




Step-by-step recommendations utilizing four-dimensional intracardiac echocardiography in left atrial appendage procedures

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Abstract

Introduction: Four-dimensional (4D) intracardiac echocardiography (ICE) is a novel cardiac imaging modality that has been applied to various workflows, including catheter ablation, tricuspid valve repair, and left atrial appendage occlusion (LAAO). The use of this type of advanced ICE imaging may ultimately allow for the replacement of transesophageal echocardiography (TEE) for LAAO, providing comparable imaging quality while eliminating the need for general anesthesia.

Methods: Based on our initial clinical experience with 4D ICE in LAAO, we have developed an optimized workflow for the use of the NUVISION™ 4D ICE Catheter in conjunction with the GE E95 and S70N Ultrasound Systems in LAAO. In this manuscript, we provide a step-by-step guide to using 4D ICE in conjunction with compatible imaging consoles. We have also evaluated the performance of 4D ICE with the NUVISION Ultrasound Catheter versus TEE in one LAAO case and present those results here.

Results: In our comparison of 4D ICE using our optimized workflow with TEE in an LAAO case, ICE LAA measurements were similar to those from TEE. The best image resolution was seen via ICE in 2-dimensional and multislice modes (triplane and

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biplane). The FlexiSlice multiplanar reconstruction tool, which creates an en-face image derived from a 4D volume set, also provided valuable information but yielded slightly lower image quality, as expected for these volume-derived images. For this case, comparable images were obtained with TEE and ICE but with less need to reposition the ICE catheter.

Conclusion: The use of optimized 4D ICE catheter workflow recommendations allows for efficient LAAO procedures, with higher resolution imaging, comparable to TEE.

KEYWORDS

catheter, catheter ablation, left atrial appendage occlusion, transesophageal echocardiography, tricuspid valve, workflow

1 | INTRODUCTION

The left atrial appendage (LAA) is the major nidus for thrombus formation and subsequent embolization in atrial fibrillation (AF). Traditional oral anticoagulation remains the mainstay of treatment to prevent thromboembolism in AF. However, it is not without any adverse events, such as bleeding, a narrow therapeutic window, drug interactions, and poor patient compliance. LAA occlusion (LAAO) has excited clinical interest in reducing thromboembolic risk in patients with nonvalvular AF, with several clinical trials demonstrating high procedural success, and a significant reduction in postprocedural major hemorrhagic events compared with warfarin.¹ Despite adequate preprocedural planning for LAAO, intraprocedural imaging is vital for assessment of LAA anatomy, ruling out thrombus, and device implantation.²

1.1 | Rationale for 4-dimensional (4D) intracardiac echocardiography (ICE)

Multimodality imaging with fluoroscopy and transesophageal echocardiography (TEE) is the standard approach to LAA closure. While the standard 4 angles with transesophageal omniplane (0°, 45°, 90°, and 135°) suffice to evaluate the basic LAA anatomy and the closure criteria, these views can be limited by esophageal position, intervening structures, and compromise of relative change in omniplane angle when the probe is flexed and repositioned. This may lead to inadvertently missing an exposed lobe, particularly on the posterior side of the LAA. Iodinated contrast appendograms provide important adjunctive information to understand the global LAA anatomy and identify incomplete closure. Additional limitations exist, including the need for general anesthesia, the need for additional personnel to manipulate the TEE probe, contraindications to TEE, and risk of injury from the probe.

ICE offers a different means of complementing fluoroscopic imaging. While studies have demonstrated that ICE-guided LAAO is as effective as TEE imaging, it is still not widely utilized.³ Its utility is limited when viewing the LAA from other chambers, such as from the right atrium (RA), right ventricle (RV), and coronary sinus (CS). From the proximal

pulmonary artery (PA), ICE may provide utility in ruling out thrombus before a transeptal puncture (TSP). Placed in the left atrium (LA) with unprecedented proximity to the LAA and the LAAO device, ICE offers high-resolution near-field detail. However, that same proximity results in a narrow field of view, such that visualization into the distal appendage to evaluate for thrombus or to understand global LAA structure utilizing surrounding anatomical landmarks is challenging. Historically, this is further compromised by its 2-dimensional (2D) limitations and lack of omniplane. This can, to some extent, be overcome with catheter manipulation to approximate TEE omniplane angulation using standardized views,⁴ but scanning the ostial circumference or obtaining four true orthogonal slices is not reproducible.

Four-dimensional ICE, also known as 3-dimensional (3D) real-time ICE imaging, is a novel cardiac imaging modality (**Graphical Abstract**). The multiplanar imaging feature of 4D ICE is created using real-time 3D images with overlaying cross-sectional planes.^{5,6} Four-dimensional ICE has been applied to various workflows, including catheter ablation,^{7,8} tricuspid valve (TV) repair,⁹ and LAAO.^{10–13} The advent of such advanced ICE imaging may permit the replacement of TEE for LAAO in the hands of operators with adequate LAAO and catheter manipulation experience in the LA.^{14,15} The use of 4D ICE provides measurements that are comparable to those obtained with TEE,¹² with no differences in rates of technical success or periprocedural complications.^{3,16} Unlike TEE, however, ICE can be completed under conscious sedation, which eliminates the need for general anesthesia^{3,11,16,17} and expedites the procedure logistics.⁴

1.2 | Overview of the 4D ICE catheter and compatible imaging consoles

The NUVISION™ Ultrasound Catheter (Biosense Webster, Inc., Irvine, CA; Figure 1) is a new diagnostic ultrasound imaging catheter intended for intracardiac visualization. An imaging transducer assembly is housed within the catheter tip to provide a 2D piezo-electric array capable of real-time 3D imaging. To simplify ultrasound workflow, the independent tip rotation (ITR), in combination with deflection of the distal catheter segment, provides the user with the ability to adjust the imaging tip

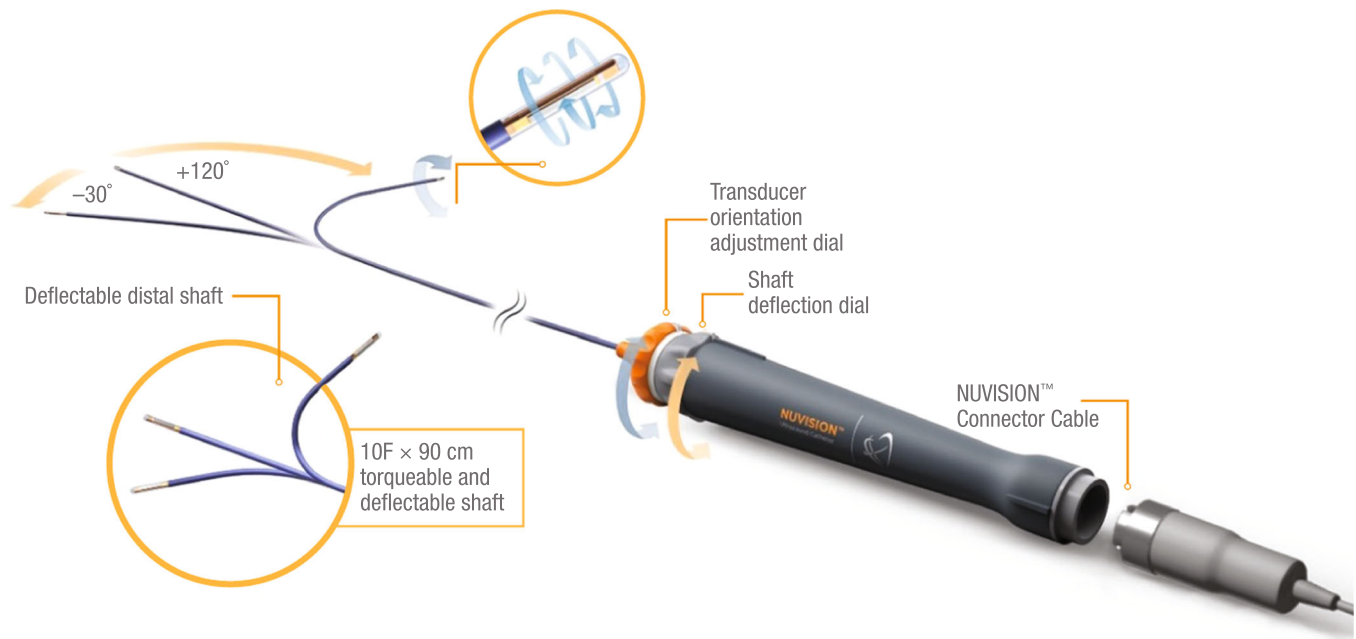


FIGURE 1 NUVISION™ Ultrasound Catheter diagram. F, French. Image courtesy of © Biosense Webster, Inc. All rights reserved.

