Hospital Volume and Selection of Valve Type in Older Patients Undergoing Aortic Valve Replacement Surgery in the United States

Erik B. Schelbert, MD; Mary S. Vaughan-Sarrazin, PhD; Karl F. Welke, MD; Gary E. Rosenthal, MD

Background—Hospital volume has been linked to quality of care. The relation between hospital volume and recommended use of bioprosthetic valves in older patients undergoing aortic valve replacement (AVR) is unknown.

Methods and Results—We identified 80,470 patients aged ≥65 years undergoing isolated AVR (with or without bypass surgery) in 1045 US hospitals during 1999–2001 from Medicare Part A files. International Classification of Diseases, Ninth Revision, Clinical Modification codes were used to identify patients undergoing bioprosthetic valve (35.21) or mechanical valve (35.22) AVR. The sample was categorized into deciles on the basis of the valve surgery volume of the hospital. Generalized estimating equations determined the relative risk of receiving a bioprosthetic valve in different volume deciles, with adjustment for age, gender, race, comorbidity, and other factors. Bioprosthetic valve use increased (P<0.001) from 44% in 1999 to 52% in 2001 and with age (from 36% in patients aged 65 to 69 years to 60% in patients aged ≥90 years). Rates were directly related (P<0.001) to volume, rising from 28% in the 1st decile to 68% in the 10th decile. With the use of generalized estimating equations, the relative risk of bioprosthetic valve use, relative to the 1st decile, progressively increased from 1.2 (95% CI, 1.1 to 1.4) in the 2nd decile to 2.3 (95% CI, 1.9 to 2.7) in the 10th decile.

Conclusions—Hospital volume was a strong predictor of bioprosthetic valve use in older patients undergoing AVR. The lower use of bioprosthetic valves in low-volume hospitals is at odds with recent guidelines recommending bioprosthetic valves in patients aged ≥65 years. These findings further support the use of volume as a marker of hospital quality. (Circulation. 2005;111:2178-2182.)

Key Words: epidemiology ■ surgery ■ valves

The relation between hospital volume and quality of care for a number of surgical procedures has received widespread attention in the medical literature1–4 and from healthcare purchasers.5 Although specific factors underlying the better outcomes in higher-volume centers have not been elucidated, such centers are believed to benefit from more experienced surgeons, greater availability of subspecialists and technology, and more optimal staffing of intensive care units.6 Prior volume outcome studies have largely focused on mortality as an end point. However, relationships between volume and other end points might reveal additional insight about relationships between volume and quality of care.

See p 2152

In 1998, both the American Heart Association (AHA) and the American College of Cardiology (ACC) issued guidelines for the use of both mechanical and bioprosthetic valves.7 These guidelines recommend the use of bioprosthetic valves for aortic valve replacement (AVR) surgery for most patients aged ≥65 years because it is believed that the risks of complications from anticoagulation required for mechanical valves exceed the risk of reoperation for failure of bioprosthetic valves.8,9 This recommendation largely reflects the increasing risk of anticoagulant-related hemorrhage and the increased lifespan of bioprosthetic valves in older patients.10,11 Moreover, unlike mortality, which is likely to reflect the culmination of multiple elements of care, valve selection is driven largely by physician choice and decision making and may represent an interpretable end point in volume-outcome studies. Thus, valve type selection represents an opportunity to assess quality of care.

To examine the relation between hospital volume and valve type selection for older patients undergoing AVR, we analyzed claims data for Medicare beneficiaries from all 50
states for a 3-year period (1999–2001) after publication of the ACC/AHA guidelines. The analysis first identified patient characteristics related to valve type and then determined associations with hospital volume after adjustment for these patient factors.

Methods

Before we embarked on the study, approval was obtained from the institutional review board.

