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Does the Size Matter? A Retrospective Study of Patients following Aortic Valve Replacement

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Abstract: ***Purpose: Prosthesis - patient mismatch (PPM) occurs when the implanted prosthesis is too small compared to the patient's body surface area (BSA). We analyzed an Aortic Valve Replacement (AVR) study population to investigate PPM prevalence and the importance of aortic valve size. Methods: We conducted a retrospective study of patients aged 18 years and above with isolated aortic valve pathology who underwent AVR with a mechanical prosthetic valve at our center between January 2018 and December 2022. Patients with combined valve pathology and other concomitant surgeries were excluded. EOAi was predicted by calculating patients' BSA and matching to the valve - specific EOAi calculator. Results: Of the 177 patients with isolated mechanical AVR included in this study, PPM was not observed in 106 patients, while 71 patients had moderate PPM. All valves with moderate PPM were single leaflets, and 71% had PPM. The patients' age and BSA were significantly associated with the valve size. Also, BSA was substantially lower in subjects having PPM (p = 0.025). Conclusions: PPM after aortic valve replacement is associated with higher post - operative morbidity and mortality. Despite more frequent PPM experienced by patients with single - leaflet mechanical valves, the clinical conditions of all patients in our study improved with no negative immediate post - operative outcomes. We propose confirming the EAOi chart before implanting single leaflet mechanical valves and a longer follow - up period for the patients' best interests.***

Keywords: Aortic valve replacement, prosthesis - patient mismatch, effective orifice area, body surface area

1. Introduction

Prosthesis - patient mismatch, or PPM, is the term used to describe a small, implanted prosthesis in relation to the body surface area (BSA) of the patient [1]. Rahimtoola originally identified PPM in 1978 as occurring when an efficient prosthetic valve has a smaller surface area than a typical human valve. PPM causes an excessively high postoperative transvalvular gradient [2, 3]. A prosthetic heart valve with a small effective orifice area (EOA) causes high - residual pressure gradients across the valve after implantation which leads to PPM [4]. In order to estimate the postoperative EOA for an implanted prosthesis, accurate EOA data are used [5].

Aortic valve replacement (AVR) is considered a gold standard therapy for those with severe symptomatic aortic valve (AV) stenosis [6]. In AVR patients, the prevalence of moderate PPM ranges from 27.9 to 71%, while severe PPM ranges from 11.8% to 22.8% [7, 8]. PPM has been linked to a worse rate of survival following the replacement of the aortic valve [4, 9]. When compared to individuals with non-significant PPM, the probability of death was raised 11.4 - fold in patients with severe PPM and increased 2.1 - fold in those with moderate PPM [10, 11]. The calcification and fibrosis of the aortic annulus may have reduced its size, and this relative blockage of the prosthesis' structural support may have contributed to the development of PPM [12]. According to reports, preoperative risk factors leading to PPM development include valvular stenosis, a smaller prosthesis, advanced age, a higher BSA, and a higher body mass index (BMI) [13].

By matching the estimated EOA of prosthesis to the BSA of the patient and then choosing the largest prosthesis to be implanted, PPM can be avoided. However, the architecture of the aortic root and the surgical conditions may not be the sole factors in determining the optimal prosthetic AV size [14]. According to multiple studies, the prosthetic AV size inserted was less than predicted based on preoperative measurements [6]. We investigated our AVR cohort in this research to evaluate PPM prevalence and whether the size of the aortic valve impacts.

2. Methods

Study and patients

We retrospectively reviewed all patients who underwent AVRat our center from January 2018 to December 2022. We collected the perioperative and postoperative data from electronic and paper medical records. We included patients aged 18years and above with isolated aortic valve pathology who underwent AVR with a mechanical prosthetic valve. The study participants were divided into two groups: PPM - free and PPM groups. Patients with combined valve pathology and other concomitant surgery were excluded.

Informed consent was obtained from all participants, and the institution's ethics committee approved the study. Baseline characteristics, operative profiles, New York Heart Association (NYHA) status, and institutional electronic database were utilized for retrieving the echocardiographic parameters.

Effective orifice area (EOA) was measured in the operating room using valve sizers. PPM is best measured using indexed EOA (EOAi), which is calculated by dividing EOA of the patient by body surface area (BSA) [EOAi=EOA/body surface area (BSA)]. EOAI 0.85 is currently regarded as the PPM threshold. If EOAI ranged from 0.65to 0.85, it is considered as moderate PPM, and if EOAI ranges less than 0.65, it is considered as severe PPM [2, 4].

Statistical data analysis

STATA software (Stata Corp., College Station, TX, USA, Version 17 for Windows) was applied for analyzing the data. Descriptive analysis was conducted. Continuous variables were calculated using mean and standard deviations, while categorical data were analyzed using frequencies. Mean ± SD and percentages as required were calculated to obtain the results. Continuous variables were compared applying the Student t - test and for categorical variables Pearson's chi - square test was used. One - way ANOVA was applied to compare the three groups. A p - value of <0.05 was considered statistically significant.

