Safety of continuous left atrial phased-array intracardiac echocardiography during left atrial ablation for atrial fibrillation

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BACKGROUND Pulmonary vein (PV) isolation using radiofrequency ablation (RFA) to treat atrial fibrillation (AF) requires delivery of contiguous transmural lesions at the PV antra while avoiding injury to the esophagus. Continuous 2-dimensional phased-array intracardiac echocardiography (ICE) from within the left atrium (LA) can provide consistent high-resolution images of catheter tip contact and location during ablation.

OBJECTIVE The purpose of this study was to compare near-term safety outcomes of therapeutic AF ablation with and without ICE imaging from within the LA.

METHODS The study cohort included 590 consecutive patients undergoing RFA for AF including continuous ICE imaging during ablation from within either the right atrium (RA) or the LA. Subjects were followed prospectively, and periprocedural complications within 30 days were identified and recorded.

RESULTS All subjects had RA ICE imaging to guide transseptal catheterization. Ultrasound imaging from both RA and LA was used in 243 (41.2%). Respectively, the LA vs RA only imaging cohorts were comparable with respect to age (median 64 [interquartile range 57.4–71.2] years vs 64 [56.2–70.6] years; $P = .425$); history of hypertension (64.0% vs 67.2%; $P = .421$); diabetes mellitus (23.1% vs 19.4%; $P = .268$); previous cerebrovascular accident/transient ischemic attack (10.8% vs 8.4%; $P = .331$); and AF type ($P = .241$). There were no significant differences in major complications within 30 days between the 2 cohorts ($P = .649$) and no identified cases of esophageal or phrenic nerve injury or PV stenosis.

CONCLUSIONS Routine continuous LA ICE imaging seems to be safe and holds potential to facilitate lesion delivery during RFA for AF.

KEYWORDS Atrial fibrillation; Catheter ablation; Intracardiac echocardiography; Radiofrequency ablation; Ultrasound Imaging

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Introduction

Radiofrequency ablation (RFA) of atrial fibrillation (AF) requires accurate lesion delivery to achieve durable, contiguous, and transmural lesion at the pulmonary vein (PV) antra while avoiding complications such as PV stenosis, esophageal injury, or excess energy delivery with steam pops. Intracardiac echocardiography (ICE) can visualize cardiac structures, guide transseptal access, measure local wall thickness and tissue echogenicity, and identify transient tissue changes coincident with RFA energy delivery.[1–3] These original reports used rotational ultrasound. More recent studies describe phased-array ultrasound from the right atrium (RA) to guide transseptal catheterization,[4] identify left atrial (LA) thrombus,[5] delineate the esophagus,[6] and help create 3-dimensional constructs of the LA and PV morphology to guide LA ablation.[7–9] However, routine use of RA ICE to guide LA ablation can be limited by long imaging distances and the need to image through the interatrial septum, aorta, or other thoracic structures, which can negatively impact image quality.

In contrast, ICE imaging from within the LA has the potential to provide consistent high-resolution images of the catheter tip–tissue interface because of unobstructed near-field views and would be expected to facilitate assessment of ablation catheter tip–tissue contact, confirm lesion delivery at the intended targets locations, and allow easy assessment of catheter tip proximity to the esophagus.

The purpose of this study was to compare procedural characteristics and near-term safety outcomes of therapeutic AF

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KEY FINDINGS

- Left atrial (LA) imaging with phased-array intracardiac echocardiographic (ICE) imaging during radiofrequency ablation (RFA) for atrial fibrillation is safe and comparable to LA ablation without LA ICE with regard to major or minor periprocedural complications.
- Use of LA ICE can facilitate consistent unambiguous images of the esophagus relative to ablation target sites at the pulmonary vein antra, ligament of Marshall, and atrial diverticula.
- Future prospective studies are needed to assess whether imaging with LA ICE reduces RFA ablation, LA dwell, or total procedural times.

ablation with and without ICE imaging from within the LA to guide RFA lesion delivery during therapeutic catheter ablation for AF.

