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Safety and efficacy of zero fluoroscopy transseptal puncture with different approaches

Tina Baykaner, MD, MPH¹, Kenneth K. Quadros, MBBS, MSc², Amit Thosani, MD³, Babak Yasmeh, MD⁵, Raman Mitra, MD, PhD⁴, Emerson Liu, MD³, William Belden, MD³, Zhigang Liu⁵, Alex Costea, MD⁵, Chad R. Brodt, MD¹, Paul C. Zei, MD, PhD⁶

¹Department of Medicine, Stanford University, Stanford, California

²Department of Medicine, Brigham and Women's Hospital, Boston, Massachusetts

³Cardiovascular Institute, Allegheny Health Network, Pittsburgh, Pennsylvania

⁴Department of Medicine, Beacon Health System, South Bend, Indiana

⁵Department of Medicine, University of Cincinnati, Cincinnati, Ohio

⁶Department of Medicine, Brigham and Women's Hospital, Boston, Massachusetts

Abstract

Introduction—Atrial fibrillation (AF) ablation requires access to the left atrium (LA) via transseptal puncture (TP). TP is traditionally performed with fluoroscopic guidance. Use of intracardiac echocardiography (ICE) and three-dimensional mapping allows for zero fluoroscopy TP.

Objective—To demonstrate safety and efficacy of zero fluoroscopy TP using multiple procedural approaches.

Methods—Patients undergoing AF ablation between January 2015 and November 2017 at five institutions were included. ICE and three-dimensional mapping were used for sheath positioning and TP. Variable technical approaches were used across centers including placement of J wire in the superior vena cava with ICE guidance followed by dragging down the transseptal sheath into the interatrial septum, or guiding the transseptal sheath directly to the interatrial septum by localizing the ablation catheter with three-dimensional mapping and replacing it with the transseptal needle once in position. In patients with pacemaker/implantable cardiac defibrillator leads, pre-/poststudy device interrogation was performed.

Results—A total of 747 TPs were performed (646 patients, age 63.1 ± 13.1 , 67.5% male, LA volume index 34.5 ± 15.8 mL/m², ejection fraction $57.7 \pm 10.9\%$) with 100% success. No punctures required fluoroscopy. Two pericardial effusions, two pericardial tamponades requiring pericardiocentesis, and one transient ischemic attack were observed during the overall ablation procedure, with a total complication rate of 0.7%. There were no other periprocedural

Correspondence: Tina Baykaner, MD, MPH, Department of Cardiovascular Medicine, Stanford University, Stanford, CA 94305. tina4@stanford.edu.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

complications related to TP, including intrathoracic bleeding, stroke, or death both immediately following TP and within 30 days of the procedure. In patients with intracardiac devices, no device-related complications were observed.

Conclusion—TP can be safely and effectively performed without the need for fluoroscopy.

Keywords

fluoroscopy reduction; low fluoroscopy; transseptal puncture; zero-fluoroscopy

1 | INTRODUCTION

Catheter ablation for atrial fibrillation (AF), atrial tachycardia, and ventricular arrhythmias are commonly performed procedures,^{1–3} often requiring access to the left atrium (LA) and ventricle. By far, the most common method to gain access to the LA is through a transseptal puncture (TP) procedure of the thin, membranous interatrial septum using an appropriately shaped needle under fluoroscopic guidance to allow passage of a sheath, through which a mapping and/or ablation catheter is advanced into the LA.

TP techniques were first described in 1959 by Ross and Cope.^{4,5} In the originally described technique, a combination of fluoroscopic landmarks and hemodynamic monitoring was used to ensure proper localization of the interatrial septum and proper and safe access to the LA. Iodinated contrast injection under fluoroscopy has been used by some operators to further ensure correct access to the LA. This original technique had been utilized by most operators for many years. The development and introduction of phased array intracardiac echocardiography (ICE)⁶ created an additional modality for imaging intracardiac structures in real time. With further refinement in the ICE image quality, catheter maneuverability, and three-dimensional electroanatomic mapping (EAM) integration, a more detailed and consistent visualization of intracardiac structures has been achieved. This in turn has enabled increased reliance on ICE imaging to guide catheter and other instrument maneuvering during complex ablation or other procedures.

