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Review of Ten Years' Use of St. Jude Medical Prosthetic Valve Replacement and Postoperative Management at Niigata University Hospital

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Summary. **A ten-year period of using St. Jude Medical (SJM) prosthetic heart valves at Niigata University Hospital was reviewed. Between December 1979 and August 1990, 261 patients, 118 males and 143 females, ages ranging 6-75 years, underwent SJM prosthetic valve replacement. Aortic valve replacement was performed in 72 patients, mitral valve replacement in 140 patients, combined aortic and mitral valve replacement in 37 patients, and miscellaneous valve replacement in 12 patients. The actuarial survival rates at 10 years including hospital deaths were: AVR; 86.1±4.4%, MVR; 92.0±2.5%, and AVR+MVR; 78.4±6.1%. The causes of death were cardiac failure in 11 patients, sudden death in 2 patients, infection in 4 patients, carcinoma in 3 patients, and miscellaneous in 6 patients. Eleven patients suffered from thromboembolic episodes 3 months to 8 years after surgery. The actuarial thromboembolism-free rates at 10 years were: AVR; 96.2±2.6%, MVR; 91.6±3.0% and AVR+MVR; 95.5±4.4%. Four patients suffered from acute intravascular hemolysis and underwent a second replacement. Three of the 4 patients who showed chronic hemolysis were able to avoid reoperation due to successful drug therapy and limited daily activity. Of the 5 patients who developed prosthetic valve endocarditis, 3 patients survived without reoperation. Late postoperative cardiac catheterization revealed the excellent performance of prosthetic heart valves, and adequate left ventricular performance in all but 8 patients. Six patients developed malignant diseases, and 3 patients endured radical resection.**

In conclusion, excellent performance and high-quality survival rates were attainable with SJM prostheses, due to their flow characteristics, and to the improved postoperative management.

INTRODUCTION

Several articles have discussed mid- and long-term use of St. Jude Medical prosthetic valves.[1-4,6-10] All have emphasized the valves' excellent hemodynamic characteristics and lower complication rates. The new design of the St. Jude Medical (SJM) device, different from any other prosthesis available in past decades, demonstrated improved hemodynamic performance and a high-quality survival rate.[7-10] The prosthesis' excellent performance has been attributed to:

1) the flow characteristics of the hinged, bileaflet valve,
2) lower thrombogenicity, and
3) long-term *in vitro* durability.

As we surveyed both the literature and our own ten-year experience with SJM prosthetic valves, we thought that new methods of postoperative management may well have contributed to the excellent results obtained with the SJM devices. This paper reports our ten-year use of the valves between December 1979 and August 1990. We emphasize the importance of postoperative examination of the performance of both the prosthesis and the ventricle, and the management of both cardiac and non-cardiac morbidity.

Patient Population

The patient population consisted of 261 patients, 118 males and 143 females, ages ranging 6-75 years,

mean±standard deviation, 48.0±13.3 years. We excluded from the present study patients receiving both double or triple valve replacement plus another type of prosthesis. Among the patients, 46 patients had undergone 49 previous valve procedures including 26 prosthetic valve replacements. Six patients required emergency surgery due to left ventricular deterioration or active prosthetic valve endocarditis (PVE).

Operative Procedures

Table 1 lists the valve lesions and associated diseases of 261 patients. Table 2 lists the indications for surgery, and Table 3 the associated procedures at the time of prosthetic valve implant.

We used a Bos CM-40® or Maxima® membrane oxygenator during the cardiopulmonary bypass surgery, and maintained moderate hypothermia during aortic cross clamping. Since 1985, we have substituted St. Thomas Hospital's solution for the cold GIK solution.[16]

As a routine surgical procedure, we use the everting mattress suture with pledget, and prefer to preserve the posterior mitral leaflet whenever we can place a 27 or 29 mm prosthesis. Since 1982, we have been orienting the mitral valve perpendicular to the natural leaflet; before that we used parallel orientation.