orientation to visualize structures of interest without the need to compromise the chosen tip location. The catheter handle is connected to an umbilical connector cable, which is then connected to an ultrasound imaging console with 4D ICE software.

The compatible imaging consoles, the GE E95 and S70N Ultrasound Systems (GE HealthCare), offer several modalities, which can reconstruct the 4D volume data set in distinct ways. The manipulations fall into two broad categories: deriving multiple 2D slices from the volume image and showing the volume image itself, cropped and rotated. These imaging modes have distinct uses for highlighting cardiac anatomy and guiding procedures. The most relevant modes described here are chosen from a larger set of available choices.

Any slice from within the 3D volume can be displayed for the user, such that omniplane is available. Three-dimensional imaging relies on the acquisition and display of volume data sets, compared with 2D imaging, where individual tomographic slices are acquired to display an area of interest. Real-time 3D imaging relies on high spatial resolution (i.e., the ability to distinguish two objects separated in space) and high temporal resolution (i.e., the ability to detect whether an object has moved over time). At present, the rectangular arrangement of the ICE array results in some image degradation since the narrowest part of the array is approached at 90°. Just as with 2D imaging, spatial and temporal resolution are inversely related—with an increase in one causing a decrease in the other, thus impacting the ultrasound probe design—but even more so with ICE, where restricted catheter diameter limits transducer size and number of cables.

Nevertheless, as a result of the proximity of the catheter to the LAAO device, full 3D reconstruction and multiplanar reconstruction (MPR) allow for consistent evaluation of the full circumference of the device where it makes tissue contact, decreasing the possibility of missing a leak.

1.3 | Initial clinical experience with 4D ICE

Initial clinical experience using the 4D ICE catheter demonstrated its safety and utility as an intracardiac and intraluminal guidance catheter for visualization of intracardiac and great vessel anatomy.^{18,19} The catheter was used to guide LAAO ($n = 2$), catheter ablation of AF ($n = 20$), and other arrhythmias ($n = 6$). Fifteen patients were placed under conscious sedation and 13 under general anesthesia throughout imaging during the index procedures. There were no procedure- or device-related complications through 7-day follow-up, and performance endpoints were met in all 28 procedures. Formal survey feedback utilizing a Likert scale confirmed that the operators were, overall, very satisfied with imaging, catheter movement, and catheter performance within their respective electrophysiology workflows. Further refinement of 4D ICE manipulation and interpretation skills may, in experienced hands, lead to obviating the need for contrast angiography and fluoroscopy.¹⁴ However, it is highly recommended that a standardized approach with ICE be used for optimal LAAO intraprocedural imaging.²

In this paper, we discuss recommended workflows using the 4D ICE catheter in conjunction with the GE E95 and S70N Ultrasound Systems for LAAO procedures.

2 | ICE IN LAAO WORKFLOW

The 4D ICE catheter uses a 2D piezo-electric matrix array mounted on the distal end of a 10F two-way steerable catheter (anterior-posterior). The marker setup is conventional, with the marker position on the left side of the image sector, indicating that the shaft of the catheter is to the left of the image while the tip of the catheter is on the right. The ICE catheter is inserted via the 11F femoral venous

introducer sheath and advanced into the RA. The technical aspects of ICE catheter advancement from the femoral vein to RA have been previously described. Catheter manipulation involves either clockwise or counterclockwise catheter rotation, clockwise or counterclockwise ITR, probe advancement/withdrawal, or manipulation of a two-way deflection mechanism. Catheter manipulation should generally be performed with ITR at 0 and omniplane at 0. When minimizing use of fluoroscopy during this stage, slow incremental advancement while maintaining constant visualization of the vessel wall will identify entrance into a side branch before development of meaningful force on the catheter tip. Slight ITR adjustments with flexion will identify both the long axis of the vessel and the direction of blood flow by visualization of spontaneous echocardiographic contrast.

2.1 | Catheter access and positioning

Two right femoral venous access sites are obtained under ultrasound guidance. With anticoagulation, high target activated clotting times (ACTs), and multiple large-bore ipsilateral venipuncture sites, it is common to use a means of facilitating hemostasis, such as VASCADE[®], Perclose ProGlide[™], or figure-of-eight suture. A 10F sheath is used to advance the 4D ICE catheter into the RA. Upsizing to 11F is convenient for ACT checks or rapidly infusing saline to achieve target LA pressure. Heparin is administered before transseptal (TS) access is achieved, aiming at targeting a periprocedural ACT ≥ 300 s, with patients having initiated aspirin the day before the procedure. Most patients are taking uninterrupted anticoagulation or have held a single dose the morning of the procedure. The ICE catheter with ITR at 0 is rotated to the home view to visualize the TV and anteflexed to direct the tip across the TV towards the RV anteflexion is released and the ITR utilized to view the coumadin ridge and LAA ostial region. Omniplane and V-plane may be adjusted to ascertain the presence of thrombus in the ostial region. While 2D ICE catheters, such as the 10F ACUSON AcuNav[™] Ultrasound catheter, can easily be placed into the PA, this anatomical location may be challenging with NUVISION. Advancing the ICE catheter into the PA should be performed with caution given the thin wall of the right ventricular outflow tract (RVOT) and easily built-up force in a highly flexed catheter. Small movements of retroflexion and anteflexion can help confirm absence of contact of the tip of the catheter with the wall of the outflow tract to reduce the risk of perforation.

2.2 | Acquiring images from the RA

As with 2D ICE, the basic ICE view starts with the home view, with the 4D ICE catheter positioned in the mid-RA. The home view (with minimal clockwise and counterclockwise rotation, dependent upon the inferior vena cava angle) provides visualization of the RA, TV, cavotricuspid isthmus, aortic cusps, and RV (Figure 2A). From slightly superior to the home view (i.e., mid-RA

view), clockwise rotation brings into view the mitral valve, interatrial septum, LA, and LAA. This is the view often used for a TSP with slight posterior tilt to create space between the septum and the ICE catheter, thus improving perspective on the sheath location. With slight counterclockwise rotation (keeping the TV near field), the catheter is slightly flexed, providing a short-axis view of the aortic valve and LAA (Figure 2B). Additional imaging of LAA can be obtained by advancing the catheter into the RV, RVOT, and subsequently into the left PA. However, one must be cautious manipulating the catheter near the thin-walled RVOT free wall.

An additional limitation, unless all the way out in the mid-PA, is the distance to the LAA, such that only the ostium and about 1 cm distal are all that can be confidently seen from here (Figure 2C, the catheter is positioned in distal RA, near the tricuspid annulus). (*The distal gold-colored knob rotates the shaft of the ICE catheter and steers the direction of the ultrasound beam, thereby preventing the rotation of the main body of the handle and, thus, overcoming the instability that comes from torque building up.*) This view can be used for LAA ostial measurement (Figure 2C). The RA views are usually insufficient to appreciate complex LAA anatomy due to variable interatrial septum anatomy, the distance of LAA from the imaging transducer, and far-field tissue resolution compromise with an increase in imaging depth.

