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Zero-exchange workflow for cryoballoon ablation in pulmonary vein isolation using a direct over-the-needle transseptal access with the FlexCath sheath: A multicenter observational study

Short title: Zero-exchange workflow for cryoballoon ablation in PVI — less is more?

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WHAT'S NEW?

Cryoballoon ablation for pulmonary vein isolation is an established technique for the treatment of atrial fibrillation. One of the crucial steps of the procedure is the transseptal puncture allowing for left atrial catheterization. It is usually performed with a transseptal needle advanced through a fixed curve 8–8.5 F sheath, that due to a large diameter of the therapy device, needs to be exchanged for a larger bore device delivery sheath, bringing concerns about the exchange-related complications. This is the first study evaluating the feasibility, safety and efficacy of a fluoroscopy-guided zero-exchange workflow in cryoballoon ablation for the treatment of symptomatic atrial fibrillation by performing a direct transseptal puncture with a transseptal needle advanced through a 15 F steerable device delivery sheath (FlexCath Advance, Medtronic) compared to the standard approach with sheath exchange.

ABSTRACT

Background: Transseptal puncture (TSP) is a crucial step during cryoballoon ablation (CBA) allowing for left atrium access. During the procedure an over-the-wire sheath exchange is required, which brings concerns about the exchange-related complications. An alternative option is performing the TSP through a steerable sheath and thus avoiding the exchange.

Aims: We aimed to evaluate the feasibility, efficacy and safety of a simplified zero-exchange workflow for CBA procedure.

Material and methods: Patients undergoing CBA (with Arctic Front Advance Pro, Medtronic) at 3 centers in Poland were prospectively enrolled and assigned to the standard approach (n = 62) or the no-exchange group (n = 62). The TSP in the standard approach group was performed through a fixed-curve sheath that was exchanged for a 15F steerable sheath (FlexCath Advance, Medtronic). In the no-exchange group the puncture was performed through the steerable sheath.

Results: TSP was successfully performed in all patients. In the no-exchange group compared to the standard approach group the median (interquartile range) procedure time and left atrium dwell time were significantly shorter (75.0 [60.0–90.0] min vs. 80.5 [70.0–100.0] min; *P* = 0.02 and 47 [40.0–56.0] min vs. 51.5 [43.25–64.5] min; *P* = 0.04, respectively) with comparable median (interquartile range) fluoroscopy time (14.0 [8.5–20.4] min vs. 12.25 [10.0–17.6] min; *P* = 0.74). Only one potentially TSP-related complication has occurred in each group.

Conclusion: A direct TSP with the FlexCath Advance sheath is a feasible, safe and efficient alternative to the standard approach.

Key words: cryoballoon ablation, pulmonary vein isolation, transseptal puncture, zero-exchange workflow

INTRODUCTION

Cryoballoon ablation (CBA) for pulmonary vein isolation is an established technique in the management of atrial fibrillation [1, 2]. The standard approach for obtaining a left atrium (LA) access during the procedure is to perform transseptal puncture (TSP) with a transseptal needle advanced through a fixed-curve transseptal sheath (usually 8–8.5 F size with the curvature chosen accordingly to the patients individual anatomy) under fluoroscopic or

echocardiographic guidance. After confirming the correct needle position in the LA with either contrast injection, pressure recording or transesophageal/intracardiac echocardiography, the sheath and the dilator assembly is gently advanced over the needle through the interatrial septum. The needle is then withdrawn and exchanged for a J-shaped guidewire, which is advanced through the sheath deep into the left superior pulmonary vein to serve as a rail for sheath exchange [3]. After withdrawing the fixed-curve sheath a large bore steerable sheath is advanced over the wire into the LA, allowing for the introduction of the cryoballoon device. However, performing this maneuver carries significant risks, including a possibility of losing an access to the LA or air aspiration resulting in an air embolism.

We hypothesized that a direct transseptal puncture through a steerable 15 F device delivery sheath (FlexCath Advance, Medtronic) might be a feasible, efficient and safe alternative to the standard approach and could further simplify the workflow, reduce procedure time and mitigate the risk of such complications.

