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Comparison of Post Operative Clinical Outcomes Between "Made in India" TTK Chitra Mechanical Heart Valve Versus St Jude Mechanical Heart Valve in Valve Replacement Surgery

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ABSTRACT

Background: The TTK Chitra mechanical heart valve prosthesis (CHVP) is a mono-leaflet, tilting disc design heart valve, which was developed in India and relatively cheaper than western Mechanical Prosthetic valve. Very limited studies are available for the comparison of CHVP versus western mechanical prosthetic heart valve. This study was designed to compare the Indian valve vs. western valve.

Methods: It was a single centre, retrospective-prospective follow-up study. The study was approved by the Institutional Ethics Committee(Ethical clearance was not required) and written informed consent was obtained from all participants. Among records of the hospital management system 531 medical records screened, 378 subjects met the inclusion-exclusion criteria and were included for analysis. SPSS software was used for analysis.

Results: The results of this study indicate that the long term performance of the St. Jude Mechanical heart valve and TTK Chitra mechanical valve prostheses is comparable in terms of clinical benefits, adverse events and mortality.

Conclusions: The CHVP offers equivalent results at almost half the cost of an imported St Jude Mechanical heart valve making the prospect of cardiac surgery available to a large number of deserving patients in resource-limited settings.

Key Words: CHVP, SJM, TTK Chitra, Mechanical Prosthetic Valve

INTRODUCTION

Valvular heart disease (VHD) a major contributor to morbidity and mortality worldwide, especially in the developing nations where chronic rheumatic heart disease (RHD) still accounts for the vast majority of Valvular heart disease.[1] in resources limited setting, not all patients requiring cardiac surgery can afford it. Hence, there existed a large unmet need for a low cost and efficacious prosthetic heart valve in India. It is to bridge this gap that the TTK Chitra mechanical heart valve prosthesis (CHVP) was developed in the 1980s. It is in widespread use for the past two decades and more than 70,000 implantations have been done so far.[2]

The CHVP is a monoleaflet, tilting disc design heart valve. A multicentric clinical trial in 2001 reported excellent clinical outcomes with CHVP.[3] However, literature is still divided on the comparative advantages of a particular heart valve design over others. The oldest generation of heart valves, with caged ball design, are not in wide use anymore. The most commonly used valves currently are those with a bileaflet design. Relative merits and disadvantages between the mono-leaflet and bileaflet designs are not very well established as most clinical trials report Outcomes from follow up of a single valve type. Few comparative studies suggest that both valve types have similar clinical performance and durability. [4, 5]

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St. Jude Medical bileaflet valve and Medtronic Hall mono-leaflet valve were most commonly implanted valves till 2009 when Medtronic stopped production of its mono-leaflet valve. [6] In this context, the CHVP could offer patients suffering from VHD, comparable clinical outcomes to existing bileaflet and mono-leaflet valves at a much lower cost. Comparative clinical outcome data between this mono-leaflet valve model and the existing bileaflet valves are not available. We had planned to conduct this study to systematically analyse the outcomes of patients receiving CHVP and compare it to commonly used bileaflet valves.

MATERIALS AND METHODS

Study design

We conducted a single centre, a retrospective-prospective follow-up study to compare the long term outcome of patients undergoing isolated mitral or aortic valve replacement with the tilting disc (CHVP) or commonly used bileaflet valves. The study was conducted in LPS institute of Cardiology and cardiothoracic vascular surgery, Kanpur in between July 2016 to July 2018. It was approved by the Institutional Ethics Committee and written informed consent was obtained from all participants.

As the most commonly used bileaflet valve at our centre during the study period was St. Jude Medical Bileaflet valve (100%), this was chosen as a standard comparator. Subjects were identified from the hospital medical records system (operation executed section) using keywords "MVR" for mitral valve replacement and "AVR" for aortic valve replacement and "CHVP" for TTK Chitra valve or "SJM" for St. Jude Medical valve.

