

**Original Research Paper** 

Cardiology

# COMPARATIVE STUDY BETWEEN BILEAFLET AND TILTING DISC AORTIC MECHANICAL VALVE PROSTHESIS - A RETROSPECTIVE ANALYSIS

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**ABSTRACT** When a patient needs a valve replacement today, there are several options for the valve substitute. The most often used mechanical valve prosthesis is "Bileaflet" or "Tilting disc". To determine which is the best valve prosthesis3 for a particular patient, we have to look at the results of different kind of valve substitutes in large mainly retrospective series. In our centre around 60% of all open heart procedures per annum are valve replacements of which 20% are isolated aortic valve replacement done using mechanical valve prosthesis either "bileaflet" or "tilting disc" from different marketing companies. This study designed retrospectively to analyse ease of procedure on valve orientation and placement, immediate post-operative hemodynamics, post op left ventricular function, gradient across the valve, incidence of valve thrombosis, Embolic and hemorrhagic complications, valve related mortality, freedom from complications for 6 months after discharge and in a group of 150 patients operated in our hospital.

**KEYWORDS**: Bileaflet valve, Tilting disc valve, Aortic valve replacement, Echocardiography

#### Introduction

The ideal valvular prosthesis, as described by **Harken**<sup>1</sup>, the prosthesis should have hemodynamic performance similar to a healthy native valve, durable with longevity approaching that of a native valve, Thrombogenicity would be non-existent, no valve related long-term morbidity and mortality, should be easy to implant, should last forever and should have good availability in all sizes, finally, growth commensurate with that of the recipient would be possible. None of the valve prosthesis,, that are available today, fulfill this entire criterion. It remains the Holy Grail of cardiac surgery. When a patient needs a valve replacement today, there are several options for the valve substitute. The most often used mechanical valve prosthesis is "bileaflet" or "tilting disc". In order to determine which is of the best valve prosthesis is for a particular patient, we cannot rely on large prospective randomized studies proving that at any given age of a patient one kind of valve prosthesis is superior to all others. The reason for this is that such studies are not available. Therefore, we have to look at the results of different kind of valve substitutes in large mainly retrospective series. This study designed retrospectively to analysis short term outcomes between "bileaflet" and "tilting disc" mechanical valve prosthesis for aortic valve replacement.

## **Materials and Methods**

**Centre**: Department of cardiothoracic surgery, Rajiv Gandhi Government General Hospital and Madras medical college

Duration of the Study: 2 year (September 2015 to January 2017)

Study Design : Retrospective study

**Subject Selection**:All the patients according to the following criteria and willing to be participate in the study after written informed consent were included

**Inclusion Criteria**: All patients who underwent Aortic valve replacemet for aortic stenosis and regurgitation.

**Exclusion Criteria** :All patients with Multi Valvular lesions ,Severe LV dysfunction (EF <30 %),Associated coronary artery disease,Previous Thromboembolic & Hemorrhagic

history,Concomitant cardiac / non cardiac major surgeries,Age above  $60\,$ 

#### METHODOLOGY

The patients underwent full clinical evaluation, including routine laboratory tests and radiologic and electrocardiographic examination with elective pre-operative anesthetic assessment. Transthoracic ECHO cardiographic evaluation is done pre operatively,

trans esophageal ECHO for selected cases.

#### **Aortic valve replacement**

#### Aortic tilting disc valve(Fig 1)





Aortic valve repalcement(Fig 2)

Cardio pulmonary bypass established except RA double stage cannulation. LA venting done to decompress the LV and blood less field. Through transverse aortotomy, coronary ostial antegrade cold

(4'C) cardioplegia for AR, AS/AR cases, whereas antegrade root cardioplegia was given for pure AS cases. Aortic valve morphology assessed. After excising the aortic valves, sizing done. <sup>2</sup> Using 2 0 pledgetted interrupted everting sutures placed for intra annular valve placement. For some cases, on benefit of bigger size valve inverting type sutures taken to keep valve at supra annular position. Post-operative echocardiogram usually done on 7<sup>th</sup> POD. Post op echo assessment includes valve position, function, mean gradient, Paravalvular leak, LV function. Patient discharged at 10 th POD after suture removal.

