Physiologic Illness Severity, Technical Performance (Residual Lesion Scores), Case Complexity, Risk Stratification and Clinical Outcomes in Pediatric Cardiac Surgery

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Abstract

Introduction: Clinical outcomes in pediatric cardiac surgery depend on multiple factors, including case complexity, preoperative baseline physiology, intraoperative course, surgical technical performance, and postoperative care. Our objective was to evaluate surgical technical performance as measured by residual lesion scores, as a predictor of clinical outcomes in a risk-stratified manner, and its interplay with physiologic illness severity.

Methods: Technical performance was defined as "the adequacy of the intended anatomic surgical repair". We quantitatively assessed technical performance using a scoring system of postoperative residual lesions. Specifically, we graded each sub-procedure of an operation using pre- discharge echocardiogram and the need for postoperative reintervention. Three technical performance score (TPS) classes were defined: Class 1, optimal, no residual lesions detected; Class 2, adequate, mild residual lesions; and Class 3, inadequate, significant residual lesions or the need for reintervention to correct them. The interplay of TPS with the pre- and postoperative physiologic illness severity as measured by Pediatric Risk of Mortality (PRISM) III scores was examined across a broad spectrum of pediatric cardiac surgery operations in neonates and infants. The association of TPS with early and midterm outcomes was assessed.

Results: Technical performance scoring criteria were created for more than 90% of all congenital cardiac operations. TPS was the most important factor in determining early clinical outcomes in complex neonatal and a wide range of infant cardiac repairs, with optimal TPS attenuating the

effects of high case complexity and poor preoperative physiologic illness severity. Clinical outcomes were unaffected by intraoperative surgical revisions, provided the final TPS was at least adequate. TPS predicted early and midterm outcomes and the need for unplanned future reinterventions. In addition, early postoperative physiologic illness severity, as measured by PRISM III scores, showed a strong association with hospital mortality, postoperative reinterventions, poor technical performance, and major postoperative complications in complex neonatal cardiac procedures.

Conclusions: TPS emerged as an important predictor of outcomes across a range of ages and disease complexity and can serve as an important tool for self-assessment and quality improvement. The association of TPS with early and midterm survival and the need for unplanned future reinterventions can be used to prospectively identify patients at ongoing risk of mortality. Early postoperative physiologic illness severity as measured by PRISM III may be used as an early surrogate of TPS to initiate a search for and correction of technical deficiencies.

The impact of TPS on other subtle outcomes, such as patient neurodevelopment and healthcare costs, will need to be further investigated. The expansion of this quality initiative to other centers to revalidate our observations and further refine the technical performance scoring system based on prospective multicenter studies will form the basis of future studies with potential benefits to patients. Surgical competency also encompasses other non-technical skills such as situational awareness, leadership, and team interaction, each of which may also contribute to outcomes and should be taken into consideration.

The nomenclature of TPS was subsequently changed to Residual Lesion Scores (RLS) to indicate that measures of adequacy of the anatomic repair are better reflected by the term residual lesions initially referred to as technical performance.

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Dedication

This thesis is dedicated to my family and all my teachers for their encouragement and support over my lifelong learning process as I strive for excellence.

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The general introduction and general conclusions were written with excerpts taken from a review and book chapters that I coauthored (Karamichalis & Nido, 2013; Karamichalis, Barach et al., 2012; Nathan & Karamichalis, 2015). My original manuscripts are also included in this thesis. For better presentation, the review paper in Progress in Pediatric Cardiology (Karamichalis, Barach, et al., 2012) is included below in the general introduction section, along with the abstract of the book chapter "Quality Improvement: Methods, Principles and Role in Healthcare" (Karamichalis & Nido, 2013). The book chapter "Quality Improvement: Surgical Performance" (Nathan & Karamichalis, 2015) is included in the general conclusion section.

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GENERAL INTRODUCTION

Incidence of Congenital Heart Defects

According to the Centers for Disease Control and Prevention (CDC) and the Congenital Heart Public Health Consortium (CHPHC), of the nearly 4 million infants born in the United States (U.S.) each year, approximately 3% have some type of birth defect (Control & Prevention, 2008; Karamichalis, Colan et al., 2012; Nathan & Karamichalis, 2015; Pediatrics, 2020). In the U.S., congenital heart defects (CHDs) occur in nearly 1% of births (Hoffman & Kaplan, 2002; Moller, Taubert, Allen, Clark, & Lauer, 1994; O'Sullivan & Freedman, 2009; Oster et al., 2013). Worldwide, CHDs affect 1 in 110 births or 1.35 million live births each year (Pediatrics, 2020; van der Linde et al., 2011).

CHDs are also the leading cause of illness and death associated with birth defects. Each year, over 10,000 or 25% of infants with CHDs in the U.S. have defects severe enough to require life-saving surgery or other interventions before they reach one year of age (Control & Prevention, 2008; Moller et al., 1994; Oster et al., 2013; Pediatrics, 2020). Australian data suggest that CHDs are among the largest killers of infants less than one year old and account for approximately 20% of perinatal deaths, with more than 5000 years of life lost and 2500 years of life associated with disability (Karamichalis, Barach et al., 2012). Based on Canadian data extrapolated to 2010 U.S. Census data, 12% of 1 million children and 1.4 million adults living in the U.S. were affected by severe CHDs (Marelli et al., 2014).

Fifteen to 20% of all patients with CHD have associated genetic conditions, and 20% to 30% have physical, developmental, or cognitive problems (Fuller et al., 2009; Mahle, 2001; Marino et al., 2012; Pediatrics, 2020). Patients with CHD

are at risk for lifetime health problems, including heart problems, sudden cardiac arrest, stroke, kidney failure, breathing problems, seizures, mental health challenges, and increased risk of cancer (Pediatrics, 2020). In addition, CHD can have lifelong neurodevelopmental and neurocognitive effects that negatively impact social relationships, education and employment (Pediatrics, 2020).

Surgical correction or palliation is now feasible for most of these patients. In 2011, 33,733 congenital cardiac procedures were reported to the Society of Thoracic Surgeons (STS) (Nathan & Karamichalis, 2015). Between 1999 and 2006, CHD was listed as the primary cause of death for 27,960 people. Among these, 48% were infants, often following complex interventions and prolonged intensive care unit (ICU) stay.

Outcomes in the surgical treatment of congenital heart disease

Mortality associated with different types of CHD has decreased among both children (Boneva et al., 2001) and adults (Pillutla, Shetty, & Foster, 2009). Since more patients survive to adulthood, the prevalence of CHD has increased among adults (Khairy et al., 2010). More specifically, survival of infants with critical CHD increased from 67% between 1979 and 1993 to 82.5% between 1994 and 2005 (Oster et al., 2013).

Over the last two decades, advances in the understanding of the pathophysiology, diagnosis and surgical treatment of congenital cardiac lesions have resulted in a mortality reduction from 100% over 4 decades ago to 4% for highly complex cases to almost 0% for low complexity cases (Castañeda, 2005; Karamichalis, Barach et al., 2012). According to the STS database, hospital survival following congenital heart surgery was 97.3% overall in 2017. This

was 92.6% for neonates (<1 month old), 97.4% for infants (1 month to 1 year old), and 98.9% for children between 1-18 years of age (Jacobs et al., 2018). These improvements can be attributed to significant advances in surgical techniques, pediatric cardiac anesthesia, cardiopulmonary bypass, and preoperative/postoperative care in specialized ICUs.

In the U.S., mortality declined over time among patients with CHD operated upon between 1982 and 2003 who survived their first CHD surgery but remains

8.2 times higher than that among the general population. This rate varies by disease severity (35 times higher for single ventricle CHD and 4.3 times higher for milder forms of CHD) (Spector et al., 2018).

Despite the recent progress in surgical and medical management, CHD has a significant impact on society in terms of morbidity, healthcare resource use, and mortality. Thus, this patient population presents an enormous challenge to the healthcare system where optimal care can greatly influence not only short- term but also long-term psychosocial, intellectual and physical outcomes (Control & Prevention, 2008; Nathan & Karamichalis, 2015).

Healthcare costs associated with congenital heart defects

In 2004, the estimated costs for hospitalization of individuals with CHD in the U.S. were $1.4 billion (Control & Prevention, 2008; Nathan & Karamichalis, 2015). In 2013, hospital costs for all patients with CHD exceeded $6.1 billion, representing 27% of all birth defect-associated hospitalization costs (Arth et al., 2017). However, costs vary by age and type of CHD. The hospitalization costs were highest for infants with a critical lesion and for patients who died in the hospital. The average medical cost for CHD patients younger than 3 years of age

was 10 to 20 times higher than for patients of the same age without CHD (Boulet, Grosse, Riehle-Colarusso, & Correa- Villasenor, 2010). The greatest cost burden is incurred by patients younger than 1 year of age. In addition, all adults with CHD, even those with mild to moderate disease, have much higher rates of resource utilization and costs than their age-matched peers, with 3-4 times higher rates of emergency room visits, hospitalizations, and ICU stays than the general population (Mackie, Pilote, Ionescu-Ittu, Rahme, & Marelli, 2007).

The importance of costs in healthcare delivery has gained increasing attention in recent years. Health plans have focused on discounts and administrative control of members and providers rather than developing a distinctive ability to offer superior health value to patients (Porter & Teisberg, 2006). Healthcare costs have been correlated with outcomes and with increasing resource use in high complexity cases with complicated postoperative recovery. This situation increased the pressure on healthcare providers and institutions to closely monitor outcomes and reduce costs. The concept of “Pay for Performance” was introduced to incentivize and reward excellence in healthcare delivery. The increased awareness of the rapid changes in this field has led to greater expectations from the public and medical community. In addition, the current evolution of healthcare towards performance-based reimbursements has resulted in increased scrutiny and monitoring of surgical competencies and results in pediatric cardiac surgery. This change has prompted demands for increasing transparency and public reporting of outcomes with intense focus on the complex micro and macroenvironments of the systems and related healthcare costs. It is crucial to realign healthcare competition with value for patients where value is defined as the health outcome per dollar of cost expended (Porter & Teisberg, 2006).

Outcomes measurement more than any other policy is the best way to eliminate substandard care in the system. Providers must shift their strategies, structures, and management process and learn to measure and improve their results (Porter & Teisberg, 2006). Mandatory measurement and reporting of results are perhaps the most important steps in reforming the healthcare system and aligning it with value-based competition. Results of value-based competition must be widely available to encourage additional stakeholders to join in the quality improvement endeavor. Quality control and quality improvement in pediatric cardiac surgery programs are important to ensure that safety and best care practices are in place for patient care. The development of self-assessment measures for programs and specifically for surgeons remains key to continuous improvement in the field.

Surgical Performance: Surgeon vs Institution Outcomes

In pediatric cardiac surgery, quantifying surgical competence is a challenging task (Karamichalis, Barach et al., 2012). Distinguishing between the competence of individual surgeons and the performance of a congenital heart program is crucial. Until recently (Nathan & Karamichalis, 2015), cumulative sum (CUSUM) analysis of hospital mortality was used to measure technical performance in congenital heart surgery (Stark et al., 2001; Welke, Karamlou, Ungerleider, & Diggs, 2010). However, raw mortality data cannot account for factors that potentially affect outcomes.

The Hospital Standardized Mortality Ratio (HSMR) is an alternative measure of overall deaths in a hospital; a portion of these deaths will be preventable. Thus, the HSMR can be used as an indicator of quality of care (Jarman et al.,

1999). This method provides an easy, inexpensive calculation of patients' predicted risk of death from benchmark data. Nonetheless, the HSMR has multiple limitations (Mohammed et al., 2009).

Risk-adjusted in-hospital death rates can be used to assess institutional performance but are inappropriate for measuring the performance of individual providers. In-hospital death rates are impacted by too many factors outside an individual surgeon’s control (Karamichalis JM, Barach P et al. 2012). High-risk and high-complexity procedures are also difficult to assess with this measure.

For quality improvement purposes and to appropriately compare results of operations of similar complexity between programs and surgeons, a sophisticated risk-stratified analysis of important outcomes was developed over the years using the European Association of Cardiothoracic Surgeons– Society of Thoracic Surgeons (EACTS-STS) risk-stratified system (O'Brien et al., 2009). Using a consensus-based method, another earlier risk stratification system for in-hospital mortality after congenital heart surgery was developed: Risk Adjustment for Congenital Heart Surgery (RACHS-1) (Jenkins et al., 2002).

A tool that better differentiates the contribution of each system and team members in the overall outcome would be very valuable in delineating and implementing effective changes in an already complex environment caring for children undergoing cardiac surgery. This tool would aid in identifying areas of underperformance in the system and its infrastructure for improvement and could translate into lower costs of care due to lower complication rates and higher quality patient care. Reliable comparative analysis of outcomes across different centers and surgeons requires a clear understanding of the factors that influence the risk of mortality for children undergoing cardiac surgery.

Outcomes in congenital cardiac surgery are multifactorial (Nathan & Karamichalis, 2015) and may be affected by the following: (1) case complexity and preoperative physiologic status, such as patient factors (e.g., birth weight, gestational age, complexity of CHD), hemodynamic stability or physiologic illness severity, the adequacy of diagnostic evaluation, and appropriateness of the surgical plan; (2) intraoperative factors, such as conduct of anesthesia and cardiopulmonary bypass, surgical technique, and early post-bypass hemodynamic management; and (3) postoperative course, such as serious adverse events and complications.

From an institutional perspective, other factors determining outcomes include the size and infrastructure of the program, the volume and complexity of the cases performed, and the coordinated interaction of sophisticated systems dealing with complex medical problems. The influence of human factors and errors in pediatric cardiac surgery has been previously studied (de Leval, Carthey, Wright, Farewell, & Reason, 2000).

Among these factors, technical adequacy of repair is likely a significant determinant of successful outcome. More importantly, the surgeon mostly has control over the technical steps needed for sufficient lesion repair (Nathan & Karamichalis, 2015). It is hypothesized that intraoperative technical excellence is one of the key factors in determining outcomes, especially in high acuity operations. Indeed, the degree to which a congenital heart operation achieves its intended result may be the single most important factor determining long- term medical outcomes and costs. In addition, non-technical skills, are thought to contribute to surgical performance and outcomes. Other factors, such as mentorship or coaching of junior surgeons by experienced surgeons, add safety and value in the maturation process of surgeons and improve their performance over time.

Recently, centralization or regionalization of pediatric cardiac surgery services has been the focus of many professional and governmental authorities, with the intention of improving results and reducing the cost of complex procedures in children with heart disease (Welke et al., 2020). This change may create significant inconvenience to patients and their families living in geographically remote areas, especially in dispersed countries such as the USA, UK and Australia. The need for frequent follow-up of these patients may be an additional challenge for providing adequate and accessible care for this vulnerable population of patients, especially after heart surgery in the neonatal period.

The establishment of a well-coordinated healthcare delivery system among different providers across different centers who care for these patients is of paramount importance. This will ensure continuity of care while allowing patients to access care locally whenever possible and provide evidence-based guidelines on the quality of care provided at specific centers caring for pediatric patients with different lesion complexity. Monitoring outcomes and having quality control tools in place at these centers are perhaps the most important factors in ensuring the provision of the same level of standard of care.

Surgical Competency

Surgical competence in pediatric cardiac surgery is very difficult to quantify or measure directly (Karamichalis, Barach et al., 2012). It encompasses multiple aspects of skills including both technical skills, clinical judgement and other non-technical skills. Surgical technical competency is the ability of the surgical microsystem to successfully and safely execute the necessary steps to perform a

specific operation for a patient (Mohr, Batalden, & Barach, 2004).

While the precise execution of the technical aspects of an operation is an important component of surgical competency, surgical competency encompasses many more team skills and attitudes beyond the technical maneuvers required in surgery. These include non-technical skills such as situational awareness, cognitive flexibility, and team leadership preoperatively, intraoperatively, and postoperatively. In addition, decision-making, anticipation and clinical judgement ensuring that the right operation is selected and performed are important. Communication and delivery of timely information to the patient's family and other healthcare providers also play a key role (Baker, Salas, King, Battles, & Barach, 2005).

The assessment of surgical competency remains an elusive concept (Karamichalis, Barach et al., 2012). Surgeons must possess specific competencies defined as knowledge, skills and attitudes (KSA), such as the ability to exchange information and coordinate individual team members (Baker et al., 2005; Barach & Weinger, 2007). KSA deficiencies can be recognized using reliable and valid measures, and supportive, accurate feedback can be provided. Additionally, appropriate instructional strategies for remediation can be selected and implemented. When performed on a regular basis, this deliberate practice can lead to sustained expertise and standards (Ericsson, Charness, & Hoffman, 2006).

Finding ways to evaluate, monitor and improve surgical competency becomes important in improving outcomes in pediatric cardiac surgery (Karamichalis, Barach et al., 2012). It is imperative to first define optimal or acceptable surgical performance. Limited data are available on the importance of surgical technical performance in determining outcomes independent of anatomic

factors and perioperative care management. Although risk-adjusted mortality evaluations allow for a better understanding than general mortality rates, they are not intended to evaluate individual competency or performance. Furthermore, congenital heart surgeons have few available tools for systematic self-assessment as part of an on-going quality improvement evaluation process. While outcomes are dependent on multiple factors including the patient's underlying pathology, case complexity, age, physiologic status, and healthcare delivery systems, the adequacy of the surgical anatomic repair quantified by the presence of residual lesions is an important component in this evaluation.

Surgical excellence, beyond excellent three-dimensional perception and manual dexterity, involves less measurable aspects such as the ability to prevent or deal with complications, understand cardiovascular physiology, cardiopulmonary bypass and myocardial protection, and address and mitigate the impact of human factor components such as fatigue, situational awareness, decision-making skills, multitasking and prioritizing (Carthey, de Leval, & Reason, 2001; Catchpole et al., 2006; Schraagen et al., 2011).

Physiologic Illness Severity

Risk stratification in congenital cardiac surgery poses unique challenges. Beyond the variability in case complexity, variations in anatomy may dramatically alter the degree of difficulty for a given operation (Jeffries et al., 2015). Comorbidities, frequently encountered in children with congenital cardiac disease, may often increase the risk of mortality independent of the operative procedure being performed. There are many models designed to predict pediatric cardiac surgical mortality based on operative complexity or anatomy. These models include RACHS (Jenkins et al., 2002), European

Association of Cardiothoracic Surgery - Society of Thoracic Surgeons (STAT) Congenital Heart Surgery scores (Jacobs et al., 2012; O'Brien et al., 2009), and Aristotle scores (Lacour-Gayet et al., 2004). All these scores assess overall cardiac surgical mortality across the entire care process but do not shed light on individual components of pre- or postoperative care. Moreover, none of them assess the physiologic condition and severity of illness at the time of admission to ICU to predict ICU morality (Thiagarajan & Nathan, 2015).

Physiologic illness severity or the degree of patient's sickness as measured by physiologic parameters both before and after the surgery is assumed to be an important factor in determining the postoperative course of the patient and their outcomes. Finding ways to quantify illness severity would offer an objective measurable parameter that can be used to assess and evaluate a patient's pre- and postoperative course and examine its correlation with surgical performance and patient risk factors.

The Pediatric Risk of Mortality (PRISM), a risk-adjusted tool first published in 1988 (Pollack et al., 1988), is a generic severity-scoring system developed to measure the probability of death on the basis of the hypothesis that preoperative physiologic instability reflects mortality risk. The newer and improved PRISM III, developed in 1996 (Pollack et al., 1996), is more accurately calibrated and achieves good discrimination for individual patient mortality risk assessments.

The interplay of baseline physiologic status, anatomic risk factors, technical performance and postoperative recovery in this patient population has been mainly defined on the basis of patient-specific or anatomic risk factors (prematurity, lower weight, intact atrial septum, smaller ascending aorta, etc.) or procedure-specific risk factors (anatomic characteristics that make repair more complicated, e.g., moderate or greater atrioventricular valve regurgitation, deficient mural leaflet and or single papillary muscle in repair of complete atrioventricular canal defect) and procedural factors (e.g., longer circulatory

arrest time, adequacy of myocardial protection, management of the ascending aorta).

To better understand how these complex relationships between modifiable and intrinsic (non-modifiable) risk factors affect outcomes, we sought to investigate the individual contribution of these factors to outcomes, with particular attention to technical performance.

Objectives

Our aims were as follows:

1. We sought to establish a technical performance assessment tool in congenital cardiac surgery to serve as a self-assessment and quality control tool for surgeons; and

2. We aimed to define and explore the association of preoperative baseline physiology, case complexity, technical performance and postoperative outcomes assisted by risk and case complexity adjustment tools and physiologic illness severity scoring systems.

We proposed the following hypotheses:

1. The establishment of a technical performance scoring system, later also known as residual lesion sores, is feasible in congenital cardiac surgery.

2. Technical performance is associated with early and midterm clinical outcomes in pediatric cardiac surgery, with suboptimal performance predicting worse outcomes.

3. A technically optimal operation could mitigate the effects of baseline physiology and high case complexity on outcomes in complex neonatal heart surgeries.

The terms “technical performance” and “technical performance scores” (TPS) were replaced in later studies by the term “Residual Lesion Scores” (RLS). Since the initial concept of measuring technical performance was to assess the adequacy of the anatomic repair of a procedure as reflected by the residual lesions left behind unintentionally, it was intuitive to rename TPS to RLS. This differentiates it from the concept of technical performance in surgery, which may imply a broader range of technical aspects such as technical skills, techniques used, and the adequacy of the surgeon’s techniques, including the adequacy of the anatomic repair or unintended residual lesions.

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Assessment of technical competency in pediatric cardiac surgery

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ABSTRACT

Outcomes in pediatric cardiac surgery have improved dramatically since its infancy 40 years ago. Mortality has been reduced from as high as 90–100% in the initial years to around 4% for high complexity cases and virtually no mortality for simple cardiac defects. While part of this improvement can be attributed to advances in pediatric cardiac anesthesia, pediatric cardiopulmonary bypass and development of highly specialized pediatric cardiac intensive care units, outcomes continue to depend on the technical quality of the surgical repair. In this article we address the importance of the surgical technical performance on the outcomes and discuss the currently available tools for measurement of surgical competency. Our studies showed that the final technical (anatomical) result score had the strongest association with patient outcomes. We offer suggestions for a competency model that continues to evolve as we explore the use of immersive learning, deliberate practice, reflection in action, mentorship by senior surgeons and lifelong learning.

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1. Introduction

Each year approximately 35,000 babies are born with congenital heart disease (CHD) in the United States (USA) and over 10,000 of these have CHD severe enough to require surgery before they are one year of age. Australian data suggest that congenital heart defects are one of the biggest killers of infants less than one year old and account for approximately 20% of perinatal deaths, more than 5000 years of life lost and 2500 years of life associated with disability [24]. Advances over the last two decades in the understanding, diagnosis and surgical treatment of congenital cardiac lesions have resulted in mortality reduced from 100% forty years ago to around 4% for highly complex cases to almost 0% for low complexity cases [1]. The increased awareness of the advances in this field has led to greater expectations from the public and medical community. In addition, the current evolution of health care towards performance based reimbursements (i.e. Pay-for-Performance) along with the implementation of several quality control and improvement programs has resulted in increased scrutiny and monitoring of surgical competencies and outcomes in pediatric cardiac surgery.

Surgical competence in pediatric cardiac surgery is very difficult to quantify or measure directly. One very important distinction is to distinguish between an individual surgeon's competence and an entire congenital heart program's performance. This article will focus on the individual surgeons' performance. Until recently, hospital mortality, often in the form of cumulative sum (cusum) analysis, had been used as a surrogate measure of technical performance in congenital heart surgery [2–4]. Raw mortality data, however, do not correct for the case complexity or other associated factors that might affect outcomes. One alternative, the Hospital Standardized Mortality Ratio (HSMR) is intended as an overall measure of deaths in hospital, a proportion of which will be preventable. High ratios may thus suggest potential problems with quality of care [5]. The HSMR is a complex, but inexpensive and a relatively easy method to calculate from national or other benchmark data the patients' predicted risks of death. However, there are a number of methodological challenges in HMSR's construction and interpretation, in large part due to the fact that they are based on administrative databases [6].

While risk-adjusted in-hospital death rates may be a reasonable measure of institutional performance, this measure is inadequate to assess the performance of individual practitioners due to the many additional factors such as the contribution and impact of other team members, outside the control of an individual surgeon. This is especially problematic for high risk operations, which require a complex

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multi-departmental microsystem consisting of dedicated teams composed of many individuals and specialties.

Finding ways to evaluate, monitor and improve surgical competency becomes important in improving outcomes in pediatric cardiac surgery (PCS). It is imperative first to define optimal or acceptable surgical performance. There is little available data on the importance of technical performance in determining outcomes independent of the anatomic factors and perioperative care management. Although risk-adjusted mortality evaluations allow for a better understanding than general mortality rates, they are not intended to evaluate individual competency or performance. Furthermore, congenital heart surgeons have few available tools for systematic self-assessment as part of an on-going quality improvement evaluation process. While outcomes are dependent on multiple factors including the patient's underlying pathology, case complexity, age, physiologic status, healthcare delivery systems, the adequacy of the surgical repair is an important component in this evaluation.

We have piloted a method to measure surgical technical performance for congenital heart disease as part of a quality improvement evaluation process [7–10]. This work has demonstrated that technical performance defined as the adequacy of the anatomic repair, can be assessed in congenital heart surgery. Technical performance scores correlate with early outcomes especially in the high complexity operations such as the stage I Norwood procedure. Technical excellence during surgery, with little to insignificant residual defects, has the best outcomes along the entire spectrum of case complexity. This was particularly important in determining outcomes as case complexity increased [9,10].

2. Surgical competency and technical performance

The assessment of surgical competency however, remains an elusive concept. Surgeons must possess specific competencies defined as the knowledge, skills and attitudes (KSA) such as the ability to exchange information and coordinate individual team members [12]. Surgical technical competency is the ability of the surgical microsystem to successfully and safely execute the necessary steps in order to perform a specific operation for a patient [11]. KSA deficiencies can be recognized using reliable and valid measures, and support, accurate feedback can be provided, and appropriate instructional strategies for remediation can be selected and implemented. When done on a regular basis, this deliberate practice, can lead to sustained expertise and standards [25]. While the precise execution of the technical aspects of an operation is an important component of surgical competency, surgical competency encompasses many more team skills and attitudes beyond the technical maneuvers required in surgery. These include: (a) team interaction and leadership both pre-, intra- and post-operatively; (b) decision making ensuring that the right operation is selected and performed; and, (c) delivery of timely information to the patients family and other health care providers [13].

Surgical excellence, beyond excellent three-dimensional perception and manual dexterity involves less measurable aspects such as the ability to prevent or deal with complications, understand cardiovascular physiology, cardiopulmonary bypass and myocardial protection, as well as address and mitigate the impact of human factor components such as fatigue, situational awareness, decision making skills, multitasking and prioritizing [14–16].

3. Development of technical performance scoring tool

The concept of assessing the technical performance of surgeons in congenital cardiac surgery, defined as the adequacy of anatomic repair, was recently introduced at Boston Children's Hospital in Massachusetts. The technical steps leading to the anatomic repair of a lesion are mostly under the control of the surgeon. Intraoperative technical performance is one of the most important aspects of the therapeutic process and determines patient outcomes especially in high acuity operations [9,10,17,18]. This tool was designed to be used for peer and self-assessment as none of the currently available quality monitoring tools measure technical performance per se. It was initially piloted in selected surgical procedures including repairs of ventricular septal defect, Tetralogy of Fallot, complete common atrioventricular canal, arterial switch and later the stage I Norwood procedure [7–9]. The use was then expanded to include a variety of other operations [10]. The score was created by dividing the surgical procedure into individual components defined as sub-procedures, which are based on the specific anatomic regions subject to the surgical intervention (please see Table 1 examples for a VSD repair, arterial switch operation and a stage I Norwood operation).

The parameters of the score assessment were defined and piloted by a modified Delphi consensus process of cardiologists and cardiac surgeons. The score was based primarily on pre-discharge echocardiographic measurements but also on cardiac catheterization data, the need for post-operative catheterization laboratory or operating room based re-interventions. The technical tool defined three possible categories for each sub-procedure: "optimal", "adequate" and "inadequate". An overall summary score for the main surgical procedure was also defined, wherein the operation was graded as *optimal* if all the sub-procedures were optimal; *adequate*, if the sub-procedures were optimal or adequate, but none inadequate; and *inadequate*, if one or more sub-procedures were inadequate.

The anatomic regions operated on were scored by subdividing the complex procedures into basic components where each component of a given repair was scrutinized and analyzed separately. The technical performance of a given surgeon that closed a VSD, for example, was not just studied by looking at the technical score for isolated VSD procedures but rather all VSDs repaired by the surgeon would be included in the technical analysis, thus increasing the statistical reliability of the assessment.

The initial pilot study demonstrated that despite PCS procedural diversity and complexity, the adequacy of the surgical repair can be assessed using a reliable technical performance scoring system. The main limitation of the assessment of technical performance is that it is primarily based on echocardiography, an operator-dependent technique with well known limitations [19]. These limitations include the assessment of aortic arch gradients, valve gradients and repair, aortopulmonary shunt patency, and the dependency on thoracic windows. Conversely, for a scoring system to be widely used simplicity and reliability are key factors. Echocardiography fulfills this criterion because it is a bedside test that is widely available and has proven to be valid and reliable as a stand-alone test in the preoperative and postoperative evaluations of children with congenital heart lesions. Furthermore, in most congenital centers, it is routinely used intraoperatively and/or prior to discharge.

4. Technical performance and outcomes

Subsequent studies have demonstrated a strong impact of technical performance on hospital survival in patients undergoing stage I Norwood procedure [8,9]. Avoiding a technically inadequate outcome was a major determinant of patient survival. This indicates that technical scores could be an especially useful tool to improve surgical performance by offering reflective feedback that would help to reduce morbidity in high complexity operations. Furthermore, low mortality rates were observed in the optimal category suggesting that excellent technical results are necessary for survival, however, they may not be sufficient for good patient outcomes, especially in the highly complex cohort. A large role is also likely played by other factors such as structural or procedural factors or patient specific risk factors such as patient's weight, prematurity, chromosomal anomalies, the presence of preoperative shock or poor physiological status, etc.

Table 1
Examples of technical performance scoring criteria.

Subprocedures	Optimal	Adequate	Inadequate
a. Ventricular septal defect repair[a]			
ASD repair	No or trivial residual shunt (1 mm)	Small residual shunt 2–3 mm	Reintervention or residual shunt > 3 mm
VSD repair, membranous	No or trivial residual shunt (1 mm)	Residual defect 2–3 mm	Reintervention or residual defect > 3 mm
VSD closure, muscular	No or trivial residual shunt (1 mm)	Residual defect 2–3 mm	Reintervention or residual defect > 3 mm
PDA closure	No residual PDA	Residual PDA 1 mm	Reintervention or residual defect > 1 mm
Conduction	Normal conduction No change from pre-op	Normal conduction No change from pre-op	Need for permanent pacemaker
b. Arterial switch operation[a]			
ASD repair, secundum	No or trivial residual shunt 1 mm	Small residual defect (2–3 mm)	Reintervention or residual shunt > 3 mm
VSD repair	No or trivial residual shunt 1 mm	Small residual defect (2–3 mm)	Reintervention or residual shunt > 3 mm
VSD repair, muscular	No or trivial residual shunt 1 mm	Small residual defect (2–3 mm)	Reintervention or residual shunt > 3 mm
Pulmonary outflow tract repair	No residual gradient (peak gradient < 15 mm Hg)	Mild gradient 15–30 mm Hg	Reintervention or gradient > 30 mm Hg
PA reconstruction (plasty), branch	No or trivial branch PA narrowing or gradient (peak gradient < 15 mm Hg)	Mild narrowing Mild residual gradient 15–30 mm Hg	Reintervention or gradient > 30 mm Hg
Systemic outflow tract repair	No or trivial gradient (peak < 15 mm Hg)	Mild gradient 15–30 mm Hg	Reintervention or gradient > 30 mm Hg
Coronaries reimplantation	No obstruction to coronary flow	No obstruction to coronary flow	Reintervention Coronary flow compromise, ischemia/infarction, with echo and/or ECG findings
Aortic arch (when applicable)	No or trivial gradient peak < 15 mm Hg	Mild gradient 15–30 mm Hg	Reintervention Moderate to severe gradient. Gradient > 30 mm Hg based on echo
Relief of RVOT obstruction (when applicable)	No or trivial residual obstruction, peak gradient < 15 mm Hg	Mild residual gradient 15–30 mm Hg	Reintervention or gradient > 30 mm Hg
Conduction	Normal conduction No change from pre-op	Normal conduction No change from pre-op	Need for permanent pacemaker
c. Stage I Norwood operation[b]			
Proximal arch reconstruction	No or trivial gradient < 10 mm Hg No evidence of coronary ischemia	Mild peak gradient at proximal aortopulmonary anastomosis or proximal arch gradient 10–25 mm Hg (echo or cath)	Need for reintervention during initial hospital stay More than mild gradient > 25 mm Hg (echo or cath)
Distal arch reconstruction	No or trivial narrowing or flow acceleration by echo peak gradient < 15 mm Hg	Mild gradient 15–30 mm Hg (by echo or cath)	Need for reintervention during initial hospital stay Peak gradient > 30 mm Hg (echo or cath)
Coronary perfusion	Unobstructed flow into proximal coronary arteries	Unobstructed flow into proximal coronary arteries	Need for reintervention during initial hospital stay Evidence for obstructed coronary flow (e.g. echo, cath, EKG)
Atrial septectomy	No or trivial gradient mean gradient 1–2 mm Hg Restrictive atrial septum left on purpose	Mean gradient 3–4 mm Hg (unless intended)	Need for reintervention during initial hospital stay Mean gradient > 4 mm Hg (unless intended)
Source of pulmonary blood flow			
a. Modified BT shunt	Patent	Patent Downsizing of shunt because of pulmonary overcirculation	Need of reintervention for or presence of kinking, clot, obstruction/distortion of the BT shunt or the Branch PAs
b. RV-PA conduit	Patent	Patent Downsizing of shunt because of pulmonary overcirculation	Need of reintervention for or presence of: kinking, clot, obstruction/distortion of the BT shunt or the Branch PAs

[a] Modified from Ref. [7].
[b] Modified from Ref. [8].

While the previous studies demonstrated that technical performance has a major effect on outcomes after stage I Norwood operations, the interplay of baseline physiologic status, anatomic risk factors, and technical performance was subsequently studied [9]. The association of preoperative baseline physiology was measured using the Pediatric Risk of Mortality III scoring system (PRISM III), case complexity was measured by Aristotle's comprehensive score, and the technical performance and outcomes were defined following the stage I Norwood procedure. The study confirmed previous findings and demonstrated a significant association between preoperative physiologic illness severity score (as measured by PRISM III and partially by Aristotle), case complexity measured by the Aristotle's score, technical performance and patient outcomes. Optimal technical performance attenuated the impact of preoperative illness severity and resulted in better outcomes regardless of the pre-operative illness severity or case complexity.

Notably, inadequate technical performance resulted in poor outcomes regardless of the preoperative illness severity or case complexity. Specifically, patients with optimal technical scores undergoing the stage I Norwood procedure had an overall 1.2% in-hospital mortality versus 34.8% in those with inadequate technical scores [9] (Fig. 1A). Patients with inadequate performance scores had significantly longer hospital and ICU stays, longer ventilation times and a greater occurrence of major post-operative complications ($p<0.0001$ for each comparison, Fig. 1B) [9].

An adequate technical performance resulted in better outcomes for lower preoperative illness severity or case complexity and poorer outcomes for higher preoperative illness severity or case complexity (see Fig. 2). In other words, the clinical outcomes for patients with adequate technical performance were dictated by their baseline physiology and anatomy, whereas, the outcomes for patients with optimal or inadequate performance were dependent more on the actual technical results, rather than on the baseline physiology or anatomy. The technical performance had the *highest* predictive value for patient outcomes. Specifically, the receiver operating characteristic (ROC) analysis showed significant ability of technical performance scores to discriminate mortality, with an area under the curve of 0.84 ($p<0.001$;95% CI, 0.74–0.94) illustrating the impact of sound intraoperative technique. The technical performance emerged as a powerful predictor of clinical outcomes for stage I Norwood operation.

5. Risk stratification

Risk adjustment is critical in considering the underlying risks of taking care of sick patients. Risk adjustment is essential to avoid penalization of clinicians and institutions treating complex cases. The main risk adjustment systems such as the Risk Assessment in Congenital Heart Surgery – 1 (RACHS-1), the Aristotle Basic and Comprehensive complexity scoring system, and the newly developed European Association of Cardiothoracic Surgery–Society of Thoracic Surgeons (EACTS-STS) system are aimed at risk stratifying outcomes based on the case complexity of the operation [20,21]. These scoring systems take into consideration other factors such as the anatomic and physiological status, age, prematurity, and genetic anomalies. This enables a standardized analysis of outcomes between different surgeons and centers after adjusting for case mix and risk.

Risk adjustment is a challenge that is not addressed by the presently used technical scores. Should a technical score include patient-specific non-modifiable risk factors? These might include factors such as the weight or prematurity, as is typically done in clinical performance risk-adjusted methods such as RACHS-1, or Aristotle's system, or should it include only technique-specific anatomic risk factors such as a single papillary muscle in complete atrioventricular septal defect or anomalous coronary arteries in an Arterial Switch Operation? Some kind of risk adjustment is therefore necessary in the interpretation of technical scores in operations that are of different case complexity or acuity.

6. Technical performance and post-operative physiologic illness severity

Technical performance was demonstrated to have a significant impact on postoperative physiologic illness severity when measured by PRISM III, with higher PRISM III scores associated with inadequate performance [8]. The severity of illness as measured by the PRISM III on the first post-operative day after a stage I Norwood operation, had a high association and discrimination in regard to hospital mortality, postoperative re-intervention, inadequate technical performance and the occurrence of major postoperative complications. The PRISM III therefore may be used as an early surrogate of technical performance and it could be used to initiate a timely search for

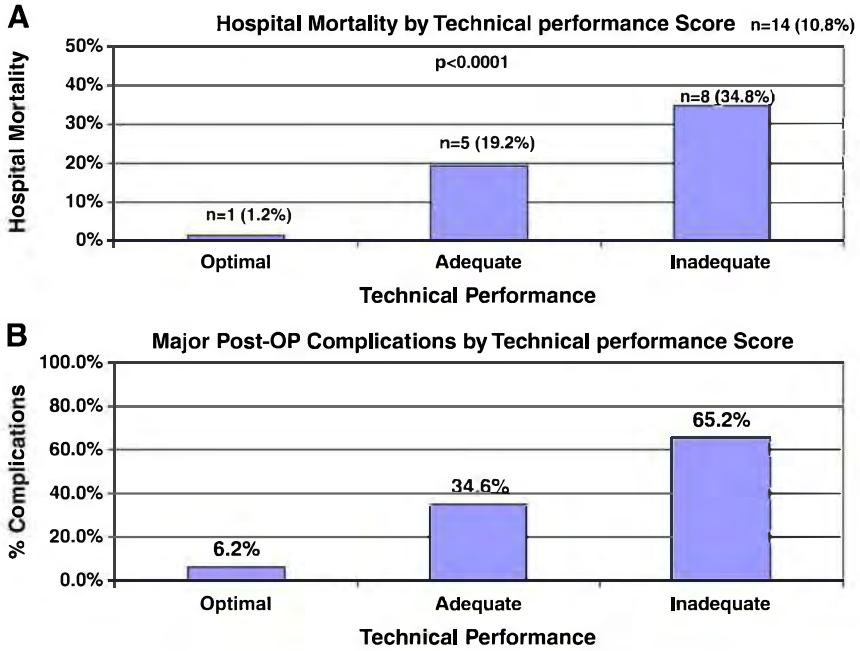


Fig. 1. A, B. Modified from Ref. [9].

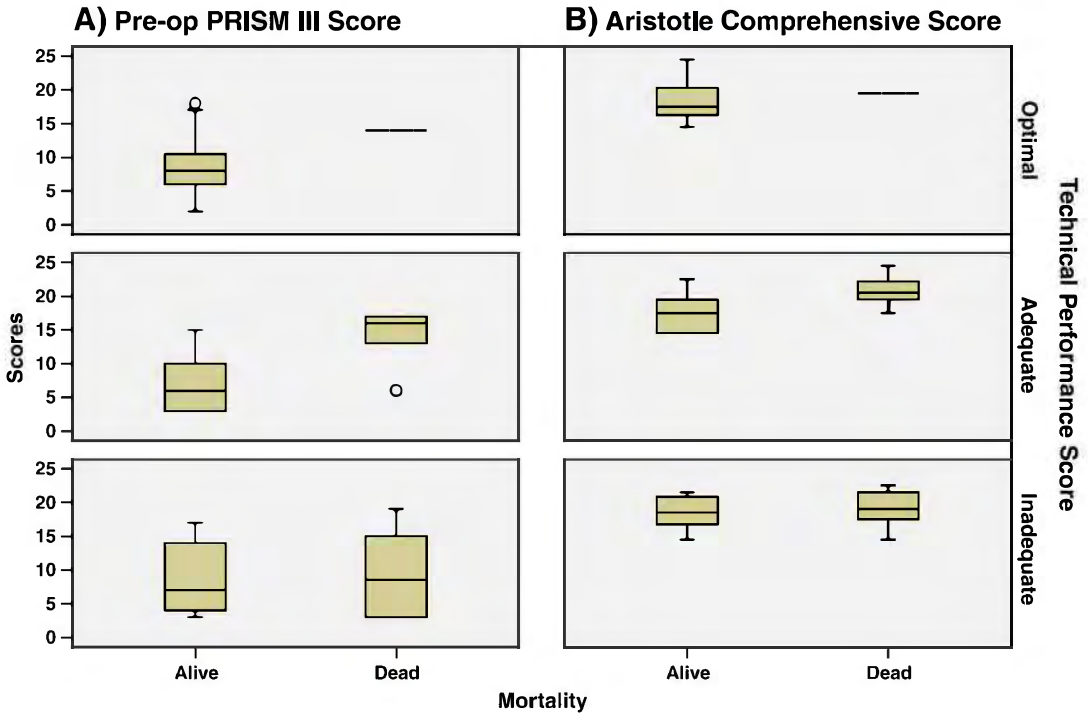


Fig. 2. Subgroup analysis measured by technical performance score and peri-operative physiologic status (measured by PRISM III score) or case complexity (measured by Aristotle's score) versus mortality in stage I Norwood procedure.
Modified from Ref. [9].

technical deficiencies the institution of supportive measures and re-interventions to address them.

7. Technical performance predicts post-operative morbidity

The technical performance score was one of the main predictors of postoperative morbidity in a prospective study of 166 neonates and infants (less than 6 months of age) undergoing a wide variety of low and high complexity heart surgery [10]. Optimal technical scores predicted low post-operative adverse events. Adequate technical scores were associated with higher post-operative morbidity in patients with higher case complexity and lower morbidity in those with lower case complexity (see Fig. 3). Notably, inadequate technical scores were associated with higher morbidity irrespective of case

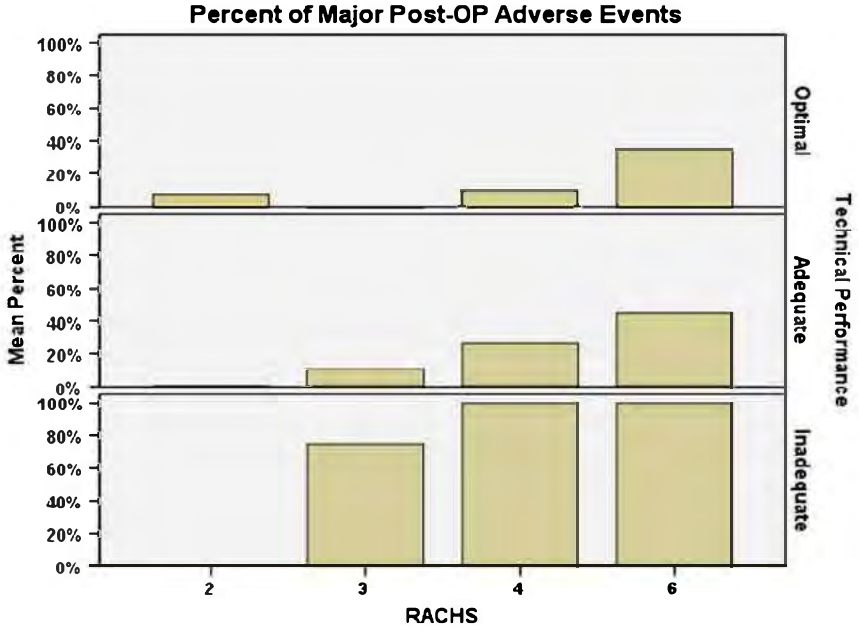


Fig. 3. Major postoperative adverse events based on technical scores and RACHS-1 categories for 166 patients less than 6 months of age undergoing heart surgery. This figure outlines the percentage of patients with major postoperative adverse events comparing the technical performance and RACHS-1 risk categories. Optimal technical performance had a low occurrence of adverse events, whereas adequate technical performance had low rates of events in the low complexity groups (RACHS-1 categories 2 and 3), but higher percentage of adverse events in the higher risk categories (RACHS-1 categories 4 and 6). Inadequate technical performance had the highest percentage with adverse events in all categories of the RACHS-1 system. RACHS, Risk Adjustment in Congenital Heart Surgery. Post-OP = postoperative.
Modified from Ref. [10].

complexity. The patient outcomes were not affected by intra-operative adverse events, such as re-institution of cardiopulmonary bypass and surgical revisions, provided technical performance score was at least adequate [10].

