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Operative Management – Patient-Prosthesis Mismatch

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1. Introduction

The main objective of aortic valve replacement (AVR) is to relieve left ventricular (LV) burden and normalized LV mass (LVM). During AVR, many surgeons make final decision to select the size of the prosthetic valve based on intraoperative measurement. It is ideal to place an aortic prosthesis that is appropriately sized to the patient. However, this is not always possible owing to insufficient aortic annular dimensions. Patients receive a prosthesis that is too small in relation to their body size have persistent abnormally high gradients across the valve and may even show deterioration of symptoms and hemodynamics after AVR. Rahimtoola 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" [1]. The optimal prosthetic valve should have several characteristics, including a sufficiently large effective orifice area (EOA) with a reduced transvalvular pressure gradient around zero, long-term durability, and anticoagulability. There is no optimal, commercially available prosthesis. The normal aortic valve has 3.0-4.5 cm^2 of EOA, but this is rarely achieved with present commercially available prostheses, which means that the result of AVR may be suboptimal in many patients. In general, PPM is considered to be present when an indexed EOA (IEOA) adjusted for body surface area (BSA) is <0.85 cm^2/m^2 [2-4]. Although, many studies have shown that PPM adversely affects survival and postoperative cardiac function [2-4], many studies contradict these findings [5-12]. Thus, there is considerable controversy regarding the effects of PPM on survival and postoperative recovery of cardiac functions. Patients with a small aortic annulus is still challenging and usually require several surgical measures to minimize the PPM, such as use of supra-annular implantation technique, high-performance prostheses, aortic annular enlargement, or the Ross procedure. The surgical strategy is determined based on the individual patient's conditions, including the size of the aortic annulus, patient's age, BSA, preoperative activity level, and ventricular function. Avoiding the risk of severe PPM defined as an IEOA <0.70 cm^2/m^2, which may prevent symptom resolution and regression of left ventricular hypertrophy and may adversely affect late cardiac events and survival, must always be considered by taking appropriate surgical strategies, but, it is more important

to consider whether the benefits of avoiding PPM overcome the drawbacks of other complicated measures in each individual patient.

2. General consideration

2.1 Left ventricular-aortic pressure gradients

Gradients are minimal after AVR with aortic and pulmonary autograft or allograft but are present after mechanical or bioprosthetic AVR in virtually all patients. Their magnitude varies greatly, determined primarily by the characteristics of the prosthesis itself, the size of the prosthesis relative to the size of the patient, and the cardiac output (whether the study was done during rest or exercise). Smaller-sized stented bioprostheses and mechanical prostheses can result with residual transvalvular gradients. In clinical, conventional mechanical prostheses and bioprostheses larger than the 21-mm size can provide satisfactory performance in most adults. On the other hand, the small resting gradients associated with conventional 19-mm prostheses may become 30 to 50 mmHg during periods of increased cardiac output. However, in patients with small body size, when the patient's body surface area is less than 1.5 m^2, (with their smaller cardiac output) conventional 19-mm devices may perform satisfactorily. The relationship between peak left ventricular-aortic gradient and prosthesis size was mainly dependent on the patient's BSA.

3. Definitions of PPM

In general, PPM is considered to be present when an IEOA is <0.85 cm^2/m^2 [2-4]. IEOA has been reported as an index that correlates with the severity of PPM [2-6]. In present chapter, mild to moderate PPM is defined as when an IEOA of ≥0.70cm^2/m^2 and <0.85 cm^2/m^2, and severe PPM is defined as when an IEOA of less than 0.69 cm^2/m^2.

3.1 Effect of PPM on valve related event and survival

Blais et al. reported the results of 2981 patients who underwent AVR with a stented bioprosthesis [3]. According to the literature, patients with an EOAI <0.75 cm^2/m^2 was a significant risk factor for increased operative mortality and valve related deaths during the follow-up period. Medalion et al. reported the long-term results of 892 patients who underwent AVR [7]. Moderate PPM had no influence on survival, but advanced age, chronic obstructive pulmonary disease, chronic renal failure, and smoking were significant risk factors. Urso et al. showed improvement in postoperative NHYA class and regression of LVMI during long-term follow-up in patients who underwent AVR with a 19-mm mechanical valve [12]. We also showed that PPM with an EOAI ≥0.75 cm^2/m^2 but <0.85 cm^2/m^2 has no effect on operative, short-term, and long-term survival and the effect of PPM with an IEOA <0.75 cm^2/m^2 on survival appeared to decrease over time [11]. Surviving patients with an IEOA <0.75 cm^2/m^2 showed good long-term survival. Although, the effect of PPM on postoperative valve related event and late survival could not be definitively determined due to lack of a radomised large population and long-term follow-up study, in some patients with mild to moderate PPM could be tolerable in patients with preserved LV function without any impact on overall survival.

