Outcome and safety of intracardiac echocardiography guided left atrial appendage closure within zero-fluoroscopy atrial fibrillation ablation procedures

yi he chen[1], Liangguo Wang[1], Xiaodong Zhou[1], ying fang[1], Lan Su[1], Shengjie Wu[1], weijian huang[1], and Fangyi Xiao[1]

[1]The First Affiliated Hospital of Wenzhou Medical University

September 27, 2021

Abstract

Background: Simultaneous atrial fibrillation (AF) catheter ablation and left atrial appendage closure (LAAC) is sometimes recommended for both rhythm control and stroke prevention. However, the advantages of intracardiac echocardiography (ICE) guidance for this combined procedure have been scarcely reported. To evaluate the clinical outcomes and safety of ICE guided LAAC within a zero-fluoroscopy catheter ablation procedure. Methods and Results:From April 2019 to April 2020, 56 patients with symptomatic AF underwent concomitant catheter ablation and LAAC. ICE with a multi-angled imaging protocol mimicking the TEE echo windows was used to guide LAAC. Successful radiofrequency catheter ablation and LAAC was achieved in all patients. Procedure-related adverse event rate was 3.6%. During the 12-month follow-up, 77.8% of patients became free of arrhythmia recurrences and oral anticoagulants were discontinued in 96.4% of patients. No ischemic stroke occurred despite two cases of device-related thrombosis versus an expected stroke rate of 4.8% based on the CHA2DS2-VASc score. The overall major bleeding events rate was 1.8%, which represented a relative reduction of 68% versus an expected bleeding rate of 5.7% based on the HAS-BLED score of the patient cohort. The incidence of iatrogenic atrial septal defect secondary to a single transseptal access dropped from 57.9% at 2 months to 4.2% at 12 months TEE follow-up. Conclusion:The combination of catheter ablation and LAAC under ICE guidance was safe and effective in AF patients with high stroke risk. ICE with our novel protocol was technically feasible for comprehensive and systematic assessment of device implantation.

Outcome and safety of intracardiac echocardiography guided left atrial appendage closure within zero-fluoroscopy atrial fibrillation ablation procedures

Yi-He Chen[1], Liang-Guo Wang[1], Xiao-Dong Zhou[1], Ying Fang[1], Lan Su[1], Sheng-Jie Wu[1], Wei-Jian Huang[1, *], Fang-Yi Xiao[1, *]

[1]Department of Cardiology, The First Affiliated Hospital of Wenzhou Medical University, 325000, Nanbaixiang, Wenzhou, Zhejiang, China.

[*]Correspondence author: Fang-Yi Xiao, MD, PhD and Wei-Jian Huang, MD

Tel +86 577 55578166, Fax +86 577 55578033, E-mail address: harry686896@126.com

Abstract

Background: Simultaneous atrial fibrillation (AF) catheter ablation and left atrial appendage closure (LAAC) is sometimes recommended for both rhythm control and stroke prevention. However, the advantages of intracardiac echocardiography (ICE) guidance for this combined procedure have been scarcely reported. To evaluate the clinical outcomes and safety of ICE guided LAAC within a zero-fluoroscopy catheter ablation procedure.

Methods and Results:From April 2019 to April 2020, 56 patients with symptomatic AF underwent concomitant catheter ablation and LAAC. ICE with a multi-angled imaging protocol mimicking the TEE echo windows was used to guide LAAC. Successful radiofrequency catheter ablation and LAAC was achieved in all patients. Procedure-related adverse event rate was 3.6%. During the 12-month follow-up, 77.8% of patients became free of arrhythmia recurrences and oral anticoagulants were discontinued in 96.4% of patients. No ischemic stroke occurred despite two cases of device-related thrombosis versus an expected stroke rate of 4.8% based on the CHA_2DS_2-VASc score. The overall major bleeding events rate was 1.8%, which represented a relative reduction of 68% versus an expected bleeding rate of 5.7% based on the HAS-BLED score of the patient cohort. The incidence of iatrogenic atrial septal defect secondary to a single transseptal access dropped from 57.9% at 2 months to 4.2% at 12 months TEE follow-up.

Conclusion:The combination of catheter ablation and LAAC under ICE guidance was safe and effective in AF patients with high stroke risk. ICE with our novel protocol was technically feasible for comprehensive and systematic assessment of device implantation.