An important point is that none of our studies showed that longer cross clamp times were associated with worse outcomes [8–10]. In the past, the focus on "speedy surgery" and short cross-clamp times had dominated the thinking and has lead to shortcuts and a reluctance to go back and fix problems for fear of ventricular dysfunction due to long ischemic times. The final technical (anatomical) result scores had the strongest association with patient outcomes [15,16,22,23]. With excellent cardioplegia solutions available nowadays and refined myocardial protection and cardiopulmonary bypass methods, the myocardial ischemic time (i.e. cross clamp time) is a lesser factor that impacts clinical outcomes to a significant degree.

8. Conclusions

The comprehensive assessment of surgical competency remains an elusive though important concept. The continued performance monitoring of congenital cardiac surgeons is vital and might one day become a requirement of national boards and regulators as a quality control measurement. Our studies have shown that technical performance has emerged as an important predictor of outcomes in congenital surgery. We describe a "technical imperative", defined as an absolute rule whereby it is imperative to leave the operating room with a good or better yet, an optimal technical result, even if this requires surgical revision and going back on bypass [8–10,17]. Cross clamp times were not associated with poor outcomes but rather it was the end result of the adequacy of anatomic repair that counted the most. Thus, a focus on the intraoperative assessment of the adequacy of the anatomic repair primarily by echocardiography but also by pressure measurements and even intraoperative angiography is paramount. Increasing intraoperative vigilance, the detection and immediate repair of significant residual lesions remains of prime importance. The development and implementation of a system for measuring technical performance in congenital cardiac surgery operations can be used for surgeons' self and peer assessments. The use of the technical score in conjunction with a risk adjustment system such as RACHS-1, Aristotle or EACTS-STS, was found to be a useful tool in quality improvement and the monitoring of surgical performance.

We have proposed a model of assessing technical performance in congenital heart surgery that is focused primarily on the outcome and the adequacy of the anatomic repair that is felt to be under the surgeon's control. Other quality metrics in the surgeon's performance should also be included such as leadership skills and abilities to communicate and function effectively within a multidisciplinary team which might be just as important in determining patient outcomes.

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Chapter

QUALITY ASSURANCE AND TECHNICAL PERFORMANCE IN THE OPERATING ROOM

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ABSTRACT

Outcomes in pediatric cardiac surgery have improved dramatically since its infancy 50 years ago. Mortality has been reduced from as high as 90-100% in the initial years to around 4% for many high complexity cases and virtually no mortality for simple cardiac defects. While part of this improvement can be attributed to advances in pediatric cardiac anesthesia, pediatric cardiopulmonary bypass and development of highly specialized pediatric cardiac intensive care units, outcomes continue to depend on the technical quality of the surgical repair. In this article we address the importance of the surgical technical performance on outcomes and discuss the currently available tools for measurement of surgical competency. Our studies showed that the final technical (anatomical) result score had the strongest association with patient outcomes. We offer suggestions for a competency model that continues to evolve as we explore the use of immersive learning, deliberate practice, reflection in action, mentorship by senior surgeons and life long learning. We expand our discussion to include the applicability of such a quality assurance tool in adult cardiac surgery.

Keywords: Surgical competency, pediatric cardiac surgery, technical performance, risk stratification, outcomes, patient safety

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Stage I Norwood: Optimal technical performance improves outcomes irrespective of preoperative physiologic status or case complexity

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Objective: Interplay of baseline physiologic status, case complexity, technical performance, and outcomes in high-acuity operations has been poorly defined. This study explored these interactions to determine whether a technically optimal operation can mitigate effects of baseline physiology and high case-complexity on outcomes for the stage I Norwood procedure.

Methods: Technical performance was categorized as optimal, adequate, or inadequate from adequacy of the anatomic repair of the stage I subprocedures according to anatomic areas where intervention is performed. Physiological illness severity statuses in preoperative and postoperative periods were determined with *Pediatric Risk of Mortality* III system, which uses 17 physiologic variables. Case complexity was calculated with Aristotle comprehensive system. All patients undergoing stage I procedure from January 2004 to December 2007 were retrospectively studied.

Results: One hundred thirty-five procedures were included. Five were excluded from the technical performance assessment because of inadequate postoperative data. Eighty-one (62.3%), 26 (20%), and 23 (17.7%), respectively, were scored as optimal, adequate, and inadequate. Overall hospital mortality was 14.1%. Inadequate technical performance, high-complexity Aristotle comprehensive scores, and high preoperative illness severity scores correlated with significantly higher hospital mortality, longer stay, and greater frequency of major postoperative complications. In subgroup analysis of patients with optimal technical performance, outcomes were favorable irrespective of high or low preoperative physiologic illness severity or case complexity.

Conclusions: In stage I Norwood procedures, optimal technical performance attenuated effects of poor preoperative physiologic status and high case complexity, with reduced hospital mortality. Inadequate technical performance resulted in poor outcomes regardless of preoperative status. (J Thorac Cardiovasc Surg 2010;139:962-8)

CHD

The stage I Norwood procedure remains one of the most challenging operations in congenital heart surgery. It is technically extremely delicate, and apart from the reduction in pulmonary overcirculation there is no immediate physiologic benefit. We have previously shown that technical performance has a major effect on outcomes, including mortality, of patients undergoing the stage I Norwood operation.[1] The interplay of baseline physiologic status, anatomic risk factors, technical performance, and postoperative recovery in this patient population has been mainly defined on the basis of patient-specific or anatomic risk factors (prematurity, lower weight, intact atrial septum, smaller ascending aorta, etc) or procedure-specific risk factors (longer circulatory arrest time, shunt originating from the neoaorta, management of the ascending aorta, etc).[2-5]

In one risk-stratification system, the Aristotle comprehensive system,[6-8] preoperative physiologic risk factors were included as part of an assessment of an overall risk profile. The Aristotle score is a complexity score that is based on the patient's baseline physiology and anatomy as well as the type of surgical procedure and its potential for mortality, morbidity, and anticipated technical difficulty. The basic and comprehensive Aristotle score values have been previously described.[6-8]

The *Pediatric Risk of Mortality* (PRISM), a risk-adjustment tool first published in 1988,[9] is a generic severity-scoring system developed to measure the probability of death on the basis of the hypothesis that preoperative physiologic instability reflects mortality risk. The newer and improved PRISM III,[10] developed in 1996, is more accurately calibrated and achieves good discrimination for individual patient mortality risk assessments.

The aim of this study was to define and explore the associations of preoperative baseline physiology, case complexity, technical performance, and postoperative outcomes with these various scoring systems. Our hypothesis was that a technically optimal operation could mitigate the effects

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Abbreviations and Acronyms
CI = confidence interval
ECMO = extracorporeal membrane oxygenation
ICU = intensive care unit
PRISM = *Pediatric Risk of Mortality* instrument

of baseline physiology and high case complexity on outcomes for the stage I Norwood procedure.

MATERIALS AND METHODS

The Children's Hospital Boston institutional review board approved this study. A waiver of informed consent was obtained. Patient data were rendered anonymous in our database in compliance with the hospital requirements.

Technical Performance Measurement Tool

The predischarge technical score created in our previous study was used.[1] In brief, the surgical procedure was divided into individual components defined as subprocedures, which were based on the specific anatomic regions subject to intervention. The subprocedures for the stage I Norwood were as follows: atrial septectomy, aortic root reconstruction (coronary perfusion), proximal aortic (distal to sinotubular junction but proximal to the innominate artery) reconstruction, distal aortic arch reconstruction, and source of pulmonary blood flow. Individual subprocedures were scored as optimal, adequate, or inadequate. The parameters for score assessment were based on clinical, echocardiographic, and cardiac catheterization data.[1] An overall score for each patient was also defined, wherein the operation was graded as optimal if all subprocedures were optimal, adequate if at least 1 subprocedure was adequate but none were inadequate, and inadequate if 1 or more subprocedures were inadequate. Additional procedures performed, such as valvuloplasties, were taken into account in measuring technical performance, and the scores were modified as necessary by using similar principles. The only modification from the previous score was a downgrading from optimal to adequate if an otherwise optimal technical result was achieved by means of a second cardiopulmonary bypass run.

PRISM III Scoring System

The PRISM III score has 17 physiologic variables subdivided into 26 ranges, which are age adjusted. These include the worst values of cardiovascular and neurologic vital signs, acid–base balance, blood gas values, chemistry and hematologic tests (systolic blood pressure, heart rate, temperature, pupillary reflexes, acidosis, total carbon dioxide, pH, arterial Po_2, Pco_2, glucose, potassium, creatinine, blood urea nitrogen, white blood cell count, prothrombin or partial thromboplastin time, and platelet count) from the first 12 or 24 hours after admission to the intensive care unit (ICU).

PRISM III scores were calculated by using the standardized scoring system[10] at 24 hours before the stage I Norwood procedure and at 24 and 48 hours separately afterward. Patients with no preoperative arterial blood gas values within 24 hours of the operation, were scored for a Po_2 between 42 and 49.9 mm Hg (3 points), because Po_2 falls within this range for most patients undergoing the stage I Norwood procedure.

Aristotle Comprehensive Scoring System

The basic score value for the stage I Norwood procedure is 14.5. The comprehensive score further adjusts the complexity according to the specific patient and procedural characteristics, including anatomic factors, associated procedures, age, and such other clinical and physiologic factors as shock (persistent or resolved at time of surgery), mechanical ventilation to treat cardiorespiratory failure, and renal, endocrine, neurologic, or hepatic dysfunction. The comprehensive score can add a maximum of 10 additional points to the 14.5 points of the basic score. Five points can be added for the procedure-dependent factors and associated procedures, with another maximum of 5 points for the procedure-independent factors (Table 2). The Aristotle comprehensive score was calculated by using preoperative and perioperative data.[8]

Outcomes

In-hospital mortality was defined as death before hospital discharge or within 30 days of the operation for discharged patients. Patients transferred back to their referring hospital were followed up through their discharge. A death occurring late at a referring hospital was counted in the mortality figures. Postoperative hospital and intensive care unit stays and ventilation time were measured in days after the stage I operation. Major postoperative complications were defined as stroke or major neurologic deficit, initiation of extracorporeal membrane oxygenation (ECMO), reoperation for bleeding, unplanned reoperation for residual defect, cardiac arrest with cardiopulmonary resuscitation, phrenic nerve paralysis requiring diaphragm plication, and mediastinitis.

Data Collection

A retrospective review was performed on all patients undergoing stage I Norwood palliation from January 2004 to December 2007 at Children's Hospital Boston. Clinical data (echocardiograms, clinical evaluation, and catheterization results) were collected for assessment. Other variables collected for analysis included surgeon identification and preoperative, procedural, morphologic, and postoperative patient characteristics and outcomes listed in Tables 1, 2, and 3. Patients with inadequate clinical or echocardiographic data relevant to the technical score (n = 5) were excluded from the analysis involving technical performance. Because their PRISM III and Aristotle scores were calculated, however, they were included in other analyses.

Statistical Methods

Patient and procedural characteristics were summarized with frequencies and percentages for categoric variables and the medians and ranges for continuous variables. Relationships between technical performance score and patient outcomes were assessed with the Pearson χ^2 test for categoric variables and the Kruskal–Wallis test for continuous variables. Relationships between PRISM III and Aristotle comprehensive scores and dichotomous patient outcomes were evaluated with the Mann–Whitney test. Associations with continuous outcomes were examined with the Spearman rank correlation coefficient. These analyses were repeated within subgroups defined by technical performance score. The ability of PRISM III and Aristotle scores to discriminate between patients who died in hospital and those who did not was assessed by calculating areas under the receiver operating characteristic curve, and 95% confidence intervals (CIs) were calculated. Relationships between death and patient and procedural factors were also explored with logistic regression analysis; because of the small number of in-hospital deaths, however, no more than 2 explanatory variables could be included in a single multivariable model. Statistical analysis was performed with SPSS 14.0 for Windows (SPSS Inc, Chicago, Ill).

RESULTS

One hundred thirty-five patients in the stage I Norwood palliation population were identified. This included all patients who underwent the stage I Norwood procedure, including 3 patients who had attempted biventricular repairs that failed and were subsequently converted to stage I palliation, 1 at a later stage and the other 2 during the same

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TABLE 1. Patient and procedural characteristics (n = 135)

Age at operation (d, median and range)	5 (2-42)
Age >14 d at operation (no.)	7 (5.2%)
Weight (kg, median and range)	3.2 (1.3–4.7)
Weight <2500 g (no.)	21 (15.6%)
Prematurity* (no.)	14 (10.4%)
Morphologic variants (no.)	
AA/MA	30 (22.2%)
AA/MS	21 (15.6%)
AS/MA	1 (0.7%)
AS/MS	43 (31.9%)
Others	40 (29.6%)
Preoperative catheter-based interventions (fetal or postnatal)	32 (23.7%)
Fetal interventions	22 (16.3%)
Postnatal	21 (15.6%)
Bypass time (min, median and range)	145 (87–312)
Crossclamp time (min, median and range)	63 (0–189)

AA, Aortic atresia; *MA*, mitral atresia; *MS*, mitral stenosis; *AS*, aortic stenosis. *Prematurity was defined as gestational age less than 36 weeks.

TABLE 2. Aristotle procedure-dependent (most frequent, maximum 5 points), procedure-independent factors, and associated procedures (maximum 5 points)

	No.	%
Procedure-independent factors		
Preoperative mechanical ventilation for cardiopulmonary failure	41	30.4%
Weight <2.5 kg	21	15.6%
Shock resolved at time of surgery	17	12.6%
Extracardiac and genetic anomalies	11	8.1%
Heterotaxy	5	3.7%
Genetic or chromosomal anomaly	3	2.2%
Dextrocardia	2	1.5%
Tracheoesophageal fistula	1	0.7%
Prematurity (32–35 wk)	8	5.9%
Severe prematurity (<32 wk)	3	2.2%
Renal dysfunction	5	3.7%
Procedure-dependent factors		
Aortic atresia	53	39.3%
Obstructed (intact or restrictive atrial septum)	23	17%
AV valve regurgitation, grade 3 or 4	5	3.7%
Interrupted aortic arch repair	3	2.2%
TAPVC repair	3	2.2%
Aberrant right subclavian artery (except in Sano)	2	1.5%
Age >1 mo	2	1.5%
Associated procedures		
Aortic valvuloplasty	15	11.1%
Mitral valvuloplasty	10	7.4%
Pulmonary valvuloplasty	1	0.7%
Tricuspid valvuloplasty	2	1.5%
Endofibroelastosis resection*	15	11.1%

AV, Atrioventricular; *TAPVC*, total anomalous pulmonary venous connection. *Endofibroelastosis resection was not listed as an associated procedure in the Aristotle system, but it was given the equivalent score for aortic or mitral valvuloplasty; if endofibroelastosis resection was performed with mitral or aortic valvuloplasty, no additional points were given for the endofibroelastosis resection.

operation. Five patients did not have reliable postoperative data for calculation of technical performance scores, mainly because they required intraoperative ECMO support and could never have full evaluation of the repair. Four of these 5 were high-risk patients. All 5 patients were excluded from the analyses involving technical performance scores but were included in the analyses involving PRISM III and Aristotle scores and postoperative outcomes.

Six attending surgeons performed 3%, 10.4%, 14.1%, 21.5%, 25.2%, and 25.9% of the operations. A complete postoperative echocardiogram was performed before discharge in all cases. The median age at operation was 5 days (range, 2–42 days). Table 1 summarizes the demographic, morphologic, and procedural characteristics, including preoperative catheter-based interventions (fetal and postnatal). Table 2 summarizes the patients' Aristotle procedure-independent and procedure-dependent factors, including associated procedures performed during the stage I procedure. In-hospital mortality for the entire study group was 19 of 135 (14.1%), or 16 of 132 (12.1%) after exclusion of the 3 patients who initially had biventricular repairs converted to stage I Norwood procedures. Other outcomes, such as use of ECMO, major complications, and hospital and ICU stays, are shown in Table 3. The technical performance was graded as optimal in 81 cases (62.3 %), adequate in 26 (20.0%), and inadequate in 23 (17.7%). Preoperative and 24- and 48-hour postoperative PRISM III scores ranged from 2 to 24 (median, 8), 8 to 39 (median, 18), and 8 to 31 (median, 17), respectively. Aristotle comprehensive scores ranged from 14.5 to 24.5 (median, 18.5).

Technical Performance and Outcomes

Patients with inadequate performance had significantly higher mortality, longer hospital and ICU stays, longer ventilation time, and greater occurrence of major postoperative complications ($P < .0001$ for each comparison; Table 4). Technical performance also had a significant impact on PRISM III scores at 24 postoperative hours ($P = .003$, median 17 in optimal, 19 in adequate, and 23 in inadequate groups; Figure 2), reflecting a higher degree of physiologic illness severity with inadequate performance. Receiver operating characteristic analysis showed significant ability of technical performance scores to discriminate mortality, with an area under the curve of 0.84 ($P < .0001$; 95% CI, 0.74–0.94).

PRISM III Score and Outcomes

Preoperative and 24- and 48-hour postoperative PRISM III scores differed significantly between patients who died and those who did not, reflecting a higher degree of illness severity in both the preoperative and immediate postoperative periods among the nonsurvivors (median, 8 vs 12 for

TABLE 3. Technical performance scores and patient outcomes (n = 130)

	Overall	Optimal (n = 81)	Adequate (n = 26)	Inadequate (n = 23)
In-hospital mortality (no.)	19 (14.1%)	1 (1.2%)	5 (19.2%)	8 (34.8%)
Hospital stay (d, median and range)	18 (1–293)	15 (7–96)	20 (4–138)	46 (1–293)
Intensive care stay (d, median and range)	9 (1–293)	8 (3–60)	9 (3–58)	29 (1–293)
Ventilation time (d, median and range)	6 (1–293)	5 (1–47)	7 (2–58)	19 (1–293)
Major postoperative complications (no.)	34* (25.2%)	5 (6.2%)	9 (34.6%)	15 (65.2%)
Extracorporeal membrane oxygenation (no.)	25† (18.7%)	3 (3.7%)	5 (19.2%)	13 (56.5%)

All differences $P < .0001$. *Includes 5 patients without technical performance scores. †Includes 4 patients without technical performance scores.

preoperative PRISM III; $P = .034$; median, 17 vs 25 for 24-hour postoperative PRISM III; $P < .0001$; median, 17 vs 21 for 48-hours postoperative PRISM III; $P = .011$). Of preoperative and 24- and 48-hour postoperative PRISM III scores, discrimination for mortality was best for the 24-hour postoperative score, with areas under the curve of 0.65 ($P = .035$; 95% CI, 0.50–0.81), 0.83 ($P < .0001$; 95% CI, 0.75–0.92), and 0.70 ($P = .011$; 95% CI, 0.55–0.84), respectively.

Aristotle Comprehensive Score and Outcomes

Aristotle comprehensive score had a significant association with mortality ($P = .003$, median 18 for live patients vs 21 for dead patients). It also correlated significantly with hospital and ICU stays and with ventilation time ($P < .0001$ for each correlation test, with Spearman correlation coefficients of 0.330, 0.322, and 0.328, respectively). Receiver operating characteristic analysis showed significant ability of the Aristotle score in discriminating mortality, with an area under the curve of 0.71 ($P = .003$; 95% CI, 0.59–0.83).

TABLE 4. Factors tested in multivariable analysis for mortality

Patient-specific factors
Age (as continuous variable)
Weight (both as continuous variable and as <2.5 kg)
Sex
Prematurity (<36 wk gestation)
Major extracardiac, chromosomal, other genetic anomaly
Anatomic factors
Aortic atresia
Total anomalous pulmonary venous connection
Obstructed pulmonary venous return (intact or restrictive atrial septum)
Surgery-specific factors
Surgeon
Cardiopulmonary bypass time
Crossclamp time
Circulatory arrest time
Type of shunt
Preoperative catheter-based intervention (fetal or postnatal)
Associated procedures
Endofibroelastosis resection
Valvuloplasty (aortic, mitral, tricuspid, or pulmonary)
Complexity-adjusted score
Aristotle comprehensive score
Illness severity measurements
Preoperative PRISM-III
PRISM III at 24 postoperative h
PRISM III at 48 postoperative h
Technical performance scores

PRISM, Pediatric Risk of Mortality.

Mortality

Multivariable analysis. In a univariate analysis, the variables from Table 4 that showed significant correlation with mortality (in addition to PRISM III, Aristotle comprehensive, and technical performance scores) were weight, obstructed pulmonary venous return, and cardiopulmonary bypass time. In the logistic regression models containing 2 explanatory variables simultaneously, the models that included the following performed best according to coefficient of determination (R^2): technical performance with Aristotle comprehensive score and technical performance with preoperative PRISM III score. For the model including technical performance and Aristotle score, the odds of a patient dying with inadequate and adequate technical performance were 43.8 and 21 times (95% CI, 5.0–387.1 and 2.3–195.7 times), respectively, the odds of a patient dying with optimal performance. For the model including technical performance and preoperative PRISM III score, the odds of a patient dying with inadequate or adequate technical performance were 42.6 or 20.2 times (95% CI, 4.8–377.6 and 2.2–187.3 times) the odds of a patient dying with optimal technical performance.

Analyses stratified by technical performance score (Figure 1). A subgroup analysis of the patients according to technical performance scores showed the following: (1) In the optimal technical performance group, there were no differences according to mortality status in preoperative PRISM III score or complexity as measured by Aristotle score (median 8 in live patients vs 14 in dead patients, $P = .198$, and median 17.5 in live patients vs 19.5 in dead patients, $P = .667$, respectively). (2) In the adequate technical performance group, mortality was associated with higher preoperative PRISM III scores and higher Aristotle comprehensive scores (median 6 in live patients vs 16 in dead patients, $P = .006$, and median 17.5 in live patients vs 20.5 in dead patients, $P = .023$, respectively). In the inadequate

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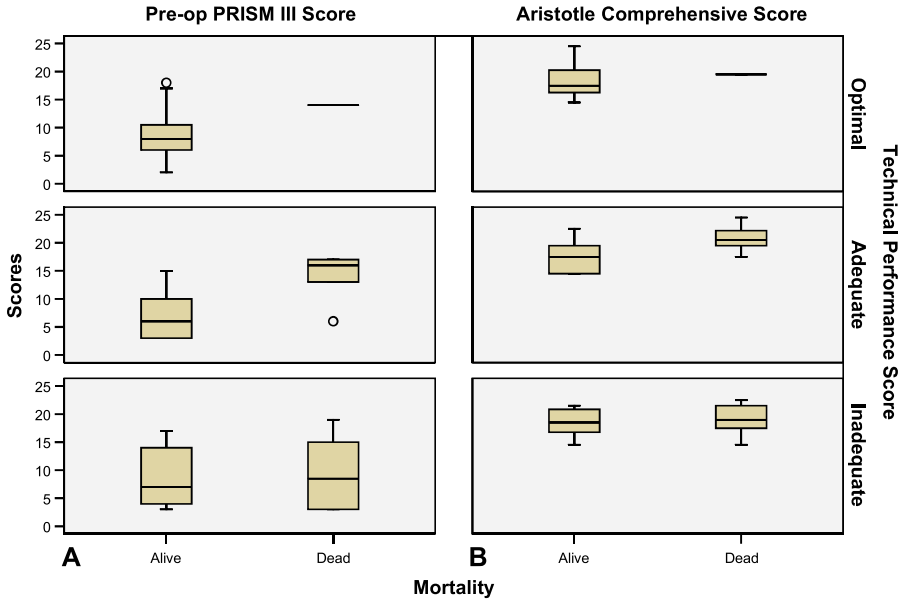


FIGURE 1. Subgroup analysis by technical performance score and preoperative *Pediatric Risk of Mortality (pre-op PRISM)* III score or Aristotle score versus mortality.

technical performance group, there was no difference in preoperative PRISM III scores or Aristotle scores according to mortality status (median 7 in live patients vs 8.5 in dead patients, $P = .985$, and median 18.5 in live patients vs 19 in dead patients, $P = .648$, respectively).

DISCUSSION

Measurement of technical competence is inherently difficult.[11] We previously developed a technical scoring system for common congenital heart procedures[12] and subsequently expanded this to the stage I Norwood palliation procedure.[1] The most recent previous study showed that inadequate technical performance had a significant association with higher mortality and longer hospital stay. This study, which included all patients from 2007, has confirmed those findings and shown a significant association between preoperative physiologic illness severity (measured by PRISM III and partially by Aristotle), case complexity (Aristotle), technical performance, and outcomes. Optimal technical performance attenuated the impact of preoperative illness severity and resulted in good outcomes regardless of preoperative illness severity or case complexity. Inadequate technical performance resulted in poor outcomes regardless of preoperative illness severity or case complexity. An adequate technical performance resulted in good outcomes for lower preoperative illness severity or case complexity and poor outcomes for higher preoperative illness severity or case complexity. In other words, the clinical scenario for patients with adequate technical performance was dictated by baseline physiology and anatomy, whereas outcomes for patients with optimal or inadequate performance were dependent more on the actual technical results, rather than on baseline physiology or anatomy.

A recent review of 412 pancreatic resections showed similar findings. Escalating physiologic risk worsened postoperative morbidity and increased cost, but these effects were attenuated by improved operative performance.[13] A similar interaction, or effect modification, between baseline physiology and technical performance was seen in our study. In our regression model to predict mortality, the best models, according to coefficient of determination (R^2), included both

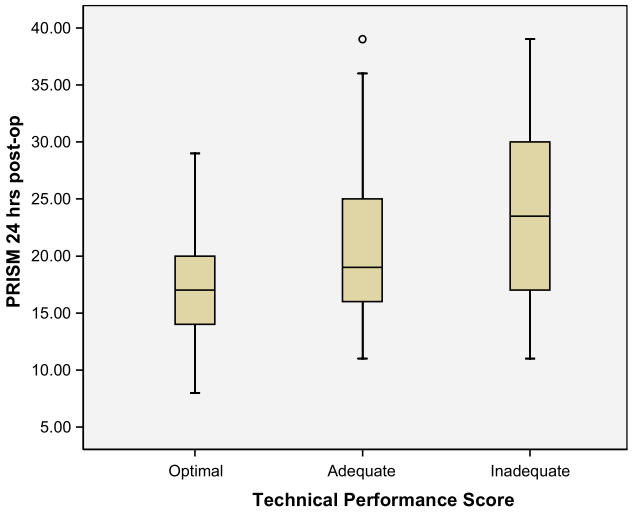


FIGURE 2. *Pediatric Risk of Mortality (PRISM)* score 24hours postoperative *(post-op)* and technical performance score.

technical performance with preoperative PRISM III score and technical performance with Aristotle comprehensive scores. All other risk factors for mortality dropped out.

Interestingly, we found no correlation between preoperative PRISM III or Aristotle comprehensive score and technical performance, suggesting that patient-specific variables such as weight or anatomy are less likely to be responsible for technical performance. As expected, higher postoperative physiologic illness severity scores (PRISM III scores at 24 and 48 hours) were associated with worse technical scores and also with worse outcomes. When compared with the Aristotle score, postop PRISM III scores also performed better in the ability to predict mortality. With the original PRISM scoring system, a previous study had demonstrated this in a prospective fashion.[14] Technical performance still had the highest predictive value (area under the curve of 0.84), however, illustrating the impact of sound intraoperative techniques. Not surprisingly, inadequate technical performance had a significant correlation with higher PRISM III score at 24 postoperative hours, irrespective of preoperative risk.

There are several important limitations worth mentioning. (1) This was a single-center, retrospective analysis. In addition to the bias inherent in a retrospective study, these results may be institution specific. For example, hospitals with a cardiac surgical team comprising 2 surgeons only or an ICU in which poor results are obtained despite optimal technical performance might not find the same results. (2) The PRISM system was not designed for cyanotic patients and thus has inherent flaws in that respect.[15] Patients with ECMO support, for example were scored according to their laboratory values, with no additional changes made to the score because of mechanical support. (3) Weight as a continuous variable was significantly associated with mortality in the univariate analysis. Because it is included in the Aristotle score, weight could not be used in the multivariable analysis; however, it is possible that weight alone, a simpler variable, might be a good surrogate for the more complex case complexity calculations. (4) The technical scoring system is an expert opinion-based consensus system that remains somewhat subjective. Some variables that are not entirely under surgeon control had to be included as surrogates for technical performance. For example, it is well documented that the shunt is a significant source of complications in the stage I Norwood procedure; however, objectively judging the technical performance of a shunt is difficult. Downsizing a shunt because of pulmonary overcirculation reduced the score from optimal to adequate, and revision of a shunt because of acute thrombosis resulted in an inadequate score (need for reintervention). Both occurrences clearly affect outcomes negatively, but both could also be the result of patient-specific factors, such as lower then expected pulmonary resistance or a dysfunctional coagulation cascade, both well-documented postoperative occurrences in stage I Norwood procedures but not necessarily the result of poor technical performance. (5) One might argue that because technical performance is the paramount influence on outcomes, preoperative risk optimization by stabilization is not necessary. The concept of preoperative stabilization is prevalent in our ICU, however, and thus all patients were managed according to this concept. Therefore this study could not test that hypothesis. In addition, most surgeons had an even distribution of technical scores (surgeon as risk factor dropped out in the regression model), and thus optimal technical performance is not guaranteed even for the ''best'' surgeons. (6) These results are specific to the fragile population undergoing the stage I Norwood procedure. Our first study, which looked at technical scores for the arterial switch, ventricular septal defect, tetralogy of Fallot, and complete atrioventricular canal repairs, did not elicit an association between technical scores and clinical outcomes for these procedures, which are also characterized by an immediate postoperative physiologic benefit.[12] Specifically, the impact of technical performance on mortality may only be valid for the stage I Norwood population.

In conclusion, technical performance emerged as a powerful predictor of clinical outcomes for the stage I Norwood operation. Optimal technical performance significantly attenuated the impact of preoperative illness severity and case complexity, whereas inadequate technical performance resulted in poor outcomes regardless of preoperative status. These findings should be confirmed by other institutions or in a multicenter study.

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Early Postoperative Severity of Illness Predicts Outcomes After the Stage I Norwood Procedure

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Background. **We hypothesize that a measure of the immediate postoperative severity of illness after the stage I Norwood operation reflects technical performance or the adequacy of anatomic repair and can serve as a predictor of hospital mortality, reinterventions, and clinical outcomes.**

Methods. **One hundred thirty-five patients undergoing stage I were retrospectively studied (2004 to 2007). The severity of illness on postoperative day 1 (POD1) was measured using the Pediatric Risk of Mortality III (PRISM) scoring system. Technical performance scores (optimal, adequate, inadequate) were calculated before hospital discharge. Hospital mortality, postoperative reinterventions, and complications were recorded. Postoperative reintervention was defined as need for cardiac catheterization laboratory or operating room based procedure that included balloon dilation or repair of arch obstruction, shunt revision, reoperations for bleeding, and extracorporeal membrane oxygenation support.**

Results. **Hospital mortality was 14.1% (n = 19). The rate of complications and reinterventions was, respectively, 28.1% (n = 38) and 26.7% (n = 36). The POD1 PRISM score was associated with technical performance (p = 0.003). Higher POD1 PRISM scores were associated with mortality ($p < 0.001$), complications ($p < 0.001$), and reinterventions ($p = 0.001$). The POD1 PRISM score had high discrimination for mortality, complications, reinterventions, and inadequate technical performance (areas under the receiver operating characteristic curve were 0.835, 0.776, 0.773, and 0.710, respectively; $p \leq 0.001$ for all).**

Conclusions. **The severity of illness as measured by PRISM score on POD1 after the stage I Norwood operation has strong association and discrimination with hospital mortality, postoperative reinterventions, inadequate technical performance, and major postoperative complications. It may be used as an early surrogate of technical performance to initiate a search for and correction of technical deficiencies.**

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Outcomes after the stage I Norwood procedure have been correlated with various factors including patient specific anatomic or physiologic variables (prematurity, lower weight, intact atrial septum, smaller ascending aorta, and so forth) as well as procedure-specific or technical factors (circulatory arrest time, shunt originating from the neoaorta, management of the ascending aorta, and so forth) [1–3]. We have previously examined the interaction between preoperative baseline physiology, case complexity, technical performance or adequacy of anatomic repair, and postoperative outcomes, focusing on hospital mortality [4]. We concluded that optimal technical performance attenuated the effects of poor preoperative physiologic status and high case complexity with reduced hospital morbidity and mortality, whereas inadequate technical performance resulted in poor outcomes regardless of preoperative status.

The Pediatric Risk of Mortality (PRISM) scoring system, a risk adjustment tool first published in 1988 [5], is a generic severity-scoring system developed to measure the probability of death on the basis of the hypothesis that physiologic instability reflects mortality risk. The newer and improved PRISM III [6] scoring system, developed in 1996, is more accurately calibrated and discriminates mortality well for individual patients.

Although it appears intuitive that a higher physiologic illness severity in the immediate postoperative period may be associated with higher mortality rate, this has not been previously tested for the stage I Norwood procedure. Early identification of patients likely to have postoperative complications attributable to poor technical performance may facilitate early intervention to correct the technical inadequacies, which may mitigate their

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impact. The potential use of a new tool available in the immediate postoperative period, with high predictive ability of outcomes, technical deficiencies, and need for reintervention could be used as a trigger for timely institution of diagnostic tests and necessary reinterventions, averting adverse outcomes. Certain perioperative monitoring strategies that include venous oximetry and near-infrared spectroscopy, and peak blood lactate levels in the postoperative period have been used to guide interventions and patient management [7–10], but a measurement of the postoperative physiologic illness severity by the constellation of different physiologic variables in a previously validated scoring system, such as the PRISM III, has not been tested. Although the measurement of technical performance in the stage I Norwood procedure, as shown in our previous studies [4, 11], offers invaluable information, it incorporates data collected retrospectively at the time of patient discharge, and thus has a limited utility in prospectively guiding patient management.

Therefore, we hypothesize that a measure of the immediate postoperative severity of illness after the stage I Norwood operation reflects technical performance and adequacy of anatomic repair and can serve as a predictor of hospital mortality, reinterventions, and clinical outcomes.

Patients and Methods

The Children's Hospital Boston Institutional Review Board approved this study. A waiver of informed consent was obtained. Patient data were rendered anonymous in our database in compliance with the hospital requirements.

Physiologic Illness Severity Measurement Tool

The PRISM III scoring system [6] was used as a measurement tool of the severity of illness. The PRISM III score has 17 physiologic variables, subdivided into 26 ranges that are age adjusted. These include the worst values of cardiovascular and neurologic vital signs, acid–base balance, blood gas values, chemistry, and hematologic tests, from the first 12 or 24 hours after admission to the intensive care unit (Table 1). Postoperative day 1 (POD1) PRISM III scores were calculated by using the standardized scoring system at 24 hours after the stage I Norwood procedure.

Technical Performance

The predischarge technical performance was judged based on criteria of the adequacy of anatomic repair, as previously described [4, 11, 12], and was categorized as optimal, adequate, or inadequate. In brief, the stage I Norwood procedure was divided into individual components defined as subprocedures, which were based on the specific anatomic regions subject to intervention. These subprocedures included atrial septectomy, aortic root reconstruction (coronary perfusion), proximal arch reconstruction, distal arch reconstruction, and source of pulmonary blood flow (either modified Blalock-Taussig shunt or right ventricle to pulmonary artery conduit). The variables for score assessment were based on clinical, echocardiographic, and cardiac catheterization data [4, 11].

Table 1. Pediatric Risk of Mortality (PRISM) III Physiologic Variables

Physiologic Variable
Cardiovascular and neurologic vital signs
Systolic blood pressure, heart rate, temperature, pupillary reflexes, mental status
Acid–base/blood gases
Acidosis, total CO_2, pH, paO_2, pCO_2
Chemistry
Glucose, potassium, creatinine, blood urea nitroge
Hematology
White blood cell count, prothrombin time or partial thromboplastin time, platelet count

Modified from Pollack et al [6].

Mortality

In-hospital mortality was defined as death before hospital discharge or within 30 days of the operation. Patients transferred back to their referring hospital were followed up through their discharge, and a death occurring at a referring hospital was counted in the mortality figures. Postoperative hospital and intensive care unit stays and ventilation time were measured in days after the stage I operation.

Major Complications

Major postoperative complications were defined as stroke or major neurologic deficit, cardiac arrest with cardiopulmonary resuscitation, and postoperative reinterventions, which included intraoperative or postoperative initiation of extracorporeal membrane oxygenation (ECMO) for resuscitation, reoperation for bleeding for hemodynamic instability, unplanned reoperation for residual defect or shunt revision, phrenic nerve paralysis requiring diaphragm plication, and mediastinitis with sternal debridement.

Postoperative Reinterventions

Postoperative reinterventions, many of which were also part of the major postoperative complications, were classified as catheterization laboratory–based or operating room–based. Catheterization laboratory–based postoperative reinterventions included balloon dilation of residual stenoses such as restrictive atrial septal defects, aortic arch obstructions, branch pulmonary artery, pulmonary vein or shunt stenoses, or catheter-based clot lysis. Operating room–based postoperative reinterventions included reoperations to correct residual aortic arch obstruction, modified Blalock-Taussig shunt, or right ventricle to pulmonary artery conduit deficiencies such as stenosis or clotted shunts, including downsizing of shunts, postoperative institution of ECMO for resuscitation, postoperative reexploration for bleeding for hemo-

dynamic instability, sternal debridement for mediastinitis, and diaphragm plication after phrenic nerve injury.

Data Collection

A retrospective review was performed on all patients undergoing stage I Norwood palliation from January 2004 to December 2007 at Children's Hospital Boston. Clinical data (echocardiograms, clinical evaluation, and catheterization results) were collected for assessment. Other variables collected for analysis included surgeon identification and preoperative, procedural, morphologic, and other patient characteristics referenced in our previously published report [4]. Patients with inadequate clinical or echocardiographic data relevant to the technical score (n = 5) were excluded from the analysis involving technical performance.

Statistical Methods

Patient and procedural characteristics were summarized with frequencies and percentages for categorical variables and medians and ranges for continuous variables. Relationships between technical performance score and patient outcomes were assessed with the Pearson χ^2 test for categorical variables and the Kruskal-Wallis test for continuous variables. Relationships between POD1 PRISM score and dichotomous patient outcomes were evaluated with the Mann-Whitney test. Relationships between POD1 PRISM score and mortality were also evaluated within subgroups defined by technical performance score. The ability of POD1 PRISM score to discriminate between patients who experienced each outcome versus patients who did not was assessed by calculating areas under the receiver operating characteristic curve (AUC), with 95% confidence intervals (CI). Relationships between outcomes and POD1 PRISM score, adjusting for other patient and procedural factors, were explored with logistic regression analysis. In the analysis of mortality, technical performance was considered as an explanatory variable. The AUC was calculated for each model, as well as for the Cox and Snell pseudo R^2. Because of the relatively small numbers, no more than two explanatory variables were included in a single multivariable model. Statistical analysis was performed with SPSS 14.0 for Windows (SPSS Inc, Chicago, IL).

Results

One hundred thirty-five patients in the stage I Norwood palliation population were identified. This group included all patients who underwent the stage I Norwood procedure, including 3 patients who had attempted biventricular repairs that failed and were subsequently converted to stage I palliation, 2 at the same operation and 1 at a later stage. Table 2 summarizes the patients' demographic, morphologic, preoperative, and procedural characteristics. Five patients, 4 of whom were high risk, did not have reliable postoperative data for calculation of technical performance scores, mainly because they required intraoperative ECMO support and could never have full evaluation of the repair. All 5 patients were excluded from the analyses involving technical performance scores but were included in the analyses involving POD1 PRISM score and postoperative outcomes. Six attending surgeons performed 3.0%, 10.4%, 14.1%, 21.5%, 25.2%, and 25.9% of the operations, respectively. In-hospital mortality for the entire study group was 19 of 135 (14.1%), or 16 of 132 (12.1%) after exclusion of the 3 patients who initially had biventricular repairs converted to stage I Norwood procedures. These included 1 patient who died intraoperatively and 1 who died of unknown cause after transfer to the referring hospital. The median hospital length of stay was 18 days (range, 1 to 293 days), median intensive care unit length of stay was 9 days (range, 1 to 293 days), and median ventilation time was 6 days (range, 1 to 293 days). Thirty-eight patients (28.1%) had one or more major postoperative complication, and 1 patient had a catastrophic intraoperative complication resulting in intraoperative death. Thirty-six patients (26.7%) had postoperative reinterventions (Table 3).

Table 2. Patient Characteristics (n = 135)

Characteristic	Number (%) or Median (Range)
Age at operation, days	5 (2–42)
Age more than 14 days old at operation	7 (5.2%)
Weight, kg	3.2 (1.3–4.7)
Weight less than 2,500 g	21 (15.6%)
Female	54 (40.6%)
Prematurity, gestational age less than 36 weeks	14 (10.4%)
Extracardiac and genetic/chromosomal anomalies	11 (8.1%)

Modified from Karamichalis et al [4].

Postoperative Day 1 PRISM Scores and Outcomes

The POD1 PRISM score ranged from 8 to 39 (median, 18; Fig 1).

Technical Performance

The technical performance was graded as optimal in 81 cases (62.3 %), adequate in 26 (20.0%), and inadequate in 23 (17.7%). Hospital mortality differed based on technical performance, and was 1.2% (1 patient died) in the optimal group, 19.2% (5 patients died) in the adequate group, and 34.8% (8 patients died) in the inadequate group ($p < 0.0001$). Patients with inadequate performance had significantly higher mortality, longer hospital and intensive care unit stays, and longer ventilation time ($p < 0.0001$ for each comparison). The POD1 PRISM scores had a strong association with technical performance ($p = 0.003$; POD1 PRISM score median 17 in optimal, 19 in adequate, and 23 in inadequate groups), reflecting a higher degree of physiologic illness severity with inadequate performance. The POD1 PRISM score discriminated inadequate technical performance, with AUC 0.710 ($p = 0.002$, 95% CI: 0.574 to 0.847; Fig 2). Of the 23 patients with inadequate performance, technical inadequacies were noted most commonly in the arch (14 patients; 2 in the

proximal and 12 in the distal arch), followed by shunt inadequacies (10 patients). Sixteen of the 23 patients had postoperative reinterventions to correct inadequacies; 6 of these died. Of the 8 patients who died in the inadequate group, 4 of them had arch and the other 4 had shunt inadequacies. Six of the 8 patients who died had reinterventions, 2 to correct distal arch and 4 shunt inadequacies. The other 2 had proximal arch inadequacies; 1 of them died intraoperatively, and the other shortly after.

Table 3. Patients and Outcomes: Technical Performance, Complications, and Reinterventions Based on Mortality Status

Patients	Total (n = 135)	Alive (n = 116)	Dead (n = 19)
Technical performance	130[b]	116	14[b]
Optimal	81 (62.3%)	80	1 (1.2%)
Adequate	26 (20%)	21	5 (19.2%)
Inadequate	23 (17.7%)	15	8 (34.8%)
Complications	38 (28.1%)	21	17[c]
ECMO, intraoperative and postoperative	22	8	14
Reoperative for bleeding	12	6	6
Reoperative for residual defect	4	2	2
Sternal debridement for Mediastinitis	4	2	2
Phrenic nerve injury with diaphragm plication	2	2	0
Stroke	4	3	1
Cardiac arrest with CPR	13	5	8
Reinterventions	36 (26.7%)	21	15
OR based[a]	32	18	14
Catheter based	9	7	2
Arch dilation	4	3	1
Shunt dilation	1	1	0
Other	6	5	1
Catheterization laboratory and OR based	5	4	1

[a] Operating room (OR)-based reinterventions includes reoperative for bleeding (12 patients), postoperative extracorporeal membrane oxygenation (ECMO [17 patients]), reoperative for residual defect (4 patients), shunt revisions (15 patients), sternal debridement for mediastinitis (4 patients), and diaphragm plication for phrenic nerve injury (2 patients). Certain patients had more than 1 complication or reintervention. The χ^2 test of association showed that the presence of major complications (n = 38), postoperative cardiopulmonary resuscitation (CPR [n = 13]), total reinterventions (n = 36), OR-based reinterventions (n = 32), shunt revisions (n = 15), ECMO intraoperative and postoperative (n = 22), ECMO postoperative (n = 17), and reoperative for bleeding (n = 12) were significantly higher among the patients who died compared with patients who lived ($p < 0.0001$ for all comparisons). Ten of the 17 patients who went on ECMO postoperatively did so after the first 24 postoperative hours. [b] Five patients did not have technical performance scores owing to inadequate postoperative data. [c] Two patients died in addition to the 17 shown, 1 intraoperatively and the other after transfer to the referring facility after an uneventful postoperative hospital course.

