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Perioperative Support, Not Volume, is Necessary to Optimize Outcomes in Surgical Management of Necrotizing Enterocolitis

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Abstract

Background—This study examines the relationship between hospital volume of surgical cases for necrotizing enterocolitis (NEC) and patient outcomes.

Methods—A retrospective cross-sectional review was performed using the HCUP SID for California from 2007-2011. Patients with NEC who underwent surgery were identified using ICD-9CM codes. Risk-adjusted models were constructed with mixed-effects logistic regression using patient and demographic covariates.

Results—23 hospitals with 618 patients undergoing NEC-related surgical intervention were included. Overall mortality rate was 22.5%. There were no significant differences in the number of NICU beds ($p=0.135$) or NICU intensivists ($p=0.469$) between high and low volume hospitals. Following risk adjustment, no difference in mortality rate was observed between high and low volume hospitals respectively (24.0% vs. 20.3%, $p=0.555$).

Conclusions—Our observation that neonates with NEC treated at low-volume centers have no increased risk of mortality may be explained by similar availability of NICU and intensivists resources across hospitals.

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Disclosure

The authors have no conflicts of interest

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INTRODUCTION

Necrotizing enterocolitis (NEC) is a devastating intestinal illness in neonates, with many patients requiring surgical intervention. NEC is the most common gastrointestinal surgical emergency among neonates¹, affecting approximately 7-8% of extremely low birth weight infants. Greater than 30% of low birth weight infants with necrotizing enterocolitis require surgical treatment². Though the etiology remains unclear; the disease is characterized clinically by feeding intolerance, abdominal distention, hemodynamic instability, and potential multiple organ failure³. Risk factors include preterm birth and low birth weight. The estimated mortality for NEC ranges between 20 -50%, with highest rates among infants that require surgery^{2, 3}. Although infants with mild NEC can often be managed non-operatively with bowel decompression, bowel rest, broad-spectrum intravenous antibiotics and hyperalimentation, surgical intervention remains the mainstay for more advanced disease².

Necrotizing enterocolitis remains an important area of research, as it has been difficult to eradicate despite advances in neonatal intensive care. Affected patients incur high health care costs and often endure lasting neurodevelopmental morbidities⁴. Due to the complex nature of perioperative care required for these patients, many are transferred to tertiary centers. Previous studies^{5, 6} have shown that hospitals with high surgical volume have lower mortality rates than those at hospitals that are less experienced (low surgical volume centers, LSVC). High surgical volume centers (HSVC) are more likely to have specialists, technology, and better staffing of intensive care units^{5, 6}. Surgical volume is increasingly used as a surrogate for the quality of surgical care; however this relationship has not been well studied in the pediatric population. This study examines the relationship between hospital volume of necrotizing enterocolitis cases requiring surgical intervention and patient outcomes with the objective of determining whether surgery at a high surgical volume center (HSVC) improved overall mortality (death prior to discharge from the hospital) as compared to surgery at a low surgical volume center (LSVC). A secondary aim was to determine if hospital characteristics interacted with the relationship between hospital volume and outcomes.

METHODS

Data Sources

We obtained patient level data from the Healthcare Cost and Utilization Project (HCUP) State Inpatient Database (SID) for California for the years 2007-2011 to perform a retrospective cross-sectional review. The SID is an administrative, all-payer data set aggregated by the Agency for Healthcare Research and Quality (AHRQ) to inform health related decisions⁷. The Institutional Review Board at our institution deemed the study exempt from review as the data are de-identified, protected and publically available.

Hospital characteristics were assessed using the American Hospital Association (AHA) Annual Survey Database from 2011. This nationwide database contains information categorizing an institution's organizational structure, facility and service lines, operation

expenses, and staffing⁸. We linked the patient level data from HCUP SID to the AHA annual survey for hospital data.

Patient and Hospital Characteristics

Patients included for study were between birth and 1 year of age, carried a diagnosis of necrotizing enterocolitis, and underwent a surgical intervention. The diagnosis and procedures were identified by International Classification of Diseases, 9th Revision, Clinical Modification, (ICD9) codes for necrotizing enterocolitis (777.51-3) and various surgical interventions, including exploratory laparotomy (54.11), small bowel resection (45.01-2, 45.10, 45.29, 45.31-32, 45.60-63, 45.33-4, 45.50-52), large bowel resection (45.03, 45.26, 45.41-43, 45.49, 45.72-76, 45.76, 45.79, 45.8, 46.99), stoma creation (46.01-4, 46.10-11, 46.13-14, 46.20-24, 46.31-32, 46.39-43, 46.50-52, 46.60-64, 47.91), primary anastomosis (45.91, 45.93-95, 46.73-76, 46.79, 46.93-94), and lysis of adhesions (46.79, 46.81, 47.99, 54.11, 54.51, 54.59, 54.95). We extracted demographic data from HCUP including sex, race (Caucasian, African-American, Hispanic, other), insurance status (Medicaid, Private, Self-Pay), number of diagnoses and whether the patient was born in the hospital where they had surgery (Table I).

