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ORIGINAL ARTICLE

Neonatal surgery in low- vs. high-volume institutions: a KID inpatient database outcomes and cost study after repair of congenital diaphragmatic hernia, esophageal atresia, and gastroschisis

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Abstract

Background/purpose The volume–outcome relationship and optimal surgical volumes for repair of congenital anomalies in neonates is unknown.

Methods A retrospective study of infants who underwent diaphragmatic hernia (CDH), gastroschisis (GS), and esophageal atresia/tracheoesophageal fistula (EA/TEF) repair at US hospitals using the Kids' Inpatient Database 2009–2012. Distribution of institutional volumes was calculated. Multi-level logistic/linear regressions were used to determine the association between volume and mortality, length of stay, and costs.

Results Total surgical volumes were 1186 for CDH, 1280 for EA/TEF, and 3372 for GS. Median case volume per institution was three for CDH and EA/TEF, and four for GS. Hospitals with annual case volumes ≥ 75th percentile were considered high volume. Approximately, half of all surgeries were performed at low-volume hospitals. No clinically meaningful association between volume and outcomes was found for any procedure. Median cost was greater at high- vs. low-volume hospitals [CDH: \$165,964 ($p < 0.0001$) vs. \$104,107, EA/TEF: \$85,791 vs. \$67,487 ($p < 0.006$), GS: \$83,156 vs. \$72,710 ($p < 0.0009$)].

Conclusions An association between volume and outcome was not identified in this study using robust outcome measures. The cost of care was higher in high-volume institutions compared to low-volume institutions.

Level of evidence III

Keywords Surgical outcomes · Neonatal surgery · Surgical volume · Congenital anomalies · Hospital variation · KID Database

Abbreviations

CDH	Congenital diaphragmatic hernia
EA/TEF	Esophageal atresia with/without tracheoesophageal fistula
GS	Gastroschisis
NICU	Neonatal intensive care unit
KID	Kids' Inpatient Database
LOS	Length of stay
ECMO	Extracorporeal membrane oxygenation

Introduction

Gastroschisis (GS), esophageal atresia with or without a tracheoesophageal fistula (TEF), and congenital diaphragmatic hernia (CDH) are among the most common birth defects in the United States, affecting over 3000 newborns annually. These conditions require surgical repair in the neonatal period, defined as less than 4 weeks of age, by pediatric general surgeons. Post-surgical care for these high-risk procedures requires an institution to have a Level 3 or 4 neonatal intensive care unit, both of which require around the clock pediatric surgical support [1]. Care of these conditions requires close collaboration between the pediatric surgeons, neonatologists, and the care teams of their respective units—all contributing significantly to the ultimate outcome

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of the patient. As in other pediatric and adult conditions, the volume of procedures each unit and team is exposed to may be critical for the development of specialized skills and teamwork needed to optimize efficiency and outcomes [2, 3]. The Kids' Inpatient Database (KID) is part of the Healthcare Cost and Utilization Project, an all-payer administrative database that collects a 1-year, 80% sample of pediatric discharges from over 4000 hospitals throughout the United States approximately every 3 years. These data can generate a representative weighted sample that estimates a national volume for specific diagnoses and procedures [4]. KID also includes data on clinical outcomes and hospital characteristics including cost and charges.

Materials and methods

Study design

A retrospective cohort study utilizing 2 years of administrative data from the Kids' Inpatient Database (KID).

For this study, we utilized KID data from the 2009 and 2012 to examine the annual institutional volume of each procedure performed. We also evaluated length of stay, mortality and the estimated cost of care comparing low- and high-volume institutions. The overall goal was to determine if volume-quality benchmarks could be identified using large administrative datasets as has been done for adult conditions.

Data source

The KID obtains an 80% random sample of all pediatric discharges from over 4000 community and non-rehabilitation hospitals across 44 states. KID constitutes data from over 3 million discharges of children aged 0–17 years and represents all payers. Each patient record in KID contains up to 15 diagnosis and procedure codes for a given hospital admission as defined by the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) along with age at admission and geographic region of the hospital as defined by the US Census Bureau. In addition, sampling weights, based on the survey design, were included and allowed calculation of national estimates of operative frequency.

