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Original Research Paper

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HEMODYNAMIC CHANGES IN MECHANICAL VALVES: ARE BI-LEAFLET BETTER THAN TILTING DISC ONE LEAFLET VALVE?

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ABSTRACT All available prosthetic valves are associated with valve-related complications that influence their clinical use. So this prospective study was conducted to compare hemodynamic parameters measured by the Doppler echocardiography of bi-leaflet (St. Jude, ATS, ON-X) heart valve prosthesis with tilting disc (TTK Chitra) mechanical valve in the mitral area. Study was also aimed to assess mitral valve area (MVA) by using the Continuity Equation (CE) and Pressure Half Time (PHT) method and trans-valvular gradient with tilting disc (TTK Chitra) mechanical valve. This analytical, post- operative prospective observational study was conducted in a medical college on 142 patients operated only 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. Both Group 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 bi-leaflet valves-(St. Jude, ATS and ON-X) were easier to insert and gave more favourable post-operative hemodynamic performance with lesser gradients and larger effective orifice area.

KEYWORDS : Echocardiography, Hemodynamics, mechanical valve prosthesis, mitral valve area (MVA)

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]

Heart valve replacement is commonly performed a safe procedure however, at present there is not a single valve which can be considered ideal. All available prosthetic valves are associated with valve-related complications that influence their clinical use. Worldwide the commonly used prosthetic valves are tilting disc valve (TTK Chitra Valve) and bi-leaflet St. Jude (SJM), ATS and ON-X valves.

TTK Chitra valve is most commonly used valve because of its low cost and proven efficacy. Though various studies had been expressed its safety and efficacy, limited study had assessed its echocardiographic characteristics.[3]

The St. Jude Valve(SJM) may have a slight advantage for use in the small left ventricle.[4] The bi-leaflet central flow design of SJM provides a lower trans-valvular pressure gradient and the total pyrolytic carbon construction suggested it would be durable and thromboresistant.[5]

The On-X bi-leaflet mechanical valve is manufactured from pure pyrolytic carbon and had flared inlet.[6] There have been a number of proposed benefits of ON-X like a lower required target international normalized ratio.[7]

So this prospective study was conducted to compare hemodynamic parameters measured by the Doppler echocardiography of bi-leaflet (St. Jude, ATS, ON-X) heart valve prosthesis with tilting disc (TTK Chitra) mechanical valve in the mitral area. Study was also aimed to assess mitral valve area (MVA) by using the Continuity Equation (CE) and Pressure Half Time (PHT) method and trans-valvular gradient with tilting disc (TTK Chitra) mechanical valve.

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 142 patients operated only for mitral valve replacement in whom single tilting -TTK Chitra valve (CHVP) and bi-leaflet (St Jude, ATS, 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.

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 ± 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: Pre-Operative And Operative Clinical Profile

Variables	Tilting disc TTK Chitra	Bi-leaflet group (SJM, ATS & ON-X)	p-value
Age (yrs)	33±10.1	31.2±9.21	0.145
Female sex (%)	64.08	63.1	0.845
NYHA class	2.856±0.362	3.265±0.542	0.245
AF	40	49	0.214
LVEF	54.76±8.65	57.524±7.65	0.521
MVA (cm^2)	0.901±0.312	0.845±0.736	0.352
Preservation of PML (%)	85.64	92.01	0.354
LA Size	52.23±11.124	52.01±10.321	0.354

Table 2: Showing The Average Post-Operative 2-D ECHO Data Of Different Valve Sized Single Tilting Disc- TTK Chitra, Bi-leaflet- St.Jude Medical , ATS and ON-X Mitral Valve Prosthesis .

Valve size	No of patients	AOA (cm^2)	PK_{prmc} (Cm/Sec)	MG (mmHg)	PHT (ms)	Mitral valve area (MVA)	
						CE (cm^2)	Pr MVA/PHT (cml)
TTK							
25	04	3.14	1.74±0.16	5.0±2.0	85±11.41	1.06±0.17	2.11±0.46
27	22	3.8	1.64±0.12	4±0.87	76.44±8.92	2.09±020	2.41±0.33
29	38	4.52	1.60±0.14	3.94±1.16	92.67±12.42	2.24±0.12	2.91±8.32
31	10	NA	1.54±0.14	3.91±1.0	71.86±9.85	2.52±0.30	2.65±0.42
St. Jude Bileaflet Mitral Valve							
25	9	2.5	1.38±0.12	3.84±1.02	84.0±4.0	1.67±0.32	2.11±0.12
27	19	2.6	1.34±0.14	3.40±1.16	81.3	1.94±0.12	2.22±0.22
29	13	3.5	1.28±0.12	3.34±7.20	78±4	2.03±0.12	2.45±0.32
ATS							
25	3	4.59	1.40±0.15	3.92±1.01	83.0±3.9.0	1.84±0.31	2.04±0.15
27	5	5.35	1.38±0.21	3.42±1.12	81.8	1.92±0.11	2.23±0.21
31	2	5.45	1.32±0.14	3.29±7.22	78.5±4.3	2.10±0.14	2.42±0.34
ON-X							
25	2	4.11	NA	4.9±1.3	98.0±0.10	2.2±0.8	2.56±0.12
27/29	8	4.11	NA	4.5±1.6	100.0±11	2.4±0.6	2.74±0.12
31/33	4	4.11	NA	4.0±2.2	101.0±11	2.4±0.8	2.94±0.12
25/33	2	4.11	NA	4.0±1.98	101±11	2.2±0.8	2.65±0.11

