Left Atrial Appendage Occlusion/Exclusion: Procedural Image Guidance with Transesophageal Echocardiography



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Atrial fibrillation is the most common arrhythmia worldwide and is a major risk factor for embolic stroke. In this article, the authors describe the crucial role of two- and three-dimensional transesophageal echocardiography in the pre- and postprocedural assessment and intraprocedural guidance of percutaneous left atrial appendage (LAA) occlusion procedures. Although recent advances have been made in the field of systemic anticoagulation with the novel oral anticoagulants, these medications come with a significant risk for bleeding and are contraindicated in many patients. Because thromboembolism in atrial fibrillation typically arises from thrombi originating in the LAA, surgical and percutaneous LAA exclusion/occlusion techniques have been devised as alternatives to systemic anticoagulation. Currently, surgical LAA exclusion is typically performed as an adjunct to other cardiac surgical procedures, which limits the number of eligible patients. Recently, several percutaneously delivered devices for LAA exclusion from the systemic circulation have been developed, some of which have been shown in clinical trials to reduce the risk for thromboembolism. These devices use an either purely endocardial LAA occlusion approach, such as the Watchman and Amulet procedures, or both an endocardial and a pericardial (epicardial) approach, such as the Lariat procedure. In the Watchman and Amulet procedures, a transseptally delivered structure composed of nitinol is placed in the LAA orifice, thereby excluding the LAA from the systemic circulation. In the Lariat procedure, a magnet link is created between a transseptally delivered endocardial wire and epicardially delivered pericardial wire, followed by epicardial suture ligation of the LAA. (J Am Soc Echocardiogr 2018;31:454-74.)

Keywords: Transesophageal echocardiography, 3D, Left atrial appendage occlusion, Lariat device, Watchman device, Amulet device

Atrial fibrillation (AF) is the most common cardiac arrhythmia, affecting >3 million people in the United States alone. The prevalence of AF increases with age. The incidence of AF in the United States is projected to increase to 7.56 million by 2050 because of the aging population.

Because of its significant morbidity and mortality, AF is associated with substantial personal, societal, and economic costs. AF is estimated to cost the United States approximately \$6 billion each year.²

Systemic thromboembolism is the major complication of both valvular and nonvalvular AF. The left atrial appendage (LAA) is the most common site of thrombus formation, accounting for 91% of

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Copyright 2017 by the American Society of Echocardiography. https://doi.org/10.1016/j.echo.2017.09.014 left heart thrombi in patients with nonrheumatic AF and 57% of thrombi in patients with rheumatic AF.³

Anticoagulation with orally, intravenously, or subcutaneously administered compounds is the most common method of preventing thromboembolism in patients with AF. Antiplatelet agents such as aspirin or clopidogrel can be used as an alternative to systemic anticoagulation but have been shown to have inferior efficacy compared with anticoagulation.

Satisfactory anticoagulation with oral warfarin with a target international normalized ratio of ≥ 2 to 3 has been demonstrated to reduce the risk for stroke and systemic embolism by 67% compared with placebo⁴ and by 45% compared with aspirin.⁵ Newer anticoagulants (such as dabigatran, apixaban, and rivaroxaban) have been shown to be at least noninferior to warfarin in non-valvular AF.⁶⁻⁸

Unfortunately, all anticoagulants have significant bleeding risk and may be contraindicated in certain patients. The risk for major bleeding (typically defined as a reduction in hemoglobin level of ≥ 2 mg/dL, transfusion of 2 U of packed red cells, or symptomatic bleeding occurring at a critical site or resulting in death) with either warfarin or newer agents is estimated at 1.4% to >3% per year.

Because most thrombi related to nonvalvular AF typically reside in the LAA, surgical or percutaneous techniques of LAA exclusion have been developed as alternatives to systemic anticoagulant and antiplatelet therapy. These exclusion procedures act locally at the level of the LAA to prevent thrombi from entering the systemic circulation.

Abbreviations

2D = Two-dimensional

3D = Three-dimensional

AF = Atrial fibrillation

ASD = Atrial septal defect

LAA = Left atrial appendage

PDL = Para-device leak

PEF = Pericardial effusion

TEE = Transesophageal echocardiography

Surgical techniques used for LAA exclusion have included ligation, clipping, stapling, and amputation. ¹⁰⁻¹² A major limitation of these procedures is that they are typically performed as adjuncts to other cardiac procedures, and therefore only a small number of patients with AF are eligible for them.

Percutaneous LAA occlusion/ exclusion devices (Figure 1) include the PLAATO (eV3, Plymouth, MN; no longer on the market), Watchman (Boston

Scientific, Maple Grove, MN), Amplatzer LAA occluders (Amplatzer Cardiac Plug and Amulet; St. Jude Medical, Minneapolis, MN), ¹³⁻¹⁵ and Lariat (Sentre-HEART, Palo Alto, CA). ¹⁶⁻¹⁸

In the United States, currently the only device specifically approved by the US Food and Drug Administration for LAA occlusion is the Watchman device, which was cleared for general clinical use in March 2015.

The Lariat device has received class II clearance from the Food and Drug Administration via the 510(k) protocol. This device is not specifically approved for percutaneous LAA exclusion but rather for "facilitating suture placement and knot tying in surgical applications in which soft tissue is being approximated and/or ligated with a pretied polyester suture." Nevertheless, the Lariat has entered into clinical practice. There is increasing use of both devices in the United States.

The Amplatzer Cardiac Plug US pivotal trial began enrollment in 2013, but it was discontinued because of slower enrollment. The second-generation Amplatzer LAA occluder, referred to as the Amulet device, is currently being investigated in the United States in the Amulet trial.

The Watchman, Amplatzer Cardiac Plug, and Amulet device are delivered using peripheral venous access and transseptal puncture (a fully endovascular approach). In contrast, the Lariat procedure uses both an endocardial and a pericardial (epicardial) approach to create a magnet link between endocardial and pericardial wires, followed by epicardial suture ligation of the LAA. Another device that can ligate the LAA using an endocardial and a pericardial approach is the LASSO device (Aegis Medical Innovations, Vancouver, BC, Canada). This system uses electrical mapping rather than a magnetic link to locate and ligate the LAA and is currently being tested in the open-label LASSO AF trial.

All percutaneous LAA occlusion/exclusion procedures would not be possible without two-dimensional (2D) and three-dimensional 3D transesophageal echocardiography (TEE). In this review, we discuss the role of 2D and 3D TEE for periprocedural guidance of the percutaneous LAA occlusion/exclusion devices either currently commercially available or under clinical investigation in the United States, namely, the Watchman, Amulet, and Lariat.

LAA ANATOMY

Detailed knowledge of LAA anatomy is essential for successful percutaneous LAA closure procedures. The LAA is a complex "fingerlike" projection from the anterolateral portion of the left

atrium. Internally, it begins with an orifice that is typically ovoid and thus has a major and a minor orifice diameter. This orifice opens to its neck region, then its body, and ultimately ends in its apex (Figure 2).

The anatomic definition of LAA "orifice" is typically different from the "orifice" defined as the landing zone for various LAA occluder devices. This is addressed in detail with each individual occluder device description below.

The LAA orifice is separated from the left-sided pulmonary veins by the ligament of Marshall (also referred to as the left lateral or "Coumadin" ridge). The LAA may contain one or more lobes, defined as protrusions from its main body. ¹⁹

Anatomic variants of the LAA are well described²⁰ and include the windsock, the broccoli (or cauliflower), the cactus, and the chicken wing (Figure 3). Of the known LAA variants, the chicken-wing morphology is the most common. However, it is also known to cause the greatest procedural difficulty with regard to LAA occlusion/exclusion. This is due to its broad width and shallow depth, which create a difficult situation regardless of the type of device used.

LAA anatomy is typically established during the screening process using gated cardiac computed tomographic angiography. It may also be confirmed using both intraprocedural TEE and fluoroscopy.

Correspondence of Fluoroscopic and Transesophageal Echocardiographic Views of the LAA

It is important that a common language be developed between interventionalists, who are typically most familiar with fluoroscopy, and echocardiographers performing intraprocedural TEE.

The right anterior oblique caudal view is equivalent to approximately 135° on TEE and typically reveals the major axis of the LAA orifice (Figure 4).

The right anterior oblique cranial view is equivalent to approximately 45° on TEE and typically reveals the minor axis of the LAA orifice (Figure 5).

OVERVIEW OF PERCUTANEOUS LAA OCCLUSION/ EXCLUSION PROCEDURES

Irrespective of the LAA occlusion/exclusion device used, the basic steps are common to all percutaneous LAA occlusion/exclusion procedure. All percutaneous LAA occluder implantation procedures begin with peripheral venous access, which is typically obtained through the right femoral vein. Subsequently, a transseptal puncture is performed to gain access to the left atrium. Thereafter, specific steps for deployments of individual occluder devices are taken.

TRANSSEPTAL PUNCTURE FOR PERCUTANEOUS LAA OCCLUDERS

Overview

After peripheral venous access is obtained, typically through the femoral vein, a transseptal needle delivery catheter and dilator are passed through the inferior vena cava into the right atrium and temporarily placed in the superior vena cava. Thereafter, a transseptal needle is advanced through the delivery catheter.

HIGHLIGHTS

- The LAA is the most common site of thrombus formation in nonvalvular atrial fibrillation.
- In nonvalvular atrial fibrillation, percutaneous LAA occlusion/exclusion is an alternative method of thromboembolism prevention for patients who are either ineligible for or too high risk to receive systemic anticoagulation therapy.
- 2D/3D transesophageal echocardiography has a critical role in all percutaneous LAA occlusion/exclusion procedures, including screening for eligibility, device sizing, intraprocedural guidance, and postprocedural follow up.
- The most commonly used percutaneous LAA occlusion/ exclusion devices worldwide include the Watchman, Amulet, and Lariat.

