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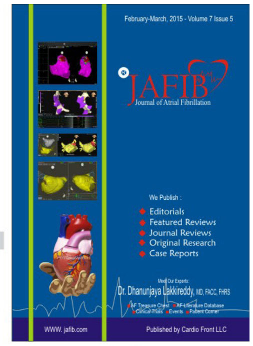

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# Catheter Ablation Of Atrial Fibrillation Without Radiation Exposure Using A 3D Mapping System

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**Abstract**

Transcatheter ablation procedures have been traditionally performed under fluoroscopic guidance. However, x-ray exposure is afflicted by the risk of developing malignancies as well as other deterministic effects of radiation. For this reason, radiation doses in the interventional laboratory should be reduced "As Low As Reasonably Achievable", with respect to the safety of the patients and the medical staff. This is of utmost importance in atrial fibrillation (AF) ablations, which are usually lengthy procedures. With the improvement of technology, the development of additional imaging tools and the widespread of 3D electroanatomic mapping systems (EAM), near-zero fluoroscopy AF ablation procedure is becoming a reality, limiting fluoroscopy use mainly to guide transseptal puncture.

In the present paper we reviewed the risks to health related to x-ray exposure and we discussed the current state of knowledge of catheter ablation of AF without fluoroscopy in the 3D EAM system era.

## Introduction

Catheter ablation is nowadays a well-established therapy for treatment of atrial fibrillation (AF).[1] Historically, conventional fluoroscopy-guided ablations were lengthy procedures, posing a risk to the patient and the physician related to radiation exposure. This risk of radiation-related dermatitis, cataracts, reproductive system damage and malignancy is cumulative and lifelong, and is of a greater concern for particularly sensitive population groups like children and pregnant women, but also for patients who are potentially exposed to multiple ablation procedures, as for AF ablation.[2-4]

As technology and operator experience improved, procedural and fluoroscopic times have progressively decreased.[5] In the past few years, development of new tools like 3D navigation systems have enabled a potential non-fluoroscopic approach to almost all right-sided arrhythmias.[6] However, left-sided ablations, especially AF ablation, currently represent the majority of everyday electrophysiological (EP) practice. The main limitation in fluoroscopy reduction or complete x-ray elimination for AF ablation is due to safety concerns, mainly related to transseptal puncture. With the improvement of technology, the development of tools like intracardiac echocardiography (ICE) and the widespread of 3D electroanatomic mapping systems (EAM), near-zero fluoroscopy AF ablation procedure is becoming a reality.[7, 8]

**Disclosures:**
None.

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This review discusses the current state of knowledge of catheter ablation of AF without radiation exposure in the 3D mapping system era.

## Radiation risks

### Biological Effects Of Radiation

Nowadays, we are exposed to a variety of radiation sources in our everyday life, at least in the developed countries. Harley et al. reported that natural background radiation was responsible for an effective annual dose equivalent of 3 mSv in the United States and Canada.[9] Moreover, the major cause of human-made radiation source is certainly attributable to exposure related to medical imaging and tests.[10] The American College of Cardiology guidelines recommend that all invasive catheterization laboratories adopt the ALARA principle, that is to say reducing the radiation dose 'As Low As Reasonably Achievable' in order to protect the patient and the medical staff.[11]

The biological effect of radiation is related to hydroxyl radical creation and to its interaction with DNA, causing DNA ionization, strand breaks and base damage. Two injury mechanisms to DNA have been described: the stochastic mechanism caused by unrepaired damage of a single viable cell, and the deterministic effect, in which a significant number of cells are involved and sufficiently damaged so as to cause observable injury. The stochastic effect occurs by chance and without a threshold level of dose. The main stochastic effect of radiation exposure is cancer, whose probability is proportional to the dose of radiation but its severity is independent of the dose. Deterministic effects, on the other side, have a threshold below which the effect does not occur. Examples of deterministic effects

