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ORIGINAL ARTICLE

Risk stratification in gastroschisis: can prenatal evaluation or early postnatal factors predict outcome?

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Abstract
Purpose The prenatal or postnatal factors that predict complex gastroschisis in patients (atresia, volvulus, necrotic bowel and bowel perforation) remain controversial. We evaluated the prognostic value of prenatal ultrasonographic parameters and early postnatal factors in predicting clinical outcomes.
Methods We analyzed maternal and neonatal records of 46 gastroschisis patients treated from 1998 to 2007. Information regarding demographics, prenatal ultrasound data when available, intrapartum and postnatal course was abstracted from medical records. Outcome variables included survival, ventilator days, TPN days, time to full enteral feeds, complications and length of stay. Univariate or multivariate analysis was used, with $P < 0.05$ considered as significant.
Result A total of 75% of complex patients were categorized within 1 week of life. Interestingly, prenatal bowel dilation (>17 mm) and thickness (>3 mm) did not correlate with outcome or risk stratification into simple versus complex ($P < 0.05$). Complex patients had increased morbidity compared to simple patients (sepsis 58 versus 18%; $P = 0.021$, NEC 42 versus 9%; $P = 0.020$, short bowel syndrome 58 versus 3%; $P = 0.0001$, ventilator days 24 versus 10; $P = 0.021$; TPN days 178 versus 38; $P = 0.0001$ and days to full feeds 171 versus 31; $P = 0.0001$; and length of stay 90 versus 39 days, $P = 0.0001$).
Conclusions Prenatal bowel wall dilation and/or thickness did not predict complex patients or adverse outcome. Complex gastroschisis patients can be identified postnatally and have substantial morbidity.

Keywords Gastroschisis · Prenatal ultrasound · Complex gastroschisis · Abdominal wall defect

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Introduction

Gastroschisis is characterized by the herniation of bowel through a full-thickness anterior abdominal wall defect, usually on the right side of the umbilicus, without a covering membrane. The reported incidence of gastroschisis ranges from 0.4 to 11.7 cases per 10,000 live births; studies in the United States, Europe and Japan suggest that the incidence has markedly increased in the past decade [1–3]. Despite a survival rate typically reported to be above 90% for neonates with gastroschisis [4], there is a large subset of infants with significant short- and long-term morbidity, and this reflects the wide spectrum of secondary bowel anomalies that correlate strongly with poor neonatal outcomes [5].

Research examining prenatal prognostic factors has shown promise in the area of ultrasonographic characteristics of the exposed viscera, specifically, bowel dilation and increased bowel wall thickness [6]. While some studies have found positive correlation between the presence of

these characteristics and neonatal morbidity and mortality [7–10], there still remains significant skepticism about their prognostic abilities [6, 11–14]. Furthermore, since different definitions of dilated bowel have been used in competing studies (17 vs. 10 mm), it is often difficult to compare these studies [15]. Stratification of gastroschisis infants early in the postnatal period may also predict the overall outcome. Studies have shown that complex gastroschisis (atresia, volvulus, necrotic bowel and bowel perforation) patients have a poor outcome [16–19].

The prenatal and early postnatal characteristics that are predictive of morbidity and mortality remain uncertain. The aim of the current study was to evaluate the prognostic value of prenatal ultrasonographic parameters or early postnatal factors in predicting clinical outcomes.

Methods

This is a retrospective analysis of the medical records of 46 neonates with gastroschisis treated at a single institution between June 1998 and March 2007. After receiving the Institutional Review Board approval, maternal and neonatal patient records were analyzed. The ultrasound records for 25 mothers were available and reviewed by a single physician (MCT) experienced in ultrasound, who was blinded to the clinical outcome. Bowel wall thickness and bowel dilation were retrospectively reassessed. Ultrasound records were also reviewed for amniotic fluid index and percentile, estimated fetal weight (EFW) and percentile, size of defect, and placental position and grade. Data were organized according to estimated gestational age (EGA) by grouping sonographic evaluations performed between 15 and 17 weeks, 18 and 20 weeks, 21 and 23 weeks, 24 and 26 weeks, 27 and 29 weeks, 30 and 32 weeks, 33 and 35 weeks, and 36 and 38 weeks. Additionally, maternal charts were reviewed for age, race, gravida, para and complications during pregnancy and delivery.

