Short communication

Percutaneous left atrial appendage closure using the LAmbre device. First clinical results in Poland

Marian Burysz1, Radoslaw Litwinowicz2, Magdalena Bryndza2, Radomir Skowronek1, Wojciech Ogorzeja1, Krzysztof Bartus2

1Department of Cardiac Surgery, Regional Specialist Hospital, Grudziadz, Poland
2Department of Cardiovascular Surgery and Transplantology, Institute of Cardiology, Jagiellonian University Medical College, Krakow, Poland

Adv Interv Cardiol 2019; 15, 2 (56): 251–254
DOI: https://doi.org/10.5114/aic.2019.86019

Introduction
In adult populations, atrial fibrillation (AF) is the major arrhythmia and successful treatment rates are low [1]. In recent years, left atrial appendage occlusion (LAAO) has become an alternative method for stroke prevention in patients in whom oral anticoagulation (OAC) is ineffective or contraindicated or in patients with life-threatening complications [2, 3]. Previous studies have demonstrated that the LAAO procedure is safe and effective in the prevention of thromboembolic events, including in high risk patients [4–10].

In the medical market, there are a number of available devices including endocardial and epicardial devices [4, 5, 9]. However, in some cases, the anatomy of the left atrial appendage (LAA) may constitute a contraindication to implantation of these devices. The LAmbre device is a novel system, designed especially for LAA closure when problematic morphology is present [11, 12].

Aim
Herein, we present the first use of the LAmbre device in Poland in patients with AF.

Material and methods
A retrospective, single-center study was performed in 24 consecutive patients with non-valvular AF, who underwent LAAO with the LAmbre device (Lifetech Scientific Corp., Shenzhen, China) between 2016 and 2018 (Figure 1).

The LAmbre occluder system was previously described [13]. LAmbre device selection was based on operators’ decision. All procedures were performed under general anesthesia. Patient characteristics are presented in Table I. The LAA anatomy was assessed with computed tomography before each procedure. Oral anticoagulation therapy was discontinued and unfractionated heparin was used during the procedure. After the procedure, aspirin (75 mg/dose/day) and clopidogrel (75 mg/dose/day) for 6 months were recommended in each patient.

Leak was defined as the presence of flow from the left atrium to the LAA < 3 mm [14].

Follow-up visits, including transesophageal echocardiography, were performed at 3 and 6 months post-procedure. Data on mortality, causes of mortality and serious adverse events (SAE) were collected.

Statistical analysis
Data are expressed as mean ± standard deviation or median (interquartile range; Q1 – 25th percentile and Q3 – 75th percentile), unless otherwise stated. Categorical variables were expressed as counts and percentages.

Results
All procedures were successfully completed with no perioperative complications. The LAAO procedure or device related mortality was 0%. The mean time for the procedure was 62.92 ± 14.21 min. Eleven different sizes of occluder were implanted during the procedures, depending on the size and shape of the left atrial appendage. The choice of device size was made by the operator during the procedure based on intraprocedural transesophageal echocardiography (TEE) examination. There was a 100% success rate with no complications. No post-procedural leaks were observed. Half of the patients were discharged from hospital on the second or third day following the procedure.

The overall follow-up was 349 months. During the follow-up period, there were 4 (16.7%) deaths; 1 case with...
acute exacerbation of chronic renal failure complicated by heart failure (5 months after the procedure), 1 case of out-of-hospital cardiac arrest (5 months after the procedure), 1 case of post neurosurgery complications due to cerebral artery aneurysm (15 months after the procedure) and in 1 case, the cause of death was unknown. There were no deaths connected to the procedure. Gastrointestinal bleeding were observed in 2 (8.34%) cases. There was 1 (4.17%) case of transient ischemic attack and 1 (4.17%) case of stroke, 16 and 3 months after the procedure, respectively. In both cases control TEE examination showed no device thrombus. In the remaining patients follow-up TEE showed no device thrombi or LAA leaks (Table I).

Discussion

We present the first results in Poland of the LAAO procedure with LAmbre devices, with a 100% success rate and with no perioperative complications. From our initial experience, implantation is associated with a high success rate and good clinical outcomes.

Our results are similar to the most popular endocardial devices such as the Watchman or Amplatzer [4, 15]. Surprisingly, in our study, there was a larger number of postprocedural bleeding episodes, which were observed in 8.34% of patients, compared to other endocardial trials [4, 15]. However, in our study, patients had a very high risk of bleeding (HAS-BLED score 4) and, in more than 60% of patients, the indication for LAAO was previous bleeding episodes. Of note, all bleeding episodes were among patients who were receiving antiplatelet therapy, and none were receiving OAC.

