Review

Patient-Prosthesis Mismatch: The Japanese Experience

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The concept of patient-prosthesis mismatch (PPM) was defined as existing "when the effective prosthetic valve area, after insertion into the patient, is less than that of a normal valve". However, based on the correlation between the mean transvalvular pressure gradient and the corrected effective orifice area (EOA), PPM is currently defined as an EOA corrected by a body surface area (BSA) of ≤0.85 cm^2/m^2. The surgical procedure will differ for each patient, not only because of variations in the size of the aortic annulus, but also because of the patient's age, sex, level of activity, level of motivation, and complications. However, minimizing the risk of PPM must always be considered by selection of appropriate surgical strategies, including aortic root enlargement, use of a supra-annular or high performance prosthesis, and the use of a stentless bioprosthesis, aortic homograft, or pulmonary autograft. We reviewed our results for aortic valve replacement (AVR) for 1991-2002, when we routinely performed aortic root enlargement in patients >65 years old, while supra-annular implantation of a bioprosthesis was done in patients ≥65 years old with a small aortic annulus. We discuss our present strategy after the introduction of a new high performance prosthesis, since the EOAs are dramatically increased. (Ann Thorac Cardiovasc Surg 2006; 12: 159–65)

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

Introduction and Review

Since the invention and improvement of artificial valves, the treatment of valvular heart disease has changed dramatically. Aortic valve replacement (AVR) is performed to control the symptoms of heart failure, by reducing the pressure overload, volume overload, or both on the left ventricle. Elimination of the transvalvular pressure gradient is important and the gradient needs to be reduced to around zero to allow remodeling of the failed heart. Rahimtoola[1] first described the concept of patient-prosthesis mismatch (PPM), which was defined as existing "when the effective prosthetic valve area, after insertion into the patient, is less than that of a normal valve." In fact, most of the prosthetic valves available have a smaller orifice area than that of the normal native aortic valve, which means that the result may be suboptimal in many patients. The normal aortic valve area is 3.0-4.5 cm^2, and this is rarely achieved with bioprosthetic or mechanical valves. PPM occurs when the effective orifice area (EOA) of a prosthetic valve is too small relative to the patient's body size. Eichinger[2] reported that mismatch occurred in 100% of patients receiving a 19-mm valve and concluded that neither bovine nor porcine stented bioprostheses measuring 19 mm in diameter could be recommended, except in patients with a high risk of aortic root enlargement or those with such a small body surface area (BSA) that mismatch did not occur. Although this conclusion is not considered to be clinically realistic at present, mismatch can occasionally be a severe problem and patients may even show deterioration of symptoms and/or hemodynamics after AVR. Based on the correlation between the mean transvalvular pressure gradient and the corrected EOA,

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PPM is currently defined as an indexed EOA (iEOA) correced by a BSA of ≤0.85 cm^2/m^2.[3,4] When iEOA is >0.85, there is a relatively small (<10 mmHg) and acceptable residual transvalvular pressure gradient. Moderate PPM is defined as an iEOA >0.65 and ≤0.85, while severe PPM is defined as an iEOA ≤0.65. Moderate and severe PPM increase the short-term mortality rate (operative death) by 2.1-fold and 11.4-fold, respectively, compared with the rate in patients without PPM.[5] However, Sommers and David,[6] and Carrier[7] reported that the operative mortality rate after aortic annular enlargement was twice that after standard AVR. In patients with a small aortic annulus, either annular enlargement or the use of one of the hemodynamically improved new prosthetic valves may be required to minimize the transprosthetic gradient. Recently, patients who require AVR are becoming older and thus have more risk factors and complications. In patients ≥65 years old with a small BSA, aortic annular enlargement cannot be done due to the increased risk of such surgery, but a high-performance prosthesis can be selected with a small outer diameter and large iEOA. We have previously reported that the 19-mm Carpentier-Edwards Perimount pericardial bioprosthetic valve (CEP valve: model 2900; Edwards Lifesciences, Irvine, CA) is reliable when used in elderly Japanese patients with a small aortic annulus.[8] We have shown that the mean pressure gradient measured in the catheter laboratory was only 12.0±4.9 mmHg after implantation of a 19-mm CEP valve in patients with a mean BSA of 1.39±0.11 m^2. Based on these findings, we have been freely selecting the 19-mm CEP valve for elderly patients with a BSA of <1.45 cm^2. In addition to the poor short-term outcome, patients with PPM will achieve less symptomatic improvement after AVR because residual stenosis leads to less improvement of left ventricular hypertrophy. Although some authors have found no influence of a small prosthesis on late survival, the existence of PPM is still believed to adversely affect long-term survival.[5,9-12]