LAA visualization from the right heart chambers is limited by far-field imaging. Although the imaging from 4D ICE provides significantly higher detail compared with conventional 2D ICE, this can be limited by patient anatomy and probe position. As such, positioning the ICE catheter into the LA provides high-resolution LAA imaging.

Following TS access, the ICE catheter is advanced into the LA via either a single TSP or a second TSP. We recommended a single TSP technique for ICE-guided LAAO. After the initial TSP, the guidewire is advanced into the left superior pulmonary vein (LSPV), and dilatation of TSP is performed via the sheath and dilator. The ICE catheter is then advanced into the LA using the guide wire as a fluoroscopic and ultrasonographic reference (Figure 3A).

The three critical views for ICE-guided LAAO include the mid-LA view (resembling the 45° TEE view; it is the preferred view during the landing of the LAA device), the LSPV view (resembling a lower-angle TEE view), which provides an LAA long-axis view or depth visualization, and the peri-mitral view (resembling the 135° TEE view; it provides an LAA short-axis view and is the preferred view for assessing device position, seal, and compression). This is entirely dependent upon the operator's skills, experience, and ability to maneuver the ICE catheter in the LA while deploying the device. This requirement for ICE manipulation to various locations in the LAA might ultimately hinder widespread utilization of 2D ICE-guided LAAO.

The 4D ICE catheter's ability to simultaneously provide multiplanar imaging, with minimal catheter manipulation, is advantageous. Following the TSP access, the ICE catheter (from a mid-LA view) is deflected down and gently advanced into the left ventricle (LV), keeping the mitral valve near field (Figure 3B). To image LAA, the catheter deflection is released, and the tip rotated to visualize the

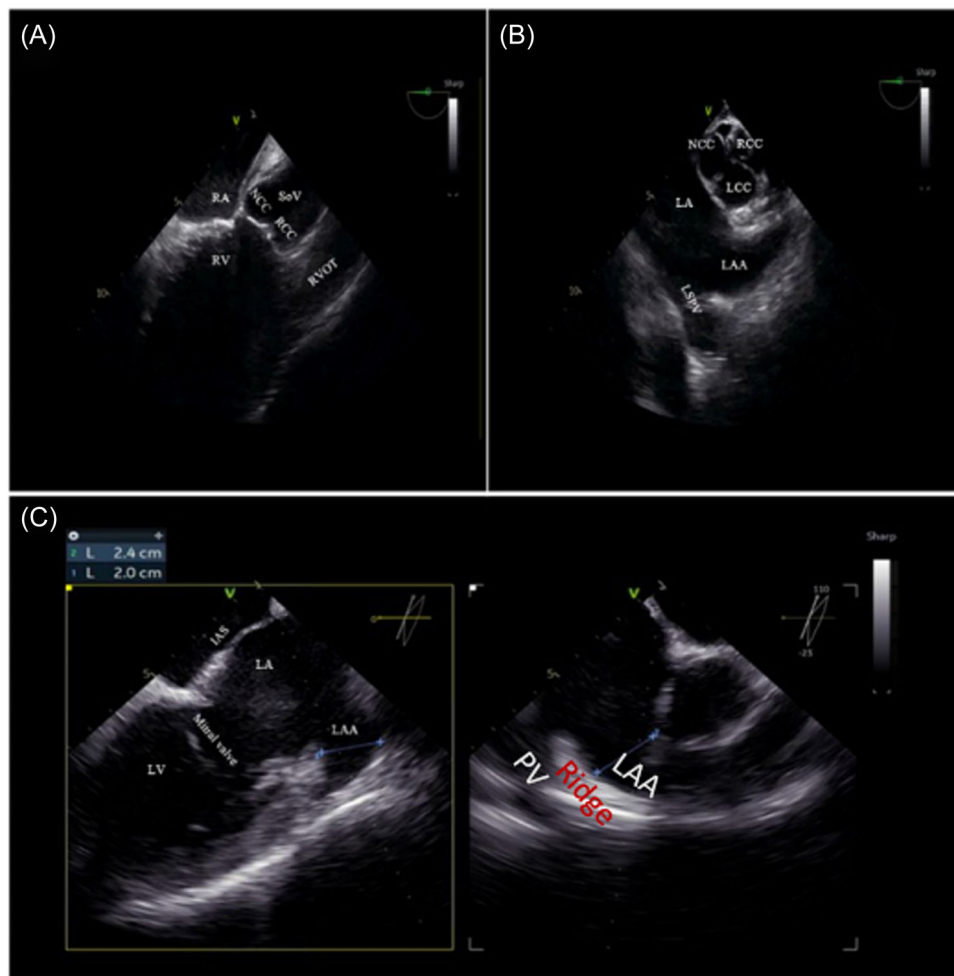


FIGURE 2 ICE catheter positioned in the RA. IAS, interatrial septum; ICE, intracardiac echocardiography; LA, left atrium; LAA, left atrial appendage; LCC, left coronary cusp; LSPV, left superior pulmonary vein; NCC, noncoronary cusp; PV, pulmonary vein; RA, right atrium; RCC, right coronary cusp; RV, right ventricle; RVOT, right ventricular outflow tract; SoV, sinus of Valsalva. Images courtesy of © Biosense Webster, Inc. All rights reserved.

base of the LV (near field), circumflex artery, great cardiac vein, and LAA. Multiplanar imaging provides all the necessary views for LAA size assessment, en-face view of LAA ostium (elliptical vs circular) (Figure 3C–F) and, subsequently, LAAO device sizing and deployment (Figure 3).

2.3 | LA access to clear the LAA

If anatomical or catheter steering constraints prevent PA access, the LAA is cleared by ICE from within the LA. This can be accomplished by gently probing for a patent foramen ovale (PFO) or advancing the ICE catheter through a TSP that has been dilated to at least 10F. Imaging of the distal LAA, particularly around the bend of a wing, may be limited, even from the LSPV or from within the LAA itself. Furthermore, evaluating for LAA thrombus from within the LA carries a risk of mechanical dislodgement of a thrombus if the LAA is unintentionally instrumented with the TS apparatus or ICE catheter.

The techniques for placing the ICE catheter into the LA are via the same TS as the LAAO device access sheath or using a separate puncture to limit sheath-catheter interaction. When utilizing the same puncture for both ICE and the LAAO device, we complete the TS with the Versa Cross Connect™ 12F outer diameter (OD) dilator placed inside the 12F inner diameter (ID) LAAO access sheath, which is then advanced into the LA and withdrawn back to the RA to take advantage of its 14F 4.8 mm OD. The wire will then be used as a visual guide by ICE and/or fluoroscopy to advance the ICE catheter into the LA. With the wire and ICE both in the LA, ICE can be used to confirm LAA morphology as appropriate for the TS location. Thereafter, the LAAO access sheath will be advanced into the LA over the retained wire, after which the dilator and wire are withdrawn. As per the authors' experience, using the same TS access for both ICE and the delivery sheath may on occasion limit the maneuverability of the ultrasound probe, especially when trying to perform a peri-mitral view of the LAA. Additionally, it is more likely that, when manipulating the sheath to deploy the LAAO closure device, the

