European Society for Vascular Surgery (ESVS) 2023 Clinical Practice Guidelines on Radiation Safety

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GLOSSARY

Absorbed dose: The mean energy imparted to matter of mass by ionising radiation. The SI unit for absorbed dose is joule per kilogram and is usually denoted in Gray (Gy). Organ absorbed doses are often quoted.

Air kerma (AK): The quotient of the sum of the kinetic energies of all charged particles liberated by uncharged particles in a mass, dm, of air. The AK is measured or calculated at a reference point 15 cm from the isocentre in the direction of the focal spot cumulated from a whole Xray guided procedure.

Air-kerma area product (KAP, or Dose Area product, DAP): The KAP is the integral of the air kerma free in air (i.e. in the absence of backscatter) over the area of the Xray beam in a plane perpendicular to the beam axis (usually measured in Gy.cm2). The IRCP now recommends referring to those values as Air-Air-kerma area product ($\mathbf{P}_{\mathbf{KA}}$).

C arm: A fixed or mobile Xray system used for diagnostic imaging and for fluoroscopic guidance during minimally invasive procedures. The name C arm is derived from the C shaped arm that connects and maintains fixed in space, the Xray source and Xray detector.

Collimation: The process of shaping the Xray beam to minimise the radiation field size to the required area of interest using metallic apertures within the Xray source.

Computed Tomography Angiography (CTA): The combination of Computed Tomography cross sectional imaging with intravenous contrast in order to visualise arterial anatomy and pathology.

Cone Beam Computed Tomography (CBCT): A modality, available in modern endovascular operating rooms, that allows rotational acquisition and provides cross sectional imaging of the patient whilst still on the operating table.

Deterministic effects: Deterministic effects of radiation exposure are related to a threshold dose of radiation exposure above which the severity of injury increases with increasing dose. Deterministic effects include harmful tissue reactions and organ dysfunction that result from radiation induced cell death, e.g. skin lesions and lens opacities.

Diagnostic Reference Levels (DRLs): Used for medical imaging with ionising radiation to indicate whether, in routine conditions, the patient radiation dose for a specified procedure is unusually high or low for that procedure. DRL values are usually defined as the third quartile of the distribution of the median values of the appropriate DRL quantity observed at each healthcare facility.

Digital Subtraction Angiography (DSA): The acquisition of multiple images in succession within one field of view, with the subsequent digital subtraction of images taken prior to contrast injection, leaving a contrast enhanced image of the vessels, and removing non-vascular structures such as bone.

Effective dose: The tissue weighted sum of the equivalent doses in all specified tissues and organs of the body, calculated in Sievert (Sv).

Endovascular operator: Any person carrying out an Xray guided procedure on the vasculature.

Endovascular operating room: Any environment where endovascular procedures are carried out with Xray guidance using a C arm as part of a mobile or fixed imaging system.

Endovascular procedure: Any procedure on the vasculature that uses Xray guidance.

Entrance skin dose (ESD): The dose absorbed by the skin at the entrance point of the Xray beam measured in Gy. This includes the back scattered radiation from the patient.

Equivalent dose: Equivalent dose is the mean absorbed dose in a tissue or organ multiplied by the radiation weighting factor. This weighting factor is 1 for Xrays. Equivalent dose is measured in Sievert (Sv).

European Basic Safety Standards (EBSS) Directive: Describes the standards for protection against the risks associated with exposure to ionising radiation, including radioactive material and natural radiation sources, and also preparedness for the management of emergency exposure situations in the European Union. This is a European Council directive.

Filtration: The materials of the Xray tube window and any permanent or variable or adjustable filters that predominantly attenuate the low energetic Xrays in the beam.

Fluoroscopy time: The cumulative time spent using fluoroscopy during an endovascular procedure.

Gray (Gy): The unit of absorbed radiation dose used to evaluate the amount of energy transferred to matter. One Gy is equivalent to 1 Joule/kg.

Image intensifier: This component of an imaging system relies on the fact that when Xrays are absorbed in a phosphor screen they convert into light photons. These photons impinge upon a photocathode that emits electrons in proportion to the number of incident Xrays. These photo-electrons are then accelerated across a vacuum in an image intensifier to produce an amplified light image.

International Commission on Radiation Protection (ICRP): An independent, international organisation that advances for the public benefit the science of radiological protection, in particular by providing recommendations and guidance on all aspects of protection against ionising radiation.

Medical Physics Expert (MPE): An individual or, if provided for in national legislation, a group of individuals, having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence in this respect is recognised by the competent authority.

Peak Skin Dose (PSD): The dose delivered, by both the primary beam and scatter radiation, at the most irradiated area of the skin.

Pulse rate: The number of radiation pulses per second.

Radiation exposed worker: Those over the age of 18 years who may be at risk of receiving radiation doses greater than the stipulated public exposure limit of 1 mSv per year of effective dose.

Sievert (Sv): The unit used to measure both «effective dose» and «equivalent dose». For Xrays,1 Sievert equals 1 Gray (Gy).

Stochastic effects: Stochastic effects of radiation exposure are those which occur by chance and as such the probability of them occurring, but not the severity, increases with increasing dose. A Linear No Threshold model has been adopted internationally, acknowledging that there is no threshold dose. The development of malignancy is the most common stochastic effect of radiation exposure.

LIST OF ABBREVIATIONS

2D	2 Dimensional
3D-IF	3 Dimensional Image Fusion
AI	Artificial Intelligence
AIF	Artificial Intelligence Fluoroscopy
ALARA	As Low As Reasonably Achievable
AK	Air Kerma
ABC	Automatic Brightness Control
AEC	Automatic Exposure Control
AP	Anterior Posterior
APD	Active Personal Dosimeter
CAK	Cumulative Air Kerma
CBCT	Cone Beam Computed Tomography
CT	Computed Tomography
CTA	Computed Tomography Angiography
DAP	Dose Area Product
DICOM	Digital Imaging and Communications in Medicine
DNA	Deoxyribonucleic Acid
DQE	Detective Quantum Efficiency
DRL	Diagnostic Reference Level
DSA	Digital Subtraction Angiography
E	Effective Dose
EBSS	European Basic Safety Standards Directive
EJVES	European Journal of Vascular and Endovascular Surgery
EM	Electromagnetic
ENS	Endovascular Navigation System
ESC	European Society of Cardiology
ESD	Entrance Skin Dose
ESVS	European Society for Vascular Surgery
EU	European Union

EVST	European Vascular Surgeons in Training
eV	Electron Volt
EVAR	Endovascular Aortic Repair
FDA	US Food and Drug Administration
FEVAR	Fenestrated Endovascular Aortic Repair
FOV	Field Of View
FPD	Flat Panel Detector
FORS	Fiber Optic RealShape
FT	Fluoroscopy Time
GC	Guideline Committee
GWC	Guideline Writing Committee
Gy	Gray
Hp	“personal dose equivalent” in soft tissue below body surface
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
IFU	Instructions For Use
II	Image Intensifier
IPE	In room Protective Equipment
IRR	Ionising Radiation Regulations
KAP	Air Kerma Area Product
kV	Kilo Voltage
kVp	Peak Kilo Voltage
LAO	Left Anterior Oblique
LAR	Lifetime Attributable Risk
LEAD	Lower Extremity Peripheral Arterial Disease
LFA	Lead Free Apron
LNT	Linear No Threshold
mA	Milliamperage
MPE	Medical Physics Expert
MPR	Multiplanar Reconstructions
NCRP	National Council on Radiation Protection and Measurements
OCI	Operator Controlled imaging

OSL	Optical stimulated luminescence
OSLD	Optically Stimulated Luminescence Dosimeters
Pb	Lead
PPE	Personal Protective Equipment
PROSPECT	PROficiency based StePwise Endovascular Curricular Training program
PSD	Peak Skin Dose
QA	Quality Assurance
RAK	Reference Air Kerma
RCT	Randomised Controlled Trial
RIC	Radiation Induced Cataract
RNA	RiboNucleic Acid
ROI	Region Of Interest
Sv	Sievert
TAAA	Thoraco-abdominal Aortic Aneurysm
TEVAR	Thoracic Endovascular Aortic Repair
TLD	Thermoluminescent Dosimeter
UK	United Kingdom
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation
VR	Virtual Reality

Chapter 1. Introduction and general aspects

1.1 The need for radiation protection guidelines

The past two decades have witnessed an exponential rise in the number of Xray guided minimally invasive procedures in vascular surgery.[1-4] With time, many of these endovascular procedures have been validated and have established themselves as the preferred treatment modality based on lower morbidity, mortality, and reduced length of hospital stay, compared with the open surgical alternatives. A large proportion of all vascular interventions are now performed using Xray guided endovascular techniques. Advances in technical expertise, evolving materials technology and improved imaging capabilities have led to increasingly complex endovascular solutions which are associated with prolonged fluoroscopy times and consequently a rise in radiation exposure to both the patient and the endovascular operating team. There is growing concern regarding the increasing radiation exposure, to the patient, and to the whole endovascular team.[5, 6] Endovascular operators are key personnel for promoting radiation safety and should work with other key stakeholders in a team approach to protect the patient and all healthcare staff in the endovascular operating room. The risks of radiation exposure are not universally recognised by all, however, because of a poor understanding of key concepts and paucity of educational material directly relevant to vascular surgery.[7] The present guidelines on the subject of radiation safety are the first to be written under the auspices of a vascular surgical society. Their explicit aim is to inform the reader about radiation physics and radiation dosimetry, raising awareness of the risks of ionising radiation, and describing the methods available to protect against radiation exposure. Key issues of relevance to radiation protection for endovascular operators and all allied personnel have been outlined, and recommendations provided for best practice. This will no doubt also result in better radiation protection for the patient but a focus on patient radiation protection has been reserved, including during diagnostic procedures that require radiation exposure, for future iterations of the guideline.

The guideline was written and approved by 14 members who, as well as vascular surgeons and interventional radiologists, included a Radiation Protection Scientist and a Medical Physicist. The collated work is based on the best available evidence but also relies on the expert opinion of the aforementioned individuals who, as part of the process of gathering the evidence, identified several areas where future studies would better guide opinion. The reader should note that this document offers guidance and does not aim to dictate standards of care.

1.2 Methodology

1.2.1. Strategy

The grading of each recommendation in these guidelines was agreed by a virtual meeting on 18th February 2022. If there was no unanimous agreement, discussions were held to decide how to reach a consensus. If this failed, then the wording, grade, and level of evidence was secured via a majority vote of the Guidelines Writing Committee (GWC) members. The final version of the guideline was submitted in July 2022. These guidelines will be updated according to future evidence and to the decisions made by the European Society for Vascular Surgery (ESVS) Guidelines Committee (GC).

1.2.2. Literature search and selection

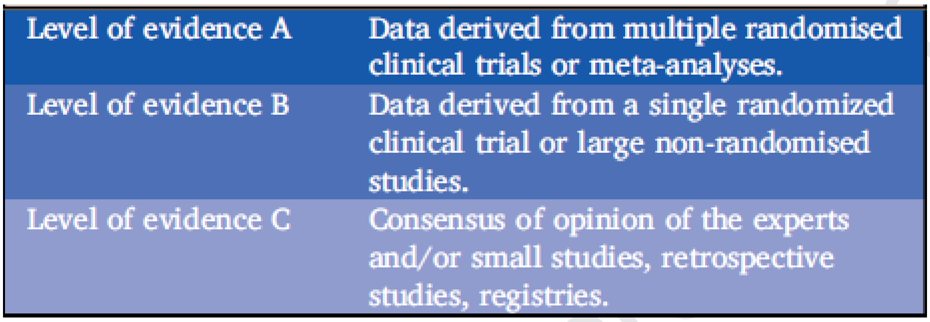
The GWC performed a literature search in Medline (through PubMed), Embase, Clinical Trial databases, and the Cochrane Library up to July 2022. Reference checking and hand search by the GWC added other relevant literature. The GWC selected literature based on the following criteria: (1) Language: English; (2) Level of evidence (table 1). (3) Sample size: Larger studies were given more weight than smaller studies. (4) Relevant articles published after the search date or in another language were included, but only if they were of paramount importance to this guideline.

1.2.3. Weighing the evidence

The recommendations in the guidelines in this document are based on the European Society of Cardiology (ESC) grading system. For each recommendation, the letter A, B, or C marks the level of current evidence (Table 1). Weighing the level of evidence and expert opinion, every recommendation is subsequently marked as either Class I, IIa, IIb, or III (Table 2).

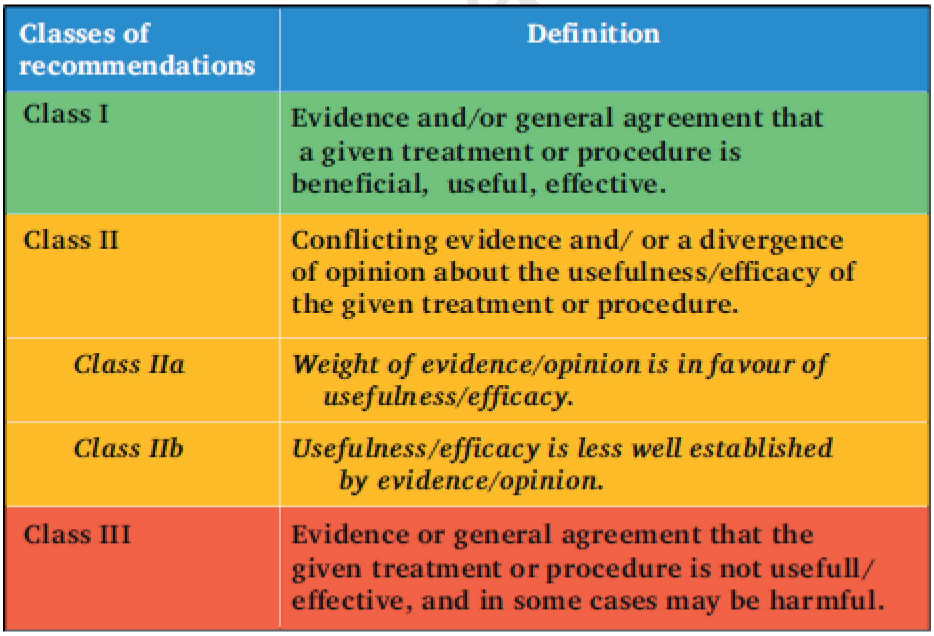
It is important to note that for the general aspects of radiation safety, international bodies such as the International Commission on Radiological Protection (ICRP), the American Association of Physicists in Medicine, the European Federation of Organisations for Medicine and the International Atomic Energy Agency (IAEA) regularly carry out a thorough synthesis of available evidence to publish guidance documents and inform legislation pertaining to safety standards. Legislation in this context refers to statutory regulations that form the main legal requirements for the use and control of ionising radiation. These overview documents, rather than individual literature citations, have been used in the present guidelines to inform recommendations where this was thought to be appropriate. The present radiation protection guidelines are unique in that several of the recommendations made are actually based on legislation that derives from physics principles and extensive, irrefutable evidence that is the basis of this legislation. There have been extensive discussions within the GWC and Guidelines Committee as we have not been confronted previously with this issue in other guidelines. The conclusion agreed between all parties involved is that we could not make recommendations for what are legal requirements but that it is important for the guidelines to highlight areas where law “must” be followed. For this reason, we have, by unanimous decision, used the wording that recommendations based on legislation “must” be followed and the level of evidence has been marked as “law”. It must be noted that in some instances these are not “global or universal laws” and that the level of evidence denoted as “law” means law under most jurisdictions. The recommendations that are based on law are automatically Class I or III. This guideline also has several recommendations, where the evidence is based on physics principles and the results of studies are absolute truths even in small series. For example, increasing distance from the source of radiation reduces the amount of exposure. This is a principle of physics. The level of evidence used to make this type of recommendations reflects this concept and each of these recommendations is marked with a footnote as a “physics principle.”

Table 1. Levels of evidence according to European Society of Cardiology.



Level of evidence A	Data derived from multiple randomised clinical trials or meta-analyses.
Level of evidence B	Data derived from a single randomized clinical trial or large non-randomised studies.
Level of evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

Table 2. Classes of recommendations according to European Society of Cardiology.



Classes of recommendations	Definition
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.
Class II	Conflicting evidence and/ or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.
Class IIa	*Weight of evidence/opinion is in favour of usefulness/efficacy.*
Class IIb	*Usefulness/efficacy is less well established by evidence/opinion.*
Class III	Evidence or general agreement that the given treatment or procedure is not usefull/ effective, and in some cases may be harmful.

1.2.4. Contributors to guideline.

The GWC was selected by the ESVS to represent both physicians and scientists with expertise in the management of radiation exposure. The members of the GWC have provided disclosure statements of all relationships that might be perceived as real or potential sources of conflict of interest.

The ESVS Guidelines Committee (GC) was responsible for the review and ultimate endorsement of these guidelines. All experts involved in the GWC have approved the final document. The guideline document underwent the formal external expert review process and was reviewed and approved by the ESVS GC. This document has been reviewed in three rounds by 25 reviewers, including vascular surgeons, interventional radiologists and medical physics experts. All reviewers approved the final version of this document.

1.3 The patient and public perspective

1.3.1 Background and aims

Patient and public perceptions of radiation safety pertaining to endovascular surgery were captured. This section was written in partnership with patients and members of the public, to ensure the patient perspective is adequately represented in these guidelines and that medical professionals are aware of these views. The individuals consulted included (i) volunteers from the joint Health Protection Research Unit Public and Community Oversight Committee (https://crth.hpru.nihr.ac.uk/wider-engagement/), from the Scottish Environment Protection Agency, and from the Society and College of Radiographers; and (ii) patients who had undergone endovascular procedures at Guy’s and St Thomas’ NHS Foundation Trust. The group was consulted about the guidelines and asked what they understood by the risks of radiation exposure. The patients’ opinion on the information that they would have liked pertaining to radiation exposure prior to their endovascular procedure was sought. We explored whether they would have found this useful despite the fact that there are many unknowns about the risks associated with low dose radiation exposures.

The following was understood by the group. First that endovascular surgery, involving the blood vessels, referred to as minimally invasive procedures (those which use only small incisions, resulting in the need for only a small number of stiches) is used to diagnose and treat problems affecting the blood vessels (vascular disease). Second that endovascular surgery requires use of ionising radiation, which is radiation of high enough energy to cause damage to cells, potentially resulting in health effects such as cancer. Diagnosis prior to surgery and surveillance commonly requires computed tomography angiography (CTA) using Xrays. It was explained that the use of ionising radiation is in most countries very tightly controlled through legislation, however, the regulations do not cover all the detailed technical aspects of the use of radiation. As such it is important that appropriate guidance is provided to ensure that use of radiation for each specific discipline is justified and safe. We explained that these ESVS guidelines have been prepared by physicians and scientists who are members of the GWC, selected by ESVS on the basis of their expertise in relevant areas of vascular surgery and radiation protection.

The aims of the Guidelines are to outline for medical professionals the key issues of relevance to protect against exposure to ionising radiation. The Guidelines are written for doctors who perform vascular procedures and all allied personnel to provide recommendations for best practice. The Guidelines cover a range of topics including how to measure radiation exposure, the evidence for radiation effects, the current legislation and how to control exposure of the medical personnel through appropriate use of the equipment in the operating room and personal protection, education and training, and the requirements for the future. The Guidelines and recommendations are based on the state of the art in terms of scientific evidence (based on the available studies), as reviewed by the committee, and regular updates are anticipated.

1.3.2 Feedback from stakeholders

The group stated that medical practitioners must have a good understanding of patient perceptions and expectations. In recent years information has become easy to come by, however, the benefits and risks of health effects associated with ionising radiation are not well understood by the non-specialist, and there is a lot of misinformation around. The majority perceived the main risk of radiation exposure to be development of cancer. Further, the real and perceived risk varies greatly depending on the source of radiation and how it is used, as well as on the basis of individual experience. It is generally accepted by the public that imaging involving radiation is an important tool, however, practitioners must ensure that the basic concepts such as what radiation is and why it is being used, as well as the value and risks of the specific procedure are clearly explained to every patient. This can be done both face to face, as part of the consent process, and by providing written literature.

Recommendation 1	**Class**	**Level**	**References**

Anecdotally, some patients reported that this has not happened. Some patients also do not feel it is appropriate to question their doctor and they may say that they understand information provided when this may not be the case. The group, therefore, stated that generic literature about the procedures should include specific mention of the radiation risks and that the medical practitioner spends time explaining possible risks to the patient to ensure mutual understanding is reached as far as is practical. The explanation should include a clear explanation to the patient who should be aware that it is acceptable to ask questions. It should also be noted that paediatric exposures are not considered here as endovascular procedures on children are very rare, however, this is something that should perhaps be further considered in future iterations of these Guidelines.

Information regarding the risks of radiation exposure must be provided in plain, easy to understand language to patients before undertaking endovascular procedures.	I	Law	EBSS (2013)[8]

The group stated that it was important for physicians to be aware that the use of ionising radiation in general is based on three principles. First, the principle of justification which requires that use of radiation should do more good than harm. Second, the principle of optimisation requires that radiation doses should be kept as low as reasonably achievable. Thirdly, the principle of dose limitation requires that the dose to individuals from planned exposure situations, other than medical exposure of patients, should not exceed the appropriate limits. In contrast to non-medical uses of ionising radiation, which are solely process based, medical uses of radiation also depend on the requirements of the individual patient. When ionising radiation is used for medical purposes, exposure of the patient is carried out on the basis of the principles of justification and optimisation. Dose limitation is not considered relevant because a dose of ionising radiation that is too low is undesirable as the images produced may not be of high enough quality to perform a procedure.

1.3.3 Responsibilities of the endovascular operator to justify and explain radiation exposure to patients

Justification of radiation exposure for each procedure ensures that the benefit the patient receives from exposure outweighs the radiation detriment and that associated risks are minimised. Justification is the legal responsibility of the registered healthcare professional (which may or may not be the vascular surgeon). The medical practitioner then takes responsibility to ensure that the patient understands the potential risks and that they understand and agree that the risks are worth taking, after weighing against the benefit of the procedure. If the procedure is justified, optimisation ensures that the procedure is carried out in the best possible way to deliver the best medical goal with the least radiation detriment.

In medical settings such as during vascular surgery, where the operator of the imaging equipment is not a radiographer or radiologist, the primary responsibility for ensuring the radiation safety of the patient lies with the medical practitioner. In endovascular surgery, ionising radiation is used only for real time imaging purposes, to allow the surgeon to ‘see’ what they are doing inside the body. As such, in practice, the vascular surgeons themselves have direct responsibility for how much radiation the patient receives as it is the vascular surgeon who directly controls when and how often imaging occurs (through use of a pedal or similar).

The doses received by patients undergoing endovascular surgery vary depending on a number of factors including the type and complexity of the procedure. There are only a small number of studies which look explicitly at the doses patients receive, and more work is clearly needed here. In general, as discussed in Chapter 2 and Appendix 2, information about the risks associated with ionising radiation exposure come from information gathered through many years of use of ionising radiation in medical and nuclear settings, as well as from experience following atomic bomb testing and radiation accidents. For the doses experienced by patients, direct “tissue reactions” such as skin burns are rare. However, such effects do occur, and the risks and severity vary on a patient by patient basis. Further research is ongoing to better understand and guard against such effects. The patients and members of the public who have contributed to this chapter suggest that future research focuses more clearly on the patient specific dose levels involved in different procedures and how these vary on a case by case basis, which will facilitate clearer discussions on risk between patients and medical professionals prior to procedures being carried out; how cumulative doses might be recorded and used within the medical profession as a whole (something which is not generally done yet), and on the doses received by the practitioners themselves to underpin appropriate protection.

Radiation exposure of the patient who receives specific limited exposure as part of treatment or diagnosis does slightly increase the average risk of late effects such as radiation induced cancer, which depends on cumulative lifetime dose, perhaps up to about 5% for a vascular surgery patient, depending on the type of procedure. However, the combined data from all studies suggests that the risk of developing cancer associated with ionising radiation is very small compared with the overall lifetime risk of all cancers, which is now about 50%. Such a risk is acceptable because it is significantly outweighed by the high risk of early death associated with not having the vascular procedure. Hence the procedure is justified. Patients thought they had very little information about radiation exposure and risks prior to their intervention and universally said they would want more despite the fact that some of the exact risks are unknown. Several felt that being empowered with information, either in the form of written information or a dedicated website, would raise their curiosity and make them want to find out more. They thought it was essential that they were counselled about the risks of radiation exposure prior to their procedure but that it was unlikely that the risks would impact their decision to undergo the procedure.

It was also noted that the current legislation and guidelines (including the present Guidelines) are based on the current state of the art in terms of scientific understanding. With further longer term studies on radiation risk currently underway, things may change in the future. The group confirmed that it is important that these Guidelines are regularly updated to reflect that.

In summary, in recent decades, ionising radiation has become an essential resource to perform more and more complex surgical procedures. In most cases, use of ionising radiation is essential to the success of the procedure and as such, the risks of exposure are clearly outweighed by the need to use radiation to save or extend the life of the patient. These Guidelines were deemed essential to continue to ensure medical processes using radiation are undertaken carefully, responsibly and appropriately. However, more work, including on the topics outlined above, is needed to better understand patient risks and allow further optimisation in the setting of endovascular surgery.

1.4 Plain language summary

Operations carried out on the blood vessels of the body are increasingly performed by techniques that use stents inserted into the blood vessel under Xray guidance. Inevitably, the Xray used is absorbed not only by the patient but also by operators and there is evidence to suggest that exposure to Xray energy has health consequences. With these guidelines strategies that will help minimise Xray exposure during these operations are outlined. The training and educational needs of colleagues are also discussed to ensure they are well informed about radiation protection measures.

