ESC European Society of Cardiology

European Heart Journal - Case Reports (2024) **8**, 1–6
https://doi.org/10.1093/ehjcr/ytad629

CASE REPORT
Structural intervention

A giant left atrial appendage: a case report on the feasibility of closure with a custom-made device

Federico Barocelli[1], Filippo Luca Gurgoglione[1,2], Marco Covani[2], Maria Alberta Cattabiani[3], and Luigi Vignali [1]*

[1]Cardiology Department, Azienda Ospedaliero-Universitaria of Parma, Via Gramsci 14, 43126 Parma, Italy; [2]Cardiology Department, University of Parma, Parma, Italy; and [3]Cardiology Department, Micone Hospital, Genova, Italy

Received 3 July 2023; revised 30 November 2023; accepted 13 December 2023; online publish-ahead-of-print 8 January 2024

Background Transcatheter left atrial appendage occlusion (LAAO) is a valuable therapeutic option for stroke prevention in patients with atrial fibrillation (AF) at high bleeding risk. However, complex LAA anatomies sometimes preclude the adoption of commercially available LAAO devices. The design of a custom-made LAAO device is a promising strategy in these cases. However, few examples of custom-made devices in case of giant LAAs have been reported.

Case summary An 85-year-old man with permanent AF with CHA_2DS_2-VASc 4 and recurrent active gastrointestinal major bleedings was referred for transcatheter LAAO at Parma University Hospital after multidisciplinary team evaluation. Pre-procedural coronary computed tomography angiography revealed a giant windsock LAA, with a maximum ostium diameter of 44 mm, a landing zone diameter of 34 mm, and maximal length of 49 mm. Patient's management was particularly challenging given that available LAAO devices were too small to completely exclude the LAA. In accordance with the manufacturer, a custom-made LAmbre™ Closure System (Lifetech Scientific, Shenzhen, China), which specifically fitted with patient's LAA anatomy, was designed and successfully deployed under transoesophageal echocardiography (TEE) and fluoroscopic guidance. Periprocedural TEE confirmed the appropriate position of the device and the absence of peri-device leaks. No adverse ischaemic and haemorrhagic events were reported at 3-months follow-up.

Discussion We present a case of a successful transcatheter LAAO procedure by deploying a custom-made LAmbre device 38/46 mm to mechanically exclude a giant windsock LAA. This case illustrates the effectiveness of a custom-made device strategy, which potentially enables the closure of all complex LAA anatomies.

Keywords Case report • Atrial fibrillation • Giant left atrial appendage • Left atrial appendage occlusion • Custom-made device • LAmbre™ device

ESC curriculum 5.3 Atrial fibrillation • 2.1 Imaging modalities

Learning points

- A giant left atrial appendage occasionally precludes the adoption of conventional left atrial appendage occlusion (LAAO) devices.
- A custom-made LAAO device is an innovative and effective strategy in case of LAA complex anatomies.

* Corresponding author. Tel: +39 0521 704313, Fax: +39 0521 702189, Email: luvignali@ao.pr.it
Handling Editor: Claudio Montalto
Peer-reviewers: Kashan Ali; Edin Begic; Josip Andelo Borovac
Compliance Editor: Nikesh Jathanna

Introduction

Atrial fibrillation (AF) is a common arrhythmia associated with a nearly five-fold higher risk of systemic thromboembolism, in particular ischaemic stroke, as compared to general population.[1] Therefore, according to most recent guidelines, oral anticoagulation (OAC) is recommended for stroke prevention in males with a CHA_2DS_2-VASc (congestive heart failure, hypertension, age, diabetes, stroke history, vascular disease, and sex category) score ≥ 2 and in females with a score ≥ 3.[1] However, the occurrence of haemorrhagic complications or the diagnosis of medical conditions predisposing to bleeding events often imposes the withdrawal of OAC therapy.

