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The Risks and Benefits of Reoperative Aortic Valve Replacement

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ABSTRACT

Background: Many patients are advised to have mechanical aortic valve replacement (AVR) because their expected longevity exceeds that of tissue prostheses. This strategy may avoid the risks of reoperation but exposes patients to the risks of long-term anticoagulation therapy. Which risk is greater?

Methods: We reviewed the records of 1213 consecutive, unselected AVR patients, 60% of whom had concomitant procedures, who were treated from 1994 through 2002. Of these patients, 887 were first-time AVR patients, and 326 underwent reoperation. Of the reoperation patients, 134 had previously undergone AVR (redo). We constructed a risk model from these 1213 cases to assess the factors that predicted mortality and to examine the extent to which reoperation affected outcome.

Results: Multiple logistic regression analysis indicated that factors of reoperation and redo operation did not predict mortality. In fact, the mortality rate was 4.1% for all first AVR operations and 3.1% for all reoperation AVR ($P = .891$). Significant predicting factors (with odds ratios) were reoperative dialysis (6.03), preoperative shock (3.68), New York Heart Association class IV (2.20), female sex (1.76), age (1.61), and cardiopulmonary bypass time (1.26).

Conclusions: In this series, the risk of reoperation AVR is comparable with the published risks of long-term warfarin sodium (Coumadin) administration after mechanical AVR. Any adult who requires AVR may be well advised to consider tissue prostheses.

INTRODUCTION

Surgeons and cardiologists have generally recommended tissue aortic valve replacement (AVR) for patients older than 65 to 70 years and for those who have shorter life expectancies [Rahimtoola 2003]. This strategy reduces exposure to the rigors of warfarin sodium (Coumadin) administration in those patients unlikely to require reoperation. The reverse of the same logic has led surgeons and cardiologists to recommend mechanical valves to younger patients. The results of the 15-year randomized controlled trial of Hammermeister and coworkers that were finally reported in 2000 supported these ideas by demonstrating significantly better survival, particularly for younger aortic valve patients who received mechanical aortic valves [Grover 1990, Hammermeister 1993, 2000]. This study also found that most causes of morbidity, including thromboembolism, in the 2 groups were the same except for the higher bleeding rate in the mechanical valve group and the higher reoperation rate in the tissue group.

Twenty years ago, we began practice with the null hypothesis that, in general, the risks of each approach were similar enough, if not equivalent, for us to encourage patients to select the valve that best fit with their notion of a full life. We believed, for example, that one 50-year-old patient might find the idea of a second operation frightening enough to embrace the burdens of taking warfarin sodium, whereas another patient might prefer a decade of maintenance-free service followed by reoperation. This approach requires a lengthy discussion with the patient and family well in advance of the operation and excludes those patients with specific issues that direct us to recommend one valve type over another. It also requires that the mortality risks of each approach are comparable. In this report, we examine the effect of a previous median sternotomy on the outcome of a subsequent AVR in our hands.

MATERIALS AND METHODS

Patients

From 1994 through 2002, we implanted 1023 tissue valves, 169 mechanical valves, and 21 other valves in consecutive, unselected AVR patients. This series included all AVR patients, regardless of concomitant procedures performed. Of these procedures, 887 were first-time operations, and 326 were reoperations for any prior cardiac surgery (ReOP). Of the ReOP patients, 134 had previously undergone AVR (ReAVR) (Table 1); the other 192 patients had previously undergone a median sternotomy in some other cardiac operation. Trained personnel collected data for operations performed since 1994 according to the Society of Thoracic Surgeons national database protocol and definitions.

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Table 1. Prosthesis Type by Operative Incidence*

	Bioprosthesis, n	Mechanical, n	Other, n	Total, n
All AVRs	1023 (84%)	169 (14%)	21 (2%)	1213
First operation	785 (89%)	93 (10%)	9 (1%)	887
ReOP	238 (73%)	76 (23%)	12 (4%)	326
Previous AVR	75 (56%)	48 (36%)	11 (8%)	134
Previous other ReOP	163 (84%)	28 (15%)	1 (1%)	192

*AVR indicates aortic valve replacement; ReOP, reoperation for any prior cardiac surgery.

