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# Post Operative Outcome of Mitral Valve Replacement with respect to TTK Chitra Mechanical Heart Valve and St Jude Mechanical Heart Valve

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**ABSTRACT**:
**Background:** In day to day practice both St. Jude mechanical heart valve and TTK chitra mechanical heart valve are widely used for cases undergoing mitral valve replacement. However, the efficiency of these valves remains a unsolved debate. Hence this study was intended to examine the results of individuals who had their mitral valves replaced with either a CHVP, a mono leaflet valve, or a St. Jude valve, a bileaflet valve.
**Methods:** To assess the short-term results of patients having isolated mitral valve replacement with the tilting disc (CHVP) or frequently utilised bileaflet valves (St. Jude valve), we conducted a single-center prospective cohort research. Between January 2022 and June 2023, the study was carried out at the MMC Institute of Cardiology and Cardiothoracic Vascular Surgery in Chennai. There were a total of 60 cases that required replacement of the mitral valve. The remaining 30 instances received MVR using the TTK Chitra valve, while 30 cases underwent MVR using the St. Jude valve. Using a systematic proforma, demographic, clinical, and echocardiographic data were extracted from the hospital records. On-site follow-up data collection took place during scheduled review visits. The Statistical Package for Social Sciences was used to conduct the statistical analysis.
**Results:** Mean left atrium size, ejection fraction, LVDD, LVSD and gradient across mitral value were found to be similar in both group SJ and group C, respectively. In comparison with the baseline, at post operative one month mean ejection fraction, mean gradient, mean LVSD and mean LVDD were found to be similar. On assessing the mortality, there were 10% and 3.3% of cases died within one month post valvular replacement in group SJ and group C, respectively.
**Conclusion:** TTK Chitra mechanical heart valve offers similar outcomes at approximately half the price of an imported St Jude Mechanical heart valve, enabling many worthy patients in environments with limited resources to consider cardiac surgery.

**KEYWORDS:** TTK chitra, St. Jude, mitral valve replacement, mechanical valve

## I. INTRODUCTION

For stenotic and regurgitant lesions, valve replacement has had positive outcomes. Hufnagel replaced the first valve ever for aortic regurgitation by inserting a valve in the descending aorta[1]. With the introduction of new metals and alloys, prosthetic valves have undergone significant alterations. The single tilting disc and then the bileaflet valves were designed with similar goals in mind as the ball valve: to provide good hemodynamics, longevity, and freedom from problems[1]. No mechanical valve design, however, has ever been flawless.

Globally, valvular heart disease (VHD) is a significant cause of morbidity and mortality, particularly in poor countries where chronic rheumatic heart disease (RHD) continues to be the main cause of valvular heart disease, including anomalies of the mitral valve. Notably, not all patients in need of heart surgery can afford it in an environment with limited resources. As a result, India had a significant unmet need for a reliable and affordable replacement heart valve. The TTK Chitra mechanical heart valve prosthesis (CHVP) was created in the 1980s to fill this gap. It has been implanted more than 70,000 times during the previous 20 years and is in use widely[2]. The CHVP is a heart valve with a single leaflet and a tilting disc. Excellent clinical outcomes with CHVP

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were reported in a multicentric clinical investigation[3]. It has a strong potential for more widespread use in industrialised countries due to its inexpensive cost and shown efficacy. Although there are numerous studies supporting its long-term efficacy and safety[4][5], none have evaluated its echocardiographic features.

The relative benefits of one heart valve design over another are currently debated in the literature. Heart valves from the earliest generation, including caged ball designs, are no longer widely used. Currently, bileaflet-style valves are the most widely utilised valves. The relative benefits and drawbacks of the mono-leaflet and bileaflet designs are not well established because the majority of clinical trials only provide results for one kind of valve. Few comparison studies imply that the clinical efficacy and durability of the two valve types are comparable[6] [7].

Until 2009, when Medtronic ceased manufacturing their mono-leaflet valve, St. Jude Medical's bi-leaflet valve and Medtronic's Hall mono-leaflet valve were the two valves that were most frequently implanted[8]. In this situation, the CHVP could provide significantly more affordable clinical outcomes for patients with VHD than the current bileaflet and mono-leaflet valves. There are no clinical result comparisons between this mono leaflet valve variant and the current bileaflet valves. This study was intended to examine the results of individuals who had their mitral valves replaced with either a CHVP, a mono leaflet valve, or a St. Jude valve, a bileaflet valve.

