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RESEARCH ARTICLE

EFFICACY OF TTK CHITRA MECHANICAL HEART VALVE VERSUS ST JUDE MECHANICAL HEART VALVE IN AORTIC VALVE REPLACEMENT

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Abstract

Background: For patients having aortic valve replacement (AVR), the St. Jude and TTK Chitra mechanical heart valves are both often utilised in daily practise. The effectiveness of these valves is still up for discussion, though. Therefore, the purpose of this study was to investigate the outcomes of patients who underwent AVR with a St. Jude mechanical valve (SJMV) or a Chitra heart valve prosthesis (CHVP).

Methods: We performed a single-center prospective cohort study among patients undergoing isolated aortic valve replacement at the MMC Institute of Cardiology and Cardiothoracic Vascular Surgery in Chennai between January 2022 and June 2023. An aortic valve replacement was necessary in 60 patients in total. Thirty cases underwent AVR with the St. Jude valve and the remaining thirty cases were treated with the TTK Chitra valve. Data were collected and analysis was carried out using the Statistical Package for Social Sciences.

Results: Group SJ had 90% of instances with RHD, whereas group C had 93.3% of cases with RHD. In groups SJ and C, calcified AV was observed in 33.3% and 40% of patients, respectively, and bicuspid AV in 26.7% and 23.3% of cases, respectively. Both group SJ and group C's baseline cardiac parameters were determined to be comparable. Both at baseline and one month after surgery, the mean EF, LVSD, and LVDD in groups SJ and C were comparable. At one month after surgery, both groups' mean gradient across the aortic valve was significantly lower than baseline. Groups SJ and C had mortality rates of 6.7% and 3.3%, respectively.

Conclusion: Aortic valve replacement patients in low-resource countries can now explore cardiac surgery because to the TTK Chitra mechanical heart valve, which provides comparable results at around half the cost of an imported St. Jude mechanical heart valve with similar efficacy and safety.

Introduction:-

The most prevalent acquired valvular heart disease among adults and the elderly in developed nations is aortic stenosis, which typically necessitates surgery. Aortic stenosis can be caused by degenerative, rheumatic, or congenital bicuspid aortic valves. In developing nations, rheumatic valvular heart disease is still a significant issue.

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The best course of action is surgery (valve replacement), which has a 3% average hospital death rate and great long-term outcomes. Patients who choose not to have surgery have a significant risk of sudden cardiac death and irreparable cardiac damage[1].

An average annual increase in aortic jet velocity of 0.3 m/s, a mean trans-aortic pressure gradient of 7 mmHg, and a decrease in aortic valve area of 0.1 cm2 have been found in prospective studies examining the hemodynamic progression rate of patients diagnosed with aortic stenosis. Predicting hemodynamic progression in individual patients is challenging due to significant individual variance, even if the overall rate of hemodynamic progression is rather steady across studies[2,3]. It is less clear which clinical characteristics are linked to the development of hemodynamic instability than it is to the existence of calcific valvular disease. In addition, the majority of these investigations rely on retroactive analyses.

Operative death rates for aortic valve replacement have been reported in recent surgical series to be as low as 1%, up to 9% in higher-risk patients. After valve replacement, the long-term survival rate is 80% after three years, and the age-corrected survival rate following surgery is almost normal. Significant postoperative morbidity, which ranges from 2% to 3% year, is uncommon and includes hemorrhagic complications from anticoagulation, prosthetic valve malfunction, endocarditis, and thromboembolism[4].

All the variants, meanwhile, are dependent on one another, and prosthetic valves are a major contributor to this pathophysiology. There was a significant unmet demand in India for an affordable prosthetic heart valve that worked well. TTK CHVP was created in the 1980s in an effort to close this gap. For the past 20 years, it has been widely used, and more than 70,000 implantations have been completed[5].

The CHVP is a tilting disc heart valve with a monoleaflet configuration. Excellent clinical outcomes with CHVP were reported in a multicentric clinical trial[6]. On the relative benefits of one heart valve design over another, the literature is still split. Heart valves from earlier generations, including a caged ball design, are no longer often used. At the moment, valves with a bileaflet design are the most widely utilised. The advantages and disadvantages of the mono-leaflet and bileaflet designs are not clearly established because the majority of clinical trials report on the results of a single valve type's follow-up. There aren't many research that compare the clinical performance and durability of the two types of valves[7,8]. St. Jude Up until 2009, when Medtronic stopped producing their mono-leaflet valve, the most often implanted valves were the medical bileaflet valve and the Medtronic Hall mono-leaflet valve. Six In this situation, the CHVP might provide patients with VHD with clinical results that are on par with those of current bileaflet and mono-leaflet valves, but at a significantly lower cost. With these in view this study was conducted to assess the efficacy of TTK Chitra valve and St. Jude mechanical valve in aortic valve replacement cases.