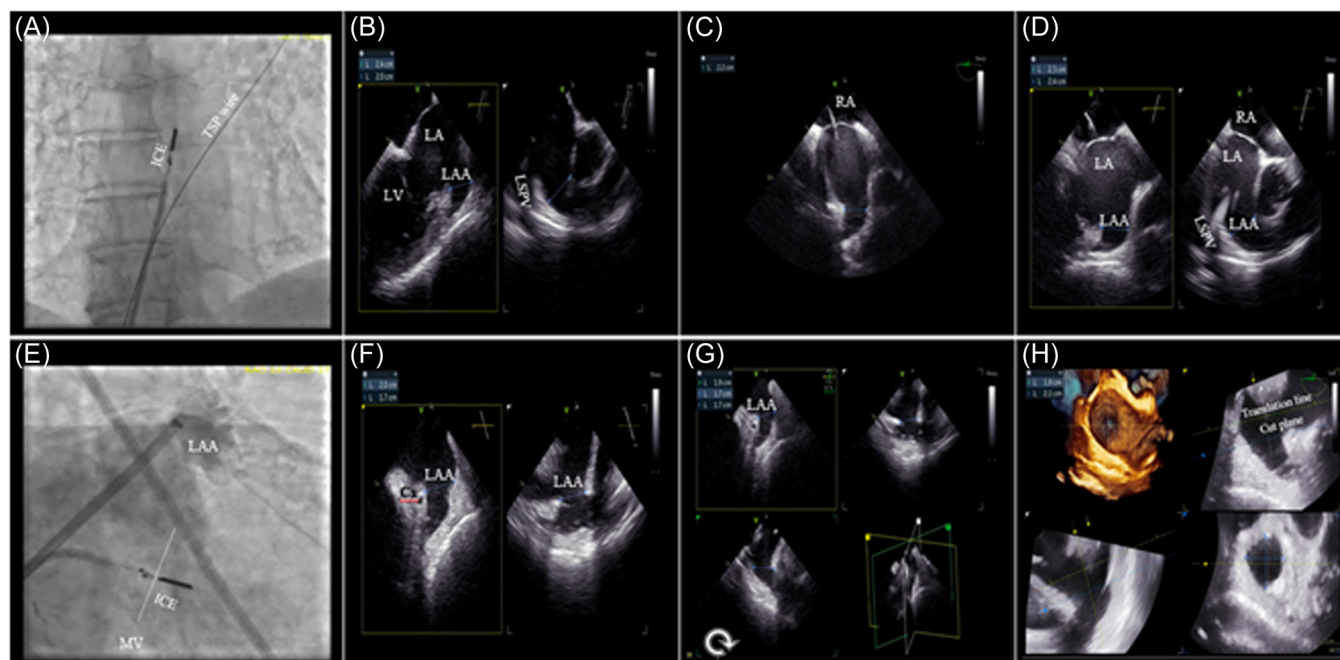


FIGURE 3 Four-dimensional ICE imaging-guided LAA measurement from both mid-RA and mid-LA using MPR planes, including the en-face view of the LAA ostium in the coronal plane. The green line (image H) or the translation line defines the image filtering on the volume-rendered image, while the blue line is the cut plane that defines the level of the coronal plane (in this case, the LAA ostium). Cx, circumflex artery; ICE, intracardiac echocardiography; LA, left atrium; LAA, left atrial appendage; LSPV, left superior pulmonary vein; LV, left ventricle; MPR, multiplanar reconstruction; MV, mitral valve; RA, right atrium; TSP, transseptal puncture. Images courtesy of © Biosense Webster, Inc. All rights reserved.

ICE catheter may lose LAA visualization at a critical moment. As an alternative, the ICE catheter is used to visualize a first TS access, which is dilated with the sheath-dilator assembly but then withdrawn. A second TS access is achieved immediately thereafter in the same manner. This second site will be the one used for the LAAO system, and ICE is then navigated across the first puncture localized by either 2D or by color.

2.4 | Optimizing TS position

In TEE-guided procedures, the choice of TS position is classically made with heavy reliance on the high-angle (135°) TEE view for anterior-posterior positioning within the fossa ovalis, with some influence from the 90° view for superior-inferior position.

Given the need to obtain this data from ICE placed within the LA itself, some modification of the workflow may be necessary. Visualization of the LAA via ICE from within the CS can indicate the relative position of a wing as posterior or anterior before TS. Alternatively, the tricuspid annular view with MPR or omniplane rotation can evaluate the LAA. Quality imaging of the LAA from the tricuspid annular view with either 3D or omniplane is generally limited. When learning these new views where electronic steering, MPRs, omniplane, or 3D volumes are available, it is best practice to place 4D markers on adjacent known structures to maintain orientation.

The initial puncture will, in the absence of a PFO, be completed before having the ICE catheter in the LAA. As such, other than the

possibility of estimating LAA shape and position from the CS, tricuspid annular, or PA view, the operator will be blind to the ideal location for a TS tailored to a specific LAA anatomy. Unique to ICE workflow, as opposed to TEE, the RA imaging location will allow sighting along the exact linear trajectory from TS to LAA os. Using this line of sight to choose the anteroposterior position while remaining low would be the suggested initial puncture site and, via that site, the ICE catheter is placed into the LA with a final decision made confirming this was the optimal TS position. If that TS is deemed inadequate, the ICE catheter can then be withdrawn into the RA and an alternative TS performed or an exchange made for a different curve sheath.

The process of placing the ICE catheter into a previously dilated TSP can be time consuming, requiring both fluoroscopy and color flow. In addition to standard 2D imaging, V-Plane is useful in clearly defining the trajectory of the TS needle. The V-Plane initially shows two identical 2D views (Figure 4). The angle separating the 2D views is controlled from the trackball. With the 4D ICE catheter aimed at the atrial septum, V-Plane can be used to sweep anteriorly or posteriorly to confirm that the TS needle is ideally aimed, minimizing physical manipulation of the catheter. The ability to adjust this 2D fan within the 90 × 90 field of view without moving the catheter is a major advantage of 4D ICE. Usually, the ICE catheter is maneuvered to place the TS (or any anatomic target) to the middle of the view while the ITR knob is centered. To cross the target TSP site after centering, anteflexion is gradually increased so that the catheter bends in plane and directly at the target. Once we begin to flex, we

