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PRACTICAL EP

Practical guidance to reduce radiation exposure in electrophysiology applying ultra low-dose protocols: a European Heart Rhythm Association review

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Abstract

Interventional electrophysiology offers a great variety of treatment options to patients suffering from symptomatic cardiac arrhythmia. Catheter ablation of supraventricular and ventricular tachycardia has globally evolved a cornerstone in modern arrhythmia management. Complex interventional electrophysiological procedures engaging multiple ablation tools have been developed over the past decades. Fluoroscopy enabled interventional electrophysiologist throughout the years to gain profound knowledge on intracardiac anatomy and catheter movement inside the cardiac cavities and hence develop specific ablation approaches. However, the application of X-ray technologies imposes serious health risks to patients and operators. To reduce the use of fluoroscopy during interventional electrophysiological procedures to the possibly lowest degree and to establish an optimal protection of patients and operators in cases of fluoroscopy is the main goal of modern radiation management. The present manuscript gives an overview of possible strategies of fluoroscopy reduction and specific radiation protection strategies.

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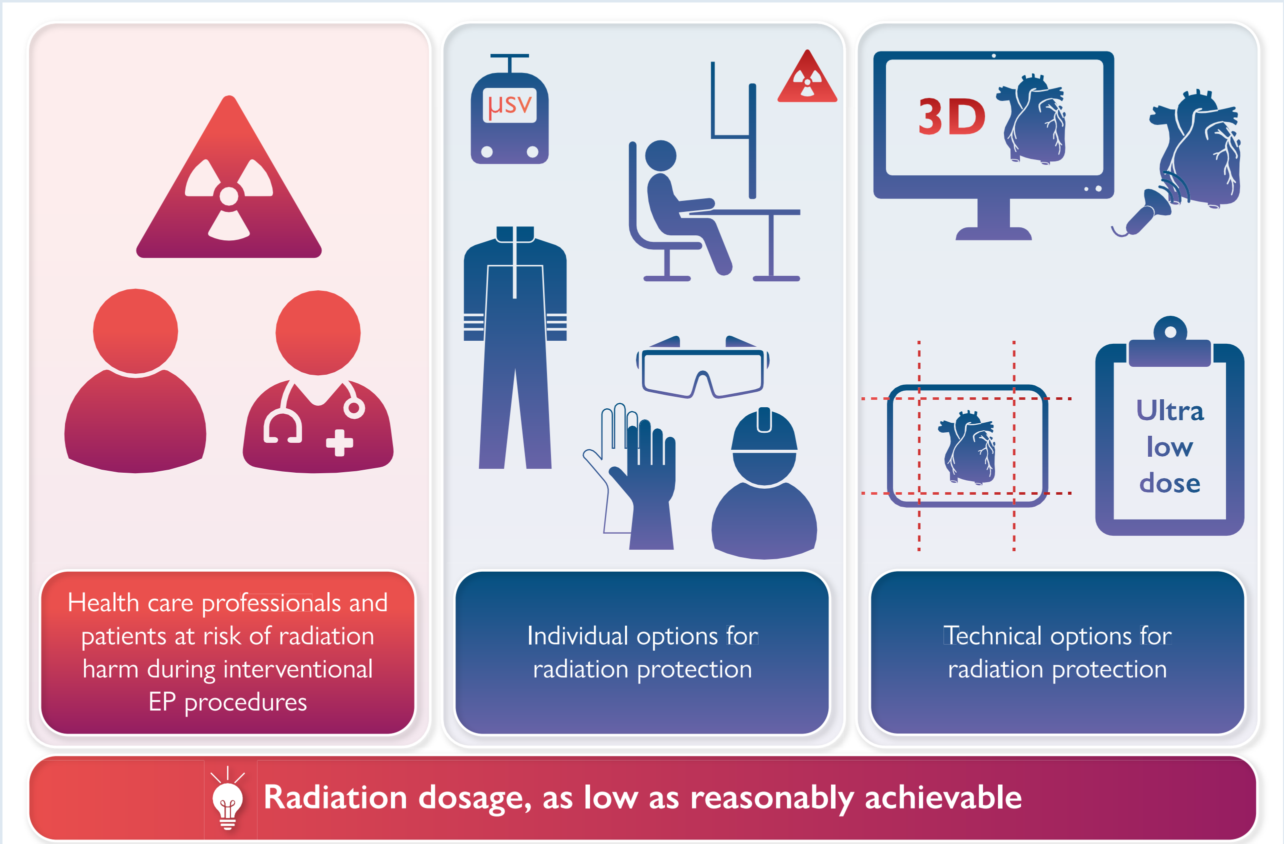
Graphical Abstract



3D, 3-dimensional; EP, electrophysiology; µSv, µSievert.

Keywords Radiation protection • Ultra low-dose protocols • Radiation awareness • Radiation dosage reduction

What's new?

- The as low as reasonably achievable principle is still valid—also in the light of new ultra low-dose protocols.
- X-ray exposure in electrophysiology procedures can be minimized using easy-to-apply rules.
- Technological tools make zero-fluoroscopy procedures possible.

Introduction

Typical conversation if two electrophysiologists meet: 'How much radiation do you have in a PVI?' Answer: 'Around 7 min.' And the dose? Answer: 'About 400.'

Are we communicating on the right level with regards to this important topic? At the end, it is the radiation exposure that is part of the bodily harm we are causing to our patients (besides vascular puncture etc.). And importantly, radiation exposure is not only relevant to our patients but also to ourselves and the staff in the electrophysiology (EP) lab. X-ray technology has evolved dramatically in the recent decades—resulting in a significant reduction of radiation dose emitted by the X-ray systems. In parallel, an increasing awareness of the potentially harming effects can be observed especially among the younger generation of EP again resulting in reduced radiation usage.

The purpose of this manuscript is to create awareness of the potentially harming effects of using X-ray for our procedures, to quantify the risk of causing malignancies, to demonstrate ways of self-protection by reducing exposure or even better by reducing the radiation dose emitted by the X-ray system, and to show alternative imaging modalities.

Finally, we will try to answer the question if radiation exposure still is a cause for concern or if current technologies overcame this issue.

Medical radiation hazards

X-rays have marked a turning point in medical advancement since introduction to clinical practice. The increasing use and complexity of imaging and interventional techniques has introduced undesirable hazards. Complex catheter-based procedures performed by interventional cardiologists commonly expose to relevant radiation doses.[1]

Operators in interventional catheter labs have traditionally focused on potential harms to patients. Radiation-induced deterministic effects related to predictable changes in the tissues (e.g. skin injuries and cataract) and occurring above specific dose thresholds are well known.[2–4] To limit stochastic effects related to an unpredictable, dose-independent potential future harm to tissues (e.g. radiation-induced carcinogenesis and germ cell mutagenesis), unjustified and non-optimized radiation use is carefully avoided.[5–7]

On the other side, operators and paramedical staff have posed minor attention on protecting themselves from radiation exposure harms.

