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Intracardiac vs transesophageal echocardiography for left atrial appendage occlusion: An updated systematic review and meta-analysis

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ABSTRACT

BACKGROUND Multiple studies continue to evaluate the use of intracardiac echocardiography (ICE) and transesophageal echocardiography (TEE) for guiding left atrial appendage occlusion (LAAO).

OBJECTIVE The purpose of this study was to conduct an updated meta-analysis comparing the effectiveness and safety outcomes of both imaging modalities.

METHODS PubMed, Cochrane, and Embase were searched for studies comparing ICE vs TEE to guide LAAO. Odds ratios (ORs) with 95% confidence intervals (CIs) were pooled using a random-effects model. The primary effectiveness endpoint was procedural success. The primary safety endpoint included the overall complications rate. Additional safety outcomes were assessed as secondary endpoints. Subgroup analysis of primary endpoints was conducted according to device type (Amulet, LAmbre, Watchman, Watchman FLX) and study region (American, Asia, Europe). R Version 4.3.1 was used for all statistical analyses.

RESULTS Our meta-analysis included 19 observational studies encompassing 42,474 patients, of whom 4415 (10.4%) underwent ICE-guided LAAO. Compared with TEE, ICE was associated with a marginally higher procedural success (OR 1.33; 95% CI 1.01–1.76; $P = .04$; $I^2 = 0\%$). There was no significant difference in the overall complications rate (OR 1.02; 95% CI 0.77–1.36; $P = .89$; $I^2 = 5\%$). However, ICE showed higher rates of pericardial effusion (OR 2.11; 95% CI 1.47–3.03; $P < .001$; $I^2 = 0\%$) and residual iatrogenic atrial septal defect (iASD) (OR 1.52; 95% CI 1.15–2.03; $P < .004$; $I^2 = 0\%$). Subgroup analysis revealed variations in procedural success within the ICE group across study regions ($P = .02$).

CONCLUSION In this updated meta-analysis, the increasing adoption of ICE-guided LAAO demonstrated higher procedural success rates compared to TEE, although with limited statistical significance. Overall complication rates were similar; however, ICE showed higher rates of pericardial effusion and residual iASD.

KEYWORDS Left atrial appendage occlusion; Atrial fibrillation; Intracardiac echocardiography; Transesophageal echocardiography; Outcomes

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Introduction

Left atrial appendage occlusion (LAAO) is a therapeutic option for patients with atrial fibrillation at moderate to high risk of stroke who are poor candidates for long-term oral anticoagulation.[1] The Watchman LAAO device (Boston Scientific) received Food and Drug Administration approval in 2015 for stroke prevention in atrial fibrillation based on the results of the PROTECT AF (WATCHMAN Left Atrial Appendage System for Embolic PROTECTion in Patients With Atrial Fibrillation) and PREVAIL (Prospective Randomized Evaluation of

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the WATCHMAN LAA Closure Device in Patients With Atrial Fibrillation [AF] Versus Long Term Warfarin Therapy) trials, which demonstrated its noninferiority and safety compared to warfarin.[2,3] Similarly, the Amplatzer Amulet device (Abbott) gained Food and Drug Administration approval after the positive outcomes of the Amulet IDE (Amplatzer Amulet Left Atrial Appendage Occluder Versus Watchman Device for Stroke Prophylaxis) trial.[4] Other LAAO devices currently are available on the market, providing cardiologists with various options that can be tailored to the patient's anatomic considerations, thromboembolic risk profile, and operator expertise.[5]

Procedural imaging is essential for ensuring safety and successful device implantation during LAAO procedures. Expert consensus recommends the utilization of intraprocedural imaging modalities, including transesophageal echocardiography (TEE) or intracardiac echocardiography (ICE), in addition to standard fluoroscopy to guide LAAO.[5] TEE has traditionally been favored because of its widespread availability, familiarity among cardiologists, and pivotal role in the PROTECT AF and PREVAIL trials.[2,3] However, ICE has emerged as a promising alternative or adjunct, offering real-time, high-resolution visualization of cardiac structures without the need for sedation or general anesthesia, thereby facilitating device placement in certain cases and improving patient comfort.[6,7]

Previous meta-analyses have demonstrated comparable safety and effectiveness between ICE and TEE.[8,9] However, an increasing number of clinical studies worldwide continue to evaluate and compare the procedural outcomes of these 2 imaging modalities with various LAAO devices.[10–13] In addition, a recent analysis of postmarketing data from the American College of Cardiology LAAO Registry examined trends in the use of ICE and TEE after U.S. approval of the Watchman FLX device.[14] These aggregated data offer an opportunity to evaluate contemporary procedural outcomes on a larger scale and conduct further analyses. Therefore, we conducted an updated meta-analysis to evaluate the comparative effectiveness and safety of both imaging modalities as guiding strategies for LAAO procedures.

