Transseptal puncture for ablation of atrial fibrillation in a patient with an implanted atrial flow regulator: a case report

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Received 30 March 2020; first decision 21 April 2020; accepted 3 July 2020

Background
Atrial flow regulator (AFR) (Occlutech, Helsingborg, Sweden) are self-expanding, circular devices. A flexible waist in the centre connects the two discs and has a centrally located shunt.

Case summary
We report a case of an 80-year-old woman undergoing a repeat left atrial ablation for persistent atrial fibrillation with an implanted AFR. The AFR was implanted 1 year prior to the procedure for heart failure with preserved ejection fraction as part of the AFR-PRELIEVE trial. A single, fluoroscopy-guided, transseptal puncture was performed infero-posterior to the device, allowing the positioning of the mapping (LASSO® 20 mm, Biosense Webster, Irvine, CA, USA) and ablation (Thermocool SmartTouch SF, CARTO®, Biosense Webster, Irvine, CA, USA) catheter in the left atrium. Three-dimensional mapping (CARTO®, Biosense Webster, Irvine, CA, USA) and left atrial ablation were successfully performed. After the procedure, fluoroscopy and transthoracic echocardiography showed an unchanged device position.

Discussion
To our knowledge, this is the first case report of a transseptal puncture in a patient with an implanted AFR. Transseptal puncture in patients with an implanted AFR seems to be safe and feasible. With device diameters of 21–23 mm and based on previous studies on similar devices, transseptal puncture should be possible in most patients, as opposed to puncture through the device.

Keywords
Atrial flow regulator • Transseptal puncture • Atrial fibrillation • Ablation • Case report

Learning points
• Transseptal puncture and left atrial procedure in patients with implanted atrial flow regulator (AFR) seems to be safe and feasible.
• The transseptal puncture can be performed fluoroscopy-guided only.
• The diameter of the AFR device is 21–23 mm, which should allow for enough free septal area for a transseptal puncture in most patients.
Introduction

Atrial flow regulator (AFR) (Occlutech, Helsingborg, Sweden) are self-expanding, circular devices implanted in the interatrial septum as a study treatment for heart failure with preserved ejection fraction.\cite{1}

A flexible waist in the centre connects the two discs and has a centrally located shunt.\cite{1}

In this case report, we describe a patient undergoing a left atrial ablation procedure for persistent atrial fibrillation with an implanted AFR.

Timeline

| Date       | Event                                                                 |
|------------|------------------------------------------------------------------------|
| March 2017 | Initial diagnosis of persistent atrial fibrillation - electrical cardioversion |
| November 2017 | Pulmonary vein isolation                                                |
| November 2018 | Heart failure with preserved ejection fraction                         |
| November 2018 | Implantation atrial flow regulator (AFR) as part of AFR-PRELIEVE trial |
| November 2019 | Recurrence of atrial fibrillation                                      |
| March 2020  | Repeat left atrial ablation - transseptal puncture with implanted AFR | Result of the procedure:  
\begin{itemize}  
\item AFR in unchanged device position  
\item Patient in stable sinus rhythm  
\item No other post-procedural complications  
\end{itemize} |

Case presentation

We report a case of an 80-year-old woman undergoing a repeat pulmonary vein isolation for persistent atrial fibrillation with an implanted AFR. The AFR was implanted 1 year prior to the procedure for heart failure with preserved ejection fraction as part of the AFR-PRELIEVE trial. The AFR-PRELIEVE trial sought to assess the effects of transcatheter AFR implantation on symptoms and surrogate parameters of heart failure in patients with reduced or preserved left ventricular ejection fraction.\cite{1}

Relevant pre-existing conditions were ischaemic cardiomyopathy, persistent atrial fibrillation, and history of transient ischaemic attack. The first pulmonary vein isolation took place two and a half years prior to the ablation procedure and resulted in sinus rhythms maintenance for 24 months and significant symptom improvement. Relevant medication consisted of a betablocker and oral anticoagulation with Apixaban.

The 12-lead electrocardiography at hospital admission showed atrial fibrillation with normal ventricular response at a heart rate of 85 b.p.m. A preprocedural transoesophageal echocardiography (TOE) showed the AFR in an anterosuperior position in the fossa ovalis with sufficient free septal area posterior and inferior to the device (Figure 1), as well as a normal left ventricular ejection fraction and absence of left atrial thrombi. Oral anticoagulation was discontinued the day prior to the procedure. The ablation procedure was performed under sedation using propofol, midazolam, and fentanyl. After obtaining triple femoral venous access (TSX\textsuperscript{TM} Fixed Curve Transseptal Sheath, Boston Scientific, Marlborough, MA, USA) through the right femoral vein and positioning of a decapolar coronary sinus catheter, a fluoroscopy-guided single transseptal puncture (TSXT\textsuperscript{TM} Transseptal Needle, Boston Scientific) infero-posterior to the AFR was performed (Figure 2). Immediately after ensuring successful transseptal puncture, a weight-adjusted heparin bolus was administered, with successive boluses every 30 min based on a targeted activated clotting time of >300 s. According to our clinical routine, the ablation catheter (Thermocool Smarttouch SF, CARTO\textsuperscript{R}, Biosense Webster, Irvine, CA, USA) was guided along the wire into the left atrium, omitting the need for a second transseptal puncture. Subsequently, a three-dimensional map (LASSO\textsuperscript{R} 20 mm, Biosense Webster, Irvine, CA, USA) of the left atrium was created (CARTO\textsuperscript{R}, Biosense Webster, Irvine, CA, USA). All pulmonary veins were shown to be isolated, therefore, ablation of complex fractionated atrial electrograms was performed. Since extended catheter ablation only transiently leads to conversion in a left atrial tachycardia, external electrical cardioversion was performed at the end of the procedure. Oral anticoagulation with Apixaban was continued on the same evening.

