



## Variability in outcomes after gastroschisis closure across U.S. children's hospitals☆☆☆★



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### ABSTRACT

**Background:** In patients undergoing gastroschisis closure, the effects of timing of closure and patient and hospital-level characteristics on length of stay (LOS) and time to enteral autonomy are unknown.

**Study design:** Using the Pediatric Health Information System, we compared neonates who underwent early (within 1 day of birth) versus delayed (>1 day after birth) gastroschisis closure from 2005 to 2013. We evaluated the relationship between time to closure and both LOS and days on total parenteral nutrition (TPN).

**Results:** Of 4459 neonates with gastroschisis, 43.9% underwent early closure and 56.1% underwent delayed closure. Delayed closure, complicated gastroschisis, government insurance, lower birth weight, older age at closure, and complex chronic conditions were associated with longer LOS and days on TPN (all  $p < 0.05$ ). There was significant inter-hospital variability in both outcomes, after adjusting for patient- and hospital-level characteristics, including hospitals' gastroschisis and neonatal volumes, median age at closure, and percentages of complicated and delayed gastroschisis patients, ( $p < 0.01$ ).

**Conclusion:** Delayed gastroschisis closure is associated with longer LOS and duration of TPN, even after excluding complicated cases. Furthermore, after controlling for hospital volume, rate of complicated gastroschisis, and timing of closure, the persistent inter-hospital variability suggests that practice variability is partially responsible for these differences.

**Type of study:** Retrospective study.

**Level of evidence:** III

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Gastroschisis is a common birth defect, presenting in 2 to 5 per 10,000 live births [1]. There are no broadly-applied standardized protocols or practice patterns for the care of neonates born with gastroschisis. Across institutions, there is variability in the management of patients with gastroschisis, not only in closure technique preferences, but also in the timing of surgery and post-operative feeding protocols [2–16]. The variability in care likely leads to differences in resource utilization

and cost. In a review of inter-hospital cost variation for the 30 most costly pediatric surgical operations, cost variation at the hospital level was greatest for gastroschisis [17].

Outcomes in patients with gastroschisis are thought to depend on many factors, including the presence of complicated gastroschisis, timing of closure, patient-level comorbidities (e.g., prematurity and low birth weight), and hospital-level factors (e.g., neonatal volume). Although there are single institution reports, it is not yet known whether across US tertiary children's hospitals, the timing of gastroschisis closure affects the length of hospitalization and time to intestinal autonomy, two of the most important outcomes in this patient population [18,19]. The extent of differences in these outcomes across hospitals also remains unclear. After accounting for patient risk factors, persistent differences across hospitals in patients' lengths of stay (LOS) and days to intestinal autonomy would emphasize the need for protocol-driven care. This study aimed to characterize outcomes among neonates with gastroschisis, specifically LOS and days on total parenteral nutrition (TPN). In addition, we aimed to determine whether there was

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variability across hospitals that could be explained by key patient- and hospital-level factors, including the presence of complicated gastroschisis and the timing of closure.

## 1. Methods

### 1.1. Data source and cohort identification

We utilized the Pediatric Health Information System (PHIS) to conduct a retrospective multi-institutional cohort study of neonates with gastroschisis. The PHIS is a multi-institutional hospital discharge database that includes data from 49 tertiary children's hospitals on inpatient, observation, emergency department, and ambulatory surgery encounters. Diagnoses and procedures in this database can be identified using International Classification of Disease, 9th Edition, Clinical Modification (ICD-9-CM) codes. Patients treated at the 37 PHIS hospitals that continuously contributed clinical and financial data on inpatient encounters from 2005 to 2014 were included.

Patients born between 2005 and 2013 who had an ICD-9-CM diagnosis code for gastroschisis (756.79 or 756.73) during a hospitalization at which the patient's age at admission was <1 week were included. We only included patients who also had an ICD-9-CM procedure code for gastroschisis repair (54.71) performed within the first month of life. As a focus of this study was on hospital variability in outcomes, if patients were treated at hospitals with a low volume of gastroschisis cases (<30 during the entire study period), they were excluded. In a subset analysis of only patients with uncomplicated gastroschisis, we excluded patients with features of complicated gastroschisis. This included patients with diagnosis and/or procedure codes for intestinal resections (45.6–45.9), ostomy creation/closure (46.0–46.3), atresia (751.1–751.2), volvulus (560.2), perforation (569.83, 777.6), or necrotizing enterocolitis (NEC; 777.50–777.53).

