Original Article

Evaluation of St. Jude Medical Valve's Long-term Function by Doppler Echocardiography

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In this study, the long-term function of the St. Jude Medical valve (SJM valve) is evaluated by Doppler echocardiography.

The subjects were 191 patients who underwent mitral or aortic valve replacement using the SJM valve in our institute since July 1978 and had no clinical problem showing more than 50% of left ventricular ejection fraction. The patients were classified into 3 groups according to the measurement period (within 5 years, 10 years and 15 years and more), and further classified by valve size and their results were compared.

In every valve-size group, there was no significant difference among the groups in terms of the measurement period. In the mitral valve position, peak pressure gradient and pressure half-time were not significantly different among groups of varying valve sizes. On the other hand, in the aortic valve position, the pressure gradient in the 21-mm group was significantly higher among the 21-mm, 25-mm, and 27-mm groups, showing a negative correlation with size.

As a result, it was suggested that the SJM valve functioned well more than 15 years after operation. From these results, it was considered that patients with a small annulus of the aortic valve needed an annulus-enlarging procedure or use of Hemodynamic Plus series valves to keep the size of more than 23 mm. (Ann Thorac Cardiovasc Surg 2001; 7: 216–22)

Key words: St. Jude Medical valve, prosthetic valve, valve replacement, Doppler echocardiography

Introduction

At present, the St. Jude Medical valve (SJM valve, St. Jude Medical Inc., St. Paul, MN) is the most reliable prosthetic valve all over the world in the aspects of long-term durability and anti-thrombogenesis because it has good hemodynamics due to its central blood flow.[1-5] We were the first to use this valve in Japan in July 1978 and have shown stable results for 20 years using it as the primary option among prosthetic valves.[5,6] In this study, the long-term function of this value is evaluated by continuous wave and color Doppler echocardiography.

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Patients and Methods

The subjects were the 191 patients who underwent aortic or mitral valve replacement using a SJM valve in our institute between July 1978 and September 1998 showing more than 50% of left ventricular ejection fraction at the M mode echocardiography. The measuring devices were SSH-60A, SSA-380A and SSA-260A (Toshiba Medical Inc., Tokyo, Japan) and the dispatch frequency of the probe used was 2.5 or 3.75 MHz. The patients were classified into 3 groups according to measurement period, the short-term group; (within 5 years with 74 in the aortic valve position and 101 in the mitral valve position), and the mid-term group; (10 years with 47 in the aortic valve position and 67 in the mitral valve position) and the long-term group; (15 years and more with 33 in the aortic valve position and 44 in the mitral valve position), and further classified by size and their results were compared.

By continuous wave Doppler echocardiography, peak velocity of the aortic prosthetic valve at the aortic valvular distal position was determined on the two chamber view in the apex and that of the mitral prosthetic valve at the left ventricular influx site was determined on the four chamber view in the apex. Peak pressure gradient of the aortic and mitral prosthetic valves was calculated by simple Bernoulli's formula. On the replaced mitral valve, pressure half time, which is the time until peak velocity at the mitral prosthetic valve is reduced to $1/\sqrt{2}$, was determined and the effective orifice area (=220/ pressure half time) was calculated by the formula Hatle et al.[7] proposed. Using color Doppler echocardiography, regurgitation on the aortic and mitral prosthetic valves was examined on the left ventricular long axial cross section and the four chamber view respectively. The evaluation of regurgitation is as follows: on the aortic valve position, the cavity of the left ventricle was divided into 4 parts and the case was classified into grade I to IV according to the range of regurgitation. On the mitral valve position, the cavity of the left atrium was divided into 4 parts and the case was classified into grade I to IV similarly. And further, the left ventricular diastolic diameter (LVDd), left ventricular ejection fraction (EF) and % fractional shortening (%FS) were determined because the left ventricular function may have an influence on the above measured values. Each parameter was the mean during 10 continuous heart rates.

