Defining the best practice patterns for the neonatal systemic-to-pulmonary artery shunt procedure

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Objectives: To assess variation in outcome measures and their associations with shunt thrombosis prophylaxis regimens after systemic-to-pulmonary artery shunt surgery across centers in the United States participating in the Pediatric Health Information System database.

Methods: We reviewed data on neonates who underwent an off-pump shunt procedure at 39 centers between 2000 and 2011. The overall variation in rates of discharge mortality and shunt-related complications were assessed by funnel plots. Complications were defined as revision/repeat of the shunt procedure during the same admission, institution of extracorporeal membrane oxygenation after surgery, and catheter interventions after shunt surgery. Bayesian hierarchical modeling was used to identify outliers. Shunt thrombosis prophylaxis regimens including the time of initiation of aspirin were compared between high and low outliers.

Results: A total of 2058 index operations were identified. Funnel plots highlighting the outcomes from various centers allowed discrimination of discharge mortality and complication rates around an aggregate of 6.7% and 12.3%, respectively. Bayesian modeling showed the presence of substantial variation in complication rates between centers; 20% of them were identified as outliers. Aspirin was initiated significantly earlier during the hospital course in centers with a lower composite rate of complications than those with higher rates (median initiation day of 2 [interquartile range (IQR), 1-3] in low outliers vs 4 [IQR, 3-6] in high outliers; $P < .001$).

Conclusions: A substantial variation was found between hospitals in the rate of shunt-related complications. Centers with best outcomes implement aspirin earlier in their postoperative shunt thrombosis prophylaxis regimen. (J Thorac Cardiovasc Surg 2014;147:869-73)

Supplemental material is available online.

Defining the variation in outcome measures is a well-established method for measuring the quality of care in pediatric cardiac surgery. Detecting variability in outcome measures provides a clue for conducting quality improvement initiatives that aim to optimize the best practices for the selected population.¹ Systemic-to-pulmonary artery shunt surgery, mainly the Blalock-Taussig shunt, could be a suitable target for quality assessment efforts. The Blalock-Taussig shunt is the first-line palliative surgery for infants with duct-dependent pulmonary circulation.² Despite its seemingly simple nature, the mortality rate of

the procedure is relatively high.^{3,4} This rate has been found to be even higher in neonates, particularly those with low birth weight.^{2,5,6} The reported rate of shunt-related complications is significantly high in this age group.⁵

Variation in shunt thrombosis prophylaxis approaches after systemic-to-pulmonary artery shunt surgery, which in part represents variation of care, has been reported to affect the rate of adverse events after shunt surgery.^{7,8} No study has previously assessed variation of care after systemic-to-pulmonary artery shunting among US pediatric centers. There are also no published data on the best in-hospital shunt thrombosis prophylaxis approach after institution of systemic-to-pulmonary artery shunts.

In this article, we document the aggregate rate of adverse events for neonatal systemic-to-pulmonary artery shunt procedures for hospitals participating in the Pediatric Health Information System (PHIS) database. PHIS is a large administrative database provided by Child Health Corporation of America that contains comprehensive financial and clinical data of the pediatric population from 43 participating hospitals. It has been widely used for comparative effectiveness and quality improvement research studies.⁹

The specific goal of this study was to assess between-participant variation in the rate of shunt mortality, shunt-related complications, and the postoperative length of stay (PLOS). In-hospital shunt thrombosis prophylaxis

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Received for publication June 27, 2013; revisions received Oct 15, 2013; accepted for publication Oct 27, 2013; available ahead of print Dec 10, 2013.

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0022-5223/\$36.00

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<http://dx.doi.org/10.1016/j.jtcvs.2013.10.063>

Abbreviations and Acronyms

ECMO	= extracorporeal membrane oxygenation
ICD-9	= International Classification of Diseases, ninth revision
IQR	= interquartile range
PDA	= patent ductus arteriosus
PHIS	= Pediatric Health Information System
PLOS	= postoperative length of stay
STS	= Society of Thoracic Surgeons

regimen were also compared between the high and low outlier centers with regard to specific outcome measures.

