An empirically based tool for analyzing morbidity associated with operations for congenital heart disease

Marshall L. Jacobs, MD,[a] Sean M. O'Brien, PhD,[b] Jeffrey P. Jacobs, MD,[c] Constantine Mavroudis, MD,[d] Francois Lacour-Gayet, MD,[e] Sara K. Pasquali, MD,[f] Karl Welke, MD,[g] Christian Pizarro, MD,[h] Felix Tsai, MD,[i] and David R. Clarke, MD[j]

Objective: Congenital heart surgery outcomes analysis requires reliable methods of estimating the risk of adverse outcomes. Contemporary methods focus primarily on mortality or rely on expert opinion to estimate morbidity associated with different procedures. We created an objective, empirically based index that reflects statistically estimated risk of morbidity by procedure.

Methods: Morbidity risk was estimated using data from 62,851 operations in the Society of Thoracic Surgeons Congenital Heart Surgery Database (2002-2008). Model-based estimates with 95% Bayesian credible intervals were calculated for each procedure's average risk of major complications and average postoperative length of stay. These 2 measures were combined into a composite morbidity score. A total of 140 procedures were assigned scores ranging from 0.1 to 5.0 and sorted into 5 relatively homogeneous categories.

Results: Model-estimated risk of major complications ranged from 1.0% for simple procedures to 38.2% for truncus arteriosus with interrupted aortic arch repair. Procedure-specific estimates of average postoperative length of stay ranged from 2.9 days for simple procedures to 42.6 days for a combined atrial switch and Rastelli operation. Spearman rank correlation between raw rates of major complication and average postoperative length of stay was 0.82 in procedures with n greater than 200. Rate of major complications ranged from 3.2% in category 1 to 30.0% in category 5. Aggregate average postoperative length of stay ranged from 6.3 days in category 1 to 34.0 days in category 5.

Conclusions: Complication rates and postoperative length of stay provide related but not redundant information about morbidity. The Morbidity Scores and Categories provide an objective assessment of risk associated with operations for congenital heart disease, which should facilitate comparison of outcomes across cohorts with differing case mixes. (J Thorac Cardiovasc Surg 2013;145:1046-57)

CHD

Supplemental material is available online.

Earn CME credits at http://cme.ctsnetjournals.org

Contemporary efforts to describe and compare congenital heart surgery outcomes across institutions have evolved to include (1) use of clinical registry data, rather than administrative data from the hospital bill to evaluate outcomes; (2) use of empiric rather than opinion-based models to adjust for differences in case complexity across institutions; and (3) recognition that focusing solely on in-hospital mortality overlooks 96% of patients who survive to hospital discharge and the important morbidities that they may experience.[1]

In 2009, an empirically based tool for analyzing mortality associated with congenital heart surgery was introduced. The Society of Thoracic Surgeons-European Association for Cardiothoracic Surgery (STS-EACTS) Congenital Heart Surgery Mortality Score and Categories are based on analysis of 148 different types of operations performed in 77,294 patients.[2] Procedures are assigned to 1 of 5 categories on the basis of a similar risk of in-hospital death.

From the Department of Pediatric and Congenital Heart Surgery,[a] Cleveland Clinic, Cleveland, Ohio; Department of Biostatistics,[b] Duke University School of Medicine and Duke Clinical Research Institute, Duke University Medical Center, Durham, NC; The Congenital Heart Institute of Florida,[c] All Children's Hospital and Children's Hospital of Tampa, Cardiac Surgical Associates of Florida, University of South Florida College of Medicine, St Petersburg and Tampa, Fla; Congenital Heart Institute,[d] Florida Hospital for Children, Orlando, Fla; Pediatric Cardiac Surgery Department,[e] Montefiore Children's Hospital, Montefiore Medical Center, New York, NY; Department of Pediatrics,[f] Duke University School of Medicine and Duke Clinical Research Institute, Duke University Medical Center, Durham, NC; Cardiothoracic Surgery,[g] Seattle Children's Hospital, Seattle, Wash; Nemours Cardiac Center,[h] Wilmington, Del; Cardiac Surgery,[i] Children's Hospital of the King's Daughters, Norfolk, Va; and Department of Cardiothoracic Surgery,[j] The Children's Hospital, Aurora, Colo.

Disclosures: Authors have nothing to disclose with regard to commercial support.
Received for publication Dec 29, 2011; revisions received April 26, 2012; accepted for publication June 12, 2012; available ahead of print July 26, 2012.

Address for reprints: Marshall L. Jacobs, MD, 6019 Goshen Rd, Newtown Square, PA 19073 (E-mail: marshall.jacobs@comcast.net).