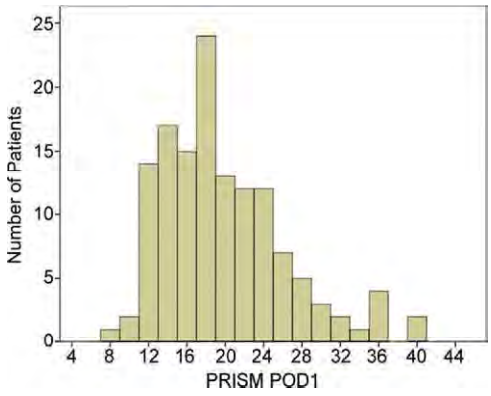


Fig 1. Postoperative day 1 (POD1) Pediatric Risk of Mortality (PRISM) score distribution: median 18 (range, 8 to 39).

Mortality

The POD1 PRISM scores differed significantly between patients who died and those who did not, reflecting a higher degree of illness severity in the immediate postoperative periods among the nonsurvivors (median POD1 PRISM 17 versus 25, respectively; $p < 0.0001$; Fig 3). The POD1 PRISM scores showed excellent discrimination for mortality, with AUC of 0.835 ($p < 0.0001$; 95% CI: 0.751 to 0.919; Table 4).

The POD1 PRISM score remains significantly associated with mortality after adjusting for other risk factors shown in Table 5, including technical performance. Technical performance and POD1 PRISM score together had the best discrimination according to pseudo R^2.

Major Complications and Reinterventions

The POD 1 PRISM scores differed significantly between patients who had complications or reinterventions and patients who did not ($p < 0.001$; Table 4), reflecting a higher degree of illness severity in the immediate postoperative periods among the patients who experienced postoperative complications or reinterventions during their hospital stay (Fig 3).

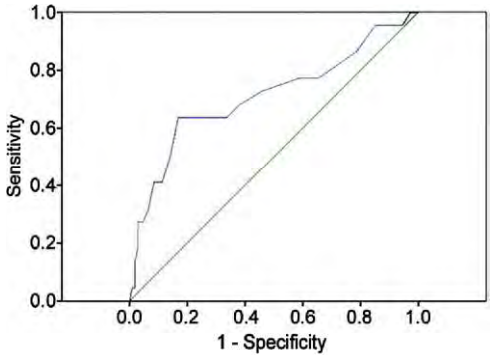


Fig 2. Receiver operating characteristic (ROC) curve analysis of ability of postoperative day 1 (POD1) Pediatric Risk of Mortality (PRISM) score to discriminate inadequate technical performance. Diagonal segments are produced by ties. Area under the ROC curve 0.710 (p = 0.002, 95% confidence interval: 0.574 to 0.847).

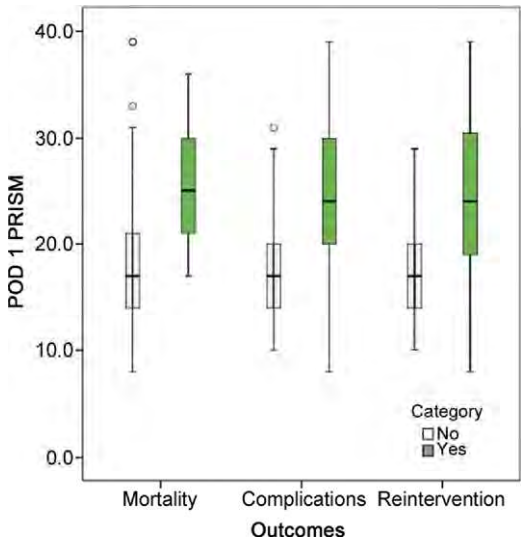


Fig 3. Postoperative day 1 (POD1) pediatric risk of mortality (PRISM) score and outcomes. Mortality: median POD1 PRISM score 17 (range, 8 to 39) for patients who died versus 25 (range, 17 to 36) for patients who lived ($p < 0.0001$). Complications: median POD1 PRISM score 17 (range, 10 to 31) versus 24 (range, 8 to 39), respectively ($p < 0.0001$) Reinterventions: median POD1 PRISM score 17 (range, 10 to 29) versus 24 (range, 8 to 39), respectively ($p = 0.001$).

The POD 1 PRISM scores were able to discriminate the occurrence of major complications (n = 38; AUC 0.776; $p < 0.0001$, 95% CI: 0.676 to 0.875), and reinterventions (n = 36; AUC 0.773; $p < 0.0001$, 95% CI: 0.669 to 0.878), or operating room–based reinterventions (n = 32; AUC 0.843; $p < 0.001$, 95% CI: 0.638 to 0.864; Table 4).

In logistic regression analysis, after adjusting for each other risk factor shown in Table 5, the POD1 PRISM score remained significantly associated with both postoperative major complications and reinterventions. The two-variable model that performed best according to coefficient of determination (R^2) included POD1 PRISM score and bypass time. Technical performance as an additional explanatory variable could not be added in this model because certain postoperative complications and reinterventions are part of the technical performance scoring criteria.

Table 4. Receiver Operating Characteristic Curve Analysis

Outcome	AUC	*p* Value	95% CI
Inadequate technical performance	0.710	0.002	0.574–0.847
Hospital mortality	0.835	< 0.001	0.751–0.919
Complications	0.776	< 0.0001	0.676–0.875
Total reinterventions	0.773	< 0.0001	0.669–0.878
Operating room based	0.843	< 0.0001	0.638–0.864
Reoperative for bleeding	0.706	< 0.0001	0.539–0.872
ECMO, postoperative	0.813	< 0.0001	0.680–0.947
Shunt revisions	0.673	0.029	0.500–0.846
Catheterization based	0.637	0.171	0.421–0.852

Pediatric Risk of Mortality score on the first postoperative day discriminates outcomes and inadequate technical performance.

AUC = area under the curve; CI = confidence interval; ECMO = extracorporeal membrane oxygenation.

Table 5. Factors Tested in Multivariate Analysis

Patient-specific factors
Age (as continuous variable)
Weight (both as continuous variable and as <2.5 kg)
Prematurity (<36 weeks gestation)
Major extracardiac or chromosomal or other genetic anomaly
Anatomic factors
Aortic atresia
Obstructed pulmonary venous return (intact or restrictive atrial septum)
Surgery-specific factors
Cardiopulmonary bypass time
Cross-clamp time
Circulatory arrest time
Illness severity measurements
Pediatric Risk of Mortality score 24 hours postoperatively
Other
Technical performance scores—only for mortality analysis

Comment

In the present study, we have shown a strong correlation of early postoperative severity of illness, measured by the PRISM III scoring system, after the stage I Norwood procedure and clinical outcomes.

Our previous studies [4, 11] have shown a significant association between preoperative physiologic illness severity (measured by preoperative PRISM III score and partially by Aristotle), case complexity (Aristotle), technical performance, and outcomes. Optimal technical performance attenuated the impact of poor preoperative illness severity or high case complexity and resulted in good outcomes. Inadequate technical performance resulted in poor outcomes regardless of preoperative illness severity or case complexity. The outcomes for patients with adequate technical performance were dictated by baseline physiology and anatomy, with good outcomes for lower preoperative illness severity or case complexity and poor outcomes for higher preoperative illness severity or case complexity. Similar observations were made in a study of pancreatic resections [13]. Given the relationship between technical performance score and outcomes in this patient population, it would be very useful to be able to use its predictive value in managing this high-risk group in the early postoperative period. Since technical performance score depends, in part, on events further along the hospital course, developing an early surrogate could prove to be of great value in assessing patient risk and need for early reintervention.

The present study, which utilized the same database as our last, focused on examining the associations of the immediate postoperative physiologic illness severity as measured by PRISM III score and technical performance, postoperative major complications, reinterventions, and mortality. This was done for a set of patients undergoing

a uniform, high-acuity operation, the stage I Norwood procedure, in a single high-volume center with an established standardized protocol-driven intensive care unit management that would negate the impact of the variability that might be observed in the postoperative management of these patients by different individual physician preferences. The impact of technical performance on outcomes was well demonstrated, and its measurement could serve as an indicator of performance in quality control programs and for individual self-assessment. However, it leaves little room to alter patient management during the hospitalization as its calculation is based on certain criteria that are based primarily on predischarge echocardiographic findings and reinterventions. In contrast, POD1 PRISM score is available in the immediate postoperative period, and our present study confirms that the degree of physiologic illness severity on POD1 after the stage I procedure reflects technical performance and correlates with postoperative reinterventions, major complications, and hospital mortality. Its usefulness lies in its strong association and discrimination with these outcomes, its availability in the immediate postoperative period, and its objectivity, namely, it is based on a calculation of absolute numbers such as blood pressure, heart rate, arterial blood gas values, rather than on a subjective assessment. Most importantly, its calculation on day 1 after surgery can make it useful to guide decisions for patient management such as initiation of an early search and detection of residual lesions or technical inadequacies that need correction.

One of the important findings in the present study is the significant ability of the POD1 PRISM score to discriminate inadequate technical performance with AUC of 0.710 ($p = 0.002$). The significantly higher mortality demonstrated in the inadequate group of 34.8% compared with 19.2% and 1.2% in the adequate and optimal group, respectively, underscores the importance of achieving a technically sound operation; moreover, it emphasizes the importance of identifying inadequate technical performance early on to correct them in a timely fashion and perhaps avert otherwise inevitable deaths.

Obviously, our study is limited by the flaws inherent in a retrospective study and the limited sample numbers involved. In addition, the PRISM III scoring system is not cardiac specific and was developed to predict mortality based on physiologic illness severity in a more general pediatric population upon admission to the intensive care unit. These findings should be confirmed by other institutions or in a multicenter study. Furthermore, scoring systems such as the PRISM III could potentially be modified to better serve the cardiac surgical population. In addition, the use of PRISM III could be coupled with other tools, such lactate levels, venous saturations, and cerebral oximetry, routinely employed in the postoperative management of these patients to facilitate the care of these patients and perhaps prompt the intensive care unit team to rethink the management strategies for certain high-risk patients.

In conclusion, technical performance has a significant impact on postoperative physiologic illness severity, with higher PRISM III scores associated with inadequate performance. The severity of illness on the first postoperative day, as measured by the PRISM III scoring system, after the stage I Norwood operation has high association and discrimination with hospital mortality, postoperative reintervention, inadequate technical performance, and the occurrence of major postoperative complications. It may be used as an early surrogate of technical performance, and it should be used to initiate a timely search for technical deficiencies and the institution of supportive measures and reinterventions to address them.

We would like to thank Meena Nathan, MD, for her editorial help on the manuscript.

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CHD

Intraoperative adverse events can be compensated by technical performance in neonates and infants after cardiac surgery: A prospective study

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Objective: Our objective was to define the relationship between surgical technical performance score, intraoperative adverse events, and major postoperative adverse events in complex pediatric cardiac repairs.

Method: Infants younger than 6 months were prospectively followed up until discharge from the hospital. Technical performance scores were graded as optimal, adequate, or inadequate based on discharge echocardiograms and need for reintervention after initial surgery. Case complexity was determined by Risk Adjustment in Congenital Heart Surgery (RACHS-1) category, and preoperative illness severity was assessed by Pediatric Risk of Mortality (PRISM) III score. Intraoperative adverse events were prospectively monitored. Outcomes were analyzed using nonparametric methods and a logistic regression model.

Results: A total of 166 patients (RACHS 4-6 [49%]), neonates [50%]) were observed. Sixty-one (37%) had at least 1 intraoperative adverse event, and 47 (28.3%) had at least 1 major postoperative adverse event. There was no correlation between intraoperative adverse events and RACHS, preoperative PRISM III, technical performance score, or postoperative adverse events on multivariate analysis. For the entire cohort, better technical performance score resulted in lower postoperative adverse events, lower postoperative PRISM, and lower length of stay and ventilation time ($P < .001$). Patients requiring intraoperative revisions fared as well as patients without, provided the technical score was at least adequate.

Conclusions: In neonatal and infant open heart repairs, technical performance score is one of the main predictors of postoperative morbidity. Outcomes are not affected by intraoperative adverse events, including surgical revisions, provided technical performance score is at least adequate. (J Thorac Cardiovasc Surg 2011;142:1098-107)

Supplemental material is available online.

Outcomes after repair of complex congenital cardiac defects in infants have improved remarkably in the past 4 decades. These improvements can be attributed not only to advances in surgical techniques but also to significant developments in pediatric cardiac anesthesia, pediatric cardiopulmonary bypass (CPB), and preoperative and postoperative care in specialized intensive care units.

It is also widely known that outcomes, both immediate and long-term, after complex cardiac repairs in neonates and infants are dependent on multiple and interrelated factors such as case complexity, preoperative physiologic status (''severity of illness''), conduct of operation (including intraoperative anesthetic management, CPB, intraoperative adverse events, and surgical technique), volume of cases at a given institution, and postoperative management, including the occurrence of postoperative major adverse events.[1-4]

Previous studies have looked at these factors in isolation or have studied a single diagnostic group or operation[1-4] in both a retrospective and a prospective fashion. Other studies have looked at the impact of human factors on outcomes and concluded that human factors have an important role to play, although hidden and harder to measure, in outcomes after cardiac surgery.[3,5] Previous retrospective work at our institution has focused on technical performance and established that technical performance, as measured by a technical score specific to each operation, is one of the major contributors to outcomes.[1,4] We also found that optimal technical performance could neutralize the detrimental effects of poor preoperative physiology or case complexity.

The aim of this study is to prospectively define the role and relationship of each of these factors in a group of

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Abbreviations and Acronyms
CPB = cardiopulmonary bypass
ICU = intensive care unit
PRISM = Pediatric Risk of Mortality
RACHS = Risk Adjustment in Congenital Heart Surgery

neonates and infants undergoing a wide range of open cardiac repairs. Our hypothesis was that technical performance would be the most important determinant of outcomes and that technical performance would attenuate the effects of case complexity and preoperative physiologic status and neutralize the deleterious effects of intraoperative adverse events.

PATIENTS AND METHODS

Institutional review board approval was obtained for conduct of this study. Data were collected prospectively. Patients were observed intraoperatively from induction of anesthesia to transfer to the intensive care unit, and their postoperative course was followed prospectively until discharge.

Data Collection

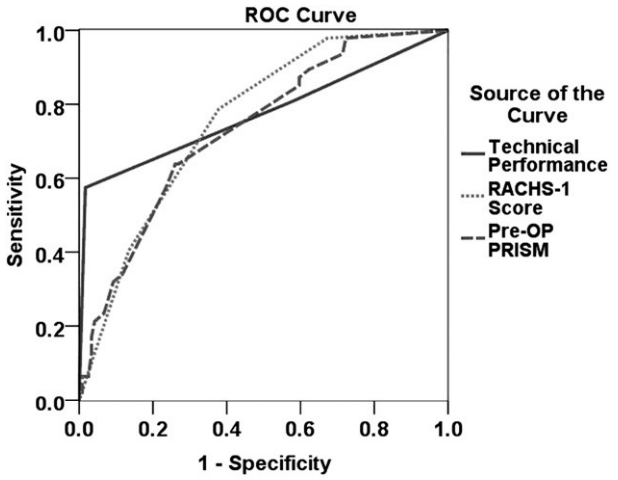
Intraoperative observations of infants less than 6 months of age and Risk Adjustment in Congenital Heart Surgery (RACHS) categories 2 to 6 were performed from October 2008 to April 2010. All observations were performed by fully trained pediatric cardiac surgeons. All adverse events (minor or major) related to conduct of anesthesia, the operative procedure, CPB, and events related to communication were documented. Patients of 6 surgeons (experience levels in years of practice after completion of pediatric cardiac surgery training: 1 year, 5 years, 11 years, 11years, 20 years, and 25 years) were prospectively followed up from intraoperative observation until discharge from the hospital. Clinical data including physiologic status measurements (vital signs), laboratory tests, echocardiograms, and cardiac catheterization data were collected. Variables collected for analysis included age, weight, prematurity, presence of extracardiac and genetic abnormalities, case complexity and technical performance scores, preoperative and postoperative Pediatric Risk of Mortality (PRISM) III scores, and preoperative and postoperative lactate. The following time variables were also collected: CPB times, crossclamp times, deep hypothermic circulatory arrest and regional perfusion times (where applicable), postoperative and total intensive care unit (ICU) and hospital length of stay, and postoperative ventilation days. Need for intraoperative surgical reintervention or postoperative surgical or catheter-based reinterventions were documented.

Predictor Variables

The main predictor variables that were included in our analysis were case complexity, physiologic status, and technical performance.

Case complexity was scored on the basis of the RACHS-1 scoring system.[6,7]

The preoperative and postoperative physiologic status was determined using the PRISM III scoring system[8] and lactate levels. For the PRISM III score, 17 physiologic variables were used. Data were collected in the 24 hours before surgery and for 48 hours after surgery. In infants who did not have preoperative arterial blood gas measured, an empiric score of 6 was given for all cyanotic lesions based on a presumed arterial oxygen tension of 40 mm Hg, and a presumptive value of 1 was assigned for lactate level. The highest lactate level in each 24-hour time period was used for scoring lactate levels.



Area Under the curve

	Area	p Value	95% CI
Technical performance	0.774	<0.0001	0.681-0.867
RACHS-1 Score	0.756	<0.0001	0.681-0.832
Pre-Op PRISM	0.732	<0.0001	0.650-0.814

FIGURE 1. ROC curve analysis of ability of technical performance, RACHS-1 categories, and preoperative PRISM to predict major postoperative adverse events. On logistic regression, technical performance had a higher (albeit small difference) significance in predicting occurrence of postoperative adverse events with an area under the curve of 0.774 (95% CI, 0.681-0.867) versus 0.756 (95% CI, 0.681-0.832) for RACHS-1 category versus 0.732 (95% CI, 0.650-0.814). *ROC,* Receiver operator characteristic; *RACHS,* Risk Adjustment in Congenital Heart Surgery; *PRISM,* Pediatric Risk of Mortality; *CI,* confidence interval.

Technical performance was scored as previously reported from our center,[9,10] based on intraoperative course, predischarge echocardiogram, catheterization data, and clinical status at discharge. In brief, 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 catheterization and clinical criteria. Any intraoperative reinterventions resulted in the score being downgraded to adequate, even if the final score was "optimal." Any postoperative surgical/catheter-based reinterventions for residual defects resulted in an inadequate score. At discharge, echo and clinical status were reviewed, and for the procedure of interest, if all subcategories were optimal, then the final score was optimal; however, if one of the subcategories had an adequate score, it was scored as adequate. If any subcategory was scored as inadequate, then the final score was inadequate. Technical scores were thus graded as "optimal," "adequate," or "inadequate" for each patient for the index operation.

Outcome Variables

The outcome variables that were analyzed were the following:

- Primary: Occurrence of major postoperative adverse events
- Secondary: ventilation time, ICU length of stay, and hospital length of stay

TABLE 1. Intraoperative surgical reintervention (n = 12; 7%)

No.	RACHS	Diagnosis	Intraoperative reintervention	Final technical score	Outcome
1	RACHS 2	Multiple VSDs	Closure of residual and unidentified VSD	2	DC
2		VSD, RVOTO	Further RVOT resection	2	DC
3	RACHS 3	TOF/APV	Revision of RPA anastomosis	2	DC
4		CAVC	Repair of right AVV	2	DC
5		CAVC	Revision of VSD patch for AVVR	2	DC
6		TGA/IVS	Revision of PA anastomosis for supra systemic RV pressures	2	DC
7		TOF/CAVC	Further closure of LAVV cleft and further restriction of ASD	2	DC
8	RACHS 4	TGA/VSD	Plication of LPA to move away from left coronary button	2	DC
9		TOF/MAPCAs	Fenestration of VSD	3	DC
10	RACHS 6	Unbalanced CAVC, hypoplastic arch	Repair AVV for residual AVVR	3	Died
11		HLHC, ALCAPA	Revision of ALCAPA button	2	DC
12		HLHS	Clot extraction from proximal RCA	2	DC

All patients who underwent intraoperative surgical reinterventions to correct residual defects identified either on transesophageal or epicardial echocardiography or based on clinical status after initial weaning from cardiopulmonary bypass. *RACHS,* Risk Adjustment in Congenital Heart Surgery; *VSD,* ventricular septal defect; *DC,* discharged; *RVOTO,* right ventricular outflow tract obstruction; *RVOT,* right ventricular outflow tract; *TOF,* tetralogy of Fallot; *APV,* absent pulmonary valve; *RPA,* right pulmonary artery; *CAVC,* complete atrioventricular canal; *AVV,* atrioventricular valve; *AVVR,* atrioventricular valve regurgitation; *TGA,* transposition of the great arteries; *IVS,* intact ventricular septum; *PA,* pulmonary artery; *RV,* right ventricular; *LAVV,* left atrioventricular valve; *ASD,* atrial septal defect; *LPA,* left pulmonary artery; *MAPCA,* major aortopulmonary collateral artery; *HLHC,* hypoplastic left heart complex; *ALCAPA,* anomalous left coronary arising from pulmonary artery; *HLHS,* hypoplastic left heart syndrome; *RCA,* right coronary artery.

An adverse event was defined as "a complication that is associated with a health care intervention and is associated with suboptimal outcome."[11] A major postoperative adverse event "is a complication that causes increased consumption of resources (above and beyond average), or permanent morbidity."[11]

The following postoperative major adverse events were included for analysis: stroke or major neurologic deficit, need for extracorporeal membrane oxygenation, cardiac arrest requiring cardiopulmonary resuscitation, reoperation for bleeding or low cardiac output state, reoperation for residual defects, unexpected catheter-based reintervention, need for a permanent pacemaker, mediastinitis requiring surgical debridement, diaphragmatic paralysis requiring surgical plication, in-hospital mortality, or mortality in less than 30 days if discharged (per The Society of Thoracic Surgeons database criteria).

Statistical Methods

Categorical variables are summarized as numbers and percentages, and continuous variables are summarized as means ± standard deviation with (medians and range). Patient characteristics for those with and without major postoperative adverse events were compared using the χ^2 test for categorical variables and the Mann-Whitney test and Kruskal-Wallis test for continuous variables. Variables significant at the .05 level were considered for inclusion in a multivariable logistic regression model. Forward selection was used to fit the model. For coding "technical performance," optimal technical performance was used as reference. For coding the "RACHS-1 categories," RACHS-1 category 2 was used as the reference. Discrimination of these factors for predicting a major postoperative adverse event was assessed using the receiver operator characteristic curve (Figure 1).

Relationships between continuous outcomes variables and continuous patient characteristics were evaluated using the Spearman rank correlation coefficient. For categorical characteristics, median values of the outcomes were compared using the Mann-Whitney test for variables with 2 categories and the Kruskal-Wallis test for variables with 3 or more categories.

A subgroup analysis was performed comparing patients who had intraoperative surgical reinterventions, patients who had postoperative surgical or catheter-based reinterventions, and those requiring no reinterventions.

IBM SPSS Statistics 18 for Window (SPSS, Inc, Chicago, Ill) was used for statistical analysis.

RESULTS

A total of 166 patients were prospectively observed and all were included in the analysis.

There were 94 (57%) male patients. The mean age was 49.1 ± 49.4 days (range, 0-156 days). Mean weight was 3.9 ± 1.2 kg (range, 1.7-7.2 kg). Thirteen (8%) weighed less than 2.5 kg. Neonates accounted for 50% (n = 83). There were 10 premature infants (<35 weeks). Twenty-nine (17%) had defined chromosomal abnormalities and 15 (9%) had extracardiac abnormalities.

Eighty-four (51%) were RACHS 2 and 3 (categorized as low risk) and 82 (49%) were RACHS 4, 5, and 6 (categorized as high risk). Diagnoses and procedures performed are represented in Tables E1 and E2.

For the entire cohort, preoperative PRISM III score was 6.3 ± 4.3 (mean and range, 6, 0-21), Preoperative lactate level was 1.6 ± 1.3 (1, 0.6-13.2), CPB time was 140 ± 59 (132, 38-379), aortic crossclamp time was 77 ± 38 (75, 0-194), deep hypothermic circulatory arrest time was 22 ± 19 (12, 1-75) (n = 57), and regional low-flow perfusion time was 48 ± 18 (46, 5-86) (n = 46). PRISM III score on postoperative day 1 was 11.3 ± 6.4 (10, 0-34), and lactate level on postoperative day 1 was 5.7 ± 5.2 (3.8, 0-28). Postoperative hospital length of stay was 26 ± 32 (15, 1-191), postoperative ICU length of stay was 15.4 ± 24 (8, 1-188), and postoperative ventilator time (in days) was 10 ± 20 (4, 1-188).

Intraoperative revisions requiring reinstitution of CPB (n = 12, 7%), unexpected postoperative surgical reinterventions (n = 14, 11 patients, 8%) and postoperative catheter-based reinterventions (n = 22, 19 patients, 11%) are represented in Tables 1, 2, and 3. Table E3 depicts all intraoperative adverse events that were documented. Table E4 depicts

TABLE 2. Postoperative surgical reinterventions (n = 14; 11 patients; 8%)

No.	RACHS	Diagnosis	Postop surgical intervention	Postop cath intervention	Intraop revision	Assigned tech score	Tech score based on DC echo	Outcome
1	3	TOF/right-dominant CAVC, PAPVR	Repair of recurrent MR from torn cleft sutures	No	No	3	2	DC home
2	3	HLHC: BDG, TV plasty, aortic valve plasty, TD of RV-PA conduit	1. TV replacement 2. Repair paravalvar leak and reconnection of RV-PA conduit (PPM for CHB)	No	No	3	3	Died
3	4	Truncus arteriosus	Revision of RV-PA conduit, partial closure of ASD	BD of RV-PA conduit and LLPA, LLPA stent	No	3	3 (RVP still 2/3 systemic after BD)	Died
4	4	TOF, PA, MAPCAs	Revision of unifocalized RPA, banding of RV-PA conduit	BD of RPA, RLLPA, LPA stent	No	3	2	DC home
5	4	TGA/VSD	Closure of residual ASD	LPA stenting	No	3	2	DC
6	4	HLHC- CoA, VSD, small left-sided structures	1. Reimplantation of torn AL papillary muscle 2. MV replacement (PPM for CHB)	No	No	3	3	Transplanted
7	5	Neonatal Ebstein	RV-PA conduit, TV repair and repositioning	RVOT stenting	No	3	2	Died
8	6	Shone, IAS	Early BDG and LPA plasty	MV BD in attempt to delay BDG	No	2	1	DC
9	6	UnbCAVC s/p stage I, Sano, AVV septation for AVVR	1. AVV repair 2. AVV repair	No	No	3	3	Died
10	6	HLHS, ALCAPA	Conversion of BTS to RV-PA conduit	No	Revised ALCAPA button)	3	2	DC
11	6	d-TGA, VSD, hypoplastic RV, straddling TV	TV and MV repair (PPM for CHB)	BD of innominate vein, coiling VV collaterals	No	3	3	DC

All patients who underwent postoperative surgical reintervention for residual defects. Note that there is higher proportion of patients in the higher RACHS-1 categories. *RACHS,* Risk Adjustment in Congenital Heart Surgery; *cath,* catheter; *DC,* discharge; *TOF,* tetralogy of Fallot; *CAVC,* complete atrioventricular canal; *PAPVR,* partial anomalous pulmonary venous return; *MR,* mitral regurgitation; *HLHC,* hypoplastic left heart complex; *BDG,* bidirectional Glenn; *TV,* tricuspid valve; *TD,* takedown; *RV-PA,* right ventricle–pulmonary artery; *PPM,* permanent pacemaker; *CHB,* complete heart block; *ASD,* atrial septal defect; *BD,* balloon dilation; *LLPA*, left lower pulmonary artery; *RVP,* right ventricular pressure; *PA,* pulmonary atresia; *MAPCA,* major aortopulmonary collateral artery; *RPA,* right pulmonary artery; *RLLPA,* right lower left pulmonary artery; *LPA,* left pulmonary artery; *TGA,* transposition of the great arteries; *VSD,* ventricular septal defect; *CoA,* coarctation of the aorta; *AL,* anterolateral; *RVOT,* right ventricular outflow tract; *IAS,* intra-aortic septum; *MV,* mitral valve; *UnbCAVC,* unbalanced complete atrioventricular canal; *s/p,* status post; *AVV,* atrioventricular valve; *AVVR,* atrioventricular valve regurgitation; *HLHS,* hypoplastic left heart syndrome; *ALCAPA,* anomalous left coronary arising from pulmonary artery; *d-TGA,* dextro-transposition of the great arteries; *RV,* right ventricle; *VV,* venovenous.

intraoperative reinterventions and postoperative surgical or catheter-based reinterventions based on RACHS-1 categories.

Major postoperative adverse events occurred in 47 (28%) and are represented in Table E5. Thirteen (8%) required ECMO (1 preoperative only, 1 preoperative and postoperative, 11 postoperative).

There were 7 (4.2%) deaths of which 5 occurred in neonates (Table E6). Inasmuch as the number of deaths was

TABLE 3. Postoperative catheter interventions (n = 22; 19 patients, 11%)

No.	RACHS	Diagnosis	Postop cath interventions	Postop surgical intervention	Intraop revision	Assigned tech score	Tech score based on DC echo	Outcome
1	3	TOF, APV	BD of LUPV	No	Revision of RPA anastomosis	2	2	DC
2	3	LCA occlusion and RV-PA conduit regurg s/p neonatal Ross Konno	BD of RPA stenosis	No	No	3	3	DC (required OHT)
3	3	TOF, CAVC	ASD creation for PHTN	No	No	3	3 (severe PR)	DC (late death)
4	3	TA/PA, TGA VSD, s/p BTS	BD of BTS insertion and branch pulm arteries	No	No	3	3 (2nd cath 1 mo later to redialte BTS and branch pulm arteries	DC
5	4	Truncus arteriosus, discontinuous RPA	BD of RPA and coil APC	No	No	3	2	DC
6	4	Truncus arteriosus	BD of RV-PA conduit and LLPA, LLPA stent	Revision of RV-PA conduit, partial closure of ASD	No	3	3 (RVP still 2/3 systemic after BD)	Died
7	4	TOF, MAPCAs	BD of RPA and LPA, APC coiling	No	Fenestration of VSD	3	3	DC
8	4	TOF, PA, MAPCAs	BD of RPA, RLLPA, LPA stent	Revision of unifocalized RPA, banding of RV-PA conduit	No	3	2	DC
9	4	TOF, PA, MAPCAs, premie 34 wk, SGA	1. Bilateral pulm artery dilatation and stenting 2. Bilateral stented pulm artery dilatation	No	No	3	3	DC, late death
10	4	d-TGA, PS, hypoplastic RV	BD of both bilateral pulm arteries, APC coiling	No	No	3	2	DC
11	4	TGA/VSD	LPA stenting	Closure of residual ASD	No	3	2	DC
12	4	TGA, VSD, arch hypoplasia	ASD dilatation and LPA stenting	No	No	3	2	DC
13	4	TGA, VSD, arch hypoplasia	BD of RCA	No	No	3	2	DC
14	5	Neonatal Ebstein	RVOT stenting	RV-PA conduit and TV repositioning and repair	No	3	2	Died
15	6	Shone, IAS	MV BD in attempt to delay BDG	Early BDG and LPA plasty	No	2	1	DC
16	6			No	No	3	1	DC

(Continued)

TABLE 3. Continued

No.	RACHS	Diagnosis	Postop cath interventions	Postop surgical intervention	Intraop revision	Assigned tech score	Tech score based on DC echo	Outcome
		HLHC, s/p stage I BTS	BD and stenting of distal BTS and ASD dilatation					
17	6	Heterotaxy, aortic arch hypoplasia, TAPVR s/p DKS, arch augmentation, TAPVR repair	1. BD of pulm veins 2. BD of pulm veins	No	No	3	3	DC
18	6	HLHS, ALCAPA	1. Cath to stent LCA and BD of RPA 2. Stent distal RV-PA conduit	No	No	3	3	Died
19	6	d-TGA, VSD, hypoplastic RV, straddling TV	BD of innominate vein, coiling of APC, TV and MV repair (PPM for CHB)	TV and MV repair (PPM for CHB)	No	3	3	DC

All patients who underwent postoperative catheter-based reinterventions for residual defects. Note that there is a higher preponderance of patients in the higher RACHS-1 categories. *RACHS,* Risk Adjustment in Congenital Heart Surgery; *cath,* catheter; *DC,* discharge; *TOF,* tetralogy of Fallot; *APV,* absent pulmonary valve; *BD,* balloon dilation; *LUPV,* left upper pulmonary vein; *RPA,* right pulmonary artery; *LCA,* left coronary artery; *RV-PA,* right ventricle–pulmonary artery; *s/p,* status post; *OHT,* orthotopic heart transplant; *CAVC,* complete atrioventricular canal; *ASD,* atrial septal defect; *PHTN,* pulmonary hypertension; *PR,* pulmonary regurgitation; *TA,* tricuspid atresia; *PA,* pulmonary atresia; *TGA,* transposition of the great arteries; *VSD,* ventricular septal defect; *BTS,* Blalock-Taussig shunt; *APC,* aortopulmonary collateral artery; *LLPA,* left lower pulmonary artery; *RVP,* right ventricular pressure; *MAPCA,* major aortopulmonary collateral artery; *LPA,* left pulmonary artery; *RLLPA,* right lower left pulmonary artery; *SGA,* small for gestational age; *d-TGA,* dextro-transposition of the great arteries; *PS,* pulmonary stenosis; *RV,* right ventricle; *RCA,* right coronary artery; *TV,* tricuspid valve; *RVOT,* right ventricular outflow tract; *IAS,* intra-aortic septum; *BDG,* bidirectional Glenn; *HLHC,* hypoplastic left heart complex; *TAPVR,* total anomalous pulmonary venous return; *DKS,* Damus-Kaye-Stansel; *HLHS,* hypoplastic left heart syndrome; *ALCAPA,* anomalous left coronary arising from pulmonary artery; *MV,* mitral valve; *PPM,* permanent pacemaker; *CHB,* complete heart block.

small, statistical analysis of mortality as a separate outcome measure did not have enough power to correctly detect significance; therefore it was included as a component of major postoperative adverse event.

Major postoperative adverse events and postoperative ventilation times, as well as postoperative length of ICU and hospital stay, were the major and minor outcomes included in our analysis.

There was no significant difference in the rate of postoperative major adverse events or the rates of intraoperative or postoperative surgical or catheter-based reinterventions between surgeons.

On univariate analysis, higher RACHS-1 scores were associated with higher occurrence of major postoperative adverse events ($P < .0001$), with longer ventilation days ($P < .0001$), longer ICU lengths of stay ($P < .0001$), and higher hospital lengths of stay ($P < .0001$). Younger age ($P < .001$) and lower weight ($P < .003$) were associated with higher occurrence of major postoperative adverse events ($P < .003$), and both were associated with higher ventilation days and postoperative ICU and hospital lengths of stay ($P < .0001$). There was no significant difference for occurrence of major postoperative adverse events by prematurity ($P = .547$), by presence of extracardiac or genetic abnormalities ($P = .098$), or by need for intraoperative surgical reintervention ($P = .689$). However, the presence of extracardiac or genetic abnormalities was associated with longer ventilation days and postoperative ICU and hospital lengths of stay ($P < .01$, $P < .001$, $P < .002$, respectively), whereas this was not significant in premature infants ($P = .745$, $P = .231$, $P = .437$, respectively). Longer median CPB times and aortic crossclamp times were associated with significantly longer ventilation times (P, .0001 and $P < .005$, respectively), longer postoperative ICU lengths of stay ($P < .000$ and $P < .024$, respectively), and longer postoperative hospital lengths of stay ($P < .0001$ and $P < .047$, respectively). The results of univariate analysis are included in Table 4. Bivariate association was used to choose variables with $P < .05$ for inclusion in logistic regression. Of note, prematurity, weight, neonates, and intraoperative adverse events (which included intraoperative surgical reinterventions), aortic crossclamp time, and preoperative lactate level, were found to be nonsignificant on logistic regression.

Technical performance score, RACHS category, and preoperative PRISM in combination performed best in the logistic regression analysis (Figures 1 and 2). Technical performance score, RACHS, and CPB times in combination were also significant, but slightly less powerful.

TABLE 4. Univariate analysis

	Major postoperative adverse events		
Variables	**No (n = 119)**	**Yes (n = 47)**	***P* value**
Low birth weight (<2.5 kg)	4.2%	17%	.006
Prematurity	6.7%	4.3%	.547
Gender = female	46.2%	36.2%	.239
Extracardiac anomaly	6.7%	14.9%	.098
Genetic anomaly	20.2%	10.6%	.145
Intraop adverse event	28.6%	57.4%	.001
Intraop surgical reintervention	6.7%	8.5%	.689
RACHS high risk	37.8%	78.7%	.000
Technical performance			
Optimal	42%	19.1%	.000
Adequate	56.3%	23.4%	.000
Inadequate	1.7%	57.4%	.000
Neonate	39.5%	76.6%	.000
Weight	3.9	3.4	.003
CPB time	123	176	.000
Aortic crossclamp time	72	81	.047
Hypothermic arrest (if applicable)	9	16	.392
Regional perfusion (if applicable)	42	48	.290
Ventilation (d)	3	13	.000
Postop ICU length of stay	5	23	.000
Postop hospital length of stay	11	44	.000
Preop PRISM	6	9	.000
Preop lactate	1	1.7	.000
Postop day 1 PRISM	8	16	.000
Postop day 1 lactate	2.6	8.6	.000

Categorical variables are represented as percentages and continuous variables are represented as medians. *RACHS,* Risk Adjustment in Congenital Heart Surgery; *CPB,* cardiopulmonary bypass; *ICU,* intensive care unit; *PRISM,* Pediatric Risk of Mortality.

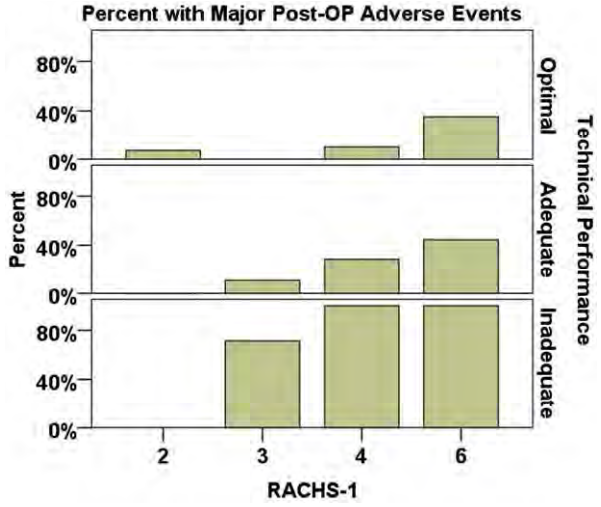


FIGURE 2. Major postoperative adverse events based on technical scores and RACHS-1 categories. This figure outlines the percentage of patients with major postoperative adverse events comparing technical performance and RACHS-1 risk categories. Optimal technical performance had a low occurrence of adverse events, whereas adequate technical performance had low rates of adverse events in the low complexity groups (RACHS-1 categories 2 and 3, but higher percentage of adverse events in the higher risk categories (RACHS-1 categories 4 and 6). Inadequate technical performance had the highest percentage with adverse events in all categories of the RACHS-1 system. *RACHS,* Risk Adjustment in Congenital Heart Surgery.

We performed a subgroup analysis comparing patients who had intraoperative surgical revisions with the group that required postoperative surgical or catheter-based interventions. There was a significant difference in the discharge technical score of those who had intraoperative interventions versus those who required postoperative surgical or catheter-based reinterventions ($P < .0001$). On comparing duration of ventilation and ICU and hospital lengths of stay, there was again a significant difference ($P < .001$, $P < .001$, $P < .005$, respectively) (Figure 3, Figure E1). Mortality and occurrence of major postoperative adverse events was also significantly different (Figure E2).

DISCUSSION

This study demonstrates that, across a broad spectrum of complex neonatal and infant cardiac repairs, technical performance score had the strongest association with outcomes. In addition, it points to what can be called a "technical imperative," an absolute rule whereby it is "imperative" to leave the operating room with a good or better yet optimal technical result, even if this requires surgical revision. Indeed, the patients who required intraoperative revisions did not do significantly worse than the patients who had no intraoperative and no postoperative reinterventions. On the other hand, failure to detect and intervene on intraoperative findings of inadequate technical result led to delayed intervention, either surgical or catheter-based, with its resultant increase in occurrence of postoperative adverse events, prolonged lengths of stay and ventilation time, as well as mortality.

It is obvious that surgical outcomes are not solely dependent on the technical prowess of the surgeon. This study also showed that the RACHS-1 score, a risk stratification paradigm currently most used by insurance companies, performed almost as well as the technical score in predicting outcomes, followed closely by the preoperative PRISM score, an index of physiologic illness severity. Whereas the RACHS-1 class is a fixed value that cannot be modified, the physiologic status of an infant can often be improved by medical means before surgical repair. This therefore also vindicates another surgical dogma, namely, to not operate on an infant if there is a possibility of improving the infant's physiologic status.[12]

This study is a single-center study and looks at cases by 6 surgeons of vastly different experience levels. We did not restrict ourselves to a single procedure or diagnosis. Thus, this

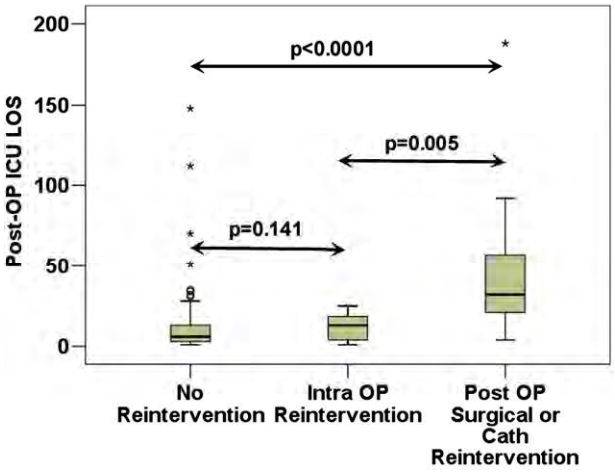


FIGURE 3. Postoperative ICU LOS for intraoperative surgical reinterventions versus postoperative surgical reinterventions or catheter-based reinterventions when compared with those who had no intervention: The was no statistical difference in the median LOS for patients who had no reinterventions (6 days) versus patients with intraoperative reinterventions (13 days) ($P = .141$). However, patients who had postoperative surgical or catheter-based reinterventions had a significantly longer LOS (32 days) ($P = .005$ vs intraoperative reinterventions, $P < .0001$ vs no reinterventions). *Outliers. *ICU,* Intensive care unit; *LOS,* length of stay.

prospective study is likely to be as good a representative snapshot as possible from a large pediatric heart center. Furthermore, all observers were trained pediatric cardiac surgeons, increasing the quality of the observed intraoperative data, and minimizing the likelihood of missing an important event. Previous work from our institution had shown the importance of technical performance in outcomes, specifically for the Norwood stage I procedure where it had a direct impact on hospital survival. Optimal technical performance also attenuated the effects of case complexity and physiologic severity of illness.[1] A similar effect (postoperative morbidity escalated by worse physiologic status, but attenuated by improved surgical technique) was also shown for another high-risk surgical procedure, namely, pancreatic resection, in a prospective study of 412 patients.[13]

For ''routine'' cases of complete atrioventricular canal, tetralogy of Fallot, and ventricular septal defect repairs, as well as arterial switches, in part owing to the very low mortality seen with these procedures, the impact of technical scores on mortality was not as dramatic. Many researchers have therefore switched to indices of morbidity,[14] such as the occurrence of major postoperative events as used in the present study. The study's focus on complex infant repairs further improved our ''yield.'' In accordance with many other studies, we found that a substantial number of infants have significant adverse events during the postoperative period.[15,16] Defining and addressing the factors that contribute to those is a logical way to improve patient outcomes and also decrease health care cost.

Pediatric cardiac surgery outcomes often depend on the function of fragile microstructures. Thus, it is not surprising that a certain number of patients require intraoperative revision. This study is the first to compare patients who underwent intraoperative revisions with those who required postoperative interventions. The results are unequivocal and show that it is the end result that counts. Technical compensation was able to neutralize the deleterious effects of having to go back on CPB a second time. CPB time came in as a close fourth behind technical scores, RACHS-1, and PRISM III scores for inclusion in the logistic regression analysis. Longer time was significantly associated with a higher incidence of major postoperative adverse events, a finding that is not surprising given the known deleterious effects of prolonged CPB times, especially in neonates. However, we do not think that there is a proven cause and effect relationship in this respect, and our study supports the fact that technical outcome is by far more important than shortening CPB time.

Study limitations include the fact that this is a single-center study, with results that may not be generalizable to other centers. The numbers in each risk category are relatively small, inasmuch as a wide range of diagnoses was included. The PRISM score has not been validated for cyanotic heart disease, but there is currently no accepted way to measure preoperative illness severity.

In conclusion, this prospective study involving 166 complex neonatal and infant cardiac repairs shows that optimal technical performance scores result in best outcomes, even if an intraoperative revision has to be performed, and attenuates the effects of poor preoperative physiology across a wide spectrum of diagnoses and procedures.

