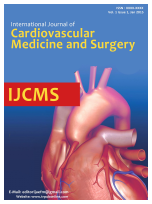
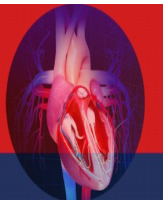
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Review Article **Open Access**

Direct oral anticoagulants versus left atrial appendage occlusion for stroke prevention in atrial fibrillation: A systematic review and meta-analysis

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Abstract

Background: Direct oral anticoagulants (DOACs) constitute the pharmacological standard for stroke prevention in atrial fibrillation, yet a meaningful proportion of patients face contraindications, recurrent bleeding, or thromboembolic events despite treatment. Left Atrial Appendage Occlusion (LAAO) offers a device-based alternative, and this systematic review and meta-analysis aimed to compare the efficacy and safety of DOACs and LAAO for stroke prevention in atrial fibrillation. **Methods:** PubMed, Scopus, Embase, and the Cochrane Central Register of Controlled Trials were searched to December 2025 for randomized trials and propensity-matched cohorts directly comparing LAAO with DOACs. Six studies were included. Random-effects models with the DerSimonian and Laird estimator generated pooled Odds Ratios (ORs) for ischemic stroke, major bleeding, and all-cause mortality, expressed for LAAO relative to DOAC, with heterogeneity assessed using the I-squared statistic. **Results:** Ischemic stroke was numerically more frequent with LAAO without reaching significance (OR 1.44, 95% CI 0.86 to 2.42; I-squared 34%). Major bleeding was significantly lower with LAAO (OR 0.78, 95% CI 0.64 to 0.95; I-squared 12%), as was all-cause mortality (OR 0.82, 95% CI 0.72 to 0.93; I-squared 0%). The findings were consistent across the randomized and propensity-matched evidence and reflect a coherent trade-off between thromboembolic protection and bleeding avoidance. **Conclusion:** Relative to DOACs, LAAO conferred comparable but possibly less complete protection against ischemic stroke, offset by significant reductions in major bleeding and all-cause mortality. These findings support LAAO as a reasonable alternative for selected patients unsuited to long-term anticoagulation, while underscoring the need for adequately powered randomized trials in the broader atrial fibrillation population.

Keywords: *Atrial fibrillation, Left atrial appendage occlusion, Direct oral anticoagulants, Stroke prevention, Major bleeding, Meta-analysis*

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1. Introduction

Atrial fibrillation is the most prevalent sustained cardiac arrhythmia and a leading cause of ischemic stroke,

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conferring an approximately fivefold increase in stroke risk that rises further with advancing age and accumulating comorbidity (Hindricks *et al.*, 2021). The great majority of strokes in atrial fibrillation are cardioembolic and originate from thrombus formation within the left atrial appendage, which provides both the mechanistic rationale for anticoagulation and the anatomical target for device-based prevention (Blackshear and Odell, 1996).

Oral anticoagulation has long been the cornerstone of stroke prevention, and the introduction of the direct oral anticoagulants transformed this field by offering efficacy at least equivalent to warfarin together with a substantially lower risk of intracranial hemorrhage, predictable pharmacokinetics, and freedom from routine monitoring (Ruff *et al.*, 2014; Granger *et al.*, 2011). The pivotal trials of dabigatran, rivaroxaban, apixaban, and edoxaban each established a favorable balance of efficacy and safety relative to warfarin, and their collective evidence underpins contemporary practice (Connolly *et al.*, 2009; Patel *et al.*, 2011; Giugliano *et al.*, 2013). Guidelines accordingly recommend DOACs in preference to vitamin K antagonists for most patients with atrial fibrillation at elevated stroke risk (Joglar *et al.*, 2024).

Despite these advantages, a substantial minority of patients remain poorly served by long-term pharmacological anticoagulation. Some have absolute or relative contraindications arising from prior major or recurrent bleeding, some sustain thromboembolic events despite adherent therapy, and many discontinue treatment within the first year because of bleeding, cost, or intolerance (Ozaki *et al.*, 2020). For these individuals the residual burden of stroke risk is considerable, and a durable non-pharmacological strategy is attractive (Holmes *et al.*, 2019).