Using transesophageal echocardiographic guidance, the whole system is then withdrawn from the superior vena cava into the right atrium and positioned against the inferior and posterior portion of the interatrial septum. The deliver catheter is then advanced against the interatrial septum to tent the interatrial septum at an appropriate location. Fluoroscopy and TEE are essential in guiding the proper location of tenting. The needle is then advanced, creating a transseptal puncture.

The inferoposterior puncture position allows the most direct route to the anterolaterally located LAA. This is in contrast to other transseptal procedures such as MitraClip (Abbott Vascular, Abbott Park, IL) implantation and transcatheter mitral valve replacement, which require a superior and posterior transseptal puncture to ensure adequate height above the mitral valve.

Two commonly used transseptal delivery catheters are the Mullins introducer (Medtronic, Minneapolis, MN), and the Agilis steerable introducer (St. Jude Medical). The most commonly used transseptal needle is the Brockenbrough needle (Medtronic), but a radiofrequency needle (Baylis Medical, Montreal, QC, Canada) can be helpful to cross thick, fibrotic, or patched septa. Transseptal catheters and needles are depicted in Figure 6.

Once the transseptal puncture of the procedure has been completed, the dilator and sheath are then advanced to avoid left atrial wall injury. A wire is subsequently passed into the left atrium and typically positioned in the left superior pulmonary vein; the dilator and sheath are then removed.

Echocardiographic Guidance of Transseptal Puncture

Although transseptal puncture can be performed with adequate safety using a combination of operator tactile feedback and fluoroscopy, echocardiography (2D TEE, intracardiac echocardiography, and 3D transesophageal biplane imaging) can improve transseptal puncture safety and overall procedural success.²²

Using 2D and 3D TEE, assessment of the interatrial septum first includes identification of the position, thickness, and mobility of the fossa ovalis. Subsequently, color Doppler imaging is used to assess for baseline patent foramen ovale or atrial septal defect (ASD).

Using biplane imaging of the interatrial septum (anterior-posterior in one plane, superior-inferior in the other) the transseptal needle is guided toward the inferior and posterior portion of the fossa ovalis. After slight needle assembly advancement toward the left atrium,

the tenting of the interatrial septum identifies the location of the transseptal needle on echocardiography (Figure 7, Video 1 available at http://www.onlinejase.com). It is of utmost importance to do the transseptal puncture in the inferior and posterior aspect of the interatrial septum (Figure 8).

When the echocardiographer provides real-time TEE to an interventionalist, it is useful to label superior, inferior, anterior, and posterior locations on the echocardiographic image.

After transseptal puncture has been performed, 3D TEE using 3D zoom of the interatrial septum may be helpful to confirm that the transseptal puncture has occurred in a favorable location. A step-by-step approach for the production of high-quality views of the interatrial septum by 3D TEE has been previously described using the TUPLE (tilt up, then left) maneuver. ²³

Atrial septal aneurysm and marked lipomatous hypertrophy of the interatrial septum may present anatomic challenges to successful transseptal puncture. The presence of a large atrial septal aneurysm should be communicated to the interventionalist, as excessive advancement of the transseptal needle may lead to perforation of the left atrial free wall. In the presence of lipomatous hypertrophy, it is important to guide the transseptal puncture through the thin central portion of the fossa ovalis rather than the hypertrophied limbs.²⁴

WATCHMAN PROCEDURE

Overview

The Watchman is a transseptally delivered, self-expanding nickel titanium device with fixation barbs, covered by a permeable polyester fabric. The device is delivered under fluoroscopic and echocardiographic guidance and is available in five sizes (21, 24, 27, 30, and 33 mm) on the basis of the device diameter on its left atrial side (Figure 9)

The Watchman procedure begins with venous access and transseptal puncture, as described previously. Subsequently, the Watchman 12-Fr delivery system with a pigtail catheter is advanced into the left atrium over the wire and then placed into the LAA. Next, iodinated contrast is injected into the LAA to define its anatomy on fluoroscopy. The Watchman device is then positioned and delivered in the LAA ostium. Finally, the device is released after stability and optimal position are confirmed by both echocardiography and cine fluoroscopy with intravenous contrast. An animated description of the Watchman procedure can be viewed on YouTube: https://www.youtube.com/watch?v=8O2Hba-JQoQ&feature=youtu.be&list=PL63i2jgsqsT_Jzpx5tTAI_rM56xo6JDUj.

Of all percutaneous LAA occluder devices, the Watchman has the most outcomes data, which have demonstrated its noninferiority to chronic warfarin therapy in a randomized trial.¹⁵ Possible procedural complications include pericardial effusion (PEF), device embolization, and procedure-related stroke.²⁵ After device implantation, patients typically require warfarin therapy for 45 days, followed by dual-antiplatelet therapy (with aspirin and clopidogrel) for 6 months and then aspirin alone for life to prevent clot formation.¹⁵

Baseline Comprehensive Assessment

All percutaneous LAA occlusion/exclusion devices require comprehensive baseline intraprocedural 2D and 3D TEE. This echocardiographic assessment focuses on establishing the presence or absence of any preexisting intracardiac thrombus (which would lead to procedure cancellation), baseline degree of PEF, as well as anatomic

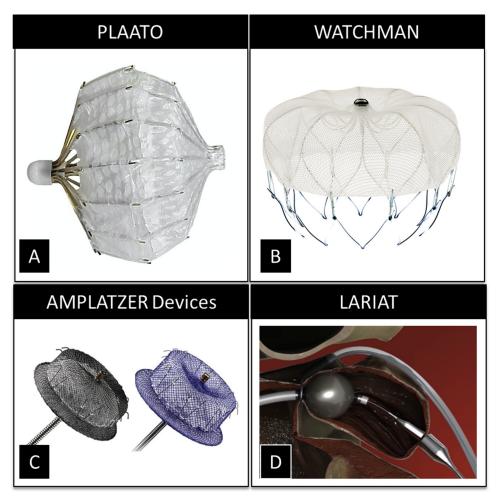


Figure 1 Percutaneous LAA occlusion/exclusion devices. Images of percutaneously delivered LAA occluder devices. (A) The PLAATO LAA occluder is no longer on the market. (B) The Watchman device is currently approved by the Food and Drug Administration and is in use in the United States. (C) The Amplatzer cardiac plug (left) is not available in the United States. The Amplatzer Amulet device (right) is currently undergoing clinical investigation in the United States. (D) The Lariat device is currently in use in the United States by way of a 510(k) approval.

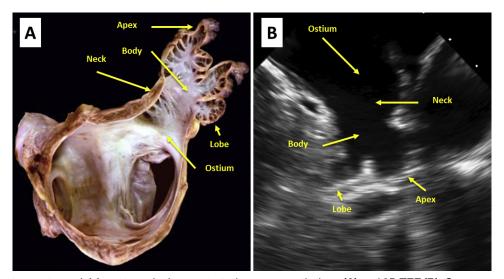


Figure 2 LAA diameter anatomy. LAA anatomy is demonstrated on gross pathology (A) and 2D TEE (B). Corresponding structures are labeled on pathology and 2D TEE (yellow arrows).

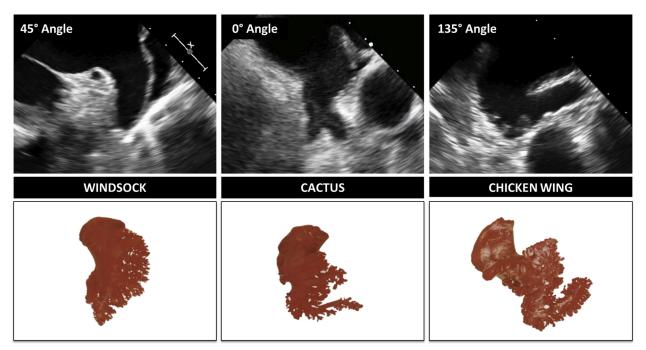


Figure 3 LAA shapes. Three main LAA morphologies are demonstrated on 2D TEE and pathologic specimen casts. The cast images are modified with permission from Ernst G, Stöllberger C, Abzieher F, Veit-Dirscherl W, Bonner E, Bibus B, Schneider B, Slany J. Morphology of the left atrial appendage. Anat Rec 1995;242:553–561.

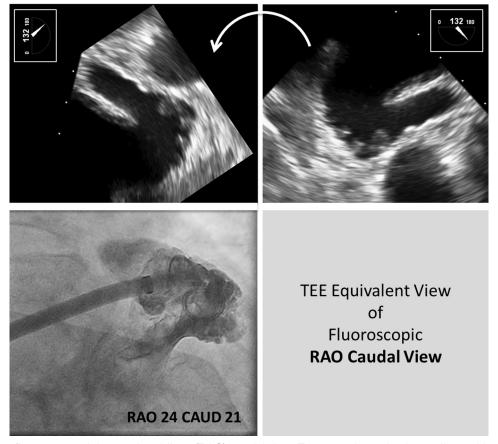


Figure 4 TEE versus fluoroscopy, right anterior oblique (RAO) caudal view. Transesophageal echocardiographic equivalent views of the RAO caudal (CAUD) fluoroscopic view are demonstrated. The RAO caudal view can be simulated on 2D TEE by obtaining a long-axis view of the LAA (typically about 135°) and then rotating the image counterclockwise.