The study used Medicare Provider Analysis and Review (MEDPAR) Part A public use data files, which were purchased from the Centers for Medicare and Medicaid Services. The Part A files contain data available on the UB-92 hospital discharge abstract for a 100% sample of Medicare patients discharged from acute care hospitals and have been used extensively in health services research.12 Data elements included the following: demographic information; patients' state of residence; primary and secondary diagnoses and procedures, as captured by International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes; the diagnosis-related group; admission and discharge dates; disposition at the time of hospital discharge; and a 6-digit unique hospital identifier. In addition, Part A files are matched quarterly to the Medicare Enrollment database to obtain dates of death for Medicare beneficiaries who died after hospital discharge.

Patients undergoing AVR in calendar years 1999–2001 who were aged ≥65 years were identified (n = 87,585) on the basis of specific ICD-9-CM procedure codes (35.21 and 35.22). Patients simultaneously receiving either a prosthetic mitral (n = 5735), tricuspid (n = 126), or pulmonary (n = 20) valve were excluded from this cohort. Patients undergoing AVR at facilities that did not perform AVR during the entire study period (n = 1192) were also excluded, as were patients with obvious data coding errors (eg, date of discharge before the date of AVR) (n = 42). These exclusions left a final study cohort of 80,470. ICD-9-CM procedural codes were used to classify patients as either undergoing bioprosthetic valve AVR (35.21) or mechanical valve AVR (35.22).

Hospital valve replacement volume for all heart valve replacement surgery (aortic, mitral, pulmonic, and tricuspid) was determined by summarizing the patient-level MEDPAR data. On the basis of the mean annual valve surgery volume for each facility, hospitals were categorized into volume deciles, as used in prior studies.4 Mean annual valve surgery volume for the 10 deciles were 20, 30, 41, 51, 65, 82, 103, 135, 181, and 573.

Additional hospital-level information was obtained from the 2000 American Hospital Association Annual Survey, including teaching status and ownership. Hospitals were classified as major teaching hospitals on the basis of membership in the Council of Teaching Hospitals (COTH). Ownership was categorized as nonprofit, for-profit, and government (non–federal government). COTH membership was missing for a small subset of eligible patients (n = 2248; 2.8%).

Bivariates associations between valve type and demographic variables and primary and secondary diagnosis and procedure codes that represented potential patient risk factors were determined with the use of the Wilcoxon test or the χ² statistic. Variables associated (P < 0.05) with the use of bioprosthetic valves in bivariate analyses were entered into a stepwise logistic regression. Variables related to valve type (ie, bioprosthetic or mechanical) were identified by a statistical criterion of P < 0.01. In the risk adjustment model, age was expressed as 5 indicator variables (70 to 74, 75 to 79, 80 to 84, 85 to 89, ≥90 years), with a referent category of 65 to 69 years. Race was expressed with the use of 2 indicator variables for patients who were classified in the database as either “black” or “other nonwhite race.” Patients with missing race designation (n = 270; 0.34%) were classified as “white race,” which represented the vast majority. Diabetes was defined by ICD-9-CM codes with the use of the criteria of Elixhauser et al.13 Surgical priority was expressed with the use of 2 indicator variables for emergent and urgent admissions, relative to elective admissions. Admission source was expressed as indicator variables for patients transferred to the hospital from another acute care facility and patients admitted through the emergency department, with a referent category that primarily included patients referred by a physician.

The bivariate association between hospital volume deciles and the use of bioprosthetic valves was determined by the χ² test for trend. Bivariate associations between volume deciles and those patient characteristics that were identified as multivariable predictors of valve type were also examined by ANOVA for continuous variables and the χ² test for linear trend for categorical variables. The risk-adjusted association between volume and the use of bioprosthetic valves was determined by adding indicators for hospital volume to the multivariable risk adjustment model that included patient-specific risk factors.

