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Indexed effective orifice area after mechanical aortic valve replacement does not affect left ventricular mass regression in elderly

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Abstract

Objective: After aortic valve replacement, the effects of a small functional prosthesis on the extent and pattern of regression of left ventricular hypertrophy and on clinical outcomes may be less significant in older patients with low cardiac output requirements. The objective of this study was therefore to determine whether patient-prosthesis mismatch affects left ventricular mass regression in the elderly. **Methods:** The population studied was made up of 88 patients over 65 years of age with pure aortic stenosis who underwent mechanical aortic valve replacement. The effective orifice area index was calculated for each patient on the basis of the projected prosthesis in vivo effective orifice area. It was considered a continuous variable and influence of its entire range of values on the extent of left ventricular mass regression was analyzed in a multivariate prediction model. **Results:** Even though, in the group with prosthesis-patient mismatch there was a trend for lower postoperative left ventricular mass index (115 ± 24 g/m^2 vs 102 ± 27 g/m^2, $p = 0.24$) and postoperative peak trans-prosthetic gradients (32 ± 9.8 mmHg vs 28.9 ± 7.79 mmHg, $p = 0.35$) these differences were not statistically significant. The prevalence of residual left ventricular hypertrophy at follow-up was 50% in the group with patient-prosthesis mismatch and 50% in the group without patient-prosthesis mismatch ($p = 0.83$). In multivariate analysis the only factors associated with indexed left ventricular mass were the follow-up time ($p = 0.015$, $r^2 = 0.22$) and preoperative indexed left ventricular mass ($p = 0.0012$, $r^2 = 0.11$). **Conclusions:** The major finding of our study is that patient-prosthesis mismatch does not affect left ventricular mass regression in patients older than 65 with pure aortic stenosis who underwent mechanical aortic valve replacement. In older patients with low cardiac output requirements, even a small change in the valve effective orifice area after aortic valve replacement with modern efficient mechanical prosthesis, will result in a marked reduction of pressure gradient and this will be associated with a significant regression of left ventricular mass.
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Keywords: Heart valve; Mechanical; Aortic valve; Replacement; Valve disease

1. Introduction

In patients with aortic valve stenosis, left ventricular hypertrophy (LVH) develops as an adaptive process in response to elevated pressure in the left ventricle. Aortic valve replacement (AVR) is effective for relief of excessive afterload, but significant LVH often remains following AVR. Because severe LVH is a well-known hazard of cardiac events [1,2], its regression is a major concern. Lund et al. [3] recently showed that the indexed left ventricular mass (ILVM) and its regression following AVR is closely linked to long-term survival. After AVR, prosthesis-patient mismatch (PPM) occurs when the effective prosthesis area is consistently smaller than that of a normal valve [1], and it has been reported to be a predictor of postoperative elevated trans-valvular gradients and residual LVH [1–3]. However, other studies have shown the absence of any proof of a PPM effect on left ventricular mass regression and survival [4–7].

The effect of PPM after AVR on LVM regression should be analyzed using homogeneous criteria in terms of population (patients' ages, type of implanted prosthesis). Most observations have been made on groups of patients with a wide age range. The impact of age and, therefore, of various levels of physical activity on the extent of myocardial mass regression may be a frequent confounding factor in studies on the consequences of aortic valve prosthesis-patient mismatch. In this context, most investigations have concluded that the wide range age of the patients may have contributed to the difference of findings, making result interpretation difficult. The influence of a possible mismatch on the extent and pattern of regression of left ventricular hypertrophy and on clinical outcomes may be less significant in older patients with low cardiac output requirements. This could explain why some patients with PPM may exhibit substantial regression of LVM.

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The objective of this study was therefore to determine whether PPM affects LVM regression in elderly patients with pure aortic stenosis who underwent mechanical AVR on long-term follow-up.

