. The patient population of Participant E tended to be younger by about 10 to 20 years on the average. The average age of patients for Participant E in the neurointerventional work was only 31 years with a maximum age of 46 years (12 patients), whereas the average age for the other populations hovered around 52 years (20 patients) with a maximum of 72 years.

The body mass index for Participant F (non-Asian) in all procedures averaged about 25 kg/m^2, whereas that for other participants was about 22 kg/m^2, with the exception of biliary procedures of Participant D for which the BMI averaged 25 kg/m^2 (Table 15).

These differences probably reflect the varying types of patient populations and treatments that are available in the countries of the different participants.

6.3.2. Dosimetry for non-cardiac cases

The methodology for estimating MSD was different in non-cardiac studies and in cardiac studies.

Dosimetry in the cardiac part of the study benefited from the fact that all participants used Gafchromic media to record maximum skin dose. Because all films were read

out by a single laboratory, the comparison of doses from the different participants was reliable. This is not the case for non-cardiac procedures where participants had to rely on their own resources to measure maximum skin dose.

Whereas maximum skin dose using Gafchromic media was defined as the part of the film demonstrating the darkest development, some of the techniques used by alternative methods measured the average of the maximum skin dose in the field, and others measured it at a point, but not necessarily the highest dose point. Therefore, when comparing doses from different sites, some of the differences could be attributed to their method of estimating maximum skin dose and not necessarily to their procedures.

6.3.3. Neurointervention

The data of Table 16 indicate some interesting differences among participants for their neuroembolization procedures. Fluoroscopy times for Participant D tended to be slightly lower than that of others, while times for Participant F tended to be considerably higher. The KAP for Participant D also tended to be lower than that of the others, while the KAPs of the three other participants were nearly the same. It is impossible to judge why Participant D's fluoroscopy times and KAPs are lower because a quantitative assessment of the difficulty of the procedures in the various populations is not possible.

The maximum skin doses of Participant F tended to be higher than the others. Longer fluoroscopy times for Participant F might seem to be a legitimate explanation. However, Participant F estimated the dose from a portal dosimeter. Because this type of dosimeter integrates dose continually and does not take into account changes in beam angle, their estimate of dose might be consistently high. The other participants used Gafchromic media to estimate dose. This difference could account for at least some of the results.

The relations shown in Figures 10A and 10B show the pooled data graphically. While the data of the participants differ on the averages, the trends of MSD versus fluoroscopy on-time and KAP tend to be similar.

For the most part, the data in Table 17 indicate that maximum skin dose is significantly correlated with fluoroscopy time. However, the scatter of the data shown in Figure 10A demonstrates that time is not necessarily a good indicator of skin dose for individual patients. Note in one case there is an on-time of 140 minutes with a dose of nearly 3 Gy. However, at least four other cases resulting in that level of dose are present and the fluoroscopy times in those cases range only from 40 minutes to 100 minutes. These variations probably reflect different uses of serial imaging during each procedure that contribute markedly to skin dose while not contributing at all to fluoroscopy on-time.

KAP on the other hand (Table 16) is more tightly correlated with skin dose for these procedures as shown for the pooled data from each participant in Figure 10B. The tighter trends probably reflect the fact that dose from serial imaging is recorded in its entirety with KAP. KAP therefore could be used more reliably to estimate skin dose, but there exist many caveats in this use. As Table 17 shows, the trends for each participant are very different. The MSD for a given KAP are higher for Participant F

than for Participant B, for example. This might be due to real differences in the radiation delivery, or it might represent a difference in difficulties of procedures, or it might just represent a difference in methodology of dose measurement. Therefore, to use KAP as an indicator of potential skin dose, a thorough investigation into establishing the trends for each physician and each machine would be necessary. And, it would have to be remembered that deviations from standard procedures, like the use of an unusually high geometric or electronic magnification during the procedure, might severely alter the reliability of such a relationship.

6.3.4. Hepatic embolization

Data were acquired for a wide variety of hepatic embolization procedures. It is therefore not surprising that there exist wide variations in fluoroscopy times, KAP, and MSD among the participants.