Surgical Techniques

We performed all reoperations through the previous sternotomy. Beginning in 1997, we began performing some first-time AVR operations with the ministernotomy approach. Three hundred eighteen patients in this study were so treated. We never actively cool the patient during cardiopulmonary bypass, and the lowest temperature rarely goes below 34.5°C. We routinely use cold retrograde cardioplegia.

Table 2. Patient Characteristics*

		Reoperation	
	First Operation (n = 887)	ReAVR (n = 134)	Other ReOp (n = 192)
Average age, y	71.1	64.1	71.8
Female sex	43.1%	29.9%	31.3%
Renal failure	7.3%	13.4%	13.0%
Stroke	7.7%	10.4%	10.9%
Diabetes	19.3%	13.4%	29.2%
Peripheral vascular disease	16.9%	14.9%	34.4%
Chronic obstructive pulmonary disease	18.0%	19.4%	18.2%
New York Heart Association class			
I	5.5%	3.7%	1.0%
II	27.8%	18.7%	12.5%
III	38.9%	43.3%	42.2%
IV	27.7%	34.3%	44.3%
Congestive heart failure	75.2%	82.1%	81.8%
Angina	29.9%	45.5%	50.0%
Myocardial infarction	4.7%	2.2%	8.9%
Hypertension	63.1%	46.3%	66.7%
Endocarditis			
Active	1.4%	7.5%	1.0%
Treated	2.0%	16.4%	1.0%
No. of diseased vessels			
None	55.8%	63.4%	30.7%
Single	14.2%	14.9%	2.6%
Double	11.7%	8.2%	7.8%
Triple	18.3%	13.4%	58.9%
Ejection fraction	51.6%	50.0%	44.0%
No. of prior cardiac operations			
1	—	73.9%	76.0%
2	—	20.1%	17.7%
3	—	5.2%	5.2%
4	—	0.7%	1.0%

*ReAVR indicates reoperation for previous aortic valve replacement; ReOP, reoperation for any prior cardiac surgery.

Statistical Methods

The reoperative and operative characteristics were presented as percentages for discrete variables and as mean values for continuous variables. Logistic regression was used to estimate the effect of risk factors on early mortality, which was defined as hospital mortality or 30-day mortality, whichever was longer. The C statistic (area under the receiver operating characteristic curve) was used to measure model discrimination [Grunkemeier 2001]. The Hosmer-Lemeshow goodness-of-fit test was used to measure model calibration [Hosmer 1980]. The risk-adjusted cumulative sum (Cusum) technique was used to assess the cumulative observed-minus-expected mortality for first-time AVR and ReOP [Grunkemeier 2003]. Expected mortality was produced by a logistic regression model based on our data. The Cusum line fluctuates randomly around the horizontal zero line if the observed mortality is equal to the expected. Excursions above the horizontal zero line indicate more deaths than predicted by the model, and excursions below the line indicate fewer deaths than predicted. Statistical analysis was done with SPSS 10.0 (SPSS, Chicago, IL, USA) and S-Plus 2000 (Insightful Corporation, Seattle, WA, USA) software packages.

RESULTS

Table 2 shows the patient characteristics of the studied population. Approximately 26% of the ReAVR patients and 24% of the other ReOP patients had undergone more than 1 previous sternotomy. Table 3 lists the concomitant procedures. In contrast to some studies [Peterstein 1999, Carrier 2001, Sidhu 2001, Akins 2002], we did not exclude any AVR patients, even if they had concomitant mitral valve or ascending aorta procedures. The incidence of concomitant coronary

Table 3. Operative Characteristics*

		Reoperation	
	First Operation (n = 887)	ReAVR (n = 134)	Other ReOP (n = 192)
Status			
Elective	69.9%	57.5%	54.2%
Urgent	28.3%	39.6%	44.3%
Emergent	1.6%	3.0%	1.6%
Concomitant procedures			
CABG	36.2%	25.4%	47.9%
MVV	3.0%	3.0%	3.1%
MVR	9.4%	23.1%	17.2%
Tricuspid procedure	1.1%	8.2%	5.2%
Cardiopulmonary bypass time, min	85	102	97
Clamp time, min	67	82	76

*ReAVR indicates reoperation for previous aortic valve replacement; ReOP, reoperation for any prior cardiac surgery; CABG, coronary artery bypass graft; MVV, mitral valve repair; MVR, mitral valve replacement.

