Improving and standardizing capture of pediatric cardiac surgical complications

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Objective: Our objective was to establish baseline data and develop a tool to allow for systematic evaluation of pediatric cardiac surgical complications. As a first step, we examined the incidence and distribution of complications, risk stratified by case complexity in a single institution. With improving mortality rates for congenital heart surgery, the next frontier for improving patient outcomes is characterizing and reducing complications. Currently, no standardized approach is available to monitor the incidence and severity of all complications associated with a congenital cardiac surgery program.

Methods: Complications occurring in pediatric cardiac surgical patients (January 2006 to March 2009) were collected by database review applying standardized definitions. The surgical procedures were stratified by complexity to analyze the distribution of complications over the risk spectrum. Each complication was assigned a severity coefficient (1–3) used to calculate the combined effect of frequency and severity. The cumulative sum method was used to determined the trend of the adverse outcomes.

Results: Of 292 procedures, 84 (28.8%) were associated with a total of 150 complications. Of the 150 complications, 37 occurred in patients who died. The most common complications were arrhythmias (14.5%), cardiac (12.6%), and operative (12.6%). There was a linear relationship between the frequency and severity of complications and surgical complexity, as stratified using the Risk Adjustment for Congenital Heart Surgery category or Aristotle basic complexity levels (Spearman's coefficient = 1).

Conclusions: When examined in a systematic fashion, the risk of complications in pediatric cardiac surgical patients is considerable. Our data illustrate that it is possible to track complications over time in a consistent manner. The effect of complication monitoring on patient outcomes remains to be proved. (J Thorac Cardiovasc Surg 2012;144:570-6)

Pediatric cardiac surgery is a discipline in evolution, with progressively improving mortality rates. As public demand for institutional reporting of outcomes has grown, the profession has searched for accurate and objective measures of program performance. Mortality is a well-defined, universally captured, and readily measured outcome. The reporting and comparison of institutional outcomes, to date, has focused on overall operative mortality, currently 4% in large multi-institutional data sets.[1] However, a large proportion of adverse outcomes are attributable to nonfatal complications that are not captured in mortality reports. Morbidity is defined as ''a state of illness or lack of health that includes physical, mental or emotional disability'' by the Multi-Societal Committee for Pediatric and Congenital Heart Disease.[2] Hence all operations are accompanied by some degree of morbidity. A complication, however, is defined as ''an event or occurrence that is associated with disease or a healthcare intervention that is (a) a departure from the desired course of events and (b) may cause or be associated with suboptimal outcome.''[2] Complications can negatively affect patient outcomes, including length of stay in the intensive care and hospital and long-term quality of life.[3] Complications can also be associated with an increased cost to the healthcare system. Although in some reports of adult cardiac surgery, complications are associated with mortality,[4] there is evidence to suggest that complications might reflect something different to mortality and could be worth examining as a separate indicator of program performance. For example, Silber and colleagues[5] reported that the hospital characteristics associated with mortality were not associated with complications. Shroyer and associates[6] also reported no significant correlation between risk-adjusted mortality and risk-adjusted complications.

Although many centers collect and report series of pathology-specific or case-specific complication data, no systematic method of reporting the incidence or distribution of complications for an entire surgical program is available. Specifically, no benchmarks are in use for intra- or

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Abbreviations and Acronyms
ABC = Aristotle basic complexity
CUSUM = cumulative sum
ECMO = extracorporeal membrane oxygenation
RACHS = Risk Adjustment for Congenital Heart Surgery

interinstitutional comparison of risk-adjusted complications, even though up to 30% of congenital heart surgery admissions can be associated with complications.[7] An important step toward the meaningful collection of complication data was the Multi-Societal Committee for Pediatric and Congenital Heart Disease definition list of surgical complications.[2]

The objective of the present study was to report the frequency of complications in a retrospective single-institution pediatric cardiac surgical cohort using standardized definitions. Our secondary objective was to develop a complication reporting system to accurately capture pediatric cardiac surgery complications and to examine the incidence and distribution of complications, stratified by surgical case complexity. Rather than trying to provide specific complication data for a given operation or diagnosis, we have attempted to develop a tool that will allow programs to monitor their own outcomes in real time, to be able to respond quickly to any changes in the incidence of complications, and to thus enhance patient outcomes.