Abbreviations

CI: confidence interval

iASD: iatrogenic atrial septal defect

ICE: intracardiac echocardiography

LAAO: left atrial appendage occlusion

OR: odds ratio

ROBINS-I: Risk of Bias in Nonrandomized Studies of Interventions

TEE: transesophageal echocardiography

Methods

This systematic review and meta-analysis were performed and reported following the Cochrane Collaboration Handbook for Systematic Reviews of Interventions[15] and Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statements guidelines[16] (Supplemental Methods 1 and 2) and were registered at the International Prospective Register of Systematic Reviews (PROSPERO; CRD42024500563).

Data source and search strategy

We systematically searched PubMed, Embase, and Cochrane from inception to December 2023 using the terms "atrial fibrillation," "atrial appendage," "transesophageal echocardiography," and "intracardiac echocardiography" to identify studies evaluating the procedural outcomes of ICE vs TEE as guiding strategies for LAAO procedures. There was no restriction concerning the publication date or language. Two authors (FS, JMF) independently screened titles and abstracts and evaluated the articles in full for eligibility based on prespecified criteria. Discrepancies were resolved in a panel discussion with a third author (AR). Moreover, we used backward snowballing (ie, review of references) to identify relevant texts from articles identified in the original search. The complete search strategy is given in Supplemental Methods 3.

Eligibility criteria

Studies were considered eligible for inclusion if they met the following criteria: (1) included patients undergoing LAAO with ICE or TEE guidance; and (2) compared the safety and procedural outcomes between the ICE vs TEE. Case reports, abstracts, editorials, review articles, conference presentations, expert opinions, and studies without original data were excluded from the present analysis.

Data extraction

The characteristics of each study, including baseline patient characteristics, enrollment period, data source, procedural characteristics, endpoint definitions, and procedural outcomes, were extracted independently by 2 authors (AR, MAPB) using a standardized form (Supplemental Methods 4–6). Any discrepancies were resolved by consensus between the authors after examining the complete text of the article.

Endpoints

The primary effectiveness endpoint was procedural success, which was defined as the reported successful device implantation in each included study (Supplemental Table 1). The primary safety endpoint was the overall complications rate, which encompassed the composite of all reported procedure-related complications in the included studies (Supplemental Table 2). Additional secondary safety endpoints included major adverse events (all-cause mortality, major bleeding, vascular complications, stroke, cardiac tamponade, pericardial effusion) and device-related complications (device embolization, device-related thrombus, peridevice leak, residual iatrogenic atrial septal defect [iASD]). Detailed primary endpoint definitions for each included study are given in Supplemental Methods 7.

Sensitivity and subgroup analyses

We performed a "leave-one-out" sensitivity analysis to assess the impact of individual studies on the overall meta-analysis results. Subgroup analysis was conducted to screen potential determinants of primary endpoints. Based on the study characteristics of the eligible studies, subgroup analysis was performed for device type (Watchman vs Watchman FLX vs Amulet vs LAmbre) and study region (America vs Asia vs Europe).

Quality assessment

Two independent authors (BA, IFF) assessed the risk of bias in the included nonrandomized studies using the Cochrane tool for assessing the Risk of Bias in Non-Randomized Studies of Interventions (ROBINS-I). Any disagreements were resolved by a third author (FS). We explored the potential for publication bias by visual inspection of the comparison-adjusted funnel plots and the Egger regression test for the primary effectiveness and safety endpoint.[17]

Statistical analysis

We used the Mantel-Haenszel (MH) random-effects model for all outcomes. We used odds ratio (OR) and 95% confidence interval (CI) as the measure of effect size for binary endpoints and weighted mean differences (MD) and 95% CI to pool continuous endpoints. The restricted maximum likelihood estimator was used to calculate heterogeneity variance. We assessed heterogeneity with the Cochrane Q statistic and the Higgins and Thompson I statistic, with $P \leq .10$ indicating statistical significance. We determined the consistency of the studies based on I values of 0%, ≤25%, ≤50%, and >50%, indicating no observed, low, moderate, and substantial heterogeneity, respectively. All tests were 2-tailed, and $P < .05$ was considered significant. If necessary, means and standard deviations were estimated.[18] All statistical analyses were performed using R Version 4.3.1 (R Foundation for Statistical Computing, Vienna, Austria) with the extension package "meta."[19]

Results

Study selection and baseline characteristics

Our systematic search yielded 3234 potential results. After deduplication and initial title and abstract screening, 33 full-text articles were retrieved and reviewed in full for possible inclusion. Nineteen nonrandomized studies met all the inclusion criteria and were included in the analysis.[10–14,20–33] Comprehensive details of the study selection are detailed in Figure 1.

