

REVIEW

2019 Chinese expert consensus statement on left atrial appendage closure in patients with atrial fibrillation

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Abstract

The left atrial appendage closure (LAAC), the efficacy and safety of which has been proved by a number of randomized controlled trials and registries, is recommended by several guidelines to prevent stroke in high-risk patients with non-valvular atrial fibrillation. However, current guidelines only discuss the indications and contraindications of LAAC, as an emerging technology, there still lacks comprehensive recommendations involved with LAAC, including devices, image assessment modality, identification and treatment of complications, perioperative medication, and postoperative management. Therefore, the Chinese Society of Cardiology (CSC) of Chinese Medical Association (CMA) and the Editorial Board of Chinese Journal of Cardiology jointly issued the expert consensus statement on LAAC in the prevention of stroke in patients with atrial fibrillation after comprehensive discussion by experts with different backgrounds. This consensus provided three levels of recommendations to guide and standardize the clinical application of LAAC based on existing evidence and clinical practice experience, including appropriate (more potential benefits or fewer harms), uncertain (somehow reasonable but need more evidence), and inappropriate (unlikely to benefit, or have more complications).

KEYWORDS

atrial fibrillation, China, expert consensus, left atrial appendage closure, stroke

Abbreviations: AF, atrial fibrillation; ACP, Amplatzer Cardiac Plug; ACC, American College of Cardiology; ACT, activated clotting time; AHA, American Heart Association; AO, aorta; ASD, atrial septal defect; CABG, coronary artery bypass grafting; CCTA, cardiac computed tomography angiography; CSC, Chinese Society of Cardiology; CSPE, Chinese Society of Pacing and Electrophysiology; CSA, Chinese Society of Arrhythmia; CMA, Chinese Medical Association; DAPT, double antiplatelet therapy; DRT, device-related thrombosis; DSA, digital subtraction angiography; ESC, European Society of Cardiology; GFR, glomerular filtration rate; HRS, Heart Rhythm Society; INR, international normalized ratio; ICE, intracardiac echocardiography; LA, left atrium; LAAC, left atrial appendage closure; LAA, left atrial appendage; LMWH, low-molecular-weight heparin; LSPV, left superior pulmonary vein; LVEF, left ventricular ejection fraction; NOAC, novel oral anticoagulant; NSAIDs, nonsteroidal anti-inflammatory drugs; NIHSS, National Institutes of Health stroke severity scale; NYHA, New York Heart Association; OAC, oral anticoagulants; RA, right atrium; RAO, right anterior oblique; SAPT, single antiplatelet therapy; RCTs, randomized controlled trials; SVC, superior vena cava; TEE, transesophageal echocardiography; TIA, transient ischemia attack; TTE, transthoracic echocardiography; VKA, vitamin K antagonist

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TABLE 1 The appropriateness criteria linked with LAAC* and its relevant techniques

Definition	Appropriateness class
LAAC and its relevant techniques are reasonable to perform for more clear benefits or fewer procedure-related complications.	Appropriate
LAAC and its relevant techniques are relatively reasonable for possible benefits or fewer procedure-related complications, but needs more evidence for routine clinical use.	Uncertain
LAAC and its relevant techniques are not necessarily reasonable for routine clinical use because of unlikely clinical benefits or more procedure-related complications.	Inappropriate

LAAC, left atrial appendage closure.

1 | BACKGROUND

Atrial fibrillation (AF), one of the most rapidly growing areas of cardiovascular diseases, has made great progress in therapeutic conception, medications, and techniques. Since first clinically applied in 2001 and recommended by 2012 European Society of Cardiology (ESC) guidelines for AF management, the left atrial appendage closure (LAAC) technology has achieved rapid development. Currently, there are dozens of LAAC devices for clinical use, including the plug-like occluders (represented by Watchman/Watchman FLX, USA) and the pacifier ones (represented by LAmbre/LAcbes, China and Amplatzer Cardiac Plug (ACP)/Amulet, USA).¹ The efficacy and safety of LAAC has been confirmed by two randomized controlled trials (RCTs, PROTECT AF and PREVAIL)²⁻⁵ and several long-term follow-up registries,^{6,7} and LAAC is recommended for the prevention of stroke in non-valvular atrial fibrillation (NVAF) by current guidelines in China, the United States, Europe, and other countries.⁸⁻¹²

LAAC in clinical practice involves not only indications and contraindications but also comprehensive application of various devices and operations, imaging evaluation, guidance and follow-up, identification and treatment of complications, perioperative and postoperative medication, and postoperative management. Current evidence, however, is unable to cover all aspects of LAAC, and the technique and operation of LAAC are lack of specific recommendations from current guidelines. Consequently, the Chinese Society of Cardiology (CSC) of Chinese Medical Association (CMA) and the Editorial Board of Chinese Journal of Cardiology jointly issued the expert consensus statement on LAAC in the prevention of stroke in patients with AF after comprehensive discussion by experts with different backgrounds, so as to guide and standardize the clinical application of LAAC. Based on understanding of the potential benefits and adverse effects of each technical detail of LAAC from existing evidence and clinical practice, the consensus provided with three levels of recommendation criteria including appropriate (reasonable, with more potential benefits or fewer harms), uncertain (somehow reasonable but need more evidence), and inappropriate (unlikely to benefit, or have more complications) (Table 1),

2 | PREVALENCE OF ATRIAL FIBRILLATION

AF is the most common arrhythmia in the elderly. A European epidemiological investigation showed that the incidence of AF is below 2% under 50 years, 2.2% to 4.2% aged from 50 to 61 years, 7.3% to 11% aged from 62 to 72 years, 14.4% between 73 and 79 years, and 17.6% for the population over 80 years, respectively.¹³ An American survey in 2013 reported that about 6–7 million patients were diagnosed with AF.¹⁴ According to the report of Chinese cardiovascular disease in 2013, the prevalence of AF was 0.77% for the Chinese population aged 30–85 years. It is estimated that there are 8 to 10 million AF cases in China.¹⁵ AF incidence will continue to increase due to population aging and the improvement of AF screen and diagnosis, and its relevant symptoms and complications will become a major health problem in modern society.

3 | STROKE RISK EVALUATION AND ANTICOAGULATION TREATMENT IN ATRIAL FIBRILLATION

Thromboembolic events, especially ischemic stroke, are the leading causes of disability and deaths for AF patients. The overall risk of ischemic stroke in patients with AF is 20%–30%, regardless of the type of AF.⁸ And strokes caused by AF account for 20% of all strokes. What is more, AF patients tend to have comorbidities, such as hypertension, diabetes, heart failure, coronary disease, and so on, which is not only related to occurrence and recurrence of AF but also increases risks of ischemic stroke and other systemic thromboembolic events.

Since first introduced in the 2010 ESC guidelines for the management of AF,¹⁶ CHA₂DS₂-VASc score (Table 2) has been widely used to assess the risk of stroke and decide whether to initiate anticoagulation. According to the 2016 ESC AF management guideline,⁸ long-term anticoagulation treatment is recommended for CHA₂DS₂-VASc score ≥ 2 points in men and ≥ 3 points in women (I, A).

Anticoagulation treatment, however, objectively increases the bleeding risks. Patients may also have some subjective reasons for

TABLE 2 CHA₂DS₂-VASc score

Risk factors	Score
Chronic heart failure/ejection fraction \leq 40%	1
Hypertension	1
Age \geq 75 years	2
Diabetes	1
Stroke/TIA ^a /thromboembolic events	2
Vascular disease	1
Age \geq 65 years	1
Sex category (female)	1
Total	9

TIA, transient ischemia attack.

poor adherence or intolerance (such as fear of bleeding, refuse, or not follow medical directions). According to RCTs like ARISTOLE,¹⁷ ROCKET-AF,¹⁸ RE-LY,¹⁹ the annual incidence of major bleeding events ranged from 2.13% to 3.6%, and a cumulative annual incidence of major and minor bleeding events ranged from 14.4% to 25.6% for patients treated with vitamin K antagonist (VKA) or novel oral anticoagulant (NOAC). Discontinuation rate was as high as 16.6%–25.3% due to bleeding events or fear of bleeding, which may be even higher in real world. Based on a study from Europe, only 50% of patients with AF received anticoagulation therapy,²⁰ and discontinuation rate of anticoagulation after 5 years was as high as 70%.²¹ Whereas, only less than 10% of AF patients in China received anticoagulation therapy,²² beyond this, the discontinuation rates increased gradually, with 22.1% of patients at the third month, 44.4% at 1 year, and nearly 60% at 2 year after initiating anticoagulation.²³ Since the value of anticoagulation therapy in the prevention of stroke in AF is limited by the existence of subjective and objective factors such as bleeding risks, poor adherence and tolerance, and so on, an alternative method with high safety and efficacy is needed.

4 | THE THEORETICAL BASIS OF LAAC, TECHNIQUE FEASIBILITY, AND EVIDENCE

Thromboembolic events related to AF are caused by detachment of the thrombus in the left atrium (LA). Previous studies found that in patients with NVAf, more than 90% of left atrial thrombi are located in the left atrial appendage.^{24–26} What is more, a recent study showed that left atrial appendage thrombosis was an absolute finding in NVAf patients who had developed cardiogenic thrombosis, regardless of the existence of extra-appendage thrombosis.²⁷ Theoretically, most thrombosis and thromboembolic events can be prevented by using any tech-

niques to isolate the left atrial appendage from the circulation, which is the theory foundation of LAAC.

