A zero-exchange approach for left atrial access in pulmonary vein isolation with pulsed field ablation

Alexandru Gabriel Bejinariu, Maximilian Spieker, Hisaki Makimoto, Nora Augustin, Malte Kelm, Obaida R. Rana

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A zero-exchange approach for left atrial access in pulmonary vein isolation with pulsed field ablation

Alexandru Gabriel Bejinariu MD[1] | Maximilian Spieker MD[1] | Hisaki Makimoto MD[2] | Nora Augustin MD[1] | Malte Kelm MD[1,3] | Obaida R. Rana MD[1,3]

[1]Division of Cardiology, Pulmonology and Vascular Medicine, Medical Faculty, Heinrich-Heine University, Düsseldorf, Germany

[2]Data Science Center/Cardiovascular Center, Jichi Medical University, Shimotsuke-City, Japan

[3]CARID, Cardiovascular Research Institute Düsseldorf, Medical Faculty, Heinrich-Heine-University, Düsseldorf, Germany

Correspondence
Alexandru Gabriel Bejinariu, MD, Department of Cardiology, Pulmonology, and Vascular Medicine, Heinrich-Heine University Hospital, Duesseldorf 40225, Germany.
Email: alexandru.bejinariu@med.uni-duesseldorf.de

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Abstract

Introduction: Pulsed field ablation (PFA) has emerged as an innovative technique for pulmonary vein isolation (PVI). Typically, a transeptal puncture (TSP) with a standard sheath precedes a switch to the larger diameter sheath in the left atrium. This study aimed to describe the safety and feasibility of direct TSP using the large diameter Faradrive sheath before performing PVI with PFA.

Methods: We prospectively enrolled 166 consecutive patients with paroxysmal or persistent atrial fibrillation (AF) undergoing PVI with PFA at our institution. TSP was performed in all cases with transesophageal echocardiography guidance, using the Faradrive sheath and a 98 cm matched Brockenbrough needle. The primary endpoint was the occurrence of pericardial tamponade during or within the first 48 h after the procedure. The secondary endpoint was the occurrence of any major complication.

Results: All 166 patients were included into the final analysis (44% female): 64% of patients had paroxysmal AF and 36% persistent AF (68 ± 11 years old, median CHA_2DS_2Vasc Score 3, median left atrial volume index 31). The median duration of the procedure was 60 min, median time to TSP was 15 min, and the median fluoroscopy dose was 595 cGy × cm^2. The primary endpoint occurred in one patient: a non-TSP related pericardial tamponade, which was managed with pericardial puncture.

Conclusion: Direct TSP with skipping sheath exchange using the large diameter Faradrive sheath for PVI with PFA was safe, feasible, and reduced costs in all patients. Large scale studies and registries are needed to verify this workflow.

KEYWORDS

pulmonary vein isolation, pulsed field ablation

1 | INTRODUCTION

Pulmonary vein isolation (PVI) is the cornerstone of interventional therapy in the management of atrial fibrillation (AF). Traditionally, PVI can be achieved using thermal methods, such as radiofrequency energy or cryoballoon ablation. More recently, the pulsed field ablation (PFA) emerged as a novel, non-thermal method for achieving durable PVI and is currently being intensively studied. The main advantages of the PFA are tissue selectivity, allowing only damage to the myocardium while sparing other tissues in the proximity, and lesion durability.

Regardless of the type of method used, thermal or non-thermal, the transseptal puncture (TSP) represents an indispensable step of the PVI. The most common approach to perform TSP is using a fixed-curve long sheath (i.e., Swartz; Abbott) and a transseptal needle (i.e., BRK-1; Abbott).[1] Once the sheath is advanced into the left atrium, it is usually exchanged to large diameter steerable sheath with an over-the-wire technique (i.e., FlexCath [15.0 F], Medtronic; Polarsheath [15.9 F], Boston Scientific). However, there are operators preferring a direct approach using a steerable sheath and the transseptal needle for the puncture. Direct TSP with the following steerable sheaths has been previously described[2]: Agilis Nx-T (Abbott), Vizigo (Johnson & Johnson), FlexCath Advance (Medtronic). Generally, a larger diameter and longer sheath without the use of transoesophageal echocardiography (TEE) or intracardiac echocardiography guidance may increase the risk for complications.

