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Fluoroless Catheter Ablation of Atrial Fibrillation: Integration of Intracardiac Echocardiography and Cartosound Module

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Abstract

Objectives: To evaluate the feasibility, safety, and clinical efficacy of non-fluoroscopic radiofrequency catheter ablation of atrial fibrillation (AF) in comparison to traditional fluoroscopy-guided ablation in a local Canadian community cohort.

Methods: We retrospectively studied consecutive patients with paroxysmal and persistent AF undergoing pulmonary vein isolation (PVI) guided by intracardiac echocardiography (ICE) and Carto system (CartoSound module). ICE-guided PVI without fluoroscopy (Zero-fluoro group) was performed in 116 patients, and conventional fluoroscopy-guided PVI (Traditional group) was performed in 131 patients.

Results: Two hundred and forty-seven patients with AF (60.7% male; mean age: 62.2 ± 10.6 years; paroxysmal AF =63.1%) who underwent PVI were studied. Mean procedure times were similar between both groups (136.8 ± 33.4 minutes in the zero-fluoro group vs. 144.3 ± 44.9 minutes in the traditional group; p=0.2). Acute PVI was achieved in all patients. Survival from early AF recurrence was 85% and 81% in the zero-fluoro and traditional groups, respectively (p = 0.06). Survival from late AF recurrence (12-months) between the zero-fluoro and traditional groups was also similar (p=0.1). Moreover, there were no significant differences between complication rates, including hematoma (p = 0.2) and tamponade (p = 1), between both groups.

Conclusions: Zero-fluoroscopy ICE and CartoSound-guided AF ablation may be safe and feasible in patients undergoing PVI compared to conventional fluoroscopy-guided ablation.

Introduction

Radiofrequency ablation (RFA) of atrial fibrillation (AF) is performed under fluoroscopic guidance and, therefore, carries a risk of radiation for both the patients and the medical staff attending to the procedure¹⁻⁴. Although three-dimensional (3D) mapping and newer imaging modalities have allowed for catheter visualization and successful ablation, there has been increasing interest to use minimal or zero fluoroscopy during AF ablation to limit radiation dose exposure ⁵⁻⁷. Recently, fluoroless RFA procedures guided by intracardiac echocardiography (ICE) and 3D mapping were safely performed with high success for complex arrhythmias ⁸⁻¹². To better understand the applicability of these findings in a local Canadian population, the present analysis examined the feasibility, safety, and clinical efficacy of

Key Words

Atrial Fibrillation; Catheter Ablation; Intracardiac Echocardiography; Fluoroscopy; Three-Dimensional Mapping.

Corresponding Author Alfredo Pantano, Southlake Regional Health Centre 602-581 Davis Drive, Newmarket, ON, L3Y 2P6, Canada non-fluoroscopic RFA in comparison to traditional fluoroscopy-guided ablation in patients with AF.

Materials and methods

Study population and protocol

From October 2017 to November 2020, 247 consecutive patients undergoing RFA for symptomatic, drug-refractory paroxysmal AF (PAF) or persistent AF were retrospectively studied. To minimize inter operator bias, one operator (AP) conducted RFA. Our center has performed Fluoroless AF ablations as the standard of care and first option since 2019. Cases before and after the implementation of the Fluoroless AF program were compared. During Fluoroless ablations, the operator and other medical staff attending to the procedure did not wear lead aprons and the fluoroscopy system was inactivated and removed. The operator (A.P) has been practicing Fluoroless AF ablation for two years. The study was approved by the local Institutional Research Ethics Board.

Procedure duration, acute procedural success, complications, and recurrence rates were recorded. Procedure duration was recorded from

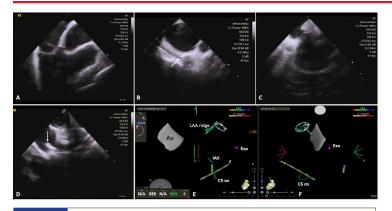


Figure 1: Illustratrive description of fluoroless AF ablation (ICE+CartoSound).

A:Main view showing aortic root, tricuspide valve, RV, and RVOT; B: Clockwise rotation of ICE catheter showing posterior aspect of left atrium along with esophagus and tip of esophagial probe (arrow); C: Interatrial septum; D: View of LAA ridge (arrow) between LAA and LSPV; E-F: Carto images of anatomical landmarks obtained by ICE. Left lateral and PA views showing aorta (Ao), interatrial septum (IAS), coronary sinus ostium (CS os), left atrial appendage ridge (LAA ridge), and tip of esophagial probe (Eso).

initial venous access until final sheath removal after the completion of the RFA procedure. Acute pro¬cedural success was determined by both entrance and exit blocks of the pulmonary veins. Recurrence was defined by the occurrence of arrhythmia after the blanking period (three months) following RFA.