Methods

This was a single-center, retrospective observational cohort (case-control) study evaluating the safety of ICE from within the LA to guide RFA lesion delivery during catheter ablation for AF. The study cohorts included all consecutive adult patients undergoing clinically indicated RFA procedures for AF at Duke University Medical Center from September 1, 2009, through June 30, 2013, who were treated by the 4 experienced operators who had performed more than 100 AF ablations each, consistent with another large comparative study of therapeutic ablation.[10] All subjects were assigned to their treatment group retrospectively, based on whether LA ICE had been used to guide ablation as chosen by the operator based on preference and clinical judgement. Most subjects underwent ablation with RFA only (n = 572); however, cryoballoon only (n = 6), cryoballoon plus RFA (n = 11), or RFA plus focal cryothermy ablation (used in 1 subject to complete posterior wall antral ablation near the esophagus) were used for a minority of subjects in this consecutive patient series. All procedures were performed with patients under general anesthesia. Heparin was administered at the time of transseptal puncture, and activated clotting times were maintained between 300 and 400 seconds. RFA was performed with open-irrigated or nonirrigated catheters (Biosense Webster, Irvine, CA, Thermocool™ or Celcius DS™ 8 mm; or St. Jude Medical, Saint Paul, MN, Cool Path Duo™ or Safire BLU™ Duo, and cryothermy ablation was done with the first generation cryoballoon or 6mm cryocatheter (Arctic Front and Freezor Xtra, respectively, Medtronic, Inc, Minneapolis, MN). An electroanatomic mapping system was used for all cases (CARTO™, Biosense Webster, Inc.; or NavX, St. Jude Medical). RFA with irrigated catheters was performed in power control mode at 20–40 W, and for nonirrigated catheters in temperature control mode with target temperatures of 50°–52°C (up to 55 W). Intracardiac ultrasound from the RA was used in all cases to guide transseptal access. Pulmonary vein isolation (PVI) was performed using circumferential antral ablation with documentation of entrance and exit block using a circular decapolar mapping catheter. Catheter ablation targeting LA or RA sites apart from the PV antra was performed at the discretion of the operator. Anticoagulation was continued for a minimum of 3 months postprocedure and thereafter according to guideline recommendations based on the CHA_2DS_2-VASc score.[11]

One group was treated with the ICE catheter (8F AcuNav™, Siemens Healthcare, Issaquah, WA) kept in the RA for the duration of the procedure and used to image LA ablation when possible (no LA-ICE group). The LA-ICE group was treated using the same ICE catheter, initially placed in the RA to guide transseptal access and then advanced to the LA through a long sheath (8.5F Swartz SR0 or SL1, 71 cm, Abbott Cardiovascular, Plymouth, MN) for the duration of LA ablation. For the LA-ICE group, direct visualization of the catheter–tissue interface and proximate structures was maintained during all RFA energy delivery, allowing for adjustment of the ablation catheter to maintain consistent tissue contact, mitigation of ablation near the esophagus (either avoidance by at least 5 mm or significant down-titration of radiofrequency [RF] energy delivery) and confirmation that RFA was being delivered to the antrum of and not within the PVs. During infrequent instances when rapid increases in tissue echogenicity were observed, RF energy delivery was stopped. For all subjects, the ablation catheter was advanced through steerable or standard long sheaths (Agilis, St. Jude Medical; Swartz SR0 or SL1, Abbott Cardiovascular) positioned in the LA. The left PVs usually were imaged by directing the ICE catheter toward the LA appendage (but not inside) with retroflexion of the tip (large steering ring of the ICE catheter turned counterclockwise) to direct the imaging plane towards the PV. The imaging plane could then be adjusted to sweep from the "top" of the left superior PV to the "bottom" of the left inferior PV by adjusting catheter torque or with the small steering ring of the ICE catheter. The right PVs were imaged by withdrawing the ICE catheter into the long sheath and imaging through the sheath with torque adjustment resulting in the imaging plane sweeping from the septal aspect of the right superior PV to the posterior aspect of the right inferior PV. During testing for PVI, the ICE catheter was repositioned in the RA for all subjects and directed to image the circular mapping catheter that had replaced the ICE catheter in the long sheath, and the ablation catheter, both in the LA.

The primary safety outcome was the occurrence of any major adverse event (AE) within 30 days of ablation. A major AE was defined as any clinical event that resulted in *de novo* hospitalization, prolonged hospitalization (>72 hours postprocedure), transfusion of blood products, invasive procedure to treat an event (eg, thrombin injection of pseudoaneurysm), transient loss of function (eg, transient ischemic attack [TIA] or stroke), or any disability. Specified major AEs tallied included TIA, cerebrovascular accident, groin hematoma/fistula/aneurysms, fluid overload, cardiac perforation or tamponade, retroperitoneal hemorrhage,

esophageal injury, phrenic nerve injury, PV stenosis, and mortality.