0022-5223/$36.00

http://dx.doi.org/10.1016/j.jtcvs.2012.06.029

Abbreviations and Acronyms

CrI	= credible interval
ICU	= intensive care unit
PLOS	= postoperative length of stay
STSCHSD	= Society of Thoracic Surgeons Congenital Heart Surgery Database
STS-EACTS	= Society of Thoracic Surgeons-European Association for Cardiothoracic Surgery

Category 1 has the lowest risk of death, and category 5 has the highest risk of death. In addition, each procedure receives a numeric score ranging from 0.1 to 5.0 that expresses mortality risk on a more continuous scale. The STS-EACTS Mortality Categories are intended to facilitate analysis of outcomes by grouping procedures with similar risk of in-hospital mortality.

Although congenital heart surgery outcomes analyses have traditionally focused on mortality, comprehensive assessment requires attention to other end points. Nonfatal events, such as stroke and renal failure, are major determinants of hospital cost and patients' health status after surgery. In addition, postprocedure length of hospital stay provides useful direct information about resource use and indirect proxy information about a patient's condition.[3,4] Although such measures are captured in clinical registries, tools for analyzing these end points are lacking.

The goal of the present study was to develop a new system for classifying congenital heart surgery procedures on the basis of their potential for morbidity using empirical data from the STS Congenital Heart Surgery Database (STSCHSD). There were 4 specific objectives:

- to develop a morbidity metric based on both the occurrence of complications that have a significant and durable impact on patient health and utilization of health care resources;
- to estimate the average amount of patient morbidity by procedure type;
- to convert these procedure-specific morbidity estimates into a scale ranging from 0.1 to 5.0 (range was chosen for consistency with the STS-EACTS Mortality Score[2]); and
- to group procedures with similar estimated morbidity risk into 5 relatively homogeneous categories that were designed to minimize within-category variation and to serve as a stratification variable that can be used to adjust for case mix when analyzing outcomes and comparing institutions.

The Morbidity metric was developed primarily for the purpose of grouping types of procedures to better describe case mix, as was the STS-EACTS Mortality metric. The intent was not to assess or predict outcomes for an individual patient or surgeon, for which other types of analyses may be used.

MATERIALS AND METHODS

Study Population

The STSCHSD has been described.[5] The Duke Clinical Research Institute serves as the data analysis center for STS databases and has an agreement and institutional review board approval to analyze the aggregate deidentified data for research purposes. For this study, operations were included if they took place between January 1, 2002, and December 31, 2008, and were 1 of the 148 types of cardiovascular procedures for which the STS-EACTS Mortality Score is defined.[2] Operations performed at centers with no more than 10% missing data for complications, mortality, or postoperative length of stay (PLOS) were eligible for inclusion in the analysis. From eligible centers, individual operations with missing data for complications, mortality, or PLOS were excluded. Of 63,297 potentially eligible operations, 446 individual operations were excluded on the basis of missing data regarding complications (n = 273), PLOS (n = 151), or mortality (n = 22).

Additional inclusion and exclusion criteria were identical to those used for developing the STS-EACTS Mortality Score.[2] Only the first operation of each hospital admission was analyzed. The final study population consisted of 62,851 operations classified into 148 procedure types at 68 centers. Results are presented for the subset of 140 procedure types having at least 10 eligible cases (62,819 total operations; 99.9%).

Classification of Multiple-Procedure Operations

Several operations in the analysis represent combinations of 2 or more procedures. These are analyzed as combined procedures because the complexity of the combination is regarded as being different from the complexity of the component procedures when performed in isolation. For each of these combined procedures, unique procedure codes were subsequently assigned in STSCHSD version 3.0. Because all data in this analysis predate version 3.0, classification of multiple-procedure operations in this study follows guidelines set forth previously in development of the STS-EACTS Mortality Score and Categories.[2]

End Points

Morbidity was quantified for each procedure on the basis of the proportion of patients experiencing major complications and by the average PLOS (Table 1). Major complication was defined as the occurrence of any 1 or more of the 6 complications listed in Table 2. These complications represent definitive outcomes that can be ascertained reliably and that are likely to have significant and durable impact on patient health. The unadjusted rate of major complications is defined as the percent of operations that were associated with the occurrence of 1 or more of the major complications listed in Table 2. PLOS was defined as the number of days from the date of operation to the date of discharge and was determined for all patients, including those who died in-hospital.

Analysis

Statistics calculated for each procedure type included the number of eligible operations, the percent of patients experiencing major complications, the 95% binomial confidence interval for the probability of major complications, and the average and interquartile range (25th and 75th percentiles) of PLOS. Model-based estimates of each procedure's average risk of major complications and average PLOS were calculated by hierarchical modeling and presented along with 95% Bayesian credible intervals (CrIs). Details of these calculations are provided in Appendix 1.

Creation of Morbidity Scores

To facilitate ranking and grouping of procedures, average risk of major complications and average PLOS were combined into a single composite morbidity measure. To account for different measurement scales, the 2 individual measures were rescaled to have the same standard deviation (Appendix 3). They were then summed together. The resulting composite morbidity measure was the basis of the proposed Morbidity Scores and

CHD