It is technically feasible to deliver a device using catheter delivery system to cover or fill the left atrial appendage in order to isolate the blood flow between the LAA and left atrium, which is the design principle of LAAC devices. Under the premise of standardized operation, the learning curve of LAAC is not very long, and the safety of procedure has been improved with the accumulation of clinical experience. In the PROTECT-AF trial performed in 2005, the reported LAAC success rate with Watchman device was only 91%, but the procedure-related complication rate was as high as 8.4%.² With the accumulation of operating experience, improvement of device design, and the establishment of “PASS” principle, the reported LAAC success rate increased to 95.1% in the PREVAIL trial conducted between 2010 and 2014, with only a 4.2% of perioperative major adverse events within 7 days post-procedure.³ Later in 2016, a large multi-center registry named EWOLUTION achieved further progress with the 98.5% LAAC success rate and 2.7% perioperative complication rate.²⁸ Other LAAC devices such as ACP/Amulet and LAMBRE share the similar success rate and safety regardless of different designs and procedures.^{29–33}

Watchman is the first LAAC device with enrollment of clinical trial, subsequent approval by the FDA and sole recommendation by the guidelines. It is also the most evidence-based LAAC device. PROTECT AF and PREVAIL are the key two RCTs which focus on comparing Watchman device with warfarin in patients eligible for oral anticoagulants (OACs).^{3–5} Based on their medium- and long-term follow-up results, the Watchman device was non-inferior or somewhat superior to warfarin for the composite endpoints of stroke, systemic embolism and cardiovascular death, and even superior in all-cause death, disabling or fetal stroke, hemorrhagic stroke, and major bleeding.^{3–5} The post hoc analysis of 707 patients in PROTECT AF trial and 566 patients in CAP registry showed that the net annual clinical benefits of Watchman deducted from warfarin's benefits on ischemic stroke, intracranial hemorrhage, major bleeding, pericardial effusion, and death are 1.73% in PROTECT AF and 4.97% in CAP registry, respectively. The net clinical annual benefit of patients with previous ischemic stroke or TIA was higher in CAP registry than PROTECT AF trial (8.68% vs. 4.3%). The findings of this study also favored that patients with higher CHADS₂ score could have more clinical benefits.⁷

There are currently no large-scale trials comparing LAAC with NOACs; however, the first randomized trial of PRAGUE-17³⁴ was designed to determine whether LAAC was noninferior to NOACs in the composite endpoint of all-cause stroke, TIA, systemic cardioembolic event, clinically significant bleeding, cardiovascular death, or a significant periprocedural or device-related complications after 24-months follow-up. According to the preliminary results with an average follow-up of 20 months released in 2019 ESC congress, LAAC was noninferior to NOAC in preventing major AF-related cardiovascular, neurological, and bleeding events. Besides, recent results of two meta-analyses also showed noninferiority or superiority of LAAC to NOACs, and the benefits of which increase over time.^{35,36} Except for Watchman and ACP/Amulet devices, evidence for other types of devices is relatively

TABLE 3 HAS-BLED bleeding risk score

Letter	Clinical characteristic ^a	Points awarded
H	Hypertension (systolic blood pressure > 160 mm Hg)	1
A	Abnormal renal or liver function (1 point each)	1 or 2
S	Stroke	1
B	Bleeding	1
L	Labile INRs	1
E	Elderly (e.g. age >65 years)	1
D	Drugs or alcohol (1 point each)	1 or 2
	Total	Maximum 9 points

^a Hypertension' is defined as systolic blood pressure ≥ 160 mmHg. 'Abnormal kidney function' is defined as the presence of chronic dialysis or renal transplantation or serum creatinine ≥ 200 mmol/L. 'Abnormal liver function' is defined as chronic hepatic disease (e.g. cirrhosis) or biochemical evidence of significant hepatic derangement (e.g. bilirubin ≥ 2 x upper limit of normal, in association with aspartate aminotransferase/alanine aminotransferase/alkaline phosphatase ≥ 3 x upper limit normal, etc.). 'Bleeding' refers to previous bleeding history and/or predisposition to bleeding, e.g. bleeding diathesis, anaemia, etc. 'Labile INRs' refers to unstable/high INRs or poor time in therapeutic range (e.g. $\geq 60\%$). Drugs/alcohol use refers to concomitant use of drugs, such as antiplatelet agents, non-steroidal anti-inflammatory drugs, or alcohol abuse, etc. INR $\frac{1}{4}$ international normalized ratio.

inadequate. Now there is an ongoing trial of Amulet IDE comparing Amulet and Watchman.³⁷ LAmbré device (Lifetech Scientific corporation, Shenzhen) is a novel device made in China. Studies of LAAC with LAmbré device showed the 99%–100% procedure success rate and 3.3%–6.7% perioperative complication. After 1-year follow-up, no device-related thrombosis (DRT) was observed and only one TIA case and three minor bleeding events occurred in 152 patients who received LAAC with LAmbré device, indicating the similar safety and efficacy to other devices.^{32,33}

5 | RECOMMENDATION ON INDICATIONS AND CONTRAINDICATIONS OF LAAC

5.1 | Indications of LAAC

Although LAAC has been applied clinically since 2001, it is not recommended until 2012 ESC guidelines for AF management. According to the 2012 ESC guideline,³⁸ LAAC is reasonable in NAVF patients who were contraindicated to long-term anticoagulation, or at high risk of bleeding (HAS-BLED ≥ 3 , Table 3) unsuitable for long-term anticoagulation (IIb).⁸ There were no significant updates in 2016 ESC guidelines due to lack of new RCTs. Soon afterwards, however, the Munich consensus in 2017³⁹ and EHRA/EAPCI expert consensus statement update in 2019⁴⁰ provided recommendations for potential indications, devices during the procedure, imaging assessment, and some tips of LAAC.

The approval of LAAC in the United States was relatively late. Due to lack of sufficient evidence and approval of FDA, LAAC got no recommendation for stroke prevention in AF patients by the American College of Cardiology (ACC)/American Heart Association (AHA)/Heart Rhythm Society (HRS) in 2014.⁴¹ However, the AHA/American Stroke Association guideline suggested that LAAC could be applied in stroke prevention in 2014 (IIb).¹⁰

In March 2015, Watchman device got approval by FDA, and indications suitable for medical insurance coverage were specified.⁴² With more evidence of efficacy and safety of medium-to-long-term accumulated, LAAC was finally recommended for stroke prevention in NVAF patients with high risks of stroke and intolerance of long-term anticoagulation (IIb) by AF management guidelines of ACC/AHA/HRS in 2019.¹¹ In Current Knowledge and Management Recommendations of Atrial Fibrillation-2015⁹ and Current Knowledge and Management Recommendations of Atrial Fibrillation-2018¹² by Chinese Society of Pacing and Electrophysiology (CSPE) and Chinese Society of Arrhythmia (CSA), LAAC was recommended in prevention of thromboembolic events for NVAF patients (IIa, evidence of level B).

However, current recommendations of LAAC by guidelines mainly focus on the management of AF based on indications and contraindications, it is necessary to have a comprehensive expert consensus to guide and standardize the LAAC operation process and its relevant technical application. Consequently, the consensus expert committee believes that different levels of recommendations should be given to the indications of LAAC and the application of related technologies based on different clinical situations, including stroke risk score, the possibility and feasibility of long-term adherence to anticoagulants, bleeding risk assessment, and patients' wishes (Table 4).

5.2 | Contraindications of LAAC

Patients with any of the following conditions are not recommended for an immediate LAAC procedure:

1. suspected thrombus or confirmed thrombus in left atrium or left atrial appendage detected by transesophageal echocardiography (TEE) or cardiac computed tomography angiography (CCTA);

TABLE 4 Recommendations on LAAC indication in patients with NVAF

Clinical situation	Appropriateness level
Patients with high risks of stroke (CHA ₂ DS ₂ -VAsc score:male ≥ 2 , female ≥ 3), who have contradictions for long-term OAC but can tolerate short-term anticoagulation (2–4 weeks) with a single anticoagulant or dual antiplatelet-therapy, should be considered for LAAC.	Appropriate
Patients with high risks of stroke (CHA ₂ DS ₂ -VAsc score:male ≥ 2 , female ≥ 3), who have life-threatening bleeding or other bleeding that cannot be corrected (e.g., intracranial/intraspinal bleeding, severe gastrointestinal/pulmonary/urinary bleeding) due to OAC, should be considered for LAAC.	
Patients with high risks of stroke (CHA ₂ DS ₂ -VAsc score:male ≥ 2 , female ≥ 3), who have high risks of bleeding (HAS-BLED score ≥ 3), may be considered for LAAC.	Uncertain
Patients with high risks of stroke (CHA ₂ DS ₂ -VAsc score:male ≥ 2 , female ≥ 3), who have a history of ischemic stroke or other systematic thromboembolic events during OAC therapy, may be considered for LAAC.	
Patients with high risks of stroke (CHA ₂ DS ₂ -VAsc score:male ≥ 2 , female ≥ 3), who are unable adherent to/tolerate long-term OAC (e.g., living alone, dementia, or disability), but may tolerate short-term (2–4 weeks) single anticoagulant or dual antiplatelet therapy, may be considered for LAAC.	
Patients with previous thrombus in LAA detected by TEE or CCTA, but dissolved after anticoagulation therapy, may be considered for LAAC.	
Patients with high risks of stroke (CHA ₂ DS ₂ -VAsc score:male ≥ 2 , female ≥ 3), but without high risk of bleeding (HAS-BLED score < 3), who are unwilling or not compliant to long-term anticoagulation therapy even if without contradictions for OAC, may be considered for LAAC.	
Patients who have received or are going to receive electrical isolation ablation of LAA, LAAC may be considered as a simultaneous or staging procedure with catheter ablation.	
Patients with low risks of stroke (CHA ₂ DS ₂ -VAsc score ≤ 1), who has no evidence of thrombosis detected by TEE or CCTA, should not be considered for LAAC.	Inappropriate
Patients with high risks of stroke (CHA ₂ DS ₂ -VAsc score:male ≥ 2 , female ≥ 3) and low bleeding risk (HAS-BLED score < 3), who has no contradictions of OAC and are willing to receive long-term anticoagulation therapy, should not be considered for LAAC.	
Patients with previous severe disabling ischemic stroke, who have severe paralysis, aphasiac or immobilization, or other situations resulting life expectancy less than 1 year after active rehabilitation, should not be considered for LAAC.	

CCTA, cardiac computed tomography angiography; LAAC, left atrial appendage closure; NVAF, non-valvular atrial fibrillation; OAC, oral anticoagulants; TEE, transesophageal echocardiography.

- the anatomy of left atrial appendage is too complicated to close the LAA successfully (no suitable LAAC device for the too large or too small ostium size or the complicated anatomy);
- left ventricular ejection fraction (LVEF) $< 30\%$ measured by transthoracic echocardiography (TTE);
- more than 10 mm unexplained pericardial effusion at the base of heart or posterior wall;
- the existence of other conditions, excepted for AF, need long-term anticoagulation therapy, such as mechanical valve replacement, spontaneous or recurrent venous thromboembolism, and so on;
- the presence of rheumatic heart valve disease, mitral stenosis (valve opening area $< 1.5 \text{ cm}^2$), or after mechanical valve replacement;
- Severe heart valve disease or abnormal heart structure needs surgical treatment (such as huge atrial septal defect [ASD] or ventricular septal defect), or coronary heart disease requiring coronary artery bypass grafting (CABG);
- Patients with new-onset ischemic stroke/TIA without hemorrhagic transformation are not suitable for immediate anticoagulation treatment assessed by National Institutes of Health stroke severity scale (NIHSS)⁸ and neurology physicians;
- Patients with acute ischemic stroke with hemorrhagic transformation or intracranial hemorrhage caused by anticoagulation

are not eligible for anticoagulation after multidisciplinary evaluation;

- life expectancy < 1 year; and
- uncontrolled heart failure with New York Heart Association (NYHA) IV class.

