JACC: CARDIOVASCULAR INTERVENTIONS VOL. ■, NO. ■, 2023

Intracardiac Echocardiography to Guide Watchman FLX Implantation

The ICE LAA Study

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ABSTRACT

BACKGROUND Intracardiac echocardiography (ICE) is increasingly used to guide left atrial appendage closure (LAAC).

OBJECTIVES The aim of this study was to investigate the efficacy and safety of ICE-guided LAAC with the Watchman FLX device.

METHODS The ICE LAA (I Can See Left Atrial Appendage) study was a prospective, multicenter study with independent adjudication of echocardiographic data by a core laboratory and clinical events by a clinical events committee. Patients with atrial fibrillation with CHA_2DS_2-VASc scores ≥2 and clinical indications for LAAC were eligible. Preplanning with either cardiac computed tomography or transesophageal echocardiography (TEE) within 7 days prior to LAAC was mandatory. Intraprocedural ICE was carried out from the left atrium. The primary outcome was the rate of significant peri-device leaks (>5 mm) at 45-day TEE.

RESULTS A total of 100 patients were enrolled. The mean age was 76 ± 8 years, the mean CHA_2DS_2-VASc score was 4.0 ± 1.5, and the mean HAS-BLED score was 2.5 ± 0.9. The incidence of the primary outcome of significant peridevice leak (>5 mm) was 0%; all patients evaluated by TEE at 45 days had effective LAAC. All patients received Watchman FLX devices, and technical success was 100%. The number of devices per case was 1.0 ± 0.1. ICE successfully guided the assessment of device release criteria, including device compression (19.2% ± 7.1%; recommended range: 10%-30%). No subject required conversion to TEE. Procedural complications were 4 access-site bleeds. There was no stroke, transient ischemic attack, systemic embolization, pericardial effusion, device embolization, or device-related thrombus during the procedure or 45-day follow-up.

CONCLUSIONS ICE can be used to successfully guide LAAC with the Watchman FLX, with excellent procedural success, a high rate of effective LAAC, and minimal periprocedural complications. (I Can See Left Atrial Appendage [ICELAA] Clinical Study; NCT04196335) (J Am Coll Cardiol Intv 2023;■:■-■) © 2023 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

Manuscript received June 19, 2022; revised manuscript received October 4, 2022, accepted October 11, 2022.

ISSN 1936-8798 https://doi.org/10.1016/j.jcin.2022.10.024

ABBREVIATIONS AND ACRONYMS

2D = 2-dimensional

3D = 3-dimensional

AF = atrial fibrillation

CT = computed tomography

ICE = intracardiac echocardiography

LAA = left atrial appendage

LAAC = left atrial appendage closure

LUPV = left upper pulmonary vein

PASS = position, anchoring, sizing, and sealing

TEE = transesophageal echocardiography

Percutaneous left atrial appendage closure (LAAC) has become a frequently used intervention for stroke prevention in patients with atrial fibrillation (AF) who are unsuitable for long-term oral anticoagulation.[1,2] The anatomical variation of the left atrial appendage (LAA) is huge, and intraprocedural imaging is required to achieve optimal device implantation with the device in a good position and complete sealing of the LAA. Recent studies have indicated that significant peridevice leaks have a negative impact on clinical outcomes of LAAC.[3,4] Intraprocedural imaging is also important for procedural safety, as it can help diagnose adverse events such as pericardial effusion, thrombus formation on sheaths and wires, and device migration. LAAC has evolved with transesophageal echocardiography (TEE) as the standard intraprocedural imaging modality, and device release criteria for Watchman devices (Boston Scientific) are based on TEE. However, TEE can be associated with significant challenges. It typically requires an anesthesiology team, tracheal intubation, and a trained transesophageal echocardiographer, which all can make scheduling and logistics difficult. Many LAAC patients are elderly and fragile with comorbidities, leading to an increased risk from general anesthesia. TEE may cause significant damage to the esophageal mucosa,[5] and patients with gastroesophageal disorders such as esophageal varices are contraindicated for TEE.

Intracardiac echocardiography (ICE) has been used for several years to guide patent foramen ovale and atrial septal defect closure, transseptal puncture, and electrophysiological procedures. Recently, its use has been expanded to other structural heart interventions, such as LAAC.[6] The preferred position of the intracardiac echocardiographic catheter for guiding LAAC is inside the left atrium.[7,8] This position gives high-resolution images of the LAA, adjacent anatomical structures, the device delivery system, and the LAA device itself.[7,8] The main advantages of ICE are that it can be carried out with local anesthesia and can be performed by the LAAC operator. Previous studies suggest that the efficacy and safety of an ICE-guided LAAC approach are similar to those of a TEE-based work flow.[9-13] ICE was also used successfully to guide implantation of the novel Watchman FLX device in recent studies.[14-16] However, most of these studies were single center, with self-reported data and no independent adjudication of events and echocardiographic data by a core laboratory.

