

# Catheter Management of Left Atrial Appendage Closure Devices

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## Continuing Education Activity

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For patients with atrial fibrillation, percutaneous left atrial appendage closure (LAAC) emerged as a valid alternative to oral anticoagulation. This activity reviews the evaluation, indications/contraindications, pre/post-procedural management of percutaneous LAAC and highlights the role of the interprofessional team in evaluating and treating this condition.

### Objectives:

- Identify indications and contraindications for percutaneous left atrial appendage closure.
- Describe pre-procedural planning and preparation to perform successful percutaneous left atrial appendage closure.
- Summarize the complications of percutaneous left atrial appendage closure.
- Explain the importance of collaboration and communication amongst the interprofessional team to ensure the appropriate selection of candidates for percutaneous left atrial appendage closure and to enhance post-procedural management.

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## Introduction

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Atrial fibrillation (AF) is the most common type of heart arrhythmia affecting 33.5 million people worldwide.[1][2] The most dreaded complication of this disease is stroke, which is also the leading cause of disability in the United States.[3] AF increases the risk of ischemic stroke by 4 to 5 fold in all ages when left untreated.[3][4] Moreover, AF is correlated with a higher risk of extracranial thromboembolic aortic events and also in the mesenteric, renal, and peripheral arteries.[5] The number of strokes attributed solely to AF increases with age approaching 23.5%. [4][6] In AF patients, oral anticoagulants (OACs) remain the gold standard treatment. The role of OACs in preventing strokes is well established, yet it is contraindicated in patients with an increased risk of bleeding.[7][8] Hence, left atrial appendage occlusion (LAAO) has risen as an alternative approach in this subset of patients.

## Anatomy and Physiology

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The left atrial appendage (LAA) is a trabeculated long tubular structure connected to the venous portion of the left atrium (LA) through a narrow junction. The size and shape vary widely, but in about 70% of the patients, the appendage has a bent or spiral axis.[9] LAA divides anatomically into three portions; the ostium, the neck, and the lobar region.[10] Remodeling of LAA leading to dilation, stretching, and reduction of pectinate muscle volume occurs in chronic AF patients. [11] On transesophageal echocardiography (TEE), about 5% to 15% of AF patients have atrial

thrombi, which are situated in LAA in about 91% of non-rheumatic AF patients.[12][13][14][15][16]

During the sinus rhythm, the contraction of LAA causes vigorous blood flow in and out of the appendage cavity. When there is a contractile dysfunction in the LAA, as in AF, it can predispose to local stasis, thrombosis, and systemic embolization. Changes in the left ventricular function (which may be impaired in AF) influence the extent of LAA filling and emptying more than the LAA function.[17] In normal conditions, the ventricular filling produces a suction effect inside the cavity that affects LA and LAA emptying and loading.

## Indications

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The majority of the institutions consider LAAC when AF patients are at high thromboembolic risk (with a CHADS<sub>2</sub>DS<sub>2</sub>-Vasc score of greater than or equal to 3 or CHADS<sub>2</sub> score of greater than or equal to 2) with contraindication for long term oral anticoagulants (OACs), as well as patients with thromboembolic events despite adequate use of OACs. It is also indicated when there is a high probability of therapeutic non-compliance to OACs and patients with OAC intolerance. The 2019 American College of Cardiology (ACC) and the American Heart Association (AHA) guidelines on the management of atrial fibrillation gave a class IIb recommendation for percutaneous LAAC in patients with an increased risk of stroke who cannot tolerate long term anticoagulation.[18] There was a similar recommendation by the European Society of Cardiology (ESC) and the European Stroke Organization (ESO) in their 2016 guidelines for managing atrial fibrillation.[19]