6 | PREPROCEDURAL PREPARATION

6.1 | Preprocedural examination and assessment

Laboratory tests should be conducted before the procedure, including coagulation function, renal/liver function, routine blood test, and so on. Preprocedural imaging is essential for understanding anatomy features of LAA and heart function. Appropriateness reviews of imaging modalities are shown in Table 5.

6.1.1 | Transthoracic echocardiography (TTE)

Procedural TTE assessment is essential for understanding the anatomy features, including size of left atrium, atrial septum, valves, LVEF, pericardial effusion, and so on. It is recommended to perform TTE examination within 1 week before LAAC.

TABLE 5 Appropriateness of preprocedural imaging evaluation

Imaging evaluation	Appropriateness
TTE: routine TTE should be performed within 1 week before LAAC to evaluate the left ventricular function, dimension of left atrium, atrial septum, valves, pulmonary artery pressure and pericardial effusion. TEE: TEE should be performed within 48 h before LAAC to determine the anatomical characteristics of the left atrial appendage (morphology, ostial width and depth of LAA, lobes, and distributions of pectinate muscles), thrombus/grades of spontaneous echo contrast, atrial septum, systolic function and emptying velocity of LAA. CCTA could serve as an alternative method to evaluate anatomical characteristics and thrombus for patients who are unable to tolerate TEE.	Appropriate
Routine CCTA serve as the tool for preprocedural evaluation. Routine TEE or CCTA may be performed more than 2 days before LAAC.	Uncertain
Only under TTE evaluation, LAAC should not be performed without preprocedural evaluation by TEE/CCTA/ICE.	Inappropriate

CCTA, cardiac computed tomography angiography; ICE, intracardiac echocardiography; LAAC, left atrium appendage closure; TEE, transesophageal echocardiography; TTE, transthoracic echocardiography.

6.1.2 | Transesophageal echocardiography (TEE)

2D TEE and 3D TEE play the most important role in procedural assessment of LAAC, which can provide static and dynamic information of anatomy, including the ostium's width and depth of LAA using as a reference of device selection, identifying thrombus and evaluating the degree of spontaneous echo contrast, and finding out the situation not suitable for LAAC operation. Consequently, TEE has been recommended by a number of international guidelines or consensus^{43,44} for periprocedural evaluation, procedural guidance, and postprocedural follow-up. The SCAI/ACC/HRS institutional and operator requirements for left atrial appendage occlusion in 2015⁴⁴ mentioned that TEE equipment and specialist are necessary for LAAC procedure. Therefore, we recommend TEE as the routine assessment tool for periprocedural evaluation, procedural guidance, and postprocedural follow-up.

When performing TEE examination, four views should be taken at 0°, 45°, 90°, and 135° to determine the anatomical features, including lobes, largest measurements of ostium and depth of LAA (maximum landing zone dimension), thrombus, grades of spontaneous echo contrast, and position and distribution of pectinate muscles. In addition, it is necessary to describe atrial septum (such as defects, aneurysm, and patent foramen ovale [PFO]) and the adjacent structures of mitral valve and pulmonary veins. A research showed that there was a slight difference in the width of ostium measurement between TEE (usually smaller), LAA angiography, and CCTA,⁴⁵ which cannot be ignored during the device size selection. As for patients with contraindications for TEE examination, intracardiac echocardiography (ICE) could serve as an alternative method for procedural guidance and CCTA is another tool for preprocedural evaluation and postprocedural follow-up. It is suggested that TEE should be performed within 48 h before LAAC or ICE assessment just before LAAC procedure when contraindicated to TEE, to exclude thrombus in left atrium and left atrial appendage following by LAAC procedure.

6.1.3 | Cardiac computed tomography angiography (CCTA)

CCTA could serve as an alternative of preprocedural evaluation and postoperative follow-up for patients who are unable or unwilling to perform TEE examination. The measurement of ostium's width by CCTA is usually 3 mm larger than TTE,⁴⁶ which must be considered during device selection. What is more, CCTA has lower sensitivity and specificity of thrombus detection than TEE,⁴⁷⁻⁵² which may be linked with a number of pectinate muscles and insufficient contrast agent filling. Therefore, electrocardiograph modulated CCTA or delayed imaging techniques should be performed by experienced radiologists to determine that the contrast agent fills fully into the distal LAA.

6.1.4 | Other examination

Most of the patients who will undergo LAAC are older, some had cerebral infarction or cerebral hemorrhage, and some patients may have lung disease, so other examination methods, including CT, magnetic resonance imaging (MRI), pulmonary functional test, or other laboratory tests should be conducted as preprocedural assessments, so as to better understand the baseline characteristics of patients and the procedure risks of LAAC.

6.2 | Perioperative medication

6.2.1 | Perioperative anticoagulation

Anticoagulation strategy will be readjusted according to patients's bleeding risk and previous treatment after admission.

Patients who already received NOAC or warfarin should continue administration of previous OAC regimen until the day before LAAC. Patients who took warfarin before operation should be monitored the

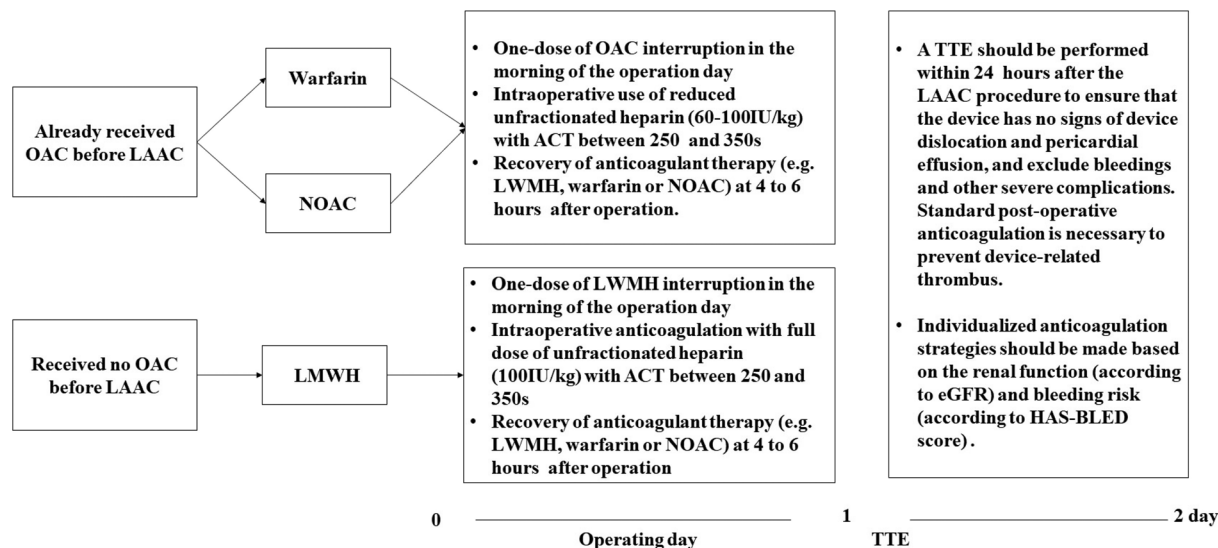


FIGURE 1 Perioperative anticoagulation strategy of LAAC. ACT, activated clotting time; eGFR: estimated glomerular filtration rate; LAAC, left atrial appendage closure; LMWH, low-molecular-weight heparin; NOAC, non-vitamin K antagonist; OAC, oral anticoagulation; TEE, transesophageal echocardiography

international normalized ratio (INR) every day. One-dose of OAC interruption is necessary in the morning of the operation day. During the LAAC procedure, it is important to administer with reduced unfractionated heparin (60–100 IU/kg) for a target activated clotting time (ACT) of 250–350 s. Repeat ACT monitoring and supplemental heparin may be necessary to achieve a therapeutic and safe ACT level.

Patients who received no OAC treatment before admission should be administered low-molecular-weight heparin until the morning of the operation day. One-dose of low-molecular-weight heparin should be interrupted in the morning of the operation day. During the LAAC procedure, full dose of unfractionated heparin (100 IU/kg) should be given for a target ACT time of 250–350 s. Repeat ACT monitoring and supplemental heparin may be necessary to achieve a therapeutic and safe ACT level.

Timely recovery of anticoagulant therapy (e.g., low-molecular-weight heparin, warfarin, or NOAC) is needed depending on the metabolic features of heparin (usually at 4–6 h post-operation) after the exclusion of cardiac tamponade, pericardial effusion, or other severe bleeding events. A TTE examination should be performed within 24 h after the LAAC procedure. After exclusion of the device dislocation, pericardial effusion (compared with the baseline), or other severe bleeding events, individualized anticoagulation strategies should be made based on patient's renal function and bleeding risk (Figure 1, Table 6).

6.2.2 | Other medications

TEE monitoring during the LAAC procedure or combined procedure with catheter ablation and LAAC often makes injuries of esophageal mucosa. Especially in severe cases, some patients may develop atrial-esophageal fistulas after AF catheter ablation. Consequently, this consensus recommends routine intravenous administration of proton

pump inhibitors from the day of LAAC procedure until discharge, followed by oral proton pump inhibitors for 2–4 weeks after discharge.

6.3 | Perioperative nursing

Prior to the procedure, all patients should receive routine nursing of cardiovascular intervention. Venous access is obtained. Dentures should be removed. All patients should keep fasting and absolutely dieted including water and oral drugs for 8 h.

6.4 | Procedure scheme

Operators should be familiar with patient's baseline features and confirm the indications of LAAC. Prior to the LAAC procedure, operators should review examinations of TTE, TEE, or CCTA in details and give further assessment of LAAC, including the LAA anatomy (e.g., ostium width, depth, pectinate muscles, and lobes of LAA), size of left and right atrium, pericardial effusion, thrombi, and whether atrial septal repair or occlusion were performed, and whether pulmonary surgery, thoracic deformity, cardiac transposition, and other special conditions, and predict the difficulty of atrial septal puncture, suitable type, and size of device, and make a comprehensive procedure scheme and alternative plans.

