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Original article

Left atrial appendage occlusion using LAmbre Amulet and Watchman in atrial fibrillation

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ABSTRACT

Background: Left atrial appendage closure (LAAC) has been suggested as an alternative to anticoagulation in non-valvular atrial fibrillation (AF). The present study aimed to compare a LAmbre LAA occluder system [Lifetech Scientific (Shenzhen) Co. Ltd., Shenzhen, China] with the most investigated Amulet (St. Jude Medical Inc., St. Paul, MN, USA) and Watchman (Boston Scientific, Plymouth, MN, USA) devices in terms of peri-procedural and short-term outcomes.
Methods: This is a prospective observational study.
Results: Overall, 140 patients (50 female, mean age 76.2 ± 8.4 years) were consecutively enrolled. Mean CHA2DS2-VASc score was 3.8 ± 1.5, and mean HAS-BLED score was 3.9 ± 1.1. Baseline clinical characteristics were comparable between the three groups (LAmbre, $n = 30$; Amulet, $n = 74$; Watchman, $n = 36$); the LAmbre group had significantly more patients with complicated LAA morphology ($p = 0.006$). The implant success rate was 100% in LAmbre, 99% in Amulet, and 100% in Watchman group ($p = 0.638$). The number of device repositions was not significantly different between groups (0.7 ± 1.1 in LAmbre, 1.0 ± 2.0 in Amulet, and 1.4 ± 1.8 in Watchman group, $p = 0.345$). Fluoroscopic and procedural times were similar between groups. Major peri-procedural adverse events did not differ between groups (0% vs. 0% vs. 2.8%, $p = 0.233$). Six months' follow-up showed good device stability and patients' clinical condition in all groups.
Conclusion: LAmbre, Amulet, and Watchman exhibit remarkable implant success rate, low risk of peri-procedural adverse events, and good clinical outcomes.
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Introduction

Around 20–30% strokes are attributable to atrial fibrillation (AF), and more may be associated with undiagnosed subclinical AF [1,2]. One main strategy for stroke prevention in AF is oral anticoagulation therapy using vitamin K Antagonists (VKA, e.g. warfarin) or novel oral anticoagulants (NOACs), and both have been shown to significantly reduce the rate of stroke in patients with AF [3]. However, despite the efficacy of the pharmacotherapy, complex drug interactions, poor patient compliance, risk of bleeding particularly in patients with impaired liver or renal function limit their clinical use in selected patient groups [4,5]. Thus, a non-pharmacological approach for prevention of stroke in patients with AF seems rational and warranted.

Previous research showed that up to 90% of left atrial thrombi were located in the left atrial appendage (LAA) among patients with non-valvular AF [6]. A device-based therapeutic strategy that has shown promising results is the percutaneous trans-catheter LAA closure (LAAC) using the LAA occluder (LAAO). Prior randomized trials have shown that LAAC was non-inferior to conventional warfarin therapy in non-valvular AF [7,8]. Along with the development of the device design and implantation experience, the procedural success rate is increasingly higher and complications have been remarkably decreased, however, there are still technically or anatomically complicated cases where novel devices with better design could facilitate the procedure and potentially improve the patients' clinical outcome.

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In this prospective cohort observational study, we compared a novel LAmbre LAAO [Lifetech Scientific (Shenzhen) Co. Ltd., Shenzhen, China] with the most investigated Amulet (St. Jude Medical Inc., St. Paul, MN, USA) and Watchman (Boston Scientific, Plymouth, MN, USA) devices in terms of peri-procedural and acute clinical outcomes.

Methods

Patients

Between April 2016 and September 2017 patients with non-valvular AF who were scheduled for percutaneous LAAC were consecutively included in the study at the Cardioangiologische Centrum Bethanien Frankfurt, Germany.

The inclusion criteria were: (1) 18 years and older, (2) both genders, (3) paroxysmal, persistent, or permanent non-valvular AF, (4) high risk for stroke (CHA2DS2-VASc $\geq$ 2), (5) contraindications for oral anticoagulation therapy, e.g. bleeding events after anticoagulation, intolerance, or refusal to receive anticoagulation therapy; we also included AF patients who had LAA isolation after multiple AF ablation procedures.

The exclusion criteria were: (1) patients with rheumatic, degenerative or congenital valvular heart diseases, artificial heart valve replacement operation. (2) Acute myocardial infarction or unstable angina, decompensated heart failure (New York Heart Association functional class III–IV), or heart transplantation. (3) Stroke or transient ischemic attack within 30 days. (4) Patients with atrial septal occluder. (5) Clinical conditions not allowing transesophageal echocardiography (TEE) and sedation. (5) Very poor peripheral vessel access not allowing device delivery. (6) Left ventricular ejection fraction $\leq$30%, left atrial thrombus; significant mitral valve stenosis. (7) $\geq$Moderate pericardial effusion.

