Application of Intracardiac Echocardiography in Left Atrial Appendage Closure

Ke-Wei Chen MD., PhD[1,4], Ju-Hsin Chang MD., PhD[2,4], Yu-Chen Wang MD., PhD[3], Ping-Han Lo MD.[1], Kuan-Cheng Chang, MD., PhD[1,4]

[1]*Division of Cardiovascular Medicine, Department of Medicine, China Medical University Hospital, Taichung, Taiwan*
[2]*Department of Anesthesiology, China Medical University Hospital, Taichung, Taiwan*
[3]*Division of Cardiovascular Medicine, Asia University Hospital, Taichung, Taiwan*
[4]*School of Medicine, China Medical University, Taichung, Taiwan*

Abstract

The application of intracardiac echocardiography (ICE) in left atrial appendage closure (LAAC) is emerging as a viable alternative to the traditional transesophageal echocardiography (TEE)-guided method. The 2023 ACC/AHA/ACCP/HRS guidelines have upgraded LAAC to a Class IIa recommendation for stroke prevention in atrial fibrillation (AF) patients contraindicated for long-term anticoagulant use. ICE-guided LAAC, performed under local anesthesia, enhances patient comfort and reduces hospital stays, making it particularly beneficial for elderly and frail patients. Clinical studies indicate that ICE-guided LAAC has similar procedural success rates and complication profiles to TEE-guided procedures. Despite higher initial costs, ICE may reduce overall medical expenses by lowering the need for anesthesia and specialized staff. Potential advantages of ICE include streamlined procedures, reduced radiation exposure, and quicker postoperative recovery. However, the high cost of ICE catheters and the need for operator proficiency in ultrasound imaging remain challenges. Ongoing trials like the ICETEE are expected to provide further comparative data by 2025. In summary, ICE-guided LAAC shows promise in patient management and procedural efficiency for high-risk and elderly populations, with further research needed to optimize its clinical application.

Keywords: intracardiac echocardiography (ICE), left atrial appendage closure (LAAC), atrial fibrillation (AF)

Introduction

In the newly released 2023 ACC/AHA/ACCP/HRS guidelines for the diagnosis and management of atrial fibrillation (AF), left atrial appendage closure (LAAC) has been upgraded to a Class IIa recommendation.[1] It is now considered a primary alternative treatment for stroke prevention in AF patients with a CHA2DS2-VASc score of ≥2 who have contraindications for long-term

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Address for correspondence: Kuan-Cheng Chang, M.D., Ph.D, FESC.
China Medical University Hospital; 2, Yude Road, Taichung 404327, Taiwan
Tel: +886-4-22052121 ext. 12626; Fax: +886-4-22038883; E-mail: kuancheng.chang@gmail.com

anticoagulant use. This recommendation likely stems from the safety profile of LAAC observed in real-world data.[2-6] Upcoming large-scale trials, including CHAMPION and CATALYST, are expected to provide more precise results regarding the efficacy of LAAC in the era of direct oral anticoagulants (DOACs). Additionally, since LAAC is a preventive procedure mainly performed on high-risk, comorbid, and generally frail elderly populations, minimizing procedural complications, simplifying the procedure, and accelerating postoperative recovery are key goals in the execution of this procedure.

Traditionally, LAAC is a transesophageal echocardiography (TEE)-guided procedure, where both the intraoperative positioning of the device and the assessment of successful occlusion rely on TEE. The preoperative evaluation also typically uses TEE to analyze the left atrial appendage's size and morphology and check for thrombi. Most institutional protocols recommend TEE or cardiac computed tomography at 45 to 90 days post-procedure to assess device seal and detect device-related thrombus (DRT).[7] However, many patients, especially the elderly and frail, cannot tolerate repeated TEE. Consequently, preoperative analysis or postoperative follow-up using three-dimensional computed tomography (3D CT) imaging is becoming increasingly common.[8-10] Additionally, intracardiac echocardiography (ICE)-guided LAAC, which does not require general anesthesia, is gradually becoming the mainstream approach in some medical centers. This article will explore the current clinical evidence on ICE-guided LAAC, analyze the advantages and disadvantages based on evidence, and provide practical guidelines and techniques for performing ICE-guided LAAC.

