ST. JUDE MEDICAL PROSTHESIS IN VALVULAR CARDIAC SURGERY(*)

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Sixty-two St. Jude Medical prosthesis were implanted in 50 cases. The range of follow-up was 1 to 30 months (mean 15 months). All of the patients were evaluated in the early and late postoperative periods; by clinical events, thrombosis, embolism, hemolysis, prosthetic valve endocarditis, valve failure, the incidence of mortality. There were 25 male (58%), and 21 female (42%) patients. The youngest patient was 4 and the eldest 68 years old. The average age was 36.2 years. Of the 62 valve replacements, 22 were in mitral, 13 in aortic, 1 in tricuspid position, (11 multiple valve replacements). Concomitant procedures as well as valve replacement were performed in another 4 patients. Hospital mortaliy was 6% (4 cases), and there was no late mortality was 0%. The incidence of thromboembolism was 4% (2 cases) in the early follow-up period. There were no valve thrombosis, prosthetic valve endocarditis, periprosthetic leakage, severe hemolysis and reoperation in any of the cases.

Key words: Valvular heart surgery, mechanical bileaflet prosthesis, St Jude Medical prosthesis.

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The St. Jude Medical (SJM) valve was first used clinically in 1977. The SJM cardiac valve is a hinged, bileaflet, low-profile, central flow prosthesis, made entirely of pyrolytic carbon, except for the sewing cuff, which is of double-velour Dacron. In closed position the leaflet meets the valve housing at an angle of 30 to 35 degrees, depending on the valve size, and the leaflet opens to an angle of 85 degrees. (Fig 1). Each leaflet is impregnated with tungsten (5-10% by weight) before it is coated with pyrolitic carbon to ensure adequate radiographic visualization. The valve design allows for a high ratio of orifice to tissue annulus diameter. The favorable flow charecteristics of the SJM valve, with nearly central laminary flow, and minimal areas of blood stasis behind the valve, in combination with the use of a thromboresistant pyrolytic carbon coating, was expected to result in a lower incidence of thromboembolism.

MATERİAL and METHODS

Between May and December 1987, 62 SJM cardiac valves were implanted in 50 patients. The youngest patient was 4, and the oldest was 68 years old. The average age was 36 years. There were 29 male

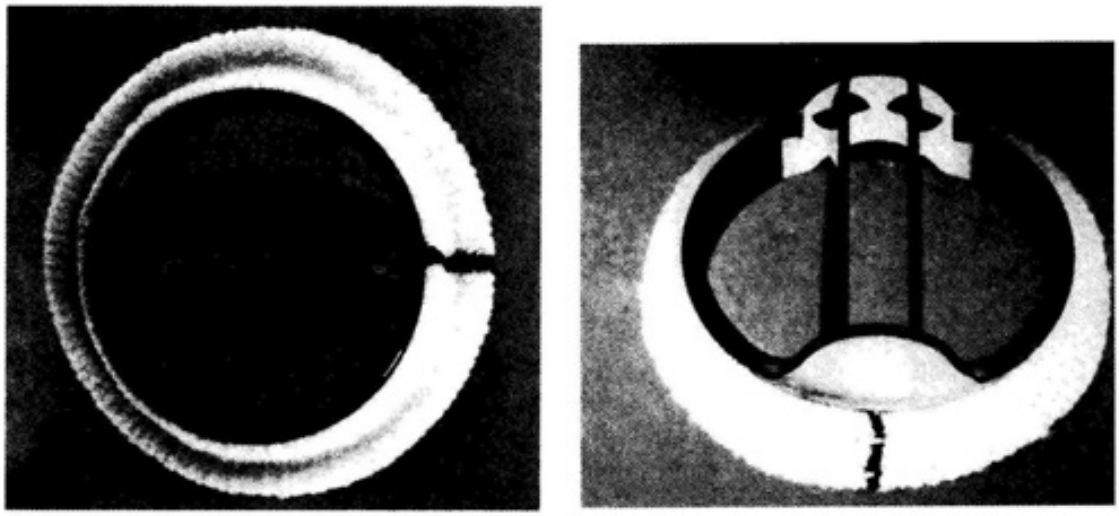

***Figure 1**. SJM valve prosthesis*

(58%) and 21 female patients (42%). The distribution according to the age groups is shown in Fig 2.