#### Anticoagulation

In our institution, first day we start acinocoumarol (acitrom) 2 mg with fist two days heparin coverage. INR checked every 48 hours and acitrom level readjusted according to INR levels. In case of severe atrial fibrillation, high risk cases aspirin 75 mg added to maintain anticoagulation.

#### **Follow up**

Patient followed up in CTS department outpatient for first 6 months by predefined method Every week – first 1 month Every fortnight – next 2 months Every month – last 3 months

Investigations including ECG, ECHO, and CHEST X RAY repeated on every 45 days.

# DATA HANDLING AND STATISTICS

All the data were handled with care to maintain patient confidentiality. Records were maintained in both computer and paper formats. Statistical analysis was carried out as appropriate. Continuous variables were compared using student's t test and categorical variables were compared with a Pearson chi-squares (<sup>2</sup>) test with SPSS statiscal data analysis software (SPSS Inc. Chicago.ver 17) and are reported with 95% confidence limits. Comparison between groups were made with formula

$$z = \frac{P_x - P'_x}{\sqrt{(SE[P_x])^2 + (SE[P'_x])^2}}$$

This is defined in Colton. Results were considered statistically significantly at the p < 0.05 level<sup>20</sup>.

#### Discussion

In government general hospital, Chennai, we analysed 150 patients as two groups each of 75 patients in a group. However, the reality was that they were initially used in different manufacturer labels. In each groups with widely different characteristics was an obstacle to make any conclusions about their comparative analysis. Therefore, a retrospective comparative study of these two type of prostheses "**Bileaflet**" or "**tilting disc**" and in both groups was conceived and carried out from september 2015 to Jan2017.

Eventhough , ease of procedure was purely subjective and not studied by others ,during the changing time from long term bileaflet usage to tilting disk, we observed significant difficulty in positioning and orientation of valve in tilting disk type (3.1% for BL,46.7% for TD in MVR group, 4.3%BL and 14.3 %TD in AVR group).. we detected difficulty in placing valve is not due to the type of valve, it is instead aortic annulus per se, although easy to impaint is bileaflet.

Post operative hemodynamics<sup>7</sup> was stormy in respect to each type valve (15.2% BL,21.4%TD) hemodynamics showing higher incidence of stormy hemodynamics in tilting disc. But this is not

statistically significant.

The true fact reflecting the valve performance are transvalvular mean gradient.

Which is truly inherent nature of valve by opening and closing mechanism, hinge and pivotting system. Higher grdients which is more than 5.1 and above were observed in bileaflet velve types (12.3% BL, 4.8% TD in MVR / 26.1% BL, 21.4% in AVR).

Post operative LV dysfunction was slightly higher in bileaflet in tilting disk types have shown higher incidence (17.4% BL, 21.4% in AVR). without reaching the statiscal significance on either side. Severe LV dysfunction was not truly related to valve type as it is confounded by lot of factors including per op cross clamp time, type and extent of myocardial protection, disease nature, (AS>AR) ,pre operative failure status etc..

Valve thrombosis as we referred with echocardiogram higher 6 months incidence in bileaflet side. Perhaps, it is attributed to poor anticoagulation profile, this can be valve nature on the side thrombosis. In this study, we observed same incidence observed in aortic group (13% BL, 14.3%TD in AVR) without statistical significance. Nearly 70-75% patient who have had valve thrombosis developed embolism.

Embolic and hemorrhagic complications after heart valve replacement is related to the level of anticoagulation, which differs among studies. In our study the target levels of anticoagulation were the same for both the **Bileaflet**" and "tilting disc" valves. Recent recommendations are for a target INR of 2.5 to 3.5 for all mechanical valves.

The comparative study by Anthunes et al did not detect a statistically significant difference in freedom from thromboembolism at 5 years between the St. Jude Medical valve (92%  $\pm$  4%) and the Medtronic Hall valve (89%  $\pm$  4%). All western studies (Fiore et al) were indicated less incidence of thromboembolism in bileaflet without statistical significance. In our study paradoxically, we observed more incidence of embolism and hemorrhages occurred in bileaflet as compared with tilting disk in mitral group. (9.2% BL,6.7% TD in MVR) (10.9% BL, 21.4 TD% in AVR) looking into aortic valve group reflects western study results. Again it is not statistically significant in any of the side<sup>3</sup>.

