The role of intracardiac echocardiography in reducing radiation exposure during atrial fibrillation ablation

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Abstract

Aims: Intracardiac echocardiography (ICE) is a relatively young technique used during complex electrophysiology procedures, such as atrial fibrillation (AF) ablation. The aim of this study was to assess whether the use of ICE modifies the radiation exposure at the beginning of the learning curve in AF ablation. Materials and methods: In this retrospective study, 52 patients, in which catheter ablation for paroxysmal or persistent AF was performed, were included. For 26 patients we used ICE guidance together with fluoroscopy, whereas for the remaining 26 patients we used fluoroscopy alone, all supported by electroanatomical mapping. We compared total procedure time and radiation exposure, including fluoroscopy dose and time between the two groups and along the learning curve. Results: Most of the patients included were suffering from paroxysmal AF (40, 76%), pulmonary vein isolation being performed in all patients, without secondary ablation sites. The use of ICE was associated with a lower fluoroscopy dose (11839.60±6100.6 vs. 16260.43±8264.5 mGy, p=0.041) and time (28.00±12.5 vs. 42.93±12.7 minutes, p=0.001), whereas the mean procedure time was similar between the two groups (181.54±50.3 vs 197.31±49.8 minutes, p=0.348). Radiation exposure was lower in the last 9 months compared to the first 9 months of the study (p<0.01), decreasing gradually along the learning curve. Conclusions: The use of ICE lowers radiation exposure in AF catheter ablation from the beginning of the learning curve, without any difference in terms of acute safety or efficacy. Awareness towards closest to zero radiation exposure during electrophysiology procedures should increase in order to achieve better protection for both patient and medical staff.

Keywords: intracardiac echocardiography (ICE); radiation exposure; atrial fibrillation (AF); catheter ablation; learning curve

Introduction

Since catheter ablation became standard therapy for symptomatic atrial fibrillation (AF) [1], the awareness regarding radiation exposure during electrophysiology (EP) procedures has increased. New techniques are continuously developing in order to achieve radiation doses as low as reasonably achievable (ALARA principle) for both patients and medical staff [2,3].

Intracardiac echocardiography (ICE) is a relatively new technique used for the guidance of EP procedures that offers high resolution and real-time images of cardiac anatomy. Its main advantages include a better view of the interatrial septum and left atrium making transseptal puncture safer, direct assessment of catheter contact and location and real-time visualization of evolving radiofrequency lesions and complications (cardiac tamponade, thrombus formation, etc.) [2,4-10].

ICE has emerged as the most-widely used ultrasound-technique in EP procedures, replacing in part transesophageal echocardiography and being able to reduce radiation exposure [2,4,5,11]. Moreover, zero-
or near-zero-fluoroscopy AF catheter ablation has been shown to be achievable in experienced centers where the use of ICE has become essential [12-15], no differences in terms of safety or efficacy being observed [10,16-18]. Although the beneficial effects of ICE are already well known, there are few studies assessing radiation exposure during the ICE learning curve.

We present our experience with ICE-guided AF catheter ablation. The aim of this study was to assess whether the use of ICE reduces radiation exposure in AF ablation from the beginning of the learning curve.

**Material and methods**

After approval from the local Ethics Committee, seventy-eight patients who had undergone catheter ablation for paroxysmal or persistent AF at the Clinical Rehabilitation Hospital in Cluj-Napoca, Romania between 1st of January 2018 and 1st of June 2019 were retrospectively enrolled. After excluding patients that had undergone AF ablation using cryoenergy (16 patients), with AF and atrial flutter ablation during the same procedure (6 patients) and those presenting complications that led to cancellation and postponement of the procedure (4 patients), 52 patients qualified as the study population. All of these patients had undergone AF catheter ablation using radiofrequency energy for which they had signed informed consents. All operators performing the ablation procedures (3 operators) were senior staff with experience in catheter navigation under the 3D electroanatomical mapping system, but with no previous experience in ICE guidance.

