

REVIEWER'S REPORT

Manuscript No.:IJAR-54534 Date: 28/10/2025

Title:IDEAL MECHANICAL VALVE IN INDIAN SCENARIO : A RETROSPECTIVE CASE STUDY

Recommendation:

Accept as the article aims to demonstrate comparable clinical performance between the two valves while highlighting the significant cost advantage of the TTKCHV.

Adding recommendation

Rating	Excel.	Good	Fair	Poor
Originality	✓			
Techn. Quality	✓			
Clarity	✓			
Significance	✓			

Reviewer Name:Mrs. Shreya Vaz

Date:28/10/2025

Reviewer's Comment forPublication.

This retrospective single-center case study, conducted at Grant Government Medical College and Hospital in Mumbai (January 2021–January 2025), compared the clinical outcomes and cost-effectiveness of the indigenously developed TTK Chitra Heart Valve (TTKCHV) against the imported St. Jude Medical Valve (SJMV) in patients undergoing mechanical valve replacement. The study demonstrates comparable clinical performance between the two valves while highlighting the significant cost advantage of the TTKCHV.

Detailed Reviewer's Report

This article is based comprises a brief contents.

This retrospective single-center case study, conducted at Grant Government Medical College and Hospital in Mumbai (January 2021–January 2025), compared the clinical outcomes and cost-effectiveness of the indigenously developed TTK Chitra Heart Valve (TTKCHV) against the imported St. Jude Medical Valve (SJMV) in patients undergoing mechanical valve replacement. The study demonstrates comparable clinical performance between the two valves while highlighting the significant cost advantage of the TTKCHV.

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Study Overview and Significance

****Research Context and Rationale****

India faces a substantial burden of rheumatic heart disease, affecting 2 to 2.5 million patients, predominantly from young and low socioeconomic backgrounds. The TTK Chitra Heart Valve represents an important indigenous innovation developed over 12 years at the Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) in Thiruvananthapuram, Kerala. This tilting disc, monoleaflet valve offers a critical solution for resource-limited settings by providing affordable valve replacement options.

****Research Objective****

The study aimed to examine whether the low-cost TTKCHV could offer equivalent clinical outcomes compared to the widely-used imported bileaflet St. Jude Medical Valve, thereby supporting broader accessibility to cardiac surgery in India.

Methodology Assessment

****Study Design and Population****

The research employed a single-center retrospective design with clearly defined inclusion and exclusion criteria. A total of 134 patients were enrolled:

- 78 patients (58.2%) received TTKCHV (48 mitral valve replacements [MVR], 30 aortic valve replacements [AVR])
- 56 patients (41.7%) received SJMV (36 MVR, 20 AVR)

Patients undergoing simultaneous cardiac procedures, double valve replacements, or coronary artery bypass grafting were appropriately excluded to control for confounding variables.

****Data Collection and Follow-up****

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The study collected comprehensive demographic, clinical, and echocardiographic data including left ventricular ejection fraction (LVEF), left ventricular dimensions, valvular gradients, left atrial size, and operative parameters (crossclamp time, bypass time, ICU stay, hospital stay). Follow-up assessments occurred at baseline (within 5 days post-surgery) and at 30 days post-surgery.

****Surgical Technique****

All surgeries were performed by experienced consultant surgeons using standardized techniques. A notable technical difference existed in valve positioning: TTKCHV was implanted in anatomical position for mitral replacements and with tilting disc facing the greater curvature of the aorta, while SJMV was positioned in anti-anatomical fashion for MVR and with pivot perpendicular to the interventricular septum for AVR.

Key Findings

****Mitral Valve Replacement Outcomes****

Baseline characteristics between groups were well-matched with no statistically significant differences in age, gender, functional class, atrial fibrillation prevalence, or echocardiographic parameters. Clinical and echocardiographic outcomes at 30 days showed:

- ****Functional Class Improvement:**** Median NYHA class improved from III to I in both groups
- ****Ejection Fraction:**** Minimal change from baseline in both groups (TTKCHV: 50.4% to 52.1% vs. SJMV: 48.3% to 50.6%, $p=0.3008$)
- ****Valvular Gradient:**** Both groups showed significant improvement (TTKCHV: 10.5 to 7.2 mmHg vs. SJMV: 12 to 8.4 mmHg, $p=0.1657$)
- ****Left Ventricular Dimensions:**** No statistically significant differences between groups

