PROPHYLACTIC REPLACEMENT OF BJÖRK-SHILEY CONVEXO-CONCAVE VALVES AT RISK OF STRUT FRACTURE

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Objective: Prophylactic replacement of Björk-Shiley convexo-concave valves (Shiley, Inc., Irvine, Calif.) has been advised for selected groups of patients. If prophylactic replacement is considered, risks of postoperative morbidity and mortality have to be weighed against benefits of replacement. Here we report the results of prophylactic replacement of Björk-Shiley convexo-concave valves at risk of strut fracture in The Netherlands. **Methods:** We reviewed medical records of 36 patients undergoing prophylactic replacement of their Björk-Shiley convexo-concave valves before August 1995. Replacement was judged to be prophylactic if the risk of strut fracture outweighed that of death from reoperation, or the patient wished to have the valve replaced although it was not recommended. The procedure was also considered to be prophylactic if a concomitant pathologic condition, not likely to require cardiac surgery in the near future, was present or if preoperative examination revealed an unexpected cardiac pathologic condition. **Results:** Twenty-two 70-degree and 16 60-degree Björk-Shiley convexo-concave valves and one spherical valve were replaced (25 aortic and 14 mitral, including three double-valve replacements). Early mortality was 2.8% (1/36) (exact 95% confidence interval [CI] 0.1 to 14.5). Mean follow-up was 33 months. One- and 3-year survivals were 94% (95% CI 79% to 99%) and 91% (95% CI 74% to 97%), respectively. All three deaths were sudden. **Conclusions:** If special care is taken in selecting patients, the risk of prophylactic replacement is comparable to that of primary valve replacement. More data are needed to assess whether the risk of sudden death is possibly increased. (J Thorac Cardiovasc Surg 1998;115:577-81)

Replacement of prosthetic heart valves in general carries a higher risk of death and morbidity than primary valve replacement.^{1,2} For some recipients of the Björk-Shiley convexo-concave (BSCc) valve (Shiley, Inc., Irvine, Calif.), nevertheless, the risk of fracture of the outlet strut of their valve(s) may outweigh the risk of mortality and morbidity associated with valve replacement, and prophylactic re-

placement has been recommended.³⁻⁸ The risk of prophylactic replacement, however, is unknown.

Since 1991, several Dutch recipients of the BSCc valve were reoperated on based on the results of the Dutch BSCc follow-up study,³ a decision analysis of the data,⁷ or sometimes the explicit wish of a patient to have the valve explanted.

In this study we report on perioperative morbidity and mortality and long-term survival in patients who had prophylactic replacement of their BSCc valve in The Netherlands.

Patients and methods

Patients. Data were recorded at all cardiac surgery centers in The Netherlands. All patients who underwent prophylactic replacement of their BSCc valve before August 1995 were included in this study. If documented, the considerations, including a possible formal decision analysis⁷ for the prophylactic replacement of each of the BSCc valve(s), were recorded from the patient records and a comprehensive clinical profile, including relevant aspects of the medical history, details of physical examination,

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Table I. Characteristics of patients that underwent prophylactic replacement

Sex	Valve				Primary reason	Secondary reason	Medical history and preoperative findings	Concomitant surgery	Perioperative complications	Follow-up	Status
	Age	Position	Angle (degree)	Size							
Male	26	A	60	21	R	—	—	—	—	8 days	Dead
Female	68	A	60	21	R	—	—	—	—	22 mo	Alive
Male	41	A	60	23	R	PVL	History of endocarditis	—	—	25 mo	Alive
Male	63	A	60	23	R	—	—	—	—	39 mo	Alive
Female	29	A	60	25	R	PVL	Marfan's disease VSD closed (1975) Enlargement of aortic valve (1978)	—	—	17 mo	Alive
Male	35	A	60	25	W	PVL	History of endocarditis	—	Complete AV block (pacemaker necessary)	29 mo	Alive
Male	40	A	60	25	R	—	Prior reoperation for PVL (1983) Preoperative finding: PVL	Reconstruction anterior mitral leaflet	—	22 mo	Alive
Male	46	A	60	27	R	—	History of endocarditis	—	—	14 mo	Alive
Male	51	A	60	27	W	—	Strut fracture mitral valve (1990) with complicated postoperative course*	—	—	45 mo	Alive
Male	41	A	60	29	R	—	—	—	—	35 mo	Alive
Female	47	M	60	27	R	—	—	—	—	24 mo	Dead
Female	46	M	60	31	R	—	—	—	—	19 mo	Alive
Female	58	M	60	31	W	—	—	—	—	34 mo	Alive
Male	36	A	60	23	—	—	—	—	—	30 mo	Alive
Female	40	M	60	31	R	—	—	—	Transfusion reaction—multi-organ failure and excessive bleeding	42 mo	Alive
		M	Spherical	19	—	—	—	—			
		M	60	27	R	—	—	—			
Male	47	A	70	23	R	—	—	—	—	3 mo	Alive
Male	54	A	70	23	W	—	—	—	—	89 mo	Alive
Male	26	A	70	27	R	PVL	—	Replacement aortic root	—	34 mo	Alive
Male	42	A	70	27	R	—	—	—	Prolonged unexplained fever and acute hepatitis	41 mo	Alive

A, Aortic; AV, atrioventricular; CAD, coronary artery disease; M, mitral; PVL, paravalvular leakage; R, high fracture risk; TIA, transient ischemic attack; VSD, ventricular septal defect; W, patient's explicit wish to have the valve explanted.

