Early outcome of aortic valve replacement with mechanical prosthesis in patients with aortic stenosis. Is patient-prosthesis mismatch a significant clinical problem?

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Abstract

Introduction: Prevalence of aortic valve disease increases with a population's aging. Aortic valve replacement (AVR) is one of the most frequently performed procedures in cardiac surgery centres. Patient-prosthesis mismatch (PPM) is believed by some authors to be a significant clinical problem.
The aim of the present study was to assess early results of AVR in patients with isolated aortic valve stenosis, with special regard to haemodynamic parameters and PPM.
Material and methods: Forty-eight consecutive patients (28 men and 20 women) aged mean 59.3±12.1 years, who underwent AVR with a mechanical prosthesis, in the Department of Cardiac Surgery, Medical University of Lodz, Poland in 2003, were retrospectively analyzed.
Results: The in-hospital postoperative mortality in the study group was 4.2%. The most common postoperative complications were arrhythmia and low cardiac output syndrome (LCOS), which occurred in 5 patients (10.4%) each. At discharge from hospital no patient met the criterion of PPM (effective orifice area index – EOAI of 0.85 cm^2/m^2 or lower). Significant improvement was observed in mean New York Heart Association (NYHA) class and mean maximal valvular gradient (respectively 2.3±0.5 vs. 1.4±0.7 and 87.1±19.1mmHg vs. 26.4±6.5 mmHg, $p<0.05$ for both values).
Conclusions: In the analyzed group the early results of AVR with mechanical prosthesis are good and no case of PPM was observed.

Key words: aortic valve replacement, patient-prosthesis mismatch.

Introduction

Prevalence of aortic valve disease increases with a population's aging. In a significant subset of patients the disease consists of left arterial ostium stenosis, mostly accompanied by massive calcifications of cusps and annulus. The only way to treat this pathology is aortic valve replacement (AVR). Annually in Germany, AVR is performed on more than 10 000 patients with mortality of 2.5% after mechanical valve and 3.8% after biological valve implantation in 2004 [1]. In the USA the risk of isolated AVR was 4.3% in 1999 and age has been identified as an independent risk factor [2]. Nowadays, more and more cardiac surgeons decide to implant biological

prostheses (xenografts) especially in the an older population: however, patients with mechanical prostheses implanted remain a large subgroup.

Patients with a small aortic annulus requiring implantation of a small prosthesis are at risk of patient-prosthesis mismatch (PPM) development. The concept of PPM was introduced by Rahimtoola et al. in the late 1970s [3] to describe a situation when effective orifice area (EOA) of aortic valve prosthesis is lower than that of a normal human valve and causes a high residual valve gradient. A standard definition of PPM was published by the Quebec group in 2003 [4]. The EOA of aortic valve prosthesis was divided by body surface area (BSA) of the patient to calculate the EOA index (EOAI). Moderate PPM was defined as EOAI of 0.65-0.85 cm^2/m^2 and severe PPM as EOAI lower than 0.65 cm^2/m^2. Some authors [5-9] find PPM as the common clinical situation and believe that it is associated with worse short- and long-term results of AVR.

The aim of the present study was to assess early results of AVR with mechanical prosthesis, in patients with isolated aortic valve stenosis, with special regard to haemodynamic parameters and PPM.

Material and methods

The study group consisted of 48 consecutive patients (28 men and 20 women) aged from 33 to 77 years (mean 59.3±12.1 years) who underwent AVR with mechanical prosthesis in the Department of Cardiac Surgery, 1st Chair of Cardiology and Cardiac Surgery, Medical University of Lodz, in the second half of 2003. The exclusion criteria comprised maximal aortic valve gradient lower than 50 mmHg, presence of significant aortic regurgitation, presence of other heart or aortic pathologies requiring additional procedures and implantation of a biological prosthesis. The preoperative data of the study group are presented in Table I.