3.2 The significance of IEOA

Recently, aortic valve stenosis has become the leading type of valvular heart disease in developed countries, and such stenosis is no longer caused by rheumatic fever but is due to aging. Consequently, the age of candidates for AVR have increased markedly and have more risk factors and complications. These findings suggest that surgery becomes more complicated. Moreover, most patients with aortic stenosis have calcific aortic valve sclerosis, which typically becomes clinically significant in seventh or eighth decade of life. Therefore, the incidence of patients with a small aortic annulus with calcification is also increasing, especially in Japan. This may result in increasing number of patients with PPM after AVR. Some previous studies have reported that the risk factors for AVR patients with aortic stenosis developing PPM postoperatively are female gender and advanced age [2-4, 10]. Aortic annular enlargement procedures should achieve the optimal measurements to prevent PPM, but these procedures lengthen the cardiopulmonary bypass and cross clamp times, increasing the surgical risks. Several reports demonstrated that aortic annular enlargement is related to increased operative mortality [15]. In such circumstance, surgery should be restricted to the minimum necessary. The EOA of commercially available prosthetic valves was only 49 - 66% that of a normal aortic valve [1-9]. PPM patients have significantly higher persistent pressure gradients across the valve prosthesis than patients without significant PPM. It is well recognized that the transvalvular pressure gradient increases exponentially with a decrease in prosthetic valve EOA [4]. A small decrease in EOA results in a relatively large increase in the transvalvular pressure gradient. Several reports demonstrated that PPM increases LV workload due to the residual pressure gradient, which prevents regression of LVM and increases operative mortality and valve-related events [1-6]. The definition of the threshold degree of severe PPM that must be avoided due to an adverse effect on survival is important. Tasca et al. reported that there was a positive correlation between LVM and IEOA, and patients with an IEOA <0.80 cm^2/m^2 showed inadequate regression of LVM after AVR. Moreover, an inadequate regression of LVM positively affected the rate of valve-related events after AVR and patients with an IEOA <0.70 cm^2/m^2 showed regression of indexed LVM; LVMI (LVM adjusted for BSA), but LVMI increased again during the follow-up period [6]. This phenomenon suggests that AVR contributes to decreasing the pressure gradient across the valve to less than that of the preoperative state. Decreased workload to the left ventricle can lead to regression of LVMI in the postoperative acute phase. However, LV workload remains high after AVR due to persistent PPM, which may increase LVM again during the follow-up period. On the other hand, many studies have been reported that mild to moderate PPM appears to have little or no effect on postoperative recovery of cardiac function, late cardiac events and survival[5-12]. Such degree of PPM may be acceptable in not only elderly patients but also younger patients[7]. We also reported that the postoperative peak pressure gradient across the prosthesis was significantly higher in patients with PPM than in patients without PPM, but postoperative cardiac function, including LV function, LVMI, and NYHA class, improved in all patients despite having PPM; the degree of improvement in cardiac function in patients with PPM compared favorably to that in patients without PPM [11]. Avoiding the risk of severe PPM, must always be considered, but, it is more important to consider whether the benefits of avoiding PPM overcome the drawbacks of other complicated measures in each individual patient. There is controversy about

applying a unified standard for avoiding PPM to every patients requiring AVR regardless of their age and preoperative condition. The current perception of PPM based on the value of IEOA may need to be reconsidered for select populations. Based on these findings, IEOA ranges from 0.70 cm²/m² to 0.75 cm²/m² may be a lower tolerable threshold limit [5-11].

3.3 Optimal surgery for patients with advanced age

In general, elderly patients have decreased physiological reserve, and unexpected bleeding could occur during the operation due to tissue fragility, which may result in difficulty achieving hemostasis. In such circumstances, surgery should be restricted to the minimum necessary to obtain improved performance. Elderly patients with a short stature, in a relatively inactive, if the patient's LV function remains preserved, then it is not necessary to replace the valve with a larger prosthesis to ensure an IEOA ≥0.85 cm²/m², or even to perform additional aortic root enlargement. PPM with an IEOA <0.85 cm²/m² and ≥0.70 cm²/m² could be tolerable without any impact on overall survival[5-11].