Making an appropriate choice with regard to the prosthesis is very important. The surgical procedure will differ for each patient, not only because of variations in the size of the aortic annulus, but also because of the patient's age, sex, level of activity, etiology, expected survival time, level of motivation, and complications. Minimizing the risk of PPM must always be considered by selection of appropriate surgical strategies, including aortic root enlargement, use of a supra-annular or high performance prosthesis, and the use of a stentless bioprosthesis, aortic homograft, or pulmonary autograft. Rao et al.[10] have indicated that the iEOA calculated at the time of surgery is an independent predictor of postoperative mortality. Patient values are easily calculated from the EOA reference values for the type and size of prosthesis being implanted. The projected iEOA calculated at the time of operation can accurately predict whether or not there will be PPM and a postoperative transvalvular pressure gradient.[11] We should also be aware that the EOA sometimes decreases further *in vivo* because of tissue ingrowth at the outflow tract after surgery.

Our Clinical Experience

Based on our previous study that demonstrated less improvement of a left ventricular mass after AVR with a 21-mm Bjork-Shiley valve,[13] our strategy for aortic valve disease was changed to performing AVR without using a 19- or 21-mm St. Jude Medical (SJM) standard valve (St. Jude Medical, Inc., St. Paul, MN) in patients <65 years old. We therefore routinely performed aortic root enlargement to allow implantation of a 23-mm SJM valve in patients <65 years old, while supra-annular implantation of a bioprosthesis (CEP valve) was done in patients ≥65 years old with a small aortic annulus. This option was chosen because elderly patients are usually smaller and perform less physical activity. However, younger patients with a small aortic orifice are now becoming rare and the introduction of new high-performance (larger EOA) valves has also reduced the need for aortic root enlargement.

1. Results for 1991-2002

During this period, 181 adults underwent isolated or combined AVR at our institution. The mean age of the patients was 57.2±13 years (range: 16-85 years), and they included 155 men, and 26 women. Fifty-three patients underwent AVR with a CEP, while the other 128 patients received a SJM standard mechanical valve (St. Jude Medical, Inc., St. Paul, MN). Concomitant surgical procedures were performed in 47 of the 181 patients, including coronary artery bypass grafting in 4 (2.2%) and mitral valve replacement in 39 (21.5%). Twenty-four patients (13.3%) required enlargement of a small aortic annulus, with Manouguian's[14,15] double valve replacement being selected for 18 patients and Nicks[16] procedure being done in 6 patients.

Outcome[17]

The average 10-year actuarial survival rate (including

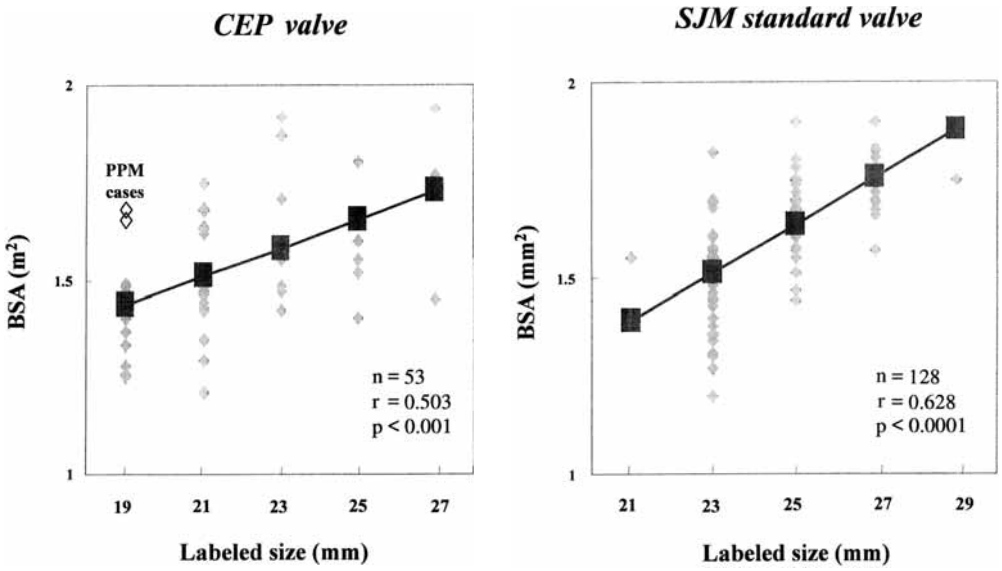


Fig. 1. Correlation between labeled size of prosthesis and body surface area (BSA).
CEP, Carpentier-Edwards Perimount; SJM, St. Jude Medical; PPM, patient-prosthesis mismatch.

