ST. JUDE MEDICAL CARDIAC VALVES IN SMALL AORTIC ROOTS: FOLLOW-UP TO SIXTEEN YEARS

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Prosthetic aortic valve replacement in the small aortic root raises concerns of its long-term effects. Between 1978 and 1994, 270 patients received only small aortic prostheses (≤ 21 mm). There were 117 men (43.3%) and 153 women (56.7%) with a mean age of 64.3 ± 11.6 years (range 19 to 87 years). The body surface areas ranged from 1.2 to 2.26 m^2 (mean $1.71 \pm 0.27 \text{ m}^2$). Ninety-one percent of patients had New York Heart Association class III or IV symptoms and 33% underwent concomitant coronary artery bypass grafting. The operative mortality rate was 3.3% (9 deaths) and follow-up (100%) extended from 1 to 16 years (mean 6.2 ± 3.9 years) with cumulative survival of 1676 patient-years. There were 55 late deaths (3.28% per patient-year). The linearized rates of morbidity reported as percent per patient-year were as follows: structural failure, 0%; paravalvular leak, 0.12%; prosthetic endocarditis, 0.24%; anticoagulant-related morbidity, 1.24%; and thromboembolism, 1.10%. In 89% of the survivors New York Heart Association functional performance had improved to class II or I. The actuarial survival with 95% confidence intervals at 5, 10, and 16 years was 86.9% (82.5%, 91.3%), 68.6% (60.6%, 76.6%), and 53.6% (36.6%, 70.6%), respectively. Freedom from late valve-related events (95% confidence intervals) at 10 and 16 years was as follows: thromboembolism, 91.2% (86.6%, 95.8%) and 78.3% (62.6%, 94%); anticoagulant-related morbidity, 89.1% (83.8%, 94.4%) and 81.0% (65.1%, 96.9%); and prosthetic endocarditis, 98.8% (97.5%, 100%) and 98.8% (97.5%, 100%), respectively. Multivariate analysis revealed age at operation, myocardial infarction, and endocarditis affected the long-term survival. The risk of sudden death irrespective of body surface area and valve size was not statistically different. Thus the long-term performance of the St. Jude Medical valve in small aortic roots is satisfactory. (*J Thorac Cardiovasc Surg* 1997;113:499-509)

The use of an aortic valve prosthesis in the small anulus raises a concern about harmful effects of residual obstruction to the left ventricular outflow tract, which may cause significant hemodynamic limitations. Since June of 1978 at Rhode Island Hospital, small sizes of St. Jude Medical aortic prostheses (19 mm and 21 mm) have been used

without aortic root enlargement. We believe the good hemodynamic quality of this prosthesis justifies its use in the native small aortic anulus.

Excellent hemodynamic performance of the St. Jude Medical mechanical prosthesis has been reported by many investigators.¹⁻³ St. Jude Medical mechanical prostheses in sizes 19 mm and 21 mm are designed and demonstrated in *in vitro* studies to have a resting gradient of 6 mm Hg and peak gradient of less than 15 mm Hg.^{3,4} Kratz and associates⁵ reported good results in patients with a body surface area (BSA) less than 1.9 m^2 with the use of 19 mm and 21 mm St. Jude Medical prostheses, but reported an increased incidence of late sudden death among those with a BSA less than 1.9 m^2 . This study reports our experience with 19 mm and 21 mm St. Jude Medical prostheses in patients with a small aortic root and attempts to

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Received for publication March 27, 1996; revisions requested April 25, 1996; revisions received July 26, 1996; accepted for publication July 31, 1996.

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0022-5223/97 \$5.00 + 0 12/1/77139

Fig. 1. Preoperative and follow-up NYHA functional class presentation. *Pts*, Patients.

investigate the risk factors for long-term morbidity and mortality, particularly as related to valve size and large BSA.