2. Materials and methods

The study population was made up of 88 patients over 65 years of age with pure aortic stenosis who underwent mechanical AVR between September 1991 and April 2000. The choice of mechanical valve had been dictated by patient–surgeon preference. Patients with more than mild aortic regurgitation, previous myocardial infarction, previous cardiac surgery and concomitant surgical procedure were excluded. The implanted prostheses were Carbomedics bileaflet (20 cases), St Jude Medical bileaflet (64 cases), and Sorin Bicarbon bileaflet (4 cases). Prosthesis sizes were 17 mm in four patients, 19 mm in 20 patients, 21 mm in 48 patients, and 23 mm in 16 patients. The effective orifice area index (IEOA) was calculated for each patient from the projected prosthesis in vivo (EOA), obtained from literature sources (Table 1) [8], divided by the body surface area (BSA), as indicated by Pibarot et al. [9]. This index was considered an expression of the individual functional prosthesis size; a possible mismatch was defined as an IEOA less than 0.75 cm^2/m^2, a generally accepted criteria for a prosthesis size–patient body size mismatch [2,10], and was classified as a grouping variable to divide the patients into two study groups. Due to the arbitrary definition of the 0.75 cut-off value, the IEOA was also considered a continuous variable and influence of its entire range of values on the extent of LVM regression analyzed in a multivariate prediction model and as indicated in the data analysis section.

3. Doppler echocardiographic measurements

The preoperative and postoperative echocardiographic examination were performed by experienced echocardiographers using a Sonos 2500 or Sonos 5000 machine (Hewlett-Packard, Andover, MA, USA), interfaced with a 2.5-MHz transducer. The dimensions of the LV were assessed using two-dimensional guided M-mode tracings, with the measurements being made according to the recommendations of the American Society of Echocardiography (ASE) [11]. If the M-mode recordings were technically inadequate, two-dimensional measurements were used. LVM was calculated with the corrected ASE formula [12]:

$$LVM = 0.8[1.04((IVS_d + LVID_d + PWT_d)^3 - LVID_d^3)] - 13.6$$

Table 1
Normal effective orifice areas for mechanical prostheses (mm^2)

	Prosthetic valve size (mm)			
	19	21	23	25
Carbomedics bileaflet	1.25 ± 0.36	1.42 ± 0.36	1.69 ± 0.29	2.04 ± 0.37
St Jude medical standard	1.01 ± 0.24	1.33 ± 0.32	1.6 ± 0.43	1.93 ± 0.45
Sorin bicarbon	1.36 ± 0.13	1.46 ± 0.2	1.98 ± 0.23	2.39 ± 0.29

where IVS_d is the end-diastolic interventricular septum thickness; $LVID_d$, the LV end-diastolic internal diameter; and PWT_d is the LV end-diastolic posterior wall thickness. Residual LVH was defined as an ILVM more than 131 g/m^2 in males and more than 100 g/m^2 in females [13]. Left ventricular systolic performance was evaluated by means of the ejection fraction calculated using Simpson's rule. The peak and mean valve gradients were calculated using the modified Bernoulli equation.

4. Statistical analysis

The data were statistically analyzed using MedCalc Software. Comparisons of baseline variables between groups were performed by the *t*-test, χ^2-test, or the Fisher exact test, as appropriate. The projected prosthesis in vivo IEOA was considered as a continuous variable with several patients and prosthesis related factors, and included in a correlation analysis to identify variables associated with postoperative ILVM. The Spearman's coefficient of rank correlation was used for categorical variable. Only those factors that were significantly correlated with postoperative ILVM were included in a multiple linear regression model to identify predictors of the final ILVM. The possible predictors analyzed were gender, age, body surface area, history of diabetes, hypertension of chronic pulmonary obstruction disease (CPOD), preoperative creatinine, follow-up time, prosthesis size (manufacturer's labeled size), the projected prosthesis in vivo EOA, IEOA, preoperative ILVM, preoperative left ventricular ejection fraction (LVEF), and preoperative and postoperative peak trans-prosthetic gradients, the peak trans-valvular gradient absolute regression, and the type of implanted prosthesis. Variables are presented as mean ± 1 standard deviation. A probability (p) value less than 0.05 was considered statistically significant.

