Prosthesis-Patient Mismatches in Aortic Valve Replacement a Study in Ibn Al-Bitar Hospital for Cardiac Surgery

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ABSTRACT:

BACKGROUND:

Use of new generation small prostheses for aortic valve replacement has decreased the need for annular enlargement and rarely increased the incidence of severe patient-prosthesis mismatch;

OBJECTIVE:

Of this study is to evaluate the impact of using this type of prosthesis (St.Jude. HP, Regent) on operative mortality.

PATINETS & METHODS:

We reviewed our experience (59) consecutive patients who had isolated and combined aortic valve replacement in our hospital between February 2001 and February 2007.

RESULTS:

The mean age was 36, and 60 % of patients were female.valvular disease was primarily pure aortic regurgitation 47%, combined aortic disease 29% and pure aortic stenosis was present in 24%.

CONCLUSION:

Evaluation of the impact of newly designed small prosthesis on thirty-day mortality revealed: thirty-day mortality was 8% and the strongest independent predictors in multivariate analysis in decreasing order of statistical power were functional class IV, patient-prosthesis mismatch, advanced age (65 year), very small valve size (labeled valve size 17-mm), isolated aortic valve replacement surgery without other concomitant procedure (P=0.022) and obese patients (body mass index >33 kg/ m²).

***KEY WORDS*:** small aortic root; aortic annular enlargement prosthesis-patient mismatch; small prosthetic valve.

INTRODUCTION:

Controversy exists regarding the importance of patient size and prosthesis internal orifice size on both early and late mortality after AVR surgery, the term prosthesis-patient mismatch has been used to describe the use of a prosthesis of a given type that is too small for a patient of a given size, it was defined to occur when the effective prosthetic valve area, after insertion in to the patient, is less than that of a normal human valve. [1] Prosthesis- patient mismatch (PPM) may occur if the implanted prosthesis isequal or < 19 mm and the patient body surface area (BSA) is greater than 1.7 m².[2] Based on the correlation between the mean transvalvular pressure gradient and the corrected effective orifice area (EOA), PPM is currently defined as an indexed EOA (iEOA) corrected by a BSA of ≤0.85 cm²/m². When iEOA is >0.85, there is a relatively small (<10 mmHg) and acceptable residual transvalvular pressure gradient. Moderate PPM is defined as an iEOA >0.65 and ≤0.85, while severe PPM is defined as an iEOA ≤0.65. Moderate and severe PPM increase the short-term mortality rate (operative death) by 2.1-fold and 11.4-fold, respectively, compared with the rate in patients without PPM. [3].

Other studies concluded that severe PPM is rare after aortic valve replacement and PPM, abnormal gradient, and the size of the valve implanted do not influence left ventricular mass index or intermediate-term survival. [4] some other studies do not advocate the practice of using arbitrary cutoff values of effective orifice area (EOA)/BSA as a decision tool to determine the type or the manufacturer's labeled size of the valve to be utilized in a given patient in an attempt to decrease operative mortality. In terms of selecting the type of valve or technique of valve replacement, primary consideration should be given to factors such as durability, surgeon experience, technical ease, and speed of implantation and influencing the choice of a bioprosthetic over a mechanical valve and vice versa, once these factors have been considered it may be reasonable to give preference to valves with consistently higher projected in vivo EOA values, as there is insufficient data to

