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Three-dimensional-guided and ICE-guided transseptal puncture for cardiac ablations: A propensity score match study

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Abstract

Introduction: Transseptal puncture (TSP) is routinely performed for left atrial ablation procedures. The use of a three-dimensional (3D) mapping system or intracardiac echocardiography (ICE) is useful in localizing the fossa ovalis and reducing fluoroscopy use. We aimed to compare the safety and efficacy between 3D mapping system-guided TSP and ICE-guided TSP techniques.

Methods: We conducted a prospective observational study of patients undergoing TSP for left atrial catheter ablation procedures (mostly atrial fibrillation ablation). Propensity scoring was used to match patients undergoing 3D-guided TSP with patients undergoing ICE-guided TSP. Logistic regression was used to compare the clinical data, procedural data, fluoroscopy time, success rate, and complications between the groups.

Results: Sixty-five patients underwent 3D-guided TSP, and 151 propensity score-matched patients underwent ICE-guided TSP. The TSP success rate was 100% in both the 3D-guided and ICE-guided groups. Median needle time was 4.00 min (interquartile range [IQR]: 2.57–5.08) in patients with 3D-guided TSP compared to 4.02 min (IQR: 2.83–6.95) in those with ICE-guided TSP ($p = .22$). Mean fluoroscopy time was 0.2 min (IQR: 0.1–0.4) in patients with 3D-guided TSP compared to 1.2 min (IQR: 0.7–2.2) in those with ICE-guided TSP ($p < .001$). There were no complications related to TSP in both group.

Conclusions: Three-dimensional mapping-guided TSP is as safe and effective as ICE-guided TSP without additional cost.

KEYWORDS

intracardiac echocardiogram, three-dimensional electroanatomic mapping, transseptal puncture

1 | INTRODUCTION

Transseptal puncture (TSP) is routinely performed to obtain left atrial access for left atrial ablation procedures.[1,2] TSP, as originally described, relied heavily on the use of fluoroscopy.[3] However, fluoroscopy only allows visualization of the cardiac silhouette and exposes patients and healthcare personnel to radiation and its detrimental effects.[3-5] Although the safety of fluoroscopy-guided TSP in experienced hands is well established, fluoroscopy does not necessarily identify the thinnest part of the interatrial septum or fossa ovalis (FO), where TSP is the easiest to perform.[6] Over the years, imaging modalities such as transesophageal echocardiography (TEE), intracardiac echocardiography (ICE), and three-dimensional (3D) mapping systems have been used as adjunctive tools or as the sole imaging technique to guide TSP, allowing less fluoroscopy and improved safety and efficacy in patients with challenging cardiac anatomy.[6-15] However, intraprocedural TEE and especially ICE significantly increase the cost of ablation procedures, which may prohibit routine use in several healthcare systems.

In this study, we aimed to compare the success rate, needle time, fluoroscopy time during TSP, and complication rates between 3D mapping-guided and ICE-guided TSP techniques.

2 | METHODS

2.1 | Study design and study population

Adult patients presenting for a left atrial cardiac ablation procedure at the University of Michigan Samuel and Jean Frankel Cardiovascular Center (Ann Arbor, MI, USA) and the Ann Arbor Veteran's Affairs Hospital (Ann Arbor) were prospectively studied. The study was approved by the Institutional Review Board of both institutions.

2.2 | Transseptal puncture

After femoral venous access was achieved using ultrasound guidance and the Seldinger technique, at least two femoral venous sheaths were inserted. Intravenous heparin (5000–10 000 units) was administered after inserting femoral venous sheaths. After successful TSP, additional intravenous heparin boluses were administered as needed to maintain an activated clotting time between 250 and 350 s. Transseptal puncture needle time (TSPNT) and transseptal puncture fluoroscopic time (TSPFT) were defined as the needle dwell time and fluoroscopy time, respectively, measured from the time the TSP needle was initially inserted into the body until the time the TSP needle was removed from the body after left atrial access was achieved.

