SYSTEMATIC REVIEW

Efficacy and Safety of Percutaneous Left Atrial Appendage Occlusion (LAAO) in Atrial Fibrillation Patients with Cancer: A Systematic Review and Meta-Analysis

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ABSTRACT

Introduction: Ischemic thromboembolic stroke is a significant complication in patients with atrial fibrillation. Cancer will aggravate this event due to increased clot formation and thromboembolism processes but simultaneously propose high-risk bleeding for oral anticoagulation. Left Atrial Appendage Occlusion (LAAO) is an alternative strategy to prevent stroke events with promising efficacy features without the bleeding risk of anticoagulation. This systematic review and meta-analysis aimed to compare LAAO as a safety choice for ischemic stroke prevention in atrial fibrillation patients with and without cancer. **Materials and methods:** We conducted systematic literature searching from the database until August 2023. Studies were eligible if cohort studies performed LAAO in atrial fibrillation patients with and without cancer. A risk of bias assessment was performed using the Newcastle-Ottawa Scale (NOS). **Results:** Three studies met the criteria, comparing 318 patients with cancer and 544 without cancer. Among these, two were included in the meta-analysis. The pooled analysis showed no significant difference between the two groups in stroke incidence (Hazard Ratio (HR) 0.62; 95% CI 0.26–1.50; p= 0.93), bleeding episodes (HR 0.93; 95% CI 0.47–1.84; p= 0.45), and death (HR 1.34; 95% CI 0.87–2.07; p= 0.19) following the procedure. Regarding device-related complications, there was also no difference (HR: 1.3; 95% 0.81–2.08; p= 0.28). **Conclusion:** LAAO has safety features in atrial fibrillation patients with cancer and has no significant differences in outcome, such as stroke incidence, bleeding episodes, death, and device-related complications, compared with non-cancer patients.
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INTRODUCTION

Atrial Fibrillation (AF) is the most common cardiac arrhythmia, with its global prevalence tripling over the past 50 years and reaching epidemic levels in the 21st century (1,2). This increases the risk of stroke, mainly ischemic stroke, as a result of slow blood flow in the atrium, which can lead to the forming of blood clots (3). Although patients with AF often do not die from the arrhythmia itself, associated comorbidities and complications contribute significantly to mortality, particularly in cancer populations (1,4). Cancer will aggravate stroke events due to increased clot formation and thrombo-embolism process (5). Although patients with cancer are more likely to develop AF, little is known about how different cancer types influence this risk. Emerging evidence also shows a correlation between new-onset AF and subsequent cancer diagnosis (6,7). According to the 2020 ESC guidelines, anticoagulation remains central to AF stroke prevention. However, in cancer patients, anticoagulant use presents a greater risk of bleeding, creating clinical challenges in balancing embolic protection and safety (4). As cancer survival rates improve and the population continues to age, the prevalence of atrial fibrillation (AF) is also increasing. This presents a growing challenge for clinicians in managing the complex risks associated with both AF and cancer (8). Given these overlapping risks, there is an urgent need for safer alternatives to conventional anticoagulation therapy. Left Atrial Appendage Occlusion (LAAO) devices have been developed to address the earlier challenges in thromboembolic prophylaxis in patients with AF (9). The current last updated AMPLATZER Cardiac Plug (ACP) clinical trial in 2017 has shown favorable safety and efficacy outcomes for devices like ACP and Amplatzer Amulet, particularly in patients with contraindications to anticoagulation (10). For this reason, we performed a systematic review

and meta-analysis of data from the currently available relevant studies to evaluate the efficacy and safety of LAAO in preventing ischemic strokes in atrial fibrillation with cancer patients.