MATERIAL AND METHODS

Study population

Patients with symptomatic paroxysmal or persistent atrial fibrillation, older than 18 years old and undergoing pulmonary vein isolation with cryoballoon ablation (with Arctic Front Advance Pro) at 3 centers in Poland (Department of Cardiology, Stefan Cardinal Wyszynski Province Specialist Hospital, Lublin; Department of Cardiology, Medical University of Lublin, Lublin; "IKARDIA" Hospital of Invasive Cardiology, Naleczow) were prospectively enrolled in the study and assigned to the standard approach group with sheath exchange or the no-exchange group with transseptal puncture performed directly through the device delivery sheath (Figure 1). The transseptal puncture method was chosen at operator's discretion, usually in an alternating manner to maintain a 1:1 ratio, with no pre-specified criteria. The study was approved by the local ethics committee. All patients provided written informed consent.

Periprocedural management

All patients underwent transesophageal echocardiography (TEE) in order to exclude LA thrombi prior to the procedure. The morning oral anticoagulant dose was omitted on the day of the procedure and resumed approximately 5 hours later, after proper hemostasis was ensured. Transthoracic echocardiography was performed after the procedure to exclude pericardial effusion. Proton pump inhibitors were prescribed for 6 weeks and oral anticoagulation for at least 2 months (depending on the individual ischemic risk assessed by CHA_2DS_2-VASc score)

following the ablation, as suggested by the current expert consensus statement [4]. Patients were discharged home the day after the procedure if no significant adverse events have occurred.

Transseptal puncture

Detailed TSP techniques and procedural details were previously described [5]. In brief, in standard approach after obtaining femoral vein access with a Seldinger technique a short 8 F sheath was introduced. A long J-shaped guidewire was then advanced into the superior vena cava (SVC) under fluoroscopic guidance. The short sheath was then exchanged and a non-steerable transseptal sheath with a dilator (Swartz, Abbott) was introduced over-the-wire into the SVC. After replacing the wire with a 71 cm transseptal needle (BRK, Abbott) and removing the protective stylet, the assembly was rotated to approximately 4–5 o'clock position and slowly retracted under fluoroscopy (in AP view) until two "jumps" were seen, confirming the correct position on the fossa ovalis. Proper orientation of the assembly was then confirmed under RAO 45 and LAO 30 degree fluoroscopic views. After verifying the correct position on the interatrial septum the transseptal needle was advanced under fluoroscopy guidance (30 degree LAO view) and contrast was administered to confirm obtaining LA access. Next, the sheath with a dilator was gently advanced over-the-needle into the LA and the needle was replaced with the same J-shaped guidewire, which was introduced deep into the left superior pulmonary vein (LSPV). At this point the Swartz sheath with a dilator was retracted and replaced with the steerable FlexCath Advance (Medtronic) sheath with a dilator, advancing them over-the-wire into the LSPV. After retracting the dilator with the guidewire, a cryoballoon with an inner lumen mapping catheter (Achieve, Medtronic) was introduced into the vein.

In the no-exchange group, after placing the long J-shaped guidewire in the desired position in SVC, the FlexCath Advance sheath with the dilator was introduced over-the-wire. Next, the sheath was slightly flexed to achieve an approximately 20–30 degree curve. After replacing the guidewire with a 89 cm transseptal needle (BRK, Abbott) and removing the protective stylet, the assembly was rotated to 4–5 o'clock position (Figure 2A) and slowly retracted into the desired position in the LA (Figure 2B), similarly to the standard approach. After confirming the correct position, the needle was advanced outside the dilator (Figure 2C). LA access was confirmed with contrast injection and the assembly was gently advanced over-the-needle into the LA. The sheath was then disconnected from the dilator and slightly advanced further over-the-dilator into the desired position near LSPV. The dilator with the

needle was slowly retracted and replaced with the cryoballoon with an inner lumen mapping catheter (Achieve, Medtronic) that was placed in the LSPV (Figure 2D).

Unfractionated heparin was administered immediately after confirming successful TSP (approximately 120 IU/kg to reach a target activated clotting time of above 300 seconds). Rigorous flushing of the equipment was ensured throughout the procedure in both groups.

