Left atrial appendage occlusion with the LAmbre device: early experience in an Argentine hospital

Cierre de orejuela auricular izquierda con dispositivo LAmbre. Experiencia inicial en un centro argentino

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ABSTRACT

Left atrial appendage occlusion is an increasingly common practice worldwide. Two devices have given us enough evidence and experience regarding their efficacy and safety profile. The varied anatomy of the appendage cannot always be succesfully overcome by these devices. For this reason, we wanted to present the first 10 case reports with a new device in Argentina.

Keywords: *percutaneous left atrial appendage close, left atrial appendage closure,structural heart disease.*

RESUMEN

La oclusión de orejuela auricular izquierda es una práctica cada vez más frecuente. Distintos dispositivos son utilizados en el mundo con los cuales existe suficiente experiencia y evidencia. Las dificultades anatómicas que plantea la orejuela no siempre pueden ser abordadas con éxito por ellos, por lo cual hemos querido presentar los primeros 10 casos con un nuevo dispositivo existente en la Argentina.

Palabras clave: *cierre de orejuela izquierda percutáneo, cierre de orejuela izquierda, cardiopatía estructural.*

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INTRODUCTION

Percutaneous eft atrial appendage (LAA) occlusion has become a therapeutic alternative of embolic prevention for patients with non-valvular atrial fibrillation (NVAF) with a contraindication for long-term oral anticoagulation[1,2]. Also, 2 landmark studies and 1 meta-analysis that combined both studies showed that the percutaneous LAA occlusion with the Watchman device (Boston Scientific Corporation, Malborough, MA, United States) is non-inferior and, in some aspects, even superior to warfarin therapy in patients eligible to receive long-term DOAC therapy[3-5].

The 2 most widely used devices today are the Watchman (Boston Scientific Corporation, Malborough, MA, United States) and the Amulet (Abbott Vascular, Santa Clara, CA, United States). The former is mainly used in the United States. The latter is mostly used in Europe, Asia, and Latin America. The rates of success are increasingly higher, and the rates of complication are increasingly lower, especially since the appearance and later approval by the FDA of the second-generation Watchman device, the Watchman Flex, available in our country since April 2022. It overcomes certain anatomical limitations in the morphology of the LAA that made successful implantation with previous devices challenging as the Pinnacle clinical trial confirmed[6].

The LAmbre device (Lifetech Scientific Shenzhen Co Ltd) is available in our country since June 2020 prior to the arrival of the Watchman Flex. Its design characteristics could turn it into an additional option to overcome such limitations.[7]

As far as we know, to this date, we still don't have safety and effectiveness data on LAA closures with such device in Argentina.

MATERIAL AND METHOD

The main characteristics of the LAmbre device [Lifetech Scientific (Shenzhen) Co. Ltd, Unifarma (Argentina)] are: 8-Fr and 10-Fr delivery sheath with a double distal curve of 45º x 30º, and a 45º single curve (unlike the 12-Fr and 14-Fr of the Amulet, and the 14-Fr of the Watchman) (**Figure 1a),** different disc sizes for the same umbrella sizes (called special measurements for conical morphologies), and a double stabilization mechanism with hooks that attach to the wall and U-shaped anchors, atraumatic, that eventually become trapped in the pectineus muscles and their trabeculations **(Figures 1b, 1c, 1d)**.

In Argentina, between August 2021 and May 2022, we implanted 10 devices in 10 consecutive patients that are the ones included in the study.

Procedures were performed under general anesthesia with orotracheal intubation and under transesophageal echocardiography (TEE) guidance following the routine technique for this kind of procedures.

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TABLE 1. Baseline characteristics.

Sex	Men, 70%
Age	77 ± 5 years
AHT	90%
DBT	40%
DLP	50%
PreviousAnti Vit K	60%
Previous DOAC	40%
Typeof AF	
- Paroxysmal	40%
- Permanent	60%
- Persistent	0%
LAVI	45,5 ± 8
EF	57,9% ± 6
Ischemic stroke	50%

TABLE 3. Left atrial appendage morphology.