Measurements were expressed as mean ± standard deviations. The Scheffe's method was used for intragroup analysis and Spearman's correlation tests were performed to evaluate the relationship between the peak gradient or pressure half time and prosthetic valve size. The level of significance was set at $p<0.05$.

Results

Aortic prosthetic valve

As to the measurement time, the short-term group was 0.1 to 4.9 years after surgery (an average of 2.5 years), mid-term group was 5.2 to 13.6 years after surgery, (average 8.1 years) and the long-term group was 15.1 to 20.0 years after surgery (average 17.1 years). The age, gender, duration after surgery, diagnosis, prosthetic valve size and body surface area (BSA) of patients are shown in Table 1. There were significant differences between the 21 mm and 23 mm, 25 mm, and 27 mm in the short- and mid-term group, and between the 21 mm and 23 mm, and the 25 mm in the long-term group ($p<0.05$).

Left ventricular function: LVDd in the short-term, mid-term and long-term group was 52.2±6.6, 52.4±6.1, and 53.6±6.4 mm, respectively. EF in the early-term, mid-term and long-term group was 63.5±9.4, 65.1±9.5, and 61.4±7.4%, respectively. %FS in the short-term, mid-term and long-term group was 35.0±7.1, 36.1±7.2, and 33.2±5.6%, respectively. There were no significant differences in each parameter between the three groups.

Peak velocity and pressure gradient (Figs. 1, 2): In the short-term group, peak velocity in the 21-mm, 23-mm, 25-mm and 27-mm size was 2.35±0.28, 2.21±0.37, 1.83±0.33, and 1.78±0.31 m/sec, respectively. In the mid-term group, peak velocity in the 21-mm, 23-mm, 25-mm and 27-mm size was 2.44±0.14, 2.40±0.55, 1.96±0.31, and 1.82±0.20 m/sec, respectively. In the long-term group, peak velocity in the 21-mm, 23-mm, 25-mm and 27-mm size was 2.46±0.09, 2.22±0.22, 2.03±0.20, and 1.59m/sec, respectively.

In the short-term group, peak pressure gradient in the 21-mm, 23-mm, 25-mm and 27-mm size was 22.4±4.8, 20.1±6.9, 13.9±4.5, and 13.2±4.9 mmHg, respectively. In the mid-term group, peak pressure gradient in the 21-mm, 23-mm, 25-mm and 27-mm size was 23.9±2.7, 19.8±6.2, 15.7±4.7, 13.5±3.0 mmHg, respectively. In the long-term group, peak pressure gradient in the 21-mm, 23-mm, 25-mm and 27-mm size was 24.3±1.8, 20.1±3.5, 16.7±3.2, and 10.1 mmHg, respectively. In the short- and mid-term group, there were significant differences between the 21 mm and 25 mm and 21 mm and 27 mm. In the long-term group, although there were no significant differences because there was only one patient in the 27-mm group, there were significant differences between the 21 mm and 25 mm. There was a significant negative correlation between the peak gradient and prosthetic valve size (Fig. 2, $r=-0.648$, $p<0.01$).

Regurgitation of the prosthetic valves: Regurgitation was recognized in 50 cases (67.6%; grade I: 49, grade II: 1) in the short-term group, in 31 cases (66.0%; grade I: 30, grade II: 1) in the mid-term group and in 22 cases (66.7%; grade I: 22, grade II: 0) in the long-term group, there were no significant differences between the three groups. The regurgitation was physiological regurgitation in the prosthetic valves and abnormal regurgitation was not recognized.

