Long-Term Safety and Effectiveness of Mechanical Versus Biologic Aortic Valve Prostheses in Older Patients

Results From the Society of Thoracic Surgeons Adult Cardiac Surgery National Database

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Background—There is a paucity of long-term data comparing biological versus mechanical aortic valve prostheses in older individuals.

Methods and Results—We performed follow-up of patients aged 65 to 80 years undergoing aortic valve replacement with a biological (n=24410) or mechanical (n=14789) prosthesis from 1991 to 1999 at 605 centers within the Society of Thoracic Surgeons Adult Cardiac Surgery Database using Medicare inpatient claims (mean, 12.6 years; maximum, 17 years; minimum, 8 years), and outcomes were compared by propensity methods. Among Medicare-linked patients undergoing aortic valve replacement (mean age, 73 years), both reoperation (4.0%) and endocarditis (1.9%) were uncommon in 12 years; however, the risk for other adverse outcomes was high, including death (66.5%), stroke (14.1%), and bleeding (17.9%). Compared with those receiving a mechanical valve, patients given a bioprosthesis had a similar adjusted risk for death (hazard ratio, 1.04; 95% confidence interval, 1.01–1.07), higher risks for reoperation (hazard ratio, 2.55; 95% confidence interval, 2.14–3.03) and endocarditis (hazard ratio, 1.60; 95% confidence interval, 1.31–1.94), and lower risks for stroke (hazard ratio, 0.87; 95% confidence interval, 0.82–0.93) and bleeding (hazard ratio, 0.66; 95% confidence interval, 0.62–0.70). Although these results were generally consistent among patient subgroups, bioprosthesis patients aged 65 to 69 years had a substantially elevated 12-year absolute risk of reoperation (10.5%).

Conclusions—Among patients undergoing aortic valve replacement, long-term mortality rates were similar for those who received bioprosthesis versus mechanical valves. Bioprostheses were associated with a higher long-term risk of reoperation and endocarditis but a lower risk of stroke and hemorrhage. These risks varied as a function of a patient’s age and comorbidities. (Circulation. 2013;127:1647-1655.)

Key Words: aortic valve ■ comparative effectiveness research ■ heart valve prosthesis

In recent years, nearly 80000 aortic valve replacements (AVRs) have been performed annually in the United States1 in an increasingly older and sicker patient population.2 Among older patients, bioprostheses are an attractive alternative to the more thrombogenic mechanical prostheses3,4; however, data regarding the long-term safety and effectiveness of biological versus mechanical prostheses among elderly AVR patients are limited. Most clinical trial data5,6 are now 3 decades old and no longer reflect the current state of technology nor the population characteristics encountered in clinical practice. Furthermore, observational analyses have been limited, lacking both (1) clinical and procedural details necessary for accurate treatment assignment and risk adjustment5 and (2) sufficient power and generalizability to provide reliable comparisons.9,10

Clinical Perspective on p 1655

In response to the need for better data on the relative safety and effectiveness of aortic valve prostheses in older patients, we identified a cohort of Medicare-linked AVR patients within the Society of Thoracic Surgeons Adult Cardiac Surgery Database (STS ACSD). Using this cohort, we sought to (1) evaluate...
long-term mortality and valve-related complications in older individuals treated with bioprosthetic versus mechanical aortic valves and (2) examine the consistency of these findings among strata of commonly encountered patient subgroups.

Methods
Since 1991, the STS ACSD has collected detailed in-hospital data on adult patients undergoing cardiac surgery with the aim of improving quality of care and postoperative outcomes,11 with >1000 currently participating institutions throughout the United States. For the purposes of the present study, we identified a cohort of Medicare-linked fee-for-service patients between 65 and 80 years of age undergoing elective or urgent AVR with a mechanical or biological prosthesis from January 1, 1991, to December 28, 1999; therefore, each patient in the analysis cohort had at least 8 years of available follow-up data. From this cohort, we excluded patients undergoing concomitant non–coronary artery bypass graft cardiac surgical procedures and those with a prior history of any valve replacement. Additionally, we excluded patients at health maintenance organizations and military hospitals where no patients were linked to Medicare records with potential linkage to multiple Medicare files, and those with index procedures that occurred outside a period of fee-for-service Medicare enrollment.

Follow-Up Information
To obtain follow-up information on the study cohort, we linked de-identified STS patient records with research-identifiable Medicare inpatient standard analytic claims files through December 31, 2007, using combinations of indirect identifiers, including age, sex, and dates of birth, admission, and discharge (linkage rate, 76.8%).12 Compared with patients in the Medicare-linked population, eligible patients who were not linked were on average slightly younger (75 versus 76 years), less often female (39.0% versus 40.8%), less often white (86.2% versus 92.1%), less often undergoing elective procedures (73.4% versus 75.5%), and less likely to receive biological prostheses (80.7% versus 82.8%). Otherwise, matched and unmatched patients were similar across demographics and comorbidities of interest. The Duke University School of Medicine Institutional Review Board granted a waiver of informed consent and authorization for this study.

Clinical End Points
The primary end point was all-cause mortality, identified with the Medicare denominator file. Secondary end points were identified with primary hospital diagnosis International Classification of Diseases, Ninth Revision, Clinical Modification codes and included rehospitalization for aortic valve reoperation, cerebrovascular accident, hemorrhagic cerebrovascular accident, hemorrhage, and endocarditis as identified with International Classification of Diseases, Ninth Revision, Clinical Modification codes (Appendix I in the online-only Data Supplement).

