Journal of Cardiovascular Disease Research

ISSN: 0975-3583,0976-2833 VOL14, ISSUE 02, 2023

ORIGINAL RESEARCH

Impact of Prosthesis Patient Mismatch In Patients Undergoing Aortic Valve Replacement-A Tertiary Centre Based Study

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Received: 11 February, 2023 Accepted: 16 March, 2023

Abstract

Background and Aim: Patient prosthesis mismatch is known to alter post-operative remodeling of left ventricle adversely in aortic stenosis patients. An indexed orifice area of 0.85 is considered as conventional cutoff for patient prosthesis mismatch based on hemodynamic principles. Many patients have smaller annulus and annulus enlargement techniques may be required to avoid this benchmark which complicates the surgery. Present study was done with an aim of Evaluation of effect of prosthesis-patient mismatch (PPM) on clinical and echocardiographic outcome in patients undergoing aortic valve prosthesis due to aortic valve disease with predominant aortic stenosis.

Material and Methods: Present Prospective, longitudinal and comparative study was done at the Department of Cardio Vascular and Thoracic Surgery, Tertiary care teaching institute of India. Patients undergoing aortic valve replacement due to aortic valve disease with predominant aortic stenosis were included in the study. Present study was done on 30 patients for the duration of 2 years. Candidates undergoing aortic valve replacement were examined preoperatively to determine NYHA functional class, BODY SURFACE AREA (BSA), BODY MASS INDEX (BMI). Preoperative echocardiography with Doppler to assess chamber sizes, peak and systolic pressure gradient across the valve, LV mass indexed to BSA, End systolic volume and End diastolic volume. Patients were evaluated with post operative ECHO Doppler and Dobutamine Stress Echo at 6 month and at 1 year

Results: Pre operative and post operative mean gradient at rest as well as with dobutamine, in PPM+ positive groups remain more than PPM- groups ($p \leq 0.05$). With dobutamine, in both the groups mean gradient increase. PPM+ and PPM- in both the groups LV mass index regresses significantly. The regression does not differ much between the groups.

Conclusion: Based on this analysis it is seen that, though the Post operative residual gradient at rest as well as with dobutamine stress remains more in Patients with PPM but the LV Mass index regression, improvement of cardiac index and QUALITY OF LIFE statistically significant in both groups.

Key Words: Aortic stenosis, Aortic valve replacement, Dobutamine, Patient prosthesis mismatch

ISSN: 0975-3583,0976-2833 VOL14, ISSUE 02, 2023

Introduction

Aortic stenosis (AS) is the third commonest cardiovascular disease and the commonest valvular heart disease in the developed world.[1] In India, presently, it is the third commonest valvular heart disease after mitral stenosis and mitral incompetence.[2] AS is characterized by progressive narrowing of aortic valve and subsequent left ventricular hypertrophy (LVH). This results in the development of symptoms and adverse events that characterize the later stages of the disease. Hypertrophy of the LV due to AS is known to be associated with increased incidence of stroke, congestive heart failure, and sudden cardiac death.[3-5] Medical interventions presently available are incapable of delaying or halting the progression of LVH. It decreases (or eliminates) the pressure gradient between the left ventricle and ascending aorta and consequently leads to a gradual regress of left ventricular (LV) hypertrophy.[6,7] LV hypertrophy caused by severe aortic valve stenosis is associated with a high risk of sudden death, congestive heart failure, and stroke.2 On the other hand, incomplete regression of LV hypertrophy after AVR has been shown to significantly reduce 10-year survival.[8,9]

The concept of prosthesis-patient mismatch (PPM) was first introduced by Rahimtoola in 1978 as the situation in which "the effective prosthetic valve area, after insertion into the patient, is less than that of a normal human valve".[9] In other words, PPM is deemed to occur when the effective orifice area of the implanted prosthetic valve is too small in relation to the patient's body size, despite normal prosthesis function, resulting in an abnormally high postoperative pressure gradient.[10,11] Patient-Prosthesis Mismatch (PPM) represent a controversial issue in current clinical practice. The negative impact of PPM on patient prognosis after aortic valve replacement has been reported in several studies showing increased all-cause and cardiac mortality. Although some authors claim that PPM is a rarely observed phenomenon without relevant clinical implications,[12-14] many others have argued that it occurs frequently and has important clinical consequences.[15-18]Patient Prosthesis Mismatch was calculated using the effective orifice area of the prosthesis divided by the patient's body surface area. We defined nonsignificant, moderate, and severe Patient Prosthesis Mismatch as effective orifice area indexes of >0.85 cm2 /m, 0.85-0.66 cm2 /m2 , and ≤0.65 cm2 /m2 , respectively.[19]

Dobutamine stress echo (DSE) has been used in many institutes for estimating not only the viability of the myocardial wall but also valvular disease. Dobutamine Increases cardiac output and blood flow through the prosthetic valve in which the condition and performance of the prosthetic valve can be estimated properly.

