

Psychological distress among recipients of Björk-Shiley convexo-concave valves: the impact of information

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Abstract

Objective—To establish whether there is more psychological distress among recipients of Björk-Shiley convexo-concave (BScc) valves than among recipients of other valves not known to fracture.

Design—Cross sectional study.

Patients—137 patients who received either a BScc valve or a Sorin Biomedical spherical valve during a randomised trial between 1982 and 1983 at St Antonius Hospital, Nieuwegein. Systematic notification of the risk of strut fracture in recipients of BScc valves was carried out at St Antonius Hospital in 1991.

Mean outcome measures—Psychological distress as assessed with the General Severity Index from the Symptom Checklist 90.

Results—Psychological distress between recipients of BScc and Sorin valves did not differ irrespective of whether the recipients knew their valve type. More recipients of BScc valves, however, knew their valve type and of problems associated with artificial heart valves.

Conclusions—Information about an increased risk of strut fracture does not induce psychological distress among well informed recipients of BScc valves. All recipients of heart valves should be systematically informed about their valve type—for example, by issuing data cards with valve serial numbers and other relevant information.

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Recipients of Björk-Shiley convexo-concave (BScc) valves have been informed that their valve is prone to fracture at the outlet strut. Although prophylactic replacement of BScc valves has been advised for selected recipients,¹⁻³ the best course of action for many is to live with the valve rather than undergo the risk associated with explantation. The possibility of prosthesis failure in some recipients with BScc valves may, however, produce substantial anxiety.^{1,4,5} Apart from the ethical discussion of whether patients have a right to know their valve type and its associated risks,⁴ there has also been debate about whether such notification may have a substantial negative effect.^{4,6}

The focus of this study was to assess whether recipients of BScc valves experience more psychological distress than those with other artificial heart valves not known to fracture.

Methods

PATIENTS

Systematic notification of the individual risk of strut fracture^{2,7} in recipients of BScc valves from St Antonius Hospital, Nieuwegein was carried out in 1991.

The present study was a cross sectional study. The patient population consisted of former participants of a trial conducted between 1 July 1982 and 1 January 1984 at St Antonius Hospital during which 316 consecutive patients were randomised to receive either a BScc (Shiley Inc, Irvine, California, USA) or a Sorin Biomedical (Sorin Biomedica, Saluggia, Italy) spherical valve. The objective of the study was to examine differences in survival and valve related morbidity between the recipients of the two valves. Randomisation was successful. In the present study (started in August 1993), living patients whose valves were not explanted were included. Other eligibility criteria were informed consent and literacy.

Of the original 316 recipients, 63 with BScc valves and 97 with Sorin valves were invited to participate in the present study. Of the 156 patients who did not meet the eligibility criteria, 97 had died, 37 had had their valve explanted, 13 could not read or write, four suffered from dementia according to their general physician, two were admitted to a nursing home for dementia, one suffered from Korsakoff's syndrome, and two were lost to follow up. More recipients with BScc valves had died (35% v 27%) or had their valve explanted (16% v 8%) than those with Sorin valves (table 1). Five patients with BScc valves died because of a strut fracture. Three recipients of BScc valves were successfully reoperated on after a strut fracture. Twelve patients with BScc valves had prophylactic valve replacement: two because of anxiety.

STUDY INSTRUMENTS

Questionnaires

The questionnaire included the Dutch version of the Symptom Checklist 90 (SCL-90),⁸⁻¹⁰ a measure of psychological distress, and 20 questions addressing the patient's knowledge of the valve. The SCL-90 is a well validated measure of psychological distress, with good psychometric properties.⁸⁻¹⁰ The General

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Table 1 Eligibility of the former participants of the BScC-Sorin trial and participation of valve recipients eligible for inclusion

	BScC recipients (n = 150)	Sorin recipients (n = 166)
	Number (%)	Number (%)
<i>Not eligible for inclusion</i>		
Death	52 (35)	45 (27)
Replacement of valve	24 (16)	13 (8)
Not able to read or write Dutch	7 (5)	6 (4)
Suffering from dementia or Korsakoff's syndrome	2 (1)	5 (3)
Lost to follow up	2 (1)	0 (0)
<i>Eligible for inclusion</i>		
Participated	63 (42)	97 (58)
Refused to participate	52*	85†
Withdrew/questionnaire not returned	2	0
	9	12

*Questionnaires filled in by two respondents were not suitable for analysis; †Questionnaires filled in by three respondents were not suitable for analysis.