## II. METHODS

To assess the short-term results of patients having isolated mitral valve replacement with the tilting disc (CHVP) or frequently utilised bileaflet valves (St. Jude valve), we conducted a single-center prospective cohort research. Between January 2022 and June 2023, the study was carried out at the MMC Institute of Cardiology and Cardiothoracic Vascular Surgery in Chennai. All participants provided written informed consent, which was obtained after it was authorised by the institutional ethics committee. Patients having a coronary artery bypass graft, a double valve replacement, or other cardiac operations concurrently were not included. There were a total of 60 cases that required replacement of the mitral valve. The remaining 30 instances received MVR using the TTK Chitra valve, while 30 cases underwent MVR using the St. Jude valve. Utilising computer-generated random numbers, cases were assigned. Using a systematic proforma, demographic, clinical, and echocardiographic data were extracted from the hospital records. On-site follow-up data collection took place during scheduled review visits.

Using a structured proforma, demographic information including socioeconomic status, gender, and age at operation were obtained. Clinical information was gathered on the causes of valve illness, functional class (NYHA), pulmonary artery hypertension, and the heart's natural rhythm. All patients underwent 2D transthoracic echocardiography and Doppler evaluation at baseline and during follow-up. Documented measurements were left ventricular ejection fraction, dimensions (in systole and diastole), gradient across the diseased valves, left atrial size, and aortic diameter. We longitudinally examined these variables at baseline and 30 days after surgery to analyse the outcomes. Deaths and adverse occurrences were also recorded.

The Statistical Package for Social Sciences was used to conduct the statistical analysis. Data were shown using the applicable mean or percentage. As necessary, the chi-square, Fisher's exact test, independent sample t test, Mann-Whitney test, paired sample t test, and Wilcoxon test were utilised.

## III. RESULTS

In this study, mean age of the study participants was reported as 42.5 years and 44.2 years in group SJ and group C, respectively. Also this study showed female predominance in both groups. RHD was reported among 93.3% and 86.7% of cases in group SJ and group C, respectively. Notably mitral valve prolapse was noted in three and two cases in group SJ and group C, respectively. Post balloon Mitral valvotomy, mitral regurgitation was noted in one case, in each group. NYHA functional class and PAH classes in both the groups were also similar at the start of study. Atrial fibrillation was reported in 86.7% and 90% of cases in group SJ and group C, respectively. (Table 1)

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**Table 1: Characteristics of study participants at start of study**

| Variables | Group SJ | Group C | p value |
|---|---|---|---|
| **Mean age at surgery (in years)** | 42.5±14.7 | 44.2±13.6 | 0.6437 |
| **Gender** | | | |
| Male | 13 (43.3) | 14 (46.7) | 0.7952 |
| Female | 17 (56.7) | 16 (53.3) | |
| **Rheumatic Heart Disease** | | | |
| Present | 28 (93.3) | 26 (86.7) | 0.3894 |
| Absent | 2 (6.7) | 4 (13.3) | |
| **Mitral valve prolapsed** | | | |
| Yes | 3 (10) | 2 (6.7) | 0.6404 |
| No | 27 (90) | 28 (93.3) | |
| **Post balloon Mitral valvotomy - Mitral Regurgitation** | | | |
| Present | 1 (3.3) | 1 (3.3) | 1.000 |
| Absent | 29 (96.7) | 29 (96.7) | |
| **Emergency MVR** | | | |
| Yes | 0 | 1 (3.3) | 0.6237 |
| No | 30 (100) | 29 (96.7) | |
| **NYHA - Functional Class** | | | |
| Class III | 17 (56.7) | 16 (53.3) | 0.7952 |
| Class IV | 13 (43.3) | 14 (46.7) | |
| **Pulmonary artery hypertension class** | | | |
| Class 0 | 1 (3.3) | 3 (10) | 0.4581 |
| Class 1 | 11 (36.7) | 12 (40) | |
| Class 2 | 9 (30) | 10 (33.3) | |
| Class 3 | 9 (30) | 5 (16.7) | |
| **Atrial fibrillation/flutter** | | | |
| Present | 26 (86.7) | 27 (90) | 0.8263 |
| Absent | 4 (13.3) | 3 (10) | |

MVR - Mitral valve Replacement, NYHA- New York Heart Association

In this study mean left atrium size, ejection fraction, LVDD, LVSD and gradient across mitral value were found to be similar in both group SJ and group C, respectively.

