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Mechanical versus bioprosthetic valve replacement in middle-aged patients

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Abstract

Objective: The current trend towards decreasing the age for selection of a tissue over a mechanical prosthesis has led to a dilemma for patients aged 50—65 years. This cohort study examines the long-term outcomes of mechanical versus bioprosthetic valves in middle-aged patients.

Methods: Patients (N = 659) aged between 50 and 65 years who had first-time aortic valve replacement (AVR) and/or mitral valve replacement (MVR) with contemporary prostheses were followed prospectively after surgery. The total follow-up was 3402 patient-years (mean 5.1 ± 4.1 years; maximum 18.3 years). Outcomes were examined with multivariate actuarial methods. A composite outcome of major adverse prosthesis-related events (MAPE) was defined as the occurrence of reoperation, endocarditis, major bleeding, or thromboembolism.

Results: Ten-year survival was 73.2 ± 4.2% after mechanical AVR, 75.1 ± 12.6% after bioprosthetic AVR, 74.1 ± 7.4% after mechanical MVR, and 77.9 ± 7.4% after bioprosthetic MVR (P = NS). Ten-year reoperation rates were 35.4% and 21.3% with aortic and mitral bioprostheses, respectively. Major bleeding occurred more often following mechanical MVR (hazard ratio [HR]: 3.3; 95% confidence interval [CI] 1.2, 9.0; P = 0.022), and the incidence of any thromboembolic event was more common after mechanical MVR (HR: 4.7; CI 1.4, 13.3; P = 0.01). Overall freedom from MAPE at 10 years was 70.2 ± 4.1% for mechanical AVR patients, 41.0 ± 30.3% for bioprosthetic AVR patients, 53.3 ± 8.8% for mechanical MVR patients, and 61.2 ± 9.2% for bioprosthetic MVR patients. Although a trend existed towards more MAPE amongst middle-age patients with tissue valves, multivariate analysis did not identify the presence of a bioprosthesis as an independent risk factor for MAPE (HR: 1.3; CI 0.9, 2.0; P = 0.22).

Conclusions: In middle-aged patients, MAPE may occur more often in patients with bioprosthetic valves, but definitive conclusions necessitate the accumulation of additional follow-up. At present, these data do not support lowering the usual cutoff for implantation of a tissue valve below the age of 65.

Keywords: Aortic valve replacement; Mitral valve replacement; Heart valve; Bioprosthesis; Heart valve; Mechanical; Outcomes (includes mortality; morbidity)

1. Introduction

The choice between a mechanical and tissue prosthetic valve for a patient undergoing valve replacement surgery involves a careful consideration of the risks and benefits associated with each type of prosthesis. In patients aged 50—65, the implications of implanting a bioprosthesis to avoid the risk of mechanical valve thromboembolism or anticoagulant-related hemorrhage may mean that a repeat procedure will be necessary 10—15 years later because of structural bioprosthetic valve degeneration. With reports of very low rates of structural bioprosthetic failure in elderly patients [1,2], particularly with newer models [3], many surgeons and cardiologists are decreasing the age cutoff for recommenda-
aged 50—65 years who had first time aortic valve replacement (AVR), mitral valve replacement (MVR), or double valve replacement (DVR) between January 1977 and July 2002, who received prostheses that are still commercially available today, and who survived the perioperative period. Valves were implanted with interrupted horizontal mattress sutures using pledgeted 2-0 non-absorbable braided polyester. Primary valve repair procedures were excluded from this study. Follow-up was 100% complete for all patients, and 67% of patients had recent follow-up (1999 and thereafter). The study closing date was December 2002. The total follow-up for the entire cohort was 3402 patient-years (mean 5.1 ± 4.1 years; maximum 18.3 years). The follow-up period for aortic patients was 1919 patient-years (mean 4.9 ± 3.9 years; maximum 15.8 years), and for mitral patients 1290 patient-years (mean 5.5 ± 4.6 years; maximum 18.3 years).

