Decision Guidelines for Prophylactic Replacement of Björk-Shiley Convexo-Concave Heart Valves
Impact on Clinical Practice

M.J. van Gorp, MD, PhD; E.W. Steyerberg, PhD, MSc; Y. van der Graaf, MD, PhD

Background—Because of risk of outlet strut fracture, prophylactic replacement should be considered for Björk-Shiley convexo-concave (BScc) valve recipients. We assessed the effects of epidemiological and decision-analytic guidelines on actual BScc valve replacement.

Methods and Results—We performed a retrospective cohort study including all 2263 Dutch BScc patients with a mean follow-up of 11.3 years (range, 0 to 23 years). Outcomes were outlet strut fracture, mortality, and BScc valve replacement. For the surviving patients in 1992 (n=1330), we calculated the expected differences in life expectancy (LE) with and without BScc valve replacement according to decision guidelines developed in 1992. Differences in LE were compared with actual replacements. During 8 years of follow-up, there were 494 deaths (40%), and 11 patients had suffered outlet strut fracture. Of 1330 patients, 96 (10%) had undergone BScc valve replacement, particularly in years after introduction of initial and updated guidelines. One hundred seventeen patients (9%) had an estimated gain in LE after BScc valve replacement. These patients were more likely to undergo replacement than patients with an estimated loss of LE (hazard ratio, 6.6; 95% CI, 4.4 to 10; P<0.0001). A loss in LE after reoperation was predicted for 8 of 11 patients who experienced outlet strut fracture after guidelines were available.

Conclusions—Valve replacement for BScc heart valve patients was largely in concordance with guidelines in the Netherlands. Individualized guidelines that are based on high-quality epidemiological data and are updated and implemented rigorously can influence clinical practice in complex decision problems. (Circulation. 2004;109:2092-2096.)

Key Words: follow-up studies ▪ prevention ▪ prosthesis ▪ surgery ▪ valves

The Björk Shiley convexo-concave (BScc) valve was introduced in 1979 as a successor of the Björk Shiley spherical valve. In 1986, the BScc valve was withdrawn from the market after repeated reports of outlet strut fracture. By this time, >86,000 patients had undergone valve replacement with a BScc valve. For these patients, prophylactic replacement had to be considered to avert possible catastrophic events. From a decision-analytic point of view, prophylactic replacement of the BScc valve is indicated when long-term fracture risks outweigh short-term reoperation risks. Epidemiological studies have been successful in determining individual risk factors for valve fracture, long-term survival, and operative mortality. Great efforts have been made to achieve adherence to the published decision guidelines in the Netherlands. In 1992, the Dutch BScc Follow-up Study, a retrospective cohort study, identified 4 risk factors for outlet strut fracture that were relatively easy to determine in the BScc patient: opening angle, valve size, mitral position, and young age. This publication led to worldwide notification by registered mail of all cardiologists and cardiothoracic surgeons. Subsequently, a formal decision model was introduced for the prophylactic replacement of BScc valves using the results of the Dutch BScc Follow-Up Study. In 1994, a more detailed model was developed with manufacturing characteristics that became available from Shiley Inc. Throughout the years, the decision guidelines were repeatedly refined according to new follow-up results. After closure of the Second Dutch BScc Follow-Up Study in 1998, a mailing was sent to all Dutch cardiothoracic centers with detailed individualized risk estimates for each of their patients. Figure 1 illustrates the time path with relevant information on decision guidelines and support.

Reducing uncertainty and managing risks with decision models and guidelines have become an integral part of current clinical practice. Although it has been shown that decision guidelines can improve quality of care, there is limited knowledge of their effectiveness in daily practice.

In the present study, we assessed the impact of epidemiological analyses and formal decision guidelines for the
prophylactic reoperation of BScc heart valve patients. Here, we compared differences in estimated life expectancy with actual decisions in the Dutch BScc cohort.

Methods

Patients
This retrospective cohort study included all 2263 Dutch BScc valve recipients, as described in detail previously.5,13 For the present analyses, all Dutch BScc patients were identified and followed up until December 2001. The 2263 patients received 60° (n = 2254) and 70° (n = 279) valves from 1979 to 1985. Of these, 1122 patients (50%) underwent aortic valve replacement, 800 (35%) had mitral valve replacement, and 341 (15%) underwent double valve replacement.

Follow-Up
We obtained follow-up data from the municipal registries and data on reoperations from all Dutch centers for cardiothoracic surgery. Information on the cause and mode of death was collected from the patient’s general practitioner or from clinical records. Mean duration of follow-up was 11.3 years (range, 0 to 23 years). Sixty-nine patients (3%) were lost to follow-up.

