

Bioprosthetic aortic valve replacement: Revisiting prosthesis choice in patients younger than 50 years old

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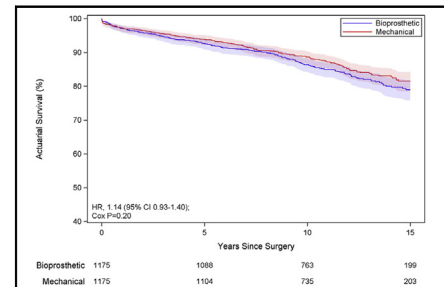
ABSTRACT

Objective: Aortic prosthesis choice is controversial in young adults because robust comparative outcome data are lacking. We therefore compared mortality and morbidity in young adults after bioprosthetic versus mechanical aortic valve replacement.

Methods: This was a retrospective analysis of 5111 patients aged 18 to 50 years undergoing primary aortic valve replacement in California and New York State from 1997 to 2006. Median follow-up time was 11.8 years (maximum 18.9 years). The primary endpoint was mortality; secondary endpoints were stroke, bleeding, and reoperation. Propensity score matching yielded 1175 patient pairs.

Results: Bioprosthetic valves increased from 14% to 47% of aortic valve replacements between 1997 and 2014 ($P < .001$). There was no survival difference with bioprosthetic versus mechanical aortic valves in the propensity score-matched cohort: actuarial 15-year survival was 79.0% (95% confidence interval [CI], 75.8%-81.8%) versus 81.5% (95% CI, 78.5%-84.2%) respectively (hazard ratio [HR], 1.14; 95% CI, 0.93-1.40, $P = .20$). No interaction was found between age and prosthesis choice on survival ($P_{\text{interaction}} = 0.16$). After bioprosthetic valve replacement, stroke rates were lower (5.4% [95% CI, 3.8%-7.2%] vs 8.1% [95% CI, 6.3%-10.2%], HR 0.62 [95% CI 0.43-0.91]), bleeding rates were lower (4.2% [95% CI, 3.0-5.6%] vs 8.4% [95% CI, 6.6-10.4%], HR 0.48 [95% CI, 0.33-0.69]), but reoperation rates were greater (24.5% [95% CI, 21.3%-27.8%] vs 9.3% [95% CI, 7.2%-11.7%], HR 5.9 [95% CI 3.2-11.0]) at 15 years versus mechanical valve replacement.

Conclusions: Although lifetime risks are represented incompletely, these findings suggest that in adults aged 18-50 years, bioprostheses are a reasonable alternative to mechanical valves for aortic valve replacement. (J Thorac Cardiovasc Surg 2017; ■:1-9)



Survival in propensity score-matched patients aged 18 to 50 years according to aortic prosthesis.

Central Message

Bioprosthetic aortic valve replacement is associated with similar survival at 15 years in adults aged younger than 50 years compared with mechanical valves, supporting expanded use of bioprostheses in young adults.

Perspective

Prosthesis choice in young adults is controversial, primarily because of the lack of robust comparative data on long-term outcomes. We quantify the recent shift in practice toward implanting bioprosthetic valves in adults aged 18 to 50 years. The similar survival, and the differences in major morbidity at 15 years support this shift in practice and should inform the valve choice in this patient cohort.

See Editorial Commentary page XXX.

Adults younger than 50 years of age comprise approximately 20% of patients undergoing aortic valve replacement surgery.¹ The optimal choice between bioprosthetic versus mechanical aortic valve replacement

is unclear, primarily because patients younger than 50 years of age have been underrepresented in the clinical trials and large registry analyses that have informed practice in older patients.²⁻⁶ Traditionally, the increased risk of reoperation for bioprosthetic valve failure was the main rationale for recommending mechanical valve replacement in younger

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Abbreviations and Acronyms

CI	= confidence interval
HR	= hazard ratio
ICD-9-CM	= <i>International Classification of Diseases, Ninth Revision, Clinical Modification</i>

patients.^{7,8} However, mechanical valves require life-long anticoagulation and substantial lifestyle modification and carry a greater long-term risk of major thromboembolic and hemorrhagic events, such as stroke, compared with bioprosthetic valves.

Consensus guideline recommendations recently were modified to include the patient's desire to avoid lifelong anticoagulation as a class I indication for implantation of a bioprosthetic rather than a mechanical valve.⁹⁻¹¹ These factors may have contributed to the recent and substantial increase in use of bioprosthetic valves in younger patients.¹ This major change in practice has occurred despite limited supporting data. We therefore designed this study with the aim of comparing long-term survival, stroke, major bleeding, and reoperation rates after bioprosthetic versus mechanical aortic valve replacement in adults aged 18 to 50 years.