Of the 52 patients included in our study, for 26 of them we used ICE (fig 1) and fluoroscopy guidance during the procedure, being defined as Group 1 and for the other 26 we performed the procedure using fluoroscopy guidance, being defined as Group 2, all supported by electroanatomical mapping. The selection of ICE patients was 1:1, non-randomized, for the entire period of the study.

We used ViewMate™ Z Ultrasound Console, along with the ViewFlex™ PLUS ICE Catheter from Zonare (9 F catheter, transducer frequency between 4.5 to 8.5 Mhz) and 3D electroanatomical mapping systems from two different vendors during the procedures (CARTO3, Ensite NavX). Percutaneous access for all patients was via the right femoral vein. All procedures were performed under local anesthesia and without the use of concomitant transesophageal echocardiography.

We compared total procedure time and radiation exposure, including fluoroscopy dose and total fluoroscopy time between the two groups. Also, we assessed the learning curve by comparing the procedure time and radiation exposure between the first 9 months and the last 9 months of the study. Total ablation time was defined as the time from the groin puncture until the withdrawal of all catheters.

**Statistical analysis**

Normality was tested using the Kolmogorov-Smirnov test. Continuous data was expressed as mean ± SD if the data had a normal distribution and as frequencies in the case of categorical variables. Comparisons of fluoroscopy dose and time and total procedure time between ICE and non-ICE patients were performed using t-tests. Correlations between the same parameters were tested using the Pearson coefficient. Other comparisons between categorical data were performed with the chi² test. Statistical analysis was performed using R Core Team 2019 (Vienna, Austria). A p value of <0.05 was considered significant.

**Results**

The demographic data of the study groups and data about AF type, mean procedure time, radiation dose and time are detailed in Table I. Electrical disconnection of all pulmonary veins was achieved in all patients, sinus rhythm being present at the end of the procedure in all of them. Acute success rate was 100%, without the ablation of secondary left atrium sites.

We found that the mean procedure time was similar between the two groups (p<0.05). Nevertheless, the use of ICE was associated with lower fluoroscopy dose and time (al p>0.05) (fig 2). Also, we found moderate correlations between total procedure time and fluoroscopy...
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In order to analyse the learning curve in the group where ICE was used, we compared radiation exposure (fluoroscopy dose and time) and total procedure time between the first and last 9 months of the study. The analysis showed that in group 1, fluoroscopy dose, time and total procedure time significantly decreased in the last 9 months of the study (all \( p<0.05 \)). Figure 3 shows how both radiation exposure and total procedure time decrease during the 18 months study duration in paroxysmal AF patients. In contrast, in the non-ICE group there were no significant differences in terms of procedural time or radiation exposure between the first and the last 9 months of the study. Also, given the small number of persistent AF patients included in the study, radiation exposure was similar along the learning curve in both ICE and non-ICE persistent AF patients.

There were no intraprocedural complications in any of the study patients. Also, no pericardial effusion or other mechanical complication were evidenced after ablation.

Discussion

We showed in the present study that the use of ICE for AF catheter ablation guidance, supported by electroanatomical mapping, significantly reduced radiation exposure for both paroxysmal and persistent AF ablation. The ablation procedure included one transseptal puncture and isolation of all pulmonary veins. There were significant reductions in the fluoroscopy time and the dose in the group where ICE-guidance was used, despite the fact that the total procedure time was similar between the studied groups.