The aim of this study was to evaluate the efficacy and safety of ICE to guide implantation of the Watchman FLX using a rigorous design with independent evaluation of data by a core echocardiography laboratory and an independent clinical events committee. It was carried out as a single-arm, prospective multicenter clinical study involving 7 different LAAC centers across Europe (the ICE LAA [I Can See Left Atrial Appendage] clinical study).

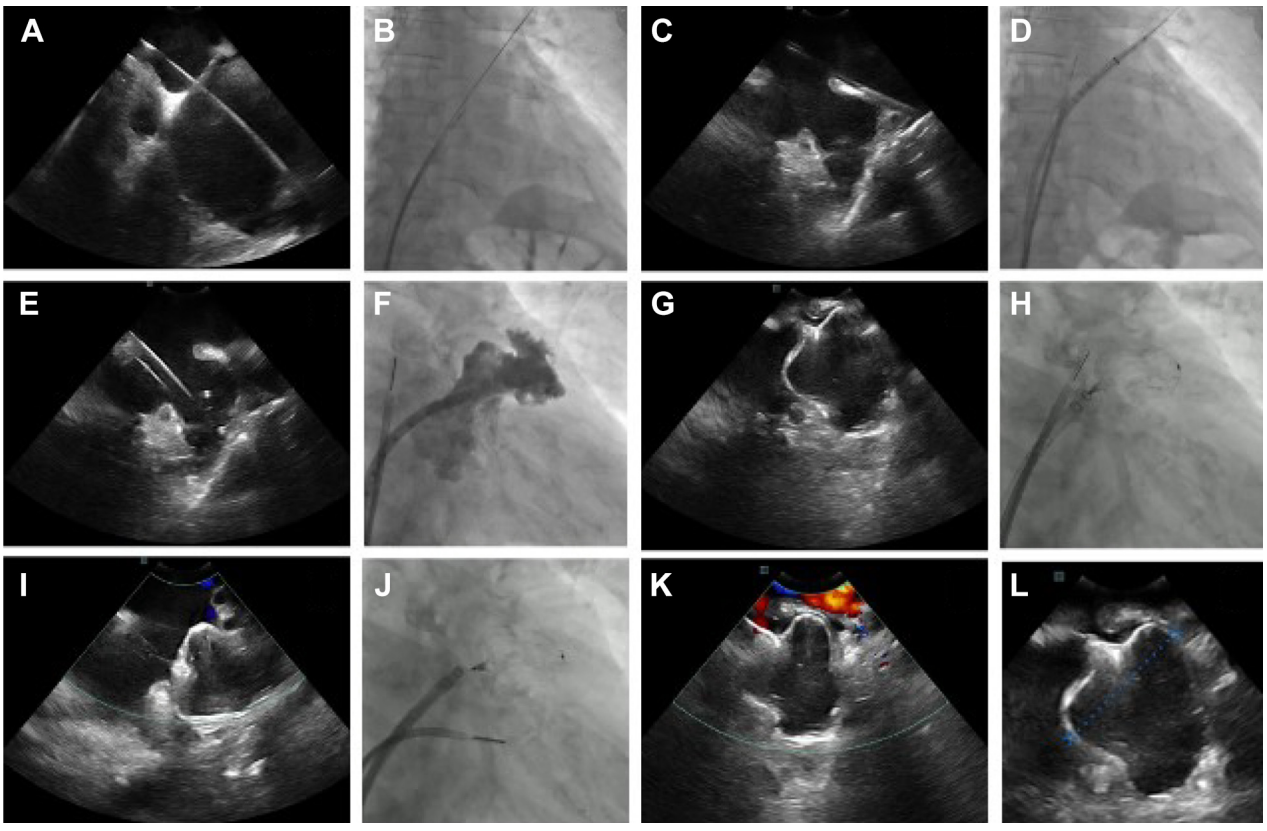
METHODS

STUDY POPULATION. The ICE LAA clinical study was designed to assess the use of ICE to guide LAAC with the Watchman FLX. ICE LAA is a single-arm, prospective, multicenter study. In brief, patients were eligible for the study if they had nonvalvular AF, had CHA_2DS_2-VASc scores of ≥2, were able to undergo ICE and TEE, fulfilled all inclusion criteria, did not satisfy any exclusion criteria, and provided informed consent. Detailed inclusion and exclusion criteria are listed in the clinical trial protocol (Supplemental Appendix). The study was conducted in accordance with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guidelines for Good Clinical Practice and the ethical principles outlined in the Declaration of Helsinki. The study was sponsored by Boston Scientific and registered with ClinicalTrials.gov (NCT04196335). The study was approved by relevant ethics committees, and all patients provided written informed consent. The data and study protocol for this clinical trial may be made available to other researchers in accordance with Boston Scientific's data sharing policy (http://www.bostonscientific.com/en-US/data-sharing-requests.html).

