The Amplatzer Amulet Device

Technical Considerations and Procedural Approach

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KEYWORDS

• AMPLATZER Amulet • Left atrial appendage occlusion • Nonvalvular atrial fibrillation
• Transseptal puncture • Chicken wing anatomy

KEY POINTS

- Percutaneous left atrial appendage occlusion (LAAO) is recognized as an alternative approach to oral anticoagulation in patients with nonvalvular atrial fibrillation.
- The AMPLATZER Amulet, the second-generation device of the AMPLATZER Cardiac Plug, is currently one of the most commonly used devices for LAAO.
- Implantation of the AMPLATZER Amulet requires a step-by-step technical approach following several technical considerations.

INTRODUCTION

Percutaneous left atrial appendage occlusion (LAAO) is currently recommended as an alternative to oral anticoagulation (OAC) in patients with nonvalvular atrial fibrillation (NVAF).[1] Several devices are under clinical investigation, among which a few have already received approval. The AMPLATZER Cardiac Plug (ACP) received CE Mark in December 2008. It was the first AMPLATZER device specially designed by Dr Kurt Amplatz to close the appendage.[2] The AMPLATZER Amulet is a second-generation LAAO device. The Amulet became commercially available in Europe in January 2013 (AGA Medical, Plymouth, MN, USA acquired by St Jude Vascular, St Paul, MN, USA, followed by Abbott Vascular, Santa Clara, CA, USA).[3] In United States, the approval by the US Food and Drug Administration is still pending despite that it is one of the most widely used devices in the world.

This article reviews the key characteristics of the AMPLATZER Amulet and describes step-by-step technical considerations relevant to the implantation in the left appendage.

DEVICE DESIGN AND MAIN FEATURES OF THE AMPLATZER AMULET

The AMPLATZER Amulet is a transcatheter self-expanding device specifically designed for left atrial appendage (LAA) closure. The configuration maintains the concept and the basic structure of the original version (ACP) but was intended to improve device performance and increase safety of the device (including sealing and stability). This device consists of a distal lobe that anchors the device to the LAA body or neck (landing zone) and a proximal disc that seals the LAA orifice (ostium). Both parts of the Amulet are connected by a central waist. The main structure is made of a nitinol mesh with 2 polyester

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patches sewed into both the lobe and the disc. In comparison with the ACP, the Amulet device offers the following improvements:

- A device already preloaded within the delivery system
- A wider proximal disc diameter being 6 to 7 mm greater than the distal lobe diameter (4–6 mm for the ACP)
- A thicker distal lobe length (2–3 mm thicker than the ACP)
- Stiffer stabilizing wires
- Increased number of stabilizing wires (from 6 pairs in the ACP to up to 10 pairs for the Amulet)
- Longer waist length (from 4 mm in the ACP to 5.5 mm or 8 mm depending on the size of the device)
- An inverted attaching screw on the proximal disc
- Larger sizes up to 31 and 34 mm.

LEFT ATRIAL APPENDAGE OCCLUSION CLOSURE INDICATIONS AND PROCEDURAL PLANNING

The current indications for percutaneous LAAO with the Amulet device refer to patients with NVAF requiring long-term OAC therapy.[4] Since 2012, the European Society of Cardiology implemented a class IIB recommendation for patients with high stroke risk and contraindications to long-term OAC.[1] The main contraindications for LAA closure whatever the type of device implanted are the presence of thrombus in the left atrium (which is most of the time located into the distal part of the LAA) and ongoing endocarditis or other active infectious disease.[5]

In this context, preprocedural imaging of the left atrium is warranted for each potential LAAO candidate. Investigation usually consists of performing a transesophageal echocardiography (TEE) and/or a computed tomographic (CT) scan to exclude preexisting LAA thrombus and to assess the suitability for closure, especially for sizing and device selection. Because tamponade is a potential complication of such a procedure, it is also a commendable practice to detect any preexisting pericardial effusion.

IMPLANTATION OF THE AMPLATZER AMULET DEVICE: TECHNICAL APPROACH

Intraprocedural Imaging

In terms of intraprocedural imaging, TEE is extremely helpful and is used by most operators. In that case, the procedure is typically performed under general anesthesia. Intracardiac echography is an alternative and less-invasive option.[6] In that case, the tip of the probe can be placed in various locations but most often in the left atrium using or not the same venous access and the same transseptal puncture. This technology is well adapted to the Amplatzer given that the device is deployed in the proximal portion of the appendage. Fluoroscopy-only guided LAAO is far less optimal and should be used as a last option and by expert operators.

Real-time 3-dimensional (3D) TEE is not mandatory but is useful to provide a better spatial visualization of the anatomy. 3D is also helpful upon the final steps of the procedure notably to evaluate the stability of the occluder during the tug test and to visualize the relationship of the disc with the surrounding structures within the left atrium (using the "en face" view).

Left Atrial Appendage Occlusion Access by the Transseptal Approach

Similarly to the first generation, the AMPLATZER Amulet device is implanted through the venous system via the transseptal technique and is fully retrievable and repositionable. Like the other devices on the market, the right femoral vein is usually the preferred access site given a more direct access to the atrial septum. Transseptal puncture is then performed using a standard technique (typically using an SL1 sheath and a BRK needle; Abbott Vascular). Precision of the transseptal puncture is critical for procedural success, and the optimal site in the atrial septum is posteroinferior. A more anterior puncture is sometimes performed to reach reverse chicken wing anatomy with more anterior ostium. Of note, some operators use a patent foramen ovale or a preexisting atrial septal defect to gain access to the left atrium, thereby eliminating the need for transseptal puncture.[7] In that case, it may be acceptable to deploy an Amulet device, but in case of malalignment, a traditional transseptal approach should be done. Intravenous heparin is administered before and/or immediately following transseptal puncture to maintain an activated clotting time >250 seconds. It is also important to reach an adequate mean left atrial pressure (at least 12 mm Hg) with fluid bolus for accurate device selection.

Left Atrial Appendage Occlusion Fluoroscopic Calibration and Amulet Device Sizing

Following transseptal puncture, LAA angiograms are performed to obtain LAA measurements. For this purpose, the tip of the transseptal sheath is positioned at the level of the LAA ostium and a