Age Thresholds for Prophylactic Replacement of Björk-Shiley Convexo-concave Heart Valves

A Clinical and Economic Evaluation

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Background. Björk-Shiley convexo-concave heart valves have an increased risk of mechanical failure. One might consider prophylactic rereplacement as a preventive measure to avert the disastrous consequences of these failures. We investigated the effect that prophylactic rereplacement has on survival of individual patients and on the medical costs.

Methods and Results. Quantitative estimates for the surgical risks of prophylactic replacement of Björk-Shiley valves, long-term survival, and the risk of outlet strut fracture were derived insofar as possible from a detailed analysis of a follow-up study conducted in The Netherlands, including 2303 patients with a mean follow-up of 6.6 years. On the basis of these estimates, we calculated life expectancy with and without prophylactic replacement. For the various valve types, age thresholds were determined below which rereplacement prolongs (discounted quality-adjusted) life expectancy. We also calculated the cost per year of life gained as a function of age. The age thresholds below which prophylactic rereplacement increases life expectancy (expressed in simple future years of life) for male patients without comorbidity, if the surgical mortality after rereplacement is equivalent to that of primary replacement, are 27, 48, 51, and 65 years for small and large 60° and for small and large 70° mitral valves, respectively. For aortic valves, these age thresholds lie somewhat higher: 39, 52, 56, and 76 years, respectively. Repeat analyses indicated that for women, all age thresholds lie about 1 or 2 years higher. These age thresholds decrease considerably if the surgical mortality after rereplacement is considered to be higher after prophylactic rereplacement than after primary replacement or if comorbidity is present. The costs per discounted and quality-adjusted year of life gained depend on type and position of the Björk-Shiley convexo-concave heart valve and rise steeply as the patient's age approaches the threshold for rereplacement.

Conclusions. The results of the Dutch follow-up study allow guidance for prophylactic replacement of the Björk-Shiley convexo-concave valve on an individual basis. Rereplacement compares favorably with expectant management in some patient subgroups with both 60° and 70° valves. Age thresholds may serve as a first step in identifying patients in whom rereplacement might be beneficial. (Circulation 1993;88:156-164)

Key Words • aortic valve • mitral valve • life expectancy • cost analysis

The Björk-Shiley convexo-concave heart valve was withdrawn from the market in 1986 after repeated reports of mechanical failure. This type of heart valve had been developed in the early 1970s by Shiley Inc. as an improvement on the spherical disk valve. About 86,000 patients had received the Björk-Shiley convexo-concave (BScc) valve worldwide, about 82,000 with an opening angle of 60° and about 4000 with an opening angle of 70°. By November 1991, 466 outlet strut fractures had been reported to Shiley, which must be considered an underestimate of the true incidence.1

Recently, the results of a retrospective cohort study were reported that provided detailed information on all patients in The Netherlands with BScc valves.2 It described experience with 2588 BScc valves implanted in 2303 patients between 1979 and 1985 and followed up for a mean of 6.6 years. Information on vital status was obtained from municipality registers, and information about the cause and mode of death was obtained from the patient's general practitioner or retrieved from clinical records. The yearly risk of strut fracture appeared to be constant over time. It was demonstrated that the risk was greater for larger valves (≥29 mm), for valves with an opening angle of 70°, for valves implanted in the mitral position, and for valves of younger patients.
Prophylactic replacement of BScc valves is generally not recommended.\textsuperscript{3-5} It has been suggested only for patients with early-production 70° BScc valves with a diameter $\geq$ 29 mm (group 1 valves), which are known to be especially vulnerable.\textsuperscript{5} The findings in the Dutch follow-up study, however, show that a high risk of strut fracture is not limited to these early-production series of the 70° valves.

In the present study, we evaluate the effects of prophylactic rereplacement using prognostic information obtained from the Dutch follow-up study. For each valve type, the age of the patients is determined below which rereplacement is beneficial. We also evaluated the cost-effectiveness of rereplacement as a function of the patient's age.