STUDY DEVICE AND PROCEDURE. Watchman FLX is the newest generation LAAC device, designed with a closed distal end for atraumatic navigation of the partially deployed device in the LAA, additional rows of anchors and struts to increase radial strength and safe anchoring, shallower depth, and coverage of the proximal face of the device with polyethylene terephthalate fabric.[14]

Patients underwent preprocedural imaging with cardiac computed tomography (CT; or 3-dimensional [3D] TEE if CT was not performed) to assess appendage anatomy and device sizing and exclude the presence of LAA thrombus. The intracardiac echocardiographic catheter was controlled by the implanter, whereas a nurse or technician handled the echocardiographic machine. Procedures were carried

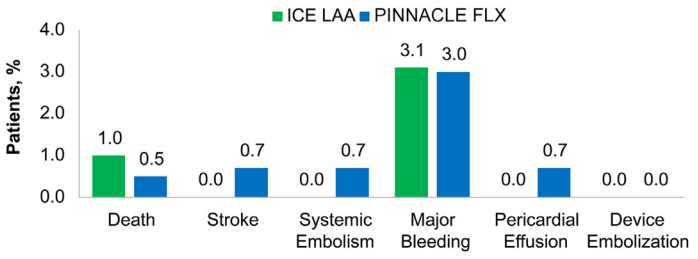
FIGURE 1 **Watchman FLX Implantation Guided by Intracardiac Echocardiography**



(A) Intracardiac echocardiography to guide transeptal puncture in the inferoposterior part of the interatrial septum. **(B)** A stiff guidewire is inserted into the left upper pulmonary vein (LUPV) through the transseptal puncture hole. The intracardiac echocardiographic catheter is advanced along the wire into the left atrium. **(C)** Intracardiac echocardiographic image of the left atrial appendage (LAA) as seen in the LUPV view. **(D)** The tip of the intracardiac echocardiographic catheter is near the LUPV ostium. The Watchman FLX delivery sheath is inserted into the LUPV. **(E)** The delivery sheath with a pigtail catheter is advanced into the LAA. **(F)** Selective LAA angiography. **(G,H)** The Watchman FLX device (35 mm) deployed in the LAA; LUPV view and fluoroscopy. **(I,J)** The Watchman FLX device seen in the supramitral view. **(K)** Color Doppler to evaluate LAA sealing by the FLX device. **(L)** "Shoulder-to-shoulder" measurement of the implant device diameter (28 mm) to evaluate the degree of device compression (28 mm/35 mm; 20%). The PASS (position, anchoring, sizing, sealing) criteria had to be fulfilled before device release.

out under local anesthesia with either no sedation or supplemental low doses of midazolam and fentanyl according to local practice and patient preference. The intracardiac echocardiographic catheters used were 2-dimensional (2D) catheters, the AcuNav (Biosense Webster) or ViewFlex Xtra (Abbott Vascular). The novel 3D intracardiac echocardiographic catheters from Philips and Biosense Webster are not yet Conformité Européenne marked and are not available in Europe. ICE was used to guide the transseptal puncture and, in most cases, single transseptal access was used to introduce both the intracardiac echocardiographic catheter and the delivery sheath into the left atrium. A double transseptal puncture was used in a minority of cases. ICE from the left atrium was used to guide the procedure and allow the investigator to implant the Watchman FLX device in the optimal position and to verify that adverse events did not occur during the implantation procedure. The intracardiac echocardiographic catheter was positioned near the left upper pulmonary vein (LUPV) ostium, in the midportion of the left atrium (mid left atrial view), and just above the mitral valve (supramitral view) to obtain both short-axis and long-axis views of the LAA[7] and to comply with the PASS (position, anchoring, sizing, and sealing) release criteria. Anchoring was documented by the tug test, sizing by compression measurements, and sealing by color Doppler interrogation and prerelease angiography (**Figure 1**). Implanters were to have performed a minimum of 10 ICE-guided LAAC procedures prior to the study. Supplemental Table 1 shows experience

FIGURE 2 Clinical Outcomes in the ICE LAA and PINNACLE FLX Studies



Clinical outcomes in the ICE LAA (I Can See Left Atrial Appendage) study (N = 100) were similar to those from the PINNACLE FLX (Protection Against Embolism for Nonvalvular AF Patients: Investigational Device Evaluation of the Watchman FLX LAA Closure Technology) study (n = 400),[17] in which transesophageal echocardiography was used to guide left atrial appendage closure.

