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Journal
Journal of Pediatric Surgery, 51(10)

ISSN
0022-3468

Authors
Sacks, Greg D
Ulloa, Jesus G
Shew, Stephen B

Publication Date
2016-10-01

DOI
10.1016/j.jpedsurg.2016.04.009

Journal of Pediatric Surgery 51 (2016) 1650–1654

Contents lists available at ScienceDirect

Journal of Pediatric Surgery

journal homepage: www.elsevier.com/locate/jpedsurg

Is there a relationship between hospital volume and patient outcomes in gastroschisis repair?

Greg D. Sacks [a,b,*], Jesus G. Ulloa [b,c], Stephen B. Shew [a]

[a] Department of Surgery, David Geffen School of Medicine, University of California, Los Angeles
[b] Veterans Affairs Greater Los Angeles Healthcare System
[c] Department of Surgery, University of California, San Francisco

ARTICLE INFO

Article history:
Received 8 January 2016
Received in revised form 7 March 2016
Accepted 10 April 2016

Keywords:
Volume outcome
Gastroschisis
Newborn surgery
Regionalization

ABSTRACT

Purpose: Given the well-established relationship between surgical volume and outcomes for many surgical procedures, we examined whether the same relationship exists for gastroschisis closure.
Methods: We conducted a retrospective analysis of infants who underwent gastroschisis closure between 1999 and 2007 using a California birth-linked cohort. Hospitals were divided into terciles based on the number of gastroschisis closures performed annually. Using regression techniques, we examined the effects of hospital volume on patient mortality and length of stay while controlling for patient and hospital confounders.
Results: We identified 1537 infants who underwent gastroschisis repair at 55 hospitals, 4 of which were high-volume and 42 of which were low-volume. The overall in-hospital mortality rate was 4.8% and the median length of stay was 46.5 days. After controlling for other factors, patients treated at high-volume hospitals had significantly lower odds of inpatient mortality (OR 0.40; 95% CI 0.21, 0.76). There was a near-significant trend towards shorter hospital length of stay at highvolume hospitals ($p = 0.066$).
Conclusions: Patients who undergo gastroschisis closure at high-volume hospitals in California experience lower odds of in-hospital mortality compared to those treated at low-volume hospitals. These findings offer initial evidence to support policies that limit the number of hospitals providing complex newborn surgical care.

Infants born with congenital defects require complex, coordinated, and interdisciplinary care. The management of infants with gastroschisis, for example, typically requires intensive nursing care and nuanced decision-making regarding nutritional support and abdominal wall closure timing and technique. Ensuring successful outcomes therefore depends on a myriad of interacting factors, including surgeon experience, closure technique, prenatal care, and nursing care. Considering the required coordination, it is plausible that hospitals that care for such patients more frequently, may also deliver higher quality care and have better patient outcomes.

The relationship between surgical volume and patient outcomes has been demonstrated repeatedly [1–3]. This is particularly true for complex surgical procedures that require elaborate, interdisciplinary care, such as esophagectomy [4–6] and pancreatectomy [7–9]. Most neonatal surgical treatments, including those for gastroschisis, meet these criteria, however the relationship between hospital volume and patient outcomes is not well understood for this patient population. In Canada, where care for infants with gastroschisis is regionalized to a few qualifying centers, patients experience similar mortality, length of stay, and days on total parenteral nutrition (TPN) regardless of the modest differences in volume across the centers [10]. In the United States, however, care for infants with congenital surgical conditions remains decentralized, resulting in many hospitals treating only a few number of these patients each year. Therefore, in a system with a broad range of case volumes across hospitals, such as that in the United States, it remains possible that an association exists between higher case volumes and better patient outcomes for patients with gastroschisis.

Using a statewide cohort of patients treated for gastroschisis in California, we sought to determine whether infants treated at high-volume centers experience better outcomes than those treated at low-volume centers. These results would offer valuable data to inform policies that aim to ensure safe and efficacious care of infants with gastroschisis.

1. Methods

1.1. Data source and study population

The study was approved by the Institutional Review Boards at the University of California, Los Angeles and the California Office of Statewide Health Planning and Development (OSHPD). We performed a retrospective analysis using data from a linked maternal-neonatal

Abbreviation: OSHPD, Office of Statewide Health Planning and Development.
Financial disclosures: The authors have no financial relationships relevant to this article to disclose.
Conflicts of interest: None.