Pre- and intra-procedural description

Transesophageal echocardiography was performed to rule out intracardiac thrombus in the left atria and the left atrial appendage. Antiarrhythmic drugs were discontinued for approximately five halflives except for amiodarone, which was discontinued for >2 weeks before the RFA procedure. Patients were asked to hold oral anticoagulation 24 hours before the procedure and a bolus of heparin (100 U/kg) was administered intravenously before the transseptal puncture. Intravenous heparin was administered to target an activated clotting time above 300 seconds.

Under sterile draping in the usual fashion, three 9 French venous sheaths were placed in the right femoral groin. An 8-French Soundstar catheter (Biosense Webster, Irvine, CA) was inserted into the right atrium. After activation of the Carto Sound module, the following anatomical landmarks were marked in the mapping system: aorta, interatrial septum, coronary sinus ostium, and left atrial appendage ridge. An esophageal temperature probe was placed adjacent to the posterior wall of the left atrium and the level of the tip of the probe was marked on the mapping system with the help of ICE and CartoSound (Figure 1). A diagnostic catheter (IBI Inquiry, Abbott Medical) was placed into the coronary sinus under ICE, EGM, and CartoSound guidance. Transseptal access was obtained under ICE guidance as follows: the wire was advanced into the right atrium, and once identified, directed into the superior vena cava (SVC). A long SL-1 sheath and dilator (Abbott Medical) were advanced over the wire into the SVC. After the wire was removed, a transseptal puncture needle (Brocken brough, Abbott Medical) was advanced to within the dilator tip. The unit was pulled inferiorly and directed to a particular region of the interatrial septum. Once "tenting" was observed, a puncture was performed and confirmed with both ICE visualization and microbubble

injection. Single transseptal access was obtained in all patients (Figure 2 and Supplementary Video). In case of failure to obtain proper tenting of the septum, we used an ablation catheter to direct the SL1 sheath to the septum, which was marked on the mapping system. The ablation catheter was then removed and replaced with a dilator and BRK needle. Transseptal puncture was performed afterward. Then, a circular Lasso catheter (Biosense Webster, Irvine, CA) was placed in the left atrium and detailed electro-anatomical mapping of the left atrium was performed with the CARTO 3 system (Biosense Webster, Irvine, CA). Following the completion of mapping, the Lasso catheter was exchanged with a contact-force (CF) sensing bidirectional Thermo cool Smart Touch catheter (Biosense Webster, Irvine, CA) to start the RFA procedure. Point-by-point wide antral circumferential ablation with RF was performed in all patients. RF energy was applied at 30 to 35 Watts in the anterior aspect of pulmonary veins; however, in the posterior aspect of the pulmonary veins, RF energy was applied at 20-25 Watts due to the close proximity to the esophagus. Targeted CF was 10-20 grams except in areas that were in close proximity to the esophagus where targeted CF was 5-10 grams. Ablation index was used (450 for the anterior wall, 350-400 for the posterior wall). If AF persisted after isolation, electrical cardioversion was performed to restore sinus rhythm. Additional lesion delivery was left at the operator's discretion and could have included LA roofline, LA posterior wall isolation, and mitral isthmus line. It is worth mentioning that CartoSound was used in order to guide the Fluoroless procedure, including annotation of adjacent tissues (esophagus, aorta, interatrial septum, LAA ridge),

Baseline characteristics of patients undergoing traditional and zero-fluoro ablation of atrial fibrillation.

	Total (n = 247)	Zero-fluoro (n = 116)	Traditional (n = 131)	P-Value
Age (years)	62.2 (10.6)	61.9 (10.6)	62.6 (10.6)	0.5
Gender, male	150 (60.7%)	86 (65.6%)	64 (55.2%)	0.1
PAF	152 (63.1%)	78 (62.4%)	74 (63.8%)	0.9
Comorbidities				
Hypertension	129 (52.4%)	65 (50%)	64 (55.2%)	0.4
Diabetes	28 (11.4%)	14 (10.8%)	14 (12.1%)	0.9
Sleep Apnea	67 (27.2%)	34 (26.2%)	33 (28.4%)	0.7
Stroke	9 (3.7%)	3 (2.3%)	6 (5.2%)	0.3
CAD	38(15.4%)	16(12.3%)	22(19%)	0.2
Ischemic CM	16(6.5%)	5(3.8%)	11(9.5%)	0.1
нсм	7(2.8%)	1(0.8%)	6(5.2%)	0.09
BMI (kg/m²)	29.8 (5.5)	29.84 (6.2)	29.65 (4.6)	0.7
Ejection Fractiona 1 2 3 4	204 (87.2%) 20 (8.5%) 6 (2.6%) 4 (1.7%)	108 (90.8%) 5 (4.2%) 3 (2.5%) 3 (2.5%)	96 (83.5%) 15 (13%) 3 (2.6%) 1 (0.9%)	0.08
LA size (mm)	41.6 (5.5)	41.5 (5.2)	41.7 (5.7)	0.7
Implanted device				
РРМ	23 (9.3%)	4 (3.1%)	19 (16.4%)	<0.001
ICD	6 (2.4%)	1 (0.8%)	5 (4.3%)	0.1