For each subject, baseline demographics, medical history, discharge summary, imaging studies, laboratory data, the index operative report, other available medical records, and concurrent medical therapies were reviewed and abstracted. In addition to chart review of primary data, assessment of symptoms and AEs was performed by direct patient phone call at 1 week, 3 months, and 6 months postprocedure, and at scheduled clinic visits to assure capture of all 30-day AEs that may have occurred out of hospital or were treated at other centers.[12]

Statistical analysis

Univariable data are described using count (percentage) for categorical variables or median [25th–75th interquartile range] for continuous variables. Mean ± SD was used for RF time because it was normally distributed. Univariable comparisons of baseline and ablation characteristics were made using the χ^2 or Fisher exact test (expected cell counts <5) for categorical variables and the *t* test or Wilcoxon rank sum test for continuous variables, as appropriate. AEs were tabulated as a binary variable (any major AE vs no major AE). The breakdown of AE types is reported, but summary statistics and comparisons are not reported because of the low counts.

This study was approved by the Duke University Institutional Review Board, which granted a common rule exemption to the requirement of individual patient informed consent. The de-identified data were analyzed by Duke Biostatistics, Epidemiology, and Research Design Methods Core using SAS Version 9.4 (SAS Institute, Cary, NC).

Results

Baseline characteristics

A total of 590 procedures met the inclusion criteria for the study, of which 41.2% (n = 243) utilized ICE from the LA during AF ablation and 58.8% (n=347) did not. Overall, 69.0% (N = 407) of the cohort were male, and median age was 64.2 [56.6–70.8] years. During the study interval, there were 4 operators who satisfied the criterion of having performed more than 100 AF ablation procedures. The 4 operators contributed 171, 138, 206, and 75 cases to the series, and used LA ICE in 83%, 35%, 4%, and 59% of their cases, respectively. Table 1 details the patient characteristics at baseline. Although the 2 groups were similar, a history of obstructive sleep apnea was more common in the LA-ICE patients vs the no LA-ICE patients (102 [42.0%]) vs 107 [31.1%]), respectively; $P = .007$). Additionally, LA-ICE patients were more likely to be prescribed beta-blockers (169 [69.5%] vs 210 [60.5%]; $P = .024$) and calcium channel blockers (111 [46%] vs 116 [33%]; $P = .002$) before ablation.

AF and ablation characteristics

There were no significant differences with regard to type of AF, LA diameter, and rates of *de novo* vs repeat ablation comparing the LA-ICE and no LA-ICE cohorts (Tables 1 and 2). The no LA-ICE patients were more likely to be receiving no antiarrhythmic drug therapy preablation (62 [25.5%] vs 122 [35.2%]; $P = .013$), whereas LA-ICE patients were more likely to receiving class III antiarrhythmic drug therapy (123 [50.6%] vs 133 [38.3%]; $P = .003$). Overall, almost one-third of patients underwent LA roof ablation (N = 183 [31.0%]), and 95 (16.1%) underwent RA ablation including cavotricuspid isthmus and superior vena cava ablation. Patients in the LA-ICE group were more likely to have undergone adjunctive ablation apart from PVI, including linear ablation at the lateral mitral isthmus, LA roof, and posterior LA adjacent to the coronary sinus (CS) for CS isolation (Table 2). Coincident with an increased prevalence of LA ablation beyond PVI, the LA-ICE cohort had longer total procedural times (273 vs 224 minutes; $P < .001$), during which time more RF energy was delivered (65 vs 47 minutes; $P < .001$); however, fluoroscopy times were not significantly longer in the LA-ICE group. With adjustment for operator and potential confounding clinical characteristics (ejection fraction, history of sleep apnea, AF type), there was no significant difference in procedural time between the LA-ICE and no LA-ICE study groups ($P = .75$).

Safety outcomes

Thirty-day postprocedural safety outcomes are given in Tables 3 and 4, and Figure 1. Although numerically fewer procedures resulted in AEs when LA ICE was used, there were no significant differences in the occurrence of major AEs within 30 days of ablation comparing those treated with vs without LA ICE imaging [7 (2.9%) vs 13 (3.7%), respectively; $P = .649$] (Table 3). Overall, 3.4% of patients had a major AE within 30 days of ablation. No cases of esophageal injury (defined as clinical symptoms with injury confirmed by computed tomography or endoscopy), phrenic nerve injury, or PV stenosis were identified. Stroke/TIA rates were exceedingly low for both cohorts, and no mortality events were identified. There were no statistically significant differences in minor AEs between the LA-ICE and no LA-ICE cohorts (7.0% vs 8.4%; $P = .544$) (Table 4). The 2 most common minor AEs were a combination of groin hematomas/fistulas/aneurysm (N = 15 [2.5%]) and urinary tract infections (N = 9 [1.5%]).