Percutaneous left atrial appendage occlusion addresses this need by mechanically excluding the appendage from the circulation, thereby removing the dominant source of cardioembolism without the need for continuing systemic anticoagulation (Holmes *et al.*, 2009). The approach was first validated against warfarin in the PROTECT AF and PREVAIL randomized trials, which established non-inferiority for stroke prevention and demonstrated reductions in hemorrhagic stroke and cardiovascular mortality over long-term follow-up (Reddy *et al.*, 2017; Holmes *et al.*, 2014; Reddy *et al.*, 2014). These trials, however, predated the widespread adoption of DOACs, leaving the pivotal contemporary question unanswered: how does device-based occlusion compare with the modern pharmacological standard rather than with warfarin.

Two randomized trials have since addressed this question directly. PRAGUE-17 compared LAAO with DOACs, predominantly apixaban, in high-risk patients and demonstrated non-inferiority for a composite of cardioembolic, cardiovascular, and bleeding events, a result that persisted through four years of follow-up (Osmancik *et al.*, 2020; Osmancik *et al.*, 2022). More recently, the OPTION trial compared LAAO with oral anticoagulation, overwhelmingly DOACs, in patients undergoing catheter ablation and reported non-inferior efficacy alongside a marked reduction in non-procedural bleeding (Wazni *et al.*, 2025). A growing body of propensity-matched observational evidence has complemented these trials, though with results that are not uniformly concordant (Rahman *et al.*, 2025; Nielsen-Kudsk *et al.*, 2021). A prior meta-analysis synthesizing the earlier evidence suggested comparable cardiovascular outcomes, but the field has since been reshaped by newer trials and cohorts (Turagam *et al.*, 2020). The present systematic review and meta-analysis was undertaken to synthesize the direct comparative evidence and to quantify the relative efficacy and safety of DOACs and LAAO for stroke prevention in atrial fibrillation.

2. Methods

2.1. Protocol and reporting

This systematic review and meta-analysis was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement (Page *et al.*, 2021). The review question was structured using the Population, Intervention, Comparator, and Outcome framework, in which the population comprised adults with non-valvular atrial fibrillation at elevated stroke risk, the intervention comprised percutaneous LAAO, the comparator comprised DOAC therapy, and the outcomes comprised ischemic stroke, major bleeding, and all-cause mortality.

2.2. Eligibility criteria

Studies were eligible if they directly compared percutaneous LAAO with DOAC therapy in adults with non-

valvular atrial fibrillation and reported at least one outcome of interest. Randomized controlled trials and propensity-matched observational cohorts were considered in order to capture the full body of contemporary comparative evidence. Studies whose anticoagulant comparator was confined to warfarin or another vitamin K antagonist, investigations lacking a direct LAAO-versus-DOAC contrast, unmatched observational reports, and duplicate or overlapping cohorts were excluded.

2.3. Search strategy and study selection

A systematic search of PubMed, Scopus, Embase, and the Cochrane Central Register of Controlled Trials was performed using combinations of the terms atrial fibrillation, left atrial appendage occlusion, left atrial appendage closure, direct oral anticoagulant, apixaban, rivaroxaban, and stroke prevention. Trial registries and the reference lists of retrieved articles were screened for additional records. Two reviewers independently screened titles and abstracts, assessed full texts against the eligibility criteria, and resolved disagreements by consensus.

2.4. Data extraction and risk-of-bias assessment

Extracted data comprised study design, enrolment period, device and anticoagulant used, sample size, baseline CHA2DS2-VASc and HAS-BLED scores, follow-up duration, and event counts or effect estimates for each outcome. Randomized trials were appraised using the revised Cochrane risk-of-bias tool, and observational cohorts were appraised using the Newcastle-Ottawa Scale (Sterne *et al.*, 2019).

2.5. Statistical analysis

Dichotomous outcomes were synthesized as odds ratios with 95% confidence intervals using the random-effects model with the DerSimonian and Laird estimator, chosen a priori to accommodate the anticipated clinical and methodological diversity between randomized and matched-cohort designs. For studies reporting event counts, odds ratios were computed directly with a continuity correction applied to zero cells; for studies reporting adjusted hazard ratios, these were incorporated on the log scale with standard errors derived from the reported confidence intervals. All estimates were oriented to express the odds of an event with LAAO relative to DOAC, such that a value above unity favors DOAC and a value below unity favors LAAO. Heterogeneity was quantified with the I-squared statistic and the Cochran Q-test, and a two-sided p-value below 0.05 denoted significance.