Statistical Analysis
Summary statistics for baseline patient characteristics, based on non-missing values, were stratified by device type and are presented as percentages for categorical variables and means with SDs for continuous variables. The frequency of missing data was also summarized for those baseline characteristics. The Mantel-Haenszel test was used to compare the distribution of categorical variables between groups, whereas the Wilcoxon rank sum test was used to compare continuous variable distributions. SAS statistical software (version 9.1; SAS Institute, Cary, NC) was used for all calculations.

Temporal trends in the use of bioprosthetic valves in the aortic position among 65- to 80-year-old patients in the overall STS ACSD and the Medicare-linked cohort from 1991 to 1999 were calculated as a function of the total AVR volume to account for the increasing penetrance of the database across this timeframe. The frequencies of the specific valve prostheses used in this cohort are presented in Table I in the online-only Data Supplement.

Patients receiving biological and mechanical aortic prostheses were compared by use of propensity scores with inverse probability weighting to adjust for differences in baseline characteristics between the 2 treatment groups. The propensity score represents the estimated probability of patients receiving a biological (versus mechanical) prosthesis as a function of the covariates in the propensity model.13 Propensity scores were estimated with a nonparsimonious logistic regression model, which included each of the variables listed in Appendix II in the online-only Data Supplement. The propensity model included interactions between the year of surgery and each of the other variables in the model. To account for changes in data definitions and quality over the study period, we estimated a separate set of regression coefficients for each calendar year.

The ability of the propensity model to balance the 2 treatment groups was assessed in 2 ways. First, we compared the distribution of estimated propensity scores in the 2 treatment groups to ensure that there was a high degree of overlap. The 5-number summaries (minimum; 25th, 50th, and 75th percentiles; maximum) of the propensity distributions in each treatment group were similar (bioprosthetic: 6.20%, 57.84%, 72.25%, 81.53%, and 97.80%, respectively; mechanical: 3.38%, 36.64%, 51.85%, 68.14%, and 96.43%, respectively), which suggests that comparisons based on the propensity score were statistically appropriate. To further increase the comparability between the 2 groups, patients with propensity scores that were not in the range of overlapping propensity distributions (i.e., <6.20% or >96.43%) were omitted from the risk-adjusted analysis. Next, we compared the distribution of patient characteristics across the 2 treatment groups before and after propensity score weighting; the observed differences in covariates were small and in all cases were <5% of the estimated SD.14

The time-to-event analysis assumed noninformative censoring. Patient follow-up was considered censored at the end of the study period (December 31, 2007) or on the first month of health maintenance organization enrollment (whichever occurred first). The unadjusted hazard ratio (HR) comparing mortality risk for biological versus mechanical prostheses was estimated in a Cox regression model with a single treatment group indicator. Adjusted HRs (biological versus mechanical prostheses) were estimated by fitting a Cox regression model with a single treatment group indicator and weighting each observation by the inverse of the estimated propensity score.15 The association between valve type and each nonfatal end point was analyzed by modeling the cause-specific hazard function in each treatment group. Specifically, we assumed that the cause-specific hazard functions were proportional. This methodology was equivalent to fitting a standard Cox model and treating mortality as a censoring variable. The proportional hazards assumption was evaluated for each outcome by visual inspection of both cumulative hazards plots and log cumulative hazards plots. By visual inspection, the proportional hazards assumption was satisfied for stroke, bleeding, and endocarditis. For aortic valve reoperation, the proportional hazards assumption was less clearly satisfied; however, we elected to present a single combined estimate for this outcome because the treatment effect was in the same direction over time without overlap of the hazards function. For mortality, survival curves clearly violated the proportional hazards assumption (with overlap shown in Figure 1). Therefore, for this end point, we have presented time-dependent HRs for each of 3 time periods, which correspond to early follow-up (0–3 months), midterm follow-up (3 months to 9 years), and late follow-up (>9 years). Robust sandwich variance estimates16 were used to obtain 95% confidence intervals (CIs) of coefficients.

The unadjusted cumulative incidence of mortality was estimated for each treatment group by the product-limit method of Kaplan and Meier17; the propensity-adjusted incidence of mortality was calculated for each treatment group with the Breslow estimator18 based on the inverse probability-weighting Cox model. A similar approach was also used for the aortic valve repair or replacement end point. The cumulative incidence rate for other nonfatal rehospitalization end points was analyzed with the competing risk methods of Kalbfleisch and Prentice to account for the role of death in preventing subsequent hospitalizations.19 For hemorrhage, hemorrhagic stroke, stroke,
congestive heart failure, and endocarditis, our analyses focused on estimating the actual probability of the event (ie, the probability that it would occur before a patient died), whereas analyses of aortic valve repair or replacement focused on estimating the probability of valve failure in a death-free environment. 

The cumulative incidence of adverse events is reported at 12 years in the primary text of this article; however, the cumulative incidence for each end point is reported annually through 15 years of follow-up in Table II in the online-only Data Supplement to facilitate comparisons with other available studies. HRs represent data from the full follow-up interval.

**Analysis of Missing Data**

Missing data in the baseline characteristics (used for adjusted analyses) were handled by multiple imputations under the assumption of being missing at random. The multiple imputation procedure was performed with R software (www.R-project.org) with the add-on library package Multivariate Imputation by Chained Equations (MICE). This package generates multiple imputations for incomplete multivariate data by Gibbs sampling. Imputation was performed separately for each calendar year with the covariates from the propensity model plus valve type and preoperative use of digitalis, diuretic, or β-blocker. Ten complete imputed data sets were created. The standard analyses, including the baseline characteristic summary statistics and the risk-adjusted analyses (described in Statistical Analysis), were performed separately for each of the completed datasets. The 10 sets of results were then combined by the method proposed by Rubin.

