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ORIGINAL RESEARCH

Effect of Fluoroscopy-Only Versus Transesophageal Echocardiography/ Intracardiac Echocardiography Guidance in Left Atrial Appendage Occlusion on Stroke Prevention: Analysis From the RECORD I Study

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BACKGROUND: Evidence regarding the link between imaging modality and stroke prevention outcomes of left atrial appendage occlusion is currently lacking.

METHODS: The RECORD (Registry to Evaluate Chinese Real-World Clinical Outcomes in Patients With AF Using the WATCHMAN Left Atrial Appendage Closure Technology) trial prospectively enrolled 3096 consecutive patients undergoing left atrial appendage occlusion from 39 Chinese centers between April 1, 2019, and October 31, 2020. In the current analyses, patients were stratified into the echocardiographic guidance (transesophageal echocardiography/intracardiac echocardiography) group and the fluoroscopy-only group. The primary end point was the composite end point of death, stroke, or systemic embolism at 3 years. Outcomes were estimated using the Kaplan–Meier method. Inverse probability of treatment weighting and 1:1 propensity score matching were performed to calculate hazard ratios (HRs) for each outcome at the time of interest.

RESULTS: Among 3096 participants, 2603 (84.1%) underwent transesophageal echocardiography/intracardiac echocardiography–guided procedures and 493 (15.9%) underwent fluoroscopy-only guided procedures. Before discharge, procedural complications occurred in 34 patients (1.4%) in the transesophageal echocardiography/intracardiac echocardiography group and 3 patients (0.6%) in the fluoroscopy-only group (inverse probability of treatment weighting–adjusted absolute difference, −0.67 [95% CI, −1.39 to 0.05], *P*=0.066). At 3-year follow-up (completed by 2989 patients, 97.0%), the primary end point occurred in 269 (10.5%) patients in the transesophageal echocardiography/intracardiac echocardiography group and 52 (10.6%) patients in the fluoroscopy-only group (inverse probability of treatment weighting–adjusted HR, 1.13 [95% CI, 0.81–1.57], *P*=0.469). Ischemic stroke was comparable between groups (3.0% versus 4.1%, inverse probability of treatment weighting–adjusted HR, 1.66 [95% CI, 0.95–2.89], *P*=0.073). These findings remained consistent across patient risk profiles and operator experience levels.

CONCLUSIONS: Fluoroscopy-only guidance, without compromising long-term stroke prevention efficacy, may serve as a streamlined and potentially accessible alternative for left atrial appendage occlusion procedures performed with the first-generation WATCHMAN 2.5 device, and these findings apply to select patients and experienced centers.

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Key Words: atrial fibrillation ■ fluoroscopy ■ intracardiac echocardiography ■ left atrial appendage occlusion ■ stroke ■ transesophageal echocardiography

CLINICAL PERSPECTIVE

What Is New?

- Different modalities of intraprocedural imaging guidance exert no significant effect on the long-term efficacy of left atrial appendage occlusion for stroke prevention.

What Are the Clinical Implications?

- Fluoroscopy-only guidance for left atrial appendage occlusion is a streamlined, accessible alternative that does not compromise long-term stroke prevention efficacy, potentially expanding left atrial appendage occlusion accessibility without sacrificing safety or outcomes.

Nonstandard Abbreviations and Acronyms

BARC	Bleeding Academic Research Consortium
CHA_2DS_2-VASc	congestive heart failure, hypertension, age ≥75 years, diabetes, previous stroke or transient ischemic attack, vascular disease, age 65 to 74 years, and sex category
DRT	device-related thrombosis
HAS-BLED	hypertension, abnormal renal/liver function, stroke, bleeding history or predisposition, labile international normalized ratio, elderly, drugs/alcohol concomitantly
ICE	intracardiac echocardiography
IPTW	inverse probability of treatment weighting
LAAO	left atrial appendage occlusion
PSM	propensity score matching
RECORD	Registry to Evaluate Chinese Real-World Clinical Outcomes in Patients With AF Using the WATCHMAN Left Atrial Appendage Closure Technology
SE	systemic embolism
SMD	standardized mean difference
TEE	transesophageal echocardiography

Atrial fibrillation (AF), the most common sustained cardiac arrhythmia, significantly increases the risk of stroke—its most serious complication and a leading cause of severe disability.[1] Percutaneous left atrial appendage occlusion (LAAO) is a nonpharmacological strategy for stroke prevention in patients with AF. Current guidelines in the United States and Europe give LAAO a respective class IIa and class IIb recommendation for use in patients with AF and a contraindication or ineligibility for long-term oral anticoagulation.[2,3]

For LAAO procedures, the European Heart Rhythm Association and the European Association of Percutaneous Coronary Intervention expert consensus has endorsed transesophageal echocardiography (TEE) or intracardiac echocardiography (ICE), both of which provide accurate information on cardiac anatomy, as the real-time imaging modality of choice to use.[4] However, TEE requires general anesthesia, is limited by esophageal and gastric conditions,[5] while the use of ICE is expensive and demands dedicated expertise.[6] Consequently, LAAO using fluoroscopy-only is increasingly being adopted as a streamlined "minimalistic approach."[7–9] While there are data supporting comparable safety and efficacy of LAAO guided by fluoroscopy-only or echocardiography,[10,11] other studies have reported a lower risk of procedural complications with TEE/ICE guidance compared with fluoroscopy-only.[12] Notably, most of these reports enrolled a limited number of patients and focused primarily on periprocedural and short-term outcomes.

As a prophylactic treatment, LAAO lacks an immediate benefit for patients, and the impact of procedural configurations (eg, the impact of accurate sizing, location, and reducing residual leak) on its stroke-preventing effects requires time to become evident.[13] Therefore, in the current cohort study, we evaluate the immediate and long-term outcomes of LAAO procedures guided by TEE/ICCE or fluoroscopy-only in a real-world setting.

METHODS

Data Availability

The data that support the findings of this study are available from the corresponding author on reasonable request.

