# The St. Jude Medical cardiac valve versus the Björk-Shiley prosthetic valve in the mitral position: a preliminary report[1]

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The St. Jude Medical (SJM) prosthetic valve has become a valuable alternative in patients in whom a mechanical valve prosthesis is preferred or medically indicated. This report summarizes and compares the authors' experience with the Björk-Shiley (BS) and SJM valves in the mitral position. Between 1974 and 1981, 73 patients (mean age, 55.1 years) underwent valve replacement with BS valves, and from 1980 to 1983, 38 patients underwent valve replacement with SJM prostheses in the mitral position (hospital mortality, 10%). Age, sex, dominant mitral pathology, incidence of atrial fibrillation, severity of coronary artery disease, and postoperative anticoagulation were equivalent for both groups. Complete follow-up results are available for all operative survivors to July 1983. SJM valves appear to be superior to BS valves in terms of late deaths (0 SJM; 6.0 BS per 100 patient years) and valve thrombosis (0 SJM; 1.3 BS per 100 patient years). In patients who require a mechanical mitral valve prosthesis, the SJM valve merits consideration.

**Index terms:** Heart valve prosthesis • Heart valves

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Mitral valve replacement (MVR) has been performed for more than 20 years, but with less than ideal prostheses. An ideal prosthesis must have good hemodynamic performance, durability, low incidence of thromboembolic phenomena, and must not produce hemolysis.[1]

Mechanical cardiac valves such as the Starr-Edwards valve have proved to be durable, but require long-term anticoagulation.[2] The Björk-Shiley (BS) tilting disc prostheses was designed to achieve the same durability, but with improved hemodynamic performance, and less he-

499

**Table.**  The St. Jude Medical cardiac valve versus the Björk-Shiley prosthetic valve—complications and mortality

|  | BS | BS (2 yr) | SJM |
|---|---|---|---|
| Mean follow-up (mo) | 70.0 | 23.0 | 22.0 |
| Hemorrhagic complications—major (per 100 patient years) | 2.1 | 0.8 | 3.2 |
| Thromboembolic episodes (per 100 patient years) | 3.6 | 0.8 | 3.2 |
| Valve thrombosis (per 100 patient years) | 1.3 | 0.8 | 0 |
| Late deaths (per 100 patient years) | 6.0 | 6.9 | 0 |

BS = Björk-Shiley prosthetic valve and SJM = St. Jude Medical cardiac valve.

molysis and thromboembolic phenomena.[3] However, strut fracture and disc embolization have been reported.[4] Thrombosis of the BS valve has also been found to be a problem.[5] An improved BS valve with a convexoconcave disc and stronger struts was introduced in 1978.[6] Various bioprostheses are now also available, with excellent hemodynamic performance and an acceptable incidence of thromboembolic events without long-term anticoagulation. However, the durability of bioprostheses is not certain beyond six to eight years.[7,8] The St. Jude Medical (SJM) valve was first implanted clinically in October 1977.[1] As a mechanical valve with a low-profile double-tilting disc constructed of pyrolytic carbon, it was designed to provide durability, good hemodynamic performance, and low thrombogenicity.[9] Little data are as yet available on its long-term use, especially in the mitral position. At the Cleveland Clinic, it has been used as an alternative prosthesis since 1980, and our initial data on its use in the aortic position were satisfactory.[10] This study was conducted to evaluate our experience with this valve in the mitral position and to compare it to the BS valve.

**Materials and methods**

Between 1974 and 1981, 73 patients had BS valves implanted, and from 1980 to 1983, 38 patients had the SJM prosthesis implanted in the mitral position. The BS valve group consisted of 25 males and 48 females with a mean age of 56.1 years (range, 36–76 years). The SJM group con-

sisted of 8 males and 30 females with a mean age of 55.1 years (range, 2–79 years). Fifty-two (71%) patients in the BS group and 24 (63%) in the SJM group were New York Heart Association (NYHA) Functional Classes III and IV. Coronary artery disease was documented angiographically in 21 patients (29%) in the BS group and in 8 patients (21%) in the SJM group. Forty-three patients (59%) in the BS group and 20 patients (53%) in the SJM group gave a history of atrial fibrillation. Fifty-five (75%) of the BS patients and 24 (63%) of the SJM patients had mitral regurgitation, with or without mitral stenosis. Mean left ventricular end-diastolic pressure was 14.1 mm Hg for the BS group and 13.2 mm Hg for the SJM group. Thirteen patients (18%) in the BS group and 13 patients (34%) in the SJM group had undergone previous cardiac surgery.

