Patient-prosthesis mismatch in the mitral position affects midterm survival and functional status

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BACKGROUND: The definition and incidence of patient-prosthesis mismatch (PPM) in the mitral position are unclear.

OBJECTIVES: To determine the impact of PPM on late survival and functional status after mitral valve replacement with a mechanical valve.

METHODS: Between 1992 and 2005, 714 patients (mean [± SD] age 60±10 years) underwent valve replacement with either St Jude (St Jude Medical Inc, USA) (n=295) or Carbomedics (Sulzer Carbomedics Inc, USA) (n=419) valves. There were 52 concomitant procedures (50 tricuspid annuloplasties, 25 foramen oval closures and 20 radiofrequency mazes). The mean clinical follow-up period was 4.4±3.3 years. The severity of PPM was established with cut-off values for an indexed effective orifice area (EOAi) of lower than 1.2 cm²/m², lower than 1.3 cm²/m² and lower than 1.4 cm²/m². Parametric and nonparametric tests were used to determine predictors of outcome.

RESULTS: The prevalence of PPM was 3.7%, 10.1% and 23.5% when considering values of lower than 1.2 cm²/m², lower than 1.3 cm²/m² and lower than 1.4 cm²/m², respectively. When considering functional improvement, patients with an EOAI of 1.4 cm²/m² or greater had a better outcome than those with an EOAI of lower than 1.4 cm²/m² (OR 1.98; P=0.03). When building a Cox-proportional hazard model, PPM with an EOAI of less than 1.3 cm²/m² was an independent predictive factor for midterm survival (HR 2.24, P=0.007). Other factors affecting survival were age (HR 1.039), preoperative New York Heart Association class (HR 1.96) and body surface area (HR 0.31).

CONCLUSIONS: In a large cohort of patients undergoing mitral valve replacement with mechanical prostheses, PPM defined as an EOAI of lower than 1.3 cm²/m² significantly decreased midterm survival. This level of PPM was observed in 10.2% of patients. Patients with an EOAI of 1.4 cm²/m² or greater had greater improvement of their functional status.

Key Words: Mitral valve; Prosthesis; Surgery; Valvuloplasty

La disproportion patient-prothèse en position mitrale nuit à la survie à moyen terme et au statut fonctionnel

HISTORIQUE : La définition et l'incidence de disproportion patient-prothèse (DPP) en position mitrale ne sont pas claires.

OBJECTIFS : Déterminer les conséquences d'une DPP sur la survie à long terme et le statut fonctionnel après un remplacement de la valvule mitrale au moyen d'une valve mécanique.

MÉTHODOLOGIE : De 1992 à 2005, 714 patients (âge moyen [±ÉT] de 60±10 ans) ont subi un remplacement valvulaire au moyen d'une valve St Jude (St Jude Medical Inc., États-Unis) (n=295) ou Carbomedics (Sulzer Carbomedics Inc., États-Unis) (n=419). Cinquante-deux interventions concomitantes avaient été effectuées (50 annuloplasties tricuspides, 25 fermetures du foramen ovale et 20 interventions du labyrinthe par radiofréquence). La période de suivi clinique moyenne était de 4,4±3,3 ans. La gravité de la DPP a été évaluée selon les valeurs seuils de la surface de l'orifice efficace de référence (SOEr) inférieure à 1,2 cm²/m², à 1,3 cm²/m² et à 1,4 cm²/m². Des tests paramétriques et non paramétriques ont permis de déterminer les prédicteurs d'issue.

RÉSULTATS : La prévalence de DPP était de 3,7 %, 10,1 % et 23,5 % lorsqu'on tenait compte de valeurs inférieures à 1,2 cm²/m², à 1,3 cm²/m² et à 1,4 cm²/m², respectivement. Lorsqu'on tient compte de l'amélioration fonctionnelle, les patients dont la SOEr était de 1,4 cm²/m² avaient une meilleure issue que ceux dont la SOEr était inférieure à 1,4 cm²/m² (RR 1,98; P=0,03). Selon un modèle de hasards proportionnels de Cox, une DPP dont la SOEr était inférieure à 1,3 cm²/m² était un facteur prédicteur indépendant de survie à moyen terme (RRR 2,24, P=0,007). Les autres facteurs influant sur la survie étaient l'âge (RRR 1,039), la catégorie préopératoire de la *New York Heart Association* (RRR 1,96) et la surface corporelle (RRR 0,31).