3. Results

Study cohort characteristics

Table 1 represents the baseline and procedural characteristics of the 177 patients withisolated mechanical AVR done from Jan 2018 – Dec 2022. The mean age at the time of the procedure was 48.6 ± 13.6 years, 49 (27.7%) patients were females and 128 (72.3%) were males. The echocardiography data showed that 84% had aortic stenosis (AS), 5% had aortic regurgitation (AR), and 11% had both. The average preoperative (62.2 ± 2.4) and postoperative (62.4 ± 2.4) ejection fraction were not significantly different. The mean (SD) BSA was 1.63 ± 0.08, and mean (SD) aortic valve area was 0.96 ± 0.08. Average preoperative and postoperative aortic gradient was 65.4 ± 3.4 and 18.7 ± 5.04 respectively. Both Single (n=90) and Bi - Leaflets (n=87) prosthetic valve were used.

Table 1: Overall demographic characteristics of subjects (n=177)

Patient characteristics	Frequency	Percent (%)
Gender		
Male	128	72.3
Female	49	27.7
Diagnosis		
Aortic regurgitation (AR)	09	5.1
Aortic stenosis (AS)	149	84.2
Both AS/AR	19	10.7
	Mean	Standard deviation
Age (years)	48.6	13.6
Body Surface Area	1.63	0.08
Aortic Valve Area	0.96	0.08
Ejection fraction (EF)		
Preoperative EF	62.15	2.38
Postoperative EF	62.39	2.38
Mean aortic gradient		
Preoperative gradient	65.35	3.39
Postoperative gradient	18.74	5.04

Note: No patient had severe PPM in this study cohort.

PPM and valve prosthesis size

PPM was not observed in 106 patients (EOAi>0.85 cm^2/m^2), while 71 patients had moderate PPM (EOAi ≤0.85 - 0.65 cm^2/m^2). All valves with moderate PPM were single leaflet.71% (71/100) of single leaflet mechanical valves had PPM (Table 2).

Table 2: Indexed effective orifice area (EOA) based on the size of aortic valve prosthesis

	>0.85 cm^2/m^2	≤0.85 - 0.65 cm^2/m^2
	(No PPM)	(Moderate PPM)
19 - mm St Jude Medical aortic valve	48	0
19 - mm TTK Chitra valve	03	55
21 - mm St Jude Medical aortic valve	39	0
21 - mm TTK Chitra valve	16	16
Total	106	71

We analysed the correlation among age, BSA, and valve size. The data analysis showed that BSA (p<0.0001), but not age, was correlated to valve size (P< 0.01) significantly (Fig.1).

Among 71 subjects with PPM were 63.4% were males and 36.6% were females, however the PPM was present significantly (p=0.03) in female population (Table 3). In subjects with and without PPM, the mean age was not statistically distinct significantly (p =0.819), however the BSA was significantly lower in subjects with PPM (p = 0.025) (Table 3).

Table 3: Characteristics of subjects with and without PPM (n=177)

Variables	PPM absent (n=106)	PPM present (n=71)	P value
Gender			
Male	83 (78.3%)	45 (63.4%)	0.030
Female	23 (21.7%)	26 (36.6%)	
Diagnosis			
Aortic regurgitation (AR)	03 (2.8)	06 (8.5)	0.024
Aortic stenosis (AS)	87 (82.1)	62 (87.3)	
Both AS/AR	16 (15.1)	03 (4.2)	
Age (years)	48.8 ± 13.3	48.3 ± 14.1	0.819
Body Surface Area	1.64 ± 0.09	1.61 ± 0.08	0.025
Aortic Valve Area	0.96 ± 0.07	0.96 ± 0.09	0.998
Ejection fraction (EF)			
Preoperative EF	62.2 ± 2.5	62.0 ± 2.2	0.615
Postoperative EF	62.3 ± 2.4	62.5 ± 2.4	0.615
Mean aortic gradient			
Preoperative gradient	65.2 ± 3.3	65.5 ± 3.5	0.585
Postoperative gradient	19.1 ± 6.3	18.3 ± 1.9	0.308

Table 4 shows the postoperative improvement in NYHA functional class for the groups with and without PPM. In both groups, there was a significant clinical improvement in NYHA class.

Table 4: NYHA class correlation between groups with and without PPM

Groups	Pre - operative	Post - operative	P value
PPM present (71)	**Class III** 11 (15.5%) **Class IV** 60 (84.5%)	**Class I** 03 (4.2%) **Class II** 68 (95.8%)	<0.0001
PPM absent (106)	**Class III** 09 (8.5%) **Class IV** 97 (91.5%)	**Class I** 06 (5.7%) **Class II** 100 (94.3%)	0.025

NYHA: New York Heart Association

4. Discussion

The most prevalent valvular disorder is aortic valve stenosis (AS) affecting 9 million worldwide. Currently, 4 - 7% of people older than 65 years old have AS [15]. AS is characterised by increasing constriction of the aortic valve and left ventricular hypertrophy (LVH). Heart failure, arrhythmia, and cardiovascular mortality have all been strongly associated with LVH [16]. The usual course of action is AVR, which can relieve left ventricle stress, enable left ventricular mass reduction (LVMR), and extend life. PPM, a non - structural malfunction, is one of the most serious side effects of AVR [17]. A recent meta - analysis of 34 observational studies observed that individuals with PPM following AVR had significantly worse long - term overall and cardiac related mortality [12, 18].