The depth of the left atrial appendage must be at least longer than the width of the ostium of the LAA for optimal device deployment and closure of LAA. The United States Food and Drug Administration (FDA) approved only one device for stroke and systemic embolism reduction in 2015, the Watchman (Boston Scientific, Natick, MA, USA). However, its use is limited to patients at increased stroke risk and can tolerate short-term anticoagulation. Another device used off-label for LAAC is the Lariat (SentreHeart Inc., Redwood City, CA, USA), which is FDA-approved for facilitating percutaneous ligation of LAA. Percutaneous LAAC is performed off-label for patients intolerant to OACs and at high risk of stroke. However, there is a lack of strong evidence supporting its use in these patients. In AF patients undergoing cardiac surgery, concomitant surgical ligation of the left atrial appendage is a class IIb indication.[20]

## Contraindications

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Patients with a low risk for stroke with CHADS<sub>2</sub>DS<sub>2</sub>-Vasc score less than 3 or a CHADS<sub>2</sub> score of less than 2 are not recommended to have LAAC. Valvular heart disease, such as mitral stenosis, is another contraindication for the intervention. Patients with left atrial thrombus or tumor, active infection, the presence of atrial septal defect (ASD), or a prior patent foramen ovale (PFO) closure device are not recommended for trans-septal catheterization. Patients who have other indications for long-term or lifelong OACs, such as patients with a prosthetic valve, pulmonary embolism, deep vein thrombosis, and thrombi in the left atrium or ventricle, should not undergo left atrial appendage closure.[21] The left atrial appendage closure is also contraindicated if the depth of the LAA is significantly shorter than the width of the ostium of LAA. Based on current guidelines, patients who are unable to tolerate short-term oral anticoagulation are contraindicated to undergo percutaneous LAAC.

## Equipment

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## **PLAATO**

In 2001, Sievert achieved the first-in-human percutaneous LAAC using the PLAATO device (Appriva Medical, Sunnyvale, CA).[22] The device had a self-expanding metal cage made of nitinol, coated with non-thrombogenic polytetrafluoroethylene, with anchors along three struts to help anchor the device into the LAA, and was available in different sizes from 15 mm to 32 mm. It was delivered through a 14-Fr delivery sheath guided by fluoroscopy and transesophageal echocardiography (TEE). The device was withdrawn from the market in 2006 despite a favorable clinical trial.[23]

## **Watchman and Watchman FLX**

Watchman device (Boston Scientific, Natick, MA) is the only device that has been evaluated in randomized clinical trials.[24][25][26] It is composed of a 10-strut semi-spherical self-expanding nitinol frame with a 160 µm permeable polyethylene terephthalate membrane fabric cap facing into the body of LA. The device size is based on the diameter of the proximal shoulder of the device, which is its widest portion. The model comes in 21 mm, 24 mm, 27 mm, 30 mm, and 33 mm sizes. The open distal end is fixed in 1 row by ten active fixing anchors. The device is connected by a threaded insert inside the proximal cap to a delivery cable. The outer diameter of the transseptal access sheath is 14F and comes in anterior, double, and single curves. The double curve is used in more than 90% of the procedures. The device needs to be 8% to 20% larger than the body of LAA. This device is used to occlude LAAs about 17 mm to 30 mm in diameters as long as there is adequate depth to accommodate the device, the length of which is approximately equal to its fully expanded diameter. Before release from the delivery cable, the device can be partially recaptured and redeployed if the location of the implant is too deep, and it can also be fully recaptured and removed if a different device size is required or it is deployed too proximally. The device is authorized for use in the United States and is CE marked in the European Economic Area for sale.

The WATCHMAN FLX (Boston Scientific) is a second-generation device fully covered by the polyethylene terephthalate membrane cap to minimize peri-device leaks.[27] It is available in 5 sizes (20 mm, 24 mm, 27 mm, 31 mm, and 35 mm) for 15 mm to 32 mm LAA ostia and is 10% to 20% shorter than the previous generation unit. Combined with greater radial strength, the increased number of struts (18), and anchors (12 in 2 rows), it provides improved tissue fixation. While a greater compression (10% to 37%) was initially permitted, an increased risk of device embolization with excessive oversizing was observed. The WATCHMAN FLX got the CE-mark approval in 2015 but was removed from the European market in March 2016 due to increased implant embolization incidents.