All patients underwent valve replacement under standard cardiopulmonary bypass technique. Prior to 1978, myocardial protection consisted of systemic cooling; since then, cold crystalloid cardioplegia has been added to our protocol. The BS prosthesis constituted the entire series. The mitral prosthesis has always been inserted with interrupted sutures. In patients with a history of atrial fibrillation, the atrial appendage was obliterated. Simultaneous coronary artery bypass grafting was performed in 19 (26%) of the patients in the BS group and in 7 (18%) of the SJM group.

Anticoagulation with warfarin was usually instituted on the third postoperative day. Careful monitoring of the drug was done until the prothrombin time was stabilized in the therapeutic range. Of the operative survivors with BS prosthesis, 65 (96%) were discharged from the hospital and received warfarin; 2, dipyridamole (Persantine); and 1, aspirin. Thirty-two (100%) of the survivors with SJM prostheses were discharged and received warfarin; none received dipyridamole or aspirin.

Follow-up was obtained by clinic visit or by telephone contact with the patient, family member, or local physician. The closing month of the study was July 1983. Complete follow-up was available for 100% of both the BS group and SJM group. All data were analyzed by computer. Fisher's exact test was used to calculate $P$ values.

**Results**

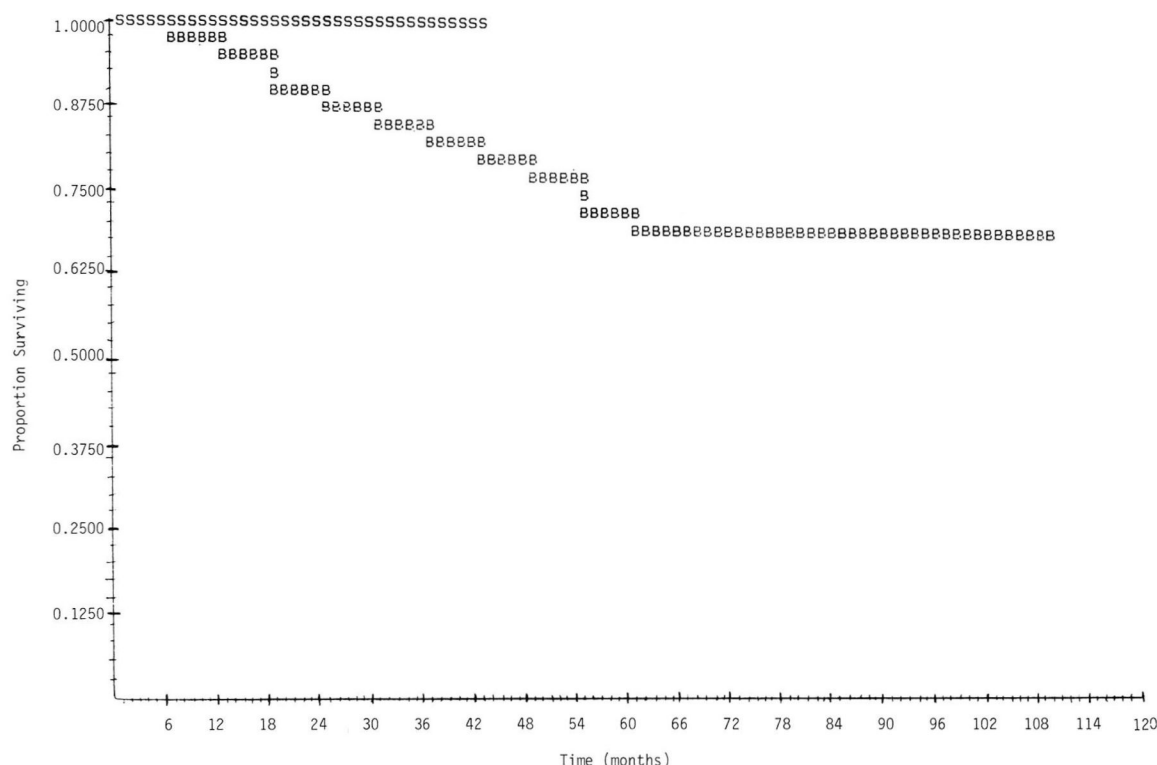*Early postoperative results.* Hospital mortality

**Figure.**   Comparison of cumulative proportion survival of patients with the Björk-Shiley prosthetic valve (*B*) and the St. Jude Medical cardiac valve (*S*).

consisted of 5 patients (7%) in the BS group and 6 patients (16%) in the SJM group. Four patients (5%) in the BS group had perioperative cerebrovascular accidents; none of the SJM patients had stroke. One SJM patient had a postoperative peripheral embolus.

