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Radiation Protection in Newer Medical Imaging Techniques: Cardiac CT

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RADIATION PROTECTION IN NEWER MEDICAL IMAGING TECHNIQUES: CARDIAC CT

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JOINTLY SPONSORED BY THE
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WORLD HEALTH ORGANIZATION AND THE
INTERNATIONAL SOCIETY OF RADIOLOGY,
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FOREWORD

Medical imaging has seen many developments as it has evolved since the mid-1890s. In the last 30–40 years, the pace of innovation has increased, starting with the introduction of computed tomography (CT) in the early 1970s. During the last decade, the rate of change has accelerated further, in terms of continuing innovation and its global application. Most patient exposure now arises from practices that barely existed two decades ago.

These developments are evident in the technology on which this volume is based — multislice/detector CT scanning and its application in cardiac imaging. However, this advance is achieved at the cost of a radiation burden to the individual patient, and possibly to the community, if its screening potential is exploited. Much effort will be required to ensure that the undoubted benefit of this new practice will not pose an undue level of detriment to the individual in multiple examinations.

For practitioners and regulators, it is evident that innovation has been driven by both the imaging industry and an increasing array of new applications generated and validated in the clinical environment. Regulation, industrial standardization, safety procedures and advice on best practices lag (inevitably) behind the industrial and clinical innovations. This series of Safety Reports (Nos 58, 60 and 61) is designed to help fill this growing vacuum, by bringing up to date and timely advice from experienced practitioners to bear on the problems involved.

The advice in this report has been developed as part of the IAEA's statutory responsibility to establish standards for the protection of people against exposure to ionizing radiation and to provide for the worldwide application of these standards. The Fundamental Safety Principles and the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) were issued by the IAEA and co-sponsored by organizations including the Food and Agriculture Organization of the United Nations (FAO), the International Labour Organisation (ILO), the OECD Nuclear Energy Agency (OECD/NEA), the Pan American Health Organization (PAHO) and the World Health Organization (WHO), and 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 radiation protection of patients encourages the reduction of patient doses without losing diagnostic benefits. To facilitate this, the IAEA has issued specific advice on the application of the BSS in the field of radiology in Safety Reports Series No. 39. This Safety Report is a further contribution to the resources provided by the IAEA in support of the implementations of the BSS. In addition, it has embarked on a series of coordinated research projects in radiology, mammography and CT, the results from which will appear in other IAEA publications.

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 Safety Report — the second in a series (the others being Nos 58 and 61) — is issued in this spirit. They provide guidance and advice for those involved in one of the more dose intensive areas developing in radiology and cardiology today. It is jointly sponsored by WHO and the International Society of Radiology, with contributions from the International Commission on Radiological Protection.

The IAEA thanks F. Mettler, Jr., for his role in compiling the initial text. In addition, the major role of J. Malone in bringing the final draft to fruition is gratefully acknowledged. The IAEA officer responsible for this publication was M.M. Rehani of the Division of Radiation, Transport and Waste Safety.

EDITORIAL NOTE

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1. INTRODUCTION

1.1. BACKGROUND

Computed tomography (known as CT or CAT scanning) uses an X ray tube that rotates around the body to produce detailed anatomical images. There are several generations of CT scanners. The earlier machines obtained a single slice image using a single set of detectors. The patient table was then moved or indexed and an image of another slice obtained. This type of system took 10–20 min to complete a thorax scan. In more recent generations, the X ray tube rotates continuously around the patient and the table is moved through the gantry at a constant speed. Multi-detector spiral scanners are capable of obtaining images of multiple slices with a single rotation of the tube around the patient. Scans of the entire chest or abdomen can be obtained in a few seconds. The images are usually depicted in 2D slice cross-sectional formats or sometimes in 3D. These systems are now achieving widespread application in new areas, including cardiac imaging.

