Safety and feasibility of radiofrequency redo pulmonary vein isolation ablation for atrial fibrillation after Amulet implantation and device electrical characteristics

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Introduction

Left atrial appendage occlusion (LAAO) devices are increasingly being used in patients with elevated stroke risk who also have high bleeding risk, but who are unable to take long-term anticoagulation.[1] Safety of atrial fibrillation (AF) ablation following Watchman (Boston Scientific, Natick, MA) device implantation has been reported.[2] However, there is limited data on the feasibility and safety of pulmonary vein isolation (PVI) after implantation of other LAAO devices. We present the case of a patient with history of PVI using cryotherapy and prior implantation of an Amulet device (Abbott, Lake Bluff, IL) who underwent a redo radiofrequency (RF) ablation PVI at our institution.

Case report

A 64-year-old man with past medical history of hypertension, transient ischemic attack, chronic obstructive pulmonary disease, and paroxysmal AF with prior cryoballoon PVI therapy presented for repeat ablation for symptomatic AF. Twenty-four months prior to the presentation, the patient underwent acutely successful isolation of pulmonary veins using a second-generation 28 mm cryoballoon device (Arctic Front Advance; Medtronic, Minneapolis, MN) for symptomatic paroxysmal AF. Ten months ago, the patient underwent successful implantation of a 28 mm AMPLATZER Amulet (Abbott, Lake Bluff, IL) LAAO device. The patient's procedural transesophageal echocardiogram (TEE) showed normal left ventricular function and appropriate seating of the device, with no residual leak around the device. Surveillance TEE imaging at 45 days and 6 months demonstrated stable position of the Amulet device and no evidence of peri-device leak. The patient continued to have symptomatic episodes of AF and after discussion of procedural benefits and risks, he decided to proceed with a repeat ablation procedure.

Written informed consent was obtained prior to the procedure. The patient was placed under general anesthesia and underwent TEE, which did not demonstrate intracardiac thrombus. Bilateral common femoral vein access was obtained via modified Seldinger technique under vascular ultrasound guidance.

A decapolar catheter (Biosense-Webster, Irvine, CA) was placed in the coronary sinus and an intracardiac echocardiography catheter was placed into the right atrium. Double transseptal access was performed using an SL-1 long sheath (Abbott, Lake Bluff, IL) and Baylis RF needle (Baylis

KEY TEACHING POINTS

- Radiofrequency ablation is a feasible and safe method of pulmonary vein isolation in patients with preexisting Amulet (Abbott, Lake Bluff, IL) devices.
- As compared to the Watchman device (Boston Scientific, Natick, MA), no electrograms and no myocardial tissue capture were observed on the surface of the Amulet device.
- Lack of capture and lack of high-amplitude signal on the surface of the Amulet device may suggest incomplete endocardialization of the Amulet device.
- Incomplete endocardialization of the Amulet device may be associated with higher risk of thrombosis.

KEYWORDS Amulet; Atrial fibrillation; Endocardialization; Left atrial appendage occlusion; Radiofrequency ablation
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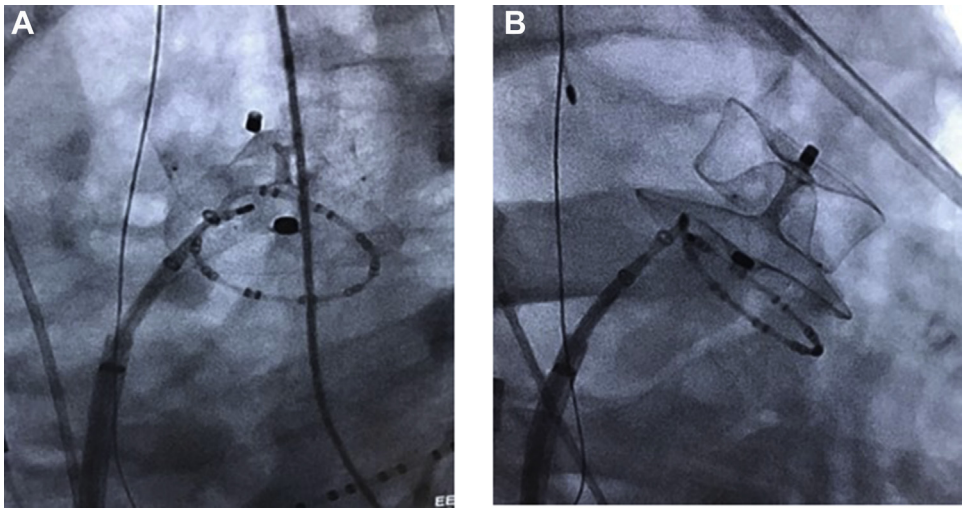

Figure 1 Lasso mapping catheter placed on the surface of Amulet device (Abbott, Lake Bluff, IL). **A:** Left anterior oblique projection. **B:** Right anterior oblique projection.

