7 Radiation Exposure and Safety

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About Us Royal Stoke University Hospital (RSUH) is a tertiary surgical center performing both coronary and structural interventions. The Cardiac Department serves a large geographic area with a population of approximately two million. RSUH is affiliated with University Hospitals of North Midlands NHS Trust and Keele University Medical School.

RSUH was at the forefront of adopting transradial (TR) practice in the UK. Since then, it has developed a recognized TR program of teaching and research. Our center performs around 2000 percutaneous coronary interventions predominantly via the radial artery per year. Furthermore with EP studies, implantation of simple and complex pacing devices also being performed, great emphasis is placed on the importance of radiation protection.

The following highlights current issues regarding radiation safety and strategies that we employ to decrease radiation exposure.

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Introduction

Coronary angiography is a widely available diagnostic and therapeutic modality. Radiation exposure is set to increase as a result of greater complexity of coronary and structural cases now being undertaken. Therefore all cardiologists need to be aware of not only the risks of radiation but also strategies to minimize radiation exposure for both patients and catheter laboratory staff.

This chapter aims to provide a brief overview of basic radiation physics, highlight associated risks of radiation, and emphasize strategies to minimize radiation exposure.

Basic X-Ray Physics and Scatter

Basic Radiation Physics

- Coronary angiography relies on X-rays that pass through the patient before being transformed into recognizable images. X-rays are a form of ionizing radiation at the short-wavelength end of the electromagnetic spectrum.
- Typical wavelengths and frequencies are in the range of 0.01–10 nm and 30×10^{15}–30×10^{18} Hz, respectively.
- X-rays are composed of distinct packets (quanta) of energy called *photons*. The typical energy range for diagnostic X-rays is 5–150 keV.

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- X-rays are generated in a vacuum tube when accelerated electrons from a heated cathode filament collide into an anode. The collision releases energy mostly as heat. However about 1% is in the form of X-rays.
- The majority of cardiac catheter laboratories have a "*C-arm*" and a "*floating*" patient table. The C-arm consists of two components, first a radiation source and second an image receptor.
- The radiation source produces X-rays in a beam that travels through the patient to an image intensifier. The ability of X-rays to penetrate tissue is dependent on the energy of the photon but also on the atomic makeup, density, and thickness of the absorbing tissue. The image intensifier converts X-rays into images that may be stored (Fig. 7.1).

Radiation Scatter

Operators and medical staff are mainly exposed to scatter radiation rather than direct exposure. There are three types of scatter radiation:

1. Scatter radiation: This occurs from the X-rays bouncing off the patient's body and is the main source of radiation to operator and assistant.
2. Backscatter: This type of scatter radiation is created from behind the image intensifier and directed back towards the X-ray tube. To prevent backscatter lead screens are placed in front and behind the image intensifier for added protection.
3. Side scatter: Caused by objects within the catheter laboratory. To minimize side scatter modern catheter laboratories have patient table in the middle of the room with only a minimal