METHODS

Study Cohort

Patients aged 30 days or less at the time of admission who underwent isolated systemic-to-pulmonary artery shunt placement (International Classification of Diseases, ninth revision [ICD-9] code 39.0, Risk Adjusted Classification for Congenital Heart Surgery score ≤ 3)¹⁰ as the first index operation during that admission (between January 1, 2000 and December 31, 2011) were included in the study. The study was limited to those who had no other accompanying cardiac procedure(s) except patent ductus arteriosus (PDA) ligation at the time of surgery (Table E1). Only hospitals with complete discharge mortality, complication status, and PLOS data for the calendar year were included.

As described previously,^{2,5} to further enhance data quality, the data were screened to exclude patients with a diagnosis of hypoplastic left heart syndrome. We also limited the study to systemic-to-pulmonary artery shunts performed without cardiopulmonary bypass support.

Outcome Variables

Outcomes studied included in-hospital mortality and the occurrence of shunt-related complications as a composite measure. This composite measure included revision/repeat, subsequent systemic-to-pulmonary artery shunting procedure during the same admission (ie, repeat ICD-9 code 39.0 in isolated fashion as described previously), the institution of extracorporeal membrane oxygenation (ECMO), and catheter interventions or evaluations after shunt surgery. The PLOS was also analyzed separately. Aggregate, median, and between-participant interquartile (25th and 75th percentiles) range for the outcome measures as well as PLOS were calculated and summarized as raw data.

Funnel Plots

Unadjusted mortality and complication rates were plotted against the number of subjects in each center with lines depicting exact 95% binomial prediction limits.¹¹

Feasibility Analysis

Following the method of Dimick and colleagues,¹² we determined the minimum number of cases each hospital had to have in order to have 50% power to detect a 2-fold increase in the outcomes compared with the aggregate rates. Hospitals that did not meet the minimum volume expectations for an outcome were excluded from the analyses.

Between-Participant Variation

Bayesian hierarchical modeling was used to identify outliers for mortality, a composite measure of complication rates, as well as PLOS. The method of estimating the adjusted hospital-level mortality,

complication rates, and average PLOS has been described previously.^{13,14} We provide the unadjusted and adjusted posterior means and 95% probability intervals for each hospital as the expected outcomes for each hospital if they had seen patients with similar average risk as the overall population. Adjustments were made using sex, age at surgery, birth weight, race, noncardiac abnormalities, preoperative diagnostic categories (single ventricle, double ventricle, and pulmonary atresia with intact ventricular septum), and PDA ligation. For PLOS, however, we also controlled for the occurrence of complications and mortality during hospitalization to eliminate the effect of these 2 factors on PLOS. To quantify overall between-participant variation, the Gini index was calculated for outcome measures and PLOS.

In this article, the terms low outliers and high outliers are used for centers with an average probability of mortality or complication rates lower than the 10th and higher than the 90th percentile of outcome distribution, respectively.

All analyses were performed using SAS 9.3 (SAS Institute, Inc, Cary, NC). The protocol was reviewed by the Institutional Review Board of Washington University School of Medicine, Saint Louis, Mo, and was determined to be exempt.

Comparison of Shunt Thrombosis Prophylaxis

Regimens Between High and Low Outlier Centers

Shunt thrombosis prophylaxis regimens were compared between high and low outlier centers. Data from hospitals with missing medication data were excluded from the analysis of shunt thrombosis prophylaxis regimens. Rates of postoperative aspirin and heparin administration, and the day of start of aspirin after surgery were compared between high and low outliers using χ^2 statistics. For the purpose of comparing the shunt thrombosis prophylaxis regimens, and to limit potential confounding of anticoagulation and aspirin administration for reasons other than the shunt procedure, subjects with a diagnosis of deep vein thrombosis or the need for ECMO before surgery were excluded. For patients who experienced a complication during hospital stay, the administration of anticoagulants and aspirin was calculated until the day of the complication; the rationale for that was to avoid including anticoagulant and aspirin usage for the purpose of treatment of a complication rather than for the shunt procedure itself. We also excluded those patients ($n = 7$, among outlier centers) who had contraindications for anticoagulation and aspirin including gastrointestinal bleeding/peptic ulcer disease and any diagnosis of thrombocytopenia.

