Research Square

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Preliminary study on the safety and efficacy of simultaneous atrial septal defect/patent foramen ovale occlusion and left atrial appendage occlusion

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Research Article

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Abstract

Objectives

To explore the feasibility, safety and efficacy of one-stop treatment of left atrial appendage (LAA) occlusion (LAAO) in combination with concomitant closure of atrial septum defect (ASD)/patent foramen ovale (PFO) in patients with ASD/PFO and concurrent atrial fibrillation (AF).

Methods

Retrospectively analyzed the clinical data of 18 ASD/PFO patients with concurrent AF admitted to Zhuhai People's Hospital from October, 2022 to June, 2025. The effects of closure of LAA and ASD/PFO were evaluated immediately after operation. The location, exterior thrombosis status, and residual leak of the occluders of LAA and ASD/PFO in parallel with patients' clinical manifestations were evaluated on 45th ,90th, and 180th days of follow-up.

Results

All patients were successfully implanted with WATCHMAN™ device and double-plate ASD/PFO occluder. The WATCHMAN™ device operation was in accordance with the PASS principle. An instant and satisfactory sealing by WATCHMAN™ and ASD/PFO occluders were obtained upon operation: all occluders were fixed in proper position with no residual shunts. There were no exterior device thrombosis, cardiac tamponade, or vascular complications throughout the operation. The follow-up results showed that all 18 patients were protected from newly developed ischemic/hemorrhagic stroke, angina pectoris, myocardial infarction, and worsening heart function. Meanwhile, there was no displacement, surface thrombosis or gradual residual leak of the devices.

Conclusion

For congenital ASD/PFO patients concurrent with non-valvular AF, one-stop treatment of concomitant ASD/PFO and LAA occlusion is safe and convenient with favorable short- and mid-term clinical outcomes, thus being a feasible and promising strategy for treatment of this cohort.

Introduction

Atrial fibrillation (AF) is a common arrhythmia, and oral administration of anticoagulant drugs is an important strategy for preventing stroke in patients with AF[1, 2]. However, some patients are unable to tolerate or are unwilling to receive long-term anticoagulant therapy[3]. For such patients with nonvalvular AF, left atrial appendage occlusion (LAAO) is an alternative measure for preventing stroke[4, 5].

Atrial septal defect (ASD) and patent foramen ovale (PFO) are risk factors for stroke, particularly in high-risk PFO patients[6, 7]. If interatrial communication alone is closed in patients with ASD/PFO complicated with AF, the presence of a metal occluder greatly increases the difficulty of interatrial septal puncture and prevents intervention via the left atrium/atrial appendage and pulmonary vein[8]. This study aimed to investigate the safety, efficacy, and prognosis of simultaneous ASD/PFO occlusion and LAAO for patients with ASD/PFO complicated with AF and a CHA2DS2-VASC score ≥ 2

Subjects and methods

Study subjects

This study retrospectively analyzed the data of 18 patients (12 males and 6 females) with ASD/PFO complicated with AF who underwent ASD/PFO occlusion and LAAO at Zhuhai People's Hospital between October 2022 and June 2025. The patients had a mean age of 69.4 ± 8.7 years, a mean ejection fraction (EF) of 59.7 ± 9.14%, a mean CHA2DS2-VASC score of 3.7 ± 1.6, and a mean (HAS-BLED) score of 2.4 ± 0.9,meanwhile,we also includes the history of previous transient ischemic attack/stroke, comorbidities, atrial fibrillation type and duration, and surgery duration, hypertension, abnormal renal/liver function, stroke, bleeding history or predisposition, labile international normalized ratio, elderly, drugs/alcohol concomitantly.

The inclusion criteria were as follows: (1) PFO with grade III or IV right-to-left shunting on transcranial contrast-enhanced transcranial Doppler ultrasound (cTCD), (2) foramen secundum ASD with a defect diameter of 5-36 mm, a distance from the defect edge to the coronary sinus, superior vena cava, inferior vena cava, or pulmonary vein ≥ 5 mm, and a distance from the defect edge to the atrioventricular valve ≥ 7 mm, (3) nonvalvular AF, (4) age > 45 years, and (5) CHA2DS2-VASC score ≥ 2[9, 10].

Exclusion criteria were as follows: (1) mechanical valve implantation or moderate to severe mitral stenosis, (2) mural thrombosis in the left atrium or other cardiac chambers, (3) maximum diameter of the left atrial appendage (LAA) opening > 31 mm or < 17 mm, (4) EF < 35%, and (5) long-term anticoagulant therapy use for other diseases, such as pulmonary embolism and lower extremity venous thrombosis. The studies were approved and conducted by the Research Ethics Committees of Zhuhai People's Hospital, Affiliated Hospital of Jinan University and those of the American Physiological Society. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the institution's human research committee[11]. All subjects signed the informed consent. Clinical information of the patient is shown in Table1.