Table I. Preoperative characteristics of the study group

Age (years)	35-77, mean 59.3±12.1
Male gender (n)	28 (58%)
Mean NYHA class	2.3±0.5
Mean maximal valvular gradient (mmHg)	87.1±19.1
Mean LVEF (%)	52.1±11.5

NYHA - New York Heart Association, LVEF - left ventricular ejection fraction

Table II. Types and sizes of implanted mechanical prostheses

Size	Bileaflet SJM	Tilting HM
19 mm	6	–
20 mm	–	4
21 mm	13	2
23 mm	15	–
25 mm	5	2
27 mm	1	–
Total	40	8

SJM- St. Jude Medical, HM- Hall Medtronic

All patients were operated on electively in normothermia. Myocardial protection was obtained by selective, interrupted administration of cold crystalloid cardioplegia (St. Thomas Hospital) to coronary ostia. Mean cardiopulmonary bypass (CPB) time was 81±23 minutes and mean aorta cross-clamping time was 57±17 minutes. After excessive decalcification of aortic annulus, the biggest possible mechanical valve prosthesis was implanted in a subannular way, using interrupted mattress sutures. Either bileaflet St. Jude Medical (SJM) or tilting Hall-Medtronic (HM) prosthesis was used. No case of aortic annuloplasty was performed.

The retrospective analysis concerned basic demographic data of the patients, their clinical state before and after the operation according to New York Heart Association (NYHA) functional classification, type and size of implanted prosthesis and postoperative course until discharge from hospital. Among analyzed haemodynamic parameters were pre- and postoperative mean and maximal aortic valve gradient and left ventricular ejection fraction (LVEF) measured by echocardiography. Presence of PPM was assessed according to the Quebec group definition [4]. The EOA of prosthesis was derived from the manufacturer's brochure and BSA calculated from the Dubois and Dubois formula ($BSA = H^{0.725} \times W^{0.425} \times 0.007184$, where H stands for patient's height in metres and W for patient's weight in kilograms). PPM was recognized when EOAI was 0.85 cm^2/m^2 or lower.

The statistical analysis for qualitative data was based on chi-square test with Yates amendment. Quantitative data were expressed as mean ± standard deviation (SD) and analyzed by *t* test for independent samples. A p value <0.05 was considered significant.

Results

Forty patients (83.3%) had SJM bileaflet prosthesis and 8 patients (16.7%) HM tilting prosthesis implanted. In 10 patients (20.8%) it was necessary to implant a prosthesis of size lower than 21 mm (in 6 patients SJM 19 mm and in 4 patients HM 20 mm). Data on implanted prostheses are shown in Table II. The in-hospital mortality was 4.2% (2 patients). Both died from severe low cardiac output syndrome (LCOS). The most common postoperative complications were arrhythmia and LCOS, which occurred in 5 patients (10.4%) each. One patient (2.1%) needed re-thoracotomy due to excessive postoperative bleeding, and another one (2.1%) had to undergo

a redo AVR because of early prosthesis dysfunction. The complete data on postoperative mortality and morbidity are shown in Table III. The mean postoperative hospital stay was 9±3 days including 2±1 days in the intensive care unit (ICU). Forty-six patients (95.8%) were discharged from hospital in good clinical condition, on oral anticoagulation (target international normalized ratio - INR: 2.5-3.5). At discharge mean NYHA class of patients was significantly lower than before the operation (1.4±0.7 vs. 2.3±0.5, p<0.05) and maximal aortic valve gradient was significantly lower than preoperatively (26.4±6.5 mmHg vs. 87.1±19.1 mmHg, p<0.05), whereas mean LVEF remained at the same level. Mean EOAI was 1.3±0.24 cm^2/m^2. In 6 patients (12.5%) EOAI was 1 cm^2/m^2 or less but in no patient did it reach the cutoff value of 0.85 cm^2/m^2 to meet the criterion for PPM. In 8 patients (16.7%) EOAI was higher then 1.5 cm^2/m^2. In most of the patients (70.8%) it ranged between 1.1 and 1.5 cm^2/m^2. The detailed haemodynamic and clinical data are shown in Tables IV and V.