Methods:-

We performed a single-center prospective cohort study to evaluate the short-term outcomes of patients undergoing isolated AVR with CHVP or St. Jude valve. The study was conducted at the MMC Institute of Cardiology and Cardiothoracic Vascular Surgery in Chennai between January 2022 and June 2023. Written informed permission was given by each participant, after approval by the institutional ethics committee. Individuals undergoing simultaneous cardiac procedures such as double valve replacement, coronary artery bypass grafting, or other procedures were excluded. An aortic valve replacement was necessary in 60 patients in total. Thirty cases underwent AVR with the St. Jude valve and the remaining thirty cases were treated with the TTK Chitra valve. Cases were assigned using randomly generated numbers produced by a computer. Data on demographics, clinical conditions, and echocardiography were taken from the hospital files using a methodical proforma. Follow-up data was collected on-site during prearranged review visits.

Demographic data, such as age at surgery, gender, and socioeconomic level, were gathered using a structured proforma. Clinical data about the natural cardiac rhythm, functional class (NYHA), and aetiology of valve disease were collected. At baseline and during follow-up, all patients had 2D transthoracic echocardiography and Doppler examination. The measurements that were recorded included the aortic diameter, gradient across the diseased valves, diameters (both in diastole and systole), and left ventricular ejection fraction. To assess the results, we looked at these characteristics longitudinally at baseline and 30 days post-surgery. Adverse events and deaths were also noted. The statistical analysis was carried out using the Statistical Package for Social Sciences. Data were shown with

respect to the relevant mean or percentage. The chi-square, Wilcoxon test, Mann-Whitney test, independent sample t test, paired sample t test, and Fisher's exact test were used as needed.

Results:-

Mean age of participants in group SJ and group C was reported as 42.6 years and 43.6 years, respectively and overall there were female predominance noted in this study. RHD was present in 90% and 93.3% of cases in group SJ and group C respectively. Similarly calcified or degenerative AV was noted in 33.3% and 40% of cases in group SJ and C, respectively and Bicuspid AV in 26.7% and 23.3% of cases in group SJ and C respectively. Notably infective endocarditis was reported in 3.3% and 6.7% of cases in group SJ and C respectively (Table 1).

Table 1:- Clinical profile of study participants at start of study.

Variables	Group SJ	Group C	p value
Mean age at surgery (in years)	42.6±13.1	43.6±12.6	0.7642
Gender			
Male	15 (50)	13 (43.3)	0.6047
Female	15 (50)	17 (56.7)	
Rheumatic Heart Disease (RHD)			
Present	27 (90)	28 (93.3)	0.6404
Absent	3 (10)	2 (6.7)	
Calcified/ Degenerative AV			
Present	10 (33.3)	12 (40)	0.5920
Absent	20 (66.7)	18 (60)	
Bicuspid AV			
Present	8 (26.7)	7 (23.3)	0.7655
Absent	22 (73.3)	23 (76.7)	
Infective Endocarditis			
Present	1 (3.3)	2 (6.7)	0.5536
Absent	29 (96.7)	28 (93.3)	
NYHA - Functional Class			
Class II	17 (56.7)	16 (53.3)	0.7952
Class III	13 (43.3)	14 (46.7)	

AV – Aortic valve, NYHA- New York Heart Association

In the present study at baseline, mean ejection fraction, aortic valve gradient, aortic diameter, left ventricle systolic dysfunction and left ventricle diastolic dysfunction were found to be similar in both group SJ and group C. (Table 2)

Table 2:- Cardiac profile of study participants.

Variables	Group SJ	Group C	p value
Mean Ejection fraction (%)	54.6±10.3	52.8±11.4	0.5236
Mean Aortic valve gradient (mmHg)	42.4±26.4	41.6±27.7	0.09092
Mean Aortic diameter (mm)	33.5±5.2	32.4±6.1	0.4553
Mean LVSD (mm)	36.7±10.2	37.5±11.6	0.7777
Mean LVDD (mm)	55.4±12.3	57.6±13.6	0.5137

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

Median NYHA class was I after one month of AVR in both the groups however the same was II at baseline. Mean EF in group SJ and C were similar at baseline and also at one month post op. However the mean gradient across aortic valve was significantly less in both groups at one month post op compared to baseline. LVSD and LVDD were similar in both groups at one month post op compared to baseline. (Table 3)

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

Variable / Group	Baseline	Post op 1 month	p value
Median NYHA functional class			
Group SJ	II	I	-
Group C	II	I	
Mean Ejection fraction (%)			