All clinical, peri-procedural, and echocardiographic data were collected. The study complied with the Declaration of Helsinki. Informed consent was obtained from the included patients before the procedure.

Device introduction

The LAmbre device

As shown in Fig. 1, the LAmbre occluder is a Conformité Européenne (CE) recognized LAA closure device. It is a self-expanded device consisting of: (1) 10.4–12.3 Fr (outer diameter) sheath (delivery system), (2) hook-embedded umbrella, and (3) size adaptive cover [9]. The umbrella has 8 small distal hooks engaging into LAA walls and 8 U-shaped ends trapping in LAA trabeculations (double stabilization design). The umbrella and the cover are connected with a short central waist that acts as an articulating, compliant connection between both, allowing the cover to self-orient to the atrium wall. The LAmbre occluder is constructed from a nitinol mesh and polyester membranes. The proximal cover is filled with sewn in polyethylene terephthalate fabric.

The Amulet device

As shown in Fig. 1, the Amulet is a second-generation self-expanded LAAO. The design was based on the AMPLATZER™ Cardiac Plug (ACP) (St. Jude Medical Inc.) incorporating several design improvements. The device system consists of: (1) 14.4–16.5 Fr (outer diameter) delivery sheath, (2) lobe and stabilization hook, and (3) fixed size cover disk.

The Watchman device

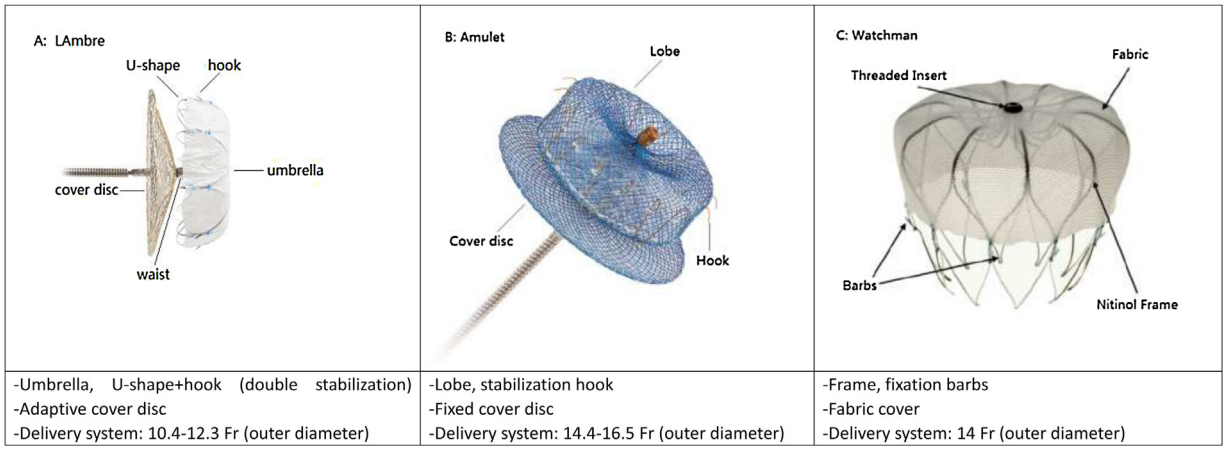
As shown in Fig. 1, the Watchman is the most investigated LAAO. The device system consists of: (1) 14 Fr (outer diameter), (2) frame with fixation barbs, and (3) fabric cover.

Device implantation

Device selection was based on operators' discretion, however, the operators selected LAmbre device if the patients had poor groin access condition (difficult groin puncture or difficult wire/sheath movement based on operators' experience), and the operators tended to select LAmbre device if the patients had complicated LAA morphology (chicken-wing, double wing, multi-lobe morphology, or other types with difficult anatomy). The device implantation was reported previously [10,11]. In brief, patients were under deep sedation by using boluses of midazolam and a continuous infusion of propofol (1%).

After a single transseptal puncture, one 8-Fr sheath (SL1, St. Jude Medical) was introduced into the left atrium, and a single heparin bolus (80–100 IE/kg of body weight) was administered. The transseptal sheath was exchanged with LAAO delivery sheath and continuously flushed with heparinized saline (20 mL/h). The LAAO was implanted under guidance of fluoroscopy and TEE (Vivid E95 Cardiac Ultrasound, GE, Boston, MA, USA). The activated clotting time was adjusted to between 250 s and 300 s throughout the procedure.