Therefore, this study aims to describe the feasibility and safety of direct TSP using a large diameter sheath (Faradrive 16.8 F) with TEE guidance before performing PVI using PFA (Farapulse; Boston Scientific).

2 | MATERIALS AND METHODS

2.1 | Study ethics

The study protocol was approved by the local ethics committee of Heinrich Heine University Düsseldorf (Study Number 2019-555_4) and complies with the Declaration of Helsinki. Informed written consent was obtained from all study participants.

2.2 | Study population

We prospectively enrolled all consecutive patients undergoing PVI with PFA at our institution. The PVI was indicated following the recent guideline recommendations from the European Society for Cardiology.[3] Patients with paroxysmal or persistent AF refractory to antiarrhythmic treatment (class I and III antiarrhythmics) were considered eligible if they were older than 18 years of age, and provided informed consent before inclusion. Patients were excluded if they had previous AF ablation, contraindication to oral anticoagulation, left atrial (LA) thrombus on preprocedural TEE, or valvular AF. Comorbidities, medications, and epidemiological data were recorded and analyzed.

The primary endpoint of this study was the occurrence of pericardial tamponade during or within the first 48 h after the procedure. The secondary endpoint was the occurrence of any major complications (stroke, groin complication, pericardial effusion, phrenic nerve injury, air embolism).

2.3 | Procedural workflow

The procedures were performed with deep sedation using propofol and midazolam as well as opiates as needed to achieve optimal analgesia.[4] The first step was to exclude LA thrombi by means of TEE using a Vivid T8 machine (GE Healthcare). The procedures were performed by physicians with vast experience in periinterventional cardiac imaging (defined as a minimum of 500 cases). Second, the femoral venous access was obtained with ultrasound guidance. After administering Heparin to achieve and maintain a target activating clotting time of 300–400 s, the TSP was performed under TEE (with the TEE scope left in position after excluding thrombi) and fluoroscopic guidance, followed by the ablation procedure. After successful PVI the sheaths were removed and a figure of eight suture was applied for hemostasis and pericardial effusion was excluded with transthoracic echocardiography.

2.4 | TSP

The TSP was performed in all cases using TEE-guidance. The 8 F groin sheath was exchanged to the long steerable Faradrive sheath "over the wire" in the superior vena cava (SVC). A matched-length Brockenbrough needle (BRK-1 98 cm; Abbott) was inserted in the Faradrive sheath, then the sheath and needle were retracted from the SVC into the right atrium while fluoroscopically documenting the "jump" in the fossa ovalis. The position of the sheath and transseptal needle was assessed both fluoroscopically, right anterior oblique (RAO) 30° for antero-posterior orientation and left anterior oblique (LAO) 40° for superior-inferior orientation, and echocardiographically, 45° for antero-posterior adjustment and 90–110° for superior-inferior adjustment (Figure 1). After advancing the needle into the left atrium, first the dilator and then the sheath were advanced carefully under TEE guidance. Afterwards, the needle and dilator were removed, leaving the sheath in the left atrium (Figure 2). The TEE scope was removed after ruling out pericardial effusion. The described zero-exchange workflow is shown in Figure 3 as compared to the standard workflow with standard sheath (i.e., SL1; Abbott) and exchange "over-the-wire." This nomenclature refers strictly to the lack of exchange of the standard transseptal sheath for the Faradrive sheath.

2.5 | Ablation procedure

The Farawave ablation catheter (Farapulse; Boston Scientific) was introduced into the left atrium over the steerable Farapulse sheath. The pulmonary vein angiographies were performed over the Farapulse sheath in standard RAO and LAO projections and PVI was performed with the Farastar generator at 2 kV, as previously reported with minor modifications.[5] Briefly, every pulmonary vein was ablated using pairs of impulses: three pairs in the "basket" configuration and four to five pairs in the "flower" configuration. Between each two pairs, the catheter was rotated to achieve circumferential coverage of the antrum.

