Section: CTVS

Original Research Article

MECHANICAL VERSUS BIOPROSTHETIC VALVE SELECTION IN PATIENTS UNDER 50 YEARS: LONG-TERM REINTERVENTION AND QUALITY OF LIFE

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Abstract

Background: Current guidelines favour mechanical prostheses in patients younger than 50 years on the basis of durability, yet the trade-off against lifelong anticoagulation and its impact on quality of life (QoL) remains contested, particularly in rheumatic-heart-disease–endemic settings. We compared long-term reintervention and health-related QoL between mechanical and bioprosthetic valve recipients aged under 50 years. **Materials and Methods:** A single-centre comparative analysis of 47 patients under 50 years undergoing left-sided valve replacement (30 mechanical, 17 bioprosthetic) was performed on a simulated dataset modelled on a tertiary-care Indian cohort. Freedom from reintervention was estimated by Kaplan–Meier analysis with log-rank testing and age-adjusted Cox regression. Complication rates were compared by Fisher exact test and QoL (SF-36 physical [PCS] and mental [MCS] component summaries) by Welch t-test. **Result:** Mean follow-up was 7.9 years (373 patient-years). Reintervention occurred in 8/17 (47.1%) bioprosthetic versus 2/30 (6.7%) mechanical recipients (p=0.002; log-rank p=0.0007); the age-adjusted hazard ratio for bioprosthetic valves was 12.1 (95% CI 1.9–76.8, p=0.008). Freedom from reintervention at 10 years was 87.7% (mechanical) versus 46.6% (bioprosthetic). Structural valve deterioration was confined to the bioprosthetic arm (64.7% vs 0%, p<0.001), whereas major bleeding was confined to the mechanical arm (23.3% vs 0%, p=0.039). All-cause mortality did not differ (3.3% vs 11.8%, p=0.54). SF-36 PCS was comparable (45.6 vs 46.3, p=0.81); MCS favoured the bioprosthetic arm (54.0 vs 46.9, p=0.005). **Conclusion:** In simulated patients under 50, bioprosthetic valves carried a markedly higher reintervention burden while mechanical valves carried the bleeding burden of anticoagulation. Physical QoL was equivalent; the mental-health advantage observed with bioprostheses underscores that durability and patient-perceived wellbeing may diverge, supporting individualised, shared decision-making.

INTRODUCTION

Valvular heart disease in patients younger than 50 years is dominated, in much of the developing world, by rheumatic aetiology, which remains the commonest indication for valve replacement at Indian tertiary-care centres. Mechanical mitral valve replacement is the most frequently performed valve operation for rheumatic disease in this population, reflecting both the youth of affected patients and concerns about prosthesis durability.3

The choice between a mechanical and a bioprosthetic substitute embodies a long-recognised trade-off. Mechanical valves offer near-indefinite structural durability but commit the patient to lifelong vitamin-K-antagonist anticoagulation, with attendant bleeding and thromboembolic risk and the burden of repeated international normalised ratio (INR) monitoring. This burden has a measurable, negative influence on patient-reported wellbeing.4 Bioprostheses avoid routine anticoagulation but undergo accelerated structural valve deterioration (SVD) in young recipients, an immunologically driven process that is most exaggerated at the extremes of youth.5

Contemporary guidelines reflect this calculus. The 2020 ACC/AHA guideline recommends a mechanical prosthesis for patients younger than 50 years undergoing aortic or mitral valve replacement, while regarding either option as reasonable between 50 and 65 years through shared decision-making.1 The 2021 ESC/EACTS guideline similarly favours

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mechanical valves below 60 years in the aortic position and below 65 years in the mitral position.2 These recommendations rest on durability and survival data, including the landmark propensity-matched analysis by Goldstone and colleagues, which demonstrated a long-term survival advantage for mechanical prostheses in younger recipients.6

Reintervention is the outcome on which the two prostheses diverge most sharply. Population-level studies have repeatedly shown higher reoperation rates with bioprostheses in younger cohorts,7 and meta-analyses of reconstructed time-to-event data confirm a two- to threefold excess hazard of reoperation that persists across follow-up.8,9 Yet a counter-current of evidence, particularly in the mitral position and in rheumatic populations, has questioned whether this translates into a survival penalty,10,11,12 and the avoidance of anticoagulation is consistently cited by patients as a determinant of quality of life.