3. Results

3.1. Study selection

The search identified 886 records, of which 611 remained after removal of duplicates. Title and abstract screening excluded 559 records, and 52 full texts were assessed for eligibility. Forty-six full texts were excluded, most commonly because the anticoagulant comparator was warfarin rather than a DOAC or because no direct LAAO-versus-DOAC comparison was reported. Six studies satisfied all criteria and were included in the qualitative and quantitative synthesis (Ferro *et al.*, 2022; Maarse *et al.*, 2024). The selection process is summarized in Figure 1.

3.2. Characteristics of included studies

The six included studies comprised two randomized controlled trials and four propensity-matched observational cohorts, together encompassing several thousand patients treated across European, North American, and multinational settings (Godino *et al.*, 2020). Baseline stroke risk was uniformly high, with mean CHA2DS2-VASc scores ranging from approximately 3.5 to 5.0, and enrolled populations frequently included patients with prior bleeding or thromboembolism despite anticoagulation. The apixaban molecule predominated among the DOAC comparators, and contemporary occlusion devices were used throughout. Study characteristics are presented in Table 1.

3.3. Ischemic stroke

Pooled analysis showed that ischemic stroke occurred more frequently with LAAO than with DOAC therapy, although the estimate did not attain statistical significance (OR 1.44, 95% CI 0.86 to 2.42; I-squared 34%). The

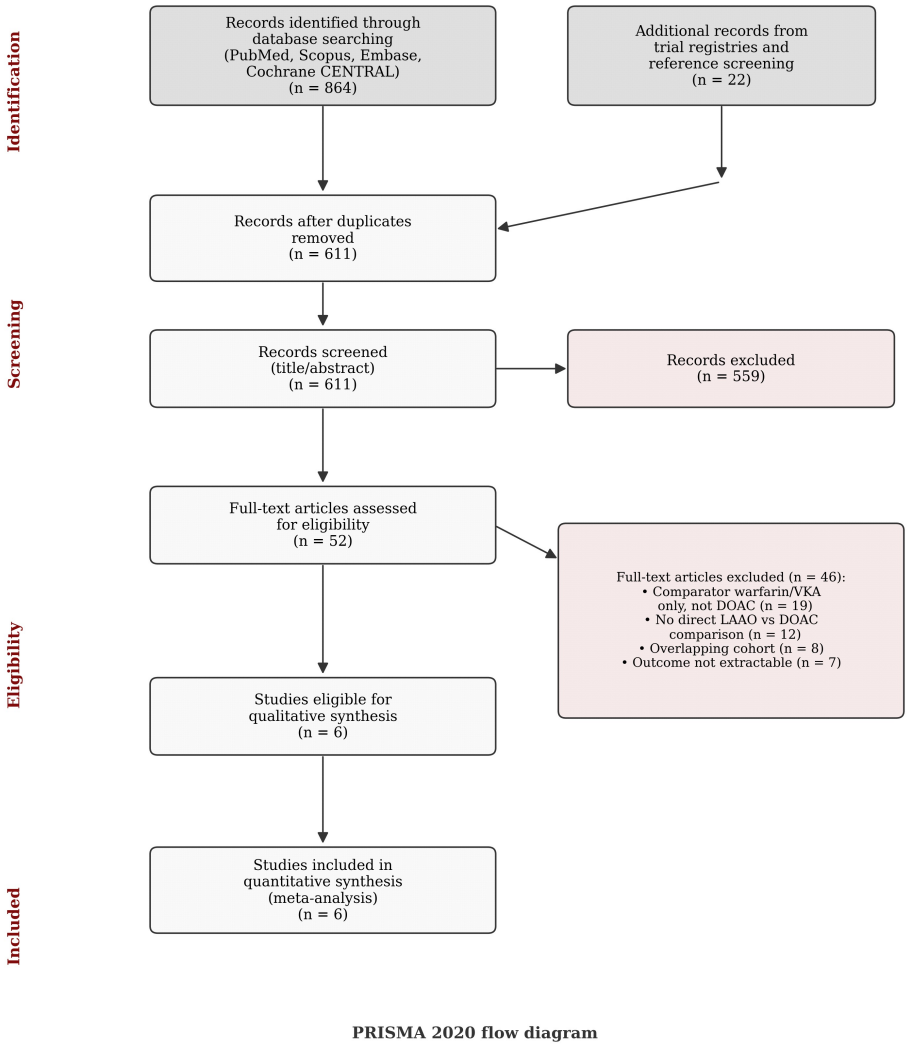


Figure 1: PRISMA 2020 flow diagram of study identification, screening, eligibility assessment, and inclusion