Study Population

The RECORD (Registry to Evaluate Chinese Real-World Clinical Outcomes in Patients With AF Using the WATCHMAN Left Atrial Appendage Closure Technology) study (NCT03917563) was a prospective registry that included 3096 consecutive patients from 39 centers in China between April 1, 2019, and October 31, 2020.[14] Patients were suitable for inclusion if they were eligible to receive the first-generation WATCHMAN 2.5 device as per the physician's discretion in accordance with appropriate local and international guidelines. Procedural configurations and postprocedural medications were left to the operators' discretion. A total of 159 operators with varying levels of experience in implanting the device participated in the study. All participants included in RECORD provided informed consent for the data and samples to be used for scientific purposes. The study adhered to the international rules for scientific studies and the Declaration of Helsinki. Central or local ethics committee approval was obtained in all participating centers.

In the current analyses, participants were stratified into the fluoroscopy-alone group or the TEE/ICE group according to the intraprocedural imaging performed during LAAO. All patients underwent preprocedural computed tomography angiography (CTA) or TEE screening to rule out LAA thrombus, characterization of LAA anatomy, and LAA measurements. After LAAO, scheduled clinical visits were conducted at 45 days (±14 days), 6, 12, 24, and 36 months (±30 days). For patients unable or unwilling to attend these visits, telephonic follow-ups were implemented as substitutes.

Clinical Outcomes

The primary outcome was a composite end point of death, stroke, and systemic embolism (SE) at 3 years. Events included any death, any stroke, SE, transient ischemic attack, device-related thrombosis (DRT), residual leak, and Bleeding Academic Research Consortium (BARC)–defined type 2, 3, or 5 bleeding events. Death, stroke, SE, and bleeding events were adjudicated by an independent clinical event committee consisting of 5 physicians with expertise in electrophysiology and/or interventional cardiology. The adjudication of events was based on the definitions included in the consensus document for percutaneous LAAO: the Munich consensus document on definitions, end points, and data collection requirements for clinical studies.[15] Bleeding was evaluated by the BARC criteria.[16] Successful implantation was defined as the device being deployed and implanted in the correct position. General anesthesia included patients with mechanical ventilation, while patients with monitored anesthetic care or sedation without mechanical ventilation were defined as having local anesthesia.

Statistical Analysis

Continuous variables with normal distribution are summarized as mean±SD and compared with Student *t* test, while those with a skewed distribution are presented as median±interquartile range (IQR) and assessed by Wilcoxon rank sum test. Categorical data are summarized as absolute numbers and proportions and compared with Fisher exact test. Multivariable-adjusted absolute differences were calculated using a logistic regression model. Time-to-event outcomes at 3 years were estimated using the Kaplan–Meier method. Cox proportional hazard regression models were used to estimate hazard ratios (HRs) for each outcome at the time point of interest, and the proportional hazard assumptions were tested and met in all models. Outcomes of patients who were lost to follow-up or withdrew consent were censored at their last contact date.

Sensitivity analyses were conducted to assess the robustness of the findings. In the best-case scenario, all patients who were lost to follow-up were assumed to be alive, while in the worst-scenario, they were all assumed to be dead. Moreover, inverse probability of treatment weighting (IPTW) and 1:1 propensity score (PS) matching analysis were performed to adjust for differences in baseline characteristics and potential confounders that may lead to bias. Adjusted covariates included age, sex, BMI, diabetes, hypertension, previous stroke, previous thromboembolism, New York Heart Association class, coronary artery disease, previous PCI, previous coronary artery bypass graft, concomitant use of antiplatelets or NSAIDs, CHA_2DS_2-VASc score, HAS-BLED (hypertension, abnormal renal/liver function, stroke, bleeding history or predisposition, labile international normalized ratio, elderly, drugs/alcohol concomitantly) score, in combination with ablation, and operator volume. The PS matching approach was performed using the nearest-neighbor method with caliper of width equal to 0.1 of the SD of the logit of the PS. All analyses were performed first in the whole cohorts and then in the PS-matched cohorts. Statistical analysis was performed using R project version 4.2.3 (R Foundation for Statistical Computing). Statistical significance was defined as a 2-tailed *P* value <0.05.

RESULTS

From April 1, 2019, to October 31, 2020, 3569 consecutive patients with an indication for an LAAO device were screened for enrollment in the 39 participating centers. Of these, 168 patients refused to provide consent, 162 declined to adhere to follow-up owing to the COVID-19 pandemic, and 143 were already participating in other studies; these patients were excluded, leaving 3096 participants in the RECORD study. Among

