RADIATION IN THE CARDIAC CATHETER LABORATORY

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In 2001, Wilde and colleagues reviewed the role of radiation awareness in cardiology in general.¹ They described the legislative framework and its consequences, particularly the then novel Ionising Radiation (Medical Exposures) Regulations 2000 (IRMER).² In the cardiac catheterisation laboratory, cardiologists act as “referrers”, “practitioners”, and “operators” under the regulations. As practitioners, they are responsible for the act of justification for any exposure, which can be partitioned into three questions that demand answer:

- ▶ (1) Does the investigation proposed answer the clinical question set by the referrer?
- ▶ (2) Could the same question be answered by an alternative non-ionising technique?
- ▶ (3) Do the benefits of the procedure outweigh the individual detriment of the radiation dose?

IRMER fits with disciplines where the practitioner is often in the best position to rule on questions 1 and 2—for example, in radionuclide imaging. In the cardiac catheter laboratory they are more a matter of specialist cardiological knowledge. Question 3 requires deeper knowledge of radiation risk. Even so, it is not an easy task to reconcile small but significant radiation risks with the clinical risk of not doing the procedure if no non-ionising alternative is available. Whenever serious congenital or acquired heart disease is present, the decision to justify is relatively easy to make, as the condition is usually life threatening. In less serious disease, or in the younger patient when disease is being screened for and may not be present, the decision is less easy. There is no binding legislation or direction to help; IRMER simply demands that someone competent makes the decision.

The other situation that requires a difficult balance is when alternative ionising procedures are available. For example, it is becoming clear that multidetector computed tomography (CT) can produce images of the coronary arteries that compete with selective coronary angiography, but at a higher radiation dose.³ CT is less invasive and, on balance, less of a physical risk, and CT will be cheaper and more convenient. IRMER makes allowance for cost and availability, allowing the practitioner to factor them into the final decision.

If a procedure is justified, IRMER does clearly give the practitioner a combined responsibility, together with the operators concerned, to achieve the exposure at the least radiation burden to patient and staff.

I hope that the following paragraphs will help with these decisions.

IRMER TOPICS

Employers

IRMER gives prime responsibility for its observance to the “employer”, but this is not defined in the sense of the Employment Act—that is, it is not necessarily the person or organisation who hires the staff or owns the equipment. Fortunately, Department of Health guidelines⁴ say that in a National Health Service (NHS) environment the employer will be the Trust that operates the radiological installation.

Practitioners

IRMER puts an emphasis on the “patient journey” through the stages of referral, justification, authorisation, and exposure (by one or more operators). Referral is made to a practitioner, who will justify and authorise the exposure. The sequence is well suited to a department of radiology; in cardiological practice it is less easy to apply. Wilde and colleagues¹ gave two scenarios where the patient may arrive at the catheter laboratory by either referral from another physician, or by self referral by the cardiologist (the more usual route). Another route is when a cardiologist may determine that an angiogram is to be done but his or her junior does the procedure. Typically there is no request card system for cardiology, and it can become debatable just who is justifying and authorising the exposure, let alone who has referred it. The solution adopted in my Trust is to regard the process which leads up to the patient being booked for angiography to be the referral process, recorded in the patient’s notes, and that the act of justification occurs when the catheterising doctor decides to proceed with the angiogram. Hence the catheterising doctor is the

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practitioner for the case. When he or she actually begins the procedure, they also become an operator.

Operators

An operator is anyone who has a material effect on a patient's exposure. It should be now well recognised that the doctor performing a cardiac catheterisation is an operator in the IRMER sense, and that their employer can justifiably demand proof of adequate training both in the theory and in the practice of cardiac angiography. In 2003 the Joint Committee on Higher Medical Training recognised this in their syllabus for registrar training, and it could be argued that registrars who have finished their training can demonstrate that they have been adequately trained. During training, they must be assessed and entered on the employer's lists of approved operators and practitioners if they are to undertake unsupervised procedures. They may gain a certificate of training from a formal course of instruction for cardiologists. IRMER has a schedule of training to act as a guide, but it must be emphasised that an operator must be trained in the practical aspects of equipment technique, and a certificate confined to the theories of radiation protection is inadequate. None of these certificates is essential; the employer can make its own assessment of a candidate. On the other hand, a certificate from a valid institution is to be taken as proof of adequate training.

