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Outcomes of Complex Gastroschisis

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ABSTRACT

BACKGROUND
Gastroschisis, an anterior abdominal wall defect, is associated with significant morbidity and mortality. This study aims to evaluate the early outcomes of neonates with complex gastroschisis and correlate outcomes with prevalent types of complications, such as a line infection and NEC.

METHODS
A retrospective review was performed at multiple pediatric surgical centers (January 2001 and December 2019). Statistical analysis of categorical variables between the cohorts of the primary closure versus silo placement was conducted and 95% confidence intervals (CI) for variables were calculated.

RESULTS
Two hundred and thirty-four neonates with gastroschisis were identified. The cohort of neonates having undergone silo closure had a longer duration of total parenteral nutrition (TPN) (32.5 vs. 48.17; P = .006), prolonged hospitalization (40.18 vs. 54.15; P = .007) and higher incidence of concomitant of bowel atresia (0.12 vs.0.20; P= .004). There was no difference observed in survival. Multivariate logistic regression demonstrated that time to closure and number of surgeries were significantly related to LOS as an independent variable.

CONCLUSION
The time to silo closure is the most significant variable related to the duration of TPN and hospitalization in gastroschisis patients, determined by the number of surgeries and severity of the disease. Furthermore, NEC and line infection were high after primary closure.

Keywords: *Gastroschisis, Total parenteral nutrition (TPN), Necrotizing enterocolitis (NEC), Silo closure*

1. INTRODUCTION

Gastroschisis, a congenital anterior abdominal wall defect, has a reported incidence of 5 in 10,000 live births (1, 2). It is the most common abdominal wall defect in the UK. The condition is still associated with significant morbidity; however, the mortality rate is low at around 2% (2, 3). Whilst the etiology is unknown, numerous theories have been proposed for its pathophysiology. The most widely accepted theory is the failure of mesoderm, and subsequently the ventral body, to form leading to herniation of the bowel, however, this is debated in the literature (4).

Gastroschisis can be further categorized into; simple, complex, and complicated, depending on the disease pathology, outcomes, and surgical care. Simple gastroschisis is defined as an intact bowel without any gastrointestinal compromise whereas complex gastroschisis (cGS) is associated with additional gastrointestinal diseases: atresia, volvulus, perforation, or necrosis (3, 6). These patients have significantly poorer outcomes, in terms of mortality, post-surgical care, and complications. Common complications include the requirement for total parenteral nutrition (TPN), ventilatory support, central line infections, and necrotizing enterocolitis (NEC).

In terms of surgical management, two well-established techniques have been reported: primary fascial closure or staged reduction with artificial silos. Newer techniques, such as sutureless closure, may be considered for small defects however these have been reported to have a higher incidence of umbilical hernias (7). Operative primary reduction with sutured fascial defect closure has become the standard initial surgical strategy, whereas staged reduction is frequently used as a rescue strategy when reduction is deemed unsafe or inappropriate due to the degree of viscero-abdominal disproportion (8). Overall, it is recommended that surgery, whether primary or staged closure, should take place as soon as possible after birth, if appropriate.

Whilst treatment paradigms are determined on a case-by-case basis, there is still significant ambiguity regarding the surgical management of gastroschisis. Therefore, the primary aim of this study is to evaluate the early outcomes of neonates with complex gastroschisis. Secondary objectives include focusing on specific complications and post-surgical care such as length of TPN and hospital stay, undescended testes, NEC, and central line infections.

2. METHODS

A retrospective review was performed at multiple pediatric surgical centers, NHS hospitals UK, and the Clinical Medical Centre, in Baku, Azerbaijan, medical records of all patients diagnosed with and treated for gastroschisis between January 2001 and December 2019 were evaluated. Both electronic medical records and individual paper charts were used to confirm the diagnosis of gastroschisis and collect demographic and clinical data.

