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ORIGINAL ARTICLE

Risk Factors for Interstage Mortality Following the Norwood Procedure: Impact of Sociodemographic Factors

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Abstract Interstage mortality remains significant for patients undergoing staged palliation for hypoplastic left heart syndrome and other related single right ventricle malformations (HLV). The purpose of this study was to identify factors related to demographics, socioeconomic position, and perioperative course associated with post-Norwood hospital discharge, pre-stage 2, interstage mortality (ISM). Medical record review was conducted for patients with HLV, born from 1/2000 to 7/2009 and discharged alive following the Norwood procedure. Sociodemographic and perioperative factors were reviewed. Patients were determined to have ISM if they died between Norwood procedure hospital discharge and stage 2 palliation. Univariable and multivariable logistic regressions were performed to identify risk factors associated with ISM. A total of 273 patients were included in the analysis; ISM occurred in 32 patients (12 %). Multivariable analysis demonstrated that independent risk factors for interstage mortality included teen mothers [adjusted odds ratio (AOR) 6.6, 95 % confidence interval (CI) 1.9–22.5], single adult caregivers (AOR 4.1, 95 % CI 1.2–14.4), postoperative dysrhythmia (AOR 2.7, 95 % CI 1.1–6.4), and longer ICU stay (AOR 2.7, 95 % CI 1.2–6.1). Anatomic and surgical course variables were not associated with ISM in multivariable analysis. Patients with HLV are at increased risk of ISM if born to a teen mother, if they lived in a home with only one adult caregiver, suffered a postoperative dysrhythmia, or experienced a prolonged ICU stay. These risk factors are identifiable, and thus these infants may be targeted for interventions to reduce ISM.

Keywords Interstage mortality · Hypoplastic left ventricle · Norwood · Sociodemographic

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Introduction

Hypoplastic left heart syndrome and other related single right ventricle malformations (HLV) are among the most serious of congenital heart diseases, accounting for 25 % of cardiac mortality in the first week of life in the absence of surgical intervention [14]. Although operative care has brought about improvements in survival rates, mortality and morbidity remain significant. The highest risk period following hospital discharge is the first interstage period, the time between Norwood hospital discharge and second stage palliation, with mortality rates between 10 and 15 % [1, 12]. There are limited data regarding specific risk factors for interstage mortality (ISM), the time period between hospital discharge from the Norwood procedure and stage 2 palliation. Identification of risk factors for ISM may assist in the formation of target patient groups for increased education or monitoring during the interstage period.

The literature to date has primarily described the effects of anatomic and physiologic factors on the risk of ISM [5, 9, 13]. A recent Pediatric Heart Network study found that in addition to surgical and anatomic factors, socioeconomic status as measured by census block, patient ethnicity, and gestational age were associated with ISM [8]. The aim of this study was to assess the influence of factors related to social position on ISM. Defining the profile of those at risk of ISM is important to enhance resource investment and direction in interstage monitoring programs. Improved understanding of risk factors for ISM will be valuable to allow efficient direction of resources and interventions.

Methods

A medical record review was conducted for patients with HLV born between January 1, 2000, and June 30, 2009, who had undergone the Norwood procedure at the University of Michigan C. S. Mott Children's Hospital. This study protocol was approved by the Institutional Review Board of the University of Michigan; written informed consent was not required. Patients were excluded if they died prior to hospital discharge from the Norwood procedure or remained in the hospital until stage 2 palliation. Patients were also excluded if they received cardiac transplantation rather than proceeding with staged palliation, or if deemed not a candidate for stage 2 palliation. Interstage mortality was defined as death after hospital discharge from the Norwood procedure and before admission for stage 2 palliation (Fig. 1). The time frame studied preceded development of the formal home monitoring program at our center.