However, mean aorta size was significantly low in group C compared to group SJ. (Table 2)

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**Table 2: Cardiac profile of study participants**

| Variables | Group SJ | Group C | p value |
|---|---|---|---|
| Mean Left atrium size (mm) | 52.3±10.4 | 51.5±11.7 | 0.7805 |
| Mean Aorta size (mm) | 28.1±5.4 | 26.9±4.3 | 0.0462* |
| Mean Ejection fraction (%) | 55.3±7.7 | 53.4±8.2 | 0.3461 |
| Mean LVDD (mm) | 50.4±11.3 | 49.6±11.5 | 0.8432 |
| Mean LVSD (mm) | 32.4±7.2 | 32.5±7.6 | 0.9312 |
| Mean gradient across mitral valve (mmHg) | 7.3±6.4 | 7.5±6.8 | 0.7241 |

Significant; LVDD-Left ventricle end diastolic dimension, LVSD-left ventricle end systolic dimension

In comparison with the baseline, at post operative one month mean ejection fraction, mean gradient, mean LVSD and mean LVDD were found to be similar. (Table 3)

**Table 3: Comparison of baseline and postoperative one month cardiac status**

| Variable / Group | Baseline | Post op 1 months | p value |
|---|---|---|---|
| **Median NYHA functional class** | | | |
| Group SJ | III | I | - |
| Group C | III | I | - |
| **Median PHA functional class** | | | |
| Group SJ | I | 0 | - |
| Group C | I | 0 | - |
| **Ejection fraction (%)** | | | |
| Group SJ | 55.3±7.7 | 54.6±6.8 | 0.7429 |
| Group C | 53.4±8.2 | 53.1±7.9 | 0.9357 |
| **Gradient (mmHg)** | | | |
| Group SJ | 7.3±6.4 | 7.1±6.5 | 0.8347 |
| Group C | 7.5±6.8 | 7.4±6.5 | 0.8427 |
| **LVSD (mm)** | | | |
| Group SJ | 32.4±7.2 | 31.8±7.3 | 0.7356 |
| Group C | 32.5±7.6 | 31.9±7.8 | 0.6787 |
| **LVDD (mm)** | | | |
| Group SJ | 50.4±11.3 | 49.9±10.4 | 0.8352 |
| Group C | 49.6±11.5 | 49.9±10.1 | 0.951 |

NYHA- New York Heart Association, PAH – Pulmonary artery hypertension, LVDD-Left ventricle end diastolic dimension, LVSD-left ventricle end systolic dimension

On assessing the mortality, there were 10% and 3.3% of cases died within one month post valvular replacement in group SJ and group C, respectively. However on assessing the complications like embolism, haemorrhage, and prosthetic valve thrombosis, though the proportions were slightly different, the differences in proportions were not significant. (Table 4)

**Table 4: Complications and mortality among the study participants**

| Complications and Mortality | Group SJ | Group C | p value |
|---|---|---|---|
| **Mortality** | | | |
| Present | 3 (10) | 1 (3.3) | 0.3006 |
| Absent | 27 (90) | 29 (96.7) | |
| **Embolism** | | | |
| Present | 1 (3.3) | 1 (3.3) | 1.000 |
| Absent | 29 (96.7) | 29 (96.7) | |
| **Haemorrhage** | | | |
| Present | 2 (6.7) | 1 (3.3) | 0.5535 |
| Absent | 28 (93.3) | 29 (96.7) | |
| **Prosthetic valve thrombosis** | | | |
| Present | 3 (10) | 1 (3.3) | 0.3006 |
| Absent | 27 (90) | 29 (96.7) | |

## IV. DISCUSSION

In this study, mean age of the study participants was reported as 42.5 years and 44.2 years in group SJ and group C, respectively. Also this study showed female predominance in both groups. RHD was reported among 93.3% and 86.7% of cases in group SJ and group C, respectively. Notably mitral valve prolapse was noted in three and two cases in group SJ and group C, respectively. Post balloon Mitral valvotomy, mitral regurgitation was noted in one case, in each group. NYHA functional class and PAH classes in both the groups were also similar at the start of study. Atrial fibrillation was reported in 86.7% and 90% of cases in group SJ and group C, respectively. Mean left atrium size, ejection fraction, LVDD, LVSD and gradient across mitral value were found to be similar in both group SJ and group C, respectively. However, mean aorta size was significantly low in group C compared to group SJ. In comparison with the baseline, at post operative one month mean ejection fraction, mean gradient, mean LVSD and mean LVDD were found to be similar. On assessing the mortality, there were 10% and 3.3% of cases died within one month post valvular replacement in group SJ and group C, respectively. However on assessing the complications like embolism, haemorrhage, and prosthetic valve thrombosis, though the proportions were slightly different, the differences in proportions were not significant.

These findings were comparable with the findings of the following studies. Singh A et al[9] demonstrated that the long-term performance of the TTK Chitra mechanical valve prosthesis and the St. Jude mechanical heart valve were comparable, in terms of clinical benefits, side events, and mortality. They argued that CHVP gives comparable outcomes for roughly 50% less than an imported St Jude Mechanical heart valve, allowing many worthy patients in situations with limited resources to consider cardiac surgery.

