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Beyond Conventional Therapy? Real-World Outcomes of Simultaneous Transcatheter Left Atrial Appendage and Congenital Atrial Septal Defect Closure

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ABSTRACT

Objectives To evaluate the safety and efficacy of simultaneous transcatheter left atrial appendage (LAA) and atrial septal defect (ASD) closure versus ASD closure alone in a real-world cohort of patients with concurrent ASD and atrial fibrillation (AF).

Methods Between January 2016 and June 2026, 289 ASD and AF patients were assigned to simultaneous LAA and ASD closure or the conventional ASD closure alone group based on clinical decision-making and anatomical suitability. To reduce potential confounding bias between groups, propensity score matching (PSM) was performed

using 1:1 nearest-neighbor matching. The perioperative, 30 d, 90 d, and 180 d safety and efficacy of the two groups were assessed, and then the embolism, bleeding, and other complications were recorded at outpatient telephone visits every year, and the results of the follow-up.

Results A total of 79 ASD with AF patients were included in the simultaneous occlusion group, of whom 27 received LACBES and 52 received LAmbre LAA occluders, while 79 ASD with AF patients who underwent ASD closure alone were matched by PSM. In the simultaneous occlusion group, three patients developed cardiac tamponade at 8, 20, and 30 h after occlusion, respectively. During follow-up, the simultaneous occlusion group had a lower incidence of bleeding events (2.53% vs. 13.92%, P = 0.017). No statistically significant difference was observed in the incidence of embolism events between the two groups (5.06% vs. 15.19%, P = 0.062). Compared with ASD closure alone, simultaneous LAA+ASD occlusion was associated with a lower risk of all thromboembolic events (HR = 0.333, 95% CI: 0.125–0.888, P = 0.0455) and a significantly lower risk of bleeding events (HR = 0.182, 95% CI: 0.061–0.539, P = 0.0126).

Conclusion In this real-world observational cohort, simultaneous percutaneous LAA and ASD closure in carefully selected patients was associated with favorable long-term safety and effectiveness, particularly in reducing thromboembolic events and bleeding events risk compared with ASD closure alone.

Keywords

atrial septal defect, atrial appendage, atrial fibrillation, cardiac catheterization,

embolism

Introduction

In adults with atrial septal defect (ASD), atrial fibrillation (AF) is frequently observed, with studies indicating a significantly higher incidence of AF among elderly individuals with ASD[1]. Even following ASD closure treatment, patients with ASD who do not initially present with AF remain at an elevated risk of developing AF in the future compared to the general population. Furthermore, even small ASDs are associated with an increased prevalence of atrial arrhythmias[2]. Atrial fibrillation contributes to thrombosis, with research demonstrating that 90% of thrombi form in the left atrial appendage (LAA), thereby substantially increasing the risk of cerebral embolism. Closure of the LAA has been shown to be effective in preventing cerebral embolism[3]. Current guidelines recommend LAA closure for patients with non-valvular AF who are unable to undergo anticoagulation and who have a high risk of thromboembolism[4].Based on our preliminary clinical experience and other studies, the simultaneous percutaneous closure of the LAA and ASD has demonstrated promising short-term outcomes[5]. It is now imperative to validate the advantages of simultaneous LAA and ASD closure compared to traditional ASD closure alone among ASD with AF patients and to assess the long-term therapeutic outcomes.

Methods

Study design and population

Consecutive patients aged 36 to 71 years with documented ASD with AF who underwent transcatheter closure between January 2016 and June 2026 were screened for eligibility. In this study, all enrolled patients undergoing simultaneous percutaneous LAA and ASD closure meet the clinical criteria as follows: (1) persistent atrial fibrillation; (2)age ≥18 years old; (3) endured long-term administration of clopidogrel and aspirin; (4) contraindication or intolerance to the administration of warfarin or DOACs; (5) candidate for transcatheter closure for congenital interatrial communication. Either simultaneous LAA+ASD closure or ASD closure alone was determined by the treating physicians based on clinical judgment, LAA anatomy, and patient preferences, without randomization. All patients underwent standard preoperative assessments, including physical examinations, chest computed tomography (CT), electrocardiography (ECG), Holter ECG, and transthoracic echocardiography (TTE). For those receiving simultaneous occlusion treatment, transesophageal echocardiography (TEE) and cardiovascular CT angiography were additionally required. The Ethics Committee of the General Hospital of Northern Theater Command approved the study (No. XXN-LAA-01), and each patient provided informed written consent before interventional occlusion.

