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)

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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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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)