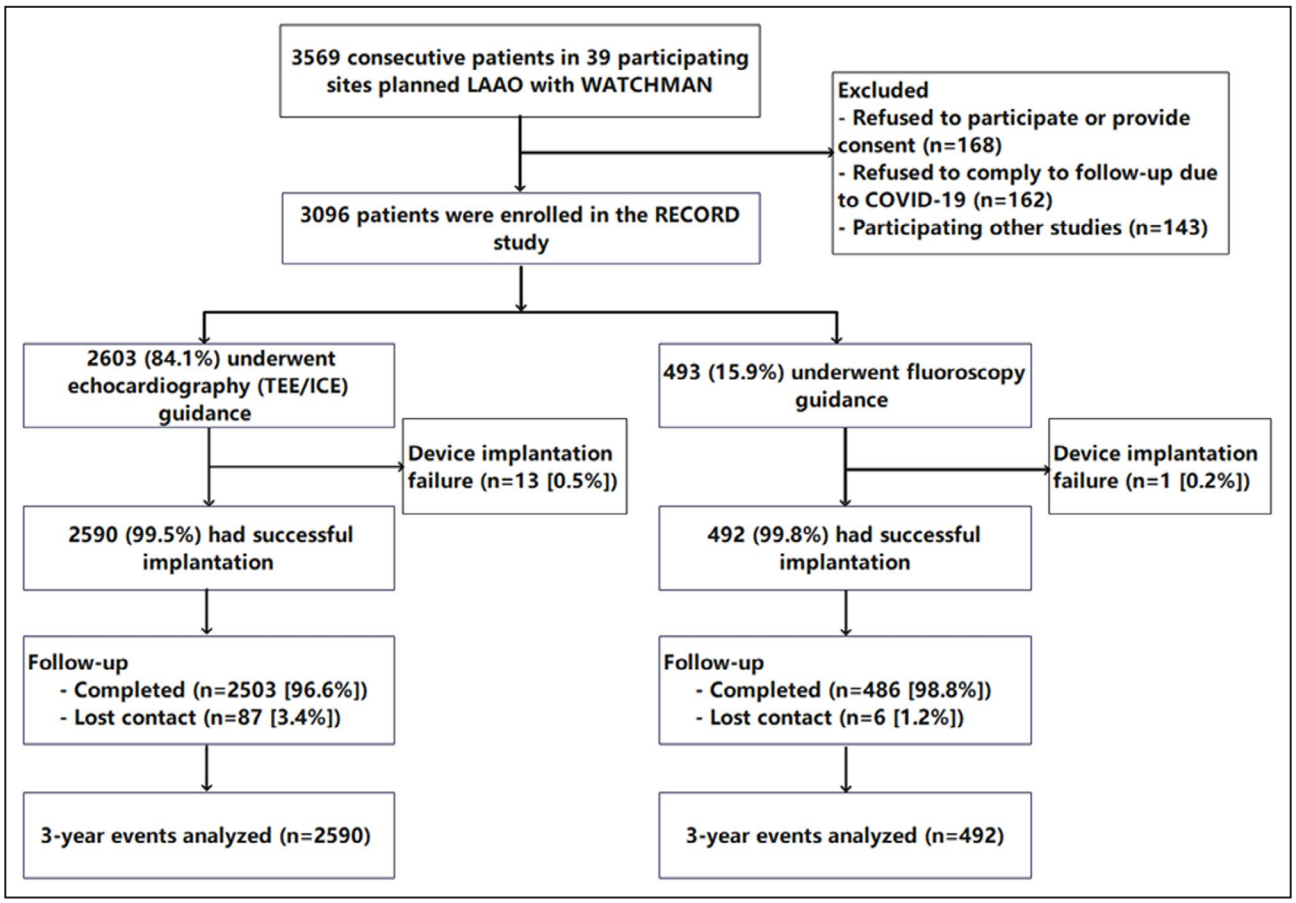

Figure 1. Study flowchart.
ICE indicates intracardiac echocardiography; LAAO, left atrial appendage occlusion; RECORD, Registry to Evaluate Chinese Real-World Clinical Outcomes in Patients With AF Using the WATCHMAN Left Atrial Appendage Closure Technology; and TEE, transesophageal echocardiography.

these patients, 84.1% (2603 of 3096) were guided by TEE or ICE, and 15.9% (493 of 3096) were guided by fluoroscopy only. Device implantation success rates were 99.5% (2590 of 2603) in the TEE/ICE group and 99.8% (492 of 493) in the fluoroscopy-only group. The current analysis excluded 14 patients in whom the device could not be successfully implanted (Figure 1). The propensity score matching (PSM) data set included 427 matched pairs of patients, accounting for 16.5% of the TEE/ICE cohort and 86.8% of the fluoroscopy-only cohort. Figure S1 shows the PS distributions in the TEE/ICE and fluoroscopy-only groups. Table S1 presents the distribution of missing data.

Baseline characteristics are shown in Table 1. Patients were on average 69 years old in the TEE/ICE and fluoroscopy-only cohorts, and more than half of the population were men. Compared with the TEE/ICE group, patients in the fluoroscopy-only group had a lower prevalence of previous stroke and bleeding history, and lower CHA_2DS_2-VASc (congestive heart failure, hypertension, age ≥75 years, diabetes, previous stroke or transient ischemic attack, vascular disease, age 65 to 74 years, and sex category) and HAS-BLED scores. The fluoroscopy-only group also had fewer release attempts (1.07±0.30 versus 1.11±0.37), a lower rate of second device use (1.4% versus 3.6%), less frequent general anesthesia (0.4% versus 69.4%), and a higher proportion of LAAO combined with ablation (62.2% versus 38.2%). In addition, annual center and operator volumes were significantly lower in the TEE/ICE-guided group than in the fluoroscopy-only group. Procedural complications occurred in 34 (1.4%) and 3 (0.6%) patients in the TEE/ICE and fluoroscopy-only group, respectively (absolute $\text{difference}_{\text{crude}}$, −0.75 [95% CI, −1.82 to 0.32], P=0.260; absolute $\text{difference}_{\text{IPTW}}$, −0.67 [95% CI, −1.39 to 0.05], P=0.066; absolute $\text{difference}_{\text{PSM}}$, −0.94 [95% CI, −0.69 to 2.76], P=0.287) (Table 2). The antithrombotic drug regimens after LAAO are presented in Table S2.

The median follow-up was 1374 days (IQR, 1204–1511 days). At 3 years, the primary end point occurred in 269 (10.5%) patients in the TEE/ICE group, compared with 52 (10.6%) in the fluoroscopy-only group (HR_{crude}, 1.01 [95% CI, 0.75–1.35], P=0.966; HR_{IPTW}, 1.13 [95%