## **AMPLATZER Cardiac Plug and Amulet**

The AMPLATZER Cardiac Plug (ACP; Abbot Vascular, Santa Clara, CA) is a self-expanding nitinol mesh with a proximal polyester fabric disk and distal lobe connected by an articulated waist.[28] The device length is less than its diameter, accommodating to shorter LAAs. There are six pairs of stabilizing wires in the lobe aimed to be implanted in the orifice of LAA at 10 mm, while the disk is designed to seal the ostium at the left atrial side. Its delivery sheath (TorqVue TM) has two 45° curves to help with positioning. Eight different sizes based on the lobe dimensions, from 16 mm to 30 mm, are available (12.6 mm to 28.5 mm for landing zone measurements). If required, the ACP can be recaptured and re-positioned.

The Amulet device (Abbot Vascular) is based on ACP device design but with improvements facilitating implantation and reducing procedural complications.[28] Eight different sizes of this device ranging from 16 mm to 34 mm, are available, which fit LAA sizes of 11 mm to 31 mm (landing zone measurements). The distal lobe of the Amulet device is 2 mm to 3 mm longer, and the diameter of the proximal disk is 6 mm to 7 mm larger than the distal lobe diameter when compared to the ACP device and has more stabilizing wires and a longer waist improving stability. Furthermore, to reduce device thrombosis, the proximal end screw was recessed. As a result, less oversizing is needed for this device due to its more stable design.[29] Both the ACP and the Amulet have been approved with the CE mark.

### **WaveCrest**

The WaveCrest device (Biosense Webster, Diamond Bar, CA) is a single-lobe nitinol device with polyurethane foam facing the LAA and an expanded polytetrafluoroethylene cover on the left atrial side and has 20 anchoring points.[30] The occluder and anchoring systems can be independently manipulated in the device, and the contrast can be injected either proximally through the delivery sheath or distally through the occluder, ensuring good sealing. In addition, the device does not require delivery sheath placement in LAA, as the device is intended for proximal positioning in the neck of LAA, making it particularly beneficial for small LAA anatomies. In 2013, the WaveCrest (Biosense Webster Inc.) earned CE mark approval.

### **Occlutech LAA Occluder**

The Occlutech LAA Occluder (Occlutech International AB, Helsingborg, Sweden) is a self-expanding conical-shaped nitinol wire mesh and is anchored at the distal margin through the closed loops.[31] The polyurethane coverage of the device promotes sealing and endothelization. It received the CE mark in 2016.

### **Lambre LAA Closure System**

The LAMBRE LAA Closure System (Lifetech Scientific Co, Ltd, Shenzhen, China) is another nitinol device with a left atrial cover and a distal self-expanding umbrella, protected by a double polyethylene terephthalate membrane and attached with a central articulating waist.[32] A double stabilization mechanism with eight distal hooks and eight proximal U-shaped anchors secures the device. With hooks recessed until deployment, the distal umbrella is the first to be deployed, and the proximal cover is then released. Two types of LAMBRE devices, including the standard and the special address single- and double-lobe anatomy, respectively. The special type is especially useful for multilobed or small LAAs. It has a low profile (8F to 10 F) and is fully recapturable and repositionable. This device earned its CE-mark approval in 2016.

### **Ultraseal LAA Closure Device**

Another self-expanding device is an Ultraseal LAA closure device (Cardia Inc, Eagan, MN), which is comprised of two sections: a soft distal bulb for anchoring the device and a 3-leaflet proximal sail for occlusion of LAA. Both are connected with a dual articulating joint, enabling multidirectional mobility and optimum adjustment of various ostium angles and shapes.[33] The device has 12 stabilizing hooks to prevent dislodgement. It is available in 9 bulb sizes ranging from 16 mm to 32 mm, and oversizing of 25% to 33% is usually recommended. The proximal sail is 6 mm larger than the distal bulb, with a covering of polyvinyl acetate foam, with diameters of 22 mm to 38 mm. Two available delivery sheaths range from 10F to 12F, namely a single curve (45 degrees) and a double curve (45 degrees –45 degrees).

