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Left atrial appendage occlusion with lambre in atrial fibrillation: Initial European experience☆,☆☆

Jai-Wun Park [a,d,1], Horst Sievert [b,f,1], Caroline Kleinecke [a], Laura Vaskelyte [b], Steffen Schnupp [a], Kolja Sievert [b], Yat-Yin Lam [c], Barbara E. Stähli [d], Deyuan Zhang [e], Anning Li [e], Johannes Brachmann [a,*]

[a] Medical Clinic II (Cardiology/Intensive Care Medicine), Klinikum Coburg, Coburg, Germany
[b] CardioVascular Center Frankfurt (CVC), Frankfurt, Germany
[c] Department of Medicine and Therapeutics, Prince of Wales Hospital, Hong Kong
[d] Department of Cardiology, Charité Berlin – University Medicine, Campus Benjamin Franklin, Berlin, Germany
[e] LifeTech Scientific Corporation, Shenzen, China
[f] Anglia Ruskin University, Chelmsford, UK

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ABSTRACT

Background: We here report the first European experience with the novel LAmbre left atrial appendage (LAA) occluder, a self-expanding device consisting of an umbrella and a cover connected by a central waist.
Methods and results: A total of 60 patients (74.4 ± 8.3 years; 66.7% men; CHA2DS2-VASc: 4.0 ± 1.6, HAS-BLED score: 3.2 ± 1.3) with atrial fibrillation and contraindications to oral anticoagulation underwent left atrial appendage occlusion (LAAO) with the LAmbre device at two German centers between November 2013 and September 2015.
Device success defined as correct placement of the device was achieved in all patients (100%). Resizing of the device was necessary in 3 (5%) patients. Device-related complications included 2 (3.3%) pericardial effusions on day 8 and 33 after the index procedure requiring pericardiocentesis. Transesophageal echocardiography at 6 months showed complete sealing of the LAA (residual jet flow of <5 mm) in 51/54 (94.4%) patients. No device-related thrombus was documented. At 12 months transient ischemic attack was observed in 1 patient (1.6%) and minor bleeding in 3 patients (5%).
Conclusions: Although minimizing procedure-related complications remains challenging, LAAO with the LAmbre showed high device success and good mid-term performance regarding prevention of stroke and bleeding.

1. Introduction

Cerebrovascular events are dreaded complications in patients with atrial fibrillation, given the associated substantial morbidity and mortality [1]. Over the last decade, dedicated systems for left atrial appendage occlusion (LAAO) such as the Watchman device emerged as promising alternatives to oral anticoagulation in patients with non-valvular atrial fibrillation and at increased risk for cardioembolic events [2,3].

Although high procedural success rates have been reported with contemporary systems for LAAO [5,13] device-related complications such as device embolisation, pericardial tamponade, and periprocedural stroke continue to exist and are partly attributable to the heterogenous anatomy of the LAA.

Hence, there is an unmet clinical need to further advance both device design and implantation techniques for LAAO, aiming at increased procedural success rates and improved clinical outcomes in this high-risk patient population. The LAmbre LAA occluder was recently introduced into clinical practice given promising pre-clinical data in animal models [6]. This nitinol-based, self-expanding occluder consists of an umbrella and a cover connected by a central waist. Seventeen sizes accommodate varying LAA anatomies. The easy to handle delivery system is relatively small (8–10 French) and has the advantages of full recapture and repositioning capabilities [7].

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* Corresponding author at: Coburg Hospital, Medical Clinic II (Cardiology/Intensive Care Medicine), Ketschendorfer Straße 33, 96450 Coburg, Germany.
E-mail address: brachmann.laptop@extern.klinikum-coburg.de (J. Brachmann).
[1] These authors have contributed equally to this work.

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This study investigated feasibility and safety of the LAmbre LAA occluder in patients with atrial fibrillation and contraindications to oral anticoagulation.

