Inadequate Technical Performance Scores Are Associated With Late Mortality and Late Reintervention

Meena Nathan, MD, Frank A. Pigula, MD, Hua Liu, MS, Kimberlee Gauvreau, ScD, Steven D. Colan, MD, Francis Fynn-Thompson, MD, Sitaram Emani, MD, Christopher A. Baird, MD, John E. Mayer, MD, and Pedro J. del Nido, MD

Departments of Cardiac Surgery and Cardiology, Children’s Hospital Boston, Harvard Medical School, Boston, Massachusetts

Background. We have shown previously that technical performance score (TPS) is strongly associated with early mortality and major postoperative adverse events in a diverse group of patients. We now report evaluation of the validity of TPS in predicting late outcomes in the same group of patients.

Methods. Patients who underwent surgery between June 1, 2005 and June 30, 2006 were included. The TPS were assigned based on discharge echocardiograms and certain clinical criteria as previously described. Follow-up data for up to 4 years were retrospectively collected. Cox proportional hazards models were used for analysis.

Results. A total of 679 patients were included in the analysis. One hundred twenty-three (18%) were neonates, 213 (31%) infants, 291 (43%) children, and 52 (8%) adults. Four hundred ninety-one (72%) were in low-risk adjustment in congenital heart surgery (RACHS; 1 to 3), 109 (16%) in high risk (4 to 6), and 27 (4%) were less than 18 years and could not be assigned a RACHS score. Three hundred thirty-one (48%) had an optimal TPS, 283 (42%) adequate, 61 (9%) inadequate, and 4 (1%) could not be scored. There were 34 (5%) late deaths and 149 (22%) late unplanned reinterventions. By univariate analysis, age, RACHS-1 categories, and TPS were all significantly associated with late reintervention (p < 0.001 for all), while TPS and RACHS-1 were significant factors for mortality (p < 0.001). On multivariable modeling, inadequate TPS was strongly associated with both late mortality (p = 0.001; HR [hazard ratio] 3.8, CI [confidence interval] 1.7 to 8.4) and late reintervention (p = 0.002, HR 2.1, CI 1.3 to 3.3) after controlling for RACHS-1 and age.

Conclusions. The TPS has a strong association with late outcomes across a wide range of age and disease complexity and may serve as a tool to identify patients who are at a higher risk for late reintervention or mortality.

(Congenital Heart 2013;96:664–9) © 2013 by The Society of Thoracic Surgeons

Congenital heart defects (CHD) are the commonest type of birth defect affecting 1% of the population (40,000 births per year) [1]. Congenital heart defects are the leading cause of birth defect-associated illness and death. Among all patients with CHD, 15% had associated genetic conditions and 20% to 30% had physical, developmental, or cognitive problems. In 2004, health care cost for hospitalization for individuals with CHD was about US $1.4 billion. In 2005, based on the privately insured population, estimated medical care costs for an infant with any CHD was $100,000 and the costs were higher for the more serious defects.

It is now feasible to offer surgical correction or palliation to a majority of these patients. In 2011, 33,733 congenital cardiac procedures were reported to the Society for Thoracic Surgery Congenital Database [2]. Between 1999 and 2006 [1], CHD was listed as the primary cause of death in 27,960 people. Among these, 48% were infants, often after complex interventions and prolonged intensive care unit stay. Despite recent advances in surgical management, CHD has a significant societal impact in terms of morbidity, mortality, and health care resource utilization. Thus, this patient population presents significant challenge to the health care system where optimal care can greatly influence not only early but long-term physical, intellectual, and psychosocial outcomes.

Multiple factors can influence outcomes in congenital cardiac surgery, including the following: (1) preoperative factors, such as birth weight and gestational age, hemodynamic stability, complexity of CHD, adequacy of diagnostic evaluation, and appropriateness of the surgical plan; (2) intraoperative factors, such as conduct of cardiopulmonary bypass, surgical technique, and early post-bypass hemodynamic management; and (3) postoperative course, including intensive care unit course, serious adverse events, and complications. Among these many factors, technical adequacy of repair is likely a significant


Address correspondence to Dr Nathan, Department of Cardiac Surgery, Children’s Hospital Boston and Harvard Medical School, 300 Longwood Ave, Bader 273, Boston, MA 02215; e-mail: meena.nathan@cardio.chboston.org.

Accepted for publication April 15, 2013.
determinant of successful outcome [3–7]. Indeed, the degree to which a congenital heart operation achieved its intended result may be the single most important factor determining long-term medical outcomes and costs.

