Perioperative mechanical circulatory support in children: An analysis of the Society of Thoracic Surgeons Congenital Heart Surgery Database

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Objectives: Analyses of mechanical circulatory support (MCS) in pediatric heart surgery have primarily focused on single-center outcomes or narrow applications. We describe the patterns of use, patient characteristics, and MCS-associated outcomes across a large multicenter cohort.

Methods: Patients (aged <18 years) in the Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database (2000-2010) were included. The characteristics and outcomes of those receiving postoperative MCS were described, and bayesian hierarchical models were used to examine variations in the adjusted MCS rates across institutions.

Results: Of 96,596 operations (80 centers), MCS was used in 2.4%. The MCS patients were younger (13 vs 195 days, $P < .0001$) and more often had STS-defined preoperative risk factors (57.2% vs 32.7%, $P < .0001$). The operations with the greatest MCS rates included the Norwood procedure (17%) and complex biventricular repairs (arterial switch, ventricular septal defect, and arch repair [14%]). More than one half of the MCS patients did not survive to hospital discharge (53.2% vs 2.9% of non-MCS patients; $P < .0001$). MCS-associated mortality was greatest for truncus arteriosus and Ross-Konno operations (both 71%). The hospital-level MCS rates adjusted for patient characteristics and case mix varied by 15-fold across institutions, with both high- and low-volume hospitals having substantial variation in MCS rates.

Conclusions: Perioperative MCS use varied widely across centers. The MCS rates were greatest overall for the Norwood procedure and complex biventricular repairs. Although MCS can be a life-saving therapy, more than one half of MCS patients will not survive to hospital discharge, with mortality >70% for some operations. Future studies aimed at better understanding the appropriate indications, optimal timing, and management of MCS could help to reduce the variation in MCS use across hospitals and improve outcomes. (J Thorac Cardiovasc Surg 2014;147:658-65)

CHD

Mechanical circulatory support (MCS) has been used perioperatively in the care of critically ill children with congenital heart disease and is often life-saving. Although several devices are being investigated, including those being evaluated currently in the National Institutes of Health in the Pumps for Kids, Infants, and Neonates (PumpKIN) trial, the most common form of pediatric MCS has been extracorporeal membrane oxygenation (ECMO). ECMO can be rapidly and simply initiated. It was first used in a pediatric patient in 1974 at Orange County Medical Center (Los Angeles, Calif), and Robert Bartlett, MD, first successfully supported a neonate with ECMO (to treat meconium aspiration).[1] Since then, the application of ECMO has expanded to include cardiopulmonary support of patients with congenital heart disease. As the surgical repair of congenital heart disease has become increasingly complex, ECMO use has become more common. Reports of its use in this population have included bridging to heart transplantation, rescue cardiopulmonary resuscitation, and failure to wean from cardiopulmonary bypass.[2-4] However, these reports have primarily included small cohorts, were most often from single institutions, and tended to be narrowly focused on a specific patient population. Currently, understanding is limited regarding the use and outcomes associated with ECMO after congenital heart surgery across institutions.

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Abbreviations and Acronyms
ECMO = extracorporeal membrane oxygenation
ELSO = Extracorporeal Life Support Organization
MCS = mechanical circulatory support
STS = Society of Thoracic Surgeons

The Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database collects perioperative information on all patients at participating institutions undergoing pediatric and congenital heart surgery, including information regarding the use of perioperative MCS. Approximately 85% of all US pediatric heart surgery centers participate in this database, and, therefore, it is a valuable repository of information regarding the use of MCS in congenital heart surgery patients.[5] The primary objective of the present study was to use the STS Congenital Heart Surgery Database to describe the patterns of use, patient characteristics, and outcomes associated with MCS across a large multicenter cohort.

METHODS

Data Source

The STS Congenital Heart Surgery Database contains operative, perioperative, and outcomes data on >250,000 patients who have undergone congenital heart surgery since 1998 and currently includes information from 105 participating hospitals. Data from all patients undergoing pediatric and congenital heart surgery at participating centers are entered into the database. Data quality and reliability are ensured through intrinsic verification of data and a formal process of site visits and data audits.[6] The Duke Clinical Research Institute serves as the data warehouse and analytic center for all STS national databases. The Duke University institutional review board and STS Access and Publications Committee approved the present analysis.

