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ORIGINAL ARTICLE

WILEY Congenital Heart Disease

Practice trends over time in the care of infants with hypoplastic left heart syndrome: A report from the National Pediatric Cardiology Quality Improvement Collaborative

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Abstract

Objective: The National Pediatric Cardiology Quality Improvement Collaborative (NPC-QIC) was established in 2008 to improve outcomes of hypoplastic left heart syndrome (HLHS) during the interstage period. They evaluated changes in patient variables and practice variation between early and late eras.

Design: Data including demographic, operative, discharge, and follow-up variables from the first 100 patients (6/2008–1/2010) representing 18 centers were compared with the most recent 100 patients (1/2014–11/2014) from these same centers.

Results: Prenatal diagnosis increased from 69% to 82% ($P = .05$). There were no differences in gestational age or weight at Norwood. A composite of any preoperative risk factor occurred more frequently in the early era (59% vs. 34%, $P < .01$). While mean age at Norwood was similar (8.3 vs. 6.6 days, $P = .2$), the standard deviation was significantly lower in the recent era (10.4–6.4 days, $P = .04$). Use of RV-PA conduit increased (67%–84%, $P < .01$). Rates of complete discharge communication with both the primary care physician (31%–97%, $P < .01$) and primary cardiologist (44%–97%, $P < .01$) increased substantially. There were limited changes in feeding strategies. Use of home monitoring program increased (76%–99%, $P < .01$) with all participants in the late era monitoring both oxygen saturation and weight.

Conclusions: Among NPC-QIC centers contributing patients to both eras, there were significant changes in preoperative risk factors, surgical strategy, discharge communication, and interstage care. Further study is required to determine an association between these changes and decreased mortality.

KEYWORDS

hypoplastic left heart syndrome, quality improvement, mortality, outcomes research, pediatrics, congenital heart disease

1 | INTRODUCTION

Despite great advancements in the care of children born with congenital heart disease (CHD), hypoplastic left heart syndrome (HLHS) remains a challenging condition to manage. The transplantation-free survival rate at 12 months among infants undergoing surgical palliation for HLHS was 69% in the multicenter Single Ventricle Reconstruction (SVR) trial (2005-2008).[1] Focused on improving these suboptimal outcomes, the National Pediatric Cardiology Quality Improvement Collaborative (NPC-QIC) began a project "to reduce mortality and improve the quality of life of infants with HLHS" though application of quality improvement science.[2] The first phase focused on the interstage period defined as the period starting from hospital discharge after stage I (Norwood) palliation and ending at stage II (bidirectional Glenn)

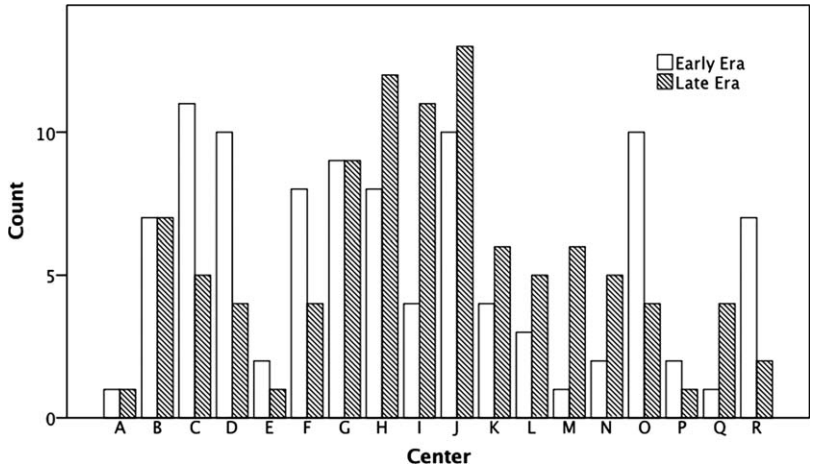

FIGURE 1 Illustrates the number of patients in the early and late eras at 18 centers

palliation. Mortality rate during the interstage period was 15% in the SVR trial.[1]

The initial publications from NPC-QIC reported significant practice variation among the first 100 enrolled patients with regards to preoperative, intraoperative, and postoperative care surrounding stage I palliation as well as in care during the interstage period.[3–5] Almost a half-decade later, NPC-QIC has grown to incorporate 56 cardiac care centers and hundreds of clinicians and parents and who convene up to twice per year to discuss care strategies. Centers participating in the NPC-QIC registry at the time of this publication can be found in Appendix. Interstage mortality within NPC-QIC has decreased from 9.5% to 5.3% since the start of NPC-QIC.[6] Our objective was to evaluate changes in patient enrollment characteristics, care strategies and practice variation that may have paralleled this mortality reduction. We hypothesized that there have been reductions in patient specific risk factors as well as practice variation as measured by discharge processes, nutrition care, interstage monitoring, and surgical timing.