Demographic, clinical and echocardiographic data were collected from the hospital records using a structured proforma. Follow up data was obtained during scheduled review visits in person. Those lost to follow up for more than 12 months were contacted over telephone or telephonic interview conducted for the collection of follow up data. Consecutive patients who underwent isolated aortic or mitral valve replacement receiving CHVP or SJM mechanical prosthesis from January 2016 to December 2017 were included. Patients undergoing double valve replacement, redo surgery or other cardiac surgeries concomitantly (e.g. coronary artery bypass graft) were excluded.

Follow up duration was calculated as the number of days from surgery to death, valve explanation or till closing date of data collection for patients who follow up till closing date was available. For those lost to follow up, time from surgery to last follow up and status at that time were entered.

Data Collection

Demographic details including age at surgery, gender and socioeconomic status were collected using a structured proforma. Clinical data regarding aetiology of valve disease, functional class (NYHA), and pulmonary artery hypertension and baseline cardiac rhythm were recorded. 2D transthoracic echocardiography and Doppler evaluation was done in all patients at baseline and on follow up. Left ventricular ejection fraction, left ventricular dimensions (in systole and diastole), and gradient across the diseased valves, left atrial size and aortic diameter were documented.

For analysis of outcomes, we compared these parameters longitudinally at baseline, 30 days after surgery and at last available follow-up. Data was also collected regarding the type of valve implanted, its size, duration of hospital and intensive care stay after surgery. Therapeutic INR was defined as between 2.0-3.0 for AVR and 2.5 - 3.5 for MVR. Time in therapeutic range anticoagulation (TTR) was calculated using the traditional formula (Percent of Visits in Range).

Adverse events were identified from hospital records and interviewing during regular follow up visits or telephonic interview with patient or relative in those lost to follow up. Hospital deaths, late deaths, and valve-related events were defined according to the published guidelines for reporting mortality and morbidity after cardiac valve interventions from the Society of Thoracic Surgeons and American Association of Thoracic Surgery, 2008.[7] Prosthetic valve thrombosis (PVT) was defined as confirmed PVT if there was documentation of increased gradients, thrombus and reduced leaflet movement on echocardiography and/or fluoroscopic evidence of restricted valve movements in and PVT was presumed when there was history suggestive of PVT and patient died after treatment at the local hospital, but records are not available for confirmation. Both presumed and confirmed PVT was included in the final analysis.

Outcome variables

The primary outcome variable was all-cause mortality, early deaths and valve-related mortality. Secondary outcome variables included adverse events on follow up, cumulative survival, event-free survival and clinical and echocardiographic parameters. For event-free survival analysis, mortality from any cause and valve-related complications were considered as events.

Statistical analysis

Statistical analysis was carried out using Statistical Package for Social Sciences (SPSS Inc, Chicago, Illinois, USA, V. 16). Data were represented as mean or percentage as applicable with SEM/SD as dispersion measure. Chi-square or Fisher's exact test as applicable was used to compare proportions. Kaplan-Meier survival analysis with log-rank test was used to compare survival durations and event-free survival between the groups.

RESULTS

Among 531 medical records screened, 378 subjects met the inclusion-exclusion criteria and were included for analysis. Baseline characteristics of the entire cohort are shown. (Table 1).

Mean age at surgery was 42.8±12.6 years. More than 6 months follow up was available in 99% of patients.

Table 1: Baseline characteristics of the entire cohort

Variable	CHVP	SJM
Number of patients, n (%)	253 (66.9)	125 (33)
MVR (n=261)	193 (74)	68 (26)
AVR (n=117)	60 (51.2)	57(48.7)
Age at surgery (yrs.)	41.1+12.5	43.0+12.5
Male gender (%)	58.9	51.2
Low socioeconomic status (%)	89.4	62.1

Mitral valve replacement

For MVR, follow up was 964.9 patient-years. Patients in the CHVP group were older at the surgery and belonged to lower socioeconomic status. Rheumatic heart disease was the commonest indication for surgery accounting for 88.5% of all patients undergoing MVR.

Baseline functional class, pulmonary artery hypertension and number of patients with atrial fibrillation or flutter were similar between the groups. The groups were also matched for left atrial size, mean gradient across the mitral valve, baseline ejection fraction and left ventricular dimensions at baseline (Table 2).