The size of the device was chosen based on angiographic and TEE measurements. LAA angiographic assessment was performed in the right anterior oblique 30° plus cranial and caudal view. TEE of LAA was assessed in the mid-esophageal view from 0° to 180°. The maximal diameter of the LAA ostium and the LAA landing zone on either angiography or TEE was measured for selecting the size of



-Umbrella, U-shape+hook (double stabilization) -Adaptive cover disc -Delivery system: 10.4-12.3 Fr (outer diameter)	-Lobe, stabilization hook -Fixed cover disc -Delivery system: 14.4-16.5 Fr (outer diameter)	-Frame, fixation barbs -Fabric cover -Delivery system: 14 Fr (outer diameter)

Fig. 1. Device system design of LAmbre vs. Amulet vs. Watchman.

the device. For patients scheduled for Watchman device, the LAA length was also measured. We performed the device implantation using the recommended right anterior oblique 30° plus caudal (or plus cranial) view.

The degree of device over-sizing was based on the anatomy of the LAA, manufacturer's recommendation, and the experience of the operator, principally 2–6 mm larger than the average LAA diameter and no less than the largest LAA diameter measurement. The degree of sealing was assessed behind the cover of the LAAO device by angiography and TEE. Successful device implantation was defined as stable device position with no or minimal contrast leak (≤3 mm) into LAA. If the device position was not satisfactory, we either considered repositioning or selecting a device with a different size. If the initial attempts failed to achieve a satisfactory position, we considered switching to another device in a second procedure.

Major adverse events were defined as procedure-related death, stroke, embolism, cardiac tamponade, pericardial effusion, and major bleeding. Minor adverse events were defined as minor bleeding or vascular complications without the need for further intervention or transfusion or prolonged hospitalization.

Recommended antithrombotic therapy post-implantation for Watchman group was 6 weeks of oral anticoagulation plus aspirin, in case of good sealing and without device-related thrombosis, dual antiplatelet therapy including clopidogrel and aspirin was administered until completion of the 6-month follow-up visit; thereafter aspirin was continued lifelong. In Amulet and LAmbre groups: patients were treated with 3–6 months of dual antiplatelet therapy, followed by single antiplatelet therapy. For any patient with high risk of bleeding, reduced or shortened antithrombotic therapy would be considered.

Follow-up was performed during conventional clinical visits. Six weeks and six months after the procedure patients were scheduled for a TEE follow-up in order to evaluate the devices' stability, LAA sealing, and to rule out pericardial effusion or thrombosis.

Statistical analysis

The results for continuous variables were described as mean ± standard deviation (SD) for normally distributed data. Median and interquartile ranges were used when appropriate. Categorical variables were presented as counts and percentages. Continuous variables were compared using ANOVA test or Mann–Whitney test when appropriate. Categorical variables were compared using chi-square test or the Fisher exact test. A p-value <0.05 was considered statistically significant. Statistical analyses were performed using SPSS software version 17.0 (Chicago, IL, USA).

Results

Clinical characteristics

During the study period, 140 patients (50 female, mean age 76.2 ± 8.4 years) underwent percutaneous LAAC (LAmbre, n = 30, Amulet, n = 74, Watchman, n = 36). All patients had non-valvular AF (44 paroxysmal and 96 non-paroxysmal AF). The mean CHA2DS2-VaSc was 3.8 ± 1.5. The mean HAS-BLED score was 3.9 ± 1.1. Eighty-seven (62%) patients had clinical bleeding events and of them thirty-nine (45%) patients had gastrointestinal (GI) bleeding. As shown in Table 1 the baseline clinical characteristics are comparable between the three groups.