7 | IMPLANTATION TECHNIQUE

7.1 | Anesthesia

General anesthesia allows the immobilization of patients and all the steps under the guidance of TEE, which can improve the suc-

TABLE 6 Post-operative anticoagulation strategy after LAAC

	Recommendations	Appropriateness
0–3 months after LAAC	Patients with GFR \geq 30 mL/min and HAS-BLED score < 3: administrations with NOAC + aspirin/clopidogrel or warfarin (INR 2.0–3.0) + aspirin/clopidogrel for 3 months. Patients with GFR \geq 30 mL/min and HAS-BLED score \geq 3: administrations with full dose of NOAC (e.g., rivaroxaban, edoxaban, apixaban, or dabigatran) or warfarin (INR 2.0–3.0) for 3 months. Patients with GFR < 30 mL/min and HAS-BLED score < 3: administrations with warfarin (INR 2.0–3.0) + aspirin for 3 months. Patients with GFR < 30 mL/min and HAS-BLED score \geq 3: administrations with warfarin (INR 2.0–3.0) or aspirin + clopidogrel for 3 months.	Appropriate
	Patients should not receive no antithrombotic therapy or only use single antiplatelet therapy with aspirin or clopidogrel.	Inappropriate
3–6 months after LAAC	Stop OAC, treat with aspirin + clopidogrel for 3 months.	Appropriate
	Continue OAC therapy (e.g., warfarin or NOAC) or transfer from OAC to single antiplatelet therapy with aspirin or clopidogrel.	Uncertain
>6 months after LAAC	Stop any antithrombotic therapy including OAC and antiplatelet medicine	Inappropriate
	Administered with aspirin (clopidogrel if not suitable for aspirin) in long-term.	Appropriate
Special clinical situations	Continue anticoagulation therapy, or stop antiplatelet therapy.	Inappropriate
	If a residual leak over 5 mm was detected after LAAC, patients should be considered as LAAC failure and administrated with long-term anticoagulation if no remedies. If patients develop into severe bleeding events during OAC treatment, stop OAC therapy and give corresponding antagonist if necessary. When bleeding control achieves, patients may be given reduced dose of OAC or DAPT for short term if necessary. If DRT detected by TEE or CCTA, patients should receive more aggressive anticoagulation therapy (e.g., warfarin/NOAC + aspirin/clopidogrel) for 2–3 month until DRT disappears proved by TEE. Patients with warfarin should maintain the INR level between 2.5 and 3.5; patients with NOAC should use full dose, but dabigatran is not recommended. LMWH for 2–4 weeks is also suggested.	Appropriate

CCTA, cardiac computed tomography angiography; DRT, device-related thrombus; GFR, glomerular filtration rate; INR, international normalized ratio; LAAC, left atrial appendage closure; LMWH, low-molecular-weight heparin; NOAC, non-vitamin K antagonist oral anticoagulants; OAC, oral anticoagulants; TEE, transesophageal echocardiography.

cess rate and safety of the procedure. Besides, in case of severe complications (e.g., malposition of device or cardiac tamponade), it is more convenient for doctors to treat the complications when patients are under general anesthesia. General anesthesia for LAAC is the most common clinical practice in America, Europe, and China. Recently, some researches have reported the noninferiority of LAAC procedure with ICE under local anesthesia to the routine procedure.^{53,54} However, patients under local anesthesia have difficulties in keeping immobilized and calming the breath, which may affect the efficacy and safety of LAAC. Consequently, general anesthesia by assessment of anesthetists for LAAC is recommended (Table 7).

7.2 | TEE for LAAC

TEE plays an important role in LAAC, including guiding the trans-septal puncture, monitoring the steering of the delivery system, sheaths, wires and pigtail catheter in the left atrium, guiding the positioning, deployment, tug test and release of the device, and detecting the complications (i.e., cardiac tampon-

ade, thrombus, etc.). TEE guidance is recommended for LAAC (Table 8).

TABLE 7 Appropriateness review of anesthesia for LAAC

Recommendations	Appropriateness
AF patients should receive TEE-guided LAAC under general anesthesia.	Appropriate
AF patients who are intolerant to TEE may receive ICE-guided LAAC from experienced interventionists with exclusion of thrombus by pre-procedural CCTA. AF patients may receive TEE-/ICE-guided LAAC under local anesthesia or sedation.	Uncertain
AF patients should not routinely receive LAAC under local anesthesia or sedation.	Inappropriate

AF, atrial fibrillation; CCTA, cardiac computed tomography angiography; ICE, intracardiac echocardiography; LAAC, left atrial appendage closure; TEE, transesophageal echocardiography.

TABLE 8 Recommendations on imaging, evaluation and operation in LAAC

Recommendations	Class
After general anesthesia, TEE is performed first to reconfirm whether there is thrombus in the LAA/LA, and to clarify the anatomical characteristics of the LAA afterwards. TEE can clearly show the superior, inferior, anterior, and posterior of the interatrial septum. TEE and X-ray are recommended to be routinely used as the guidance of the transseptal puncture. LAA fluoroscopy is usually performed under RAO30° + CAU20° or other suitable angulations, and an appropriate device is selected according to the ostium diameter and available depth or width of anchor zone measured by DSA and TEE. TEE views of 0°, 45°, 90°, 135° are routinely performed after the device is landed in the LAA. A tug test under TEE or DSA is required to assess the stability of the device and whether it meets the standard of deployment (such as "PASS criteria" and "COST criteria"), after which the device can be completely released. Multiplanar TEE is performed again after the device is completely released to assess the existence of the device displacement, residual leak, impact on surrounding structures such as the pulmonary vein and the mitral valve, and pericardial effusion.	Appropriate
If the patient has an esophageal disorder that cannot tolerate TEE examination or there is difficulty in inserting the TEE probe, ICE-guided LAAC under local anesthesia is considerable if preoperative CCTA examination has clarified the anatomical features of the LAA and excluded thrombus.	Uncertain
It is not recommended to perform LAAC only under DSA without TEE/ICE guidance.	Inappropriate

PASS criteria is the standard of deployment for plug devices, and COST criteria is the standard of deployment for pacifier devices. CCTA, cardiac CT angiography; DSA, digital subtraction angiography; ICE, intracardiac echocardiography; LAAC, left atrial appendage closure; TEE, transesophageal echocardiogram.

7.2.1 | Reassessment by TEE at the beginning of LAAC

Reassessment by TEE should be performed after anesthesia to detect the thrombus, as well as sludge (cloudiness echo is also included) and pericardial effusion. If a thrombus is found, the procedure must be cancelled. The patient should be given a standard anticoagulation therapy for 2–3 months until the thrombus disappears.

7.2.2 | TEE guidance for trans-septal puncture

TEE plays a crucial role in a successful trans-septal puncture by providing an accurate puncture site. It is usually performed using a bicaval view (superior–inferior view) with an imaging plane of 90°–100° and an aortic valve short axis view with an imaging plane of 45°–50° (anterior–posterior view). It is better to set the multi-D mode when performing the trans-septal puncture. An inferior-and-back fossa position is usually the best puncture site (Figure 2).

7.2.3 | TEE guidance for LAAC and assessment for device implantation

Besides detecting thrombus, pericardial effusion, and cardiac tamponade, TEE is also necessary for deployment of the device and final assessment after device release. Before the device deployment, 0°, 45°, 90°, and 135° TEE views are performed to evaluate the device landing, device compression with an acceptable ratio of 8%–30%, peri-device leak assessed by color Doppler, device protrusion. A tug test is performed to assess the stability of the device. A Watchman device must meet the "PASS" criteria prior to the release of a device. The "PASS" criteria refers to position (device landed in a proper position),

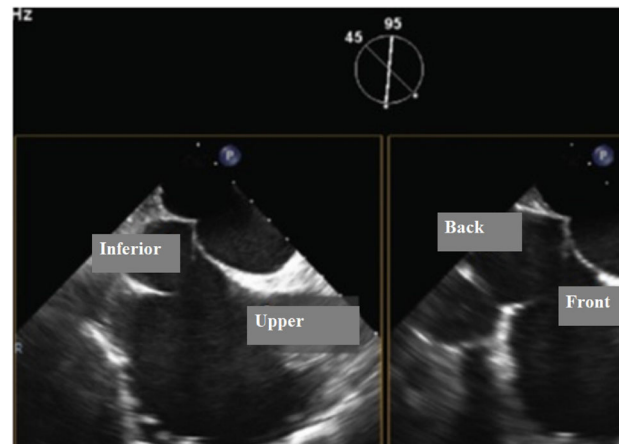


FIGURE 2 The TEE views of the transseptal puncture site. A, Inferior-and-low fossa position. AO, aorta; SVC, superior vena cava; TEE, transesophageal echocardiography [Color figure can be viewed at wileyonlinelibrary.com]

anchor (fixation anchors engaged), size (device is properly compressed of original size), and seal (no peri-device leak).

7.3 | ICE for LAAC

Patients who are intolerant of TEE or general anesthesia could receive ICE-guided LAAC under local anesthesia or sedation by experienced physicians (Figures 4 and 5). CCTA should be performed pre-procedurally to preclude the thrombus in LA or LAA. The procedure using ICE is described as follow. First, a venous access via femoral vein for ICE is obtained using an 11F sheath. Then, advance the ICE probe into right atrium or other sites through the inferior vena cava to observe the LA anatomy, thrombus, and atrial septum (Figure 3).^{55,56} Before the trans-septal puncture, an exclusion of the thrombus in the



FIGURE 3 ICE views of the atrial septum. ICE, intracardiac echocardiography; LA, left atrium; LAA, left atrial appendage; RA, right atrium [Color figure can be viewed at wileyonlinelibrary.com]

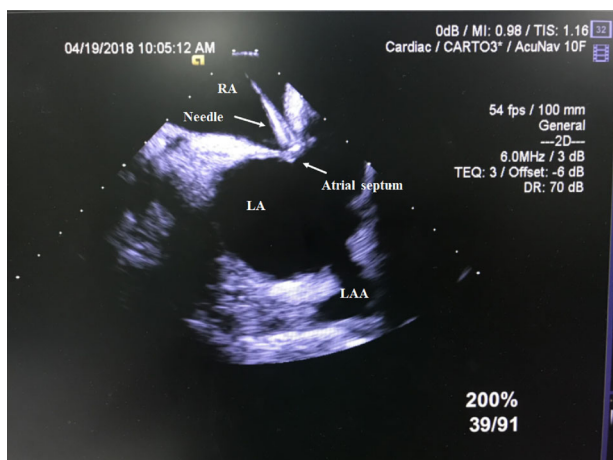


FIGURE 4 Trans-septal puncture under the guidance of ICE. ICE, intracardiac echocardiography; LA, left atrium; LAA, left atrial appendage; RA, right atrium [Color figure can be viewed at wileyonlinelibrary.com]

LA or the LAA is necessary (Figure 4). After crossing the atrial septum, a long guidewire is advanced through the access sheath into the left superior pulmonary vein (LSPV). To dilate the puncture site, the access sheath could be moved back and forth. Subsequently, keep the wire in the LSPV and withdraw the sheath to the right atrium. Then, the ICE probe is advanced through the puncture site to the LV or the LSPV to view the anatomy, size of the LAA, and the existence of the thrombus. Next, keep the ICE probe in the LA or the LSPV and advance the access sheath to the LA to complete the LAAC (Figure 5).⁵⁷

Several studies have reported that an ICE-guided LAAC has similar success rate to that of a TEE-guided LAAC.^{58,59} The main advantage of using ICE in LAAC is to avoid general anesthesia, reduce injuries of esophageal mucosa induced by TEE, and the use of contrast. However, ICE is expensive and only provides limited views. ICE is therefore used as a complementary method to TEE in current clinical practice.