Table 1. Baseline Characteristics

	Unmatched				Matched			
	TEE/ICE, n=2590	Fluoroscopy, n=492	*P* value	SMD	TEE/ICE, n=427	Fluoroscopy, n=427	*P* value	SMD
Age (SD), y	69.1 (9.4)	69.2 (8.9)	0.789	0.013	69.1 (9.7)	68.8 (8.9)	0.781	0.019
Men, n (%)	1490 (57.5)	281 (57.1)	0.904	0.008	250 (58.8)	255 (60.0)	0.889	0.014
Body mass index, SD	24.8 (3.5)	25.0 (3.6)	0.199	0.064	25.2 (4.0)	25.1 (3.6)	0.671	0.029
Heart rate, beats per min (IQR)	78.0 (68.0–91.0)	80.0 (69.0–92.0)	0.020	0.116	80.0 (70.0–94.0)	80.0 (69.0–92.0)	0.705	0.027
LVEF (IQR), %	61.0 (56.0–65.0)	61.0 (57.0–65.2)	0.676	0.038	61.0 (57.0 –65.0)	61.7 (57.0–65.8)	0.582	0.032
Diabetes, n (%)	607 (23.4)	107 (21.7)	0.698	0.060	89 (21.0)	100 (23.5)	0.723	0.079
Hypertension, n (%)	1782 (68.8)	338 (68.7)	0.825	0.039	287 (67.5)	299 (70.4)	0.555	0.045
Previous stroke, n (%)	1211 (46.8)	200 (40.7)	0.015	0.123	156 (36.7)	163 (38.4)	0.672	0.034
Ischemic stroke	1084 (41.9)	177 (36.0)	0.017	0.121	152 (35.8)	159 (37.4)	0.670	0.034
Hemorrhagic stroke	94 (3.6)	12 (2.4)	0.233	0.069	8 (1.9)	9 (2.1)	0.812	0.033
Bleeding history or predisposition, n (%)*	277 (10.7)	36 (7.3)	0.028	0.118	27 (6.4)	31 (7.3)	0.683	0.037
Coronary artery disease, n (%)	749 (28.9)	126 (25.6)	0.117	0.117	100 (23.5)	102 (24.0)	0.578	0.044
Previous PCI	284 (11.0)	42 (8.5)	0.102	0.121	41 (9.6)	37 (8.7)	0.722	0.033
Previous CABG	40 (1.5)	6 (1.2)	0.732	0.028	8 (1.9)	5 (1.2)	0.576	0.057
Alcohol abuse, n (%)	350 (13.5)	67 (13.6)	0.883	0.022	72 (16.9)	62 (14.5)	0.642	0.064
Current smoker, n (%)	291 (11.2)	42 (8.5)	0.134	0.110	44 (10.4)	41 (9.7)	0.989	0.024
Classification of AF, n (%)			0.710	0.060			0.082	0.178
Paroxysmal	1053 (40.7)	192 (39.0)			175 (41.0)	166 (38.9)		
Persistent	1064 (41.1)	206 (41.9)			144 (33.7)	176 (41.2)		
Long-standing persistent (>1 y)/permanent	473 (18.3)	94 (19.1)			108 (25.4)	85 (20.0)		
NYHA class, n (%)			0.306	0.117			0.976	0.031
I	279 (10.8)	41 (8.3)			40 (9.4)	38 (8.9)		
II	1888 (72.9)	369 (75.0)			322 (75.4)	325 (76.1)		
III	382 (14.7)	78 (15.9)			61 (14.3)	61 (14.3)		
IV	38 (1.5)	4 (0.8)			4 (0.9)	3 (0.7)		
Abnormal thyroidal function, n (%)	114 (4.4)	18 (3.6)	0.625	0.065	19 (4.5)	22 (5.0)	0.976	0.031
Chronic heart failure, n (%)	145 (5.6)	31 (6.3)	0.428	0.079	32 (7.5)	30 (7.0)	0.895	0.018
ATRIA score, SD	6.3 (3.0)	5.9 (2.9)	0.009	0.129	5.9 (3.0)	6.0 (3.0)	0.638	0.032
$CHADS_2$ score, SD	2.3 (1.4)	2.1 (1.4)	0.002	0.151	2.1 (1.3)	2.2 (1.4)	0.220	0.084
CHA_2DS_2-VASc score, SD	4.0 (1.8)	3.8 (1.8)	0.011	0.126	3.7 (1.7)	3.8 (1.8)	0.308	0.070
HAS-BLED score, SD	2.4 (1.2)	2.2 (1.1)	<0.001	0.182	2.2 (1.1)	2.3 (1.1)	0.366	0.062
Device size, n (%)			0.994	0.118			0.995	0.091
21 mm	157 (6.0)	30 (6.1)			23 (5.4)	24 (5.6)		
24 mm	527 (20.3)	104 (21.1)			87 (20.4)	85 (20.0)		
27 mm	778 (30.0)	140 (28.4)			122 (28.7)	122 (28.7)		
30 mm	595 (22.9)	118 (23.9)			104 (24.5)	103 (24.2)		
33 mm	533 (20.5)	100 (20.3)			89 (20.9)	91 (21.4)		
No. of releases, SD	1.10 (0.36)	1.07 (0.30)	0.039	0.108	1.07 (0.32)	1.07 (0.31)	0.914	0.007
Usage of a second device, n (%)	93 (3.6)	7 (1.4)	0.019	0.139	5 (1.2)	6 (1.4)	>0.999	0.021
Anesthesia, n (%)			<0.001	2.097			>0.999	<0.001
General	1797 (69.4)	2 (0.4)			2 (0.5)	2 (0.5)		

(*Continued*)

Table 1. Continued

	Unmatched				Matched			
	TEE/ICE, n=2590	Fluoroscopy, n=492	*P* value	SMD	TEE/ICE, n=427	Fluoroscopy, n=427	*P* value	SMD
Localized	799 (30.6)	490 (99.6)			423 (99.5)	423 (99.5)		
In combination with ablation, n (%)	989 (38.2)	306 (62.2)	<0.001	0.495	262 (61.4)	255 (59.7)	0.672	0.034
Center volume (IQR), y	71.0 (42.0–98.0)	91.0 (77.0–102.0)	<0.001	0.277	94.0 (77.0–98.0)	86.0 (77.0–98.0)	0.892	0.026
Operator volume (IQR), y	40.6 (20.3–62.9)	56.5 (26.0–68.6)	<0.001	0.024	40.0 (21.3–61.0)	56.5 (20.3–68.6)	0.151	0.074

AF indicates atrial fibrillation; ATRIA, Anticoagulation and Risk Factors in Atrial Fibrillation; CABG, coronary artery bypass graft; HAS-BLED, hypertension, abnormal renal/liver function, stroke, bleeding history or predisposition, labile international normalized ratio, elderly, drugs/alcohol concomitantly; ICE, intracardiac echocardiography; IQR, interquartile range; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; SE, systemic embolism; SMD, standardized mean difference; and TEE, transesophageal echocardiography.

*Bleeding history or predisposition includes previous major hemorrhage or anemia or severe thrombocytopenia, defined according to the HAS-BLED score.