TABLE 1 Baseline Characteristics (N = 100)

Age, y	75.8 ± 7.7 (100)
Female	33 (33)
Weight, kg	80.6 ± 19.3 (99)
BMI, kg/m^2	28.8 ± 16.4 (99)
CHA_2DS_2-VASc score	4.0 ± 1.5 (100)
HAS-BLED score	2.5 ± 0.9 (100)
Medical history	
Diabetes mellitus	27 (27)
Severe liver disease/cirrhosis	4 (4)
Hypertension	79 (79)
Chronic obstructive pulmonary disease	11 (11)
Major bleeding	63 (63)
Congestive heart failure	13 (13)
Ischemic stroke or TIA	26 (26)
Hemorrhagic stroke	17 (17)
Peripheral vascular disease	9 (9)
Type of atrial fibrillation	
Paroxysmal	44 (44)
Persistent	3 (3)
Long-term persistent	12 (12)
Permanent	41 (41)
Indications for LAA closure	
History of major or minor bleeding (with or without OAC therapy)	75 (75)
Increased risk for bleeding because of physical condition and/or comorbidities	32 (32)
Inability to take OACs for reasons other than high risk for bleeding	23 (23)
Thromboembolic event or documented presence of thrombus in the LAA despite adequate OAC therapy	4 (4)
Echocardiographic characteristics	
LVEF, %	55.7 ± 8.9 (92)
LAA ostium maximum diameter, mm	23.9 ± 5.2 (99)
LAA ostium minimum diameter, mm	19.5 ± 5.0 (78)
LAA maximum length, mm	32.5 ± 8.4 (98)

Values are mean ± SD (n) or n (%).

BMI = body mass index; LAA = left atrial appendage; LVEF = left ventricular ejection fraction; OAC = oral anticoagulant; TIA = transient ischemic attack.

with ICE-guided LAAC among participating implanters. Postprocedural antithrombotic regimen was at the discretion of the operator.

Standard TEE was used for the 45-day follow-up visit (median 50 days; IQR: 30-89 days) and was performed by trained individuals in accordance with the core laboratory instructions. At 45-day follow-up, TEE was performed to assess flow through and around the device, to ensure sealing, and to verify the absence of thrombus on the surface of the device prior to stopping dual antiplatelet inhibition or anticoagulant medication.

STUDY ENDPOINTS. The primary endpoint of ICE LAA was the rate of leak (>5 mm) at 45 days post-implantation as assessed by the echocardiography core laboratory (Medstar Health Research Institute). Clinical endpoints included death, bleeding, device embolization, device migration, device thrombus, major endovascular intervention, pericardial effusion, and stroke or transient ischemic attack. A clinical events committee reviewed and adjudicated clinical endpoint events.

COMPARISON WITH IMPLANTATION GUIDED BY TEE. A post hoc comparison of the ICE LAA study with the PINNACLE FLX (Protection Against Embolism for Nonvalvular AF Patients: Investigational Device Evaluation of the Watchman FLX LAA Closure Technology) study,[17] in which TEE was used to guide Watchman FLX implantation, was performed. Patient baseline characteristics, procedural characteristics, 45-day clinical outcomes, and closure at 45 days were compared (**Figure 2,** Supplemental Tables 3-6).

STATISTICAL ANALYSIS. Continuous variables are expressed as mean ± SD and discrete variables as counts and percentages. For the primary endpoint, a performance goal of 5.5% was based on an expected effective LAAC rate of 97.5%, with a 3% delta. To declare success, the 1-sided 97.5% upper confidence limit of the observed failure rate (peridevice flow >5 mm) had to be less than the performance goal of 5.5%. All implanted subjects with completed 45-day TEE were considered for the endpoint analysis. Statistical analyses were performed using SAS version 9.4 (SAS Institute).