operative mortality) was respectively 83.5±6.5%, 87.5±6.8%, and 91.9±3.2% for patients with a CEP prosthesis, SJM standard valve without annular enlargement, and SJM standard valve with annular enlargement. There were no significant differences among the three groups (p=0.2). The incidence of thromboembolism, prosthetic valve endocarditis, and reoperation was similar in these groups (always <1% for each category), and there were no significant differences among the three groups in the occurrence of thromboembolism, prosthetic valve endocarditis, and reoperation. These results demonstrated that annular enlargement improved the long-term outcome and that our criteria for selection of the valve and surgical procedures for AVR were appropriate.

Relation between BSA and prosthesis size[17]
The prosthetic valve size was closely correlated with the BSA of the patient for both standard SJM and CEP valves (Fig. 1). This indicated that the choice of prosthesis size and indications for performing enlargement of a small annulus were generally appropriate to obtain a reasonable EOA.

Incidence of PPM[17]
PPM was defined as an iEOA ≤0.85 cm^2/m^2, and the iEOA value was calculated as the published *in vivo* EOA value[11,18] divided by the BSA. Twenty-four patients aged <64 years (18.8%) had a small aortic annulus and received Manouguian's[14,15] double valve replacement (n=18) or the Nicks[16] procedure (n=6) for annular enlargement. None of the patients were implanted with a standard SJM valve <19 mm in size or had an iEOA ≤0.85 cm^2/m^2. Two of the 53 patients aged ≥65 years (3.8%) developed PPM. Both of them underwent AVR with a 19-mm CEP valve (Fig. 1).

Figure 2 displays iEOA data for the patients who underwent Manouguian's[14,15] procedure with a 23-mm SJM standard valve. All of the patients had an iEOA >0.85 cm^2/m^2 and avoided PPM. If a 23-mm SJM standard valve had not been implanted instead of a 19-mm valve in 18 of our patients after the enlargement of a small annulus by Manouguian's[14,15] procedure, all of them would have developed PPM after AVR. The results obtained with the 19-mm standard SJM, hemodynamic plus (HP), and Regent® valves are also shown in these patients.

2. Recent results
New high performance prostheses have been developed for implantation in a small aortic annulus and have contributed to avoiding PPM without the need to perform aortic annular enlargement. Figure 2 demonstrates the possibility of avoiding PPM by choosing high-performance mechanical valves such as 19-mm SJM HP or 19-mm SJM Regent® with a small outer sewing ring diameter and larger orifice area (Table 1). On the basis of these data, our procedure for patients with a small aortic root

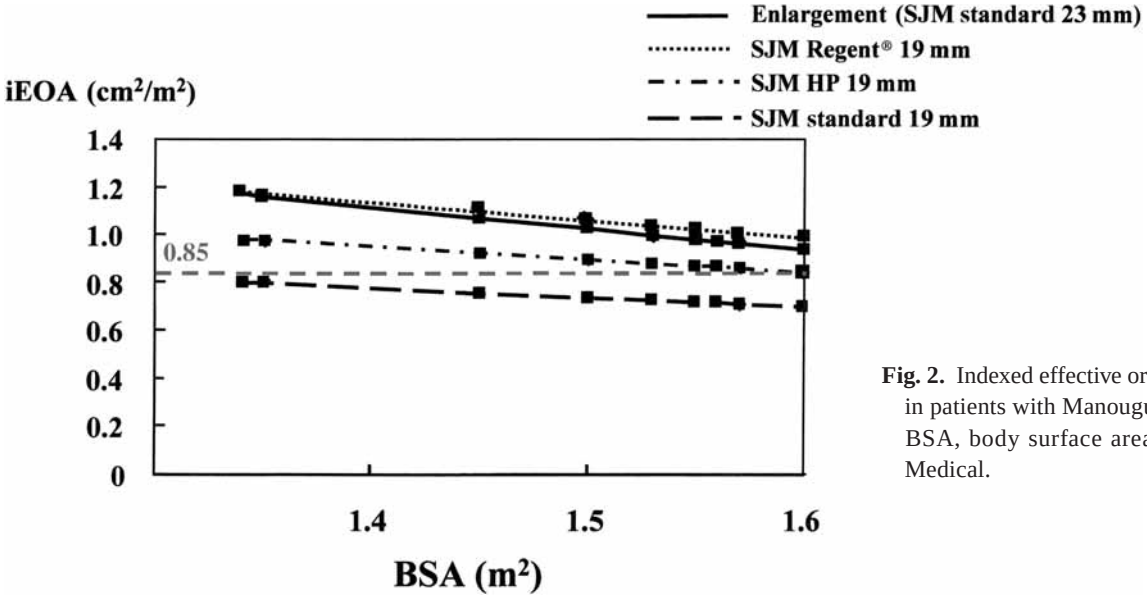
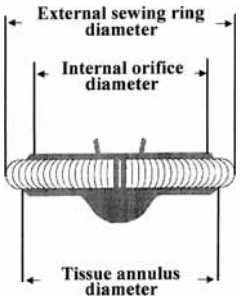


