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CASE REPORT

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Practical Applications of Concomitant Pulmonary Vein Isolation and Left Atrial Appendix Closure Device Implantation

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ABSTRACT

Pulmonary vein isolation (PVI) using cryoballoon causes acute tissue edema of the osteal region of the pulmonary veins and the left atrium. In two cases combining PVI with an implantation of a left atrial appendage closure device led to malsizing of the device, device shouldering, and a paraprosthetic residual flow. (**Level of Difficulty: Advanced.**) (J Am Coll Cardiol Case Rep 2021;3:1409–1412) © 2021 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

In patients with atrial fibrillation (AF) and a high risk of stroke and a contraindication for long-term use of oral anticoagulation due to a high risk of bleeding, implantation of a left atrial appendage occluder (LAAO) is effective and safe (1). Concomitant pulmonary vein isolation (PVI) and implantation of an LAAO in the era of patient comfort, time slots, and cost effectiveness for many is attractive. However, it may lead to suboptimal procedural outcome and potential risks. This paper describe 2 cases in which PVI and LAAO implantation were performed concomitantly. Combining these procedures led to device malsizing, device shouldering, and paraprosthetic residual flow.

LEARNING OBJECTIVE

- To understand why concomitant PVI with a cryoballoon and implantation of an LAAO device may lead to paraprosthetic leakage and suboptimal results.

PATIENT 1

A 50-year-old male patient with known persistent symptomatic AF was referred for PVI with the use of a cryoballoon. His echocardiogram revealed a normal systolic function, no valvular abnormalities, and a slightly dilated left atrium. The patient used phenprocoumon with adequate international normalized ratio (INR) between 2.0 and 3.0 to prevent thromboembolic events. Because of high thromboembolic risk with recurrent ischemic stroke and the presence of hypertension ($CHA_2DS_2VASc = 3$) as well as a moderate risk of bleeding (HASBLED) score of 2 based on a stroke history and use of phenprocoumon predisposing to bleeding (HASBLED is a scoring system for risk of major bleeding in patients taking oral anticoagulation therapy), a LAAO was considered indicated.

The procedure was performed with the patient under general anesthesia. Two cryo applications were performed in all 4 pulmonary veins. A minimum

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ABBREVIATIONS AND ACRONYMS

AF = atrial fibrillation

LAA = left atrial appendage

LAAO = left atrial appendage occluder

PVI = pulmonary vein isolation

TEE = transesophageal echocardiography

of −55°C was reached on the left-sided pulmonary veins. After 20 minutes there were no signs of reconduction. The transseptal sheath was replaced with a 14-F Watchman sheath (Aritech). The positioning of the LAAO device (21-mm Watchman, Atritech) was guided by angiography and transesophageal echocardiography (TEE). Measurements of the LAA and limbus were performed to determine the size of the LAAO and showed significant changes before and after PVI (**Figure 1**). TEE measurements after PVI suggested a 21-mm device. After the first placement, minor residual flow was observed inferior of the occluder device. A second placement led to a satisfactory result without residual flow (**Figure 2A,** Video 1). Carbasalate calcium, 100 mg once daily, was added to phenprocoumon therapy directly after the procedure. Phenprocoumon was discontinued after 3 months and was replaced by clopidogrel, 75 mg once daily, for 3 months, after which the patient continued on a single antiplatelet therapy using carbasalate calcium, 100 mg once daily.

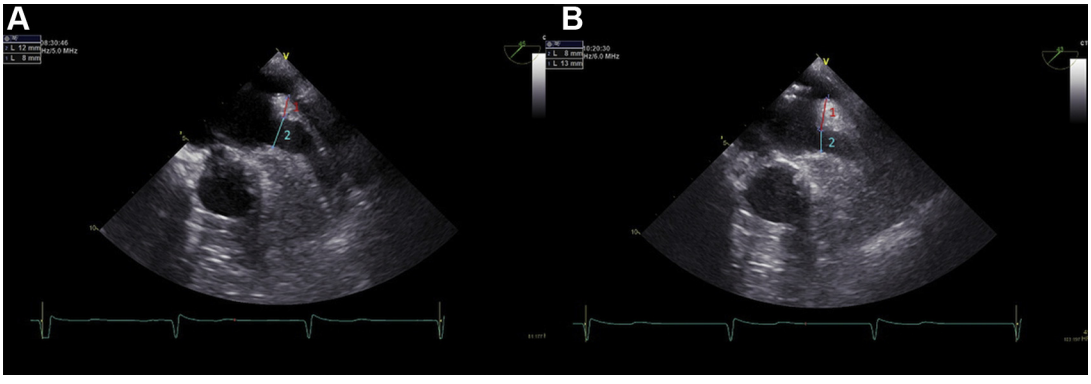
During a routine 3-month TEE follow-up, device shouldering was noticed with paraprosthetic residual flow of <5 mm, which was followed by TEE and persisted during the following years (**Figure 3A,** Video 3). Recurrent episodes of AF were noticed during follow-up. After 15 months, a recurrence of stroke occurred. A direct oral anticoagulant, rivaroxiban (Xarelto, Janssen), 20 mg once daily, was restarted even though TEE did not reveal a LAA thrombus and the residual paraprosthetic flow remained minimal (<5 mm).

