

Valve Prosthesis-Patient Mismatch: Clinical Implications in Japanese Patients

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Introduction

Aortic valve replacement (AVR) improves survival in patients with severe aortic stenosis (AS). Following recent advances in Doppler echocardiography, detailed evaluation of results after AVR is now based not only on the degree of alleviation of symptoms but also the degree of functioning of the prosthetic valve and the heart after surgery. Selection of a prosthetic valve is now viewed as an important factor determining postoperative cardiac function and improvement of patient quality of life (QOL). When dealing with a small aortic annulus, which is often seen in patients with AS, the implanted prosthesis size is particularly important. It has been reported that when a prosthesis too small for the body size was used for AVR, early and long-term operative results were worsened by prosthesis-patient mismatch (PPM). On the other hand, there are many reports of lack of clinical problems following AVR using small sized valves. The latter view appears to be predominant in Japan. When selecting a prosthetic valve for Japanese patients, whose body size is in general small, will avoidance of PPM improve outcome or have no effect on postoperative results?

Prosthesis-Patient Mismatch

PPM occurs when the effective orifice area (EOA) of an artificial valve is inadequate for the recipient. PPM can result in persistent left ventricular (LV) outflow obstruction, which increases LV work and reduces left ventricular mass regression, with presumed shortening of lifespan.

Blais et al.¹⁾ proposed a definition of PPM. PPM was defined as not clinically significant if the indexed EOA (IEOA), calculated by dividing the EOA by the body surface area (BSA), was $>0.85 \text{ cm}^2/\text{m}^2$, as moderate if it was

>0.65 and $0.85 \text{ cm}^2/\text{m}^2$, and as severe if it was $0.65 \text{ cm}^2/\text{m}^2$. These investigators concluded that, like other known risk factors, PPM was a strong predictor of short-term mortality. They also showed that, unlike other risk factors, PPM could be avoided with the use of a prospective strategy at the time of operation. Rao et al.²⁾ examined the results for 2,981 patients after stented bioprosthesis insertion and concluded that PPM significantly increased both early and late valve-related mortalities. They recommended the use of valves with an IEOA larger than $0.75 \text{ cm}^2/\text{m}^2$.

However, the effects of PPM are still controversial. Hanayama et al.³⁾ examined the results of AVR in 1,129 cases, using a definition of PPM of IEOA less than $0.6 \text{ cm}^2/\text{m}^2$, and found no significant difference between the PPM group and non-PPM group in terms of regression of the LV mass index (LVMI), 7-year survival rate, or improvement in New York Heart Association (NYHA) functional class. They concluded that PPM did not influence LVMI regression or intermediate-term survival. Blackstone et al.⁴⁾ examined the results of AVR carried out at 9 facilities on 13,258 patients, using indexed internal prosthesis orifice area as an indicator, and concluded that prosthesis-patient size mismatch affected neither intermediate- nor long-term survival. Thus, even in Western countries, in studies involving large number of cases, conclusions drawn concerning the impact of PPM differ greatly among reports.

Views Concerning PPM in Japan

Most papers published in Japan on this topic have addressed the relationship between the manufacturer's labeled size of prosthetic valves and postoperative outcome. Most of such reports state that no problem occurred following AVR with small size valves. According to one report,⁵⁾ a large pressure gradient remained across the 19-mm prosthesis (over 40 mmHg) after surgery, but significant regression of LVMI occurred and significant improvement was noted in NYHA functional class and QOL. The report thus concluded that 19-mm valves were fa-

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avorable. According to another report,⁶ 19-mm valves were acceptable if used for patients with a BSA less than 1.45 m².

Since many of the patients for whom 19-mm valves are used have a small BSA, PPM is unlikely to occur, and even if PPM does occur in such patients, the impact of PPM will probably be small since many of them are elderly and have limited daily activities. However, the numbers of patients analyzed at each facility in these studies were small, and follow-up periods were short. In addition, in some reports, postoperative LVMI was much larger than normal although the degree of regression of LVMI was statistically significant.⁶

Analysis of Our Cases

Defining PPM using a criterion of IEOA less than 0.85 cm²/m², we examined the results of AVR for AS.⁷ The 150 cases in which calculation of IEOA was possible were divided into a PPM group (n=71) and a non-PPM group (n=79). The freedom from valve-related events at 10 years did not differ significantly between the PPM group (67.7±9.7%) and the non-PPM group (70.9±5.8%). Although the freedom from cardiac-related death at 10 years was slightly lower in the PPM group (61.9±13.8%) than in the non-PPM group (87.5±4.1%), this difference was not statistically significant. The pressure gradient across the prosthetic valve was slightly higher in the PPM group (37±15 mmHg) than in the non-PPM group (32±15 mmHg). LVMI exhibited significant regression in both groups, though regression was greater in the non-PPM group (-30±25%) than in the PPM group (-20±20%). Thus, operative results were favorable irrespective of the presence/absence of PPM, though LVM regression was greater in patients free of PPM.

Issues for the Future

The lack of major impact of PPM on early or late survival does not clearly indicate that PPM is without effects on other major indices of clinical outcome. Tasca et al.⁸ recently pointed out that, following AVR for pure AS, the extent of regression of LV hypertrophy was significantly less in patients with PPM. There is no doubt that a large pressure gradient remains across the pros-

thetic valve in patients with PPM. Poor regression of LV hypertrophy in patients with PPM may be reflected in differences in long-term outcome of surgery. If a larger valve, tailored to body size, is inserted in patients with high daily activity levels, hemodynamics may be improved to a greater degree, and the benefits of AVR may be greater. However, it is very difficult to prove this assertion.⁹ It is desirable to examine in detail, in many cases, whether the use of prosthetic valves smaller for body size (i.e., with PPM) is also a risk factor for poor prognosis in Japanese patients, whose body size is in general smaller than that of Western patients.

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