In total, 42,474 patients who underwent LAAO were included in the study. Among these patients, ICE was used as the primary imaging modality in 4415 patients (10.4%). In this pooled analysis, subjects were mostly male (61.9%), with mean age of 73.9 years, mean CHA_2DS_2-VASc score of 4.3, and mean HAS-BLED score of 3.02. The remaining baseline characteristics are given in Table 1.

Endpoints

Compared with TEE, ICE-guided LAAO was associated with higher procedural success (OR 1.33; 95% CI 1.01–1.76; $P = .04$; $I^2 = 0\%$) (Figure 2A), although the CI was close to null, suggesting limited statistical significance. There was no significant difference in the overall complications (OR 1.02; 95% CI 0.77–1.36; $P = .89$; $I^2 = 5\%$) (Figure 2B). However, ICE was more likely to be associated with pericardial effusion (OR 2.11; 95% CI 1.47–3.03; $P < .001$; $I^2 = 0\%$) (Figure 2C) and residual iASD (OR 1.52; 95% CI 1.15–2.03; $P = .004$; $I^2 = 0\%$) (Figure 2D). There was no significant difference in any peridevice leaks between groups (OR 0.91; 95% CI 0.80–1.03; $P = .147$; $I^2 = 0\%$) (Supplemental Figure 1). Similarly, no significant differences were found between both imaging modalities when evaluating other secondary safety endpoints (Supplemental Figure 1).

Subgroup and sensitivity analyses

Subgroup analysis based on device type revealed no significant subgroup interactions in the primary endpoints between the use of ICE and TEE (Figure 3). There was no significant subgroup interaction between the study region and procedural success (Figure 4). Although the number of events was small and the included studies had limited data availability, we found a significant subgroup interaction between overall complications and study region ($P = .002$), in which we found a significant reduction associated with ICE in Europe (OR 1.33; 95% CI 1.00–1.76; $P = .04$; $I^2 = 0\%$) but no significant differences in America or Asia. Leave-one-out sensitivity analysis demonstrated that the results were consistent after each included study was omitted in the procedural success endpoint (Supplemental Figure 2).

Quality assessment

The Cochrane Collaboration ROBINS-I tool identified 11 studies with a serious risk of bias and 8 with moderate concerns of bias (Supplemental Figure 3). Funnel plot analysis and Egger regression test did not detect evidence of publication bias for the primary endpoints of procedural success ($P = .38$) and overall complications ($P = .06$) (Supplemental Figure 4).

Discussion

This updated meta-analysis of 19 nonrandomized studies enrolling 42,474 patients compared the effectiveness and safety of using ICE vs TEE as guiding techniques for LAAO procedures. Our main findings were as follows. First, ICE-guided LAAO was associated with higher procedural success than TEE, although with limited statistical significance. Second, there was no difference in the overall complications between both imaging modalities. Third, ICE-guided LAAO was more likely to be associated with pericardial effusion and residual iASD. Fourth, subgroup analysis revealed slight differences in procedural success across study regions within the ICE group.

Unlike previous meta-analyses, we found that ICE was more likely to be associated with procedural success than TEE. This suggests that operators are increasingly adopting ICE and gaining more experience in its use. However, these results should be interpreted with caution because the statistical significance was close to null, indicating that further surveillance is needed. Despite variations in the definition of procedural success across the included studies, the apparent improvement in performance, along with the comparable safety profile, is reassuring for operators performing LAAO procedures. Considering the high procedural success rate (≥95%) with ICE reported in European and U.S. registries,[8,14] this imaging modality could potentially become a more widely available option for guiding LAAO procedures in the future.

When analyzing individual safety endpoints, we observed that the ICE-guided group was more likely to be associated with pericardial effusion compared to TEE. Unlike TEE, ICE involves inserting an ultrasound probe at the catheter's tip, which then is placed through the femoral vein and guided into the heart chambers.[34] This catheter insertion and manipulation can potentially cause trauma to the pericardium, thus increasing the risk of pericardial effusion and potentially explaining the higher rates observed in our study.

Pericardial effusion during LAAO procedures has been associated with increased in-hospital mortality, prolonged hospital stays, and higher hospitalization costs.[28] However, it is important to note that the absolute rate of this adverse event has been reported to be approximately ≤1%.[35] Additionally, analysis from the LAAO Registry indicates a downward trend of pericardial effusion in the United States,[14] suggesting a learning curve with the utilization of ICE.