**Methods**

**Structure**

The structure of the problem is represented by the decision tree shown in Figure 1. The model contains four health states (“alive with a BScc valve,” “alive without a BScc valve,” “alive with severe morbidity without a BScc valve,” and “dead”). A Markov process was applied to calculate the patient’s life expectancy.\textsuperscript{6} In a Markov process, the patient’s prognosis is represented as a sequence of particular states of health and the possible transitions among them during fixed time intervals (Markov cycle).\textsuperscript{7} The duration of the Markov cycle in the present model is 1 year. The crux of this approach is that we estimate after each subsequent year the probability that a patient is in one of the defined health states; in other words, we construct hypothetical survival curves. These survival estimates allow us now to calculate the expected lifetime a patient will spend in each of the health states. The calculations were performed with Decision Maker computer software (New England Medical Center, 1988).

**Probability Estimates**

The probability estimates required for this analysis were 1) surgical mortality and morbidity after prophylactic rereplacement, 2) age-specific annual risk of death, 3) annual risk of strut fracture, and 4) mortality and morbidity after strut fracture. When possible, these probabilities were derived from the Dutch follow-up study, including 2303 patients with a mean duration of follow-up of 6.6 years.\textsuperscript{2} We reanalyzed the data from this study using logistic regression and Poisson regression to derive prognostic models for surgical mortality, age-specific risk of death, and risk of fracture. Variable selection was performed with a forward stepwise procedure based on the significance level of the partial likelihood ratio test (limit for significance to enter, 0.10). First, we estimated the effects of prophylactic rereplacement for patients without comorbidity. Later, we explored to some extent the effect of comorbidity, such as a poor ventricular function.

**Surgical Mortality and Morbidity of Prophylactic Rereplacement**

Data about the risks associated with prophylactic replacement of artificial valves are scarce.\textsuperscript{8,9} It has been emphasized that, when estimating the risks of prophylactic rereplacement, one must take into account not only the increased hazard for death during the early postoperative period (for example, the first 30 days after surgery) but also the increased hazard during the entire first postoperative year.\textsuperscript{3} This opinion, however, is not supported by the observation that mortality after rereplacement for reasons other than an increased risk of mechanical failure seems to decline rapidly to a constant level even after 2 weeks.\textsuperscript{10} Therefore, we defined surgical mortality of rereplacement as that occurring during the first 30 days after surgery. Furthermore, we assumed it to be equivalent to the 30-day mortality after primary valve replacement.

Surgical mortality after rereplacement is then estimated with a logistic model derived from the Dutch follow-up study. Surgical mortality for a 40-year-old patient without any risk factor is 1.5% (odds, 0.015). Age (odds ratio, 1.022; 95% CI, 1.000–1.044 for each additional year), a BScc in the mitral position (odds ratio, 2.6; 95% CI, 1.6–4.1), concomitant bypass surgery during valve replacement (odds ratio, 1.5; 95% CI, 1.0–2.5), acute endocarditis (odds ratio, 2.2; 95% CI, 1.2–4.4), poor ventricular function (odds ratio, 2.9; 95% CI, 1.5–5.7), and valve replacement as emergency treatment (odds ratio, 6.3; 95% CI, 2.6–15.5) are incremen-
tal risk factors. In the Dutch cohort study, left ventricular function was classified from the right oblique view of the left ventricular angiogram as good, reduced, or poor. 2

For example, the surgical mortality of a 50-year-old male patient with a large mitral BScc valve without comorbidity can be estimated as 4.6% (odds, 0.015×1.0227×2.6).

Information on the risk of permanent morbidity after valve surgery is derived from the results of a follow-up study on neurological complications of coronary bypass surgery by Shaw and coworkers. 11 In this study, four of the 304 patients who survived surgery were considered to have severe permanent neurological disability. Thus, the risk of permanent severe morbidity is estimated to be 1.3%.

