OBSTRUCTION OF ST JUDE MEDICAL VALVES IN THE AORTIC POSITION: SIGNIFICANCE OF A COMBINATION OF CINERADIOGRAPHY AND ECHOCARDIOGRAPHY

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Background: Obstruction of the St Jude Medical valve (St Jude Medical, Inc, St Paul, Minn) is a rare but serious complication.

Methods: Cineradiographic and echocardiographic evaluations of aortic St Jude Medical valves were simultaneously performed on 54 patients, with no signs of prosthetic valve dysfunction late after surgery.

Results: Although closing angles of the leaflets corresponded closely with the manufacturer data, restricted opening of the leaflets (opening angle $\geq 20^\circ$) was found in 16 (group D) of the 54 patients by means of cineradiography. The opening angles were equal to or less than 14° in the other 23 patients (group N) and between 15° and 19° in the remaining 15 (group M). Doppler-derived transprosthetic pressure gradients were significantly higher ($P = .03$) and the velocity index was significantly lower ($P = .003$) in group D than in group N. However, no significant differences were found in those values between group N and group M. Replacement of the aortic St Jude Medical valves was performed in 5 of the 16 patients, and the remaining 11 have been followed up because of relatively low pressure gradients. The cause of restricted leaflet movement was pannus formation without thrombosis in 4 patients and valve thrombosis with pannus formation in one.

Conclusions: Reduced valve orifice area and restricted opening of the leaflets resulting from excess growth of pannus probably led to obstruction of the aortic St Jude Medical valves. A combination of cineradiography and echocardiography makes it possible to provide an accurate and detailed diagnosis of obstruction of the valve. (J Thorac Cardiovasc Surg 2000;120:142-7)

The St Jude Medical (SJM) valve (St Jude Medical, Inc, St Paul, Minn) is now one of the most widely used cardiac valve prostheses in the world because of its excellent hemodynamic performance and extremely low incidence of valve-related deaths and complications.¹⁻⁴ Among the valve-related complications, prosthetic valve obstruction, such as valve thrombosis and pannus formation, is a rare but often serious complication.^{5,6} In most cases of prosthetic valve obstruction, hemodynamic deterioration is acute and quickly becomes life-threatening; however, clinical presenta-

tion is occasionally insidious. We recently observed obstruction of aortic SJM valves in asymptomatic patients in the late period after surgery. These valves demonstrated restricted leaflet movement on cineradiograms. We therefore performed echocardiographic and cineradiographic evaluations of aortic SJM valves to assess hemodynamic performance and prosthetic valve function in the late postoperative period.

The purpose of this report is to clarify the incidence and causes of restriction of leaflet movement and to establish the optimal method for the diagnosis of obstruction of aortic SJM valves.

Patients and methods

Patients. Until the end of 1998, 605 patients underwent aortic valve replacement (AVR) with the SJM valve at our hospital. Among the 605 patients, 54 patients who annually or biannually visited our outpatient department between February 1999 and August 1999 received simultaneous echocardiographic and cineradiographic evaluations of the aortic SJM valves. These 54 patients form the basis of this study. All patients were clinically asymptomatic and had no signs of prosthetic valve dysfunction. There were 28 male and

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Table I. Clinical characteristics of the patients

No. of patients	54
Age (y)	61 ± 13 (17-79)
Sex (male/female)	28/26
Valve lesions	
Stenosis	14
Regurgitation	25
Stenosis/regurgitation	12
Prosthesis dysfunction	3
Valve sizes	
17-mm Hemodynamic Plus	1
19-mm Standard	2
21-mm Standard	20
23-mm Standard	23
25 mm	7
27 mm	1
Operative procedures	
Isolated AVR	28
AVR + MVR	23
AVR + replacement of the ascending aorta	2
Aortic root replacement + MVR	1
Time between operation and evaluation (mo)	66 ± 40 (5-192)

AVR, Aortic valve replacement; MVR, mitral valve replacement.

26 female patients whose ages ranged from 17 to 79 years (mean, 61 ± 13 years) at the time of this study. Echocardiography and cineradiography were performed at a mean interval of 66 ± 40 months (range, 5 to 192 months) after surgery. Clinical characteristics of the patients, including the sizes of the SJM valves used for AVR, are summarized in Table I.

The standard technique of cardiopulmonary bypass with moderate hypothermia (28°C-30°C) was used, and cold potassium cardioplegia combined with topical hypothermia was routinely used for myocardial protection until July 1995, when we began to use cold blood cardioplegia. In our early operations the pivot of the SJM valve was implanted parallel to the ventricular septum, and since 1983, the valve has been placed perpendicular to the septum.

Postoperative anticoagulant therapy, consisting of warfarin and a platelet inhibitor, was usually instituted within 48 hours after the operation, and the thrombotest level was kept at about 20% or a prothrombin time ratio of 1.5 to 2.0 in relation to the control value.