a Ejection Fraction: 1 = Normal = LVEF 50% to 70% (midpoint 60%); 2 = Mild dysfunction = LVEF 40% to 49% (midpoint 45%); 3 = Moderate dysfunction = LVEF 30% to 39% (midpoint 35%); Severe dysfunction = LVEF less than 30%.

Abbreviations: AAD = Anti-Arrhythmic Drug; AF = Atrial Fibrillation; BMI = Body Mass Index; CAD = Coronary Artery Disease; HCM = Hypertrophic Cardiomyopathy; ICD = Implantable Cardioverter Defibrillator; Ischemic CM = ischemic cardiomyopathy; LA = Left Atrial; PAF = Paroxysmal Atrial Fibrillation; PPM = Permanent Pacemaker

Table 2:	Previous s	Previous studies reporting on fluoroless catheter ablation for atrial fibrillation								
Study	No. of fluoroless ablations	Setting	Study design	Type of AF	3D mapping system	Utilization of ICE	Energy usage	Patients with cardiac devices (%)	Procedure duration (min)	Complications
Ferguson et al. (2009) ¹¹	n = 21 No control group	USA	Cohort study, Prospective	PAF + PeAF	Yes (EnSite NavX)	Yes(100%)	RF	NA	208 (188 to 221)	
Reddy et al. (2010) ¹²	n = 20 No control group	USA	Cohort study, Prospective	PAF	Yes (EnSite NavX)	Yes (100%)	RF	15	244 ± 75	
Bulava et al. (2015) ⁹	Zero-fluoro group, n = 40 Traditional group (Control), n = 40	Czech Republic	Single-center RCT	PAF	Yes (CARTO)	Yes (45%)	RF	NA	92.5 ± 22.9	
Sánchez et al. (2016) ¹⁹	n = 56 No control group	USA	Cohort study, Retrospective	PAF + PeAF	Yes (EnSite NavX)	Yes (70.4%)	RF	10	126 ± 50	
Percell et al. (2016) ²⁰	n = 20	USA	Cohort study, Retrospective	PAF + PeAF	Yes (EnSite Precision or CARTO)	Yes (100%)	RF or cryoballoon	NA	210	Tamponade (1.2% in the fluorless group)
Razminia et al. (2017) ¹³	n = 186 No control group	USA	Cohort study, Retrospective	PAF + PeAF + longstanding PeAF	Yes (EnSite NavX or CARTO)	Yes (100%)	RF or cryoballoon	10	194.4	2 pts with tamponade, 1 pt with atrioesophageal fistula
Liu et al. (2018) ²¹	Zero-fluoro group, n = 200 Traditional group (Control), n = 50	USA	Cohort study, Retrospective	PAF + PeAF	No	Yes (100%)	RF	9.5	90.3 ± 17.7	1 pt with partial phrenic palsy, 1 pt with pseudoaneurysm
Lyan et al. (2018) ¹⁵	Zero-fluoro group, n = 245 Traditional group (Control), n = 236	Russia and Kazakhstan	Cohort study, Retrospective	PAF	Yes (CARTO)	Yes (100%)	RF	2.4	108.8 ± 18.2	3 pts with tamponade in the Fluoroless group
Sommer et al. (2018) ¹⁴	n = 1000 No control group	Germany	Clinical Registry	PAF + PeAF + longstanding PeAF	Yes (EnSite Precision)	No	RF	NA	120 ± 40.4	Femoral pseudoaneurysm (n= 10), Pericardial effusion (n = 7), arteriovenous fistula (n= 1), phrenic nerve palsy (n= 1), stroke (n= 1)
Cha et al. (2020) ¹⁸	Zero-fluoro group, n = 30 Traditional group (Control), n = 30	South Korea	Cohort study, Retrospective	PAF + PeAF	Yes (CARTO)	Yes (100%)	RF	NA	163.9 ± 59.7	1 pt with pericardial effusion in the Fluoroless group
Salam et al. (2020) ²²	n = 325 No control group	USA	Case series	PAF + PeAF	Yes (CARTO)	Yes (100%)	RF	NA	134.0 ± 30.5	
Zei et al. (2020) ²³	Zero-fluoro group, n = 100 Traditional group, n = 60	USA	Clinical Registry	PAF + PeAF	Yes (CARTO)	Yes (100%)	RF	1	192 ± 37	1 pt with TIA in the Fluoroless group
Jan et al. (2020) ²⁴	n = 144 No control group	Slovenia	Cohort study, Prospective	PAF	Yes (EnSite NavX or CARTO)	Yes (100%)	RF	NA	175 ± 40	4 pts with pericardial effusion w/o tamponade, 2 pts with pseudoaneurysm of femoral artery, 1 pt with tamponade, 1 pt with transient phrenic nerve injury
Žižek et al. (2020) ²⁵	n = 451 No control group	Slovenia	Cohort study, Retrospective	PeAF	Yes (EnSite NavX or CARTO)	Yes (100%)	RF	5.4	161 ± 64	6 pts with pericardial effusion, 2 pts with PSA intervention, 1 pt with tamponade, 1 pt with transient phrenic palsy, 1 pt with CIED lead dislocation
Lurie et al. (2020) ¹⁶	Zero-fluoro group, n = 147 Traditional group (Control), n = 176	Canada	Cohort study, Retrospective	PAF + PeAF	Yes (EnSite or CARTO or Rhythmia)	Yes (100 %)	RF	2.7	176 ± 46	2 pts with pericardial effusion or tamponade, 1 pt with atrioesophageal fistula in the Fluoroless group
Present study (2020)	Zero-fluoro group, n = 116 Traditional group (Control), n = 131	Canada	Cohort study, Retrospective	PAF + PeAF	Yes (CARTO)	Yes (100 %)	RF	2	136.85± 33.4	1 pt with tamponade in the Fluoroless group