Severity Index (GSI) (range 90–450), which is the summary measure of the SCL-90, provides a measure of the overall level of psychological distress. The SCL-90 has been standardised to represent a general adult population.^{8–10} Higher scores are reported in women, the elderly, those living alone, and those who are less educated.^{10–12} Mean (SD) scores for a general Dutch population were: 117.2 (27.3) for men and 128.9 (36.4) for women.¹⁰

The general level of psychological distress, as assessed with the GSI from the SCL-90, was chosen in advance as the primary outcome measure.

STATISTICAL ANALYSIS

Chi-square and Wilcoxon tests were used when appropriate. GSI scores are reported as means (SD) and their distribution is illustrated by box plots. The significance of differences in mean GSI scores between the study groups was tested by Student's *t* tests. Analysis of variance was used to control the effects of marital status.

Results

A total of 137 patients (86%) participated in the study: two refused, 10 who were initially willing to participate withdrew later, and 11 did not return the questionnaire. Five returned questionnaires were not suitable for analysis because too few questions were completed by the respondents (table 1). Except for marital status, demographic characteristics and the New York Heart Association classification of the recipients were comparable (table 2).

There were no significant differences in mean GSI scores between recipients of BScC valves (127.2 (33.7)) and those with Sorin

Table 2 Demographic characteristics and functional status of recipients with BScC and Sorin valves

	BScC recipients (n = 50)	Sorin recipients (n = 82)
Mean (SD) age (years)	59.7 (12.6)	61.5 (11.0)
Number of men (%)	33 (66)	49 (60)
Number with only primary school education (%)	19 (38)	36 (44)
Number single/divorced/widowed (%)	16 (32)	12 (15)
Functional status		
NYHA I (%)	37 (74)	69 (84)
NYHA II (%)	9 (18)	6 (7)
NYHA III (%)	2 (4)	2 (2)
NYHA IV (%)	2 (4)	5 (6)

NYHA, New York Heart Association heart failure classification.

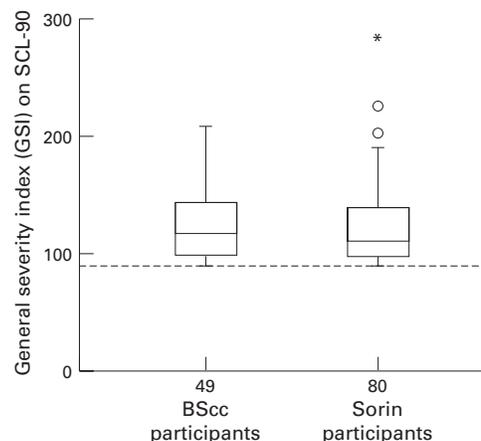


Figure 1 Distribution of GSI scores of BScC and Sorin study groups. Dotted line is the lowest score possible on GSI of SCL-90 (90). * extreme value; *, outlier.

valves (123.0 (34.6)) ($p = 0.5$). As fig 1 shows there was considerable data overlap; removing outliers did not change the results. Adjustment for marital status, because of the unbalanced distribution of marital status between the study groups, also did not change the results.

Recipients of BScC valves correctly identified their valve type more frequently than Sorin recipients (68% *v* 29%; $p < 0.01$) (table 3). Nine recipients of Sorin valves (11%) thought that they had a BScC valve. Although recipients who claimed to know their valve type more frequently knew about problems associated with artificial heart valves, more recipients of BScC valves were able to indicate this prosthesis as the “trouble valve” (97% *v* 42%; $p < 0.01$). Recipients who were knowledgeable with respect to their valve were significantly better educated and younger.

GSI scores of recipients of BScC valves who were unaware of their valve type were comparable to those of their Sorin counterparts ($p = 0.5$) (table 4). GSI scores of recipients of BScC valves who correctly knew their valve type were higher than those with Sorin valves ($p = 0.07$). After adjustment for marital status, this difference was not apparent ($p = 0.4$) (table 4). Figure 2 shows box plots for the GSI of married recipients; there is also considerable data overlap. Box plots for recipients who were living alone, widowed, or divorced were not informative because of the small numbers.