Keywords

atrial fibrillation; intracardiac echocardiography; left atrial appendage closure; catheter ablation; outcomes

Introduction

Atrial fibrillation (AF) is the most prevalent arrhythmia worldwide and leads to an increased risk of ischemic stroke as high as 5% per year.[1] Despite the beneficial effect of catheter ablation in improving AF-induced symptoms, long-term sinus rhythm maintenance remains challenging.[2] Furthermore, solid evidence of a proven role of AF catheter ablation in stroke prevention is lacking.[3] The latest guideline does not recommend discontinuation of oral anticoagulation post-ablation in patients with high stroke risk.[4]

The left atrial appendage (LAA) is the main source of thrombi in patients with nonvalvular AF, and mechanical exclusion of the LAA has emerged as a nonpharmacologic approach for long-term stroke prevention.[5] Thus, combining catheter ablation and LAA closure (LAAC) in a single procedure has been proposed as a promising therapeutic strategy for simultaneously alleviating symptoms and reducing the risk of thromboembolic or bleeding events..[6,7] However, intraprocedural transesophageal echocardiography (TEE) guidance for device implantation is associated with a significant logistical burden, gastroesophageal damage, and risk associated with routine general anesthesia.[8]Intracardiac echocardiography (ICE) with the potential to overcome these shortcomings has therefore been performed as an alternative to TEE for LAAC.[9,10] However, systemic assessment of LAA device deployment accompanied by AF ablation under ICE monitoring remains uncertain.

We aimed to report the outcomes and safety of ICE-guided LAAC within zero fluoroscopy radiofrequency catheter ablation procedure using a novel "FLAVOR" protocol with multi-angled imaging assessment.

Methods

This prospective, single-center study involved patients aged [?]18 years with documented drug-resistant nonvalvular AF at high risk of stroke treated by ICE-guided AF catheter ablation and LAAC. Informed consent was obtained from all patients, and the study procedure was approved by the ethics committee of the first affiliated hospital of Wenzhou medical university.

Catheter ablation was performed prior to LAAC under conscious sedation with fentanyl and midazolam. The procedure was performed via both the left and right femoral veins. A decapolar coronary sinus electrode (Abbott, Saint Paul, MN, USA) was advanced through the left femoral vein access using a long 25-cm 7-Fr insertion sheath. Double right femoral vein access was obtained for introducing the 10-Fr ICE catheter (SoundStar; Biosense Webster, Irvine, CA, USA) and transseptal puncture. The geometry map of the left atrium (LA) including the LAA was created by ICE probe manipulation at the right median atrial septum and at the entrance of the coronary sinus using a three-dimensional mapping system (CARTO 3; Biosense Webster). Single transseptal puncture was guided by ICE. A contact force-sensing catheter (Thermocool

SmartTouch; Biosense Webster) supported by a steerable sheath (Agilis NxT; Abbott) was used to perform circumferential pulmonary vein isolation (PVI). The ablation power was set to 45 W with a target ablation index (AI) of 450 for the anterior wall and 40 W with a target AI of 350 for the posterior wall. The Visitag (CARTO3; Biosense Webster) settings included: inter-lesion distance [?]5 mm, minimum force 5 g, force-over-time 50%, minimum time 3 seconds, maximal range 2 mm, and lesion tag size 2 mm (Figure 1). In patients with persistent AF, cardioversions were delivered to restore sinus rhythm after PVI. Substrate mapping and additional ablation were then conducted.

A 6-Fr pigtail catheter was advanced to the LAA to perform LAA angiography, with LA pressure of [?]12 mmHg, at right anterior oblique and caudal projections. The Agilis NxT sheath was further exchanged with a 10-Fr delivery sheath to pre-dilate the transseptal puncture site. The delivery sheath was then retracted into the inferior vena cava while keeping the guidewire in the left superior pulmonary vein (LSPV) to allow the ICE catheter advance into the LA through the same site, which was tagged on the image guided by the CARTOSOUND system without fluoroscopic exposure. The echocardiographic LAA ostium and landing zone diameters were measured using the "Four Long-Axis Views around Orifice" (FLAVOR) approach at 90°, 135°, 0°, and 45° (Figures 2 and 3). The delivery sheath was cautiously advanced again to the LA over the guidewire. An appropriately sized LAmbre device was selected based on both angiographic and echocardiographic measurements. Fluoroscopy- and ICE-guided LAAC with the LAmbre device was performed using our previously described modified method.[11] The position of the device and the degree of residual peri-device flow were assessed with ICE (Figure 3). The device was released when the COST criteria were met (umbrella deployed beyond Circumflex artery, umbrella fully Open, optimal peri-device Sealing (leak of [?]3 mm), and device stability confirmed by Tug test) and the cover of the device was not impinging the mitral valve and/or pulmonary vein ostium. Otherwise, recapture and/or resizing of the device was attempted. Repeated ICE assessment was performed after release of the device.