Outcome events during follow-up were outlet strut fracture, replacement of the BScc valve, and death as a result of all causes. Outlet strut fracture was defined as a separation of both legs of the minor strut of the valve, which was ascertained after emergency valve replacement operation or at necropsy.

Risk Calculations
For decision-making purposes, calculations were performed for patients who were alive and still had their valve in 1992. That year was used as the point of reference because it corresponds to the publication of the results of the First Dutch BScc Follow-Up Study in February 1992.3 For these patients, we estimated the loss of life expectancy as a result of fracture using a decision-analytic model based on the 1992 data.6 This loss can be compared directly with the loss of life expectancy caused by surgical mortality. If the loss of life expectancy caused by surgical mortality was estimated to be higher than the loss of life expectancy resulting from fracture, surgery was not beneficial in terms of life expectancy. If the estimated surgical mortality was lower than the loss in life expectancy, surgery was expected to result in a gain in life expectancy.

Data Analyses
We constructed Kaplan-Meier curves for the cumulative incidence of outlet strut fracture, a BScc replacement, and survival of all 2263 patients. We estimated valve replacement rates for each year on the basis of the total number of patients at risk for that year. A smoothed nonparametric curve was constructed with the Lowess algorithm.14 The differences in life expectancy with and without valve replacement estimations were categorized in 6 groups and subsequently compared with the number of BScc valve replacements during 8 years of follow-up. Cox regression analysis was used to determine whether patients with an estimated gain in life expectancy after valve replacement were more likely to undergo replacement of their BScc valve than patients with an estimated loss of life expectancy. In addition, characteristics, individual risks, and outcome of patients who suffered an outlet strut fracture after 1992 were assessed.

Results
Among the initial cohort of 2263 patients, 154 died within 30 days, 1193 died during follow-up, and 230 underwent replacement of a BScc valve. In total, 52 patients suffered an outlet strut fracture, which was fatal in 34 (65%). Figure 2 shows cumulative survival, BScc replacements, and outlet strut fractures.
strut fractures. The replacement rates per year are depicted in Figure 3. An increase in replacements was observed during several periods of follow-up. The first increase in replacements occurred in 1980 and 1981, and 2 other increases were noted in 1992 and 1998, which followed the notification of the first and second Dutch BScC Follow-Up Study.

Cohort From 1992
On February 1, 1992, a total of 1330 BScC patients were alive and still had their valve in situ. Baseline patient characteristics and valve characteristics are presented in Table 1. After 8 years of follow-up, 494 deaths had occurred (40%). Reoperation with replacement of a BScC valve was performed in 96 patients (10%). In 3 patients, this was an emergency replacement after outflow strut fracture. Eleven patients suffered an outlet strut fracture, which concerned a mitral valve in 9 and an aortic valve in 2 cases. Mortality was 78% (7 of 9) and 100% (2 of 2) for patients with mitral and aortic strut fractures, respectively.

Patients with an estimated gain in life expectancy after valve replacement (117, 9%) were more likely to actually undergo a BScC replacement than patients with an estimated loss of life expectancy (1213, 91%) (hazard ratio, 6.6; 95% CI, 4.4 to 10; P<0.0001). Table 2 shows the number of BScC replacements and the replacement rate for the different categories in expected gain in life expectancy after BScC valve replacement.

Most patients (8 of 11) who suffered an outlet strut fracture were those for whom a loss of life expectancy after BScC valve replacement was estimated (Table 3). Two patients had a considerable estimated gain in life expectancy after BScC valve replacement (11% and 28%). Inquiry into the rationale for a conservative strategy (nonreplacement) in these 2 patients revealed that both patients had received negative advice about replacement from their cardiothoracic surgeon because of supposedly outweighing surgical mortality risks. According to the decision model, these mortality risks were relatively low (5% and 1%).

Discussion
Results of this study with >20 years of follow-up show that decision guidelines positively influenced replacement of fracture-prone valves in Dutch BScC valve recipients. Most outlet strut fractures that occurred after guidelines were available could not have been prevented with the available epidemiological knowledge.

The number of replacements in our study population showed several striking increases. The first peak of replacements was observed during the early years of implantation of the BScC valve. This peak may be explained by recurrence of endocarditis in a relatively large group of patients that often requires repeated surgery, especially in prosthetic valve recipients.15–17 The second and third replacement peaks coincide with the identification and publication of risk factors for outlet strut fracture in 1992 and the nationwide mailing of individual risk estimates to all Dutch cardiothoracic centers in 1998, respectively. The consequences of disclosing such important information are now shown empirically.

