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Comparison of the Efficacy and Safety of Percutaneous Left Atrial Appendage Closure Versus Direct Oral Anticoagulants and Vitamin K Antagonists in Patients With Permanent Atrial Fibrillation and High Risk of Adverse Events: A Literature Review

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Abstract

Introduction and purpose

Atrial fibrillation (AF) is the most common sustained supraventricular arrhythmia and a major cause of ischemic stroke and systemic thromboembolism. In non-valvular AF, most thrombi originate in the left atrial appendage (LAA). Oral anticoagulation with vitamin K antagonists (VKAs) or direct oral anticoagulants (DOACs) remains the cornerstone of stroke prevention; however, long-term therapy may be limited by bleeding risk and adherence challenges.

Percutaneous left atrial appendage closure (LAAC) has emerged as an anatomy-based alternative. This review aimed to compare the efficacy and safety of LAAC with DOACs and VKAs in patients with permanent AF at high risk of adverse events.

Material and methods

A qualitative literature review was conducted using PubMed, Embase, Cochrane Library, and Web of Science. Randomized controlled trials, meta-analyses, pooled analyses, and large cohort or registry studies published between 2015 and 2025 were included. Outcomes of interest included ischemic stroke, systemic embolism, major bleeding, mortality, and procedure-related complications.

Results

Across randomized trials and observational studies, LAAC, DOACs, and VKAs demonstrated comparable efficacy in preventing ischemic stroke and systemic embolism. Randomized data confirmed the non-inferiority of LAAC compared with warfarin and DOAC therapy. Safety profiles differed: DOACs showed lower rates of major bleeding than VKAs, whereas LAAC presented higher early procedural risk but fewer late bleeding events.

Conclusions

LAAC provides stroke prevention efficacy comparable to oral anticoagulation and may offer long-term safety advantages in selected high-risk patients. Individualized treatment strategies remain essential in permanent AF.

Keywords

“LAAC” “left atrial appendage occlusion,” “LAAO,” “NOAC”, “permanent atrial fibrillation,” “DOAC”, “VKA” , “stroke prevention,” “systemic embolism

1. Introduction

Atrial fibrillation is the most common sustained supraventricular arrhythmia, affecting approximately 2–4% of adults worldwide, with rising prevalence driven by population aging and cardiometabolic comorbidities [1]. It is characterized by disorganized atrial activity leading to blood stasis in the left atrial appendage (LAA), the source of ~90% of thrombi in non-valvular AF [1,2]. Consequently, stroke and systemic thromboembolism remain its most serious complications, associated with substantial morbidity and mortality despite contemporary prophylaxis[2,3]. Although oral anticoagulation remains the cornerstone of stroke prevention, with vitamin K antagonists (VKAs) inhibiting vitamin K–dependent factors and direct oral anticoagulants (DOACs) selectively targeting factor Xa or thrombin, long-term therapy is limited by bleeding risk and adherence challenges despite the lower intracranial hemorrhage risk and lack of INR monitoring associated with DOACs [1,4,5,6]. Percutaneous left atrial appendage closure (LAAC) represents an anatomy-based strategy that has emerged as a robust mechanical alternative to OAC [2] . The procedure involves transseptal implantation of an occlusion device that seals the LAA to isolate the primary source of thrombus formation [2,3]. Over the past decade, technical advancements and increased operator experience with devices like the WATCHMAN® and Amplatzer™ Amulet™ have significantly improved procedural safety with outcomes assessed using standardized efficacy endpoints (ischemic stroke and systemic embolism), safety endpoints (major bleeding, all-cause mortality, and procedure-related complications such as pericardial effusion), and device-related imaging endpoints, including device-related thrombus and peri-device leak [5, 7, 8, 9, 10, 11]. Short-term post-procedural antithrombotic therapy is required until complete device endothelialization occurs [12]. However, while LAAC has demonstrated comparability to warfarin, its definitive role and relative performance compared to contemporary DOAC therapy—particularly regarding patient selection and integration into treatment algorithms—remain subjects of active clinical investigation [3,5].

The aim of this study is to systematically compare the efficacy, safety, and clinical applicability of oral anticoagulants (DOACs and VKAs) and LAAC for stroke prevention in high-risk patients with permanent AF. By synthesizing contemporary evidence, this review seeks to clarify their relative benefits and limitations to support individualized, risk-adapted clinical decision-making.