Abbreviations: AF = atrial fibrillation; CIED = cardiac implantable electronic devices; NA = not available; PAF = paroxysmal atrial fibrillation; PeAF = persistent atrial fibrillation; PVI = pulmonary vein isolation; PSA = pseudoaneurysm; RF = radiofrequency; RCT = randomized clinical trial; TIA = transient ischemic attack



Figure 2: Visualization of superior vena cava (A) and wire in the SVC (B). Tenting of the septum is visulazied (C).

transseptal puncture, catheter stability, and catheter insertions (coronary sinus catheter). However, the LA shell was created with the Lasso catheter. Additionally, the Lasso catheter was used to check the PV isolations at the end of the procedure.

For the traditional fluoroscopy group, the transseptal puncture was performed with ICE and fluoroscopy guidance using standard projections and contrast agents.

Catheters were removed at the end of the procedure, and venous hemostas is was provided by a figure-of-eight suture with a three-way stop cock technique.

Follow up

AF recurrence was defined as any documented episode of AF/atrial tachycardia >30 seconds. The first 90 days (3 months) immediately following the RFA procedure were considered to be the blanking period. Early recurrence was defined as any recurrence of AF/AT in 90 days. Late recurrence was defined as any recurrence at 12 months. Patients were evaluated at the outpatient clinic at 3, 6, and 12 months after the RFA procedure. A 12-lead electrocardiogram (ECG) and 48-hour Holter data were collected. Additional ECG monitoring was instructed if patients exhibited symptoms suggestive of AF. Anti arrhythmic drugs were discontinued in all patients after the blanking period, and oral anticoagulation was continued according to their CHA₂DS₂VASc score.

Statistics

Baseline characteristics were described as mean ±standard deviation for continuous variables and frequencies and percentages for categorical variables. Comparisons between the zero-fluoro and traditional groups were made using the Student's t-test or using the chi-squared test or their non-parametric counterparts, as appropriate. Kaplan Meier analyses were performed to analyze the survival free from early and late arrhythmia recurrence and to compare arrhythmia recurrence between patients in the zero-fluoro and traditional groups during follow-up. Cox proportional-hazards models were developed to compare the risk of early and late recurrence of arrhythmia between the two groups during follow-up. All models were adjusted for age, gender, left atrial diameter, ejection fraction, body mass index, and comorbidities regardless of their significance in the univariate model. All statistical analyses were performed using R Studio (Version 1.2.5042) and R version (Version 4.0.3) with two-sided statistical significance set at an alpha = 0.05.