**Table 1:** Main studies investigating the impact of EAM systems on fluoroscopy and procedural time in AF ablation

| | EAM System | Ablation technique | Patients | Fluoroscopy time (min) | Procedural time (min) |
|---|---|---|---|---|---|
| Estner et al., Europace 2006 | NavX | PVI | 64 | 38.9 ± 19.3 | 188 ± 63 |
| Richmond et al., JCE 2008 | NavX Fusion | PVI + LL+ CFAE | 23 | 37 ± 12 | 207 ± 61 |
| Piorkowski et al., Europace 2008 | NavX Fusion | PVI + LL+ CFAE | 36 | 35 ± 12 | 187 ± 35 |
| De Chillou et al., JICE 2008 | CartoMerge | PVI | 30 | 18 ± 8 | 205 ± 32 |
| Steven et al., JCE 2009 | NavX | PVI | 30 | 22 ± 6.5 | 134 ± 12 |
| Bertaglia et al., Europace 2009 | CartoXP/Merge | PVI | 333 | 55 ± 24 | 204± 65 |
| Della Bella et al., JCE 2009 | CartoMerge | PVI | 145 | 56 ± 18 | 170 ± 20 |
| Stevenhagen et al., JCE 2009 | CartoMerge | PVI | 68 | 40 ± 13 | 182 ± 30 |
| Augello et al., Heart Rhythm 2009 | CartoRMT | PVI | 25 | 2.5 ± 0.9<br>+<br>5 ± 2 for Lasso validation | 105 |
| Dong et al., JCE 2009 | CartoXP | PVI | 110 | 32 ± 7 | 154 ± 29 |
| Scaglione et al., Europace 2011 | CartoMerge | PVI + LL | 40 | 10 ± 4 | 85 ± 25 |
| Scaglione et al., Europace 2011 | Carto3 | PVI + LL | 40 | 2 ± 2 | 89 ± 16 |
| Stabile et al., Europace 2012 | CartoXP | PVI | 123 | 26 ± 15 | 159 ± 65 |
| Stabile et al., Europace 2012 | Carto3 | PVI | 117 | 16 ± 12 | 157 ± 67 |
| Forleo et al., JICE 2013 | NavX | PVI + LL +CFAE + SVC isolation + GP ablation | 545 | 49.5 ± 35.4 | 196.5 ± 72.8 |
| Brooks et al., Int J Cardiol 2013 | CartoXP | PVI + LL + CFAE | 30 | 65.3 ± 17.8 | 232 ± 60 |
| Brooks et al., Int J Cardiol 2013 | CartoSound | PVI + LL + CFAE | 30 | 50.8 ± 12.2 | 223 ± 48 |

CFAE: complex fractionated atrial electrograms; EAM: electroanatomic mapping; GP: ganglionic plexi; LL: linear lesions; PVI: pulmonary vein isolation

of radiation include skin erythema, hair loss, cataracts and sterility.

### Radiation Exposure To The Patient

One hour of fluoroscopy for lengthy and complex EP procedures like AF ablation was the rule and not the exception until few years ago. Lickfett et al.[12] demonstrated that catheter ablation of AF required significantly greater fluoroscopy duration and radiation exposure (more than four-fold) than simpler catheter ablation procedures. Similar data have been reported also by Macle et al.[13], although using a less sensitive method to assess the peak skin doses. Kidouchi et al.[14] reported that the mean fluoroscopy time for AF ablation (70 minutes) was 2 to 3 times longer than for patients undergoing ablation for other forms of tachycardia (34 minutes). These investigators found that the average entrance skin dose for the AF group was 1.5 to 3 times bigger than for the non-AF group. The more recent position document of the ESC Association of Cardiovascular Imaging, Percutaneous Cardiovascular Interventions and Electrophysiology, showed that, in patients undergoing an AF ablation procedure, the effective radiation dose was 16.6 mSv (ranging from 6.6 to 59.2 mSv), equivalent to 830 chest x-rays.[15]