2.2. Choice of prosthesis

The selection of a mechanical or bioprosthetic valve was made following a detailed preoperative discussion between the surgeon, the patient, and family members (when applicable). The pros and cons of mechanical or bioprosthetic valves were described, including the need for anticoagulation after mechanical valve implantation or the possible need for reoperation after tissue valve implantation. The decision of mechanical or bioprosthetic selection was left entirely to the individual patient and his/her caregivers. Specific contraindications to anticoagulation were taken into account, including a bleeding diathesis or the refusal of blood transfusion (Jehovah’s Witness). The prostheses model implanted was at the discretion of the operating surgeon. Medtronic-Hall valves (Medtronic, Minneapolis, MN, USA) were implanted between 1985 and 2001, St. Jude Medical valves (St. Jude Medical, St. Paul, MN, USA) 1988—2002, CarboMedics valves (Sorin Biomedica, Via Crescentino, Italy) 1992—2001, On-X valves (MCRI, Dallas, TX, USA) 2000—2001, Hancock valves (Medtronic, Minneapolis, MN, USA) 1977—2002, and Edwards valves (Edwards Lifesciences, Irvine, CA, USA) 1977—2001. Aortic homografts were implanted between 1989 and 2002, most often for acute endocarditis.

2.3. Anticoagulation

During the postoperative period, anticoagulated patients initially received unfractionated heparin (5000 units subcutaneously every 12 h) until the International Normalized Ratio (INR) or prothrombin time was within therapeutic range. Patients with mechanical prostheses or chronic atrial fibrillation were anticoagulated with warfarin according to guidelines in effect at the time, as previously described [4]. Briefly, these consisted of a target prothrombin time or INR of 2.0—3.0× normal after mechanical AVR and 2.5—3.5× normal after mechanical MVR. The addition of aspirin (81 mg daily) to warfarin was left to the discretion of the surgeon, cardiologist, or primary care physician. In patients who underwent bioprosthetic valve implantation, warfarin anticoagulation was used at the discretion of the surgeon for a period of three months after operation. Warfarin was subsequently discontinued if sinus rhythm was maintained and no other indication for anticoagulation was present. Non-anticoagulated patients with bioprosthetic valves were kept on 325 mg of aspirin daily unless contraindicated.

2.4. Outcomes

Long-term outcomes after valve replacement surgery, including survival and freedom from reoperation, were compared between patients with mechanical and bioprosthetic valves. Prosthesis-related complications were recorded according to the Guidelines for Reporting Morbidity and Mortality after Cardiac Valvular Operations [5]. Briefly, stroke was defined as the presence of a neurological deficit lasting more than three weeks and was confirmed with computerized tomography of the head [4,5]. Bleeding events were classified as major if they required surgery, hospital admission, blood transfusion, were intracranial in location, or caused death. Reoperation was defined as any operation that repaired, altered, or replaced a previously operated valve [3,5]. In an attempt to provide an overall comparison of major morbidity between mechanical and bioprosthetic valves, a composite outcome termed major adverse prosthesis-related event (MAPE) was developed, defined as the composite outcome of any reoperation, major bleeding, thromboembolic event, or endocarditis during late follow-up.

2.5. Statistical analyses

Data were imported and analyzed in Intercooled Stata 8.0 (Stata, College Station, TX, USA). Continuous data were presented as mean ± standard deviation, except for survival and events rates, which are reported as mean ± standard error. For Kaplan—Meier analyses of the various outcomes in this study, patients were censored at the time of their last follow-up visit or at the time of death if the outcome of interest had not occurred, and censoring was assumed to be independent of predictors and outcomes. Potential univariate predictors of outcomes were individually tested for equality with a log-rank test. In order to account for positive or negative confounding, multivariate Cox proportional hazards models were developed by incorporating all variables that had a P value of 0.20 or less on log-rank testing using multivariate model selection procedures (both stepwise forward selection and backward elimination techniques). In order to account for the large interval of time over the period of the study, the effect of time was studied by entering either surgical year or surgical era (five-year intervals) into the multivariate models. Patients with DVR were analyzed separately from AVR and MVR patients.

3. Results

3.1. Patient characteristics

The preoperative characteristics of the middle-aged cohort are presented in Table 1. Compared to patients that received bioprostheses, mechanical valve patients had a higher preoperative incidence of smoking and diabetes mellitus (P < 0.05). The initial operation consisted of AVR in 388 patients (mechanical in 306, bioprosthetic in 82), MVR...
in 236 patients (mechanical in 188, bioprosthetic in 48), and DVR in 35 patients (mechanical in 34, bioprosthetic in 1). Concomitant coronary artery bypass (CABG) was performed in 28.8% of patients. Table 2 shows the types of prostheses implanted and the follow-up periods for each type of prosthesis.