Is ICE-guided LAAC safe? Or necessary?

When discussing the ICE-guided procedure, the most frequently asked questions concern the necessity and safety of using ICE. These points have been extensively discussed in recent literature. In terms of necessity, ICE is generally not required in most cases, as TEE can be used to efficiently and safely perform most LAAC procedures. However, ICE is not intended to replace TEE completely; instead, it is an alternative in specific clinical scenarios where: 1. The patient is unsuitable for prolonged general anesthesia; 2. The patient cannot undergo transesophageal examination or has a potential risk of esophageal injury (e.g., esophageal varices, esophageal cancer with or without surgery, buccal cancer post-radiation therapy or surgery, dysphagia lusoria); 3. TEE cannot provide precise imaging.

Moreover, the comfort and convenience of a streamlined procedure that does not require general anesthesia can be significant for patients. For instance, at the Mayo Clinic, which pioneered 3D ICE-guided LAAC in humans[11], patients undergoing ICE-guided LAAC can have "day surgery," meaning they are discharged on the same day of the procedure. Post-discharge, patients receive guidance for home wound care and return for follow-up after a period. This care model accelerates postoperative recovery and reduces the impact on patients' and their families' daily lives. It also decreases hospital bed occupancy and reduces the demand for anesthesia and nursing staff, creating a win-win situation for hospitals and patients. Initial cost-benefit analyses suggest that although ICE-guided LAAC increases the cost of consumables (ICE catheters are expensive and single-use), it reduces the need for anesthesiologists, nurses, and ultrasound specialists, potentially lowering overall medical expenses.

Regarding safety, the primary concern about ICE is that it is more invasive than TEE, requiring an additional catheter to be placed in the heart chambers, thereby posing a risk of cardiac injury. Many early studies and ongoing RCTs are attempting to assess the safety of using ICE in LAAC procedures.[12]

Current evidence of ICE-guided LAAC

In a 2018 multi-center registry study in Italy[13], it was shown that TEE-guided LAAC had relatively shorter procedural and fluoroscopy times (delta 12 minutes between ICE and TEE groups), with no difference in procedure success rate and complication rate, compared to ICE-guided LAAC. This indicates that ICE-guided LAAC still requires time to complete the learning curve. However, these data represent early results, and later studies involving more experienced operators (with over 10 ICE-guided LAAC cases) showed that the procedure time decreased from 100 minutes to under 50 minutes.

M. Alkhouli et al. (2020) compared the clinical outcomes and complications of ICE-guided LAAC and TEE-guided LAAC.[12] They found no difference in technical success between the two groups (ICE: 97.8% vs. TEE: 97.4%, p=0.8). Major procedure-related events, including pericardial effusion requiring intervention, major vascular complications, procedure-related stroke, device embolization, and in-hospital death, also showed no statistical difference (ICE: 3.3% vs. TEE: 4.1%, p=0.76).

In the ICE LAA study (J. Am. Coll. Cardiol. Intv., 2023)[14], a prospective cohort of 100 ICE-guided LAAC cases was analyzed. The technical success rate was 100%, and there were no cases of pericardial effusion or device embolization during the 45-day postoperative follow-up. Peri-device leakage greater than 5 mm was 0%.

Currently, the clinical evidence on ICE-guided LAAC is still limited to observational studies (Table 1). Most show that regardless of the type of LAAC device used (Watchman, Watchman FLX, Amplatzer Cardiac Plug (ACP), or Amulet), the procedural success rate and complication rate are comparable to those of TEE-guided LAAC. However, some registries' TEE groups used earlier devices, such as the ACP and data from the early days of LAAC, which may overestimate the complication rate and underestimate the success rate in the TEE group. Therefore, rigorously designed RCTs are still needed to provide a definitive comparison between ICE-guided LAAC and TEE-guided LAAC. An ongoing RCT directly comparing ICE-guided LAAC and TEE-guided LAAC (the ICETEE trial) is expected to provide preliminary data by the end of 2025.