**Age-Specific Annual Risk of Death**

In general, life expectancy of patients with mechanical valves is lower than that of the general population. 10, 12 To obtain age-specific mortality rates, we carried out Poisson regression for death after primary valve replacement. Patients with strut fractures were considered censored observations. Patients who did not survive the first year were left out because of the reported higher mortality during the first postoperative year (compared with mortality during later years) after primary valve replacement (see also above). 3 The annual mortality rate for a female patient <40 years old without any risk factor is 0.0061 [annual risk of death is 1−exp(−0.0061) = 0.6%]. Age (hazard ratios for patients between 40 and 49 years old, 1.26; 95% CI, 0.66−2.44; between 50 and 59 years old, 2.16; 95% CI, 1.23−3.79; between 60 and 69 years old, 3.64; 95% CI, 2.08−6.37; and between 70 and 79 years old, 7.32; 95% CI, 3.94−13.60), concomitant bypass surgery (hazard ratio, 1.43; 95% CI, 1.14−1.84), a BScc valve in the mitral position (hazard ratio, 1.62; 95% CI, 1.26−2.08), and male sex (hazard ratio, 1.29; 95% CI, 1.00−1.67) are incremental risk factors. From this Poisson model, we approximated the age-specific annual risk of death for patients after valve replacement. This approximation is based on the assumption that mortality after the operative period depends on the attained age and the condition of the patient rather than on the time elapsed since valve replacement. The age-specific hazard rates were assumed to be constant for patients <35 years old, whereas those for patients >80 years old were estimated on the basis of exponential extrapolation. The age-specific annual risks of death are based on the condition of the patient at the time of primary valve replacement and the present age. For example, the annual risk of death for a 20-year-old male patient with a large mitral BScc valve without comorbidity is 1−exp(−0.0061×1.62×1.29) = 1.3%; for a 65-year-old female patient with a small aortic BScc valve, this risk is 1−exp(−0.0061×3.64) = 2.2%.

**Annual Risk of Outlet Strut Fracture**

The results of the Dutch follow-up study indicated that the annual risk of strut fracture is constant over time and depends on valve characteristics and age at implantation. We performed Poisson regression to estimate the effects of these characteristics on the annual risk of valve fracture (see Table 1). For example, the annual risk of strut fracture for a 20-year-old male patient with a large 60° mitral valve who was 12 years old at implantation is 1−exp(−0.0009×3.75×3.25) = 1.1% (95% CI, 0.6−2.1%); for a 65-year-old female patient with a small aortic 60° valve who was 57 years old at implantation, this risk is 1−exp(−0.0009×0.30) = 0.03% (95% CI, 0.01−0.06%).

We present the observed 8-year risk of strut fracture in Table 2 together with the predicted 8-year risk for the various valve types. The predicted probabilities were calculated with the split-quarter method. This implies that the cohort was randomly split into four groups of equal size and that a model was estimated on three of the four groups (training set). The fourth group (test set) was then used to predict the annual fracture risk. This was repeated four times so that all four groups served as a test set once. The results of this cross-validation procedure indicate that the performance of this prognostic model is adequate.

### Table 1. Poisson Regression Model of Strut Fracture of Björk-Shiley Convexo-concave Heart Valves

<table>
<thead>
<tr>
<th>Valve Type</th>
<th>Baseline Hazard (n = 0)</th>
<th>Hazard Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline hazard (&lt;40 years old and no risk factors)</strong></td>
<td>0.0009 (0.0003−0.0022)</td>
<td></td>
</tr>
<tr>
<td><strong>Hazard ratio</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age at valve implantation (years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>40−50</td>
<td>0.42 (0.017−1.05)</td>
<td></td>
</tr>
<tr>
<td>&gt;50</td>
<td>0.30 (0.015−0.59)</td>
<td></td>
</tr>
<tr>
<td>Position of BScc valve</td>
<td></td>
<td></td>
</tr>
<tr>
<td>aortic → mitral</td>
<td>3.25 (1.27−8.30)</td>
<td></td>
</tr>
<tr>
<td>Valve size</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;27 mm → &gt;29 mm</td>
<td>3.75 (1.61−8.72)</td>
<td></td>
</tr>
<tr>
<td>Opening angle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>60° → 70°</td>
<td>5.82 (3.12−10.85)</td>
<td></td>
</tr>
</tbody>
</table>

Values in parentheses are 95% CI.