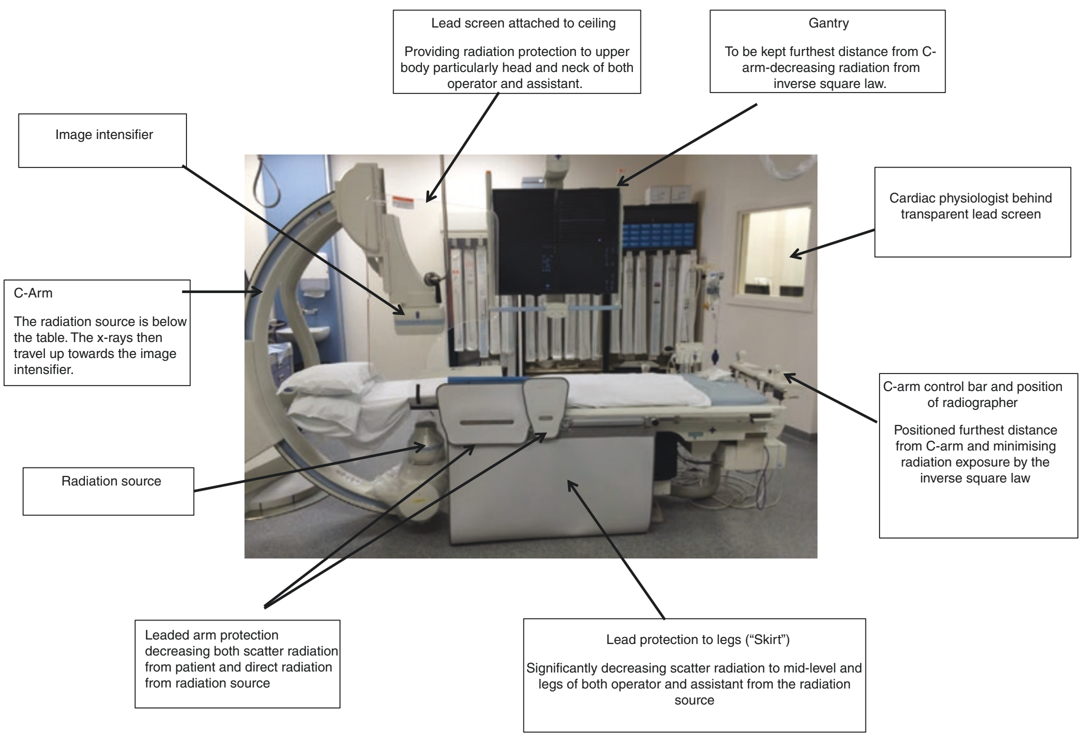

Fig. 7.1 The Royal Stoke University Hospital cardiac catheter laboratory setup

number of other objects. This isolates X-rays as much as possible and decreases side scatter.

Radiation Measures and Terminology

- We are all exposed to background radiation from the environment. However a number of common cardiac imaging modalities make use of ionizing radiation. These include noninvasive computerized tomography coronary angiography, nuclear imaging, and invasive coronary angiography (Fig. 7.2).
- Radiation dose is an important concept and determines the risk of adverse effects. Radiation dose exposure to living tissue is expressed as "delivered energy" rather than actual radiation itself.
- There are a number of radiation measures available (Table 7.1). However the most commonly used parameters are screening time (seconds) and dose area product (DAP) (Gy.cm^2).

Deterministic and Stochastic Effects of Radiation

- Adverse effects are thought to be rare. However they may be higher than thought firstly due to a lack of awareness or recognition of signs or symptoms by either clinician or patient.