2.2.1 | Three-dimensional mapping-guided TSP

A ThermoCool SmartTouch™ mapping and ablation catheter (Biosense Webster Inc.) was inserted through an SL-0 sheath and placed in the right atrium, and the 3D mapping system (CARTO3; Biosense Webster Inc.) was initialized. The mapping catheter was advanced from the inferior vena cava (IVC) into the right atrium, guided by contact force and electrogram monitoring to ensure safe advancement without fluoroscopy use. Once atrial electrograms were recorded, fast anatomical mapping was used to create an electroanatomic (EA) map of the superior vena cava (SVC), IVC, right atrium, and coronary sinus. The His position was tagged on the 3D map where the His potential was recorded. After the creation of an adequate 3D map, the mapping catheter was carefully advanced into the SVC. The FO protrusion was then identified on the 3D map by withdrawing the catheter and sheath inferiorly from the SVC as displayed in two views (septal view and left anterior oblique (LAO) view [Figure 1A]), until a clear "drop" was identified (Figure 1B). The contact force on the mapping catheter was used throughout this process to ensure safety. After tagging the FO on the 3D map, the mapping catheter was then repositioned in the SVC, and the SL-0 sheath was advanced over the mapping catheter until the color of the distal bipole on the mapping catheter turned black on the 3D map. This step ensured the tip of the SL-0 sheath was positioned at the same level as the mapping catheter in the SVC. The mapping catheter was removed, and the dilator was then inserted into the SL-0 sheath over a wire to prepare for TSP. The mapping catheter was then inserted into the other femoral venous sheath and placed in the coronary sinus.

A BRK or BRK-1 needle (Abbott) was inserted through the dilator for the TSP. The tip of the transseptal needle was configured as a bipolar catheter using standard alligator clips to connect the transseptal needle to the CARTO 3 system. However, the configuration is not true bipolar because the transseptal needle does not have separate electrodes. After the transseptal needle was almost fully inserted, the SL-0 sheath and dilator assembly were carefully withdrawn over the transseptal needle until the tip of the transseptal needle was slightly exposed to be displayed on the 3D map (Figure 2A). This step ensured that the transseptal needle did not inadvertently perforate the SVC. The orientation of the transseptal needle appeared as a perpendicular line to the tip of the transseptal needle on the 3D map since it was not a true bipolar catheter. Although the orientation of the line did not represent the direction of the transseptal needle, the position of the line accurately represented the position of the transseptal needle tip. The whole needle–dilator–sheath assembly was slowly withdrawn inferiorly from the SVC while the tip of the transseptal needle was monitored on the 3D map in the septal and LAO views until the aforementioned "jump" was appreciated as the needle engaged the FO (Figure 2B). The position of the needle was also confirmed relative to the right atrial geometry and compared to the previously tagged FO position obtained by the mapping catheter. A SafeSept guidewire (Pressure Products Inc.) was inserted and advanced through the transseptal needle across the FO. As the SafeSept guidewire exited the transseptal needle, the tip displayed on the 3D map immediately represented the tip of the SafeSept guidewire instead of the transseptal needle tip. The SafeSept guidewire was then advanced

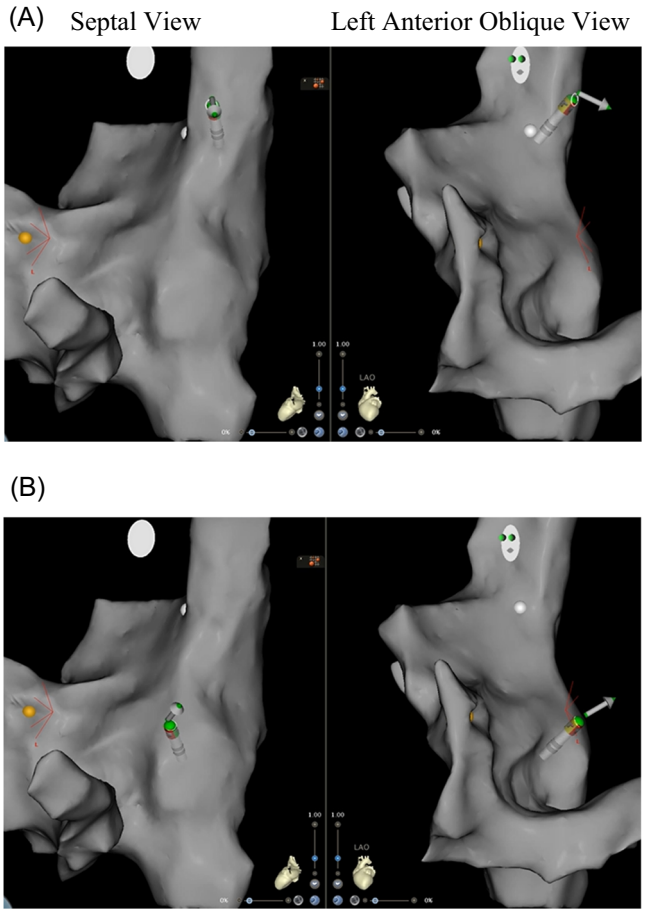

FIGURE 1 The fast anatomical map of the left atrium, superior vena cava (SVC), coronary sinus, and inferior vena cava in the septal view and left anterior oblique (LAO) view. The fossa ovalis (FO) area was identified by the protrusion of the septal plane. The mapping catheter was positioned in the SVC (A) and withdrawn while the tip was deflected until a clear drop was demonstrated (B). This process was repeated a few times to confirm the location of the FO.