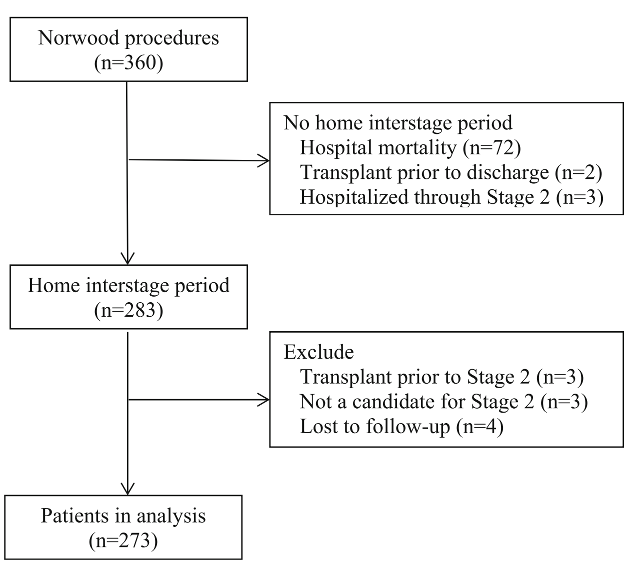

Fig. 1 Cohort inclusions and exclusions

Variables related to demographics and socioeconomic position (maternal age, family structure, insurance status, census block group variables, access to care variables, and race), underlying anatomy (anatomic subtype, the presence of obstructed pulmonary veins, ascending aortic diameter), surgical course [age at Norwood, shunt type, need for extracorporeal membrane oxygenation (ECMO), necrotizing enterocolitis (NEC), intensive care unit (ICU) length of stay (LOS)], and the postoperative period [tricuspid valve regurgitation, right ventricular systolic function, dysrhythmias, use of nasogastric (NG) tube at discharge] were reviewed. Insurance status was defined as having public or private insurance at the most recent hospital discharge.

Each patient was linked by current patient address, as recorded in the medical record, to his or her respective census block group from the 2000 U.S. census. Neighborhood *Z*-scores were calculated as a summary measure of overall neighborhood socioeconomic status, according to the methods of Diez-Roux et al. This metric comprises high school and college graduation percentages, median household income, median housing value, percent of households with interest/dividend/rent income, and percent of households with executive/manager/professional occupations [2]. In our study sample, a higher neighborhood *Z*-score reflects higher socioeconomic status for a given neighborhood. Additional census variables analyzed included percent unemployment, percent receiving public assistance, and percent with family income less than 200 % of the poverty level.

Patient access to care was also assessed using information obtained from the American Hospital Association database. Access to care was defined as distance from patient residence to the nearest hospital with a listed pediatric intensive care unit (PICU), calculated using Esri ArcMap v9.3 (Esri, Redlands, CA).

Demographic and clinical data were presented as frequency (%) for categorical variables and mean ± standard deviation (SD) or median [interquartile range (IQR)] for normally and non-normally distributed continuous variables, respectively. Associations with ISM were analyzed with Chi-square tests or Fisher's exact tests, as appropriate, for categorical variables and *t* tests for normally distributed continuous variables.

Continuous variables that were not normally distributed were dichotomized either at the 75th percentile or at a clinically meaningful cutoff, including maternal age (teen mother was defined as ≤19 years of age vs >19 years) and number of home caregivers (single adult caregiver vs >1 adult caregiver). Univariable and multivariable logistic regressions based on the available data were used to calculate unadjusted and adjusted odds ratios (OR) and 95 % confidence intervals (CI) for factors associated with ISM. Variables with at least five events and $P < 0.20$ on univariable analysis were considered for multivariable regression. Given a correlation between race and single caregiver status, and the high number of missing values for race, race was not included as a candidate variable for the multivariable model. Similarly, hospital LOS was strongly correlated with ICU LOS; ICU LOS was included in the multivariable model rather than hospital LOS given the stronger association of ICU LOS with ISM on univariable analysis. Education and income variables were components of the overall neighborhood *Z*-score and thus would have created inherent redundancies in the model. Shunt type remained in the model given the finding from the Pediatric Heart Network's Single Ventricle Reconstruction (SVR) Trial which demonstrated that an aorto-pulmonary artery shunt was associated with increased risk of ISM [11].

Model selection from multivariable logistic regressions was conducted using backward stepwise method with improvements in the model fit evaluated by the model Chi-square statistics. Multicollinearity for the variables included in the multivariable model was examined using variance inflation factor (VIF). If VIF for each variable in the model is less than 10, then it is acceptable to include all variables in the model, as VIF > 10 suggests multicollinearity. VIF for each variable in this model was <1.0. All analyses were conducted using SAS version 9.3 (SAS Institute, Cary, NC) with a significance set at $P \leq 0.05$.