1.2. OBJECTIVE

The purpose of this publication is to address some of the requirements of the Fundamental Safety Principles [1] and the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the BSS) [2], issued by the IAEA. It will bring the principles and standards in these foundational publications, particularly with respect to justification and optimization, to bear on the new applications in this field. It particularly focuses on radiation protection of the patient when using CT for:

- Coronary artery calcium scoring;
- Visualization of the coronary arteries (angiography);

and is provided within the framework envisaged in the supporting Safety Reports Series No. 39, Applying Radiation Safety Standards in Diagnostic Radiology and Interventional Procedures Using X Rays [3].

1.3. SCOPE

The focus of this publication is on when it is appropriate to use these techniques in symptomatic and/or asymptomatic screening populations. This is important given the widespread concern about high patient doses in spiral and multislice CT [4–6]. It also provides some information on patient dose and risk levels which should help those working with these techniques in the quest for optimization (Sections 5 and 6). Some background information is provided on cardiac CT in Sections 2 and 3, and the concepts of justification and optimization, which are central to the BSS approach to patient protection, are outlined in Section 4.

2. COMPUTED TOMOGRAPHY AND CORONARY ARTERY CALCIUM SCORING

Coronary artery disease is the leading cause of death in many Western countries. Calcification correlates with atherosclerosis and may be one of the first signs of coronary artery disease. However, patients can have significant coronary artery disease without evident coronary artery calcification.

On the basis of several meta-analyses, there is a moderately increased risk of very serious cardiac events associated with calcification detected by CT in asymptomatic populations with several risk factors [7, 8]. In the last few years, CT evaluation of middle aged and older patients for the amount of calcium in the coronary arteries has become widespread [9–11]. Recently, some authors have suggested the use of CT calcium scoring in healthy 40–50 year old subjects [12].

CT coronary artery calcium scoring can be done with either a multi-detector spiral CT or an ultra-fast electron beam CT (EBCT) scanner [13]. No intravenous contrast is used. The CT scan is used to detect count, measure and score calcifications in the coronary arteries (Fig. 1) [14]. Coronary calcification is usually defined as a plaque of at least three consecutive pixels (area = 1.03 mm^2) with a density of less than or equal to 130 HU (Hounsfield Units). Detectable calcification is found in 20–40% of persons in their forties and in 70–80% of persons in their sixties.

The calcium score is normally combined with conventional risk factors to fully assess an individual's future risk of myocardial infarction. The calcium score is often expressed on the Agatston scale, introduced in 1990, and

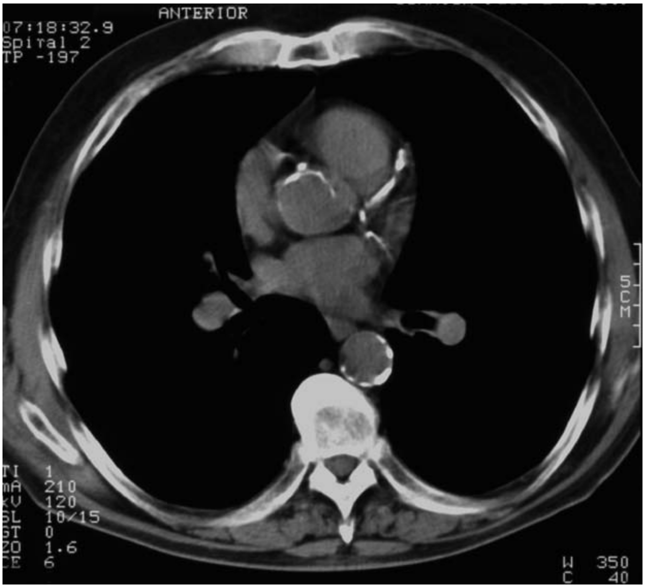

FIG. 1. Coronary artery calcification. Heart CT shows dense calcification at the proximal portion of the left anterior descending coronary artery. (Image courtesy of F. Mettler, Jr.)

calculated by multiplying the lesion area by a co-factor that depends on the peak value of its intensity in Hounsfield Units [14]. Patients with an Agatston score <100 have a low cardiac event rate and those with a score >400 are at a moderate to high risk of coronary events in the next 2–5 years, especially those with several known cardiac risk factors. It has also been suggested that calcium scoring may provide additional information that could be helpful in behaviour modification programmes, and possibly be useful in assessing the response to lipid decreasing drugs [15].