Neonatal records were analyzed for type of delivery, location of delivery, EGA at birth, birth weight, gender, race, Apgar scores, meconium or bile staining and fluid replacement over the first 5 days. Operative data were reviewed for assessment of bowel, size of defect, type of closure (primary versus staged), time to closure, bowel resection, presence of associated anomalies and in-hospital complications. Complex patients were selected based on the definition proposed by Molik et al. [19], Abdullah et al. [16] and Arnold et al. [17] wherein complex patients are defined as those with atresia, perforation, necrotic segments and/or volvulus.

The outcome variables evaluated were survival, number of ventilator days, number of days on total parenteral nutrition, time to first and full enteral feeds, time to full oral feeds and length of stay in the neonatal intensive care unit. Comparisons were made among groups using Fisher's exact test values, Pearson's χ^2 test, Student's t test for continuous variables or ANOVA when appropriate. Statistical analysis was performed using SPSS 15.0. Values of P less than 0.05 were considered to be significant.

Results

Of the 46 gastroschisis patients, 45 (98%) were diagnosed prenatally. The mean maternal age was 22.6 ± 4.5 years and 26 of 45 (57%) were nulliparous. The average gestational age at diagnosis was 19.9 ± 3.4 weeks gestation. Mean Apgar scores at 1 and 5 min were 6.8 ± 2.1 and 8.2 ± 1.1, respectively. The average birth weight was 2.4 ± 0.6 kg and the average gestational age at birth was 35.6 ± 2.5 weeks. Of the fetuses, 52% were male. The majority of patients were Caucasian (78%) or African–American (10.9%); 6.5% represented other ethnicities (Table 1).

Table 1 Population characteristics ($N = 46$)

Variable	Mean ± SD
Maternal age (years)	22.6 ± 4.5
EGA at birth (weeks)	35.6 ± 2.5
Weight at birth (kg)	2.4 ± 0.6
Apgar 1 min	6.8 ± 2.1
Apgar 5 min	8.2 ± 1.1
Variable	***n* (%)**
Gender	
Males	24 (52.2)
Females	22 (47.8)
Location of delivery	
Inborn	34 (73.9)
Outborn	12 (26.1)
Type of delivery	
Vaginal	20 (43.5)
Cesarean section	26 (56.5)
Elective	13 (28.3)
Emergent	13 (28.3)
Race	
Caucasian	36 (78.3)
African–American	5 (10.9)
Other	3 (6.5)
Unknown	2 (4.3)
Type of closure	
Primary	10 (21.7)
Staged	35 (76.1)[a]
Meconium/bile-stained amniotic fluid	25 (59.5)

[a] Missing patient had gastroschisis that closed prior to birth

Table 2 Co-existing abnormalities

	n (%)
Bowel-related abnormality	
Bowel atresia	6 (13)[a]
Necrotic bowel	5 (10.9)[a]
Bowel stenosis	3 (6.5)[a]
In utero volvulus	3 (6.5)[a]
Meckel's diverticulum	2 (4.3)[a]
Non-bowel-related abnormality	
Undescended testis	6 (13)
Cardiac anomaly (PDA, ASD, and/or VSD)	4 (8.7)

[a] Patients with multiple co-existing diagnoses were included in multiple categories

Table 3 In-hospital complications

Complication	n^a (%)
Sepsis	13 (28.3)
Bowel obstruction	9 (19.6)
Necrotizing enterocolitis	8 (17.4)
Wound infection	6 (13)
Bowel perforation	4 (8.7)
Pneumonia	3 (6.5)
Fistula	3 (6.5)
Chronic lung disease	2 (4.3)
Bowel volvulus	1 (2.2)

[a] Patients with multiple complications were included in multiple categories

Of the 46 patients, 22 (48%) were born with an associated abnormality or co-existing diagnosis. As much as 13% of infants were born with an atresia (three colonic, three small bowel; Table 2).

Of the 46 patients, 26 (57%) suffered in-hospital complications. The most common complication was sepsis (28.3%). Bowel obstruction (19.6%) was the second most common complication with 7/9 patients requiring surgical intervention. (Table 3).

Of the 46 patients in this study, 25 received serial ultrasonographic evaluations between 2001 and 2007. Ultrasonographic information was classified according to the EGA of the fetus at evaluation. Bowel wall dilation on ultrasound between weeks 30 and 32 was a significant indicator for the presence of atresia ($P = 0.015$). When patients were evaluated based on the presence or absence of bowel wall dilation >10, >17 and >20 mm, ultrasonography was not able to significantly predict bowel condition or outcome.