Transcatheter left atrial appendage occlusion (LAAO) is a valuable therapeutic option for the prevention of thromboembolic events reserved for patients with non-valvular AF and high bleeding risk. This procedure is non-inferior for stroke prevention as compared to OAC.[2–4] The rationale lies in the opportunity to mechanically exclude the LAA, which is responsible for thrombus formation in more than 90% of cases.[5]

The LAA is highly variable in terms of shape, length, number of lobes, and the presence of thrombus. Therefore, a pre-procedural meticulous characterization of the LAA anatomy, by transoesophageal echocardiography (TEE) and/or cardiac computed tomography angiography (CCTA), is crucial to assess the anatomic suitability of transcatheter LAAO and to guide the proper device selection.[6]

While technical feasibility is guaranteed in most procedures, the recognition of complex LAA anatomic features, such as a giant LAA (with the ostium diameter > 30 mm), might occasionally preclude the use of conventional devices. In these cases, a custom-made LAAO device, fitting with the individual LAA anatomy, could represent an innovative and effective strategy.[7,8]

However, few examples of custom-made LAAO devices have been reported.[7,9]

Summary figure

Schematic overview of patient's management (from clinical presentation to successful LAAO procedure). AF, atrial fibrillation; CHA_2DS_2-VASc, congestive heart failure, hypertension, age, diabetes, stroke history, vascular disease, and sex category; LAA, left atrial appendage; LAAO, left atrial appendage occlusion; OAC, oral anticoagulation.

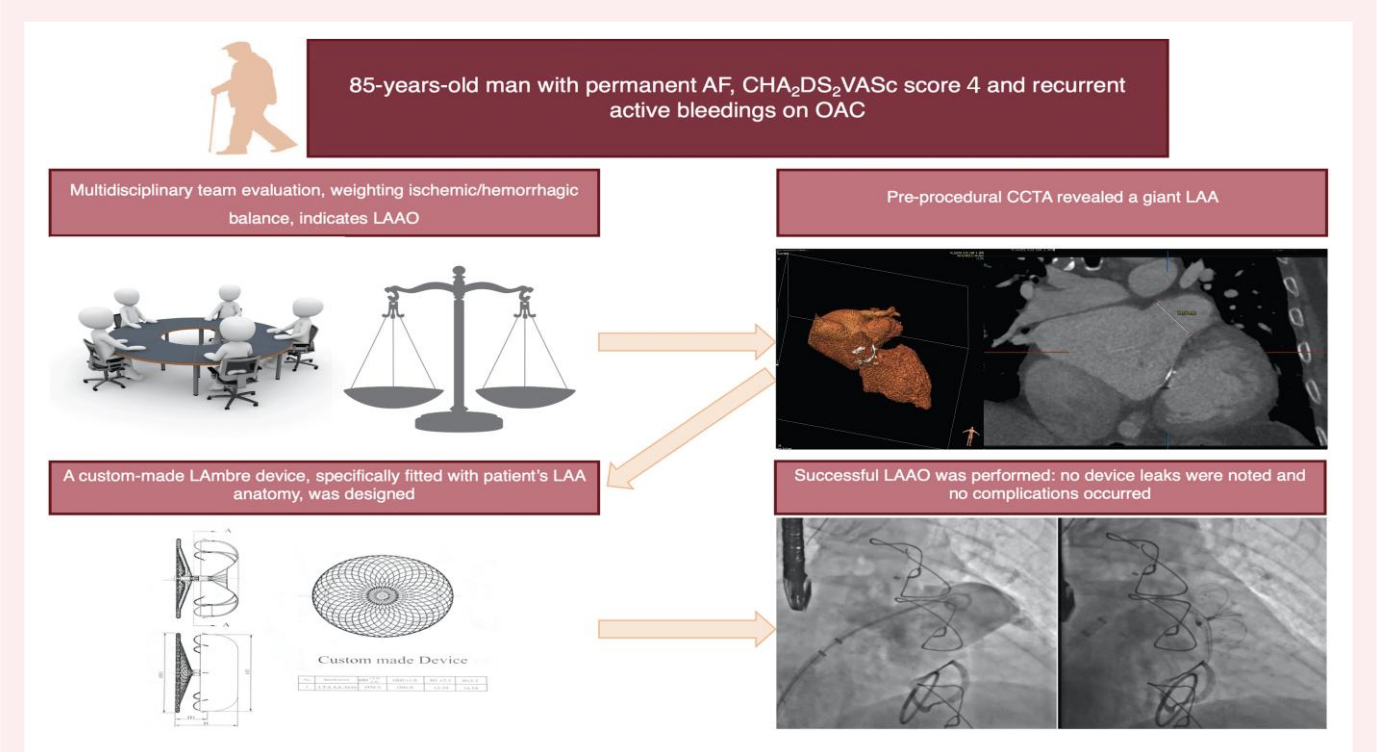
Case presentation

An 85-year-old man with multiple cardiovascular risk factors (hypertension, dyslipidaemia, chronic kidney disease), permanent AF, CHA2DS2-VASc 4, and HAS-BLED 3 was referred for transcatheter LAAO at Parma University Hospital.