Benefits and shortcomings of ICE-guided LAAC

The most apparent drawback of ICE is its high cost and single-use nature. In Taiwan, the National Health Insurance (NHI) conditionally covers ICE for patients with refractory atrial fibrillation requiring repeat ablation. However, it remains an out-of-pocket expense for other structural heart disease interventions, including LAAC. ICE-guided procedures also require the interventionist to handle the imaging catheter, which can be challenging for physicians unfamiliar with ultrasound imaging, thereby extending the learning curve. Early concerns about ICE causing cardiac perforation or ventricular arrhythmia have proven less significant.

The primary advantages of using ICE include streamlining the surgery, allowing local anesthesia or mild sedation, shortening operating room time, and speeding up patient recovery. It also avoids the risks associated with esophageal and airway intubation and anesthesia-related complications, which is particularly important for elderly, comorbid, and frail patients.

Some studies have indicated that the imaging specialists operating TEE at the patient's head experience the highest radiation exposure in structural heart disease interventions.[20,21] ICE can mitigate this risk. Additionally, ICE allows the interventional cardiologist to adjust the required images in real-time without spending extra time communicating with a separate imaging specialist, enhancing their understanding of the anatomical structures.

ICE is expected to be applied gradually to various structural heart disease interventions. In more complex procedures, such as tricuspid

Table 1. Clinical studies of ICE-guided LAAC

Author	Year	Journal	N	Study type	Device	Procedural MAEs	Procedural success	Peridevice leakage >5mm at follow-up
Korsholm K, et al.[15]	2017	JACC Cardiovasc. Interv.	216 patients (n=107 TEE, n=109 ICE)	Single-center, cohort study	Amplatzer Cardiac Plug or Amulet	TEE=4.7%, ICE=1.8%; p=0.28	TEE=94.4%, ICE=94.5%; p=0.99	TEE=1, ICE=0
Frangieh AH, et al.[16]	2017	Catheter Cardiovasc. Interv.	76 patients (n=44 TEE, n=32 ICE)	Single center, single operator, cohort study	Watchman	One esophageal erosion/ bleeding in TEE group	100% in both groups	NA
Kim et al.[17]	2018	Int J Cardiovasc. Imaging	144 patients (n=103 TEE, n=41 ICE)	Multi-center registry	Amplatzer Cardiac Plug, Amulet, or Watchman	TEE=6.8%, ICE=2.4%; p=0.73	TEE=97.1%, ICE=100%; p=1.00	NA
Berti S, et al.[13]	2018	JACC Cardiovasc. Interv.	604 patients (n=417 TEE, n=187 ICE)	Multi-center registry	Amplatzer Cardiac Plug or Amulet	TEE=6.5%, ICE=4.2%; p=0.327	TEE=93.5%, ICE=95.8%; p=0.587	NA
Nielsen-Kudsk, et al.[18]	2019	JACC Cardiovasc. Interv.	1085 patients (n=995 TEE, n=130 ICE)	Multi-center, post-market study	Amulet	TEE=10.4%, ICE=10.7%; p=0.93	TEE=99%, ICE=99%; p=1.0	TEE=0.2%, ICE=0%
M. Alkhouli, et al.[12]	2020	JACC Clin Electrophysiol.	286 patients (n=196 TEE, n=90 ICE)	Single center, prospective registry	Watchman	TEE=4.1%, ICE=3.3%; p=0.76	TEE=97.4%, ICE=97.8%; p=0.88	TEE=3.3%, ICE=1.2%; p=0.32
Pommier et al.[19]	2021	Clin. Cardiol.	224 patients (n=49 TEE, n=175 ICE)	Single-center, cohort study	Amplatzer Cardiac Plug or Watchman	TEE=10%, ICE=5%; p=0.689	TEE=100%, ICE=97%; p=0.895	TEE=3, ICE=9; p=0.99
Nielsen-Kudsk JE, et al.[14]	2023	JACC Cardiovasc. Interv.	100 (n=100 ICE)	Single-arm, prospective, multicenter study (ICE LAA study)	Watchman FLX	NA	ICE=96%	ICE=0%