* **Mortality and Morbidity After Outlet Strut Fracture**

A patient sustaining an outlet strut fracture of a mechanical valve may die immediately or after an attempted emergency valve replacement. The mortality after aortic strut fracture is high: in the Dutch cohort study, six of seven reported patients died (86%). Mortality after mitral strut fracture was lower: of the 35

### Table 2. Observed and Expected 8-Year Probabilities of Outlet Strut Fracture for the Various Björk-Shiley Convexo-concave Valve Types

<table>
<thead>
<tr>
<th>Valve Type</th>
<th>Observed 8-year probability</th>
<th>Expected 8-year probability</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mitral valves</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small 60° (n = 305)</td>
<td>0 (0.0−1.5)</td>
<td>0.9</td>
</tr>
<tr>
<td>Large 60° (n = 677)</td>
<td>4.2 (2.7−6.5)</td>
<td>3.3</td>
</tr>
<tr>
<td>Small 70° (n = 55)</td>
<td>7.2 (3.4−20.8)</td>
<td>5.8</td>
</tr>
<tr>
<td>Large 70° (n = 93)</td>
<td>17.3 (9.1−31.6)</td>
<td>19.8</td>
</tr>
<tr>
<td><strong>Aortic valves</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small 60° (n = 1241)</td>
<td>0.2 (0.0−0.8)</td>
<td>0.3</td>
</tr>
<tr>
<td>Large 60° (n = 86)</td>
<td>0 (0.0−5.1)</td>
<td>1.5</td>
</tr>
<tr>
<td>Small 70° (n = 115)</td>
<td>3.7 (1.2−11.1)</td>
<td>1.7</td>
</tr>
<tr>
<td>Large 70° (n = 16)</td>
<td>8.3 (1.2−46.1)</td>
<td>8.1</td>
</tr>
</tbody>
</table>

Values in parentheses are 95% CI.
reported patients, 18 died (51%). These mortality rates were adopted in the present analysis.

It is assumed that 50% of the survivors of an outlet strut fracture will have severe permanent morbidity. This estimate is based on an evaluation of the functional status of the Dutch patients who survived the outlet strut fracture.

Outcomes

We calculated life expectancy with and without replacement of the BScC valve. To account for the fact that most patients are risk averse (in other words, they attach more value to nearby years of life than to years of life in the distant future), we investigated the effects of discounting future life years at 5% per year13 (this implies that the value of each additional year decreases by 5%) and also the effects of adjusting for the quality of life by weighing the time spent with severe permanent morbidity from valve surgery or outlet strut fracture with a quality adjustment factor of 0.5 (each year for a patient with severe morbidity is worth half a year in full health).

We represent the direct medical costs for rereplacement and expectant management in 1990 Dutch guilders (1$ US was approximately f2). The costs of prophylactic rereplacement are estimated to be f20000 (angiography, surgery, 3 days in intensive care, and 10 days in low care). The costs of an outlet strut fracture amount to f15000 for a patient who dies after admission to hospital (surgery and 5 days intensive care). Furthermore, it is assumed that 50% of the patients who die after an outlet strut fracture die outside the hospital. The costs for patients who survive after an outlet strut fracture are f45000 (surgery for valve replacement, 5 days in intensive care, and 20 days in low care followed by surgery for removal of the fractured strut, 1 day in intensive care, and 12 days in low care). Future costs were discounted to present value at a 5% per year discount rate.

Simplifications

Our analysis was subject to the following simplifying assumptions: 1) the surgical mortality of prophylactic rereplacement is equivalent to the 30-day mortality after primary valve replacement; 2) survival of patients with an artificial valve is determined by their attained age and clinical condition and not by the time elapsed since primary valve replacement; 3) replacement of the BScC valves obviates the risk of strut fracture without affecting long-term mortality and morbidity; 4) the annual risk of strut fracture is constant over time; and 5) the possibility that any mechanical heart valve (whether of the BScC type or not) may have a finite life span, even without strut fracture, is not entered into our analysis.