CONCLUSIONS : Dans une vaste cohorte de patients subissant un remplacement de la valvule mitrale par des prothèses mécaniques, la DPP définie comme une SOEr inférieure à 1,3 cm²/m² réduisait considérablement la survie à moyen terme. Ce taux de DPP s'observait chez 10,2 % des patients. Les patients dont la SOEr était de 1,4 cm²/m² ou plus profitaient d'une meilleure amélioration de leur état fonctionnel.

Patient-prosthesis mismatch (PPM) in the aortic position has been studied for a decade and is a widely accepted concept, although its exact influence on long-term outcome remains controversial (1). Despite the fact that the cardiac output is the same through the aortic and the mitral valve, the adequacy between a patient's surface area and the valve's area has been less studied in the mitral position. The consequence of Poiseuille's law related to the given cardiac output that flows through a restrictive mitral valve is more obscure in the mitral position. Thus, the clinical impacts might be more difficult to identify and the threshold ratio between the effective orifice area (EOA) of the valve and the body surface area (BSA) defined as the indexed EOA (EOAI)

remains to be defined. A strong correlation was identified between the persistence of residual pulmonary hypertension after mitral valve replacement and an EOAI of lower than 1.2 cm²/m² (2). The same threshold was associated with recurrent heart failure and worse long-term survival (3,4). Some studies on this subject have included bioprosthetic valves that are subject to deterioration, especially in the mitral position, with a theoretical orifice area that could be overestimated compared with the actual one, especially a few years after implantation. The main objective of the present study was to evaluate the incidence of mitral PPM in a large population of patients with mechanical mitral valve replacement and its effect on long-term outcome.

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TABLE 1
Patient characteristics

	Complete cohort (n=714)	No mismatch (n=546)	EOAi	
			1.3 cm ² /m ² to 1.4 cm ² /m ² (n=94)	<1.3 cm ² /m ² (n=74)
Age, years	59.5±10.2	60.4±9.8	57.3±10.4	56.5±14.0
Sex (female), %	70.2	74.7	51.7	63.0
Bypass time, min	100.9±41.9	98.6±39.7	101.5±35.4	144.0±79.1
Cross-clamp time, min	73.5±29.2	71.4±27.7	76.4±28.3	101.3±44.6
Preoperative NYHA class, %				
I	0.9	0.7	2.1	0
II	15.9	16.5	17.0	14.8
III	74.3	73.1	70.2	77.8
IV	8.9	9.6	8.5	7.4
Associated procedures, %				
Tricuspid annuloplasty	16.6	17.2	9.2	2.12
Biological tricuspid valve replacement	1.7	1.7	1.4	4.3
ASD closure	8.5	8.6	9.2	8.2
Arrhythmia surgery	3.0	3.4	2.8	0
Chronic AF	42.7	44.4	38.3	46.4
Etiology, %				
Rheumatic	46.4	47.6	48.2	33.3
Degenerative	53.6	52.4	51.8	76.7
Pulmonary pressure (systolic)	51.7±16.9	52.1±17.4	49.9±14.2	59.8±15.0
LV dysfunction (ejection fraction <50%), %	20.9	23.9	10	12

Data presented as mean ± SD unless otherwise indicated. AF Atrial fibrillation; ASD Atrial septal defect; EOAi Indexed effective orifice area; LV Left ventricular; NYHA New York Heart Association

METHODS

All the patients undergoing mechanical mitral valve replacement between 1992 and 2005 were identified in the cardiac surgery institutional database of the Montreal Heart Institute in Montreal, Quebec. Patients with concomitant procedures other than tricuspid annuloplasty or replacement, patent foramen ovale closure or arrhythmia surgery were excluded. A total of 756 patients were identified. Proper follow-up data could not be obtained for 42 patients (5.6%). The remaining 714 patients are the subjects of the present report. Of these, 419 patients received a mitral mechanical prosthesis from Sulzer Carbomedics Inc (USA) and 295 patients received a St Jude Medical Standard prosthesis (St Jude Medical Inc, USA). Follow-up survival information and New York Heart Association (NYHA) functional status were obtained by reviewing the database of the Heart Valve Clinic at the Montreal Heart Institute. All patients undergoing an operation at the Montreal Heart Institute are followed annually by either coming for a clinical visit or by filling out, with their attending physician, a written report form. The mean (± SD) follow-up period for these patients is 1871±1178 days. Values of EOA were collected from the literature (5-7). To have values coming from a large enough sampling of patients from the two valve companies, the values used have been obtained by the continuity equation method from normally functioning valves. These EOA values correlate with EOAs obtained clinically, for each valve size and company, in the institution.

