



ON-X VALVE VERSUS TTK CHITRA MECHANICAL MITRAL VALVE PROSTHESES: EARLY HAEMODYNAMICS

Cardiology

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ABSTRACT

This prospective study was conducted to compare hemodynamic parameters measured by the Doppler echocardiography of ON-X heart valve with TTK Chitra mechanical valve in the mitral area. The study was conducted on 100 patients operated only for mitral valve replacement. At the time of discharge and in follow-up visits detailed 2-D Echo with Colour Doppler examination was done focusing on trans-valvular mean gradient, mitral valve area by Pressure Half Time (PHT) and Continuity Index. Both the groups of prosthesis provided a satisfactory hemodynamic and clinical outcome in early postoperative period for valve sizes greater or equal to 25 mm. From our study result we conclude that the haemodynamic data were not significantly different between the two groups. Both TTK Chitra and ON-X mechanical valves provided a satisfactory hemodynamic and clinical outcome in early postoperative period for valve sizes greater or equal to 25 mm. ON-X valve was easier to insert and gave more favourable post-operative hemodynamic performance with lesser gradients and larger effective orifice area. ON-X valve are technically easier to implant especially when total preservation of sub-valvular apparatus is done.

KEYWORDS

Echocardiography, Haemodynamics, mechanical valve prosthesis, mitral valve area (MVA), TTK Chitra valve, ON-X valve.

INTRODUCTION:

India is a developing country. The most common cause of valvular heart disease in India is rheumatic heart disease (RHD). In India, the prevalence of Rheumatic Fever/RHD among school children is 2-11 per 1000 with a mean of 6 per 1000.¹ While prevalence in adults ranges between 123 and 200 per 100,000 population.² Sometimes heart valves can't be repaired and must be replaced. Now a day different bi-leaflet and tilting disc mechanical heart valves are available.

The Sree Chitra Tirunal Institute for medical sciences and technology, Thiruvananthapuram, India developed the TTK Chitra valve in late 1970's. It has an ultra-high molecular weight polyethylene disc, Haynes-25 alloy cage and polyester suture ring. It is manufactured by TTK Healthcare limited (based at Bangalore).³ The On-X bi-leaflet mechanical valve (On-X Life Technologies Inc., Austin, TX, USA), introduced in 1996 uses purepyrolytic carbon and has a flared inlet orifice designed to reduce flow turbulence and the support of a full annulus to protect the opening of the valve from tissue encroachment.^{4,5} These technological improvements have been hypothesized to limit morbid events in patients.

TTK Chitra valve and On-X bi-leaflet valves are well designed. Most of the studies which have been proven their efficacy were limited by sample size and a short follow-up period. Not a single study was focused on mitral valve. In previous studies, echocardiographic hemodynamic parameters were not studied. Doppler echocardiography can provide the information on the gradients across and the mitral valve area (MVA) which is comparable to those obtained at invasive cardiac catheterization.

So this study was aimed to compare the early haemodynamic data of the TTK Chitra heart valve and the On-X bi-leaflet mechanical heart valve prostheses in mitral valve replacement surgeries.

MATERIAL AND METHODS:

This analytical, post-operative prospective observational study was conducted in a medical college from January 2017 to October 2018 after ethics committee approval on 100 patients operated only for mitral valve replacement in whom single tilting -TTK Chitra valve and bi-leaflet ON-X prosthetic heart valves were used. Indications for the mitral valve replacement were rheumatic heart disease and mitral valve prolapse. Patients with bio prosthetic heart valve and double valve replacement were excluded from study. Also patients with hemodynamic instability and unsatisfactory echo cardiogenic window were excluded.

After written informed consent, particulars of patient, detailed clinical examination for NYHA class, atrial fibrillation was done. Investigations like hemogram, coagulation profile, renal functions, liver functions, chest X-ray, ECG, 2-D Echo with Color Doppler were performed. All the patients who were more than 50 years of age, with history of tobacco abuse, chest pain, diabetes or had ECG evidence of ischemia were subjected for coronary angiography. The two groups were matched for age and body surface area.

Patients were continued on digoxin till the day of surgery. If the patients were on aspirin and/or warfarin, it was omitted at least 7 days prior to the surgery. All were operated using conventional cardiopulmonary bypass through a median sternotomy at moderate hypothermia, using membrane oxygenator and ante grade intermittent cold blood cardioplegia. Anti-coagulation regime was started on the 1st postoperative day with oral 5 mg warfarin sodium. An International Normalized Ratio (INR) was maintained between 3 and 3.5 for mitral valve replacement.