MATERIALS AND METHODS

Data Sources and Search Strategy

A literature search of PubMed, PubMed, Scopus, the Cochrane Library, and MEDLINE was conducted using the following keywords: "percutaneous left atrial appendage occlusion (LAAO)," "atrial fibrillation," "cancer," "stroke prevention," "safety," "efficacy." The aim was to evaluate the efficacy and safety of LAAO in preventing ischemic strokes in atrial fibrillation patients. This comparison was made between patients diagnosed with cancer and those without cancer, utilizing data from relevant studies. We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and the PRISMA checklist has been provided as a supplementary document. (11). [FM2.1]The protocol was prospectively registered with the International Prospective Register of Systematic Reviews (PROSPERO) under registration number CRD42023479628. This meta-analysis was an updated study based on previously published data. Consequently, obtaining ethical approval or informed consent was unnecessary for this research.

Eligibility Criteria[FM3.1][FM4.1]

Full-text articles were obtained to assess their eligibility for inclusion in our analysis. In our selection process, we included full-text articles that investigated adult patients (≥18 years) with both atrial fibrillation and cancer who underwent Left Atrial Appendage Occlusion (LAAO). These studies were required to evaluate one or more of the following outcomes: stroke, bleeding events, device-related complications, and all-cause mortality. Additionally, studies had to provide adequate information on patient baseline characteristics, procedural details, and follow-up duration. Both observational studies (prospective or retrospective) and clinical trials (randomized or non-randomized) were considered. Studies were excluded if they were case reports, case series, animal studies, or reviews.[FM5.1]

Statistical Analysis

Our statistical analysis was centered on time-to-event data using the log-rank test to compare the survival distributions of the two patient groups (cancer and non-cancer patients). We utilized the Cox proportional hazards model to analyze the risk of events over time. A meta-analysis used fixed-effects models to calculate pooled hazard ratios (HRs). Heterogeneity among the studies was examined using the I statistic and the Chi-square test. An I value lesser than 50% or a p-value <0.05 was considered statistically significant. All statistical analyses were performed using Review Manager (RevMan) software version 5.4.1.

Quality of Evidence Assessment

We evaluated the included cohort studies using the Newcastle-Ottawa Scale (NOS), which assesses selection, comparability, and outcome domains (12). Higher scores on the NOS's 9-point scale indicate higher quality. Scores were assigned based on the representativeness of cohorts, selection of non-exposed subjects, ascertainment of exposure, and absence of the outcome at the start of the selection domain. Comparability was assessed based on the control of important factors and additional factors. The assessment strategy, follow-up sufficiency, and follow-up adequacy of cohorts determined the quality of study outcomes. The publication bias was visualized using funnel plots. Asymmetry in the funnel plot would indicate the presence of publication bias.

RESULTS

Study Selection [FM6.1]

A total of 123 records were initially identified through database searching. After removing 33 duplicate records and 15 records flagged as ineligible (e.g., title-only entries, retracted publications), an additional 44 records were excluded. These included non-English articles with no translation available, publications without accessible abstracts, or those unrelated to LAAO despite initial relevance based on their titles. Of the remaining 92 records screened, 67 were excluded after reviewing titles and abstracts due to irrelevance to our population (e.g., studies on general atrial fibrillation or cancer patients without LAAO intervention). The remaining 25 reports were sought for full-text retrieval, but 13 could not be retrieved due to unavailable access despite institutional subscriptions or missing links. Twelve full-text articles were assessed for eligibility. Among these, six were excluded because they were abstract-only conference proceedings that did not present outcome data. Two studies were excluded as "other types of study" because, although they initially appeared relevant based on the title or abstract, they did not meet the predefined study design criteria. These included narrative reviews, study protocols, and letters to the editor, which lacked original patient data or outcome measures necessary. One article could not be retrieved in full despite multiple access attempts. Ultimately, only three studies met all predefined inclusion criteria and were included in this systematic review and meta-analysis (13–15). Study selection is described in the PRISMA flow diagram (Figure 1).