Results

Patient Characteristics

A total of 360 patients diagnosed with HLV who underwent the Norwood procedure were reviewed, and 273 patients (76 %) met inclusion criteria. Of the 273 patients included, 70 % were males, 78 % Caucasian, 8 % African-American, and 14 % other/unknown race (Table 1). There were 32 interstage deaths (12 %).

Univariable Analysis

Demographic Factors

On univariable analysis, African-American race ($P = 0.0002$), younger maternal age (≤19 years) ($P = 0.004$), and living with a single adult caregiver in the home ($P = 0.02$) were associated with increased risk of ISM (Table 1).

Census Block Group and Neighborhood Z-Score

Census block group and access to care analyses are summarized in Table 1. Census information was available for 258 subjects (95 %). Twelve of the unavailable subjects (4 %) listed addresses as post office box only, two addresses (<1 %) were not found in the geocoding software, and one patient lived in a census block group with only seven residents, and thus census block information was not available. Risk of ISM was elevated in census block groups with lower average percentage of high school graduates ($P = 0.05$), and lower average rent or dividend income ($P = 0.05$). There was a trend toward increased risk of ISM with lower mean combined neighborhood *Z*-score ($P = 0.10$), but this did not meet statistical significance. Rate of unemployment and need for public assistance showed no significant relationship with ISM.

Access to Care

Access to care variables were available for 259 subjects (94.9 %). Among these subjects, median distance to the nearest PICU was 21.7 miles (IQR 9.4–44.3 miles). There was no association between distance to nearest PICU and ISM ($P = 0.83$).

Surgical Factors

Risk of ISM was not associated with cardiac diagnosis or other anatomic variables. Four percent of patients with RVPA shunts and 13 % of patients with BT shunts experienced ISM, although this difference did not meet statistical significance ($P = 0.09$).

Perioperative Factors

Interstage mortality was increased for subjects with post-Norwood ICU LOS greater than or equal to 15 days ($P = 0.009$). Similarly, hospital LOS greater than or equal to 29 days demonstrated a trend toward increased risk of ISM, though this was not statistically significant ($P = 0.10$). Postoperative dysrhythmia was associated with increased risk of ISM ($P = 0.03$).

Multivariable Analysis

Candidate risk factors included in multivariable modeling are shown in Table 2. The final multivariable logistic regression demonstrated that independent risk factors for ISM included teen mothers (AOR 6.6, 95 % CI 1.9–22.5), single adult caregivers (AOR 4.1, 95 % CI 1.2–14.4), postoperative dysrhythmia (AOR 2.7, 95 % CI 1.1–6.4), and longer ICU LOS (AOR 2.7, 95 % CI 1.2–6.1) (Table 3).

Table 1 Risk factors for interstage mortality: univariable analysis ($N = 273$)

Demographic	Overall $N = 273$	Interstage death $N = 32$	Survivor $N = 241$	$P^{§}$
Male sex	190 (69.6)	20 (62.5)	170 (70.5)	0.35
Race				
Caucasian	213 (78.0)	18 (56.3)	195 (80.9)	
African-American	23 (8.4)	9 (28.1)	14 (5.8)	**0.0002**
Hispanic	11 (4.0)	1 (3.1)	10 (4.1)	0.99
Other/unknown	26 (9.5)	4 (12.5)	22 (9.1)	0.27
Prenatal diagnosis	192 (70.3)	25 (78.1)	167 (69.3)	0.34
Preterm (gestational age <37 weeks)	30 (11.0)	4 (12.5)	26 (10.8)	0.76
Birth weight (kg), mean ± SD	3.2 ± 0.6	3.2 ± 0.5	3.2 ± 0.6	0.41
Teen mother (age ≤19 years)	15 (5.5)	6 (18.8)	9 (3.7)	**0.004**
Single adult caregiver	15 (5.5)	5 (15.6)	10 (4.1)	**0.02**
Siblings at home				
0	96 (35.2)	11 (34.4)	85 (35.3)	0.27
1	96 (35.2)	8 (25.0)	88 (36.5)	
2+	80 (29.3)	13 (40.6)	67 (27.8)	

