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Nonfluoroscopic catheter ablation of paroxysmal atrial fibrillation

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Abstract

Aims: Radiofrequency catheter ablation of atrial fibrillation (AF) is one of the most complex ablation procedures. Both patients and operators are exposed to scattered radiation. This study evaluated the safety and efficacy of intracardiac echo (ICE)-guided pulmonary vein isolation (PVI) without fluoroscopy.

Methods: We retrospectively analyzed the data of 481 consecutive patients with paroxysmal AF undergoing radiofrequency PVI with the CARTO 3 system (Biosense Webster, Diamond Bar, CA, USA). ICE-guided PVI without fluoroscopy and without CT/MRI integration (Nonfluoro group) was performed for 245 patients, and conventional fluoroscopy-guided PVI (Fluoro group) was performed for 236 patients. The primary safety endpoint was the incidence of major adverse events. The primary efficacy endpoint was freedom from AF during follow-up. Secondary endpoints included procedure duration, fluoroscopy duration, and acute PVI rate.

Results: Mean procedure times between groups were similar (108.8 ± 18.2 minutes in the Nonfluoro group vs 113.6 ± 26.8 minutes in the Fluoro group; P = not significant [NS]). Acute PVI was achieved in all patients, with mean radiofrequency application times of 43.4 ± 7.5 and 44.4 ± 10.7 minutes for the Nonfluoro and Fluoro groups, respectively (P = NS). The incidence of cardiac tamponade was 1.2% (3/245 patients) in the Nonfluoro group and 0.8% (2/236 patients) in the Fluoro group (P = NS). During 15.2 ± 4.1 months of follow-up, after a single procedure, AF recurrence was documented in 65 of 245 (26.5%) patients and 61 of 236 (25.8%) patients in the Nonfluoro and Fluoro groups, respectively (P = NS).

Conclusions: Nonfluoroscopic ICE-guided catheter ablation of AF without prior cardiac image integration or angiography is feasible and safe. PVI without fluoroscopy did not affect procedure duration or long-term efficacy.

KEYWORDS

atrial fibrillation, arrhythmia, catheter ablation, intracardiac echocardiography, nonfluoroscopic ablation, three-dimensional systems

1 | INTRODUCTION

Over the past decade, catheter ablation has become the therapy of choice for many patients with symptomatic atrial fibrillation (AF).[1] The complex electroanatomical substrate of AF demands careful catheter manipulation in the atria during catheterization, transseptal puncture, mapping, and ablation of the pulmonary vein (PV) and non-PV sources, resulting in long procedural times.[1–3] Conventional catheter ablation procedures are usually fluoroscopy-guided. Both the patient and operator are exposed to scattered x-rays for long periods.[4] Ionizing radiation is known to result in deterministic and stochastic adverse effects in patients as well as the medical staff.[5] In addition, to assess PV ostia and left atrial (LA) anatomy, angiography is usually performed by injecting contrast media. Contrast media can cause nephrotoxicity,

thus providing additional risk, particularly to patients with impaired renal function.[6] Novel technologies such as robotic navigation have been developed to reduce the operator's exposure to ionizing radiation. However, because of safety concerns, longer procedure durations, and increased costs, robotic navigation is not widely used.[7,8]

The combination of the three-dimensional (3D) mapping system with intracardiac echocardiography (ICE) allows catheter ablation of AF to be performed, including initial catheterization and transseptal puncture, without fluoroscopy.[9–12] However, concerns about the safety of this approach have been raised. A few single-center studies with relatively small cohorts have shown that the zero-fluoroscopy approach using 3D mapping systems, ICE, and computed tomography (CT) imaging integration does not compromise the safety and efficacy of PV isolation (PVI).[9,11–14] The aim of this multicenter study was to assess the safety and clinical efficacy of nonfluoroscopic radiofrequency (RF) catheter ablation without CT or magnetic resonance imaging (MRI) integration and without using contrast media for the treatment of AF in a large cohort of patients.

2 | METHODS

2.1 | Study population

In this study, a retrospective analysis was performed involving 481 consecutive patients who underwent catheter ablation for symptomatic, paroxysmal AF between January 1, 2014 and March 31, 2016, at four centers (centers 1,3–5). Patients underwent RF PVI using either the nonfluoroscopic approach (Nonfluoro group) or the standard fluoroscopy-guided approach (Fluoro group). The nonfluoroscopic approach has been performed since October 1, 2013, to completely exclude ionizing radiation exposure. Forty-five patients, treated with nonfluoroscopic approach in this implementation period were not included in study. The approach (fluoroscopic vs nonfluoroscopic) was left to the discretion of the operator on an individual basis and was neither randomized nor systematic. The decision was determined preprocedurally and was based on several criteria such as the operator's preference and other patient-specific criteria such as young age, obesity, or patient's preference.

The primary safety endpoint was defined as the incidence of major procedure-related adverse events. The primary efficacy endpoint was defined as freedom from documented AF/atrial tachycardia (AT) during follow-up. Secondary endpoints included procedure duration, fluoroscopy duration, and acute PVI rate.

The Institutional Review Board of four centers approved this study. The work was performed as a retrospective study and was granted a waiver of informed consent.