Present study was done with an aim of Evaluation of effect of prosthesis-patient mismatch (PPM) on clinical and echocardiographic outcome in patients undergoing aortic valve prosthesis due to aortic valve disease with predominant aortic stenosis.

Material and Methods

Present Prospective, longitudinal and comparative study was done at the Department of Cardio Vascular and Thoracic Surgery, Tertiary care teaching institute of India. Patients undergoing aortic valve replacement due to aortic valve disease with predominant aortic stenosis were included in the study. Present study was done on 30 patients for the duration of 2 years. Stratified and quota sampling technique was utilized for the sample selection.

Exclusion Criteria were

- Aortic valve replacement due to any etiology other than predominant aortic stenosis
- Double valve pathology

Patients were divided in two groups

Those with EOAI < .85 as PPM+

Those with EOAI > .85 as PPM-

Candidates undergoing aortic valve replacement were examined preoperatively to determine

ISSN: 0975-3583,0976-2833 VOL14, ISSUE 02, 2023

NYHA functional class, BODY SURFACE AREA (BSA), BODY MASS INDEX (BMI). Preoperative echocardiography with Doppler to assess chamber sizes, peak and systolic pressure gradient across the valve, LV mass indexed to BSA, End systolic volume and End diastolic volume. Patients underwent AVR under cardiopulmonary bypass. Effective orifice area index (EOAI) was estimated using manufacturer provided FDA approved chart. Patients were categorized as par EOAI, mild, moderate and severe PPM. Postoperatively patients underwent echocardiography with Doppler at discharge and at 6 months interval All the valves were implanted in supra annular position with interrupted horizontal mattress suture with 2-0 ethibond. Patients were evaluated with post operative ECHO Doppler and Dobutamine Stress Echo at 6 month and at 1 year

ECHO was done to evaluate:

LV study

Determination of LV mass

Trans-prosthetic mean gradient

Cardiac index

EOAI

Effective Orifice Area (EOA) was determined using continuity equation with help of colour Doppler.

Statistical analysis

The recorded data was compiled and entered in a spreadsheet computer program (Microsoft Excel 2007) and then exported to data editor page of SPSS version 15 (SPSS Inc., Chicago, Illinois, USA). For all tests, confidence level and level of significance were set at 95% and 5% respectively.

Results

Table 1: Demographic details of study population

Patient group	n	Age	BSA
PPM+	16 (male-12 female –4)	47±10.05 (35 – 72 yr)	1.7±.13
PPM-	14 (male- 8 Female –6)	48 ±10.3 (38- 68 Yr)	1.4±0.13

Table 1 shows that in PPM+ group 12 were males and 4 were females, while in PPM- group 8 were males and 6 were females respectively. Mean age of both groups were 47±10.05 and 48 ±10.3 respectively in PPM+ and PPM- groups. Average BSA of the PPM+ patients were 1.7 sq mt and for the PPM – patients were 1.4 sq mt (p value <0.001)

Table 2: Transvalvular Mean gradient among study population

Groups	Pre op mean gradient at rest	post op mean gradient at rest	p value versus baselines
PPM +	54.67± 9.6	22.86± 6.31	<0.001
PPM –	41.28± 3.48	11.87± 3.48	< 0.001
p value b/w groups	0.0007*	0.03*	

* indicates statistically significance at p≤0.05

Table 2 describes Transvalvular Mean gradient among study population. In both groups reduction in mean gradient compared to baseline is statistically significant (p value <0.001)

Table 3: Trans prosthetic gradient at rest and with DSE among study population

Groups	post op mean gradient at rest	Post op mean gradient at stress with dobutamine	Compared with baseline

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PPM+	22.86± 6.31	27.47 ± 10.41	p value 0.06
PPM-	11.87± 3.48	18.14± 4.09	p value 0.5
p value b/w groups	0.03*	0.008*	

*** indicates statistically significance at p≤0.05**

Pre operative and post operative mean gradient at rest as well as with dobutamine, in PPM+ positive groups remain more than PPM- groups (p≤0.05). With dobutamine, in both the groups mean gradient increase (p value 0.06 and 0.5 respectively) (Table 3)

Table 4: NYHA class among study population

Groups	Pre op	Post op	p value versus baseline
PPM +	3.2 ± .41	1.3± 0.49	< 0.001
PPM -	3.07 ± 0.47	1.28± 0.46	<0.001
p value b/w groups	0.06	0.9	

Statistically significance at p≤0.05

Improvement of post operative NYHA class and Karnofsky performance scale is statistically significant in both the groups compared to baseline or preoperative level (p value < 0.001) (Table 4) Post operative level in between the groups did not differ much (p value 0.9)

Table 5: Karnofsky Performance Scale

Groups	Pre op	Post op	p value versus baseline
PPM +	61.33 ± 6.4	84± 5.07	< 0.001
PPM -	67.14 ± 6.11	86.4± 4.9	<0.001
p value b/w groups	0.08	0.9	

Statistically significance at p≤0.05

Table 6: Regression of LV Mass Index

	Pre operative	Post operative	p value versus baseline
PPM +	210.7 ± 63.76	172± 55.8	0.05
PPM -	204.9± 45.05	145± 31.2	0.001
p value b/w groups	0.65	0.1	

Statistically significance at p≤0.05

PPM+ and PPM- in both the groups LV mass index regresses significantly (p value 0.05 and 0.001 respectively). The regression does not differ much between the groups (p value 0.1).