Socioeconomic position (census and geographic)	Overall $N = 258$	Interstage death $N = 30$	Survivor $N = 228$	$P^{§}$
Neighborhood *Z*-score, mean ± SD	0 ± 5.2	−1.48 ± 4.46	0.19 ± 5.25	**0.10**
High school graduate (%), mean ± SD	83.5 ± 9.8	80.2 ± 9.2	83.9 ± 9.8	**0.05**
College graduate (%), mean ± SD	20.8 ± 14.4	17.1 ± 12.0	21.3 ± 14.7	**0.14**
Log household income, mean ± SD	4.63 ± 0.18	4.59 ± 0.17	4.64 ± 0.18	0.21
Log housing value, mean ± SD	4.99 ± 0.23	4.96 ± 0.23	5.00 ± 0.23	0.40
Dividend/rent income (%), mean ± SD	35.9 ± 15.5	30.8 ± 14.6	36.6 ± 15.5	**0.05**
Manager/professional (%), mean ± SD	30.7 ± 13.4	28.0 ± 10.2	31.0 ± 13.8	0.26
Unemployment (%), median (IQR)	4.6 (2.4–6.9)			
≥6.9 % (75th percentile)	67 (26.0)	10 (33.3)	57 (25.0)	0.33
Receiving public assistance (%), median (IQR)	2.2 (0.2–4.2)			
≥4.2 % (75th percentile)	66 (25.6)	8 (26.7)	58 (25.4)	0.89
Income <200 % poverty level (%), median (IQR)	24.3 (14.2–37.3)			
≥37.3 % (75th percentile)	65 (25.2)	6 (20.0)	59 (25.9)	0.49
Distance to nearest PICU (miles), median (IQR)	21.7 (9.4–44.3)			
≥44 miles (75th percentile)	65 (25.1)	8 (26.7)	57 (24.9)	0.83

Perioperative	Overall $N = 273$	Interstage death $N = 32$	Survivor $N = 241$	$P^{§}$
Age at Norwood (days), median (IQR)	6 (5–8)			
<8 days	189 (69.2)	26 (81.3)	163 (67.6)	**0.12**
Cardiopulmonary bypass (min), median (IQR)	84 (71–115)			
≥115 min (75th percentile)	72 (26.4)	10 (31.3)	62 (25.7)	0.51
Aortic cross-clamp (min), median (IQR)	40 (36–46)			
≥46 min (75th percentile)	75 (27.5)	13 (40.6)	62 (25.7)	**0.08**
Circulatory arrest (min), median (IQR)	38 (32–44)			
≥44 min (75th percentile)	74 (27.1)	11 (34.4)	63 (26.1)	0.33
Use of regional cerebral perfusion	41 (15.0)	7 (21.9)	34 (14.1)	0.29
Shunt revised	23 (8.4)	5 (15.6)	18 (7.5)	**0.17**
Shunt				

Table 1 continued

Perioperative	Overall $N = 273$	Interstage death $N = 32$	Survivor $N = 241$	$P^{\S}$
BT or central	227 (83.2)	30 (93.8)	197 (81.7)	**0.09**
RV to PA	46 (16.8)	2 (6.3)	44 (18.3)	
Anatomy				
MS/AA	67 (24.5)	6 (18.8)	61 (25.3)	**0.13**
MS/AS	109 (39.9)	11 (34.4)	98 (40.7)	
MA/AA	89 (32.6)	12 (37.5)	77 (32.0)	
MA/AS	8 (2.9)	3 (9.4)	5 (2.1)	
Known genetic anomaly	10 (3.7)	1 (3.1)	9 (3.7)	0.99
Ascending aorta ≥2 mm	232 (85.0)	28 (87.5)	204 (84.6)	0.99
Obstructed pulmonary vein	16 (5.9)	3 (9.4)	13 (5.4)	0.41
Severe tricuspid regurgitation, preoperative	5 (1.8)	1 (3.1)	4 (1.7)	0.47
Severe tricuspid regurgitation, postoperative	12 (4.4)	3 (9.4)	9 (3.7)	**0.15**
Moderately–severely depressed ventricular function, preoperative	20 (7.3)	5 (15.6)	15 (6.2)	**0.07**
Moderately–severely depressed ventricular function, discharge	22 (8.1)	5 (15.6)	17 (7.1)	**0.16**
Postoperative dysrhythmia	53 (19.4)	11 (34.4)	42 (17.4)	**0.03**
ECMO required	23 (8.4)	4 (12.5)	19 (7.9)	0.33
NEC	31 (11.4)	6 (18.8)	25 (10.4)	0.23
GERD	115 (42.1)	11 (34.4)	104 (43.2)	0.32
NG feeding tube at discharge	238 (87.2)	31 (96.9)	207 (85.9)	0.23
Vocal cord paresis	17 (6.2)	2 (6.3)	15 (6.2)	0.99
Tracheostomy	7 (2.6)	1 (3.1)	6 (2.5)	0.59
Arrest requiring CPR	19 (7.0)	4 (12.5)	15 (6.2)	0.26
Seizures	25 (9.2)	5 (15.6)	20 (8.3)	**0.19**
Dialysis	10 (3.7)	3 (9.4)	7 (2.9)	**0.10**
Discharge weight (kg), mean ± SD	3.4 ± 0.6	3.3 ± 0.5	3.4 ± 0.6	0.46
ICU LOS (days), median (IQR)	9 (7–15)			
≥15 days (75th percentile)	75 (27.5)	15 (46.9)	60 (24.9)	**0.009**
Hospital LOS (days), median (IQR)	20 (15–29)			
≥29 days (75th percentile)	77 (28.2)	13 (40.6)	64 (26.6)	**0.10**