Study cohort

The study included infants less than 30 days of age with ICD9 codes indicating gastroschisis (GS), esophageal atresia with or without tracheoesophageal fistula (EA/TEF), or congenital diaphragmatic hernia (CDH) and an accompanying procedure code indicating surgical repair for these conditions within the first 28 days of life. Since all three procedures require a hospital stay of greater than 7 days, only discharge records indicating a hospital stay longer than 7 days with age of admission ≤ 28 days were included in the study. All procedure and diagnosis codes used for the cohort definition are included in Appendix A.

Institutional volume and outcomes

The total procedure volume for both KID data years was calculated for each condition and multiplied by 1.25 to account for the 80% sampling rate for the KID. As there is not current definition of "high volume" for these conditions, the volume distributions across hospitals were examined to assess for natural cutoffs in the data. Given the skewed volume distribution of volume, a decision was made through consensus of the study team and neonatal providers to use a statistical volume cutoff at the 75th percentile such that >75th percentile would be categorized as high volume and ≤ 75th percentile volume were categorized as low volume. We assessed the distribution operative outcomes by measuring in-hospital mortality, length of stay, and total hospital cost for the surgical admission. Cost measures in KID are calculated using standard cost-to-charge ratios.

Study covariates included Insurance (Private, Medicaid/Medicare and "Other"); hospital region (Northeast, Midwest, South and West); gender (male, female); presence of congenital heart disease; prematurity, and use of extracorporeal membrane oxygenation (ECMO). All ICD9 codes used for variable definitions can be found in the supplemental appendix.

Analytic strategy

For descriptive analyses, weighted frequencies and measures of central tendencies were calculated. Bivariate analyses were performed using the Rao–Scott Chi square statistic for categorical data and linear regression on log-transformed values of continuous data (LOS and hospital cost). Multivariable mixed effects linear regression of continuous outcomes (LOS in days and cost in dollars) was performed, accounting for clustering of patients within hospitals. Both LOS and costs were log-transformed to achieve normality. Multivariable mixed effects logistic regression was performed to estimate the association between hospital volume and mortality. Covariates that were associated both with the exposure, hospital surgical volume, and with the outcome of interest were entered into a multivariable model. We set the level of association between the covariable and the outcome at 0.25 for the model-building process [5]. Variables

were removed from the model in order of decreasing p value until the p values of the remaining variables were <0.05. All statistical testing was two-sided and a predetermined α of 0.05 was used as the threshold of statistical significance. SAS survey commands (SAS 9.4, SAS Institute Inc., Cary, NC) were used to account for the weighted stratified sample design of the KID.

Results

Surgical volume

Congenital diaphragmatic hernia

A total of 1186 infants who underwent CDH repairs were identified in the available data years (KID 2009 and 2012). Across all hospitals, the median annual surgical volume was three, with a range of 1–25 and 75th percentile of five. A total of 506 (42.6%) infants underwent repairs in low-volume institutions where 5 or fewer repairs were performed per year, and 680 (57.4%) procedures were performed in high-volume institutions, where 6 or more repairs were performed per year. Within volume categories, the median number of CDH repairs for low-volume institutions was three, and the median number for high volume institutions was ten (Table 1). There were 21 institutions in the high-volume group in 2009 and 22 in 2012. Most children were not premature (85%), and a 25% were placed on ECMO.

Esophageal atresia and tracheoesophageal fistula

A total of 1280 infants who underwent EA/TEF repair were identified. Across all hospitals, the median annual surgical volume was 3 cases, with a range of 1–18 cases and 75th percentile of 5 cases. A total of 695 (54.3%) infants underwent repairs in low-volume institutions where 5 or fewer repairs were performed per year, and 585 (45.7%) procedures were performed in high-volume institutions where 6 or more repairs were performed per year. Within volume categories, the median number of EA/TEF repairs for low-volume institutions was three cases and the median number for high-volume institutions was eight cases (Table 1). There were 27 institutions in the high-volume group in 2009 and 33 in 2012. Similar to CDH, most EA/TEF patients were not premature (72%).

