Original Investigation

Survival and Outcomes Following Bioprosthetic vs Mechanical Mitral Valve Replacement in Patients Aged 50 to 69 Years

Joanna Chikwe, MD; Yuting P. Chiang, BA; Natalia N. Egorova, PhD; Shinobu Itagaki, MD; David H. Adams, MD

IMPORTANCE In nonelderly patients with mitral disease requiring valve replacement, deciding between bioprosthetic and mechanical prosthetic valves is challenging because long-term survival and morbidity are not well defined.

OBJECTIVE To quantify survival and major morbidity after mitral valve replacement in patients aged 50 to 69 years.

DESIGN, SETTING, AND PARTICIPANTS Retrospective cohort analysis of 3433 patients (aged 50-69 years) who underwent primary, isolated mitral valve replacement in New York State hospitals from 1997-2007. Follow-up ended November 30, 2013; median duration was 8.2 years (range, 0-16.8 years). Propensity score matching for 19 baseline characteristics yielded 664 patient pairs.

EXPOSURES Bioprosthetic vs mechanical prosthetic mitral valve replacement.

MAIN OUTCOMES AND MEASURES All-cause mortality, stroke, reoperation, and major bleeding events.

RESULTS No survival difference was observed between use of mechanical prosthetic and bioprosthetic mitral valves in patients aged 50 to 69 years matched by propensity score or in a subgroup analysis of age by decade. Among patients matched by propensity score, the incidences of stroke and bleeding events were both significantly higher in those who received mechanical prosthetic mitral valves compared with those who received bioprosthetic mitral valves; however, the incidence of reoperation was lower in the mechanical prosthesis group compared with the bioprosthesis group.

Outcome at 15 Years | Bioprosthetic (n = 664) | Mechanical Prosthetic (n = 664) | Hazard Ratio (95% CI)
--- | --- | --- | ---
Death | 221 | 209 | 0.95 (0.79-1.15)
Actuarial 15-year survival, % (95% CI) | 59.9 (54.8-65.0) | 57.5 (50.5-64.4) | 1.62 (1.10-2.39)
Stroke | 41 (6.8) [4.5-8.8] | 65 (14.0) [9.5-18.6] | 0.59 (0.37-0.94)
Reoperation | 47 (11.1) [7.6-14.6] | 28 (5.0) [3.1-6.9] | 1.50 (1.05-2.16)
Bleeding events | 49 (9.0) [6.4-11.5] | 72 (14.9) [11.0-18.7] | 1.62 (1.10-2.39)

CONCLUSIONS AND RELEVANCE Among patients aged 50 to 69 years undergoing mitral valve replacement in New York State, there was no significant survival difference at 15 years in patients matched by propensity score who underwent mechanical prosthetic vs bioprosthetic mitral valve replacement. Mechanical prosthetic valves were associated with lower risk of reoperation but greater risk of bleeding and stroke. Even though these findings suggest bioprosthetic mitral valve replacement may be a reasonable alternative to mechanical prosthetic valve replacement in patients aged 50 to 69 years, the 15-year follow-up was insufficient to fully assess lifetime risks, particularly of reoperation.


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n patients with severe, symptomatic mitral valve disease unsuitable for surgical repair, mitral valve replacement reduces symptoms and improves survival.1,2 Bioprosthetic valves are recommended in patients older than 70 years, in whom the likelihood of needing reoperation for bioprosthetic valve degeneration is low.1,2 The best prosthetic valve type for patients younger than 70 years is less evident.1-6 Bioprosthetic structural valve degeneration has an accelerated course in younger patients who consequently face a much higher lifetime risk of reoperation.6 Reoperation rates are much lower for mechanical prosthetic valves, but the increased risk of thromboembolic and hemorrhagic complications, and lifestyle limitations associated with lifelong anticoagulation are major disadvantages.1-6

Current consensus guidelines for prosthetic heart valve selection recommend either type of prosthetic valve for patients aged 60 to 70 years and mechanical prosthetic valves for patients younger than 60 years.3,2 These recommendations are based primarily on the results of 3 randomized clinical trials that found no significant difference in late survival.7-9 Two of these trials compared mechanical prosthetic and bioprosthetic valve models implanted in the 1970s and 1980s,7,8 and the third is a more recent study that included only patients undergoing aortic valve replacement.9 Contemporary data are limited to small, single-center series.10-12 The aim of this multicenter study was to compare long-term survival, stroke, reoperation, and bleeding events after bioprosthetic vs mechanical prosthetic mitral valve replacement among patients aged 50 to 69 years.