7.4 | Transseptal puncture

Under anterior–posterior projection, the transseptal sheath is sent to the superior vena cava along the 0.032-inch (1-inch = 0.0254 m) long steel wire. The steel wire is withdrawn afterwards, and the transseptal needle connected with the contrast medium is fixed (usually shaped into a certain curve according to the size of the left and right atria) 1 cm from the top of the sheath. Pull down the transseptal sheath to the interatrial septum slowly under the guidance of TEE in Multi-D mode and tenting should be visualized when the tip of the sheath engages the septum. If an appropriate puncture site is located under TEE guidance, the puncture needle can be delivered to the top of the sheath slowly in the 45° right anterior oblique (RAO) view and perform the puncture with a proper clockwise rotation. To confirm the puncture, small amounts of contrast or saline can be injected to visualize the transit of the bubble in the left atrium under TEE. Once the needle accesses the left atrium, fix it with the right hand. The transseptal sheath can be advanced a little into the left atrium and fixed under anterior–posterior projection. Then the needle is withdrawn slowly and the guidewire can be sent into the LSPV. The transseptal sheath is pushed into LSPV after crossing the interatrial septum back and forth to dilate the puncture site. An existence of a leathery or thickened septum often makes the puncture needle difficult to break through the septum and get into the LA, in this condition, the stylet provided with the needle or the back end (hard end) of the coronary intervention guidewire can be used to facilitate puncture. If necessary, the electric surgical knife can be used (electric cutting function, 10–20 Watts, duration: < 2 s). Once the puncture is completed, heparin (usually 60–100 IU/kg) is administered through the sheath. Blood is drawn 5 min later to monitor ACT with a target value between 250 and 350 s (if the procedure time is long, repeated monitoring is needed, and additional heparin is administered if necessary). In those patients who have heparin resistance, heparin-induced thrombocytopenia, or a very high risk of bleeding, bivalirudin can be used instead of heparin.

7.5 | LAA angiography and device implantation

7.5.1 | LAA angiography and measurement

Once the transseptal puncture has finished, remove the dilator and guidewire, and advance a 0.035-inch super-stiff wire with 2.6 m long into distal LSPV through the transseptal sheath. Then the wire is fixed, and the transseptal sheath can be withdrawn, and the occluder access sheath can be carefully sent to the ostium of LSPV via the super-stiff wire. The pigtail catheter (5 or 6 F) is advanced into the ostium of LSPV after removal of the wire and dilator. In general, the pigtail catheter tip should be moved toward the most distal part of the LAA, with the access sheath located at the ostium under RAO caudal 30°/20° (or other appropriate angulations to expose fully the LAA). The contrast agent is injected simultaneously from the flush conduit of access sheath (air excluded) and the pigtail catheter (air excluded) from slow to fast so that each lobe at the ostium and bottom of the LAA can be filled adequately. The maximum ostium diameter and working depth and width

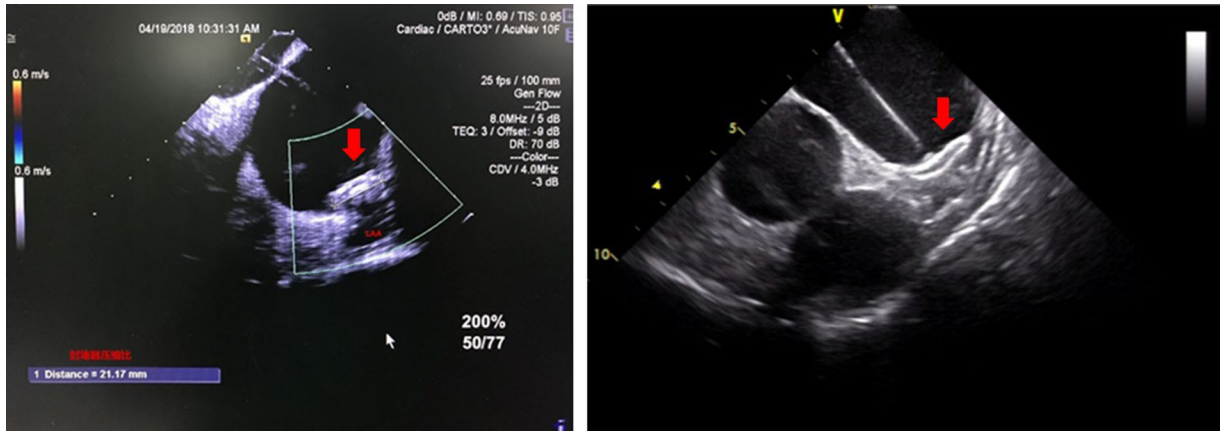


FIGURE 5 Intracardiac echocardiography (ICE) in the left atrium to guide and assess the device deployment. Left panel, the red arrow indicates the WATCHMAN device; right panel, the red arrow indicates the LAMBRE device [Color figure can be viewed at wileyonlinelibrary.com]

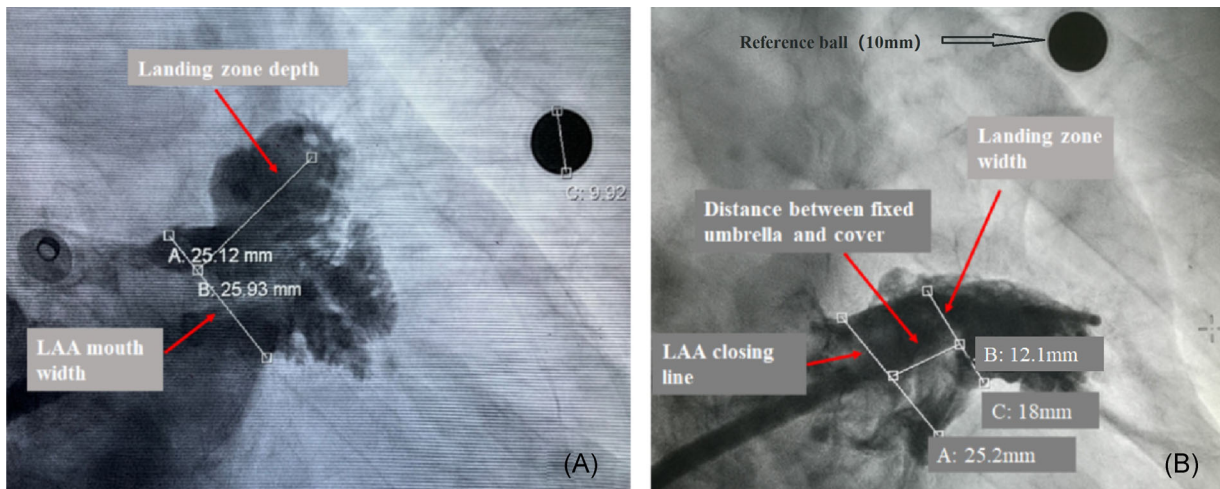


FIGURE 6 Measurement of the left atrial appendage (LAA) under fluoroscopy. (A) The measurements needed for the implantation of a WATCHMAN device; (B) the measurements needed for the implantation of a LAMBRE device [Color figure can be viewed at wileyonlinelibrary.com]

in the landing zone are measured under DSA with a clear display of the shape, ostium, and lobes of the LAA. The border of the LAA is traced on the operation screen with a marker pen when the angiography image is frozen. The sealing line, anchoring area, and working axis are determined for the later selection of device (Figure 6).

7.5.2 | Deployment and TEE evaluation of plug devices

Since Watchman is the most commonly used plug device, we take it as an example to introduce the deployment and TEE evaluation of plug devices. The size of the device (usually 4–6 cm bigger than the orifice measurement) is selected according to the maximum orifice diameter and the working depth of the LAA measured by DSA, combined with the TEE measurement. The device is prepared in vitro and connected

firmly to the delivery cable. The position of the tip of the device should be reconfirmed aligning with the marker band on the tip of the delivery system after repeated flushing to remove air. (It is acceptable to gain a little depth with the 5 mm reserved distance from the distal marker band when the depth is not enough). The operator can first insert the pigtail catheter to the distal part of the anchor zone along the anticipated working axis and then push forward the access sheath carefully to the bottom of LAA. Fix the access sheath and remove the pigtail catheter carefully. The valve of the sheath must stay open to allow blood flowing out from the sheath to flush the air out. Then insert the delivery system carefully with an assistant operator keeping flushing. After half delivery, the contrast agent is connected to the flush conduit at the end of the delivery system, and the device is slowly advanced such that the distal marker band aligns with the distal marker band of the Watchman access sheath (The assistant may inject a small amount of contrast to observe the distance between the tip of the sheath and

the distal wall of the LAA when the device is near the tip of the access sheath. The delivery system can be withdrawn slightly if the distance is too close to the wall of LAA). The delivery system and the access sheath are then locked when the device is in place. The delivery cable is fixed with the right hand of the operator and the access sheath is withdrawn carefully with the left hand after the sheath valve is loosened by the assistant as the device is slowly unfolded to complete the pre-release. The valve is tightened after the pre-release, and the contrast agent is injected to observe whether there is a peri-device leak (tangent angulation is recommended, and large caudal degrees if necessary). Size, shoulder extrusion, peri-device leak, and compression ratio (8%–30%) are checked from different TEE views (0°, 45°, 90°, and 135°) at the same time. Suppose the location of the device is acceptable with complete occlusion (no peri-device leak or less than 5 mm) and no prominent protrusion (less than ¼–1/3 of the device size), a tug test is performed under TEE or DSA. The device cannot be released until there is no change in position or compression ratio, which conforms to the “PASS” criteria of deployment. If TEE indicates any of the following situations, including inappropriate device position, apparent peri-device leak, wrong device size, or the device shape mismatch the LAA, the device can be partially or fully recaptured, and the location or the device size needs adjustment. The process of device redeployment or adjustment needs to be reevaluated by DSA and multiplanar TEE to ensure compliance with the “PASS” criteria.

