Abstract

Objective—To develop an easy-to-use tool for decision-making on prophylactic replacement of Björk-Shiley convexo-concave heart valves.

Design—Decision analysis comparing elective replacement with observation.

Setting—Referral centres for patients with artificial heart valves.

Patients—Quantitative estimates were obtained from a follow up study conducted in The Netherlands, including 2303 patients with a mean follow up of 6.6 years and from recently published studies.

Intervention—Elective valve replacement with a new artificial heart valve.

Main outcome measure—Loss of life-expectancy.

Results—A simple graph was constructed to present the loss of life-expectancy caused by strut fracture for combinations of basal life-expectancy (life-expectancy without strut fracture) and lethal fracture risk (strut fracture risk multiplied by lethality of fracture). This loss can be compared directly with the loss of life-expectancy caused by surgical mortality. This quantitative approach takes into account individual patient characteristics, such as age, gender, cardiac comorbidity, and position of the valve, but the final estimation of surgical mortality also requires clinical judgment. The calculations can be made easily by hand or with a simple computer application.

Conclusions—This decision support tool enables the direct estimation of the gain or loss of life-expectancy that is likely with replacement of a Björk-Shiley convexo-concave heart valve. It can be used to evaluate individual patients as well as groups of patients, and allows for easy incorporation of revisions of fracture risk estimates.

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Keywords: aortic valve, mitral valve, life-expectancy, decision analysis

There is a considerable risk of mechanical failure with Björk-Shiley convexo-concave (BScc) heart valves. To avert this risk prophylactic replacement of a BScc valve may be considered. We aimed to develop a simple tool to quantify the gain or loss of life-expectancy if a BScc valve were to be replaced and hence aid decision-making in individual patients. Moreover, it should help the clinician to assess the impact on various subgroups of patients of the recent and forthcoming revisions of the estimates of fracture risks.

BScc heart valves were withdrawn from the market in 1986 after reports of mechanical failure (outlet strut fracture). Estimates of the risk of fracture were reported in several studies. The largest of these is a follow up study of 2588 BScc valves implanted in 2303 patients. This study calculated the risk of strut fracture on the basis of valve characteristics (site of implantation, size of the valve, opening angle) and the patient’s age at implantation. Recent revisions of the fracture risk estimates include production characteristics such as weld date and remilling status, thus distinguishing a large number of subgroups of BScc valves. The welder of the valve is also regarded as a risk factor for strut fracture, and the most recent estimates for 60° valves incorporate this characteristic.

Two decision analyses have quantitatively compared the risk of strut fracture that accumulates over time if the valve is not replaced with the risk of elective surgical prophylactic replacement. These decision analyses presented surgical risk thresholds or age thresholds below which elective replacement increases the life-expectancy. The published presentation of these analyses does not allow the clinician to calculate the expected number of years gained or lost by replacement in individual patients with specific risk profiles. Moreover, both analyses used risk estimates that differ from recent estimates, both for fracture risk and surgical risk of reoperation. We aimed to overcome these drawbacks with a flexible and easily applicable decision support tool. This tool quantifies the benefit of elective replacement as compared with no replacement, taking into account individual fracture risk estimates, the patient’s age, gender, position of the valve (aortic/mitral), and cardiac comorbidity.

Methods

To calculate the loss of life-expectancy caused by valve replacement and the loss caused by strut fracture we used a Markov model. We assumed that the fracture risk is constant over time: this accords with published figures.
We assumed that the life-expectancy of those surviving the perioperative period is identical to the life-expectancy of a patient with a BScc valve without any fracture risk. This assumes that the replacement valve has the same haemodynamic characteristics as the BScc valve and that the surgical procedure has no adverse effects on the myocardium or other determinants of long-term survival.

The loss of life-expectancy was calculated relative to the basal life-expectancy, which is the life-expectancy of a patient with a mechanical heart valve that is similar to a BScc valve, but has no risk of strut fracture. The loss of life-expectancy caused by replacement is by definition equal to the elective surgical mortality. The loss of life-expectancy caused by strut fracture depends on the combination of the yearly fracture risk and the lethality of fracture. Moreover, the loss of life-expectancy caused by the fracture decreases with decreasing basal life-expectancy, because the annual risk of a lethal fracture is relatively less important if the basal life-expectancy is low. We calculated the loss of life-expectancy caused by fracture as a function of basal life-expectancy and of the lethal fracture risk (yearly fracture risk multiplied by lethality of fracture). This approach is based on the simplification that the loss is independent of the specific combination of fracture risk and lethality. For example, a lethal fracture risk of 1% a year is present in a valve with a fracture risk of 2% and a lethality of 50% or in a valve with a fracture risk of 1% and a lethality of 100%. Further, estimated life-expectancy can be 25 years both for a 40 year old man with a BScc mitral valve and no comorbidity and for a 48 year old man with a BScc aortic valve and no comorbidity. To evaluate the effect of these simplifications, we varied the combinations of fracture risk, lethality, and basal life-expectancy and we found that the differences in life-expectancy were always very small (< 0·1 year).