Fortunately, professional societies have started to promote awareness and provide specific recommendations to limit radiation exposure's detrimental effects.[8,9] *Figure 1* shows a schematic set up of X-ray systems. However, thorough consciousness and knowledge by prescribers and practitioners is lacking. As an example, most physicians, including interventional cardiologists, grossly underestimate the lifetime cancer risk related to medical radiation exposure.[10,11]

Radiation exposure confers distinct professional health risks to operators and paramedical staff in the catheter lab.[12] Typical lifetime work-related exposure is in the range of 50–200 mSv, corresponding to a whole-body dose equivalent of 2500–10 000 chest X-rays (CXR) and an attributable excess cancer risk of 1 in 100.[13] Notably, dose area product (DAP) units of the different manufacturers vary between one another (*Table 1* and *Figure 2*). Despite carcinogenesis affecting exposed patients, repetitive low-dose occupational radiation exposure has also been related to several non-carcinogenic effects (*Table 2*).[15] Long-term cancer risk is a feared consequence of X-ray professional exposure.[12] More specifically, tumours on the left side of the brain, which is commonly more exposed and least protected by traditional shielding,[24] have been reported.[16,25] Extremely large cohort studies would be necessary to establish a clear epidemiological association. Biomarkers may overcome this limitation: telomere shortening and circulating microRNAs have recently shown great potential. To date, they are considered suitable to serve as early markers of most common cancers (e.g. breast, colon, lung, prostate, pancreas, gastric, ovarian, oesophagus, and liver). Interventional cardiologists, compared to non-exposed colleagues or controls, have reported significantly increased cell-free DNA or mitochondrial DNA plasma levels and chromosomal damage in circulating lymphocytes.[26,27]

In terms of non-cancerogenic consequences, potentially affecting fertility and future child's health, a direct effect on the gonads and the hypothalamic-pituitary-gonadal axis in women and men, is a matter of concern.[28,29] Exposed male health workers have shown worse semen quality than unexposed controls, with higher incidence of DNA fragmentation and hypermethylated spermatozoa.[17] Pilot data show higher prevalence of genomic instability in specific 'hot-spots' of the Y chromosome, a genetic marker of impaired spermatogenesis that can also be transmitted to offspring and predispose to congenital abnormalities when spermatozoa are formed.[18,30–32] Chronic occupational radiation exposure may also be associated with an increased incidence of cataract, early atherosclerosis, accelerated vascular aging and vascular, as well as neurocognitive decline.[19–23]

Eventually, indirect occupational radiation exposure effects have been described. Orthopaedic injuries and musculoskeletal pain have been related to wearing heavy leaded aprons, while high arousal inherent to radiation managing for continued periods has been related to psychological states as stress and anxiety.[33–35]

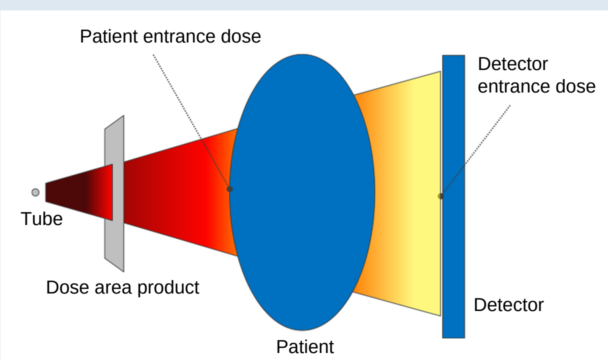


Figure 1 Schematic setup of X-ray systems. The patient entrance dose is relevant for deterministic radiation injuries and is measured in Gy (air kerma). The dose area product is measured between the tube and the patient's body, and the unit is Gy*cm^2.

Technical options for radiation protection

Introduction

Although the best option would be a zero-fluoroscopy procedure, the use of radiation is crucial for most EP procedures. Therefore, effort should be taken to optimize radiation protection. The radiation exposure is even more relevant to the operator than the patient. First, the patient undergoes only one or a few EP procedures in life, whereas the operator experiences a daily exposure to radiation during the complete physician's life. Second, the fluoroscopy exposure to the patient is part of the procedure and the potential cancer risk is part of the interventional risk, whereas for the operator, it is an occupational health risk. Generally, in every EP lab, the top priority should be to minimize radiation dose and to use all technical options aiming at protection of the patient and the operator. A variety of technical tools have been developed and are currently used in different ways to reduce fluoroscopy exposure. Radiation exposure can be reduced either by technical settings such as frame rates and collimation or technical tools such as led shields and led apron. A recent European Heart Rhythm Association (EHRA) survey demonstrated a very different adoption of technical options for radiation protection (*Figure 3*).[36] The use is limited by costs and applicability. The Zero-Gravity system (Biotronik SE & Co KG, Berlin, Germany) for instance is a highly effective method to minimize fluoroscopy exposure to the operator. However, the system is costly and requires adoption of the individual workflow. Lead-containing gloves are several times more expensive

Table 1 Dose area product units of the different manufacturers

Company	Siemens (µGy*m^2)	Philips (cGy*cm^2)	GE (Gy*cm^2)	Toshiba/Canon (Gy*cm^2)
Siemens (µGy*m^2)	NA	NA	×100	×100
Philips (cGy*cm^2)	NA	NA	×100	×100
GE (Gy*cm^2)	:100	:100	NA	NA
Toshiba (Gy*cm^2)	:100	:100	NA	NA

DAP unit is modifiable in modern X-ray systems. The standard unit is Gy*cm^2. Start with the line and look for the factor in the column. Example: the DAP from Siemens needs to be multiplied by 100 to give an equivalent to GE. NA, not available.

than conventional gloves. In addition, the tactile feedback is impaired due to the thickness of the gloves. Fluoroscopy system customization is often a simple and cheap method to reduce radiation exposure at a price of a lower image quality. *Table 3* summarizes recent available options for fluoroscopy protection.

System customization and workflow adoption

The amount of radiation for both the patient and the operator as well as the image quality depends on multiple parameters including the tube current, the pulse duration, tube voltage, and the copper filtration. A higher image quality often results in a higher amount of increasing radiation. Different settings with different image qualities can often be preselected aiming at an optimal balance between image quality and radiation amount for each individual procedure. For instance, a high-resolution image is required for visualization of the coronary arteries in epicardial ablation procedures, whereas a low-resolution image is required sufficient in patients undergoing common type flutter ablation.

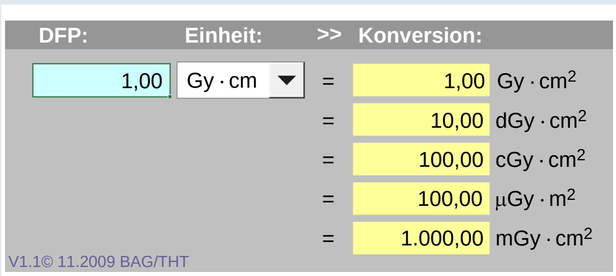


Figure 2 Calculator for different units used for the dose area product. Typically, $\mu Gy*m^2$ or $Gy*cm^2$ are used. The multiple manufacturers use different units. © www.bfs.de (Bundesamt für Strahlenschutz).

Frame rate settings

Many fluoroscopy units have a default setting of 12.5–25 frames per second (fps). For instance, a reduction from 25 to 3.75 fps is associated with a six- to eight-fold reduction of the radiation dose.

Collimation

Collimating the area of interest has two advantages. First, it results in dose reduction and second X-ray scatter reduction, thereby improving image quality. It is one of the most significant and efficient techniques to reduce the radiation dose to the patient and the operator. The collimation field should be continuously adjusted throughout the procedure.

Magnification

Magnification increases the dose. Therefore, magnification should be minimized.

Beam angulation

Scattered radiation is the main source of exposure for the operator and other persons in the lab. Most scatter originates from the beam

Table 2 Medical radiation hazards within catheter lab operators and paramedical staff

Radiation-induced effects	Description	Author, year
Cancerogenesis	Fifteen cardiac cath lab personnel, median individual effective dose 46 mSv (IR 24–64)→risk of (fatal and nonfatal) cancer 1 in 192 (IR 1 in 137–370)	Venneri *et al.*[13]
	Two brain cancers in Ontario cardiologists→an unusual cluster	Finkelstein[14]
	Six interventional cardiologists and 3 interventional radiologists with brain malignancies in the left hemisphere	Roguin *et al.*[16]
Non-cancerogenic		
Reproductive	Eighty-three exposed and 51 non-exposed subjects→different semen motility, viability, morphological abnormalities, and DNA fragmentation ($P < 0.05$–0.0001); higher hypermethylated spermatozoa ($P < 0.05$)	Kumar *et al.*[17]
Teratogenic	Ninety-three cath lab personnel (exposed 3 months prior to conception) and 164 age-matched unexposed subjects→low birth weight in offspring 13% vs. 5.3%, $P = 0.02$; increased azoospermia factor region c microdeletion and microduplications (1.53 ± 0.8 vs. 1.02 ± 0.4, $P = 0.0005$)	Andreassi *et al.*[18]
Neurodegenerative	One hundred and thirty-two interventional cardiologists and 83 non-exposed subjects→brain-specific miR-134 ($P = 0.002$) and miR-2392 ($P = 0.003$) significantly down-regulated	Borghini *et al.*[19]
Cardiovascular	Two hundred and twenty-three cath lab personnel and 222 unexposed subjects→left and right carotid intima-media thickness significantly increased ($P < 0.04$); leucocyte telomere length significantly reduced ($P = 0.008$)	Andreassi *et al.*[20]
Cataractogenesis	A total of 67 246 eligible US radiologic technologists→5-year lagged exposure related with self-reported cataract, an excess hazard ratio/mGy of 0.69×10^{-3} ($P < 0.001$)	Little *et al.*[21]
	Survey on 1478 board-certified cardiologists→above 10 000 h radiation exposure independently related to cataracts (adjusted OR 1.72; 95% CI 1.24–2.37, $P = 0.001$)	Thirumal *et al.*[22]
	Pooled analysis on 2559 subjects (exposed = 1224)→posterior lens opacity higher in exposed subjects (RR = 3.21; 95% CI 2.14–4.83, $P < 0.00001$)	Elmaraezy *et al.*[23]

IR, interquartile ranges; OR, odds ratio; RR, relative risk; CI, confidence interval.