Cineradiography and echocardiography for the aortic SJM valves. Cineradiography⁷⁻⁹ was performed to obtain a tangential view of the implanted SJM valve. The opening and closing angles were determined by means of a frame-by-frame analysis of a single cardiac cycle and were measured in 3 cardiac cycles for each patient. Both angles (in degrees) were calculated as the distance between the two leaflets in the fully open and closed positions, respectively, as shown in Fig 1.

In echocardiography¹⁰ the velocity profiles across the SJM valve were obtained by placing the transducer in the apical position. For continuous wave Doppler measurements, the transmitted beam was placed as close to perpendicular to the plane of the valve ring as possible. Peak transvalvular velocity (aortic jet) was measured in meters per second, and the

Fig 1. Measurement of the opening and closing angles. Schematic presentation of leaflets of a SJM valve, illustrating the opening (*O*) and closing angles (*C*).

Fig 2. Cineradiograms showing restricted leaflet movement of an SJM valve in the aortic position. **A**, Opening angle of 40°; **B**, closing angle of 126°.

peak pressure gradient (in millimeters of mercury) was calculated by using the modified Bernoulli equation ($p = PV^2 \times 4$, where p is the pressure gradient and PV is the maximal velocity in meters per second). Peak flow velocity in the left ventricular outflow tract was measured approximately 0.5 cm upstream from the prosthetic valve.

Statistical analysis. Data are expressed as mean values ± SD. The statistical significance of the differences was analyzed by use of the Student *t* test.

Results

Cineradiographic and echocardiographic evaluations. In this study the leaflets and leaflet movement of the SJM valves were both plainly observed by cineradiography, and measurements of the opening and closing angles were possible in all of the 54 patients. The opening angle measured on cineradiograms ranged from 9° to 50° (mean, 20° ± 12°), and the closing angle ranged from 116° to 126° (mean, 122.2° ± 2.4°) for 17- to 25-mm diameter valves and was 130° for a 27-mm diameter valve, as shown in Fig 2. In our previous study the opening angle of normally functioning aortic SJM

Table II. Doppler-derived data for the aortic SJM valves

Valve size	n	Peak velocity (m/s)	Peak pressure gradient (mm Hg)	Valve area (cm ²)	Velocity index
17-mm HP	1	3.42	46.8	0.92	0.33
19-mm ST	2	3.58 ± 1.0	53.1 ± 27.0	0.93 ± 0.1	0.30
21-mm ST	20	3.10 ± 0.5	39.0 ± 13.0	1.2 ± 0.2	0.37 ± 0.08
23-mm ST	23	2.80 ± 0.5	32.4 ± 12.1	1.3 ± 0.3	0.38 ± 0.08
25 mm	7	2.60 ± 0.4	24.0 ± 13.0	1.7 ± 0.8	0.36 ± 0.07
27 mm	1	1.85	13.7	1.7	0.38

HP, Hemodynamic Plus; ST, standard.

Table III. Doppler-derived data for the SJM valves in group D

Valve size	n	Peak velocity (m/s)	Peak pressure (mm Hg)	Valve area (cm ²)	Velocity index
17-mm HP	1	3.42	46.8	0.92	0.33
19 mm	0	—	—	—	—
21 mm	7	3.30 ± 0.3* (2.90 ± 0.6)	44.0 ± 6.5* (35.7 ± 14.3)	1.0 ± 0.1§ (1.2 ± 0.3)	0.32 ± 0.02 (0.40 ± 0.09)
23 mm	5	3.30 ± 0.6* (2.60 ± 0.4)	44.5 ± 14.2* (28.4 ± 8.5)	1.1 ± 0.2 (1.4 ± 0.3)	0.33 ± 0.07 (0.40 ± 0.08)
25 mm	2	2.60 ± 0.3† (2.40 ± 0.5)	26.6 ± 3.1‡ (20.9 ± 12.5)	1.5 ± 0.5 (1.6 ± 0.7)	0.35 ± 0.05 (0.37 ± 0.06)
27 mm	1	1.85	13.7	1.7	0.38

Doppler-derived data of group N is shown in parentheses. HP, Hemodynamic Plus valve.

*P = .01 versus group N.

†P = .04 versus group N.

‡P = .003 versus group N.

