

Over 1-year efficacy and safety of left atrial appendage occlusion versus novel oral anticoagulants for stroke prevention in atrial fibrillation: A systematic review and meta-analysis of randomized controlled trials and observational studies



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BACKGROUND A direct comparison of the efficacy and safety profiles of left atrial appendage occlusion (LAAO) devices and novel oral anticoagulants (NOACs) for stroke prevention in atrial fibrillation is warranted but currently unavailable.

OBJECTIVE The aim of this study was to compare the >1-year efficacy and safety of LAAO devices and NOACs for stroke prevention in patients with atrial fibrillation.

METHODS We performed a systematic review on randomized controlled trials (RCTs) and observational studies. RCTs were analyzed by means of a network meta-analysis method using warfarin as a bridge to compare LAAO to individual NOAC or all NOACs as a whole. Observational studies were analyzed with the meta-proportion function where pooled event rates were compared.

RESULTS A total of 6 RCTs and 27 observational studies were included. A network meta-analysis of RCTs indicated that LAAO was less effective than NOACs for stroke prevention (odds ratio 0.86), but had a lower rate of hemorrhagic events during follow-up. However, a

meta-proportion analysis of observational studies revealed that LAAO devices were associated with a lower rate of both thromboembolic events (1.8 events per 100 patient-years vs 2.4 events per 100 patient-years) and major bleeding events during follow-up (2.2 events per 100 patient-years vs 2.5 events per 100 patient-years) as compared with NOACs. With prolonged follow-up duration after LAAO implantation, the rate of thromboembolic events decreased (2.1, 1.8, and 1.0 events per 100 person-years for 1, 1–2, and > 2 years, respectively).

CONCLUSION Although superiority of LAAO over NOACs was not demonstrated by RCTs in terms of stroke prevention, LAAO was found to be consistently associated with a lower rate of both thromboembolic and hemorrhagic events as compared with NOACs in observational studies.

KEYWORDS Atrial fibrillation; Stroke prevention; Left atrial appendage occlusion; Novel oral anticoagulant; Meta-analysis

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Introduction

Atrial fibrillation (AF) is the most common arrhythmia, the prevalence of which increases progressively with aging. Specifically, patients with AF have a 5-fold increased risk of

stroke or systemic embolism (SE), and ~25% of all strokes in the elderly population are a consequence of AF.¹ Therefore, prevention of stroke or SE events is essential to optimally manage AF. Vitamin K antagonists, such as warfarin or Coumadin, are highly effective and have been the criterion standard therapy for stroke prevention in nonvalvular AF over the past decades. Nevertheless, the narrow therapeutic window for warfarin has clinical implications in both undertreatment and overtreatment of patients, which increase the risk of thromboembolic events and bleeding, respectively.

The novel oral anticoagulants (NOACs), that is, dabigatran, rivaroxaban, apixaban, and edoxaban, are proved to be noninferior or even superior to warfarin by several large phase 3 randomized controlled trials (RCTs). An alternative

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strategy for stroke prevention in AF is exclusion of left atrial appendage (LAA) from systemic circulation, as ~91% of thrombi in nonvalvular AF are formed in the LAA.² For patients with AF who are elderly, have a bleeding history, and/or are noncompliant, left atrial appendage occlusion (LAAO) may be a better stroke prevention strategy than oral anticoagulation. These new therapies highlight the need to reconsider their comparative efficacy and safety. Unfortunately, interventional treatment by LAAO devices (Amplatzer, St Jude Medical, St Paul, MN or Watchman, Boston Scientific, Natick, MA) and medical therapy by NOACs have never been directly compared so far. This kind of head-to-head comparison, however, unlikely could be accomplished in the near future because of large sample size and high cost required. In view of this, we performed a systematic review of both RCTs and real-world observational studies on NOACs and LAAO devices and performed network meta-analysis and meta-proportion analysis to compare and explore their difference in terms of efficacy and safety of stroke prevention in AF, especially on an > 1-year follow-up basis.

Methods

Study search

We performed multiple literature searches, the latest of which was performed on September 28, 2015, using PubMed and EMBASE databases to identify articles. Key words used

were as follows: *atrial fibrillation, atrial appendage closure, atrial appendage occlusion, dabigatran, rivaroxaban, apixaban, edoxaban, and stroke* (Figure 1). Abstracts and meeting presentations were not reviewed for inclusion. The study was approved by the institutional review board of Beijing Anzhen Hospital, Capital Medical University.

