Percutaneous Left atrial appendage closure using the Amplatzer Amulet device: experience of Habib Thameur Hospital Cardiology department, about 8 cases

Fermeture percutanée de l'auricule gauche à l'aide du dispositif Amplatzer Amulet : expérience du service de cardiologie de l'hôpital Habib Thameur, à propos de 8 cas.

Ghassen telili, Hela Bouzidi, Ala eddine Ayadi, Ihsen zairi, khadija Mzoughi, Sofien Kamoun, Sondos kraiem

Cardiology department of Habib thameur hospital of Tunis

Summary

Background : Since left atrial appendage is the principal source of thromboembolism in patients with atrial fibrillation, left atrial appendage closure (LAAC) presents itself as an interesting alternative to long term anti-coagulation in patients at high bleeding risk. The Amplatzer Amulet device proved to be effective and safe for percutaneous LAAC. Its use in a Tunisian cohort is yet to be investigated.

Methodology : We conducted a retrospective study in the form of a case series including procedures of percutaneous LAAC using the Amplatzer Amulet device performed in the cardiology department of Habib Thameur Hospital over 6 years.

Results : Eight patients were included. Half of our patients were at least 80 years --old, with comorbidities. The CHA2DS2-VASc and HASBLED scores showed that all our patients had a high thromboembolic risk and a high bleeding risk. All patients were on oral anticoagulation and had bleeding complications. The diameter of the left atrium appendage was measured on transesophageal echocardiography. All the procedures were performed using the Amplatzer Amulet device which the diameter was between 20 and 31 mm. Only one complication occurred immediately after the procedure; one patient had minor bleeding from the puncture site. All patients were put on double antiplatelet therapy for 6 months. The follow-up was between 6 and 104 months. No device-related complications were reported, and none of the patients had major bleeding or stroke.

Conclusion : The percutaneous LAAC using the Amplatzer Amulet device seems to be effective and safe in Tunisian population

Keywords

Atrial fibrillation, percutaneous closure, Left atrial appendage, high hemorrhagic risk, anticogulation

Résumé

Introduction : L'appendice auriculaire gauche est la principale source des accidents thrombo-emboliques chez les patients en fibrillation auriculaire. La fermeture de l'auriculaire gauche (FAG) se présente comme une alternative intéressante à l'anticoagulation à long terme chez les patients présentant un risque hémorragique élevé. Le dispositif Amplatzer Amulet s'est avéré efficace et sûr pour les procédures de fermetures percutanées.

Méthodologie : Nous avons mené une étude rétrospective au service de cardiologie de l'hôpital Habib Thameur de Tunis, sur 6 ans sous la forme d'une série de cas comprenant des procédures de FAG à l'aide du dispositif Amplatzer Amulet.

Résultats : Huit patients ont été inclus. La moitié de nos patients étaient âgés d'au moins 80 ans avec des comorbidités. Les scores CHA2DS2-VASc et HASBLED ont montré que tous nos patients avaient un risque thromboembolique et hémorragique élevé. Tous les patients étaient sous anticoagulation orale et ont eu des complications hémorragiques.

Le diamètre de l'auricule gauche a été mesuré par échocardiographie transœsophagienne .

Toutes les procédures ont été réalisées à l'aide du dispositif Amplatzer Amulet dont le diamètre était compris entre 20 et 31 mm.

Une seule complication mineure est survenue après la procédure: un saignement au point de ponction.

Tous les patients ont été mis sous double thérapie antiplaquettaire pendant 6 mois. Après un suivi de 6 à 104 mois, aucune complication liée au dispositif ni hémorragie majeure ou AVC n'a été observée.

Conclusion : La FAG percutanée utilisant le dispositif Amplatzer Amulet semble être efficace et sûre dans la population tunisienne.

Mots-clés

fibrillation atriale , fermeture percutanée, auricule gauche , haut risque hémorragique, anticoagulation