§P = .001 versus group N.

valves was $11.0^\circ \pm 1.4^\circ$, and the closing angle was $120.2^\circ \pm 0.7^\circ$ for 19- to 25-mm diameter valves and $130.2^\circ \pm 0.4^\circ$ for 27-mm valves.⁷ Although the closing angles of the leaflets corresponded closely with the manufacturer's in vitro data and our previous data, restricted leaflet movement was found, to varying degrees, in 31 of the 54 patients. When we examined the opening angles, 23 (43%, group N) of the 54 patients had opening angles equal to or less than 14° , 15 (28%, group M) had opening angles between 15° and 19° , and the other 16 (30%, group D) had opening angles equal to or greater than 20° . On the basis of our previous data as well as those of others,^{7,8,11} leaflet movement in group N was considered normal; however, that in group D was obviously restricted, even taking into account the possibility of technical errors in measuring the opening angle. The sizes of the aortic SJM valve in group D were 17-mm Hemodynamic Plus in 1 patient, 21 mm in 7 patients, 23 mm in 5 patients, 25 mm in 2 patients, and 27 mm in one patient. The mean follow-up period (the time between AVR and cineradiography) was 65 ± 35 months in group N, 74 ± 38 months in group M, and 58 ± 46 months in group D. There was no significant correlation between the opening angles and the follow-up period among the 3 groups.

Similarly, cineradiographic evaluation of the mitral SJM valves was also performed on 23 of the 54 patients. These 23 patients underwent simultaneous mitral valve replacement with AVR. In the mitral SJM valves, the opening angle ranged from 8° to 17° ($13^\circ \pm 3^\circ$), and the closing angle ranged from 128° to 133° ($131^\circ \pm 2.0^\circ$). No restriction of leaflet movement for opening and closing were found in any of the 23 patients.

Echocardiographic evaluation of the aortic SJM valves was performed at the same time as cineradiography. Doppler-derived data for the aortic SJM valve obtained in the 54 patients are shown in Table II. As shown in Table III, the mean values of the Doppler-derived peak velocities and peak pressure gradients of group D were significantly higher ($P = .03$) than those of group N; however, there was a wide range of peak velocities and gradients, and the overlap between velocities and gradients from valves of different sizes was rather large. No significant differences were found in all of the Doppler-derived values between group N and group M. The ratio of peak velocity in the left ventricular outflow tract to that of the aortic jet (Doppler velocity index) was 0.39 ± 0.07 in group N, 0.38 ± 0.09 in group M, and 0.33 ± 0.04 in group D, respectively.

Fig 3. The Doppler velocity indices in groups N and D.

Table IV. Doppler echocardiographic and cineradiographic data in 5 patients who underwent replacement of the aortic SJM valves

Patient	Age (y)	Sex	Valve size	Cineradiography		Doppler echocardiography				Time from AVR (mo)	Causes of restriction
				Opening angle	Closing angle	PV (m/s)	PPG (mm Hg)	Valve area (cm ²)	VI		
1	63	F	21	35	120	3.39	46	1.16	0.33	24	Pannus
2	59	F	21	50	120	3.50	49	0.99	0.30	21	Thrombus
3	69	F	21	45	120	3.70	55	0.80	0.27	40	Pannus
4	68	F	23	50	123	4.12	68	0.72	0.25	108	Pannus
5	69	F	23	40	126	3.38	46	0.99	0.33	196	Pannus

PV, Peak velocity; PPG, peak pressure gradient; VI, velocity index.

There was a significant difference ($P = .003$) in the Doppler velocity index between groups N and D. Some overlap was observed among the individual indices in each of the 2 groups; however, the velocity index in group D was equal to or less than 0.35 in 13 of the 16 patients, as shown in Fig 3.

Causes of restricted leaflet movement of the aortic SJM valves. Causes of restricted leaflet movement of the aortic SJM valves are listed in Table IV. Of the 16 patients in group D, 5 underwent replacement of the aortic SJM valve because of high peak pressure gradients or small effective valve areas on echocardiograms at rest in addition to fear of abrupt progression of prosthetic valve obstruction. The opening angles of these 5 valves, as determined by cineradiography, were 35°, 40°, and 45° in 1 patient each and 50° in 2 patients. At operation, the cause of the restricted leaflet movement was pannus formation without thrombus in 4 patients and valve thrombosis with pannus formation in 1

patient. Pannus formation was observed on the inflow aspect of the SJM valve in all 5 patients. The pannus protruded into the prosthetic valve orifice over the housing and pivot guards of the valve and involved the ends of the straight edge of the leaflet (Fig 4). The patient with valve thrombosis had a history of withdrawal of warfarin 2 months before this evaluation because of operations for cataracts of both eyes at a different hospital. The remaining 11 patients in group D have been followed up for a further 3 to 7 months by means of echocardiography and cineradiography because of relatively low peak pressure gradients, refusal to undergo replacement of the SJM valves, or both. No rapid progression of restricted leaflet movement on cineradiograms or deterioration of hemodynamic performance by echocardiography has been observed in these 11 patients.