In these analyses, volume was represented by 9 indicator variables representing patients undergoing valve replacements in hospitals in the 2nd through 10th deciles of increasing hospital volume. The regression coefficients associated with these indicator variables were exponentiated to provide the adjusted odds of receiving a bioprosthetic valve in each volume deciles, relative to patients in the first decile. Because the outcome of interest (bioprosthetic valve use) was common (>10%), odds ratios were converted to relative risk estimates to avoid inflation of the likelihood of receiving a bioprosthetic valve.14 All logistic regression models were fit with the use of generalized estimating equations to account for the clustering of patients within individual hospitals.15

Secondary analyses were conducted in which additional hospital characteristics (COTH membership and ownership) were added to the model with patient factors and hospital volume. These analyses excluded patients in hospitals in which COTH membership could not be determined. Hospital ownership type was expressed as 2 indicator variables representing hospitals classified as for-profit or non–federal government, with a referent category of not-for-profit hospitals.

The discrimination of the full logistic regression models and of individual variables was determined with the use of the c statistic;16 model calibration was assessed with the Hosmer-Lemeshow goodness-of-fit statistic.17 Statistical analysis was performed with the use of the SAS software system for Windows version 8 (SAS Institute).

Results

Patient Characteristics

The mean age of the study population was 76 years; 42% of patients were women, and 94% were white. Overall, 48% (n = 38,843) of patients received bioprosthetic valves. The use of bioprosthetic valves was directly related to age, increasing from 36% in patients aged 65 to 69 years to 60% in patients aged ≥90 years (P < 0.001; Table 1). The use of bioprosthetic valves was relatively similar in men and women (49% versus 48%; P = 0.03) but was higher in whites than nonwhites (49% versus 42%; P < 0.001). The use of bioprosthetic valves also increased over time, from 44% in 1999, to 48% in 2000, to 52% in 2001 (P < 0.001).

Rates of bioprosthetic valves differed according to several other clinical characteristics, although the absolute magnitude of differences was relatively small for each of these variables (Table 1). The use of bioprosthetic valves was higher (P < 0.05) in patients with congestive heart failure, anemia, peptic ulcer disease, coagulopathy, a history of nonmetastatic neoplastic disease, a history of prior myocardial infarction, or a primary diagnosis of acute myocardial infarction. The use of bioprosthetic valves was also higher in patients undergoing concurrent coronary artery bypass surgery and in patients whose admission was classified as emergent. In contrast, the
use of bioprosthetic valves was lower in patients with chronic renal insufficiency. The use of bioprosthetic valves did not vary (P>0.05) according to diabetes, hypertension, endocarditis, prior coronary artery bypass surgery, arthritis, hypothyroidism, neurological disease, psychosis, arthritis, and endocarditis.

**Risk Adjustment Model**

Nine risk factors met criteria for inclusion in the multivariable risk adjustment model (Table 2): age (expressed as 5 indicator variables); year of AVR surgery; female gender; angina pectoris; and several comorbid conditions (peripheral vascular disease, nonmetastatic cancer, coagulopathy, peptic ulcer disease, and primary diagnosis of acute myocardial infarction). The $c$ statistic for the model was 0.59. Among the patient-level variables, the highest relative risk was associated with the indicator variables for age. After adjustment for other risk factors, the relative risk of bioprosthetic valve use was 1.6 among patients aged ≥90 years relative to patients aged 65 to 69 years.

**Hospital Characteristics**

Hospital volume was strongly associated (P<0.001) with bioprosthetic valve use, which increased from 28% in hospitals in the lowest-volume decile to 68% in hospitals in the highest-volume decile (Figure). In contrast, the use of bioprosthetic valves was lower in major teaching hospitals than in other hospitals (44% versus 55%, respectively; P<0.001) and in for-profit hospitals than in not-for-profit hospitals (40% versus 49%, respectively; P<0.001).

Relationships between hospital valve surgery volume deciles and age as well as other patient variables included in the multivariable model were statistically significant. However, the absolute magnitude of these differences was small. For example, mean age was 75.8 years in the 1st decile compared with 76.4 years in the 10th decile. Similarly, the proportion of patients with peripheral vascular disease in the 1st and 10th deciles was 8.4% and 10.2%, respectively, whereas the proportion of patients with angina in the 1st and 10th deciles was 9.2% and 8.3%, respectively.