Discussion

The issue of patient-prosthesis mismatch after aortic valve replacement and its clinical impact, described for the first time by Rahimtoola [3] in 1978, has had some adherents and some opponents.

Walther et al. [5] analyzed 4.131 patients who underwent stented mechanical or biological AVR during an 8-year period. In 26.7% of patients they found moderate PPM and in 2.3% of patients severe PPM. When no PPM was present, in-hospital mortality was 6.9%, when moderate PPM was observed early mortality was 10.6% and in the case of severe PPM it was 5.2%. Moderate PPM was found to be an independent predictor of 30-day mortality. Also long--term survival during mean follow-up of 5.2±3.5 years was significantly better in patients without PPM (81.4±1.0% vs. 76.8±1.7%, p<0.01). Pibarot et al. [6] estimate that PPM is present in as many as 20-70% of all patients after AVR, and it is associated with worse hemodynamic function, less regression of left ventricular hypertrophy, more cardiac events and lower survival. Moon et al. [7], who defined PPM as EOAI <0.75 cm^2/m^2, found that it had a negative impact on survival for young patients, patients of average size and for large patients with mechanical prostheses. Also Mohan et al. [8] and Mohty-Echahidi et al. [9] reported that severe PPM was associated with poorer survival. Bakhtiary et al. [10], using magnetic resonance, found that even moderate PPM led to decreased rates of coronary flow reserve (CRF) after all types of prostheses AVR. Bove et al. [11] compared midterm survival of 145 patients after biological stentless AVR and 110 patients after biological stented AVR. In univariate analysis PPM was one of the predictors of adverse outcome, but it was not confirmed in multivariate analysis. The use of stentless bio-prosthesis significantly reduced the

Table III. Postoperative mortality and morbidity

Death	2 (4.2%)
Arrhythmia	5 (10.4%)
AV block	1 (2.1%)
Re-thoracotomy (excessive bleeding)	1 (2.1%)
Pneumothorax	3 (6.3%)
Redo-AVR (early dysfunction of prosthesis)	1 (2.1%)
LCOS	5 (10.4%)

AV - atrioventricular, AVR - aortic valve replacement, LCOS - low cardiac output syndrome

Table V. Effective orifice area index (EOAI) at discharge from hospital

EOAI (cm^2/m^2)	n
≤0.85 (PPM)	-
0.86-1.0	6
1.1-1.5	32
>1.5	8

PPM - patient prosthesis mismatch

Table IV. Clinical and haemodynamic state of patients before and after AVR

	Before AVR	After AVR	
Mean NYHA class	2.3±0.5	1.4±0.7	p<0.05
Mean EOAI (cm^2/m^2)	–	1.3±0.24	–
Mean max. gradient (mmHg)	87.1±19.1	26.4±6.5	p<0.05
Mean LVEF (%)	52.1±11.5	53.3±8.1	ns
Mean hospital stay (days)	–	9±3	–
Mean ICU stay (days)	–	2±1	–

AVR - aortic valve replacement, NYHA - New York Heart Association, EOAI - effective orifice area index, LVEF - left ventricular ejection fraction, ICU - intensive care unit

occurrence of PPM (18% vs. 41%, p<0.01).

On the other hand, Howell et al. [12] analyzed 1418 patients after AVR, whose in-hospital postoperative mortality was 5.3%. The criterion of PPM in this material was met in 8.6% of patients. In multivariate analysis no association was found between presence of PPM and in-hospital mortality. Also 5-year survival estimate was similar for patients with and without PPM (83.8% vs. 94%, ns). Blackstone et al. [13] after analyzing in a multicentre study a very large cohort of patients (more than 13 000), found only a small increase (1%) in early postoperative mortality when using small aortic prostheses. However, PPM did not affect mid- and long-term survival after AVR. Furthermore, surgical attempts towards enlargement of the aortic root to avoid PPM are known to be burdened with a significant increase of mortality and morbidity [14]. Minardi et al. [15] assessed 19 patients aged mean 69.2±7.3 years after 17 mm mechanical bileaflet SJM AVR. They measured haemodynamic parameters using rest and dobutamine stress echocardiography. The conclusion of their study was that this kind of prosthesis can be safely implanted in the aortic position in relatively old patients, offering a satisfactory haemodynamic performance both at rest and during moderate exercise, regardless of mild PPM presence.