Discussion

ICE imaging from within the LA to guide AF ablation has been described in a limited number of studies. Two reports described rotational LA ICE during AF ablation, but safety data were limited.[13–15] Matsubara et al[16] described LA ICE imaging during AF ablation to allow creation of the LA chamber geometry using an electroanatomic mapping system, but ICE imaging was not used to guide RFA lesion delivery. We believe this is the first report on the safety of

Table 1 Baseline characteristics by LA ICE use

	Total (N = 590)	LA ICE (N = 243)	No LA ICE (N = 347)	*P* value
Age at index procedure (y)	64 [56.6–70.8]	64 [57.4–71.2]	64 [56.2–70.6]	.425
Male	407 (69.0)	169 (69.5)	238 (68.6)	.804
Body mass index (kg/m^2)	30 [26.4–34.1]	31 [26.7–34.2]	30 [26.2–34.0]	.416
CHA_2DS_2-VASc score	2.0 [1.0–4.0]	2.0 [1.0–4.0]	2.0 [1.0–4.0]	.673
Hypertension	387 (65.9)	155 (64.0)	232 (67.2)	.421
Obstructive sleep apnea	209 (35.6)	102 (42.0)	107 (31.1)	.007
Diabetes mellitus	123 (20.9)	56 (23.1)	67 (19.4)	.268
COPD	30 (5.1)	12 (5.0)	18 (5.2)	.889
Stroke or TIA	55 (9.4)	26 (10.8)	29 (8.4)	.331
Anemia	21 (3.6)	10 (4.1)	11 (3.2)	.653
AF type				.241
Paroxysmal	228 (38.6)	86 (35.4)	142 (40.9)	
Persistent	314 (53.2)	133 (54.7)	181 (52.2)	
Long-standing persistent	48 (8.1)	24 (9.9)	24 (6.9)	
Valvular heart disease				
Mitral regurgitation	39 (6.6)	19 (7.8)	20 (5.8)	.400
Mitral stenosis	3 (0.5)	2 (0.8)	1 (0.3)	.369
Mitral valve replacement	15 (2.5)	7 (2.9)	8 (2.3)	.792
Aortic stenosis	2 (0.3)	0 (0.0)	2 (0.6)	.515
Aortic regurgitation	2 (0.3)	1 (0.4)	1 (0.3)	1
Aortic valve replacement	22 (3.7)	8 (3.3)	14 (4.0)	.640
Left atrial diameter (cm)	4.1 [3.7–4.7]	4.2 [3.7–4.7]	4.1 [3.6–4.6]	.225
Left ventricular ejection fraction (%)	55.0 [55.0–55.0]	55 [55.0–55.0]	55 [55.0–55.0]	.494
Serum creatinine (mg/dL)	1.0 [0.8–1.1]	1.0 [0.8–1.2]	1.0 [0.8–1.1]	.434
Preablation medications				
Beta-blocker	379 (64.2)	169 (69.5)	210 (60.5)	.024
Calcium channel blocker	227 (38.5)	111 (45.7)	116 (33.4)	.003
Digoxin	48 (8.1)	20 (8.2)	28 (8.1)	.944
ACE inhibitor	161 (27.3)	67 (27.6)	94 (27.1)	.897
ARB	92 (15.6)	45 (18.5)	47 (13.5)	.101
Aldosterone antagonist	35 (5.9)	11 (4.5)	24 (6.9)	.227
Preablation AAD medications				
None	184 (31.2)	62 (25.5)	122 (35.2)	.013
Class IC	92 (15.6)	36 (14.8)	56 (16.1)	.663
Class III	256 (43.4)	123 (50.6)	133 (38.3)	.003
Amiodarone	59 (10.0)	24 (9.9)	35 (10.1)	.933
Baseline anticoagulation				.150
Warfarin	462 (78.3)	195 (80.2)	267 (76.9)	
Dabigatran	74 (12.5)	33 (13.6)	41 (11.8)	
Rivaroxaban	7 (1.2)	3 (1.2)	4 (1.2)	
None	47 (8.0)	13 (4.9)	35 (10.1)	

Values are given as median [25th–75th interquartile range] or count (percentage) unless otherwise indicated.