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validate the practice of using EOA/BSA ratio as a method for selecting the valve to be used in a given patient. [5]. Prosthesis size can be based on either geometric dimensions or functional performance of the prosthesis. Geometric expressions of prosthesis size include labeled size and internal orifice size. The adjusted geometric orifice area (GOA) is mentioned by manufacturers and may be a good parameter. However, studies found that the adjusted GOA showed a poor correlation with the postoperative pressure gradient and concluded that it should not be used for prediction of patient-prosthesis mismatch (PPM). [11]Whereas Functional expressions of prosthesis size include both in vitro and in vivo effective orifice area (EOA).And as PPM is currently defined as an indexed EOA (iEOA) corrected by a BSA of ≤0.85 cm²/m².subsequently they depend on the iEOA. As the EOA is a physiologic variable and represents the cross-sectional area occupied by transvalvular flow, while the GOA represents imply the geometric area of the valve orifice and ignores the influence of valve leaflets that always occupy part of the orifice. Table 1 demonstrate the EOA and iEOA of the routinely used mechanical valve used in our study.The aim of this study is to verify that whether this type of small prosthesis (new generation) affect the operative mortality following AVR and whether PPM is the cause of operative mortality.

1.1 *Clinical Implications:*

A Preventive Strategy .Contrary to other risk factors for short-term mortality, moderate-severe PPM can be largely prevented by implementing a simple three-step previously validated prospective strategy as follows. [11,19]:

(1)Calculate patient's body surface area from patient's weight and height;

(2)Multiply body surface area by 0.85 cm²/m², the result being the minimal EOA that the prosthesis to be implanted should have in order to avoid moderate-severe PPM; for instance, if patient's body surface area is 1.60 m², then 1.60×0.85=1.36 cm²=minimal EOA to avoid moderate-severe PPM;

(3)Verify if the reference EOA for the model and size of prosthesis selected by the surgeon is equal or greater than the result of step 2 (i.e., >1.36 cm² in the example chosen); if not, there is a risk of moderate-severe PPM and the surgeon should either attempt to implant another type of prosthesis with a larger EOA (e.g., stentless prosthesis, homograft, mechanical prosthesis) or alternatively, perform an aortic root enlargement to accommodate a larger valve of the same type.1.2 *Surgical options to avoid prosthesis-patient mismatch*

Options to avoid PPM include use of valves that have better flow characteristics in small sizes, such as supra-annular mechanical valves, stentless bioprosthesis, or homograft. A larger size stented bioprosthesis or mechanical valve can be placed using procedures to enlarge the aortic annulus. Techniques for dealing with small aortic annulus include annular enlargement, either from anterior or posterior approach. [2, 6]

1) Posterior enlargement Using the technique of Nicks-Nunez posterior enlargement of small annulus, the aortotomy may be extended through the mid-noncoronary sinus down onto the anterior leaflet of the mitral valve, Another posterior enlargement technique was introduced by Manougian with aortotomy extended into the commissure between the left and noncoronary cusp and carried down into the mitral valve apparatus.

2) Anterior enlargement The Kono-Rastan procedure, involves a more complex reconstruction of the aortic outflow tract, the ventricular septum, and the right ventricular outflow tract. It's particularly useful in children with hypoplastic aortic roots or. [5]1.3 *Operative Mortality* The in hospital or 30-day mortality for isolated AVR is 2-5% and mortality increased to 6-15% by a prior median sternotomy and to 6% when CABG is added to AVR and increased to 10% by the addition of mitral valve replacement. Major risk factors for increased operative mortality are age, body surface area, diabetes, renal failure, hypertension, chronic lung disease, peripheral vascular disease, stroke, infectious endocarditis, prior cardiac operation, myocardial infarction, cardiogenic shock, NYHA functional status, and pulmonary hypertension.[2].

PATIENTS AND METHODS:

2.*1 Patient population:*Selection of patients were done with AVR using the newer designs small mechanical valves which are introduced in our hospital in 2001 for St.Jude Medical hemodynamic plus(HP) and in 2004 for St.Jude Regent. Total patients were 59, isolated and combined AVR . The data were obtained retrospectively between February 2001 till February 2007, from patients records, the preoperative and intraoperative characteristics of those patients are given in Table 2.The definition of mortality was updated in 1996 and the guidelines distinguish two type of mortality: hospital mortality and 30-day mortality. Hospital mortality refers to death occurring at any time before discharge during a patient's initial hospital stay. Thirty-day mortality, also referred to as operative mortality, is death that occurs at any time or place within 30 days of operation. [9]

