Effect of Hospital Volume on Prosthesis Use and Mortality in Aortic Valve Operations in the Elderly

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Background. **This study was designed to examine the effect of hospital procedural volume on outcomes in aortic valve replacement (AVR) in the elderly.**

Methods. **The study included 277,928 Medicare beneficiaries who underwent AVR from 2000 through 2009 at one of 1,255 participating hospitals. Operative mortality and the use of mechanical prostheses were analyzed according to hospital annual procedural volume. Annual AVR volume was divided into 5 different categories: the smallest volume group with less than 10 AVRs per year to the largest group averaging more than 70 AVRs per year.**

Results. **The overall observed operative mortality rate was 7.3%; for isolated AVR it was 5.5%. Lower-volume hospitals exhibited increased adjusted operative mortality: 10 cases or fewer per year—odds ratio (OR), 1.55; 95% confidence interval (CI), 1.39 to 1.72; 11 to 20 cases per year—OR, 1.35; 95% CI, 1.23 to 1.47; 21 to 40 cases per year—OR, 1.15; 95% CI, 1.06 to 1.25; 41 to 70 cases per year—OR, 1.10; 95% CI, 1.01 to 1.20 relative to those hospitals performing more than 70 cases per year. The discrepancy in operative mortality between low- and high-volume hospitals diverged during the study. Mechanical valve use decreased with increasing hospital volume ($p = 0.0001$). Mechanical valves were used in 64.5% of AVRs in hospitals with an annual AVR volume less than 10 in contrast to only 25.4% in hospitals with an annual AVR volume more than 70. After adjustment, the use of mechanical valves was independently associated with increased operative mortality (OR, 1.15; 95% CI, 1.11–1.19).**

Conclusions. **Low-volume centers were characterized by increased adjusted operative mortality and greater use of mechanical prostheses, a trend that persisted during the 10-year course of the study. These data would support the center-of-excellence concept for AVR and may be particularly relevant in the elderly population.**

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Volume-outcome relationships in cardiovascular operations continue to be a topic of great interest. Previous reports have shown higher operative mortality for aortic, mitral valve, and coronary artery bypass (CABG) operations at lower-volume centers [1–4]. A recent study reported that 30-day mortality of AVR in Medicare beneficiaries significantly decreased between 1999 and 2011. During the same period, mechanical valve use in the elderly (>65 years) fell significantly [5]. Given that previous studies have suggested a volume-outcome relationship, there may be a discrepancy in the surgical outcomes of hospitals of differing volumes as well as differing magnitudes of improvement, which may be an equally important factor when considering health care improvement strategies.

Aortic valve replacement (AVR) is the most commonly performed valve operation in the United States. With the aging of the US population and improving surgical outcomes over the years, it is likely that the number of aortic procedures will continue to increase [6–10]. In addition, the introduction of transcatheter aortic valve placement has created an alternative to AVR in selected patients [11]. The National Coverage Determination by the Centers for Medicare and Medicaid Services (CMS) sets specific volume thresholds for transcatheter aortic valve placement, thereby restricting it to higher-volume centers with multidisciplinary teams [12]. Accordingly, we felt a contemporary analysis of the effect of volume on outcomes of AVR in the elderly would provide a useful benchmark for consideration of this system of care elsewhere. Therefore we examined outcomes among Medicare beneficiaries undergoing AVR between 2000 and 2009 stratified by annual hospital procedural volume.

Patients and Methods

The study was approved by our local institutional review board (Springfield Committee for Research Involving Human Subjects). Data were obtained from the Medicare Provider Analysis and Review (MEDPAR) files and corresponding Beneficiary Annual Summary Files (BASF) from 1999 through 2009. The Vital Status file as of February 2012 was used to calculate survival.

All Medicare beneficiaries 65 years of age or older, who underwent AVR (International Classification of Diseases, Ninth Edition, Clinical Modification [ICD-9-CM] code 35.21 or 35.22) from 2000 through 2009 were considered

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for inclusion. Patients were excluded if they had undergone closed-heart valvuloplasty, surgical intervention for congenital anomalies, or heart transplantation; were awaiting organ transplant status; had undergone previous left ventricular, right ventricular, or biventricular circulatory support implantation or removal; had undergone implantation of an external cardiac support device; had a history of having a ventricular assist device or an artificial heart, aortic fenestration, concomitant carotid endarterectomy, ruptured papillary muscle, endocarditis, unspecified valve repair, or unspecified valve replacement; or had undergone excision of a ventricular aneurysm. Also excluded from the analysis were patients with missing sex information; Medicare status codes 20 (disabled without end-stage renal disease [ESRD]), 21(disabled with ESRD), and 31 (ESRD only, not aged); and emergent admission status. Patients were also excluded if they did not have 12 months of Medicare Part A and Part B coverage or if they were enrolled in a Medicare managed plan in the year preceding their index admission. Finally, patients who had an ICD-9-CM code reflective of both a tissue and mechanical valve during the index admission were also excluded. Comorbidities were determined using the ICD-9-CM diagnostic codes from both the index admission and any hospitalizations during the 12-month period before the index admission.