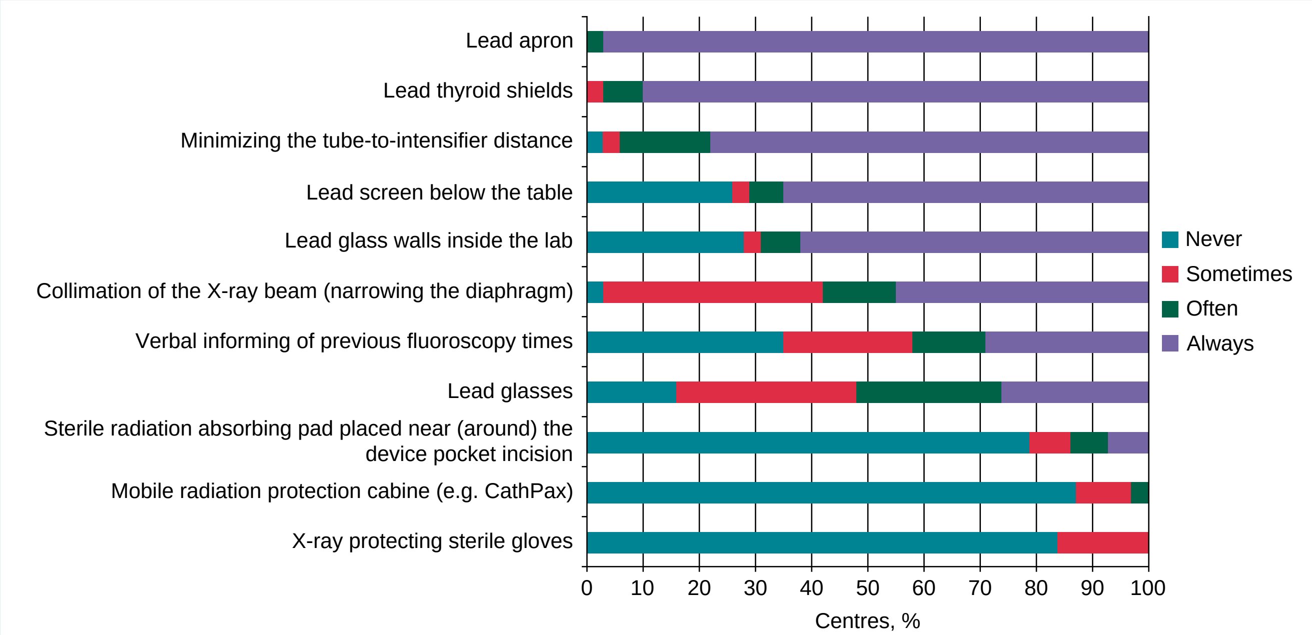


Figure 3 Safety measures and techniques used to decrease X-ray radiation during electrophysiology procedures.[36]

Table 3 Recent available options for fluoroscopy protection

Technical options for radiation protection	Patient protection/ benefit	Operator protection/ benefit	Type of radiation protection	Costs
Frame rates	+	+	System customization	No cost
Collimation (maximize)	+	+	Workflow	No cost
Magnification (minimize)	+	+	Workflow	No cost
Beam angulation	+	+	Workflow	No cost
Cine vs. storage of the last fluoroscopic sequence	+	+	Workflow	No cost
Lead apron	–	+	Technical option	Low
Thyroid collar	–	+	Technical option	Low
Protective glasses, visors, and headwear	–	+	Technical option	Low
Lead gloves	–	+	Technical option	Moderate
Table-suspended lead	–	+	Technical option	Low
Lead glass (separate stand or ceiling suspended)	–	+	Technical option	Low
Separate stand lead for allied professionals	–	+	Technical option	Low
Radioprotective cabin	–	+	Technical option	High
Ceiling-mounted suspended radiation protection system	–	+	Technical option	High
Led mattress	+	+	Technical option	Low
3D-mapping systems	+	+	Technical option	Moderate
MRI-guided ablation	+	+	Technical option	High
Robotic magnetic navigation	–	+	Technical option	High
Robotic navigation	–	+	Technical option	High

entrance site. Therefore, the operator is exposed to more scattered radiation in left anterior oblique (LAO) projection when the operator is positioned on the right side of the table (e.g. procedures performed from the groin, right-sided device implantations) and in right anterior oblique (RAO) projection when the operator is positioned on the left side of the table (e.g. left-sided device implantation).

A recent study demonstrated that LAO caudal angulation is associated with the greatest increase in radiation dose compared to the posterior–anterior angulation, while LAO cranial angulation and RAO cranial and caudal angulations increase radiation dose to a lesser extent.[37]

Cine vs. storage of the last fluoroscopic sequence

The radiation dose is about 10-fold higher in cine mode as compared to the fluoroscopic mode. Therefore, whenever possible, storing the last fluoroscopic sequence should always be preferred to cine.

Technical tools

Personal Shielding

The minimum protection for everyone inside the lab should be a lead apron and thyroid collar. Importantly, the lead apron requires regular inspections (e.g. twice annually) as it may break over time. Mostly, lead is used as a shielding material for protection against X-ray. Recently, the high-density metal wolfram carbide has been introduced as a light, environmentally friendly and non-toxic alternative to lead. Other polymeric composite materials for radiation shielding are under evaluation.[38] Optional protective shielding includes protective goggles, visors, headwear, and gloves (*Figure 4*). Glasses provide excellent eye protection with a typical lead thickness of 0.5–0.75 mm. Visors protect the entire face and brain, but lead thickness is only 0.1 mm. Caps fully protect the skull but additional weight and limited heat dissipation impair the operator's comfort. Lead-containing gloves are significantly thicker thus impairing the tactile feedback. In addition, they reduce the radiation exposure only by 10–30%.

Lab shielding including suspended radiation protection system and radioprotection cabin

Two shields should be used during each procedure. A lead glass shield above the patient (*Figure 5*) and a lead shield below the table including an overlapping shield flap. The lower shield is typically fixed at the table and moving with the table. The lead glass shield above the patient is either fixed at the ceiling or at a separate stand. Scattered radiation can further be reduced by up to 70% by using a simple lead mattress above or below the patient's pelvis. The main disadvantage is that a fluoroscopic visualization of this region is not possible. More advanced tools include the ceiling-mounted suspended radiation protection system 'Zero-Gravity' or the radioprotection cabin. It optimizes shielding and reduces radiation exposure to background levels, including complete protection of eyes, brain, and the axillary region (*Figure 6*). Another major advantage of these systems is the orthopaedic relief avoiding orthopaedic injuries resulting from routinely wearing heavy protective apparel. Additional lead shields for allied professionals or anaesthesiologists should be provided. Particularly in younger patients, gonad protection should be used (*Figure 7*).