Data are presented as *N* (%) unless otherwise noted

Bolded values indicate *P* value less than 0.2. Of these variables, the ones included in the multivariable model are listed in Table 2

PICU pediatric intensive care unit, *BT* Blalock–Taussig, *RV* right ventricle, *PA* pulmonary artery, *MS* mitral stenosis, *AA* aortic atresia, *MS* mitral stenosis, *AS* aortic stenosis, *ECMO* extracorporeal membrane oxygenation, *NEC* necrotizing enterocolitis, *GERD* gastroesophageal reflux disease, *NG* nasogastric, *CPR* cardiopulmonary resuscitation, *ICU* intensive care unit, *LOS* length of stay

§ *P* value from χ^2 or *Fisher*'s exact test (as appropriate) for categorical variables and *t* test for continuous variables

Discussion

We found that ISM occurred in 12 % of subjects during the study period, which is consistent with the multicenter SVR trial results [8, 11]. The study period predates development of the formal home monitoring program at our center. We did find an association between sociodemographic factors and ISM; an increased risk of ISM was independently associated with a greater than 2-week stay in the ICU, having a teenage mother, and living in a home with only one adult caregiver as well as postoperative dysrhythmia.

In this study, we focused on addressing demographic factors and variables related to socioeconomic position in three ways: (1) analyzing census information, (2) assessing proximity to care, and (3) understanding social factors at the individual level.

Perhaps our most novel findings were that independent risk factors for ISM included children of teenage mothers

Table 2 Risk factors for interstage mortality on univariable analysis: candidates for multivariable model

Characteristics	Odds ratio (OR)	95 % CI of OR (lower, upper)	P value[§]
Demographic			
Teenaged mother	5.8	1.6, 19.9	0.004
Single adult caregiver	4.2	1.1, 14.8	0.02
Perioperative			
<8 days of age at Norwood	2.1	0.8, 5.2	0.12
≥46 min of aortic cross-clamp time	2.0	0.9, 4.2	0.08
Shunt revision	2.3	0.6, 7.1	0.17
BT or central shunt	3.4	0.8, 14.5	0.09
Severely depressed preoperative ventricular function	2.7	0.7, 8.7	0.07
Severely depressed ventricular function at discharge	2.4	0.6, 7.5	0.16
Postoperative dysrhythmia	2.4	1.1, 5.5	0.03
Seizure	2.0	0.5, 6.2	0.19
ICU LOS ≥ 15 days	2.6	1.2, 5.6	0.01
Census			
Neighborhood Z-score	0.9	0.9, 1.0	0.10

BT Blalock–Taussig, *ICU* intensive care unit, *LOS* length of stay

[§] P value from univariable logistic regression modeling risk of interstage death; exact OR/P value reported as appropriate

Table 3 Independent risk factors for interstage mortality

Characteristics	Adjusted odds ratio (OR)	95 % CI of OR (lower, upper)	P value[§]
Teenaged mother	6.6	1.9, 22.5	0.003
Single adult caregiver	4.1	1.2, 14.4	0.03
BT or central shunt	4.0	0.9, 18.1	0.08
Postoperative dysrhythmia	2.7	1.1, 6.4	0.03
ICU LOS ≥ 15 days	2.7	1.2, 6.1	0.02