The constructed LAA geometry map on the anteroposterior projection was adjusted rightward and upward until the LAA orifice was adequately exposed. Guided by Carto-Sound feature, the ICE probe was manipulated to achieve the proposed four imaging planes (the angle between adjacent imaging planes was approximately 45deg) for comprehensive evaluation of the LAA or device. Each plane was adjusted to show the long-axis view of the LAA or device. The ICE probe was initially advanced to the top of the left atrium with slight posterior flexion to obtain the first view similar to the 90deg TEE view which we defined as the 90deg ICE view showing the LAA, short-axis view of the left circumflex artery [LCX] and mitral valve. The second view similar to the 45deg TEE view which was defined as the 135deg ICE view could be achieved through rightward and anteflexion of the ICE probe. The ICE probe was usually placed at the entrance of the LSPV. The pulmonary vein ridge, LAA, short-axis view of the LCX and short-axis view of aortic sinus were most commonly visualized in this view. Next, the ICE probe was frequently positioned at the entrance of the left inferior pulmonary vein (LIPV) on the LA posterior wall by further rightward flexion to form the third view similar to the 0deg TEE view which was defined as the 0deg ICE view with excellent display of the LAA, short-axis view of the LCX, short-axis ascending aorta and concomitant pulmonary artery. Finally, the ICE catheter was rotated anticlockwise and advanced to the mitral isthmus with posterior flexion to form the fourth view resembling the 135deg TEE view which was defined as the 45deg ICE view. This view showed the LAA and the pulmonary artery. This systematic approach allowed comprehensive evaluation of the LAA or device by mimicking TEE echo windows (Figures 2 and 3).

Outpatient follow-up was scheduled at 3, 6, 12 months post-procedure with a detailed documentation of clinical events. A standard 12-lead electrocardiogram and 24h Holter recording was performed at each visit and 7-day Holter monitoring was obtained at the 12-month follow-up for recurrence of atrial tachyarrhythmia. TEE was conducted at 2 and 12 months after implantation to assess LAA occlusion and rule out thrombi. Successful sealing of the LAA was defined as complete occlusion or residual peri-device flow of [?]3 mm. If the sealing criteria were met, anticoagulation was interrupted at 3 months, followed by dual antiplatelet therapy for 3 months and finally lifelong single antiplatelet therapy.

The primary efficacy endpoints were (1) the rate and degree of residual peri-device flow, (2) iatrogenic atrial

septal defect (ASD) at the TEE evaluation, and (3) the combined endpoint of stroke/transient ischemic attack (TIA)/systemic embolism (SE) over the 12-month follow-up. The primary safety endpoints were (1) assessment of bleeding events, (2) all-cause mortality, and (3) the fluoroscopy time during the procedure. The secondary endpoints included (1) AF/atrial tachycardia-free survival, (2) periprocedural complications, and (3) device-related thrombosis (DRT). AFrecurrence was defined as any documented AF, atrial flutter, or atrial tachycardia lasting >30 seconds after a 3-month blanking period.

All statistical analyses were performed using SPSS version 20.0 (IBM Corp., Armonk, NY, USA). Continuous variables are presented as mean +- standard deviation. Categorical variables are reported as median with interquartile range. A P-value of <0.05 was considered statistically significant.

Results

From April 2019 to April 2020, 56 patients (57.1% male; mean age, 69.4 +- 7.5 years) underwent combined radiofrequency ablation and LAAC with ICE guidance. The patients' baseline demographic characteristics are summarized in Table 1. In terms of stroke risk, the median CHA_2DS_2-VASc score was 4.0 (3.0–5.0); in terms of hemorrhage risk, the median HAS-BLED score was 3.0 (2.0–3.0). Ischemic stroke or TIA occurred in 46.4% of patients.

The acute ablation endpoints and device implantation were achieved in all patients. First-pass PVI was achieved in 49/56 (87.5%) patients. The mean fluoroscopy time was 6.3 +- 5.3 minutes with zero fluoroscopic exposure during radiofrequency ablation. The mean radiofrequency ablation time was 14.6 +- 2.7 minutes. The mean time for assessment of the device position and peri-device leakage with the FLAVOR approach was 2.1 +- 0.4 minutes. After device release, ICE showed complete sealing of the LAA in 46/56 (82.1%) patients, and the remaining 10/56 (17.9%) patients had minimal residual peri-device flow of [?]3 mm. The mean post-detachment peri-device leakage was 1.6 +- 0.5 mm, with the majority of leaks occurring in the 45deg or 90deg ICE view (Table 2, Figure 4). The total periprocedural complication rate was 3.6%, including one case of pericardiac tamponade that occurred during transseptal puncture and was resolved with pericardiocentesis and one case of a groin hematoma. No stroke/TIA/SE, device embolization, or death occurred.