The data of Table 17 tell a story similar to that of the cardiac data. There is only a mild influence of BMI on skin dose to patients, suggesting again that factors other than BMI are more important in predicting the final skin dose result. None of the data suggest a significant correlation between maximum skin dose and body mass index (Table 17).

As shown in Figures 11A and C, both MSD and KAP show a weak tendency to increase with increasing fluoroscopy-on time in a linear way for hepatic embolization procedures. However, the variations from the trend line again reflect variations in field sizes and the use of serial imaging. The relationship of MSD to fluoroscopy time being weak most of the time (Table 17), demonstrates the unreliable nature of fluoroscopy time in predicting skin dose for these procedures.

Figure 11B demonstrates that the use of KAP to predict skin dose for hepatic procedures must be approached with caution. While generally there exists a linear relationship between MSD and KAP for Participant F and E (Table 17), it is much less the case for Participant D.

The data for Participant F in Table 17 demonstrate the potential for relating KAP to maximum skin dose in hepatic procedures. A consistent behavior in use of beam orientation, geometry, and machine settings is likely to result in tight variation around a linear trend line. Consistency in execution is the key to making KAP a useful tool to estimate skin dose.

6.3.5. Biliary drainage

Table 17 tells a story for biliary drainage similar to that of the previous studies. BMI has no particular influence on MSD. There does appear to be a relationship of MSD to fluoroscopy-on time, but the scatter of the data about the regression suggests an unreliable relationship for predicting MSD. The relationship between MSD and KAP is equally unreliable for predicting dose from these procedures.

6.3.6. ERCP

The relationship between MSD and fluoroscopy on-time is relatively linear for ERCP procedures and the correlation is significant (Table 17). However, there is still some

marked deviation of a few data points from the linear regression line. The relationship between MSD and KAP is much tighter about the regression line and also significant (Table 17), at least for Participant F. This indicates that KAP is more reliable at predicting MSD for these procedures because, unlike fluoroscopy time, dose from spot imaging is included in the readout. For procedures in which the set up of the procedure is very reproducible, MSD can be reasonably well predicted. The data of Fig. 12B also demonstrate that for procedures where local dosimeters can be well positioned on the skin at the beam entrance site, accurate measurement of dose is possible.

6.4. IMAGE QUALITY AND PATIENT DOSE

In the cases evaluated for image criteria, 77% were graded as **visually sharp reproduction** and 23% as **reproduction.** All of these procedures were performed under appropriate image quality. Some patient-related factors were considered to influence the image quality including enlarged liver in the hepatic arterial embolization and high-flow arteriovenous shunt in the neurointervention.

There was an apparent tendency among the countries to grade image criteria in one category. In hepatic interventions, all cases in Participant C were graded as **reproduction** and all cases in Participant A and 86% cases in Participant E were graded as **visually sharp reproduction.** Biliary intervention was evaluated in the cases from Participant A, where all cases were graded as **visually sharp reproduction.** Because the grading mostly depends on the subjective decision of the operator, some question exists as to whether this predominance in grading among the countries represents the real difference in image quality.

In general, interventional procedures that produce the best quality of images, i.e. higher-dose mode, high-frequency pulsed fluoroscopy and magnification, will be associated with increased radiation use. In reality, from Figure 13 the patient's doses were lower for Participant A and Participant E than for Participant C while the image criteria were graded as being better in Participant A and Participant E than in Participant C. While it is tempting to conclude that the higher doses for Participant C are related to the assessed lower image quality, such a conclusion is only one possible explanation for the result. Other possible explanations include observer variations in quality assessment and possible variances in equipment performance. The BMI index does not appear to rationally explain the differences since the BMI for Participant C for these procedures was within average ranges of 23.

6.5. HIGH SKIN DOSES

The explanations for the high doses received by some patients during this project are multiple. Participant F learned from this project that the doses for that facility seemed higher than the rest. Upon investigation, it was learned that the outputs under fluoroscopy were much higher in some operating modes than in others. This occurred when the kVp reached above 100 and for high magnification modes. Doses as high as 190 mGy per minute were found, which is about four times more than expected.

Some physicians did not use collimation very often and this resulted in overlap of fields when the beams were changed to a different orientation. Without overlap, the

maximum skin doses would have been much lower. These habits are likely related to experience and training.

