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Translational

Impact of Watchman and Amplatzer Devices on Left Atrial Appendage Adjacent Structures and Healing Response in a Canine Model

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Objectives This study was designed for conducting a comparative evaluation of the healing response after Watchman (WM) (Boston Scientific, Plymouth, Minnesota) and Amplatzer Cardiac Plug (ACP) (St. Jude Medical, Minneapolis, Minnesota) in a canine left atrial appendage (LAA) model.

Background There is no direct comparison of the WM and ACP device in pre-clinical or clinical settings.

Methods The LAA from canine (n = 6) and human (n = 19) hearts were compared to determine the feasibility of the canine model and its relevance to clinical applications. Subsequently, implantation of WM and ACP in the canine LAA was performed (n = 3 per device) to evaluate the device conformation to the LA anatomy as well as the healing response at 28 days.

Results The LAA is a variable tubular structure in both canine and human hearts. Gross examination showed that the WM was properly seated inside the LAA ostium, in comparison to the ACP where the disk was outside of the LAA orifice and extended to the edge of the left superior pulmonary vein and mitral valve. At 28 days, complete neo-endocardial coverage of the WM was observed; however, the ACP showed an incomplete covering on the disk surface especially at the lower edge and end-screw hub regions.

Conclusions There are differences in conformation of LAA surrounding structures with variable healing response between WM and ACP after LAA closure in the canine model. WM does not obstruct or impact the LAA adjacent structures, resulting in a favorable surface recovery. In comparison, the disk of ACP could potentially jeopardize LAA neighboring structures and leads to delayed healing. (J Am Coll Cardiol Intv 2014;7:801–9) © 2014 by the American College of Cardiology Foundation

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Percutaneous approaches to occlude the left atrial appendage (LAA) represent an emerging, device-based alternative to long-term pharmacologic therapy in the prevention of atrial fibrillation (AF)-associated stroke. Several transcatheter devices have been developed (1,2). Currently, the 2 most commonly implanted devices, are the Watchman (WM) (Boston Scientific, Plymouth, Minnesota), and the Amplatzer Cardiac Plug (ACP) (St. Jude Medical, Minneapolis, Minnesota).

Anatomically, the LAA has a complex geometric structure with an oval-shaped orifice. It is a gestational remnant that originates from primordial atrial tissue, whereas the rest of the left atrium, which is smooth, is formed from the absorption of the pulmonary veins and its branches (3). The atrial appendage overlaps the pulmonary trunk, bulging anteriorly, with its tip pointing cranially in most cases (4). It is in close proximity with several adjacent structures, including the lateral ridge between the LAA ostium and the left superior pulmonary vein (LSPV), mitral valve (MV) annulus, left main, left anterior descending and the left circumflex (LCX) coronary arteries, and the great cardiac vein. The LAA is a trabeculated structure that is described to be 3× larger in volume in patients with AF than in those without AF. It is believed to be the source of thrombosis in AF that may lead to systemic emboli and stroke (4,5). Therefore, we compared the LAA of human and canine anatomies to understand the relevance of the findings of WM and ACP when implanted in the LAA canine model.

Abbreviations and Acronyms

ACP = Amplatzer Cardiac Plug
AF = atrial fibrillation
LA = left atrium
LAA = left atrial appendage
LCX = left circumflex artery
LSPV = left superior pulmonary vein
MV = mitral valve
TEE = transesophageal echocardiography
TIMI = Thrombolysis In Myocardial Infarction
WM = Watchman left atrial appendage system

Whereas both devices have shown reasonable safety and efficacy in clinical and pre-clinical settings (6–10), there has been no prospective study comparing the 2 devices. The current pre-clinical study was therefore designed to evaluate the healing response of the 2 devices in a 28-day canine model. In addition, we validated in vitro the canine model for pre-clinical testing.

Methods

Measurement of LAA and surrounding structures in canines and humans. Six healthy canine (25.2 ± 4.5 kg, 7 to 25 months of age in either sex) hearts and 19 human (101.4 ± 19.8 kg, 18 to 78 years of age in either sex) hearts from the CVPath autopsy registry were selected to compare the LAA dimension and the relationship of the LAA with the adjacent structures. Each heart was incised through the roof of the LA and opened along the posterior ventricular septum to expose the LAA and surrounding anatomic structures. Photographs of the external surface of the LAA and the opened LA were obtained. LAA is lined by pectinate muscle, whereas the LA is a smooth structure and the measurements are taken at this transition zone in the long- and short-axes of the LAA ostium (11). Measurements included: 1) external length of the LAA; 2) distance from the LAA ostium to the left main coronary artery bifurcation; 3) the closest distance from LAA ostium to the LCX; 4) LAA orifice dimension, in the long and short axes; 5) distance from LAA ostium to the LSPV; and 6) distance from LAA ostium to the MV annulus.

Device characteristics. The WM LAA system consists of a parachute-shaped device with a self-expanding nitinol frame structure covered on the proximal half with a 160-μm permeable polyester fabric membrane (12). It has a row of fixation barbs at mid-perimeter to help secure the device in the LAA. Following successful deployment, the device acts as a filter in the initial phase allowing passage of blood but not thrombi. Subsequently over the next few months, the surface of the device is covered with neo-endocardial tissue that is impermeable to both blood and thrombi. The surface membrane can lead to a thrombus formation, thus the need for continuation of antithrombotic agents until the device is completely endothelialized. The device is available in 5 sizes ranging from 21 to 33 mm and is deployed using a 12-F delivery system. To ensure adequate closure and stability, the device that is chosen is 10% to 20% larger than the LAA ostium.

The ACP LAA system is a self-expanding device constructed from nitinol and consists of a lobe and a disk connected by a central waist. The lobe has fixation wires to ensure its stabilization, and the disk of the ACP device is placed in the outer part of the LAA ostium. The device is available in 8 different sizes based on the lobe diameter, that is, 16 to 30 mm, in stepwise 2-mm increments. The appropriate device chosen is usually 3 to 4 mm larger than the diameter of the proximal part of the LAA body (landing zone). The diameter of the proximal disk is greater than the distal lobe diameter by 4 to 6 mm and is connected by a disk end-screw hub with the device intended to cover the mouth of the ostium.

Ex vivo device implantation. Unfixed hearts from male mongrel canine (21 kg, 8 months of age) were obtained, and the right atrium and atrial septal wall were carefully trimmed to allow deployment of either the WM or ACP into the LAA under direct visualization. The smallest devices from WM (21 mm) and ACP (16-mm lobe with 20-mm disk) were selected and alternately placed in the canine hearts. Photographs of the device surfaces after each deployment were obtained. The device conformation to the LAA, and the relationship to the LSPV as well as the annulus of the MV were assessed.