Prosthetic Valve Type for Patients Undergoing Aortic Valve Replacement: A Decision Analysis

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Background. In two large, randomized, clinical trials long-term survival after aortic valve replacement (AVR) was similar for patients receiving tissue and mechanical aortic heart valve prostheses. Higher bleeding rates among patients with mechanical valves, who must receive permanent oral anticoagulation to prevent thromboembolism, were offset by higher reoperation rates for valve degeneration among patients with tissue valves. Because the average age of patients undergoing AVR and clinical practices have changed considerably since the randomized clinical trials were conducted, we performed a decision analysis to reassess the optimal valve type for patients undergoing AVR.

Methods. We used a Markov state-transition model to simulate the occurrence of valve-related events and life expectancy for patients undergoing AVR. Probabilities of clinical events and mortality were derived from the randomized clinical trials and large follow-up studies.

Results. Although the two valve types were associated with similar life expectancy in 60-year-old patients (mean age of patients in the randomized clinical trials), tissue valves were associated with greater life expectancy than mechanical valves (10.7 versus 11.1 years) in 70-year-old patients (currently mean age of AVR patients). For 70-year-old patients, the effects of major bleeding complications (24%) with mechanical valves substantially outweighed those of reoperation for valve failure (12%) with tissue valves at 12 years. Of the clinical practice changes assessed, the recommended valve type was most sensitive to changes in bleeding rates with anticoagulation. However, bleeding rates would have to be 68% lower than those reported in the European randomized clinical trial to affect the recommended valve type for 70-year-old patients. Reoperation rates would have to be five times higher, and mortality rates at reoperation would have to be four times higher to affect the recommended valve type for 70-year-old patients.

Conclusions. Although mechanical valves are preferred for AVR patients less than 60 years old, most patients currently undergoing AVR are elderly and would benefit more from tissue valves.

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The choice between mechanical and tissue prosthetic valves for patients undergoing aortic valve replacement (AVR) involves careful consideration of the risks and benefits of each type of prosthesis. Although mechanical prostheses have excellent durability, they require life-long anticoagulation therapy to minimize risks of thrombosis and embolism. Anticoagulation is associated with increased risks of bleeding. Although tissue valves do not require anticoagulation, they degenerate over time, necessitating reoperation for valve replacement. Two large, randomized clinical trials, each initiated in the 1970s, compared the outcomes of patients receiving each valve type [1, 2]. In these trials, higher bleeding rates observed among patients receiving mechanical valve prostheses were offset by higher rates of reoperation for prosthetic valve failure among patients receiving tissue valves, resulting in equivalent survival rates for patients receiving each valve type.

Since these studies were conducted, changes in the characteristics of patients undergoing AVR have taken place that may affect the relative risks and benefits of tissue and mechanical valves. With the declining incidence of rheumatic valve disease, AVR is now performed primarily for degenerative valve disease in increasingly older patients [3–5]. In elderly patients, mechanical valves may be less favorable because risks of anticoagulation-related bleeding increase with age [6–15]. In addition, tissue valve failure, which typically occurs 10 to 15 years after valve implantation, may be of lesser concern for older patients who have lower valve failure rates and shorter life expectancies [16].

Several important changes in clinical practices since the randomized clinical studies were conducted may also impact the relative risks and benefits of the valve types.
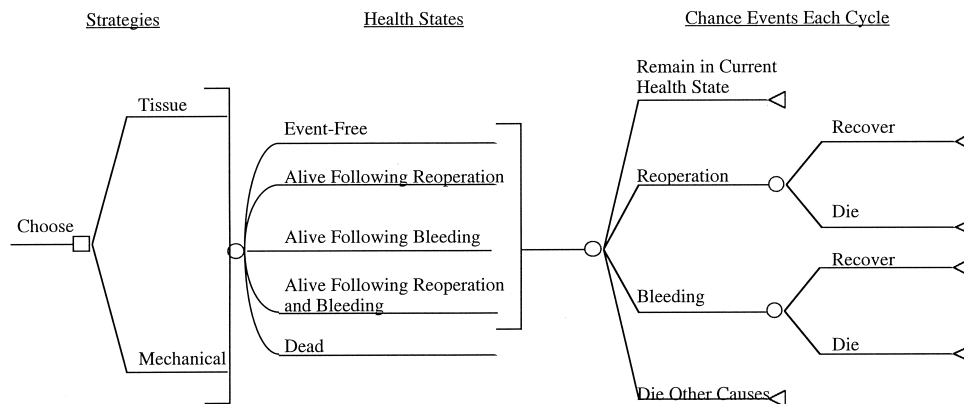
Fig 1. Schematic of decision model structure. All patients are initially in the event-free state. With each 1-year cycle of the model, they can move to a different state or remain in the same state according to chance events specified under "Chance Events Each Cycle." (Event-Free = alive without reoperation or major bleeding; Alive Following Reoperation = alive following reoperation for prosthetic valve failure; Alive Following Bleeding = alive following a major (requiring hospitalization or blood transfusion) bleeding event; Dead = dead from any cause.)