We calculated the (discounted and quality-adjusted) life expectancy of patients with one BScC valve; the effects of prophylactic valve rereplacement in patients with more than one artificial valve have not been dealt with.

Results

The effects of prophylactic rereplacement on life expectancy of patients with BScC valves are first presented for a fictitious 40-year-old male patient with a 29-mm 60° mitral BScC valve and no comorbidity. According to the prognostic models presented earlier, for this patient we estimated the annual risk of strut fracture to be 1.1%, surgical mortality 3.7%, and "basal life expectancy," i.e., life expectancy if the strut fracture risk is assumed to be zero, 25.0 years. The life expectancy of this patient increases from 23.1 to 24.1 years if prophylactic rereplacement is performed. Thus, prophylactic rereplacement adds 1.0 year (or 4.3%) to the life expectancy. Expressed in terms of loss, prophylactic rereplacement gives rise to a 53% reduction of the loss in life expectancy that is attributable to outlet strut fracture (1.0 from 1.9 years).

To investigate how sensitive these results are to variations in the quantiative estimates, we varied each estimate one by one over wide ranges. Figure 2 shows the effects of these variations on the difference in life expectancy. A positive difference indicates that prophylactic rereplacement results in an extension of life expectancy. This figure demonstrates that all estimates have a substantial independent effect on this difference. Rereplacement gives a higher life expectancy in the 40-year-old patient, for example, if the surgical mortality after valve rereplacement is ≤7.7%, if basal life expectancy is ≥10.3 years, if the annual risk of strut fracture is ≥0.50%, or if mortality after strut fracture is ≥23.9%.

Figure 3 presents the effects of variations in the preferences for length and quality of life. The difference in discounted life expectancy decreases to zero if the discount rate of future years of life increases from 0% to 10%. If the quality adjustment factor decreases from one (morbidity is equivalent with full health) to zero (morbidity is equivalent with death), the advantageous effect of rereplacement increases.

In Figure 4, the age thresholds for prophylactic replacement of BScC valves are shown for patients without comorbidity. For each valve type, we calculated age thresholds, first using simple future years of life, second using discounted years of life, and third using discounted and quality-adjusted years of life. To account for the statistical uncertainty, we indicated CIs for these age thresholds using the upper and lower limits of the 95% CI of the estimated strut fracture risk. It can be read from Figure 4A that life expectancy (in simple future years of life) for male patients with a small 60° mitral valve is higher with than without prophylactic rereplacement if they are <27 years old. For male patients with a 60° large mitral BScC valve, this age threshold is 48 years. The age thresholds are considerably higher for valves with an opening angle of 70°: 51 and 65 years for small and large mitral valves, respectively. The age thresholds for aortic valves are somewhat higher than for mitral valves. They are 39 and 52 years for small and large 60° aortic valves and 56 and 76 years for small and large 70° BScC aortic valves, respectively. For female patients, all age thresholds lie 1 or 2 years higher (Figure 4B).

The effect of discounting future years of life and adjusting for the quality of life on the age thresholds is relatively small for most valve types. Only for small 60° valves in either the mitral or aortic position do the age thresholds decrease considerably when discounted future years of life are used.

The age thresholds presented so far are based on the assumption that surgical mortality for prophylactic rereplacement is the same as that after primary valve replacement. In Figure 5A, we present the age thresholds for male patients without comorbidity if 1% or 3% is added to the surgical mortality as well as to the risk of
permanent morbidity after prophylactic rereplacement. If 3% is added to these surgical risks, prophylactic rereplacement always gives a lower life expectancy for male patients with small 60° mitral valves. With this increase of 3%, the age thresholds (based on simple future years of life) decrease by approximately 5 years for the other valve types in the mitral position. For small 60° aortic valves, life expectancy with prophylactic replacement is always lower than with an expectant management. For the other valve types in the aortic position, the effect of an increase in the surgical risks is somewhat larger than for mitral valves: the age thresholds decrease by about 8 years for large 60° and small 70° valves and by 16 years for large 70° valves.