Table 4. Operative Results*

	First Operation (n = 887)	Reoperation ReAVR (n = 134)	Reoperation Other ReOP (n = 192)
Operative death	4.1%	3.0%	3.2%
Cerebrovascular accident	4.7%	2.2%	5.2%
Transient ischemic attack	5.4%	3.0%	4.2%
Myocardial infarction	0.5%	0.0%	0.0%
Prolonged ventilation	11.9%	13.4%	18.2%
Reexploration for bleeding	4.6%	6.0%	4.7%
Pneumonia	4.4%	5.2%	5.7%
Complete heart block	7.7%	9.7%	9.9%
Gastrointestinal complications	1.6%	3.0%	2.1%
Renal failure	3.4%	4.5%	8.3%
Deep sternal infection	0.1%	0.0%	0.0%
Postoperative length of stay, d	8.4	8.6	10.4

*ReAVR indicates reoperation for previous aortic valve replacement; ReOP, reoperation for any prior cardiac surgery.

bypass was highest in those other ReOP patients who had not undergone a previous AVR (Table 3). This finding was likely because this group was much older and the previous operation was a coronary bypass (Table 2). Thus, more of these patients now required additional grafting as well as an AVR.

The highest incidence (58.9%) of triple-vessel disease occurred in the oldest group (Table 2), but surprisingly, these patients' operative mortality rate was not higher despite higher percentages of prolonged ventilation, renal failure, and longer length of stay (vide infra).

Tables 3 and 4 summarize operative characteristics and results. Operative death occurred in 4.1% of all first-time AVR patients and in 3.1% of all ReAVR patients (P = .89). Patients who underwent isolated ReAVR had the lowest absolute mortality rate, 1.8% (n = 55), probably because the average age of these patients was approximately 10 years younger than the average ages of the other groups. Naturally, overall mortality rises with age, but the risks of first operation and reoperation were commensurate in all age groups (Figure 1).

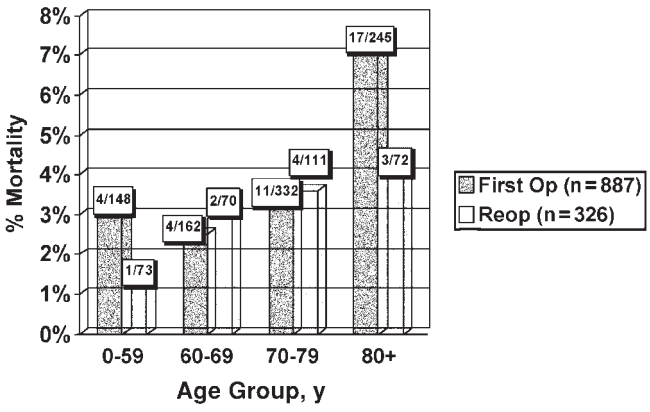

Figure 1. Mortality by age in both the first (First Op) and subsequent operations (Reop).

Table 5. Multiple Logistic Regression Risk Factors*

Risk Factor	P	Odds Ratio (95% CI)
Preoperative dialysis	.002	6.03 (1.91-19.1)
Preoperative cardiogenic shock	.006	3.68 (1.46-9.24)
New York Heart Association class IV	.020	2.20 (1.13-4.29)
Female sex	.075	1.76 (0.94-3.30)
Age (10 y)	.001	1.61 (1.15-2.25)
Cardiopulmonary bypass time (30 min)	.001	1.26 (1.10-1.44)
ReOP	NS	
ReAVR	NS	

*CI indicates confidence interval; ReOP, reoperation for any prior cardiac surgery; ReAVR, reoperation for previous aortic valve replacement.

By multivariate logistic regression analysis, we found that preoperative dialysis, preoperative cardiogenic shock, New York Heart Association class IV, female sex, perfusion time, and age were independent risk factors for early mortality (Table 5). A concomitant valve procedure, whether in the mitral position or in any position other than the aortic, was not a statistically significant risk factor in the model (P = .15). The model showed good discrimination (C statistic, 0.806) and good calibration (Hosmer-Lemeshow statistic, 0.420). Neither ReOP (P = .26) nor ReAVR (P = .90) was a significant risk factor.