4. Introduction of high-performance prostheses

4.1 Prosthetic performance

In contrast to other risk factors, PPM can be largely avoided with the use of a prospective strategy at the time of operation. Determine patient's BSA and estimate the minimum required prosthetic size for patient. Confirm the indicated sizer pass through the patient's aortic annulus. Currently, high-performance mechanical or bioprosthetic valves that have a larger EOA than those of corresponding labeled sizes of conventional prostheses have been introduced [13, 14]. These valves have a low incidence of PPM without performing annular enlargement, especially in the small valve sizes. In recent years, patients who require AVR are becoming older and thus have more risk factors and complications. In such circumstances, operative invasiveness should be minimized, and there is a tendency to perform isolated AVR with a high-performance prosthesis instead of performing aortic annular enlargement. However, there are several drawbacks and advantages in high-performance prostheses. Stentless prosthesis can avoid PPM with excellent hemodynamics, but implantation of this prosthesis is more complicated than that of standard AVR. SJM Regent valve has a larger EOA than the corresponding same-labeled size of SJM standard valve. On the other hand, the thickness of the external sewing ring of SJM Regent valve is very thin, so that considerable concern might exist about the fit between the external sewing ring and the native aortic annulus. Making an appropriate choice with regard to the prosthesis is important.

Table 1 shows currently available several types of high-performance mechanical prostheses, which includes the conventional type of St. Jude Medical Standard aortic valve (Medtronic, Minneapolis, MN, USA) for comparison; St. Jude Medical Hemodynamic Plus; St. Jude Medical Regent; and ATS AP 360 (ATS Medical Inc, Minneapolis, MN, USA). For each type and size of prosthetic valve, the estimates of the prostheses' EOAs were obtained from the manufacturers' instructions.

The spectrum of biological valve substitutes for the small aortic annulus includes stented and stentless porcine valves, stented pericardial valves, aortic or pulmonary homografts, and pulmonary autografts. Table 2 shows currently available several types of high-

performance bioprostheses, which includes the conventional type of Carpentier-Edwards Perimount aortic valve (Edwards Lifesciences, Irvine, CA, USA) for comparison; Carpentier-Edwards Perimount Magna; Mosaic Porcine Bioprosthesis (Medtronic, Minneapolis, MN, USA); and Freestyle Aortic Root Bioprosthesis (Medtronic). For each type and size of prosthetic valve, the estimates of the prostheses' EOAs were obtained from the manufacturers' instructions.

Prosthesis

Size (mm)	16	17	18	19	20	21	22	23	25
SJM Standard				1.00		1.30		1.60	1.80
SJM HP		1.00		1.30		1.60			
SJM Regent		1.30		1.70		2.00		2.50	2.60
ATS AP360	1.20		1.50		1.70		2.10		

Results are the effective orifice area (cm^2)

SJM, St. Jude Medical; HP, Hemodynamic Plus;
ATS, ATS Medical

Table 1. Effective orifice area of each high-performance mechanical prosthesis

Prosthesis

Size (mm)	19	21	23	25	27	29
CEP	1.28	1.69	1.87	1.89		
CEP Magna	1.58	1.90	2.07	2.33		
Mosaic	1.20	1.30	1.50	1.80	2.00	2.10
Freestyle-s	1.10	1.40	1.60	2.00	2.40	2.70
Freestyle-f	1.20	1.40	1.70	2.10	2.40	2.70

Results are the effective orifice area (cm^2)

CEP, Carpentier-Edwards Perimount

Freestyle-s, Freestyle subcoronary

Freestyle-f, Freestyle full root

Table 2. Effective orifice area of each high-performance bioprosthesis

5. Surgery for small aortic annulus

Ideally, a patient with a small aortic annulus should be identified preoperatively, so that alternative measures, such as an aortic root-enlarging procedure or a selection of high-performance prosthesis, might be considered. Occasionally, the precise size of the aortic annulus cannot be determined until the time of operation.