MAEs: major adverse events

valve repair or replacement, the TEE probe requires more maneuvers and deeper insertion into the stomach (deep transgastric view), increasing the risk of esophageal mucosal injury or perforation. Studies have shown that some degree of gastroesophageal injury occurs in up to 86% of TEE-guided structural heart disease interventions.[22,23] ICE, which enters through the same pathway as the device delivery catheter, might be a more reasonable choice in such cases.

How to perform ICE-guided LAAC

Clearly, the imaging requirements for ICE and TEE are somewhat different, prompting the development of modified ICE PASS (Position, Anchor, Size, and Seal) criteria for Watchman LAAC. These criteria use two ICE views (mid-LA [long-axis ICE view] and mitral valve inflow view [short-axis ICE view]) to assess the PASS criteria. However, the basic requirements remain unchanged. Qualified ICE imaging must be able to detect baseline pericardial effusion and left atrial appendage thrombus, measure the LAA ostium size from multiple angles, evaluate the occluder from various angles, and confirm postoperative pericardial effusion and iatrogenic atrial septal defect (ASD) flow direction.

Considering the preventive nature of LAAC, the core concept in ICE-guided LAAC procedures is for the operator to achieve the aforementioned imaging objectives with minimal movement of the imaging catheter within the cardiac chambers.

Below is an example of the practical steps for ICE-guided LAAC:

1. **Anesthesia and Setup:** The patient receives local anesthesia or conscious sedation. The procedure is conducted in a standard catheterization lab.
2. **Groin Access:** Right groin access is obtained, with a 10 Fr 45 cm sheath for the ICE catheter (some brands of ICE catheters use 9 F sheaths) and a 16 Fr 30 cm sheath for the LAAC guiding catheter separately. Echo-guided puncture is used to place the two sheaths as close as possible, reducing the risk of bleeding when performing figure-8 suture hemostasis.
3. **Guide Wire Placement:** A J-tip guidewire is placed into the IVC via the device sheath.
4. **ICE Catheter Insertion:** The ICE catheter is introduced into the right atrium along the guidewire (under PA view, just above the diaphragm), achieving a "Home view" (ICE image shows tricuspid valve and right ventricle).
5. **ICE Catheter Manipulation:** The ICE catheter is manipulated using "P" flexion, +/- "L" as needed. The goal here is to align the "eyes" of the ICE (the ultrasound probe crystals) parallel to the plane of the target structure. Before performing the transseptal puncture, the ICE needs to directly visualize the atrial septum and clearly observe the fossa ovalis. Therefore, the ICE probe is tilted back to align parallel with the atrial septum itself. With the new generation 4D ICE catheter (VeriSight, Philips, US), the 45-degree X-plane function can be used to achieve the superior-inferior, anterior-posterior views typically obtained with traditional TEE-guided LAAC. The puncture is performed once clear tenting is seen. For ICE systems without X-plane functionality, small clockwise/counterclockwise rotations are used to determine the anterior-posterior relationship after identifying the superior-inferior relationship (counter-clockwise rotation brings the view forward, while clockwise rotation brings the view backward) (Figure 1).
6. **Transseptal Puncture:** The basic steps are the same as in TEE-guided LAAC, but there are differences based on the operator's preference. In Taiwan, the BRK series needles are commonly used, with the option of using a PTCA guidewire for protection after the puncture. For complex cases where BRK puncture fails, the Taiwan NHI covers atraumatic devices like the Balis radiofrequency needle, and the VersaCross radiofrequency system (Baylis Medical, Canada; Boston Scientific, US) might be introduced in the

