Cryoablation of atrial fibrillation in patients with atrial septal occluder devices: An in-depth case series analysis

Alessio Marinelli, MD, Alessandro Costa, MD, Stefano Bonapace, MD, Guido Canali, MD, Laura Lanzoni, MD, Giulio Molon, MD

From the IRCCS Sacro Cuore Don Calabria, Negrar di Valpolicella, Italy.

Introduction

Patients with atrial septal defects (ASD) seem to have higher risk of developing atrial arrhythmias and atrial fibrillation (AF).[1–5] Over the past decade, AF catheter ablation has developed as an effective therapeutic approach.[6,7] Transseptal access to the left atrium (LA) is mandatory for the ablation, and transseptal puncture (TSP) in patients with atrial septal occluder (ASO) devices is likely to be more frequent in the future. However, the ASO makes the TSP more difficult and riskier, which represents a major obstacle to the widespread adoption of catheter ablation in patients with prior ASD closure.[8] It has been reported that transesophageal echocardiography (TEE) or intracardiac echocardiography could be used for TSP in patients with ASO.[8,9] In this case series, we summarize our experience of TSP in patients with ASO during cryoballoon (CB) catheter AF ablation using TEE.

Case report

From the ablation database at our institution, all cases of index CB catheter AF ablation in patients with ASO (Amplatzer Septal Occluder; Abbott, Minneapolis, MN) were identified from June 2017 to December 2022. A total of 5 cases were collected. A retrospective review of medical records was conducted to gather anamnestic, clinical, procedural data and results. This study received approval from the Institutional Review Board, and written informed consent was obtained from all patients.

The 5 drug-refractory AF patients were all male, the youngest 46 years old, the oldest 56 years old (mean 51 ± 3.7 years). All of them had percutaneous ASD closure performed from more than 6 months (minimum 31 months, maximum 73 months, mean 59.4 ± 16.5 months). Three of them had patent foramen ovale and the other 2 had ostium secundum ASD. The smallest diameter of the occluder was 20 mm; the largest was 25 mm. One patient had a history of AF before the percutaneous device closure. All of them had still normal or mildly dilated LA (anterior-posterior diameter <55 mm) and normal left ventricular ejection fraction. Patient and procedure characteristics are summarized in Table 1.

KEY TEACHING POINTS

- Patients with atrial septal defects seem to have higher risk of developing atrial arrhythmias and fibrillation.
- Transseptal access to the left atrium is mandatory for the ablation, and transseptal puncture in patients with atrial septal occluder devices is likely to be more frequent in the future.
- Previous studies using radiofrequency catheters concluded that it is reasonable and safe to perform atrial fibrillation ablation in patients with an atrial septal occluder device.
- To the best of our knowledge, the present study reports the largest series of patients using cryoballoon 12F transseptal sheaths in patients with atrial septal occluder devices. No iatrogenic atrial septal defects have been reported in our patients and there have been no other significant complications.
- Transesophageal echocardiogram provides a great assembly of imaging planes, allowing for detailed visualization of the atrial device and the residual native septum, making the transseptal puncture feasible and safe.

Transseptal puncture and cryoballoon AF ablation

All antiarrhythmic drugs were discontinued at least 5 half-lives before the procedure. Cardiac computed tomography

KEYWORDS Atrial fibrillation; Atrial septal defect; Septal defect closure device; Cryoablation; Transseptal puncture
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Address reprint requests and correspondence: Dr Alessio Marinelli, IRCCS Ospedale Sacro Cuore Don Calabria, Via Don A Sempreboni, Negrar di Valpolicella, Italy. E-mail address: alessio.marinelli@sacrocuore.it.