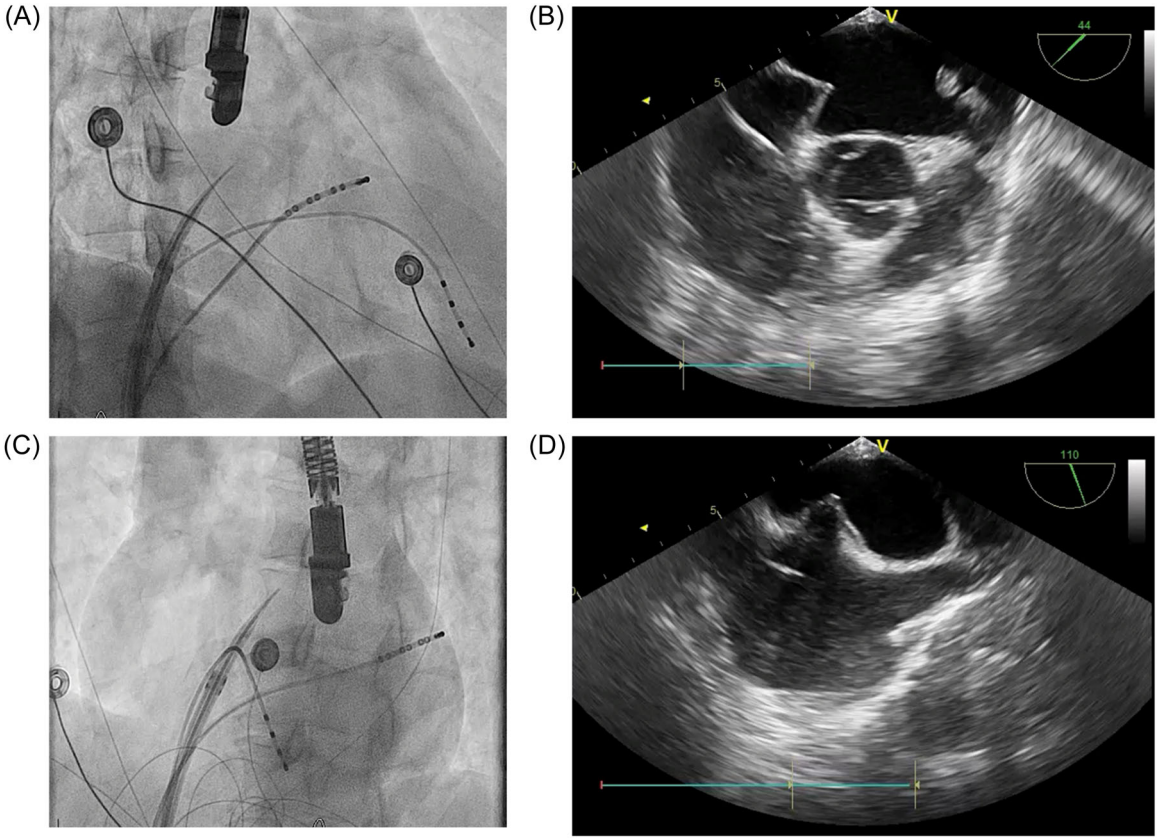


FIGURE 1 Positioning of the sheath with transseptal needle. (A) Antero-posterior adjustment, fluoroscopy, RAO 30°. (B) Antero-posterior adjustment, TEE short axis. (C) Supero-inferior adjustment, fluoroscopy, LAO 40°. (D) Supero-inferior adjustment, TEE bicaval view. LAO, left anterior oblique; RAO, right anterior oblique; TEE, transesophageal echocardiography.