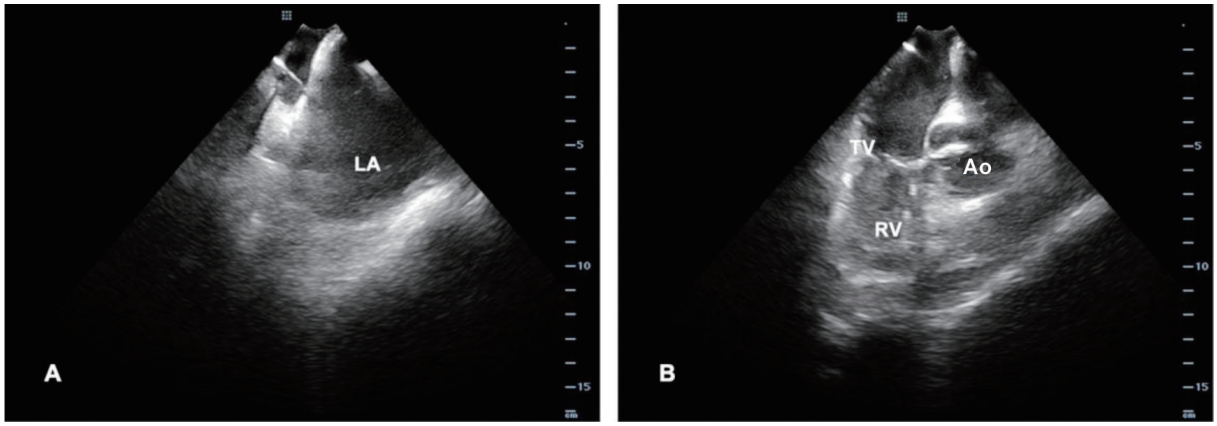

Figure 1. A. In the right atrium view, determine the superior-inferior relationship. If the tenting position on the left atrium side allows visualization of the left atrial appendage, the trajectory can be confirmed. **B.** Make slight clockwise rotations of the ICE catheter. If the aortic valve, tricuspid valve, and right ventricle are visible, it indicates that the orientation is too anterior, and the puncture position should be adjusted. (LA: left atrium, TV: tricuspid valve, RV: right ventricle, Ao: aorta)

future. The puncture site is chosen based on the left atrial appendage anatomy or procedural workflow, such as posterior-inferior for anterior LAA anatomy or middle-middle for combined atrial fibrillation ablation.[24] With ICE, the trajectory from the atrial septum to the left atrial appendage is directly observed (ICE catheter "P" flexion + counter-clockwise rotation). The best puncture site is where the left atrial appendage is most clearly seen.

7. **Dilation and Sheath Insertion:** After the transseptal puncture, a stiff guidewire is placed, and the LAAC sheath is used to dilate the atrial septum 2-3 times to facilitate ICE catheter passage. The ICE catheter is then advanced into the left atrium under fluoroscopy, ideally using an LAO or LAO-cranial angle. Biplane imaging in catheter labs aids in determining the 3D positioning. If passing through the atrial septum is difficult, additional sheath dilation or a 16 mm PTA balloon septostomy can be used. Most cases can be completed within a few minutes.
8. **ICE Views in the Left Atrium:** The left atrial appendage and device are observed using three main ICE views: the left upper pulmonary vein view, the mid-left atrium view, and the supra-mitral annular view.[25]
   1) **Proximal left superior pulmonary vein view:** The ICE catheter is advanced into the pulmonary vein and slightly retracted to rest on the coumadin ridge, looking downward. This angle is similar to a 0-degree TEE view, close to the LAA and occluder, useful for evaluating PVL but potentially interacting with the device. This view has been used less frequently in more experienced centers to reduce the risk of pericardial effusion.
   2) **Mid-left atrium, retroflexion view:** ICE observes the LAA and device at a 60-90-degree angle with the LAAC guiding catheter, equivalent to a 45-degree TEE view. This angle is used for continuous observation during device deployment (Figure 2).
   3) **Supra-mitral annular, retroflexion +/- L/R:** The ICE catheter is rotated 180 degrees from the mid-LA view and retroflexed against the mitral annulus edge, adjusted as needed. This corresponds to a 135-degree TEE view. Color flow can be used in all three angles to detect residual leakage.
9. **Device Deployment:** After the device is deployed, the compression rate, residual leakage, and shoulder protrusion are assessed

