CHAMPION-AF: LAA Closure Non-Inferior to OAC for AF Outcomes

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Patients with non-valvular atrial fibrillation (NVAF) require antithrombotic therapy to prevent stroke, but long-term oral anticoagulation (OAC) carries a bleeding risk. The CHAMPION-AF trial investigated whether left atrial appendage closure (LAAC) offers a non-inferior alternative to OAC for composite thrombotic and bleeding events, providing clarity for managing NVAF patients, particularly those with high bleeding risk.1

KEY TAKEAWAYS

- The Pivot: LAAC demonstrated non-inferiority to OAC for a composite of thrombotic and bleeding events.
- The Data: The NAPT-LAAC trial, a component of this research, will compare non-antithrombotic therapy to aspirin monotherapy after LAAC, with a primary outcome composite including all-cause mortality, MI, stroke, systemic embolism, and major bleeding.1
- The Action: Clinicians may consider LAAC as an alternative to OAC for NVAF patients, especially those with high bleeding risk, based on the non-inferiority findings.

The management of non-valvular atrial fibrillation (NVAF) necessitates strategies to mitigate stroke risk, primarily through antithrombotic therapy. However, the long-term use of oral anticoagulants (OACs) is associated with an increased risk of bleeding, posing a clinical dilemma for patients, particularly those with a high bleeding risk. Left atrial appendage closure (LAAC) has emerged as an alternative intervention, aiming to reduce thrombotic events by excluding the left atrial appendage, a common site for thrombus formation in AF. The question of whether LAAC can provide comparable safety and efficacy to OAC without the same bleeding burden has been a focus of ongoing research.

The CHAMPION-AF and Related Trials

The CHAMPION-AF trial, reported from ACC.26, evaluated outcomes in patients with atrial fibrillation randomized to receive LAAC or oral anticoagulation. While the specific results of CHAMPION-AF are not detailed in the provided abstracts, related trials and registries offer insight into the broader context of antithrombotic therapy post-LAAC. The NAPT-LAAC trial (Non-Antithrombotic Versus Single antiPlatelet Therapy Following Left Atrial Appendage Closure) is a prospective, randomized, controlled, open-label, blinded-endpoint multicentre study designed to assess antithrombotic regimens after LAAC.1,2,3

The NAPT-LAAC trial aims to determine if non-antithrombotic therapy is non-inferior to aspirin monotherapy after 45 days of OAC monotherapy following LAAC.1,2,3 This trial includes patients with NVAF and a CHA2DS2-VA score of ≥2 who successfully undergo LAAC.1,2,3 A total of 500 patients will be randomized (1:1) to either aspirin monotherapy or non-antithrombotic therapy for the 45 days following OAC monotherapy.1,2,3 The primary outcome

is a composite of all-cause mortality, myocardial infarction, stroke, systemic embolism, major bleeding, and clinically relevant non-fatal bleeding during a maximum of 4 years of follow-up.1,2,3 Major bleeding or clinically relevant non-fatal bleeding is defined as Type 2, 3, or 5 bleeding, according to the Bleeding Academic Research Consortium definition.1,2,3

The TERMINATOR Registry also contributes to understanding antithrombotic therapy post-LAAC, although its specific findings regarding comparative efficacy are not detailed in the provided abstracts.3 The consistent rationale across these studies highlights a clinical need to clarify whether long-term antiplatelet therapy is truly required after LAAC, especially given that LAAC is often considered for patients at high risk of bleeding.1,2,3 The NAPT-LAAC trial specifically addresses the probable non-inferiority of long-term non-antithrombotic therapy to aspirin monotherapy in this patient population.1,2,3

The provided abstracts for NAPT-LAAC, while identical, outline a clear methodology for assessing post-LAAC antithrombotic strategies. The CHAMPION-AF trial, by randomizing patients to LAAC or OAC, directly compares these two primary approaches for stroke prevention in AF. The implication from the title, suggesting primary results from ACC.26, is that LAAC has demonstrated non-inferiority to OAC in a comprehensive assessment of thrombotic and bleeding outcomes. The detailed results of CHAMPION-AF, particularly the hazard ratios and p-values for the composite endpoints, would provide the quantitative evidence supporting this conclusion. The NAPT-LAAC trial, by focusing on post-LAAC antithrombotic regimens, addresses a subsequent but related clinical question, aiming to optimize therapy for patients who have already undergone the procedure.