Table 4 summarizes the relation between the prosthesis size and the body surface area (BSA): In the aortic position, the 21, 23 and 25 mm prosthesis were the most popular. We implanted the small, 19 mm, prosthesis in only 9 of 109 patients. These 9 patients had a BSA of 1.34±0.51 m². In the mitral position, 85% of 177 patients received 27 or 29 mm prostheses. A 23 mm prosthesis was used in only one patient, a 9-year-old child, whose BSA was 0.65 m². This child, who had undergone a mitral commissurotomy 3 years earlier, received the prosthesis for a congenital mitral stenosis.

Table 1. Patient population

Age	6-75 y. o. (48.0±13.3)
Sex	118 males
	143 females
Previous valve procedures	46 (17.6%)
Emergent operation	6 (2.3%)
Type of diseases	
Aortic	52
Aortic+mitral	20
Aortic+ascending aortic	14
Mitral	51
Mitral+tricuspid	91
Aortic+mitral+tricuspid	23
Tricuspid	5
Pulmonic	5
Total	261

Table 2. Indications for surgery and operative procedures

	No. of patients
Indication	
NYHA class II	32
III	153
IV	35
With coronary ostial stenosis	2
With aortic aneurysm	8
With intractable infection	6
With prosthetic failure	25
Total	261
Procedures	
AVR	54
AVR with composite graft or repair of aneurysm	11
AVR+mitral repair	7
MVR	54
MVR+tricuspid plasty	86
AVR+MVR	37
MVR+TVR	3
TVR	4
PVR	5
Total	261

NYHA=New York Heart Association, AVR=aortic valve replacement, MVR=mitral valve replacement, PVR=pulmonic valve replacement, TVR=tricuspid valve replacement

Table 3. Associated procedures done at time of valve inplant

Procedure	No. of patients
Coronary bypass surgery	5
Enlargement of child's aortic annular ring	1
Repair of periannular defects, composite graft, or repair of ascending aortic aneurysm	3
Tricuspid annuloplasty	86
Double or triple valve replacement	37
Miscellaneous *	12

* Included pulmonic valve replacement and combined mitral and tricuspid valve replacement

Postoperative Management and Follow-up

Follow-up. Duration of follow-up ranges from 4 months to 11 years, averaging 5.5±3.3 years. No patient was lost during the follow-up period. We amassed a total of 1272.9 patient-years for follow-up: 309.2 after aortic valve replacement (AVR), 793.8 after mitral valve replacement (MVR), and 169.9 after combined aortic and mitral valve replacement (AVR+MVR). Twelve patients with tricuspid valve replacement, pulmonic valve replacement, and combined mitral and tricuspid valve replacement were excluded from statistical data because of the small number of such cases. Once discharged, patients were encouraged to visit the hospital every 2 to 4 weeks for a physical examination and a thrombotest check. Electrocardiographic and chest X-ray were performed every 1-2 years, and echocardiographic examination when necessary. Of the 231 hospital survivors after mitral and/or aortic valve replacement, 108 patients received cardiac catheterization 1-4 years after surgery. A total of 172 patients received late postoperative echocardiography and/or cardiac catheterization.

Anticoagulant Therapy. All patients received anticoagulant therapy starting at 1-3 days after surgery. Target thrombotest level was 10-25%. Of the 231 patients who received aortic and/or mitral valve replacement and survived hospitalization, 170 patients received Warfarin therapy; most received a capsule of bucolome as well. Sixty-one patients received both Warfarin and antiplatelet therapy, 48 with MVR and 13 with AVR+MVR.

Patients suffering from permanent or transient neurological defects or a sudden peripheral ischemic attack were referred to our hospital or a follow-up clinic. Brain computed tomography with or without cerebrovascular angiograms were performed to determine the presence of cerebral emolism or intracranial hemorhage. Intravenous thrombolytic therapy was routinely employed in the event of acute cerebral embolism. Since 1989, 2 patients have undergone selective revascularization within 4 h after the onset of cerebral embolism.