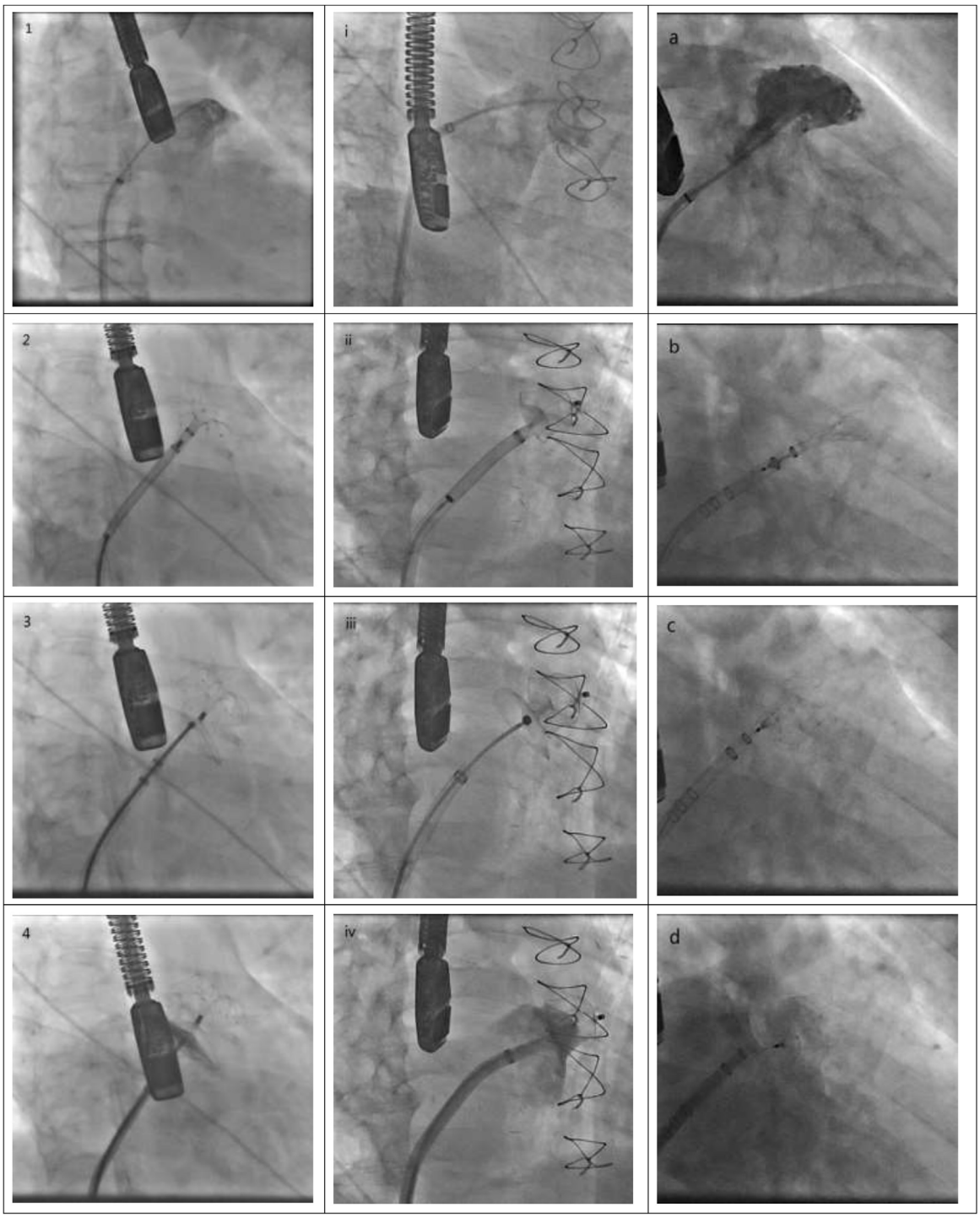
Peri-procedure outcome

The angiography and TEE-guided device implantation process are demonstrated in Figs. 2 and 3. The peri-procedural outcome data are presented in Table 2. Overall, the implant success rate was 99%; respectively 100% (30/30) in LAmbre, 99% (73/74) in Amulet (1 patient was not implanted because of oversized LAA anatomy), and 100% (36/36) in Watchman group (p = 0.638). The measurements of the LAA size, LAAO device size, and device-to-LAA oversize were comparable between groups. The average device reposition seemed similar between groups (p = 0.345), and the number of patients who needed more repositions seemed less in LAmbre (3.3%) and Amulet (4.1%) groups as compared with Watchman group (16.7%, p = 0.038). One patient in the Amulet group needed to change the device size because of unsatisfactory device position.

Table 1
Patients' baseline characteristics.

	LAmbre	Amulet	Watchman	p-Value
N	30	74	36	
Female, *n* (%)	15 (50.0%)	25 (33.8%)	10 (27.8%)	0.151
Age (y)	77.6 ± 8.9	76.0 ± 7.9	75.3 ± 8.8	0.705
Height (cm)	170.5 ± 9.9	170.8 ± 10.7	171.9 ± 9.3	0.482
Weight (kg)	76.9 ± 14.9	81.0 ± 18.3	80.5 ± 12.0	0.05
BMI	26.5 ± 3.9	27.9 ± 5.6	27.2 ± 3.6	0.056
Paroxysmal AF, *n* (%)	14 (46.7%)	22 (29.7%)	8 (22.2%)	0.093
Non-paroxysmal AF, *n* (%)	16 (53.3%)	52 (70.3%)	28 (77.8%)	0.093
Heart failure, *n* (%)	4 (13.3%)	15 (20.3%)	5 (13.9%)	0.581
Hypertension, *n* (%)	22 (73.3%)	63 (85.1%)	33 (91.7%)	0.120
Age > 75, *n* (%)	20 (66.7%)	44 (59.5%)	22 (61.1%)	0.791
Diabetes, *n* (%)	9 (30%)	22 (29.7%)	10 (27.8%)	0.973
Previous stroke/TIA, *n* (%)	4 (13.3%)	16 (21.6%)	6 (16.7%)	0.581
Vascular diseases, *n* (%)	5 (16.7%)	12 (16.2%)	1 (2.8%)	0.111
Coronary artery disease, *n* (%)	15 (50%)	31 (41.9%)	15 (41.7%)	0.725
Liver/renal dysfunction, *n* (%)	15 (50)	22 (29.7)	9 (25%)	0.070
Labile INR, *n* (%)	2 (6.7%)	3 (4.1%)	2 (5.6%)	0.844
Bleeding events, *n* (%)	21 (70%)	45(60.8%)	21 (58.3%)	0.587
GI bleeding, *n* (%)	12 (57.1%)	18 (45.0%)	9 (42.9%)	0.246
Non-GI bleeding, *n* (%)	9 (42.9%)	27 (55.0%)	12 (57.1%)	0.811
CHA2DS2-VASc score	3.9 ± 1.5	3.9 ± 1.5	3.6 ± 1.5	0.586
HAS-BLED score	4.1 ± 1.0	3.9 ± 1.1	3.8 ± 1.0	0.536