### 3.2. Late survival

Fig. 1 displays the long-term survival of patients in the cohort. The overall 5-, 10-, and 15-year survival was 89.0 ± 2.1%, 73.2 ± 4.2%, and 65.3 ± 6.0% after mechanical AVR; 87.6 ± 5.7%, 75.1 ± 12.6%, and 37.5 ± 27.3% after tissue AVR; 85.0 ± 3.2%, 74.1 ± 4.6%, 45.0 ± 15.2% after mechanical MVR; and 94.0 ± 4.1%, 77.9 ± 7.4%, and 58.4 ± 10.2% after tissue MVR, respectively. The overall 5- and 10-year survival after DVR was 86.9 ± 6.3% and 74.1 ± 10.1%, respectively. There was no significant difference in survival between patients who underwent AVR versus those who underwent MVR, and no significant survival difference between patients implanted with a mechanical versus a bioprosthetic valve in either of the implant positions. Independent risk factors for decreased long-term survival after AVR included age at surgery (hazard ratio [HR]: 1.1 per additional year; 95% confidence interval [CI]: 1.0, 1.2; \( P = 0.02 \)), worsening left ventricular (LV) function (HR: 1.4 per unit increase in LV grade; CI 1.0, 1.9; \( P = 0.05 \)), and a trend existed for a history of atrial fibrillation (HR: 3.0; CI 0.9, 10.4; \( P = 0.08 \)). After MVR, worsening LV function (HR: 2.1 per unit increase in LV grade; CI 1.2, 3.7; \( P = 0.007 \)) was an independent risk factor for late death, and a trend existed for age at surgery (HR: 1.1 per additional year; CI: 1.0, 1.3; \( P = 0.08 \)). Preoperative left atrial diameter, preoperative New York Heart Association (NYHA) class, and year of surgery had no significant effect on survival after AVR or MVR.

### 3.3. Thromboembolism

#### 3.3.1. Stroke

The 10-year freedom from late postoperative stroke was 90.0 ± 2.7% for mechanical AVR patients, 97.6 ± 1.7% for bioprosthetic AVR patients, 87.9 ± 4.1% for mechanical MVR.
patients, and 91.1 ± 5.0% for bioprosthetic MVR patients. No strokes occurred in the 35 DVR patients. There was no difference in the stroke risk between mechanical and bioprosthetic valves in either implant position.

3.3.2. All thromboembolism

The 10-year freedom from any postoperative thromboembolic event (stroke, transient ischemic attack, or peripheral embolus) was 79.2 ± 3.9% for mechanical AVR patients, 97.6 ± 1.7% for bioprosthetic AVR patients, 69.0 ± 7.5% for mechanical MVR patients, and 87.6 ± 6.0% for bioprosthetic MVR patients. There were three events in the mechanical DVR group (10-year freedom: 91.1 ± 4.9%), and there was no thromboembolism in the one tissue DVR patient. On multivariate testing, there was a tendency towards more thromboembolic events amongst AVR patients with a history of smoking (HR: 2.0; CI 0.9, 4.6; \(P = 0.10\)). Following MVR, independent risk factors for a thromboembolic event included the presence of a mechanical valve (HR: 4.1; CI 1.3, 12.7; \(P = 0.01\)) and female gender (HR: 2.4; CI 1.1, 5.3; \(P = 0.03\)). Preoperative left atrial diameter, preoperative NYHA class, LV grade and year of surgery had no significant effect on thromboembolism after AVR or MVR.

3.4. Major bleeding

The 10-year freedom from major bleeding was 97.1 ± 1.3% for mechanical AVR patients, 97.6 ± 2.4% for bioprosthetic AVR patients, 88.9 ± 4.3% for mechanical MVR patients, and 97.8 ± 2.2% for bioprosthetic MVR patients. There were no major bleeding episodes in DVR patients. The presence of a mechanical prosthesis had no significant effect on major bleeding after AVR (\(P = 0.74\)). However, the presence of a mechanical prosthesis was an independent risk factor for major bleeding after MVR (HR: 3.3; CI 1.2, 9.0; \(P = 0.02\)).

