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EDITORIAL

Reduction of radiation exposure in catheter ablation of atrial fibrillation: Lesson learned

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Abstract

Over the last decades, the concern for the radiation injury hazard to the patients and the professional staff has increased in the medical community. Since there is no magnitude of radiation exposure that is known to be completely safe, the use of ionizing radiation during medical diagnostic or interventional procedures should be as low as reasonably achievable (ALARA principle). Nevertheless, in cardiovascular medicine, radiation exposure for coronary percutaneous interventions or catheter ablation of cardiac arrhythmias may be high: for ablation of a complex arrhythmia, such as atrial fibrillation, the mean dose can be > 15 mSv and in some cases > 50 mSv. In interventional electrophysiology, although fluoroscopy has been widely used since the beginning to navigate catheters in the heart and the vessels and to monitor their position, the procedure is not based on fluoroscopic imaging. Therefore, non-fluoroscopic three-dimensional systems can be used to navigate electrophysiology catheters in the heart with no or minimal use of fluoroscopy. Although zero-fluoroscopy procedures are feasible in limited series, there may be difficulties in using no fluoroscopy on a routine basis. Currently, a significant reduction in radiation exposure towards near zero-fluoroscopy procedures seems a simpler task to achieve, especially in ablation of complex arrhythmias, such as atrial fibrillation. The data reported in the literature suggest the following three considerations. First, the use of the non-fluoroscopic systems is associated with a consistent reduction in radiation exposure in multiple centers: the more sophisticated and reliable this technology is, the higher the reduction in radiation exposure. Second, the use of these systems does not automatically lead to reduction of radiation exposure, but an optimized workflow should be developed and adopted for a safe non-fluoroscopic navigation of catheters. Third, at any level of expertise, there is a specific learning curve for the operators in the non-fluoroscopic manipulation of catheters; however, the learning curve is shorter for more experienced operators compared to less experienced operators.

Key words: Catheter ablation; Atrial fibrillation; Radiation exposure; Fluoroscopy time; Dose area product; Electro-anatomic mapping

Core tip: After 25 years from the formulation of the ALARA principle, the awareness of the potential hazard related to radiation exposure has greatly increased in medicine. Non-fluoroscopic three-dimensional systems, introduced in interventional electrophysiology to support complex procedures, have the potential to significantly decrease the use of fluoroscopy. In interventional electrophysiology, the clinical perspective is to perform procedures with minimal use of fluoroscopy without endangering the safety and efficacy. However, to achieve this task the use of the non-fluoroscopic system has to be optimized and a learning curve is necessary even for operators experienced in fluoroscopy-based electrophysiology.

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NEED FOR REDUCTION OF RADIATION EXPOSURE IN ELECTROPHYSIOLOGY PROCEDURES

Over the last years, the awareness of the risk related to the use of ionizing radiation in medicine has progressively increased. Cardiac imaging procedures lead to substantial radiation exposure in many patients: in a population-based analysis[1], the median cumulative effective dose over 3 years was 15.6 mSv and, among patients receiving a high annual dose (> 20-50 mSv), repeat cardiac catheterization procedures are the largest contributors to the radiation dose. The potential risks related to this radiation exposure are expected to be vastly outweighed by the benefits, especially if the procedure is appropriately justified and carefully optimized[2]. Although it is difficult to assess the consequences of the deterministic (dose-dependent) and stochastic (non dose-dependent) effects for the exposure to low-dose ionizing radiations used in cardiovascular imaging, the estimate of lifetime additional risk of cancer spans between 1/2000 and 1/1000 per single cardiovascular procedure[3]. It should be also taken into account that several patients undergo repeat procedures and that a younger patient population is more sensitive to the induction of cancer than an older patient population[4]. Similarly, the risk related to radiation exposure is not negligible for the medical staff. Noteworthy, according to a survey undertaken in Tuscany, Italy[5], interventional cardiologists and electrophysiologists represent more than 60% of the medical staff receiving the highest annual radiation exposure (> 6 mSv), with no statistically significant difference between physicians and nurses/technicians. This radiation exposure is by far greater than the one of the urologists, radiologists, and personnel of nuclear medicine. Moreover, according to the same source[5], the median lifetime professional exposure is 54 mSv, leading to an estimate lifetime attributable risk of cancer of 1 out of 200.

