

Clinical Outcomes of Ablation for Persistent Atrial Fibrillation with Zero or Minimal Fluoroscopy

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Purpose: Recent developments in electroanatomical mapping (EAM), intracardiac echocardiography, and sheath technology have allowed for a pronounced reduction or complete elimination of fluoroscopy during catheter ablation of atrial fibrillation (AF). This real-world study evaluates the procedural efficiency, clinical effectiveness, and safety of a zero- to minimal-fluoroscopy workflow in an exclusively persistent AF (PsAF) population.

Methods: Data on consecutive PsAF catheter ablations performed with a fluoroscopy minimization workflow by three operators at a single high-volume center in the United States between January 2017 and December 2018 were collected and analyzed. All procedures were performed with EAM guidance and a contact force ablation catheter. Patients were followed for a year post-ablation for safety, arrhythmia recurrences, and reablation. Outcomes of interest included procedural efficiency measures, single-procedure success (freedom from reablation at any time or recurrence after 90-day blanking), and procedure-related complications.

Results: The study included 406 PsAF patients (age 67.8 ± 10.1 years, 65.3% male, and CHA₂DS₂-VASc score 2.9 ± 1.5). Over 85% of ablations were performed without fluoroscopy, and ablations utilizing fluoroscopy averaged only 0.6 ± 1.5 minutes for a mean fluoroscopy time of 0.1 ± 0.6 minutes overall. Mean procedure time was 89.5 minutes, with 96.3% of the procedures including ablation beyond the pulmonary veins. Single-procedure success was 73.6% (95% confidence interval: [68.7%, 77.8%]). Eight patients (2.0%) experienced a procedure-related complication.

Conclusion: Minimal-fluoroscopy ablation was performed safely and without compromise to procedural efficiency or clinical effectiveness in a real-world population of PsAF patients, despite more extensive ablation than a typical paroxysmal AF population.

Keywords: atrial fibrillation, catheter ablation, zero fluoroscopy, minimal fluoroscopy, contact force

Introduction

Atrial fibrillation (AF) prevalence has tripled over a 50-year period based on data from the Framingham Heart Study, and the Global Burden of Disease project estimated worldwide prevalence at approximately 46.3 million cases in 2016.¹ Radiofrequency (RF) catheter ablation, with pulmonary vein isolation as the cornerstone, has become an increasingly common and effective alternative to antiarrhythmic drugs in AF management.^{2,3}

RF ablation has historically required fluoroscopic imaging to guide catheter movement and positioning.⁴ However, a patient undergoing AF ablation is exposed to an estimated effective radiation dose equivalent to 830 chest x-rays.⁵ Radiation-related risks to patients and operators include skin injury, cataracts, thyroid disorders, and potentially fatal malignancies such as breast, hematologic, lung, and stomach cancers.^{6–8} In addition, a recent survey found that 83% of interventional cardiologists complained of the physical toll associated with the heavy lead aprons required for radiation protection and 90.7% were willing to perform procedures without radiation.⁹

In recent years, non-fluoroscopic three-dimensional electroanatomical mapping (EAM) and navigation have allowed for a pronounced decrease in fluoroscopy use during catheter ablation of AF.^{4,10} Advances in intracardiac echocardiography (ICE) and the availability of EAM-visualizable sheath technology enable further reduction or complete elimination of fluoroscopy without compromising safety or effectiveness outcomes.^{11–15} There is now a growing body of evidence documenting the

safety and effectiveness of minimal- to zero-fluoroscopy catheter ablation procedures,^{4,14–17} primarily in paroxysmal AF (PAF) populations.