Bowel wall thickness was also assessed both by thickness at specific time intervals and by threshold cut-offs at any time during gestation. Bowel wall thickness based on specific gestational ages was not significantly associated with bowel condition or outcome.

Both EFW and amniotic fluid index were available for 33 patients in this study. Polyhydramnios was observed in one pregnancy (3.0%) and oligohydramnios was observed in six (18.2%) cases, but did not correlate with outcome. EFW percentile across all gestational ages was not associated with altered neonatal morbidity or mortality.

We examined the differences between complex and simple gastroschisis patients. Complex patients accounted for 12 out of 46 patients (26.1%). A total of 75% of complex patients were categorized within 1 week of life. Complex patients were not significantly different from the simple patients on comparing EGA at birth, birth weight, gender, race, location or type of delivery, or Apgar scores at 1 and 5 min. On the other hand, significant differences existed on examining in-hospital complications and outcome variables (Table 4).

Lower birth weight and prematurity were associated with worse outcomes. Patients who weighed less at birth were significantly more likely to develop sepsis ($P = 0.003$) and were significantly less likely to survive ($P = 0.046$). In order to examine the effects of EGA on the clinical course, we divided the patients into three different groups: <35 weeks, 35–37 weeks and >37 weeks. This stratification revealed that significant differences existed between groups based on days to enteral feeds ($P = 0.021$) and number of days in NICU ($P = 0.047$).

The majority of infants were inborn (73.9%). There were no statistically significant differences between the patient characteristics based on birth weight, EGA at birth, type of delivery, type of closure, associated anomalies, in-hospital complications and outcome variables. Predictably, outborn patients did have a significantly longer period of time from birth to silo placement (414 vs. 88 min, $P = 0.0001$), but this variable was not predictive of complications or outcome. Despite the fact that there was a dramatic difference in the time required between birth and silo placement, these patients did not require significantly more fluid during the first 24 h of life ($P = 0.024$).

A total of 20 patients (43.5%) were born by vaginal delivery with 26 patients (56.5%) delivered by cesarean section of which 13 were elective and 13 were emergent. There were no significant differences between patient groups based on the type of delivery.

As much as 21% of patients were closed primarily. Of the 10 patients closed primarily, all patient survived compared with 31 of 35 (89%) of patients closed by staged reduction. Patients closed by the two different methods did not have significant differences in postnatal complications. When the method of closure was compared to the outcome variables, only ventilator days were significantly different between primary and staged (3.6 ± 2.1 and

Table 4 Simple versus complex gastroschisis patients

Variable	Simple $n = 34$ (76%) n (%)	Complex $n = 12$ (24%) n (%)	P value
Survival	32 (94)	9 (75)	0.101
Sepsis	6 (18)	7 (58)	0.021
NEC	3 (9)	5 (42)	0.020
Short bowel syndrome	1 (3)	7 (58)	0.0001
Variable	Mean ± SD	Mean ± SD	P value
No. of days on ventilator	10.3 ± 15.0	23.7 ± 18.6	0.021
No. of days on TPN	37.8 ± 42.0	177.7 ± 143.9	0.0001
No. of days to start enteral feeds	15.0 ± 9.77	32.0 ± 22.9	0.001
No. of days to full enteral feeds	30.8 ± 34.7	171.3 ± 116.0	0.0001
No. of days to full oral feeds	25.0 ± 16.7	287.8 ± 253.6	0.0001
No. of days in NICU	38.6 ± 31.8	90.4 ± 48.3	0.0001
No. of days in hospital	41.3 ± 32.5	90.4 ± 48.3	0.0001

16.9 ± 18.4 days; $P = 0.028$,). Time from birth to primary closure (mean 230.8 ± 125.4 min) or time to silo placement (mean 147.0 ± 171.8 minutes) was not significantly associated with any in-hospital complications or outcome variables.

The defect size at birth was available in 21 of the 46 patients (45.6%). The mean size of the defect was found to be significantly smaller in patients that were closed primarily (2.4 ± 0.5 vs. 3.8 ± 0.8 cm; $P = 0.004$), had an atresia (2.1 ± 1.3 vs. 3.7 ± 0.853 cm; $P = 0.005$), or developed short bowel syndrome (SBS) (2.0 ± 0.2 vs. 3.6 ± 0.9 cm; $P = 0.038$). Patients with smaller defects were also significantly more likely to spend more time on TPN ($P = 0.018$).