Of the 62 valve replacements, 22 (44%) were in mitral, 13 (36%) in the aortic, 1 (2%) in the tricuspid position, (11 multipl valve replacement, one of them AVR-MVR-TVR). Concomitant procedures as well as valve replacement were performed in another 4 patients (one patient AVR-MVR-tricuspid annuloplasty, one patient MVR-tricuspit annuloplasty, one patient AVR-mitral comissurotomy one patient AVR-VSD repair)(Table I).

According to the NYHA functional classification, 12 (24%) cases were in Class II, 30 (60%) in Class III, and 8 (16%) were in Class

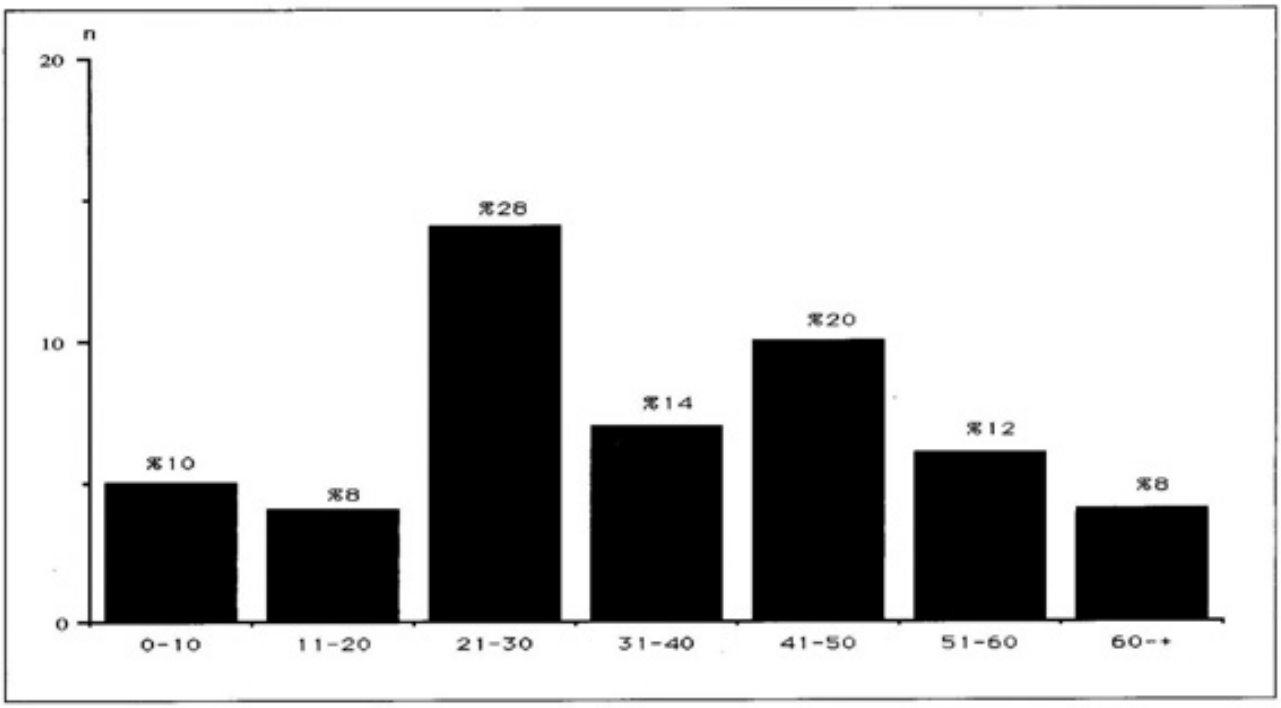

***Figure 2.** The distribution of patients with regard to age. Percentages on bars show the rate of the age group to total number of patients.*

Table I. Distribution of procedures performed in50 patients.	
Surgical procedure (s)	n
MVR	22 (44%)
AVR	13 (26%)
TVR	1 (2%)
AVR-MVR	9 (18%)
AVR-MVR-TVR	1 (2%)
AVR-MVR-tricuspid annuloplasty	1 (2%)
MVR-tricuspid annuloplasty	1 (2%)
AVR-AMK	1 (2%)
AVR-VSD repair	1 (2%)
Total	50

IV. Preoperative cardiac rhythm was sinus in 36% (18 cases) and atrial fibrillation in the remaining (64%).

Echocardiographic studies were performed in all patients. Hemolysis was evaluated with serum haptoglobin, reticulocyte hemoglobin and urinery hemosiderin levels. Early and late results of valves were evaluated by general clinical condition, thromboembolic episode, hemolysis, infection and prosthetic insufficiency. Complications, morbidity and mortality incidences were compared with other mechanical prosthesis.

