St. Jude Medical prosthesis in children

From December 1980 through April 1992, 20 children 2 to 18 years of age underwent valve replacement with the St. Jude Medical prosthesis. Nine children underwent aortic valve replacement, eight underwent mitral valve replacement, and the three children with corrected transposition underwent left-sided tricuspid valve replacement. Of the 20 patients, 17 underwent 23 previous procedures. All but five patients received adequate adult-sized prostheses. There was one hospital death (5%). All hospital survivors received maintenance doses of sodium warfarin. Follow-up was 100% complete with a total of 106 patient-years. There were no late deaths and no thromboembolic or anticoagulant-related bleeding. None of the patients had prosthetic valve endocarditis or a periprosthetic leak. Reoperation was not required in any patient. The great majority of the children (16 of 19) were in New York Heart Association functional class I, two were in class II, and one with complex congenital heart disease was in class III at the time this article was written. This study illustrates the excellent results of cardiac valve replacement with the St. Jude Medical prosthesis in children and confirms the safety of sodium warfarin in this age group. (*J THORAC CARDIOVASC SURG* 1994;108:52-6)

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Accelerated calcification and valvular dysfunction of bioprostheses in children¹⁻⁷ have made the use of mechanical prostheses for this particular age group more acceptable to cardiac surgeons. However, the problem of somatic growth,^{8,9} resulting in patient/valve mismatch, remains a matter of concern. In addition, the decision to maintain children anticoagulation therapy in children and the type of anticoagulant used after mechanical valve replacement remain controversial.¹⁰⁻¹⁸ We present our experience with the St. Jude Medical prosthesis (St. Jude Medical, Inc., St. Paul, Minn.) in children.

Patients and methods

From December 1980 through April 1992, 20 children, ranging from 2 to 18 years of age (mean 10.3 years), underwent

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cardiac valve replacement with the St. Jude Medical prosthesis at the Royal Victoria Hospital. Fig. 1 shows age distribution of the study population: 11 boys and 9 girls. Eleven (55%) children were in New York Heart Association (NYHA) class III or IV before the operation.

Nine children underwent aortic valve replacement (AVR), eight underwent mitral valve replacement (MVR), and three patients who had congenitally corrected transposition of the great arteries underwent replacement of the morphologically tricuspid left atrioventricular valve. Table I shows the original lesions of the valves replaced with the St. Jude Medical prosthesis.

Seventeen patients underwent 23 previous operations as shown in Table II. Five patients in the MVR group underwent eight previous operations on the mitral valve. Among these patients, one had two previous mitral valve replacements with a bioprosthesis. One patient who had a parachute mitral valve required MVR after two unsuccessful valvotomies. Six patients had valve replacement at their initial operation. Three had corrected transposition of the great vessels. Repair was attempted but was unsuccessful. In the remaining three cases, one attempted repair was unsuccessful, another in a patient with acute rheumatic fever was thought to involve bacterial endocarditis, and the case involving traumatic mitral regurgitation was also not repairable. Of the nine patients in the AVR group, six required eight previous operations on the aortic valve. In the other three patients (Marfan's syndrome, myxomatous degeneration, and acute bacterial endocarditis) replacement was mandatory.

Cardiopulmonary bypass and systemic hypothermia were used for all procedures. Myocardial protection was provided with cold crystalloid or blood cardioplegic solution and topical

Fig. 1. Age at valve replacement with the St. Jude Medical prosthesis. *L-TVR*, Left-sided tricuspid valve replacement.

hypothermia. All valves were implanted by means of a continuous suture technique. Four patients required additional procedures (Table III). Three of the four patients were in the AVR group. The size of the St. Jude Medical prostheses used is shown in Table IV. All but five patients received adequate adult-sized prostheses. One patient 2 years of age who required two previous valvotomies for congenital mitral stenosis, received a 19 mm aortic prosthesis; another patient required enlargement of the aortic root with a pericardial patch to allow insertion of a 19 mm valve. A 29 mm prosthesis was inserted in the aortic position in two patients. One of these two patients had Marfan's syndrome, and the other had dilated aortic root without aneurysm formation.