Despite appreciable improvement in procedural efficiencies made possible by the adoption of recent technologies,¹⁸ PsAF ablations remain characterized by lengthy procedures (178 to 197 minutes) and fluoroscopy times (15 to 23 minutes).^{19–21} Evidence that zero- to minimal-fluoroscopy workflows are safe and effective for PsAF ablation could have a widespread effect on reducing radiation exposure for both patients and operators, as well as the need for lead personal protection equipment during PsAF ablations. A reduction in fluoroscopy for this population would have a significant impact overall given that 56.7% of AF ablation procedures in a recent US registry study were performed in PsAF patients.²²

The present study was aimed at evaluating the procedural efficiency, clinical effectiveness, and safety of a minimal-fluoroscopy workflow using a contact-force ablation catheter for PsAF ablation in a real-world setting. In addition, we sought to understand the impact of patient characteristics on clinical effectiveness through 12 months post ablation.

Methods

Study Design

This retrospective study analyzed data on PsAF catheter ablations performed by three operators at a single high-volume US center between January 2017 and December 2018. All enrolled patients were evaluated and treated per standard of care. Data were collected prospectively from the patients' electronic medical records into standardized data collection forms.

The Western Institutional Review Board provided a waiver of informed consent and authorization for analysis and publication of de-identified records on March 30, 2021.

Patient Population

The study population was comprised of consecutive patients aged 18 or older who underwent a de novo PsAF ablation at the study site with a porous-tip contact force (CF) sensing catheter. Eligibility was limited to patients with symptomatic PsAF. Pregnant women, patients with PAF or long-standing PsAF (>1 year), and those with a history of left atrial ablation were excluded.

Ablation Procedure Workflow

All procedures were performed with the THERMOCOOL SMARTTOUCH SF Catheter (STSF) and CARTO 3 System (Biosense Webster, Inc., Irvine, CA). RF ablation was performed under general anesthesia. Following intravenous access, the catheter was introduced via the right femoral vein and guided by EAM until positioned in the right atrium. A deflectable decapolar catheter was placed into the coronary sinus, guided by EAM and/or ICE. Single or double transseptal puncture was guided by ICE with no fluoroscopy (Figure 1), as previously described.¹² Intravenous heparin was given prior to and after transseptal access, as needed, to obtain a target activated clotting time > 350 seconds. The left atrium geometry and voltage were then obtained via fast anatomic mapping (FAM) using a multipolar catheter (Pentaray™) with continuous mapping. Wide area circumferential RF ablation around ipsilateral pulmonary veins (PVs) was performed in the standard fashion, guided by EAM and ICE. Additional left atrial ablations were performed as needed per investigators' discretion. During the study period, it was normal practice for patients undergoing persistent AF ablation at our institution to also have ablation of the cavotricuspid isthmus. Ablation of additional non-PV targets was performed for patients with moderate to severe LA dilatation and areas of low voltage on EAM.

Patient Follow-Up

Patients were followed for up to a year after the ablation procedure for safety, AF/atrial tachycardia (AT)/atrial flutter (AFL) recurrences, and reablation. Follow-up visits were routinely scheduled at 10–12 weeks and 12 months. Patients underwent regular arrhythmia recurrence monitoring, including electrocardiograms at all visits and 4- to 7-day cardiac patch monitoring, interrogation of implanted cardiac rhythm management devices, or event monitors at 6 and 12 months.