Namboodri N. et al[10] evaluated the functional assessment of this tilting disc mitral prosthesis by comparing the derivation of mitral valve area (MVA) using the continuity equation and the more popular pressure half-time (PHT) technique. According to their findings, the mean Doppler gradient varied between 1.7 and 9.2 mmHg, whereas the peak gradient ranged from 5 to 21 mmHg. Increase in actual orifice area (AOA), which is calculated using the valve orifice diameter provided by the manufacturer, was negatively linked with mean gradient. With an increase in AOA, the mitral valve area computed using the PHT and continuity equation both increased significantly. Whether the PHT is less than or greater than 110ms, the average mitral valve area

determined by the continuity equation was 1.56 cm2, which was smaller than the PHT.

To determine the advantages of bileaflet and tilting disc valves, Fiore AC et al[11]. undertook a study. They claimed that there was no discernible difference between operative mortality and late mortality. There were no discernible differences in the groups based on the analysis of actuarial survival and freedom from valve-related events over a 10-year period. The St. Jude group had a better rate of freedom from reoperation. There were no discernible changes between the two prostheses when patient functional status and echocardiographic hemodynamic parameters were compared at the time of follow-up. Their research indicates that there are no differences between the St. Jude and Medtronic Hall prostheses in terms of late clinical performance or hemodynamic outcomes, and does not support the selection of either prosthesis in preference.

A study by Venkatavijay K et al[12]. evaluated the results of MVR using the tilting disc TTK Chitra valve, compared pre and postoperative valve gradients among tilting disc prosthetic valves, and examined the dimensions of the left ventricle (LV) before and after MVR, as well as complications related to posterior leaflet excision. They claimed that the TTK Chitra valve can be utilised safely and can produce results on par with those of more current generations of valves. Regardless of how far along the disease process is, mitral stenosis surgery greatly reduces PAH. The LV characteristics did not significantly change, and the EF was unchanged before and after surgery.

In another study, one mitral valve replacement patient experienced valve thrombosis among the 122 instances that underwent surgery, according to Malhotra A. et al[13]. Embolic problems occurred in three patients who underwent mitral valve replacement. The aortic and mitral locations' average peak gradient, mean gradient, and average peak velocity were discovered to be equivalent to those of other frequently used valves. They asserted that this valve performs on par with other commonly used valves in terms of hemodynamic problems, mortality, and morbidity. Hemodynamic gradients are better for follow-up because they are more repeatable than effective orifice area. In another study conducted by Joshi LM et al[14], 78 cases of mitral valve replacement with the TTK chitra valve were used. They had a 2.02% early mortality rate and a 5.4% late mortality rate. There were no signs of structural degradation, non-structural dysfunction, blocked valves, or prosthetic valve endocarditis. For valves in both places, actuarial independence from reoperation at 10 years was 100%. Actuarial survival rate was 89.87% after 10 years.

In another study, 735 patients who underwent solitary MVR were included in the study, according to Kaushik R et al[15]. Patients with CHVP were less experienced and came from a lower socioeconomic background. On follow-up, the mortality rates for all causes, valve-related deaths, prosthetic valve thromboses, emboli, haemorrhages, and infective endocarditis were comparable for both SJM and CHVP valves. Estimated event-free survival in the SJM group was 2302 days while it was 2484 days in the CHVP group. After controlling for baseline data, time spent in the therapeutic range, and aspirin use, valve type was not a reliable predictor of adverse outcomes. Except for a higher prevalence of IE with SJM, subgroup analysis of patients who received MVR showed similar functional improvement and outcomes.

In a research done over an 11-year period to examine the mid- to long-term clinical results of two comparable bileaflet heart valves, Bernet FH et al[16]. As part of separate or combination surgeries, 604 SJM and 601 ATS prostheses were placed altogether. SJM and ATS both had 30-day overall mortality rates of 4.1% and 3.4%, respectively. At 10 years, cumulative survival and independence from valve-related mortality for SJM and ATS valves were 66% and 68%, respectively, and 96% and 97%. For both valve types, there were no structural valve failures. At 10 years, 79% of SJM patients had no total valve-related problems, compared to 66% of ATS patients. The linearized rates for adverse valve-related events for SJM and ATS valves were, respectively, thromboembolism (0.9%), major bleeding requiring transfusion (0.3%), prosthetic endocarditis (0.1%), para valvular leak (0.1%), and thromboembolism (1.1%) per patient year.

