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Hemodynamic results of TTK-Chitra valve in aortic position in patients undergoing aortic valve replacement for aortic stenosis

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Abstract

TTK Chitra valve is one of the most extensively used prosthetic heart valves in our country, yet not many studies of this valve are available pertaining to the Indian population. TTK Chitra valve is commonly used in our Institute and we decided to do a prospective study on short and mid-term results of TTK Chitra valve in aortic position in patients with aortic stenosis. Patients were taken up for aortic valve replacement after detailed informed consent including consent for lifelong anticoagulation and its management. Aortic valve replacement was done under general anaesthesia, on cardiopulmonary bypass as per existing standard operating practice detailed later. The intra-operative and postoperative data were collected in the study Performa. Echocardiography was performed postoperatively, on the day of surgery, prior to shifting to ward, prior to discharge, once at three months and once at one year follow up and then yearly thereafter. Sixty seven of 75 patients [89.3%] were in NYHA II, 7 patients [9.3%] and 1 patient [1.3%] in class III and IV respectively. There was significant improvement in functional class post operatively following the aortic valve replacement. 70 patients [93.3%] patients were in NYHA class I following surgery.

Keywords: Hemodynamic results, TTK-Chitra valve, aortic valve replacement

Introduction

Aortic stenosis is the most common acquired valvular heart disease in adults and elderly in developed countries and in most cases requires surgery. The causes of aortic stenosis are congenital bicuspid aortic valve, rheumatic and degenerative. Rheumatic valvular heart disease remains a major problem in developing countries. Surgical treatment (valve replacement) is the gold standard and has an average hospital mortality rate of 3% and excellent long term results. There is considerable amount of risk of irreversible myocardial damage and sudden death among patients who do not undergo surgery^[1].

Prospective studies on the rate of hemodynamic progression in patients diagnosed with aortic stenosis document an average rate of increase in aortic jet velocity of 0.3 m/s per year, with an increase in mean trans-aortic pressure gradient of 7mmHg per year and a decrease in aortic valve area of 0.1 cm² per year. Although the average rate of hemodynamic progression is relatively constant between studies, there is marked individual variation, which makes prediction of hemodynamic progression in individual patients difficult^[2,3].

The clinical factors associated with hemodynamic progression are not as well established as the associations with the presence of calcific valvular disease. Moreover, most of these studies are based on retrospective analyses.

Recent surgical series report operative mortality rates for aortic valve replacement as low as 1%, increasing to 9% in higher-risk patient. Long-term survival after valve replacement is 80% at 3 years, with an age-corrected survival postoperatively that is nearly normalized. Significant postoperative morbidity, such as thrombo-embolism, hemorrhagic complications from anticoagulation, prosthetic valve dysfunction and endocarditis are rare and occur at a rate of 2% to 3% per year^[4].

TTK Chitra valve is one of the most extensively used prosthetic heart valves in our country, yet not many studies of this valve are available pertaining to the Indian population. TTK Chitra valve is commonly used in our Institute and we decided to do a prospective study on short and mid-term results of TTK Chitra valve in aortic position in patients with aortic stenosis.

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Methodology

Patients were classified into NYHA Class I to IV based on their symptoms of angina and dyspnoea.

NYHA I – patients with cardiac disease, with symptoms present at unaccustomed work only. NYHA II- patients with cardiac disease, symptoms present during accustomed work.

NYHA III- in patients with cardiac disease, symptoms present during less than accustomed activity.

NYHA IV- in patients with cardiac disease, symptoms present at rest.

Echocardiograms for the assessment of functional and hemodynamic valve performances were always carried out by the same echocardiographer. Dimensions were measured from the standard two-dimensional and M-mode echocardiography. Flow velocity in the left ventricular outflow tract and across the valve was measured by means of pulsed and continuous wave Doppler ultrasonography, respectively.

The following parameters were collected from each patient: left ventricular ejection fraction [%], mean and peak prosthetic valve gradients, valve effective orifice

Area (EOA), LVIDd, PWTID and IVSTD. The modified Bernoulli equation was used to calculate peak and mean pressure gradients across the prosthesis. EOA is calculated with the continuity equation, similar to native aortic valve area by the velocity time integral method. $EOA = CSA (LVOT - VTI / VTIAo)$; where, CSA – Cross sectional area, VTIAo is the velocity time integral across the prosthetic valve.