Demographic characteristics were collated into a database and included date of birth, sex, gestational age (GA), birth weight (BW), mode of delivery (vaginal or cesarean section), and secondary diagnoses at birth. Operative data included the number, type, and date of operative procedures during the initial hospitalization and whether an inflammatory peel was present, as documented in the operative notes. Nutritional data included the start and stop dates of TPN in addition to the start date of enteral nutrition (EN). Complex gastroschisis patients were further divided based on the surgical procedure: primary closure or staged silo reduction. On average, staged silo reduction, using preformed silos, occurred sooner post-partum compared to primary closure (17 and 21 hours respectively).

3. STATISTICAL ANALYSIS

Statistical analysis was computed via SPSS Version 25.0. Categorical variables between the cohorts of the primary closure versus silo placement were conducted using t-tests and Pearson's chi-squared tests. 95% confidence intervals (CI) for variables were calculated. P-values of less than 0.05 were considered statistically significant.

4. RESULTS

Two hundred and thirty-four neonates in total with gastroschisis (34 complex and 163 complicated gastroschisis) were identified. In this sub-group of 197 patients, neonates with silo closure had more time of total parenteral nutrition (TPN) (32.5 vs. 48.17; P =0.006), prolonged length of stay (LOS) (40.18 vs. 54.15; P =0.007), greater days of enteral feeds (32.34 vs. 45.57; P=0.137), more numbers of bowel atresia (0.12 vs.0.20; P= .004). However, patients with primary closure had significantly more necrotizing enterocolitis (NEC) (0.22 vs. 0.20; P=0.539) and line infections (0.32 vs.0.28; P=0.215) [Tables 1 and 2]. Furthermore, there were four (1.7%) patients with cryptorchism at birth. Three patients underwent spontaneous migration of the testes and one patient only required orchiopexy.

Table 1. Overview of surgical outcomes and recovery times

	Surgery	N	Mean	Std. Deviation	Std. Error Mean	P-value
Days to full feeding	Primary	143	32.34	19.678	1.646	0.137
	Silo	54	45.57	27.85	3.79	
TPN Time in Days	Primary	143	32.50	21.956	1.836	0.006
	Silo	54	48.17	27.083	3.656	
Length of stay	Primary	143	40.18	23.306	1.949	0.007
	Silo	54	54.15	30.445	4.143	
Bowel atresia	Primary	143	0.12	0.325	0.027	0.004
	Silo	54	0.20	0.407	0.055	
Line Infection	Primary	143	0.32	0.469	0.039	0.215
	Silo	54	0.28	0.452	0.062	
Necrotizing enterocolitis	Primary	143	0.22	0.418	0.035	0.539
	Silo	54	0.20	0.407	0.055	

Table 2. Univariate analysis of all outcome variables for the primary closure and silo groups of complex and complicated patients

				95% Confidence Interval for Exp(B)	
	Surgery	Sig.	Exp(B)	Lower Bound	Upper Bound
Days to start feeding	Primary	0.362	0.983	0.949	1.019
	Silo	0.362	1.017	0.981	1.054
Birth weight in grams	Primary	0.687	1	0.999	1.001
	Silo	0.687	1	0.999	1.001
Age at time of surgery in hours	Primary	0.202	1.035	0.982	1.091
	Silo	0.202	0.966	0.917	1.018
Number of surgeries	Primary	0	0.273	0.161	0.464
	Silo	0	3.659	2.157	6.206
Gestational age in weeks	Primary	0.351	0.879	0.671	1.152
	Silo	0.351	1.138	0.868	1.491
Days to full feeding	Primary	0.71	0.996	0.978	1.015
	Silo	0.71	1.004	0.985	1.023
TPN Time in Days	Primary	0.908	0.998	0.971	1.026
	Silo	0.908	1.002	0.975	1.029
Length of stay	Primary	0.985	1	0.977	1.023
	Silo	0.985	1	0.977	1.024
Gender	Primary	0.204	0.879	0.762	3.561
	Silo	0.204	0.607	0.281	1.312
Bowel atresia	Primary	0.903	1.077	0.326	3.56
	Silo	0.903	0.928	0.281	3.068
Line Infection	Primary	0.228	1.775	0.698	4.517

	Silo	0.228	0.563	0.221	1.433
Necrotizing enterocolitis	Primary	0.963	0.976	0.355	2.685
	Silo	0.963	1.024	0.372	2.818

5. COMPLEX PATIENTS ONLY

Thirty-four patients with cGS were identified, of which twenty underwent primary closure and fourteen underwent staged silo reduction. The total survival rate was 97%, the only death being in the primary closure group. There were no significant predisposing factors for this patient.