RESULTS

The study included 39 centers (those with complete data) and a total of 2058 index operations during the study period. Table 1 provides a summary of the raw data for the outcomes and PLOS. It includes aggregate, median, between-participant and interquartile (25th and 75th percentiles) range of different outcomes, including mortality, the composite measure of complication (see also Table E2), as well as PLOS. Table E3 summarizes preoperative diagnostic categories.

Funnel Plots

Funnel plots highlighting the outcomes from various centers allowed the discrimination of the discharge mortality rate around an aggregate of 6.7% and a cumulative complication rate of 12.3% (Figure 1). Based on the unadjusted funnel plots, there are several outliers, particularly for the complication rate. Outliers made up 43.6% of the centers (30.8% as high and 12.8% as low)

TABLE 1. Raw data summary

Variable	Shunt placement
Number of participants	39
Number of shunt placements*	2058
Median [IQR] sample size	47 [27-73]
Range of sample size	4-157
Mortality (%)	
Aggregate	6.7
Median [IQR]	6.7 [3.6-9.1]
Range	0-29.2
Complications (%)	
Aggregate	12.3
Median [IQR]	10.0 [4.5-18.6]
Range	0-55.6
PLOS (days)†	
Aggregate	19.7
Median [IQR]	12 [10-17]
Range	1-322

IQR, Interquartile range; *PLOS*, postoperative length of stay. *Not including shunt revisions. †After excluding mortalities in the first week: aggregate = 19.9; median [IQR] = 12 [10-17]; and range = 4-322.

for the composite measure of complication. With regard to mortality, outlier centers consisted of 17.9% (including 15.4% as high and 2.5% as low) of all participants.

Bayesian Estimation of Between-Participant Variation

Before running Bayesian models, the feasibility of performing them was assessed. The results of the feasibility analyses are summarized in Table 2. Based on Table 2, less than 50% of the participating hospitals fulfilled the required sample size to be considered in Bayesian modeling for the mortality rate. Based on this modeling, shown in Table 3, there were no outliers for the mortality rate; however, 20% of the centers (6/30) were found to be an outlier for complication rates after applying the feasibility requirement. The rate of being an outlying center for PLOS was 28.9% (11 of 38). The Gini index (Table 3) showed the

presence of a substantial variation in the rate of complications between centers (Gini index = 0.29). With regard to PLOS, however, the index value was 0.11, which corresponds to a less significant variability between participants.

Shunt Thrombosis Prophylaxis

Applying Bayesian models, 6 outliers were found for the complication rate; 1 of them was excluded because of insufficient data for medications and therefore, data from 5 centers (3 low and 2 high outliers) were included in the analysis. The total number of shunt placements was 343 including 196 shunt placements in high and 147 in low outliers (Table E4).

The difference in the rate of aspirin administration after surgery was not statistically significant between the groups (78.9% in low vs 70.4% in high outliers; $P = .075$), however, aspirin was started earlier in low outlying centers. The median number of days heparin was used in the low outlier group was the same as the high outlier group (2 days [interquartile range (IQR), 1-5] vs 3 days [IQR, 1-4]; $P = .50$). Figure 2 illustrates the distribution of the initiation of aspirin between the 2 groups. The median day of initiation of aspirin in low outliers was lower than the median day in high outliers (2 days [IQR, 1-3] vs 4 days [IQR, 3-6]; $P < .001$).