A study was included for analysis if it met the following prespecified criteria: (1) >10 patients with AF were enrolled; (2) it provided primary data on clinical outcomes, including the occurrence of stroke and safety events of the procedure; and (3) the mean follow-up duration was ≥ 1 year for RCTs and observational studies on LAAO or ≥ 10 months for observational studies on NOACs. Studies were excluded if they were a secondary analysis of previously published primary data; if the patients were included in another study with a larger sample size or longer follow-up; or if patients underwent concomitant procedures, including valve surgery or AF ablation.

Two investigators (X.L. and S.N.W. or S.N.L.) independently reviewed the titles and abstracts of articles to exclude those that clearly did not meet the inclusion criteria. The full article was reviewed when necessary. The study selection process and results are shown in Figure 1.

Data extraction

Two investigators (X.L. and S.N.W. or S.N.L.) independently extracted the data from the selected articles. A

Flow chart of study search and selection

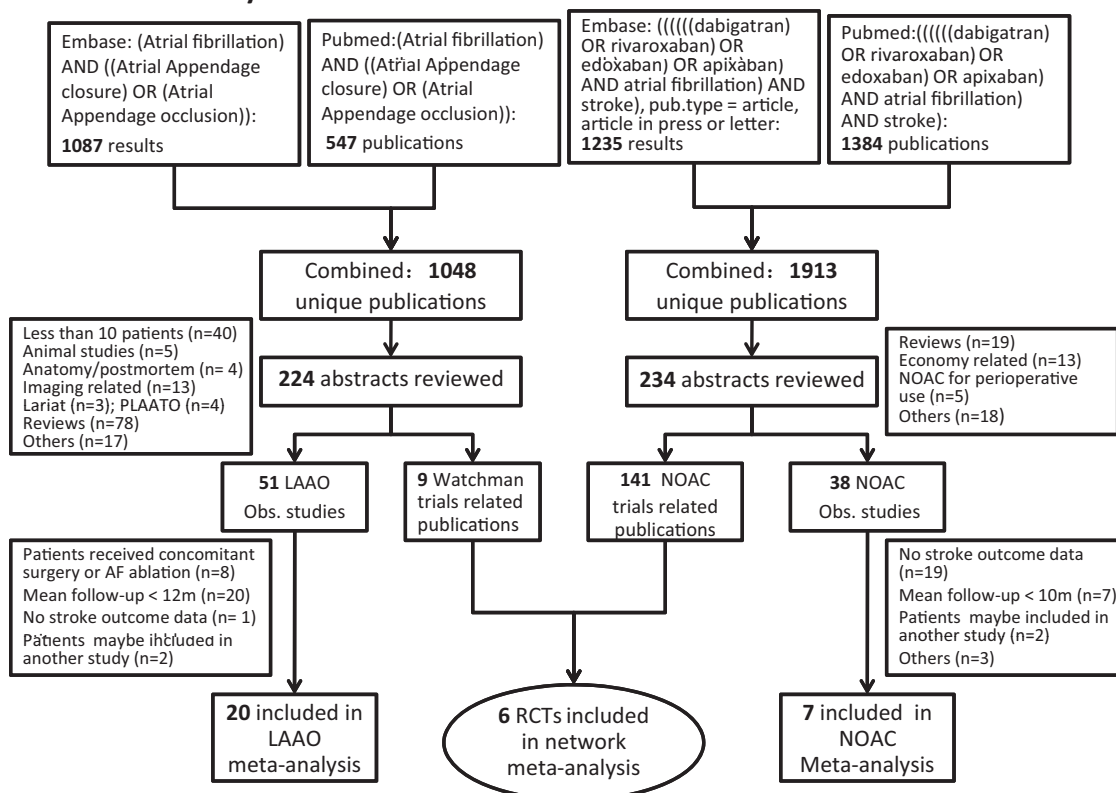


Figure 1 Flowchart of study search and selection. LAAO = left atrial appendage occlusion; NOAC = novel oral anticoagulant; Obs. = observational; RCT = randomized controlled trial.

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