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Very Long-Term Survival Implications of Heart Valve Replacement With Tissue Versus Mechanical Prostheses in Adults <60 Years of Age

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Background—Several centers favor replacing a diseased native heart valve with a tissue rather than a mechanical prosthesis, even in younger adult patients. However, long-term data supporting this approach are lacking. We examined the survival implications of selecting a tissue versus a mechanical prosthesis at initial left-heart valve replacement in a cohort of adults <60 years of age who were followed for over 20 years.

Methods and Results—Comorbid and procedural data were available from 6554 patients who underwent valve replacement at our institution over the last 35 years. Of these, 1512 patients contributed follow-up data beyond 20 years, of whom 567 were adults <60 years of age at first left-heart valve operation (mean survivor follow-up, 24.0±3.1 years). Late outcomes were examined with Cox regression. Valve reoperation, often for prostheses that are no longer commercially available, occurred in 89% and 84% of patients by 20 years after tissue aortic and mitral valve replacement, respectively, and was associated with a mortality of 4.3%. There was no survival difference between patients implanted with a tissue versus a mechanical prosthesis at initial aortic valve replacement (hazard ratio 0.95; 95% CI: 0.7, 1.3; $P=0.7$). For mitral valve replacement patients, long-term survival was poorer than after aortic valve replacement (hazard ratio 1.4; 95% CI: 1.1, 1.8; $P=0.003$), but again no detrimental effect was associated with use of a tissue versus a mechanical prosthesis (hazard ratio 0.9; 95% CI 0.5, 1.4; $P=0.5$).

Conclusions—In our experience, selecting a tissue prosthesis at initial operation in younger adults does not negatively impact survival into the third decade of follow-up, despite the risk of reoperation. (*Circulation*. 2007;116[*suppl I*]:I-294–I-300.)

Key Words: aortic valve ■ mitral valve ■ surgery ■ survival ■ valves

Only 2 large randomized control studies have documented survival and valve-related complications associated with the use of tissue versus mechanical prostheses for aortic and mitral valve replacement.^{1–4} These studies have helped define the current recommendations for the selection of prosthesis type according to patient age.⁵ These 2 studies, however, did not focus on specific age groups, had a considerable proportion of redo-thoracotomy/sternotomy patients at initial valve implantation (with implications for subsequent reoperation), and reported perioperative mortalities at initial operation and at reoperation that were high (in excess of 14%)⁴ by modern standards,⁶ thus potentially biasing against use of a tissue prosthesis.

Published data indicate that strong consideration should be given to choosing a tissue over a mechanical prosthesis in patients over 60 years of age,^{7,8} but the issue remains largely unsettled in patients under 60 years of age.^{9,10} In this regard, data with sufficient follow-up duration to adequately capture tissue prosthesis reoperations and long-term mortality in

younger patients have been lacking and, in our opinion, are necessary to compare the presumably more evenly distributed hazard of having a mechanical prosthesis against the later phase hazard of surgically replacing a tissue prosthesis. Since the 1980s, our institution has had a liberal policy of using tissue prostheses in younger patients undergoing valve replacement. This, in combination with the existence of a dedicated follow-up valve clinic, allowed for a comparison of very long-term outcomes to take place, which constitutes the focus of the present study.

Methods

Patient Population and Follow-Up

Between 1969 and 2004, 6554 patients underwent heart valve replacement at the University of Ottawa Heart Institute. This study examines a cohort of adult patients who were 60 years or less of age at the time of first time aortic valve replacement (AVR), mitral valve replacement (MVR), or combined aortic and mitral (“double”) valve replacement (DVR), who survived the operation, who were prospec-

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tively followed in a dedicated valve clinic, and who contributed 20-year follow-up information.

Prosthesis type and model selection at initial operation was not randomized and was individualized for each patient according to 1 or several of the following: prosthesis availability and past performance, patient preferences and lifestyle, child-bearing potential, anticipated long-term survival, perceived patient compliance, and urgency of operation. Valve prostheses were implanted and oriented according to the manufacturer's instructions. Their type and size were recorded for all patients.