*Late postoperative results (Table).* The mean length of follow-up was 70 months (range, 4–111 months) for the BS group and 22 months (range, 3–43 months) for the SJM group. Results were also calculated for the first two years in the BS group (BS, two years). This group had a mean follow-up of 23 months, similar to the 22 months for the SJM group.

*Thromboembolic complications.* Late thromboembolic complications included four peripheral embolic events and 10 strokes. Twelve BS patients (18%) had thromboembolic complications, compared to 2 SJM patients (6%), which is equivalent to 3.6 and 3.2 episodes per 100 patient years, respectively. There was no statistically significant difference between the two groups.

*Hemorrhagic complications.* Major hemorrhagic complications were considered to be those re-

quiring hospitalization. Seven patients (10%) in the BS group and 2 patients (6%) in the SJM group had major anticoagulant-related hemorrhage. Three of these episodes were related to death in the BS group.

*Valve failure.* Three patients required replacement of a BS mitral valve two to six years after the initial valve replacement. In all three cases, in spite of adequate anticoagulation with warfarin, there was prosthetic valve dysfunction due to thrombosis, and a replacement prosthesis was successfully implanted. None of the SJM patients has so far required replacement of the prosthesis. In addition, 2 patients had autopsy-proved thrombosis of their respective BS valves as the cause of death.

*Late survival.* The late death rate for the BS group was higher than for the SJM group at two years or for the full length of follow-up ($P = 0.06$). An actuarial survival curve for the two groups is shown in the *Figure*. There is a steady attrition of patients in the BS group over the course of seven years. Autopsies confirmed thrombosis of the BS valve as the primary cause

of death in two late deaths in the BS group. One of these patients was not, however, receiving anticoagulant treatment at the time of death.

## Discussion

Opinions vary regarding choice of prosthesis for mitral valve replacement. Many surgeons routinely use mechanical valves whenever possible, while those who prefer bioprostheses also select a group of patients for whom the superior durability of a mechanical valve outweighs other considerations. It is generally agreed that the BS valve has good hemodynamic characteristics and is not associated with significant hemolysis. However, although the durability of the prosthesis itself appears satisfactory, it has been associated with a considerable incidence of valve thrombosis and other thromboembolic phenomena.[5, 11, 12] Daenen et al,[12] reporting on 313 patients with BS mitral valve replacement, found an incidence of valve thrombosis of only 1.3% at 3.7 years, while Karp noted 13% at four years. By excluding patients not properly anticoagulated and those with perivalvular leaks or endocarditis, Daenen et al found a valve failure rate of 0.06 per 100 patient years. In our series, the incidence of BS valve thrombosis was 1.3 per 100 patient years, and each of the 3 patients who required subsequent valve replacement for valve dysfunction had thrombosis of the BS prosthesis in spite of adequate anticoagulation therapy. No paravalvular leak, strut fracture, or endocarditis developed in any of our patients.

The SJM valve is theoretically unlikely to thrombose because of its central flow characteristic and its pyrolytic carbon construction. However, sporadic reports of thrombosis of the SJM prosthesis in the mitral position have occurred, although all of these cases were related to lack of anticoagulation.[13, 14] It appears likely that the SJM valve, like other mechanical valves, requires long-term anticoagulation,[15] especially when placed in the mitral position. In our series, all patients with SJM valves had received anticoagulation with warfarin without the development of valve thrombosis.

There appears to be no significant difference between the BS group and the SJM group in hemorrhagic complications and only a slightly higher incidence of thromboembolic complications for the SJM group in two years. Our incidence of thromboembolic complications for SJM patients of 3.2 per 100 patient years is somewhat higher than the 1.7 reported by Lillehei[16] for the

mitral position. A low incidence of thromboembolic phenomena in SJM patients receiving anticoagulation therapy was also found by Hunt et al.[17]

A high incidence of sudden death on late follow-up of patients with BS prosthesis has been noted by Karp et al[11] and Daenen et al.[12] Daenen et al obtained postmortem examination results on 5 of the 19 patients who died suddenly, and found all the BS valves to be intact and thrombus-free. They, therefore, proposed that arrhythmias were the cause of death in these patients. In our series, results of three postmortem examinations were obtained, two of which showed thrombosis of the BS valve. One of these patients had not, however, been receiving warfarin at the time of death. There were an additional 9 patients with BS valves who died of congestive heart failure, and although autopsy evidence is not available, it may be speculated that valve thrombosis was involved in some of these cases. As indicated on the *Table* and *Figure*, the rate of death in patients with BS prostheses appears higher ($P = 0.06$) than in those with SJM prostheses, even when only the first two years of follow-up is used for the BS group.