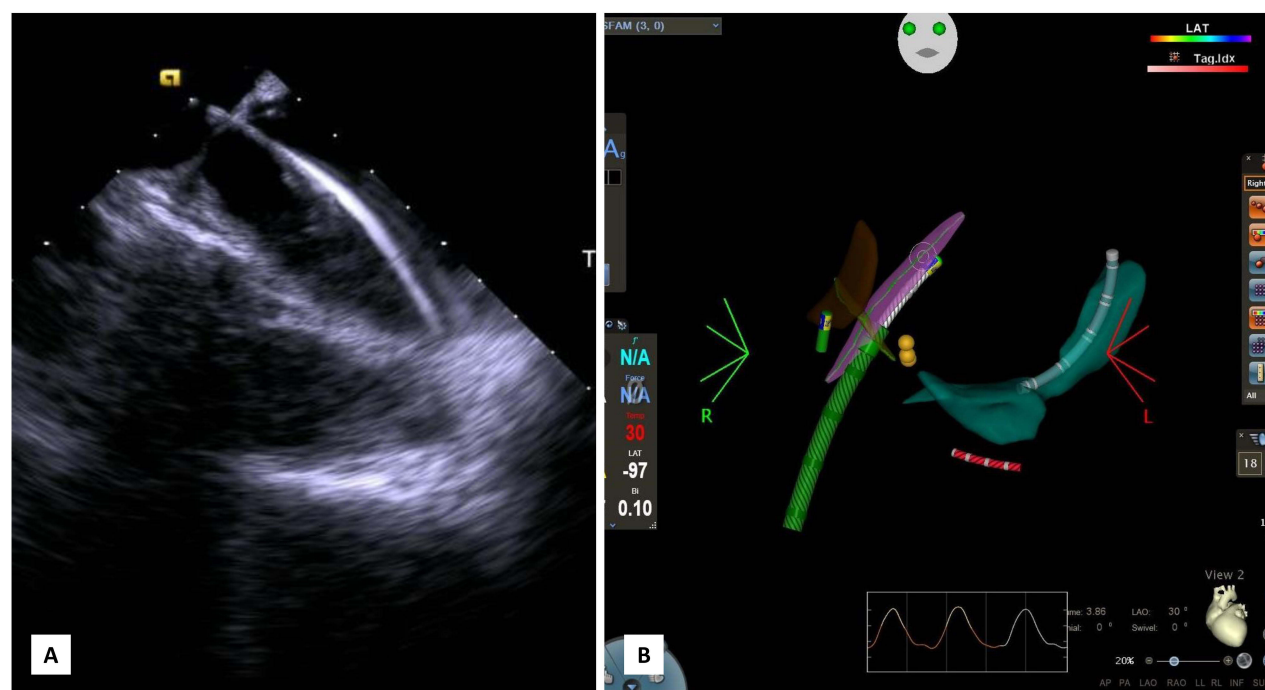


Figure 1 Transseptal Puncture Views: (A) Ultrasound view via intracardiac echocardiography (ICE) catheter (B) Electroanatomical map view via CARTO System.

Study Outcomes

Procedural efficiency outcomes included fluoroscopy utilization, procedures time, first pass isolation of left and right PVs, and fluid volume delivered via the ablation catheter. The primary clinical effectiveness outcome was single-procedure success, defined as freedom from any AF/AT/AFL recurrence of >30 seconds after a 90-day blanking period through 12 months post ablation with no reablation at any time within 12 months. Other effectiveness outcomes of interest included recurrences and reablations within 12 months (during and after blanking). Safety was evaluated by collecting all procedure-related complications occurring up to 12 months post-ablation.

Statistical Analysis

All available baseline patient characteristics, procedural details and efficiency, effectiveness, and safety outcomes were summarized by descriptive statistics.

Kaplan–Meier analysis was conducted to estimate the primary effectiveness outcome (single-procedure success rate at 12 months). Univariable and multivariable Cox regression models were used to explore whether baseline patient characteristics were statistically significant predictors of single-procedure success at 12 months. Variables were first tested individually, and if significant at a level of 0.05, were evaluated for inclusion in a multivariable model.

Statistical analysis was performed using SAS software, version 9.4 (SAS Institute Inc., Cary, NC, USA).

Results

Baseline Characteristics

A total of 406 patients who underwent a de novo PsAF catheter ablation with an STSF catheter at the study site were included. Patients' mean age was 67.8 ± 10.1 years and most were male (65.3%) [Table 1]. Of 301 patients with available height and weight data, average body mass index was 31.6 ± 10.1 kg/m². Hypertension was the most prevalent comorbidity (79.1%) and mean CHA₂DS₂-VASc score was 2.9 ± 1.5 . On average, patients had mild left atrial enlargement (mean diameter 4.4 ± 0.7 cm). Approximately half of the patients (47.0%) had failed at least one antiarrhythmic drug prior to ablation.