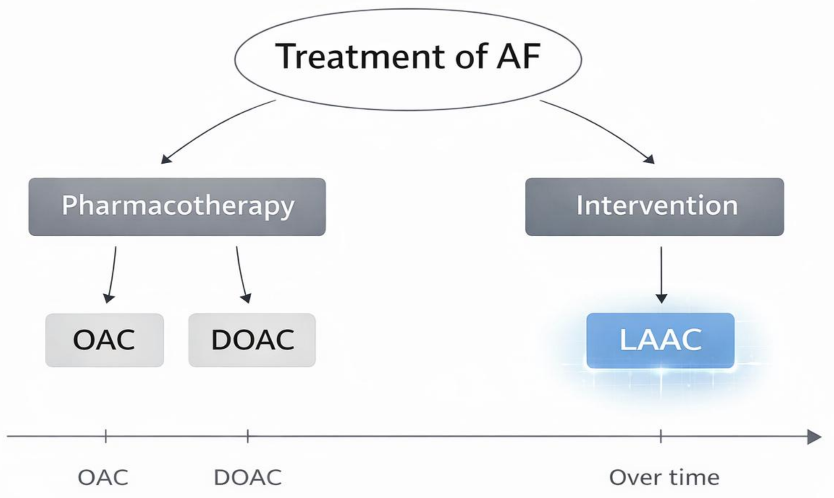

Figure 1. Conceptual overview of stroke prevention strategies in atrial fibrilation, illustrating the evolution from pharmacological anticoagulation (VKA, DOAC) to device-based left atrial appendage closure (LAAC).

2. Methods

The literature review was conducted using the electronic databases PubMed, Embase, Cochrane Library, and Web of Science. The search strategy included combinations of the following keywords: “atrial fibrillation,” “left atrial appendage closure,” “LAAC,” “LAAO,” “direct oral anticoagulants,” “DOAC,” “vitamin K antagonists,” “VKA,” “stroke prevention,” and “systemic embolism.” The search encompassed publications between January 2014 and March 2025, reflecting the contemporary era of DOACs and second-generation LAAC devices. Only articles published in English were considered.

Studies were eligible if they were randomized controlled trials, meta-analyses, pooled analyses, or large prospective or retrospective cohort or registry studies involving adult patients with permanent atrial fibrillation at elevated thromboembolic risk (typically CHA_2DS_2-VASc ≥2–3, consistent with landmark trials). Studies focusing on pediatric populations, case reports, small case series, or non-clinical experimental data were excluded.

Study selection was based on title and abstract screening followed by full-text evaluation of potentially relevant articles. Data extraction focused on key clinical outcomes, including ischemic stroke, systemic thromboembolism, major and clinically relevant non-major bleeding, all-cause mortality, and device- or procedure-related complications associated with LAAC.

Particular attention was given to studies involving patients with contraindications to long-term oral anticoagulation, as LAAC is primarily recommended in this population. Large real-world registries were included due to their clinical relevance, despite their observational design.

Given the heterogeneity of available evidence, a qualitative comparative synthesis was performed rather than a formal meta-analysis. The results were interpreted in the context of study design, patient population, and potential sources of bias.

3. Results

3.1 Left Atrial Appendage Closure Versus Vitamin K Antagonists: Evidence from Randomized Controlled Trials

Randomized controlled trials comparing LAAC with VKA provide the historical and methodological foundation for evaluating this interventional strategy in stroke prevention among patients with non-valvular atrial fibrillation [5,13]. The pivotal evidence in this context derives from the PROTECT AF and PREVAIL trials, which offered the first direct comparisons between LAAC and long-term warfarin therapy [4,5]. In the PROTECT AF trial, patients with established indications for oral anticoagulation were randomized to LAAC or warfarin, and LAAC demonstrated non-inferiority to warfarin for a composite endpoint of stroke, systemic embolism, and cardiovascular death [4,5]. The PREVAIL trial was designed to address safety concerns identified in PROTECT AF and to further evaluate clinical outcomes in centers with greater procedural experience [4]. Compared with PROTECT AF, PREVAIL demonstrated a significant reduction in periprocedural complications, supporting improved procedural safety and reflecting the impact of the procedural learning curve [4,5]. Long-term follow-up analyses extending up to five years showed comparable efficacy between LAAC and warfarin in preventing stroke and systemic embolism [5,13]. Importantly, LAAC was associated with significantly lower rates of fatal bleeding events and intracranial hemorrhage compared with long-term VKA therapy, indicating a more favorable long-term safety profile for LAAC in this patient population [5,13].