Preoperative transesophageal echocardiographic(TEE) evaluation

The Philips IE33 ultrasound diagnostic system with a X7-2t esophageal probe was used for TEE. The left atrial appendage (LAA) morphology was observed on the 0°, 45°, 90° and 135° views, and the diameter of the opening of the LAA and the depth of the LAA were measured. Contraindications for device closure of the LAA were evaluated.

cTCD

Brief description of the relevant steps: First, venous access was established in the left cubital vein and connected to a three-way tube. Two 10-ml syringes were prepared, one with 8 ml of 0.9% NaCl solution (normal saline) and the other with 1 ml of air. One milliliter of blood was collected using the first syringe, and the air, sampled blood, and sodium chloride solution were thoroughly mixed and stored in a syringe. The activated NaCl solution (mixed liquid) was quickly injected into the cubital vein. The right or left middle cerebral artery was observed at 45-60 mm depth to determine the presence of a microembolic signal at rest and during the Valsalva maneuver (within 10 s). The following bilateral grading criterion was used for the quantitative classification of cTCD results based on the number of microbubbles: grade I: 0 microembolic signals, grade II: 1-20 microembolic signals (1-10 unilateral signals), grade III: > 20 microembolic signals (> 10 unilateral signals) that do not follow a curtain pattern, and grade IV: microembolic signals that follow a curtain pattern.

Procedure of LAAO

The WATCHMANTM occluder was used for LAAO in this study. The brief procedure is described as follows. The patients underwent LAAO with tracheal intubation under general anesthesia. The operation was performed under the monitoring of esophageal ultrasound. The right femoral vein was punctured, followed by placement of an 8F vascular sheath. An SL1 sheath and transseptal needle was inserted through the interatrial septum (at a slightly inferior and posterior site) under TEE guidance[12, 13]. After the SL1 sheath was inserted into the left atrium, a stiff wire was used to deliver a 14F deliver sheath of Watchman^{TM} to the left atrium, and then a 6F pigtail catheter was inserted and rotated in the left atrium into the LAA. LAA angiography was performed with the patient in the supine position with RAO 30° and CAU 20°. The diameter of the opening of the LAA and the depth of the LAA were measured both by TEE and angiography. According to the measurement values, the dimensions of the occluder were determined, and the LAA occluder was selected accordingly. The WATCHMAN^{TM} occluder was inserted via the delivery sheath. After the occluder reached the expected site, the delivery sheath was withdrawn and the occluder was released to occlude the LAA[14, 15]. The position and shape of the occluder were observed by TEE, and the compression ratio, excessive shoulder, and leak flow of the device were measured. Under TEE and digital subtraction angiography (DSA) guidance, the push-pull maneuver was performed to confirm the secure position of the occluder according to the PASS principle (Position, Anchor, Size, Seal). Then, the occluder was released. The position and shape of the device was examined by TEE again. The esophageal echocardiographic probe was withdrawn, and PCI was initiated[16].

ASD/PFO occlusion

According to the procedures for ASD occlusion, the guidewire was retained from the femoral vein to the left superior pulmonary vein after LAAO. The diameter of the ASD occluder was determined by adding 4-6 mm to the average size of the ASD measured by preoperative echocardiography and intraoperative TEE. The model of the PFO occluder was selected based on the size and morphology of the PFO

measured by TEE. After the ASD or PFO occluder was selected, a matching delivery sheath was inserted along a reinforced guidewire to the opening of the left superior pulmonary vein. Under fluoroscopy, the occluder was sent along the sheath into the occluder in the left atrium, and the left atrial umbrella of the occluder was opened. Then, the occluder was retraced to the left atrial side of the interatrial septum while circumventing the LAA occluder, and the delivery rod was fixed. Next, the sheath was retraced, and the right atrial umbrella of the occluder was opened. Finally, the occluder was released after a satisfactory occlusion effect was achieved, as shown on repeated fluoroscopic and echocardiographic evaluations[17, 18].

Postoperative antithrombosis

All patients received anticoagulation treatment with rivaroxaban (15 mg Qd) for 45 days, followed by anticoagulation treatment with aspirin (0.1 Qd) + clopidogrel (75 mg Qd) for 6 months after surgery. Afterwards, they received long-term treatment with single antiplatelet drugs.

Postoperative follow-up

TEE/transthoracic echocardiography results, electrocardiograms, new stroke events, angina pectoris, myocardial infarction, and changes in cardiac function were recorded at 45 days, 90 days, and 180 days after surgery. TEE was performed at 45 days after surgery to record the position, morphology, residual shunting, and presence of thrombus on the occluder surface.