Gastroschisis

A total of 3372 neonates who underwent gastroschisis repair were identified in the available data years (KID 2009 and 2012). Across all hospitals, the median annual surgical volume was 4, with a range of 1–43 and 75th percentile of 9 cases. A total of 1621 (48.1%) infants underwent repairs in low-volume institutions where 8 or fewer repairs were performed per year, and 1752 (52%) procedures were performed in high-volume institutions, where 9 or more repairs were performed per year. Within volume categories, the median number of GS repairs for low-volume institutions was 4 cases, and the median number for high-volume institutions was 14 cases (Table 1). There were 41 institutions in the high-volume group in 2009 and 56 in 2012. Less than 50% of infants were premature (46%).

Surgical outcomes

The results of bivariable and multivariable analysis, including covariates that were retained in each model, are shown in Tables 2, 4, and 5. Unless otherwise described in the results, covariates did not meet criteria for inclusion in the models.

Table 1 Surgical volume of institutions performing specified surgeries, Kids' Inpatient Database 2009 and 2012

	CDH ($n=1186$)	TEF ($n=1280$)	Gastroschisis ($n=3372$)
Low volume institutions ($\leq$75th percentile)[a]			
#Patients undergoing surgery	506 (42.6%)	695 (54.3%)	1621 (48.1%)
#Institutions performing surgery (2009, 2012)[b]	82, 96	106, 157	165, 222
High-volume institutions (>75th percentile)[a]			
#Patients undergoing surgery	680 (57.4%)	585 (45.7%)	1752 (52.0%)
#Institutions performing surgery (2009, 2012)[b]	24, 28	27, 31	39, 61
Range of # of surgeries	1–25	1–18	1–43
Median (IQR) # of surgeries	3 (1–5)	3 (1–5)	4 (3–9)

[a]CDH 75th percentile number of cases: 5; TEF 75th percentile number of cases: 5 cases; Gastroschisis 75th percentile number of cases: 9

[b]Number of institutions performing surgery reported by year because the hospital identifiers changed between 2009 and 2012

Table 2 Characteristics of CDH patients by hospital volume, Kids' Inpatient Database 2009 and 2012 ($n = 1186$)

	High volume, *n* (%)	Low volume, *n* (%)	*p* value
LOS (median # of days, range)[a]	31 (8–303)	30 (8–328)	0.15
Cost (median $, range)	165,964 (19,528–1,707,487)	104,107 (16,878–1,198,913)	< 0.0001
Mortality	85 (12.6)	61 (12.0)	0.83
ECMO	189 (27.7)	108 (21.3)	0.09
Congenital heart disease	94 (13.9)	56 (11.1)	0.29
Prematurity status			
Not premature	597 (87.8)	428 (84.5)	0.56
≤ 28 weeks	< 10	< 10	
29–32 weeks	13 (1.9)	12 (2.4)	
33–36 weeks	67 (9.9)	62 (12.3)	

[a]Excluding patients who received ECMO

Mortality

Congenital diaphragmatic hernia

Overall mortality was 12%. On bivariate analysis, there was no significant difference in mortality between high- and low-volume institutions (Table 2). In multivariable analysis, first for solely ECMO, and then adjusting for ECMO, prematurity and congenital heart disease (to account for other medical complexities), no significant association between mortality and volume was identified (Table 5). No other covariates met criteria for inclusion in the model.

Esophageal atresia and tracheoesophageal fistula

Overall mortality was 3.4%. On bivariate analysis, there was no significant difference in mortality comparing high- and low-volume institutions (Table 3). There was also no difference in mortality in a multivariable model (Table 5).

