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Comparing Vitamin K Antagonists and Direct Oral Anticoagulants in Patients With Atrial Fibrillation Undergoing Transcatheter Aortic Valve Replacement: A Meta-Analysis

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Abstract

Aortic stenosis (AS) is the most prevalent valvular disease in the elderly population and the prevalence of atrial fibrillation (AF) increases in the elderly population. Transcatheter aortic valve replacement (TAVR) becomes an important treatment for patients with AS at high surgical risk. This metanalysis aimed to compare the efficacy and safety of vitamin K antagonists (VKAs) and direct oral anticoagulants (DOACs) in patients with AF undergoing TAVR. We searched the different databases for articles published before January 31, 2022. In total, 7 studies including 25,255 patients were analyzed. Data on demographics, comorbidities, CHA2DS2-VASc score, Society of Thoracic Surgeons (STS) score, and incidences of all-cause mortality, major bleeding, intracranial hemorrhage (ICH), stroke, and thromboembolic events were obtained and analyzed. The VKA group had a lower CHA2DS2-VASc score (3.2 ± 1.2 vs 3.3 ± 1.2; $P < .001$) and a higher STS score (6.6 ± 3.2 vs 6.1 ± 2.9; $P < .001$) than the DOAC group. The risks of all-cause mortality (odds ratio [OR]: 0.88; 95% confidence interval [CI], 0.67-1.16), ischemic stroke (OR: 1.06; 95% CI, 0.90-1.24), and thromboembolism (OR: 1.24; 95% CI, 0.63-2.47) in the DOAC group were comparable to the VKA group. The risks of major bleeding (OR: 0.77; 95% CI, 0.71-0.84) and ICH (OR: 0.62; 95% CI, 0.42-0.90) were lower in the DOAC group compared to the VKA group. DOACs were associated with lower risks of major bleeding and ICH, and comparable risks of all-cause mortality, ischemic stroke, and thromboembolism in patients with AF undergoing TAVR compared to VKAs.

Keywords

aortic stenosis, atrial fibrillation, vitamin K antagonists, direct oral anticoagulants, transcatheter aortic valve replacement

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Introduction

Aortic stenosis (AS) is the most prevalent valvular disease in the elderly population and is both a diagnostic and a therapeutic challenge in elderly patients.[1,2] Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia in the general population and the prevalence of AF increases in the elderly population.[3] Transcatheter aortic valve replacement (TAVR) is a percutaneous intervention modality for patients with AS at high surgical risk, especially in the elderly population.[4] AF develops in ≥ 40% of patients undergoing TAVR and is associated with an increased risk of both subacute and late stroke development.[5,6] Additionally, AF is associated with more

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than 2-fold increased risk of all-cause and cardiovascular mortality in high-risk patients with severe AS undergoing TAVR, irrespective of the AF type. Furthermore, the gradient of risk directly correlates with the CHA2DS2-VASc score.[7] Therefore, anticoagulant use is crucial for patients with severe AS with AF undergoing TAVR to prevent AF-related stroke.

According to the randomized studies comparing vitamin K antagonists (VKAs) and direct oral anticoagulants (DOACs) for stroke prevention in patients with nonvalvular AF, the efficacy and safety of DOACs are comparable to those of VKAs.[8–11] However, it is unclear whether the efficacy and safety of VKAs and DOACs are comparable in patients with AF undergoing TAVR. Seeger reported a high mortality in patients with AF undergoing TAVR compared to patients in sinus rhythm and apixaban use was associated with lower life-threatening bleeding in patients with AF compared to VKA use.[12] Geis reported similar mortality, stroke, embolism, and severe bleeding rates between DOAC versus VKA monotherapy without additional antiplatelet therapy in patients with concomitant indications for oral anticoagulant after TAVR.[13] Further studies comparing VKAs and DOACs have shown similar thromboembolism, bleeding, and mortality rates or better survival rate in patients with AF undergoing TAVR.[14,15] Moreover, the large Society of Thoracic Surgeons (STS)/American College of Cardiology Transcatheter Valve Therapy Registry (ACC TVT) registry study showed that DOAC use was associated with comparable stroke risk and significantly lower risks of bleeding, intracranial hemorrhage, and death at 1 year in patients with AF undergoing TAVR compared to VKA use.[16] However, Jochheim reported a borderline higher ischemic event rate with DOACs in patients with AF undergoing TAVR compared to VKA, and the distribution of DOACs in patients receiving DOACs were rivaroxaban (53.7%), apixaban (39.2%), and dabigatran (7.1%), and more than half of the patients received combined antiplatelet therapy.[17] Moreover, in a recent randomized controlled study comparing edoxaban and warfarin in patients with AF undergoing TAVR, edoxaban was noninferior to VKA in terms of primary efficacy outcome, but the risk of major bleeding, especially gastrointestinal bleeding, was higher in patients with edoxaban than in patients with VKA. [18] Therefore, the eligibility for DOAC for patients with AF undergoing TAVR remains inconclusive. Accordingly, we conducted this meta-analysis to compare the efficacy and safety of VKAs and DOACs in patients with AF undergoing TAVR.