Group SJ	54.6±10.3	54.9±8.5	0.9463
Group C	52.8±11.4	54.5±10.6	0.5673
Mean Gradient across aortic valve (mmHg)			
Group SJ	42.4±26.4	14.6±7.4	<0.0001*
Group C	41.6±27.7	13.7±6.2	<0.0001*
Mean LVSD (mm)			
Group SJ	36.7±10.2	33.8±6.8	0.2002
Group C	37.5±11.6	33.1±7.3	0.0840
Mean LVDD (mm)			
Group SJ	55.4±12.3	50.3±8.7	0.0688
Group C	57.6±13.6	51.9±10.4	0.0734

NYHA- New York Heart Association, LVDD-Left ventricle end diastolic dimension, LVSD-left ventricle end systolic dimension

In this study the mortality was 6.7% and 3.3% in group SJ and C respectively; hemorrhage was 3.3% in both the groups and Prosthetic valve thrombosis was reported in 3.3% of case in group SJ only. (Table 4)

Table 4:- Complications and mortality among the study participants.

Complications and Mortality	Group SJ	Group C	p value
Mortality			
Present	2 (6.7)	1 (3.3)	0.5536
Absent	28 (93.3)	29 (96.7)	
Hemorrhage			
Present	1 (3.3)	1 (3.3)	1.000
Absent	29 (96.7)	29 (96.7)	
Prosthetic valve thrombosis			
Present	1 (3.3)	0	0.3132
Absent	29 (93.3)	30 (100)	

Discussion:-

In an aortic pulsatile flow model, five sizes of St. Jude and Hancock valves were examined by Baumgartner H et al[9] to assess potential reasons for discrepancies between Doppler and catheter gradients across prosthetic valves. Significant discrepancies were seen in the St. Jude valve between the Doppler and catheter gradients recorded 30 mm downstream from the valve: the Doppler gradients were 81% higher than the mean and peak catheter gradients of 10 mm Hg or more. There were strong early pressure recoveries and high localised gradients at the valve plane as the catheter was pushed back through the valve's tunnel-like central orifice. Gradients at the same level were only 46% of the gradients from the central orifice when the catheter was drawn back through the large side orifices. Excellent agreement was observed between the Doppler peak and mean gradients and the greatest central orifice catheter gradients. For the Hancock valve, there was a noticeably improved agreement between the Doppler and catheter gradients at 30 mm, even if the Doppler peak and mean gradients were still somewhat higher. Doppler gradients were 13% and 18% higher, respectively, than catheter gradients. The greatest gradients were recorded at 20 mm distal to the valve ring when the catheter was pushed back through the valve. These catheter gradients were in perfect agreement with the Doppler peak and mean gradients. As a result, Doppler gradients correctly depict the largest catheter gradients that can be found, which are found in the Hancock valves 20 mm distal to the prosthesis and between the two leaflets of the St. Jude valves. However, because of localised gradients and pressure recovery, Doppler gradients may be much larger than catheter gradients reported further downstream. Therefore, the reason why Doppler and catheter gradients differ from one another is not because Doppler overestimates, but rather because the two methods measure gradients at different sites. The restored pressure distal to the valve is measured by catheterization, whereas Doppler measurements show the highest gradient along the interrogation line. In Hancock valves, the difference in magnitude is not clinically significant; but, in St. Jude valves, it might be, especially when the valve diameters are lower and the flow rates are higher.

According to Vitale N et al[10]., the clinical hemodynamic performances of St Jude Medical Hemodynamic Plus valves, which have a diameter of 21 and 23 mm, are much better at gradients than standard cuff valves and closely match standard cuff valves in terms of hemodynamic performance. As a result, using this valve could reduce the requirement for aortic annulus expansion. In another study, in order to evaluate the short and mid-term effects of the

TTK Chitra valve in the aortic position in patients with aortic stenosis, Rao A et al[11]. conducted a study. 89.3% of patients were in class II of the NYHA, 9.3% in class III, and 1.3% in class IV. Following the aortic valve replacement, there was a post-operatively observed considerable improvement in functional class. After surgery, 93.3% of patients were in NYHA class I. However, the impact of implanting 19-mm or 21-mm St. Jude Medical standard prostheses on the long-term clinical result was confirmed by Milano AD et al[12]. In group 1, operational mortality was 7.5%, while in group 2, it was 8.5%. Upon discharge, 18% of group 1 and 5% of group 2 had a significant patient prosthesis mismatch. Peak transprosthetic gradients and effective orifice area index were considerably better in group SJ - 21 mm at the final follow-up left ventricular mass reduction. There was a significant decrease in sudden death, valve-related death, and cardiac events among the SJ-19 mm group. The authors arrived at the conclusion that, while the long-term outcomes following AVR with small-sized St. Jude Medical standard prostheses are satisfactory, recipients of the 19-mm valve exhibit a high prevalence of significant patient prosthesis mismatch, with less obvious functional improvement and a higher rate of cardiac events. These findings suggest that this prosthesis should be used very cautiously.

