

SAFETY AND FEASIBILITY OF FLUOROSCOPY-GUIDED TRANSSEPTAL PUNCTURE DURING CRYOBALLOON ABLATION FOR PAROXYSMAL ATRIAL FIBRILLATION: A SINGLE-CENTER DESCRIPTIVE STUDY

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Cryoballoon pulmonary vein isolation (PVI) is an established rhythm-control strategy for atrial fibrillation (AF), with transseptal puncture (TSP) typically guided by transesophageal or intracardiac echocardiography to optimize safety and accuracy. However, in resource-constrained settings, transseptal puncture is frequently performed using fluoroscopic guidance alone, despite the limited evidence regarding its safety and efficacy. This study evaluated the procedure-related safety and efficacy of fluoroscopy-guided TSP in 24 patients with paroxysmal AF undergoing first-time cryoballoon ablation at the Vietnam National Heart Institute, Bach Mai Hospital between November 2023 and August 2025. All TSP procedures were successfully completed without complications. The mean number of needle attempts was 3.2 ± 1.5 , mean fluoroscopy time was 9.2 ± 1.8 minutes, and mean TSP time was 12.0 ± 2.5 minutes. A total of 100 pulmonary veins were acutely isolated; Except for two right inferior pulmonary veins with suboptimal occlusion, which were successfully isolated using the pull-down maneuver, all remaining veins achieved optimal occlusion. At 6-month follow-up, AF recurrence occurred in one patient (4.2%), with a marked reduction in AF burden. Fluoroscopy-guided transseptal puncture alone during cryoballoon ablation for atrial fibrillation appears feasible, with high acute procedural success, a favorable 6-month atrial fibrillation recurrence rate, and no observed TSP-related complications in this preliminary cohort.

Keywords: Atrial fibrillation; Cryoballoon ablation; Transseptal puncture.

I. INTRODUCTION

Atrial fibrillation is one of the most prevalent cardiac arrhythmias, affecting approximately 1-2% of the global population. Its incidence and prevalence increase markedly with advancing age and are strongly associated with established cardiovascular risk factors, including hypertension, diabetes mellitus, and obesity. Beyond its substantial impact on

health-related quality of life, atrial fibrillation is associated with significant morbidity and mortality, particularly due to ischemic stroke and heart failure. Cryoballoon-based pulmonary vein isolation has emerged as an effective interventional strategy for the management of atrial fibrillation. Accumulating evidence from randomized controlled trials and real-world studies has demonstrated that this technique is non-inferior to conventional radiofrequency ablation in patients with both paroxysmal and persistent AF.¹⁻³

Transseptal puncture during cryoballoon pulmonary vein isolation is commonly

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guided by transesophageal or intracardiac echocardiography to optimize puncture site selection, facilitate subsequent procedural steps, and minimize the risk of complications.⁴⁻⁵ However, these imaging modalities increase costs, prolong procedure time, require expertise and additional equipment. In many centers, particularly in developing countries, fluoroscopy-guided transeptal puncture remains widely used due to its feasibility and cost-effectiveness. Nevertheless, evidence regarding the safety and efficacy of this technique during cryoballoon ablation for atrial fibrillation remains scarce.

This study aims to describe a fluoroscopy-guided standardized transeptal puncture protocol at our center and evaluate its safety, acute procedural success and 6-month arrhythmia outcome in patients undergoing first-time cryoballoon ablation for paroxysmal AF.

II. METHOD

1. Study population

A descriptive study consecutively enrolled patients aged 18-80 years with paroxysmal atrial fibrillation (defined as AF terminating spontaneously or with intervention within 7 days of onset) undergoing first-time cryoballoon pulmonary vein isolation at the National Heart Institute - Bach Mai Hospital between November 2023 and August 2025. Exclusion criteria included prior AF ablation, cardiac surgery within 3 months, valvular atrial fibrillation, congenital

septal abnormalities, intracardiac thrombus, severe renal impairment (eGFR <30 mL/min), inability to complete follow-up, contraindications to anticoagulation, and contraindications to general anesthesia. This study represents a preliminary single-center experience and included all consecutive eligible patients during the study period. All procedures were performed using fluoroscopy-guided transeptal puncture without adjunctive transesophageal or intracardiac echocardiographic guidance.