Methods

Study Design

A retrospective cohort study comparing long-term outcomes after mitral valve replacement was performed with either a mechanical prosthetic or bioprosthetic valve using the Statewide Planning and Research Cooperative System (SPARCS), an administrative database in which all inpatient hospitalizations in New York State are reported. All patients aged 50 to 69 years who underwent primary mitral valve replacement in New York State from January 1, 1997, to December 31, 2007, were identified.

Mechanical prosthetic and bioprosthetic valve replacements were differentiated using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure codes 35.23 and 35.24, respectively. The following patients were excluded: residents outside New York State; patients who had undergone prior replacement of any heart valve; and those undergoing concomitant replacement of the aortic, pulmonary, or tricuspid valves; repair of the aortic or pulmonary valves; concomitant coronary artery bypass graft surgery; or concomitant thoracic aortic surgery (definitions appear in eTable 1 in the Supplement).

The ICD-9-CM diagnosis codes documented in the index hospitalization and all inpatient admissions within the prior 2 years were used to identify baseline comorbidities (definitions appear in eTable 2 in the Supplement). For the index hospitalization, only those diagnoses identified as present at admission were used to avoid conflating baseline comorbid conditions with postoperative complications.

This study was approved by the New York State Department of Health data protection review board as well as the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai (the latter included a waiver of informed consent).

Study End Points

The primary end point was all-cause mortality. The secondary outcomes were stroke, reoperation, and major bleeding events. To identify deaths, the SPARCS database was linked to the Social Security Death Master File (current as of November 30, 2013). Additionally, all subsequent hospital admissions or available ambulatory and emergency department visits were searched for patient deaths. All secondary end points were defined using ICD-9-CM diagnosis and procedure codes (eTable 3 in the Supplement).

Stroke was defined as any cerebrovascular accident documented during the index hospitalization as well as any subsequent hospital admission in which the principal diagnosis was hemorrhagic or ischemic stroke (not including transient ischemic attacks). Reoperation was defined as any subsequent mitral valve replacement. Reoperations were included (including concomitant procedures); however, subsequent cardiac surgery that did not involve mitral valve replacement was excluded. A major bleeding event was defined as any subsequent hospital admission in which the principal diagnosis was intracerebral hemorrhage, hemopericardium/cardiac tamponade, gastrointestinal hemorrhage, hematuria, hemorrhosis, hemoptysis, or retinal hemorrhage. In the absence of death, stroke, reoperation, or a major bleeding event, patients were censored on December 31, 2012 (most recent data available from SPARCS).

Statistical Analysis

Baseline patient characteristics are represented as means with standard deviations for normally distributed continuous variables and proportions for categorical variables. To compare baseline differences in comorbidity between patients receiving mechanical prosthetic and bioprosthetic valves, the t test was performed for continuous variables, the Pearson χ2 test was performed for categorical variables, and standardized differences were calculated for all variables.

Confounding due to differences in baseline characteristics was addressed using propensity score matching13 (a similar method has been previously described43). To calculate the propensity score, a hierarchical logistic regression model was fitted with bioprosthetic implantation as the outcome. This multilevel model imposes a nested structure onto the data, whereby patients are grouped according to their surgeons and individual practice variations are controlled.

Covariates entered into the model include all measured baseline characteristics: year of surgery, age, sex, race/ethnicity, admission urgency, active endocarditis or sepsis, coagulation or platelet disorders, hypertension, diabetes,
coronary artery disease, peripheral vascular disease, cerebrovascular disease, congestive heart failure, atrial fibrillation, chronic obstructive pulmonary disease, chronic kidney disease, liver disease, and cancer. The area under the receiver operating characteristic curve for this model was 0.80. A 1:1 match was then performed using a caliper of 0.01 of the logit of the propensity score computed by this model. The baseline characteristics of the patient pairs matched by propensity score were compared using the paired $t$ test for continuous variables and the McNemar test for categorical variables. The 30-day complication rates (definitions appear in eTable 4 in the Supplement) were compared using the McNemar test.