His past medical history reported a left hemicolectomy due to adenocarcinoma (2014), a surgical aortic valve replacement with biological prothesis, mitral valve annuloplasty, and coronary artery bypass grafting (2015). In the same year, AF was diagnosed and patient was initially managed with vitamin K antagonist. In March 2022, already on gastroprotective therapy, the patient was hospitalized for severe anaemia (nadir of haemoglobin of 7.9 g/dL) and a gastric Dieulafoy's lesion was treated by diathermocoagulation.

After the procedure, fondaparinux 7.5 mg was started and then switched to rivaroxaban 15 mg (glomerular filtration rate of 42 mL/min), as indicated by the guidelines.[1] In the following six months, the patient experienced recurrent active bleedings (nadir of haemoglobin of 7.1 g/dL) requiring two other hospitalizations. Therefore, after multidisciplinary team evaluation, OAC therapy was stopped and patient was proposed for transcatheter LAAO.

Pre-procedural CCTA, performed in November 2022, revealed a giant windsock LAA (*Figure 1*): at the level of the ostium, measurement of the LAA was 44 mm (maximum diameter) and 32 mm (minimum diameter), with a landing zone diameter of 34 mm, along with a maximal length of 49 mm. Given that available LAAO devices were not large



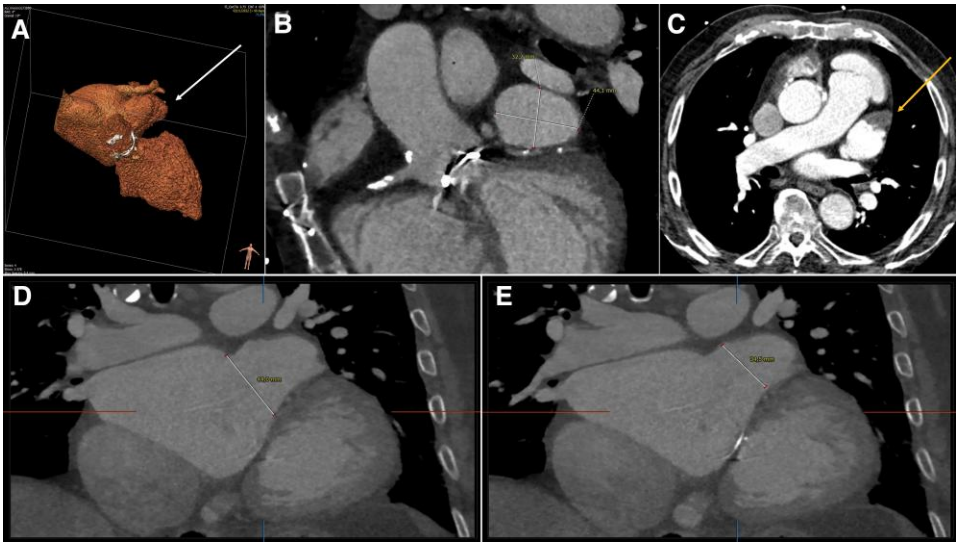
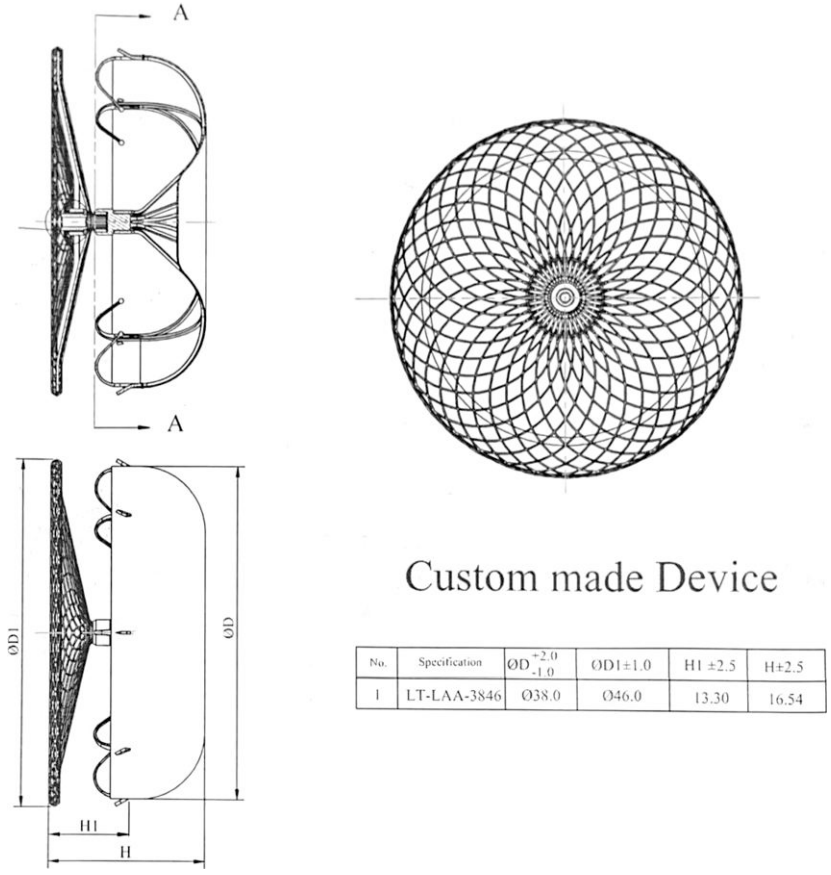


