

Patient Prosthesis Mismatch in Double Valve Replacement - A Retrospective Study at a Tertiary Care Center in Bangalore

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ABSTRACT

BACKGROUND

Valve replacement has become the mainstay of management for rheumatic heart diseases. However, an important and frequent complication of valve replacement is patient prosthesis mismatch (PPM). The present study was undertaken to evaluate a single institution experience on the clinical pattern and presentation of PPM, and the outcomes of double valve replacement surgery.

METHODS

This retrospective, regional study was carried out among 316 consecutive patients who underwent concomitant aortic and mitral valve surgery (with or without tricuspid annuloplasty) in this tertiary care hospital. Particulars regarding the clinical profile and procedure details (valve types and sizes and priority of surgery) of these patients were documented from the medical records.

RESULTS

In this institute, the valves used were predominantly mechanical (92.6 %) when compared to bioprosthesis in 7.4 % (47/632 valves - 23 mitral position and 24 in aortic position). The most common sizes used in the aortic and mitral position were 21 mm & 27 mm respectively. In spite of the seemingly lower sizes used in the patients undergoing double valve replacement (DVR) the incidence of PPM is less owing to the fact that the population under study had a lower body surface area (BSA) and body mass index (BMI) - 1.17 ± 0.3 & 19.86 ± 3.9 respectively.

CONCLUSIONS

It may be emphasized that if the valve size required to be implanted is derived based on the patient's BSA and indexed effective orifice area, the incidence of patient prosthesis mismatch can be minimized drastically and with it the in-hospital mortality and morbidity.

KEYWORDS

Aortic Stenosis, Double Valve Replacement, Mitral Valve, Prosthesis, Rheumatic Heart Disease

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BACKGROUND

Rheumatic heart disease (RHD) continues to be prevalent in India and is associated with high rates of morbidity, mortality, and disability among the younger population. The overall prevalence of RHD is about 1.5 - 2 per 1000 population in all age groups in India and, with an overall population of 1.3 billion, it has been estimated that there are about 2.0 to 2.5 million patients of RHD in the country.¹ The current hospital mortality rate ranges from 5 % to 15 % with a ten-year survival of 50 - 70 %.^{2,3} Valve replacement for RHD, especially in combined mitral and aortic valve disease was first advocated in the 1960's and has become the mainstay of management.⁴ It is one of the cornerstones in the management of patients with valvular heart disease. In successful and uncomplicated cases, valve replacement significantly better the quality of life by relieving the symptoms.

Pulmonary hypertension is relieved following mitral valve replacement and there is regression of ventricular hypertrophy and/or dilatation following aortic valve replacement. However, an important and frequent complication of valve replacement is patient prosthesis mismatch. Globally, the prevalence of PPM has been reported to range between 20 % - 70 %.⁵ The mismatch occurs mainly because of two factors. First, the in vitro effective prosthetic valve area of almost all valve types is lesser than the normal human valve; which is further reduced by tissue ingrowth and endothelialization. Second, the size of the valve that can be inserted is limited by the size of the annulus and the cavity in which the prosthesis must lie.

Despite valve replacement devices being stenotic, patients do experience an improvement in their symptomatic state. There is no observed appreciable gradient across the valve. Ventricular performance improves and compensatory mechanisms regress. This is because unless the effective orifice area is reduced to a critical level, there is no appreciable gradient above which it rises precipitously. Although early outcomes of the surgery remain unaffected, studies have documented the impact of PPM on left ventricular function, and associated hypertrophy, resulting in long term complications.

Objective

The present study was undertaken to evaluate a single institution experience on the clinical pattern and presentation of PPM and the outcomes of double valve replacement surgery.

METHODS

This is a retrospective, regional study of 316 consecutive patients who underwent concomitant aortic and mitral valve surgery (with or without tricuspid annuloplasty) in Sri Jayadeva Institute of Cardiovascular Sciences and Research, Bangalore, a tertiary cardiac care hospital, for a period of five years from January 2009 to December 2013. Particulars

regarding the clinical profile (demographic particulars and clinical comorbidities) and procedure details (valve types and sizes and priority of surgery) of these patients were retrieved from the medical records department. Laboratory and echocardiographic data as to the presence of lesion predominance, severity and presence of pulmonary hypertension were noted. Cases of mitral valve repairs were not included in this study as the main objective was to define the presence of patient prosthesis mismatch in double valve replacement population and data regarding posterior mitral leaflet preservation were not collected.