Table 7: Cardiac Index among study population

	post op Cardiac index at rest	Post op cardiac index at stress with dobutamine	p value versus baselines
PPM +	2.98± .45	4.3 ± .79	<0.001
PPM –	2.88± .38	3.7± .6	< 0.001
p value b/w groups	0.5	0.3	

Statistically significance at p≤0.05

In both the groups Cardiac Index increases significantly with dobutamine stress compared to its level at rest (p value < 0.001) The increased level of Cardiac index with stress in both the groups did not differ much (p value 0.3).

Discussion

Even though early long-term and short-term follow-up studies had shown a significantly increased incidence of mortality as well as morbidity in patients with PPM, later reports appeared to be contradictory.[20-23] Howell et al. reported that there is no difference in medium-

ISSN: 0975-3583,0976-2833 VOL14, ISSUE 02, 2023

and long-term mortality in patients with PPM.[24-25] Hong et al. observed a higher 12- year mortality for patients with severe PPM.[26] Fuster et al. has reported that PPM adversely impacts LV mass regression up to 1 year. This study also suggested that impaired LV mass regression occurs more in severely hypertrophied hearts.[27] Ruel et al. observed that PPM affected outcome only in patients with severe LV dysfunction.[28]

In both groups reduction in mean gradient compared to baseline is statistically significant (p value <0.001) Similar observations were made by Medalion and Lapar as well.[29,30] Sportelli et al. reported an incidence of 53.8% of PPM. But there was no significant difference in mortality or clinical status in patients with PPM.[31] Hernández-Vaquero et al. observed that PPM is not associated with any adverse outcome in young and middle-aged individuals .[32]

Pre operative and post operative mean gradient at rest as well as with dobutamine, in PPM+ positive groups remain more than PPM- groups ($p \leq 0.05$). With dobutamine, in both the groups mean gradient increase (p value 0.06 and 0.5 respectively) Dayan et al. observed an increased perioperative and overall mortality in patients with PPM and recommended avoidance of severe PPM in all patients less than 70 years.[33] An Indian study by Joshi et al. showed no difference between early outcomes in PPM patients.[34]

Improvement of post operative NYHA class and Karnofsky performance scale is statistically significant in both the groups compared to baseline or preoperative level (p value < 0.001) (Table 4) Post operative level in between the groups did not differ much (p value 0.9) Dare et al. have also reported that predominant pathology in aortic stenosis was degenerative which accounts for 51%; 36% were bicuspid aortic valves and 14% rheumatic. Our data concurred with these findings. But this observation was in contrast with the previous Indian data published in 2006 which showed rheumatic etiology in 75.5% and degenerative causes in 24.5% patients.[35,36]

PPM+ and PPM- in both the groups LV mass index regresses significantly (p value 0.05 and 0.001 respectively). The regression does not differ much between the groups (p value 0.1). These findings were also similar in two recent publications, from Minardi[37] and from Modi[38]. Hanayama et al.[39] in their paper published in 2002, in 1,037 patients who underwent AVR with mechanical or biological prostheses found no significant relationship between severe PPM and regression of left ventricular hypertrophy or a negative impact on mid-term survival. However, follow-up data were limited at 7 years, a great number of patients during follow-up remained with a higher abnormal left ventricular mass index, freedom from III to IV NYHA class at 6 years was less than 80%. Singh et al. studied LV regression in rheumatic AS in Indian population and found out that LV regression was independent of the valve size.[32]

In both the groups Cardiac Index increases significantly with dobutamine stress compared to its level at rest (p value < 0.001) The increased level of Cardiac index with stress in both the groups did not differ much (p value 0.3) Pibarot et al. [10] following 392 patients during a 7-year follow-up after AVR, found that cardiac index decreased significantly after 3 years from operation only in patients with PPM (p< 0.65 cm2 /m2 .

Conclusion

Based on this analysis it is seen that, though the Post operative residual gradient at rest as well as with dobutamine stress remains more in Patients with PPM but the LV Mass index regression, improvement of cardiac index and QUALITY OF LIFE statistically significant in both groups. Still at very immature stage but provided with the facts it is evident that PPM had hardly an effect on the outcome of the patients with aortic valve replacement in Indian scenario.

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