Postoperatively, patients were given annual appointments to our valve clinic, where they underwent a medical history focused on the determination of functional status and the occurrence of valve-related complications, physical examination, ECG, chest radiograph, complete blood count, serum chemistries, and international normalized ratio determinations (when applicable). Missing information, when applicable, was completed with the patient's primary physician, the patient him/herself, or the patient's family. Prosthesis-related complications were recorded according to the "Guidelines for Reporting Morbidity and Mortality after Cardiac Valvular Operations".¹¹ Patients for whom anticoagulation treatment was indicated were managed as previously described.¹² The methods of the valve clinic were reviewed and approved by the Research Ethics Board of the University of Ottawa Heart Institute.

Twenty-year follow-up information was provided by patients who were followed for 20 years or more after their initial valve replacement at our institution, and by patients who died during follow-up before the 20-year mark. Twenty-year follow-up data were available on 1512 patients, of whom 567 were adults <60 years of age at the time of their initial left-heart valve replacement. The mean follow-up of this cohort's survivors was 24.0±3.1 years (maximum 35.0 years) after surgery. In patients who died before the 20-year mark, the mean time to death was 9.9±7.4 years. The mean follow-up of the entire cohort of 567 patients, including early and late deaths, was 13.4±9.0 years. Up-to-date survival information was available and analyzed for all patients.

Statistical Analyses

Data were imported and analyzed in Stata 9.2. Preoperative characteristics were compared with a Student *t* test or Fisher exact *t* test as appropriate.

Failure time (time to event) analysis was used to examine the main outcomes in this study. Potential outcome predictors were initially tested for equality with a log-rank test. For multivariate models, an assumption of proportional hazards was tested by examining the parallelity of $-\ln(-\ln[\text{time to event}])$ versus $\ln(\text{analysis time})$ curves for each category of nominal or ordinal covariates, and by using generalized Cox-Snell residuals. If the assumption was met, Cox proportional hazards models were developed by incorporating into each model (1) variables that had $P < 0.05$ on log-rank testing, (2) preoperative characteristics that differed between the groups as outlined in Table 1, (3) year of initial valve replacement surgery, and (4) previously identified risk factors for decreased survival after AVR¹³ and MVR¹⁴—namely, age, atrial fibrillation, preoperative heart failure functional class, the presence of left ventricular dysfunction, and coronary artery disease—regardless of their probability value on log-rank testing. Preoperative renal function, diabetes, and essential hypertension were not adequately captured during the earlier portion of the study and consequently were not entered as covariates in the analyses. No automated model selection procedure was used and all covariates that met any 1 of the above 4 conditions were simultaneously incorporated into the models. Models that were not statistically significant were not used.

Proportional hazards models were subjected to 1000 bootstrap replications, as described previously.¹³ The 95% CI and probability value of reported hazard ratios (HR) were derived from the 1000 replications, by using a bias-corrected method.

The authors had full access to the data and take responsibility for their integrity. All authors have read and agree to the manuscript as written.

Results

Patient Characteristics and Prostheses

The study's 567 patients included 314 patients who had AVR alone, 214 who had MVR alone, and 39 who had DVR as their initial valve replacement operation. Within implant sites, there was no significant difference in preoperative characteristics between patients who received tissue versus mechanical prostheses, except for differences in (1) age, which was older in patients who had tissue versus mechanical DVR and (2) left ventricular dysfunction, which was more

TABLE 1. Preoperative Patient Characteristics

	AVR (n=314)		MVR (n=214)		DVR (n=39)	
	Tissue (n=170)	Mechanical (n=144)	Tissue (n=121)	Mechanical (n=93)	Tissue (n=15)	Mechanical (n=24)
Age	47.6±10.3	48.2±9.4	48.9±8.2	48.2±9.2	52.2±7.2‡	44.7±9.9‡
Female gender	38 (22.4%)	38 (26.4%)	80 (66.1%)	53 (57.0%)	13 (86.7%)	14 (58.3%)
NYHA class						
I	61 (35.9%)	54 (37.5%)	19 (15.7%)	14 (15.1%)	5 (33.3%)	5 (20.8%)
II	56 (32.9%)	51 (35.4%)	33 (27.3%)	13 (14.0%)	3 (20.0%)	2 (8.3%)
III	40 (23.5%)	26 (18.1%)	52 (43.0%)	46 (49.5%)	6 (40.0%)	12 (50.0%)
IV	13 (7.7%)	13 (9.0%)	17 (14.1%)	20 (21.5%)	1 (6.7%)	5 (20.8%)
LV dysfunction*	53 (31.2%)§	26 (18.1%)§	35 (28.9%)	35 (37.6%)	6 (40.0%)	9 (40.0%)
Coronary artery disease	30 (17.7%)	25 (17.4%)	14 (11.6%)	13 (14.0%)	2 (13.3%)	1 (4.2%)
Atrial fibrillation	19 (11.2%)	10 (6.9%)	42 (34.7%)	38 (40.9%)	6 (40.0%)	7 (29.2%)
Operative indication for insufficiency †	53 (31.2%)	45 (31.3%)	57 (47.1%)	38 (40.9%)	10 (66.7%)	13 (54.2%)

Continuous data presented as mean±SD; categorical data presented as No. (%).