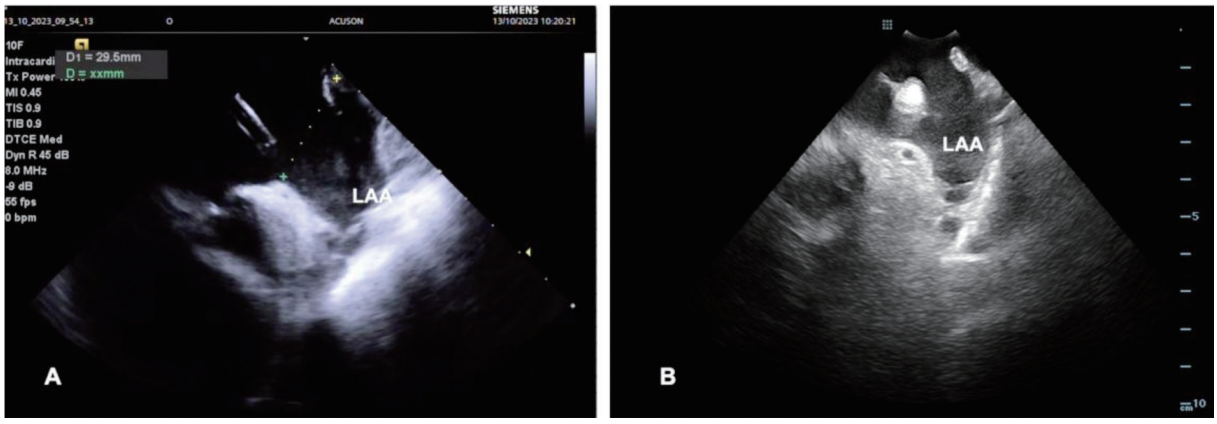

Figure 2. A. In the mid-left atrium (mid-LA) view, observe whether the sheath trajectory is coaxial with the left atrial appendage (LAA), and measure the LAA ostium size (Device: Watchman FLX, Boston Scientific, US; ICE catheter: AcuNav, Siemens, US). **B.** In the mid-LA view, observe the axial relationship between the spherical device tip and the LAA (Device: Amulet, Abbott, US; ICE catheter: ViewFlex, Abbott, US). (LAA: left atrial appendage)

from two angles (middle left atrium view and supra-mitral annular view). For example, when using the Watchman FLX device, the compression rate should evaluate to between 10-30% from two angles that allow clear imaging of the LAA ostium and occluder boundary. Additionally, it must be ensured that the shoulder protrusion does not exceed 30-50% of the expansion height, and any residual leakage or compression of the circumflex artery must be assessed using color flow. The device is released once the PASS criteria for Watchman or CLOSE criteria for Amulet are met (Figure 3).

10. **Post-Deployment Evaluation:** Pericardial effusion is evaluated from two views: 1) Anteflexion in the middle left atrium view: Looking towards the mitral valve. 2) Right atrium view: The ICE catheter is retracted to the right atrium and positioned against the atrial septum with anteflexion, achieving a near 4-chamber view.