Results

In this study, 18 patients were successfully implanted with an ASD/PFO occluder and a WATCHMAN^{TM} LAA occluder. The size, compression ratio, excessive shoulder, and leak flow of the WATCHMAN^{TM} occluder are 27.5±3.9mm, 19.7±6.5%, 3.3±2.9mm, and 0.17±0.5mm respectively. The specific implantation conditions are shown in Table 2. Images taken before and after implantation are shown in Figs. 1-3, and TEE images taken on the 45th day of follow-up are shown in Fig. 4.

No pericardial tamponade, atrioventricular block, or peripheral vascular complications were observed during or after surgery. TEE images obtained on the 45th day of follow-up (45 days after surgery) indicated stable LAA occluder positions, no significant change in the residual shunting compared with measurements taken immediately after surgery, no thrombus on the occluder surface or in the other cardiac chambers, stable ASD/PFO occluder positions, and no significant residual shunting in all patients. No cardiovascular events (stroke, angina pectoris, myocardial infarction) or hemorrhagic events (skin ecchymosis, gastrointestinal hemorrhage, cerebral hemorrhage) occurred in any patients on the 90th, and 180th of follow-up. The results of transthoracic echocardiography performed on the 90th and 180th days of follow-up also suggested stable occluder positions in all patients. After surgery, 1 patient with preoperative heart failure and a preoperative EF of 36% experienced improvement of cardiac function, with EFs of 53% on the 45th day, 65% on the 90th day, 71% on the 180th day, and 62% on the 360th day after surgery, and showed spontaneous cardioversion.

Discussion

AF is a common complication of ASD. ASD leads to an increase in blood volume in the right heart system, pulmonary artery, and atria and an increase in the volume load; these changes cause atrial muscle fibrosis, thereby increasing the incidence of AF[19]. AF and PFO are risk factors for stroke, and PFO occlusion is an important measure for preventing PFO-associated stroke. There are currently no specific guidelines for the timing, safety, and efficacy of combined left atrial appendage closure for PFO or ASD. Some centers have made preliminary explorations, and we are one of them. Regarding the indications for PFO closure, our criteria are patients with migraine or TIA symptoms and a TCCD bubble test showing grade III-IV right-to-left shunt, which is in line with the current guidelines[20]. For patients with ASD/PFO complicated with AF, the simple closure of interatrial communication will greatly increase the difficulty of atrial septal puncture and exclude the possibility of catheter ablation and LAAO. Combining LAAO with interventional ASD/PFO occlusion is the key to solving this problem[21].

Past studies have demonstrated the high safety and effectiveness of interventional ASD/PFO combined with LAAO in patients with ASD/PFO complicated with AF[22]. Kuwata et al reported satisfactory safety and effectiveness of concomitant ASD/PFO closure (closure of interatrial communication) and LAA closure in 13 patients older than 40 years with ASD/PFO (ASD > 20 mm, PFO with left atrial enlargement > 40 mm) but without AF after a two-year follow-up[23]. These finding also prompted an EHRA/EAPCI expert consensus statement in 2019, which indicates that for some patients with ASD but no AF who have a high risk for AF, LAAO can be considered for the “primary prevention” of stroke[7, 24].

To provide more evidence of the safety and efficacy of this type of surgery, all 18 patients included in this study had ASD/PFO. During the surgery, WATCHMAN™ occluders were used for LAAO. The success rate of surgery was 100%[23]. Atrioventricular block, pericardial tamponade, and vascular complications did not occur during or immediately after surgery. TEE results obtained on the 45th day of follow-up showed stable occluder positions and no thrombus on the occluder surface. No cardiovascular events (stroke, angina pectoris, myocardial infarction) or hemorrhagic events (skin ecchymosis, gastrointestinal hemorrhage, cerebral hemorrhage) occurred in any patients on the 90th, 180th, or 360th days of follow-up[25]. Three patients who underwent simultaneous PFO combined with LAAO and radiofrequency ablation all maintained sinus rhythm. One patient who received ASD combined with LAAO had better cardiac function and spontaneous cardioversion after surgery[26]. Patients who have undergone left atrial appendage occlusion can opt for anticoagulation for 1 month, followed by dual antiplatelet therapy for half a year, and then lifelong single antiplatelet therapy. For patients who have undergone patent foramen ovale (PFO) closure, they start with dual antiplatelet therapy and then switch to single antiplatelet therapy. Currently, there are no guideline-recommended antithrombotic regimens for these one-stop patients[27, 28]. We attempt to provide patients with dual antiplatelet therapy for half a year to 1 year, followed by lifelong single antiplatelet therapy, to observe their long-term outcomes and accumulate our experience[29].

Regarding the investigation of primary preventive LAAO in patients with ASD and high risk for AF, the EHRA/EAPCI expert consensus statement indicates that attention should be paid to the management of AF or risk of AF in patients who require closure of interatrial communication[30, 31]. For patients with ASD/PFO complicated with AF, simultaneous ASD/PFO occlusion and LAAO is recommended. However, recent studies have found that the incidence of AF increases after PFO occlusion, which raises a new risk of stroke in patients[32, 33].