Gastroschisis

Overall mortality was 1.3%. On bivariate analysis, there was no significant difference in mortality comparing high- and low-volume institutions (Table 4). There was also no difference in mortality in a multivariable model (Table 5).

Length of stay

Congenital diaphragmatic hernia

Median LOS across hospitals was 30 days with a range of 8–328. On bivariate analysis, there was no significant difference between LOS and volume (Table 2). However, in a multivariable model adjusting for ECMO and insurance, LOS was statistically significantly shorter in low- vs. high-volume institutions (OR, 95% CI; Table 5). However, median LOS differed by only 1 day (30 vs. 31).

Esophageal atresia and tracheoesophageal fistula

Median LOS across hospitals was 29 days with a range of 8–291. There was no significant difference between LOS and volume in either the bivariable or multivariable analyses (Tables 3, 5).

Table 3 Characteristics of TEF patients by hospital volume, Kids' Inpatient Database 2009 and 2012 ($n = 1280$)

	High volume, *n* (%)	Low volume, *n* (%)	*p* value
LOS (median # of days, range)	30 (8–291)	27 (8–289)	0.44
Cost (median $, range)	85,791 (20,215–829,398)	67,487 (12,934–1,415,676)	0.006
Mortality	20 (3.3)	23 (3.4)	0.95
Congenital heart disease	76 (13.0)	60 (8.7)	0.03
Prematurity status			
Not premature	432 (73.7)	491 (70.7)	0.46
≤ 28 weeks	< 10	10 (1.4)	
29–32 weeks	41 (7.1)	51 (7.3)	
33–36 weeks	110 (18.7)	143 (20.5)	

Table 4 Characteristics of gastroschisis patients by hospital volume, Kids' Inpatient Database 2009 and 2012 ($n=3372$)

	High volume, *n* (%)	Low volume, *n* (%)	*p* value
LOS (median # of days, range)	35 (9–365)	36 (8–332)	0.72
Cost (median $, range)	83,156 (3,660–884,528)	72,710 (5,606–1,289,069)	0.0009
Mortality	23 (1.3)	22 (1.3)	0.93
Congenital heart disease	21 (1.2)	28 (1.7)	0.24
Prematurity status			
Not premature	856 (48.9)	694 (42.9)	0.05
≤28 weeks	< 10	< 10	
29–32 weeks	75 (4.3)	71 (4.4)	
33–36 weeks	819 (46.8)	852 (52.6)	

Table 5 Multivariable associations between outcomes and low- vs. high-volume institutions, Kids' Inpatient Database 2009 and 2012

	Mortality[a]	Cost (%)[b]	LOS (%)[b]
CDH	1.3 (0.7–2.2)[c]	– 0.33, 0.08 (< 0.0001)[c]	– 0.12, 0.06 (0.03)[d]
TEF	1.0 (0.5–2.1)	– 0.15, 0.07 (0.03)[e]	– 0.10, 0.06 (0.09)[e]
Gastroschisis	1.0 (0.5–2.1)[f]	– 0.08, 0.07 (0.27)[g]	– 0.01, 0.03 (0.66)[f]

[a]Odds ratio (95% CI)

[b]β, SE (*p* value); log-transformed values

[c]Adjusted for ECMO and bedsize

[d]Adjusted for ECMO and in-hospital birth

[e]Adjusted for congenital heart disease and hospital bedsize

[f]Adjusted for prematurity

[g]Adjusted for in-hospital birth

Gastroschisis

Median LOS across hospitals was 36 days with a range of 9–365. There was no significant difference between LOS and volume in either the bivariable or multivariable analyses (Tables 4, 5).

Hospitalization costs

Congenital diaphragmatic hernia

The median total cost for CDH patients at high-volume institutions was $165,964 compared to $104,107 ($p<0.0001$) at low-volume institutions (Table 2). In multivariable analysis controlling for ECMO use, higher cost was significantly associated with care at high- vs. low-volume hospitals, despite no statistical difference in the number of procedures per patient.

