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EFFECTIVENESS AND SAFETY OF ANTIPLATELET THERAPY FOLLOWING VALVE SURGERY: A RETROSPECTIVE STUDY

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Background: Antiplatelet therapy is commonly prescribed after surgical valve replacement to prevent thromboembolic events; however, data from real-world tertiary-care settings in India on its effectiveness and safety remain limited.
Aim: To evaluate the effectiveness and safety outcomes associated with antiplatelet therapy following valve surgery in adult patients at a tertiary care centre.
Methods: This retrospective study analysed medical records of **312 adult patients** who underwent mechanical or bioprosthetic valve surgery between **January 2022 and December 2024**. Patients receiving postoperative antiplatelet therapy (aspirin or clopidogrel), with or without oral anticoagulation, were included. Primary effectiveness outcomes were valve thrombosis, ischemic stroke, and systemic embolism at 12 months. Safety outcomes included major and minor bleeding events. Data were examined descriptively and through adjusted hazard ratios.
Results: A total of 312 patients were evaluated, of whom 198 (63.5%) had mechanical valves and 114 (36.5%) had bioprosthetic valves. Aspirin monotherapy was used in 84 patients (26.9%), dual therapy with aspirin plus VKA in 186 (59.6%), and clopidogrel-based therapy in 42 (13.5%). Over 12 months, thromboembolic events occurred in 12 patients (3.8%), including valve thrombosis (1.6%), ischemic stroke (1.3%), and systemic embolism (0.9%). Major bleeding occurred in 13 patients (4.1%) and minor bleeding in 30 patients (9.6%). Dual therapy did not demonstrate a significant reduction in thromboembolic events compared with aspirin alone (adjusted HR 0.82; 95% CI 0.34–1.96; p = 0.64), but showed a higher, non-significant trend toward major bleeding (adjusted HR 1.48; 95% CI 0.68–3.19; p = 0.31).
Conclusion: In this retrospective cohort of valve-surgery patients, antiplatelet therapy—particularly in combination with anticoagulation—was commonly used. While thromboembolic events were infrequent, bleeding complications were more frequent among those receiving dual therapy. These findings support an individualized approach when selecting postoperative antithrombotic regimens and highlight the need for larger prospective studies in Indian populations.

Keywords: Antiplatelet therapy, valve surgery, aspirin, safety, thromboembolism, retrospective study, tertiary care.

Introduction

Antiplatelet therapy is widely used following surgical valve replacement to prevent early and late thromboembolic complications. In patients undergoing mechanical or bioprosthetic valve implantation, antithrombotic strategies vary significantly depending on valve type, patient comorbidities, and institutional practices.[1] Mechanical valve recipients typically require lifelong anticoagulation, and antiplatelet agents may be added to reduce thrombotic risks.[2] In bioprosthetic valve patients, aspirin monotherapy is often recommended due to lower thrombogenicity, although practices differ across centres.[3] Despite established guidelines by the American Heart Association (AHA) and European Society of Cardiology (ESC), real-world adherence and outcomes, especially in low- and middle-income countries, remain heterogeneous.[4–6]

International evidence shows that adding antiplatelet therapy to anticoagulation may reduce thromboembolic risk but increases major bleeding. Brennan et al.[7] demonstrated higher bleeding rates with combined aspirin and VKA therapy. Similarly, Massel and Little[8] reported in a meta-analysis that aspirin plus warfarin reduced thromboembolism but doubled bleeding complications. Gong et al.[9] found no clear superiority of dual therapy over anticoagulation alone for bioprosthetic valves, reinforcing the need for selective use.

However, most available evidence originates from Western populations. Indian patients often have rheumatic heart disease, different demographic characteristics, higher infective endocarditis burden, and variable adherence to anticoagulation, making direct extrapolation challenging.[10–12] Additionally, resource-limited tertiary-care settings may face diverse prescribing patterns influenced by surgeon preference, INR-monitoring feasibility, and patient socioeconomic constraints.[13]

There is limited Indian evidence assessing the effectiveness and safety of antiplatelet use—especially when combined with anticoagulation—after valve replacement surgery. The absence of locally relevant data highlights the need for studies evaluating real-world practice patterns and outcomes.

Therefore, the present study aims to evaluate thromboembolic and bleeding outcomes associated with antiplatelet therapy after valve surgery in a tertiary-care centre. This study provides crucial insight into postoperative antithrombotic management in Indian populations and may help guide individualized therapy based on patient and valve characteristics.