To reduce potential confounding bias between groups, propensity score matching (PSM) was performed using a logistic regression model. Variables potentially associated with both exposure and outcomes were included in the propensity score model. Patients were matched using 1:1 nearest-neighbor matching without replacement with a caliper width of 0.2 standard deviations of the logit of the propensity

score. Balance between groups before and after matching was assessed using standardized mean differences (SMDs), with an SMD <0.1 considered indicative of adequate balance

Occluder devices

In this study, the following LAA occluders were used: the LAmbre occluder (Shenzhen Xianjian Medical Technology Co., Ltd.)[6] and the LACBES occluder (Shanghai Pushi Medical Technology Co., Ltd.)[7]. The LAmbre LAA occluder is characterized by a double-disc configuration, consisting of a braided nickel-titanium alloy fixation disc and an occlusion disc (Figure 1A). The fixation disc, designed with a barbed structure, is specifically engineered for intramural fixation of the left atrial appendage. A coupling nut connects the discs to the delivery cable. The diameter of the occlusion discs in the LAmbre LAA occluder typically exceeds that of the fixation discs by 4 – 6 mm or 12 – 14 mm, accommodating the diverse anatomical variations of the LAA. The LACBES LAA occluder is designed with a nickel-titanium alloy anchoring disk and a sealing disk that features small barbs integrated along its edge (Figure 1B). The size of the occluders ranges from 16 to 34 mm, determined by the waist diameter of the anchoring disk, while the sealing disk is 4 to 6 mm larger than the diameter of the anchoring disk.

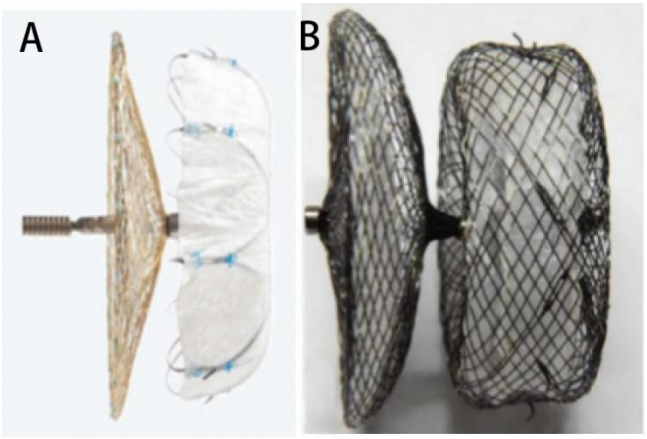


Fig. 1 LAA Occluders. **A** LAmbre LAA Occluder; **B** LACBES LAA Occluder

In this study, the SHSMA ASD occluder (Shanghai Shape Memory Medical Device Company)[8] was employed for the transcatheter closure of interatrial communication. This ASD occluder also features a double-disc design, constructed from a woven nitinol memory alloy, and incorporates polyester patches within the discs. It is available in various models and is widely utilized in clinical practice.

Transcatheter Occlusion

The morphology of the LAA was assessed using preoperative TEE at angles of 0°, 45°, 90°, and 135°, and the diameter of the LAA opening was measured. Coronary angiography is generally performed on patients aged 50 years or older. The procedure begins with right heart catheterization, followed by the insertion of a 6F pigtail catheter into the LAA via the delivery sheath to obtain multiprojection imaging for evaluating the LAA opening and landing zone diameters. Prior to the deployment of the LAA occluder, it is essential to assess the impact of occlusion, stability, and adjacent structures, including mitral valve function, the left upper pulmonary vein, and the

pericardium.

For simultaneous closure or ASD closure alone, the catheter is navigated to the left atrium through the interatrial communication, with the exchange guidewire positioned in the left upper pulmonary vein, and the delivery sheath is inserted into the left atrium. The ASD closure is performed using an appropriately sized occluder, with TEE or TTE monitoring, confirmed for effectiveness through ultrasound and X-ray imaging.