CI, 0.81–1.57], *P*=0.469; HR_{PSM}, 1.12 [95% CI, 0.73–1.73], *P*=0.593) (Figure 2; Table 3). In addition, the sensitivity analyses of best-case and worst-case scenarios (assuming all patients who were lost to follow-up were alive or died) showed consistent results (Table S3). No significant differences were observed in the incidences of death (7.3% versus 6.5%; HR_{IPTW}, 0.98 [95% CI, 0.65–1.46], *P*=0.906; HR_{PSM}, 0.95 [95% CI, 0.56–1.61], *P*=0.844), stroke (3.9% versus 4.8%; HR_{IPTW}, 1.42 [95% CI, 0.85–2.38], *P*=0.177; HR_{PSM}, 1.82 [95% CI, 0.87–3.79], *P*=0.111), or SE (0.3% versus 0.0%) between the TEE/ICE and fluoroscopy-only groups, respectively (Table 3). The incidences of transient ischemic attack, DRT, residual leak (≥3 mm), or BARC-defined type 2, 3, or 5 bleeding were also numerically similar between the 2 groups. Stratification analyses by sex, age, CHA_2DS_2-VASc score, HAS-BLED score, the combination of ablations, and annual procedures per operator showed no significant differences in the 3-year death, stroke, and SE events between the two imaging groups (*P* interaction for all >0.05; Figure 3).

The association between variables and 3-year death, stroke, or SE was analyzed (Table 4). Multivariable analysis demonstrated that each 5-year increase in age (HR, 1.32 [95% CI, 1.22–1.43]; *P*<0.001), New York Heart Association class (HR, 1.37 [95% CI, 1.13–1.67]; *P*=0.002), and HAS-BLED score ≥3 (HR, 1.62 [95% CI, 1.09–2.40]; *P*=0.016) independently predicted the primary end point.

DISCUSSION

The key findings of this research can be outlined as follows:

1. The rate of successful device implantation with fluoroscopy only was numerically similar to that with TEE/ICE guidance; the incidence of procedural complications was comparably low in both groups.
2. Outcomes for death, stroke, or SE at 3 years were comparable between LAAO procedures using TEE/ICE guidance and those using fluoroscopy only, with this finding consistent among patients with different risk profiles and irrespective of the operator's procedural experience.

Our study, along with previous reports,[10–12,17] indicates a consistently high (≥96%) rate of successful deployment of LAAO devices. The safety and efficacy of ICE- and TEE-guided LAAO have been previously demonstrated.[5] Therefore, recent guidelines recommend the use of such imaging methods to guide LAAO.[4] Yet, current data remain controversial regarding whether adding intraprocedural echocardiographic guidance to fluoroscopy further improves LAAO safety. The single-center Bern registry[12] demonstrated that TEE/ICE guidance was associated with a lower risk of procedure-related complications compared with fluoroscopy only. In contrast, a cohort study involving 101 patients who underwent TEE and 107 who received fluoroscopy only showed comparable rates of pericardial effusions.[10] In our study, periprocedural complication rates in the TEE/ICE and fluoroscopy-only groups were 1.4% and 0.6%, respectively, with no statistical significance. Hilberath et al[18] reported that the rate of TEE-related complications in an intraoperative setting ranges from 0.2% to 1.2%, which is consistent with our findings.

In the current analysis, the proportion of general anesthesia was significantly higher in the TEE/ICE group (69.4%) compared with the fluoroscopy-only group (0.4%), reflecting a fundamental divergence in clinical practice. Patients in the former group predominantly underwent TEE-guided LAAO, which typically required general anesthesia with longer procedural preparation and postanesthesia recovery. In contrast, fluoroscopy-only procedures were performed under

Table 2. Periprocedural Complications

	Imaging guidance		Crude		IPTW-adjusted		Imaging guidance		PS matching	
	TEE/ICE, n=2590	Fluoroscopy, n=492	Difference (95% CI)	*P* value	Difference (95% CI)	*P* value	TEE/ICE, n=427	Fluoroscopy, n=427	Difference (95% CI)	*P* value
Procedural complications*	34 (1.4)	3 (0.6)	−0.75 (−1.82 to 0.32)	0.260	−0.67 (−1.39 to 0.05)	0.066	6 (1.4)	2 (0.5)	−0.94 (−0.69 to 2.76)	0.287
Vascular access-related	3 (0.1)	0 (0.0)	…	…	…	…	2 (0.5)	0 (0.0)	…	…
Device-related	12 (0.5)	0 (0.0)	…	…	…	…	1 (0.2)	0 (0.0)	…	…
Cardiac tamponade	11 (0.4)	0 (0.0)	…	…	…	…	1 (0.2)	0 (0.0)	…	…
Pneumothorax	1 (0.0)	0 (0.0)	…	…	…	…	0 (0.0)	0 (0.0)	…	…
Pericardial effusion	18 (0.6)	2 (0.4)	…	…	…	…	3 (0.7)	1 (0.2)	…	…
Others	1 (0.0)	1 (0.2)	…	…	…	…	0 (0.0)	1 (0.2)	…	…
Esophageal	0 (0.0)	1 (0.2)	…	…	…	…	0 (0.0)	1 (0.2)	…	…
Adverse reaction to anesthesia	1 (0.0)	0 (0.0)	…	…	…	…	0 (0.0)	0 (0.0)	…	…

ICE indicates intracardiac echocardiography; IPTW, inverse probability of treatment weighting; PS, propensity score; and TEE, transesophageal echocardiography.

*Procedural complications were presented as absolute numbers and proportions, and the *P* value was estimated by Fisher exact test.

local anesthesia, allowing for a streamlined workflow with faster room turnover and reduced periprocedural resource utilization. These distinctions in anesthetic strategy have important implications for procedural efficiency and institutional resource allocation.