Following recommendations for lower intensity oral anticoagulation, made possible by the standardization of measurement and dosing with the international normalized ratio, and the use of specialized clinics to monitor anticoagulation, would result in decreased bleeding risks associated with mechanical valves [17]. Changes have also taken place that may improve the performance of tissue valves. Newer generation tissue valves, including porcine valves treated with agents to retard calcification and homografts made available through heart transplantation, may have improved durability compared to older types of tissue valve prostheses [18]. In addition, risks of mortality with AVR have declined [19], as have risks of mortality with cardiac surgery in general [20–22].

In this study, we used a Markov state-transition model to assess the effects of increasing age and changes in clinical practices on the choice between tissue and mechanical valves for patients undergoing AVR.

Material and Methods

Decision Analysis

Decision analysis is a quantitative method for synthesizing data from numerous sources to evaluate treatment alternatives [23]. All decision analyses involve the following steps: the alternative therapeutic strategies and potential outcomes are specified in a decision model, the probability that each outcome will occur is estimated using the best available data, and the model is analyzed to calculate the expected value of each treatment alternative.

Markov Model

In this study, we used a Markov state-transition model to simulate the occurrence of valve-related events and to estimate life expectancy (LE) for patients undergoing aortic valve replacement (Fig 1). This type of decision model is used for analyzing clinical problems involving risks that change or that can occur repeatedly over time [23, 24]. With this type of model, a large hypothetical

cohort of patients is followed over time. With each cycle of the model, the cohort is redistributed among specified health states according to transition probabilities that are estimated from the medical literature. The model continues to run until all of the members of the cohort have died or reached the "dead" health state. Life expectancy is then calculated for each therapeutic strategy as the sum of the average cycles spent in living health states.

Our Markov model structure is depicted graphically in Figure 1. The model consists of two treatment strategies: AVR with a tissue valve prosthesis or AVR with a mechanical valve prosthesis. All patients are initially in the Event-Free state after AVR with one of the two prothesis types. With each cycle (equivalent to 1 year in our model) of the model patients redistribute among the given health states according to transition probabilities specified under "Chance Events Each Cycle." Thus, with every cycle patients could remain in their current health state or could experience: bleeding (which may or may not be fatal), valve failure followed by reoperation (which may or may not be fatal), or death from other causes. The model continues to run until all of the hypothetical cohort patients died. All of these analyses were performed using DATA (TreeAge Software, Inc, Williamstown, MA), a decision analysis software program.

Assumptions

We incorporated several important simplifying assumptions into the model for this decision analysis. First, we only explicitly modeled events that have been proven to differ in incidence by valve type. Events that were associated with valve replacement but did not differ by valve type in the randomized clinical trials and other studies (perioperative mortality with primary AVR, prosthetic valve endocarditis, and thromboembolism [1, 2, 25–27]) were not explicitly modeled, but were captured in the valve-related excess mortality rates described below. Thus, our model estimates LE for survivors of primary aortic valve replacement who have no other indication (eg, atrial fibrillation) or contraindication (eg, women of

Table 1. Model Input Variables

Parameter	Parameter Calculation	Data Source
Overall mortality		
General population mortality rates	Age- and sex-specific rates	U.S. Vital Statistics [31]
Excess mortality rates in survivors of AVR (exclusive of bleeding and reoperation)	Constant (1.4%/year)	Long-term relative survival studies of AVR patients in Sweden [33] and Norway [32]
Risks related to valve failure		
Tissue valve failure rate	Weibull function (decreasing with patient age but increasing with time since valve implantation)	Long-term follow-up study of 2785 AVR patients from two centers [16]
Mechanical valve failure rate	Constant (0.4%/year)	Clinical trials of 211 [1] and 394 [2] AVR patients randomized to receive either tissue or mechanical valves
Mortality at reoperation	Logistic regression model (increasing with patient age)	Population-based study of 2570 consecutive AVR patients in Northern New England (1992-7) [19, 34]
Risks related to bleeding		
Mechanical valve bleeding rate	Exponential function (increasing with patient age and INR)	Prospective cohort study of major bleeding events among 13,326 patients on oral anticoagulant therapy in the Netherlands [15]
Tissue valve bleeding rate	Exponential function (increasing with patient age)	[2, 15, 33]
Mortality with bleeding	Exponential function (increasing with patient age)	Clinical trial of 1100 artrial fibrillation patients randomized to receive either aspirin or warfarin for stroke prophylaxis [6]