Mitral prosthetic valve

As to measurement time, the short-term group was 0.1

Table 1. a: Patients' characteristics in aortic valve's case

Aortic valve			Short-term group	Mid-term group	Long-term group
Number			74	47	33
Age (y.o.)			48.3±10.7	44.7±10.6	43.2±7.7
Gender (M : F)			39 : 35	26 : 21	18 : 16
Duration after surgery (years)			2.5 ± 1.5 (0.1-4.9)	8.1 ± 2.3 (5.2-13.6)	17.1 ± 1.9 (15.1-20.0)
Diagnosis	21 mm	AS	9	8	4
		AR	7	8	5
		ASR	6	3	3
		re-Op	1	1	0
	23 mm	AS	8	6	6
		AR	7	4	3
		ASR	5	2	2
		re-Op	1	1	0
	25 mm	AS	11	4	5
		AR	8	4	3
		ASR	3	1	1
		re-Op	0	0	0
	27 mm	AS	2	1	0
		AR	7	5	1
		ASR	1	0	0
		re-Op	0	0	0
Size	21 mm		22	20	12
	23 mm		20	12	11
	25 mm		22	9	9
	27 mm		10	6	1
Body surface area	21 mm		1.42 ± 0.09	1.43 ± 0.09	1.41 ± 0.09
	23 mm		1.63 ± 0.18	1.61 ± 0.15	1.57 ± 0.13
	25 mm		1.63 ± 0.16	1.64 ± 0.09	1.75 ± 0.14
	27 mm		1.75 ± 0.17	1.75 ± 0.17	1.76

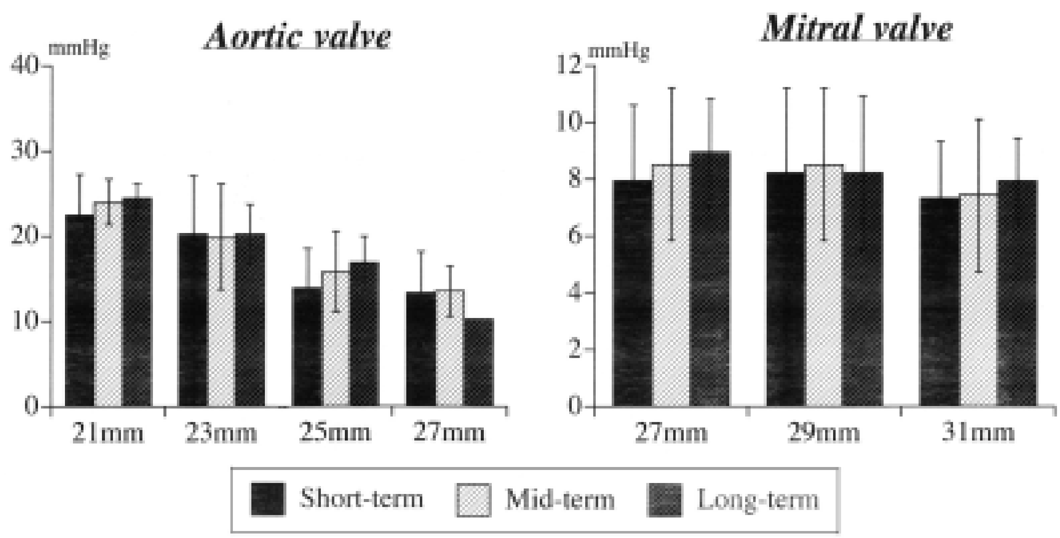

Fig. 1. Peak gradient at short, mid and long-term.

Table 1. b: Patients' characteristics in mitral valve's case

Mitral valve			Short-term group	Mid-term group	Long-term group
Number			101	67	44
Age (y.o.)			49.4 ± 11.0	43.3 ± 11.5	40.9 ± 10.3
Gender (M : F)			50 : 51	33 : 34	23 : 21
Duration after surgery (years)			2.2 ± 1.1 (0.1-4.9)	8.9 ± 2.9 (5.2-14.5)	16.9 ± 1.7 (15.2-20.0)
Diagnosis	27 mm	MS	21	12	7
		MR	15	7	3
		MSR	9	6	2
		re-Op	3	3	1
	29 mm	MS	24	14	12
		MR	14	9	6
		MSR	6	7	5
		re-Op	4	2	1
	31 mm	MS	6	6	4
		MR	4	4	1
		MSR	2	2	4
		re-Op	0	1	1
Size	27 mm		45	25	12
	29 mm		44	30	23
	31 mm		12	12	9
Body surface area	27 mm		1.48 ± 0.12	1.50 ± 1.12	1.50 ± 0.12
	29 mm		1.59 ± 0.13	1.58 ± 0.12	1.52 ± 0.15
	31 mm		1.68 ± 0.10	1.69 ± 0.09	1.57 ± 0.11