Hemolysis. Acute hemolysis was clinically diagnosed as intravascular hemolysis occurring within 30 days of prosthetic valve replacement. Reoperation was indicated with acute hemolytic anemia. Serum lactate dehydrogenase (LDH) was checked, and both hematological and echocardiographic examinations were used for evaluation of the causes and degree of hemolysis. Progressive anemia was treated by either conservative therapy or reoperation, depending upon the individual case.

Antibiotic Therapy. Antibiotics were given all patients for 5-7 days after surgery. If a patient was suspected of having infective endocarditis, antibiotic therapy was started based on serial blood culture results, and was continued until the C-reactive protein test became negative. If PVE was documented and the patient exhibited either a mild or no cardiac failure, antibiotic therapy was continued for at least 8 weeks, especially in cases of alpha streptococci or staphylococcus epidermis.

Analysis and Statistics

Continuous variables are expressed as mean ± standard deviation; comparisons of variables between 2 groups were made by the unpaired t test. Incidences were compared by $\chi 2$ analysis. Survival and thromboembolism-free curves were constructed by actuarial methods following Kaplan and Meier. Definitions of mortality and morbidity follow Edmunds' guideline.[5]

Table 4. Prosthetic size versus body surface area

Aortic	No. of patients	BSA (m^2)	Mitral	No. of patients	BSA (m^2)
19 A	9	1.34±0.15			
21 A	34	1.42±0.13			
23 A	37	1.44±0.24	23 M	1	0.65
25 A	22	1.65±0.13	25 M	17	1.32±0.13
27 A	6	1.54±0.10	27 M	85	1.43±0.18
29 A	1	1.58	29 M	65	1.51±0.16
			31 M	9	1.55±0.12
Total	109		Total	177	

BSA=body surface area

RESULTS

Incidence and Causes of Mortality. The overall hospital mortality rate was 7.2% following AVR and/or MVR. The causes were: cardiac failure in 3 patients, intractable graft infection or infective endocarditis in 3 patients, and graft-versus-host diseases in 1 patient following AVR. AVR had a 30-day mortality of 2.8%, and a hospital mortality rate of 9.7%.

MVR had a 30-day mortality rate of 2.1%, and a hospital mortality rate of 2.8%. Of the 4 deaths following MVR, 3 were from cardiac failure and 1 from severe acute hemolysis with progressive anemia.

AVR+MVR had a 30-day mortality rate of 10.8%, and a hospital mortality rate of 18.9%. Of the 37 AVR+MVR patients, 4 patients died within 30 postoperative days: 3 patients died of cardiac failure, 1 patient of intracranial bleeding. Three additional patients died during hospitalization within 6 months, 2 patients of hepatic failure, and 1 patient of multiple organ failure.

Of the 12 miscellaneous valve replacements, 2 patients died of cardiac and hepatic failure after combined mitral and tricuspid valve replacement.

Of the 231 patients who had undergone AVR and/or MVR and were discharged, 9 patients died 4 months to 5 years after surgery. Two patients died of cardiac failure 3 years following AVR. Six patients died following MVR: 3 of carcinoma, 1 of celiac embolism, 1 of PVE, and 1 of sudden death with documented severe left ventricular dysfunction. One AVR+MVR patient with left ventricular dysfunction succumbed to sudden death. Including hospital death, the actuarial survival rates at 10 years were: AVR; 86.1±4.4%, MVR; 92.0±2.5% and AVR+MVR; 78.4±6.1%. (Fig. 1)