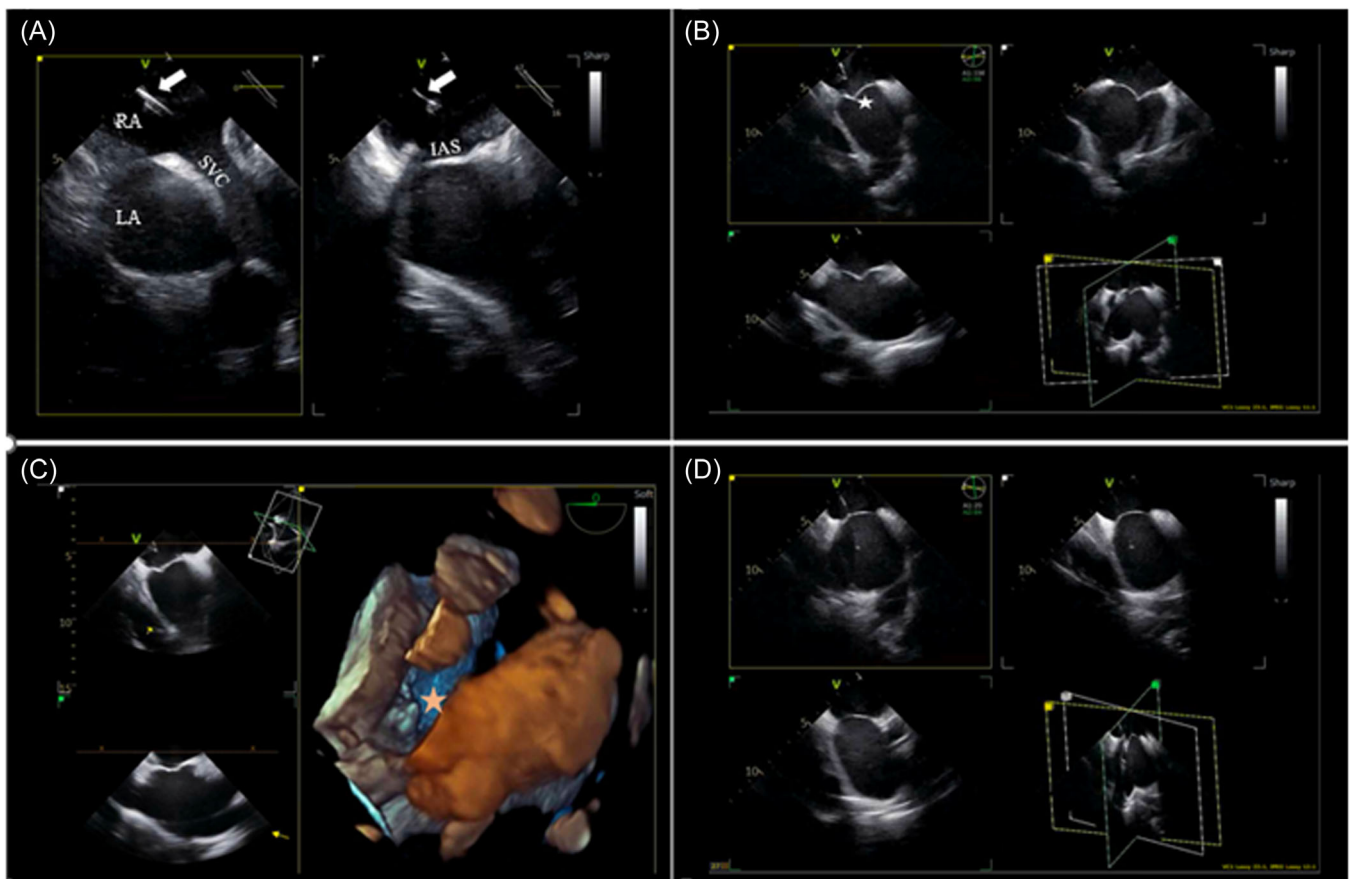


FIGURE 4 Real-time visualization, multiplanar imaging (with simultaneous display of three orthogonal planes) and volume-rendered imaging of TSP. (A) Biplanar imaging of TS needle and SL-0 sheath in the SVC. (B) Tenting of the IAS while pushing the TS needle (white star). (C) Volume-rendered imaging of tenting of the IAS from the LA (yellow star). (D) The SL-0 sheath across the IAS in the LA. IAS, interatrial septum; LA, left atrium; RA, right atrium; SVC, superior vena cava; TS, transseptal; TSP, transseptal puncture. Images courtesy of © Biosense Webster, Inc. All rights reserved.

lose sight of the target but, by maintaining the wire in the near-field view, we can maintain the catheter in the proper plane to reach the puncture.

Localizing a specific TS target within the fossa ovalis by ICE can be challenging in regard to maintaining perspective on relative anatomy to demarcate superior-inferior and anterior-posterior position. Simple triplane imaging can allow standard visualization comparable to TEE bicaval and aortic short axis. To minimize the need for the ICE operator to keep the sheath and tenting in view, the console operator can use V-Plane to digitally scan away from the centerline. The 3D function can also facilitate appropriate placement. Initially, 2D multiplane imaging can be used to place 3D markers on known anatomical landmarks, such as the aorta and superior vena cava (SVC). The 4D view is then displayed with the top-down function and z axis rotated so that the SVC marker is at the top of the screen and the aortic marker at screen right. Due to the thin tissue, the fossa often appears as “drop out” or black rather than as a reflective tissue membrane. When visualizing the fossa directly in the 4D volume, the TS apparatus may be difficult to see as compared to 2D, V-Plane, or triplane. The TS sheath pull down from the SVC can be undertaken in this view, and active participation from the ICE

console technician can slowly roll the perspective from looking up at the SVC to a more top-down perspective on the fossa (using the trackball control on the console).

2.5 | Acquiring images from the LA

Once both the ICE catheter and the access sheath are in the LA, imaging is started from the LSPV. An advantage of the LSPV is its proximity to the LAA and its predictable views. In addition, it contains the movement of the ICE catheter, making it simple to adjust the steer and rotation without moving out of plane or interfering with the LAAO device equipment. However, due to the thickness of the coumadin ridge or the distance from an anterior chicken wing, alternative locations may be necessary, such as peri-mitral. Triplane mode is often coaxial with the LAA long axis and can display three orthogonal 2D cuts of the LAA without a need for MPRs. One can activate the multidimensional tool to view multiple panels: a composite view of the three planes joined at a center axis, separated by 60°, and three 2D views for each 2D vantage point. Each 2D image has a colored border that corresponds to a plane on the

composite image. Two of the angles can be individually optimized using the “angle” knob.

Measurements of the appendage and compressed device can be made within each triplane window without the need to physically reposition the catheter. Additionally, angle optimization is useful to better visualize the LAA anatomy, improve measurements, and detect additional lobes/pouches.

Ideally, the target landing zone is centered in the view so that the ICE catheter does not need to be manipulated as different angles are selected. Depending on the position within the LSPV and the relative position of the LAA, the initial angle of zero on the ICE console can be equivalent to around 30° to nearly 90°. As such, any increase in the digital angle will be added to this baseline angle to approximate the TEE equivalent. It is thus better to use the surrounding anatomy and other context clues to determine where the anterior and posterior lobes are, as well as the takeoff of the appendage relative to the LV.

For initial device placement, the goal is approximation of the angle, focusing more on “opening up” the LAA for that view. In other words, when the PA is well elongated and seen to abut the LAA lobe (or wing before a posterior turn) this should be assumed to represent a high angle. The distinctive features of the high-angle view make it an ideal reference angle from which to back-calculate the other angles (Figure 5, Supporting Information S1: Video S1). As long as the PA remains more or less in the view and abuts the LAA, small adjustments can then be made to optimize the maximum LAA width and still consider this high angle. If a sheath is in the LAA, it can also be used to prove that it is a high-angle equivalent,

such that counterclockwise sheath rotation will move the sheath toward the anterior lobe/PA, whereas clockwise rotation will move the sheath tip away from the PA, all while remaining in plane. One can then calculate backwards from this angle by 45° to obtain the 90° equivalent while verifying anatomical details such as visualization of the mitral valve and lateral mitral annulus. Similarly, visualization of the aortic valve will represent the 0° view when adding approximately 45° to the previously confirmed high-angle view. It may be necessary to briefly alter the depth, given the lateral placement of the imaging device within the PV.

2.5.1 | FlexiSlice

FlexiSlice is an MPR tool that creates images derived from a 4D volume set. This mode is useful for assessing the placement of the closure device. FlexiSlice also creates a coronal cut of the LAA's ostium, where multiple measurements can be taken at once. This view may most closely correlate to preprocedural computed tomography imaging. FlexiSlice has several different layouts, but the most useful for LAA closure shows the 4D volume image, two 2D images separated by 90°, and the derived en-face view. Each 2D window is identified by a differently colored border. FlexiSlice is activated by selecting a “4D Zoom Prepare” on the touch panel. The region of interest is defined and then “top down” is selected. The volume image shown by either method should be fine-tuned by adjusting the volume size in each plane to focus on relevant anatomy.