2. Transeptal puncture procedure

All procedures were performed under general anesthesia. The needle used for atrial septal puncture is BRK needle (St.Judes Medical). The standard adult BRK needle has a 19° angle between the distal curved part and the needle shaft, while the adult BRK-1 needle has 53° angle, offering increased curvature. The proximal end has a flange with an arrow that points towards the needle tip. BRK needles can be used with a variety of sheaths. We routinely used the Swartz SL sheath series with an 8-Fr inner diameter, offering multiple distal curve configurations to accommodate variations in atrial anatomy.

Step 1 (establishing anatomical landmarks): A diagnostic catheter was positioned in the coronary sinus via either the femoral vein or the left subclavian vein. A 0.014-inch guidewire was advanced via the radial artery into the non-coronary cusp, serving as a fluoroscopic landmark for the aortic root.

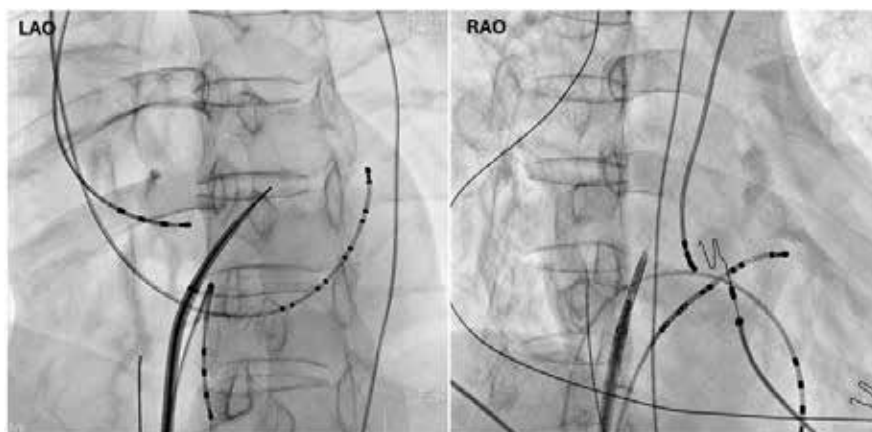


Figure 1. Catheters positioned in the coronary sinus and the non-coronary sinus of aortic root as anatomical landmarks

Step 2 (advancing the transseptal system to the superior vena cava): An SL sheath was advanced from the right femoral vein over a 0.032-inch guidewire into the superior vena cava, then exchanged for a BRK transseptal needle.

Step 3 (withdrawal to the right atrium): The system was slowly withdrawn into the right atrium with the needle oriented at 4-5 o'clock (or 6 o'clock for a more posterior puncture site). During withdrawal, two characteristic dilator "jumps" were typically observed: entry into the right atrium and engagement of the fossa ovalis after crossing its limbus.⁶

Step 4 (confirmation of fossa ovalis position): In the RAO view, the puncture site was located posteroinferior to the aortic valve (marked by the guidewire) at a distance of approximately 1-3 cm (≈ 0.5 -1 vertebral body), and posterosuperior to the coronary sinus ostium. In the LAO view, the transseptal system was positioned centrally, between the coronary sinus catheter and the aortic root guidewire.^{7,8} The transseptal system was aligned parallel to the coronary sinus catheter in both RAO and LAO views-corresponding to the plane of the coronary sinus and the posterior left atrial wall-to minimize the risk of posterior wall perforation.

In the RAO 30-40° projection, the interatrial septum was visualized en face. The transseptal assembly was slightly rotated anteriorly or posteriorly to achieve a tip orientation perpendicular to the interatrial septum, maintaining a vertical position without anterior or posterior deviation.⁷⁻⁹

Septal staining with 1-2 mL of contrast injected through the needle may be used to delineate the fossa ovalis.^{6,10}

Step 5 (septal puncture): Once the dilator tip is confirmed at the fossa ovalis, the needle is advanced through the septum under LAO view. Successful puncture is indicated by a sudden loss of resistance, with confirmation by aspiration of oxygenated blood and/or contrast injection into the left atrium. After left atrial entry, the needle is stabilized while the sheath and dilator are advanced over it into the left atrium. The needle and dilator are then withdrawn and replaced with a 0.032-inch guidewire.