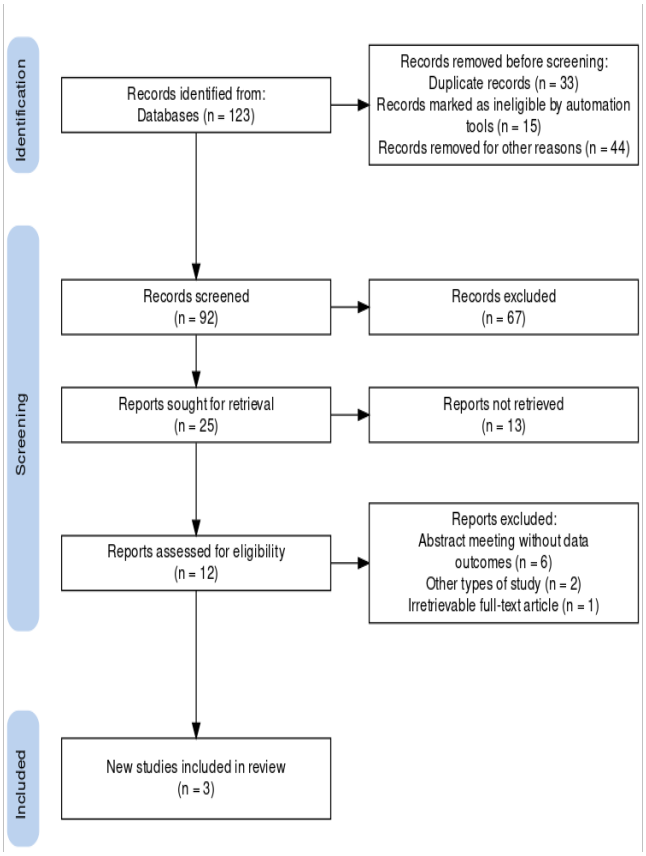

Figure 1: Identification of new studies via databases

Study Characteristics

Our study summarizes findings from three separate studies on AF patients undergoing LAAO, comparing those with and without cancer (Table I). Two studies found no significant differences in stroke, bleeding events, or death between cancer and non-cancer individuals (13, 14). One study observed a slight increase in the LAAO procedures among cancer patients, as well as a greater occurrence of in-hospital deaths following the treatment (15). These findings suggest that, despite comparable procedural risks, there may be differences in postoperative outcomes for cancer patients. Overall, LAAO was relatively safe for AF patients regardless of cancer status.

Table I: Characteristics of Included Studies

Author (Year)	Study design	AF patients		Overall median follow-up	Outcomes
		Cancer	Non-cancer		
Shabtaie et al. (2023)	Retrospective cohort	55	212	1.6 years (1.1-2.6)	Ischemic stroke, bleeding complications, and death were not significantly different from those who received LAAO without cancer.
Kumar et al. (2023)	Prospective cohort	57	332	354 days (85-790)	Patients with and without cancer had similar mortality, major bleeding episodes, and stroke three years after the procedure. Postprocedural mortality, stroke, and significant bleeding did not differ across groups. Cancer patients can safely have percutaneous left atrial appendage closure.
Hobohm et al. (2019)	Retrospective cohort	206	N/A	5 years	Over the five years, there was a slight increase in the frequency of the total number of percutaneous LAA closures in cancer patients. Cancer was associated with in-hospital mortality in hospitalized patients following percutaneous LAA closure.

Risk of Bias in Studies

Our risk of bias assessment for the included studies revealed a low risk overall (Table II). Two studies, by

Habohm et al. and Shabtaie et al., received high-quality scores of 8 out of 10, indicating they complied well with research quality criteria. These studies were marked by solid sample representation, appropriate cohort selection, and reliable outcome assessment measures. The study by Kumar et al. received a slightly lower score of 7 out of 10, yet it still qualifies as a good quality study.

Table II: Risk of Bias Summary

No.	First Author, Year	Selection				Comparability	Outcome			Quality Rating
		Representativeness of the sample	Selection of the non-exposed cohort	Outcome of interest was not present at the start of study	Ascertainment of the exposure		Assessment of outcome	Was follow-up long enough for outcomes to occur	Adequacy of follow-up of cohorts	
1.	Habohm et al., (2019)	★	★	★	★	★	★	★	★	8/10
2.	Shabtaie et al. (2023)	★	★	★	★	★	★	★	★	8/10
3.	Kumar et al. (2023)	★	★	★	★	★	★		★	7/10