AAD = antiarrhythmic drug; ACE = angiotensin-converting enzyme; AF = atrial fibrillation; ARB = angiotensin receptor blocker; CHA_2DS_2-VASc = Congestive Heart Failure, Hypertension, Age (≥75), Diabetes Mellitus, Stroke or TIA, Vascular Disease, Age (65-74), Sex category (Female); COPD = chronic obstructive pulmonary disease; ICE = intracardiac echocardiography; LA = left atrium; TIA = transient ischemic attack.

routine phased-array ICE imaging from within the LA to guide lesion delivery during RFA for AF in a large consecutive series with >500 patients. In this single-center controlled cohort study of complications within 30 days postprocedure, we found that continuous LA ICE imaging with phased-array ICE during RFA for AF is safe and comparable to LA ablation without LA ICE with regard to major or minor periprocedural complications.

Whereas ICE imaging from the RA has been reported to facilitate transseptal puncture, define LA morphology and esophageal location, and identify complications such as pericardial effusion,[3,4,7,8] in our experience there often are significant limitations in image resolution and the ability to acquire consistent imaging of LA ablation target regions from the RA, particularly in the setting of atrial hypertrophy or aortic calcification, or for imaging of the right-sided PV ostia. In distinction, LA ICE imaging is accomplished within a few centimeters of the target locations[17] and yields consistent unambiguous images of LA ablation target sites. Figure 2 shows representative images of the left and right PV antra. Accordingly, LA ICE imaging has the potential to facilitate therapeutic ablation by providing consistent real-time assessment of regional cardiac anatomy and catheter tip–tissue contact location relative to important structures such as the PV ostia, esophagus, atrial diverticula, and prosthetic mitral valve when present. In our experience,

Table 2 Ablation characteristics by LA ICE use

	Total (N = 590)	LA ICE (N = 243)	No LA ICE (N = 347)	*P* value
Ablation history				.339
De novo	457 (77.5)	193 (79.4)	264 (76.1)	
Redo	133 (22.5)	50 (20.6)	83 (23.9)	
Procedural duration (min)	248 [204.0–293.0]	273 [235.0–305.0]	224 [191.0–275.0]	<.001
Total RF time (min)	54 ± 23.7	65 ± 22.0	47 ± 22.3	<.001
Total fluoroscopy time (min)	54 [40.1–71.8]	55 [42.2–71.4]	52 [38.2–73.0]	.362
LA ablation performed				
Mitral isthmus line	49 (8.3)	29 (11.9)	20 (5.8)	.008
LA roof	183 (31.0)	98 (40.3)	85 (24.5)	<.001
Substrate only (CFAE)	101 (17.1)	32 (13.2)	69 (19.9)	.033
Coronary sinus line	57 (9.7)	34 (14.0)	23 (6.6)	.003
Non-LA ablation (CTI, SVC)	95 (16.1)	39 (16.0)	56 (16.1)	.977

Values are given as count (percentage), median [25th–75th interquartile range], or mean ± SD unless otherwise indicated.
CFAE = complex fractionated electrogram; CTI = cavotricuspid isthmus; RF = radiofrequency; SVC = superior vena cava; other abbreviations as in Table 1.

the advent of new mapping systems, contact force sensing catheters, and new RF delivery strategies (eg, high-power, short-duration RF delivery) do not obviate potential benefits of real-time LA ICE imaging, such as (1) allowing independent verification of the fidelity of electroanatomic maps created with contemporary mapping systems which at times do not completely reveal the exact location of the ligament of Marshall, atrial diverticula, or the PV ostia; (2) revealing when RF target sites are in close proximity to the esophagus (Figure 2), atrial diverticula, or the PV ostium; and (3) identifying sudden rapid increases in tissue echogenicity that may herald "steam pops" and recommend discontinuation of RF energy delivery, especially during high-power RF ablation.[8]

In this series, 2 instances of cardiac perforation with tamponade occurred in patients for whom LA ICE was not used. One transient ischemic event occurred in the LA-ICE group, with no embolic complications noted in the no LA-ICE group. Overall, there were numerically fewer complications in the LA-ICE group even though this group had a greater proportion of patients with persistent AF who received linear ablation or ablation of complex fractionation with corresponding longer total RF times. Event rates are too low to allow for statistical analyses regarding the significance of these small differences, including the small differences in specific types of complication between the groups, making the study underpowered to provide a definitive conclusion on safety consequences of LA ICE imaging with regard to stroke or other specific major complications. Nonetheless, the finding of low and equivalent event rates between groups suggests that AEs associated with LA ICE use are rare. An additional observation of potential interest is that more RF energy was delivered per unit of procedural time when LA ICE was used, which is consistent with possible improved "efficiency" of lesion delivery. Specifically, on average the LA-ICE group received 1 minute of RF energy delivery for every 4.2 minutes of procedural time compared to 4.7 minutes for the no LA-ICE group. The current study is not powered to draw definitive conclusions in this regard, and additional studies of AF ablation with vs without LA ICE imaging are required to better describe this or other potential impacts of LA ICE imaging on procedural outcomes.