The observed mortality rate (16.6%) was also higher than that reported in other endocardial device trials [4, 15]. However, none of the deaths were related to the procedure. Boersma et al. observed a 9.8% mortality rate at 12 months of observation in a Watchman device trial [4]. Importantly, all deceased patients were free of thrombus on the occluder and from postprocedural leak at 3-month and 6-month visits. Additionally, no device thrombi were observed, despite not receiving OAC, even in transient ischemic attack (TIA) and stroke patients. Similar data were obtained by Huang et al. [14].

The LAA morphology, including the LAA shape, ostium width and depth, plays a critical role in the choice of device. The most popular devices such as the Watchman, with its umbrella-like shape, should be avoided in
The LAmbre device is available in a larger range of device sizes (16–36 mm) compared to the Watchman (21–30 mm) and ACP (16–34 mm) devices. It is also highly adaptive to many LAA sizes due to its smaller umbrellas with larger covers. Therefore, the larger choice of sizes and favorable device properties may make the LAmbre device more suitable for complex LAA anatomies, such as chicken wing or shallow LAA [13].

Conclusions

The LAAO procedure with the LAmbre device is associated with a high success rate and good short term clinical results.

Conflict of interest

The authors declare no conflict of interest.

References

1. Kirchhof P, Benussi S, Kotecha D, et al. 2016 ESC Guidelines for the management of atrial fibrillation. Eur Heart J 2016; 37: 2893-962.
2. Kirchhof P, Benussi S, Kotecha D, et al. 2016 ESC Guidelines for the management of atrial fibrillation. Eur J Cardiothorac Surg 2016; 50: e1-88.
3. Litwinowicz R, Konstanty-Kalandyk J, Goralczyk T, et al. Dabigatran level monitoring prior to idarucizumab administration in patients requiring emergent cardiac surgery. J Thromb Thrombolysis 2018; 45: 9-12.
4. Boersma LV, Ince H, Kische S, et al. Efficacy and safety of left atrial appendage closure with WATCHMAN in patients with or without contraindication to oral anticoagulation: 1-year follow-up outcome data of the EWOLUTION trial. Heart Rhythm 2017; 14: 1302-8.
5. Litwinowicz R, Bartus M, Ceranowicz P, et al. Stroke risk reduction after LAA occlusion in elderly patients with atrial fibrillation: long-term results. Pol Arch Intern Med 2018; 128: 327-9.
6. Bartus K, Myc J, Bartus M, et al. Rapid left atrial appendage thrombus formation in epicardial percutaneous LAA suture ligation with LARIAT. Adv Interv Cardiol 2018; 14: 435-7.
7. Bartus K, Litwinowicz R, Dziewierz A, et al. Coronary artery bypass grafting after left atrial appendage ligation – is anti-inflammatory treatment recommendation post LARIAT effective? Adv Interv Cardiol 2018; 14: 438-9.
8. Litwinowicz R, Bartus M, Burysz M, et al. Long term outcomes after left atrial appendage closure with the LAmbre device – stroke risk reduction over five years follow-up. PLoS One 2018; 13: e0208710.
9. Chen S, Schmidt B, Bordignon S, et al. Feasibility of percutaneous left atrial appendage closure using a novel LAmbre occluder. J Cardiovasc Med 2019; 10: 75-82.
10. Chen S, Schmidt B, Bordignon S, et al. Feasibility of percutaneous left atrial appendage closure using a novel LAmbre occluder.
in patients with atrial fibrillation: initial results from a prospective cohort registry study. J Cardiovasc Electrophysiol 2018; 29: 291-7.

12. Park JW, Sievert H, Kleinecke C, et al. Left atrial appendage occlusion with lambre in atrial fibrillation: Initial European experience. Int J Cardiol 2018; 265: 97-102.

13. Reinsch N, Ruprecht U, Buchholz J, et al. Initial experience of percutaneous left atrial appendage closure using the LAmbré device for thromboembolic prevention. J Cardiovasc Med (Hagerstown) 2018; 19: 491-6.

14. Huang H, Liu Y, Xu Y, et al. Percutaneous left atrial appendage closure with the lambre device for stroke prevention in atrial fibrillation: a prospective, multicenter clinical study. JACC Cardiovasc Interv 2017; 10: 2188-94.

15. Landmesser U, Schmidt B, Nielsen-Kudsk JE, et al. Left atrial appendage occlusion with the AMPLATZER Amulet device: periprocedural and early clinical/echocardiographic data from a global prospective observational study. Eurointervention 2017; 13: 867-76.