Correspondance

Ghassen Telili

INTRODUCTION

Atrial fibrillation (AF) is the most common cardiac arrhythmia. It is associated with a five-fold increased risk of cardioembolic stroke (1), and the left atrial appendage (LAA) has been identified as a principal source of thromboembolism in these patients (2). AF requires long-term anticoagulation in patients at high thromboembolic risk, which increases the risk of potentially serious hemorrhagic events and complicates the management of these patients. Left atrial appendage closure (LAAC) is an alternative to long-term anticoagulation for patients at high bleeding risk in non-valvular AF. In the latest European Society of Cardiology (ESC) guidelines for the management of atrial fibrillation, published in 2024, surgical closure of the left atrium for any AF patient scheduled for cardiac surgery has been upgraded from a class IIB level of evidence C to a class I level of evidence B (3). However, even in the presence of positive results from randomized trials conducted on percutaneous LAAC, the latter is recommended only for patients with contraindications to long-term anticoagulation in the ESC guidelines (class IIB level of evidence C), pending the results of ongoing studies and registries. In the guidelines of the American Society of Cardiology, percutaneous LAAC for patients with contraindications to long-term anticoagulation should be considered (II A). It may also be considered for patients with a high risk of major bleeding on oral anticoagulation (IIB) (4). To our knowledge, only one study investigating percutaneous LAAC in a Tunisian population was conducted at Fattouma Bourguiba Hospital in Monastir. All procedures in this study were performed using the Watchman device (5). Our case series aims to investigate the epidemiological characteristics of Tunisian patients who have undergone percutaneous LAAC using the Amplatzer Amulet device, the immediate outcomes (in terms of safety and effectiveness) and long-term follow-up of these patients.

PATIENTS AND METHODS

This study employed a retrospective cohort design to describe the outcomes of left atrial appendage closure (LAAC) procedures using the Amplatzer Amulet device, performed at the cardiology department of Habib Thameur Hospital between March 2016 and July 2024. Given the small size of our series, we attributed a number to each patient (P1,P2 .. P8) and we described the clinical cases in the form of summary tables. We included all patients who underwent LAAC using the Amplatzer Amulet device during the study period.

Data Collection: Data were extracted from electronic and physical health records. It included baseline demographic information, contraindications and possible hemorrhagic events on anticoagulation, clinical characteristics, procedural details: date, type of device used and complications (if any), and post-procedural outcomes: the length of hospital stay, the incidence of periprocedural complications (e.g, bleeding, device embolization, stroke), and the long-term outcomes (e.g., stroke and systemic embolism, major bleeding, leaks, etc ..). Incomplete medical records that hindered data analysis were excluded.

RESULTS

Clinical characteristics

Half of our patients were at least 80 years old (4/8), with a history of arterial hypertension, diabetes and dyslipidemia. Three of our patients had a history of heart failure and three of them had coronary disease. About one-third of our patients had a history of thromboembolic events. The CHA2DS2-VASc and HASBLED scores showed that all our patients had a high thromboembolic risk and a high bleeding risk. All patients were on oral anticoagulation with Vitamin K antagonist (VKA) and had bleeding complications due to anticoagulant (table 1).

Table 1. Clinical characteristics

Patient	Age	Hypertension	Diabetes	Dyslipidemia	Heart failure	Thromboembolic events	Chads2vasc	HASBLED	Hemorrhagic complication
P1	86	Yes	Yes	No	Yes	No	5	3	Digestive tract bleeding
P2	57	Yes	Yes	Yes	No	No	5	3	hemorrhagic stroke
P3	69	Yes	Yes	Yes	Yes	No	7	5	hemorrhagic stroke
P4	64	No	No	No	No	Yes	2	2	hemorrhagic stroke
P5	80	No	No	No	No	Yes	4	3	hemorrhagic stroke
P6	69	Yes	Yes	No	No	No	4	4	hemorrhagic stroke
P7	81	Yes	Yes	Yes	No	No	4	3	hemorrhagic stroke
P8	80	Yes	No	Yes	Yes	Yes	5	4	anemia

Echocardiographic characteristics

All patients but one had preserved left ventricular ejection fraction (LVEF). The diameter of the left atrium appendage was measured on transesophageal echocardiography in all patients. We also verified the measurements using a CT scan in one patient, which showed a comparable result to the echo measurement (Table 2).

Table 2. Echocardiographic characteristics

Patient	LVEF	LAA diameter	Thrombus
P1	50	25,0	No
P2	66	17,0	No
P3	60	18,0	No
P4	60	18,0	No
P5	58	16,0	No
P6	50	21,0	No
P7	65	20,0	No
P8	35	16,0	No

Procedural characteristics

All the procedures were performed using the Amplatzer Amulet device. The diameter of the devices used was between 20 and 31 mm. Only one complication occurred immediately after the procedure; one patient had minor bleeding from the puncture site. The procedural characteristics are summarized in Table 3 below.

Table 3. Procedural characteristics

Patient	Device type	Device diameter	Procedural complications
P1	Amplatzer Amulet©	31	No
P2	Amplatzer Amulet©	20	No
P3	Amplatzer Amulet©	22	Bleeding
P4	Amplatzer Amulet©	22	No
P5	Amplatzer Amulet©	20	No
P6	Amplatzer Amulet©	25	No
P7	Amplatzer Amulet©	25	No
P8	Amplatzer Amulet©	30	No

All patients but two had uneventful hospital stays.

One patient had a cardiac arrest (Ventricular fibrillation) the following day of the procedure and acute heart failure, which we deemed not linked to the procedure since the onset was 24 hours after the procedure, and the echo showed that the device was in place.