Coronary angiography was performed in 44 cases [patients > 40 years, chronic smokers, chest pain, ECG evidence of ischemia], to rule out coronary artery disease.

Patients were taken up for aortic valve replacement after detailed informed consent including consent for lifelong anticoagulation and it's management. Aortic valve replacement was done under general anaesthesia, on cardiopulmonary bypass as per existing standard operating practice detailed later. The intra-operative and postoperative data were collected in the study Performa. Echocardiography was performed postoperatively in ICU on the day of surgery, once prior to shifting to ward, prior to discharge, once at three months and once at one year follow up and then yearly thereafter.

Surgical Procedure

Under general anaesthesia, with a central venous access, arterial access for blood pressure monitoring and arterial gas sampling and peripheral venous line, the patient is positioned supine, parts painted and draped. Our surgical approach was a standard median sternotomy. The thymus was split and pericardium was opened in the midline. Heparin was administered at a dose of 4-6mg/kg and an ACT above at least 400 seconds (3 times the baseline) maintained. If the desired ACT level was not achieved then FFP was administered and re- heparinised. CPB is established by aortic and two-staged venous cannulation. Left ventricle is vented through a cannula passed via right superior pulmonary vein. Antegrade, ostial and retrograde cardioplegia used to arrest the heart. To prevent fibrillation, systemic cooling is avoided until left ventricular vent is in place. After CPB is initiated and LV is vented, patient is cooled to 28 degree centigrade, the aorta dissected and cross-clamp applied and retrograde cool sanguineous St. Thomas cardioplegia is administered intermittently, 30ml/kg initially and 20ml/kg in subsequent doses. The retrograde cardioplegia pressure is

monitored and 30ml/kg plegia is administered. An oblique aortotomy (inverted hockey stick incision) is made 1 cm above the right coronary artery origin and ostial cardioplegia administered as well. Aortic valve is inspected. A moist sponge is placed in the left ventricle through the aortic valve to prevent calcific debris from entering the left ventricular cavity. Traction sutures are placed through the top of each commissure and the diseased valve excised. Calcification on the annulus is debrided using a rongeur. Meticulous attention is paid to ensure prompt removal of calcific debris by high power end-hole-wall suction. After debridement, the sponge is removed from the left ventricle and a thorough wash is given. Annulus is sized, using TTK Chitra valve sizers. Then 2-0 polyester horizontal mattress sutures are taken on aortic annulus with pledgets on either the left ventricular side [16 cases] or the aortic side [52 cases] depending on the size of the annulus. The aortic annulus is sized again after taking all sutures. Valve sutures are then passed through the sewing ring of the prosthetic valve. Valve sutures are tied and valve tested for disc opening. Aortotomy was closed in 2 layers directly using 4-0 polypropylene or with a pericardial patch in selected cases [in 6 cases, where the aorta is thinned out]. Patient is re-warmed to 36⁰ centigrade, an aortic root vent is placed (either through the aortic suture line or through a separate purse-string suture), the heart is de-aired, perfusate infusion is started through retrograde cardioplegia cannula and continued for about one minute after release of cross-clamp, 1mg/Kg Xylocaine is administered on pump and then the cross-clamp is released. Internal cardioversion is employed if the heart fibrillates [20 joules]. Temporary ventricular epicardial pacing wires are placed. Retrograde cardioplegia cannula is then removed. After resumption of satisfactory myocardial contractility and rhythm, the patient is weaned off cardiopulmonary bypass. Satisfactory haemostasis is ensured and the cannulae removed. Protamine [1mg for every 100 units heparin] is administered, drains inserted and sternum closed with 6 steel interrupted sutures. Subcutaneous tissue and skin are approximated with 2-0 and 3-0 polyglycolic acid [vicryl] sutures respectively. Dressings are applied and the patient is shifted to post-operative ICU with all monitoring lines.