Similarly, we observed that ICE-guided LAAO was more likely to be associated with residual iASD. The persistence of iASD is influenced by various factors such as sheath diameter, procedural complexity, and device type.[36] Several studies have examined the incidence of residual iASD

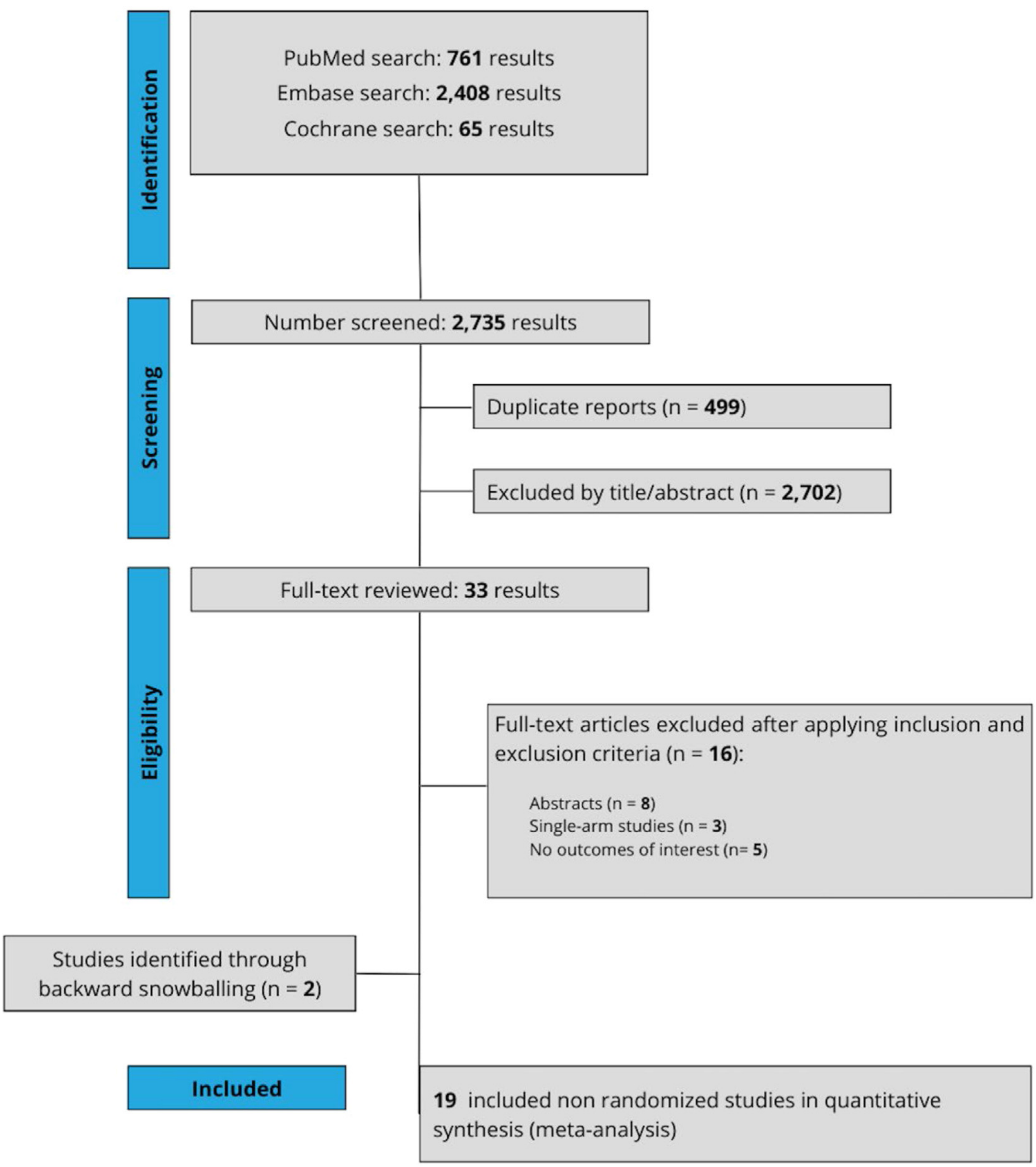

Figure 1
Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) Flow diagram of study screening and selection.