For the primary end point, survival curves and 15-year estimates were derived from the life table. For the secondary end points of stroke, reoperation, and major bleeding, a competing risk analysis was performed to construct cumulative incidence function curves and to calculate 15-year estimates. For all end points, marginal Cox proportional hazards regression models with robust sandwich variance estimators were fitted with only prosthesis type entered as a covariate. The difference in overall survival was compared using the Cox model, whereas the differences in secondary end points were evaluated using the Gray test.

We reanalyzed all end points using the entire study population with a multilevel Cox model, specifying patients as being nested within their surgeons and fitted with prosthesis type and all baseline characteristics entered as covariates. Two additional analyses were performed to separately evaluate the outcomes of patients aged 50 to 59 years and 60 to 69 years. First, after splitting the entire study population into these 2 age cohorts, all end points were reevaluated by fitting Cox models with prosthesis type and all baseline characteristics entered as covariates. Second, the prosthesis type $\times$ age cohort interaction was evaluated for the entire study population by fitting a Cox model with prosthesis type, propensity score, and all baseline characteristics (replacing the original continuous age variable with a binary variable for age cohort) entered as covariates. All tests were 2-tailed with an $\alpha$ level of .05. All statistical analyses were performed using SAS version 9.3 (SAS Institute Inc).

Results

Study Population

Mitral valve replacement was performed in 8410 patients aged 50 to 69 years. The study cohort of 3433 patients included 795 patients (23.2%) with bioprosthetic valves and 2638 patients (76.8%) with mechanical prosthetic valves. Out-of-state residents (7.0%, $n = 585$) were excluded as well as patients with 1 or more of the following criteria: any previous valve replacement (7.8%, $n = 658$) or other concomitant valve replacement (21.9%, $n = 1845$), concomitant aortic or pulmonary valve repair (1.1%, $n = 94$), coronary artery bypass graft surgery (33.4%, $n = 2809$), or thoracic aortic surgery (1.2%, $n = 98$).

Patient Characteristics

Between 1997 and 2012, use of bioprosthetic mitral valve replacement increased from 8% (263/322) to 60% (1813/302) of patients ($P < .001$; eFigure 1 in the Supplement). Patients in the study cohort who received a mechanical prosthetic valve ($n = 2638$) compared with those who received a bioprosthetic valve ($n = 795$) were younger (mean [SD] age, 59.7 [5.7] years vs 61.2 [5.9] years, respectively; $P < .001$) and less likely to have a history of diabetes (17% vs 25%, $P < .001$), unrevascularized coronary artery disease (25% vs 32%, $P < .001$), congestive heart failure (53% vs 58%, $P = .03$), coagulation or platelet disorder (5% vs 7%, $P = .046$), liver disease (4% vs 8%, $P < .001$), and cancer (2% vs 5%, $P < .001$) (Table 1). Patients who received mechanical prosthetic valves were more likely to have a history of atrial fibrillation (51% vs 43% in the bioprosthesis group, $P < .001$).

Propensity-score matching produced 664 patient pairs. Age and all baseline comorbidities were balanced between the 2 groups (Table 2). There was no significant difference in 30-day mortality (5% in the bioprosthesis group vs 4% in the mechanical prosthesis group, $P = .12$) after valve replacement. Bioprosthetic valves were associated with more respiratory failure (21% vs 16% in mechanical prosthesis group, $P = .01$), but no other differences in 30-day outcomes were observed (Table 3). In the propensity-score matched cohort, median follow-up time was 8.2 years (interquartile range [IQR], 6.1-10.6 years) with maximum follow-up of 16.8 years. Median follow-up time was 8.1 years (IQR, 6.1-10.5 years) in the mechanical prosthesis group compared with 8.2 years (IQR, 6.2-10.7 years) in the bioprosthesis group. The baseline characteristics of patients who received bioprosthetic valves but who were not matched are listed in eTable 5 in the Supplement.

Mortality

Among patients matched by propensity score, there was no difference in long-term survival between the mechanical prosthetic and bioprosthetic mitral valve replacement. A total of 209 deaths occurred in the mechanical prosthesis group and 221 deaths occurred in the bioprosthes group. Actuarial 15-year survival was 57.5% (95% CI, 50.5%-64.4%) in the mechanical prosthesis group compared with 59.9% (95% CI, 54.8%-65.0%) in the bioprosthesis group (hazard ratio [HR], 0.95 [95% CI, 0.79-1.15]; $P = .62$; Figure 1).