5. Results

The patients' preoperative and operative characteristics are shown in Table 2. Characteristics of patients with IEOA $< 75\ mm^2/m^2$ and those with IEOA $\geq 75\ mm^2/m^2$ were similar to those shown in the said table except for body and EOA. The prevalence of LVH before operation was more than 90% in both groups. Postoperative echocardiographic examination was complete in all patients. The mean follow-up time was 84 ± 39 months in IEOA $< 75\ mm^2/m^2$ group and 102 ± 27 in IEOA $\geq 75\ mm^2/m^2$ group ($p = 0.23$). Echocardiographic findings at follow-up are shown in Table 3. Marked regression of ILVM was observed in both groups ($p = 0.0003$ in IEOA $< 75\ mm^2/m^2$ group and $p = 0.0001$ in IEOA $\geq 75\ mm^2/m^2$ group). After AVR, improvement of LVEF was noticeable in both groups ($p = 0.01$ in IEOA $< 75\ mm^2/m^2$ group and $p = 0.01$ in IEOA $\geq 75\ mm^2/m^2$ group). There was a significant reduction in peak gradient in both groups ($p < 0.00001$ in IEOA $< 75\ mm^2/m^2$ group and $p < 0.00001$ in IEOA $\geq 75\ mm^2/m^2$ group). Although in the IEOA $\geq 75\ mm^2/m^2$ group there was a trend for lower postoperative LVM, postoperative ILMV, ILVM relative and absolute regression, postoperative peak trans-prosthetic gradients, and a higher peak trans-

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Table 2
Patient and procedural characteristics

	IEOA < 75 mm^2/m^2 ($n = 48$)	IEOA ≥ 75 mm^2/m^2 ($n = 40$)	p value
Age (years)	70 ± 3.5	67 ± 1.9	0.06
Sex (male/female)	24/24	16/24	0.46
Body surface area (m^2)	2.01 ± 0.15	1.65 ± 0.22	<0.0001
Hypertension (%)	50 (24/48)	42.5 (17/40)	0.6
Diabetes (%)	25 (12/48)	10 (4/40)	0.12
COPD (%)	56 (27/48)	50 (20/40)	0.72
Preoperative creatinine (mg/dl)	0.97 ± 0.27	1.2 ± 0.6	0.24
Preoperative NHYA functional class	2.75 ± 0.65	2.4 ± 0.87	0.29
EOA (mm^2)	1.17 ± 0.22	1.489 ± 0.14	<0.001
IEOA (mm^2/m^2)	0.62 ± 0.07	0.90 ± 0.11	<0.000001
Mean prosthesis size (mm)	20.16 ± 1.58	21.4 ± 1.26	0.06
St Jude prosthesis (%)	73 (35/48)	60 (24/40)	0.29
Carbomedics prosthesis (%)	25 (12/48)	32.5 (13/40)	0.58
Sorin prosthesis (%)	2 (1/48)	7.5% (3/40)	0.48
Preoperative ILVM (g/m^2)	162.08 ± 28.1	162.1 ± 27.9	1
Preoperative LVM (g)	341 ± 79	283.4 ± 88.5	0.11
LVH (% of patients)	91	90	0.9
Preoperative peak trans-valvular gradient (mmHg)	96.75 ± 22.96	105.6 ± 26.5	0.38
Preoperative LVEF (%)	55 ± 5.1	54 ± 4.8	0.1
Cardiopulmonary bypass time (min)	83.58 ± 14.1	78.2 ± 27.71	0.5
Aortic cross-clamp time (min)	62.6 ± 12.2	55.6 ± 19.2	0.3

LVM: left ventricular mass; ILVM: left ventricular mass index; LVEF: left ventricular ejection fraction; IEOA: effective orifice area index; EOA: effective orifice area; COPD: chronic pulmonary obstruction disease.