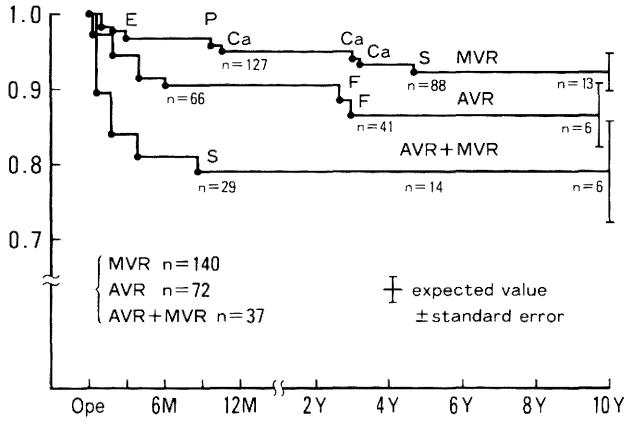

Fig. 1. Actuarial survival rate after SJM prosthetic valve replacement. AVR=aortic valve replacement, MVR=mitral valve replacement, M=month, Y=year. Causes of late death are expressed as follows; P=prosthetic valve endocarditis, Ca=carcinoma, E=embolism, S=sudden death, F=cardiac failure.

Thromboembolism. Eleven patients suffered postoperative thromboembolic episodes 3 months to 8 years after surgery. Of those patients treated with Warfarin therapy, 2 patients ceased to take Warfarin and suffered cerebral emboli within 6 months. A prolonged coma was observed in 1 patient. Seven other patients suffered severe or mild cerebral infarction; only 2 patients recovered completely from their neurological impairment. Of those patients treated with combined Warfarin and antiplatelet therapy, 2 patients suffered cerebral emboli, one on the 30th postoperative month, the other on the 70th. Both arrived at the hospital by ambulance in deep comas. Bilateral carotid and vertebral angiograms revealed semitotal occlusion of the basilar artery. Both patients were successfully revascularized using an infusion of 420,000 units of urokinase or 5,000,000 units of tissue plasminogen activator.[17] One patient recovered within a few days, with only a slight diplopia, and resumed his employment. The other recovered with resulting infirmities and underwent rehabilitation.

Risk factors for thromboembolism, which include atrial fibrillation, left atrial thrombi, and a history of previous thromboemboli, were comparable between the two groups; one receiving Warfarin alone, and the other Warfarin plus antiplatelet therapy. As shown in Table 5, no significant difference was found in the linearized rates of thromboembolism between the two groups (0.89%/patient-year in the Warfarin group; 0.77%/patient-year in the Warfarin plus antiplatelet group).

Five patients underwent pulmonic with or without tricuspid valve replacement, receiving SJM prostheses for pulmonic and tricuspid regurgitation following repair of the tetralogy of Fallot. Of these 5 patients, 2 patients experienced thrombosed valves at 10 and 18 months following the valve implant. One patient underwent successful thrombolytic therapy using 240,000 units of urokinase; the second patient had a second replacement with a Carpentier-Edwards Model 6650 porcine prosthesis at the tricuspid position.[11]

The actuarial thromboembolism-free rate at 10 years were: AVR; 96.2±2.6%, MVR; 91.6±3.0% and AVR+MVR; 95.5±4.4%. (Fig 2)

Hemorrhage. One 63-year-old male suffered an

Table 5. Incidence of thromboembolism after MVR with/without AVR

	Warfarin group	Warfarin+Anti-platelet group	p-valve
Number	105	61	
Follow-up	675 pt-years	258 pt-years	
AVR+MVR	17 (16.2%)	13 (21.3%)	N. S.
Atrial Fibrillation	81 (77.1%)	52 (85.2%)	N. S.
Left Atrial Thrombus	13 (12.4%)	14 (23.0%)	N. S.
Prevous Embolism	26 (24.8%)	17 (27.9%)	N. S.
Thromboembolic Episodes	6	2	
Linearized Rate	0.89%/pt-years	0.77%/pt-years	N. S.