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Table 1 Patient and procedure characteristics

Variables	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Mean ± SD
Sex	M	M	M	M	M	–
Age, y	53	46	56	50	50	51 ± 3.7
BMI	25	23.1	24.2	27	22	24.6 ± 2.5
ASO diameter, mm	22	20	25	22	25	22.8 ± 2.1
LVEF, %	56	58	61	62	60	59.4 ± 2.4
LA diameter, mm	51	49	52	50	48	50 ± 1.5
Nature of ASD	PFO	PFO	OsII	PFO	OsII	–
Type of AF	PAF	PAF	PAF	PAF	PAF	–
AF before ASD closure	N	Y	N	N	N	–
Time from ASD closure to cryo (months)	31	73	68	60	65	59.4 ± 16.5
Procedure time (min)	170	105	200	137	150	152.4 ± 35.6
TSP time (min)	9.2	7.2	11.5	6.1	5.7	7.94 ± 2.4
Diameters of septum used for TSP (mm)	13	16	11	13	8	12.2 ± 2.9
Site of TSP related to ASO	PS	PS	PI	AS	AS	–
Fluoroscopy time (min)	31	24.2	43.6	17.3	25	28 ± 4.2
Follow-up after cryo (months)	72	48	30	24	18	38.4 ± 21.8
Antiarrhythmic drug therapy after cryo	N	Y	Y	N	N	
AF recurrences	N	Y	N	N	N	

AF = atrial fibrillation; AS = anterosuperior; ASD = atrial septal defect; ASO = atrial septal occluder; BMI = body mass index; LA = left atrium; LVEF = left ventricular ejection fraction; N = no; OsII = ostium secundum ASD; PAF = paroxysmal atrial fibrillation; PFO = patent foramen ovale; PI = posteroinferior; PS = posterosuperior; TSP = transseptal puncture; Y = yes.

(CT) scan was performed the day before the procedure to assess pulmonary vein (PV) anatomy, to identify the native atrial septum, and to study the anatomic relationships among the septum, right atrium, LA, aortic root, and the ASO device and possible left atrial appendage thrombi. Long-term therapeutic administration of warfarin or new oral anticoagulants was not discontinued during the perioperative period. During general anesthesia, an intraprocedural TEE was performed to identify the native atrial septum. A steerable decapolar and/or a quadripolar catheter was positioned within the coronary sinus and/or His position via the left femoral vein, as anatomical reference. An 8.5F transseptal sheath and a dilator (SL1; St. Jude Medical, Minneapolis, MN) were advanced over a 0.032-inch guidewire to the superior vena cava. Then the guidewire was removed and a Brockenbrough transseptal needle (St. Jude Medical) was introduced into the dilator and advanced to just proximal to the sheath tip. On the fluoroscopic left anterior oblique 30° view, an entire apparatus composed of the sheath, dilator, and transseptal needle was oriented toward the interatrial septum (4- to 5-o'clock position) and withdrawn down the superior vena cava and interatrial septum smoothly until the dilator tip "jump" was observed, which indicated the site of the device or the fossa ovalis (FO) located around the ASO. On the right anterior oblique 45° view, the transseptal assembly was slightly rotated clockwise to the posterior of the device or counterclockwise to the anterior, guided by the TEE operator, where an adequate and safe area was identified (a distance of at least more than 5 mm and preferably around 10 mm from the aorta root or the posterior wall, below or above the device, was accepted). Then the needle was advanced beside the device across the septum. Under TEE guidance, radiography, and pressure line to confirm that the needle was in the proper location, the septum puncture was performed, and the dilator was advanced over the needle into the LA. Unfractionated heparin bolus was administered and continuous infusion was given to maintain the activated clotting time between 300 and 350 seconds. After withdrawal of the needle, the SL1 sheath was then exchanged for the 12F steerable transseptal sheath (FlexCath, CryoCath; Medtronic Inc, Minneapolis, MN) over a stiff guidewire (0.032-inch, 180-cm, Rossen J-tip) positioned in the left superior PV. The 28-mm CB (Arctic Front Advance; Medtronic Inc, Minneapolis, MN) and the inner circular catheter (Achieve mapping catheter; Medtronic Inc, Minneapolis, MN) were used in all patients for PV isolation (PVI). After guiding the balloon toward the respective PV ostia, adequate occlusion was confirmed with 50% diluted contrast through the CB catheter's central lumen. PV potentials were monitored using the Achieve catheter. If a clear time to PVI effect was observed within the first 30 seconds (either a temperature of -40°C or a clear PVI by the Achieve catheter), the number of therapies was reduced to 1, lasting 180 seconds; otherwise, a second CB application was delivered up to 240 seconds (for a maximum for each vein of 480 seconds and lower temperature accepted of -60°C). For all cases, CB ablation was performed in the following order: left superior, left inferior, right superior, and ultimately the right inferior PVs. In all 5 patients, TSP was obtained through the native septum, showed a sufficiently large portion of the native septum as confirmed by intraprocedural TEE (mean diameter 12.2 ± 2.9 mm; see Table 1 for details).