5.1 Supra-annular implantation

One-size up prosthesis implantation can be allowed using supra-annular position or single suture technique. Other approach to the slightly smaller aortic annulus is to implant prosthesis at a slight angle to the plane of the annulus [16]. After the sutures are placed in the annulus for a supra-annular position, they are passed through the sewing ring and lowered into place so that the sewing ring is below the left and right coronary arteries but angled upward at the noncoronary sinus. The left and right annulus sutures are tied first, thereby securing the sewing ring to the annulus below the left and right coronary ostia. The sutures that correspond to the noncoronary annulus are tied last, allowing the valve to ride slightly above the annulus in this region.

5.2 Aortic root enlargement

Annular enlargement procedures are alternatives for those patients in whom a prosthesis being implanted is too small in relation to body size (at least 19-mm cannot be implanted). Although, Manouguian's or the Nicks procedure for annular enlargement may increase operative risks, these procedures can allow larger prosthesis implantation in patients with small aortic annulus [15]. Among surviving patients, aortic annular enlargement improved long-term outcome. Recently, with the introduction of high-performance prostheses and changes in the patient's age group, the need for aortic annular enlargement has decreased dramatically in our clinical practice.

5.3 Nicks procedure

Nicks et al. reported a technique for the enlargement of a small aortic root by an operation whereby the small aortic root has been enlarged by insertion of a Dacron fabric gusset that it will accommodate a larger sized prosthesis [17]. In many cases, enlarging the annulus by 2-4 mm may be sufficient. One technique associated with minimal increase in morbidity is to create a posterior annular split at noncoronary cusps, leaving the anterior mitral leaflet and the left atrium intact. The aortic incision is carried downwards posteriorly through the noncoronary aortic sinus across the aortic annulus as far as the origin of the mitral valve, just above the confluence of the intervalvular trigone, left atrial wall, and mitral annulus. A tongue of Dacron fabric is sutured down to the fibrous origin of the mitral annulus.

5.4 Manoughian procedure

Manoughian et al. reported when greater annular enlargement is desired, a posterior incision is made at the commissure between the left and noncoronary cusp and extended through the annulus and the intervalvular trigone into the center of the anterior mitral leaflet [18]. The free edge and body of the anterior leaflet remain intact. The left atrium, which is entered at its attachment with the aortic root, can be opened further to facilitate exposure.

An elliptical patch is used to close the defect in the anterior mitral leaflet. Interrupted horizontal mattress sutures are placed in the annulus and also through the patch. The prosthesis is thus seated, using the patch as part of the annulus. The incision in the left atrial wall is closed by continuous sutures by incorporating the atrial edges as the patch is sutured to the defect in the anterior mitral leaflet. The superior portion of the patch is incorporated into the aortotomy closure. Mitral regurgitation due to distortion of the anterior mitral leaflet may occur.

5.5 Konno procedure
Patients with congenital aortic stenosis have associated hypoplasia of the aortic annulus. In such cases, valvotomy is of limited value, and standard AVR is unfeasible because of the narrow aortic root. In such cases, Konno procedure is indicated [19]. The procedure consists of a longitudinal incision in the aortic septum placed in the midportion of the two coronary ostia, a vertical incision in the outflow tract of the right ventricle to join the septal incision, AVR with prosthetic valve, and patch reconstruction of the outflow tracts of both ventricles by means of two layers of a fusiform Dacron patch.

5.6 Stentless bioprosthesis
The stentless porcine bioprosthesis has become increasingly popular, because stentless xenograft valves have several advantages over the traditional stent mounted tissue valves. Notably, stented xenograft valves are intrinsically obstructive due to the space occupied by the stent and sewing ring. For a given external diameter, the internal diameter of the stentless valve is 2 to 4 mm larger than a stent mounted xenograft valve due to lack of a stent. This translates to an ability to place a bioprosthesis with a greater EOA, reduce mean transvalvular gradients, and results in greater regression of LV hypertrophy compared to the stented bioprosthesis. An increased understanding of the functional anatomy of the aortic root has reinforced the concept of the dynamic relationships among the valve cusps, annulus, sinus of Valsalva, and sinotubular junction. The use of a stentless valve maintains these interactions resulting in improved hemodynamic performance. Stentless valves can be implanted in the subcoronary position, as an aortic root replacement, or as a root inclusion. Although, subcoronary implantation, aortic root replacement, and root inclusion are similar to techniques, implantation of a stentless xenograft aortic valve is technically more difficult than a stented valve but easier than an allograft used in the subcoronary position. Two valves approved for use by the United States Food and Drug Administration are the Toronto SPV (St. Jude, Minneapolis, MN) and the Freestyle valve (Medtronic, Minneapolis, MN). The Toronto SPV is comprised of the valve and supporting aortic wall only, and is designed as a subcoronary implant.