Discussion

The principal finding of this cross sectional study is that psychological distress does not differ between recipients of BScC and Sorin valves, irrespective of whether the recipients know their valve type. There was a major difference in knowledge concerning valve type between recipients of BScC valves and those with Sorin valves. Recipients of BScC valves more frequently knew their valve type and the problems associated with this prosthesis. Most patients with Sorin valves (60%) did not know their valve type and another 11% thought that they had a BScC valve. As all recipients of the BScC valve were informed about their valve and its associated risks, the difference in knowledge

Table 3 Valves actually implanted and those thought by recipients to cause problems

BSc recipients (n = 50)		Sorin recipients (n = 82)			
Type of valve thought to have received					
	BSc valve	Did not know	Sorin valve	BSc valve	Did not know
A		4	2		14
B	1	11	12	1	25
C	33	1	10	8	10

A, did not know about problems with heart valves; B, knew of problems with heart valves but was unable to name type of problem valve; C, knew of problems with heart valves, named BSc valve as the problem valve.

Table 4 Psychological distress among BSc and Sorin recipients related to knowledge of valve received

Participants	BSc study group		Sorin study group		p value*
	Mean (SD)	n	Mean (SD)	n	
Correct knowledge of type of valve received	129.2 (35.5)	34	115.0 (23.6)	24	0.4
Incorrect knowledge of type of valve carried	122.6 (30.0)	15	126.4 (38.0)	56	0.5

Values are means scores on the GSI from the SCL-90. For one BSc and two Sorin participants results on the SCL-90 could not be analysed because answers on too many items were missing. *Analysis of variance (p value for study group difference), adjusting for marital status. Mean GSI scores for married BSc and Sorin recipients who correctly knew what valve they carried were 119.8 (30.9) and 113.1 (23.0), respectively.

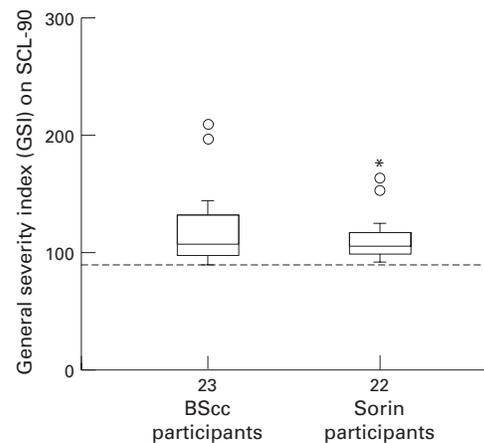


Figure 2 Distribution of GSI scores of married BSc and Sorin participants who correctly knew what valve they carried. Dotted line is the lowest score possible on GSI of SCL-90 (90). ° extreme value; *, outlier.

between the two study groups is not surprising. Despite notification, however, 32% of recipients of BSc valves were unable to recall their valve type.

Our findings suggest that the psychological wellbeing of patients with BSc valves is comparable to that of others with valves not known to fracture. Moreover, the GSI scores of both study groups of long term survivors of valve surgery were comparable to documented scores of an average Dutch population.¹⁰

What is the generalisability of these data? There was a disproportionate loss of patients in the original BSc study group as a result of death due to strut fracture and prophylactic explantation. Although this finding affected the power of our study, we believe that the negative result in this study is a true negative result: there was considerable data overlap between both study groups and the scores of these groups of long term survivors of valve surgery were similar to those of a general adult population. Furthermore, improving the

power of our study would not have yielded clinically significant differences between the study groups.

The validity of our study would have been compromised if patients lost from the study had been selective. If anxious patients died suddenly undiagnosed, had operations elsewhere, or committed suicide, it would dramatically alter the conclusions. As all patients were followed up, including data on reoperations (elsewhere) and causes of death, we know that no anxious patients were "lost" for these reasons. As for patients who died, there is no way of knowing whether they experienced more anxiety. Apart from recipients of BSc valves who died as a result of a strut fracture, the numbers and characteristics of patients who died in both groups did not differ. Therefore, we do not think that the psychological profile of the deceased patients in both subgroups was different.

Are the study groups of this randomised trial still comparable more than 10 years after the original trial? More recipients of BSc valves were single, divorced, or widowed or had had their valve explanted. As marital status could account for the differences observed,¹³ we adjusted for marital status in our analyses. Nevertheless, because two patients had undergone explantation because of anxiety,⁵ this may have resulted in a slight underestimation of the level of psychological distress.

