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A COMPARATIVE RETROSPECTIVE STUDY OF TTK CHITRA AND ST JUDE'S MASTERS MECHANICAL PROSTHETIC CARDIAC VALVES AT KURNOOL MEDICAL COLLEGE HOSPITAL

First and corresponding

Dr Mrs Benedicta Coelho, MS MCH
Assistant Professor
Kurnool Medical College, Kurnool ,AP state

Second Author

Dr C Prabhakara Reddy, MS MCH ,PROF & HOD
Kurnool Medical College, Kurnool ,AP state

ABSTRACT

Background

Rheumatic heart disease is prevalent despite early diagnosis and preventive measures set in place by our health policies for Acute Rheumatic Fever. Most of these people go unnoticed, and hence present for treatment at a late stage where valve replacement is the only option. As India is still a developing country, majority of the affected population is below the poverty line and cannot afford the expensive imported valve options. TTK Chitra Valve is an indigenously designed and manufactured tilting disc valve which has emerged as an economical solution. In this study, we compare the performance of SJM and TTK Chitra mechanical valves in a government setup.

Methods and Materials

This is a retrospective study performed in the department of Cardiovascular and Thoracic surgery. All patients who underwent valve replacement between 2016-2023 were included. Preoperative echo findings, surgical aspects and post operative parameters such as gradients across the valve, ventricular function and complications were recorded.

Results

There were significant differences between the two groups, except with clinical, NYHA functional, and Echocardiographic parameters, where TTK showed a better post-operative outcome.

Conclusion

The SJM and TTK Chitra valve are comparable in pre-, intra- and post-operative parameters. As TTK is a cost-effective option, it can be considered for those patients with financial constraints.

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INTRODUCTION

Despite the great strides we have made in healthcare over the last few decades, acquired valvular diseases of Rheumatic aetiology continues to be very prevalent in developing economies [1]. As per the Ministry of Health and Family Welfare (MoHFW), Government of India's 2015 publication [2], the prevalence of rheumatic heart disease (RHD) is estimated at 0.9 cases per 1000 children in the age-group of 5-14 years. Assuming 20% of the country's total population is in 5-14 years age-group, it is estimated that there are around 2.18 lakh cases of RHD in the country. Most of these cases are usually diagnosed a decade after acquiring the acute rheumatic fever. As a result, they are in their middle age and usually belong to the working class, when they show up for treatment. This can result in a significant financial constraint on the family with increased healthcare costs. Despite the decline in the number of acute rheumatic fever cases, carditis patients continue to present with severe form of valvular heart diseases, which are not amenable for minimally invasive procedures like Percutaneous Balloon Mitral Valvuloplasty (PBMV). In cases of severe Mitral Stenosis, valve replacement is the preferred treatment. While imported options such as St. Jude Medical Masters series valves are available for mechanical valve replacement, TTK Chitra heart valve emerged as a promising indigenous alternative [3]. Also, there are only a few studies comparing the efficacy, the complications and cost effectiveness of various mechanical valves for aortic valve replacement.

Hence, the aim of this the study was to retrospectively compare the imported St Jude Master series mechanical (SJMV) valve with the indigenous TTK Chitra mechanical valve (TTKCHV), which was commercialized during 1990s.

METHODS AND MATERIALS

- A single centre retrospective observational comparative study at the CTVS department.
- *Study period:*
    - September 2016 to Sept 2019 → SJMV was used.
    - October 2019 to March 2023 → TTCHV was used .

Demographic, clinical functional class (NYHA) Pulmonary artery hypertension, baseline cardiac rhythms, Echocardiographic data, Doppler evaluation and gradients across the diseased valves were collected from the departmental records using a structured form. For non-local

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distant patients, follow-up details were obtained from the outpatient / inpatient records and over telephonic interviews.

INCLUSION CRITERIA

Patients presented with valvular pathology not amenable for repair and only of chronic Rheumatic etiology were included.

EXCLUSION CRITERIA

Pediatric patients of less than 12 years of age, redo-sternotomy, patients with documented infective endocarditis or root abscesses, valvular diseases due to other etiological factors like Mitral Valve Prolapse (MVP), Marfan's syndrome, connective tissue disorders, age related Sclerotic Aortic valves, Aortic Stenosis (AS) and ischemic Mitral Regurgitation (MR), etc.

DATA COLLECTION

Case records satisfying the inclusion criteria were extracted and data regarding the demographic details, history, co-morbidities, socio-economic status (as per modified Kuppuswamy classification), intraoperative details, post-operative outcomes at 1week, 1month and 6 months were all collected.

For analysis of outcomes, we compared the parameters longitudinally at baseline, 1month, 3 months and 6 months. Data regarding the type of valve implanted, valve size, duration of CT-ICU stay, hospital stay were also collected and tabulated. The therapeutic anticoagulation levels were defined as INR (prothrombin time) of 2 - 3 for Aortic Valve Replacement (AVR) and 2.5 - 3.5 for Mitral Valve Replacement (MVR) and Dual Valve Replacement (DVR).

