Intracardiac Echocardiography for Detection of Thrombus in the Left Atrial Appendage: Comparison with Transesophageal Echocardiography in Patients Undergoing Ablation for Atrial Fibrillation. The Action-Ice I Study

Running title: Baran et al.; ICE for left atrial appendage imaging

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Abstract:

**Background** - Transesophageal echocardiography (TEE) is the gold standard for the exclusion of left atrial appendage (LAA) thrombi before ablation for atrial fibrillation (AF). Intracardiac echocardiography (ICE) is used to assist AF ablation; however, it can be also used for LAA imaging. The aim of our study was to determine whether ICE could replace TEE and to identify the optimal ICE placement for LAA visualization.

**Methods and Results** - Seventy-six consecutive patients (56 men, mean age 55 ± 9.6 years) scheduled for AF ablation underwent TEE before the procedure and LAA assessment by ICE. An 8Fr AcuNav probe was introduced into right atrium (RA), pulmonary artery (PA), and coronary sinus (CS). LAA structure was analyzed by the echocardiographer and electrophysiologist who were blinded to the results of TEE. ICE probe was positioned in the RA in all patients, in the PA in 64/74 (86%) patients, and in the CS in 49/74 (66%) patients. The LAA was properly visualized in 56/64 (87.5%) patients from the PA vs. 13/49 (26%) patients from the CS (p < 0.001). From RA the whole LAA cavity could not be seen in any patient. In those patients in whom LAA was visualized properly by ICE, a perfect agreement between ICE and TEE was obtained (both techniques detected LAA thrombus in 2 patients and excluded LAA thrombus in the remaining patients).

**Conclusions** - ICE can be used safely and effectively for the evaluation of LAA in patients undergoing AF ablation. ICE imaging from PA is very accurate for LAA visualization.

**Clinical Trial Registration** - URL: http://clinicaltrials.gov; Unique Identifier: NCT01371279

**Key words:** left atrial appendage, intracardiac ultrasound, atrial fibrillation, transesophageal echocardiography, thrombus
Background

Transesophageal echocardiography (TEE) is the gold standard for the exclusion of thrombi in the left atrial appendage (LAA) before ablation for atrial fibrillation (AF)\(^1\). However, the sensitivity of TEE in excluding LAA thrombi is not perfect, especially when adequate LAA imaging cannot be achieved\(^2\). In addition, in some situations TEE is contraindicated (esophageal injury or diverticulum) or not feasible under conscious sedation (dysphagia or inability to swallow TEE probe)\(^3\). Thus, alternative tools are needed for LAA imaging.

In many hospitals, intracardiac echocardiography (ICE) has been used during AF ablation for guiding the transseptal puncture and further imaging during the procedure. The ICE probe is usually positioned in the right atrium (RA)\(^4,5\). It is not known whether ICE can be used effectively for LAA imaging and which ICE views are the most accurate for this purpose. The standard RA views do not provide adequate consistent visualization of the complete LAA cavity because of the relatively long distance from the LAA to the ICE probe. Placing the ICE catheter in locations that are more proximate to the LAA, such as the pulmonary artery (PA) or the coronary sinus (CS), might improve sensitivity and specificity in detecting the LAA thrombus. The results of a retrospective study have already supported the use of ICE in patients with equivocal TEE findings obtained prior to electrophysiological procedures\(^2\). However, the issue of ICE probe placement, and whether this technique is not only additive to TEE but may also replace TEE in some patients, has not yet been addressed\(^6,7\). The present study aimed at answering these questions.

Methods

Patients. The study group included consecutive patients who were scheduled for AF ablation at our institution between September 2011 and August 2012. In total, 76 patients (56 men; age, 55
± 9.6 years) who gave informed written consent for participation in the study were enrolled. The study protocol was approved by the Ethics Committee of the Postgraduate Medical School, Warsaw, Poland. Most patients had paroxysmal AF (84%), whereas the remaining participants had persistent AF (10%) or long-standing persistent AF (6%). Baseline demographic and clinical characteristics are described in Table 1.