Methods

Search Strategies, Trial Selection, Quality Assessment, and Data Extraction

Two cardiologists (WCL and HYF) performed a systematic literature search of PubMed, Embase, ProQuest, ScienceDirect, Cochrane Library, ClinicalKey, Web of Science, and ClinicalTrials.gov databases for articles published before January 31, 2022. The databases were searched for relevant studies without language restrictions using the key terms "aortic stenosis," "atrial fibrillation," "transcatheter aortic valve replacement," "vitamin K antagonists," and "direct oral anticoagulants." Any disagreements were resolved by a third reviewer (PJW). Randomized controlled studies and observational studies that compared the efficacy and safety outcomes of VKAs and DOACs in patients with AF undergoing TAVR were included in this analysis. The inclusion criteria were human studies with a parallel design and comparison of the efficacy and safety of VKAs and DOACs in patients with AF undergoing TAVR. The exclusion criteria were case reports or series, animal studies, review articles, conference abstracts, unpublished data, and studies not including patients with AF. We did not set any language limitations to increase the number of eligible articles. Figure 1 (PRISMA flow chart) illustrates the literature search and screening protocol.

Outcomes

Outcomes of interest in this study were all-cause mortality, major bleeding, intracranial hemorrhage (ICH), ischemic stroke, and thromboembolism.

Statistical Analysis

The frequency of each evaluated outcome was extracted from each study, and data were presented as cumulative rates. A random effects model was employed to pool individual odds ratio (OR), and all analyses were performed using Comprehensive Meta-Analysis software version 3 (Biostat, Englewood, NJ, USA). To assess heterogeneity across trials, we used the chi-square test ($P \leq .10$ was considered significant) and I^2 statistics to examine each outcome from low to high heterogeneity (25% to 75%, respectively). Potential publication bias was assessed by Egger's test via funnel plots and statistical significance was set at $P \leq .10$. Statistical significance was set at $P < .05$ for the comparison between the VKA and DOAC groups.

Results

Characteristics of Included Studies

The study selection process is displayed in Figure 1. Seven studies met the inclusion criteria. A total of 25,255 participants (mean age, 84 ± 4.7 years; 55.4% men) were included. The study design, period, participant characteristics, combination of antiplatelet agents, and follow-up period are described in Table 1. Most of the enrolled studies included AF population (94%-100%).

Patient Demographics

Supplemental Table 1 describes patients' demographics, comorbidities, average CHA2DS2-VASc scores, and STS scores. The VKA group was older and had a higher prevalence of diabetes mellitus, advanced chronic kidney disease/dialysis and prior