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Discussion

Dr Marc R. de Leval *(London, United Kingdom).* I congratulate Dr Nathan for this very clear presentation. This work is an addition to the already impressive list of contributions of Dr Bacha and colleagues to outcome analysis, risk management, and patient safety research. In a previous study, they had introduced the concept of technical performance as measured by technical scores specific to each operation. The technical scores are graded as optimal, adequate, and inadequate.

In this study, they have undertaken a prospective analysis of the impact of technical performance on outcomes for the whole spectrum of congenital heart defects in infants in a single institution, the operations being performed by 6 different surgeons at various stages of their training and experience. The RACHS scoring system was used for the case complexity and the PRISM scoring system was used to score the preoperative and postoperative physiologic status.

The findings were as follows:

1. Technical performance is the single most important determinant of outcomes.
2. Optimal technical performance mitigates the effects of case complexity and physiologic severity of the illness.
3. Optimal technical performance leads to good outcomes even if an intraoperative revision is required. The technical compensation neutralizes the deleterious effects of having to go back on CPB a second time.
4. Intraoperative revisions lead to better results than postoperative interventions.
5. The physiologic status of the patient can often be improved by medical means before surgery and this improves the overall results.

I have 1 comment and 3 questions. I find the term "technical performance" somewhat misleading. It gives the impression that it relates essentially to surgical dexterity. I personally believe that going back on CPB and revising successfully a complex repair in a sick infant requires as much cognitive skills as technical skills. There is some analogy within sports psychology where studies of physical, technical, and mental skills show that the only predictor of final Olympic achievements, the difference between gold and silver medalists, was the mental readiness, which is made of commitment, confidence, and positive thinking. What you have actually analyzed is the quality of the repair rather than technical performance. What do you think about this comment? This is my first question.

The aviation industry has introduced crew resource management training to manage adverse events. Do you think this could be applicable to surgery by the so-called nontechnical skills technique training, and do you think that this could be introduced in the curriculum of medical schools and residency programs? This is my second question.

The operations were performed by 6 surgeons. Was there a difference in the outcomes of those 6 surgeons?

My last point is a minor point. You do not discuss in the manuscript what kind of investigations were done intraoperatively to assess the quality of the repair. I assume that assessments were made by transesophageal echocardiogram. I wonder whether the reintervention rate intraoperatively could be increased by refining the intraoperative assessment of your repair, thus reducing the need for postoperative interventions.

Dr Nathan. Thank you, Dr de Leval, for your questions. I agree that the term "technical performance" seems to implicate the surgeons, whereas outcomes in surgery for congenital cardiac disease are not only dependent on the way the surgery is performed but on several of other factors, including the postoperative course and ICU care. We have therefore decided to refine our statement and call this technical performance scores rather than just technical performance.

I agree that the airline industry has excellent simulation programs, and I think there are several centers beginning simulation programs, including our center, for management of events in the operating room.

There were 6 surgeons involved in this study, and there was no significant difference among the technical performance scores of these surgeons.

We did use intraoperative transesophageal echocardiography for the bigger babies, and if the babies were really small, we used epicardial echocardiography. We are in the process of defining criteria for each of these methods of investigation and are also developing a technical performance score for intraoperative assessment.

Dr Muhammad Mumtaz *(Norfolk, Va).* I have 2 questions. Do I understand from your conclusions that if the outcome in the operating room is less than optimal, revising the result to make it the ideal outcome does not affect any adverse events? That is to say, if one goes back on for a second pump run on the pump and revises, whether it was a residual ventricular septal defect or whatever, then it does not affect how the baby is going to do? Do I understand that correctly?

Dr Nathan. Yes, you do.

Dr Mumtaz. It sounds a little bit odd. I would just intuitively disagree with that.

Second, I want to focus on the premature babies. There are 10 noted in your series, and you said you defined them by less than

35 weeks at birth. At what age were these babies offered surgery? Were these offered surgery at less than 35 weeks of corrected age or were they offered surgery at a different corrected age?

Dr Nathan. The majority of them are operated on in the first week of life; unless their diagnosis warranted surgery at 2 to 3 months, as is the case with tetralogy of Fallot and complete atrioventricular canal defects, which are operated on a few weeks later.

Dr Mumtaz. So at your institution, the protocol for premature babies does not consider the corrected age? Do I understand that correctly?

Dr Nathan. It depends on the complexity of the case and need for intervention. We did not use prematurity as an indicator to postpone surgery for any length of time if the case was complex and needed immediate surgery.

Dr Mumtaz. Thank you.

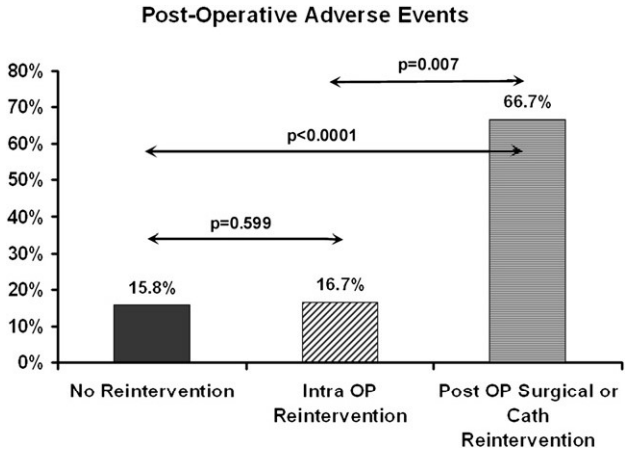


FIGURE E1. Comparison of occurrence of major adverse events for no intervention versus intraoperative intervention versus postoperative surgical or catheter-based interventions. There was significantly higher incidence of major postoperative adverse events in the postoperative surgical/catheter reinterventions group ($P < .0001$ vs no intervention, $P = .007$ intraoperative surgical reinterventions).

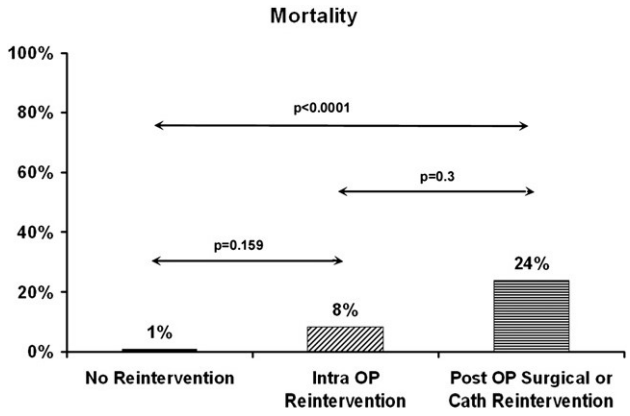


FIGURE E2. Comparison of mortality for no intervention versus intraoperative intervention versus postoperative surgical or catheter-based interventions. There is a significantly higher mortality for patients who underwent postoperative surgical/catheter reinterventions when compared with those who had no reintervention ($P < .0001$).

TABLE E1. List of diagnoses in 166 patients

VSD = 15	Truncus arteriosus = 6	DORV = 3
TOF/PS = 19	AP window = 2	DOLV = 1
TOF/PA/single ductlike collateral = 2	TGA/IVS = 7	Malposed atrial septum = 1
TOF/PA/MAPCAs = 6	TGA/VSD = 9	LV-aorta tunnel = 1
TOF/APV = 2	Tricuspid atresia = 4	AS/AR = 5
TOF/CAVC = 4	HLHS = 24	MR = 1
CAVC = 13	HLHC = 9	PA/IVS = 2
Transitional AVC = 2	Neonatal TAPVR = 4	Supra AS/PS = 1
CoA, arch hypoplasia = 1	UCAVC = 4	Neonatal Ebstein = 1
IAA = 3	DILV = 1	
CoA/VSD = 5	Heterotaxy/UnbCAVC/TAPVR, etc = 8	

VSD, Ventricular septal defect; *TOF,* tetralogy of Fallot; *PS,* pulmonary stenosis; *PA,* pulmonary atresia; *MAPCA,* major aortopulmonary collateral artery; *APV,* anomalous pulmonary vein; *CAVC,* complete atrioventricular canal; *AVC,* atrioventricular connection; *CoA,* coarctation of the aorta; *IAA,* interrupted aortic arch; *AP,* aortopulmonary; *TGA,* transposition of the great arteries; *IVS,* interventricular septum; *HLHS,* hypoplastic left heart syndrome; *HLHC,* hypoplastic left heart complex; *TAPVR,* total anomalous pulmonary venous return; *UCAVC,* unbalanced complete atrio-ventricular canal; *DILV,* double-inlet left ventricle; *UnbCAVC,* unbalanced complete atrioventricular canal; *DORV,* double-outlet right ventricle; *DOLV,* double-outlet left ventricle; *LV,* left ventricle; *AS,* aortic stenosis; *AR,* aortic regurgitation; *MR,* mitral regurgitation.

TABLE E2. List of all procedures performed based on RACHS-1 categories (n = 166)

RACHS 2 (n = 40)	TV repair = 2	TOF/PA full repair with unifocalization = 5
AP window repair = 2	CAVC = 13	IAA/VSD = 2
Common atrial septation = 1	RMBTS = 2	Rastelli = 3
TOF, TAP = 2	TAPVR = 1	Neonatal Ross Konno = 2
TOF valve sparing = 15	ASO = 7	ASO/VSD = 8 (with arch = 5)
RVOT patch = 1	Transitional AVC = 1	Arch augmentation/pulmonar artery band = 2
BDG = 3	Aortic valve repair = 2	Biventricular repair for Shone complex = 2
Kawashima = 1	Valve sparing root replacement = 1	CoA + arch = 1
VSD = 15	Supra AS/PS repair = 1	**RACHS 5 (n = 1)***
RACHS 3 (n = 44)	LV-aorta tunnel = 1	Neonatal Ebstein's repair = 1
DORV/VSD baffle = 2	**RACHS 4 (n = 47)**	**RACHS 6 (n = 34)**
MV repair = 2	Neonatal TAPVR = 5	Norwood BTS = 9
TOF/APV or pulmonary artery conduit = 2	VSD + arch = 6	Norwood Sano = 21
Conduit change = 2	Truncus arteriosus repair = 6	DKS = 4
TOF/CAVC = 4	Comprehensive stage II = 2	
TOF supramitral ring = 1	Unifocalization only = 3	

RACHS, Risk Adjustment in Congenital Heart Surgery; *AP,* aortopulmonary; *TOF,* tetralogy of Fallot; *TAP,* transannular patch; *RVOT,* right ventricular outflow tract; *BDG,* bidirectional Glenn; *VSD,* ventricular septal defect; *DORV,* double-outlet right ventricle; *MV,* mitral valve; *APV,* absent pulmonary valve; *CAVC,* complete atrioventricular canal; *TV,* tricuspid valve; *RMBTS,* Blalock-Taussig shunt; *TAPVR,* total anomalous pulmonary venous return; *ASO,* arterial switch operation; *AVC,* atrioventricular canal; *AS,* aortic stenosis; *PS,* pulmonary stenosis; *LV,* left ventricle; *IAA,* interrupted aortic arch; *CoA,* coarctation of the aorta; *DKS,* Damus-Kaye-Stansel. *The single patient in RACHS-1 category 5 was included in category 6 for analysis.

TABLE E3. Intraoperative adverse events patient (n = 61; 37%)

Main problem area
- Bleeding (17)
  - Bleeding intraoperatively = 9 (cannula site, ductus arteriosus, descending thoracic aorta)
  - Reexploration for bleeding = 7 (chest initially closed in 3)
  - Factor VII for uncontrolled ongoing bleeding = 1
- Perfusion/CPB
  - Venous line fell on floor during circulatory arrest = 1
  - Air in oxygenator secondary to failure of low level indicator = 1 (successfully picked up and purged—no patient adverse event)
  - Inadvertent drainage of patient during CPB wean (new machine) = 1
  - Manifold leak in circuit requiring change = 1
  - High membrane pressure, high filling pressures on ECMO = 1
  - Lower body malperfusion = 1
  - Inadvertent venous decannulation = 1
  - Air in venous line from failure to clamp = 2
  - Air lock in venous line = 1
- Airway/pulmonary
  - Difficulty in ventilation from abnormal lung compliance = 2
  - Difficult intubation = 1
- Arrhythmias
  - SVT requiring cardioversion = 3
  - VT/VF requiring cardioversion = 5
  - CHB/JR/EAT requiring pacing = 16
  - SVT requiring urgent cannulation =1
- Technical
  - Reinstitution of CPB for revision of residual defects = 12
  - Inadvertent inclusion of left main in suture to control bleeding from RV-PA conduit (recognized and suture removed) = 1
  - LPA dissection = 1
  - Reinitiation of CPB to repair SVC cannulation = 1
  - ST changes from air in coronary = 1
  - ST changes after ALCAPA repair = 2 (1 revised in operating room, 1 required LCA stent)
  - Pulmonary valve tear after BD requiring repair = 3 (1 required conversion to TAP)
- Miscellaneous
  - Cardiac arrest = 5 (pre-CPB arrest = 3, post-CPB arrest urgent cannulation = 2)
  - Reinstitution of CPB for period of rest for LCOS, RV hypertension, hyperkalemia, air embolus, arrhythmia, LV distention = 8
  - Hypotension during epicardial echo = 1
  - Post-CPB arrest, CPR, cardioversion = 2
  - Difficulty in CVL access = 1
  - Chest reopened for LCOS, arrhythmia = 5
  - ST changes in RVDCC requiring higher perfusion pressures = 1
  - ECMO for inability to wean off CPB = 3
  - Clipping of BTS for pulmonary overcirculation = 1
  - Delay in arrival of blood products = 1

Intraoperative adverse events: This includes events related to anesthesia, operative procedure, cardiopulmonary bypass, and events related to communication (some patients had more than 1 event). *CPB,* Cardiopulmonary bypass; *ECMO,* extracorporeal membrane oxygenation; *SVT,* supraventricular tachycardia; *VT,* ventricular tachycardia; *VF,* ventricular fibrillation; *CHB,* complete heart block; *JR,* junctional rhythm; *EAT,* ectopic atrial tachycardia; *RV-PA,* right ventricle–pulmonary artery; *LPA,* left pulmonary artery; *SVC,* superior vena cava; *ALCAPA,* anomalous left coronary arising from pulmonary artery; *LCA,* left coronary artery; *BD,* balloon dilation; *TAP,* transannular patch; *LCOS,* low cardiac output state; *RV,* right ventricle; *LV,* left ventricle; *CPR,* cardiopulmonary resuscitation; *CVL,* central venous line; *RVDCC,* right ventricle–dependent coronary circulation; *BTS,* Blalock-Taussig shunt.

TABLE E4. Rates of reinterventions based on RACHS-1 categories

RACHS-1 categories	Intraop reinterventions	Postop surgical reinterventions	Postop catheter-based reinterventions	Median ventilation time (d)	Median postop ICU LOS (d)	Median postop hospital LOS (d)	Major postop adverse events	Mortality
RACHS-1 category 2 (n = 40)	5%	0%	0%	1	3	6	2.5%	0%
RACHS-1 category 3 (n = 44)	11.4%	4.6%	9.1%	3	6	12	20.5%	2.3%
RACHS-1 category 4 (n = 47)	4.3%	10.6%	21.3%	7	11	21	38.3%	6.4%
RACHS-1 category 6 (n = 35)	8.6%	11.4%	14.3%	10	17	29	54.3%	8.6%

Comparison of rates of intraoperative reinterventions and postoperative surgical or catheter-based reinterventions based on RACHS-1 categories. There were no RACHS-1 category 1 patients in our study population. The single RACHS-1 category 5 patient was included with the RACHS-1 category 6 patients for analysis. *RACHS,* Risk Adjustment in Congenital Heart Surgery; *ICU,* intensive care unit; *LOS,* length of stay.

TABLE E5. List of all major postoperative adverse events (n = 47; 28%)

Neurologic = 10
Subdural hemorrhage = 1
Intraventricular hemorrhage = 3
Cerebrovascular accidents = 4
Seizures from small vessel emboli = 2
Reexploration for bleeding = 12
Reexploration for hemodynamic issues = 16
Low cardiac output state = 10
Restrictive right ventricular physiology = 1
Hypoxia = 1
Cardiac arrest = 1
Blalock-Taussig shunt/Sano clipping = 2
Removal of clip from shunt = 1
Unbanding of right ventricle–pulmonary artery conduit = 1
Cardiac arrest/unstable rhythm = 3
Cardiopulmonary resuscitation = 1
Cardioversion =1
Pericardiocentesis for tamponade = 1
Postoperative extracorporeal membrane oxygenation = 12
Postoperative surgical reinterventions for residual defects = 12
Postoperative catheter reinterventions for residual defects = 18
Complete heart block requiring intervention = 5
Diaphragm plication = 1
Sternal debridement = 2
Miscellaneous = 2
Fasciotomy for lower extremity ischemia = 1
Exploration of retroperitoneal hematoma = 1

Some patients had more than 1 event.

TABLE E6. Mortality data (n = 7; 4.2%)

	Diagnosis (age)	RACHS-1 category	Technical score	Cath reintervention	Surgical reintervention
1	HLHS, BDG, TV repair, aortic valvotomy (100 d)	3	3	0	Reop-TVR Reop-repair of paravalvular leak
2	TOF/PA/MAPCAs (96 d)	4	2	0	0
3	Truncus arteriosus (3 d)	4	3	BD of RV-PA conduit and LLPA	Revision of RV-PA conduit and clot extraction, ASD restriction
4	Neonatal Ebstein (1 d)	5	3	RVOT stenting	Reop RV-PA conduit and TV repair
5	Heterotaxy, AA, CAVC, severe AVVR (5 d)	6	3	0	Reoperation × 2 to repair AVVR
6	UnbCAVC, arch hypoplasia, AVVR (23 d)	6	3	0	0
7	HLHC, dysplastic MV, ALCAPA (2 d)	6	3	2 (a) Stenting of LCA and RPA dilatation; (b) RPA dilatation; stenting of RV-PA conduit	0

This table lists all patients who died, the cause of mortality, and any intraoperative or postoperative reinterventions that were performed. *RACHS,* Risk Adjustment in Congenital Heart Surgery; *Cath,* catheter; *HLHS,* hypoplastic left heart syndrome; *BDG,* bidirectinal Glenn; *TV,* tricuspid valve; *TVR,* tricuspid valve replacement; *TOF,* tetralogy of Fallot; *PA,* pulmonary atresia; *MAPCAs,* major aortopulmonary collateral artery; *BD,* balloon dilation; *RV-PA,* right ventricle–pulmonary artery; *LLPA,* left lower pulmonary artery; ASD, atrial septal defect; *RVOT,* right ventricular outflow tract; *AA,* aortic atresia; *CAVC,* complete atrioventricular canal; *AVVR,* atrioventricular valve regurgitation; *UnbCAVC,* unbalanced complete atrioventricular canal; *HLHC,* hypoplastic left heart complex; *MV,* mitral valve; *ALCAPA,* anomalous left coronary arising from pulmonary artery; *LCA,* left coronary artery; *RPA,* right pulmonary artery.

Technical Performance Scores in Congenital Cardiac Operations: A Quality Assessment Initiative

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Background. **Technical performance in congenital cardiac operations and its association with clinical outcomes was previously examined in infants and neonates. The purpose of this study was the development and implementation of a system for measuring technical performance in the majority of congenital cardiac operations to be used as a surgeon's self-assessment tool.**

Methods. **Using the methodologic framework piloted at our institution, measures of technical performance were created for more than 90% of all congenital cardiac operations. Each operation was divided into multiple subprocedures to be assessed separately. Criteria for technical scores were created using a consensus panel of senior clinicians and were based primarily on the predischarge echocardiographic findings and need for early postoperative reinterventions. This system of procedure modules was then piloted by prospectively assigning technical scores to all patients undergoing operations.**

Results. **Thirty modules were created covering more than 90% of the cardiac operations performed. One hundred eighty-five patients were enlisted. One hundred one (54.6%) cases were scored as class 1 (highest), 46 (24.9%) cases as class 2, 22 (11.9%) cases as class 3 (lowest); 16 cases (8.6%) could not be scored. The results were further analyzed by RACHS (Risk Adjustment for Congenital Heart Surgery) categories and outcomes. Valve-procedure–specific criteria were calibrated to reflect specific echocardiographic measurements.**

Conclusions. **The development and implementation of a broad technical performance self-assessment system for congenital cardiac operations is possible. Based on this scoring system, the impact of a less than optimal (2 or 3) technical score depends on case risk category, with higher mortality in the higher risk group, and increased resource use for lower risk procedures.**

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Surgical performance in congenital cardiac operations is difficult to quantify or measure directly because patient survival or physiologic status after repair, the most commonly reported endpoints, often are determined by multiple factors. Nevertheless, for purposes of self-assessment and to determine the impact of surgical performance on individual patient outcome as well as to assess overall institutional performance, a quantifiable metric is highly desirable. One very important feature of such a metric is the ability to differentiate between an individual surgeon's performance and that of an entire congenital heart program or institution. An individual practitioner's surgical performance includes the technical domain and other nontechnical skills such as cognitive flexibility, decision making, anticipation, situational awareness, communication, team work, and leadership [1–3]. Although risk-adjusted mortality evaluations allow for a better understanding than do general mortality rates, they are a measure of institutional performance and are not intended to evaluate an individual surgeon's competency of performance in a specific procedure or within a patient group [4, 5]. Although outcomes are dependent on multiple factors—including the patient's underlying pathologic process, case complexity, age, physiologic status, and health care delivery systems [6–10]—technical performance, defined as "the adequacy of the surgical anatomic repair intended," is an important component in this process [11–16].We previously developed a method to measure surgical technical performance as part of a quality improvement evaluation process to be used for peer and self-assessment [11–15]. This was initially piloted in selected surgical procedures, including repairs of ventricular septal defect, tetralogy of Fallot, complete common atrioventricular canal defects, arterial switch operations, and the stage I Norwood procedure [12–14]. It was then expanded to include most operations in infants [15]. This initial work demonstrated that despite the proce-

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dural diversity and complexity, technical performance or the adequacy of the anatomic repair can be assessed in congenital cardiac operations, and technical performance scores are strongly associated with early outcomes, especially in infant and neonatal high-complexity operations such as the stage I Norwood procedure. In addition, we found that optimal technical performance during surgical procedures correlates with the best outcomes across the entire spectrum and attenuates the effects of poor preoperative physiologic condition and high complexity. This was particularly important in determining outcomes as case complexity increased [14, 15].

The purpose of this study was to determine the feasibility of development and implementation of a much broader system, measuring technical performance in the majority of congenital cardiac operations, to be used as a surgeon's self-assessment tool and a quality metric at our institution.

Patients and Methods

The requirement for patient consent for this study was waived by the Children's Hospital Boston Institutional Review Board, as it was considered a quality improvement initiative. Patient data were collected prospectively and rendered anonymous in our database in compliance with the hospital's requirements.

Creation of Technical Performance Scoring System

Using the methodologic framework that was piloted at our institution [12–15], measures of technical performance were created for more than 90% of congenital cardiac operations. All operations included in the European Association of Cardiothoracic Surgery–Society of Thoracic Surgeons (EACTS-STS) mortality [17] and the Risk Adjustment in Congenital Heart Surgery (RACHS) categories [18, 19] were reviewed. The majority of these procedures were selected and placed into modules. Each operation was divided into multiple subprocedures to be assessed separately. The technical scoring tool created defined 3 possible performance categories for each procedure and its component subprocedures: classes 1, 2, and 3 in descending order of performance and previously described as optimal, adequate, and inadequate, respectively. Scoring criteria for the categories were based primarily on echocardiographic measurements of the patient's predischarge echocardiogram and the need for early postoperative reintervention. These scoring criteria were decided by consensus of an expert panel consisting of 12 pediatric cardiologists (3 intensivists, 2 interventionalists, 4 echocardiographic specialists, and 3 general cardiologists) and 8 pediatric cardiac surgeons, which met biweekly during the development phase of this project and continued to provide ongoing feedback during the collection and analysis of the data. If all subprocedures for an operation were scored as class 1, the overall score was class 1; if subprocedures were scored as class 1 or 2, the overall score was class 2; if any subprocedures were scored as class 3, the overall score was class 3. It is important to note that only the anatomic areas *intended* to be operated on were scored.

Scoring System Implementation and Data Collection

The technical performance scoring system was piloted by prospectively assigning technical scores (class 1, 2, and 3), relating to the index procedure performed, to all weekly discharged or deceased patients who underwent congenital cardiac operations at Children's Hospital Boston during randomly selected periods between January and June 2011. The patients' postoperative course was followed through hospital discharge, and their scores were determined by consensus of all the pediatric cardiac surgeons based on the scoring criteria developed for this system.

The patient procedures were risk stratified according to the RACHS categories and were divided into a low-risk group defined as RACHS categories 1 to 3 and a high-risk group for RACHS categories 4 to 6. Each patient's characteristics—such as weight, age, bypass and cross-clamp times, and attending surgeon identification—were collected.

Outcome Variables

The outcome variables analyzed were in-hospital mortality, defined as death before hospital discharge or within 30 days of the operation, and postoperative hospital and intensive care unit (ICU) length of stay and ventilation times, measured in days, after each operation. Other outcomes collected included postoperative adverse events defined as stroke or major neurologic deficit, reoperation for bleeding with hemodynamic instability, postoperative unplanned reoperations for residual lesions, initiation of extracorporeal membrane oxygenation for resuscitation, mediastinitis with sternal debridement, and new onset of complete heart block after the index procedure requiring permanent pacemaker insertion. Postoperative unplanned reinterventions in the operating room or catheterization laboratory for residual lesions and new onset of complete heart block requiring permanent pacemaker insertion were excluded in the analysis of postoperative adverse events and technical scores because these are components of the technical performance scoring criteria.

Statistical Methods

Patient and procedural characteristics were summarized with frequencies and percentages for categorical variables and medians and ranges for continuous variables. Relationships between technical performance scores and patient outcomes were assessed with the Pearson χ^2 test for categorical variables and the Kruskal-Wallis test for continuous variables. Relationships between technical performance scores and mortality were also evaluated within subgroups defined by RACHS categories. Statistical analysis was performed with PASW Statistics 18 for Windows (SPSS Inc, Chicago, IL).

Results

Thirty modules composing more than 90% of congenital cardiac operations were created (Table 1). Technical performance scoring criteria for classes 1, 2, and 3 were agreed on based on lesion and procedure-specific predischarge echocardiographic measurements and the need for early postoperative reinterventions. Valve pro-

Table 1. Procedure Modules

1. Patent ductus arteriosus closure, surgical
2. ASD repair, patch/primary, common atrium
3. Partial anomalous venous connection repair, including repair for scimitar syndrome
4. Sinus venosus defect
5. VSD repair, patch, primary, multiple
6. ASD repair, partial (incomplete), transitional, complete
7. Tetralogy of Fallot repair, ± ventriculotomy, ± transannular patch, valve sparing
8. Coarctation repair, end-to-end, extended end-to-end, ± flap or patch plasty, ± interposition graft
9. ASO (+ other variations D-TGA/IVS, D-TGA/VSD, D-TGA ± VSD/arch, Taussig-Bing shunt)
10. Total anomalous pulmonary venous connection repair (supracardiac, cardiac, infracardiac, mixed)
11. IAA ± VSD ± ASD, coarctation + VSD, aortic arch ± VSD repair
12. Truncus arteriosus repair ± IAA
13. Shunt, systemic to pulmonary; modified Blalock-Taussig shunt
14. Norwood procedure
15. Glenn (unidirectional or bidirectional cavopulmonary anastomosis; unidirectional or bidirectional Glenn procedure) ± PA reconstruction
16. Fontan procedure, lateral tunnel, ± fenestrated
17. Fontan procedure, external conduit, ± fenestrated
18. Aortic stenosis, subvalvar repair ± supravalvar repair ± valvar aortic stenosis repair
19. Aortic valve replacement, including truncal valve, mechanical, bioprosthetic, homograft
20. Ross procedure, Ross-Konno procedure, modified Konno procedure
21. Aortic root replacement, valve sparing or homograft
22. Valvuloplasty, mitral for stenosis or regurgitation, supramitral ring, mitral valve replacement, bioprosthetic, mechanical
23. Valvuloplasty, aortic, truncal valve, for stenosis or regurgitation
24. Valvuloplasty, tricuspid
25. Tricuspid valve replacement
26. Ebstein's anomaly repair/Cone's procedure
27. Pulmonary valve replacement, RVOTO relief, RV-PA conduit ± MPA, branch PA, plasty PA, reconstruction (plasty), main (trunk) or branch PAs (or both), conduit reoperation
28. Hypoplastic left heart syndrome, biventricular repair
29. Transplantation, cardiac
30. Mechanical assist devices

ASD = atrial septal defect; ASO = arterial switch operation; D-TGA = D-transposition of great arteries; IAA = interrupted aortic arch; IVS = intact ventricular septum; MPA = main pulmonary artery; PA = pulmonary artery; RVOTO = right ventricular outflow tract obstruction; RV-PA = right ventricular to pulmonary artery; VSD = ventricular septal defect.

cedure-specific criteria were calibrated to reflect specific echocardiographic measurements such as peak or mean gradients, velocities, and vena contracta because of valve-related variability and fluctuation of the results. Evidence-based criteria were used when available in the literature. The detailed list with the scoring criteria for all the procedures could be obtained by e-mailing meena.nathan@cardio.chboston.org.

One hundred eighty-five patients, representing a randomly selected subset of patients undergoing congenital heart operations during the study period, were prospectively enlisted in this study and were given technical scores based on the primary operation performed. Of those 185 primary operations performed, 169 (91.4%) patients required cardiopulmonary bypass and 16 (8.9%) patients did not. These procedures were performed by 6 attending surgeons each performing 25 (13.5%), 14 (7.6%), 21 (11.4%), 24 (13.0%), 51 (27.6%), and 50 (27.0%) of the procedures studied, respectively. There were 101 (54.6%) male patients. The median patient age was 1.7 years (2 days–53 years), the median weight was 10.5 kg (2 kg–111 kg). The patient characteristics, RACHS categories, technical scores, and outcomes are shown in Table 2 and in Figs 1 to 3.

Twenty-two (11.9%), 50 (27.0%), 51 (27.6%), 22 (11.9%), and 3 (1.6%) cases were RACHS categories 1, 2, 3, 4, and 6, respectively (there were no cases in RACHS 5 category in this study).Twenty-five cases (13.5%) were in the higher risk group (RACHS categories 4–6), of which 24 received technical scores; 123 (66.5%) were in the lower risk group (RACHS categories 1–3), of which 115 were scored (Table 2, Fig 4). Thirty-seven (20.0%) cases could not be assigned to a RACHS category.

Technical Performance Scores

One hundred one patients (54.6%) were scored as class 1, 46 (24.9%) as class 2, and 22 (11.9%) as class 3. Sixteen patients (8.6%) could not be scored (Figs 4, 5). The distribution of each surgeon's technical performance scores is depicted in Fig 6. There was no significant difference between each attending surgeon's technical scores ($p = 0.062$). Technical performance scores were risk stratified and analyzed according to their RACHS categories (Table 2, Figs 1, 3, 4). Univariate analysis showed an association between technical performance class scores and RACHS categories ($p = 0.043$).

Outcomes

MORTALITY. There were 6 deaths corresponding to 3.2% overall hospital mortality. None were in the low-risk group (RACHS categories 1–3) and 5 were in the high-risk group (RACHS categories 4–6). One death could not be assigned a RACHS category (Fig 1). Univariate analysis between RACHS category and mortality showed an association ($p < 0.0001$).Three deaths were in technical performance class 3 and 1 death was in class 2. Two deaths could not be assigned a technical performance class (Fig 2). Univariate analysis showed an association of technical performance scores and mortality ($p = 0.001$).

OTHER OUTCOMES. The median postoperative ventilation times and ICU and hospital lengths of stay in days for all patients were 0.65 (range, 0–104), 2.2 (range, 1–123), and 7.2 (range 1–153), respectively. Cross-tabulation of these outcomes according to their RACHS category and technical performance scores is shown in Table 2. The me-

Table 2. Patient Characteristics, RACHS Categories, Technical Scores, and Outcome

RACHS Category	Technical Performance	Age (d)	Weight (kg)	Postoperative Hospital LOS (d)	ICU LOS (d)	Ventilation (d)	CPB Time (min)	Cross-Clamp Time (min)
				Median (Min-Max)				
Low risk (1–3) (n = 115)	Class 1	613 (4–6417)	10 (2–82)	5 (2–23)	1 (0–14)	0 (0–9)	77 (32–231)	42 (0–163)
	Class 2	526 (3–6553)	8 (2–56)	6 (3–40)	2 (0–29)	0 (0–17)	119 (54–362)	87 (32–238)
	Class 3	695 (20–6442)	9 (3–74)	9 (4–153)	3 (0–123)	1 (0–104)	136 (75–334)	95 (0–200)
	p value	0.830	0.781	0.005	0.006	0.001	0.000	0.000
High risk (4–6) (n = 24)	Class 1	7 (1–5775)	3 (2–59)	13 (5–67)	8 (1–25)	3 (0–11)	171 (52–349)	102 (19–233)
	Class 2	233 (0–4336)	5 (2–26)	13 (5–23)	8 (1–20)	1 (0–11)	155 (88–339)	114 (87–278)
	Class 3	8 (5–151)	3 (2–6)	27 (6–87)	27 (6–87)	2 (1–42)	167 (70–363)	141 (66–279)
	p value	0.782	0.938	0.388	0.241	0.834	0.996	0.339
Total (N = 139)	Class 1	363 (1–6417)	8 (2–82)	7 (2–67)	2 (0–25)	0 (0–11)	84 (32–349)	48 (0–233)
	Class 2	489 (0–6553)	8 (2–56)	7 (3–40)	2 (0–29)	0 (0–17)	131 (54–362)	89 (32–278)
	Class 3	174 (5–6442)	6 (2–74)	11 (4–153)	7 (0–123)	1 (0–104)	149 (70–363)	110 (0–279)
	p value	0.849	0.872	0.005	0.003	0.009	0.001	0.000

There were a total of 123 patients in the low-risk group and 25 in the high-risk group, of which only 115 and 24 received technical scores, respectively.
CPB = cardiopulmonary bypass; ICU = intensive care unit; LOS = length of stay; RACHS = Risk Adjustment in Congenital Heart Surgery.

dian ventilation times and ICU and hospital lengths of stay in days was higher in patients who experienced a postoperative adverse event than in those who did not (9 versus 1, 16 versus 3, and 27 versus 7 days, respectively, with $p < 0.001$ for all). Technical performance class 3 was associated with higher occurrence of postoperative adverse events ($p < 0.001$).

Risk-Stratified Technical Scores and Outcomes

The outcomes were further analyzed based on their technical score classes and risk stratified into 2 groups by RACHS categories: low-risk group, RACHS categories 1 to 3, and high-risk group, RACHS categories 4 to 6 (Table 2, Figs 1, 3). On univariate analysis, higher RACHS categories were associated with worse technical scores ($p = 0.043$). Patients with worse technical performance scores had higher mortality in the high-risk group (RACHS categories 4–6) ($p = 0.005$) and longer ventilation times ($p = 0.001$) and ICU and hospital lengths of stay ($p = 0.001$, 0.006, and 0.005, respectively) in the lower risk group (RACHS categories 1–3).

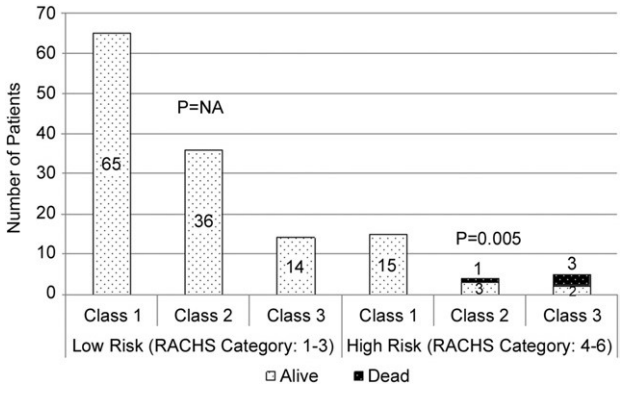


Fig 1. Impact of technical performance scores by risk category–mortality. Of a total of 6 deaths, 5 were in the high-risk group (RACHS [Risk Adjustment for Congenital Heart Surgery] categories 4–6). One death could not be assigned to a RACHS category. Three deaths were in technical performance class 3 and 1 was in class 2. Two patients could not be assigned a technical score. (NA = not applicable.)

Comment

In the present study we have shown that development and implementation of a technical performance scoring system covering the majority of congenital cardiac operations is feasible. In addition, we have demonstrated the association of technical performance scores with early outcomes across the spectrum of congenital cardiac operations. The impact of less than optimal technical scores depended on case risk category assessed by RACHS, with higher mortality in the higher risk group (RACHS categories 4–6) and longer ventilation times and ICU and hospital lengths of stay, with likely increased resource use, in the lower risk group (RACHS categories 1–3).

In our previous studies [13–16], which were primarily focused on infant and neonatal operations, we showed a strong correlation of technical scores with outcomes, with

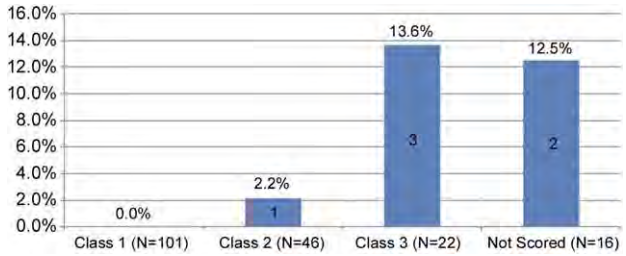


Fig 2. Mortality stratified by technical performance scores ($p = 0.001$).

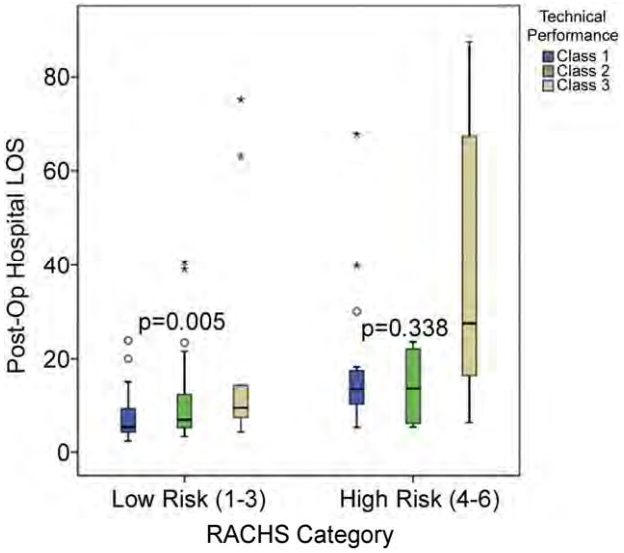


Fig 3. Impact of technical performance scores by risk category–length of stay (LOS). (RACHS = Risk Adjustment for Congenital Heart Surgery.)

higher mortality for worse technical scores, especially in high-risk operations, and higher morbidity for all patients across the board. We have demonstrated similar results in our present study spanning almost all congenital cardiac operations, especially for mortality, although our present results are limited by the small number of patients in the high-risk group.

This study underscores again the importance of what is called *technical imperative*, an absolute rule whereby it is imperative for patients to leave the operating room with a good or, better yet, optimal result.

The use of a risk-stratification system to adjust for the patient's case complexity is essential to avoid misjudging surgeons and programs whose case volume varies in terms of case complexity. We used the RACHS system for risk adjustment, in which categories correlate with increasing mortality as case complexity increases by RACHS category. The RACHS categories were found to be associated with technical scores as well. This allows a risk-stratified assessment of a surgeon's technical performance, which is meant to be used for self-assessment as well as peer assessment and improvement. In our institution, technical scores for each of the 6 surgeons ana-

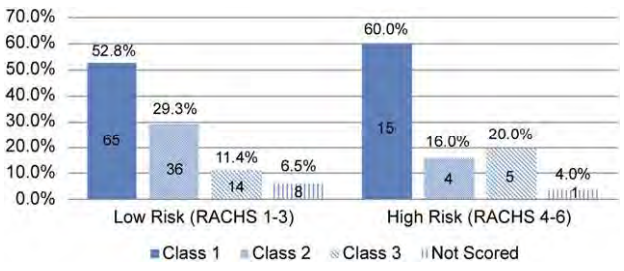


Fig 4. Technical performance by RACHS risk group. (RACHS = Risk Adjustment for Congenital Heart Surgery.)

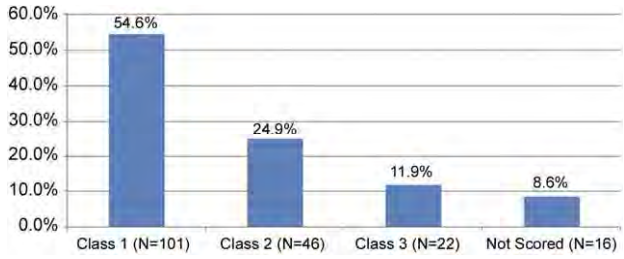


Fig 5. Distribution of technical performance scores.

lyzed showed no differences in the overall performance, although because of small numbers, specific comparisons by RACHS categories could not be made. With a larger sample size, however, this type of analysis could be done with a longer period for data accumulation, depending largely on institutional volume. Similar and additional analyses of technical scores can be performed to identify specific areas of surgeon underperformance for specific lesions—eg, ventricular septal defect repair, certain types of operations with high RACHS categories, or neonatal operations—which can then be used to target areas of potential deficiencies that might need improvement; this can be an invaluable quality control and quality self-improvement system. One could even envision a mechanism for "observerships," in which surgeons could visit other institutions with a goal of acquiring technical details of procedures that could be targeted to specific lesions or procedures. In the case of trainees, this type of analysis could also be used for guiding case selection by individual residents or program directors.

The development of a standardized system for assessing technical performance scores in congenital cardiac operations has its own challenges. It was developed based on our previous studies and observations, and the criteria used to score each technical category were primarily based on an expert panel consensus from a single institution and could be viewed as subjective. Efforts were made to use evidence-based data from the literature when available, similar to the methodology used by core sites that review echocardiographic studies in large multicenter trials. Ultimately, however, the decisions on the scoring criteria were based on the consensus of the panel. Although these criteria might vary between different institutions or even between experts within the same

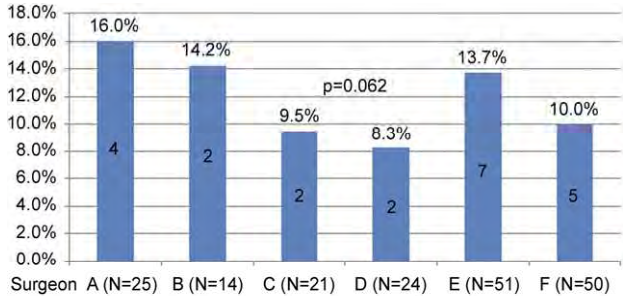


Fig 6. Distribution of technical performance class 3 by surgeons (n = total number of patients operated on by specific surgeon).

institution, it provided a framework to use to build a system that will need to be constantly reassessed, validated, and modified as patient data accumulate and are analyzed. A critical component of the scoring system is calibration of the technical performance scores to reflect criteria that have a real impact on patient outcomes, whether that is survival or delayed or even incomplete recovery after a procedure. Too strict or too loose criteria could render the technical performance metric of little value as a discriminator to be applied for purposes of improving individual or even program performance. As such, the current methodology described and the criteria used in this study are validated by the fact that there are enough of patients in each category for statistical comparisons, particularly with respect to patient outcomes.

Study Limitations

The creation of technical performance scoring criteria for valve-related procedures such as valve repairs or replacements posed a particular challenge. Eliminating valve regurgitation or stenosis after repair is not always possible. The echocardiographic assessment of the technical result may vary depending on the hemodynamic status of the patient, whereas echocardiographic assessments are often unreliable in assessing the durability of the repair, which might vary even within the same hospitalization especially after aortic valve repairs for regurgitation. In addition, implanted artificial valves carry an inherent gradient or regurgitant fraction, or both, which varies based on the manufacturer, valve size, and valve type. At the same time, many of the gradient values given by the manufacturer were calculated assuming their implantation in an adult and not the pediatric patient population.

The implementation of our technical performance assessment system, which is primarily based on echocardiography, requires commitment to a procedure-specific standardized and reproducible complete echocardiographic assessment of the anatomic repair of the specific defect being repaired that eliminates personal biases of the interpretation of the results. In addition, the threshold for reintervention, either in the catheterization laboratory or in the operating room, adds another surgeon-specific bias to the scoring system, since the need for postoperative reintervention is an integral part of the scoring criteria and another potential area of variability between surgeons and institutions.

The present report represents a pilot study of the feasibility and implementation of such a broad system at our institution. Accumulation and analysis of additional data will allow reassessment, further validation, and adjustment of the scoring system. The approach presented here is based on our previously published work [12–16], and it represents a single institution's experience and observations. Our observations and system will need to be verified by other institutions to achieve uniformity in the criteria used, whereas the validity, feasibility, and reproducibility of this system will likely require a multicenter trial.

In conclusion, the development and implementation of a technical performance self-assessment system for congenital cardiac operations is possible. Based on the scoring criteria that was used in this study, the impact of less than optimal technical score depended on case risk category, with higher mortality in the higher risk group and increased use of resources for lower risk procedures. This technical performance system permits individual surgeons to self-assess technical performance and provide procedure-specific benchmarks.