BMI: body mass index, AF: atrial fibrillation, TIA: transient ischemic attack, INR: international normalized ratio, and GI: gastrointestinal.



--LAmbre: 1. LAA angiography, 2. Umbrella deployment, 3. Disc deployment, 4. Post-implant angiography

--Amulet: i. LAA angiography, ii. Lobe deployment, iii. Disc deployment, iv. Post-implant angiography

--Watchman: a. LAA angiography, b. device position, c. device expansion, d. post-implant angiography

Fig. 2. Angiography guided LAAO implantation. LAmbre: 1. LAA angiography, 2. Umbrella deployment, 3. Disk deployment, 4. Post-implant angiography. Amulet: i. LAA angiography, ii. Lobe deployment, iii. Disk deployment, iv. Post-implant angiography. Watchman: a. LAA angiography, b. Device position, c. Device expansion, d. Post-implant angiography. LAAO, left atrial appendage occluder.

Fluoroscopic and procedure time

The fluoroscopic time (3.5 ± 1.9 min in LAmbre, 4.0 ± 3.6 min in Amulet, and 3.9 ± 2.2 min in Watchman, $p = 0.766$) and procedure time (29.0 ± 10.1 min in LAmbre, 31.2 ± 17.3 min in Amulet, and 34.7 ± 13.2 min in Watchman, $p = 0.293$) were similar between the LAmbre, Amulet, and Watchman groups.

Additionally, we performed a uni-variable analysis (as shown in Table 3) between patients with "zero reposition" and patients with "≥1 reposition". Variables including age, gender, body mass index,