Medical, Mississauga, ON, Canada). The patient was started on intravenous heparin and the activated clotting time was maintained between 300 and 350 seconds during the procedure. A transesophageal temperature probe was inserted to monitor for potential thermal injury to the esophagus. Mapping of the left atrium was performed using an 8F Lasso 2515 catheter (Biosense Webster, Irvine, CA). The patient had 4 pulmonary veins: 2 right pulmonary veins, superior and inferior; and 2 left pulmonary veins, superior and inferior. The right superior, left superior, and left inferior pulmonary veins had reconnected. Only the right inferior pulmonary vein was isolated from prior cryotherapy ablation. RF lesions were applied using an 8F ThermoCool STSF DF Curve ablation catheter (Biosense-Webster, Irvine, CA) anterior and superior to the ostium of left superior pulmonary vein, along the ridge between the LAA and left superior pulmonary vein. Lesions in this area resulted in an isolation of both the left superior pulmonary vein and left inferior pulmonary vein. The right superior pulmonary vein had a gap in an area located anterior and superior to its ostium. RF ablation in this area resulted in isolation of the right superior pulmonary vein. Postablation exit and entrance block was demonstrated in all 4 pulmonary veins. Next, the voltage mapping using the Lasso mapping catheter was performed over the surface of the Amulet left atrial appendage (LAA) device (Figure 1). There were no measurable electrocardiogram recordings over the surface of the occluder device. Pacing from the surface of the Amulet LAA device was performed without capture of atrial tissue (Figure 2). Catheters were removed from the left atrium and heparin infusion was discontinued. The patient did not experience any complications and was discharged home the following day.

Discussion

Catheter ablation of AF is a frequently performed procedure and adoption of LAAO devices is expected to increase as well. Understanding the healing process of the devices post-implantation and the differences between endothelialization and endocardialization may impact ablation strategies for treatment of left atrial arrhythmias. Based on a canine model, the healing process of implanted device is initiated by fibrin accumulation followed by endothelialization. Even if the device surface is endothelialized, it is usually only 1–2 cell layers thick. Disruption of the endothelial layer by the catheter before it has been endocardialized can expose the fibrin layer and lead to thrombus formation.[3,4] Risks of ablation in the surrounding of the Amulet device are device dislodgment, device perforation, and thrombus formation. In addition, PVI may not be completed if the device is covering the ridge.

Observational studies demonstrated that PVI ablation can be performed as early as 45 days after LAAO device placement.[5,6] However, the optimal timing for ablation after implantation remains unknown. Hybrid PVI and implantation of Watchman devices during the same procedure has been suggested to be feasible and safe.[5] There is limited data on the safety of repeat AF ablation procedures following implantation of the LAAO device. Walker and Phillips[7] analyzed 10 consecutive patients who had previously undergone a combined pulmonary vein electrical isolation and Watchman device implant procedure and were referred for left atrial arrhythmia catheter ablation for recurrent AF or atrial tachycardia. In this single-center study, repeat ablation of AF, left atrial mapping, and ablation of left atrial tachycardia were shown to be safe and not associated with significant complications. Arrhythmia targets included left atrial flutters, a focal tachycardia, left atrial complex fractionated atrial electrogram zones, and pulmonary vein electrical isolation. In 3 out of 10 patients, complex fractionated atrial electrogram–guided focal ablation was performed, safely targeting the left atrial roof or dome, interatrial septum, and the ridge between left superior pulmonary vein and LAA, or at the base or mouth of the LAA.