Ablation procedure

The standard cryoballoon ablation protocol for PVI used in our center aimed to achieve a target temperature of –40°C to –60°C with a 240 seconds application time in each vein. If the temperature dropped below –60°C the application was terminated and the balloon was repositioned. In case of an early isolation (defined as time to isolation below 60 seconds) or reaching a target temperature of –40°C or below before 60 seconds of application the cryoablation time was reduced to 180 seconds. In case of failure to reach the designated temperature goals the balloon was repositioned for a bonus freeze. All cryoablations were performed using the 28 mm cryoballoon. The isolation was confirmed with the Achieve catheter during and after the freeze. Diaphragm function was monitored with phrenic nerve stimulation during applications in the right PVs. Hemostasis after the procedure was achieved using a figure-of-eight suture. After the procedure all patients underwent transthoracic echocardiography in order to rule out pericardial effusion. All of the procedures were performed with conscious sedation.

Study protocol

Feasibility, efficacy and safety of a no-exchange approach with a direct transseptal puncture using a 15F deflectable sheath (FlexCath Advance) compared to the standard approach with sheath exchange were analyzed. We compared the number of complications, total procedure time (defined as the time from obtaining a venous access to sheath removal), LA dwell time (defined as the time from successful transseptal puncture to retraction of sheaths and catheters from the LA) and total fluoroscopy time in each group. Complications during the procedure were categorized as TSP-related and procedure-related.

Statistical analysis

Statistical analyses were performed with the RStudio software. The normality of distribution was verified with the Shapiro–Wilk test. The patients were divided into two groups depending on the procedure approach (standard vs. direct). A comparison between these two groups was

performed using the Wilcoxon rank-sum test, χ^2 test or Fisher's exact test (if any expected count was <5), depending on the data type. For the binary outcomes, such as complications, odds ratios were calculated. A *P*-value below 0.05 was considered significant. The continuous variables data was presented as median (interquartile range), and categorical variables data was presented as percentages.

RESULTS

Between July 2019 and August 2022 124 patients were enrolled and assigned to the standard approach group (n = 62) or the direct approach group (n = 62). All patients who consented to participate in the study were included. The baseline characteristics of both groups are shown in Table 1.

The TSP was successfully performed in all patients. The median (interquartile range [IQR]) nadir temperature, freeze time per vein and total application times were –49°C (–46 to –53°C), 240 s (180–240 s) and 840 s (726.5–900 s) in the no-exchange group and –49°C (–46 to –53°C), 240 s (180–240 s) and 875 s (780–903.75 s) in the standard approach group, respectively. Only 2 potentially TSP-related complications have occurred — one ST-segment elevation in inferior leads after sheath exchange in the standard-approach group and one pericardial effusion occurring <1 hour after the procedure in the direct-approach group. Four minor vascular access-related complications have occurred (defined as any hematoma that did not require prolonged hospital stay or additional medical intervention beyond prolonged compression) - all in the standard approach group. Overall complication rate was higher in the standard approach compared to the direct approach group (9 vs. 2; odds ratio, 5.09; *P* = 0.04)

The median (IQR) procedure time and LA dwell time were significantly shorter (75.0 [60.0–90.0] min vs. 80.5 [70.0–100.0] min; *P* = 0.02 and 47 (40.0–56.0) min vs. 51.5 (43.25–64.5) min; *P* = 0.04 , respectively) in the direct approach compared to the standard approach group, while the median (IQR) fluoroscopy time was similar (14.0 [8.5–20.4] min vs. 12.25 [10.0–17.6] min; *P* = 0.74). Procedural characteristics are shown in Table 2.

DISCUSSION

In our study we assessed the feasibility, efficacy and safety of a zero-exchange workflow with a transseptal puncture performed directly through a steerable 15F deflectable sheath (FlexCath Advance) compared to the standard approach requiring sheath exchange during cryoballoon ablation for pulmonary vein isolation in patients with symptomatic atrial fibrillation (Figure 3).

An over-the-needle approach for CBA was previously described to be feasible and safe under TEE guidance [6]. The use of a dedicated system (FlexCath Cross, Medtronic) for a zero-exchange workflow under intracardiac echocardiography guidance has also been described [7], however it requires additional equipment and further increases the procedure complexity and costs. Other data regarding the zero-exchange approach for CBA is scarce [8, 9], however similar studies investigating this approach for pulse field ablation are available [10, 11].

In our study, the success rate of the TSP was 100% in both groups. Ultrasound guidance for vascular access was used in 28.22 % of patients (27.41% in the standard approach group and 29.03% in the no-exchange group). TEE guidance was required in only 2 patients (one in the no-exchange group due to multiple unsuccessful TSP attempts under fluoroscopy guidance and one in the standard approach group due to an aortic aneurysm). Although repeat LA catheterization after previous PVI procedure is a known risk factor for challenging TSP [12] [13, 14] no issues were reported in redo procedures in either group. Procedures in both groups were performed by highly experienced operators (defined as >200 TSP performed) as well as trainees (defined as <50 TSP performed). Trainees performed 33.87% of the procedures in the no-exchange group and 20.98% of the procedures in the standard approach group ($P = 0.16$).