to 4.9 years after surgery (average 2.2 years), the mid-term group was 5.2 to 14.5 years after surgery (average 8.9 years), and the long-term group was 15.2 to 20.0 years after surgery (average 16.9 years). The age, gender, duration after surgery, diagnosis, prosthetic valve size and BSA of patients are shown Table 2. There were no significant differences in each parameter between the three groups.

Left ventricular function: LVDd in the short-term, mid-term and long-term group was 48.5±7.1, 52.1±8.9, and 46.7±9.9 mm, respectively. EF in the short-term, mid-term and long-term group was 61.8±9.2, 62.3±7.9 and 60.7±8.1%, respectively. %FS in the short-term, mid-term and long-term group was 33.7±6.8, 34.2±5.7, and 32.9±6.1%, respectively. There were no significant differences in each parameter between the three groups.

Peak velocity and pressure gradient (Fig. 1): In the short-term group, peak velocity in the 27-mm, 29-mm and 31-mm size was 1.38±0.25, 1.40±0.25, and 1.33±0.17m/sec, respectively. In the mid-term group, peak velocity in the 27-mm, 29-mm and 31-mm size was 1.44±0.23, 1.44±0.22, and 1.33±0.26m/sec, respectively. In the long-term group, peak velocity in the 27-mm, 29-mm, and 31-mm size was 1.49±0.17, 1.40±0.23, and 1.39±0.14m/sec, respectively. There were no significant differences between the three groups.

In the short-term group, peak pressure gradient in the 27-mm, 29-mm and 31-mm size was 7.9±2.7, 8.2±3.0, and 7.3±2.0 mmHg, respectively. In the mid-term group, peak pressure gradient in the 27-mm, 29-mm and 31-mm size was 8.5±2.7, 8.5±2.7, 7.4±2.7 mmHg, respectively. In the long-term group, the peak pressure gradient in the 27-mm, 29-mm and 31-mm size was 8.9±1.9, 8.2±2.7, and 7.9±1.5 mmHg, respectively. There were no significant differences between the three groups. There was no significant correlation between the peak gradient and prosthetic valve size (r=–0.047).

Pressure half time and effective orifice area (Fig. 3): In the short-term group, pressure half time in the 27-mm, 29-mm and 31-mm size was 89.0±14.0, 95.3±27.2 and 90.7±5.0 m/sec, respectively. In the mid-term group, pressure half time in the 27-mm, 29-mm and 31-mm size was 84.7±12.5, 97.9±18.9, and 93.8±9.8m/sec, respectively. In the long-term group, pressure half time in the 27-mm, 29-mm and 31-mm size was 89.3±16.3, 89.3±15.2 and 94.3±8.0 m/sec, respectively. There were no significant differences between the three groups. There was a significant correlation between the pressure half

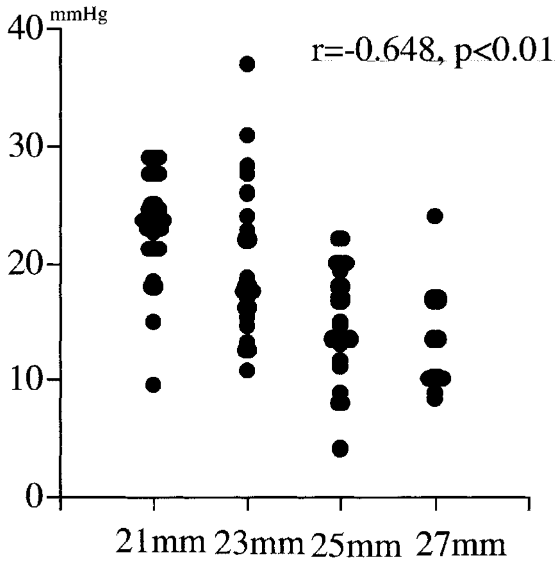

Fig. 2. Correlation between pressure gradient and prosthetic valve size in the aortic position