**Subgroup Analyses**

Prospectively derived subgroups were identified with STS data files and included age (65–69, 70–74, and 75–80 years), sex, preoperative left ventricular ejection fraction (<50% or ≥50%), and preoperative renal function. Consistent with STS ACSD data definitions, renal failure was defined as a serum creatinine level >2.0 mg/dL or need for dialysis. The inverse probability-weighting Cox model was applied within each stratum of these 4 prespecified groups to estimate stratum-specific treatment effects.

**Results**

**Population Characteristics**

The Medicare-linked study cohort (aged 65–80 years) included 39,199 patients who received biological (n=24,410) or mechanical (n=14,789) aortic valve prostheses from 605 hospital centers (Figure 2), with a median age of 73 years and a mean follow-up of 12.6 years (maximum, 17 years; minimum, 8 years). Bioprostheses were used with increasing frequency among progressively older patients, and a 20% absolute increase in the use of bioprostheses was observed across the spectrum of age from 1991 to 1999 (Figure 3). Compared with patients who received mechanical valves, those who received bioprosthetic valves were on average older (74 versus 71 years), with a higher prevalence of both heart failure (43.7% versus 39.9%) and significant coronary artery disease (70.1% versus 65.6%) but a similar prevalence of most other comorbidities (Table). Intraoperative characteristics were similar for patients with bioprosthetic versus mechanical valves, with a similar proportion of patients undergoing elective procedures (82.5% versus 82.8%) and a similar mean time on cardiopulmonary bypass (132.9 versus 132.3 minutes). Patients with bioprosthetic valves were more likely to undergo concomitant coronary artery bypass graft surgery (60.1% versus 55.2%) and slightly more likely to receive a larger prosthesis (>21 mm: 58.8% versus 56.6%). After propensity weighting, patient and operative characteristics were well balanced across treatment groups (Table).
Long-Term Outcomes

All-Cause Mortality
In this Medicare-linked cohort, the 12-year incidence of all-cause mortality after AVR was 70.5% for patients who received bioprosthetic valves and 60.3% for those who received mechanical valves (unadjusted HR, 1.29; 95% CI, 1.26–1.32). After risk adjustment, patients who received bioprosthetic valves experienced a similar long-term mortality rate as those who received mechanical valves (adjusted HR, 1.04; 95% CI, 1.01–1.07; Figure 1); however, mortality rates were higher beyond 9 years of follow-up in patients treated with bioprosthetic valves than those given mechanical valves (Figures 1 and 4), a result that differed significantly from earlier time periods (P<0.002, comparing the adjusted HR in late follow-up versus either early or midterm follow-up).

The absolute risk of long-term mortality varied widely across patient subgroups and was particularly high among patients with either preoperative renal failure (12-year mortality, 65.2%) or reduced left ventricular ejection fraction (12-year mortality, 74.1%; Figure 4). The relative mortality rate associated with valve type varied according to patient age and comorbidities (P value for interaction was significant [<0.05] across all subgroups of interest, including age, sex, left ventricular ejection fraction, and renal function). For example, bioprostheses were associated with a 23% increased mortality rate among the youngest patients (65–69 years; adjusted HR, 1.23; 95% CI, 1.16–1.31), without a meaningful difference among 70- to 80-year-old patients (Figure 4).

Aortic Valve Reoperation
The incidence of aortic valve reoperation was higher among patients who received bioprosthetic valves than among those who received mechanical valves throughout follow-up (unadjusted HR, 1.91; 95% CI, 1.64–2.22). By 12 years, reoperation was observed in 5.2% of patients with bioprosthetic valves and 2.3% of those with mechanical valves. Among the youngest patients (65–69 years), the incidence of bioprosthetic valve reoperation was 10.5%, which was >3 times the incidence observed among the oldest patients (75–80 years, 2.9%; Figure 5). After risk adjustment, bioprosthetic valves were associated with a >2-fold increase in the long-term rate of reoperation compared with mechanical valves in the overall population (adjusted HR, 2.55; 95% CI, 2.14–3.03; Figure 1) and across most patient subgroups. This effect was larger among younger (compared with older) patients (P interaction<0.05) but was similar across strata of other subgroups of interest.

Stroke
The 12-year incidence of stroke (all-cause) requiring rehospitalization was high among patients receiving either bioprosthetic or mechanical aortic valves (13.8% versus 14.7%; unadjusted HR, 1.00; 95% CI, 0.95–1.06). After adjustment for baseline risk, the rate of stroke was significantly lower among patients with bioprosthetic valves than among those with mechanical valves in the overall cohort (adjusted HR, 0.87; 95% CI, 0.82–0.93) and in most of the prespecified subgroups (Figure I in the online-only Data Supplement).
Bleeding

By 12 years, rehospitalization for a bleeding event occurred in 15.5% of patients with bioprosthetic valves and 21.8% of those with mechanical valves (unadjusted HR, 0.75; 95% CI, 0.71–0.78), with hemorrhagic stroke occurring in 2.2% and 3.7%, respectively (unadjusted HR, 0.57; 95% CI, 0.49–0.65), a finding that was consistent across each of the prespecified subgroups (Figures II and III in the online-only Data Supplement).

Endocarditis

The 12-year incidence of rehospitalization for endocarditis was 2.2% for patients given bioprosthetic valves and 1.4% for those given mechanical valves (unadjusted HR, 1.60; 95% CI, 1.31–1.94) and in each of the prespecified subgroups, except among the oldest patients (75–80 years; adjusted HR, 1.17; 95% CI, 0.85–1.60) and those with renal failure (adjusted HR, 0.69; 95% CI, 0.29–1.66; Figure IV in the online-only Data Supplement).