Stroke

The cumulative incidence of stroke at 15 years after mitral valve replacement was significantly higher in the mechanical prosthesis group (14.0%; 95% CI, 9.5%-18.6%) compared with the bioprosthesis group (6.8%; 95% CI, 4.5%-8.8%) (HR, 1.62 [95% CI, 1.10-2.39]; $P = .01$; Figure 2A). A total of 106 strokes occurred during follow-up (65 in the mechanical prosthesis group vs 41 in the bioprosthesis group), for which the associated 30-day mortality was 8.5%. Of these, 24 were cerebrovascular events that occurred postoperatively during the index hospitalization (12 in each group). Of the 82 strokes that occurred after the index admission, 18 strokes were hemorrhagic and 64 were ischemic. Of the 18 hemor-
rhagic strokes, 12 occurred in the mechanical prostheses group and 6 occurred in the bioprosthesis group. Of the 64 ischemic strokes, 41 occurred in the mechanical prostheses group and 23 occurred in the bioprosthesis group.

Reoperation
The cumulative incidence of mitral valve reoperation at 15 years was significantly lower in the mechanical prosthesis group (5.0%; 95% CI, 3.1%-6.9%) compared with the bioprosthesis group (11.1%; 95% CI, 7.6%-14.6%) (HR, 0.59 [95% CI, 0.37-0.94]; P = .03; Figure 2B). Forty-seven patients in the bioprosthesis group and 28 patients in the mechanical prosthesis group underwent reoperation during the study follow-up period (30-day mortality of 5.3%).

Bleeding Events
The cumulative incidence of bleeding events at 15 years after mitral valve replacement was significantly higher in the mechanical prosthesis group (14.9%; 95% CI, 11.0%-18.7%) compared with the bioprosthesis group (9.0%; 95% CI, 6.7%-11.7%).

Table 1. Patient Baseline Characteristics in the Overall Cohort According to Type of Mitral Valve Replacement

<table>
<thead>
<tr>
<th>Demographics</th>
<th>All Patients (N = 3433)*</th>
<th>Type of Mitral Valve Replacement†</th>
<th>Standardized Difference, %</th>
<th>P Value</th>
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Abbreviations: CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention.

* Data are expressed as No. (%) unless otherwise indicated.

b Percentages may not equal 100% due to rounding.
CI, 6.4%-11.5%) (HR, 1.50 [95% CI, 1.05-2.16], P = .03; Figure 2C). Forty-nine patients in the bioprosthesis group and 72 patients in the mechanical prosthesis group experienced a bleeding event during the study follow-up period (30-day mortality of 7.4%).

Unadjusted survival curves based on the entire study population of 3433 patients are presented in eFigure 2 in the Supplement. Multivariable analysis of the primary and secondary end points using the entire study population produced similar results to the analysis of the groups matched by propensity score (eTable 6 in the Supplement). The results of the subgroup analyses by age cohort (50-59 years and 60-69 years) for all end points are presented in eTable 7 and eFigure 3 in the Supplement. In addition, no significant interaction was found between prosthesis choice and age cohort for any of the end points (P = .07 for mortality, P = .62 for stroke, P = .56 for reoperation, and P = .94 for major bleeding). The 10-year estimates of actuarial survival and cumulative incidence of stroke, reoperation, and major bleeding are provided in eTable 8 in the Supplement and

### Table 2. Baseline Characteristics After Propensity Score Matching

<table>
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<tr>
<th>Demographics</th>
<th>Type of Mitral Valve Replacement*</th>
<th>Standardized Difference, %</th>
<th>P Value</th>
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<td>11.2</td>
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<td>105 (16)</td>
<td>7.7</td>
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Abbreviations: CAGB, coronary artery bypass graft; PCI, percutaneous coronary intervention.
<sup>a</sup> Data are expressed as No. (%), unless otherwise indicated.
<sup>b</sup> Percentages may not equal 100% due to rounding.
The choice between mechanical prosthetic and bioprosthetic mitral valve replacement in patients younger than 70 years is controversial. During the past decade, the use of bioprosthetic mitral valve replacement in patients aged 50 to 69 years has steadily increased from a small minority of patients to 69 years has steadily increased from a small minority of patients, and it now exceeds the use of mechanical prosthetic mitral valve replacement in patients aged 50 to 69 years has steadily increased from a small minority of patients, and it now exceeds the use of mechanical prosthetic mitral valve replacement. However, no large-scale trials. In patients with the same level of baseline comorbidity, choice of mitral valve prosthesis does not appear to be associated with any difference in survival. This was also the case in subgroup analysis of patients aged 50 to 59 years in our study cohort.