Table 3
Echocardiographic findings at follow-up

	IEOA < 75 mm^2/m^2 ($n = 48$)	IEOA ≥ 75 mm^2/m^2 ($n = 40$)	p value
Mean follow-up time (months)	84 ± 39	102 ± 27	0.23
Postoperative LVM (g)	210 ± 67	170 ± 36	0.1
Final ILVM (g/m^2)	115 ± 24	102 ± 27	0.24
LVM absolute regression (g)	132.5 ± 62.6	112.9 ± 78.5	0.51
LVM relative regression (%)	$-27 \pm 14\%$	-37 ± 12	0.09
Postoperative peak trans-valvular gradient (mmHg)	32 ± 9.8	28.9 ± 7.79	0.35
Trans-valvular gradient absolute reduction (mmHg)	64.2 ± 23.6	76.7 ± 26.06	0.26
Residual LVH (% of patients)	50	50	0.83
Postoperative LVEF (%)	60.7 ± 7.1	63 ± 9.5	0.1

LVM: left ventricular mass; ILVM: left ventricular mass index; LVEF: left ventricular ejection fraction; IEOA: effective orifice area index.

valvular gradient absolute regression, these differences were not statistically significant. The prevalence of residual LVH at follow-up was 50% in IEOA < 75 mm^2/m^2 group and 50% in IEOA ≥ 75 mm^2/m^2 group ($p = 0.83$). Results of a correlation analysis showed that the factors associated with postoperative ILVM were body surface area ($p = 0.017$), follow-up time ($p = 0.04$), preoperative ILVM ($p = 0.009$) and postoperative peak trans-prosthesis gradient ($p = 0.018$). In multivariate

Table 4
Independent predictors of ILVM in multiple regression analysis[a]

	Standardized coefficients (β)	p value	r^2
Body surface area	19.5	0.12	0.1
Time of echocardiography follow-up	−0.31	0.0154	0.22
Preoperative ILVM	0.56	0.0012	0.11
Postoperative peak trans-valvular gradient (mmHg)	0.50	0.16	0.15

ILVM: left ventricular mass index.
[a] Model: $r = 0.76$; $r^2 = 58\%$.

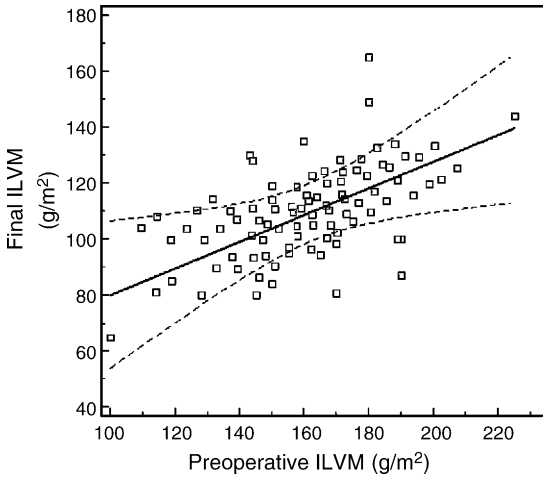

Fig. 1. Regression line and 95% confidence interval between preoperative and the final left ventricular mass index (ILVM, g/m^2) (regression equation: $y = 32.5652 + 0.4754x$, $r^2 = 0.24$, $p = 0.02$).

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analysis the only factors associated with final ILVM were follow-up time ($p = 0.015$, $r^2 = 0.22$) and preoperative ILVM ($p = 0.0012$, $r^2 = 0.11$) (Table 4). The relation between preoperative ILVM and final ILVM is presented graphically in Fig. 1.

The New York Heart Association functional class improved significantly at follow-up (2.5 ± 0.7 vs 1.34 ± 0.54, $p < 0.00001$) with no difference between groups ($p = 0.49$).