Although multiple studies have shown the benefits of ICE on radiation exposure in the past two decades [2,18,19], ICE still remains a controversial technique in present literature [20,21]. Over the last years, considerable efforts were made in order to achieve fluoroscopy doses following the ALARA principle as there is no magnitude of ionizing radiation exposure that is known to be completely safe [2]. Complex electrophysiology procedures, such as AF catheter ablation, may require long procedure times, which most of the time mean higher radiation exposure, making both patients and staff prone

| Characteristics               | Group 1 (n=26) | Group 2 (n=26) | p-value |
|-------------------------------|---------------|---------------|---------|
| Age (years old)              | 57 ± 9        | 61 ± 8        | 0.07    |
| Gender (males, n, %)         | 21 (80.7)     | 18 (69.2)     | 0.05    |
| Type of AF (paroxysmal, n, %)| 20 (76.9)     | 20 (76.9)     | 1       |
| Previous AFL ablation (n, %) | 3 (11.5)      | 1 (3.8)       | 0.037   |
| Fluoroscopy dose (mean, mGy) | 11839.60±6100.6 | 16260.43±8264.5 | 0.041   |
| Fluoroscopy time (mins, mGy) | 28.00±12.5    | 42.93±12.7    | <0.001  |
| Total procedure time (mins)  | 181.54±50.3   | 197.31±49.8   | 0.348   |
| Acute success rate (n, %)    | 26 (100)      | 26 (100)      | 1       |

The data are expressed as number (%) or mean ± standard deviation. AF: atrial fibrillation, AFL: atrial flutter.
to developing secondary effects such as skin and lens injuries, birth defects or malignancies [12,13,18,22]. According to Venneri et al [23], interventional cardiologists and electrophysiologists represent more than 60% of the medical staff receiving the highest radiation exposure, leading to a lifetime risk of cancer of about 1/200 [3,23]. In addition, Roguin et al reported brain and neck tumors leading to a lifetime risk of cancer of about 1/200 [3,23].

Equally important, vulnerable populations, including children, pregnant woman and obese patients also present an increased risk of developing radiation side-effects [3,12,25]. ICE has been shown to reduce radiation exposure by lowering fluoroscopy time and dose during AF catheter ablation in experienced centres [2,4,5,9,20,21]. Furthermore, multiple studies have proven the feasibility of performing zero- or near-zero-fluoroscopy AF catheter ablation by combining 3D electroanatomical mapping systems with ICE [12-15]. No differences in terms of safety and short- and mid-term efficacy were found [10,17,18], including persistent AF patients in which the ablation was not limited to pulmonary veins isolation [17]. De Ponti et al [3] showed that radiation exposure reduction is proportional with the electrophysiologist experience, being maximal in the hands of a more experienced electrophysiologist. Although ICE guidance showed beneficial effects in reducing radiation exposure during electrophysiology procedures, there are few studies to directly assess changes in fluoroscopy dose and time during the ICE learning curve.

In our study we compared radiation exposure in AF catheter ablation with ICE guidance between two periods along the learning curve. We found that both fluoroscopy dose and time, as well as total procedure time decreased in the last 9 months compared to first 9 months of the study, in paroxysmal AF patients. Moreover, we showed that in these patients, radiation exposure decreased gradually during the 18 months study duration. In contrast, in the non-ICE group there were no significant differences in terms of radiation exposure between the first and the last 9 months of the study, which confirms that the decrease of radiation exposure during group 1 learning curve is the result of ICE guidance. Also, no radiation exposure improvements were seen in persistent AF patients, which probably is related to the small number of subjects included.

The significant reductions in fluoroscopy dose and time observed in our study are consistent with those obtained by Sommer et al [15] in a series of 1000 patients, showing that a composite of nonfluoroscopic catheter visualization techniques, including ICE, reduced radiation exposure along the learning curve. However, most of the included subjects (62%) were persistent AF patients. Also, Barthel et al [2] showed that interventional cardiologists could fully benefit from the advantages of ICE after a brief learning curve, and Enriquez et al [9] demonstrated that certain manoeuvres, such as transseptal puncture and catheter placement, could be performed exclusively by ICE guidance, after a short learning curve. These studies highlight the importance of training and learning curves in low-experienced centres in order to achieve lower radiation exposure.