Table 3: Comparison Of Post-Operative Resting Trans-valvular Mean Diastolic Gradient Between Single Tilting Disc And Bi-Leaflet Valves

Size of valve (mm)	Mean Diastolic Gradient (mmHg)		P value
	Single tilting disc (n=74)	Bi leaflet valves (n=68)	
25	5±2	3.13±1.91	1.021
27	4±0.87	3.77±0.98	1.301
29	3.94±1.16	3.92±1.10	0.985
31	3.91±1.0	3.64±0.6	1.031

Table 4: Comparison Of Post-Operative Mitral Valve Area Between Single Tilting Disc And Bi Leaflet Valves

Size of valve (mm)	MVA (cm^2) CI				P value
	Single tilting disc CE (n=74)	PHT	By leaflet valves CE (n=68)	PHT	
25	1.06±0.17	2.11	1.90±2.12	2.23	1.021
27	2.09±020	2.41	2.08±1.321	2.39	0.084
29	2.24±0.12	2.91	2.21±0.895	2.59	0.215
31	2.52±0.30	2.65	2.25±1.301	2.67	0.068

Table 5: Coefficient Of Dispersion In Percentage In Continuing Index And PHT Is Showing Different Values For The Different Valve Size.

Valve size	No of pt.	AOA (cm^2)	Effective Orifice Area (EOA)				Coefficient of dispersion in percentage in CI	Coefficient of dispersion in percentage in PHT
			CI (cm^2)	p value	Pr MVA/PHT (cml)	p value		
TTK								
25	04	3.14	1.06±0.17	<0.001*	2.11±0.46	<0.001*	41.1±11.12	55.4±13.02
27	22	3.8	2.09±020	<0.001*	2.41±0.33	<0.001*	45.7±10.21	55.1±12.12
29	38	4.52	2.24±0.12	<0.001*	2.91±8.32	<0.001*	43.1±13.02	54.1±10.12
31	10	NA	2.52±0.30	NA	2.65±0.42	NA	NA	NA
SJM								
25	9	2.5	1.67±0.32	<0.001*	2.11±0.12	<0.001*	39.8±13.12	53.4±11.02
27	19	2.6	1.94±0.12	<0.001*	2.22±0.22	<0.001*	46.9±11.02	54.4±11.04
29	13	3.5	2.03±0.12	<0.001*	2.45±0.32	<0.001*	44.1±10.12	54.1±10.12

ATS								
25	3	4.59	1.84±0.31	<0.001*	2.04±0.15	<0.001*	38.1±09.12	52.9±10.02
27	5	5.35	1.92±0.11	<0.001*	2.23±0.21	<0.001*	45.6±10.01	54.1±11.02
31	2	5.45	2.10±0.14	<0.001*	2.42±0.34	<0.001*	44.7±12.12	53.1±9.12
ON-X								
25	2	4.11	2.2±0.8	<0.001*	2.56±0.12	<0.001*	37.01±09.12	51.4±10.42
27/29	8	4.11	2.4±0.6	<0.001*	2.74±0.12	<0.001*	45.4±10.15	53.4±10.12
31/33	4	4.11	2.4±0.8	<0.001*	2.94±0.12	<0.001*	43.4±11.21	52.1±11.01
25/33	2	4.11	2.2±0.8	<0.001*	2.65±0.11	<0.001*	47.4±09.02	52.1±11s.12

DISCUSSION:

The present comparative study was conducted on 142 patients operated for MVR with the objective to compare different mechanical mitral valve prosthesis like single tilting disc –TTK Chitra and bi-leaflet –St. Jude Medical, ATS, ON-X and to assess mitral valve area by 2-D color Doppler echocard iographic method using PHT and CE methods and diastolic trans-valvular gradients in postoperative mitral valve.