For hospital level analysis, we first determined annual volume of surgical NEC cases from HCUP data. Each hospital was placed into one of five quintiles based on procedure volume per year. The procedure volume cutoffs that are used most closely result in an equal distribution of patients throughout the quintiles. Hospitals were then further separated into high surgical volume centers (HSVC) (highest quintile, 11-15 cases per year) and low surgical volume centers (LVSC) (lowest four quintiles, 1-9 cases per year). Hospital level explanatory variables contained within the AHA Annual Survey database included number of pediatric beds, number of NICU beds, number of neonatal intensivists, and NICU intensivist to NICU bed ratio.

Statistical methods

The primary outcome of interest was risk adjusted mortality, defined as patients who died prior to discharge from the hospital. Descriptive statistics of the study population were calculated using arithmetic means with standard deviations for continuous variables and proportions for categorical variables. Population unadjusted mortality was obtained using a simple proportion of number of inpatient mortalities by the total population. For determining hospital mortality, a weighted mean as a function of individual hospital volume was used. Risk adjusted mortality was calculated using a mixed-effects logistic regression model with fixed effects for patient sex, race, insurance status, number of concurrent diagnoses, and location of birth (same vs. different hospital). Model fit was assessed using the Akaike Information Criterion and C-statistic. All statistical analyses were performed using STATA version 13 (StataCorp LP, College Station, TX).

RESULTS

The study sample included 618 patients with surgical necrotizing enterocolitis at 23 hospitals. The study population was 61% male, 50% Hispanic, 55% had Medicaid as the

primary payer, and 28% of patients were born in the hospital in which they underwent surgery (i.e. inborn) (Table I). The overall unadjusted mortality rate for all hospitals was 22.5% (Figure I). Following risk adjustment for sex, race, insurance status, and inborn status, no difference in mortality rate was observed between hospitals in the highest quintile (11-15 cases per year) and the lower four quintiles in aggregate (1-9 cases per year) (24.0% vs 20.3%, $p=0.555$).

Of the 23 hospitals included, 4 (17%) were high surgical volume centers (HSVC) and 19 (83%) were considered low surgical volume centers (LSVC). The average annual volume for surgical NEC cases across all hospitals was 5 cases per year. Of the four HSVC, the average volume of patients with NEC that were operated on was 62 ± 9.5 patients, while the average volume at LSVC was 19.5 ± 11.5 . The mean number of pediatric beds, NICU beds, and NICU intensivists were 67, 47, and 8 respectively (Table I). In comparing hospital characteristics, HSVC had a significantly greater number of pediatric beds (152.8 vs 47.4 beds, $p<0.001$). However, the number of NICU beds (63.5 vs 43.4 beds, $p=0.135$) and NICU intensivists (6.2 vs 8.4 intensivists, $p=0.469$) did not differ between HSVC and LSVC. The NICU intensivist to NICU bed ratio was also the same across hospitals (.12 vs .23, $p=0.224$).

DISCUSSION

The primary goal of this study was to investigate if a difference exists in the mortality rates for neonates with surgical necrotizing enterocolitis between high surgical volume centers (HSVC) and low surgical volume centers (LSVC). Secondly, we wanted to determine if hospital characteristics interacted with the relationship between hospital surgical case volume and outcomes. The overall unadjusted mortality rate of the study population was 22.5%, which is consistent with current data citing an 18-60% mortality rate for patients with necrotizing enterocolitis, with higher rates for those neonates requiring surgical intervention^{3-4, 9-10, 11}. Using HCUP-SID we found that neonates with surgical necrotizing enterocolitis treated at LSVC do not exhibit an increased risk adjusted mortality when compared to those treated at HSVC. After risk adjustment, the only statistically significant difference in hospital characteristics was the number of pediatric beds which was higher at HSVC.

There was no statistical difference between the number of NICU beds, NICU intensivists or the NICU intensivist to bed ratio, suggesting that perioperative resources and support may be more integral to these neonates' survival than surgical intervention performed at a HSVC. It is also possible that pediatric surgeons who work at HSVC also have commitments to LSVC, therefore these patients are receiving similar surgical care despite the difference in surgical volume. The level of care provided by the NICU however, may impact outcomes. A study by Phibbs et al suggests that mortality in very low birth weight infants is dependent both on the overall hospital volume, as well as the level of care provided by the NICU¹¹. Only 28% of our study population had surgery in the hospitals in which they were born; indicating that these patients are being triaged to centers with the appropriate resources. In another study conducted in California, infants born into the lowest level NICUs were well triaged and had higher rates of acute transfer and shorter birth hospital length of stay¹⁰.