Table 1 Baseline Patient Characteristics and Medical History

Characteristic	Value (N = 406)
Age at procedure, years	67.8 ± 10.1
Sex, male	265 (65.3%)
Body mass index (N = 304), kg/m ²	31.6 ± 7.2
Previously failed antiarrhythmic drug (Class I or III)	191 (47.0%)
Medications	
Antiarrhythmic drug (Class I or III)	234 (77.8%)
Oral anticoagulant	388 (95.6%)
Beta-blocker	223 (54.9%)
Any implantable cardiac device capable of detecting atrial fibrillation	68 (16.7%)
Pacemaker	51 (12.6%)
Implantable cardioverter defibrillator	15 (3.7%)
Insertable cardiac monitor	4 (1.0%)
Comorbidities/medical history	
Congestive heart failure	79 (19.5%)
Diabetes	101 (24.9%)
Hypertension	321 (79.1%)
Stroke/transient ischemic attack/thromboembolism	39 (9.6%)
Vascular disease	97 (23.9%)
CHA ₂ DS ₂ -VASc score	2.9 ± 1.5
Left ventricular ejection fraction, % (N = 328)	52.2 ± 10.7
Left atrial diameter, cm (N = 316)	4.4 ± 0.7
Left atrial scar, % (N = 180)	29.3 ± 20.4

Notes: Results are displayed as n (%) or mean ± standard deviation.

Procedural Details and Efficiency

The great majority of procedures (90.4%) included both pulmonary vein isolation (PVI) and cavotricuspid isthmus ablation, either with or without substrate modification (SM) – 55.7% and 34.7%, respectively [Table 2]. Data on fluoroscopy use were available for 396 procedures, with an overall mean fluoroscopy time of 0.1 ± 0.6 min. The majority (85.4%) of the procedures were completed without fluoroscopy, while the remaining procedures were performed with minimal fluoroscopy, averaging 0.6 ± 1.5 minutes per ablation. On average, procedure time was 89.5 ± 34.6 minutes and 677 ± 232 mL of fluids were delivered via the ablation catheter. First pass isolation was achieved in 78.1% and 60.6% of the left and right PVs, respectively.

Table 2 Procedural Details and Efficiency

Procedural Details/Efficiency	Value (N = 406)
Lesion set	
PV only	12 (3.0%)
PV+CTI	141 (34.7%)
PV+CTI+SM	226 (55.7%)
PV+SM	24 (5.9%)
SM, mitral isthmus (N = 352)	148 (42.0%)
SM, posterior wall (N = 372)	234 (62.9%)
First pass isolation	
Left PVs (N = 399)	304 (78.1%)
Right PVs (N = 388)	235 (60.6%)

(Continued)

Table 2 (Continued).

Procedural Details/Efficiency	Value (N = 406)
Total fluoroscopy time (N = 396)	0.1 ± 0.6
Fluoroscopy use (N = 396)	
No	338 (85.4%)
Yes	58 (14.6%)
Fluoroscopy time (N = 58)	0.6 ± 1.5
Total procedure time, minutes (N = 402)	89.5 ± 34.6
Radiofrequency time, minutes (N = 400)	36.5 ± 13.3
Total fluids delivered, mL (N = 395)	1054 ± 333
Intravenous fluids, mL (N = 303)	363 ± 225
Catheter fluids, mL (N = 308)	677 ± 232

Notes: Results are displayed as n (%) or mean ± standard deviation.

Abbreviations: PV, pulmonary vein; CTI, cavotricuspid isthmus; SM, substrate modification.

Clinical Effectiveness

The Kaplan–Meier estimate of single-procedure success was 73.6% (95% confidence interval: [68.7%, 77.8%]) [Figure 2]. There were 56 patients who had a recurrence within the 90-day blanking period and 99 patients with continuing or new recurrences beyond 90 days. Reablations were performed in 53 patients (13.1%) within 12 months, of which 7 occurred within the 90-day blanking period.

Univariable and multivariable analyses of variables associated with single-procedure success are summarized in Table 3. The multivariable Cox regression model of patient characteristics showed that female sex (hazard ratio: 1.47; $p = 0.0555$) and increased age (hazard ratio per 10 years: 1.29; $p = 0.0296$) were at least marginally associated with a higher risk of reablation or post-blanking recurrence through 12 months post-procedure.

