Perioperative Risk Profiles and Volume-Outcome Relationships in Proximal Thoracic Aortic Surgery

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Background. **Using the national Society of Thoracic Surgeons Adult Cardiac Surgery Database data for thoracic aortic surgical procedures for aortic aneurysm, this study aimed to (1) characterize patients' risk profiles and outcomes, (2) evaluate center volume-outcome relationships across US centers, and (3) identify risk factors for operative mortality.**

Methods. **Between 2011 and 2016, 53,559 operations for ascending aortic aneurysm performed across 1,045 centers in the United States were identified. Logistic regression related baseline characteristics and comorbidities to operative mortality. Ten-fold cross-validation was performed to estimate sensitivity and specificity across a range of the discrimination threshold. Centers were stratified into five strata by average annual case volume. Predicted probability of operative mortality was calculated from the model and was used to evaluate patients' risk profiles across the volume strata.**

Results. **Operative mortality occurred in 3.2% of all cases and in 2.2% of elective cases. Only 24 (2.3%) centers performed ≥50 cases annually, whereas 609 (58.3%) centers performed fewer than five cases annually. Multiple logistic regression, of which the c-index was 0.80, revealed that compared with centers with ≥50 cases, centers with fewer than five cases had an increased risk of mortality (odds ratio, 2.50; 95% confidence interval, 2.08 to 3.01; $p < 0.0001$). The predicted probability of operative mortality was similar across the volume strata, but the observed mortality rate varied significantly, with lower volume yielding higher operative mortality.**

Conclusions. **Proximal thoracic aortic surgical procedures for aortic aneurysms in the United States are associated with a low operative mortality rate of 2.2% for elective cases. Risk of operative death decreases significantly at an annual center volume of more than 20 to 25 cases per year.**

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Prophylactic thoracic aortic surgical procedures are recommended by national and international guidelines for aneurysms greater than certain diameters, with the aim of preventing acute aortic dissection, rupture, or sudden death [1–4]. A previous study using the national Society of Thoracic Surgeons (STS) database for proximal aortic replacement between 2004 and 2009 identified risk factors for perioperative mortality and morbidity and reported an operative mortality for elective cases of 3.4% [5]. Since then, a significant number of centers initiated reporting, resulting in more than 1,000 centers reporting at least one proximal aortic surgical procedure. In addition, variables pertinent to aortic operations, such as axillary or femoral cannulations, use of adjunctive cerebral perfusion, deep hypothermic circulatory arrest, deep hypothermic circulatory arrest time, and intraoperative neuromonitoring, became available in 2011, thus allowing for characterization of contemporary practice patterns of proximal thoracic aortic surgical procedures in greater detail. Using the national STS Adult Cardiac Surgery Database (ACSD) data between 2011 and 2016, we aimed to (1) characterize the contemporary patient characteristics and outcomes of thoracic aortic surgical procedures for aortic aneurysms, (2) evaluate center volume-outcome relationships in

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proximal thoracic aortic surgical procedures across US centers, and (3) identify risk factors for perioperative mortality and quantify patients' risk profiles in relation to center case volumes.

Patients and Methods

Data Source and Definitions

The STS ACSD currently houses data from >1,000 participating centers, representing >90% of the cardiac surgical centers in the United States [6]. Clinical sites enter data using uniform STS definitions for patients' characteristics and outcomes. The quality of the data has been rigorously assessed by comparison with independent national and local datasets [7]. The present study was approved by the Participant User File (PUF) Research Program Committee of the STS Workforce and by the Yale University (New Haven, CT) Institutional Review Board (protocol ID: 2000020933).

The primary outcome variable was operative mortality, defined as death from any cause either in hospital or within 30 days of the index proximal aortic operation. Those variables previously identified in the peer-reviewed literature as potential predictors of outcome in aortic surgical procedures were included in regression models, in addition to variables from existing STS 30-day operative mortality and morbidity risk models [8]. Further specifications of the STS ACSD data definitions are available from STS [9]. Exploratory analysis demonstrated that missing data were rare (<2% for all variables, except for ejection fraction, which was missing in 6%). Missing data were handled as has been done for existing STS risk models [8] (details for treatment of missing data are available in the Supplemental Material).