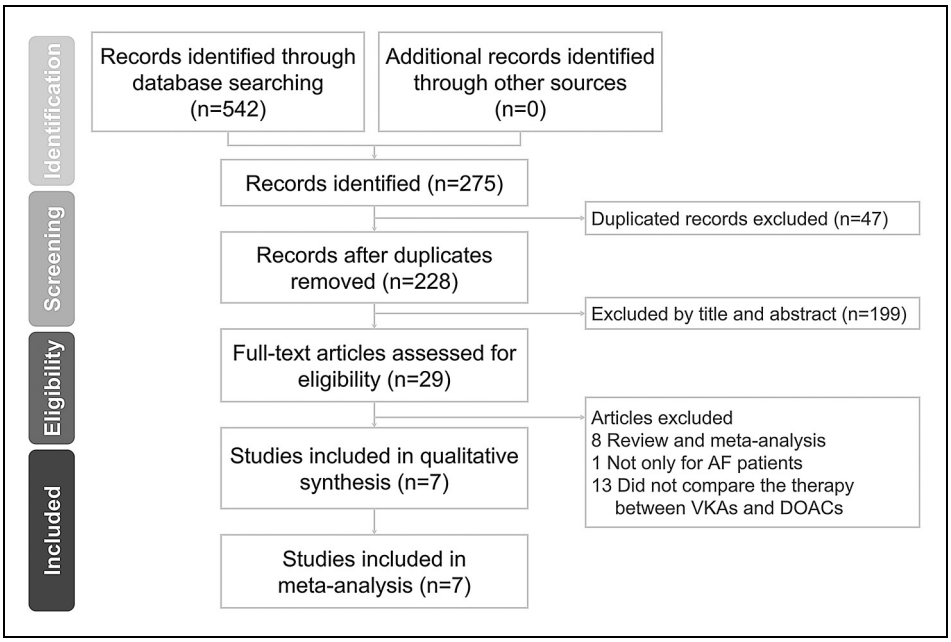

Figure 1. Flowchart of the selection strategy and inclusion and exclusion criteria for this meta-analysis. Abbreviations: AF, atrial fibrillation; DOACs, direct oral anticoagulants; VKAs, vitamin K antagonists.

Table 1. Characteristics of the 7 Included Studies.

First author (year)	Patients number (male %)	Age (years)	Study period	AF (%)	The combination of antiplatelet therapy (%)	Comparison of groups	Follow up
Seeger J (2017)	272 (51)	81 ± 6	N/A	100	100%; single (66.2%); dual (33.8%)	VKA versus apixaban	1 year
Geis NA (2018)	326 (47)	83 ± 5	July 2008 to April 2017	94.0	0	VKA versus DOACs	6 months
Jochheim D (2019)	962 (48)	81 ± 6	June 2007 to February 2017	99.3	82.8%; single (61.7%); dual (21.1%)	VKA versus DOACs	1 year
Kawashima H (2020)	403 (33)	84 ± 5	October 2013 to May 2017	100	68.8%; single (63.3%); dual (5.5%)	VKA versus DOACs	2 years
Butt JH (2021)	735 (54)	82 ± 4	January 2012 to June 2017	100	78.5%; single (61.8%); dual (16.7%)	VKA versus DOACs	3 year
Van Mieghem NM (2021)	1426 (53)	82 ± 5	January 2012 to August 2017	100	48%; single or dual (48%)	VKA versus edoxaban	2 year
Tanawuttiwat T (2021)	21131 (57)	84 ± 5	January 2013 to May 2018	100	87.5%; single (73.6%); dual (13.9%)	VKA versus DOACs	1 year

Abbreviations: AF, atrial fibrillation; DOACs, direct oral anticoagulants; N/A, not available; VKA, vitamin K antagonist.

cardiac surgery than the DOAC group. Additionally, the VKA group had a lower CHA2DS2-VASc score (3.2 ± 1.2 vs 3.3 ± 1.2; $P < .001$) and a higher STS score (6.6 ± 3.2 vs 6.1 ± 2.9; $P < .001$) than the DOAC group.

Pooled OR of All-Cause Mortality

The overall OR of all-cause mortality in the DOAC group compared to the VKA group was 0.88 (95% confidence interval [CI], 0.67-1.16) (Figure 2), with moderate heterogeneity (Cochran's Q, 19.571; *df*, 6; I^2, 69.343%; $P = .003$). Egger's test revealed a nonsignificant publication bias regarding the overall OR of all-cause mortality (*t*, 0.339; *df*, 5; $P = .748$). The funnel plot for the log OR of all-cause mortality is shown in Supplemental Figure 1.