Statistics

Results are expressed as mean ± SD or percentages unless otherwise indicated. Continuous variables were analyzed by an unpaired Student's *t* test and categorical variables by the χ^2 test. Multivariate

TABLE 2
Valve types

Valve size, mm	Patients in study, n	Geometric orifice area, cm ²	Internal diameter, cm	EOA/number of patients used to establish EOA, cm ² /n
Carbomedics (Sulzer Carbomedics Inc, USA)				
23	2	2.56	18.5	1.63/29
25	32	3.16	20.5	1.98/30
27	154	3.84	22.5	2.41/13
29	157	4.44	24.2	2.63/4
31	58	4.44	24.2	2.63/4
33	16	4.44	24.2	2.63/4
St Jude (St Jude Medical Inc, USA)				
25	21	3.09	20.4	1.8/14
27	128	3.67	22.3	2.43/6
29	95	4.41	24.1	2.66/5
31	31	5.18	26	3.08/3
33	20	5.18	26	3.08/3

EOA Effective orifice area

Figure 1) Distribution of indexed effective orifice area (EOAi)

analyses of hospital mortality and functional class improvement were performed using backward, stepwise logistic regression. Survival analysis was performed using the Cox methodology. Variables with a value of *P* < 0.25 on univariate analysis were incorporated into the model in a stepwise manner. *P* values of less than 0.05 were considered to be statistically significant. Statistical analysis was performed using SPSS statistical software (SPSS Inc, USA) and SAS 9.1.3 (SAS Institute Inc, USA).

RESULTS

Patient characteristics

Patient preoperative and intraoperative characteristics are presented in Table 1. The most often associated procedure was tricuspid annuloplasty (16.6%). The distribution of implanted valves is summarized in Table 2 and the EOAi distribution is illustrated in Figure 1. Percentile 10 of the distribution of the EOAi was 1.29 cm²/m², percentile 20 was 1.38 cm²/m² and percentile 30 was 1.43 cm²/m². Twenty-seven patients (3.7%) had an EOAi of lower than 1.2 cm²/m², 74 patients (10.2%) had an EOAi of lower than 1.3 cm²/m² and 168 (23.5%) had an EOAi of lower than 1.4 cm²/m². A total of 419 patients had a Carbomedics valve implanted and the mean EOAi in this group was 1.49±0.187 cm²/m². In the 295 patients with a St Jude valve, the mean EOAi was 1.7±0.244 cm²/m². This difference in mean EOAi

Figure 2) Mismatch frequency related to valve size. EOAi Indexed effective orifice area; PPM Patient-prosthesis mismatch

Figure 3) Actuarial survival stratified by an indexed effective orifice area (EOAi) of 1.3 cm²/m² or greater, or lower than 1.3 cm²/m²

between the two groups was significant ($P < 0.0001$). In the group with Carbomedics mitral valves, 23 patients (5.4%) had an EOAi of lower than 1.2 cm²/m². In the St Jude group, four patients (1.3%) were below this value; this difference was statistically significant ($P < 0.004$). The number of patients with an EOAi of lower than 1.3 cm²/m² according to the valve size is detailed in Figure 2, as well as for patients with an EOAi of lower than 1.4 cm²/m².

Survival

The perioperative mortality of all patients who underwent mitral valve repair (MVR) was 4.6% (33/714) and there was no statistical difference compared with perioperative mortality of patients with an EOAi of lower than 1.2 cm²/m² (three of 27, 11.1%; $P = 0.28$), lower than 1.3 cm²/m² (four of 73, 5.4%; $P = 0.9$) or lower than 1.4 cm²/m² (eight of 168, 4.8%; $P = 0.9$). Survival at one, five and 10 years after MVR for patients with an EOAi of lower than 1.3 cm²/m² was $88.5 \pm 4.7\%$, $75.2 \pm 6.2\%$ and $53.9 \pm 16.3\%$, respectively. In contrast, patients with a higher EOAi had significantly greater long-term survival at one, five and 10 years ($92.5 \pm 1.1\%$, $83.6 \pm 1.7\%$ and $67.4 \pm 4.2\%$, respectively) (Figure 3) compared with survival of patients with PPM, even when adjusted for age and sex, pulmonary artery pressure, valve etiology, presence of tricuspid regurgitation, valve type, BSA, preoperative NYHA class, left ventricular ejection fraction and preoperative

Figure 4) Improvement of functional status in patients with an indexed effective orifice area (EOAi) of lower than 1.4 cm²/m²

atrial fibrillation (HR 2.24; 95% CI 1.23 to 4.04; $P = 0.007$). Other factors affecting survival were age (HR 1.039), preoperative New York Heart Association class (HR 1.96) and body surface area (HR 0.31).