Fig. 2. Indexed effective orifice area (iEOA) in patients with Manouguian's procedure. BSA, body surface area; SJM, St. Jude Medical.

Table 1. Geometry and EOAs of the SJM valves

Model	External sewing ring diameter (mm)	Tissue annulus diameter (mm)	Internal orifice diameter (mm)	Geometric orifice area (cm^2)	Effective orifice area (cm^2)
SJM					
Standard 19	22.2	19.0	14.7	1.63	1.0
HP 19	23.6	19.2	16.7	2.06	1.3
Regent® 19	22.6	19.4	17.8	2.36	1.7
Standard 23	26.2	23.0	18.5	2.55	1.6

EOA, effective orifice area; SJM, St. Jude Medical; HP, hemodynamic plus.



has been switched to performing simple AVR with the selection of a high performance mechanical valve. In elderly patients, the Mosaic valve (Medtronic Inc., Minneapolis, MN) is another option for a small annulus (19 mm), because implantation is easier (smaller sewing ring diameter) and it has almost the same effective orifice area as a 19-mm CEP valve (Table 2).

Geometry of Artificial Valves and EOA

The valves that are available and commonly used in Japan are listed in Tables 1-3 and their geometry is compared. It can be seen that the labeled valve size does not represent the tissue annulus diameter, with some exceptions. In addition, the diameter of the external sewing ring is always larger than the labeled size and its thickness differs between valves. This is one reason that the correct valve has to be selected by using the sizer provided by each manufacture. It also means that comparing hemodynamic results between different prostheses based on the labeled valve size is meaningless. The adjusted geometric orifice area (GOA) is mentioned by manufacturers and may be a good parameter. However, Pibarot et al.[11] found that the adjusted GOA showed a poor correlation with the postoperative pressure gradient and concluded that it should not be used for prediction of PPM, unlike the iEOA. EOA is a physiologic variable and represents the cross-sectional area occupied by transvalvular flow, while the GOA represents simply the geometric area of the valve orifice and ignores the influence of valve leaflets that always occupy part of the orifice.

As demonstrated in Table 1, the 19-mm Regent® SJM (most recently introduced) has a larger EOA than the 19-mm standard and HP valves, and its EOA is almost the same as that of a 23-mm SJM standard valve. Thus, choosing a high performance valve allows a larger EOA to be readily obtained. Figure 2 showed the iEOAs of our patients, if they received a 19-mm SJM Regent® valve for

Table 2. Geometry and EOAs of bioprosthetic valves

Model		External sewing ring diameter (mm)	Tissue annulus diameter (mm)	Internal orifice diameter (mm)	Geometric orifice area (cm^2)	Effective orifice area (cm^2)
CEP	19	26	19	18.0	2.54	1.2
	21	29	21	20.0	3.14	1.3
Mosaic	19	25	19	16.5	ND	1.2
	21	27	21	18.5	ND	1.3

EOA, effective orifice area; CEP, Carpentier-Edwards Perimount; ND, no available data.

Table 3. Geometry and EOAs of mechanical valves

Model		External sewing ring diameter (mm)	Tissue annulus diameter (mm)	Internal orifice diameter (mm)	Geometric orifice area (cm^2)	Effective orifice area (cm^2) (No)
Carbomedics TopHat	19	23.7	18.8	14.7	1.60	0.9
	21	26.1	20.8	16.7	2.10	1.3
On-X®	19	23.6	19.0	17.4	2.00	1.5
	21	26.0	21.0	19.4	2.53	1.7
ATS AP	18	23.6	18.2	16.8	2.02	1.5
	20	25.5	20.2	18.8	2.56	1.7

EOA, effective orifice area.