The increasing utilization, sophistication, and anatomic accuracy of EAM systems, as well as contact force sensing technology, have contributed to the progressive trend toward diminished fluoroscopy use. To date, there have not been systematic reports of the safety and efficacy of TP without fluoroscopy. Several groups have reported single-operator or single-institution case series demonstrating safe and effective AF and other left-sided procedures with minimal or no fluoroscopy.^{7–9} Some of these approaches have used specific systems that enable integration of fluoroscopic images with EAM¹⁰ to reduce the use of fluoroscopy. In this multi-center study, we hypothesized that TP could be performed safely and effectively without fluoroscopy, primarily guided by intracardiac ultrasound, using a variety of techniques and tools by multiple operators.

2 | METHODS

Retrospective analysis included consecutive patients undergoing AF ablation between January 2015 and November 2017 at five institutions. The institutions included both

academic teaching and private hospitals, with multiple operators at each institution. All institutions were high-volume centers (>500 TP per year) with adoption of a reduced fluoroscopy work-flow for ablation procedures. The study protocol was approved by each local Institutional Review Board. Patients with cardiac implantable electronic device (CIED) leads placed or revised within 3 months of ablation procedure were excluded. After informed consent, patients were placed under general anesthesia (GA). Patients were monitored for adverse outcomes from the time of procedure up to 30 days postoperatively. Descriptive statistics are provided in the form of mean and standard deviation for normally distributed variables, median and interquartile range (IQR) otherwise.

2.1 | TP workflow

Vascular access via the femoral venous system is obtained using a modified Seldinger technique, typically guided by ultrasound visualization, without fluoroscopy. In institutions performing two TPs routinely, a total of four femoral sheaths were introduced (7F, 8.5F, 8.5F, and 9F), and in institutions performing a single TP, three femoral sheaths were introduced (7F, 8.5F, and 9F). An intracardiac ultrasound (ICE) catheter was then advanced into the right atrium (RA) without fluoroscopy, using tactile feedback and ICE images to visualize the venous system during advancement of the catheter without resistance. The interatrial septum and key left atrial structures, including the left atrial appendage, pulmonary veins, and the posterior wall of the LA, were visualized on ICE.

Before advancing the J-tip wire and the long sheath to the RA, a clear view of the superior vena cava (SVC) is routinely obtained by retroflexing and applying clockwise rotation to the ICE catheter.

In all centers, heparin was administered following vascular access and prior to TP, to aim for an ACT of >300 s. In cases with failed transseptal LA access with mechanical attempts using the BRK-1 needle, monopolar radiofrequency (RF) energy using bovie set to *cut* at 10–20 W was applied to the proximal needle handle of the BRK™ needle. In patients with indwelling pacing and/or defibrillator leads, a baseline device interrogation is obtained. If a SOUNDSTAR® ICE catheter (Biosense Webster, CA) is employed, the leads are traced at the beginning of the study, with close attention to the RA lead loop and position relative to the interatrial septum. The course of the leads is then maintained on the electroanatomic map during catheter manipulation. During the TP, lead visualization is performed through ICE, rather than fluoroscopy. At the conclusion of the procedure, visualization of lead position via ICE and a final device interrogation are performed to assess for any changes, possibly due to either TP or catheter manipulation during the procedure.

2.2 | Description of each TP technique utilized

Two different technical approaches for TP are described below and shown in the Figure 1 and examples of individual steps are shown in the Supporting Information Video.