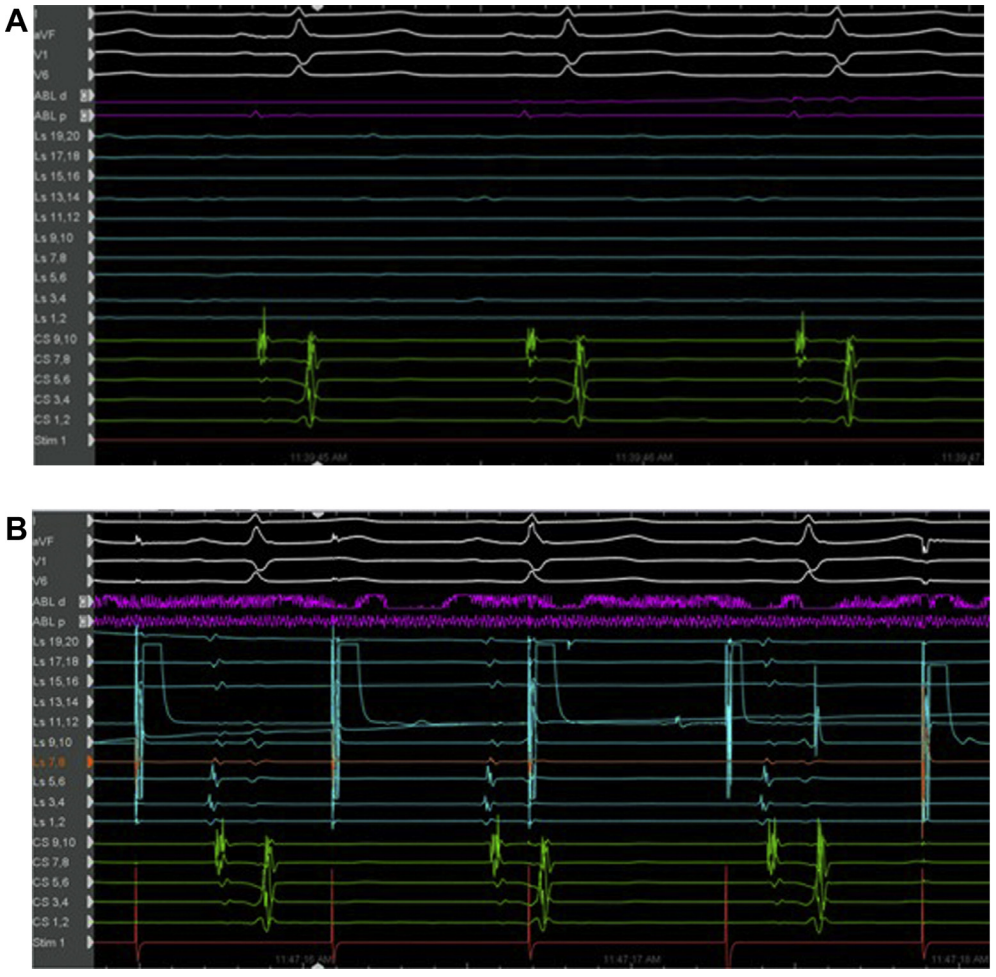

Figure 2 Low-amplitude signals recorded from the surface of Amulet device (Abbott, Lake Bluff, IL) (**A**) with lack of capture when paced from Lasso catheter (Biosense Webster, Irvine, CA) (**B**).

Huang and colleagues[8] demonstrated that cryoballoon ablation is a feasible alternative modality for PVI in patients with LAAO devices. Interestingly, it was shown that high-amplitude LAA-like electrograms were present on the surface of Watchman device 9 months after implantation, suggesting endocardialization (coverage with myocardium) of the device surface had occurred. In contrast, in our patient there were no significant near-field electrogram recordings during mapping or atrial tissue capture when pacing from the surface of the Amulet device 24 months after implantation. These findings suggest either incomplete or absence of endocardialization of the Amulet device or, instead, that endothelialization of the device with electrically inert tissue had occurred. Chronic studies of Watchman LAAO devices in canine models and human autopsy studies have demonstrated different healing stages, starting with device endothelialization with fibrin coverage filling gaps between wall and the device, and with eventual complete endocardialization of the device surface with atrial muscle tissue, on average around 3 months post-implant. Our patient's redo ablation procedure was well beyond 3 months after device implantation and it would have been expected that the LAAO device's surface should have been already endocardialized at that time point.

The findings of this case study suggest that there are differences in healing processes/responses between the Watchman and Amulet LAAO devices after implantation in the human heart. Kar and colleagues[9] compared healing response of the Amplatzer Cardiac Plug and Watchman in a canine LAA model. One of the major differences between the LAAO devices was that the Watchman device was only in direct contact with LAA tissue, potentially resulting in more favorable surface recovery. It was noted that Amplatzer Cardiac Plug implantation could potentially jeopardize neighboring structures, resulting in delayed healing.

The differences between endothelialization vs endocardialization and the device shape/size may have implications on the ability to electrically isolate the appendage. Turagam and colleagues,[10] in a retrospective multicenter AF registry of 60 patients with Watchman LAAO devices who underwent ablation for AF, demonstrated that electrical isolation of active LAA was successful in 10 out of 17 patients with electrical active appendage. Repeated imaging showed

short-term peri-device leaks, and there was a reported 100% recurrence of atrial arrhythmia originating from the LAA. Based on this publication, electrical isolation of the left atrium with implanted Watchman device is ineffective and has potential risk for peri-device leaks.

Based on this single case study, it appears that the Amulet device implantation may not be associated with device surface endocardialization, which has been observed after Watchman device placement. The clinical significance of these findings is unclear, and further studies are needed to ascertain the significance in regards to the effects on outcomes of subsequent left atrial ablation procedures, the role that the lack of endocardialization plays in future arrhythmogenesis, and safety using various types of ablation energy sources.

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