

# Eliminating transseptal sheath exchange for pulsed field ablation procedures using a direct over-the-needle transseptal access with the Faradrive sheath

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## Aims

Pulsed field ablation (PFA) for pulmonary vein isolation (PVI) combines the benefits of high procedural efficacy and safety. Transseptal puncture (TSP) to obtain left atrial (LA) access during PVI remains an important source of complications during LA procedures. For PFA procedures, TSP is generally performed using a standard transseptal sheath that is then exchanged over the wire for a dedicated PFA sheath, which might be a potential source for air embolism. We aimed to prospectively evaluate the feasibility and safety of a simplified workflow using the PFA sheath (Faradrive, Boston Scientific) directly for TSP.

## Methods and Results

We prospectively enrolled 100 patients undergoing PVI using PFA at two centres. TSP was performed using the PFA sheath and a standard 98 cm transseptal needle under fluoroscopic guidance. TSP via the PFA sheath was successfully performed in all patients and no complications occurred. The median time from the first groin puncture to the completed LA access was 12 min (IQR 8–16 min).

## Conclusion

An over-the-needle TSP directly with the PFA sheath proved feasible and safe in our study. This simplified workflow has the potential to reduce the risk of air embolism, to shorten procedure time, and to reduce cost.

## Keywords

Pulsed field ablation • Transseptal puncture • Air embolism

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### What's new?

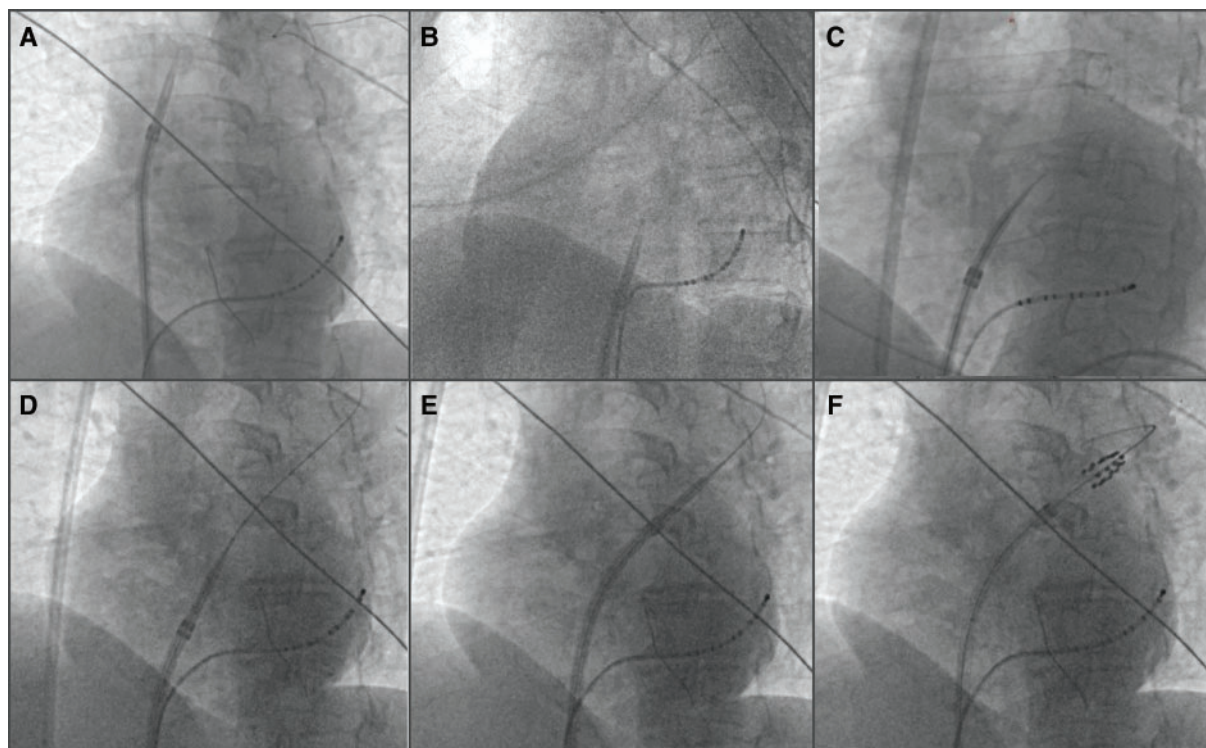
Pulsed field ablation (PFA) for pulmonary vein isolation (PVI) combines the benefits of high procedural efficacy and safety. Transseptal puncture (TSP) to obtain left atrial (LA) access during PVI remains an important source of complications during LA procedures. It is generally performed using a standard transseptal sheath. Following TSP, the sheath is exchanged for a dedicated PFA delivery sheath, which might be a potential source for air embolism. Thus far, there are no data on the feasibility and safety of direct over-the-needle TSP using a PFA delivery sheath. Our pilot study evaluated this simplified workflow in 100 consecutive patients undergoing a PFA procedure. Transseptal puncture via the PFA sheath was successfully performed in all patients and no complications occurred, thus suggesting that direct over-the-needle TSP is a feasible and safe technique. Our proposed workflow has the potential to reduce the risk of air embolism, to shorten procedure time, and to reduce cost.