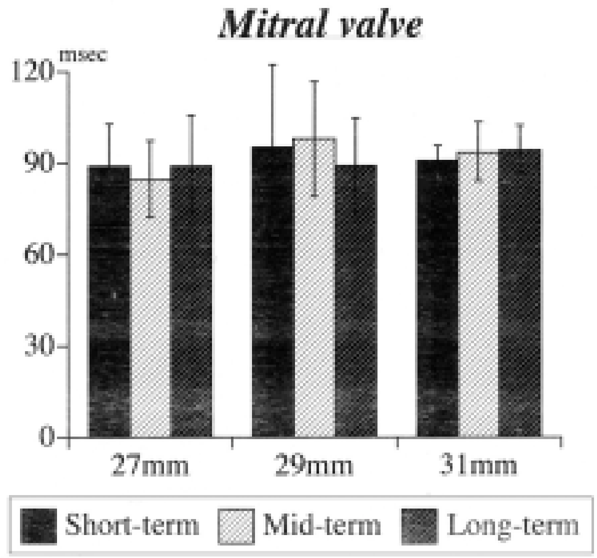

Fig. 3. Pressure half time in the mitral position at short, mid and long-term.

time and prosthetic valve size (r=–0.148).

In the short-term group, the effective orifice area in the 27-mm, 29-mm and 31-mm size was 2.53±0.41, 2.48±0.63, and 2.43±0.14 cm^2, respectively. In the mid-term group, the effective orifice area in the 27-mm, 29-mm and 31-mm size was 2.66±0.41, 2.34±0.48, and 2.37±0.27 cm^2, respectively. In the long-term group, the effective orifice area in the 27-mm, 29-mm and 31-mm size was 2.55±0.48, 2.55±0.52 and 2.35±0.23 cm^2, respectively. There were no significant differences between the three groups.

Regurgitation of the prosthetic valves: Regurgitation was recognized in 38 cases (37.6%; grade I: 37, grade II: 1) in the short-term group, 25 cases (37.3%; grade I: 24, grade II: 1) in the mid-term group and 17 cases (38.6%; grade I: 16, grade II: 1) in the long-term group, there were no significant differences between the three groups. The regurgitation was physiological regurgitation in the prosthetic valves and abnormal regurgitation was not recognized.

Discussion

The SJM valve was developed as the first bileaflet valve, which has a lower pressure gradient and a larger effective orifice area than ball and tilting valves due to its central blood flow, and was first used clinically in 1977. Since then, it has been implanted into more than one million patients all over the world and stable long-term results have been reported. Therefore, it has been used widely as the most reliable mechanical valve at present.[1-6,8] There are, however, problems in bleeding caused by anticoagulant therapy and thromboembolism. It was reported that the incidences of thromboembolism, thrombotic valve and bleeding caused by anticoagulant therapy at 10 postoperative years and more were 0.20-1.49, 0.03-0.30, and 0.20-0.90%/pt-year, respectively.[1,4,8] Recently it has been reported that the pannus tends to be formed between the left ventricle and the orifice due to its structural feature, and then the annulus of prosthetic valves should be improved and suture methods and the direction should be reconsidered.[9]