### 1.2. Patient and hospital-level covariates

We compared patients who underwent early versus delayed closure of gastroschisis. Patients with early closure were defined as those who underwent only 1 gastroschisis closure procedure (54.71), either on their date of birth or 1 day after their date of birth. Patients with delayed closure were defined as those who underwent their initial gastroschisis closure >1 day after their date of birth, or patients who had undergone multiple gastroschisis closure procedures. We also examined age in days at closure as a continuous variable. A number of patient-level characteristics were assessed and included in multivariable analyses, including gestational age, birth weight, gender, race, ethnicity, primary payer, the presence of complex chronic conditions, and technology-dependence (including the need for specialized medical equipment, such as tracheostomy, mechanical ventilator, supplemental oxygen, oximetry, neuromonitoring devices, etc). A number of hospital-level characteristics were also examined, including the percentage of patients with complicated gastroschisis, percentage of patients with delayed closure, median patient age at closure, average annual hospital volume of gastroschisis patients and the average annual hospital neonatal volume during the study period. These patient and hospital-level characteristics were chosen for inclusion in multivariable analyses because they were hypothesized both to affect outcomes and to vary across hospitals.

### 1.3. Outcomes

The outcomes investigated included total hospital LOS and total number of days on TPN. Total number of days on TPN was defined as the number of days from the first day on TPN until the last day on TPN, even if there were intermittent breaks during the period.

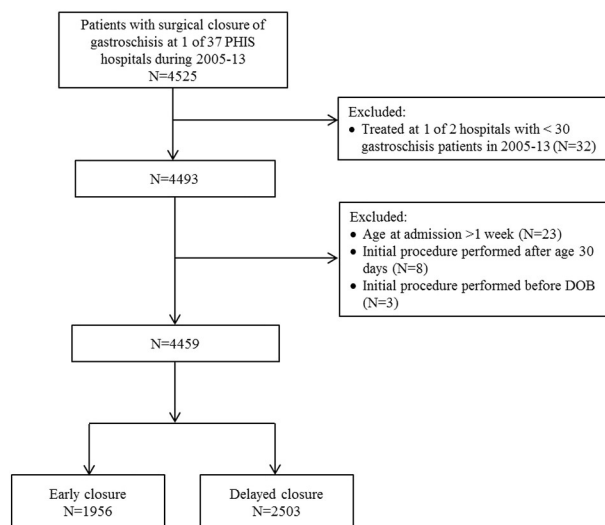
### 1.4. Statistical analysis

Patient and hospital characteristics in the study cohort were reported using medians and interquartile ranges (IQRs) for continuous variables and frequencies and percentages for categorical variables. Patient characteristics were compared between the early and delayed closure groups using chi square or Fisher exact tests for categorical variables and Mann–Whitney U tests for continuous variables. Hospital LOS and days on TPN were each modeled using a gamma mixed effects model with a log link function in order to evaluate their associations with early versus delayed closure, after adjustment for other patient- and hospital-level characteristics. These models were also used to evaluate inter-hospital variability in each outcome before and after adjustment for all observed patient characteristics that were associated at  $p < 0.20$  with early versus delayed closure, as well as all evaluated hospital characteristics. A global test for the significance of interactions between being a complicated case and all other patient and hospital-level variables was performed for each model to evaluate whether the effects of any observed patient or hospital characteristics on LOS or days on TPN differed between simple and complicated cases. As this test yielded a  $p$ -value <0.05 for both outcomes, a second analysis, identical to that previously described, was performed including only simple gastroschisis cases. Sensitivity analyses were performed including only patients with early closure and, subsequently, excluding low birth weight patients. In order to retain all patients in the multivariable analyses, missing data on birth weight and gestational age were imputed using Markov Chain Monte Carlo multiple imputation to form 10 complete datasets. All patient- and hospital-level variables, including outcomes, were used to impute the missing data. All statistical analyses were performed using SAS v9.4 (SAS Institute Inc., Cary, NC).

This study was approved by the Nationwide Children's Hospital Institutional Review Board with a waiver of informed consent.

## 2. Results

From 2005 through 2013, there were 4525 patients with gastroschisis who underwent surgical closure at one of the 37 included hospitals (Fig. 1). Of those patients, 4493 were managed at 35 hospitals



**Fig. 1.** Cohort development. Of 4525 neonates with gastroschisis, 32 were excluded because they were managed at one of two hospitals that treated fewer than 30 patients with gastroschisis. An additional 64 patients were excluded because they were either admitted at the included hospital when they were older than 1 week, or their initial surgical procedure was performed after they were older than 30 days, or because their procedure was listed as being performed before their date of birth (data error). PHIS: Pediatric Health Information System. DOB: date of birth.

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