2.2 | Ablation procedure

All patients were treated with novel oral anticoagulants (NOACs) or warfarin for at least 3 weeks before the procedure. NOAC or warfarin was continued without interruption during the procedure. All procedures were performed under conscious sedation using a continuous infusion of 1% propofol. A bolus of heparin (100 U/kg) was administered before the transseptal puncture, and anticoagulation therapy was continued throughout the intervention with a targeted activated clotting time of more than 300 seconds. All manipulations during the procedure for both groups were performed using ICE (AcuNav 10F; Siemens AG, Berlin, Germany) control combined with the 3D mapping system (CARTO 3; Biosense Webster, Inc., Diamond Bar, CA, USA), which provided visualization of all diagnostic and ablation catheters as well as chamber reconstruction. ICE was also used to exclude intracardiac thrombi.[15] Contrast media was not used for the Nonfluoro group.

For the Fluoro group, fluoroscopy was used following the ALARA (as low as reasonably achievable) principle, and PV angiography was performed to identify the PV ostia.[16] Otherwise, the procedure was performed as for the Nonfluoro group. Cavatricuspid isthmus (CTI) ablation was performed for patients with documented or induced intraoperative CTI-dependent atrial flutter.

2.3 | Right atrial access

For the Nonfluoro group, vascular access was obtained through the left femoral vein for the ICE catheter (AcuNav 10F; Siemens AG) and through the right femoral vein for two transseptal introducers. Either right femoral vein or right internal jugular vein access was used for coronary sinus (CS) catheter placement. The ICE probe was introduced via the inferior vena cava (IVC) and placed in the right atrium (RA). In the case of inadvertent engagement of the ICE probe in the collateral iliac vein or one of the side branches, the probe was replaced by withdrawing and carefully readvancing it, with appropriate bending and extension of the catheter under direct ultrasound visualization (Supplementary Video S1).

A deflectable 10-pole CS catheter (Webster CS 6F; Biosense Webster, Inc.) was advanced through the IVC or superior vena cava (SVC) to the RA and placed into the CS under electrogram guidance and direct ultrasound visualization of the CS ostium, or under fast anatomical map (FAM) guidance (Figure 1). For patients in the Nonfluoro group and for the minority of patients in the Fluoro group in whom the design of the ablation procedure included PVI only and CS electrogram monitoring was unnecessary, we refrained from performing CS catheterization according to the operator's discretion. In the Fluoro group, ICE probe insertion, CS catheterization, and transseptal puncture were performed under fluoroscopic guidance.

2.4 | Double transseptal puncture

For the Nonfluoro group, two long 0.032-inch guidewires were introduced along the interatrial septum (IAS) into the SVC under direct ultrasound control, and the ICE probe was deflected slightly posteriorly to the right to view the IAS-SVC transition. After intravenous administration of heparin, two transseptal sheaths (SL1; St. Jude Medical, Inc., St. Paul, MN, USA) were advanced over the wires to the SVC (Supplementary Video S1). The exact position of the sheaths was verified by infusing a small amount of saline through the lumen. Then, the angle of the ICE probe was adjusted to align the left PV with the IAS. After the transseptal needle was inserted (BRK-1; St. Jude

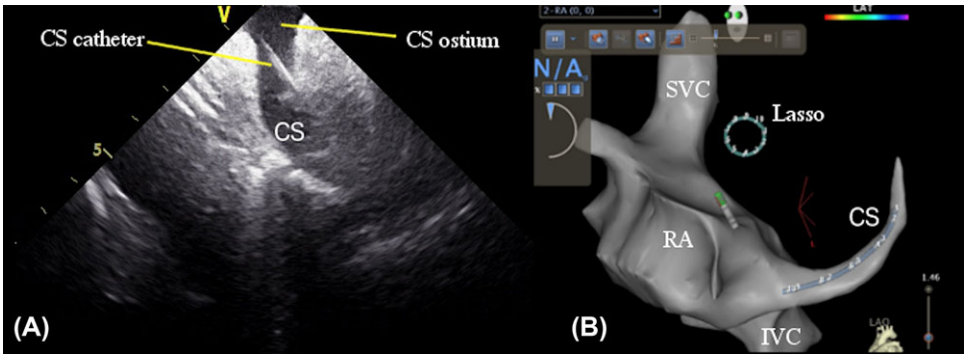

FIGURE 1 Nonfluoroscopic catheterization of the CS guided by ICE (A) and FAM of CS (B). CS = coronary sinus; FAM = fast anatomical map; ICE = intracardiac echo; IVC = inferior vena cava; Lasso = circular mapping catheter; RA = right atrium; SVC = superior vena cava [Color figure can be viewed at wileyonlinelibrary.com]

Medical, Inc.) into the first sheath, this assembly was pulled back under ultrasound-guided control until good IAS tenting was achieved. The appropriate positioning of the assembly against the IAS in the short axis with the aortic root, left PV, and LA posterior wall on the plane was additionally confirmed. Under ICE guidance, a transseptal needle was advanced out of the dilator to cross the IAS, and it was subsequently confirmed via a saline injection. If careful advancement of the dilator and sheath over the needle to the LA was not possible due to the stiffness of the IAS, the dilator was advanced over the wire, which was introduced in the left superior PV. The same manipulations were repeated for the second transseptal sheath, with subsequent irrigation of both sheaths with heparinized saline (Figure 2; Supplementary Videos S2 and S3).

