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Occlusion of Large Left Atrial Appendage Using the LAmbre Device: Procedural and Short-term Outcomes

Running Title: LAmbre for Occluding Large Left Atrial Appendage

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Classifications: LAA Closure, Innovation, Atrial Fibrillation, Ischemic Stroke

Abbreviations:

DRT = Device-related thrombus

LAA = Left Atrial Appendages

LAAO =Left atrial appendage occlusion

PDL = Peri-device leak

TEE = Transesophageal echocardiogram

Introduction

The commonly used left atrial appendage (LAA) occlusion (LAAO) devices, Watchman (*Boston Scientific, Marlborough, MA, USA*) and Amulet (*Abbott, Plymouth, Minnesota, USA*), both rely on oversizing for stabilization. Therefore, occluding large LAA (ostium >=31mm for Watchman or landing zone >=31mm for Amulet) are not possible. LAmbre (*Lifetech Scientific Co., Shenzhen, China*) device has an additional stabilization mechanism by catching the LAA trabeculations using its 8 claws[1]. This potentially allows LAmbre in occluding large LAA with ostium up to 40mm, i.e. size of its largest cover. The study aimed to evaluate procedural and short-term outcomes of LAmbre device in occluding large LAA.

Methods

We retrospectively analyzed consecutive patients who underwent LAAO at 3 centers in Hong Kong and China (Prince of Wales Hospital, Hong Kong; Shanghai Tenth Hospital, Shanghai and Ningbo First Hospital, Ningbo) from June 2009 to June 2018 to identify LAmbre implantations for large LAA. Large LAA was defined by maximal ostium diameter >=31mm based on the larger dimension obtained by core-lab analysis (Prince of Wales Hospital) of intra-procedure cine-angiogram and transesophageal echocardiogram (TEE). Patients with no images for core-lab analysis or used devices that were not commercially available were excluded. Device success was defined as successful device implantation without significant peri-device leak (PDL, i.e. <=5mm leak), detected by final angiogram or TEE (**Figure 1**). The primary endpoint was the device success rate and the secondary endpoints included the percentage of device-related thrombus (DRT) and significant PDL (>5mm) at follow-up TEE, performed 1.5-6 months after implantation.

Results

During the study period, 964 patients underwent LAAO in the 3 centers. After core-lab adjudication, 27 patients were included for final analysis **(Table 1)**. LAmbre implantations were performed under TEE guidance in 66.7%, under fluoroscopic guidance alone[2] in 33.3% patients. The median LAA maximum ostium diameter was 33mm (range: 31-41mm). The device success rate was 89.9% (**Table 2**). The 36/40 (umbrella/cover) device was used most-commonly (41.7%). Misalignment of device cover with the LAA ostium were seen in all 3 failed cases **(Figure 2)**. There were 2 cases (6.7%) of coronary air embolism during procedure; otherwise, no cardiac tamponade, device embolization or 30-day mortality. Follow-up TEE was completed in 95.8% patients. There was 1 (4.3%) DRT and no significant PDL (>5mm). Minor PDL was seen in 30.4% patients (**Table 2**). At 30-day, 1 patient (4.2%) developed ischemic stroke. The patient was diagnosed lung carcinoma 2 weeks after LAAO, self-stopped anti-platelets, refused TEE and developed stroke 1 week after.

Discussions

The principle finding of this study is that LAmbre device was feasible and safe in occluding large LAA with ostium >=31mm. This study was the first and largest reported series of endovascular closure of large LAA using a single device. Importantly, there was no device embolization, supporting the safety of the device's unique additional anchor mechanism. However, the common failure mechanism suggested that alignment of LAmbre cover with LAA ostium might not be always possible, which could be limited by the transseptal site and LAA morphology. Besides, minor PDL (30.4%) was not uncommonly seen. This could be related to the large LAA occluded and the adoption of fluoroscopy guidance alone in 33.3% procedures. Air embolism was not reported in other LAmbre study[3] and 10-French delivery sheath was used even in large devices, which theoretically would not increase air embolism risk. Therefore, we believed that the 2 cases of air embolism were more likely coincidence.

Study Limitations

First, this study was a retrospective registry with limited sample size. Second, large LAA was classified based on LAA angiogram alone in 33.3% of cases. Third, majority of cases were performed or proctored by experienced LAmbre operators, reproducibility remained uncertain. Forth, all subjects included were Asians, which might have a different LAA anatomy than Caucasians[4].

