The Society of Thoracic Surgeons Adult Cardiac Surgery Database: 2016 Update on Research

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The Society of Thoracic Surgeons Adult Cardiac Database (ACSD) is an international voluntary effort that is the foundation of our specialty's efforts in clinical performance assessment and quality improvement. Containing nearly 6,000,000 patient records, the ACSD is a robust resource for clinical research. Seven major original publications and four review articles were generated from the ACSD in 2015. The risk-adjusted outcome analyses and quality measures reported in these studies have made substantial contributions to inform daily clinical practice. This report summarizes the ACSD-based research efforts published in 2015.

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> If we are to provide the best possible care for all patients coming to us with heart disease now and in the future, we must do many things, including the continual evaluation of the results of our cardiac operations and a comparison of these results with those of other patient management programs and with the natural history of the disease. Such is a part of the science of surgery.—John W. Kirklin, MD, Connor Lecture, American Heart Association Meeting, 1973 [1]

Cardiac surgeons have long recognized the value of detailed outcomes analysis [1]. The Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database (ACSD) was established in 1989 in response to the urgent need for more reliable outcome assessment after cardiac operations and to specifically address the shortcomings of report cards using unadjusted claims-based data. The ACSD has since been expanded and refined to become a model for clinical data registries, with total patient records now approaching 6 million. The ACSD currently receives data from 1,087 participants in the United States (U.S.) and Canada, 18 international participants, and 3,086 surgeons. This translates to the inclusion of comprehensive demographic, clinical, operative, and outcome data from 90% to 95% of all eligible cardiac operations performed in the 50 U.S. states [2–4]. Internal data quality checks and audits are continually performed for accuracy and completeness [2, 5].

The Duke Clinical Research Institute provides not only data collection and warehousing for the STS ACSD but also state-of-the-art statistical analyses for robust risk-adjustment, continual quality improvement initiatives, and clinical research. Procedural risk models are updated periodically on the STS Web site to reflect contemporary data, and calculators for predicted risk of mortality (PROM) and major morbidity are available for use by the cardiac surgical and cardiology communities, health policy researchers, and patients. A major step forward in outcomes research based on the ACSD is the recently acquired ability to link the ACSD to U.S. Centers for Medicare and Medicaid Services claims data, permitting longer-term follow-up analyses [5].

The STS ACSD is a leading instrument for driving quality, research, and patient safety activities [2]. It is at the forefront of numerous trends in U.S. health care, such as data-driven decision making, observational outcomes research, and cost assessment. Analyses from the ACSD have had national effect on value-based reimbursement strategies, best-practice protocols, public reporting, and clinical guideline development [3, 4]. Quality indicators

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Abbreviations and Acronyms

ACSD	=	Adult Cardiac Surgery Database
AVR	=	aortic valve replacement
CABG	=	coronary artery bypass grafting
HAI	=	hospital-acquired infection
MVRR	=	mitral valve repair/replacement
PROM	=	predicted risk of mortality
Re-SAVR	=	reoperative surgical aortic valve replacement
SAVR	=	surgical aortic valve replacement
STS	=	The Society of Thoracic Surgeons
TAVR	=	transcatheter aortic valve replacement
U.S.	=	United States

have been developed, including composite performance measures that reflect risk-adjusted mortality and major morbidity for specific procedures in cardiac surgery [3]. External audits and linkages have documented high reliability, completeness, and accuracy of the ACSD, thus validating the data for performance assessment and clinical research [4, 5]. Submission of research protocols is open to all STS members. Through the ASCD access and publications process, the database provides clinical data for 30-day and in-hospital outcome analysis.

This article, the second in a series of ACSD annual reports, summarizes the 2015 research productivity of the ACSD in two principle areas: primary 30-day outcome analyses through the access and publications process [6–10] and important new quality initiatives with the introduction of two composite measures [11–14].