Chapter 2. Measuring radiation exposure and the associated risks of exposure

2.1 Radiation exposure during Xray guided procedures

The European Directive on Basic Safety Standards for protection against the dangers arising from exposure to ionising radiation,[8] obligates Member States in the European Union to improve radiation safety for patients and workers in medical practice. Occupational exposure during Xray guided procedures is closely related to patient exposure and, therefore, both should be managed using an integrated approach.[9] Radiation doses for some complex Xray guided procedures are equivalent to several hundred chest radiographs, necessitating quality assurance programmes that include optimal radiation protection. Adequate training in radiation protection includes an awareness of the principles of working with radiation and safe exposure limits and this training should be repeated on a regular basis to ensure that it remains current. The ICRP has recognised that there is a substantial need for education and guidance in view of the increased use of radiation in endovascular procedures.[10, 11]

2.2 Dosimetric parameters

2.2.1 Direct Dose parameters:

Understanding the metrics and definitions used to evaluate the amount of radiation exposure from various sources is key to raise awareness and promote radiation safety. Gray (Gy) is used to report mean organ doses and Sievert (Sv) to report the equivalent and effective dose. These quantities are not measured directly and are estimated by computational methods. Both quantities may be used for a rough estimation of radiation risks and to compare these risks between imaging procedures.

Gray (Gy) is the unit of "absorbed dose" used to evaluate the amount of energy transferred to matter. **Absorbed dose** is the mean energy imparted to matter of mass by ionising radiation. The SI unit for absorbed dose is joule per kilogram and its special name is gray (Gy).

Sievert (Sv) is the unit used to measure two different quantities:

1. **Equivalent dose:** The mean absorbed dose in a tissue or organ multiplied by the radiation weighting factor. This weighting factor is 1 for X-rays
2. **Effective dose** is the tissue-weighted (see section 2.4.1.1) sum of the equivalent doses in all specified tissues and organs of the body

Table 3. Definitions of direct dose parameters

2.2.2 Indirect Dose parameters:

One practical approach to audit radiation exposure during Xray guided interventional procedures is to use the dosimetric information generated by the C arm. The amount of radiation generated is typically expressed as "Air Kerma" (AK), measured in mGy. AK is the quotient of the sum of the kinetic energies of all charged particles liberated by uncharged particles in a given mass of air. The position at which the cumulative air kerma is measured is known as the **patient entrance reference point**, which is located 15 cm from the isocentre in the direction of the focal spot of the Xray tube (Figure 1). This value reasonably represents the air kerma incident on the patient's skin surface.

Figure 1: Illustration of the patient entrance reference point. Xray source is underneath the table. Image intensifier (I.I) or Flat Panel Detector (FD) above the patient.

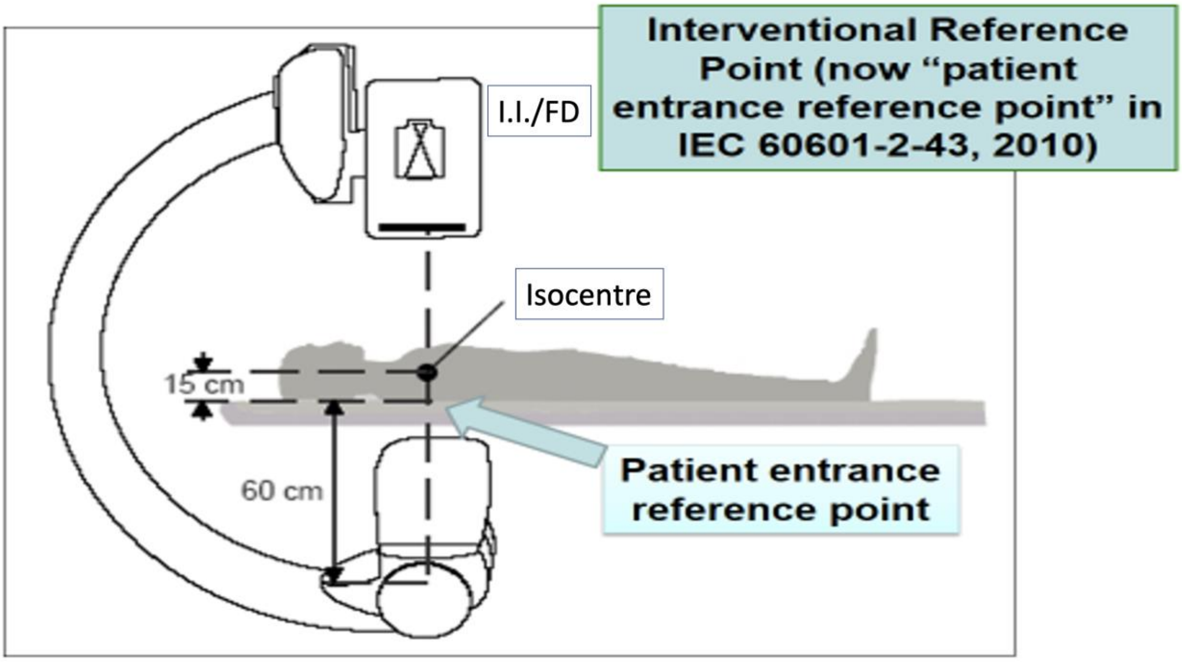


Table 4: Definitions of indirect dose parameters

Air kerma (AK) This is measured in mGy and refers to the dose delivered by the Xray beam to a volume of air and reflects the kinetic energy released in matter**.**

Air Kerma (AK) at the patient entrance reference point: The AK is measured or calculated at 15 cm from the isocentre in the direction of the focal spot cumulated from a whole Xray procedure (see figure 1), usually expressed in mGy. The selected position reasonably represents the AK incident on the adult patient's skin surface. The US Food and Drug Administration uses the term **"cumulative air kerma (CAK)"** for this parameter.

Air-kerma area product (KAP, or Dose Area product, DAP): The KAP is the product of two factors, namely the air kerma free in air (i.e., in the absence of backscatter) over the area of the Xray beam in a plane perpendicular to the beam axis (usually measured in Gy.cm^2). The ICRP now recommends referring to those values as Air-kerma area product ($\mathbf{P_{KA}}$).

The C arm can record the rate of delivery of these dose quantities, measured in $Gy.cm^2/sec$, during the procedure. Other parameters or related dosimetric quantities, usually included in dose reports produced by the C arm, are the fluoroscopy time (FT) and the number of images (typically digital subtraction angiography (DSA) images) acquired. FT is the cumulative time spent using fluoroscopy and can be used as an indirect dose indicator but its use is limited by the fact that it does not account for the C arm settings, Xray field of view, C arm position or imaging modes used (see chapter 5). Moreover, FT is calculated and displayed differently depending on the C arm and the manufacturer and correlates poorly with other dose indicators.[12-14] Even though FT can reflect the complexity of a procedure and the efficiency of the operator performing it, dose parameters such as KAP and AK are better for objectively quantifying the amount of radiation exposure and should be used preferentially.[15]

2.3 Existing literature informing radiation exposure during endovascular procedures

A literature review was conducted to identify published data on intra-operative radiation doses during endovascular procedures from Dec 2015 – July 2022 The review focused on standard endovascular aortic repair (EVAR), complex EVAR (fenestrated or branched endovascular aortic repair, F/BEVAR) and endovascular treatment of lower extremity peripheral arterial disease (LEPAD), respectively, because these are the most radiating and common procedures in vascular surgery. Deep vein recanalisation procedures were also included, as this is a rapidly developing area of activity on a population that includes young women of childbearing age who may be at particular risk with radiation exposure. The dose parameters collected were KAP ($Gy.cm^2$), CAK (mGy) and the absorbed doses to which the operators or staff were exposed. The results of this literature review are presented in Table A1 to A3 of the appendix. For the sake of clarity, graphical representations of the available KAP data and a single table are presented in this chapter.

Thirty nine EVAR studies were identified, including 3207 patients with dose reports (based on median KAP) varying by a factor of 28 (from 9.17 (6.83-14.74) to 337 (232–609) $Gy.cm^2$) (Figure 2, Appendix

Table A1). Reported radiation doses are relatively constant over time with a plateau trend over the period examined. The above lead apron exposure to the endovascular operating team was also reported in several publications and ranged from 5 to 300 µSv per procedure.

The highest doses for endovascular procedures were reported for F/BEVAR procedures (Figure 3, Appendix Table A2). Seventeen reports were identified, one was excluded because it reported a mixture of EVAR and F/BEVAR procedures. There is a clear trend toward a reduction in KAP during these complex procedures, which may be a consequence of the learning curve and a wider use of modern imaging equipment. It can also be noted that the published series present increasingly large cohorts. Several studies reported cases in whom intra-operative radiation data exceeded the thresholds (especially CAK>5Gy) that should trigger systemic initiation of dedicated patient monitoring for skin injuries. Not surprisingly, where evaluated, operators' exposures were also higher than during other endovascular procedures (from 120 to 370 µSv over the lead apron). Eleven studies, totalling more than 13 000 patients, reported dose parameters during LEPAD endovascular treatment which included crural vessel disease (Figure 4, Appendix table A3). Reported doses tended to be higher for iliac than for femoropopliteal procedures, and for cross over than for anterograde procedures. Radiation data for isolated procedures below the knee were not reported in this analysis. The current data available are limited and heterogeneous. Furthermore, the fact that the leg tissue is thin at this level means that Xrays can readily penetrate and even for long and complex procedures, the radiation dose remains relatively low compared with supra-inguinal procedures.

Only four studies (Table 5) reported radiation dosage during deep vein procedures. It is interesting to note that the dose delivered could reach up to 17.4 mSv, and a little more than one mSv at pelvic level, underlining the need for increased vigilance during these interventions mostly performed in young women.

Figure 2: Graphical representation of studies reporting air Kerma-area product (KAP, Gy.cm²) in the literature between 2015 and 2022 for endovascular aortic aneurysm exclusions (EVAR). The area of each bubble corresponds to the number of patients represented. The dotted line indicates the trend in KAP over time. It can be seen that the published radiation levels are relatively constant with a plateau trend over the period examined.

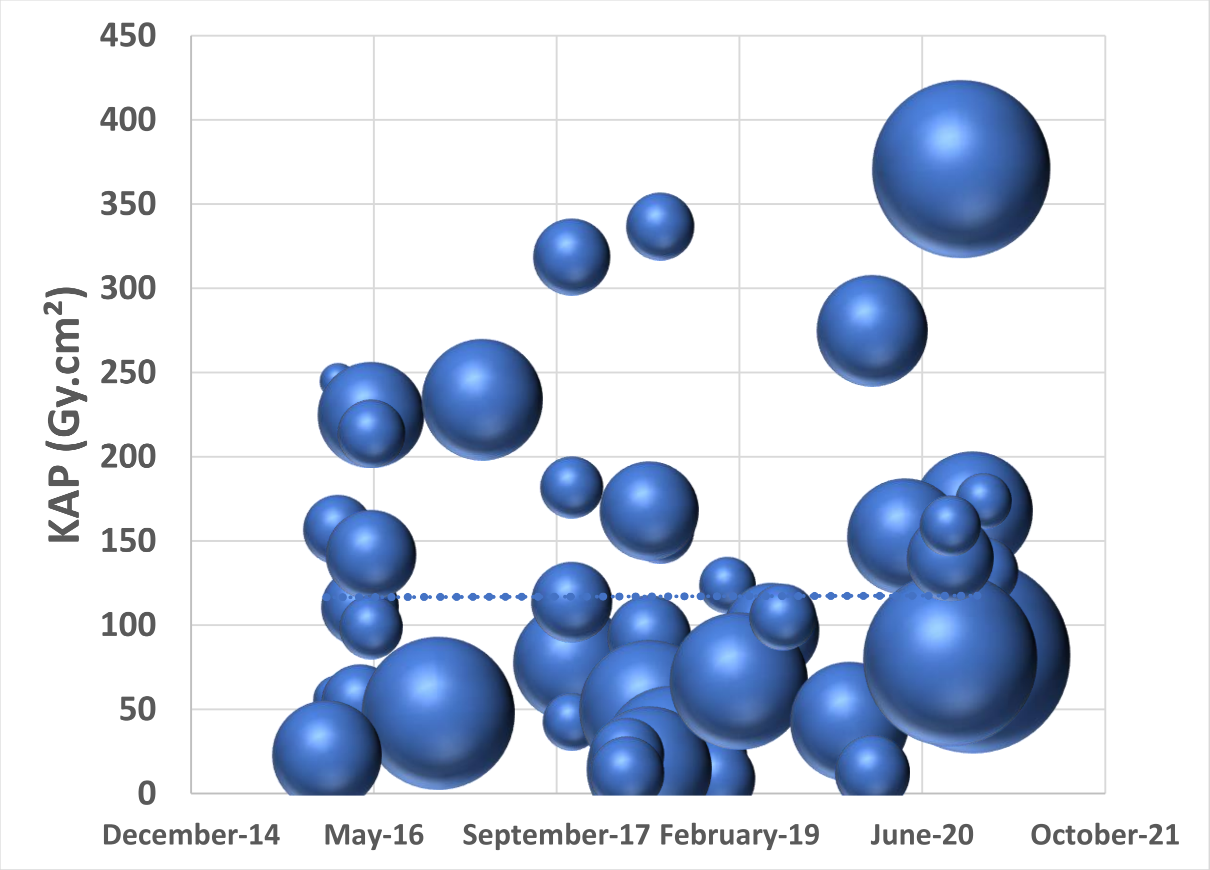


Figure 3: Graphical representation of studies reporting air Kerma-area Product (KAP, Gy.cm²) in the literature between 2015 and 2022 for fenestrated and/or branched endovascular aortic aneurysm repairs (F/BEVAR). The area of each bubble corresponds to the number of patients represented. The dotted line indicates the trend in KAP over time. There is a clear trend toward a reduction in KAP during these complex procedures, which may be a consequence of the learning curve and a wider use of modern imaging equipment. It can also be noted that the published series present increasingly large populations.

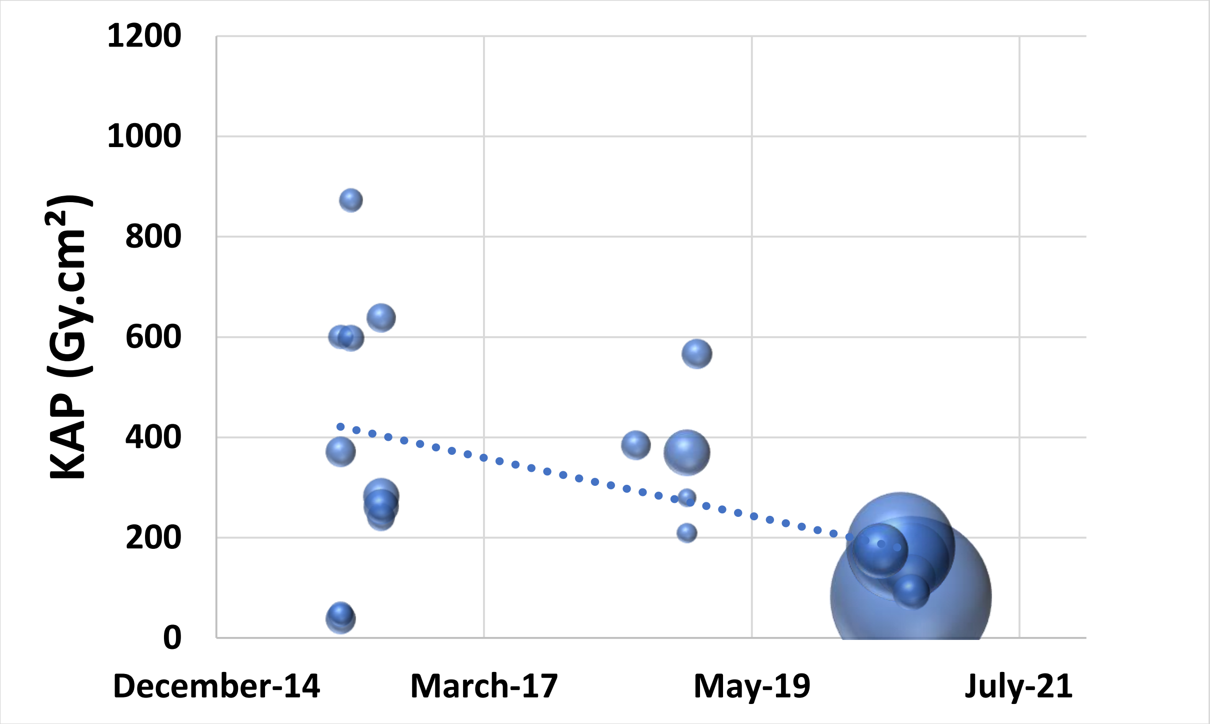


Figure 4: Graphical representation of studies reporting air Kerma-area Product (KAP, Gy.cm²) in the literature between 2015 and 2022 for lower extremity peripheral arterial disease (LEPAD) endovascular treatment. The area of each bubble corresponds to the number of patients represented. The dotted line indicates the trend in KAP over time. There is a clear trend toward a reduction in KAP during these procedures.

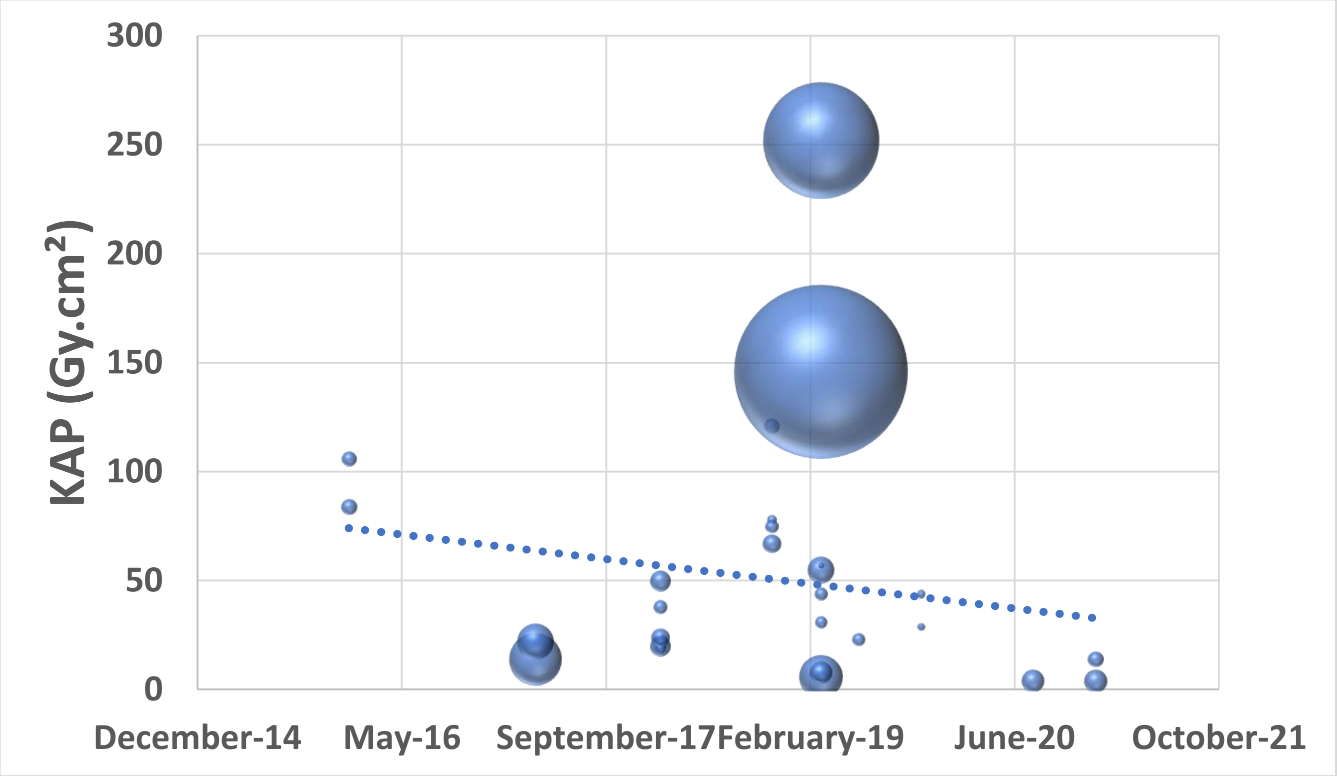


Table 5: Literature review of published dose reports after endovascular treatment of deep venous disease between 2016 and 2022. Results are reported in means with standard deviation (SD) or (*) in median with range, or interquartile range (IQR) if stated. ¤, Dose measurement above the lead protections. ALARA: As Low As reasonable Achievable; KAP: Kerma-Area Product; CAK: Cumulative Air-kerma; DVT: Deep Vein Thrombosis; IVC: Inferior Vena Cava.

Author	**Year**	**Groups**	**Imaging System**	**Number of procedures**	**DAP (Gy.cm²)**	**CAK (mGy)**	**Pelvic ESD (mSv)**	**E (mSv)**
Chait[16]	2019	Iliofemoral venous stenting	Mobile C-arm	40	-	1.08 (±0.55)	-	0.221
Barbati[17]	2019	Iliofemoral venous stenting	Mobile C-arm	78	74.6* (IQR 29.5-189.5)	393.5* (IQR 178-955)	1.06* (IQR 9.27-2.59)	17.4* (IQR 7.16-33.12)
Lim[18]	2020	DVT thrombolysis (lower extremity)	Fixed C-arm (endovascular operating room)	20	9.2* (0.2-176.0)	-	-	-
		DVT thrombolysis		91	2.0*			

		(upper extremity)			(0.1-11.7)			
		unilateral chronic iliofemoral venous stenting		56	32.4* (0.1-289.6)			
		-IVC reconstruction		39	60.8* (2.5-269.1)			
Baccellieri[19]	2021	Iliofemoral venous stenting without CBCT	Fixed C-arm (endovascular operating room)	15	24.0* (IQR 19.3–35)	69.8* (IQR 19.3–35)		
		Iliofemoral venous stenting with CBCT		10	70.5* (IQR 56.9–97.3)	244.6* (IQR 190.3–323.7)		

2.4 Diagnostic reference levels

Radiation exposures associated with endovascular procedures can vary significantly depending on the complexity of the procedure (section 2.3). The degree of variability, when the same procedure is performed by different operators and in different centres, suggests that there should be a move towards standardisation of doses for a particular procedure.[20,21]

Diagnostic Reference Levels (DRLs) are used in medical imaging with ionising radiation to indicate whether, in routine conditions, the patient dose or administered activity (amount of radioactive material) from a specified procedure, standardised to the patient's height and weight, is unusually high or low for that procedure.[22]

The ICRP recommends the use of KAP and AK as the main dosimetric quantities for setting DRLs. DRL values are usually defined as the third quartile (50th – 75th percentile) of the distribution of the median values of the appropriate DRL quantity observed at each healthcare facility.

This allows comparison of local median dose values related to a particular procedure with the recognised DRL for that procedure. Reasons for the doses being substantially higher or lower than the DRL can then be investigated. Fluoroscopy time and the number of acquired images (typically digital subtraction angiogram (DSA) images) may also be used to complement DRLs and to help in the optimisation.

In principle, a DRL could be too low i.e. below which there is insufficient radiation dose to achieve a suitable medical image or diagnostic information. This local review should include the protocols used during the clinical procedures and the equipment setting, in order to determine whether the protection has been adequately optimised. For interventional practices, it is recommended to take into account the complexity of the procedure and its impact on patient dose values. Achieving acceptable image quality or adequate diagnostic information, consistent with the medical imaging task should always be the priority. DRLs should be used to help manage the radiation dose to patients, so that the dose is commensurate with the clinical purpose. A DRL should be used for groups of patients but not be applied to individual patients or considered as a dose limit.[23, 24] It is acknowledged that there is significant variation in technique, equipment used, as well as the type and severity of disease for each patient, nevertheless, efforts to define outliers in normal practice are valuable with close involvement of medical physics experts to investigate and set DRLs.

Recommendation 2	**Class**	**Level**	**References**
Air-Kerma Area Product (KAP, Gy.cm^2) and the Cumulative Air Kerma (CAK, mGy) must be recorded for all endovascular procedures.	I	Law	NRCP report No. 168 (2010),[15] ICRP publication 135 (2017)[23]

Recommendation 3	**Class**	**Level**	**References**
Establishment of bodies that set national and regional diagnostic reference levels (DRLs) for endovascular procedures is recommended.	I	C	EBSS (2013),[8] ICRP publication 135 (2017),[23] Rial et al. (2020)[24]

Recommendation 4	**Class**	**Level**	**References**
Review of patient dose values for endovascular procedures at each centre and comparison with the national diagnostic reference levels (DRLs) is recommended.	I	C	EBSS (2013),[8] ICRP publication 135 (2017),[23] Rial et al. (2020)[24], Farah et al. (2020)[21]

2.5 Biological risk related to radiation exposure

The following section provides an overview of the biological risks of radiation exposure, with a review of literature related to the biological effects of radiation exposure.

2.5.1 Stochastic and Deterministic Effects of Radiation Exposure

The harmful effects of ionising radiation can be divided into deterministic and stochastic effects. Stochastic effects are those which occur by chance and as such the probability of them occurring, but not the severity, increases with increasing dose. There is no threshold dose. The development of malignancy is the most common stochastic effect of radiation exposure. Non-stochastic, deterministic effects, or 'tissue reactions', are related to a threshold dose of radiation exposure above which the severity of injury increases with increasing dose. Deterministic effects include harmful tissue reactions and organ dysfunction that result from radiation induced cell death. Two examples of tissue reactions that occur after radiation exposure are skin lesions and lens opacities. [25-28]

2.5.1.1 Estimators of stochastic risks

The Lifespan study, monitoring the victims of the Hiroshima and Nagasaki nuclear bombs, has shown that the incidence of solid cancers increases proportionately after high and moderate radiation exposures.[29] In the medical field, however, both patients and operators are exposed to much lower, although repeated, doses of radiation (< 100 mSv) compared with the high exposures that these bomb victims received in a single, acute manner. Reliable evidence does not exist, therefore, to inform risk associated with exposures below 100 mSv. The Biological Effects of Ionizing Radiation VII (BEIR VII) report and ICRP recommendations, however, conclude that with exposures below 100 mSv, the likelihood of stochastic effects occurring remains proportional to the amount of radiation exposure, and is not threshold dependent i.e. even the lowest exposures could represent a risk to humans.[30] This is known as the linear no threshold (LNT) model. While alternative models to LNT have been proposed which may better reflect the radiobiological complexity for certain endpoints, it should be noted that the aim here is provision of a pragmatic tool for estimation of all cancer risk, for radiation protection purposes only.[31, 32] As such, the scientific consensus remains that LNT remains the model for practical radiation protection.

