Aortic Valve Replacement With a Small Mechanical Valve Prosthesis
--- A Clinical and Echocardiographic Study of a St Jude Medical Valve Prosthesis ---

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The use of small aortic valve prostheses raises concerns about harmful effects of residual obstruction to left ventricular outflow. The present study was undertaken to examine long-term clinical and echocardiographic results in 193 patients who underwent isolated aortic valve replacement (AVR) with a St Jude Medical (SJM) valve of 25 mm or smaller. The study subjects comprised 128 male and 65 female patients with a mean age of 54.1 years. The patients were divided into 2 groups according to the size of the valve prosthesis used for AVR. Small valves (19 or 21 mm) were implanted in 49 patients (group S) and large valves (23 or 25 mm) were used in 144 patients (group L). The group S patients were mainly female, older, and had smaller body surface areas. There were no significant differences in early and late mortality in group S as compared with group L. Furthermore, there was no difference in the incidence of valve-related or cardiac, non-valve-related death, including the incidence of sudden death, between the 2 groups, and they enjoy a similar level of daily routine activity regardless of the valve size used. Left ventricular (LV) function (ejection fraction, fractional shortening, LV mass index, LV end-systolic volume index, and LV end-diastolic volume index) measured by echocardiography improved significantly and returned to normal values after AVR in both groups. Moreover, no significant differences were observed in the postoperative variables of the LV function. These results suggest that 19-mm and 21-mm SJM valves can be safely used for AVR in the majority of Japanese patients. (Jpn Circ J 1998; 62: 244–248)

Key Words: Aortic valve replacement; Small mechanical valve; St Jude Medical valve

Recent advances in operative technique and in the design of, and materials used for, prosthetic heart valves, as well as in techniques of myocardial protection, have resulted in remarkable decreases in operative mortality and postoperative morbidity in patients who have undergone valve replacement for heart valve diseases. However, the choice of mechanical prostheses or bioprostheses and the optimal size of valve prostheses that are used for valve replacement remain controversial. Thrombogenicity necessitating anticoagulation in the case of mechanical prostheses and durability in the case of bioprostheses are the major factors that increase the risk of postoperative mortality and morbidity. The size of a heart valve prosthesis can also affect operative mortality and morbidity, particularly in aortic valve replacement (AVR), because the use of small valve prostheses for AVR causes residual obstruction of left ventricular outflow.

In this study, we performed clinical and echocardiographic evaluations in patients who underwent AVR with small mechanical valve prostheses.

Patients and Methods

Patients
Between July 1987 and October 1995, 273 patients underwent isolated AVR at Kurume University Hospital. A St Jude Medical (SJM) valve prosthesis was used in all patients. Of the 273 patients, 193 received AVR with a SJM valve of 25 mm or smaller. These 193 patients form the basis of the present study. There were 128 male and 65 female patients, age range 9–82 years with a mean age of 54.1 ± 14.8 years. The clinical characteristics of the 193 patients are summarized in Table 1. In this study, patients who received coronary artery bypass grafting (CABG) at the same time as AVR or who required annular enlargement for AVR were excluded. Patients with a SJM valve of 27 mm or larger and with a SJM Hemodynamic Plus valve in the aortic position were also excluded. The patients were divided into 2 groups according to the size of the valve prosthesis used for AVR. Small valves (19 or 21 mm) were implanted in 49 patients (group S) and large valves (23 or 25 mm) were used in 144 patients (group L). The 49 patients included 30 patients with aortic stenosis (AS) and 19 with aortic regurgitation (AR). A 19-mm valve was implanted in 10 patients (AS, 7 patients; AR, 3 patients) and a 21-mm valve in 39 (AS, 23; AR, 16). According to the mode of left ventricular (LV) overload, the 2 groups were divided into 4 subgroups. Subgroup s consisted of 55 patients (group S; 21 patients, group L; 34 patients) who had mainly stenotic
Table 1 Clinical Characteristics in Patients Who Underwent AVR With a SJM Valve

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Group S</th>
<th>Group L</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>193</td>
<td>49</td>
<td>144</td>
<td></td>
</tr>
<tr>
<td>Gender (male/female)</td>
<td>128/65</td>
<td>20/29</td>
<td>108/36</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Age (years)</td>
<td>54.1±14.8</td>
<td>61.5±10.8</td>
<td>51.9±15.1</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>NYHA class</td>
<td>2.5±0.7</td>
<td>2.5±0.7</td>
<td>2.5±0.7</td>
<td>N.S.</td>
</tr>
<tr>
<td>BSA (m²)</td>
<td>1.56±0.7</td>
<td>1.46±0.13</td>
<td>1.60±0.16</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

BSA, body surface area; NYHA, New York Heart Association; N.S., not significant.

valve lesions [LV—aortic pressure gradient (PG) ≥50 mmHg, aortic valve regurgitation (AR) ≤g 2], and subgroup r consisted of 102 patients (group S; 12 patients, group L; 90 patients) who mainly suffered from regurgitation (LV—Ao PG <50 mmHg, AR ≥grade 3). The remaining 46 patients underwent AVR for mixed lesions.

