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Review

Direct oral anticoagulants versus vitamin K antagonists after heart valve bioprosthetic replacement or repair: A systematic review and meta-analysis

Vito D. Bruno[a,*], Tom Lester[b], Enrico Poletti[c], Bleri Celmeta[a], Tommaso Viva[a], Arturo Bisogno[a], Antonio Miceli[a], Mattia Glauber[a]

[a] Department of Minimally Invasive Cardiac Surgery, IRCCS Galeazzi-Sant'Ambrogio Hospital, 20157 Milan, Italy
[b] School of Medicine, University of Bristol, Bristol BS8 1UD, UK
[c] Department of Cardiology, Hartcentrum Middelheim ZNA, 2020 Antwerp, Belgium

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ABSTRACT

Vitamin K antagonists are used as a temporary anticoagulation method after bioprosthetic valve replacement or repair. However, the novel direct oral anticoagulants may be a preferred method of anticoagulation because of their improved patient compliance. This meta-analysis aimed to evaluate the safety of direct oral anticoagulants versus vitamin K antagonists after biological valve replacement or repair. A systematic review and meta-analysis were performed for studies reporting the effect of direct oral anticoagulants versus vitamin K antagonists after biological valve replacement or repair. The inclusion criteria were studies of adults undergoing bioprosthetic mitral or aortic valve replacement or repair, comparing direct oral anticoagulants versus vitamin K antagonists in the early postoperative period. The main outcomes were thromboembolic and bleeding events, and short- and mid-term death rates. Six observational studies and one randomized controlled trial were included, with a total of 2994 direct oral anticoagulant recipients and 16,894 vitamin K antagonist recipients. There were no significant differences between the groups in terms of thromboembolic events (odds ratio: 0.82, 95% confidence interval: 0.45–1.49; $P = 0.52$) or bleeding events (odds ratio: 0.89, 95% confidence interval: 0.70–1.14, $P = 0.36$). Higher 30-day and mid-term death rates were observed in patients receiving direct oral anticoagulants, but this analysis was reported inconsistently, and was heavily influenced by a single study. In a mixed population of individuals undergoing bioprosthetic valve replacement or repair, there was no statistically significant difference between direct oral anticoagulants and vitamin K antagonists in terms of reducing thromboembolic or bleeding events. Further studies are needed to establish the optimal anticoagulation regimen in this context.

1. Abbreviations

AF atrial fibrillation
CI confidence interval
DOAC direct oral anticoagulant
OR odds ratio
PRISMA Preferred Reporting Items for Systematic reviews and Meta-Analyses
RCT randomized control trial
VKA vitamin K antagonist

2. Background

Current clinical guidelines endorse anticoagulation for at least 3 months after valve replacement with a biological prosthesis [1,2], although recommendations for the use of vitamin K antagonists (VKAs) in patients with bioprosthetic valves are mostly directed by limited evidence [3]. Similar indications exist even for heart valve repairs [2]. Direct oral anticoagulants (DOACs) are anticoagulation pharmacotherapies that have been progressively implemented for the treatment of non-valvular atrial fibrillation (AF) and the prevention of thrombosis in several cardiovascular contexts [4], but with a controversial indication and potentially inappropriate use in patients with artificial heart valves [5,6]. Despite this, DOACs have several advantages compared with VKAs, including fewer monitoring requirements and less frequent follow-up, fewer food interactions and more immediate drug onset and offset effects [4]. Therefore, their use after biological valve replacement or repair would have significant beneficial effects on the quality of life of

* Corresponding author. Department of Minimally Invasive Cardiac Surgery, Level 13, Room 55, IRCCS Galeazzi-Sant'Ambrogio, Via Cristina Belgioioso 173, 20157 Milano, Italy.
E-mail address: vitodomenico.bruno@grupposandonato.it (V.D. Bruno).

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Table 1
Inclusion and exclusion criteria.