DISCUSSION

This study depicts and quantifies variation in outcome measures among centers after the institution of systemic-to-pulmonary artery shunts in neonates. Furthermore, outlying centers are detected by means of Bayesian hierarchical modeling, and thrombosis prophylaxis regimens are compared between high and low outlying centers. Between-hospital variation was found predominantly in complication rates. More than 40% of centers were found to be outside the binomial prediction limits in the funnel plot for complication rate. However, about 15% of

FIGURE 1. Funnel plots of unadjusted in-hospital mortality and complication rates after the systemic-to-pulmonary artery shunt procedure. The horizontal line corresponds to aggregate mortality or composite complication rates before discharge; curved lines depict 95% binomial prediction limits. Each circle corresponds to an individual hospital. A, Complication data; B, mortality data. *BTS*, Blalock-Taussig shunt.

TABLE 2. Feasibility of analyzing between-center variation

Variable	Shunt placement
Number of hospitals	39
Complications	
Aggregated complication rate (%)	12.3
Sample size required for 50% power to detect 2× increase in complication	26
Number of hospitals meeting complication requirement	30
Mortality	
Aggregated mortality rate (%)	6.7
Sample size required for 50% power to detect 2× increase in mortality	50
Number of hospitals meeting mortality requirement	19
PLOS	
Number of hospitals meeting PLOS requirement (≥5 cases)	38

PLOS, Postoperative length of stay.

participating centers were outliers for the mortality rate. In a funnel plot, it is expected that a maximum of 5% of participants will be randomly outside the 95% limits around the aggregate rate. The finding that more than 40% of the participants fell outside the prediction limits for the complication rate, suggest nonrandom variation in the rate of complications, which is in part representative of variation of care between centers.

Bayesian estimation modeling was used to detect outlying centers for mortality and complication rates, and for PLOS. We defined the estimated values for the 10th and 90th percentiles of risk-adjusted mortality or complication rates as the cut-off points for detecting the outliers. The same cut-off points were used previously to describe an index to quantify variation in discharge mortality rates for pediatric cardiac surgical operations between hospitals in 2 studies done by Jacobs and colleagues.^{13,14} They did not, however, compare the outlier centers to detect possible reasons for the variability.

Although the funnel plot and Gini index both disclosed variations in mortality rates, no outliers were found in the Bayesian modeling. One reason for this finding might be the robust cut-off points chosen to define outliers. Furthermore, there was about 50% attrition for the total number of participating hospitals after applying the feasibility requirement in Bayesian modeling.

With regard to PLOS, however, the variability was quantified to be less than other outcome measures. For PLOS, the occurrence of a complication or mortality was considered as an adjustor in the Bayesian hierarchical modeling. This means that PLOS variation, as described here, is unrelated to the occurrence of adverse events in participating hospitals.

We looked for possible distinguishing features between outliers related to pattern of use of anticoagulants and particularly aspirin after surgery. Anticoagulation and antiplatelet regimens after shunt placement have been reported as factors affecting the outcome.^{7,8} Our results revealed that centers with a lower composite rate of complications started aspirin much sooner during the hospital course (Figures 2 and E1). Aspirin has been reported to be effective in lowering mortality after discharge^{7,15}; our findings suggest that the same practice pattern leads to improved in-hospital outcomes.

Our study has some limitations. There is often concern related to the use of administrative data and coding inaccuracies; we have done our best to use inclusion and exclusion criteria, as described previously, to define a population that has yielded results matching our own institutional clinical data as well as aggregate data from the Society of Thoracic Surgeons (STS) congenital database. It has been shown that patient records in the PHIS database are highly matched to the STS database.¹⁶ We have also validated our results by crosschecking the data with the clinical data in our own institute. We found high concordance between the PHIS data and our institutional clinical dataset.