For the Fluoro group, transseptal puncture was performed with ICE guidance as well as fluoroscopy guidance using standard projections (right anterior oblique [RAO], 30°; left anterior oblique [LAO], 40°) and contrast agents.

2.5 | Chamber reconstruction and PV mapping

For the Nonfluoro group, a deflectable circular mapping catheter (10-pole Lasso, 15 mm; Biosense Webster Inc.) and a 3.5-mm irrigated-tip ablation catheter (SmartTouch ThermoCool F-curve; Biosense Webster, Inc.) were advanced into the LA under ICE guidance (Supplementary Video S4). Anatomy of the LA and of the PV was reconstructed using the FAM mode of the CARTO 3 system at a precision level of 12 combined with an algorithm of respiratory movement compensation. Acquisition of the PV ostia on the LA map was guided by the reconstructed geometry of the PV and PV antra and was confirmed using ICE (Figure 3; Supplementary Videos S5 and S6).

For the Fluoro group, catheter manipulations during LA mapping were performed using fluoroscopy, if required. PV angiography using standard projections (RAO, 30°; LAO, 40°) was performed to delineate the PV ostia.

2.6 | PVI

Circumferential antral electrical isolation of the right and left ipsilateral PV was performed in a point-by-point manner with manual acquisition of the ablation points. A dragging technique was not used. RF energy was applied with a target contact force of 10–40 g and was limited to 25–30 watts for 30 seconds per lesion at the posterior wall and 35–40 watts for 60 seconds per lesion at the remaining left atrium. Since it was available, we used an automatic lesion annotation "*VisiTag*" for some patients. "*Ablation Index*" was not used because it was not available at the performing centers at that time. During ablation, PV potentials were continuously recorded with the Lasso catheter that was positioned within one ipsilateral PV. The PV entrance and exit blocks were confirmed with a Lasso catheter in sinus rhythm (Figure 4; Supplementary Videos S7 and S8). If AF persisted after PVI, electrical cardioversion was performed to restore the sinus rhythm. No additional lesion or substrate modification was performed.

The precise positions of the ablation catheter and Lasso catheter were confirmed using the CARTO 3 system and ICE imaging in both groups; in addition, fluoroscopy was used for the Fluoro group.

2.7 | CTI ablation

CTI ablation was only performed for patients with documented or intraoperatively induced CTI-dependent atrial flutter. FAM reconstruction of the CTI, CS ostium, and the His region was conducted in the Nonfluoro group. Linear ablation of the CTI was performed under ICE guidance. RF energy was limited to 40 watts and 60 seconds at each point with a target contact force of 10–40 g. A bidirectional block was confirmed by pacing maneuvers from the CS ostium and lateral CTI. In the Fluoro group, the position of the ablation catheter was located by fluoroscopy with an LAO projection of 40°.

2.8 | Follow-up

All patients were evaluated at the outpatient clinic at 3, 6, and 12 months after the procedure and underwent an interview, physical examination, 12-lead surface electrocardiography, and 24-hour Holter monitoring. Patients were instructed to undergo electrocardiography if they had symptoms suggestive of arrhythmia recurrence. For patients who experienced symptoms suggestive of arrhythmia recurrence, an additional 24-hour Holter monitoring was conducted. Recurrent AF was defined as any documented episode of AF/AT lasting more