## **Pfm Device**

The Pfm device (Pfm Medical, Köln, Germany) is a nitinol frame device consisting of three parts: a primary distal anchor, a middle connector, and a proximal disk with a secondary anchor. [34] The middle connector has an adjustable length accommodating variable LAA lengths. The device consists of a 10F to 12F delivery sheath and is secured by a barbless anchor, minimizing perforation risk.

## **Epicardial Devices**

### **Lariat**

The Lariat (SentreHeart, Redwood City, CA) device enables the percutaneous delivery of pretied surgical sutures to ligate the LAA. It is cleared by the FDA for the approximation of soft tissue. [35] It is used off-label for LAAC. It consists of 0.025-inch and 0.035-inch magnet-tipped guidewires (FindrWIRZ) and 15-mm compliant occlusion balloon catheter (EndoCATH). It combines both endocardial and epicardial access. Computed tomographic (CT) screening is essential before the procedure to determine the suitability of LAA anatomy for the device. The contraindications for the device use include LAA diameter greater than 40 mm, prior cardiac surgery, pectus excavatum deformity, multilobed LAA, and posteriorly oriented LAA. However, the latest generation of LARIAT+ delivery devices has an increased snare width from 40 mm to 45 mm, enabling treatment for LAAs greater than 40 mm. The device received its CE-mark approval in 2015.

### **Sierra Ligation System**

The Sierra Ligation System (Aegis Medical Innovations, Vancouver, Canada) is an epicardial device having single access through subxiphoid through electrographic navigation. [36] No transeptal puncture is required, unlike the Lariat system. The device consists of a LAAC grasper and a ligator, the former having articulating jaws with mounted electrodes to identify electric activity from the LAA.

## **Personnel**

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The procedure is performed in a standard cardiac catheterization laboratory. An anesthesiologist, an imager, and the implanter are the main participants in the procedure. The patient is given general sedation to protect the airway during extended TEE imaging and prevent potential sudden movements by the patient, which may cause cardiac perforation while manipulating LAA. The C-arm fluoroscopy is positioned just to the left of the operator, allowing more freedom of movement for the echocardiographer, who sits at the head of the table. Echocardiographers and anesthesiologists are provided with appropriate radiation shielding. The operator can see TEE images in real-time with the ultrasound machine slaved to the boom. [29][37]

## **Preparation**

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A pre-procedural transesophageal echocardiogram (TEE) is used for evaluating suitable candidates and determining the LAA morphology and dimensions. Important elements to be determined are the shape and size of the ostium, the width of the landing zone, the LAA length, and the number, shape, and location of the lobes, if possible. [38] The landing zone is defined as the area within the LAA where the device will be positioned. Additional pre-procedural imaging with computed tomography (CT) or magnetic resonance imaging (MRI) should be considered in the presence of large LAA neck width (greater than 26 mm) or a complicated LAA anatomy.

Given size limitations associated with each device, good pre-procedural planning avoids unnecessary termination of the LAA closure procedure after the patient has undergone induction with general anesthesia.[39][37][40][41]

Also, the LAA size depends on LA pressure and the presence of sinus rhythm or AF. Hence, certain operators prefer measuring LAA dimensions during the procedure after saline infusion establishes an LA pressure of greater than 10 mm Hg. To rule out post-procedural pericardial effusion and device embolization, many institutions and centers perform a chest radiograph and a TTE. To verify the complete sealing of the LAA and the absence of a thrombus, a TEE is recommended after 45 days. Post LAA closure, various antithrombotic/anticoagulation regimens have been used, including warfarin, dual antiplatelet therapy (DAPT), direct oral anticoagulants (DOAC), aspirin monotherapy, and no therapy. Therapy with either DAPT or DOAC does not significantly increase the incidence of device thrombus, stroke, or bleeding compared with standard warfarin therapy.[42]

## **Technique or Treatment**

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### **Implantation of the device**