Perioperative and postoperative medications

During the perioperative period, both groups received prophylactic treatment with antibiotics and low molecular weight heparin. The group that underwent simultaneous closure received oral clopidogrel at a dose of 75 mg once daily and aspirin at 100 mg once daily for a period of 6 months postoperatively, followed by long-term aspirin therapy at 100 mg once daily. For patients in the group that only had ASD closure, rivaroxaban was administered at a dose of 20 mg orally once daily .

Follow-up

During the perioperative period, as well as at 30, 90, 180 days, and annually thereafter conducted by outpatient physicians, TTE was performed on both groups. Additionally, in the group undergoing simultaneous interventional occlusion, TEE was required at 180 days post-treatment to assess occlusion efficacy, device thrombosis, and residual shunt. Electrocardiograms were utilized to monitor arrhythmias in both groups. Complications, including stroke and hemorrhage, were documented during outpatient

visits or telephone follow-ups. Serious adverse events included death, cerebral embolism, cerebral or gastrointestinal hemorrhage, cardiac tamponade, rehospitalization due to cardiac function deterioration, and complications necessitating surgical intervention.

Statistical Analysis

Data analysis was performed using SPSS version 16.0. Continuous variables were expressed as means or medians, while categorical variables were presented as frequencies or percentages. The chi-square test and Fisher's exact test were employed for the analysis of categorical data between the two groups. Kaplan–Meier curves were constructed to estimate cumulative event-free survival for thromboembolic and bleeding events, with between-group differences assessed by the log-rank test. The difference was considered statistically significant at $P < 0.05$.

Results

Baseline characteristics

A total of 289 eligible patients were included in this cohort. 79 patients underwent simultaneous LAA and ASD closure, while the other 210 patients received traditional ASD closure alone. Propensity score matching was applied to adjust for 10 covariates, among which only the covariate history of diabetes had an SMD of 0.122, exceeding 0.1. Therefore, 79 patients in each of the two groups were analyzed in this study. Baseline characteristics did not exhibit significant differences between the

simultaneous LAA+ASD closure group and the group receiving ASD closure alone (Table 1).

Table 1 Baseline demographic and clinical characteristics

Variable	LAA+ASD (N =79）	ASD closure （N = 79）	*P* value	SMD
Age,(years)	60.05 ± 7.62	61.49 ± 7.35	0.780	0.052
Male, n(%)	28(35.4%)	25(31.6%)	0.736	0.072
Congestive heart failure,n(%)	58(73.4%)	51(64.6%)	0.302	0.097
Hypertension,n(%)	20(25.3%)	27(34.2%)	0.296	0.082
Diabetes mellitus,n(%)	8(10.1%)	13(16.5%)	0.349	0.122
Stroke,n(%)	5(6.3%)	2(2.5%)	0.443	0.093
TIA,n(%)	3(3.8%)	1(1.3%)	0.620	0.088
Bleeding history, n (%)	2(2.5%)	0(0.0%)	0.497	0.091
CHA2DS2VASc score, (mean)	2.6±1.5	2.5±1.4	0.728	0.063
HAS-BLED score, (mean)	3.1±1.0	2.8±1.1	0.074	0.098

LAAC, left atrial appendage closure; ASD = arial septal defect;AF, Atrial Fibrillation; TIA, transient ischemic attack;CHA2DS2VASc,Congestive heart failure, Hypertension, Age ⩾75, Diabetes, Stroke/Transient ischemic attack, Vascular disease, Age 65–74, Sex category;HAS-BLED,Hypertension, Abnormal renal/liver function, Stroke, Bleeding history or predisposition, Labile international normalized ratio, Elderly, Drugs/alcohol concomitantly

Perioperative outcomes

In the simultaneous occlusion group, 27 patients received LACBES occluders, while 52 patients were treated with LAmbre LAA occluders (Figure 2). The immediate

procedural success rate was 100% in both groups, with postoperative assessments indicating immediately satisfactory occlusion results. In the LAA+ASD closure group, serious complications were observed, including cardiac tamponade in three patients (3.8% of cases), occurring at 8, 20, and 30 hours post-procedure, respectively, involving two cases with LACBES and one case with LAmbre LAA occluders. The first two patients experienced recovery following pericardial puncture and drainage, while the third case required surgical intervention for intracardiac repair. Consequently, the group undergoing simultaneous LAA+ASD closure achieved a perioperative success rate of 98.7%.