This study was performed retrospectively, and clearly, the two groups of patients are not perfectly matched. The length of follow-up for the BS group is also much greater than for the SJM group. However, our data raise serious concern about the long-term risk of thrombosis of the BS prosthesis in the mitral position.

Only by following a series of patients such as ours from five to ten years will it be possible to assess the durability of the SJM valve and to compare it with other prostheses. However, our initial data suggest that the SJM valve merits serious consideration in the mitral position and may be superior to the BS valve.

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## References

1. Nicoloff DM, Emery RW, Arom KV, et al.   Clinical and hemodynamic results with the St. Jude Medical cardiac valve

prosthesis: a three-year experience. J Thorac Cardiovasc Surg 1981; **82:** 674–683.

2. Teply JF, Grunkemeier GL, Sutherland HD, et al. The ultimate prognosis after valve replacement: an assessment at twenty years. Ann Thorac Surg 1981; **32:** 111–119.

3. Björk VO, Olin C. A hydrodynamic evaluation of the new tilting disc valve (Björk-Shiley) for mitral valve replacement. Scand J Thorac Cardiovasc Surg 1970; **4:** 37–43.

4. Larrieu AJ, Puglia E, Allen P. Strut fracture and disc embolization of a Björk-Shiley mitral valve prosthesis: localization of embolized disc by computerized axial tomography. Ann Thorac Surg 1981; **34:** 192–195.

5. Björk VO, Henze A, Hindmarsh T. Radiopaque marker in the tilting disc of the Björk-Shiley heart valve: evaluation of in vivo prosthetic valve function by cineangiography. J Thorac Cardiovasc Surg 1977; **73:** 563–569.

6. Björk VO. The improved Björk-Shiley tilting disc valve prosthesis. Scand J Thorac Cardiovasc Surg 1978; **12:** 81–84.

7. Oyer PE, Miller DC, Stinson EB, Reitz BA, Moreno-Cabral RJ, Shumway NE. Clinical durability of the Hancock porcine bioprosthetic valve. J Thorac Cardiovasc Surg 1980; **80:** 824–833.

8. Pelletier C, Chaitman BR, Baillot R, Guiteras P, Bonan R, Dyrda I. Clinical and hemodynamic results with the Carpentier-Edwards porcine bioprosthesis. Ann Thorac Surg 1982; **34:** 612–624.

9. Yoganathan AP, Chaux A, Gray RJ, DeRobertis M, Matloff JM. Flow characteristics of the St. Jude prosthetic valve: an in-vitro and in-vivo study. Artif Organs 1982; **6:** 288–294.

10. Gill CC, King HC, Lytle BW, et al. Early clinical evaluation after aortic valve replacement with the St. Jude Medical valve in patients with a small aortic root. Circulation 1982; **66** (suppl I): 147–149.

11. Karp RB, Cyrus RJ, Blackstone EH, Kirklin JW, Kouchoukos NT, Pacifico AD. The Björk-Shiley valve: intermediate-term follow-up. J Thorac Cardiovasc Surg 1981; **81:** 602–614.

12. Daenen W, Nevelsteen A, van Cauwelaert P, de Maesschalk E, Willems J, Stalpaert G. Nine years' experience with the Björk-Shiley prosthetic valve: early and late results of 932 valve replacements. Ann Thorac Surg 1983; **35:** 651–663.

13. Commerford PJ, Lloyd EA, De Nobrega JA. Thrombosis of St. Jude Medical cardiac valve in the mitral position. Chest 1981; **80:** 326–327.

14. Kafka H, Parker JO, Charrette EJ, Salerno TA. Malfunction in a St. Jude Medical mitral valve prosthesis: a clinical diagnostic dilemma. Can J Surg 1983; **26:** 84–86.

15. Nuñez L, Iglesias A, Sotillo J. Entrapment of leaflet of St. Jude Medical cardiac valve prosthesis by miniscule thrombus: report of two cases. Ann Thorac Surg 1979; **29:** 567–569.

16. Lillehei CW. Worldwide results with the St. Jude Medical valve. Proceedings of the First European Symposium, Paris, June 21, 1980, pp 49–71.

17. Hunt D, Sloman G, Sutton L. The St. Jude Medical valve: the Australian experience. Med J Aust 1981; **2:** 276–278.