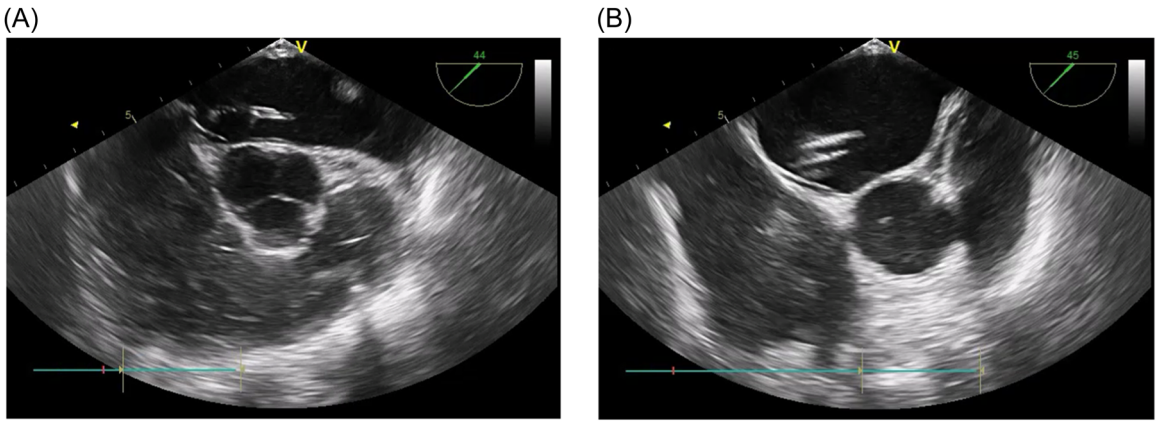


FIGURE 2 Steps after puncturing with the TSP needle. (A) Advancement of dilator into the LA. (B) Advancement of the Faradrive sheath while removing the dilator. LA, left atrium; TSP, transseptal.

2.6 | Postprocedural monitoring

Therapeutic anticoagulation was resumed on the evening after the procedure after transthoracic echocardiography for excluding pericardial effusion. The patients were monitored on the ward for at least 48 h (telemetry).

2.7 | Statistics

Data were analyzed using SPSS statistical software version 26 (SPSS Inc.). Continuous variables are expressed as mean ± standard deviation (or median and interquartile range [IQR]), and categorical parameters are expressed as counts and

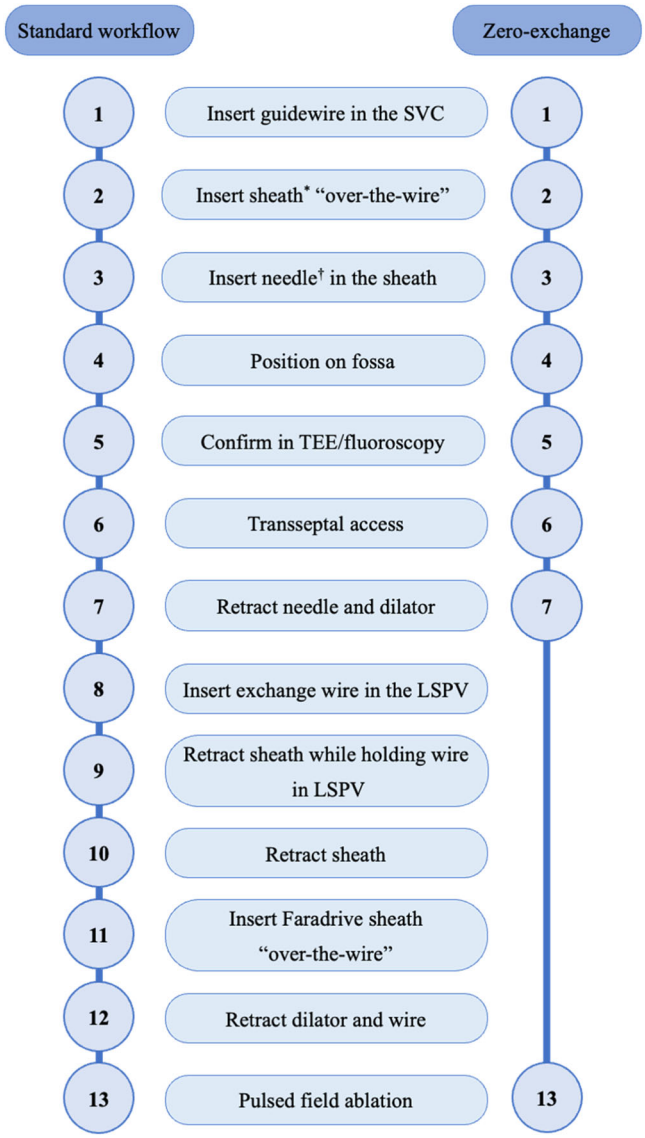


FIGURE 3 Steps of the standard workflow for transseptal access (left) as compared to the zero-exchange approach (right). LSPV, left superior pulmonary vein; SVC, superior vena cava; TEE, transesophageal echocardiography. *SL1 in the standard workflow, Faradrive in the zero-exchange workflow. †Matched length needle.

percentages. Normal distribution was assessed using the Shapiro–Wilk test.