A decade ago, a document[6] endorsed by the main American scientific societies in cardiovascular medicine was published. This document states the clinical competence required for physicians performing fluoroscopically-guided invasive cardiovascular procedures to optimize patient safety and image quality. Importantly, it also highlights the ALARA principle, previously proposed by the United States National Council on Radiation Protection and Measurements[7]: due to both the stochastic and deterministic effect of radiation, there is no magnitude of radiation exposure that is known to be completely safe and, therefore, the use of ionizing radiations should be As Low As Reasonably Achievable. This principle confers to physicians the responsibility for reducing as much as possible the dose of radiation during cardiovascular procedures, in order to minimize the radiation injury hazard to the patients, to the professional staff and to themselves. The dose delivered to the patient depends on the following three factors: (1) type and setting of the X-ray equipment; (2) patient size; and (3) physician conduct. Consequently, all these three factors should be considered and optimized to comply with the ALARA principle. Importantly, opposite to what is commonly thought, fluoroscopy time poorly expresses the dose delivered to the patient. In fact, this value only reflects the operator's attitude to use radiation during a given procedure. Moreover, the same value of fluoroscopy time may correspond to a very different radiation exposure, depending on the predominant use of low-dose fluoroscopy or high-dose cine loop acquisition. Therefore, a reliable surrogate measurement for the total amount of X-ray energy delivered to the patient is the dose-area product (DAP), expressed usually in $Gy \cdot cm^2$ and automatically measured by X-ray systems[6].

In the real world, after the dissemination of the ALARA principle, the process of optimization is still ongoing. Optimization depends on several factors, some of which are difficult to identify and control. Considering again the data by Chen *et al*[1], based on a population enrolled between 2005 and 2007, after the ALARA principle was diffused, percutaneous coronary interventions or electrophysiologic procedures were the main determinants of radiation exposure in the population receiving the highest radiation dose (> 20 mSv). As mentioned above, one of the determinants of the dose to the patient is the physician's conduct, which may be very much dependent on the physician's experience in a given procedure. In fact, in the very early phase of a physician's learning curve, the workflow can be far from being optimized and this can result in an excessive use of fluoroscopy. In this context, newer methodologies of teaching and learning can be effectively used. One small study performed in our center[8] shows that the training implemented by a high-fidelity hybrid simulator reduces from 10 to 5 min, on average ($P < 0.0001$), the fluoroscopy time per patient spent by fellows novice in electrophysiology to position catheters in the conventional sites at the beginning of the procedure. In the future, if this or similar training modalities are not considered, we may face a new paradox: while the more experienced operators minimize radiation exposure in complex procedures using established techniques and technologies, the less experienced physicians use a higher dose for a standard and relatively simple procedure.

Recently, the European Society of Cardiology published two position papers on the appropriate and justified use of medical radiation in cardiovascular imaging[9] and on the practical ways to reduce radiation dose for patients and staff during electrophysiology procedures[10]. Focusing on the field of interventional electrophysiology, these papers report the radiation dose to the patients for electrophysiology procedures. This dose may vary from 3.2 mSv for a simple diagnostic electrophysiology study to a higher value for complex procedures, such as atrial fibrillation ablation, for which the median dose is 16.6 mSv, ranging from 6.6 to 59.6 mSv[10]. Another review of 17 studies, 12 of them published after the year 2000, reports an effective dose even higher (20.3 mSv) for catheter ablation of cardiac arrhythmias, in general, including ablation of less complex arrhythmias[11]. As suggested by the consensus document[10], this situation still requires further improvement, once optimization of X-ray equipment and shielding of the laboratory personnel are obtained. In fact, non-fluoroscopic three-dimensional systems, namely the Ensite-NavX (St.Jude Medical, United States) and the CARTO (Biosense Webster, United States), widely used since the late nineties for ablation of complex arrhythmias, can be used effectively to reduce radiation exposure during electrophysiology procedures. In a randomized study[12], the use of these systems for catheter ablation of cardiac arrhythmias reduced X-ray exposure with a similar efficacy and safety compared to the conventional approach. However, it should be highlighted that the use of these systems does not *per se* reduce radiation exposure, but the operators should develop procedural workflows to rely on non-fluoroscopic guidance as much as possible without compromising safety[10]. Especially for complex left atrial procedure during which the operator may face different anatomic variants, integration in these systems of pre-acquired three-dimensional imaging from computed tomography or magnetic resonance scan has the potential to drastically reduce the radiation exposure during the procedure[9].