The lifetime risk for a fatal malignancy associated with a single AF ablation procedure has been estimated to be 0.15% for female and 0.21% for male patients.[12] The respective risk normalized to 60 minutes of fluoroscopy was 0.07% and 0.1% for female and male

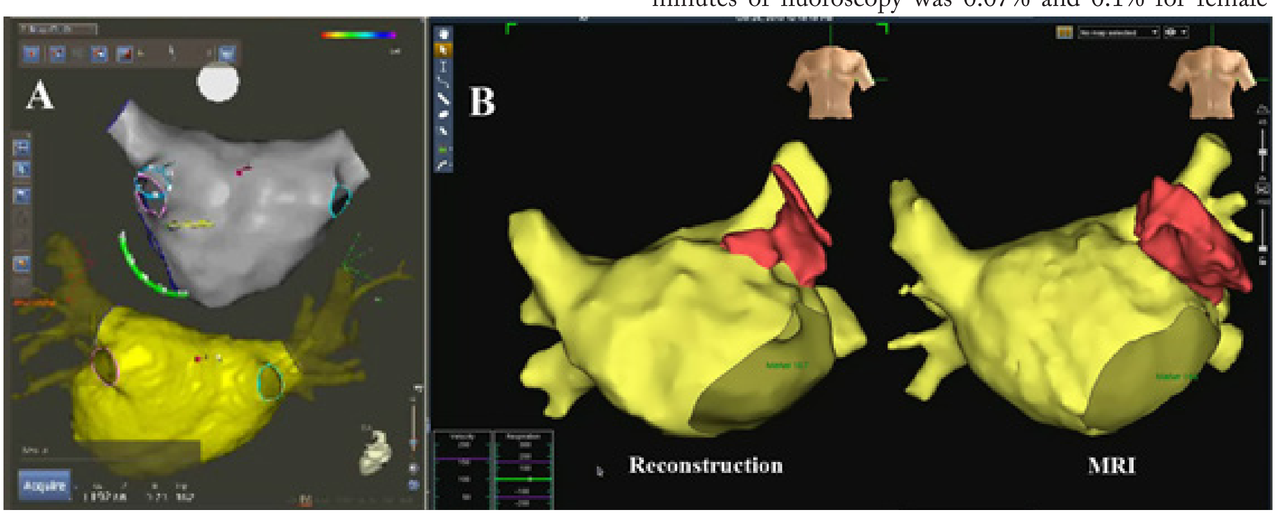


**Figure 1:** A – upper panel: Carto 3 electroanatomic reconstruction of the left atrium obtained with the mapping catheter (postero-anterior view). A – lower panel: MRI of the left atrium. B – left panel: NavX electroanatomic reconstruction of the left atrium obtained with the mapping catheter (antero-posterior view). B – right panel: MRI of the left atrium. With both EAM systems, the reconstructed cardiac anatomy is very similar to that obtained with MRI

**Table 2: Main studies evaluating the impact of imaging integration on AF ablation**

| | Fluoroscopy time (min) | | | Long-term success rate (%) | | | Complication rate (%) | | |
|---|---|---|---|---|---|---|---|---|---|
| | Carto | CartoMerge | P | Carto | CartoMerge | P | Carto | CartoMerge | P |
| Kistler et al., JCE 2006 | 62 ± 26 | 49 ± 27 | 0.03 | 49 | 68 | <0.01 | 0.06 | 0.02 | ns |
| Martinek et al., PACE 2007 | 55 | 63 | 0.06 | 68 | 85 | 0.02 | 0.09 | 0.04 | ns |
| Kistler et al., Eur Heart J 2008 | 57 ± 23 | 53 ± 18 | 0.1 | 56 | 50 | 0.9 | 0.03 | 0.05 | ns |
| Tang et al., Chin Med J 2008 | 28 ± 13 | 20 ± 7 | <0.01 | 79 | 74 | 0.5 | 0.02 | 0.02 | ns |
| Bertaglia et al., Europace 2009 | 55 ± 23 | 54 ± 25 | 0.9 | 58 | 77 | <0.01 | 0.04 | 0.02 | ns |
| Caponi et al., Europace 2010 | 34 ± 1 | 15 ± 1 | <0.01 | 52 | 55 | ns | 0.04 | 0.03 | ns |