Table 1 Baseline characteristics of included studies

Authors	Country	No. of subjects (total/ICE/TEE)	Mean age, y (total/ICE/TEE)	Female [n (%)]	Device used	Preprocedural planning (ICE/TEE)	No. PAF (total/ICE/TEE)	No. previous stroke/TIA (total/ICE/TEE)	Mean CHA_2DS_2-VASc score (total/ICE/TEE)	Mean HAS-BLED score (total/ICE/TEE)
Shang, 2023	China	302/193/109	64.6/65/64.2	124 (41.1)	Watchman	TEE/TEE	139/95/44	144/98/46	3.64/3.87/3.41	2.1/2.19/2.07
Ferro, 2023	USA	34,107/2272/31,825	76.1/75.8/76.4	13,925 (40.8)	Watchman FLX	CT/CT	20,992/1257/19,735	7375/524/6851	4.8/4.8/4.8	2.45/2.5/2.4
Chen, 2023	China	190/69/121	71.9/73/70.8	60 (31.6)	LAmbre	TEE/TEE	N/A	105/37/68	4.4/4.4/4.4	2.75/2.6/2.9
Grazina, 2023	Portugal	88/45/43	74.9/75.5/74.2	28 (31.8)	ACP Amulet Watchman LAmbre	TEE or CT: not specified	N/A	N/A	4.05/4.0/4.1	3.6/3.6/3.6
Pastormerlo, 2023	Italy	772/149/623	76.5/77/76.3	263 (35)	Watchman FLX	TEE or CT/TEE or CT	N/A	160/27/133	4.14/4.2/4.1	3.69/3.5/3.7
Morcos, 2022	USA	790/395/395	70.6/70.7/70.4	285 (36.1)	N/A	N/A	342.4/158/184.4	N/A	N/A	N/A
Su, 2022	China	3096/95/2508	N/A	1314 (42.4)	Watchman	TEE or CT/TEE or CT	1249/N/A	1380/N/A	4.0/N/A	2.4/N/A
Gianni, 2021	USA	190/122/68	73.5/72/75	68 (35.8)	Watchman FLX	N/A	N/A	N/A	4.2/4.1/4.3	2.7/2.7/2.7
Pommier, 2021	France	224/175/49	75.5/76/75	67 (30.0)	ACP Watchman	CT/CT	62/51/11	153/122/31	4.35/4.2/4.5	4.0/4.07/3.93
Streb, 2020	Poland	23/10/13	75/77/73	8 (34.8)	Amulet	TEE/TEE	12/4/8	7/4/3	5.0/5.0/5.0	2.5/3.0/2.0
Alkhouli, 2020	USA	286/90/196	75.5/75.7/75.2	121 (42.3)	Watchman	TEE or CT/TEE or CT	N/A	116/32/84	4.75/4.7/4.8	2.85/2.8/2.9
Korsholm, 2020	Denmark	91/8/83	N/A	68 (75.0)	Watchman FLX	CT/CT	N/A	38/N/A	3.9/N/A	2.4/N/A
Nielsen-Kudsk, 2019	Global Registry	1085/130/955	75/75/75	289 (26.6)	Amulet	TEE or CT/N/A	N/A	89/54/35	4.15/4.1/4.2	3.25/3.2/3.3
Hemam, 2019	USA	104/53/51	76.5/77/76	40 (38.5)	Watchman	N/A	N/A	39/22/17	4.5/4.5/4.5	N/A
Berti, 2018	Italy	604/417/187	75/74/76	210 (34.8)	ACP Amulet	TEE or CT/TEE or CT	N/A	N.R	4.26/4.25/4.27	3.2/3.15/3.25
Kim, 2018	Korea	144/41/103	71.9/71.4/72.3	69 (47.9)	ACP Amulet Watchman	TEE/TEE	42/14/28	64/20/44	4.3/4.3/4.3	3.05/3.0/3.1
Reis, 2018	Portugal	86/N/A	N/A	33 (35.4)	ACP Amulet Watchman	TEE/TEE	25/N/A	34/N/A	4.7/N/A	3.3/N/A
Frangieh, 2017	Switzerland	76/44/32	77.4/81/76	25 (32.9)	Watchman	TEE/TEE	N/A	18/9/9	4.0/4.0/4.0	3.0/3.0/3.0
Korsholm, 2017	Denmark	216/107/109	73/73.0/73.0	69 (31.9)	ACP Amulet	CT or TEE/CT	97/52/45	109/50/59	4.25/4.1/4.4	4.1/4.1/4.1

ACP = Amplatzer cardiac plug; CT = computed tomography; ICE = intracardiac echocardiography; N/A = not available; PAF = paroxysmal atrial fibrillation; TEE = transesophageal echocardiography; TIA = transient ischemic attack.