*LV dysfunction=ejection fraction <50%.

†Insufficiency 3+ or more.

‡ $P=0.01$, double valve tissue vs double valve mechanical.

§ $P=0.008$, aortic tissue vs aortic mechanical.

NYHA indicates New York Heart Association Functional Class; LV, left ventricular.

TABLE 2. Prostheses Implanted at the Initial Valve Replacement Operation

	AVR (n=314)		MVR (n=214)		DVR (n=39)	
	Tissue (n=170)	Mechanical (n=144)	Tissue (n=121)	Mechanical (n=93)	Tissue (n=15)	Mechanical (n=24)
Bjork-Shiley		2		1		1
Carbomedics*		5		7		
Carpentier Edwards*	2		1			
Harken		67		40		9
Homograft*	8					
Ionescu-Shiley	136		86		13	
Lillehei Kaster		31		8		3
Medtronic Hall*		22		22		9
Medtronic Hancock*	24		34		2	
Starr Edwards				1		
St. Jude Medical*		17		14		2

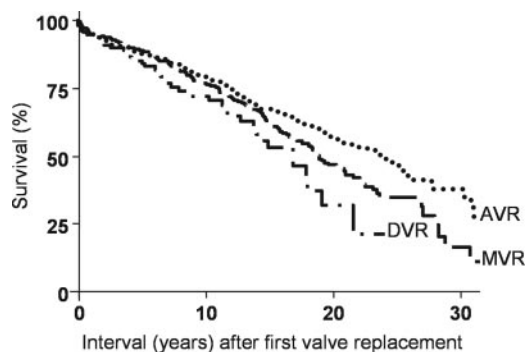
*Denotes prostheses that are still commercially available

prevalent in AVR patients who received a tissue versus a mechanical prosthesis (Table 1). Table 2 shows the types of prostheses implanted.

Long-Term Survival

Between Implant Sites

Figure 1 displays the long-term survival of AVR, MVR, and DVR patients. Survival was significantly lower in DVR versus AVR or MVR patients, both in an unadjusted fashion (data not shown), and after adjustment for age, atrial fibrillation, preoperative heart failure functional class, the presence of left ventricular dysfunction, coronary artery disease, and year of surgery (adjusted HR: 1.8; 95% CI: 1.3, 2.4; $P=0.001$). Similarly, the survival of MVR patients was lower than AVR patients, both in an unadjusted fashion and after multivariate adjustment (adjusted HR: 1.4; 95% CI: 1.1, 1.8; $P=0.003$).



Number of cohort patients at beginning of each interval				
AVR	314	192	117	10
MVR	214	127	68	5
DVR	39	18	6	-

Figure 1. Survival after AVR, MVR, or DVR in a cohort of 567 adult patients <60 years of age at the time of first heart valve replacement and who contributed 20-year follow-up information, as described in the Methods section. Survival in DVR patients was significantly worse than MVR or AVR patients, and survival of MVR patients was worse than AVR patients.

Within AVR Patients

Figure 2 (top) displays the survival of adults under age 60 at first AVR, according to the type of prosthesis that they received at their first valve operation. Twenty-year and 25-year survival were $65.5\pm 3.2\%$ and $51.7\pm 4.8\%$, respectively, in AVR patients initially implanted with a tissue prosthesis, and $52.3\pm 4.4\%$ and $41.2\pm 5.2\%$, in those with a mechanical prosthesis. The independent risk factors for mortality were age, coronary disease, atrial fibrillation, and earlier year of surgery (Table 3). The choice of a tissue versus a mechanical prosthesis was not associated with a significant difference in survival. These analyses were repeated and restricted only to patients implanted with currently available prostheses as denoted on Table 2, and the choice of a tissue versus a mechanical prosthesis again did not influence survival. Similar analyses restricted to patients <50 years of age at initial AVR were also performed and did not show a significant difference in survival (HR: 0.8, initial AVR tissue versus mechanical in adults <50 years old; 95% CI: 0.5, 1.2; $P=0.3$).