Operative Technique

Standard cardiopulmonary bypass with a disposable bubble or membrane oxygenator and moderate hypothermia was used for valve replacement. Myocardial protection was achieved by cold crystalloid or blood cardioplegia. After meticulous debridement of the valve annulus, the annulus was measured with a snugly fitting sizer. All valves were implanted perpendicular to the interventricular septum with pledged mattress sutures.

Postoperatively, intravenous administration of heparin was started on the first postoperative day and continued until the thromboplast level or a prothrombin time level could be regulated by oral anticoagulation with warfarin. Anticoagulant therapy, consisting of warfarin and a platelet inhibitor, was usually initiated within 48 h after the operation; the thromboplast level was kept at about 20% or the international normalized ratio (INR) was maintained at 1.5—2.0.

Assessment of Postoperative Cardiac Functional Class by the Specific Activity Scale

To determine the degree of cardiovascular disability in Japanese patients rather than European or American patients, the specific activity scale (SAS) system by Asano6 was employed. The most strenuous activity performed was investigated by questionnaire or by telephone interview.

Echocardiographic Evaluation of Left Ventricular Function

Echocardiography was performed by an experienced echocardiographer in our outpatient department and was carried out using a Hewlett-Packard Sonos-1000 ultrasound system with a 2.5-MHz transducer (HP Andover, MA, USA). Parasternal long-axis views of the LV were obtained on paper at speeds of 50 mm/sec and, in addition to measurements of the end-systolic dimension (LVDs) and the end-diastolic dimension (LVDd) of the LV, the interventricular septal thickness (IVST) and the posterior wall thickness of the LV (LVPWT) were measured. Then, ejection fraction (EF): fractional shortening (%FS), end-diastolic volume index (LVEDV), end-systolic volume index (LVESVI), and mass index (LVMI) were calculated as follows:

\[
EF = 100 \times \frac{(\pi/3 \times LVDd)^3 - (3/\pi \times LVDs)^3}{(\pi/3 \times LVDD)^3}
\]

\[
%FS = 100 \times \frac{(LVDd - LVDd)/LVDd}
\]

\[
LVEDVI = (\pi/3 \times LVDd)^3/BSA
\]

\[
LVESVI = (\pi/3 \times LVDs)^3/BSA
\]

\[
LVMI = 1.04 \times ([IVST + LVDd + LVPWT] - LVDd)^3 - 13.6
\]

where BSA is body surface area. All calculations were the average of 3 cardiac cycles.

Follow-Up

A total of 187 out of 191 hospital survivors were examined annually or biannually by ourselves at our outpatient department and were surveyed by written questionnaire (97.9% follow-up) or by telephone. Four patients (2.1%) could not be located and were considered lost to follow-up. Early death within 30 days of surgery, hospital death, and late death as documented at the time of a follow-up study were recorded. All valve-related deaths, complications, and non-valve-related complications were analyzed according to the guidelines developed by the Society of Thoracic Surgeons. The mean period of follow-up was 4.4±2.4 years, with a maximum of 106 months. Total follow-up was 817.8 patient—years (p—y).

Statistical Methods

Data are presented as mean±standard deviation. Actuarial estimates were calculated by the Kaplan—Meier technique, and comparisons of these estimates among groups were performed with analysis of variance. Simple comparisons were performed using a standard chi-square-test, or a non-paired t test. Paired t test or repeated measures analysis of variance was used for continuous variable comparison. A p value of less than 0.05 was considered significant.

Results

Age and Sex

Patients with small valves (≤21 mm) were predominantly female (59.2%), whereas those with large valves (≥25 mm) were predominantly male (75.0%). There were also differences in patient age between valve sizes. A large number of small valves were implanted in older patients. In addition, the area BSA of the patients with small valves was significantly smaller than that of the patients with large valves, as shown in Table 1.