In contrast to studies focusing on short-term outcomes, research examining the impact of imaging guidance on long-term outcomes remains scarce and limited by small sample sizes. As the primary objective of LAAO is to prevent thromboembolic ischemic stroke, its definitive efficacy requires confirmation through long-term follow-up data. The present study, with a larger sample size, supports the notion that the type of imaging guidance employed during the LAAO does not affect stroke-prevention efficacy. This finding aligns with Su and colleagues' research on short-term outcomes, where adjusted 30-day rates of death, stroke, SE, or major bleeding did not differ significantly among TEE-, ICE-, and fluoroscopy-only guided procedures.[19] Notably, a numerical trend toward higher incidence of ischemic stroke events was observed in the fluoroscopy-only group, although this difference

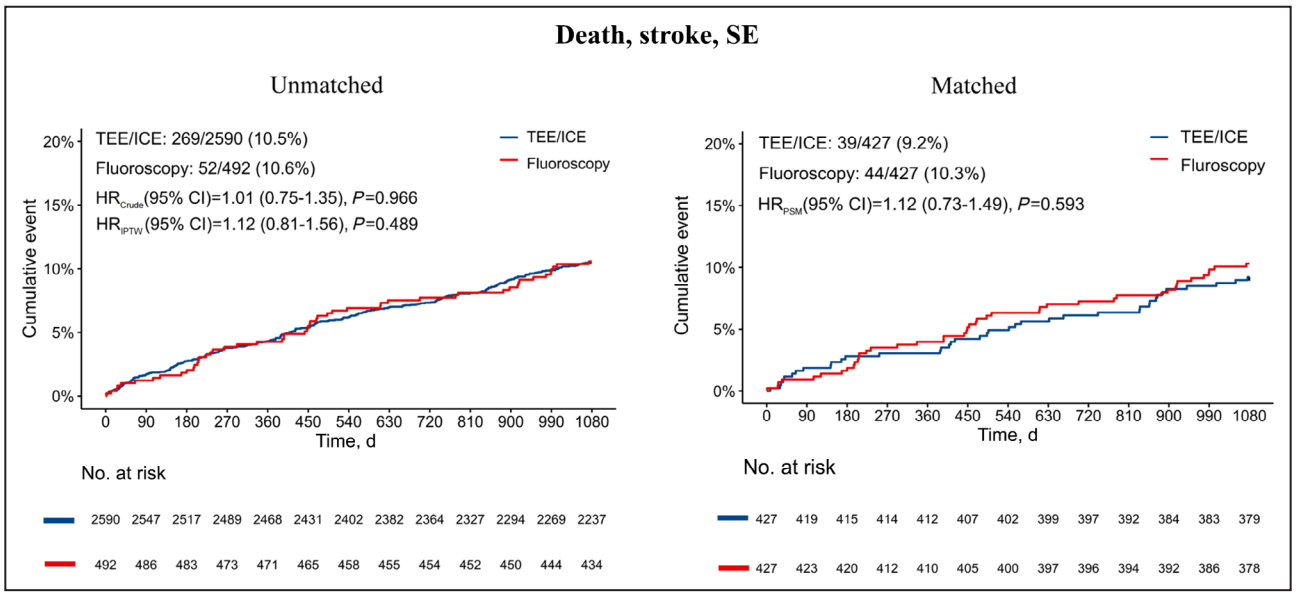

Figure 2. Kaplan–Meier curves for the composite end point of death, stroke, and SE.
HR indicates hazard ratio; ICE, intracardiac echocardiography; IPTW, inverse probability of treatment weighting; PSM, propensity score matching; SE, systemic embolism; and TEE, transesophageal echocardiography.

Table 3. Three-Year Outcomes in TEE/ICE and Fluoroscopy-Only Groups

	Imaging guidance						Imaging guidance			
	TEE/ICE, n=2590	Fluoroscopy, n=492	Crude HR (95% CI)	*P* value	IPTW adjusted HR (95% CI)	*P* value	TEE/ICE, n=427	Fluoroscopy, n=427	PS matching HR (95% CI)	*P* value
Death, stroke, or SE	269 (10.5)	52 (10.6)	1.01 (0.75–1.35)	0.966	1.13 (0.81–1.57)	0.469	39 (9.2)	44 (10.3)	1.12 (0.73–1.73)	0.593
Death, stroke, SE, or BARC 2, 3, or 5 bleeding	360 (14.0)	69 (14.0)	1.00 (0.77–1.29)	0.974	1.11 (0.84–1.48)	0.463	55 (13.0)	57 (13.4)	1.03 (0.71–1.49)	0.894
Individual components										
Death	188 (7.3)	32 (6.5)	0.88 (0.60–1.27)	0.490	0.98 (0.65–1.46)	0.906	28 (6.6)	27 (6.3)	0.95 (0.56–1.61)	0.844
Cardiovascular death	149 (5.8)	28 (5.7)	0.97 (0.65–1.45)	0.879	1.07 (0.70–1.66)	0.746	21 (5.0)	23 (5.4)	1.08 (0.60–1.95)	0.806
Noncardiovascular death	39 (1.6)	4 (0.9)	0.52 (0.19–1.47)	0.219	0.61 (0.21–1.77)	0.361	7 (1.7)	4 (1.0)	0.56 (0.16–1.92)	0.358
Stroke	99 (3.9)	23 (4.8)	1.22 (0.77–1.91)	0.399	1.42 (0.85–2.38)	0.177	11 (2.6)	20 (4.8)	1.82 (0.87–3.79)	0.111
Ischemic stroke	76 (3.0)	20 (4.1)	1.38 (0.84–2.25)	0.204	1.66 (0.95–2.89)	0.073	9 (2.2)	17 (4.1)	1.88 (0.84–4.22)	0.125
Hemorrhagic stroke	27 (1.1)	4 (0.8)	0.77 (0.27–2.21)	0.633	0.80 (0.24–2.67)	0.714	3 (0.7)	4 (0.9)	1.33 (0.30–5.94)	0.709
SE	8 (0.3)	0 (0.0)	…	…	…	…	…	…	…	…
TIA	14 (0.6)	3 (0.6)	1.12 (0.32–3.89)	0.860	0.70 (0.20–2.54)	0.592	3 (0.7)	2 (0.5)	0.66 (0.11–3.96)	0.652
Device-related thrombosis*	62 (3.3)	3 (1.2)	0.35 (0.11–1.13)	0.078	0.30 (0.09–1.02)	0.054	8 (2.9)	3 (1.3)	0.46 (0.12–1.72)	0.247
Residual leak (≥3 mm)*	111 (6.0)	13 (5.0)	0.84 (0.48–1.50)	0.561	0.79 (0.41–1.52)	0.480	12 (4.4)	12 (5.3)	1.25 (0.56–2.78)	0.588
BARC bleeding										
Type 2, 3, or 5	135 (5.3)	24 (4.9)	0.92 (0.60–1.43)	0.722	1.00 (0.62–1.61)	0.996	21 (5.0)	19 (4.5)	0.89 (0.48–1.66)	0.719
Type 3 or 5	58 (2.3)	8 (1.7)	0.72 (0.34–1.50)	0.378	0.83 (0.37–1.86)	0.649	8 (1.9)	8 (1.9)	0.99 (0.37–2.64)	0.983
Type 5	16 (0.6)	1 (0.2)	0.33 (0.04–2.46)	0.276	0.30 (0.04–2.25)	0.242	2 (0.5)	1 (0.2)	0.49 (0.04–5.43)	0.563
Type 3	42 (1.6)	7 (1.4)	0.87 (0.39–1.93)	0.727	1.02 (0.43–2.44)	0.962	6 (1.4)	7 (1.7)	1.16 (0.39–3.44)	0.795
Type 2	78 (3.1)	16 (3.3)	1.07 (0.63–1.83)	0.803	1.12 (0.62–2.01)	0.711	13 (3.1)	11 (2.6)	0.84 (0.38–1.87)	0.667