AVR=aortic valve replacement, MVR=mitral valve replacement

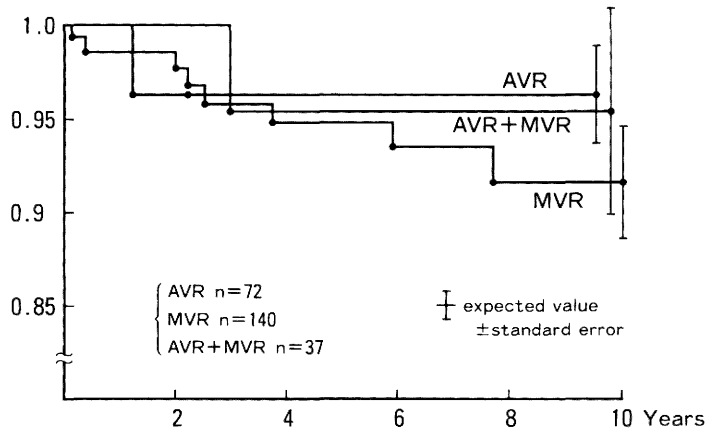

Fig. 2. Actuarial thromboembolism-free rate after SJM prosthetic valve replacement. AVR=aortic valve replacement, MVR=mitral valve replacement.

intestinal hemorrhage 13 months after mitral valve replacement. Despite gastroduodenal and colorectal fiberscopy and selective abdominal arteriograms, the source of the bleeding could not be determined. The hemoglobin level decreased to 5.7 g/dl within a few months. He underwent a second replacement with a Carpentier-Edwards Model 6650 porcine valve on March 1, 1990. A mild anticoagulation therapy (thrombotest level>30%) raised the hemoglobin level to 12 g/dl and he has been doing well.

Hemolysis. Of the 261 patients, 4 patients (1.5%) suffered from acute intravascular hemolysis required second replacements of the SJM prostheses within 30 days after implant. A 58-year-old female who received both aortic and mitral valve replacement, suffered from severe hemolysis and low cardiac output. Although intraoperative examination failed to document any periprosthetic leakage, another replacement was performed using a Björk-Shiley monostrut prosthesis.

Periprosthetic leakage was documented by two-dimensional color doppler echocardiography in the remaining 3 patients who exhibited acute intravascular hemolysis. Two of the 3 patients exhibited periprosthetic leakage between the SJM valve and mitral annulus from which a previous Starr-Edwards prosthesis had been removed.

Of the 4 patients who had abnormally elevated serum LDH levels after discharge, only 1 patient had documented periprosthetic leakage. This patient, a 43-year-old male, exhibited regurgitation following a previous mitral valvuloplasty, and underwent a re-operative MVR with a 27 mm SJM prosthesis. The LDH levels following MVR was 7 times higher than the normal level, and he exhibited clinical signs of hemolytic anemia. After surgery which involved a

reinforced second replacement using a 25 mm SJM prosthesis to release the left ventricular outflow tract narrowing by a relatively smaller size prosthesis, the serum LDH level decreased to within 4 times of the normal level. The remaining three patients with abnormally elevated serum LDH levels received iron sulfate, and 1 patient received subcutaneous recombinant human erythropoietin. In all 4 patients, daily strenuous activities were restricted and vasodilator therapy was offered. At the end of a year of therapy, 2 patients recovered normal hemoglobin levels; the other 2 patients were able to maintain hemoglobin in the 8-9 g/dl range.

Prosthetic Valve Endocarditis (PVE). Five patients, 4 male and 1 female, developed PVE 4 months to 6 years following implant of a SJM prosthesis (Table 6). Blood cultures revealed the causative organisms in 4 patients; in the fifth, case 3, Staphylococcus cultured previously caused the late endocarditis. Endocarditis was considered recurrent in 2 partients who had received AVR for active infective endocarditis. Cerebral bleeding from a mycotic aneurysm of middle cerebral artery occurred in 1 patient.

Fortunately, 3 of the 5 patients were effectively treated without reoperation, because the etiologic organisms were sensitive to penicillin. Of the 5 patients who developed PVE, 2 patients underwent reoperation due to progressive cardiac failure. Case 3 (Table 6) had a second replacement of a SJM prosthesis by the translocation method and died of cardiac failure 2 years after reoperation. Case 5 (Table 6), who suffered from endocarditis due to a methicillin-resistant staphylococcus aureus, exhibited aorto-left ventricular discontinuity with a giant left ventricular aneurysm and underwent a Cabrol operation, but died of cardiac failure. In our patient population, 9 patients had previously undergone prosthetic valve replacement for infective endocarditis. Among them, 2 (22%) underwent reoperation for recurrent infective endocarditis as described above.