LAAO Outcomes in Patients with and Without Cancer

Three studies with a total of 318 cancer patients and 544 without were assessed, with two of these studies being eligible for meta-analysis. The combined data from these studies revealed no statistically significant difference in the incidence of stroke between cancer and non-cancer, with a pooled Hazard Ratio (HR) of 0.62 (95% Confidence Interval (CI): 0.26 to 1.50; p = 0.93). This evidence suggests that the presence of cancer did not notably affect the risk of stroke post-LAAO. Similarly, for bleeding episodes, the analysis yielded an HR of 0.93 (95% CI: 0.47 to 1.84; p = 0.45), demonstrating that the risk of bleeding complications was equal between the two cohorts (Figure 2).

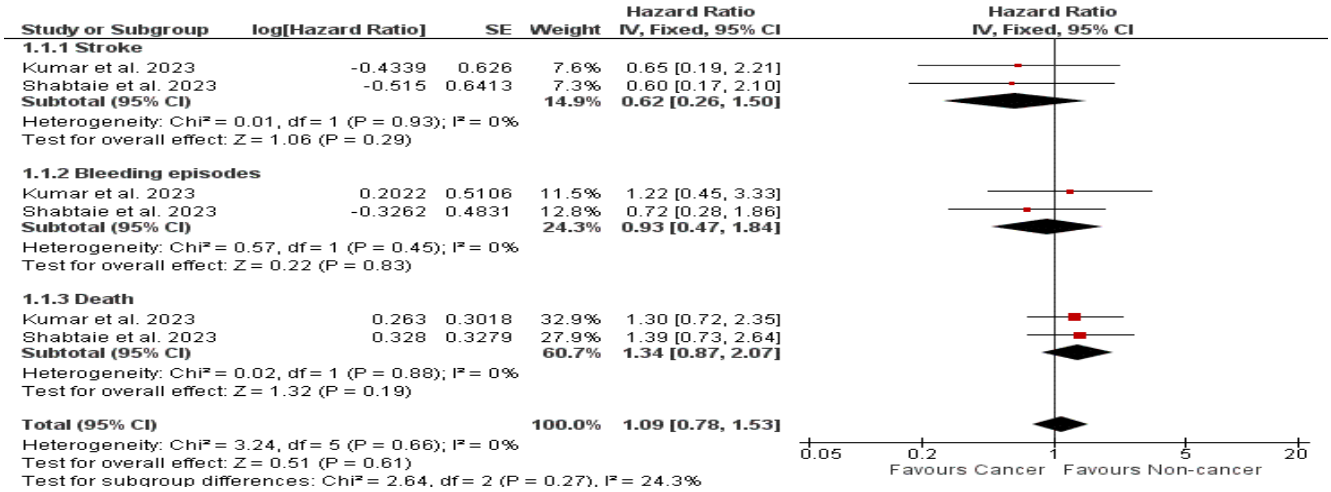

Figure 2: Forest plot of the effectiveness of percutaneous LAAO in both cancer and non-cancer patients

Furthermore, mortality outcomes were consistent across groups, with an HR of 1.34 (95% CI: 0.87 to 2.07; p = 0.19), indicating that cancer did not significantly alter the risk of death following the LAAO procedure. The analysis of device-related complications revealed no significant difference, with a Hazard Ratio (HR) of 1.3 (95% CI: 0.81 to 2.08; p = 0.28) (Figure 3). The low heterogeneity observed for all measured outcomes across the studies indicates reasonable consistency in the findings.

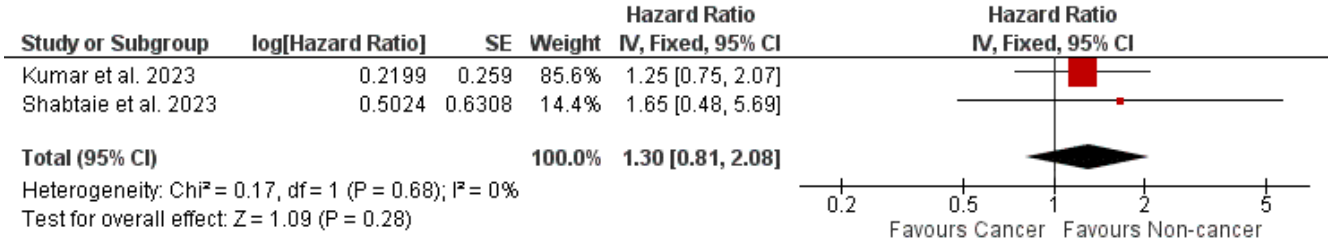

Figure 3: Forest plot of the safety outcomes of percutaneous LAAO in both cancer and non-cancer patients