Functional outcome

Functional evolution after MVR was better in patients who benefitted from a mitral valve size conferring an EOAi of 1.4 cm²/m² or greater compared with patients with an EOAi of lower than 1.4 cm²/m² (OR 1.98; $P = 0.03$). In the patient group with an EOAi of 1.4 cm²/m² or greater, 89% (364/411) of the patients had their NYHA functional class improved by one class (164/411; 40%), two classes (181/411; 44%) or three classes (18/411; 4%). These figures were significantly better than the figures for patients with an EOAi of lower than 1.4 cm²/m², where 81% (110/135) had their NYHA functional class lowered by one class (57/135; 42%), two classes (48/135; 36%) or three classes (five of 135; 4%) (Figure 4). In a multivariable logistic regression model, including an EOAi of 1.4 cm²/m² or greater, age, sex, pulmonary artery pressure, valve etiology, presence of tricuspid regurgitation, valve type, BSA, left ventricular ejection fraction and preoperative atrial fibrillation, only an EOAi of greater than 1.4 cm²/m² was predictive of improvement in NYHA class (OR 1.75, 95% CI 1.03 to 2.97; $P = 0.038$).

DISCUSSION

Since its first description in 1978 by Rahimtoola (8), and a description in 1981 by Rahimtoola and Murphy (9), PPM has been extensively described, but mostly in the aortic position. Although some studies clearly show a negative impact on survival (10,11), some authors are still questioning the reality of PPM in the aortic position (12,13). Because the cardiac output is the same through the aortic and the mitral valves, PPM is theoretically possible but the mitral annulus is larger than the aortic annulus and usually admits a larger prosthesis. Because conventional hydrodynamic flow resistance is a function of the fourth power of the radius, prosthesis size rapidly decreases it and the larger mitral prostheses have been neglected as possible obstacles to blood flow. However, extreme PPM may occur with the same effect as in the aortic position: increase in upstream pressure. This increase in pressure may hinder the output out of the pulmonary vascular bed and have an effect on the functional status of the patient, and even on survival, after MVR (14-16).

The purpose of the present study was to determine whether PPM in the mitral position was relevant. For this purpose, only patients with a mechanical prosthesis were studied because they are less prone to idiosyncratic calcification and unpredictable changes in EOA over time than those receiving a bioprosthesis. In this cohort of patients who underwent mechanical MVR with only minor associated procedures, we observed that patients with an EOAI of lower than $1.3 \text{ cm}^2/\text{m}^2$ had a decreased long-term survival and that patients with an EOAI of lower than $1.4 \text{ cm}^2/\text{m}^2$ had a worse functional outcome.

In the aortic position, PPM is defined using the ratio of EOA to BSA because it best represents the geometric properties of a prosthetic valve. An absolute threshold value between the presence of mismatch and no mismatch probably does not exist, but an inflection point in the curve relating the EOA/BSA ratio to mismatch is chosen to help the decision-making process in valve implantation. In the aortic position, an EOA/BSA ratio of lower than $0.85 \text{ cm}^2/\text{m}^2$ has been associated with worse outcome (17). In the mitral position, only a few studies have been conducted. Lam et al (3) reported a negative impact on survival when the EOA/BSA ratio was lower than $1.22 \text{ cm}^2/\text{m}^2$. In the present study, we used three thresholds ($1.2 \text{ cm}^2/\text{m}^2$, $1.3 \text{ cm}^2/\text{m}^2$ and $1.4 \text{ cm}^2/\text{m}^2$) and found the same negative impact on long-term survival at the $1.3 \text{ cm}^2/\text{m}^2$ threshold, with 10.1% of the patients presenting such a mismatch. This compares well with the report by Lam et al of 13.8% of the patients with a ratio lower than $1.22 \text{ cm}^2/\text{m}^2$. The small difference could be related to the choice of EOA values for different prostheses, which are still subject to debate.