Results

Population demographics

Overall, 247 patients with AF who underwent PVI for AF were studied. The mean age was 62.2 ± 10.6 years;60.7% were male, and 63.1%had PAF. ICE-guided PVI without fluoroscopy (Zero-fluoro group) was performed in 116 patients (47%), and conventional fluoroscopyguided PVI (Traditional group) was performed in 131 patients (53%). Baseline characteristics of the population are summarized in Table 1. The mean fluoroscopy time in the traditional group was $12.5 \pm$ 9.8 minutes. Patients in the traditional group had more permanent pacemakers compared to the zero-fluoro group (16.4% vs. 3.1%; p = <0.001). Otherwise, there were no significant differences in baseline characteristics before ablation between the groups. A chronological description of similar studies describing Fluoroless RFA of AF is depicted in Table 2.

Procedural outcomes

ICE was used in all patients. Initial rhythm, site of ablation, and need for direct current cardioversion post-RFA were similar between both groups. In all cases, RFA was successfully performed. Procedure-related details are summarized in Table 3. Mean procedure times were similar between both groups (136.8 \pm 33.4 minutes in the zero-fluoro group vs. 144.3 \pm 44.9 minutes in the traditional group; p = 0.2) (Figure 3).

Adverse events

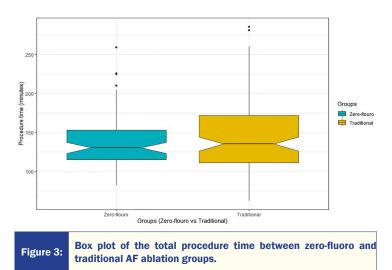
There were no significant differences between complication rates, including hematoma and tamponade, between both groups. The incidence of hematoma was 1 (0.8%) in the zero-fluoro group compared to 4 (3.4%) in the traditional group (p = 0.2). Moreover, the incidence of tamponade was 1 (0.8%) in the zero fluoro group and none in the traditional group (p = 1). The one tamponade in the zero-fluoro group occurred during LA ablation, likely due to a steam pop in the anterior aspect of the RSPV. No other complications occurred in this group.

Recurrence

Survival from early AF recurrence was 85% and 81% in the zerofluoro and traditional groups, respectively (p=0.06) (Figure 4). Twelvemonth survival rates from late AF recurrence were 50% in the zerofluoro group and 68% in the traditional group, respectively (Figure 5). Moreover, survival from late AF recurrence (12-months) in the zero-

Table 3:	Procedural details of patients undergoing traditional and zero- fluoroablation of atrial fibrillation.							
		Total	Zero-fluoro	Traditional	P-Value			
General A	nesthesia	140(57.4%)	104(79.4%)	36(31.9%)	<0.001			
Initial Rhy SR AT AF	thm	175(71.7%) 4(1.6%) 65(26.6%)	92(70.8%) 2(1.5%) 36(27.7%)	83(72.8%) 2(1.8%) 29(25.4%)	0.9			
Additional lesion delivery LA Roof Line LA Posterior Wall Mitral Isthmus		4(1.6%) 5(2%) 2(0.8%)	0(0%) 1(0.8%) 0(0%)	4(3.5%) 4(3.5%) 2(1.7%)	0.1 0.3 0.4			
Concurren	t AFL	4(1.6%)	0(0%)	4(3.5%)	0.1			
DCC Post	procedure	111(44.9%)	55(42%)	56(48.3%)	0.3			
Procedure	duration, min	140.5 ± 39.1	136.8 ± 33.4	144.3 ± 44.9	0.2			

Abbreviations: AF = Atrial Fibrillation; AFL = Atrial Flutter; AT = Atrial Tachycardia; DCC = Direct Current Cardioversion; ICE = Intracardiac Echocardiography; LA = Left Atrial; SR = Sinus Rhythm



fluoro and traditional groups were not significantly different (p=0.1).

A Cox proportional-hazards multivariate analysis of the variables, including age, gender, type of AF (PAF vs. persistent AF), presence of hypertension, diabetes, left atrial size, left ventricular ejection fraction, and body mass index showed no significant differences in the risk of early and late AF recurrence (12-months) between the zero-fluoro and traditional groups during follow-up (Traditional vs. Zero-fluoro: early recurrence: Hazard ratio (HR) = 1.7[0.9-3.2], late recurrence: HR0.5[0.2-1.02]).