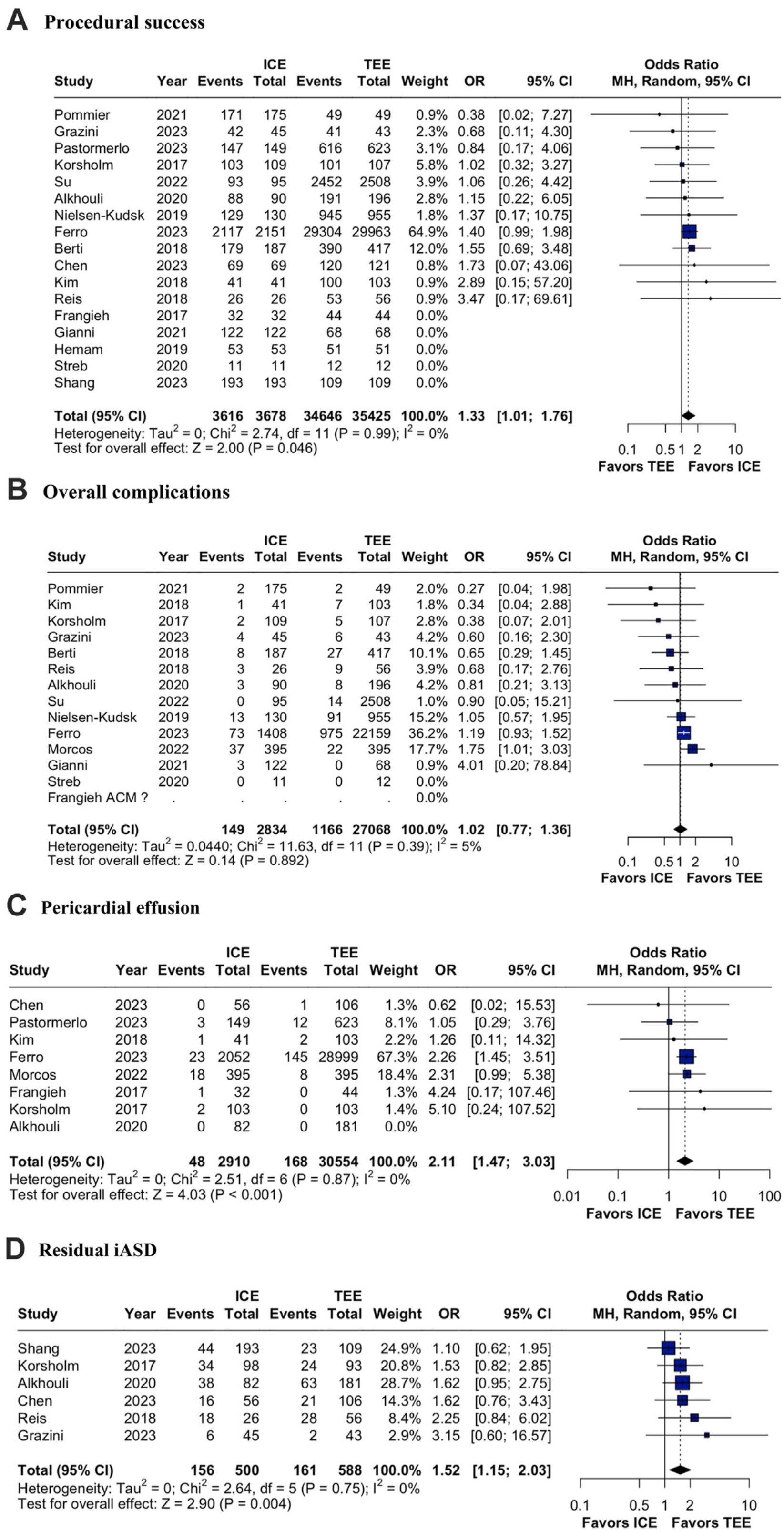

Figure 2
Meta-analysis of effectiveness and safety endpoints in patients undergoing left atrial appendage occlusion procedures guided by intracardiac echocardiography (ICE) or transesophageal echocardiography (TEE). Forest plots presenting the odds ratio (OR) and 95% confidence interval (CI) for procedural success (**A**), overall complications (**B**), pericardial effusion (**C**), and residual iatrogenic atrial septal defect (iASD) (**D**).