The mean time of TSP was 7.94 ± 2.4 minutes, total fluoroscopy time 28 ± 4.2 minutes, and total procedure time 152.4 ± 35.6 minutes. The CB ablation procedures were successfully concluded. No periprocedural complications were reported.

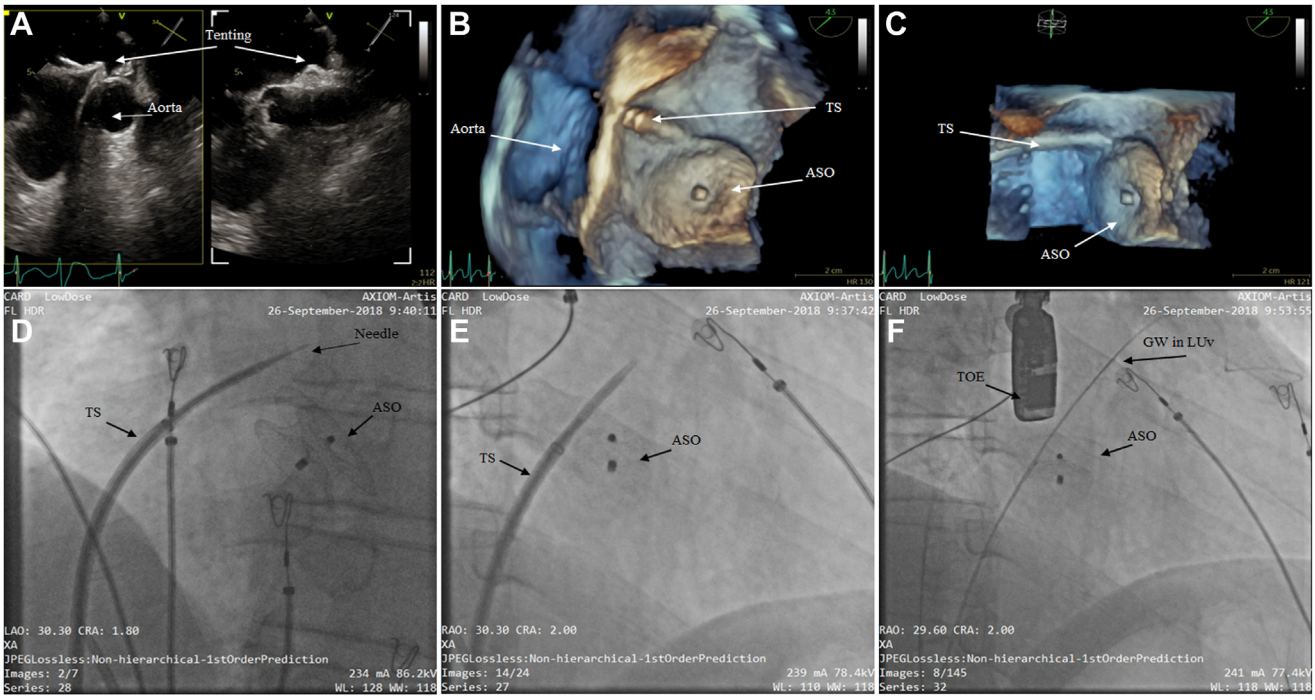

Figure 1 Anterosuperior transseptal puncture compared to the atrial septal occluder (ASO) device in native septum. **A:** Two-dimensional X-plane transesophageal echocardiography (TEE) imagine showing needle tenting on the native septum. **B, C:** Three-dimensional TEE reconstructions showing the puncture anterosuperior in the native atrial septum above the device occluder (ASO) and the 12F transseptal sheath (TS). **D:** Fluoroscopy, left anterior oblique showing the 8.5F TS and needle. **E:** Right anterior oblique (RAO) view. **F:** RAO view; after puncture the guidewire (GW) was advanced in the left upper (LU) pulmonary vein.