1. Method 1

Following femoral venous access with the US guidance, an ICE catheter is advanced into the RA with direct visualization of the vascular lumen at all times, and if SOUNDSTAR/® ICE

catheter is used, with additional visualization of an upright position of the catheter tip on EAM. Prior to advancement of any long wires and sheaths, a mapping and ablation catheter is advanced through the short femoral venous sheath into the RA, where a detailed electroanatomic map is created to visualize the RA and coronary sinus (CS) anatomy. A decapolar catheter (Polaris X™, Boston Scientific, MA) is then advanced into the RA without fluoroscopy, visualized with EAM, and guided into the CS. An alternative to this sequence was advancing a decapolar catheter (DECANAV®, Biosense Webster, CA) into the CS using EAM alone following femoral vascular access.

A 180-cm 0.032" J-tip wire is then advanced into the SVC under ICE guidance. Specifically, the ICE catheter is positioned to visualize the RA, tricuspid valve (TV), and a portion of the right atrial appendage (RAA). The wire is advanced into the SVC, and the RAA and TV are avoided. The ICE catheter is then manipulated into the SVC in order to visualize the wire tip. Once the wire location in the SVC is confirmed, the short venous sheath is exchanged over the wire for a long transseptal sheath and dilator (SR-0 or SL-1 Fast-Cath™, Abbott, IL or TorFlex™, Baylis Medical, QC). Care is taken to visualize the sheath and dilator advancement over the wire. Once the sheath position in the SVC is confirmed, the wire is removed and an NRG® radiofrequency (Baylis, QC) or BRK™ transseptal needle is advanced just short of the dilator tip, as visualized by ICE. The sheath/dilator/needle system is then pulled down in a typical 3 to 7 o'clock position slowly while pulling down the ICE catheter in order to maintain visualization of the dilator tip. Once tenting of the interatrial septum is confirmed on ICE, the needle is advanced just beyond the dilator tip, and radiofrequency energy is delivered through a built-in cable for NRG® system or using electrocautery with the BRK needle, allowing discrete puncture across the interatrial septum with minimal forward pressure. Visualization of microbubbles in the LA is used to confirm correct left atrial access with the needle tip. Correct left atrial access is further confirmed by measurement of left atrial pressure through the needle lumen, and microbubble injection into the LA under ICE visualization. The dilator is then positioned in the mid-chamber of the LA, directed toward the anterior aspect of the LA. Advancement of the dilator and subsequently the sheath is monitored via ICE. Only when difficulty advancing either the dilator or sheath across the interatrial septum into the LA is encountered, typically due to either an excessively fibrotic or aneurysmal interatrial septum, an exchange length 0.32" J-tip Amplatz Super Stiff™ guidewire (Boston Scientific, MA) or ProTrack™ Pigtail Wire (Baylis, QC) is advanced through the dilator lumen into the LA. The guidewire is then directed into the left sided pulmonary vein (PVs) (or curled inside the LA for the pigtail wire) under ICE guidance and used as a "rail" to advance the dilator and sheath into the LA. Once correct placement of the sheath in the mid-chamber of the LA is confirmed, the dilator and needle are slowly withdrawn. The sheath is then flushed and connected to a continuous infusion line free of air bubbles. A mapping or contact force sensing ablation catheter is then advanced into the LA, with visualization of catheter exit from the sheath seen via ICE. If indicated, a second TP is then performed in a similar fashion. Existing pacing leads are directly visualized with ICE and carefully avoided throughout the transseptal procedure. In all cases, continuous ICE monitoring throughout the case for catheter dislodgement, pericardial effusion, and entrapment is performed.