Table 2: Baseline characteristics of patients undergoing mitral valve replacement

Variable	CHVP	SJM	P-value
Number of patients, n (%)	193 (73.9)	68 (26.1)	
Age at surgery (yrs.)	43.5±12.5	39.9±12.0	P=0.409
Male gender (%)	42.1	39.4	P=0.609
Low socioeconomic category (%)	96.2	63.1	P=0.046
Rheumatic Heart Disease(RHD) (%)	90.9	86.0	
Mitral Valve Prolapse(MVP) (%)	7.6	10.3	
Post Ballon Mitral Valvotomy(BMV) Mitral Regurgitation (MR)(%)	1.5	2.6	
Emergency MVR (%)	-	1.1	
Functional class (%) NYHA II/III/IV(New York Heart Association)	47.9/49.2/2.9	46.2/51.5/2.3	P=0.858
Pulmonary Artery Hypertension(PAH) (%) 0/1/2/3	17.5/32.8/28.0/21.7	15.9/35.6/28.8/19.7	P=0.903
Atrial Fibrillation/Atrial Flutter (%)	52.3	54.8	P=0.116
Left Atrium(LA) size (mm)	50.8±9.8	51.5±11.3	P=0.677
Aorta size (mm)	27.0±4.5	28.0±5.5	P=0.035
Ejection Fraction(EF) (%)	52.1±8.6	54.1±8.5	P=0.986
Left Ventricle End Diastolic Dimensions(LVDD) (mm)	49.9±10.4	50.9±11.2	P=0.358
Left Ventricle End Systolic Dimensions(LVSD) (mm)	32.5±7.8	32.3±7.4	P=1.000
Mean gradient across mitral valve (mmHg)	7.5±6.9	7.2±6.5	P=0.911

Median valve size used for MVR was 27 in both the groups (range, SJM: 17-33, CHVP: 23-31, p=0.944). Perioperative hospital stay (1 day, p=0.581) and postoperative intensive care unit stay (≈ 3 days, p=0.083) were similar in both groups.

Warfarin was the anticoagulants used and during follow up, percentage of time spent in the therapeutic range of INR was low in both the groups (SJM: 29.2%±23.0, CHVP: 33.7%±27.1, p=0.381).

Similar improvements in functional status and pulmonary artery hypertension and LV Dimensions and gradient were noted at 30 days and on last follow up in both the valve groups (Table 3).

Table 3: Clinical and echocardiographic outcomes in MVR

Variable	Baseline (CHVP/SJM)	30 days (CHVP/SJM)	Last Visit (CHVP/SJM)	Effect of valve type (CHVP/SJM)
Median NYHA Functional Class	III III	I I	I I	-
PAH Functional Class	I I	0 0	0 0	-
EF (%)	64.2±8.5/ 64.2±8.6	61.1±8.2/ 62.5±8.3	60.6±8.1/ 62.2±8.0	p=3.064 P=0.081
Gradient (mmHg)	12.3±6.5/ 12.6±7.0	5.0±3.1/ 4.2±1.5	5.9±3.9/ 4.9±1.8	p=2.638 P =0.105
LVSD (mm)	32.3±7.2/ 32.5±7.3	31.8±6.4/ 31.9±6.6	32.0±6.3/ 31.3±5.7	p =0.053 P=0.819
LVDD (mm)	50.9±10.9/ 50.1±10.5	46.7±7.2/ 47.2±7.1	47.1±7.7/ 47.3±6.5	p=0.001 P=0.970

Aortic valve replacement

Baseline characteristics are shown in Table 4. Patients in the CHVP group belonged to lower socioeconomic classes. Rheumatic heart disease was the commonest indication for surgery accounting for 43.0% of all patients undergoing AVR. Calcific/degenerative aortic valve disease and bicuspid aortic valve were the other common indications. Baseline functional class was similar between the groups' majority (98.2%) was in sinus rhythm in both valve groups. The groups were also matched for mean gradient across the aortic valve, baseline ejection fraction, aortic diameter and left ventricular dimensions at baseline.