Outcome Analysis Research

Five ACSD-based articles focused on patient outcomes have made substantial contributions to our understanding of aortic valve [6–8] and aortic root operations [9] and the assessment of hospital-acquired infections [10].

With the evolving management of aortic valve disorders in the era of transcatheter aortic valve replacement (TAVR), documenting the contemporary results of surgical AVR (SAVR) is of extreme relevance to clinical decision making. An ACSD study was performed in low-risk, intermediate-risk, and very high-risk patients to define contemporary SAVR outcomes [6]. This analysis included 141,905 patients who underwent isolated primary SAVR from 2002 to 2010. Patients were divided into three groups by their estimated STS PROM: (1) a low-risk group (PROM <4%) representing 80% (n = 113,377) of patients, (2) an intermediate-risk group (PROM 4% to 8%), representing 13.8% (n = 19,769) of patients, and (3) a high-risk group (PROM >8%) representing 6.2% (n = 8,759) of patients. Most patients (80%) were categorized as low risk, and only 6.2% were identified as high risk. The mean age was noticeably younger for low-risk patients (65 years; $p < 0.0001$) compared with intermediate-risk and high-risk patients (both 77 years).

Operative mortality was defined as death during the same hospitalization or after discharge but within 30 days of SAVR. Compared with the calculated PROM, observed mortality was lower than expected in all patients. Observed vs predicted mortality was 1.4% vs 1.7% in group 1, 5.1% vs 5.5% in group 2, and 11.8% vs 13.7% in group 3 ($p < 0.0001$). Two periods were analyzed: 2002 to 2006 (n = 63,754) and 2007 to 2010 (n = 78,151). In the most recent surgical era (2007 to 2010), operative mortality fell significantly in groups 2 (5.4% vs 6.4%, $p = 0.002$) and 3 (11.9% vs 14.4%, $p = 0.0004$), but the already low mortality of group 1 remained similar.

Given the continuing improvements in mortality rates for SAVR, mortality risk models need to be updated frequently, and comparisons of SAVR and TAVR outcomes need to be based on contemporaneous patient series. This large real-world assessment of excellent SAVR outcomes provides an important outcome benchmark as TAVR is being introduced in lower-risk populations [6]. A completely new set of risk models for coronary artery bypass grafting (CABG), valve, and combined operations will be submitted for publication in 2016.

A similar study [7] showed that accurate risk assessment of patients presenting for aortic valve therapy after prior CABG is essential for appropriate selection of SAVR or TAVR. This analysis involved 6,534 patients with prior CABG undergoing elective, isolated SAVR through a redo sternotomy between October 2009 and December 2013 [7]. Case-specific PROM was calculated from the STS SAVR risk model, and observed-to-expected ratios were evaluated across the spectrum of risk. A cohort-specific recalibration equation was derived using logistic regression. The proportion of patients classified as low (PROM <4%), intermediate (4% to <8%), high (8% to <12%), and very high risk (>12%) was calculated using the recalibration equation.

The performance of the cohort-specific recalibration equation was compared with the risk equations used for quarterly STS reports. This study showed that the STS online risk calculator overestimated risk for low-risk, intermediate-risk, and high-risk categories. The recalibrated risk equation was used to reclassify a substantial proportion of patients: 25.5% from intermediate to low risk, 39.7% from high to intermediate risk, and 41.5% from very high to high risk. Thus, the STS online risk calculator overestimated the risk of patients presenting for SAVR after previous CABG for all but the lowest risk patients. Using a cohort-specific recalibration equation would result in a substantial proportion of patients being downgraded to lower risk categories.

A comparison of the cohort-specific recalibration equation to the standard quarterly STS model recalibration (which results in an observed-to-expected ratio of 1 for each year) demonstrated similar results, which provides reassurance that the annual recalibration risk equation used to generate performance feedback reports is accurate. These important findings are critical in the contemporary evaluation of TAVR vs SAVR. This study also supports periodic recalibration of the