First-in-human experience with the Cardia Ultraseal left atrial appendage closure device: The feasibility study

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Introduction

Atrial fibrillation (AF) remains the most common cardiac arrhythmia, affecting 3–5% of the population aged 65–75 years. It is associated with substantial mortality and morbidity, particularly due to stroke. Over 90% of clinically apparent embolisms in AF originate from the left atrial appendage (LAA). Nowadays, oral anticoagulation still remains the state-of-the-art therapy for patients with AF. Since the first percutaneous LAA occlusion (LAAO) in 2002 [1] many studies have shown the safety and efficacy of this therapy using different closure devices [2–9]. Percutaneous LAAO is a valuable therapeutic option for selected high-risk patients with AF and contraindications for oral anticoagulation therapy. Currently, there are several types of devices available for LAAO: Watchman, ACP-Amplatzer Cardiac Plug, Coherex WaveCrest, and Cardia Ultraseal. These devices represent a variety of designs and thus offer uniquely different approaches to the mechanical closure of the LAA. The Cardia Ultraseal LAA closure device is a newly designed device, representing a novel concept of LAAO. Recently, first in vivo study demonstrated the feasibility and safety of Cardia device in the canine model [10]. Herein, we present first-in-human original experience with Cardia device.

The Cardia Ultraseal LAA device is a unique next generation design which combines the advantages of a distal anchoring bulb with the proven performance of a proximal sail to close the LAA orifice. These two components are connected with a dual articulating joint allowing the device to conform naturally to the most tortuous of LAA anatomies. It is constructed with a nitinol frame and designed in a manner which produces a soft and flexible device. The combination of these characteristics provides an attractive design which easily conforms to the LAA and surrounding structures with minimal risk of residual shunt or anatomical distortion (Fig. 1A). The device is available in 9 different bulb sizes ranging from 16 mm to 34 mm. The sail diameter is 6 mm larger than the distal bulb and delivery sheath sizes range from 10 Fr to 12 Fr (Fig. 1A, B).

Sizing and device selection

The LAA should be measured at a depth of 10–12 mm from the intended sail location. This rep-
represents the landing zone for the anchoring hooks of the device. The selected device should have a bulb diameter at least 25% to 33% greater than the largest diameter of the landing zone. The proximal pin of the device is grasped using the delivery forceps, then the device is pulled into the loader and flushed. The distal end of the sheath should be positioned in the LAA at the intended landing zone. Holding the sheath in place, the forceps are advanced until the entire bulb section of the device is deployed. The anchor markers of the bulb should appear to have a non-symmetric shape. This indicates that the bulb is properly under compression. The bulb should be kept in the same position and then the sheath is retracted until the entire sail section of the device is deployed. To confirm a stable position, a gentle pushing and pulling maneuver should be performed. Transesophageal echocardiography (TEE) should confirm the position of the device and the distance of the sail from other cardiac structures including mitral valve and pulmonary veins should be at least 5 mm. If the position of the device and complete closure of LAA is confirmed in TEE, the device can be released. The device can easily be partially and/or fully retrieved and redeployed (maximum 5 times) before release (Fig. 1C–H).

Methods and results

Six patients aged 64–70 (mean 72.8) years were selected for LAA closure. The primary indications for LAAO were gastrointestinal bleedings and nose bleedings. Mean HAS-BLED and CHA₂DS₂-VASC scale were 3.8. Mean LAA diameter was 20.8 (range 14.7–25) mm as measured by TEE and 20.5 (range 14.3–28) mm as measured by fluoroscopy. Patient data, indication for LAA closure, anatomy, and diameter of LAA are summarized in Table 1.