A minority of patients who have had a myocardial infarction (often due to soft plaque) do not have significant calcification. In a community setting, there appears to be little relationship between incident chest pain and coronary artery calcium [12].

Some position statements on CT coronary artery calcium screening are available from professional societies. In 2000, a consensus statement of the American College of Cardiology and the American Heart Association recommended against CT calcium scoring in asymptomatic individuals [7–8]. More recently, they suggested a modest role for this still controversial test in adding incremental risk prediction for patients who already have an intermediate risk profile. They are awaiting further studies to enable definitive evaluation of many possible applications of this technique [4–7].

A 2003 position statement of the Cardiac Society of Australia and New Zealand states that while the procedure provides useful information in population studies, there is not yet sufficient evidence to provide practical value to an individual above that obtained from a thorough assessment of cardiac risk [16]. The 2004 statement of the US Preventive Services Task Force recommends against CT scanning for calcium scoring of coronary stenosis in adults at low risk for coronary events. They also found insufficient evidence to recommend for or against these procedures in adults at increased risk for coronary heart disease [17]. European guidelines issued on behalf of eight societies are somewhat more positive in tone and find that the calcium score "is an important parameter to detect asymptomatic individuals at high risk for future CVD events, independent of traditional risk factors" [18, 19].

3. COMPUTED TOMOGRAPHY AND CORONARY ANGIOGRAPHY

Coronary arteries can be visualized using modern CT scanning (Fig. 2). This is usually done with multidetector CT (MDCT), but can also be done with EBCT. The information provided by coronary angiography is essentially different to that provided by calcium scoring. Although there is a correlation

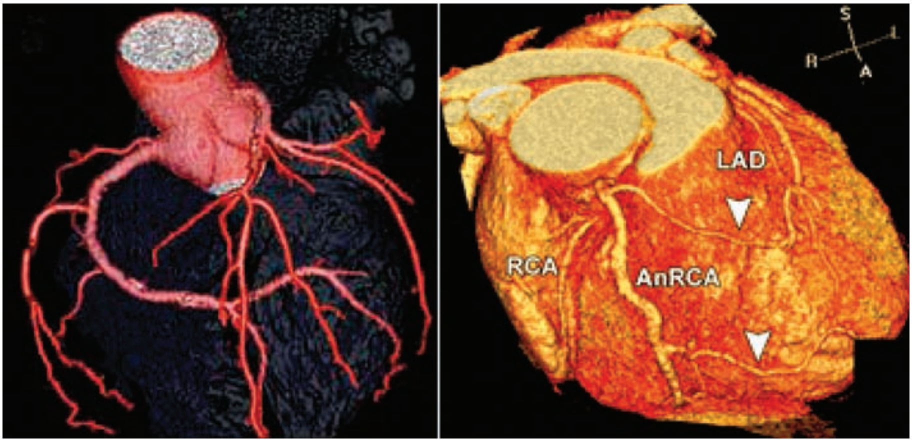

FIG. 2. A CT coronary angiogram. A 3D reconstruction of a cardiac CT scan clearly shows the anatomy of the coronary arteries.

between patterns of coronary calcification and atherosclerotic plaques, significant stenosis or narrowing may occur in areas without calcium deposits.

Thus, while CT coronary angiography (CTA) is not a screening procedure, its uses include evaluation of coronary artery anomalies, bypass-graft patency and surgical planning [20, 21]. In some patients with suspected coronary artery disease, CTA obviates the need for invasive arterial catheterization and the risks associated with conventional radiographic coronary angiography [22]. The value of CTA in patients with a low to intermediate likelihood of coronary artery disease is still to be fully determined, but it has emerged as a good 'rule-out' test in defined clinical circumstances [23].