Therefore, transfer to a tertiary care center may not be mandatory if patients are at a LSVC that also have the necessary NICU resources to support them. This is not to suggest that those neonates born at LSVC without appropriate NICU capabilities should not be transferred, but rather highlights the importance of various hospital characteristics in assessing a center's ability to maximize outcomes.

The relationship between volume and outcomes has been demonstrated in the adult population, but there are few studies that explore the relationship between surgical volume and outcomes in the pediatric population, which our study sought to address. Furthermore, while previous studies have cited hospital volume as a surrogate for quality^{5, 6}, other evidence suggests that volume may not be the only characteristic that assures quality. Multiple factors such as patient characteristics and hospital attributes, as well as the interactions between them, define the care delivery microenvironment (CDM). The relative contribution of each of these aspects should be taken into account when considering surgical outcomes. For example, a study by Funk et al described a decrease in mortality for elderly patients undergoing esophagectomy in low surgical volume hospitals with certain systems characteristics such as high nurse ratios, complex medical oncology services, and PET scanners¹².

Despite advances in neonatal intensive care, the overall mortality rate of necrotizing enterocolitis remains high at 25%. As more preterm and very low birth weight infants survive, and the deregionalization of neonatal care continues, it will be important to identify the systems factors that limit mortality despite low surgical volume. In addition to recognizing system and hospital level characteristics, research efforts should continue toward clarifying the etiology of NEC as it continues to be difficult to treat and eradicate. Identifying neonates with clear risk factors for necrotizing enterocolitis as well as continued efforts toward prevention will also be beneficial. By identifying these patients early on, parents can be encouraged to pursue care high NICU level institutions prenatally, that may or may not have high surgical volume, decreasing the need for urgent and emergent transfer.

This study is limited by its use of an administrative data set for a single state in which it is difficult to completely capture the nature of disease and severity of illness using ICD-9 codes. The accuracy of coding and completeness of the data set for each year is variable, but the limited number of codes for necrotizing enterocolitis and the well-defined diagnostic criteria allow for a reliable analysis of the data. Additionally, there is no patient level acuity data available for comparison within the patient dataset. Neonates at HSVC may have more comorbidities than those at LSVC, such that the higher complexity of disease removes the associated survival advantage of increased operative volume. Our risk adjusted statistical analysis helps control for some of these factors, but there are covariates that remain unmeasured such as maternal risk factors additional congenital defects, as well as a specific indicator of the level of surgical care such as knowing the number of surgeons at each institution

In conclusion, neonates with surgical necrotizing enterocolitis that are treated at LSVC do not exhibit increased mortality compared with those that have surgery at HSVC. Interestingly, the level of NICU care provided at both high and low surgical volume

hospitals was similar. A more comprehensive study of the hospital characteristics and systems capabilities at LSVC that exhibit similar mortality to their high volume counterparts could make an impact on the decision tree for neonates with surgical necrotizing enterocolitis. Ultimately, a clearer understanding of the disease process itself is needed to improve overall mortality rates.

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Figure I.

Unadjusted and Risk Adjusted Comparisons between High and Low Volume Hospitals. (A) Depicts unadjusted overall mortality (B) depicts risk adjusted mortality (C&D) depicts comparison of hospital characteristics (pediatric beds, NICU beds, NICU intensivists, NICU intensivists/Bed ratio) * $P < 0.05$.

Table I

Baseline characteristics of study population and hospitals.

Characteristic	Frequency (%), Mean (SD)
PATIENT CHARACTERISTICS (N=618)	
Gender	
Female	243 (39.3%)
Male	375 (60.7%)
Race	
White	132 (21.4%)
Black	76 (12.3%)
Hispanic	310 (50.2%)
Asian	30 (4.9%)
Other	70 (11.3%)
Insurance Type	
Medicaid	337 (54.5%)
Private	197 (31.9%)
Self-Pay/Other	84 (13.6%)
Family Income, by Zip Code (Quartile)	
1 st	263 (42.6%)
2 nd	153 (24.8%)
3 rd	129 (20.9%)
4 th	73 (11.8%)
Hospital Birth (In Hospital of Surgery)	
Yes	173 (28.0%)
No	445 (72.0%)
Number of Diagnoses	18.7 (6.5)
HOSPITAL CHARACTERISTICS (N=23)	
Annual Volume (cases per year)	5.4 (4.0)
NICU Beds	47.0 (24.3)
NICU Intensivists	8.0 (5.3)
NICU Intensivist/NICU Beds	0.21 (0.16)
Pediatric Beds	66.5 (61.0)

NICU- Neonatal Intensive Care Unit