Conclusion

One-stop occlusion is safe and effective for the treatment of patients with ASD/PFO and non-valvular AF. Further studies are needed to determine whether ASD/PFO occlusion combined with LAAO should be performed in patients with ASD/PFO and concurrent AF.

Declarations

Clinical trial number

Not applicable.

Acknowledgments

None.

Authors' contributions

XJ drafted the manuscript. DDY and ZLT participated in manuscript writing. YQY, WK and YY participated in data collection and data analysis. ZH and LGD participated in interventional therapy. JXF participated in the design of the study. All authors read and approved the manuscript.

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Data availability

The datasets used during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

This study was approved by the Ethics Committee of Zhuhai People's Hospital. Written informed consent was obtained from all participants. The study was conducted in accordance with the Declaration of Helsinki.

Consent for publication

All authors agree to publication, and there are no permissions needed.

Competing interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

References

1. Hijazi Z, Lindbäck J, Oldgren J, Alexander JH, Benz AP, Berg DD *et al*. Evaluation of the updated ABC-AF-bleeding score 2.0 in patients with atrial fibrillation treated with a direct oral anticoagulant or warfarin. Journal of thrombosis and haemostasis : JTH. 2026;24(2):399-407.
2. Sanz Segura P, Jimeno Sánchez J, Senzolo M, Grygier M, Bernal-Monterde V, Pérez de Prado A *et al*. Left atrial appendage closure for atrial fibrillation patients at high risk of gastrointestinal bleeding. An evidence-based multidisciplinary review for gastroenterologists. Revista espanola de enfermedades digestivas. 2026.
3. Zahid SI, Ansari AK, Mahmood AA, Zahid NI, Tamimi K. The Amulet Device as Rescue Therapy in a Patient With Atrial Fibrillation and a Recurrent Gastrointestinal Bleed: A Case Report. Cureus. 2025;17(12):e99663.
4. Alseid A, Abunemr IO, Prashad R. Impact of Age on Clinical Outcomes Following Left Atrial Appendage Occlusion: A Meta-Analysis And Systematic Review of Observational Studies. Cureus. 2025;17(12):e98603.
5. Alabdaljabar MS, Al-Abcha A, Alkhouli M, Hibbert B, Liu XK, Simard T *et al*. Outcomes of Left Atrial Appendage Occlusion in Patients With Hypertrophic Cardiomyopathy, Rheumatic Heart Disease, and Cardiac Amyloidosis. JACC Clinical electrophysiology. 2026.
6. Lin C, Liu L, Liu Y, Leng J. Recent developments in next-generation occlusion devices. Acta biomaterialia. 2021;128:100-119.
7. Dimitriadis K, Pyrpyris N, Aznaouridis K, Adamopoulou E, Soulaidopoulos S, Beneki E *et al*. Transcatheter Structural Heart Disease Interventions and Concomitant Left Atrial Appendage Occlusion: A State of the Art Review. The Canadian journal of cardiology. 2024;40(12):2395-2407.
8. Khalaph M, Lucas P, Schenker N, Rillig A, Heeger CH, El Hamriti M *et al*. Transseptal puncture for catheter ablation of atrial fibrillation in patients with septal occluder devices. Heart rhythm. 2025;22(9):e578-e585.
9. Oliva L, Huszti E, Barker M, Frankfurter C, Hall R, Horlick E *et al*. New-onset atrial fibrillation following percutaneous closure of patent foramen ovale: a systematic review and meta-analysis. Journal of interventional cardiac electrophysiology : an international journal of arrhythmias and pacing. 2021;60(2):165-174.
10. Lim I, Teo YH, Fang JT, Teo YN, Ho JSY, Lee YQ *et al*. Association of Shunt Size and Long-Term Clinical Outcomes in Patients with Cryptogenic Ischemic Stroke and Patent Foramen Ovale on

Medical Management. Journal of clinical medicine. 2023;12(3).