The following sections will focus on reducing radiation exposure in catheter ablation of atrial fibrillation. This is an increasingly used procedure especially in patients with paroxysmal forms and, moreover, the use of fluoroscopy in such a complex and demanding procedure can be high. Therefore, reduction of radiation exposure in this procedure is expected to increase the net benefit of the procedure, minimizing the risks, which can be also related to the radiation exposure especially in case of repeat procedures.

ZERO OR NEAR-ZERO FLUOROSCOPY FOR ATRIAL FIBRILLATION ABLATION?

Unlike percutaneous coronary interventions, electrophysiologic procedures are based on recording and interpretation of intracavitary electrograms. Therefore, although fluoroscopy is very useful to maneuver and check the position of catheters, imaging based on ionizing radiations is not an integral part of the electrophysiologic procedure. In fact, ablation of various types of supraventricular and ventricular tachycardia with no use of fluoroscopy is feasible both in children[13-18] and adults[19-22] using non-fluoroscopic three-dimensional systems. Also a complex procedure, such as pulmonary vein isolation to treat atrial fibrillation, is feasible with no use of fluoroscopy[23,24]. Although these studies certainly demonstrate the feasibility of zero-fluoroscopy procedures, this issue deserves several considerations, especially in the case of complex procedures such as atrial fibrillation ablation. First, the majority of the reported series and in particular those on catheter ablation of atrial fibrillation are small and from very experienced centers. Even for senior electrophysiologists there may be a learning curve in the transition from fluoroscopically based procedures to zero-fluoroscopy procedures[17]. Second, even in the best scenario of published data on procedure planned to be with no fluoroscopy, very limited radiations are used in some cases[23] to assist a part of the procedure. Extrapolating these data to a wider population, it is unlikely that in the near future electrophysiologists will be able to work in laboratories not equipped with X-ray systems. Therefore, the zero-fluoroscopy strategy does not seem to bring any benefit in term of laboratory costs. Third, in ablation of atrial fibrillation with no fluoroscopy, some technologies, which require specific expertise and add costs in centers in which they are not routinely used, become necessary. In fact, to safely navigate catheters in the heart with no fluoroscopy, intracardiac ultrasounds is mandatory and imaging integration with pre-acquired computed tomography or magnetic resonance imaging very useful to obtain a high resolution anatomy of the left atrium and pulmonary veins[23,24]. The use of the recently introduced contact force sensing technology should be also considered mandatory to avoid excessive tissue/catheter contact when catheters are maneuvered with no fluoroscopy[22]. Fourth, the workflow of a zero-fluoroscopy procedure requires accurate cardiac chamber reconstruction before non-fluoroscopic catheter navigation. This can be done correctly only by experienced operators and, in any case, may significantly prolong the procedure duration, especially at the beginning of the specific learning curve in zero-

Table 1 Techniques and technologies for catheter ablation of atrial fibrillation in the four patient cohorts considered in our center