Table 4: Baseline characteristics of patients undergoing aortic valve replacement

Variable	CHVP	SJM	P-value
Number of patients, n (%)	60 (51.2)	57 (48.7)	-
Age at surgery (yrs.)	42.4±13.0	41.1±12.5	P=0.482
Male gender (%)	81.6	82.0	P=0.938
Low socioeconomic category (%)	81.6	57.7	P<0.001
RHD (%)	48.2	37.8	
Calcified/degenerative (%)	26.3	33.3	
Bicuspid aortic valve (%)	21.9	19.8	
Infective endocarditis (%)	0.9	3.6	
Others (%)	2.6	5.4	P=0.386
NYHA I/II/III	0/60.5/39.5	0.9/62.1/36.9	P=0.564
EF (%)	52.1±10.7	52.3±12.1	P=0.901
Aortic valve gradient (mmHg)	40.7±27.2	41.3±28.0	P=0.804
Aortic diameter (mm)	32.0±5.4	31.5±6.4	P=0.579
LV systolic dimension (mm)	38.1±11.6	37.7±11.4	P=0.839
LV diastolic dimension (mm)	58.1±13.0	58.2±12.4	P=0.944

Median valve size used for AVR was 21 (range 17-29) in SJM and 23 (range 17-29) CHVP group (p=0.001). Perioperative hospital stay (≈11 days, p=0.509) and postoperative intensive care unit stay (≈ 3 days, p=0.834) were similar in both groups. All patients were on oral anticoagulants.

Similar improvement in functional class was noted at 30 days and on last follow up in both the valve groups, Ejection fraction, gradient across the aortic valve and left ventricular dimensions improved to a similar extent (Table 5).

Table 5: Clinical and echocardiographic, parameters on follow up in AVR cohort

Variable	Baseline (CHVP/SJM)	30 days (CHVP/SJM)	Last Visit (CHVP/SJM)	Effect of valve type (CHVP/SJM)
NYHA Functional Class (Median)	II II	I I	I I	- -
EF (%)	52.3±12.1/ 52.0±10.7	54.6±12.9/ 52.3±9.4	54.3±12.2/ 54.6±8.7	p=0.540 P=0.463

Table 5: *(Continued)*

Variable	Baseline (CHVP/SJM)	30 days (CHVP/SJM)	Last Visit (CHVP/SJM)	Effect of valve type (CHVP/SJM)
Gradient across aortic valve (mmHg)	41.3±28.0/ 40.0±26.9	13.9±8.3/ 13.4±5.5	13.9±7.3/ 13.6±6.7	p=0.218 P=0.641
LVSD (mm)	37.7±11.4/ 38.3±11.6	31.6±9.8/ 33.2±8.3	30.9±7.3/ 30.4±6.5	P=0.348 P=0.556
LVDD (mm)	58.2±12.4/ 58.5±12.8	48.4±9.2/ 49.4±8.3	48.2±7.0/ 47.8±6.7	P=0.093 P=0.761

On repeated measures analysis, there was no significant effect of valve type as a between-subjects factor on any of the above outcomes, suggesting that improvement in echocardiographic parameters was similar in both groups and independent of the type of prosthesis.

For the entire cohort, estimated cumulative survival after valve replacement was 1409.28+41.9 days for the SJM group and 1332±26.6 days for CHVP (p=0.864). Estimated cumulative event-free survival was also similar, there was no significant difference between the groups in all-cause mortality, early mortality and valve-related mortality. Major complications like prosthetic valve thrombosis, embolism, haemorrhage and need for reintervention were similar in both the groups. (Table 6)