METHODS

The research ethics board of the IWK Health Centre approved the retrospective cohort analysis of complications occurring in congenital cardiac surgical procedures from January 1, 2006, to March 31, 2009. The IWK Health Centre is the tertiary referral center for Atlantic Canada and is a full-service cardiac surgical center, with the exception of cardiac transplantation and long-term ventricular assist device implantation. All cardiac surgical procedures performed during the study period were included in the analysis, with the exception of surgical closure of patent ductus arteriosus in premature neonates, primary extracorporeal membrane oxygenation (ECMO) and cardiac pacemaker and defibrillator implantations. Complications were collected by database review using the short list of 52 complications as defined by the Multi-Societal Committee for Pediatric and Congenital Heart Disease.[2] Complications were identified by 1 clinic nurse on a quarterly basis by scanning each patient chart and identifying the complications recorded in the progress notes and discharge summaries (completed contemporaneously with patient discharge by the attending pediatric cardiologist and dictated by the attending pediatric cardiac surgeon). On a quarterly basis, the pediatric cardiologists and cardiac surgeons met and reviewed each of the patients and all the complications. Any discussion regarding complication identification or reclassification led to additional chart review and a final record of the complications was made. On an annual basis, the entire cohort and all the complications were reviewed numerically to inform the group of the overall program performance. Complications that did not fit into the standardized definition list were included under the heading ''other complications.''

The surgical procedures were risk stratified according to surgical complexity using either the Risk Adjustment for Congenital Heart Surgery (RACHS)[8] or Aristotle basic complexity (ABC) scores.[9] The RACHS category is an expert consensus ranking of 79 surgical procedures that was developed as a risk-adjustment tool according to the differences in surgical complexity and validated for comparing mortality outcomes. The ABC score is determined by expert consensus of surgical complexity and the likelihood of complications. The surgical complexity score was assigned according to the highest risk procedure in the event that an operation involved 2 or more procedures performed concurrently.

Mortality was classified as intraoperative or postoperative, including all deaths occurring within 30 days postoperatively or during the index hospitalization. To factor in the severity of complications to our model, each complication was weighted by assigning a severity coefficient (range, 1–3), according to expert consensus, ranging from the lowest severity (severity coefficient 1, defined as mild or temporary deficit, predicted to minimally affect the patient's course and outcome) to the greatest severity (severity coefficient 3, defined as a severe and/or permanent complication predicted to significantly impair the patient's outcome and possibly precede death). For calculations in which patients experiencing mortality were included in the analysis, death was assigned a severity coefficient of 5. Because of the debate surrounding the inclusion of ''mortality'' as a complication, we included death as a category of complication for the first part of the analysis and excluded cases with mortality for the second part of the analysis. Complications categorized as ''other'' were not assigned a severity coefficient.

To determine the total magnitude of complications (a variable we have termed ''morbidity burden'') in a single surgical complexity stratum, the weighted complications were stratified by RACHS category or ABC level and then summed (morbidity burden = Σ [frequency $\times$ severity]) for each procedure in a particular category. RACHS categories 5 and 6 were collapsed into a single category owing to the small number of procedures in each category. Because of the unequal distribution of procedures across the RACHS categories (Table 1), the morbidity burden was divided by the number of procedures in the corresponding surgical stratum to generate a variable we termed ''indexed morbidity,'' which is a reflection of the average morbidity burden per procedure in each risk category (indexed morbidity = morbidity burden/number of procedures in category).

The cumulative sum (CUSUM) method was applied to track adverse outcomes over time. To construct a CUSUM plot, consecutive cases were plotted as a single unit on the x axis and the occurrence of any adverse event was plotted by the movement of 1 unit on the y axis. The construction of alarm limits on the CUSUM curves is possible using the technique described by Rogers and colleagues.[10] The following values were used to construct the alarm limits. First, using our retrospective data, the ''acceptable'' morbidity rate was set at 28.8%. Second, the unacceptable morbidity rate was set at 1.5 times the acceptable mortality rate (43.2%). Third, the type 1 (α) error rate was set at 5%. Finally, the type 2 (β) error rate was set at 5%.

Statistical Analysis

The raw frequency data were obtained for each complication. We compared the incidence and severity of the complications separately in the survivors and deceased patients. A CUSUM plot was derived for the complications of the entire cohort.

RESULTS

Demographics

From January 1, 2006 to March 31, 2009, 268 patients (median age, 178 days; range, 1 day to 18 years) underwent 292 procedures (Table 1). Of the 268 patients, 50 were neonates (17.1%) and 132 were infants (45.9%). Most (205/292) procedures were RACHS category 2 or 3. Procedures performed 5 or more times accounted for 208 (71%) of the 292 procedures.