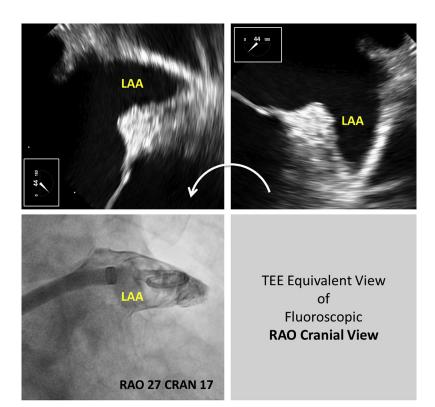


Figure 5 TEE versus fluoroscopy, right anterior oblique (RAO) cranial view. Transesophageal echocardiographic equivalent views of the RAO cranial fluoroscopic view are demonstrated. The RAO cranial view can be simulated on 2D TEE by obtaining a short-axis view of the LAA (typically about 45°) and then rotating the image counterclockwise.

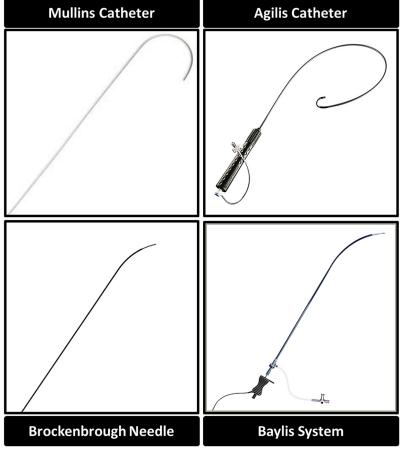


Figure 6 Transseptal devices. Commonly used devices for transseptal puncture worldwide.

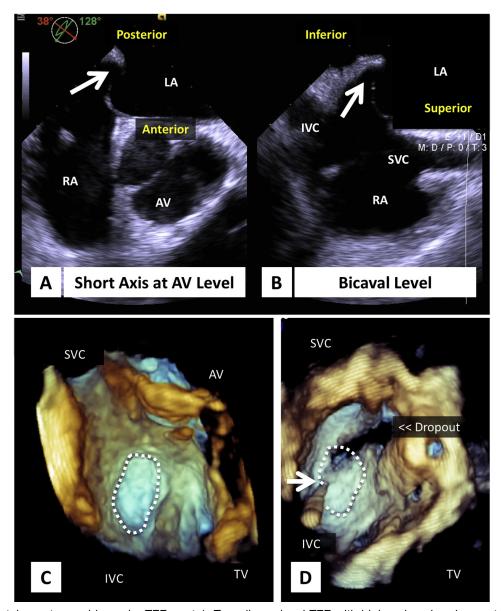


Figure 7 Transseptal puncture guidance by TEE: part 1. Two-dimensional TEE with biplane imaging demonstrates the interatrial septum in the midesophageal short-axis and bicaval views during the transseptal puncture portion of an LAA occlusion/exclusion procedure (A,B). Note the tenting in the inferior and posterior portion of the fossa ovalis, which is the ideal location for puncture. Video 1 corresponds to (A) and (B). Three-dimensional TEE of the interatrial septum from the right atrial perspective at baseline before transseptal puncture (C) and following transseptal puncture (D). This view demonstrates the anatomic location of the fossa ovalis (white dotted circles) at baseline (C) and catheter-related dropout (D). The white arrows point to the transseptal catheter. AV, Aortic valve; IVC, inferior vena cava; LA, left atrium; RA, right atrium; SVC, superior vena cava; TV, tricuspid valve.

characteristics of the LAA and interatrial septum. The size and position of the LAA body and LAA orifice, the presence or absence of valvular abnormalities, mobile aortic atheroma (>4 mm), and intracardiac shunt are also established.

LAA Sizing Specific to the Watchman

LAA landing zone size and LAA depth are measured during the baseline procedural assessment for the Watchman procedure. On 2D TEE, the LAA is imaged at 0° , 45° , 90° , and 135° (Figure 10). Measurements of the LAA are performed at these imaging angles to determine the maximal diameter of the anticipated landing zone and appendage depth. For the Watchman, the LAA landing zone is measured from

the top of the mitral valve annulus or circumflex coronary artery to a point 2 cm below the tip of the left upper pulmonary vein limbus. Depth is measured from the plane of the LAA orifice to the LAA apex.

Because of the tomographic nature of 2D imaging, there is a degree of uncertainty that the 2D transesophageal echocardiographic landing zone diameter measurements are done in the same plane. This limitation can be overcome using multiplanar reconstruction 3D TEE. In multiplanar reconstruction mode, two long axes of the LAA are aligned to visualize the short-axis plane of the LAA, allowing precise measurement of the landing zone diameter (Figure 11).

Once echocardiographic measurements have been performed, the largest LAA landing zone diameter is selected for device sizing. The

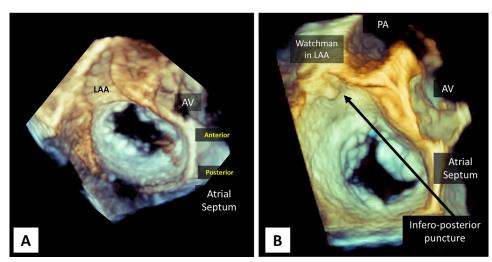


Figure 8 Transseptal puncture guidance by TEE: part 2. (A) Three-dimensional TEE demonstrating the LAA in its anatomic orientation and relationship to the interatrial septum. (B) The ideal path to the LAA is demonstrated, which is facilitated by transseptal puncture in the inferior and posterior portion of the interatrial septum. AV, Aortic valve; PA, pulmonary artery.

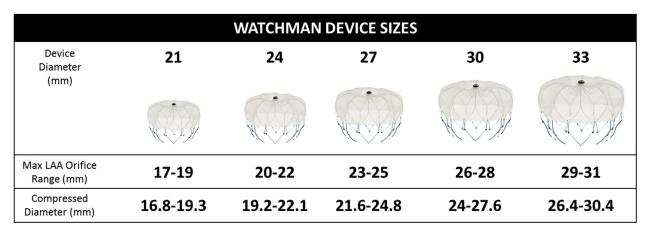


Figure 9 Watchman device sizes. Chart demonstrating available Watchman device sizes (21- to 33-mm diameter), maximal LAA orifice range for each Watchman device size, and compressed Watchman diameters after implantation.

device is typically oversized compared with the largest measured LAA diameter by 8% to 20%.

LAA Anatomic Exclusion Criteria for the Watchman Device

- LAA orifice diameter that is either too small (<16.8 mm) or too large (>30.4 mm).
- LAA depth that is too shallow (LAA depth less than largest LAA orifice diameter).
- The depth of a secondary LAA lobe (if present) cannot be too close to the LAA orifice (must be >1 cm away), which could lead to an uncovered portion of the LAA.

Other Possible Exclusion Criteria for the Watchman Device

- Atrial septal aneurysm excursion distance >15 mm. Atrial septal aneurysm may be considered an indication for anticoagulation even if LAA is excluded.
- Large interatrial shunt. This is a semiquantitative criterion; no specific definition for a large shunt on color Doppler or after agitated saline injection is given.

- Mobile aortic plaque >4 mm in thickness.
- Significant mitral stenosis (mitral valve area < 1.5 cm²).
- PEF with thickness > 2 mm.

Echocardiographic Guidance for the Watchman Procedure

After transseptal puncture has been guided by fluoroscopy and echocardiography, the Watchman 12-Fr delivery system with a pigtail catheter is advanced into the left atrium. The delivery system is then guided into the left atrium with both fluoroscopic and 2D or 3D transesophageal echocardiographic guidance. Three-dimensional TEE has the advantage of allowing visualization of the entire lengths of catheters as they traverse the left atrium to reach the LAA.

It also provides clear imaging of the distance between the tip of the guide catheter in the left atrium relative to the atrial septum to prevent accidental transseptal puncture site decannulation back into the right atrium.

After the guide catheter is advanced toward the LAA orifice, a pigtail catheter is threaded through the guide catheter, and contrast angiography is performed to fluoroscopically evaluate the LAA. On 2D and 3D echocardiography, this produces copious amounts of bubbles that obscure imaging.

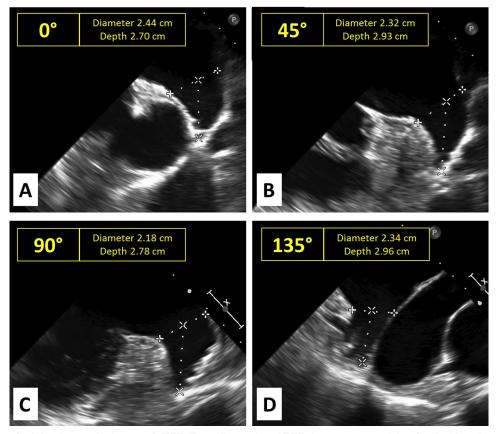


Figure 10 LAA sizing for Watchman device on 2D TEE. Two-dimensional TEE demonstrates sizing for the Watchman device. The LAA orifice diameter and depth are measured at 0° (A), 45° (B), 90° (C), and 135° (D).

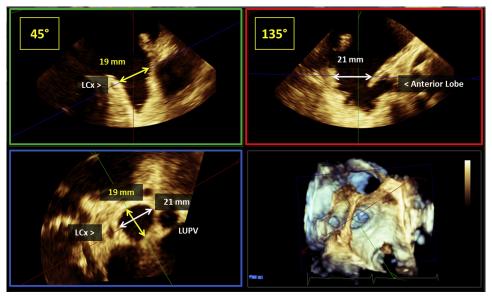


Figure 11 LAA sizing for Watchman device on 3D TEE. Three-dimensional TEE multiplanar reconstruction (MPR) demonstrating LAA orifice sizing. Using a single-beat 3D zoom capture, the entire LAA and surrounding structures are acquired. Using 3DQ software within QLAB (Philips Healthcare, Amsterdam, the Netherlands), an MPR is obtained. It is advantageous to have the red and green planes locked, leaving the blue plane free for adjustment. The red and green planes are oriented toward the LAA apex. The blue plane is then oriented toward the plane of the LAA orifice, typically at the level of the left circumflex coronary artery (LCx). This allows corresponding measurements to be performed in multiple axes. *LUPV*, Left upper pulmonary vein.