Several studies have demonstrated important inter-institutional variability in outcomes of congenital heart surgery and have explored factors that might be responsible for center differences, particularly for mortality and postoperative morbidity [8–10]. Among these factors, the technical performance of the surgeon may be one of the most important, but has been difficult to assess. The technical performance score (TPS) is a novel tool for assessing operative performance and is based upon expert opinion and postoperative echocardiographic findings. In preliminary work at our institution, we developed and validated the TPS as a system for scoring technical performance for a subset of common operations for CHD [3, 4] and were able to demonstrate that optimal technical performance could mitigate the effects of preoperative severity of illness in the Norwood population [5].

Subsequently, we performed a prospective study [6] that included intra-operative observations of operations in risk adjustment for congenital heart surgery (RACHS-1) categories 2 to 6, in infants less than 6 months, to define the relationship between technical performance and major postoperative adverse events. Optimal TPS also resulted in lower postoperative adverse events independent of RACHS-1 category, or preoperative severity of illness as measured by the Pediatric Risk of Mortality (PRISM) score.

This same group of neonates and infants was prospectively followed from index surgery [7] for a minimum of 1 year. By univariate analysis, inadequate TPS were associated with mortality (p < 0.0001) and unplanned reintervention (p = 0.034). On logistic regression, inadequate TPS were also associated with late mortality (p = 0.017). We then used the methodological framework that was piloted at our institution [3, 4, 11, 12], to develop measures of technical performance for over 90% of all congenital cardiac operations using 30 procedural modules. The current manuscript reports the validation of this scoring system across a wide range of diagnoses, age groups, and case complexity, and determines if an association exists between TPS and late outcomes.

Material and Methods

A retrospective review of patients who underwent repair of congenital cardiac defects on cardiopulmonary bypass between June 1, 2005, and June 30, 2006, was performed with Institutional Review Board approval. Follow-up data were obtained in this cohort up to December 31, 2011. We excluded patients who underwent lung or heart transplantation, ventricular assist device implants as the primary procedure, and patients with congenital diaphragmatic hernia who required cardiac surgery. Only patients who survived to discharge from index operation were included in the analysis.

Technical performance was scored as previously reported from our center [3, 4, 11, 12], based on the pre-discharge echocardiogram and clinical status at discharge from the index operation of record. Briefly, each operative procedure was divided into subcategories and each subcategory was assigned an optimal, adequate, or inadequate score based on specific echocardiographic and in some instances clinical criteria. Any postoperative, pre-discharge surgical or catheter based reinterventions for residual defects were assigned an inadequate score. At discharge, echocardiographic and clinical status were reviewed, and for the procedure of interest, if all subcategories were optimal, then the final score was optimal; however, if any one of the subcategories had an inadequate score, then the TPS score was inadequate. For example, if the subcategory included postoperative reintervention due to a residual defect, then the TPS score was inadequate.

Figure 1. Flow chart depicts the number of patients included in the study initially and the number of patients lost to follow-up (FU) over the 4-year period. (RI = reintervention.)
Adequate score, it was scored as adequate. If any subcategory was scored as inadequate, then the final score was inadequate. The RACHS-1 categorization [13, 14] was used for determining case complexity at index operation. The RACHS-1 is a method that was developed to adjust for baseline case-mix differences in comparisons of discharge mortality among groups of pediatric patients undergoing congenital cardiac surgery. In this system, various congenital cardiac operations are risk stratified into 1 to 6 mortality risk groups, based on a few clearly defined criteria; RACHS-1 category 1 (eg, atrial septal defect repair) carrying the lowest risk of mortality versus RACHS-1 category 6 (eg, Norwood stage I) carrying the highest risk of mortality [13, 14]. The RACHS-1 has been shown to be an accurate risk predictor in pediatric open heart surgery both in the United States as well as in Europe. We created 2 additional categories to include...
adults, as well as patients under the age of 18 whose procedures could not be assigned a RACHS category in order to include the entire cohort in the analysis.

Outcome variables analyzed included the following: (1) late mortality or need for transplant (any death or transplant that occurred after discharge from index operation); and (2) late unplanned reinterventions, either surgical or catheter-based, in the anatomic area addressed at the index operation that occurred after discharge from index operation. Routine staged palliation after a stage I (ie, uncomplicated bidirectional Glenn or Fontan) were not included as a late reintervention.

Categoric variables are represented as frequencies and percentages. The Pearson $\chi^2$ test was used to examine associations between categoric variables. Distributions of times to late death or transplant and late reintervention were estimated using the Kaplan-Meier method. Multivariable Cox proportional hazards models were used to evaluate the relationships between technical performance scores and the 2 outcome variables, adjusting for baseline patient risk (age and case complexity). Follow-up began on the day of hospital discharge, and patients who did not experience the outcomes were considered to be censored on the day of their last known follow-up. Hazard ratios were estimated along with 95% confidence intervals. The IBM SPSS Statistics, version 18, for Windows (SPSS Inc, Somers, NY) was used for statistical analysis.

