Cardiology in the Young

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Original Article

Cite this article: Bates KE, Yu S, Lowery R, Pasquali SK, Brown DW, Manning PB, Uzark K. (2018). Examining variation in interstage mortality rates across the National Pediatric Cardiology Quality Improvement Collaborative: do lower-mortality centres have lower-risk patients? *Cardiology in the Young* page 1 of 6. doi: 10.1017/S1047951118000926

Received: 16 February 2018
Revised: 1 May 2018
Accepted: 5 May 2018

Key words:
CHD; hypoplastic left heart syndrome; Norwood operation

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Examining variation in interstage mortality rates across the National Pediatric Cardiology Quality Improvement Collaborative: do lower-mortality centres have lower-risk patients?

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Abstract

Background: Although interstage mortality for infants with hypoplastic left heart syndrome has declined within the National Pediatric Cardiology Quality Improvement Collaborative, variation across centres persists. It remains unclear whether centres with lower interstage mortality have lower-risk patients or whether differences in care may explain this variation. We examined previously established risk factors across National Pediatric Cardiology Quality Improvement Collaborative centres with lower and higher interstage mortality rates. *Methods:* Lower-mortality centres were defined as those with >25 consecutive interstage survivors. Higher-mortality centres were defined as those with cumulative interstage mortality rates >10%, which is a collaborative historic baseline rate. Baseline risk factors and perioperative characteristics were compared. *Results:* Seven lower-mortality centres were identified (n = 331 patients) and had an interstage mortality rate of 2.7%, as compared with 13.3% in the four higher-mortality centres (n = 173 patients, $p < 0.0001$). Of all baseline risk factors examined, the only factor that differed between the lower- and higher-mortality centres was postnatal diagnosis (18.4 versus 31.8%, $p = 0.001$). In multivariable analysis, there remained a significant mortality difference between the two groups of centres after adjusting for this variable: adjusted mortality rate was 2.8% in lower-mortality centres compared with 12.6% in higher-mortality centres, $p = 0.003$. Secondary analyses identified multiple differences between groups in perioperative practices and other variables. *Conclusions:* Variation in interstage mortality rates between these two groups of centres does not appear to be explained by differences in baseline risk factors. Further study is necessary to evaluate variation in care practices to identify targets for improvement efforts.

The period between discharge following the stage 1 palliation (Norwood) and the stage 2 palliation – superior cavopulmonary anastomosis – for hypoplastic left heart syndrome is particularly high risk, with interstage mortality rates historically ranging from 10 to 15% in patients discharged home between procedures.[1–3] The National Pediatric Cardiology Quality Improvement Collaborative was founded in 2006 to improve interstage care and outcomes.[4] Using collaborative learning and quality improvement methods, the National Pediatric Cardiology Quality Improvement Collaborative recently reported a reduction in overall interstage mortality within the collaborative from 9.5 to 5.3% since its founding.[5]

Despite this overall success, variation in outcomes across collaborative centres persists, and the factors underlying this variation remain unclear. For example, it is not known whether these differences may be related to case-mix such that centres with lower interstage mortality rates care for lower-risk patients. Previous studies in the congenital heart surgery population have demonstrated that key baseline patient characteristics known to influence outcome can vary significantly across centres.[6] Alternatively, it may be that differences in care practices across centres may explain this variation. Further elucidating the underlying mechanisms is a key first step in better understanding and addressing the current variation in interstage outcomes across collaborative centres.

The primary goal of this study was to examine variability in interstage mortality rates within National Pediatric Cardiology Quality Improvement Collaborative centres, and to compare key baseline patient characteristics across centres with lower versus higher interstage mortality rates. We also explored differences in perioperative patient characteristics and practices across these centres.

Materials and method

Patient population

The National Pediatric Cardiology Quality Improvement Collaborative includes a voluntary registry that receives data from 60 paediatric cardiac programmes that have joined on a rolling basis since the first centre cohort in 2008. There is a standard data set with data definitions, online web-based data entry, and data quality checks. The deidentified data are housed in a secure server at Cincinnati Children's Hospital Medical Center. Individual institutional review boards at each institution reviewed and approved participation in the registry. All infants followed up at participating centres who meet the following criteria are eligible for enrollment into the registry: diagnosis of single-ventricle disease requiring stage 1 procedure or variant, and survival to, and discharge from, the hospital before stage 2 procedure or transplant. Before enrollment, families provide consent for each individual patient. The University of Michigan institutional review board approved this study.