The effective orifice area of the prosthesis divided by the patient's body surface area (BSA) gives us the indexed effective orifice area (EOA) and this is the only value that consistently tallies with post-operative gradients. The indexed effective orifice area for each prosthesis was derived from the reference normal values of EOA. PPM was defined as mild if the indexed EOA $> 0.85 \text{ cm}^2/\text{m}^2$, moderate if it was $> 0.65 \text{ cm}^2/\text{m}^2$ and $< 0.85 \text{ cm}^2/\text{m}^2$ and severe if it was $< 0.65 \text{ cm}^2/\text{m}^2$.⁶

RESULTS

In this study, 316 patient's data (38 % female) was retrospectively analyzed. The incidence of patient prosthesis mismatch for the mitral position, graded as mild, moderate and severe were 181 (57 %), 24 (7.6 %) & 6 (1.9 %) respectively. For the aortic position the incidence of PPM graded as mild, moderate and severe were 6 (1.9 %), 18 (5.7 %) & 2 (0.6 %) respectively. Overall, in-hospital mortality was 3.79 %. (Figures 1 & 2)

Most of these patients belonged to New York heart association (NYHA) class III - the disease entity being predominantly of rheumatic aetiology - various combinations of stenosis and regurgitation were observed. Tricuspid annuloplasty was done along with double valve replacement in 29 % of patients.

There was no correlation between the severity of PPM and the mortality risk. In this institute the valves used were predominantly mechanical (92.6 %) when compared to bioprosthesis in 7.4 % (47/632) valves (23 mitral position and 24 in aortic position). The most common sizes used in the aortic and mitral position were 21 mm & 27 mm respectively. (Table 1 & 2).

In spite of the seemingly lower sizes used in the patients undergoing DVR the incidence of PPM is less owing to the fact that the population under study had a lower body surface area and body mass index 1.17 ± 0.3 & 19.86 ± 3.9 respectively. The list of the commonly used types of valves in both mitral and aortic valve replacement is given in tables 3 & 4.

Mitral Valve Size	Frequency	Percent
23	13	4.1
25	52	16.4
27	160	50.5
28	1	0.3
29	77	24.3
31	13	4.1
Total	316	100

Table 1. Sizes of Mitral Valves Used and Their Frequency of Usage in Our Patient Population

Aortic Valve Size	Frequency	Percent
16	3	0.9
17	16	5
18	25	7.9
19	80	25.2
20	18	5.7
21	84	26.5
22	15	4.7
23	54	17
24	3	0.9
25	16	5
27	1	0.3
Total	316	100

Table 2. Aortic Valve Sizes Used in Our Patients Who Underwent DVR

Mitral Valve	Frequency	Percent
ATS	57	18
Carpentier Edward's bioprosthesis	1	0.3
Carpentier Edward's peri mount	6	1.9
Carpentier Edward's peri mount magna	1	0.3
Carpentier Edward's pericardial prosthesis	1	0.3
Edwards life sciences bioprosthesis	2	0.6
Hancock cinch	1	0.3
Hancock II	10	3.2
Medtronic Hall	2	0.6
Medtronic Hall easy fit	7	2.2
Medtronic mosaic	8	2.5
St Jude Biocor	9	2.8
St Jude mechanical	122	38.5
TTK Chitra	89	2.1
Total	316	100

Table 3. A List of All Bioprosthetic and Mechanical Valves Used in the Mitral Position in Our Double Valve Replacement Patients

Aortic Valve	Frequency	Percent
ATS	59	18.6
Carpentier Edwards peri mount	8	2.5
Edwards life sciences bioprosthesis	1	0.3
Hancock Cinch	1	0.3
Hancock II	9	2.8
Medtronic Hall	4	1.3
Medtronic Hall easy fit	3	0.9
Medtronic Mosaic	8	2.5
St. Jude Biocor	11	3.5
St Jude mechanical	128	40.4
Soprano	2	0.6
TTK Chitra	82	25.9
Total	316	100

Table 4. A List of All Mechanical and Bioprosthetic Valves Used in the Aortic Position in Our Patient Population