Patient Population

For the present study, 1,32,854 cardiac operations (with or without cardiopulmonary bypass) performed on patients aged <18 years from 2000 to 2010 at 96 hospitals participating in the STS Congenital Heart Surgery Database were eligible for inclusion. A total of 16 centers with >15% missing data on study variables were excluded. Although the STS DATABASE contains nearly complete data for the standard data fields required to calculate operative mortality, not all centers submit complete data for all variables, such as patient preoperative characteristics or postoperative complications. Therefore, it has been standard practice to exclude centers with data missing for key study variables to maximize data integrity and minimize missing data.[7] From the remaining 80 centers, the patients with data missing for the study variables were also excluded, leaving a final study population of 96,596 patients.

Data Collection

The data collected from the STS Congenital Heart Surgery Database included demographic information, cardiac diagnoses, presence of a noncardiac/genetic abnormality, and the presence of any STS-defined preoperative risk factors.[8] The operative data included information regarding the primary procedure of the index (first) cardiovascular operation of the admission, which was analyzed individually and also categorized using the STS-European Association for Cardiothoracic Surgery risk stratification system (category 1, lowest mortality risk; category 5, greatest mortality risk).[9] This system was recently developed using empiric data from nearly 80,000 patients and includes a greater number of operations than other risk stratification systems.[9] The number of previous cardiothoracic operations and cardiopulmonary bypass times were also collected. The use of both pre- and postoperative MCS (of any type) was collected. In the earlier years of data collection, detailed information regarding the specific type of MCS was not collected in the database; therefore, the present study analyzed MCS use in aggregate. In addition, detailed information regarding the timing of the initiation and duration of MCS is not currently collected in the database. The outcomes data included in-hospital mortality and postoperative length of stay.

Statistical Analysis

The preoperative, operative, and outcomes data were described for the overall cohort and for the subgroups of patients undergoing the most common operations using standard summary statistics. The data were compared between those who received MCS and those who did not using the chi-square test or Wilcoxon rank sum test. Most of the analysis focused on postoperative MCS use, given the relative rarity of preoperative MCS use.

To examine the variation in postoperative MCS rates across hospitals, bayesian hierarchical models were used to calculate the adjusted postoperative MCS rates for each hospital. The models were adjusted for patient characteristics and case mix to account for any differences across hospitals, including patient age, gender, weight at surgery, the presence of any STS-defined preoperative risk factors or noncardiac/genetic abnormality, previous cardiothoracic surgery, the use of preoperative MCS, STS-European Association for Cardiothoracic Surgery category, and date of surgery. This method also accounted for the increased variability in outcomes from centers with a smaller sample size and shrinks the estimates form smaller centers toward the population average to provide more stable estimates.[10] The distribution of adjusted MCS rates across hospitals was described and plotted against the hospital-average annual overall cardiac surgical volume. Finally, to further investigate the relationship between center volume and MSC rates, we also calculated the adjusted MCS rates across center volume categories (<150, 150-249, 250-349, and ≥350 total cardiac cases annually) as follows: adjusted rate = observed rate/predicted rate × sample average rate, where the predicted rates were from a marginal logistic model, including the aforementioned patient and operative factors. All analyses were performed using Statistical Analysis Systems, version 9.3 (SAS Institute, Inc, Cary, NC), and WinBUGS, version 1.4.3 (the Bayesian inference Using Gibbs Sampling project, Cambridge, UK). $P < .05$ was considered statistically significant.

RESULTS

A total of 96,596 congenital cardiac operations from 80 hospitals were included. The included hospitals were diverse geographically (44% South, 24% Midwest, 21% West, and 11% Northeast). The overall MCS rate was 2.8% (n = 2750), including preoperatively (0.5%; n = 463), postoperatively (2.2%; n = 2136), or both (0.1%; n = 151). Additional analysis focused on the group receiving any postoperative MCS (n = 2287, 2.4%). ECMO support accounted for >95% of the instances of postoperative MCS.

Study Population Characteristics

The characteristics of the study cohort overall and those who received postoperative MCS and those who did not are listed in Table 1. The patients receiving postoperative MCS were younger, weighed less, and more often had an STS-defined preoperative risk factor than did the patients without