RESULTS

BASELINE CHARACTERISTICS. Patients were enrolled in the ICE LAA study between July 29, 2020, and August 12, 2021, at 7 centers in Europe (Denmark, Italy, Spain,

TABLE 2 Procedural Outcomes (N = 100)

Device success (implantation of device without in-hospital mortality)	100 (100)
Technical success (successful deployment and release, no conversion to TEE, and effective closure of LAA at implantation [no leak <5mm])	100 (100)
Procedural success (device success plus absence of in-hospital device or procedure-related CEC-adjudicated events)	96 (96)[a]
Conversion to standard TEE during implantation	0 (0)
Total fluoroscopy time, min	17.8 (10.7-25.0)
Procedure time, min (time between venous access and sheath removal)	50.5 (38.0-65.0)
Number of Watchman FLX devices implanted	100
Number of Watchman FLX devices used	101
20 mm	7 (6.9)
24 mm	26 (25.7)
27 mm	30 (29.7)
31 mm	25 (24.8)
35 mm	13 (12.9)

Values are n (%) or median (IQR). [a]Procedural success was not met because of bleeding at the access site (2 patients) and groin hematoma (2 patients).

CEC = clinical events committee; LAA = left atrial appendage; TEE = transesophageal echocardiography.

and the United Kingdom). Two consented patients were excluded because of intracardiac thrombus, leading to an enrollment of 100 patients. Among these 100 patients, 45-day follow-up was performed in 96 patients; 1 patient died on day 10 after the procedure, 1 patient withdrew, and 2 patients were lost to follow-up. A total of 76 patients underwent 45-day transesophageal echocardiographic follow-up (1 study was not evaluable), 10 patients underwent cardiac CT instead of TEE (1 computed tomographic study was not evaluable), and 14 patients had no 45-day imaging. The relatively low rate of 45-day TEE was due primarily to restrictions caused by the COVID-19 pandemic. The total rate of 45-day imaging follow-up (TEE and CT) was 86 of 100 (86%).

The mean age of enrolled patients was 76 years, and the majority (67%) were men (Table 1). Nearly one-half of the patients (44%) had paroxysmal AF, the mean CHA_2DS_2-VASc score was 4.0 ± 1.5, and the mean HAS-BLED score was 2.5 ± 0.9, indicating a high-risk population. Additional baseline information is provided in Table 1.

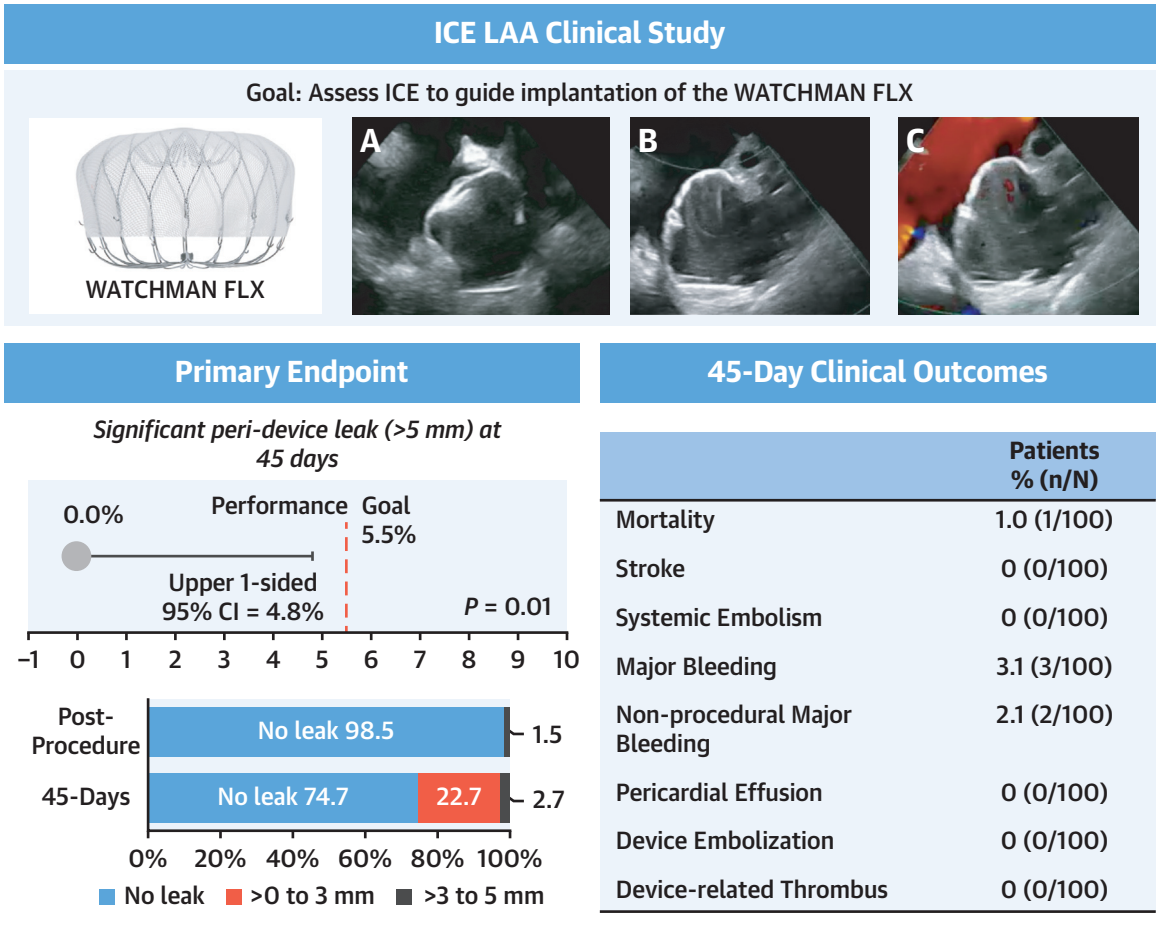
PROCEDURAL OUTCOMES. The median procedure time was 50.5 minutes (IQR: 38.0-65.0 minutes) (Table 2). All 5 available device sizes were implanted successfully in the study; the 27-mm device was the most commonly implanted device size. Both device success, defined as implantation of a device without in-hospital mortality, and technical success, defined as successful device deployment and release with no conversion to TEE and effective closure of LAA at implantation, were 100% (Table 2). Procedural success, defined as device success in the absence of in-hospital device or procedure-related clinical events committee-adjudicated events, was 96% (96 of 100). The 4 patients who did not meet procedural success criteria experienced bleeding at the access site treated with sutures (n = 2), groin hematoma that was not treated (n = 1), or groin hematoma treated with compression and anticoagulant agent discontinuation (n = 1). No patient required conversion to standard TEE during implantation. There were no unexpected findings on intraprocedural ICE such as LAA thrombus additional to the preprocedural imaging, and in only 1 of 100 cases was the size of the initially chosen device changed to another size. Most patients (60%) were prescribed dual antiplatelet therapy postimplantation; 50% were receiving dual antiplatelet therapy at 45 days (Supplemental Table 2).