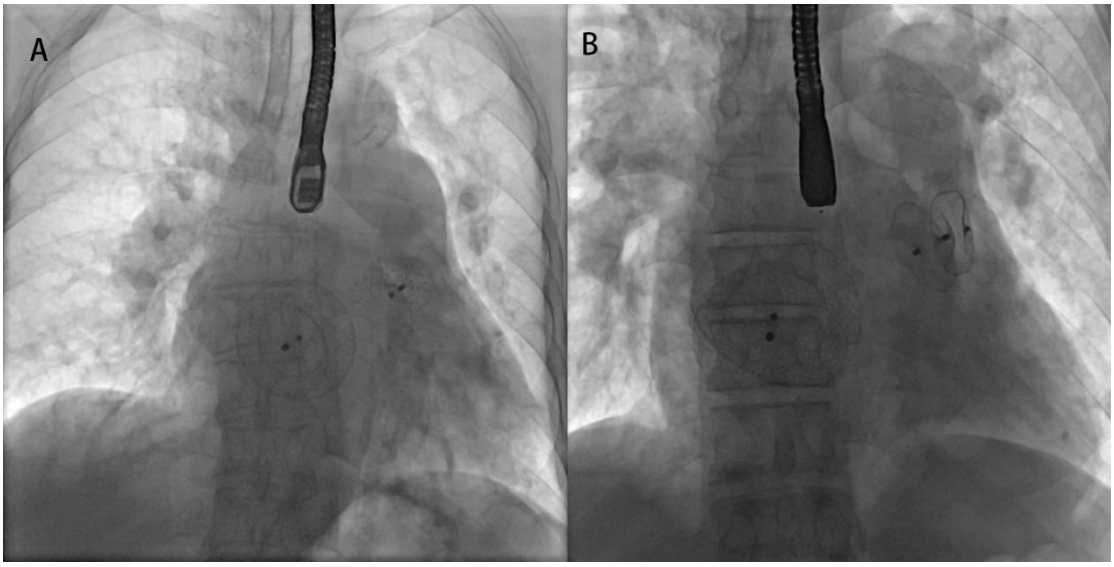


Fig. 2 Angiography of the simultaneous LAA+ASD closure treatment group. **A** A 22/28 LAmbre LAA occluder and a 24mm SHSMA ASD occluder were implanted simultaneously; **B** A 32mm LACBES LAA occluder and a 52mm SHSMA ASD were implanted simultaneously.

Follow-up results

The median follow-up duration for all patients was 61.6 months. Both groups'

postoperative TTE or TEE reexaminations confirmed the optimal positioning of the LAA and ASD occluders, without device thrombus or residual shunt (Figure 3). During the follow-up period, complications are detailed in Table 2, revealing a total of 16 (10.13%) embolic events, which include 7 (4.43%) ischemic strokes, 8 (5.06%) transient ischemic attacks (TIAs), and 1 (0.63%) embolism in the systemic circulation. Notably, no thrombotic events were associated with the device. The simultaneous occlusion group had a numerically lower incidence of embolism events compared with the ASD closure alone group (5.06% vs. 15.19%) , though this difference was not statistically significant (p = 0.062). Additionally, 13 bleeding incidents (8.23%) were recorded, including 2 cerebral hemorrhages (1.23%), 4 gastrointestinal hemorrhages (2.53%), and 7 other bleeding events (4.43%). The overall bleeding events rate was significantly lower in the simultaneous LAA+ASD occlusion group (2.53% vs. 13.92%, p=0.017). Kaplan-Meier analysis (Figure 4) indicated that the simultaneous LAA+ASD occlusion group had a lower risk of all thromboembolic events compared with the ASD closure alone group (hazard ratio [HR] = 0.333, 95% confidence interval [CI]: 0.125–0.888, p = 0.0455). The group undergoing simultaneous LAA+ASD occlusion demonstrated a significantly reduced risk of hemorrhagic events (hazard ratio [HR] = 0.182, 95% confidence interval [CI]: 0.061 – 0.539, P = 0.0126).