3D-mapping systems

Introduction of 3D-mapping systems has resulted in a dramatic reduction of radiation dose. These systems include the CARTO system (Biosense Webster), the Ensite X system (Abbott Medical), and the Rhythmia system (Boston Scientific). 3D-mapping systems do not only allow for non-fluoroscopic catheter visualization (NFCV) but also for 3D-mapping of complex arrhythmias. In addition, other image modalities such as computed tomography, magnetic resonance imaging, or intracardiac echocardiography can be integrated and allow precise visualization of the heart and adjacent structures. Hence, 3D-mapping systems are recommended for most ablation procedures.[39] Novel

Figure 4 Left operator protected with protective visors. Right operator protected with protective gloves (dark grey), protective goggles, and a brain cap.

tools such as the CARTOUNIVU™ module combine fluoroscopic imaging and 3D-mapping (*Figure 8*).

Robotic magnetic navigation systems/robotic ablation

Robotic magnetic navigation systems and robotic navigation systems have been developed aiming at more accurate and precise catheter navigation without radiation exposure to the operator. Robotic magnetic navigation systems (Stereotaxis) use powerful magnets to control catheter movement. Mechanical robotic navigation systems (Hansen) were used to robotically steer sheaths. For both systems, the operator steers the catheter in the control room. Remote navigation systems are complex and expensive. A clinical benefit has not been proven.[40] Therefore, these systems are only used in a minority of EP centres.

Figure 5 Lead shield below the table including an overlapping shield flap (grey). Scattered radiation can further be reduced using a simple lead mattress.

Cardiac magnetic resonance imaging

Interventional cardiac magnetic resonance imaging (MRI) has been established as a radiation-free alternative compared to standard fluoroscopy-guided catheter ablation. Until today, this technique has only been used for cavotricuspid isthmus-dependent atrial flutter ablation. Although this technique requires extensive material effort, it allows detailed anatomic visualization and observation of lesion formation during ablation.[41]

How low can we go (with unchanged workflow) by optimizing the X-ray system?

There are several well-established radiation protection strategies to minimize radiation exposure, such as use of collimation, short detector-to-patient distance, avoiding LAO angulation, X-ray ray shielding/protection, or reduced fluoroscopy duration. These conventional strategies have the common aim to reduce the proportion of produced radiation hitting the operator or the patient. However, a more recent technological achievement in EP is the development of ultra low-dose (ULD) fluoroscopy protocols, which are technically optimized for their use in EP laboratories. In addition to conventional radiation protection strategies, ULD fluoroscopy significantly reduces the dose of generated radiation in the X-ray tube.[42–44]

Ultra low-dose fluoroscopy—technically optimized for electrophysiology

Though fluoroscopy systems were technically optimized for high-resolution coronary angiography, there is no need for high-resolution fluoroscopic imaging in EP, where visualization of electrodes, catheters,

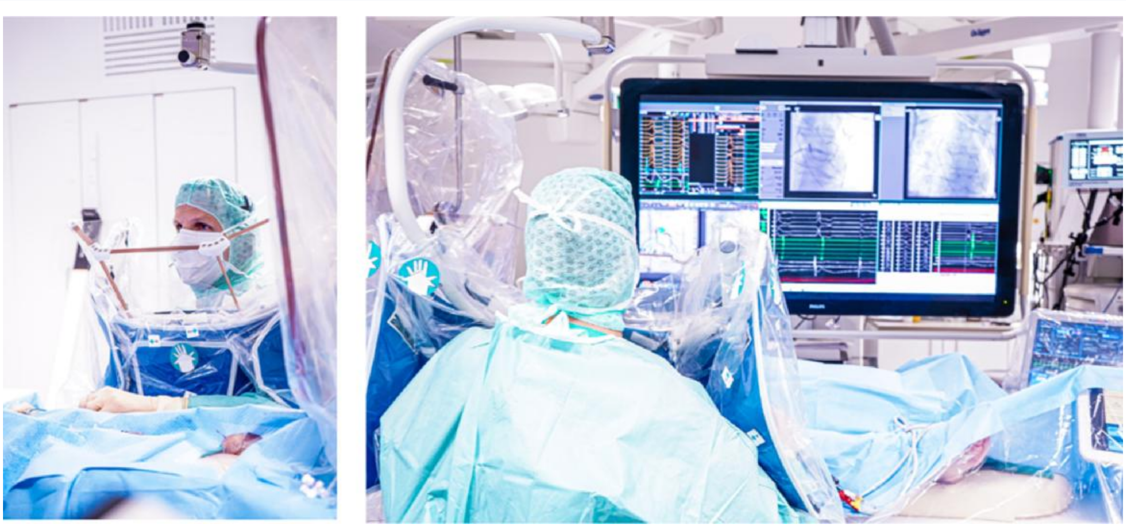


Figure 6 Suspended radiation protection system ‘Zero-gravity’.

Figure 7 Gonad protection (female right, male left).

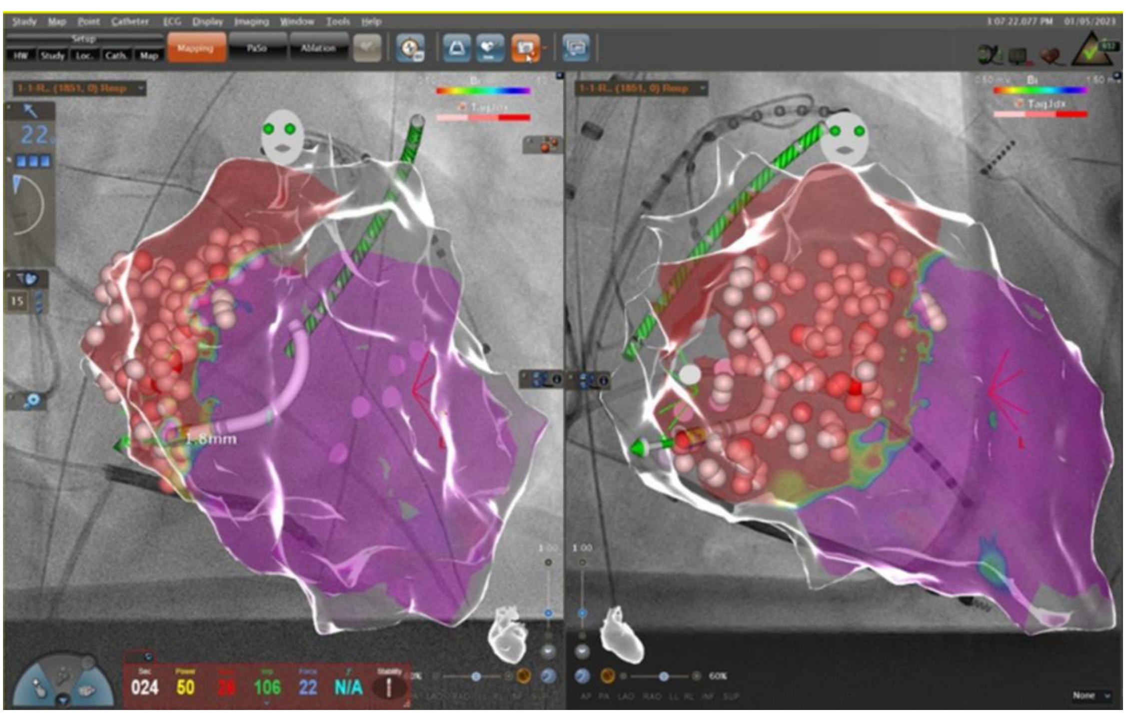


Figure 8 Combination of a 3D map (CARTO) with a fluoroscopic image. 3D map of the left ventricle in left anterior oblique (left image) and right anterior oblique projection (right image).

sheaths, and the cardiac silhouette is the main purpose of using fluoroscopy. Therefore, ULD fluoroscopy protocols are technically designed and optimized for their use in EP procedures. They acquire images at radiation doses just sufficient to perform EP procedures. In ULD fluoroscopy, the detector entrance dose per fluoroscopic pulse, necessary to create a fluoroscopic image, is dramatically reduced compared to conventional fluoroscopy. Notably, in ULD protocols, the X-ray tube voltage is identically chosen (for example 81 kV for cine-loops and 90 kV for pulsed fluoroscopy) compared to conventional fluoroscopy in order to prevent that softer X-ray radiation (lower kV) might create better image quality but be more harmful to tissue. *Figure 9* depicts fluoroscopic acquisitions of EP catheters at systematically varied detector entrance doses in a phantom model experiment.[42]