2.2 Patient and prosthesis sizeAssessment of the effect of aortic prosthesis size on the outcome should take into account the patient size. In our study patient size has been quantified on the basis of height, weight and body surface area (BSA). BSA was estimated for each

patient using the Dubois and Dubois formula [10]: BSA (m2) = 0.007184 × height (cm) 0.725 ×Weight (kg) 0.425.2.3 Echocardiography Preoperative echocardiography was performed for all patients to determine valve pathology, chamber dimension, pressure gradient, aortic ring and LV function.Postoperative echocardiography was also done for all patients to assess valve function.

2.4 Surgical technique Standard cardiopulmonary bypass was used with moderate hypothermia (26-32c°), and myocardial protection achieved. After debriding the aortic annulus, prosthesis size and model were used to according the surgeon's discretion. During operative era (2001-2007) only mechanical prosthetic valves were used to replace the diseases aortic valve. Valve implantation was performed using horizontal mattress sutures reinforced with Teflon pledges in intra-annular position; extremely small aortic root were managed by anterior or posterior enlargement of aortic root. In the era (2004-2007) the routine implantation of very small mechanical valves in aortic position was undertaken in a supra-annular position.2.5 Postoperative outcome

The postoperative outcome was obtained retrospectively from patient's records and charts, operative mortality was defined and the incidences with the cause of death were recorded in table3. 2.6 Statistical analysis The analysis included the subpopulation of patients who underwent aortic valve replacement using the newly designed small mechanical valve (manufacturer's labeled size 17 and 19) with a total of 59 patients, who submitted to computerized statistical analysis. Variables in form of words were translated into numerical codes. Statistics were performed using the "SPSS and Statistica"statistical programs and is tested by the chi-square test. [12, 13]

RESULTS:

3.1 Distributions of patients During this period (59) patients underwent AVR, isolated (23) and combined (36). in our institution, concomitant surgical procedure were mitral valve replacement(MVR) 28 patients, AVR combined with MVR and tricuspid repair (4),AVR with CABG (1) AVR with anterior enlargement (1), AVR with posterior enlargement (2).the preoperative and operative patients characteristic were illustrated in table 2.The mean age was 36 years (range: 9-65 years). Female (35)(58%), male (24)(42%) The body surface area (BSA) was ranged between (0.9-2).in our study, the IEOA range (0.58-1.49) with mean value 0.96 cm^2/m^2.Among those 59 patients, 68% had no patient-prosthesis mismatch (PPM), 30% had moderate PPM, and 2 % had severe PPM,Fig.1, 2 .AVR with history of prior cardiac surgery were done for (2) patients; and history of endocarditis were also present in (2) patients. Patient's NYHA functional class were 45.7% in III,15.3% classIV,32.2% and 6.8% for class II and I respectively. Left ventricular (LV) function was assessed by ejection fraction (EF), the results were (56.7%) and EF> 60 %,(25.4%) had EF 50-60% and (17%) had EF<50%.; mean LV. end-diastolic dimension (EDD) 54 mm, mean LV .end-systolic dimension(ESD) 34 mm. Aortic valve pathology were AR: 28.8%; AS: 23.7%; combined AS/AR: 47.5%.Cardiac catheterization were done in 43 (73%) patients, of them 1 patient (1.6%) had significant coronary artery disease which was treated by CABG.The models of mechanical valves used during this period were St.Jude Medical -HP in 16 (27%) patients, St.Jude Regent in 43 (73%) patients. Regarding Valve sizes, 20(34%) patients had labeled size 17 and 39(66%) patients had labeled size 19. Aortic ring range (14-27) mm.