Operative Mortality

Two of the 193 patients died of low cardiac output syndrome within 30 days after surgery, and the operative mortality rate was 1.0% overall. Both patients had large valves in the aortic position. There were no hospital deaths in either group.

Postoperative Morbidity

Late Mortality. Seven patients (3.7%) died by the date of the last assessment. The causes of late death were valve related in 5 patients (prosthetic valve endocarditis, 2; thromboembolism, 1; hemorrhage, 1; sudden death, 1) and non-cardiac related in 2 (liver cirrhosis, 1; peritonitis, 1). The large valve was used in 4 of the 5 patients and sudden death occurred in 1 patient with a small valve. There were no cardiac-related deaths.

The actuarial survival, including early deaths, at 5 and 8 years was 97.9% in group S, and 93.5% and 89.8%, respectively, in group L. There was no statistically signifi-
significant difference in the actuarial survival rate at 8 years between the 2 groups.

Valve-related Complications. Eleven patients (1.3%/p−y) sustained a thromboembolic event. The thromboembolic events occurred in 9 patients with large valves and in 2 with small valves during the follow-up period. Valve thrombosis developed in 2 patients (0.24%/p−y), and both of these patients were in group L. Three patients (0.36%/p−y) in group L had hemorrhagic complications related to anticoagulant therapy. Four patients (0.5%/p−y) had prosthetic valve endocarditis. Of these, 3 were in group L and 1 in group S. In total, 3 patients (0.37%/p−y) had non-structural dysfunction such as paravalvular leaks or entrapment of the leaflets by pannus formation. But no change in valve function occurred as a result of an intrinsic abnormality or any structural failure. Seven patients (0.85%/p−y) underwent reoperation; causes of reoperation were non-structural dysfunction in 3 patients, prosthetic valve endocarditis in 3, and valve thrombosis in 1. The probability of freedom from all complications, including early deaths, at 5 and 8 years was 89.2% in group S, and 86.7% and 83.3%, respectively, in group L. There was no significant difference in the probability of freedom from all valve-related complications at 8 years between group S and group L.

Postoperative New York Heart Association (NYHA) Functional Class and Specific Activity
Scale Functional Class
In total, the preoperative NYHA functional class of 2.5±0.7 was improved to 1.6±0.7 postoperatively. In group S, it improved from 2.5±0.7 preoperatively to 1.6±0.7 postoperatively, and also changed from 2.5±0.7 preoperatively to 1.6±0.7 postoperatively in group L. A significant difference (p<0.01) was found between the preoperative and postoperative NYHA functional classes. However, no significant difference was observed in the postoperative NYHA functional class between group S and group L. The mean value of the SAS in 180 late survivors was 5.6±1.1 metabolic equivalents of activity (METs) as a whole, and it was 5.7±1.1 METs in group S and 5.5±1.1 METs in group L. No significant difference was found in SAS between the 2 groups.

Echocardiographic Evaluation of Left Ventricular Function
EF and %FS. In group S, postoperative echocardiography performed late after surgery showed EF of 70.1±13.2% and %FS of 34.4±9.3%, which had been 69.8±15.6% and 34.9±11.5%, respectively, before surgery. In group L, the EF changed from 68.4±10.7% preoperatively to 68.0±8.7% postoperatively and %FS changed from 32.7±7.6% preoperatively to 32.2±6.5% postoperatively. However, there were no significant differences in the preoperative and postoperative EF and %FS values between the 2 groups, nor were there any differences in both groups between the mean values of the preoperative and postoperative EF and %FS.

LVMI, LVEDVI, and LVESVI
According to the mode of LV overload, the 2 groups were divided into 4 subgroups. Subgroup s consisted of 55 patients who had mainly stenotic valve lesions (LV−Ao PG ≥50 mmHg, AR=grade 2), and subgroup r consisted of 102 patients who mainly suffered from regurgitation...
(LV–Ao PG <50 mmHg, AR ≥ grade 3). LVMI was measured for patients in subgroup s, and LVEDVI and LVESVI for patients in subgroup r.

LVMIIs before and after surgery in subgroup s are shown in Fig 1. LVMI fell from 248.2 ± 135.8 g/m² to 149.6 ± 52.9 g/m² in subgroup S-s and decreased from 258.4 ± 88.4 g/m² to 144.6 ± 41.0 g/m² in subgroup L-s. Although the decreases in LVMI in the 2 subgroups were statistically significant (p < 0.01), there were no significant differences in the preoperative and postoperative LVMIIs between subgroup S-s and subgroup L-s.