Overall, 89% of our patients survived. The mortality rate was higher in patients with necrotic segments of bowel compared to those judged to have viable bowel at birth, but was not statistically significant (50 vs. 7.2%; $P = 0.083$). Survival was significantly associated with birth weight and EGA at delivery. Non-survivors were significantly younger on average (32.7 vs. 35.9 weeks; $P = 0.005$) and had lower birth weights (1.85 vs. 2.43 kg; $P = 0.046$). Many in-hospital complications were significantly associated with increased mortality including sepsis ($P = 0.018$), pneumonia ($P = 0.028$), gastrointestinal bleeding ($P = 0.010$), chronic lung disease ($P = 0.010$) and bowel obstruction ($P = 0.014$).

Discussion

In this study, prenatal bowel wall dilation and/or thickness did not predict complex patients or adverse outcome. The majority of complex gastroschisis patients were identified within the first week of life and they had substantial morbidity. Low birth weight, prematurity and small defect size were associated with worse outcomes. However, the mode of delivery, surgical technique and inborn status did not affect the outcomes. Overall, despite a high survival rate of 89%, there was significant morbidity in 30% of patients.

The use of prenatal ultrasound to predict the condition of the bowel has been a focus of research for the past two decades. The initial report by Bond et al. [10] identified the presence of bowel wall dilation and mural thickening as highly correlated with severe intestinal damage and poor clinical outcomes. While some studies have found positive correlation between the presence of these characteristics and neonatal morbidity and mortality [7–10], there still remains significant skepticism about their prognostic abilities [11–14]. In the current study, we investigated the predictive value of specific threshold dilation values that were considered to be clinically significant by other authors and also investigated the predictive value of bowel wall dilation at specific times during gestation. When we examined bowel dilation thresholds of >10 mm [13], >17 mm [7, 12, 15], and >20 mm [14], we found that these thresholds were not significantly predictive of intestinal damage or worse clinical outcome. It has long been acknowledged that significant variation exists in the exact bowel wall dilation measurement between various ultrasonographers [11]. In our study, by examining bowel wall dilation of >10 and >20 mm, we hoped to take into account some of the sonographers' variation in bowel wall measurement. Because neither >10 nor >20 mm thresholds were significantly associated with complex gastroschisis patients or outcome, we agree with previous authors that

bowel wall dilation is not predictive of neonatal outcome [11–14]. However, our conclusions are tempered by the relatively small number of patients ($n = 25$) who had available ultrasound examinations. Similarly, given the small data set, we are unable to comment on the prognostic significance of progressive bowel dilation in a given patient. We did, however, see a correlation between bowel wall dilation present at 30–32 weeks gestation and bowel atresia in two patients with bowel dilation of 19 and 29 mm, respectively. The predictive value of bowel wall dilation during this time period requires further research.

Several investigators examined the prognostic value of bowel wall thickening, as assessed on prenatal ultrasound [7, 10, 12]. In the current study, we evaluated the clinical significance of bowel wall thickening >3 and >4 mm. Our results indicate that bowel wall thickening is not predictive of bowel condition at birth or poorer clinical courses. Although bowel wall thickening was noted by Bond et al. [10] to predict severity of intestinal damage, to our knowledge no other author has been able to reliably establish the predictive value of bowel wall thickening in gastroschisis.

Caniano et al. [18] were the first authors to coin the term "complex" in reference to a separate group of patients that had significantly worse outcomes. In 2001, Molik et al. [19] proposed the division of patients into two different risk categories. Complex cases of gastroschisis were considered high risk and defined as those in which the patient had intestinal atresia, stenosis, perforation, necrotic segments and volvulus. The validity of these risk categorizations was evident in the initial studies and has been further supported by more recent studies of 4,344 patients with intestinal atresia, necrotic segments, perforations and volvulus [16, 17]. In our data set, we found these categories to be very effective at predicting significant morbidity. Importantly, we were able to categorize the majority of patients (75%) into a simple or complex category within the first week of life. The risk categorization, however, was unable to predict mortality in our population ($P = 0.103$) as it had in previous studies. We believe that this lack of significance is due primarily to the fact that of the five patients that did not survive, two were very premature (EGA 28 and 28 weeks). When these patients are excluded from the statistical analysis, the complex categorization was able to significantly predict the mortality in our data set ($P = 0.017$).