1. Method 2

Following vascular access, advancement of the ICE catheter into the RA, and advancement of a long J-tip guidewire into the SVC with direct visualization on ICE, as described earlier, a steerable or nonsteerable introducer sheath (Agilis™, SL1- Fast Cath™ or SL0-Fast Cath™, Abbott, IL) is advanced over the wire into the inferior vena cava. An ablation catheter (Smart Touch SF™, F/J or D/F curve, Biosense Webster, CA) is then advanced through the sheath, and a volumetric map of the RA, SVC, and CS is made with the ablation catheter. The ablation catheter is then positioned onto the fossa ovalis under ICE guidance, followed by advancement of the sheath over the ablation catheter until mild tenting of the fossa ovalis is seen. The ablation catheter is then withdrawn with forward traction of sheath to maintain tenting of the interatrial septum by ICE, followed by advancement of dilator and BRK™ (Abbott, IL) or NRG® radiofrequency transseptal needle (Baylis, QC) together through the sheath. Once the needle is seen to tent the septum, electrocautery or RF is used to puncture the septum and LA pressure waveform is observed. The dilator is slightly advanced as the needle is removed and a 0.32" J-tip Amplatz Super Stiff™ guidewire is advanced into one of the left sided PVs before advancing the dilator and sheath into the LA under ICE guidance. The CS catheter (DECANAV®, Biosense Webster, CA) is then placed without fluoroscopy using the RA and CS geometry previously acquired with the ablation catheter.

3 | RESULTS

3.1 | Procedural features

Patient characteristics are shown in Table 1. A total of 747 TPs with no fluoroscopy were performed in 646 patients during the study period. A total of 68% of the patients had paroxysmal AF and 31% had persistent AF, with a prior history of AF ablation in 16%. All procedures were indicated for AF ablation, which composed of pulmonary vein isolation in all patients. Ablation of lines (17% with roof, 7% with mitral, and 23% with cavotricuspid isthmus), rotational activity (<1% of patients), and complex fractionated atrial electrogram (<1% of patients) were performed per provider discretion.

Three institutions routinely used a single transseptal approach, and two institutions used a double transseptal approach for their AF ablation procedures. In the centers performing double transseptal approach, second transseptal access was obtained via a separate TP. Overall n = 545 patients underwent single and n = 101 patients underwent double TP.

Outcomes are shown in Table 2. A total of 100% of patients underwent successful TP, with no punctures requiring fluoroscopy. Thirty-day follow-up revealed the following adverse events: n = 2 pericardial effusions that did not require intervention, n = 2 pericardial tamponades requiring drainage, and n = 1 transient ischemic attack (TIA).

In patients with intracardiac devices, no device-related complications were observed. Only two centers routinely used fluoroscopy, typically to confirm and document stable pacing lead positions at the conclusion of the case, or at the time of CS catheter placement in patients with indwelling LV leads. Fluoroscopy, for the remainder of the procedure, was more frequently used in patients with intracardiac devices (52.2%) compared to patients with no

intracardiac devices (11.3%, $P < .01$). In the patients without intracardiac devices, fluoroscopy was occasionally used to mark the esophagus on EAM.

3.2 | Safety of zero fluoroscopy TP

Two pericardial effusions without tamponade, two pericardial effusions with tamponade requiring pericardial drain placement, and one TIA comprised the 30-day complications in the overall cohort. In addition, 46 patients had pre-existing implanted pacing leads, and in these patients, no complications including lead dislodgement and/or degradation in lead pacing parameters were observed. All patients with implanted devices underwent pre- and postprocedure device interrogations. Notably, it is unclear whether the occurrences of pericardial effusions and/or tamponade were the direct result of the TP or occurred subsequently during left atrial mapping and/or ablation.

In patients with indwelling pacemaker or defibrillator leads, only two centers used fluoroscopy, typically to confirm and document stable pacing lead positions at the conclusion of the case, or at the time of CS catheter placement in patients with indwelling LV leads. However, in *method 2*, described in this study, lead visualization was performed entirely through ICE imaging. Avoidance of lead dislodgement and/or degradation of lead pacing/sensing parameters was confirmed in all cases with poststudy device interrogation.