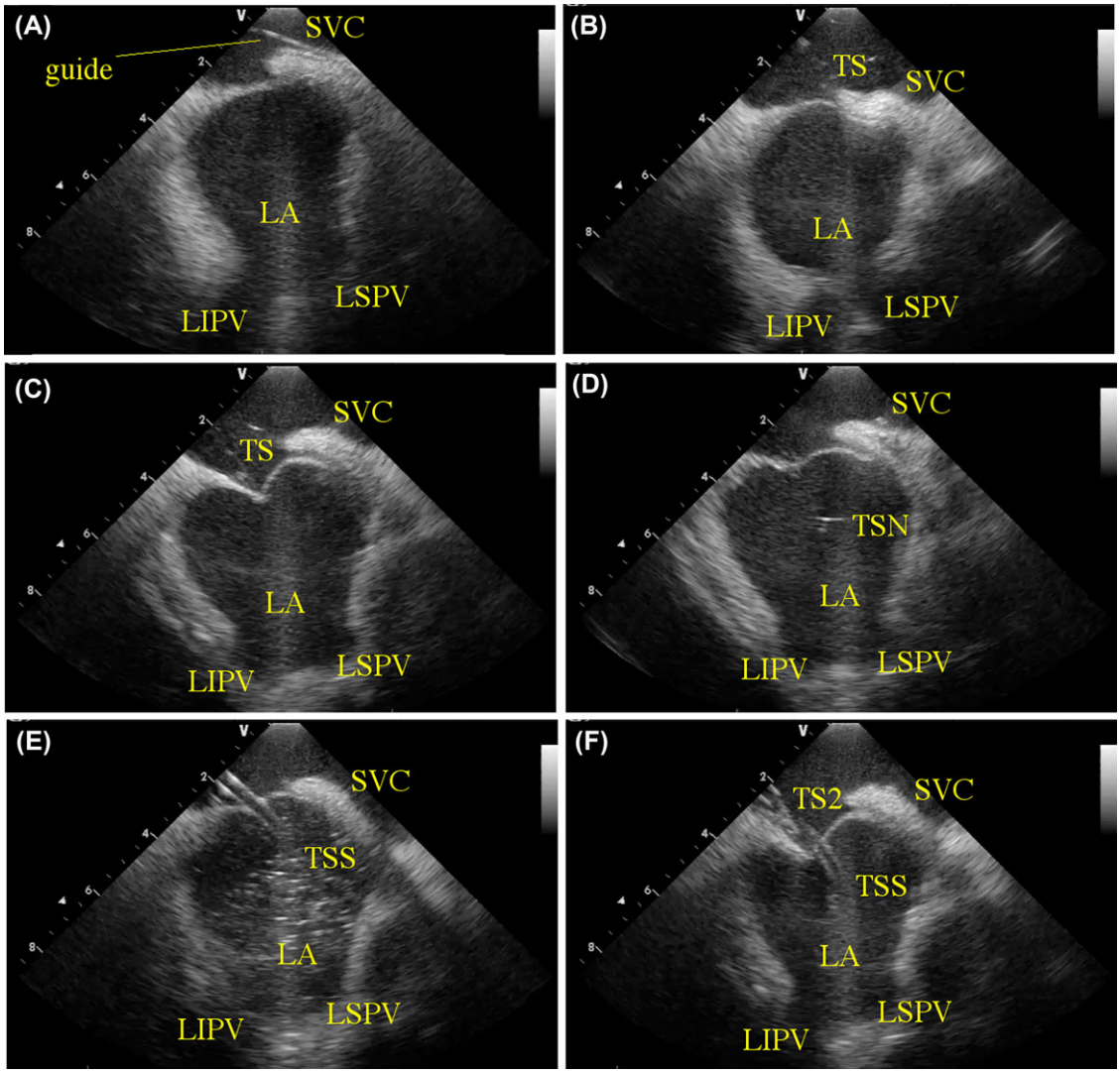

FIGURE 2 Nonfluoroscopic transseptal puncture guided by ICE. The ICE probe is positioned in the RA with a slight posterior-right tilt to visualize the SVC-RA transition. A, A long guidewire is positioned in the SVC. B, Sheath-needle assembly is pulled down toward the RA. The transient position of the assembly against the SVC-RA transition is visualized. C, After further pulling of the sheath-needle assembly, its position against the membranous part of the septum is achieved. Tenting of the interatrial septum is visualized. D, The septum is punctured by the transseptal needle (its tip is visualized in the LA). E, The transseptal sheath is advanced to the LA over the needle. Irrigation of the sheath with saline produces a bubble in the LA. F, The second transseptal puncture is performed in the same manner. Advancement of the second transseptal assembly produces tenting of the septum just inferior to the first sheath. ICE = intracardiac echo; LA = left atrium; LIPV = left inferior pulmonary vein; LSPV = left superior pulmonary vein; RA = right atrium; TS = transseptal sheath and needle assembly; TSN = transseptal needle; TSS = transseptal sheath; SVC = superior vena cava [Color figure can be viewed at wileyonlinelibrary.com]

than 30 seconds. The 90 days immediately following the procedure were considered to be a blanking period, and no data were collected. After the blanking period, antiarrhythmic drugs were immediately withdrawn from all patients and oral anticoagulation was continued.

2.9 | Data analysis

Continuous variables are expressed as mean ± standard deviation. Categorical variables are expressed as absolute numbers and percentages. Differences between means were compared using a nonparametric Kruskal-Wallis one-way analysis of variance test for continuous variables and a nonparametric χ^2 test or Fisher's exact test, when appropriate, for categorical variables. A Kaplan-Meier analysis was used to determine the percentage of patients who were free from AF after the initial procedure. Any differences in the AF-free survival rate were evaluated using a log-rank test. $P \leq 0.05$ was considered statistically significant. SPSS software version 20.0 (IBM Corp., Armonk, NY, USA) was used for the statistical analysis.

3 | RESULTS

Among the 481 patients with paroxysmal AF, 245 (50.9%) patients underwent the nonfluoroscopic procedure and 236 (49.1%) patients underwent the fluoroscopic-guided procedure. Baseline characteristics of the patients are summarized in Table 1.