into the left atrium towards a left-sided pulmonary vein (Figure 2C). Fluoroscopy was briefly used to confirm the positioning of the SafeSept guidewire in the left pulmonary vein. The whole needle–dilator–sheath assembly was advanced over the SafeSept guidewire into the left atrium and the position was confirmed by fluoroscopy (Supporting Information: Video 1).

2.2.2 | ICE-guided TSP

After obtaining the right femoral venous access, an ICE catheter (Ultra ICE Plus; Boston Scientific/Acuson AcuNav Ultrasound Catheter; Siemens-Biosense Webster/Soundstar Ultrasound Catheter; Biosense Webster/ViewFlex Xtra ICE catheter; Abbott) was advanced through the femoral vein sheath into the right atrium and then the SVC. The ICE catheter then was withdrawn to visualize the FO. A transseptal needle–dilator–sheath assembly was positioned in the SVC and withdrawn until the needle's "tenting" of the FO was

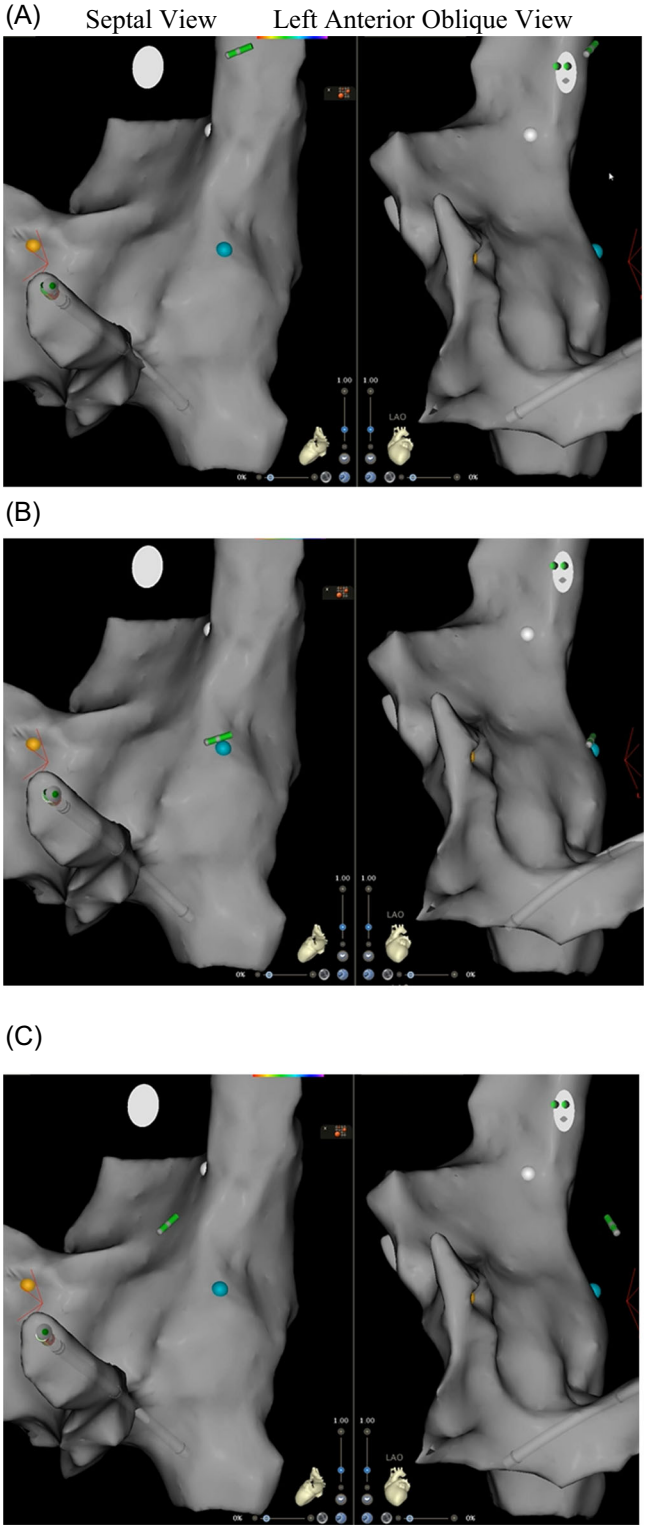

FIGURE 2 The transseptal needle was inserted into the dilator of the SL-0 sheath with the tip slightly exposed. The needle tip was displayed on the 3D map as a green line perpendicular to the needle axis (A) because it was not a true bipolar catheter. The whole assembly was withdrawn until it dropped into the previously tagged fossa ovalis (FO) location (B). A SafeSept wire was inserted into the transseptal needle and punctured the FO. The tip of the SafeSept wire was displayed on the 3D map instead of the transseptal needle as it advanced into the left atrium (C).

appreciated on ICE. A SafeSept guidewire was then advanced while the needle–dilator–sheath assembly was held against the FO. The SafeSept guidewire was advanced until it was positioned in a left-sided pulmonary vein as confirmed by fluoroscopy or ICE.

After the achievement of the first TSP, the ICE catheter then was withdrawn from the body. For the second left atrial access, most electrophysiologists at our institutions advanced the ablation catheter through the second SL0 sheath through the same opening in the FO under 3D EA guidance rather than performing a second TSP. Of note, fluoroscopy use was at the discretion of the operator and, as such, a routine "zero-fluoroscopy" approach was not pursued.

2.3 | Statistical analysis

2.3.1 | Propensity score matching

Full matching: A total of 216 patients were included in the study: 65 patients in the 3D-guided group and 151 patients in the ICE-guided group. As this was not a randomized study, propensity score matching with full matching was used to group patients into matched sets each containing at least one 3D-guided TSP patient (treated) and at least one ICE-guided TSP patient (comparison). After propensity score matching, multiple logistic regression was used on the matched samples to compare the groups. Variables used for propensity matching included: the presence of a transvenous pacemaker or implantable cardioverter-defibrillator; prior TSP; body mass index; gender; age, left atrial size diameter; left ventricular ejection fraction; and prior cardiac surgery.