5.7 Apicoaortic bypass
Surgical relief of LV outflow tract obstruction may be difficult to achieve by conventional methods. Creation of a LV "vent" was accomplished by the anastomosis of a valved conduit graft from LV apex to the abdominal aorta [20]. A median sternotomy incision is made and extended into the linear alba after the decision is made to insert the conduit. The supraceliac aorta is exposed and clamped while the anastomosis is performed. During temporary cardiopulmonary bypass a plug of myocardium is removed from the

apex of the left ventricle. The rigid inlet tube attached to a sewing ring and fabric graft is sutured to the ventricular ostium. The graft passed into the abdomen through an incision in the diaphragm and the composite conduit is anastomosed end to end fashion.

5.8 Ross procedure

The Ross Procedure is a type of specialized aortic valve surgery where the patient's diseased aortic valve is replaced with his or her own pulmonary valve [21]. The pulmonary valve is then replaced with cryopreserved pulmonary allograft. In children and young adults, or older particularly active patients, this procedure offers several advantages over traditional aortic valve replacement with manufactured prostheses. Longevity of the pulmonary autograft in the aortic position is superior to bioprostheses such as porcine valves, which tend to degenerate after only a few years in patients under 35 years of age. Furthermore, anticoagulation is not required as with mechanical valves. Thus, individuals can lead an active life without the risks associated with anticoagulation therapy. This is especially important for women of child bearing age needing aortic valve replacement, as anticoagulation is contraindicated in pregnancy. However, lifelong follow-up for pulmonary autograft, implanted allograft, and the ascending aortic diameter must be required.

6. Conclusions

PPM with an IEOA <0.70 cm^2/m^2 should always be avoided. This degree of PPM adversely affects operative mortality and postoperative recovery of cardiac functions. However, in some cases, PPM with an IEOA <0.85 cm^2/m^2 and ≥0.70 cm^2/m^2 could be acceptable in patients with preserved LV function without any impact on overall survival. The current perception of PPM may need to be reconsidered with respect to the unified standard regardless of each patient's condition. On the other hand, introduction of high-performance prostheses reduces the incidence of PPM without performing annular enlargement, especially in the small valve sizes. Making an appropriate choice, including the surgical strategy and the prosthesis, based on each individual patient's preoperative condition is very important.

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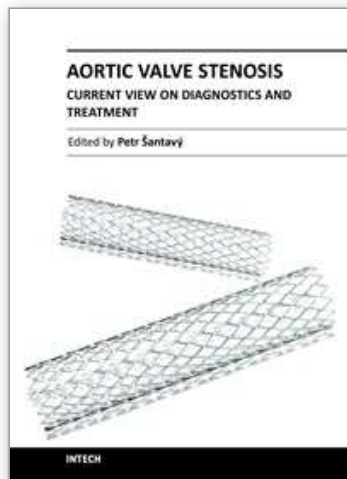
Aortic Valve Stenosis - Current View on Diagnostics and Treatment

Edited by Dr. Petr Santavy

Currently, aortic stenosis is the most frequent heart valve disease in developed countries and its prevalence increases with the aging of the population. Affecting 3-5 percent of persons older than 65 years of age, it makes a large personal and economical impact. The increasing number of elderly patients with aortic stenosis brings advances in all medical specialties dealing with this clinical entity. Patients previously considered too old or ill are now indicated for aortic valve replacement procedures. This book tries to cover current issues of aortic valve stenosis management with stress on new trends in diagnostics and treatment.

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Koji Tsutsumi (2011). Operative Management – Patient-Prosthesis Mismatch, Aortic Valve Stenosis - Current View on Diagnostics and Treatment, Dr. Petr Santavy (Ed.), ISBN: 978-953-307-628-7, InTech, Available from: http://www.intechopen.com/books/aortic-valve-stenosis-current-view-on-diagnostics-and-treatment/operative-management-patient-prosthesis-mismatch

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