Esophageal atresia and tracheoesophageal fistula

The median total cost for TEF patients at high-volume institutions was $85,791 compared to $67,487 at low-volume institutions, which was significant in bivariable analysis ($p=0.006$). In multivariable analysis, this association remained marginally significant, controlling for congenital heart disease (Tables 3, 5).

Gastroschisis

The median total cost for Gastroschisis patients at high-volume institutions was $83,156 compared to $72,710 at low-volume institutions ($p=0.0009$) (Tables 4, 5). In multivariable analysis, this association between cost and volume was not significant.

Discussion

In this retrospective study of nearly 6000 neonates undergoing high-risk procedures for correction of complex congenital anomalies, we found remarkably low-procedure volumes across most hospitals. We were unable to make meaningful assessments about the impact of volume on patient outcomes and whether volume quality metrics for these procedures should be supported. However, we did identify significantly higher costs of care among the highest volume hospitals for some conditions—likely indicating either different practices, sicker patients, or both. This work emphasizes the need for the development of national registries for patients with birth defects that require surgical repair in the neonatal period [6].

For select complex surgical conditions, in both adults and children, improved outcome have been associated with a higher surgical volume both for the institution as well as the surgeon [7–11]. Most likely, this positive effect on outcomes is a result of increased experience with a particular procedure and condition on both the part of the surgeon, their team members, and the hospital care in general. Despite the high process and outcomes variation for these neonatal procedures, few studies have been performed to determine if institutional volume may be a critical factor in outcomes or more standardized processes [12, 13]. Although it is possible that such a relationship exists, the complexity of these conditions, the heterogeneity of the neonatal patients as well as the relative infrequency of these conditions makes it difficult to establish a volume outcomes relationship using readily available data sources and traditional outcomes metrics. To our knowledge, there are only a few studies in the literature using administrative data to evaluate differential outcomes for these neonatal surgery conditions based on volume or availability of specialty care. Results of such studies have been mixed, highlighting the challenges of using these data sources to reproducibly identify volume cutoffs and safety benchmarks [7, 14–18].

There are several reasons why the impact of not only volume but other institutional factors on patient outcomes needs to be further explored. First, there has been a large increase in the number of approved pediatric surgery training programs which may lead to lower procedure volume per trainee in general [19]. Second, with lower complex procedure volumes per provider/hospital, come concerns about the maintenance of competency among all pediatric surgeons, surgical teams, and hospital units that care for these patients [20, 21]. Finally, correctly or incorrectly, the assumption that volume–outcome metrics are meaningful in children as they are in adults has resulted in a belief that regionalization of care for the complex neonate with surgical disease is necessary to maintain quality [22].

Recently, the ACS Committee on Children's Surgery task force published recommendations regarding requirements for operative volume and anesthesia support for institutions caring for infants and children with surgical needs [22]. These guidelines and recommendations are set to evolve into a certification system for children's surgery centers following a verification process akin to trauma center certification, yet currently no data exist to support or refute these recommendations in terms of volume cutoffs and outcomes benchmarking.

Unlike similar research for complex adult surgical procedures, investigation of variation in surgical outcomes in neonates (attributable to volume or other hospital factors) is hampered by low case volumes [8–10]. Surprisingly, we identified very few institutions performing > 20 cases per year for any of the three conditions. The median number of cases per institution in our study was only three cases for CDH and EA/TEF and four cases for GS. Many institutions cared for only one infant with these conditions per year. These case numbers seem questionably low, but they are reflective of previous reports [23, 24]. These low volumes are both statistically and clinically problematic as they result not only in an inability to study variation in outcomes for these conditions but also an inability for most surgical teams and hospitals to gain experience with and resources for ensuring consistent care.