Operative technique:
All operations were performed under standart cardiopulmonary bypass, with a bubble oxygenator, moderate hemodilution and systemic hypothermia (28-32°C), and anoxic cardiac arrest. Patients with left ventricular dysfunction in NYHA group IV, and patients with severe aortic stenosis and left ventricular hypertrophy received 350-500 cc (10 cc/kg) cardioplegia solution at 4°C via aortic root, or directly into the coronary ostia.

Topical pericardial cooling was used for myocardial protection. Aortic cross clamping time ranged from 20 to 90 minute for mitral valve replacement (mean 43 min), 52-143 min for aortic (mean 67 min) and 63-100 min (mean 77 min) for multiple valve replacements.

Postoperative management and follow up:
The range of follow up lasted from 1 to 30 months (mean 15 months). All of the patients were evaluated in the early and late post operative periods; clinical events, thrombosis, embolism, hemolysis, prosthetic valve endocarditis, valve failure, the incidence of mortality. In all patients oral anticoagulation with sodium warfarin was performed and antiaggregant drugs dipyridamole and acetyl salysylic acid were administered.

RESULTS

Two patients died during surgery due to myocardial failure (4%). Both of these patients had preoperative congestive heart failure, were in NYHA class IV, and had multivalvular lesions. AVR-MVR was performed in both.

Two patients died in the early postoperative period (4%). One of these patients had a preoperative sequel of cerebral vascular accident with right hemiglepia who was in NYHA group III, and had triple valve replacement. Hepatic failure developed, probably due to hal-

Table II. Early postoperative complications: (Pericardial tamponade, halothane hepatitis, congestive heart failure all were seen in one patient)

Complications	n	%	Result
Mediastinitis	1	2%	
Cerebral embolism	2	4%	exitus
Halothane hepatitis	1	2%	
Pericardial tamponade	1	2%	
Congestive heart failure	1	2%	exitus

othane entoxication, 9th postoperative day, and the patients was lost two weeks later.

AVR and MVR was performed to the second patient. This patient had recent myocardial infarction 3 years ago, and had a cerebrovascular accident with left hemiplegia 2 years ago. The patient was in NYHA functional Class IV. Intraoperation left atrial thrombosis and a calcified mitral valve was detected. The patient was stable up to 14 postoperative day, and he had recurrent fatal cerebral emboli.

Early postoperative complications are shown in Table II. Two patients had cerebral embolism in the early postoperative period. One of them died.

The surviving patients were followed up to a mean of 15 months. There was no mortality in this period. There were also no complications in this late postoperative period.

Control echocardiographic studies revealed that valvular function were with in the normal range. On mitral valve replacement transvalvular diastolic pressure gradient was between 2-8 mmHg (mean 4 mmHg), on the aortic valve mean systolic pressure gradient was 14 mmHg (6-24 mmHg).

We performed test for hemolysis (serum haptoglobin, reticulocyte count, hemoglobin, hemosiderin in urine) on all of the patients. We found low serum haptoglobin levels (≤ 38 mg/

Table III. Serum haptoglobin, reticulocyte count, hemosiderinuria, hemoglobin as an index of hemolysis.

	Serum Haptoglobin (70-380 mg/dl)	Reticulocyte count (0.4-1%)	Hemosiderinuria (-)	Hemoglobin (11-14 gm/ 100 ml) mean
MVR (n:23 cases)	≤ 38 mg/dl	0.5% (0.4-0.9%)	(-)	12.45 gm (11.50-13.40)
AVR (n:15 cases)	≤ 38 mg/dl	0.6% (0.4-1.5%)	1 case (+)	11.30 gm (11.00-11.50)
MVR-AVR (n: 10 cases)	≤38 mg/dl	0.5% (0.4-1.3%)	1 case (+)	11.05 gm (11.00-11.20)

Table IV. Comparison of various valve types use in our clinic with regard to mortality