"Chickenwing" morphology with an early bend	5
Windsock	3
Cauliflower	2
Success	100%
Complications	0%
Post-implantation therapy	
- DAPT	7
- SAPT	3
- DOAC	0

DAPT: dual antiplatelet therapy.
SAPT: single antiplatelet therapy.
DOAC: direct oral anticoagulant drugs.

TABLE 2. Indications for closure.

Digestive hemorrhage	5
Recurring hematuria	2
Cerebral hemorrhage	2
Vitreous hemorrhage	1

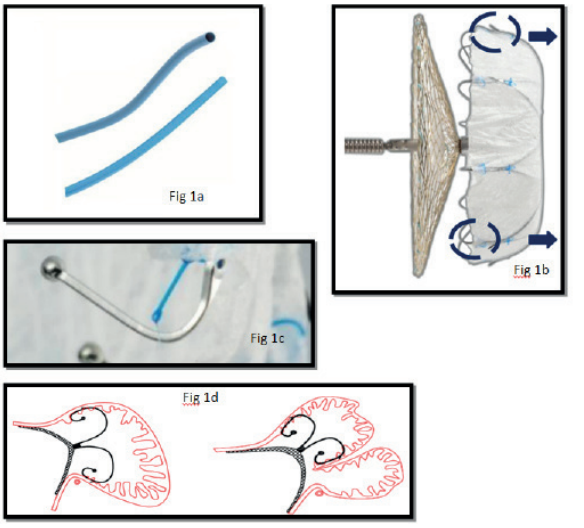

Figure 1. *a. Delivery sheath. b. Device with stabilization hooks. 1c. U-shaped anchors. d. Configuration of the device in place.*

RESULTS

The baseline characteristics of the population and the corresponding indication are shown on **Table 1** and **Table 2**.
Implantation was successfully performed in all the patients. No complications were reported despite the complex ("chicken wing" morphology in 5 patients, all with an early bend), and conical anatomies seen in 3 patients understanding as conical anatomy a difference in diameter of > 10 mm between ostium and landing zone. The remaining 2 patients had cauliflower-type morphologies that, however, did not jeopardize implantation with other devices. No immediate complications were reported either or at the follow-up TEE performed the next day. At discharge treatment consisted of double or simple antiplatelet therapy (DAPT, SAPT). None of the patients were anticoagulated after hospital discharge **(Table 3).**
One of the patients was implanted through 1 patent foramen ovale without a transseptal puncture and after seeing that the guidewire was aiming directly at the LAA through it.
The conical morphologies of 1 of the 3 implants performed was particularly pronounced, with a difference in diameter between ostium and landing zone of 14 mm, which is why it was decided to use the special measurement of 22 mm x 34 mm to achieve successful implantation and complete sealing.

DISCUSSION

The early clinical trials that triggered the FDA approval of the LAA closure with Watchman device implantation[3 4] achieved non-inferiority in primary endpoints and superiority in secondary endpoints. These trials included patients with high risk of stroke and systemic embolism according to CHADS scores ≥ 2, and low risk of bleeding to receive oral anticoagulation with warfarin. Although non-inferiority in efficacy endpoints was achieved in the Protect AF trial, safety endpoints, particularly greater tolerance to ischemic strokes in the implantation group generated doubts that eventually triggered an FDA request to the authors: to submit additional studies (the Prevail trial) that did meet the safety endpoints. A meta-analysis of these additional studies was added to assess non-inferiority in the efficacy endpoints of stroke/systemic embolism, and superiority in endpoints such as hemorrhagic stroke/cardiovascular mortality (P = .04 and P = .006, respectively).[5] Therefore, in 2015, the FDA approved the LAA occlusion with the Watchman device for patients with low-risk of bleeding with warfarin. This increased the number of implantation procedures performed in the United States dramatically. This procedure ended up replacing DOAC in patients of Medicare and Medicaid. Patients just needed to say they wanted to undergo the new procedure even in the age of new oral anticoagulants as first-line therapy.[7] Issues regarding the cost-benefit ratio allow such indications in the United States (elevated cost of hospital stay per day due to bleeding caused by DOAC, cost of hemoderivatives, etc.) In the rest of the world and in our country in particular, procedures and interventions are pretty much indicated and reimbursed by the social security systems for high-risk populations or with contraindication for DOAC. Evidence in this population group comes from a randomized clinical trial[9] that demonstrated the non-inferiority of the procedure compared to new anticoagulants (predominantly apixaban). Also, from registries and case series that proved the non-inferiority and even superiority of the procedure of the Watchman, and Amplatzer Amulet devices compared to warfarin.[10 11 12] However, some anatomi-