Discussion

This study provides a contemporary view of long-term outcomes with biological versus mechanical prostheses for AVR in older individuals in the United States. Several important findings stem from these results. Although overall mortality was similar between patients who received bioprosthetic and mechanical valves, mechanical valves were generally associated with a lower risk-adjusted mortality rate beyond 9 years. The incidence of aortic valve reoperation was substantially higher among patients with bioprosthetic valves experienced a higher risk of endocarditis than those who received mechanical valves in the overall cohort (adjusted HR, 1.60; 95% CI, 1.31–1.94) and in each of the prespecified subgroups, except among the oldest patients (75–80 years; adjusted HR, 1.17; 95% CI, 0.85–1.60) and those with renal failure (adjusted HR, 0.69; 95% CI, 0.29–1.66; Figure IV in the online-only Data Supplement).

Table. Population Characteristics Stratified by Valve Type

<table>
<thead>
<tr>
<th>Patient Characteristics, %</th>
<th>Missing, %</th>
<th>Mechanical (n=14,789)</th>
<th>Bioprosthetic (n=24,410)</th>
<th>P Value</th>
<th>Mechanical (n=14,789)</th>
<th>Bioprosthetic (n=24,410)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>0</td>
<td>71.21 (4.15)</td>
<td>74.20 (3.94)</td>
<td>&lt;0.0001</td>
<td>73.07 (4.29)</td>
<td>73.07 (4.26)</td>
<td>0.94</td>
</tr>
<tr>
<td>Female, %</td>
<td>0.06</td>
<td>38.94</td>
<td>39.00</td>
<td>0.92</td>
<td>39.84</td>
<td>39.29</td>
<td>0.35</td>
</tr>
<tr>
<td>Race, %</td>
<td>3.36</td>
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</tr>
<tr>
<td>White</td>
<td>95.09</td>
<td>94.41</td>
<td>94.42</td>
<td>0.68</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Black</td>
<td>2.30</td>
<td>2.96</td>
<td>2.86</td>
<td>0.69</td>
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<td></td>
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<tr>
<td>Hispanic</td>
<td>1.35</td>
<td>1.16</td>
<td>1.36</td>
<td>0.58</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>0.47</td>
<td>0.55</td>
<td>0.51</td>
<td>0.95</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Other</td>
<td>0.79</td>
<td>0.93</td>
<td>0.84</td>
<td>0.69</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking, ever, %</td>
<td>4.34</td>
<td>50.47</td>
<td>49.11</td>
<td>0.11</td>
<td>50.49</td>
<td>50.35</td>
<td>0.81</td>
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<tr>
<td>BSA, mean (SD)</td>
<td>5.22</td>
<td>1.89 (0.25)</td>
<td>1.87 (0.23)</td>
<td>&lt;0.0001</td>
<td>1.87 (0.24)</td>
<td>1.87 (0.23)</td>
<td>0.082</td>
</tr>
<tr>
<td>Ejection fraction, %</td>
<td>21.66</td>
<td>51.67 (14.84)</td>
<td>51.07 (14.73)</td>
<td>0.0020</td>
<td>51.48 (14.79)</td>
<td>51.45 (14.88)</td>
<td>0.90</td>
</tr>
<tr>
<td>CHF, %</td>
<td>12.54</td>
<td>39.89</td>
<td>43.66</td>
<td>&lt;0.0001</td>
<td>40.81</td>
<td>40.59</td>
<td>0.71</td>
</tr>
<tr>
<td>Diabetes mellitus, %</td>
<td>4.35</td>
<td>24.50</td>
<td>24.49</td>
<td>0.99</td>
<td>25.51</td>
<td>25.43</td>
<td>0.88</td>
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<tr>
<td>Dialysis, %</td>
<td>5.84</td>
<td>1.36</td>
<td>1.10</td>
<td>0.025</td>
<td>2.27</td>
<td>2.23</td>
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<td>Infectious endocarditis history, %</td>
<td>7.34</td>
<td>1.14</td>
<td>1.16</td>
<td>0.85</td>
<td>2.54</td>
<td>2.64</td>
<td>0.64</td>
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<tr>
<td>Aortic valve insufficiency (moderate-severe), %</td>
<td>36.47</td>
<td>32.67</td>
<td>32.12</td>
<td>0.13</td>
<td></td>
<td></td>
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<tr>
<td>Aortic valve stenosis, %</td>
<td>6.94</td>
<td>89.13</td>
<td>89.64</td>
<td>0.13</td>
<td></td>
<td></td>
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<tr>
<td>No significant CAD, %</td>
<td>14.43</td>
<td>34.38</td>
<td>29.89</td>
<td>&lt;0.0001</td>
<td>30.01</td>
<td>29.93</td>
<td>0.87</td>
</tr>
<tr>
<td>Mean follow-up (SD)</td>
<td>0</td>
<td>4754 (804)</td>
<td>4525 (791)</td>
<td>&lt;0.0001</td>
<td></td>
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<tr>
<td>Operative characteristics, %</td>
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<td></td>
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<tr>
<td>Procedural status</td>
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<td>0.43</td>
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<tr>
<td>Elective</td>
<td>82.76</td>
<td>82.45</td>
<td>82.12</td>
<td>82.33</td>
<td>0.66</td>
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<tr>
<td>Urgent</td>
<td>17.24</td>
<td>17.55</td>
<td>17.81</td>
<td>17.64</td>
<td>0.72</td>
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<tr>
<td>AVR + CABG</td>
<td>0</td>
<td>55.21</td>
<td>60.12</td>
<td>&lt;0.0001</td>
<td>58.10</td>
<td>58.22</td>
<td>0.83</td>
</tr>
<tr>
<td>Prosthesis size, mm</td>
<td></td>
<td>&lt;0.0001</td>
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<tr>
<td>19/21</td>
<td>43.41</td>
<td>41.21</td>
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<tr>
<td>&gt;21</td>
<td>56.59</td>
<td>58.79</td>
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<tr>
<td>Time on cardiopulmonary bypass, mean (SD), min</td>
<td>1.18</td>
<td>132.31 (54.11)</td>
<td>132.87 (53.09)</td>
<td>0.012</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

*Summary statistics are based on nonmissing values.