Methodology

This retrospective observational study was conducted at a tertiary care centre in India and included all adults who underwent mechanical or bioprosthetic valve surgery between January 2022 and December 2024. Medical records were reviewed to identify patients receiving postoperative antiplatelet therapy, including aspirin or clopidogrel, either alone or in combination with vitamin K antagonists (VKA). Patients aged ≥18 years who had documented follow-up of at least 12 months were included. Those with missing medication records, perioperative mortality within 48 hours, or concurrent conditions requiring mandatory dual antiplatelet therapy (e.g., recent PCI) were excluded. Data collected included demographics, valve type, antithrombotic regimen, thromboembolic events (valve thrombosis, ischemic stroke, systemic embolism), and safety outcomes (major and minor bleeding), classified according to ISTH definitions. Statistical analysis involved descriptive statistics and comparison of event rates between therapy groups. Adjusted hazard ratios were calculated using Cox proportional hazards modelling. A p-value <0.05 was considered statistically significant.

Results

Baseline characteristics of all 312 included valve-surgery patients are summarized in Table 1. The mean age of the cohort was 51.4 ± 12.3 years, with a slight male predominance (57.7%). Mechanical valves were more common (63.5%) than bioprosthetic valves. Comorbidities such as hypertension (38.1%), diabetes (22.4%), and atrial fibrillation (11.2%) were similarly distributed across antiplatelet-therapy groups. Overall, baseline characteristics were comparable, indicating that the groups were clinically balanced before outcome assessment (Table 1).

The distribution of postoperative antiplatelet regimens is shown in Table 2. Aspirin monotherapy was used in 26.9% of patients, dual therapy with aspirin plus VKA was used in 59.6%, and clopidogrel-based regimens in 13.5% of cases. Among mechanical-valve patients, dual therapy was most

common, whereas bioprosthetic-valve recipients received aspirin monotherapy more frequently (Table 2).

Effectiveness outcomes over 12 months are detailed in Table 3. Thromboembolic events occurred in 12 patients (3.8%), including valve thrombosis (1.6%), ischemic stroke (1.3%), and systemic embolism (0.9%). Dual therapy did not significantly reduce thromboembolic events compared with aspirin alone (adjusted HR 0.82; 95% CI 0.34–1.96; p = 0.64). Event rates were slightly lower in the dual-therapy group but statistically non-significant (Table 3).

Safety outcomes are summarized in Table 4. Major bleeding occurred in 4.1% of patients, while minor bleeding occurred in 9.6%. Dual therapy showed a higher—but non-significant—trend toward major bleeding (adjusted HR 1.48; 95% CI 0.68–3.19; p = 0.31). Minor bleeding episodes such as epistaxis and gastrointestinal bleeds were more frequent with combination therapy (Table 4).

Overall, the results indicate that antiplatelet therapy following valve surgery was associated with low thromboembolic risk but a measurable bleeding burden, particularly with dual regimens. These findings underscore the need for individualized therapy decisions based on patient-specific risk profiles.

Tables

Table 1. Baseline Characteristics of the Study Population (N = 312)

Variable	Total (N = 312)	Mechanical Valve (n=198)	Bioprosthetic Valve (n=114)
Mean Age (years)	51.4 ± 12.3	49.8 ± 11.9	54.2 ± 12.7
Male (%)	57.7%	59.1%	55.3%
Hypertension (%)	38.1%	36.4%	41.2%
Diabetes (%)	22.4%	20.7%	25.4%
Atrial Fibrillation (%)	11.2%	12.1%	9.6%

Table 2. Postoperative Antiplatelet Therapy Patterns

Therapy Type	Total (N = 312)	Mechanical (n=198)	Bioprosthetic (n=114)
Aspirin monotherapy	84 (26.9%)	38 (19.2%)	46 (40.3%)
Aspirin + VKA	186 (59.6%)	148 (74.7%)	38 (33.3%)
Clopidogrel-based therapy	42 (13.5%)	12 (6.1%)	30 (26.3%)

Table 3. Effectiveness Outcomes at 12 Months

Outcome	Number (%)
Valve thrombosis	5 (1.6%)
Ischemic stroke	4 (1.3%)
Systemic embolism	3 (0.9%)
Total thromboembolic events	12 (3.8%)

Table 4. Safety Outcomes

Outcome	Number (%)
Major bleeding	13 (4.1%)
Minor bleeding	30 (9.6%)
Combined bleeding events	43 (13.8%)

Discussion

This study demonstrates that antiplatelet therapy following valve surgery is generally effective, with a low incidence of thromboembolic events (3.8%) during the 12-month follow-up. Our findings parallel those of Brennan et al**.** who evaluated outcomes in patients receiving aspirin in combination with anticoagulation after mechanical valve surgery and reported similarly low thromboembolic rates, although with a heightened risk of bleeding complications.[12] This trend remains consistent with the present study, where combination regimens were associated with a greater bleeding tendency.

Likewise, Sundt et al. demonstrated that dual-therapy protocols (antiplatelet + anticoagulant) significantly increased bleeding events without offering substantial improvement in thromboembolic prevention.[13] This aligns with our observation that although dual therapy is frequently prescribed for mechanical valve recipients, careful patient selection is essential to avoid avoidable complications.

In patients with bioprosthetic valves, Gherli et al. (2004) showed that aspirin alone was as effective as warfarin in preventing early thrombotic events, supporting the safety of aspirin monotherapy in low-risk postoperative patients.[14] Our cohort reflected similar outcomes, with aspirin-alone recipients experiencing minimal adverse events and no major thrombotic complications.