During a mean follow-up of 12 months, 77.8% of patients were free from AF recurrence. Five patients underwent repeated catheter ablation and maintained sinus rhythm until the last visit. A first follow-up TEE was performed at 2 months post-procedure in 49/56 (87.5%) patients. LAA occlusion was complete in 26 patients, while small peri-device leakage of [?]3 mm was present in the remaining 23 patients. A total of 48/56 (85.7%) patients underwent TEE and 2 other patients who refused repeat TEE exam underwent cardiac CT angiography at least 12 months post-procedure. A complete or satisfactory (residual peri-device flow of [?]3 mm) seal of the LAA was found in 32 and 18 patients, respectively. In accordance with the findings from ICE assessment after release, subsequent TEE evaluation showed similar sites of residual peri-device flow (commonly detected in 90deg or 135deg TEE views, which resembled the 90deg and 45deg ICE views) (Table 3). Two DRTs which were absent at 2-month TEE were detected at the 12-month TEE follow-up. The patients were subsequently continued on novel oral anticoagulant therapy. One patient died of a hepatoma 10 months after the procedure.

All 56 patients were discharged with an oral anticoagulant (rivaroxaban in 41, dabigatran in 10, and warfarin in 5). After the 3-month follow-up, oral anticoagulant therapy was discontinued in all of the implanted patients. At 12 months, almost all patients were still withdrawn from oral anticoagulants except two patients with DRTs.

Notably, there was no evidence of thromboembolic events during 12 months of follow-up despite an expected stroke rate of 4.8% without anticoagulation[12] (Figure 5). Only one patient developed severe gastrointestinal bleeding, representing a 68% relative risk reduction for major bleeding events based on the expected bleeding rate according to the HAS-BLED score (1.8% vs. 5.7%).[13]

An iatrogenic ASD was detected in 57.9% of patients at 2 months; this proportion decreased to 4.2% at 12 months.

Discussion

The present study demonstrated the promising outcomes and safety of combining AF catheter ablation and LAAC under ICE guidance for patients with symptomatic drug-refractory AF and high stroke risk. The study data showed an excellent efficacy profile in avoiding ischemic stroke despite two device-related thrombi and confirmed the impressive lowering rate of major bleeding events during 12 months of follow-up. Specifically, this report proposed an original multi-planner ICE protocol (FLAVOR approach) providing four views equivalent to TEE planes under Carto-Sound feature guidance for assessment of LAA occluder implantation during the procedure with minimal fluoroscopic exposure. In addition, this study revealed most of the iatrogenic ASDs developed by a single transseptal access for left atrial ICE to guide LAAC could closed spontaneously during 12 months follow-up.

The application of ICE during AF ablation has increased over the years and is associated with lower procedural complications and in-hospital mortality.[14] Very few studies to date have evaluated the feasibility and outcome of zero-fluoroscopy catheter ablation of AF with combined use of a three-dimensional electroanatomic mapping system and ICE.[15,16] Our study applied the currently available technologies: ICE, CARTOSOUND electroanatomical mapping system and contact force sensing catheter, along with high power ablation strategy[17] and AI guidance[18]. This study demonstrated that AI-guided high-power fluoroless ablation for AF under ICE guidance is fully effective and safe.

The feasibility of ICE to guide LAAC was recently established, and ICE is now considered an alternative to TEE to decrease esophageal injury, logistical burden, and risk associated with general anesthesia.[19,20] In most studies, the ICE probe is placed at one or two positions in the left atrium.[9,10,21] In some of these studies, the probe was placed only at the entrance of the LSPV.[9,21] Hemam et al.[22] imaged the LAA from four different locations to evaluate the LAA and device, including the central LA body, deeper into the LSPV and LIPV, and transmitral. However, without using the LA geometry map described in the present study, this approach is limited by the varied anatomical relationships among the LAA, pulmonary veins, and mitral valves and the technical challenges in manipulation with ICE catheter. Additionally, the technique might increase the risk of complications such as LA rupture or pulmonary vein laceration. However, no contemporary studies have provided a fully comprehensive, reproducible method to guarantee efficient and safe LAAC with ICE guidance. Our present work introduced the novel step-by-step FLAVOR approach, which presents comparable ICE images with the four standard views of TEE. The three-dimensional LA geometry map improved the reproducibility and safety of ICE probe manipulation without fluoroscopy and facilitated thorough assessment of the LAA and device. The LAA ostium is highly eccentric, and Westcott et al.[23]revealed that 52% of implant leaks occurred along the posterior segment of the LAA ostium using a clock-face representation (6:00 to 9:00 axis corresponding to the 135deg TEE view). An explanation might be that the long axis of the LAA ostium usually centers along the 135deg axis of the TEE view. Accordingly, in our study cohort, the LAA ostium was numerically the largest in the 0deg to 45deg ICE view and the smallest in the 135deg ICE view. Most of the leaks after device release were detected at45deg and 90deg ICE views, none at 135deg ICE view. In consistence, peri-device leaks were most frequently detected in the TEE 135deg view (79.3%) and 90deg view (65.2%) at the 2-month follow-up. This suggests that ICE protocols with fewer views, especially only one view from the entrance of the LSPV, may have significant limitations in comprehensive and accurate evaluation of the position and peri-device leakage of LAA occluders. Furthermore, ICE-guided catheter ablation and LAAC with the FLAVOR approach resulted in low X-ray exposure with a mean assessment time of only 2.1 minutes. The FLAVOR approach was facilitated by the ICE probe which was soft, blunt and flexible, that would allow for safe manipulation in LA under Carto-Sound integrated into a 3D mapping system.