Figure 1 Pre-procedural CCTA of patient's LAA: (*A*) CCTA three-dimensional reconstruction image showing a giant LAA (white arrow); (*B*) measurements of the LAA at the level of the ostium, with diameters measuring 44mm × 32 mm; (*C*) CCTA revealed the presence of a thrombus in the LAA (corresponding to the arrow); (*D*) ostium maximum diameter: 44 mm; (*E*) landing zone diameter: 34 mm. CCTA, cardiac computed tomography angiography; LAA, left atrial appendage.



No.	Specification	$ØD^{+2.0}_{-1.0}$	ØD1±1.0	H1 ±2.5	H±2.5
1	LT-LAA-3846	Ø38.0	Ø46.0	13.30	16.54

Figure 2 Characteristics of custom-made LAmbre™ device, specifically fitted with patient's LAA anatomy. LAA, left atrial appendage.

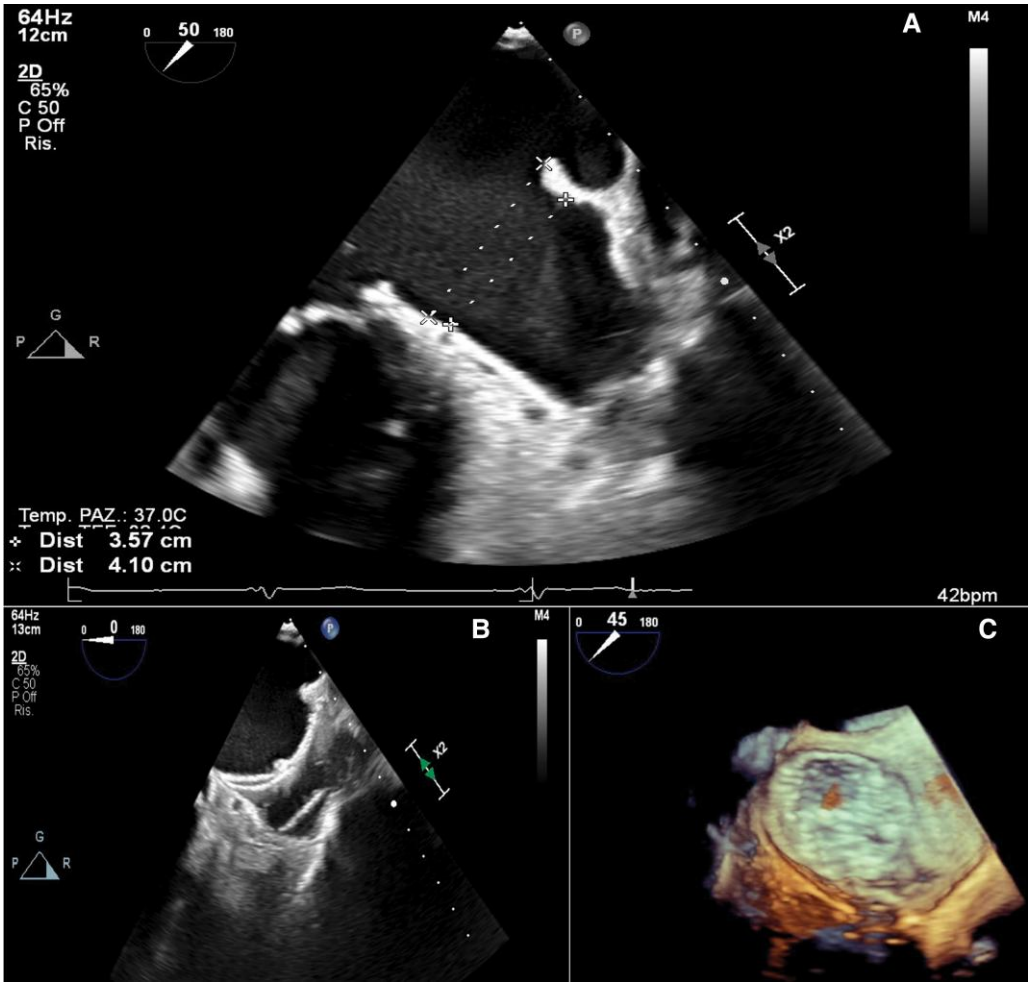


Figure 3 Periprocedural TEE images: (*A*) pre-procedural TEE image at 50°. (*B*) Post-procedural TEE at 0° showing the appropriate position of LAmbre™ 38/46 mm. (*C*) Three-dimensional TEE at 45° showing the disk of the device covering the entrance of LAA. LAA, left atrial appendage; TEE, transoesophageal echocardiography.

enough to completely exclude LAA, proper management of this patient was particularly challenging.

In accordance with the manufacturer, leveraging a three-dimension CCTA reconstruction of patient's LAA, a custom-made LAmbre™ Closure System (Lifetech Scientific, Shenzhen, China)[7] 38/46 mm (lobe/disc), specifically fitted with patient's LAA anatomy was designed (*Figure 2*). There was no conflict of interest between the authors and the industry, and the patient gave consent to the implantation of a device that has not been tested before in a clinical trial.