Sodium warfarin therapy was started on the second postoperative day for all patients. The warfarin dose was modified to keep the prothrombin time measured as International Normalized Ratio (INR) between 2.0 to 2.5 (prothrombin time ratio of 1.7 to 1.9). The actuarial method was used to summarize overall mortality. Survival estimates are recorded $\pm$ the standard error of the estimate (Fig. 2).

Results

There was only one hospital death (5%). This patient was 9 years of age and was known to have bicuspid aortic valve and coarctation of the aorta. She had *Staphylococcus aureus* endocarditis and underwent AVR and exclusion of a mycotic aneurysm of the aorta with the use of a pericardial patch. After the operation, she had a septic renal infarct and, at reoperation, through a thoracotomy, a large mycotic aneurysm of the descending aorta distal to the coarctation was found. Resection of the coarctation

Table I. Original lesions of valves replaced with St. Jude Medical prostheses

Lesion	No. of patients
MVR	
Parachute mitral valve	1
Dysplastic mitral valve	2
MR with AV canal defect	2
Congenital MR (cleft leaflets)	1
Acute rheumatic fever	1
Traumatic MR	1
L-TVR	
Ebstein's anomaly of left-sided TV	2
TR (thickened and retracted leaflets)	1
AVR	
Bicuspid aortic valve	5
AR associated with VSD	1
AR caused by BE	1
Marfan's syndrome	1
Myxomatous degeneration	1
Total	20

MR, Mitral regurgitation; AV, atrioventricular; L-TVR, left-sided tricuspid valve replacement; TV, tricuspid valve; TR, tricuspid regurgitation; AR, aortic regurgitation; VSD, ventricular septal defect; BE, bacterial endocarditis.

together with the mycotic aneurysm and end-to-end anastomosis was performed; however, the patient's septicemia did not subside, and she died 2 months after the first operation.

Table II. Previous procedures

<i>Procedure</i>	<i>No. of patients</i>	<i>No. of previous operations</i>
MVR group		
Coarctation repair, mitral valvotomy	1	3 (1 + 2)
Repair of A-V canal defect	2	3
Repair of cleft mitral leaflets	1	1
Previous MVR	1	2
L-TVR group		
Pulmonary valvotomy	1	1
Pulmonary valvotomy and VSD repair	1	1
Coarctation repair	1	1
AVR group		
Aortic valvotomy	3	3
Aortic and pulmonary valvotomy, then aortic valve repair and myotomy	1	2
Patch enlargement of pulmonary OT	1	1
Aortic valve repair	1	1
Repair of aortic valve and VSD	1	2
Ligation of patent ductus arteriosus	2	2
Total	17	23

A-V, Atrioventricular; L-TVR, left-sided tricuspid valve replacement; VSD, ventricular septal defect; OT, outflow tract.

Table III. Additional procedures

<i>Procedure</i>	<i>No. of patients</i>
Replacement of ascending aorta aneurysm (Marfan)	1
Resection of subaortic stenosis	1
Patch closure of mycotic aneurysm	1
Aortic root enlargement with pericardial patch	1

The mean follow-up period was 5.3 ± 0.78 years, ranging from 0.47 to 11.77 years. The total follow-up was 106 patients-years. No patients were lost to follow-up. There was no late mortality or any thromboembolic or anticoagulant-related bleeding necessitating medical attention. The mean of the last five INR results for the whole group of patients was 2.3 ± 0.07 (range 1.90 to 2.98). Actuarial survival at 6 years was $95\% \pm 5\%$ (Fig. 2). No patient had prosthetic valve endocarditis (PVE) or required reoperation. The majority of patients (16 of 19) were in NYHA functional class I, and two patients were in class II. Only one patient was in class III. This patient had left-sided tricuspid valve replacement and had subvalvar pulmonary stenosis. Fifteen of the 19 survivors were in sinus rhythm, whereas only one patient was in atrial fibrillation at the time this article was written. Three patients required insertion of a permanent pacemaker that was not related to valve replacement (two before the operation and one late after the operation). Of these three patients, two had Ebstein's anomaly of the left-sided tri-