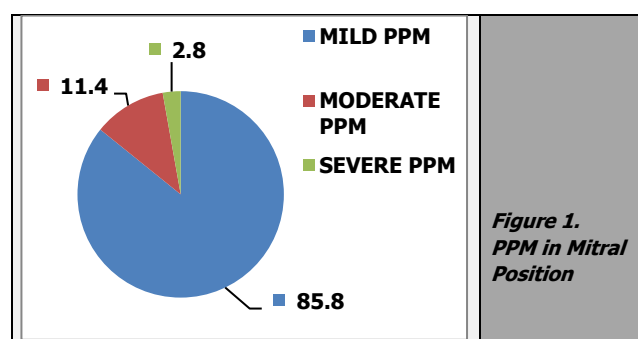


Figure 1. PPM in Mitral Position

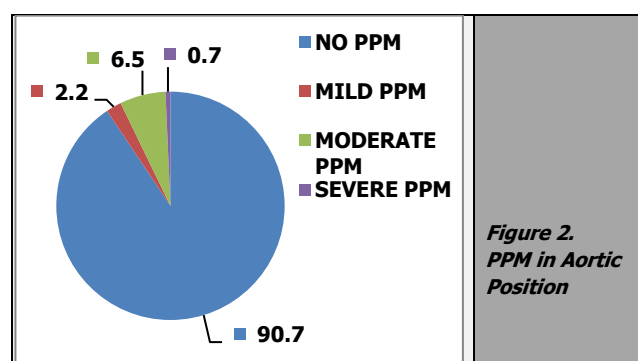


Figure 2. PPM in Aortic Position

DISCUSSION

The concept of patient prosthesis mismatch (PPM) was introduced in 1978 by Rahimtoola et al. and continues to play a large role in valve replacements till date.⁴ Rao et al. demonstrated that indexed EOA calculated at the time of surgery was an independent predictor of post-operative mortality. Review of literature reveals that the reports of occurrence, and factors predicting the outcomes of PPM, are mainly from western countries. The published works on PPM in Indian population are surprisingly scant.^{7,8} PPM has been shown to be more likely to occur in elderly patients with the larger BSA, smaller prosthesis size and valvular stenosis as the predominant lesion before the operation.⁹ Presence of PPM has been associated with worse hemodynamic function, less regression of left ventricular hypertrophy, more cardiac events, and lower survival.¹⁰ Theoretical comparison of mean transvalvular pressure gradient in patients receiving the same prosthetic valve but having different body surface areas has shown increased gradients with higher BSA.¹⁰

Technically, patients with higher BSAs have higher cardiac output requirements as opposed to the smaller patients. This probably leads to the pathologic process producing a greater narrowing of their valvular annulus in relation to their body size which predisposes them to mismatch. Nevertheless, the incidence of mismatch is inversely related to prosthesis size, and higher gradients are seen in patients with a valve size of 21 mm. The final hemodynamic outcome is determined by the relation between prosthesis size and body size rather than each factor taken separately. Hence, patients receiving a prosthesis size 21 mm may also have severe mismatch. Thus, patients who received a smaller prosthesis probably had a smaller aortic annulus with regard to their body size. In this study, in spite of the seemingly lower sizes used in the patients undergoing DVR the incidence of PPM is less owing to the fact that the population under study had a lower BSA and BMI - 1.17 ± 0.3 & 19.86 ± 3.9 respectively. This could be attributed to be the reason for lesser incidence of significant patient prosthesis mismatch and in turn lower mortality when compared to available data from other studies. Stenotic native valves generally have smaller valvular annuli as opposed to regurgitant valves and in older patients undergoing aortic valve replacement, calcific aortic stenosis is the commonest lesion. It is hence no surprise that mismatch occurs more frequently in patients with stenotic native valves and in older patients.

It is important to consider whether the benefits of avoiding PPM overcome the drawbacks of other complicated techniques. Baba et al. sought to determine whether the small indexed effective orifice area (EOAI) increased mortality and morbidity after aortic valve replacement (AVR) in patients over 75 years of age. In this study, they found that moderate PPM ($0.7 \text{ cm}^2/\text{m}^2 < \text{or} = \text{EOAI}$) is acceptable in elderly patients.¹¹

In our study, there was no correlation between severity of PPM and mortality. In a review of articles from the past 10 years addressing the prevalence, outcomes and options for prevention and treatment of PPM after AVR; prevalence of PPM ranged from 8 % to almost 80 % in individual

studies. PPM was thought to have an impact on mortality, mainly in patients with severe PPM, although severe PPM accounted for only 10 – 15 % of cases. Outcomes of patients with moderate PPM were not significantly different to those without PPM. PPM was associated with higher rates of perioperative stroke and renal failure.¹² In another study, prosthesis-patient mismatch had a negative impact on survival for young patients, but its impact on older patients was minimal. In addition, although prosthesis-patient mismatch was not important in small patients, prosthesis - patient mismatch negatively impacted survival for average - size patients and for large patients with mechanical valves.¹³