	Inclusion criteria	Exclusion criteria
Design	Any clinical or observational study	Case reports, review articles, letters, comments, opinions, patents and preclinical/veterinary studies
Population	Adults aged > 18 years who were having bioprosthetic mitral/aortic valve replacement or surgical mitral/aortic valve repair	Children aged < 18 years; focus exclusively on the population with AF, transcatheter procedures or mechanical valve replacements
Intervention/comparison	Any DOAC compared with a VKA	No use of DOACs or VKAs
Outcomes	Ischaemic stroke, TIA, thromboembolic event, major or clinically relevant minor bleeding, death	No reporting on any of the outcomes specified in the inclusion criteria
Publication	Written in English; available in full	No English version available; no full text available

AF: atrial fibrillation; DOAC: direct oral anticoagulant; TIA: transient ischaemic attack; VKA: vitamin K antagonist.

patients undergoing these surgeries. However, little is known about the impact of DOACs on short- and long-term outcomes in such patients after surgery. With this systematic review and meta-analysis we aimed to investigate the safety and efficacy of DOACs versus VKAs after surgical repair or biological replacement of heart valves.

3. Methods

The systematic review and meta-analysis were performed according to the 2020 Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement [7].

3.1. Inclusion/exclusion criteria

We included any clinical or observational (prospective or retrospective) study conducted on adult patients (aged ≥ 18 years), who were either receiving a bioprosthetic mitral or aortic valve replacement or were undergoing a mitral or aortic valve repair, that compared the use of DOACs and VKAs in the postoperative period. Studies were excluded if they had an alternative study design or if the pure focus was on transcatheter procedures, mechanical prostheses or exclusively patients with AF. The full inclusion/exclusion criteria are detailed in Table 1.

3.2. Search strategy

A preliminary search was conducted on the PubMed database, using broad search terms related to the topic of interest, which helped to determine keywords for the search strategy. A thorough search for English language papers published before 03 June 2023 was conducted using the online databases PubMed, Scopus and Medline. The specific search strategy for each database is detailed in Appendix A.

3.3. Data collection strategy

All publications derived from the three databases were exported to the screening tool Rayyan® [8], and duplicates with > 95% similarity were removed automatically. Manual inspection was used for all other possible duplicates with < 95% similarity. A two-stage process was used in the manual screening of publications. First, two independent researchers (T. L. and E. P.) screened the titles and abstracts of all publications to remove unrelated literature, and the remaining publications then had their full text screened, adhering to the predefined inclusion/exclusion criteria. In the case of disagreement, a consensus was reached through discussion between the two researchers and a third senior experienced author (V. D. B.), if required. The included publications, as well as papers that underwent full-text screening, then had their reference lists examined for any additional related publications.

3.4. Risk of bias assessment

The assessment of study quality is presented in Appendix B; this was conducted according to the Cochrane Risk of Bias 2 tool for randomized control trials (RCTs) [9] and the Newcastle-Ottawa scale for observational studies, and was converted into Agency for Healthcare Research and Quality (AHRQ) standards [10].

3.5. Outcomes

The primary safety outcomes of interest were short-term thromboembolic events (comprising stroke, transient ischaemic attack, systemic emboli, venous thromboembolism, myocardial infarction and intracardiac thrombi within 90 days of the operation) and short-term bleeding events (defined as a composite of major bleeding, clinically relevant non-major bleeding and reoperation for bleeding at 90 days). The 90-day period for assessing thromboembolic and bleeding events was selected based on the recommended duration for anticoagulation in the guidelines from the USA and Europe [1,2], as this timeframe represents the highest risk period for the occurrence of valve thrombosis [11]. The secondary safety outcomes were all-cause 30-day death rates and mid-term death rates.

3.6. Statistical analysis

Individual study variables and characteristics are presented as counts and percentages for categorical values, and as mean ± standard deviation or median (interquartile range) for continuous numerical variables. The estimation of mean ± standard deviation from median (interquartile range) was done using the Box-Cox method [12]. Short-term death rates and thromboembolic and bleeding event rates were analysed using odds ratio (OR) random effects models, using the Mantel-Haenszel method. The Haldane-Anscombe correction was applied to all cells. Mid-term survival rate analysis was conducted with estimated treatment effect and the relative standard error, which were calculated from the estimated hazard ratio and the log-rank variance [13], obtained directly from the Kaplan-Meier curves of the studies (using WebPlotDigitizer https://automeris.io/WebPlotDigitizer) or from the reported hazard ratio, if available. The heterogeneity between studies was estimated using χ^2-based Q statistics, and I^2 and funnel plots were used to estimate effect estimates for individual studies and potential biases (Fig. A.1, Fig. A.2, Fig. A.3 and Fig. A.4). Additionally, sensitivity (leave-one-out) analysis was conducted to check robustness to influential studies. The alpha error was set at 0.05, and the statistical analysis was conducted in R, version 4.4.0 (The R Project for Statistical Computing, Vienna, Austria; https://www/r-project.org/).