Material and methods

Between June 1978 and June 1994, 593 adult patients underwent aortic valve replacement with the St. Jude Medical mechanical prosthesis. Among these were 327 patients (55%) who received a small prosthesis (≤ 21 mm). Patients with double valve replacement were excluded from the study. Two hundred seventy (46%) patients received small aortic valves only (17 mm, 1 patient; 19 mm, 79; 21 mm, 190). There were 117 men (43.3%) and 153 women (56.7%) between the ages of 19 and 87 years with a mean age of 64.3 ± 11.6 years. The

BSAs ranged from 1.20 to 2.26 m² (mean 1.71 ± 0.27 m²). Thirty-four patients (13%) had had previous cardiac operations. Ninety patients (33%) underwent a concomitant coronary artery bypass grafting (CABG) procedure. Preoperative New York Heart Association (NYHA) class presentations were as follows: NYHA class II, 24 patients; NYHA class III, 162 patients; and NYHA class IV, 84 patients (91% in NYHA class III or IV). Two hundred eighteen patients (81%) underwent operation electively, whereas operation was done urgently in 40 patients and on an emergency basis in 12 patients.

Operative technique. Before 1987, moderate hypothermic (25° to 28° C) cardiopulmonary bypass was used including bicaval cannulation with snares and a membrane oxygenator. The left ventricle was vented via the right superior pulmonary vein. Myocardial protection was

Fig. 2. Cumulative survival curves of mortality for three NYHA classes.

Table I. Freedom from late events

Events	5 Yr		10 Yr		16 Yr	
	Estimate (%)	95% CI (%)	Estimate (%)	95% CI (%)	Estimate (%)	95% CI (%)
Late death	86.9	82.5, 81.3	68.6	60.6, 74.6	53.6	36.6, 70.6
Cardiac death	95.3	92.6, 98	85.6	70.9, 92.3	94.9	54.4, 95.4
Thromboembolism	94.8	91.8, 97.8	91.2	86.6, 95.8	78.3	62.6, 94
Anticoagulation-related hemorrhage	94.3	91.4, 97.2	89.1	83.8, 94.4	81	65.1, 96.9
Valve-related reoperation	98.8	97.5, 100	98.8	97.5, 100	98.8	97.5, 100
Prosthetic endocarditis	98.8	97.5, 100	98.8	97.5, 100	98.8	97.5, 100
Paravalvular leak	99.6	98.8, 100	98.9	97.3, 100	98.9	97.3, 100
Valve-related complications	85.5	81, 90	79.9	63.2, 78.6	56.7	41.7, 71.7

achieved with the use of cold crystalloid cardioplegia followed by multidose cold blood cardioplegia. Topical myocardial cooling was done with ice-cold saline slush. After 1987, we routinely used normothermic (37° C) cardiopulmonary bypass.⁶ The technique of myocardial protection remained unchanged during the entire period. The aortic anulus was debrided meticulously and measured with a snugly fitting sizer. The St. Jude Medical valve prosthesis was implanted intraannularly with use of evert-ing interrupted and pledget-supported transverse mattress sutures. One hundred sixty-six patients (61%) had pure aortic stenosis, 10 patients (4%) pure aortic regurgitation, and 94 patients (35%) a mixed aortic lesion. Pathologic features of the explanted valves studied in our series were as follows: bicuspid in 204 patients (76%), rheumatic valve disease in 44 patients (16%), myxomatous degeneration in 10 patients (4%), and infective in 12 patients (4%).

Anticoagulation. All patients received anticoagulation therapy with warfarin beginning on postoperative day 2. We used prothrombin time to guide the dosage of warfarin before 1992. Before 1985 prothrombin time was kept between 2 and 2.5 times the control value and during the period from 1985 to 1992 it was kept between 1.5 and 2 times the control value. Since 1992 we have been using the international normalized ratio as control and kept the value between 3.0 and 3.5. All patients since 1992 have been followed up to receive a warfarin dosage to keep the international normalized ratio in the range of 3.0 to 3.5.

Follow-up. All patients were followed up annually (100% follow-up) by their referring physician or cardiologist. Follow-up information was obtained from these sources. We contacted all the surviving patients again by telephone during the fall of 1995. They were questioned by a trained person with a standard questionnaire. All

Fig. 3. Kaplan-Meier actuarial survival curve for late death. Dotted lines represent the 95% CIs.

hospital records for patient admissions were analyzed to enumerate valve-related problems. Follow-up ranged from 1 year to 16 years. Mean follow-up was 6.2 ± 3.9 years and cumulative patient survival was 1676 patient-years (pt-yrs). Mortality and morbidity were stringently defined per guidelines published by The Society of Thoracic Surgeons and The American Association for Thoracic Surgery.⁷ All data were stored in a Fox-pro database specially written for our use.