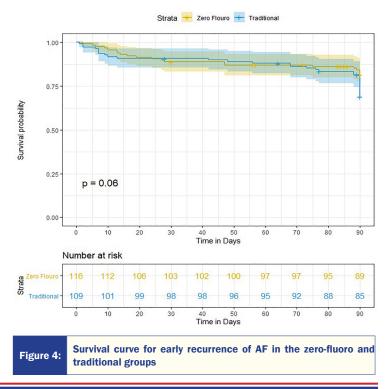
Discussion

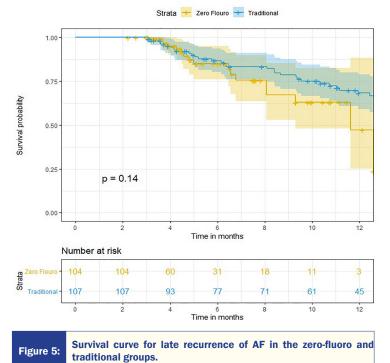
In this single-center study of a local Canadian community, we showed that zero-fluoroscopy RFAhad similar efficacy and safety profiles compared to the traditional fluoroscopy-guided approach. Furthermore, the procedure duration between zero-fluoroscopy and traditional groups was comparable. Freedom from AF was also comparable between both groups. In this study, we showed the safety and feasibility integration of imaging (ICE and CartoSound) and EGM guidance in order to perform fluoroless catheter ablation in patients with PAF and persistent AF.

An increasing number of studies have recently reported on the feasibility and safety of zero-fluoroscopy AF ablation (Table2). Ferguson et al.first demonstrated this technique in 21 patients with AF usingrotational ICE and 3D mapping. The mean procedure duration was 208 minutes, and there were no complications¹¹. This was followed by Reddy et al., who described a series of 20 consecutive patients who underwent PVI for PAF using zero-fluoroscopy. The procedure duration was 244 ± 75 minutes, with 97% acute procedural success¹². The only randomized clinical trial to compare the nonfluoroscopic approach with the traditional approach was performed in 80 patients with PAFin a single-center experience. The authors found no differences in the procedural outcomes or overall safety between the two groups 9. Most of these studies have been limited by their small scale or a predominant focus on acute procedural outcomes. Razminia et al. reported 5-year experience of zero-fluoroscopy ablation by using ICE and the Ensite system and demonstrated that it was feasible and safe ¹³. The largest study employing zero-fluoroscopy during AF ablation was conducted by Sommer et al. with their experience of 1,000 patients treated without

fluoroscopy with the Mediguide system ¹⁴. ICE was not used to guide the procedure. Another large-scale study reporting on the long-term safety and efficacy following fluoroless AF ablation retrospectively reviewed 481 consecutive patients with PAF¹⁵. These authors compared ICE-guided PVI (n = 245) with conventional fluoroscopy-guided PVI (n = 236) and reported no differences in procedural outcomes, complication rates, and AF recurrence. Based on this evidence, zerofluoroscopy AF ablation utilizing ICE and 3D mapping appears to be feasible, safe, and effective compared to fluoroscopy-guided ablation. Our cohort included 247 consecutive patients with PAF or persistent AF and included 131 patients in the fluoroscopy-guided RF ablation group and 116 patients in the zero-fluoroscopy ablation group. CARTO 3D mapping was utilized during all our procedures. Lurie et al. recently detailed their first-ever Canadian experience with 323 consecutive AF patients. Of these, 176 patients were treated with fluoroscopy-guided RF ablation, and 147 patients were treated with zero-fluoroscopy ablation and utilized3D mapping systems (EnSite, n = 175; CARTO, n = 144; Rhythmia, n = 3). Minimal fluoroscopy was used in 17 patients in the zero-fluoroscopy group (median 3 seconds, IQR 1.2 - 4.8)¹⁶. Both studies (Lurie et al. and our cohort) included patients with cardiac devices as well. In comparison with other previous studies, our cohort revealed high acute procedural success rate of 100%, a complication rate of 0.9%, and aprocedure duration of 136.85 ± 33.4 minutes. The low complication rate with the zero-fluoroscopy technique may be due to visualizing the guide wires and the catheters while advancing into the heart to avoid injuries.

It has been reported that the learning curve for zero-fluoroscopy AF ablation occurs over the first 20 cases ¹⁷. For an experienced operator, zero-fluoroscopy AF ablation might be achieved safely and feasibly within 5 to 10 cases ¹⁸. Our recommendation, based on experience, is for operators with less experience to avoid Fluoroless AF ablation in patients with cardiac devices in order to prevent any inadvertent lead





issues such as dislodgement. Operators experienced in the utilization of ICE may not view this as a limitation. We believe that if the operators perform zero-fluoroscopy procedures as routine practice, adverse effects of ionizing radiation could be significantly reduced in both patients and the medical staff.