PRIMARY OUTCOME. The primary endpoint of the ICE LAA study was peridevice leak (>5 mm), evaluated on 45-day postimplantation TEE and assessed by the echocardiography core laboratory. The primary endpoint was met (Central Illustration); the rate of leak >5 mm was 0.0%, with an upper 1-sided 95% confidence limit of 4.8%, which is lower than the prespecified performance goal of 5.5% ($P = 0.01$).

Ten patients underwent cardiac CT instead of TEE at 45-day imaging follow-up because of COVID-19-related restrictions. Nine of those scans were evaluable by the imaging core laboratory and showed no leaks in 8 patients and a 0- to 5-mm leak in 1 patient. The number of leaks >5 mm for the group of patients evaluated by the core laboratory by either TEE or CT was 0 of 84 (0.0%), no leaks were observed in 64 of 84 (76.2%), and 0- to 5-mm leaks were observed in 20 of 84 (23.8%).

CLINICAL OUTCOMES. Within 45 days, 1 patient died of cardiac arrest 10 days after an uncomplicated implantation procedure (Central Illustration). This patient had a history of cardiac arrest as well as renal failure, coronary artery disease, and stroke. No patients experienced stroke, systemic embolism, pericardial effusion, device-related thrombus, or device migration or embolization. Three patients (3.0%) experienced major bleeding (Bleeding Academic Research Consortium type 3a) within 45 days of the procedure (Central Illustration).These episodes occurred on postprocedure days 2, 4, and 10, with the

CENTRAL ILLUSTRATION **Intracardiac Echocardiography to Guide Watchman FLX Implantation**



Nielsen-Kudsk JE, et al. J Am Coll Cardiol Intv. 2023;■(■):■–■.

Primary endpoint and clinical outcomes from the ICE LAA (I Can See Left Atrial Appendage) study. Left atrial appendage closure using the Watchman FLX device was guided by intracardiac echocardiography in a prospective multicenter study (N = 100) with independent data adjudication by an echocardiography core laboratory and a clinical events committee. Intracardiac echocardiographic images **(A-C)** from the left atrium showing the Watchman FLX implanted into the left atrial appendage (LAA). **(A)** Left upper pulmonary vein view, **(B,C)** supramitral view, and **(C)** color Doppler used for evaluation of LAA sealing.

earliest related to the procedure and vascular access. The 2 other bleeds were unrelated to the procedure.