The lack of survival difference refocuses the emphasis in decision making on the relative risks of major complications, and also on quality of life. We confirmed that mechanical prosthetic mitral valve replacement is associated with a lower risk of reoperation (5.0% 15 years after mechanical prosthetic valve replacement vs 11.1% after bioprosthetic valve replacement). Importantly, the adverse effects of mitral valve reoperation in contemporary practice seems limited. The 30-day mortality after reoperation was 5.3% in this multicenter cohort, and experienced centers report even lower operative mortality and excellent functional outcomes.

Conversely, the 15-year cumulative incidence of stroke in patients with mechanical prosthetic valves was 14.0%, which is significantly higher than that of patients who received bioprosthetic valves (6.8%). Increased likelihood of stroke after mechanical prosthetic compared with bioprosthetic mitral valve replacement has been reported in previous observational studies. remains a constant risk over the lifetime of the patient, and has been shown to persist even with optimal anticoagulation. The incremental stroke risk that we observed with mechanical prosthetic valves is unlikely to be related to patient risk factors such as cerebrovascular disease, atrial fibrillation, or coagulation disorders, which had the same prevalence in each group of
our study. The adverse effect of stroke on patients was substantial. In this cohort, stroke carried a 30-day mortality of 8.5%. Similar to stroke, major bleeding events were more common in patients with mechanical prosthetic valves, and associated with 30-day mortality of 7.4%.

Consensus guidelines have increasingly emphasized patient preference in preoperative decision making.\textsuperscript{1,2,22,23} Quality-of-life surveys indicate that many patients view the distant possibility of reoperation as a reasonable trade-off for freedom from lifelong anticoagulation, reduced quality of life, and poorer perceived health status associated with mechanical prosthetic valves.\textsuperscript{24} Our data strongly suggest that the incremental risks of stroke and bleeding associated with mechanical prosthetic valve replacement should also be a major consideration in any discussion of prosthesis choice.

**Strengths and Limitations**

The main strength of using a mandatory, statewide database is that it enabled us to analyze a large volume of nonelderly patients undergoing mitral valve replacement in contemporary practice, with long-term follow-up that included key clinical outcomes in addition to survival. The main limitations of using an administrative dataset, such as SPARCS, are the accuracy of coding and the absence of potential confounding variables that could not therefore be adjusted for, including etiology of valve disease, extent of coronary artery disease, and ventricular dysfunction. As a result, there may not have been adequate control for selection bias. However, other than a higher incidence of postoperative respiratory failure in the bioprosthesis group, there were no significant differences in 30-day mortality and morbidity in this large cohort, suggesting that the treatment groups were well matched.

This dataset includes no information on specific models of valve prosthesis, echocardiographic parameters, functional status, or quality of life and no data on medical management, including anticoagulation regimens. The number of patients at risk at 15 years is relatively small, which reduces the precision of our end point risk estimates. In addition, we were unable to determine when patients were hospitalized out of state, potentially causing us to underestimate the rate of the secondary end points. However, we believe that movement out of state would affect both groups equally.

Our estimates of major bleeding may also be underestimated because we did not include iatrogenic hemmorhages related to subsequent procedures as part of our definition. These events were left out because it is impossible to differentiate between major and minor hemorrhages based on ICD-9-CM codes alone. Last, the incidence of bioprosthetic valve degeneration accelerates with time; therefore, 15-year follow-up may not be representative of the relative lifetime risks in this patient age group. A randomized study with longer follow-up, including information on quality-of-life data, could address these limitations and more fully inform clinical decision making and future guideline recommendations.
Conclusions

Among patients aged 50 to 69 years undergoing mitral valve replacement in New York State, there was no significant survival difference at 15 years in patients matched by propensity score who underwent mechanical prosthetic vs bioprosthetic mitral valve replacement. Mechanical prosthetic valves were associated with lower risk of reoperation but greater risk of bleeding and stroke. Even though these findings suggest bioprosthetic mitral valve replacement may be a reasonable alternative to mechanical prosthetic valve replacement in patients aged 50 to 69 years, the 15-year follow-up was insufficient to fully assess lifetime risks, particularly of reoperation.