Table 2
Study characteristics.

Study	Year	Study population	Study design	Type of DOAC	Number of patients; DOACs versus warfarin	Mean age (years)[a]; DOACs versus VKAs	AF (%); DOACS versus VKAs
Beller et al. [16]	2020	BVR or CABG	Retrospective	Unspecified	1395 vs. 4668	71 (64–77) vs. 71 (64–77)	98.6 vs. 81.9
Noohi et al. [17]	2020	MV repair	Mixed (PS matched)	Rivaroxaban	104 vs. 104	50.3 ± 12.9 vs. 49.6 ± 15.3	14.4 vs. 17.3
Pasciolla et al. [14]	2020	BVR	Retrospective	Unspecified	127 vs. 70	71.9 ± 9.19 vs. 74.5 ± 9.39	93.7 vs. 91.4
Stuart et al. [19]	2021	BVR	Retrospective	Unspecified	54 vs. 23	68 ± 1.4 vs. 65 ± 8.5	35.2 vs. 39.1
Shim et al. [15]	2023	MV repair or BVR	RCT	Edoxaban	109 vs. 109	67 ± 12.3 vs. 67.7 ± 10	59.6 vs. 61.5
Mazur et al. [18]	2023	MV repair	Retrospective	Apixaban	127 vs. 499	58 (52–66) vs. 58 (50–66)	32.3 vs. 23.4
Schwann et al. [20]	2023	MV repair or mitral BVR ± CABG	Retrospective	Unspecified	1078 vs. 11,421	73 (69–77) vs. 73 (69–77)	71.7 vs. 55

AF: atrial fibrillation; BVR: bioprosthetic valve replacement; CABG: coronary artery bypass graft; DOAC: direct oral anticoagulant; MV: mitral valve; PS: propensity score; RCT: randomized clinical trial; VKA: vitamin K antagonist.
[a] Data are expressed as median (interquartile range) or mean ± standard deviation.

4. Results

The initial search strategy retrieved 1404 references, which were reduced to 882 after the removal of duplicates. After screening of titles and abstracts, 43 papers were assessed and six of them [14–19] met the predetermined inclusion criteria (one RCT [15] and five retrospective studies). One week after the initial selection, a further large retrospective study was published [20], which was then included in the final selection of seven studies. Fig. A.5 shows the PRISMA flowchart of the selection process. Table 2 describes the characteristics of the studies, which included a total of 19,888 patients, with 2994 (15.06%) patients in the DOAC group and the remaining 16,894 (84.94%) patients in the VKA group. The majority of the patients were male (11,711, 58.88%): 62.53% (95% CI: 60.78–64.24%) of the DOAC group and 58.24% (95% CI: 57.49–58.98%) of the VKA group ($P = 0.89$). Patients in the DOAC group were slightly younger (mean age 70.08 years, 95% CI: 69.86–70.31) than those in the VKA group (mean age: 72.45 years, 95% CI: 72.35–72.56; $P = 0.94$). Among the entire set of studies, 12,776 patients were in AF (overall prevalence 64.24%, 95% CI: 63.57–64.90%); notably, patients in the DOAC group were more frequently in AF (80.33%, 95% CI: 78.86–81.71%) than those in the VKA group (61.39%, 95% CI: 60.65–62.12%; $P = 0.02$).

4.1. Thromboembolic events

Six studies [14–16,18–20] reported thromboembolic outcomes (Fig. 1A). The definition of thromboembolic outcome differed between the studies: Beller et al. [16] defined it as postoperative permanent stroke and postoperative venous thromboembolism; Pasciolla et al. [14] defined it as venous thromboembolism; Stuart et al. [19] defined it as a combined outcome, including cerebrovascular accident, transient ischaemic attack, acute coronary syndrome, venous thromboembolism, valve thrombosis or other vascular occlusion; Mazur et al. [18] defined it as stroke and transient ischaemic attack; Schwann et al. [20] defined it as stroke; and Shim et al. defined it as a composite of stroke, myocardial infarction, symptomatic valve thrombosis, systemic embolism, deep vein thrombosis or pulmonary embolism [15]. There were 87 events in the DOAC group (3.09%, 95% CI: 2.51–3.80%) and 454 events in the VKA group (2.86%, 95% CI: 2.62–3.14%). The analysis (Fig. 1A) showed no significant difference in terms of thromboembolic events between the two groups, with an overall OR of 0.82 (95% CI: 0.45–1.49; $P = 0.52$). Leave-one-out sensitivity analysis showed that the study by Beller et al. [16] exerted considerable influence, with its exclusion altering the pooled effect direction without affecting the statistical significance, whereas the exclusion of the study by Schwann et al. [20], although not influencing the direction, impacted the statistical significance (Fig A.6).