For many current CT angiographic applications, 16 slice multi-detector spiral scanners are the minimum level of technology needed and 64 slice scanners are needed for good visualization of lesions [24]. Current studies indicate that 64 slice CTA is highly accurate for exclusion of significant coronary artery stenosis (>50% luminal narrowing) with negative predictive values in excess of 95% unless there is heavy arterial calcification [25–28]. CTA is not normally advised when a patient has an irregular heart rhythm, a heart rate greater than 70 beats per minute and contraindications to medication for heart rate control or is likely to require revascularization surgery [29]. Standard invasive coronary angiography remains the gold standard for evaluation of coronary anatomy.

4. GENERAL ASPECTS OF RADIATION PROTECTION OF THE PATIENT

The International Commission on Radiological Protection (ICRP) has recommended a multi-step approach to protection of the patient [30]. First, a practice is identified (such as the use of CT scanning to detect and score coronary artery calcification). The second step is to justify this practice; that is, does CT coronary artery calcium scoring contribute more benefit to society than harm? This is assessed by performing large clinical population studies. If the practice is justified, then it should be optimized (i.e. can the practice be implemented at a lower radiation dose while maintaining its efficacy and accuracy?).

Two subsequent steps apply to the individual having the CT scan. There should be individual justification. This asks whether the examination will really benefit the patient about to be studied. For example, coronary artery calcium scoring is not likely useful for individuals who are very young, very old or who have well known and characterized coronary artery disease. Such a decision is best made by a physician familiar with the patient and the medical history. The last step is optimization of the examination for that specific individual. This step asks whether the examination can be effectively carried out in a way that reduces dose for the particular patient (for example, can a lower dose be used because the patient is very thin or the irradiated volume is reduced?).

5. DOSES FROM CT SCANNING OF THE HEART AND POSSIBILITIES FOR DOSE REDUCTION

As with other radiology procedures, there is often a wide variation in doses reported for the same type of CT scan. The actual absorbed dose received during a cardiac CT scan varies depending on the type of scanner, protocol and the technique used [30]. However, this document concentrates on the effective doses and stochastic risk as good practice should eliminate deterministic risks and the possibilities of skin injuries [31].

Effective dose values reported in the literature for EBCT calcium scoring are relatively low, ranging from 0.7 to 1.3 mSv, with tissue doses from 2.8 to 4.3 mGy (Table 1). However, this manifestation of CT technology is now deployed less frequently. On the other hand, with MDCT calcium scoring, effective doses range from 0.8 mSv to a high of 12 mSv and tissue doses range from 4.8 to 92 mGy [13, 30, 32–34].

Contrast enhanced MDCT for coronary angiography results in a higher effective dose (5–15 mSv) or close to the effective dose from a standard MDCT scan of the chest. These doses should be susceptible to conventional dose reduction approaches. The effective dose from EBCT coronary angiography has been reported to be about 1.5–2 mSv [20, 30–36]. These doses have recently been reviewed and are summarized in Table 1 [4].

There are clearly opportunities for dose reduction with almost any type of CT scan [5, 6]. For cardiac CT specifically, use of body weight adapted MDCT protocols has been shown to reduce the effective dose by about 12% in males and 25% in females. Careful consideration of technical factors such as kVp and mAs may also be effective. In addition, studies with mA modulation during the cardiac cycle and new prospective gating techniques offer prospects of significant extra reductions [37–51].

TABLE 1. EFFECTIVE DOSES IN MSV WITH CORONARY CT, CORONARY ARTERY CALCIUM SCORING AND CARDIAC CATHETERIZATION
(adapted from the American Heart Association scientific statement by Budoff et al. [4])

Reference	EBCT calcium scoring	MDCT calcium scoring	MDCT prospective trigger	MDCT retrospective gating	EBCT angiography	MDCT angiography	Cardiac catheterization
[37]				3.0 (m) 4.0 (f)			
[33]						2.8–10.3 (m) 3.6–12.7 (f)	
[38]			1.9 (m) 2.5 (f) 1 (m)[a] 1.4 (f)[a]				
[32]	1 (m) 1.3 (f)	1.5–5.2 (m) 1.8–6.2 (f)		3 (m) 3.6 (f)	1.5 (m) 2.0 (f)	6.7–10.9 (m) 8.1–13.0 (f)	2.1 (m) 2.5 (f)
[35]	0.7		1.0	2.6–4.1	1.1	9.3–11.3	
[39]				5–6 (m) 6–7 (f)			
[40]				3.9–5.8	1.7		
[41]			0.5 (m) ECG trig Ca 0.7–0.8 (f) ECG trig Ca	1.9–2.2 (m) ECG gated Ca 2.8–3.1 (f) ECG gated Ca		5.7–7.1 (m) ECG gated 8.5–10.5 (f) ECG gated	