2 | METHODS

The NPC-QIC Registry Database has been described in prior publications.[4] General inclusion criteria for NPC-QIC registry enrollment consists of: (1) univentricular heart disease necessitating stage I Norwood operation or its variants; and (2) survival to and discharge from the hospital into the outpatient interstage prior to bidirectional Glenn. For purposes of the present study, univentricular hearts of left ventricular type were excluded. Patients undergoing the hybrid variant of the Norwood procedure were excluded because this group (a) might include patients bridged to transplant as the intended pathway, and (b) might represent the experience of a centers performing hybrids disproportionately.

We defined two eras for comparison—early and late. The early cohort represents patients from the 6/2008 to 1/2010. This cohort includes many of the patients from the initial NPC-QIC studies.[3–5] The late cohort represented patients from 1/2014 to 11/2014. Using the same 18 centers for both early and late cohorts, data was collected on 100 consecutive patients meeting inclusion criteria within each era. Institutional review board approval or exemption is obtained at each contributing site prior to participation in the registry.

Baseline demographic information obtained included birth variables, cardiac anatomic diagnosis, major genetic and organ system problems, and pre-operative morbidity variables. Operative information obtained included age at Norwood surgery, shunt type, and duration of cardiopulmonary bypass, aortic cross clamp, and circulatory arrest. Initial interstage information included nutrition route, caloric content, self-reported measures of discharge communication to primary care physician and primary cardiologist, and details on interstage monitoring. Subsequent follow-up data included weight and timing of Glenn and mortality outcomes.

Summary statistics for baseline, operative, and interstage variables were compared between the early and late era cohorts. Categorical variables were compared using Fisher's exact test. Continuous variables were compared using either Student *t*-test or Mann-Whitney U test for where appropriate. Median is reported with interquartile range for nonnormally distributed continuous variables and range for categorical variables. Variation of continuous variables was compared using Levene's Test for Equality of Variances. Kaplan-Meier survival analysis was used to calculate interstage survival with patients censored at early withdrawal from the database or transplantation. Statistically significant differences were defined as $P < .05$. As part of a secondary analysis, a univariate analysis was performed with center as a blocking variable to account for nonindependence of the observations since the eras are comprised of patients from the same centers.

3 | RESULTS

The early and late cohorts were comprised of 100 patients each, representing 18 institutions (Figure 1). Table 1 demonstrates baseline and preoperative differences between the cohorts as well as breakdown of underlying cardiac diagnoses. The prenatal diagnosis rate increased from 72% to 82% ($P = .07$) between cohorts. There was no difference in gestational age at Norwood palliation though weight at the time of surgery was less in the early era. There were significant decreases in incidence of preoperative risk factors mechanical ventilatory support and

TABLE 1 Baseline and preoperative variables

	Early ($n = 100$)	Late ($n = 100$)	P value
Prenatal Dx	72	82	.07
Gestational age (d)	39 (31-43)	39 (33-41)	.7
Norwood weight (kg)	3.1 ± 0.4	3.3 ± 0.6	.03
Norwood weight (Z score)	−1 ± 0.8	−0.7 ± 1	.01
Any noncardiac system anomaly	12	6	.2
Major syndrome	12	11	.6
Preop Risk Factors (Any)	58	34	<.01
Mechanical ventilatory support	41	17	<.01
Acidosis	26	8	<.01
Renal insufficiency	6	1	.1
Arrhythmia	4	1	.4
NEC	1	0	1.0
Sepsis	1	2	1.0
Primary cardiac diagnosis			
Hypoplastic left heart syndrome			<.01
Mitral & aortic atresia	40	33	
Mitral & aortic stenosis	18	21	
Mitral stenosis, aortic atresia	11	29	
Mitral atresia, aortic stenosis	5	1	
Other single ventricle types	26	16	

Data reported as mean ± standard deviation or median with range.

acidosis. A composite of any preoperative risk factor (mechanical ventilation, acidosis, renal insufficiency, arrhythmia, NEC, sepsis) occurred more frequently in the early era (58% vs. 34%, $P < .01$). Irrespective of era, infants with prenatal diagnosis had lower rates of ventilatory support (22% vs. 52%, $P < .01$), acidosis (11% vs. 37%, $P < .01$), and renal insufficiency (2% vs. 9%, $P = .05$) prior to Norwood. Differences in underlying cardiac diagnoses between cohorts are listed in Table 1.

