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Percutaneous Left Atrial Appendage Closure With the Ultraseal Device

Insights From the Initial Multicenter Experience

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ABSTRACT

OBJECTIVES This study sought to evaluate the feasibility, safety, and efficacy of the Ultraseal device for left atrial appendage closure (LAAC) (Cardia, Eagan, Minnesota) in patients with nonvalvular atrial fibrillation at high bleeding risk.

BACKGROUND The Ultraseal device is a novel bulb-and-sail designed LAAC device, with an articulating joint enabling conformability to heterogeneous angles and shapes of appendage anatomy.

METHODS This was a multicenter study including consecutive patients undergoing LAAC with the Ultraseal device at 15 Canadian and European sites. Periprocedural and follow-up events were systematically collected, and transesophageal echocardiography at 45 to 180 days post-procedure was routinely performed in all centers but 3.

RESULTS A total of 126 patients (mean age 75 ± 8 years; mean CHA_2DS_2-VASc score 5 ± 2; mean HAS-BLED score 4 ± 1) were included. The device was successfully implanted in 97% of patients. A major periprocedural adverse event occurred in 3 (2.4%) patients (clinically relevant pericardial effusion [n = 1], stroke [n = 1], device embolization [n = 1]). Ninety percent of patients were discharged on single or dual antiplatelet therapy. Follow-up transesophageal echocardiography was available in 89 (73%) patients, with no cases of large (>5 mm) residual leak and 5 (5.6%) cases of device-related thrombosis (all successfully treated with anticoagulation therapy). At a median follow-up of 6 (interquartile range: 3 to 10) months, the rates of stroke and transient ischemic attack were 0.8% and 0.8%, respectively, with no systemic emboli. None of the events occurred in patients with device-related thrombosis.

CONCLUSIONS In this initial multicenter experience, LAAC with the Ultraseal device was associated with a high implant success rate and a very low incidence of periprocedural complications. There were no late device-related clinical events and promising efficacy results were observed regarding thromboembolic prevention at midterm follow-up. Larger studies are further warranted to confirm the long-term safety and efficacy of this novel device. (J Am Coll Cardiol Intv 2018;■:■–■) © 2018 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

AF = atrial fibrillation

DRT = device-related thrombosis

LAA = left atrial appendage

LAAC = left atrial appendage closure

MAE = major adverse event(s)

TEE = transesophageal echocardiography

Anticoagulation with vitamin K antagonists or direct oral anticoagulant agents remains the mainstay of thromboembolic prevention in patients with nonvalvular atrial fibrillation (AF), with robust reductions in the risk of stroke and death (1,2). Nevertheless, oral anticoagulation has been associated with increased bleeding risk in a commonly old and comorbid population. Also, more than one-third of AF patients at high risk for stroke still fail to receive optimal thromboembolic prophylaxis in contemporary practice (3). In recent years, left atrial appendage closure (LAAC) has emerged as an alternative treatment to anticoagulation in patients with nonvalvular AF and a broad spectrum of LAAC devices have been developed, mainly targeting high-risk patients deemed ineligible for oral anticoagulation (4).

The Ultraseal LAAC device (Cardia, Eagan, Minnesota) is a new, self-expandable bulb-and-sail occluder, specifically designed for transcatheter LAAC. The first-in-human experience with this device, including a total of 18 patients from 2 centers, showed promising preliminary feasibility data (5,6), and the device received Conformité Européenne mark approval in March 2016. This first multicenter international experience aimed to evaluate the safety, feasibility, and preliminary efficacy of LAAC with the Ultraseal device in a larger patient population.

METHODS

STUDY POPULATION. This multicenter study included consecutive patients with nonvalvular AF who underwent LAAC with the Ultraseal device from 15 centers in Europe and Canada between January 2015 and January 2018. All participating centers but 1 had previous LAAC experience, with a mean experience time of 4 ± 3 years and a median of 79 (interquartile range: 40 to 118) and 43 (interquartile range: 12 to 95) procedures per center and per operator, respectively. The procedure was performed by interventional cardiologists, electrophysiologists, or both in 73%, 13%, and 13% of the participating centers, respectively. Canadian patients were treated on the basis of a compassionate clinical use program and each procedure was approved by Health Canada. In Europe, all patients were treated following Conformité Européenne mark approval of the device. All patients provided informed consent for the procedures. The device was implanted on an all-comer basis in unselected patients undergoing LAAC, in the absence of LAA thrombus. Baseline and periprocedural events were collected prospectively in each participating center. Device success was defined as successful device implantation in correct position and technical success as LAA exclusion in the absence of device-related complications (device embolization, device erosion, interference, thrombus, fracture, infection, perforation, allergy) and no leak >5 mm on color Doppler transesophageal echocardiography (TEE) during the procedure and index hospitalization, in accordance to the Munich consensus statement (7). Major adverse events (MAEs) during the procedure and index hospitalization included death, stroke or transient ischemic attack, systemic embolism, major bleeding (defined as type ≥3 of Bleeding Academic Research Consortium, including cardiac tamponade) (8), myocardial infarction, major vascular complication according to the Valve Academic Research Consortium-2 criteria (9), and device embolization. Cardiovascular events during follow-up included death, stroke or transient ischemic attack, systemic embolization, major bleeding, and device-related complications.

DEVICE CHARACTERISTICS AND IMPLANTATION. The Ultraseal LAAC device is a fully retrievable and repositionable self-expandable nitinol device composed of 2 parts: a soft distal bulb that anchors the device to the LAA through 12 stabilizing hooks and a 3-leaflet multilayered sail with a proximal polyvinyl alcohol foam and a distal polyester layer, for LAA occlusion (**Figure 1**). Both sections are connected by a dual articulating joint enabling multidirectional movement and optimal adjustment to different ostium angles and shapes. The device is available in 9 different bulb sizes ranging from 16 to 32 mm (fitting landing zone measurements from 11 to 26 mm), with the proximal sail being 6 mm larger than the distal bulb diameter, and requires a minimum LAA depth of 16 mm. A bulb-to-landing zone oversizing of at least 25% is generally recommended. The bulb offers low radial force, which allows for permissive oversizing if needed.

The Cardia Delivery System includes 3 components: the delivery forceps, the introducer, and the delivery sheath. The delivery forceps is flexible and has jaws enabling holding and release of the device at a grasping knob located at the center of the proximal sail, whereas a forceps handle locking mechanism prevents device detachment. A hemostatic introducer allows introduction of the device into the delivery sheath. The Cardia delivery sheath, ranging from 10-F to 12-F, is currently available in 2 different preformed curves: single (45°) and double (45° to 45°).