The total procedure times in our study were similar between the two groups (p>0.05). Multiple studies proved that ICE does not prolong total procedure time [10,18,21], some studies showing even a reduction in total procedure times by using ICE guidance [20]. Nevertheless, during zero-fluoroscopy AF ablation using ICE, Reddy et al [12] obtained higher total procedure times compared to simple pulmonary veins isolation, but authors admitted to intentionally spending more time for certain manoeuvres in their series. Despite ICE’s increasing availability and growing use, fluoroscopy continues to be considered indispensable in many electrophysiology laboratories [21]. Fluoroscopy provides sufficient information for performing safe AF ablation in most cases, but variations in septal anatomy, aortic root dilatation, the need of multiple transseptal punctures and complex LA anatomy can make it inadequate [5,6]. The high resolution and excellent visualization of the interatrial septum and left atrium (LA) make ICE very useful for the guidance of EP procedures, particularly for AF ablation [5]. Moreover, ICE possesses multiple applications during EP procedures, its principal practical uses including: a) catheter contact and location assessment; b) septal puncture guidance; c) direct visualization of evolving lesions during radiofrequency (RF) energy delivery through tissue echogenicity change and microbubbles formation; d) assessment of pulmonary vein anatomy, including left atrial appendage and ridge; e) real-time complication assessment (e.g. cardiac tamponade, thrombus formation, etc.); and f) scar assessment during ventricular tachycardia ablation [4,5,7-10]. Furthermore, all these benefits could be amplified by improved image quality, using 3D-ICE, finally increasing AF ablation safety and efficacy [26].

Acute success rates were 100% among both groups included in our study which shows that ICE-guided AF ablation is non-inferior in terms of efficacy compared to fluoroscopy guidance. These results are consistent with several other studies, showing similar acute success rates with ICE guidance as with fluoroscopy alone.
Moreover, recently, an integration module has been developed that incorporates the electroanatomical map to a map obtained by ICE. It allows 3D reconstruction of cardiac chambers using real-time 2D ICE acquisitions, showing superiority compared to fluoroscopy landmark registration, promising better efficiency for the future [4,5,27,28].

Although the use of ICE has been shown to have multiple advantages over fluoroscopy or transesophageal echocardiography, socio-economic aspects remain its main limitation [2,4,15]. Therefore, it is essential to carefully weigh the high costs of the ICE catheter against the possible savings from avoiding anaesthesia and acute complications, translating into a shorter hospital stay, and from long-term radiation-related complications reduction. Currently, in middle- and low-income countries, ICE is not widely used because of its low availability and high costs. This study aims to increase the awareness regarding radiation exposure side-effects and the necessity to take all possible measures in order to minimize them [2]. Other limitations of ICE guidance are the necessity of an extra venous access using 10F shafts which increases the risk of local vascular complications and the potential risk of thromboembolic complications by manoeuvring the ICE catheter in the right heart [4,5,29]. However, most research proved no differences in terms of safety with ICE guidance [10,16-18], with some of them outlining the possible increased safety by reducing major complications [29,30]. In the present study we recorded no complications, including acute and during hospital stay complications, suggesting similar safety between the two groups.

This study has several potential limitations. The most important limitation was the inclusion of a relatively small number of subjects, due to the small number of AF ablation procedures performed in our department. Second, it was a single centre, retrospective, observational study, that did not include after discharge follow-up data, any conclusion about safety and efficacy, other than acute, being difficult to consider. Third, we excluded from our study, patients with complications that led to cancellation or postponement of the procedure, as it was not intended to establish comparative safety for widespread applicability. Fourth, the available tools and mapping systems varied over the study period. Thus, randomized, multicentre studies are necessary in order to confirm these results and to determine comparative safety and efficacy.

In conclusion, ICE guidance lowers radiation exposure from the beginning of the learning curve during AF catheter ablation without any difference in terms of acute safety or efficacy compared to fluoroscopy. Finally, awareness towards closest to zero radiation exposure during EP procedures should increase in order to achieve better protection for both patient and medical staff, ICE occupying a key role in our striving to reach the ALARA principle. Further longitudinal investigations on larger populations need to be conducted in order to support these results.

Conflict of interests: none.

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