In our current study, 5 out of 46 patients (10.8%) died, an additional 9 (19.6%) patients were complex patients, and a total of 17.4% of patients developed short bowel syndrome. The result is that over 30% of our patient population experienced considerable morbidity and mortality. Additionally, 28% of patients developed sepsis, 23.9% of patients had a portion of bowel resected during their initial stay and 17.4% of patients were diagnosed with NEC during their initial hospital stay. All these complications were independently associated with considerably longer time on TPN, longer days to start and continue on full enteral feeds, longer stays in the NICU and hospital, and significantly more expensive initial hospital visits. In our current study, only 18 of the 46 (39.1%) patients had no associated abnormalities and experienced no in-hospital complication. While the frequently reported 90% survival is a vast improvement over the very low survival rate in the initial half of the twentieth century, at least 3 out of 10 infants will have a complication that will result in either mortality or a long and difficult initial hospital stay and potentially significant long-term morbidity. The high rate of overall complications underscore the significant morbidity associated with gastroschisis. In particular, the high incidence of NEC (42%) and short bowel syndrome (58%) in complex patients illustrate the substantially worse morbidity in this subset of patients. Of note, patients did not routinely receive ranitidine.

Since Lenke et al. [20] reported the benefit of preterm cesarean section in the treatment of patients with gastroschisis, there has remained serious contention in literature over the optimal mode of delivery. Our experience supports that the route of delivery does not significantly influence the outcome for patients with gastroschisis.

The benefit of in utero transfer of patients to a regional medical center has remained a topic of debate. Differences in outcomes have been examined by numerous authors [21–23], and there seems to consistently be no significant difference between patients born at a regional medical center and those who were transferred soon after birth and initial resuscitation. Our experience supports the observation that while outborn patients tend to have significantly longer periods from birth to primary closure or silo placement, this does not appear to significantly impact the outcomes for these patients. Outcomes appear less dependent on the location of the delivery than the complexity of the patient's gastroschisis. Since prenatal ultrasound evaluation cannot accurately predict complex patients, we still recommend delivery at a tertiary care facility, which facilitates the mother being present at the same site with a potentially sick infant.

Debate continues over the optimal surgical treatment of gastroschisis. Some authors have found better results by inserting a spring-loaded silo and allowing the gradual reduction of the viscera in patients whenever primary closure is not possible[24–28]. In 2001, our center began to routinely insert a spring-loaded silo in the NICU, whenever primary reduction of the viscera was not readily achievable. On comparing the results of patients treated by spring-loaded silo and gradual closure (28) versus primary closure (6), we found that patient populations were

comparable between simple and complex patients. Our finding that the type of closure did not significantly impact on the patient's time on the ventilator, length of time on TPN, the time to start and continue on full enteral feeds or the duration of the hospital stay supports the notion that placement of a silo with gradual reduction of the intestines does not produce worse outcomes than patients closed primarily. This equivocal result agrees with the finding of other authors [29]. Therefore, we support that spring-loaded silo placement is a safe alternative to primary closure and should be used readily whenever fear of inducing abdominal compartment syndrome exists.

Tibboel et al. [30] supported the notion that the size of the defect in the abdominal wall can significantly impact on the condition of the bowel at birth. They reported that the constriction of the intestines and mesentery at the abdominal wall was significantly associated with bowel ischemia and atresia. Langer et al. [31] further supported the deleterious effects of small defect size in a study on fetal lambs. Other investigators have argued that the size of the defect is not predictive of intestinal damage [10, 32]. We found that smaller defects were significantly associated with the presence of an atresia and the future diagnosis of SBS.

This study confirms the high survival rate of gastroschisis, but also underscores the significant morbidity in a subset of complex patients. Although we did not have a large data set, we were unable to identify reliable prenatal ultrasonographic characteristics that would predict complex gastroschisis patients. The ability of bowel dilation in the third trimester to predict bowel atresia needs further investigation. Other areas needing investigation include prenatal assessment of defect size. We have confirmed the prognostic utility of categorizing patients postnatally into simple and complex groups, which appears to be possible within the first week of life in most infants. Furthermore, low birth weight, prematurity and small defect size are associated with worse outcomes. Mode of delivery, surgical technique, and inborn status did not affect outcomes. The findings from our study are helpful for prenatal counseling, specifically preparing parents for the outcomes, including short and long-term morbidity, associated with the subset of complex gastroschisis patients. Patients are counseled that categorization into simple and complex patients is most reliably made within the first week of life. Nevertheless, we continue to collect data on bowel dilation, wall thickness and defect size throughout gestation using serial prenatal ultrasounds. Lastly, the high incidence of bowel complications such as NEC in our population has made us more vigilant about proper silo placement, avoiding abdominal compartment syndrome and recognizing the early signs of bowel ischemia.

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