Percutaneous LAA closure is generally performed with general anesthesia guided by TEE and fluoroscopy. Prior to the procedure, antibiotic prophylaxis is usually given. Vascular access is achieved via a femoral vein, and transseptal puncture using a standard transseptal needle and sheath is done for the delivery system. The puncture site in the fossa is preferably inferior and posterior to have a good alignment with the LAA axis. Furthermore, there are different curves of sheaths available for accessing LAA. A bolus of unfractionated heparin should be provided after the puncture to obtain an activated clotting time (ACT) of more than 250 s. The size of the device is chosen based on LAA dimensions (ostium, neck width, depth) with the help of TEE and contrast angiography (right anterior oblique 30°/ cranial 30°). The desired implantation angulation of the C-arm may vary greatly from patient to patient. TEE and fluoroscopy ensure the location of the device in the LAA. The sheath over the device reduces the risk of perforation, and the device is subsequently deployed. A ‘tug test’ is performed once the device is in position to confirm device stability. Color Doppler imaging verifies complete sealing. The device is finally released from the delivery cable, and potential complications (e.g., pericardial effusion) are ruled out. The individual steps differ from one device to another and are described below.

### **Watchman**

The device is selected by determining LAA size by the combination of TEE and fluoroscopic measurements. TEE excludes the presence of LAA thrombus before the procedure. However, cardiac CT can also be used for pre-procedural planning.[43] In the inferoposterior part of the interatrial septum, a 14-Fr double- or single- curved access sheath is inserted into the LA through a transseptal puncture. The 14-Fr sheath is placed deep inside the LAA and often telescoped over a diagnostic pigtail catheter to prevent laceration and perforation of LAA. The device is preloaded in a delivery system and is attached to a delivery cable. It is advanced to the tip of the access sheath, and the sheath is withdrawn. The device deployment follows this. TEE and fluoroscopy guide the device implantation, with TEE playing a critical role in determining the adequacy of the device employment. It is then released if the required TEE and fluoroscopic measurements are met by the counterclockwise rotation of the delivery cable.[44]

### **Amplatzer Cardiac Plug and Amulet**

The landing zone is estimated between 12 mm to 15 mm from the LAA orifice both for ACP and Amulet.[45] The 12 Fr to 14 Fr double-curved delivery sheath is introduced into the LAA from the right femoral vein through a transseptal puncture. Post-procedural antiplatelet therapy is recommended for ACP for 1-6 months without OACs, and following it, aspirin is given indefinitely.[45] It is best to avoid appendages with more than 40 mm diameter, lobes behind the pulmonary artery, and posterior orientation of LAA.

### **Lariat**

Cardiac CT determines the anatomic eligibility for the procedure. A second-generation device is larger and allows appendages up to 45 mm in diameter. The procedure requires an intact pericardium; hence it cannot be performed in patients with prior cardiac surgery. It is also discouraged in patients with prior pericarditis as the pericardial adhesions may prevent manipulation in the pericardial space and impede procedural success. Using an epidural or micropuncture needle under fluoroscopic guidance, a 14-Fr, slightly curved, and the soft-tipped sheath is advanced into the anterior pericardial space. Using the standard technique, after pericardial access is achieved, a transseptal sheath of 8.5-Fr is inserted into the LA from the right femoral vein; an inferoposterior location is usually favored in the interatrial septum. Through the transseptal sheath, a magnet-tipped guidewire is progressed into the anterior portion of the LAA, and a complementary magnet-tipped guidewire is progressed through the pericardial sheath and attached to the magnet-tipped wire in the LAA, forming a rail upon which the snare is delivered.

TEE and fluoroscopy guide the snare advancement into the pericardial sheath and over LAA, and LAA ostium is closed later. The snare is composed of a preloaded and tied surgical suture. Using a suture-tensioning device, the operator releases the suture with a proximal actuator and then tightens the pretied knot, after which the snare is withdrawn, and the suture is cut using a suture cutter. The pericardial sheath is substituted for a drain and remains in place for 4 to 6 hours, at least. The procedure can be summarized into four steps: Pericardial and transseptal puncture, endocardial magnet-tipped wire advancement into LAA apex, endocardial and epicardial magnet-tipped guidewires connection over which the Lariat snare is advanced, and the snare positioning and LAA ostium capture with the help of TEE-guided placement of inflated EndoCATH balloon catheter, and subsequently LAA suture ligation.[46]