DISCUSSION

This is the first prospective clinical study on ICE-guided LAAC using independent adjudication of echocardiographic data and clinical events. Both intraprocedural intracardiac echocardiographic and follow-up transesophageal echocardiographic data were evaluated by an independent core laboratory. Only 76 of 100 patients (76%) underwent 45-day TEE, and 10 patients underwent cardiac CT instead of TEE (86% had 45-day imaging). This was due mainly to restrictions caused by the COVID-19 pandemic. The incidence of the primary endpoint of significant leak (>5 mm) was 0%; 100% of patients had effective closure on the basis of 45-day TEE or CT as assessed by the core laboratory. The prespecified statistical hypothesis was met, as the 95% 1-sided upper confidence bound of the primary endpoint was less than the performance goal of 5.5%. Technical and device success were 100%, and no subject required conversion to standard TEE during implantation.

The study results also indicate a high degree of procedural safety using an ICE-guided approach to

LAAC. There were no episodes of pericardial effusion, device embolization, or periprocedural stroke, and there were no adverse events related to the use of the ICE catheter itself. The only procedural complications were 4 vascular access-site bleeds, which all resolved. Clinical outcomes within the first 45 days did not show any stroke or transient ischemic attack, pericardial effusion, device embolization or migration, or device-related thrombus. Three patients had major bleeding events (Bleeding Academic Research Consortium type 3a), which is not unexpected in an AF population with a high risk for bleeding. One patient died 10 days after implantation, unrelated to the procedure or device.

A 3D imaging modality is optimal for LAA device sizing.[18] Procedural preplanning was mandatory in this study, and it was performed using cardiac CT in 79 patients and using 3D TEE in 21 patients. The intracardiac echocardiographic catheters used were 2D catheters, providing monoplane imaging with a 4-way deflectable catheter tip, but such catheters are suboptimal for the precise measurement of LAA dimensions and device landing zone. With a 2D ICE-guided approach to LAAC, it is advisable to perform preprocedural imaging with a 3D modality for device sizing.[7] Recently, 3D intracardiac echocardiographic catheters have become available, but so far it is unclear if they are adequate for LAA device sizing.

This study did not have a control group with Watchman FLX implantation guided by standard TEE. However, the patient population in the ICE LAA study (mean age 76 years, mean CHA_2DS_2-VASc score 4.0, mean HAS-BLED score 2.5) was comparable with the patient population in the PINNACLE FLX trial (mean age 74 years, mean CHA_2DS_2-VASc score 4.2, mean HAS-BLED score 2.0), in which TEE was used to guide LAAC.[17] Supplemental Tables 3 to 6 show a direct comparison of the ICE LAA and PINNACLE FLX studies on baseline characteristics, procedural outcomes, 45-day clinical outcomes, and LAA sealing. Technical success was 100% in ICE LAA, compared with 98.8% in PINNACLE FLX. The efficacy of LAAC at 45 days achieved in ICE LAA (leaks >5 mm, 0%; leaks 0-5 mm, 22.7%; no leak, 74.7%) was comparable with that reported for PINNACLE FLX (leaks >5 mm, 0%; leaks 0-5 mm, 17.2%; no leak, 82.8%). The number of Watchman FLX devices used per case was 1.2 ± 0.4 in PINNACLE FLX and 1.0 ± 0.1 in ICE LAA. Procedural safety and clinical outcomes were also comparable between ICE LAA and PINNACLE FLX (**Figure 2**).

The procedure and fluoroscopy times were longer in the ICE LAA study (median 50.5 minutes [IQR: 38.0-65.0 minutes] and 17.8 minutes [IQR: 10.7-25.0 minutes]) than in PINNACLE FLX (mean 37.9 ± 21.9 and 8.2 ± 7.2 minutes). This might be related to a relatively limited ICE experience at some of the participating centers. At a high-volume LAAC center routinely using ICE, the procedure and fluoroscopy times for Watchman FLX implantation were 38 and 11 minutes, respectively.[14] The median length of stay was 1 day in both ICE LAA (IQR: 1-2 days) and PINNACLE FLX (IQR: 1-1 days), whereas the number of patients discharged on the same calendar day as the procedure was higher in ICE LAA at 19% (19 of 100) than in PINNACLE FLX at 5% (23 of 400).

All sizes of the Watchman FLX device were used in a wide range of different anatomies in the ICE LAA study. ICE successfully guided implanters to fulfill the release (PASS) criteria for Watchman FLX. The recommended device compression range for Watchman FLX is 10% to 30%, and in the ICE LAA study, the mean device compression achieved was 19.2% ± 7.1%. The LAA was visualized in a systematic way with an intracardiac echocardiographic catheter tip position near the ostium of the LUPV, in the midportion of the left atrium (mid left atrial view), and just above the mitral valve (supramitral view), giving at least 2 orthogonal projections.[7] Color Doppler with a Nyquist limit set to approximately 0.25 m/s was used for evaluation of LAA sealing.