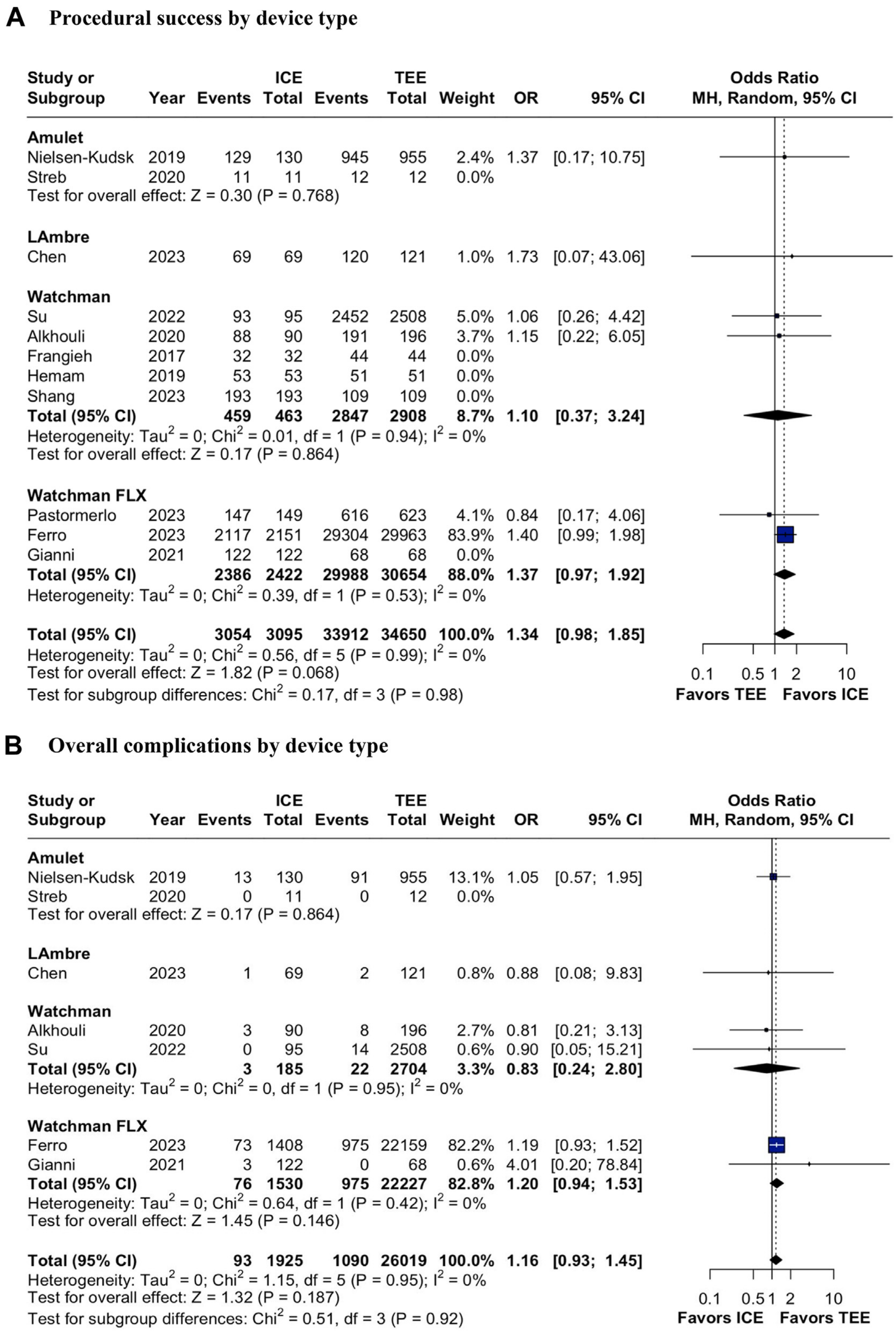

Figure 3

Subgroup analysis of primary effectiveness and safety endpoints by device type in patients undergoing left atrial appendage occlusion procedures guided by intracardiac echocardiography (ICE) or transesophageal echocardiography (TEE). Forest plots presenting the odds ratio (OR) and 95% confidence interval (CI) for procedural success (A) and overall complication rate (B).

following LAAO procedures.[37,38] Initial comparisons between ICE and TEE suggested a potentially higher incidence with ICE. However, more recent studies have indicated that ICE-guided LAAO is not associated with an increased risk of iASD[11] or adverse events during follow-up.[36] Given the current uncertainty regarding the implications of this outcome,

