Improving interstage survival after Norwood operation: Outcomes from 10 years of home monitoring

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Objective: Infants who undergo Norwood stage 1 palliation (S1P) continue with high-risk circulation until stage 2 palliation (S2P). Routine care during the interstage period is associated with 10% to 20% mortality. This report illustrates the sustained reduction of interstage mortality over 10 years associated with use of home monitoring.

Methods: Daily monitoring of oxygen saturation and weight was done for all patients discharged to home after S1P. Notification of the care team occurred for oxygen saturation <75% or >90%, weight gain < 20 g over 3 days, weight loss > 30 g, or intake < 100 cc/kg/d. Breach of these criteria marked an interstage event. Interstage outcomes are reported. Patient characteristics and perioperative variables were compared between patients with and without interstage events.

Results: Over 10 years, 157 patients were discharged after S1P with home monitoring. Interstage survival was 98%. Breach of home criteria occurred in 59% (93 out of 157), with violation of oxygen saturation <75% the most common event. Patient characteristics, operative data, and early postoperative morbidity did not differ between patients with and without events.

Conclusions: Home monitoring after S1P is associated with excellent interstage survival. Although a breach of monitoring criteria occurred in more than half of patients, our analysis failed to identify independent predictors of interstage events. Analysis of variables predicting mortality could not be assessed due to the low frequency of death in this cohort. Failure to identify specific variables for interstage events suggests that home monitoring, as part of an interstage surveillance program, should be applied to all S1P hospital survivors. (J Thorac Cardiovasc Surg 2014;148:1540-7)

CHD

Advances in surgical and perioperative care of infants undergoing Norwood stage 1 palliation (S1P) have resulted in 80% to 95% survival to hospital discharge.[1-5] The continued risk of death during the interstage period, following S1P hospital discharge and before stage 2 palliation (S2P) with the superior cavopulmonary connection, highlights the ongoing vulnerability inherent to single ventricle anomalies. Specifically, these infants are subject to systemic to pulmonary artery shunts, excessive volume loading on the systemic ventricle, and cyanosis. Several single-center studies report interstage mortality rates of 10% to 20%.[4,6-11] Comparably, interstage mortality was 12% in the multicenter Pediatric Heart Network Single Ventricle Reconstruction (SVR) trial of infants with hypoplastic left heart syndrome (HLHS) and single right ventricle variants.[6,13]

Interstage mortality has been associated with various patient characteristics; anatomic risk factors, including residual lesions; surgical technique at initial palliation; postoperative complications; arrhythmias; and acquired intercurrent illness.[4,6-12,14-17] Several of these factors can lead to excessive hypoxemia, hypovolemia, alteration in systemic vascular resistance, and/or progressive myocardial dysfunction. These derangements consequently place infants with parallel circulation and minimal myocardial reserve at risk for interstage death before S2P. Without the ability to definitively predict who is at risk for interstage death, home monitoring strategies have been implemented to detect physiologic variances that may precede clinical deterioration. Early experience with home monitoring of daily oxygen saturation levels and weight change has been associated with a marked reduction in interstage mortality after S1P and before S2P through timely recognition of physiologic vulnerability.[7,9,18] Since our initial report of interstage surveillance for HLHS, the home monitoring program (HMP) at Children's Hospital of Wisconsin has undergone a series of modifications in

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Abbreviations and Acronyms
ECMO = extracorporeal membrane oxygenator
HLHS = hypoplastic left heart syndrome
HMP = home monitoring program
mBTs = modified Blalock-Taussig shunt
S1P = stage 1 palliation
S2P = stage 2 palliation
SpO_2 = oxygen saturation
SVR = Single Ventricle Reconstruction

response to ongoing quality improvement cycles in the face of continued interstage morbidity and mortality. This report illustrates the impact of 10 years of our HMP targeted at reducing interstage mortality in patients undergoing the Norwood operation.

METHODS

Patient Population

Since October 2000, all patients discharged to home following S1P at Children's Hospital of Wisconsin have been enrolled in the interstage HMP as a standard of clinical practice. All S1P survivors discharged to home before S2P comprised this study cohort. Patients who remained hospitalized to S2P were excluded from the primary analysis; however, their outcomes are reported here. Local institutional review board approval and parental consent was obtained for perioperative and interstage prospective data collection.