*The BSc aortic valve was not replaced during the emergency procedure after strut fracture of the mitral valve in 1990.

cardiac catheterization and/or echocardiography, and, if performed, coronary angiography. Also, the type of surgical procedure, possible concomitant procedures, perioperative, and postoperative complications were recorded.

Prophylactic replacement. A replacement was judged to be prophylactic if either the treating cardiac surgeon or cardiologist considered the risk of outlet strut fracture for that individual patient higher than his or her risk of death from reoperation, or if the patient wished to have the valve replaced although replacement was not directly advised by his or her cardiac surgeon and cardiologist. If a concomitant pathologic condition was already present

before replacement of the valve was considered, but was not likely to require cardiac surgery in the near future, the reoperation was still considered prophylactic. This was also true if preoperative examination revealed an unexpected cardiac pathologic condition.

Follow-up. Follow-up data on functional and vital status were collected from the clinical records and the municipality registers. Early mortality was defined as death occurring within 30 days or before hospital discharge. The cause of death was determined on the basis of medical records from the hospital (including autopsy reports if present) or the patient's general practitioner.

Table I. *Cont'd*

Sex	Age	Valve			Primary reason	Secondary reason	Medical history and preoperative findings	Concomitant surgery	Perioperative complications	Follow- up	Status
		Position	Angle (degree)	Size							
Male	50	A	70	27	R	—	—	—	—	36 mo	Alive
Male	54	A	70	27	R	—	Amaurosis fugax (1970)	—	—	32 mo	Alive
Male	60	A	70	27	R	—	—	—	Complete AV block (pacemaker necessary)	35 mo	Alive
Male	64	A	70	27	R	—	—	—	—	47 days	Dead
Male	66	A	70	27	R	—	—	—	—	40 mo	Alive
Male	48	A	70	29	W	—	—	—	—	39 mo	Alive
Male	62	A	70	29	W	—	—	—	—	90 mo	Alive
Male	66	A	70	29	R	—	—	—	—	36 mo	Alive
Female	43	M	70	27	R	—	—	—	—	25 days	Alive
Female	47	M	70	27	R	—	History of myocardial infarction, TIA, and lung embolism; open commisurotomy mi- tral valve (1978); severe tricuspid re- gurgitation	—	—	41 mo	Alive
Female	30	M	70	29	R	—	Prior mitral valve re- placement (1979)	—	—	32 mo	Alive
Female	53	M	70	29	R	—	—	—	—	41 mo	Alive
Female	65	M	70	29	R	—	—	—	—	44 mo	Alive
Male	46	M	70	31	R	—	Prior mitral valve re- placement (1979); history of endocardi- tis	—	—	17 mo	Alive
Female	63	M	70	31	R	—	Closed commisur- otomy mitral valve (1958)	—	—	39 mo	Alive
Female	64	M	70	31	R	—	TIA (1978); CAD	Coronary ar- tery bypass grafting	—	38 mo	Alive
Male	66	A M	70 70	25 29	W	—	History of endocardi- tis; CAD	Coronary ar- tery bypass grafting	—	38 mo	Alive

Data analysis. Proportions are presented with an exact 95% CI.⁹ Cumulative survival was estimated by the Kaplan-Meier product limit method.¹⁰

Results

Until August 1995 37 Dutch BSCc valve recipients from nine centers underwent prophylactic replacement of their valves; on one surviving patient no further data were available. The BSCc valves of 29 patients were explanted because the treating cardiac surgeon and cardiologist thought that prophylactic replacement compared favorably with expectant management; formal decision analysis was used to support this decision in nine of these patients. Seven patients insisted on having their valves replaced,

although replacement was not directly recommended by their physicians.

Table I shows patient and surgical characteristics. The series consisted of 23 men and 13 women. The mean age was 49 years (± 12 standard deviation; extremes 26 to 68 years). Five patients had a history of endocarditis. Before reoperation, all patients were in New York Heart Association functional class I or II. At preoperative screening, angiography demonstrated severe tricuspid regurgitation in one patient, coronary artery disease in two patients, and paravalvular leakage in five patients.

Twenty-two aortic valve replacements, 11 mitral valve replacements, and three double-valve replacements were performed. Ten large-size (≥ 29 mm)

and 12 small-size (<29 mm) 70-degree BSc valves and four large-size and 12 small-size 60-degree BSc valves were replaced. Concomitant procedures comprised tricuspid valve plasty in one patient, coronary artery bypass grafting in two patients, reconstruction of the previously damaged anterior mitral leaflet in one patient, and replacement of the aortic root by a homograft in one patient.