**Design of the study.** All patients underwent computed tomography (CT) of the heart 24–48 h before the procedure. TEE was then performed and patients underwent ablation within 24 h from TEE. The ICE probe was inserted at the beginning of the ablation procedure and placed consecutively in the RA, pulmonary artery (PA), and coronary sinus (CS) for left atrium (LA) and LAA imaging. The electrophysiological procedure was then started with the ICE probe that was kept inserted in the RA to assist the transseptal puncture and for the entire ablation procedure to visualize the cardiac structures and catheters, as well as to monitor potential complications.

**Computed tomography.** Cardiac CT images were obtained using Somatom Definition or Somatom Definition Flash equipment (Siemens Ag Medical Solution Munich, Germany). The LA cavity shape, volume, and dimensions were assessed. The number and diameter of the pulmonary veins were analyzed. The LA and LAA cavities were examined for the presence of thrombus. The LAA morphology was analyzed according to Wang et al.8 The “Chicken Wing” LAA is an anatomy characterized by an obvious bend in the proximal or middle part of the dominant lobe or folding back of the LAA anatomy on itself at some distance from the perceived LAA ostium. The “Wind Sock” LAA is an anatomy in which 1 dominant lobe of sufficient length is the primary structure. Variations of this LAA type depend on the location and number of secondary or even tertiary lobes arising from the dominant lobe in the inferior direction. The
“Cauliflower” LAA is an anatomy that has limited overall length with more complex internal characteristics, a number of significant lobes, lack of 1 dominant lobe, and the close proximity of internal separations or prominent pectinate ridges to the perceived LAA ostium. The “Cactus” LAA is an anatomy where there is a dominant central lobe with secondary lobes extending from the central lobe in both superior and inferior directions. Variations in anatomy are because of the variable number, location, and orientation of the secondary lobes.

**Transesophageal echocardiography.** TEE was performed according to the standard practice guidelines using a multiplane TEE probe 6T (Vivid 9, GE Vingmed Ultrasound, Horten, Norway).

**Intracardiac echocardiography.** The AcuNav electronic phased-array diagnostic ultrasound catheter (Siemens Ag Medical Solution, Munich, Germany)(5.5–10 MHz, 8F) was introduced through a 10F or 11F hemostatic sheath, positioned in the left femoral vein and moved under fluoroscopic guidance to the RA. Next, a 7F multipolar diagnostic catheter (CS) (Biotronic, Vicath 10, Berlin, Germany, 2–6–2 spacing –40 mm long from distal to proximal pole) was introduced via the left femoral vein and positioned in the CS. The ICE probe was then advanced into the CS and LAA imaging was performed. In the next stage, the CS catheter and ICE probe were introduced into the PA, and positioned parallel in close proximity to each other. The CS catheter was used not only as a “guiding wire” for the ICE while introducing it into the right ventricular outflow tract (RVOT) and PA, but also to ensure the position of the ICE in the PA, above the pulmonary valve, by examining intracardiac signals recorded from the CS catheter. We also felt that it was safer to introduce a more flexible diagnostic catheter first, followed by a stiffer ICE probe. The distance between the tip of the ICE probe with proper visualization of the LAA and level of pulmonary valve was calculated based on the distance between the tip of
diagnostic catheter and the most distal pole where intracardiac signals were recorded. To summarize, the diagnostic catheter was used as a marker for the CS and PA to guide the ICE probe insertion and to measure certain distances (the ICE probe does not record intracardiac potentials). Both fluoroscopic imaging (right anterior oblique and left anterior oblique views) and intracardiac signals were used to ensure the correct position of the ICE probe.

Images obtained by the ICE probe were analyzed online using an echocardiographic system (Cypress, Siemens Ag Medical Solution, Munich, Germany). Fluoroscopy was performed with a single plane digital angiographic system (Integris Philips Healthcare DA Best, The Netherlands).