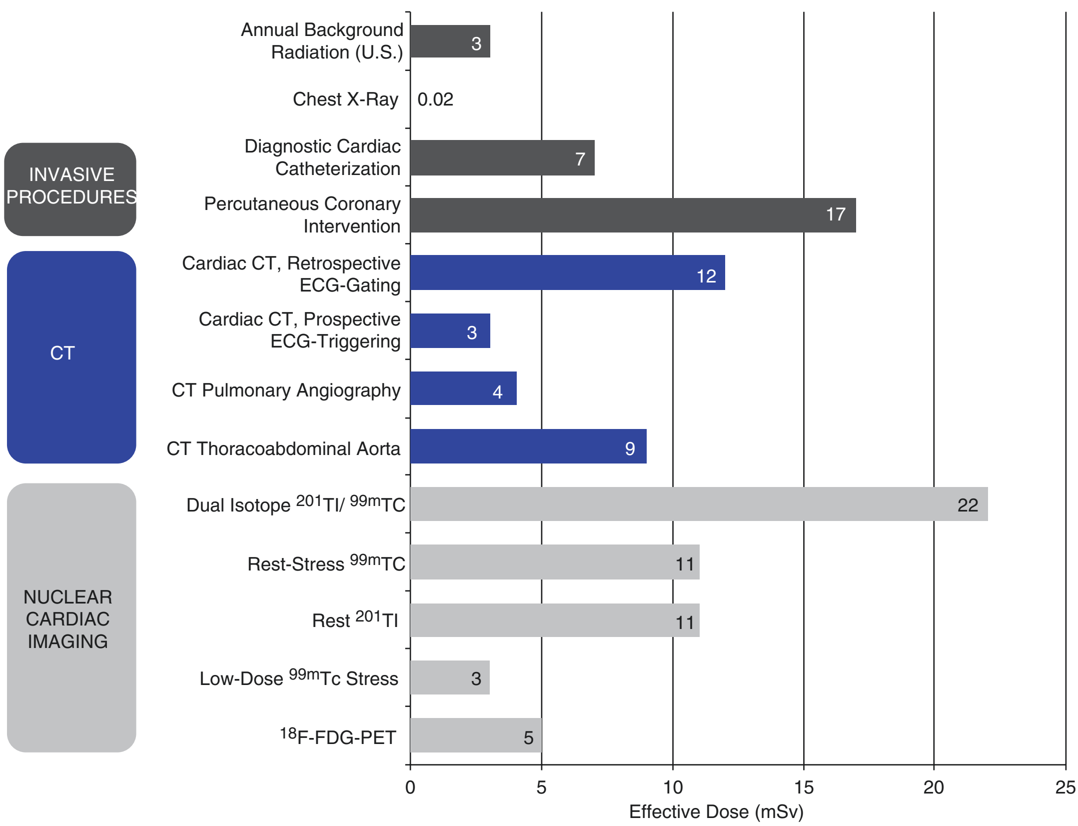

Fig. 7.2 Effective radiation doses associated with common cardiovascular imaging tests. Reproduced with permission from Meinel FG, et al. (2014) Radiation risks from cardiovascular imaging tests. *Circulation* 29;130(5):442–5. Key: *CT* computed tomography, *18F-FDG-PET* 18F-fluoro-deoxyglucose positron-emission tomography

Table 7.1 Commonly used radiation measures, definitions, and usage

Measurement	Unit	Definition	Measure	Use
Absorbed dose	Gray (Gy)	The amount of ionizing radiation deposited per unit mass	Measure of the concentration of energy absorbed in tissue	Assess the potential biological risk
Air kerma	Gray (Gy)	The dose delivered per unit mass of air	Measure of the amount of radiation energy	**K**inetic **E**nergy **R**eleased per unit **MA**ss (KERMA) of air
Dose-area-product (DAP)	$Gy.cm^2$	The quantity used in assessing radiation risk and is defined by the absorbed dose multiplied by the area irradiated	Dose absorbed multiplied by area irradiated	An estimate of the energy delivered to the patient and used to monitor/measure operators' procedural doses
Effective dose	Sievert (Sv)	Tissue-weighted sum of the equivalent doses in all tissues and organs. Takes into account the type of radiation and nature of each organ or tissue being irradiated	Overall calculated dose of the sum of each organ dose	Represents an estimate of stochastic risk to the staff/patient. The biological factor to convert absorbed X-ray doses (Gy) to equivalent doses (Sv) is 1
Entrance skin dose	Gray (Gy)	The absorbed dose on the skin includes backscattered radiation	Amount of radiation absorbed by skin	Assess the risk of adverse effects of radiation on skin
Equivalent dose	Sievert (Sv)	The radiation dose applied to a specific tissue or organ	Effect of radiation on a particular tissue	Measures the risk of radiation to specific organs/tissues
Fluoroscopy time	Minutes or seconds	Total fluoroscopy time used during a procedure	Time in minutes and seconds	Measure of the length of radiation time

- Secondly, there may be a latent period from radiation exposure to clinical features of excessive radiation exposure. Radiation injuries are likely to become a more common finding as a consequence of longer procedure times seen in more complex interventions.
- There are two mechanisms in which radiation may induce adverse effects. These are "deterministic" or "stochastic" effects.

Deterministic Effects

- These describe an almost linear relationship between radiation dose received and adverse effect. The higher the radiation dose the greater the adverse effect. These occur as a consequence of direct toxicity by X-rays causing cellular death or changes in biochemical response of the exposed tissue.
- Therefore deterministic adverse effects are both predictable and dose dependent.

Stochastic Effects

- These are random and may occur after a single exposure to a radiation dose. May occur as a consequence of modification(s) to DNA that may result in mutations causing cancer or heritable genetic defects. Therefore they may take several years to clinically manifest.
- Stochastic effects are probabilistic, with likelihood of adverse effect(s) proportional to the dose received.

Linear-No-Threshold Model of Radiation

- This model is derived from both deterministic and stochastic effects. This principle confers that no radiation dose is safe and greater risk of adverse effects is associated with higher radiation doses.

Adverse Effects of Radiation

Despite the beneficial use of X-ray radiation the operator must also appreciate adverse effects of ionizing radiation and methods on reducing exposure.

Adverse Effects on Skin

- The most common deterministic adverse effect is on the skin that receives the greatest dose at the beam site. Although staging procedures may allow time between procedures for the skin to repair, injury may still occur.
- Importantly there may be a lag from radiation exposure to presentation. Skin injury can manifest as erythema due to increased capillary permeability resembling mild sunburn peaking by 24 h.
- These may progress to marked erythema as a result of damage from the epidermal cell layer associated with itching and discomfort. Epilation or hair loss may occur up to a month after exposure as a consequence of depleted germinal layers of hair follicles. Epilation may be temporary but may result in only sparse hair regrowth.
- More severe injuries include ischemic dermal necrosis or skin ulceration that may be resistant to healing and require skin grafting.

