Effects of institutional volumes on operative outcomes for aortic root replacement in North America

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Objectives: Hospital procedure volume has been strongly associated with postoperative mortality for a number of complex cardiovascular procedures. Although not yet described, a similar relationship might be expected for surgical procedures involving the aortic root and/or ascending aorta. The present study sought to evaluate the relationship between the volume of aortic root replacement procedures and the operative results for centers in North America.

Methods: Patient-level data for 13,358 elective aortic root and aortic valve-ascending aortic procedures performed from 2004 through 2007 were obtained from 741 North American hospitals participating in the Society of Thoracic Surgeons Adult Cardiac Surgery Database. Marginal logistic regression modeling was used for risk adjustment. The hospital procedure volume was the primary predictor variable. Patient demographics, comorbid conditions, and operative characteristics were included as the predictor variables for risk adjustment. The primary outcome measures included unadjusted operative mortality and adjusted odds ratio for mortality.

Results: The preoperative patient risk profiles were similar at all center volume levels, and the overall unadjusted operative mortality was 4.5%. The unadjusted operative mortality increased with decreasing case volume, from 3.4% in the highest volume centers to 5.8% in the lowest volume centers. Whether hospital volume was assessed as a categorical or continuous variable, its relationship with the adjusted odds ratio for mortality was nonlinear. A negative association was seen between the hospital procedural volume and adjusted odds ratio for mortality ($P < .001$) that was most pronounced among hospitals performing fewer than 30 to 40 procedures annually.

Conclusions: Patients undergoing elective aortic root or combined aortic valve-ascending aortic surgery at North American hospitals that performed fewer than 30 to 40 of such procedures annually have greater risk-adjusted mortality than those undergoing surgery in higher volume hospitals. Causative factors for this inverse association between hospital volume and mortality deserve additional analysis. (J Thorac Cardiovasc Surg 2013;145:166-70)

ACD

Hospital procedure volume has been shown to be strongly associated with postoperative mortality for a number of complex cardiovascular and thoracic surgical procedures, including esophagectomy,[1] lung cancer resection,[2] open descending thoracic aortic aneurysm repair,[3] and both open and endovascular abdominal aortic aneurysm repair.[4] Although not yet described, a similar hospital volume–outcomes relationship might be expected for surgical procedures involving the aortic root and/or ascending aorta. Perhaps even more so than with other cardiothoracic procedures, operations involving the aortic root require a high degree of complex peri- and postoperative care. This complexity is reflected in the results of a recent survey analysis of the Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database (ACSD) showing an approximately 10% overall mortality rate after aortic root or simultaneous aortic valve and ascending aortic surgery,[5] a proportion considerably greater than previously published reports from high-volume thoracic aortic centers.[6-9]

Thus, the purpose of the present study was to determine the relationship between the hospital procedure volume and postoperative outcomes after elective aortic root surgery for centers in North America using the STS ACSD. We hypothesized that patients undergoing elective aortic root procedures at higher volume centers would achieve superior risk-adjusted postoperative outcomes compared with patients undergoing these procedures at lower volume centers.

METHODS

The STS ACSD was established in 1989 to report surgical outcomes after cardiothoracic surgical procedures.[10] The sites enter patient data using uniform definitions (available at: http://www.sts.org) and certified

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Abbreviations and Acronyms
ACSD = Adult Cardiac Surgery Database
NIS = Nationwide Inpatient Sample
STS = Society of Thoracic Surgeons

software systems. Although participation in the STS ACSD is voluntary, data completeness is high, with overall preoperative risk factors missing for fewer than 5% of submitted cases. At present, more than 90% of North American cardiac surgery centers submit data. The accuracy of submitted cases has been confirmed in an independent comparison of the hospital coronary artery bypass graft surgery volume and mortality rates reported to the STS ACSD versus those reported to the Centers for Medicare and Medicaid Services.[11] In addition, database accuracy is ensured annually using randomly selected on-site audits.

For the present study, patients who underwent either aortic root replacement or combined aortic valve replacement with simultaneous ascending aortic replacement in 741 hospitals participating in the STS ACSD from 2004 to 2007 were included. Because of measured similarities in patient baseline characteristics and raw unadjusted mortality, together with uncertainties regarding the exact procedural details in the data set, all categories of patients involving aortic root replacement or aortic valve plus ascending aortic replacement were analyzed as 1 population. Aortic dissection and nonelective cases were excluded; thus, the final analysis included patient-level data for 13,358 elective aortic root/aortic valve-ascending aortic procedures.