All patients survived the reoperation without technical problems. Four patients had postoperative complications (Table I). At hospital discharge no persistent neurologic deficits were documented. The median length of hospital stay was 11 days and ranged from 8 days to 267 days. The mean follow-up was 33 months (extremes 8 days to 90 months).

One patient died (2.8%, exact 95% CI 0.1% to 14.5%), 8 days after the operation after just having been released from the hospital. Two patients died later during follow-up at 47 days and at 745 days, respectively. All three patients died suddenly. An autopsy was performed in one of these deaths and no cause of death could be determined. The survival was 94% at 12 months (95% CI 79% to 99%) and declined to 91% at 36 months (95% CI 74% to 97%).

Discussion

The patients described in this study represent a carefully selected group of patients because the treating cardiac surgeon weighed the risk of outlet strut fracture against the individual risk of morbidity or mortality from reoperation for each of these patients to the best of his or her abilities. The risk estimates applied by the cardiac surgeons were based on the available literature at that time^{3, 6-8, 11-14} and on institution-specific experiences with rereplacement of prosthetic heart valves. Except for the patients who wished to have their valve replaced, the cardiac surgeons believed the risk of outlet strut fracture outweighed that reoperation. The fact that decision analytic support was used for only nine patients to support the decision to explant the BSc valve does not mean that the decision making was less prudent in the other patients; it merely reflects the decision process in clinical practice and underscores the fact that many obstacles to the understanding and acceptance of formal decision analysis still exist.¹⁵⁻¹⁷

The results from our study add significantly to the understanding of risks associated with prophylactic replacement of artificial valves after several other studies with subgroups of similarly young patients

undergoing elective valve reoperation have been published.^{13, 18} Contrary to patients undergoing prophylactic replacement, those undergoing elective replacement always have some underlying heart condition requiring valve replacement at that moment. Furthermore, in contrast to our study, these studies only reported on in-hospital mortality. Little has been written on the operative risk associated with prophylactic replacement of artificial heart valves. The few studies that actually dealt with prophylactic replacement of well-functioning artificial heart valves concerned Braunwald-Cutter aortic prostheses (Cutter Biological, Berkeley, Calif.) and date almost 20 years back.^{11, 12} Prophylactic replacement of these valves, because of predicted failure, seemed to be associated with a low risk of perioperative mortality. In the past prophylactic replacement of BSc valves was advised for selected groups of patients.^{3, 4, 7} Some authors have claimed that elective replacement of BSc valves, because of its inherent morbidity and mortality, cannot be recommended.¹⁹⁻²¹ Other clinical studies, however, have suggested that reoperative valvular surgery in an elective setting has perioperative morbidity and mortality similar to initial valve replacement.^{12-14, 18} Early mortality in this study was similar to that of primary valve replacement in our original cohort³ and in accordance with what was assumed in several decision analyses^{4, 7} and therefore seems acceptable, especially because six patients (17%) were reoperated on previously. However, the one patient who died early was a 26-year-old man in perfect health before the operation. The sudden death of another 64-year-old patient, 47 days after the operation, most likely was also related to the procedure. If this death would be accounted for as operative death, the operative mortality would increase to 5.6% (95% exact CI 0.7% to 18.7%). Furthermore, all deaths in this study were sudden. Sudden death has been found to be the second most common mode of death in patients undergoing primary valve replacement.¹ Despite the small number of events, the sudden death rate in this study during the first year of follow-up was 7.8 (95% CI 1.8% to 34.0%; Cox regression) times higher than in our original cohort study.³ Given the small number of patients in this study, it remains highly speculative whether this was a chance finding or whether prophylactic replacement really carries a higher risk of sudden death. More data are needed to assess the risk of sudden death after prophylactic replacements. On the other hand, BSc valves still fracture. Forty-six fractures

had been documented until August 1995. Six large fractures (≥ 29 mm) 60-degree BScv valves (five mitral and one aortic) were reported after the closing date of this study.

Thus prophylactic replacement still seems advisable for selected subgroups of BScv valve recipients, but evidence from this study indicates that proper decision making is warranted.

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Appendix

Participating centers: Academisch Medisch Centrum (BAJM de Mol; 2 patients), Onze Lieve Vrouwe Gasthuis Amsterdam (L Eijssman; 11 patients), Academisch Ziekenhuis Leiden (H Huysmans; 1 patient), Dijkzigt Ziekenhuis Rotterdam (LA van Herwerden; 5 patients), Academisch Ziekenhuis Utrecht (JJ Bredee; 1 patient), Sint Antonius Ziekenhuis Nieuwegein (JJAMT Defauw; 12 patients), Medisch Centrum de Klokkenberg (ThR van Geldorp; 3 patients), Ziekenhuis de Weezenlanden Zwolle (MMP Haalebos; 1 patient).