Type of valve	n	Mortality	
		Early	Late
St. Jude (1987)	50	4%	0.0%
Björk-Shiley (Delrin and Standart) (1969-1985)	820	8.2 %	8.2%
Björk-Shiley (Monostrut) (1984-1988)	743	5.3%	4.6%
Starr-Edwards 6120 (1966-1985)	513	10.4%	23.3% (3.2% pt-yr)
Carpentier-Edwards Bioprosthesis (1976-1985)	69	4.3%	1.4%

dl). In all of these patients, reticulocyte count (0,4-1,5%) and hemoglobin values(11,00-13,40 gr/100 ml) were in the normal range. Only urine samples from 2 patients were positive for hemosiderin. No serious episode of hemolysis was observed (Table III).

DISCUSSION

Some theoretical advantages of SJM bileaflet, prosthetic valves are; the low profile which provides maximal central laminar flow, prevention of catastrophic monodisc dysfunction, minimal regurgitation, and less possibility of thrombus formation.

Of the patients receiving SJM valves, two died intraoperatively. The operative mortality was 4%. In the early postoperative period two patients died with a 4% mortality rate. Cause of death in these cases was releated to myocardial dysfunction and there was no relation directly effected by the valve. There was no late mortality in the follow up period.

Reported early mortality rates in SJM valves varies between 4-7,7%, and late mortality varies between 3,3-15,2%[1-6]. Operations performed on the pediatric age groups have similar results[7-12]. The high mortality reported in certain series is thought to be due to the complex congenital malformations [8,10,12]. Ten year follow-up in Harada et all[7] series showed satisfactory results regarding actuarial survival and complication-free rate. Therefore they conclude that St. Jude Medical prosthesis is a cardiac valve substitute of choice for the pediatric age group.

Table IV shows the mortality rates of SJM valves and other prosthetic valves. Looking at these results, despite the low mortality reported with Carpentier-Edwards (C-E) bioprosthetic valves which carry the disadvantage of long durability, SJM and monostrut Björk-Shiley (B-S) gives better results when compared with other valves. The large series of monostrut B-S with 743 cases makes the results of this study more meaningfull.

The most important complication following valve replacement is tromboembolism (TE). This is an important parameter for long-term follow-up studies. The valves design is important in TE incidence. The bileaflet design has been shown to create a laminar flow through the orifice which decreases turbulence and creates lesser wall tension [13]. The pyrolitic carbon coverage creates a smooth surface resisted to thrombus formation. The dacron velour on the sewing rim enables early closure by a homogenous endotelial surface.

Prevention of TE complications postoperatively on all mechanical valves requires sufficent

Table V. Comparison of various valve types use in our clinic with regard to thromboembolic episode.

Type of valve	n	Thromboembolism	
		Early	Late
St. Jude Medical (1987)	50	4.0%	0.0%
Björk-Shiley (Delrin ve Standart) (1969-1985)	820	2.0%	2.0%
Björk-Shiley (Monostrut) (1984-1988)	743	2.1%	0.0%
Starr-Edwards 6120 (1966-1985)	513	4.4%	1.4%
Carpentier-Edwards Bioprosthesis (1976-1985)	69	0.0%	5.6%

anticoagulation therapy. In children valvular trombus formation and thromboembolic risk may be outweight by potential hemorrhagic complications and with the difficulty of adjusting dose. Pass et al[10] have reported 34 pediatric patients with SJM valve replacement without anticoagulation postoperatively. Their avarage follow up time was 24 months. However more follow-up is required to decide whether anticoagulation in children is necessary or not.

Baudet[14] et all have reported the importance of valve position in preventing thrombus formation and for a physiological valve function in addition to anticoagulation for the SJM valve.In a paper by Glenn W. Laub et all[15], they have demonstrated that antianatomic orientation can improve leaflet clearance to the posterior ventricle and this can theoretically decrease the risk of impingement in certain cases, further supporting antianatomic orientation of the St. Jude Medical valve.