Discharge Criteria

Continuous pulse oximetry, daily weights, and fluid intake are monitored with set goals before hospital discharge. Target oxygen saturation (SpO_2) is >75% while awake and asleep. Patients with oxygen-responsive hypoxia that is not secondary to an anatomic lesion may be discharged to home on supplemental oxygen. All patients discharged must consume a minimum of 100 cc/kg/d and demonstrate weight gain before discharge. A caloric goal of 110 to 130 kcal/kg/d is generally needed for somatic growth; however, patients able to gain weight with fewer calories do not need to meet the specified caloric goal. Patients unable to consume sufficient enteral volume or calories with oral feeds have a surgical gastrostomy tube placed without Nissen fundoplication. Patients remained as inpatients throughout the interstage period if they had complex extracardiac medical needs or concerning circulatory instability determined by the cardiac critical care team.

In preparation for home monitoring, parents undergo a comprehensive education program before discharge that includes proper use of the infant scale and pulse oximeter, review and calculation of fluid volume and nutritional intake goals, calculation of incremental changes in daily weight, accurate data recording in an individualized home monitoring log book, and comprehensive review of predetermined physiologic parameters for which a breach requires immediate reporting. Furthermore, parents are provided contact information for the interstage cardiac care team to report concerns.

HMP

As originally described, the HMP is dependent on parental involvement, and includes discharge to home with a pulse oximeter (rental charge, $350-$580 per month) and infant scale sensitive within 10 g (rental charge, $60-$190 per month). Private insurance or Medicaid almost universally covered oximeter expenses, whereas scales were reimbursed approximately 90% of the time. In the event scale coverage was not approved, scales obtained via donation were loaned to families. A parent or guardian recorded daily observations of SpO_2 and weight change. Through consensus of institutional cardiologists, cardiac intensivists, surgeons, and advance practice nurses, initial monitoring criteria necessitating notification to the interstage cardiac care team member included SpO_2 <75%, any weight loss of 30 g, or failure to gain 20 g over 3 days. Modifications to monitoring and subsequent notification were made based on quality improvement measures, and feedback solicited from families and providers. Specific modifications to notification criteria, including SpO_2 > 90 or intake < 100 cc/kg/d (June 2005) were implemented after an interstage death in 2005. Furthermore, the HMP expanded to include weekly interstage follow-up telephone contact (May 2004) between parents and the HMP team as well as development of a multidisciplinary cardiac specialty clinic for interstage infants (November 2005). At our institution, care of postoperative S1P infants through the interstage period is provided by a core group of cardiac intensivists, pediatric cardiologists, and cardiac nurse practitioners with daily management of HMP infants incorporated into the existing roles of these team members. No staff members have been added or exclusively designated to support the HMP.

Interstage events were defined as breach of the aforementioned arterial saturation or weight change criteria. Breach of predetermined parameters are immediately triaged by a member of the interstage cardiac care team who is available 24 h/d, 7 d/wk. As part of the triage process, physiologic trends, including the daily heart rate, are reviewed. The circumstances and severity of the interstage event prompt either follow-up telephone call within 24 hours, outpatient clinic or emergency room evaluation, and/or hospital admission. Parent-identified concerns beyond breach of saturation and weight criteria were addressed but not classified as events due to infrequent occurrence.

Data Collection and Analysis

Prospective perioperative and interstage databases were queried for the following variables: race; gender; birth weight; socioeconomic status; additional cardiac or extracardiac diagnosis; anatomic subtype; presence of aortic atresia; diameter of ascending aorta; age and shunt type at S1P; operative time; need for extracorporeal membrane oxygenator (ECMO) support; hospital length of stay; nutrition support, including need for enteral feeding tube; interstage breach of criteria events with interventions; and age and weight at S2P. Socioeconomic status was defined by the median income at residing ZIP code during the interstage period. Anatomic subtype was dichotomized as "HLHS" and "other" based on criteria established from the International Working Group for Mapping and Coding of Nomenclatures for Paediatric and Congenital Heart Disease.[19] Patients were considered high-risk at S1P if gestational age $\leq$ 35 weeks, birth weight < 2.5 kg, or additional cardiac or extracardiac diagnosis were present.

Data Analysis

Patient variables are summarized as count and percent, mean $\pm$ standard deviation, or median and range as appropriate. A bivariate analysis was performed comparing those with interstage events and those who did not breach criteria, and a second model compared those who remained as inpatients during the interstage period with those who were discharged home. A Student t test was used to test the difference between groups for continuous variables and Fisher exact test for categorical variables. Descriptions of interstage interventions are provided. Kaplan-Meier actuarial survival analysis with log-rank comparison between groups was used to compare overall survival. A significance level of $P \leq .05$ was used throughout. Analysis was performed with IBM-SPSS version 20 (Armonk, NY).

RESULTS

From October 2000 to October 2010, 203 patients underwent S1P with 95% (192 out of 203) survival to hospital