Because AF ablation is considered only symptomatic treatment, clinical practice guidelines recommend undefined long-term oral anticoagulation in patients with high risk of thromboembolic events following catheter ablation therapy.[4] Recent studies have proved the efficacy and safety of combined catheter ablation and LAAC for treatment of AF.[6,7] Nevertheless, the combined procedures require general anesthesia and TEE guidance. A recent study showed that the use of TEE for guiding structural heart disease interventions,

including LAAC, was associated with a significant degree of esophageal or gastric injury.[24] Esophageal injury during catheter ablation for AF was not uncommon. Whether the two aggravate esophageal damage remains a great concern. The use of ICE in combined procedures prevents this problem. Although the cost of an ICE catheter limits its extensive application, it would be appealing for patients undergoing combined AF ablation and LAAC because the catheter would be needed for transseptal punctures, LA geometry mapping, and guiding ablation.

A single transseptal access for LAAC under left atrial ICE guidance is commonly used in ICE-guided LAAC. Iatrogenic ASDs secondary to catheterization have become an issue of great concern. The PROTECT-AF trial showed an encouraging spontaneous closure rate of iatrogenic ASDs with a 14-Fr outer diameter Watchman transseptal sheath. A total of 87% of iatrogenic ASDs were detected immediately after catheterization, with 7% remaining at 1 year.[25] Korsholm et al.[20] compared ICE-guided LAAC under local anesthesia with TEE-guided LAAC under general anesthesia using an Amplatzer Cardiac Plug or Amulet device. Follow-up TEE at a mean of 55 days after the procedure showed no significant difference in the incidence (35% vs. 26%) or size of iatrogenic ASDs between the two groups. The incidence of iatrogenic ASD in the long term after left atrial ICE guided LAAC using a single transseptal access remains unknown. Intriguingly, our study demonstrated a 57.9% incidence of iatrogenic ASD at 2 months and a 4.2% incidence at 1 year. It therefore seems safe to perform left atrial ICE guided LAAC with the LAmbre device using a single transseptal access.

This is a pilot, single center prospective observational study with small-scale. We did not compare this strategy with combined treatment under TEE guidance. We only used the LAmbre device and SoundStar ICE catheter; hence, the study results cannot be fully extrapolated to other LAA occluders and ICE catheters. Finally, the ICE catheter was maneuvered by experienced electrophysiologists. Further large-scale, multicenter prospective clinical trials are required to confirm the efficacy and safety of this strategy.

Conclusion

Our study showed that ICE-guided LAAC within a zero-fluoroscopy AF catheter ablation procedure was safe and effective for patients with symptomatic AF and high stroke risk. Our original ICE based "FLAVOR" approach provided a comprehensive assessment of LAA geometry and guided reliable device sizing and deployment.

Conflict of Interests Statement

All authors have no conflict of interests to disclose.

Acknowledgment

We thank Angela Morben, DVM, ELS, from Liwen Bianji (Edanz) (www.liwenbianji.cn/) for editing the English text of a draft of this manuscript.

Funding

This work was supported by the Key Research and Development Program of Zhejiang (2019C03012), Project of the Science and Technology of Wenzhou (Y20180647) and the Research Incubation Project of the First Affiliated Hospital of Wenzhou Medical University (FHY2019069).

References

1. Go AS, Hylek EM, Phillips KA et al. Prevalence of diagnosed atrial fibrillation in adults: national implications for rhythm management and stroke prevention: the AnTicoagulation and Risk Factors in Atrial Fibrillation (ATRIA) Study. JAMA. 2001;285:2370-5.

2. Steinberg JS, Palekar R, Sichrovsky T et al. Very long-term outcome after initially successful catheter ablation of atrial fibrillation. Heart Rhythm. 2014;11:771-6.

