

Practical ways to reduce radiation dose for patients and staff during device implantations and electrophysiological procedures

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Despite the advent of non-fluoroscopic technology, fluoroscopy remains the cornerstone of imaging in most interventional electrophysiological procedures, from diagnostic studies over ablation interventions to device implantation. Moreover, many patients receive additional X-ray imaging, such as cardiac computed tomography and others. More and more complex procedures have the risk to increase the radiation exposure, both for the patients and the operators. The professional lifetime attributable excess cancer risk may be around 1 in 100 for the operators, the same as for a patient undergoing repetitive complex procedures. Moreover, recent reports have also hinted at an excess risk of brain tumours among interventional cardiologists. Apart from evaluating the need for and justifying the use of radiation to assist their procedures, physicians have to continuously explore ways to reduce the radiation exposure. After an introduction on how to quantify the radiation exposure and defining its current magnitude in electrophysiology compared with the other sources of radiation, this position paper wants to offer some very practical advice on how to reduce exposure to patients and staff. The text describes how customization of the X-ray system, workflow adaptations, and shielding measures can be implemented in the cath lab. The potential and the pitfalls of different non-fluoroscopic guiding technologies are discussed. Finally, we suggest further improvements that can be implemented by both the physicians and the industry in the future. We are confident that these suggestions are able to reduce patient and operator exposure by more than an order of magnitude, and therefore think that these recommendations are worth reading and implementing by any electrophysiological operator in the field.

Keywords Interventional electrophysiology • Radiation • Radioprotection • Exposure • Risk

Introduction

Over the last 20 years, interventional electrophysiology (EP) has expanded significantly, both in the field of diagnostic studies, ablations, and device implantation. Most of those interventions are being performed under fluoroscopic guidance. Moreover, newer X-ray based technology [such as pre-procedural cardiac computed tomography (CT) or per-procedural rotational angiography], that offer highly accurate three-dimensional (3D) images, are often used to improve the anatomical information in combination with the mapping systems or in the 2D–3D fluoroscopic solutions

(‘merging’). Combined with more procedures and more complex anatomical situations, this evolution leads to a higher cumulative radiation exposure, both of the patients and the staff. The patients may develop acute radiation injury, or have an increased risk of lifetime malignancy. Also, the staff are exposed to increasing radiation hazards, ranging from cataract to malignancy. Recent reports have for instance revealed that there may be an excess risk of brain tumours among interventional cardiologists.¹

On the other hand, there are many technological tools and new developments that may help to reduce patient and operator exposure. Different systems allow for non-fluoroscopic

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What's new?

- To evaluate radiation exposure, think 'effective dose' (in mSv), not 'fluoroscopy time'. Estimate effective dose by converting dose-area product values, with conversion factors adjusted for age and female gender.
- Reduce the frame rate of fluoroscopy to $\leq 3/\text{sec}$, reduce the energy per frame (ask for low-dose settings), do not use cine but store from fluoroscopy, and optimise collimation to only visualise what you really need to see.
- Adjust frame rate, energy per frame and collimation throughout the procedure: assign a nurse with that specific task.
- Also with a non-fluoroscopic system, exposure reduction measures are needed.
- Shield yourself (ideally behind a cabin or suspended system that also protects your head) and shield other cathlab personnel.
- Report the procedural effective dose in the patient chart and to your team at the end of the procedure: daily feedback is the best motivator to improve on radiation dose reduction.

('electroanatomical') localization of the catheters and the creation of 3D images. Magnetic resonance imaging is being used offline for 3D imaging, and being pioneered for online imaging during EP procedures as well. Moreover, also for the X-ray use, which will remain a mainstay of the EP procedures in the near future, there are possibilities for filtration, pulsed fluoroscopy, collimation, real-time digital fluoro processing, and more, that should be used in all the labs. Indeed, by properly implementing these techniques, electrophysiologists can reduce the radiation dose dramatically. Radiation should always be reduced according to the ALARA principle, i.e. 'as low as reasonably achievable'.

This does not mean that no radiation is the ultimate goal, since appropriate imaging is often crucial in performing complex EP procedures effectively and safely. The risk of radiation exposure always needs to be balanced vs. the benefits of the imaging itself. Radiological protection is based on three principles: justification, optimization, and responsibility for dose limitation. Physicians should be aware of their obligation to evaluate the appropriateness of radiation towards patients ('justification'), which can be guided by the 'diagnostic reference levels' (DRLs) as indicated by the European Directives and recommended by the International Commission on Radiological Protection (ICRP). Other texts have discussed the justification issue.^{2,3} On the other hand, technology by itself is not enough to reduce the radiation exposure in clinical practice: physicians need to be aware of how that technology can be used to effectively reduce the radiation dose. This text wants to focus on techniques to 'optimize protection'. Dose limits for staff are discussed in the section "Radiation in context: natural, medical, and professional sources of radiation", and should be used as a guide in the efforts to optimize protection. Our aim is to show that radiation dose reduction while maintaining sufficient image quality can be easily implemented in the daily cath lab setup and organization. There should be no excuse for not implementing it.

Radiation in context: natural, medical, and professional sources of radiation

Sources of radiation: why cardiology and electrophysiology?

The use of radiation in medical examinations and procedures is the largest man-made source of radiation exposure. It has increased six-fold over the last 20 years,⁴ accounting for a mean effective dose (ED) of 3.0 mSv per head per year,⁵ which is equivalent to the radiological risk of 150 chest X-rays (Figure 1), even higher than natural background radiation.⁶

Cardiologists are responsible for about 40% of the entire cumulative ED to the US population from all medical sources except radiotherapy. On top, cardiologists are also responsible for 85% of the nuclear medicine exposure.^{7,8} The most active and experienced interventional cardiologists have a personal annual ED of about 5 mSv, three times higher than radiologists and nuclear physicians, and they have a professional lifetime attributable excess cancer risk in the order of magnitude of 1 in 100.⁹ Recent reports have also hinted to an excess risk of brain tumours (predominantly at the more exposed left side) among interventional cardiologists¹⁰ and (left-sided) breast cancer in female cardiologists.^{11,12} Eye cataract can develop in one out of two operators after a lifetime exposure if the radiation protection tools have not been used.¹¹ Although the former data indicated comparable yearly exposure for the interventional cardiologists [performing diagnostic caths and percutaneous coronary interventions (PCIs)] and the electrophysiologists (performing ablations), there is a trend for decline in ablationists due to the introduction of non-fluoroscopic mapping (NFM) systems and lower need for cine imaging.^{9,13} With adequate measures, as outlined below, radiation exposure during ablation can significantly be reduced further. Nowadays, the main risk group in EP are those implanting devices.

Dose exposure and projected cancer risk for patients

The radiological ED of common cardiological procedures ranges from 1 to 60 mSv, with an average of 15 mSv for an atrial fibrillation (AF) radiofrequency catheter ablation, PCI, multi-detector coronary angiography, or a myocardial perfusion imaging scintigraphy (Table 1). However, for the same procedure, the ED varies by a factor of 10. As a general rule of thumb, the absolute lifetime risk of fatal cancer for an adult increases by 0.05% for every 10 mSv of exposure (vs. a background fatal cancer risk of about 20%).^{8,14} An ED of 15 mSv is associated with an excess (fatal and non-fatal) cancer risk of 1 in 750 men of 50 years old. Or expressed differently: for every 100 mSv exposure there is 1 additional cancer on 100, with half of these cancers being fatal. Moreover, that risk is 38% higher in females (1 in 500), three- to four-fold higher in children (1 in 200), but one-half in the elderly (1 in 1500 in an 80-year-old patient). Small individual risks multiplied by millions of examinations become a significant public health risk.

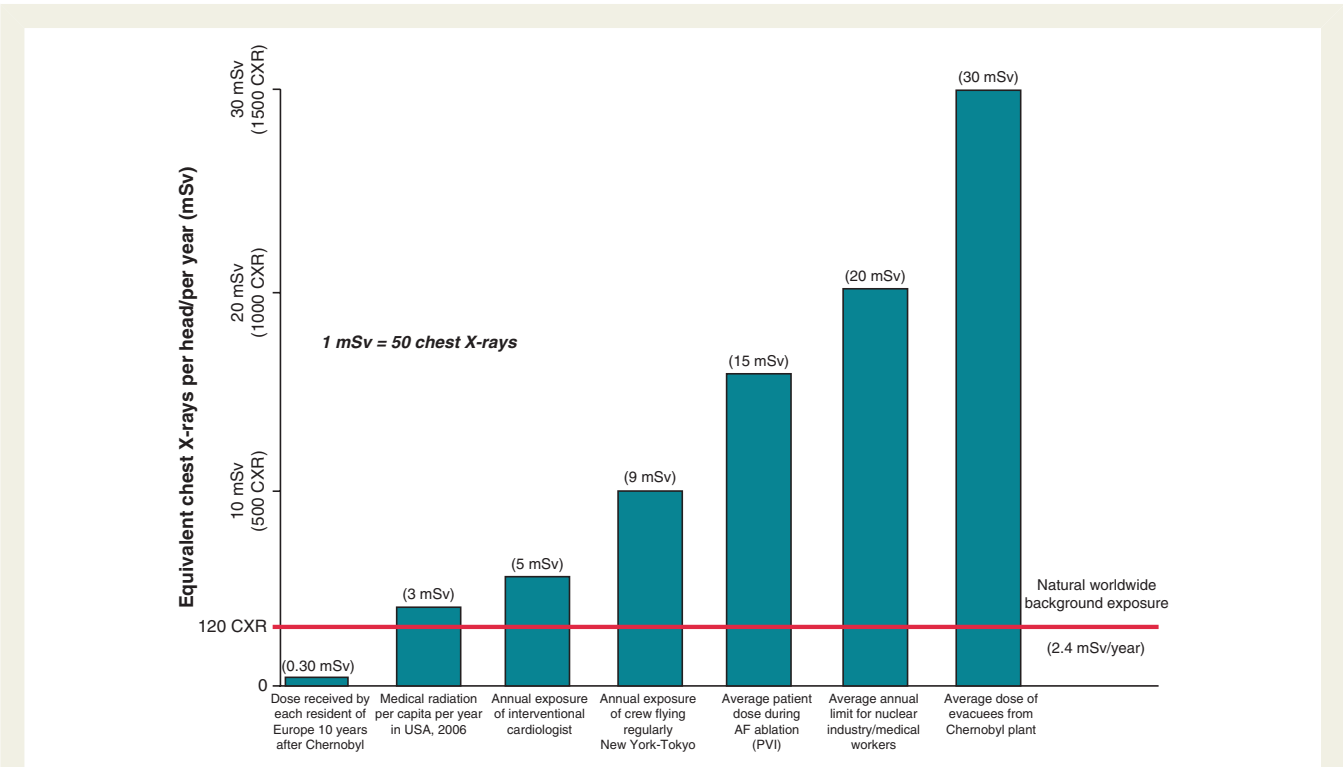


Figure 1 Medical, natural, and accidental sources of radiation. An ED of 1 mSv is equivalent to 50 chest X-rays. Modified from Picano,⁴ updated with Mettler *et al.*,⁵ and Peplow.⁶

