POINT: Prosthesis–patient mismatch does not affect survival for patients greater than 70 years of age undergoing bioprosthetic aortic valve replacement

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Objective: The purpose of this investigation was to examine the impact of prosthesis–patient mismatch after bioprosthetic aortic valve replacement on long-term survival in patients greater than 70 years of age compared with those less than or equal to 70 years of age.

Methods: Between 1992 and 2007, 1399 patients underwent bioprosthetic aortic valve replacement, including 881 (63%) patients older than 70 years of age. Prosthesis–patient mismatch was defined as severe (prosthetic effective orifice area/body surface area $< 0.65 \text{ cm}^2/\text{m}^2$), moderate ($0.65\text{--}0.85 \text{ cm}^2/\text{m}^2$), or absent ($>0.85 \text{ cm}^2/\text{m}^2$). For patients less than or equal to 70 years of age, mismatch was severe in 62 (12%), moderate in 251 (48%), and absent in 205 (40%). For patients greater than 70 years of age, mismatch was severe in 109 (12%), moderate in 451 (51%), and absent in 321 (37%). There was no difference in the distribution of prosthesis–patient mismatch between age groups ($P = .50$).

Results: For patients less than or equal to 70 years, prosthesis–patient mismatch was associated with impaired long-term survival ($P = .02$). Survival at 5 and 10 years was $61\% \pm 7\%$ and $28\% \pm 12\%$ for severe mismatch, $65\% \pm 3\%$ and $40\% \pm 5\%$ for moderate mismatch, and $73\% \pm 5\%$ and $46\% \pm 9\%$ for no mismatch. For patients greater than 70 years, prosthesis–patient mismatch did not affect long-term survival ($P = .25$). Survival at 5 and 10 years was $62\% \pm 5\%$ and $42\% \pm 6\%$ for severe mismatch, $62\% \pm 2\%$ and $30\% \pm 5\%$ for moderate mismatch, and $53\% \pm 4\%$ and $29\% \pm 5\%$ for absent mismatch.

Conclusions: After bioprosthetic aortic valve replacement, prosthesis–patient mismatch had a negative impact on late survival for patients less than or equal to 70 years of age, but for patients greater than 70 years of age, prosthesis–patient mismatch did not influence late survival.

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When aortic valve replacement (AVR) is being performed, it is generally accepted that putting a small valve into a large patient is suboptimal, but the degree to which prosthesis–patient mismatch (PPM) affects outcome in specific patient subgroups remains unclear. A handful of studies suggest that increased transvalvular gradients negatively affect left ventricular (LV) mass regression and long-term outcomes,^{1–4} whereas other large, multicenter studies demonstrate no impact of PPM on long-term survival.^{5–7} The magnitude to which varying degrees of PPM affect early

and late survival may depend on specific patient characteristics in addition to the ratio of valve to body size.^{2,3,8–10} In a previous report from our institution, multivariate analysis of patients undergoing AVR (mechanical or bioprosthetic) identified age and body surface area as important factors when evaluating the impact of PPM,⁸ whereas a recent study from Reul and colleagues⁹ documented the importance of LV dysfunction on outcomes with PPM. The purpose of the current investigation was to focus on patients undergoing bioprosthetic AVR to determine the impact of PPM on long-term survival in young patients versus older patients. Our hypothesis was that the impact of PPM on long-term outcome would be related to patient age, with younger patients more likely to have a negative impact from PPM.

PATIENTS AND METHODS

During a 15-year period (June 1992 to July 2007), 2085 patients underwent AVR at Washington University School of Medicine (Barnes–Jewish Hospital and Christian Hospital Northeast) by 22 different surgeons. Of these, 1399 (67%) underwent bioprosthetic AVR and are the subject of this analysis. Figure 1 demonstrates a shift toward bioprosthetic prostheses in the later years of the study. There were 818 (58%) men and 581 (42%) women with a mean age (± 1 standard deviation) of 71 ± 13 years (range, 19–95 years). Of these bioprosthetic recipients, 1187 (85%) were greater than 60 years of age, 881 (63%) were greater than 70 years of age, and 321 (23%) were greater than 80 years of age. Indications for AVR included stenosis (59%), regurgitation (13%), combined stenosis and regurgitation

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Abbreviations and Acronyms

AVR = aortic valve replacement
BSA = body surface area
CI = confidence intervals
EOA = effective orifice area
LV = left ventricular
OR = odds ratios
PPM = prosthesis–patient mismatch

(19%), and endocarditis (9%). A total of 60 (4%) patients previously underwent AVR and 154 (11%) previously underwent coronary artery bypass grafting. Concomitant coronary artery bypass grafting was performed in 643 (46%) patients with an average of 2.2 ± 1.1 grafts, and concomitant mitral valve repair or replacement was performed in 149 (11%) patients (64 repair, 85 replacement).