childbearing age) to anticoagulation. Our model assumes that patients with mechanical valves who experience major bleeding will continue to receive oral anticoagulation therapy because studies have shown that risks of thromboembolism in patients with mechanical valves who are not anticoagulated exceed the risks of recurrent bleeding in those that are [28–30]. Finally, we made the simplifying assumption that patients undergoing reoperation for valve failure receive mechanical valves at reoperation. In this way, our analysis focuses on the implications of the initial valve decision, not subsequent decisions. Using a more complex, Monte Carlo simulation model, we tested the effect of this assumption. Because the results of this analysis were essentially identical to those of our baseline analysis, they are not reported here.

Model Input Variables
All model input variables and the sources of this information are described in Table 1. Where applicable, specific formulas for calculating model parameters are given in the Appendix.

Overall and Valve-Related Excess Mortality
Population-based age- and sex-specific mortality rates were derived from actuarial tables [31]. Survivors of primary heart valve replacement have shorter life expectancy than the general population, largely because of coexisting coronary heart disease [32, 33]. To account for

this, excess mortality rates (1.4% per year) were added to population-based mortality rates (specific for age and sex, US vital statistics data) in the model.

Risks Related to Valve Failure
Risks of tissue valve failure increase over time and are accelerated in younger patients. We modeled tissue valve failure based on a study that fit several parametric models to actuarial tissue valve failure curves and determined that the Weibull model provided the best fit to the data [16]. In this model the cumulative hazard of tissue valve failure is a function of patient age at valve implantation and the number of years since valve implantation. The instantaneous risk of tissue valve failure is equal to the first derivative of the cumulative hazard. Mechanical valves have a constant, low rate of failure [1, 2].

Risk of perioperative mortality with reoperation was estimated using a multivariate logistic regression model based on primary data from the Northern New England Cardiovascular Disease prospective heart valve registry [19, 34]. This model is based on data from all patients (n = 2,542) undergoing AVR between 1989 and 1996 in Maine, New Hampshire, or Vermont. Risks of mortality increase with patient age (relative risk, 3.4% per year) and for patients undergoing reoperation (relative risk, 2.2). Because published mortality rates with reoperation for valve failure vary, we tested the effects of both higher and lower mortality with reoperation in sensitivity analyses.
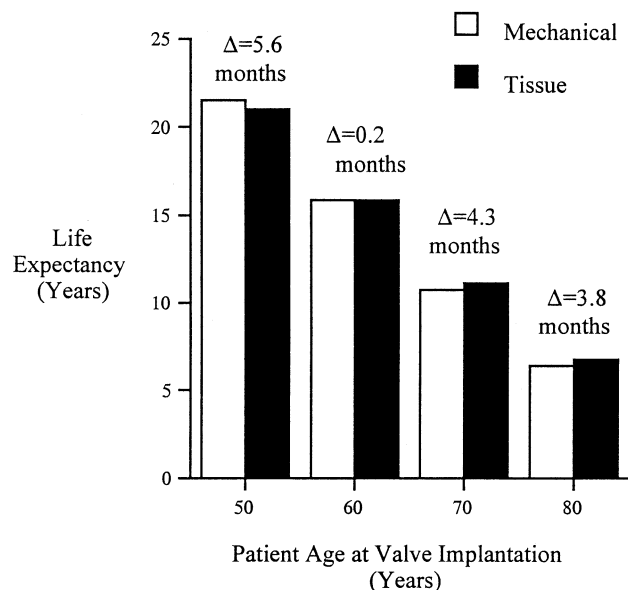
Fig 2. Life expectancy by age and valve type. Δ is the difference between tissue and mechanical valves in life expectancy.