For both first-time operation and ReOP patients, the Cusum lines hover around the horizontal zero line and within the pointwise 95% confidence limit lines (Figure 2), meaning that the observed mortality is not significantly different than the expected for both groups.

COMMENT

For the past 20 years, our profession has debated how best to treat surgical aortic valve disease, especially in younger patients. The 1998 paper of Akins et al thoroughly delineated the controversy, and these workers reported the lowest mortality rate, 7.8%, for ReAVR to that date [Akins 1998]. Our population demographics and risks are remarkably similar to these results, but we do not treat double-valve replacement as a separate category. We report lower mortality rates of 3.4% for ReOP and 3.1% for ReAVR. Our lower mortality rate is likely the result of a more current series of operations performed by 2 surgeons using identical operative strategies. In another important contribution, Akins summarized the results of mechanical AVR reported for several large series and found a composite linearized rate of major anticoagulation therapy complications that averaged 0.7% to 2.5% [Akins 1995]. We believe that the risks of reoperation and long-term anticoagulation treatment considered over a 10-year horizon are sufficiently close that we ask patients who require AVR to choose the risks they prefer to endure. In fact, both risks are moving targets. Butchart et al have shown that better anticoagulation strategies will reduce bleeding complications [Butchart 2002], newer tissue prostheses will provide better durability [David 2001, Kon 2002, Oxenham 2003], and as we have seen, surgical outcomes will improve. Although the randomized trial of

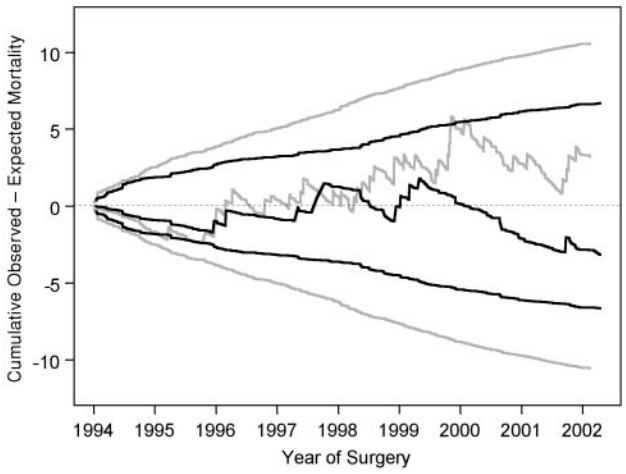

Figure 2. Risk-adjusted cumulative sum plots of operative mortality for reoperation in patients with any prior cardiac surgery patients (gray lines) and patients with first-time operations (black lines). The jagged lines are the risk-adjusted cumulative sums of the observed mortality minus the expected mortality based on a logistic regression model using the study data. Excursions above the dashed horizontal line indicate excess deaths relative to expected, and excursions below the horizontal line indicate lives saved. The smooth lines are the pointwise 95% confidence limits.

Hammermeister et al is an impressive achievement, these workers never reported operative mortality from reoperation, and most of the prostheses described in this study are no longer used. In fact, these workers' graphs comparing mortality at 15 years in the bioprosthetic AVR group versus the mechanical AVR group show precisely the statistically significant but clinically small differences that encourage us to involve our patients in the decision.

Twenty-year results from the other important randomized comparison of mechanical and tissue valves, the Edinburgh trial, recently became available [Taylor 2003]. From these data alone, the investigators recommend mechanical valves for AVR patients with a life expectancy of more than 10 years. However, the accompanying editorial interprets the presented data in the context of the currently evolving demographics of AVR patients and concludes that the "pendulum of preference for mechanical valves" may be swinging toward a neutral position and "may swing even further."

In the next decade this debate may change substantially. Better prostheses will emerge as will better drugs for anticoagulation therapy. Until our armamentarium changes, we will continue to inform patients diligently and ask them to choose which risks and benefits they prefer. Our study has no information about patients who had a previous operation but died without being referred for ReAVR, and it presents no new information about the risks of long-term anticoagulation therapy. However, it does show that the risks of AVR are largely a function of the patient's physiologic state at the time of operation, and that reoperation per se has no statistically significant effect. From the literature, we conclude that the risks of long-term anticoagulation therapy are roughly comparable with the risks of ReAVR reported here. We believe our results justify a policy of offering all patients the choice of a tissue or mechanical AVR with a thorough explanation of the risks and benefits of each.

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