Details of full matching: First, all 10 observed pretreatment baseline characteristics were used to generate a propensity score by the generalized boosted model (GBM) with a 3D-guided TSP technique as the treatment, and the aforementioned characteristics were used as predictors. The predicted probability from this model (the estimated propensity score) was then assigned to individuals, representing the "predicted" probability of being treated (by 3D-guided TSP technique). Once the propensity score was obtained, we used the propensity score to match individuals using full matching.

Measures of effectiveness of matching procedures: We then measured the result of matching to determine if the matching method reduced the bias in the estimated treatment (3D technique) effect. A similarity between treatment (3D) and comparison (ICE) groups in terms of observed covariates would imply minimal bias due to the differences in observed covariates. Standardized bias was used to measure the balance of covariates between the two groups. The standardized bias for a given covariate was defined as a weighted difference in means divided by the standard deviation in the original full comparison group. These weighted standardized differences were calculated from the full matching strata. This value, at less than 0.25, implies well-matched between groups.[16]

The success of full matching: The propensity score model collapses a set of observed covariates into a single measure (the propensity score) reflecting the probability of receiving treatment (3D technique). We first assessed the propensity score given the set of matching variables. For the full matching model, all available individuals were included. R package MatchIt was used to perform the full matching model. We compared the distributions of covariates in the resulting matched treatment and comparison groups by GBM. GBM approach provided a Love plot (Supporting Information: Figure 1) that produced the closest matched sample with minimal standardized biases on almost all observed variables. Therefore, we concluded that full matching rendered a well-matched result between groups.

Data analysis after full matching: We used a weighting approach to estimate treatment effects (i.e., the effects of the 3D technique) after full matching. Continuous variables were presented as mean/median ± standard deviation. Categorical variables were presented as numbers and frequencies. Differences between continuous variables were calculated using Student's *t*-test (normal distribution) or Mann–Whitney *U* test (not a normal distribution). Comparisons between categorical data were analyzed using the χ^2 test (Pearson's or Fisher's exact test). For all analyses, $p < .05$ was considered statistically significant. Analyses were performed using R software version 3.6.3 (R Foundation for Statistical Computing).

3 | RESULTS

The baseline characteristics of unmatched and propensity-matched comparison subjects are shown in Table 1. Among the unmatched cohort, the 3D-guided group had a higher prevalence of male patients ($p < .001$), a higher proportion of persistent AF ($p = .001$), and fewer prior catheter ablation procedures ($p < .001$). No patients in either group had prior atrial septal patch closure or atrial septal defect occluder devices.

