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STRUCTURAL: ATRIAL INTERVENTION FOCUS

Percutaneous Left Atrial Appendage Closure With the LAmbre Device for Stroke Prevention in Atrial Fibrillation

A Prospective, Multicenter Clinical Study

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ABSTRACT

OBJECTIVES The authors sought to assess the clinical outcomes of left atrial appendage (LAA) closure with the LAmbre closure system in patients with nonvalvular atrial fibrillation (NVAF).

BACKGROUND Over 90% of thrombi are located in the LAA in NVAF patients.

METHODS A prospective, multicenter study was conducted in 153 NVAF patients with $CHADS_2$ score ≥1.

RESULTS The LAA was successfully occluded in 152 patients. Serious complications occurred in 5 patients. During the 12-month follow-up, ischemic stroke occurred in 2 patients, 1 patient had incomplete LAA sealing, and there was no device embolization.

CONCLUSIONS LAA closure with the LAmbre device shows encouraging results for stroke prevention. (J Am Coll Cardiol Intv 2017;10:2188–94) © 2017 Published by Elsevier on behalf of the American College of Cardiology Foundation.

Atrial fibrillation (AF) is the most common sustained arrhythmia observed in clinical practice and is a major cause of morbidity and mortality due to cardioembolic stroke, which is responsible for 15% to 20% of all ischemic strokes (1). The incidence of ischemic stroke among patients with nonvalvular AF (NVAF) is approximately 5% per year, a 5.6-fold increase when compared with an

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age-matched population in sinus rhythm (2). There is a great deal of published reports on stroke prevention demonstrating that oral anticoagulation with warfarin is the current most common and effective therapy to prevent stroke associated with AF (3-5). Unfortunately, this treatment is generally underused due to its several limitations, including the narrow therapeutic window, the drug and food interactions, the need for repeated monitoring, and the poor patient tolerance.

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Autopsy and echocardiography studies have shown that more than 90% of atrial thrombi in patients with NVAF locate in the left atrial appendage (LAA) (6,7). Therefore, percutaneous LAA closure has been developed as an alternative strategy to warfarin for stroke prophylaxis in AF patients. Many studies demonstrated the effectiveness of percutaneous LAA closure in stroke prevention in patients with AF (8-16). The PROTECT-AF (WATCHMAN Left Atrial Appendage System for Embolic Protection in Patients With Atrial Fibrillation) study showed that percutaneous LAA closure with WATCHMAN device (Boston Scientific, Natick, Massachusetts) was superior to warfarin in patients with NVAF for the prevention of stroke, systemic embolization, cardiovascular death, and all-cause mortality after 3.8 years of follow-up (13). In addition, another LAA-occluding device, the Amplatzer Cardiac Plug (St. Jude Medical, Saint Paul, Minnesota), has shown favorable efficacy for the prevention of AF-related thromboembolism (16). LAmbre (Lifetech Scientific, Shenzhen, China) is a new, self-expanding LAA occluder, specifically designed for LAA closure. Preliminary study suggested the percutaneous LAA closure with LAmbre device is feasible with a high success rate in canines (17). However, there are no data available on the clinical safety and efficacy of this device. This prospective, multicenter clinical study reported the initial experience of LAmbre implantation for NVAF patients in China.

METHODS

STUDY POPULATION. This was an open-label, nonrandomized pilot trial designed to assess the safety, feasibility, and efficacy of deploying the LAmbre LAA occlusion device. One hundred fifty-three consecutive patients who underwent percutaneous LAA closure with the LAmbre device at 12 hospitals in China between March 2014 and January 2015 were prospectively studied. All patients had a diagnosis of NVAF, over 18 years of age, scored at least 1 point according to the congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, and prior stroke or transient ischemic attack ($CHADS_2$) score, and were not suitable for long-term anticoagulation with warfarin (presence of a cerebrovascular or gastrointestinal bleeding history, increased bleeding tendency, poor compliance, or warfarin allergy). All patients received transthoracic and transesophageal echocardiography (TEE) before the LAmbre implantation procedure. Patients found to have thrombus formation in the left atrium, a left ventricular ejection fraction <30%, or a LAA orifice diameter ≤12 mm were excluded from the study. Other exclusion criteria included symptomatic carotid disease, acute myocardial infarction or unstable angina, New York Heart Association functional class IV, prior stroke or transient ischemic attack within 30 days, acute infective endocarditis, hemorrhagic disease, pregnancy, life expectancy <2 years, presence of a prosthetic valve, or presence of an atrial septal repair or closure history. Informed consent was obtained from all studied patients, and the study was approved by the institutional review board.

ABBREVIATIONS AND ACRONYMS

AF = atrial fibrillation

$CHADS_2$ = congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, and prior stroke or transient ischemic attack

CHA_2DS_2-VASc = congestive heart failure, hypertension, age ≥75 years (doubled), diabetes mellitus prior stroke or transient ischemic attack (doubled). vascular disease, age 65 to 74 years, and sex category (female)

LAA = left atrial appendage

NVAF = nonvalvular atrial fibrillation

TEE = transesophageal echocardiography

DEVICE IMPLANTATION. The LAmbre LAA closure system comprises an implant and a delivery system, and is designed for device implantation via the transseptal route into the LAA. The LAmbre implant is a self-expanding, nitinol-based device consisting of an umbrella and a cover connected by a short central waist. The distal umbrella comprises 8 claws with individual stabilizing hooks with a polyethylene terephthalate membrane on the distal face. The proximal cover is filled with sewn-in polyethylene terephthalate fabric (Figure 1). The LAmbre implant is available in 15 diameter sizes referring to the umbrella, that is, 16 to 36 mm. The delivery system consists of a double-curve configuration delivery sheath (8-F to 10-F in size) and a delivery cable, allowing for contrast injection and device positioning. The implantation was performed under general anesthesia by the femoral vein approach under fluoroscopic, angiographic, and continuous TEE guidance. After transseptal puncture, intravenous heparin was immediately administered to patients to achieve activated clotting time of at least 250 s. The delivery sheath was then placed in the proximal part of LAA. The diameters of the orifice and length of LAA are measured from LAA angiography in right anterior oblique cranial projection. The size of the implant would be 4 to 8 mm larger than the measured LAA orifice, based on the clinical judgment of the