* Corresponding author at: Department of Surgery, David Geffen School of Medicine, at UCLA 757 Westwood Plaza B7-11, Los Angeles, CA 90095.
E-mail address: gsacks@mednet.ucla.edu (G.D. Sacks).

http://dx.doi.org/10.1016/j.jpedsurg.2016.04.009
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database of hospital discharges from 1999 to 2007 in California, as maintained by the California Office of Statewide Health Planning and Development (OSHPD). We identified infants born with gastroschisis using International Classification of Diseases, Ninth Edition (ICD-9) codes. During the study period, one ICD-9 diagnosis code was shared between the abdominal wall defects, gastroschisis and omphalocele. We therefore used this diagnosis code combined with a procedure code specific for gastroschisis closure to identify our study population (diagnostic code 756.73 and procedure code 54.71). This method has previously been used [11] and validated by showing greater than 96% agreement between gastroschisis codes in the cohort file and prenatal ultrasound findings [12].

We assigned patients to a hospital based on the location of the first gastroschisis closure, not the hospital of birth. This first procedure refers to the first time a relevant procedure code appeared in the patient's record. We also recorded whether a patient was transferred between the time of birth and first procedure. Therefore, patients who underwent gastroschisis closure prior to a hospital transfer were excluded from this analysis. Inpatient hospitalization served as our unit of analysis and patients were therefore followed until the time of death or hospital discharge. The administrative data available precluded us from determining whether the closure was staged or definitive, or whether a silo was used.

1.2. Outcomes

We analyzed 2 outcome variables: mortality and length of stay (LOS). Mortality was defined as death of any cause after the first attempt at gastroschisis closure and prior to hospital discharge. LOS was calculated as the time from birth to hospital discharge, including the time spent before or after hospital transfer. We analyzed LOS as a continuous variable to calculate risk-adjusted predictions of LOS and also as a categorical variable in our regression models. For these models, we defined prolonged LOS as greater than the 75th percentile (55 days).

1.3. Covariates

Our main explanatory variable of interest was hospital volume, which we calculated based on the average number of patients in our cohort for each hospital per year. Hospitals were ranked according to mean average volume and divided into terciles based on volume cutoffs that most closely created terciles with similar numbers of patients [13]. The cutoff for the average number of operations performed at low-, medium-, and high-volume hospitals was <5, 5–9, and 9–17, respectively. Of note, each hospital's volume was relatively consistent throughout our study time frame, as noted by the high correlation between annual operative volume and assigned volume tercile (correlation coefficient = 0.83).

To control for the resources available at each hospital, we controlled for the designated neonatal intensive care unit (NICU) level, as defined by the American Academy of Pediatrics [14,15]. Since the vast majority of cases (98.7%) in our sample were from level 3C or 3B NICUs, we categorized NICU level as a binary variable (3C vs. 3B, 3A, or 2B). Most patients (70.5%) treated at hospitals with level 3B NICUs were treated at low volume hospitals and the remainder (29.5%) were treated at medium volume hospitals. We also controlled for patient level factors including gender, gestational age, low birthweight (<2500 g), maternal age, the infant's age on the day of the procedure, and the severity of disease. For the latter concept, we included variables for the presence of necrotizing enterocolitis (ICD-9777.5-777.53), intestinal perforation (ICD-9777.6), and respiratory distress syndrome (ICD-9769), as identified by ICD-9 codes [16]. We also controlled for whether or not the patient was transferred from another facility prior to defect closure. Of note, comparing transferred and non-transferred patients, there was no statistically significant difference in gestational age, maternal age, low birthweight, necrotizing enterocolitis, or intestinal perforation. There was, however, a higher proportion of patients with respiratory distress syndrome among patients who were transferred (3.4%) compared to those who were not transferred (1.3%, p = 0.003 from chi-squared test).

1.4. Statistical analysis

We first determined the distribution of patients across volume tercile. Chi-squared tests and Kruskal–Wallis tests were used to determine differences in demographics by tercile for categorical and continuous variables, respectively.

We then created a hierarchical logistic regression model to predict mortality based on hospital volume using a random intercept for the hospital. This model controlled for patient and maternal demographics, disease severity, and NICU factors using the variables listed in Table 1. To analyze length of stay, we used two separate modeling strategies. First, we categorized length of stay as a binary variable, with prolonged length of stay defined as greater than the 75th percentile (55 days). We then built a hierarchical logistic regression model to predict prolonged length of stay controlling for all covariates. Second, we analyzed length of stay as a continuous variable, using a negative binomial multivariate regression model, again controlling for the previously mentioned covariates and accounting for clustering of cases within hospitals using robust standard errors. Negative binomial regression is used to model count data and is particularly useful when there is over-dispersion as we noted in our data. Using this model, we calculated a risk-adjusted length of stay for each hospital-volume tercile. All statistical analyses were performed using Stata version 13.1 (College Station, Texas).

