IDEAL MECHANICAL VALVE IN INDIAN SCENARIO : A RETROSPECTIVE CASE STUDY

INTRODUCTION

India has 2 to 2.5 million patients of Rheumatic heart disease (RHD) [1]. Most of the patients are young and belong to low socio-economic group. At presentation in chronic RHD, the valves are damaged, leading to regurgitation or stenosis and are unsuitable for repair [2]. So prosthetic valve replacement is needed for these patients. Until 1990s, most of the artificial heart valves implanted in India were imported. TTK Chitra heart valve (TTKCHV), developed in the late 1980s at the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram, (SCTIMST) Kerala, is a low-cost mechanical heart valve prosthesis [3]

The TTK Chitra Heart Valve (TTKCHV) is a tilting disc valve with monoleaflet configuration. It was developed over a period of 12 years at SCTIMST by renowned cardiac surgeon Dr M S Valiathan [4]. The tilting disc is made from Ultra High Molecular Weight Poly Ethylene (UHMWPE), pivoted eccentrically in the metallic frame made of Cobalt-Chromium alloy. The sewing ring of Poly Ethylene Terephthalate (PET) is fitted snugly around the frame and is used to suture the valve at the intended position in the heart [5].

Bileaflet valves such as the St Jude Medical valve (SJMV) are the most widely utilised, however their advantages over the mono-leaflet valve is not clearly established. The TTK Chitra Heart valve (TTKCHV) being low cost is a good solution for low and middle income countries like India where most of the patients are dependent on social welfare schemes for their treatment because these schemes rarely cover the cost of the imported valves.

This retrospective study was aimed to examine if the low cost TTK Chitra valve can offer equivalent outcomescompared to the more commonly used importedbileaflet valves like the St Jude Medical valve (SJMV).

METHODS

The study was conducted at Grant Govenrnment Medical College and Hospital in Mumbai between January 2021 and January 2025. We performed a single-center retrospective study including all patients who underwent isolated MVR or isolated AVR with TTKCHV or SJMV. Individuals who underwent simultaneous cardiac procedures such as double valve replacement, coronary artery bypass grafting, or other procedures were excluded from the study. The study population was randomised into 2 groups based on whether SJMV or TTKCHV valve was used. The follow up data was obtained at baseline i.e. post operative (within 5 days of surgery) and at 30 days after surgery. An aortic valve replacement was necessary in 50 patients in total. 20 cases underwent AVR with the SJMV and the remaining 30 cases were implanted with the TTKCHV. Similarly, 84 patients underwent MVR , 36 patients with the SJMV and 48 with the TTKCHV. The surgery in the study period was done by consultant surgeons well versed with the procedures and the technique of surgery was same in both groups with valve being secured in position by ethibond pledgeted sutures in interrupted horizontal mattress fashion. In case of MVR, the TTKCHVwas implanted with the larger orifice oriented posteriorly (anatomical position) whereas with the SJMV, the mitral valve were placed such as the prosthetic valve commissure is perpendicular to native valve commissure (anti-anatomical position). In case of AVR, the TTKCHVwas implanted with its tilting disc facing the greater curvature of the Aorta and the SJMV was implanted such that the pivot of the valve is perpendicular to the interventricular septum.

Data Collection

Demographic details including age at surgery, gender and socioeconomic status were collected. Clinical data regarding aetiology of valve disease, functional class (NYHA), and pulmonary artery hypertension and baseline cardiac rhythm were recorded. 2D transthoracic echocardiography reports at baseline and on follow up was obtained in all patients. Left ventricular ejection fraction, left ventricular dimensions (in systole and diastole), gradient across the diseased valves, left atrial size and aortic diameter were documented. Data on variables like crossclamp time, bypass time, type of valve implanted, its size, duration of ICU stay and of hospital stay were also obtained. For analysis of outcomes, we compared these

parameters longitudinally at baseline i.e. post operative (within 5 days of surgery) and at 30 days after surgery. Therapeutic INR was defined as between 2.0-3.0 for AVR and 2.5 - 3.5 for MVR [9].

RESULTS

Table 1: Baseline characteristics of the entire cohort

Sl.No.	**TTKCHV**	**SJMV**
Number of patients n (%)	78(58.2)	56(41.7)
MVR (n=)	48(57.1)	36(42.8)
AVR (n= 28)	30(60)	20(40)
Age at surgery (yrs.)	46.4 ±12.5	43.8 ± 12.0
Male gender (%)	45.8	46.7

A total of 134 patients were included in the study. Of them 78 patients underwent implantation with TTKCHV, 48 MVR and 30 AVR. 56 patients underwent SJMV implantation, 36 for MVR and 20 for AVR.