7.5.3 | The deployment and TEE evaluation of pacifier devices

The pacifier devices include LAmBre, ACP/Amulet, LACbes, and others, which are quite different from the plug devices represented by Watchman in design and deployment. The pacifier devices are implanted close to the ostium of the LAA, therefore, the depth of the LAA is not strictly required. However, the position and axis of the transseptal puncture are still required similar to the plugs. A good axis between the fixing umbrella, the sealing disk, and the access sheath needs to be considered during occlusion. In addition, the influence on surrounding tissues (such as the pulmonary vein and the mitral valve) and displacement after deployment (warped or indented) should be taken into account since the sealing disk (external disk) is usually large in pacifiers.

The LAmBre device is the most widely used pacifier device in China at present. Similar to the other pacifiers, LAmBre is composed of a small fixing umbrella (inner disk) and a large sealing disk (outer disk) connected by a steel cable. A special-designed model with a small umbrella and a large disk is also available. The distance between the disk and the umbrella is 10 mm under a pre-assembly state, which is suitable for different shapes of LAA. Besides, the access sheath of the device is 10–12 F, which is smaller than that of the Watchman device (14 F), causes less damage to the puncture site of the femoral vein and the interatrial septum. Major differences can be seen in device deployment and TEE evaluation compared with those of plug devices represented by Watchman. The specific steps are as follows.

Appropriate device size is selected according to the DSA and TEE measurements and the manufacturer's instructions. In general, a device 2–6 mm larger than the anchor zone is favorable, while a special device (small umbrella with large disk) is preferred if the diameter of the ostium is 6 mm or larger than the anchor zone. The device is advanced to the marker band at the tip of the access sheath by inserting the delivery cable after pre-assembled in vitro and repeated flushing to remove air. The fixing umbrella (inner disk) is unfolded by pushing out the device slowly, and then the access sheath is retracted after fixing the delivery sheath to unfold the sealing disk (outer disk). Fluoroscopy and multiplanar TEE (0°, 45°, 90°, and 135°) are required before deployment to evaluate whether the device conforms to the “COST criteria.” First, C refers to the circumflex artery, as the fixing umbrella should be unfolded distal to the circumflex artery. Second, O refers to fully open, as the fixing umbrella has to be fully unfolded in the anchor zone. Third, S refers to sealing, the outer disk should achieve the best sealing effect (peri-device leak ≤ 3 mm). Fourth, T refers to the tug test, which requires pulling the fixing umbrella before deployment to ensure the stability of the device. In addition, it should also be taken into account whether surrounding structures such as the mitral valve and the LSPV are affected after the outer disk is unfolded, and whether the outer disk has shifted (whether the side of the outer disk is warped or indented) after the tug test. If TEE indicates that the ostium of the LAA is completely occluded by the device, and no impact on surrounding structures such as the mitral valve and the LSPV. If there is no position change between two tugs, the device can be fully deployed. TEE is performed again to assess the displacement, peri-device leak and impact on surrounding structures after complete deployment (Table 8).

8 | POSTOPERATION OBSERVATION AND NURSING (DURING HOSPITALIZATION)

8.1 | Vital signs and heart signs

ECG monitoring is routinely required for 24 h after LAAC procedure to observe heart rate, blood pressure, respiration, and oxygen saturation. It is necessary to closely observe whether there is respiratory depression and aspiration linked with general anesthesia or sedatives used during the operation. Need to be alert to urinary retention, catheterization in time when necessary.

8.2 | Cardiac tamponade and pericardial effusion

In addition to possible acute cardiac tamponade during operation, a small number of patients may have delayed or chronic pericardial effusion (small bleeding might be caused by the anchors of the occluder penetrating the wall of LAA because of oversized compression ratio or fiercely tugging test). Therefore, after returning to the ward, patients should be closely observed for complaints (such as chest discomfort, shortness of breath, irritability, etc.) and signs (such as paleness, sweating, weak pulse, tachycardia or bradycardia, reduced blood pressure,

etc.). Once upon the situation as above occurs, acute cardiac tamponade should be considered, and bedside TTE examination has to be performed immediately. After the diagnosis is confirmed, emergent pericardial puncture and drainage are required, and surgical incision drainage and pericardial repair are needed if the situation is not improved. Except for the immediate bedside TTE examination for symptoms of acute cardiac tamponade, TTE should be performed regularly within 24 h after operation to confirm whether the device is in its primary place, and circumstances, such as delayed cardiac tamponade and pericardial effusion.

8.3 | Vascular access-site complications

Hematoma at the puncture site should be closely observed within 24 h after operation to determine whether there is a puncture complication. Standard anticoagulation can be initiated if serious complications at the puncture site, device dislocation under TTE examination, and cardiac tamponade or obvious pericardial effusion are excluded on the second postoperative day. The patient may be discharged 2–3 days after operation.

9 | POSTOPERATIVE ANTICOAGULATION MANAGEMENT AND IMAGING FOLLOW-UP AFTER LAAC

9.1 | Postoperative anticoagulation management and prevention of device-related thrombosis

Although the efficacy and safety of LAAC in preventing stroke related to AF has been confirmed by the medium and long-term follow-up results of randomized controlled studies^{2–5,34} and multiple registration studies.^{6,7} The incidence of DRT (3.7%–7.2%)^{3,60–64} and the potential increased risk of stroke⁶² also attract wide concern.

The occurrence of DRT after LAAC is not only related to the device, operation and patients' own factors, but also closely related to the intensity and duration of anticoagulation. However, up to now, high-quality prospective RCT studies and specific recommendations of guidelines are still lacking for the most effective anticoagulation regimen to prevent DRT after LAAC. There is no uniform standard in postoperative anticoagulation regimen and duration in real-world clinical practice except for the specific anticoagulation protocols in PROTECT-AF and PREVAIL studies (aspirin + warfarin for 45 days, double antiplatelet therapy [DAPT] with aspirin + clopidogrel till 6 months after TEE exclusion of DRT, and then long-term aspirin). Since the anticoagulation regimen studied by PROTECT AF and PREVAIL is aimed at patients who can tolerate warfarin, doctors still have many concerns on patients with high risk of bleeding in the real world. In the French registered study reported in 2008, of all 487 patients after LAAC, only 4.6% received OAC + single antiplatelet therapy (SAPT), 28.9% used OAC alone, 23.2% took DAPT, and 35.8% used SAPT to prevent DRT, while up to 7.7% of patients did not receive any antico-

agulant or antiplatelet therapy after operation.⁶² In the Evolution registration study, of all those successfully implanted the device, patients who received SAPT, DAPT, and OAC within 3 months after operation are, respectively, 7%, 60%, and 27%, and 6% of patients did not take anticoagulant or antiplatelet therapy; patients who took SAPT, DAPT, and OAC for 3–6 months after operation accounted for 55%, 28%, and 8%, respectively, and 9% of patients did not receive anticoagulation or antiplatelet therapy.⁶¹

The safety of combined therapy with NOAC (rivaroxaban, dabigatran, or apixaban) + clopidogrel (75 mg) for 6–12 months (the annual incidence of TIMI major bleeding is from 1.4% to 2.1%) in patients AF complicated with coronary heart disease has been confirmed by Pioneer-AF PCI study,⁶⁵ RE-DUAL PCI study,⁶⁶ and AUGUSTUS study,⁶⁷ especially the results of AUGUSTUS study,⁶⁷ which further showed that the bleeding risk of combined therapy with apixaban and clopidogrel was significantly lower than that of warfarin and aspirin. The above data indicate that the combined therapy of "NOAC + clopidogrel" may become an effective alternative to the combination with warfarin and aspirin for anticoagulation management after LAAC. In addition, there is limited evidence that the combined therapy with an anticoagulant and an antiplatelet is better than DAPT or SAPT in preventing DRT after LAAC.⁶⁸ In view of the fact that most patients with AF who receive LAAC have a high risk of stroke and a much different risk of bleeding, and some patients are not able to tolerate NOAC due to severe renal insufficiency, this consensus suggests that DRT prevention after LAAC should be individualized according to patients' renal function (assessed by glomerular filtration rate [GFR]) and bleeding risk (assessed by HAS-BLED score).

9.1.1 | Patients without severe renal insufficiency (GFR \geq 30 mL/min)

When the patient has no severe renal insufficiency (GFR \geq 30 mL/min): (1) If the risk of bleeding is low (HAS-BLED score < 3 points), the combined therapy with NOAC or warfarin + clopidogrel or aspirin is given for 3 months, followed by DAPT of aspirin + clopidogrel if DRT and severe peri-device leak (> 5 mm) are excluded by TEE at 3 months. (2) If the risk of bleeding is high (HAS-BLED score \geq 3 points), routine doses of solo NOAC or warfarin should be given for 3 months, and DAPT of aspirin + clopidogrel is prescribed if DRT and severe peri-device leak (> 5 mm) are excluded by TEE at 3 months. If DRT and severe peri-device leak (> 5 mm) are excluded by TEE at 6 months, the long-term aspirin treatment is continued. (Clopidogrel can be an alternative if aspirin is not tolerated).

9.1.2 | Patients with severe renal insufficiency (GFR < 30 mL/min)

When the patient has severe renal insufficiency (GFR < 30 mL/min) (most NOACs are contraindicated or used cautiously on this condition): (1) if the risk of bleeding is low (HAS-BLED score < 3 points), treatment

with warfarin + aspirin combination is given for 3 months (with INR 2.0–3.0). Then, DAPT with aspirin and clopidogrel is followed if DRT and severe peri-device leak (> 5 mm) are excluded by TEE at 3 months. (2) If the risk of bleeding is high (HAS-BLED score ≥ 3 points), it is recommended to use warfarin alone for 3 months under strict monitoring of INR (INR maintained 2.0–3.0), and DAPT of aspirin + clopidogrel is continued for 3 months if DRT and severe peri-device leak (> 5 mm) are excluded by TEE at 3 months; or DAPT of aspirin + clopidogrel may be used directly after LAAC for 6 months. The long-term aspirin treatment is maintained if DRT and severe peri-device leak (> 5 mm) are excluded by TEE at 6 months. (Clopidogrel can be used instead if aspirin is not tolerated).

9.1.3 | Special circumstances

Special circumstances: (1) LAAC is considered to be a failure if a peri-device leak more than 5 mm is detected by TEE or CCTA at any time post-LAAC, and long-term oral anticoagulation therapy should be prescribed if there were no remedies. (2) If DRT is detected by TEE at any time during follow-up, intensive anticoagulation should be given (warfarin or NOAC + aspirin or clopidogrel may be used) for 2–3 months until it disappears. Based on limited evidence, it is recommended to maintain INR 2.5–3.5 if warfarin is used; if NOAC is chosen, it is recommended to use standard dose of rivaroxaban or apixaban instead of dabigatran⁶⁹; low molecular weight heparin may also be used for 2–4 weeks. (3) Anticoagulants have to be discontinued immediately if severe bleeding occurs after operation; when necessary, a selective antagonist of the anticoagulant should be given. Low-intensity anticoagulation or dual antiplatelet therapy is given under bleeding control, and the duration of therapy can be shortened if necessary (Table 6).