2. Results

There were 1537 patients who underwent gastroschisis repair at 55 unique hospitals in our sample. The majority of patients were male

Table 1
Patient characteristics at high- and low-volume hospitals for gastroschisis repair.

	Total	Low-volume hospitals	Medium-volume hospitals	High-volume hospitals
Number of patients	1537	516	567	454
Unadjusted mortality (%)	4.8	6.0	4.6	3.5
Unadjusted median length of stay (days)*	46.5	49.0	46.9	43.3
Gender (%)				
Female	48.2	48.6	45.7	50.7
NICU level (%)*				
3B, 3A, 2B	36.8	78.1	28.6	0
3C	63.2	21.9	71.4	100
Gestational age, weeks (%)				
>37	52.1	54.3	49.2	53.3
34–37	36.8	37.6	38.1	34.1
<34	11.1	8.1	12.7	12.6
Maternal age, years (%)				
20–35	64.4	66.7	65.4	60.6
>35	1.4	1.7	1.2	1.1
<20	34.2	31.6	33.3	38.3
Low birthweight, <2500 g (%)	50.4	49.4	51.9	49.6
Complicated gastroschisis (%)				
Necrotizing enterocolitis	3.3	3.3	3.2	3.5
Intestinal perforation	3.8	3.7	3.4	4.4
Respiratory distress syndrome	2.0	2.9	0.9	2.2
Days until initial procedure, mean*	1.4	3.2	0.4	0.5
Transfer from outside hospital (%)*	35.7	17.1	33.5	59.7

* P < 0.001; none were significant at an alpha-level between 0.001 and 0.05. p-values calculated using chi-squared test for categorical variables and Kruskal–Wallis test for continuous variables.

Table 2
Risk-adjusted odds of mortality and prolonged length of stay by hospital volume tercile.

	Number of hospitals	Mean volume	Risk-adjusted odds of mortality	Risk-adjusted odds of prolonged length of stay
Hospital volume				
Low (<=5)	42	3.1	1 (Ref)	1 (Ref)
Medium (5–9)	9	7.4	0.60* (0.38,0.94)	0.93 (0.59,1.49)
High (> = 9)	4	13.4	0.40** (0.21,0.76)	0.71 (0.37,1.34)

p-values calculated using hierarchical logistic regression.
* $P < 0.05$.
** $P < 0.01$.

(51.8%), greater than 37 weeks gestational age (52.1%), and below 2500 g at birth (Table 1). The median maternal age was 21 years (interquartile range (IQR) 19–24); only 1.4% of mothers were over age 35. More than half the patients (63.2%) were treated in 3C level NICUs. In unadjusted analyses, the only covariate factors that differed significantly across volume terciles were NICU level, age at first procedure, and transfer status ($p < 0.001$ for all). The overall in-hospital mortality rate was 4.8%, 6.0% in low-volume hospitals, and 3.5% in high-volume hospitals. The overall median length of stay was 46.5 days, significantly longer at low-volume hospitals (median 49.0 days) than at high-volume hospitals (median 43.3 days; $p < 0.001$).

There were 4 hospitals that were categorized as high-volume, 9 as mid-volume, and 42 as low-volume. Of note, patient transfer prior to gastroschisis closure was not significantly associated with mortality in our multivariate model (OR 1.29, $p = 0.374$). Hospital-volume tercile was an independent and significant predictor of in-hospital mortality (Table 2). In comparison to low-volume hospital, the odds of inpatient mortality were 40% lower at medium-volume hospitals (95% confidence interval (CI) 0.38,0.94; $p = 0.025$) and 60% lower at high-volume hospitals (95% CI 0.21,0.76; $p = 0.005$). In comparison to low-volume hospitals, patients treated a medium- and high-volume hospitals experienced 7% (OR 0.93, 95% CI 0.59,1.49; $p = 0.775$) and 29% (OR 0.71, 95% CI 0.37,1.34; $p = 0.292$) lower odds of prolonged length of stay, although these results did not reach statistical significance.