Ideally, the actual effective orifice area (EOA) would have been determined for each patient's prosthesis, but postoperative echocardiography was inconsistent throughout this retrospective series. Thus, estimated prosthetic EOA for each valve type and size was obtained from referenced normal valves.^{8,11,12} Mean body surface area (BSA) was 1.93 ± 0.26 m². Indexed EOA was defined as prosthetic EOA divided by BSA, and PPM was defined as severe (EOA/BSA < 0.65 cm²/m²), moderate (EOA/BSA between 0.65 cm²/m² and 0.85 cm²/m²), or absent (EOA/BSA > 0.85 cm²/m²).

Survival data were obtained for all patients during a 2-month closing interval ending September 2007 through interrogation of the Barnes–Jewish Hospital medical records database and the Social Security Death Index. Cumulative long-term follow-up totaled 5331 patient-years. Mean follow-up for all patients was 46 ± 40 months, and 813 (58%) patients were alive an average of 53 ± 39 months postoperatively. This study was approved by the Washington University School of Medicine Institutional Review Board, and informed consent and permission for release of information were obtained.

Data Analysis

Operative mortality included any death that occurred during the initial hospitalization or within 30 days of operation for discharged patients. Late survival data included death from all causes. Continuous data are reported as mean $\pm$ 1 standard deviation and were compared between groups by analysis of variance. Clinically important ratios are reported with 95% confidence limits. Actuarial survival estimates were calculated by the Kaplan–Meier method and were compared by the log–rank test. Variability of the actuarial estimates is expressed as $\pm$ 1 standard error of the mean. Multivariate analysis (stepwise backward regression) was used to determine the preoperative and intraoperative risk factors that were significant, independent predictors of PPM and death (SigmaStat 2.03; SPSS Inc, Chicago, Ill). Odds ratios (OR) are reported with 95% confidence intervals (CI), and regression coefficients for continuous variables are reported with standard error of the mean. Twenty-three variables were analyzed: age, year of operation, gender, hypertension, diabetes, pulmonary disease, cerebrovascular disease, peripheral vascular disease, chronic renal insufficiency, history of myocardial infarction, smoking history, congestive heart failure, ejection fraction, status (urgent, elective), ascending aortic aneurysm, endocarditis, New York Heart Association class, LV dysfunction (ejection fraction < 0.40), previous cardiac operation, concomitant coronary artery bypass grafting, concomitant mitral repair or replacement, BSA, and degree of PPM. We did not believe that it was important to specifically analyze the impact of the brand of valve implanted or prosthesis size on the incidence of PPM inasmuch as this would have represented a circular argument hampered by selection bias.

FIGURE 1. Numbers of bioprosthetic (solid circles) and mechanical (open circles) prostheses implanted in the aortic position between 1992 and 2007.

RESULTS

Patient Characteristics

For patients less than or equal to 70 years of age, PPM was severe in 62 (12%), moderate in 251 (48%), and absent in 205 (40%). For patients greater than 70 years of age, PPM was severe in 109 (12%), moderate in 451 (51%), and absent in 321 (37%). There was no difference in the distribution of PPM between age groups ($P = .50$). Important preoperative patient characteristics are summarized in Table 1. Multivariate analysis identified 5 factors to be independent predictors of severe PPM: (1) earlier operative year ($P < .001$, coefficient = -0.011 ± 0.002), (2) increased BSA ($P < .001$, 0.274 ± 0.033), (3) female gender ($P < .001$, OR = 2.4 [95% CI, 1.7–3.3]), (4) diabetes mellitus ($P < .001$, 2.7 [1.9–3.7]), and (5) emergency or urgent status ($P = .01$, 1.8 [1.2–2.8]). Severe or moderate PPM was less common in later years, potentially owing to the introduction of bioprostheses with a higher EOA or a change in surgical technique (Figure 2).