Within MVR Patients

Figure 2 (middle) displays the survival of adults less than age 60 at first MVR, according to their initial type of prosthesis. Twenty-year and 25-year survival were $51.4\pm 4.4\%$ and $33.8\pm 5.3\%$, respectively, in patients implanted with a tissue prosthesis, and $43.2\pm 5.7\%$ and $40.8\pm 5.9\%$ in those with a mechanical prosthesis. The risk factors for mortality are depicted on Table 4. As for AVR patients, the choice of a tissue versus a mechanical prosthesis in MVR patients was not associated with a significant difference in survival, and this again did not differ when the analysis was restricted to currently available prostheses. Similar analyses restricted only to patients who were <50 years of age at initial MVR also did not show a significant difference in survival (HR 0.9 after initial MVR tissue versus mechanical in adults <50 years old; 95% CI: 0.5, 1.4; $P=0.5$).

Within DVR Patients

The bottom graph on Figure 2 displays the survival of adults under age 60 at first DVR, according to prosthesis type. In the

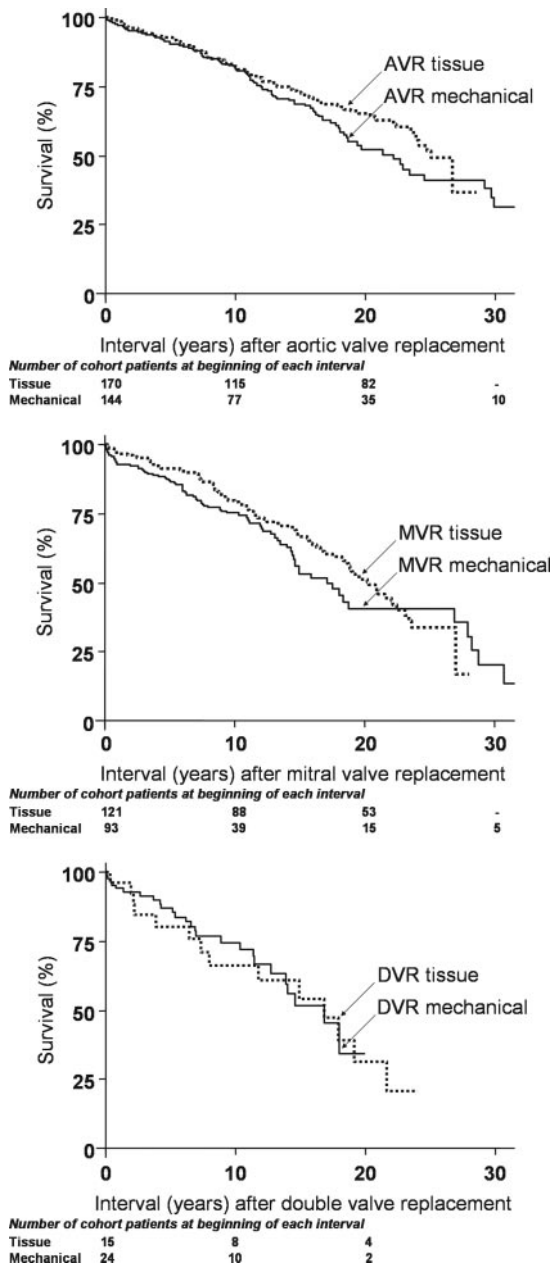


Figure 2. Crude survival after first AVR, MVR, or DVR, according to the type of prosthesis used at initial valve replacement. There was no significant difference between tissue and mechanical prostheses in any of the implant positions, and after adjustment for potential confounders (see Results section).

multivariate model (not tabulated), the survival of DVR patients was not significantly different between those implanted with tissue versus mechanical prostheses (HR: 0.9, tissue versus mechanical DVR; 95% CI: 0.4, 2.0; $P=0.8$). The limited number of DVR patients did not allow for further comparisons between subgroups of DVR patients.

Modes of Death

Reoperation

There were 277 valve reoperations in the study cohort during the follow-up period: 198 patients underwent reoperation once, 33 twice, 3 patients had 3 reoperations, and 1 patient

had 4 reoperations. As expected, frequent crossovers occurred between tissue and mechanical prostheses at reoperation, as well as occurrences of other native left-heart valve pathology requiring valve replacement. These are outlined in Table 5. Ten reoperations were performed in the setting of acute infective endocarditis.