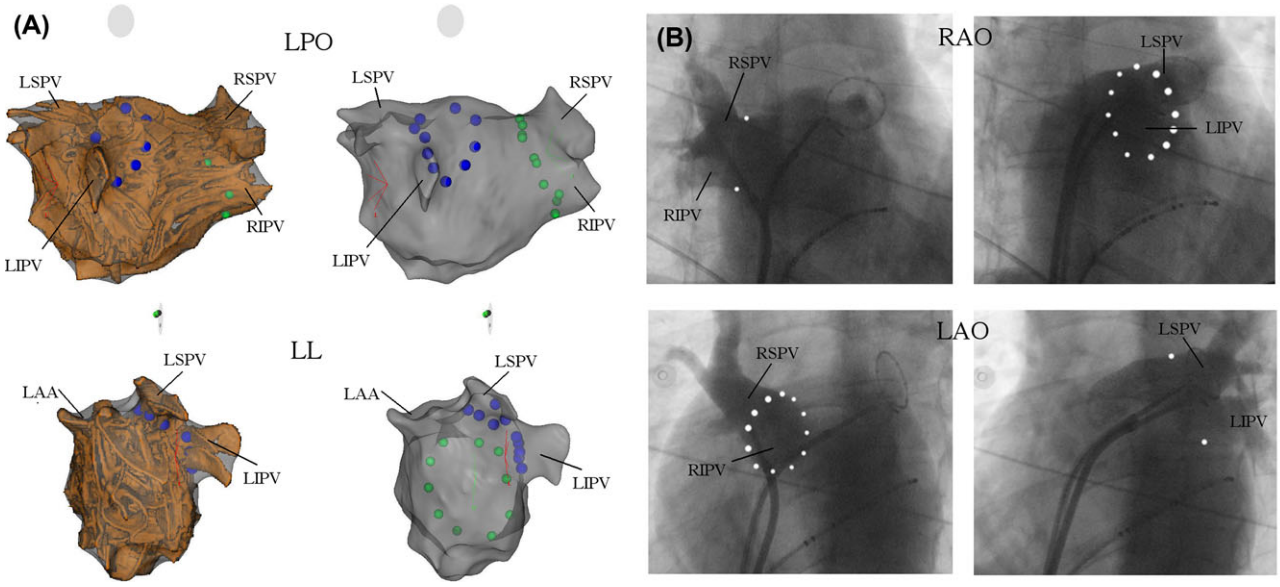

FIGURE 3 Reconstruction of the left atrium and PVs guided by FAM for the Nonfluoro group (A) and by angiography for the Fluoro group (B). FAM = fast anatomical map; LAA = left atrial appendage; LAO = left anterior oblique; PVs = pulmonary veins; RAO = right anterior oblique; RIPV = right inferior pulmonary vein; RSPV = right superior pulmonary vein. Other abbreviations as in Figure 2 [Color figure can be viewed at wileyonlinelibrary.com]