Statistical analysis. Statistical analyses were done with the SAS statistical software package. Discrete variables are presented as counts and percentages. Continuous variables are presented as mean plus or minus the standard deviation. Late events were also calculated as linearized rates (number of events divided by years at risk) and presented as percent per patient-year. Statistical significance (p value) was at the nominal level of 0.05.

The Kaplan-Meier product limit method was used to calculate the freedom from an event.⁸ The number of patients at risk for an interval is shown in the graphs, along with the 95% confidence limits for the estimates. Variables considered to be risk factors (NYHA class at implantation, BSA, CABG, age at operation, and preimplantation valve pathologic condition) were examined by the Kaplan-Meier product limit method, and the stratified log-rank test was used to determine statistical significance.

A Cox proportional hazard model with time-dependent covariates⁹ was done to determine the model that best predicted time to mortality. The importance of the covariates was evaluated singly and in combination by stepwise procedures. The model that best fit the data included age at implantation and the events endocarditis and myocardial infarction.

Results

Operative mortality. The overall operative mortality rate was 3.3% (9 patients). Among the 34 patients who underwent a second operation there were 2 deaths for a reoperation mortality rate of 5.9%. There were 4 deaths (mortality rate 4.5%) in 90 patients who had undergone concomitant CABG. Mortality according to NYHA functional class showed no operative deaths among 24 patients in NYHA class II, 3 deaths in 162 patients in NYHA class III (mortality rate 1.9%), and 6 deaths in 84 patients in NYHA class IV (mortality rate 7%).

Functional class. All patients were assessed for functional performance by NYHA classification during follow-up. Fig. 1 shows the preoperative and follow-up presentations. Survival curves by the functional class are shown in Fig. 2. Survival according to the NYHA class was not statistically significant (p value = 0.42).

Late mortality. Fifty-five patients died during follow-up for a linearized rate of late mortality of 3.3%/pt-yr. There were 32 patients with cardiac-related deaths for a linearized rate of 1.9%/pt-yr. Among the cardiac deaths, 21 deaths (1.3%/pt-yr) were a result of myocardial infarction and 11 deaths (0.7%/pt-yr) were from sudden cardiac events. Seven patients (0.4%/pt-yr) died as a result of major

Fig. 4. Cumulative survival curves of mortality for two age groups: 69 years and younger and 70 years and older.

stroke. The remaining 16 deaths (0.95%/pt-yr) were caused by noncardiac causes. Survival statistics with freedom from the late events are shown in Table I. Actuarial survival (Fig. 3) by the Kaplan-Meier method with 95% confidence intervals (CIs) was 86.9% (82.5%, 91.35%) and 53.6% (36.6%, 70.6%) at 5 and 16 years, respectively.

The influence of age on long-term survival showed decreased survival in patients with ages older than 70 years. Fig. 4 shows the survival curves for patients divided into two age groups: ages 69 years and younger and 70 years and older. The log-rank test showed statistical significance with $p = 0.01$.

Sudden death might be influenced by residual outflow obstruction across the prosthetic aortic valve. From the published data for orifice area of St. Jude Medical prosthetic valves, the calculated valve area index for a patient with a BSA of 1.9 m^2 and an implanted 19 mm or 21 mm prosthesis is $0.86 \text{ cm}^2/\text{m}^2$ or $1.08 \text{ cm}^2/\text{m}^2$, respectively. Therefore a BSA of 1.9 m^2 or greater was considered a potential risk factor for sudden death. The relationship of BSA to incidence of late sudden death was studied. In this series, a size 19 mm prosthesis was implanted in 77 patients with a BSA less than 1.9 m^2 and in 2 patients with a BSA 1.9 m^2 or greater, and a size 21 mm prosthesis was implanted in 131 patients with a