3. Packer DL, Mark DB, Robb RA et al. Effect of Catheter Ablation vs Antiarrhythmic Drug Therapy on Mortality, Stroke, Bleeding, and Cardiac Arrest Among Patients With Atrial Fibrillation: The CABANA

Randomized Clinical Trial. JAMA. 2019;321:1261-1274.

4. 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 for Cardio-Thoracic Surgery (EACTS). Eur Heart J. 2021;42:373-498.

5. Holmes DR, Reddy VY, Turi ZG et al. Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomised non-inferiority trial. Lancet. 2009;374:534-42.

6. Wintgens L, Romanov A, Phillips K et al. Combined atrial fibrillation ablation and left atrial appendage closure: long-term follow-up from a large multicentre registry. Europace. 2018;20:1783-1789.

7. Phillips KP, Romanov A, Artemenko S et al. Combining left atrial appendage closure and catheter ablation for atrial fibrillation: 2-year outcomes from a multinational registry. Europace. 2020;22:225-231.

8. Alkhouli M, Hijazi ZM, Holmes DR, Jr., Rihal CS, Wiegers SE. Intracardiac Echocardiography in Structural Heart Disease Interventions. JACC Cardiovasc Interv. 2018;11:2133-2147.

9. Nielsen-Kudsk JE, Berti S, De Backer O et al. Use of Intracardiac Compared With Transesophageal Echocardiography for Left Atrial Appendage Occlusion in the Amulet Observational Study. JACC Cardiovasc Interv. 2019;12:1030-1039.

10. Alkhouli M, Chaker Z, Alqahtani F et al. Outcomes of Routine Intracardiac Echocardiography to Guide Left Atrial Appendage Occlusion. JACC Clin Electrophysiol. 2020;6:393-400.

11. Xiao Fangyi, Chen Yanyan, Chen Yihe et al. Delayed pericardial effusion after left atrial appendage closure with the LAmbre device: Importance of a fully open umbrella. J Cardiovasc Electrophysiol. 2021; doi: 10.1111/jce.15020. [Online ahead of print]

12. Friberg L, Rosenqvist M, Lip GYH. Evaluation of risk stratification schemes for ischaemic stroke and bleeding in 182 678 patients with atrial fibrillation: the Swedish Atrial Fibrillation cohort study. Eur Heart J. 2012;33:1500-10.

13. Roldan V, Marin F, Fernandez H et al. Predictive value of the HAS-BLED and ATRIA bleeding scores for the risk of serious bleeding in a "real-world" population with atrial fibrillation receiving anticoagulant therapy. Chest. 2013;143:179-184.

14. Isath A, Padmanabhan D, Haider SW et al. Does the use of intracardiac echocardiography during atrial fibrillation catheter ablation improve outcomes and cost? A nationwide 14-year analysis from 2001 to 2014. J Interv Card Electrophysiol. 2020.

15. Jan M, Zizek D, Kuhelj D et al. Combined use of electro-anatomic mapping system and intracardiac echocardiography to achieve zero-fluoroscopy catheter ablation for treatment of paroxysmal atrial fibrillation: a single centre experience. Int J Cardiovasc Imaging. 2020;36:415-422.

16. Lurie A, Amit G, Divakaramenon S, Acosta JG, Healey JS, Wong JA. Outcomes and Safety of Fluoroless Catheter Ablation for Atrial Fibrillation. CJC Open. 2021;3:303-310.

17. Leshem E, Zilberman I, Tschabrunn CM et al. High-Power and Short-Duration Ablation for Pulmonary Vein Isolation: Biophysical Characterization. JACC Clin Electrophysiol. 2018;4:467-479.

18. Ioannou A, Papageorgiou N, Lim WY et al. Efficacy and safety of ablation index-guided catheter ablation for atrial fibrillation: an updated meta-analysis. Europace. 2020;22:1659-1671.

19. Berti S, Pastormerlo LE, Santoro G et al. Intracardiac Versus Transesophageal Echocardiographic Guidance for Left Atrial Appendage Occlusion: The LAAO Italian Multicenter Registry. JACC Cardiovasc Interv. 2018;11:1086-1092.

20. Korsholm K, Jensen JM, Nielsen-Kudsk JE. Intracardiac Echocardiography From the Left Atrium for Procedural Guidance of Transcatheter Left Atrial Appendage Occlusion. JACC Cardiovasc Interv. 2017;10:2198-2206.

21. Kim DY, Shin SY, Kim JS, Kim SH, Kim YH, Lim HE. Feasibility of intracardiac echocardiography imaging from the left superior pulmonary vein for left atrial appendage occlusion. Int J Cardiovasc Imaging. 2018;34:1571-1579.