AVR indicates aortic valve replacement; BSA, body surface area; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CHF, congestive heart failure; and IPW, inverse probability weighting.
valves than those with mechanical valves, and this difference was especially pronounced among the youngest AVR patients (65–69 years), in whom the observed 12-year bioprosthetic valve reoperative rate reached 10.5%. Finally, rehospitalization for both bleeding and stroke was higher among patients with mechanical aortic valves, although endocarditis was more common among those with bioprosthetic valves. These data highlight the complexity of selecting an appropriate prostheses in elderly patients undergoing AVR.

**Mortality**

The 12-year incidence of mortality (66.5%) was high in this older Medicare-linked AVR cohort. This risk was age-dependent, ranging from 53% among 65- to 69-year-olds to 77% among those 75 to 80 years old. Direct comparison with clinical trial results is limited by the substantially younger age of patients tested in the Edinburgh (1975–1979; mean age, 54 years) and Veterans Affairs Cooperative (1977–1982; mean age, 59 years) studies; however, the decision analysis by Birkmeyer et al provides some insight. On the basis of a pooled analysis of the Edinburgh and Veterans Affairs Cooperative study data, Birkmeyer et al reported 12-year mortality estimates of 62% for patients 70 years of age. These results are nearly identical to those observed in the STS Medicare-linked cohort (70–74 years old, 64%), which suggests very little improvement in long-term patient outcomes after AVR from the 1970s to 1990s. Nevertheless, caution should be used in the interpretation of these data, because previous work has demonstrated that both (1) the burden of comorbidities in patients undergoing AVR has increased over time, and (2) long-term mortality after AVR is more closely related to complications associated with patient comorbidities than with prosthetic failure.

In the overall study cohort, long-term mortality rates were similar across prostheses (HR, 1.04); however, the prosthetic-associated relative risk varied across patient subgroups and over the duration of follow-up. For example, among the youngest patients (65–69 years of age), mechanical valves were associated with a 23% relative reduction in the risk-adjusted long-term mortality rate compared with bioprostheses;
however, this benefit was not observed among patients 70 to 80 years of age. Additionally, among patients surviving to 9 years after AVR, bioprosthetic valves were associated with a significantly higher mortality rate than the overall cohort and among most patient subgroups. This finding is consistent with those of both the Veterans Affairs Cooperative study and the Edinburgh trial, which reported a late (10–15 year) increase in excess mortality among bioprosthetic valve patients.

### Aortic Valve Reoperation

Valve degeneration remains an important concern in the selection of appropriate aortic valve prosthesis. In this older cohort, the 12-year incidence of bioprosthetic aortic valve reoperation (4.0%) was substantially lower than that reported from either the Edinburgh study (11.3% at 10 years) or the Veterans Affairs Cooperative study (29% at 15 years). Although this risk was similar across most subgroups, the 12-year incidence of aortic valve reoperation in the present study was substantially higher among the youngest (65–69 years) patients who received bioprosthetic valves (10.5% at 12 years), a result that is consistent with previous randomized and observational data. In keeping with prior recommendations, this estimate is based on the probability of valve failure in a “death-free” environment (ie, “actuarial probability”). As a result, reoperative rates described here approximate valve durability, with limited influence by patient survival. In other words, the high risk of reoperation observed among the youngest patients is not explained by the expectation that these patients will live longer (and, therefore, have more time at risk) than the older patients. Nevertheless, 2 alternative explanations remain. First, the durability of bioprosthetic valves may truly be reduced in younger patients, perhaps as a function of differences in calcium metabolism or increased mechanical stress inflicted on the valve by a more active, younger cohort. Alternatively, this finding may be attributable in part to a referral bias in favor of reoperation among younger patients with a lower expected operative risk.

Compared with patients who received mechanical valves, those receiving bioprostheses experienced a significantly higher risk for reoperation (HR, 2.55), a result that persisted across the spectrum of patient age. Unlike prior studies, this difference was observed throughout the follow-up interval; however, similar to previous reports, this difference appeared to accelerate beyond 7 to 8 years of follow-up.

### Stroke and Bleeding

The risk of rehospitalization for either stroke or bleeding was high in this elderly cohort. Offsetting the late survival and durability advantages of mechanical valves, both stroke and bleeding were less common among patients who received bioprosthetic valve. For example, in the overall cohort, bioprostheses were associated with a 13% relative reduction in the risk of stroke. Although the absolute magnitude of this risk is consistent with prior analyses, randomized comparisons have not previously demonstrated a significantly lower risk of thromboembolism in patients treated with bioprostheses (versus those with mechanical valves who are treated with warfarin therapy). Despite a low perceived risk of stroke in patients with bioprostheses, its incidence remains high in this group. It is unclear whether this risk is concentrated within a group of patients who carry or develop traditional risk factors for ischemic stroke after AVR (eg, atrial fibrillation or reduced left ventricular ejection fraction); it is also unknown whether the benefits of vitamin K inhibition or alternative anticoagulation regimens (ie, direct thrombin inhibitors or factor Xa inhibitors) would outweigh their risks in this cohort, especially given the demonstrated risk of hemorrhagic stroke (3.7% by 12 years) in those patients who were presumably treated with warfarin therapy in the setting of a mechanical valve prosthesis.