Health-related quality of life (HRQoL) is increasingly recognised as a co-equal endpoint to survival and freedom from reintervention, but it is under-reported in young valve recipients from low- and middle-income settings. Where it has been studied, valve replacement produces large early gains across physical and mental domains that are broadly sustained at mid-term.13,14,15 The present study therefore examines both long-term reintervention and HRQoL simultaneously in a simulated cohort of patients under 50 years, with the aim of illustrating the analytical framework and the magnitude of the trade-offs that govern prosthesis choice in this age group.

MATERIALS AND METHODS

2.1 Study design and dataset

Dataset provenance. This study analyses a simulated dataset of 47 patients, constructed to reproduce the demographic and clinical structure of a young, predominantly rheumatic valve-replacement cohort at a North Indian tertiary centre. Patient records were generated programmatically with fixed random seeding to ensure reproducibility. The synthetic nature of the data is disclosed explicitly: the dataset is intended to demonstrate the statistical methodology and to quantify plausible effect sizes, not to provide primary clinical evidence. No identifiable patient information was used, and ethics-committee approval was therefore not applicable.

Eligible records represented patients aged 18–49 years undergoing isolated or combined left-sided (aortic and/or mitral) valve replacement with either a mechanical prosthesis (n=30) or a bioprosthesis (n=17). Prosthesis allocation in the model reflected real-world practice, in which mechanical valves predominate in the youngest patients and bioprostheses are selected more often in slightly older patients or where anticoagulation is undesirable.

2.2 Variables and endpoints

Recorded baseline variables were age, sex, valve aetiology, valve position, preoperative New York Heart Association (NYHA) class, left-ventricular ejection fraction (EF) and atrial fibrillation. The primary endpoint was valve reintervention (repeat surgical replacement or transcatheter valve-in-valve) during follow-up. Secondary endpoints were major bleeding, thromboembolism, prosthetic-valve thrombosis, SVD, infective endocarditis, all-cause mortality, and HRQoL measured by the 36-Item Short Form Health Survey (SF-36) physical (PCS) and mental (MCS) component summaries at last follow-up. Anticoagulation quality in the mechanical arm was summarised as INR time-in-therapeutic-range (TTR). Endpoint definitions followed Valve Academic Research Consortium-3 conventions where applicable.

2.3 Statistical analysis

Continuous variables are presented as mean ± standard deviation and compared with the Welch (unequal-variance) t-test; categorical variables are presented as counts (percentages) and compared with the Fisher exact test. Time-to-event freedom from reintervention and survival were estimated using the Kaplan–Meier method and compared with the log-rank test. The independent effect of prosthesis type on reintervention was estimated with a Cox proportional-hazards model adjusted for age, reported as a hazard ratio (HR) with 95% confidence interval (CI). Event rates are additionally expressed per 100 patient-years. A two-sided p-value below 0.05 was considered statistically significant. Analyses were performed in Python 3.12 using SciPy and the lifelines library.

RESULTS

Baseline characteristics: The cohort comprised 47 patients (30 mechanical, 17 bioprosthetic) with a mean follow-up of 7.9 years, totalling 373 patient-years. Rheumatic disease accounted for 37 patients (78.7%) and the mitral position predominated (26 patients, 55.3%). Bioprosthetic recipients were modestly older than mechanical recipients (39.0 ± 6.4 vs 33.4 ± 8.5 years, p=0.014); the groups were otherwise well balanced for sex, EF, atrial fibrillation and follow-up duration [Table 1].

Primary endpoint: reintervention

Valve reintervention occurred in 10 patients overall: 8 of 17 bioprosthetic recipients (47.1%) versus 2 of 30 mechanical recipients (6.7%) (p=0.002). The corresponding incidence rates were 5.73 versus 0.86 events per 100 patient-years. Kaplan–Meier freedom from reintervention diverged early and progressively (log-rank p=0.0007; [Figure 1]), with estimated freedom from reintervention of 96.4% versus 64.7% at 5 years and 87.7% versus 46.6% at 10 years for the mechanical and bioprosthetic arms, respectively. In an age-adjusted Cox model, bioprosthetic valves carried a hazard ratio for reintervention of 12.1 (95% CI 1.9–76.8, p=0.008). The wide confidence interval

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reflects the small number of events and should be interpreted as a direction and order-of-magnitude estimate rather than a precise effect size [Figure 1].