Clinical application

From an operator standpoint, ULD fluoroscopy creates a different, reduced image quality (*Figure 10*). Although unfamiliar, the reduced

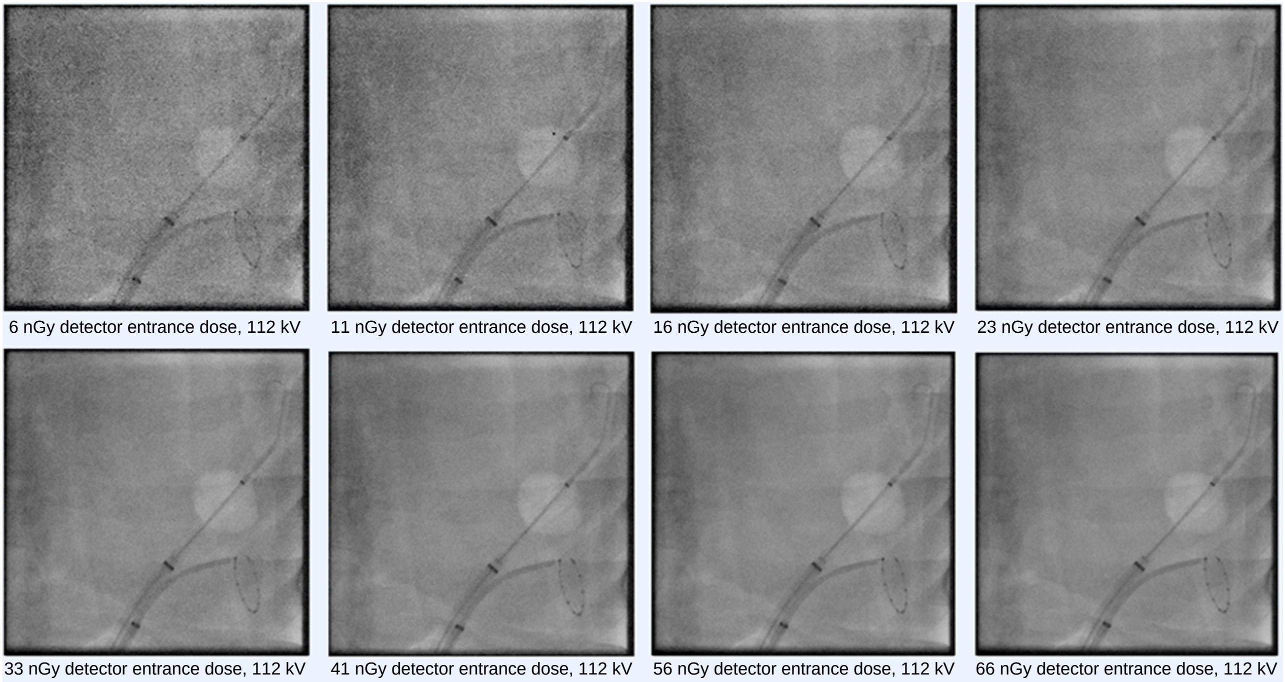


Figure 9 Fluoroscopic acquisitions of electrophysiology catheters (cryoballoon and circular mapping catheter) placed inside a thoracic phantom model. The detector entrance doses of the fluoroscopy system (Artis zee, Siemens AG, Forchheim, Germany) were systematically increased from 6 nGy per pulse to 66 nGy per pulse at a constant X-ray tube voltage of 112 kV. Increasing the dose results in improvement of overall image quality, however relevant details (markers and electrodes) can still be identified at the lowest dose level (6 nGy).

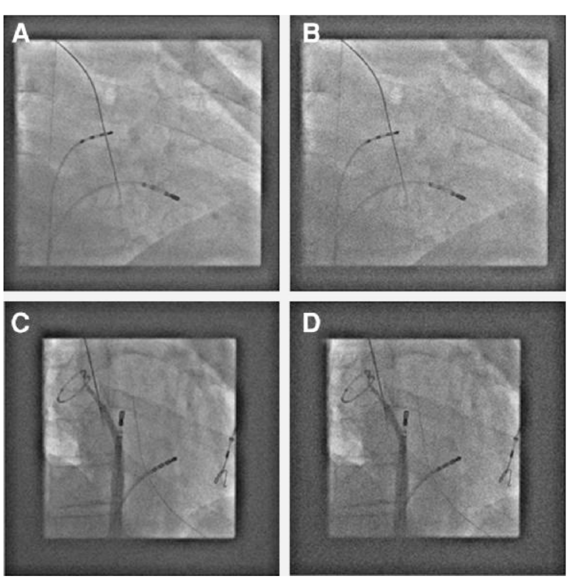


Figure 10 Corresponding clinical fluoroscopic images displayed in standard (*A*, *C*) and ULD (*B*, *D*) settings.

image quality did not significantly affect procedure times, clinical outcome, or radiofrequency (RF) times and did not result in higher complications. Implementing ULD fluoroscopy in the clinical workflow results in a highly-significant reduction of X-ray doses. Recent data show a 30-fold reduction of DAP using ULD fluoroscopy in complex ablation procedures compared to standard fluoroscopy.[36,42,45]

Radiation doses in atrial fibrillation ablation procedures in 2005–2022: looking at facts

Reviewing data on radiation during atrial fibrillation (AF) ablation over the past years, there are a few explanatory statements and definitions to consider. First, the following studies were selected as the majority addressed radiation reduction by specific interventions. Therefore, they may deviate from real-life data but on the other hand may demonstrate achievable reduction in radiation dose. Second, radiation dose data are provided as published, namely fluoroscopy time and kerma area product (KAP). The latter, formerly known as DAP, was converted into a uniform unit ($cGycm^2$) for comparability. In addition, the estimated effective dose (eED), which is an indicator of the risk of tumour development, was calculated from the published data [eED = KAP (in $cGycm^2$) $\times$ 0.002; the correction factor for women (1.38) was neglected for reasons of simplification]. This calculated eED was put into perspective with the eED of a CXR (0.02mSv) and thus converted to the unit 'equivalent number of CXR' in order to illustrate the meaning and magnitude of these values.[46] Hence, for the presented studies in the subsequent paragraphs, one may find the data on the respective low-dose cohort in parenthesis and in the following order: analysed study period, fluoroscopy time, KAP, factor of KAP reduction, eED, and CXR equivalents (*Table 4*).

Table 4 Summary of study indication changes in radiation dosages during atrial fibrillation ablations by radiofrequency ablation (A) and single-shot devices (B)