At the time of discharge and in follow-up visits detailed 2-D Echo with Color Doppler examination was done focusing on trans-valvular mean gradient, mitral valve area by Pressure Half Time (PHT) and Continuity Index. Flow velocity across the mitral prosthesis was recorded with continuous-wave Doppler guided by color flow. Color flow Doppler was used in evaluating the direction of flow into the left ventricle and optimizing Doppler recordings of jet velocity. From the tracing of prosthetic inflow velocity, maximal velocity, peak gradient, and mean gradient were measured.

Mitral valve area calculation was done using the Pressure Half-Time as well as by using CE as the ratio of the aortic forward stroke volume over the Trans mitral time-velocity integral.

Patients were advised to follow up once in 2 weeks for the first month and then monthly for repeated INR check. A chest x-ray, ECG and 2D-echo with color Doppler were done at least once between 3 months to one year. Collected data was analyzed statistically.

Statistical analysis:

The results are presented in frequencies, percentages and mean \pm SD. Paired t-test was used for comparisons. Pearson correlation coefficient was calculated. The p-value less than 0.05 were considered significant. All the analysis was carried out on SPSS 16.0 version.

RESULT:**Table 1: Average post-operative Hemodynamic data on TTK Chitra-Single Tilting Disc valve prosthesis**

Valve size (mm)	No of patients	Peak Velocity (Cm/Sec)	Mean Diastolic Gradient (mmHg)	PHT (ms)	Mitral Valve Area (MVA)	
					Continuity Equation (CE) (cm ²)	Pr MVA/PHT (cm ²)
25	04	1.74±0.16	5±2	85±11.41	1.56±0.17	2.11±0.46
27	22	1.64±0.12	4±0.87	76.44±8.92	2.09±0.20	2.41±0.33
29	38	1.60±0.14	3.94±1.16	92.67±12.4	2.24±0.12	2.91±8.32
31	10	1.54±0.14	3.91±1.0	71.86±9.85	2.52±0.30	2.65±0.42

Table 2: Average post operative Hemodynamic data on ON-X-bileaflet valve prosthesis

Valve size (mm)	No of patients	Peak Velocity (Cm/Sec)	Mean diastolic gradient (mmHg)	PHT (ms)	Mitral Valve Area (MVA)	
					Continuity Index (CI) (cm ²)	Pr MVA/PHT (cm ²)
25	2	1.42±0.12	4.9±1.3	98.0±0.10	2.2±0.8	2.56±0.12
27/29	8	1.33±0.19	4.5±1.6	100.0±11	2.4±0.6	2.74±0.12
31/33	4	1.42±0.17	4.0±2.2	101.0±11	2.4±0.8	2.94±0.12
25/33	2	1.59±0.18	4.0±1.98	101±11	2.2±0.8	2.65±0.11

Table no 3: Comparison of post operative resting transvalvular mean diastolic gradient

Size of valve (mm)	Mean Diastolic Gradient (mmHg)		P value
	TTK (n=74)	ON-X (n=16)	
25	5±2	4.9±1.3	0.362
27	4±0.87	4.5±1.6	0.052
29	3.94±1.16	NA	
31	3.91±1.0	4.0±2.2	0.0954

Table 4: Comparison of postoperative prosthetic mitral valve area

Size of valve	MVA (cm ²) CE			P value
	TTK (n=74)	ON-X (n=16)	PHT (cm ³)	
25	1.06±0.17	2.2±0.8	2.56±0.12	0.320
27	2.09±0.20	2.4±0.6	2.74±0.12	0.142
29	2.24±0.12	2.4±0.8	2.94±0.12	0.210
31	2.52±0.30	2.2±0.8	2.65±0.11	0.102

DISCUSSION:

The present study was the first study where Haemodynamic 2-D ECHO comparison of single tilting disc TTK Chitra was done with bileaflet ON-X valve. Valve sizes 25-31mm were used. ON-X prosthetic valve is being compared for the first time with TTK Chitra valve.

In this study we found that in different valve size ranging from 25mm to 31mm were being used. In single Tilting disc group (TTK Chitra), 29 mm valve size was used most commonly (51%) and 25 mm valve size was least common (5.3%).

TTK Chitra valve size is most commonly used in valve replacement surgeries. Because of its low cost and proven efficacy, it has a high potential for more widespread use. Although various studies substantiating its long-term safety and efficacy are available, limited study had assessed its echocardiographic characteristics. Pawan Kumar et al, 2004 also observed the same fact. 23mm valve size is least commonly used whereas 31mm valve size is not used in any patient.

In this study we found that TTK Chitra-single Disc valve prosthesis, for 25 mm valve MVA by PHT is 2.11cm² while EOA is 1.56cm² and MVA provided by manufacturer (AOA) is 2.54cm². For 27 mm valve MVA by PHT is 2.411cm² while EOA is 2.09cm² and MVA provided by manufacturer (AOA) is 3.14cm². For 29 mm valve MVA by PHT is 2.91cm² while EOA is 2.24cm² and MVA provided by manufacturer (AOA) is 3.8cm². For 31 mm valve MVA by PHT is 2.65cm² while EOA is 2.52cm² and MVA provided by manufacturer (AOA) is 4.52cm².

