Med Ultrason 2021:0, 1-6 *Online first*
DOI: 10.11152/mu-2888

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

Ioan-Alexandru Minciună, Mihai Puiu, Gabriel Cismaru, Radu Roşu, Raluca Tomoaia, Gelu Simu, Sabina Istratoaie, Bogdan Caloian, Horațiu Comșa, Gabriel Gușetu, Dumitru Zdrenghea, Dana Pop

Clinical Rehabilitation Hospital, Cardiology Department, ”Iuliu Hațieganu” University of Medicine and Pharmacy, Cluj-Napoca, Romania

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-

Received 18.11.2020 Accepted 08.02.2021
Med Ultrason
2021:0 Online first, 1-6
Corresponding author: Radu Roşu
Clinical Rehabilitation Hospital,
Cardiology Department, 46-50 Viilor Street,
400066, Cluj-Napoca, Romania
Phone: +40723202947
E-mail: rosu.radu1053@gmail.com

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.

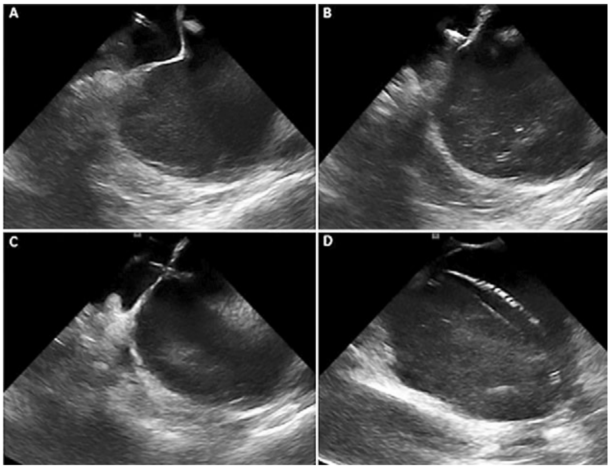

Fig 1. Intracardiac echocardiography guidance of transseptal puncture and catheter positioning. A. Tenting of interatrial septum showing the right needle position. B and C. Transseptal puncture. D. Catheter placement in the left inferior pulmonary vein.

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 chi^2 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

Table I. General and procedural characteristics of the patients

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.

dose (R=0.5, p=0.0001) and time (R=0.48, p=0.0002) and strong correlation between fluoroscopy dose and time (R=0.66, p=0.000005). These results were similar for both patients with paroxysmal or persistent AF.

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 group 1 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 electro-anatomical 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 thedose 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

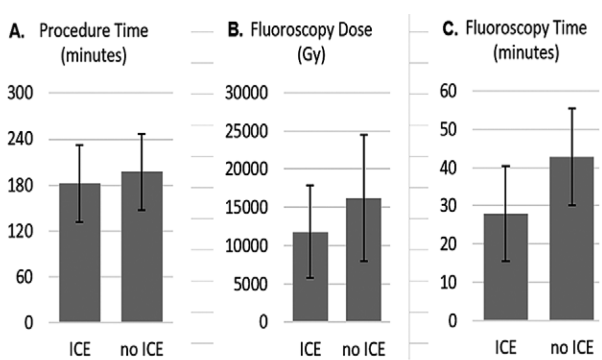

Fig 2. Comparison between total procedure time (A) and fluoroscopy total dose (B) and time (C) between the two groups. The procedure time was similar but the fluoroscopy dose and time was lower in group 1 (with ICE)

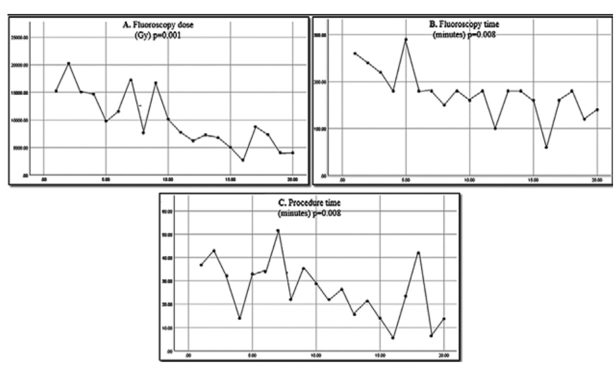

Fig 3. Line graphs showing gradual decrease of (A) fluoroscopy total dose, (B) fluoroscopy time and (C) total procedure time during the 18-month study duration in paroxysmal atrial fibrillation patients in which ICE guidance was used.

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 in 31 interventional cardiologists and radiologists. In 22 out of 26 cases (85%) in which location data was available, the malignancy was left-sided, which is closest to radiation exposure in electrophysiology procedures [24]. 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 nonflouroscopic 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

[3,10,18,20]. 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-economical 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.