For the purposes of this study, we included all National Pediatric Cardiology Quality Improvement Collaborative centres with at least 25 enrolled patients at the time of the study initiation in February 2015 (n = 57 centres). We excluded one centre that primarily performed hybrid procedures, as the primary focus of the present study was on the interstage period between the traditional surgical Norwood and stage 2 procedure. At the included centres, all enrolled patients who had completed the interstage period were included. One patient who was lost to follow-up during the interstage was excluded.

The assessment of centre performance in the setting of low event rates is a known challenge across many fields. [7,8] Given the relatively low overall event rate and centre-level sample sizes in our population, we chose a statistical method designed to detect changes in rare events to identify lower-mortality centres. We therefore used individual National Pediatric Cardiology Quality Improvement Collaborative centre g-charts, a statistical process control chart designed for sensitive detection of changes in rates of rare events such as mortalities.[5,9–11] Lower-mortality centres were defined as those centres with at least 25 consecutive interstage survivors at the time of data collection in March 2015. Higher-mortality centres were defined as those centres with an interstage mortality rate higher than the National Pediatric Cardiology Quality Improvement Collaborative historic baseline rate of 10%.

Data collection

Data collected from the registry included demographic and clinical data at birth, the stage 1 procedure perioperative period, discharge from the stage 1 procedure, and interstage outcomes. Average annual enrollment in the collaborative was recorded for each centre.

Statistical analysis

Data are reported as frequency with percentage (%) for categorical variables and mean ± standard deviation or median with interquartile range for continuous variables as appropriate. Patient characteristics were compared between the lower- versus higher-mortality centres using χ^2 test or Fisher's exact test for categorical variables and two-sample t-test or Wilcoxon rank sum test for continuous variables. We primarily focused on evaluating patient baseline characteristics, including demographics, diagnoses, and other comorbidities, that have been previously established as risk factors for adverse outcomes.[2,12] This portion of the analysis focused on patient characteristics that would be present at birth or at the time of admission and therefore unlikely to be influenced by differences in practices as the primary goal was to understand whether these factors differed across centres and could explain differences in centres' interstage mortality rates.

After univariate evaluation of baseline characteristics described above, we then performed a multivariable analysis to assess whether a significant mortality difference between the two groups of centres remained after accounting for any differences found in univariate analysis. We used a hierarchical logistic regression model with interstage mortality as the outcome. Individual patient characteristics were included as fixed effect, as well as a random intercept for centre, to account for within-centre correlations. The adjusted mortality rate in the two centre groups was calculated as (observed-to-expected mortality ratio) × (mortality rate in the overall cohort, 6.3%). The expected interstage mortality rate in each group was obtained by summing the predicted probability of mortality in each centre within each group from the model. A 95% confidence interval for the adjusted mortality rate was also reported.

In a subsequent analysis, we also further examined other preoperative factors that may be influenced both by patient risk or severity of illness, as well as differences in centre practices. For example, some centres may have a lower threshold for preoperative intubation and mechanical ventilation than others, and thus the use of preoperative mechanical ventilation in a specific patient reflects an interaction between the patient's innate characteristics and the centre's management strategies. In this portion of the analysis, we used a similar modelling strategy as described above.

Finally, descriptive secondary analyses were performed to explore differences in perioperative practices between the two groups of centres to identify potential targets for future study. We used χ^2 test or Fisher's exact test for categorical variables and two-sample t-test or Wilcoxon rank sum test for continuous variables. All analyses were performed using SAS version 9.4 (SAS Institute, Cary, North Carolina, United States of America), with statistical significance level of 0.05 using a two-sided test.

Results

Study population and variation in centre interstage mortality rates

On the basis of our definitions, we identified seven lower-mortality centres (n = 331 patients) and four higher-mortality centres (n = 173 patients). The interstage mortality rate in the lower-mortality group of centres was 2.7 versus 13.3% in the higher-mortality group (Fig 1, $p < 0.0001$), nearly a 5-fold difference.