Stochastic risk is determined by calculating the effective dose (E) of radiation exposure, measured in Sv, where E is the cumulative dose absorbed by organs and tissues, taking into account individual organ/tissue sensitivities to radiation. E represents the same stochastic risk as a uniform equivalent whole body dose of the same value. The most radiosensitive organs are the bone marrow, colon, lung, stomach and breast.[28, 33]

The E represents an estimation of stochastic risk in an average individual given a certain amount of radiation. The estimate is not always reliable as it requires complex calculations and mathematical modelling, for example Monte Carlo simulations.[34-36] Given the different types and amounts of radiation exposure, these stochastic risk estimates are, therefore, not recommended for routine audit purposes and are more useful for estimating theoretical risk in specific cohorts such as pregnant individuals (See section on pregnant exposed 3.3).

Estimation of risk related to radiation exposure should also take into account the age and sex of the individuals exposed. Of note is the fact that endovascular procedures are more frequently carried out in the elderly and less often in paediatric patients. Given that stochastic effects correlate with time after exposure, therefore, elderly patients are at less excess lifetime malignancy risk. For example, the lifetime attributable risk (LAR) of cancer after a coronary computed tomography CT scan in a 80 year old woman would be 0.075% (one induced cancer for 1338 scans), but would rise to 0.7% (one cancer induced for 143 examinations) for a 20 year old woman.[30] This issue is further complicated by the use of multiple scans in some patients, particularly younger patients.[37]

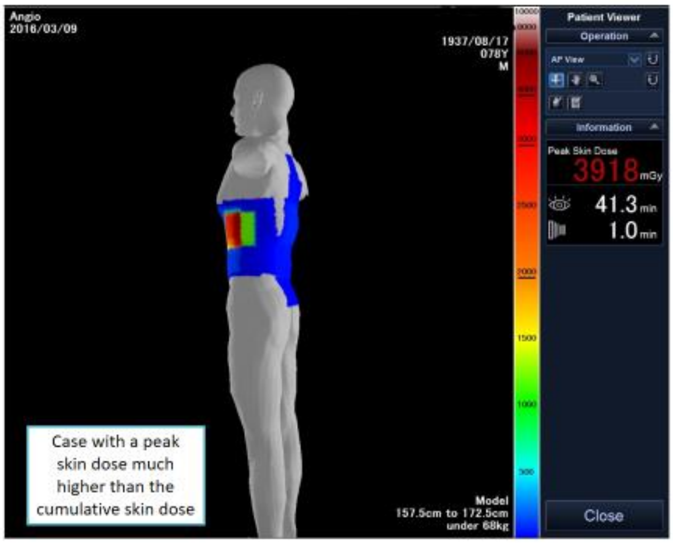
The assessment and interpretation of effective dose from medical exposures of patients also needs to consider that some organs and tissues receive only partial exposures or a very heterogeneous exposure, which is the case especially with diagnostic and interventional procedures.[23]

2.5.1.2 Estimators of deterministic risks

Entrance skin dose (ESD, in Gy) is the dose absorbed by the skin at the entrance point of the Xray beam. The Peak Skin Dose (PSD) is the dose delivered, by both the primary beam and scatter radiation, at the most irradiated area of the skin. PSD is used as a predictor for the occurrence of deterministic effects (also called tissue reactions) which are mainly radiation induced dermatitis and erythema and can occur in Xray guided procedures once the radiation exposure to the skin exceeds a given threshold dose. This risk of skin radiation injuries derived from high dose endovascular procedures are considered in some countries, as an “unintended medical exposure” and necessitate recording, analysis and declaration to the competent authority. The patient is also informed, and arrangements are made for appropriate clinical follow up.

Skin dose can be measured with either thermoluminescent dosimeters (TLDs),[38] radiochromic films,[39] or optically stimulated luminescence dosimeters (OSLD).[40] (See Chapter 4). Air Kerma (AK) at a reference point can also be used as a surrogate to assess the risk of deterministic effects, however, it is not always a good indicator for PSD as the Xray beam angulation may be modified during the procedure and the irradiated skin area may be different. Both KAP and CAK can be used to avoid skin injuries when using them as trigger values.[41]

Some state of the art fixed C arms incorporate software that displays skin dose maps and peak skin dose during procedures (Figure 5).[42-44] This can prompt proactive intra-operative measures, such as adjusting the C arm angulation, in an effort to avoid persistently irradiating the same skin area during the case. This type of dose measurement and depiction is also valuable to determine whether clinical follow up for potential skin injuries should be considered.[45, 46] Skin dose map systems should be validated by a medical physics expert (MPE) as the performance of individual systems and their quality varies.



Case with a peak skin dose much higher than the cumulative skin dose

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Figure 5: Example of a skin Dose Map software. The area on the left flank depicted in red represents a peak skin dose that is much higher than the cumulative skin dose.

Patient dose values after Xray guided procedures must be registered, allowing protocols to be implemented to decide whether clinical follow up for potential skin radiation injuries is advisable. Suggested thresholds that indicate high risk of skin injuries and should prompt closer patient follow up are:[47]

1. Peak skin dose, more than 3 Gy
2. Air Kerma at the patient entrance reference point: 5 Gy
3. Kerma-area-product: 500 Gy cm2

It is good practice to centrally store patient dose values using dose registration software and regularly evaluate these. This is an important tool for both optimisation of radiation doses as well as for training staff (See section 2.3 and 8.2.8)

2.5.2 The biological response to radiation exposure

Ionising radiation causes damage to cells either directly, by energising nucleic acids in cells, or indirectly, through interaction with the molecular environment. In either case, this results in the generation of reactive oxygen/nitrogen species, damage to the cellular deoxyribonucleic acid (DNA) structure and the activation of DNA repair mechanisms. This biological response can be detected in the blood of patients and operators who are exposed to low dose radiation. Increased levels of phosphorylated histone protein H2AX (γ-H2AX) and phosphorylated ataxia telangiectasia mutated (pATM), two proteins that are markers of DNA damage/repair, are seen in the lymphocytes of patients and operators after endovascular surgery and return to normal by 24 hours, reflecting DNA damage and repair after exposure.[6] This response to radiation varies between individuals who are exposed to similar doses, a phenomenon that reflects individual variation in sensitivity to radiation induced DNA damage. Radiation protection to the lower extremities mitigates this damage. Raised levels of ɣ-H2AX, pATM and p53 have also been detected in patients after cross sectional imaging as well as fluoroscopically guided cardiovascular procedures.[48] The analysis of cellular ɣ-H2AX foci has been used to predict that a five fold increase in the estimated lifetime attributable cancer mortality following low dose radiation exposure.[49]

2.5.3 Biomarkers of radiation exposure

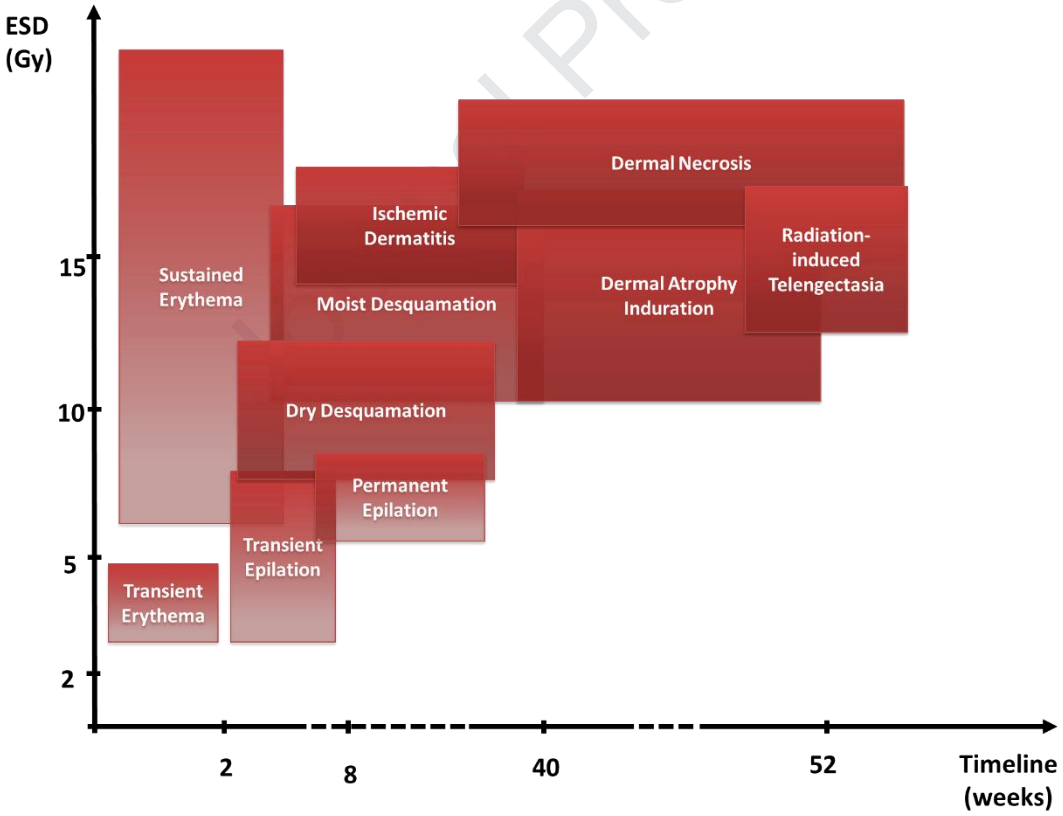
The level of expression of the DNA damage response proteins γ-H2AX and pATM in circulating lymphocytes may be used as a biomarker of radiation exposure.[6] Despite initiation of the DNA repair pathway, misrepair can occur and this can lead to chromosomal aberrations such as dicentrics and micronuclei. Micronuclei have been more frequently detected in lymphocytes isolated from hospital workers chronically exposed to low dose occupational radiation.[50] Higher dicentre frequencies have been detected in interventional cardiologists and radiologists compared with control populations not involved in fluoroscopically guided interventions.[51] Changes in gene expression have also been found in the lymphocytes of patients after CTA,[52] which has implications for those who undergo regular CT surveillance following complex EVAR. There is also increasing evidence that microRNAs (RiboNucleic Acid), non-coding RNAs that post-transcriptionally regulate gene expression, are upregulated in interventionalists following exposure to ionising radiation.[53] The cellular responses described above can be technically difficult to measure and do not lend themselves to high throughput analysis. Furthermore, there is a lack of standardisation in identification of biomarkers and none have been validated for chronic low dose radiation exposure in endovascular surgery.[54]

2.5.4 Risks associated with occupational radiation exposure to patients

Patients who undergo endovascular procedures are exposed to radiation during the index procedure and also when post-operative surveillance with CT is required. Long term follow up of the EVAR 1 trial suggested a higher incidence of malignancy in patients who had endovascular as opposed to open aortic aneurysm repair[55] but the study was not designed for this endpoint. A study similarly found a weak signal that patients have an increased risk of post-operative abdominal cancer after EVAR as opposed to open aortic aneurysm surgery but this conclusion is made less reliable because of multiple confounders.[56] In patients who have had TEVAR, cumulative radiation exposures over two years can exceed 100mSv.[57] This level of exposure is estimated to account for up to a 2.7% increase in the lifetime risk of leukaemia and solid tumour malignancies.[11]

Harmful tissue reactions such as skin injuries (Figure 6) generally occur following relatively high radiation exposures and can be seen in patients within hours to days after exposure. At peak skin doses of 2 to 5Gy, the main risk is development of transient erythema, whereas permanent epilation, ulceration and desquamation occur at higher doses. The risk of radiation induced skin injury is higher after more complex procedures that require a longer fluoroscopy time and multiple DSA acquisitions.[58] Despite the fact that the threshold of 2Gy is exceeded in up to 30% of EVAR procedures,[59] skin injuries are not commonly reported. This is also the case for more complex EVAR with higher cumulative doses.[60-62] This may be in part due to under reporting as skin injury can appear up to four weeks after exposure by which time the patient has left the hospital and longer term monitoring of the skin for evidence of damage is not widely practiced.

Figure 6: Skin changes that may appear depending on entrance skin dose (ESD) and the expected timeline for changes to develop.



2.5.5 Risks associated with occupational radiation exposure to operators

Reports to date have signalled an increased incidence of thyroid, brain, breast and melanomatous skin cancer after occupational radiation exposure in medical workers.[63-65] Non-melanomatous skin cancers, such as basal cell carcinoma, are also more prevalent after occupational radiation exposure, especially in those with lighter hair colour.[66] Positive associations between protracted low dose radiation exposure and leukaemia have also been reported.[67] Overall, medical workers exposed to repeated low dose radiation have a 20% increased risk of cancer when compared with radiation naïve practitioners.[68, 69] One study found that individuals may have up to a 45% excess cancer related mortality risk after working more than 40 years as an interventional radiologist.[70] The higher radiation exposure to the left and centre of the head compared with the right[71] and reports of a higher prevalence of left sided tumours in interventionalists suggests the possibility of a causal relationship to occupational radiation exposure[72]. There are, however, other studies that refute a causal relationship between occupational radiation exposure to the head and development of malignant brain tumours[73]. Multiple confounders, absence of studies in large long term cohorts of workers and an inadequate dose history have meant, however, that there is as yet no conclusive evidence that occupational radiation exposure leads to a higher incidence of malignancy. Better designed longitudinal studies that monitor the long term health effects of radiation exposure in endovascular operators are needed.

Until recently, radiation induced cataracts were thought to be a deterministic sequela of radiation exposures of 5 Gy per single acute exposure and 8 Gy for protracted exposures. It is now thought that lens opacification can occur at exposures lower than 2Gy and that there may, in fact, be no safe dose threshold.[74-77] In fact, the increased risk in lens opacity has been reported for doses below 0.5Gy.[78] It seems that cardiac interventionists have a three to six fold higher risk of cataracts than the general population.[79, 80]

Radiation induced cardiovascular disease is thought to occur as a result of accelerated atherosclerosis; several studies have reported an increase in the risk of cardiovascular disease in patients treated with radiotherapy.[81-84] Medical radiation workers have, similarly, been found to have a higher risk of ischaemic heart and cerebrovascular disease.[85]

Chapter 3. Legislation regarding exposure limits for radiation exposed workers

3.1 Framework for radiation safety legislation

The legal basis for protection of the public and radiation exposed workers is defined in the European Basic Safety Standards Directive (EBSS).[8] These standards are developed following detailed review of the published scientific evidence by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the ICRP and then agreed through a rigorous process of consultation with relevant bodies, industry, and individual stakeholders within the European Union member states themselves.

The EBSS describes the standards for protection against the risks associated with exposure to ionising radiation. For medically exposed populations, the EBSS particularly emphasises the need for justification of medical exposure, introduces new requirements concerning patient information and strengthens the basis for recording and reporting doses from radiological procedures. It promotes the use of DRLs (see chapter 2) and outlines optimal radiation safety pertaining to endovascular operators.[8, 86, 87] Justification and optimisation of ionising radiation for medical use are detailed chapter 5.10.

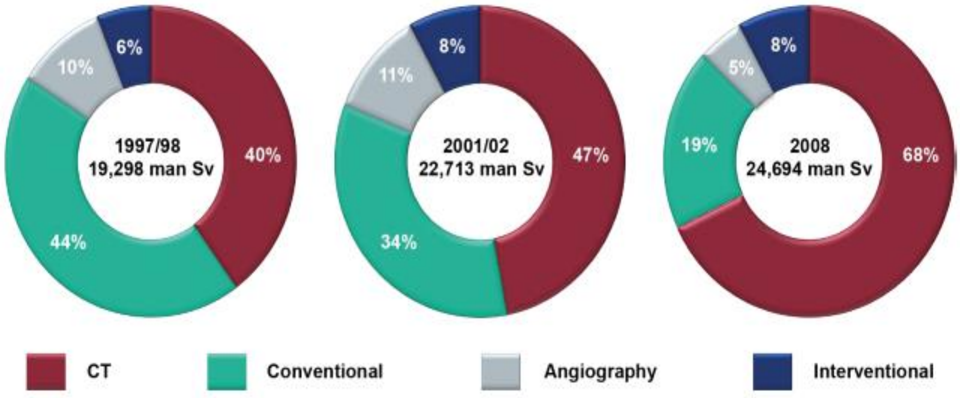
ICRP guidance, published in 2012,[28] collated the most up to date research in radiation protection and made a number of recommendations which indicated potential changes to the radiation protection regulations. The EBSS was subsequently updated in 2013 and implemented into European Law in February 2018. The updated EBSS contains a number of changes, most notably highlighting a need for increased protection of the lens of the eye with a revised exposure dose limit. Other notable new stipulations were the recommendations for use of DRLs and the need for recording of dosimetric information by imaging systems and its transfer to the examination report (see chapter 5).

Ultimately, however, the EBSS is a council directive that sets out high level regulations, devolving the responsibility for their interpretation and implementation to the member states.

3.2 Current legislation defining safe radiation exposure limits

Radiation exposed workers are defined as those over the age of 18 who may be at risk of receiving radiation doses greater than the stipulated public exposure limit of 1 mSv per year of effective dose. It is worth noting that members of the public are exposed to varying levels of natural background radiation, including terrestrial gamma radiation, cosmic rays and radionuclides such as radon. In the United Kingdom (UK) medical radiation exposure accounts for approximately 16% of the 2.7 mSv average annual exposures for members of the public (PHE https://www.phe-protectionservices.org.uk/radiationandyou/), the equivalent of approximately 0.43 mSv. The average annual medical imaging effective dose in Europe is approximately 1.1 mSv. In the United States (US), non-therapeutic doses contribute approximately 48% of the average level, but it is worth noting that between 2006 and 2016 the average individual annual medical effective dose from medical radiation has decreased from 2.92 to 2.16 mSv.[88-90] Exposures that occur as a consequence of CT imaging account for a large proportion of this medical exposure, significantly increasing in recent years (e.g. figure 7, for the UK). In the same time frame, exposure from conventional Xray has decreased.

Figure 7. UK collective dose from diagnostic Xray procedures.[91]



For occupational exposures, including for trainees and students, the effective whole body dose limit is 20 mSv/year. In addition, the equivalent dose limit for the lens of the eye is 20 mSv in a single year or 100 mSv in any five consecutive years subject to a maximum dose of 50 mSv in a single year.[8] The equivalent dose limit for the skin and extremities is 500 mSv in a year. For the skin this is averaged over any area of 1 cm^2, regardless of the total area exposed.

Depending on the probable occupational exposure risk, workers may be classified into either category "A" or category "B".[8] Category A workers are those likely to (i) exceed an effective exposure dose of 6 mSv/year; or (ii) an equivalent dose greater than 15 mSv per year to the lens of the eye; or (iii) an equivalent dose greater than 150 mSv per year to the skin and extremities. Radiation exposed workers who are not expected to exceed the limits stipulated for category A are classified as category B. Category A workers must be subject to systematic individual monitoring of dose carried out by approved radiation dosimetry service.[8] A dosimetry service refers to a nationally accredited or otherwise appointed provider of dose monitoring devices, including but not limited to dose badges, as further discussed in Chapter 4. Alternatives to monitoring by a dosimetry service, for category B workers, include estimates based on workplace surveillance or using approved calculations methods. In practice, most member states deal with this by designating category A workers as "classified". Once designated as classified, they are subject to appropriate evaluation of the magnitude of the likely exposures, optimisation of their radiation protection, education and training and medical surveillance on an annual basis.[8, 9] For category B workers some member states of the European Union (EU) may require individual monitoring but regulations vary from country to country. The advice of a MPE (or radiation protection expert) and a preliminary evaluation of the probable exposure risk is required to categorise the worker into A or B and to decide the individual's dosimetry and radiation protection strategy. Whatever framework for protection is implemented in practice, there is clear evidence that interventionists can mitigate the risks associated with ionising radiation exposures by following the established safety practices.[92]

Table 6. Radiation exposure limits set by the European Basic Safety Standards Directive.[8]

		Annual limits			
Individual	**Sub-classification**	**Whole body**	**Skin and extremities**	**Lens of the eye**	**Additional considerations/Notes**
Radiation workers	Category A workers (those potentially exposed to > 6 mSv/year effective dose or > 15 mSv/year lens dose)	20 mSv	500 mSv (for skin, averaged over any area of 1 cm^2)	20 mSv (averaged over 5 years but not exceeding 50 mSv in any single year)	Requirement for systematic monitoring based on individual measurements carried out by a dosimetry service, as described in chapter 4.3
	Category B workers (those potentially exposed to < 6 mSv effective dose or < 15 mSv lens dose), including trainees over 18				
	Pregnant workers				The foetus must be protected as a member of the public, i.e. exposure limited to 1 mSv
	Trainees aged 16-18 y	6 mSv	10 mSv	15 mSv	
Members of the general public		1 mSv			Justification for all medical exposures is a legal requirement. There is no set medical dose limit but exposures should be kept as low as possible

The European Directive on Basic Safety Standards[8] (Table 6) includes the roles and responsibilities of the "Medical Physics Expert" (MPE). The Directive indicates that the MPE should be involved in interventional radiology practices and should take responsibility for dosimetry, including the evaluation of the dose delivered to the patient. Give advice on medical radiological equipment, contribute to optimisation of radiation protection (including the use of DRLs). The MPE should also contribute to the definition and performance of quality assurance of the medical radiological equipment, the acceptance testing, the surveillance of the medical radiological installations, the analysis of events involving, or potentially involving, accidental or unintended medical exposures and the training of practitioners and other staff in relevant aspects of radiation protection.

Recommendation 5	**Class**	**Level**	**References**
All personnel who may be exposed to ionising radiation in the workplace must comply with European and National legislation	I	Law	ICRP publication 118 (2012),[28] EBSS (2013),[8] Casar et al. (2016),[87] Stahl et al. (2016),[92] ICRP publication 139 (2018),[9] Weiss et al. (2020)[93]

Recommendation 6	**Class**	**Level**	**References**
Employers must monitor compliance of radiation exposed personnel with legislation regarding radiation exposure limits	I	Law	ICRP publication 118 (2012),[28] EBSS (2013),[8] ICRP publication 139 (2018)[9]

3.3 Pregnancy and radiation exposure

Radiation exposure in the pregnant worker is worthy of special consideration to ensure adequate protection of the foetus. The National Council on Radiation Protection and Measurements (NCRP), Measurements Report on Preconception and Prenatal Radiation Exposure and ICRP document 117 provide comprehensive reviews of the health effects associated with pre-natal doses, as well as guidance on protective equipment (discussed in Chapter 6).[10, 90, 94, 95] In terms of preconception risks, there is no direct evidence that ionising radiation can cause heritable disease in the children of irradiated individuals.[96-98] Pregnant and breastfeeding workers are subject to additional limits with the unborn child subject to the same protection as members of the public. There is evidence that ionising radiation can cause genetic mutations in the foetus that are associated with disease, therefore this risk must be considered and doses to the embryo of > 0.1 Gy may be associated with deterministic risks such as congenital malformations and growth or intellectual disability.[10, 97] Foetal death is considered a risk only when exposures exceeds 2 Gy, and this is only evidenced by animal studies.[10, 90, 97] The ICRP 117 report[10] recommends that the foetal dose is kept below 1 mSv during the course of pregnancy for medical radiation workers.[8] It should be noted that the dose to the healthcare worker and the foetus is usually < 0.3mSv and < 0.1mSV, respectively.[99] Studies in operators performing endovascular procedures have found minimal exposure to the foetus.[92, 100] Radiation risks are most significant during pre-implantation and organogenesis and portions of the first trimester, somewhat less in the second trimester, and least in the third trimester.[101] More education about the need for special considerations for pregnant workers is needed as this is not well understood by staff and employers.[95] Perceptions of radiation exposure risk should be managed with a realisation that foetal dose from occupational exposure usually remains well below recommended limits and that female endovascular operators can integrate pregnancy safely into their careers.

A pregnant staff member should be able to seek a confidential consultation with the

the radiation protection expert, MPE, or equivalent to review dose history to determine if any work practice changes are required. More frequent monitoring of radiation dose is usually implemented. The practical difficulties relating to employees' willingness to declare pregnancies prior to 12 weeks gestation, seen as the time after which the pregnancy is most likely to proceed to term, must be acknowledged.[102] The ICRP is clear that discrimination on the basis of gender and potential or actual pregnancy should be avoided, and further specific guidance around ensuring the woman has sufficient radiation protection training and understanding so that she is in a position to make appropriate decisions is also given in ICRP 117.[10] The onus is on the pregnant woman to make the decision regarding when the employer is informed.

A survey of 181 female vascular surgeons found that over half of the 53 respondents became pregnant during training or practice and > 60% performed endovascular procedures whilst pregnant.[94] With implementation of a programme for declaring pregnancy, assessment of radiation doses and use of adequate protection during pregnancy, it is possible for medical staff to perform procedures and normal activities without incurring significant risks to the foetus.[103]

Recommendation 7	**Class**	**Level**	**References**
A well defined pathway must exist at each institution for pregnant employees to declare their pregnancy in order to manage subsequent occupational radiation exposures	I	Law	Dauer et al. (2015),[104] Sarkozy et al. (2017),[105] Shaw et al. (2012),[94] Bordoli et al. (2014),[95] Stahl et al. (2016),[92] Suarez et al. (2007),[102] ICRP publication 117 (2010),[10] Chu et al. (2017)[103]

Chapter 4. Measuring, monitoring and reporting occupational radiation exposure

4.1 Background and Introduction

In contrast to patients who usually have a limited number of higher dose exposures, endovascular operators are regularly exposed to low dose radiation throughout their working lifetime and recording cumulative dose absorbed by the operator is important.[9, 106-110] The two values that are usually measured by the occupational dosimeters are the "personal dose equivalent" in soft tissue at 0.07 mm below body surface denoted as Hp (0.07) and at 10 mm below body surface, Hp (10). Hp(3mm) is also available for eye lens dosimetry.