Four experienced operators contributed to the overall patient cohort reported in this study; however, not all operators contributed equally to the comparative study groups. Accordingly, observed differences between the study cohorts could have been due in part to differences in operator-specific technique or patient selection. Although there was no difference among operators with regard to AF type being treated, there were differences in sleep apnea history and medication use. Importantly, analysis controlling for patient characteristics, AF type, and operator suggested that there was no significant difference in procedural time for patients who had LA ICE vs no LA ICE and that use of LA ICE did not itself lead to significantly longer procedural times.

Table 3 Number of subjects with major adverse events within 30 days of ablation*

	Total (N = 590)	LA ICE (N = 243)	No LA ICE (N = 347)	*P* value
No. of subject procedures with at least 1 event	20 (3.4)	7 (2.9)	13 (3.7)	.649
Transient ischemic attack	3 (0.5)	0 (0.0)	3 (0.9)	
Stroke	1 (0.2)	1 (0.4)	0 (0.0)	
Groin hematoma/fistula/ aneurysm	7 (1.2)	3 (1.2)	4 (1.2)	
Fluid overload	3 (0.5)	0 (0.0)	3 (0.9)	
Cardiac perforation/ tamponade	2 (0.3)	0 (0.0)	2 (0.6)	
Retroperitoneal hemorrhage	1 (0.2)	1 (0.4)	0 (0.0)	
Arteriovenous fistula	1 (0.2)	0 (0.0)	1 (0.3)	
Emphysematous gastritis	1 (0.2)	0 (0.0)	1 (0.3)	
Pneumonia and hematoma	1 (0.2)	1 (0.4)	0 (0.0)	
Pneumonia	1 (0.2)	1 (0.4)	0 (0.0)	
Treated PE	1 (0.2%)	0 (0.0%)	1 (0.3%)	

Values are given as n (%) unless otherwise indicated.
PE = pulmonary embolism; other abbreviations as in Table 1.
*Totals for breakdown of major adverse events may not add up to total N because some patients had multiple events.

Table 4 Number of subject procedures with minor adverse events within 30 days*

	Total (N = 590)	LA ICE (N = 243)	No LA ICE (N = 347)	*P* value
No. of subject procedures with at least 1 event	46 (7.8)	17 (7.0)	29 (8.4)	.544
Transient ischemic attack	1 (0.2)	1 (0.4)	0 (0.0)	
Groin hematoma/fistula/aneurysm	15 (2.5)	6 (2.4)	9 (2.6)	
Fluid overload	5 (0.8)	3 (1.2)	2 (0.6)	
Cardiac perforation/tamponade	2 (0.3)	0 (0.0)	2 (0.6)	
Arteriovenous fistula	1 (0.2)	0 (0.0)	1 (0.3)	
Dizziness/chest discomfort	1 (0.2)	1 (0.4)	0 (0.0)	
Elevated creatinine	1 (0.2)	0 (0.0)	1 (0.3)	
Mild pericarditis, aspiration PNA	1 (0.2)	0 (0.0)	1 (0.3)	
Admitted with INR >10	1 (0.2)	0 (0.0)	1 (0.3)	
Scrotal edema	1 (0.2)	0 (0.0)	1 (0.3)	
Infection				
UE cellulitis	1 (0.2)	1 (0.4)	0 (0.0)	
Prostatitis	1 (0.2)	0 (0.0)	1 (0.3)	
Upper respiratory	1 (0.2)	1 (0.4)	0 (0.0)	
Aspiration PNA	1 (0.2)	0 (0.0)	1 (0.3)	
Pneumonia	3 (0.5)	2 (0.8)	1 (0.3)	
Pressure ulcer, stage 2	1 (0.2)	0 (0.0)	1 (0.3)	
Proarrhythmia (AT/AFL)	1 (0.2)	0 (0.0)	1 (0.3)	
Return to ED with AF	1 (0.2)	0 (0.0)	1 (0.3)	
Fever and SOB after discharge†	1 (0.2)	1 (0.4)	0 (0.0)	
Dysphagia	1 (0.2)	0 (0.0)	1 (0.3)	
Swollen elbow	1 (0.2)	1 (0.4)	0 (0.0)	
UTI	9 (1.5)	2 (0.8)	7 (2.0)	

Values are given as n (%) unless otherwise indicated.