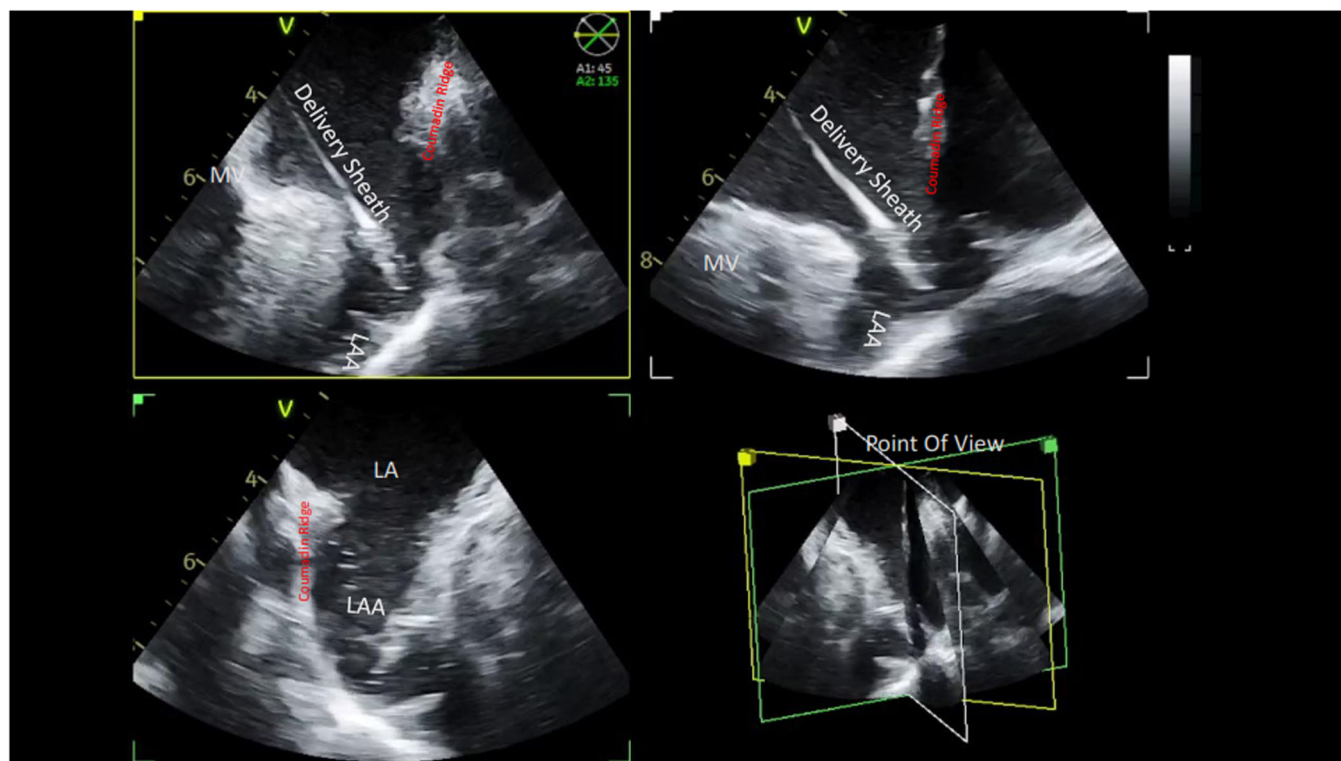


FIGURE 5 Four-dimensional ICE catheter high-angle view to determine LAAO device placement positioned from the LA posterior to the counadin ridge. ICE, intracardiac echocardiography; LA, left atrium; LAA, left atrial appendage; LAAO, left atrial appendage occlusion; MV, mitral valve. Images courtesy of © Biosense Webster, Inc. All rights reserved.

A smaller volume size and proper translation adjustment yield higher temporal and spatial resolution in the final image and crop irrelevant details and artifacts.

The various functions for FlexiSlice are accessed by placing the cursor with the trackball in different portions of the image pane. A unique icon is displayed for each function as the cursor hovers over different portions of the image. The functions are engaged by pressing and holding one of the oval buttons alongside the trackball. The controls affect the angle and position of each axis, define the boundaries of the region of interest, set the level of the coronal cut, and control the rotation of the 2D image.

The general strategy for optimizing the FlexiSlice environment is to move the two long axis planes such that one line is oriented along the vertical axis of the device and the other across the shoulders. This phase should be done with the planes “unlocked” so they can move independently of one another. The topmost red and green dashed line is then adjusted towards the appendage, affecting the “translation” of the image, and cropping unneeded detail from the near field. The blue line controls the distal portion of the window and is placed in the plane of the closure device’s diameter. This strategy is repeated in the other 2D image pane. As a result, the four panes will display a 4D volume, two perpendicular long-axis views of the closure device, and an en-face coronal cut of the device. Finally, the planes are adjusted to be 90° to one another in the en-face view and then locked.

Thereafter, by rotating the planes in the en-face view, one maintains two orthogonal views with the ability to see the full device

circumference. Measurements in multiple angles of the LAA ostium can be made from the cross-sectional view with the measurement tool; however, depending on distortion or compression of the device, the cross-sectional view may not represent the “shoulder level” for the entire circumference.

2.5.2 | Image optimization

Several parameters will affect the clarity and usefulness of the ultrasound image:

- Adjusting the standard 2D gain and compression controls will optimize brightness and contrast.
- The frame rate controls the image sample rate in frames per second. There is a tradeoff between temporal and spatial resolution. At low frame rates, image resolution is higher, but the image takes on a “jumpy” quality. Frame rate is also optimized by narrowing both the 2D and 4D imaging sectors.
- Frequency adjustments can improve image detail or penetration. The higher-value frequencies highlight tissue detail. Lower frequencies will penetrate deeper into tissue at the expense of a slightly lower image resolution. Placing the 4D ICE catheter in the LA removes near-field obstacles that are encountered from imaging in the RA, and it is likely that high frequency imaging will be useful.