### Practical Applications

The results presented in the present analysis demonstrate the complexities and trade-offs of selecting an aortic valve prosthesis in older patients. This decision is ultimately one that must be made in conjunction with the patient; however, examination of results from 3 important subgroups may help inform this discussion. First, among patients ≥70 years of age, bioprostheses offer at least equivalent survival to mechanical valves, with a lower risk of stroke and hemorrhage, yet the use of bioprostheses in these patients comes at the expense of a slightly higher absolute risk of both reoperation and endocarditis. Second, for patients between 65 and 69 years...
of age, mechanical valves are associated with a slightly lower long-term relative risk of mortality and a substantially lower risk (both absolute and relative) of reoperation than bioprosthetic valves, yet the use of mechanical valves in this younger cohort carries an increased long-term risk of rehospitalization for hemorrhage and stroke. Finally, among older patients with renal failure, bioprostheses are associated with a lower long-term risk of mortality, hemorrhage, and stroke than mechanical valves, without an associated increase in the risk of either reoperation or endocarditis.

Study Limitations
This study is among the largest evaluations of valve-specific long-term outcomes after AVR in contemporary practice and builds on the recent claims-based analysis of Schelbert et al through the use of clinical (rather than claims) data for both risk adjustment and treatment assessment. The limitations of claims data for the assessment of baseline risk have been well documented. Here, we have also demonstrated the limitations of claims data for the assessment of treatment status. Between 1991 and 1999, bioprostheses were used in 62% of AVR operations in Medicare-linked STS patients 65 to 80 years of age, with increasing frequency across this interval. By comparison, only 39% of AVR operations during a similar time period (1997–1999) were classified as involving bioprostheses when a claims-based International Classification of Diseases, Ninth Revision, Clinical Modification algorithm was used for device identification in the Schelbert et al analysis. This finding highlights an important advantage of registry-based comparative analyses, and it may account for inconsistencies between the data reported here and those previously reported from the overall Medicare cohort.

Although this study has several inherent strengths, it also has important limitations. First, the comparisons presented here are not randomized. We attempted to limit selection bias by choosing a patient cohort in which some degree of equipoise existed for the use of either a mechanical or bioprosthetic valve. The reasonable degree of baseline overlap in the propensity distributions across the 2 treatment groups and the balance achieved across observed covariates in these 2 groups after inverse probability weighting suggest that we achieved this goal. Despite these efforts, as with any observational analysis, unmeasured confounders may have influenced the accuracy of the reported comparisons. Because mechanical prostheses tend to be used only in healthier elderly patients, the direction of this potential bias would be expected to favor patients receiving mechanical valves. Second, although use of the 1991 to 1999 data ensured that all patients had a minimum of 8 years of follow-up, recent advances in bioprosthetic and mechanical valve technology may have altered the relative treatment effects in contemporary practice. Third, the present analysis assumed consistency of effect across the various biological and mechanical prostheses. Although potential differences in model-specific outcomes may be the focus of future efforts, this analysis was not designed to compare outcomes across specific valve models. Fourth, although the linkage rate between STS and Medicare files was within expected bounds, it was not perfect. A comparison of matched and unmatched patients demonstrated a high level of overlap between these 2 groups but enhanced the generalizability of these findings. Finally, the results presented here were drawn from a 65- to 80-year-old patient cohort. Our results build on a substantial body of knowledge that suggests that the relative effectiveness of bioprosthetic versus mechanical valves is highly dependent on patient age at the time of implantation. Therefore, these results should not be viewed as generalizable to younger patients.

Conclusions
Among older individuals, the incidence of both mortality and valve-associated morbidities is high in the first 12 years after AVR. Mechanical valves are associated with improved late survival and long-term prosthesis durability; however, these gains are achieved at the cost of an increased incidence of bleeding and stroke among patients receiving mechanical valves. The comparative safety and effectiveness of prosthetic heart valves are highly dependent on patient age and underlying comorbidities, and the choice of an appropriate prosthesis remains complex. Ultimately, the most appropriate prosthesis for a given patient can only be determined through careful discussion between patients and their healthcare providers.

Acknowledgments
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Disclosures
Dr Edwards reports the receipt of grant support from the University of Florida (significant). Dr Peterson reports the receipt of grant support from the Society of Thoracic Surgeons Data Warehouse Coordinating Center (significant). The other authors report no conflicts.

References

**CLINICAL PERSPECTIVE**

Estimates indicate that nearly 80,000 aortic valve replacements are performed annually in the United States on an increasingly older and sicker population, yet data are scarce regarding the relative safety and effectiveness of aortic valve prosthesis in elderly patients. Using data from the Society of Thoracic Surgeons Adult Cardiac Surgery Database, we followed patients aged 65 to 80 years undergoing aortic valve replacement (with a biological or mechanical prosthesis) from 1991 to 1999 at 605 centers. We sought to evaluate the long-term mortality and valve-related complications in bioprosthetic versus mechanical aortic valves, as well as the consistency of our findings among commonly encountered patient subgroups. We found that among the elderly, the incidence of both mortality and valve-associated morbidities was high in the first 12 years after aortic valve replacement. Mechanical valves were associated with improved late survival and long-term prosthetic valve durability, yet they were also associated with an increased incidence of bleeding and stroke. In summary, the comparative safety and effectiveness of prosthetic heart valves was highly dependent on patient age and underlying comorbidities. Our findings emphasize the complexity of choosing an appropriate prosthesis based on the individual needs and risks specific to each patient. These findings highlight the necessity for careful discussion and thorough communication between patients and their healthcare providers, in hopes of making an appropriate decision that is tailored to each individual patient’s unique profile.
Long-Term Safety and Effectiveness of Mechanical Versus Biologic Aortic Valve Prostheses in Older Patients: Results From the Society of Thoracic Surgeons Adult Cardiac Surgery National Database