BARC indicates Bleeding Academic Research Consortium; HR, hazard ratio; ICE, intracardiac echocardiography; IPTW, inverse probability of treatment weighting; PS, propensity score; PS, propensity score; SE, systemic embolism; TEE, transesophageal echocardiography; and TIA, transient ischemic attack.

*Data on the device-related thrombosis and residual leak were available for 1912 patients in the TEE/ICE group and 259 in the fluoroscopy-only group.

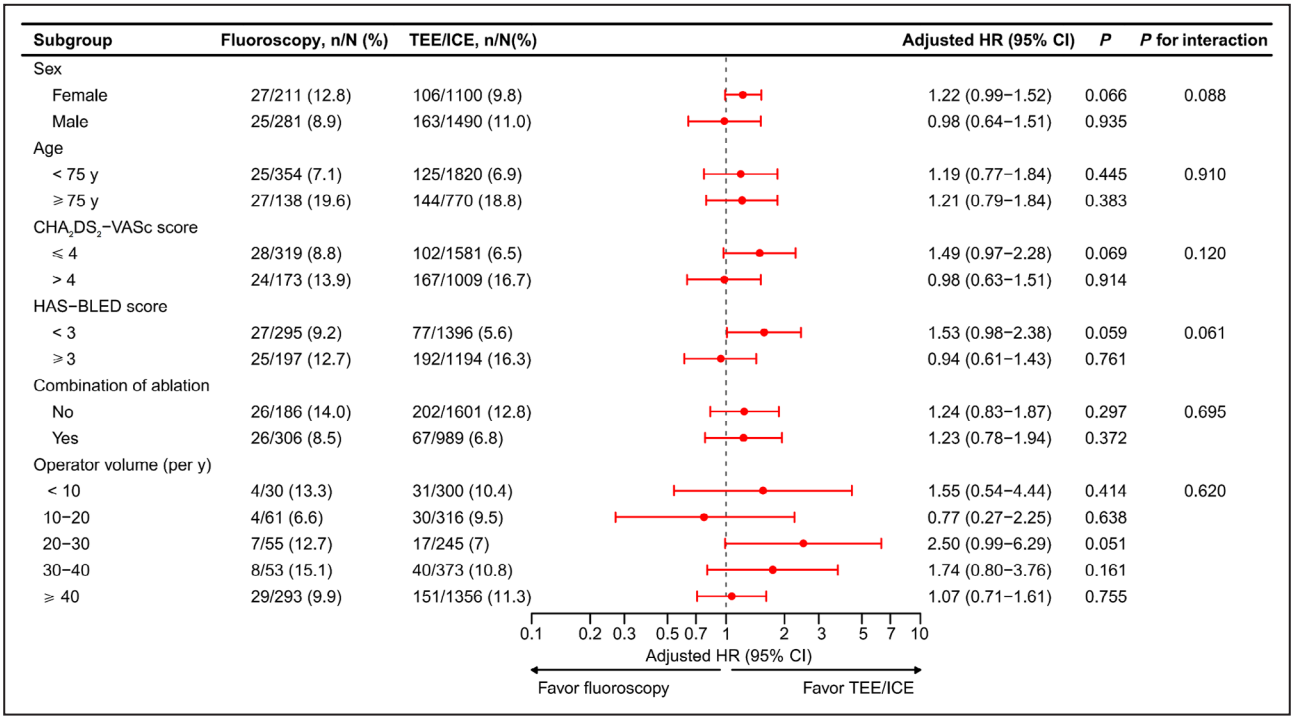

Figure 3. Forest plot showing the impact of TEE/ICE versus fluoroscopy only on the primary end point in different subgroups. CHA_2DS_2-VASc indicates congestive heart failure, hypertension, age ≥75 years, diabetes, previous stroke or transient ischemic attack, vascular disease, age 65 to 74 years, and sex category; HAS-BLED, hypertension, abnormal renal/liver function, stroke, bleeding history or predisposition, labile international normalized ratio, elderly, drugs/alcohol concomitantly; HR, hazard ratio; ICE, intracardiac echocardiography; and TEE, transesophageal echocardiography.

did not reach statistical significance. This trend may be related to subtle differences in device positioning, residual leak, or the formation of DRT between the 2 groups. However, incomplete TEE/CTA imaging during follow-up limited robust assessment of DRT and peridevice (residual) leak. The rate of DRT may have been underestimated, as inconspicuous DRT or subtle peridevice leak could not be identified in patients without TEE/CTA. In addition, nonuniform distribution of missing imaging may have introduced selection bias in between-group comparisons and reduced statistical power, precluding reliable assessment of mechanistic associations with ischemic stroke. Consequently, our study was not adequately powered to validate these mechanistic relationships. Large-scale prospective studies with consistent, standardized TEE/CTA follow-up imaging are therefore warranted to minimize such bias, enable robust comparative analyses, and further elucidate the underlying mechanisms of this clinical trend.

