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Does the American College of Surgeons National Surgical Quality Improvement Program pediatric provide actionable quality improvement data for surgical neonates?

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ABSTRACT

Background/Purpose: The purpose of this project was to examine the American College of Surgeons National Surgical Quality Improvement Program Pediatric (ACSNSQIP-P) Participant Use File (PUF) to compare risk-adjusted outcomes of neonates versus other pediatric surgical patients.
Methods: In the ACS-NSQIP-P 2012–2013 PUF, patients were classified as preterm neonate, term neonate, or nonneonate at the time of surgery. The primary outcomes were 30-day mortality and composite morbidity. Patient characteristics significantly associated with the primary outcomes were used to build a multivariate logistic regression model.
Results: The overall 30-day mortality rate for preterm neonates, term neonate, and nonneonates was 4.9%, 2.0%, 0.1%, respectively ($p < 0.0001$). The overall 30-day morbidity rate for preterm neonates, term neonates, and nonneonates was 27.0%, 17.4%, 6.4%, respectively ($p < 0.0001$). After adjustment for preoperative and operative risk factors, both preterm (adjusted odds ratio, 95% CI: 2.0, 1.4–3.0) and term neonates (aOR, 95% CI: 1.9, 1.2–3.1) had a significantly increased odds of 30-day mortality compared to nonneonates.
Conclusion: Surgical neonates are a cohort who are particularity susceptible to postoperative morbidity and mortality after adjusting for preoperative and operative risk factors. Collaborative efforts focusing on surgical neonates are needed to understand the unique characteristics of this cohort and identify the areas where the morbidity and mortality can be improved.

Mandates for performance improvement and patient safety efforts as well as transparent reporting of outcomes are rapidly increasing [1]. Measuring surgical treatments delivered and their impact on quality outcomes is difficult and costly [2]. Critically important in these metrics is appropriate risk adjustment to enable valid comparisons between institutions. However, the evidence of association between participation in quality improvement (QI) programs and improvement in surgical outcomes is variable [3,4]. One possibility for the weak association with participation in QI programs and improvement in outcomes is a possible lack of actionable data which allows users to make programmatic decisions to support quality improvement efforts [5].

Several studies have demonstrated that neonates undergoing operations have a disproportionate morbidity and mortality compared to older children and adults [6,7]. It is unclear whether this is because of unique physiologic characteristics of neonates or because of an increase in perioperative risk factors predisposing to adverse events. A challenge for any QI program focusing on surgical neonates is the small number of surgical procedures involved at essentially all Children's hospitals. This small number of procedures is related to the low frequency of infants requiring surgery and the diversity of surgical pathology [8]. Importantly, even with this low volume there is significant heterogeneity in many neonatal surgical conditions. For example, in comparison to appendectomy and other common surgical procedures, the busiest children's hospitals perform significantly fewer neonatal surgical procedures (e.g. congenital diaphragmatic hernia repair, esophageal atresia repair, surgery for necrotizing enterocolitis) [9].

The National Surgical Quality Improvement Program Pediatric (NSQIP-P), a joint project between the American College of Surgeons and the American Pediatric Surgical Association, was developed to identify risk factors and outcomes of infants and children undergoing surgical procedures [7,10]. The goals of the NSQIP-P program are twofold: (1) provision of individual hospital performance feedback reports that are risk adjusted for patient comorbidities, acuity, and characteristics

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of the surgery performed, and (2) generation of a Participant Use File (PUF) to allow for general QI research in pediatric surgical patients. The NSQIP-P has been shown to provide broad risk-adjusted models for various outcomes and specialty-specific complication rates for hospitals participating in the program [7,10]. However, it is not well known if the PUF file can be used to identify high risk cohorts that could be targets for QI initiatives.

Given the major differences in neonatal surgery versus surgery involving older children with more common conditions, the purpose of this project was to examine the PUF to compare risk-adjusted outcomes of neonates versus other pediatric surgical patients and to examine the ability of NSQIP-P PUF to provide data that can be used for QI for surgical neonates. We hypothesize that neonates will have a significantly higher adjusted risk of 30-day morbidity and mortality after controlling for clinically relevant risk factors.

1. Methods

1.1. Data sources and measures

The data source in this study was the 2012 and 2013 Participant Use Files of the NSQIP-P Program. NSQIP-P uses trained surgical case reviewers (SCR) to collect clinical data, including demographics, preoperative comorbidities, laboratory results, characteristics of the surgery performed, and postoperative complication diagnoses ("occurrences"). Hospitals collect the first 35 consecutive cases meeting inclusion criteria in an 8 day cycle period. Postoperative occurrences, which are logged for up to 30 days postoperatively, are rigorously defined and are generally treated as dichotomous variables with unique data fields. The data definitions and methodology for NSQIP-P have been described previously [7].