### Results

There were 679 patients included in the analysis. A total of 123 (18%) were neonates, 213 (31%) infants, 291 (43%) children, and 52 (8%) adults at index operation; 491 (72%) were in low-risk RACHS (1 to 3), 109 (16%) in high-risk (4 to 6), 27 (4%) were less than 18 years but could not be assigned a RACHS score, and 52 (8%) were adults. Three hundred and thirty-one (48%) had an optimal TPS, 283 (42%) adequate, 61 (9%) inadequate, and 4 (1%) could not be scored. There were 34 (5%) late deaths or transplants and 149 (22%) late reinterventions. Follow-up data are represented in Figure 1.

Univariate analysis results are depicted in Tables 1 and 2. In addition to RACHS-1 risk categories, we also looked at Society of Thoracic Surgeons and European Association of Cardiothoracic Surgery Mortality Category (STAT category) and use of either risk adjustment methods did not affect outcomes; ie, both methods were strongly associated with occurrence of late outcomes and the rate of adverse late outcomes increased as risk category increased. However, a greater number of patients, including adults, could be categorized using the STAT system. We chose to use 4 groups during this analysis; low risk (RACHS-1 category 1–3) and high risk (RACHS-1 category 4–6), RACHS-1 category non-scorable, and adults to allow for adequate numbers in each group for meaningful analysis.
Cox multivariate regression analysis results are outlined in Tables 3 and 4. There was a strong independent association between technical performance score and late mortality and late reintervention after controlling for age and case complexity. Figures 2, 3, and 4 represent the Kaplan-Meier survival analysis curves for mortality and late reinterventions based on technical performance scores, RACHS-1 risk categories, and age.

Comment

Technical performance score has been found to be associated not only with early outcomes such as occurrence of major adverse events, but also with resource utilization as measured by length of time on the ventilator and intensive care unit and hospital lengths of stay [6, 11, 15]. The TPS has also been found to be associated with midterm outcomes in a subset of patients [7]. In our study, we were able to demonstrate that TPS was strongly associated with late mortality and need for late reinterventions.

In unadjusted analysis for late mortality, an inadequate technical performance score (class 3: major residual or need for in-hospital reintervention for residual defect at index hospitalization) as well as higher RACHS-1 and STAT categorization were strongly associated. However, age did not have an association with late mortality. On multivariable modeling, only TPS showed significant association with late mortality.

There was a strong association between late reinterventions and inadequate technical performance, younger age, and higher RACHS-1 and STAT categorization by unadjusted analysis for late reinterventions. Multivariable modeling showed that both inadequate TPS and high-risk RACHS category had a strong association with late unplanned reintervention. Regression analysis controlling for age and complexity showed a persistently strong association between TPS and late reintervention.

It should be noted that patient follow-up is variable in our study group. Therefore, we did not analyze the proportions of patients experiencing late death or late reintervention, knowing that patients with shorter follow-up time would be less likely to experience an event than those with longer follow-up time. Instead, our outcome variables were time from hospital discharge to death and time from discharge to reintervention. We applied survival analysis techniques, including the Kaplan-Meier method and Cox proportional hazards regression, which appropriately account for differences in follow-up time [16]. Each patient contributes information only over the time period where they were observed. Survival analysis techniques allow valid estimation of mortality and reintervention rates at specific time points after hospital discharge, despite differences in follow-up times.

Our findings support the utility of TPS as a self-assessment and quality metric tool for individual surgeons and for health care systems, and as a benchmark for individual and system-wide improvement. It may also allow for the development of indications for early reintervention for residual anatomic problems, thus potentially improving long-term physical, neurologic, and psychological outcomes.
and psychosocial development in this vulnerable, high-risk population. As a result, widespread application of TPS and timely measures to address residual lesions may decrease the financial, social, and psychological burden of prolonged illness. Indeed, our previous studies have shown that if an inadequate technical result is addressed and corrected early after the index procedure, the adverse impact of the inadequate technical performance is counteracted.

This is a retrospective study, and complete follow-up information is not available in all patients. We accounted for this loss to follow-up by using specialized survival analysis techniques [16]. While this study covers a wide range of operations, across a wide range of ages, further study on specific procedural groups is needed to further validate the association between TPS and long-term outcomes such as post discharge mortality or transplant and need for surgical or catheter based reinterventions. Further studies in a multi-institutional setting are required to ascertain the importance of each component of the TPS for a specific procedural group. This study was limited to major outcomes such as death, transplant, and reintervention post discharge from a procedure. However, associations between TPS and more subtle outcomes such as cognitive development after congenital cardiac surgery and impact of multiple admissions on resource use and psychosocial development have not been analyzed. These outcomes need to be studied, preferably across multiple centers.

We would like to acknowledge Emile Bacha, MD, and Kathy Jenkins, MD, for their contributions to the development of the technical performance score.

References