The electrophysiologist performing the ICE examinations, and an experienced echocardiographer who attended the electrophysiology laboratory and assessed the LAA images, were blinded to the pre-procedural TEE results, which were performed by another echocardiographer. The thrombus was a well-defined mass, which could be immobile or show varying degrees of mobility. The quality of visualization of the LAA from the PA and CS was measured on a 6-grade scale: grade 5, excellent view (entire LAA was imaged); grade 4, good (entire LAA was imaged but quality was <5); grade 3, average (only the ostium of the LAA to LA and proximal part of LAA trunk was imaged); grade 2, low (only the ostium of the LAA to LA was imaged); grade 1, poor (only a part of LAA was visualized as part of the trunk without clear image); grade 0, no diagnostic view. The presence of a thrombus in the LAA was assessed using a binary scale (yes or no). When it was not possible to image the entire LAA, the result was graded as 3. The presence of a spontaneous echo contrast was also assessed, but was not subjected to statistical analysis in the present study because it did not influence the decision to perform the AF ablation procedure as much as the thrombus did.
After completing the ICE examination, a transseptal puncture, ablation, and if necessary, an intra-procedural electrical cardioversion were performed on the condition that the pre-procedural TEE had excluded the LAA thrombus.

The time spent from the RA to the PA and CS to achieve a proper view of the LAA was measured. The time spent advancing the ICE from the RA to the CS and PA to achieve a satisfactory view was limited to 15 min each, following which the attempt was regarded as a failure and the view was graded 0. Additional radiation exposure during ICE probe positioning in the PA and CS was also measured.

Statistical analysis. The results are presented as mean ± SD or as numbers and percentages. Qualitative variables were compared using Chi-square or Fisher test. The McNemar's test for paired binary data was used to compare the percentages of view grades 4 and 5 from PA and CS. A p value <0.05 was considered significant. A learning curve was constructed as a classical Kaplan–Meier plot to present and compare the learning progress of the operator. In addition, the number of procedures after which the success rate was constant was identified. The event of interest was “getting an excellent and good quality image” instead of a typical survival event usually considered in context of the Kaplan–Meier formalism.

Results

Overall results. Out of 76 patients enrolled in the study, 74 underwent TEE and were enrolled in the study. TEE was not performed in 2 patients because of the presence of esophageal varices in 1 patient and inability to swallow the TEE probe in the other patient. CT and ICE excluded thrombus in the LAA, and both patients underwent uneventful AF ablation. In another 2 patients, a thrombus in the LAA was detected both by TEE and ICE. The anticoagulation regimen was modified and ablation deferred. The patients’ flowchart is presented in Figure 1.
Intracardiac echocardiography. Positioning of the ICE probe in the RA was possible in all patients, in the PA in 64 (86%) patients, and in the CS in 49 (66%) patients. In those patients in whom the ICE probe was positioned in a prespecified location, the LAA was properly visualized with a grade 4 or 5 image quality in 56/64 (87.5%) patients from the PA, in 13/49 (26.5%) from the CS, and in none of the patients from the RA (usually the distal part of the LAA was not clearly seen). Visualization of the LAA was possible in 58/74 patients (78%), regardless of the ICE probe position. The LAA was significantly better visualized when the ICE was located in the PA than in the CS (p < 0.001). Representative ICE images of the LAA from the CS and from the PA are presented in Figures 2–4. Fluoroscopic views of the catheters positioned in the CS and PA are shown in Figure 5.

In those patients in whom the LAA was clearly visualized ICE from the PA, an excellent agreement between TEE and ICE was obtained. Of these 56 patients, 43 subjects had grade 5 on ICE and the remaining 13 had grade 4. In 13 patients visualization of the LAA from the CS had perfect agreement with TEE. 5 patients had grade 5 on ICE and the remaining 8 had grade 4. The mean time for achieving a satisfactory image of the LAA from the PA was 4 ± 4.5 min and from the CS was 4.2 ± 3 min (NS). Examination of the LAA by ICE from the PA and the CS increased the fluoroscopy time by a mean 6.8 ± 3.8 min.