One patient had minor bleeding from the puncture site which did not need transfusion.

Short and long term follow up

All patients were put on double antiplatelet therapy (DAPT) for 6 months, and then on single antiplatelet therapy for life.

The follow-up was between 6 and 104 months. No device-related complications were reported, and none of the patients had major bleeding or stroke.

DISCUSSION

A similar case series about percutaneous LAAC in Tunisian patients was published in 2021(5). To our knowledge, no other studies nor case series were published including Tunisian patients. In the first study, the Watchman device was used in all procedures. In our case series, the device with which all procedures were performed was the Amplatzer Amulet device.

What is the differences between the Ampltzer Amulet and other devices used for LAAC?

Initially, the Watchman 2.5 (Boston Scientifics) and Amplatzer Cardiac Plug (Abbott Vascular) devices were the first-generation devices most used worldwide for percutaneous LAAC. Recently, their iterations Watchman FLX and Amulet were approved by the FDA in 2020 and 2021, respectively and more recently, the latest iteration Watchman FLX PRO has been released. (6)

The Amplatzer Amulet device is a Self-expanding nitinol device with a distal lobe and a proximal disc, that offers 8 available sizes. Its access system is a steerable sheath with the ability of bidirectional co-axial alignment allowing 120 degrees deflection.

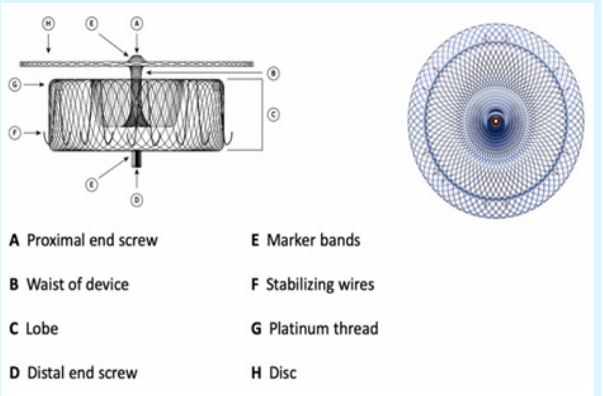

Figure 1. Amulet device construction(6)

We compare the three most used devices for LAAC nowadays in table 4 below.

Table 4. Main characteristics of LAAC devices (6)

Parameter	Amulet	Watchman FLX	Watchman FLX Pro
Constract of the device	Self-expanding nitinol device with a distal lobe and a proximal disc	Self-expanding nitinol frame with PET with distal fluoroscopic marker	Self-expanding nitinol frame with HEMOCOAT tecnology covering
Anchor mechanism	Stabilizing wines	Dual-row anchors	Dual-row anchors with three radiopaque markers
Available sizes	8	5	6
Size range	16 mm, 18 mm, 20 mm, 22 mm, 25 mm, 28 mm, 31 mm, 34 mm	20 mm, 24 mm, 27 mm, 31 mm, 35 mm	20 mm, 24 mm, 27 mm, 31 mm, 35 mm, 40 mm
Ostium coverage	11 - 31 mm	14 - 31.5 mm	14 - 36 mm
Sealing mechanism	Dual seal mechanism (disc and lobe)	Single seal mechanism (single lobe)	Single seal mechanism (single lobe)
Access system	• Amplatzer steerable seath with the ability of bidirectional co-axial alignment allowing for 0-120° deflection	• Watchman TreSeal (14 Fr) access system availale in a single, anterior, and double curver; • Watchman FXD (15 Fr) access system availale in a single and double curver; TreeSteer (17 Fr)	• Watchman FXD (15 Fr) access system availale in single and double curver; • TrueSteer (17 Fr)

The Amplatzer Amulet device proved its noninferiority to the watchman device in a randomized controlled trial : Amulet IDE trial (7). The trial was a multicenter, open-label, randomized controlled study involving 1878 patients with non-valvular AF at increased risk of stroke. Patients were randomly assigned (1 :1) to receive either LAAC using the Amulet occluder or the Watchman device.

The primary endpoints included safety (composite of procedure-related complications, all-cause death, or major bleeding at 12 months), effectiveness (composite of ischemic stroke or systemic embolism at 18 months), and the rate of LAA occlusion at 45 days. Prespecified secondary endpoints included a composite of all stroke, systemic embolism, or cardiovascular/unexplained death at 18 months, major bleeding at 18 months, and a superiority test of the third primary endpoints.

The study showed similar results in terms of safety and effectiveness, higher rate of successful LAA occlusion and higher rate of complications with the Amulet device :

• Safety: The Amulet occluder was found to be noninferior to the Watchman device regarding the primary safety endpoint (14.5% vs. 14.7%).