The descriptive statistics of the patient characteristics and outcomes are presented as group mean values for continuous variables and frequencies or percentages for the categorical variables. The Wilcoxon rank sum test was used to compare the distribution of continuous variables between groups, and the Mantel-Haenszel test was used for categorical variable comparisons. The primary outcome variable was operative mortality, defined as death from any cause, either in-hospital or within 30 days of the index thoracic aortic operation. The average annual hospital volumes were determined from the operations submitted to the STS ACSD from January 2004 to December 2007 (the period when data collection form version 2.52 was used). The average annual volume for each hospital was calculated as the number of procedures during the study period divided by the number of months that the hospital participated in the database during the study period multiplied by 12. The hospital-specific average annual volumes ranged from 0.25 to about 100 cases annually. The association between operative mortality and volume was assessed by managing volume as either a continuous or a categorical variable with 4 categories (group 1, lowest to group 4, highest). The cutpoints (<6, 6–13, 13–30, and 30–100 cases/yr) were selected to ensure an approximately equal number of patients in each category. The marginal logistic regression model using generalized estimating equations method was used for risk adjustment to account for the correlation among patients within the same participant group. The unadjusted and risk adjusted odds ratios of operative mortality and the corresponding 95% confidence intervals are reported for each volume category relative to the performance of the hospitals with fewer than 6 cases annually.

To allow for possible nonlinear effects, the volume was also modeled as a continuous variable, using restricted cubic splines with knots at 3 (10th percentile), 13 (50th percentile), and 63 (90th percentile) cases annually. Sensitivity to the number of knots and the choice of knot locations was assessed by refitting the logistic models with the knots at various percentiles of the empirical distribution of hospital volume. The shape of the estimated volume–outcome association was generally consistent across these different model specifications. The risk-adjusted results, determined from the model with smaller Akaike's Information Criteria, are presented. The risk-adjusted models included the following covariates: age, left ventricular ejection fraction, body surface area, serum creatinine, time trend, active endocarditis, need for dialysis, atrial fibrillation, female gender, hypertension, immunosuppressive treatment, presence of an intra-aortic balloon pump, inotrope use, peripheral vascular disease, unstable angina (no myocardial infarction <7 days), left main disease, aortic stenosis, aortic insufficiency, mitral stenosis, mitral insufficiency, tricuspid insufficiency, chronic lung disease, cerebrovascular disease or cerebrovascular accident, diabetes, number of diseased coronary vessels, myocardial infarction, race, admission status, congestive heart failure, New York Heart Association class, reoperation, and concomitant coronary artery bypass grafting. The use of circulatory arrest during a procedure was not available as a coding variable on the data collection form version 2.52 used for the present analysis. The coding details for these variables have been previously described.[12] All analyses were performed using SAS, version 8.2, software (SAS Institute, Cary, NC).

RESULTS

Of the 741 centers included in the present study, 72% (n = 534) were in the lowest volume category (<6 cases/yr), and 3% (n = 22) performed the highest volume (30–100 cases/yr). Thus, 25% of the total cases (n = 3404 of 13,358) were performed at the 3% of centers in the highest volume category. The preoperative patient risk profiles were minimally different between low- and high-volume centers (Table 1). Two major exceptions to this finding were the number of patients who had undergone previous cardiac surgery (eg, coronary artery bypass graft surgery, valve, other) and the number with endocarditis, with both groups more likely to undergo surgery in the higher volume hospitals.

The overall unadjusted 30-day/in-hospital mortality rate for all 13,358 patients in the study was 4.48% and the overall stroke rate was 2.25%. The rates of other major complications for the entire cohort included the need for reoperation (11.37%), perioperative myocardial infarction (2.27%), prolonged ventilation (14.49%), and renal failure (5.27%). The mean postprocedural length of stay was 8.6 days (interquartile range 5.0–9.0).

An increasing institutional case volume was associated with lower unadjusted and risk-adjusted mortality ($P < .001$; Table 2). Patients undergoing aortic root or combined aortic valve plus ascending aortic replacement were 58% less likely to experience operative mortality when undergoing surgery in a highest volume versus lowest volume center. When volume was assessed as a continuous variable, the relationship was nonlinear, with a significant negative association between risk-adjusted mortality and procedural volume observed in the lower volume range (procedural volumes <30–40 cases/year; Figure 1). The most common cause of 30-day/in-hospital mortality was cardiac and did not vary significantly between the lower and higher volume centers (Table 3).

The unadjusted rates of major morbidity stratified by center procedural volume are presented in Table 4. Cardiopulmonary bypass and aortic crossclamp times averaged 181 minutes (interquartile range, 130–215) and 134 minutes