When analyzing length of stay as a continuous variable, there was also a near-significant trend towards decreased length of stay across volume tercile ($p = 0.066$). After adjusting for patient and NICU characteristics as well as procedural volume, the risk-adjusted length of stay was 46.6 days at low-volume hospitals compared to 42.0 days at high-volume hospitals (Fig. 1).

3. Discussion

In this retrospective analysis of a California linked maternal-neonatal database of hospital discharges, we identified 1537 infants that underwent gastroschisis repair at 55 unique facilities. Our data demonstrate a significant reduction in the odds of mortality for patients treated at high-volume hospitals. We also demonstrated a trend towards shorter length of stay for patients treated at high-volume hospitals, although this finding did not reach statistical significance.

To our knowledge, there has only been one prior study evaluating the volume-outcome relationship for gastroschisis repair [10]. This study, by Baird and colleagues, analyzed patterns of care for patients with gastroschisis in Canada and found no difference between high- and low-volume centers in hospital length of stay, duration of total parenteral nutrition (TPN) use, or overall mortality. Another study using the same database did, however, demonstrate higher success rates for primary closure at high-volume hospitals, possibly because of preferential use of delayed closure on more complicated patients at these high-volume hospitals [17]. The Canadian health care system differs substantially from that in the US and therefore prior to our study, it remained unclear whether Canadian results might generalize to the US system. Most notably, gastroschisis care in Canada, as well as care for other complex neonatal conditions, is regionalized to a few specialized centers that are equipped with the necessary resources and specialists to care for these infants. Therefore, despite the comparable population sizes in California and Canada, there are far fewer hospitals that perform gastroschisis repair in Canada ($n = 16$ in the Baird study) than in California ($n = 55$ in our study). As a result, the average volume per center was significantly higher in the Canadian study (6.5 average cases per year vs. 3.7 in our study), possibly resulting in their inability to detect a volume-outcome relationship because of fewer low-volume hospitals.

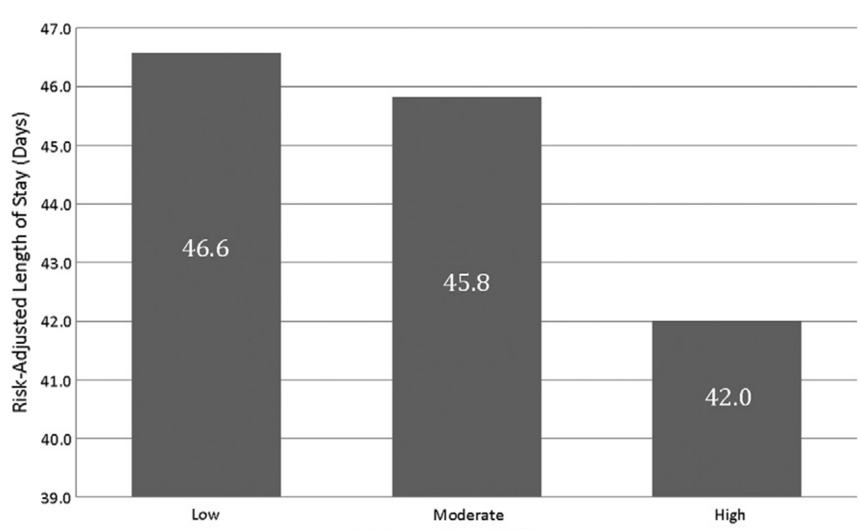

Fig. 1. Multivariate regression analysis of length of stay according to hospital volume tercile. Models are adjusted for patient characteristics and amount of NICU resources available. p-value for trend is 0.066. p-value calculated using negative binomial regression.

While studies on the volume-outcome relationship are limited for pediatric surgery operations, there is extensive data from the adult literature that repeatedly identify improved outcomes for patients treated at high-volume hospitals [13,18]. In fact, these effects appear to be increasing over time [19]. These findings are particularly pronounced for operations that are technically challenging, require extensive hospital resources, and benefit from the expertise of multidisciplinary care, such as abdominal aortic aneurysm repair [20], esophagectomy [6,21], and pancreatectomy [2]. Gastroschisis repair certainly meets many of these criteria, suggesting that better outcomes may be obtained at high-volume hospitals, as demonstrated by our study. These hospitals may benefit from streamlined processes of care, better knowledge on best surgical and perioperative practices, and improved care coordination between maternal fetal medicine physicians, neonatologists, pediatric surgeons, and other integral providers that are critical in both the pre- and post-natal period. In fact, another study demonstrated that those infants born in a high-volume hospital had significantly improved outcomes compared to those transferred in from other hospitals, even after controlling for other confounding factors, including hospital volume [22].