	1st cohort	2nd cohort	3rd cohort	4th cohort
No. of patients	30	30	30	30
Procedure technique	Double TSP-C Circular mapping catheter Imaging integration (CT scan)	Unchanged	Unchanged	Unchanged
NF technology	2nd generation NF 3-DS (CARTO XP)	3rd generation NF 3-DS (CARTO3)	Unchanged	CARTO3 + contact force sensing
Technology feature for NF use	NF visualization of the mapping/ablation catheter	NF visualization of all inserted catheter	Unchanged	Monitoring of the electrode/tissue contact added
NF 3-DS optimization	Yes	No	Yes (Table 2)	Yes (Table 2)
Timing	Last 30 cases with CARTO XP	First 30 cases with CARTO3	After 12 mo	After 12 mo

3-DS: Three dimensional system; CT: Computed tomography; NF: Non-fluoroscopic; TSP-C: Transseptal catheterization.

fluoroscopy procedures.

After these considerations, it can be concluded that zero-fluoroscopy procedures are a very interesting perspective for the future, but they are not common practice at present. Certainly, children and pregnant women are ideal candidates for zero-fluoroscopy catheter ablation, when other treatments fail or are not feasible. On the other hand, currently, every effort should be made by every operator to decrease as much as possible the use of radiation without endangering the procedure safety and efficacy until near-zero fluoroscopy procedures become routine.

LESSON LEARNED IN THE REDUCTION OF RADIATION EXPOSURE FOR ATRIAL FIBRILLATION ABLATION

Even in very experienced hands, catheter ablation of atrial fibrillation without a non-fluoroscopic three-dimensional system is associated with a fluoroscopy time of approximately 60 min[25] and, consequently, with a relatively high radiation exposure. However, as already mentioned[10], a non-fluoroscopic system without a workflow aimed at optimizing its use does not necessarily reduce the radiation exposure. In fact, in catheter ablation of atrial fibrillation, the sporadic use of non-fluoroscopic systems may paradoxically double the fluoroscopy time and radiation exposure when the system is used, due to the complexity of the procedure[26]. In a retrospective analysis[27] spanning 6 years (2004-2009) and including four cohorts of patients who showed comparable clinical characteristics and underwent catheter ablation of atrial fibrillation by using in a non-randomized way fluoroscopy or one of the non-fluoroscopic systems (Ensite NavX, CARTO XP, CARTO3), a third generation non-fluoroscopic system (CARTO 3) was associated with the shortest fluoroscopy time with no difference with the other 3 groups in term of procedural data and clinical outcomes. Although the reduction was statistically significant, the average fluoroscopy time using CARTO 3 in this study was still close to one hour (52 ± 21 min). This underlines the complexity of the variables that may determine the reduction of radiation exposure, which is not merely due to the use of a specific non-fluoroscopic system. Another study[28] further supports this concept. In this study, over six months, 120 patients were randomly assigned to use fluoroscopy only, a second generation (CARTO XP), or a third generation (CARTO3) non-fluoroscopic system to support catheter ablation of atrial fibrillation. The procedure was performed by operators with a specific experience in reduction of radiation exposure. While there was no difference in the clinical and anatomic variables among the three groups, the fluoroscopy time was shorter and less than 3 min for the whole procedure when the third generation non-fluoroscopic system was used with an optimized procedural workflow.

We evaluated the process of reduction of radiation exposure in catheter ablation of atrial fibrillation using a non-fluoroscopic three-dimensional electroanatomic system both in a single- and multicenter experience[29,30]. In our center, the procedural data of four cohorts of patients, sampled sequentially, were considered[29]. Each cohort included atrial fibrillation patients undergoing the first procedure of pulmonary vein isolation. The technologies and techniques used in each cohort are reported in Table 1. Among the four cohorts there was no significant difference in the clinical characteristics of the patients, in term of age, sex, body mass index, type and duration of atrial fibrillation, which reflects the homogeneous criteria used to select candidates for atrial fibrillation ablation in the considered time interval. The procedure was standardized as described elsewhere[31] and it was alternatively performed by two operators with a similar experience in atrial fibrillation ablation (> 400 procedures each), although the background in interventional electrophysiology was different (23 years *vs* 10 years, respectively). Importantly, the radiation exposure for the pre-procedure computed tomography scan was very low (< 1 mSv) due to an optimized acquisition protocol[31]. In the 3rd and 4th cohort, the use of a third generation non-fluoroscopic three-dimensional system was optimized by adopting the features listed in Table 2, including in the 4th cohort the recently introduced