Author	System/technique	Year of inclusion	Fluoroscopy time in min	KAP change	KAP in $cGycm^2$	eED in mSv	CXR equivalents
(A) 3D-mapping system (radiofrequency ablation, point-by-point)							
Estner *et al.*[47] (doi:10.1093/europace/eul079)	*3D-mapping* vs. fluoroscopy only	2005	38.9	**−39%**	5660	**11.3**	**566**
Lee *et al.*[48] (doi: 10.1093/europace/euv186)	*Contact force* vs. non-contact force	2009–2014	9.5	**−70%**	104	**0.2**	**10**
Christoph *et al.*[43] (doi:10.1093/europace/euu334)	*NFCV* vs. conventional 3D-mapping	2013	6.4	**−49%**	3726	**7.5**	**373**
Huo *et al.*[49] (doi:10.1016/j.hrthm.2015.05.018)	*NFCV* vs. conventional 3D-mapping	2014	1.8	**−73%**	652	**1.3**	**65**
Sommer *et al.*[50] (doi:10.1093/europace/eux378)	*NFCV*: last 250 vs. first 250 patients	2012–2017	0.5	**−94%**	152	**0.3**	**15**
Khalaph *et al.*[51] (doi: 10.1111/pace.14555)	*Visualizable steerable sheath* vs. non-visualizable sheath	2019–2021	7.0	**−35%**	507	**1.0**	**51**
Knecht *et al.*[52] (doi:10.1093/europace/euv006)	*Zero-Fluoro after TSP* vs. 'normal-fluoro' after TSP	2014	4.2	**−25%**	1320	**2.6**	**132**
Lehrmann *et al.*[53] (doi:10.1093/europace/euw334)	Radiation dose *over time*	2005	53.0		4635	**9.3**	**464**
		2015	5.0	**−96%**	185	**0.4**	**19**
Voskoboinik *et al.*[54] (doi:/10.1016/j.hrthm.2017.02.014)	Radiation dose *over time*	2010	30.6			**9.0**	**450**
		2015 (CF PVI only)	11.4	**−66%**		**3.1**	**155**
Bourier *et al.*[42] (doi:10.1093/europace/euv364)	*Optimized X-ray programme* vs. previous settings	2014–2015	8.6	**−77%**	200	**0.4**	**20**
Attanasio *et al.*[45] (doi:10.1111/pace.14205)	Optimized X-ray programme	2015–2018	6.2		91	**0.2**	**9**
Schreiber *et al.*[55] (doi:/10.1007/s00399-021-00762-7)	Optimized X-ray programme	2020	9.4		128	**0.3**	**13**
(B) Single-shot devices for AF ablation							
Hoffmann *et al.*[56] (doi:10.1093/europace/euz155)	*Cryoballoon* vs. RF	2011–2016	23.4	+39%	2487	**5.0**	**249**
Rubesch-Kütemeyer *et al.*[57] (doi:/10.1007/s10840-019-00564-5)	Cryoballoon *over time*	2013	11.7		1428	**2.9**	**143**
		2017	5.1	**−57%**	617	**1.2**	**62**
Reissmann *et al.*[58] (doi:10.1093/europace/eux066)	Cryoballoon *optimized* vs. standard X-ray programme	2016	10.0	**−82%**	389	**0.8**	**39**
Kühne *et al.*[59] (doi: 10.3389/fcvm.2021.664538)	Cryoballoon *without PV occlusion testing* vs. standard	2017–2019	11.0	**−81%**	368	**0.7**	**37**

Continued

Table 4 *Continued*

Author	System/technique	Year of inclusion	Fluoroscopy time in min	KAP change	KAP in cGycm²	eED in mSv	CXR equivalents
Rottner et al.[60] (doi:10.3389/fcvm.2022.967341)	Cryoballoon *Kodex-EPD version 1.4.6* vs. 1.4.8	2019–2021	10.9	−58%	294	**0.6**	**29**
Huang et al.[61] (doi:10.1111/jce.14546)	Laserballoon *low dose* (ICE, 3D-mapping system) vs. standard	2018–2019 (standard)	16.9		1980	**4.0**	**198**
		2018–2019 (low dose)	1.7	**−91%**	181	**0.4**	**18**
Magni et al.[62] (doi:10.3389/fcvm.2022.959186)	Pulsed-field ablation	2021–2022	13.5		658	**1.3**	**66**
Lemoine et al.[63] (doi:10.1007/s00392-022-02091-2)	Pulsed-field ablation	2021–2022	16.0		505	**1.0**	**51**
Bohnen et al.[64] (doi:10.1093/europace/euac111)	Pulsed-field ablation	2021	16.0		125	**0.3**	**13**

The table only includes studies that reported kerma area product (KAP). The bold numbers show the reduction of Kerma area product (KAP) by the use of 3 D mapping systems.
CXR, chest X-ray; eED, estimated effective dose; ICE, intracardiac echocardiography; NFCV, non-fluoroscopic catheter visualization; PV, pulmonary vein; RF, radiofrequency; TSP, transseptal puncture.

Point-by-point ablation using 3D-mapping systems

3D-mapping systems have revolutionized radiation dose reduction in point-by-point AF ablation. One of the earliest studies by Estner *et al.* showed 49% reduction in fluoroscopy time with the NavX system.[47] An 86% decrease in fluoroscopy time was also demonstrated for the Carto system several years later.[65] Since then, several technical innovations, namely (i) contact force, (ii) NFCV technology, (iii) visualizable steerable sheaths, and (iv) improvements in transseptal puncture (TSP) technique, enabled further reductions of radiation dose.

Contact force

In an 'all comers' retrospective study cohort of over 1500 patients, using contact force ablation catheters resulted in ∼19% reduction of procedure time, ∼77% decrease of fluoroscopy time, and ∼71% reduction of radiation dose. Despite a relatively long fluoroscopy time, excellent X-ray settings led to one of the lowest radiation doses published to date, apart from zero-fluoroscopy AF ablation.[48]

Non-fluoroscopic catheter visualization technology

The NFCV technology enables integration of fluoroscopy images into 3D-mapping systems. This technology enables real-time visualization of catheters superimposed on previously acquired X-ray images, allowing catheter movement in X-ray environment without repeat fluoroscopy. Several smaller studies that evaluated the CartoUnivu™ system showed varying amounts of fluoroscopy time and dose reduction.[43,49] The largest study to date in 1000 patients using the Mediguide™ system could nearly omit fluoroscopy. After a learning curve, comparing the first 250 with the last 250 patients, the need for fluoroscopy markedly decreased with experience.[50]

Visualizable steerable sheaths

Steerable sheaths support precise positioning and stabilization of the ablation catheter during pulmonary vein isolation (PVI). In general, placement is guided fluoroscopically. Recently, steerable sheaths have been introduced capable of being visualized in 3D-mapping systems. Compared to a matched control cohort, their use could significantly reduce fluoroscopy time by 30% as well as radiation dose.[51,66]

Transseptal access

Several publications have identified catheter placement and TSP as the main source of radiation during AF ablation.[54] After TSP, fluoroscopy could be completely avoided in 29 of 30 patients in a study by Knecht *et al.*, using a 3D-mapping system together with a radiation awareness protocol.[52] In addition, using a patent foramen ovale (PFO) for left access, a zero-fluoroscopy approach of the entire PVI was possible in 87% of patients in a study by Kühne *et al.*[67] Therefore, a further reduction of radiation during PVI may be achieved by zero-fluoroscopy TSP. Apart from guidance by intracardiac (ICE) or transoesophageal echocardiography, recent studies investigated the feasibility of a fluoroscopy-free TSP by direct visualization of the needle on the 3D-mapping system.[68,69] The advantage of these approaches is the widespread availability of these systems while avoiding additional costs, patient discomfort or the need for general anaesthesia.

Ablation in magnetic resonance interventional suites (iCMR)

Another way of coming down to zero fluoroscopy is to treat patients in a non-fluoroscopic environment like MRI. Since 2010, constant progress has been made in this field and recently, a MR-conditional ablation system has received CE mark and is available for ablation of typical atrial flutter. In the first series of patients being published, the procedure seemed safe and feasible[70]—but still further progress has to be made until the potential advantages of tissue visualization will become a relevant factor in ablation procedures.

Variability in published radiation doses for radiofrequency atrial fibrillation ablation procedures

Studies investigating radiation in AF ablation consistently show a dose reduction over time. Lehrmann *et al*. showed a decrease in radiation dose in 2005–2015 from an eED of 9.3 to 0.4 mSV and in 2010–2015 from 9.0 to 3.1 mSv, respectively.[53,54] Even with optimal use of 3D-mapping systems including all technical advances, the resulting radiation dose still varies greatly between centres despite reporting the same fluoroscopy time. This may be explained by two reasons: lack of radiation awareness and different X-ray settings. Regarding lack of radiation awareness, Estner *et al.* published the results of an EHRA survey in 2015. More than 25% of operators used an unnecessarily high frame rate of ≥12 fps, and more than 40% of centres did not use collimation or only occasionally.[36] On the other hand, some centres have developed special EP low-dose programmes with improved image post processing [typical optimized EP programme: reduced frame rate 2–3 fps (fluoroscopy) and 7.5 fps (cine-angiography); 8 and 36 nGy detector entrance dose for fluoroscopy and cine-angiography, respectively]. Three exemplary studies show very low radiation doses using this optimized approach for AF ablation, despite a considerable amount of fluoroscopy time.[45,55,71] *Table 4A* summarizes data on changes in fluoroscopy times in RF-PVI.