3.2 LAAC Versus DOACs: Contemporary Comparative Evidence

Research comparing DOACs and LAAC for preventing embolic complications of AF is gradually emerging. Recent observational data have begun to address this gap. Two large retrospective studies presented by Patel, Ghanshyam et al. compared LAAC with apixaban and rivaroxaban [14,15]. In cohorts of 9,518 and 4,389 patients, respectively, LAAC was associated with significantly lower all-cause mortality and major bleeding compared with both agents [14,15]. Long-term data from Melillo et al. demonstrated that in high-bleeding-risk patients (HAS-BLED ≥3), LAAC and DOAC therapy showed comparable overall safety and effectiveness at 5 years, although cumulative bleeding was significantly higher in the DOAC group (25.0% vs. 13.7%) [13]. Furthermore, a study by Turagam, Mohit K., et al. reported that ischemic strokes occurring after LAAC were less frequently disabling or fatal compared with those under DOAC therapy; however, baseline differences between groups characteristics limit definitive conclusions [16]. Recent randomized evidence has now solidified the role of LAAC in this contemporary landscape, moving beyond observational data [1,5]. The PRAGUE-17 trial, the first head-to-head randomized comparison, demonstrated non-inferiority of LAAC versus DOAC therapy (primarily apixaban) for a composite endpoint of stroke, TIA, systemic embolism, cardiovascular death, and major bleeding, with annual event rates of 10.99% versus 13.42% at a median follow-up of nearly 20 months [5]. This non-inferiority was recently reinforced by the OPTION trial, the largest dataset to date, which confirmed the safety and efficacy of LAAC as an alternative to DOACs in patients following AF ablation [10,17]

3.3 Bleeding Outcomes and High-Risk Populations

Comprehensive meta-analyses from 2024 and 2025 further highlight that while LAAC and DOACs offer comparable protection against systemic embolism, LAAC significantly reduces the risk of hemorrhagic stroke (RR 0.34) and late, non-procedural clinically relevant bleeding (RR 0.49–0.55) [1,10]. Despite these long-term advantages, LAAC remains limited by inherent upfront procedural risks, with major complications such as pericardial effusion or device embolization occurring in 2.1% to 4.5% of cases in modern cohorts [5,10]. Furthermore, following the LAAC implantation, patients require mandatory short-term antithrombotic therapy to prevent device-related thrombosis (DRT) during device endothelialization phase [10, 2].Traditionally, this post-procedural regimen has consisted of 45 days of warfarin plus aspirin, followed by 6 months of dual antiplatelet therapy (DAPT); however, more recent protocols from PRAGUE-17 and OPTION trials have successfully implemented 3 months of DOAC therapy or even simplified antiplatelet monotherapy in selected high-bleeding-risk patients [1, 4, 5, 10, 18]. NCDR LAAO Registry data show that DOAC monotherapy after LAAC reduces major bleeding and adverse events at 45 days and 6 months versus DOAC plus aspirin without increasing stroke, TIA, or device-related thrombosis, with contemporary registries supporting single antiplatelet therapy in high-bleeding-risk patients [12,18,19]. Ultimately, personalizing post-implant regimens among patients remains crucial [10].

3.4 Mortality and Long-Term Clinical Outcomes

Recent comprehensive meta-analyses incorporating the latest trial data indicate that LAAC is associated with a significantly lower risk of all-cause death (RR 0.78) and cardiovascular or unexplained death (RR 0.69) compared to oral anticoagulation [10]. In fact, network meta-analyses have ranked LAAC as the most beneficial treatment strategy for reducing overall mortality, with a probability of 96.4% [1]. These findings are mirrored in large-scale retrospective real-world data, where LAAC significantly reduced all-cause mortality compared to both apixaban (10.5% vs. 20.6%) and rivaroxaban (10.5% vs. 20.1%) [13,14,15]. Long-term outcomes after LAAC appear favorable, with less severe breakthrough ischemic strokes, fewer disabling or fatal events (mRS 3–5), and lower three-month mortality compared with DOAC therapy [16]. This benefit is largely driven by a 66% reduction in hemorrhagic stroke and fewer late non-procedural bleeding events after the initial post-implant phase [10], whereas higher mortality observed in some high-risk cohorts likely reflects baseline comorbidity rather than treatment effect [13,14,15].

4. Discussion

Despite major advances in pharmacological stroke prevention, important limitations persist in patients at the highest bleeding risk [1,10]. Although DOACs reduce the incidence of intracranial hemorrhage by approximately 50% compared with VKA’s [20,21], long-term anticoagulation remains problematic in patients with extreme bleeding vulnerability. In this context LAAC has emerged as a viable mechanical alternative, particularly as procedural safety has improved substantially over time [5]. Data from the PREVAIL trial and contemporary cohorts demonstrate a marked reduction in early procedural complications, largely attributable to improved device technology and the mitigation of the operator learning curve [4, 5,10,17].