4.2. Bleeding events

Bleeding events were reported by seven studies [14–20] (Fig. 1B), and even for this outcome the definition differed between studies: Beller et al. [16] defined bleeding as reoperation for bleeding; Noohi et al. defined it as major or clinically relevant non-major bleeding [17]; Pasciolla et al. [14] defined it as bleeding from a critical site that compromised organ function, a drop in haemoglobin ≥ 2 g/dL, administration of two or more units of packed red blood cells or haemodynamic instability; Stuart et al. [19] defined it as major bleeding, according to the World Health Organization bleeding scale score of ≥ 3; Shim et al. [15] based their definition of major bleeding on the International Society on Thrombosis and Haemostasis criteria; Mazur et al. defined it as reoperation for bleeding and bleeding complications after discharge to 30 days; and Schwann et al. defined it as hospital readmission for bleeding (including haemorrhagic stroke) [20]. Eighty-five bleeding events were recorded in the DOAC group, with a prevalence of 2.92% (95% CI: 2.36–3.59%), and 498 bleeding events were recorded in the VKA group, with a prevalence of 3.12% (95% CI: 2.86–3.4%). The overall random effect model did not find significant differences between the two groups (OR: 0.89, 95% CI: 0.70–1.14; $P = 0.36$).

Leave-one-out sensitivity analysis showed that exclusion of individual studies did not materially change the pooled effect size (Fig. A.7).

4.3. Short-term deaths

Four studies [16,18–20] reported on short-term death (Fig. 2A), defined as death within 30 days of the surgical procedure in three of the studies [16,18,20], and within 90 days in one study [19]. There were a total of 37 events in the DOAC group, with a prevalence of 1.39% (95% CI: 1.01–1.92%), and 148 events in the VKA group, with a prevalence of 0.89% (95% CI: 0.76–1.05%). There was a significantly higher death rate in the DOAC group in the pooled analysis, with an OR of 1.74 (95% CI: 1.13–2.68; $P = 0.01$). This analysis was notably influenced by a single study: the leave-one-out sensitivity analysis indicated that the