Similarly, Singh A et al[13] contrast the western valve (SJ) with the Indian valve (TTK - CHVP). According to the study's findings, the clinical advantages, side effects, and mortality rates of the TTK-CHVP and the St. Jude Mechanical heart valve are similar over the long run. They came to the conclusion that CHVP provides comparable outcomes at about half the price of an imported St Jude Mechanical heart valve, opening up the possibility of cardiac surgery to many worthy patients in environments with limited resources. In another study, using TTK-CHVP in AVR demonstrated early mortality of 2.02% and late fatalities of 5.4%, according to Joshi LM et al[14]. There were no signs of prosthetic valve endocarditis, blocked valves, non-structural dysfunction, or structural degeneration. For valves in both placements, the actuarial freedom from reoperation at ten years was 100%. At ten years, the actuarial survival rate was 89.9%.

The clinical results of SJM and CHVP valves in MVR and AVR cases were studied by Kaushik R et al[15]. CHVP patients were younger and from a poorer socioeconomic background. There were 2836 patient-years of follow-up for the study cohort. During follow-up, both valves showed comparable rates of all cause death, valve-related mortality, prosthetic valve thrombosis, embolism, bleeding, and infective endocarditis. In the SJM group, the estimated event-free survival was 2302 days, while in the CHVP group it was 2484 days. Once baseline data, time in therapeutic range, and aspirin use were taken into account, valve type was no longer an independent predictor of adverse outcomes. AORtic position subgroup study of patients undergoing MVR and AVR revealed similar functional improvement and outcomes, with the exception of a greater incidence of IE associated with SJM. They found that in aortic or mitral placements, low-cost, locally produced CHVP performs as well clinically in the midterm as SJM. Additionally, Nagarajan M et al[16] included 64 mitral and 65 aortic implants; the remaining valves were double valves, all of which were performed with CHVP. They stated that infectious endocarditis was the cause of one early death. One late death occurred in the double valve group, three in the aortic group, and three in the mitral group. Two patients' endocarditis and two patients' choking valves were the causes of the late deaths. The reason of death in the remaining cases was unknown. Clinical and echocardiographic evaluations were conducted on the remaining 144 individuals. Eleven patients (7.2%) experienced thrombo-embolic episodes, with a linearized rate of 1.8 percent every patient year. Of these, five experienced significant events. Studies on postoperative hemodynamics in patients with various prosthetic valves showed similar results. At five years, the thromboembolism-free survival rate was 82%. After five years, the actuarial survival was 78%.

The objective of Muralidharan S et al[17] was to record the 10-year results of patients who had CHV-assisted valve replacement. The age range of the participants was stated to be 8 to 62 years old. The ratio of men to women was 1.6 to 1. 58.5% of the 65 patients had their mitral valve replaced, 29.3% had their aortic valve replaced, and 12.3% had their double valves replaced. Hospital mortality was nonexistent. Twenty.9% was the long-term mortality rate. 2.3% had a myocardial infarction, 4.6% had valve thrombosis, 4.6% had prosthetic valve endocarditis, 2.3% had reduced cardiac output as a result of significant left ventricular dysfunction. In the remaining 6.9% of instances, the cause of death was unknown. In this patient group, there were no observed structural problems. Mandiye SS et al[18] contrasted the results of mechanical and bioprosthetic valve replacements for aortic or double valve replacements. Before surgery, the two groups were similar, with the exception that patients who received biological valves were more likely to be female and to live in rural areas. Both groups' 30-day mortality rates were comparable. Complications connected to valves were far more common in the mechanical valve group. About three years after the initial procedure, two patients with mechanical valves needed a second procedure to fix a blocked prosthetic valve. The mechanical valve group saw two deaths, both of which were caused by a prosthetic valve that became stuck. There

were no reports of prosthetic valve endocarditis in either group. There was no structural valve malfunction at five years. They came to the conclusion that, in Indian patients, mechanical valves are linked to a noticeably greater rate of complications as compared to biological valves. Therefore, biological valves might be especially appropriate for the Indian context.

Conclusion:-

TTK Chitra mechanical heart valve, which is less expensive than the imported St Jude mechanical heart valve and provides safety and comparable results for aortic valve replacement cases, opens up the possibility of cardiac surgery for many deserving patients living in underdeveloped areas.

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