Future directions in this system will be to evaluate the impact of technical performance on mid- and late outcomes, establish a multicenter evaluation of technical performance metrics to develop national benchmarks, and assess the impact of implementation of this system on technical development and training of surgeons.

We wish to acknowledge the help of the following physicians with the development of this system: Drs Emile Bacha, Kathleen Jenkins, Kimberly Gauvreau, Peter Lang, Thomas Kulik, Melvin Almodovar, Andrew Powell, Lisa Bergersen, Oscar Benavidez, Ravi Thiagarajan, and Michelle Gurvitz, and Ms Heidi Moses.

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DISCUSSION

DR JAMES JAGGERS (Aurora, CO): One thing, I will take the prerogative of sitting up here and ask you a quick question.

Does your technical performance score incorporate residual defects? I know you have previously described this, but how do residual defects play into that?

Secondly, has this score been validated with the trainee? I am assuming that the technical scores that are reported are assigned to the attending surgeon. Have you taken the next step in using this as an evaluation tool for the trainee?

DR KARAMICHALIS: Thanks for your questions. I will take the first question first.

This is an example, shown up on the screen here, of what we define residual defects for the arterial switch operation and the corresponding technical scores.

There are specific echocardiographic- based measurements defining residual lesions in each technical score class. We are in the process of developing procedure-specific echo modules, which will standardize the predischarge echo and specify the exact numbers in terms of millimeters or gradients for valves of what is considered a residual defect.

In regard to the second question, we have not examined the relationship of technical scores to trainees performing the surgery. We believe that this system will be an invaluable tool to provide feedback for trainees' technical skills and progress. We would also be able to make comparisons of the technical scores between trainees, junior surgeons versus senior surgeons, and so forth. We feel that will be 1 of the invaluable uses of our system.

DR TARA B. KARAMLOU (Seattle, WA): That was a great presentation. I guess I was intrigued that the variability in the technical performance scores was somewhat constant across the spectrum of increasing case complexity, and I found that not to be really intuitive.

Have you looked at the impact of surgeon volume or experience on technical performance scores? I wonder whether that has something to do with the lack of variability among the RACHS cases, in other words are the more experienced surgeons or the higher volume surgeons potentially doing the more difficult cases.

Emile, perhaps you may want to comment whether you plan to look at volume as a modulator of technical performance score.

Thank you. Very nice presentation.

DR KARAMICHALIS: Thanks for your question.

We have examined the association of RACHS categories and technical scores in this study. There was no difference in technical scores between the low-risk (RACHS categories 1–3) and the high-risk (RACHS 4–6) groups, though our sample size in the high-risk group was small, only 25 patients. When the analysis is performed using the 6 RACHS categories, there seemed to be an association of technical scores and RACHS, with worsening technical scores as the complexity increases.

DR EMILE A. BACHA (New York, NY): John, I am going to interrupt you for a second. Were the surgeons compared in a risk-adjusted fashion or not? I think that is what Tara is asking. When you compared surgeons, was that done in a risk-adjusted fashion or not?

DR KARAMICHALIS: This is the technical performance comparison between the surgeons.

DR BACHA: Is this risk adjusted?

DR KARAMICHALIS: This was not risk adjusted because the number of operations performed by each surgeon in each of the 6 RACHS categories was not large enough to allow such comparisons, but we should be able to do it with larger sample size.

DR BOHDAN MARUSZEWSKI (Warsaw, Poland): You have used the postoperative length of stay and ICU stay as the measures of quality of outcome. How did you address the issue of preoperative patient condition even in the very low categories? You can still have the patient with a high risk of postoperative complication, which is not due to the technical skills of the surgeons, but it is due to the nonoperative or nonsurgical things like preoperative patient condition. How do you address this issue?

DR KARAMICHALIS: In this specific study, we have not addressed the preoperative status of the patient. We just used the RACHS in order to risk stratify the complexity of the patients.

We looked at patient's preoperative physiologic status in our previous studies and adjusted for that.

DR DEL NIDO: I just wanted to answer Bohdan's question because I think it is a very important question.

The quality metric is the technical performance score. It is not the length of stay. The length of stay is what may occur depending on the quality metric, but the quality metric is the outcome, so it only measures the anatomic defect, what you intended to do, and how well you accomplished what you intended.

It has nothing to do with the patient's condition. You may have chosen, as a surgeon, to not treat a particular part of the defect, so that is not included in the technical performance. I think it is an important differentiation that you have to make.

Surgical technical performance scores are predictors of late mortality and unplanned reinterventions in infants after cardiac surgery

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Objective: We have previously shown that surgical Technical Performance Scores (TPS) are important predictors of early postoperative morbidity across a wide spectrum of procedures and that intraoperative recognition and intervention of residual defects resulted in improved outcomes. We hypothesized that these scores would also be important predictors of midterm outcomes.

Methods: Neonates and infants aged younger 6 months were prospectively followed from the index surgery for a minimum of 1 year. The TPS were calculated using previously published criteria, including intraoperative course, predischarge echocardiograms or catheterizations, and clinical data, and graded as optimal, adequate, or inadequate. Case complexity was determined by the Risk Adjustment for Congenital Heart Surgery-1 category. The primary outcome was mortality, and the secondary outcome was the need for unplanned reinterventions. Outcomes were analyzed using nonparametric methods and a logistic regression model.

Results: A total of 166 patients were included in our study, with 7 early deaths. The remaining 159 patients (Risk Adjustment for Congenital Heart Surgery-1 category 4-6, 76 [48%]; neonates, 78 [49%]) were followed for a minimum of 1 year after surgery. There were 14 late deaths or late transplantations and 55 late reinterventions. On univariate analysis, the TPS were associated with mortality ($P < .001$) and reintervention ($P = .04$). On logistic regression analysis, inadequate TPS was associated with late mortality ($P < .001$; odds ratio, 7.2; 95% confidence interval, 2.2-23.6), and Risk Adjustment for Congenital Heart Surgery-1 category ($P = .004$; odds ratio, 3.7; 1.5-8.8) at index surgery was associated with need for late unplanned reintervention.

Conclusions: Technical performance affects midterm survival after infant heart surgery. Inadequate TPS can be used to prospectively identify patients at ongoing risk of demise and the need for reintervention. An aggressive approach to diagnosing and treating residual lesions at the initial operation is warranted. (J Thorac Cardiovasc Surg 2012;144:1095-101)

CHD

Supplemental material is available online.

The outcome of congenital cardiac surgery, particularly in neonates and young infants, is dependent on multiple factors. These include preoperative physiologic status and disease complexity, intraoperative management, and postoperative events.[1-6] In addition, human factors play an important contributory role.[7-9]

In initial work from our institution,[10,11] we had developed a Technical Performance Score (TPS) for several individual procedures, including ventricular sepal defect repair, complete atrioventricular canal repair, tetralogy of Fallot repair, arterial switch operation, and stage I Norwood repair. The TPS grades the performance of the planned surgical procedure according to how closely the anatomic and functional result achieved the intended optimal outcome. In these studies, we have shown that the TPS correlates highly with the risk of complications and mortality and length of hospital stay in high-risk procedures. In a subsequent study,[2] we were also able to show that in high-risk infants, an optimal technical score was able to mitigate the contribution of greater case complexity and greater preoperative illness severity.

In our latest published study,[1] we prospectively followed 166 infants younger than 6 months of age, who underwent correction of congenital cardiac defects on cardiopulmonary bypass and found that technical performance

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Abbreviations and Acronyms
RACHS-1 = Risk Adjustment for Congenital Heart Surgery-1
TPS = Technical Performance Score

correlated highly with the occurrence of major postoperative adverse events, after correcting for disease complexity and physiologic status. In our present study, we considered the midterm outcomes in the same cohort of patients. We hypothesized that the TPS would be able to predict the midterm outcomes and, thus, serve as a tool that could guide early intervention and ultimately improve long-term results.

MATERIALS AND METHODS

The institutional review board approved the present study.

In the initial cohort of 166 neonates and infants younger than 6 months old who had been followed prospectively from October 2008 to April 2010 from admission to discharge (data previously published),[1] 7 early deaths occurred. In the present study, the remaining 159 patients were followed after discharge from their index operation. Our endpoints of interest were mortality or the need for transplantation and the need for late intervention, either surgical or catheter based, or both, during the follow-up period, which ended March 2012.

Case complexity was scored using the Risk Adjustment for Congenital Heart Surgery-1 (RACHS-1) scoring system.[4-6] The TPS was assigned according to the anatomic and functional information obtained from the discharge echocardiogram and clinical status at discharge from the index operation as optimal, adequate, or inadequate using a previously published method.[10,11] The need for surgical or catheter-based reintervention for residual or recurrent lesions on the operated structures or the need for permanent pacemaker placement before discharge from index operation resulted in a TPS of inadequate.

Late mortality was defined as death or transplantation occurring more than 30 days after the index surgery for those patients discharged home less than 30 days after surgery. For patients discharged home more than 30 days after the index surgery, late mortality was defined as death or transplantation occurring any point after discharge.

Late reinterventions included any unplanned surgical or catheter-based intervention to treat a residual or recurrent lesion that occurred after discharge from the index surgery. For the purposes of the present study, for the neonates who underwent a Norwood stage I operation as their index procedure, a straightforward second-stage procedure or bidirectional Glenn procedure was not considered a reintervention.

Statistical Analysis

Categorical variables are represented as numbers and percentages, and continuous variables are summarized as median and range or mean ± standard deviation. The Pearson χ^2 test was used to compare proportions for categorical variables. A bivariate association was used to choose variables, with $P < .05$ for inclusion in logistic regression analysis. Multivariate logistic regression analysis was used to examine the association between technical performance and late outcomes, adjusting for age and case complexity. IBM SPSS Statistics, version 18, for Window (SPSS Inc, Somers, NY) was used for statistical analysis.

RESULTS

A total of 159 patients were included in the present study. Of these, 89 (56%) were male, and 78 (49%) were neonates at the index surgery. Of the 159 patients, 40 (25%) were in RACHS-1 category 2, 42 (26%) were in RACHS-1 category 3, 43 (27%) were in RACHS-1 category 4, and 34 (21%) were in RACHS-1 category 6. The discharge TPSs were as follows: optimal in 59 (37%), adequate in 77 (48%), and inadequate in 23 (14%; Table 1). Table E1 outlines the percentage of distribution of RACHS-1 categories in each of the TPS groups.

The mean duration of follow-up was 17 ± 8 months. The median duration of follow-up was 17 months (range, 1-35).

Of the 159 patients, 14 died or required late transplantation (4 late transplants). Of these 14 patients, 6 were in the optimal group (10.2%), 1 in the adequate group (1.3%), and 7 in the inadequate group (30%). Also, 55 patients (35%) required 78 reinterventions.

The reinterventions included surgical or catheter interventions on the right ventricular outflow tract or main or branch pulmonary arteries in 37 patients; surgical or catheter interventions on the ascending aorta or arch in 10; surgical or catheter interventions on the Sano or Blalock-Taussig shunt in 8; surgical or catheter interventions on the atrial septum in 4; surgical or catheter interventions on the pulmonary veins in 3 (2 after total anomalous pulmonary venous return repair and 1 after tetralogy of Fallot/absent pulmonary valve repair); surgical or catheter interventions on atrioventricular valve in 5; surgical or catheter interventions on systemic vein in 2; closure of residual atrial or ventricular septal defect in 2; late permanent pacemaker in 2; surgical intervention in subaortic region in 2; and transplantation in 4.

Table E2 outlines the initial index operation and indications for late reinterventions. Figures E1 to E6 depict the occurrence of mortality and the need for late reintervention according to TPS, RACHS-1 category, and age at intervention.

Late Mortality/Transplantation

On univariate analysis, a worse TPS was significantly associated with mortality ($P < .001$). However, the RACHS-1 category and age at index surgery were not significantly associated with late mortality (Table 2). A significant association was seen between late mortality and late reinterventions ($P = .033$; Table E3).

On stratified analyses, mortality was greater in the inadequate group for both neonates and non-neonate infants and in both higher and lower RACHS categories (Table E4). This indicates that the greater mortality in the inadequate group did not result from confounding by either age or complexity.

On bivariate logistic regression analysis, an inadequate TPS was associated with greater late mortality compared with the risk of death in the optimal/adequate groups, adjusting for either age or RACHS category ($P = .001$; odds ratio, 7.2; 95% confidence interval, 2.2-23.6). We could

TABLE 1. Patient characteristics

Characteristic	Value
Age at surgery (d)	
Median	32
Range	0-156
Neonate	
Yes	78 (49%)
No	81 (51%)
RACHS-1 risk category	
2-3 (low risk)	83 (52%)
4-6 (high risk)	76 (48%)
TPS	
Optimal	59 (37%)
Adequate	77 (48%)
Inadequate	23 (14%)
Any late reintervention	
None	104 (65%)
Catheter based	25 (16%)
Surgical	9 (6%)
Catheter based and surgical	21 (13%)
Late death or transplant	
No	145 (91%)
Yes	14 (9%)

RACHS-1, Risk Adjustment for Congenital Heart Surgery-1; *TPS,* Technical Performance Score.

not adjust for age and complexity simultaneously owing to the relatively small number of deaths (Table 3).

Need for Any Late Reintervention

On univariate analysis, the TPS was significantly associated with the need for surgical or catheter-based reinterventions in the area considered inadequate ($P = .04$), as were the RACHS-1 category ($P < .001$) and patient age at the index operation ($P = .02$; Table 4).

On stratified analyses, no relationship was found between the TPS and the need for late reintervention in neonates. In older infants, however, the inadequate group was associated with a greater reintervention rate ($P = .03$; Table E5). Similarly, no relationship was found between the TPS and reintervention in patients in higher RACHS-1 categories. However, among the lower RACHS-1 categories, an inadequate TPS was associated with a greater rate of reinterventions ($P = .03$; Table E4).

On multivariate logistic regression analysis, RACHS-1 category ($P = .004$; odds ratio, 3.7; 95% confidence interval, 1.5-8.8) was significantly associated with the need for late unplanned reintervention. However, after adjusting for age and complexity, the odds of late reintervention were not significantly greater in the inadequate TPS group (Table 5).

TABLE 2. Univariate analysis of late mortality/transplantation

Variable	Patients (n)	Deaths (n)	*P* value
TPS			<.001
Optimal	59	6 (10.2%)	
Adequate	77	1 (1.3%)	
Inadequate	23	7 (30.4%)	
TPS group			<.001
Optimal/adequate	136	7 (5.2%)	
Inadequate	23	7 (30.4%)	
Neonate			.10
Yes	78	10 (12.8%)	
No	81	4 (4.9%)	
RACHS-1 category			.27
2-3	83	5 (6.0%)	
4-6	76	9 (11.8%)	

TPS, Technical Performance Score; *RACHS-1,* Risk Adjustment for Congenital Heart Surgery-1.

TABLE 3. Bivariate logistic regression analysis of late mortality/transplantation

Variable	OR	95% CI	*P* value
TPS for patient age			
Optimal/adequate	1.0	—	—
Inadequate	7.2	2.2-23.6	.001
Neonate			
Yes	2.3	0.7-8.0	.20
No	1.0	—	—
TPS for RACHS-1 category			
Optimal/adequate	1.0	—	—
Inadequate	7.4	2.2-24.4	.001
RACHS-1 category			
2-3	1.0	—	—
4-6	1.5	0.4-5.0	.53

OR, Odds ratio; *CI,* confidence interval; *TPS,* Technical Performance Score; *RACHS-1,* Risk Adjustment for Congenital Heart Surgery-1.

DISCUSSION

The TPS of surgical procedures performed on young infants with congenital heart defects have been shown to correlate highly with early mortality and/or morbidity.[1,2,11] In the present study, we have followed the same cohort of

TABLE 4. Univariate analysis of need for late reintervention factors associated with late reintervention

Variable	Patients (n)	Reintervention (n)	*P* value
TPS			.04
Optimal	59	23 (39.0%)	
Adequate	77	20 (26.0%)	
Inadequate	23	12 (52.2%)	
TPS group			.06
Optimal/adequate	136	43 (31.6%)	
Inadequate	23	12 (52.2%)	
Neonate			.02
Yes	78	34 (43.6%)	
No	81	21 (25.9%)	
RACHS-1 category			<.001
2-3	83	17 (6.0%)	
4-6	76	38 (50.0%)	

TPS, Technical Performance Score; *RACHS-1,* Risk Adjustment for Congenital Heart Surgery-1.

CHD

TABLE 5. Multivariate logistic regression analysis of need for late reintervention

Variable	OR	95% CI	*P* value
TPS			
Optimal/adequate	1.0	—	—
Inadequate	1.8	0.7-4.6	.21
Neonate			
Yes	1.0	0.4-2.3	.98
No	1.0	—	—
RACHS-1 category			
2-3	1.0	—	—
4-6	3.7	1.5-8.8	.004

OR, Odds ratio; *CI,* confidence interval; *TPS,* Technical Performance Score; *RACHS-1,* Risk Adjustment for Congenital Heart Surgery-1.

patients[1] and found that the TPSs can also predict the midterm outcomes after correcting for other risk factors such as disease complexity and age.

In unadjusted analyses, the inadequate group was significantly worse than the optimal/adequate group with respect to occurrence of late death. Although the late mortality rates are greater in neonates and infants in higher RACHS categories, these differences are not statistically significant.

The stratified analyses suggest that mortality is greater in the inadequate group for both neonates and non-neonates and in both higher and lower RACHS categories. This indicates that the greater mortality in the inadequate group was not due to confounding by either age or procedure complexity. The relationship between inadequate technical performance and greater mortality remained after controlling for age, and for RACHS-1 risk category.

The relationship between TPS and late reintervention was weaker than the relationship between TPS and late mortality; however, there is still some evidence that the inadequate group is more likely to experience late reintervention than the optimal/adequate group. The rates of late reintervention were greater among neonates and those in greater RACHS categories. However, stratified analyses suggest that no relationship was found between the TPS and reintervention in neonates (rates of reintervention were consistently high in neonates compared with older infants, regardless of the TPS). In older infants, however, the inadequate group was associated with a greater reintervention rate. Similarly, no relationship was found between the TPS and reintervention in patients in higher risk categories. However, among the lower risk categories, inadequate TPS was associated with a greater reintervention rate. Thus, the TPS did not have a demonstrable effect on the reintervention rate in the highest risk infants. This observation might have been because of the greater mortality rate in this subgroup, such that an inadequate TPS in the higher complexity and risk procedures likely results in a more life-threatening abnormality in physiology. Alternatively, it could be that the nature of the TPS, because it is based on findings from the early postoperative echocardiogram, is not sensitive enough to detect subtle imperfections in technical performance that affect only late outcomes.

The present study cohort consisted of infants younger than 6 months old, with 49% neonates and 48% in the high risk RACHS-1 categories. Thus, this cohort represented a relatively broad distribution across risk categories. We chose the postdischarge mortality and need for reinterventions as our intermediate outcomes of interest because these are well-documented hard endpoints. Despite the cohort size, our findings suggest that the TPS can predict the midterm outcomes. Although late mortality and the need for late reintervention are reasonable outcomes to follow, the rapidly improving outcomes of surgery for even the most complex of congenital defects suggests that more sensitive outcomes measures might need to be followed. To this end, we are also evaluating the neurodevelopmental outcomes in a subset of these patients to determine whether the technical performance correlates with this measure.

Future Directions

Mortality has long been used as an outcome measure, particularly for early outcomes in database research. However, several studies have shown that the use of mortality data might not effectively reflect a surgeon's performance because of the multiple associated factors that can contribute to mortality in any specific congenital cardiac diagnosis.[12,13] Although risk adjustment does allow a more uniform comparison, the use of clinical and administrative databases to derive this information has the inherent problem of voluntary data submission and incomplete/partial data collection. Few data are available on the long-term outcomes from such database research. Several initiatives are in place to unify data collection methods so more accurate and complete data can be accrued in each diagnostic group,[14-20] particularly, long-term data such as late mortality and late reinterventions. The TPS can serve as a surrogate, and its inclusion into national and international databases could allow the expansion of this tool to a wider group of patients for validation.

Study Limitations

The present study included a small number of patients and in a specific age group. Additional study is required to validate this finding across a broad spectrum of diagnosis and procedures, and for all age groups.

Long-term data, not only on mortality, but also on more subtle outcomes, such as quality of life, neurodevelopmental outcomes, and psychosocial adjustments for the patients, as well as the family, might also be important measures of the efficacy of surgical performance in this group.[21-23] Resource use in the form of multiple readmissions could be another important factor that should be measured. Whether the TPS might well serve as surrogate for

measurement of these outcomes as well, not only in the short term, but also in the intermediate and long term, needs to be determined, because studies[22,23] have shown that patient-related and environmental factors are more likely to contribute to neurodevelopmental outcomes in specific subset of patients such as those undergoing the Norwood stage I procedure and arterial switch operation.

Although this tool has been validated in 1 center for specific outcomes and specific subsets of patients, a multicenter study is necessary to establish its reproducibility across a wide range of diagnostic and procedural categories and across a wide range of programs. The use of echocardiography as the principle component of the TPS is advantageous, because it is routinely obtained perioperatively and during long-term follow-up in all centers. However, its disadvantage is the variability in the interpretation of the findings. We believe that standardization of the TPS modules will allow for more uniform data collection.

CONCLUSIONS

The TPS, based on early operative results determined by echocardiography at discharge and the need for early reintervention to correct residual or recurrent defects, correlates highly with both early- and intermediate-term outcomes. The present study underscores the need for early assessment of adequacy of the surgical procedure in addressing important hemodynamic lesions and justifies an aggressive approach to early intervention of residual defects.

We would like to acknowledge Kimberly Gauvreau, ScD, for assistance with statistics, and Kathy Jenkins, MD, and the Program for Patient Safety and Quality for pilot funding of this project.

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Discussion

David M. Overman *(Minneapolis, Minn).* Meena, congratulations on an excellent presentation and thank you for providing the report well in advance of the meeting for review.

This work builds on a characteristically expansive foundation of human factors research laid by Marc de Leval nearly 20 years ago. Human factors are, of course, quite complex and difficult to quantify. They include individual, technical, and organizational dimensions. Dr Bacha and his colleagues should be commended for successfully filtering out 1 specific human factor, intraoperative technical performance, and exploring its effect on outcomes through a series of investigations now dating back to 2007.

The present study assesses the role of the TPS on late mortality and unanticipated reintervention at a mean follow-up of 17 months. It extends the analysis of a prospective cohort of newborns

and infants presented at last year's American Association for Thoracic Surgery, a study that demonstrated the ability of technical performance to mitigate the effects of adverse intraoperative events. The main findings of the present study are that the TPS is strongly associated with late mortality or the need for transplantation. Although this association is somewhat weaker when adjusted for age and complexity, it is particularly sobering to note that survival at 2 years is a startling 50% among patients whose TPS was inadequate.

Second, age and complexity did not correlate with late mortality or the need for transplantation, although this is probably explained by inadequate statistical power. The TPS is more weakly associated with late reintervention and in the report this association is limited to non-neonates and patients with lower complexity.

Finally, on multivariate analysis, complexity alone was associated with the need for late reintervention; notably, patients requiring reintervention had a mortality rate of 15%.

I have 3 questions for the authors.

Number 1, it strikes me as counterintuitive that an inadequate TPS does not significantly increase the risk of the need for reintervention. The significant incidence of mortality among patients undergoing reintervention and the strong association of TPS with late mortality would seem to support a connection between TPS and reintervention. Can you share with us more specific information regarding the nature of these reinterventions, and does that data offer any explanation for this apparent paradox?

Dr Nathan. I would like to bring to your attention that in the initial cohort of 166 patients we had 7 early deaths, and most of them, 6 of the 7 were in the high-risk category and were in neonates, and 6 of the 7 had an inadequate technical performance. Thus, if these patients had survived, the chances are that they would have required multiple reinterventions or would have had late deaths.

Unfortunately, our study was underpowered, because we only had 159 patients. Also, if we had a larger subset of patients, we probably could prove that inadequate TPSs would definitely be associated with the need for late reintervention, in addition to late mortality.

Dr Overman. Second, the TPS is based almost entirely on postoperative echocardiographic assessment of residual disease. This method has some potential weaknesses. One of these is that by equating residual disease and technical performance, we introduce confounding variables that impair the evaluation of technical performance alone. For instance, what if the surgeon intentionally leaves a residual gradient at the level of the pulmonary valve during tetralogy repair, should that be considered technically less than optimal? Should imperfect native anatomy really effect TPS?

Dr Nathan. I agree that the TPS is not yet a perfect system, and we are in the process of tweaking it, particularly for certain diagnostic groups such as valve-sparing tetralogy repairs, valve repairs, and, in fact, even for canal repairs, because often in canal repairs, we accept trivial to mild regurgitation as acceptable, but that would classify it as an adequate score, rather than an optimal score.

We are in the process of modifying our TPS, and, hopefully, after we have accrued enough data on each of these subgroups, we might come up with a refined score.

Dr Overman. Finally, we all know that one can perform a technically perfect operation but still lose the patient to the hazards of the early postoperative environment, many of these hazards being human factors. Have the authors considered study designs that attempt measurement of other types of human factors, either alone or combined with TPS and whether there any human factors you would consider particularly important investigative targets for those in the audience who might want to take up the baton?

Dr Nathan. I agree with the discussant that there are several factors, in addition to technical performance, that will contribute to the outcomes and a many of them are human factors, namely, the cognitive factors, communication between the various teams involved in the care of the patient, both intraoperatively and postoperatively, and several other human factors that are closely interrelated. We concentrated on the TPSs and, hopefully, once we have refined it, we will study these other human factors, which we also believe play an important part in outcomes.

Dr Overman. Thank you and congratulations on this work.

Dr V. Mohan Reddy *(Stanford, Calif).* Meena, I would like to ask a question. I agree that technical performance is an important factor in early and late outcomes, but the paper is so abstract when you say "highly complex" and "interventions." Can you tell me 1, 2, 3, in each category, what were the most complex diagnoses, what were the 1, 2, 3 residual defects that required reintervention.

Dr Nathan. I have a list of the 55.

Dr Reddy. Just give me the top 3.

Dr Nathan. Most of them were pulmonary artery reinterventions. Most of them, in the stage 1 and in the Tet groups, especially the Tet pulmonary atresia MAPCAs, the other was arch interventions, and the third was either redo valve repair or subaortic interventions in the canals.

Dr Reddy. So how many were single ventricle or is this 2-ventricle patients who participated?

Dr Nathan. About 50% to 60% were single ventricle. A number of the reinterventions were in the single-ventricle group, which is to be expected. Even when they had an optimal technical performance, at their discharge echocardiogram, a number of them required reinterventions.

Dr Christopher A. Caldarone *(Toronto, Ontario, Canada).* Dr Nathan, it is no secret I am a big fan of this work that you have been pioneering. A couple questions.

One, I noticed on a couple of the slides, I think it was the late interventions, and it might have even been early mortality, that the "optimals" actually seemed to fare worse than the "adequates." I assume that was not statistically significant, but it was a bit of a trend. Do you have any explanation for that? Because it certainly would not have been expected.

Dr Nathan. The reason for that is a lot of the stage 1 cases, more than 50% of the stage 1 cases, were in the optimal group, but a number required either arch reintervention or reintervention on their shunts. We do have a very aggressive interventional cardiac program; and during pre-bidirectional Glenn cardiac catheterization, even if they see a minor arch gradient, they tend to balloon dilate, and those patients were included in our reintervention group.

Also, a number of the adequate group belonged in the low-risk RACHS category, namely, tetralogy of Fallot and canals; and, in them, even an adequate technical score did not seem to require late reintervention. Also, that might explain why the "adequates"

seem to have done a little better in the various survival and reintervention curves than the optimal patients.

Dr Caldarone. However, your first example was that some patients, for example Norwood, might have had an optimal outcome in terms of the paradigm of the TPS but might have actually had a lesion that required reintervention.

Dr Nathan. Yes. Not at discharge but developed that lesion subsequently.

Dr Caldarone. Subsequently, I see.

Dr Nathan. Yes, they had an optimal score at discharge.

Dr Caldarone. So, presumably as your TPSs are modified and calibrated to the patient populations, they will come more in line with expectations and the prediction of reintervention.

Dr Nathan. Yes. We are in the process of accruing about 100 to 150 patients in each of these diagnoses so that we can further modify the TPSs.

Dr Caldarone. Do you think you will be adding additional parameters to measure, or will you be redefining the cutpoints among optimal, adequate, and inadequate?

Dr Nathan. We will initially redefine the cutpoints because we find that what we classify as mild regurgitation on discharge echocardiography in canals is often read as trivial on the follow-up echocardiogram, even though the vena contracta appears the same.

So, we will initially redefine the cutoff among optimal, adequate, and inadequate and then we will consider weighting each of the subcategories and procedures to determine which is more important and is more likely to need reintervention or cause an adverse outcome late during follow-up. For example, in a Norwood procedure, is arch reobstruction more significant than a restrictive atrial septum or a slightly narrow shunt? All of that needs to be redefined.

Dr Caldarone. So you redefine the cutpoints and add coefficients or weighting coefficients?

Dr Nathan. Yes.

Dr Marshall Jacobs *(Newtown Square, Pa).* I want to compliment you as everyone has. We have followed this research with great interest since the initial development of the tool. Also, one of my recollections of your earlier reports of the short-term outcomes and resource use is that the relationship between the TPS and those measures varied between procedure groups, that there are procedures for which suboptimal technical performance might be associated with longer hospital stay or different measures of outcome.

What you did in this study certainly makes sense. It is a very logical next step. But, really, this was an example of lumping, where the previous analyses were examples of splitting. Also, you really only stratified the patients here by their theoretical complexity as measured by RACHS, which is based on the estimated risk of mortality. So I wonder, going forward, as you accrue more data on more patients, as you have said you have to do, whether it will not be most appropriate to consider these midterm outcomes in relation to specific procedural groups.

I mean being left with a residual ventricular septal defect after a ventricular septal defect repair has very different physiologic consequences than being left with arch obstruction after a Norwood operation. Also, the overall expectations of a suboptimal outcome for 1 operation in terms of the survivability and functional status of the patient are very different than the overall expectations of the midterm outcomes for another operation.

So I compliment you on taking this to the next step, which was a natural progression, but I think really to find insights into the midterm associations with TPS, it is going to have to be broken down into procedural groups, isn't it?

Dr Nathan. I totally agree with you, and we are in the process of accruing these data. In our previous work on the initial presentation of 166 patients, we did show that an inadequate technical performance in the high-risk group was associated with increased mortality across all ranges. Thus, if you had an adequate technical performance, you did well if you were low risk, but did poorly if you were high risk. Also, if you had optimal technical performance, you did relatively well in all risk categories. We agree that considering specific procedures will give us a better insight into what lesions need preemptive reintervention.

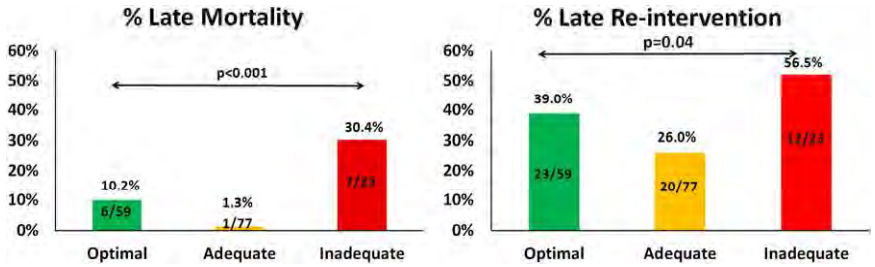


FIGURE E1. Relationship between Technical Performance Scores and late mortality and need for late reintervention. An inadequate Technical Performance Score was associated with a significantly greater late mortality and need for late reintervention.

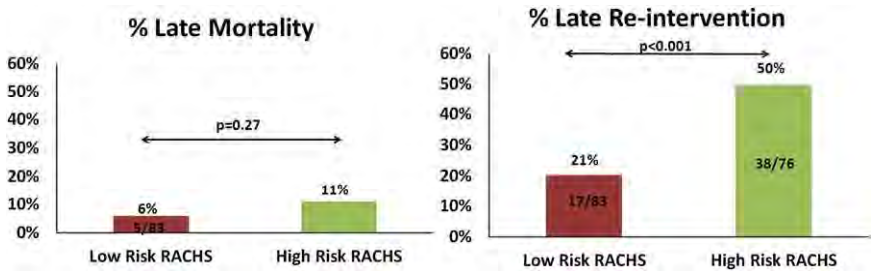


FIGURE E2. Relationship between Risk Adjustment for Congenital Heart Surgery-1 *(RACHS-1)* category and late mortality and need for late reinterventions. High-risk RACHS-1 category (RACHS-1 category 4-6) was associated with a significantly greater need for late reintervention.

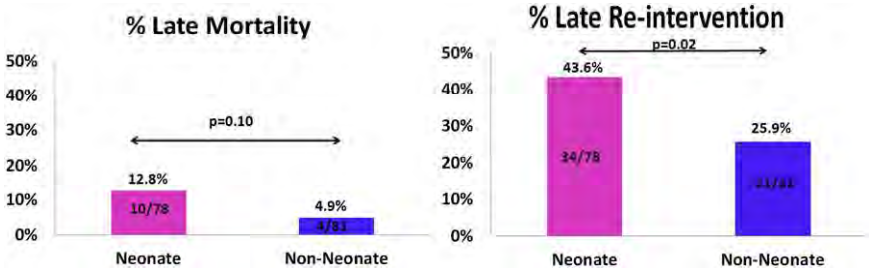


FIGURE E3. Relationship between neonates and late mortality and need for late reintervention. Neonatal age was associated with a significantly greater need for late reintervention.

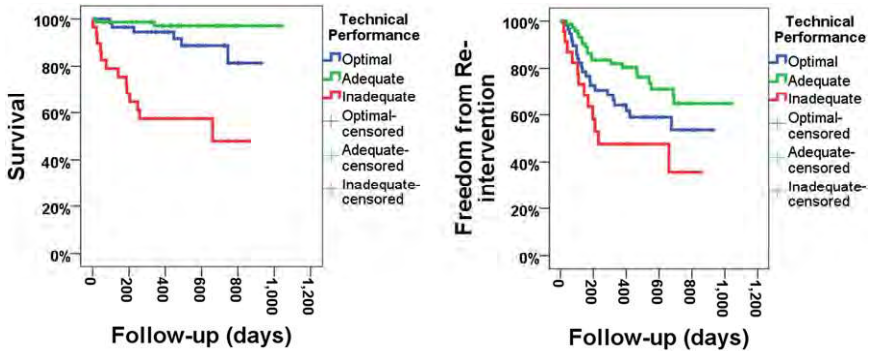


FIGURE E4. Kaplan-Meier curve representing freedom from late mortality and need for late reinterventions according to age at index surgery. Patients who were neonates at the index surgery had a significantly greater need for late reinterventions.

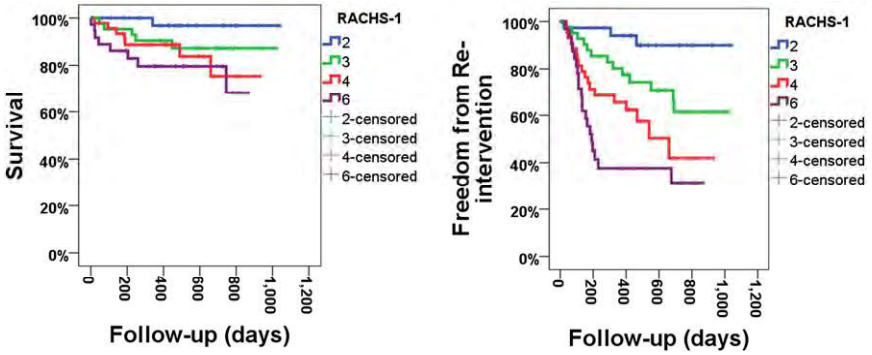


FIGURE E5. Kaplan-Meier curve representing freedom from late mortality and need for late reinterventions according to Technical Performance Score. Inadequate Technical Performance Score was associated with significantly greater late mortality and need for late reintervention. *RACHS-1,* Risk Adjustment for Congenital Heart Surgery-1.

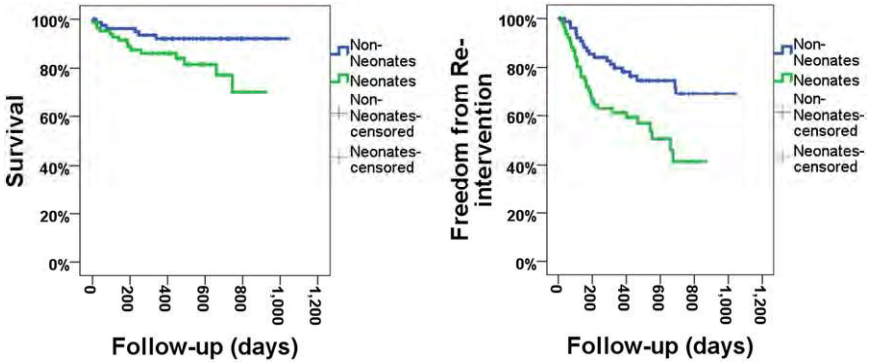


FIGURE E6. Kaplan-Meier curve representing freedom from late mortality and need for late reinterventions according to Risk Adjustment for Congenital Heart Surgery-1 *(RACHS-1)* category. High-risk RACHS-1 category (RACHS-1 category 4-6) was associated with a significantly greater need for late reintervention.

TABLE E1. Distribution of RACHS-1 categories across TPS groups

	RACHS-1 category				
TPS	**2**	**3**	**4**	**6**	**Total**
Optimal	14 (35%)	10 (24%)	18 (42%)	17 (50%)	59
Adequate	26 (65%)	25 (59%)	15 (35%)	11 (32%)	77
Inadequate	0 (0%)	7 (17%)	10 (23%)	6 (18%)	23
Total	40	42	43	34	159

RACHS-1, Risk Adjustment for Congenital Heart Surgery-1; *TPS,* Technical Performance Score.

TABLE E2. Late reinterventions stratified by RACHS-1 category and TPS

RACHS-1 category	Diagnosis	Procedure	TPS	Reintervention detail
Category 6 (n = 21)				
	HLHS	Stage I	1	BD of CoA, LPA, OHT
	HLHS	Stage I	1	BD of CoA, TV-plasty at BDG
	HLHS	Stage I	1	Stenting of Sano, stenting of ASD before BDG, atrial septectomy at BDG
	HLHS	Stage I	1	BD of ASD and PA, stenting of ASD
	HLHS	Stage I	1	Stenting of Sano, atrial septectomy at BDG
	HLHS	Stage I	1	Stenting of Sano
	HLHS	Stage I	1	Arch augmentation and pulmonary vein debridement at BDG
	HLHS	Stage I	1	Stenting of ASD and Sano
	HLHS	Stage I	1	BD of ASD and PA, stenting of Sano
	HLHS	Stage I	1	BD of innominate vein
	HLHS	Stage I	1	BD of RPA, Sano stent
	HLHC	Stage I	1	LPA stent
	HLHS	Stage I	2	BD of Sano
	HLHS	Stage I	2	Sano stent
	HLHS	Stage I	2	Sano and ASD stent
	UCAVC	Stage I	2	BD of PA and arch
	UCAVC	Stage I	2	Atrial septectomy at BDG
	HLHS	Stage I	3	BD arch and PA
	HLHS	Stage I	3	Upsize BTS, TV repair and PA-plasty, pulmonary vein dilation
	HLHS	Stage I	3	BD of PA before BDG, BD of arch after BDG, BD of MV
	DILV, TAPVR	Stage I	3	BD of pulmonary veins
Category 4 (n = 17)				
	Hypoplastic arch, VSD	Arch augment, PA band	1	BD of PA band, surgical removal of PA band
	TAPVR	TAPVR repair	1	BD of pulmonary veins
	HLHS	Comprehensive stage II	1	LPA stent
	HLHS	Comprehensive stage II	1	BD of ascending aorta, aortoplasty at Fontan
	Tet/PA/MAPCAS	Unifocalization	1	BD of PAs
	UCAVC, CoA	Arch augmentation	1	AVV repair
	IAA	IAA repair	1	BD of arch
	DOLV/PA	Rastelli	1	Late pacemaker for 2° block
	Truncus	Truncus repair	2	BD of PAs, PA-plasty,
	Tet/PA/MAPCAS	Unifocalization	2	BD and conduit stent × 2, BD PA
	Tet/PA/MAPCAS	Unifocalization	2	Multiple PA rehabilitation, PVR
	Heterotaxy, discontinuous PAs	Unifocalization	2	BD of PA, central PA-plasty at BDG
	Hypoplastic arch, VSD	Arch augment, VSD closure	2	Sub-AS resection
	TGA/VSD	ASO, VSD	3	OHT
	TGA/VSD	ASO, VSD	3	BD of branch PAs
	Tet/PA/MAPCAS	Unifocalization	3	PA rehabilitation
	Truncus	Truncus repair	3	PA rehabilitation, PA-plasty
Category 3 (n = 14)				
	Tet/PA	Repair with RV-PA conduit	1	Conduit change
	DORV, straddling TV and hypoplastic RV	BTS	1	Catheter to BD, PA after BiV repair, reoperation for residual VSD, pacemaker
	HLHC	Aortic and mitral valve plasty	1	BD of MV
			1	TV and mitral valve-plasty

(Continued)

TABLE E2. Continued

RACHS-1 category	Diagnosis	Procedure	TPS	Reintervention detail
	Aortic regurgitation and root dilation, CT disorder	Valve sparing; aortic root replacement and ASC aortic replacement		
	TOF/CAVC	Tet canal repair	2	BD of pulmonary valve and RPA
	William's	Aortoplasty, MPA and LPA plasty	2	BD of PAs
	TGA/IVS	ASO	2	BD of supra-PS
	Tet/PA, single collateral	Tet PA repair with RV-PA conduit	2	BD of distal conduit, conduit change, stent in second conduit
	CAVC	CAVC repair	2	Sub-AS resection
	TOF/APV	Repair with RV-PA conduit	2	RPA BD, conduit change
	Tricuspid atresia	BTS	3	BD of PAs, PA-plasty at BDG, PA-platy after BDG
	CAVC	CAVC repair	3	Redo ASD and cleft closure
	Previous IAA repair with Ross Konno, now with LCA and conduit stenosis	Intraoperative stenting of LCA, conduit change	3	BD of PA, OHT
	Tet/AVC	Tet canal repair	3	ASD stent and BD of pulmonary veins
Category 2 (n = 3)				
	TOF	TOF repair	2	BD of supra-PS
	TOF	TOF repair	2	BD of RVOT
	Pulmonary atresia/IVS, after BTS	BDG	2	BD to rehabilitation PA, stenting of PA, BD of SVC anastomosis to PA

RACHS-1, Risk Adjustment for Congenital Heart Surgery-1; *TPS,* Technical Performance Score; *HLHS,* hypoplastic left heart syndrome; *BD,* balloon dilation; *CoA,* coarctation of aorta; *LPA,* left pulmonary artery; *OHT,* orthotopic heart transplantation; *TV,* tricuspid valve; *BDG,* bidirectional Glenn; *ASD,* atrial septal defect; *PA,* pulmonary artery; *RPA,* right pulmonary artery; *UCAVC,* unbalanced complete atrioventricular canal; *BTS,* Blalock-Taussig shunt; *MV,* mitral valve; *DILV,* double inlet left ventricle; *VSD,* ventricular septal defect; *TAPVR,* total anomalous pulmonary venous return; *Tet,* tetralogy; *RV,* right ventricle; *ASO,* arterial switch operation; *TGA,* transposition of great arteries; *PS,* pulmonary stenosis; *MAPCA,* major aortopulmonary collateral; *AVC,* atrioventricular canal; *IAA,* interrupted aortic arch; *DOLV,* double outlet left ventricle; *BiV,* biventricular; *CT,* connective tissue; *TOF,* tetralogy of Fallot; *RVOT,* right ventricular outflow tract; *CAVC,* complete atrioventricular canal; *MPA,* main pulmonary artery; *LCA,* left coronary artery; *SVC,* superior vena cava; *HLHC*, hypoplastic left heart complex; *AVV*, atrioventricular valve; *IVS*, intact ventricular septum.

TABLE E3. Late mortality/transplantation and relationship to late reinterventions

	Late mortality		
Late reintervention	Alive	Dead	Total
No	98	6	104 (6%)
Yes	47	8	55 (15%)
Total	145	14	159

TABLE E4. Effect of stratified TPS, by age and then RACHS-1 category for late death/transplantation

Variable	Patients (n)	Deaths (n)	*P* value
Neonate			
TPS			.02
Optimal/adequate	63	5 (7.9%)	
Inadequate	15	5 (33.3%)	
Non-neonate			
TPS			.05
Optimal/adequate	73	2 (2.7%)	
Inadequate	8	2 (25.0%)	
RACHS category 2-3			
TPS			.05
Optimal/adequate	76	3 (4.0%)	
Inadequate	7	2 (28.6%)	
RACHS category 4-6			
TPS			.02
Optimal/adequate	60	4 (6.7%)	
Inadequate	16	5 (31.3%)	

TPS, Technical Performance Score; *RACHS-1,* Risk Adjustment for Congenital Heart Surgery-1.