Table 2 Features of the third generation non-fluoroscopic system CARTO 3 useful to minimize fluoroscopy during an electrophysiology procedure

Feature	Function
Imaging integration with pre-acquired CT or MRI image	Allows high resolution visualization of the LA and PVs; once registered in the system, the mapping/ablation catheter can be navigated with minimal use of fluoroscopy
Display in stable mode of the icon of the mapping/ablation catheter	Allows stable visualization of the mapping/ablation catheter on the system, similar to the one visualized on fluoroscopy
Colors on the distal part of the mapping/ablation catheter	Indicate the direction of the deflection of the distal part of the catheter
Catheter projection	Estimates the distance from the catheter tip to the surface of the electroanatomic map or to the surface of the CT/MRI image
Contact force sensing	Measures in grams the contact between the catheter tip and the tissue; used to avoid excessive contact during catheter manipulation and to optimize contact during ablation
Real time display of the circular mapping catheter	Allows real time visualization of the circular mapping catheter during positioning into the PVs
Highlight of the circular mapping catheter electrodes	Identify the position of the electrodes of the circular mapping catheter; used to identify the site of a conducting gap during circumferential PV ablation
Catheter snapshot	Shows a memorized position of a catheter (*e.g.*, circular mapping catheter); used to precisely re-navigated a previous catheter positioning

CT: Computed tomography; LA: Left atrium; MRI: Magnetic resonance imaging; PV: Pulmonary vein.

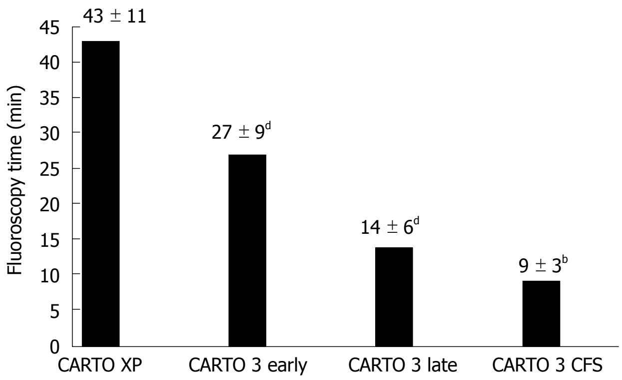

Figure 1 Histogram of fluoroscopy time (in minutes) for the whole procedure of pulmonary vein isolation in four cohorts of patients with atrial fibrillation, using the non-fluoroscopic CARTO system with progressively new technologies and protocols. There is a progressive and significant reduction in fluoroscopy time, but the greatest percent reduction (-48%) is observed between the second and third cohort, CARTO 3 early *vs* CARTO 3 late. In these two cohorts the technology was the same, but in the second one the system was used with an optimized protocol to reduce fluoroscopy. $^bP < 0.001$ *vs* the previous cohort; $^dP < 0.0001$ *vs* the previous cohort. CFS: Contact force sensing.

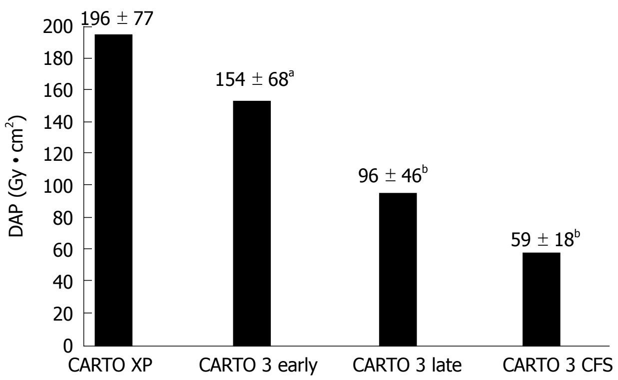

Figure 2 Histogram of dose area product values (in Gy•cm^2) for the whole procedure of pulmonary vein isolation in the same cohorts shown in Figure 1. As in Figure 1, there is a progressive and significant reduction in radiation exposure, expressed by the dose area product value. $^aP < 0.05$ *vs* the previous cohort; $^bP < 0.0001$ *vs* the previous cohort. DAP: Dose area product; CFS: Contact force sensing.