Operative Mortality

Operative mortality was $9\% \pm 1\%$ overall (124/1399 patients), but increased as the complexity of the procedure increased from 4% for an elective, nonendocarditis AVR to 20% to 22% for an AVR combined with a mitral valve procedure (Table 2). Operative mortality was $7\% \pm 2\%$ for patients less than or equal to 70 years of age (38/518) and $10\% \pm 2\%$ for patients greater than 70 years (86/881) ($P = .15$). For patients less than or equal to 70 years of age, operative mortality tended to be higher with severe PPM ($13\% \pm 8\%$)

TABLE 1. Patient characteristics

	No PPM	Moderate PPM	Severe PPM	<i>P</i> value
No. of patients	526	702	171	
Age (y)	70 ± 13	72 ± 12	71 ± 12	= .07
Patients greater than 70 y	321 (61%)	451 (64%)	109 (64%)	= .50
BSA (m ²)	1.87 ± 0.25	1.94 ± 0.25	2.09 ± 0.26	< .001
Female gender	214 (41%)	264 (38%)	103 (60%)	< .001
Diabetes mellitus	128 (24%)	174 (25%)	80 (47%)	< .001
Emergency/urgent status	43 (8%)	89 (13%)	31 (18%)	< .001

PPM, Prosthesis–patient mismatch; BSA, body surface area. Continuous variables are mean ± standard deviation. Groups were compared using analysis of variance or χ^2 test as appropriate. *P* values refer to the comparison among all three groups.

versus moderate PPM (7% ± 3%) or no PPM (6% ± 3%), but the difference did not reach statistical significance (*P* = .20). For patients greater than 70 years of age, there was no difference in operative mortality with severe PPM (10% ± 6%), moderate PPM (9% ± 3%), or no PPM (11% ± 3%) (*P* = .49). Multivariate analysis identified 5 factors to be independent predictors of operative mortality: (1) chronic renal insufficiency (*P* < .001, OR = 4.2 [95% CI, 2.8–6.5]), (2) peripheral vascular disease (*P* = .002, 2.3 [1.5–3.5]), (3) congestive heart failure (*P* < .001, 3.6 [2.2–6.0]), (4) simultaneous mitral valve procedure (*P* < .001, 3.4 [2.2–5.4]), and (5) emergency or urgent status (*P* < .001, 3.8 [2.4–6.1]).

Late Survival

Among the 1275 operative survivors, there were 586 late deaths. For all patients, PPM was not associated with im-

paired long-term survival (*P* = .65). Survival at 5 and 10 years was 61% ± 4% and 40% ± 6% for severe PPM (mean survival 92 months), 63% ± 33% and 33% ± 3% for moderate PPM (90 months), and 60% ± 3% and 35% ± 5% for no PPM (86 months) (Figure 3). To exclude patients with limited expected survival, survival analyses were repeated including only patients who survived greater than 12 months. Similarly, late survival was independent of the degree of PPM (10-year survival: 51% ± 7% severe PPM, 40% ± 3% moderate PPM, and 42% ± 6% no PPM; *P* = .30). Multivariate analysis identified 7 factors to be independent predictors of late death: (1) diabetes mellitus (*P* < .001, OR = 1.4 [95% CI, 1.1–1.8]), (2) chronic renal insufficiency (*P* < .001, 3.6 [2.5–5.2]), (3) peripheral vascular disease (*P* < .001, 1.8 [1.3–2.4]), (4) New York Heart Association class IV (*P* < .001, 1.5 [1.1–1.8]), (5) simultaneous mitral valve procedure (*P* = .002, 2.1 [1.5–3.0]), (6) advanced age (*P* = .002, coefficient = 0.006 ± 0.001), and (7) earlier operative year (*P* < .001, –0.054 ± 0.002).

For patients less than or equal to 70 years of age, PPM was associated with impaired long-term survival (*P* = .02). Survival at 5 and 10 years was 61% ± 7% and 28% ± 12% for severe PPM (mean survival 77 months), 65% ± 3% and 40% ± 5% for moderate PPM (92 months), and 73% ± 5% and 46% ± 9% for no PPM (98 months) (Figure 4). To determine whether higher levels of acuity were responsible for the difference in younger patients, we compared survivals between PPM groups excluding patients with endocarditis and emergency or urgent surgery. Similarly, for younger patients, PPM was associated with impaired

FIGURE 2. Impact of operative year on the incidence of severe and moderate prosthesis–patient mismatch (PPM) during bioprosthetic aortic valve replacement.

TABLE 2. Operative mortality based on the complexity of the operation

AVR only	6% ± 2% (40/661)
AVR only: elective	5% ± 2% (28/610)
AVR only: elective, nonendocarditis	4% ± 2% (25/566)
AVR, CABG	9% ± 2% (52/589)
AVR, MVR	22% ± 8% (21/95)
AVR, MVR, CABG	20% ± 11% (11/54)

AVR, Aortic valve replacement; MVR, mitral valve replacement; CABG, coronary artery bypass grafting.