The possibility of obtaining high quality images of the LAA (grades 4 or 5) from the PA and CS was independent of factors such as sex, age, hypertension, coronary artery disease, history of myocardial infarction, diabetes mellitus, heart failure, morphology of the LAA based on CT images, or type of AF (all NS) (Table. 2).

Based on the success rate and time required for visualization of the LAA, a learning curve for the electrophysiology lab was drawn (Figure 6), which shows that after 28 procedures
an operator gained enough experience in LAA evaluation by ICE. Analysis performed after 28 examinations showed no significant differences between ICE and TEE in the assessment of thrombi. ICE grades 5 or 4 were significantly more often obtained after performing 28 ICE examinations from the PA than during the first 28 procedures (12 [44%] vs. 44 [92%], \( p = 0.0001 \)). The likelihood of obtaining good LAA images from the PA (grade 4 or 5) steadily increased throughout the study: procedures 1–10, 20%; procedures 11–20, 50%; procedures 21–30, 70%; procedures 31–40, 90%; procedures 41–50, 100%; procedures 51–60, 100%; procedures 61–74, 93%. The time needed to achieve grade 4 or 5 LAA images from the PA was significantly shorter after completing 28 ICE examinations (8.2 ± 3 min vs. 2.9 ± 4.3 min, \( p < 0.0001 \)).

**Procedural complications.** In 1 adverse event, a woman aged 57 years with paroxysmal AF and normal ejection fraction (60%) reported chest pain when the ICE probe was advanced from the RV to the RVOT. The ICE probe was withdrawn to the RA to the “home view” position and pericardial effusion was detected with 6–8 mm of fluid in the pericardial space in front of the RV. Standard transthoracic echocardiography (TTE) confirmed these findings. The procedure was discontinued and the patient recovered fully without hemodynamic consequences or other sequelae.

**Discussion**

The present study showed that (1) ICE is a useful tool for evaluating the LAA to detect a thrombus, (2) the PA seems to be the optimal location for the ICE probe for this purpose, and (3) ICE can be used effectively when TEE is unequivocal or not possible to perform.

The optimal location of the echocardiographic probe for LAA imaging has not yet been established. In clinical practice, TEE is usually used for this purpose and the TEE probe
obviously can be positioned only in the esophagus, whereas the ICE probe can be placed in various sites inside the cardiac chambers. Hence, identification of the best site for LAA imaging with ICE is possible. In an animal study, RVOT and PA have been suggested as good locations to visualize the whole LAA\(^\text{11}\). However, no data concerning this issue in humans have been published.

The anatomical proximity of the LAA to the site location of the ICE probe is of paramount importance. The PA and the LAA are located very close to each other. CT scans and pathology specimens analysis revealed only a few millimeters of pericardial space present between these 2 structures\(^\text{12,13}\). Such a localization of the PA enables a satisfactory view of the every part of the LAA, from the proximal ostium to the middle trunk and distal LAA appendix. To visualize the entire LAA cavity an operator has to rotate the ICE probe clockwise at different levels. When the ICE is located at the pulmonary valve level, usually only the LAA entrance is visualized. However, advancing the ICE further into the PA and repeating rotating maneuvers gives additional views of the LAA and enables scanning of the entire LAA. When the ICE probe is located approximately 1 cm above the PA, the LAA in a “long axis” can be seen and an operator may notice trabeculation inside the LAA. The view obtained by locating the ICE probe >3 cm above the pulmonary valve in the main trunk of the PA or in the left PA can be named the “short axis”. In this position, additional lobes of the LAA, the apex, and even the space between the apex of the LAA and pericardium can be imaged.