PPM is now understood to be a condition in which the implanted valve prosthesis' effective orifice area does not correspond to the body size of the patient. It has been demonstrated that PPM observed in the aortic position is linked to worse results, including long - and short - term cardiac mortality. According to a recent analysis, PPM is a potent and reliable predictor of short - term death in individuals who have had AVR [19 - 21]. According to reports, the death rates for mild, moderate, and severe PPM were 3%, 6%, and 26%, respectively. Severe PPM raises the risk of death by 11 times compared to non - significant PPM [10]. Compared to patients with normal LVEF, individuals with preoperative LVEF < 40% have a 77 times higher mortality risk for PPM [10].

PPM is a pervasive and changeable risk factor that leads to poor hemodynamic functions in the postoperative phase, slower ventricular function recovery, more cardiac events, and worse survival. It is necessary to methodically calculate the EOAI predicted to prevent PPM. EOAI is used in this description to indicate the effective valve area. After the aortic valve was replaced, Pibarot and Dumesnil proposed three methods to lower the PPM: calculating BSA, choosing the right prosthesis, and calculating the minimal (0.85 cm^2/m^2) EOA to supply the necessary EOAI [9]. The EOAI decision varies depending on the patient's clinical state and what they want to achieve from the procedure. In contrast to the elderly and sedentary individuals with normal EF, who may tolerate mild PPM, young and active patients should avoid PPM [12] (Table 2). When choosing a valve prosthesis, especially for individuals with a narrow aortic annulus, this should be borne in mind. Depending on the risk of moderate to severe PPM, prosthesis with aortic root expansion or a larger EOA may be implanted. Operative mortality is increased by 3.5–7% with aortic root expansion operations [23] (Fig.2).

The EOA for a specific valve size and type may be calculated using data provided by the valve manufacturer and then indexed for the patient's BSA. The anticipated orifice area estimate successfully identifies patients at risk for PPM prior to implantation and gives time to consider various PPM preventive methods. Given the availability of data from valve manufacturers and the ease with which PPM can be anticipated, especially in patients defined as being at risk of PPM, particularly severe, the regular prediction of iEOA is acceptable [24 - 30].

Female gender, younger age, high BSA, aortic root size, left ventricular end systolic diameter, diabetes, hypertension, renal failure, and use of bioprosthesis were all observed to enhance the risk of PPM [31]. Due to increased knowledge of PPM, wider adoption of preventative measures, and enhanced design and better hemodynamic performance of current generation prostheses, the occurrence of severe PPM has tended to decline over the past ten years. Alternative solutions should be taken into account for patients who are predicted to acquire PPM based on the patient's overall clinical condition [22].

In our study, we recorded a 40% overall PPM incidence in the present study. PPM was not observed in 106 Patients (EOAi>0.85 cm^2/m^2), while 71 patients had moderate PPM (EOAi ≤0.85 - 0.65 cm^2/m^2). None of patients had severe PPM. All valves with moderate PPM were single leaflet, and 71% of single leaflet mechanical valves had PPM. However, both groups had significant improvement in NYHA class post - operation. Kim et al. identified remarkable PPM in 27.6% of patients and 1.3% had severe PPM based on incidence of PPM [6]. Alassal et al. also noted that none of the patients had severe PPM, and that 25% of the patients had mild PPM [32]. Additionally, Zhang et al. showed that eight survivors had severe PPM (8.8%), while the bulk of PPM survivors (91.2%) had mild PPM [33].

Our study reported no difference in age between PPM and without PPM group. Similar to this, Tao et al [34] showed that age was not a factor in the PPM group and non - PPM group, but the majority of the PPM group consisted of females. PPM - positive patients had a much younger median age than PPM - negative patients, according to Zhang et al [33]. Kim et al [6] noted that PPM patients were of higher age, had more BSA, higher BMI, and higher blood pressure.

5. Conclusion

Patients who replace their aortic valve are at risk for PPM, which has been linked to a poor haemodynamic and symptomatic state. Mortality and cardiac problems are common among PPM patients. In this study, mild PPM, but not severe PPM, was often identified following AVR.

If PPM is predicted, other choices should be taken into account given the patient's general clinical state and the risk to benefit ratio. The estimated indexed EOA should be methodically computed during surgery to evaluate the risk of PPM. It should be emphasised that the frequency of patient prosthesis mismatch and in - hospital mortality and morbidity can be significantly reduced if the valve size needed to be implanted is determined based on the BSA of the patient and indexed EOA. In this AVR group, size did not appear to be a factor clinically. To determine the long - term prognosis in this patient population, more follow - up is required.

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Figure Legends:

Fig.1 Boxplot showing distribution of age ($p>0.05$) and body surface area (BSA) ($p<0.0001$), respectively, as per the aortic valve size implanted

Fig.2 Incidence of PPM in TTK Chitra valve (21 and 19mm) and St Jude Medical aortic valve (21 and 19mm) based on indexed EOA (EOAi)