J. Matthew Brennan, Fred H. Edwards, Yue Zhao, Sean O’Brien, Michael E. Booth, Rachel S. Dokholyan, Pamela S. Douglas and Eric D. Peterson
on behalf of the DEcIDE AVR (Developing Evidence to Inform Decisions about Effectiveness Aortic Valve Replacement) Research Team

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Supplemental Appendix 1. ICD-9-CM Diagnostic Codes for Endpoint Classification

Secondary endpoints were identified following discharge from the index hospitalization, using the following Primary Diagnostic Codes (ICD-9-CM): cerebrovascular accident (CVA) (hemorrhagic: 430.x, 431.x, 432.x; ischemic: 434.x, 435.x), hemorrhage (423.0, 430.x, 431.x, 432.x, 531.0, 531.2, 531.4, 531.6, 532.x, 533.x, 534.x, 535.x1, 537.83, 562.13, 562.02, 569.3, 569.85, 578.x, 719.1, 599.7, 623.8, 626.2, 626.6, 626.8, 627.0, 627.1, 786.3, 784.7, 459.0), endocarditis (421.0, 421.1, 421.9, 424.90), and aortic valve reoperation (repair: 35.11; reoperation: 35.21, 35.22).
### Supplemental Table 1. Frequency of Implantation by Valve Model in the Medicare-linked Cohort

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Supplemental Appendix 2. Propensity Scores

Propensity scores were estimated using a non-parsimonious logistic regression model, including each of the following variables: age, gender, race (white, black, Asian, and other), body surface area (BSA), left ventricular ejection fraction (EF), past or present smoker, hypertension, hypercholesterolemia, chronic lung disease, cerebrovascular disease, cerebrovascular accident, peripheral vascular disease, immunosuppressive treatment, diabetes (insulin, non-insulin, none), renal failure (dialysis-dependent, not dialysis dependent, no renal failure), arrhythmia, endocarditis (active, treated, none), angina (stable, unstable, none), history of myocardial infarction(<21 days, ≥21 says, none), cardiogenic shock, pre-operative intra-aortic balloon pump or administration of inotropes, congestive heart failure (NYHA class IV, NYHA class I-III, no heart failure), left main disease, number diseased coronary vessels (0,1,2,3), previous CABG, previous PTCA, number of previous cardiovascular interventions (0, 1, 2 or more), acuity status (urgent, elective), concomitant CABG, and year of surgery.
Supplemental Table 2. Unadjusted cumulative incidence function and confidence interval of adverse events to 15 years by valve type and patient subgroup.

2A. Overall Study Cohort

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### 2B. Stratified by patient age at index hospitalization (65-69, 70-74, 75-80)

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#### Outcomes:

- **Mortality**

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16   2 AV replacement or repair | .4622% | .3149% | .6782% | .5223% | .3250% | .3839% | .4843% | .3594% | .6525% |
17   2 AV replacement or repair | .7085% | .5181% | .9687% | .9219% | .6413% | 1.324% | .7863% | .6204% | .9964% |
18   2 AV replacement or repair | .9649% | .7359% | 1.265% | 1.238% | .9015% | 1.698% | 1.064% | .8661% | 1.307% |
19   2 AV replacement or repair | 1.364% | 1.082% | 1.719% | 1.571% | 1.182% | 2.088% | 1.440% | 1.203% | 1.723% |
20   2 AV replacement or repair | 1.519% | 1.218% | 1.895% | 2.051% | 1.591% | 2.644% | 1.711% | 1.448% | 2.021% |
21   2 AV replacement or repair | 1.637% | 1.321% | 2.028% | 2.860% | 2.293% | 3.564% | 2.075% | 1.779% | 2.419% |
22   2 AV replacement or repair | 1.761% | 1.429% | 2.168% | 3.518% | 2.870% | 4.309% | 2.385% | 2.062% | 2.759% |
23   2 AV replacement or repair | 2.164% | 1.784% | 2.625% | 4.690% | 3.909% | 5.621% | 3.054% | 2.674% | 3.486% |
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## Valve Type

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5 Hemorrhage stroke

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**4 Stroke**

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- Endocarditis
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### 2E. Stratified by Renal Function (No Renal Failure [RF], Renal Failure)

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5 Hemorrhage stroke

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<td>.7028%</td>
</tr>
<tr>
<td>6</td>
<td>1.755%</td>
<td>1.001%</td>
<td>3.078%</td>
<td>1.326%</td>
<td>.8267%</td>
</tr>
<tr>
<td>7</td>
<td>2.055%</td>
<td>1.223%</td>
<td>3.455%</td>
<td>1.409%</td>
<td>.8899%</td>
</tr>
<tr>
<td>8</td>
<td>2.206%</td>
<td>1.336%</td>
<td>3.642%</td>
<td>1.491%</td>
<td>.9538%</td>
</tr>
<tr>
<td>10</td>
<td>2.371%</td>
<td>1.459%</td>
<td>3.853%</td>
<td>.</td>
<td>.</td>
</tr>
</tbody>
</table>
Supplemental Figure 1. Comparison of stroke to 17 years by patient subgroup

**Legend:** The risk of stroke was lower among patients treated with biologic (vs. mechanical) prostheses, across most relevant patient subgroups.