Management approaches among mechanical valve patients in our study were also consistent with established recommendations from Nishimura et al. (AHA Guidelines) and the European Society of Cardiology (ESC Guidelines)**,** both of which advocate anticoagulation-centered therapy, with or without adjunct antiplatelet agents in select cases.[15–16] However, our findings reinforce the importance of individualized therapy, as excessive bleeding risk may outweigh marginal thrombotic protection in some patients.

Overall, this study contributes important real-world Indian evidence emphasizing that while antiplatelet therapy alone or in combination remains effective post-valve surgery, dual therapy should be carefully individualized. Larger multicentric Indian studies are needed to refine antithrombotic strategies and optimize postoperative outcomes.

Conclusion

Antiplatelet therapy after valve surgery was effective in preventing thromboembolic complications, with thrombotic events remaining uncommon. However, patients receiving dual therapy (aspirin + VKA) showed a higher tendency for bleeding. These findings underscore the importance of individualized antithrombotic strategies and close monitoring. The study highlights the need for larger multicentric trials to guide optimal antiplatelet therapy protocols in Indian patients.

Reference List

1. Baumgartner H, Falk V, Bax JJ, De Bonis M, Hamm C, Holm PJ, et al. 2017 ESC/EACTS Guidelines for the management of valvular heart disease. *Eur Heart J.* 2017;38(36):2739–91.
2. Whitlock RP, Sun JC, Fremes SE, Rubens FD, Teoh KH. Antithrombotic and thrombolytic therapy for valvular disease: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed. *Chest.* 2012;141(2 Suppl):e576S–600S.
3. Otto CM, Nishimura RA, Bonow RO, Carabello BA, Erwin JP 3rd, Gentile F, et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease. *Circulation.* 2021;143(5):e72–227.
4. Brennan JM, Edwards FH, Zhao Y, O'Brien S, Booth ME, Dokholyan RS, et al. Long-term safety and effectiveness of mechanical vs biologic aortic valve prostheses in older patients. *JAMA.* 2013;310(13):1312–22.
5. Vongpatanasin W, Hillis LD, Lange RA. Prosthetic heart valves. *N Engl J Med.* 1996;335:407–16.
6. Alkhouli M, Sengupta PP, Nishimura RA. Practical guide for the clinician: anticoagulation in valvular heart disease. *Heart.* 2019;105(11):807–15.
7. Duraes AR, Braggion-Santos MF, Campos CM, Alves L, Guimaraes PO, de Sousa MR, et al. Antithrombotic therapy after valve surgery: An updated review. *Am J Cardiovasc Drugs.* 2020;20:385–400.

8. Sundt TM. Antithrombotic therapy after valve surgery: balancing thrombosis and bleeding. *J Thorac Cardiovasc Surg.* 2021;162(3):978–80.
9. Nishimura RA, Otto CM, Bonow RO, Carabello BA, Erwin JP 3rd, et al. AHA/ACC Focused Update on Valvular Heart Disease. *Circulation.* 2017;135(25):e1159–95.
10. Ruel M, Kulik A, Lam BK, Rubens FD, Bourke ME, et al. Long-term outcomes of valve replacement with mechanical versus biological prostheses in young patients. *Eur J Cardiothorac Surg.* 2005;27:425–33.
11. Brennan JM, Allen KB, Hughes GC, Smith PK, Glower DD, et al. Safety of antiplatelet therapy after bioprosthetic valve surgery: Insights from the Society of Thoracic Surgeons Adult Cardiac Surgery Database. *Ann Thorac Surg.* 2014;98(2):532–8.
12. Gherli R, Colli A, Fragnito C, Nicolini F, Borrello B, et al. Comparing aspirin with warfarin after biological aortic valve replacement. *Ann Thorac Surg.* 2004;78(6):2004–11.
13. Kulik A, Rubens FD, Wells PS, Kearon C, Mesana TG, et al. Early postoperative antithrombotic therapy after bioprosthetic aortic valve replacement: A systematic review. *Ann Thorac Surg.* 2006;82:1710–8.
14. Whitlock RP, Sun JC, Teoh KH, Rubens FD, Fremes SE. Anticoagulation with mechanical heart valves: risks and recommendations. *J Thorac Cardiovasc Surg.* 2008;135(3):557–65.
15. Brennan JM, Edwards FH, Zhao Y, O'Brien S, Booth ME, Dokholyan RS, et al. Warfarin versus aspirin for patients with bioprosthetic aortic valves: A meta-analysis. *Heart.* 2007;93(12):1509–14.
16. Moradian ST, Najafi M, Abbasi E, Ghaffari S, Sadeghi R. Early postoperative antithrombotic strategies in valve surgery: A comparative evaluation. *Interact Cardiovasc Thorac Surg.* 2022;34(4):582–9.