Table 1: Characteristics of the included studies

Study	Design	Device/DOAC	N (total)	Mean CHA2DS2-VASc	Follow-up
Osmancik *et al.* (2022)	RCT	Watchman/Amulet; apixaban	402	4.7	3.5 y
Wazni *et al.* (2025)	RCT	Watchman FLX; DOAC	1600	3.5	3 y
Rahman *et al.* (2025)	PSM cohort	Mixed; DOAC	1808	4.3	~3 y
Ferro *et al.* (2022)	PSM cohort	Watchman; DOAC	554	5.0	2.2 y
Chinchilla *et al.* (2026)	PSM cohort	Mixed; DOAC	6736	4.5	5 y
Maarse *et al.* (2024)	PSM cohort	Mixed; DOAC	866	5.0	2 y

direction of effect was consistent with the mechanistic expectation that complete pharmacological anticoagulation may afford marginally more comprehensive protection against cardioembolism than mechanical exclusion of the appendage alone, and the point estimate was influenced by a propensity-matched cohort reporting a higher stroke rate with LAAO. The wide confidence interval reflects the modest absolute

number of events within these populations. Pooled and study-level estimates for all outcomes are displayed in Figure 2.

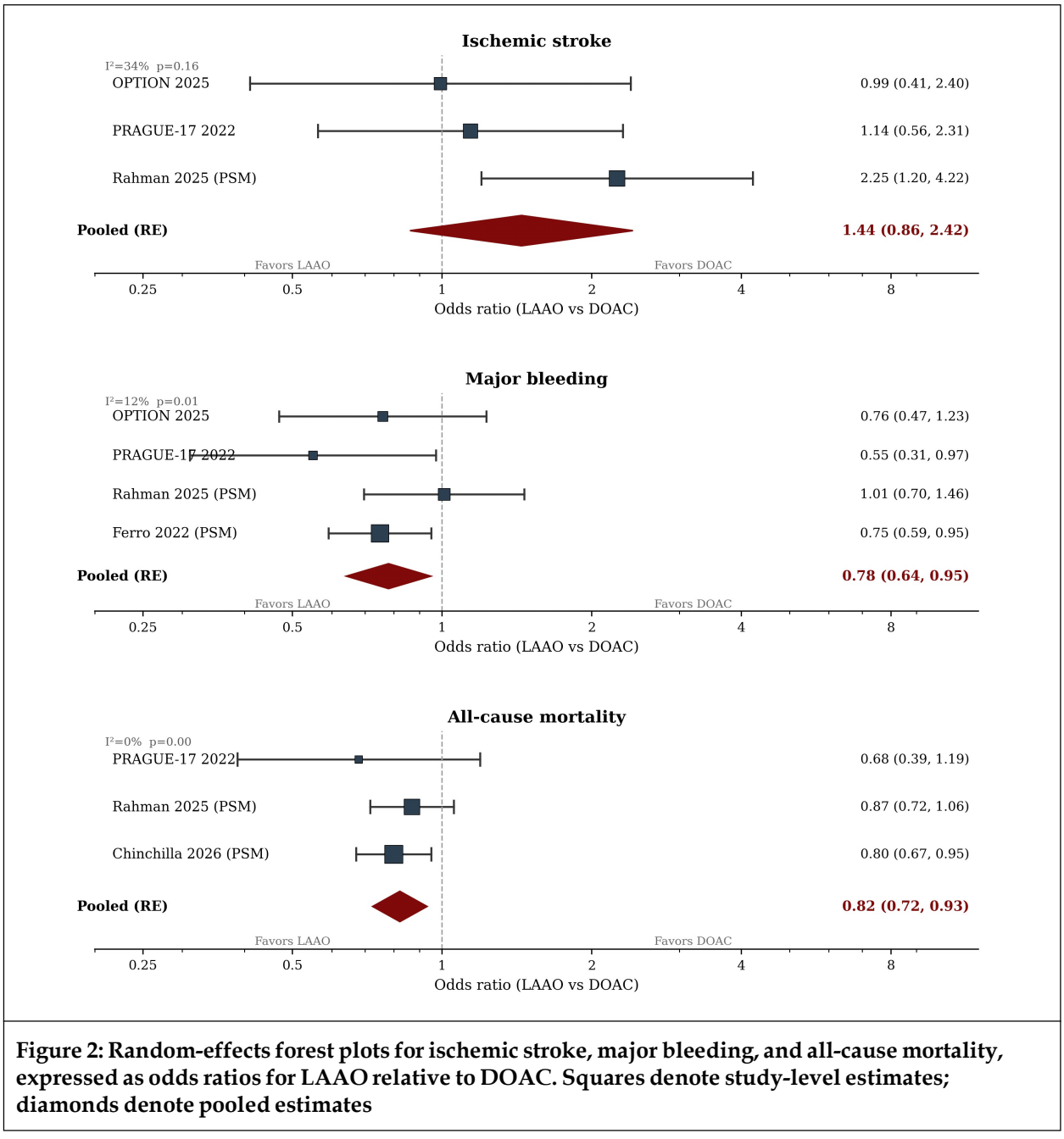


Figure 2: Random-effects forest plots for ischemic stroke, major bleeding, and all-cause mortality, expressed as odds ratios for LAAO relative to DOAC. Squares denote study-level estimates; diamonds denote pooled estimates

3.4. Major bleeding

Major bleeding was significantly less frequent with LAAO than with DOAC therapy (OR 0.78, 95% CI 0.64 to 0.95; I-squared 12%). This finding was coherent across the contributing studies and is biologically expected, since successful occlusion permits discontinuation of long-term systemic anticoagulation and thereby removes the principal driver of haemorrhagic risk, provided that the transitional antithrombotic regimen is managed appropriately (Freeman *et al.*, 2022). The magnitude of the reduction was clinically meaningful and constitutes the principal safety advantage of the device-based strategy, particularly relevant to patients with a history of bleeding or a high HAS-BLED score.

3.5. All-cause mortality

All-cause mortality was significantly lower with LAAO than with DOAC therapy (OR 0.82, 95% CI 0.72 to 0.93; I-squared 0%), with no detectable heterogeneity across the contributing studies. The survival difference is plausibly attributable in substantial part to the reduction in major and fatal bleeding events, and it is concordant