Funnel Plots

The funnel plots from our systematic review exhibit a symmetrical distribution of study data on LAAO safety and effectiveness, implying low publication bias (Figure 4). This symmetry supports our meta-analytic, which confirms equivalent risks of stroke, bleeding, mortality, and complications between cancer and non-cancer patients undergoing LAAO. With only two studies in the funnel plot, the usual assumption of a funnel shape indicating no bias is less reliable. Hence, the limited number of studies represented warrants caution in interpreting this apparent lack of bias.

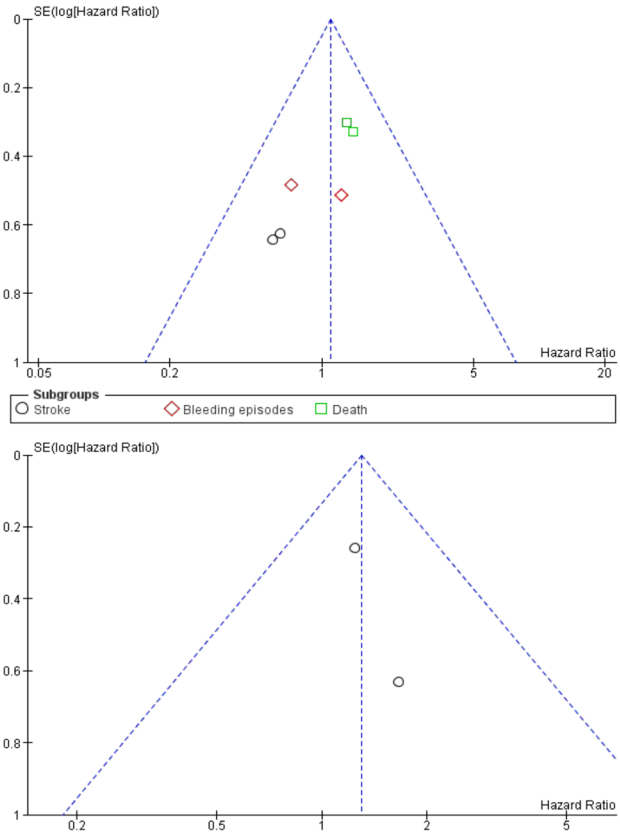

Figure 4: Funnel plot of the study

DISCUSSION

AF incidence increases with age and creates severe clinical burdens, such as embolic stroke, pulmonary embolism, and heart failure, which have a significant impact on morbidity and mortality in older people (4). Based on data in 2017, there were 37.57 million prevalent cases and 3.05 million incident cases of AF globally, contributing to 287,241 deaths (16). According to the 2020 European Society of Cardiology (ESC) guidelines for AF, the 'Atrial Fibrillation Better Care' (ABC) pathway was introduced to manage AF. This ABC pathway encompasses three key components: 'A' for 'Anticoagulation/Avoid Stroke', 'B' for 'Better Symptom Management', and 'C' for 'Cardiovascular and Comorbidity Optimization'. In terms of Anticoagulation to avoid stroke events in AF, it should be important to minimize bleeding risk while reducing embolic event risk during Anticoagulant usage (4).

One of the specific populations who is at risk for AF is Cancer patients. Cancer patients have a higher risk of AF than the general population, which has a two-fold risk of developing AF (8, 17). The prevalence of AF among cancer patients is around 20% (17). Two main factors have been proposed, provoking AF occurrence in cancer patients. Pro-inflammatory state in cancer patients, as well as cancer therapy, may induce cardiac problems, and in terms of arrhythmia, AF is the most frequent one. Several modalities of cancer treatment are known for their cardiotoxicity, such as cancer surgical treatments, chemotherapies, radiotherapies, hormone therapies, and target therapies (18).