PATIENT 2

A 74-year-old male patient was known to have paroxysmal AF and a dual-chamber pacemaker implanted for a sick sinus syndrome. The patient used oral anticoagulation (acenocoumarol) to prevent thromboembolic events (CHA_2DS_2VASc score of 3 based on his age and presence of hypertension). However, he experienced a spontaneous intracranial bleeding event with the need for emergency craniotomy, from which he fully recovered. The INR was in the therapeutic range at the time of the event and there were no other modifiable risk factors. Because of symptomatic episodes of persistent AF and the contraindication for oral anticoagulation therapy after the spontaneous intracranial bleeding (HASBLED score of 3 based on a prior major bleeding and >65 years of age and liable INR), he was referred for PVI using cryoballoon and implantation of a LAAO.

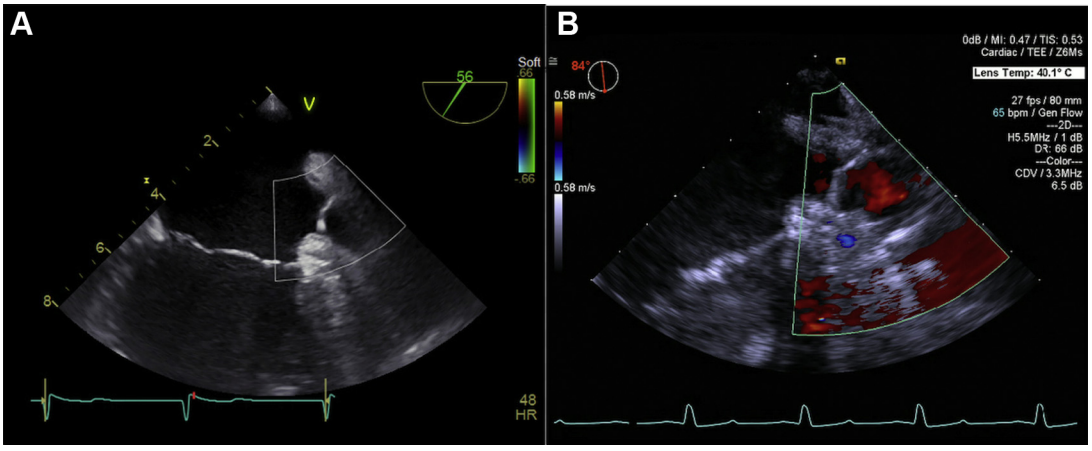
With the patient under general anesthesia, 2 cryo applications were performed of all 4 pulmonary veins with a minimum of −60°C. There were no signs of reconduction after 30 minutes. TEE measurements suggested a 24-mm device. Following the positioning of the LAAO device (24-mm Watchman, Atritech), TEE showed no residual flow in the LAAO (**Figure 2B,** Video 2). After the procedure, dabigatran, 110 mg twice daily, and carbasalate calcium, 100 mg once

FIGURE 1 Measurement of LAA and Limbus Using Transesophageal Echocardiography



(A) The ridge between the left superior pulmonary vein (LSPV) and left atrial appendage (LAA) (8 mm, **red line 1**) and the ostium of the LAA (12 mm, **blue line 2**) before cryo ablation of the left pulmonary veins. **(B)** The same measurements directly after the cryo application of the left pulmonary veins with the ridge 13 mm **(red line 1)** and LAA ostium measuring 8 mm **(blue line 2)**.

FIGURE 2 Transesophageal Echocardiogram Directly After Implantation



(A) The position of the left atrial appendage occluder (LAAO) in patient 1 directly after implantation using transesophageal echocardiogram (TEE). No paraprosthetic residual flow was present. **(B)** The TEE image of patient 2 directly after implantation also without paraprosthetic residual flow

daily, were started. After 3 months, dabigatran was discontinued.