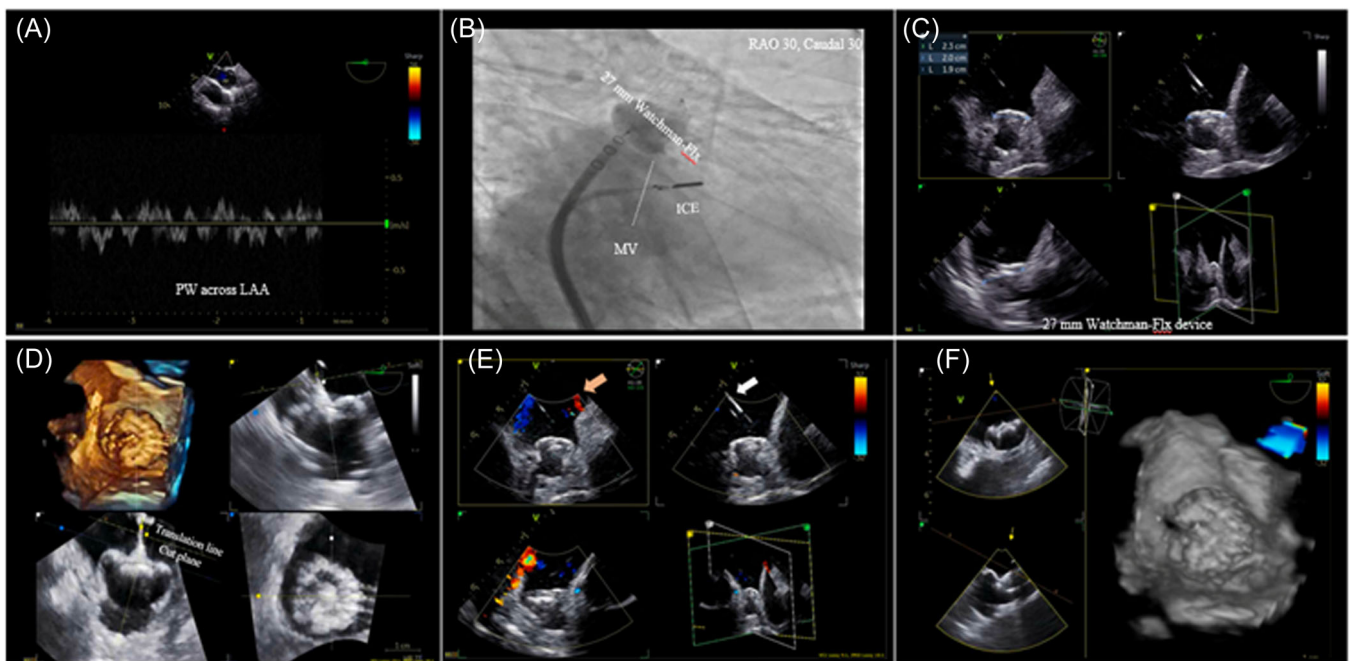


FIGURE 6 Four-dimensional ICE imaging-guided LAAO from the mid-LA using MPR planes, including LAAO device compression diameter, the en-face view of the LAAO device, and peridevice leak. The green line (image D) or the translation line (or crop line) defines the image filtering on the volume-rendered image, while the blue line is the cut plane and defines the level of the coronal plane (in this case, the 27-mm LAAO device). ICE, intracardiac echocardiography; LA, left atrium; LAA, left atrial appendage; LAAO, left atrial appendage occlusion; MPR, multiplanar reconstruction; MV, mitral valve; PW, pulsed wave; RAO, right anterior oblique. Images courtesy of © Biosense Webster, Inc. All rights reserved.

3 | DEVICE RELEASE AND POST-IMPLANT IMAGING

The mid-LA, left superior pulmonary, and peri-mitral views are useful to evaluate the LAAO device stability. Before the release, a final check for device position should be performed in all three

views (Figure 6, performed with ease with multiplanar imaging compared with 2D ICE catheter maneuvering to obtain multiple views) to verify position relative to the circumflex, device compression, and peridevice leak, if any (Figure 6).

Volume imaging helps determine the placement of the LAAO device and whether adjustments are necessary (Figure 7, Supporting

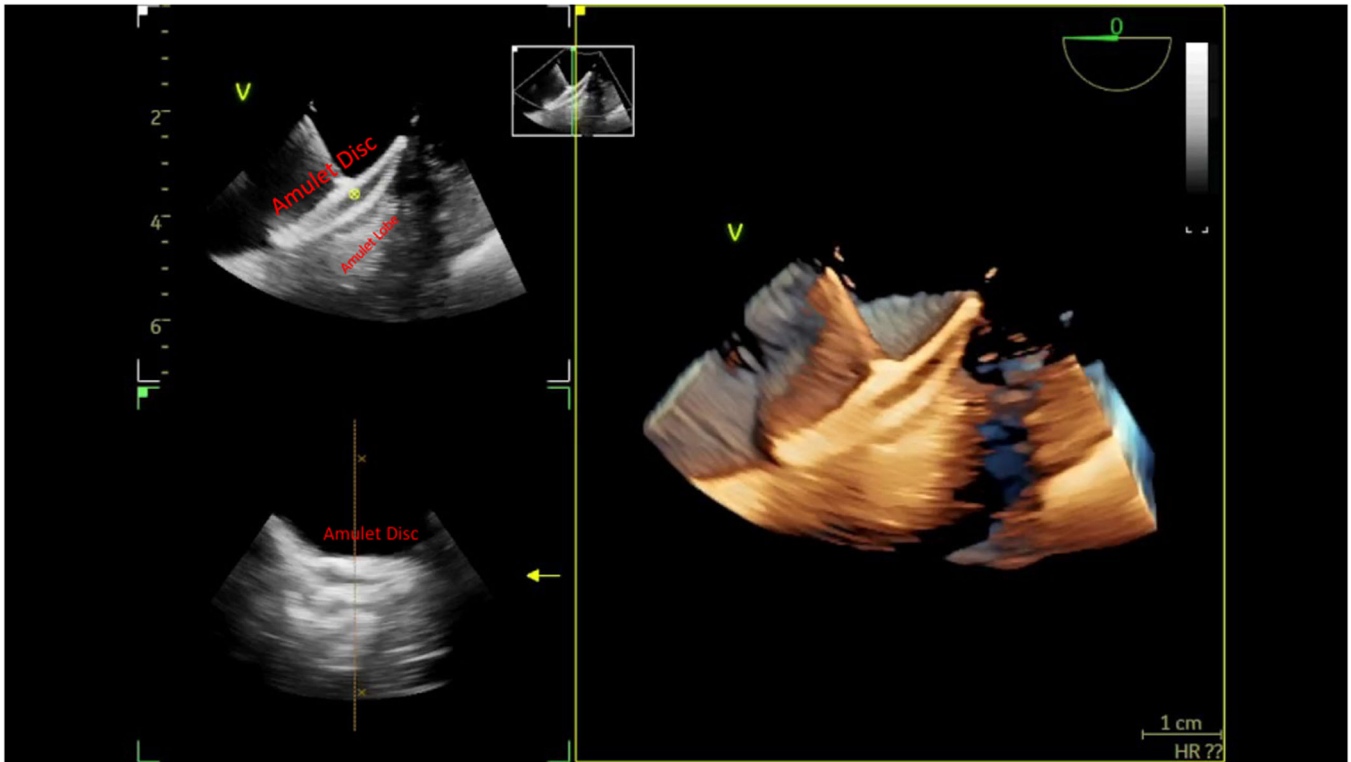


FIGURE 7 Volume imaging feature to determine interaction between LAAO implant and surrounding anatomical structures. HR, heart rate; LAAO, left atrial appendage occlusion. Images courtesy of © Biosense Webster, Inc. All rights reserved.

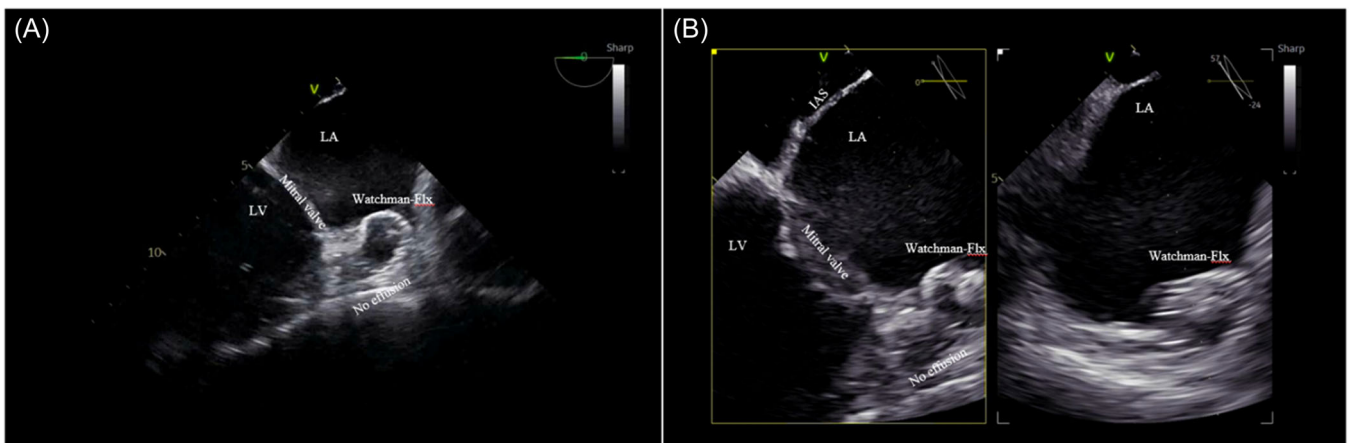


FIGURE 8 Four-dimensional ICE imaging after device release demonstrating well-seated 27-mm LAAO device and no pericardial effusion in biplanar imaging planes. IAS, interatrial septum; ICE, intracardiac echocardiography; LA, left atrium; LAAO, left atrial appendage occlusion; LV, left ventricle. Images courtesy of © Biosense Webster, Inc. All rights reserved.