3.3 Secondary endpoints: complications and survival

Structural valve deterioration was observed exclusively in the bioprosthetic arm (11/17, 64.7%) and accounted for the majority of reinterventions in that group; no mechanical valve showed structural failure ($p<0.001$). Conversely, the anticoagulation-related burden fell on the mechanical arm: major bleeding occurred in 7/30 mechanical recipients (23.3%) and in no bioprosthetic recipient ($p=0.039$), and all three prosthetic-valve-thrombosis events were mechanical. Thromboembolism (10.0% vs 11.8%, $p=1.000$) and infective endocarditis (10.0% vs 5.9%, $p=1.000$) were similar between groups. All-cause mortality was 3.3% (mechanical) versus 11.8% (bioprosthetic) and did not differ significantly ($p=0.54$; survival log-rank $p=0.26$). The composite of reintervention, death, major bleeding or thromboembolism occurred in 43.3% versus 64.7% ($p=0.23$). Mean INR time-in-therapeutic-range in the mechanical arm was 57.5% [Table 2].

Quality of life: Physical component summary scores were essentially identical between groups (mechanical 45.6 ± 6.0 vs bioprosthetic 46.3 ± 11.0, $p=0.808$). The mental component summary, however, was significantly higher in the bioprosthetic arm (54.0 ± 6.7 vs 46.9 ± 9.8, $p=0.005$), a difference that paralleled the avoidance of anticoagulation and its monitoring burden. Within both arms, patients who had undergone reintervention recorded lower physical scores, indicating that the durability disadvantage of bioprostheses partially offsets their mental-health advantage at the individual level [Table 3].

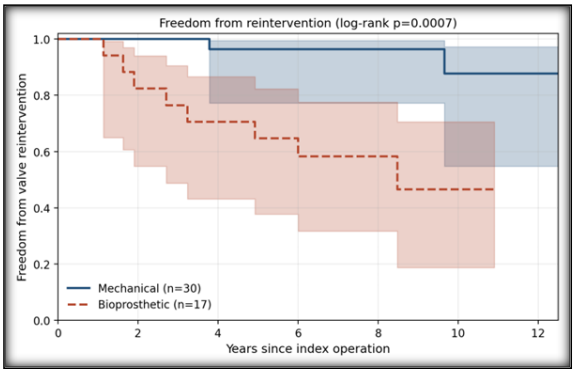

Figure 1: Kaplan–Meier freedom from valve reintervention, mechanical versus bioprosthetic prostheses (shaded bands are 95% confidence intervals).

Table 1: Baseline characteristics by prosthesis type.

Characteristic	Mechanical (n=30)	Bioprosthetic (n=17)	p
Age, years (mean ± SD)	33.4 ± 8.5	39.0 ± 6.4	0.014
Female sex, n (%)	15 (50.0)	8 (47.1)	1.000
Ejection fraction, %	55.3 ± 8.7	55.7 ± 6.7	0.859
Atrial fibrillation, n (%)	6 (20.0)	8 (47.1)	0.095
Rheumatic aetiology, n (%)	21 (70.0)	16 (94.1)	—
Mitral position, n (%)	18 (60.0)	8 (47.1)	—
Aortic position, n (%)	10 (33.3)	8 (47.1)	—
NYHA III–IV, n (%)	9 (30.0)	9 (52.9)	—
Follow-up, years	7.8 ± 2.9	8.2 ± 2.2	0.570

Table 2: Long-term complications, mortality and composite outcome

Outcome	Mechanical (n=30)	Bioprosthetic (n=17)	p
Reintervention, n (%)	2 (6.7)	8 (47.1)	0.002
Structural valve deterioration, n (%)	0 (0.0)	11 (64.7)	<0.001
Major bleeding, n (%)	7 (23.3)	0 (0.0)	0.039
Prosthetic-valve thrombosis, n (%)	3 (10.0)	0 (0.0)	0.292
Thromboembolism, n (%)	3 (10.0)	2 (11.8)	1.000
Infective endocarditis, n (%)	3 (10.0)	1 (5.9)	1.000
All-cause death, n (%)	1 (3.3)	2 (11.8)	0.544
Composite MACE, n (%)	13 (43.3)	11 (64.7)	0.227