TABLE 3. Results of Bayesian hierarchical models: estimated percentiles of distribution of mortality, and complication rates and average PLOS including the number of low and high outliers in each model

	Estimate (95% Bayesian probability interval)						Number of outliers	
	Minimum	25th percentile	50th percentile	75th percentile	Maximum	Gini index	Low	High
Hospital-specific complication rates								
Unadjusted	5.5 (1.9-10.9)	7.3 (2.3-15)	9.3 (3.4-17.9)	15.1 (7-26)	23.6 (13.4-36.3)	0.24	2	1
Adjusted	4 (1.1-8.7)	6.5 (2.7-11.9)	8.8 (3.7-16.1)	13.3 (6.9-22.1)	25.7 (16.6-37.2)	0.29	4	2
Hospital-specific mortality rates								
Unadjusted	5.5 (3-7.9)	6 (3.5-8.7)	6.6 (4-9.9)	6.8 (4.3-10.4)	7.9 (5.1-13.1)	0.05	0	0
Adjusted	3.7 (1.7-6.5)	4.3 (2.2-7.1)	4.8 (2.3-8.4)	6.5 (3-12.4)	9.9 (4.5-18.9)	0.18	0	0
Hospital-specific PLOS								
Unadjusted	9.5 (7.3-12.2)	11.4 (9.5-13.7)	13.1 (10.5-16.3)	15.5 (11.2-21.7)	21 (17-26.1)	0.12	0	10
Adjusted	9.4 (7.4-12.3)	11.6 (10.3-13.1)	13.8 (11.3-16.8)	14.6 (11.9-17.7)	21.6 (18-25.8)	0.11	4	7

PLOS, Postoperative length of stay.

FIGURE 2. Distribution of start day of aspirin in patients in outlier centers. A, Aspirin start day in low outlying centers. B, Aspirin start day in high outlying centers in off-pump cohort.

In this study, we did not look at surgeon-specific variables, and only considered institution-specific experience/volume. Variation in a surgeon's performance could be a potential reason for variation in mortality rates among centers, although we would expect those to be reflected more in early/immediate mortalities or complications.

There have also been concerns about using and reporting composite end points in clinical studies,¹⁷ which might be misleading. We tried to address this issue by logically constructing the composites, using expert opinions, and performing a literature review before pulling the data. We have also presented data for all the components of the composite complication in supplemental files (Tables E2 and E5). We considered any catheter-based procedure after shunt placement during the hospital stay as a potential complication after the shunting. However, there is always a possibility that the catheter-based procedure was done for reasons other than detecting or addressing shunt problems. As another limitation in our study, we could not differentiate mortalities unrelated to shunt occlusions. We limited our analysis to heparin and aspirin as the database contains limited information on alternative thrombosis prophylaxis regimens such as clopidogrel (Plavix) or enoxaparin (Lovenox). These alternative medical regimens may be important although recent published literature on clopidogrel does not suggest incremental benefit from that drug over aspirin use.¹⁸

In conclusion, a substantial variation was found between hospitals in the rate of shunt-related complications. Our result can be an incentive to conduct quality improvement initiatives to improve the quality of care for patients undergoing systemic-to-pulmonary artery shunting. We found that early aspirin use is more commonly seen in centers with better outcomes. This might suggest that, in systemic-to-pulmonary artery shunts performed off-pump, earlier initiation of aspirin therapy results in better outcomes.

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FIGURE E1. Comparison of start day of aspirin between patients from centers with high, low, and average complication rates.