Of the seven lower-mortality centres, six had an average annual volume of enrolled interstage patients ⩾ 10 and the remaining centre had an annual average volume of five to nine patients. Similarly, for the four higher-mortality centres, three had an average annual volume ⩾ 10, and the remaining centre had an average annual volume of five to nine patients. An internal audit completed in 2015 estimated that the lower-mortality centres had enrollment rates from 91.3 to 100% of infants who survived stage 1 procedure and are discharged home, whereas the higher-mortality centres ranged from 90.4 to 100%; across all National Pediatric Cardiology-Quality Improvement Collaborative centres, 89% were enrolled in the registry.

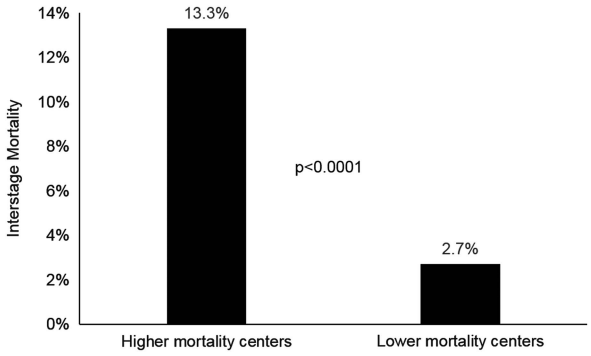

Figure 1. Interstage mortality in lower- versus higher-mortality centres.

Patient characteristics in lower- versus higher-mortality centres

In our primary analysis, we examined the frequency of previously established baseline risk factors for adverse outcomes between the lower- and higher-mortality centres (Table 1). Of all risk factors examined, only postnatal cardiac diagnosis significantly differed between the lower- and higher-mortality centre groups. Lower-mortality centres had lower rates of postnatal cardiac diagnosis (18.4 versus 31.8%, p = 0.001). All other factors evaluated were similar between the lower- and higher-mortality centres, including sex, race, ethnicity, gestational age/prematurity, birth weight, primary and secondary diagnoses, and the presence of major syndromes or anomalies (Table 1). In multivariable analysis, there remained a significant mortality difference between the two groups of centres after adjusting for postnatal diagnosis; adjusted mortality rate was 2.8% (95% confidence interval 1.3–5.3) in lower-mortality centres compared with 12.6% (95% confidence interval 8.0–18.9) in higher-mortality centres, p = 0.003.

We subsequently evaluated other preoperative characteristics that may be influenced by both severity of illness and centre care practices (Table 2). We found that the lower-mortality centres had lower rates of mechanical ventilation, arrhythmia, and acidosis, and further evaluated these factors in multivariable analysis. For arrhythmia, a multivariable analysis was not feasible owing to the small number of events. In addition, both acidosis and mechanical ventilation were significantly correlated with postnatal diagnosis (p < 0.0001) and could not be included in the previously constructed multivariable model described above. Therefore, we performed two separate hierarchical logistic regression models for each of these two characteristics and again found that statistically significant differences in mortality rates remained between the two groups of centres after adjustment for acidosis and mechanical ventilation, respectively. Controlling for acidosis, the adjusted mortality rate for the lower-mortality centres was 2.9% – with a 95% confidence interval of 1.3–5.5 – compared with 12.0% – with a 95% confidence interval of 7.6–18.0 – in higher-mortality centres (p = 0.01). Adjusting for mechanical ventilation, the adjusted mortality rate for lower-mortality centres was 3.0% – with a 95% confidence interval of 1.3–5.6 – compared with 11.6% – with a 95% confidence interval of 7.3–17.3 – in higher-mortality centres (p = 0.01).

Secondary analyses: variation in perioperative practices

Variability in perioperative practices was also explored in secondary analysis (Table 2). In terms of operative variables, lower-mortality centres more frequently performed the Norwood operation with a right ventricle-to-pulmonary artery conduit. In the postoperative period, lower-mortality centres had shorter time to extubation, lower rates of extracorporeal membrane oxygenation or ventricular assist device use, and fewer arrhythmias. There was no difference in hospital length of stay after stage 1 procedure. Lower-mortality centres discharged more patients on oral feeds and without supplemental oxygen. Lower-mortality centres also discharged more patients on digoxin but fewer patients on ACE inhibitors, antibiotics, and opiates. Finally, lower-mortality centres had a younger age at stage 2 procedure admission (median 4.6 versus 5.4 months, p<0.0001) and shorter interstage duration (median 3.3 versus 4.1 months, p<0.0001).