3.5. Endocarditis

The 10-year freedom from endocarditis was 95.9 ± 2.4% for mechanical AVR patients, 96.4 ± 3.5% for bioprosthetic AVR patients, 94.8 ± 4.5% for mechanical MVR patients, and 92.4 ± 4.2% for bioprosthetic MVR patients. There were two endocarditis events amongst the mechanical MVR patients (10-year freedom: 90.0 ± 6.8%), and there was no endocarditis in the one tissue DVR patient. The presence of a bioprosthesis was not an independent risk factor for endocarditis after AVR (\(P = 0.77\)), but there was a trend towards greater endocarditis risk amongst MVR patients with tissue valves (HR: 5.2; CI 0.9, 30.0; \(P = 0.07\)).

3.6. Reoperation

The 10-year freedom from reoperation was 96.0 ± 1.8% for mechanical AVR patients, 64.6 ± 26.4% for bioprosthetic AVR patients, 95.3 ± 3.1% for mechanical MVR patients, and 78.7 ± 7.8% for bioprosthetic MVR patients. There was one reoperation in the mechanical DVR group (10-year freedom: 94.4 ± 5.4%), and there were no reoperations in the one tissue DVR patient. After AVR, independent risk factors associated with the need for reoperation included a bioprosthetic valve (HR: 7.1; CI 1.8, 27.8; \(P = 0.005\)) and persistent LV hypertrophy during late follow-up (HR: 13.5; CI 1.5, 122.6; \(P = 0.02\)). Following MVR, the presence of tissue valve was the only independent risk factor for reoperation (HR: 4.9; CI 1.5, 15.5; \(P = 0.007\)). Smoking, gender, a history of hypertension and year of surgery were not independent risk factors associated with reoperation in this cohort.

3.7. Major adverse prosthesis-related events

The composite outcome of major adverse prosthesis-related event included any reoperation, major bleeding, thromboembolic event, or endocarditis during late follow-up. Fig. 2 displays the freedom from MAPE for this middle-aged cohort. The 10-year freedom from MAPE was 70.2 ± 4.1% for mechanical AVR patients, 41.0 ± 30.3% for bioprosthetic AVR


Fig. 2. Actuarial rates of freedom from major adverse prosthesis-related events (MAPE) after any (A), aortic (B), or mitral (C) valve replacement in middle-aged adults. The curves suggest worse freedom from MAPE amongst patients with bioprostheses, but the presence of a bioprosthesis was not an independent risk factor for MAPE on multivariate analysis. Mech, mechanical valve; Bio, bioprosthetic valve; CI, confidence interval.
patients, 53.3 ± 8.8% for mechanical MVR patients, and 61.2 ± 9.2% for bioprosthetic MVR patients. There were five events in the mechanical DVR group (10-year freedom: 80.6 ± 8.2%), and there was no MAPE in the one tissue DVR patient. There was a trend towards more MAPE amongst AVR patients with atrial fibrillation (HR: 2.4; CI 0.9, 6.8; \( P = 0.09 \)). Following MVR, there was a trend towards more MAPE amongst females (HR: 1.6; CI 0.9, 2.8; \( P = 0.09 \)).

Fig. 2A (all patients) and B (aortic patients) suggest that the presence of a bioprosthesis may be associated with more MAPE. However, the presence of a bioprosthesis was not an independent risk factor for MAPE amongst the entire cohort (HR: 1.3; CI 0.9, 2.0; \( P = 0.22 \)), AVR patients (HR: 1.3; CI 0.7, 2.5; \( P = 0.42 \)), or MVR patients (HR: 0.8; CI 0.5, 1.5; \( P = 0.57 \)). The presence of a bioprosthesis was also not an independent risk factor for MAPE following the removal of aortic homografts from the entire cohort (HR: 1.3; CI 0.8, 2.0; \( P = 0.30 \)) or from the AVR group (HR: 0.9; CI 0.4, 2.4; \( P = 0.88 \)). Furthermore, the presence of a tissue valve was not an independent risk factor for MAPE in different middle-age subgroups, including AVR and MVR patients older or younger than 60 years of age.