patients respectively. Beir et al.[16] showed the same results (0.065% fatal cancer risk from a radiofrequency ablation procedure requiring 60 minutes of fluoroscopy), and also found a 0.0001% genetic defect risk in the United States population, meaning that, in 1 million patients undergoing a typical radiofrequency (RF) ablation procedure, 650 extra malignancies and 1 birth defect were expected in addition to the naturally occurred events.[17] Therefore, the individual cancer risk (fatal and non-fatal) of a patient admitted in a modern cardiology ward has been estimated as 1/200(18). Moreover, obese patients have been shown to receive significantly higher radiation exposure during pulmonary vein isolation for AF than the general population. Ector et al.[19] reported effective radiation doses of 15 ± 8 mSv in non-obese patients compared to 27 ± 12 mSv in obese patients (BMI greater or equal to 30 kg/m2). In the latter group of patients, the mean attributable lifetime risk of malignancy is increased to 0.15%. The radiation risk is further increased if a pre-procedural computed tomography (CT) scan is performed to define the anatomy of the left atrium and the pulmonary veins, and by possible repetitive ablation procedures for AF recurrences. For this reason, our and several other groups decided to perform a magnetic resonance imaging (MRI) in order to avoid this additional risk.[20-22] Although single-procedure radiation exposure appears to constitute a very low cancer risk, repeated procedures may indeed begin to cause a measurable increased risk.

### Radiation Exposure To The Medical Staff

If the safety of the patient is of utmost importance, the exposure of the physician performing the ablation procedure should be considered as well.[23] Even if interventional procedures account for the 2% of all radiological procedures, they are responsible for an exposure of the interventional cardiologist per-head per-year 2 to 3 times higher than that of a radiologist.[24] The risk coefficient for cancer induction in medical staff is 5% per Sv of effective dose, which for an interventional cardiologist corresponds to receiving a maximal occupational dose each year (50 mSv) for 20 years of work. The evaluated risk of fatal cancer to the operator per EP procedure ranges between 1/500,000 and 1/1,000,000,[25] but the lifetime attributable risk of fatal cancer following a 15-year radiological exposure exceeding 50 mSv is 1/200 exposed subjects.[4] Somatic DNA damage has also been described in interventional cardiologists compared with clinical cardiologists,[26] implying reproductive system and birth defects.[3] Moreover, occupational risks related to x-ray exposure include orthopedic complications such as neck and back pain, which could be reduced or avoided with apron lead elimination.[27]

## 3D EAM Systems

The advent of EAM systems, able to reconstruct the cardiac chambers of interest and to simultaneously visualize multiple catheters, has allowed to perform ablation reducing or completely eliminating radiation exposure without affecting the safety of the procedure, giving the high level of accuracy and spatial resolution of 3D EAM.[28] To date, there are 2 main non-fluoroscopic 3D systems that allow catheter visualization and mapping.

### EnSite NavX

EnSite NavX (St. Jude Medical, St. Paul, Minnesota, USA) bases its methodology on the principle of applying an electrical current between surface patches positioned on the patient's chest. Electrodes from standard EP catheters sense the electrical signals transmitted between the patches and interact with the electrical field, so that the system reproduces and shows catheters' position and real-time motion. With the EnSite NavX system, an additional patch is positioned on the abdomen of the patient and is used as a reference during venous axis navigation at the initial phase of the procedure.[29]

### Carto

In the Carto system (Biosense Webster, Diamond Bar, California, USA) location of the sensor at the tip of a dedicated EP catheter is triangulated with three magnetic fields created by skin patches on patient's chest and back. This system allows 3D reconstruction of the chamber of interest and navigation within the map. Carto3, the new generation of the system, includes a hybrid technology that combines