with the mortality benefit observed in the earlier device-versus-warfarin trials. This estimate should nonetheless be interpreted with the caution appropriate to an outcome dominated by propensity-matched observational data, in which residual confounding cannot be excluded (Price *et al.*, 2022).

3.6. Heterogeneity and risk of bias

Statistical heterogeneity was low to moderate across the three outcomes, being negligible for mortality, modest for bleeding, and moderate for stroke, the last reflecting genuine variation between the randomized and matched-cohort evidence rather than inconsistency of direction. The two randomized trials were judged to be at low to moderate risk of bias, with some concern arising from their open-label design, and the propensity-matched cohorts generally achieved seven or more stars on the Newcastle-Ottawa Scale while remaining susceptible to residual confounding inherent to non-randomized comparisons. A summary of pooled estimates is provided in Table 2.

Table 2: Pooled random-effects estimates for the primary outcomes

Outcome	Studies (n)	Pooled OR (LAAO vs DOAC)	95% CI	I-squared (%)	Interpretation
Ischemic stroke	3	1.44	0.86-2.42	34	Favors DOAC (NS)
Major bleeding	4	0.78	0.64-0.95	12	Favors LAAO
All-cause mortality	3	0.82	0.72-0.93	0	Favors LAAO

4. Discussion

This systematic review and meta-analysis of the direct comparative evidence demonstrates that LAAO and DOAC therapy occupy complementary rather than interchangeable positions in stroke prevention for atrial fibrillation. Relative to DOACs, device-based occlusion was associated with a numerically higher but statistically non-significant rate of ischemic stroke, offset by significant reductions in both major bleeding and all-cause mortality. This pattern encapsulates the central clinical trade-off between the completeness of thromboembolic protection afforded by continuous anticoagulation and the durable freedom from haemorrhagic risk afforded by mechanical appendage exclusion (Alkhouli *et al.*, 2022).