Conclusion

ICE has been used for years in arrhythmia ablation and in guiding atrial septal puncture, but its application in imaging guidance for various structural heart diseases is still in development. ICE-guided LAAC is a pioneering application in this field. Many medical centers worldwide have started using it and have accumulated significant experience, showing that ICE-guided LAAC is comparable to TEE-guided LAAC in terms of safety and efficacy. Upcoming clinical trials are expected to provide more evidence in this regard. The operation of ICE also requires a longer learning curve, with at least 10 cases needed to become an experienced operator. It is also recommended that TEE be used to guide the procedure during the first ICE case. In Taiwan, two ICE catheters without 3D imaging capabilities are currently available: AcuNav (Siemens) and ViewFlex Xtra (Abbott). The next-generation ICE catheter with 3D imaging capabilities, VeriSight (Philips), is expected to be introduced in Asia this year (Table 2 compares the characteristics and functions of different ICE catheters). ICE-guided LAAC is currently not covered by health insurance, and patients need to pay approximately 3,000 USD out of pocket to use this medical device.

For interventionists performing structural heart disease interventions, becoming proficient

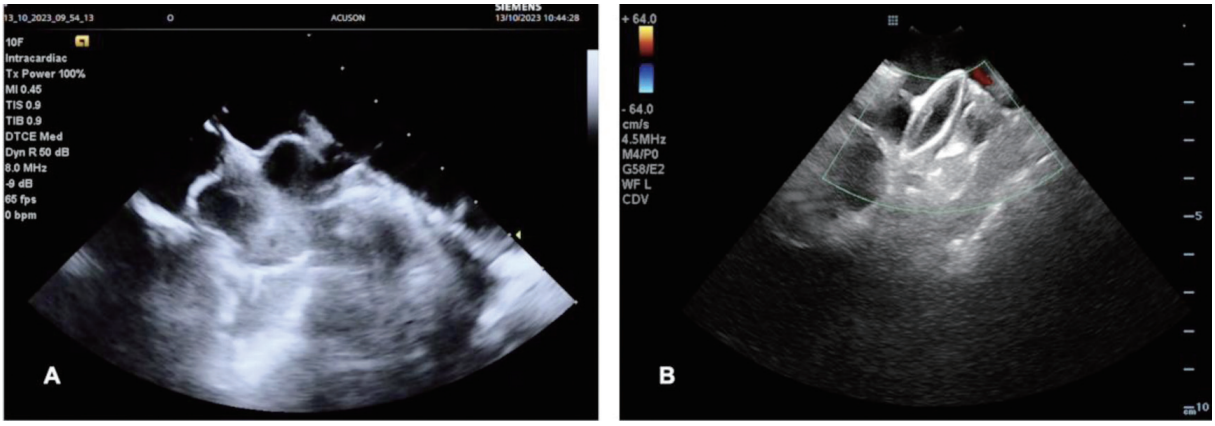

Figure 3. A. In the mid-LA view, observe whether the deployed Watchman FLX meets the PASS criteria. **B.** In the mid-LA view, observe whether the deployed Amulet meets the CLOSE criteria.

Table 2. Comparison of ICE catheters

Feature/Brand	VeriSight (Philips)	ACUSON AcuNav (Siemens)	ViewFlex Xtra (Abbott)
Company	Philips	Siemens	Abbott
Product Name	VeriSight ICE Catheter	ACUSON AcuNav ICE Catheter	ViewFlex Xtra ICE Catheter
Catheter size, F	9	8 or 10	9
Length, cm	90	90	90
Frequency, MHz	5-10	5-10	4.5-8.5
Transducer, number of elements	840	64	64
Tip deflection	4 ways (AP, RL)	4 ways (AP, RL)	4 ways (AP, RL)
Tip deflection angle	90° x 90°	120°	160°
3D Imaging	Yes, 3D imaging with xMatrix technology	No, primarily 2D imaging	No, primarily 2D imaging
Compatibility	Epiq CVx and Epiq CVxi ultrasound systems	ACUSON SC2000, X700 ultrasound systems	Various Abbott vascular imaging systems
FDA Approved	Yes	Yes	Yes
Available in Taiwan	No	Yes	Yes

with ICE can offer greater freedom and superior image quality during procedures. This proficiency can also simplify procedural processes and enhance the patient experience.

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