Pooled OR of Major Bleeding Events

The OR of major bleeding events in the DOAC group compared to the VKA group was 0.77 (95% CI, 0.71-0.84) (Figure 3A), with low heterogeneity (Cochran's Q, 1.724; *df*, 6; I^2, 0%; $P = .943$). Egger's test revealed a nonsignificant publication bias regarding the overall OR of major bleeding events (*t*, 0.361; *df*, 5; $P = .733$). The funnel plot for the log OR of major bleeding events is shown in Supplemental Figure 2.

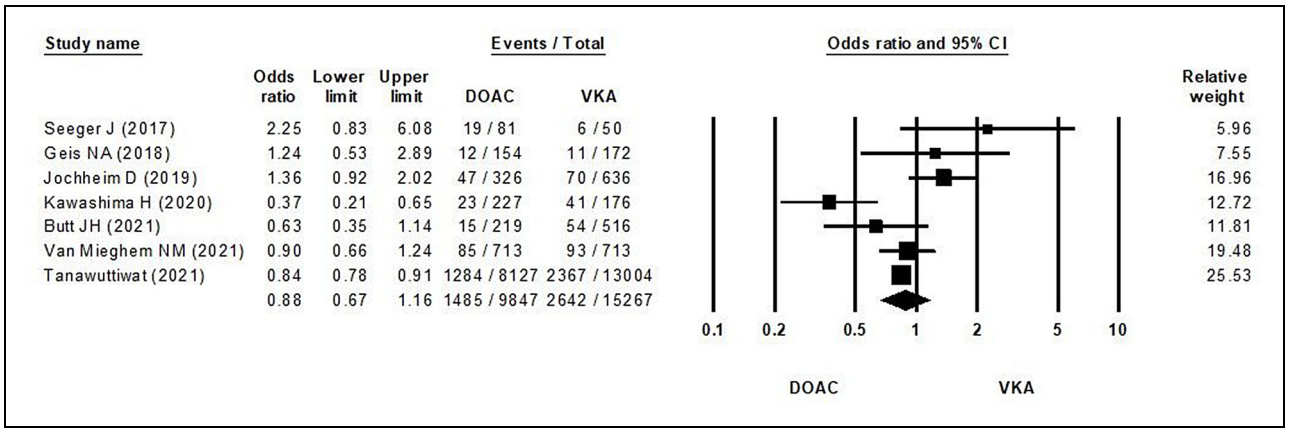

Figure 2. Forest plots demonstrating the risk of all-cause mortality between the VKA and DOAC groups in 7 studies. Abbreviations: DOAC, direct oral anticoagulant; VKA, vitamin K antagonist.