****Aortic Valve Replacement Outcomes****

Similarly, baseline characteristics were comparable between groups. Post-operative outcomes at 30 days demonstrated:

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- **Functional Class Improvement:** Median NYHA class improved from II to I in both groups
- **Ejection Fraction:** Similar trajectory to MVR group (TTKCHV: 50.1% to 52% vs. SJMV: 53.6% to 54.6%, $p=0.3180$)
- **Aortic Valve Gradient:** Significant improvement in both groups (TTKCHV: 50.7 to 20.4 mmHg vs. SJMV: 55.8 to 22.8 mmHg, $p=0.2372$)
- **Safety Profile:** No mortality or stuck mechanical valve incidents occurred in either group during the study period

Cost Comparison[1]

The most compelling finding involved economic analysis:

Valve Type	Cost (2016)	Current Cost
TTKCHV	Rs 18,000–20,000	Approximately doubled
SJMV	Rs 45,000–55,000	Approximately doubled

The TTKCHV costs approximately 60% less than imported alternatives, representing a crucial advantage in a healthcare system where government welfare schemes rarely cover the full cost of imported prostheses.

Strengths of the Study

The research demonstrates several methodological strengths:

1. **Well-Matched Cohorts:** Baseline characteristics were comparable between groups, minimizing selection bias
2. **Standardized Surgical Technique:** Experienced surgeons performed procedures with controlled methodology
3. **Comprehensive Data Collection:** Multiple clinically relevant variables were systematically recorded
4. **Clear Outcomes:** The study provided objective measurements of functional improvement and hemodynamic performance

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5. ****Practical Relevance:**** The research addresses a genuine healthcare need in resource-limited settings

Limitations

The study has several important limitations that warrant consideration:

****Temporal Limitations****

The 30-day follow-up period, while providing early outcome data, precludes assessment of long-term valve durability, thromboembolism rates, hemorrhagic complications, and reoperation rates. Long-term durability comparisons require extended follow-up periods extending to years.

****Design Limitations****

The retrospective single-center design may limit generalizability to broader patient populations across different healthcare settings and geographic regions within India. External validation through prospective multi-center studies would strengthen the findings.

****Scope Limitations****

While cost differences were highlighted, the study did not include comprehensive socioeconomic analysis examining long-term treatment-related expenses (anticoagulation management, complications, readmissions) or quality-of-life outcomes, which are relevant to overall cost-effectiveness assessment.

****Population-Specific Limitations****

The study population may not represent all Indian demographic groups or healthcare settings, particularly private centers or tertiary institutions with different patient demographics.

Clinical and Public Health Implications

****Comparable Safety and Efficacy****

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The study provides evidence supporting the use of TTKCHV as a clinically equivalent alternative to imported mechanical valves in the short-term, with no increased mortality or adverse events.

****Healthcare Access and Equity****

By offering equivalent performance at nearly 60% lower cost, the TTKCHV emerges as a viable solution for expanding cardiac surgery accessibility in low and middle-income countries where cost remains a significant barrier to treatment.

****Government Healthcare Integration****

The findings support incorporation of TTKCHV into government welfare schemes, as affordability aligns with the objective of inclusive healthcare delivery for non-affording populations.

Recommendations for Future Research

1. ****Long-term Follow-up Studies:**** Prospective studies with extended follow-up (5–10 years) assessing durability, thromboembolism rates, and need for reoperation
2. ****Multi-center Validation:**** Prospective multi-center studies across different cardiac centers and geographic regions to establish generalizability
3. ****Comprehensive Economic Analysis:**** Detailed cost-effectiveness analysis incorporating long-term complications, anticoagulation management costs, and quality-of-life measures
4. ****Subgroup Analysis:**** Investigation of valve performance across specific patient populations (age groups, etiology of valve disease)

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5. ****Mechanistic Studies:**** Research into hemodynamic differences between tilting-disc and bileaflet valve designs

Conclusion

This retrospective case study provides evidence that the indigenously developed TTK Chitra Heart Valve offers comparable short-term clinical outcomes to the St. Jude Medical Valve while providing substantial cost savings. The study effectively demonstrates that technological innovation addressing affordability need not compromise clinical safety or efficacy. However, the findings should be considered within the context of limited follow-up duration and single-center design. Prospective multi-center studies with long-term follow-up would strengthen the evidence base for broader adoption of the TTKCHV in cardiac surgery programs across resource-limited settings.