Table 1. Patient baseline characteristics in lower- versus higher-mortality centres.

	Centre group		
	Lower mortality (7 centres, n = 331)	Higher mortality (4 centres, n = 173)	p-Value
Male sex	207 (62.5)	112 (64.7)	0.63
Caucasian race	249 (75.2)	140 (80.9)	0.07
Hispanic ethnicity	57 (17.2)	33 (19.1)	0.78
Postnatal cardiac diagnosis	61 (18.4)	55 (31.8)	**0.001**
Gestational age, weeks	39 (38-39)	39 (38-39)	0.71
Premature (< 37 weeks)	29 (8.8)	16 (9.2)	0.88
Birth weight, kg	3.20 ±0.53	3.21 ± 0.51	0.89
Primary diagnosis			
HLHS versus other	242 (73.1)	136 (78.6)	0.21
Secondary diagnosis			
Restrictive atrial septum	38 (11.5)	24 (13.9)	0.27
⩾ Moderate AV valve regurgitation	7 (2.1)	5 (2.9)	0.54
⩾ Moderate ventricular dysfunction	8 (2.4)	1 (0.6)	0.28
Other	48 (14.5)	18 (10.4)	0.31
Major syndrome	23 (6.9)	7 (4.0)	0.18
Major anomaly	24 (7.3)	7 (4.0)	0.16

AV = atrioventricular; HLHS = hypoplastic left heart syndrome. Bold text indicates p-values that are statistically significant (p < 0.05)

Discussion

This study documents variability in interstage mortality rates across National Pediatric Cardiology Quality Improvement Collaborative centres despite the overall improvement in mortality outcomes within the collaborative. Our comparison of lower- versus higher-mortality centres suggests that differences in interstage mortality rates do not appear to be explained by lower rates of baseline patient risk factors at lower-mortality centres. However, despite the similarity of these patient cohorts at baseline, we found that many practices diverged throughout the perioperative period, suggesting that further study of care

Table 2. Perioperative and interstage characteristics and practices in lower- versus higher-mortality centres.