IRMER also demands some regular, recorded CME, without specifying the amount. Records must be kept and be easily available to the inspectorate.

RADIATION BIOLOGY

An x ray photon may pass through the body with neither affected. Alternatively it will strike an atom and be removed from the primary beam: this is how a shadow image, the radiograph, is generated. Its impact ionises the atom, energising a free electron, which causes a short, local track of typically 30 secondary ionising events. This transfer of energy may be to the electron completely (photoelectric absorption) or partially (Compton scattering). In the latter

process the balance of energy is liberated as another x ray photon which is of lesser energy than its parent and whose direction is at an angle to it. This is the cause of x ray scatter, of which more later. Both events are complete in nanoseconds. In both, the ionisation track causes physical and chemical damage to the cell. The results of it are divided into two groups, deterministic and stochastic.

Deterministic effects

Here, the effect is general damage to the cell, causing inflammation and, at high exposure, cell death. There is a threshold below which no demonstrable harm is done, and above which there is a linear relation between dose and effect. At the photon energy (kV) used in radiography, the skin at the entry point bears the brunt of this effect. It is perhaps not well known that in a typical adult the body absorbs a considerable majority of the incident beam. The first 5 cm of the body removes half of the beam; hence most of the deterministic damage is found in the superficial tissues. The next and subsequent 7 cm layers will each halve the intensity of the beam. Since the image detector (intensifier or flat plate) will require a certain minimum number of photons to make an image, it follows that for every extra 7 cm of patient thickness, the incident beam needs to be doubled to maintain the desired output. Failing to use full inspiration also increases patient density: an expiratory acquisition will generally have twice the radiation dose of one in full inspiration—and will be of lesser quality (fig 1).

A cardiac operator may have to dwell over the same area of skin for a long time, risking a damaging dose to the skin at the entry point of the beam. Such cases are typically difficult angioplasties or ablations. The consequence will vary from mild, transient erythema to chronic ulceration. It will not appear until 36–48 hours following the procedure. Those who monitor the patient's exposure must have a threshold value above which a medical physicist is asked to estimate the absorbed skin dose. If this too is high, the clinician must be

Figure 1 The effect of inspiration. The image on the left is in poor inspiration, driving the kV to 95 (amperage was maximal). The vessel is invisible below the diaphragm, and above it is partly "burnt out" due to too high a dose. On the right is an immediate repeat in full inspiration: the whole vessel can be appreciated and the contrast is better. The kV was 80, so the radiation dose was less than half that of the first run.

alerted that skin damage is possible. The clinician in turn must ensure that the patient is advised and the area of skin exposed inspected.

Radiation burns can be avoided. General measures to reduce radiation exposure described below apply here. Relatively minor shifts in the radiographic projection will spread the dose over a larger area of skin.

Stochastic effects

This is a more difficult topic. There is no doubt that ionisation can cause chromosomal damage, and that this leads to inheritable genetic consequences and to latent carcinogenesis. Unlike deterministic effects, it is a majority opinion that there is no threshold level. This is despite the fact that very efficient DNA repair mechanisms exist, as there are many other agents that damage DNA frequently. However, there is no direct evidence for a zero threshold. Various groups of subjects with occupational, accidental, or warfare exposure have provided the data, but the assumption that the principle applies to diagnostic levels of exposure is made on a mathematical extension.

There is a minority view that doubts the zero threshold principle, holding that diagnostic exposures may well not generate stochastic effects. Also there are some data that suggest that low dose radiation may have benefits in terms of overall longevity ("radiation hormesis"⁵). A study of British radiologists working in the second half of the last century found that cancer rates were higher than normal but that longevity was greater.⁶ The debate is energetic, and far from resolved.

The ALARP principle

IRMER paragraph 7(1) makes it mandatory that an exposure is made at the lowest radiation dose practicable. This is the ALARP principle ("as low as reasonably practicable"). This is also known as ALARA with "achievable" replacing "practicable". The employer must take active steps to ensure that the practitioners and operators for whom it is responsible follow its written procedures to minimise dose (among other things). The National Radiological Protection Board is constructing a series of dose reference levels (DRLs) for average sized patients which are to be used to ensure that the equipment and the procedures used with them conform to a national level.