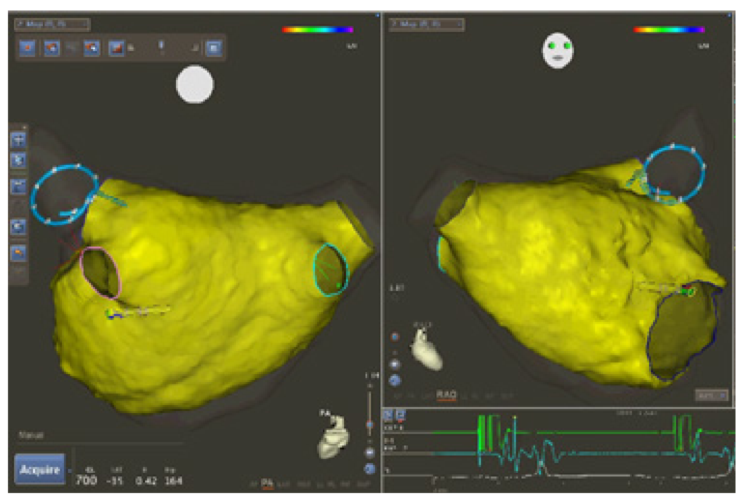


Figure 2: The Carto3 electroanatomic reconstruction obtained with the mapping catheters and the MRI are merged (postero-anterior and right anterior oblique views respectively); the system allows a reliable visualization of all the catheters inside the heart chamber. Yellow catheter, ablation catheter inside the left atrium; blue catheter, circular mapping catheter inside the left superior pulmonary vein

the magnetic location technology with current-based visualization data, allowing an even more accurate visualization of the tip and curve of the ablation catheter itself combined with the visualization of all the other diagnostic catheters.[30]

**Reduction Of Fluoroscopy**

One of the first papers reporting the ability of EAM in reduction of fluoroscopy time during EP procedures was published in 2000.[31] Since that year, several studies have demonstrated that EAM systems permitted to decrease or eliminate radiation exposure, especially in pediatric populations, with a similar success and complication rate compared to standard ablation procedures.[32-35] In our personal experience, we demonstrated that the combination of EAM systems with cryoablation and RF energy allowed to perform fluoroless slow-pathway ablation for atrioventricular nodal reentrant tachycardia in children and adolescents, with a high efficacy and safety, comparable to conventional fluoroscopy guided procedures.[36]

AF ablation procedure is technically challenging and highly fluoroscopy and time consuming, because of the need of targeting large ablation areas. The left atrium is a complex 3D structure, with variability of structure and pulmonary vein anatomy.[37] Ablation usually involves pulmonary vein isolation at the ostium level, carefully avoiding ablation inside the veins to reduce the risk of pulmonary vein stenosis. Moreover additional ablation such as linear lesions (roof, mitral isthmus lines, etc.) and ablation of complex fractionated atrial electrograms is sometimes required. These difficulties have encouraged the use of EAM to reconstruct cardiac anatomy, thus facilitating the procedure.

Moreover, EAM systems have permitted to significantly reduce x-ray exposure in the setting of AF ablation. Since the advent of EAM, literature reports a huge number of experiences using EAM to guide AF ablation. In the majority of the studies, fluoroscopy times ranged from around 5 minutes to one hour and a half, depending on the ablation strategy (Table 1). With technological improvements of the EAM systems, further x-ray reduction has been demonstrated. Our group showed a significant reduction in total fluoroscopy time between patients assigned to fluoroscopy alone, EAM integration with CartoMerge (Biosense Webster, Diamond Bar, California, USA), that allows to visualize only the ablation catheter, and EAM integration with Carto3, that permits visualization of either the ablation and other diagnostic catheters (18’09” ± 5’00”, 9’48” ± 3’41” and 2’28” ± 1’40” respectively; $p < 0.001$).[22] Stabile et al.[38] showed a significant reduction of fluoroscopy exposure with Carto3 compared to CartoXP (Biosense Webster, Diamond Bar, California, USA): 15.9 ± 12.3 minutes and 26.0 ± 15.1 respectively; $p < 0.001$. Despite this last work was not able to replicate the same minimal fluoroscopy time as reported in our paper, it demonstrated anyway that every physician was able to reduce his own fluoroscopy time thanks to the EAM system. This result supports the use of EAM system in daily AF ablation practice.