	Centre group		
	Lower mortality (7 centres, n = 331)	Higher mortality (4 centres, n = 173)	p-Value
Preoperative variables			
Extracorporeal membrane oxygenation	2 (0.6)	4 (2.3)	0.19
Arrhythmia requiring therapy	3 (0.9)	9 (5.2)	**0.005**
Acidosis	32 (9.7)	42 (24.3)	**< 0.0001**
Mechanical ventilation support	77 (23.3)	70 (40.5)	**< 0.0001**
Renal insufficiency	32 (9.7)	9 (5.2)	0.08
Septicaemia	8 (2.4)	2 (1.2)	0.51
Necrotizing enterocolitis	2 (0.6)	2 (1.2)	0.61
Neurological defects	3 (0.9)	0 (0.0)	0.55
Seizure	4 (1.2)	1 (0.6)	0.66
Other	49 (14.8)	19 (11.0)	0.22
Operative variables			
Age at Stage 1, days	5 (4–8)	6 (4–8)	0.14
Type of Stage 1			**< 0.0001**
Norwood with BT shunt	95 (28.7)	88 (50.9)	
Norwood with RV-PA conduit	212 (64.0)	67 (38.7)	
Hybrid Norwood	7 (2.1)	12 (6.9)	
Other	17 (5.1)	6 (3.5)	
Cardiopulmonary bypass time, minutes	132 (99–154)	140 (101–187)	0.08
Postoperative variables			
Time to extubation, days	6 (3–11)	7 (5–11)	**0.001**
Postoperative extracorporeal membrane oxygenation	12 (3.6)	14 (8.1)	**0.03**
Reoperation other than routine delayed sternal closure	68 (20.5)	31 (17.9)	0.45
Postoperative catheter-based intervention	29 (8.8)	20 (11.6)	0.86
Postoperative complication(s)	212 (64.0)	109 (63.0)	0.95
Any infectious complication	65 (19.6)	36 (20.8)	0.71
Postoperative rhythm abnormality requiring treatment	74 (22.4)	54 (31.2)	**0.03**
Bleeding requiring reoperation	8 (2.4)	6 (3.5)	0.57
Phrenic nerve injury/paralysed diaphragm	13 (3.9)	2 (1.2)	0.08
Cardiac arrest	20 (6.0)	11 (6.4)	0.87
Ventricular assist device placement	11 (3.3)	16 (9.2)	**0.005**
Pericardial effusion requiring drainage	6 (1.8)	4 (2.3)	0.74
Pneumothorax	12 (3.6)	2 (1.2)	0.15
Pleural effusion requiring drainage	20 (6.0)	13 (7.5)	0.51
Chylothorax	27 (8.2)	14 (8.1)	1.00
Sternal dehiscence	11 (3.3)	1 (0.6)	0.07
Hospital length of stay after Stage 1, days	28 (20–45)	28 (18–45)	0.84
Discharge characteristics			
Any oral feeding combination versus no oral feeds	262 (79.2)	120 (69.4)	**0.01**
Oxygen saturation	82.3 ± 4.9	81.5 ± 5.0	0.09
Home oxygen	33 (10.0)	49 (28.3)	**< 0.0001**
Medications			
Lanoxin/digoxin (without arrhythmia)	116 (36.1)	31 (19.1)	**0.0001**
ACE inhibitor	104 (31.4)	72 (41.6)	**0.02**
Antibiotics (any)	14 (4.2)	22 (12.7)	**0.0004**
Opiates (e.g. Methadone)	6 (1.8)	22 (12.7)	**< 0.0001**
Interstage variables			
Home surveillance Strategy	319 (96.4)	151 (87.3)	**< 0.0001**
Age at stage 2, months	4.6 (4.0–5.4)	5.4 (4.5–6.5)	**< 0.0001**
Length of interstage, months	3.3 (2.6–4.0)	4.1 (3.2–5.2)	**< 0.0001**

ACE = Angiotensin converting enzyme; BT = Blalock–Taussig shunt; RV-PA = right ventricle-pulmonary artery. Bold text indicates p-values that are statistically significant ($p < 0.05$)

practices and processes is necessary in order to fully elucidate the mechanisms underlying this variability in interstage outcomes and to design improvement initiatives.

Interstage mortality rates have been reported by single centres[1–3] and in the context of a multicentre randomised controlled trial,[13] but to our knowledge this is the first report of variation in interstage mortality rates across a broader multicentre cohort. We identified nearly a 5-fold difference in interstage mortality between our two groups of centres. In addition, the interstage mortality rate of 2.7% in the group of lower-mortality centres is substantially lower than historically reported rates, which have typically ranged from 10 to 15% in the literature,[2,3] and is lower than the overall rate recently reported for all National Pediatric Cardiology Quality Improvement Collaborative centres following the implementation of improvement activities (5.3%).[5] These data

suggest that further improvements across the collaborative may require a better understanding of the specific care practices and processes used in particular at lower-mortality centres.

Examining existing variation and underlying mechanisms has been shown to be a key first step in developing tailored strategies to reduce variation and improve outcomes, as shown by multiple collaboratives starting with the Northern New England Cardiovascular Disease Study Group.[14] As an initial step, it is first important to understand whether these differences across collaborative centres could simply be explained by differences in patient characteristics or the type of patients treated at centres with different outcomes. Pasquali et al[6] recently found significant variation in patient risk factors across a large group of centres and types of congenital heart surgeries. If differences were completely explained by patient characteristics, then there would not be a need to pursue understanding differences in care practices. However, we found that only one baseline risk factor – postnatal diagnosis – differed between the lower- and higher-mortality centres, and that mortality differences between these two groups persisted even after accounting for this. Similarly, even after we accounted for other preoperative characteristics that may be influenced by a combination of both severity of illness and care practices, mortality differences between the two groups of centres persisted. In contrast, there were multiple differences between the two groups of centres in operative and postoperative variables that may be related to different care processes or practices. Variation in nearly all aspects of perioperative care in this population has also been documented previously in an analysis of data from the Pediatric Heart Network Single Ventricle Reconstruction trial.[15]