Another major factor is in differences in equipment or in use of it. Some machines had no variable pulse rate fluoroscopy or the physician did not use pulse rates that were commonly used at other centers. In some cases, the automatic exposure rate control would permit machines to operate at too low a kVp (e.g., below 70 kVp for fluoroscopy in some adults). These factors are expected to lead to higher skin doses.

The complexity of procedures cannot be overlooked as a possible factor in dose differences. It is very difficult to assess complexity in an objective way. It is likely that variations among the size and ages of patients seen in different countries is a sign that differences in complexity or difficulty of procedures do exist. For example, larger patients require higher kVps and produce more scatter, both of which make a procedure more difficult by reducing image contrast. The influence of complexity on the variances observed among participants cannot be ignored and cannot be accounted for adequately.

7. CONCLUSIONS

7.1. RADIATION RISKS

Radiation-induced cancer is a long term risk of about one incidence per 1000 patients receiving a KAP of 80 Gy•cm^2 at the age of 60. It is about four times this amount for the same KAP in a patient of age 10.
Radiation injury is a near-term radiation effect that can be debilitating in severe cases.

Radiation injury has occurred in patients undergoing complex interventional procedures, many have been severe. A mild radiation injury occurred in the skin of a participating patient during this project. Severe effects are rare in relation to the number of procedures performed worldwide. A number of mild radiation skin injuries may go unnoticed if patients are not followed up after having received more than 2 Gy at the skin.

7.2. RESULTS ON DOSE MEASUREMENTS

The body mass index of a patient is only weakly related to the risk for high skin dose in the interventional procedures of this project. This means that the size of a patient is far less an important predictor of the dose to be delivered than are other factors, such as complexity or difficulty of a procedure. A large patient will only contribute to the elevation of a high dose delivery during a complex and difficult procedure.

Many injuries occur in patients who undergo multiple procedures. Multiple procedures are implicated in this project as being an important contributor to the accumulation of dose in a patient's skin.

Monitoring radiation dose to a patient's skin to manage near-term adverse effects is an important aspect of patient care.

Monitoring radiation dose to patients with sufficient accuracy is problematical and requires that resources be available to assure a quality result.

Fluoroscopy time is correlated with dose to the patient but is a poor predictor of it because it does not account for the effects of image acquisition modes (which account for more of 60% of the dose in diagnostic procedures) and various uses of different beam geometries and output modes of operation.

Kerma-area product is more significantly correlated with skin dose than is fluoroscopy time. This is because KAP registers radiation during image acquisition. Under careful application and in certain circumstances, maximum skin dose may be estimated from KAP. But this cannot be conducted under application of a conversion factor obtained from some external source. The MSD/KAP varies depending on the procedure, the equipment, and the physician. The conversion ratio must be verified through independent testing on-site. Use of any rule to derive MSD from KAP must be done carefully with attention paid to consistency in performance for the on-site circumstances. Variations in routine can significantly alter the ratio of MSD/KAP.

Gafchromic media ("film") proved to be a highly valuable tool in dose assessment. It provided consistency and reliability in measurement among centers. Use of a dose calibration strip can assist in the real time use of this material, but it must be applied carefully to assure accuracy. However the Gafchromic films do not record very oblique or lateral projections and are difficult to check in real-time while the procedure is performed.

Use of small-area skin monitors proved difficult and should not be used for any procedure where the beam will be reoriented during the procedure or where the position of the monitor in the field cannot be continually verified. Skin dose monitors are very useful only in situations where beam orientation can be predicted ahead of time and wherein it will be fixed in that position for nearly the entire procedure.

Experience of interventionalists in efficiently completing a procedure is a major factor in dose management. Even under well monitored and controlled training conditions, it was demonstrated that significant increases in dose to the patient result from interventionalists who are less skilled than others.

Dose monitoring is a valuable tool. During this project, some participants were surprised at the doses delivered during their procedures. In one case, dose monitoring motivated an investigation that uncovered unsuspected and unusually high dose rates from some equipment when used in certain operating modes. Only by monitoring can such events be found, even when quality control is routinely performed, as it was for the facilities in this project.