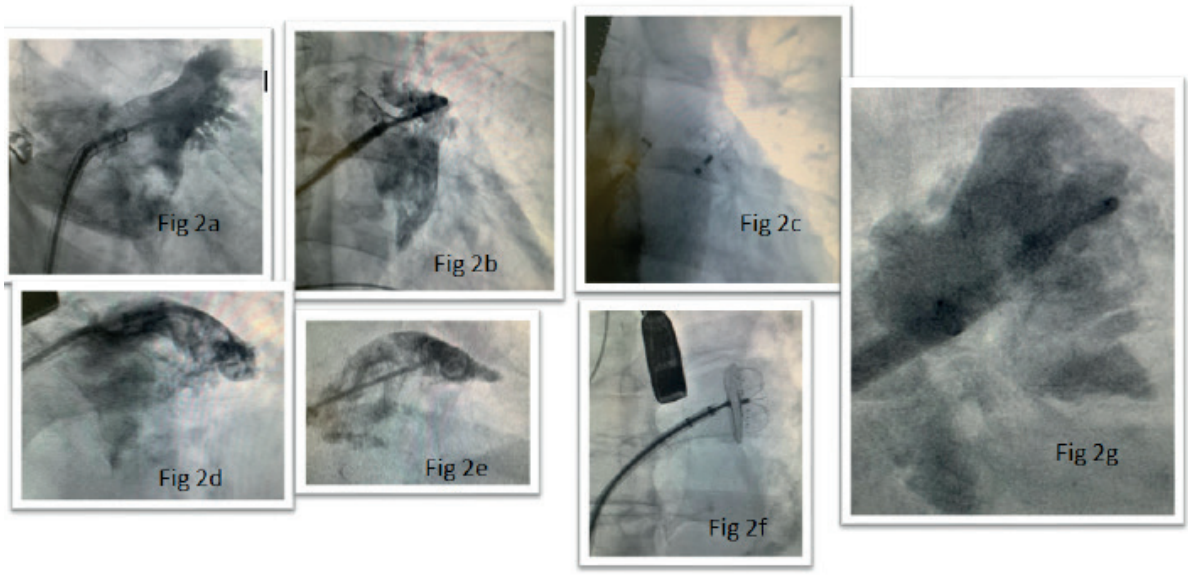

Figure 2 *a. Bi-lobulated morphology. b and c. "Chicken wing" morphology with an early bendand device configuration after implantation. d. Large sized left atrial appendage. e and f. Conical morphology and device configuration after implantation. g. Multilobulated large sized morphology.*

cal morphologies of the LAA make implantation with these 2 devices challenging and pose some limitations to achieve successful implantations. The FDA recently approved the second-generation Watchman device—Watchman Flex—whose design will allow us to overcome some of these limitations. This device has just become available in our country. Such anatomical morphologies are bi- or multilobulated **(Figure 2a),** not too deep **(Figures 2b, 2c)** extreme sized, very small or very large **(Figure 2d),** conical left atrial appendages **(Figures 2e, 2f)** or a combination of all **(Figure 2g).** Even implantation with the presence of thrombus deep inside the left atrial appendage would be an absolute contraindication with the former generation of Watchman devices since a deeper intubation of the delivery sheath would be required. However, this procedure is feasible with the LAmbre device given its ability to enter the ostium from the outside without having to selectively introduce the delivery sheath inside the LAA (the so-called non-touch technique). Our own experienced with LAA closure procedures may explain the good results obtained. Anyways, the design of the LAmbre device can play an important role thanks to its sheath of a smaller diameter that would cause fewer vascular complications, and the special measurements we used to implant 4 patients (3 conical and 1 "chicken wing" morphologies with very early bend). (Figure 2 b, c and 2 e, f).