TABLE E5. Effect of TPS, stratified by age and RACHS-1 category for late reintervention

Variable	Patients (n)	Late reintervention (n)	*P* value
Neonate			
TPS			1.0
Optimal/adequate	63	27 (42.9%)	
Inadequate	15	7 (46.7%)	
Non-neonate			
TPS			.03
Optimal/adequate	73	16 (21.9%)	
Inadequate	8	5 (62.5%)	
RACHS Category 2-3			
TPS			.03
Optimal/adequate	76	13 (17.1%)	
Inadequate	7	4 (57.1%)	
RACHS category 4-6			
TPS			1.0
Optimal/adequate	60	30 (50.0%)	
Inadequate	16	8 (50.0%)	

TPS, Technical Performance Score; *RACHS-1,* Risk Adjustment for Congenital Heart Surgery-1.

Technical Performance Scores are strongly associated with early mortality, postoperative adverse events, and intensive care unit length of stay—analysis of consecutive discharges for 2 years

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Objectives: Previous work in our institution has indicated that the Technical Performance Score (TPS) is highly associated with early outcomes in select subsets of procedures and age groups. We hypothesized that the TPS could predict early outcomes in a wide range of diagnoses and age groups.

Methods: Consecutive patients discharged from January 2011 to March 2013 were prospectively evaluated. The TPS was assigned according to the discharge echocardiographic findings and the need for reinterventions in the anatomic area of interest. Case complexity was determined using Risk Adjustment for Congenital Heart Surgery (RACHS-1) categories. Early mortality and postoperative adverse events were recorded. Relationships between the TPS and outcomes were assessed after adjusting for the baseline patient characteristics.

Results: The median age of the 1926 patients was 1.8 years (range, 0 days to 68 years). Bypass was used in 1740 (90%); 322 (17%) were neonates, 520 (27%) infants, 873 (45%) children, 211 (11%) adults. TPS was class 1 (optimal) in 956 (50%), class 2 (adequate) in 584 (30%), and class 3 (inadequate) in 226 (12%); 160 patients (8%) could not be scored. A total of 51 early deaths (2.6%) and 111 adverse events (5.7%) occurred. On univariate analysis, age, RACHS-1 category, and TPS were significantly associated with mortality and the occurrence of adverse events. On multivariate modeling, class 3 (inadequate) TPS was strongly associated with mortality (odds ratio, 16.9; 95% confidence interval, 6.7-42.9; $P < .001$), adverse events (odds ratio, 6.9; 95% confidence interval, 4.1-11.6; $P < .001$), and postoperative intensive care unit length of stay (coefficient, 2.3; 95% confidence interval, 2.0-2.6; $P < .001$) after adjusting for other covariates.

Conclusions: The TPS is strongly associated with early outcomes across a wide range of ages and disease complexity and can serve as important tool for self-assessment and quality improvement. (J Thorac Cardiovasc Surg 2014;147:389-96)

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Supplemental material is available online.

Multiple factors appear to influence the outcomes after congenital cardiac surgery, with success dependent on several components. These components include (1) preoperative factors, such as the preoperative physiologic status of the patient, complexity of the defect, adequacy of diagnostic evaluation, and appropriateness of the surgical plan[1]; (2) intraoperative factors, such as cardiopulmonary bypass, surgical technique, and hemodynamic management[2-4]; and (3) postoperative course, including intensive care unit (ICU) events. Among these many factors, the technical adequacy of the repair is likely a significant determinant of a successful outcome.

More than 33,000 surgical procedures are performed annually for congenital heart defects in the United States.[5] Data from the Centers for Disease Control and Prevention[6] website have shown that the healthcare costs for hospitalizations for congenital heart defects in the United States were about $1.4 billion in 2004, with severe congenital heart defects accounting for 37% ($511 million) of the hospital costs associated with congenital heart defects.

The Technical Performance Score (TPS) is a novel tool for assessing operative performance. In previous work at our institution, we developed and validated the TPS initially for 5 procedures.[7-9] The TPS was further validated in a prospective study of neonates and infants.[2,10] We have

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Abbreviations and Acronyms

AUC = area under the receiver operating characteristics curve
CI = confidence interval
ICU = intensive care unit
RACHS-1 = Risk Adjustment in Congenital Heart Surgery
TPS = Technical Performance Score
VSD = ventricular septal defect

subsequently developed TPS modules to assess >90% of congenital cardiac procedures.[11,12] The purpose of the present study was to assess the utility of TPS for a wide range of procedures, from simple to complex, in a prospective fashion.

METHODS

Consecutive patients who were admitted after congenital heart surgery from January 2011 to March 2013 were included and prospectively followed up from admission to discharge. The institutional review board approved the present study. Only the index surgery per admission was included in the analysis. The TPS was assigned according to the discharge echocardiographic findings and/or the need for surgical or catheter-based reinterventions in the anatomic area of interest. The Risk Adjustment for Congenital Heart Surgery (RACHS-1) category was used to determine the case complexity. Major postoperative adverse events (excluding unplanned reinterventions) and mortality were recorded. The length of time on the ventilator, ICU stay, and postoperative hospital stay were recorded. Additional information on risk factors such as prematurity, presence of chromosomal anomalies, and other noncardiac anomalies, and patient demographics such as age and gender were documented.

Technical Performance Score

The TPS was assigned according to the echocardiographic findings and clinical status at discharge from the index operation. The procedures were subdivided into components, and each component was scored as class 1 (optimal), class 2 (adequate), or class 3 (inadequate) using specific echocardiographic criteria. The final score for each operation was determined by the subprocedure scores and was considered class 1 (no residual defect, optimal) if all subprocedure scores were optimal, class 2 (minor residual, adequate) if $\geq$1 subprocedures were adequate, and class 3 (major residual, inadequate) if $\geq$1 subprocedures were graded as inadequate. Any unplanned reintervention, whether surgical or catheter based, on the anatomic area initially treated at the index surgery or the need for permanent pacemaker placement resulted in a class 3 (inadequate) score.[1,2,7-12] Only operations or catheter reinterventions performed on the anatomic area treated at the index operation (eg, closure of a residual ventricular septal defect [VSD], repeat repair of a semilunar or an atrioventricular valve, conversion of an infundibular patch to a transannular patch in valve-sparing tetralogy repair, branch pulmonary artery stenting after pulmonary artery-plasty) were considered class 3 (inadequate). Planned reinterventions such as delayed chest closure and planned pulmonary artery rehabilitation were not considered TPS class 3. For the purpose of the present study, to avoid bias and allow inclusion of all patients, we included a fourth category labeled "not assigned," for those patients for whom a TPS could not be assigned because no echocardiogram had been performed, because the postoperative studies were incomplete, or the involved procedures, such as vascular rings, pacemakers, ventricular assist device, and others for which a score has not been developed.

RACHS-1 Mortality Category

The RACHS-1 method was developed to adjust for baseline case mix differences in risk when comparing in-hospital mortality among groups of patients aged <18 years undergoing congenital heart surgery. Procedure and diagnosis codes were used to place the surgical procedures into 6 predefined categories with similar risks of in-hospital mortality. Category 1 had the lowest risk of death and category 6, the highest. Patients with combinations of cardiac surgical procedures (eg, repair of coarctation of the aorta and VSD closure) were placed in the risk category corresponding to the single greatest risk procedure.[13,14] For the purposes of the present study, to include the entire cohort, even those for whom the RACHS-1 method has not been validated, we created 2 additional categories—category 7 and category 8. Category 7 included all patients aged <18 years who could not be assigned a RACHS-1 score. This group of patients included patients who were aged <18 years, who were undergoing other complex procedures that could not be assigned a RACHS-1 category, such as biventricular recruitment, ventricular assist devices, transplants (eg, heart and lung). Category 8 included all adults.

Outcomes of Interest

The outcomes included in the present analysis were early mortality, adverse events, and postoperative ICU length of stay. Early mortality was defined as death in the hospital or death within 30 days of the index operation if discharged before 30 days. Adverse events included those events included in the Society of Thoracic Surgeons criteria,[15,16] such as (1) the need for extracorporeal membrane oxygenator support; (2) re-exploration for bleeding; (3) cardiac arrest requiring resuscitation; (4) re-exploration for hemodynamic instability; (5) diaphragm plication for paralysis or paresis of the diaphragm; (6) stroke; (7) mediastinitis requiring exploration and debridement; and (8) renal failure requiring dialysis. Unplanned surgical or catheter-based reinterventions in the treated anatomic area and placement of permanent pacemakers were not included as adverse events, because they are components of the TPS.

Statistical Analysis

Categorical variables are summarized as numbers and percentages and continuous variables as medians and ranges. The rates of in-hospital mortality and complications were compared across TPS classes using the chi-square test, and the postoperative ICU length of stay was compared using the Kruskal-Wallis test. Similarly, mortality and complication rates were compared by the baseline patient characteristics using the chi-square test. The Mann-Whitney *U* and Kruskal-Wallis tests were used for the postoperative ICU length of stay. To adjust for baseline patient characteristics, multivariate logistic and linear regression analysis was used. For TPS, class 1 (optimal) technical performance was used as the reference group. For the RACHS-1 categories, categories 1 and 2 were combined to serve as the reference group (because no deaths or adverse events occurred in RACHS-1 category 1). In the logistic regression models, discrimination of the factors for predicting mortality and major postoperative adverse events was assessed using the area under the receiver operating characteristic curve. For the linear regression model, the coefficient of determination is presented. A log transformation was applied to the outcome, postoperative ICU length of stay, because of the skewed distribution of this variable. IBM SPSS Statistics, version 18, for Windows (SPSS Inc, Chicago, Ill) was used for statistical analysis.

RESULTS

A total of 1926 operations were done in 1714 unique patients. The baseline patient characteristics for the 1926

TABLE 1. Patient characteristics

Characteristic	Value
Male gender	1059 (55)
Age at surgery	
≤30 d	322 (16.7)
31 d to 1 y	520 (26.9)
1 y to <18 y	873 (45.3)
≥18 y	211 (10.9)
Weight (kg)	11 (1-147)
Prematurity (<37 wk)	67 (3.4)
Extracardiac and chromosomal anomaly	369 (19.1)
RACHS-1 risk category	
1	179 (9.2)
2	526 (27.3)
3	594 (30.8)
4	186 (9.6)
6	62 (3.2)
7 (Could not assign, <18 y)	168 (8.7)
8 (Adults)	211 (10.9)
STS/EACTS category	
1	726 (37.6)
2	569 (29.5)
3	138 (7.1)
4	346 (17.9)
5	98 (5.0)
Could not assign	49 (2.5)
TPSs	
Class 1, optimal, no residual	956 (49.6)
Class 2, adequate, minor residual	584 (30.3)
Class 3, inadequate, major residual, or predischarge reintervention	226 (11.7)
NA, TPS score not assigned	160 (8.3)
Early or in-hospital mortality	51 (2.6)
Adverse Events (excluding unplanned reinterventions)	111 (5.8)
Ventilator use (d)	1 (0-424)
ICU stay (d)	2 (0-424)
Hospital (d)	7 (1-424)

Data presented as n (%) for categorical variables and median (range) for continuous variables. *RACHS-1*, Risk Adjustment in Congenital Heart Surgery; *STS/EACTS*, Society of Thoracic Surgeons/European Association for Cardio-Thoracic Surgery; *TPS*, Technical Performance Score; *NA*, not assigned; *ICU*, intensive care unit.

admissions are presented in Table 1. A total of 51 deaths (2.6%) and 111 adverse events (5.8%) occurred, and the median ICU length of stay for the entire cohort was 2 days (range, 0-424). An unadjusted comparison of the outcomes based on the TPS is presented in Table E1 and Figure E1. The relationship between the TPS and RACHS-1 for mortality and adverse events is presented in Figure E2.

Mortality

On univariate analysis, TPS, age, RACHS-1 category, prematurity, and the presence of chromosomal or other noncardiac anomalies were all significantly associated with mortality ($P \leq .001$; Table E2). On multivariate modeling, after adjusting for variables that were significant on univariate analysis, the TPS remained strongly associated with mortality. A class 3 (inadequate) TPS had an odds ratio of 16.9 (95% confidence interval [CI], 6.8-42.9; $P < .001$) for mortality compared with a class 1 (optimal) TPS (Table 2).

Adverse Events and Complications

Similarly, on univariate analysis TPS, age, RACHS-1 category, and prematurity were all significantly associated with these outcomes ($P < .001$). However, the presence of chromosomal or other noncardiac anomalies was not a significant factor ($P = .354$; Table E3). On multivariate modeling, after adjusting for other significant variables, TPS remained strongly associated with adverse events. A class 3 (inadequate) TPS had an odds ratio of 6.9 (95% CI, 4.1-11.7; $P < .001$) compared with class 1 (optimal) TPS for adverse events (Table 3).

Postoperative ICU Length of Stay

On univariate analysis, TPS, age, RACHS-1 category, prematurity, and the presence of chromosomal or other noncardiac anomalies were all significantly associated with the postoperative ICU length of stay ($P < .001$; Table E4, Figure E3). On multivariate modeling, after adjusting for these significant variables, the TPS remained strongly associated with the postoperative ICU length of stay ($P < .001$). A class 3 (inadequate) TPS had a coefficient of 2.3 (95% CI, 2.0- 2.6; Table 4).

We performed a subgroup analysis of the patients with TPS class 3 (inadequate). In the entire cohort of 1926 patients, 226 (12%) had class 3 (inadequate) TPS.

TABLE 2. Multivariate modeling for mortality (n = 51/1926)

Variable	OR	95% CI	*P* value
RACHS-1 risk category			
1-2	1.0	—	—
3	2.3	0.6-8.9	.222
4	4.8	1.2-20.4	.031*
6	3.8	0.7-20.9	.126
7 (NA, <18 y)	8.1	2.0-32.4	.003*
8 (Adults)	11.0	1.8-68.8†	.010*
Age at surgery			
≤30 d	5.9	2.1-16.9	.001*
31 d to 1 y	3.8	1.4-10.5	.009*
1-18 y	1.0	—	—
Prematurity	5.8	2.4-13.9	<.001*
Extracardiac and genetic anomalies	3.1	1.5-6.2	.002*
TPS			
Class 1, optimal	1.0	—	—
Class 2, adequate	0.7	0.2-2.7	.576
Class 3, inadequate	16.9	6.7-42.9	<.001*
NA, TPS not assigned	2.6	0.7-9.7	.151

OR, Odds ratio; *CI*, confidence interval; *RACHS-1*, Risk Adjustment in Congenital Heart Surgery; *NA*, not assigned; *TPS*, Technical Performance Score. *Statistically significant. †Only 3 deaths occurred in adults, explaining the large 95% CI.

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TABLE 3. Multivariate modeling for adverse events (n = 111/1926)

Variable	OR	95% CI	*P* value
RACHS-1 risk category			
1-2	1.0	—	—
3	2.5	1.2-5.5	.018*
4	6.6	2.9-15.0	<.001*
6	7.7	2.8-21.2	<.001*
7 (NA, <18 y)	7.4	3.2-17.5	<.001
8 (Adults)	2.6	0.7-9.0	.139
Age at surgery			
≤30 d	3.0	1.6-5.7	.001*
31 d to 1 y	2.7	1.5-4.8	.001*
1-18 y	1.0	—	—
Prematurity	2.9	1.4-6.0	.004*
Extracardiac and genetic anomalies	1.2	0.7-2.0	.516
TPS			
Class 1, optimal	1.0	—	—
Class 2, adequate	0.7	0.4-1.4	.346
Class 3, inadequate	6.9	4.1-11.7	<.001*
NA, TPS not assigned	1.0	0.4-2.5	.977

OR, Odds ratio; *CI*, confidence interval; *RACHS-1*, Risk Adjustment in Congenital Heart Surgery; *NA*, not assigned; *TPS*, Technical Performance Score. *Statistically significant.

Among the 139 patients undergoing surgical or catheterization reintervention, 21 (15%) were assigned TPS class 3 because of the need for a permanent pacemaker. The distribution of TPS echocardiographic scores in the pacemaker patients was 29% class 1 (optimal), 57% class 2 (adequate), and 14% class 3 (inadequate). Of the other 118 patients (85% of reinterventions) who had undergone an unplanned surgical or catheter-based reintervention (excluding pacemakers) and were therefore placed in class 3 (inadequate), 101 (86%) had preintervention echocardiograms that could be coded, and all belonged to class 3 (inadequate). The remaining 17 patients (14%) either had echocardiograms that could not be classified or had no echocardiogram but had undergone an unplanned reintervention because of clinical indications.

TABLE 4. Multivariate modeling for postoperative ICU length of stay as surrogate for resource usage (n = 1926)

Variable	Coefficient	95% CI	*P* value
RACHS-1 risk category			
1-2	—	—	—
3	1.7	1.6-1.9	<.001
4	2.3	2.0-2.7	<.001
6	2.8	2.2-3.5	<.001
7 (NA and age <18 y)	2.3	2.0-2.7	<.001
8 (Adults)	1.4	1.2-1.6	<.001
Age at surgery			
≤30 d	2.6	2.3-3.0	<.001
30 d to 1 y	1.6	1.5-1.8	
Prematurity	1.8	1.4-2.2	<.001
Extracardiac defect	1.2	1.1-1.3	<.001
TPS			
Class 1, optimal	—	—	—
Class 2, adequate	1.2	1.1-1.3	<.001
Class 3, inadequate	2.3	2.0-2.6	<.001
NA, TPS not assigned	0.8	0.7-1.0	.024

All *P* values were statistically significant. R^2 = 40%. *CI*, Confidence interval; *RACHS-1*, Risk Adjustment in Congenital Heart Surgery; *NA*, not assigned; *TPS*, Technical Performance Score; *ICU*, intensive care unit.

All analyses were repeated using only the 1714 unique patients, and the findings were similar, with TPS an independent predictor for mortality, complications, and postoperative ICU length of stay after adjusting for other important predictive variables.

The robustness of the models in predicting outcomes is presented in Figure 1. The model for mortality had an area under the receiver operating characteristics curve (AUC) of 0.92 (95% CI, 0.88-0.96), and the model for adverse events had an AUC of 0.86 (95% CI, 0.82-0.89). The addition of TPS increased the AUC from 0.87 to 0.92 for mortality and from 0.81 to 0.86 for adverse events.

DISCUSSION

In previous work, we have demonstrated that class 1 (optimal) technical performance was associated with lower adverse event rates and a lower postoperative ICU length of stay[2] and that class 1 (optimal) TPS was able mitigate the effects of the preoperative severity of illness in a specific subset of high-risk procedures (ie, stage I Norwood procedure).[1,9] An association was also found between TPS and midterm outcomes.[10,17]

The present study has demonstrated the ability of TPS to predict early outcomes such as mortality, adverse events, and increased resource use in a diverse set of patients in a single institution. We included all consecutive patients in the present study, and the greater power allowed for better risk adjustment. We were also able to include other important preoperative variables such as prematurity, age, and presence of genetic and other noncardiac anomalies in our model, which have previously been shown to play important roles in the outcomes after congenital cardiac surgery.[18-20] We chose not to include intraoperative variables and postoperative variables in our analysis because of the high co-linearity between the TPS and these variables.

Although mortality has been routinely used as an important benchmark of a center's performance, advances in surgical technique in the past 2 decades have significantly improved survival. Therefore, mortality has become less useful in comparisons between hospitals for performance evaluation.[18] The TPS might thus serve as an important bench mark for evaluation of each center's performance.

Congenital cardiac surgery admissions (admissions included both medical and surgical) have a reported complication rate as great as 32%.[19,20] Furthermore, these studies showed a greater risk of mortality in patients with complications after adjusting for other important

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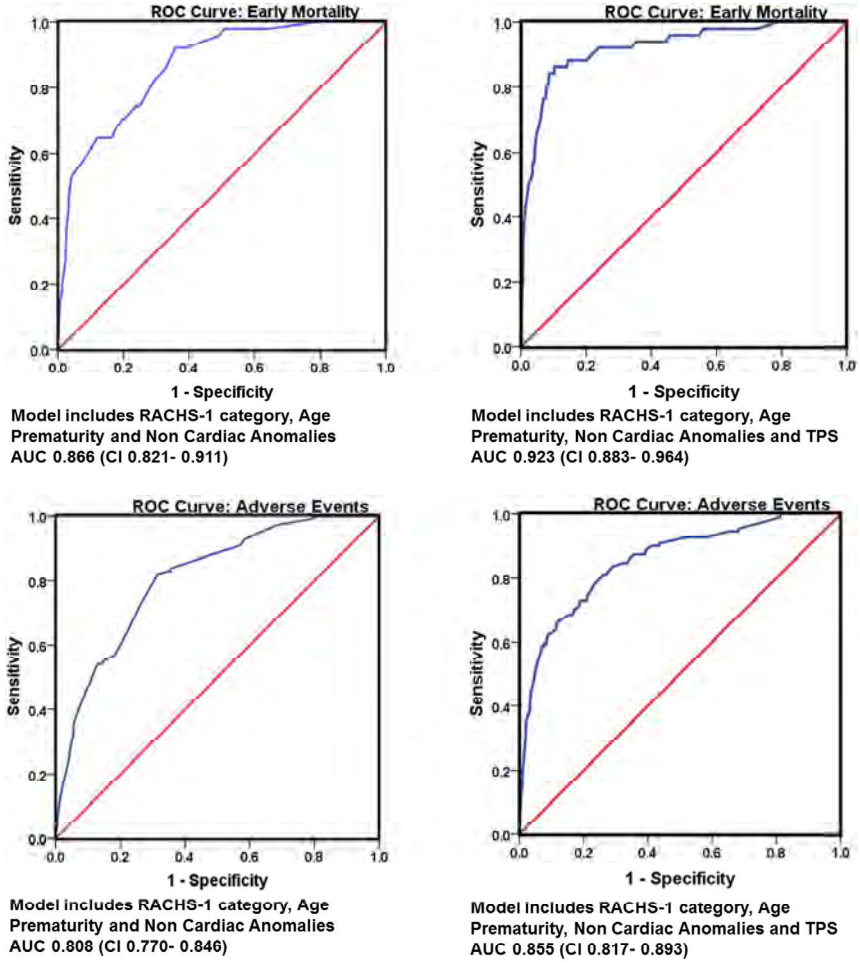


FIGURE 1. Area under the receiver operator characteristics (*ROC*) curve (*AUC*) for mortality and adverse events. *Top*, ROC curves for mortality, with (*left*), the entire model and (*right*), curve for Technical Performance Score. *Bottom*, ROC curves for adverse events, with (*left*), the entire model and (*right*), the ROC curve for Technical Performance Score. *RACHS-1*, Risk adjustment in congenital heart surgery; *CI*, confidence interval.

predictive variables. Our study had a complication rate of 5.8% related to the use of the more stringent Society of Thoracic Surgeons criteria for adverse events, with additional exclusion of unplanned surgical and catheter reinterventions and unplanned permanent pacemaker placement. Despite these lower rates, the TPS had a strong association with the occurrence of adverse events, with an odds ratio of 6.8 and the TPS having an AUC of 0.69 (Figure 1). Early recognition of an inadequate repair and intervention, perhaps even in the operating room, might help reduce the complication rate and associated mortality.[2]

Congenital heart disease has been well documented to be associated with high resource usage.[6] Furthermore, mortality and complications after congenital heart surgery are known to be associated with greater resource use.[21] Although healthcare costs remain an important measure of resource use, the psychosocial effect of prolonged hospitalization and/or multiple complications and mortality might well be more important[20,22] in the long term for both patients and family. The TPS, with its ability to predict midterm outcomes such as postdischarge mortality and unplanned reinterventions,[10,17] might thus serve as a tool that recognizes a subgroup of patients who need closer monitoring.

Our subgroup analysis of patients with TPS class 3 (inadequate) showed that a little less than two thirds (62%) were assigned a TPS class 3 (inadequate) only because of the need for unplanned reinterventions and not from echocardiographic class 3 (inadequate) results. Among those for whom the unplanned reintervention was in the treated anatomic area at the index operation, 86% had had echocardiograms before the reintervention that were scored as class 3 (inadequate), clearly indicating a strong association between technical adequacy and the need for reintervention.

It was also interesting to note that among the RACHS-1 categories, as expected, the RACHS-1 category 6 had greater mortality and adverse events and a longer post-operative ICU length of stay. Although this was expected, we also noted that those in RACHS-1 category 7

(those who were <18 years and for whom the RACHS-1 category could not be assigned) also had greater mortality and adverse events and a longer postoperative ICU length of stay. This could have been because this group predominantly consisted of patients who have undergone more complex procedures, such as biventricular recruitment in hypoplastic left heart, biventricular conversion after single ventricle palliation, VADS for end-stage heart failure, and certain complex heart and lung transplants.

Study Limitations

The present study represents a single center's experience with validation of the TPS. Testing the reproducibility of this tool across multiple centers is necessary. Furthermore, validation of the association of TPS with long-term outcomes is required. We are in the process of collecting long-term prospective data for this cohort. Although the present study included larger numbers of patients in each of the RACHS-1 categories, ideally, the association between TPS and early outcomes should be studied in individual procedural groups. We are currently involved in a multicenter study to validate the TPS prospectively in specific procedural groups, and we anticipate that this will allow us to weight each component of the score and determine the predictive value of each component. This information will be particularly important, because it would allow the TPS to be used as a tool that can help determine which patient would warrant early intervention to avoid morbidity.

CONCLUSIONS

The TPS has been shown to have a strong association with early outcomes such as mortality, adverse events, and increased resource use. It might thus allow the development of predictors for early intervention for residual anatomic problems. We speculate that it could lead to an improvement in the long-term physical, neurologic, and psychosocial development in this vulnerable high-risk population by identifying patients who would benefit from early intervention and decrease the burden of prolonged illness on patients with congenital heart disease and their families.

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

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Discussion

Dr Christopher A. Caldarone *(Toronto, Ontario, Canada).* My only disclosure is that I am a fan of technical performance scores.

"Mirror, mirror on the wall, who's the fairest of them all," so said the witch. She wanted to know how she stacked up against her peers. How did her blemishes compare to the blemishes of others? As surgeons, we all want to know the same. Aside from

comparing gross measures of mortality, we have very little ability to compare the residual lesions we commonly leave behind.

Dr Nathan and her team should be congratulated for extending the pioneering work of Emile Bacha in developing the concept of technical performance scores, a systematic approach to identifying the significance of residual lesions. You have shown us that residual lesions are common, and they contribute to mortality. This is a deceptively simple, yet transformative, concept, a mirror that we all need.

I have a few questions that will focus on a critique of the method.

First, your team evaluates numerous components for the surgical procedure and grades each component into 3 categories. This approach provides simplicity but results in inevitable loss of important information. Supporting this notion is your finding that there is very little difference between the adequate and optimal score categories—suggesting a loss of information by categorization. Why did you not create a scoring system in which continuous variables are maintained and derive a score that is itself a continuous variable? This would avoid potentially sensitive terms such as ''inadequate'' and provide greater discrimination of outcomes.

Second, your methodology includes the laudable concept of downgrading a technical performance score to match the lowest component score. This is based on the premise that each component has equal clinical significance. However, the clinical significance of 1 residual lesion could be different from another. How will you refine your scoring system in the future to take into account the difference in clinical significance of these various components?

Third, in the current version of your scoring system, when a region is not addressed by the surgeon, it is not included in the TPS. Thus, a patient with residual tricuspid insufficiency, for example, is included in the scoring system if the surgeon addressed the tricuspid valve but is not included in the scoring system if the surgeon chose not to address the residual lesion. Although this approach keeps the scoring system focused on the interventions of the surgeon, it ignores the effect of untouched residual lesions, which are of importance to the patient. Dr Nathan, should an assessment of surgical performance be limited to the subroutines performed by the surgeon or should performance be determined by the patient's overall freedom from residual lesions?

Finally, as you know, the Congenital Heart Surgeons Society, in collaboration with members of your team, has developed a web-based data entry system to provide a technical performance ''mirror'' for our participants. This system will provide new information for us to improve our patient care, but it is not clear how we will transform the concept of a TPS into improved outcomes. How do you distribute, discuss, and use TPS in Boston to improve patient outcomes? I want to thank the Association for the privilege to discuss this study.

Dr Nathan. Thank you, Dr Caldarone. Let me answer your first question, which was why we use a categorical system of scoring. The reason we chose a categorical system of scoring is because it is easily reproducible and can be used across centers. Although this does lead to some loss of information, this will allow us to test and validate the score across multiple institutions. We are actually in the process of accruing patients for a prospective multi-institutional trial. However, it is important that we also consider other methods of assessing this score.

Your second question was why all components are scored equally, and I agree with you that this is something that needs clarification. For example, a residual VSD in tetrology of Fallot is an entirely different beast than a residual VSD in primary VSD repairs. If you had a large residual VSD in tetrology of Fallot, the patients tend to do worse. Now that we have gathered data for about 2 to 3 years, we are studying the subcomponents for each procedure, and we are going to determine which of these subcomponents is important for each procedure. Hopefully, we will have the analysis in a year or 2.

Your third question was related to why we did not score residual lesions that are not intervened on. When we initially started the score, the plan was to assess the intent to treat, but only the components that the surgeon operated on were assessed. But I do agree with you, for example, in a VSD, if after a repair, you were left with greater than mild tricuspid regurgitation, I think the score would be inadequate, and we are in the process of refining the score to reflect this.

Your final question had been about how we used the score to assess how well we did. We have weekly conferences, and we review each of the surgeon's scores and determine how a procedure that had an inadequate score could have been performed better. We also have monthly mortality and morbidity conferences. Currently, we now assign scores for the intraoperative echocardiograms, and we will compare these with the discharge echocardiograms. Perhaps that will help us determine when the intervention needs to be done; thus, this tool could serve not only as an assessment tool, but also as an interventional tool.

I hope I answered all your questions.

Dr Caldarone. You did.

Dr Francois G. Lacour-Gayet *(New York, NY).* Dr Nathan, I enjoyed very much your presentation, and we have followed this TPS that was initiated by Dr Bacha with great interest. I have a question of method. How can you predict early death using a discharge echocardiogram?

Dr Nathan. I know that is an important question. Currently, the tool is just a retrospective assessment of outcomes based on the discharge echocardiogram. This is one of the reasons we are taking more interest in the intraoperative score, because I think the intraoperative score will be able to help us determine what needs to be done to prevent mortality.

Glenn Van Arsdell *(Toronto, Ontario, Canada).* That was a beautiful study, and I fully agree with it but have a little caveat. One year ago, we presented a similar controversial report that suggested if you chase after all these residual lesions in the operating room, you shift error to the ICU and that the intensive care performance also affects the outcome. I think back to a book from your institution in 1994 in which Aldo Castaneda said, nowhere in the practice of medicine is it more important to have a harmonious action between many different segments of medicine, intensive care, anesthesia, perfusion, nursing, and so forth.

Why do you suppose in your study we do not see that importance? It appears in your study that it really is only surgical performance that matters, not diagnostic performance, not intensive care performance. In our study, we saw each of those components being very important.

Dr Nathan. Thank you. I do agree that care in the ICU plays a role in the ultimate outcome; however, if a procedure is done well, I think it can mitigate some of these effects. In a previous study, we had shown that in the stage I population, if they had an optimal score, it was able to mitigate the effects of preoperative status, as determined by Pediatric Risk of Mortality scores and also postoperative status determined by Pediatric Risk of Mortality and other ICU variables.

Also, although all components shown in this chart are important for outcomes, I think the TPS perhaps has a more important role to play. If you can achieve a good operation, I think you minimize a number of the problems seen in the postoperative period.

Dr Carl L. Backer *(Chicago, Ill).* I congratulate you on using this TPS to try and improve the quality of our outcomes. The question I have is, do you have information about what the surgeon did with the intraoperative transesophageal echocardiographic results? Your performance score mostly relies on echocardiographic residual lesions. We use intraoperative transesophageal echocardiogram to identify residual lesions, and then, in a certain percentage of our patients, we correct those residual lesions immediately in the operating room. What percentage of patients underwent attempts to address those residual lesions in the operating room at the original procedure according to an intraoperative transesophageal echocardiogram?

Dr Nathan. We are studying that data now; however, approximately 3% to 4% had a return to bypass to fix a residual lesion, and this is mostly related to valve repairs. That is why it is important that we consider those intraoperative scores and discharge scores and see what the difference is in outcomes.

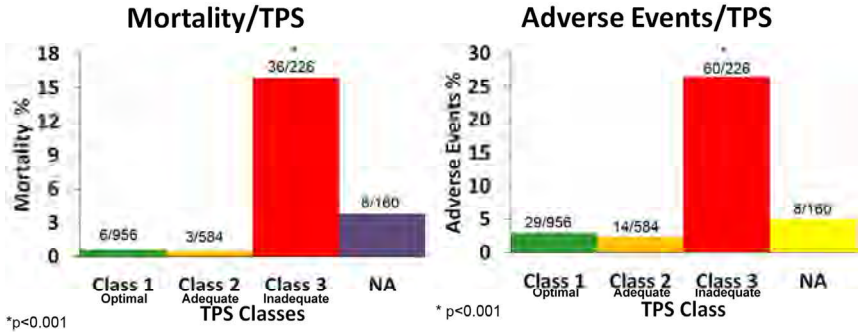


FIGURE E1. Mortality and adverse events according to Technical Performance Score (*TPS*). The number of events and total number of patients in each group is presented above each bar. *NA*, Technical performance score could not be assigned.

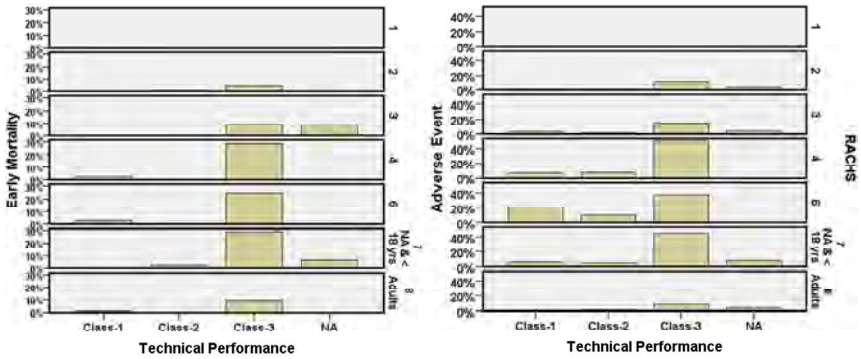


FIGURE E2. Postoperative intensive care unit (*ICU*) length of stay according to Technical Performance Score (*TPS*). The postoperative intensive care unit length of stay for each TPS class is represented as a box plot. The outliers are represented by *asterisks* and *open circles*. The median is represented by the *line in the center of each box*, and the *whiskers* represent the 25th and 75th percentile. Class 3 (inadequate) TPS had a significantly greater median length of stay (*LOS*). *NA*, No TPS score could be assigned; *RACHS*, Risk Adjustment in Congenital Heart Surgery.

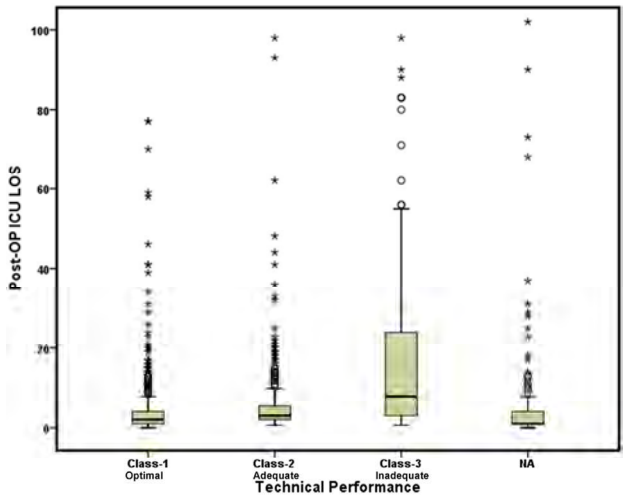


FIGURE E3. Mortality and adverse events across Risk Adjustment for Congenital Heart Surgery (*RACHS-1*) category according to the Technical Performance Score (*TPS*). The percentage of early mortality and adverse events in each TPS class using the RACHS-1 category. Class 3 (inadequate) TPS was significantly associated with greater rates of mortality and adverse events across RACHS-1 categories 2 and more, with the higher RACHS-1 categories having greater events rates. *NA &<18 years,* Patients aged <18 years who could not be assigned a RACHS-1 category. *ICU*, Intensive care unit; *LOS*, length of stay.

CHD

TABLE E1. Unadjusted comparison of outcomes according to technical performance score (n = 1926)

Variable	TPS			
	Class 1 (optimal; n = 956)	Class 2 (adequate; n = 584)	Class 3 (inadequate; n = 226)	NA (TPS not assigned; n = 160)
In-hospital mortality	6/956 (0.6)	3/584 (0.5)	36/226 (15.9)	6/160 (3.8)
Adverse events	29/956 (3.0)	14/584 (2.4)	60/226 (26.5)	8/160 (5.0)
Postoperative ICU LOS	2 (0-366)	3 (1-98)	8 (1-424)	1 (0-376)

Categorical variables presented as n (%) and continuous variables as median (range). Class 3 (inadequate) TPS had a $P < .001$ for all outcomes. *TPS*, Technical Performance Score; *NA*, not assigned; *ICU*, intensive care unit; *LOS*, length of stay.

CHD

TABLE E2. Univariate analysis of in-hospital mortality (n = 51/1926)

Variable	Total	In-hospital death (n)	Mortality rate (%)	*P* value
TPS				<.001*
Class 1, optimal	956	6	0.6	
Class 2, adequate	584	3	0.5	
Class 3, inadequate	226	36	15.9	
NA, no TPS could be assigned	160	6	3.8	
RACHS-1 risk category				<.001*
1	179	0	0.0	
2	526	3	0.6	
3	594	13	2.0	
4	186	14	7.5	
6	62	5	8.1	
7 (NA, age <18 y)	168	14	8.3	
8 (Adults)	211	2	1.4	
Age at surgery				<.001*
≤30 d	322	25	7.8	
31 d to 1 y	520	17	3.3	
1-18 y	873	6	0.7	
Prematurity				<.001*
Yes	67	13	19.4	
No	1859	38	2.0	
Extracardiac and/or genetic anomaly				.001*
Yes	369	19	5.1	
No	1557	32	2.1	

Patients age ≥18 years constituted both RACHS-1 risk category NA and adult and age at surgery category ≥18 years; these 211 patients were included under RACHS-1 risk category only (category 8). *TPS*, Technical Performance Score; *RACHS-1*, Risk Adjustment in Congenital Heart Surgery; *NA*, not assigned. *Statistically significant.

TABLE E3. Univariate analysis of adverse events (n = 111/1926)

Variable	Total	In-hospital adverse events (n)	Adverse event rate (%)	*P* value
TPS				<.001*
Class 1, optimal	956	29	3.0	
Class 2, adequate	584	14	2.4	
Class 3, inadequate	226	60	26.5	
NA, no TPS could be assigned	160	8	5.0	
RACHS-1 risk category				<.001*
1	179	0	0.0	
2	526	10	1.9	
3	594	29	4.9	
4	186	31	16.7	
6	62	14	22.6	
7 (NA, age < 18 y)	168	23	13.7	
8 (Adults)	211	4	1.9	
Age at surgery				<.001*
≤30 d	322	48	14.9	
31 d to 1 y	520	36	6.9	
1-18 y	873	23	2.6	
Prematurity				<.001*
Yes	67	16	23.9	
No	1859	95	5.1	
Extracardiac and/or genetic anomaly				.354
Yes	369	25	6.81	
No	1557	86	5.5	

Patients aged ≥18 years constituted both RACHS-1 risk category NA and Adult and age at surgery category ≥18 years; these 211 patients were included under RACHS-1 risk category (category 8) only. *TPS*, Technical Performance Score; *RACHS-1*, Risk Adjustment in Congenital Heart Surgery; *NA*, not assigned. *Statistically significant.

TABLE E4. Univariate analysis for median postoperative ICU length of stay as surrogate for resource usage (n = 1926 admissions)

	Total (n)	Median postoperative ICU LOS	*P* value
TPS			<.001*
Class 1, optimal	956	2 (0-366)	
Class 2, adequate	584	3 (1-98)	
Class 3, inadequate	226	8 (1-424)	
NA, not able to assign TPS	160	1 (0-376)	
RACHS-1 risk category			<.001*
1	179	1 (0-366)	
2	526	2 (0-365)	
3	594	3 (1-256)	
4	186	7 (1-270)	
6	62	12 (1-70)	
7 (NA and age <18 y)	168	5 (1-424)	
8 (Adults)	211	2 (1-28)	
Age at surgery			<.001*
≤30 d	322	7 (1-376)	
31 d to 1 y	520	3 (0-424)	
1-18 y	873	2 (0-366)	
Prematurity			<.001*
Yes	67	8 (1-376)	
No	1859	2 (0-424)	
Extracardiac and/or genetic anomaly			<.001*
Yes	369	3 (1-424)	
No	1557	2 (0-424)	

Data in parentheses are ranges. Adults were analyzed only once as a part of the RACHS-1 category (category 8). *TPS*, Technical Performance Score; *RACHS-1*, Risk Adjustment in Congenital Heart Surgery; *NA*, not assigned; *ICU*, intensive care unit; *LOS*, length of stay. *Statistically significant.

GENERAL CONCLUSIONS

CHAPTER 134

QUALITY IMPROVEMENT: SURGICAL PERFORMANCE

Meena Nathan • John M. Karamichalis

CHAPTER OUTLINE

BACKGROUND
DEVELOPMENT OF THE TECHNICAL PERFORMANCE SCORE
PILOTING THE TECHNICAL PERFORMANCE SCORE
STANDARDIZATION OF METHODOLOGY
VALIDATION OF TECHNICAL PERFORMANCE SCORE
FUTURE DIRECTION
APPENDIX 134-1: BOSTON CHILDREN'S HOSPITAL TECHNICAL PERFORMANCE SCORE

BACKGROUND

According to the Centers for Disease Control and Prevention (CDC),[1] congenital heart disease (CHD) is the most common type of birth defect, affecting 1% of the population (40,000 births/year). CHD is the leading cause of illness and death associated with birth defects. Fifteen percent of all patients with CHD have associated genetic conditions, and 20% to 30% have physical, developmental, or cognitive problems.[2-5] In 2004, the health care cost for hospitalization of individuals with CHD was approximately $1.4 billion.[1] It is now feasible to offer surgical correction or palliation to most of these patients. In 2011, 33,733 congenital cardiac procedures were reported to the Society of Thoracic Surgeons (STS).[6] Between 1999 and 2006, CHD was listed as the primary cause of death in 27,960 people. Among these, 48% were infants, often following complex interventions and prolonged ICU 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 an enormous challenge to the health care environment where optimal care can greatly influence not only short-term but also long-term physical, intellectual, and psychosocial outcomes.

Outcomes in congenital cardiac surgery are multifactorial and may be affected by (1) preoperative status, such as patient factors (e.g., birth weight, gestational age, complexity of CHD), hemodynamic stability, adequacy of diagnostic evaluation, and appropriateness of the surgical plan; (2) intraoperative factors, such as conduct of anesthesia and cardiopulmonary bypass, surgical technique, and early post-bypass hemodynamic management; and (3) postoperative course, such as serious adverse events and complications. Among these many factors, technical adequacy of repair is likely a significant determinant of successful outcome. Indeed, the degree to which a congenital heart operation achieves its intended result may be the single most important factor determining long-term medical outcomes and costs.

Until recently, hospital mortality, often in the form of cumulative sum (CUSUM) analysis, had been used as a surrogate measure of technical performance in congenital heart surgery.[7-9] Raw mortality data, however, do not correct for case complexity or other associated factors that can affect outcomes. One alternative, the hospital standardized mortality ratio (HSMR), is intended as an overall measure of in-hospital deaths, a proportion of which are preventable. High ratios may thus suggest potential problems with quality of care.[10] The HSMR is a complex but inexpensive and relatively easy method to calculate, from national or other benchmark data, the patients' predicted risk of death. However, there are a number of methodological challenges in HMSR's construction and interpretation, largely because they are based on administrative databases.[11] Although risk-adjusted in-hospital death rates may be a reasonable measure of institutional performance, this measure is inadequate to assess the performance of individual physicians because many additional factors outside the control of an individual surgeon (e.g., the contribution and impact of other team members) must also be considered. This is especially problematic for high-risk operations, which require a complex multidepartmental microsystem of dedicated teams composed of many individuals and specialties.

The technical performance score (TPS), developed to address the lack of systematic methods for evaluating operative technical adequacy across diagnoses and centers,

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is a novel tool for assessing technical competency based on widely available clinical and echocardiographic characteristics.