4 | DISCUSSION

In this study, goal of each operator was to perform the safest, most effective TP possible. Multiple centers and operators have arrived at a zero fluoroscopy approach using ICE and EAM as it provides a very accurate and effective approach for TP. We report the safe and effective elimination of fluoroscopy from the TP procedure as part of commonly performed electrophysiology procedures. There was 100% success in achieving TP and access to the LA. Given the clear risks and adverse effects of excessive radiation exposure, reduction, if not elimination of fluoroscopy, is a reasonable goal in the field of electrophysiology. With the recent improvements in ICE and to a lesser extent EAM, TP can be safely and effectively performed entirely through ICE guidance. These observations were consistent across all participating centers, which included both academic and private institutions, with varying techniques utilized, as described, across a large number of patients. In a recent study, learning curve of reduced fluoroscopy use was assessed when it was first adopted in an academic teaching center where in just 43 procedures, median fluoroscopy time per procedure was reduced to 9 s, from 3.8 min without any significant change in total procedure time, suggesting a rapid learning curve.¹¹

There are several key steps in ICE-guided transseptal in our series that ensure safety and efficacy. These include: assessing for preexisting pericardial effusion with ICE at the beginning of the procedure, especially in patients with heart failure; visualization of a long guidewire, specifically in the SVC or use of a contact force sensing ablation catheter, which allow safe advancement of the transseptal sheath and needle into the SVC; visualization of the sheath/dilator/needle apparatus as it is dragged inferiorly from the SVC, past the aortic knob, and into the interatrial septum; visualization of the transseptal apparatus tenting the interatrial septum; the relationship of the transseptal apparatus to the left atrial walls, which

ensures a safe distance and minimizes perforation risk; pressure monitoring from the tip of the transseptal assembly; and finally visualization of the passage of the mapping or ablation catheter through the transseptal sheath into the left atrial space. In cases where it is challenging to place or visualize the guidewire in the SVC without fluoroscopy, directly placing the transseptal sheath in the fossa ovalis as mentioned in method 2 could be helpful. Each of these steps helps to ensure correct positioning of catheters, while monitoring for complications. Moreover, periodic surveillance for the development of pericardial effusion adds additional reassurance. Fluoroscopy reduction techniques highly relying upon ICE can introduce an extra cost to the ablation procedure at centers that do not use ICE routinely; we believe method 2 can easily be adopted to eliminate fluoroscopy during TP, by continuous visualization of fossa ovalis on TEE, advancement of ablation catheter to this location with the help of EAM, and advancement of the transseptal sheath and dilator system directly to the fossa ovalis. Other techniques beyond the techniques we described in this manuscript, such as visualizing the transseptal needle on EAM¹² or monitoring wire/needle potentials on the intraatrial septum,¹³ have proven safety in smaller cohorts.

It is of importance to note that our data reflect the safety of zero fluoroscopy TP for radiofrequency AF ablation, and for patients under GA. Cryoballoon ablation for AF is a widespread technology, for which the role of fluoroscopy reduction is at its early stages of investigation.^{14–16} Furthermore, GA use in all cases was solely an institutional preference, acknowledging that it is not a requirement, with known safety of zero fluoroscopy approach with conscious sedation during AF ablation.^{8,12}

Although not specifically evaluated in this study, patients with large body habitus typically require significantly higher radiation doses during fluoroscopy in order to create adequate fluoroscopic images during EP procedures.¹⁷ In this population, elimination or reduction in fluoroscopy exposure has likely added benefit. In our study population, 46 patients had indwelling permanent pacing/defibrillator leads. In this subset, fluoroscopy use was higher in the centers that used fluoroscopy to visualize leads during portions of the procedure, although in two centers, with ICE visualization of the leads, no additional fluoroscopy was required during the TP or throughout the entire procedure. Moreover, no adverse effects on lead function or position were noted.

Current fluoroscopy use has indeed decreased significantly over the past decade, likely due to a combination of factors, including development of ICE, improved EAM, contact force ablation catheters, and overall increased experience. Kalman et al has reported a steady decrease in fluoroscopy use during AF procedures over 12 years with fluoroscopy times decreasing from 61 ± 27 min to 17 ± 9 min.¹⁸ This is certainly a vast improvement but may not be as low as reasonably achievable with advances in imaging and mapping technology. Radiation exposure, to the patient, the operator, and EP lab staff, is dose dependent.¹⁹ Furthermore, in addition to the steps to reduce fluoroscopy time, fluoroscopy dose reduction methods such as beam collimation, decreasing the distance between patient and image detector, discouraging oblique projections, and others, can play an important role in decreasing radiation exposure.²⁰ Moreover, the use of lead aprons, particularly during longer procedures, exacts an orthopedic toll.^{21,22} Radiation protection cabins can allow performing

catheter ablation procedures without compromising catheter manipulation, and with negligible radiation exposure for the operator.²³