QUANTIFICATION

The presented estimates of basal life-expectancy and lethality of fracture were obtained from a large follow up study conducted in the Netherlands. This study included 2303 patients with a mean follow up of 6·6 years. Basal life-expectancy was dependent on age, gender, position of the valve, and concomitant bypass surgery. The lethality of strut fracture was found to be 86% (six out of seven died, 95% confidence interval 47% to 99%) and 51% (18 out of 35 died, 95% confidence interval 34% to 69%) for aortic and mitral valves respectively.

Recently published revised estimates of fracture risk include production characteristics such as weld date (five periods for 60° aortic valves and six periods for 60° mitral valves), welder (group A, B, or C for 60° valves), and remilling status (for 70° valves). Other valve characteristics are site of implantation (aortic/mitral), size, and opening angle (60°/70°).

Table 1 shows these recent risk estimates for the 49 aortic valve subgroups and 56 mitral valve subgroups.

The estimates of elective surgical mortality in the case of replacement were based on a recent analysis of 2246 prosthetic valve reoperations in 1984 patients. Twelve risk factors were used in a logistic regression function as influencing the surgical mortality of reoperation. Only age, weight, New York Heart Association (NYHA) functional class, and number of previous operations are relevant for most BScc patients, assuming that the other risk factors are absent.

Table 1  Fracture risk estimates (%/year) for BScc valves according to position, opening angle, and size. Estimates for 60° valves were further subdivided by weld date and welder (group A/B/C, if available). Estimates for 70° valves were subdivided by remilling status.

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*Hypothetical patient (see text).*
Results
A graph (figure) forms the central element of the decision support tool. It shows the loss of life-expectancy caused by fracture in relation to basal life-expectancy and lethal fracture risk. This loss can be compared directly with the surgical mortality of elective replacement. We illustrate the practical use of the tool with a hypothetical 40 year old male patient without comorbidity, who is being considered for elective replacement of a mitral BScc valve, opening angle 60⁰, size 29 mm.

Basal life-expectancy can be read from table 2. This 40 year old man with a mitral BScc valve has a life-expectancy of 25-0 years. Next, we calculate the loss of life-expectancy caused by replacement—that is, surgical mortality. Table 2 shows estimates of the surgical mortality according to combinations of age, number of previous operations, NYHA class, and weight (60 kg is regarded as an average weight for female patients and 80 kg for male patients). For the fictitious 40 year old male patient we assume a weight of 80 kg, NYHA class I, and one previous open heart operation and estimate surgical mortality as 0.9%.

The loss of life-expectancy caused by fracture is calculated in four steps. First, the yearly fracture risk has to be estimated, for example from table 1.¹ The mitral valve of our fictitious patient with an opening angle of 60⁰, size 29 mm, if produced in December 1981 by a welder from group B, has an estimated annual fracture risk of 0.35% (table 1). Second, the lethality of fracture has to be estimated. The mean lethality in the Dutch follow up study was 51% for mitral valves. Third, the annual lethal fracture risk is calculated by multiplying...
the fracture risk and the lethality of fracture: $0.35 \times 51\% = 0.18\%$ per year. Finally, we use the graph (figure) to determine the loss of life-expectancy caused by fracture. Our hypothetical patient with a basal life-expectancy of 25 years and a lethal fracture risk of 0.18% per year, has an estimated loss of around 2.7%.

Comparison of the loss of life-expectancy (2.7%) caused by fracture with the surgical mortality (0.9%) reveals that replacement of this particular BScc valve would improve life-expectancy in this patient. The magnitude of this difference in years is calculated by multiplying the relative losses and the basal life-expectancy. The expected number of years lost owing to surgery is 0.9% $\times 25 = 0.23$ year, while the loss caused by strut fracture would be $2.7\% \times 25 = 0.68$ year. The advantage of surgery is relatively small: $0.68 - 0.23 = 0.45$ year.