Table 1 Typical EDs of some sources of radiation

Source	Typical dose (mSv)	Equivalent number of PA Chest X-rays	Equivalent period of natural exposure (years)
Medical			
Chest X-ray (posteroanterior, PA)	0.02	1	0.008
Sestamibi myocardial perfusion imaging (MPI)	9	450	3.75
64-slice coronary CTA	15 (3–32)	750 (150–1600)	6.3
Coronary angiography	7 (2–16)	340 (100–800)	2.9
Percutaneous coronary intervention (PCI)	15 (7–57)	750 (350–2800)	6.3
Cardiac radiofrequency ablation	15 (2–57)	750 (100–2850)	6.3
Dual isotope MPI	25	1250	10.4
Professional			
Annual exposure of interventional cardiologist/cardiac electrophysiologist	5	250	2.1
Annual exposure of airline crew flying regularly between New York and Tokyo	9	450	3.7
Average annual limit for nuclear industry/medical workers	20	1000	8.3
Average total dose received by liquidators at Chernobyl	120	6000	50
Upper annual limit allowed for Fukushima emergency workers	250	12500	104
Natural			
Average annual background radiation globally	2.4	120	1

PA, posteroanterior; MPI, myocardial perfusion imaging; CTA, computed tomography angiography.

Dose estimates in the electrophysiology laboratory: 'fluoroscopy time' is not adequate

According to a clinical competence statement of the ACC/AHA in 2005, the 'radiation dose delivery to a patient during a procedure is both a measure of stochastic risk and a potential quality indicator. Physicians should be made aware of the exposures they deliver to their patients and how they compare with the established norms'.¹⁵ Radiation in the catheterization laboratory is generated by using two different modes: fluoroscopy or cine angiography. Fluoroscopy is used for catheter placement and involves 95% of the total X-ray operation time in EP. However, it only causes roughly 40% of the total radiation exposure to the staff and the patients. Cine is used to acquire diagnostic images and to generate a permanent record of the procedure. Although it represents only 5% of the total X-ray tube operation time, roughly 60% of the total radiation exposure to the staff and the patients occurs during cine. Among the practical advices to minimize occupational radiation doses, there is the need to minimize fluoroscopy time but mainly the number of cine images.¹⁶

However, neither fluoroscopy nor cine times are tightly correlated with true radiation exposure. Exposure is also the result of good imaging chain geometry and settings, use of collimation, positioning of the operator in the low-dose scatter area, use of protective shielding, and—perhaps most importantly—appropriate training of the operator and the staff.¹⁷ Staff ED values may vary by a factor of 40 due to positioning during fluoroscopy and by a factor of 11 due to radiation protection equipment.¹⁸ In any case, the radiation levels in the EP room are not negligible and grossly comparable with those obtained during PCIs.

Radiological risk: from population to personalized risk

The challenging task ahead is to translate, for both patients and professionally exposed staff, the generic population risk obtained from

epidemiological age- and gender-based risk into a personalized risk. Several genetic, environmental, and dietary variables can affect the variability of damage observed to any given level of radiation. For instance, radiation-associated chromosomal damage in interventional cardiologists is amplified by smoking and by genetic polymorphism of the genes involved in DNA repair.¹⁹ It would lead us beyond the scope of this text, to delve into these personal risk factors.

Biological effects of ionizing radiation, and how to quantify those: what is a 'safe limit'?

Stochastic and deterministic effects

Biological effects of ionizing radiation can be classified as stochastic (carcinogenic and genetic effects) and deterministic (also called tissue reactions). The most widely accepted model for the stochastic effects is the 'Linear Non Threshold' model, i.e. any small amount of radiation involves an increase in cancer risk without any threshold, and the probability increases linearly with increasing radiation dose.^{14,20} For the deterministic effects (e.g. skin injuries, cataracts, etc.), there is a threshold of dose (below this threshold, the effect is not produced) and the severity increases with the dose (Figure 2). The threshold for skin injuries is considered at 2–3 Gy, but for radiation-induced opacities in the eye lens, the ICRP has recently proposed 500 mGy as the threshold.²¹ In this recent statement, the ICRP also gives the new dose threshold for the non-cancer effects of ionizing radiation in circulatory disease of 500 mGy to the heart, recommending particular emphasis on optimization in medical procedures.²¹

Radiation quantities and units

The radiation quantities and the units used to estimate the radiation risks in fluoroscopy-guided procedures are 'absorbed dose' or 'kerma' (at one point or as mean value for an organ or tissue) that

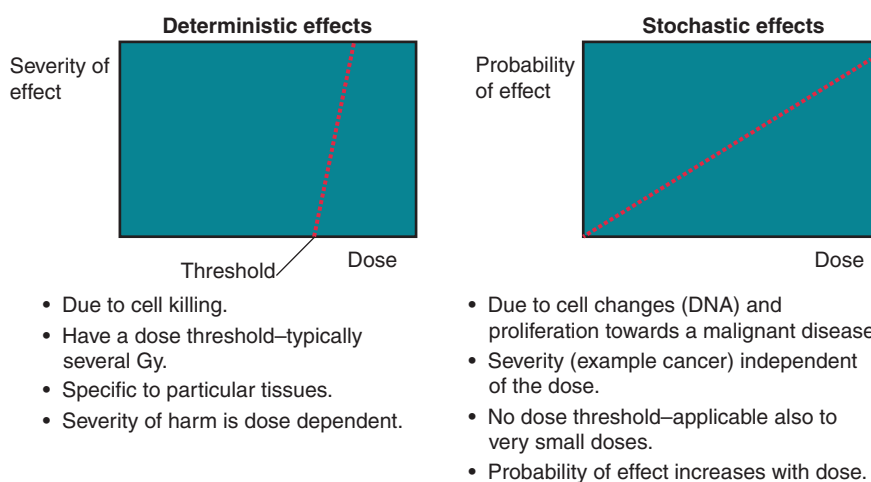


Figure 2 Deterministic and stochastic radiation risks. Source: IAEA free training material: https://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/1_TrainingMaterial/Radiotherapy.htm.

Table 2 Radiation measures

Radiation quantity	Most used unit	Comment
Equivalent dose	mSv	Allows to estimate risk in a tissue or organ
Effective dose (ED)	mSv	Allows to estimate global risk
Air kerma area product (KAP), or dose area product (DAP)	Gy. cm ²	Measured or calculated by the X-ray system (allows the calculation of overall risk, i.e. conversion to ED)
Cumulative air kerma	mGy	Measured by the X-ray system (allows to estimate the skin dose)
Personal dose equivalent	mSv	Measured by the personal occupational dosimeters

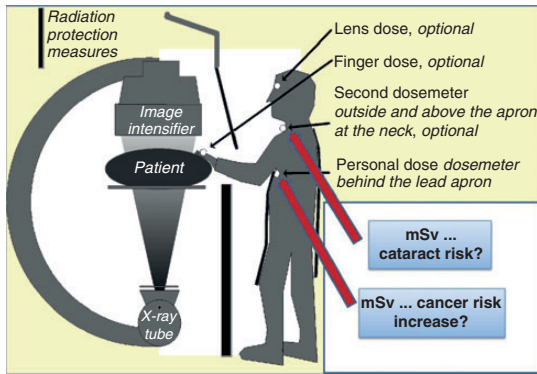


Figure 3 Recommended use of at least two dosimeters, one above and one underneath the lead apron. They allow risk estimation for the deterministic effects (such as cataract) and the stochastic effects (such as cancer risks), respectively.

represents the energy per unit of mass, typically measured in milliGray (mGy).²² When referring to organ doses, the term ‘equivalent dose’ is used, measured in milliSieverts (mSv). For X-rays, milliGray and milliSieverts are numerically equivalent. It is possible to combine the equivalent doses for all the organs and the tissues, taking into account their radiosensitivities, to obtain a global quantity called ‘effective dose’ (also measured in milliSieverts). Effective dose was introduced to estimate the radiological risk of workers, but it is also widely used to estimate the radiological risk for patients. *Table 2* offers a summary of these quantities and units.

All the modern X-ray systems provide information to the users on the amount of patient exposure during the procedures. The standard quantities are the air ‘kerma area product’ (KAP) also called ‘dose area product’ (DAP), which is typically reported in Gy.cm² (or in cGy.cm² or μGy.m², both of the latter yielding the same numerical values), and ‘cumulative air kerma’ at the ‘patient entrance reference point’, reported in milliGray.²³ These quantities are usually reported for fluoroscopy (in addition to the fluoroscopy time (FT)) and for

cine acquisition. All the dose values need periodic calibration of the imaging system. ‘Peak skin dose’ evaluation requires additional calculations made by a medical physicist.

For the staff, personal dosimeters give values of ‘personal dose equivalent’ (in milliSieverts), that can be used to estimate the organ doses (hands or eye lens), or EDs. The ICRP recommends the use of two personal dosimeters for the staff working in catheterization laboratories, one under the protective garment, usually at waist height, and another one outside any protective garment (which yields information concerning radiation to the eye and the brain), as shown in *Figure 3*.²² Effective doses are estimated with better accuracy when using the readings of both dosimeters. For some procedures, it could be convenient to also use a hand or ring dosimeter. Recently, real-time dosimeters have been developed, that provide immediate visual feedback to all cathlab personnel about their exposure.²⁴ It is worthwhile to explore in how far such feedback may help to change procedural workflow habits.