DEVELOPMENT OF THE TECHNICAL PERFORMANCE SCORE

TPS was developed at Boston Children's Hospital to assess the adequacy of anatomic repair. The technical steps toward an adequate anatomic repair of a lesion are mostly under the control of the surgeon. Intraoperative technical excellence is one of the key factors in determining outcomes, especially in high-acuity operations.[12-14] A deficit in tools available to measure technical adequacy of a surgical procedure was key to the development of the TPS. This tool was designed to be used for peer and self-assessment and was initially piloted in selected surgical procedures, including repairs of ventricular septal defect, tetralogy of Fallot, complete common atrioventricular canal, arterial switch, and, later, the stage I Norwood procedure.[15,16] The use was then expanded to include more than 90% of congenital cardiac surgery operations.[17]

The score was created by dividing the surgical procedure into individual subcomponents or subprocedures, based on specific anatomic regions intervened on surgically. TPS is then assessed based on echocardiographic criteria that are designed to capture the individual components of specific operations, as well as unplanned surgical or catheter-based re-interventions prior to discharge in the anatomic areas relevant to the surgical procedure. The components of the score were defined and piloted by a modified consensus process of cardiologists and cardiac surgeons at our center. Based on these prespecified components (subprocedures) that were particular to each operation, each discharge echocardiogram could be classified into one of three categories (class 1 = optimal, class 2 = adequate, or class 3 = inadequate). If all subprocedures have a class 1 optimal score, the overall score for the entire procedure will be class 1 (optimal). If any individual subprocedure is scored as class 1 or 2, the overall TPS for the procedure will be class 2 (adequate). If any subprocedure is scored as class 3 (inadequate), or if the patient undergoes at least one surgical or catheter-based re-intervention in the anatomic area of interest prior to discharge, the TPS will be class 3. Certain specific procedures that result in an unexpected implantation of a permanent pacemaker will also result in the procedure being scored as inadequate (class 3).

PILOTING THE TECHNICAL PERFORMANCE SCORE

Initial validation was performed in four procedural groups—ventricular septal defect, tetralogy of Fallot, complete common atrioventricular canal, and arterial switch operation—using data from 2004.[15] Despite significant diversity and complexity among procedures, technical adequacy of repair could be successfully determined in this group of congenital cardiac procedures using the TPS tool.

TABLE 134-1 **Association between Technical Performance Score and Outcomes in the Norwood Population**

	Optimal	Adequate	Inadequate	*P* Value
Hospital LOS median (range)	18 (2-96)	19 (4-141)	33 (1-125)	0.02
Hospital mortality	4 (5%)	2 (11%)	3 (27%)	0.02
ECMO	6 (8%)	2 (11%)	8 (53%)	<0.001

ECMO, Extracorporeal membrane oxygenation; *LOS,* length of stay.

The TPS tool was then validated for the stage I procedure by a retrospective analysis of 110 patients from January 2004 to December 2006. There were 77 (70%) in the optimal group, 18 (16%) in the adequate group, and 15 (14%) in the inadequate group. Inadequate technical performance was significantly associated with greater early mortality, occurrence of adverse events (such as need for extracorporeal membrane oxygenation), and length of stay (Table 134-1).[16]

A subgroup analysis of TPS in the Norwood population showed that optimal technical performance attenuated the effects of preoperative physiologic status and case complexity with reduced hospital mortality.[12]

STANDARDIZATION OF METHODOLOGY

As part of standardization of the tool for use among multiple institutions, we developed standardized echo protocols for echo acquisition and developed anatomic modules that could be used to standardize the images obtained by the echocardiographer performing the discharge echocardiogram. These anatomic modules (Appendix 134-1) also enable the clinician finalizing the TPS to be able to accurately score all components adequately.

VALIDATION OF TECHNICAL PERFORMANCE SCORE

In subsequent studies we were able to show that TPS was useful in predicting both short- and mid-term outcomes.[13,18-21] Specifically, to define the relationship between TPS and major postoperative adverse events, we performed a prospective study[13] that included intraoperative observations of operations in risk adjustment for congenital heart surgery (RACHS-1)[22,23] categories 2 through 6 in 166 infants younger than 6 months. For the entire cohort, optimal TPS resulted in lower postoperative adverse events, lower postoperative pediatric risk of mortality (PRISM)[24] score, lower length of intensive care unit (ICU) stay and hospital stay, and shorter ventilation time ($P < 0.001$). Optimal TPS also resulted in low postoperative adverse events independent of RACHS-1 category, or preoperative PRISM (Fig. 134-1). In multivariable logistic regression, the strongest independent predictors of postoperative major adverse events were TPS, RACHS-1 category, and preoperative PRISM. In a

prospective follow-up study of our cohort of neonates and infants from index surgery for a minimum of 1 year, 7 of the 166 patients had early mortality.[18] Among the remaining 159 patients, late death occurred in 13, and late unplanned interventions (in the anatomic area operated on at index surgery) were performed in 55. Using univariate analysis, inadequate TPS was associated with postdischarge mortality ($P < 0.0001$) and re-intervention ($P = 0.034$). However, on multivariable modeling, inadequate TPS was an independent predictor of only postdischarge mortality ($P = 0.017$) (Fig. 134-2). To expand the number of patients available for analysis and thereby to improve power, we performed a retrospective study of 725 patients who were followed for a minimum of 4 years[21]; TPS was an independent predictor in multivariable analysis of both late postdischarge mortality and unplanned re-interventions (Fig. 134-3).

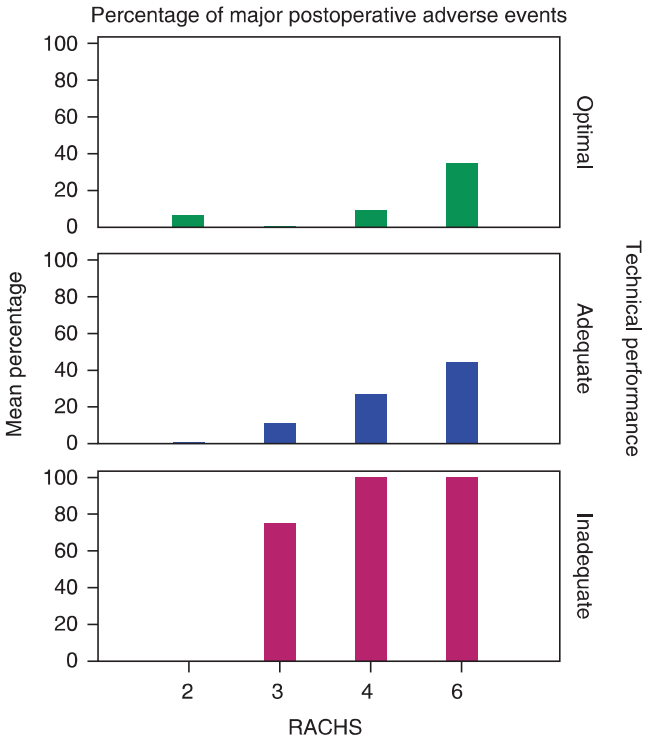


FIGURE 134-1 ■ Major postoperative adverse events as predicted by technical performance score and risk adjustment for congenital heart surgery (RACHS-1) risk categories in a prospective cohort of 166 infants younger than 6 months of age.

We also studied the association of TPS with neurodevelopmental outcomes using the Bayley Scale of Infant Development (BSID) III scores in a group of 140 children who underwent their initial cardiac operation in the first year of life.[19] Inadequate TPS was an independent predictor of poor neurodevelopmental outcomes after adjusting for other significant patient-related factors (Table 134-2).

To enhance the simplicity and reproducibility of TPS assessment, we subsequently modified the TPS to exclude intraoperative revisions (the initial five modules included such revisions as a criterion by which TPS automatically fell to class 2 [adequate]). We created 30 procedural modules and then validated these modules by prospectively assigning TPS to all discharged patients undergoing operations for CHD at our center. All patients who were discharged between January 1, 2011, and April 30, 2013, were included in this study.[20] TPS was optimal in 956 (50%), adequate in 584 (30%), inadequate in 226 (12%), and indeterminate in 160 patients (8%). There were 51 (2.6%) early deaths and 111 (5.7%) major adverse events (Fig. 134-4). In univariate analyses, mortality and occurrence of adverse events were significantly associated with age, RACHS-1 categories, and TPS. In multivariable regression analyses, inadequate TPS was a strong independent predictor of mortality ($P < 0.001$; OR [odds ratio], 16.9; 95% confidence interval [CI], 6.7-42.9), adverse events ($P < 0.001$; OR, 6.9; 95% CI, 4.1-11.6), and ICU length of stay ($P < 0.001$; coefficient, 2.3; 95% CI, 2.0-2.6).

We subsequently analyzed hospital cost data in this group of patients and found that class 3 (inadequate) TPS was associated with a significantly higher hospital cost after adjusting for other significant variables such as RACHS-1 risk category, age, prematurity, genetic syndromes, presence of extracardiac nonchromosomal anomalies, weekend admissions, and the need for multiple procedures at index surgery (Table 134-3; Fig. 134-5).[24a] TPS was an independent predictor of increased total hospital cost with the percentage of variance explained (R^2) increasing from 42% to 53% when TPS was added to the

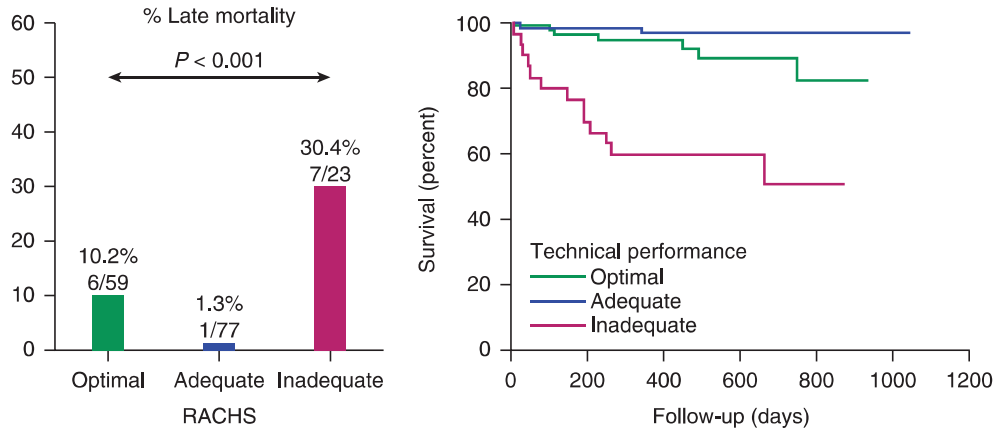


FIGURE 134-2 ■ Association between technical performance score and postdischarge mortality in a prospective cohort of 166 infants younger than 6 months of age. *RACHS,* Risk adjustment for congenital heart surgery.

TABLE 134-2 Multivariable Analysis of Bayley Scale of Infant Development (BSID) Cognitive Composite Score Adjusting for Preoperative Factors (Total R^2 = 14.6%)

	Regression Coefficient (SE)	*P* Value	Regression Coefficient (SE)	*P* Value	Partial R^2
Chromosomal anomalies	−15.1 (5.3)	0.005	−14.4 (5.2)	0.007	5.4%
Nonchromosomal anomalies	−10.4 (4.2)	0.02	−10.2 (4.2)	0.02	4.2%
RACHS-1 category 6	−11.4 (5.0)	0.03	−7.7 (5.3)	0.15	1.5%
TPS (vs. optimal)					
Adequate	—		−2.4 (3.1)	0.45	3.9%
Inadequate	—		−12.5 (5.1)	0.02	

The model on the left includes all presurgical and surgical risk factors significant at the 0.10 level. The model on the right adds in TPS. Inadequate TPS was significantly associated with a lower score after adjusting for chromosomal and nonchromosomal anomalies and RACHS-1 category.
RACHS-1, Risk adjustment for congenital heart surgery; *TPS,* technical performance score.

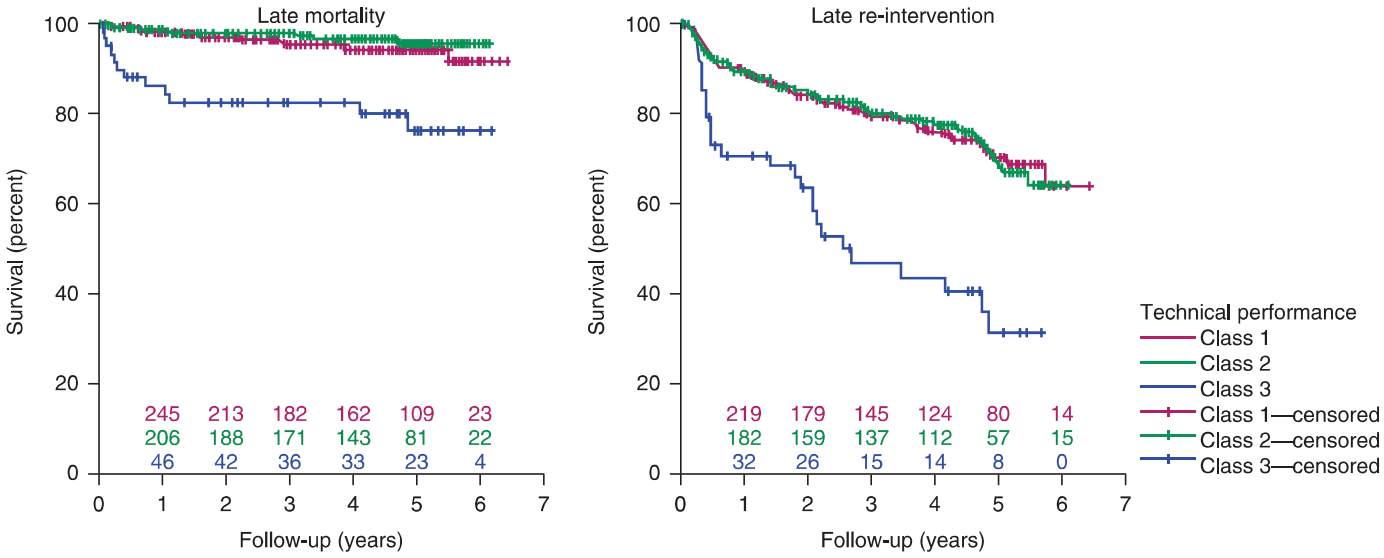


FIGURE 134-3 ■ Association between technical performance score and postdischarge mortality and postdischarge unplanned re-intervention in a cohort of 725 patients followed for 4 years.

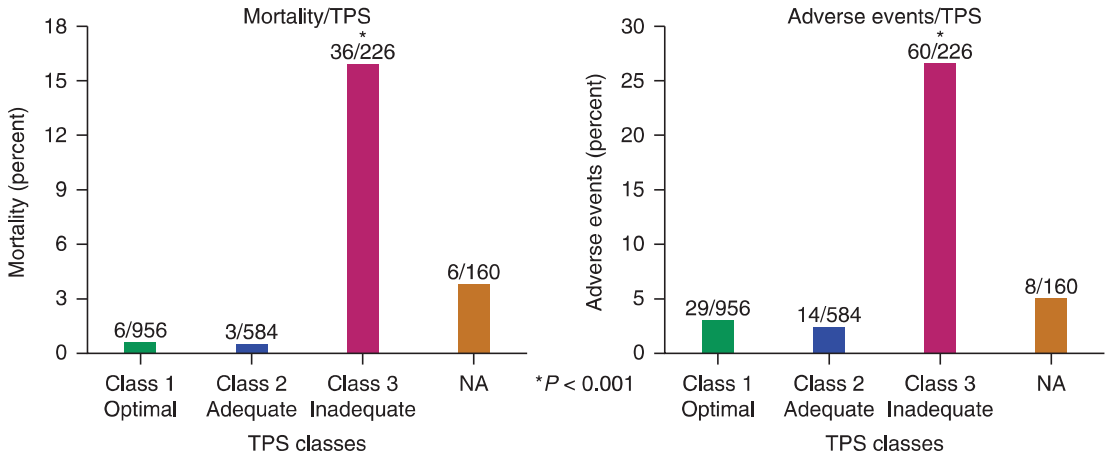


FIGURE 134-4 ■ Mortality and adverse events based on technical performance score in a prospective cohort of 1926 patients. *NA,* TPS could not be assigned; *TPS,* technical performance score.

model, indicating that TPS explained a large additional fraction of variability in total hospital cost.

To explore the predictive validity of TPS within the multicenter environment of the Pediatric Heart Network, we recently performed a secondary analysis using the database of the Single Ventricle Reconstruction (SVR) trial. Specifically, in this 15-center study, we demonstrated that inadequate TPS was an independent predictor of longer time to extubation, higher early mortality, longer Norwood hospital length of stay (Fig. 134-6), greater

TABLE 134-3 **Multivariable Analysis of Total Hospital Costs ($n = 1762$)***

Variable	*n*	Coefficient	Confidence Interval	*P* Value
RACHS-1 category				<0.001 all
1	179	Ref	—	
2	474	1.31	(1.18, 1.44)	
3	532	1.89	(1.71, 2.09)	
4	166	2.35	(2.07, 2.67)	
6	60	2.78	(2.32, 3.33)	
NA < 18 yr	143	2.64	(2.32, 3.00)	
Adults	208	1.87	(1.67, 2.09)	
Age				<0.001 all
Neonate	315	1.76	(1.62, 1.92)	
Infant	427	1.29	(1.21, 1.38)	
Children	779	Ref	—	
Prematurity				<0.001
Yes	63	1.47	(1.28, 1.69)	
Genetic syndromes				<0.001
Yes	93	1.24	(1.11, 1.39)	
Extracardiac anomalies				<0.001
Yes	116	1.36	(1.22, 1.50)	
Weekend admission				<0.001
Yes	98	1.34	(1.20, 1.51)	
Multiple procedures at index surgery				<0.001
Yes	250	1.31	(1.21, 1.41)	
Technical performance score				
Optimal	879	Ref	—	0.036
Adequate	544	1.07	(1.00, 1.13)	<0.001
Inadequate	198	2.01	(1.84, 2.20)	<0.001
Not scorable	141	0.61	(0.55, 0.67)	

*Inadequate TPS was associated with higher costs after adjusting for all variables known to be associated with higher hospital costs.

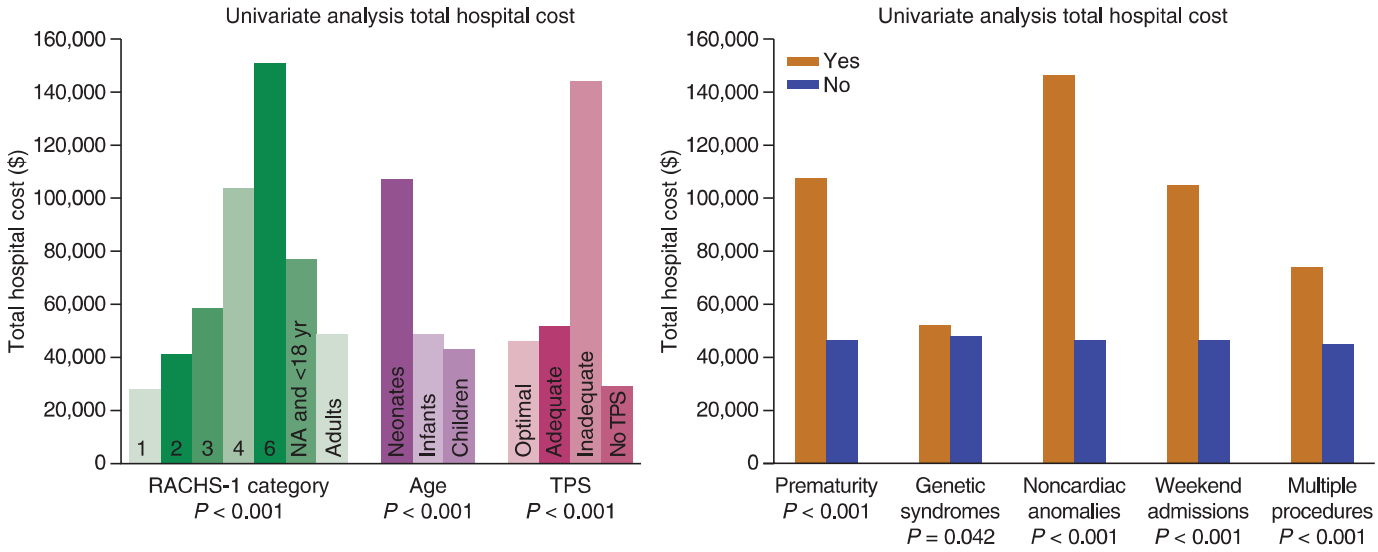


FIGURE 134-5 ■ Inadequate technical performance score (TPS) is associated with higher hospital costs. *NA,* Noncategorizable in RACHS-1 category; *RACHS,* risk adjustment for congenital heart surgery.

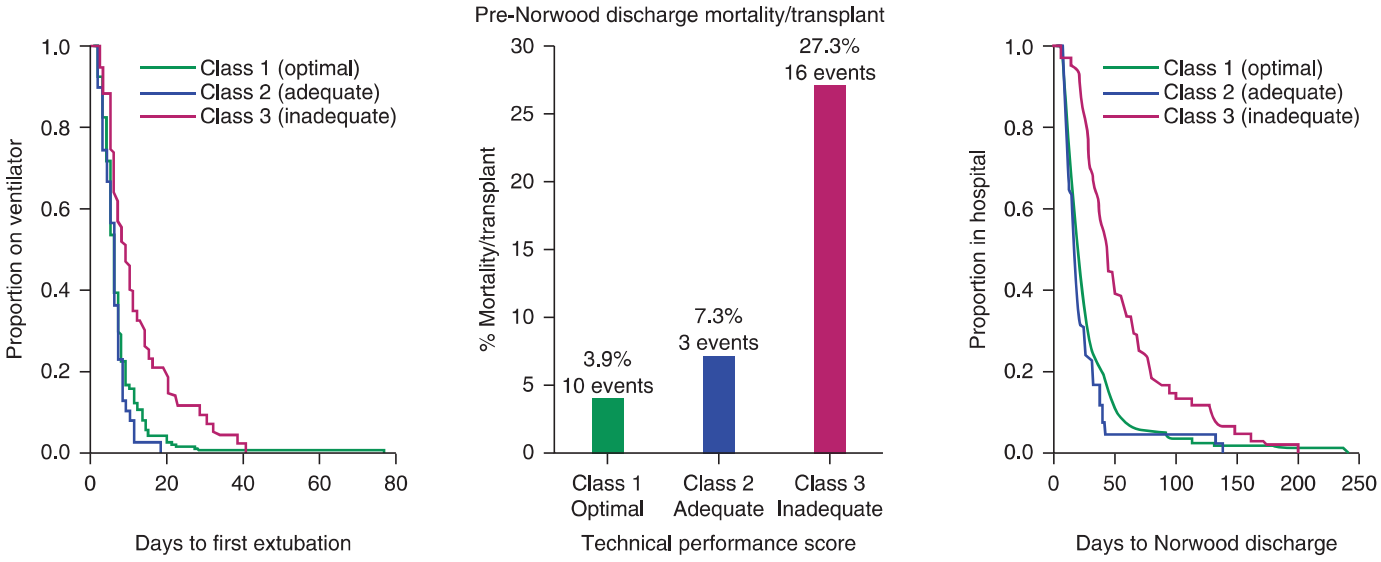


FIGURE 134-6 ■ Inadequate technical performance score is associated with longer time to extubation, higher mortality, and longer Norwood hospital length of stay in the Single Ventricle Reconstruction trial cohort.

proportion of pre–stage II re-interventions and lower Psychomotor Development Index scores at 14 months after adjusting for important preoperative factors.[25]

FUTURE DIRECTION

Mortality and adverse events are no longer considered to be major outcome measures of quality of care. With current advances in surgical and other related technologies, attention is being turned to more subtle measures such as neurodevelopmental outcomes, resource utilization in the form of length of stay, readmissions, and unplanned postdischarge re-intervention. Although the role of human factors in outcomes after surgery has been well described,[26-28] technical adequacy of the repair may still be the single most important factor in determining these more subtle outcomes; this has been demonstrated in other surgical fields.[29-31] Models of surgical skills assessment, including video recordings of skill tests and other methods, have been developed as part of surgical training programs.[32-35] However, the use of a routine test (i.e., a test that is clinically indicated) as a tool for assessment of technical adequacy has not been described.

Our studies have shown that technical adequacy of the repair, as measured by TPS, has emerged as an important predictor of outcomes in congenital surgery. We describe a "technical imperative," defined as an absolute rule whereby it is imperative to leave the operating room with a good or, better yet, an optimal technical result, even if this requires surgical revision and going back on bypass.[12-14,16] Thus, a focus on the intraoperative assessment of the adequacy of the anatomic repair, primarily by echocardiography but also by pressure measurements and even intraoperative angiography, is paramount. Increasing intraoperative vigilance so as to detect and immediately repair significant residual lesions remains of prime importance. Our studies also indicate that residual defects repaired in a timely fashion, which usually means immediately in the operating room or within 24 hours of surgery, result in no significant impact on patient outcome, even in highly complex cases.

The development and implementation of a system for measuring technical performance in congenital cardiac surgery operations can be used not only as an outcomes measurement tool but also as a tool for surgeons' self and peer assessments. It can help determine how much of the interinstitutional variation can be attributed to adequacy of surgical repair versus other contributory factors, such as patient- and institution-related factors. The use of the TPS in conjunction with a risk adjustment method, such as RACHS-1, Aristotle, or STS-EACTS,[22,23,36-38] allows for quality improvement for specific risk populations and enables a structured approach to management based on procedural complexity. TPS need not be limited to congenital cardiac procedures but may be applied to adult cardiac operations and, in fact, could potentially be expanded across all surgical specialties. This system may also be applicable to noncardiac procedures, such as interventional cardiac catheterization, electrophysiologic ablations, and radiologic interventions.

Prospective multicenter validation of this tool will allow for further refinement of the score, particularly for procedures such as valve repairs and prosthetic valve replacement. Accrual of data on sufficiently large numbers in each procedural group will allow us to determine the relative importance of the various components of each procedure and will lead to the development of a weighted scale for the components of each procedure. This will then enable us to determine which patient with a TPS of class 2 or class 3 would warrant closer follow-up and perhaps earlier intervention to optimize outcomes, thus improving quality of life while minimizing resource utilization and indirectly having a positive impact on health care costs. Development of TPS for intraoperative post-bypass transesophageal echocardiograms and epicardial echocardiograms would allow for timely correction of residual defects and lead to significant improvements in physical, psychosocial, and fiscal costs.

APPENDIX 134-1: BOSTON CHILDREN'S HOSPITAL TECHNICAL PERFORMANCE SCORE

Subprocedures	1	2	3	Other Modules
Aortic Arch, Descending Aorta				
Descending aorta	No or trivial gradient Peak gradient < 20 mm Hg	Mild gradient Peak gradient 20-40 mm Hg	Moderate to severe gradient Peak gradient > 40 mm Hg	
Aortic arch	No or trivial gradient Peak gradient < 20 mm Hg No apparent narrowing by imaging or color Doppler jet width	Mild gradient Peak gradient 20-40 mm Hg or < 30% narrowing by imaging or color Doppler jet width	Moderate to severe gradient Peak gradient > 40 mm Hg or > 30% narrowing by imaging or color Doppler jet width	
Aortic Valve/Truncal Valve (Repair)				
Aortic valve repair Truncal valve repair	No or trivial stenosis Peak gradient < 20 mm Hg No or trivial regurgitation VC < 1 mm if < 10 kg VC < 2 mm if > 10 kg	Mild stenosis Peak gradient 20-40 mm Hg Mild regurgitation VC 1-2 mm if < 10 kg VC 2-4 mm if > 10 kg	Moderate to severe stenosis Peak gradient > 40 mm Hg Moderate to severe regurgitation VC > 2 mm if < 10 kg VC > 4 mm if > 10 kg	LVOT Supra-aortic anastomosis/ repair
Aortic Valve/Truncal Valve Replacement				
Prosthetic valve implantation	Trivial or no stenosis Peak velocity < 2.5 m/sec Trivial to no regurgitation	Mild stenosis Peak velocity < 3.5 m/sec Minor paravalvular leak (VC < 2 mm)	Moderate or severe stenosis Peak velocity > 3.5 m/sec Significant paravalvular leak (VC > 2 mm)	LVOT Supra-aortic anastomosis
Autograft implantation	No aortic valvar regurgitation or stenosis VC < 2 mm	Trivial to mild regurgitation or stenosis VC 2-4 mm Peak gradient < 30 mm	Moderate or severe stenosis Peak gradient > 30 mm Moderate or severe regurgitation VC > 4 mm	LVOT Supra-aortic anastomosis
Atrial Septum/Atrial Septectomy				
Atrial septectomy	No or trivial gradient Mean gradient < 2 mm Hg (Restrictive atrial septum left on purpose; higher gradient acceptable)	Mild residual obstruction Mean gradient 2-4 mm Hg (unless intended)	Moderate to severe residual obstruction Mean gradient > 4 mm Hg (unless intended)	
ASD Repair, Patch/Primary, Common Atrium/Sinus Venosus				
ASD repair	No or trivial residual shunt <2 mm if > 10 kg <1 mm if < 10 kg	Small residual shunt 2-3 mm if > 10 kg 1-2 mm if < 10 kg	Residual shunt >3 mm if > 10 kg >2 mm if > 10 kg	
SVC (for superior sinus venosus defect) IVC (for inferior sinus venosus defect)	No SVC obstruction Mean gradient < 2 mm Hg No IVC obstruction Mean gradient < 2 mm Hg	Trivial to mild SVC obstruction Mean gradient 2-4 mm Hg Trivial to mild IVC obstruction Mean gradient 2-4 mm Hg	Mild or greater SVC obstruction Mean gradient > 4 mm Hg Mild or greater IVC obstruction Mean gradient > 4 mm Hg	

Subprocedures	1	2	3	Other Modules
AVV Plasty				
Left AV valve plasty (subaortic AV valve)	No or trivial stenosis Mean gradient < 3 mm Hg No or trivial regurgitation VC < 1 mm if < 10 kg VC < 2 mm if > 10 kg	Mild stenosis Mean gradient 3-6 mm Hg Mild regurgitation VC 1-2 mm if < 10 kg VC 2-4 mm if > 10 kg	Moderate or severe stenosis Mean gradient > 6 mm Hg Moderate or severe regurgitation VC > 2 mm if < 10 kg VC > 4 mm if > 10 kg	
Right AV valve plasty (subpulmonary AV valve)	No or trivial stenosis Mean gradient < 3 mm Hg No or trivial regurgitation VC < 3 mm if < 10 kg VC < 4 mm if > 10 kg	Mild stenosis Mean gradient 3-6 mm Hg) Mild regurgitation VC 3-5 mm if < 10 kg VC 4-6 mm if > 10 kg	Moderate or severe stenosis Mean gradient > 6 mm Hg Moderate or severe regurgitation VC > 5 mm if < 10 kg VC > 6 mm if > 10 kg	
Tricuspid valve annulus plication (cone)	No anatomic disruption of plication No coronary injury	No anatomic disruption of plication No coronary injury	Dehiscence of plication Coronary artery injury	
RV/RA plication/ excision (cone)	No anatomic disruption of plication No coronary injury	No anatomic disruption of plication No coronary injury	Dehiscence of plication Coronary artery injury	
AVV Replacement				
Mitral valve implantation	Trivial or no stenosis Mean velocity < 1.5 m/sec No paravalvar leak (follow manufacturer's guidelines for stenosis for prosthetic valve)	Mild stenosis Mean velocity 1.5-2.5 m/sec Minor paravalvular leak (VC < 2 mm)	Moderate or severe stenosis Mean velocity > 2.5 m/sec Significant paravalvular leak (VC > 2 mm)	Coronary
Tricuspid valve implantation	Trivial or no stenosis Mean velocity < 1.5 m/sec No paravalvar leak (follow manufacturer's guidelines for stenosis if prosthetic valve)	Mild stenosis Mean velocity 1.5-2.5 m/sec Minor paravalvular leak (VC < 2 mm)	Moderate or severe stenosis Mean velocity > 2.5 m/sec Significant paravalvular leak (VC > 2 mm)	Coronary
Branch Pulmonary Artery Reconstruction				
Branch pulmonary artery reconstruction	No residual stenosis Peak gradient < 20 mm Hg No discrete narrowing by imaging or color Doppler jet width	Mild residual stenosis Peak gradient 20-40 mm Hg or < 30% narrowing by imaging or color Doppler jet width	Moderate to severe residual stenosis Peak gradient > 40 mm Hg or > 30% narrowing by imaging or color Doppler jet width	
BT/Sano/Other Systemic to Pulmonary Artery Shunts, Including Unifocalization				
BT/Sano/other systemic to pulmonary artery shunts	Patent	Patent	Partial or complete occlusion, distortion of branch pulmonary arteries	
Cavopulmonary Anastomosis				
SVC-PA anastomosis Main pulmonary artery patch plasty	No obstruction No pulmonary artery distortion Mean gradient < 2 mm	Mild distortion or obstruction Mean gradient 2-4 mm Hg	Moderate to severe obstruction Mean gradient > 4 mm Hg	
IVC inflow	No or trivial obstruction Mean gradient < 2 mm Hg	Mild obstruction Mean gradient 2-4 mm Hg	Moderate to severe obstruction Mean gradient > 4 mm Hg	
Tunnel/conduit–pulmonary artery anastomosis	No or trivial obstruction Mean gradient < 2 mm Hg	Mild distortion or obstruction Mean gradient 2-4 mm Hg	Moderate to severe obstruction Mean gradient > 4 mm Hg	
Fenestration (if present)	Patent	Patent	Fenestration not patent	
Coronary Reimplantation/Unroofing				
Coronaries reimplantation/ unroofing/baffle	No obstruction to coronary flow	No obstruction to coronary flow	Coronary flow compromise, ischemia/ infarction, with echo and/or ECG findings	Aortic valve Supra-aortic anastomosis

Continued

Subprocedures	1	2	3	Other Modules
LVOT/Sub-Aortic Stenosis Resection				
LVOT	Trivial LVOT obstruction (MIG < 20 mm Hg)	Mild LVOT obstruction (MIG 20-40 mm Hg)	Moderate or severe LVOT obstruction (MIG > 40 mm Hg)	Aortic valve Supra-aortic anastomosis
PDA Ligation/Division				
PDA closure	No residual PDA	Residual PDA ≤ 1 mm	Re-intervention *or* Residual PDA > 1 mm	Arch and descending aorta Branch pulmonary arteries
Pulmonary Valve Intervention				
Pulmonary valve reconstruction Valve sparing	No residual obstruction RVOT peak gradient < 20 mm Hg No or mild pulmonary valve regurgitation VC < 3 mm if < 10 kg VC < 5 mm if > 10 kg	Mild residual obstruction RVOT peak gradient 20-40 mm Hg Mild PR VC 3-5 mm if < 10 kg VC 5-8 mm if > 10 kg	Moderate to severe residual obstruction RVOT peak gradient > 40 mm Hg Moderate to severe PR VC > 5 mm if < 10 kg VC > 8 mm if > 10 kg	Suprapulmonary anastomosis Main pulmonary artery Branch pulmonary arteries
Transannular patch	No residual obstruction RVOT peak gradient < 20 mm Hg PR—no consequence	Mild residual obstruction RVOT peak gradient 20-40 mm Hg PR—no consequence	Moderate to severe residual obstruction RVOT peak gradient > 40 mm Hg PR—no consequence	Suprapulmonary anastomosis Main pulmonary artery Branch pulmonary arteries
Pulmonary Valve Replacement				
Pulmonary valve replacement	Trivial or no stenosis Peak velocity < 2.5 m/sec No paravalvular leak (follow manufacturer's guidelines for stenosis if prosthetic valve)	Mild stenosis Peak velocity 2.5-3.5 m/sec Minor paravalvular leak (VC < 2 mm)	Moderate or severe stenosis Peak velocity > 3.5 m/sec Significant paravalvular leak (VC > 2 mm)	Suprapulmonary anastomosis Main pulmonary artery Branch pulmonary arteries Subpulmonary outflow
Pulmonary Veins				
Pulmonary vein confluence or baffle	No or trivial obstruction Mean gradient < 2 mm Hg	Mild obstruction Mean gradient 2-4 mm Hg	Moderate or severe obstruction Mean gradient > 4 mm Hg	
Scimitar vein baffle to left atrium	No or trivial obstruction Mean gradient < 2 mm Hg	Mild obstruction Mean gradient 2-4 mm Hg	Moderate or severe obstruction Mean gradient > 4 mm Hg	
Unroofing of coronary sinus	No obstruction Mean gradient < 2 mm Hg	Mild obstruction Mean gradient 2-4 mm Hg	Moderate or severe obstruction Mean gradient > 4 mm Hg	
RVOT Reconstruction/Sub-Pulmonary Stenosis Resection				
Relief of RVOT obstruction	No or trivial residual obstruction Peak gradient < 20 mm Hg	Mild residual obstruction Peak gradient 20-40 mm Hg	Moderate or severe residual obstruction Peak gradient > 40 mm Hg	Pulmonary valve Suprapulmonary Branch pulmonary arteries
RV-PA Conduit				
RV-PA conduit	Trivial to no valvar stenosis Peak gradient < 20 mm Hg Trivial to no valvar regurgitation VC < 3 mm	Mild stenosis Peak gradient 20-40 mm Hg Mild regurgitation VC 3-5 mm	Moderate or severe stenosis Peak gradient > 40 mm Hg Moderate or severe regurgitation VC > 5 mm	Subpulmonary Suprapulmonary Branch pulmonary arteries

Subprocedures	1	2	3	Other Modules
Supra-aortic Anastomosis/Repair				
Ascending aortic reconstruction	No residual gradient or narrowing	Mild narrowing or mild residual gradient	Moderate or severe residual stenosis	Aortic valve Aortic arch
Supra-aortic anastomosis	Peak gradient < 10 mm Hg	Peak gradient 10-20 mm Hg	Peak gradient > 20 mm Hg	
Suprapulmonary Anastomosis/Repair				
Main pulmonary artery reconstruction	No residual gradient or narrowing	Mild narrowing or mild residual	Moderate or severe residual stenosis	Pulmonary valve Branch pulmonary arteries
Suprapulmonary anastomosis	Peak gradient < 10 mm Hg	Peak gradient 10-20 mm Hg	Peak gradient > 20 mm Hg	
Systemic Venous Baffle				
Systemic venous baffle	No or trivial obstruction Mean gradient < 2 mm Hg	Mild obstruction Mean gradient 2-4 mm Hg	Moderate to severe obstruction Mean gradient > 4 mm Hg	
Transplant				
Left atrium anastomosis	No or trivial obstruction Mean gradient < 2 mm Hg	Mild obstruction Mean gradient 2-4 mm Hg	Moderate or severe obstruction Mean gradient > 4 mm Hg	
Aortic anastomosis	No obstruction Peak gradient < 10 mm	Mild obstruction Peak gradient 10-20 mm Hg	Moderate or severe obstruction Peak gradient > 20 mm Hg	
Pulmonary artery anastomosis	No obstruction Peak gradient < 10 mm Hg	Mild obstruction Peak gradient 10-20 mm Hg	Moderate or severe obstruction Peak gradient > 20 mm Hg	
SVC/IVC anastomosis	No or trivial obstruction Mean gradient < 2 mm Hg	Mild obstruction Mean gradient 2-4 mm Hg	Moderate or severe obstruction Mean gradient > 4 mm Hg	
PFO closure	No or trivial residual shunt <2 mm if > 10 kg <1 mm if < 10 kg	Small residual shunt 2-3 mm if > 10 kg 1-2 mm if < 10 kg	Residual shunt >3 mm if > 10 kg >2 mm if > 10 kg	
Ventricular Assist Devices				
Left ventricular/left atrial cannula	No obstruction to flow	Mild obstruction	Moderate or severe obstruction	
Ascending aortic cannula	No obstruction Peak gradient < 10 mm Hg	Mild obstruction Peak gradient 10-20 mm Hg	Moderate or severe obstruction Peak gradient > 20 mm Hg	
Pulmonary artery anastomosis	No obstruction Peak gradient < 10 mm Hg	Mild obstruction Peak gradient 10-20 mm Hg	Moderate or severe obstruction Peak gradient > 20 mm Hg	
Right atrial cannula	No obstruction	Mild obstruction	Moderate or severe obstruction	
VSD Repair				
VSD repair	No or trivial residual shunt <2 mm if > 10 kg <1 mm if < 10 kg	Residual defect 2-3 mm if > 10 kg 1-2 mm if < 10 kg	Residual defect >3 mm if > 10 kg >2 mm if < 10 kg	Aortic valve Tricuspid valve

If PFO was left open, fenestrated ASD closure was performed, or fenestrated VSD closure was performed, then ASD and VSD were not scored. Additional muscular VSDs not intervened on at time of surgery also were not scored.

ASD, Atrial septal defect; *AV,* atrioventricular; *AVV,* atrioventricular valve; *BT,* Blalock-Taussig; *ECG,* electrocardiogram; *IVC,* inferior vena cava; *LVOT,* left ventricular outflow tract; *MIG,* maximum instantaneous gradient; *PFO,* patent foramen ovale; *PR,* pulmonary regurgitation; *RVOT,* right ventricular outflow tract; *RV-PA,* right ventricle to pulmonary artery; *SVC,* superior vena cava; *SVC-PA,* superior vena cava to pulmonary artery; *VC,* vena contracta; *VSD,* ventricular septal defect.

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Introduction

Quality improvement in pediatric cardiac surgery has become an essential component of top-tier programs to ensure that safety goals and best practices are met for each patient. The development of program-specific measures and tools for surgeon self- assessment remain key to continuous improvement in this field. While the outcomes following pediatric cardiac surgery are determined and influenced by multiple factors (case complexity; patient physiology and anatomy; and preoperative, intraoperative, and postoperative care), the adequacy of the anatomic repair otherwise known as technical performance, or recently as residual lesion scores, emerged as an important predictor of outcomes across a wide range of ages and disease complexity. Patients' pre- and postoperative physiologic illness severity scores as measured by PRISM III are also significantly associated with technical performance scores and clinical outcomes.

Summary of the Studies

A technical performance scoring (TPS) system was developed at Boston Children's Hospital to assess the adequacy of the anatomic repair (Nathan, Karamichalis, et al., 2014). The technical steps toward an adequate anatomic repair of a congenital heart lesion are mostly under the control of the surgeon. A deficit in tools available to measure the technical adequacy of surgical procedures was key to the development of the TPS. This tool was designed for peer and self-assessment and was initially piloted in selected surgical procedures, including repairs of ventricular septal defect, Tetralogy of Fallot (TOF), complete atrioventricular septal defect, arterial switch

(Larrazabal et al., 2007), and stage I Norwood procedures (Bacha et al., 2008), demonstrating the feasibility of such studies and its potential importance in clinical outcomes. Building on these concepts and on the initial work at our institution, this research was then expanded over the following years to include complex pediatric cardiac operations in neonates and infants; next, we expanded to more than 90% of congenital cardiac surgery operations (Karamichalis, Barach, et al., 2012), which forms the basis of the work included in this thesis. Three TPS classes were defined: Class 1, optimal, no residual lesions detected; Class 2, adequate, mild residual lesions; and Class 3, inadequate, significant residual lesions, or the need for reinterventions to correct them. TPS was recently renamed as residual lesion scores (RLS) (Nathan, Trachtenberg et al. 2020; Nathan, Levine, et al. 2021). A brief synopsis of the studies presented here is shown below:

Karamichalis, J. M., Thiagarajan, R. R., Liu, H., Mamic, P., Gauvreau, K., & Bacha, E. A. (2010). Stage I Norwood: optimal technical performance improves outcomes irrespective of preoperative physiologic status or case complexity. J Thorac Cardiovasc Surg, 139(4), 962-968. doi:10.1016/j.jtcvs.2009.10.011

The first study included in this thesis was a retrospective review of 135 consecutive patients undergoing a high acuity operation, the stage I Norwood procedure, between January 2004 and December 2007. This study examined the interactions of baseline physiologic status measured by PRISM III scores, case complexity as measured by Aristotle comprehensive scores, technical performance, and outcomes. Technical performance emerged as a powerful predictor of clinical outcomes for the stage I Norwood operation. Optimal technical performance significantly attenuated the impact of poor preoperative physiologic illness severity and high case complexity with reduced

hospital mortality. Inadequate technical performance resulted in poor outcomes regardless of preoperative status.

Karamichalis, J. M., del Nido, P. J., Thiagarajan, R. R., Jenkins, K. J., Liu, H., Gauvreau, K., . . . Bacha, E. A. (2011). Early postoperative severity of illness predicts outcomes after the stage I Norwood procedure. *Ann Thorac Surg, 92*(2), 660-665. doi:10.1016/j.athoracsur.2011.03.086

During the first study, we hypothesized that a measure of immediate postoperative severity of illness after the stage I Norwood procedure reflected technical performance or the adequacy of the anatomic repair and can serve as a predictor of hospital mortality, reinterventions and clinical outcomes. The physiologic illness severity as measured by the PRISM III score on postoperative day number 1 after the stage I Norwood procedure had a strong association and discrimination with hospital mortality, postoperative reinterventions, inadequate technical performance and major postoperative complications ($p<0.001$). Such a tool may be used as a potential surrogate of technical performance to identify and correct anatomical technical deficiencies early in the postoperative period.