Better outcomes at high-volume centers has been used as an argument for regionalizing care to fewer high-volume centers [23]. A recent retrospective cohort study echoed this argument by demonstrating lower mortality for infants with necrotizing enterocolitis treated at high-volume NICU's in California. Despite these findings, the study also pointed out that in 2011, only 28.6% of infants with necrotizing enterocolitis were born in high-volume centers, suggesting that deregionalization of care actually appears to be increasing over time, possibly exposing more infants to the potentially inferior quality care at low-volume hospitals [24]. Yet, only four hospitals in our study were high-volume centers in which the mortality benefit was observed, making it unfeasible to limit care to only these centers. While calls for regionalizing care are also a natural extension of our study's findings, it will be important to ensure that newborn surgical care is not regionalized to the extent that access to high-quality care is jeopardized, as appears to have occurred for liver transplant surgery [25].

One of the consequences of regionalizing care is a greater reliance on patient transfer from low-volume centers to high-volume centers. In our cohort, a relatively large number of patients treated at high-volume centers (59.7%) and a smaller proportion treated at medium-volume hospitals (33.5%) were transferred from another hospital prior to undergoing gastroschisis closure. By controlling for patient transfer in our multivariate model, we intended to adjust for the possibility that transferred patients might require more complex care than those that remained at their birth hospital, which may then reflect poorly on the outcomes of high-volume hospitals. However, we note that in our multivariate model, the variable for patient transfer was not a significant predictor of patient mortality after adjusting for all other variables. One possible explanation for this finding is that the benefits of treatment at a high-volume center outweigh any negative effects associated with patient transport. Alternatively, the selection of which patients are transferred may have less to do with disease severity and more to do with other factors, such as local practice culture, insurance status, or surgeon availability.

There are limitations to our study. Because of the absence of a distinct ICD-9 code for gastroschisis during our study time frame, we relied on a combination of diagnosis codes and procedure codes to identify our cohort in order to exclude patients with other causes of congenital abdominal wall defects, such as omphalocele. While this method does not allow discrimination between staged and primary closure, it does accurately identify the desired patient cohort [11,12]. Our use of administrative data also potentially limits our ability to risk-adjust for severity of illness at the time of the operation, including the presence of complicating factors such as intestinal atresia, the condition of the bowel at birth, as well as the exact reason for patient transfer prior to the operation [26]. However, because high-volume hospitals would be expected to treat sicker, more complex patients, it is possible that use of high-quality clinical data to more accurately account for this greater severity of disease would have resulted in an even larger improvement in outcomes detected at high-volume centers. Our data also limited our ability to measure all relevant hospital-level factors. Since other studies in California have demonstrated relatively low mortality rates at medium-volume centers, there are likely other important hospital characteristics, in addition to volume, that influence patient outcomes [27,28]. In the context of this study, hospitals may differ in terms of their enteral/parenteral feeding practices, their use of a multidisciplinary feeding team, adherence to care bundles or standardized pathways, and other practices that may influence the outcomes for infants with gastroschisis. Further research will be needed to identify how these hospital characteristics influence outcomes for these patients. The limits of administrative data in these types of analyses make a strong case for the development of clinical registries targeted towards infant surgery [16]. While previous studies have demonstrated the importance of surgeon volume, we did not have surgeon identifiers in our data [7]. Also, our study is limited to a single state and may therefore not be generalizable to the entire nation. However, California is a large and diverse state and over many years of data, we were able to identify and analyze a large sample of patients.

4. Conclusion

Infants born with gastroschisis in California have significantly increased odds of mortality when treated at low- compared to high-volume hospitals. We also identified a non-significant trend towards increased length of stay for patients treated at low-volume hospitals. Persistent secular trends towards deregionalization of NICU services may place infants born with gastroschisis at higher risk of adverse outcomes. Our data offer initial evidence supporting efforts to regionalize care for infants with gastroschisis at fewer centers, where care processes can be carefully analyzed and standardized.

Acknowledgements

GDS and JGU were supported by the Robert Wood Johnson Foundation (RWJF)/Veterans Affairs Clinical Scholars program at the University of California, Los Angeles. RWJF had no role in the preparation, review, or approval of the manuscript.

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