TABLE 1. EFFECTIVE DOSES IN MSV WITH CORONARY CT, CORONARY ARTERY CALCIUM SCORING AND CARDIAC CATHETERIZATION
(adapted from the American Heart Association scientific statement by Budoff et al. [4]) (cont.)

Reference	EBCT calcium scoring	MDCT calcium scoring	MDCT prospective trigger	MDCT retrospective gating	EBCT angiography	MDCT angiography	Cardiac catheterization
				1-1.5 (m)[b] ECG gated Ca 1.4–2 (f)[b] ECG gated Ca		2.9–5 (m)[a] 4.2–7.4 (f)[a]	
[42]		2.9 (m) 3.6 (f) 1.6 (m)[a] 2 (f)[a]				8.1 (m) 10.9 (f) 4.3 (m)[a] 5.6 (f)[a]	
[43]						13 (m) 18 (f)	

Note: (m): male; (f): female.
[a] With dose modulation.
[b] With ECG pulsing.

TABLE 2. APPROXIMATE EFFECTIVE DOSE FROM CT CALCIUM SCORING AND CTA COMPARED TO OTHER COMMON SOURCES

Source	Approximate effective dose (mSv)
CT calcium scoring	1–5 (multidetector helical CT) 1 (electron beam CT)
CT coronary angiography	5–15 (multidetector helical CT) 1–2 (electron beam CT)
CT scan of thorax	10
Conventional invasive coronary angiography	2–6
Chest X ray (one film)	0.02
Annual natural background	2.4
Typical annual effective dose to transatlantic pilot	4.0

It is instructive to compare the dose from the various cardiac CT procedures with that from standard radiographic contrast coronary angiography. While there is variation related to the difficulty of the procedure, effective doses of about 2–6 mSv have been reported for diagnostic coronary angiography [32, 52–54]. A comparison of doses is presented in Table 2. This comparison is based on radiation risks only, and does not address the other risks inherent in the procedures.

The BSS and other IAEA publications [1, 3] recommend the use of formally established reference or guidance doses for medical procedures to assist in the implementation of optimization programmes. The dose values cited here provide a valuable basis for comparison and represent what has been achieved in experienced centres. However, they are not guidance or reference levels as these remain to be established in the future.

Both ultrasound and magnetic resonance imaging (MRI) are also currently used for cardiac imaging and have the advantage of not using any ionizing radiation and do not have any known cancer risk. Currently, ultrasound is not useful as a general screening test for coronary artery disease and MRI is not useful for identifying or scoring calcium deposits. MRI can, however, visualize coronary arteries and whether MRI cardiac scanning will ultimately replace either CT coronary angiography or standard contrast coronary angiography is unknown.

6. RADIATION RISK FROM CT CARDIAC EXAMINATIONS

The radiation risk at the doses of interest from a cardiac CT scan is the potential for radiogenic cancer induction. Individual radiation risk from a CT examination varies significantly depending upon many factors including the absorbed dose, age and sex of the patient, and expected lifespan. Risk is generally higher in younger patients and is slightly higher in females than in males. CT scanning during pregnancy is occasionally performed for specific medical reasons but requires special consideration of the risk to the foetus.

Excess cancer risk has not been demonstrated by epidemiological studies at doses below 100 mSv. Since doses from cardiac CT scans are lower than this, the potential risk can only be estimated by assuming a dose response relationship [55, 56]. The ICRP has estimated that the radiogenic fatal cancer risk for an adult population is about 5%/Sv [57] or (by using the linear non-threshold dose–response hypothesis) 0.005%/mSv. The US National Academy of Sciences BEIR VII Committee has recently provided radiogenic cancer estimates of risk by age [58]. Potential radiation risks can be compared to the spontaneous fatal cancer risk of about 20% and the spontaneous cancer incidence of about 40% (Tables 3 and 4).