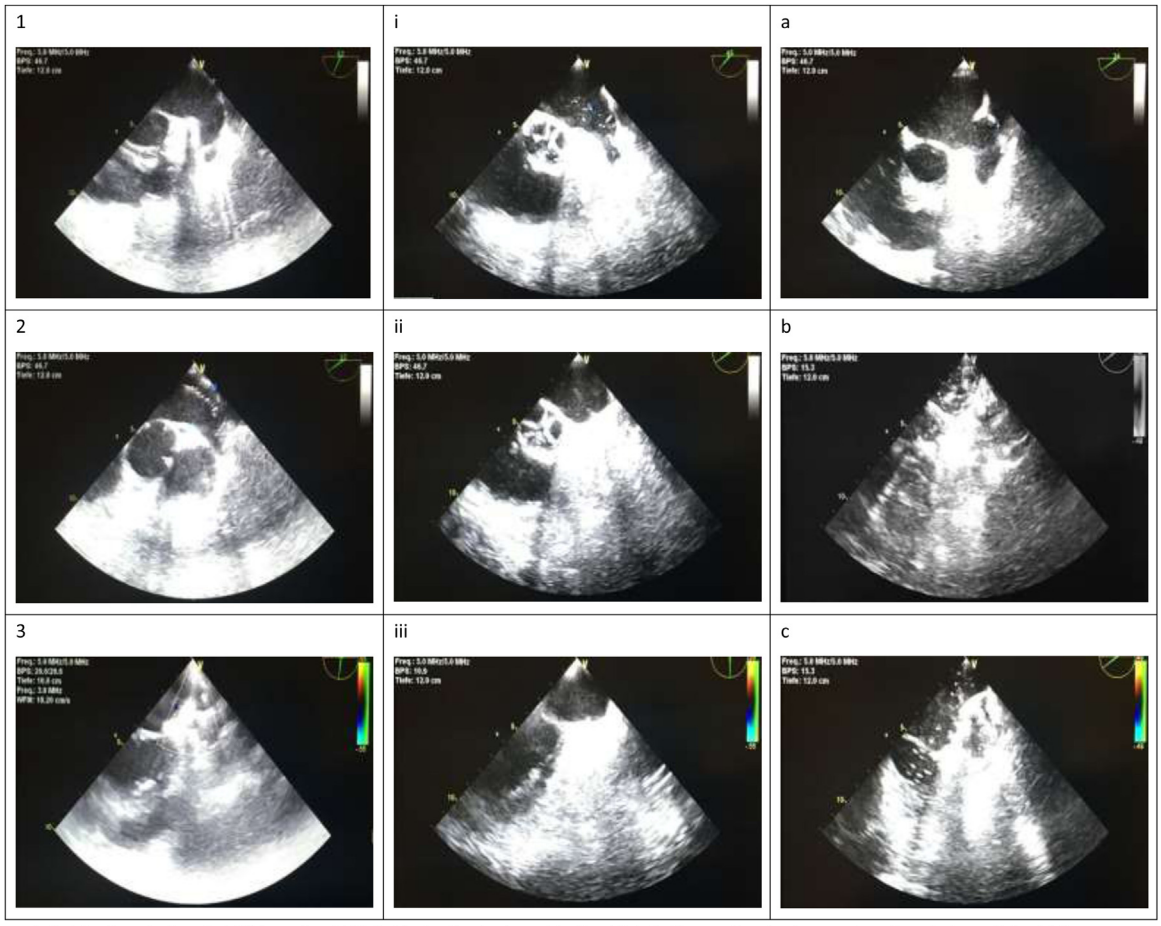


Fig. 3. TEE guided LAAO implantation. Left: LAmbre device, 1. LAA baseline TEE, 2. Umbrella deployed in the LAA, 3. Cover disk deployment and occlusion of the LAA. Middle: Amulet device, i. LAA baseline TEE, ii. Lobe deployed in the LAA, iii. Cover disk deployment and occlusion of the LAA. Right: Watchman device: a. LAA baseline TEE, b. Device positioned in the LAA, c. Device expansion and occlusion of the LAA. TEE, transesophageal echocardiography; LAAO, left atrial appendage occluder.

CHA2DS2-VASc score, HAS-BLED score, percentage of chicken-wing anatomy, and diameter of LAA landing-zone were similar between the two groups. Only the fluoroscopic time and procedural time were significantly longer in the patients with "≥1 reposition" as compared with patients with "zero reposition".

Peri-procedural adverse events

As shown in Table 2, there were no peri-procedural adverse events in the LAmbre group. In the Amulet group, two patients had minimal transient ST change, one patient needed intubation after procedure and it was confirmed not procedure-related. In the Watchman group, two patients had minimal transient ST change; one had pericardial effusion. As shown in Table 2, the major peri-procedure adverse events were similar between three groups (0% vs. 0% vs. 2.8%, $p = 0.233$). The puncture site complication was 0 (0%) in LAmbre group, 0 (0%) in Amulet group, and 1 mini-hematoma (2.7%) in Watchman group. The hospitalization days for each patient were two days unless the patient had major adverse events. In this study cohort only one patient had major adverse event, the hospitalization for this patient was three days.

Acute clinical follow up

Acute clinical follow-up results are shown in Table 2. All patients were scheduled for conventional clinical visit. Due to patients' clinical unsuitability or patients' refusal, TEE follow up (6 weeks to 6 six months post-procedure) was performed in 122 (87.1%) patients. Of them, all TEE follow-up examinations showed good results in terms of device stability, LAA sealing (<3 mm), and no pericardial effusion. One patient had minimal thrombosis formation in the LAmbre group at six-week TEE follow up; the patient's antiplatelet therapy was consequently changed to anticoagulation and no significant clinical adverse events were observed during follow up thereafter.

Antiplatelet and anticoagulation therapy

The antithrombotic therapy after LAAC procedure is summarized in Table 2. In detail, in the LAmbre group, post-procedure dual antiplatelet therapy was administered after the implant in 25 (83.3%) patients; another three patients received their dual antiplatelet therapy since discharge; another one patient had LAA isolation before LAAC and another one patient was found to have minimal peri-device thrombosis in LAA at TEE follow up and thus the anticoagulation therapy was continued.

In the Amulet group, post-procedure dual antiplatelet therapy was administered after the implant in 67 (90.5%) patients; another four patients received dual antiplatelet therapy since discharge; another three patients had LAA isolation before LAAC and their anticoagulation therapy was maintained.

Table 2
Peri-procedural and follow-up outcome.