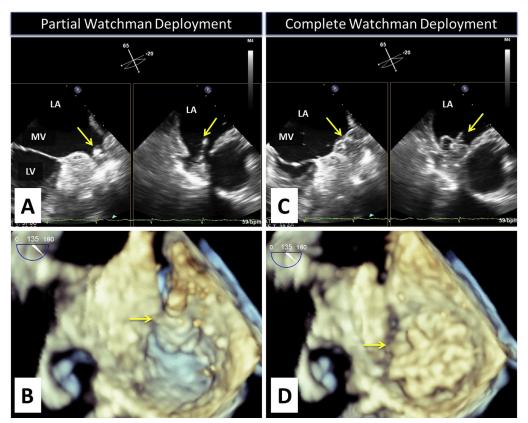


Figure 12 Watchman device deployment. Two-dimensional TEE with biplane imaging and 3D TEE demonstrating partial (A,B) and complete (C,D) deployment of the Watchman LAA occluder device within the LAA (yellow arrows). Video 2 corresponds to (A) and (C), while Video 3 corresponds to (B) and (D). LA, Left atrium; LV, left ventricle; MV, mitral valve.

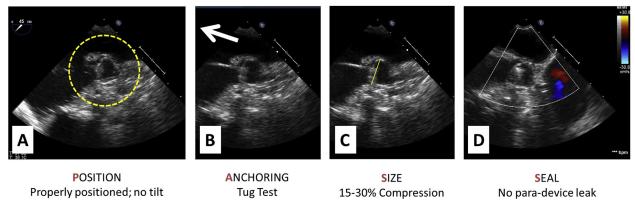


Figure 13 Watchman device PASS implantation criteria. Before release of the Watchman LAA occluder device, the four so-called PASS criteria (position, anchor, size, and seal) must be met. (A) First, the Watchman device (yellow circle) must be properly positioned within the LAA orifice (i.e., not tilted). (B) Second, the device cannot demonstrate excessive motion on the "tug test" (i.e., the device is pulled backward (direction of white arrow) while still attached to the threaded insert and visualized using fluoroscopy and echocardiography). Video 4 corresponds to (B). (C) Third, compression measurements are performed at 0°, 45°, 90°, and 135°. A line is drawn from shoulder to shoulder with the threaded insert in view (this is located at the center of the device) to ensure that the device is measured at the location of its maximal width. (D) Finally, a PDL of <5 mm is considered an adequate seal between the device and the LAA. If any of the PASS criteria are not met, the Watchman device can be recaptured and then repositioned, or a new device size may be selected.

The guide catheter/pigtail combination is then is navigated such that the corresponding radiopaque marker band for the device size is aligned with the LAA ostium. Once the guide catheter is properly positioned, the pigtail is removed. The

Watchman device is then unsheathed slowly but remains attached to the delivery cable. This is observed using 2D and 3D TEE (Figure 12, Videos 2 and 3 available at http://www.onlinejase.com).

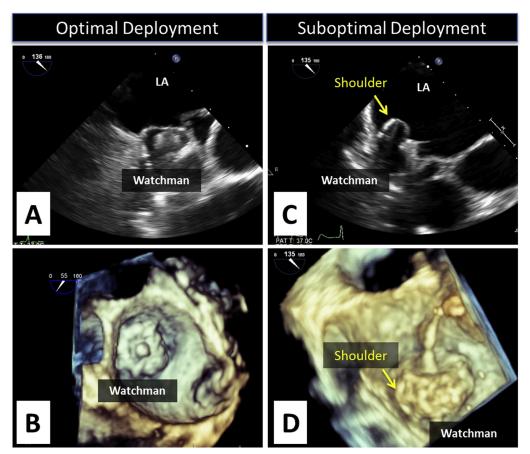


Figure 14 Suboptimal Watchman device deployment. Two-dimensional TEE at 135° view and 3D TEE demonstrating optimal and suboptimal Watchman device deployment. The device should be optimally be deployed parallel to the LAA orifice (A,B). Video 5 corresponds to (A) and (B). If the device is excessively tilted, a device "shoulder" will be visualized (C,D). To ensure an adequate seal, the extent of the shoulder cannot be >40% to 50% of the device height. Video 6 corresponds to (C) and (D). LA, Left atrium.

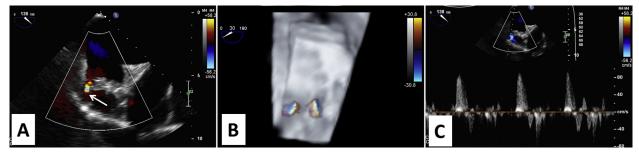


Figure 15 Watchman PDL. Color Doppler demonstrates a PDL (white arrow) on the inferior edge of a Watchman LAA occluder on 2D TEE (A and Video 7) and 3D TEE (B). Spectral pulsed-wave Doppler confirms that a communication is present between the left atrium and LAA, adjacent to a Watchman LAA occluder (C).

Watchman Device Release

Before device release, the four "PASS" criteria (position, anchor, size, and seal) must be met (Figure 13, Video 4 available at http://www.onlinejase.com):

- Position: Ideally, the "shoulder" of the device (the curved portion
 of the device at the level of the LAA orifice) should not protrude
 excessively from the LAA (Figure 14, Videos 5 and 6 available at
 http://www.onlinejase.com). If an excessive shoulder protrusion
 is present, it must be <40% to 50% of the device depth.
- Anchor: A "tug test" is performed. The deployment knob is retracted and let go under transesophageal echocardiographic or

- fluoroscopic visualization to ensure that the device returns to its original position.
- Size: The device diameter compression is obtained by 2D TEE at 0°, 45°, 90°, and 135° and ideally should be 8% to 20%. Compression is measured from the device "shoulder to shoulder," while ensuring that the central metallic portion of the left atrial side of the device named the "threaded insert" is in view.
- Seal: Assessment for para-device leak (PDL) vena contracta is performed using 2D TEE with color Doppler at 0°, 45°, 90°, and 135°.
 The vena contracta of PDL is defined as the narrowest cross-section in the plane where the device is closest to the LAA wall. A PDL vena contracta of <5 mm is considered acceptable (Figure 15,

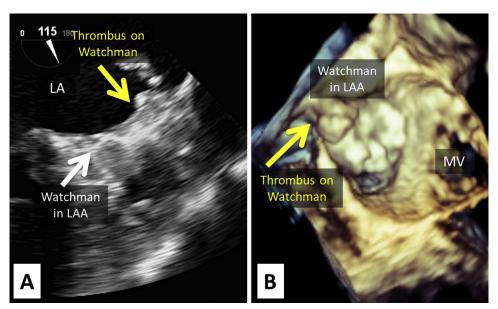


Figure 16 Watchman device—associated thrombus. Two-dimensional (A) and 3D (B) TEE demonstrates a Watchman-associated thrombus. The thrombus originates at the "threaded-insert" portion of the Watchman device and propagates outward. Video 8 corresponds to this figure. *LA*, Left atrium; *MV*, mitral valve.

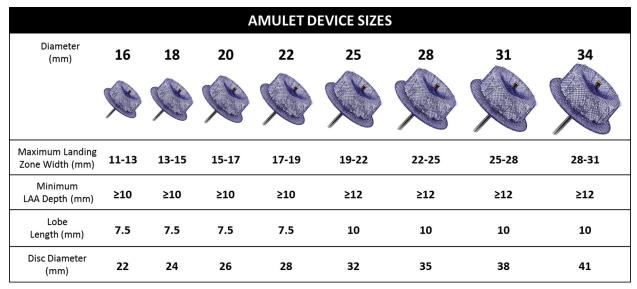


Figure 17 Amulet device sizes. Chart demonstrating available Amulet device sizes, maximum landing zone width, minimum LAA depth, lobe length, and disk diameter. Note that the disk diameter is 7 mm plus the Amulet diameter for sizes 25 to 34 mm and 6 mm plus the Amulet diameter for sizes 16 to 22 mm.

Video 7 available at http://www.onlinejase.com) When a PDL ≥5 mm is present, the existing Watchman device is recaptured and either repositioned or replaced with a larger one.

A low Nyquist limit (20–30 cm/sec) is recommended to detect low-velocity flow and increase detection sensitivity. Three-dimensional TEE with color Doppler imaging may also be performed to assess the circumferential extent of PDL.

After the Watchman device is deployed, the delivery catheter is withdrawn from the LAA. Color Doppler is then applied to the interatrial septum to assess the degree of procedurally related ASD at the site of transseptal puncture. An ASD of <10 mm is considered acceptable.

Procedural ASDs > 10 mm are unusual and may require percutaneous ASD closure.

Immediate Complications

PEF is the most important complication to assess for using TEE in all LAA occlusion/exclusion procedures. PEF typically occurs as a result of intraprocedural perforation of cardiac chambers such as the right atrium, left atrium, and LAA.