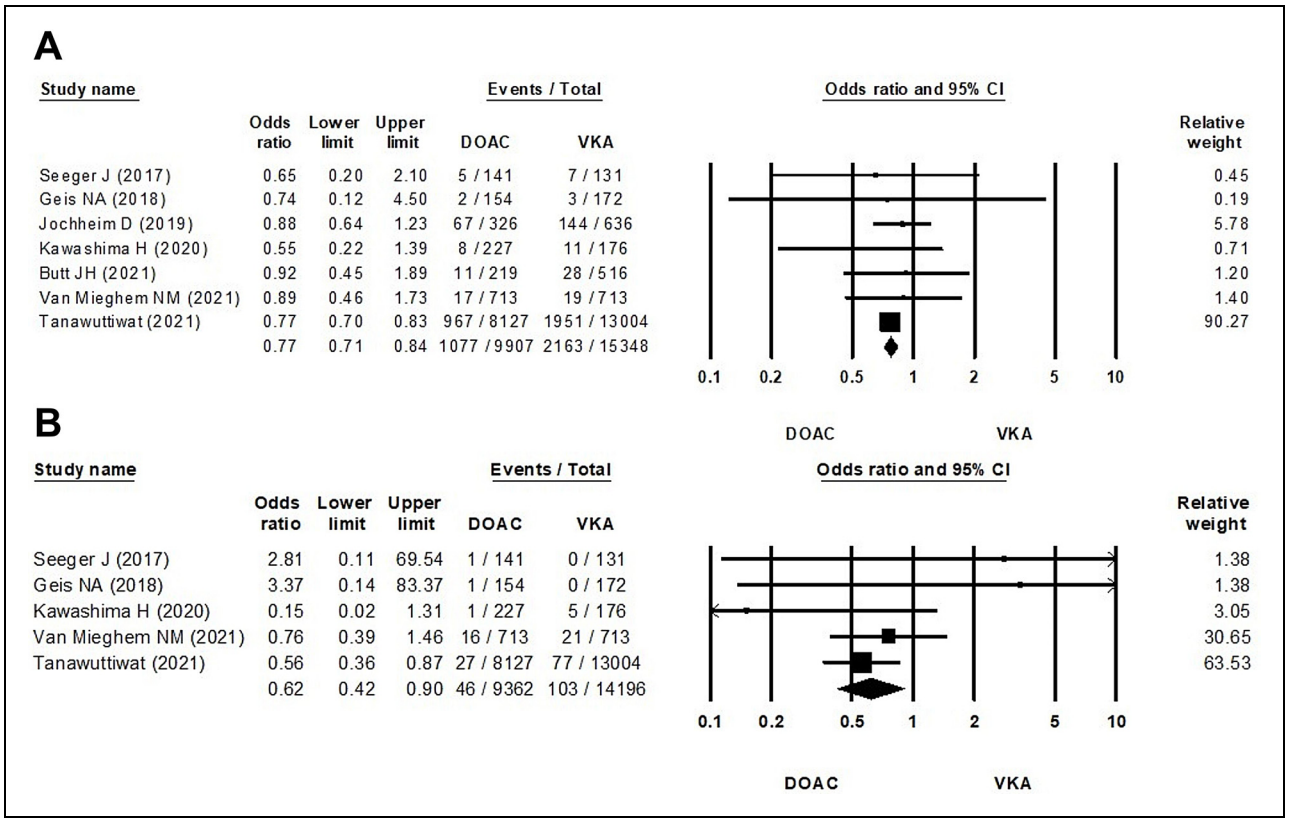

Figure 3. (A) Forest plots demonstrating the risk of major bleeding events between the VKA and DOAC groups in 7 studies. (B) Forest plots demonstrating the risk of ICH between the VKA and DOAC groups in 5 studies. Abbreviations: DOAC, direct oral anticoagulant; ICH, intracranial hemorrhage; VKA, vitamin K antagonist.

Pooled OR of ICH Events

According to 5 studies, the OR of ICH events in the DOAC group compared to the VKA group was 0.62 (95% CI, 0.42-0.90) (Figure 3B), with low heterogeneity (Cochran's Q, 4.122; *df*, 4; I^2, 2.952%; $P = .390$). Egger's test revealed a non-significant publication bias regarding the overall OR of ICH events (*t*, 0.566; *df*, 3; $P = .611$). The funnel plot for the log OR of ICH events is shown in Supplemental Figure 3.

Pooled OR of Ischemic Stroke Events

According to 6 studies, the OR of ischemic stroke events in the DOAC group compared to the VKA group was 1.06 (95% CI, 0.90-1.24) (Figure 4A), with low heterogeneity (Cochran's Q, 3.554; *df*, 4; I^2, 0%; $P = .615$). Egger's test revealed a nonsignificant publication bias regarding the overall OR of ischemic stroke events (*t*, 0.273; *df*, 4; $P = .798$). The funnel plot for the log OR of stroke events is shown in Supplemental Figure 4.