After adjustment for patient-level predictors of bioprosthetic valve use, annual volume remained a strong predictor of valve type. The relative risk of receiving a bioprosthetic valve increased steadily with increasing volume deciles. Relative to patients undergoing valve replacement in the lowest-volume decile, the relative risk of receiving a bioprosthetic valve increased steadily from 1.2 in the 2nd decile to 2.3 in the highest-volume decile (Table 2). The relative risk associated with the 5 largest volume categories was higher than the relative risk associated with any other variable. Furthermore, the $c$ statistic associated with the indicator variables for volume (0.64) was higher than the $c$ statistic associated any other variable. The variable with the second highest level of discrimination was age, with a $c$ statistic of 0.57. The $c$ statistics for other variables in the patient-level

### TABLE 1. Patient-Level Factors (P<0.01) Included in Risk-Adjustment Models Related to Use of Bioprosthetic Aortic Valves in Generalized Estimating Equations

<table>
<thead>
<tr>
<th>Patient Risk Factor</th>
<th>Relative Risk</th>
<th>95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVR during 2000†</td>
<td>1.09</td>
<td>1.06–1.22</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>AVR during 2001</td>
<td>1.17</td>
<td>1.14–1.42</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Age 70–74 y†</td>
<td>1.28</td>
<td>1.24–1.33</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Age 75–79 y</td>
<td>1.41</td>
<td>1.36–1.45</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Age 80–84 y</td>
<td>1.50</td>
<td>1.44–1.55</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Age 85–89 y</td>
<td>1.54</td>
<td>1.48–1.60</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Age ≥90 y</td>
<td>1.57</td>
<td>1.47–1.67</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Female gender</td>
<td>0.98</td>
<td>0.97–0.99</td>
<td>0.004</td>
</tr>
<tr>
<td>Angina</td>
<td>1.04</td>
<td>1.02–1.06</td>
<td>0.001</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>0.91</td>
<td>0.88–0.94</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Cancer (without metastasis)</td>
<td>1.04</td>
<td>1.02–1.07</td>
<td>0.002</td>
</tr>
<tr>
<td>Coagulopathy</td>
<td>1.07</td>
<td>1.05–1.10</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Peptic ulcer disease</td>
<td>1.09</td>
<td>1.03–1.15</td>
<td>0.003</td>
</tr>
<tr>
<td>Primary myocardial infarction</td>
<td>1.05</td>
<td>1.01–1.08</td>
<td>0.005</td>
</tr>
</tbody>
</table>

*Variables not related (P<0.01) to bioprosthetic valve use were race, prior myocardial infarction, or concurrent coronary bypass surgery, prior angioplasty, cardiac catheterization, heart failure, diabetes, cerebrovascular disease, hypertension, renal insufficiency, chronic obstructive pulmonary disease, iron deficiency anemia, emergent AVR, neurological disease, hypothyroidism, psychosis, arthritis, and endocarditis.

†Referent category is during 1999. ‡Referent category is age 65–69 years.

### TABLE 2. Relative Risk of Receiving Bioprosthetic Valve During AVR Surgery by Hospital Volume Decile After Adjustment for Patient-Level Risk Factors Using Generalized Estimating Equations

<table>
<thead>
<tr>
<th>Hospital Volume Decile</th>
<th>Relative Risk*</th>
<th>95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>2nd Volume decile</td>
<td>1.24</td>
<td>1.08–1.42</td>
<td>0.003</td>
</tr>
<tr>
<td>3rd Volume decile</td>
<td>1.47</td>
<td>1.27–1.68</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>4th Volume decile</td>
<td>1.56</td>
<td>1.34–1.79</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>5th Volume decile</td>
<td>1.82</td>
<td>1.60–2.04</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>6th Volume decile</td>
<td>1.96</td>
<td>1.68–2.23</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>7th Volume decile</td>
<td>2.08</td>
<td>1.82–2.33</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>8th Volume decile</td>
<td>2.17</td>
<td>1.87–2.44</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>9th Volume decile</td>
<td>2.25</td>
<td>1.92–2.56</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>10th Volume decile</td>
<td>2.32</td>
<td>1.86–2.73</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*Referent category is the 1st volume decile.