Dose limits for professionals and diagnostic reference levels for patients

Dose limits are applied to workers and to the members of the public. In Europe, the practical dose limit for ED in workers is 20 mSv/year. For the eye lens, a new annual dose limit for workers of 20 mSv/year has recently been recommended by the ICRP instead of the current 150 mSv/year.²¹

Dose limits do not apply to patients because the priority is always the clinical benefit, and radiation is only an ‘instrument’ to diagnose or to guide the procedure. Any medical procedure involving ionizing radiation should be based on the clinical benefit without forgetting the radiological risk for the patient (e.g. repeated life-saving ventricular tachycardia (VT) ablation in an elderly patient vs. repeated symptomatic persistent AF ablations in a young patient; e.g. ablation of incessant VT in a pregnant woman vs. haemodynamic deterioration of the mother). If this balance is positive (more benefit than risk), the procedure is justified. The ICRP recommends the use of ‘diagnostic reference levels’ (DRLs) to help in the good management of radiation exposure during diagnostic and interventional procedures. Diagnostic reference levels are applicable to groups of standard patients for a kind of procedure and not for individual cases. They are indicative of good practice. Diagnostic reference levels are a tool to help in optimizing the practice. If the patient dose values are consistently higher than the established DRLs (e.g. about the 75th percentile), the practice or the setting of the X-ray systems should be reviewed to introduce corrective actions. Sometimes, the optimization suggests the need for training (or re-training) of the professionals involved in the procedures. This is formally required by European legislation.²⁵ One limitation is that DRL range values may be difficult to compile for highly complex procedures with inherent large variation in exposure. In general, the radiation dose for an individual patient should never be a reason to stop any clinical procedure except in the case of an exceptional breakdown in the X-ray system. Some high values of patient doses (>500 Gy. cm² or >5 Gy as cumulative skin dose) may prompt clinical follow-up for potential skin injuries.^{26,27}

Most of the modern X-ray systems used for interventional procedures have the capability to produce complete patient dose reports with all the relevant dose values, such as radiographic parameters and

geometry factors (including angulations of the C-arm), allowing retrospective calculation of the peak skin dose if necessary. DICOM 'radiation structured dose' reports, allowing the transfer of information to the electronic information systems in hospitals, are already available.

From exposure, to dose, to risk: from kerma area product/dose area product to milliSieverts to risk

The most accurate estimation of radiological risk for patients is to calculate organ doses with a stochastic approach (Monte Carlo simulations), and from these values, to estimate the integrated radiological risk (quantified by an 'effective dose', ED), by taking into account the age and the gender of the patient. There are several computer programs allowing such calculations,²⁸ but such an approach is difficult to be used in routine practice. However, it is recommended for research and scientific communications.

In routine practice, the ED can most simply be derived with a conversion factor from the DAP or the KAP values (see above) provided by the X-ray system, which for adults is: $\text{mSv} = \text{KAP} (\text{Gy} \cdot \text{cm}^2) \times 0.20$.²⁹ The kerma area product readings should be included in the patient records, and the same can be done for the ED estimates using the appropriate calibration factor. Thus, a value of $10 \text{ Gy} \cdot \text{cm}^2$ (which is $1000 \text{ cGy} \cdot \text{cm}^2$ or $1000 \mu\text{Gy} \cdot \text{m}^2$) for a cardiac procedure of medium complexity represents about 2 mSv in ED. Although different conversion factors have been calculated depending on Monte Carlo-based refinements in the calculations, we recommend using the internationally accepted value of $0.2 \text{ mSv}/(\text{Gy} \cdot \text{cm}^2)$, realizing that the ED is intrinsically a very inaccurate quantity, i.e. with a 50% accepted inaccuracy as being 'normal'. For women and children, the conversion factor is higher since they have a higher risk of cancer development by radiation (see also above). The proposed estimates for different age groups are: 3.7 ± 0.2 in neonates, 1.9 ± 0.2 above 1 year, 1.0 ± 0.1 above 5 years, 0.6 ± 0.1 above 10 years, and 0.4 ± 0.1 mSv between 15 and 20 years.³⁰ On the other hand, the risk to the unborn foetus seems relatively modest provided that the radiation is reduced as much as possible and direct radiation to the uterus is avoided.³¹ For a maternal dose of 7 mSv for a coronary angiography, the foetal dose has been estimated to be around 1.5 mSv.³² Again, it should be balanced against the potential benefit of the EP intervention to the foetus (e.g. in case of serious arrhythmias in the mother): potential curative treatment should not be withheld because of inadequate balancing with overly conservative treatment options. For women, the relative risk is 1.38 compared with men, at all ages. Therefore, one could opt to adapt the conversion factor accordingly in female patients (e.g. $0.2 \times 1.38 = 0.28$ in adult women).

Sources and amount of radiation during electrophysiological procedures

Conventional fluoroscopy-guided procedures

Interventional electrophysiological procedures

Radiation exposure during EP procedures shows significant variation in clinical practice. Some ranges of doses for typical cardiac

Table 3 Typical patient radiation doses for common EP procedures

Type of study	Dose to patient mSv median and range
Diagnostic EP study	3.2 1.3–23.9
Ablation procedure	15.2 1.6–59.6
AF	16.6 6.6–59.6
AT – AVNRT – AVRT	4.4 1.6–25
VT	12.5 3–≥45
VVI/DDD PM or ICD implant	4 1.4–17
CRT implant	22 2.2–95
Coronary angiography	7 2.0–16
Percutaneous coronary intervention	15 7–57

Data summarized from different references.^{2,3,8,34–44}

procedures are reported in Table 3.³³ Ablative EP interventions expose patients to higher radiation than diagnostic procedures, with a median ED of 15.2 vs. 3.2 mSv, respectively.³⁴ The UK Health Protection Agency (former National Radiological Protection Board) lists the ED for a generic cardiac ablation procedure as 3–21 mSv,³⁵ but other authors reported a wider variation, ranging from 1.6 to 59.6 mSv.^{34,36–38,45,46} The substantial variation for the same type of ablation among centres, patients, and operators is highly dependent on training, the use of the available reduction resources, and awareness (Table 4). By using the multiple approaches discussed below, a reduction of the overall radiation exposure is feasible everywhere. Some technology can even lead to almost complete avoidance of any radiation exposure.

The estimated operator ED per procedure was 40–65 μSv in the UK report, as measured by dosimeters,³⁴ but varies again largely in other reports.

Device implantation procedures

The radiation ED for patients undergoing conventional VVI or DDD pacemaker implantation ranges between 1.4 and 1.7 mSv.^{36,47,48} Shielding is much more difficult to achieve during pacemaker or implantable cardioverter-defibrillator (ICD) implantation than during ablation, resulting in higher scatter exposure for the operator. Occasionally, mobile C-arms are used for device implantation, especially when performed in an operating theatre environment. This may however be associated with higher doses. Contrast injections with cine imaging, as in the coronary sinus for left ventricular (LV) lead placement, often require different imaging sequences at higher resolution and hence result in higher doses. The type of implant (*de novo* or upgrade), the number and the location of

Table 4 Factors modulating doses in the cardiac EP lab

		Lower doses	Higher doses
Operator-dependent	Operator background	Expert	Beginner
	Training with simulators	Yes	No
	Awareness	Radiation aware	Radiation unaware
	Written report	Includes KAP/DAP	Omits KAP/DAP
	Projection	RAO	AP or LAO
	Pulsed fluoroscopy	Low rate (≤ 6 fps)	High rate (> 12.5 fps)
	Cine duration	Short	Long
	Cine substitution by stored fluoroscopy	Yes	No
	Fluoroscopy during catheter withdrawal	No	Yes
	Collimation	Optimized, and adapted	Wide open, and fixed throughout the procedure
Patient-dependent	Pelvic radiation	Avoided	During introduction and removal of the catheters
	Anaesthesiologists/AP	Allowed to halt the procedure	Also exposed when in close proximity
	Body habitus	Lean	Obese
Technology-dependent	Arrhythmic lesion to be ablated	Supraventricular tachycardia	Atrial fibrillation or VT
	X-ray system	Tuned for the EP, inspected for QC and maintained	No specific EP settings, not tested, not maintained
	Combination with CT (pre-procedural/rotational)	No	Yes
	Non-fluoroscopic mapping systems	Yes (Ensite; Carto; Mediguide; . . .)	No
	Shielding	Above and below the table; cabin	Minimal, only above the table

leads [especially cardiac resynchronization therapy (CRT) devices], the underlying anatomy, and the experience of the operator all play a substantial role in the overall exposure to radiation.^{39,49,50} As a result, complex procedures, such as CRT implantation, may be associated with a high radiation dose, both for the patients (2.2–95 mSv)³⁶ and the physicians.⁴⁰

Cardiac computed tomography

Most studies reporting the ED of contrast-enhanced cardiac CT refer to coronary CT, with doses ranging from 5 to 32 mSv.^{8,41,51–54} However, in the field of EP, left atrial (LA) 3D visualization is the most commonly used sequence, performed to assist ablation procedures by integrating the 3D images into the navigation system. In this regard, imaging depends mostly on electrocardiogram (ECG)-gated acquisition which however increases the radiation ED if not prospectively triggered (non-gated or prospectively gated ± 4 mSv vs. retrospectively ECG-gated ± 15 mSv).^{8,55} Also, the setting of the tube voltage has an impact on the ED: a standard protocol of 120 vs. a 100 kVp protocol results in ED of 6.4 vs. 5 mSv, respectively.⁵⁶

Three-dimensional rotational angiography

Three-dimensional (atrial) rotational tomography (3DRA) has been recently introduced to obtain 3D images to guide ablation procedures. Three-dimensional atrial rotational tomography has been shown to provide optimal LA and pulmonary veins (PVs) anatomy and to correlate well with the images derived from pre-procedural acquired multislice computed tomography (MSCT) images.⁵⁷ The reported ED of an atrial 3DRA is 1.3–6.6 mSv.^{57–59} Similar rotational

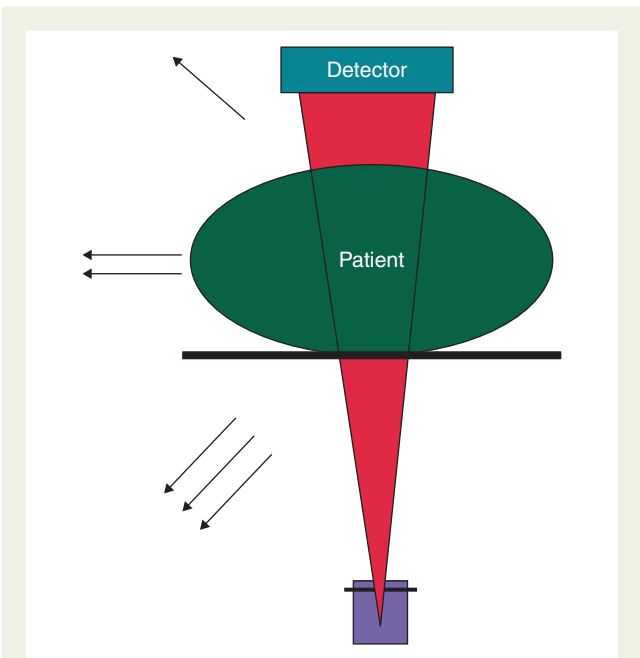


Figure 4 Scattered radiation. Scattered radiation is the main source of exposure for the operator and the other persons in the room. The arrows indicate the intensity of the scattered radiation. Most scatter originates from the beam entrance site, which is much closer to the operator during procedures from the groin for the LAO tube, but is closer to the operator during implantations in the shoulder region for the RAO tube.