11. Liang S, Guan M, Liu Z, Ruan X, Huang H, Zhong H. Sailing between scylla and charybdis-anticoagulation dilemma in a patient with calciphylaxis and mechanical cardiac valve replacement: a case report and literature review. Renal failure. 2023;45(2):2264401.
12. Freixa X, Abualsaud A, Chan J, Nosair M, Tzikas A, Garceau P *et al*. Left atrial appendage occlusion: initial experience with the Amplatzer™ Amulet™. International journal of cardiology. 2014;174(3):492-496.
13. Cimmino G, Loffredo FS, Gallinoro E, Prozzo D, Fabiani D, Cante L *et al*. Percutaneous Left Atrial Appendage Occlusion: An Emerging Option in Patients with Atrial Fibrillation at High Risk of Bleeding. Medicina (Kaunas, Lithuania). 2021;57(5).
14. Lam SC, Bertog S, Gafoor S, Vaskelyte L, Boehm P, Ho RW *et al*. Left atrial appendage closure using the Amulet device: an initial experience with the second generation amplatzer cardiac plug. Catheterization and cardiovascular interventions : official journal of the Society for Cardiac Angiography & Interventions. 2015;85(2):297-303.
15. Tzikas A, Bergmann MW. Left atrial appendage closure: patient, device and post-procedure drug selection. EuroIntervention : journal of EuroPCR in collaboration with the Working Group on Interventional Cardiology of the European Society of Cardiology. 2016;12 Suppl X:X48-x54.
16. Whitler C, McClellan B, Patel H, Rajpurohit D, Kalaba F, Kado H *et al*. Improved left atrial appendage closure procedural efficiency using radiofrequency transseptal wire system. Catheterization and cardiovascular interventions : official journal of the Society for Cardiac Angiography & Interventions. 2023.
17. Gorenflo J, Ziesenitz V, Farag M, Loukanov T, Gorenflo M. Outcome in Patients with Secundum Type Atrial Septal Defect Referred for Percutaneous or Surgical Closure: A Single-Center Experience. The Thoracic and cardiovascular surgeon. 2026;73(S 03):e1-e8.
18. Rojko M, Suligoj NC, Zvan B, Zorc M, Kar S, Noc M. Long-term Echocardiographic Features After Percutaneous Closure of Patent Foramen Ovale. Interventional cardiology (London, England). 2026;21:e01.
19. Arvidsson PM, Clausen H, Sjöberg P. Closure of atrial septal defect normalizes left and right ventricular hemodynamic forces in children and adolescents. Journal of cardiovascular magnetic resonance : official journal of the Society for Cardiovascular Magnetic Resonance. 2026:102704.
20. Varia A, Roberts D. When Should Physicians Consider Referring Elderly Patients with Suspected PFO-Related Stroke for Device Closure? Journal of clinical medicine. 2025;15(1).
21. He T, Lu C, Zhang Z, Zeng J. Transcatheter Closure for Prevention of Stroke in an Octogenarian Woman With Dual Left Atrial "Appendages". Catheterization and cardiovascular interventions : official journal of the Society for Cardiac Angiography & Interventions. 2026;107(3):818-823.
22. Zhang ZH, Yao Q, Huang HY, Zhu P, Xu X, Song ZY *et al*. "One-stop shop": safety and efficacy of combining atrial septal defect occlusion and left atrial appendage closure for patients with atrial septal defect and atrial fibrillation. BMC cardiovascular disorders. 2020;20(1):444.

23. Gafoor S, Franke J, Boehm P, Lam S, Bertog S, Vaskelyte L *et al*. Leaving no hole unclosed: left atrial appendage occlusion in patients having closure of patent foramen ovale or atrial septal defect. Journal of interventional cardiology. 2014;27(4):414-422.
24. Wang G, Jie Q, Xu K, Luo J, Dong J, Xie D *et al*. "One-stop" combined percutaneous left atrial appendage and atrial septal defect closure in atrial fibrillation: safety and feasibility from a single-center cohort. Frontiers in cardiovascular medicine. 2025;12:1579786.
25. Mofidi F, Kavand S, Doaei S, Shahrabi M, Javid Z, Norouzi M *et al*. Probiotic supplementation and postoperative antioxidant response in patients undergoing open-heart surgery: a randomized controlled trial. Cardiovascular endocrinology & metabolism. 2026;15(1):e00351.
26. Koermendy D, Nietlispach F, Shakir S, Gloekler S, Wenaweser P, Windecker S *et al*. Amplatzer left atrial appendage occlusion through a patent foramen ovale. Catheterization and cardiovascular interventions : official journal of the Society for Cardiac Angiography & Interventions. 2014;84(7):1190-1196.
27. Franke A, Kühl HP. The role of antiplatelet agents in the management of patients receiving intracardiac closure devices. Current pharmaceutical design. 2006;12(10):1287-1291.
28. Guedeney P, Farjat-Pasos JI, Asslo G, Roule V, Beygui F, Hermida A *et al*. Impact of the antiplatelet strategy following patent foramen ovale percutaneous closure. European heart journal Cardiovascular pharmacotherapy. 2023;9(7):601-607.
29. Laudani C, Ortega-Paz L, Franchi F, Rollini F, Zgheib A, El Khoury G *et al*. The pharmacology and clinical evidence for the use of dual versus single antiplatelet therapy. Expert review of clinical pharmacology. 2026:1-18.
30. Kaba RA, Rajkumar C, Mattace-Raso F. Guideline commentary on the ESC/EACTS 2024 guidelines for atrial fibrillation: a focus on managing AF in the older population. Age and ageing. 2026;55(1).
31. Urbani A, Kheir JA, Urbanek L, Schaack D, Rocchetti M, Steyer A *et al*. Percutaneous left atrial appendage closure: evolution of devices and expanding clinical applications. Expert review of medical devices. 2026:1-11.
32. Saver JL, Carroll JD, Thaler DE, Smalling RW, MacDonald LA, Marks DS *et al*. Long-Term Outcomes of Patent Foramen Ovale Closure or Medical Therapy after Stroke. N Engl J Med. 2017;377(11):1022-1032.
33. Guedeney P, Laredo M, Zeitouni M, Hauguel-Moreau M, Wallet T, Elegamandji B *et al*. Supraventricular Arrhythmia Following Patent Foramen Ovale Percutaneous Closure. JACC Cardiovasc Interv. 2022;15(22):2315-2322.