22. Hemam ME, Kuroki K, Schurmann PA et al. Left atrial appendage closure with the Watchman device using intracardiac vs transesophageal echocardiography: Procedural and cost considerations. Heart Rhythm. 2019;16:334-342.

23. Westcott SK, Wung W, Glassy M et al. A novel clock-face method for characterizing peridevice leaks after left atrial appendage occlusion. Catheter Cardiovasc Interv. 2020;96:E387-E392.

24. Freitas-Ferraz AB, Bernier M, Vaillancourt R et al. Safety of Transesophageal Echocardiography to Guide Structural Cardiac Interventions. J Am Coll Cardiol. 2020;75:3164-3173.

25. Singh SM, Douglas PS, Reddy VY. The incidence and long-term clinical outcome of iatrogenic atrial septal defects secondary to transseptal catheterization with a 12F transseptal sheath. Circ Arrhythm Electrophysiol. 2011;4:166-71.

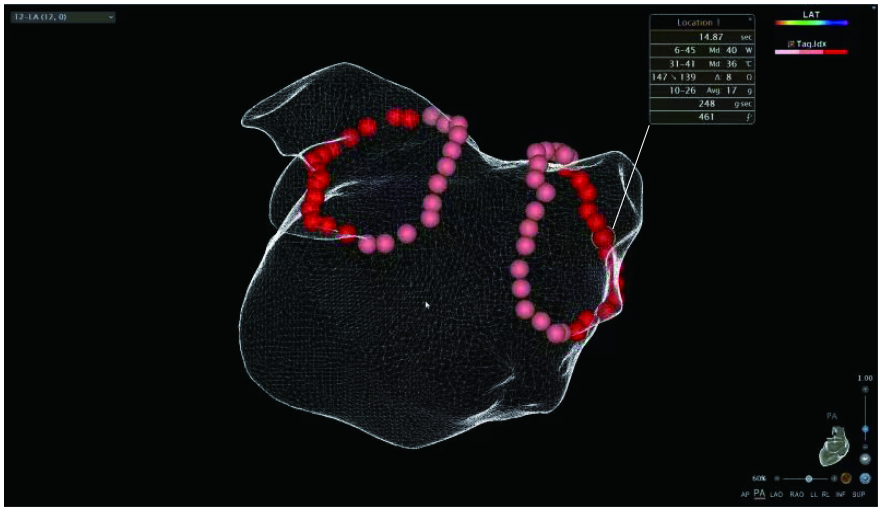
Figure 1. Representative image of ablation index-guided high-power atrial fibrillation catheter ablation under Carto-Sound system.

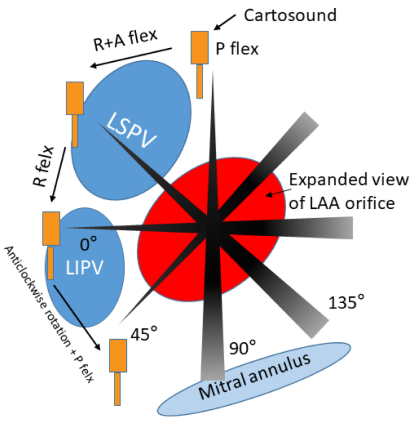
Figure 2. Step-by-step illustration of FLAVOR approach. LAA, left atrial appendage; P, posterior; R, right; A, anterior; PA, posteroanterior; LSPV, left superior pulmonary vein; LIPV, left inferior pulmonary vein.

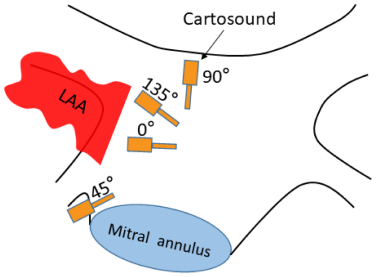
Figure 3. Illustration of ICE with FLAVOR approach to measure LAA orifice and landing zone and to assess the position of the device and residual flow at four angles (90deg, 135deg, 0deg, and 45deg). Expanded view of LAA orifice and ICE planes at 90deg (A), 135deg (G), 0deg (M), and 45deg (S). Posteroanterior (B, H, N, T) and left lateral views (C, I, O, U) of three-dimensional reconstruction of the left atrium and the corresponding position of the ICE catheter are shown. Measurement of the LAA orifice and landing zone (D, J, P, V) and assessment of the device position and residual flow (E, K, Q, W) using ICE with long-axis views at the four angles after release are also depicted. Pre-procedural TEE views of the LAA at 90deg, 45deg, 0deg, and 135deg (F, L, R, X) were similar to the ICE views at 90deg, 135deg, 0deg, and 45deg (D, J, P, V). LAA, left atrial appendage; ICE, intracardiac echocardiography. TEE, transesophageal echocardiography.