Propensity score matching rendered good comparable characteristics between the 3D-guided and ICE-guided groups. All potential confounders were balanced as indicated by a standard mean difference of less than 0.2.

TSP was successfully performed in all patients in both groups without any TSP-related complications. The median TSPNT was 4.00 min (interquartile range [IQR]: 2.57–5.08) in patients with 3D-guided TSP compared to 4.02 min (IQR: 2.83–6.95) in those with ICE-guided TSP ($p = .205$). The mean TSPFT was 0.2 min (IQR: 0.1–0.4) in patients with 3D guided compared to 1.2 min (IQR: 0.7–2.2) in those with ICE-guided TSP ($p < .001$) (Table 2).

4 | DISCUSSION

ICE has been increasingly utilized to guide TSP and has become a standard technique in several electrophysiology laboratories across the world. ICE allows detailed visualization of intracardiac structures, transseptal needles, and sheaths, providing more information than fluoroscopy alone, especially in patients with challenging cardiac anatomy. Therefore, ICE-guided techniques can potentially improve the success and reduce the risks of TSP with prompt recognition of

complications, especially for inexperienced operators. However, the routine use of ICE for TSP is expensive and can be cost-prohibitive in several healthcare systems. Moreover, data on the safety and benefit of routine use of ICE for TSP in experienced operators is limited. A recent large retrospective study showed that over 99% of TSP could be performed with a low complication rate with fluoroscopy alone without additional imaging techniques.[6]

TABLE 1 Demographic data

	3D-guided ($n = 65$)	Fluoroscopic-guided ($n = 151$)	p
Age (mean (SD))	67.38 (9.83)	67.38 (9.59)	.85
Gender (male [%])	57 (87.6)	105 (69.5)	<.001
BMI (median [IQR])	30.77 (25.73, 35.50)	30.37 (25.89, 36.35)	.743
Existing device (%)			.273
BIV	0 (0.0)	3 (2.0)	
Dual chamber device	5 (7.7)	15 (9.9)	
Single chamber device	1 1.5)	0	
None	59 (910.8)	133 (88.1)	
Arrhythmia diagnosis			.001
PAF	17 (26.2)	64 (42.4)	
Persistent AF	46 (70.8)	67 (44.4)	
Others	2 (3.1)	20 (13.2)	
Prior RFA (AF)	11 (16.9)	70 (46.4)	<.001
LA size (mm, median [IQR])	44.00 (38.00, 47.00)	44.00 (41.00, 49.50)	.295
LVEF (median [IQR])	55.00 (50.00, 62.00)	60.00 (55.00, 65.00)	.075
CAD (%)	18 (27.7)	27 (17.9)	.148
Valve surgery (%)	0 (0.0)	7 (4.7)	.374

Abbreviations: 3D, three dimensional; AF, atrial fibrillation; BIV, biventricular; BMI, body mass index; CAD, coronary artery disease; IQR, interquartile range; LA, left atrial; LVEF, left ventricular ejection fraction; PAF, paroxysmal atrial fibrillation; RFA, radiofrequency ablation; TSP, transseptal puncture.

Due to the anatomy of the thin FO and prominent limbus, the FO can be easily and reliably identified with 3D mapping of the right atrial septum in most cases by FO protrusion from applying contact force to the mapping catheter. The deepest point of the FO protrusion is usually at the same or close to the point where the mapping catheter drops when it is withdrawn from the SVC. However, the FO protrusion may be less prominent in some patients with prior TSP due to fibrotic scar.[17] Although the FO is usually thin, the voltage of the FO is low in only one-half of patients. Therefore, low-voltage-guided identification of the FO may not be reliable.[18]

This study shows that TSP guided by 3D mapping with limited fluoroscopy is feasible. All TSPs guided by 3D mapping in this study were successfully and safely performed without any complications. In general, it takes an additional 5–10 min to create the right atrial geometry for 3D mapping-guided TSP and an additional 3–5 min to prepare the ICE catheter and obtain a proper view for ICE-guided TSP. Troisi et al.[19] compared EA guidance and conventional fluoroscopy during TSP for atrial fibrillation. All TSPs were successfully performed and there were no significant complications related to TSP. The total procedure duration was similar in both groups, but the fluoroscopy time was significantly shorter in the EA guidance group. However, the study did not report the procedure duration and fluoroscopy time specifically related to the TSP.