Multiple windows are necessary to provide a complete assessment for PEF, specifically the transgastric views and midesophageal fourchamber view with clockwise manipulation of the probe to focus

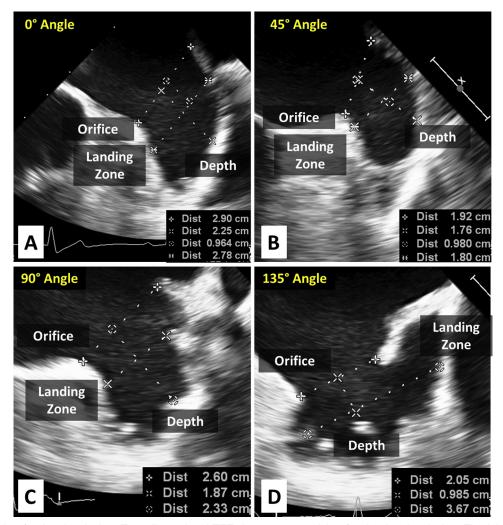


Figure 18 LAA sizing for Amulet device. Two-dimensional TEE demonstrates sizing for the Amulet device. The LAA ostium diameter, landing zone diameter, and depth are measured at 0° **(A)**, 45° **(B)**, 90° **(C)**, and 135° **(D)**. Note that the landing zone diameter is measured 10 to 12 mm from the ostium and that the depth is measured from the ostium to the LAA wall in a plane perpendicular to the ostium.

on the right ventricular-right atrial junction. Comparison with the baseline level of PEF is crucial. Additionally, a prominent pericardial fat pad should not be confused with PEF.

The rate of PEF related to the Watchman procedure was reported in recent series at 2.2% to 5.0% of cases.²⁵ This rate has decreased over time, which may be attributable to better operator experience and the use of pigtail catheters to avoid blunt LAA injury by the guide catheter.²⁷

Other possible procedural complications are device embolization and procedure-related stroke. The device embolization rate for the Watchman device is approximately 0.6%. Regarding procedure-related stroke, one study demonstrated a very low incidence, approximately 0.9%.²⁵

Watchman Device: Postprocedural Follow-up

After the Watchman device is implanted, it takes approximately 45 days for device endothelialization to occur. Therefore, a 45-day follow-up transesophageal echocardiographic examination was performed in the major clinical trials evaluating the Watchman ^{15,28} and is now mirrored in clinical practice. Until 45 days, patients remain on warfarin and aspirin therapy. If the Watchman device meets the prespecified echocardiographic criteria described below, warfarin is

discontinued and replaced with dual-antiplatelet therapy (clopidogrel and aspirin) until 6 months. After 6 months, clopidogrel is discontinued, and aspirin is continued for life.

The major goals of the 45-day follow-up transesophageal echocardiographic examination are as follows.

- Reassess the device position and its stability: TEE is typically performed at 0°, 45°, 90°, and 135° to ensure that the Watchman device has not embolized or shifted position, possibly uncovering an LAA lobe. Device embolism may be asymptomatic, highlighting the importance of the routine follow-up TEE for detection. Removal techniques with loop snare or surgical interventions have been described.²⁵
- Assess for any residual or new PDL: TEE is again performed at 0°, 45°, 90°, and 135° with color Doppler at a low Nyquist limit, similar to the immediate post–Watchman implantation assessment described earlier. PDLs <5 mm are fairly common, occurring in approximately 32% of cases, but they are not necessarily associated with increased risk for thromboembolism.²⁹ Thus, a PDL of <5 mm is considered adequate for the discontinuation of warfarin.

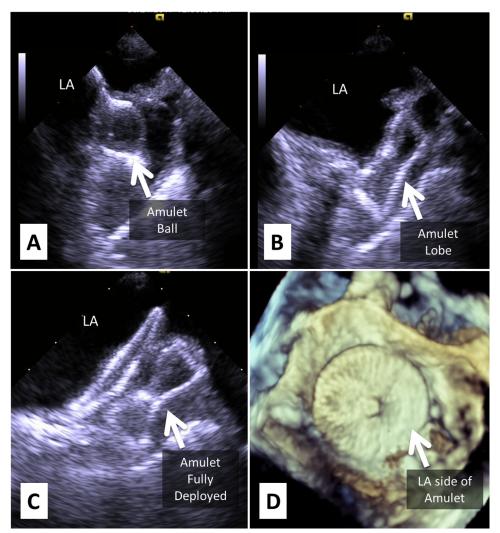


Figure 19 Amulet device deployment. Two-dimensional and 3D TEE demonstrates the stages of Amulet deployment. First, the partially deployed Amulet lobe, also known as the "ball," is deployed (A). Subsequently, the lobe is fully deployed (B). Finally the disk is deployed and the Amulet is released (C,D). Video 9 corresponds to this figure. LA, Left atrium.

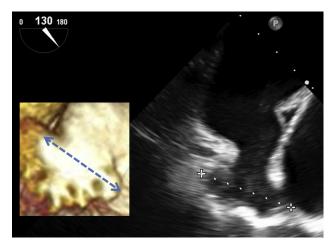


Figure 20 LAA sizing for Lariat procedure. Three-dimensional computed tomographic volume-rendered image superimposed on a 2D transesophageal echocardiographic image demonstrating the LAA maximum width, which should be ≤45 mm.

- Assess for thrombus: Thrombus must be visualized on the left atrial side of the device to be considered a device-associated thrombus; thrombus on the excluded LAA side is considered normal. Device associated thrombi are most commonly associated with the Watchman threaded insert, as endothelialization at this site may be delayed (Figure 16, Video 8 available at http://www.onlinejase.com). Thrombus may also occur on uncovered LAA trabeculations. Device-associated thrombi are uncommon, occurring in 4.2% of patients in the PROTECT-AF study. Of the patients with DAT, there was a 15% incidence of associated ischemic stroke.²⁵
- Look for a residual shunt across the interatrial septum: Septal
 healing after transseptal puncture is common, and the majority of procedure-related ASDs either partially or completely
 seal after Watchman implantation. An ASD >10 mm in
 diameter may need to be percutaneously closed with a
 device.
- Perform a complete study to assess the remaining cardiac structures: It is important to complete assessment of the non-LAA structures to determine any change from baseline. Significant PEF should be excluded. In addition, device

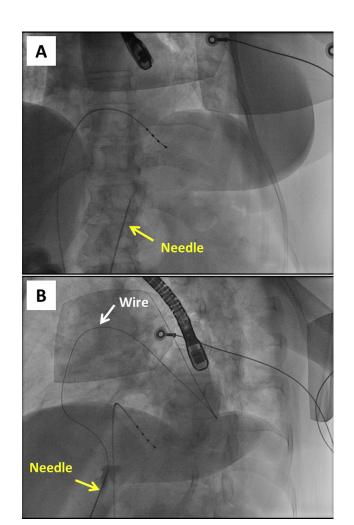


Figure 21 Lariat procedure: pericardial access. Fluoroscopic quidance of pericardial access (A). Anteroposterior view demonstrates the path of the pericardial needle (arrow) (B). In the next step, a wire (white arrow) is introduced into the pericardial space through the needle (yellow arrow). Reproduced with permission from Laura DM, Chinitz LA, Aizer A, Holmes DS, Benenstein R, Freedberg RS, et al. The role of multimodality imaging in percutaneous left atrial appendage suture ligation with the Lariat device. J Am Soc Echocardiogr 2014;27:699–708.

erosions or infections have been reported and should be excluded as well.³⁰

THE AMULET PROCEDURE

Overview

The Amulet device is the second-generation Amplatzer LAA occluder. It consists of self-expanding nitinol mesh, forming a lobe and a disk, and is connected by a central articulating waist. The lobe is implanted approximately 10 to 12 mm distal to the anatomic LAA orifice and serves as the key anchoring mechanism, supported by stabilizing wires located circumferentially. The central "proximal end screw" (similar to the "threaded insert" of the Watchman) is recessed, which theoretically may reduce the risk for thrombus formation on the atrial side of the device.

The disk is deployed in the left atrium and abuts the LAA orifice, helping create a seal. Both the lobe and the disk are covered in hand-sewn polyester mesh. The Amulet comes in eight sizes, which correspond to the lobe diameter (16, 18, 20, 22, 25, 28, 31, and 34 mm; Figure 17).

Disk diameters are equal to the lobe diameter plus 6 mm for Amulet sizes 16 to 22 mm and the lobe diameter plus 7 mm for sizes 25 to 34 mm. Waist lengths are 5.5 mm for sizes 16 to 22 mm and 8 mm for sizes 25 to 34 mm.

Compared with the Watchman, the Amulet device can accommodate both larger and smaller LAA orifice sizes. At the higher end, the Amulet can be used for LAA diameters up to 32 mm compared with up to 30.4 mm for the Watchman. At the lower end, the Amulet can be used for LAA diameters as small 14 mm compared with 16.8 mm for the Watchman.

Similar to the Watchman device, the Amulet procedure begins with transfemoral venous access and transseptal puncture, as described above. Subsequently, a delivery sheath is advanced into the left atrium and is positioned into the LAA. The Amulet device is then advanced to the tip of the delivery sheath and positioned in the "landing zone" of the LAA, which is located approximately 10 to 12 mm distal to the LAA ostium. The device lobe and disk are then sequentially deployed. If the position, angulation, and seal are optimal, the entire system is released.³¹

An animated description of the Amulet procedure can be viewed on the manufacturer's website: http://videos.sjm.com/pro/product/ sh/Amulet-091814-17mb_final.mp4.

There are currently only observational data available for the Amulet device. These data have demonstrated high implantation success rates and low periprocedural and early adverse events.³² To investigate the Amulet device more thoroughly, the AMULET trial is currently under way in the United States. This randomized controlled trial aims to investigate the safety and efficacy of the Amulet device compared with the Watchman device.

Baseline Comprehensive Assessment

Overall, the baseline comprehensive assessment for the Amulet procedure is similar to that of the Watchman procedure described above.