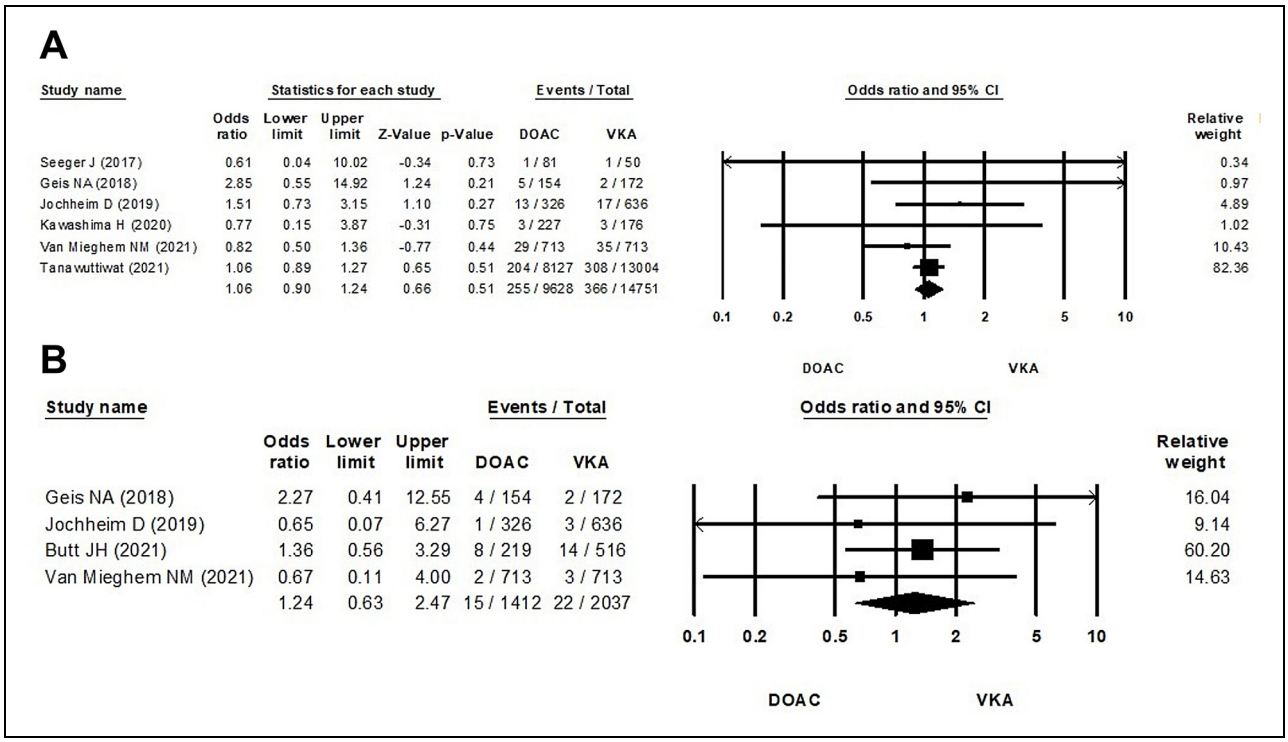

Figure 4. (A) Forest plots demonstrating the risk of stroke between the VKA and DOAC groups in 6 studies. (B) Forest plots demonstrating the risk of thromboembolic events between the VKA and DOAC groups in 4 studies. Abbreviations: DOAC, direct oral anticoagulant; VKA, vitamin K antagonist.

Pooled OR of Thromboembolic Events

According to 4 studies, the OR of thromboembolic events in the DOAC group compared to the VKA group was 1.24 (95% CI, 0.63-2.47) (Figure 4B), with low heterogeneity (Cochran's Q, 1.294; *df*, 3; I^2, 0%; $P = .730$). Egger's test revealed a nonsignificant publication bias regarding the overall OR of thromboembolic events (*t*, 0.667; *df*, 2; $P = .573$). The funnel plot for the log OR of thromboembolic events is shown in Supplemental Figure 5.

Discussion

This study showed that compared to VKA, DOACs were associated with lower risks of major bleeding and ICH, and comparable risks of all-cause mortality, ischemic stroke, and thromboembolism in patients with AF (almost 100% AF) undergoing TAVR, despite higher CHA2DS2-VASc score in the DOAC group.