4. Discussion

Valve replacement in the middle-aged adult leads to a difficult choice between the lifelong anticoagulation of a mechanical prostheses versus a bioprosthesis with limited long-term durability necessitating eventual reoperation. In this follow-up study of 659 patients between 50 and 65 years of age who underwent aortic and/or mitral valve replacement with modern prostheses, multivariate analyses indicated that: (1) long-term survival is equivalent between patients who underwent AVR and those who underwent MVR, with no significant survival difference between patients implanted with a mechanical versus a bioprosthetic valve in any of the implant positions; (2) the incidence of stroke and major bleeding events in this middle-aged cohort is similar to that of young adults less than fifty years of age (mean age 40.1 years) [6] and nearly half that of a regular age cohort (mean age 61.4 years) [4]; (3) the incidence of thromboembolic events and bleeding events is greater in patients with mechanical valves, especially those with MVR; (4) the incidence of reoperation is more common in patients with bioprosthetic valves; and (5) more MAPE may occur amongst middle-aged patients with bioprostheses, especially more than 10 years after surgery, but definitive conclusions will not be possible until more follow-up accrues.

The ultimate aim of heart valve surgery is to extend life expectancy and improve quality of life. This study demonstrated that amongst middle-aged patients, survival does not appear to be affected by the type of prostheses. These results confirm those reported by others who have also found that the choice of prosthesis does not have a significant effect on survival after valve replacement in patients younger than 65 years of age [7,8]. Regarding quality of life, Perchinsky et al. studied the quality of life of 200 patients aged 51–65 years who had undergone either mechanical or tissue AVR 2–12 years earlier. Postoperatively, the quality of life was equivalent between the two groups and was comparable to the general population for the same age group [9]. Mechanical valve patients were more bothered by valve sounds, were more concerned about the frequency of medical visits and blood tests, and were more worried about the possibility of anticoagulant-related bleeding events. Bioprosthetic valve patients, on the other hand, were more fearful of the need for reoperation. Nevertheless, 97% of patients reported that they would make the same decision again with regards to valve replacement, with no significant difference between the two groups [9].

In patients older than 65 years of age, evidence supports the use of bioprostheses because of low rates of structural valve deterioration and a low incidence of thromboembolic and hemorrhagic complications [1,2,10–13]. However, in younger patients, tissue valves develop early calcification due to an increased turnover of calcium, fatigue-induced lesions, and collagen degeneration [14,15]. While more promising results of newer generation bioprostheses have been reported in younger populations [16], younger age remains a risk factor for reoperation after implantation of a bioprosthesis [3]. Carrier et al. [7] reported an impressive 10-year freedom from valve replacement of 93 ± 3% for patients 55–65 years old with Carpentier-Edwards pericardial valves in the aortic position. These figures are higher than the 10-year freedom from reoperation of 64.6 ± 26.4% for bioprosthetic AVR patients observed in this cohort. These discrepancies may be explained by the use of different valve substitutes in the aortic position during the period of this study, including a large number of homografts and very few Carpentier-Edwards pericardial valves, as well as the younger age of the present cohort.

Although mechanical prostheses are used frequently for valve replacement in middle-aged patients, they have important drawbacks, including the need for lifelong anticoagulation. The results of this cohort study confirm the results presented by other groups demonstrating a higher incidence of thromboembolic [4,8] and bleeding [7,8] complications with mechanical valves compared to bioprostheses. Major bleeding occurred more often following mechanical MVR amongst the middle-aged patients in this study, likely related to the more aggressive anticoagulation and higher incidence of atrial fibrillation in MVR patients. Fortunately, thromboembolic and hemorrhagic complications occur less frequently and result in less death in patients less than 65 years of age compared to older patients [4,17]. Other risk factors for death and thromboembolism, such as coronary artery disease, atrial fibrillation and poor ventricular function, are also less common in younger patients [4]. Nonetheless, the need for long-term anticoagulation and the associated restrictions on an active lifestyle are a burden that should not be underestimated.