![Figure 1. A. The Cardia Ultraseal left atrial appendage (LAA) device consists of proximal disc (to cover the LAA orifice) and a distal atraumatic soft lobe (to secure the device in the LAA) connected by a double articulating center for optimal positioning and repositioning within the appendage; 12 stabilizing anchors enabling secure engagement to the LAA; The discs (B) are 6 mm larger for lobe sizes 16 mm to 32 mm (A). B. The Cardia Ultraseal LAA device selection. C–H. Technique of implantation. C. Sizing the orifice of LAA; D. Landing zone — approximately 10–12 mm from the orifice; E. Positioning of the sheath; F. Positioning of the body of the device; G. Opening the sail of the device — the device is fully opened, but still connected with delivery system; H. Releasing of the device; LZD — landing zone diameter). I, J. The optimal position of Cardia Ultraseal LAA device in LAA of patient 4 documented in the two-dimensional-transesophageal echocardiography (I) and three-dimensional-transesophageal echocardiography imaging (J).]
Table 1. Patient data, indication for left atrial appendage (LAA) closure, anatomy and diameter of LAA, device selection, procedural parameters.

<table>
<thead>
<tr>
<th>No.</th>
<th>Sex</th>
<th>Age [years]</th>
<th>Indication for LAA closure</th>
<th>A</th>
<th>B</th>
<th>Diameter of LAA Echo [mm]</th>
<th>Diameter of LAA Fluoro [mm]</th>
<th>Anatomy of the LAA</th>
<th>LAA device size</th>
<th>Fluoroscopy time [min]</th>
<th>Procedure time [min]</th>
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<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>79</td>
<td>a</td>
<td>4</td>
<td>3</td>
<td>14.7</td>
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<td>Cauliflower</td>
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<td>19.7</td>
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<td>a</td>
<td>5</td>
<td>6</td>
<td>23</td>
<td>14.3</td>
<td>Windsock</td>
<td>26/18</td>
<td>23.8</td>
<td>100</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>64</td>
<td>b</td>
<td>2</td>
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<td>19</td>
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<td>a</td>
<td>4</td>
<td>3</td>
<td>22</td>
<td>21.9</td>
<td>Windsock</td>
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</tr>
<tr>
<td>5</td>
<td>F</td>
<td>75</td>
<td>c</td>
<td>3</td>
<td>3</td>
<td>21</td>
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<td>6</td>
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<td>77</td>
<td>a</td>
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<td>28</td>
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<td>20.5</td>
<td></td>
<td></td>
<td>19.7</td>
<td>65</td>
</tr>
</tbody>
</table>

A — HAS-BLED scale; B — CHA2DS2-VASC scale; Indication for LAA closure: a — gastrointestinal bleeding; b — bleeding from the nose; c — bleeding hemorrhoids; Patient No. 2 — procedure abounded; M — male; F — female

Patients were catheterized and prepared for the LAA closure procedure utilizing standard techniques. The transseptal puncture was performed under TEE guidance. The delivery sheath was positioned within the LAA under fluoroscopic and TEE guidance. In 5 patients, the Cardia Ultrasel LAA device was implanted without any difficulty or technical problems. Procedure time was 58 (range 45–80) min and fluoroscopy time was 18.9 (range 19.7–34) min. The final position of all devices was correct, and there was no residual leak documented by TEE imaging (Fig. II, J). In 1 patient (No. 2), the anatomy of the LAA and surrounding structures were not suitable for device implantation and the procedure was discontinued. In the 1-month-follow-up TEE examination, the position of all devices was optimal. There was no thrombus formation, and no residual leak and all LAAs have been fully occluded.

In summary, the Cardia Ultrasel LAA closure device presents a new concept in LAOO procedures. The construction of the device is unique, and the device is easy to use and suitable for a broad spectrum of LAA anatomy. The dual articulating joint is very useful and allows superior positioning of the device in difficult angulated LAAs. Due to its soft construction and flexibility, the device fully adapts to the LAA anatomy and the sail easily conforms to the surrounding structures closing the LAA orifice with a very high rate of total occlusion. Our initial experience with this device included 5 implants with 30-day follow-up. An extensive clinical investigating is warranted to confirm the benefits of the Cardia Ultrasel LAA device and this new unique approach to close LAA.

Conflict of interest: None declared

References