Enlargement of the mitral annulus is technically difficult, but techniques such as removal of the leaflets with GORE-TEX neochordae (WL Gore & Associates Inc, USA) formation, oversizing of the prosthesis, aggressive debridement of annular calcification, and choosing a prosthesis with the best EOAI are feasible. It is, therefore, important to consider the existence of PPM in the mitral position and its potential negative influence on long-term survival. The inclusion of patients with bioprostheses in the study by Lam et al might also explain the difference in the required incidence of PPM.

Contrary to Li et al (2), we did not find a significant correlation between postoperative systolic pulmonary pressure and EOAI. However, the data on pulmonary pressure were only available in 60% of the cohort. Preoperative pulmonary pressure, the presence of tricuspid regurgitation and the need for tricuspid repair were not associated with increased long-term mortality.

Recently, Magne et al (4) reported a significant effect of PPM in the mitral position on long-term survival. Using the definition of moderate PPM as an EOAI of lower than $1.2 \text{ cm}^2/\text{m}^2$ and severe PPM as an EOAI of lower than $0.9 \text{ cm}^2/\text{m}^2$, they showed that patients with severe PPM had a worse long-term survival on multivariate analysis (HR 2.3, $P=0.02$). Moderate PPM did not reach statistical significance, but there was a negative graphical trend. In their study, patients with a bioprosthesis (15.1%) were also included as were the 30% of patients with a concomitant coronary artery bypass graft. Although the sizes of the prosthesis implanted in the present study and in the study by Magne et al were quite similar (size varied from 23 mm to 33 mm in both studies; 53.1% of patients in the study by Magne et al and 47.1% in the present study had a size of 27 mm or less), 78% of the patients in the study by Magne et al were having some degree of PPM. This large proportion is most likely related to the different reference values chosen for the EOA. We used values given in the literature, which correlate to our own institutional *in vivo* values. Using those values, to have an impact on survival in our study, the EOAI had to be inferior to $1.3 \text{ cm}^2/\text{m}^2$. This corresponded to 10.2% of our patients. At the present time, no clear reference values have been firmly established for each valve size and brand; thus, there is a need for further studies. We believe that if PPM in the mitral position truly exists, only a minority of patients suffer from it rather than more than one-half of patients, as stated by Magne et al.

A persistent elevated pulmonary artery pressure in a PPM patient may not always negatively affect mortality, but it could still affect functional status of the patients (18) – a situation that could be encountered with lower degrees of PPM. For this reason, $1.4 \text{ cm}^2/\text{m}^2$ was chosen as the cut-off value to study functional outcome.

Significantly less functional improvement was observed in patients in the mismatch group (81%) compared with the nonmismatch group (89%) ($P=0.038$). This observation has not, to the best of our knowledge, been previously reported.

In practice, the EOA can only be determined once the prosthesis has been inserted, after contractility, preload and afterload are normalized following weaning from cardiopulmonary bypass. The degree of PPM is only reliable on an individual basis at long-term follow-up after surgery (19,20). The purpose of establishing and defining values for PPM in the mitral or aortic position is to help the surgeon in the decision-making process at the time of valve implantation and to help determine the necessity of the time-consuming process of annulus enlargement or decalcification. For this, the surgeon must dispose of reliable predictive values. The EOA values we chose were derived from normal functioning valves, but those values are not uniform in the literature and are not readily obtainable from the manufacturers. In this study, EOAs of normally functioning valves from different sources were used. With those values, an impact on survival and functional improvement was observed, confirming that PPM in the mitral position truly exists and warrants further research, especially in the reporting of the EOA values of normal functioning valves.

Limitations

The present study was retrospective in design and, hence, selection bias or unidentified confounders may have influenced the results.

For multiple reasons, two different mechanical valve prostheses are inserted in the mitral position at the Montreal Heart Institute and selection is left to the surgeon's discretion. In the present study, the two valve types were included because the purpose of the study was to examine the population of patients with mechanical valve replacement. Some differences between the two valve types were observed; however, caution must be exerted because the valve specifications were those given by different groups of investigators (5-7) and the comparison of the two valve types was beyond the scope of the present study. We designed the study retrospectively to maximize the number of patients in the study as well as to have a long follow-up time, allowing observation of the effect of mitral PPM on long-term follow-up. Unfortunately, this design did not allow the use of EOA values coming from the individual patients of our cohort.

DISCLOSURE: The authors had full access to the data and take full responsibility for its integrity. They have all read and agree to the article as written.

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