Single-shot devices for atrial fibrillation ablation

Most single-shot devices are not integrated into 3D-mapping systems and rely on fluoroscopy.[72] The effect of radiation dose reduction by optimized X-ray settings is therefore aggravated. Avoiding repeated cine-angiography for assessment of pulmonary venous anatomy/occlusion and/or replacing it by fluoroscopic film imagery can further reduce radiation dose.[58] Various studies reported shorter fluoroscopy times during RF-PVI compared to cryoballoon (CB) ablation, e.g. the Fire and Ice trial or the Circa-Dose trial.[73,74] Radiation doses, unfortunately, were not published. The FREEZE cohort study, a multicentre trial comparing RF to CB ablation, reported X-ray data in >4100 patients. Atrial fibrillation ablation showed significant reduction in fluoroscopy time and radiation dose compared to a CB procedure.[56] A smaller single-centre study presented data on CB-PVI between 2013 and 2017 in >1000 patients.[57] Procedural changes enabled radiation dose reduction in two recent studies.[57,59] Recently, a new 3D-mapping system (Kodex-EPD™) was used in conjunction with the CB and the circular mapping catheter (Achieve™) for PVI, leading to further reduction of radiation dose.[60] Comparison of CB-PVI and laserballoon (LB) PVI at highly experienced centres revealed similar fluoroscopy times between both techniques in a cohort of 200 patients.[75] Huang *et al.* reported fluoroscopy time and radiation dose during conventional LB-PVI and during low-dose LB-PVI utilizing ICE, a 3D-mapping system and a multipolar mapping catheter.[61] In a multi-national pulsed-field ablation survey, mean fluoroscopy time was 13.7 min.[76] Three studies reported similar fluoroscopy times but varying radiation doses.[62–64] The RF balloon on the other hand is integrable into a 3D-mapping system. However, currently published fluoroscopy times in a multicentre trial vary between centres and appear to differ by type of sedation.[77] *Table 4B* summarizes data on changes in fluoroscopy times in single-shot ablation.

Safety and efficacy of radiation reduction efforts

The aforementioned studies demonstrated similar efficacy and safety in the conventional or low-dose radiation arm. This is also confirmed in a meta-analysis of more than 2200 patients comparing low-dose or zero fluoroscopy to conventional AF ablation procedures. The 1-year risk of AF recurrence, repeat procedures, and procedural complications were similar between the groups. The weighted mean difference in fluoroscopy time and KAP were significantly reduced.[78]

Zero-fluoroscopic procedures using intracardiac echocardiography—worth the effort?

The ICE represents a major advancement in cardiac imaging. Due to its potential to guide TSP, visualize ablation catheter, and to reveal complications (e.g. cardiac tamponade, thrombus formation, microbubbles during overheating with imminent danger 'pops', and pulmonary vein stenosis), it makes part of percutaneous interventional and EP procedures.[79] Moreover, ICE can be easily performed using conscious sedation unlike transoesophageal echocardiography, which requires intubation and general anaesthesia in most cases with its inherent risks including oesophageal injury by the probe.[80]

Available intracardiac echocardiography technologies

Two types of ICE are available: (i) rotational ICE using a piezoelectric crystal mounted on the tip of the catheter providing cross-sectional images in a 360° radial plane and (ii) phased-array ICE using a 64-element transducer mounted on the distal end of an 8- or 10-French steerable catheter. The catheter can be deflected aft and forward in two planes and produces a wedge-shaped image that is displayed on an ultrasound workstation. Due to easier probe handling, intuitive imaging and possible acquisition of Doppler and colour flow imaging, phased-array ICE represents a prevailing ICE modality (*Table 5*). The fact that ICE is the only interventional tool offering real-time imaging predestines this technology as suitable to reduce or even eliminate fluoroscopic exposure during catheter ablation.

Barriers to zero-fluoroscopic approach

Two barriers prevent total elimination of fluoroscopy during catheter ablation despite using 3D-mapping systems with advanced possibilities of catheter visualization: (i) introduction of catheters into the heart and (ii) performance of TSP for left access. Once all catheters are deployed, the use of 3D-mapping may omit fluoroscopy regardless of ICE, especially when contact force-sensing catheters are used.[81–83] However, ICE may help with safe navigation of the catheters. While fluoroscopy during catheter introduction will probably not be completely eliminated, performance of contemporary impedance-based 3D-mapping systems, allowing continuous tracking of catheters from the groins to the heart, can eliminate use of fluoroscopy in the majority (i.e. 94–97%) of cases.[81,84] Using a PFO to access the left atrium can be an alternative to TSP, but it is only feasible in a limited number of cases.[85] Moreover, such an access to the left atrium is usually too superior and anterior to allow for a comfortable manipulation with the ablation

Table 5 Presently available intracardiac imaging devices and their capabilities

Device	Company	Description
ACUSON AcuNav Volume ICE Catheter	Siemens Healthineers	Side-looking, 64-element phased-array, 4 planes steerability, 8F and 10F, greyscale, colour Doppler, tissue Doppler, compatible with ACUSON SC2000 PRIME Ultrasound System
ViewFlex Xtra ICE Catheter	Abbott Vascular	Side-looking, 64-element phased-array, 4 planes steerability, 8F, compatible with the ViewMate Z and ViewMate II ultrasound consoles
CartoSound	Biosense Webster	Side-looking, 64-element phased-array, 4 planes steerability 10F device with integrated ultrasound array with the CARTO magnetic sensors in the tip, which permits integration of ICE and 3D electroanatomical maps
Foresight ICE system	Conavi Medical	Forward-looking ICE, provides colour Doppler, pulsed wave Doppler, 2-D and 3-D measurements and electrocardiogram-gated 3D image acquisition