An evaluation of the Chitra TTK heart valve, which was used in 65 aortic and 64 mitral implants, was done by Nagarajan M et al[17]. They stated that one early death from infective endocarditis occurred. There were 7 late deaths, 3 of which occurred in the aortic, 3 in the mitral, and 1 in the double valve groups. Endocarditis and clogged valves were the causes of the late deaths in two individuals each. The cause of death couldn't be determined in the other cases. Follow up with the remaining 144 patients included clinical and echocardiographic examination. 7.2% of the patients experienced thrombo-embolic episodes, with 5 of those episodes being serious and the remaining incidents being minor, with a linearized rate of 1.8 percent patient year. Studies on

hemodynamics in people who have undergone surgery compared it to other prosthetic valves. At five years, 82% of patients survived without thromboembolism. At five years, the actuarial survival was 78%.

However, in another study, Muralidharan S et al[18] recorded the results after ten years for patients who received CHV valve replacement. According to their findings, out of 65 patients, 58.5% had their mitral valve replaced, 29.3% had their aortic valve replaced, and 12.3% had their double valves replaced. Hospital mortality was nonexistent. The mortality rate throughout the long period was 20.9%. Valve thrombosis and prosthetic valve endocarditis were each present in 4.6% of instances, whereas myocardial infarction and poor cardiac output due to significant left ventricular dysfunction were both present in 2.3% of cases. In the remaining 6.9% of instances, the cause of death could not be determined. In this group of individuals, there were no structural issues reported.

Heart valve actuarial survival utilising TTK Chitra at 15 years was 82.3% for AVR, 60.7% for MVR, and 52.2% for DVR, according to Varma PK et al[19]. For AVR, MVR, and DVR, respectively, freedom from all valve-related mortality and morbidity at 15 years was 73.8%, 64.8%, and 61.9%. In one instance, the valve disc's structural collapse caused significant valvar regurgitation. Incidences of valve thrombosis were 1 in AVR, 6 in MVR, and 1 in DVR. 50 patients experienced thromboembolic episodes, and 24 patients suffered from significant bleeding.

In a study using the TTK Chitr heart valve, Bagale KK et al[20]. found that the AVR, MVR, and DVR rates were 82.3%, 60.7%, and 52.2%, respectively. For AVR, MVR, and DVR, respectively, freedom from all valve-related mortality at 15 years was 73.8%, 64.8%, and 61.9%. A total of 167 TTK Chitra valves were implanted in the aortic and/or mitral locations, according to Motilal M et al[21]. MVR was performed on 80 patients, AVR on 19, and DVR on 28. Nine patients underwent coronary artery bypass grafting (CABG) with MVR, while seven underwent CABG with AVR. The patients were between the ages of 18 and 65. The majority of the patients (48%) ranged in age from 31 to 50. In the study population, 58% of the participants were men, with the remaining participants being women.

The outcomes of 148 patients who had mechanical heart valve replacement in the mitral and aortic positions with ATS and St. Jude were presented by Hamidi MR et al[22]. In their study, there were 46.6% more male patients than female patients, and the patients' ages ranged from 11 to 65. 63.5% of the patients underwent MVR, 25.6% underwent AVR and 10.8% needed a DVR. Overall mortality for all three types of valve replacement was 10.8%. Early mortality was 4.1%, and after a three-year follow-up, late mortality was 6.7%. Hemodynamically, ATS and St. Jude mechanical heart valves have very good regarding trans valvular gradient and function, but low prosthetic valve noise is only seen in ATS mechanical heart valve. The INR was maintained between 2.5 and 3.5 in both ATS and St. Jude mechanical heart valves for mitral position, and 2-3 for aortic position.

Mandiye SS et al[23]. examined the results of mechanical versus bioprosthetic valve replacements for the mitral, aortic, or double valves. Preoperatively, all groups were equivalent, with the exception that patients getting biological valves tended to be more female and to live in rural areas. In both groups, the 30-day death rate was comparable. The mechanical valve group experienced significantly more valve-related problems. About three years after their initial surgery, two patients who had mechanical valves needed another procedure to fix a blocked prosthetic valve. In the mechanical valve group, there were two fatalities, both from prosthetic valves that became trapped. There were no cases of prosthetic valve endocarditis in either group. At five years, structural valve malfunction was not common. They came to the conclusion that in Indian patients, mechanical valves are substantially more likely to cause complications than biological valves.

## V. CONCLUSION

The TTK Chitra mechanical heart valve offers similar outcomes at approximately half the price of an imported St Jude Mechanical heart valve, enabling many worthy patients in environments with limited resources to consider cardiac surgery.

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