Cataracts

- Cataract formation is a recognized complication of radiation exposure and occurs at the posterior subcapsular region.
- The radiation dose, and the latent period from exposure to cataract formation and subsequent visual impairment, remains unknown.
- Recently the International Commission on Radiological Protection (ICRP) has reduced the previous recommended dose threshold for cataracts to 0.5 Gy and equivalent dose limits to 20 mSv/year (maximum of 100 mSv in a given 5-year period, with no single year exceeding 50 mSv).
- Therefore wearing protective glasses is now highly recommended.

Risk of Cancer

- The risk of cancer has been mainly derived from longitudinal studies of the survivors of the atomic bomb. These have found survivors exposed to radiation dose in the range of 5–150 mSv and mean of 40 mSv had a significantly increased risk of developing cancer.
- This is equivalent to a patient undergoing a nuclear scan, coronary angiogram, and then subsequently percutaneous coronary intervention.
- The estimated risk of cancer in men has been suggested to be 6% per Sievert. Accordingly, a coronary angiographic procedural dose of 10 mSv would be associated with a lifetime risk of cancer induction of 0.06%.
- The overall risk ranges from 0.1 to 0.24% based on complexity of intervention with the greatest risk in younger patients.

Radiation Exposure Risk to Cardiac Catheterization Laboratory Staff

- Without any radiation protection the operator receives almost the same radiation dose as patients. However with appropriate radiation protection the dose received by the operator may be significantly reduced.
- Not only is the operator exposed to radiation, but also second operators, technicians and radiographers, are exposed to 30% and 1%, respectively, of operators' dose. Historical studies have reported increased risks of cancers including leukemia and breast cancer among radiologists and radiographers. Recently, a cluster of left-sided cerebral neoplasms among interventional cardiologists has been reported.

- Therefore all cardiac catheter laboratory staff must be aware of and ensure appropriate radiation protection.

Regulatory Bodies

There are a number of regulatory bodies mandating the safe use of radiation. Regulations governing the medical use of ionizing radiation have been in existence for a number of years. These statutory legal requirements form the official code of practice for radiation exposure for patients, members of the public, and medical staff. A summary of the most important regulations follows below.

Ionising Radiations Regulations 1999 (IRR'99)

- A statutory requirement forming the official code of practice and legal requirements for the control and use of ionizing radiation in the UK enforced by the Health and Safety Executive (HSE). These UK regulations came into force in January 2000 and were based on the European Basic Safety Standards Directive produced by the International Commission on Radiological Protection.
- IRR'99 sets the maximal received annual radiation dose exposed to both staff and general public. These regulations are legal requirements of employers ensuring the safe use of ionizing radiation by appointing radiation protection supervisors and advisors.

Ionising Radiation (Medical Exposure) Regulations 2000 [IR(ME)R 2000]

- These regulations are set to ensure radiation protection of patients undergoing fluoroscopic procedures. This legal requirement requires the identification of named medical professionals involved in patient welfare.
- These regulations mandate employers to adhere to the recommended national dose reference levels (see section "The National Patient Dose Database (NPDD)"). Therefore all trainees are required to have undergone online IR(ME)R 2000 training from the Health Education England web site:
- http://www.e-lfh.org.uk/programmes/radiation-protection-for-cardiology/.

The National Patient Dose Database (NPDD)

- The National Patient Dose Database (NPDD) collates patient doses from radiographic and fluoroscopic X-ray imaging procedures from a number of hospitals in the UK.
- The Health Protection Agency (HPA) analyzes and reviews this data every 5 years and recommends national reference doses (RNRD) or more recently known as National Diagnostic Reference Levels (NDRLs).
- These tend to be based on the 75th percentile value of the distributions of mean doses observed in the NPDD. While the most commonly used parameters are mean screening time (seconds) and mean DAP ($Gy.cm^2$), several other measures are quoted. All hospitals must adhere to NDRL or local reference levels if they are lower than the NDRL.

ALARA/ALARP Principle

- The IRR'99 and IR(ME)R 2000 documents give rise to the principle of keeping the radiation dose *"as low as reasonably achievable/practicable"*—the ALARA/ALARP principle.
- ALARA/ALARP principle provides practical tips on reducing radiation dose. Practical tips are summarized in Table 7.2.