These principles are easiest applied to examinations such as plain film radiography when a set number of views are required. It is less easy in angiography when the dose can rise as a result of lengthy fluoroscopy and multiple acquisition runs. Also, and particularly in cardiac angiography, image quality generally increases with increasing dose. ALARP suggests that images should be of only just diagnostic quality, but there is no guidance on how quality can be measured. Heart disease in either the adult or child is a serious matter, and it is understandable that many clinicians cannot easily reconcile clinical management with the ALARP principle, sometimes to the extent of ignoring it. This was neatly summarised by Rita Watson in her editorial of 1997 entitled "Radiation exposure: clueless in the cath lab, or sayonara ALARA".⁷

What are the risks for stochastic effects?

A generally quoted figure for the risk of cancer induction is 6% per man Sievert. Diagnostic coronary angiography has an average dose of around 10 milliSievert (mSv). Thus, crudely,

an angiogram carries a risk of 0.06%. This risk is over and above the general lifetime risk of malignancy, which is in the order of 30%, and compared to it the risk increment seems small indeed. When compared to the risks of the disease being investigated or treated, it can be trivial. It sounds less benign to say that for every 1600 angiograms, one case of fatal cancer might be generated. The acceptability of these risks remains an individual decision; however, it is interesting that a working party of the British Cardiac Society⁸ considered that a risk of congenital malformation of the fetus of a pregnant interventional cardiologist of 1 in 4166 is tolerable.

At diagnostic levels of radiation, there is a latent period between the exposure and the appearance of the tumour, typically 20 years in the adult for solid tumours, but less for leukaemia. This affects the risk, and over the age of 55 years the risk per Sievert falls away to be less than 1% at age 85. High doses in the elderly are therefore of relatively less concern unless they risk deterministic effect. A man aged 75 having an angioplasty where the dose is 30 mSv has an incremental cancer risk of only 0.04%. As genetic effects are unlikely, it is no surprise that stochastic effects are often of little consequence when serious heart disease is present in those over 55. For comparison, the same dose in a woman of 60 carries an incremental risk of 0.1%, in a man of 30 it is 0.25%. Induced second malignancies are well recognised as a consequence of radiotherapy. Even so, despite the dose being hundreds of times greater than diagnostic, the latent period is still an average of 10 years.

In the young patient the latent period is easily satisfied—the lifetime risk per Sievert rises to a peak of 11–15% in the infant. However, the latent period seems to be longer, perhaps 40 years for an infant. It is the case that the exposure to an infant is less than in larger children, simply as a consequence of lower weight. However, their higher sensitivity to radiation effects means that the effective dose is higher. Incremental risks in interventional procedures in the child are generally higher than in the adult, but it would be unusual for it to rise above 1%. For example, a 20 mSv exposure in a 1 month old male infant carries a lifetime risk increment of 0.3%; this particular example was of a procedure which entailed an hour of fluoroscopy and seven acquisition runs.

Figure 2 The distribution of scattered radiation in a cardio-radiological installation. The main source is the input (tube) side of the patient. Adapted from Balter.¹⁰

Figure 3 Scatter is real. In this bone scintigram, the nuclide injection has partly resided in the left arm. On the left, with the arm by the side, a glow of activity in the soft tissues of the flank is caused by scattered radiation from Compton interactions with the 120 kV photons from the injection. The activity is considerable despite the scattered photons exiting at right angles to the incident "beam". On the right, the phenomenon disappears when the arm is adducted.

Attendant staff

Cardiac operators are exposed to scattered radiation and they will accumulate a dose over many investigations, so the ALARP principle is equally important for them. Protection for the operator is a well established topic: leaded protection must be available in the catheter laboratory, including personal lead coats, goggles, and thyroid shields. Most laboratories also have suspended or mobile lead glass screens. The number of workers within the controlled area must be minimised, and those within the area should try to employ the inverse square rule and stand as far away from the patient as practicable.