No PPM	526	270	110	71	42	23
Moderate PPM	702	504	379	214	103	50
Severe PPM	171	124	90	46	31	17

FIGURE 3. Impact of prosthesis–patient mismatch (PPM) on late survival for all patients undergoing bioprosthetic aortic valve replacement. The numbers of patients at risk for each mismatch group are reported at 0, 2, 4, 6, 8, and 10 years.

long-term survival in elective, nonendocarditis patients (10-year survival: 22% $\pm$ 12% severe PPM, 39% $\pm$ 6% moderate PPM, and 47% $\pm$ 10%, no PPM; $P = .009$).

For patients greater than 70 years of age, PPM did not affect long-term survival ($P = .25$). Survival at 5 and 10 years was 62% $\pm$ 5% and 42% $\pm$ 6% for severe PPM (mean survival 96 months), 62% $\pm$ 2% and 30% $\pm$ 5% for moderate PPM (87 months), and 53% $\pm$ 4% and 29% $\pm$ 5% for absent PPM (77 months) (Figure 5). Similarly, when excluding endocarditis and emergency or urgent indications for surgery, long-term survival was independent of PPM in older patients (10-year survival: 43% $\pm$ 7% severe PPM, 30% $\pm$ 4% moderate PPM, and 29% $\pm$ 6%, no PPM; $P = .28$).

To determine whether a different cutoff age would yield dissimilar results with regard to the impact of PPM on survival, we repeated analyses with cutoff ages of 60 years

No PPM	205	101	46	29	26	10
Moderate PPM	251	170	122	80	33	21
Severe PPM	62	41	25	14	4	4

FIGURE 4. Impact of prosthesis–patient mismatch (PPM) on late survival after bioprosthetic aortic valve replacement in patients less than or equal to 70 years of age. The numbers of patients at risk for each mismatch group are reported.

No PPM	321	171	66	44	26	14
Moderate PPM	451	338	256	148	73	31
Severe PPM	109	86	66	46	28	15

FIGURE 5. Impact of prosthesis–patient mismatch (PPM) on late survival after bioprosthetic aortic valve replacement in patients greater than 70 years of age. The numbers of patients at risk for each mismatch group are reported.

and 80 years. For patients less than or equal to 60 years of age, PPM had a negative impact on survival (10-year survival: 25% $\pm$ 19% severe PPM, 26% $\pm$ 10% moderate PPM, and 62% $\pm$ 13%, no PPM; $P = .03$). However, for patients greater than 60 years of age, survival was independent of PPM (10-year survival: 41% $\pm$ 6% severe PPM, 33% $\pm$ 3% moderate PPM, and 32% $\pm$ 5%, no PPM; $P = .73$). For patients less than or equal to 80 years of age, PPM had a negative impact on survival, but to a lesser degree than with a 60 or 70 age cutoff (10-year survival: 40% $\pm$ 6% severe PPM, 37% $\pm$ 3% moderate PPM, and 42% $\pm$ 5%, no PPM; $P = .05$). As expected, for patients greater than 80 years of age, avoidance of PPM did not improve survival (10-year survival: 34% $\pm$ 15% severe PPM, 20% $\pm$ 5% moderate PPM, and 11% $\pm$ 7%, no PPM; $P = .01$). Looking specifically at patients in their seventies ($n = 560$), PPM did not affect survival (10-year survival: 44% $\pm$ 7% severe PPM, 34% $\pm$ 4% moderate PPM, and 39% $\pm$ 7%, no PPM; $P = .49$).

To minimize the potential impact of obesity on the incidence of PPM, we repeated the analyses replacing actual body weight with ideal body weight using the height-based formula of Devine as discussed by Pai and Paloucek.¹³ The incidence of severe and moderate PPM fell only slightly from 12% and 50% using actual body weight to 11% and 46% using ideal body weight. In addition, the impact of PPM on late survival remained important in younger patients ($P = .04$), but not in older patients ($P = .20$).

Comment

Previous studies have demonstrated improved LV mass regression with larger valves (increased EOA)^{9,14} and a higher incidence of congestive heart failure and diminished exercise capacity with smaller valves in young patients,^{3,15,16} but the impact of PPM on survival remains

unclear.^{1,4,6-8} Most previous studies have pooled together all patients undergoing AVR for statistical analyses, making it difficult to tease out the importance of mismatch in specific patient subgroups. One of the early major studies to examine the impact of PPM on survival was from the combined Toronto and Vancouver groups.¹ Rao and coauthors¹ reviewed 2154 patients who underwent bioprosthetic AVR and reported no difference in overall survival for the entire cohort, either with mismatch, defined as EOA/BSA less than $0.75 \text{ cm}^2/\text{m}^2$, or without mismatch. They did notice, however, a fall in freedom from valve-related death when mismatch was present. One of the arguments tempering the importance of their finding was verbalized by Eugene Blackstone during the discussion of his paper presented at the 80th Annual Meeting of The American Association for Thoracic Surgery in Toronto when he reminded us that it generally does not matter to patients whether they experience a valve-related or non–valve-related death.⁶ In an elegant multicenter study, Blackstone and colleagues⁶ used advanced statistical techniques to demonstrate no impact on long-term survival with PPM after AVR. More recent reports have performed subgroup analyses to elucidate differences in survival with PPM.^{8,9}