Several important factors can be identified for the relative success of the decision guidelines. First, media attention was substantial when information became available on the increased risk of mechanical failure of 60° BScC valves in 1992. In addition, because identified risk factors were credible and easy to comprehend, the 1992 results could lead to straightforward recommendations about prophylactic reoperation. Second, no alternatives were available for managing the complex decision-making scenarios that subsequently arose for BScC patients and their physicians. Further assistance in decision making was offered when age thresholds for prophylactic reoperation. Second, no alternatives were available for managing the complex decision-making scenarios that subsequently arose for BScC patients and their physicians. Further assistance in decision making was offered when age thresholds for prophylactic valve replacements were introduced in 1993. Third, when guidelines were extended with the latest follow-up data in 1998, individualized risk estimations were put at the disposal of all Dutch cardiothoracic centers. In this way, the decision guidelines were effective in identifying most high-risk valves and in making proper recommendations, including prevention of unnecessary reoperations. Finally, confidence

![Image](http://circ.ahajournals.org/)

**Figure 3. Replacement of BScC valves at risk per calendar year expressed as percentage of total number of BScC patients alive in that year. Open circles indicate replacement rates; vertical lines, 95% CIs; and dotted line, smoothed nonparametric line.**
in the decision guidelines was apparently high. For the different guidelines, essential components include (1) surgical mortality after prophylactic replacement, (2) age-specific annual risk of death, (3) annual risk of strut fracture, and (4) mortality and morbidity after strut fracture. The accuracy of the guidelines is determined by the validity and precision of these components. The complete model was not prospectively validated, but the robustness of the different risk estimates was substantiated in several studies. Estimation of surgical mortality after prophylactic replacement is the most uncertain component because data are sparse. However, we recently developed and validated a prediction rule that was able to give individualized estimates of the risk of mortality after reoperation.

Despite all efforts, the decision guidelines probably could not serve as a basis for rational decisions for all Dutch BScc patients because they ignore specific individual circum-

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<th>TABLE 2. Observed BScc Valve Replacements During an 8-Year Period After Publication of Guidelines</th>
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<td>Estimated Gain in LE After BScc Valve Replacement, %</td>
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Numbers and percentages are given per category of estimated gain in life expectancy (LE) after BScc valve replacement calculated for the living BScc valve recipients on February 1, 1992.

* Patients with an emergency replacement of a fractured valve were excluded (n = 3).
† The 8-year cumulative incidence estimated with Kaplan-Meier.
‡ Negative values indicate an estimated loss of life expectancy after BScc valve replacement according to the 1992 guidelines.

Our study illustrates that decision guidelines may have a practical impact when physicians are uncertain about appropriate practice and when epidemiological data can provide a solution. Methodological standards for evidence-based guideline development should be consulted to warrant a meticulous construction and validation process. However, not every medical dilemma that needs some sort of prognosis can comply with these standards. Lack of time and alternatives may force physicians and epidemiologists to come up with guidelines whose effectiveness in clinical practice remains to be proven. Furthermore, the development of decision guidelines is a continuous process that does not stop with guideline publication. To prevent outdated recommendations, extensive communication with physicians and regular updates of guidelines are necessary. The controllable development phase of guidelines is usually followed by an unpredictable implementation phase that includes the physician’s appreciation of the decision guidelines and the patient’s view of the uncertainty of his or her future. Clearly, the patient’s perspective and choice should dominate the

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<th>TABLE 3. Characteristics, Risk Profile, and Outcome of 11 BScc Valve Patients Who Suffered Outlet Strut Fracture Between February 1992 and December 2001</th>
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* Age at outlet strut fracture.
† Negative values indicate an estimated loss of life expectancy (LE) after BScc valve replacement.
outcome of the decision-making process, yet this outcome may not always correspond with recommendations. In addition, discrepancies between guidelines and the physician’s clinical judgment are major impediments for successful guideline implementation. It is therefore essential to develop a credible instrument that can reduce uncertainty for both patients and physicians.

Conclusions
In the present study, we demonstrated that the introduction of guidelines for BScc valve replacement had a positive effect on actual decision making in clinical practice. Mainly patients with outweighing fracture risks underwent BScc valve replacement, and an unknown number of unnecessary reoperations were prevented. High-quality epidemiological data prove essential to manage uncertainty for physicians and patients involved in complex medical decisions. However, guidelines should be constantly updated and publicized to warrant a meticulous decision-making process.

Acknowledgment
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References
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