3 | RESULTS

Between July 2022 and 2023, a total of 166 patients were included (64% paroxysmal AF, 36% persistent AF).

The baseline characteristics of the cohort are summarized in Table 1. Mean age was 68 ± 11 years. Patients were symptomatic with a median EHRA class 3, and a median CHA2DS2VAsc score of 3 points. The median body mass index was 27.5 kg/m^2 (IQR: 24–32) and the median LA volume index was 31 mL/m^2 (IQR: 23–40).

TABLE 1 Patient characteristics.

Patient characteristics (n = 166)	
Age (years)	68 ± 11
Gender—n (%)	
Male	93 (56)
Female	73 (44)
BMI—kg/m^2 (IQR)	27.5 (24–32)
AF pattern—n (%)	
Paroxysmal	106 (64)
Persistent (%)	60 (36)
Hypertension—n (%)	93 (56)
CAD—n (%)	50 (30)
Heart failure—n (%)	57 (34)
Obstructive sleep apnea—n (%)	19 (11)
Diabetes mellitus—n (%)	31 (19)
Echocardiography	
Left ventricular EF—% (IQR)	58% (52–62)
Left atrial volume index—mL/m^2 (IQR)	31 (23–40)
CHA_2DS_2-VASc score (IQR)	3 (2–4)
EHRA class (IQR)	3 (2–3)

Abbreviations: AF, atrial fibrillation; BMI, body mass index; CAD, coronary artery disease; EHRA, European Heart Rhythm Association; IQR, interquartile range; NYHA, New York Heart Association.

TABLE 2 Procedural characteristics.

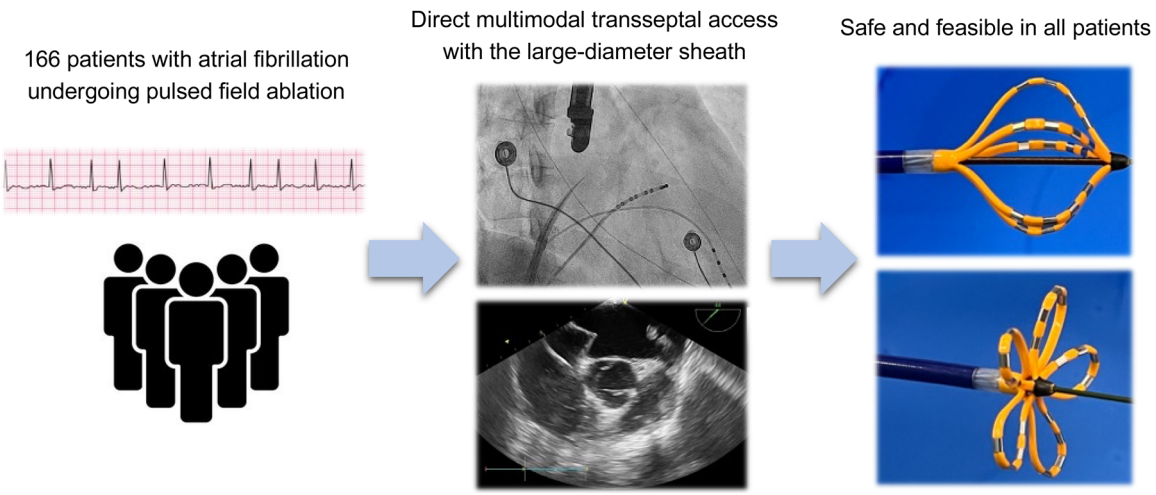
Procedural characteristics (n = 166)	
Procedural duration—min (IQR)	60 (52–70)
Time to TSP—min (IQR)	15 (13–19)
Fluoroscopy time—min (IQR)	19 (15–24)
Dosis area product—cGy × cm^2 (IQR)	595 (406–882)

Abbreviations: IQR, interquartile range; TSP, transseptal puncture.