Fluoroscopy at the end of the procedure as well as transthoracic echocardiography performed on the next day showed an unchanged device position (Figure 3). Significant pericardial effusion was excluded and no other post-procedural complications were observed during the hospital stay.

Discussion

Transseptal puncture is routinely performed in left atrial procedures. To our knowledge, so far no data exist on transseptal puncture in patients with an implanted AFR.

The AFR is a self-expanding, double-disc, circular device made of nitinol wire mesh.\cite{1} A flexible waist in the centre connects the two discs and has a centrally located shunt. The devices are produced in two sizes with transverse diameters of 21 and 23 mm, and shunt sizes of 8 mm and 10 mm, respectively.\cite{1} Our patient had a device diameter of 21 mm and a shunt size of 8 mm, an opening judged too small for direct positioning of both catheters through the shunt, while still allowing adequate manoeuvrability. The transseptal rather than ‘transdevice’ route into the left atrium was also felt to be safer concerning device dislodgement.

Previously, other case reports and studies showed the safety of transseptal punctures in challenging patients. Gloeckler et al.\cite{2} reported a successful transseptal puncture through an Amplatzer Atrial Septal Occluder for left atrial appendage closure using fluoroscopy guidance only, with subsequent closure of the access hole with a small atrial septal occluder (ASO).

Li et al.\cite{3} presented a case series of nine patients with implanted ASOs undergoing left atrial ablation for atrial fibrillation. Alike in the case presented, in six patients, left atrial access was obtained performing a double puncture through the septum infero-posterior to the device. In the remaining three patients a single puncture through
the device with subsequent balloon dilatation was performed. Most of the punctures were fluoroscopy-guided only.

Sang et al.⁴ presented a case series of 16 patients with implanted ASOs, undergoing ablation for atrial fibrillation. Preprocedural imaging using three-dimensional computed tomography (CT) was performed in all patients and used to determine possible entry points. A single puncture was performed through the septum in 11 patients, thereof infero-posterior to the device (as in our case) in eight patients and infero-anterior to the device in three patients. A single puncture was performed through the device in the rest of the patients, with subsequent balloon dilatation. Transseptal punctures were successful in all patients with no puncture-related complications.

We showed that transseptal puncture in a patient with AFR is safe and feasible using fluoroscopy guidance only. Li et al.³ reported that transseptal access through the ASO may be necessary in patients

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**Figure 1** Pre-procedural transoesophageal echocardiography [midoesophageal 120° (A) and 60° (B) views] showing adequate septal area for transseptal puncture inferior and posterior to the atrial flow regulator (*), respectively.

**Figure 2** Fluoroscopy showing transseptal puncture infero-posterior to the atrial flow regulator device in antero-posterior (A) and left anterior oblique (B) views as well as mapping and ablation catheters positioned in the left atrium (C).
with a device diameter >26 mm, whereas Sang et al. reported successful transseptal puncture in ASOs as large as 32 mm in favourable cases. The diameter of the AFR device is 21–23 mm, which should allow for enough free septal area for a transseptal puncture in most patients. Our chosen entry point was infero-posterior to the device, which was also the most frequently used entry point in the ASO studies.

We used preprocedural TOE to help planning the transseptal approach. In our centre, we do not routinely use TOE imaging for transseptal puncture as fluoroscopy only guidance allows successful puncture in most patients with low complication rates, although TOE is available as backup in the setting of difficult anatomy. In this case, the transseptal puncture was easily performed using fluoroscopy only, so no TOE guidance was required.

**Figure 3** Post-procedural transthoracic echocardiography (four-chamber view) showing the atrial flow regulator in loco typico.

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**Conclusion**

Transseptal puncture in patients with an implanted AFR seems to be safe and feasible and can be performed fluoroscopy-guided only. Preprocedural imaging (CT or TOE) can help to plan the approach. The diameter of the AFR device is 21–23 mm, which should allow for enough free septal area for a transseptal puncture in most patients.

**Lead author biography**

Cornelia Biller is a clinical fellow at the Department of Electrophysiology at the University Hospital of Cologne, Germany. Her current research focus is on atrial fibrillation and device therapy.

**Supplementary material**

Supplementary material is available at *European Heart Journal - Case Reports* online.

**Slide sets:** A fully edited slide set detailing this case and suitable for local presentation is available online as Supplementary data.

**Consent:** The author/s confirm that written consent for submission and publication of this case report including image(s) and associated text has been obtained from the patient in line with COPE guidance.

**Conflict of interest:** none declared.

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