Limitations

The study was performed by a single operator at a single center, and therefore results of this study may not be applicable to other centers. For context, three operators perform around 450 to 500 AF ablations a year; however, only one operator in the practice performs Fluoroless AF ablation. Another limitation was our study's retrospective and nonrandomized design. There were very few patients with cardiac devices in the zero-fluoroscopy arm; therefore, more data are required before adopting a zero-fluoroscopy approach in patients with cardiac devices. Detailed procedure measures such as time to transseptal puncture and left atrial dwell time were not recorded, which could differ between zero-fluoroscopy and traditional groups. Another limitation was that an esophageal temperature probe (Smiths Medical, Minneapolis, MN, USA) with a single sensor was used. Only one point was marked on the map. This may not be sufficient since the esophagus has a longer course. Lastly, this technique may not be adaptable to other mapping systems as the CARTOSOUND® Module with SOUNDSTAR® Catheter are only compatible with CARTO® 3 System and proprietary to Biosense Webster.

Conclusion

Fluoroless RFA was associated with similar safety and efficacy profiles as the traditional AF ablation. In addition, AF ablation without fluoroscopy did not prolong the total mean procedure time or compromise the recurrence rate during long-term follow-up.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Please Click for Supplementary Appendix

Please Click for Supplementary Video

References

- Lindsay BD, Eichling JO, Ambos HD, Cain ME. Radiation exposure to patients and medical personnel during radiofrequency catheter ablation for supraventricular tachycardia. Am J Cardiol 1992;70:218–23. https://doi.org/10.1016/0002-9149(92)91278-c.
- Venneri L, Rossi F, Botto N, Andreassi MG, Salcone N, Emad A, et al. Cancer risk from professional exposure in staff working in cardiac catheterization laboratory: insights from the National Research Council's Biological Effects of Ionizing Radiation VII Report. Am Heart J 2009;157:118–24. https://doi.org/10.1016/j. ahj.2008.08.009.
- Roguin A, Goldstein J, Bar O. Brain tumours among interventional cardiologists: a cause for alarm? Report of four new cases from two cities and a review of the literature. EuroIntervention 2012;7:1081–6. https://doi.org/10.4244/EIJV7I9A172.
- Andreassi MG, Piccaluga E, Guagliumi G, Del Greco M, Gaita F, Picano E. Occupational Health Risks in Cardiac Catheterization Laboratory Workers. Circ Cardiovasc Interv 2016;9:e003273. https://doi.org/10.1161/ CIRCINTERVENTIONS.115.003273.
- Pires LM, Leiria TLL, Kruse ML, de Lima GG. Non-fluoroscopic catheter ablation: A randomized trial. Indian Pacing and Electrophysiology Journal 2019;19:189–94. https://doi.org/10.1016/j.ipej.2019.06.002.
- Zoppo F, Licciardello C, Favaro G, Scalon A, Bacchiega E, Lupo A, et al. Safety steps for a non-fluoroscopic approach in right-sided electrophysiology procedures: A point of view. Indian Pacing and Electrophysiology Journal 2019;19:183–8. https:// doi.org/10.1016/j.ipej.2019.03.006.
- Lahiri A, Srinath SC, Roshan J. Radiofrequency ablation of recurrent, drug refractory, left posterior fascicular ventricular tachycardia in a pregnant lady without the use of fluoroscopy. Indian Pacing and Electrophysiology Journal 2019;19:119–24. https:// doi.org/10.1016/j.ipej.2019.02.002.
- Matsubara TJ, Fujiu K, Shimizu Y, Oshima T, Matsuda J, Matsunaga H, et al. Fluoroless and contrast-free catheter ablation without a lead apron in routine clinical practice. Sci Rep 2020;10:17096. https://doi.org/10.1038/s41598-020-74165-y.
- 9. Bulava A, Hanis J, Eisenberger M. Catheter Ablation of Atrial Fibrillation Using Zero-Fluoroscopy Technique: A Randomized Trial. Pacing Clin Electrophysiol

2015;38:797-806. https://doi.org/10.1111/pace.12634.