Prosthetic Valve Performance. Table 7 lists the calculated effective orifice area of the SJM prostheses measured by the Gorlin-Gorlin formula at the time of late cardiac catheterization. With the 19 mm aortic prosthesis, the left ventricular-aortic peak systolic pressure gradient was 42 mmHg at rest, and 78 mmHg during exercise. The effective orifice area was 1.03 cm^2 at rest, and 0.89 cm^2 during exercise.

With the 21 mm aortic prostheses, the left ventricular aortic pressure gradient was 27 ± 2 mmHg at rest, and 46 ± 6 mmHg during exercise. The effective orifice area of the 21 mm prostheses was 1.34 ± 0.11 cm^2 at rest, and 1.43 ± 0.15 cm^2 during exercise. The 25 mm aortic prostheses showed an effective orifice area 3 cm^2 or wider.

The effective orifice area of the 27 mm mitral prostheses was 2.78 ± 0.88 cm^2 at rest, and 2.50 ± 0.49 cm^2 during exercise. The 29 mm prostheses had effective orifice areas of 2.74 ± 0.59 cm^2 at rest, and 3.41 ± 0.88 cm^2 during exercise.

Ventricular Performance. At the time of the late postoperative study, ventricular deterioration was found in 8 of 172 patients (Table 8). Four of these patients died 9 months to 5 years after prosthetic valve replacement. Possible causes of ventricular dysfunction were: (1) severe preoperative left ventricular dilatation in 4 patients; (2) intraoperative myocardial injury in 1 patient; (3) late postoperative myocardial infarction in 1 patient; and (4) progressive cardiac failure due to repeated operations, and residual regurgitation in 2 patients.

Malignancy. Of the 136 patients with MVR who

Table 6. Prosthetic valve endocarditis

Case		Operation	Interval	Microorganism	Clinical	Therapy
1	46 y. o. M	AVR+MVR	6 years	St. epidermis	Cerebral bleeding Mycotic aneurysm	Chemotherapy Cured
2	60 y. o. F	AVR+MVR	4 years	α-Streptococci	Mild aortic regurgitation	Chemotherapy Cured
3	57 y. o. M	AVRf or IE	15 months	negative	Cardiac failure	Translocation Late death
4	38 y. o. M	AVRf or IE	4 months	MRSA	Aorto-ventricular discontinuity Cardiac failure	Cabrol ope Death
5	58 y. o. M	MVR	2 years	St. epidermis	Mild mitral regurgitation	Chemotherapy Cured

M=male, F=female, AVR=aortic valve replacement, MVR=mitral valve replacement, IE=infective endocarditis, MRSA=methicillin-resistant staphylococcus aureus

survived hospitalization, 6 patients developed malignant diseases 10-39 months after surgery. Two were males and 4 were females, their ages ranging from 42 to 66 years (51.2±8.4 years). Three patients died of advanced, inoperable carcinomas: one with pancreatic carcinoma with pleuritic carcinomatosis, one with gastric cancer with peritoneal dissemination, and one with hepatocellular carcinoma with multiple intrahepatic metastasis (Table 9). Breast cancer in 2 patients and gastric cancer in one were detected on routine visits, and the patients underwent successful radical mastectomy or splenototal gastrectomy. No recurrences of the carcinomas occurred at 6 months to 4 years following the resection of carcinomas.

Other Types of Morbidity. We found no type of prosthetic deterioration other than thrombosed or infected valves, and no nonstructural dysfunction other than paravalvular leakage.

