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

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 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 enced operators who had performed more than 100 AF ablations each, consistent with another large comparative study of therapeutic catheter ablation 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.
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 χ2 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, 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 hematoma/istulas/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 al16 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
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 locations17 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,
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 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.

| 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) | |
| Goitn 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.

*Totals for breakdown of major adverse events may not add up to total N because some patients had multiple events.
Previous studies have demonstrated the safety of LA ICE for a variety of percutaneous cardiovascular procedures other than AF ablation. Masson et al\textsuperscript{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.\textsuperscript{18} A study by Korsholm et al\textsuperscript{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\textsuperscript{20} documented the safety of ICE guidance from the LA via a single transseptal puncture during LA appendage occlusion procedures. Matsubara et al\textsuperscript{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.
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 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...
LA ICE imaging improves the acute or long-term outcomes of AF ablation.

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**Authorship:** All authors attest they meet the current ICMJE criteria for authorship.

**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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