2. Methods

2.1. Study cohort

Patients with atrial fibrillation and contraindications to oral anticoagulation were scheduled for LAAO and prospectively enrolled in the German LAmbre registry. All patients underwent LAAO with the LAmbre (Lifetech Scientific Corp., Shenzhen, China) device at two centers (Department of Cardiology, Klinikum Coburg, Germany, and Cardiovascular Center Frankfurt (CVC), Frankfurt, Germany) between November 2013 and September 2015. The indication for LAAO was made based on current guidelines and recommendations.

Inclusion criteria comprised age ≥ 18 years, presence of nonvalvular paroxysmal, persistent or permanent atrial fibrillation ≥3 months, a high risk for cardioembolic events and contraindications to oral anticoagulation, CHA2DS2-VASc Score ≥ 2, eligibility for clopidogrel and aspirin, ability to understand the requirements of the study and willing to follow study instructions, provide written informed consent and agreement to comply with all study requirements, including the required study follow-up visits.

Exclusion criteria comprised pregnancy or breastfeeding, rheumatic, degenerative or congenital valvular heart disease, prior surgical removal of the LAA, prior heart transplantation, symptomatic carotid artery disease, recent or acute myocardial infarction or unstable angina, mechanical valve prosthesis, history of stroke or transient ischemic attack within 30 days, signs or symptoms of infection, cardiac tumors or other malignancies with an estimated life expectancy of ≤2 years, allergy to nitinol, pre-procedural pericardial effusion, single episode of transient atrial fibrillation, scheduled electrophysiological ablation procedure, scheduled pharmacological or electrical cardioversion, decompensated heart failure (NYHA class III-IV), heart rate > 110 beats per minute, thrombocytopenia (platelet ≤100.000 per microliter), LA diameter ≥ 65 mm, LAA orifice <12 mm or >30 mm, presence of LAA thrombus, left ventricular ejection fraction ≤30%, complex atherosclerotic plaques (≥4 mm) in the ascending aorta. The study complies with the Declaration of Helsinki. It was approved by the local ethical committees, and all patients provided written informed consent prior to enrollment.

2.2. The LAmbre left atrial appendage closure system

The name "LAmbre" derives from "umbrella in the left atrial appendage". The LAmbre LAA closure system comprises the LAA occluder and a delivery system. The self-expanding occluder consists of an umbrella and a cover connected by a central waist. The connecting hub is recessed into the cover to prevent thrombus formation (Fig. 1). The umbrella is a nitinol framework including 8 claws allowing complete collapse and repositioning. The occluder anchors with small stabilizing hooks into the landing zone of the LAA. The cover is a flat, nitinol mesh disc that is 4 to 6 mm larger than the umbrella, to optimally seal the LAA orifice. The flexible, articulating waist between the umbrella and the cover allows the cover to self-orientate towards the cardiac wall after delivery. The umbrella is coated and the cover is filled with a polyethylene terephthalate (PET) membrane to ensure complete sealing of the LAA. The LAmbre device is available in 17 different sizes. The delivery system comprises a delivery sheath (8–10 French), a delivery cable, and a loader. The delivery sheath is available with 45° single or 45° × 30° double curves. The delivery system provides full recapturing and multiple repositioning of the device [7]. After the procedure, all patients received dual antiplatelet therapy with aspirin and clopidogrel for 3 months, followed by aspirin alone.

2.3. Procedural details

Transesophageal echocardiography (TEE) was performed before and during the procedure to rule out LAA thrombus formation and to determine the LAA size with measurements of orifice, landing zone, and depth from different angles (0°, 45°, 90°, and 135°). All procedures were performed by experienced operators in LAAO (>100 previous procedures with Amplatzer and/or Watchman devices). The procedure was performed either under local or general anesthesia according to the operator's preference. Having obtained venous access, TEE-guided transseptal puncture was performed in an infero-posterior location, and heparin was administered to achieve an activated clotting time > 250 ms. Then, an LAA angiogram was performed with a pigtail catheter in right anterior oblique caudal and cranial projections. Device sizing was based on both angiographic and echocardiographic measurements. The umbrella was sized 4 to 6 mm larger than the maximal diameter of the LAA landing zone, the cover 4 mm larger than the maximal diameter of the LAA orifice. After sizing, the delivery sheath was placed into the very proximal part of the LAA.