The other problem that should be considered in patients with AF and cancer is the complexity of anticoagulant prescribing caused by additional risks in both bleeding risk and thrombosis (19). Various thromboembolic events, such as venous thromboembolism and stroke, are increased by hypercoagulable state in cancer, while some chemotherapies contribute to high bleeding risk (20). Thus, some strategies may be needed that could provide benefits for preventing thromboembolic events but have no or minimal bleeding risk. One of the strategies is Left Atrial Appendage (LAA) closure (21).

The left atrial appendage is a structure that has a significant role in thrombus formation in AF. The rationale for left atrial appendage (LAA) closure in atrial fibrillation (AF) patients is primarily for those who have a high risk of bleeding and demonstrate intolerance to long-term oral anticoagulants. Based on the newest ESC guideline for AF, LAA closure has a class IIb recommendation for stroke prevention in patients with AF. In our meta-analysis from two recent studies about LAA closure performing in cancer and AF, we found no significant differences in terms of stroke events, bleeding episodes, and death compared to non-cancer patients. From both studies, LAA closure has provided evidence of stroke prevention in patients with AF and malignancy without added significant bleeding or adverse events. Adding anticoagulants in AF and malignancy patients may be complex because there are many independent risk factors for high-risk bleeding that happen in patients, such as older age, renal failure, coagulopathy, prior chemotherapy, and anemia (22). Therefore, LAA closure, which does not impact the status of blood clotting, can offer advantages in preventing strokes in AF patients who have cancer.

From the early study of LAA closure in AF patients using the WATCHMAN device as an LAA closure device, after a mean follow-up of 2.3 years, the primary efficacy (all-stroke, systemic thromboembolism and cardiovascular death) event rates were similar in the device and warfarin groups (3.0 vs 4.3 %) demonstrating non-

inferiority of LAA closure using device compared with warfarin therapy (23, 24). Even in cancerous patients, from the very first study using LAA closure in specific AF and cancer patient populations, there were no significant differences in device-related complications, ischemic stroke, and bleeding events compared with non-malignancy patients. Device-related complications include device thrombus and peridevice-leak. The former should be a concern because it is associated with an increased risk of ischemic stroke (13). Another concern after the LAA closure procedure is post-procedural pericardial effusion, a rate from 0.68% to 3.1%, which might result in longer in-hospital stays (22).

Our study has limitations, which include only two studies to be analyzed for meta-analysis. From those small populations formed, there were no specific types of malignancies to be classified, which have different risks of thrombosis and bleeding and thus might affect the results. Breast and prostate cancer are classified as lower risk, while hematologic, lung, stomach, and brain cancers present a much higher risk. Another limitation is the short follow-up time because LAA closure in both studies was just implanted from 2018 – 2019. A longer period of follow-up is needed for a better conclusion about the safety of LAA closure in AF patients with cancer comorbidity. However, the limited number of included studies reflects the novelty and specificity of the research question and provides valuable early evidence on the use of LAAO in patients with both AF and cancer. Although only two studies were included in the meta-analysis, both provided robust procedural and outcome data, allowing for an initial quantitative synthesis of safety and efficacy in this high-risk group. Our findings highlight the need for further research to differentiate outcomes based on malignancy-associated thrombotic and bleeding risks. This systematic review is one of the first to focus on this high-risk group and highlights the urgent need for further research.[F

CONCLUSION

Our findings demonstrate that LAAO is a safe and viable option for AF patients with cancer. Importantly, the outcomes reported in these patients were found to be comparable to those recorded in non-cancer AF patients, including the frequency of stroke, bleeding episodes, death, and device-related problems. This equivalence in clinical results highlights the potential of LAAO as an effective treatment approach for controlling AF in patients with concurrent cancer conditions. Future research should further investigate these findings in larger and more diverse cohorts to confirm LAAO's effectiveness in this population.

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