For 25mm Narayan Nambodiri et al, 2007 also found less mitral valve area by PHT than AOA and EOA. But Pawan Kumar et al, 2004 found MVA 2.8 cm² in their study. For 27mm valve size also found less mitral valve area by PHT 2.12 ± 0.36 cm² in their study. But Pawan Kumar et al, 2004 found MVA 3.1 ± 0.7 cm². For 29 mm Narayan Nambodiri et al⁶ also found less mitral valve area by PHT 2.30 ± 0.71 cm². But Pawan Kumar et al, 2004 found MVA 2.9 ± 0.7 cm². P value is significant for MVA derived by PHT method. P value is significant for MVA derived by CE method.⁷ For 25 mm valve Mean gradient (MG) is 5.12 mmHg. For 27 mm valve Mean gradient (MG) is 4.02 mmHg. For 29 mm valve Mean gradient (MG) is 3.94 mmHg. For 31 mm valve Mean gradient (MG) is 3.91 mmHg. Narayan Nambodiri et al also found 11.0 ± 3.7 mmHg peak gradients.

Nagarajan et al reported mean gradients of 5.09 ± 2.14 mmHg in the mitral position for TTK Chitra valve.⁸ Narayan Nambodiri et al found 1.64 m/s peak velocity and B Shreenuvas et al found mean gradient 4.8 ± 2.1 mmHg in 2016 while in this study mean gradient is 3.68 mmHg for all valve. Peak velocity is 1.61 m/s for all valves.⁹

In our study we found that ON-X valve prosthesis shows different value of hemodynamic echocardiographic variables according to different valve size.

For 25 mm valve MVA by PHT is 2.56 cm² while EOA is 2.2cm² and MVA provided by manufacturer (AOA) is 4.11cm². For 27/29 mm valve MVA by PHT is 2.74cm² while EOA is 2.42cm² and MVA provided by manufacturer (AOA) is 4.11 cm². For 31/33 mm valve MVA by PHT is 2.94cm² while EOA is 2.42cm² and MVA provided by manufacturer (AOA) is 4.11cm². For 25/33 mm valve MVA by PHT is 2.65cm² while EOA is 2.22cm² and MVA provided by manufacturer (AOA) is 4.11cm². For 25 mm valve Mean gradient (MG) is 4.9 mmHg and Peak velocity is 1.42 m/s. For 27/29 mm valve Mean gradient (MG) is 4.5 mmHg and Peak velocity is 1.33 m/s. For 31/33 mm valve Mean gradient (MG) is 4.0 mmHg and Peak velocity is 1.42 m/s which is good for prosthetic mitral valve. For 25/33 mm valve Mean gradient (MG) is 4.0 mmHg and Peak velocity is 1.59 m/s.

Doppler echocardiography has significantly improved the non-invasive evaluation of prosthetic valves. In the assessment of prosthetic mitral valves, current methods have included the derivation of peak and mean gradients and the calculation of valve area by pressure half-time (PHT). To date, there have been no studies evaluating the applicability of the continuity equation in mechanical valves in the mitral position. We found this parameter provides an improved assessment of valve function than the sole use of gradients and PHT when compared with actual geometric orifice areas.

The haemodynamic data were not significantly different between the two groups. Both Group of prosthesis provided a satisfactory hemodynamic and clinical outcome in early postoperative period for valve sizes greater or equal to 25 mm.

Mean diastolic gradient averaged 5±2 mmHg for TTK Chitra valve and 4.9±1.3 mmHg for ON-X valves. Comparatively postoperative prosthetic mitral valve area is more for ON-X valve as compared to TTK Chitra valve for small valve size. ON-X valve was easier to insert and gave more favourable post-operative hemodynamic performance with lesser gradients and larger effective orifice area. ON-X valve is technically easier to implant especially when total preservation of subvalvular apparatus is done.

CONCLUSIONS:

The hemodynamic 2-D ECHO Doppler parameters obtained with TTK Chitra valve in the mitral position are comparable with ON-X prosthetic valve. The hemodynamic data shows no significant difference between the two groups. In this selected group of patients with TTK Chitra valve and ON-X valve assessment of EOA by the PHT method is comparable with that found by the Continuity Equation. However, mitral valve areas by both methods were smaller than the AOA provided by the manufacturer. ON-X valve was easier to insert and gave more favourable post-operative hemodynamic performance with lesser gradients and larger effective orifice area.

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