

Version 3.0

Central Committee on Cardiac Service Effective date: 1 April 2019 Last review date: 15 March 2024

Left Atrial Appendage Occlusion (LAAO) (左心耳封堵術)

Document no.: PILIC0275E version3.0 Page 1 of 4

# <u>Left Atrial Appendage Occlusion (LAAO)</u>

#### Introduction

Atrial fibrillation (AF) is the most common cardiac arrhythmia, affecting 3-5% of the population aged 65-75years, and increasing to >8% of those older than 80 years. It is associated with substantial mortality and morbidity, particularly due to fatal or disabling stroke. The risk of ischemic stroke in patients with non-valvular AF is 3-5% per year, which is a fivefold increase compared with the unaffected population.

For prevention of this complication, oral anticoagulation (OAC) is the standard treatment in patients with AF and at high risk for stroke. This anticoagulant therapy has been proven to effectively prevent thromboembolic strokes, but the increased risk of serious bleeding prevents many patients from taking this therapy. Therefore, alternative treatment option for stroke prevention – without increasing the risk of bleeding – in patients with AF with increased stroke risk are needed.

Percutaneous left atrial appendage occlusion (LAAO) is a minimally invasive therapy, which should be taken into consideration in those patients with AF with a high stroke risk and not suitable for long-term use of OAC.

## **Pre-Procedure Preparation**

- Doctor will review your medical record, history and current medications to confirm you are suitable for LAAO.
- Trans-esophageal echocardiogram (TEE) will be performed to assess and confirm the anatomy of left atrial appendage, to see whether you are suitable for LAAO.
- Doctor will explain to you and your relatives the benefits and details of the procedure, together with the possible risks and complications. You have to sign a consent form.
- Before the procedure, your doctor may prescribe oral anticoagulation or antiplatelet medications for you to prevent blood clot formation. You will be given antibiotic to decrease your chance of infection on the date of procedure.
- Oral anticoagulation medication or Metformin (for diabetes) may have to be stopped several days before the procedure. Drugs such as steroid may be prescribed as prophylaxis for allergy.
- Fasting of 4-6 hours is required prior to the procedure. An intravenous drip may be set up. Shaving may be required over the puncture sites.
- If you are a female, please provide your last menstrual period and avoid pregnancy before the procedure as this procedure involves exposure to radiation.



Central Committee on Cardiac Service Effective date: 1 April 2019 Last review date: 15 March 2024 Version 3.0 Left Atrial Appendage Occlusion (LAAO) (左心耳封堵術)

Document no.: PILIC0275E version3.0 Page 2 of 4

### The Procedure

- Placement of the left atrial appendage occluder will be performed by cardiologists experienced in intervention for structural heart diseases. This procedure will be performed in a well-equipped cardiac catheterization laboratory guided by fluoroscopy and TEE. Intra-cardiac echocardiography may also be used for guidance of procedure.
- This procedure is performed under sterile conditions with general anesthesia (GA) or monitored anesthetic care (MAC) delivered by an anesthetist. The procedure may also be performed using local anaesthetic.
- Electrodes will be adhered on the chest to monitor the heart rate and rhythm. Blood oxygen monitor through your fingertip will be set up. Measurement of blood pressure from your arm will be taken during the procedure.
- Your doctor may perform TEE during the procedure. This test uses sound waves (ultrasound) to take a closer look at the structures of the heart. To perform the test, you will swallow a thin flexible tube with a special tip. This tube sits in the esophagus (the tube that connects the mouth to the stomach). The special tip of the tube sends out sound waves that echo within the chest wall. The esophagus is located behind the heart so these echoes are picked up and create a picture of the heart that is displayed on a video monitor. The pictures will allow your doctor to take a closer look at your left atrial appendage (LAA).
- A small wound is made over the groin for access to your vein. Both groins may be used. Sheaths will be placed inside the vein. Catheters are advanced to the heart. Pressures within the heart are measured.
- The septum separating the left and right atrium is punctured by a special needle under echocardiographic or fluoroscopic guidance. Contrast injection may be required for the procedure.
- Appropriate size of LAAO device will be chosen according to the repeated measurement over your LAA by echocardiographic and fluoroscopic assessment.
- After deployment of the LAAO device, your doctor will confirm the device is located at optimal position with firm stability, adequate size compression, and adequate sealing over all lobes of LAA. After the final release of the LAAO device, the device will be detached from the catheter that will be removed out of your body.