References

1. Hindricks G, Potpara T, Dagres N, et al. 2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association of Cardio-Thoracic Surgery (EACTS). Eur Heart J 2021;42:373-498.
2. Bartel T, Müller S, Biviano A, Hahn RT. Why is intracardiac echocardiography helpful? Benefits, costs, and how to learn. Eur Heart J 2014;35:69–76.
3. De Ponti R. Reduction of radiation exposure in catheter ablation of atrial fibrillation: Lesson learned. World J Cardiol 2015;7:442-448.
4. Issa Z, Miller J. Clinical Arrhythmology and Electrophysiology: A Companion to Braunwald's Heart Disease. 3rd edition. Elsevier 2018.
5. Lancellotti P, Zamorano JL, Habib G, Badano L. (Eds.). The EACVI Textbook of Echocardiography. 2nd edition. Oxford University Press 2017.
6. Kautzner J, Peichl P. Intracardiac echocardiography in electrophysiology. Herzschrittmacherther Elektrophysiol 2007;18:140–146.
7. Saliba W, Thomas J. Intracardiac echocardiography during catheter ablation of atrial fibrillation. Europace 2008;10 Suppl 3:iii42–iii47.
8. Ren JF, Marchlinski FE, Callans DJ, Schwartzman D. (Editors). Practical Intracardiac Echocardiography in Electrophysiology. Oxford, UK: Blackwell Science Ltd; 2005.
9. Enriquez A, Saenz LC, Rosso R, et al. Use of intracardiac echocardiography in interventional cardiology working with the anatomy rather than fighting it. Circulation 2018;137:2278–2294.
10. Razminia M, Willoughby MC, Demo H, et al. Fluoroless Catheter Ablation of Cardiac Arrhythmias: A 5-Year Experience. Pacing Clin Electrophysiol 2017;40:425–433.
11. Ruisi CP, Brysiewicz N, Asnes JD, et al. Use of intracardiac echocardiography during atrial fibrillation ablation. Pacing Clin Electrophysiol 2013;36:781–788.
12. Reddy VY, Morales G, Ahmed H, et al. Catheter ablation of atrial fibrillation without the use of fluoroscopy. Heart Rhythm 2010;7:1644–1653.
13. Haegeli LM, Stutz L, Mohsen M, et al. Feasibility of zero or near zero fluoroscopy during catheter ablation procedures. Cardiol J 2019;26:226–232.
14. Ferguson JD, Helms A, Mangrum JM, et al. Catheter ablation of atrial fibrillation without fluoroscopy using intracardiac echocardiography and electroanatomic mapping. Circ Arrhythmia Electrophysiol 2009;2:611-619.

15. Sommer P, Bertagnolli L, Kircher S, et al. Safety profile of near-zero fluoroscopy atrial fibrillation ablation with non-fluoroscopic catheter visualization: Experience from 1000 consecutive procedures. Europace 2018;20:1952–1958.
16. Scaglione M, Ebrille E, Di Clemente F, Gaita F, Bradfield JS. Catheter Ablation of Atrial Fibrillation Without Radiation Exposure Using A 3D Mapping System. J Atr Fibrillation 2015;7:1167.
17. Di Biase L, Horton R, Trivedi C, et al. Zero Fluoroscopy Ablation of Atrial Fibrillation: A Safety and Feasibility Study. Circulation 2014;130 Suppl 2:A16237.
18. Bulava A, Hanis J, Eisenberger M. Catheter Ablation of Atrial Fibrillation Using Zero-Fluoroscopy Technique: A Randomized Trial. Pacing Clin Electrophysiol 2015;38:797–806.
19. Marrouche NF, Martin DO, Wazni O, et al. Phased-array intracardiac echocardiography monitoring during pulmonary vein isolation in patients with atrial fibrillation: Impact on outcome and complications. Circulation 2003;107:2710–2716.
20. Goya M, Frame D, Gache L, et al. The use of intracardiac echocardiography catheters in endocardial ablation of cardiac arrhythmia: Meta-analysis of efficiency, effectiveness, and safety outcomes. J Cardiovasc Electrophysiol 2020;31:664–673.
21. Romero J, Patel K, Briceno D, et al. Fluoroless Atrial Fibrillation Catheter Ablation: Technique and Clinical Outcomes. Card Electrophysiol Clin 2020;12:233–245.
22. Miwa Y, Ueda A, Komeda M, et al. Reducing radiation exposure during atrial fibrillation ablation using lectures to promote awareness. Open Heart 2019;6:e000982.
23. Venneri L, Rossi F, Botto N, et al. Cancer risk from professional exposure in staff working in cardiac catheterization laboratory: Insights from the National Research Council's Biological Effects of Ionizing Radiation VII Report. Am Heart J 2009;157:118–124.
24. Roguin A, Goldstein J, Bar O, Goldstein JA. Brain and neck tumors among physicians performing interventional procedures. Am J Cardiol 2013;111:1368–1372.
25. Ector J, Dragusin O, Adriaenssens B, et al. Obesity is a major determinant of radiation dose in patients undergoing pulmonary vein isolation for atrial fibrillation. J Am Coll Cardiol 2007;50:234–242.
26. Brysiewicz N, Mitiku T, Haleem K, et al. 3D real-time intracardiac echocardiographic visualization of atrial structures relevant to atrial fibrillation ablation. JACC Cardiovasc Imaging 2014;7:97–100.
27. Yen Ho S, Ernst S. Anatomy for Cardiac Electrophysiologists: A Practical Handbook. Cardiotext Publishing, LLC. 2012.
28. Pratola C, Baldo E, Artale P, et al. Different image integration modalities to guide AF ablation: Impact on procedural and fluoroscopy times. Pacing Clin Electrophysiol 2011;34:422–430.
29. Aldhoon B, Wichterle D, Peichl P, Čihák R, Kautzner J. Complications of catheter ablation for atrial fibrillation in a high-volume centre with the use of intracardiac echocardiography. Europace 2013;15:24–32.
30. Jongbloed MR, Schalij MJ, Zeppenfeld K, Oemrawsingh PV, Van Der Wall EE, Bax JJ. Clinical applications of intracardiac echocardiography in interventional procedures. Heart 2005;91:981–990.