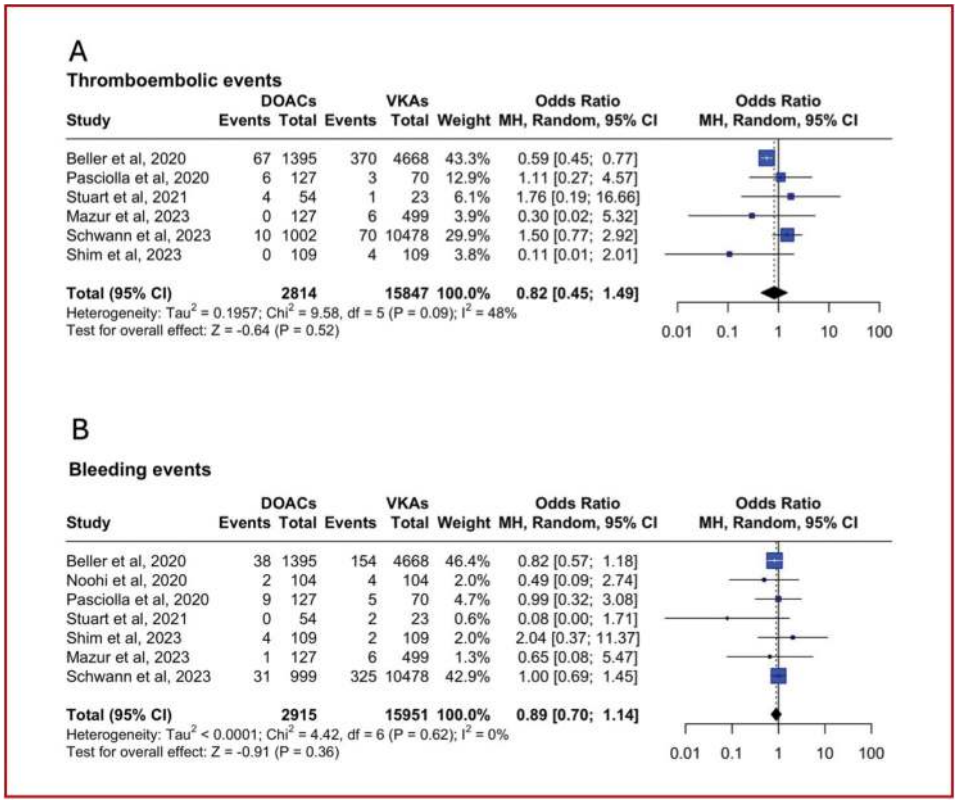


Fig. 1. A–B. Forest plots of short-term primary safety outcomes following administration of direct oral anticoagulants (DOACs) or vitamin K antagonists (VKAs). A. Short-term thromboembolic events. B. Short-term bleeding events. CI: confidence interval; MH: Mantel-Haenszel.

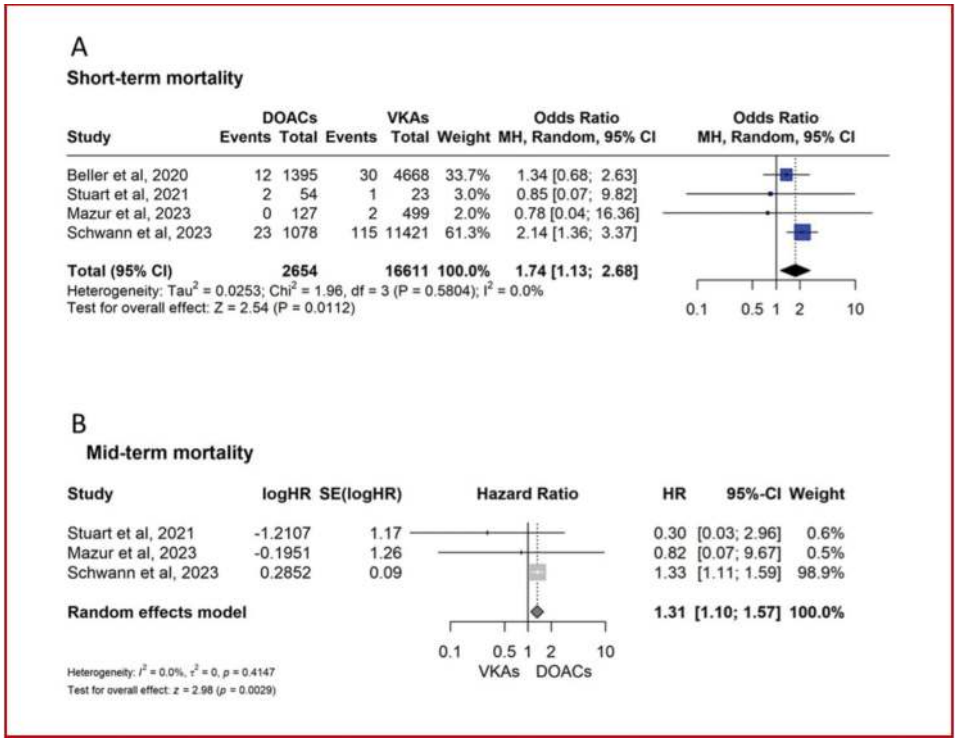


Fig. 2. A–B. Forest plots of short-term primary safety outcomes following administration of direct oral anticoagulants (DOACs) or vitamin K antagonists (VKAs). A. Short-term deaths. B. Mid-term deaths. CI: confidence interval; MH: Mantel-Haenszel.

study by Schwann et al. [20] exerted a marked impact on the pooled estimate, as its exclusion changed the overall effect from statistically significant to non-significant (Fig. A.8).

4.4. Mid-term deaths

Three studies reported mid-term death rates [18–20] (Fig. 2B): Stuart et al. reported this outcome with a follow-up of 180 days, whereas Mazur et al. had a mean follow-up of 3 years and Schwann et al. had a mean follow-up of 7 years. For this outcome, the overall effect was significantly worse for patients in the DOAC group, with a hazard ratio of 1.31 (95% CI: 1.10–1.57; $P < 0.01$) [20]. The pooled effect was notably influenced by two studies [18,20], whose exclusion shifted the overall results toward non-significance (Fig. A.9).