While these approximate radiation related cancer risks may seem low in terms of percentage, the situation is somewhat different if the potential risk is expressed in terms of numbers of excess cancer cases. An example of the possible effect is as follows: if 100 000 persons received a CT coronary angiogram (10 mSv effective dose) each year from age 40 to 70, there might be about 2500 excess cases of cancer and leukaemia, and about 1300 excess fatalities [59]. This would be in addition to the spontaneous cancer cases of about 40 000 and cancer fatalities of about 20 000. This level of detriment would have to be set against the lives saved/disease averted by cardiac CT applied to angiography. From the above, it is clear that in the opinion of the professional societies involved, these benefits are too tenuous to warrant use of cardiac CT in mass screening programmes. On the other hand, less frequent referrals of patients with well identified risk profiles, combined with dose reduction methodology, provides a more favourable risk–benefit profile and in the opinion of the professional bodies is justified [4–6].

TABLE 3. ESTIMATION OF AVERAGE DOSE AND RISK FROM SEVERAL TYPES OF CARDIAC IMAGING PROCEDURES PERFORMED ON AN ADULT POPULATION

Approximate effective dose (mSv)	Approximate risk per scan of fatal radiogenic cancer (%)[a]	Approximate spontaneous risk of fatal cancers (%)
1	0.005	20
2	0.01	20
3–5	0.015–0.25	20
10	0.05	20
2–50	0.01–0.25	20

[a] Radiogenic and spontaneous cancer incidence is approximately twice the fatal risk.

TABLE 4. POTENTIAL LIFETIME RADIOGENIC FATAL CANCER RISK AFTER AN EFFECTIVE DOSE OF 10 mSv AS A FUNCTION OF SEX AND AGE FOR CARDIAC CT SCANNING
(adapted from BEIR VII Table 12 D-2 [59])

Age, sex at exposure	Fatal radiogenic cancer/leukaemia risk (%)
30, male	0.038
40, male	0.038
50, male	0.036
60, male	0.032
70, male	0.025
80, male	0.015
30, female	0.054
40, female	0.051
50, female	0.047
60, female	0.041
70, female	0.032
80, female	0.019

Note: Approximate risk can be calculated for scans of varying doses by using a simple proportional relationship (for 5 mSv divide risk by two). Radiogenic and spontaneous cancer incidence is approximately twice the fatal risk.

7. SUMMARY

CT scanning for coronary artery calcium scoring remains a somewhat controversial screening test and is not generally recommended in asymptomatic individuals. However, European guidelines do recommend calcium scoring for identifying individuals at high risk of a coronary event.

CTA has not been recommended as a general screening examination but may be useful for certain persons with suspected coronary artery disease. Since CTA has a high negative predictive value, it may be useful in excluding significant coronary artery narrowing in individuals at intermediate risk. This test should be considered as a complementary and not a replacement modality for invasive coronary angiography.

Health authorities and professional groups should evaluate many factors before recommending adoption of these tests for screening asymptomatic persons. The factors include, but are not limited to, prevalence and severity of disease in the population, age of the proposed screening group, accuracy of the test, costs (including false positive and false negative results), effect on outcome, possibility for radiation dose reduction and evaluation of potential risks. The radiation dose from these procedures is relatively well documented and the potential risk of radiogenic cancers can be estimated. In addition, the combination of conventional dose reduction techniques and newer technological developments is likely to reduce the dose levels reported at present. Outside of screening programmes, persons who are symptomatic should be individually evaluated by a physician to determine what medical care is appropriate and necessary (including justification and optimization of the radiological examination).

Finally, while the above considerations are valuable in initiating the justification and optimization processes envisaged in the BSS, they are not comprehensive. Much remains to be done in further resolving the appropriate referral patterns, optimization of technique and developing guidance or reference levels.

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