An additional finding of this study was the suggestion that more MAPE occurs amongst middle-aged patients with bioprosthetic valves. Although multivariate analysis failed to identify a bioprosthetic valve as an independent risk factor for MAPE, according to our data, it appears likely that the rates of MAPE will differ with additional follow-up beyond 10 years. Similar results have been reported by Khan et al. in an adult population (mean age 68 years). The rate of tissue valve reoperation outweighed the constant risk of anticoagulant-related hemorrhage with mechanical valves, yielding a higher
overall valve complication rate at 10 years in patients with bioprostheses [8]. Similarly, in a cohort of patients aged 55—65, Carrier et al. [7] demonstrated that the use of a mechanical valve significantly decreased the global risk of all valve-related complications in the aortic position, with a 10-year freedom rate from all valve-complicated related complications of 90% for mechanical valves versus 83% for bioprostheses (P = 0.01). Based on this published data and that presented herein, it appears that the use of a mechanical prosthesis is at least as good as, and possibly better, than that of a bioprosthesis in middle-aged patients. Therefore, a mechanical prosthesis likely remains a sound clinical choice for a middle-aged patient, unless there is a specific contraindication to the use of anticoagulation therapy.

4.1. Potential limitations

While there is a suggestion that more MAPE occurs in middle-aged patients with bioprosthesis valves, the data presented must be interpreted in the context of the study design. An observational study, group differences and known confounders were controlled for in the multivariate analysis. Despite the statistical adjustment applied, however, unmeasured and unknown confounders may have influenced the results. Furthermore, it is possible that patients lost to follow-up after a number of visits may have had subsequent outcomes that were not accounted for in the analyses. Thus, the follow-up duration, the numbers of patients in each group, and patients lost during follow-up may have impacted the power of the statistical analyses. Patients with homografts and tilting-disc valves were included in the study since these prostheses are still favored at many centers, and excluding them would have limited the statistical power. Nevertheless, the results of these analyses may not be generalizable to all patients who have undergone prosthetic valve replacement at other centers.

The composite outcome defined in this study incorporated the major morbidities associated with valve replacement in middle-aged patients. However, with MAPE, we have grouped together medical events that may be of different importance depending on one’s perspective. Most would argue that it is better to have an uncomplicated reoperation than a debilitating stroke. On the other hand, an emergency reoperation for structural valve deterioration with the presence of coronary artery bypass grafts may have more morbidity than a fully recoverable stroke. While other composite outcomes have been reported in valve cohort studies, no consensus definition of overall morbidity after valve replacement surgery has been agreed upon in the literature [5,7,8,18]. Therefore, we recognize that the definition of MAPE is debatable, and possibly over-simplistic, but intended to serve as an approximate estimation of the overall risk of a ‘major event’ within each valve class.

5. Conclusions

Although valve replacement in a middle-aged patient is a common clinical scenario, very little published data exists supporting the use of one valve type or the other in this particular age group. Despite the above limitations, the findings of this study may allow patients and clinicians to better understand and quantify long-term survival and the risk of major events after valve replacement in middle-aged adults. By combining the complications of major bleeding, thromboembolism, endocarditis, and reoperation into one composite outcome, this study addresses the question posed by many patients, ‘What is the risk that I will have a major complication after my valve operation?’. Although a randomized controlled trial would be the ideal method to address this question, the costs and necessary follow-up suggest that such a study will likely never be performed. Therefore, the surgical community must rely on observational studies such as this cohort to provide insights on this important topic.

As the largest series of middle-aged patients to date, this study suggests that tissue valves may have a higher rate of major complications compared to mechanical valves during long-term follow-up. While definitive conclusions await the accumulation of additional follow-up and further study, at this time, the data does not support lowering the usual cutoff for implantation of a tissue valve below the age of 65. Nonetheless, we believe that decisions regarding the choice of prosthesis need to be individualized and discussed between the patient and the treatment team. Factors that must be taken into account include the presence of comorbidities affecting long-term survival, the risks and inconvenience of anticoagulation, the risks associated with reoperation, lifestyle issues, and patient personal preference. In the future, newer bioprostheses more resistant to structural valve deterioration, less thrombogenic mechanical prostheses, and newer forms of anticoagulation will mandate a re-exploration of the issue of the ideal valve choice in the middle-aged patient.

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References


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