BSA less than 1.9 m^2 and in 56 patients with a BSA 1.9 m^2 or greater. The variables of a BSA less than 1.9 m^2 and a BSA 1.9 m^2 or greater as risk factors for sudden death were plotted on a survival curve (Fig. 5). We found no statistical significance by log-rank test ($p = 0.79$) for incidence of sudden death. However, when we analyzed influence of preimplantation valvular lesion on sudden death, sudden death significantly increased in patients with pure aortic stenosis ($p = 0.01$). Fig. 6 graphically illustrates this finding. Preimplantation aortic stenosis was not statistically significant for all cardiac deaths ($p = 0.5$) or late mortality ($p = 0.45$). Larger BSA had no statistically significant effect on long-term survival among patients who received 19 mm or 21 mm valves, although the number of patients who received a size 19 mm prosthesis with a BSA 1.9 m^2 or greater was small. The relevant survival curves are shown in Fig. 7 ($p = 0.48$).

The influence of concomitant CABG on late mortality was analyzed. Survival at the end of 10 years for those with CABG and without CABG with the 95% CIs was 68.4% (59.3%, 77.5%) and 61.2% (45.4%, 77%), respectively, without statistical significance ($p = 0.84$).

Late morbidity

Structural deterioration. No patient had structural malfunction of the valve in this series.

Fig. 5. Cumulative survival curves for sudden death in two groups by BSA: BSA less than 1.9 m² and BSA 1.9 m² or greater.

Paravalvular leak. Two patients had a paravalvular leak, for a linearized rate of 0.12%/pt-yr. One patient had a hemodynamically insignificant jet and remains free of symptoms. The other patient underwent reoperation with aortic root replacement and is alive at 6 years after operation and doing well. Freedom from paravalvular leak with the 95% CIs at 16 years was 98.9% (97.3%, 100%).

Thromboembolism. There were no detected cases of valve thrombosis. Eighteen patients had a stroke, for a linearized rate of 1.10%/pt-yr. There were 11 permanent and 7 transient neurologic deficits. No other embolic complications were noted. The survival statistics are given in Table I. The dosages of warfarin and the levels of anticoagulation were varied for the different times: 1978 to 1984, 1985 to 1992, and after 1992. Statistical analysis showed no difference in the incidence of thromboembolism ($p = 0.25$) or anticoagulation-related hemorrhage ($p = 0.61$) during the respective periods.

Anticoagulation-related hemorrhage. Anticoagulation-related hemorrhage occurred in 20 patients, who required hospitalization and transfusion. No patient required surgical intervention. The linearized rate was 1.24%/pt-yr. Table I shows the survival statistics.

Prosthetic endocarditis. Prosthetic valve endocarditis occurred in four patients, for a linearized rate of 0.24%/pt-yr. Three patients underwent reoperation, with one death. One patient was treated conservatively and is alive, remaining in NYHA class II. The freedom from endocarditis in our series with the 95% CIs was 98.8% (97.5%, 100%) at 16 years.

Reoperation. Three patients underwent reoperation with one death. The linearized rate for reoperation was 0.18%/pt-yr. Fig. 8 shows freedom from all valve-related complications and Table I shows the survival statistics.

Discussion

Management of the small aortic root is a challenge to the surgeon with regard to operative technique and selection of the prosthesis. The hemodynamic performance of small-sized valve prostheses in the native aortic root is of genuine concern, especially for patients with a larger BSA. It is feared that any significant pressure gradient across the prosthetic aortic valve will adversely affect late left ventricular performance. The Björk-Shiley tilting disc prosthesis is reported to have an exercise gradient of greater than 40 mm Hg across a 21 mm valve.¹⁰ Small Hancock porcine prostheses have

Fig. 6. Survival curves for freedom from sudden death in the patients with only aortic stenosis (*stenosis only*) and with other lesions. *Insuff*, Aortic insufficiency; *mixed*, mixed aortic lesions.