Table 2: Baseline characteristics of patients undergoing mitral valve replacement

Baseline characteristics	**TTKCHV**	**SJMV**	**p - value**
Number of patients, n (%)	48(57.1)	36(42.8)	
Age at surgery (yrs.)	42.5 ± 8.4	39.8 ± 9.5	P = 0.1719
Male gender (%)	43.1	39.8	

			P = 0.7628
Rheumatic Heart Disease(RHD) (%)	86.4	90.2	P = 0.5977
Mitral Valve Prolapse(MVP) (%)	10.8	7.4	P = 0.5984
NYHA Functional class III/ IV (%)	46.2/3.2	48.5/2.6	P = 0.8354 / 0.8728
Atrial Fibrillation	50.2	52.8	P = 0.8146
Left Atrium(LA) size (mm)	46.8 ± 7.8	48.5 ± 8.3	P = 0.3390
Ejection Fraction(EF) (%)	50.4 ± 7.2	48.3 ± 8.7	P = 0.230
Mean gradient across mitral valve (mmHg)	10.5 ± 5.4	12 ± 3.5	P = 0.1502
Left Ventricle End Systolic Dimensions (LVSD) (mm)	32.9 ± 6.3	31.8 ± 5.4	P = 0.4028
Left Ventricle End Diastolic Dimensions (LVDD) (mm)	45.9 ± 8.9	48.8 ± 9.5	P = 0.1549

The baseline characteristics, including age at surgery, gender, cause of mitral valve disease, degree of functional impairment of the patient, preexisting atrial fibrillation, ejection fraction,

mean gradient across the diseased mitral valve, left atrium dimension and left ventricle dimensions during systole and diastole were similar across both the groups.

Predominantly middle age population was affected by mitral valve disease. Female were most commonly affected. The most common reason for mitral valve disease was rheumatic heart disease followed by mitral valve prolapse according to the study. Approximately 50 % patients already had atrial fibrillation at the time of presentation to the hospital.

Table 3: Clinical and echocardiographic outcomes in MVR

Variable	**TTKCHV**	**SJM**	**P - value**
Median NYHA Functional Class Baseline 30 days	 III I	 III I	
EF (%) Baseline 30 days	50.4 ± 7.2 52.1 ± 5.4	48.3 ± 8.7 50.6 ± 7.8	P = 0.230 P = 0.3008
Mean Gradient across mitral valve (mmHg) Baseline 30 days	 10.5 ± 5.4 7.2 ± 3.6	 12 ± 3.5 8.4 ± 1.5	 P = 0.1502 P = 0.1657
LVSD (mm) Baseline 30 days	32.9 ± 6.3 31.4 ± 5.8	31.8 ± 5.4 30.8 ± 5.2	P = 0.4028 P = 0.6253

LVDD (mm) Baseline	45.9 ± 8.9	48.8 ± 9.5	P = 0.1549
30 days	44.8 ± 7.2	47.8 ± 8.6	P = 0.0859

Table 3 shows the outcomes after mitral valve replacement surgery compared at baseline and at 30 days post surgery were not statistically significant irrespective of the type of valve used.

Table 4: Baseline characteristics of patients undergoing aortic valve replacement

Variable	**TTKCHV**	**SJMV**	**p - value**
Number of patients, n (%)	30(60)	20(40)	
Age at surgery (yrs.)	52.8 ± 7.8	50.8 ± 10.5	P = 0.4435
Male gender (%)	64.5	72	P = 0.5829
Calcified/degenerative (%)	55.2	48.6	P = 0.6504
Bicuspid aortic valve (%)	15.3	25.4	P = 0.3805
RHD (%)	24.9	23.8	0.9301
NYHA III/ IV	62.8 / 35.5	60.4 / 34.9	P = 0.8655 / 0.9656

EF (%)	50.1 ± 9.7	53.6 ± 10.2	P = 0.2267
Mean Aortic valve gradient (mmHg)	50.7 ± 17.8	55.8 ± 22.0	P = 0.3712
Aortic diameter (mm)	31.6 ± 6.4	34.5 ± 5.4	P = 0.2597
LV systolic dimension (mm)	36.2 ± 8.6	38.7 ± 9.4	P = 0.3368
LV diastolic dimension (mm)	58.2±12.4	58.5±12.8	P=0.944

The baseline characteristics, including age at surgery, gender, cause of aortic valve disease, degree of functional impairment of the patient, ejection fraction, mean gradient across the diseased aortic valve, diameter of aorta and Left Ventricle dimensions during systole and diastole were similar across both the groups.

Aortic valve disease predominantly affected middle aged people more commonly a decade older than mitral valve affection in the study population. Male were the most commonly affected gender. The most common reason for isolated aortic valve disease was degenerative aortic valve disease followed almost equally by bicuspid aortic valve and rheumatic heart disease in our study.