- Gaita F, Guerra PG, Battaglia A, Anselmino M. The dream of near-zero X-rays ablation comes true. Eur Heart J 2016;37:2749–55. https://doi.org/10.1093/ eurheartj/ehw223.
- Ferguson JD, Helms A, Mangrum JM, Mahapatra S, Mason P, Bilchick K, et al. Catheter ablation of atrial fibrillation without fluoroscopy using intracardiac echocardiography and electroanatomic mapping. Circ Arrhythm Electrophysiol 2009;2:611–9. https://doi.org/10.1161/CIRCEP.109.872093.
- Reddy VY, Morales G, Ahmed H, Neuzil P, Dukkipati S, Kim S, et al. Catheter ablation of atrial fibrillation without the use of fluoroscopy. Heart Rhythm 2010;7:1644–53. https://doi.org/10.1016/j.hrthm.2010.07.011.
- Razminia M, Willoughby MC, Demo H, Keshmiri H, Wang T, D'Silva OJ, et al. Fluoroless Catheter Ablation of Cardiac Arrhythmias: A 5-Year Experience. Pacing Clin Electrophysiol 2017;40:425–33. https://doi.org/10.1111/pace.13038.
- Sommer P, Bertagnolli L, Kircher S, Arya A, Bollmann A, Richter S, et al. Safety profile of near-zero fluoroscopy atrial fibrillation ablation with non-fluoroscopic catheter visualization: experience from 1000 consecutive procedures. Europace 2018;20:1952–8. https://doi.org/10.1093/europace/eux378.
- Lyan E, Tsyganov A, Abdrahmanov A, Morozov A, Bakytzhanuly A, Tursunbekov A, et al. Nonfluoroscopic catheter ablation of paroxysmal atrial fibrillation. Pacing Clin Electrophysiol 2018;41:611–9. https://doi.org/10.1111/pace.13321.
- Lurie A, Amit G, Divakaramenon S, Acosta JG, Healey JS, Wong JA. Outcomes and Safety of Fluoroless Catheter Ablation for Atrial Fibrillation. CJC Open 2020:In Press. https://doi.org/10.1016/j.cjco.2020.11.002.
- Kochar A, Ahmed T, Donnellan E, Wazni O, Tchou P, Chung R. Operator learning curve and clinical outcomes of zero fluoroscopy catheter ablation of atrial fibrillation, supraventricular tachycardia, and ventricular arrhythmias. J Interv Card Electrophysiol 2020. https://doi.org/10.1007/s10840-020-00798-8.
- Cha M-J, Lee E, Oh S. Zero-fluoroscopy catheter ablation for atrial fibrillation: a transitional period experience. J Arrhythm 2020;36:1061–7. https://doi.org/10.1002/ joa3.12448.
- Sánchez JM, Yanics MA, Wilson P, Doshi A, Kurian T, Pieper S. Fluoroless catheter ablation in adults: a single center experience. J Interv Card Electrophysiol 2016;45:199–207. https://doi.org/10.1007/s10840-015-0088-z.
- Percell RL, Pike JL, Olmsted RK, Beideck JE, Nunes HL, Johnson KN, et al. The Grand SANS FLUORO (SAy No Series to FLUOROsopy) Study: Examining Fluoroscopy Use in More than 1,000 Ablation Procedures. J Innov Card Rhythm Manag 2020;11:4224–32. https://doi.org/10.19102/icrm.2020.1100903.
- Liu X, Palmer J. Outcomes of 200 consecutive, fluoroless atrial fibrillation ablations using a new technique. Pacing Clin Electrophysiol 2018;41:1404–11. https://doi. org/10.1111/pace.13492.
- 22. Salam T, Wilson L, Bohannan S, Morin M. Safety and Effectiveness of a Novel Fluoroless Transseptal Puncture Technique for Lead-free Catheter Ablation: A Case Series. J Innov Card Rhythm Manag 2020;11:4079–85. https://doi.org/10.19102/ icrm.2020.110405.
- 23. Zei PC, Quadros KK, Clopton P, Thosani A, Ferguson J, Brodt C, et al. Safety and Efficacy of Minimal- versus Zero-fluoroscopy Radiofrequency Catheter Ablation for Atrial Fibrillation: A Multicenter, Prospective Study. J Innov Card Rhythm Manag 2020;11:4281–91. https://doi.org/10.19102/icrm.2020.111105.
- 24. Jan M, Žižek D, Kuhelj D, Lakič N, Prolič Kalinšek T, Štublar J, et al. Combined use of electro-anatomic mapping system and intracardiac echocardiography to achieve zero-fluoroscopy catheter ablation for treatment of paroxysmal atrial fibrillation: a single centre experience. Int J Cardiovasc Imaging 2020;36:415–22. https://doi. org/10.1007/s10554-019-01727-1.
- 25. Žižek D, Antolič B, Prolič Kalinšek T, Štublar J, Kajdič N, Jelenc M, et al. Intracardiac echocardiography-guided transseptal puncture for fluoroless catheter ablation of left-sided tachycardias. J Interv Card Electrophysiol 2020. https://doi.org/10.1007/ s10840-020-00858-z.