AF = atrial fibrillation; AFL = atrial flutter; AT = atrial tachycardia; ED = emergency department; INR = international normalized ratio; PNA = pneumonia; SOB = shortness of breath; UE = upper extremity; UTI = urinary tract infection; other abbreviations as in Table 1.

*Totals for minor adverse effect breakdown may not add up to total N because some patients had multiple events.

†Prompting return to the ED.

Previous studies have demonstrated the safety of LA ICE for a variety of percutaneous cardiovascular procedures other than AF ablation. Masson et al[18] reported a pilot study of LA ICE use vs transesophageal echocardiography during LA appendage occlusion procedures in 37 patients. In their study, LA ICE facilitated LA occlusion, which was achieved in 97% of subjects with reduced contrast administration, and a trend toward lower fluoroscopy and procedural times.[18] A study by Korsholm et al[19] which compared LA appendage closure transesophageal echocardiography vs ICE, demonstrated the noninferiority of ICE guidance with respect to procedural success (94.5% vs 95.5%), and a reduction in major procedural complications in the ICE group compared to transesophageal echocardiography group (4.7% vs 1.8%). Aguirre et al[20] documented the safety of ICE guidance from the LA via a single transseptal puncture during LA appendage occlusion procedures. Matsubara et al[16] demonstrated the safety and efficacy of LA ICE imaging as a replacement for the administration of contrast media associated with computed tomography or cardiac magnetic resonance imaging to reveal LA morphology in 200 consecutive patients with paroxysmal and persistent AF undergoing AF ablation, but ICE was not used to guide RF energy delivery.

Although the dataset used for this study did not include structured and comprehensive postablation assessments for AF recurrence, review of medical records revealed that there were no significant differences in patients' report of AF symptoms after the blanking period up to 1 year of follow-up, or in documented AF recurrences by clinically indicated electrocardiography or ambulatory monitoring. Overall, 145 patients (25.9%) reported symptoms of AF, and 165 (29.4%) had some electrocardiographic documentation of AF within the first 12 months (after a 3-month blanking period). Furthermore, there were no significant differences between the no LA-ICE and LA-ICE groups for these endpoints (26.6% vs 24.9%, respectively, $P = .65$; and 29.0% vs 29.9%, respectively, $P = .81$).

Thus, we found no evidence that routine LA ICE imaging is associated with an increase in major complications such as cardiac perforation and tamponade, which in theory could be associated with continuous manipulation of the ICE catheter in the LA, or in minor complications such as access site hematomas, arteriovenous fistulas, or pseudoaneurysms, which in theory could occur with additional sheath manipulation during LA ICE imaging. Accordingly, these data suggest that AF ablation can be performed using continuous LA ICE imaging to guide RFA lesion delivery with no compromise in patient safety.

Given the potential benefits of LA ICE imaging to guide ablation to desired targets while avoiding ablation within the PV os or near the esophagus, we conclude that there should be no impediment to implementing this technique more broadly given the lack of associated complications, demonstrated feasibility, and no added cost for centers where ICE is already used to guide transseptal puncture.