Our finding is consistent with several previous, smaller studies. Zhang et al[10] enrolled 208 patients and found no difference in death or DRT at 1 year between fluoroscopy- and TEE-guided groups. Kleinecke et al,[20] in a propensity-matched analysis of 532 patients, reported comparable 2-year cardiovascular death, stroke, and SE rates. Similarly, Yuniadi et al[11] observed similar stroke and death events at 3 years irrespective of guidance modality. Collectively, current evidence and our results argue against an additional long-term benefit in stroke prevention from routine echocardiographic guidance during LAAO.

As a prospective registry reflecting real-world clinical practice, the RECORD trial included operators with varying experience levels, representing approximately 19% (159) of all LAAO operators in China.[21] This resulted in baseline imbalances, particularly as fluoroscopy-only guided cases were more frequently performed by more experienced operators. Although operator experience was accounted for as a confounding variable in multivariable models and in stratified analyses, no notable interaction was observed between operator experience and imaging modality. Moreover, 3-year adverse event rates were similar between the TEE/ICE and fluoroscopy-only groups, irrespective of operator experience. Our findings should be interpreted within the context of the patient population and institutional expertise represented in this registry. They suggest that fluoroscopy-only guidance may be a reasonable option for carefully selected patients with relatively low thromboembolic and bleeding risk, when performed by experienced, high-volume operators—consistent

Table 4. Independent Predictors of Death, Stroke, and SE

	Univariable		Multivariable	
	HR (95% CI)	*P* value	HR (95% CI)	*P* value
Demographic characteristics				
Age per 5 y	1.43 (1.34–1.53)	<0.001	1.32 (1.22–1.43)	<0.001
Men	1.05 (0.84–1.32)	0.643		
BMI	0.95 (0.92–0.98)	0.003	0.98 (0.95–1.02)	0.259
Diabetes	1.54 (1.22–1.95)	<0.001	1.23 (0.93–1.63)	0.149
Hypertension	1.67 (1.28–2.17)	<0.001	1.01 (0.74–1.42)	0.891
Previous stroke	1.48 (1.19–1.84)	<0.001	1.24 (0.74–2.07)	0.421
Previous thromboembolism	1.45 (1.16–1.80)	0.001	0.85 (0.51–1.40)	0.523
Bleeding history or predisposition	1.52 (1.11–2.07)	0.009	1.05 (0.74–1.49)	0.782
Current smoker	1.05 (0.74–1.48)	0.793		
Coronary artery disease	1.68 (1.34–2.10)	<0.001	1.09 (0.82–1.45)	0.565
NYHA class	1.56 (1.31–1.87)	<0.001	1.37 (1.13–1.67)	0.002
Previous PCI	1.86 (1.40–2.49)	<0.001	1.16 (0.80–1.66)	0.437
Previous CABG	2.25 (1.20–4.22)	0.012	1.88 (0.98–3.59)	0.056
Concomitant use of antiplatelet or NSAID	1.61 (1.29–2.01)	<0.001	1.92 (0.68–1.23)	0.555
CHA_2DS_2-VASc score >4	3.69 (2.73–4.98)	<0.001	1.33 (0.89–2.01)	0.165
HAS-BLED score ≥3	2.68 (2.12–3.39)	<0.001	1.62 (1.09–2.40)	0.016
Procedural characteristics				
TEE/ICE guidance	0.99 (0.74–1.34)	0.966		
In combination with ablation	0.55 (0.43–0.70)	<0.001	0.65 (0.50–0.84)	0.001

HRs and their 95% CIs were calculated by multivariable Cox regression analysis.

BMI indicates body mass index; CABG, coronary artery bypass graft; HAS-BLED, hypertension, abnormal renal/liver function, stroke, bleeding history or predisposition, labile international normalized ratio, elderly, drugs/alcohol concomitantly; HR, hazard ratio; ICE, intracardiac echocardiography; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; SE, systemic embolism; and TEE, transesophageal echocardiography.

with existing evidence showing an inverse association between operator volume and procedural complications.[22] Accordingly, this approach should not be viewed as a universally applicable strategy, and its broader application warrants further validation.

LIMITATIONS

There are several limitations to this study. First, the RECORD registry enrolled only Chinese patients; therefore, extrapolation of these results to the other ethnic groups requires caution. Second, the observational nature of the study may have introduced bias and unmeasured confounders that may not have been accounted for in the multivariable analyses. Definitive conclusions about the causal relationship between imaging modality and LAAO outcomes cannot be drawn and need to be confirmed in randomized trials. Third, follow-up TEE/CTA was not performed in a sizable proportion of patients, which limited the assessment of DRT and residual leaks in both study groups. Fourth, postprocedural antithrombotic regimens were left to the operators' discretion, as the optimal anticoagulant strategy for patients after LAAO remains uncertain due to the lack of randomized trial data. The upcoming RECORD III study (NCT05960721) will further discuss this issue. Fifth, although multivariable adjustment accounted for imbalances in baseline characteristics and operator experience, unmeasured confounding related to patient selection and operator expertise cannot be fully eliminated, which represents an important limitation of this prospective registry. Finally, the device used in the current study was the WATCHMAN 2.5 instead of the latest iteration, the WATCHMAN FLX, because it was not commercially available at the time of the study. However, the latter has been designed and modified to facilitate ease of positioning and to simplify the procedure,[23,24] which may not impact our results.

CONCLUSIONS

As a streamlined alternative, fluoroscopy-only guidance was associated with similar long-term stroke prevention efficacy for LAAO with the first-generation WATCHMAN 2.5 device.

ARTICLE INFORMATION

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Disclosures

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Supplemental Material

Figure S1
Tables S1–S3
STROBE Checklist

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