been reported to have gradients of as high as 125 mm Hg.¹¹ Cohn¹² and Jones¹³ and their coworkers recommended that a small Hancock porcine valve should not be used because of these excessive pressure gradients. Many investigators have reported acceptable pressure gradients across small St. Jude Medical prostheses at rest and after exercise.^{3, 4, 14} Rahimtoola¹⁵ identified an aortic valve area index of 0.75 cm²/m² or less as severe aortic stenosis in patients who did not undergo operation. As calculated from the published orifice area of St. Jude Medical valve prostheses, aortic valve area indexes of 0.86 cm²/m² and 1.08 cm²/m², respectively, would result when 19 mm or 21 mm prostheses were implanted in patients with a BSA of 1.9 m². These postimplantation aortic valve area index values suggest significant residual aortic stenosis and lead to the concerns of poor long-term cardiac performance. Nevertheless, a moderate improvement in the left ventricular outflow orifice reduces the valve gradient exponentially because the relationship of the gradient to valve area is curvilinear.¹⁵ Long-term improvement in the cardiac performance is a major finding of this study, on the basis of patients' clinical improvement as judged by NYHA class. Many patients did well in the early and late

postoperative periods even when only moderate improvement of severe left ventricular obstruction was expected.

In this series late mortality was 3.3%/pt-yr (55 patients). The incidences of sudden death and cardiac death were low irrespective of the BSA. Among the operative survivors with preoperative NYHA class III or IV symptoms, 93% patients had improved postoperative functional class in our series. Analysis of survival by NYHA class (Fig. 2) showed 16-year survival for classes II, III, and IV with the 95% CIs as 59.9% (34.5%, 85.3%), 52.1% (32.7%, 71.5%), and 60.9% (45.3%, 76.5%), respectively. This demonstrates good long-term performance and overall improvement with use of 19 mm and 21 mm St. Jude Medical prostheses without annular enlargement. With advanced age the resting cardiac output diminishes, hence a small enlargement in outflow orifice area results in considerable restoration of basal circulation and a marked improvement in functional class. Because the majority of our patients were elderly (average age of 64), this may explain the observed vast clinical improvement among our patients.

Kratz and associates⁵ found that a BSA of 1.9 m² was an independent risk factor for sudden death, but

Fig. 7. Cumulative survival curves of mortality for four variables: patients with 19 mm valve and BSA less than 1.9 m², patients with 19 mm valve and BSA 1.9 m² or greater, patients with 21 mm valve and BSA less than 1.9 m², and patients with 21 mm valve and BSA 1.9 m² or greater.

they did not mention the number of patients at risk who received size 19 mm or 21 mm prostheses. In our series, of patients with a BSA of 1.9 m² or greater, two received a size 19 mm prosthesis and 56 received a size 21 mm. In contrast, we did not find a BSA of 1.9 m² or greater as a risk factor for adverse long-term results. As shown in Figs. 5 and 7, our analyses of long-term survival and incidence of sudden death demonstrated no significant statistical difference between patients with a larger BSA and their smaller counterparts. However, as noted in Fig. 6 native aortic stenosis did statistically increase the incidence of sudden death.

The operative mortality rate in this series was 3.3%, which is comparable with the findings of others.^{2, 5, 16-18} In this series 33% of patients underwent concomitant CABG and the actuarial survival at 10 years was 68.4% (59.3%, 77.5%) and at 16 years was 60% (47.2%, 78.8%), which compares well with findings of the reported series. Czer¹⁷ and Arom² and their associates reported 9-year survivals at 51% and 75.5%, respectively, with a high proportion of the implanted valves larger than 21 mm.

Risk factors for long-term survival. In our experience long-term survival was affected by advanced

age at operation and postimplantation events of endocarditis and myocardial infarction. The Cox proportional hazard model with time-dependent covariates showed these events decreased the time to mortality ($p = 0.003$, 0.04, and 0.0001 with risk ratios with 95% CIs of 1.04 [1.02, 1.07], 4.69 [3.21, 25.65], and 9.07 [1.11, 19.92], respectively). Age at operation was found to be an independent risk factor (age ≥ 70 years increased the late mortality, $p = 0.01$). This study showed survival in two groups, patients 69 years and younger and patients 70 years and older, with 95% CIs at 10 years, to be 73.7% (64.7%, 82.7%) and 53.7% (39.6%, 67.8%), respectively. Despite overall relative disadvantages of increased age, the long-term survival of older patients remains substantial. Preoperative NYHA class and BSA, size of the implant, and concomitant CABG did not affect the long-term survival in this series.