Follow-up

After ablation, anticoagulation and antiarrhythmic drug therapy (ADT) were continued for 3 months. At 3 months, anticoagulation was continued according to the stroke risk, whereas ADT was continued on the decision of the treating physician. The first 3 months were set as the blanking period. Transthoracic echocardiography with color Doppler (all patients showed good transthoracic ultrasound windows) was performed to detect thrombus, residual interatrial shunt, or device deformation both on the day after the ablation procedure and 3 months after the procedure. A 12-lead electrocardiogram-Holter was performed at each office visit. Recurrence was defined as any episode of AF or atrial tachycardia lasting for at least 30 seconds after a blanking period.

At the follow-up 3 months after the ablation, the echocardiography showed no thrombus or interatrial shunt in any of the patients. After a follow-up of 38 ± 21 months, sinus rhythm was maintained in 4 patients (80%); 1 was on flecainide and the others were not taking any ADT. One patient had a recurrence of AF 2 years after first ablation procedure, while on ADT (flecainide). This patient already had AF before the ASO procedure. A redo ablation, via standard electroanatomical mapping and radiofrequency catheter, was planned and achieved with 2 separate TSP posteriorly to the ASO device, the same area of the previous CB procedure. No procedure-related complications, including hemopericardium, thromboembolic events, iatrogenic ASD, groin hematoma, vascular complication, bleedings, atrial-esophageal fistula, and pulmonary vein stenosis, were observed.

Discussion

The presence of an ASO is commonly perceived as an almost insurmountable obstacle to perform AF ablation and data about its feasibility and safety are scarce[8,10,11]; particularly, no data are available in the peculiar setting of ASO regarding AF ablation by CB. To the best of our knowledge, the present study reports the largest series of patients using an AF CB 12F catheter in patients with ASO in Italy and in the literature.

During AF ablation using radiofrequency, Santangeli and colleagues[8] reported a 90% TSP obtained through the native septum, whereas Guo and colleagues[12] report a TSP through the device in 54% of their population depending on the dimension of the ASO. No patient in these or other studies showed any major procedural complications, including device distortion or dislodgement.[10,13] There have been some studies describing iatrogenic ASD after AF ablation.[8–18] The percentage was about 17%–20% of the populations investigated. One study showed a high spontaneous closure rate (82% of the patients affected) at 1 year.[19] Guo and colleagues, despite TSP performed through the ASO, even with the assistance of balloon dilatation (12 patients over 35), did not report any iatrogenic septal defect.[12] Therefore, the authors concluded that it is reasonable and safe to perform AF ablation in patients with an ASO. Our case series seems consistent with these findings. We also emphasize the pivotal intraprocedural function of TEE in guiding the site selection for TSP in real time. TEE facilitates detailed evaluation of anatomical structures and their spatial relationship with the