Operator Total Radiation Dose

Every operator must have total radiation doses measured and assessed quarterly per annum. These are obtained from dosimeters worn under

Table 7.2 Summary of the strategies used at the Royal Stoke University Hospital to minimize radiation dose and exposure

Fluoroscopic considerations	Minimizing patient-to-intensifier distance decreasing patient radiation exposure and scatter radiation to catheter laboratory staff Maximizing distance of operator from X-ray source (inverse square law) Limiting fluoroscopic and more importantly cineangiographic acquisitions Collimating filters to regions of interest Minimizing magnified fluoroscopy and cineangiographic acquisitions Fluoroscopic optimization by decreasing frame rate, use of fluoroscopic image store, and replay varying angulations during lengthy procedures Minimizing or avoiding steep C-arm angulations Use of extension tube and mobile transparent screen (Figs. 7.3 and 7.4)
Shielding	Optimizing all radiation barriers and shields available within the catheter laboratory Mandating the use of all available personal lead shielding including lead aprons, glasses, thyroid and shin shields
Audit	Regular auditing of procedural doses and screening time against current regulatory body recommendations

Fig. 7.3 Mobile protective shielding. This protective shield has wheels to allow mobility and a transparent leaded screen for visualization. This allows catheter laboratory staff added protection. However full-body radiation protection must still be worn

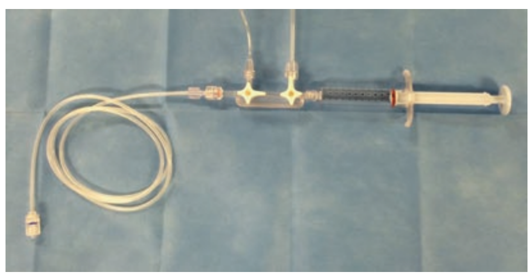

Fig. 7.4 Extension tubing. Extension lead attached to the manifold that allows the operator and assistant to stand further away from the radiation source and therefore decrease radiation exposure by the inverse square law. This extension lead is 1 m long

radiation protection apron(s), finger dosimeters, and total lens dose (TLD) from dosimeters worn on left side of the thyroid shield on the side of the operator closest to the radiation source.

Radiation Protection

Radiation protection measures may be divided into cardiac catheter laboratory and personal protective measures.

Cardiac Catheter Laboratory

All cardiac catheter laboratories have lead reinforcement shielding within the walls and lead windows to allow visualization from review rooms (Fig. 7.1).

Personal Protection

- Personal protection includes lead aprons, thyroid and shin shields, and glasses to be worn to decrease the risk of cataracts. Lead

head caps have been advocated for further decreasing radiation doses to the brain. However they may not provide significantly more protection than careful use of a lead glass shield.
- A transparent lead glass shield is suspended from the ceiling and significantly reduces radiation exposure to upper body, face, and head of both operator and assistant.
- Fitted mobile lead drapes or "lead skirts" on the procedure table decrease lower limb exposure to the operator and assistant. Additional lead flaps at the operators' mid-level and side-arm flaps reduce scatter exposure to the operator and assistant.
- The use of leaded aprons on the patient's abdomen and pelvis undergoing coronary angiography via the radial artery approach is controversial. Despite being shown to reduce scatter radiation to operator an associated doubling of radiation dose to patient has been found. Therefore caution has been advised.
- A mobile leaded shield that consists of a transparent leaded screen provides further protection. This provides added protection for cardiac catheter laboratory staff (Fig. 7.3).

Factors Affecting Radiation Exposure

These can be divided into three main categories—patient, practical, and technical factors. Table 7.2 summarizes the strategies used at RSUH in reducing radiation dose and exposure. These are described below.

Patient Factors

Procedural Complexity

Higher procedural complexity (e.g., chronic total occlusions, multivessel, or graft interventions) is an independent predictor of higher radiation dose. This must be borne in mind when consenting patients.

Body Mass Index

Body mass index (BMI) was found to be an important predictor of radiation dose. Higher radiation doses are required to penetrate subcutaneous fat for satisfactory images to be formed.

Practical Factors

Inverse Square Law

Increasing the distance between operator and radiation source reduces radiation dose by a factor of $1/x^2$. In other words—doubling the distance decreases the radiation dose by a factor of 4. Therefore the operator should stand as far away from the radiation source as possible. The use of extension tubes may facilitate this by allowing both operator and assistant to stand at a considerable distance from the radiation source (Fig. 7.4).

Source-to-Image Distance

The image intensifier should be as close as possible to the patient. Minimizing source-to-image distance (*SID*) decreases radiation dose exposure to patient and scattering radiation dose to operator.