Radiation exposure to an operator is principally caused by scattered radiation from the patient, most of which radiates from the entry point of the beam on the patient (fig 2); the x ray tube and the intensifier are lesser sources of scatter. This seems illogical unless it is remembered that a scattered photon can be liberated at any angle. At lower photon energies, typically those absorbed at the input to the patient, much of the scatter is backwards towards the source. At higher energies, typically in the beam as it exits the patient, the scatter is in line with the primary direction. This means that much of it will head for the detector and fog the image. Scatter is a doubly detrimental phenomenon and its control is central to achieving a balance between dose and image quality (fig 3).

ALARP AND EQUIPMENT

I will not review all aspects of equipment performance, but will touch on three aspects that are under the operator's control or influence. Despite the trend towards automation in cardiac angiographic exposure factors, the operator's skills are still a major influence on patient and operator dose.

Tube filtration

An x ray tube produces a spectrum of x ray photon energies. Low energy "softer" photons will be mainly absorbed in the superficial tissues of the entry zone and increase the risk of deterministic damage. They can be reduced by having a sheet of aluminium across the beam, which blocks soft radiation more than hard; 2 mm or so of aluminium is mandatory for all tubes, and this is called the fixed filtration. Greater degrees of filtration can be achieved by adding thin layers of

copper, achieving a very efficient spread of penetration which, with care, will minimise skin dose without seriously affecting image quality. However, the filter will increase the loading of the tube required to deliver a diagnostic image as it lessens all elements of the beam. This is not a problem in children and small adults where the tube is working well below its maximal loading. With increasing patient size, the tube can only deliver a sufficient dose by operating at a higher level of kV when its efficiency of conversion of power to useful x rays rises with the kV (roughly, a rise of 10 kV doubles the tube output). However, the higher kV levels have too great a penetration and image contrast falls. Also, secondary scatter in the image increases with kV. It is becoming common now for the tube to be fitted with a series of copper filters of differing thickness. The thickest can be used in children to good effect, and can also be used for filtering fluoroscopy when image quality is less critical. For large adult acquisition, the filter has to be thin or absent as the tube output would otherwise be compromised. The last moment of screening before an acquisition run determines the filter level, but the filter is adjusted just before the acquisition is begun. This requires good technique—if the last moment of screening is not the image required, both in terms of projection and inspiration, a thin filter is likely to be set and the image will have been collected at a greater exposure than necessary.

Copper filtration is often added during fluoroscopy, to a level greater than will be used for an acquisition run in the same projection. This adds to other reasons why, despite its inherently lower dose rate, fluoroscopic image contrast is not as good as subsequent acquisition. Some installations can retain fluoroscopic scenes for incorporation into the final Dicom set of images. This is valuable, as they are usually good enough to act as a record, removing the need for an acquisition dose.

Fluoroscopy is made more efficient by using pulsed radiation, and most modern installations will offer this facility. However, the eye requires a minimum aggregate amount of radiation per second for adequate image quality, so the slower frame rates may have a greater dose per frame, and not be as dose effective as anticipated. Beware also of acquisition frame rates lower than 10 per second. If you want

Figure 4 Fluoroscopic definition. The upper image is a frame grab from normal fluoroscopy. The lower half is of equivalent magnification but using air gap magnification without an antiscatter grid, at a lower radiation dose. Because fluoroscopy is performed on fine focal spot, image definition is if anything improved by the air gap.

to try these, make sure they are not high dose-per-frame options designed for peripheral angiography: if they are, their exposure times may be well over 10 ms and unsuitable for cardiac studies.

X ray tubes are very sophisticated now, ceramic or metallic tube bodies are replacing glass, and liquid bearings conduct waste heat away from the tungsten target very well. The long term heat dissipation of these tubes is excellent. They can cope with frequent exposures, and extended fluoroscopy times, without overheating. They are extremely durable. However, one aspect has not changed: the instantaneous loading limit of the tube during acquisition is not much different to older models, so the problems of high kV for acquisition in large patients are much the same.