Tables

Table 1 Patient clinical information (n=18)

No.	Gender	Age	CHA2DS2-VASC	HAS-BLED	NYHA	EF%	ASD/PFO□mm□	LAA □mm□
1	male	82	4	3	□	68	21	21
2	Female	72	3	3	□	36	27	24
3	Female	75	4	2	□	66	15	25
4	male	65	2	4	□	62	16	26
5	Female	76	5	3	□	60	1.8	21
6	male	78	7	3	□	41	1.8	25
7	male	52	3	2	□	66	2.3	19
8	male	70	3	2	□	55	4,3,5 (Cribriform type)	21
9	male	65	3	2	□	66	1.7	21
10	male	59	4	2	□	50	1.8	26
11	male	39	2	1	□	62	1.8	33
12	male	59	3	1	□	55	1.3	35
13	Female	73	4	3	□	73	25	30
14	Female	60	6	4	II	64	33	34
15	Female	63	5	2	□	62	10	32
16	male	62	2	2	□	60	1.5	29
17	male	81	6	4	□	67	1.3	40
18	male	58	1	1	□	61	1.8	46

CHA2DS2-VAS score (C, congestive heart failure: 1; H, hypertension: 1; A2, age ≥ 75 years: 2; D, diabetes mellitus: 1; S2, history of stroke, transient ischemic attack, or systemic circulation embolism: 2; A, age 65-74 years: 1; Sc, female: 1; total maximum score of 9); HADS-BLED score (H, hypertension: 1; A, liver and kidney dysfunction: 1 each; S, stroke history: 1; B, bleeding history: 1; L, international normalized ratio fluctuation: 1; E, old age (> 65 years): 1; D, drug or alcohol abuse: 1 each; total maximum score of 9)

Abbreviations: ASD atrial septal defect, *PFO* patent foramen ovale, *LAA* left atrial appendage

Table 2 Detailed information of ASD/PFO occluder and a WATCHMAN^{TM} occluder

No.	WATCHMAN™ occluder				ASD/PFO occluder
	Size （mm）	Compression ratio (%)	Excessive shoulder (mm)	Leak flow (mm)	Size (mm)
1	30	15	4	1	28
2	33	12	6	2	32
3	33	13	8	0	20
4	33	15	7	0	22
5	27	15	0	0	30/30
6	33	20	5	0	30/30
7	24	15	0	0	30/30
8	27	19	0	0	40/40
9	24	17	4	0	30/30
10	30	17	8	0	30/30
11	27	24	0	0	30/30
12	27	22	0	0	30/30
13	21	24	0	0	32
14	30	42	4	0	40/40
15	24	23	4	0	16
16	27	21	5	0	25/25
17	24	19	5	0	30/30
18	21	23	0	0	30/30