Proportion (percentage) of patients receiving bioprosthetic valves (BPV) according to hospital volume deciles.
This robust volume effect suggests that “nonbiological” factors, such as provider preferences, exert a strong influence on selection of valve type and that such factors may be more important in lower-volume hospitals. Given that a majority of surgeries occurred nationally at hospitals with relatively low volumes, our findings support the benefits that have been proposed for the regionalization of specialty services to centers of excellence.1,5,19–21

The AHA/ACC guidelines cite patient age as a critical determinant in recommending the most appropriate valve type, given the highly age-dependent nature of risks related to mechanical and bioprosthetic valves.7 The most relevant factors include (1) the diminishing risk of structural valve deterioration with increasing age, (2) the increasing risk of serious bleeding complications with age, and (3) the diminishing life expectancy of those aged >65 years.8,9 These factors provide a firm empirical basis for the AHA/ACC guideline recommendations for the primary use of bioprosthetic valves in the majority of older patients and likely drive the results of analytical decision models,8,9 which found that bioprosthetic valves would confer greater life expectancy in most older patients. Nonetheless, in practice, such decisions should be informed by patients’ preferences about which risks should be primarily avoided.

We concur with Birkmeyer et al,8 who believe that the frequent use of mechanical valves in those aged >65 years represents problems in clinical decision making. This problem probably arises from legitimate but inflated concern about the risk of structural valve deterioration of bioprosthetic valves and the need for subsequent reoperation; overestimation of life expectancy; and underestimation of serious bleeding (or embolic) events with the chronic anticoagulation required for mechanical valves. The effects of overuse of mechanical valves on patient health are unknown. The associated hazard of anticoagulation is likely significant because it increases with patient age.10 Furthermore, the costs of anticoagulation are also likely significant because elderly patients require closer monitoring.22 Further research is needed to gauge the consequences of overuse of mechanical valves.

Our study has several limitations. First, to our knowledge, no prior studies have examined the reliability of the coding for bioprosthetic and mechanical valves in administrative data. Our findings, however, agree with prior reports that cite predominant use of mechanical valves in older patients.8,23–25 Moreover, if misclassification of valve type occurs, it would likely be random and unrelated to hospital volume. Thus, our findings may underestimate the true association between hospital volume and valve type. Nonetheless, these findings should be replicated in clinical databases that are assembled with stricter data collection protocols.

Second, our analysis did not account for physician volume or experience, which is likely to be related to valve choice. Similarly, our analysis did not account for other organizational factors, such as the preoperative risk assessments and recommendations by other physicians (eg, cardiologists or general internists), which may underlie the volume-outcome relationships we observed.
Third, given the administrative nature of the data, our analysis did not account for relevant comorbidities (eg, systolic function, risk factors for thromboembolism) or the severity of the comorbidities that were assessed. Perhaps most importantly, we were unable to identify patients with preoperative atrial fibrillation in whom receipt of a mechanical valve would be more likely because their need for some type of anticoagulation persists regardless of valve type. However, the reported rate of preoperative atrial fibrillation for AVR in older patients is only 16%.26 and does not likely account for the rates of mechanical valves observed in our analysis. Furthermore, some who have indications for anticoagulation but also questionable tolerance of anticoagulation might still receive a bioprosthetic valve to avoid the absolute and perpetual indication for chronic anticoagulation that mechanical valves pose.11 Finally, we were unable to quantify patient preference and the role it played in selection of valve type. In summary, our analysis provides important new data on a very strong association between volume and a potentially important indicator of the quality of care, ie, valve type selection, in patients undergoing AVR. Although our analysis was unable to account for certain clinical factors that may influence valve type, our findings highlight the substantial departure of practice from the recommendations proposed by AHA/ACC guidelines in 1998. These data suggest that there are substantial opportunities to improve the care provided to older Americans undergoing AVR.

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References

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