6. Discussion

Patient-prosthesis mismatch after AVR has long been considered to influence LVM regression and long-term survival [14]. However, the evidence to support the theory that PPM produces poor LVM regression is not abundant. In fact, Hanayama et al. [4] found that patients with and without PPM were similar with respect to postoperative left ventricular mass index, 7-year survival ($95.1 \pm 1.3\%$ vs $94.7 \pm 3.0\%$; $p = 0.54$). Amarelli et al. [15] reported in 35 patients (mean age, 63.4 ± 17 years; median age, 70 years; age range, 16–84 years) underwent isolated aortic valve replacement with a 17-mm St Jude Medical Hemodynamic Plus or a St Jude Medical Regent prosthesis a significant regression of the ILVM (postoperative mean value, 107.8 ± 22.8 g/m^2; $p < .0001$), despite a mean indexed effective orifice area of 0.67 ± 0.14 cm^2/m^2 (median, 0.66 cm^2/m^2). In contrast, Del Rizzo et al. [16] found a strong relationship between the IEOA and the extent of LVM regression following AVR. Also, Tasca et al. [17] found that the absolute and relative left ventricular mass regression were significantly ($p = 0.002$ and $p = 0.01$, respectively) lower in patients with prosthesis-patient mismatch (-48 ± 47 g, $-17 \pm 16\%$) compared to those with no prosthesis-patient mismatch (-77 ± 49 g, $-24 \pm 14\%$). However, it should be emphasized that in this study all patients have received a bioprosthesis and the projected IEOA was derived from the published normal in vitro EOA values for the type and size of implanted prosthesis divided by the patient's BSA. Physiological studies have shown that in vitro EOAs tend to overestimate in vivo EOAs by 10–15% [18–20]. These aspects could make it difficult to compare the results reported by Tasca with our findings.

It must be noted that most observations have been made on groups of patients with a wide age range. In this context, the wide range of the patients' ages may have contributed in most investigations to the difference of findings, which makes it difficult to interpret the results. The influence of a possible mismatch on the extent and pattern of regression of left ventricular hypertrophy and on clinical outcomes may be less important in older patients with low cardiac output requirements.

The major finding of our study is that PPM does not affect LVM regression in patients older than 65 years with pure aortic stenosis who underwent mechanical AVR on long-term follow-up. The results of the present study suggest that in older patients with low cardiac output requirements also small change in valve EOA after AVR with modern highly efficient mechanical prosthesis will result in a marked reduction of pressure gradient and this will be associated with a significant regression of LVM. Previous studies have found that the relationship between IEOA and trans-valvular pressure gradients is curvilinear, and the turning point on this curve, the point that separates the steep from the flat portion of the curve, is close to an IEOA of 0.8–0.9 cm^2/m^2 [18–21]. Below this threshold, the curve is steep, and, as a consequence, a small change in valve EOA will result in a major reduction of pressure gradient. Our results confirm that the reduction of pressure gradient obtained with small functional prosthesis will result in significant LVM regression.

However, as reported with other studies [4,22,23,17], we found residual LVH in 50% of studied patients at follow-up. The incomplete regression of hypertrophy after the removal of the hypertrophic trigger may be explained by potentially irreversible changes in the hypertrophied myocytes and interstitium that may occur as a consequence of long-standing disease [24–25].

7. Study limitations

In the present study, the functional prosthesis size was expressed by means of the Doppler IEOA, which is a clinically estimated measure and varies in different physiological conditions. However, use of the Doppler IEOA for evaluation of the individual prosthetic valve performance has been validated by Dumesnil et al. [18], and it has been widely applied to estimate the prosthesis-patient size and a possible mismatch. It could be argued that in our series no individual measurements were performed, but prosthetic EOAs were estimated according to published reference values for the various types of valve prosthesis.

The multivariate model obtained in this study only explains 58% of the variance of final LVM (Table 4). This suggests that other factors may also influence the regression of LVH.

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