Accumulating evidence indicates that LAAC is associated with a favorable cerebrovascular safety profile with a 66–80% reduction in hemorrhagic stroke compared with OAC [1,10]. Furthermore, ischemic strokes occurring after LAAC are generally less severe and less frequently fatal than those observed with DOAC therapy, as demonstrated by a lower rate of hemorrhagic transformation (9.6% vs 22.7%), a complication strongly associated with post-stroke disability and mortality [16]. These benefits likely stem from mechanical exclusion of the left atrial appendage combined with systematic pre-procedural transesophageal echocardiography, which actively screens for and excludes pre-existing thrombi, thereby reducing thromboembolic burden, limiting infarct size, and enhancing neurological recovery [16].

Patient selection remains central to clinical decision-making [8,22]. Current evidence supports LAAC primarily in patients with contraindications to long-term anticoagulation, although utilization is expanding among elderly and frail individuals in whom polypharmacy and drug–drug interactions represent significant concerns rendering the discontinuation of chronic anticoagulation after LAAC particularly attractive [1,9,12,22]. Contemporary practice is shifting toward individualized antithrombotic de-escalation [12], as registry data (including the NCDR LAAO Registry) suggest that simplified regimens such as DOAC monotherapy [18] or even SAPT in selected high-bleeding-risk patients reduce bleeding without increasing thromboembolic events [2,19]. Given that device endothelialization is largely complete within three months , protocols such as those used in CHAMPION-AF study typically restrict post-procedural therapy to this period, supporting both safety and long-term cost-effectiveness compared with lifelong DOAC therapy [3,10,12,].

Post-procedural antithrombotic management continues to evolve, with growing emphasis on individualized de-escalation strategies [5,12]. Registry and observational data suggest that reduced-intensity regimens, including DOAC monotherapy or single antiplatelet therapy, may lower bleeding risk without compromising thromboembolic protection in selected high-risk patients [3,18,19].

Despite these advances, important evidence gaps remain [10,12]. The PRAGUE-17 trial, while demonstrating non-inferiority of LAAC, was underpowered to definitively draw conclusions for thromboembolic events alone as reflected by the wide confidence interval for stroke/TIA (95% CI: 0.40 to 2.51) [3,5]. Ongoing large-scale randomized studies, including CHAMPION-AF enrolling 3,000 patients are expected to clarify the role of LAAC as a potential first-line alternative to anticoagulation in broader atrial fibrillation populations through long-term, stroke-focused endpoints [3].

5. CONCLUSIONS

This review provides a qualitative comparative synthesis of randomized trials, observational studies, and contemporary meta-analyses evaluating ischemic stroke, systemic thromboembolism, bleeding, mortality, and device- or procedure-related complications associated with LAAC. Across the available evidence, LAAC, DOACs and VKA demonstrated comparable efficacy in preventing thromboembolic events in selected patients with non-valvular AF with randomized data confirming the non-inferiority of LAAC compared with both warfarin and DOAC therapy [1,5,13]. Clinically meaningful differences were primarily driven by safety profiles. DOACs were associated with lower rates of major bleeding and intracranial hemorrhage compared with VKA therapy, while LAAC showed a distinct temporal risk pattern, characterized by higher early procedure-related risk but fewer late bleeding events during long-term follow-up [1,5,13]. Particular benefit of LAAC was observed in patients at high bleeding risk or with contraindications to long-term oral anticoagulation, supported by data from randomized studies and large real-world registries [1,5,13,18]. Given the limited and heterogeneous evidence regarding combined long-term DOAC and LAAC therapy, post-procedural antithrombotic strategies were considered only when aligned with established clinical practice.

Table 1. Comparative clinical outcomes of left atrial appendage closure (LAAC) versus oral anticoagulation strategies in atrial fibrillation

Outcome	LAAC	DOAC	VKA
Ischemic stroke / systemic embolism	=	=	=
Major bleeding (long-term)	↓	↓↓	↑
Intracranial hemorrhage	↓	↓	↑
Early procedural risk	↑	–	–
Long-term anticoagulation required	No	Yes	Yes
Optimal population	High bleeding risk / OAC contraindication		Limited

A comparative overview of stroke prevention efficacy and safety outcomes across LAAC, DOAC, and VKA strategies is summarized in Table 1, highlighting similarities in thromboembolic protection and differences in bleeding risk profiles that inform individualized therapeutic decision-making.

Author contribution

Conceptualization:JS, KK; methodology: JS, KK; validation: HA, ZK; formal analysis: MD, KG; resources: KG, MD; data curation: JS,KK; writing - original draft preparation: KG, MD, ZK; writing - review and editing: HA, ZK; visualization: ZK; supervision: JS, KK.
All authors have read and agreed to the published version of the manuscript.

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Conflict of interest statement

The authors declare no conflicts of interest.

Declaration of the Use of Generative AI and AI-Assisted Technologies in the Writing Process

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