The rate of serious complications was 1.6 % with an overall complication rate of 8.9% (8.8% in the trainees subgroup and 8.9% in experienced operators subgroup; $P = 1.00$), consistent with previously published data [15, 16]. Their distribution between groups was uneven, with a significantly higher rate in the standard approach group. However, most of the complications were not related to the TSP (hemoptysis, phrenic nerve palsy, groin hematoma). The three cases of hemoptysis were most likely caused by mechanical trauma to the vascular wall due to excessive advancement of the guidewire into the vein. This conclusion is supported by the fact that ACT levels, nadir temperatures, and total application times were within the median range.

Only one potentially TSP-related complication has occurred in each group - in the standard approach group a case of an asymptomatic transient ST-segment elevation after sheath exchange and in the no-exchange group a case of a pericardial effusion occurring after the end of the procedure. The association between TSP and above complications is not clear. The suggested mechanism for the transient ST-segment elevation includes air embolism, thromboembolism and most commonly a vasospasm secondary to the stimulation of the paraseptal ganglionated plexi located in this region [17, 18]. Delayed pericardial effusion could potentially be associated with TSP, but it may also be a result of an inflammatory response to a thermal injury to adjacent tissues (such as pericardium) [19, 20].

In our study the mean total procedure time was significantly shorter in the no-exchange compared to the standard approach group, which could potentially lower the risk of thromboembolic complications [21]. Those results differ from the data published by Ströker et al. [6], where no significant difference in total procedure time was observed between two groups. However, the data published by Yap et al. [7] aligns with our findings, with lower procedure times in the zero-exchange group. The total fluoroscopy time did not differ between two groups, comparable to the previous studies [6, 7]. The LA dwell time was significantly shorter in the no-exchange group.

The main limitation of this study is the relatively low number of patients included, which makes it most likely underpowered for an adequate comparison of the complication rates. Moreover, only univariate analyses were performed. Despite that, there was no signal of increase in complications in the investigated approach. The lack of randomization may have introduced bias in patient selection for the investigation versus control arms, as well as in the allocation of patients to experienced versus non-experienced operators.. Although variations in operators' experience could have affected procedure times, this approach has been shown to be viable even for electrophysiologists in training. Larger studies are required for a proper comparison of the complication rates.

To our best knowledge, this is the first study evaluating an over-the-needle, zero-exchange approach for CBA using fluoroscopy guidance only and thus eliminating the need for engaging an echocardiographist, improving patient comfort, further simplifying the workflow and lowering the overall cost of the procedure.

CONCLUSION

The direct-approach TSP is a feasible and safe alternative to the standard-approach TSP during cryoballoon ablation for PVI and can further shorten the procedure time, lower the costs and eliminate the risk of potential exchange related complications.

Article information

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Table 1. Baseline characteristics of the patient groups

Variable	Direct approach Median (IQR)/n (%)	Standard approach Median (IQR)/n (%)	*P*-value
Age	67.0 (58.75–71.0)	67.5 (60.0–72.0)	0.56
BMI, kg/m^2	29.0 (26.37–30.19)	28.41 (27.2–30.85)	0.52
LVEF, %	60.0 (55.0–60.0)	58.0 (53.0–60.0)	0.50
Left atrium diameter, mm	43.0 (39–45.0)	42.5 (40–46.0)	0.70
Male sex	37 (59.68)	31 (50.00)	0.37
EHRA class: ● 2a ● 2b ● 3 ● 4	 11 (17.74) 19 (30.65) 32 (51.61) 0 (0)	 11 (17.74) 19 (30.65) 31 (50.00) 1 (1.61)	0.65
Redo	3 (4.84)	2 (3.23)	1
Heart failure	11 (17.74)	15 (24.19)	0.51
Hypertension	49 (79.03)	49 (79.03)	1

Diabetes	14 (22.58)	12 (19.35)	0.83
Stroke	2 (3.23)	5 (8.06)	0.27
Vascular disease	12 (19.35)	16 (25.81)	0.52
Paroxysmal AF	45 (72.58)	50 (80.65)	0.40