4.2. Monitoring radiation exposure during endovascular interventions

Radiation exposure varies depending on the type of endovascular procedure, with more complex procedures carrying a greater radiation burden (see chapter 2).[111, 112] Radiation exposure is also influenced by the type of C arm used. Mobile configurations and older generation equipment produce images using a higher radiation dose compared with appropriately configured, state of the art fixed imaging systems. Variations in the positioning and operating of the C arm may significantly alter radiation dose to both patients and staff. During endovascular repair of thoraco-abdominal aortic aneurysms (TAAA), a complex Xray guided procedure, the operator effective dose averaged at 0.17 mSv/case.[112] One study, measuring radiation exposure during EVAR, found a significant exposure to the temple region of the head (side of the head behind the eyes) of anaesthetists,[113] suggesting that it is important to consider exposures to the entire team and not just endovascular operators. It is recommended that dosimeters are worn by all personnel that are exposed to radiation regularly during work in the endovascular operating room, including trainees, nurses, circulating nurses, technicians and anaesthetists. Other visiting persons such as medical students and observers may wear a dosimeter if possible.[9, 33]

The NCRP and the ICRP recommend use of two dosimeters for monitoring radiation exposure, one under lead (shielded by the protective apron, worn on the front of the body, in the area of the main torso, anywhere from waist to neck) and one unshielded above the apron at collar level.[9, 33, 114, 115] The dosimeter above the apron allows estimating the lens doses, and the combination of the two readings of the dosimeters, provides the best available estimate of effective dose. By recommendation of the NCRP, dosimeter data are used to estimate the whole body exposure (E) combining Hp(10) from both, body/waist (HW) and collar/neck (HN) dosimeters: Effective dose E (estimate) = 0.5HW + 0.025HN.[115]

The aforementioned use of a dosimeter placed at collar level outside the lead apron provides an estimate of the eye lens exposure but may be supplemented by placing an additional, dedicated dosimeter to measure exposure at the eye level as some endovascular operators may receive annual eye lens doses close to the ICRP dose limit.[9, 33, 114, 116, 117]

Recommendation 8	**Class**	**Level**	**References**
Two radiation dosimeters, one shielded under the protective apron and one unshielded above the apron, must be worn by all personnel regularly exposed to radiation in the endovascular operating room.	I	Law	ICRP publication 139 (2018),[9] ICRP publication 103 (2007)[33]

Additional dosimeters can also be placed on the fingers but an awareness of the risk of sterility issues is advised. Doses for the eyes, hands and feet are generally greater on the side closest to the radiation source, owing to the position of the operator with respect to the radiation source and direction of travel of the scatter radiation.[118, 119]

Recommendation 9	Class	Level	References
Endovascular operators may consider wearing additional dosimeters: (i) at the eye level and (ii) on the finger	IIb	C	Bacchim et al. (2016),[114] Albayati et al. (2015),[120] Bordy et al. (2011),[116] European Commission Radiation Protection No. 160 (2009)[121]

4.3 Personal radiation exposure monitoring devices

The use of personal radiation monitoring devices and the periodic evaluation of personal dosimetry data promote safer occupational practices.[122, 123] Regulatory dosimeters are used in radiation safety programs to measure the average monthly occupational radiation dose equivalence to which personnel in the endovascular operating room are exposed. Different personal dosimeters may be used, including passive thermoluminescent dosimeters (TLDs) and active personal dosimeters (APDs). Personal TLD dosimeters are usually processed on a monthly basis and cannot provide real time dose and dose rate information during the procedure. The APDs, however, do provide immediate and continual measurement of radiation exposure that can be visible to the staff member during the procedure. This type of feedback may allow correction of behaviours that result in increased exposure, thereby reducing the cumulative personal radiation dose during the procedure (see chapter 5).[124, 125]

A thermoluminescent dosimeter (TLD) is a commonly used personal radiation dosimeter consisting of a piece of a thermoluminescent crystalline material inside a radiolucent package.[106] When a thermoluminescent crystal is exposed to ionising radiation, it absorbs and partially traps energy of the radiation in its crystal lattice. When heated, the crystal releases the trapped energy in the form of visible light, the intensity of which is proportional to the intensity of the ionising radiation the crystal was exposed to. A specialised detector measures the intensity of the emitted light, and this measurement is used to calculate the approximate dose of ionising radiation the crystal was exposed to. TLDs have high sensitivity and allow doses lower than 1 mGy and higher than 1 Gy to be accurately measured.[126]

Optically stimulated luminescence (OSL) dosimetry is another well established method of reporting individual doses.[127] These passive dosimeters work similarly to TLD dosimeters but much faster with a better or at least the same efficiency; but in addition, provide repeated readouts unlike TLD, which is a device that is processed once and is disposable. OSL has also emerged as a practical real time dosimeter for in vivo measurements and may become the first choice for point dose measurements in clinical applications.

Real time dosimeters, also called active personal dosimeters (APD), measure and record radiation exposure in real time and using a wireless connection continuously display the amount of personal exposure.[128, 129] Besides displaying real time information these systems can optionally emit an acoustic or optical warning when certain real time radiation dose limits are exceeded. The use of this type of dosimetry is increasing and has been shown to reduce radiation exposure to personnel during endovascular procedures.[129-132] The accuracy of some APD is questionable, advise from an MPE is thus required when using such devices.

Recommendation 10	Class	Level	References
Real time dosimetry should be considered by all personnel in the endovascular operating room in addition to personal dosimetry.	IIa	C	Müller et al. (2014),[132] Chida et al. (2016),[128] Inaba et al. (2018)[129]

4.4 Monitoring and reporting occupational radiation doses

Dose recordings are usually evaluated by an independent service and not by the institution employing the medical professional. All dose measurements should be performed by an ISO 17025 standard accredited dosimetry service expert in determining equivalent dose estimation to reliably ensure compliance with dose limits.[133]

Records of occupational exposure should include information on the nature of the work, exposure inclusive of all employments, outcomes of health surveillance, education and training on radiological protection (including refresher courses), results of exposure monitoring, dose assessments and results of any investigations of abnormal exposure values. Employers must provide staff with access to records of their own occupational exposure.[9]

Education, training and feedback related to radiation dosimetry should be strengthened. Institutions must have a dedicated Medical Physics Expert (MPE) and Radiation Protection Officer (RPO) to manage distribution of dosimeters to staff and monitoring of individual staff exposures.[134, 135]

Recommendation 11	**Class**	**Level**	**References**
Vascular services should pre-emptively identify personnel who can establish regular pre-determined feedback mechanisms with staff to inform them of personal radiation doses and proactively manage any irregularities to support continuous improvements.	I	C	ICRP publication 139 (2018),[9] Sailer et al. (2017),[134] Borrego et al. (2020)[135]

4.5 Inaccuracy and uncertainty associated with personal dosimetry

It must be acknowledged that a failure to wear dosimeters for every procedure, placing the dosimeter in an inappropriate location on the body and leaving the dosimeter in an environment where it is exposed to radiation can lead to unreliable cumulative exposure dose values being recorded. Formulas designed to derive occupational exposures routinely overestimate the actual effective dose.[136]

Chapter 5. Radiation safety practice in the endovascular operating room

5.1 The "As Low As Reasonably Achievable" (ALARA) principle

The benefits that ionising radiation brings to society, not least to medical science, must be balanced against the stochastic and deterministic risks of health effects (see Chapters 2 and 3). In order to do this, International Commission on Radiation Protection promotes the use of three key principals: justification, optimisation and dose limits. For medical uses of ionising radiation, the justification, that use of radiation must do more good than harm, must always be clear. For patients at least, dose limits are generally not applicable, as the benefits of the use of ionising radiation clearly outweigh the small increased risks and such limits would do more harm than good. For endovascular operators, however, dose limits must be respected.

The key concept in medical radiation protection is thus optimisation, for which is defined the 'ALARA' principle: doses to operators and patients must be 'as low as reasonably achievable'.[33, 137-142]

In common with all occupational users of ionising radiation, endovascular operators must protect their patients, trainees, the entire team and themselves from the potentially harmful effects of radiation.[143] Radiation safety begins with developing good habits involving radiation use and protection. Once the basic principles of radiation safety are understood, implementation into daily routines provides a safe working environment for all healthcare providers, personnel and patients involved with the use of radiation. As for all decisions in medicine, the use of Xrays is based on a balance between benefits and risks. The ALARA principle is thus an excellent reference in order to facilitate this.

ALARA protects both the patient and operator. This principle implies that i) a procedure should be performed only if the expected benefits are superior to the potential risks induced by an exposure to Xrays, ii) During the procedure, the lowest radiation doses should be used while maintaining a sufficient image quality to perform the case safely. The justification for use of ionising radiation should in every case be balanced against the small but non-zero risk of potential adverse health effects, as outlined in Chapter 2, and it is the responsibility of the endovascular operator and indeed every member of staff involved in treatment planning to ensure the appropriate justification applies and that the patient is given appropriate information regarding the radiation risk.

An informed discussion should always be undertaken with the patient, with special care taken to outline the risks and benefits when the procedure involves any of the following:

(i) Paediatric or young patients with anticipated exposure to radiosensitive organs such as eye, breasts, gonads and thyroid gland. Not only are children more sensitive to the effects of radiation than adults but, following radiation exposure, children have a longer post-exposure life expectancy in which to exhibit adverse radiation effects.[144]

(ii) Patients weighing either less than 10 kg or greater than 125 kg

(iii) Pregnant individuals

(iv) Procedures anticipated to result in prolonged radiation exposure due to technical difficulty

(v) Repeated exposure to same body region within 60 days

The three components of practice which contribute to ALARA are **time, distance and shielding**. Minimising the time of radiation exposure is important. Maximising the distance between the body and the radiation source will reduce exposure. Lastly, use of radiation absorbent material, including personal protection equipment, is a key component (Chapter 6.2). The practical aspects of endovascular practice which contribute to ALARA are listed in table 7.

Table 7: Aspects of practice which contribute to the "as low as reasonably achievable" (ALARA) principle are a function of three main components: 1. the number of images produced 2. the dose required to produce each image and 3. strategies to avoid unnecessary exposure

1. Limit the Number of Produced Images	**2. Limit the Dose Required to Produce Images**
Use low dose imaging protocols	Use collimation
Use pulse mode fluoroscopy	Limit C arm angulation
Limit fluoroscopy pulse rate	Optimise detector, generator, and table positions
Limit fluoroscopy time	Use imaging system auto-exposure settings
Use advanced imaging techniques (e.g. Image fusion)	Limit use of digital subtraction angiography (DSA)
Allow operator control of imaging	Avoid magnification or use digital magnification
Use DSA algorithms that limit frame rate and the number of images acquired	Use anti-scatter grid removal when appropriate
	Pre-procedural planning

3. Avoid Unnecessary Exposure

1. Use Long Sheaths to maximise operator distance from radiation source
2. Maintain distance from source throughout procedure and exit room during high exposures
3. Use shielding and protective garments

Recommendation 12	**Class**	**Level**	**References**
The As Low As Reasonably Achievable (ALARA) principles must be adhered to by all personnel in the endovascular operating room.	I	Law	ICRP publication 103 (2007),[33] ICRP publication 105 (2007),[137] Hertault et al. (2015),[138] Resch et al. (2016),[139] Maurel et al. (2017),[140] Stangenberg et al. (2018),[141] Doyen et al. (2020)[142]

5.2 Minimising radiation emitted by the C arm

An understanding of basic C arm functions and the operator's interaction with the machine and surrounding environment is essential for reducing the dose of radiation emitted. Advances in imaging hardware and software have also helped to further reduce exposure. Several imaging modes may be used for Xray guided procedures that affect the amount of radiation used, including modes related to fluoroscopy, DSA and cone beam computed tomography (CBCT). CBCT refers to a modality, available in modern endovascular operating rooms, that allows cross sectional imaging whilst the patient remains on the operating table. Similar to standard CT data, the dataset of images can be processed on a 3 Dimensional (3D) workstation and represented in multiplanar reconstructions (MPR), 3D reconstructions or maximum and minimum intensity projection type reconstruction. The patient radiation dose per image (and the image quality) may be very different depending on the settings of the Xray system and the pre-defined protocols.

5.3 Low Dose Settings

5.3.1 Fluoroscopy Time and Last Image Hold

One of the most important factors in radiation exposure to both patient and staff is 'pedal time': the time the operator has their foot on the pedal that initiates exposure to obtain images.[145, 146] Fluoroscopy should only be used when information is required such as observing objects in motion,[147] including the use of short taps of 'spot' fluoroscopy when removing wires and catheters and inflating/deflating balloons[145, 147, 148] and disengaging the pedal as soon as data acquisition is completed.[138] Fluoroscopic loop recordings can also be used to review dynamic processes,[147] even replacing DSA in some cases. 'Last image hold' is a dose reduction feature available on almost all fluoroscopic units to allow interventionists to contemplate images during procedures without the need for ongoing exposure and is a mandatory feature by the United States Food and Drug Administration (FDA). When Xray exposure is halted the average of the last few frames of fluoroscopy can be displayed as a ‘frozen’ image for viewing.[145, 149-152] It is important to appreciate that different C arms record total fluoroscopy time differently. Some systems record the total number of seconds the pedal is activated (total pedal time), and others use the more accurate accumulation of fluoroscopy pulses (total FT).

5.3.2 Dose Settings & Automatic Brightness Control

The amount of radiation produced by the C arm is dependent on the energy required to generate the Xray beam.[148] This in turn is determined by the milliamperage (mA) and peak kilovolts (kVp) applied across the tube.[148, 150, 151] The mA and kVp settings control the number of photons produced and image contrast (see appendix 1). The image quality is improved by increasing mA but at the cost of increased radiation.[148]

Modern C arms use Automatic Brightness (or Exposure) Control (ABC or AEC) algorithms that optimise image quality by automatically adjusting radiation dose according to feedback from a photodiode within the image intensifier.[138, 148, 153] If this photodiode detects low image quality, the ABC automatically increases Xray exposure to improve this, increasing the radiation dose without the operator always being aware. It is therefore important to be alert in the following situations where ABC will significantly increase dose: (i) obese patients, (ii) field containing extraneous radiodense material such as body parts outside of the area of interest or metallic objects such as anti-scatter drapes, and (iii) steep gantry angles.

Fluoroscope radiation output is determined by the energy used to generate the beam which is a product of the number of photons produced (mA) and their penetrance (kVp).[148] In addition to the basic mA and kVp settings, modern C arms offer additional low dose settings to reduce radiation dose.[139] The default settings on most modern machines are usually low dose or extra low dose,[154] but settings can be chosen to further reduce exposure while not necessarily impacting image quality, such as combining an increased kVp with corresponding lower mA.[112, 148, 150] It may be valuable to seek help from the manufacturer of C arm equipment to achieve the desired image quality per procedure type at the lowest settings. Increasing the kVp from 75 to 96kVp in this way, with a corresponding reduction in mA, can decrease entrance dose by 50%,[148] with the routine use of half dose settings significantly reducing skin dose with only minor reduction in image quality.[155] This reduction in patient doses is not always involving a similar reduction in the occupational doses for operators.[156] These exposure reductions can be achieved without negatively impacting procedural tasks.[155, 157, 158] It is important for the responsible person (endovascular operator, radiographer or MPE) to note that dose setting terminology often differs amongst manufacturers.[147]

5.3.3 Fluoroscopy and Pulse Rate

Fluoroscopy can be emitted in either a continuous manner, or in short pulsed bursts.[111, 143, 159] Continuous fluoroscopy can yield blurred images due to patient and equipment movement whereas pulsed fluoroscopy reduces blurring by counteracting movements, with the additional benefit reducing radiation exposure.[150]

Pulsed fluoroscopy is the default mode in modern C arms[111, 145, 160] with pulse rates typically available at 30, 15, 7.5, 4 and 2 pulses per second. Due to early analogue fluoroscopy initially being developed at 30 frames per second, continuous fluoroscopy was produced at 30 pulses per second. The human eye and the brain’s visual reception system can only analyse up to 12 images per second, any more than this are interpreted as an illusion of visual continuity,[161] therefore reducing pulse rates from 30 to 15 or 7.5 pulses/second decreases fluoroscopy dose by 47% and 72% respectively[150, 162] without significantly impacting image quality. The lowest pulse rate that produces an adequate image should be chosen, with studies demonstrating that complex FEVAR can be performed adequately with as low as 3 pulses/second.[111, 112, 138, 150, 152, 162, 163]

Recommendation 13	Class	Level	References
The use of pulsed rather than continuous fluoroscopy at the lowest pulse rate possible (7.5 pulses per second or less) that produces an adequate diagnostic image is recommended for endovascular procedures.	I	C	Rolls et al. (2016),[163] Panuccio et al. (2011),[112] Pitton et al. (2012),[152] Ketteler et al. (2011),[150] Hertault et al. (2015),[138] Monastiriotis et al. (2015),[111] Miller et al. (2002)[162]

5.3.4 Digital Subtraction Angiography and Frame Rate

Digital Subtraction Angiography (DSA) describes the acquisition of multiple images in succession within one field of view, with the subsequent digital subtracting of non-vascular structures, such as bone, leaving a contrast enhanced image of the vessels. The cost of these multiple high quality images is a substantial increase in radiation dose compared with fluoroscopy,[138, 164] a fact that seems to be generally underappreciated.[165] The contribution of DSA to total radiation dose during peripheral arterial and cardiac interventions has been shown to range between 70% and 90%,[152, 166] and accounts for 50 - 80% of the radiation dose during TEVAR and EVAR, even when low frame rates of 2/sec were selected.[165, 167] DSA frame rate describes the number of images recorded per second, distinct to fluoroscopy pulse rate which describes the number of bursts of radiation the fluoroscope emits per second. Compared with fluoroscopy, DSA is associated with at least 10 fold higher dose rate per frame,[164] contributing to 66% of the radiation dose while only accounting for 23% of total exposure time.[168] The patient entrance dose for one fluoroscopy image may be 10-30 µGy, 100-300 µGy for one fluoroscopy loop and 1000-3000 µGy (or more) for one DSA image. For operators, DSA leads to an eight fold higher radiation dose than fluoroscopy.[152]

If DSA runs are essential, the associated dose can be minimised by (i) reducing the number of pictures acquired per second (frame rate); (ii) minimising time per run; and (iii) limiting the number of acquisitions.[147] Reducing the frame rate will reduce dose in the same way as reducing pulse rate during fluoroscopy,[112, 147, 152, 165] with number of frames correlating highly with total radiation dose.[152] Reducing frame rates to 7.5 fps from a continuous mode, for example, results in a 90% reduction in image numbers, with an equivalent reduction in radiation dose.[138] Adequate images can be obtained even with frame rates of 2 frames per second (fps) for pelvic and upper leg interventions and 1 fps for lower leg and foot interventions.[152] It should be noted that CO_2 angiography often needs higher frame rates (4-6 fps) to obtain adequate images and may be associated with higher radiation doses.[169, 170] Some systems allow a Variable Frame Rate setting which reduces the frame rate once adequate vessel opacification has occurred and this may help further reduce radiation usage.

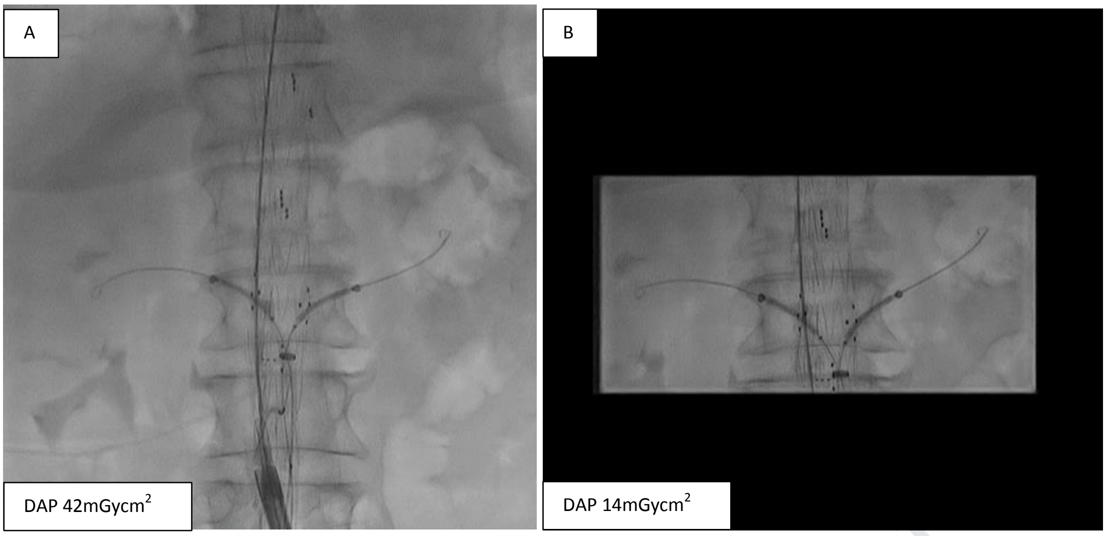
One of the most effective techniques for reducing radiation dose during endovascular procedures is to limit DSA acquisitions to key scenes and critical steps during the procedure.[152] If high quality imaging is not essential then fluoroscopy loops can often replace DSA.[111, 138, 151, 152, 160, 165, 171, 172] The endovascular operator needs to determine the lowest quality image that still maintains safety by allowing effective diagnosis, and treatment at all times during the procedure.[150] Modern C arms reduce the need for repeated DSA by allowing overlay roadmap of a DSA for target cannulation and the ability to return the table to the exact position and overlay a fade of a previous DSA.[152] Some C arms also allow this to be done using fluoroscopy, avoiding the extra radiation required for DSA to perform this function.

Recommendation 14	Class	Level	References*
It is recommended that use of Digital subtraction angiography (DSA) be limited to critical steps during endovascular procedures, and that it is carried out with the shortest time per run, lowest frame rate and least number of acquisitions possible to acquire an adequate image.	I	B	Pitton et al. (2012),[152] Ketteler et al. (2011),[150] Hertault et al. (2015),[138] Haqqani et al. (2013)[171] *Physics principle

5.4 Collimation

Collimation uses metallic apertures within the Xray source to modify the beam and minimise the radiation field size to the required area of interest.[172] By shaping the beam and absorbing photons, collimation not only produces sharper images by hardening the beam, but also reduces radiation exposure (Figure 8) to the patient and medical personnel in proportion to the reduced image size, with a consequent reduction in scatter.[62, 112, 138, 145, 150, 152, 173]

Figure 8: Collimation results in a significant radiation dose reduction from a DAP of 42mGycm^2 without collimation (A) to 14Gycm^2 with collimation (B) for an equivalent screening time.



During cardiac procedures, for example, the use of collimation reduces patient and staff radiation by 40%,[174] and meticulously collimating on a modern C arm can reduce KAP by a factor of more than 10.[175] Performing horizontal and vertical collimation significantly reduces scatter independent of each other with a 5cm collimation of each reducing scatter radiation to the operator, assistant and anaesthetist by 86%, 80% and 96% for horizontal collimation and 88%, 89% and 92% for vertical collimation respectively.[176] However, collimation reduces scatter at the cost of increased patient skin entrance dose in some cases.[176] By focusing the radiation field to a smaller area on the patient, a larger volume of the patient's tissues is available to attenuate scatter before exiting the patient and reaching staff.[176] For this reason highly collimated studies should not be performed for prolonged periods of time in one gantry position. Collimation blades can be virtually projected onto the monitor eliminating the need for fluoroscopy to adjust collimation leaf position.[138, 147] Even when a full field is required the collimator blade edges should be seen just visible on the monitor edges to ensure radiation protection extends outside of the image receptor view.[172]

Recommendation 15	**Class**	**Level**	**References***
Active use of collimation, even for full field images is recommended for endovascular procedures.	I	B	Ketteler et al. (2011),[150] Pitton et al. (2012),[152] Haqqani et al. (2012)[176] *Physics principle

5.5 Anti-scatter Grid Removal

Detectors are equipped with anti-scatter grids whose role is to filter the Xray beam from scattered radiations before it reaches the captor. This decreases the background noise and therefore improves image quality. However, those grids are responsible for some attenuation which implies that the energy carried by the Xray beam will be higher. In cases where the scatter radiation is minimal i.e. when the thickness of tissue to cross is low with minimal scatters, as typically occurs in children, arteriovenous fistulae and below knee lesions, removal of the anti-scatter grid can be considered to decrease the overall radiation use.[177] Familiarity with imaging equipment and availability of personnel to help determine when anti-scatter grid removal is advisable can help reduce overall radiation use.