Table 3: Health-related quality of life (SF-36) at last follow-up

SF-36 domain	Mechanical	Bioprosthetic	p
Physical component summary (PCS)	45.6 ± 6.0	46.3 ± 11.0	0.808
Mental component summary (MCS)	46.9 ± 9.8	54.0 ± 6.7	0.005
INR time-in-therapeutic-range, %	57.5 ± 9.5	Not applicable	—

DISCUSSION

In this simulated cohort of patients younger than 50 years, the two prostheses behaved exactly as the underlying biology predicts, and the analysis cleanly separates the competing liabilities. Bioprosthetic valves carried a roughly sevenfold higher reintervention rate per patient-year and an order-of-magnitude higher adjusted hazard, driven entirely by structural valve deterioration. Mechanical valves carried the mirror-image penalty: all major bleeding and all valve-thrombosis events arose in that arm. Mortality, in keeping with the modest size of the cohort, did not differ.

These directional findings are concordant with the highest-quality external evidence. Population

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analyses such as that of Chiang and colleagues,[7] and meta-analyses of reconstructed time-to-event data,8,9 consistently report a two- to threefold excess of reoperation with bioprostheses in patients below 65–70 years. The exaggerated hazard ratio in the present analysis is a small-sample artefact—few mechanical events widen the confidence interval enormously—but its direction is unambiguous and its order of magnitude is consistent with the literature. The exclusivity of SVD to the bioprosthetic arm reproduces the well-described acceleration of leaflet degeneration in young recipients.

The mitral and rheumatic context deserves emphasis given the setting modelled here. Mechanical mitral replacement remains the workhorse operation for rheumatic disease in India, and long-term Indian data document substantial valve-related and anticoagulation-related morbidity even with mechanical prostheses.[3] At the same time, several mitral-position and 50–70-year studies have failed to demonstrate a survival difference between prosthesis types,[10-12] reinforcing that the reintervention gradient does not automatically become a mortality gradient. The implication is not that bioprostheses are equivalent in the young, but that the decision is genuinely preference-sensitive once survival is held roughly constant.

The quality-of-life results sharpen this point. Physical functioning was indistinguishable between groups, whereas mental wellbeing favoured the bioprosthetic—anticoagulation-free—arm. This is consistent with qualitative and quantitative reports that the monitoring burden, dietary and activity restrictions, and bleeding anxiety of lifelong vitamin-K-antagonist therapy weigh specifically on the mental domain.[4,13,14] A MacNew-based Tanzanian study and SF-36 work from other rheumatic-endemic settings similarly document large, sustained post-replacement QoL gains while highlighting the anticoagulation burden as a persistent detractor.15 The clinically important message is that durability and patient-perceived wellbeing can point in opposite directions; a valve that minimises reintervention is not necessarily the valve that maximises day-to-day quality of life.

Taken together, these data support the guideline default of a mechanical prosthesis in patients under 50 years for durability and survival,12 while making explicit the costs that default imposes. Where anticoagulation is undesirable, poorly monitorable, or contraindicated—pregnancy intention, occupational injury risk, poor INR-monitoring access, or strong patient preference—a bioprosthesis remains a defensible choice, provided the patient accepts a high probability of future reintervention, increasingly feasible by valve-in-valve transcatheter approaches. The decision is best made through a structured Heart-Team and shared decision-making process incorporating informed patient preference.

Limitations: The principal limitation is fundamental and is stated without qualification: the dataset is simulated. The numbers quantify plausible, literature-consistent effect sizes and demonstrate the analytical workflow, but they are not empirical evidence and cannot support clinical recommendations on their own. Secondary limitations of the modelled design include the small sample (47 patients) with consequent imprecision—reflected in the very wide Cox confidence interval—a non-randomised allocation with a residual age imbalance favouring the mechanical arm, single-centre scope, mixed valve positions analysed together, and cross-sectional rather than longitudinal QoL capture. Prospective, adequately powered, multicentre studies with serial QoL measurement are required to translate this framework into actionable evidence.

CONCLUSION

In simulated patients under 50 years, bioprosthetic valves were associated with a markedly higher long-term reintervention burden attributable to structural valve deterioration, whereas mechanical valves concentrated the bleeding and thrombosis risk of lifelong anticoagulation. Physical quality of life was equivalent, while mental quality of life favoured the anticoagulation-free bioprosthetic arm. These divergent signals argue against a one-size-fits-all rule: durability and patient-perceived wellbeing must be weighed together, through shared decision-making, when selecting a prosthesis in young patients.

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