Cardiac computed tomography angiography revealed the presence of a thrombus in the LAA (*Figure 1C*), and patient was treated with low-dose heparin. After 3 months, TEE revealed no signs of LAA thrombus. Furthermore, patient underwent a comprehensive laboratory examination that excluded the presence of antiphospholipid syndrome and other thrombophilic conditions. Transcatheter LAAO was performed in March 2023. At hospital admission, physical examination was within normal limits: no heart murmurs, and lung sounds and signs of heart failure were detected. Through right femoral venous access, transseptal puncture was performed and a 10 F delivery sheath was used to advance the LAmbre™ device 38/46 mm, which was successfully deployed under TEE (*Figure 3*) and fluoroscopic guidance (*Figure 4*). Considering the LAA giant dimensions, an 'anatomic-tailored' deployment technique was adopted, by releasing the distal umbrella in a more internal part of the LAA than the standard procedure.[7] Periprocedural TEE confirmed the appropriate position of the device and the absence of peri-device leaks (*Figure 3*). Two days after the procedure, weighing the patient's individual risk for bleeding and thromboembolism, patient was discharged on dual antiplatelet therapy (aspirin plus clopidogrel) for 1 month, followed by clopidogrel up to 6 months.[10] No adverse ischaemic and haemorrhagic events occurred at 3-months follow-up.

Discussion

In this case, we performed a successful transcatheter LAAO procedure by deploying a custom-made LAmbre™ device 38/46 mm to mechanically exclude a giant windsock LAA (*Summary figure*).

This case is educational because it highlights the complexity of LAA anatomy along with the clinical relevance of an individual pre-procedural planning and a tailored therapy. Furthermore, it outlines several findings related to LAAO procedure, from the rationale to the evolving technologies.