Risks Related to Bleeding

In our model, major bleeding was defined as bleeding requiring hospitalization or blood transfusion. Risks of major bleeding were modeled by fitting exponential functions to age-stratified results from a large study that analyzed risk factors for bleeding complications in oral anticoagulant therapy [15]. Patients with tissue valves have bleeding rates similar to the population at large with risks increasing with patient age [1, 2]. The probability that major bleeding resulted in death was modeled by fitting an exponential function to age-stratified data from a trial comparing rates of bleeding during antithrombotic therapy with either warfarin or aspirin in patients with atrial fibrillation (see Appendix for formulas) [6].

Sensitivity Analyses

To test the stability of our results to variation in the estimates of particular model parameters (rates of anticoagulant-related bleeding, tissue valve failure, and perioperative mortality with reoperation for valve failure), we performed two–way sensitivity analyses. In these analyses, we assess the effects of patient age while varying the other parameter over a reasonable range to determine its affect on valve recommendations. Because most of these model parameters are functions of age or other factors, we applied variable relative risks to these functions in sensitivity analysis.

Results

In Figure 2, we compare LE with each valve type for patients of different ages. Mechanical valves were favored for 50-year-old patients (21.4 versus 21.0 years LE) (Fig 1). Tissue valves were favored for 60 (15.8 versus 15.9

Table 2. Mortality, Reoperation, and Bleeding Rates at 12 Years, by Patient Age at Valve Implantation

Finding	Patient Age (years) at Valve Implantation			
	50	60	70	80
Mortality				
Mechanical (%)	27	42	63	91
Tissue (%)	28	41	61	90
Reoperation				
Mechanical (%)	6	6	4	1
Tissue (%)	32	21	12	3
Major bleeding episode				
Mechanical (%)	16	21	24	22
Tissue (%)	4	5	6	5
Mortality, reoperation, or major bleeding episode				
Mechanical (%)	43	58	75	94
Tissue (%)	57	59	71	92

years LE), 70 (10.7 versus 11.1 years LE), and 80-year-old patients (6.4 versus 6.7 years LE).

To compare our results to those of the randomized clinical trials we assessed mortality, reoperation, and bleeding rates at 12 years (Table 2). Similar to the randomized clinical trials, we found little difference in mortality between the valve types for 60-year-old patients. Higher bleeding rates among patients with mechanical valves (21%) were offset by higher rates of reoperation for valve failure among patients with tissue valves (21%). However, for 70-year-old patients, bleeding rates among patients with mechanical valves (24%) substantially outweighed rates of reoperation for valve failure among patients with tissue valves (12%).

We simultaneously tested the effects of patient age and changes in clinical practices using two-way sensitivity analyses (Figs 3 to 5). The recommended valve choice was not sensitive to the effects of changes in clinical practices within the ranges tested for 70-year-old patients. Bleeding rates would have to be 68% lower than those reported in the Edinburg Heart Valve Trial to favor the use of mechanical valves for 70-year-old patients. Reoperation and mortality with reoperation rates for patients with tissue valves would have to be five and four times higher, respectively, than those reported in the randomized clinical trials to favor the use of mechanical valves in 70-year-old patients. For younger patients, particularly those 60 years or younger, the recommended valve type is sensitive to the value of these variables.