There are limitations to this study. While the use of KID allows for access to a large representative population of children hospitalized in the US, it contains only administrative data. For this reason, clinically important variables such as type of surgical repair, gap length for EA/TEF, size of defect for CDH and GS could not be measured and included in the analysis. We were able to account for some patient complexity factors including prematurity and ECMO use via ICD9 codes, but potential confounders related to the patient and hospital were unable to be measured. Although, it is unlikely this knowledge would have changed the outcomes of the study, since both the high- and low-volume institutions had a large and similar number of patients that were randomly distributed after birth. Another limitation is the use of KID data available from 2009 and 2012. We believe that it is unlikely that surgical volumes have increased across hospitals to an extent that would have changed the results of this study—regardless of more recent changes in surgical practices. There are also other statistical methods that may be superior to logistic regression for modelling volume outcomes associations. However, it is unlikely that different methods would overcome the issue of low overall volumes and volume variation [25].

A strength of using administrative data for these procedures is that they are distinct procedures with unique diagnosis and procedure codes. For this reason, there is likely minimal misclassification of patients and the low volumes across hospitals are likely real. While we were not able to use these data to provide new evidence to support or refute surgical volumes as accreditation metrics for this population, this study underscores the need to be more careful about how surgical and neonatal societies are approaching relative outcomes measurements to hold hospitals accountable for quality and safety. It is also important to have a discussion about how surgeons and hospitals can maintain competency in the care of neonates with complex congenital conditions with such low surgical volumes, especially since there is an increasing number of board-certified pediatric surgeons being trained in accredited pediatric surgery fellowship programs, as well as non-accredited subspecialty pediatric surgeons [23, 24].

Conclusions

Institutional neonatal surgical case volumes for CDH, EA/TEF, and GS are low for the majority of institutions caring for infants with these conditions, making it challenging to identify the impact of factors such as volume on patient outcomes. Even using the largest available database, this study demonstrates that the sample sizes are low. In the field of neonatal surgery, it is necessary to develop metrics that differentiate the value and safety for the care of these patients. For example, the field of pediatric cardiology has recognized the limitation of these big data metrics and developed a stratification system by risk so that stratified analyses can be conducted in the STS (The Society of Thoracic Surgeons) database. Specifically, they developed a common dataset, a stratification system to evaluate for case complexity, methods to account for quality improvement measures, and standardized follow-up of patients [26]. Similarly, the development of these metrics in neonatal surgery and the utilization of these metrics in a common neonatal registry are essential to understand the complex volume–outcome relationship in this specific patient population.

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Compliance with ethical standards

Ethical approval All the procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent The study was evaluated and approved by the Colorado Multiple Institution Review Board (COMIRB), and a waiver of informed consent as obtained due to the retrospective nature of the study and the use of the national KID.

Appendix A.

Study definitions
Congenital diaphragmatic hernia (CDH)
Age at admission 0–28 days, LOS > 7 days
Diagnosis code: 756.6 and
Procedure codes: 53.71 or 53.75 or 53.84 or 53.72 or 53.80 or 34.82 or 34.84 or 53.83
Tracheoesophageal fistula (TEF)
Age at admission 0–28 days, LOS > 7 days
Diagnosis codes: 750.3 or 530.84 and
Procedure code: 31.73
Gastroschisis (GS):
Age at admission 0–28 days, LOS > 7 days
Diagnosis codes: 756.73 or 756.79 and
Procedure code: 54.71
Patent ductus arteriosus dx and surgery indicator variable
Diagnosis code: 747.0: 1 and
Procedure code: 38.85
Congenital heart disease indicator variable
Diagnosis codes: 746.0 or 746.00 or 746.01 or 746.02 or 746.09 or 746.1 or 746.2 or 746.3 or 746.4 or 746.5 or 746.6 or 746.7 or 746.8 or 746.81 or 746.82 or 746.83 or 746.84 or 746.85 or 746.86 or 746.87 or 746.89 or 746.9
Prematurity indicator variable
Diagnosis codes = "≤ 28 weeks": 765.21 or 765.22 or 765.23 or 765.24
Diagnosis codes = "29–32 weeks": 765.25 or 765.26
Diagnosis codes = "33–36 weeks": 765.27 or 765.28

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