Figure 5B demonstrates the effect that a poor left ventricular function has on the age thresholds for prophylactic replacement (a poor ventricular function is an increasing risk factor for surgical mortality; odds

FIGURE 2. Graphs showing difference in life expectancy with and without prophylactic replacement as a function of the quantitative estimates for a 40-year-old male patient with a 29-mm 60° mitral Björk-Shiley convex-concave heart valve. A positive difference indicates that the life expectancy with prophylactic replacement is higher than without. Triangles indicate the estimates that were used for this particular patient.

FIGURE 3. Graphs showing difference in life expectancy with and without prophylactic replacement as a function of the yearly discount rate of future years of life and of the quality adjustment factor for permanent morbidity caused by prophylactic replacement or strut fracture. Same patient as in Figure 2.
replacement of Björk-Shiley Convexo-concave valves

Males without comorbidity

present age (years)

mitral valves

aortic valves

Females without comorbidity

present age (years)

mitral valves

aortic valves

FIGURE 4. Graphs showing age thresholds for prophylactic replacement in male (upper panel) and female (lower panel) patients. For each valve type, age thresholds are based on simple years of life, discounted years of life, and discounted and quality-adjusted years of life (from left to right). Thresholds indicate the age of the patient below which prophylactic rereplacement increases life expectancy. Vertical bars indicate confidence intervals, which were calculated using the upper and lower limits of the 95% CI of the strut fracture rates.

Discussion

Until recently, prophylactic replacement of BScc valves was recommended only for patients with large (≥29 mm) 70° BScc valves of an early production series.
Our study indicates that patients with other BScc valve types also may benefit from prophylactic rereplacement. Prophylactic replacement of BScc valves may increase the discounted and quality-adjusted life expectancy in patients without morbidity with large 60° mitral and aortic BScc valves if they are <45 years old and in patients with small 70° mitral and aortic valves if they are <50 years old. The age thresholds for prophylactic replacement are high for aortic BScc valves, considering the relatively low strut fracture risk is taken into account. The explanation for this result is the high mortality after aortic strut fracture on the one hand and the relatively low surgical risks and high life expectancy in patients with aortic valves on the other. The slightly higher age thresholds that we established for female patients are explained by the higher basal life expectancy of female patients. The cost-effectiveness of prophylactic rereplacement depends strongly on age, valve type, and valve position. This is to be expected, because these factors determine the extent of the survival advantage of valve replacement.

If the surgical risks after prophylactic rereplacement are thought to be higher than after primary replace-

ment, however, the age thresholds below which prophylactic rereplacement prolongs discounted and quality-adjusted survival decrease considerably for the large 60° and small 70° aortic valves and to a lesser extent for the large 60° mitral BScc valve. Conceivably, the age thresholds for prophylactic replacement are also significantly lower if a comorbid factor, such as a poor left ventricular function, is present. For patients with a large 70° BScc valve, however, with its high risk of strut fracture, the effect of comorbidity on age thresholds is small.

In a recent study, Birkmeyer and coworkers reported the operative risk thresholds below which replacement of a BScc valve increases life expectancy expressed in simple future years of life.17 The estimates of the fracture rate in this study were derived from Dutch and Swedish follow-up studies and from an international multi-institutional follow-up study of patients with 70° BScc valves.2,3,18 The strut fracture risks they used for the 70° mitral valve were on average about 40% lower than we used in our study, and their fracture risks for 60° aortic valves were more than twice as high as ours. Their recommendations for rereplacement agree with

**Figure 5.** Graphs showing age thresholds for prophylactic rereplacement in male patients without comorbidity (upper panel) and with a poor left ventricular function (lower panel). These figures present the age thresholds if 0% (●), 1% (■), or 3% (▲) is added to the surgical mortality and morbidity. Thus, the surgical mortality is estimated with a logistic model as a function of age and clinical risk factors (see “Methods”), and to this risk estimate, a fixed extra risk of 1% or 3% is added. For each valve type, age thresholds are based on simple years of life, discounted years of life, and discounted and quality-adjusted years of life (from left to right). A horizontal line at age 0 years indicates that no age threshold could be found.

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(group 1, 70° BScc valves).