### **WaveCrest**

The WaveCrest is positioned to occlude the LAA, and its position is tested to confirm adequate seal and lack of a peri-device leak. The anchors are subsequently deployed to the distal edge of the device in a separate step. The "tug test" is subsequently performed to confirm the stability of the device before the device is released. Advantages include more flexibility while closing the LAA regardless of its depth and less traumatic deployment.[47]

## **Complications**

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The most common complications are pericardial effusion or cardiac tamponade requiring intervention, device-related thrombus, device embolization, persistent atrial septal defect (ASD), cardiac perforation, and procedure-related stroke. The incidence of pericardial effusion/tamponade is about 1.2% to 5% and, in the majority of cases, is managed with pericardiocentesis.[25][48][24][49][50][51][52][53][29][54] The incidence of device embolization has been reported as high as 3.5%, requiring transcatheter removal or surgery. However, the incidence is much lower amongst experienced operators (much less than 1%).[25][48][24][49][51][52][53][29][54]

Device-related thrombus can be encountered in up to 14% of patients and is managed with a longer course of anticoagulation with a success rate approaching 95% (median treatment duration of 45 days).[55][48][51][52][53][29] The majority of these patients are asymptomatic, with an overall incidence of neurological events attributed to device-associated thrombus being very low (0.28%).[55] Persistent ASD incidence accounts for about 11% at six months and 7% at 12 months post-procedure.[56] Usually, ASD is small and does not require treatment. Cardiac perforations occur in up to 0.4% of patients and require surgical intervention.[25] Up to 1.1% of patients develop procedure-related stroke requiring management.[25][48][24][50][51][52][53][54] Other less common complications are procedure-related death and vascular complications such as hematoma, bleeding, and AV fistula formation.

## **Clinical Significance**

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Clinical outcomes have been tested in various studies. Clinical efficacy and safety of the Watchman device have been evaluated in two randomized controlled trials (RCTs) and various large registries, demonstrating consistent improvements in procedural successes and complication rates. The PROTECT-AF trial and PREVAIL compared the WATCHMAN device and anticoagulation in patients with AF. The PROTECT-AF trial showed a procedural failure rate of 9%, with procedural-related complications of 8.7%, mostly secondary to pericardial effusion (4.8%).[24] This resulted in a high rate of primary safety events in the Watchman group compared to the anticoagulation group with a rate ratio (RR) of 1.69, 95% confidence interval (CI) of 1.01-3.19. The mean follow-up was 18 months. The primary endpoint was a stroke, systemic embolism, or cardiovascular death, which occurred in 3% in the study group versus 4.9% in control (RR-0.62, 95% credible interval, 0.35-1.25). Hemorrhagic strokes were less in the WATCHMAN group, as well as a reduction in the composite endpoint of death or disabling stroke in the device arm (RR-0.41, 95% CI, 0.22-0.82). There was about 60%, 34%, and 85% reduction in cardiovascular death (RR-0.4, 95% CI, 0.21-0.75), all-cause mortality (RR-0.66, 95% CI, 0.45-0.98) and hemorrhagic stroke (RR-0.15, 95% CI, 0.03-0.49).

Subsequently, the PREVAIL trial conducted on 407 patients showed a significant drop in procedure-related complications, even though it contained higher-risk patients, and about 40% of operators were novices.[25] It compared OAC-eligible patients with WATCHMAN device versus warfarin. The results showed a seven-day safety event rate of 2.2% in the Watchman group and a substantial reduction in serious procedural-related complications rate (4.2%,  $p = 0.004$ ). Mean follow-up was for 12 months, and the non-inferiority criterion was not achieved for the first coprimary efficacy endpoint (stroke, systemic embolism, and cardiovascular death), but was achieved for the second coprimary endpoint (a stroke or systemic embolism greater than seven days; 0.02353 versus 0.02000 (risk difference, 0.0053; 95% credible interval, -0.0190 to 0.0273). Two large registries, the European EWOLUTION registry and the post-FDA approval US experience, included 1021 and 3822 patients, respectively. They demonstrated technical success rates of greater than 95% and significantly low rates of serious adverse effects within 7 days post-procedure.[54][52] Complication rates of serious pericardial effusion were 0.3% and 1.0%, respectively, with less than 0.5% of procedure-related stroke, embolization of device, and procedure-related death rates.