In the present study, in-hospital mortality was 4.2%, which is in accordance with outcomes following AVR presented in the literature. The fact that no case of PPM was observed can probably be explained by the small size of our group of patients. What is more, in the present material it was not necessary to implant a prosthesis smaller than 19 mm, or to perform any enlargement of the aortic root.

Conclusions

In the analyzed group the early results of AVR with mechanical prosthesis are good and no case of PPM was observed.

References

1. Gummert JF, Funkat A, Krian A. Cardiac surgery in Germany during 2004: a report on behalf of the German Society for Thoracic and Cardiovascular Surgery. Thorac Cardiovasc Surg 2005; 53: 391-9.
2. Jamieson WR, Edwards FH, Schwartz M, Bero JW, Clark RE, Grover FL. Risk stratification for cardiac valve replacement. National Cardiac Surgery Database. Database Committee of The Society of Thoracic Surgeons. Ann Thorac Surg 1999; 67: 943-51.
3. Rahimtoola SH. The problem of valve prosthesis-patient mismatch. Circulation 1978; 58: 20-4.
4. Blais C, Dumesnil JG, Baillot R, Simard S, Doyle D, Pibarot P. Impact of valve prosthesis-patient mismatch on short-term mortality after aortic valve replacement. Circulation 2003; 108: 983-8.
5. Walther T, Rastan A, Falk V, et al. Patient prosthesis mismatch affects short- and long-term outcomes after aortic valve replacement. Eur J Cardiothorac Surg 2006; 30: 15-9.
6. Pibarot P, Dumesnil JG. Prosthesis-patient mismatch: definition, clinical impact, and prevention. Heart 2006; 92: 1022-9.
7. Moon MR, Pasque MK, Munfakh NA, et al. Prosthesis--patient mismatch after aortic valve replacement: impact of age and body size on late survival. Ann Thorac Surg 2006; 81: 481-8.
8. Mohan S, Kohsaka S, Contreras A, et al. Prosthesis-patient mismatch affects long-term survival after mechanical aortic valve replacement. J Am Coll Cardiol 2006; 46: 282A.
9. Mohty-Echahidi D, Malouf JF, Girard SE, et al. Impact of prosthesis-patient mismatch on long-term survival in patients with small St. Jude Medical Mechanical Prostheses in the aortic position. Circulation 2006; 113: 420-6.
10. Bakhtiary F, Schiemann M, Dzemali O, et al. Impact of patient-prosthesis mismatch and aortic valve design on coronary flow reserve after aortic valve replacement. J Am Coll Cardiol 2007; 49: 790-6.
11. Bove T, Van Belleghem Y, Francois K, Caes F, Van Overbeke H, Van Nooten G. Stentless and stented aortic valve replacement in elderly patients: Factors affecting midterm clinical and hemodynamical outcome. Eur J Cardiothorac Surg 2006; 30: 706-13.
12. Howell NJ, Keogh BE, Barnet V, et al. Patient-prosthesis mismatch does not affect survival following aortic valve replacement. Eur J Cardiothorac Surg 2006; 30: 10-4.
13. Blackstone EH, Cosgrove DM, Jamieson WR, et al. Prosthesis size and long-term survival after aortic valve replacement. J Thorac Cardiovasc Surg 2003; 126: 783-96.
14. Sommers KE, David TE. Aortic valve replacement with patch enlargement of the aortic annulus. Ann Thorac Surg 1997; 63: 1608-12.
15. Minardi G, Manzara C, Creazzo V, et al. Evaluation of 17-mm St. Jude Medical Regent prosthetic aortic heart valves by rest and dobutamine stress echocardiography. J Cardiothorac Surg 2006; 1: 27.