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Males without comorbidity

![Graph showing costs per life-year gained](image)

**Figure 6.** Graphs showing costs per discounted and quality-adjusted years of life gained as a function of age for male patients with large 60° (dashed line), small 70° (dotted line), and large 70° mitral (left panel) and aortic (right panel) valves. Costs are expressed in 1990 Dutch guilders ($1 US was approximately 2 Dutch guilders).

Ours to a large extent. The operative risk thresholds they present in their study, however, are rather high, even for the 70° mitral valves. For example, according to their study, replacement of large 70° mitral BScc valves seems advantageous in patients up to 70 years of age (the operative risk thresholds are 5.3% and 6.7% for male and female patients, respectively). For patients with small 70° mitral BScc valves, rereplacement seems beneficial in patients up to 50 years of age (operative risk thresholds are 5.0% and 5.9% for male and female patients, respectively). Their results indicate that for large 70° aortic BScc valves, replacement is advantageous in even older patients (operative risk thresholds are 4.1% and 5.6% for 80-year-old male and female patients, respectively). Furthermore, this study confirms our conclusion that rereplacement of the large 60° mitral valves may be advantageous in patients without comorbidity up to 45 years old. The high operative risk thresholds for older patients in the study of Birkmeyer and coworkers can be partly explained by their assumption that the strut fracture rates are age independent, whereas the Dutch follow-up study indicated a strong decrease of the strut fracture rates with age at implantation.

In our study, we derived quantitative estimates from a detailed multivariate analysis of the Dutch follow-up study. This allowed us to develop prognostic models for valve fracture as well as for surgical mortality and life expectancy. Another reason for not using the results of studies from different countries on the strut fracture rate is some indication that the fracture rate depends on batch-related manufacturing deficiencies and that different countries have received different production series. In our view, this implies that recommendations on prophylactic rereplacement have to take into account the batch-specific strut fracture risk estimates.

When interpreting the results of the present study, one must also take into account the possibility that a number of strut fractures have remained undetected, leading to an underestimate of the risk of strut fracture as well as of mortality from strut fracture. Another element of uncertainty in this respect is the risk of strut fracture in the distant future. Our estimations of the effect of rereplacement are based on a constant fracture risk over time, which is supported by observations during the follow-up period and also by metallurgical investigations that indicated fatigue at the welding sites of the outlet strut as a possible cause of fracture. If a distinct rise or fall in the number of strut fractures is observed in the future, however, the indications for replacement of the BScc valves have to be adjusted accordingly. It is shown in our study that variations in the annual risk of strut fracture have a considerable effect on indications for prophylactic rereplacement (see Figure 2).

When considering prophylactic replacement of BScc heart valves, the patient and his or her doctor have to balance the consequences of cardiac surgery against the possibility that a strut fracture may occur at some moment in the future, with its associated high mortality. In general, most patients tend to be risk averse and consider current benefits preferable to future benefits. In other words, they consider life during the next few months more important than during later years. Therefore, we also estimated the age thresholds discounting future years of life. In addition to this attitude toward the surgical risk, a patient may wish the BScc valve to be replaced because of the fear and anxiety evoked by the possibility that the artificial valve may fail mechanically. This risk attitude is not explicitly modeled in our study. In this respect, however, it is important to note that mechanical failure is only one of the dangers that threaten patients with artificial heart valves. We demonstrated, for instance, that the life expectancy of a 40-year-old patient with a BScc mitral valve without any risk of valve fracture and without concomitant morbidity is considerably lower than the life expectancy according to the vital statistics of the general Dutch population.
(24.8 compared with 34.9 years). Finally, one has to account for postoperative morbidity, which may interfere with a patient's normal activities of daily life during at least a few months.

The results of the Dutch follow-up study allow recommendations for prophylactic replacement of the BScc valves. The age thresholds presented in this study may serve as rough guidelines for patient selection but can never substitute for definitive decision making, which should be based on an individual evaluation of the strut fracture rate (which may vary between countries), risks of surgery, life expectancy, and the patient's attitude toward the alternative options.

Acknowledgments

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