Table 6: Mortality and complications entire cohort

Parameter	CHVP (n=253)	SJM (n=125)	P-value
All-cause mortality, n (%/Percent pt -years)	27 (10.6/1.5)	13 (10.4/1.3)	P =0.894
Early Mortality, n (%)	4 (1.6)	4 (3.2)	P =0.452
Valve related mortality, n (%/Percent pt -years)	21 (8.3/1.1)	9 (7.2/0.9)	P =0.681
PVT, n (%,Percent pt -years)	25 (9.9/1.3)	7 (5.6/0.7)	P =0.155
Embolism, n (%,Percent pt -years)	29 (11.4/1.6)	15 (12/1.6)	P =0.210
Haemorrhage n (%,Percent pt -years)	19 (7.5/1.0)	8 (6.4/0.8)	P =0.959
Reintervention n (%,Percent pt -years)	9 (7.2/0.9)	7 (5.6/0.7)	P =0.102

DISCUSSION

Our results suggest comparable long term clinical outcomes between CHVP, an indigenously developed, low cost, single tilting disc valve to SJM, a commonly used bileaflet valve in aortic and mitral positions. These are the two most commonly used mechanical vales at our centre and possibly at other cardiac surgery centres of India and other developing nations, so a comparative study looking at long term outcomes as desired. Several points merit special consideration while interpreting our results in the light of available literature. Consistent with data from developing nations, our patients undergoing valve replacement were significantly younger and chronic RHD was the oetiology in the majority, both for mitral as well as aortic valve disease. Mean age at surgery was 40-43 years in other reports published from India and RHD accounted for 70 -90 % of valve replacements.[8,9,10] Data from the Western hemisphere, however, usually deals with an older population, in the range of 52-63 years.[4,11,12,13] It is known that chronic RHD is not only more prevalent in developing countries with poor socioeconomic status, but that lack of access to healthcare and noncompliance to antibiotic prophylaxis in combination with poor living conditions lead to higher recurrence rates of rheumatic fever and more severe Valvular damage which presents at a younger age compared to the West. Also, in India, mitral valve replacements outnumber 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. As a consequence, the rate of atrial fibrillation overall was also higher in our study, similar to data from other Indian studies, reflecting the higher proportion of mitral valve disease. In the MVR subgroup, the frequency of AF at time of surgery was similar in our study (40-75%) as well as other Indian and Western data. [9-11]Reported rates of early mortality with SJM at mitral and aortic positions are in the range of 3-7%. [11-13]

In our study, the early mortality rate was much lower (1%). This could be due to the younger age of our population and because of strict selection criteria resulting in the exclusion of redo surgeries, concomitant left heart surgeries and patients with severe LV dysfunction. Moreover, the earlier reports are from about a decade prior and advances in surgical techniques and perioperative care may have contributed to decreased mortality rates. The multicentric clinical study of CHVP reported in 2001 an early mortality of 6.9%, in a population similar to ours and including only isolated aortic or mitral valve replacement.[3] A drastic reduction in early mortality to 0.6-1.5% has been reported in recent studies with TTK Chitra valve.[8,9,10] As surgical expertise, techniques and

perioperative -post-operative care may differ among centres, valid conclusions about valve performance are better inferred from the single centre experience of a uniform cohort of patients. For the entire cohort, primary outcomes in terms of all causes mortality, early mortality and valve-related deaths were comparable between the valve types. On multivariate analysis, valve type was not a significant predictor of mortality or event-free survival. These results suggest that both valve designs are equally efficacious in terms of survival as well as freedom from thromboembolism, haemorrhage and infective endocarditis. We did not come across any case of structural valve deterioration in either valve group.

Limitations

Firstly, it is not a randomized control trial between the valve groups and thus certain baseline differences were found to exist between the two valve groups, although adjusting for these did not reveal any statistically significant effects. Secondly, being a retrospective-prospective study, it is prone to recall bias on follow up and data from hospital admissions outside could have been missed. Thirdly due to differences in demographics and we cannot assume that these results can be generalized to the larger population blindly. Despite these limitations, our study provides convincing evidence of comparability between these two commonly employed valve designs in actual clinical practice settings.

CONCLUSION

The CHVP offers equivalent results at almost half the cost of an imported St Jude Mechanical heart valve making the prospect of cardiac surgery available to a large number of deserving patients in resource-limited settings.

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As it was a retrospective study and no ethical clearance was required at our centre where the study was conducted. We were doing these procedures routinely.

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