JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 11, NO. 19, 2018

EDITORIAL COMMENT

Why Do We Need Yet Another Left Atrial Appendage Occluder Device?*

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Left atrial appendage occlusion (LAAO) is a mature field with multiple devices that are searching for a common goal: anatomic fit and seal, ease of implantation, and minimal sheath and transseptal footprint, with low risk of embolization or thrombus formation.

In this issue of *JACC: Cardiovascular Interventions,* Asmarats et al. (1) describe their results from a multicenter study of 126 patients with nonvalvular atrial fibrillation who were not ideal candidates for anticoagulation and who underwent LAAO with the Ultraseal device (Cardia, Eagan, Minnesota). According to this study, there was a 97% implant success rate with <1% individual rate of stroke, effusion, or device embolization, respectively. Follow-up transesophageal echocardiogram (TEE) in 73% of patients showed 5.6% with device-related thrombus (DRT) when 10% of patients were on anticoagulation.

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The Ultraseal device has certain unique characteristics. The delivery system is smaller (10- to 12-F) compared with other delivery systems (14-F), which could lead to fewer bleeding events theoretically. Like the Amplatzer Amulet Device (Abbott Vascular, Santa Clara, California), the Ultraseal device is a self-expandable, 2-part bulb-and-sail concept that has an important feature of being connected by a dual articulating joint. This can be advantageous in left atrial appendage anatomies with sharp takeoffs, which can be difficult for pure "lobe" devices, such as the Watchman Device (Boston Scientific, Natick, Massachusetts) entailing sheath placement, or difficult for lobe and disc devices with bias introduced by the disc. The Ultraseal can also be partially or fully retrievable and redeployed up to 5 times, which is more than other LAAO devices have listed in instructions for use. It is important to mention that there were 4 patients in whom the Ultraseal device could not be delivered, noted due to shallow accessory lobes or to very oval ostia leading to significant gaps that the sail could not cover adequately. Despite 9 device sizes, the authors describe how the device can only go to a landing zone of 26 mm, which is smaller compared with other LAAO devices. A flexible forceps locking mechanism grasps a knob at the center of the sail, which can lead to less "straightening" bias during deployment. Implantation technique appears similar to 2-part occlusion devices.

Registries are prone to institutional variations but reflect "real-life practice." In this study, there were 2 patients with combined procedures. Intracardiac echocardiography was used in 13.5% of patients. Most patients were discharged on single or dual antiplatelet therapy; 4% of patients were discharged on oral anticoagulation when only 44.5% of patients had absolute contraindications to oral anticoagulation. Implantation and follow-up TEEs were not adjudicated by a core lab, as in the PROTECT-AF (Percutaneous Closure of the Left Atrial Appendage Versus Warfarin Therapy for Prevention of Stroke in Patients With Atrial Fibrillation) study (2) for the Watchman device, the multicenter ACP (Amplatzer Cardiac Plug) registry (3), and the LAmbre study for the Amplatzer Amulet Device (4). Instead, TEE surveillance was up to the discretion of each participating institution.

Certain aspects of the results deserve further discussion. DRT was present in 5 of the 89 patients

*Editorials published in *JACC: Cardiovascular Interventions* reflect the views of the authors and do not necessarily represent the views of *JACC: Cardiovascular Interventions* or the American College of Cardiology.

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ISSN 1936-8798/$36.00
https://doi.org/10.1016/j.jcin.2018.07.005

(5.6%) that had TEE follow-up. This is within the range of previous studies: 26 of 469 patients (5.5%) in a recent French multicenter registry (5). In that registry, DRT was associated with a hazard ratio of 4.39 for stroke and transient ischemic attack during a mean follow-up period of 13 ± 13 months. However, thrombus is often treatable with short-term anticoagulation, with 95% success (6). Thrombus formation on the device may be exacerbated by device-related characteristics, such as the connector pin on the original Amplatzer Cardiac Plug (6). With the Ultraseal device, the knob may be acting similarly, contributing to DRT. The Ultraseal device also has a polyvinyl acetate foam component, which is different from the PET membrane (Watchman and LAmbre LAAO devices) and the ePTFE layer (WaveCrest device, Coherex Medical, Biosense Webster, Johnson & Johnson, Salt Lake City, Utah) (7). Whether different materials have different thrombogenic profiles in the left atrium and respond to different anticoagulation and antiplatelet regimens is an area worthy of further investigation. However, in the short term, the decision to move fully away from post-procedural anticoagulation consideration or post-procedural screening is not a justifiable one. The need to monitor patients with single or dual antiplatelet therapy after LAAO is higher than ever before, because we have a potential issue (thrombogenicity) and a method to treat it (anticoagulation). Successful LAAO programs have to incorporate this into their practice—this is a pathway, not just a procedure.

The overall safety of the procedure and device is reflected in the low rate of post-procedural safety events. There was 1 pericardial effusion requiring pericardiocentesis, 1 stroke/transient ischemic attack, and 1 acute device embolization, a total of 3 events in 126 patients. This is similar to 48 other studies as collected by Asmarats and Rodés-Cabau (7). Asmarats and Rodés-Cabau (7) showed that operators used the Ultraseal device in approximately 37% of their overall cases and completed the procedure in a mean of 73 min. We have reached the comfortable (or uncomfortable) period where the variations in left atrial appendage anatomy and devices are less of a concern for safe implantation as compared with the operator and program attention to detail as well as close monitoring of the patient during the post-procedural course and beyond.

Leak has traditionally been defined as <5 mm for all these devices. This is based on a subset of the PROTECT-AF study in which leaks were divided into minor (<1 mm), moderate (1 to 3 mm), or major (>3 mm) (2). Data showed no effect of peridevice flow on the primary efficacy endpoint (stroke, systemic embolism, and cardiovascular death), ischemic stroke alone, or a combination of ischemic stroke and systemic embolism (Figure 3 in the referenced paper [1]). Echocardiograms were adjudicated by the core lab in this referenced study (8). Peridevice leaks occurring in 2018 deserve further characterization—how large on 3-dimensional echocardiographic measurement, what % of the device or landing zone perimeter, whether they fill a lobe or accessory lobe, change in leak over time, and so on —and for each device, how these leaks have translated to long-term outcomes. From an LAAO device standpoint, the Ultraseal device has a hollow bulb, which puts the full responsibility on the sail for leak protection. A next-generation device may benefit from 2 layers of protection. Peridevice leak closure has been performed when the leak has been considered to be relevant (9). However, for the Ultraseal device, leak closure would be more challenging because the point of contact would have to be the flexible seal rather than the bulb because there is no fabric or tissue there to create a seal at that level.

Why do we need another LAAO device? Aside from the benefit of increased competition in the marketplace pushing for decreased prices and decreased cost to the payer, there is benefit in advanced iteration. The use of the articulating hub may be beneficial in sharp takeoffs, which can allow less stress and potentially better approximation of the LAA ostial and landing zone planes for closure. Use of different biomaterials may help us mitigate DRT. Is this device the final device in LAAO? No. Does it appear to be reasonably safe and effective? Yes, in appropriate programs when devices were placed by appropriate operators. Nevertheless, that is the case for every intracardiac device.

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KEY WORDS left atrial appendage, left atrial appendage closure, left atrial appendage occlusion, stroke, Ultraseal