5. Discussion

In recent years, DOACs have been used increasingly as the primary anticoagulation choice for non-valvular AF, and by 2016, DOAC prescriptions exceeded warfarin prescriptions for these patients [21].

Despite this, the indications for DOACs after surgical heart valve replacement are still debated because of the lack of robust data, and although there is evidence from RCTs that contraindicates their use after mechanical valve replacement [22], the evidence for their use after biological valve replacement or repair is still inconsistent. Considering that in a recent nationwide analysis conducted in France, 50.1% of patients admitted with valvular heart disease were still on anticoagulants 1 year after the indexed admission [23], it is particularly important to understand the best anticoagulation treatment for these patients. The first finding of our meta-analysis is that DOACs are non-inferior to VKAs in terms of short-term thromboembolic events and haemorrhagic events. These findings reflect the result of the only available RCT – Efficacy and Safety of Edoxaban in Patients after Heart Valve Repair or Bioprosthetic Valve Replacement (ENAVLE) [15] – which randomized 218 patients (109 to receive VKAs and 109 to receive edoxaban), and showed no deaths in either group, but most importantly demonstrated the non-inferiority of edoxaban in terms of safety and efficacy in patients undergoing biological valve replacement or repair [15], with similar thromboembolic and bleeding events in the first 90 days after surgery. In our analysis, we found similar results in terms of thromboembolic and bleeding event rates, with a low incidence of embolic events (3.09% vs. 2.86%) and bleeding events (2.92% vs. 3.12%) in both the DOAC and VKA groups, supporting the non-inferiority of DOACs after this type of surgery. This observation has relevant implications for surgical patients, because of the ease of use of DOACs compared with VKAs, and therefore the improved compliance of the patients. On the other hand, our pooled analysis showed higher short-term and mid-term death rates in the DOAC group. This is an unexpected finding that is in contrast with other studies conducted in non-valvular AF [24]. Moreover, another previous meta-analysis of RCTs in non-surgical patients supported the safety and efficacy of DOACs, with no excess bleeding and efficacy equal to or greater than conventional therapy [25]. In our meta-analysis, the higher postoperative death rate is mostly driven by a large retrospective analysis [20] and therefore is it difficult to generalize, and should be considered with caution, as it is a representation of a very asymmetrical study population. However, the study by Schwann et al. [20] was a large retrospective report from the Society of Thoracic Surgeons database, which included 26,199 patients undergoing biological mitral valve replacement or repair over a 7-year period, and showed that DOACs were associated with significantly increased risks of death and bleeding, and were not protective against stroke [20]. This study was conducted only on mitral valve surgeries; in our meta-analysis we compared VKAs and DOACs across all patients undergoing valve cardiac surgery. However, mitral and aortic valve diseases present different pathophysiological profiles and different prothrombotic environments, with mitral valve surgery being inherently associated with a higher risk of events, and sometimes catastrophic outcomes [26]. This difference could have influenced the results, particularly the observed higher risk of death, despite no significant difference being observed in terms of ischaemic events. In contrast, another large retrospective analysis [16] supported the safety of DOACs in the cardiac surgery setting, with shorter postoperative hospital stays. Both studies identified a significant increasing trend in DOAC usage over recent years [16,20], mostly driven by patients who were already in AF before surgery. It is important that these data are considered, and therefore a word of caution is needed before supporting the use of DOACs after biological or repair valve surgery, as these patients should not be viewed in the same way as those with non-valvular AF. Most importantly, our study confirms the lack of consistency of the research in this field, with most studies being retrospective, and only one RCT being currently available. Moreover, the studies were considering several different types of DOACs, and in some cases these were not specified. Another important limitation is the extensive variability in populations analysed, follow-up timelines and definitions of thromboembolic events and major bleeding between the studies, which inevitably hinders the results of the current meta-analysis, especially in terms of short- and mid-term death data, which were mostly influenced by one study [20]. Finally, a limitation to consider is related to the inclusion of mitral and aortic valve surgeries, hence including the important differences between these two different diseases and their surgical treatment.

6. Conclusions

In conclusion, our meta-analysis showed a similar incidence of thromboembolic and bleeding events in patients receiving DOACs versus VKAs after biological heart valve replacement or valve repair. Further randomized controlled trials are required to better define indications and the safety and efficacy of DOACs in patients with biological heart valve prostheses or repair (Central Illustration).