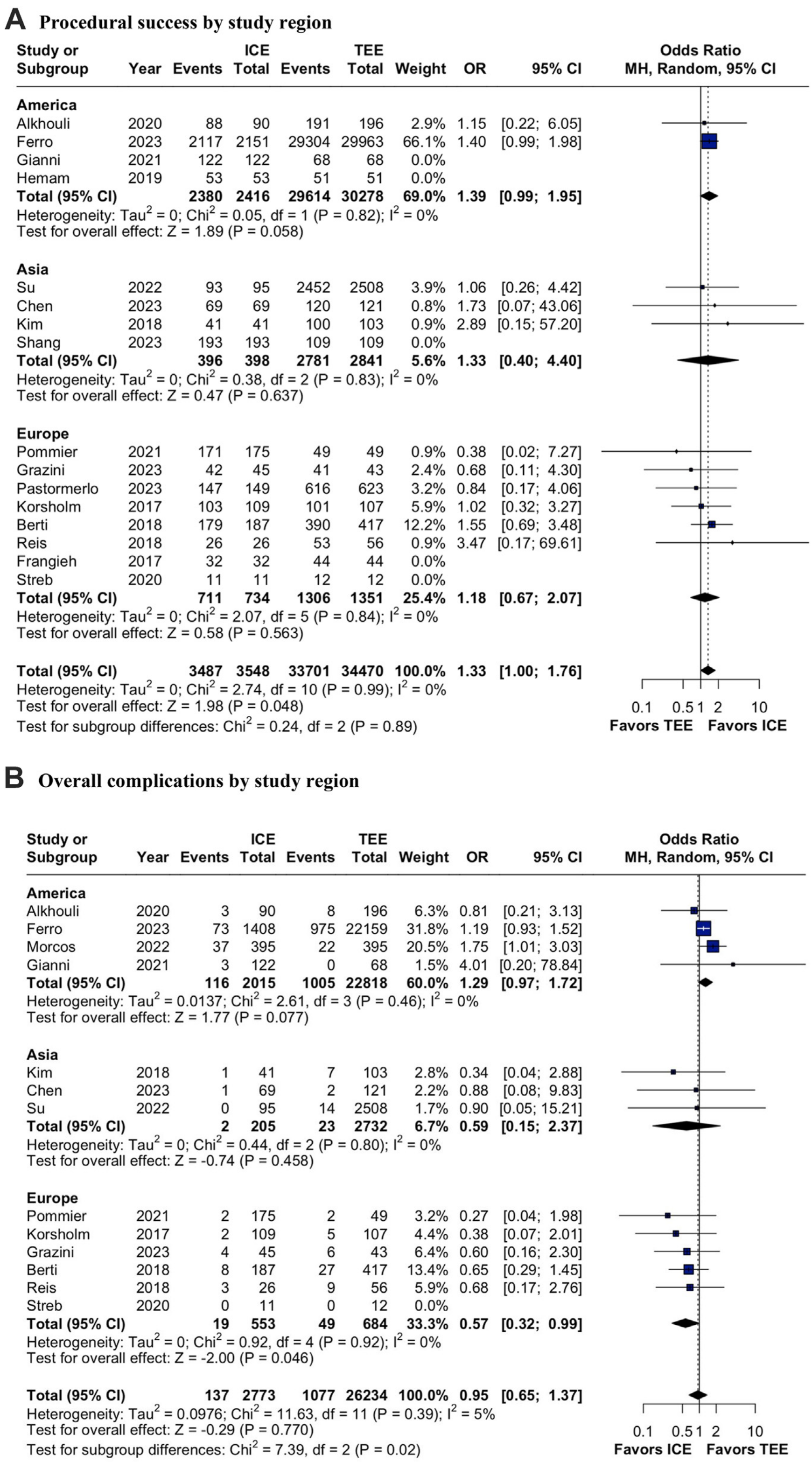

Figure 4
Subgroup analysis of primary effectiveness and safety endpoints by study region in patients undergoing left atrial appendage occlusion procedures guided by intracardiac echocardiography (ICE) or transesophageal echocardiography (TEE). Forest plots presenting the odds ratio (OR) and 95% confidence interval (CI) for procedural success (**A**) and overall complication rate (**B**).

future research should explore the impact of residual iASD on clinical outcomes more extensively and over longer follow-up periods.

Although operator experience is increasing in the United States, this growth might not be happening at a similar pace in other countries. Our subgroup analysis identified variations in procedural success within the ICE group based on study region, with no discernible differences in overall complications. These variations could be attributed to differences in equipment, technique, or patient characteristics.[39] With greater access to ICE, offering more training opportunities for new operators could improve procedural success globally.

Our study builds on previous meta-analyses by offering an updated comparison of the effectiveness and safety of the utilization of ICE vs TEE for LAAO procedures. First, we incorporated data from the largest comparison to date, sourced from the American College of Cardiology LAAO Registry, encompassing 34,107 patients not previously included in previous meta-analyses.[8,9] Second, leveraging this extensive dataset enabled a more comprehensive and updated evaluation of effectiveness and safety outcomes. Third, we conducted subgroup analysis based on study region and device type, providing valuable insights into the global trends with LAAO procedures.

Study limitations

First, the included studies in this meta-analysis were nonrandomized and observational, which could potentially introduce selection bias. However, subgroup analysis based on the risk of bias revealed no variation in the primary endpoints. Second, there was variability in how procedural success and procedure-related complications were defined or reported across studies, which we meticulously describe in Supplemental Methods 7. Third, the inclusion of studies from different regions with varying levels of operator experience may have influenced the results, thereby limiting the generalizability of our findings. Finally, significant heterogeneity was observed for several outcomes, such as procedural time, fluoroscopy time, and total room time, which limited our ability to ascertain the impact of ICE on these outcomes. Therefore, a prospective, randomized clinical trial may be considered in the future as ICE becomes more widely available. However, we acknowledge the limitations of this endeavor, as National Cardiovascular Data Registry data indicate that <10% of Watchman FLX implants currently use ICE.[14]

Conclusion

In this updated meta-analysis of patients undergoing LAAO procedures, intraprocedural guidance with ICE was associated with marginally higher rates of procedural success than TEE. Despite limited statistical significance, these findings indicate increased adoption of ICE for LAAO. Although both imaging modalities had comparable overall complication rates, ICE was associated with higher rates of pericardial effusion and residual iASD. Our findings indicate a global increase in the utilization of ICE for LAAO, stressing the need for further proctoring opportunities and technological advancements to decrease complications and improve procedural outcomes.

Appendix

Supplementary Data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrthm.2024.08.027.

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