In our series two patients (4%) had episodes of cerebral emboli. Both of these cases had AVR-MVR. One of these patients died. In various follow-up studies of the SJM valve have re-

Table VI. Comparison of various valve types use in isolated MVR with regard to thromboembolism

Type of valve	n (Series of MVR)	Thromboembolism (%)
Starr-Edwards 6120 (1966-1985)	413	13.2%
Carpentier-Edwards Bioprosthesis (1976-1985)	60	5.6%
Björk-Shiley (Delrin ve Standart) (1969-1985)	317	3.0%
Björk-Shiley (Monostrut) (1984-1988)	392	1.6%
St. Jude Medical (1987)	22	2.0%

ported TE incidence between 7,6%-3,8%/ pt-yr (MVR 0,36-3%, AVR 0,34-1,9% multiple 0-2,8%)[16-22].

Table V gives a comparrison of TE episodes for different valves and Table VI gives acomparrison of valve only in the mitral position.
For the C-E prosthetic valve the %0 TE incidences for the early period inceares sharply to 5,6% in the late follow-up. This increase is probably due to the the degenerative change seen in late period.

Conversely, no late episodes of TE for the SJM and monostrut B-S valves were seen. The study on monostrut B-S valves include a larger group of patients and a larger follow up period. The monostrut B-S prosthetic valve seems to carry an advantage over the other valves with an early 2,01% TE rate, and 1,6% TE incidence in isolated MVR.

In our series no cases of valve trombosis, PVE, and paravalvular leak was observed. In the follow-up period neither of the patients required reoperation.

All postoperative patients were evaluated with doppler echocardiography and transvalvular gradients were measured. In the mitral position diastolic mean transvalvuler pressure was 4 mmHg (2-8 mmHg) and in the aortic position systolic mean transvalvular mean gradient 14 mmHg (6-24 mmHg). In several studies transvalvular gradients in the mitral position were reported between 1,6-5,6 mmHg and for the aortic position 3,8-11,5 mmHg. For the monostrut B-S valves in the mitral position transvalvular gradient were 4,3±2,5, and in the aortic position 5-15 mmHg [16,23,24]. We found higher transvalvular gradients in the aortic position. We had used sizes 23 and 25 in these patients. Non of these patients had thrombus formation or valvular dysfunction.

Kinsley [5] et all have reported the thrombotic obstruction incidence for SJM prosthesis 0,5-2% pt/year. In the mitral position thrombotic obstruction was 8 fold higher than the aortic position. In other series mital valve thrombotic obstruction has been reported 3-4 fold higher than aortic [3, 10, 25, 26, 27]. Compare to B-S valves thrombotic obstruction has been reported to be lower with the SJM [5, 26-30].

Cooley[20] et all have reported a lower endocarditis incidence rate with the SJM in their 736 patient series. It is thought that central laminar flow and decreased turbulance, carbon covered surfaces cause additional protection against bacterial infections.

In the series of Chaux[3], Baudet [14], Cooley[4], hemolysis was not observed. Generally hemolysis is seen with paravalvular leakage. Chronic hemolysis has no serious consequences as long as valve functions are normal. Arom[1] et al have reported hemolysis with SJM without valvular dysfunction in a few patients. However no cause for hemolysis was shown. In series with pediatric patients no hemolysis was reported. In our study hemosiderinurea was observed in two patients. One of these patients had AVR+MVR with a hemoglobin level of 11,55 gm/100 ml, and reticulocyte count 0,7%. The other patient had AVR with hemoglobin 12,9 gm/100 ml, and reticulocyte count %0,6. In both patients serum haptoglobin was less than 38 mg/dl. Both of these patients hemoglobin and reticulocyte count was with in the normal range, and hemosiderinurea alone was not considered significant with regard to hemolysis.

Burchardt[2] et all reported the only case of dislocation with a SJM valve.

Low-profile, less wall tension, long durability, low TE episode rate, thromboresistant carbon layer, ease in operative handling, easy adabtibility even in small aortic annulus, central laminar flow, low transvalvular pressure gradient even with the small size valves, and a larger effective orifice are the advantages attributed to the SJM valve. However, in our study thromboembolic episode risk and transvalvular pressure gradients didn't seem to be advantages for the SJM valve. Leaflet dislocation and pivoted hinge seem to provide a potential for thrombotic dysfunction are the disadvantages of this valve. The other advantages listed above don't seem to show much differents especially when compared with B-S monostrut valves.

Despite the small number of patients and the short follow-up period in our study, we think SJM valves are a good alternative to the other currently available prosthetic valves.

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