The main limitations of this report are that it was a single-center, observational trial with a reduced number of patients, and no mid- or long-term follow-up. Therefore, these limitations do not allow us to compare the efficacy and safety profile associated with the device design, much less with the 2 most widely used and studied devices like the Watchman and the Amulet devices. However, in our own experience, we conducted transesophageal echocardiography follow-ups between 45 and 60 days after implantation in 8 out of the 10 patients and found no significant migrations, thrombi o leaks. In 7 patients the sealing was complete and in 1 patient 1 trivial leak was reported (< 1 mm of jet diameter) with the device perfectly in position. The 2 remaining patients were clinically followed in subsequent consultation visits. None of the 10 patients treated had ischemic strokes, systemic embolisms or bleeding in the short follow-up period.

The characteristics of the LAmbre device of adapting to different anatomical morphologies of LAA, having stable anchorage mechanisms, being fully recapturable and repositionable, and having a lower profile make of it a simple and safe implantation device. Therefore, many of us think it should be considered an alternative to the already known Watchman and Amulet devices even for patients with thrombi deep inside the LAA in whom anticoagulation cannot be considered not even for a short period of time.

We wanted to use this report to show the first series in our country of LAA closure with the LAmbre device. Also, to show its technical feasibility in various LAA anatomies, as well as the short-term efficacy and safety profile.

REFERENCES

1. *2019 AHA/ACC/ HRS Focused Update of the 2014 Guideline for management of Patients with Atrial Fibrillation.*
2. *2020 ESC Guidelines. 29 August 2020.*
3. *Reddy VY, Doshi SK, Sievert H, et al., PROTECT AF Investigators. Percutaneous left atrial appendage closure for stroke prophylaxis in patients with atrial fibrillation: 2.3-Year Follow-up of the PROTECT AF (Watchman Left Atrial Appendage System for Embolic Protection in Patients with Atrial Fibrillation) Trial. Circulation 2013 Feb 12;127(6):720-9.*
4. *Reddy VY, Sievert H, Halperin J, et al., PROTECT AF Steering Committee and Investigators. Percutaneous left atrial appendage closure vs warfarin for atrial fibrillation: a randomized clinical trial. JAMA 2014 Nov 19;312(19):1988-98.*
5. *Reddy VY, Doshi SK, Kar S, et al., PREVAIL and PROTECT AF Investigators. 5-Year Outcomes After Left Atrial Appendage Closure: From the PREVAIL and PROTECT AF Trials. J Am Coll Cardiol 2017 Dec 19;70(24):2964-75.*

6. *Kar S, Doshi SK, Sadhu A, et al., PINNACLE FLX Investigators. Primary Outcome Evaluation of a Next-Generation Left Atrial Appendage Closure Device: Results From the PINNACLE FLX Trial. Circulation 2021 May 4;143(18):1754-62.*
7. *Kabra R, Girotra S, Vaughan Sarrazin M. Clinical Outcomes of Mortality, Readmissions, and Ischemic Stroke Among Medicare Patients Undergoing Left Atrial Appendage Closure via Implanted Device. JAMA Netw Open. 2019 Oct; 2(10): e1914268. Published online 2019 Oct 30.*
8. *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(21):2188-94.*
9. *Osmancik P, Herman D, Neuzil P, et al., PRAGUE-17 Trial Investigators. Left Atrial Appendage Closure Versus Direct Oral Anticoagulants in High-Risk Patients With Atrial Fibrillation. J Am Coll Cardiol 2020 Jun 30;75(25):3122-35.*
10. *Boersma LVA, Schmidt B, Betts TR, et al., EWOLUTION investigators. Implant success and safety of left atrial appendage closure with the WATCHMAN device: peri-procedural outcomes from the EWOLUTION registry. Eur Heart J 2016 Aug;37(31):2465-74.*
11. *Reddy VY, Gibson DN, Kar S, et al. Post-Approval U.S. Experience With Left Atrial Appendage Closure for Stroke Prevention in Atrial Fibrillation. J Am Coll Cardiol 2017 Jan 24;69(3):253-61.*
12. *Eurointervention. August 2018.*