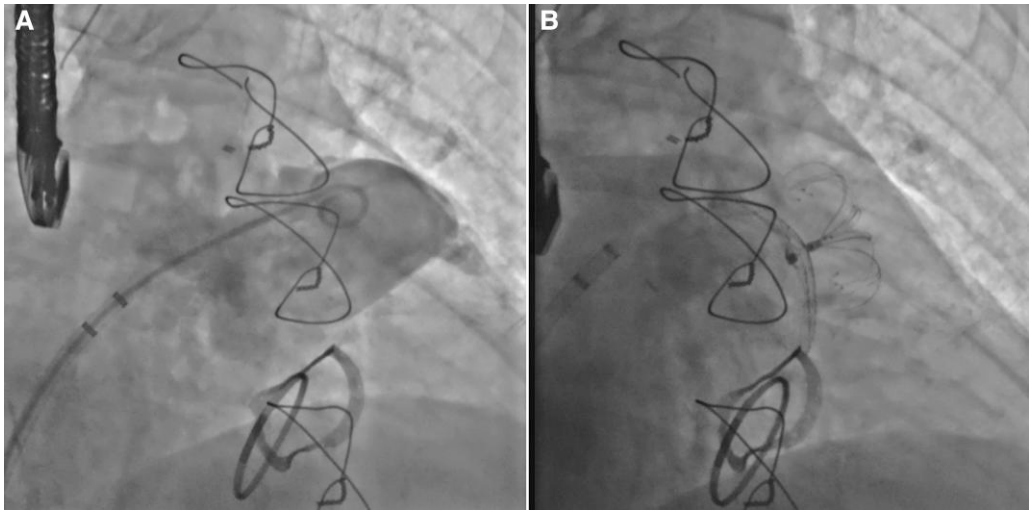


Figure 4 Intraprocedural fluoroscopic images of LAAO procedure: (*A*) contrast injection into LAA. (*B*) Custom-made LAmbre™ device release. LAA, left atrial appendage; LAAO, left atrial appendage occlusion.

From a clinical perspective, the patient was affected by permanent AF, which increases the risk of ischaemic strokes and meanwhile experienced recurrent major bleeding events that hinder long-term OAC therapy. In line with recent evidences, this patient was suitable for transcatheter LAAO.[1]

Furthermore, the CCTA detection of a thrombus in the LAA further complicates the clinical scenario and was managed with low-molecular heparin: OAC, the most adopted treatment of LAA thrombus,[11] was not considered due to the bleeding history.

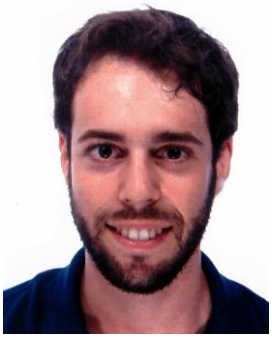
Second, this case stressed the clinical relevance of a meticulous pre-procedural imaging assessment: the individual's LAA anatomy drives the choice of LAAO device and the optimal implantation technique.[6] Furthermore, financial considerations cannot be overlooked: the intra-procedural recognition of LAA prohibitive anatomies or thrombus could result in LAAO abortion with detrimental economic impact in terms of laboratory time, personnel resources, and medications/instruments costs along with enhanced discomfort and anxiety for patients.

More importantly, this case highlighted the technical feasibility of a custom-made LAmbre™ device implantation to close a giant windsock LAA. This strategy lies in the ability of the manufacturer to design a tailored custom-made LAAO device by accurately replicating three-dimensional CCTA scans of patient's LAA. This therapeutic option potentially expands the feasibility of transcatheter LAAO. Some reports outlined the effectiveness of a combination of Watchman-Amplatzer Plug devices, the so-called 'kissing-Watchman' technology.[12,13] However, the deployment of a custom-made LAmbre™ device outperforms the latter strategy in terms of technical easiness and time consumption.

Finally, antithrombotic strategy after LAAO, essential to mitigate the risk of device-related thrombus, should be tailored. Long-term OAC is contraindicated in most patients due to a very high bleeding risk. Therefore, antiplatelet therapy is the most adopted regimen after LAAO nowadays, weighting the individual ischaemic/haemorrhagic balance.