Table 1 : SJM Regent & SJM HP Effective orifice Area Index Calculator (EOAI)

VALVE SIZE (mm)	17	19	
Reference EOA (cm²)	1.14 ([14])	1.7 ([15])	1.51 ([15])
BSA	SJM Regent	SJM Regent	SJM HP
0.6	1.9	2.83	2.51
0.7	1.62	2.43	2.15
0.8	1.42	2.13	1.88
0.9	1.26	1.89	1.67
1.00	1.14	1.70	1.51
1.1	1.03	1.55	1.37
1.2	0.95	1.42	1.25
1.3	0.87	1.31	1.16
1.4	0.81†	1.21	1.07
1.5	0.76†	1.13	1.00
1.6	0.71†	1.06	0.94
1.7	0.67†	1.00	0.88
1.8	0.63‡	0.94	0.83†
1.9	0.60‡	0.89	0.79†
2.00	0.57‡	0.85†	0.75†
2.1	0.54‡	0.81†	0.71†
2.2	0.51‡	0.77†	0.68†
2.3	0.49‡	0.74†	0.65‡
2.4	0.47‡	0.71†	0.62‡
2.5	0.45‡	0.68†	0.60‡

BSA: body surface area; SJM HP: St.Jude Medical hemody- namic plus
PPM: prosthesis- patient mismatch
EOAI > 0.85 cm²/m² -NO PPM
† 0.65 cm²/m² (EOAI ≤ 0.85 cm²/m² -Moderate PPM
‡ EOAI ≤ 0.65 cm²/m²-Severe PPM

Valve model		
St.Jude Regent	43	73
St.Jude HP	16	27
Valve size (mm)		
(17)	20	34
(19)	39	66
Aortic ring Range	14-27	
Cardiac catheterization	43	73
Mean perfusion time	127	
aortic cross clamp time	96	
Mortality (total	5	8
Cause		
Low cardiac output	4	6.8
Sudden death	1	1.6

Table 2:Selected preoperative, operative and postoperative characteristics in patients with manufacturer's labeled valve size 17 and 19- mm.

Variable	Number	%
Age/year range	9-65	
mean	36	
Sex		
Male	25	42.37
Female	34	57.63
B.S.A(m^2) Range	0.9-2	
Indexed effective orifice area cm^2/m^2 Range	0.58-1.49	
Mean	0.96	
Preoperative associated condition	5	8.4
NYHA functional class		
I ,II	4, 19	6.8, 32.2
III ,IV	27, 9	45.7, 15.3
Ejection fraction		
> 60% ,50-60%	34,15	57.6,25.4
50%<	10	17
Mean LVEDD and LVSDD	54,34	
Valve lesion by ECHO		
AR, AS	17, 14	42.4, 25.4
Combined AS/AR	28	47.5
Isolated AVR	23	42.4
AVR+MVR	28	49.2
AVR+MVR+TV.REPAIR	4	6.8
AVR+CABG	1	1.6
AVR+posterior or anterior enlargement	3	4.8

Independent variable	P-level	Statistical significance
NYHA functional class	.0001	Highly significant
PPM	.004	Highly significant
Age	.009	Highly significant
Operative procedure	.015	Highly significant
Valve size	.030	Highly significant
Weight	.043	Highly significant
IEOA	.065	Marginally significant
Aortic valve lesion	.097	Marginally significant
BSA	.099	Marginally significant

3.2 Mortality

Thirty-day mortality, hospital mortality, and the cause of death were illustrated in table 2:(continued).Of those 59 patients; thirty-day and hospital mortality were 5 (8%).The cause of death in 4 (6.8%) patients were low cardiac output and 1 patient died suddenly, 2 of the four patients were in 65years of age and three of them had NYHA functional class IV; the other 2 had NYHA functional class III.