In the primary closure group, the age at surgery was 21.90 hours (range: 2-24; p=0.170). The average gestational age was 35.65 weeks (range: 29-40; p=0.482) with birth weights of around 2.4kg (range:

1.16-3.50kg) The ratio of males to females was 1.5:1. The mean number of surgeries undertaken per patient was 1.85 (range: 1-6).

In the staged silo reduction group, the age at surgery was 17.96 hours (range: 2-24; p=0.170). The average gestational age was 36.14 weeks (range: 34-39; p=0.482) with birth weights of around 2.3kg (range: 1.39-3.28kg). The ratio of males to females was 1:1. The mean number of surgeries undertaken per patient was 3.07 (range: 1-6).

Patients with silo procedure had a longer duration of TPN (p=0.170; CI 95% -39.02 and 7.17), prolonged hospitalization (p=0.007; CI 95% -0.072 and 0.172), and longer duration of enteral feeds (p=0.137; CI 95% -36.12 and 1.30) [see Table 3].

6. OUTCOMES

With regards to outcomes in the complex gastroschisis patients only, the staged silo reduction had more cases of NEC compared to the primary closure group (28.6% and 15% respectively; p=0.351). The primary closure group had more cases of bowel atresia (70% versus 50%; p=0.251), central line infections (40% versus 28.6%; p=0.507), and death (5% versus 0%; p=0.411) [Table 3 and 4].

Table 3: Univariate independent T-tests for all outcome variables for both complex gastroschisis groups, with regards to surgical procedure (primary versus staged silo closure).

			95% Confidence Interval of the Difference	
		Sig. (2-tailed)	Lower	Upper
Gender	Equal variances assumed	.577	-.461	.261
	Equal variances not assumed	.580	-.466	.266
Gestational age in weeks	Equal variances assumed	.482	-1.903	.917
	Equal variances not assumed	.439	-1.774	.789
Birth weight in grams	Equal variances assumed	.540	-282.592	529.663
	Equal variances not assumed	.532	-275.149	522.220
Age at the time of surgery in hours	Equal variances assumed	.170	-1.777	9.649
	Equal variances not assumed	.207	-2.348	10.220
Number of surgeries	Equal variances assumed	.024	-2.267	-.176

	Equal variances not assumed	.027	-2.291	-.152
Bowel atresia	Equal variances assumed	.251	-.148	.548
	Equal variances not assumed	.261	-.158	.558
Days to start feeding	Equal variances assumed	.100	-22.593	2.079
	Equal variances not assumed	.094	-22.353	1.838
Days to full feeding	Equal variances assumed	.067	-36.116	1.302
	Equal variances not assumed	.071	-36.390	1.575
Line Infection	Equal variances assumed	.507	-.233	.461
	Equal variances not assumed	.502	-.230	.458
Necrotizing enterocolitis	Equal variances assumed	.351	-.427	.156
	Equal variances not assumed	.374	-.445	.174
TPN Time in days	Equal variances assumed	.170	-39.027	7.170
	Equal variances not assumed	.163	-38.695	6.837
Death?	Equal variances assumed	.411	-.072	.172
	Equal variances not assumed	.330	-.055	.155
Length of stay	Equal variances assumed	.411	-.072	.172
	Equal variances not assumed	.330	-.055	.155

Table 4: Outcomes for patients undergoing primary versus staged reduction repairs in our cohort. Values are expressed as n (%).