Furthermore, the results provide information on the average psychological distress experienced by recipients of BSc valves who were informed of their risk of strut fracture. Moreover, as random assignment of information about strut fracture to recipients of BSc valves was not an option, we could not study the psychological effect of notification. It has been debated whether recipients of BSc valves should be notified about the risk of strut fracture.^{4, 6, 14} There has also been discussion about whether notification of the risk of strut fracture would have a negative psychological effect.^{6, 14} Each patient who had a BSc valve implanted at the St Antonius Hospital was notified of the risk of strut fracture in October 1991. For each patient a plan of action was available. Although most high risk recipients chose to have their valve replaced and most at low risk of strut fracture were reassured, some high risk patients did not opt for prophylactic surgery, whereas a few at low risk had their valve replaced. Our findings suggest, therefore, that if counselling and support are offered, notification is at least not harmful to recipients of BSc valves.

Finally, should all valve recipients, irrespective of the valve type, be informed about their valve? Most patients with a prosthetic valve suffer some degree of stress due to the nature of press releases. Issuing cards with each patient's valve serial number and other possibly relevant information is an option. Our results indicate that most patients who are systematically informed about their valve type cannot recall this information. Some patients will erroneously believe that they have another valve. For recipients of possibly defective devices, their

families, and doctors, knowledge of their type of valve will enable them to get medical attention more quickly. For recipients of other devices, accurate knowledge of the valve type may prevent unnecessary anxiety.

- 1 Birkmeyer JD, Marrin CA, O'Connor GT. Should patients with Björk-Shiley valves undergo prophylactic replacement? *Lancet* 1992;**340**:520-3.
- 2 van der Meulen JH, Steyerberg EW, van der Graaf Y, van Herwerden LA, Verbaan CJ, Defauw JJAMT, et al. Age thresholds for prophylactic replacement of Björk-Shiley convexo-concave heart valves. A clinical and economic evaluation. *Circulation* 1993;**88**:156-64.
- 3 Steyerberg EW, van der Meulen JH, van Herwerden LA, Habbema JD. Prophylactic replacement of Björk-Shiley convexo-concave heart valve: an easy-to-use tool for decision support. *Heart* 1996;**76**:264-8.
- 4 Fielder JH. Getting the bad news about your artificial heart valve. *Hastings Cent Rep* 1993;**23**:22-8.
- 5 de Mol BA, Kallewaard M, McLellan RB, van Herwerden LA, Defauw JJ, van der Graaf Y. Single-leg strut fractures in explanted Björk-Shiley valves. *Lancet* 1994;**343**:9-12.
- 6 Hiratzka LF, Kouchoukos NT, Grunkemeier GL, Miller DC, Scully HE, Wechsler AS. Outlet strut fracture of the Björk-Shiley 60 degrees convexo-concave valve: current information and recommendations for patient care. *J Am Coll Cardiol* 1988;**11**:1130-7.
- 7 van der Graaf Y, de Waard F, van Herwerden LA, Defauw J. Risk of strut fracture of Björk-Shiley valves. *Lancet* 1992;**339**:257-61.
- 8 Derogatis LR, Lipman RS, Covi L. SCL-90: an outpatient psychiatric rating scale—preliminary report. *Psychopharmacol Bull* 1973;**9**:13-28.
- 9 Derogatis LR. *SCL-90: administration, scoring and procedures manual-I for the revised version*. Baltimore: Clinical Psychometrics Unit, Johns Hopkins School of Medicine, 1977.
- 10 Arrindell WA, Eetema JHM. *SCL-90. Handleiding bij een multidimensionale psychopathologie-indicator*. Lisse: Zwets and Seitlinger, 1986.
- 11 Correll RE. Relationship of anxiety and depression to age and sex in an acute psychiatric population. *Psychol Rep* 1984;**55**:979-86.
- 12 Kessler RC, Price RH, Wortman CB. Social factors in psychopathology: stress, social support, and coping processes. *Annu Rev Psychol* 1985;**36**:531-72.
- 13 Joung IM, van de Mheen H, Stronks K, van Poppel FW, Mackenbach JP. Differences in self-reported morbidity by marital status and by living arrangement. *Int J Epidemiol* 1994;**23**:91-7.
- 14 Advising patients with artificial heart valves [editorial]. *Lancet* 1990;**336**:152.