3.4 Determinants of thirty-day mortality

All patients (59) who underwent AVR, using the manufacturer's labeled valve size 17 and 19-mm, with 21 variables for each patient were submitted to statistical analysis(table 3) for thirty-day mortality and the following significant variables were obtained:

PPM (P=0.004), patients having functional class IV (P=0.001), advanced age (65 year) underwent surgery (P=0.009), selection of very small valve size (labeled valve size 17mm) (P=0.03), patients underwent lone AVR surgery without other concomitant procedure (P=0.022) and obese patients (weighing 91 kg, body mass index >33 kg/ m^2) (P=0.043). All these six variables predicted a greater likelihood of thirty-day mortality, with strong statistical power as (P< 0.05), while those patients who have had IEOA range (0.58-0.70) cm^2/m^2 (P=0.065), aortic stenosis valve lesion (P=0.097), and body surface area range (1.65-1.96 m^2), (P=0.099) were possibly significant predictor of thirty-day mortality (0.05<P<0.2).

All the remaining variables had no effect on thirty-day mortality with (P>0.2).

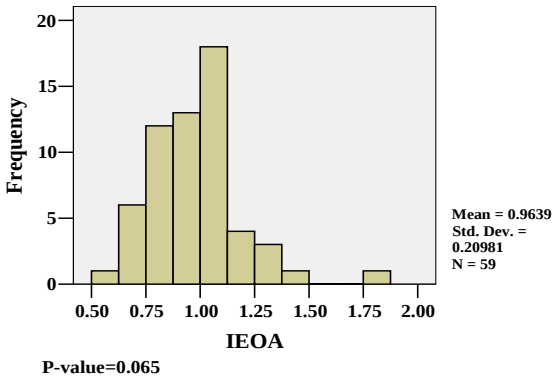
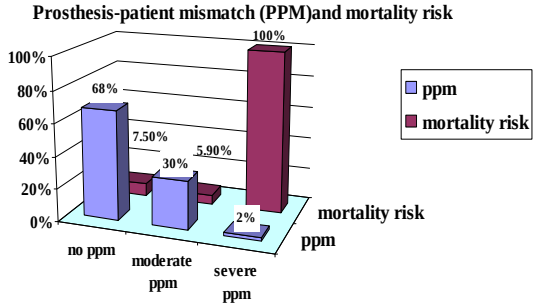


Fig.1: Distribution of Indexed effective orifice area (IEOA) in patients with high performance small prosthetic valve, (valve size 17 and 19- mm)

Table 3:Total list of 21 variables with the result of statistical analysis for the dependent variable (thirty-day mortality) in patients with manufacturer's labeled valve size 17 and 19- m(n=59)



P-value: 0.004

Fig.2: Relative risk ratio for operative mortality according to PPM in patients with high performance small prosthetic valve, (manufacturer's labeled valve size 17 and 19-mm)

DISCUSSION:

In our center, valve surgery was performed following the updated standards and guidelines adopted elsewhere in the world.

Our limitation was in the choice of prosthesis, as we were obliged to do all aortic valve replacement surgery using only prosthetic mechanical valves; bioprosthesis was not used because of the technical difficulties in valve preservation, in comparison with that at Cleveland Clinic foundation by Dr. Gosta Pettersson,[16] the choice of mechanical valve for patients less than 60 years was: mechanical in (77%) of patients, bioprosthetic valves (13%),homograft valves (5%),and Ross procedures in (5%).In this study, the predominant gender was male (78%), female constitute (22%), which is similar to study of Dr. John S. Ikonomidis, at the Medical University of South Carolina,[17] where male gender was (70%) and female (30%); the mean age in our was in the 4th decade, unlike the study by Dr. John , [17]where the mean age was in the 6th decade.In our study, the frequency of aortic valve pathology were pure Aortic regurgitation (46%), pure Aortic stenosis (14%) and combined stenosis and regurgitation (40%); in contrast to the study by Dr. Matsumura T. in Japan,[18]where they had pure aortic regurgitation in(44%),pure aortic stenosis in (36%), and combined stenosis and regurgitation (20%). As in the study by Dr. John,[17] where advanced functional class constituting the majority of patients(77%), the incidence of patients with functional class III and IV in our study was even higher (81%). In our study, although we had used new high performance