Results

ECG showed left ventricular hypertrophy with strain pattern in 54 patients [72%] and 7 patients [8%] had normal ECG. Left Axis Deviation [LAD] was present in 2 patients [2.7%], Sinus Bradycardia and Sinus Tachycardia in 1 patient [1.3%] each. Cardiomegaly was assessed on CXR by measuring CT [cardiothoracic] ratio. CT ratio of >0.5 was considered cardiomegaly.

Most patients had cardiomegaly on chest x- ray with mean cardio thoracic ratio being 0.6± 0.05.

Table 1: ECG findings

ECG	No. of patients	%
LVH with strain	54	72.0
Normal sinus rhythm	11	14.7
LAD	2	2.7
Sinus bradycardia	1	1.3
Sinus Tachycardia[ST]	1	1.3
WNL	6	8.0
Total	75	100.0

Table 2: Chest X-ray of patients studied

Chest X-Ray	No. of patients	%
≤0.5	4	5.3
0.51-0.6	38	50.7
0.61-0.7	33	44.0
0.71-8	0	0.0
Total	75	100.0

Table 3: An Evaluation of LV dimensions pre-op, follow-up 3 months and follow-up at 1 year.

Variables	Results			Significance	
	Pre op	Follow up 3 months	Follow up 1 year	Pre op - FU-3 m	Pre op - FU-12m
LVIDD[MM]	43.83±6.02	43.43±5.63	41.64±6.90	0.002**	<0.001**
PWTID[MM]	12.74±5.83	11.81±1.79	11.19±1.75	0.176	0.028*
IVSID[MM]	12.91±2.75	12.30±1.81	11.52±1.54	0.023*	<0.001**
LV MASS[G]	197.90±36.04	189.44±35.16	166.46±34.95	<0.001**	<0.001**

Table 4: Comparison of LV MASS [G] according to Valve size

Valve size	LV MASS [G]			
	Baseline	Post-Op	3 months	1Year
#19	218.26±35.18	-	211.19±33.19	197.28±41.99
#21	194.39±33.97	-	187.3±34.64	167.83±36.09
#23	189.48±37.26	-	179.52±34.27	154.28±28.54
#25	206.32±36.97	-	196.55±34.95	166.73±30.39

Sixty seven of 75 patients [89.3%] were in NYHA II, 7 patients [9.3%] and 1 patient [1.3%] in class III and IV respectively. There was significant improvement in functional class post operatively following the aortic valve replacement. 70 patients [93.3%] patients were in NYHA class I following surgery.

Table 5: NYHA grading: An Evaluation

NYHA	Baseline	Post-op	Follow up 3 months	Follow up 1 year	% change
I	0(0%)	70(93.3%)	67(89.3%)	67(93.1%)	+93.1%
II	67(89.3%)	3(4%)	6(8%)	5(6.9%)	-82.4%
III	7(9.3%)	0(0%)	0(0%)	0(0%)	-9.3%
IV	1(1.3%)	0(0%)	0(0%)	0(0%)	-1.3%
Total	75(100%)	75(100%)	75(100%)	72(100%)	0.0%

Discussion

This study was carried out to evaluate the hemodynamic and clinical results of TTK Chitra valve in aortic position in patients with Aortic Stenosis with special reference to patient prosthesis mismatch and LV mass regression.

In our study, there has been significant improvement in NYHA class following surgery. 67 patients [89.3%] were in NYHA II, 7 patients [9.3%] in NYHA III and 1 patient in NYHA IV. Post operatively there has been significant improvement in functional class with 72 patients [94%] in NYHA I.

There was no significant change in EF of patients pre and post-operatively and at 3 months. This could be explained by the LV hypertrophy and overall EF was good in most of the patients pre-operatively itself. However, statistically significant improvement occurred on follow up of 1 year, which could be explained by LV remodelling that occurred over 1 year.

The peak gradients post operatively for each valve was comparable to the study done by Joshi *et al.* [5] In our study, the post op peak gradients were as follows: 37±14.43mmHg for #21 TTK Chitra valve and 26.93±8.18mmHg for #23 TTK Chitra valve. According to Joshi *et al.*, the post-operative peak gradients for #21 TTK and #23 TTK were 30.00 ±14.16mmHg and 27.5 ±12.18mmHg respectively in aortic position. In our study, the peak gradient of # 19 TTK Chitra valve was

The LV dimensions were measured by M Mode and following data [LVIDd, PWTID and IVSID] were recorded pre operatively, at 3 months and 1 year follow up.