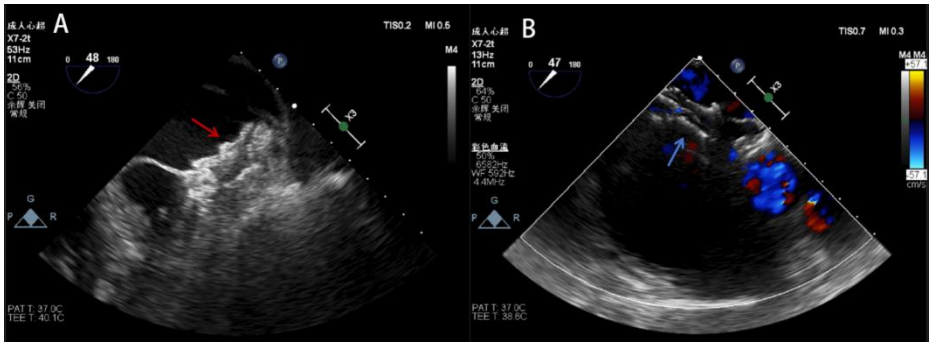


Fig. 3 6 months postoperative TEE review results of the simultaneous LAA+ASD closure treatment group. **A** The LAA occluder (red arrow) was well implanted, with no complications such as device thrombus or displacement; **B** The ASD occluder (blue arrow) was well positioned without complications such as residual shunt.

210 **Table 2** Complications and adverse events during follow-up

Complications and adverse events	**LAA+ASD (N =79)**	**ASD closure (N = 79)**	***P* value**
Thrombosis event, n (%)	4（5.06%）	12（15.19%）	0.062
Ischemic stroke, n (%)	1（1.27%）	6（7.59%）	0.117
TIA,n(%)	3（3.85%）	5（6.33%）	0.719
Systemic thromboembolism, n(%)	0	1（1.27%）	＞0.999
Device thrombosis, n (%)	0	0	＞0.999
Bleeding event, n (%)	2（2.53%）	11（13.92%）	0.017
Cerebral hemorrhage, n (%)	0	2（2.53%）	0.497
Gastrointestinal bleeding, n (%)	1（1.27%）	3（3.80%）	0.620
Other bleedings, n (%)	1（1.27%）	6 (7.59%)	0.117
Total all-cause death/total patients, n (%)	2（2.53%）	1（1.27%）	＞0.999
Cardiac death, n (%)	2（2.53%）	0	0.497
Non-cardiac death, n (%)	0	1（1.27%）	＞0.999
Non-cardiac death, n (%)	0	0	＞0.999

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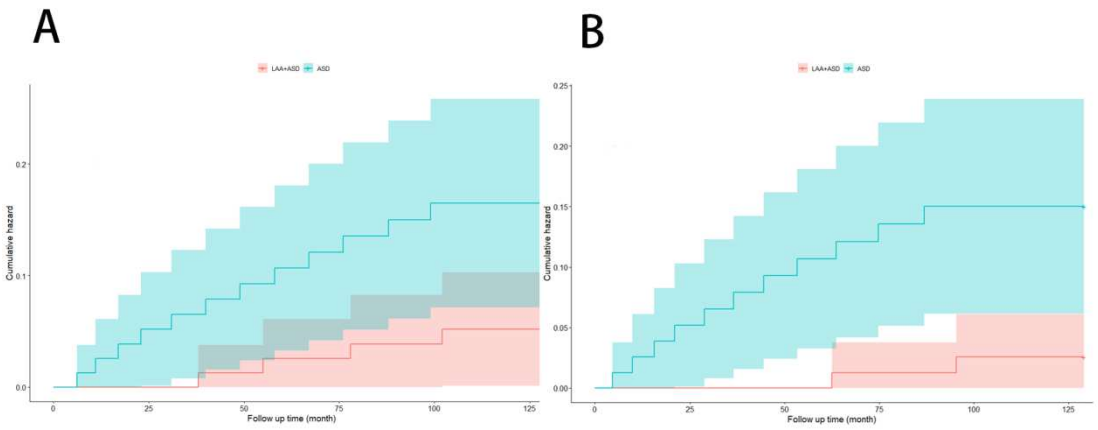