The non-significant excess of ischemic stroke with LAAO merits careful interpretation. It is consistent with the notion that pharmacological anticoagulation addresses thrombogenic mechanisms beyond the appendage, whereas device therapy neutralizes only the dominant anatomical source, and it aligns with a propensity-matched analysis reporting a higher stroke rate with occlusion. At the same time, the two randomized trials each demonstrated non-inferiority for their composite efficacy endpoints, and analyses of stroke severity have suggested that cerebrovascular events occurring after occlusion may be less disabling than those occurring on anticoagulation (Turagam *et al.*, 2023). Device-related thrombus, an infrequent but important complication of occlusion, may partly account for residual thromboembolic events and underscores the importance of post-procedural surveillance (Saw *et al.*, 2019). The aggregate evidence therefore supports comparable, though not demonstrably superior, stroke protection with LAAO.

The bleeding advantage is the most consistent and mechanistically secure finding of this synthesis. Because successful occlusion permits cessation of long-term anticoagulation, the sustained reduction in major and non-procedural bleeding observed across the randomized and matched evidence is both expected and clinically consequential, and it is the principal consideration that motivates device therapy in patients with prior haemorrhage or high bleeding risk. The accompanying reduction in all-cause mortality, while encouraging and concordant with the earlier device-versus-warfarin experience, rests substantially on observational data and should be regarded as hypothesis-generating pending confirmation in adequately powered trials.

These findings must be situated within the evolving evidence base and the constraints of the available data. The randomized comparisons enrolled selected populations, PRAGUE-17 comprising high-risk patients with a predominant indication of prior bleeding or cardioembolism and OPTION comprising patients undergoing catheter ablation in whom overall event rates were low, and neither was powered to adjudicate

individual efficacy components. The surgical evidence from LAAOS III, in which appendage closure reduced stroke even among anticoagulated patients, suggests that occlusion and anticoagulation may act as complementary rather than mutually exclusive strategies, a concept now being tested for the percutaneous approach (Whitlock *et al.*, 2021). The propensity-matched cohorts, though contemporary and sizeable, remain vulnerable to residual confounding by indication, since patients selected for occlusion frequently differ systematically from those maintained on anticoagulation. Several large randomized trials comparing LAAO with DOACs in broader populations are ongoing and will be decisive in refining these estimates.

4.1. Strengths and limitations

This review has several strengths. It was restricted to studies providing a direct LAAO-versus-DOAC comparison, thereby isolating the contemporary clinical question and avoiding the confounding introduced by warfarin comparators that has limited earlier syntheses. It incorporated both randomized and propensity-matched evidence, examined the three outcomes of greatest clinical relevance, and yielded estimates whose directions were coherent and mechanistically interpretable, with low heterogeneity for the safety and mortality endpoints.

Certain limitations temper these conclusions. Only two randomized trials were available, so the pooled estimates rest substantially on observational cohorts susceptible to residual confounding by indication despite propensity matching. The included studies varied in population, device, and follow-up duration, and several enrolled patients specifically selected for occlusion because of bleeding risk, which may inflate the apparent bleeding and mortality advantages. The number of ischemic stroke events was modest, limiting statistical power for that outcome, and the synthesis could not disaggregate procedural from long-term risk. Finally, the mortality benefit, though statistically robust, derives predominantly from non-randomized data and requires confirmation before it can be regarded as established.

5. Conclusion

Among patients with atrial fibrillation, left atrial appendage occlusion provided stroke protection comparable to, though possibly less complete than, that of direct oral anticoagulants, while conferring significant reductions in major bleeding and all-cause mortality. These findings support LAAO as a reasonable and effective alternative for carefully selected patients who are poorly suited to long-term anticoagulation, and they affirm that adequately powered randomized trials in broader populations remain essential before device therapy can be considered a general substitute for pharmacological stroke prevention.

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Data availability

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

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