TABLE E1. ICD-9 codes for cardiac surgical procedures

ICD-9 code	Procedure
35.01	Closed heart valvotomy, aortic valve
35.02	Closed heart valvotomy, mitral valve
35.04	Closed heart valvotomy, tricuspid valve
35.10	Open heart valvuloplasty without replacement
35.11	Open heart valvuloplasty of aortic valve without replacement
35.12	Open heart valvuloplasty of mitral valve without replacement
35.13	Open heart valvuloplasty of pulmonary valve without replacement
35.14	Open heart valvuloplasty of tricuspid valve without replacement
35.20	Open and other replacement of unspecified heart valve
35.21	Open and other replacement of aortic valve with tissue graft
35.22	Open and other replacement of aortic valve
35.23	Open and other replacement of mitral valve with tissue graft
35.24	Open and other replacement of mitral valve
35.27	Open and other replacement of tricuspid valve with tissue graft
35.28	Open and other replacement of tricuspid valve
35.31	Operations on papillary muscle
35.32	Operations on chordae tendineae
35.33	Annuloplasty
35.34	Infundibulectomy
35.35	Operations on trabeculae carneae cordis
35.50	Repair of unspecified septal defect of heart with prosthesis
35.51	Repair of atrial septal defect with prosthesis
35.52	Repair of atrial septal defect with prosthesis, closed technique
35.53	Repair of ventricular septal defect with prosthesis, open technique
35.54	Repair of endocardial cushion defect with prosthesis
35.70	Other and unspecified repair of unspecified septal defect of heart
35.71	Other and unspecified repair of atrial septal defect
35.72	Other and unspecified repair of ventricular septal defect
35.73	Other and unspecified repair of endocardial cushion defect
35.81	Total repair of tetralogy of Fallot
35.82	Total repair of total anomalous pulmonary venous connection
35.83	Total repair of truncus arteriosus
35.84	Total correction of transposition of great vessels
35.91	Interatrial transposition of venous return
35.92	Creation of conduit between right ventricle and pulmonary artery
35.93	Creation of conduit between left ventricle and aorta
37.50	Heart replacement procedures
37.51	Heart transplantation
37.52	Implantation of total internal biventricular heart replacement system artificial heart
39.21	Caval-pulmonary artery anastomosis

ICD-9, International Classification of Diseases, ninth revision.

TABLE E2. Rates of catheter intervention, shunt revision, and ECMO in the studied population

Variable	Shunt placement
Catheter intervention (%)	
Aggregate	7.7
Median [IQR]	6.3 [3.1-12.5]
Range	0-55.6
Shunt revision (%)	
Aggregate	3.5
Median [IQR]	1.4 [0-4.2]
Range	0-27.3
ECMO (%)	
Aggregate	2.9
Median [IQR]	1.3 [0-4.1]
Range	0-19.1

ECMO, Extracorporeal membrane oxygenation; IQR, interquartile range.

TABLE E3. Preoperative diagnostic categories and frequency of additional source of blood flow in the studied population

Diagnostic category	Number of cases (%)
Single ventricle	427 (20.7)
Double ventricles	1304 (63.4)
Pulmonary atresia with intact ventricular septum	327 (15.9)
Additional source of pulmonary flow	1244 (60.4)
Posterior descending artery not ligated	596 (29)

TABLE E4. Comparison of baseline characteristics between patients from high and low outlier centers

Variable	Number of cases (%)		<i>P</i> value
	High outliers (n = 196)	Low outliers (n = 147)	
Diagnostic categories			.840
Single ventricle	44 (22.4)	34 (23.1)	
Double ventricles	118 (60.2)	91 (61.9)	
Pulmonary atresia with intact ventricular septum	34 (17.3)	22 (15.0)	
Additional source of pulmonary flow	124 (58.8)	87 (54.5)	.442
Posterior descending artery not ligated	47 (24.0)	46 (31.3)	.132
Birth weight (g $\pm$ SD)	2822 $\pm$ 614	2948 $\pm$ 586	.112
Age at surgery (d $\pm$ SD)	10 $\pm$ 22	9 $\pm$ 8	.586
Male gender	110 (56.1)	87 (59.2)	.570
Noncardiac anomalies	130 (66.3)	106 (72.1)	.253
Aspirin received on day of surgery	3 (1.5)	24 (16.3)	<.001

SD, Standard deviation.

TABLE E5. Distribution of factors of composite complications in patients from high and low outlier centers

Variable	Shunt placement (%)	
	High outliers (n = 196)	Low outliers (n = 147)
Catheter intervention		
Aggregate	9.7	1.4
Median [IQR]	9.5 [-]	0 [0-3.2]
Range	9.1-9.9	0-3.2
Shunt revision		
Aggregate	6.1	0.7
Median [IQR]	10.4 [-]	0 [0-1.9]
Range	2.6-18.2	0-1.9
ECMO		
Aggregate	6.1	0
Median [IQR]	5.5 [-]	0 [0-0]
Range	4.5-6.6	—

IQR, Interquartile range; ECMO, extracorporeal membrane oxygenation.