Patient Population

Adult patients who underwent elective, urgent, and emergency proximal aortic surgical procedures (with or without root, arch, or aortic valve replacements), including both isolated and concomitant operations, in the period from 2011 to 2016 in the US centers participating in the STS reporting were included. STS data versions 2.73 and 2.81 were used. Patients with operative indications of acute aortic dissection, intramural hematoma, and penetrating ulcers were excluded because they had disease entities and risk profiles that differed from those in patients with proximal aortic aneurysm. Descending and thoracoabdominal aortic surgical procedures were also excluded. After the foregoing exclusions, there were 53,559 operations reported by 1,045 centers.

Statistical Analysis

Baseline patients' characteristics, operative variables, and postoperative outcomes were summarized by percentage distribution and mean with standard deviations. Centers were stratified into five strata by average annual case volume by arbitrary cutoff points of fewer than five cases, five or more and <10 cases, ≥10 and < 20 cases, ≥20 and <50 cases, and ≥50 cases. Logistic regression related baseline characteristics and comorbidities to operative mortality. Input variables are outlined in the Supplemental Tables. The final model was selected using forward, backward, and stepwise selection and was fitted over the entire dataset. Ten-fold cross validation was performed to estimate sensitivity and specificity across various values of the discrimination threshold for predicted probability of mortality classifying operations that resulted in operative mortality. The threshold was optimized on the basis of the maximum Youden index (sensitivity + specificity − 1). One model was fitted without including the annual center volume strata as a covariate to assess whether the risk-adjusted mortality associated with patient-specific variables differed across the case volume strata. The final model was fitted including the center volume strata as one of the covariates. C-statistics were calculated for each model. Predicted probability of operative mortality for individual patients was calculated from each model. Using the same input covariates as the foregoing model, restricted cubic splining function was used to assess the risk of operative mortality along the annual center case volume as the continuous variable [10]. Four knots were defined at five, 10, 20, and 50 cases per year. All analyses were conducted using SAS software version 9.4 (SAS Institute, Cary, NC) and R software (R Foundation for Statistical Computing, Vienna, Austria).

Results

Baseline patients' characteristics and operative variables of 53,559 operations reported by 1,045 centers are outlined in Table 1. During the study period, 23,550 (44.0%) operations involving the isolated ascending aorta, 17,304 (32.3%) operations involving the aortic root without the arch, 7,016 (13.1%) operations involving the aortic arch without the root, and 5,689 (10.6%) operations involving both the aortic root and arch were performed for thoracic aortic aneurysms. Operative variables by locations of the aorta involved are outlined in Table 2. Overall, 45,742 (85.4%) operations were concomitant operations, of which aortic valve replacement comprised 92.9%. Aortic cannulation was the most common cannulation strategy for all locations of aortic involvement, but it was more commonly used in cases involving the aortic root and ascending aorta (80.2% for both) compared with cases involving the aortic arch (54.4% for arch only and 56.4% for arch combined with root).

Outcomes by case status (elective, urgent, emergency, and salvage) are outlined in Table 3. In this series, operative mortality occurred in 1,720 procedures (3.2%). Major morbidities occurred in 27,203 procedures (50.8%). Incidences of select complications are as follows: atrial fibrillation in 16,324 (30.5%), prolonged ventilator support need in 7,530 (14.1%), return to the operating room for bleeding in 2,289 (4.3%), pneumonia in 1,844 (3.4%), stroke in 1,468 (2.7%), renal failure in 1,482 (2.8%), sternal wound infection in 151 (0.3%), and permanent paralysis in 122 (0.2%). Mean hospital length of stay was 9.3 ± 8.4