Our study showed that LAA imaging from the PA is more accurate than from the CS. This may be explained by the fact that the course of the CS is posterior, whereas the LAA is located more anteriorly, with the left superior pulmonary vein left behind the LAA. In addition, advancing the ICE probe into the CS was more complicated than into the RVOT and PA.
In our study, we placed the ICE probe only in the right heart cavities and CS. Placing the probe in the LA could have provided better LAA visualization (especially the ostium). However, it would require crossing the interatrial septum with the ICE probe, which is contraindicated when a thrombus in the LAA is present or suspected. Since we were blinded to the TEE results, the protocol did not allow the transseptal use of the ICE probe.

Our study shows that an electrophysiologist can quickly gain experience in the LAA visualization from the PA. Satisfactory LAA views were obtained after 28 procedures. The safety profile of this examination is acceptable, since only 1 complication occurred with no further consequences. It seems that using additional diagnostic electrodes such as a guidewire facilitates the ICE probe advancement and decreases the risk of side effects. However, we believe that ICE probe can be safely advanced to the right ventricular outflow tract and above PA without any “guiding” catheter when performed by experienced electrophysiologists.

The findings of the study are applicable only for the 8F ICE catheter since we did not use a 10F ICE catheter in our laboratory. The 10F catheter may be more supportive and stable in some intracardiac locations (such as the CS) compared with 8F, and is probably more widely used because it is commercially available in some ultrasound-based electrophysiological systems. The ICE examination from the PA is a valuable option for patients in whom TEE cannot be performed or when TEE results are equivocal. In our study, TEE could not be performed in 2 patients; ICE images of the LAA were of excellent quality and based on this examination we felt that we could proceed safely with ablation. An unequivocal result of TEE in the assessment of LAA is not uncommon. For example, data from our center showed that out of 200 consecutive TEE examinations, the experienced echocardiographer had uncertainties when analyzing the LAA images in 10% of cases (unpublished data). In addition, data from the
literature show that TEE may not be feasible in 1–2% of patients scheduled for this procedure and unequivocal results concerning LAA imaging may be as frequent as 17.8%\textsuperscript{14}.

Using ICE instead of TEE would only be clinically feasible if the likelihood of obtaining good ICE images was nearly 100%. We showed in our study that such a high success rate is achievable after performing first 28 ICE procedures. Thus, TEE can be probably replaced by ICE in some clinical situations, however, this needs to be assessed prospectively.

Imaging with ICE is invasive and increases costs. It also increases the duration of the procedure and x-ray exposure, although to a limited extent. It requires 1 standard additional puncture in the groin; however, in our study, it was well tolerated by patients and no significant local complications in the left groin (where the ICE was introduced) were observed. Moreover, in many laboratories, ICE is routinely used to assist transseptal puncture; therefore, no additional costs are present in such a situation\textsuperscript{15}.

An observational retrospective study has shown that some LAA morphologies, assessed by CT, may be associated with an increased risk of stroke in low-risk patients\textsuperscript{16}. However, the association of specific LAA morphologies with an increases the risk of thrombus development in the LAA has not been investigated. We showed that the PA–ICE approach is effective in obtaining a grade 4 or 5 image of the LAA; thus, it may become a valuable alternative to TEE or CT in the assessment of stroke risk in AF patients. However, this has to be demonstrated in larger prospective studies. In conclusion, our study showed that adequate LAA imaging can be achieved by placing the ICE probe in the PA. We believe that ICE may become a useful clinical tool for LAA assessment in patients undergoing catheter ablation of AF.

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Conflict of Interest Disclosures: J. Baran, S.M. Stec, T. Krynski, P. Kulakowski have received travel grants from J&J. All others have none.