Cryoballoon pulmonary vein isolation procedure

A 15-Fr steerable sheath (FlexCath Advance, Medtronic) was advanced over a guidewire across the transseptal puncture into the left atrium. A circular mapping catheter (Achieve,

Medtronic) was sequentially advanced in each pulmonary vein. A 28-mm cryoballoon (Arctic Front Advance™, Medtronic) was then inflated and positioned at the pulmonary vein ostium. The degree of pulmonary vein occlusion was assessed by contrast injection through the central lumen of the balloon and semiquantitatively classified according to the amount of leakage of contrast medium through the gap between the cryoballoon and pulmonary vein ostium.¹¹⁻¹³

- Grade 4 (complete occlusion): full retention of contrast medium without visible outflow

- Grade 3 (near-complete occlusion): minimal residual contrast leakage

- Grade 2 (partial occlusion): delayed and moderate contrast backflow into the left atrium

- Grade 1 (poor occlusion): immediate and large contrast backflow into the left atrium

We aimed to achieve a pulmonary vein occlusion grade (OG) of 3 or higher to ensure durable isolation.¹⁴ Once optimal occlusion was documented, cryothermal energy was delivered. All procedures were performed with a single 3-minute application for each vein. A second freeze was delivered in case of (1) no isolation after the first cycle or (2) spontaneous pulmonary vein reconnection occurrence.

In case of a massive leakage of contrast medium through the inferior aspect between the cryoballoon and pulmonary vein despite multiple FlexCath adjustments, a “pull-down” maneuver was performed to improve the OG. The “pulldown” maneuver was performed as follows: first, we tried to advance the cryoballoon on the superior aspect of the pulmonary vein and started freezing with a massive leakage at the inferior aspect of the pulmonary vein. Immediately after starting the freezing, we continuously and very slowly injected contrast medium through the central lumen of the cryoballoon to prevent

blood frozen in that lumen. The cryoballoon and FlexCath were pulled down in order to close the inferior gap when the cryoballoon temperature reached -10 °C.¹⁴

During cryoballoon ablation of the right-sided pulmonary veins, continuous phrenic nerve monitoring was performed to prevent phrenic nerve injury. A diagnostic catheter was positioned in the superior vena cava for continuous high-output phrenic nerve pacing (15 mA, pulse width 2 ms). Diaphragmatic contraction was continuously assessed by manual palpation of the right hemidiaphragm. Cryoablation was immediately terminated if there was a reduction in diaphragmatic excursion, and the balloon was rapidly deflated to minimize the risk of persistent phrenic nerve palsy.

Anticoagulation management

Oral anticoagulation was managed uninterrupted before the procedure. Intravenous heparin was administered immediately after transseptal puncture to maintain an activated clotting time >300 seconds during the procedure. Oral anticoagulation was continued for at least 2 months following ablation, after which the decision regarding long-term anticoagulation was individualized according to the CHA₂DS₂-VASc score.

Post-procedural follow-up

After discharge, patients were scheduled for follow-up visits at 1, 3, and 6 months, and every 6 months thereafter. Twenty-four-hour Holter monitoring was performed at 6-month intervals to assess arrhythmia recurrence. Atrial fibrillation recurrence was defined as any atrial tachyarrhythmia (atrial tachycardia, atrial fibrillation, or atrial flutter) lasting ≥30 seconds, documented on surface electrocardiography or Holter monitoring, beyond a 3-month blanking period.

Outcomes

The primary endpoint was the rate of successful fluoroscopy-guided transseptal puncture without major TSP-related complications. Secondary endpoints included the number of needle passes, transseptal puncture time, fluoroscopy time, acute procedural success of pulmonary vein isolation, and atrial fibrillation recurrence at 6-month follow-up.

Statistical analysis

Comparisons of continuous variables were performed using the Student's *t*-test or Mann-Whitney U test. Categorical variables were compared using the χ^2 test or Fisher's exact

test. A two-sided *p* value < 0.05 was considered statistically significant. All analyses were conducted using STATA version 16.

3. Ethics statement

The study was approved by the Institutional Review Board of Hanoi Medical University (Approval No. HMUIRB953; October 18, 2023). Written informed consent was obtained from all patients prior to enrollment.

III. RESULT

A total of 24 patients were enrolled in the study. Baseline characteristics of the study population are summarized in Table 1.

Table 1. Baseline characteristics of the study population

Characteristics	Result
Age (year)	61.5 ± 10.7
Male, n (%)	13 (54.2%)
Comorbidities, n (%):	
Hypertension	10 (41.7%)
Coronary artery disease	1 (4.2%)
Heart failure	2 (8.3%)
Diabetes Mellitus	5 (20.8%)
Dyslipidemia	4 (16.7%)
Thromboembolic risk (CHA ₂ DS ₂ -VASc score), n (%)	
High	16 (66.7%)
Low	8 (33.3%)
Bleeding risk (HAS-BLED score), n (%)	
High	0
Low	24 (100%)
Echocardiography	
LA diameter (mm)	35.0 ± 6.1
LA volume index	32.8 ± 8.2
LVEF (%)	64.3 ± 6.0