Then, the umbrella was deployed by slowly pushing out and simultaneously unsheathing the umbrella. Once the umbrella was fully expanded, the umbrella was then gently pushed forward "en-bloc" to the desired landing zone. The sheath was then withdrawn to deploy the cover, allowing it to expand in the left atrium and seal the LAA orifice by softly pushing the delivery cable forward. A gentle tug test was performed under fluoroscopy by pulling the delivery cable. Then, the device was released (Fig. 2). Echocardiographic and angiographic criteria for correct deployment were a rectangular-shaped umbrella positioned beyond the circumflex artery and a concave shape of the cover. Analysis of fluoroscopy with evaluation of device and technical success was done by the operator.

Coverage of the orifice and residual leaks were evaluated by color doppler echocardiography.

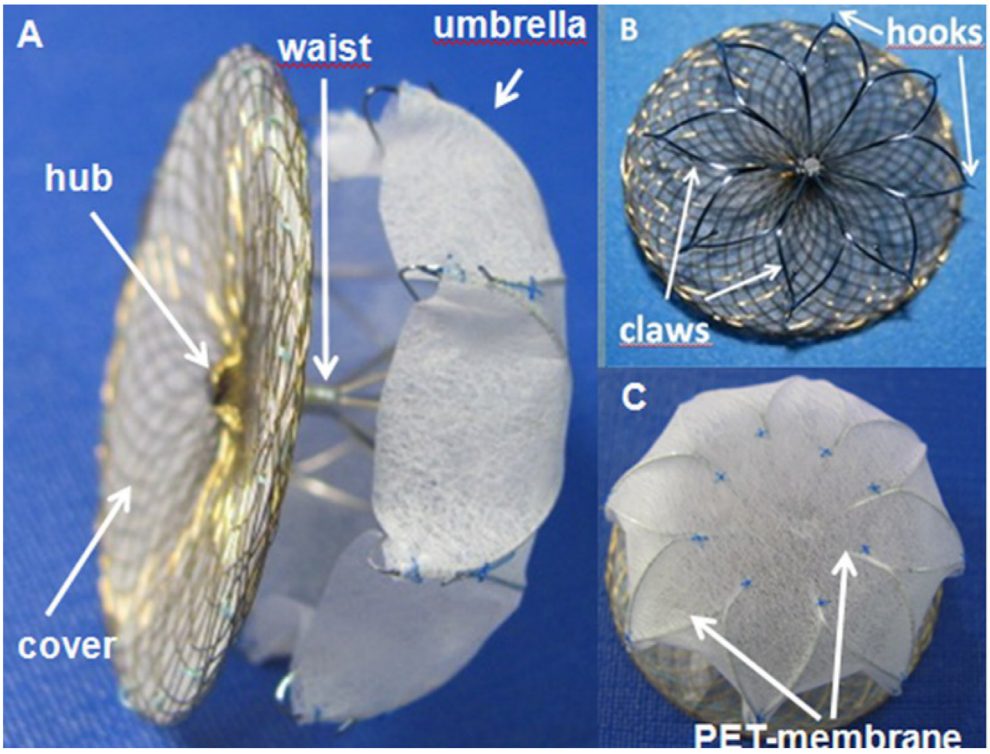

Fig. 1. The LAmbre occluder. A. The LAmbre occluder is a nitinol-based, self-expanding device consisting of an umbrella and a cover connected by a central waist. The attachment hub is recessed into the cover to avoid thrombus formation. B. The umbrella consists of 8 claws with hooks that anchor into the landing zone of the LAA. C. A polyethylene terephthalate (PET) - membrane covers the umbrella to ensure complete LAA sealing.