Consequences of Morbid Events. Ten patients required reoperation, 5 patients severe intravascular hemolysis, 2 patients for recurrent infective endocarditis, 2 patients for a thrombosed pulmonic or tricuspid valve, and 1 patient for intestinal bleeding of an undetermined origin. Linearized rates of reoperation were: AVR; 0.65%/patient-year, MVR; 0.63%/patient-year and AVR+MVR; 0.59%/patient-year.

Prosthesis-related mortality, including hospital deaths, was as follows: 2 deaths from prosthetic valve endocarditis, 2 from thromboembolism, 1 from intracranial bleeding, and 4 following reoperation. Linearized rates of valve-related mortality were: AVR; 1.29%/patient-year, MVR; 0.38%/patient-year and AVR+MVR; 1.18%/patient-year.

Table 7. Effective orifice area of the SJM prosthesis measured at the time of late cardiac catheterization

	Number	EOA at rest	EOA during exercise
19 A	1	1.03 cm^2	0.89 cm^2
21 A	2	1.34±0.11 cm^2	1.43±0.15 cm^2
23 A	6	2.04±0.56 cm^2	1.77±0.22 cm^2
25 A	9	3.41±1.44 cm^2	3.36±1.56 cm^2
27 A	1	2.72 cm^2	3.15 cm^2
29 A	1	3.07 cm^2	.....
27 M	11	2.78±0.88 cm^2	2.50±0.49 cm^2
29 M	13	2.74±0.59 cm^2	3.41±0.88 cm^2

Calculated by Gorlin-Gorlin formula based on the peak left ventricular aortic pressure gradients or the mean left atrial left ventricular pressure gradients
EOA=effective orifice area

Table 8. Postoperative cardiac performance

	No. of Hospital survivors	No. of Study patients	No. of LVEF<0.4 or %FS<20	No. of Late cardiac deaths
AVR+MVR	30	21 (10)	1	1
AVR	65	43 (22)	4	2
MVR	136	108 (70)	3	1
Total	231	172 (102)	8	4

( )=Number of cases undergoing postoperative cardiac catheterization
AVR=aortic valve replacement, MVR=mitral valve replacement, LVEF=left ventricular ejection fraction, %FS=% fractional shortening

Table 9. Malignancy after SJM prosthesis implantation

Case			Interval	Site	Therapy	Outcome
1	58 y. o. F	MVR+TAP	11 months	Pancreas	Pleuritis carcinomatosa Conservative	Death
2	43 y. o. F	MVR+TAP	39 months	Stomach	Dissemination Exploration	Death
3	50 y. o. M	MVR	34 months	Liver	Intrahepatic metastasis Anticancer agents	Death
4	42 y. o. F	MVR+TAP	23 months	Breast	Radical mastectomy	Alive
5	49 y. o. F	MVR	10 months	Breast	Radical mastectomy	Alive
6	66 y. o. M	MVR+TAP	22 months	Stomach	Splenototal gastrectomy	Alive

F=female, M=male, MVR=mitral valve replacement, TAP=tricuspid annuloplasty

DISCUSSION

The current advantages of the St. Jude Medical prostheses are summarized as follows:

1) Lower thrombogenicity and less hematologic deterioration,
2) Central flow hemodynamics and a larger effective orifice area, and
3) Better histocompatibility.

The excellent performance of St. Jude Medical prosthetic valves[2-4] has evolved valve replacement over the past decade. The lower incidence of complication rates may be partly due to better intraoperative myocardial protection, better blood preservation techniques with current membrane oxygenators, newer suture techniques, surgical materials, and instruments, and standardized postoperative care. For these reasons, the differences in the postoperative performances between the SJM and other currently available prostheses are less obvious at our institution.

Many articles have described thromboembolic occurrences following the implant of SJM prostheses at 1.6-2.6%/patient-year.[8-10] However, the data could be inaccurate unless the patients were examined by a neurologist, and had brain computed tomography. Futhermore, the anti-coagulant therapy may account for the low incidence of thromboembolic episodes. It is recommended that Coumadin dosage be determined based on a thrombotest level every 2-4 weeks.