Comment

The primary goal of this study was to explore the effects of prosthesis choice on LE for patients undergoing AVR. The optimal valve prosthesis depends heavily on patient age, reflecting the time-dependent nature of trade-offs between mechanical and tissue valves. Although mechanical valves are associated with greater LE in younger
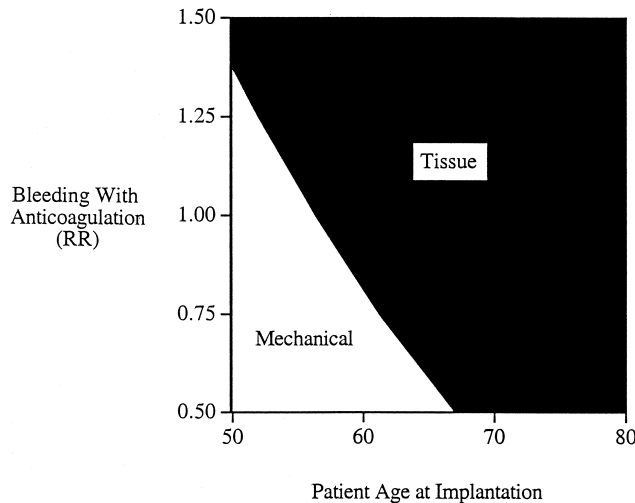
Fig 3. Two-way sensitivity analysis of the effects of anticoagulant-related bleeding and patient age at implantation on the recommended valve type. (RR = relative risk where RR = 1 is the baseline estimate; RR = 1.5 is 50% higher than the baseline estimate, and RR = 0.5 is 50% lower than the baseline estimate.)
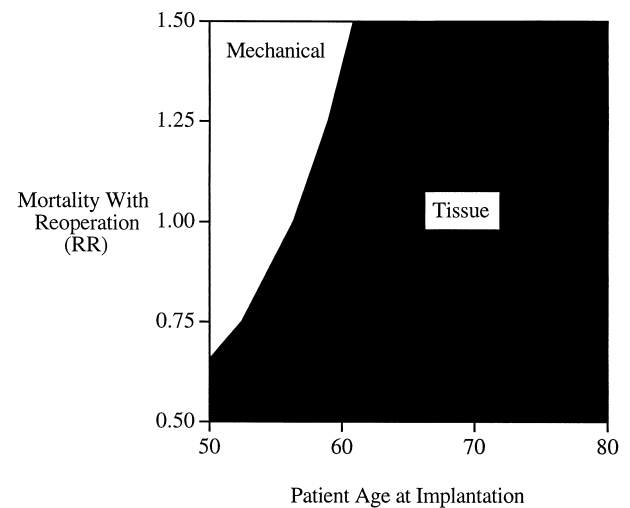

Fig 5. Two-way sensitivity analysis of the effects of mortality with reoperation and patient age at implantation on the recommended valve type. (RR = relative risk where RR = 1 is the baseline estimate, RR = 1.5 is 50% higher than the baseline estimate, and RR = 0.5 is 50% lower than the baseline estimate.)

patients, tissue valves confer greater benefit for the majority of patients undergoing AVR who are 60 years of age and older. These conclusions were generally robust when we tested the effects of different variables and assumptions of the model in sensitivity analysis.

There are two randomized [1, 2] and three nonrandomized studies [25–27] that compared survival and valve-related events among patients receiving tissue and mechanical valve prostheses. The basic recommendations derived from both the randomized and nonrandomized studies were the same with similar rates of mortality and valve-related events among AVR patients with mechanical and tissue valves. We believe that by avoiding bias
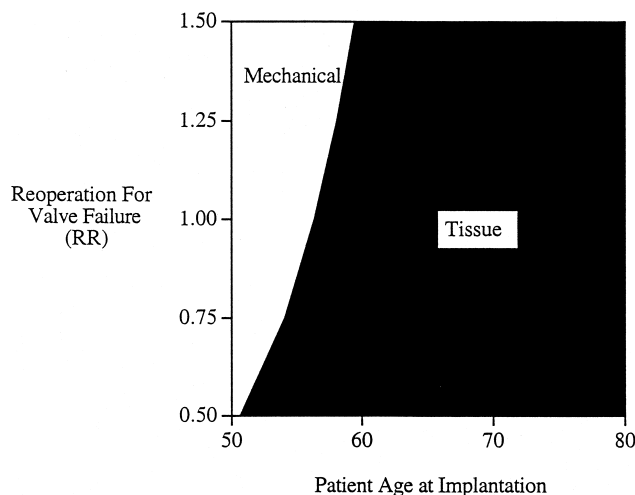

Fig 4. Two-way sensitivity analysis of the effects of reoperation for tissue valve failure and patient age at implantation on the recommended valve type. (RR = relative risk where RR = 1 is the baseline estimate, RR = 1.5 is 50% higher than the baseline estimate, and RR = 0.5 is 50% lower than the baseline estimate.)

and confounding inherent in nonrandomized studies, the randomized clinical trials represent the best evidence to date regarding the relative risks and benefits of tissue and mechanical valves. However, bleeding rates among both mechanical and tissue valve recipients were much higher in the United States than in the European randomized clinical trial. This is likely due to a relatively intense anticoagulation regimen and the frequent use of anticoagulation among patients with tissue valves in the US study. Because the anticoagulation regimen in the European study more closely resembles current recommendations, we used the bleeding rates from that study in our model. Estimates of age-specific bleeding and reoperation rates derived from more recent studies were used to refine baseline estimates to account for the effects of patient age on valve-related events.