Abbreviations: AF, atrial fibrillation; BMI, body mass index; EHRA, European Heart Rhythm Association; IQR, interquartile range; LVEF, left ventricular ejection fraction

Table 2. Procedural characteristics

Parameter	Standard approach Median (IQR)/n (%)	No-exchange approach Median (IQR)/n (%)	*P*-value
Total procedure time, minutes	80.5 (70.0–100.0)	75.0 (60.0–90.0)	0.02
Fluoroscopy time, minutes	12.25 (10–17.6)	14.0 (8.5–20.4)	0.74
Left atrium dwell time, minutes	51.5 (43.25–64.5)	47.0 (40.0–56.0)	0.04
Complications, n (%)	9 (14.5)	2 (3.2)	0.03
Major:			
● death	0 (0)	0 (0)	
● pericardial tamponade	0 (0)	0 (0)	
● pericardial effusion not requiring pericardiocentesis	0 (0)	1 (1.6)	
● transient ST-segment elevation	1 (1.6)	0 (0)	
Minor:			
● minor groin hematoma	4 (6.5)	0 (0)	
● transient phrenic nerve palsy	1 (1.6)	1 (1.6)	

• minor hemoptysis during the procedure	3 (4.8)	0 (0)	

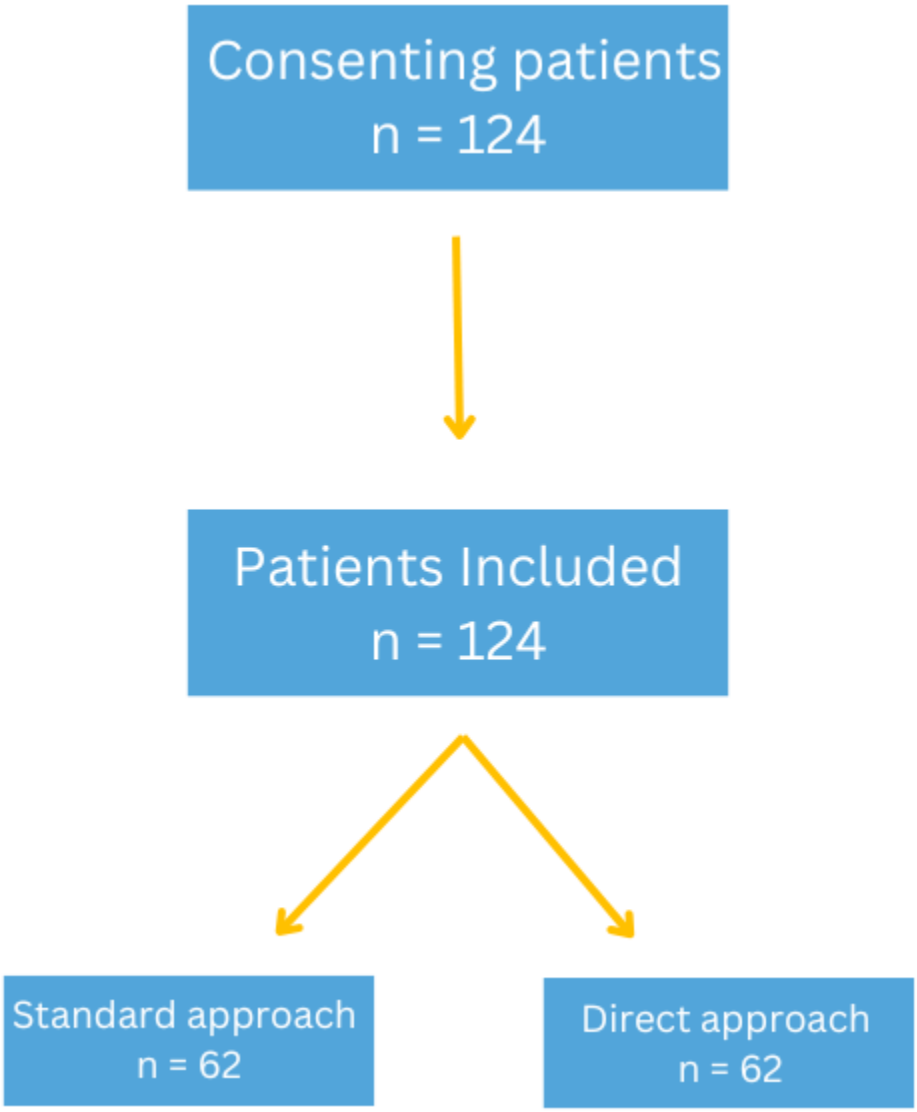

Figure 1. Patient inclusion flowchart

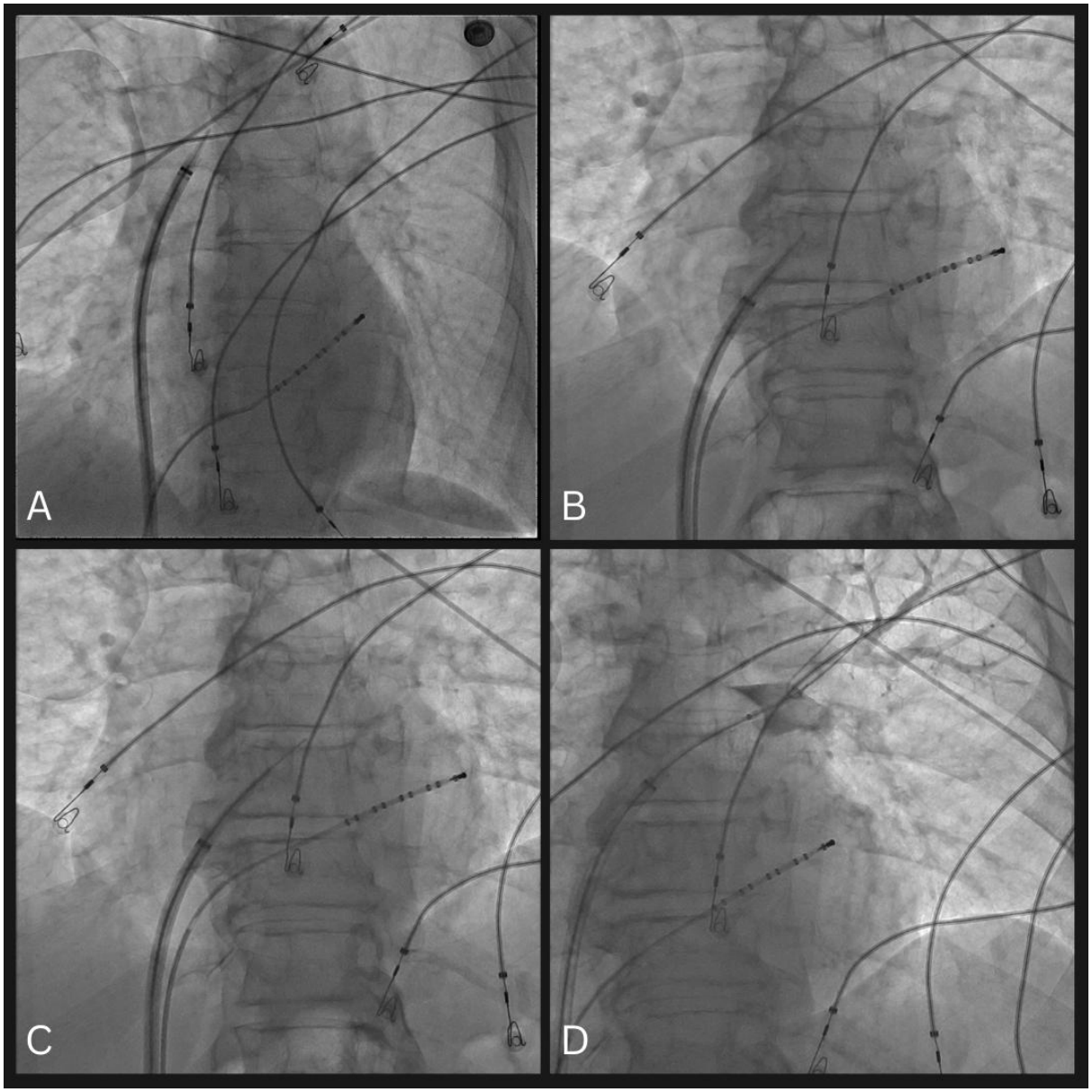

Figure 2. Fluoroscopy view of the transseptal puncture steps with a deflectable 15 F device delivery sheath (FlexCath Advance, Medtronic). **A.** Sheath is placed in the superior vena cava and flexed to approximately 30 degrees, antero-posterior view. **B.** Sheath in the desired position on the interatrial septum, 30 degree left anterior oblique (LAO) view. **C.** Needle advanced through the sheath into the left atrium, 30 degree LAO view. **D.** Selective venography of the left superior pulmonary vein after introduction of the cryoballoon, 30 degree LAO view