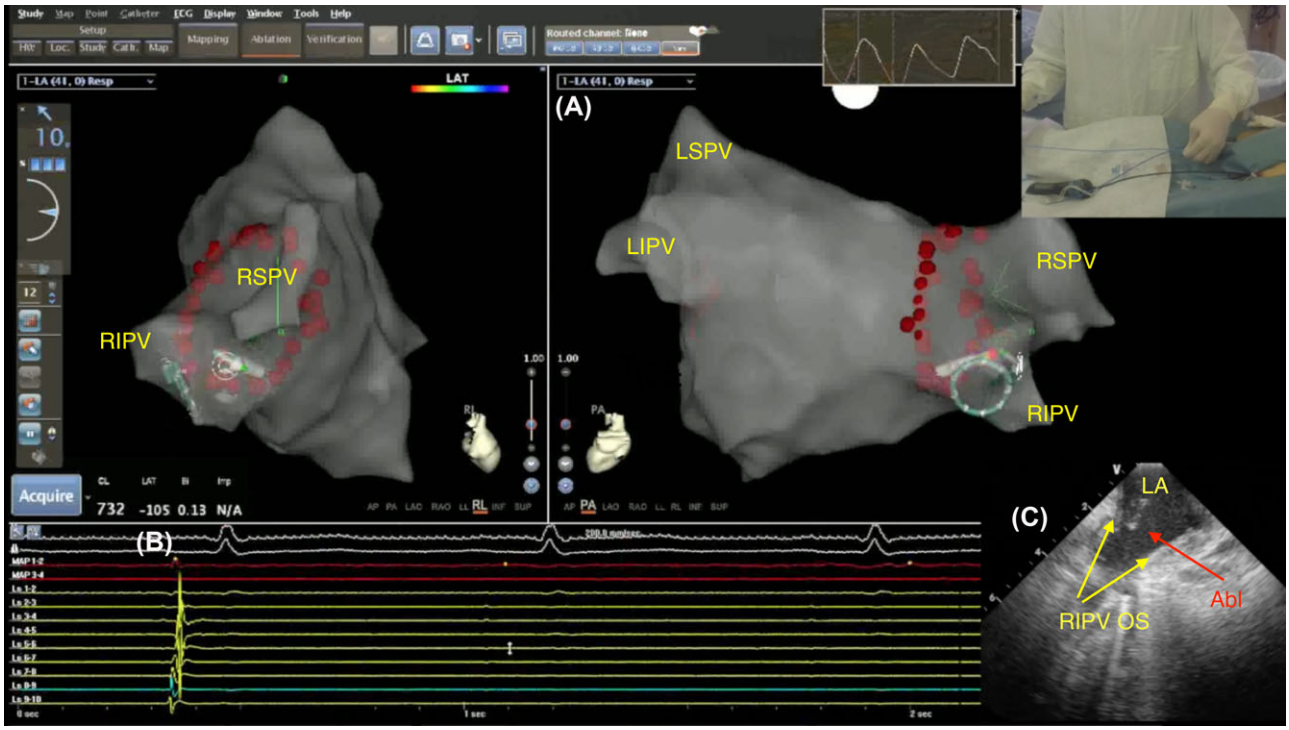

FIGURE 4 Nonfluoroscopic catheter ablation of the right PVs. A, The transparent mode of the FAM is used to visualize the real position of the ablation points. A Lasso catheter is placed into the RIPV. B, Electrical isolation of the right PVs occurs during radiofrequency application. C, Position of the ablation catheter ("Abl" arrow) at the inferior segment of the RIPV (RIPV OS arrows) is also confirmed with ICE. Abl = ablation catheter; FAM = fast anatomical map; LA = left atrium; LIPV = left inferior pulmonary vein; LSPV = left superior pulmonary vein; OS = ostium. Other abbreviations as in previous figures [Color figure can be viewed at wileyonlinelibrary.com]

Double transseptal puncture and acute PVI were successfully achieved for all patients. The mean procedure time was similar for both groups (108.8 ± 18.2 minutes for the Nonfluoro group vs 113.6 ± 26.8 minutes for the Fluoro group; P = NS). The mean fluoroscopy time in Fluoro group was 16.4 ± 6.8 minutes. Transseptal puncture times (9.0 ± 3.3 minutes vs 9.6 ± 5.6 minutes; P = NS), 3D mapping times (7.0 ± 5.4 minutes vs 7.9 ± 6.6 minutes; P = NS), and RF application times (43.4 ± 7.5 minutes vs 44.4 ± 10.7 minutes; P = NS) were similar in both groups (Table 2).

TABLE 1 Baseline characteristics*

Parameter	Nonfluoro	Fluoro	P
N	245 (50.9%)	236 (49.1%)	
Age, years	59.7 ± 11.3	60.8 ± 10.6	NS
Men	130 (53.1%)	124 (52.5%)	NS
BMI	29.0 ± 4.5	29.1 ± 4.7	NS
Structural heart disease	26 (10.6%)	19 (8.1%)	NS
Hypertension	161 (65.7%)	151 (64%)	NS
History of stroke	7 (2.9%)	2 (0.8%)	NS
Diabetes	30 (12.2%)	29 (12.3%)	NS
Number of failed AAD	1.9 ± 0.8	1.8 ± 0.9	NS
LA diameter, mm	42.0 ± 4.5	42.0 ± 4.1	NS
LVEF, %	62 ± 7.1	61.1 ± 6.8	NS
CHADS2Vasc2 score	1.3 ± 1.1	1.3 ± 1.1	NS
Implanted device	6 (2.4%)	10 (4.2%)	NS

Note: *Data are presented as a mean ± standard deviation. AAD = antiarrhythmic drugs; BMI = body mass index; LA = left atrium; LVEF = left ventricle ejection fraction; NS = not significant.

CTI ablation was performed for 40 out of 245 (16.3%) patients in the Nonfluoro group and 45 out of 236 (14.8%) patients in the Fluoro group (P = NS). A bidirectional block was successfully achieved in all 85 patients, with mean RF application times of 8.9 ± 2.1 minutes and 9.2 ± 2.4 minutes for the Nonfluoro and Fluoro groups, respectively (P = NS).

Cardiac tamponade occurred in three patients (1.2%) in the Nonfluoro group and in two patients (0.8%) in the Fluoro group (P = NS). Pericardial drainage successfully treated this complication in all cases. For three patients in the Nonfluoro group, 35, 44, and 107 seconds of fluoroscopy were required to puncture the pericardium; no other patient in this group required fluoroscopy during the whole procedure. One of the patients of the Nonfluoro group had pericardial effusion, revealed after steam pop during CTI ablation at the end of the procedure. In other four cases, pericardial effusion was diagnosed at the end of the procedure after isolation of all PVs and were most likely related to the manipulations in the LA. No other major complications occurred in any patients during the periprocedural and follow-up periods.

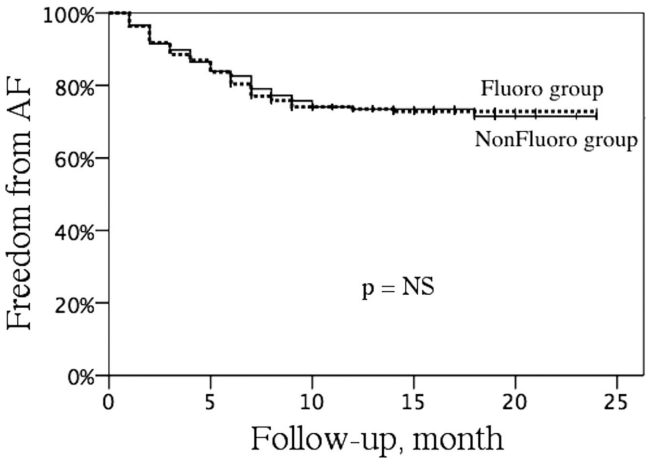

FIGURE 5 Freedom from AF during follow-up. AF = atrial fibrillation; NS = not significant

During a mean of 15.2 ± 4.1 months of follow-up, 65 of 245 (26.5%) patients in the Nonfluoro group and 61 of 236 (25.8%) patients in the Fluoro group experienced AF recurrence after a single procedure (log rank = 0.01; P = NS) (Figure 5).