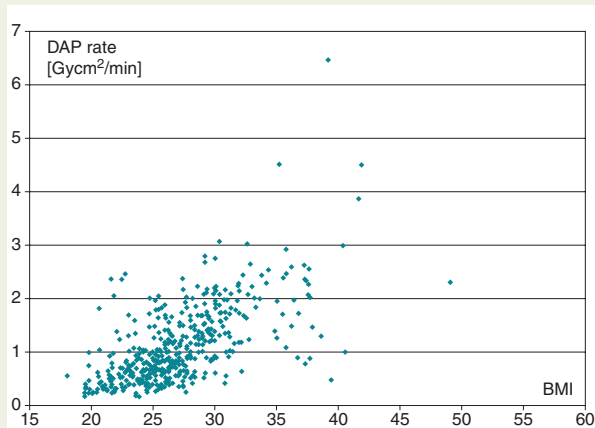


Figure 5 The impact of BMI on the radiation dose. The DAP values for 450 patients who underwent PV antrum isolation with sequential radiofrequency applications in the University Medical Center Utrecht, The Netherlands, are plotted against their BMI. Their difference in the radiation dose rate between patients with a BMI of 20 and 40 approximately is a factor of 6. The same factor also applies for the level of scattered radiation to the personnel in the cath lab.

imaging is now extended to all the four heart chambers, probably associated with similar ED values for each chamber.

Techniques to reduce the radiation exposure with conventional X-ray

Despite the 3D NFM systems, fluoroscopic guidance still is frequently used during many EP procedures. Therefore, the use of non-fluoroscopic technologies should not lead to complacency on radiation dose reduction measures. For patients, the primary beam is the only source of radiation. For the operator and the other personnel, scattered radiation from the patient is the main source of exposure and directly relates to the patient's DAP value (Figure 4). Therefore, the patient's constitution has a major influence on the dose rate for all the persons in the room (Figure 5),⁶⁰ and reducing the patient exposure will directly translate into reduced exposure of the cath lab personnel. Physicians will have to balance the imaging needs vs. the radiation exposure. X-ray equipment manufacturers are primarily concerned about image quality and their systems are usually tuned for coronary angiography and PCIs. Therefore, electrophysiologists should demand (i) customized settings for their fluoroscopy system to reduce the dose, (ii) consider workflow adaptations from their team, and (iii) ensure adequate protection for all throughout the procedure. During catheter ablation procedures, the cumulative measures described below can reduce the effective patient dose and the scatter radiation towards the workers in the cath lab by a staggering 95% or more!

Fluoroscopy system customization

Fluoroscopy systems include multiple variables to regulate the amount of radiation and image quality, such as the tube voltage

(kilovolts), the tube current (milliamperage), the pulse duration (milliseconds), and the copper filtration (that reduces the ineffective low-energy radiation). These settings are autoregulated via the signal received by the detector, mainly to compensate for the patient mass. The operator can select different **settings for the image quality levels** on the system. This implies different algorithms for autoregulation, determining the relationship between the radiation received by the detector and the settings for the X-ray tube. For example, higher kilovolts settings will allow lower current (milliamperage) and hence lower radiation exposure. The equipment thus includes a variety of options to tailor the system for specific applications such as device implantation and EP, settings that often are not present in a standard setup. Lower dose settings may result in grainier and flickering images, but in EP the margin of reduction to visualize the heart chambers and the catheters is much higher than for coronary arteries, guidewires, or stent visualization.

As a first step in reducing radiation exposure one should investigate the actual (auto-exposure) settings of the fluoroscopy system. Dose rate is displayed by the system itself and a quick analysis can be performed by using a 20 cm thick block of Perspex (Plexiglas) to simulate an 85 kg patient. With such a block in the optical centre and the detector in the anteroposterior (AP) position, the **entrance dose rate for the EP should be ≤ 3 mGy/min**. If a higher value is measured, it is advisable to demand lower settings from your supplier.

One should also consider the removal of the **antiscatter grid** from the image detector, a simple hardware adaptation.⁴² The slightly increased scatter is usually not a problem in EP settings, but will result in lower auto-exposure regulated doses. Discuss this with your vendor, since lowering detector entrance dose by choosing a different auto-exposure protocol (see above) may result in similar dose reduction while preserving image quality.

All the systems also include programmable **framerate settings**, from the nominally 25–30 frames per second (fps) down to 12 or 6 fps. Some systems allow lower rates, and even ECG (or pacing impulse) triggering. This may yield framerate of 3 or ≤ 1 fps (which in the case of triggering is also aligned with the cardiac rhythm). The framerate almost linearly relates to the exposure for the patient, the operator, and the other personnel. Therefore, a reduction from 25 fps (the nominal setting on many systems) to 3 fps (which still is comfortable during EP procedures) may be associated with a reduction of the radiation dose by up to a factor of 8 (depending on the dose/pulse compensation algorithms of the imaging system).

The systems usually have three different choices for **magnification**. With a smaller field size at higher magnification, the beam is focused on a smaller central portion of the detector and this smaller image is then enlarged to cover the complete screen. A factor 2 reduction in the field diameter (in cm) reduces the total exposed area by a factor of 4. However, depending on the system, this may be partially offset by increases in the beam intensity. As a result, the DAP often remains similar and so will the amount of scattered radiation received by the operator and the other personnel. Moreover, the patient entrance dose rate at the centre of the image increases significantly and this should be taken into consideration especially with long procedures and obese patients, because a local dose > 2 Gy may cause skin damage. Therefore, we do not recommend reducing the field size with increased magnification as a routine measure, but rather to collimate the X-ray beam if possible.

Workflow adaptations

Awareness

Electrophysiologists and cath lab personnel should develop a constant awareness to change settings and the degree of collimation throughout the procedure. There simply is no 'one setting fits all' during an intervention. To raise awareness for all the staff involved, it is desirable that the total DAP value (or the derived ED) be communicated to all at the end of a procedure and made part of the written procedure report.⁶¹ The parameters that need attention are described in the following sections.

Projection angle

During catheter ablation procedures, the left anterior oblique (LAO) (and in some studies also the posteroanterior imaging)³⁶ leads to a 40–50% higher dose rate for the patients than the right anterior oblique (RAO) projection because the spinal column and more cardiac tissue increase the tube settings. Patient doses depend on many other geometry factors and patient size, in addition to the projection angle. For the operator, the effect of the projection angle is the most relevant. With an LAO projection, the beam entrance site, where most scatter originates, is much closer to the operator than the AP or the RAO projection. The patient also poorly 'shields' that entrance site from the operator. As a result, the radiation towards the operator can be six times higher with LAO than with RAO. Minimizing LAO use thus greatly reduces both the patient and the operator exposure. With left-sided device implantation, RAO causes a higher dose rate for the operator than LAO, but the latter still causes more radiation for the patient and the other personnel because of the reasons mentioned above.

Magnification

Reduce the magnification to the lowest amount needed for accurate imaging (see above).

Cine

During cine, the radiation level usually is a factor of 10 higher than during fluoroscopy. Cine use should thus be limited as much as possible. This includes for instance angiography of the heart chambers or the PVs: it is also possible to store those as fluoroscopic movies, not cine. For many EP applications, that quality largely suffices. When high-quality cine is really needed, its acquisition should be kept as short as possible, with a reduced framerate and optimal collimation.

Detector position

The X-ray tube output is proportional to the distance between the tube and the detector. The detector should therefore be lowered onto the patient throughout the procedure. If table adjustments are required, there should be attention to lower the detector again after the table adjustments. Additional hardware, such as electroanatomical mapping systems, may result in the need to increase the tube–detector distance to prevent electromagnetic interference. Manufacturers should continue to look for technical solutions to reduce such compromises which increase radiation dose.

Collimation

There is a quasi-linear dose reduction with reduction of the irradiated surface area. In the beginning of the procedure a larger view may be desirable. Later, one usually focuses on a particular region; more collimation is then possible and desirable. Nurses and technicians should have autonomy and responsibility to adjust the collimation field while the EP operator is working. The availability of 2D–3D integration may allow for more informed collimation, since the required parts of the heart that need to be visualized are more obvious.⁶²

Framerate

The radiation dose for the patient, the operator, and the other personnel relates to the framerate of the fluoro or the cine acquisitions, *albeit* not always linearly due to the compensatory adjustments of dose per pulse depending on the system. The framerate should be set as low as possible. Most EP manoeuvres can easily be performed with 3 fps, and often 1 fps can be sufficient. Some vendors allow triggered fluoroscopy, with one image made during each QRS, pacing stimulus, or other trigger. During a transseptal puncture or during ablation in the vicinity of the AV node, however, a higher framerate may be desirable. Therefore, adjustments in the framerate are required throughout the procedure.

Auto-exposure settings

The auto-exposure settings that control the detector target dose rate also need adaptation throughout the procedure. When only catheters with big regular electrodes are being used, low-dose (grainier) imaging is sufficient, as demonstrated in *Figure 6* and online Supplemental Video S1. This needs to be tailored to the patient constitution too, with higher body mass index (BMI) patients requiring higher doses. In contrast, when smaller electrodes need to be visualized (e.g. on a multipolar catheter inside a PV), this may require switching to higher dose settings.