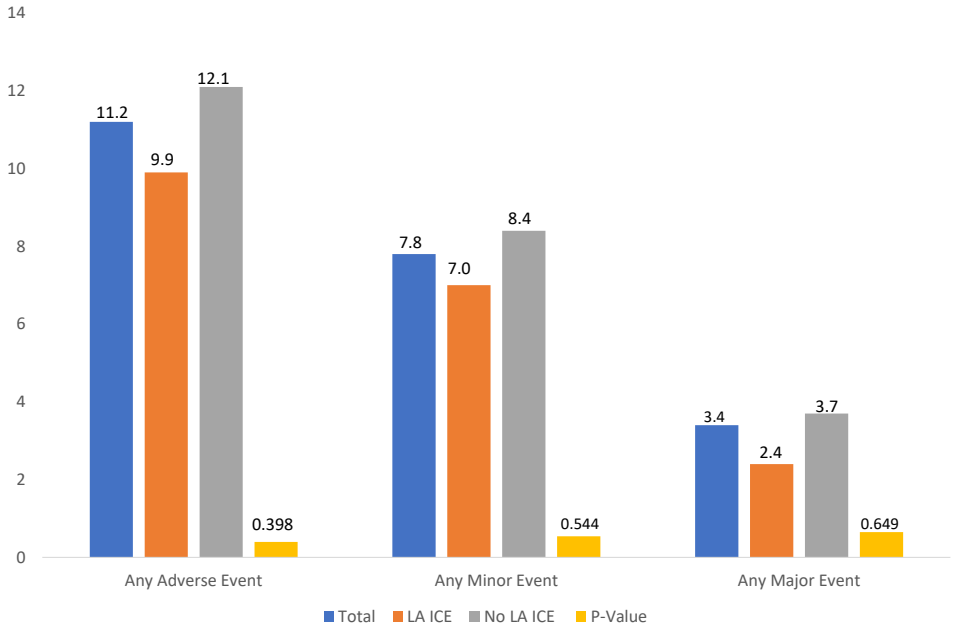

Figure 1 Number of subject procedures with at least one any, major, and minor adverse event within 30 days of ablation. ICE = intracardiac echocardiography; LA = left atrium.

Study limitations

This was a nonrandomized, single-center, comparative retrospective cohort study. The study was performed with AcuNav ICE catheters, so safety may differ with use of other ICE catheters. Although there were no significant differences between the 2 groups with respect to AEs, the present study was not designed to assess long-term clinical or ablation-related outcomes that are the subject of an ongoing study. Due to low safety event rates that were lower than anticipated and lower than observed in national and international registries from the same time period, statistical testing in the comparison of aggregate safety endpoints should be interpreted cautiously, as should comparison of specific safety event types. Additionally, alternative imaging techniques of viewing the LA, such as introduction of the ICE catheter in the CS, were not performed, so no information on the safety of this technique is provided.

Conclusion

Routine use of continuous LA phased-array ICE imaging during RFA for AF is feasible and can be performed without apparent increased risk of periprocedural complications. Prospective studies are needed to determine whether use of

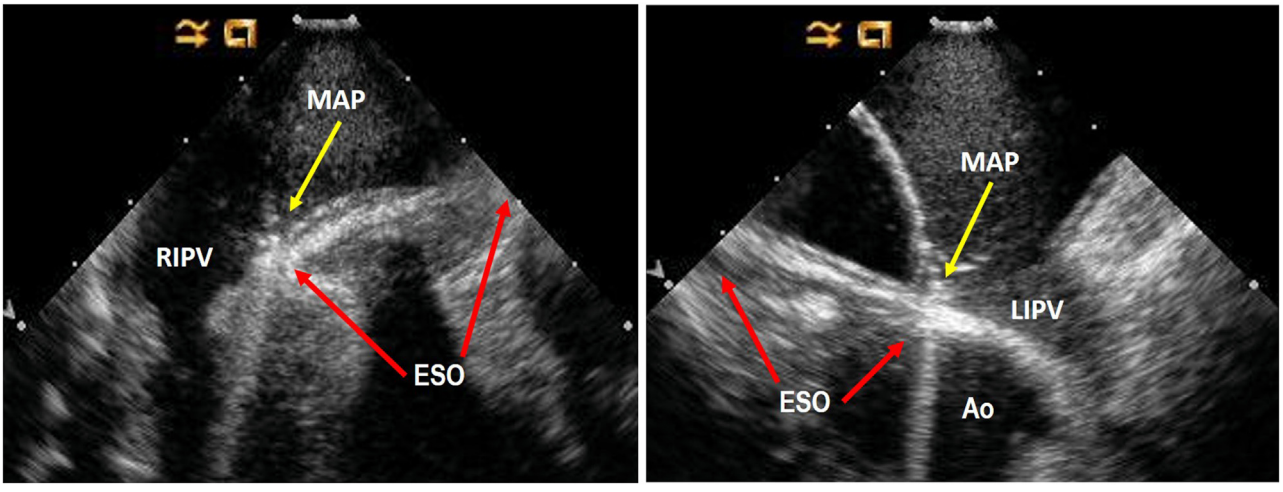

Figure 2 Left atrial intracardiac echocardiographic imaging of the right inferior pulmonary vein (RIPV) **(left)** and left inferior pulmonary vein (LIPV) **(right)** in 2 different individuals from this case series. *Yellow arrows* point to the map/radiofrequency ablation catheter tip with acoustic shadowing extending beyond the catheter tip. The extent of the esophagus (ESO) contact region is indicated by *red arrows,* and acoustic shadowing from the luminal esophageal temperature probe is seen in the left. Ablation is being delivered near the right and left borders of the esophagus in the 2 panels, respectively. Ao = aorta.

LA ICE imaging improves the acute or long-term outcomes of AF ablation.

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Patient Consent: The Duke University Institutional Review Board granted a common rule exemption to the requirement of individual patient informed consent. De-identified data were analyzed.

Ethics Statement: This study was approved by the Duke University Institutional Review Board.

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