Age at Norwood palliation was comparable between the early and late cohorts (median 5.5 vs. 5 days, $P = .7$, mean 8.3 vs. 6.6 days, $P = .2$). While there was no difference in median timing of Norwood palliation, intragroup variation in timing of this surgery, as represented by standard deviation, was significantly reduced from 10.4 to 6.4 days ($P = .03$). Irrespective of era, patients with a prenatal diagnosis had a lower median age at Norwood palliation (5 vs. 8 days, $P < .01$). Other operative variables are demonstrated in Table 2. Use of RV-PA conduit increased from 69% to 84% ($P < .01$). Differences in cardiopulmonary bypass time, aortic cross-clamp time, and circulatory arrest time are listed in Table 2, demonstrating longer cardiopulmonary bypass times and aortic cross-clamp times in the later cohort. Intragroup variation as represented by standard deviation was unchanged between eras. Irrespective of era, there was no difference in these surgical times when grouped by shunt type.

Discharge variables are listed in Table 3. Time from Norwood to discharge was unchanged. Rates of complete discharge communication with the primary care physician and primary cardiologist increased substantially between eras. Routes of nutrition between groups were also compared. In the early era, 89% of patients were discharged with some degree of oral feeding compared with 74% in the late era ($P = .01$). Of patients requiring supplementation of enteric feeds, the frequency of G-tube placement was unchanged (20% in the early era vs. 25% in the late era, $P = .5$). Median calorie content at discharge was unchanged. Weight Z-score at Glenn and weight gain between Norwood and Glenn were similar in both groups.

Use of interstage outpatient surveillance program increased from 76% to 99% ($P < .01$) with all participants in the late era monitoring both oxygen saturation and weight. Outpatient interstage follow-up was performed exclusively at or in combination with the primary Norwood center in 70% of early patients and 84% of late patients ($P = .1$).

Glenn palliation was performed in 84 patients in the early era and 82 in the later era. As demonstrated in Table 3, patients in the later era were younger at Glenn palliation and had a shorter interval between Norwood discharge and Glenn. Withdrawal from database during the interstage period occurred in 6 early patients (3 lost to follow-up, 2 deemed not Glenn candidates, and 1 for unknown reasons) and 3 late patients (2 deemed not Glenn candidates and 1 for unknown reasons). Interstage mortality occurred in 9 patients in the early era at a median time of 31 days (after Norwood discharge) and 10 patients in the late era at a median time of 57 days. Interstage survival was no different at 91% and 90%, respectively. Transplantation was performed in 1 early era and 5 late era patients.

When center was introduced as a blocking variable, the only significant change to the results can be found in Table 3. Reported P values for Age at Glenn and Interstage Duration changed to.1.

4 | DISCUSSION

Our objective was to analyze changes in care strategies and practice variation in the management of HLHS infants between an early and recent era within the NPC-QIC. We found significant changes in preoperative risk factors, Norwood surgical strategy, discharge communication, and interstage monitoring while other aspects of care remained

TABLE 2 Operative variables

	Early (n =100)	Late (n= 100)	P value
Age at Norwood (days)	5 (3, 8)	5 (4, 7)	.6
Initial shunt type			.01
BT shunt	31%	16%	
RV-PA conduit	69%	84%	
Surgical time data (minutes)			
Cardiopulmonary bypass	143 (111, 172)	163 (137, 186)	<.01
Aortic cross-clamp	57 (41, 75)	78 (57, 91)	<.01
Circulatory arrest	10 (0, 43)	11 (4, 22)	.9

Data reported as median with interquartile range.

TABLE 3 Interstage variables[a]

	Early (n = 100)	Late (n = 100)	*P* value
Time from Norwood to discharge	26 (17, 42)	28 (16, 43)	.8
Complete PCP communication	27	97	<.01
Complete 1° cardiologist communication	40	97	<.01
Nutrition Route			.1
Oral only	44	36	
NG/NJ only	8	20	
Gtube only	3	6	
Oral and NG/NJ	37	27	
Oral and Gtube	8	10	
Cal/oz at discharge	24 (20–35)	24 (19–30)	.8
Interstage monitoring	76	99	< .01
Both O2 and weight	70	99	< .01
Followed at:			.1
Norwood center	56	61	
Other center	28	15	
Combination	13	23	
Other	2	1	
Age at Glenn	153 (122, 181)	140 (117, 160)	.02[b]
Interstage duration	114 (91, 142)	101 (72, 124)	.01[b]
Weight Z score at BDG	−1.2 ± 1.1	−1.2 ± 1	.9
Weight gain between Norwood and BDG (g/d)	21 ± 5	20 ± 5	.4

All intervals and ages reported in days. Cal/oz indicates calories per ounce, or the caloric content of formula or milk. g/d indicates grams per day. Data reported as mean ± standard deviation or median with interquartile range for continuous variables and range for categorical variables.

unchanged. The strength of this study lies in the use of a multicenter quality improvement registry that has collected data from the same institutions over two different eras.