• Effectiveness: Both devices showed similar effectiveness, with a primary effectiveness endpoint rate of 2.8% for both groups.

• LAA Occlusion: The Amulet occluder demonstrated a higher rate of successful LAA occlusion 98.9% vs. 96.8%

• Procedure-Related Complications: The Amulet group had a higher rate of complications (4.5% vs. 2.5%), primarily due to pericardial effusion and device embolization. However, these complications decreased with operator experience.

In a more recent publication, a metanalysis published in 2023 including 3 randomized clinical trials (Lakkireddy et al. (7) mansour et al. (8), SWISS-APERO(9)) with 2150 patients, the Amplatzer Amulet was not superior to the Watchman device in terms of safety and efficacy. However, the Amulet occluder was associated with a higher incidence of procedure-related complications, and lower peri device leak. (10)

In our case series, the Amulet device was both effective and safe. All procedures were successful and no major procedural complications were noted. It should be noted that one patient had minor bleeding from the puncture site and one patient presented ventricular fibrillation the next day that was not linked to the procedure. It also should be noted that all procedures were performed by experienced operators.

CONCLUSION

Our case series is the first to investigate the use of the Amplatzer Amulet device for LAAC in a Tunisian population. The results did not differ from other populations reviewed in the litterature, as the device proved its safety with a high success rate for all LAA anatomies and a low rate of procedural complications.

More randomized controlled studies should be conducted investigating the use of Amplatzer Amulet device comparing it to the newer models of the Watchman device: Watchman Flex and Watchman Flex Pro.

Percutaneous LAAC is a very seductive alternative to anticoagulation when the bleeding risk is high. More studies need to be conducted in order to upgrade its level of recommendation.

REFERENCES

1. Elsheikh S, Hill A, Irving G, Lip GYH, Abdul-Rahim AH. Atrial fibrillation and stroke: State-of-the-art and future directions. Curr Probl Cardiol. 2024 Jan;49(1):102181.
2. Landmesser U, Skurk C, Tzikas A, Falk V, Reddy VY, Windecker S. Left atrial appendage closure for stroke prevention in atrial fibrillation: current status and perspectives. Eur Heart J. 2024 Jul 19;ehae398.
3. Van Gelder IC, Rienstra M, Bunting KV, Casado-Arroyo R, Caso V, Crijns HJGM, et al. 2024 ESC Guidelines for the management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS). Eur Heart J. 2024 Sep 29;45(36):3314–414.
4. Joglar JA, Chung MK, Armbruster AL, Benjamin EJ, Chyou JY, Cronin EM, et al. 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation [Internet]. 2024 Jan 2 [cited 2024 Dec 11];149(1). Available from: https://www.ahajournals.org/doi/10.1161/CIR.0000000000001193
5. Chamtouri I, Jomaa W, Abdallah W, Hamda KB, Maatouk F. Left atrial appendage closure with Watchman device: Insights from the first-ever Tunisian experience and six-year follow-up. La fermeture percutanée de l'auricule gauche par le dispositif de Watchman: aperçus de la toute première expérience tunisienne et suivi de six ans. Tunis Med. 2021;99.
6. Frazzetto M, Sanfilippo C, Costa G, Contrafatto C, Giacalone C, Scandura S, et al. Watchman vs. Amulet for Left Atrial Appendage Closure: Current Evidence and Future Perspectives. J Clin Med. 2024 Aug 8;13(16):4651.
7. Lakkireddy D, Thaler D, Ellis CR, Swarup V, Sondergaard L, Carroll J, et al. Amplatzer Amulet Left Atrial Appendage Occluder Versus Watchman Device for Stroke Prophylaxis (Amulet IDE): A Randomized, Controlled Trial. Circulation. 2021 Nov 9;144(19):1543–52.
8. Mansour MJ, Harnay E, Al Ayouby A, Mansourati V, Jobic Y, Gilard M, et al. One year outcome and analysis of peri-device leak of left atrial appendage occlusion devices. J Interv Card Electrophysiol. 2022 Jun;64(1):27–34.
9. Galea R, De Marco F, Meneveau N, Aminian A, Anselme F, Gräni C, et al. Amulet or Watchman Device for Percutaneous Left Atrial Appendage Closure: Primary Results of the SWISS-APERO Randomized Clinical Trial. Circulation. 2022 Mar 8;145(10):724–38.
10. Jaiswal V, Ang SP, Shrestha AB, Wajid Z, Endurance EO, Ayoobkhan FS, et al. Amplatzer amulet versus watchman device for percutaneous left atrial appendage closure: A systematic review and meta-analysis. Medicine (Baltimore). 2023 Jun 30;102(26):e34185.