METHODS

Study Design

This retrospective cohort study was conducted with the Office of Statewide Health Planning and Development in California State and the Statewide Planning and Research Cooperative System mandatory administrative databases, which capture all inpatient hospitalizations, ambulatory surgery records, and emergency department encounters in California and New York State. The study included all patients undergoing primary aortic valve replacement in California and New York State, aged 18 to 50 years, from January 1, 1997, to December 31, 2006. Exclusion criteria consisted of out-of-state residency; previous congenital cardiac history or procedures; previous or active endocarditis; previous valve replacement or repair or concomitant replacement or repair of any other valve; concomitant coronary bypass surgery; previous heart transplantation, and concomitant congenital cardiac procedures (Table E1).

The patient cohort was identified with *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) procedure codes: 35.21 for bioprosthetic aortic valve replacement and 35.22 for mechanical aortic valve replacement. Baseline comorbidities were identified with ICD-9-CM procedure and diagnosis codes from both the index admission and previous inpatient hospitalizations within the past 2 years of the index visit (Table E2). The study was approved by the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai, the Committee for the Protection of Human Subjects of California State, and the New York State Department of Health data protection review board. These approvals included a waiver of informed consent.

Study End Points

The primary outcome measure was all-cause mortality. Secondary outcome measures included stroke, major bleeding, and reoperation on the aortic valve. Mortality in California and New York State was identified from each state's vital death records, which were linked to the datasets through each state's Department of Health. Mortality was further identified

by discharge disposition from any inpatient, emergency department, or ambulatory surgery visits after the index admission. The Social Security Death Master File also was used. Stroke was defined as a postoperative cerebrovascular accident during the index admission or a primary diagnosis of hemorrhagic or ischemic cerebrovascular event during any subsequent admission. This definition did not include transient ischemic attacks. Major bleeding events were defined by a primary diagnosis of intracerebral hemorrhage, hemopericardium, cardiac tamponade, gastrointestinal hemorrhage, hematuria, hemarthrosis, hemoptysis, epistaxis, or ocular hemorrhage requiring inpatient admission (Tables E3 and E4). Reoperation was defined as any operation involving the aortic valve replacement. Any patient free from death, stroke, major bleeding, or reoperation was censored on December 31, 2015, which was the most recent follow-up date available for clinical events.

Statistical Analysis

Continuous variables are reported as means with standard deviations, whereas categorical variables are reported as proportions. Differences in baseline demographics between bioprosthetic and mechanical valve replacement group patients were detected with the *t* test for normally distributed continuous variables and the Pearson χ^2 test for categorical variables as appropriate. Normality was assessed in continuous variables by the Kolmogorov test, and non-normal continuous variables are reported with medians and interquartile ranges; differences in these variables were analyzed with the Wilcoxon-Mann-Whitney test. Trend analysis was performed with the Cochran-Armitage test on the patients who underwent aortic valve replacement between January 1, 1997, and December 31, 2014.

To adjust for confounding from intrinsic differences between the 2 valve replacement groups, propensity score matching was performed. Propensity scores were calculated with a hierarchical logistic regression with bioprosthetic valve implantation as the outcome and all patients clustered within their respective hospitals. All patient baseline characteristics (age, sex, race, coagulation defects, hypertension, diabetes, coronary artery disease, peripheral vascular disease, cerebrovascular disease, congestive heart failure, atrial fibrillation, chronic obstructive pulmonary disease, chronic kidney disease, liver disease, cancer), admission urgency, index surgery year, and concomitant operation of the aorta, were included as covariates. The area under the receiver operating characteristic curve for the model was 0.77. Patients were matched 1:1 using a caliper of 0.1 of the logit of the propensity score. Differences in baseline characteristics as well as 30-day complication rates were analyzed with the paired *t* test and the Wilcoxon signed rank sum test for normally distributed and non-normally distributed continuous variables, respectively; the McNemar test was used to detect differences between categorical variables. Standardized differences were reported as well.

Survival curves of the primary outcome of mortality were constructed with the Kaplan-Meier method; prostheses were compared with a marginal Cox model with a robust sandwich variance estimator. Competing risk analysis of the secondary outcomes—stroke, major bleeding, and reoperation—was performed by creating cumulative incidence functions and comparing them between prosthesis groups via the Gray test. For each end point, hazard ratios (HRs) were calculated with Cox proportional hazards models. The proportional hazards assumption was assessed in each model and found to be intact except reoperation and, if violated, the hazard ratios at different follow-up time points were reported.

To assess the robustness of the findings, all analyses were repeated in the full patient cohort as a sensitivity analysis via multivariable analysis with marginal Cox models with robust sandwich variance estimators, which we controlled for admission urgency, index surgery year, concomitant operation of the aorta, age, sex, race, coagulation defects, hypertension, diabetes, coronary artery disease, peripheral vascular disease, cerebrovascular disease, congestive heart failure, atrial fibrillation, chronic obstructive pulmonary disease, chronic kidney disease, liver disease, cancer, and clustering of patients within hospitals. We further conducted a sensitivity analysis for survival incorporating the interaction term

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