The design of the original National Pediatric Cardiology Quality Improvement Collaborative registry limited our ability to answer questions regarding outcomes beyond the interstage period and to analyse detailed data regarding different care practices. However, several ongoing updates will expand the types of analyses possible in the future. Selection bias has been an important consideration as those infants who died in hospital or were not discharged home after the stage 1 procedure have previously not been eligible for enrollment in the registry. The National Pediatric Cardiology Quality Improvement Collaborative recently expanded its enrollment to include all infants diagnosed with hypoplastic left heart syndrome who are anticipated to undergo a stage 1 procedure, which will enable more thorough data collection from prenatal diagnosis through the stage 1 procedure hospitalisation and the interstage on the entire cohort and allow a more comprehensive investigation of practices and outcomes across all of these phases. It is possible that this expanded enrollment, which will capture in-hospital mortality after the stage 1 procedure, will reveal additional differences among centres in mortality before and after the stage 1 procedure. In addition, the collaborative now collects outcomes through the first year of life and has begun to design a registry to follow patients through the Fontan palliation and beyond, enabling future work to assess long-term outcomes across centres. It is notable that, in our study, lower-mortality centres performed the stage 2 procedure at a younger age, meaning that the overall interstage time period for risk of mortality was shorter, and could be associated with some of the difference in mortality rates observed as suggested by Hill et al.[16] Ongoing work will capture additional variables such as discharge readiness criteria, frequency of outpatient clinic visits, and other factors that will be further evaluated to gain a more comprehensive understanding of best practices.

Limitations

One possible limitation of this study is our definition of lower- versus higher-mortality centres. Our definition of lower mortality is based on individual site g-charts, which are designed to detect early changes in complex systems by recognising consecutive successes. However, because there is no equivalent measure for identifying higher mortality centres, our definition was based on overall performance rather than accounting for temporal trends in mortality. Although it is possible that by using these differing metrics our definition of lower versus higher mortality is a false distinction, we found a clinically important and statistically significant difference in mortality rates between the lower- and higher-mortality centre groups that we identified with this approach, making this concern less likely. Other potential limitations include the large number of comparisons made, which may account for some of the differences identified; we did not correct for multiple statistical comparisons as this was intended to be a hypothesis-generating study. The National Pediatric Cardiology Quality Improvement Collaborative data set contains retrospective, observational data that are voluntarily submitted from programmes participating in the improvement collaborative. Therefore, limitations in the data may relate to patient selection bias and/or the heterogeneous composition of participating programmes of different sizes and geographic locations. Other potential limitations are also inherent to the National Pediatric Cardiology Quality Improvement Collaborative registry; for example, some risk factors for interstage death such as socioeconomic status[12] are not included in the registry, and differences identified could partly reflect differences in coding among centres rather than true differences in practice. Finally, we focused on analysing differences across centres, and it is possible that there may be differences across practitioners that also require further study.

Conclusion

There is important variation in centre interstage mortality rates within the National Pediatric Cardiology Quality Improvement Collaborative. Differences in mortality do not appear to be explained by differences in baseline patient risk factors across the centres we examined, and our exploratory data and data from other studies suggest that the gap in interstage mortality may be driven more by differences in perioperative care practices and processes. Efforts are underway to collect additional data to augment the current data available in the collaborative database, in order to support a comprehensive analysis of care practices that most strongly influence interstage outcomes and identify future targets for improvement.

Acknowledgements. None.

Financial Support. This research received no specific grant from any funding agency or from commercial or not-for-profit sectors. Current funding sources for the National Pediatric Cardiology Quality Improvement Collaborative include participation fees from enrolled centres; a grant from the Children's Heart Association of Cincinnati; and a federal grant to the Pediatric Center for Education and Research in Therapeutics at Cincinnati Children's Hospital Medical Center, funded by the federal Agency for Healthcare Research and Quality (#U19HS021114 AHRQ). Dr S.K.P. receives support from the Janette Ferrantino Professorship.

Conflicts of Interest. None.

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