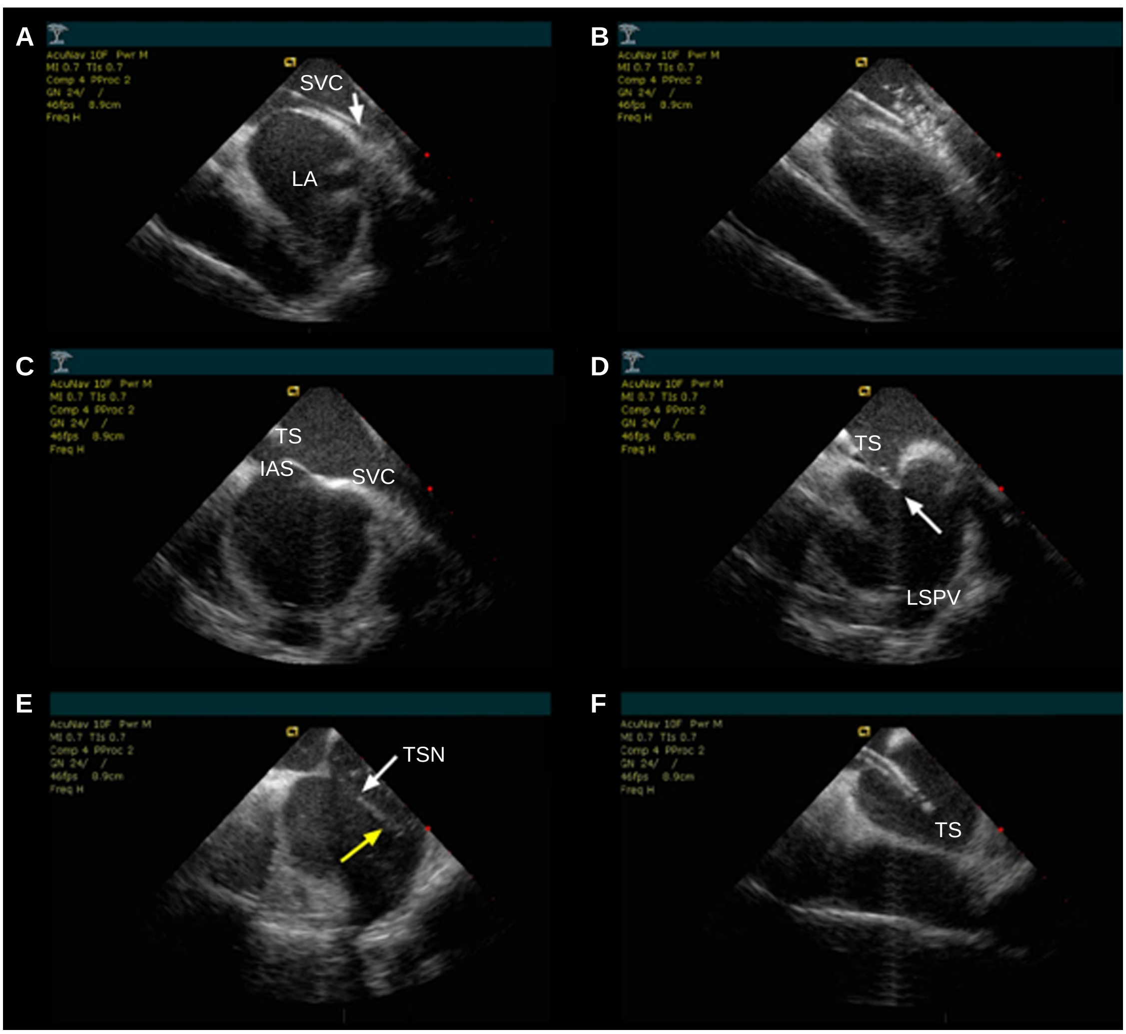


Figure 11 Crucial phases of ICE-guided transseptal puncture. (*A*) The guide wire is directed to the superior vena cava. (*B*) The transseptal sheath is advanced by the visual control over the wire, and its position is ascertained by the saline injection which forms 'bubbles' on the ICE image. (*C*) Then the needle is loaded and the whole instrument is pulled back while maintaining rotation towards the septum. (*D*) Gentle rotations clockwise and counter-clockwise allow for proper positioning of the transseptal sheath towards the septum, showing typical tenting sign (arrow). (*E*) The needle is advanced (upper arrow), and penetration to the left atrium may be clearly visualized by the saline injection forming 'bubbles' on ICE image (lower arrow). (*F*) Once the dilator is placed together with the needle in the left atrium, the sheath is advanced while keeping the dilator in a stable position with the needle retracted. IAS, interatrial septum; LA, left atrium; LSPV, left superior pulmonary vein; SVC, superior vena cava; TSN, transseptal needle; TS, tenting on the septum; TSS, transseptal sheath.

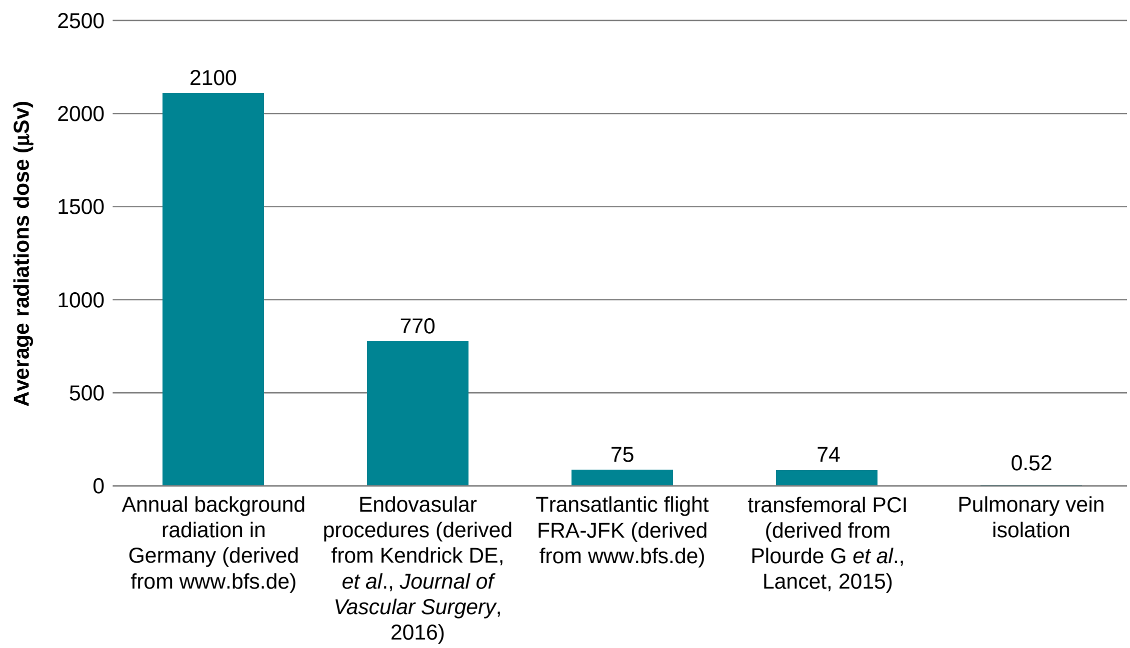


Figure 12 Comparison between annual background radiation and different interventions. PCI, percutaneous coronary intervention; FRA-JFK, Frankfurt to John F. Kennedy (adapted from Schreiber *et al.*[55]).

catheter towards the left pulmonary veins. The TSP can be fully accomplished without fluoroscopy under guidance of ICE as shown in many studies.[81,84,86] Not only that ICE allows for more direct visual guidance, but it also allows for the assessment of difficult septal anatomies.[87] A recently published trial including almost 750 ICE-only guided transseptal procedures at five institutions showed that all punctures could be accomplished with 100% success without fluoroscopy with no periprocedural complications related to puncture itself in average of 19 ± 10 min (skin-to-LA access).[88] Even in patients with intracardiac devices, no device-related complications were observed. Representative ICE images during the most important steps of zero-fluoroscopic TSP are shown in *Figure 11*.

Limitations of intracardiac echocardiography usage

The limiting factors for complete zero-fluoroscopic procedures are the following: (i) absence of large-scale randomized trials (RCT) showing clear-cut benefits of complete zero-fluoroscopic approach for patients and EP personnel, (ii) additional costs of ICE, and (iii) unwillingness to change the routine, which has been exercised for few decades using fluoroscopy as the only navigation tool for catheter deployment. In our opinion, no RCTs are realistically needed to prove enhanced safety of using ICE during complex ablation procedures. Seeing how the catheter moves inside the heart, the catheter–tissue contact, and all intracardiac structures is impressive and persuasive that even a limited experience with ICE is sufficient for any electrophysiologist to allow him or her from using this technology. Published data show that ICE not only cuts down the radiation exposure but also shortens the ablation procedure with the possibility of treating more patients during working hours. The ICE in combination with 3D-mapping can eliminate fluoroscopy completely. The attitudinal aspects toward X-ray could be overcome by a generation change in the EP with more progressive thinking ('the best radiation bill is zero bill') and expertise. Finally, additional costs of ICE could be overcome if worldwide consumption of probes puts pressure on producers to lower prices. The answer to the ultimate question whether ICE is worth the effort is definitely positive. It is worth the price: 34% relative reduction of complications reported by Goya *et al.* speaks for itself; however, not every health care system is willing to pay for it.[89] There are at least three categories of patients who might have clear benefit from zero- or limited-fluoroscopy procedures: (i) obese patients (due to inherently higher doses of radiation), (ii) pregnant women (we need to avoid radiation completely), and (iii) children (we might feel compelled to eliminate any stochastic adverse events of radiation, i.e. eliminate the lifetime risk of cancer).

Summary

Two factors have contributed to a significant decrease in radiation exposure during EP interventions in the past decade:

- Technological improvements with ULD protocols allowing to perform complex procedures with <10% of former radiation doses.
- General awareness about this topic especially by the younger generation in the EP labs worldwide.

Do we still have to do better?

Using technological innovations and considering fluoroscopy time and dosage as a quality marker finally let us achieve the goal of exposing ALARA—as low as reasonably achievable. And today, we can almost eliminate every potentially harming side-effect of using radiation (see *Figure 12*). Still, keeping the stochastic effects in mind, the only way to come to zero risk is exposing zero ionizing radiation by adding an additional real-time imaging modality: for example, by using 3D-mapping systems and ICE.

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Data availability

All relevant data are within the manuscript and its supporting information files.

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