We describe the TSP time which is defined as the time from TSP needle insertion in the body until the needle is removed from the body after successful left atrial cannulation. TSP time is usually correlated with difficulty in TSP and is probably associated with the risks related to TSP. In our study, TSP time was not different between 3D mapping-guided and ICE-guided TSP. However, the fluoroscopy time was minimal and significantly shorter in the 3D mapping-guided TSP group with fluoroscopy used only to confirm the position of the SafeSept wire and the transseptal sheath in the left atrium. It should be noted that our institution did not routinely pursue "zero fluoroscopy" ICE-guided ablations. Nevertheless, 1.2 min of TSPFT in the ICE-guided TSP group is still minimal. Regardless, our study establishes the equivalence in safety and efficacy between 3D-guided and ICE-guided TSP.

The real benefit that 3D-guided TSP brings to clinical practice is a reduction in the mean cost of procedures. Prior studies have identified an increase in the cost of left atrial ablation procedures with the use of intraprocedural imaging. Our study shows that 3D mapping-guided TSP is a useful technique that can be routinely performed for left atrial ablation procedures to reduce radiation exposure without an increase in cost.[20] Echocardiographic guidance

TABLE 2 Comparison between 3D-guided TSP and fluoroscopic-guided TSP in matched data

	3D guided	Fluoroscopic guided	p
Success rate (%)	100	100	.997
Complication rate (%)	0	0	.997
Needle time (minutes, median [IQR])	4.00 (2.57, 5.08)	4.02 (2.83, 6.95)	.22
Fluoroscopic time (minutes, median [IQR])	0.2 (0.1, 0.4]	1.2 (0.7, 2.2)	<.001

Abbreviations: 3D, three dimensional; IQR, interquartile range; TSP, transseptal puncture.

such as ICE can always be used as an adjunct in selected patients with difficult FO anatomy. This approach will offer additional cost savings which are anticipated to be increasingly important in the field of atrial fibrillation ablation as health systems worldwide face rising costs associated with accompanying modern cardiovascular care.

5 | STUDY LIMITATIONS

This study has several limitations. Because this was not a randomized study, it is possible that confounding factors that were not accounted for via propensity matching may influence the results. Still, full matching ensures that no patient data were discarded, and all identifiable covariates were distributed similarly between matched individuals. The use of a propensity score model allowed us to compare similar groups of patients who had a similar probability of receiving 3D-guided and ICE-guided TSP.

The 3D mapping-guided TSP technique in this study was performed by a single cardiac electrophysiologist. Thus, the results may not be completely generalizable to other operators or institutions. However, it should be noted that electrophysiology fellows who participated in these procedures were able to perform 3D mapping-guided TSP as primary operators with the supervision of the principal investigator. Approximately 3–5 procedures were sufficient to become proficient with 3D mapping-guided TSP. The majority of the learning curve is related to minimizing or altogether avoiding fluoroscopy. Therefore, experienced operators who are already performing "fluoroless" or "zero-fluoroscopy" procedures may find that adapting to this technique is not that challenging. While our study and a previous study show that 3D mapping-guided TSP is feasible,[19] future studies need to establish the learning curve for this technique in a larger group of electrophysiologists.

As noted previously, the routine use of the "zero-fluoroscopy" technique in the ICE group would have reduced the fluoroscopy time in the group. However, limited fluoroscopy likely only enhanced the safety of the ICE-guided TSP procedure in our study and therefore does not invalidate the finding that 3D-guided TSP is equally safe and effective.

Additionally, 3D-guided TSP was performed exclusively using CARTO 3 system (Version 6). The generalizability and reliability of visualizing the TSP needle and guidewire need to be validated with additional mapping systems (Rhythmia; Boston Scientific and Ensite; Abbott).

Despite these limitations, this study demonstrates the relative safety and efficacy of a 3D mapping system-guided approach to TSP as compared to an ICE-guided approach, which may offer significant benefits in the reduction of procedural costs and fluoroscopy use.

AUTHOR CONTRIBUTIONS

All authors had access to the data and a role in writing the manuscript. *Study conception, data collection, data analysis, and manuscript preparation*: Ronpichai Chokesuwattanaskul. *Manuscript edits*: Andrew B. Hughey. *Data analysis*: Elizabeth A. Stuart. *Study conception and manuscript edits*: Krit Jongnarangsin.

DATA AVAILABILITY STATEMENT

The authors might not be able to share the data due to patients' confidentiality.

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SUPPORTING INFORMATION

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

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