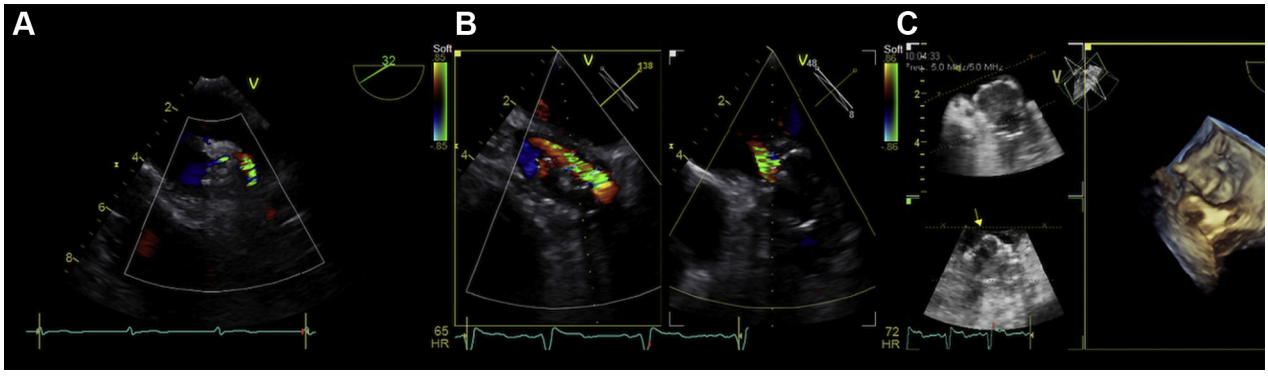
However, at 3 months follow-up, a paraprosthetic residual flow of 3 mm (**Figure 3B,** Video 4) and a clear device shouldering (**Figure 3C,** Video 5) were noticed. Despite the minor residual paraprosthetic flow and recurrent episodes of AF, carbasalate calcium was discontinued because of the patient's high risk for bleeding. No ischemic cerebral events occurred during 3-year follow-up.

DISCUSSION

This is the first case series describing a concomitant PVI and implantation of a LAAO. Although combining the procedures in the era of patient comfort, time slots, and cost effectiveness may seem attractive, in this case series it led to suboptimal procedural outcomes and potential risks.

First, the occurrence of acute tissue edema following a PVI may lead to difficulties regarding

FIGURE 3 Transesophageal Echocardiographic Images During Follow-Up



(A) The transesophageal echocardiogram (TEE) images of patient 1 with mild paraprosthetic regurgitation. **(B)** Paraprosthetic regurgitation is visible in the follow-up TEE of patient 2. **(C)** Significant device shouldering **(yellow arrow)** in patient 2 during follow-up TEE.

device sizing and potential stability in the long term. Radiofrequency (RF) ablation causes acute tissue edema which extends well beyond the ablation site into the pulmonary veins and left atrium (2), although compared to RF ablation, cryoballoon ablation also results in a significant amount of edema in the pulmonary veins and the left atrium. Edema in the ventricle after RF and cryoablation ablation resolves after approximately 2 weeks on cardiac magnetic resonance in a canine model (3). Baran et al (4) used intravascular ultrasonography (IVUS) to demonstrate that cryoballoon ablation of the PVs causes acute edema in 90% of the pulmonary veins, with local tissue changes reaching as far as 3 to 4 cm from the pulmonary vein ostium. These findings were confirmed in a small clinical trial by Miyazaki et al (5), who demonstrated diffuse left atrial tissue edema and wall thickening using intracardiac echocardiography immediately after second-generation cryoballoon ablation. In the setting of concomitant PVI and implantation of a LAAO device, the occurrence of acute tissue edema may result in device mismatch with partial or complete dislodgement and/or periprosthetic residual flow as a result with a persistent risk of ischemic stroke.

In the authors' patients, the occurrence of acute tissue edema was clearly demonstrated on the TEE images taken before and after PVI (**Figure 1**). The diameter of the ridge between the left superior pulmonary vein and LAA increased in size just after PVI, and simultaneously the LAA ostium decreased in size. This resulted in device malsizing, which became apparent during the TEE at 3-month follow-up when device shouldering (**Figure 3C,** Video 5) and paraprosthetic residual flow (**Figures 3A and 3B,** Videos 3 and 4) were noticed in both patients. Upsizing the LAAO could be considered to combat with edematous changes and malsizing. However, dislodgement and pressure necrosis during follow-up with perforation as a result should be taken into account as a serious risk. It is preferable to await the time it takes to resolve the edema before planning a procedure for LAAO. It could also be beneficial to await the full blanking period for recurrence of AF that may warrant a repeated procedure.

A combined procedure could also lead to suboptimal results from an electrophysiologic point of view, if the LAAO is regarded as a potential trigger for AF. It is known that the LAAO is a trigger site for AF in 27% of patients presenting for repeat ablation procedures (6). After LAAO device implantation, however, ablation of the LAAO in patients with recurrent AF becomes a challenge or even impossible.

CONCLUSIONS

Concomitant PVI with cryoballoon and an LAAO device implantation may lead to device mismatch due to acute tissue edema and, as a result, to paraprosthetic residual flow and on the long-term suboptimal protection against thromboembolic events. Despite better patient comfort and cost effectiveness, these authors therefore argue against a combined procedure and suggest performing the PVI at least 8 weeks prior to the LAAO placement.

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KEY WORDS atrial fibrillation, closure device, left atrial appendage, pulmonary vein isolation

APPENDIX For supplemental videos, please see the online version of this paper.