contact force sensing technology[32]. This was mainly used to avoid excessive contact force between the tip of the mapping/ablation catheter and the endocardium when the catheter was advanced non-fluoroscopically. Importantly, during non-fluoroscopic navigation of the catheter, its position was continuously monitored on the CARTO, to avoid events at risk for complications, such as entrapment of the circular mapping catheter in the mitral valve apparatus. While the procedural data, in term of procedure duration, number of pulmonary vein isolated, radiofrequency energy time, acute success and complication, was not significantly different among the four cohorts, there was a progressive decrease in fluoroscopy time and DAP values, as shown in Figures 1 and 2, respectively. Sub-analyzing data per operator, there are interesting findings when the 1st cohort is compared to the 2nd and the 2nd to the 3rd. In the first comparison, the more experienced operator obtained a 46% reduction (from 41 ± 9 to 22 ± 6 min, on average; $P < 0.0001$) in fluoroscopy time compared to only a 22% reduction (from 43 ± 13 to 33 ± 9 min, on average; $P = 0.0012$) obtained by the less experienced operator. Interestingly, an opposite phenomenon was observed in the second comparison: the more experienced operator, who had already obtained a greater reduction in the use of fluoroscopy, had a 36% reduction in fluoroscopy time (from 22 ± 6 min to 14 ± 5 min, on average; $P < 0.001$), definitely smaller than the 54% reduction obtained by the second operator (from 33 ± 9 min to 15 ± 7 min, on average, $P < 0.001$).

These data deserve two considerations, on the technology and the learning curve, respectively. First, the ability to reduce significantly radiation exposure towards a near zero-fluoroscopy procedure depends on the type and quality of the non-fluoroscopic system. A third generation non-fluoroscopic system, able to reliably visualize all the catheters inserted in the heart, allows catheter manipulation with minimal or no use of fluoroscopy leading to an immediate improvement in radiation exposure compared to the older system. This was confirmed in the multicentric study in 240 consecutive patients undergoing catheter ablation of atrial fibrillation[30]. In this study, the average fluoroscopy time decreased from 26 ± 15 min to 16 ± 12 min (P < 0.001) and the positive effect of adopting the third generation system was significant in all the participating centers. The importance of the technology is further confirmed by the observation in our center of a still significant reduction in radiation exposure when the newer contact force sensing technology was introduced. The second consideration is on the need for a specific learning curve. Although in the multicenter study[30] the reduction in the use of fluoroscopy is observed in all centers, the percent reduction spans from 25% to 56% among centers. This is likely to be related to a specific learning curve in reduction of radiation exposure. In fact, considering again the data from our center, a more experienced electrophysiologist may exhibit a shorter learning curve in the reduction of radiation exposure, while a less experienced one eventually reaches the same level of ability in non-fluoroscopic maneuvering of catheters after a longer learning curve.

CONCLUSION

Over the last years, the awareness of the radiation injury hazard to the patients and the professional staff has greatly increased. Reduction in the radiation exposure in a complex electrophysiology procedure, such as atrial fibrillation ablation, should be considered. This is an increasingly used procedure with usually longer fluoroscopy times. Therefore, the decrease in radiation exposure is expected to improve the net benefit of the procedure for the patient and to minimize the radiation injury hazard for the professional staff. The lesson learned so far tells us that sophisticated technologies have to combine with a specific know-how to achieve this task. In fact, non-fluoroscopic three-dimensional systems with their constant updating in the technology content have a key role, but minimization in the use of radiations is obtained if these technologies are used with an optimized protocol and after a specific operators' learning curve. This may last several months and be longer for less experience operators.

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