4 | DISCUSSION

This was the first multicenter study of a large cohort of patients assessing the safety and efficacy of nonfluoroscopic AF ablation without

TABLE 2 Procedural data*

Parameter	Nonfluoro	Fluoro	P
N	245	236	
Coronary sinus catheterization	45 (18.4%)	219 (92.8%)	<0.0001
Duration of the catheterization and TSP, min	9.0 ± 3.3	9.6 ± 5.6	NS
Duration of LA geometry reconstruction, min	7.0 ± 5.4	7.9 ± 6.6	NS
Acute PVI	245 (100%)	236 (100%)	NS
Total RF time, min	43.4 ± 7.5	44.4 ± 10.7	NS
CTI ablation	40 (16.3%)	45 (14.8%)	NS
CTI ablation RF time, min	8.9 ± 2.1	9.2 ± 2.4	NS
Fluoroscopy time, min	0.013 ± 0.128**	16.4 ± 6.8	<0.0001
Dose, mGy*cm^2	81.9 ± 808.3**	16352.7 ± 13714.1	<0.0001
Contrast media, ml	0.08 ± 0.78	54.2 ± 18,7	<0.0001
Total procedure time, min	108.8 ± 18.2	113.6 ± 26.8	NS
Hemopericardium	3 (1.2%)	2 (0.8%)	NS

Note: *Data are presented as a mean ± standard deviation. CTI = cava-tricuspid isthmus; LA = left atrium; NS = not significant; PVI = pulmonary vein isolation; RF = radiofrequency; TSP = transseptal puncture.
**Only three patients who required pericardiocentesis received 100% of this fluoroscopy time and dose. Other patients did not require fluoroscopy during the procedure.

preprocedural CT or MRI scans compared to a standard fluoroscopy-guided approach for the treatment of paroxysmal AF.

The major findings of this study were as follows: PVI without fluoroscopy is feasible and does not require PV angiography or CT/MRI integration and nonfluoroscopic AF ablation was associated with similar safety and efficacy profiles as the conventional AF ablation procedure.

Until recently, fluoroscopy was a prerequisite for all ablation procedures.[4] For many years, fluoroscopy was the only available technology that allowed catheter visualization inside the body. More than 15 years ago, new 3D mapping systems were developed to minimize ionizing radiation exposure and increase the accuracy of the catheter's location. Modern 3D mapping systems process catheter position data at a high rate (18 times per second in the CARTO 3 system), thus providing high accuracy for catheter movement control that is comparable to that of fluoroscopy (15 frames per second). Despite its ability to precisely reconstruct the 3D anatomy of the chambers of the heart, nonfluoroscopic mapping systems traditionally appeared to be less reliable than fluoroscopy for many operators. Nevertheless, several recent studies have shown the feasibility and safety of nonfluoroscopic AF ablation guided by ICE in combination with a 3D mapping system and preprocedural CT or MRI.[9,11,12]

4.1 | Feasibility and safety of nonfluoroscopic AF ablation

Several steps of the AF ablation procedure require conventional fluoroscopy: catheterization of the RA, catheterization of the CS, transseptal puncture, and PV ostia mapping. Our study is in line with previous studies demonstrating that hurdles could be overcome with the assistance of new nonfluoroscopic approaches.[9,11,12] Engaging of the ICE catheter in one of the branch veins during its introduction through the IVC was always resolved in our study by withdrawing and carefully readvancing the catheter with appropriate bending and extension of the catheter under direct ultrasound visualization.

The second challenge of the nonfluoroscopic approach is CS catheterization. When PVI is the sole ablation strategy, the CS catheter is used as an anatomical landmark for transseptal puncture and allows the operator to perform differential pacing maneuvers to verify CTI block or discriminate between far-field signals. Previous studies have shown the feasibility of nonfluoroscopy-guided CS catheterization, which was performed in most cases.[9,11,12] In our study, a multipolar catheter guided by electrogram or ICE or after FAM reconstruction of the LA or RA was successfully placed in the CS in only a few patients. Because the nonfluoroscopic transseptal puncture does not require CS catheter placement, a catheter was not advanced into the CS in most patients to reduce the procedure time. This probably could have shortened the mean procedure time in the Nonfluoro group and could have countervailed the longer transseptal access step. Pacing to discriminate far-field signals was performed using an ablation catheter.