	LAmbre	Amulet	Watchman	*p*-value
N	30	74	36	
Presenting AF during procedure, *n* (%)	8 (26.7%)	29 (40.3%)	16 (44.4%)	0.300
Device size (mm)	25.9 ± 5.4	24.8 ± 3.8	26.4 ± 3.9	0.126
LAA Size (mm)	21.2 ± 4.4	20.9 ± 4.1	21.9 ± 4.2	0.449
Oversize (mm)	4.7 ± 1.8	4.1 ± 1.6	4.4 ± 1.6	0.183
Difficult LAA morphology, *n* (%)	28 (93.3%)	40 (54.1%)	19 (53%)	0.006
Chicken wing LAA morphology, *n*	20	40	19	
Double wing LAA morphology, *n*	2	0	0	
Other difficult LAA anatomy, *n*	6	0	0	
Cauliflower LAA morphology, *n* (%)	2 (6.7%)	9 (12.2%)	9 (25%)	
Windsock LAA morphology, *n* (%)	0	15 (20.3%)	4 (11%)	
Other LAA morphology, *n* (%)	0	10 (13.5%)	4 (11%)	
Reposition, *n* ± SD	0.7 ± 1.1	1.0 ± 2.0	1.4 ± 1.8	0.345
Reposition = 0, *n* (%)	16 (53.3%)	34 (46.6%)	11 (30.6%)	0.142
Fluoroscopic time (min)	3.5 ± 1.9	4.0 ± 3.6	3.9 ± 2.2	0.766
Procedure time (min)	29.0 ± 10.1	31.2 ± 17.3	34.7 ± 13.2	0.293
Implant success, *n* (%)	30 (100%)	73 (99%)[a]	36 (100%)	0.638
Procedure-related death, *n*	0	0	0	
Procedure-related stroke, *n*	0	0	0	
Procedural thrombosis formation, *n*	0	0	0	
Procedural transient ST change, *n*	0	2	2	
Procedural pericardial effusion, *n*	0	0	1	
Major peri-procedure adverse events, *n* (%)	0 (0%)	0 (0%)	1 (2.8%)	0.233
Post-procedure dual antithrombotic, *n* (%)	25 (83.3%)	67 (90.5%)	32 (88.9%)	0.577
Dual antithrombotic at discharge, *n* (%)	28 (93.3%)	71 (95.9%)	35 (97.2%)	0.732
Remain anticoagulation, *n* (%)	2 (6.7%)	3 (4.1%)	1 (2.8%)	0.732
Follow up TEE (6 weeks/6 months)				
Device dislodgment, *n* (%)	0	0	0	
Thrombosis in LA, *n* (%)	1 (minimal)	0	0	
Pericardial effusion, *n* (%)	0	0	0	
Residual flow >3 mm, *n* (%)	0	0	0	
Clinical adverse events during follow up (6 months)				
Death, *n* (%)	0	0	0	
Bleeding events, *n* (%)	0	0	0	
Thromboembolic/stroke events, *n* (%)	0	0	0	

AF: atrial fibrillation, LAA: left atrial appendage, SD: standard deviation, TEE: transesophageal echocardiography, and LA: left atrium.
[a] One patient was not implanted due to oversized LAA.

Table 3
Comparison between different device reposition.

	Reposition = 0 *N* = 61	Reposition≥1 *N* = 79	*p*-Value
Age (years)	77.0 ± 7.5	75.5 ± 9.0	0.281
Female (%)	41%	31.6%	0.253
BMI	27.5 ± 4.5	27.3 ± 5.1	0.801
CHA2DS2-VASc score	4.0 ± 1.6	3.6 ± 1.4	0.148
HAS-BLED score	4.1 ± 1.1	3.8 ± 1.0	0.132
Chicken-wing anatomy (%)	52.5%	59.5%	0.405
LAA landing zone (mm)	21.0 ± 4.0	21.4 ± 4.4	0.579
Fluoroscopy time (min)	2.7 ± 1.8	4.8 ± 3.4	<0.0001
Procedure time (min)	26.9 ± 9.5	35.4 ± 17.4	0.001

BMI: body mass index and LAA: left atrial appendage.

In the Watchman group, post-procedure dual antithrombotic therapy was administered after the implant in 32 (88.9%) patients, another three patients received dual antithrombotic therapy since discharge; another one patient had LAA isolation before LAAC and the anticoagulation therapy was maintained.

Device stability and sealing

TEE follow-up was scheduled at 6 weeks and 6 months after the procedure. As summarized in Table 2, in the LAmbre, Amulet, and Watchman groups no device dislodgment was observed, and all patients in the three groups fulfilled adequate sealing (leak jet within 3 mm) [12] and showed good stability of the device.

Discussion

The results from this study are consistent with the growing evidence of favorable outcomes and safety of LAAC among patients with AF who had high risk of stroke and contraindications for oral anticoagulants. Our data showed good implant success rate and safety property of the devices for LAAC. To the best of our knowledge this is the first cohort comparing the LAmbre occluder with the Amulet and Watchman devices.