In conclusion, we reported a case of a successful transcatheter LAAO procedure with a custom-made LAmbre™ device for a giant windsock LAA. Future studies are awaited to confirm the good performance of custom-made LAmbre™ devices and to expand their clinical application.

Lead author biography



Federico Barocelli, MD, is a cardiologist and he is working at the Cardiology Unit of Parma University Hospital. He was born in Parma in 1990. In 2017, he graduated in Medicine and Surgery and in 2022, he got the Specialization in Cardiology in the University of Parma. His professional experience focuses mainly on Day Hospital, Heart Failure clinic and in Cardiomyopathy clinic, with clinical and echocardiographic assessment and follow-up. He is conducting several experimental research studies about atrial fibrillation (and related procedures such as left atrial appendage occlusion), acute myocardial infarction, heart failure, and cardiomyopathies.

Consent: The authors confirm that written consent for submission and publication of this case report including images and associated text has been obtained from patient in line with COPE guidance.

Conflict of interest: None declared.

Funding: This study received no funding.

Data availability

Data available on request.

References

1. Hindricks G, Potpara T, Dagres N, Arbelo E, Bax JJ, Blomstrom-Lundqvist C, et al. 2020 ESC guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS): the Task Force for the diagnosis and management of atrial fibrillation of the European Society of Cardiology (ESC) developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC. *Eur Heart J* 2021;**42**:373–498.
2. Reddy VY, Doshi SK, Sievert H, Buchbinder M, Neuzil P, Huber K, et al. 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;**127**: 720–729.
3. Holmes HD Jr, Kar S, Price MJ, Whisenant B, Sievert H, Doshi SK, et al. Prospective randomized evaluation of the Watchman Left Atrial Appendage Closure device in patients with atrial fibrillation versus long-term warfarin therapy: the PREVAIL trial. *J Am Coll Cardiol* 2014;**64**:1–12.
4. Osmancik P, Herman D, Neuzil P, Hala P, Taborsky M, Kapa P, et al. Left atrial appendage closure versus direct oral anticoagulants in high-risk patients with atrial fibrillation. *J Am Coll Cardiol* 2020;**75**:3122–3135.
5. Tsai LM, Lin LJ, Teng JK, Chen JH. Prevalence and clinical significance of left atrial thrombus in nonrheumatic atrial fibrillation. *Int J Cardiol* 1997;**58**:163–169.
6. Glikson M, Wolff R, Hindricks G, Mandrola J, Camm AJ, Lip GYH, et al. EHRA/EAPCI expert consensus statement on catheter-based left atrial appendage occlusion—an update. *EuroIntervention* 2020;**15**:1133–1180.
7. Huang H, Liu Y, Xu Y, Wang Z, Li Y, Cao K, 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**:2188–2194.
8. Matta M, Maltese L, Ugo F, Di Ruocco MV, Rametta F. Feasibility and safety of left atrial appendage closure in a patient with previous foramen ovale occlusion: a case report. *Eur Heart J Case Rep* 2021;**5**:ytab113.
9. Inohara T, Tsang MY, Lee C, Saw J. Closing gigantic left atrial appendage using a LAmbre Closure System: first implant experience in North America. *J Cardiovasc Electrophysiol* 2021;**32**:158–161.
10. Vignali L, Gurgoglione FL, Barocelli F, Cattabiani MA, Solinas E, Maini A, et al. Looking for optimal antithrombotic strategy after transcatheter left atrial appendage occlusion: a real-world comparison of different antiplatelet regimens. *Int J Cardiol* 2023;**371**:92–99.
11. Katic J, Borovac JA. Treatment of persistent left atrial appendage thrombus in patients with atrial fibrillation on adequate oral anticoagulation: pathways of care for all-comers and heart failure patients. *Card Fail Rev* 2023;**9**:e05.
12. Jiang L, Duenninger E, Muenzel M, Xue X, Fazakas A, Keil T, et al. Percutaneous left atrial appendage closure with complex anatomy by using the staged 'Kissing-Watchman' technology with double devices. *Int J Cardiol* 2018;**265**:58–61.
13. Xia L, Liu Y, Tao L. Kissing-Watchman technique applied in single-lobulated left atrial appendage anatomy with giant ostia. *Cardiol J* 2020;**27**:78–80.