Recommendation 16	**Class**	**Level**	**References**
Anti-scatter grid removal during endovascular procedures should be considered when scatter radiation is minimal.	IIa	C	Gould et al. (2017)[177]

5.6 Dose Reduction Hardware and Software

5.6.1 Advanced Dose Reduction Hardware & Software

The operator must be cognisant of the fact that the excellent quality images achieved with modern C arms can come at the cost of increased radiation dose. This has prompted imaging equipment vendors to focus on methods to reduce radiation dose whilst maintaining imaging quality.[178] All vendors have developed their own proprietary approach combining advances in hardware and software. These dose reduction technologies include (i) machine controls (smaller focal spots, shorter pulses, lower tube current and additional beam filtration), (ii) image processing algorithms (automatic pixel shifting, temporal averaging of consecutive imaging, spatial noise reduction, motion compensation and image enhancement) and (iii) hardware configurations to reduce entrance dose (optimising acquisition chain for different anatomical regions).[141, 159] Studies comparing upgraded systems to previous iterations have reported halving of radiation use associated with EVAR, 70% reduction in lower extremity interventions, and almost 40% reduction with embolisation.[141, 159, 179-181]

5.6.2 Pre-Operative Planning Software

Implementation and review of pre-procedural planning software from axial imaging diagnostic studies can be extremely beneficial in enhancing procedural workflow and reduction of ionising radiation use. Performing pre-operative case planning on CT imaging post-processing software on 3D workstations prior to interventions is essential to limit unnecessary diagnostic runs.[138, 182] Identifying the most appropriate angles for optimal viewing for each step of the procedure, as well as saving appropriate images for reference during the procedure reduces radiation exposure.[138] Profiling of the iliac bifurcation and the proximal aortic landing zone during EVAR, for example, often requires significant gantry angulation (e.g. 20 - 30 degrees of lateral angulation for iliacs and 5 - 15 degrees cranial angulation for the neck).[183] Repeated DSA runs carried out in these positions to determine the optimal angle contributes to the highest radiation doses and operator scatter exposure during

EVAR.[184] One study using vendor specific post-processing software resulted in the elimination of unnecessary diagnostic runs with a three fold reduction in mean DAP during EVAR.[184] Other studies using open source software to predict C arm angles pre-operatively have demonstrated a reduction in operating time by one third.[185, 186]

Recommendation 17	Class	Level	References
Detailed pre-operative procedural planning, including the use of a 3D workstation is recommended to reduce radiation exposure in endovascular procedures.	I	C	Stansfield et al. (2016),[182] Hertault et al. (2015)[138]

5.6.3 3D-Image Fusion Software

3D image fusion (3D-IF) describes the combination of pre-operative CTA images with live fluoroscopy, producing a three dimensional volume rendered angiogram which can be used as a virtual roadmap during interventions, particularly useful during complex EVAR.[187] Bony landmarks are co-registered on both the pre-operative and live images and the resultant fused 3D model automatically follows the table and gantry movements.[138] This negates the need for repeated DSA and fluoroscopy to position the table and gantry for target vessel cannulation and during subsequent stent deployment. This consequently reduces procedure time, contrast use and radiation exposure.[165, 188, 189] Studies utilising 3D-IF report up to 70% reduction in radiation during standard EVAR and complex aortic repair interventions.[138, 163, 190-193]

Co-registration of the images at the beginning of the case, however, does add additional radiation with systems requiring a full or partial cone beam CT (CBCT) spin adding approximately 5% of the total radiation dose of the procedure.[187] Replacing CBCT with two orthogonal anteroposterior (AP) and lateral fluoroscopic acquisitions reduces this additional dose by ten fold.[163, 194, 195] Another limitation of 3D-IF is inaccuracy of overlay, particularly following vessel deformation caused by the passage of stiff wires and devices, which renders the overlaid pre-op images inaccurate.[196] More sophisticated registration systems have been developed precluding the requirement for a pre-op co-registration Xray,[196] or used cloud based technologies for more accurate overlay with a consequential reduction in radiation exposure, FT and procedural time.[197] Cutting edge advances in 3D-IF use cloud based artificial intelligence (AI) to correct vessel deformation in real time. No randomised controlled trials have been designed to solely study the impact of fusion imaging. A comparative analysis of patients treated with and without fusion in the same environment demonstrated a trend towards lower DAP in the fusion group.[193] In a meta-analysis of the various studies reporting exposures during after EVAR, fusion was identified as an independent predictor of dose reduction.[198] Guidance with fusion imaging is also being used increasingly for endovascular intervention in LEPAD and evidence for a benefit during these procedures is emerging.[199]

Recommendation 18	**Class**	**Level**	**References**
Image fusion should be considered during aortic endovascular procedures to reduce radiation exposure	IIa	B	de Ruiter et al. (2016),[198] Ahmad et al. (2018)[193]

5.6.4 Detectors and image intensifiers

5.6.4.1 Image Intensifiers and Flat Panel Detectors

Detectors register Xrays that have passed through the patient from the Xray tube and an image intensifier (II) then converts these photons into light that can be viewed as an Xray image. Traditional analogue image intensifiers have now been largely replaced with digital flat panel detectors (FPD) which offer better imaging performance. Flat panel detectors have a much higher sensitivity to Xrays, a high signal to noise ratio, wide dynamic range, limited geometric distortion, absence of veiling glare or vignetting, high uniformity across the field of view, advanced image processing, and improved manoeuvrability due to their smaller size.[200-202]

5.6.4.2 Optimal use of Flat Panel Detectors to minimise Radiation Dose

With improved Detective Quantum Efficiency (DQE) converting Xrays into visible images, FPDs theoretically provide an opportunity to reduce the radiation dose required to obtain images[202, 203] but this may not be the case in practice. Numerous contradictory studies, using both patients and phantom models have resulted in uncertainty as to whether transitioning from traditional image intensifiers to FPD is associated with a radiation dose saving.[200, 201, 204] Whilst some reports suggest that patient dose could be reduced by up to 50%,[203, 205] others have noted that reduced entrance doses do not automatically lead to reduced operator radiation doses in clinical practice, measured by DAP.[200] Several studies have reported significantly higher DAP associated with FPDs, up to three times higher, compared with traditional IIs.[204, 206, 207] Suggested reasons for higher doses are that frame rate settings are typically higher with FDPs than for IIs,[208] and the additional sensitivity to noise can lead to vendors increasing dose settings to ensure that images are of sufficient quality to satisfy operators.[203] Another factor complicating direct comparisons are that FPDs are often part of more modern angiographic units that incorporate dose reduction strategies, which means the independent effect of the FDP component on dose is more difficult to ascertain.[209]

FPDs must be optimally configured, and the detector entrance dose rate in relation to the clinical detection task optimised, in order to minimise radiation dose.[201] In a direct comparison of 11 FPD systems to 9 II systems, failure to use low dose settings available on the emitter system was thought to negate the superiority of FDPs and resulted in comparable radiation doses between the two systems.[210] Several authors have stressed the importance of specialist assistance from application engineers in correctly setting up protocols in order to fully use low dose modes and achieve radiation dose savings when using FPDs.[201, 211] The configuration, optimisation and calibration of settings include fluoroscopy pulse rate, detector entrance dose, tube voltage, filtration, frame rates and post-processing imaging parameters, and these all need to be balanced against adequate image quality for clinical use.[200, 201, 210] Due to their increased DQE low dose or extra low dose modes should routinely be chosen over normal modes, as these are associated with a large radiation saving whilst maintaining excellent imaging quality.[195, 203] Reducing detector entrance dose from one setting to the next lowest setting doesn't dramatically change the image quality, but has the potential to reduce radiation dose by 15%. [206]

Recommendation 19	Class	Level	References
Flat panel detectors should be considered in preference to image intensifiers in an effort to improve imaging quality and reduce radiation exposure	IIa	C	Livingstone et al. (2015),[195] Bokou et al. (2008),[201] Suzuki et al. (2005)[209]

5.7 Magnification

5.7.1 Conventional Magnification

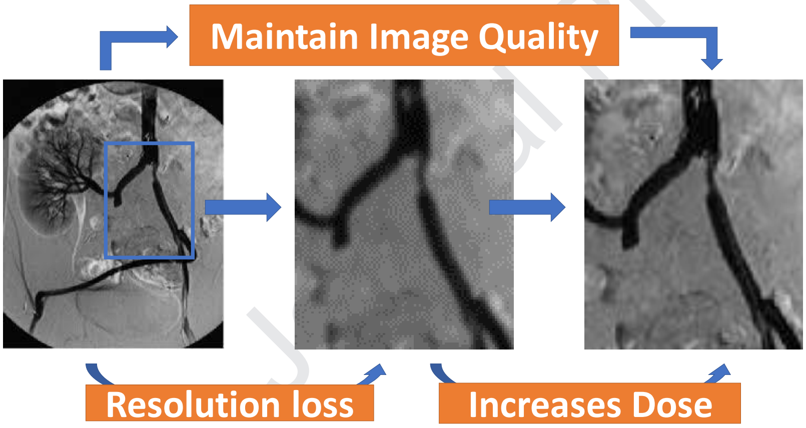
Detectors are available in a range of sizes, referred to as input Field Of View (FOV). Using the largest FOV available results in the lowest output spatial resolution and highest image distortion, but with the lowest radiation dose. This relationship is system specific. Irradiating a smaller area of the detector gives the effect of magnifying the image. If the FOV is halved, the spatial resolution is doubled thereby improving visibility.[212] The area irradiated is proportional to the square of the FOV, therefore, only a quarter of the input detector is irradiated, reducing the image brightness to a quarter of the original FOV, making it too dark to view if all other parameters are kept constant. [212] In this scenario the machine's ABC quadruples the radiation to compensate and deliver a bright usable image (Figure 9).[213] In general, the smaller the FOV, the greater the magnification, and the higher the patient dose. [212] In order to avoid irradiating non-visualised areas during magnification, collimation is applied automatically, or must be set manually. This increases entrance skin dose but reduces scatter to the operating team, therefore, a smaller FOV (increased magnification) increases CAK but decreases DAP.[7] Endovascular Operators are therefore advised to use the largest FOV as possible with judicious use of magnification.[146, 148, 151]

5.7.2 Digital Zoom

An alternative method of achieving image magnification whilst avoiding the increased radiation dose associated with conventional magnification is to instead acquire images using digital magnification (also known as digital zoom). When combined with large monitors this can produce a similar effect.[138, 147] These monitors are typically greater than 1.5m in diagonal dimension. Some C arms offer 'Live Zoom' where the image is digitally enlarged in real time, with up to 2.5 fold saving in radiation dose compared with conventional zoom.[214] It has been estimated that the use of digital zoom can reduce dose by up to 30% compared with changing FOV.[215] A recent study demonstrated that use of digital zoom during coronary procedures was not inferior to conventional zoom in a blinded test for visibility, and furthermore was associated with a saving in radiation dose of approximately 30%, with reductions in both RAK and DAP.[214]

Recommendation 20	Class	Level	References
Digital zoom, rather than conventional magnification, and appropriately sized monitors are recommended for the reduction of radiation dose during endovascular procedures	I	C	Hertault et al. (2015),[138] Machan et al. (2018)[147]

Figure 9: Impact of magnification on image quality and radiation exposure. Magnification results in resolution loss. In order to maintain image quality an increase in dose exposure is required.



5.8 Dose reports from modern Xray machines

Modern Xray systems are able to give detailed information on the radiation dose associated with fluoroscopy, DSA and CBCT. This information is very useful for optimising radiation protection as it allows endovascular operators to determine how much radiation exposure occurs during each of the three aforementioned manoeuvres in order to alter their behaviour accordingly. In fact, most modern Xray systems now report live values of air-kerma area product (KAP) and cumulative air kerma (CAK) as well as cumulative values at the end of the case. This circumvents the need to analyse the Digital Imaging and Communications in Medicine (DICOM) dose structured reports that contains the full details of dose per radiation event and has traditionally been used to obtain these data. All dose monitoring data should be recorded at institutional level.

Recommendation 21	**Class**	**Level**	**References**
Real time dose information must be provided by the C arm to optimise radiation protection during endovascular procedures	I	**Law**	EBSS (2013)[8]

5.9 Maintenance

Radiation systems must be included in ongoing quality assurance (QA) programmes to ensure they are maintained in prime working condition, remain efficient and are regularly calibrated, to ensure that high quality images are obtained using the lowest possible doses, and dosimeter readings remain accurate.[138, 164] A ten point check list designed to improve medical radiation safety culture in the UK includes evidence of appropriate management of radiation equipment and radioactive materials.[216] This includes documented evidence of management systems, equipment replacement programmes, service and maintenance contracts, QA, action on QA results, and audit of RAM policy and procedures. The responsibilities lie with the imaging facility institution through their medical physicist, and are facilitated by the C arm vendor, although legislation in this area varies between countries.

Recommendation 22	**Class**	**Level**	**References**
Maintenance and assessment of ionising radiation equipment must be performed regularly for quality and safety.	I	Law	Hirshfeld et al. (2018),’ [164] Hertault et al. (2015),[138] Chapple et al. (2016)[216]

5.10 Endovascular operating rooms: Hybrid suites & interventional platforms

5.10.1 Mobile C arms

Compared with modern fixed systems, mobile C arms generally produce inferior imaging quality, are prone to overheating and, importantly, can increase exposure to the operator due to a lack of table and ceiling mounted shields **(refer chapter 6)**.[141, 198, 217-220] In addition, they are associated with inferior ergonomics. Mobile C arms generate less radiation during EVAR compared with hybrid suites[24, 198, 221] leading to suggestions that for standard EVAR mobile C arms are of sufficient quality to perform the task, with some studies reporting similar fluoroscopy times and outcomes for EVAR performed with a mobile C arms compared with fixed systems.[222, 223] In addition mobile C arms are cheaper and more compact than fixed systems. The counter argument, however, would question the safety of performing complex or prolonged procedures with inferior imaging capabilities and increased operator dose, whilst foregoing the additional efficiencies and safety features that fixed imaging systems and hybrid suites afford, such as increased heat capacity, precise C arm movements, sophisticated overlay reference imaging and the ability to perform CBCT immediately following stent implantation.[221, 222]

5.10.2 Fixed C arms and hybrid suites

Endovascular surgery, defined as endovascular procedures typically performed by vascular surgeons in an operating room environment, has evolved from relatively simple procedures performed in traditional operating rooms using mobile C arms, to more complex procedures in dedicated facilities with fixed C arms. A Hybrid Operating Room is an advanced procedural space that combines a traditional operating room with an interventional suite that incorporates a fixed C arm along with a fluoroscopy capable surgical bed. These Xray machines are more powerful, operating at higher energies with larger beam sizes and detectors which can emit a 3 - 10 fold higher procedural radiation dose compared with mobile C arms.[141, 224] Similar reductions have been reported during EVAR and TEVAR when moving from a mobile C arm to fixed systems.[57, 225] In a systematic review to identify studies reporting dose data during EVAR and complex abdominal aortic endovascular repair (F/BEVAR), the lowest DAP levels were identified in modern hybrid rooms with fixed systems.[226] Fixed systems facilitate installation of ceiling and bed mounted lead shielding that in turn protects the operator from radiation exposure.[227] Operators must, however, ensure that they use the lowest image quality feasible as the highest quality images produced by fixed systems are not always necessary and will increase radiation dosage associated with procedure.[220, 223, 224] It is important to be familiar with and have the situational awareness to continuously employ all the radiation reducing capabilities that a hybrid suite has to offer, in order to offset the increased exposure that accompanies superior imaging.

Recommendation 23	**Class**	**Level**	**References**
An endovascular operating room with a fixed imaging system should be considered in preference to a mobile system for endovascular procedures to improve imaging quality and reduce radiation exposure.	IIa	C	Hertault et al. (2020),[226] Rehman et al. (2019),[225] McAnelly et al. (2017),[228] Zoli et al. (2012)[57]

5.10.3 Operator Controlled Imaging Parameters

Endovascular therapists working in a hybrid suite can use tableside operator controlled imaging. This ownership of control may reduce unnecessary exposures by avoiding misunderstanding between the operator and another individual tasked with operating the C arm who may misinterpret instructions by the former.[219] Discrepancies in language, ambiguous words and misinterpretations of commands to move the C arm into a specific position can all lead to unnecessary radiation exposures.[229] Just one study comparing radiographer controlled with operator controlled imaging during EVAR has concluded that median DAP is 30% lower when the operator is in control of the pedal.[230] Further data are, however, required to determine whether operator controlled fluoroscopy can reduce radiation exposure to the operator and patient. In the absence of operator control, clear and unambiguous communication between operator and individual operating the C arm can significantly reduce the time taken to move the C arm and unnecessary radiation exposure.[231]

Recommendation 24	**Class**	**Level**	**References**
Operator controlled imaging should be considered in preference to tasking another individual, for example radiographer or radiation technologist, with imaging control to reduce radiation exposure during endovascular procedures	IIa	C	Peach et al. (2012)[230]

5.11 Positioning around the patient

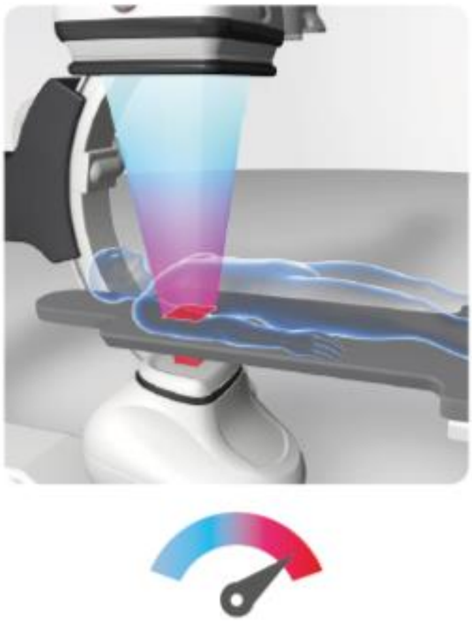
5.11.1 Imaging Chain Geometry

Imaging chain geometry describes the linear arrangement between (i) the Xray source and the patient and (ii) the patient and the detector (Figure 10). These distances have a profound independent effect on radiation scatter. The distance between the Xray source and the patient is set by the table height, with the Xray machine's position under the patient, ensuring maximum scatter occurs under the table away from the operator's head and trunk.[147] Although maximising table height from the Xray source will reduce the patient's dose,[147, 151, 160] this occurs at the cost of significantly increasing scatter to the operator's head, eyes and neck.[151, 176] The table position needs to be a reasonable distance from the detector, whilst ensuring also that the operator's chest and head is as far away from the patient as possible, as the patient's body is the main source of radiation scatter.[138] Maximum scatter occurs approximately 1.5m from the floor, this being of particular importance for endovascular therapists of short stature whose upper body are more exposed, making protection measures such as 'stepping back' during DSA vitally important.[150] In these situations, appropriate standing stools may be required to reduce exposure.

The second component of imaging chain geometry is the distance from the patient to the detector, which should be minimal.[147, 160] Added distance causes dispersion of the Xray beam and a consequential reduction in signal reaching the detector, with a compensatory dose increase initiated by the machine's automatic brightness control.[138, 145] Reducing the patient to detector distance has several benefits: (i) reduces the energy required to produce the image, thereby reducing scatter (ii) increases scatter absorption by the detector itself and (iii) produces a sharper image.[148, 176]

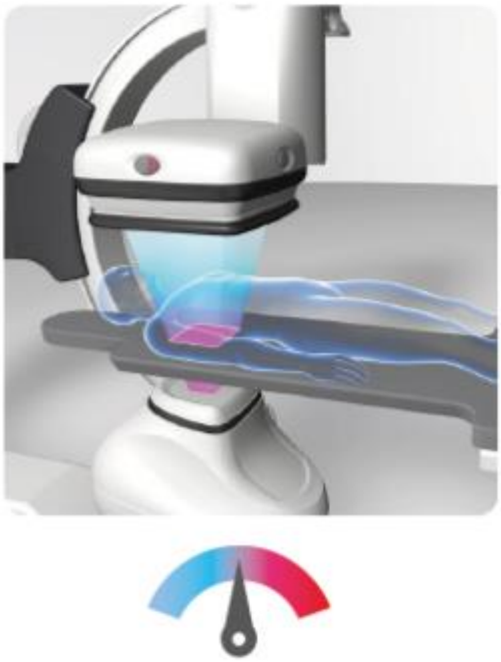
Figure 10: Effect of the relative positions of the detector to table on radiation dose measured by Air Kerma. Whilst the low detector / high table position is best for skin dose, the highest table position will actually lead to increased scatter to the operator's head and chest, and therefore isn't necessarily the optimal position for the operator. A balance needs to exist between patient skin exposures and operator exposure. When different positioning results in equal Air Karma levels, the optimal position which reduces the operator exposure is typically selected. The optimal position (low detector/high table) is highlighted in green frame (**).

High Detector / **Low** Table

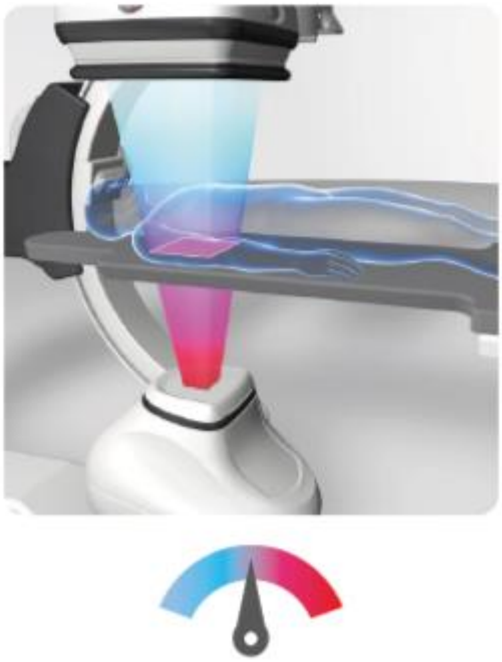


Low Detector / **High** Table

Low Detector / **Low** Table



High Detector / **High** Table



Recommendation 25	**Class**	**Level**	**References***
Positioning the patient as close as possible to the detector is recommended during endovascular procedures to improve imaging quality and reduce radiation exposure.	I	B	Durán et al. (2013),[147] Haqqani et al. (2013)[171] *Physics principle

***

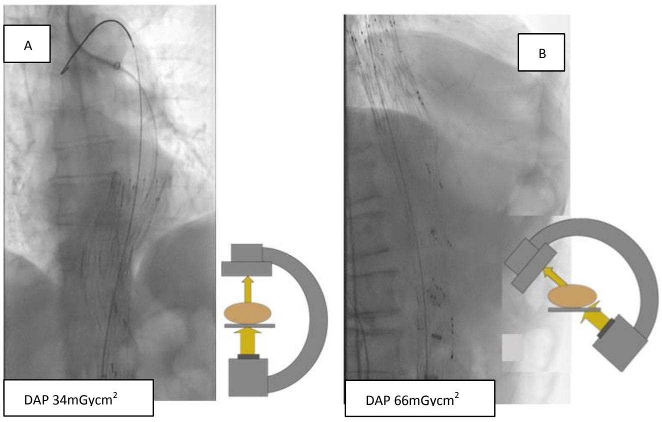
5.11.2 Gantry Angulation

Good imaging chain geometry is complemented by appreciation of the negative influence of angled C arm or gantry positions on radiation dose. Steep C arm angulations (lateral, cranial and caudal) increase radiation dose for several reasons: (i) steeper angles require the Xray machine to emit higher amounts of radiation to achieve the tissue penetration required to produce the same quality image i.e. there is an increase in the thickness of tissue crossed by the beam (ii) this in turn creates more scatter towards the upper body of the operator, increasing exponentially with lateral angulation over 30 degrees and cranial angulation exceeding 15 degrees,[138] reaching a maximum at full lateral projection;[165] and (iii) steeper angles place the Xray source closer to the patient increasing skin dose and deterministic injury risk, one study reporting 83% of all radiation skin injuries occurring with steep angulation.[111, 139, 145, 150, 171] It is advisable that whenever possible, the operators should maintain maximum distance from the radiation source.

On a phantom model, AP projections resulted in 5mSv/hr operator exposure increasing to 11mSv/hr at a 45 degree projection, and 69mSv/hr at 90 degrees.[171] Steep angulation such as that required during complex aortic repairs result in significantly higher scatter to the operator, particularly at head level,[120] with operator radiation exposure being six times higher if they are on the same side as the Xray source (Figure 11).[62] Cranial left anterior oblique projections cause the most exposure[6, 120, 147, 160, 165, 232] because the radiation source is usually on the same side as the operator in this configuration leading to maximum backscatter towards the operator.[165, 176] If possible, the Xray beam should always be positioned on the opposite side from the endovascular operator.

In prolonged cases, frequent alterations in gantry angulation have been recommended in order to reduce skin dose,[112, 146, 233] but steep cranial and lateral angles should never be used for this purpose.[233] In obese patients steep angulation compounds the risks and should be used very sparingly.[26, 145] When steep angulation is essential, it should be used for the shortest period of time with adequate collimation applied.[138]

Figure 11. Angulation of the gantry from AP position (A) to oblique (B) results in almost doubling of radiation dose, measured by DAP, from 34 Gycm^2 to 66 Gycm^2 for an equivalent screening time.



Recommendation 26	**Class**	**Level**	**References**[*]
Prolonged use of steep gantry angulation is not recommended during endovascular procedures.	III	B	Durán et al (2013),[147] Haqqani et al. (2013)[171] [*]Physics principle

5.11.3 The Inverse Square Law and Stepping Away

Scatter radiation comprises the main source of radiation exposure to staff, and by minimising patient dose, scatter consequently is reduced. However further steps can be taken to reduce exposure to scatter, the most fundamental is to observe the inverse square law ($X = 1/d^2$, X = exposure, d = distance). As scatter exits and moves away from the patient there is an exponential reduction in the number of photons per unit area, and hence potentially harmful ionising energy. Doubling the distance from the patient quarters exposure and tripling distance reduces it nine fold. This simple but highly effective act of stepping away from the patient during DSA can considerably reduce personal radiation dose and is a cornerstone technique to lower exposure.[7, 145, 147, 165, 173, 176] If there is no need to be in close proximity to the Xray source or patient, particularly during high dose acquisitions (DSA runs), then staff should step away as far away as is practical or even exit the room.[165] Indeed it has been suggested that this should be mandatory behaviour if it does not compromise the safety of the patient. A relatively safe distance is considered to be 1 - 2 m,[7] and at 5 m operator dose is effectively eliminated.[166] Whenever possible, personnel should aim to increase their distance from the radiation source because even moving away by a small distance can have a substantial effect on the amount of exposure. Standing closer to the feet of the patient rather than the abdomen during pelvic interventions has also been shown to be beneficial.[172]

5.11.4 Positioning around the Table

The highest intensity of scatter is located on the Xray beam entrance side of the patient,[147] usually under the table or in left anterior oblique (LAO) projections with the operator standing on the right of the patient. Generally, doses are much higher for primary operators compared with assistants and scrub nurses.[114, 165] During complex aortic repairs the principal operator can receive twice the dose of the first assistant standing next to them.[5] The person standing at the opposite side of the table, typically the second assistant standing at the patient's left groin or arm, will receive the next highest dose. The third assistant and scrub nurse position receives undetectable levels for most cases. Linked to gantry position, the variable radiation dose received at different table positions is due to an asymmetric scatter cloud created by interaction of scatter with the complex infrastructure of an angiographic table. Rather than scatter decreasing in predictable concentric circles according to the inverse square law, which governs radiation behaviour in a vacuum, non-conforming patterns of scatter are created around the table.[176] Lateral projections were associated with seven times higher exposure than 45 degree projections, with maximum exposure at the operator and assistant positions if on the same side as the emitter.[171] Whilst this should in no way derogate the advice to step away whenever possible, it emphasises the need to move personnel away from the patient when standing on the emitter side of the table during DSA runs, as this is where the highest radiation doses are observed. It is vital to also convey this message to anaesthetic colleagues who are often at the head of the table and close to the source and may even receive significantly higher radiation doses than the primary operator.[7]

The importance of replacing hand injections with remote contrast injectors to reduce interventionists' radiation exposure during Xray guided procedures was highlighted some 40 years ago.[234-236] For most endovascular procedures the working distance from the arterial access site (most commonly the femoral artery) to the area of interest is fixed.[148] For operators who routinely hand inject DSA runs, this accounts for 75% of their total radiation exposure,[166] and 90% of their hand and eye exposure.[236] However this distance can be extended using both power injectors for DSA runs, and extension tubing attached to catheters or sheaths for manual injections,[148, 237] allowing operators to use the inverse square law to reduce exposure. The use of power injectors is recommended where feasible,[7, 147] and has been associated with a 50% reduction in operator radiation dose,[238] but must be activated at a distance to gain this benefit.