C-Arm Angulation

The radiation delivered to the patient and scattering radiation to the operator are dependent on C-arm angulation. Steeper left or right oblique projections (≥60°) and in particular left anterior oblique angulation have been found to be associated with greater radiation dose. For example using the posteroanterior caudal view instead of left anterior oblique caudal (60°/20°) can be associated with a 60% and 90% reduction in radiation dose received by patient and operator, respectively.

Fluoroscopy and Acquisition Time

- Coronary procedures rely on both fluoroscopy and cineangiographic acquisitions.

Fluoroscopy is used to allow the operator for appropriate positioning of catheter, wires, or stents.
- Acquisition allows archiving of diagnostic higher quality images. However acquisition is typically associated with 10–20 times greater radiation dose than fluoroscopy and may account for as much as 60–70% of the total DAP.
- Reducing acquisition has been shown to be a more effective means of reducing radiation dose than fluoroscopy. Therefore the number and length of acquisitions should be kept to a minimum.

Fluoroscopic Optimization

There have been a number of technical advances that may be used to decrease radiation doses such as pulsed fluoroscopy, image store, and frame rate.

Pulsed Fluoroscopy

This allows short rapid pulses of X-rays to be delivered rather than a continuous beam. This shortens the overall duration of X-ray radiation and may significantly decrease radiation exposure.

Fluoroscopic Image Store and Replay

Modern machines allow storage of fluoroscopic images and therefore limit the number of cineangiographic acquisitions. This is particularly useful when image quality is not essential such as during balloon inflation or deployment of stents. In patients with a low BMI, acquisition may not be required if stored fluoroscopic coronary images are of adequate quality.

Frame Rate

Decreasing fluoroscopic frame rate is associated with lower radiation dose. A study found a significant difference in operator radiation exposure between frame rates of 7.5 frames/s and standard 15 frames/s. However this may be associated with decrease in image quality. The operator should optimize the frame rate in every patient ensuring optimal image quality and lowest possible radiation dose.

Filtering and Collimation Optimization

Modern machines have, as standard, filters that exclude low-energy rays produced by the X-ray tubes. This decreases artifact but more importantly radiation dose absorbed by patient.

"Wedge" filtering is used to not only optimize image quality but also decrease radiation exposure. This should be employed for example when patient lung border or diaphragm is exposed to X-rays.

Collimation allows the operator to concentrate on a specific area of interest by reducing the image field. For example when positioning a stent the image may be "*coned*" down not only highlighting the area of interest but also significantly decreasing the size of the radiated area. This also decreases scatter to the patient as well as cardiac catheter staff.

Arterial Access Site

- RSUH was one of the first to become a predominantly TR center within the UK. Since then TR angiography has risen exponentially over the last decade.
- Initial suggestions that radial access was associated with greater radiation doses have proven unfounded; many early studies did not rigorously control several important variables such as operator experience or radiation protection.
- A sub-analysis of the multicenter RIVAL study found a modest but significant increase in fluoroscopy time in radial cases performed in low–intermediate-volume centers, but not in high-volume centers. There were no significant differences in DAP between either femoral or radial access for the entire cohort. Further sub-analysis and multivariate analysis found the highest radial volume centers and operators had the lowest radiation exposure (DAP).
- The single-center REVERE trial found no difference in air kerma or DAP in 1500 patients undergoing coronary angiography by either femoral, right, or left radial artery approach.
- With greater experience, radiation exposure is reduced for radial (but also femoral) operators.

Summary

- The importance of fluoroscopy in modern-day cardiology is well recognized. However medical staff must also appreciate the potential harm of radiation. This includes recognition of adverse effects and symptoms.
- Therefore methods limiting radiation exposure not only to patients but also to medical staff are paramount. This has led to the mandatory IR(ME) R 2000 training that all medical staff performing any fluoroscopy must undergo in the UK.
- Patient doses may be limited by reducing direct radiation exposure. However scatter radiation is the main mechanism of exposure to medical staff. The mandatory use of radiation protection suits and optimizing procedural factors decrease radiation dose to both operators and other medical staff.
- All medical staff are legally required to wear dosimeters allowing total radiation doses that are measured quarterly per annum. All hospitals are legally required to collect this information from each individual and identify any medical personal at high risk of excess radiation exposure. They also conduct regular audits comparing local radiation doses to national standards. These safety standards ensure the safe use of radiation to patients and medical staff alike.

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