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Impact of mild patient prosthesis mismatch on quality of life in patients with preserved ejection fraction after isolated aortic valve replacement for aortic stenosis

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ABSTRACT

Aim: To analyze whether PPM affects QOL and functional status in patients after isolated AVR for aortic stenosis (AS) with preserved left ventricular ejection fraction (LVEF).
Methods: Consecutive patients who underwent AVR in University Hospital Center Zagreb for isolated severe symptomatic AS and preserved EF were enrolled. Echo data was obtained from complete transthoracic examinations prior and after surgery by offline analysis. Patients were divided into two groups according to the presence of PPM (effective orifice area (EOA) / body surface area (BSA) < 0,85 cm^2/m^2). QOL was assessed by telephone interview using Short Form 36-Item Health Survey (SF-36) along with functional NYHA status estimation.
Results: A total of 45 pts were included (23 female), and divided in PPM (n = 26), and non-PPM group (n = 19). Both groups were similar in pts age, LVEF, AVA/BSA prior surgery. After surgery, 57% of pts had PPM categorized as mild PPM. During follow-up of 2,5 years, 3 pts had died and 10 were lost from following. There was no difference in NYHA status after surgery between groups (p = 0,758). SF36 results showed no difference between groups. However, there was a significant improvement in Physical functioning (47,50% vs 75,47%,p = 0,000) and Role limitation due to physical health (41,41% vs 81,25%, p = 0,007) scores in the whole study population after AVR. Males had significantly better Energy/fatigue (p = 0,034), Social functioning (p = 0,004) and Pain (p = 0,017) scores.
Conclusions: Mild to moderate PPM showed no clinical relevance. All patients revealed improvement in QOL after AVR, while male sex was related to better functioning scores irrespectively of PPM.

1. Introduction

Since it was first described by Rahimtoola in 1978 [1], patient prosthesis mismatch (PPM) has caused a lot of controversies. It means that the effective orifice area (EOA) of the implanted valve is too small for the patient's body surface area (BSA). PPM is more common in patients with large BSA, but it also depends on the left ventricular outflow tract (LVOT) diameter [2–4]. In patients with aortic stenosis, due to left ventricular hypertrophy and excessive calcifications, LVOT diameter gradually gets smaller and precludes implantation of the prosthetic valve of appropriate size [4].

PPM is generally a relatively common finding, found in up to 70% AVR procedures [2,5–8]. If the EOA/BSA ratio is <0,85 cm^2/m^2, PPM is defined as mild or moderate, and as severe if the EOA/BSA ratio is <0,65 cm^2/m^2 [2]. Patient outcomes mainly depend on the severity of PPM. Severe PPM has been shown to have worse long term survival, lower cardiac-related-death survival and lower left ventricular (LV) mass reduction [9].

However, the impact of patient prosthesis mismatch on the outcomes remains unresolved. In some studies, PPM did impact long term survival and cardiac related deaths [9–11] whereas in others there was no significant difference compared to no PPM patients [8,11–12]. Studies are more uniform regarding functional capacity, with no difference compared to no PPM patients, especially in the elderly [5,7,12–16].

In younger, middle-aged patients, the impact of PPM on functional capacity and QOL remains unclear. Higher gradients and less positive remodeling of the left ventricle may have some impact on their functional capacity and the risk for reoperation [8]. The aim of the study was to investigate the impact of PPM on survival, quality of life and functional status in general population with preserved ejection fraction after isolated AVR.

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2. Methods

A retrospective observational study was conducted in the University Hospital Center Zagreb. Patients' demographic data and data regarding cardiac surgery were acquired from the hospital digital database and medical charts. Offline analysis of the previously recorded and digitally stored transthoracic echocardiographic exams was performed on the echo workstations using GE EchoPac software. Data concerning the quality of life and functional status were collected in December 2015 via telephone medical interview. Oral informed consent was obtained from each patient.

2.1. Patients

Consecutive patients with preserved ejection fraction (LVEF > 45%) and severe symptomatic aortic stenosis who underwent isolated AVR in our institution, in the period from 2010 to 2014, were enrolled. Patients with reduced ejection fraction and concomitant coronary artery disease or other valvular disease regarding intervention, those with poor acoustic echo window and no preoperative TTE, were excluded from the study. Patient inclusion and exclusion criteria were met accordingly to medical charts data. Also, patients with poor acoustic echo window on echo data prior to surgery were excluded from the study.

2.2. Echocardiography

We have retrospectively analyzed the digitally stored echocardiographic data - a complete standard transthoracic echocardiographic study was preformed prior to surgery and in the early postoperative period.

Prior to surgery, the following echo parameters were analyzed: LVEF, global longitudinal strain (GLS), maximal and mean gradients over aortic valve and aortic valve area (AVA). The left ventricular ejection fraction was calculated using Simpson Biplane method and the global longitudinal strain (GLS) was measured using 2D speckle tracking. The aortic valve area was calculated using the continuity equation and indexed for body surface area (BSA).

After AVR, the same methods were used for the quantification of the LVEF and measurement of GLS, maximum and mean pressure gradients. The effective orifice valve area values were taken from the manufacturer's data. PPM was then calculated from the expected effective orifice area (EOA) for each valve type and size, and indexed by patient's body surface area (BSA).

2.3. Patient prosthesis mismatch

According to the calculated EOA/BSA after operation, patients were divided into two groups based on PPM presence. If EOA/BSA was <0,85 cm^2/m^2, the patient was classified into PPM group.