prostheses, we found that, in patients who underwent isolated AVR with very small size prostheses (17-mm) would be at high risk for thirty-day mortality(P=0.03);compared with a similar study by Dr. Charles R. Bridges, in Philadelphia.[5] In his study he concluded that Prostheses with small effective orifice area are associated with increased operative mortality after isolated AVR, which parallel our results, Dr. Bridges. also concluded that for valves with small effective orifice area, mortality decreases as body surface area increases, which was unlike our results, where we found obese patients(body mass index > 33kg/ m²) (P=0.043) and patients with relatively large body surface area (1.65-1.96 m²) (P=0.099) as possible predictors of thirty-day mortality.

In our study, we found patients who have had indexed effective orifice area(IEOA) range(0.58-0.70) cm²/m² (P=0.065) might be at risk for thirty-day mortality, in contrast to Dr. Bridges study,[5]where he found that given EOA as covariates, IEOA are not significant predictors of operative mortality in multivariable models.According to the study of Dr.Rafael,[18]elderly patients with aortic stenosis pathology were typically at high risk for thirty-day mortality, in our study, we found patients with aortic stenosis pathology(P=0.097) might be more at high risk than other aortic valve pathologies.

In our study, operative mortality was not increased as a result of the aortic root enlargement. Nonetheless, in considering the different options, it is important to evaluate the potential benefits of avoiding moderate-severe PPM in comparison to the drawbacks of using alternative techniques.

4.2 Limitation of the Study

A retrospective, non-randomized single-center analysis over a long period and with a variety of prostheses is subjected to the effects of selection bias. Despite the fact every patient in this study have had a postoperative evaluation of the implanted mechanical prostheses by echocardiogram, reliable measurement of transvalvular residual gradient was available in a limited number of patients, however taking in to account the study by Dr. Giovanni Minardi in Italy,[17] where he examined the new high-performance small(17-mm) prostheses and concluded that these prostheses can be safely implanted in aortic position in relatively aged patients, offering a satisfactory hemodynamic performance at rest and under Dobutamine stress echocardiography, as a result only few younger population remained to be studied with regard to postoperative residual gradient, which we hope to be addressed in future studies.

CONCLUSION AND RECOMMENDATIONS:

1. Since the introduction of the new high-performance mechanical valves in our center, the number of patients with small aortic annuli having isolated or combined AVR has dramatically increased and the need for aortic root enlargement has decreased.
2. Evaluation of patients with isolated and combined AVR using the new high-performance prostheses were done with respect to thirty-day mortality, and our conclusion was: despite the fact that we had used these new prostheses, we found that severe PPM is a strong and independent predictor of thirty-day mortality and that its impact is dependent both on its degree of severity and the status of NYHA functional class. Moreover, moderate-severe PPM can be largely avoided by adopting a simple prospective strategy in every patient undergoing AVR.
3. Obese patients (body mass index > 33kg/ m²) and patients with relatively large body surface area (1.65-1.96 m²) are at high risk for thirty-day mortality, despite the usage of the high-performance prosthesis, we believe that in these few situations adoption of an alternative strategies, such as performing aortic root enlargement to accommodate larger prostheses might be more attractive and logic option to avoid the effects of PPM.
4. Patients who have had indexed effective orifice area (IEOA) range (0.58-0.70) cm²/m² are probably at risk for thirty-day mortality, an additional support for the PPM theory.
5. In our study, advanced age patients (65 years) were at high risk for thirty-day mortality, likewise patients with aortic stenosis were possible predictor of thirty-day mortality. For those elderly patients with small aortic annulus, we think that bioprosthesis may be the best option especially the latest generation(Carpentier-Edwards Perimount Magna),[20] which have been designed for a totally supra-annular seating, which allows a precise alignment of the valve orifice to the patient's tissue annulus.

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