Sensitive area

Avoid screening the pelvic area during advancement of the catheters from the groin, especially in young women. With gentle rotation, aiming the catheter curve anteriorly, the catheter generally can be advanced without need for fluoroscopic guidance. Only perform fluoroscopy when really needed.

Rotational angiography

When rotational angiography is performed, the same considerations apply: collimate as much as possible (possibly after a test bolus of contrast during low-dose fluoroscopy to define the margins of the chamber of interest), and ask your vendor to provide low-dose rotational protocols.

As a result of all these adaptations, the total fluoroscopy time (FT) is certainly not the most important factor determining patient exposure (as erroneously used in many reports), but the number of frames, their collimation, and the dose settings will have determined the ED. Reporting the DAP values (or derived ED by using conversion factors, as outlined above) is much more meaningful for comparison than FT.

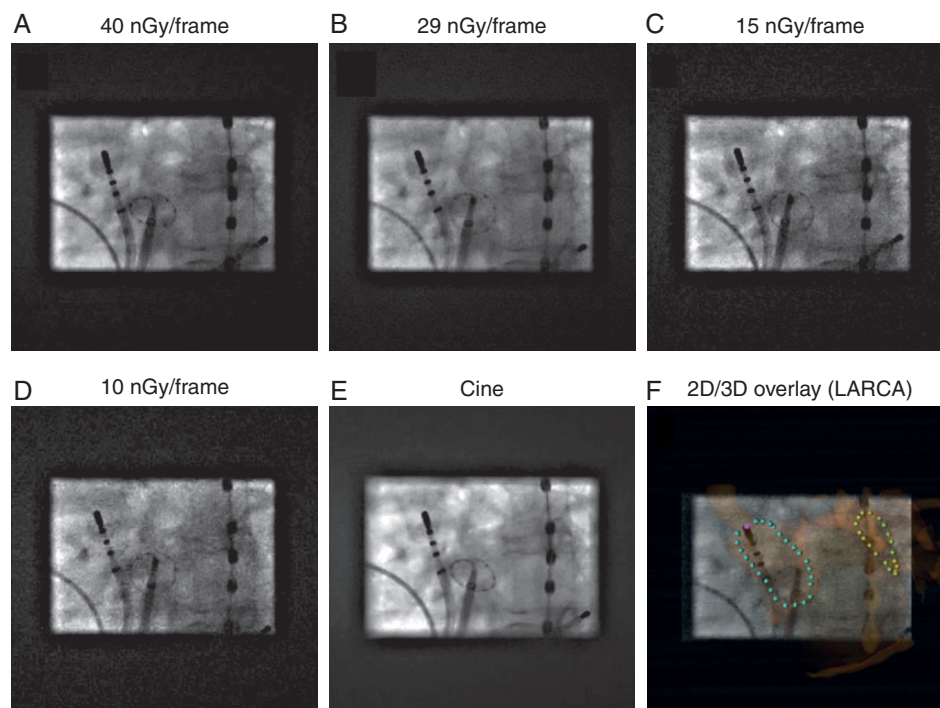


Figure 6 Fluoroscopic imaging with lower dose settings often suffices for EP applications (right PV isolation). See also Supplemental Video S1. The figure compares the images during fluoroscopy with four different settings that regulate the output for a detector entrance dose of 40 and 29 nGy/frame (standard values), 15 and 10 nGy/frame in panels A, B, C and D, respectively. The dose setting protocols also include adaptations in Cu filtering. (E) Same image with cine settings. The right PVs are being ablated, with a Lasso-catheter in the right inferior PV. Note that the optimized (symmetric) collimation in all images could easily be set due to 2D–3D overlay (here with LARCA),⁶³ as shown in panel F. Only the LAO images are shown. Although the image gets grainier with reduced dose settings, they still are largely sufficient to visualize the regular EP catheters. This can be appreciated even better in movie mode, as can be judged from the online Supplemental Video S1 (taken at 3 fps), that also shows the RAO acquisitions. In the lowest dose images, the Lasso[®] catheter becomes more difficult to see, although in this case of a slightly obese lady (172 cm, 77 kg, BMI 26) even the lowest dose setting allowed the identification of the individual electrodes. If required for verification or adjustment in more obese patients, one could temporarily switch to a higher dose setting. The optimal setting will largely depend on the patient's BMI. Therefore, the equipment should have many settings available, allowing the choice of the most appropriate one throughout different stages of the procedure.

Protection of the physician and the other cath lab personnel

Shielding is of crucial importance for exposure reduction, and can be achieved at different levels, as indicated in *Table 5*.

All the persons in the room must be protected, at least with a **lead apron**. The physician should also wear a **thyroid collar and leaded glasses**. One should be aware that this protection equipment undergoes wear and tear, requiring periodic inspections. Lead-containing protective gloves only reduce exposure to the hands by 10–30%, which should be balanced with the reduced tactile feedback by wearing thicker gloves.

The fluoroscopy systems should have two separate **shielding screens** to protect the operator, and both should be used correctly. A 0.5 mm lead screen absorbs >90% of the scattered radiation. The lower screen usually is connected to the table such that it moves with the table. Too often, however, that screen hinders table movement or is pushed aside by the X-ray tube under the table. This may lead to irritation and underuse. An elegant solution is to have the lower screen connected to the upper part of the table foot instead of to

Table 5 Protective shielding for electrophysiologists and other cath lab personnel

Structural shielding	Architectural wall shielding
Mobile shielding	Ceiling suspended leaded plastic
	Separate stand with shield/drapes
	Table-suspended drapes
	Radioprotection cabin suspended operator protection system
Personal shielding (not required if radioprotection cabin or suspended operator protection system)	Lead aprons
	Thyroid collars
	Leaded glasses
Culture of shielding	Careful personal and patient dosimetry
	Feedback of the dosimetry to the team and its mentioning in the written report
	Optimization
	Justification

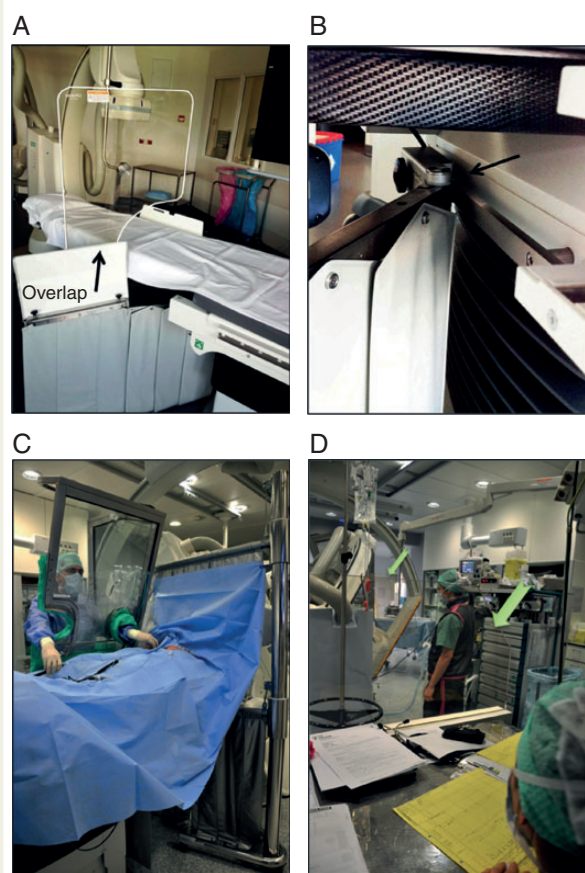


Figure 7 Shielding measures during EP procedures. (A) Lead-glass shielding screens above and below the table. Take care of the overlap between both screens. (B) Details showing the fixation of the lower lead screen to the upper part of the table foot (instead of to the moving table), avoiding hindrance by the screen during table movements. (C) Both the use of the lead flaps above and under the table, as the concomitant use of a radiation protection cabin, to optimally reduce exposure to the operator, but also to nurses working at the foot of the table. The height of the upper lead flaps support is adjusted so that the flaps just touch the patients belly, to minimize scatter towards the cath lab. Since the operator is fully protected and can perform the full procedure from within the cabin, he does not have to wear a lead apron, thyroid collar, or lead glasses anymore, while the cabin also reduces orthopaedic strain. Of course, in case the operator wants to perform part of the procedure without the cabin, or has to assist a co-worker who stands inside the cabin, lead protection is deserved. (D) Lead screens that protect the anaesthesiologist. One screen is put at the front of a small table; the other one between the patient and the equipment cart (arrows). The screens are moveable to allow for repositioning of the C-arms if needed.

the table itself. Then, it still moves up and down but not horizontally (Figure 7A and B). The upper shield should be mounted on an arm connected to the ceiling or a separate supporting stand. Both the screens should be placed such that the operator is optimally shielded from the radiation source (i.e. the patient's thorax). To improve shielding, lead flaps rather than a sturdy screen can be used: by adjusting the height of

the bar carrying the flaps above the patient, they can be adjusted to just touch the patient (Figure 7C).

Almost complete operator protection can be achieved by a **radio-protection cabin or suspended operator protection system**, that reduces exposure to near background levels, including complete protection of the eyes, the brain, and the axillary region (often partially unprotected with lead aprons) (Figure 7C).^{64,65} They have the added benefit of orthopaedic relief since the heavy lead apron can be totally omitted. All the aspects of the invasive EP procedures (including transseptal puncture and exchange of the sheaths) can be performed. Recently, a new type of cabin has been developed that also allows for device implantation, which was hard to do with the original cabin. Since device implantations currently form the major source of radiation for interventional electrophysiologists, evaluation of the practical usefulness of these cabins and suspended systems during implantations is highly recommended.

Cath lab nurses may receive high cumulative exposures when they also assist with coronary interventions where cine is frequently used.^{66,67} When **allied professionals and anaesthesiologists** are present throughout the procedure, they should create an arrangement in the cath lab so that they are: (i) maximally removed from the radiation source (patient) since radiation exposure is inversely related to the square of the distance (i.e. doubling the distance reduces scatter exposure by a factor of 4) and (ii) fully shielded by additional lead screens if possible (Figure 7D, arrows). This will also guarantee mobility of the setup, e.g. when moving the C-arm(s) during the procedure (such as during rotational angiography in a biplane room). Since the anaesthesiologists sometimes move around the patient, they should wear lead aprons too.