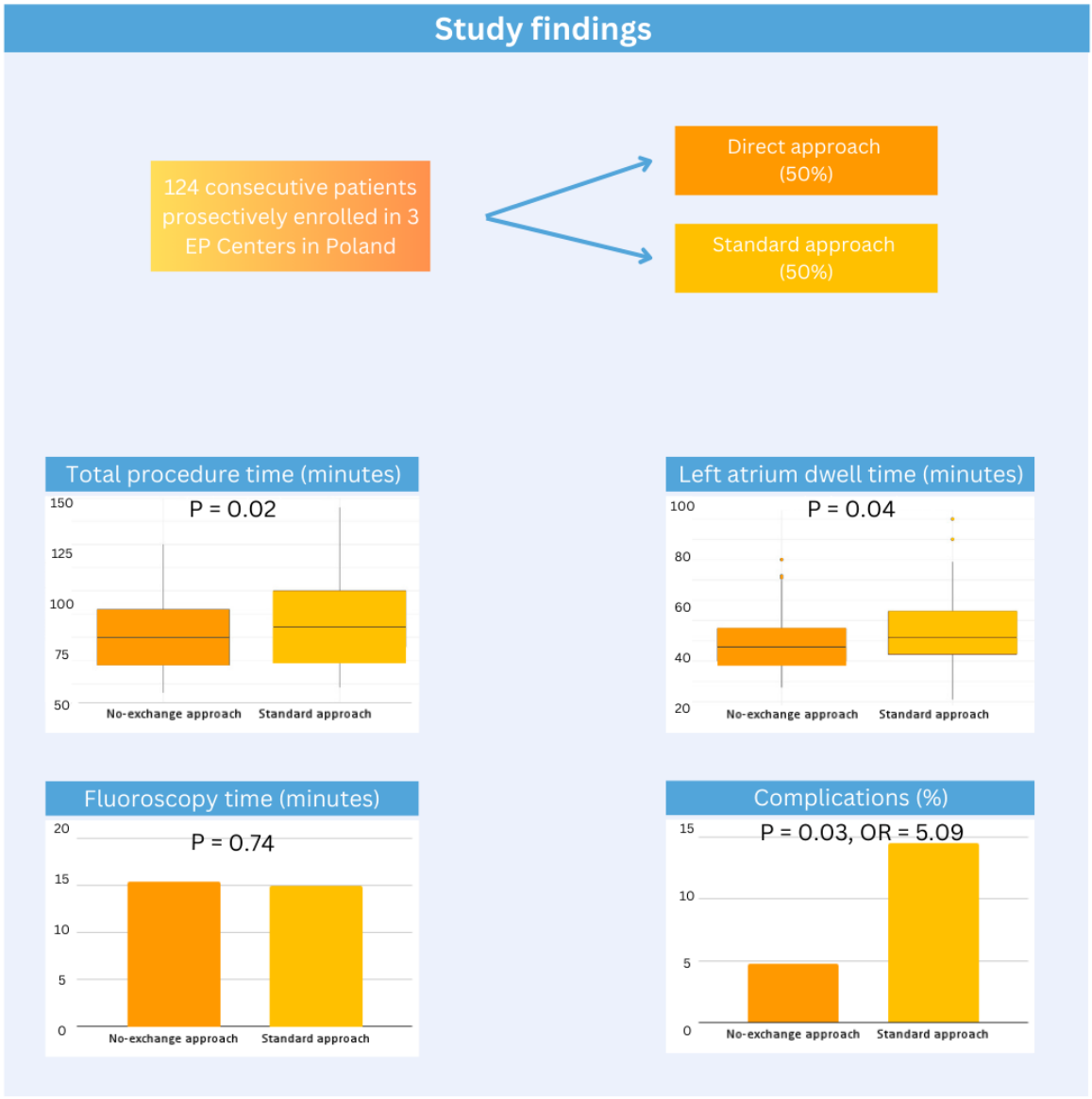

Figure 3. Central illustration