Characteristics	Result
Number of left pulmonary vein, n (%)	
2	23 (95.8%)
3	1 (4.2%)
Number of right pulmonary vein, n (%)	
2	21 (87.5%)
3	3 (12.5%)
Common trunk, n (%)	
Right	2 (8.3%)
Left	0

LA = left atrium; LVEF = left ventricular ejection fraction

The procedural parameters of transeptal puncture are presented in Table 2. Fluoroscopy-guided transeptal puncture was successfully performed in all patients. Four patients developed minor hematoma at the vascular

access site; however, no major complications were observed, including pseudoaneurysm, arteriovenous fistula, aortic root puncture, pericardial effusion, thromboembolic events, or acute myocardial infarction.

Table 2. Procedural parameters of transeptal puncture

Characteristics	Result
Number of transeptal puncture attempts	3.2 ± 1.5
Fluoroscopy time (minutes)	9.2 ± 1.8
Transeptal puncture time (minutes)	12.0 ± 2.5
Total procedure time (minutes)	120.1 ± 18.3
Total fluoroscopy time (minutes)	20.9 ± 4.6
Cryoballoon ablation time (seconds)	780.0 ± 77.1

In four cases, the long sheath required repositioning to the superior vena cava with repeat withdrawal to the fossa ovalis. These patients also exhibited the longest fluoroscopy time, transeptal puncture time, and the highest number of needle passes (see supplementary data). Compared with patients in whom

transeptal access was achieved on the first attempt, this subgroup had a significantly greater left atrial diameter and volume. Given the very small number of patients in this subgroup, these findings should be considered exploratory and hypothesis-generating only.

Table 3. Comparison of left atrial size between patients requiring repeated TSP assembly withdrawal and those with successful transeptal access at first withdrawal

	Successful at first withdrawn (n = 20)	Required repeated withdrawn (n = 4)	p value*
Left atrial diameter (mm)	32.7 ± 2.7	46.5 ± 1.7	< 0.001
Left atrial volume (mm)	31.1 ± 5.5	41.0 ± 1.4	0.01

* Mann-Whitney U test

A total of 100 pulmonary veins were targeted in 24 patients, including 49 right-sided and 51 left-sided veins. Complete pulmonary vein

isolation, confirmed by both entrance and exit block, was successfully achieved in all veins.

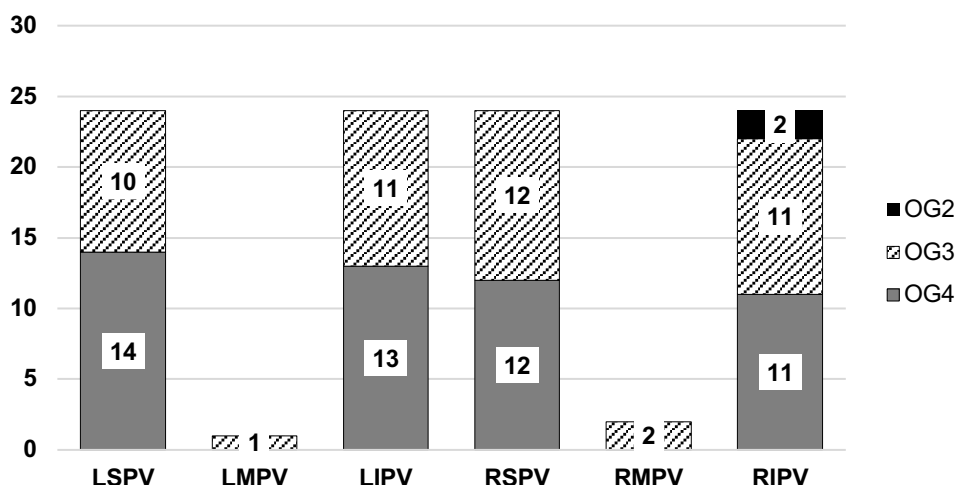


Figure 2. Distribution of pulmonary vein occlusion grades by vein group. LSPV, left superior cpulmonary vein; LMPV, left middle pulmonary vein; LIPV, left inferior pulmonary vein; RSPV, right superior pulmonary vein; RMPV, right middle pulmonary vein; RIPV, right inferior pulmonary vein; OG, occlusion grade

Except for two right inferior pulmonary veins with suboptimal occlusion (grade 2), all other veins achieved an occlusion grade ≥ 3. In these two cases, contrast leakage was observed at the inferior aspect of the vein; a pull-down maneuver was performed, resulting in successful isolation. At 6-month follow-up, atrial fibrillation recurrence was observed in one patient; however, the atrial fibrillation burden was markedly reduced compared with baseline.