The graph can be used to evaluate one patient at a time. To evaluate groups of patients, we derived formulas (presented in the Appendix) that can be easily applied by using a computer. For example, we used a spreadsheet program to assess the consequences of revisions of fracture risk for the BScc patients in our centre. We evaluated the patients by using their actual age, gender, and sex-specific weight, but we optimistically assumed that no comorbidity was present. Subsequently, we performed a more detailed and individualised examination of those patients for whom there was a calculated benefit of replacement.

**Discussion**

We present an easy-to-use tool to estimate the life-expectancy of replacement or of observation for patients with a BScc valve. This tool presents the output of a previously developed decision analysis model in such a way that newly available fracture risk estimates and surgical risk estimates can be easily included in decision-making in individual patients as well as in groups of patients.

Selection of candidates for replacement can be based on the estimated risk of fracture, with a closer examination of patients with valves associated with a relatively high risk. The impact of a certain fracture risk, however, depends on individual patient characteristics, especially age, because a higher age both increases surgical risk and diminishes life-expectancy. For example, Blackstone and Kirklin considered two hypothetical female patients of 38 and 67 years old, without comorbidity, with a fracture risk of 2% in a BScc mitral valve, and a lethality of fracture of 50%. Their analysis indicated that the advantage of surgery in the 67 old patient was minimal, and that the advantage in the 38 year old patient was somewhat larger. Our decision tool confirms these findings qualitatively, but indicates that the magnitude of the advantage of replacement in the 38 year old female patient (assuming NYHA class 1, first reoperation, 60 kg) is as large as 4-5 years, which strongly supports replacement. We propose that the selection of patients for replacement should use this expected benefit as the starting point. This benefit can easily be calculated with our decision tool, either by hand (figure) or by computer (formulas in Appendix).

There can be considerable uncertainty about the true values of estimates required for decision-making in patients with BScc valves. The advantage of our tool is that the impact of variations in estimates can be explored directly. If, for example, the estimated fracture risk is varied to the extremes of a wide but plausible range, the corresponding to these extremes is directly available. Uncertainty in the estimates of fracture risks is caused firstly by underreporting, which leads to a systematic bias both in the reported fracture risks and the lethality of fracture. Underreporting may be a particular problem in aortic BScc valves, because patients who have a strut fracture usually die within two hours, without distinct symptoms of mechanical failure. Secondly, the estimates of strut fracture risks are uncertain because of the limited number of fractures available for multivariate statistical analysis. Estimates of surgical mortality were taken from a large recently published series, but may vary because of centre-specific circumstances or the presence of risk factors not considered in the model. The predicted mortalities in table 2 are probably rather optimistic for generalisation to all surgeons in all centres with less experience in valve replacement. Clinical judgment may therefore be required for the final estimation of surgical mortality. In addition, estimates of basal life-expectancy may be lower than the figures in table 2, for example because of the presence of risk factors that have not been considered. Further, the lethality of fracture may vary because of the patient’s age, clinical condition, feasibility of urgent surgery, and training and facilities for urgent surgery. The effect of these uncertainties can be quantified directly by our method.

This analysis did not consider decision-making in patients undergoing bypass surgery or in patients with aortic as well as mitral BScc valves, because no reliable data on basal life-expectancy and surgical mortality were available for these types of patients. The approach is, however, identical to the approach followed in patients who are considered for elective replacement of one BScc valve, without concomitant bypass surgery. Again the surgical risk has to be weighed against the cumulative risk of fracture. In patients undergoing bypass surgery, surgical mortality refers to the additional risk of valve surgery compared with bypass surgery alone, and basal life-expectancy refers to the life-expectancy after successful bypass surgery. In patients with two BScc valves, surgical mortality associated with replacement of the aortic, the mitral, or both valves has to be weighed against the cumulative risk of fracture of the aortic, the mitral, or both valves respectively.

Decision-making in patients with BScc valves is difficult because the risks of strut fracture are relatively low, whereas replacement...
requires a major operation. If the reoperation itself has a negative impact on long-term survival, for example by causing myocardial damage, this may easily outweigh small advantages in life-expectancy obtained by replacement of a BSSc valve. In the future, the choice between prophylactic surgery and observation may be extended by the option to screen patients for defects in mitral BSSc valves." Selection of patients for such radiographic screening might be helped by use of our tool to assess the impact on life-expectancy of a certain fracture risk. Besides life-expectancy, other aspects may be considered in the decision-making process. For example, there may be neurological deficits after reoperation (on average 1-1% in a recent analysis, which correlated with the estimated surgical risk\(^\text{16}\)). Such permanent morbidity may, however, also persist after strut fracture. Also, time-preference may play a role. Most patients are risk averse and attach more value to nearby years than to years in the distant future. This implies that replacement, which causes a short term risk, would be less attractive. Finally, the patient's personal preferences will influence decision-making. In this context, we expect that our tool can serve as a first step in the decision-making process by supplying information about the expected benefit or harm of prophylactic replacement.