LAA Sizing Specific to the Amulet

Like the Watchman, the LAA is imaged at 0°, 45°, 90°, and 135° on 2D TEE. However, it is recommended to focus on the "short axis" (technically, the minor diameter axis of an ovoid LAA orifice; usually between 30° and 60°) and the "long axis" (technically the major diameter axis of an ovoid LAA orifice; usually between 120° and

For the Amulet, sizing measurements are different from those of the Watchman (Figure 18). The LAA ostial diameter is defined as the line from the pulmonary vein ridge to the circumflex artery.³ The landing zone diameter is then measured 10 to 12 mm distal to the ostium at an angle perpendicular to the neck axis. Both the ostial and landing zone LAA diameter measurements are usually wider on the "long-axis" view compared with the "short-axis" view. Amulet device selection is based primarily on the landing zone diameter measurement.

Amulet depth measurements are also different from those for the Watchman device. Unlike the Watchman depth, which is measured from the plane of the LAA orifice diameter toward the LAA apex, depth for the Amulet device is measured

Figure 22 Lariat guidance: balloon placement. Transesophageal echocardiographic guidance of Lariat balloon placement (A). Three-dimensional TEE biplane image demonstrates proper balloon placement (arrow) at the orifice of the LAA. Three-dimensional transesophageal echocardiographic zoom image shows inflated balloon at the orifice of the LAA (B). Reproduced with permission from Laura DM, Chinitz LA, Aizer A, Holmes DS, Benenstein R, Freedberg RS, et al. The role of multimodality imaging in percutaneous left atrial appendage suture ligation with the Lariat device. J Am Soc Echocardiogr 2014;27:699–708.

perpendicular to the plane of the LAA orifice toward the back LAA wall (along the so-called neck axis).

LAA Anatomic Exclusion Criteria for the Amulet Device

- The LAA landing zone diameter cannot be too large (>32 mm) or too small (<14 mm).
- Minimal depth is 10 mm for 16- to 22-mm Amulet devices.
- Minimal depth is 12 mm for 25- to 34-mm Amulet devices.

Other Exclusion Criteria for the Amulet Device

- Intracardiac thrombus
- Cardiac tumor
- Large interatrial shunt, defined as >20 bubbles that appear within three beats on agitated saline injection
- Atrial septal aneurysm with excursion > 15 mm or length > 15 mm beyond the plane of the atrial septum
- Complex atheroma with mobile plaque in aortic arch or descending aorta
- Significant mitral stenosis (mitral valve area < 1.5 cm²)
- PEF with thickness > 2 mm
- Placement of the device would interfere with any intracardiac or intravascular structure

Echocardiographic Guidance for the Amulet Procedure

The location of transseptal puncture for the Amulet device is similar to that for the Watchman device, which should be inferior and posterior. After the wire is positioned in the left superior pulmonary vein, the access sheath is advanced into the left atrium. For the Amulet device, there are two access sheath sizes, 12 Fr (16- to 28-mm Amulet sizes) and 14 Fr (31- and 34-mm Amulet sizes).

Once the access sheath is inserted into the LA, the wire is removed, and the sheath is guided into the LAA. The tip of the access sheath is positioned at the LAA landing zone. Subsequently, the Amulet device is then advanced to the tip of the access sheath, and the lobe is partially deployed.

The partially deployed lobe of the Amulet device is referred to as the "ball." The ball is formed in the body of the left atrium and then advanced into the LAA landing zone. Thereafter, the lobe is

fully deployed in the landing zone. If the angle and position of the fully deployed lobe are optimal, one then proceeds with disk deployment (Figure 19, Video 9 available at http://www.onlinejase.com).

Amulet Device Release

Before device release, the following five criteria must be met.

- The lobe should be tire shaped to ensure adequate compression and engagement of stabilizing wires.
- There should be a degree of separation of the lobe and the disk to ensure a good seal.
- The disk should be concave with respect to the body of the left atrium to ensure a good seal.
- The axis of the lobe should be perpendicular to the neck axis to ensure adequate stability.
- At least two thirds of the lobe should be positioned adjacent to the circumflex artery to ensure stability. To confirm stability, a gentle pull of the disk can be performed.

Similar to the Watchman, PDL is assessed using color Doppler with a low Nyquist limit (\sim 35–45 cm/sec). A small leak is defined as a jet <3 mm in diameter or multiple leaks that are cumulatively <3 mm in diameter. Medium and large leaks are defined as jet diameters (or cumulative jet diameters) of either 3 to 5 mm or >5 mm, respectively.

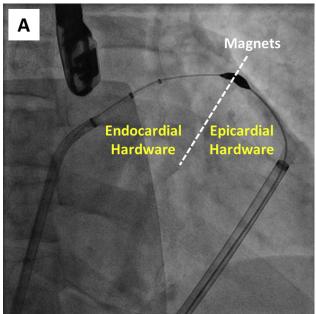
After the Amulet device is deployed, ASD size at the site of transseptal puncture is assessed.

Immediate Complications

The types of complications experienced with the Amulet device are similar to those with the Watchman. In the largest observational study of the Amulet, which evaluated >1,000 patients, the rate of stroke was 0.3%. The device embolization rate was 0.1%, the PEF rate was 0.5%, and the procedural bleeding rate was 0.7%.³⁴

Amulet Device: Postprocedural Follow-up

Similar to the Watchman protocol, postprocedural transesophageal echocardiographic follow-up is performed 45 days after Amulet



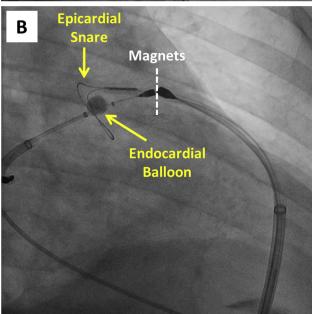


Figure 23 Lariat magnet union on fluoroscopy. Lariat procedure guidance by fluoroscopy (A). The two magnet-tipped guidewires are united at the tip of the LAA. The endocardial wire, seen on the left, is situated in the LAA with its magnetic tip in the apex. The epicardial wire, seen on the right, lies along the anterior aspect of the heart with its magnetic tip on the epicardium of the LAA apex (B). After end-to-end magnetic union of the magnet-tipped guidewires, the Lariat snare is advanced epicardially over the LAA to the ostium. Radiopaque proximal and distal markers of the endocardial balloon are observed to the left of the magnetic tip, with the proximal marker delineating the ostium of the LAA. The balloon is inflated to prevent slippage of the snare off the base of the appendage. After the snare is tightened, the endocardial balloon catheter and endocardial wire are removed from the LAA, and the epicardial suture is released from the snare and tightened, excluding the LAA from the left atrium. Reproduced with permission from Laura DM, Chinitz LA, Aizer A, Holmes DS, Benenstein R, Freedberg RS, et al. The role of multimodality imaging in percutaneous left atrial appendage suture ligation with the Lariat device. J Am Soc Echocardiogr 2014;27:699-708.

implantation. The focus is almost identical to the Watchman device: to evaluate device position and its stability, PDL, device-related thrombus, PEF, and iatrogenic ASD. Furthermore, a complete examination should be performed to assess for any significant changes from the procedural TEE.

THE LARIAT PROCEDURE

Overview

In contrast to the endovascularly delivered devices, percutaneous LAA closure with the Lariat device consists of endocardially and epicardially delivered magnetic-tipped wires that unite at the distal LAA wall. This creates a rail for delivery of a pre-tied suture that ultimately ligates the LAA. Because this procedure does not leave any device in contact with the bloodstream, ¹⁶ it does not typically require postprocedural warfarin therapy. ^{35,36} This device may be advantageous for patients who are deemed unable to tolerate even 45 days of warfarin therapy, which would be required for the Amulet or Watchman.

An animated description of the Lariat procedure can be viewed at https://youtu.be/CCKqayXzLDA.

On the basis of short-term observational data, ^{16-18,35} the Lariat procedure is feasible, but proof of its long-term efficacy in a randomized trial is still lacking. To address this issue, a randomized controlled trial named aMAZE (LAA Ligation Adjunctive to Pulmonary Vein Isolation for Persistent or Longstanding Persistent Atrial Fibrillation) is currently under way. This trial aims to assess the safety and efficacy of the Lariat procedure as an adjunct to percutaneous pulmonary vein isolation (also known as AF ablation). This is expected to provide more insight into the procedural risks and efficacy of the Lariat device.

Lariat Device: Baseline Comprehensive Assessment and Exclusion Criteria

The baseline assessment for the Lariat device is similar to that of the devices described previously. However, rather than performing a multiplanar assessment to determine the LAA orifice size, focus is instead on determining LAA position and maximal body width, typically at 135° or higher (Figure 20).

For the Lariat device, a body width of >45 mm and a superiorly oriented LAA with its apex behind the pulmonary trunk are considered exclusion criteria. Other exclusion criteria are prior cardiac surgery, a myocardial infarction within 3 months, embolic events within 30 days, and history of pericarditis.

Pericardial/Epicardial Access

The epicardial portion of the Lariat procedure is guided primarily by fluoroscopy (Figure 21) rather than echocardiography, although echocardiographic artifact from the epicardial guidewire can sometimes be seen within the pericardial space. However, imaging the right ventricle during pericardial access can be useful to demonstrate that the right ventricle has not been punctured. The midesophageal short-axis view can be extremely helpful during this portion of the Lariat procedure to demonstrate the lack of an epicardial wire across the right ventricular free wall.