9.2 | TEE or CCTA follow-up

DRT is a relatively common complication after LAAC. Once DRT occurs, if it is not detected in time or intensive anticoagulation is not given, it may increase the risk of ischemic stroke and other systemic thromboembolic events. Therefore, this consensus recommends that patients undergoing LAAC should routinely receive TEE follow-up at 3 and 6 months postoperation (if patients cannot tolerate or refuse TEE, CCTA can be used as an alternative). Once DRT is detected, intensive anticoagulation should be prescribed for 2–3 months, and then TEE should be reviewed to observe the changes of DRT, and the number of follow-ups can be increased if necessary. If a residual leak >5 mm is detected, LAAC is regarded as a failure. If there were no remedy, long-term anticoagulation therapy should be maintained.

9.3 | TTE follow-up

Routine TTE examination after LAAC cannot only be used to detect the position of the device and the status, determine the presence, and extent of pericardial effusion, but also assess cardiac systolic and

diastolic function, valve function and disease, and other anatomical changes. It is reasonable to perform a TTE examination at 1, 3, and 6 months after LAAC (Table 9).

10 | IDENTIFICATION AND MANAGEMENT OF LAAC PERIOPERATIVE COMPLICATIONS

10.1 | Pericardial effusion and cardiac tamponade

Pericardial effusion/cardiac tamponade is one of the most serious complications during LAAC operation, which needs to be timely identified and treated. In the PROTECT AF² and PREVAIL³ studies, 4.8% and 1.9% of patients, respectively, in the LAAC group developed pericardial effusion/cardiac tamponade requiring surgical repair or pericardial puncture and drainage; in the subsequent CAP registration study,⁷⁰ post-marketing LAAC clinical studies involving 3822 cases in the United States⁷¹ and EWOLUTION registration study,⁷² the incidence of pericardial effusion was 2.2%, 1.02%, and 0.5%, respectively. It shows that with the continuous improvement of device, the accumulation of operator's experience and the standardization of operation, the incidence of pericardial effusion and cardiac tamponade during LAAC perioperative period has been significantly reduced.

The causes of pericardial effusion and cardiac tamponade are related to operator's experience and LAAC device, including: (1) puncture needle or sheath pierces the atrium or aortic root during transseptal puncture; (2) guidewire or catheter improperly pierces the left atrium or appendage; (3) improper operation during device deployment leads to the tip of device piercing the appendage; (4) the appendage is pierced by the fixed anchor of device when full-recapturing the occluder; (5) the appendage is teared due to excessive force during tug test. If the patient has unexplained dropping of blood pressure, decreased pulse pressure, and increased heart rate during or after operation, TTE should be performed firstly and immediately to determine whether pericardial effusion/cardiac tamponade has occurred. Pericardial effusion/cardiac tamponade during LAAC operation can be detected timely by TEE, and signs with enlarged cardiac shadow, weakened heart beats and contrast developing in pericardial cavity under X-ray fluoroscopy. Cardiac tamponade is life-threatening. First of all, pericardial puncture and drainage should be performed immediately. If the bleeding is small and slow, patient's condition can be closely observed after drainage; if the bleeding is large and fast, pigtail catheter should be inserted for continuous pericardial drainage, and vein autotransfusion should also be performed at the same time. Surgical pericardiotomy and repair should be achieved as early as possible with the drainage maintained if there are no improvements in the above measures.

10.2 | Air embolism and thromboembolism

Air embolism or thromboembolism can occur in arteries throughout the body, most commonly in coronary arteries and cerebral arteries, resulting in ischemic/embolic symptoms in the corresponding blood

TABLE 9 Recommendations on imaging follow-up after LAAC

Methods	Recommendations	Appropriateness
TTE	TTE is routinely performed at 1, 3, and 6 months after LAAC to assess the status and extent of pericardial effusion, the position of the device and surrounding tissues and structures of the LAA.	Appropriate
TEE	TEE follow-up is routinely performed at 3 and 6 months after operation to evaluate the peri-device leak, DRT, endothelialization, presence of device dislocation and pericardial effusion post LAAC.	Appropriate
CCTA	If the patient has an esophageal disorder that cannot tolerate TEE examination or there is difficulty in inserting the TEE probe, CCTA may be considered as an alternative at 3 and 6 months after operation.	Uncertain

CCTA, computed cardiac tomographic angiography; LAAC, left atrial appendage closure; TEE, transesophageal echocardiography; TTE, transthoracic echocardiography.

supply area. The causes of air embolism are mostly related to operation, including: (1) incomplete air exclusion of the transeptal puncture catheter or the device access system, causing air to enter the left atrium; (2) the pigtail catheter is withdrawn from the access sheath too quickly, causing air inhaled into the left atrium due to negative pressure in the sheath; or air is pushed into left atrium during device insertion. (3) The pressure in the left atrium is too low (e.g., pressure < 10 mm Hg [1 m mHg = 0.133 kPa] or even negative pressure), resulting in inhalation of air into left atrium and air embolism because of negative pressure in the sheath. If the left atrium pressure is too low (e.g., < 10 mm Hg), rapid fluid infusions increasing the left atrium pressure is required through veins or through the sheath by a large syringe. LAAC operation cannot be continued until the left atrial pressure rises over 10 mm Hg.

Common causes of thromboembolism include: (1) no anticoagulation or inadequate anticoagulation before operation; (2) inadequate flush of catheter and guidewire with heparinized saline; (3) inadequate intraoperative heparin anticoagulation or lack of ACT monitoring and untimely heparin supplementation with long operation time; (4) some patients are in hypercoagulable or heparin-resistant status; and (5) preoperative or intraoperative thrombosis in the left atrium/LAA is not detected in time (TEE or ICE should be performed ahead of operation to ensure there is no thrombosis in the left atrium/LAA before further steps. It is not easy to detect thrombosis under X-ray cineangiography/fluoroscopy, thus LAAC only under X-ray guidance may increase the risk of intraoperative thrombotic complications.

The occurrence of air embolism or thromboembolism during LAAC can be avoided by standard preoperative and intraoperative anticoagulation, adequate flushing with heparinized saline and air exclusion of the device system, and standard techniques. If severe coronary air embolism or thromboembolism occurs, it can lead to acute myocardial infarction, which needs to be treated according to the principle of acute myocardial infarction. For patients with suspected cerebral infarction, brain CT examination should be performed in time, and treatment according to the principle of acute cerebral infarction should be given after definite diagnosis.

10.3 | Device dislocation

Device dislocation is one of the most serious complications of LAAC, which mostly occurs during the perioperative period. The correspond-

ing clinical manifestations vary from the location where the device falls. There may be no clinical manifestations when the device falls off to the thoracic or abdominal aorta, but it can be found under TTE; mitral valve dysfunction or LV outflow obstruction may occur when the device falls off to the left atrium or left ventricle, which leads to symptoms such as palpitations, chest distress, and ventricular arrhythmia or may even be life-threatening in severe cases.

The main reasons for device dislocation include: (1) the size of the device is too small compared to the diameter of the ostium; (2) the location of the device is too outside with unstable fixation; and (3) the pre-assembly of the device is not firm, or the connection between the delivery cable and the device is loosened after full recapture. Therefore, it is necessary to check whether the device is firmly connected with the delivery cable before flushing. The delivery cable should be rotated clockwise for two to three turns after the device is fully recaptured to ensure that the device is firmly connected with the delivery cable, so as to avoid dislodgement after the device is pushed out of the delivery sheath.

The dislodged device is usually fixed or adjusted to a relatively safe and easy to grab heart cavity using a snare or forceps, then the device is grabbed with continuing cold saline infusion through the sheath to soften the device before it can be withdrawn into the sheath. Remember to operate softly when grabbing the device to avoid iatrogenic damage to valves, blood vessels, and vital organs which leads to other serious complications. It is recommended to remove the device by cardiac surgery if it is difficult or risky using interventional methods.

It is recommended that LAAC operation center be routinely equipped with snares, forceps, 15 F adjustable bending sheaths, 14–16 F anti-folding sheaths, and vascular sutures, so that the device dislocation can be handled in time.

10.4 | Vascular injury

LAAC operation via the femoral vein access has relatively few peripheral vascular complications. However, vascular complications such as bleeding at the puncture site, hematoma, femoral artery pseudoaneurysm, and femoral arteriovenous fistula may occur if the artery is injured. Some femoral artery pseudoaneurysms or femoral arteriovenous fistulas can be closed by local compression of the puncture site, and if it does not work, a stent graft or surgical repair may be considered.

10.5 | The impact of the device on adjacent structures

The device is mainly fixed by anchors piercing the appendage wall after implantation, thus the impact of the device and the anchors on adjacent tissues should be considered. It is reported that an overly large outer disk of the pacifier device may cause abrasion of mitral valve leaflets and mitral regurgitation⁷³; pulmonary artery injury may occur if the compression ratio at the distal end of the device is too large or the anchors are prominent,⁷⁴ which is more common in patients with concurrent pulmonary artery dilation. During device implantation, attention should be paid to its impact on the adjacent mitral valve or pulmonary vein to avoid affecting their normal function. TTE/TEE should also be used to observe the impact of delayed device displacement on these adjacent structures during postoperative follow-up.

11 | OTHER ISSUES ABOUT LAAC

11.1 | Catheter ablation + LAAC one-stop combined therapy

Catheter ablation can restore sinus rhythm and relieve symptoms, but it is not able to reduce the risk of stroke; while LAAC can prevent stroke and reduce the risk of bleeding caused by long-term anticoagulation treatment, but it is not able to restore sinus rhythm and relieve symptoms. For symptomatic AF with both high risk of stroke and indication for ablation, the “catheter ablation + LAAC” one-stop combined therapy may theoretically bring more benefit than that of catheter ablation or LAAC alone.