7.3. TRAINING

Thorough training of interventionalists in the medial aspects as well as the technical aspects of a procedure is necessary to assure that radiation is properly limited in use [81, 82]. The efficient completion of a procedure is the primary factor in limiting dose delivery. Managing the technical delivery of radiation is also an essential factor in training [56, 83-85]. The interventionalist must understand the impact of all the dose management features of equipment and how to use those features properly. Staff should be well trained to assist the interventionalist in this aspect of patient care. Staff includes radiologists, cardiologists, surgeons, radiographers or technologists, and any physician involved in interventional procedures using fluoroscopy. Staff can assist in

monitoring the position of the image receptor, use of collimation, and use of variable pulsed fluoroscopy. Staff can monitor the procedure to assure arms of the patient are not in the field of view, etc.

Training should not be limited to a generalized instruction. There exists extensive variety in operating characteristics of equipment. Physicians and staff must be well versed in the specific features of individual units and know how to operate these features.

7.4. EQUIPMENT

Equipment should be well designed for the procedure. Older equipment that is devoid of modern dose-management features such as variable beam filtration, variable pulsed fluoroscopy, kerma-area product meters, and dose monitoring at the interventional reference point will necessarily result in higher dose delivery to patients. This project demonstrated wide differences in dose delivery among users. Part of this was attributable to the variations in equipment, some of which had better dose reduction features than others.

7.5. QA - EQUIPMENT

With age and time, radiation output and image quality of fluoroscopic equipment change. If left unmonitored, radiation outputs can be too low. Together with ageing image intensifiers, this is usually brought about by fading image quality that is compensated by increased dose delivery. While routine service on equipment is necessary to maintain its functionality, it is important to independently verify the performance of equipment to assure proper dose management and high image quality in all operational modes.

7.6. QA - PROCEDURE PERFORMANCE

Although fluoroscopy time is not a good predictor of patient dose, it is a very good indicator of quality in procedure performance; at least as far as radiation use is concerned. The same is true of KAP. These two quantities should be monitored routinely and reviewed to assess whether there exists any procedures for which these dose surrogates appear to exceed the normal range. The reasons for the aberration should be identified. Feed back to the interventionalist can assist in maintaining or improving dose management skills.

7.7. DOSIMETRY

There is an adage that says “You do not know what you are doing unless you know what you are doing” [89]. In this context, you do not know what dose you are delivering to your patient unless you monitor the dose so that you know what dose you are delivering to your patient. This project has demonstrated the value of dose monitoring. In our project, the easiest method of monitoring dose to the skin of a patient was with the gafchromic media. It is simple to use and produces a consistent and reliable result. Others have found similar results [90]**.** Other methods for monitoring dose have been reviewed and their discussions will not be repeated here. The reader is referred to the reference for further details [91]. We found most other methods to require a more intensive effort in execution and control to assure accuracy.

However, some modern equipment report on dose at the interventional reference point, which is located between the X ray tube and the isocenter of the c-arm in angiographic equipment at a distance of 15 centimeters from the isocenter. While not available during our project, this new feature might provide an easier method of dose monitoring for some procedures. On older equipment, an add-on KAP meter with a small area dosimeter in the center can be used for the same purpose. Such a dosimeter was used by one facility in our project and was found very useful.

We propose that each facility establish a dose monitoring methodology suitable for their purposes with a plan of actions to be taken as doses exceed certain threshold levels. These action levels need not be unduly restrictive. They might simply be the action of an assistant advising the physician what the dose level is. The physician then takes the advice into consideration in the management of the patient. In some cases, the beam might be moved to a different skin location, or in other cases the interventionalist might decide that no action is necessary.

7.8. RADIATION MANAGEMENT OF THE PATIENT

Radiation management for a patient begins before the patient is under the fluoroscope. For example, the QC and equipment maintenance are pre-procedure actions. But, more to the point, the physician might be able to review the patient's records for previous procedures. If previous procedures are noted, an examination of the patient's skin might be in order to determine if there is any residual injury that might increase the risk for the upcoming procedure. In our experience, multiple procedures did demonstrate skin effects in one patient. Furthermore, the patient's health status should be considered to determine if the patient might be at elevated risk should the procedure prove difficult and long.

During the procedure, there are many factors at the command of the physician to limit the dose [17, 51, 89]. The physician must be familiar with the specific fluoroscopic unit that is used in order to appropriately use these features.