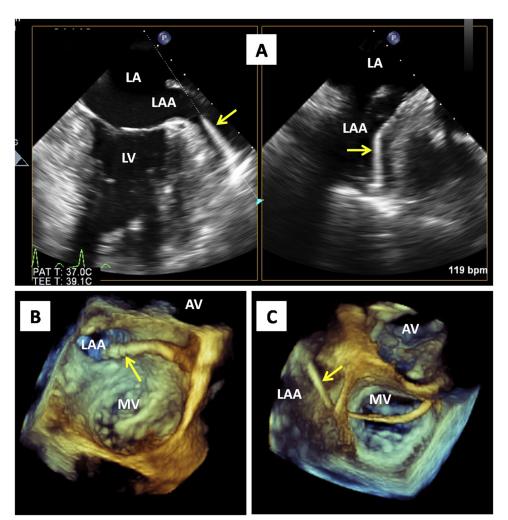


Figure 24 Lariat magnet union on TEE. Transesophageal echocardiographic guidance of endocardial magnet wire placement (A). Biplane 3D transesophageal echocardiographic image demonstrates proper placement of the endocardial magnet wire (yellow arrow) with its tip in the apex of the LAA (B,C). Three-dimensional transesophageal echocardiographic zoom imaging during endocardial magnet wire deployment. In (B), the catheter (yellow arrow) that contains the wire is guided into the orifice of the LAA above the mitral valve. In (C), the wire (yellow arrow) is advanced into the LAA. AV, Aortic valve; LA, left atrium; LV, left ventricle; MV, mitral valve. Reproduced with permission from Laura DM, Chinitz LA, Aizer A, Holmes DS, Benenstein R, Freedberg RS, et al. The role of multimodality imaging in percutaneous left atrial appendage suture ligation with the Lariat device. J Am Soc Echocardiogr 2014;27:699–708.

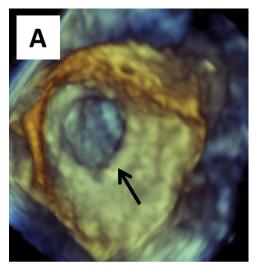
Echocardiographic Guidance for the Lariat Procedure

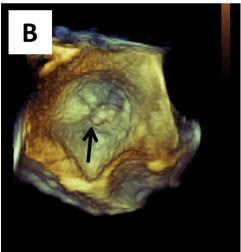
Two-dimensional and 3D transesophageal echocardiographic guidance of transseptal puncture for the Lariat procedure is similar to that for the devices described earlier. After successful transseptal puncture, a wire is inserted into the LAA that is typically positioned in the left superior pulmonary vein, and the dilator and sheath are removed. Subsequently, an 8.5-Fr SL1 catheter (St. Jude Medical) is then advanced into the left atrium and guided into the LAA. Similar to the other LAA occlusion/exclusion procedures, 3D TEE can be helpful to image the catheter position relative to the interatrial septum to avoid accidental decannulation.

Once LAA access has been achieved, a 15-mm balloon-tipped catheter (EndoCATH; Sentre-HEART) back-loaded with a magnet-tipped 0.025-inch guidewire is advanced through the SL1 catheter into the LAA under echocardiographic and fluoroscopic guidance. The magnet wire tip is placed in the LAA

apex and the deflated balloon at the ostium of the LAA. The balloon is then inflated, delineating the ostium for snare placement and ensuring that the suture does not slip off during tightening³⁷ (Figure 22). The radiopaque marker on the distal tip of the Lariat is then aligned with the proximal marker of the EndoCATH balloon, creating an end-to-end magnetic union. The Lariat snare is then advanced epicardially over the LAA to the ostium and tightened. After the snare is tightened, the endocardial balloon catheter and endocardial wire are removed from the LAA, and the epicardial suture is released from the snare and tightened, excluding the LAA from the left atrium (Figures 23 and 24).

Color Doppler is then applied to assess for any significant communication between the left atrium and LAA. A small degree of color Doppler flow can normally be seen along the EndoCATH. Once adequate positioning is confirmed, the EndoCATH balloon is deflated; the balloon and endocardial





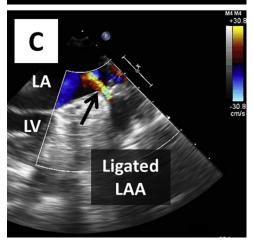


Figure 25 Lariat procedure: bowtie sign on 3D TEE. (A) Three-dimensional transesophageal echocardiographic appearance of the LAA at baseline and after ligation. Three-dimensional TEE zoom imaging demonstrates the en face view of the LAA orifice seen from the left atrial perspective. At baseline, there is a widely patent orifice of the LAA (arrow). (B) After completion of the Lariat suture ligation, the LAA orifice is completely closed. The arrow points to the location of the suture. Note the "bowtie" appearance of the ligated LAA orifice. (C) After completion of the Lariat procedure, there are typically no residual leaks between

magnet-tipped wire are then withdrawn from the LAA, and the preloaded suture is then released from the snare and tightened (Figure 25, Videos 10–12 available at http://www.onlinejase.com).

On 3D TEE, a successfully ligated LAA has what we refer to as "bowtie" appearance (Figure 26, Video 13 available at http://www.onlinejase.com).

As with the Watchman procedure, the success of the Lariat procedure is determined by the lack of 2D color Doppler flow communication between the LAA and left atrium. A 2D color Doppler flow width of <5 mm is considered adequate. Multiplanar imaging should be performed at 0°, 45°, 90°, and 135° to visualize the entire extent of the occluded LAA orifice. Similar to the Watchman device, using a low (<40 cm/sec) Nyquist limit for color Doppler is helpful to assess flow between the left atrium and LAA. Three-dimensional TEE with color Doppler imaging can sometimes aid in the assessment of residual left atrial—LAA communication.

After the Lariat device is deployed, the delivery catheter is then withdrawn from the LAA, and an assessment of the size of the transseptal-related ASD is performed, similar to the Watchman device.

Immediate Complications

Chest pain, presumably due to a degree of pericarditis, is the most common complication associated with the Lariat device. Despite this, persistent pericarditis has been noted in only 2.4% of patients. ³⁸ As the Lariat device is purely epicardially delivered, there is no risk for device embolization.

As with the Watchman, PEF is the most important procedural complication of the Lariat procedure and should be assessed using multiple views. The reported rate of PEF is low for the Lariat, as previous studies report its occurrence in only 3.7% to 5.0% of cases. ^{17,35} In most cases, the development of a significant PEF may necessitate abortion of the procedure. However, if the PEF occurs as a result of a LAA perforation using the Lariat device, completion of the procedure to completely ligate the LAA may actually be a therapeutic option. ³⁹

As the Lariat device uses endocardial wires that have direct access to the systemic circulation, catheter-related thrombus and subsequent cerebral embolism (i.e., stroke) is a theoretical risk. Unfortunately, there is a paucity of data regarding the incidence of procedurally related stroke with the Lariat device. The aforementioned aMAZE trial will hopefully provide more insight into this in the future.

Lariat Device: Postprocedural Follow-up

Unlike the Watchman or Amulet devices, follow-up after Lariat device implantation varies from institution to institution. However, the recommended protocol should emulate the aMAZE trial, which requires follow-up TEE at 30 days, 365 days, and annually for 3 years after the index procedure.

the left atrium and the LAA. If there is residual leak, it is typically solitary and central, as shown in this panel (*arrow*). Video 13 corresponds to (C). LA, Left atrium; LV, left ventricle. Reproduced with permission from Laura DM, Chinitz LA, Aizer A, Holmes DS, Benenstein R, Freedberg RS, *et al*. The role of multimodality imaging in percutaneous left atrial appendage suture ligation with the Lariat device. J Am Soc Echocardiogr 2014;27:699–708.

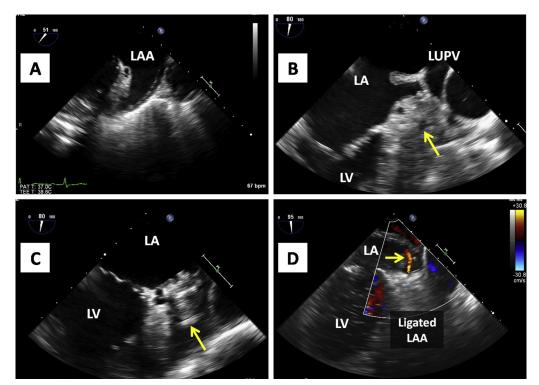


Figure 26 Lariat procedure on 2D TEE. Transesophageal echocardiographic assessment of Lariat closure of the LAA. (A) Two dimensional transesophageal echocardiographic appearance of the LAA before Lariat closure. (B) Typical appearance of the LAA after Lariat ligation. Video 10 corresponds to (B). (C) Appearance of a ligated LAA in another patient. In this patient, the presence of a PEF outlines the ligated appendage (arrow). Video 11 corresponds to (C). (D) After the LARIAT snare is deployed but before removal of the endocardial catheter from the LAA, a small degree of central leak (arrow) may be seen on color Doppler imaging. Video 12 corresponds to (D). LA, Left atrium; LV, left ventricle; LUPV, left upper pulmonary vein. Reproduced with permission from Laura DM, Chinitz LA, Aizer A, Holmes DS, Benenstein R, Freedberg RS, et al. The role of multimodality imaging in percutaneous left atrial appendage suture ligation with the Lariat device. J Am Soc Echocardiogr 2014;27:699-708.

Overall, the focus is similar to all percutaneous LAA occlusion/ exclusion devices: to ensure adequate LAA ligation (<5 mm color Doppler flow between the LAA and LA) and to exclude devicerelated thrombus and PEF. In addition, a comprehensive transesophageal echocardiographic protocol is recommended to exclude any significant changes from previous studies.

CONCLUSIONS

Percutaneous LAA occlusion/exclusion devices are growing in popularity as a potential option for stroke risk reduction in patients who are at high risk or ineligible for systemic anticoagulation. Successful implantation of these devices requires high-quality 2D and 3D TEE, used in conjunction with fluoroscopy throughout each procedure. TEE is critical to evaluate for exclusion criteria, to define LAA anatomy, to size the device, to guide transseptal puncture and catheters, and to assess procedural success and complications.