Notably, this patient had achieved optimal occlusion in all four pulmonary veins during the index procedure. This was also a technically challenging transeptal puncture due to left atrial enlargement (left atrial diameter 44 mm and volume 39 mL), requiring withdrawal of the transeptal assembly from the superior vena cava into the right atrium to facilitate optimal septal engagement.

IV. DISCUSSION

Factors that may complicate transseptal puncture can be broadly categorized into two groups: (1) factors that alter the anatomical position of the fossa ovalis, such as right or left atrial enlargement, aortic root dilatation, and severe spinal deformity; (2) factors that increase resistance to septal crossing, including a thickened or aneurysmal interatrial septum.^{10,15-17} Our findings are consistent with this observation, as patients requiring repositioning of the transseptal system exhibited significantly larger left atrial diameter and volume.

Transesophageal and intracardiac echocardiography play an important role in guiding transseptal puncture. These imaging modalities enable real-time visualization of the interatrial septum and precise localization of the fossa ovalis, thereby facilitating optimal puncture site selection, minimizing the risk of injury to adjacent structures such as the aortic root and posterior left atrial wall, and allowing early recognition of complications-particularly in patients with left atrial enlargement or complex septal anatomy.

In cryoballoon pulmonary vein isolation, the selection of an optimal transseptal puncture site is considered an important determinant of procedural success. Several authors have suggested that an anteroinferior puncture at the fossa ovalis facilitates access to the pulmonary veins and improves balloon-vein contact, particularly for the right inferior pulmonary vein, thereby enhancing isolation efficacy.^{10,18} However, findings from Erden et al indicate that although TEE-guided transseptal puncture may facilitate right inferior pulmonary vein ablation - reflected by shorter ablation time, fewer applications, and reduced overall procedure and fluoroscopy time - it does not significantly improve acute isolation rates or atrial fibrillation

recurrence compared with fluoroscopy-guided puncture alone.⁵ Similarly, Chierchia et al demonstrated that the puncture location within the fossa ovalis (anterior, mid, or posterior) as defined by TEE, was not associated with differences in acute procedural success or 12-month arrhythmia recurrence.¹⁹

The authors suggested that good catheter manipulation may facilitate optimal pulmonary vein occlusion (OG), thereby enhancing procedural efficacy despite a non-ideal transseptal puncture site. Furthermore, adjunctive techniques such as the pull-down maneuver may improve balloon-to-pulmonary vein contact and enable pulmonary vein isolation even in cases with suboptimal initial occlusion grade. These findings may partly account for the results observed in our study. In our study, although the transseptal puncture site within the fossa ovalis was not precisely localized, all pulmonary veins were acutely successfully isolated. Two right inferior pulmonary veins with suboptimal occlusion (grade 2) were successfully isolated using the pull-down maneuver, with no recurrence observed at follow-up.

However, given the strong evidence supporting the safety and efficacy of TEE and ICE, they should remain as preferred methods for patients with complex septal anatomy, such as markedly enlarged atrium, prior septal intervention, or anticipated technical difficulty. Fluoroscopy-only TSP may be considered in carefully selected patients when performed by experienced operators using strict anatomical landmarks.

LIMITATIONS

Our study was a single-center descriptive study without a control group for comparison with transseptal puncture guided by transesophageal or intracardiac echocardiography. In addition,

AF recurrence was assessed using scheduled ECG and 24-hour Holter monitoring, which may have underestimated asymptomatic or intermittent AF episodes. Therefore, the reported 6-month recurrence rate should be interpreted with caution.

CONCLUSION

Fluoroscopy-guided transseptal puncture alone during cryoballoon ablation for atrial fibrillation appears feasible, with high acute procedural success, a favorable 6-month atrial fibrillation recurrence rate, and no major TSP-related complication in this preliminary cohort. The application of adjunctive techniques, such as pulldown maneuver may help overcome technical challenges and enhance the efficacy of cryoballoon ablation using fluoroscopy-guided transseptal puncture alone. Fluoroscopy-guided TSP may be a practical alternative in carefully selected patients when performed by experienced operators, particularly in centers where transesophageal or intracardiac echocardiography is not routinely available, provided that strict adherence to anatomical landmarks and procedural principles is maintained. However, larger multicenter prospective comparative studies with longer follow-up and systematic rhythm monitoring are warranted to further evaluate its safety and efficacy.

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