Mean preoperative LV mass was 197.9± 36.04g, which showed significant reduction to 166.46±34.95 in postoperative follow-up at 3 months and one year with p value being<0.001** for each. LV mass did not return to normal in any of the patients. The LV mass for each type of valve used is mentioned below.

42.67±21.82mmHg, whereas the peak gradient with #19 TTK Chitra in the study compared [Joshi *et al.*] was 32.00±16.12mmHg.

With respect to individual valves in our study, #21 TTK Chitra valve showed a statistically significant fall in mean gradient to 23.67±9.67mm Hg. This was in concurrence to a study done by Pawan *et al.* [6], in which #21 TTK Chitra in aortic position was compared with other available mechanical valves. According to Pawan *et al.* study, post op mean gradient of TTK chitra valve was 10±5mm Hg, 24±5mm Hg for Starr Edward valve, 12±3mmHg for both St Jude and Medtronic Hall valve. Hence, our study is comparable to Pawan *et al.*

In our study, though the peak and mean gradients were relatively high immediate post op compared to other studies, the functional NYHA class of patients remained good. The gradients reduced to comparable level to other valves on subsequent follow up of 3 months and 1 year. This could also be attributed to the increased LVOT gradients due to concentric hypertrophy in aortic stenosis. Unlike other studies, in which patients with both aortic stenosis and aortic regurgitation were considered, our study focussed only on patients with aortic stenosis. On follow up as the LV mass regressed, the gradients also reduced to acceptable levels.

In terms of clinical and hemodynamic assessment, our study was also comparable to a study done by Haaverstad, Vitale, Karevold, *et al.* in 2007 [7]. It was a Scandinavian prospective multicentre study on Clinical and echocardiographic assessment of Medtronic Advantage valve. The EF of valves #21, #23 and #25 in our study was comparable to the above mentioned study. The peak and mean gradients of # 19 valve was higher in our study compared to Haaverstad, Vitale, Karevold, *et al.* The peak and mean gradient of rest of the valves were comparable in both studies.

With respect to LVM, according to Haaverstad, Vitale, Karevold, *et al.*, a significant decrease of LVM occurred from the postoperative period to 1 year (p<0.001) was observed for the cohort of patients with valve sizes 21 to 29 mm. LVM dropped significantly in patients with valve sizes 21, 23 and 25 mm, whereas it did not change or reach statistical significance in patients with size 19, 27 and 29 mm. In our study, the LV mass at 1 year was comparable to the above study. LVM dropped significantly at 3 months only with #23 valve, with p<0.001**. However, there was statistically significant LV mass reduction with #21, #23 and #25 valves at the end of 1 year. The LVM reduction with #19 valve was not statistically significant.

The EOA/BSA of our study that was measured post-operatively was comparable to Medtronic Advantage valve in the study

mentioned above. The EOA/BSA for #19 valve was $0.83 \pm 0.19 \text{ cm}^2/\text{m}^2$, for #21, #23 and #25 it was $0.96 \pm 0.1 \text{ cm}^2/\text{m}^2$, $1.12 \pm 0.14 \text{ cm}^2/\text{m}^2$ and $1.4 \pm 0.15 \text{ cm}^2/\text{m}^2$ respectively.

The definition of PPM in our study was EOA/BSA $< 0.8 \text{ cm}^2/\text{m}^2$. We had 4 patients with PPM which comprised of 3 males and 1 female. All four patients had received #19 TTK Chitra valve. In all four patients, there was no significant reduction in LV mass, peak and mean gradients post operatively, at 3 months and on 1 year follow up. All 4 patients remained in NYHA class I, which could be explained by their restricted activity. One patient had valve thrombosis at 1 year of surgery, which was treated successfully by thrombolysis.

Conclusion

- TTK Chitra valve is comparable to other mechanical valves of similar nature both hemodynamically and by its clinical performance.
- LV mass regression begins early post operatively, but significant reduction occurs by one year post surgery.
- LV mass regression was better with larger valves compared to smaller valves.

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