Pulsed field ablation (PFA) for pulmonary vein isolation (PVI) combines the benefits of high procedural efficacy and safety. The first PFA platform received regulatory approval in Europe in March 2021 (Farapulse™, Boston Scientific). It has since been used in >10 000 PVI patients.<sup>1,2</sup> Transseptal puncture (TSP) to obtain left atrial (LA) access is generally performed using a standard transseptal sheath (e.g. Abbott SL1 sheath). After gaining access, the sheath is exchanged for the 16.8 Fr dedicated PFA delivery sheath (Faradrive™, Boston Scientific) over a long stiff wire. Sheath exchange, however, is a potential source for air embolism, and LA access may be lost during the manoeuvre. A simplified workflow using the Faradrive sheath directly for

transseptal access may mitigate the risk of air embolism, shorten procedure time, and reduce cost.

We aimed to prospectively evaluate the feasibility and safety of such a simplified workflow in PFA procedures. Patients undergoing PVI using PFA at two centres were prospectively enrolled. Two femoral vein punctures were performed. A short 7 Fr sheath was used to introduce a coronary sinus catheter. A long 0.032" wire (Cook Medical Rosen Wire) was advanced to the superior vena cava (SVC). A skin incision was made. The Faradrive sheath was introduced over-the-wire without pre-dilation and advanced to the SVC (Figure 1A). A bolus of 5000 IU of Heparin was administered. The Faradrive sheath was bent to ~30°. The guidewire was replaced by a standard transseptal needle (Abbott BRK 98 cm) that was advanced to the tip of the Faradrive sheath. A pull-down was performed under fluoroscopic guidance until the tip of the sheath jumped into the fossa ovalis (Figure 1B). After checking the correct position in both RAO45° and LAO45° and aiming for a high anterior position, the needle was advanced to the LA. Left atrial access was confirmed by contrast injection and/or pressure measurement (Figure 1C). The transseptal needle was replaced by the same 0.032" wire, which was placed in the left superior pulmonary vein (Figure 1D). Over this wire, the Faradrive sheath was fully advanced into the left atrium (Figure 1E). The dilator and guidewire were slowly removed. The Faradrive sheath was gently aspirated and extensively flushed. Another bolus of heparin was administered. The PFA catheter (Farawave™, Boston Scientific) was flushed, equipped with the same 0.032" wire used before and introduced into the left atrium (Figure 1F) in order to perform PFA of all four veins. The study was approved by the local ethics committees.

This simplified workflow with direct TSP using the PFA sheath was prospectively assessed in 100 consecutive patients undergoing a PFA procedure. The median age was 66 years [interquartile range (IQR) 58–72 years], 26% of the patients were females, 62% had paroxysmal



**Figure 1** Left atrial access using a direct over-the-needle approach with the PFA delivery sheath. LA, left atrial; PFA, pulsed field ablation.

atrial fibrillation, and 24% underwent Redo procedures. Transseptal puncture via the PFA sheath was successfully performed in all patients and no complications occurred. The median time from the first groin puncture to the completed LA access was 12 min (IQR 8–16 min). No difference was observed between the first 25 patients and the last 25 patients [median to completed LA access 13 min (IQR 8–15 min) vs. 11 min (IQR 9–16 min),  $P = 0.47$  for comparison].

Transseptal puncture remains an important source of complications during LA procedures. For radiofrequency ablation, smaller 8.5 Fr sheaths (such as Abbott Agilis or SL1) are used for direct TSP. For cryoablation and PFA and left atrial appendage closure, those smaller 8.5 Fr sheaths are usually used for TSP and then exchanged for the larger dedicated delivery sheaths (ranges 14–17 Fr). For cryoballoon procedures, streamlined workflows for direct TSP have been suggested.<sup>3,4</sup> For the PFA system, this is the first description of a workflow for direct TSP using the 16.8 Fr PFA sheath. The long tapering of the dilator makes the sheath particularly suitable for both groin access and TSP without pre-dilation. Another advantage compared with the standard workflow is the steering mechanism of the Faradrive sheath, which can be particularly helpful to find the optimal puncture site for PFA patients (high anterior in our experience), particularly in difficult anatomies. While we used an over-the-needle approach, it is conceivable that an over-the-wire approach could work similarly well.<sup>4,5</sup> While additional imaging (predominantly intracardiac echocardiography) is routinely used to guide TSP in the USA and Canada, the majority of European Centers performs TSP guided by fluoroscopy.<sup>6</sup> Our TSP workflow was guided by fluoroscopy only, and we believe that it can be safely used without additional imaging. No criteria for patient selection were applied. It is, however, conceivable to use a standard approach for TSP and/or additional imaging in patients with known anatomical anomalies (e.g. persistent left-sided SVC or the presence of patent foramen ovale/atrial septal defect occluders).

Several limitations should be taken into consideration for this study. First, our pilot study is limited in terms of the number of patients enrolled. Secondly, the presented workflow was used by operators with experience in TSP and was not tested for operators in training. Prospective randomized studies need to investigate if the proposed workflow can reduce air embolism without increasing the risk for cardiac tamponade.

In conclusion, a direct over-the-needle TSP with the Faradrive sheath proved feasible and safe in our study. This simplified workflow has the

potential to reduce the risk of air embolism, to shorten procedure time, and to reduce cost.

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## Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

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