**Appendix: formulas**

For the computerised calculation of the loss of life-expectancy with surgery or observation we derived the following formulas.

(1) Basal life-expectancy was calculated with the Markov model for male and female patients with mitral or aortic valves who were not undergoing bypass surgery. We varied the patient's age from 25 to 90 years, in 5 year steps (Decision Maker software, version 7.0, New England Medical Centre, 1988). Linear regression analysis was subsequently used to estimate the basal life-expectancy for aortic and mitral valve patients separately and as a function of age and gender (SPSSPC+ statistical package, version 5.0.1). The regression models explained a very high proportion of the variance (\(r^2 > 0.99\), which indicated that the formulas closely describe the original estimates of the basal life-expectancy as calculated with the Markov model.

(2) Surgical mortality was estimated with the logistic regression formula given by Pihler et al.,\(^\text{12}\) who also presented data to estimate the confidence intervals around the estimated surgical mortality.

(3) The loss of life-expectancy caused by fracture (see figure) was calculated for patients without comorbidity, aged between 25 and 90 years (steps of 5 years), with average mortality for male and female patients and average lethality of fracture (75%). Linear regression analysis was used to estimate the loss caused by strut fracture as a function of the combination of the lethal fracture risk and basal life-expectancy. The regression model explained over 99% of the variance, indicating that the formula closely describes the curves in the figure.

(4) Finally, the life-expectancies associated with surgery and with observation were calculated, using the first three estimates. A spreadsheet program is available from the authors (e-mail: steyerberg@ckb.fgg.eur.nl). It includes the formulas presented below.

(1) Basal life-expectancy aortic valve patients = 66 - 66 - 1 - 0.66 × Age + 10.252 × Age2yr + 5.31 × Female - 0.0409 × Female × Age

(2) Surgical mortality risk = \(e^\text{0.04} / [1 + e^\text{0.04}]\), where PI = \(-6.444 + 0.5741 \times NYHA + 0.5647 \times Hsdstate + 0.6427 \times Age2yr + 0.5270 \times InvWgtKg + 0.3090 \times Renal + 0.5088 \times Double + 0.6647 \times TVincmp + 1.1512 \times PVE + 0.3331 \times OpenNumb + 1.4985 \times AAA + 1.9928 \times LVA + 0.6005 \times CABB\)^\text{0.04}.

(3) Fracture-caused loss of LE = \(-0.5134 \times \text{LEbasal} \times \text{LethFrac} + 0.1991 \times \text{LEbasal} \times \text{Sqrt(LethFrac)} - 0.959 \times 10^{-3} \times \text{LEbasal} \times \text{LethFract} + 5.69 \times 10^{-3} \times \text{LEbasal} \times \text{Sqrt(LethFrac)}\).

(4) LEsurgery = LEbasal \times (1 - Surgical mortality risk).

LEobservation = LEbasal \times (100 - % fracture caused loss of LE)/100

Advantage of surgery = LEsurgery - LEobservation.

In these formulas, Age is expressed in years; Age2yr is patient's age (years)/50; Female is 1 if female, 0 if male; NYHA is NYHA class in numerical terms (I through V); Hsdstate is haemodynamic state (0 = stable, 1 = unstable, 4 = cardiogenic shock); InvWgtKg is patient's weight (kg); Renal is 1 in the case of chronic renal failure or creatinine > 2.5 mg/dl, 0 if not; Double is 1 in the case where there is multiple valve disease, 0 where there is not; TVincmp is 1 where there is present or previous tricuspid valve incompetence requiring intervention, 0 where there is not; PVE is 1 where there is active prosthetic valve endocarditis, 0 where there is not; OpenNumb is number of previous open heart operations (1 for first reoperation); AAA is 1 if there is repair of aneurysm of the ascending aorta, 0 where there is not; LVA is 1 where there is resection of a left ventricular aneurysm, 0 where there is not; CABB is 1 in the case of coronary artery bypass grafting\(^\text{12}\); LEbasal is expressed in years; LethFract is the lethality of fracture (0.51 for mitral valves and 0.86 for aortic valves) multiplied by the annual strut fracture risk, expressed as a percentage.