Table 5: Clinical and echocardiographic outcomes in AVR

Variable	**TTKCHV**	**SJMV**	**p - value**

NYHA Functional Class (Median) Baseline 30 days	II I	II I	
EF (%) Baseline 30 days	50.1 ± 9.7 52 ± 8.6	53.6 ± 10.2 54.6 ± 9.4	P = 0.2267 P = 0.3180
Mean Gradient across aortic valve (mmHg) Baseline 30 days	50.7 ± 17.8 20.4 ± 5.8	55.8 ± 22.0 22.8 ± 8.4	P = 0.3712 P = 0.2372
LVSD (mm) Baseline 30 days	36.2 ± 8.6 35.4 ± 7.8	38.7 ± 9.4 37.8 ± 8.4	P = 0.3368 P = 0.3065
LVDD (mm) Baseline 30 days	58.2±12.4 57.8 ± 8.2	58.5±12.8 58.2 ± 11.4	P = 0.944 P = 0.8858

Table 5 shows there was no statistically significant difference observed in the outcomes of aortic valve replacement surgery irrespective of the type of the valve is used.

Table 6 : Cost comparision of TTKCHV and SJMV

Variable	**TTKCHV**	**SJMV**
Cost	Rs 18,000 - 20,000 /-	Rs 45,000 - 55, 000 /-

The TTKCHV cost around Rs 18,000 - 20000/- in 2016 in India whereas the imported mechanical valves like the SJMV cost around Rs 45,000 - 55,000/- in the same time [6 , 7]. The cost in current times for both the valves have around doubled.

DISCUSSION

Valvular heart disease are a major cause of cardiovascular morbidity and mortality worldwide and are an enormous burden on healthcare resources. Rheumatic heart disease is the most common etiology of valvular heart disease in developing countries like India. At the time of presentation the valves involved are unsuitable for repair, so valve replacement is the only option available.

In our study, the patients undergoing valve replacement were mostly of middle age group 40 - 50 years. In India, mitral valve replacements are more common than aortic valve replacements, the reverse of what is seen in developed nations as RHD affects the mitral valve preferentially compared to degenerative valvular disease more commonly affecting aortic valve.

Due to higher prevalence of valvular heart disease and need for valve replacement in this resource limited setting, this study was done to compare theaffordability and performance of the valves used for valve replacement surgery.The two most commonly used mechanical valves at our centre are TTKCHV and SJMV.

In our study, the median NYHA functional class improved from NYHA III to NYHA I at 30 day follow-up for both group of valves in case of MVR and from NYHA II to NYHA I for both groups in case of AVR. There was not much improvement in EF in both groups for both AVR and MVR at 30 days post surgery. The mean gradient across the valves also show significant improvement at 30 days follow up in both mitral and aortic positions but there was no significant differences across both the groups. Our study shows comparable results to various other studies done to compare outcomes of both the valves [8 -11]. There was no incidence of mortality or stuck mechanical valve during the period of the study in both the groups.

The results of this study indicate that performance of St. Jude Medical valve and TTK Chitra Heart valve are comparable in terms of clinical benefits, adverse events and early mortality in both aortic and mitral positions in the short term. The TTKCHV offers equivalent results at almost half the cost of imported mechanical valves like the St Jude Mechanical heart valve making cardiac surgery available to a large number of patients in this resource-limited country [8-11].

CONCLUSION

This retrospective single-center analysis demonstrates that the indigenously developed TTK Chitra heart valve provides short-term clinical outcomes equivalent to the St. Jude Medical valve in both aortic and mitral valve replacement. Improvements in functional class, echocardiographic parameters, and postoperative recovery were comparable across groups, with no significant differences in mortality or early complication rates.

Importantly, the substantially lower cost of the TTK Chitra prosthesis represents a crucial advantage in the Indian healthcare context, where affordability and accessibility remain significant considerations. By offering performance on par with internationally established prostheses at nearly half the cost, TTK Chitra emerges as a viable and sustainable alternative for patients in low and middle income countries like India where most of the patients are non affording and are dependent on government welfare schemes for their treatment because the cost of imported valves does not fit in the government approved schemes.

LIMITATIONS

This study has some limitations. First, its retrospective and single-center design may limit the generalizability of the findings to broader patient populations. Second, the follow-up period was restricted to 30 days, precluding evaluation of long-term valve durability, anticoagulation-related complications, thromboembolic or hemorrhagic events, and reoperation rates. Finally, although cost differences between the two valve types was highlighted, a comprehensive socioeconomic analysis, including long-term treatment-related expenses and quality-of-life outcomes, was beyond the scope of this study.

STATEMENT AND DECLARATION

Funding - None

Conflicts of Interests – None

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Keywords

TTK Chitra heart valve, St. Jude Medical valve, Mechanical prosthetic valve, Mitral valve replacement (MVR), Aortic valve replacement (AVR), Echocardiographic outcomes, Cost-effectiveness