In our study we found that in single tilting disc group (TTK Chitra), 29 mm valve size was used most commonly (51%) and 25 mm valve size was used least commonly (5.3%). In bi-leaflet group, 27 mm valve size was used most commonly used.

TTK Chitra valve is most commonly used in valve replacement surgeries because of its low cost and proven efficacy. [3] Though various studies had been expressed its long-term safety and efficacy, limited study had assessed its echocardiographic characteristics.

In our study we found no significant hemodynamic difference in both TTK Chitra valve and bi-leaflet valves. Goyal V et al also compared medtronic tilting disc valve with St. Jude and ATS valve of sizes 25mm-29mm. He did not found any significant hemodynamic difference for valve size greater than equal to 25mm.[8] Namboodiri N et al studied TTK Chitra and St. Jude valves only of 27mm size. Our study result is quite similar to it.[9]

In our study post-operative mitral valve area between single leaflet and bi-leaflet groups, mitral valve area is comparable in all valve sizes. Effective Orifice Area (EOA) averaged 1.06-2.60 cm for single tilting disc valve and 1.90-3.35 cm for Bi-leaflet valves. Calculation by CE also showed no difference for calculated mitral valve area (MVA) between these two groups. The MVA calculated by CE and PHT showed comparable similarity in the distribution of MVA. With use of analysis of variance, effective orifice area differentiated well among the various valve sizes ($p = 0.0002$) and correlated significantly with actual orifice area ($r = 0.68$, $p=0.0001$).

Doppler echocardiography has significantly improved the noninvasive 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). More recently, the Continuity Equation (CE) has been applied to bio prosthetic mitral valves and was demonstrated to be superior to the PHT method. Till now, no study had been evaluated 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.

CONCLUSION:

From our study results we conclude that assessment of EOA by the PHT method is comparable with that found by the CE. However, areas by both methods were smaller than the AOA and EOA provided by the manufacturer. The continuity equation was demonstrated to be superior to the PHT method. Now it is the recent methodology in hemodynamic ECHO assessment of prosthetic valves.

Calculation of mitral valve area (MVA) by Continuity Index and PHT also showed no significant difference for calculated MVA between these two groups. The MVA calculated by CE and PHT showed comparable homogeneity in the distribution of MVA. In single tilting disc group (TTK Chitra), 29 mm valve size was most commonly used. In bi-leaflet group, 27 mm valve size was most commonly used. Single tilting disc-TTK Chitra valves were most commonly used in mitral valve replacement surgeries.

Both Group of prosthesis provided a satisfactory hemodynamic and clinical outcome in early postoperative period for valve sizes greater or equal to 25 mm. bi-leaflet valves-(St.Jude, ATS and ON-X) were easier to insert and gave more favourable post-operative hemodynamic performance with lesser gradients and larger effective orifice area. Bi-leaflet valves are technically easier to implant especially when total preservation of sub-valvular apparatus is done.

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REFERENCES:

1. Padmavathy S. Rheumatic fever and rheumatic heart disease in developing countries. Bull WHO. 1978; 56: 543-55
2. Mathur KS, Wahal PK. Epidemiology of rheumatic heart disease-a study of 29,922 school children. Indian heart Journal. 1982; 34: 367-71.
3. Kumar P, Dalvi B, Chikkatur R, et al. TTK Chitra tilting disc valve: Hemodynamic evaluation. Indian J Thorac Cardiovasc Surg. 2004; 20: 117.
4. Antunes MJ. Clinical performance of St. Jude and Medtronic Hall Prostheses: A randomized comparative study. Ann Thorac Surg. 1990; 50: 743–47.
5. Arom KV, Nicoloff DM, Kersten TE, et al. Ten year experience with the St. Jude Medical Valve Prosthesis. Ann Thorac Surg. 1989; 47 : 831–37
6. Akutsu T, Matsumoto A. Influence of three mechanical bileaflet prosthetic valve designs on the three-dimensional flow field inside a simulated aorta. J Artif Organs. 2010; 13: 207–17.
7. Puskas J, Gerdisch M, Nichols D, et al. Reduced anticoagulation after mechanical aortic valve replacement: interim results from the prospective randomized on-X valve anticoagulation clinical trial randomized Food and Drug Administration investigational device exemption trial. J Thorac Cardiovasc Surg. 2014;147:1202–11
8. Goyal V, Devgarha S, Kalla S, et al. Comparative evaluation of hemodynamic performance in early post-operative period of tilting disc vs. bileaflet mechanical valve at mitral position — A prospective study .Indian J Thorac Cardiovasc Surg. 2009; 25: 52.
9. N Namboodiri et al. Doppler echocardiographic assessment of TTK Chitra prosthetic heart. Eur J Echocardiogr. 2008; 9(5): 599-604.