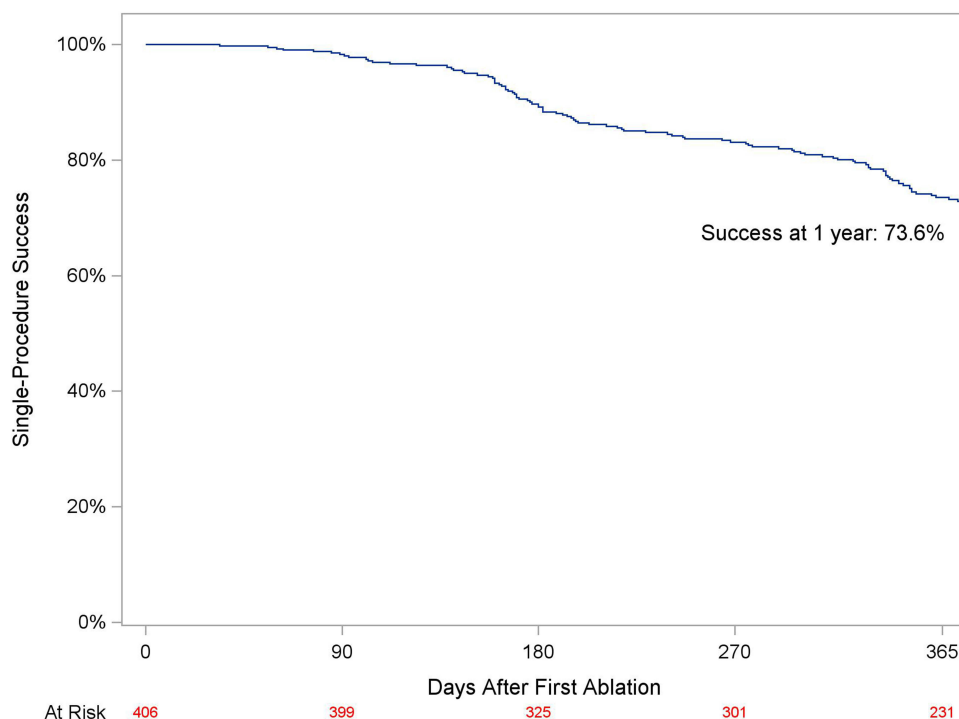
**Figure 2** Kaplan–Meier single-procedure success.

Table 3 Cox Regression Models of Single-Procedure Success for Patient Characteristics

Patient Characteristic	Hazard Ratio for Failure ^a	p-value
Single variable models		
Age at procedure	1.03	0.0125
Female (reference: male)	1.63	0.0130
CHA ₂ DS ₂ -Vasc score	1.10	0.1352
Diabetes mellitus	0.80	0.3664
Body mass index	0.99	0.3893
Left ventricular ejection fraction	1.01	0.4602
Prior transient ischemic attack or cerebrovascular accident	1.26	0.4703
Hypertension	0.87	0.5807
Vascular disease	0.89	0.6527
Left atrial diameter	1.04	0.8012
Congestive heart failure	1.01	0.9552
Multivariable model		
Age, per 10 years	1.29	0.0296
Sex (reference: male)	1.47	0.0555

Notes: ^aFor risk of reablation or post-blanking recurrence through 12 months post-procedure.

Complications

Eight of the 406 ablated patients (2.0%) experienced an ablation-related complication. The most commonly reported complication was pseudoaneurysm at the site of vascular access (3 patients), followed by cardiac tamponade/pericardial effusion (2 patients). Arteriovenous fistula, gastroparesis, and respiratory failure/flash pulmonary edema requiring intubation were recorded in one patient each.