Moreover, allied professionals and anaesthesiologists should **signal to the operator** their intent to approach the patient, so that fluoroscopy can be temporarily halted if possible.

Effective use of non-fluoroscopic guiding technology to reduce radiation exposure

Existing systems and related radiation doses

The two non-fluoroscopic mapping (NFM) systems now in common clinical use are the Ensite-NavX system (St Jude Medical) or the Carto system (Biosense-Webster). The competition between these systems has led to a 'mapping race' resulting in the systems developing increasingly similar characteristics including the ability to visualize multiple non-proprietary catheters. In addition, a new sensor-based NFM approach, developed by MediGuide and St Jude Medical, is entering the market. There have been a number of studies demonstrating the benefits of the original NFM in terms of fluoroscopy reduction, and there is a huge potential for the MediGuide system to achieve even larger radiation dose reductions since it projects the real-time catheter movement on stored fluoroscopy loops.⁶⁸ Nevertheless, using NFM technology by itself does not automatically lead to a sufficient nor significant radiation dose reduction.^{43,68,69} The operators need to develop procedural workflows to rely on non-fluoroscopic guidance as much as possible, and implement additional

measures to reduce radiation when fluoroscopy is used (as discussed in the above “Techniques to reduce the radiation exposure with conventional X-ray” section). Education in this respect is very important (see below). Also, the procedure costs are increased with NFM. Whether radiation reduction through the use of NFM is cost/effective is not proven.

Regular supraventricular tachycardia

Localisa (an earlier version of the technology now used for Ensite NavX) has been shown to reduce fluoroscopy times (FTs) more significantly for ablation of atrioventricular nodal reentry tachycardia (AVNRT) (10 vs. 24 min) than for Wolff–Parkinson–White syndrome (WPW) (23 vs. 27 min).⁷⁰ The Carto NFM system has also been shown in a randomized comparison to reduce both the FT and the X-ray dose for both paroxysmal supraventricular tachycardia (8.6 vs. 22.5 min) and WPW (5.5 vs. 29.5).⁷¹ The use of NavX originally was associated with a greater reduction in fluoroscopy dose, with even X-ray-free procedures possible,⁷² but this may now also be true with the newer versions of Carto NFM. One study has even reported average FTs of 29 s (range 0–300 s) with 76% of patients requiring no fluoroscopy at all.⁷³ Ablation of atrial flutter with the NFM systems is also associated with a reduction in the FTs.⁷⁴ The ongoing NO-PARTY trial aims to provide a more sophisticated examination of the benefits of NFM and radiation reduction by using elements like DNA damage to estimate the life-long benefits in younger patients.⁷⁵

Atrial fibrillation/tachycardia

Complex and long procedures can benefit most from NFM technology to reduce the radiation exposure. On the other hand, the transseptal puncture associated with AF ablation requires X-ray. It is possible to use the NavX system to track the position of the transseptal needle, and the use of intracardiac echo and NFM make it possible to perform AF ablation without radiation.⁷⁶ In one series, 19 of the 21 AF ablations were performed without fluoroscopy by using this approach. Whether it is cost/effective to perform radiation-free AF ablation remains unknown.

Ventricular arrhythmia

There are little data examining the impact of NFM technology on ventricular arrhythmia ablation because such systems are now considered to be the standard of care in these complex interventions. Non-fluoroscopic mapping systems have other benefits and radiation reduction is not the sole reason for using these systems. There is a small subgroup analysis ($n = 11$) demonstrating that FTs dropped from 37.7 to 14.5 min with NFM.⁷¹

Other guidance systems

Magnetic resonance imaging (MRI)-guided catheter ablation offers promise for high-resolution catheter imaging with minimal or no radiation, but is still under development and not ready yet for widespread clinical use.⁷⁷ Technical hurdles related to interference of the electrical and the imaging systems need to be cleared. Moreover, the cost–benefit of such approaches will merit evaluation.

Systems allowing remote navigation through a joystick by moving special catheters by electromagnetic fields (e.g. Niobe system from Stereotaxis and Magnetecs CGCI system), or regular catheters by

mechanical devices (e.g. the Hansen Medical Sensei system), do not necessarily lead to reductions in the radiation dose. Indeed, in most cases, the catheters are still moved under fluoroscopic guidance, and/or a combination of classical radioscopy and NFM. A study in 30 patients undergoing EnSite-guided ablation of RVOT-VT reported that magnetic navigation was associated with a 50% reduction of fluoroscopic exposure compared with manual catheter manipulation (although there was a higher failure rate of ablation, with the need for crossover to manual catheter handling in 5 of the 15 patients).⁷⁸ If a more accurate description of the target sites in the (moving) heart could be developed, or when these systems could rely almost exclusively on NFM technologies, it is conceivable that later implementations may use more automatic robotic navigation, which could reduce the radiation dose.

Pitfalls of the non-fluoroscopic systems: no dose reduction if no awareness of other measures

Use of the NFM systems does not automatically reduce the radiation dose and every other measure to reduce the dose should be employed, as outlined in the “Techniques to reduce the radiation exposure with conventional X-ray” section. The radiation dose required to eliminate a patient’s arrhythmia not only includes the procedure dose but also that of any pre-operative investigations. Computed tomography scans are often used to merge with the NFM system to provide a more accurate geometry. This additional dose can be avoided by using MRI. However, the NFM systems now produce a geometry of sufficient quality where these merging strategies are not necessary anymore in more experienced centres. Moreover, the approach of merging 3D cardiac CT images with NFM has not shown to have an effect on the procedural outcomes.⁷⁹

Towards effective dose reduction approaches with these systems

Education

The trainees’ first experience of cardiac procedures often involves X-ray as the sole method of imaging, e.g. diagnostic coronary angiography. This means that the trainees develop habits of dependence on fluoroscopic systems at the very beginning of their training, which takes some time to break. The development of increasingly sophisticated simulators could allow the trainees to familiarize themselves with the NFM systems for complex EP procedures at an earlier stage in their training and thus make this instinctive dependence less prominent. Indeed, radiation reduction by NFM is possible during:

- (1) *Creation of a cardiac chamber geometry:* A geometry for LA ablation of AF can be produced by using a PV catheter which has a circular/flat tip and is at low risk of cardiac perforation, as is illustrated in Figure 8. On the other hand, when the ablation catheters are used to create a geometry, e.g. right ventricular VT ablation, fluoroscopy can be useful for improving safety. Force sensing technologies may overcome this risk but this is yet to be proven. Entanglement within the mitral valve apparatus is still a potential risk during geometry sampling. The left atrioventricular annulus is far more accurately defined by electrograms