One of the prior nonrandomized studies focused on effects of patient comorbidity of the choice of valve prosthesis for patients undergoing AVR [27]. This study found that patients with renal disease (preoperative creatinine, >2 mg/dL), chronic pulmonary disease in patients over the age of 60 years, coronary artery disease (>75% occlusion of a coronary artery), or impaired ventricular function (ejection fraction, <40%), have less than 10 years LE and should receive tissue valves. Freedom from reoperation at 10 years exceeded 95% for each of these groups.

In contrast to the recommendations from our decision analysis, the majority of patients undergoing AVR receive mechanical valves, including elderly patients. According to the 1988 National Health Interview Survey, approximately two-thirds of US patients received mechanical valves [35]. In the United Kingdom, mechanical valve usage increased from 54% to 70% from 1986 to 1989 [36]. The results of a 1985 survey by valve manufacturers indicate that worldwide, 69% of valves implanted are

mechanical and 31% are tissue [37]. Mechanical valve usage is lowest in the southern hemisphere (57%) and highest in Europe (78%).

In considering the discordance between our results and current practices, it is important to review several limitations of our analysis. Estimates of valve-related events used in our model are based largely on the two randomized clinical trials of patients undergoing AVR in the 1970s. Although changes in patient age and clinical practices since that time have likely affected rates of valve-related events, through sensitivity analysis we have shown that these changes have only modest effects on age-specific recommendations for valve type.

Another limitation of our analysis is its use of LE as its primary outcome measure. Patient preferences and quality of life issues may also be important in clinical decisions about valve prosthesis. Anticoagulation with warfarin requires frequent office visits and phlebotomies for monitoring as well as activity and dietary restrictions. The potential for valve-related events (bleeding and reoperation) may cause substantial anxiety among patients and serious morbidity when they occur. We decided not to incorporate these factors into our model for a number of reasons. First, patient preferences regarding many of these clinical outcomes are known to vary widely. For example, a study of the effect of stroke and stroke prophylaxis on quality of life found wide variability in patients' value for life after a moderate stroke (mean utility, 0.39; 10th to 90th percentile, 0 to 0.99) and for life with warfarin therapy (mean utility, 0.987; 10th to 90th percentile, 0.95 to 1.0). Second, although there are published sources for some of the utilities that we would need to incorporate patient preferences in our model including patient utilities for anticoagulation and different types of stroke, estimates for other important variables including reoperation for valve failure are lacking. Third, under circumstances such as this where treatment alternatives differ with regard to the timing of risks of morbidity and mortality (delayed until the time of valve failure for tissue valves) patient attitudes toward risk should also be accounted for [38]. For these reasons, we decided not to include patient preferences in our model and instead suggest that patient preferences be considered on an individual basis, particularly for patients for whom the valve types would be expected to offer equivalent life expectancy.

We believe that the common use of mechanical valves in elderly patients may reflect problems in clinical decision making. In particular, clinicians may underestimate bleeding risks of anticoagulation and overestimate LE and risk of tissue valve failure in elderly patients. In addition, clinicians may not incorporate patient preferences about chronic anticoagulation and potential clinical outcomes into the choice of heart valve prosthesis. On the basis of our findings and the current demographic profile of patients with aortic valve disease, we believe that more patients undergoing AVR should be receiving tissue valves.

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Appendix

Valve Failure Risks

The probability of tissue valve failure is modeled as a Weibull function in which the cumulative hazard of tissue valve failure is equal to: $RISK \times years^{3.48}$, where $RISK = \exp(-9.92 - 0.358 \times age)$, $age = $ (patient age $-$ 60)/10, and $years = $ the number of years since valve implantation. The instantaneous risk of tissue valve failure is equal to the first derivative of the cumulative hazard: $(3.48 \times RISK \times years^{2.48})$ [16].

Reoperation Risks

The probability of death with reoperation is modeled as a multivariate logistic regression equation: $odds/1 + odds$, where $odds = e^{-4.94 + (age \times 0.033) + (reoperation \times 0.7725)}$, where $age = $ patient age at reoperation and $reoperation = 1$ [19, 34].

Bleeding Risks

The probability of bleeding is modeled as an exponential function $0.014 \times 10^{(0.033 \times age)}$ for patients with mechanical valves and $0.004 \times 10^{(0.033 \times age)}$ for patients with tissue valves, where $age = $ patient age [15], The probability that major bleeding results in death is also modeled as an exponential function $2.29 \times 10^{(0.015 \times age)}$, where $age = $ patient age [6].