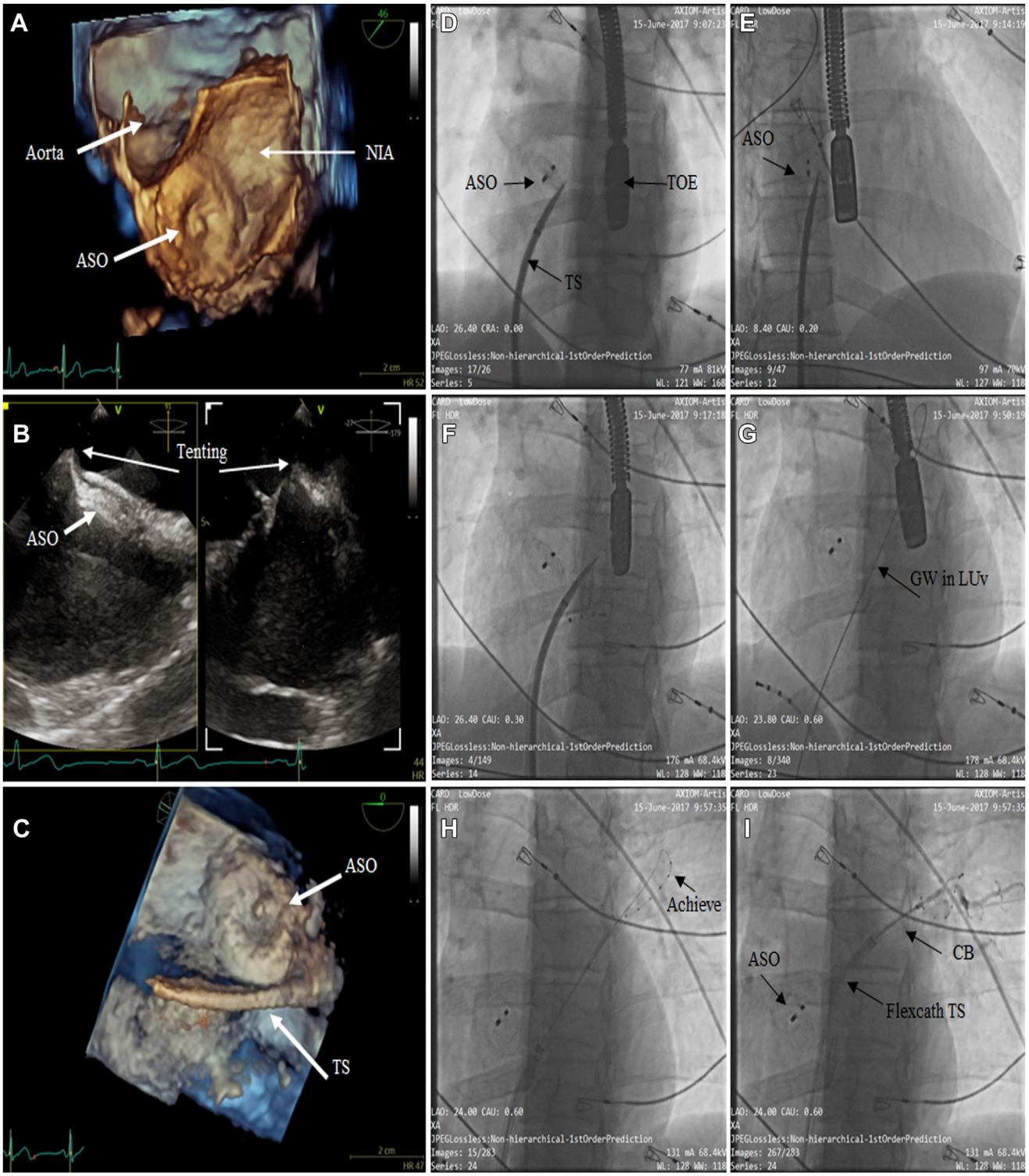

Figure 2 Posteroinferior transseptal puncture. **A:** Three-dimensional transesophageal echocardiography (TEE) reconstruction of native interatrial septum (NIA), aorta, and atrial septal occluder (ASO) showing not enough space anteriorly between the ASO and the aorta for the puncture. **B:** Two-dimensional X-plane imagines showing the needle tenting on the native septum below the ASO. **C:** Three-dimensional TEE reconstruction showing the 12F transseptal sheath (TS) posteroinferior to the ASO. **D–G:** Fluoroscopy imagines showing the TS puncture sequences. **H, I:** The multipolar catheter (Achieve; Medtronic Inc, Minneapolis, MN) in the left upper vein and the cryoballoon (CB) ablation catheter occluding the vein.

ASO, which sometimes is not as well defined as the CT images. The possibility to perform multiplane and 3D TEE provides a great assembly of imaging planes, allowing for detailed visualization of the ASO and the residual native septum, making the TSP feasible through it rather than through the device (Figures 1 and 2). Employing a TEE is

particularly beneficial, especially when dealing with robust diameter sheaths, as observed in our case series. Hence, based on our experience, TSP adjacent to the native septum alongside the ASO can certainly be considered feasible if the device diameter is $\leq$25 mm, even when using 12F sheaths, whereas direct puncture through the device may be necessary when the device is oversized in relation to the interatrial septum, especially when the device diameter is $>$28 mm.[12]

Conclusion

In this limited case series, we present findings indicating the feasibility and safety of AF CB ablation employing 12F transseptal sheaths in patients with prior closure of ASD using percutaneous occluder devices. Meticulous preprocedural planning using CT scans, along with intraprocedural TEE incorporating multiplane and 3D imaging, emerges as indispensable for procedural guidance. These modalities aid in the precise identification of the optimal site within the native septum for TSP.

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