AVR. The results suggest that there would have been no need for aortic root enlargement in this series if the Regent® valve had always been available. The 19-mm On-X® valve (Medical Carbon Research Inst. Austin, TX) or the 18-mm ATS AP valve (ATS Medical Inc., Minneapolis, MN) would be other choices to prevent PPM in patients with a narrow aortic root. After we reported on the excellent hemodynamic performance of the 19-mm CEP valve in small elderly patients, bioprosthetic valves have been used more often recently. Because of its smaller external sewing ring and the shape of the stent, the 19-mm Mosaic valve is easier to implant in a small orifice and it might be another option instead of the CEP valve. Although PPM would be a rare phenomenon in Japanese patients with the CEP and Mosaic valves, a high-performance mechanical valve like the Regent® might be selected if the projected iEOA was <0.85 even in an elderly person. The alternatives selected by some surgeons to prevent PPM include stentless valve, homografts, or pulmonary autografts. The Carpentier-Edwards Perimount Magna bioprosthesis (Edwards Lifesciences, Irvine, CA) was recently introduced in Europe and the USA. It has a larger EOA than the CEP, and will be a new option after it is marketed in Japan.

The EOAs of stentless valves are listed in Table 4. Despite the technical problems of implantation, the larger EOA is theoretically very attractive. The EOA of the stentless SJM Toronto SPV valve was reported to be excellent after surgery and also increased over time. In prospective randomized trials, Cohen et al.[19] did not detect any hemodynamic differences between the SJM Toronto SPV and a stented valve (CEP valve), but de Arenaza showed the superiority of a stentless valve with respect to iEOA and peak aortic flow velocity, although the improvement of left ventricular mass was similar (Freestyle vs. Mosaic).[20]

Table 4. Normal reference values of EOAs for stentless valves

Prosthetic valve size	19 mm EOA (cm^2)	21 mm EOA (cm^2)
Medtronic freestyle	1.15	1.35
SJM Toronto SPV	NA	1.30
Prima Edwards	0.80	1.10

EOA, effective orifice area; SJM, St. Jude Medical; NA, not available.

Conclusion

Recently, aortic valve stenosis has become the leading type of valvular heart disease in Japan, and such stenosis is no longer caused by rheumatic fever but is due to aging. Aortic regurgitation is less common and is seen in younger patients. Accordingly, the age of candidates for AVR has

increased markedly in recent years, so that the mean age of patients undergoing AVR at our department was 66 years in 2002 vs. 44 years in the 1980s.

Since 1995, our first choice for AVR in patients ≥65 years old has been a bioprosthesis (CEP valve) because of the excellent long-term results obtained in Western contries.[21-29] We have also obtained a 10-year survival rate of 83.5±6.5% and 100% freedom from structural valve failure. Nevertheless, the risk of eventual tissue valve failure still exists and longer follow-up may be necessary to prove the value of these prostheses in a country like Japan with a long life expectancy.

In our series, PPM only occurred in 4% of the patients who received a 19-mm CEP valve. We previously reported that the 19-mm CEP valve is a reliable option for elderly Japanese patients with a small aortic annulus,[8] and the present study confirmed the suitability of this valve for patients ≥65 years old, not only with regard to a good mid-term outcome but also for avoiding PPM. Patients with a bioprosthetic valve do not appear to require anticoagulant therapy, which is usually essential for those with mechanical valves, and this is an attractive point in elderly patients. The incidence of thromboembolic episodes was quite low (0.46%) in our series. If a 19-mm CEP valve is difficult to insert, a 19-mm Mosaic valve might be considered or a stentless valve could be another choice. The EOA values of stentless valves are theoretically superior, but the actual results after implantation have varied. The selection of valve size and the operative procedure (full root or subcoronary) are considered to influence the actual results. Since the durability of stentless valves has not yet been demonstrated, careful consideration is required. In rare cases, a 19-mm bioprosthetic valve cannot be implanted, and a high-performance mechanical valve (17-mm SJM Regent® or 18-mm ATS AP) might be used if annular enlargement is not preferred.

For patients <65 years old, mechanical valves were the first choice in our series. There would have been mismatch in 14% of our patients who underwent AVR if we had not performed aortic annular enlargement to allow the implantation of a standard mechanical valve. By performing aortic annular enlargement using the Manouguian et al.[14] and Nicks et al.[16] procedures, we could safely avoid PPM.[15]

However, most of the patients who required annular enlargement had rheumatic heart disease (usually associated with mitral stenosis), which we have seldom encountered recently. Thus, the need for annular enlargement has decreased dramatically in our clinical practice. When it is necessary, the safety of the Manouguian's[14,15] procedure has been confirmed by a 10-year actuarial survival rate similar to that of patients receiving simple AVR with CEP or SJM valves.[15,17]

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