Within AVR patients, the 20-year actuarial freedom from valve reoperation was $11.4 \pm 3.5\%$ in those initially implanted with a tissue prosthesis, versus $73.0 \pm 4.9\%$ in those who received a mechanical aortic valve (HR: 3.9, tissue versus mechanical; 95% CI: 2.6, 6.3; $P<0.001$). The median time to reoperation was 10.2 years in tissue AVR patients, and beyond this cohort’s maximum follow-up (ie, >35.0 years) in mechanical AVR patients.

Similar observations were noted in MVR patients, where the 20-year actuarial freedom from reoperation was $15.8\% \pm 4.6\%$ with tissue prostheses, versus $65.0\% \pm 9.6$ with mechanical prostheses. In MVR patients, the median time to reoperation was 11.8 years with tissue prostheses, and 24.4 years with mechanical prostheses.

The perioperative mortality associated with initial valve reoperation in this cohort was 10 of 235 (4.3%), and no mortality occurred at subsequent reoperation. These rates were not significantly different between implant sites. The impact of reoperation as an overall cause of death in this cohort was not significantly different between tissue and mechanical patients, both within AVR patients as well as within MVR patients (HR: 1.9, 95% CI: 0.2, 4.7; $P=0.5$).

Stroke

Thirty-five patients in the cohort died from stroke. The 20-year freedom from death attributable to ischemic or hemorrhagic stroke was $97.9 \pm 1.2\%$ in tissue AVR patients, $83.9 \pm 4.9\%$ in mechanical AVR patients, $96.1 \pm 1.9\%$ in tissue MVR patients, and $85.6 \pm 5.3\%$ in mechanical MVR patients. After adjusting for coronary artery disease and atrial fibrillation, the use of a mechanical valve was a significant risk factor for dying from stroke in either implant position (for AVR, HR: 7.0; for MVR, HR: 4.5; both $P<0.02$).

Other Causes

Other causes of death included myocardial infarction in 60 patients, other cardiovascular etiologies including heart failure in 79, cancer in 46, infective endocarditis in 9, pneumonia in 4, and other nonvalve-related causes in 83. There was no significant difference between prosthesis types with respect to the distribution of these causes of death.

Discussion

The main finding of this study is that the implantation of a tissue prosthesis at initial AVR or MVR in adults <60 years of age was associated, in our experience, with very long-term survival equivalent to that observed with the use of a mechanical prosthesis. This finding differs from the usual recommendations for prosthesis selection in this age group. The lack of difference in survival observed in our study also applied to patients implanted with contemporary prostheses, as well as to those <50 years of age at the time of their first valve replacement operation.

TABLE 3. Predictors of Late Mortality After AVR in the Study Cohort

	HR	95% CI	P
Age at operation (per increasing year)	1.03	1.01, 1.04	0.008
Coronary artery disease	1.9	1.4, 2.6	0.002
Atrial fibrillation	1.5	1.01, 2.3	0.04
Year of surgery (per increasing year)	0.95	0.93, 0.97	<0.001
Nonsignificant covariates			
Female gender	0.8	0.6, 1.1	0.2
Preoperative NYHA class (per increasing class)	1.2	0.98, 1.3	0.1
LV dysfunction*	1.3	0.9, 1.7	0.1
Tissue prosthesis (vs mechanical)	0.95	0.7, 1.3	0.7
Contemporary† tissue prosthesis (vs contemporary mechanical)	1.2	0.7, 2.0	0.5

*LV dysfunction=ejection fraction <50%.

†Contemporary=prostheses that are still commercially available (see Table 2).

NYHA indicates New York Heart Association Functional Class; LV, left ventricular.

To our knowledge, this constitutes the first study to provide long-term evidence in support of this finding, and the largest to compare very late outcomes of tissue versus mechanical valves in a cohort of young patients. Although the implications of the present finding are multiple, it is important to caution that it (1) may not be generalizable to most recent tissue and mechanical prostheses, whose materials, design, and accessory technologies, such as anticoagulation monitoring, have continuously improved, especially considering that most of the valves reported on in this study are no longer commercially available, (2) only applies to valve selection at *initial* implant operation, because crossovers were frequent in this study, (3) may apply only if the perioperative mortality of reoperation is low and consistent with modern standards,⁶ and (4) should not be extrapolated to DVR patients because of their low number in this study.