Discussion

Few studies of zero- to minimal-fluoroscopy catheter ablation procedures have included PsAF patients, and even fewer have included PsAF cases as the primary patient population.^{4,14–17} Despite encouraging findings, this scarcity of data has hindered the ability to draw robust conclusions about the safety and clinical effectiveness of minimal-fluoroscopy PsAF ablations. Our study evaluated real-world clinical outcomes of catheter ablation for PsAF patients only, using minimal fluoroscopy. A total of 406 symptomatic patients with follow-up data for up to a year after ablation with an STSF catheter were analyzed. Over 85% of PsAF ablations were performed without fluoroscopy, and ablations utilizing fluoroscopy averaged only 0.6 minutes among the remaining procedures for an overall mean fluoroscopy time of 0.1 minutes. The mean procedure time was 89 minutes. Safety and effectiveness were not compromised, as evidenced by a procedure-related complication rate of 2% and 12-month single procedure success rate of 73.6%. The ability to perform catheter ablation safely, effectively and efficiently with minimal fluoroscopy is especially meaningful given that the patients included in this study appear to represent a more advanced AF population with significant comorbidities (ie, mild LA enlargement, BMI > 30 kg/m², and mean CHA₂DS₂-VASc score of 2.9).

Optimization of Minimal-Fluoroscopy Workflow in Real-World Practice

Unlike protocol-driven clinical studies, real-world practice workflows have evolved to address practical issues, such as the imperative to minimize radiation exposure – which poses risks to both patients and operators – while ensuring the effectiveness and safety of ablation procedures.^{4,10} Our study demonstrates a vast reduction in fluoroscopy usage compared to CF PsAF ablations performed in clinical trial settings, namely PRECEPT and NO-PERSAF,^{19,20} while maintaining a similar clinical success rate (73.6%), suggesting that a zero- to minimal-fluoroscopy workflow does not compromise effectiveness. In the PRECEPT and NO-PERSAF trials, fluoroscopy time averaged 15.3 and 23.4 minutes, respectively, indicating that intentional minimization of fluoroscopy was not a primary focus in these prior studies.

Conversely, at our center, we have purposefully modified crucial procedural steps, such as transseptal access, left atrial mapping, and lesion creation, with the goal of reducing reliance on fluoroscopy.¹²

Our results revealed a 12-month single procedure success rate of 73.6%, which is favorably comparable to those of real-world PsAF ablation studies using a conventional fluoroscopy approach, despite a patient population with a higher degree of comorbidities. In contrast, the NO-PERSAF multicenter trial and a single-site prospective study reported 61.2% and 75.7% of PsAF patients remained free from atrial arrhythmia at 12 months after CF ablation with mean fluoroscopy times of 23.4 and 22.0 minutes.^{18,20} Furthermore, Sirico G et al reported on CF ablation using a mean of 27 minutes of fluoroscopy with a slightly higher single-procedure success rate (80.5%) in a population that was both younger (mean age 60.9 vs 67.8 years) and more predominantly male (79.5% vs 65.3%), supporting our finding that increasing age and female sex are negatively associated with success.²¹

Procedure-related complications (2.0%) were low in this study, within the typical range seen in other real-world studies, supporting the safety of performing PsAF ablations with minimal-fluoroscopy. This rate aligns with that reported for conventional fluoroscopy PsAF ablations performed in a real-world setting (2.7%).²¹ Similar complication rates have also been found in studies of mixed AF populations (PAF and PsAF) undergoing zero- to minimal-fluoroscopy ablation. In a majority PsAF population (62% of enrolled patients), a 2.0% complication rate was reported across 1000 consecutive AF ablations performed with near-zero fluoroscopy,¹⁷ whereas a different study reported a rate of 1.8% for acute complications.⁴ Similarly, procedure-related complications have generally been few across studies of PAF ablations using minimal-fluoroscopy workflows.^{14,15}

Another consideration associated with low-fluoroscopy workflows is whether they could inadvertently lengthen procedure times.²³ Comparison of our procedural data with those from prior PsAF ablation studies – either in a clinical trial or a real-world setting – using a conventional fluoroscopy workflow suggests that this is not the case. In fact, the total procedure time (89.5 minutes) was considerably lower in the present study, representing a considerable decrease compared to the PRECEPT and NO-PERSAF trials (178 and 197 minutes, respectively) and the Sirico G et al study (178 minutes).^{19–21} These differences in procedural efficiency are particularly noteworthy considering that procedures with ablation beyond PVs (ie, additional ablation lines or SM) were more than twice as common in our study compared to PRECEPT (96.3% vs 44.5%) and that the NO-PERSAF study included only PVI ablation. The improved efficiency is likely attributable in part to the consistent use of a well-defined workflow at our study site.