Our study provides evidence that the transseptal step in an electrophysiology procedure can be performed safely and effectively without fluoroscopy. Further studies are needed to determine whether this may be generalized to the larger EP community.

5 | LIMITATIONS

This study was a retrospective analysis subject to the biases typical of such analyses. This study did not evaluate the “learning curve” required to completely eliminate fluoroscopy during TP, as all centers and primary operators were proficient and experienced in fluoroscopy-free procedures, which creates selection bias. In addition, not all institutions have ready access to intracardiac ultrasound, which clearly adds cost to the procedure. As ICE use becomes more widespread, taking full advantage of the technology during procedures to reduce or eliminate fluoroscopy is reasonable. Patients with new CIED leads, placed within 3 months of ablation, were excluded, but the average age of existing leads was unknown due to the retrospective nature of the study. Detailed timeline during the procedure could provide insights into how much the use of zero fluoroscopy added to the total procedure time, as well as duration difference among different transseptal methods, but we did not have femoral access to TP times, or the partial fluoroscopy times up to the TP uniformly recorded in our large multi-center retrospective database. Reported complications, already very low based on historical comparators, were not clearly attributable to the TP itself. The small number of pericardial effusions reported may have resulted from the puncture, or may have been related to other portions of the procedure. Our data do not allow specific attribution.

6 | CONCLUSIONS

AF ablation is a commonly performed electrophysiology procedure that typically results in moderate to high fluoroscopy use. We demonstrate that ICE-guided TP can be safely and effectively performed without fluoroscopy and thereby, eliminates radiation exposure to the patient, operator, and staff and obviates the need for lead vests and radiation protective barriers for all individuals during the procedure.

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FIGURE 1.
Different methods of zero fluoroscopy transseptal approaches

Movie.

Different steps during transseptal puncture without fluoroscopy.

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Table 1

Baseline patient characteristics

Characteristic	Overall (n = 646)
Age (years)	63.1 ± 13.1
Male gender (%)	64.3%
Height (m)	1.74 ± 0.1
Weight (kg)	94.6 ± 24.6
Body mass index (kg/m ²)	31.7 ± 11.4
Left atrial volume index (mL/m ²)	34.5 ± 15.9
Left ventricular ejection fraction (%)	57.7 ± 10.9
Comorbid conditions (%)	
Hypertension	64.3%
Diabetes mellitus	19.6%
Congestive heart failure	21.9%

Table 2

Procedural characteristics

Characteristic	Overall (n = 646)
Total number of transseptal punctures	747
Successful transseptal puncture, n (%)	747 (100%)
Type of transseptal needle per case (Baylis/BRK)	61/585
Type of EAM per case (CARTO/NAVX)	646/0
Type of TP method (method 1/method 2, n)	179/568
Complications (30-day)	
Pericardial effusion, n (%)	2 (0.3%)
Pericardial tamponade, n (%)	2 (0.3%)
cerebrovascular accident, n (%)	0
TIA, n (%)	1 (0.1%)
Intrathoracic bleeding, n (%)	0
Death, n (%)	0
Complications by TP method (method 1/method 2, n)	
Pericardial effusion	1/1
Pericardial tamponade	1/1
TIA	0/1
Total procedure time, min	189.2 ± 53.5
Time to transseptal puncture, min	18.8 ± 9.8
Total fluoroscopy time, min	0.4 ± 2.1 (median, IQR: 0,0)

Abbreviations: EAM = electroanatomic mapping; IQR = interquartile range; TIA = transient ischemic attack; TP = transseptal puncture.