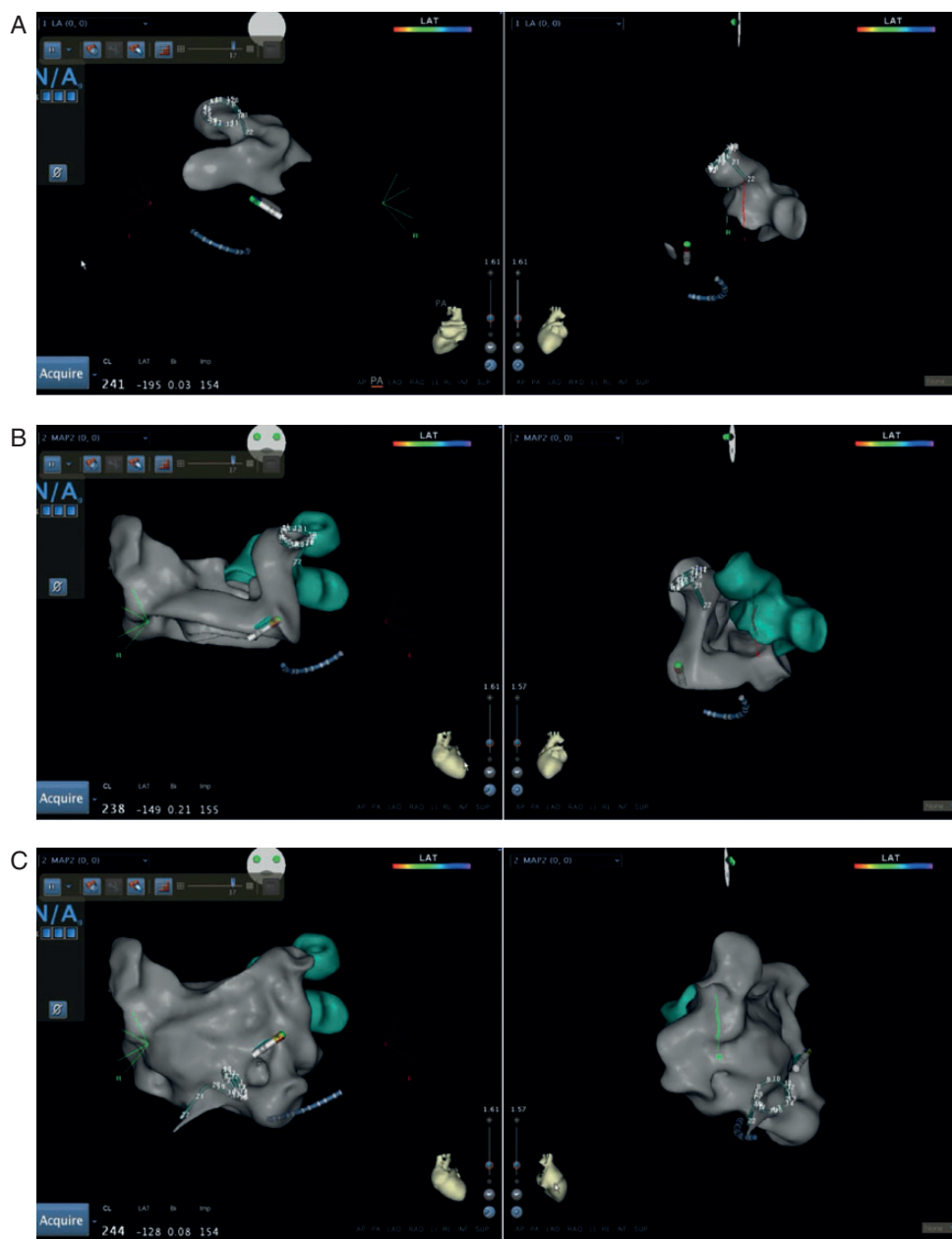


Figure 8 Radiation free construction of an LA geometry using an NFM system. See also Supplemental Video S2A and B, A geometry of the LA is being created on the Carto3 system by using the PV mapping catheter. Up to this point in the procedure, 2 min of fluoroscopy have been used to perform the transseptal punctures. From now on the AF ablation is radiation free. The geometry is created in two stages for the Carto3 to refine the anatomy between the left PVs (LPVs) and the LA appendage. (A). Creation of the left PV geometry. In this case the PV catheter starts in the left lower (LLPV) and is rotated and pushed back and forward to fill out the PV geometry. It is then pulled further back and rotated clockwise until it flicks up into the anterior and more superior left upper PV (LUPV). (B). The LPV geometry is shown and is a reference point for the rest of the geometry. The body of the LA geometry is now created. The PV catheter is rotated clockwise and pulled back until it turns into the RUPV. The catheter is then withdrawn, deflected and turned slightly anticlockwise until it is seen to drop off the RUPV. It is seen to drop briefly into the RLPV but then flicks out. Rotation clockwise allows it to turn back into the RLPV. It is then pulled out and rotated anticlockwise to move it to the anterior LA and advanced into the LAA. (C). Once these five anatomical reference points have been marked the rest of the geometry is easily filled in. The first step for this is to pull the PV catheter out of the LAA and fully deflect it while gently advancing it. The catheter inverts and can then be pulled back in this orientation to the septum without concern that it will come back through the transseptal puncture. The catheter tip will stop moving when it hits the septum and can then be advanced and retracted while rotating it to fill the septal aspect of the LA. The catheter can then be straightened and pulled back to the septum so that the shaft of the PV comes slightly back through the transseptal puncture and a tongue of tissue is seen extending back through the septum. This allows the site of the transseptal puncture to be marked so that the catheters can be advanced back into the LA without the X-ray if they are withdrawn to the right heart. The operator can now position the PV catheter in one of the PVs and the ablation can begin.

and the location of a coronary sinus catheter on NFM than by fluoroscopy.

- (2) *Energy delivery*: Many operators are anxious about the chamber geometry errors that inevitably occur with the NFM systems. The natural response is to look on the X-ray system to check the catheter position even though the fluoroscopy gives far less anatomical accuracy. It is important to remind the trainees that the catheter movement within a geometry is as important as its absolute location, i.e. if a catheter stops moving, then it has made contact with an obstacle thus defining the true position of the endocardium.
- (3) *Withdrawal of the catheters*: Even small periods of fluoroscopy that are not necessary can be cumulative and result in a large dose at the end of a long procedure. For example, there is rarely a justification for using X-ray just to withdraw a catheter.

Refinement of the technology

There are a number of key areas requiring development to refine NFM, and hence, to improve operator confidence in using NFM instead of fluoroscopy:

- (1) *Geometry accuracy*: Inaccuracies may be the result of fluid balance changes, patient and respiratory movement during geometry acquisition, or the inaccuracy of catheter location.
- (2) *Registration*: Gating to the respiratory cycle during geometry acquisition is now possible but moving the geometry with the heart's movement during respiration is still under development. Correcting for patient movement is improving with each generation of the mapping systems.
- (3) *Force/contact sensing*: This will provide confirmation of the catheter contact that would otherwise have been provided by fluoroscopy. Force sensing is likely to reduce FTs.⁸⁰
- (4) *Sheath visualization*: Sheaths are frequently used to help manipulate the catheter but are not visualized on the NFM systems, requiring additional X-rays. Robotic/magnetic navigation systems may be associated with lower fluoroscopy doses because either a sheath is integral to the ablation catheter (and therefore in effect visualized) or not used at all for the ablation procedure.
- (5) *Magnetic resonance imaging and other imaging guidance*: Integrated imaging remains a promising avenue of research to optimize the anatomical accuracy of the NFM.

Suggestions for future improvements

Radiation protection is a serious issue for all the workers in a cath lab. In clinical EP, 'ablationists' may in fact receive the lowest dose of cath lab personnel today when the fluoroscopic equipment is appropriately tailored for the EP procedures (see the "Techniques to reduce the radiation exposure with conventional X-ray" section) and because they have the availability of NFM (see the "Effective use of the non-fluoroscopic guiding technology to reduce the radiation exposure" section). In contrast, device implantation and especially the insertion of the LV epicardial electrode, causes the highest exposure today. Device implantation procedures thus are the first priority for future exposure reduction measures in EP, and the EP

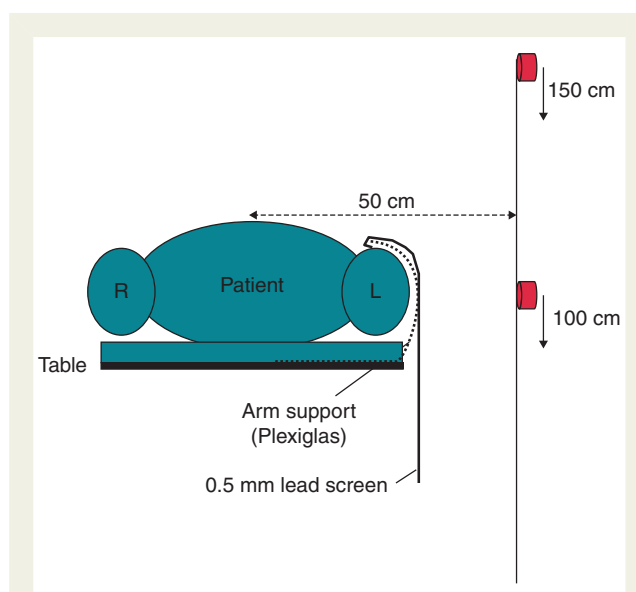


Figure 9 Optimization of the lead protection during device implantation procedures. Cross-sectional view of a patient on the fluoroscopy table. The operator usually stands on the left side of the patient and therefore the dose rates were measured at that side at 100 and 150 cm above the floor with the patients heart in the isocentre. The dosimeters are sketched in red. The custom 0.5 mm lead screen, made of 50 × 50 cm apron material, hangs on a custom Plexiglas arm support and shields both the upper part of the patients arm as well as the left side of the patient from the operator. That screen reduced the operator exposure with 22–94% depending on the projection angle and the measurement position (Table 6).

insights in doing so should stimulate the dose reduction measures in the rest of interventional cardiology too.

Device implantation

For LV lead placement, multiple cine loops are often required for venous angiography and for visualizing the course of the venous guidewire. The guidewires have the poorest visibility. Development of guidewires with a 20 cm long distal radiopaque section (instead of the usual 1–2 cm) would allow for significantly lower fluoroscopic doses. Device implantation also does not allow for the standard lead screens that are common with groin catheterizations. An alternative protection measure, using a custom 0.5 mm lead cover is shown in Figure 9. This reduces the radiation exposure for the operator with 22–94% depending on the projection angle and the measurement location (Table 6). Other measures may also include specially designed radioprotection cabin and (suspended) protection screens. The industry and the physicians should be urged to evaluate such solutions during device implantations, and continuous improvements to such solutions.⁶⁵

Newer NFM systems, like the MediGuide system, make use of very tiny location sensors which can be embedded even in guidewires. Combined with their highly accurate localization in relation to the fluoroscopic imaging field, the system allows 'virtual fluoroscopy' where the guidewire (or other catheter) is visualized on a recorded

Table 6 Measured doses with and without an arm rest lead screen during device implantations, as shown in Figure 9

Projection	Measurement height (cm)	Dose rate without the screen (μSv/h)	Dose rate with the arm screen (μSv/h)
AP	100	195	12
AP	150	90	70
RAO 45	100	425	55
RAO 45	150	230	75
LAO 45	100	160	23
LAO 45	150	7 ^a	8 ^a

Measurement of the operator exposure with the Rando phantom to simulate the situation during device implantation. During these measurements, the heart was in the isocentre and the detector was lowered as much as possible. The measurements were performed without and with a 50 × 50 cm 0.5 mm lead screen around the patients left arm as sketched in Figure 9, at three different projection angles. The dosimeters were placed at a 50 cm horizontal distance from the centre of the patient thorax and two different heights above the floor level. The custom screen reduced operator exposure with 22–94% depending on the projection angle and the measurement location.

^aThe detector shields the dosimeter. Note that the absolute values of the dose rate may be very different depending on the particular setting of the fluoroscopy mode of the X-ray system.

fluoroscopy loop. Such a technology may prove pivotal in reducing radiation dose in implantation procedures, which was not possible with the existing NFM so far.⁸¹

Framerate

As discussed in the “Techniques to reduce the radiation exposure with conventional X-ray” section, EP catheter manoeuvring can easily be performed at 3–4 fps, and even 1 fps or triggered fluoroscopy can be sufficient, especially when non-fluoroscopic 3D catheter localization is available. The fluoroscopy systems should therefore offer more easily accessible options for these different framerates to reduce practical barriers in using those during EP interventions.

Imaging technology improvements

X-ray companies continue to improve their imaging systems, both concerning emitter and detector technology as through more complicated image processing techniques, leading to better noise reduction and allowing comparable image quality with substantially lower radiation.^{82,83} Physicians should follow these evolutions and make purchase decisions also based on these features.

Collimation

Although collimation is available in all the radiographic imaging systems, its implementation is largely suboptimal. In many cath labs, collimation setting can only be performed from the command panels next to the table, not from the control room. Often the interface is non-intuitive, with the nurse or the technician struggling to quickly adapt the collimation field. This hampers frequent adjustments throughout the procedure. Moreover, optimal collimation in a biplane setup requires precise placement of the area of interest in

the iso-centre and can thus only be achieved by moving the table. Table repositioning is then required when the target area shifts, e.g. from one pair of PV ostia to the other. Collimation thus adds complexity and may lead to ‘collimation negligence’. Therefore, we call for an easier implementation of the collimation settings by cath lab vendors, with a simple and intuitive graphical user interface.

Collimation also limits the view on other catheters and the cardiac contour. The operator may want to quickly check those. Then, however, one has to open the view and re-collimate thereafter. Fluoroscopy systems should enable storage of different collimation settings and allow a quick switch between a saved collimated and uncollimated view. Multiple collimation settings could be saved (for different targets).