Furthermore, improved visualization of the anatomy of the pulmonary veins and the left atrium by merging techniques can provide an opportunity to tailor the ablation strategy to an individual’s anatomy. For this reason, many centers started to perform an imaging study, such as CT scan or MRI, before the procedure to know the anatomy in advance and to obtain a more reliable model after chamber reconstruction, so that the operator could be more confident in manipulating catheters without direct fluoroscopy visualization. However, CT scan is inherently characterized by a significant amount of x-ray exposure. To overcome this limitation, our center decided to choose the MRI instead of the CT scan.[21] Indeed, Caponi et al.,[21] comparing AF ablation procedures guided by CartoXP and CartoMerge, demonstrated that merging the pre-acquired MRI of the left atrium with the 3D EAM reconstruction did not modify the outcome of the ablation procedure, but permitted instead to obtain a significant reduction of x-ray exposure in the CartoMerge group (22.1 ± 11.4 minutes with CartoMerge vs. 40.4 ± 13.5 minutes with CartoXP in the paroxysmal AF group; 28.8 ± 14.3 minutes with CartoMerge vs. 58.0 ± 8.7 minutes with CartoXP in the persistent forms of AF). The same trend of x-ray reduction was reported by Kistler et al.[39] On the other side, Bertaglia et al.[40] did not confirm the previous results. One possible explanation of this conflicting result could be related to the multicenter fashion of the study, which involved a great number of EP centers with different level of expertise. Concerning clinical outcomes, similar conflicting results are reported in the literature.[41] A recent meta-analysis,[42] indeed, concluded that image integration for AF ablation does not result in better clinical outcomes compared to EAM alone, and therefore the usefulness of 3D EAM seems to be confined to x-ray reduction. Moreover, although displaying an ablation catheter and integrating its position within the CT/MRI geometry is possible, the accuracy of the 3D EAM is highly dependent on image quality and, more importantly, on the merge process. Possible image errors caused by the cardiac chamber volume, rhythm or respiratory state may influence the procedure parameters and outcomes. In addition, regardless the use of EAM system or fluoroscopy-guided approach, successful AF ablation remains critically dependent on appropriate catheter tip-tissue contact. Nonetheless, 3D EAM is not sufficiently predictive of good contact-derived lesions, which may make the clinical outcome uncertain.[43] Furthermore, an additional important feature is that image integration for AF ablation didn’t change the total procedural time as well as the complication rate (Table 2).[41,42] However, up to now, despite the use of 3D EAM systems, the majority of experiences still report few minutes of fluoroscopy, mainly used to guide the transseptal puncture.