Fig. 4 Results of Kaplan-Meier analysis of the two-group comparison of the risk of embolic and bleeding events. **A** Simultaneous LAA+ASD closure reduced the risk of embolic events compared with ASD closure alone; **B** Simultaneous LAA+ASD closure reduced the risk of bleeding events compared with ASD closure alone.

Discussion

Long-term hemodynamic abnormalities associated with ASD contribute to an increased incidence of AF, subsequently altering the atrial electrical anatomy [9]. Studies have indicated that interatrial communication is detected in 18.7% of AF patients using TEE, and confirmed in 57.3% through transcatheter pulmonary vein isolation[9]. A major complication of AF is cerebral embolism, with an annual incidence ranging from 1.9% to 18.2%, which is 5.6 times higher than that observed in the general population. Consequently, the prevention of cerebral embolism is a critical objective in the management of AF[10]. The PROTECT AF study demonstrated that LAA occlusion was more effective in reducing the risk of fatal strokes compared to anticoagulant therapy[11]. For patients with ASD and AF who are unable to undergo anticoagulation,

simultaneous occlusion may offer a viable strategy to prevent cerebral embolism and correct abnormal hemodynamic. However, the long-term efficacy in preventing significant adverse events such as embolisms and hemorrhage in ASD and AF patients remains uncertain.This study investigates whether the long-term outcomes of simultaneous occlusion therapy are more advantageous compared to traditional ASD closure alone, accompanied by extended anticoagulant therapy.

According to the 2023 guidelines from the American Heart Association (AHA), American College of Cardiology (ACC), and Heart Rhythm Society/American Society of Echocardiography (HRSAF), catheter ablation is recommended as an effective initial treatment for symptom improvement in patients with symptomatic paroxysmal or persistent AF when rhythm control is chosen (recommendation level 2a, evidence level B-R) [12, 13], catheter ablation may be performed either concurrently or sequentially with ASD closure in patients presenting with both ASD and AF[14, 15]. However, this approach is associated with suboptimal transcatheter ablation outcomes, a higher recurrence rate of AF, and the ongoing necessity for long-term anticoagulation. Therefore, the aforementioned treatment strategies are insufficient for preventing embolic events in patients with ASD and AF.

The presence of interatrial communication facilitates LAA occlusion without the need for septal puncture, thereby simplifying the procedure. Conversely, following the closure of interatrial communication, performing LAA occlusion presents technical challenges due to the requirement for septal puncture, with only a limited number of successful cases documented. Initial clinical investigations involving patients with

ASD and AF undergoing simultaneous occlusion have identified pericardial effusion or tamponade as a significant and frequent perioperative complication[16]. Given that this combined procedure is technically challenging and relatively new, the accumulation of a larger cohort remains difficult[17, 18]. The selection of appropriate occluders, meticulous perioperative monitoring, and the development of safer devices are essential. Kuwata et al. conducted prophylactic LAA occlusion in patients with ASD who exhibited an enlarged left atrium internal diameter. The European consensus among experts advocating for concurrent prophylactic LAA occlusion alongside interatrial communication occlusion has sparked further discussion regarding the criteria for LAA occlusion[19, 20].

There is ongoing debate concerning the effects of LAA occlusion on left heart function and the potential for device-related thrombus formation. Research suggests that LAA occlusion results in decreased left atrial compliance, leading to structural and functional compromise, which subsequently impairs left atrial performance[21]. Empirical studies have indicated that there are no significant safety concerns related to the primary endpoint of increased left atrial mean pressure following LAA occlusion[22]. However, patients with AF exhibit diverse pathophysiological mechanisms, resulting in distinct hemodynamic responses post-LAA occlusion. This study did not observe any significant decline in left ventricular function during the follow-up period. There exists a theoretical hemodynamic threshold regarding the impact of simultaneous occlusion on LV function, necessitating further clinical investigations to elucidate this effect. Current guidelines recommend the administration

of dual antiplatelet therapy for a duration of 1 to 6 months following LAA occlusion [23]. Throughout the follow-up period, no device-related thrombus was detected among patients undergoing simultaneous interventional occlusion, indicating that short-term dual antiplatelet therapy followed by long-term single antiplatelet therapy remains effective.