Background

Do DOACs reduce bleeding and embolic events after heart valve biological replacement or repair ?

Results

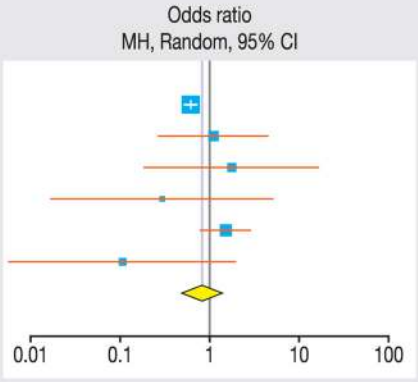
A

Thromboembolic events

Study	DOACs Events	DOACs Total	VKAs Events	VKAs Total	Weight	Odds ratio MH, Random, 95% CI
Beller et al, 2020	67	1,395	370	4,668	43.3%	0.59 [0.45-0.77]
Pasciolla et al, 2020	6	127	3	70	12.9%	1.11 [0.27-4.57]
Stuart et al, 2021	4	54	1	23	6.1%	1.76 [0.19-16.66]
Mazur et al, 2023	0	127	6	499	3.9%	0.30 [0.02-5.32]
Schwann et al, 2023	10	1,002	70	10,478	29.9%	1.50 [0.77-2.92]
Shim et al, 2023	0	109	4	109	3.8%	0.11 [0.01-2.01]
Total (95% CI)		**2,814**		**15,847**	**100%**	**0.82 [0.45-1.49]**

Heterogeneity: $Tau^2 = 0.1957$; $Chi^2 = 9.58$; df = 5 ($P = 0.09$) ; $I^2 = 48\%$

Test for overall effect: Z = -0.64 ($P = 0.52$)



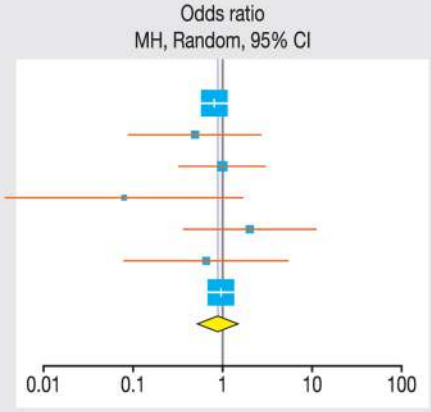
B

Bleeding events

Study	DOACs Events	DOACs Total	VKAs Events	VKAs Total	Weight	Odds ratio MH, Random, 95% CI
Beller et al, 2020	38	1,395	154	4,668	46.4%	0.82 [0.57-1.18]
Noohi et al, 2020	2	104	4	104	2.0%	0.49 [0.09-2.74]
Pasciolla et al, 2020	9	127	5	70	4.7%	0.99 [0.32-3.08]
Stuart et al, 2021	0	54	2	23	0.6%	0.08 [0.00-1.71]
Shim et al, 2023	4	109	2	109	2.0%	2.04 [0.37-11.37]
Mazur et al, 2023	1	127	6	499	1.3%	0.65 [0.08-5.47]
Schwann et al, 2023	31	999	325	10,478	42.9%	1.00 [0.69-1.45]
Total (95% CI)		**2.915**		**15,951**	**100%**	**0.89 [0.70-1.14]**

Heterogeneity: $Tau^2 < 0.0001$; $Chi^2 = 4.42$; df = 6 ($P = 0.62$) ; $I^2 = 0\%$

Test for overall effect: Z = -0.91 ($P = 0.36$)



Similar (A) embolic and (B) bleeding events for DOACs and VKAs, but worse mid-term survival rates for DOACs: HR 1.31, 95% CI [1.10-1.57] (P= 0.003).

Conclusions

No difference between DOACs and VKAs in terms of reducing thromboembolic and bleeding events. Further studies are needed to establish the optimal anticoagulation regimen in this context.

Central Illustration. Direct oral anticoagulants (DOACs) versus vitamin K antagonists (VKAs) after heart valve bioprosthetic replacement or repair: a systematic review and meta-analysis. CI: confidence interval; HR: hazard ratio.

Sources of funding

No funding was obtained for the development of this study.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.acvd.2025.11.012.

Disclosure of interest

The authors declare that they have no competing interest.

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