2.4. Quality of life survey

QOL was assessed in December 2015 by telephone interview using the Short Form 36-Item Health Survey (SF-36) Questionnaire. The doctor performing the interview has read the questions exactly as written and recorded answers in numeric form. Patients were also asked additional questions in order to estimate their functional status according to the New York Heart Association (NYHA) classification. The results were recorded in numerical form (I–IV). Questions were also asked about additional data regarding mortality and hospitalizations due to heart failure.

Standard analysis of the SF-36 questionnaire was done, using the following scores calculated from the questionnaire: Physical functioning (PF), Role limitations due to physical health (RLPH), Role limitations due to emotional problems (RLEH), Energy/fatigue (EF), Emotional well-being (EMWB), Social functioning (SF), Pain (P) and General health (GH).

2.5. Statistical analysis

Descriptive statistics was done to analyze population characteristics, ECHO parameters and QOL data. When comparing the two populations adequate tests depending on variable type and data distribution were used (chi-square, Mann–Whitney, *t*-test, ANOVA). Statistical analysis was done using SPSS v21 IBM software.

3. Results

A total of 45 patients (23 female, 22 male), aged 67,4 ± 10,7 years were included in the study. All patients had a preserved LVEF (57,3 ± 8,05%). They all had an isolated severe aortic stenosis (0,65 ± 0,2 cm^2). After AVR, 18 mechanical (40%) and 27 biological valves (60%) were implanted. Postoperative EOA/BSA was calculated and patients were divided into two groups: PPM group (n = 26), and no PPM group (n = 19). Mean EOA/BSA in no PPM group was 1,0068 cm^2/m^2. There were in total 57% patients with PPM (mean EOA/BSA 0,76 ± 0,05 cm^2/m^2, p = 0,000), categorized as mild to moderate PPM. Further subgroup analysis for moderate and severe PPM was not performed due to the small number of patients.

There was no significant difference in demographic parameters or in basic echocardiographic parameters prior to surgery between groups. Mean age of patients in no PPM group was 66,61 ± 11,07 years and in PPM group 62,5 ± 18,25 years, p = 0,472; body surface area was 1,86 cm^2/m and 1,95 m^2 respectively, p = 0,215. All patients had a preserved left ventricular ejection fraction (LVEF) prior surgery: 59,68 ± 6,07% (no-PPM group) vs 55,58 ± 8,95% (PPM group), p = 0,091. Global longitudinal strain (GLS) was reduced in both groups: −15,080% vs −11,827%, p = 0.363. Calculated aortic valve area was 0,70 ± 0,20 cm^2, indexed 0,36 ± 0,09 cm^2/m^2 in no-PPM group and 0,61 ± 0,19 cm^2, indexed 0,31 ± 0,09 cm^2/m^2 in PPM group (p = 0,156; p = 0,065 respectively).

Mechanical valves were implanted in 42% of no-PPM group and 38% of PPM group, and biological in 58% and 62% respectively (p = 0,805). The postoperative transthoracic echocardiography was preformed within 6,79 days in no PPM and 8,04 days in PPM group (p = 0,517). In this early postoperative period, we found no significant difference in LV function, although a trend toward higher values was present among patients in no-PPM group: LVEF: 60,63% vs 58,53% (p = 0,261), GLS −14,75% vs −12,08% (p = 0,428). Maximum and mean pressure gradient (PG) across implanted valve also showed no difference between the patient groups (38 vs 45 mm Hg maxPG, p = 0,149; 20 vs 25 mm Hg meanPG, p = 0,096).

The mean follow-up period was 32,95 ± 12,12 months in no-PPM and 31,23 ± 10,97 months in PPM group (p = 0,683). During this period, 3 patients had died (1 in no PPM and 2 in PPM group) and 10 pts were lost from following. In total, 32 of 45 patients (71,1%) were interviewed (13/19, 68,4% no PPM; 19/26, 73,1% PPM). No difference in functional NYHA status between groups was found (p = 0,758): all patients were in NHYA status I–III.

No significant differences between PPM groups were found in QOL SF-36 scores (Table 1). However, when compared to preoperative scores, a significant improvement in Physical functioning score (PF, p = 0,000) and Role limitation due to physical health score (RLPH, p = 0,007) was found in the whole study population, showed in Table 2.

After subgroup analysis regarding sex category, males and females were matched in demographic and echocardiographic parameters as well as in PPM incidence. Interestingly when analyzing QOL, it was found that men had a significantly better Energy/fatigue (EFS, p = 0,034), Social functioning (SF, p = 0,004) and Pain (P, p = 0,017) scores (Table 3).

Table 1
Quality of life scores in patients with and without patient prosthesis mismatch after aortic valve replacement.

	PPM	N	Mean	SD	Sig.
PF	No-PPM	13	72,31	28,18	0,564
	PPM	19	77,63	23,23	
RLPH	No-PPM	13	82,69	31,26	0,850
	PPM	19	80,26	37,80	
RLEH	No-PPM	13	94,87	12,52	0,985
	PPM	19	94,74	22,94	
EF	No-PPM	13	59,23	4,00	0,478
	PPM	19	57,37	10,18	
EMWB	No-PPM	13	75,39	2,21	0,113
	PPM	19	71,79	9,08	
SF	No-PPM	13	69,23	18,12	0,505
	PPM	19	64,47	20,52	
P	No-PPM	13	77,12	17,17	0,915
	PPM	19	76,32	22,54	
GH	No-PPM	13	63,08	15,08	0,666
	PPM	19	60,00	24,78	

PPM = patient prosthesis mismatch, PF = Physical functioning, RLPH = Role limitations due to physical health, RLEH = Role limitations due to emotional problems, EF = Energy/fatigue, EMWB = Emotional well-being, SF = Social functioning, P = Pain, GH = General health.