The use of ICE for LAAC has some obvious advantages over a TEE-guided approach. The procedure can be carried out under local anesthesia with the patient awake and responsive. The risks and postprocedural discomfort associated with general anesthesia or deeper sedation and endotracheal intubation can be avoided, and the procedure can be carried out in patients contraindicated for general anesthesia and in those with gastroesophageal diseases. An anesthesiology team and a TEE operator are not required, and the procedural turnover time is reduced. The number of LAAC procedures is expected to rise rapidly in the future, and this could be facilitated by an ICE-guided approach. There is an additional cost for the intracardiac echocardiographic catheter, but this may be neutralized by savings on personnel and increased capacity in the interventional laboratory.[13,19]

We believe that this multicenter prospective trial, adjudicated by a clinical event committee and an echocardiography core laboratory and showing a high procedural success rate and efficacy and safety

comparable with a TEE-guided approach, may help move the field of LAAC toward a simplified work flow using ICE and local anesthesia. A systematic approach with preplanning by CT (or 3D TEE) and intraprocedural ICE from the left atrium controlled by the implanter with LUPV, mid left atrial, and supramitral imaging sites was used to evaluate and fulfill the PASS criteria for device implantation. There is a learning curve for ICE-guided LAAC, and this could be accelerated by systematic training of operators at dedicated courses and workshops, simulator training, demonstration and live cases at scientific conferences, intracardiac echocardiographic simulation as an integrated feature of the computed tomographic planning software (Watchman TruPlan), and routine use of ICE for transseptal puncture and during other structural heart interventions such as patent foramen ovale and atrial septal defect closure. In addition, it is likely that the very recently introduced intracardiac echocardiographic catheters offering 3D and multiplane imaging capabilities will further shorten the learning curve.

STUDY LIMITATIONS. This was a prospective, single-arm, multicenter study evaluating ICE-guided LAAC with the Watchman FLX, but without a TEE-guided LAAC control group. However, the PINNACLE FLX trial, using standard TEE for intraprocedural imaging, had a similar design and patient population and could be compared with the ICE LAA study. There was a high clinical follow-up rate in ICE LAA (96 of 100), but the rate of transesophageal echocardiographic follow-up at 45 days was reduced (76 of 100) because of restrictions related to the COVID-19 pandemic. This was compensated by follow-up with CT instead of TEE for 10 patients, making the rate of imaging follow-up at 45 days 85 of 100 (85%).

CONCLUSIONS

This is the first study of ICE-guided LAAC using a robust prospective design with independent adjudication of imaging data and clinical events. Watchman FLX implantation was guided by ICE, with a high procedural success rate, few complications, and effective LAAC (0% peridevice leaks >5 mm at 45 days). The results were comparable with efficacy and safety results from the PINNACLE FLX trial using standard TEE for intraprocedural imaging. The results suggest that ICE is a valid alternative to TEE for guiding LAAC with the Watchman FLX device.

ACKNOWLEDGMENTS The authors thank Kristine Roy, PhD (a paid employee of Boston Scientific) for writing and editing assistance and Wen Hsieh, PhD, and Hong Wang, MS (paid employees of Boston Scientific) for assistance with statistical analysis.

FUNDING SUPPORT AND AUTHOR DISCLOSURES

The ICE LAA study was supported by Boston Scientific. Dr Nielsen-Kudsk is a proctor and an investigator for Abbott and Boston Scientific. Dr Berti is a proctor for Abbott and Boston Scientific. Dr Caprioglio has received speaker honoraria from Abbott, Philips, and GE Healthcare. Dr Ronco has received speaker honoraria from Abbott and GE Healthcare. Dr Arzamendi is a proctor for Abbott and Boston Scientific. Dr Betts is a proctor for Boston Scientific. Dr Tondo is a proctor for Abbott and Boston Scientific. Drs Christen and Allocco are full-time employees of and stockholders in Boston Scientific.

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PERSPECTIVES

WHAT IS KNOWN? ICE from the left atrium is a potential alternative to TEE to guide LAAC, but prospective studies with independent adjudication of data are missing.

WHAT IS NEW? In this prospective, multicenter, single-arm clinical study with independent adjudication by an echocardiography core laboratory and a clinical events committee, ICE-guided LAAC with the Watchman FLX device demonstrated 100% technical success, 0% significant peridevice leaks (<5 mm), and very few complications.

WHAT IS NEXT? ICE is expected to be recommended as an intraprocedural imaging modality to guide LAAC with the Watchman FLX device on par with TEE.

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KEY WORDS atrial fibrillation, ICE, intracardiac echocardiography, left atrial appendage, left atrial appendage closure, stroke prevention

APPENDIX For supplemental tables and the clinical trial protocol, please see the online version of this paper.