Valve related mortality excluding unexplained death and noncardiac death rate is revealing higher incidence valve related mortality in tilting disk type (13% BL, 21.4% TD in AVR). Both of this is absolutely not significant statistically.

Freedom from complications in short term period of 6 months contains many variables which may be giving some confounding errors. Since we have taken post op failure and also an inclusion criterion, these additional parameters also changes the trend to more volume side. However freedom from complications during 6 months follows up is almost equal in both groups. (67.4 %BL vs 64.3%TD in AVR).

Finally we can arrive at some epidemiological datas from our study. Mean age group including both valve replacements was  $33.9 \pm 9.685$  SD. Male patients had undergone higher number of mitral valve replacement (50.5% M,43.5%F in MVR)compared to female patient which is vice versa in aortic valve replacement. (25% M,75%F in AVR) But both groups are not ststistically significant. Importantly in disease pattern the stenotic lesions predominates regurgitation lesions (Mitral 60.4:17.1 Aortic 39.6:32) excluding mixed lesions in our population.

### OBSERVATION & RESULTS TYPES OF VALVES USED :

AVR			TYPE OF VALVE		
				TD	Total
COMPANY	ATS	Count	4	0	4
		% within COMPANY	100	0	
		% within TYPE OF VALVE	5.33	0	
		% of Total	2.67	0	2.67 %
	MH	Count	0	5	5
		% within COMPANY	0	100	
		% within TYPE OF VALVE	0	6.67	
		% of Total	0	3.33	3.33 %
	SJM	Count	67	0	67
		% within COMPANY	100	0	
		% within TYPE OF VALVE	89.33	0	
		% of Total	44.67	0	44.67
	SO	Count	4	0	4
		% within COMPANY	100	0	
		% within TYPE OF VALVE	5.33	0	

# POST OPERATIVE TRANSVALVULAR GRADIENT

AVR			TYPE OF VALVE		
			BL	TD	Total
GR	1.5-3	Count	36	32	68
		% within GR	52.94	47.06	
		% within TYPE OF VALVE	48	42.67	
		% of Total	24	21.33	45.33
	3.1-5	Count	30	28	58
		% within GR	51.72	48.28	
		% within TYPE OF VALVE	40	37.33	
		% of Total	20	18.67	38.67 %
	>5.1	Count	9	15	24
		% within GR	37.5	62.5	
		% within TYPE OF VALVE	12	20	
		% of Total	6	10	16
		Count	75	75	150

Pearson Chi-Square=

s no statistical significance between **"bileaflet"** and **"tilting disk**" with respect to post operative transvalvular mean gradient in aortic valve replacement.

P =

# **POST OPERATIVE LV FUNCTION**

AVR			TYPE OF VALVE		
			BL	TD	Total
LV	SEVERE LVD	Count	7	8	15
		% within EF	46.67	53.33	
		% within TYPE OF VALVE	9.33	10.67	
		% of Total	4.67	5.33	10 %

#### VOLUME-7, ISSUE-5, MAY-2018 • PRINT ISSN No 2277 - 8160 MODERATE 10 15 25 Count LVD % within EF 40 60 % within TYPE OF 13.33 20 VALVE 16.67 % % of Total 6.67 10 MILD LVD Count 12 10 22 % within EF 54.55 45.45 % within TYPE OF 13.33 16 VALVE 6.67 14.67 % % of Total 8 NORMAL Count 46 42 88 LVF % within EF 52.27 47.73 % within TYPE OF 61.33 56 VALVE % of Total 58.66 % 30.66 28 Total Count 75 75 150

Pearson Chi-Square= P=There is no statistical significance between **"bileaflet"** and **"tilting disk"** with respect to post operative LV function in a ortic valve replacement.