Information S2: Video S2). This type of imaging allows the physician to understand how the LAAO device is interacting with the LAA ostium, ridge, and surrounding anatomical structures.

In addition to imaging the LAA from the LSPV, it would be preferable to perform a peri-mitral view of the LAA, which is easily achieved by deflecting and advancing the ICE catheter across the mitral valve with the ultrasound beam pointing towards the LAA. This additional view improves visualization of the LAAO device and may help reduce the risk of otherwise undetectable peridevice leaks that would otherwise be lost in the shadow of the device.¹⁴

4 | SAFETY AND DETECTION OF COMPLICATIONS

The 4D ICE catheter has a greater length of tip stiffness compared with prior-generation 2D ICE catheters, but the risk it poses is balanced by less need for catheter manipulation to achieve optimal LAA imaging—also thereby shallowing the learning curve for ICE-guided LAAO.

Pericardial effusion is the most common complication associated with LAAO. Evaluating for pericardial effusion before TS and regularly during the procedure is essential for early assessment and

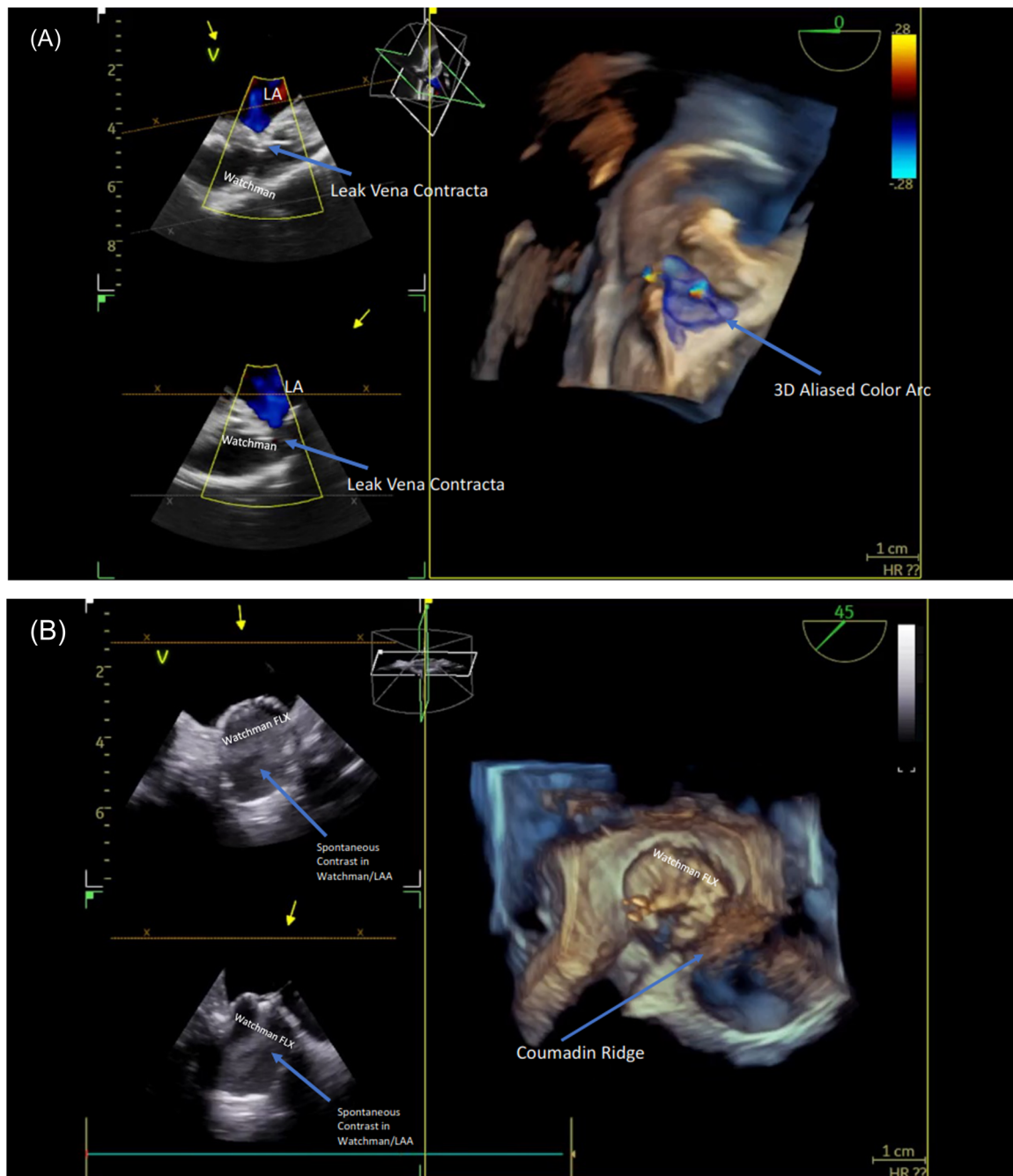


FIGURE 9 (A) Biplane and triplane images using ICE and TEE for LAAO. (B) FlexiSlice showing rotation of the 2D planes to optimize image. HR, heart rate; ICE, intracardiac echocardiography; LA, left atrium; LAA, left atrial appendage; LAAO, left atrial appendage occlusion; TEE, transesophageal echocardiography. Images courtesy of © Biosense Webster, Inc. All rights reserved.

management. From the home view in the RA, the ICE catheter is flexed across the TV and then released to rest along the superior aspect of the annulus; tip rotation will allow visualization along the RV and LV free walls. Adjustment of electronic rotation or triplane will allow for both short- and long-axis ventricular assessment (Figure 8). During the device implantation phase with ICE in the LA, the pericardial effusion assessment takes place from the peri-mitral view.

5 | ICE VERSUS TEE IN LAAO

We assessed the performance of NUVISION with simultaneous availability of TEE for comparison in one LAAO case. Both modalities were used to measure LAA and predeployment LAAO dimensions. Overall, the ICE LAA measurements were similar to those from TEE. The best image resolution was seen via ICE in 2D and multislice modes (triplane and biplane) (Figure 9A, Supporting Information S3: Video S3). The FlexiSlice MPR tool provided useful information but with some compromise of spatial resolution. This was expected since volume-derived images are typically not as detailed as 2D images. This case demonstrated that comparable images can be obtained using ICE and TEE alike; however, there is less need to reposition the ICE catheter in comparison to TEE. The most useful images, even with the degraded spatial resolution, were derived from FlexiSlice, showing rotation of the 2D planes. Also highly useful were peri-mitral (taking advantage of ITR rather than needing to rotate the catheter itself) followed by optimization with V-Plane and electronically rotating the beam angle (Figure 9B, Supporting Information S4: Video S4). As noted above, a key challenge, which lacks some predictability, is crossing the atrial septum.

6 | CONCLUSION

Four-dimensional ICE imaging provides multiplanar and real-time 3D imaging similar to conventional TEE imaging for LAAO with a high spatiotemporal resolution, thereby minimizing the need for general anesthesia and improving patient safety, comfort, and room turnaround. Optimized 4D ICE catheter workflow recommendations can lead to efficient LAAO procedures with imaging comparable to TEE.

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DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no data sets were generated or analyzed during the current study.

ETHICS STATEMENT

For first-in-human studies of the 4D ICE catheter, protocols and other study materials were approved by independent ethics committees or institutional review boards. Informed patient consent was obtained from all participating patients.^{18,19}

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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