Risk of long-term morbidity. Another principal concern of any mechanical valve is its thrombogenic potential and the need for anticoagulation. In this series there were three periods of different postoperative anticoagulation regimes with warfarin. We did not find any statistical differences in incidence of thromboembolism and anticoagulation-

Fig. 8. Kaplan-Meier curve for all valve-related complications (paravalvular leak, thromboembolism, anticoagulation-related hemorrhage, prosthetic endocarditis, and reoperations) with 95% CIs. *Dotted lines* represent the 95% CIs.

related hemorrhage between the periods. The review of Akins¹⁹ of four common mechanical prostheses revealed a linearized rate of thromboembolism of 1.6%/pt-yr (range 0.7% to 2.8%) for the St. Jude Medical mechanical prosthesis. Duncan and colleagues²⁰ reported a linearized rate of 0.99%/pt-yr for thromboembolism among the aortic valves and freedom from thromboembolism at 5 years as 97.6% (prothrombin time 1.5 to 2 times the control value) and found anticoagulation-related complications to be 1.13%/pt-yr, with one patient dying as a result of intracranial hemorrhage. Our results compare well with those of the aforementioned series and show no mortality caused by anticoagulation-related hemorrhage. Few data exist that show the ideal level of anticoagulation to minimize both thromboembolic and hemorrhagic complications. Kopf and associates²¹ used a prothrombin level of 1.3 to 1.5 times the control value and found a linearized rate of anticoagulation-related hemorrhage of 1.3%/pt-yr, which is no different than in our experience (1.24%/pt-yr). Our findings compare well with those of most of the reported series. Akins²² recently suggested use of a

composite thromboembolism and bleeding index, and in our series this turned out to be 2.3%/pt-yr, which compares well with that of all available mechanical prostheses. In our series other valve-related complications such as paravalvular leak and endocarditis were also comparable with those in reported experiences and we did not encounter any incidence of structural failure, which confirms the durability of the St. Jude Medical prosthesis.

To avoid obstruction of the left ventricular outflow tract many techniques have been used to enlarge the annulus to accommodate a larger-sized prosthesis.²³⁻²⁵ This potentially increases the risks of injury to the coronary arteries and to the conduction bundle and the risk of surgical hemorrhage. David and Uden²⁶ have described new techniques to accommodate larger-size prostheses with satisfactory short-term results; however, long-term results are not available yet. Homograft replacement of the aortic valve as an isolated procedure or as root replacement²⁷ has an added advantage of freedom from anticoagulation. Replacement of the aortic valve with pulmonary autograft may even have some growth potential.²⁸ However, these techniques will

require special training and experience and are presently not widely used. Routine availability of the homograft is also a problem. In this series we present a standard and reproducible technique with commercially available St. Jude Medical prostheses with satisfactory long-term results. Valves in the new St. Jude Medical HP (high performance) series have an effective orifice equivalent to the next larger standard valve size. The future routine use of these HP valves may further improve the surgical results.

In conclusion, we present our clinical experience with small-size St. Jude Medical valve prostheses in patients with a small native aortic anulus. Our initial operative mortality and morbidity and long-term follow-up outcome confirm the efficacy of these valves in this surgical setting. The long-term performance of aortic valve replacement with small St. Jude Medical valves (19 mm and 21 mm) without annular enlargement is satisfactory as judged by improvement in the functional class of patients, survival statistics, durability of the prosthesis, and valve-related morbidity comparable to that of other sizes. Age at operation greater than 70 years was the only independent risk factor affecting survival. Multivariate analysis showed age at operation, myocardial infarction, and endocarditis affected long-term survival. BSA greater than 1.9 m², preoperative functional class, size of prosthesis, and concomitant CABG procedure did not influence long-term survival. Therefore we conclude that the use of a size 21 mm or smaller St. Jude Medical prosthesis in a small native aortic anulus is a reasonable alternative. The effective orifice of the new high-performance St. Jude Medical valve is similar to that of the next larger standard valve, and it is reasonable to assume that the wide use of these valves might improve the results further.

We gratefully acknowledge the assistance of Sharla Williamson and Steve Reinart, who provided statistical consultations, and Merry Meyers for her assistance in the data collection.

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