Aortic annulus diameters are an essential factor for PPM occurrence. The need to index aortic annulus (iAA) to BSA is essential due to the obvious differences in anthropometry of subjects across varied origins. iAA was observed to be different for western reference subjects and Indian subjects as studied by Rajendran et al.¹⁴ Similar to our study, in a study about the Indian perspective of PPM, they discussed the low occurrence of PPM in the Indian population and the importance of iAA in relation to PPM and while cautioning us of the high incidence of PPM at iAA values of $< 16 \text{ mm/m}^2$. They concluded in this study that PPM exists but with a lower incidence and had no impact on early mortality. PPM was more common with AVR for AS than AR. Aortic annulus indexed to BSA is an important indicator of PPM with the high prediction of PPM at $< 16 \text{ mm/m}^2$ BSA.¹⁵

The body surface area and the population characteristics differ from region to region. Though there are various reports of PPM, the BSA of the patients differ. An EOAI $< \text{or} = 0.85 \text{ cm}(2)/\text{m}(2)$ seems to lead to poor symptom resolution, lesser reduction of left ventricular mass, or decreased survival as evidenced by some studies, while others have observed no adverse effects of PPM on short- and long-term results of AVR. Therefore, there seems to be a large discrepancy in the conclusions drawn concerning the impact of PPM even in studies coming from the western countries, and involving large number of patients. In this study they concluded that, it is desirable to examine in detail, in many patients, whether the use of prosthetic valves with EOAI $< \text{or} = 0.85 \text{ cm}(2)/\text{m}(2)$ is also a risk factor for poor prognosis in Japanese patients, whose body size is in general smaller than that of western patients.¹⁶ The other issue is the sizing of the prosthetic valves. The commercially available prosthetic valves are manufactured to fit the standard annular sizes. Rajendran et al. showed that the normal diameter of mitral valve annulus in the Indian population is definitely lower than the standard values and should be taken into consideration to prevent the incidence of PPM during mitral valve replacement surgery.¹⁷

Impact on LV Hypertrophy

Post-operative regression of left ventricular (LV) hypertrophy is delayed mostly due to high residual pressure gradients. The type and size of prosthesis used for valve replacement and their hemodynamic performance largely determines the extent of this regression. Nishimura et al. found that the mean wall thickness of the LV was directly related to the pressure gradient across the aortic prosthetic

valve.¹⁸ Other studies have shown that the use of stent-less aortic bioprosthesis leads to a greater reduction in transvalvular gradient and LV wall stress, along with more complete regression of LV hypertrophy, when compared to stented valves.

In a recent study with a porcine bioprosthesis, Del Rizzo et al. found a strong relation between the indexed EOA and the extent of LV mass regression.¹⁹ While it has long been proven that systolic and diastolic function and exercise capacity are largely determined by LV hypertrophy, it should be noted that most of these studies were conducted in patients with hypertensive heart disease. Whether similar results are reproducible in hypertrophy due to valvular disease remains to be seen. Indeed, hypertension associated hypertrophy has a neurohormonal component and is importantly related to interstitial fibrosis in addition to muscle hypertrophy. The valvular disease related hypertrophy could be because of the increased hemodynamic burden, which means it probably is more physiologic, shows less fibrosis and hence not have the same adverse effect on long-term prognosis. Various studies have demonstrated that exercise related physiologic hypertrophy is because of the increased burden related to the intensity of training which does not have any negative long-lasting effects.

CONCLUSIONS

The in-hospital mortality for DVR patients in this study was 3.8 % which is lesser than the observed value in various populations. The incidence of severe PPM is less in our population probably because of the lesser BMI of our patients compared to the western population.⁹ Therefore, factors which may play a role in its occurrence and the change in outcome based on the incidence of PPM cannot be ascertained and further studies and larger cohort of patients are to be studied to achieve a significant result. To conclude, it may be emphasized that if the valve size required to be implanted is derived based on the patient's BSA and indexed effective orifice area, the incidence of patient prosthesis mismatch can be minimized drastically and with it, the in-hospital mortality and morbidity can be reduced.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.

Financial or other competing interests: None.

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