Postoperative anticoagulant therapy. Postoperative anticoagulation at the time of cineradiography and

Fig 4. An SJM valve explanted 196 months after surgery from the same patient shown in Fig 2. **A**, Outflow aspect. Pannus formation is seen on the inflow side of the housing. **B**, Inflow aspect. Excess pannus growth involving the ends of the straight edge of the leaflet over the housing and pivot guards.

echocardiography was considered to be adequate in 52 patients and inadequate in 2 patients. However, the opening angles of the aortic SJM valve in the latter 2 patients were 10° and 16°, respectively.

Discussion

Valve obstruction, such as valve thrombosis and pannus formation, is one of the most serious complications of mechanical valves, with an incidence ranging from 0.2% to 4.5% per patient-year.⁶ In the present study we confirmed restricted leaflet movement of the aortic SJM valves by using cineradiography in 16 (29.6%) of the 54 patients. As we previously demonstrated,¹² restricted leaflet movement of bileaflet prosthetic valves on cineradiograms does not always mean prosthetic valve obstruction. However, Doppler echocardiographic data indicated that the aortic SJM valves in these 16 patients were obviously obstructed. These results suggest that the incidence of obstruction of aortic SJM valves might be higher than previously reported incidences.¹⁻⁴

Prosthetic valve obstruction is mainly caused by thrombus; however, pannus formation also plays an important role in the occurrence of obstruction and is occasionally its sole cause.⁶ In our 5 patients of group D who received replacement of the SJM valve, the causes of valve obstruction were pannus formation without thrombus in 4 patients and valve thrombosis with pannus formation in 1 patient who had a history of withdrawal of warfarin. Considering these operative findings and no rapid progression of restricted leaflet movement in the remaining 11 patients, pannus formation is most likely to be the cause of the restricted leaflet movement.

An SJM valve has characteristic designs (ie, the low profile structure and unique pivot systems). As a result of these structural features, both ends of the straight edge of the leaflet are very close to the edge of the pivot guards in the fully open position. In the aortic position one of the pivot guards of an SJM valve placed in the native anulus often comes into contact with the inter-ventricular septum or left ventricular wall in either valve orientation.^{13,14} This condition appears to promote excess growth of pannus over the housing and pivot guard, and this excess growth may well restrict the opening of the leaflet without restricting the closing of the leaflet, even before immobilization of the leaflet occurs. Consequently, reduced valve orifice area resulting from excess growth of pannus and restricted opening of the leaflets caused by this excess growth probably led to the obstruction of the aortic SJM valves.

The most widely used technique to detect malfunctioning prosthetic valves is echocardiography.¹⁵⁻¹⁷ Accurate evaluation of the prosthetic valve function by a single echocardiographic examination, however, is often difficult because of the wide variation among Doppler-derived pressure gradients and valve areas in valves of the same size and the overlap among velocities and gradients from valves of different sizes.¹⁵ Although peak velocity and gradient across the prosthetic valve depend on several factors, such as valve size, type, and blood flow through the valve,¹⁰ the Doppler velocity index is less dependent on valve size,^{18,19} and the averaged velocity index of normally functioning aortic SJM valves was reported to be 0.41 ± 0.09 , which was close to that found in our data.¹⁸ Therefore, application of the Doppler velocity index is considered to be a simple and useful screening test for

prosthetic valve obstruction, particularly if the valve size is not known. On the other hand, cineradiography provides information about leaflet movement of prosthetic valves.^{5,7,8} In this study both leaflets of the SJM valve were clearly observed, and leaflet movement in group D was strikingly abnormal, with the opening angles clearly outside the normal range.^{7,8,11} In 11 of the 16 patients, impairment of hemodynamic performance of the SJM valves was not considered to be severe enough to merit replacement of the valves because all mechanical prosthetic valves are inherently stenotic. These results therefore suggest that a combination of cineradiography and echocardiography provides an accurate and detailed diagnosis of obstruction of the SJM valve, including hemodynamic impairment, and that cineradiographic evaluation of leaflet movement of the SJM valves should be performed in patients with a Doppler velocity index of less than 0.35, regardless of the valve size used for AVR.

Finally, the major limitation of the present study is the number of patients. Among the 605 patients, only 54 patients were studied. Because the number of patients was very small, further observations and analyses of hemodynamic performance by cineradiography and echocardiography for the remaining patients are needed to clarify the accurate incidence and the optimal management of patients with restricted leaflet movement of aortic SJM valves.

In conclusion, cineradiographic and echocardiographic examinations were performed simultaneously to evaluate hemodynamic performance and leaflet movement of aortic SJM valves in the 54 patients with no signs of prosthetic valve dysfunction late after AVR. Although the closing angles of the leaflets corresponded closely with the manufacturer in vitro data and our previous data, restricted leaflet movement for opening (opening angle $\geq 20^\circ$) was found in 16 (29.6%) of the 54 patients by using cineradiography. Pannus formation is considered the most likely cause of this restricted leaflet movement and prosthetic valve obstruction.

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