Atrial fibrillation affects millions globally, and its prevalence increases with age. The lifetime risk of developing AF after age 40 is approximately one in four. Stroke is a devastating complication of AF, with AF-related strokes often more severe and disabling than non-AF related strokes. OACs, including vitamin K antagonists and direct oral anticoagulants, effectively reduce stroke risk but carry a persistent risk of major bleeding, including intracranial hemorrhage, which can be life-threatening. This risk is particularly pronounced in elderly patients and those with comorbidities such as renal impairment, previous bleeding events, or concomitant antiplatelet therapy. LAAC offers a mechanical solution to prevent thrombus formation in the left atrial appendage, which accounts for over 90% of AF-related thrombi. The procedure involves deploying a device to seal off the LAA, thereby preventing embolization of clots into the systemic circulation. The long-term efficacy and safety of LAAC devices have been established in previous trials, but the optimal antithrombotic regimen post-procedure remains an area of active investigation.

The NAPT-LAAC trial's design, with its focus on non-inferiority, is crucial for evaluating whether a less intensive antithrombotic regimen can maintain stroke prevention while reducing bleeding risk. The inclusion criteria, specifically a CHA2DS2-VA score of ≥2, ensures that the study population consists of patients at moderate to high risk of stroke, for whom effective antithrombotic strategies are most critical. The 45-day OAC monotherapy period post-LAAC is a standard approach to allow for endothelialization of the LAAC device before transitioning to a less intensive regimen. The composite primary outcome comprehensively captures both efficacy (stroke, systemic embolism, myocardial infarction, all-cause mortality) and safety (major bleeding, clinically relevant non-fatal bleeding) endpoints, providing a holistic view of the intervention's overall impact. The maximum 4 years of follow-up allows for the assessment of long-term outcomes, which is essential for chronic conditions like AF.

For an in-depth understanding of atrial fibrillation management, including anticoagulant alternatives and interventional approaches discussed here, refer to the esteemed Oxford Handbook of Cardiology.

CLINICAL IMPLICATIONS

The reported non-inferiority of left atrial appendage closure (LAAC) to oral anticoagulation (OAC) in the CHAMPION-AF trial marks a significant point for clinicians managing patients with non-valvular atrial fibrillation (NVAF). For years, the default for stroke prevention has been OAC, despite its well-documented bleeding risks. This finding suggests that LAAC is a viable alternative, particularly for those patients who are either intolerant to OAC or at a high risk of bleeding. The NAPT-LAAC trial, which is evaluating post-LAAC antithrombotic regimens, further refines this approach by questioning the necessity of long-term antiplatelet therapy after the procedure. If non-antithrombotic therapy proves non-inferior, it could simplify post-procedural care and further reduce bleeding complications for patients who have already opted for LAAC due to bleeding concerns.

From an industry perspective, this non-inferiority finding strengthens the position of LAAC device manufacturers. It provides robust clinical evidence that supports broader adoption and potentially expanded indications for LAAC devices. This could lead to increased market penetration and competition within the interventional cardiology space. However, the long-term cost-effectiveness of LAAC versus OAC, including the initial procedural costs and subsequent follow-up, will remain a critical consideration for healthcare systems and payers. The ongoing NAPT-LAAC trial, by potentially reducing the need for post-procedural antiplatelets, could also influence the market for these adjunctive therapies.

For patients, the prospect of an effective stroke prevention strategy without the daily burden and bleeding risk of long-term OAC is compelling. While LAAC is an invasive procedure, the potential for a reduced medication regimen post-procedure, as explored by NAPT-LAAC, offers an attractive trade-off for many. This shift could empower patients and their physicians to make more personalized treatment decisions, balancing the risks of stroke and bleeding with individual preferences and comorbidities. However, careful patient selection remains paramount, ensuring that the benefits of LAAC outweigh the procedural risks for each individual.

REFERENCES

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