Figures

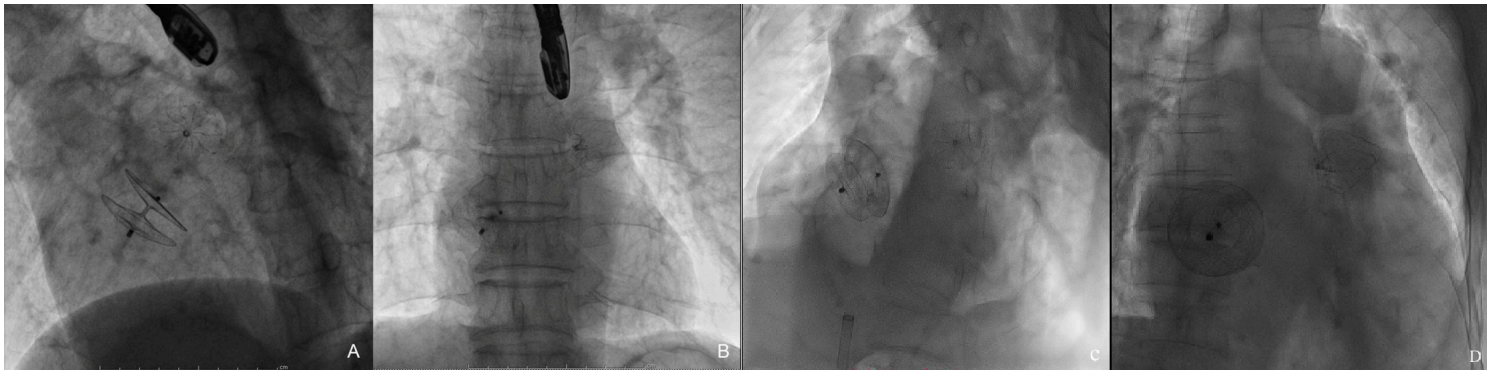


Figure 1

Radiographs taken before ASD/PFO occlusion and LAAO. Figs. 1A and 1B show images of PFO occlusion combined with LAAO;Figs. 1C and 1D show images of ASD occlusion combined with LAAO indicating stable occluder positions.

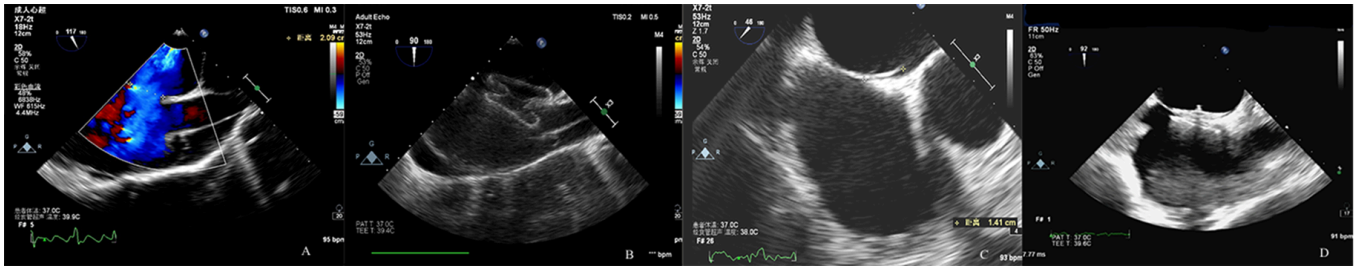


Figure 2

TEE images taken before and after ASD/PFO occlusion. Figs.2A and 2B show the manifestations of TEE before and after ASD occlusion;Figs.2C and 2D show the manifestations of TEE before and after PFO occlusion, indicating stable occluder positions and no significant residual shunting.

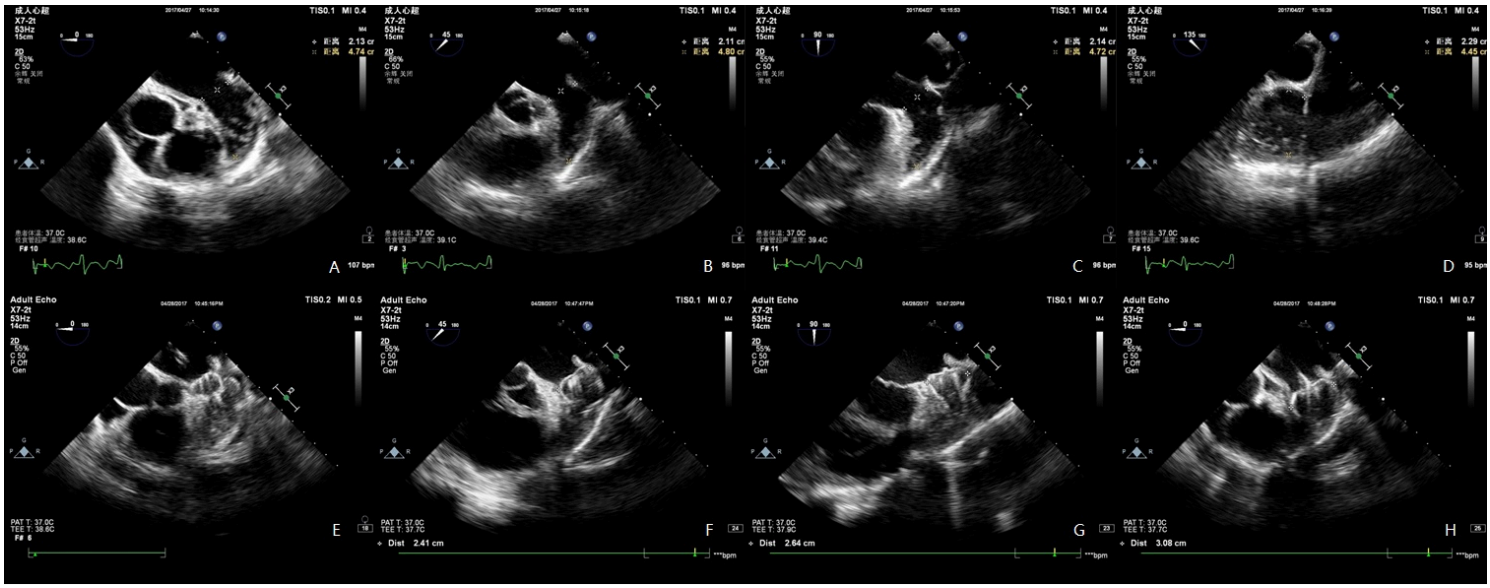


Figure 3

TEE images before and after LAAO. Figs.3A-D are 0°, 45°, 90°, and 135° sections taken before LAAO, respectively;Figs.3E-H are 0°, 45°, 90°, and 135° sections taken after LAAO, respectively, and show stable occluder positions, no apparent shoulder protrusion, and a compression ratio of 15-21%.