The TSP with the Faradrive sheath could be performed in all patients, there was no need for advanced TSP techniques, that is, radiofrequency needles or special wires (i.e., SafeSept® transseptal wire). The median time from groin puncture to TSP was 15 min (IQR: 13–19). The procedural data are shown in Table 2.

The primary endpoint was met in one patient: during the procedure a pericardial tamponade occurred, which was successfully managed with pericardial puncture. The mechanism of the pericardial tamponade was an atrial wall perforation with the 0.035-inch, straight-tip guidewire (Amplatz Extra Stiff; Cook Medical) of the PFA catheter during PVI.

The secondary endpoint did not occur in any of the patients. No further complications (i.e., minor complications) were noted during the hospital stay.



CENTRAL ILLUSTRATION 1 Pulmonary vein isolation with pulsed field ablation using a direct transseptal approach is safe and feasible.

4 | DISCUSSION

We investigated the safety and feasibility of a zero-exchange transseptal approach using a large diameter sheath (Faradrive) for PVI using PFA (Central Illustration 1). The main finding of the study is that the TEE-guided zero-exchange TSP with a large diameter sheath is safe and effective. One patient suffered a non-TSP related pericardial tamponade—type D according to the classification system proposed by Maclean et al.,[2] which was successfully managed with pericardial puncture.

There is only scarce literature regarding zero-exchange approaches for LA access. For instance, in the setting of cryoballoon PVIs an integrated dilator-needle system has been described.[6] The authors found a significant reduction in procedure time, as well as time from puncture to balloon delivery when using the integrated dilator-needle system. This reflects also the inherent time-saving potential of our technique with an additional advantage of saving costs. Furthermore, eliminating the need for sheath exchange reduces the risk for air embolism.[7]

Kueffer et al.[8] studied the feasibility and safety of a direct over-the-needle transseptal access in the setting of PVI with PFA using a long 0.032 wire in 100 patients. The authors used a fluoroscopy-based LA access, whereas our strategy employs the use of a fluoroscopy and TEE-based LA access, as the TEE scope remains in position after ruling out LA thrombi (as described in the Methods section).

The zero-exchange technique described in this manuscript abolishes the need not only for an additional dilator-needle system (implying further expenditure), but also for the fixed transseptal sheath needed for the common practice and therefore minimizes the total procedure costs.

A further strength of this technique is its safety. As already described in the literature, the majority of pericardial tamponades in the setting of LA ablations (almost 70%) are TSP-related.[2] There were no TSP-related pericardial effusions/tamponades in our patient group. Our strategy implies the use of TEE for guiding the TSP, therefore the safety advantage cannot be extrapolated to fluoroscopy-only approaches without periinterventional echocardiographic guidance. However, it should be highlighted that the risk for pericardial tamponades in the setting of PFA PVI is generally low our study may not be adequately powered to unequivocally demonstrate this safety advantage.

Of note, advanced transseptal techniques such as radiofrequency needle were not necessary, as the success rate was 100%.

To our knowledge, this is the first study investigating the safety and feasibility of a TEE-guided zero-exchange TSP using the largest diameter sheath available in the market used for PVI.[9] The technique described is safe, feasible, and saves costs in comparison with other workflows or zero-exchange systems.[6,10] A true cost-effectiveness of our workflow needs to be further assessed after studying the patient outcomes.

The main limitation of our study is the lack of a control arm, using a standard approach as described in Figure 3. However, the aim of our study was to study the feasibility and safety of this approach.

5 | CONCLUSION

This study shows that a zero-exchange approach for gaining LA access for PVI with PFA using fluoroscopy and TEE is feasible, time saving, effective, and safe in all patients. A randomized control trial with more patients is necessary to verify this modified workflow.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ORCID

Obaida R. Rana https://orcid.org/0000-0002-7956-3249

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