Recommendation 27	**Class**	**Level**	**References***
The use of power injectors for digital subtraction angiography (DSA) is recommended whenever feasible to reduce radiation exposure to the operator during endovascular procedures.	**I**	**B**	Oi (1982),[234] Goss et al. (1989),[235] Santen et al. (1975),[236] Durán et al. (2013),[147] Mohapatra et al. (2013),[7] Larsen et al. (2012)[238] *Physics principle
Recommendation 28	**Class**	**Level**	**References***
The distance from the patient to the operator and all other staff should be maximised whenever possible during endovascular procedures.	I	B	Durán et al. (2013),[147] Haqqani et al. (2013),[171] Mohapatra et al. (2013),[7] Kirkwood et al. (2015),[5] Larsen et al. (2012),[238] Patel et al. (2013),[165] Bacchim et al. (2016)[114] *Physics principle

Chapter 6. Radiation protection equipment in the endovascular operating room

6.1 Introduction

The majority of studies investigating the effectiveness of radiation shields focus on procedures performed by cardiologists. These studies are, nevertheless, relevant also for the vascular surgical setting as most involve femoral access with requirements for both abdominal and chest screening. Numerous studies have also used phantoms to simulate radiation exposure.

Passive shields can be divided in personal protective devices and shields positioned between the personnel and the patient (source of scatter). The passive shields are complementary to each other and to other measures in reducing radiation. Operator refers to the main operator and assistants refers to the rest of the scrubbed personnel.

There are three types of radiation shielding material.

The first and most well known radiation shielding material is standard lead. Manufactured with 100% lead, standard lead Xray aprons are the heaviest Xray aprons available. The weight of the apron will increase depending on the level and areas of protection required, and standard lead Xray aprons are well suited for shorter procedures.

The second radiation shielding material is a lead based composite; lead composite Xray aprons use a mixture of lead and other light weight radiation attenuating metals, reducing the weight by up to 25% compared with standard lead aprons. The third option is the total lead free apron (LFA) made of a blend of attenuating heavy metals other than lead (Pb), which is a lightweight (40% lighter than standard lead aprons) and non-toxic alternative to the traditional lead apron.

Non-Lead or Lead free Xray aprons are manufactured from a proprietary blend of attenuating heavy metals, including barium, aluminium, tin, bismuth, tungsten and titanium.

Radiation safety is multidisciplinary, with a key player in achieving a safe environment being the medical physicist.[239]

6.2 Personal protection devices

6.2.1 Wearable aprons

Lead aprons effectively lower the radiation exposure by > 90% to the operator and as such are adopted as standard safety practice in the endovascular operating room.[240] A lead apron with 0.35 mm lead thickness equivalence should be sufficient for most Xray guided procedures. For workload involving high radiation exposures (Category A workers, see Chapter 3) a wrap around lead apron with 0.25 mm lead equivalence that overlaps on the front and provides 0.25 + 0.25 = 0.5 mm lead equivalence on the front and 0.25 mm on the back is ideal.[241, 242]

The apron fit is important, especially in the axillary area under the arms since large gaps could introduce an increased exposure to breast tissue, which is relevant in female staff.[15] Breast cancer prevalence was reportedly higher among female orthopaedic surgeons compared with U.S. women.[243] The most common breast cancer site, the upper outer quadrant, may not be adequately shielded from intra-operative radiation, especially in a C arm lateral projection.[244, 245] Adding lead sleeves, wings, and/or axillary supplements at the top of the lead apron may overcome this problem and should be considered in female operators (Figure 12).[245]

Figure 12: Operator wearing additional axillary lead protection

The additional weight of the apron places staff at a risk of developing back problems.[246] Back pain was reported by 50 - 75% of interventional physicians compare with 27% in a general adult population in the United States.[247] A two piece lead garment may shift some of the weight from the shoulders to the hips. Newer generation protective aprons are made from lead composite or lead free materials resulting in a significant weight reduction while, allegedly, maintaining protection that is equivalent to that provided by lead garments.

It is not necessary to use additional lead aprons for the pregnant operator and in fact this is most likely counter productive due to the physical weight. Some facilities will have a maternity apron available which may be more comfortable, particularly towards the latter stages of pregnancy.

The apron lead equivalence requires validation before use.[248] Although several studies have shown the safety of lead free aprons[249-251] other studies of both lead containing and non-lead composite aprons have demonstrated wide variations in attenuation of scatter radiation and that they often provide significantly less radiation protection than manufacturer stated lead equivalence, even in the absence of significant defects in the apron when scanned.[252-256] In one report some lightweight aprons demonstrated significant tears along the seams, leaving large gaps in protection.[253]

Aprons should be quality checked annually for any defects to ensure that no cracks in the radio protective layer are forming that will allow radiation through to the wearer. This includes visual and tactile inspections for tears, kinks and irregularities, and an evaluation of the extent of damage to the internal radiation shields via fluoroscopy, under the guidance of a medical physicist.[257] Aprons must be handled carefully, never be folded or creased, and stored safely on purpose designed lead apron racks to ensure that the integrity of the shielding material remains intact. Cleaning is done with a damp cloth using only cold water and mild detergent.[258-260]

A recent paper reported a 63% incidence of free lead on the surface of lead aprons and this was associated with the visual appearance of the apron, type of shield, and storage method.[261] Lead exposure from free surface lead represents a potentially serious and previously unknown occupational safety issue. Further studies of this risk are warranted.

Recommendation 29	**Class**	**Level**	**References**[*]
All personnel in the endovascular operating room are recommended to always wear a well fitting protective apron with at least 0.35 mm of lead thickness equivalence	I	B	Badawy et al. (2016),[240] NRCP report No. 168 (2010)[15] [*] Physics principle
Recommendation 30			
The use of axillary supplements and or sleeves	IIa	C	Van Nortwick et al. (2021),[245]

to improve protection of the breast should be considered for female operators	🟧	🟦	Valone et al. (2016)[244]
Recommendation 31			
Protective shielding and personal protection equipment are recommended to be checked for lead equivalence and integrity by a medical physicist, before being used for the first time and then on an annual basis	I	B	Oyar et al. (2012),[259] Burns et al. (2017),[261] Finnerty et al. (2005),[252] Fakhoury et al. (2019),[253] Lu et al. (2019)[254] *Physics principle

6.2.2 Thyroid Collar

The thyroid is a radiosensitive organ and has been linked to an increased risk of carcinogenesis from external ionising radiation.[262] However, these results are limited by the age range in these studies, with limited risk seen after exposure beyond the age of 20 years. Nevertheless, the thyroid of the operator will receive significant scattered radiation if unprotected. A thyroid collar also provides protection for other neck organs, such as the thymus and the carotids, although the value of this is not clear. Consequently, a thyroid collar should always be worn and attention should be paid to minimising any gaps between the thyroid shield and the lead apron.[9, 15] Thyroid collars should also be quality checked annually.

Recommendation 32	**Class**	**Level**	**References**

All personnel in the endovascular operating room are recommended to always wear thyroid collars	I	C	Ron et al. (1995),[262] NRCP report No. 168 (2010),[15] ICRP publication 139 (2018)[9]

6.2.3 Leg shields

A recent study demonstrated DNA damage to the operators performing EVAR procedures which was abrogated by leg shielding.[6] Although the under table protective drapes should attenuate scatter reaching the lower extremities of the operator that are not shielded by the standard lead apron in most situations, additional protection with leg or tibial shields should be considered in high dose environments. Measurements of leg doses have been found to be as high as 2.6 mSv per procedure in interventional radiologists when shielding is not used.[263]

Recommendation 33	**Class**	**Level**	**References**
Endovascular operators should consider using leg shields in addition to table mounted skirts	IIa	C	El-Sayed et al. (2017),[6] Whitby et al. (2003)[263]

6.2.4 Glasses and visors

The main effect of ionising radiation on the eyes is the onset of posterior cortical and subcapsular cataracts, radiation induced cataract (RIC). Recent studies suggest that RIC shares some common mechanisms with carcinogenesis and may form stochastically, without a threshold and at low radiation doses.[264-268]

The endovascular operator can potentially receive annual eye doses above 20 mSv/year and there are several retrospective studies of operators carrying out Xray guided procedures having a higher prevalence of lens changes that may be attributable to ionising radiation exposure. While most of these changes are subclinical, they are important due to the potential to progress to clinical symptoms, highlighting the importance of minimizing staff radiation exposure.[79, 80, 269, 270] Consequently, the need for protective measures for the eyes is evident.

There are several protective eyewear with transparent lead glass screen available; eyeglasses with or without individualised prescription glasses, fit over glasses with space for personal eyeglasses under, and visor. Typical lead equivalent thickness of radiation protective eyewear is 0.75mm. Theoretically this would result in > 90% attenuation. However, the actual lens dose is higher due to exposure from the side, below, and backscatter from head.

Although use of lead eyewear efficiently reduces scatter radiation to the operator's eyes in daily practice,[271] the protection with different eyewear is far from perfect and varies substantially depending not only on the eyewear and its fitting to the face but also with the variation of radiation geometry depending on the imaging projections used. To be effective, glasses should have a good tight fit, as any gaps can significantly affect its protective ability. Scattered radiation penetrates from the side and glasses with side shields should be considered preferentially.[272]

Secondarily scattered radiation from the operator’s head contributes significantly to ocular exposure. Optimal radiation protection of the eyes during Xray guidance thus depends not only on eyeglasses with leaded glass, but also on shielding of sufficient size and shape to reduce exposure to the surrounding head.[273] Thus, to achieve an adequate protection of the eyes use of a ceiling mounted shield is vital and personal protective eyewear should only be seen as complementary.

Although there are no data showing a clinical protective effect of lead eyewear, in the form of a reduced frequency of RIC, there is enough indirect evidence to support a strong recommendation that all operators in the endovascular operating room should wear them at all times and in combination with ceiling mounted shields. (See 6.3.2 Recommendation 32).

The risk of RIC in non-operators has not been studied and given the inverse square law the risk should be considerably lower in the non-operating individuals in the endovascular operating room. Although it cannot be ruled out that non-operators may also benefit from lead glasses, this group is not included in the recommendation at this time.

Recommendation 34	**Class**	**Level**	**References**[*]
Endovascular operators are recommended to always wear appropriately fitted lead glasses with at least 0.75 mm of lead equivalence during endovascular procedures	I	B	Karatassakis et al. (2018),[80] Matsubara et al. (2020),[269] Elmaraezy et al. (2017),[79] Bitarafan Rajabi et al. (2015),[270] Maeder et al. (2006)[271] [*] Physics principle

6.2.5 Hand shields

The hand receives a significant amount of radiation (up to 1.5 mSv per procedure, or 50 mSv per year) during procedures since it is unshielded and close to the radiation source.[15, 274] However, this level of exposure is unlikely to have any adverse health impact.

Leaded gloves are available but are bulky, stiff and heavy and cannot be used when dexterity is required. The introduction of leaded (or lead free) radiation attenuating latex gloves helps address these issues. These gloves can shield the hand by 15 - 30%.[275, 276]

However, if the hand with an attenuating glove is placed in the direct radiation beam then the dose to both the patient and operator will increase because the automatic exposure control system in current Xray systems will boost the radiation output.[240]

Thus, the best method to protect the hands is to keep them away from the primary beam, and consequently, radiation protection gloves are rarely needed and are not recommended in routine clinical practice. In cases where the hands must be close to the patient such as during an Xray guided vascular puncture, protective gloves may be an option. However, for many reasons also in addition to radiation safety, routine use of an ultrasound guided puncture technique, rather than a fluoroscopy assisted puncture, is recommended,[277-280] and when that is not feasible procedure modifications such as using a long needle or syringe to extend the working length of a needle may be preferable. When gloves are used, single use, non-lead radio protective gloves are recommended since they can be safely disposed of after a procedure unlike a leaded glove.

Recommendation 35	**Class**	**Level**	**References**[*]
Routine use of an ultrasound guided artery puncture technique, rather than fluoroscopy assisted puncture, is recommended to reduce radiation exposure to the hand.	I	B	Seto et al. (2010),[277] Slattery et al. (2015),[278] Sobolev et al. (2015),[279] Stone et al. (2020)[280] [*]Physics principle

Recommendation 36	**Class**	**Level**	**References**
Routine use of radiation protective gloves is not recommended during endovascular	III	C	Badawy et al. (2016)[240]

procedures	🟥	🟦	

6.2.6 Head shields

Reports regarding operator brain tumours associated with Xray guided procedures have raised concerns regarding appropriate shielding to the head.[72, 281, 282] However, a true increased risk of brain tumours among physicians performing interventional procedures has not been established.

Older generations of lead caps, with 0.5 mm lead, effectively lower the exposure to the head.[283, 284] However, the average weight of these caps is > 1 kg, which may be uncomfortable to wear and could present a musculoskeletal occupational health and safety hazard in itself .

The reported radioprotection efficacy of newer generation lightweight lead free (bismuth oxide composite) caps varies considerably. Some suggest them to provide significant radiation protection to the head, similar to standard 0.5 mm lead equivalent caps,[71, 285-289] while others found only negligible exposure reduction.[290-292] The different results may depend on how the measurements were made. In a phantom model study a small but significant attenuation superficially on the skull, but no reduction in dose for the middle brain, was found. This was suggested to be explained by the fact that the majority of radiation to an operator's brain originates from scatter radiation from angles not shadowed by the cap, and the authors concluded that radiation protective caps have minimal clinical relevance.[292]

Thus, whether radioprotective caps actually provide dose reduction to the brain is disputed, and more importantly, whether they prevent radiation induced damage is completely unknown. Based on current evidence they are therefore not recommended in routine clinical practice. It is more effective to use the ceiling shield.[293] However, in vascular procedures that are likely to give rise to high operator dose, consideration may be given to wearing them. There is evidence to suggest that dose to the head is lower in operators taller than 180cm in height, with a decrease in dose to the head of

1% per cm of operator height above 180cm.[283] Hence, these caps may be of greater benefit in operators of shorter height.

Alternative and better head protection equipment is discussed below (See 6.3.1 Recommendation 21).

Recommendation 37	**Class**	**Level**	**References**
Use of radiation protective head caps is not indicated in routine clinical practice,	III	C	Fetterly et al. (2017),[290] Sans Merce et al. (2016),[291] Kirkwood et al. (2018),[292] Fetterly et al. (2011)[293]

In summary, the endovascular operator should always wear an apron, thyroid collar, and lead glasses (Figure 13). In addition, one should consider leg shields, but refrain from gloves and cap.

Figure 13. As minimum protection, an endovascular operator should always wear a lead apron, thyroid collar and fit over lead glasses

6.3 Other radiation shielding equipment

6.3.1 Suspended personal radiation protection systems

The suspended personal radiation protection system was designed to enhance radiation protection and at the same time improve ergonomics and comfort by eliminating weight on the operator, while maintaining a neutral or positive effect on task accomplishment. The Zero-Gravity suspended radiation protection system is currently the only commercially available system (Figure 14). It has a full body 1.25 mm lead apron and 0.5 mm lead equivalent face and head shield.[294]

Figure 14. A suspended personal radiation protection suit

Compared with a conventional lead apron, the Zero-Gravity Suit system provided a 16 to 78 fold decrease in radiation exposure for a sham operator in a simulated clinical setting.[294] In a clinical study by Savage et al. the Zero-Gravity Suit provided superior operator protection during Xray guided procedures compared with conventional lead aprons in combination with standard shields. Exposure to the eye, head, humerus, torso, tibia and back was reduced by 88 - 100% with undetectable or barely detectable radiation doses with the Zero-Gravity Suit. The Zero-Gravity Suit was furthermore regarded as more comfortable, with relief of back pain, and considered less obstructive relative to a standard lead apron and shields by the operators.[295] In a small study, the overall accumulated dose for the operator was four times higher for standard protection devices *vs.* the Zero-Gravity Suit. However, some exposure still occurred at the level of the lens and thyroid and the authors concluded that although the Zero-Gravity Suit leads to substantially lower radiation exposure to the operator additional protection is justified.[296] In a single operator the annual body and eye dose was reduced by 70 - 87% and 16 - 60%, respectively, after the introduction of a Zero-Gravity Suit system.[297] Compared with conventional lead aprons the use of suspended lead during percutaneous coronary intervention was associated with significantly less radiation exposure to the chest (0.0 μSv *vs.* 0.4 μSv, p < .00) and head (0.5 μSv *vs.* 14.9 μSv, p < .001)[298] and a 94% reduction in head level physician radiation dose.[299]

Although traditional personal protective equipment, when used together with other shields, provide comprehensive radiation protection, there are limitations, especially regarding scattered radiation to the head, eyes and lower legs. Given the demonstrated superior protective effect to the whole body by the Zero-Gravity Suit it is justified to consider the system in high dose environments.

The full body suspended radiation protection system usually replaces the traditional personal protective equipment (i.e., lead apron, thyroid shield, and shin guards) while personal protective glasses can still be worn. The use of full body suspended radiation protection systems may reduce the possibility to use ceiling mounted standard lead shields, which is suboptimal, and care should be taken for its continuous use as a complement to the full body suspended radiation protection systems.

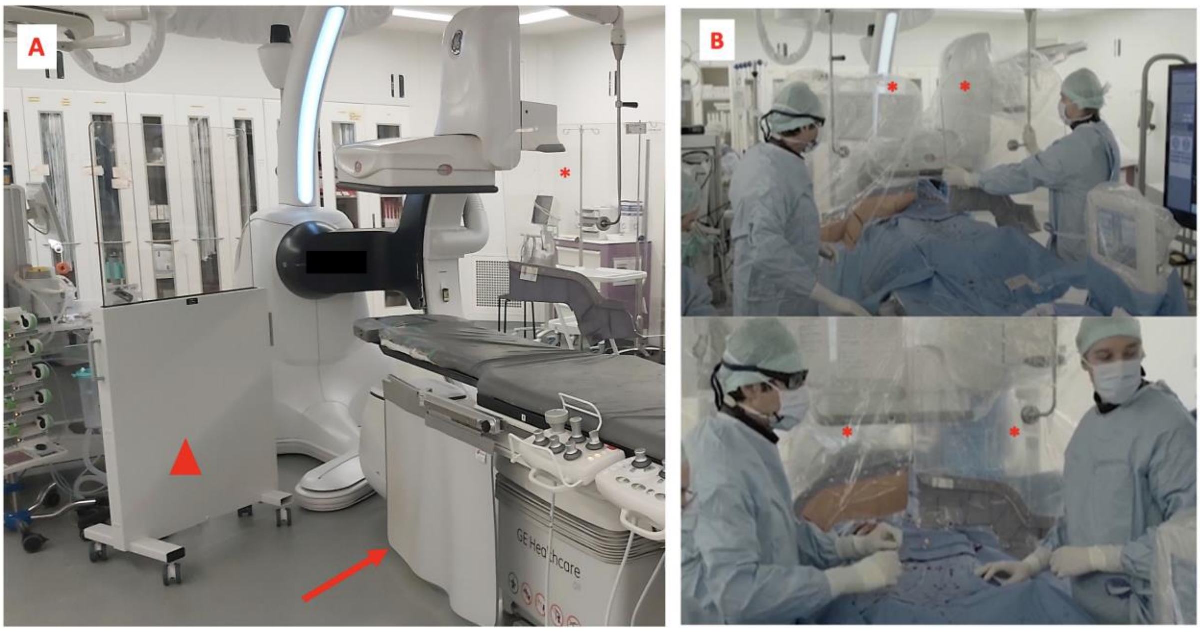
The cost can be a potential holdback in acquiring the full body suspended radiation protection system, and there is a certain learning curve to get used to the system, by both the operator and the staff who will prepare it.

Recommendation 38	Class	Level	References
A full body shield suspended radiation protection system should be considered in high dose endovascular procedures	IIa	C	Marichal et al. (2011),[294] Savage et al. (2013),[295] Haussen et al. (2016),[296] Pierno et al. (2012),[297] Madder et al. (2017),[298] Salcido-Rios et al. (2021)[299]

6.3.2 Radiation protective shielding above and below the table

Radiation protective shielding can be mounted on the ceiling, on the operating table or mobile on wheels. Ceiling mounted lead acrylic shields are common and their importance cannot be over emphasised (see figure 15). Proper use of these shields can significantly lower the radiation dose to the operator's head and neck.[271, 293, 300, 301] The protection conferred to the operator is substantially compromised if these shields are not correctly positioned and must be adjusted as the table and C arm position and C arm angle changes during the case prior to fluoroscopy and digital subtraction angiography. If the ceiling mounted shielding is placed closer to the patient, a larger solid angle is shielded but with lower efficiency. On the other hand, if the shielding is placed close to the operator, a smaller solid angle is shielded but with higher efficiency. This should be taken into account when more people are present in the operating room, as is often the case during endovascular procedures.[302] The shield is most effective for providing upper body protection during right femoral access procedures when it is positioned just cephalad to the access site and is tight to the anterior and right surfaces of the patient. A shield positioned 20cm away from the groin results in twice the scatter radiation than if it placed closer to the access site; in addition to this, a 5 cm gap between the shield and the patient’s body results in a further four fold increase in operator exposure[293] It is important to note that, although ceiling mounted shields reduce operator eye exposure by a factor of 19, they have minimal benefit on reducing radiation exposure to the hands and further measures must be taken.[271]

Figure 15: Shielding around the endovascular operating table (A) showing mobile anaesthetic protection shield (triangle), table mounted lower shield (arrow) and bilateral ceiling mounted upper shields (A asterix) and their optimal positioning (B asterix).



[redacted]

Phantom studies have shown that larger shields with patient contour cutout that allow the curved gap to adapt to the patient’s body, along with a flexible curtain below the shield that is in contact with the patient's body, reduces the dose to the operator by up to 87.5% compared with a bare shield. These soft extensions along the bottom edge maintain contact between the patient and shield to reduce the amount of scatter directed towards the operator. This configuration provides better protection to the heads of tall operators and achieves similar magnitudes of dose reduction for the assistant.[303] Other shielding such as table mounted vertical side shields should also be considered; these can be removed easily if imaging is hampered during steep C arm angulation.