Recent work from our center and from the Ottawa group suggest that the magnitude to which varying degrees of PPM affect early and late survival is not uniform and depends on specific patient characteristics such as age, body size, and the preoperative degree of LV dysfunction.^{8,9} Reul and associates⁹ from Ottawa monitored 805 patients prospectively who underwent AVR between 1990 and 2003 and reported decreased survival with PPM in patients with LV dysfunction, but not in those with normal LV function. Their series included patients undergoing mechanical (54%), bioprosthetic (39%), and homograft (7%) AVR. Preoperative LV function was defined as normal (ejection fraction $\geq 50\%$) in 548 patients versus impaired (ejection fraction $< 50\%$) in 257 patients. They found that PPM, defined as EOA/BSA less than $0.85 \text{ cm}^2/\text{m}^2$, did not affect 10-year survival or clinical symptoms in patients with normal LV function. However, patients with PPM and LV dysfunction experienced not only decreased late survival at 10 years, but also a decline in freedom from heart failure symptoms and diminished LV mass regression compared with patients with LV dysfunction but no PPM. They concluded that patients with impaired LV function preoperatively represent a “critical population” in whom PPM should be avoided.

A previous report from our center noted that although PPM was important for “average-sized” and “large” patients, PPM was not important for “small” patients.⁸ Our earlier series examined 1400 patients undergoing mechanical (467 patients, 33%) or bioprosthetic (933, 67%) AVR. Patients were separated into 3 subgroups on the basis of body size, including “small” ($\text{BSA} < 1.7 \text{ m}^2$ in 20%), “average” (BSA between 1.7 and 2.1 m^2 in 56%), and “large”

($\text{BSA} > 2.1 \text{ m}^2$ in 24%). For small patients, PPM, defined as EOA/BSA less than $0.75 \text{ cm}^2/\text{m}^2$, did not affect survival with bioprosthetic or mechanical valves. For average-sized patients, PPM was associated with impaired survival with both bioprosthetic and mechanical valves. For large patients, PPM was associated with impaired survival with mechanical but not bioprosthetic valves. In the current report, PPM was found to affect survival after bioprosthetic AVR in patients younger than 70 years of age, but not patients older than 70 years of age. Combining the results of our two analyses, one can conclude the following: (1) It is important to ensure a favorable EOA/BSA ratio in younger patients undergoing AVR, especially if they are average-sized or large, by either considering a root-enlarging procedure¹⁷ or by implanting a prosthesis with favorable flow characteristics, and (2) PPM does not affect survival in older patients, especially if they are small, such that a “get in and get out” approach may be most appropriate in this patient subgroup.

Study Limitations

The current series included 1399 patients who underwent bioprosthetic AVR by 22 different surgeons over a 15-year period. Diversity in this series was immense, in both patient selection and surgical approach. These data represent an unedited, full-disclosure report of patients undergoing bioprosthetic AVR under all clinical circumstances—no patients were excluded. Some may consider such diversity a limitation to our ability to make conclusions on the basis of these data, but we believe that this diversity not only strengthens the findings, but also increases its applicability to the everyday surgeon and everyday patient. Obviously, this series involves a retrospective, nonrandomized comparison of surgical results, including selection bias as to which patients may have had their prostheses “upsized” to avoid mismatch preemptively. Multivariate analysis was used to help account for selection bias and other confounding risk factors, but selection bias can never be eliminated completely in a retrospective review, regardless of the complexity of the statistical manipulations used for such means. Finally, the current report focused only on survival and did not address late functional state, LV mass regression, or other clinical measures. Unfortunately, postoperative echocardiographic imaging was not consistent in our experience and follow-up was performed many years after the procedure after many patients had died.

In summary, the current report demonstrates that PPM is an age-dependent phenomenon. PPM had a negative impact on survival in young patients, but its impact in older patients was minimal. For patients less than or equal to 70 years of age, the surgical focus should be to ensure a favorable EOA/BSA ratio and avoid PPM with all valves. For patients greater than 70 years of age, PPM is not important for long-term survival, such that a surgical approach that minimizes short-term risk may be most appropriate.

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