Since the Dutch doctor Swaans et al.⁷⁵ first reported the “radiofrequency ablation + LAAC” one-stop combined procedure in 2012, quite a few single-center or multi-center registration studies have confirmed the efficacy and safety of “catheter ablation (including radiofrequency or cryoballoon) + LAAC” one-stop combined therapy in recent years.^{76–78} A recent multi-center registration study showed that among the 349 patients with AF treated with “catheter ablation + LAAC” combined therapy, the LAAC procedure was successful in all patients. Serious procedure-related complications within 30 days included five (1.4%) pericardial effusions, one (0.3%) stroke, and no other serious complications occurred; after 35 months of follow-up, recurrence of AF was seen in 51% of patients. Stroke occurred in nine patients with the annual stroke rate of 0.9%, which was reduced by 78% compared with the estimated risk (3.2%) based on the CHA₂DS₂-VASc score, and the annual bleeding rate (1.1%) was 71% less than the estimated risk (3.74%) based on the HAS-BLED score.⁷⁹ In addition, Chinese scholars take the lead in discussing the sequence of ablation and occlusion in the one-stop procedure of “catheter ablation + LAAC.” The results show that if a plug device represented by WATCHMAN is used for occlusion, the safety and effectiveness of mid- to long-term follow-up are comparable for ablation first or occlusion first strategy, but the percentage of new peri-device leak is lower in the occlusion first group at 45 days after procedure; if a pacifier device (such as ACP or Lambre device) is used, it is recommended to perform ablation first consider-

ing that cover on the crest by the disk may affect subsequent catheter ablation.⁸⁰ There is still a lack of evidence from RCTs although the efficacy and safety of the “catheter ablation + LAAC” one-stop combined procedure have been confirmed by the researches above to a certain extent.

The treatment of AF should reflect the concept of comprehensive management, which not only focus on the relief of symptoms (such as the recovery of sinus rhythm) but also improve the prognosis, especially the prevention of stroke and systemic thromboembolic events. Therefore, although the current evidence of “catheter ablation + LAAC” one-stop combined therapy is not sufficient, this consensus still recommends that the one-stop combined procedure can be performed in qualified centers in symptomatic NVAf patients with high risk of stroke (CHA₂DS₂-VASc score: male ≥ 2 , female ≥ 3) and intolerance or non-compliance with long-term anticoagulation therapy if indications for both catheter ablation and LAAC are available (Table 10).

11.2 | LAAC combined with atrial septal defect/patent foramen ovale

ASD is one of the most common congenital heart diseases in adults. The incidence of atrial arrhythmia, especially atrial flutter and AF, increases with age if ASD is not treated,⁸¹ and the risk of ischemic stroke also increases.⁸² The mechanism of AF caused by ASD is still unclear, which may be related to the thickening and fibrosis of right atrial muscle caused by long-term left to right shunt. It might be linked with the enlargement of the right atrium in ASD patients, and structural changes and electrophysiological remodeling induced by the stretch of the left atrium, and pulmonary vein potential may also be involved in this mechanism.

According to the 2012 ESC guidelines for the management of AF and the 2014 and 2017 AHA/ACC/HRS guidelines, for AF patients combined with ASD or PFO, it is recommended to be more cautious to view the effect of catheter ablation although it is part of the treatment; anticoagulation therapy should be given to patients with a CHA₂DS₂-VASc score of 2 or more. LAAC may be considered for patients with a high risk of bleeding (HAS-BLED score ≥ 3 points) who are unsuitable or unwilling to take long-term anticoagulation, or who still suffer a stroke while taking anticoagulants.

There are two kinds of AF patients with combined with ASD or PFO who are planned to undergo LAAC procedure: one is patients who have previously received surgical repair or interventional occlusion, and the other not yet. It is more difficult in the former patients to perform the transeptal puncture due to the presence of surgical patches or metal occluders in the interatrial septum. Even if the puncture is successful, cases may occur that the transeptal or the access sheath cannot pass through the interatrial septum. According to the experience of Shanghai Chest Hospital, direct low-level puncture may be used to avoid the patch or occluder. If the patch is large and tough, a 20 W electrocautery connected to the puncture needle may be used to cauterize the interatrial septum. When the device is large enough to cover all possible puncture points of the interatrial septum, the puncture needle can be used to cross the disk of device, and the tail (hard end) of the coro-

TABLE 10 Recommendations on other issues about LAAC

Operation	Recommendations	Class
“Catheter ablation + LAAC” one-stop combined operation	<ul style="list-style-type: none"> LAAC and ablation can be performed simultaneously by experienced operators at qualified centers if NVAf patients with obvious symptoms and high risk of stroke (CHA₂DS₂-VASC score: male ≥ 2, female ≥ 3) have indications for both catheter ablation and LAAC. 	Uncertain
	<ul style="list-style-type: none"> It is not recommended to perform LAAC and catheter ablation simultaneously in AF patients with low risk of stroke (CHA₂DS₂-VASC score ≤ 1) 	Inappropriate
ASD/PFO combined operation	<ul style="list-style-type: none"> LAAC and PFO occlusion can be performed simultaneously if NVAf patients with PFO with moderate to massive reverse shunt have indications for both LAAC and PFO occlusion. LAAC and ASD occlusion can be performed simultaneously if the anatomical features of ASD are suitable for LAAC in NVAf patients with ASD. 	Appropriate
	<ul style="list-style-type: none"> It is not recommended to perform LAAC in NVAf patients with huge ASD if the anatomical features of ASD are not suitable for interventional occlusion or the patients are combined with severe pulmonary hypertension. 	Inappropriate

ASD, atrial septal defect; LAAC, left atrial appendage closure; NVAf, non-valvular atrial fibrillation; PFO, patent foramen ovale.

nary intervention guidewire may be used to pass through the stylet of the puncture needle and guide it into the left atrium. Then, the guidewire is withdrawn, and its tip (soft end) is sent into the LSPV. The puncture point across the occlude needs fully dilatation with a 4.0 mm or larger post-stent dilation balloon along the guidewire until the puncture sheath and access sheath are successfully inserted for subsequent LAAC operation. For those who have not received ASD/PFO treatment, LAAC may be directly performed through the ASD/PFO defect. The axial position provided by the ASD/PFO defect is often high if the patient's LAA is too low, and it is necessary to avoid the ASD/PFO defect by re-positioning and re-puncturing at an inferior posterior position of the septum. The ASD/PFO can be closed simultaneously during LAAC procedure if TEE fully evaluates the position and size of the defect before operation. Special attention should be paid to patients with a long history of ASD, which leads to a significant expansion of the pulmonary artery, and CT examination should be carried out to clarify the spatial relationship between the LAA and the pulmonary artery if necessary. It has been reported that if imaging examination suggests a quite close relationship between the LAA and the pulmonary artery, the anchors of LAAC occluder can affect the pulmonary artery, and in serious cases, it can cause pulmonary artery tear or perforation and bleeding.⁷⁴ Besides, if the ASD is too large or the anatomy is not suitable for interventional closure, surgical repair of ASD can be considered at the same time for left atrial appendectomy, or elective interventional closure of LAA may be performed after surgical repair of ASD (Table 10).

11.3 | Complicated LAAC

LAAC may become difficult in some appendages with complex anatomy, and skills and experience are acquired for the operator.

Different types of occlusion devices can be chosen according to the shapes of the LAA. The operation techniques and release principles of various types of occlusion devices should be followed during operation, and the optimal solution should be selected for different appendages.

11.3.1 | Chicken-wing appendages

There are two types of chicken-wing appendages: one is counterclockwise chicken-wing shape with the tip of the wing upward, and the other is clockwise one with the tip downward. The distance from the ostium to the landing zone of both types of chicken-wing appendages is short and the depth is not sufficient. Lacking of ideal working axis is also a disadvantage to successfully close the LAA, so a good puncture site of the interatrial septum is commonly required. For clockwise chicken-wing shape with the tip downward, if a plug device is selected, for example, the WATCHMAN device, the single curved sheath can be used. Appropriate depth may be borrowed in advance when the device is loaded, and the device is developed slowly after it is in landing zone (if the tension is too large, the access sheath together with the device can be pulled back a little slowly). For counterclockwise chicken-wing shape with the tip of the wing upward, it helps improve the success rate of LAAC with a double curved sheath, keeping the access sheath a little counter-clockwise rotation, borrowing appropriate depth in advance when the device is loaded, and developing slowly after the device gets to landing zone. Repeated adjustment and recapture are not inappropriate if the pre-release position of the device is not ideal and does not conform to the “PASS” criteria. It can be considered to re-puncture the interatrial septum at an even inferior site or perform the occlusion with a pacifier device, for example, the LAMBRE device, which does not require a deep depth.^{83,84}

11.3.2 | Cauliflower appendages

Cauliflower appendage has strong pectinate muscles and several separated lobes. When placing the LAAC device such as WATCHMAN, the device can usually enter only one of the lobes in most cases due to developed pectinate muscles and early separated lobes. In this case, the other lobes of the appendage cannot be completely closed because of the incomplete expansion of the device blocked by pectinate muscles. The LAMBRE device may be considered for this type of appendages. A LAMBRE device of normal size can be selected if the difference between the ostium width and the anchor zone width is less than 10 mm, while a device with small umbrella and large disk may be used if the difference is over 10 mm.⁷⁸ A large-sized LAMBRE device is used when the ostium is too large (> 30 mm), and if it is unsuccessful, the "Kissing-WATCHMAN" strategy with two devices^{85,86} is also considerable. Since the "Kissing-WATCHMAN" technique is demanding and difficult, it can only be used by experienced operators at qualified centers when the patient safety is fully considered.

11.4 | Team-building in LAAC

The LAAC team should be composed of interventional cardiologists with independent operational capabilities, ultrasound doctors, anesthesiologists, and perioperative nurses. Cardiac surgeons with independent surgical capabilities are required in hospitals that carry out LAAC operation or other hospitals in the same city to provide surgical support in case of emergency. In addition, the team should also have the ability to identify and deal with cardiac tamponade, device dislocation, and vascular access complications. Corresponding abilities of clinical follow-up and researches are also required.

12 | LIMITATIONS

The 2019 Chinese Society of Cardiology (CSC) expert consensus statement on left atrial appendage closure in the prevention of stroke in patients with atrial fibrillation was published in Chinese in the journal of *Zhonghua Xin Xue Guan Bing Za Zhi* on December 24, 2019. This article is an English edition translated from the 2019 CSC expert consensus under the authorization of the journal. The authors realize that the present English edition has not included the newly released RCTs (e.g., PRAGUE-17, *J Am Coll Cardiol*. 2020;75(25):3122-3135; PINNACLE FLX, *Circulation*. 2021;143(18):1754-1762, and LAAOS III, *N Engl J Med*. 2021;384(22):2081-2091 or registries (e.g., NCDR, *J Am Coll Cardiol*. 2020;75(13):1503-1518), and other updates of relative techniques or skills as well. Taking into account the authorization and faithfulness to the original edition in Chinese, the important updates mentioned as above are not added in this English edition, we hope that the consensus update in the future will be synchronously published in both Chinese and English.

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