It should also be possible to set collimation asymmetrically, which is impossible nowadays but could be easily provided since the hardware is present in most systems. A recent study indicated that asymmetric collimation during PVI procedures can result in a further 60–80% dose reduction of the fluoroscopy stages of a procedure over symmetric collimation (Figure 10)⁵⁹. It would also eliminate the hassle of table repositioning with a switch of the target area. To facilitate the use of asymmetric collimation on mono-plane systems, collimation would have to switch automatically from one setting to the other when the system is rotated from RAO to LAO. Last but not the least, collimation could be optimized based on 3D heart chamber information, when 3D–2D image integration is used.⁵⁹ We thus call for the implementation of much improved collimation technology by the system suppliers.

Angiography by stored fluoroscopy

In order to store angiographic or ablation loops one often uses cine with its much higher image quality and automatic storage, but at the cost of an ~10-fold higher radiation dose. Often however, the lower fluoroscopy quality suffices, as was discussed in the “Techniques to reduce the radiation exposure with conventional X-ray” section. The electrophysiology fluoroscopy systems should therefore also allow for automatic or easy storage of the complete fluoroscopy runs. The new systems allow to archive any fluoroscopy run in a similar way as a cine run, in DICOM. When high-quality cine is really needed, its acquisition should be kept as short as possible, with 6 or even 3 fps, and with optimal (asymmetrical) collimation.

Radiation risk mentioned in the informed consent

Informed consent for radiological examinations is often not sought, even for considerable levels of radiation exposure (>10 mSv ED, with associated long-term cancer risks of >1/1000).⁸⁴ It is preferred to communicate the risk for each examination by reporting the dose in multiples of the dose from a chest X-ray, rather than by stating the risk of extra (fatal and non-fatal) cancer since the ED estimation for patients is very inaccurate as is the estimation of increased cancer risk for an individual patient.⁸⁵ Instead, the consent form should report the DRL as recommended by the ICRP for that specific procedure. The development of simpler and more informative consent forms, discussed and signed before each procedure, will gently move the physician to be more aware of what (s)he does, and the patient more aware of what (s)he undergoes, enabling both to

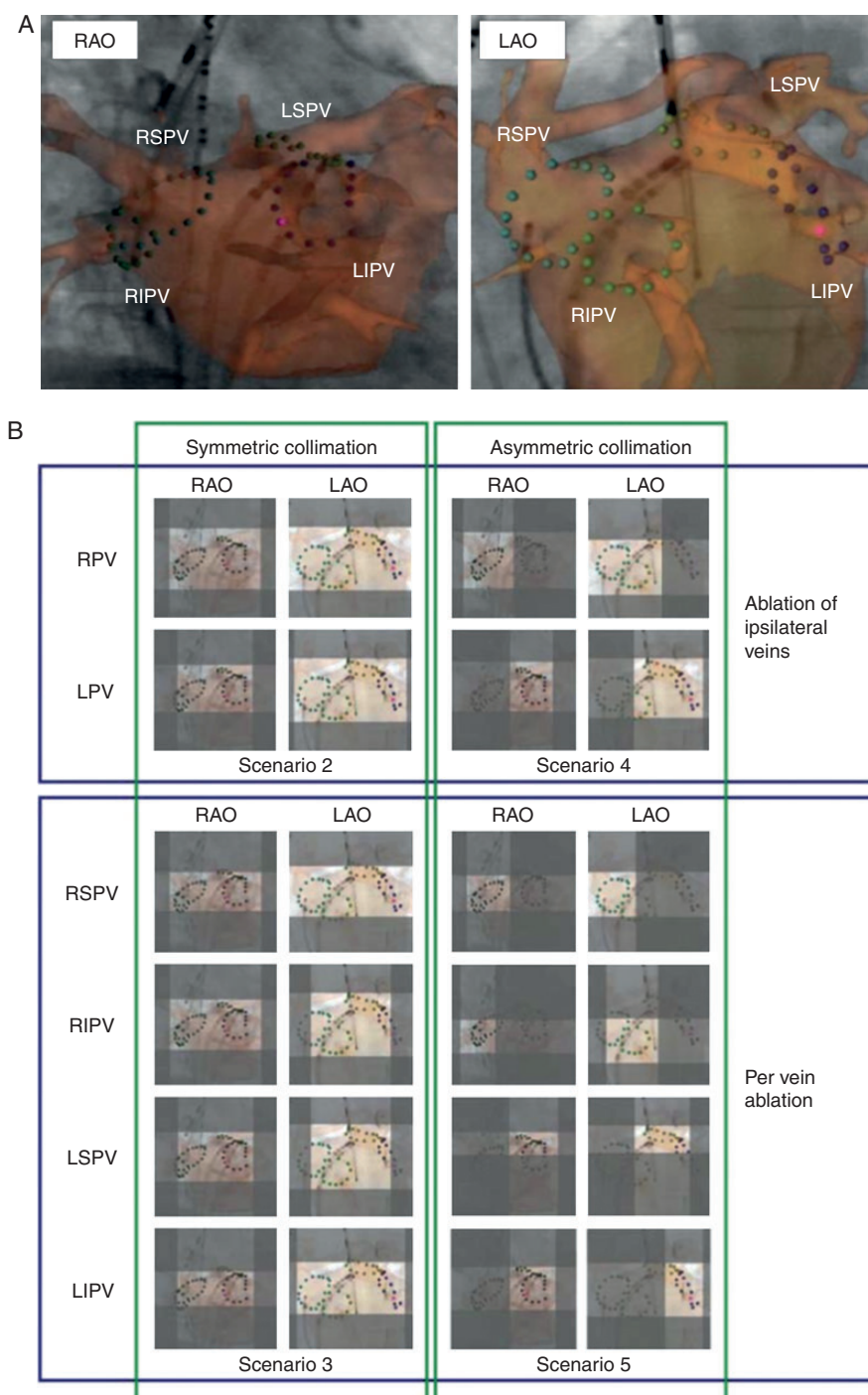


Figure 10 Importance of collimation: symmetrically or asymmetrically, (A) Fluoroscopic images in RAO and LAO view with a superimposed 3D image of the LA, the PVs, and the ostia. The collimation is wide open, revealing all the intracardiac catheters. Often such a view is used throughout a whole ablation procedure. However, mapping and ablation usually focuses on a particular part of the heart. With all the other catheters in stable position, the collimation field can be further reduced as is shown in (B), when the target is the ablation of both the ipsilateral veins with a common encircling, or when the individual veins would be targeted. The left side of the panel shows what can be achieved by classical collimation where the lamels can be adjusted only in pairs (horizontal and vertical), with equal movement of both sides ('symmetric collimation'). This results in a reduction of the field to (only) 22–43%, with near proportional reduction of the radiation dose. With movement of the table, further optimization would be possible. However, moving the table implies another intervention, which hampers its (repeated) implementation during a procedure. In biplane setups, table movement is not desirable since the isocentre position gets lost, with difficult repositioning of the table to guarantee optimal collimation in both planes. Therefore, a much more practical solution would be the implementation of asymmetric collimation, as illustrated on the right side. It could reduce the radiation dose for isolation of the four PVs by 66–89%. Such an asymmetric collimation could be implemented in a user-friendly software interface, and even semi-automated in case a 3D image of the heart chamber (from rotational or pre-acquired CT) has been registered as in this figure. Adapted from De Buck *et al.*, with permission.

make more responsible choices.⁸⁶ After the procedure, the radiation truly delivered to the patient (at least as DAP; and possibly also in estimated milliSieverts by conversion, although not required by the ICRP) as well as the patient entrance skin dose should be reported in the written report and included in the patient file.⁸⁷

Take home messages

On an average, a complex cardiac radiofrequency ablation corresponds to 750 chest X-rays (range 100–2850).

Cardiac electrophysiologists have an exposure per annum two to three times higher than that of diagnostic radiologists, which may amount to a cumulative risk after a professional lifetime in the order of magnitude of 1 extra cancer for 100 exposed workers. The same risk applies for every patient undergoing three or four complex EP procedures, including radiographic 3D imaging. Other relevant radiation-induced damages are eye lens opacities in cath lab workers (one out of two after a lifetime exposure if radiation protection tools are not used), and skin injuries in patients submitted to long procedures.

A reduction of the occupational and the procedural doses by a factor of 10 to even 100 can be achieved simply by an intensive radio-protection training programme. There are many avenues to reduce the radiation exposure through system and workflow adaptations and through the use of non-fluoroscopic imaging techniques.

European law mandates that it is the responsibility of all the physicians to balance the radiation exposure vs. the diagnostic and the therapeutic gain of the imaging ('justification'), and to minimize the hazard of radiation risk to their patients, to the other staff, and to themselves ('optimization'). We hope that our practical suggestions may help them in achieving this.

Conflicts of interest: H.H. is holder of the AstraZeneca Chair in Cardiac Electrophysiology, University of Leuven. H.H. received research funding through the University of Leuven from Siemens Medical Solutions. H.H. is Coordinating Clinical Investigator for the Biotronik-sponsored EuroEco study on health-economics of remote device monitoring. H.H. is a member of the scientific advisory board of Biosense Webster, Inc., St Jude Medical, Inc., Siemens Medical Solutions, Boehringer-Ingelheim, Bayer, and Sanofi-Aventis, and receives unconditional research grants through the University of Leuven from St Jude Medical, Medtronic, Biotronik, and Boston Scientific Inc. S.E. is/has been a consultant for Biosense Webster, Stereotaxis, St Jude Medical, and Medtronic. She has been a speaker for Biosense Webster, Stereotaxis, St Jude Medical, and Medtronic and has received grant support from Biosense Webster and St Jude Medical. L.M. has given lectures, has been consultant, and has received research funding from St Jude Medical, Medtronic, Biotronik, Sorin, and Boston Scientific Inc. E.P. received research funding through the CNR-Institute of Clinical Physiology from Sorin, Boehringer-Ingelheim, Medtronic, and Malesci. He is the inventor of a pacemaker licenced to Medtronic. R.S. is/has been a consultant for Biosense Webster, St Jude Medical, and Medtronic. He has been a speaker for Biosense Webster and St Jude Medical, and has received grant support from Boston Scientific, Biosense Webster, St Jude Medical, Hansen Medical, and Medtronic. E.V. did not

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Supplementary material

Supplementary material is available at *Europace* online.

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