Among currently available technologies for LAAC, the Watchman occluder system is the most investigated device. The PROTECT-AF trial was the first large randomized trial to test the Watchman device and assess the noninferiority of the device against chronic warfarin therapy [7]. Seven hundred and seven patients with non-valvular AF were enrolled to long-term warfarin or the device therapy. During a mean follow-up of 18 months, the primary efficacy (composite endpoint of stroke, systemic embolism, and cardiovascular death) event rate was not different in both groups. In 2014 the long-term follow-up data of the PROTECT-AF trial were published and demonstrated that during a mean follow up of 3.8 years the device group was associated with less combined endpoint of stroke, systemic embolism, and cardiovascular and all-cause death compared with warfarin. These favorable outcomes of

the device were driven largely by lower rates of hemorrhagic stroke as well as hemorrhagic stroke-related deaths [8].

In the PROTECT-AF study, the device implantation success rate was 91%, and the device group was associated with a higher risk of procedure adverse events including pericardial effusion, and procedural stroke. Peri-procedural compilations were more frequently in the device group than in the control group (7.4 vs. 4.4 per 100 patient-years; RR 1.69). In the later PREVAIL Watchman study, the implant success rate was increased to 95%, and adverse events (including death, ischemic stroke, systemic embolism, and procedure-related complications requiring intervention) were decreased to 2.2% [13].

Another device was Amplatzer cardiac plug (ACP) or Amulet occluder (St. Jude Medical). The ACP is the first-generation LAAO modified from the Amplatzer septal occluder used for atrial septal defect closure. In the largest report on the ACP device, 1047 patients from 22 centers were enrolled and underwent LAAC with the ACP device. The procedural success was achieved in 97.3%. In this multicenter study, the ACP for LAAC showed high procedural success and favorable outcome for the prevention of AF-related thromboembolism. However, there were still 52 (4.97%) peri-procedural major adverse events. Similarly to the Watchman device, issues of peri-device leak and thrombosis are critical considerations for ACP [14]. The Amulet was developed as the second generation ACP device to facilitate ease of implantation and to reduce device-related complications. Modifications incorporated into the Amulet device included increased size in lobe, waist as well as the disk cover. The stabilizing wires were also increased to improve stability. The most recent, global level, prospective Amplatzer Amulet registry study including the real-world data from 1088 patients demonstrated a high implant success rate (successful implantation was achieved in 99.0%) and a low peri-procedural complication rate (major adverse events occurred in 3.2%) in patients with non-valvular AF who had high risk of stroke and bleeding [15].

In the present study, several significances should be mentioned. Despite the fact that this is an initial clinical experience comparing LAmbre with Amulet and Watchman, our study showed good results in terms of implantation success and safety property. Overall, implantation success was achieved in 98.6% of the patients. Nearly half (44%) of the patients were successfully implanted with the devices without repositioning. The average fluoroscopic time was 3.8 min and most procedures could be completed in around 30 min (skin-to-skin). For inter-group comparison, our data suggest that the performance of the novel LAmbre LAAO appears comparable, although preliminary, to the most investigated Amulet and Watchman devices with respect to the implant success and peri-procedural safety events.

The majority of the patients in the LAmbre group had difficult LAA anatomy and poor groin access condition. The high implant success reported in our study may be explained by the increasing procedural experience in LAAC. Moreover, we should acknowledge the favorable design of novel LAAO. For the LAmbre device, its umbrella is highly adaptable to different LAA morphologies. The combination of distal hooks and the U-shaped ends (double stabilization system), as well as the option of different cover sizes for the same umbrella size may help to achieve complete sealing in complex cases. The delivery system of the LAmbre using a smaller sheath is also a significant novel feature, which may contribute to reduced risks of puncture site complications and air embolism. In review of the Watchman study, the implant success rate evolved from 91% in PROTCT-AF trial, 95% in PREVAIL study, and 98.3% in Ewolution registry [7,12,16], the Amulet device as well as the first generation of LAmbre device reported in this study exhibited good performance during implantation.

The major limitation of this study is the single center, non-randomized observational method and small sample size; however, to the best of our knowledge this is the first registry study comparing the three LAAOs. The present study only focused on the peri-procedure and acute clinical outcomes, it should be mentioned that the risk of procedure-related safety events occurring in long-term follow up was seldom based on our previous observations [10,11].

Conclusion

The present study comparing the LAmbre with the Amulet and Watchman devices shows favorable implantation outcome and safety profile of LAAO using these devices in patients with AF who had high risk of stroke and contraindications for oral anticoagulants.

Conflict of interest

The authors declare no conflict of interests with respect to the content of the study.

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