Fluoroscopy Minimization Workflow: PAF vs PsAF

The clinical effectiveness of a zero- to minimal-fluoroscopy workflow for PAF ablation with the STSF catheter has been previously explored in a study quite similar to the current study.¹⁴ Ablations were performed at the same site over the same time period, using identical patient follow-up and recurrence monitoring schedules. Compared to the present study, procedure times for ablation of PAF were approximately 10 minutes shorter (79.4 ± 33.2 minutes) and a higher percentage of ablations were completed without fluoroscopy (92% vs 85%). The differences in procedural efficiencies between the prior PAF cohort and the current PsAF cohort are likely a reflection of the more extensive ablation required in this PsAF population. Just 3.0% of the current PsAF population had PVI only, compared to 22.3% of the PAF patients, while 61.6% vs 12.6% required SM. Similarly, the fluid volume delivered via the ablation catheter was higher in the PsAF population (677 ± 232 vs 541 ± 208 mL) due to the longer ablation times. As expected, a higher single-procedure success rate (86.6%) was also reported in the PAF population, though the exact effectiveness rates are not directly comparable because the prior PAF study did not use Kaplan–Meier survival models to account for varying lengths of follow-up. In the first prospective, multicenter study demonstrating the effectiveness of a minimal- to zero-fluoroscopy approach for the ablation of PAF and PsAF with CF catheters, a very similar success rate to our own was found (76%).⁴ This study enrolled 65% PAF patients and 63% of procedures were performed with zero fluoroscopy.

Predictors of Clinical Effectiveness

Older and female patients had worse outcomes after PsAF ablation in our study. This is in line with previous studies that have also reported on both increased age and female sex negatively impacting outcomes of AF catheter ablation.^{24–27}

Further research is needed to understand the reasons leading to these patients' decreased success rates. Nevertheless, based on our experience, a minimal fluoroscopy ablation workflow is equally feasible regardless of sex or age.

Limitations

All study data were obtained from a single high-volume center, which might limit the generalizability of our findings. Procedural efficiencies will vary based on the specifics of the workflow used and effectiveness measures are known to fluctuate based on the extent of rhythm monitoring routinely performed as a part of a patient's follow-up. In addition, all measures of success may vary depending on operator experience and characteristics of the patient population, which in this case is limited to patients with PsAF of <1 year duration.

Conclusions

Minimal-fluoroscopy ablation can be performed safely and without compromise to procedural efficiency or clinical effectiveness in a real-world population of PsAF patients, despite more extensive ablation than a typical PAF population. The adoption of this approach has the potential to significantly reduce radiation exposure during catheter ablation of AF and thus limit its harmful effects on both patients and operators.

Ethics Approval

This retrospective study was conducted in accordance with ethical standards from the 1964 Helsinki Declaration and later amendments. The Western Institutional Review Board provided a waiver of informed consent and authorization for analysis and publication of de-identified records on March 30, 2021.

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Disclosure

J Osorio is a paid consultant for Biosense Webster, Inc., Abbott, Medtronic and Boston Scientific. G Morales is a paid consultant for Biosense Webster, Inc., Abbott, Medtronic, and Boehringer Ingelheim. A Rajendra is a paid consultant for Biosense Webster, Inc., Abbott, Acutus Medical, Boston Scientific, and Philips. TD Hunter is an employee of CTI Clinical Trial and Consulting Services (contracted by Johnson & Johnson), which provides consulting services to Biosense Webster, Inc. The authors report no other conflicts of interest in this work.

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