ADVERSE EVENTS:

Adverse events were identified from hospital records and during interaction with the patients at follow up visits or through telephonic interview with patient or kith and kin.

Early and late mortality and valve related events were defined according to the published guidelines for reporting morbidity and mortality after cardiac valve intervention from the society of Thoracic Surgeons [4]. Prosthetic valve thrombosis (PVT) was defined as confirmed if there

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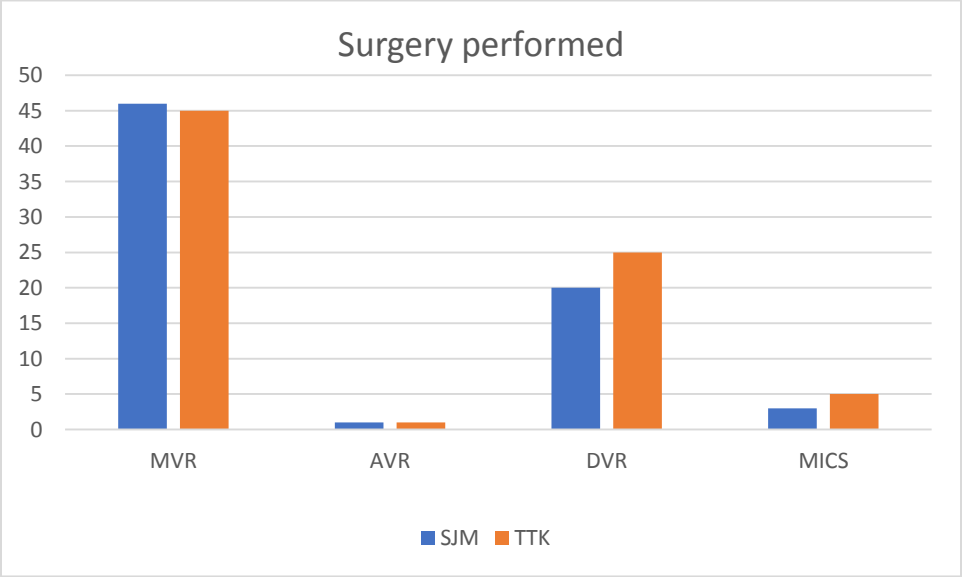
was documentation of increased gradients, thrombosis and reduced leaflet movements on Echocardiography and fluoroscopy indicating restricted valve movement. When patient died at the local hospital after the treatment, even though original records were not available, data was included in the final analysis. Primary outcome variables (all-cause mortality, early deaths, valve related mortality) were only considered as the follow-up was done at 6 months after the surgery.

OPERATIVE PROCEDURE

138 Patients were operated through a median sternotomy, a roller pump with crystalloid prime and Aorto-bicaval Cardio Pulmonary Bypass. Antegrade cardioplegia was administered through the Aortic root. Standard techniques were used with the valve(s) being replaced using interrupted sutures. Moderate hypothermia (28 – 32^{o}C) was used and cold blood cardioplegia was employed for arresting the heart in all the cases. 6 patients underwent minimally invasive cardiac surgery (MICS) procedure for the valve replacement.

STATISTICS



Data was entered into a Microsoft Excel spreadsheet and analyzed using SPSS v21. The categorical data was represented as frequency and percentage while the continuous data was represented as a mean. Any 'p' value < 0.05 was considered statistically significant.

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RESULTS

A total of 146 patients with Rheumatic valvular disease underwent valve replacement between 2016 and 2022.

Demographic parameters

The mean age of the study participants was 38.58 +/- 9.86 years, with the minimum age being 15 and the maximum being 81 years. The male-to-female ratio in this study was 1 : 3.8, which corroborates with the national statistics outlined by MoHFW. The number of mitral valve procedures was significantly higher in females than in males (p 0.0043*), while double valve replacement was more common in males.

The most common age group afflicted with mitral valve disorders was 25-35 years, with mitral stenosis being the most common lesion. However, for AVR, Bicuspid AV was the most common aetiology.

VALVE LESIONS	SJM	TTK
MITRAL STENOSIS	34 (+2 MICS)	37 (+1 MICS)
MITRAL REGURGITATION	12 (+1 MICS)	8 (+1MICS)
AORTIC STENOSIS	1	1
AORTIC REGURGITATION	0	0
DOUBLE VALVE REPLACEMENT	20 (+1-MICS)	25

The chi-square statistic is 0.4421. The *p*-value is .895438. The result is *not* significant at $p < .05$.

a) The right ventricular function was deranged in 32.91% patients, with mean Tricuspid Annular Plane Systolic Excursion (TAPSE) of 5.5 mm.
b) Severe sub-mitral disease was noted in 87.22% patients.