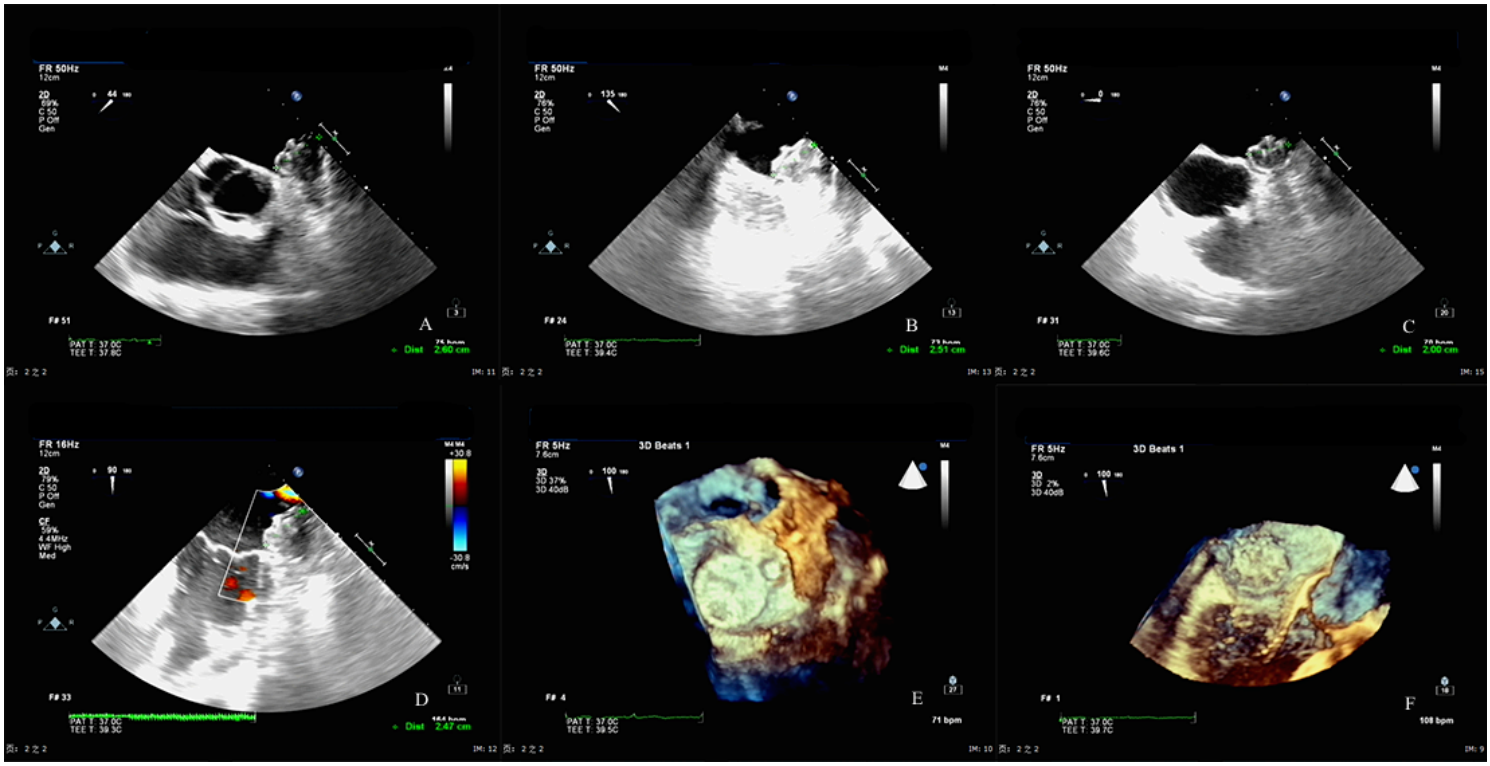


Figure 4

TEE images taken 45 days after ASD/PFO combined with LAAO (on the 45th day of follow-up). Figs.4A-D show 3°, 45°, 90°, and 135° sections of the LAA occluder 45 days after ASD/PFO combined with LAAO. Fig. 4E is a 3D image of the PFO occluder. Fig.4F is a 3D image of the LAA occluder showing a stable occluder position and no significant residual shunting or thrombus on the occluder surface.