The inclusion criteria for this study were any child undergoing surgical procedures and whose information was accrued within the dataset. A neonate was defined as any infant who was either (1) born at greater than 37 weeks gestation (Term Neonates) and was less than 29 days old on the day of operation or (2) born at less than 37 weeks gestation (Preterm Neonates) and was less than 50 full weeks postconceptual age at the time of operation, which is the official NSQIP-P definition. Nonneonates were defined as any child not meeting the definition of preterm neonate or term neonate and less than 18 years of age. Any child with incomplete age data was excluded from the study.

Preoperative and patient specific risk factors were included as defined previously in the NSQIP-P database [7]. We accounted for case-mix differences in the patient cohorts by grouping procedures in the following categories: Integumentary/Ocular, Musculoskeletal, Respiratory, Cardiovascular, Digestive, Genitourinary, and Nervous System according to CPT code.

The primary outcome was 30-day mortality. The secondary outcome was composite 30-day morbidity defined as occurrence of any one of the following: surgical site infection, wound disruption, intraoperative or postoperative transfusion of greater than 25 ml/kg blood, urinary tract infection, pneumonia, reintubation, pulmonary embolism, progressive renal insufficiency, acute renal failure, coma greater than 24 h, CVA, seizure, intraventricular hemorrhage, cardiac arrest, graft loss, cardiac arrhythmias, systemic sepsis, catheter associated blood stream infection, or unplanned return to OR. A complication was excluded if the same condition existed preoperatively, (i.e. postoperative pneumonia was excluded if the patient had preoperative pneumonia).

1.2. Statistical analysis

Data analysis was performed using SAS Version 9.4 (Cary, NC). Categorical variables were compared using χ^2 analysis. Continuous variables were compared using Student's t test or Wilcoxon rank sum test for normally or nonnormally distributed variables, respectively. All statistical tests were 2-tailed, and a p value of <0.05 was considered significant. The preoperative clinical characteristics significantly associated ($p < 0.05$) with the outcomes of interest were used to construct a forward stepwise selection multivariate logistic regression model. Separate models were constructed for 30 day mortality and composite morbidity. The preoperative clinical characteristics used in the multivariate model and their corresponding significance levels are shown in the Supplementary Table 1. The model was verified by a Hosmer Lemeshow chi-square test. This study was approved by the Human Research Protection Program at Vanderbilt University.

2. Results

2.1. Patient demographics and outcomes

Between 2012 and 2013 there were 114,267 children in the dataset. Of these, 721 records could not be determined if they fit the inclusion criteria at the time of surgery and were therefore excluded. The analysis was performed on 113,546 children. Using the predefined criteria for identification of neonates, there were 7126 neonates and 106,420 nonneonates included in the analysis. (Table 1) Neonates were more likely to be male, white, inpatient and transferred from an outside hospital compared to nonneonates. With respect to patient comorbidities, neonates had significantly more comorbidities compared to nonneonates in the majority of risk factors measured: neurologic, cardiac, pulmonary, gastrointestinal, renal, immunologic, hematologic, acuity of illness, and chronic medical conditions. Neonates were also more likely to be cared for by a pediatric subspecialty surgeon, undergo urgent or emergent procedures, and have shorter operative times compared to nonneonates. However, there was no significant difference in total anesthetic time between the two groups. A higher percentage of neonates underwent procedures on the digestive system compared to nonneonates. Only 30% of neonates were ASA-1 or ASA-2 compared to 79% of nonneonates. Among neonates, 2893 (44%) were term neonates and 3646 (56%) were preterm neonates.

2.2. Risk-adjusted morbidity and mortality

Unadjusted and adjusted outcomes for patients included in this analysis are shown in Table 2. Both preterm and term neonates had a significantly higher unadjusted mortality and composite morbidity compared to nonneonates. After adjustment for demographic, clinical, and operative risk factors both preterm and term neonates had a significantly increased risk of 30-day mortality compared to nonneonates. Additional multivariate analysis on composite morbidity demonstrated preterm and term neonates had a significantly increased risk of 30-day morbidity compared to nonneonates.

2.3. Morbidity and mortality of common neonatal procedures

The 20 most common procedures performed in all neonates according to the NSQIP-P PUF data are shown in Table 3. The most commonly performed procedures ($n = 4661$) account for 65% of all neonatal procedures in the PUF, emphasizing the low volume, high diversity nature of neonatal surgery. The mortality rate for the procedures listed ranged from 0% to 30% and the composite morbidity rate ranged from 3%–53%. The procedures with the most morbidity in the dataset included enterectomy with anastomosis or enterostomy, CDH repair, gastroschisis repair and ventriculoperitoneal shunt placement. The morbidity rate for these procedures ranged from 37%–53%. Overall the 20 most morbid procedures made up only 4% of the entire NSQIP-P PUF study cohort but they accounted for 44% of the mortality and 11% of the composite morbidity of the cohort.

3. Discussion

Neonates are a particularly vulnerable surgical population who are at high risk for postoperative morbidity and mortality. At baseline