### **Post-Procedure Care**

- After the procedure, catheters will be removed. The wound site will be compressed or sutured to stop bleeding.
- Nursing staff will check your blood pressure, pulse and wound regularly.
- Bed rest may be necessary for 4 hours. In particular, please do not move or bend the affected limb. Whenever you cough or sneeze, please apply pressure on the wound with your hand.



Central Committee on Cardiac Service Effective date: 1 April 2019 Last review date: 15 March 2024

Version 3.0

Left Atrial Appendage Occlusion (LAAO) (左心耳封堵術) Document no.: PILIC0275E version3.0

Page 3 of 4

- You should inform your nurse if you have any discomfort in particularly chest discomfort or found blood oozing from the wound site.
- Once diet is resumed, please take more fluid to help eliminate contrast by passing urine.
- Please follow instruction on the use of medications.

## **Post-Procedure Follow Up**

- Usually, you can be discharged a couple of days after the procedure.
- The wound will be inspected and covered with light dressing. Please keep the wound site clean and change dressing if wet. In general, showers are allowed after 2 days.
- Please avoid vigorous activities (household or exercise) in the first 3 days after the
  procedure. Bruising around the wound site is common and usually subsides 2-3
  weeks later. If you notice any signs of infection, increase in swelling or pain over
  the wound, please come back to the hospital or visit a nearby Accident and
  Emergency Department immediately.
- Usually, your doctor has explained to you the results of the procedure before discharge. Should you have further questions, you and your close relatives can discuss with your doctor during subsequent follow-up.
- After device implantation, your doctor will prescribe oral anticoagulant, or double anti-platelets (Aspirin and Clopidogrel) for initial 3 to 6 months and then Aspirin alone indefinitely.
- TEE would be performed around 3 months after the procedure to assess the sealing of LAA by the device.

### **Risks and Complications**

- The procedure carries certain risks.
- There is a small risk of around 0.5-1% of respiratory depression, low blood pressure or heart rate associated with GA or MAC. The sedative process will be closely monitored by an anesthetist to ensure safety.
- There is a small risk regarding TEE (less than 0.5% esophageal rupture or aspiration pneumonia) but the test would be necessary in most patients to have a clear look of LAA, to guide the operation and to monitor development of severe complications.
- The procedure is associated with major complications, including cardiac perforation and pericardial effusion/ tampndade (about 0.7-4%), device embolism (about 1%), stroke (about 0.5-0.7%), major bleeding (about 0.5-1%) and death (about 1%). (Reference 1-4)
- Other potential risks include air embolism resulting in death or neurological damage, retained foreign body such as guide wires.



Version 3.0

Central Committee on Cardiac Service Effective date: 1 April 2019 Last review date: 15 March 2024

Left Atrial Appendage Occlusion (LAAO) (左心耳封堵術)

Document no.: PILIC0275E version3.0 Page 4 of 4

• Device deployment complications include device dislodgement, device entrapment and wire fracture.

## **Fees and Charges**

- This procedure involves the use of consumables that are 'Privately Purchased Medical Items'.
- Please note that the procedure may need to be staged or re-do for various reasons. Separate charging is required for each procedure.

#### Remarks

- It is hard to mention all the possible consequences if this procedure is refused.
- The list of complications is not exhaustive and other unforeseen complications may occasionally occur. The risk quoted is in general terms.
- If complications occur, another life-saving procedure or treatment may be required immediately.
- If there is further query concerning this procedure, please feel free to contact your nurse or doctor.

### Reference

- 1. Holmes DR, Reddy VY, Turi ZG, et al. Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomised non-inferiority trial. Lancet 2009;374:534–42.
- 2. Reddy VY, Holmes D, Doshi SK, et al. 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;23:417–24.
- 3. Reddy VY, Möbius-Winkler S, Miller MA, et al. Left atrial appendage closure with the Watchman device in patients with a contraindication for oral anticoagulation: the ASAP study (ASA Plavix Feasibility Study with Watchman Left Atrial Appendage Closure Technology). J Am Coll Cardiol 2013;61:2551–6.
- 4. Tzikas A, Shakir S, Gafoor S, et al. Left atrial appendage occlusion for stroke prevention in atrial fibrillation: multicentre experience with the AMPLATZER Cardiac Plus. EuroIntervention 2016;11(10):1170-9.
- 5. Kar S, Doshi S K et al. Primary Outcome Evaluation of a Next-Generation Left Atrial Appendage Closure Device: Results From the PINNACLE FLX Trial. Circulation 2021;143(18):1754-1762.