After the procedure, an assessment should be performed of the dose. If it was high and might result in a skin reaction, the patient should be advised about this possibility. The patient should know what to look for, where to look, and what to do about it. We propose that if a reaction develops, the patient should notify the interventionalist's office. This not only serves as useful information about the safety of procedures, it also gives the physician a chance to refer the patient to a dermatologist who can be notified of the incident and its cause. Otherwise the dermatologist might not recognize the etiology for proper care.

Methods of patient management have been discussed extensively by others [17, 51, 54, 81, 86]. Strategies for monitoring dose and managing the patient are thoroughly discussed in references 81, 85, 86, and 87 and the reader is referred to references for further information. They are available on the internet at:

http://www.cancer.gov/cancertopics/interventionalfluoroscopy/;
http://www.scai.org/PDF/fluoroscopy.pdf [56];
http://www.sirweb.org/clinical/cpg/15-423.pdf [88]

APPENDIX I
TYPICAL DATA ON CARDIAC ANGIOGRAPHIC EQUIPMENT

Participant →	A	B	C	D	D	E	E	F	F	F	F
Room identification	75		Angio-1	C4	C3	SK5 Room 1	SK5 Room 2				
Manufacturer	Philips	GE	Siemens	Siemens	Philips	Siemens	Siemens	GE	GE	Siemens	Philips
Model	X-radfluoro	Innova 2000	Hicor	Angiostar Plus	Integris BH3000	Coroscop HS	Axiom Artis dBC	Advantx LC+DXL	Advantx LC+DXL	Bicor Plus	Integris H3000
Year of Installation	2001	2003	1998	2000	1995	1994	2004	2000	1995	1998	1997
Type of Generator (High Frequency, Constant Potential)	High Frequency			High Frequency	High Frequency	Polydoros C High Frequency	Polydoros High Frequency			Polydoros IS-C Multi-pulse generator	High Frequency
kW Power	25/50			100	100	100	100			100	100
kVp Range	40-150		?to 125	50-125		40-150	40-150			50 - 125	40-125
mA						1250	1000				
Pulse Rate Range			3.75, 7.5, 15, 30	3/7.5/15/30		>12.5/s	0.5-25/s			12.5/25	12.5/30

Participant →	A	B	C	D	D	E	E	F	F	F	F
X rayTube						Megalix	Megalix CAT			Megalix CAT 120 GW	Super ROTALIX SRM 05 10
Nominal focal spot size (small/large)	0.6/1.2 mm			0.3/0.6/1.0 mm	0.5/0.8 mm	0.4/0.8 mm	0.4/0.8 mm			0.4/0.8 mm	0.5/1.0 mm
Total Filtration (mmAl)	?			2.5		> 2.5	>2.5			>2.5	
Additional Cu Filtration (mm)	?			0.2		0.1	0.1			0.2 Cu	0.2 Cu
Image Intensifier						HDR	Flat Detector			Sirecon 23-3 HDR	
Size of Input Phosphor (cm)	30		23	33	23	23	25			23	23
Magnification Factors or zoom sizes	4		23,/17,/13 cm	33/22/17/13	23/17/13	2	2			17/13 cm	17/13 cm
Grid Ratio	?			17:01	10:01	11					

Participant →	A	B	C	D	D	E	E	F	F	F	F
Dose Modes											
Modes			light/ medium/ heavy for I	Cardiac, DSA Digital Pulse Fluoro	.					normal/high	low/normal/high
Continuous/ Pulsed Fluoroscopy	continuous		Pulsed	0.5-30 f/sec	Both		Both				12.5/25 p/s
KAP (DAP) Meter installed	1998		No	?		N/A					
Manufacturer	NE Tech Ltd UK			Siemens			PTW-Freiburg				
Model	DAP 2640			Diamentor			Diamentor K25				