Table IV. Size of the St. Jude Medical prostheses used and age at operation

<i>Prosthesis size (mm)</i>	<i>No. of patients</i>	<i>Age at operation (yr)</i>
AVR		
19	2	7, 9
21	1	9
23	2	14, 18
25	1	15
27	1	15
29	2	14, 18
MVR		
19	1	2
25	1	6
27	1	7
29	4	3, 8, 10, 16
31	1	14
L-TVR		
23	1	4
27	1	5
31	1	12

L-TVR, Left-sided tricuspid valve replacement.

cuspid valve, and the third patient had a complete atrioventricular canal defect with two previous attempts at repair.

Discussion

Having exhausted all the efforts to repair cardiac valves in children, we find the use of the St. Jude Medical prosthesis as a valve substitute, with its low-profile structure,

Fig. 2. Actuarial survival in children after valve replacement with the St. Jude Medical prosthesis.

appealing. Homograft replacement of the aortic valve is an attractive option but was not available for our patients. Our 5% early mortality and 0% late mortality rates compare well with those of other series, including a variety of mechanical and tissue prostheses.¹⁰⁻²⁴ However, none of the patients in our series was under 2 years of age.

Controversy continues regarding the decision to maintain anticoagulation therapy in active energetic children and the choice of the ideal anticoagulant for this particular age group.¹⁰⁻¹⁸ In our series, all patients were maintained on warfarin, and the INR was kept between 2 and 2.5. None of the patients had either a thromboembolic event or an anticoagulant-related hemorrhage. We believe that anticoagulation therapy with warfarin is essential for all children and that a therapeutic range of 2.0 to 2.5 can be achieved without difficulty. In the series of Sade and associates,¹² the authors admitted that children who did not receive anticoagulants were significantly less free of thrombotic and thromboembolic events than were the adults who did receive anticoagulants. Some authors^{10, 14, 15} reported good results with antiplatelet drugs (aspirin and dipyridamole), whereas McGrath and associates¹⁶ concluded that full-dose warfarin therapy is superior to antiplatelet drugs. Rao and associates¹⁷ recommended that aspirin and dipyridamole are adequate for mechanical aortic valves, that warfarin may be needed in patients with a mitral valve prosthesis, but that warfarin anticoagulation should be prescribed for patients with double valve replacement. Borkon and associ-

ates¹³ suggested that because of difficulties with achieving anticoagulation with warfarin, aspirin should be used for patients younger than 5 years of age, whereas older patients can be treated with warfarin.

None of the patients in our series required reoperation. Every effort was made to insert the largest possible prosthesis to avoid the problem of having to replace it in adult life. In the MVR group, the anulus was dilated enough to accept a prosthesis larger than 25 mm in diameter in all patients except two. One of these two patients received a 25 mm prosthesis. The second, who underwent two previous valvotomies for congenital mitral stenosis, had an anulus diameter of only 17 mm. A 19 mm prosthesis was implanted and offset obliquely against the atrial septum. All patients who received a mitral prosthesis larger than 25 mm in diameter were older than 6 years of age, except one who was only 3 years of age. In the Friedman, Edmunds, and Cuasco⁸ series, all three patients who underwent MVR when younger than 4 years of age required a second valve replacement 8.5 years later. This procedure will possibly apply to the 2-year-old patient who received a 19 mm prosthesis. Six of the nine patients who underwent AVR received a prosthesis larger than 21 mm in diameter, and only two required the insertion of a 19 mm prostheses. The satisfactory hemodynamic function of the implanted prostheses is clinically reflected in the fact that 16 of the 19 survivors were in NYHA functional class I and two patients were in class II. The only patient in class III had subpulmonary stenosis and was on

the waiting list for correction at the time this article was written.

The present study illustrates excellent results of valve replacement in children with the St. Jude Medical prosthesis and the safety of warfarin anticoagulation therapy in this age group. We recommend the use of this prosthesis in children if valve repair is not feasible.

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