Related Previous Work

Two studies recently provided 15-year data regarding composites of valve-related complications in patients undergoing

aortic and mitral valve replacement.^{15,16} In patients undergoing AVR, no difference was observed between tissue and mechanical prostheses in terms of survival and reoperation in patients >60 years of age, and actual freedom from valve-related mortality was equivalent in patients 51 to 60 years.¹⁵ In patients undergoing MVR, follow-up beyond 12 years was very limited in patients <60 years of age.¹⁶ In a smaller series, we previously reported that patients who underwent valve replacement at <50 years of age with mechanical versus tissue prostheses had a lower physical capacity, a higher prevalence of disability, and worse disease perception.¹⁰

Limitations

Types and Selection of Prostheses

Most prostheses implanted at first time operation in this study's cohort are no longer commercially available, as the need for very long-term follow-up, especially in the less prevalent population of young valve patients, warranted the

TABLE 4. Predictors of Late Mortality After MVR in the Study Cohort

	HR	95% CI	P
Age at operation (per increasing year)	1.03	1.01, 1.06	0.01
Female gender	0.7	0.5, 0.96	0.03
Coronary artery disease	1.5	1.01, 2.2	0.04
Year of surgery (per increasing year)	0.96	0.93, 0.98	<0.001
Nonsignificant covariates			
Preoperative NYHA class (per increasing class)	1.2	0.98, 1.4	0.09
Atrial fibrillation	1.1	0.8, 1.5	0.6
LV dysfunction*	1.2	0.9, 1.7	0.3
Tissue prosthesis (vs mechanical)	0.7	0.5, 1.01	0.06
Contemporary† tissue prosthesis (vs contemporary mechanical)	0.6	0.2, 1.2	0.2

*LV dysfunction=ejection fraction <50%.

†Contemporary=prostheses that are still commercially available (see Table 2).

NYHA indicates New York Heart Association Functional Class; LV, left ventricular.

TABLE 5. Patterns of Valve Reoperation*

	Tissue Replaced With Mechanical	Tissue Replaced With Tissue	Mechanical Replaced With Tissue	Mechanical Replaced With Mechanical	Replacement of the Other Native Left-Heart Valve†
First reoperation after AVR (n=135)	82	23	9	12	9
Second reoperation after AVR (n=25)	11	0	1	4	9
First reoperation after MVR (n=87)	63	8	9	5	2
Second reoperation after MVR (n=11)	5	2	0	2	2
First reoperation after DVR (n=13)	8	1	2	2	n/a
Second reoperation after DVR (n=2)	1	0	0	1	n/a

Data expressed as absolute No. (percentage of total reoperations, per site and reoperation No.)

*Does not include reoperations for non-left heart valve cardiac operations, such as coronary artery bypass grafting without valve intervention, tricuspid valve operations, aneurysms, etc.

†Denotes subsequent MVR in previous AVR patients, or subsequent AVR in previous MVR patients.

n/a indicates not applicable.

inclusion of previous era valve prostheses. Some prostheses, like several Ionescu-Shiley (tissue) and Bjork-Shiley (mechanical) models, were associated with higher-than-expected failure rates.^{17,18} This may influence the generalizability of this study's conclusions to today's prostheses. However, comparisons of survival within patients who were implanted with currently available prostheses and who contributed 20 year follow-up revealed observations similar to analyses that used all prostheses, whether currently available or not.

Furthermore, prosthesis type selection was not randomized and depended for each patient on one or several factors, as outlined in the methods section; consequently, selection bias may have affected results, despite attempts to account for the effects of previously identified confounders of long-term survival after valve replacement.^{13,14}

Anticoagulation

For nearly all patients in this cohort, anticoagulation was initially managed by the surgeon, and subsequently by the cardiologist or primary care physician. This does not necessarily represent optimal management by use of a home-monitored or telephone-monitored system. It is possible that newer anticoagulation monitoring may improve outcomes and quality of life, particularly in mechanical valve patients. Quality of life was not measured in this study.

Conclusions

In this cohort of adult patients <60 years of age followed for >20 years after AVR or MVR, the use of a tissue versus a mechanical prosthesis at initial implant was not associated with a significant difference in long-term survival, despite higher reoperation rates with bioprostheses. Our experience therefore suggests that a mechanical prosthesis may not necessarily be warranted in the younger adult patient population in need of first time, single left-heart valve replacement.

Disclosures

None.

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