Although the majority of energy from Xrays is deflected upward and absorbed by the patient’s body, the downward energy does not encounter such a barrier without shielding. As a result, radiation doses are high at the operator's legs; measurements of leg doses have been found to be as high as 2.6 mSv per procedure in interventional radiologists when shielding is not used.[263] Adequate shielding from the Xray beam placed under the operating table during endovascular procedures is, therefore, essential for protection against scattered radiation. Table mounted lead skirts, usually in the form of leaded slats hanging from the side of the table and close to the floor, are highly recommended. As they are flexible (and can be swung 90 degrees horizontally when needed), lead skirts can be adopted for the majority of endovascular procedures as they can accommodate a range of C arm angles. Although wearable aprons provide the majority of the shielding, table lead skirts do decrease the radiation dose even further by over 90%[293] and their adjunctive use for protection under the operating table results in a significantly lower radiation dose to the operator’s pelvis and thorax.[304] Phantom studies have shown that when ceiling suspended lead screens are combined with table mounted shielding, operator and assistant radiation exposure is reduced by up to 90%.[305]

Other members of the team, including the anaesthetist and nursing staff must be protected from radiation. This can be readily achieved by using floor standing mobile accessory lead shields that have an effective lead thickness of 0.5mm. These can reduce radiation exposure to other members of the team by over 60%.[306]

Recommendation 39	**Class**	**Level**	**References***

All operators are recommended to use ceiling mounted shields as first line protection at all times during endovascular procedures	I	B	Fetterly et al. (2011),[293] Maeder et al. (2006),[271] Thornton et al. (2010),[300] Eder et al. (2015)[303] *Physics principle
Recommendation 40			
All operators are recommended to use table mounted lead skirts as first line protection at all time during endovascula procedures	I	B	Whitby et al. (2003),[263] Fetterly et al. (2011),[293] Sciahbasi et al. (2019)[304] *Physics principle
Recommendation 41			
Ceiling and table mounted shields are recommended on both sides of the operating table when personnel exposur is anticipated on both sides	I	B	Jia et al. (2017)[305] *Physics principle

6.3.3 Radiation protective patient drapes

Radioprotective sterile drapes include covered non-lead sheets or drapes that are made of bismuth or tungsten antimony. They are placed on top of the patient to attenuate the scatter radiation that contributes to operator dose at the source.[307] Phantom studies show that these drapes reduce scatter radiation by a factor of 12, 25 and 29 for the eyes, thyroid and hands respectively compared with standard surgical drapes.[308] The dose reducing function is comparable to approximately 0.4 - 0.8 mm lead. The majority of evidence for these radioprotective drapes has been accumulated in cardiology procedures, where they have been shown to reduce the scatter radiation dose to the operator by from 20% to 80%.[309-313]

Although there is a lack of evidence for use of these drapes in endovascular surgery, a single centre study has shown that their use during infrarenal EVAR results in a dose reduction to the hand and chest of the operator by 49% and 55% respectively as well as a 48% reduction to the chest of the theatre scrub nurse.[314] One other study evaluating the effectiveness of these drapes in lower limb endovascular procedures (covering the leg closest to the operator and the chest), reported a significant dose reduction rate of 65%.[309]

Diligent and judicious use of ceiling and table mounted radioprotective shields and drapes is recommended for all endovascular procedures. In fact, when these are used in combination with other interconnecting flexible radiation resistant materials, it is possible to create an attenuation barrier so effective that operator exposure at various sites is barely detectable and approaches background levels.[315]

When placing disposable drapes on the patient, attention is required to avoid having the drapes in the primary beam, which might increase patient and operator exposure.[9] The cardiology intervention setting, where the operator maintains the same position throughout most of the procedure, may differ from the endovascular setting, where the operator often uses multiple positions making the use of protective drapes less straightforward. Furthermore, although some studies suggest that the observed reduction in dose to the operator can be achieved without increasing the dose to the patient[316] other studies have found that drapes reflect scatter radiation back to the patient thereby significantly increasing the radiation dose to the patient.[317]

Recommendation 42	**Class**	**Level**	**References**
Use of radiation protective drapes may be considered during endovascular procedures	IIb	C	Marcusohn et al. (2018),[307] King et al. (2002),[308] Power et al. (2015),[309] Vlastra et al. (2017),[310] Ordiales et al. (2017),[311] Politi et al. (2012),[312] Simons et al. (2004),[313] Kloeze et al. (2014),[314] Musallam et al. (2015)[317]

Chapter 7. Education and training in radiation protection

7.1 Introduction

Reports suggest an alarming knowledge gap related to the principles of radiation exposure protection among medical professionals, especially trainees, involved in Xray guided procedures. Only 39% of French vascular trainees responded to a survey administered in 2016 and those who responded felt only moderately satisfied with their radiation protection training. The ALARA principle was well known by these responders but basic knowledge about biological risks and radiation physics was poor.[140] In another survey, 45% of vascular surgical trainees in the US, had no formal radiation safety training, 74% were unaware of the radiation safety policy for pregnant women, and 43% did not know the yearly acceptable level of radiation exposure.[95] Similar results have been shown for trainees in cardiology,[318] urology[319], and orthopaedic surgery.[320, 321] A recent US survey (95 trainees, 27% response rate) revealed that a high number of vascular trainees are exceeding radiation exposure limits. The majority (77.9%) had received formal radiation safety education, but 25% had never received feedback on radiation exposure levels nor had 52% met their radiation safety officer.[322]

Procedures performed by less experienced operators are associated with higher radiation exposure in cardiology,[323-325] orthopaedic surgery,[326] interventional radiology and neuroradiology.[327] The learning curve in FEVAR may substantially influence operator dose[328] but the evidence on this is contradictory, with some studies reporting no difference in operator dose based on the level of training during complex endovascular procedures.[5, 165]

A recent European needs assessment for simulation based education in vascular surgery prioritised basic endovascular skills, including radiation safety, as the second most important procedural skill in vascular surgery training.[329] Radiation safety education and training should be a priority not only for vascular surgical trainees but for all personnel in the endovascular operating room, involved in procedures using radiation at every level of training.[330]

7.2 Delivery of radiation protection education and training

The primary trainer in radiation protection should be a person who is an expert in radiation safety, usually a medical physicist. Input from radiation protection certified clinicians who carry out day to day Xray guided work is valuable.[331, 332]

The training program in radiation protection should be relevant, require a manageable time commitment and be oriented towards the clinical practice of the target audience.[333] These programs should include initial basic education for all personnel in the endovascular operating room, and more in depth education and training for specialists who use ionising radiation in endovascular procedures. Recommendations on the curriculum have been provided by international organisations such as the ICRP, the European Commission and the World Health Organisation. An overview of the core knowledge that should be included within the radiation protection education and the level of knowledge and understanding that every category should obtain, is outlined in these documents.

In 2019, a European survey about radiation protection training was sent out to the European Vascular Surgeons in Training (EVST) representatives. Twenty-one of 28 European member states had a representative in the EVST council at the time. Two thirds of the countries (14 of the total of 21) are obliged to take a mandatory course during their vascular surgery training but only in half of the cases is it followed by a post-course evaluation. This mandatory course includes theory (all 14), hands on training (4/14) and or web based learning (4/14). The course should be taken during medical school (1/14), before being exposed to radiation or using it yourself (5/14) but in most cases only before board certification in vascular surgery (8/14). Re-certification is mandatory in half of the countries (7/14): yearly (1/14), every two years (3/14), or every five years (3/14). Of the countries where a radiation protection course is not mandatory, a voluntary course or training is available in four of seven.[93]

Recommendation 43	**Class**	**Level**	**References**
All personnel who may be exposed to radiation in the endovascular operating room must have had the appropriate level of radiation protection training	I	Law	ICRP publication 105 (2007),[137] ICRP publication 113 (2009),[334] EBSS (2013)[8]

7.3 Theoretical courses

The majority of radiation protection programmes focus on knowledge training using the traditional classroom format, but e-learning or web based courses are being used increasingly.[335-337] The main advantages of e-learning include flexibility in time management, easy access to resources, and learning at ones own speed but it lacks interaction with teachers and other participants.

A multicentre study has shown that after a practical 90 minute interactive training session (ELICIT, Encourage Less Irradiation Cardiac Interventional Techniques) operators use shorter FT, fewer DSA runs, consistent collimation and less steep C arm angulations, resulting in a reduction in DAP from 26.5 to 13.7 Gy.cm^2 (48.4%).[208, 338] The patient related dose reductions are consistent and long lasting.[339] Focused events on minimising radiation exposure and optimal use of Xray equipment during coronary intervention have similarly resulted in dose reductions.[340] A systematic review suggests that radiation protection training can result in a > 70% reduction in operator dose and an almost halving of the patient dose.[341] The specific instructional courses reviewed included short 90 min courses and basic and advanced theoretical courses delivered over either 20 hours or 48 hours. Implementing a culture of radiation safety, including Xray imaging and radiation safety laboratory sessions and a practical examination between 2008 - 2010, led to a 40% reduction in cumulative skin dose in the endovascular operating room over three years despite an increased participation of fellows in training.[342]

7.4 Practical training

Practical exercises and practical sessions are beneficial particularly if carried out in a similar environment to that in which the team will be operating.[333] Availability of practical courses varies between European countries but some offer hands on training in credentialed centres as part of their training program, ultimately creating a culture of respect for the hazards of radiation. [343] In Switzerland, for example, two full days of hands on radiation protection training, including an examination is mandatory to obtain board certification in any surgical specialty.[344] A curriculum in radiation protection for medical practitioners has been established in Spain and the practical aspects of training have been well received.[345] Some practical simulation sessions are solely web based and allow the operator to alter angulation, magnifications, pulse rate and immediately test the influence of each factor on the radiation dose and scatter. This type of training allows the operator to put knowledge into practice and to reduce radiation doses to patient and operators in the cardiac catheterisation laboratory, for example, with an average reduction in the monthly exposure from 0.58+/-0.14 to 0.51+/0.16 mSv for some operators.[346] Ideally, the radiation safety performances of trainees in simulated or real endovascular interventions should be evaluated regularly using a reliable rating scale to provide formative feedback.[142]

Recommendation 44	Class	Level	References
The inclusion of radiation protection content in national vascular board certification exams is recommended.	I	C	Consensus

Medical simulators are useful for learning new skills using C arms before applying them to patients. Practicing endovascular techniques, including iliac angioplasty or stenting, carotid artery stenting and

EVAR on a virtual reality (VR) simulator improves performance on the simulator with a reduction of total procedure time and FT during real cases.[347-351] These simulated modules focus on learning procedural steps and becoming familiar with new devices. The reduction in FTs may be explained by the fact that the operator steps on the fluoroscopy pedal less frequently and for a shorter duration most probably because of an improvement in both the hand eye foot coordination and use of endovascular tools. It is acknowledged that trainees require 300 coronary angiography cases to achieve the proficiency level of consultants[352] and if VR training shortens and flattens the learning curve, then training in this safe environment may also have an impact on patient and occupational radiation dose.

By integrating a medical simulator in a fully immersive simulation training with a complete surgical team, the trainee may not only improve his or her technical skills but also enhance the radiation safety behaviour of the entire team. Examples include ensuring that the entire endovascular operating team is wearing lead and asking the team to step back before DSA runs.[353]

Only a few studies have evaluated whether the reduced FT achieved using VR training translates into real life procedures. Hands on training using VR simulation for endourology, gastroenterology and orthopaedic procedures reduces FT during real life operations.[354-357] A significant reduction in FT was achieved in real life electrophysiology cases after simulator based training and, similarly, a RCT assessing the effect of simulation training on diagnostic angiography found a significant reduction in FT and radiation dose during the actual coronary angiograms carried out by the group who had had simulation training compared with the one that did not.[358-360] In the peripheral endovascular field, few RCTs have shown the transferability of endovascular skills acquired during simulation based training to real life with enhancement in the individual measures of performance including the awareness of fluoroscopy usage.[361] In the PROficiency based StePwise Endovascular Curricular Training (PROSPECT) study, consisting of e-learning and hands on simulation modules, focusing on iliac and superficial femoral artery atherosclerotic disease, those trainees who had access to simulator based training in addition to knowledge and traditional training outperformed the other groups and showed a trend towards less contrast and radiation use.[362] Simulation (VR simulation, augmented reality, 3D printing) is becoming more practical for everyday use and patient specific rehearsals may reduce the radiation exposure during these procedures.[363-365] Despite the lack of large RCTs, the benefit of learning and practicing endovascular skills in a safe, radiation free environment, should be acknowledged in reducing the radiation dose in real life endovascular procedures. This is especially important in young visiting persons (trainees, medical or nursing students, and observers) who are sometimes forced or allowed to receive large amounts of radiation while assisting or performing complex endovascular procedures. Therefore, extra care should be taken to avoid excessive radiation exposure to students and visiting persons.

Recommendation 45	**Class**	**Level**	**References**
Simulation based training should be considered to acquire the appropriate technical skills to reduce the amount of radiation during endovascular procedures	IIa	C	Chaer et al. (2006),[366] De Ponti et al. (2012),[359] Prenner et al. (2018),[358] Popovic et al. (2019),[360] Desender et al. (2016)[363]

7.5 Timing of radiation protection education and training

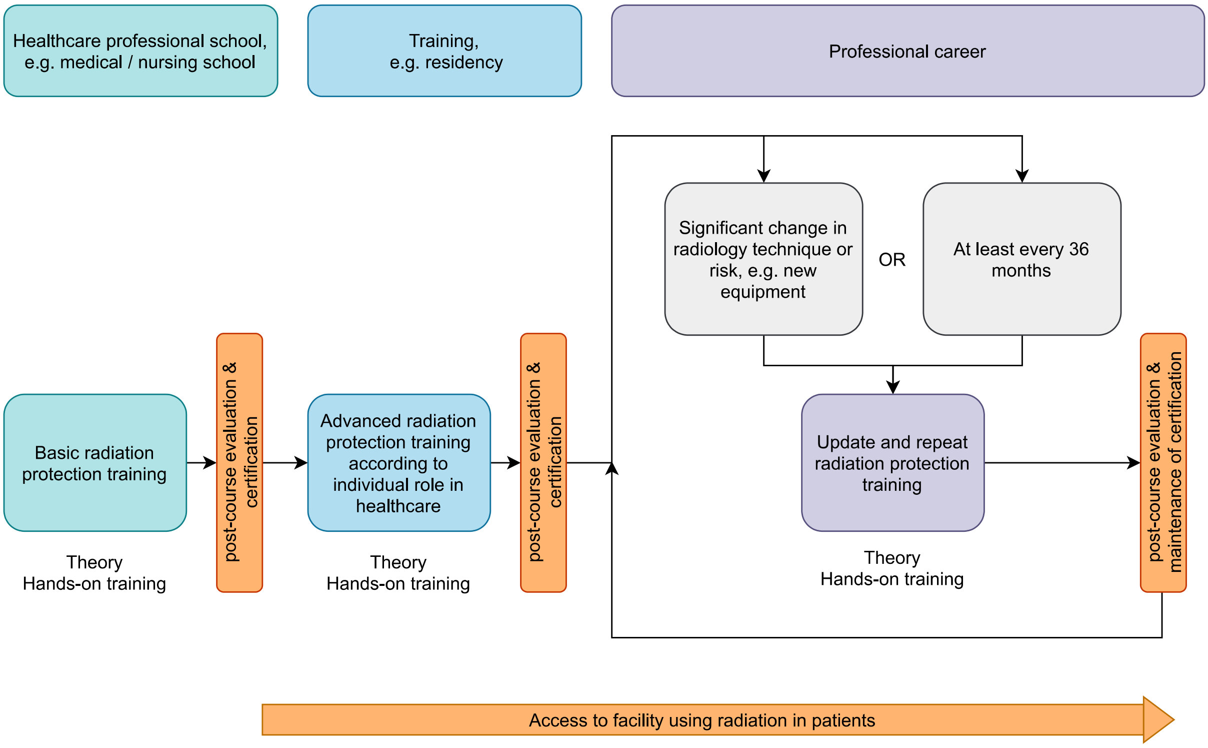
To ensure that continuing education and training after qualification is provided, radiation protection training programs should be updated regularly and re-training should be planned at least every 36 months or when there is a significant change in radiology technique or radiation risk (figure 16).[334]

Radiation protection education should be integrated into the curricula of medical, nursing or other schools ensuring the establishment of a core competency in these areas.[367] Ideally access to any facility using radiation should be prohibited until at least core knowledge has been obtained. For future endovascular operators, education and training should continue throughout residency, but especially at the beginning of the endovascular career, to establish a foundation of correct practice early on. This may be accomplished during focused specific courses, but it may also be facilitated by increased interactions and teaching with the personnel in the endovascular operating room. Evaluation and certification are crucial. Modest improvements in radiation use have been noted with a single education event alone, but regular detailed personalised feedback comparing an individual's radiation use to the rest of their local peer group and external benchmarks has a greater impact.[368]

Regulatory and health authorities can enforce radiation protection training, certification and periodic updates for the personnel in the endovascular operating room[8] (also see chapter 3). Evidence of certification should ideally be maintained in a central register. A structural chapter about radiation safety and protection should be included in the European Union of Medical Specialists to be recognised as a fellow of the European Board of Vascular Surgery. Scientific societies are ideally placed to support and promote radiation protection training by including lectures on radiation protection and offering refresher courses at scientific congresses.[333]

Recommendation 46	**Class**	**Level**	**References**
National policies regarding continuous training and certification with formal assessment in radiation protection must be followed.	I	Law	ICRP publication 105 (2007),[137] ICRP publication 113 (2009)[334] EBSS (2013),[8] Kuon et al. (2005),[338] Azpiri-Lopez et al. (2013),[340] Kuon et al. (2014)[208]

Figure 16: Timeline for radiation protection training and certification for healthcare professionals suggested by the Guideline Writing Committee.



Chapter 8. Future technologies and gaps in evidence

Many of the recommendations outlined in these guidelines are supported by level C evidence and are reliant on the expert opinion of the committee. This highlights the need for the vascular community and allied disciplines to instigate studies that will strengthen the evidence base for radiation protection matters. New technologies that offer the promise of performing endovascular procedures with a reduced requirement for Xray guidance should be embraced and evaluated carefully according to standard innovation frameworks such as Idea, Development, Exploration, Assessment, Long term study (IDEAL). This chapter will outline developments currently taking place and future areas of research that may circumvent the limitations and dangers associated with Xray guidance for procedures.

8.1 New technologies

8.1.1 Three dimensional (3D) navigation

Images of guidewires, catheters and other endovascular devices are two dimensional (2D) and only available as grayscale images, which limits the ability to assess spatial relations between the devices and the vascular anatomy. It also limits the ability to identify the three dimensional (3D) shape and orientation of devices and significantly hinders navigation in the patient.

Recently, new technologies have been developed to enable 3D navigation of endovascular devices inside the body with a significant reduction in radiation dose. Two of these technologies include electromagnetic (EM) tracking and Fiber Optic RealShape Technology (FORS) and have shown potential in pre-clinical studies.[369-372]

An EM endovascular navigation system (ENS) provides the 3D position and orientation of EM coils (and thus the endovascular devices) and visualises the location of the coil in a pre-operative CT scan. This technology enables real time 3D imaging of endovascular devices, including stent graft positioning,[373] in a radiation free environment. Pre-clinical reports are encouraging,[370, 371] especially when EM technology is used in combination with flexible robotic catheters, but clinical results are not as yet published.[374]

The Fiber Optic RealShape (FORS technology platform consists of equipment that sends laser light through a multicore optical fibre which is incorporated in endovascular guidewires and catheters. By analysing the reflected light it is possible to reconstruct the 3D shape of the full length of the optical fibre and thus of the endovascular devices (Figure 17).[372] An advantage of FORS compared with EM tracking is that FORS is able to show the endovascular devices over the entire length of the devices, whereas EM tracking technology only shows the tip of the devices, where the EM sensor is positioned. In a preclinical setting, safety and feasibility of the FORS system were demonstrated by the combined outcomes of high cannulation success, lack of hazards, positive user experience, and adequate accuracy.[372] FORS also allowed working in extreme views not achievable with standard gantry positions and also allows working simultaneously in two different angulations (e.g. AP and 90°). A first in human clinical feasibility study confirmed safety and feasibility of the FORS technology in endovascular procedures of the abdominal aorta and peripheral arteries and is now in use for catheterisation of target vessels during complex EVAR.[375,376] Clinical studies with larger series of patients, however, are necessary to determine whether FORS has an effect on technical success rates, radiation parameters and procedural time in clinical practice.

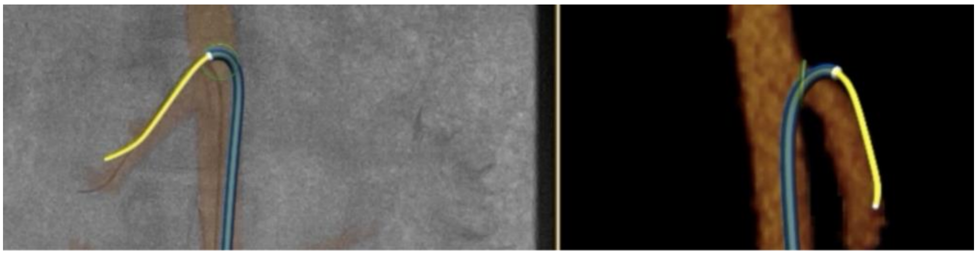


Figure 17: Endovascular procedure using FORS technology. Guidewire and catheter are shown in real time, in distinctive colours and with 3 Dimensional effects. The white dot on the devices shows the pointing direction of the tip.

8.1.2 Robotic tracking

Robotic navigation systems may improve steerability of endovascular devices while allowing remote control and may be of particular benefit for complex EVAR cases, such as F/BEVAR. Robotic catheterisation of target vessels in a model simulating fenestrated stent grafting was carried out with negligible radiation exposure to the operator. Vessel cannulation times were reduced, with a significant reduction in the number of movements compared with conventional cannulation techniques.[377]

Previous clinical evaluation of a robotic navigation system has shown that it can be used safely for cannulation of renal and visceral target arteries during complex endovascular aortic procedures. It was found to be most effective for branched and chimney grafts, with an acceptable successful cannulation rate during fenestrated stent grafting (81%).[378]

Prospective studies are, however, needed to prove the clinical advantages of robotic navigation.

8.1.3 Artificial Intelligence

Introduction of AI technologies in fluoroscopy guided interventions may also reduce radiation doses. For example, the ability to use AI to make automatic adjustments to how guidewires and catheters appear on screen, may reduce the radiation exposure associated with tracking these devices to the desired anatomical location. AI algorithms can automatically recognise devices and trigger real time segmentations and improvements in visualisation, i.e., by showing the devices in distinctive colours and in higher resolution, allowing easier tracking and requiring less radiation exposure. Several groups are currently working on development of AI technologies for this indication.[379, 380]

Another potential application of AI is automated recognition of the site of intervention within a fluoroscopy image. Radiation can then be delivered selectively to this region of interest (ROI). An integrated AI fluoroscopy (AIF) system has been used for Xray guided endoscopic procedures whereby a trained deep neural network recognises the ROI and subsequently performs ultrafast, automated collimation. In a prospective study of 100 patients, radiation exposure was compared in those who had endoscopic procedures using either a conventional or AI equipped fluoroscopy system. Radiation exposure to patients was significantly lower for the AIF system compared with the conventional fluoroscopy system, evidenced by a reduction in DAP from 5.7 mGym2 to 2.2 mGym2 (*p*

< .001) and almost 60% less radiation scatter.[381] Application of similar AIF systems for performing endovascular procedures would merit research.

Other desired AI driven technologies would include those that facilitate automated intra-operative dose reduction and also algorithms that drive warning systems, for example, those that trigger when operators fail to step back adequately during DSA acquisitions.

8.2 Gaps in practice and evidence

8.2.1 Global harmonisation of radiation safety practices

As discussed in chapter 2, the European legislation is clear in terms of dose limits and the high level needs for management of occupational, public and medical exposures. However, many of the details related to how to educate and manage the day to day practices in terms of personal protection equipment, dosimetry and monitoring are left to national regulations. Further, there is very little by way of international standardisation of regulatory practices. In order to promote global harmonisation, this standardisation needs to be established, through closer regional and national working.

An important consideration is low and middle income countries, where resources are limited. In these environments the most cost effective means of reducing radiation exposure should be identified and prioritised to allow the best protection that is feasible.

8.2.2 Radiation dose reference levels

Evaluation of the literature carried out for collation of these guidelines has shown a large variation in published radiation doses used for performing endovascular procedures. Two of the reasons for this variability are the endovascular operators' technique and the C arm equipment used. The expected radiation dose for a standard procedure should be better defined. This will come from standardised collection of procedure specific dose values for all endovascular operations. Two dosimetric parameters that should be routinely collected and are offered by most Xray guidance equipment regardless of the hardware and manufacturer are Air-Kerma Area Product and Air Kerma at the patient entrance reference point (see chapter 2.2). Working groups can then use these data to set national DRLs (see chapter 2) for endovascular procedures and facilitate the use of radiation dosage as an additional quality metric for centres performing these procedures.

8.2.3 Pregnant staff in the endovascular operating room

As discussed in chapter 2, regulations clearly stipulate that unborn children of radiation workers are subject to the public dose limits, i.e., within the EU, 1 mGy per year.[8] Some work has focused on how this is managed in practice in various different medical exposure settings, however, there is little by way of standardisation of practice in this area. Further work is urgently needed regarding how to best minimise risks and support safe normal working for pregnant staff in the endovascular operating environment. This should also include better education of personnel and employers with regard to the special considerations required for pregnant workers who are exposed to occupational radiation.

8.2.4 Biological correlates of radiation exposure

More radiobiological mechanistic and epidemiological research, and better linkage between these two areas, is needed to clearly determine the health effects of ionising radiation exposures. A key open question regards how risks vary with age, and this is especially important for younger patients who will live longer post-radiation exposure, and thus who have larger total risks of developing radiation induced cancers, for example. It is also important to increase knowledge regarding individual risks of radiation exposures, both for patients and for staff working with a variety of different exposure scenarios, with varying annual doses depending on a wide range of factors including training, use of dosimetry and personal protection equipment. Use of cutting edge biological techniques, including genetic profiling may in the future identify individuals at particular risk from occupational radiation exposure and may even guide their career decisions.[382] Validation of microRNAs and non-coding RNAs in chronically exposed personnel may reveal novel biomarkers of exposure and sensitivity to exposure. Another area that requires attention is better prospective monitoring of health outcomes in radiation exposed medical staff. Without long term data collection on the incidence of cancer in these individuals, for example, we will never know if occupational radiation exposure truly increases the risk of malignancy in these individuals. The larger studies currently available are not conclusive as risks are low and the statistical power of these studies are not high enough. The advent of innovative study design and analysis for rare events may circumvent limitations encountered to date,

8.2.5 The value of real time dosimetry

It would seem intuitive that the use of real time dosimetry, providing a second by second readout of the effect of the operator's action on radiation exposure, would promote radiation safety. This has not been proven conclusively, however, and more studies are needed to objectively determine the additional role of this adjunct in relation to the other safety behaviours adopted in the endovascular operating room. Specifically, observational studies that aim to quantify the radiation dose savings in operators wearing real time dosimeters and any behaviour modifications that result from the operator watching their dose rise. Such studies would also allow operator doses to be related to doses absorbed by the patient. Expected benefits of real time dosimetry with direct feedback need to be confirmed and quantified for endovascular procedures in clinical comparative series.

8.2.6 Operator control of C arm equipment

In most countries, trained endovascular operator control of the C arm is preferred to assistant control. It is perceived that this will reduce radiation exposure since the operator knows precisely when to initiate and cease screening based upon the intended purpose. Furthermore, the operator can specifically set the appropriate acquisition parameters such as collimation, magnification and frame rate, thereby limiting exposure and scatter and focusing upon the region of interest involved in that specific part of the procedure. There is, however, limited evidence to support this notion and further studies are needed that quantify radiation exposure according to workflow within the endovascular operating room, including the individuals who are responsible for controlling the C arm.

8.2.7 Personal protection equipment

The additional value of leg shields needs to be defined. Available evidence is so far limited to a single study and further data are needed, especially in combination with other protection devices.

The additional value of full body shields needs to be supported by clinical data. Also, the high cost of the only system available today also means that cost aspects need to be highlighted. Alternative whole body protection needs to be developed and evaluated.

Reports of potential lead contamination on lead aprons are worrying, and the extent and significance of this need to be clarified urgently.

8.2.8 Education and training

Radiation protection training is mostly regulated by national authorities. Ideally these regulations should be reviewed and compared across the European member states to study any similarities and differences, allowing authorities to optimise or adjust their regulations about radiation protection training.