First, we found important reductions in preoperative risk factors, especially mechanical ventilatory support and presence of acidosis, in the late era. The decrease in preoperative risk factors in our study was associated with an increase in the prenatal diagnosis rate, which was 82% in the most recent era among the centers in this study. There was also decreased variation in timing of Norwood palliation among the late era patients, likely related to a higher prenatal diagnosis rate corresponding to statistically significant lower median age and standard deviation. The design of this study, however, limits the conclusions that can be drawn from these findings, as addressed below in the limitations section. In addition, we cannot account general evolution of practices, for example use of near-infrared spectroscopy monitoring[7] and preoperative care transition from neonatal to cardiac intensive care units,[8] occurring independently of the NPC-QIC which may also have impacted preoperative morbidities. We can therefore speculate, but not conclude from this data, that better prenatal diagnosis may be allowing for standardization and optimization of the preoperative Norwood condition. While preoperative patient variables have previously been shown to impact Norwood survival,[9] the impact on postsurgical outcomes and potentially interstage mortality remains unproven.

Another difference involved an increase in the number of patients with the anatomic substrate of mitral stenosis and aortic atresia. Single center studies in 2008[10,11] demonstrated increased mortality in this anatomic substrate, while a subsequent single center study did not find any mortality difference and postulated that use of an RV to PA conduit rather than a BT shunt may have improved outcomes in this substrate.[12] The increased prevalence of Sano conduits in the late cohort may explain why more patients with mitral stenosis and aortic atresia reach the interstage period. Alternatively, when faced with this anatomic substrate, more centers may have opted for alternate care strategies such as hybrid Norwood or primary transplantation in the early cohort before gravitating back to standard Norwood palliation in the late cohort as evidenced emerged from the Single Ventricle Reconstruction trial that perhaps this anatomic substrate did not carry high risk for standard Norwood palliation.[13]

Next, utilization of the Sano modification of the Norwood procedure increased in the late era. This increase may be a consequence of centers switching to the Sano modification after publication of improved interstage and first year survival in this group within the SVR trial.[1] Single ventricle physiology with a Sano conduit instead of a BT shunt may have advantages in the interstage period related to higher diastolic and coronary artery pressures.[14] While there are likely multiple etiologies for improved interstage mortality over time in the entire NPC-QIC collaborative, higher Sano utilization may be one explanation for this finding.[6]

Some aspects of care have not experienced improvement or reduction in practice variation. While not NPCQIC quality improvement targets to date, cardiopulmonary bypass and aortic cross clamp times increased in the later era. This could not be explained by a greater utilization of the Sano conduit. Data on low flow cerebral perfusion was not available.

We found high rates of standardization with regards to discharge practices following the Norwood procedure as well as standardization of interstage surveillance. Use of a home monitoring program tracking daily oxygen saturation and weight after Norwood discharge was first reported in 2003 by Ghanayam et al.[15] and has been suggested to improve interstage survival in some[16–18] but not all subsequent studies.[19,20] While the extent to which home monitoring programs contribute to interstage mortality reduction can be debated, the data from the centers included in this study demonstrate that home monitoring of oxygen saturation and weight has become universally adopted within the collaborative.

Nutritional practices at Norwood discharge have evolved in a variable fashion. Oral feeding was permitted in fewer patients and represents the sole change between eras. Caloric content of formula or milk was unchanged. A similar majority of patients in both eras utilized NG or NJ tubes rather than G-tubes when supplemental enteric feeding was used. We found no improvement in weight gain outcomes. This

may be a consequence of which centers were included as a prior NPC-QIC analysis demonstrated decreased variation in interstage growth driven by improvement of the low performing centers.[21] Our methodology also included different centers, time periods, and weight gain outcome. Feeding modality seemed to not affect growth in one prior NPC-QIC analysis[22] while a separate multi-institutional analysis found better weight gain in orally fed infants.[23] Target caloric intake at discharge has recently been associated with improved interstage growth in this population.[22] With other studies highlighting a high incidence of poor weight gain in this population[24,25] and an association with worse outcomes,[26,27] effects of feeding modality should continue to be studied and pursuit of more aggressive caloric supplementation may be reasonable.