Figure 4. Residual peri-device flow detected by ICE-guided FLAVOR approach after LAmbre LAA device detachment. Color Doppler evaluation of the residual peri-device leakage in 0deg, 45deg, 90deg, and 135deg views of ICE images with LAmbre LAA device using FLAVOR approach (A–D). ICE, intracardiac echocardiography; LAA, left atrial appendage.

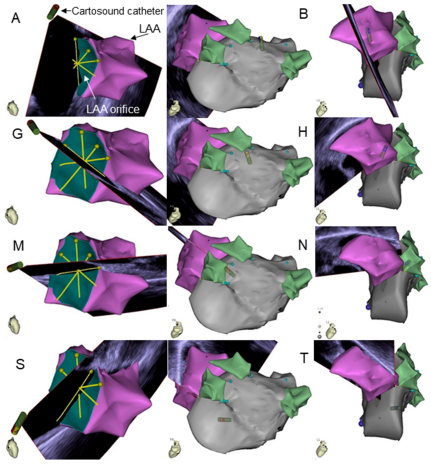
Figure 5. Observed stroke and bleeding rates during follow-up versus expected annual stroke and bleeding risk.

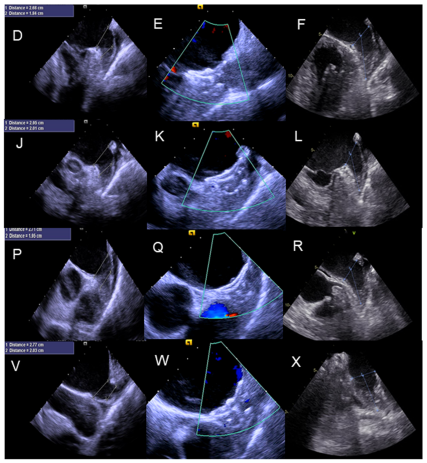


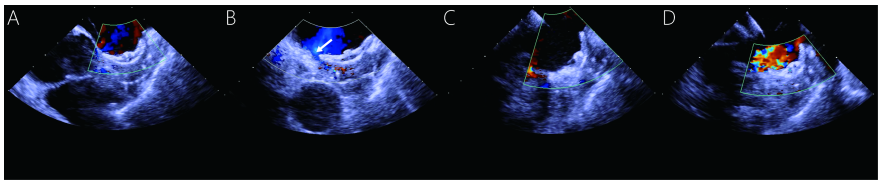


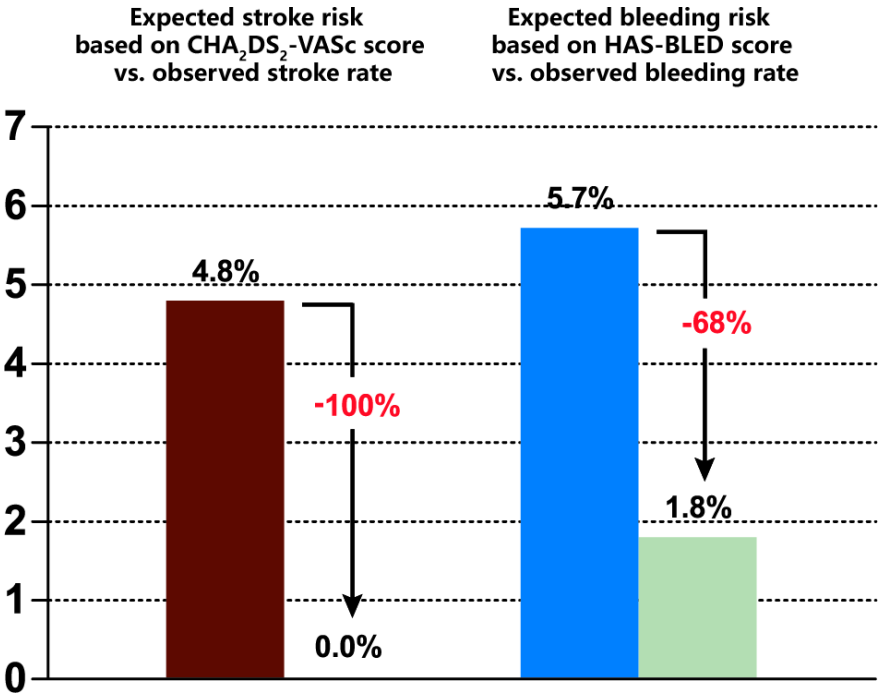


PA projection









Hosted file

`table.docx` available at https://authorea.com/users/365861/articles/539390-outcome-and-safety-of-intracardiac-echocardiography-guided-left-atrial-appendage-closure-within-zero-fluoroscopy-atrial-fibrillation-ablation-procedures