# VALVETHROMBOSIS:

AVR			TYPE OF VALVE		
			BL	TD	Total
VT	NO	Count	69	72	141
		% within VT	48.94	51.06	
		% within TYPE OF VALVE	92	96	
		% of Total	46	48	94 %
	YES	Count	6	3	9
		% within VT	66.67	33.33	
		% within TYPE OF VALVE	8	4	
		% of Total	4	2	6%
	Total	Count	75	75	150

Pearson Chi-Square= P=

There is no statistical significance between "**bileaflet**" and "**tilting disc**" with respect to valve thrombosis in a ortic valve replacement

# Results

This retrospective study enlighten the following results,

- Aortic valve replacement, tilting disc are valve not equally easier with bileaflet valve (95.7% vs 85.7%) and indicating some difficulties.But no statistical significance exist with each other in aortic valve replacements.(p=0.192)
- Although, stormy post operative hemodynamics higher in tilting disk than bileaflet type (15.2% vs 21.4%) in aortic valve replacements, it is not statistically significant. (p=0.585)
- We observed higher transvalvular gradient in bileaflet type mechanical valves in both valvular replacements. 26.1% BL vs 21.4% in AVR).Ultimately this is not a statistical significant data, but the fact is higher transvalvular grdient have been associated with significant post operative mortality and morbidity. What so ever ,we have not sub- catagorized mean gradient with other variables in this study.
- LV dysfunction after the aortic valve replacements. Tilting disc showing higher incidence (17.4% vs 21.4% in AVR) without statistical significance(p=0.114) Severe LV dysfunction not truly related to valve type as it is confounded by lot of other factors.
- We detected more or less the same incidence observed in aortic group
- (13% BL, 14.3% TD in AVR). There was no statistical significance in both group
- More incidence of embolism and hemorrhages occurred in tilting disc as compared with bileaflet in small aortic group (10.9% BL, 21.4 TD%in AVR) (p=0.309). But none of the group

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rejected the null hypothsis.

- Valve related mortality is revealing higher incidence in tilting disc type (13% BL, 21.4% TD in AVR). Both of this was absolutely not significant statistically.
- Freedom from complications during 6 months follow up is almost equal in both groups. (67.4%BL, 64.3%TD in AVR).

#### Conclusion

In this study, we came to the conclusion with the best available evidence for comparing the results between "bileaflet" and"tilting disc" offer similar excellent clinical performance for both groups . In MVR, our short term results suggest an advantage in favor of the **bileaflet** mechanical valve in terms of ease of procedure and an advantage in favors of tilting disc valve in respect to Post operative hemodynamics. Other variables in terms of transvalvular gradient, LV function, valve related mortality, valve thrombosis, embolic & hemorrhagic complications, freedom from complications during 6 months follow up did not show the statistical difference between "bileaflet" and "tilting disc" in both groups. These differences await further clarification with more patients followed up for a longer period of time.

# Bibliography

- Harken DE: Heart valves: Ten commandments and still counting. Ann ThoracSurg 1. 1989:48(suppl 3):S18-S19.
- Kirklin JW, Barratt-Boyes BG: Cardiac Surgery, 2nd ed., New York, Churchill 2. Livingstone, 1993.
- Mayer JE: In search of the ideal valve replacement device. J ThoracCardiovascSurg 3. 2001;122:8-9.
- Akins CW: Results with mechanical cardiac valvular prostheses. Ann ThoracSurg 4. 1995;60:1836-1844.
- Baudet EM, Puel V, McBride JT, Grimaud JP, Roques F, Clerc F, Roques X, 5. LabordeNLong-term results of valve replacement with the St. Jude Medical prosthesis..
- 6.
- . JThoracCardiovascSurg.1995May;109(5):858-70. Chambers J, Ely JL: Early postoperative echocardiographic hemodynamic 7. performance of the On-X prosthetic heart valve: A multicentre study. J Heart Valve Dis 1998;7:569.
- 8. Abe T, Kamata K, Kuwaki K, et al: Ten years' experience of aortic valve replacement with the Omnicarbon valve prosthesis. Ann ThoracSurg 1996; 61:1182-1187. 9
- Van Nooten GJ, Caes F, François K, Van Belleghem Y, Bové T, Vandenplas G, De Pauw M, Taeymans Y, Fifteen years' single-center experience with the ATS bileaflet valve.J Heart Valve Dis. 2009 Jul; 18(4): 444-52.
- 10. Nitter-Hauge S, Abdelnoor M. Ten-year experience with the Medtronic Hall valvular prosthesis. Circulation 1989;80(Suppl):143-8
- 11. Keenan RJ, Armitage JM, Trento A, et al: Clinical experience with the Medtronic-Hall valve prosthesis. Ann Thorac Surg 1990; 50:748.