The first hospitalization documenting an AVR during the study period was the index admission. Operative mortality was defined as any in-hospital death or mortality within 30 days of operation, in accordance with the standard Society of Thoracic Surgeons (STS) definition. Hospital annual AVR volume was defined as the average number of AVRs per year for years that the hospital reported data under Medicare. The following volume categories were selected: less than or equal to 10, 11 to 20, 21 to 40, 41 to 70, and more than 70 AVRs in Medicare beneficiaries annually. This roughly reflected 3 equal quartiles for the lowest 3 volume groups. The remaining quartile was divided among the top 2 groups. It was believed that this would allow for the documenting of trends across the volume categories and for comparisons to the hospitals with the highest AVR volumes. χ^2tests were used to compare categorical patient characteristics across the volume groups. To account for the clustering of patients within hospitals, hierarchic logistic regression was used to model operative mortality. Adjusted odds ratios (ORs) are presented, accounting for the clustering of patients within hospitals, the hospital annual aortic replacement volume, valve type, as well as the baseline patient and operative characteristics, which are presented in Table 1. All analyses were performed using SAS, version 9.3 (SAS Institute Inc, Cary, NC).

Results

There were 1,255 participating hospitals in this study. Half the hospitals (50.8%) performed 20 or fewer AVR operations on Medicare patients per year, while making up less than 15% of total AVR operations included in this study. In addition, more than one quarter (27.1%) of the hospitals performed 10 or fewer AVRs per year. In contrast, hospitals in the 2 highest-volume categories (41–70 and > 70) composed 23.5% and 9.6% of hospitals, respectively, but accounted for 62.5% of operations. High-volume hospitals (> 70 AVRs per year) accounted for 38.6% of all AVR operations.

Patient Characteristics

The study included 277,928 patients, 173,734 (62.5%) of whom received a tissue valve and 104,194 (37.5%) of whom received a mechanical prosthesis. The median age was 77 years (72–81 years) and 43.1% were women. The baseline characteristics for the overall cohort, as well as by hospital volume, are presented in Table 1. Overall, a large burden of comorbidities was observed. Heart failure was present in 44.3%, stroke in 10.6%, atrial fibrillation in 31.1%, and renal failure in 9.9% of patients. Urgent admission status was noted in 52.3% of patients. Patients presenting for reoperation composed 4.2%, whereas 52.5% and 9.2% underwent concomitant CABG or other valve operation, respectively. Higher-volume hospitals also treated patients with a higher incidence of atrial fibrillation, a history of previous cardiac operations, and a higher proportion of very elderly patients and patients who required concomitant additional valve operations (Table 1). Conversely, chronic obstructive pulmonary disease and respiratory failure were less commonly seen with increasing hospital volumes.

One of the most striking differences between high- and low-volume hospitals was seen with the use of mechanical prostheses. Mechanical valves were used in 64.5% of AVRs in hospitals with an annual AVR volume less than 10 in contrast to only 25.4% in hospitals with an annual AVR volume greater than 70. Mechanical valve use decreased with increasing hospital volume ($p = 0.0001$). As expected, mechanical valve use decreased with increasing patient age; however, in patients aged 85+ years, mechanical valves were still used in 60.6% of patients treated in the lowest-volume hospitals compared with only 20.3% of patients in the highest-volume hospitals (Table 2). Although the use of mechanical valves decreased significantly over time across all volume groups, by 2009 patients receiving care in the lowest-volume hospitals were more than 3 times as likely to receive a mechanical valve compared with patients in the highest-volume hospitals. This is in contrast to 2000, when the difference was less than 2-fold between the highest- and lowest-volume centers (Table 3).

Operative Mortality

The overall observed operative mortality rate was 7.3%, whereas for those undergoing isolated AVR (primary or reoperative) the operative mortality rate was 5.5%. Overall, operative mortality fell from 8.2% to 6.1% during the study period. There was a significant trend of decreasing mortality over time for each volume group (p for trend = 0.0001). The only exception was for the lowest-volume group (<10 AVRs per year), which showed no improvement (Table 4). Lower-volume hospitals exhibited increased adjusted operative