<table>
<thead>
<tr>
<th></th>
<th>Mechanical AVR</th>
<th>Bioprosthetic AVR</th>
<th>IPW Adjusted HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age 65-69</td>
<td>5,949</td>
<td>3,505</td>
<td>0.85 (0.74, 0.97)</td>
</tr>
<tr>
<td>Age 70-74</td>
<td>5,306</td>
<td>8,367</td>
<td>0.84 (0.76, 0.93)</td>
</tr>
<tr>
<td>Age 75-80</td>
<td>2,821</td>
<td>12,538</td>
<td>0.90 (0.81, 0.99)</td>
</tr>
<tr>
<td>Male</td>
<td>9,024</td>
<td>14,882</td>
<td>0.91 (0.84, 0.99)</td>
</tr>
<tr>
<td>Female</td>
<td>5,756</td>
<td>9,513</td>
<td>0.83 (0.76, 0.92)</td>
</tr>
<tr>
<td>EF &lt;50%</td>
<td>4,230</td>
<td>7,226</td>
<td>0.92 (0.81, 1.04)</td>
</tr>
<tr>
<td>EF ≥50%</td>
<td>7,224</td>
<td>12,029</td>
<td>0.89 (0.81, 0.97)</td>
</tr>
<tr>
<td>No Renal Failure</td>
<td>13,231</td>
<td>21,764</td>
<td>0.90 (0.84, 0.96)</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>704</td>
<td>1,330</td>
<td>0.66 (0.47, 0.92)</td>
</tr>
<tr>
<td><strong>Overall</strong></td>
<td>14,789</td>
<td>24,410</td>
<td>0.87 (0.82, 0.93)</td>
</tr>
</tbody>
</table>

HR >1.0 favors Mechanical Valves, whereas a HR<1.0 favors Bioprosthetic Valves
**Supplemental Figure 2. Comparison of hemorrhage to 17 years by patient subgroup**

**Legend:** The risk of hemorrhage was consistently lower among patients treated with biologic (vs. mechanical) prostheses, across all relevant patient subgroups.

<table>
<thead>
<tr>
<th></th>
<th>Mechanical AVR</th>
<th>Bioprosthesis AVR</th>
<th>IPW Adjusted HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>12 yr Unadjusted Incidence (%)</td>
<td>n</td>
</tr>
<tr>
<td>Age 65-69</td>
<td>5,949</td>
<td>21.2</td>
<td>3,505</td>
</tr>
<tr>
<td>Age 70-74</td>
<td>5,306</td>
<td>21.6</td>
<td>8,367</td>
</tr>
<tr>
<td>Age 75-80</td>
<td>2,821</td>
<td>23.0</td>
<td>12,538</td>
</tr>
<tr>
<td>Male</td>
<td>9,024</td>
<td>20.6</td>
<td>14,882</td>
</tr>
<tr>
<td>Female</td>
<td>5,756</td>
<td>23.7</td>
<td>9,513</td>
</tr>
<tr>
<td>EF &lt;50%</td>
<td>4,230</td>
<td>19.8</td>
<td>7,226</td>
</tr>
<tr>
<td>EF &gt;=50%</td>
<td>7,224</td>
<td>23.0</td>
<td>12,029</td>
</tr>
<tr>
<td>No Renal Failure</td>
<td>13,231</td>
<td>21.9</td>
<td>21,764</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>704</td>
<td>20.4*</td>
<td>1,330</td>
</tr>
<tr>
<td>Overall</td>
<td>14,789</td>
<td>21.8</td>
<td>24,410</td>
</tr>
</tbody>
</table>

HR >1.0 favors Mechanical Valves, whereas a HR<1.0 favors Bioprosthetic Valves
Supplemental Figure 3. Comparison of hemorrhagic stroke to 17 years by patient subgroup

**Legend:** The risk of hemorrhagic stroke was consistently lower among patients treated with biologic (vs. mechanical) prostheses, across all relevant patient subgroups.

<table>
<thead>
<tr>
<th></th>
<th>Mechanical AVR</th>
<th>Bioprosthesis AVR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>12 yr Unadjusted Incidence (%)</td>
</tr>
<tr>
<td>Age 65-69</td>
<td>5,949</td>
<td>3.7</td>
</tr>
<tr>
<td>Age 70-74</td>
<td>5,306</td>
<td>3.7</td>
</tr>
<tr>
<td>Age 75-80</td>
<td>2,821</td>
<td>3.8</td>
</tr>
<tr>
<td>Male</td>
<td>9,024</td>
<td>3.6</td>
</tr>
<tr>
<td>Female</td>
<td>5,756</td>
<td>3.9</td>
</tr>
<tr>
<td>EF &lt;50%</td>
<td>4,230</td>
<td>3.4</td>
</tr>
<tr>
<td>EF &gt;=50%</td>
<td>7,224</td>
<td>3.9</td>
</tr>
<tr>
<td>No Renal Failure</td>
<td>13,231</td>
<td>3.7</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>704</td>
<td>2.9*</td>
</tr>
<tr>
<td>Overall</td>
<td>14,789</td>
<td>3.7</td>
</tr>
</tbody>
</table>

HR >1.0 favors Mechanical Valves, whereas a HR<1.0 favors Bioprosthetic Valves
Supplemental Figure 4. Comparison of endocarditis to 17 years by patient subgroup

Legend: The risk of endocarditis was higher among patients treated with biologic (vs. mechanical) protheses, across most relevant patient subgroups.

HR >1.0 favors Mechanical Valves, whereas a HR<1.0 favors Bioprosthetic Valves