The long-term outcomes of this study didn't demonstrate that the group undergoing simultaneous occlusion experienced a significantly lower incidence of thrombosis events compared to the group undergoing ASD closure alone. Recent randomized evidence has substantially challenged the clinical value of LAAC for stroke prevention. The CLOSURE-AF trial , which randomized 912 high-risk AF patients to catheter-based LAAC versus physician-directed best medical therapy (predominantly DOACs), found that LAAC failed to meet noninferiority for the composite of stroke, systemic embolism after 3 years[24]. Meta-analyses reinforce this tempered outlook. A 2026 systematic review of 7 RCTs found no significant difference between LAAC and OAC in all-cause death, stroke, or any bleeding, though LAAC reduced nonprocedural bleeding at the cost of a numerically higher ischemic stroke risk[25].The conventional strategy for preventing strokes associated with AF involves the long-term use of oral anticoagulants. The narrow therapeutic range of warfarin and the low adherence rates to newer oral anticoagulants present significant challenges, while additional complications further limit the sustained efficacy of these medications in preventing ischemic stroke. However, modern DOACs provide highly reliable stroke prevention. Early trials often compared LAAC with warfarin, whereas newer trials mostly compare

it with DOACs, which have themselves already substantially reduced stroke risk. This disparity might become more pronounced, particularly as the sample size and follow-up time of the study increase, when compared to simultaneous occlusion as in our study. Throughout the follow-up period, the group undergoing ASD closure alone experienced more severe bleeding incidents, including cerebral and gastrointestinal hemorrhages. In contrast, the simultaneous occlusion group exhibited a significantly lower rate of bleeding events. Kaplan-Meier analysis in this study demonstrated that the simultaneous occlusion group had a reduced risk of both embolic and bleeding events compared to the ASD closure alone group, indicating that simultaneous occlusion therapy may further mitigate the risks of thrombosis and bleeding in carefully selected patients.

This single-center, retrospective study design reflects routine clinical practice and constitutes a real-world observational cohort.These findings extend previous reports by providing comparative effectiveness data derived from routine clinical practice, rather than from a tightly controlled randomized setting. This real-world observation supports the hypothesis that mechanical LAA exclusion may offer a safer alternative to pharmacological anticoagulation in this specific population, particularly for patients with high bleeding risk. Nevertheless, the higher periprocedural complication rate (cardiac tamponade in 3.8%) in the simultaneous group underscores the technical complexity of this combined procedure and highlights the need for careful patient selection, operator experience, and ongoing device refinement. These findings emphasized that the benefits of simultaneous closure must be weighed against the

upfront procedural risks.

Limitaitons

The present study had several limitations. First and foremost, as was the case during our previous study, and in accordance with a consensus reached by Chinese experts, we followed the strict inclusion/exclusion criteria. Second, occluders selection depended on the experience of operators, and we lacked a controlled cohort study design with large sample sizes for testing several types of LAA occluders. Third, two groups of patients were enrolled from only our center and therefore may not be representative of the general population. Finally, future multicenter prospective registries or large-scale observational studies are warranted to confirm these real-world findings.

Conclusion

In this study, simultaneous percutaneous LAA and ASD closure was associated with favorable long-term outcomes, including significant reductions in thromboembolic and bleeding events risk compared with ASD closure alone. These results provide practice-based evidence supporting the use of combined closure as a viable therapeutic strategy in appropriately selected patients with ASD and AF in routine clinical settings.

Funding

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Declarations

Ethics approval and consent to participate

The studies involving humans were approved by The Ethics Committee of the General Hospital of Northern Theater Command approved the study (No. XXN-LAA-01), and each patient provided informed written consent before interventional occlusion. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article. In compliance with the Declaration of Helsinki, this research was conducted.

Clinical trial number: Not applicable

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