The evaluation methods of prosthetic valves are cardiac catheterization, echocardiography, cinefluoroscopy, and prosthetic valve sound analysis.[10] Among them, echocardiography is non-invasive, and effective especially in the evaluation of replaced prosthetic valves and the diagnosis of complications. Many cases using it have been reported.[11-19] There are many cases of SJM valves examined by echocardiography, which are reported to have lower pressure gradient and a larger effective orifice area than ball and tilting valves due to the structure getting its central blood flow. On the other hand, the biological valves show sclerotization and degeneration at 5 years after operation and in some cases are necessary to be replaced, which suggests that the SJM valve is superior to the biological valve also in the aspect of durability.[11] According to previous reports on SJM valves, the peak pressure gradients at the aortic valve position in the 19, 21, 23, 25, and 27-mm size were 31.2-38.2 mmHg, 21.2-30.0 mmHg, 15.2-33.7 mmHg, 18.1-20.0 mmHg, and 13.7-16.0 mmHg, respectively,[12-16] showing the correlation between the pressure gradient and size.[15] At the mitral valve position, the peak pressure gradients in the 27, 29, and 31-mm size were 7.95-11.0, 7.0-11.0, and 7.62-12.0 mmHg, respectively. The pressure half time in the 27, 29, and 31-mm size was 71.8-137.5, 74.1-84.0 and 57.9-72.0 msec, respectively. The effective orifice area in the 27, 29, and 31-mm size was 1.60-3.13, 2.35-3.10, and 3.06-3.80 cm^2, respectively. Many researchers reported that the correlation between the size and pressure gradient or half time at the mitral valve position was either less than those of the aortic valve position, conforming with our results.[11,14–19] These previous reports, however, dealt with the data immediately after operation or at intermediate term and there is no report at a long term (more than 15 years) as far as we could see. Asano et al. reported that the peak and average pressure gradients and pressure half time of patients with mitral valve cases did not change with time for 10 years.[11] On the other hand, Shigenobu et al. classified the patients with mitral valve cases into 2 groups, within 5 years after operation (mean: 3.6 years) and 5 years and more (mean: 7.3 years) and examined their pressure gradients at rest and under load. They reported that the pressure gradients of patients 5 years after operation were high both at rest and under load and that stricture of the prosthetic valves may develop by tissue overgrowth with years.[17]

Regurgitation within the prosthetic valves was found in about 70% of the aortic valve cases and about 40% of the mitral valve cases in this series independent of the measurement period. This regurgitation could not be picked up by auscultation and there were no clinical problems. It occurred within the prosthetic valves and it was considered as the regurgitation peculiar to them. It has been reported that the regurgitation of SJM valves at the aortic and mitral valves was 30-58% and 20-36% respectively by transthoracic-echocardiography. Our results were rather higher but it seems to be due to the difference in the measuring device and staff. By transesophageal-echocardiography, regurgitation of the prosthetic valves is detected in almost all patients. It is, therefore, necessary for a patient whose regurgitation is massive or abnormal to find the exact position where the regurgitation occurs.

From these results, it is shown that the function of the SJM valve is maintained when the cardiac function is kept even in the long term. We perform the suture by interrupted suture without pledget. We think that not using pledgets prevents pannus formation. When the cardiac function is low, the thrombus and pannus may be formed by the turbulent flow and retention. Therefore, follow-up of this valve over several years is needed in patients with cardiac dysfunction. In this study, patients using a 19-mm size valve were not included, and further, we have no experience using Hemodynamic Plus (HP) series valves. Carrel et al. reported that the pressure gradient of the HP series was lower than that of the Standard series and that the HP series should be selected for the patient using a 21-mm valve and less.[20] This time, the pressure gradient of the patients using 21 mm was significantly higher than others. Therefore, as to the patients with a small annulus, further discussion will be needed including the annulus-enlarging procedure, use of HP series and follow-up of patients with a small prosthetic valve.

Conclusion

In this study, the long-term function of the SJM value is evaluated by continuous wave and color Doppler echocardiography.

In the short-term group by size, there was no significant difference among groups by measurement period. In the mitral valve group, peak pressure gradient and pressure half time were not significantly different among groups by size. On the other hand, in the aortic valve group, pressure gradient in the 21-mm group was significantly high among the 21-mm, 25-mm, and 27-mm groups, showing a negative correlation with size.

As a result, it was suggested that the SJM valve keeps functioning well more than 15 years after operation.

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