It is important that structured programmes are established for training the trainers in radiation safety. An ideal model might be for an appropriately trained medical physicist and a healthcare professional who uses radiation in day to day work in the endovascular operating room to run radiation safety courses together. In addition, the impact of radiation safety courses on the knowledge, skills and behaviour of trainees who attend should be studied in a more structured way to objectively assess benefits.

Augmented reality and VR simulation is likely to play an increasingly prominent role in preparing healthcare personnel prior to working in the endovascular operating room. Practice in environments created using these technologies may help raise awareness about factors associated with radiation exposure of endovascular team members and aid personnel in: (i) putting into practice radiation safety knowledge they have gained; (ii) learning how to use modern technologies safely; and (iii) to improve the radiation safety behaviour in endovascular practice to protect both endovascular operator and patient. Multicentre trials are needed to demonstrate any benefit related to these modern educational materials in order to justify the investment made.

The impact of radiation safety training (knowledge, skills and behaviour) on behaviours of the team members in the endovascular operating room should be evaluated regularly. This can be done by combining reliable rating scale evaluations, real time dosimeters, dose registration software, structured dose reports and possibly artificial intelligence technologies. This may provide detailed information about key aspects of the entire endovascular team's radiation safety behaviour, facilitate targeted feedback and the development of radiation safety training interventions. This allows a targeted approach adapted to the needs of that particular team.

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APPENDICES

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Appendices

Appendix 1: Basic knowledge related to x-rays

1.1. The physics of x-rays

X-rays are wave-like forms of electromagnetic energy that are carried by photons. They are characterized by a wavelength comprised of between 0.03 nm and 10 nm, which means they fall between gamma radiation and ultraviolet light on the electromagnetic spectrum. The energy associated with X-ray is usually measured in electro-volts (eV). The shorter the wavelength of an electromagnetic wave is, the higher the energy of the associated photons. For example, visible light photons have an energy of around 2eV, while X-ray photons have energies between 30 to 150keV.[1]

X-rays are classified as ionizing radiation, meaning they have the potential to interact with biological matter when they collide with it, altering its molecular bonds and producing ionisations. The process of ionisation (in which an electron is given enough energy to break away from an atom) releases energy that can damage living tissues.

There are three possible outcomes when X-rays encounter matter (Figure A1):[2]

- Transmission: once the X-ray beam hits an object it passes through it without any interaction, keeping the same direction and energy.
- Diffusion/Scattering: upon hitting the object, X-rays are reflected in different directions, without energy transfer, or with partial transfer of energy and induction of ionisation – a phenomenon known as the Compton effect.
- Absorption: the energy associated with X-ray is absorbed upon passing through an object, induction atomic ionisation – this is known as the photoelectric effect.

The production of images for medical applications is dependent on the Compton and Photoelectric effect of X-rays, which relies on ionisation and, therefore, has the potential to cause biological damage.

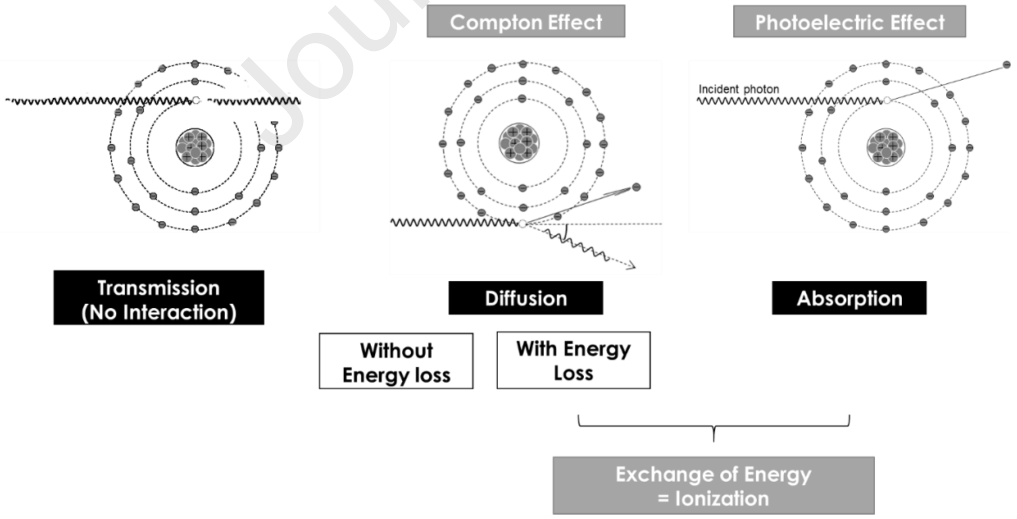

Figure A1: Main mechanisms of interaction between X-rays and matter.

1.2. X-ray production and image generation

X-ray generators (Figure A2) used in endovascular operating rooms rely on an electric current (characterized by a potential (kV)) to accelerate and induce electron collision on an anode. As much as 99% of the current's energy is transformed into heat, explaining the need for cooling systems in imaging equipment. The remaining 1% of energy is used to generate an X-ray beam that exits the X-ray tube.[3]

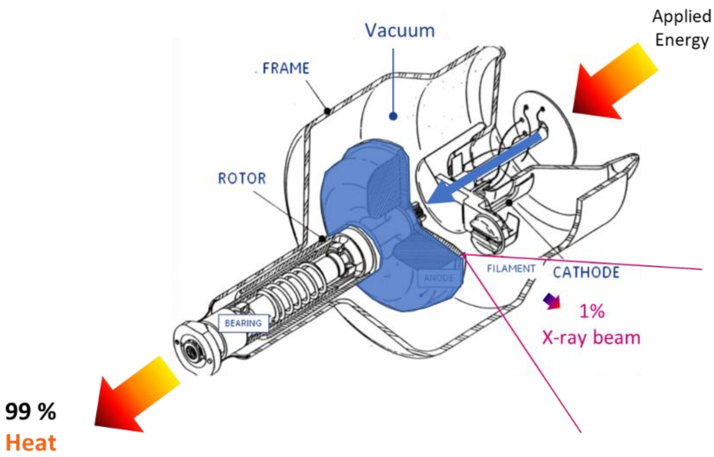

Figure A2: Example of an X-ray generator; electrons are accelerated (blue arrow) and collided on an anode (blue structure). Most of the energy is released in the form of heat, the remaining 1% forms X-rays.

The X-ray beam released travels through the operating table and the patient. Part of the beam is redirected in random directions due to the Compton effect, which accounts for scattered radiation. A proportion of the beam crosses the patient, with part of its energy being absorbed (photoelectric effect) before reaching the detector. The differences in the amount of X-ray absorbed as it passes through the body results in variable attenuation and, therefore, heterogeneous intensity of the X-rays leaving the body. Production of radiological images is ren this phenomenon.
The beam generated by X-ray machines is composed of X-rays carrying various energies (Figure A3). “Soft” X-rays carry low energy photons and are rapidly stopped by matter (absorption), they will mostly induce ionisation and are not useful for producing images.[3] “Hard” X-rays with high energy photons cross biological matter with minimal interaction also does not generate a radiological image. The “intermediate” X-rays, however, carry enough energy to allow part of the beam to cross the matter and reach the detector and the rest to be absorbed. This is the fraction of the X-ray beam that will produce images.

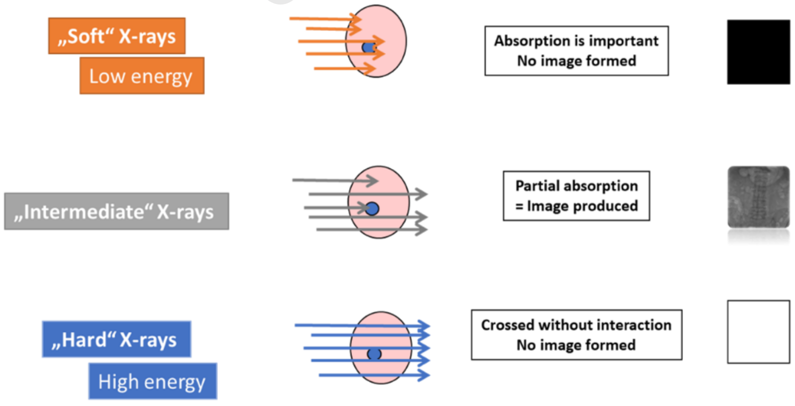

Figure A3: Differences between the X-rays produced in a generator and their role in producing an image.

Spectral filters, usually made of aluminium or copper, are positioned at the exit of the X-ray generator tube and used to stop or attenuate the low energy “soft” X-rays. Without this, the image generated by the X-ray machine would be blurred.

The filtered X-ray beam directed towards the body crosses structures that have different densities. Once the uniform X-rays enters the patient, the range of densities of the structures it crosses results in a range of attenuation, thus transforming it into a heterogenous beam,[4] that is registered as a characteristic image via the detectors (Figure A4).

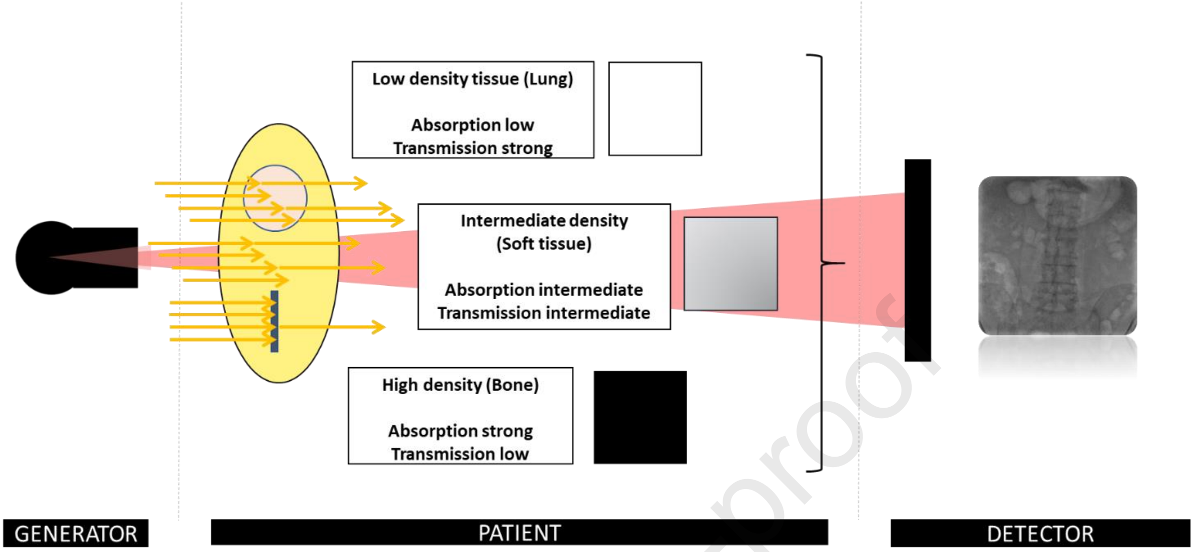

Figure A4: Image formation from the different densities of the structures crossed by the X-ray beam.

Appendix 2: Radiation exposures reported for endovascular procedures

Author	Year	Groups	Imaging System	Number of patients	KAP (Gy.cm²)	CAK (mGy)	Dose to the operator (μSv)	Dose to the staff (μSv)
De Ruiter[5]	2016		Mobile C-arm (Flat panel)	13	55.5 ± 38.9 (17.0–152.0)	300 ± 200 (100–600)	-	-
			Fixed C-arm	7	244.5 ± 142.2 (47.4–409.5)	820 ± 540 (100–1600)	-	-
			Fixed C-arm (Hybrid room)	26	157.0 ± 120.4 (25.9–418.0)	600 ± 400 (100–1600)	-	-
Antoniou[6]	2016	EVAS	Mobile C-arm	32	54 (IQR 42.1-76.8)	.	-	-
		EVAR	Mobile C-arm	32	111 (IQR 75.3-157.4)	.	-	-
Machado[7]	2016		Mobile C-arm	127	48 ± 32	.	-	-
Stansfield[8]	2016	Without preprocedure run through and brief	Fixed C-arm	61	225.11 (16.63-1671.57)	-	-	-
		With preprocedure run through and brief	Fixed C-arm	44	142.22 (20.98-635.31)	-	-	-
Nyheim[9]	2016		Fixed C-arm	80	234 (81–517)	-	-	-
Bacchim Neto[10]	2016		Fixed C-arm	30	-	-	292.6 (88.4–459.5) ¤	207.0 (73.6–407.0) ¤
Dias[11]	2016	Standard dose protocol	Fixed C-arm	25	213.83 (IQR 123.99-290.14)*	-	-	-
		Low-dose protocol, Fusion imaging	Fixed C-arm	22	98.85 (IQR 83.63-164.70)*	-	-	-
Attigah[12]	2016		Fixed C-arm (Hybrid room)	65	23 ± 25	-	620 ± 620Ɨ	470 ± 340ǂ
El-Sayed[13]	2017		Fixed C-arm	6	82.8 (53.61-144.3)	-	11 (4-74)	92 (43-203) ǂ
Tuthill[14]	2017	Centre 1	Fixed C-arm	74	77.96 ± 7.04	504.47 ± 55.07	-	-
		Centre 2		32	318.97 ± 57.97	1219.22 ± 296.48	-	-
		Centre 3		18	43.43 ± 9.94	218.09 ± 42.75	-	-

		Centre 4	Fixed C-arm (Hybrid room)	21	181.99 ± 21.41	983 ± 100.18	-	-
		Centre 5		35	114.23 ± 13.90	790.86 ± 118.11	-	-
Stangenberg[15]	2018		Fixed C-arm (Hybrid room)	25	-	581 (116.2-2695.8)*	-	-
			Fixed C-arm	52	-	1178.5 (174.9-3351.1)*	-	-
Miller[16]	2018	Baseline	Fixed C-arm	8	-	-	120 ± 70¤	-
		Use of live dosimeters	Fixed C-arm	5	-	-	190 ± 40¤	-
			Fixed C-arm (Hybrid room)	5	-	-	30 ± 20¤	-
Ruffino[17]	2018		Fixed C-arm	25	337 (232–609)*	1608 (933–2770)*	-	-
			Fixed C-arm (Hybrid room)	25	157 (113–212)*	884 (558–1379)*	-	-
De Ruiter[18]	2018		Fixed C-arm (Hybrid room)	38	93.1 (63.5-132.5)*	400 (300-700)*	28¤	16¤
Schaefers[19]	2018		Fixed C-arm (Hybrid room)	53	168.34 ± 146.92	-	-	-
			Mobile C-arm (Flat panel)	107	49.93 (± 38.06)	-	-	-
Ahmad[20]	2018	Without Fusion	Fixed C-arm (Hybrid room)	47	32.19 (IQR 14.31–49.42)*	-	-	-
		With Fusion	Fixed C-arm (Hybrid room)	105	23.44 (IQR 15.77–51.44)*	-	-	-
Hiraoka[21]	2018	Without Fusion	Fixed C-arm (Hybrid room)	62	-	880 ± 833	-	-
		With Fusion	Fixed C-arm (Hybrid room)	81	-	768 ± 529	-	-
Maurel[22]	2018	Without cloud-based fusion (Cydar)	Fixed C-arm (Hybrid room)	21	21.7 (8.9-85.9)*	142 (61-541)*	-	-
		With cloud-based fusion (Cydar)	Fixed C-arm (Hybrid room)	33	9.17 (6.83-14.74)*	70 (45-100)*	-	-
Hertault[23]	2018		Fixed C-arm (Hybrid room)	85	14.7 (IQR 10.0-27.7)*	107 (IQR 68.0-189.0)*	-	-
Ockert[24]	2018	EVAR	Mobile C-arm (Flat panel)	30	22.6*	139*	-	-

		EVAS	Mobile C-arm (Flat panel)	30	12.4*	67.7*	-	-
Tzanis[25]	2019		Not specified	17	124.3 (41.4-627.1)*		4.7±1.4¤	
Schulz[26]	2019		Fixed C-arm (Hybrid room)	50	96.6 (±90.3)			
Kaladji[27]	2019	With cloud-based fusion (Therenva)	Mobile C-arm (Flat panel)	49	70.9 (± 48.2)			
-		Without fusion (historical cohort)	Mobile C-arm (Flat panel)	103	67.3 (± 74)			
Wermelink[28]	2019		Fixed C-arm (Hybrid room)	77	43.3* (IQR 28.4-63.3)		13 to 45¤	
Tenorio[29]	2019		Fixed C-arm (Hybrid room)	24	105 (± 116)	373 (± 257)		
Rehman[30]	2020		Mobile C-arm	78	168 (± 111)			
			Fixed C-arm (Hybrid room)	208	82 (±75)			
Våpenstad[31]	2020	Patient specific rehearsal with virtual reality	Not specified	30	12* (2.9-50.9)			
		No rehearsal	Not specified	30	13* (3.4-31.5)			
Zurcher[32]	2020	Standard imaging protocol	Fixed C-arm	17	174 (±79)	795.8 (±371.5)		
		Restricted use of angiography	Fixed C-arm	26	132 (±108)	761.4 (±721.4)		
Tzanis[33]	2020		Fixed C-arm	73	153.2*			
Harbron[34]	2020		Fixed C-arm	81	75* (IQR 48-148)			
Peters[35]	2020	EVAR	Fixed C-arm (Hybrid room)	40	278* (IQR 254-348)			

		EVAS	Fixed C-arm (Hybrid room)	67	275* (IQR 240-326)			
Martinez[36]	2020		Mobile C-arm	42	61.5 (±42.4)			
Tantawy[37]	2020	Using CO2 and CEUS	Not specified	15		182* (±135)		
Rial[38]	2020		Mobile C-arm	165	80 (±58)	307 (±257)		
Doelare[39]	2020	Without Fusion	Fixed C-arm (Hybrid room)	41	139.8 (±186.8)	694.0 (±913.8)		
-		With Fusion		20	159.1 (±102.4)	810.7 (±496.7)		
Farah[40]	2020			143	39.1 (0.1–30.1)			
Haga[41]	2020		Fixed system	172	371.3 (± 186.0)	1101 (±540)		
Kakkos[42]	2021		Mobile C-arm	48	26.8 (20.8-38.1)			
Efthymiou[43]	2021		Mobile C-arm	87	36.6* (2.0–167.8)			

Table A1: Literature review of published dose reports after EVAR between 2016 and 2022. Results are reported in means with standard deviation (SD) or (*) in median with range, or interquartile range (IQR) if stated. ¤, Dose measurement above the lead protections; ł, Dose to the anesthesiologists; ǂ. ALARA : As Low As reasonable Achievable; KAP: Kerma-Area Product; CAK: Cumulative Air-kerma; CEUS: Contrast-Enhanced UltraSound; EVAR: Endovascular Aortic aneurysm Repair; EVAS: Endovascular Aortic aneurysm Sealing.

Author	Year	Groups	Imaging System	Number of patients	KAP (Gy.cm²)	CAK (mGy)	Dose to the operator (µSv)	Dose to the staff (µSv)
Kirkwood[44]	2016		Fixed C-arm	16	601	4970	21.5	13.2
			Fixed C-arm (Hybrid room)	25	372	2580	14.1	7.1
De Ruiter[5]	2016		Fixed C-arm	15	873.8 ± 652.5 (129.7–2590)	6000 ± 4700 (800 – 18000)	-	-
			Fixed C-arm (Hybrid room)	19	598.2 ± 318.5 (128.6–1362)	3700 ± 2500 (1000–10000)	-	-
Dias[11]	2016	Standard Dose protocol (FEVAR)	Fixed C-arm	36	283.24 (IQR 192.08-499.57)*	-	-	-
		Standard Dose protocol (BEVAR)	Fixed C-arm	23	638.91 (IQR 436.96-1002.66)*	-	-	-
		Low Dose protocol and Fusion imaging (BEVAR)	Fixed C-arm	21	241.72 (IQR 140.44-432.04)*	-	-	-
		Low Dose protocol and Fusion imaging (FEVAR)	Fixed C-arm	33	262.87 (IQR 202.98-367.69)*	-	-	-
Attigah[12]	2016	FEVAR	Fixed C-arm (Hybrid room)	25	39 ± 33	-	1020 ± 1530Ɨ, 690 ± 460ǂ	-
		BEVAR	Fixed C-arm (Hybrid room)	17	48 ± 38	-	1310 ± 1580Ɨ, 700 ± 650ǂ	-
Wang[45]	2018	FEVAR	Fixed C-arm (Hybrid room)	91	-	4159 ± 2573	-	-
		Fenestrated cuff	Fixed C-arm (Hybrid room)	12	-	6063 ± 3086	-	-
De Ruiter[18]	2018		Fixed C-arm (Hybrid room)	24	384.8 (265.2-522.3)*	2900 (2000-3700)*	297¤	171¤
Manunga[46]	2018		Fixed C-arm (Hybrid room)	84	-	1097 (IQR 978-1426)*	-	-

Ruffino[17]	2018		Fixed C-arm	25	567 (388–779)*	2882 (2011–4230)*	-	-
Kirkwood[47]	2018	FEVAR	Fixed C-arm (Hybrid room)	11	210*	1800*	120*¤	60*¤
		off the shelf FEVAR	Fixed C-arm (Hybrid room)	9	280*	2200*	220*¤	110*¤
		CMD	Fixed C-arm (Hybrid room)	60	370*	2950*	370*¤	210*¤
Schanzer[48]	2020	FEVAR		732	82.8 (±158.9)	2920 (±2987)		
		Fenestrated cuff after failed EVAR		161	154.6 (±218.5)	4750 (±18,304)		
Harbron[34]	2020		Fixed C-arm	66	119* (IQR 85-209)			
Juneja[49]	2020		Mobile C-arm	11		2160 (±930.0)		
Timaran[50]	2020	With magnification	Fixed C-arm (Hybrid room)	123		2458* (IQR 1706-3767)	266* (IQR 104-583)¤	
		With digital zoom	Fixed C-arm (Hybrid room)	28		1382* (IQR 999-2045)	101* (IQR 34-235)¤	
Sen[51]	2020		Fixed C-arm (Hybrid room)	334	182 (±96)	2100 (±1800)		
Tenorio[29]	2019		Fixed C-arm (Hybrid room)	85	174 (±101)	1134 (±815)		
Doelare[39]	2020		Fixed C-arm (Hybrid room)	37	91.5 (±348.4)	2337.2 (±1744.9)		

Table A2: Literature review of published dose reports after fenestrated or branched endovascular aortic aneurysm repair (F/BEVAR) between 2016 and 2022. Results are reported in means with standard deviation (SD) or (*) in median with range, or interquartile range (IQR) if stated. ¤, Dose measurement above the lead protections; ǂ, Dose to the anesthesiologists. ALARA: As Low As reasonable Achievable; KAP: Kerma-Area Product; CAK: Cumulative Air-kerma.

Author	**Year**	**Anatomical Regions**	**Procedures**	**Imaging System**	**Number of patients**	**KAP (Gy.cm²)**	**CAK (mGy)**	**Dose to the operator (µSv)**	**Dose to the staff (µSv)**
Ruiz-Cruces[52]	2016	Iliac		Fixed C-arm	48	105.7			
		Femoropopliteal	Recanalization	Fixed C-arm	57	83.9			

Maurel[53]	2017	Iliac	Patients treated in 2012	Mobile & Fixed C-arm	653	14.2 (± 18.9)			
			Patients treated in 2015	Mobile & Fixed C-arm	306	21.5 (± 37.6)			
Stangenberg[15]	2018	Femoro popliteal		Fixed C-arm	99		285.6* (IQR 152.7-486.8)		
				Fixed C-arm (Hybrid room)	35		106.0* (IQR 82.5-163.5)		
Kostova Lefterova[54]	2018	Femoro popliteal	PTA alone	Mobile C-arm	78	67* (0.6-711)			
			PTA + Stenting		20	78* (2.3-237)			
			Recanalization + PTA		39	75* (3.5-353)			
			Recanalization + stenting		52	121* (3.0-160)			
Guillou[55]	2018	Iliac	Serie n°1	Mobile C-arm	43	37.7	173.4		
			Serie n°1	Fixed C-arm	100	50	252.9		
		Femoro popliteal	Serie n°1	Mobile C-arm	56	21.5	93.8		
			Serie n°1	Fixed C-arm	99	20.2	98.1		
		Iliac & Femoro popliteal	Serie n°2	Mobile C-arm	24	19.4	66.6	0.2; 15.3¤	0.9
			Serie n°2	Fixed C-arm	76	24.2	125.8	0.3; 15.7¤	0.8
Goldsweig[56]	2019	Aortoiliac			3215	252.0 (±294.4)			
		Femoro popliteal			7203	145.6 (±212.2)			
Boc[57]	2019	Iliac	Angioplasty	Mobile C-arm	37	43.5* (IQR 28.6-87.4)			
			Stenting		161	54.9* (IQR 32.5-91.2)			
		Femoro popliteal	Angioplasty, antegrade approach		446	5.9* (IQR 4.3-8.6)			
			Angioplasty, retrograde approach		34	30.8* (IQR 22.2-48.3)			
			Stenting, antegrade approach		113	8.3* (IQR 6.0-12.3)			
			Stenting, retrograde approach		7	56.9* (20.0-93.7)			
Stahlberg[58]	2019	Iliac	With Fusion	Fixed C-arm	11	28.7* (IQR 19.7-42.2)			
			Without Fusion		15	43.8* (IQR 28.0-84.6)			

Tzanis[25]	2019	Aortoiliac		Not specified	36	23.1* (37.0-296.0)		4.4±3.6¤	
Farah[40]	2020	Iliac			130	14.4* (0.4–119.9)			
		Femoro popliteal			117	4.1* (0.1–146.8)			
Mougin[59]	2022	Iliac		Fixed C-arm	56	14*; 21.52 (±4.14)	237 (46)		
		Femoro popliteal			123	4*; 8.46 (±1.60)	80 (14)		

Table A3: Literature review of published dose reports after endovascular repair of lower extremities arterial disease between 2016 and 2020. Results are reported in means with standard deviation (SD) or (*) in median with range, or interquartile range (IQR) if stated. ¤, Dose measurement above the lead protections. ALARA: As Low As reasonable Achievable; KAP: Kerma-Area Product; CAK: Cumulative Air-kerma.

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