Previous meta-analyses for comparing DOACs versus VKA after TAVR included randomized controlled and observational studies and enrolled patients with concomitant indication for oral anticoagulation, and thus, not all enrolled studies comprised only patients with AF.[19–21] These meta-analyses for comparing DOACs versus VKA after TAVR showed different mortality and thromboembolic outcomes.[19–21]

The large STS/ACC TVT registry study reported that DOAC use was associated with comparable stroke risk and significantly lower risks of bleeding, intracranial hemorrhage, and death at 1 year in patients with AF undergoing TAVR compared to VKA use. [16] However, ENVISAGE-TAVI AF trial showed that edoxaban was noninferior to VKA in terms of primary efficacy outcome, but the risk of major bleeding, especially gastrointestinal bleeding, was higher with edoxaban than with VKA in patients with AF undergoing TAVR.[18] Further randomized controlled trials are warranted to investigate DOACs versus VKAs in patients with AF undergoing TAVR, especially in high bleeding and surgical risk population.

The 2020 American College of Cardiology/American Heart Association guideline for the management of patients with valvular heart disease recommends aspirin 75 to 100 mg daily for patients with a bioprosthetic TAVR in the absence of other indications for oral anticoagulants (Class 2a, Level of Evidence: B), and dual-antiplatelet therapy with aspirin and clopidogrel for 3 to 6 months (Class 2b, Level of Evidence: B) or anticoagulants with VKA for at least 3 months (Class 2b, Level of Evidence: B) for patients with a bioprosthetic TAVR at low risk of bleeding.[22] The 2017 European ESC/EACTS guidelines recommend lifelong use of oral anticoagulants in patients with concomitant indications for chronic anticoagulation (Class 1, Level of Evidence: C) and aspirin with clopidogrel for the first 3 to 6 months after TAVR (Class 2a, Level of Evidence: C).[23] The use of a single antiplatelet agent should be considered if the patient is at high risk of bleeding (Class 2b, Level of Evidence: C).[23] In a randomized study comparing VKA alone and VKA with concomitant clopidogrel therapy in patients

undergoing TAVR showed that concomitant clopidogrel therapy did not reduce the incidence of stroke but increased the risk of major or life-threatening bleeding.[24] A recent consensus has suggested the use of oral anticoagulants alone in patients with indications for chronic anticoagulation and without coronary stenting. [25]

Limitations

This study has several limitations. First, most studies were observational cohort studies and had selection bias. However, a total of 25,255 participants were enrolled from 7 studies including the most update studies. Second, moderate heterogeneity was found among the 7 studies in the analysis of all-cause mortality. Third, worse outcomes in terms of major bleeding and ICH events were noted in the VKA group, which might be related to unfavorable concomitant comorbidities in the VKA group compared to the DOAC group. However, DOACs was associated with better safety despite higher CHA2DS2-VASc score in the DOAC group. Fourth, the baseline characteristics of all participants in the enrolled studies were not completely available. Fifth, the different percentages of antiplatelet therapy might have influenced the results of this meta-analysis. Sixth, the comparison of clinical outcomes among different DOACs is not available in this study. Seventh, data on time in the therapeutic international normalized ratio range in the VKA group during follow up are not available. Finally, the enrolled studies had different follow-up periods. However, the population of the enrolled studies was nearly 100% comprised of patients with AF. Therefore, the present study provides important information in terms of the efficacy and safety of VKAs versus DOACs in patients with AF undergoing TAVR.

Conclusion

This meta-analysis showed that DOACs were associated with lower risks of major bleeding and ICH, and comparable risks of all-cause mortality, ischemic stroke, and thromboembolism in patients with AF undergoing TAVR compared to VKAs. Further randomized controlled trials are warranted to validate our findings.

Availability of data and materials

The study data are available from the corresponding author upon reasonable request.

Authors' Contributions

WCL designed the study and drafted the manuscript. WCL, JYS, and HYF established the study rationale. WCL and PJW performed comprehensive analyses. CYF, HCC, and YNF prepared figures. WTC did validation and visualization. MCC supervised and drafted the final manuscript. All authors have reviewed the manuscript.

Declaration of Conflicting Interests

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Supplemental Material

Supplemental material for this article is available online.

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Abbreviations

AF	atrial fibrillation
AS	aortic stenosis
CI	confidence interval
DOACs	direct oral anticoagulants
ICH	intracranial hemorrhage
OR	odds ratio
STS score	Society of Thoracic Surgeons score
TAVR	transcatheter aortic valve replacement
VKAs	vitamin K antagonists.