Dose control

The regulation of dose used to be simple when image intensifiers were used. The detector's light output was the set requirement and the generator varied tube loading to achieve a fixed output luminance. The bigger the patient, the greater the input dose to achieve the exit dose to the intensifier. It followed that when a magnified image was selected, the beam had to rise in intensity to maintain luminance of the output screen since a smaller input field was being collected. For this reason, it is never correct to try to cure "grey" images by increasing the magnification level—kV would rise and the image would get greyer. More recently, in installations still current in many places, the luminance level required can be modified by having a variable iris on the television camera. Opening the iris allows a lesser increase in beam intensity. This has to be balanced against the need to have enough radiation to make a good image. These control levels are often

Radiation in the cardiac catheterisation laboratory: key points

- ▶ IRMER (Ionising Radiation (Medical Exposures) Regulations) requires all ionising exposures to be justified by an approved practitioner and carried out by a trained operator at the lowest practicable radiation dose
- ▶ Cardioangiographic systems may have automated exposure control but poor operator skills can still promote unnecessary exposure
- ▶ Antiscatter grids increase patient dose and may be unnecessary in most adults and in all children

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available to the operator. Countering a grey image can therefore be achieved by either choosing a lesser magnification, or a smaller dose, or both.

Flat panel detectors have more sophisticated control, when image noise and contrast can be tracked and the radiation level adjusted to maximise quality. However, they are still slave to the limitations of the tube. These systems tend to give the operator less immediate control, but do have important set-up options that must be fully understood by its operators.

Reducing dose by gridless angiography

Compton scatter not only irradiates the operator but also fogs the image. Scatter is an important phenomenon and may form well over half the image content in large patients. To minimise it there is an antiscatter grid on the face of the intensifier or detector. However, a grid also stops some of the primary beam. Without the grid, the radiation dose would be much less; however, much of the time the scatter would ruin the image. There is an alternative, which is to remove the grid and also use an air gap between the patient and the detector to dissipate the scatter. The image will be magnified by the air gap so the degree of detector magnification has to be reduced. This simple procedure can significantly reduce radiation exposure without seriously affecting image quality.⁹ To use it, one needs first to do a simple test with a phantom to ensure that no focal spot unsharpness will be generated by the gap during acquisition, when a large focal spot will generally be used. Unsharpness is not a problem with fluoroscopy as most installations use fine focus for all screening (fig 4). Furthermore, the air gap will increase the range of magnification achievable during screening, which could be an advantage in angioplasty. Gridless technique is well established in paediatric radiology and should be adopted for paediatric angiocardiology.

Additional references appear on the *Heart* website—<http://www.heartjnl.com/supplemental>

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Figure 2 Flow-diagram showing classification of coronary artery stenosis based on calcium scoring (CS; thresholds of 0 and ≥ 400 , respectively) and computed tomography coronary angiography (CTCA) in comparison with conventional coronary angiography (CCA).

100% each, when applying Agatston score thresholds of 0 and ≥ 400 .

We thank Drs Vliegenthart Proença and Oudkerk for their considerations of the role of coronary calcium scoring in the management of patients with suspected significant atherosclerosis and the improved accuracy of dual-source CT-derived calcium scores.² As mentioned above, patients from our study having an Agatston score of 0 did not have significant stenoses at catheter coronary angiography. Theoretically, further CT coronary angiography (CTCA) investigation could have been omitted in almost one-fifth of patients. However (and as mentioned in the "Discussion" section of our paper), up to 5% of patients having an Agatston score of 0 indeed have significant stenosis caused by non-calcified plaques.³ Consequently, omitting coronary angiography when calcium scoring discloses no calcifications would result in up to 5% false-negative classifications. We therefore favour a

calcium score not as the sole measurement but as an important supplement for CTCA in patients with non-evaluative coronary segments; patients with one or two non-evaluative segments at CTCA but having an Agatston score of 0 will have a high likelihood of having no significant coronary stenosis. We agree that the reported high negative predictive value of calcium scoring favours the test to be the initial imaging modality when coronary artery disease is suspected. However, we believe that it should be followed by CTCA in every patient.

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CORRECTION

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Partridge J. Radiation in the cardiac catheter laboratory. *Heart* 2005;**91**:1615–20. The link for the multiple choice questions was wrong. The correct link is <http://heart.bmj.com/misc/education.dtl>.