One report emphasized the efficacy and limitations of antiplatelet therapy in reducing thromboembolism following prosthetic valve implant.[12] The optimal control of both coagulation activity and platelet aggregation rates might be more beneficial in preventing thromboembolism in patients following prosthetic valve implant.[13,14] Since 1984, we have introduced ticlopidine dehydrochloride and aspirin in a random fashion, mainly in patients with MVR and AVR+MVR. The dosage of antiplatelet agent was determined by measuring the maximum aggregation rate (MAR) of platelets every 3-6 months. The target control levels were: ADP, 10 micro Mol: MAR; 30-50% and collagen, 2 micrograms/ml: MAR; 20-40%.

The present study revealed that the antiplatelet therapy added to anticoagulation therapy did not reduce the incidence of thromboembolism when compared to anticoagulation therapy alone. Thus, antiplatelet therapy appeared to offer no benefits over the anticoagulation therapy.

In our previous reports, the clinical course and possible causes of thromboses in SJM pulmonic and tricuspid prostheses were addressed;[11] however, none of those who underwent tricuspid valve replacement for acquired combined valvular diseases suffered a valve thrombosis.

Czer et al., emphasized a less intensive Warfarin regimen for reducing hemorrhagic risk during anticoagulation therapy.[10] In the present series, cerebral bleeding occurred in one patient with active infective endocarditis. The lower incidence of intracranial hemorrhage may be related to the younger age, but a less intense Warfarin therapy might be indicated for patients over 80 years of age.

Jaffe et al., reported on the valve area as measured by doppler echocardiography. The 21 and 23 mm SJM prostheses showed an orifice area of $1.4 \pm 0.45\ cm^2$. These values are similar to our results. The calculated effective orifice area might not reflect the true effective orifice area when turbulent axial stresses are higher, but Chandran demonstrated a relative lower turbulent flow characteristic of SJM prostheses.[2]

Although several reports have described high-quality survival after implant of a SJM valve,[7-10] few investigators evaluated late postoperative ventricular function. In the present study, four of 9 deaths after discharge were cardiac deaths due to either progressive cardiac failure or possibly due to ventricular tachycardia. All 4 patients demonstrated a deteriorated left ventricular function at the time of the late postoperative study, although 2 of them with NYHA functional class II and III ratings maintatined their employment. In such patients, therapy consisting of afterload reduction, anti-arrhythmic agents, and restriction of exercise is indicated.

It was reported that massive homologous blood transfusions, valve orientation, and pre-existing, non-operated mild valvular regurgitation were considered responsible for severe hemolysis.[18] In our study, transesophageal doppler echocardiography and intraoperative examination revealed only minor paravalvular leakage in 4 of 8 patients who had hemolysis. Use of a Dacron sewing ring might increase hemolytic anemia in the presence of minimal leakages.[9] On the other hand, 3 of the 4 patients with chronic hemolysis recovered from their anemia by drug therapy and a restriction of physical activities.

Although our study exhibited a relatively higher incidence of prosthetic valve endocarditis, antibiotic therapy was successful in 3 of the 5 patients.[15] Early and optimal introduction of effective antibiotic therapy might have reduced the progression of cardiac failure in the present study.

Morbidity might be due to causes other than car-

diac and valve-related causes, but no report has addressed this issue. In our study, malignancy was the cause of 3 late deaths among patients who received a SJM mitral valve replacement. Early diagnosis during routine follow-up visit are essential for successful resections of carcinomas.

Undoubtedly, as the survival rate increases, more attention should be paid to non-cardiac morbidity.

CONCLUSIONS

An excellent performance and high-quality survival rate was documented following SJM prosthetic valve replacement. The present study confirmed a lower incidence of thromboembolism, rare intracranial hemorrahge under optimal levels of thrombotests, excellent prosthetic valve and ventricular performances following a SJM valve implant. The prosthetic valve endocarditis and intravascular hemolysis were successfully treated in most patients. The excellent results are related to the excellent flow characteristic, better histocompatibility of the prostheses, and to the improved postoperative management.

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