This study did have some limitations. First, the study was intended to re-examine aspects of HLHS care detailed in the original articles covering the first 100 patients[3–5] and therefore was limited to 100 patients in both cohorts. This study was not powered to detect differences in interstage mortality. The study was also not designed to explore associations between practice changes observed in this study and collaborative-wide reduction in interstage mortality.[6] Also, the early era cohort differed from early NPC-QIC analyses[3–5] because we limited the analysis to centers represented in both eras and we excluded hybrid Norwood patients.

Next, our study included only patients discharged home after Norwood but not those who may have died before or after Norwood or remained inpatient between Norwood and Glenn. We could not account for evolving discharge criteria over time. For example, this data shows that late era patients entering the interstage period had reductions in preoperative risk factors but does not evaluate whether risk factor reduction has occurred among all HLHS infants undergoing Norwood.

A final limitation is the inclusion of only 18 centers in this study design. The data presented reflects HLHS care at these centers and may not be representative of care throughout NPC-QIC institutions as well as those not participating in the collaborative. The most common practice trends in this data should not be taken as best practice without consideration of other studies intended to answer such questions. We limited our design to these 18 centers found in both eras in part because including all centers would have prevented our ability to identify true practice evolution within the collaborative versus simply incorporating centers with different practices. We also cannot exclude the possibility that improved discharge practices are reflective of improved documentation. Lastly, we attempted to account for statistical non-independence of observations to account for center effect, and this appeared to have minimal impact on our findings with the exception that outcomes related to earlier performance of Glenn lost statistical significance.

The previous limitations help explain why our study identified evolving practice patterns and patient variables but did not find survival and nutritional outcome improvement. One implication of this study is that the improved interstage mortality within NPC-QIC cannot be fully explained by the variables captured in this data collection. The upcoming NPC-QIC phase 2 will expand data collection and may help identify factors associated with improved outcomes.

Despite these limitations, the present study is important because it describes changing aspects of care of high risk HLHS infants. We have observed evolving practice patterns related to surgical technique and widespread standardization of discharge processes and interstage monitoring. Patients entering the interstage period have less preoperative risk factors, but it remains unclear whether this is a true reflection of better preoperative care and prenatal diagnosis due to limitations of NPC-QIC database. Earlier age at Glenn may reduce exposure to the high risk interstage period. Finally, nutritional practices in this study demonstrated little change between eras and represent potential areas for improvement. The findings in this study may influence HLHS management strategies, particularly at centers not already involved in quality improvement initiatives such as NPC-QIC.

AUTHOR CONTRIBUTIONS

Concept/design: WFC, JFC, JBA
Data analysis/interpretation: all authors
Drafting article: WFC, JFC, JBA
Critical revision of article: all authors
Approval of article: all authors

CONFLICT OF INTEREST

None.

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APPENDIX: LIST OF CENTERS PARTICIPATING IN NPC-QIC AT THE TIME OF EARLY ERA DATA COLLECTION

Cincinnati Children's Hospital Medical Center	Riley Hospital for Children
Children's Hospital Boston	Seattle Children's Hospital
Children's Hospital and Medical Center, Omaha	UC Davis Children's Hospital
Mattel Children's Hospital UCLA	University of Minnesota Amplatz Children's Hospital
Children's National Medical Center	University of Texas Health Science Center
Texas Children's Hospital	Arkansas Children's Hospital
Children's Healthcare of Atlanta	University of Chicago Comer Children's Hospital
Children's Memorial Hospital	Children's Hospital of Philadelphia
Nationwide Children's Hospital	Maria Fareri Children's Hospital
Arizona Pediatric Cardiology Consultants	Yale New Haven Children's Hospital
Children's Hospital Los Angeles	Children's Hospital of Wisconsin
UVA Children's Hospital	Duke University Medical Center
Penn State Hershey Children's Hospital	All Children's Hospital
Johns Hopkins Hospital	NYU Medical Center
Mayo Clinic–Rochester	Advocate Hope Children's Hospital
Lucile S. Packard Children's Hospital at Stanford	Children's Hospital and Research Center Oakland
Monroe Carrell Jr Children's Hospital at Vanderbilt	Cleveland Clinic Children's Hospital
Oklahoma Children's Heart Center	Methodist Children's Hospital
Doernbecher Children's Hospital	The Children's Hospital of Montefiore
Primary Children's Medical Center	Cohen Children's Medical Center
Arnold Palmer Children's Hospital	Miami Children's Hospital
Children's Medical Center Dallas	

Only centers with patients in both eras contributed data to this analysis. Centers remained de-identified for this analysis.