Conclusions

LAmbre devices appeared feasible and safe in occluding large LAA with maximal ostium >=31mm. Long term data of its efficacy in stroke prophylaxis is needed.

Impact on daily practice:

This multicenter retrospective registry showed LAmbre device was feasible and safe in occluding large LAA with ostium >31mm. It supported the use of LAmbre as device of choice in indicated patients with large LAA anatomy.

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Disclosures

Y.Y.L. is clinical proctor of Amulet (Abbott) and LAmbre (LifeTech) device. Y.W.X. is clinical proctor of Watchman (Boston Scientific) and Lambre device. H.M.C. is clinical proctor of Watchman, Amulet and Lambre devices. W.C. is clinical proctor of Watchman and Lambre devices. A.P.L. receives research equipment support from Boston Scientific and research grant from Abbott. The other authors have no conflicts of interest to declare.

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Figures Legends

Figure 1. Implantation Techniques of LAmbre in Large Left Atrial Appendages (LAA). A–Cine-angiogram; B–Biplane transesophageal echocardiogram (TEE). First, the sizes of ostium (white lines), designated landing zone (yellow lines) with abundant trabeculations (red arrows) were measured to choose an optimal LAmbre umbrella and cover size for occlusion (Upper panels). Second, the delivery catheter was positioned at designated landing zone and the umbrella of LAmbre was rolled out to catch the LAA trabeculations for anchoring (middle panels). Third, the cover of the device was unsheathed to cover the LAA ostium. Angiogram +/- colour TEE were performed to detect peri-device leak (* = minor leak) (lower panels).

Figure 2. Fluoroscopic images showing 3 failures cases. Case 1 (33mm): LAmbre 36/40 and 24/36 devices were attempted but resulted in a 7mm PDL (yellow arrow) due to poor alignment. Procedure was aborted; **Case 2 (35mm):** LAmbre 36/40 device was deployed with good initial result. Device was tilted after release, resulting in an 8mm PDL (yellow arrow) requiring intra-procedural occlusion using a 25mm Amplatzer (Abbott) patent foramen ovale occluder device (*); **Case 3 (37mm):** LAmbre 36/40 device was attempted resulting in an 8mm PDL (yellow arrow). Then simultaneous deployment of LAmbre 36/40 and 16/22 devices was performed. However, a 6mm PDL was detected after devices were released.

Tables

TABLE 1. Baseline Patient Characteristics

	n=27
Age	72.3+/-7.3
CHADS2-VASc Score	4.4 +/-1.9
HAS-BLED Score	3.3+/-1.0
Prior attempts using other devices, %	7 (25.9%)
LAA maximal ostium diameter, mm	33 (31-41)
Individual sizes, mm	
31 32 33 34 35 36 37 38 39 40 41	4 6 5 1 4 0 3 1 0 2 1
Values are n, n (%), mean +/-SD, median (range) unless otherwise indicated. LAA = Left atrial appendage	

TABLE 2.

	n=27
Intra-procedural TEE guidance	18 (66.7%)
Device success rate	24/27 (89.9%)
Recapture	
• Number of recapture(s), median (range)	1 (0-6)
• >=1 recapture(s)	15 (55.6%)
• >=3 recapture (s)	6 (22.2%)
Resizing	
• Number of re-sizing, median (range)	0 (0-2)
• >=1 Resizing	6 (22.2%)
Devices used in successful cases:	
36/40	10(41.7%)
30/36	4(16.7%)
34/38	3(12.5%)
28/34	2(8.3%)
26/38	2(8.3%)
24/36	1(4.2%)
24/32	1(4.2%)
16/30	1(4.2%)
Peri-procedural complications	
• Cardiac tamponade	0
• Device embolization	0
• Air embolization	2 (6.9%)
• 30-day mortality	0
Follow-up TEE	
• % of TEE done	23/24 (95.8%)
• Device related thrombus	1/23 (4.3%)
• Peri-device leak	7 (30.4%)
• <3mm	4 (17.4%)
• 3 to 5mm	3 (13.0)
• >5mm	0
30-day ischemic stroke	1/24 (4.2%)
Values are n, n (%), median (range) unless otherwise indicated. TEE = Transesophageal echocardiogram;