Karamichalis, J. M., Colan, S. D., Nathan, M., Pigula, F. A., Baird, C., Marx, G., del Nido, P. J. (2012). Technical performance scores in congenital cardiac operations: a quality assessment initiative. *Ann Thorac Surg, 94*(4), 1317-1323; discussion 1323. doi:10.1016/j.athoracsur.2012.05.014

To expand this work on TPS to a wider spectrum of pediatric heart operations and using the methodologic framework piloted in previous studies at our institution, measures of technical performance were created for more than 90% of all

congenital cardiac operations. A system of procedure modules was piloted by prospectively assigning technical scores to all patients undergoing heart operations. The results were further analyzed using risk stratification with RACHS-1 categories and outcomes. Despite a wide spectrum of cases, the development and implementation of a broad technical performance self-assessment system for congenital heart surgery were feasible. Based on this scoring system, the impact of a less than optimal (class 2 or 3) technical score depended on case risk category, with higher mortality in the higher risk group and increased resource utilization for lower risk procedures. This technical performance system permits each individual surgeon to self-assess technical performance and provide procedure-specific benchmarks.

Nathan, M., Karamichalis, J. M., Liu, H., del Nido, P., Pigula, F., Thiagarajan, R., & Bacha, E. A. (2011). Intraoperative adverse events can be compensated by technical performance in neonates and infants after cardiac surgery: a prospective study. J Thorac Cardiovasc Surg, 142(5), 1098-1107, 1107.e1091-1095.doi:10.1016/j.jtcvs.2011.07.003

In a subsequent prospective study of 166 consecutive neonates and infants (RACHS 4-6 [49%], neonates 50%) undergoing a variety of complex pediatric cardiac operations between 2009 and 2011, the relationship between surgical technical performance scores, intraoperative adverse events and major postoperative adverse events was defined. These patients were prospectively followed until discharge from the hospital. Case complexity was determined by RACHS-1 category, physiologic illness severity was assessed by PRISM III score, and intraoperative adverse events were prospectively monitored. Outcomes were analyzed using nonparametric methods and a logistic regression model. For the entire cohort, better TPS resulted in

lower postoperative adverse events, decreased postoperative PRISM scores and reduced length of stay and ventilation time ($p<0.001$). Patients requiring intraoperative revisions fared as well as patients without, provided the TPS was at least adequate (class 1 or 2). In neonatal and infant open-heart repairs, we concluded that TPS is one of the main predictors of postoperative morbidity. Outcomes were unaffected by intraoperative adverse events, including surgical revisions, provided TPS was at least adequate. An optimal (class 1) TPS resulted in the best outcomes, even if an intraoperative revision had to be performed, and attenuated the effects of poor preoperative physiology across a wide spectrum of diagnoses and procedures.

Nathan, M., Karamichalis, J. M., Liu, H., Emani, S., Baird, C., Pigula, F., Del Nido, P. (2012). Surgical technical performance scores are predictors of late mortality and unplanned reinterventions in infants after cardiac surgery. J Thorac Cardiovasc Surg, 144(5), 1095-1101 e1097. doi:10.1016/j.jtcvs.2012.07.081

In a subsequent study (Nathan et al., 2012), 166 neonates and infants (Nathan et al., 2011) were prospectively followed after discharge from their index operation for a minimum of 1 year. The primary outcome was mortality, and the secondary outcome was the need for unplanned reinterventions. This study confirmed that TPS affects not only early outcomes but also midterm survival. Inadequate TPS at the index procedure can be used to prospectively identify patients at risk for ongoing mortality and the need for reintervention, underscoring the importance for an aggressive approach to diagnosing and treating residual lesions at time of the initial operation.

Based on early operative results determined by echocardiography at discharge and the need for early reintervention to correct residual or recurrent defects, the TPS correlated highly with both early and intermediate-term outcomes. The TPS

underscored the need for early assessment of the adequacy of the surgical procedure in addressing important hemodynamic lesions and justifies an aggressive approach to early intervention for residual defects.

Nathan, M., Karamichalis, J., Liu, H., Gauvreau, K., Colan, S., Saia, M., . . . del Nido, P. J. (2014). Technical Performance Scores are strongly associated with early mortality, postoperative adverse events, and intensive care unit length of stay-analysis of consecutive discharges for 2 years. *J Thorac Cardiovasc Surg, 147*(1), 389-394, 396.e381-396.e383. doi:10.1016/j.jtcvs.2013.07.044

In the final study included in this thesis (Nathan, Karamichalis et al., 2014), we hypothesized that the TPS could predict early outcomes in a wide spectrum of pediatric cardiac operations and age groups. A total of 1926 consecutive patients discharged between 2011 and 2013 were prospectively evaluated and assigned the TPS in a risk-stratified fashion using the RACHS-1 categories for case complexity. Early mortality and postoperative adverse events were recorded. This study further validated our hypothesis. On multivariate modeling, class 3 (inadequate) TPS was strongly associated with mortality, adverse events and postoperative ICU stay after adjusting for other covariates ($p<0.001$). This study demonstrated the ability of TPS to predict early outcomes such as mortality, adverse events and increased resource utilization in a wide range of ages and disease complexity in a single institution.

TPS and Early and Midterm Outcomes

In summary, we piloted a method to measure surgical technical performance for CHD as part of a quality improvement evaluation process and a tool for self-

assessment (Bacha et al., 2008; Karamichalis, Colan et al., 2012; Karamichalis et al., 2010; Larrazabal et al., 2007; Nathan et al., 2011). This work demonstrated that technical performance defined as the adequacy of the anatomic repair can be assessed in congenital heart surgery. TPS correlates with early and midterm outcomes and can serve as a tool for surgeon self-assessment and programmatic quality control.

The use of TPS may allow the development of predictors for early intervention for significant residual anatomic lesions. Such an initiative can lead to an improvement in the long-term physical, neurologic, and psychosocial development in vulnerable high-risk patients by identifying who would benefit from early intervention and decreasing the burden of prolonged illness on patients with CHD and their families.

TPS and Outcomes in High Complexity Operations: Norwood Procedure

Technical excellence during surgery, with little to insignificant residual defects, has the best outcomes along the entire spectrum of case complexity. This factor was particularly important in determining outcomes as case complexity increased. In the most complex infant and neonatal heart operations such as the stage I Norwood procedure, a perfect anatomic repair across the different subcomponents of the operation is significantly associated with excellent results. In high complexity operations, optimal technical performance mitigates the impact of high preoperative physiologic illness severity as measured by PRISM III with favorable outcomes for the patient.

Nathan et al. (Nathan, Sleeper et al., 2014) conducted a multicenter retrospective study of 549 patients undergoing the stage I Norwood operation that validated our findings. TPS was an independent predictor of both early and midterm outcomes after the Norwood procedure. In the multivariable model, worse TPS was

significantly associated with a longer interval to first extubation, greater early mortality or transplantation, a longer hospital length of stay, more unanticipated interventions between discharge and the stage II procedure and lower psychomotor development index scores at 14 months of age.

In another retrospective study at our institution (Howard et al., 2016), survival to discharge was 50% for 84 neonates who were cannulated to veno-arterial extracorporeal membrane oxygenation after cardiac surgery. Many of these patients (n=70; 83%) had residual lesions after cardiac surgery, and the time to diagnosis or correction of residual lesions was significantly shorter in survivors (p=0.02), supporting our hypothesis that timely identification of residual lesions and expedient repairs of those lesions may improve survival.

Limitations of TPS and Future Direction

Intraoperative TPS and "Technical Imperative"

Our studies have shown that the technical adequacy of an anatomic repair, as measured by TPS, is an important predictor of outcomes. We described a "technical imperative," defined as an absolute rule whereby it is imperative to leave the operating room with a good or optimal technical result, even if this requires surgical revision and going back on bypass (Bacha et al., 2008; Karamichalis et al., 2011; Karamichalis et al., 2010; Nathan et al., 2011). Leaving the operating room with an optimal anatomic repair in high complexity operations attenuated the burden of intraoperative adverse events such as reinstitution of bypass for intraoperative revisions to achieve a good repair. Cross clamp times were not associated with poor outcomes; the end result and the adequacy of anatomic repair counted the most.

While our studies focused mainly on the predischarge echo result as the final measure of technical performance and the need for re-intervention prior to discharge,

they highlighted the importance of shifting the focus to the intraoperative assessment of the adequacy of the anatomic repair and measurement of TPS prior to leaving the operating room. Increasing intraoperative vigilance regarding the detection of significant residual lesions and their immediate repair prior to leaving the operating room remains of prime importance. Patients leaving the operating room with inadequate anatomic repairs show poor postoperative physiologic illness severity scores, followed by poor outcomes.

Data from a subsequent prospective cohort study of 2427 patients by Nathan et al (Nathan, Sleeper et al., 2014) showed that identification and correction of residual lesions in the operating room was associated with improved outcomes (shorter length of stay, lower postoperative adverse events and hospital costs) compared to delayed postoperative revision of residual lesions. This study emphasized that intraoperative identification of residual lesions is essential if optimal repair and superior outcomes are to be achieved during the index surgery.

Enhanced intraoperative imaging can provide important information on all aspects of a repair and is an important guiding tool to achieve optimal surgical anatomic repair before exiting the operating room. Such imaging includes transesophageal and epicardial echo, intraoperative exit angiography supplemented by visual assessment, and monitoring of physiological parameters including direct pressure measurements or saturation data.

Development and further refinement of intraoperative TPS scoring criteria would provide the additional tool needed for making intraoperative surgical decisions to reinstitute cardiopulmonary bypass and correct significant residual defects, leading to significant improvements in outcomes. The TPS system was developed using the consensus of experts' opinions from a single institution, Boston Children's Hospital, with evidence of its importance and association with both short- and long-term outcomes at this institution. Nevertheless, a prospective multicenter validation of

this tool will reinforce its significance across centers. A multicenter study would also allow for further refinement of the TPS modules using both a multi-institutional expert panel and an analysis of prospectively collected data.

As more data become available, TPS scoring criteria will need to be recalibrated on an ongoing basis to ensure that thresholds and categories are clinically meaningful, especially as patient care and technology constantly improve and evolve. Further studies of reproducibility and generalizability of TPS and refinement of scoring criteria maybe needed particularly for procedures such as valve repairs before it can be adopted as a national quality measure with the development of national benchmarks for assessing the quality of the repairs (Parthiban et al., 2016). Accrual of data on sufficiently large numbers in each procedural group will allow us to ascertain the importance of each component of the TPS for each procedural group and will lead to the development of a weighted scale for the specific subprocedures and impact on outcomes.

This system may provide a systematic and methodical review of pediatric cardiac surgery operations with the ability to further analyze specific areas that might have greater importance in outcomes. For example, inadequate repair of the left atrioventricular valve in an atrioventricular septal defect repair, other valve repairs, or an arch reconstruction in a stage I Norwood repair may have higher predictive value for future reinterventions. Additionally, each subcomponent of the overall TPS may be constructed in a weighted fashion based on the contribution of each subprocedure to outcomes. This will enable us to determine which patients with suboptimal TPS (class 1 or 2) are at higher risk for late reintervention and mortality, thus warranting closer follow-up and earlier intervention. This approach would optimize outcomes; minimize re-admissions, resource utilization and costs; and improve the patient's quality of life (Nathan & Karamichalis, 2015). Surgeons' and cardiologists' threshold of reintervention for residual lesions in the catheterization

laboratory or the operating room adds another factor of institution or physician-specific variability and bias to the scoring system since the need for postoperative reintervention is part of the TPS criteria. The need for postoperative reintervention downgrades the TPS to inadequate or class 3.

The studies in this thesis were validated in a large volume center, Boston Children's Hospital, which has a high degree of standardization and streamlined uniform preoperative, intraoperative, and postoperative care. In low volume programs where the care might not be as uniform or standardized, different factors might play critical roles in outcomes and perhaps even the best technical anatomic repair may not necessarily be associated with optimal results.

Another important distinction to make when using the TPS tool to compare surgeons across different centers is that surgeons in high volume centers may be doing operations on patients with "really difficult and complex anatomy" more often than surgeons in low volume centers. In assigning the TPS score, the difference in difficulty and complexity of the same category lesion should be further classified to denote the increased technical difficulty in achieving a technically optimal result. For example, an optimal or class 1 TPS score for a highly complex redo valve repair may technically be more difficult to achieve than a first-time valve repair. These distinctions will need to be further risk and complexity stratified and classified in a way that would offer a more uniform standard of comparing TPS scores across different centers and surgeons performing the same operation on a lesion with higher anatomic complexity.

In addition, the impact of systems and infrastructure plays a critical role in optimizing outcomes, especially in high complexity operations, which underscores the importance and need of a multicenter study to establish reproducibility and validity across different congenital cardiac surgery programs. This need is currently

being addressed by a multicenter national, prospective, observational study in the U.S., named the Residual Lesion Score (RLS) Study, funded by the National Heart, Lung and Blood Institute's Pediatric Heart Network (PHN) (Nathan et al., 2020).

Residual lesion scores

The RLS was developed from the work on TPS and the score name was changed to RLS because the term TPS may imply that residual lesions are exclusively the result of the surgeon's technical skills and performance. Residual lesions and suboptimal TPS may also be the function of complex underlying anatomy, the accuracy of the preoperative evaluation, and/or intraoperative decision-making in which a residual lesion is recognized but deemed to be insignificant, hence the change in name from TPS to RLS.

The goal of this study is to test the applicability and validate the association and influence of RLS (both intraoperative and postoperative) on early and midterm postoperative outcomes in congenital cardiac operations in multiple centers with the hypothesis that worse RLS scores will be associated with adverse outcomes (Nathan et al., 2020). The effects of RLS on midterm outcomes, unplanned reinterventions, mortality and/or transplant in the first year after discharge from the index congenital heart operation, as well as its relationship with hospital costs, are being examined. This study enrolled infants undergoing repair for TOF, stage I Norwood operation, arterial switch operation (ASO) for dextro-transposition of the great arteries, complete atrioventricular septal defect repair, and hypoplastic or interrupted aortic arch with ventricular septal defect repair. This is the first prospective multicenter validation study of a quality improvement tool such as the TPS or RLS for surgical outcome assessment in congenital heart surgery.

Future directions using these tools may explore whether incorporation of procedure- specific factors in the RLS, especially whether intraoperative RLS may facilitate optimization of care of patients undergoing repair of CHD (Nathan et al., 2020). This study was recently completed. The authors concluded that residual lesions after congenital cardiac surgery impacted in-hospital outcomes across operative complexity with greatest impact following complex operations; minor residual lesions had minimal impact (Nathan et al., 2021).

With current technological and other surgical advances in this field, attention is now being turned to more subtle measures such as neurodevelopmental outcomes, resource utilization in the form of length of stay, readmissions, and unplanned post discharge reintervention (Nathan et al., 2012). Long-term data on mortality and more subtle outcomes, such as quality of life, psychosocial adjustments for patients and their families, cognitive function, and neurodevelopment, might also be important measures of the efficacy of surgical performance in this group (Latal, Helfricht, Fischer, Bauersfeld, & Landolt, 2009; Newburger et al., 2012; Tabbutt, Gaynor, & Newburger, 2012).

Although the role of human factors in outcomes after surgery has been well described (Barach & Weinger, 2007; de Leval et al., 2000; Schraagen et al., 2011), technical adequacy of the anatomic repair may still be the single most important factor in determining these more subtle outcomes; this has been demonstrated in other surgical fields (Birkmeyer et al., 2013; Carty, Chan, Huckman, Snow, & Orgill, 2009; Faurie & Khadra, 2012; Gofton, Dudek, Wood, Balaa, & Hamstra, 2012; MacRae, 2011; Martin et al., 1997; Zevin et al., 2013). Resource use in the form of multiple readmissions is should also be measured. Whether TPS might serve as surrogate for measurement of these outcomes in the short term as well as in the intermediate and long term needs to be determined, because studies (Newburger et al., 2012; Tabbutt et al., 2012) have shown that

patient-related and environmental factors are more likely to contribute to neurodevelopmental outcomes in specific subsets of patients, such as those undergoing the Norwood stage I procedure and ASO. The TPS, with its ability to predict midterm outcomes such as post-discharge mortality and unplanned reinterventions (Nathan et al., 2012; Nathan et al., 2013), might thus serve as a tool that recognizes a subgroup of patients who need closer monitoring (Nathan et al., 2012).

Standardized echo protocols for TPS

The advantage of using echocardiography as the principal tool for the TPS system is that echocardiography is routinely used perioperatively and during follow-up in almost all centers. However, echocardiography is limited by variability in both the acquisition and interpretation of the findings. In a collaborative study between two centers conducted to evaluate reader variability for echocardiographic components of TPS and assess the quality of postoperative echo images for complete repair of TOF and ASO, Parthiban and colleagues evaluated postoperative echocardiograms in 67 children (Parthiban et al., 2016). Two readers, one from each center, interpreted each echocardiogram. Inter-reader agreement for TPS was strong. However, variation in echocardiographic interpretations had a small but important effect on TPS for ASO and TOF. This was especially true for the distinction between minor and major residual defects. Image quality was poor or suboptimal for the evaluation of branch pulmonary arteries and coronary arteries.

This study highlights the variability in the quality of postoperative echo images and interpretation. The quality of the images of the structures being evaluated may be affected by the presence of poor acoustic windows. While poor image quality or missing data do not preclude the use of TPS, its ability to accurately predict outcomes may significantly be impacted (Parthiban et al., 2016). The low and

important rate of discordant classification of TPS between readers suggests that as experience with the TPS grows, so may the need for recalibration of appropriate threshold values for categories. Thus, data on feasibility of specific image acquisition and validity (importance) of specific elements should be included in future studies aimed at refining the TPS scoring criteria.

Potentially, certain residual lesions might not be as accurately detected by different echocardiographers, and the echo interpretation may vary between physicians. Commitment to a specific standardized procedure and reproducible complete echocardiographic assessment of the anatomic repair of the specific defect eliminates personal biases of interpretation of echocardiographic findings. As part of the standardization of the tool at Boston Children's Hospital and for use among other institutions, echo protocols and anatomic modules that could be used to standardize the images obtained by the echocardiographer performing the echo were developed in our study (Karamichalis, Colan et al., 2012). These anatomic modules enable the clinician finalizing the TPS to accurately score all components uniformly and ensure uniform data collection.

Multimodality Imaging in Assessing TPS

Our studies highlight the limitations of using echocardiography in the assessment of TPS and accurate detection of residual lesions. Finding new methods and imaging modalities to better assess the anatomic repair after pediatric cardiac surgical procedures is important in refining TPS and increasing its ability to predict the durability and quality of the repair in the long term. The use of multimodality imaging (Dillon-Murphy et al., 2016; Aguib et al., 2015; Yacoub et al., 2021), such as CT scan, 3-D printed models, MRI 4-dimensional flow and computational fluid dynamics, in looking at the quality of the anatomic repair, the shape and geometry of anatomic

regions such as the aortic valve annulus and orifice, leaflet coaptation, size and shape of sinuses of Valsalva, calculation of viscous energy loss before and after surgery, and patterns of flow dynamics could further enhance the quality of our assessment of postoperative residual lesions and the adequacy of the repair achieved and its durability. Multimodality imaging was recently applied in the assessment of a new technique for shaping the aortic sinuses and conserving dynamism in the remodeling operation (Yacoub et al. 2021). This approach offers an advantage in enhancing our ability to assess the quality of our repair using sophisticated bioengineering technology.

The assessment of TPS and its future refinement would be facilitated with the involvement of biomedical engineers weighing in the quality of the repair after pediatric cardiac procedures. A multidisciplinary team consisting of cardiologists, cardiac surgeons, bedside clinical nurses, expert radiologists in cardiac MRI, and other imaging technology, echocardiographers and bioengineers would be key to advance the field of assessing the adequacy of the anatomic repair along with the ability to predict the durability of the repair and future need for reinterventions.

PRISM and TPS

Achieving a good intraoperative technical result has a direct impact on the patient's postoperative course. Technical performance had a significant impact on postoperative physiologic illness severity when measured by PRISM III, with higher PRISM III scores associated with inadequate performance (Karamichalis et al., 2011). The severity of illness as measured by PRISM III on postoperative day one after the stage I Norwood operation and other neonatal and infant cardiac surgeries has high association and discrimination in regard to hospital mortality and postoperative reintervention, inadequate technical performance, and the occurrence

of major postoperative complications (Karamichalis et al., 2011; Nathan et al., 2011).

This measure reflects the patient's intraoperative surgical course and adequacy of the repair. Therefore, PRISM III may be used as an early surrogate of technical performance and to initiate a timely search for technical deficiencies, institution of supportive measures and reinterventions to address them. A high PRISM III score may be used as an automatic trigger for a series of diagnostic tests for residual lesions, leading to timely reinterventions and prevention of adverse events.

Limitation of PRISM and future directions

PRISM III is not cardiac-specific and was designed for general pediatric intensive care unit (PICU) admissions. The postoperative care of pediatric cardiac surgery patients is constantly changing with new advances in the field of pediatric cardiac intensive care over time. The severity of illness markers used in PRISM III would need to be constantly reassessed and the coefficients in the PRISM score adjusted accordingly to reflect new advances in postoperative care (Brady et al., 2006). This will ensure adequate recalibration of PRISM III as a measure of physiologic illness severity. More importantly, severity-of-illness scores developed for the entire critical care population may not perform as well in population subsets such as cardiac surgical patients (Czaja, Scanlon, Kuhn, & Jeffries, 2011; Marcin & Pollack, 2007; Sachdeva et al., 2008; Slater, Shann, & Pearson, 2003; Wetzel, Sachedeva, & Rice, 2011), hence the need for a cardiac-specific score or perhaps a recalibration of PRISM III to reflect parameters and physiologic variables specific to pediatric cardiac surgical patients.

Recent efforts led to the development of a new mortality score and risk-adjustment tool specifically for postoperative pediatric cardiac surgical patients: Pediatric Index of Cardiac Surgical Intensive Care Mortality (PICSM). PICSM consists of 13 risk variables encompassing physiology, cardiovascular condition, and time of admission to the ICU (Jeffries et al., 2015). The introduction of the variable "admission time with respect to cardiac surgery" allowed prediction of mortality when patients are admitted to the ICU either before or after the index surgical procedure. PICSM provides an immediate postoperative assessment that serves as the baseline for the care provided in the ICU. PICSM is the first specific cardiac severity of illness tool combining anatomic and physiologic factors assessed at admission to the ICU to enable multiple approaches to improving the care provided for cardiac surgical patients in ICUs.

PICSM showed improved utility and a small improvement in its ability to discriminate mortality (area under the curve or AUC 0.87) compared to ICU severity of illness scores, Pediatric Index of Mortality-2 and 3 (AUC 0.81), PRISM III (AUC 0.82), and complexity-based scores (STAT score and STAT categories) (AUC 0.77) in a multisite cohort of pediatric cardiac surgical patients (Jeffries et al., 2015; Thiagarajan & Nathan, 2015).

These preliminary results indicate that the PICSM score is suitable for predicting ICU mortality and perhaps more appropriate for assessing ICU performance for cardiac patients than previous methods but is not significantly better than PRISM III. PICSM and other tools need to be validated over time for continued reproducibility. Moreover, the application and interplay of PICSM with TPS need to be validated in postoperative pediatric cardiac surgical patients. Specifically, the association of PICSM with inadequate class 3 TPS needs to be examined. At present, PRISM III may be used to initiate a search and treatment response for significant residual lesions in the immediate postoperative period. PICSM will also need to be

validated in the same context to determine its applicability and/or possible improved utility in adjunct with TPS.

Risk stratification

Risk adjustment for patients undergoing congenital heart surgery poses unique challenges. In addition to the wide variability in surgical case complexity, variations in the anatomy of a lesion may dramatically alter the degree of difficulty for a given operation. Different comorbidities often encountered in patients with CHD may increase the risk of mortality, independent of the surgical procedure being performed.

Existing risk stratification tools, such as RACHS, STAT categories and Aristotle scores, assess overall cardiac surgical mortality across the entire care process but do not assess severity of illness at admission to the ICU. They rely heavily on cardiac surgical procedure complexity for assigning risk of mortality, and they do not include physiological data on ICU admission. In contrast, both PRISM and PICSM include physiological variables on admission to the ICU, which also reflect the adequacy of the anatomic repair or TPS score, adding a new variable to the risk of mortality model.

The adequacy or completeness of the surgical repair adds a unique and new approach to the mortality risk model in pediatric cardiac surgery. In our research on multivariate analysis of variables with significant correlation with mortality in the stage I Norwood procedure, the logistic regression model containing 2 explanatory variables that performed best according to coefficient of determination included TPS and PRISM III scores (Karamichalis et al., 2010). The ability to explore the interplay between adequacy of the repair (TPS), risk stratification methods (e.g., RACHS and

STAT categories) and physiologic illness severity scoring systems (e.g., PRISM and PICSM) to predict mortality and outcomes will add value to a standardized evaluation and improve surgical technical performance within specific healthcare delivery systems across different centers and providers.

Among methods for risk stratification or risk prediction, there is a difference between methods that have been validated to accurately predict risk for individual cases, like PRISM or PICSM, versus only for groups of patients, like RACHS or STAT categories. Risk adjustment methods that are only valid for groups assume that anatomic risk factors are evenly distributed in the groups and the risks are no longer valid if these anatomic risk factors are not present. As certain programs and surgeons undertake high risk operations on more complex anatomy of certain lesions, the variability in complexity within the same category of lesions needs to be taken into consideration when comparing outcomes using risk adjustment. In addition, the interplay between postoperative physiologic illness severity and TPS and the relationship of TPS with different risk categories and clinical outcomes will need to undergo further refinement in the future.

Inevitably, quality metric scoring tools such as TPS and risk prediction systems will become the judges of our clinical activities (Angus et al., 1997). Designing new and improving existing quality metric systems would allow us to have an objective and robust judge of the quality of our work. The interplay between outcomes and case volumes at different programs, outcomes being better at higher volume programs and higher volumes supporting better infrastructure, requires more surgeons in a program. Having a greater number of surgeons who all need to reliably perform requires non-technical skills such as team leadership, communication, situational awareness, and mentorship of junior surgeons by more experienced surgeons. The complex interactions between teams would need to be further studied to ascertain their impact on team performance and outcomes and to find ways to improve overall

team performance in providing superior healthcare, especially for high-risk operations.

As healthcare moves more towards quality-based reimbursement and a culture of transparency, introducing measures that assign specific quality metrics to surgical teams, with data on long-term outcomes and patients' quality of life, will be of importance to patients' families, the public and healthcare authorities in choosing providers and preferred specialized healthcare systems.

TPS and Other Subtle Measures: Neurodevelopmental Outcomes and Resource Utilization

Association of TPS and neurodevelopmental outcomes

The strong impact of TPS on outcomes in pediatric cardiac surgery, with greater morbidity in children with major residual lesions (class 3), led to a focus on other subtle measures such as cognitive development, neurodevelopmental outcomes and resource utilization (Nathan et al., 2013). In earlier studies (Newburger et al., 2012; Newburger et al., 2003; Sananes et al., 2012), measures of greater global morbidity after pediatric cardiac surgery, such as more adverse events prior to hospital discharge, a longer hospital or ICU length of stay, increased the risk of neurodevelopmental delay.

In a study following 160 patients who underwent the ASO in infancy, longer postoperative ICU and hospital length of stay were associated with worse scores on tests of cognitive function at eight years of age, including full-scale of intelligence quotient (IQ), performance IQ, verbal IQ, and math achievement, even when adjusted for sociodemographic variables, perioperative events, and perfusion times (Newburger et al., 2003). ICU and hospital length of stay independently predicted

subsequent worse performance in the neurologic examination, motor function and scores on the Griffiths Medical Development Scale. Since length of stay cannot itself be etiologic, it is a surrogate variable of other factors affecting the central nervous system.

In a more recent large multicenter prospective study, neurodevelopmental impairment in survivors of the stage I Norwood procedure was associated with innate patient factors, greater number of complications, measures of greater severity of illness, longer postoperative mechanical ventilation, and prolonged hospital length of stay (Newburger et al., 2012). Similar findings were shown in a prospective study of 131 patients less than 3 months of age at time of cardiac operation (Sananes et al., 2012). Multivariable analyses showed that neurodevelopmental outcomes at 2 years of age were related mostly to patient factors, such as the complexity of the child's CHD or univentricular heart anatomy, and to the postoperative course, length of stay in the ICU and the presence of complications such as stroke, seizures, or cardiac arrest.

Since class 3 (inadequate) TPS has a strong association with greater morbidity and reintervention after congenital cardiac surgery, in a retrospective study, Nathan et al. hypothesized that a strong association would exist between class 3 TPS or major residual lesions and poorer neurodevelopmental outcomes (Nathan, Sadhwani et al., 2014). TPS was calculated at the time of discharge in 140 infants undergoing heart surgery, who were then offered neurodevelopmental testing at 1 year of age using Bayley Scales of Infant Development (BSID). After adjusting for the presence of chromosomal and non-chromosomal anomalies, RACHS-1 category, and other relevant patient factors in multivariate models, TPS class 3 was an independent risk factor for lower BSID cognitive composite score ($p=0.02$) and tended to be associated with lower BSID motor composite score. Worse technical performance

of infant heart surgery appeared to be an independent predictor of neurodevelopmental outcomes.

As a more complicated postoperative course can be triggered by the technical inadequacy of surgery, an inadequate technical performance might be a modifiable risk factor for neurodevelopmental outcomes. Children with significant residual lesions leaving the operating room after a repair should be considered at increased risk of developmental delay. Intraoperative recognition and correction of residual lesions resulted in superior medical outcomes compared with those who required reintervention before discharge (Nathan, Sadhwani et al., 2014).

Future directions in neurodevelopmental outcomes

Accrual of greater number of patients with higher complexity would further define associations between TPS and neurodevelopmental outcomes among higher and lower complexity patients. Additionally, data should be collected on the individual procedure groups to further refine this association. Prospective studies and randomized controlled studies are needed. Whether a structured program of intraoperative recognition and intervention on residual lesions can improve TPS and neurodevelopmental outcomes should be evaluated by future multicenter research studies (Nathan, Sadhwani et al., 2014).

Resource Utilization and Value-Based Healthcare Competition

TPS and resource utilization and costs

Earlier studies by Pasquali and colleagues showed the existence of significant variability in hospital costs following congenital heart surgery across centers was

predominantly related to postoperative complications and length of stay (Pasquali et al., 2011). Following bariatric surgery, greater technical skill was associated with lower complication, reoperation and readmission rates, confirming that technical adequacy of the surgical repair may be a crucial factor in outcomes (Birkmeyer et al., 2013).

Our studies demonstrated that poor TPS was associated with higher postoperative complications, hospital length of stay, and future post discharge reinterventions, resulting in higher resource utilization and hospital costs. On multivariable modeling in our study of 1926 patients (Nathan, Karamichalis et al., 2014), class 3 (inadequate) TPS was strongly associated with adverse events, increased postoperative ICU length of stay, and unplanned reinterventions, thus resulting in greater resource utilization and hospital costs after adjusting for other significant variables such as RACHS category, age, and prematurity.

In a subsequent study of 1730 consecutive patients undergoing congenital cardiac surgery, TPS was an independent predictor of hospital resource utilization (Nathan et al., 2016). Patients with class 3 TPS had significantly higher total hospital costs after adjusting for other patient risk factors associated with higher resource utilization. Maximizing the technical adequacy of a repair may play a significant role in healthcare cost containment, suggesting that TPS can be a useful benchmark for resource utilization across centers. As the association of TPS with more subtle outcomes (e.g., psychosocial and cognitive development and the impact of multiple re-admissions on resource use) is being analyzed, these outcomes need to be further evaluated across multiple institutions.

TPS and value-based healthcare

In the current era of healthcare delivery, the concept of value is pivotal to any discussion of quality improvement in the treatment of CHD. This concept has been fully developed by Michael Porter and colleagues at the Harvard Business School. Creating patient and healthcare value is an overarching strategy that at its core is defined by a simple equation: outcomes/cost. Accordingly, maximizing value for patients translates into delivery of the best outcomes at the lowest cost (Porter, 2010; Porter & Lee, 2013).

The outcomes referred to by Porter are those that matter most to patients. Although mortality is a critical determinant of success in pediatric cardiac surgery programs, for most CHDs, mortality is currently low. Outcomes beyond mortality may be metrics such as postoperative length of stay, quality of life, long-term neurodevelopment, readmissions, and even patient and family satisfaction. Porter believes the data surrounding these outcomes that matter to patients should be measured and transparently shared publicly to drive improvement (Anderson, 2020). It is important to critically assess these outcomes, especially in different healthcare systems, because certain outcome measures such as postoperative length of stay may be influenced by other factors outside the control of the healthcare providers such as social and family circumstances of the patients and their families.

As healthcare resource allocation and reimbursements are entering a new phase where outcomes, quality and performance have become important, quality improvement tools in a pediatric cardiac surgery program such as TPS could play key roles. In 2015, the U.S. Department of Health and Human Services set a goal: by 2018, 90% of all Medicare fee-for-service payments should be tied to quality or value (Burwell, 2015). The transition to value-based healthcare represents a fundamental shift where payors demand transparency, accountability, and increased efficiency from providers (Adusumalli, Fiorilli, & Saybolt, 2017; Rebolledo, 2020).

Over the last several years, increasing value for patients, where value is defined as "the health outcome per dollar of cost expended," remains a central theme and the right goal in healthcare reforms (Porter, 2009). Mandatory measurement and reporting of results are perhaps the most important steps in reforming the healthcare system. Competition is failing in healthcare because participants compete to shift costs to one another, accumulating bargaining power, limiting services, and gravitating to a zero-sum competition in which the gains of one participant come at the expense of others. Health plans have focused on discounts and administrative control of members and providers rather than developing a distinctive ability to offer superior health value to patients (Porter & Teisberg, 2006).

It is important to realign competition in healthcare with value for patients. Competition must take place where value is created and must revolve around patient results, which is far more reliable route to efficiency, quality, and rapid improvements in value (Porter & Teisberg, 2006). Competition on patient results means that healthcare providers who achieve excellence are rewarded with more business, while those who demonstrate substandard outcomes decline or cease to provide that service. Competing on patient results by delivering superior value through better outcomes achieved at lower costs is a positive-sum competition from which all system participants can benefit. This then becomes an irresistible force for transforming the healthcare system, leading to concrete and actionable, organizational, operational, strategic, and policy implications for all system participants, including government. Results of value-based competition must be widely available to encourage additional stakeholders to join in this quality improvement endeavor (Porter & Teisberg, 2006).

In pediatric cardiac surgery, only competition on results to improve the diagnosis, treatment, management, and prevention of complications from surgery will lead to true value improvements for patients. The Congenital Heart Standard Set of Health Outcome Measures that define value based on patient's and parent's perception of what matters most was recently finalized (www.ichom.org) by a multidisciplinary panel of experts and parent and patient representatives. By creating a standardized list of outcomes based on the patient's priorities along with instruments and time points for measurement, we can ensure that the patient remains at the center of the care. Through the implementation of these Standard Sets, we can begin to measure, analyze and improve outcomes achieved in the delivery of care. Since TPS is both associated with outcomes and costs, it should be an ideal driver of value-based healthcare. Future studies should examine the utility of TPS in value-based healthcare competition in congenital cardiac surgery programs.

Another principle of value-based competition demand that the focus should be on value for patients, not just lowering costs (Porter & Teisberg, 2006). When measuring value, both outcome and costs must be measured over the full cycle of care, not just for discrete interventions or procedures. Value can only be accurately measured over the cycle, not just the intervention. A low-cost surgery is no bargain if it results in avoidable complications or long-term reoccurrence of the condition. In pediatric cardiac surgery, competition must be based on results and on medical conditions over the full cycle of care. High quality care should be less costly. The use of TPS can serve as an important quality improvement metric for outcomes and can be used in a value-based competition strategy for pediatric cardiac surgery programs.

By measuring the quality of a repair, TPS can serve as a metric on how well the surgeon delivered care in specific lesions. As TPS correlates with midterm results and late reinterventions and readmissions, it provides more complete information on the full cycle of care by its association with not only in-hospital outcomes for the index

operation but also midterm and long-term results. Overwhelmingly, value is determined by how well a provider delivers care for each medical condition or diagnosis and not his/her overall breadth of services. Hence, TPS may provide information on value added and the impact on the full cycle of care.

TPS also offers information that can be used in developing comparative information with other providers and making the information transparent by communicating externally. This can have strategic implications for surgeons and healthcare providers moving to value-based competition based on results and in defining the right goal of providing superior patient value and marketing services based on excellence, uniqueness, and results. Marketing must shift from breadth and reputation to practice unit excellence and outcomes, and providers must begin to communicate their areas of unique excellence. Instead of struggling over the micromanagement of care, providers must agree to do business based on results. TPS offers a platform of systematizing knowledge development, which includes measuring and analyzing results, identifying process improvements and training staff. Substandard outcomes must be discussed and analyzed so the entire group learns and improves.

Competition on value is a positive-sum competition in which all participants in the system can win. Better health is less expensive than poor health. Competition on results can and will trigger improvements in quality and efficiency that are unimaginable in the current system. Providers will be focusing on providing services where they are truly excellent rather than attempting to offer all services. Thus, providers will focus on maximizing value for the patients they serve.

Governments can develop rules and infrastructure that enable value-based competition. This will require overseeing the development of risk-adjusted outcome measures for every medical condition, requiring mandatory reporting of results, opening up provider and health plan competition by defining new rules for pricing,

and modernizing information technology. Substandard care for any group will become glaringly obvious in a results-based system.

Measuring results and making results information widely available likely represent the most important catalyst in triggering changes in the system. Once competition on results starts working, improvements in value will no longer be discretionary. Every participant will be compelled to refocus on value. Improving care delivery will no longer be optional. Competition will continually raise the bar.

Technical performance in pediatric cardiac surgery is associated with clinical outcomes, with optimal technical performance being associated with shorter hospital length of stay and improved outcomes, resulting in lower cost of care and improved overall quality. We could therefore extrapolate technical performance to value-based competition on results. Suboptimal technical performance has been shown to correlate with higher cost of care (Nathan et al., 2016). Thus, TPS can be used as a surrogate for better quality and less costly care.

Future studies should examine the concept of TPS as a quality improvement tool to be used for measuring and comparing results of different providers and centers, identifying the areas of excellence where patient value is added. This may act as a guiding tool for value-based healthcare and competition based on outcomes in pediatric cardiac surgery. Prospective, multicenter studies could analyze the impact of TPS as a quality improvement tool and its association with results, hospital costs, value-added healthcare, and competition based on results.

What will the healthcare system look like when all participants focus on patient value? Providers will offer services where they can be truly excellent, rather than attempting to offer all services to every patient. A few programs will close, but providers will phase out less distinctive service lines and reallocate their efforts to areas where they can achieve true excellence. A growing number of excellent regional and national

providers will operate across multiple geographic areas, linked to local institutions through various medical partnerships and relationships. A TPS risk-stratified, public reporting system across different centers may facilitate the distinction between centers of excellence with the highest patient value offered in the treatment of CHD and other centers. Regionalization of specialized services may be a feasible systematic approach to provide the best value for money and TPS system may become one of the quality metrics in identifying centers of excellence.

TPS can offer a method of demonstrating the value of the services provided to patients. Hence, it can provide a platform of value-based competition based on results. TPS can be part of a system measuring health results per dollar of premiums. TPS can also be integrated into the infrastructure and rules that enable value-based competition. Future studies should aim to establish the utility of TPS in value-base healthcare and competition based on results. This will require the development of risk-adjusted outcome measures for every surgery, requiring mandatory reporting of results and opening provider and health plan competition.

It is important to note that our discussion of the healthcare economics and the use of TPS in value-based competition applies mainly in the US healthcare system, which consists of multiple payors. These assumptions may not apply in other healthcare systems such as the UK, Australian and Canadian systems where there is a national health-system in place with universal healthcare coverage provided primarily by the government.

Surgical Competency and Non-technical Skills for Surgeons

The assessment of surgical competency remains an elusive yet important concept (Karamichalis, Barach et al., 2012). Continued performance monitoring of

congenital cardiac surgeons is vital and might one day become a requirement for national boards and regulators as a quality control measurement. Studies demonstrate that technical performance is an important predictor of outcomes and the implementation of a system measuring technical performance for surgeons can be used for self and peer assessments. Our proposed model is focused on the outcome and the adequacy of the anatomic repair, which is under the surgeon's control. Tools such as TPS can help distinguish a surgeon's performance from an overall program's or institution's performance. Other quality metrics in the surgeon's performance, such as leadership skills and abilities to communicate and function effectively within a multidisciplinary team, should also be included and might be just as important in determining patient outcomes.

While the precise execution of an operation is an important component of surgical competency, surgical competency encompasses many more team skills and attitudes beyond technical maneuvers required in surgery (Karamichalis, Barach et al., 2012). These include: 1. team interaction and leadership pre-, intra- and postoperatively; 2. decision-making to ensure that the right operation is selected and performed; and 3. delivery of timely information to the patients' family and other healthcare providers. Surgical excellence also involves less measurable aspects such as the ability to prevent or deal with complications and understand cardiovascular physiology, cardiopulmonary bypass, and myocardial protection. Additionally, excellence requires addressing and mitigating the impact of human factor components such as fatigue, situational awareness, decision-making skills, multitasking and prioritizing.

Many factors can influence and determine a surgeon's intraoperative performance, though traditionally the emphasis has been placed on the value of comprehensive knowledge, sound surgical technique and good manual dexterity (Karamichalis, Barach et al., 2012; Nathan & Karamichalis, 2015). However, non-technical skills need to be an integral part of a surgeon's repertoire to optimize surgical performance.

Non-technical skills for surgeons (NOTSS) comprise four major categories that allow the definition and rating of surgeons' performance at the operating table (Flin, Youngson, & Yule, 2015). NOTSS include situational awareness, decision-making, communication and teamwork and leadership. While our work was focused on the technical performance as defined by the residual lesions or the adequacy of the anatomic repair, non-technical skills are essential in achieving a successful operation. NOTSS define and classify the elements involved in successful operative surgery. Models of surgical skills assessment, including video recordings of skill tests and other methods, have been developed as part of surgical training programs (Faurie & Khadra, 2012; Gofton et al., 2012; MacRae, 2011; Martin et al., 1997).

Surgical team performance can potentially be enhanced using simulation and event analysis via real time audio-visual recordings and operating room assessments of live surgery. The future direction of assessing surgical competence in congenital cardiac surgery should be focused on surgical technical performance as well as non-technical skills. Studies should be designed to assess the contribution of both technical and non-technical skills on patients' outcomes, which should be integrated in the training curriculum of surgeons as well as their ongoing professional evaluation and performance (Flin, Youngson, & Yule, 2015). Analyzing cognitive and behavioral skills in the operating room, inspired by training programs developed for aviation safety, may add significant value in enhancing intraoperative surgical team performance. It is inevitable and perhaps desirable that scoring and risk prediction systems will increasingly become the judges of our clinical activities (Angus & Pinsky, 1997).

Summary

In congenital cardiac surgery, the assessment of the adequacy of the anatomic repair or technical performance, recently renamed RLS, has been associated with early and midterm postoperative outcomes. Its routine use in a risk-stratified fashion offers a robust surgeon self-assessment and self-improvement tool in congenital cardiac surgery programs that can be used as a powerful quality improvement measure. Suboptimal technical performance is correlated with poorer outcomes, especially in high-risk operations. This led us to the imperative technical performance doctrine: efforts should be focused on achieving a good repair or (even better) optimal repair before leaving the operating room.

The adequacy of the repair should be checked by echo and hemodynamic measurements, with close vigilance in the operating room and in the immediate postoperative period with the option to reintervene and correct significant lesions. The use of cardiac MRI, 3-D imaging, CT scan, computational fluid dynamics in the assessment of the adequacy of the repair, shape, geometry, and flow dynamics will become vital in advancing the field of TPS in predicting the long-term durability of the repair and the need of future re-interventions. Physiologic illness severity scores are highly correlated with how well the surgical repair was performed and can be used to monitor and alert for any possible residual lesions. This system can be used to trigger an investigation to detect any residual lesions that might need to be corrected. Midterm and long-term outcomes appeared to be closely associated with technical performance scores. Nevertheless, needs to be done to establish the details of such correlations including neurodevelopmental outcomes. Systems and criteria of technical performance and physiologic illness severity will need to be continuously re-assessed, refined, and recalibrated as patient healthcare provisions continue to improve. The correlation of technical performance scores with postoperative outcomes appears to be associated with healthcare costs of

hospitalization for the specific medical condition treated and can serve as a metric for offering more cost-efficient healthcare and higher patient care value in a system that can be redefined by competition on value-based results.

Future studies will need to evaluate the impact of technical performance on midterm and long-term outcomes across different centers, including subtle outcomes such as neurodevelopmental and psychosocial development and resource utilization. Establishing a multicenter evaluation of technical performance metrics to develop national benchmarks and assess the impact of implementation of this system on the development and self-assessment of technical skills of surgeons and clinical outcomes would be invaluable.

Models of surgical skills assessment and training of surgeons in all aspects of surgical competence including non-technical skills (e.g., leadership, communication and situational awareness) would be of high value in a healthcare system that is moving towards value-based competition and pay for performance. Finding ways to achieve an excellent surgical repair before leaving the operating room as well as early detection and early reintervention of residual lesions, especially in high complexity pediatric cardiac operations, remains the end-goal.

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