APPENDIX II
TYPICAL PATIENT DATA COLLECTION CHART

Patient ID	Age	Gender	Weight (kg)	Height (cm)	BMI	Procedure	Fluoroscopy time (min)	DAP ($^{Gy.cm2}$)	MSD (mGy)
GE_2003_75G	72	M	90	185	26.3	PTCA	11.5	83.6	859.4
GE_2003_78G	79	M	80	174	26.4	PTCA	7.5	65.65	623.5
GE_2003_79G	63	M	90	170	31.1	PTCA	9.4	64.39	550.4
GE_2003_80G	85	F	50	140	25.5	PTCA	21.0	88.39	1234.7
GE_2003_81G	61	M	86	170	29.8	PTCA	6.5	67.47	706.2
GE_2003_85G	70	M	80	178	25.2	PTCA	31.5	156.82	3218.5
GE_2003_87G	57	M	85	162	32.4	PTCA	12.4	74.86	666.6
GE_2003_88G	70	M	74	165	27.2	PTCA	5.7	42.56	597.1

APPENDIX III
BSS REQUIREMENTS ON IMAGE QUALITY AND PATIENT DOSE

The medical practitioner, the technologist or other imaging staff, as appropriate, endeavour to achieve the minimum patient exposure consistent with acceptable image quality.

Registrants and licensees shall ensure for diagnostic radiology that the medical practitioners who prescribe or conduct radiological diagnostic examinations:

(i) ensure that the appropriate equipment be used;

(ii) ensure that the exposure of patients be the minimum necessary to achieve the required diagnostic objective, taking into account norms of acceptable image quality established by appropriate professional bodies and relevant guidance levels for medical exposure; and

(iii) take into account relevant information from previous examinations in order to avoid unnecessary additional examinations;

(b) the medical practitioner, the technologist or other imaging staff select the following parameters, as relevant, such that their combination produce the minimum patient exposure consistent with acceptable image quality and the clinical purpose of the examination, paying particular attention to this selection for paediatric radiology and interventional radiology:

(i) the area to be examined, the number and size of views per examination (e.g. number of films or computed tomography slices) or the time per examination (e.g. fluoroscopic time);

(ii) the type of image receptor (e.g. high versus low speed screens);

(iii) the use of antiscatter grids;

(iv) proper collimation of the primary X raybeam to minimize the volume of patient tissue being irradiated and to improve image quality;

(v) appropriate values of operational parameters (e.g. tube generating potential, current and time or their product);

(vi) appropriate image storage techniques in dynamic imaging (e.g. number of images per second); and

(vii) adequate image processing factors (e.g. developer temperature and image reconstruction algorithms).

Registrants and licensees should ensure that guidance levels for medical exposure be determined as specified in the Standards, revised as technology improves and used as guidance by medical practitioners, in order that:

(a) corrective actions be taken as necessary if doses fall substantially below the guidance levels and the exposures do not provide useful diagnostic information and do not yield the expected medical benefit to patients;

(b) reviews be considered if doses exceed the guidance levels as an input to ensuring optimized protection of patients and maintaining appropriate levels of good pracIe; and

(c) for diagnostic radiology, including computed tomography examinations, the guidance levels be derived from the data from wide scale quality surveys which include entrance surface doses and cross-sectional dimensions of the beams delivered by individual facilities for the most frequent examinations in diagnostic radiology.

I.1. III.I DOSE LEVELS AT WHICH INTERVENTION IS EXPECTED TO BE UNDERTAKEN UNDER ANY CIRCUMSTANCES

Table III.1 gives action levels of dose for acute exposure by organ or tissue.

TABLE III.I. ACTION LEVEL OF DOSE FOR ACUTE EXPOSURE: PROJECTED ABSORBED DOSE TO THE ORGAN OR TISSUE IN LESS THAN 2 DAYS

Organ or tissue	(Gy)
Whole body (bone marrow)	1
Lung	6
Skin	3
Thyroid	5
Lens of the eye	2
Gonads	3

Note: The possibility of deterministic effects for doses greater than about 0.1 Gy (delivered over less than 2 days) to the foetus should be taken into account in considering the justification and optimization of actual action levels for immediate protection.

TABLE III.2. DOSE RATE GUIDANCE LEVELS FOR FLUOROSCOPY FOR A TYPICAL ADULT PATIENT

Mode of operation	Entrance surface dose rate[a] (mGy/min)
Normal	25
High level[b]	100

a In air with Backscatter.

b For fluoroscopes that have‘an optiona’ 'high level' operational mode, such as those frequently used in interventional radiology.

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Vienna, Austria: 10-14 May 2004
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