At first glance, the transseptal puncture seems to be the "Achilles heel" of nonfluoroscopic methodology. Traditionally, the movements and position of the transseptal sheath-needle assembly are controlled by fluoroscopy according to the sheath's relationship with the heart's silhouette and CS catheter. In other words, fluoroscopy does not provide visualization of the IAS, but it is a valuable intracardiac landmark. However, ICE allows for live visualization of the IAS and the position of the transseptal assembly against it. Guidewire and sheath manipulations under ICE control seem to be more challenging and time-consuming because these tools are required to be on the ultrasound plane of view. Reddy et al. described the successful use of nonfluoroscopic single transseptal access for PVI.[12] Ferguson et al. performed a double nonfluoroscopic transseptal puncture over the needle and dilator.[11] Bulava et al. used a nonfluoroscopic double transseptal puncture over the wire without any puncture-related complications.[9] In our study, we performed a double transseptal puncture with an over-the-needle technique for most patients in both groups. The incidence of cardiac tamponade was comparable in both groups. In one patient of the Nonfluoro group pericardial effusion was diagnosed after steam pop during CTI ablation. The pericardial effusion and cardiac tamponade in other four cases occurred at the end of the procedure and no difficulties were noticed during transseptal puncture. For this reason, we suppose that tamponade was most likely caused by the manipulation in the LA. Kuhne et al. described a case series in which nonfluoroscopic LA access was obtained through the patent foramen ovale.[13] We did not use this approach for our patients, even if they had a foramen ovale, because its cranial and anterior locations compromise the catheter contact and stability.

Because complete electrical isolation of all PV is the cornerstone of the AF ablation procedure, accurate PV ostia mapping is mandatory for circumferential lesions.[17] Not only the efficacy of the PVI but also the safety of the procedure depend on the accuracy of PV ostia annotation. Ablations inside the PV can result in PV stenosis.[18] Therefore, retrograde PV angiography is the current gold standard for verifying PV anatomy.[17] In recent years, several studies have shown the feasibility and safety of PV ostia mapping without fluoroscopy.[9,11,12] All of these studies used CT/MRI merging with the electroanatomical map to prove the accuracy of mapping and PVI. Nevertheless, these imaging technologies are time-consuming, and CT is associated with significant ionizing radiation exposure. Moreover, large LA volumes affect error in the integration of electroanatomic mapping with CT or MRI.[19] In our study, we demonstrated that FAM technology combined with ICE confirmation is precise enough to map the PV ostia and perform circumferential antral PVI.

4.2 | Efficacy of nonfluoroscopic AF ablation

The results of our multicenter study have shown that AF ablation without fluoroscopy does not prolong the total procedure time or compromise the acute success rate and clinical efficacy during long-term follow-up. The first and, until now, only randomized, single-center study of 80 patients with paroxysmal AF showed that the nonfluoroscopic approach is not inferior to the fluoroscopy-guided approach.[9] This study reported that the use of CT integration with a 3D mapping system in combination with ICE can eliminate the need for fluoroscopy in patients undergoing AF ablation and result in acute PVI with 100% success. However, in our study, we demonstrated that FAM of the LA is

accurate enough to achieve acute PVI in all patients and requires neither CT merging nor PV angiography.

4.3 | Future perspectives

Nonfluoroscopic ablation in the LA requires a 3D mapping system and ICE. Although ICE allows for live visualization of the heart structures, its single-slice nature is complex and requires experience with manipulation and image interpretation. Nevertheless, new technologies such as CARTO UNIVU, MediGuide, and a transseptal sheath that is visible in the 3D mapping system are constantly evolving to help reduce the fluoroscopy time. Some animal and clinical studies have shown the feasibility of MRI-guided navigation and RF as well as cryoballoon-based ablation in the atria.[20] These technologies indicate the advent of a new MRI-guided epoch in catheter ablation.

4.4 | Study limitations

The major limitation of our study was its retrospective nonrandomized design. The approach (fluoroscopic vs nonfluoroscopic) was left to the discretion of the operator on an individual basis and was neither randomized nor systematic. The decision was based on several criteria such as the operator's preference and other patient-specific criteria such as young age, obesity, or patient's preference. For three cases in the Nonfluoro group, several seconds of fluoroscopy were required for the pericardial puncture and drainage placement. Because the operators were experienced in performing fluoroscopy-guided pericardial punctures, for safety reasons, fluoroscopy-guided pericardiocentesis was performed for emergency cases. Follow-up was limited to 24-hour Holter monitoring only. Therefore, the success rate might have been overestimated in both arms of the study. We did not perform CT routinely after the procedure to exclude asymptomatic PV stenosis. Therefore, asymptomatic PV stenosis might have remained undetected. However, no patient had dyspnea, recurrent pneumonia, or other clinical symptoms suggestive of PV stenosis during the follow-up period. Because the patients in both groups had an ICE probe inserted, comparisons regarding vascular complications between groups were of limited value. For 45 of 245 (18.4%) patients in the Nonfluoro group, we did not perform CS catheterization because our approach for paroxysmal AF patients involved PVI. For other substrate-based approaches beyond PVI in persistent AF patients, obligatory CS catheterization would have been required.

5 | CONCLUSIONS

Nonfluoroscopic RF catheter ablation of AF without CT or MRI image integration and PV angiography is feasible and safe. In this study, PVI without fluoroscopy did not affect procedure duration or long-term efficacy. Therefore, it should be considered as an alternative approach.

ACKNOWLEDGMENTS

None.

CONFLICT OF INTEREST

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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