References:


Table 1. Demographic and clinical characteristics of the studied patients

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<th>Characteristic of patient</th>
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<td>Hypertension</td>
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<td>Coronary artery disease</td>
<td>22 (29%)</td>
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<tr>
<td>Myocardial infarction</td>
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<tr>
<td>Diabetes mellitus</td>
<td>17 (22%)</td>
</tr>
<tr>
<td>Heart failure</td>
<td>12 (16%)</td>
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<td>History of stroke or TIA</td>
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<tr>
<td>AF type</td>
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<td>Banded LAA (chicken wings)</td>
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<td>Non-banded LAA (wind socks, cauliflower, cactus)</td>
<td>39</td>
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Abbreviations: TIA, transition ischemic attack; AF, atrial fibrillation; LAA, left atrial appendage
Table 2. The possibility of obtaining quality images of the LAA from PA and CS

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<td>32 (47%)</td>
<td>7 (10%)</td>
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Abbreviations: PA, pulmonary artery; CS, coronary sinus; LAA, left atrial appendage; AF, atrial fibrillation
Figure Legends:

**Figure 1.** The patients’ flowchart

**Figure 2.** The ICE image of the left atrial appendage (LAA) and left atrium (LA) from the coronary sinus. The LAA cavity is free from thrombus. The course of the LAA without bended truck is shown. The image is graded 5.

**Figure 3.** The ICE images of the left atrial appendage (LAA) from the pulmonary artery in various phases of left atrial (LA) systole function are presented. A–B The ostium of the LAA and middle part of the trunk are visualized and the LA cavity is displayed. C–D Middle and distal parts of the LAA with pectinated muscles are visualized. The morphology of the LAA is a non-bended “wind sock” type. The left main coronary artery (LMA) is displayed. The image quality is graded 5.

**Figure 4.** The ICE image of the left atrial appendage (LAA) and left atrium (LA) from the pulmonary artery (PA). The LAA morphology of “chicken wing” is visualized. The image quality is graded 5. LMA, left main artery

**Figure 5.** A fluoroscopic view (left anterior oblique, 30°) of the diagnostic catheter (CS) and ICE. A: CS and ICE probes introduced into coronary artery; B: CS and ICE probes located in the right ventricular outflow track and pulmonary artery
Figure 6. Learning curve for ICE imaging of the left atrial appendage (LAA) from the pulmonary artery (PA) (time spent to achieve grade 4 or 5 images). For example, if examination of the LAA from the PA takes >5 min for a trained electrophysiologist, there is only a 10% chance of achieving a view of the LAA of grade excellent or good. After 10 min of examination there is almost a 0% chance of achieving a view grade of 4 or 5.
76 patients scheduled for AF ablation

2 patients not eligible for TEE:
- Esophagus varicose
- Inability to swallow TEE

74 patients examined by TEE

2 thrombi in the LAA detected

76 patients examined by ICE

2 thrombi in the LAA detected

Change of oral anticoagulation therapy and scheduled for another TEE

74 AF ablation procedures performed
Intracardiac Echocardiography for Detection of Thrombus in the Left Atrial Appendage: Comparison with Transesophageal Echocardiography in Patients Undergoing Ablation for Atrial Fibrillation. The Action-Ice I Study
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SUPPLEMENTAL MATERIAL

Video number 1 - LAA PA1 – LAA imaging by ICE from pulmonary artery, ICE was rotated clockwise. The LAA with additional lobes is displayed.

Video number 2 - LAAPA2 - LAA imaging by ICE from pulmonary artery, ICE was rotated clockwise. Pectinate muscles are displayed.

Video number 3 - LAAPA3 - short movie of LAA imaging by ICE from pulmonary artery. Pectinate muscles are displayed.

Video number 4 - LAAPA4 – from the same patient as in LAAPA3, longer movie of LAA imaging by ICE from pulmonary artery is presented in order to show various phases of left atrial systole function. ICE was rotated clockwise.

Video number 5 - ICE_PA_THROMBI1 - thrombi located in the LAA visualized by ICE from the PA

Video number 6 - TEE LAA THROMBI - thrombi located in the LAA by TEE examination – the same patient as in ICE_PA_THROMBI movie

Video number 7 - ICE_PA_THROMBI2 - LAA imaging by ICE from pulmonary artery, organized thrombus filling out LAA is presented