**Zero-Fluoroscopy**

Two reports evaluated the feasibility and safety of pulmonary vein isolation with zero-fluoroscopy use combining 3D EAM and ICE.[7, 8] ICE has emerged as one of the most helpful tools in the EP laboratory, thanks to its ability of conveying real-time images during the procedure. Until recently, ICE was mainly used to assist with challenging transseptal puncture and anatomy, and to guide AF ablation with 8 mm-tip catheters to monitor over-heating and microbubble formation.[44] Nowadays, it is increasingly utilized as a guide to manipulate catheters in the left atrium.[45] Ferguson et al.[7] enrolled 21 patients undergoing AF ablation and utilized ICE to perform a double transseptal puncture. In 19 out of 21 cases, no fluoroscopy was used and the EP staff did not wear any protective lead, whereas in 2 cases 2-16 minutes of fluoroscopy were required. Reddy et al.[8] combined ICE and a 3D EAM system to perform a completely fluoroless procedure of pulmonary vein isolation in 20 patients. Transseptal puncture was deemed successful in every patient and no complication occurred. In eleven patients CT scan was used and integrated with the left atrium anatomy rendered with the 3D EAM. Despite these promising results, we have to consider that ICE still requires a dedicated operator, an additional venous puncture, potentially increasing the risk of vascular complications, and can result in longer ablation procedures, up to 4 hours. Thanks to its ability to generate multiple 2D ultrasound fans, ICE has also been used to reconstruct a 3D object with the CartoSound (Biosense Webster, Diamond Bar, California, USA) software algorithm, becoming a valuable tool for physicians to have a reliable anatomy reconstruction without the need of an imaging technique prior to the ablation procedure.[46] However, the resolution of 2D ICE imaging is lower compared to CT and MRI. Acoustical shadowing and incomplete penetration can hinder a complete 3D CartoSound rendering, which is operator dependent. Brooks et al.[47] performed a randomized controlled trial to compare image integration with CartoSound with conventional EAM system (CartoXP) in a mixed cohort of AF patients. In both groups, virtual geometries were merged to the previously acquired reconstructed CT scan. Whereas total procedure, ablation and mapping times were similar in each group, CartoSound reduced total x-ray time (51 ± 12 vs. 65 ± 18 min; $p = 0.001$), via a reduction in both mapping and remaining procedural time. It also demonstrated a reduced left atrial access time, while navigation accuracy, complication rate and AF ablation success at follow-up were similar in both groups.

Another strategy is using real-time 3D transesophageal echocardiography to guide AF ablation procedures, since it allows precise point-by-point navigation in the left atrium and visualization of both circular mapping and ablation catheter.[48]

All that considered, this is the question that might arise: is it really of utmost importance trying to reach zero-fluoroscopy by any means? Since EAM systems may reduce the fluoroscopy time to very few minutes confined to guide transseptal puncture, trying to reach zero-fluoroscopy at any cost, with the additional cost of tools like ICE or transesophageal echocardiography, the discomfort for the patient, additional vascular accesses and longer procedures, is probably not always justified. Last but not least, we should remember to apply the already existing protocols and strategies to decrease ionizing radiation exposure, such as minimizing the radiation tube-to-intensifier distance, the collimation of x-ray beam, the standard use of individual lead aprons, thyroid shields, lead glasses, x-ray protecting sterile gloves and radiation adsorbing sterile drapes together with the implementation of radiation safety programs.[23, 49]

## Future Directions

Nowadays, 3D EAM systems alone do not allow a completely zero-fluoroscopy approach to AF ablation, at least until the visualization of the transseptal needle by the non-fluoroscopic mapping system is possible. Besides 3D EAM systems, new technologies are constantly evolving to reduce fluoroscopy times and help the physician in the desirable transition between fluoroscopy and fluoroless procedures.[50] New tools such as the contact-force sensing catheters,[51] the MediGuide (St. Jude Medical, St. Paul, Minnesota, USA)[52] and the CartoUniv (Biosense Webster, Diamond Bar, California, USA) mapping systems, and the real time remote magnetic catheter navigation system (Stereotaxis Inc., St. Louis, Missouri, USA and Biosense Webster, Diamond Bar, California, USA)[53] have been introduced in the clinical practice showing favorable results.

## Conclusion

The importance of fluoroscopy reduction during AF ablation procedures cannot be ignored, with regards to both the patient and the operator. The availability of 3D EAM systems, in addition to ICE and dedicated protocols, contributes to a substantial decrease in radiation exposure. However, the reduction extent still remains operator-dependent, it requires specific training and learning curve and, above all, a mind changing. The current 3D EAM systems allow avoiding fluoroscopy, without harming the safety profile of the procedure, and potentially confining x-ray use only to guide transseptal puncture. Taking all that into account, fluoroscopy reduction shouldn't be pursued by any means, even in the zero-fluoroscopy era, and x-ray should still be used in particular situations where its lack would influence the safety of the procedure.

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