SUPPLEMENTARY DATA

Supplementary data related to this article can be found at https://doi. org/10.1016/j.echo.2017.09.014.

REFERENCES

- 1. Naccarelli GV, Varker H, Lin J, Schulman KL. Increasing prevalence of atrial fibrillation and flutter in the United States. Am J Cardiol 2009;104:1534-9.
- 2. Mozaffarian D, Benjamin EJ, Go AS, Arnett DK, Blaha MJ, Cushman M, et al. Heart disease and stroke statistics-2015 update: a report from the American Heart Association. Circulation 2015;131:e29-322.
- 3. Blackshear JL, Odell JA. Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation. Ann Thorac Surg 1996;61:
- 4. Hart RG, Benavente O, McBride R, Pearce LA. Antithrombotic therapy to prevent stroke in patients with atrial fibrillation: a meta-analysis. Ann Intern Med 1999;131:492-501.
- 5. Rasekh A. Anticoagulants and atrial fibrillation. Tex Heart Inst J 2005;32:
- 6. Connolly SJ, Ezekowitz MD, Yusuf S, Eikelboom J, Oldgren J, Parekh A, et al. Dabigatran versus warfarin in patients with atrial fibrillation. N Engl J Med 2009;361:1139-51.
- 7. Granger CB, Alexander JH, McMurray JJ, Lopes RD, Hylek EM, Hanna M, et al. Apixaban versus warfarin in patients with atrial fibrillation. N Engl J Med 2011;365:981-92.
- 8. Patel MR, Mahaffey KW, Garg J, Pan G, Singer DE, Hacke W, et al. Rivaroxaban versus warfarin in nonvalvular atrial fibrillation. N Engl J Med 2011:365:883-91.
- 9. Hughes M, Lip GY. Risk factors for anticoagulation-related bleeding complications in patients with atrial fibrillation: a systematic review. QJM 2007;100:599-607.

- Johnson WD, Ganjoo AK, Stone CD, Srivyas RC, Howard M. The left atrial appendage: our most lethal human attachment! Surgical implications. Eur J Cardiothorac Surg 2000;17:718-22.
- Healey JS, Crystal E, Lamy A, Teoh K, Semelhago L, Hohnloser SH, et al. Left Atrial Appendage Occlusion Study (LAAOS): results of a randomized controlled pilot study of left atrial appendage occlusion during coronary bypass surgery in patients at risk for stroke. Am Heart J 2005;150:288-93.
- 12. Emmert MY, Puippe G, Baumuller S, Alkadhi H, Landmesser U, Plass A, et al. Safe, effective and durable epicardial left atrial appendage clip occlusion in patients with atrial fibrillation undergoing cardiac surgery: first long-term results from a prospective device trial. Eur J Cardiothorac Surg 2014; 45:126-31.
- Park JW, Bethencourt A, Sievert H, Santoro G, Meier B, Walsh K, et al. Left atrial appendage closure with Amplatzer cardiac plug in atrial fibrillation: initial European experience. Catheter Cardiovasc Interv 2011;77:700-6.
- 14. Ostermayer SH, Reisman M, Kramer PH, Matthews RV, Gray WA, Block PC, et al. Percutaneous left atrial appendage transcatheter occlusion (PLAATO system) to prevent stroke in high-risk patients with non-rheumatic atrial fibrillation: results from the international multi-center feasibility trials. J Am Coll Cardiol 2005;46:9-14.
- 15. Holmes DR, Reddy VY, Turi ZG, Doshi SK, Sievert H, Buchbinder M, 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.
- Bartus K, Han FT, Bednarek J, Myc J, Kapelak B, Sadowski J, et al. Percutaneous left atrial appendage suture ligation using the Lariat device in patients with atrial fibrillation: initial clinical experience. J Am Coll Cardiol 2013;62:108-18.
- Stone D, Byrne T, Pershad A. Early results with the Lariat device for left atrial appendage exclusion in patients with atrial fibrillation at high risk for stroke and anticoagulation. Catheter Cardiovasc Interv 2015;86:121-7.
- Bartus K, Bednarek J, Myc J, Kapelak B, Sadowski J, Lelakowski J, et al. Feasibility of closed-chest ligation of the left atrial appendage in humans. Heart Rhythm 2011;8:188-93.
- Wunderlich NC, Beigel R, Swaans MJ, Ho SY, Siegel RJ. Percutaneous interventions for left atrial appendage exclusion: options, assessment, and imaging using 2D and 3D echocardiography. JACC Cardiovasc Imaging 2015;8:472-88.
- Beigel R, Wunderlich NC, Ho SY, Arsanjani R, Siegel RJ. The left atrial appendage: anatomy, function, and noninvasive evaluation. JACC Cardiovasc Imaging 2014;7:1251-65.
- Babaliaros VC, Green JT, Lerakis S, Lloyd M, Block PC. Emerging applications for transseptal left heart catheterization old techniques for new procedures. J Am Coll Cardiol 2008;51:2116-22.
- 22. Nucifora G, Faletra FF, Regoli F, Pasotti E, Pedrazzini G, Moccetti T, et al. Evaluation of the left atrial appendage with real-time 3-dimensional transesophageal echocardiography: implications for catheter-based left atrial appendage closure. Circ Cardiovasc Imaging 2011;4:514-23.
- Saric M, Perk G, Purgess JR, Kronzon I. Imaging atrial septal defects by realtime three-dimensional transesophageal echocardiography: step-by-step approach. J Am Soc Echocardiogr 2010;23:1128-35.
- Laura DM, Donnino R, Kim EE, Benenstein R, Freedberg RS, Saric M. Lipomatous atrial septal hypertrophy: a review of its anatomy, pathophysiology, multimodality imaging, and relevance to percutaneous interventions. J Am Soc Echocardiogr 2016;29:717-23.

- 25. Reddy VY, Holmes D, Doshi SK, Neuzil P, Kar S. Safety of percutaneous left atrial appendage closure: results from the Watchman Left Atrial Appendage System for Embolic Protection in Patients with AF (PROTECT AF) clinical trial and the continued access registry. Circulation 2011;123: 417-24
- 26. Tzikas A, Holmes DR Jr., Gafoor S, Ruiz CE, Blomstrom-Lundqvist C, Diener HC, et al. Percutaneous left atrial appendage occlusion: the Munich consensus document on definitions, endpoints, and data collection requirements for clinical studies. Europace 2017;19:4-15.
- 27. Möbius-Winkler S, Majunke N, Sandri M, Mangner N, Linke A, Stone GW, et al. Percutaneous left atrial appendage closure: technical aspects and prevention of periprocedural complications with the Watchman device. World J Cardiol 2015;7:65-75.
- 28. Holmes DR Jr., Kar S, Price MJ, Whisenant B, Sievert H, Doshi SK, et al. Prospective randomized evaluation of the Watchman Left Atrial Appendage Closure device in patients with atrial fibrillation versus long-term warfarin therapy: the PREVAIL trial. J Am Coll Cardiol 2014;64:1-12.
- 29. Viles-Gonzalez JF, Kar S, Douglas P, Dukkipati S, Feldman T, Horton R, et al. The clinical impact of incomplete left atrial appendage closure with the Watchman Device in patients with atrial fibrillation: a PROTECT AF (Percutaneous Closure of the Left Atrial Appendage Versus Warfarin Therapy for Prevention of Stroke in Patients With Atrial Fibrillation) substudy. J Am Coll Cardiol 2012;59:923-9.
- Sepahpour A, Ng MK, Storey P, McGuire MA. Death from pulmonary artery erosion complicating implantation of percutaneous left atrial appendage occlusion device. Heart Rhythm 2013;10:1810-1.
- Saw J, Lempereur M. Percutaneous left atrial appendage closure: procedural techniques and outcomes. JACC Cardiovasc Interv 2014;7:1205-20.
- Freixa X, Abualsaud A, Chan J, Nosair M, Tzikas A, Garceau P, et al. Left atrial appendage occlusion: initial experience with the Amplatzer Amulet. Int J Cardiol 2014;174:492-6.
- Parashar A, Tuzcu EM, Kapadia SR. Cardiac Plug I and Amulet devices: left atrial appendage closure for stroke prophylaxis in atrial fibrillation. J Atr Fibrillation 2015;7:1236.
- 34. Hildick-Smith D. AMULET observational study: multicenter, prospective, registry results with a left atrial appendage closure device for stroke prevention in patients with atrial fibrillation. Available at: https://www.tctmd.com/slide/amulet-observational-study-multicenter-prospective-registry-results-left-atrial-appendage. Accessed October 10, 2017.
- Massumi A, Chelu MG, Nazeri A, May SA, Afshar-Kharaghan H, Saeed M, et al. Initial experience with a novel percutaneous left atrial appendage exclusion device in patients with atrial fibrillation, increased stroke risk, and contraindications to anticoagulation. Am J Cardiol 2013;111:869-73.
- **36.** Patel TK, Yancy CW, Knight BP. Left atrial appendage exclusion for stroke prevention in atrial fibrillation. Cardiol Res Pract 2012;2012:610827.
- 37. Singh SM, Dukkipati SR, d'Avila A, Doshi SK, Reddy VY. Percutaneous left atrial appendage closure with an epicardial suture ligation approach: a prospective randomized pre-clinical feasibility study. Heart Rhythm 2010;7: 370.6
- **38.** Bartus K, Morelli RL, Szczepanski W, Kapelak B, Sadowski J, Lee RJ. Anatomic analysis of the left atrial appendage after closure with the Lariat device. Circ Arrhythm Electrophysiol 2014;7:764-7.
- Hussain A, Saric M, Bernstein S, Holmes D, Chinitz L. Hemostasis of left atrial appendage bleed with lariat device. Indian Pacing Electrophysiol J 2014;14:273-7.