Changes in LVEDVI and LVESVI in the 2 subgroups are shown in Fig 2. In subgroup S-r, the preoperative LVEDVI of 154.7 ± 99.1 ml/m² decreased significantly (p < 0.01) to 70.5 ± 25.0 ml/m² postoperatively, and LVESVI also decreased significantly (p < 0.01) from 45.8 ml/m² preoperatively to 17.9 ± 8.3 ml/m² postoperatively. The preoperative LVEDVI of 176.7 ± 54.8 ml/m² and LVESVI of 57.8 ± 26.9 ml/m² also declined significantly (p < 0.01) to 85.7 ± 28.9 ml/m² and 28.9 ± 14.2 ml/m², respectively, in subgroup L-r. However, there were no significant differences in the 2 indices between the groups either before or after the operation.

Discussion

Recent advances in operative technique and in the design of, and materials used for, prosthetic heart valves, and in techniques of myocardial protection, have resulted in remarkable decreases in operative mortality and postoperative morbidity in AVR. However, AVR in the small aortic annulus is always associated with a wide range of surgical and clinical problems. The use of small aortic valve prostheses may cause residual obstruction to left ventricular outflow and may limit the postoperative improvement. On the other hand, enlargement of the aortic annulus to insert a large prosthesis may increase operative risks of injury to the coronary arteries and to the conduction bundle and the risk of surgical hemorrhage. Furthermore, acceptable gradients with small mechanical valves, particularly recently developed valves such as the SJM, CarboMedics, or Carbomedics valves, have been reported by several investigators. Considering the good hemodynamic qualities and larger orifice areas, we have used the SJM valves in AVR and basically have implanted the valves that fit the native aortic annulus of adult patients without resorting to annulus-enlarging procedures.

Our study has confirmed the characteristic features of patients receiving small aortic valve prostheses. Those patients are mainly female, older, and have dominant AS and smaller BSA, as observed in many previous investigations. Despite concerns about harmful effects of residual obstruction to LV outflow in small aortic valve prostheses, the present study has demonstrated the satisfactory long-term clinical results after isolated AVR with small prostheses (≤21 mm), as there were no significant differences in early and long-term clinical outcome or in symptomatic recovery as judged by NYHA functional class and SAS between group S and group L. He et al attempted to analyze 11 preoperative and operative variables to investigate the determinants of long-term survival after AVR with small-size prostheses (≤21 mm). In their study, multivariable analyses revealed that prosthetic valve size did not have any influence on long-term survival and that concomitant CABG and age were independent variables in determining long-term survival. Thus, they conclude that patients with small aortic prosthetic valves may have satisfactory long-term survival after isolated AVR without aortic root enlargement procedures. Kratz et al have indicated a high incidence of sudden death in their patients who received small aortic prostheses, especially in patients with 19-mm or 21-mm valves and a BSA over 1.9 m², and suggest that 19-mm or 21-mm SJM valves can be used without any hesitation in patients with a BSA less than 1.7 m². It seems that residual obstruction of LV outflow mainly contributes to a high incidence of sudden death. Rahimtoola identified an aortic valve index of 0.75 cm²/m² or less as severe AS in patients who did not undergo operation. As calculated from the published orifice area of 19-mm and 21-mm SJM valves, the aortic valve area index (0.86 cm²/m² and 1.08 cm²/m²) of these valves would be marginal in large patients with a BSA of 1.9 m². Recently, Sawant et al performed a multivariate analysis of late postoperative mortality and morbidity in 270 patients who received small SJM aortic prostheses (≤21 mm). The analysis revealed that the determinant factors of the long-term survival were: age at operation, myocardial infarction, and endocarditis, and that the risk of sudden death was not statistically different irrespective of body surface area and valve size. In our experience, only 1 sudden death was observed in 49 patients with small valves. The fact that our patients with small valves had a mean BSA of 1.46 m², which was smaller than those in the previous reports, may partly be responsible for the low incidence of sudden death.

Several factors have been considered to contribute to this clinical improvement. First, small increases in valve area of critically narrowed valves will result in a large reduction in gradient, because the relationship of the gradient to valve area is not linear. Once the effective orifice size of the aortic valve is critically reduced to less than 35% of normal (smaller than about 1 cm²), the gradient rises precipitously. Second, small valves are more frequently required in the elderly with aortic stenosis, and resting cardiac output diminishes with age, resulting in a decrease in the expected gradient across the same valve size.