BT or central shunt was forced into the model based on findings from the single ventricle reconstruction trial

BT Blalock–Taussig, *ICU* intensive care unit, *LOS* length of stay

[§] P value from multivariable logistic regression modeling risk of interstage mortality

and children with only one adult caregiver. These variables may relate to socioeconomic status, which is historically difficult to define and is especially difficult in this retrospective review. However, it is also possible that children of teenage mothers and those with only one adult caregiver may have an increased risk of ISM which is independent of socioeconomic status. Children with HLV have multiple medical needs after discharge from the Norwood procedure. In households with few (and young) caregivers, it may be an even greater challenge with more limited resources to manage medically complex children given limited time resources.

Mackie and colleagues found that low socioeconomic status, as defined by living in a low-income zip code (<$30,000 average household income per year), reduced the likelihood of readmission after congenital cardiac surgery, suggesting that reduced access to care may impact this population [10]. In addition, analysis of the Pediatric Heart Network's SVR data demonstrated that children living in a census block at 5.4–13 % below the poverty line were at higher risk of ISM than those living in areas with fewer than 5.4 % below the poverty line, or greater than 13 % below the poverty line [8].

To examine the role of race specifically, Fixler et al. [3] demonstrated that in the first 5 years of life for infants with HLV, non-Hispanic blacks had an adjusted risk of death that was 41 % higher than that of non-Hispanic whites. The SVR study demonstrated that Hispanic ethnicity is an independent risk factor for ISM in multivariable analysis [8]. Further, in the American Association of Pediatrics review of health disparities over a 56-year period, it was found that children in all major US minority groups, including non-Hispanic blacks, had substantially greater risks of all-cause mortality after congenital heart surgery than whites [4]. Thus, in studies of patients with a variety of congenital heart diseases, including single ventricle lesions, racial minorities, and patients with families of low socioeconomic status were at a survival disadvantage, supporting the findings in our specific population.

Our finding that post-Norwood dysrhythmias were associated with increased risk of ISM is consistent with the findings from Simsic et al. [13], who found that arrhythmia in the postoperative period and decreased ventricular function at hospital discharge were independent risk factors for ISM in patients who have undergone the Norwood procedure. We also found that longer ICU stay was associated with an increased risk of ISM. Prolonged ICU LOS is likely a surrogate variable for the sickest patients. In fact, having a higher number of postoperative complications correlated with longer total LOS and was an independent risk factor for ISM in the SVR study [9].

Data from the SVR study demonstrated that ISM was higher among subjects with an aorto-pulmonary shunt compared to those who had been randomized to a right ventricle-to-pulmonary artery shunt. In our study, shunt type was not randomized, though some of our study's subjects were from the era where patients were randomized in the SVR study. Interstage mortality for the group in our study with a Blalock–Taussig or central shunt at the Norwood procedure was 13 % compared to only 4 % of those with a right ventricle-to-pulmonary artery shunt. Thus, while not statistically significant, these point estimates are consistent with the findings from the SVR study.

There are several limitations to our study. First, this is a retrospective study and as such, there could be inherent biases secondary to our clinical practices. In addition, the American Hospital Association data were limited in completeness and based on institution self-report. Potentially, hospitals with reported pediatric care may have had very limited pediatric care, and others who could provide this care may not have thoroughly reported their work. We were unable to identify which pediatric intensive care units were part of a hospital that is designated as a tertiary care facility, nor were we able to discern which pediatric intensive care units had a strong pediatric cardiology presence. Thus, there are limitations to the access to care analyses. Finally, this study's event size is small (32 interstage deaths), and we have tested multiple variables for their relationship to ISM, which may raise the possibility of false associations.

Despite these limitations, the finding that some subjects may be identifiable as having increased risk of ISM prior to hospital discharge is valuable, in order to effectively focus efforts to improve interstage survival. There has been interest in providing home monitoring to all infants during the interstage period; some reports on home monitoring have shown no interstage deaths in those patients who were monitored [6, 7]. Although the results are encouraging, resource-intensive home monitoring programs may not be possible for all infants who have undergone the Norwood procedure. Our findings provide a potential target population for home monitoring, increased home nursing visits, or more educational initiatives for parents prior to hospital discharge.

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Compliance with Ethical Standards

Conflict of interest The authors have no conflicts of interest to report.

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