ACP was first studied in 2011, demonstrating procedural success rates of 96% and serious adverse effects of 7%, of which 3.5% were pericardial effusion.[45] Another report from the largest multicenter registry studying 1047 patients showed a high procedural success rate of 97.3% with a serious adverse effects rate of 5%, of which cardiac tamponade and major bleeding

accounted for 1.2%, ischemic stroke for 0.9%, and device embolization and procedural-related death of 0.8%.<sup>[57]</sup> Another prospective study of the Amulet device studied 1088 patients. It demonstrated technical success rates of 99% and procedural or in-hospital complication rates of 3.2%, of which pericardial tamponade accounted for 1.2%, procedure-related death of 0.2%, an ischemic stroke of 0.2%, and device embolization of 0.1%.<sup>[58]</sup> Another large observational registry with 500 patients showed device repositioning and left ventricular dysfunction associated with a higher number of serious adverse effects.<sup>[59]</sup>

In patients with LAA anatomies unsuitable for endocardial devices, Lariat is a great option, although the procedure's safety is still a concern. There are many studies with the use of a Lariat device.<sup>[60][61][62][63][64][65]</sup> Results of a retrospective safety registry with 154 patients showed a high technical success rate of 94%.<sup>[60]</sup> However, major complications occurred in about 10%, significant pericardial effusion rate-10%, major bleeding rate-9%, and emergency surgery requirement-2% of the patients. High procedural complication rates, including death, have led to Lariat being confined to off-label use for LAAC based on FDA safety advisory recommendations. In another large series of the Lariat device in 712 patients showed a success rate of greater than 95% and complication rates of 5.3%, which was lower when compared to the prior studies. Complication rates were as follows: procedure-related death-0.1%, cardiac perforations requiring surgery-1.4%, and cardiac perforations not requiring surgery-2%. This decrease in cardiac perforation risk was due to the use of a micropuncture needle during pericardial access.

## Enhancing Healthcare Team Outcomes

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For AF patients, percutaneous LAAC has emerged as a valid alternative to OAC. Although randomized control trials have mostly been restricted to patients who can tolerate short-term OAC, registries have shown some benefit in patients at high risk of stroke and intolerance and/or contraindications to OAC, with consistent safety improvements as long-term efficacy of the procedure. Current recommendations from professional societies support the use of percutaneous LAAC in AF patients with high stroke risk and contraindication for long-term anticoagulation. [Level 1] Guidelines recommend 6 weeks of oral anticoagulation plus aspirin followed by aspirin plus clopidogrel up to 6 months post-procedure. Aspirin will subsequently be continued for the lifetime of the patient.<sup>[20][66]</sup>

However, the post-procedural antithrombotic regimens are sometimes modified in select patients (especially in patients with recurrent bleeding after LAAC) to balance the risk of bleeding and device-associated thrombus. Patients undergo a transesophageal echocardiogram at 6 weeks to confirm adequate sealing of LAA and rule out device-related thrombus, as this might change the duration of oral anticoagulation. An interprofessional team including an interventional cardiologist, non-invasive cardiologist specialized in multimodality imaging, cardiac anesthesiologist, nurses, and catheterization laboratory technologists work together to provide an integrated and holistic approach to pre-procedural planning, intra-procedural support, and post-procedural care to ensure an optimal outcome for the patient. Communication, shared decision-making, and collaboration between the interprofessional team members are key elements for excellent outcomes. Interprofessional care also helps identify early and late complications of percutaneous LAAC and, therefore, improves patients' prognosis and improves patient outcomes while reducing adverse events. [Level 5]

## Review Questions

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