In this study, postoperative symptomatic recovery was assessed using NYHA functional class and SAS functional class. The NYHA classification system has been used widely to categorize the functional status of patients in numerous clinical studies. This system classifies patients according to the degree of symptoms resulting from ordinary or less-than-ordinary activity. However, the precise details of the definition of the activity are obscure. Therefore, it has generally been pointed out that patients’ functional classes are not assessed accurately by this classification. Although the exercise treadmill test estimating oxygen consumption appears to be reasonable for assessing functional capacity and classification, several factors, such as fear of symptoms, habit, or leg weakness, have influence on the duration and the degree of exercise. Moreover, it takes a long time and requires special equipment. On the other hand, Goldman et al proposed the usefulness of the SAS based on the metabolic requirements of specific activities and, when compared with the reproducibility and validity of the NYHA criteria for the
assessment of cardiac functional class, those of the SAS were significantly higher. Thus, we accepted the SAS functional class modified for Japanese patients in this study. The mean value of the SAS in 180 late survivors was 5.5 METS as a whole, and it was 5.6±1.1 METS in group S and 5.5±1.2 METS in group L. No significant difference was found between the 2 groups.

With a decrease in the LV preload and afterload after AVR, LV function is improved in most patients with advanced aortic valve disease. In AS, the reduction in afterload achieved by AVR leads to a significant reduction in LV mass in almost all patients. As early as 6 weeks postoperatively, LV mass decreases by 30% of the preoperative mass. In this study, regression of LVM1 was significant in patients in both group S and group L, and no significant difference was found in postoperative LVMIs between both groups. The magnitude of reduction in LVM1 was also similar in the 2 groups. Sim et al.8 however, demonstrated that the magnitude of reduction in LVM was greater in patients with 21-mm valves than in those with 19-mm valves, and was similar in the patients with 21-mm valves and those with 23-mm valves. In our experience, a majority of patients with small valves received 21-mm valves and only 10 patients had 19-mm valves. This may partly explain the significant reduction in LVM1 in our group S patients.

In contrast to AS, AR leads to ventricular dilatation to compensate for the chronic volume overload. The greatest reduction in LVEDV generally occurs in the first 14 days after AVR. Both LVEDVI and LVESVI decreased significantly after AVR in both group S and group L, and no significant difference was seen in postoperative LVEDVI and LVESVI between the 2 groups. The magnitude of decreases in LV dimensions was again similar in the 2 groups. These data demonstrate that small aortic valve prosthesis as well as large valves provide a significant improvement in LV function and that the improvement in LV function is not necessarily restricted by AVR with small aortic valves. On the basis of their clinical and echocardiographic study in 144 patients who received small aortic valves, Arom et al.1 also conclude that, although the 19-mm and 21-mm SJM aortic valves have a higher transprosthetic gradient, AVR with both valves does not limit the improvement in LV function or symptomatic recovery in patients with BSA of less than 1.7 m². In this study, when compared with patients who received larger valves, those with small prostheses did not have significantly higher early or late mortalities, and there were no significant differences in postoperative morbidity. In addition, LV function measured by echocardiography improved significantly in both groups after AVR, and the magnitude of the improvement was similar in the 2 groups. They also enjoy a similar level of daily routine activity regardless of the valve sizes used. These results suggest that 19-mm and 21-mm SJM valves can be used safely in the majority of Japanese patients.

However, in our experience, the mean BSA in the 49 patients with small valves was 1.46 m², which was smaller than those in previous reports11,12,14,15,17 from Europe and the US, and only 10 patients received 19-mm valves. This may partly explain the excellent long-term clinical outcome and the significant improvement in LV function after surgery in our patients. Thus, further investigations of smaller valves in patients who have larger BSA (over 1.5 m²) will be needed to clarify the role of a smaller aortic prosthesis valve in patients with a small aortic annulus.

In conclusion, patients who received a 19-mm or 21-mm SJM aortic prosthesis in this study were mainly female, older, and had a smaller BSA (1.46 m²). When compared with patients who received large valves, those with small prostheses did not show any significant differences in early or late mortality. Furthermore, there were no differences in the incidence of valve-related or cardiac, non-valve-related death between the 2 groups and they enjoy a similar level of daily routine activity regardless of the valve size used in AVR. LV function studied by echocardiography significantly improved in both groups after AVR. These results suggest that 19-mm and 21-mm SJM valves can be used safely in the majority of Japanese patients.

References