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c) MS & AR were the most common paired lesion who underwent DVR and the mean age at presentation was 48+/-8 years and male being the common gender affected.

d) Majority of the study participants belonged to lower and lower middle class of Socio-economic strata as per modified Kuy classification (56.88%,34.21%)

e) Left ventricular mean ejection fraction was 42.62%.

f) 41.9% patients had mild-moderate LV dysfunction at the time of presentation

Operative details

Prosthesis size used was decided by the Body Surface Area (BSA) of the patients and was found to be between 23 - 31 for mitral position and 19 - 23 for aortic position. We found that for stenotic lesions, the valve inserted was one size smaller than what was anticipated for that BSA, but there was no statistically significant difference between the two groups.

Mean CPB time and mean cross-clamp time were comparable between the two groups, irrespective of the valve replaced. (p value 0.933)

Concomitant procedures performed with valve surgeries are most often TV valvuloplasty, CABG or ASD closure.

Concomitant surgery	SJM	TTK
CABG	6	4
ASD	1	1
TV valvuloplasty	23	28

Post-operative parameters

The median duration of ICU stay was 3 days, while the median hospital stay was 10 days. The mean duration of ventilation was 12.31 hours.

Intermediate and long-term mortality

There was one death noted following MVR due to severe biventricular dysfunction and intractable arrhythmias. At the end of the 6 months follow-up, 5 patients died due to frank pulmonary oedema (2) and stuck valve (1-TTK, 2-SJM).

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Post-operative ECHO

There was no significant difference between the two groups on the following parameters:- (p 0.738)

1. Valvar gradient
2. Paravalvular leak
3. LVIDd and LVIDs
4. TAPSE
5. LVEF

There was significant difference between the two groups, except with clinical ,NYHA functional, and Echocardiographic parameters, where TTK showed a better post-operative outcome.

DISCUSSION

In India and other Southeast Asian nations, Chronic Rheumatic heart disease is the main contributor to valvular heart disease. The causes of valvular heart disease reported from the developed world is different with the most common etiological factor being degenerative in nature; may be followed by connective tissue disorders [5].

Our results are impacted by poor Socio-economic strata and delayed referrals. The Mitral valve is most commonly affected by Rheumatic heart disease, followed by the Aortic, Tricuspid and pulmonary valves. Tricuspid valve is most commonly functionally disabled by organic pathology. The most frequent pairing are Mitral and Aortic, Mitral and Tricuspid, all the three valves together [5].

We also see a lot of females from the active reproductive age group presenting with poor functional class (NYHA- III &IV) during the second trimester of pregnancy. Such cases get referred after the initial medical stabilization with diuretics, beta blockers, Digoxin and Lomarins. We refer them for PBMV. Among Indian females of poor Socio-economic strata and with chronic iron deficiency anemia, pregnancy is of high risk, when Mitral Stenosis is critical.

As most of our patients present late, valvular replacement is considered as the appropriate treatment. The era of CMV(Closed Mitral Valvotomy) and open Mitral Valvotomy are almost

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bygone. However, when amenable, Mitral valve repair may give good long term results for mild to moderate Mitral regurgitation. Bioprosthetic and autograft valves are available and ideal among the geriatric group due to poor anticoagulant compliance and dreaded complications.

Our findings show that the long term clinical outcomes of SJM, a widely used bileaflet valve and TTK Chitra monoleaflet tilting disc valve are comparable [6]. Our patients, who underwent valve replacement were much younger in the Mitral group, than in the Aortic and DVR groups

In a study by Sampath Kumar A, et al, the average age during operation was 40-43 years, CRHD accounted for 70-90% of Valve replacements [5]. It is well known that CRHD is more common in developing nations with low socio-economic status. Poor living conditions, limited access to healthcare and non-compliance with antibiotic prophylaxis contribute to higher reverence rates of Rheumatic fever and more severe valvular damage, which manifests at an earlier age than the Western countries.

The early complication rate as well as immediate mortality was nil in the present study, which could vary with the infrastructure in the institution.

In a population like ours, the multicentric clinical study of CHVP reported an early mortality of 6.9% in 2001, with just single aortic or mitral valve replacement (7). Recent studies using the TTK Chitra valve shown a dramatic decrease in early mortality to 0.6-1.5% (8, 9, and 10). Perioperative and post-operative care may differ among centers .

Minimally invasive procedures like catheter guided valve deployment, Mitraclip, TAVI, Robotics etc., are the future of Cardiac surgery when indicated for the appropriate cause.

LIMITATIONS

Our study is a retrospective one and hence it is prone for recall bias. It is, not a randomized control trial between the valve groups and hence certain baseline differences were found to exist, although adjusting for these differences did not reveal any statistically significant difference. Also due to the demographic variables, we cannot assume that these results can be generalized to a larger population.

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CONCLUSION

According to these findings, both valve designs are equally effective in terms of survival and freedom from thrombosis, haemorrhage, and infectious endocarditis. In either valve group, we found no instances of structural valve degeneration. As the indigenous TTK Chitra valve is equally effective and efficient at a lesser cost, we recommend it to our marginalized population as a cost-effective valve .

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