Outcomes	Primary Closure (n = 20)	Staged Silo Reduction (n = 14)	P-Value
Bowel Atresia	14 (70)	7 (50)	0.251
Central Line Infection	8 (40)	4 (28.6)	0.507
Necrotising Enterocolitis	3 (15)	4 (28.6)	0.351
Death	1 (5)	0 (0)	0.411

7. DISCUSSION

In the early 21st century, Molik et al. identified the need for distinction between complex and simple gastroschisis cases due to differing pathophysiology, outcomes, and operative approaches (6). cGS is a significant prognostic factor for determining outcomes such as survival, postoperative complications, and ongoing care. These patients are more likely to have longer stays in the hospital, need ventilatory support, develop intestinal failure associated with liver disease, and undergo re-operations (1, 3, 9-12). Additionally, cGS can also be related to other systemic anomalies, such as cryptorchidism, which may have a substantial impact on the patient's psychological and sexual health in later life. Therefore, categorizing neonates into simple, complicated, and complex sub-groups at an early stage is vital to support further management and potentially, prognosis. Furthermore, a study by Puligandla et al. has validated a prognostic score with regard to outcomes for gastroschisis patients (13). These authors found that cGS patients, as defined by the presence and severity of bowel necrosis, matting, atresia, and perforation, have worse outcomes. These patients had significantly higher morbidity; including longer lengths of stay in hospital, days to parenteral feeds, and duration of TPN ($p < 0.01$) (13, 14). Therefore, this score has the potential to act as a reliable stratification tool for determining outcomes in gastroschisis patients with regard to the bowel injury assessed at birth. This is important to support perinatal counseling for families and/or carers and to determine further treatment paradigms for patients.

With regards to surgical management, there are various techniques employed as part of the staged reduction to reduce abdominal pressures prior to closure. Recent studies have suggested that preformed silos with early staged repair seem to be the most beneficial method for staged repair of cGS patients due to the complexity and/or size of the defect (1, 8-10). But this remains controversial with several discrepancies noted in the literature. A meta-analysis by Kunz et al. found that silo procedures correlated with less time requiring ventilatory support and TPN when selection bias was eliminated (1). However, other studies have identified that as the duration of silo placement increases and abdominal wall closure is delayed, the post-surgical complications increase proportionally (1, 9, 11, 12, 15, 16). Therefore, these authors have recommended that closure should occur as early as possible, following delivery. Although, it is important to note that patients requiring delayed closure are likely to have more severe underlying pathology and therefore, are likely to have additional, and more challenging, surgical procedures. Furthermore, there have been reports of gangrene, necrosis, and ischemia associated with prolonged silo use (16). Overall, there is substantial heterogeneity between studies regarding primary versus staged reduction repairs. In our study, we identified that cGS patients treated via staged reduction had a longer duration of TPN (65.43 versus 49.50 days) and a higher incidence of NEC (28.6% and 15% respectively) in comparison to those who underwent primary closure. However, there was a higher mortality rate in the primary closure group compared to staged reduction (5% and 0%), but this was not statistically significant.

Moreover, there is significant ambiguity within the literature regarding the time after birth to initial surgical intervention. Primary closure patients tend to be closed anywhere between 2 to 4 days (range 0-28 days) and staged silo patients were closed after an average of 2-8 days after silo placement (8, 17, 18). There is limited data regarding the timing of silo placement however, there are reports of immediate placement within the first 6 hours of life (19). In our cohort, on average, it took 17 hours for silo reduction placement and 21 hours for primary closure. Future randomized control trials should aim to determine the optimal time for surgical interventions following birth and whether this impacts outcomes.

Complications are common in cGS patients both pre- and post-surgically. The most common complications include sepsis and NEC (10, 16). Laje et al. reported the worst outcomes in patients who have intestinal necrosis, atresia, or vanishing gastroschisis, at the time of surgery, with respect to duration of TPN and length of stay in hospital (9).

8. HERNIATION

All gastroschisis patients have an increased risk of herniation with complications: hiatus hernias tend to lead to severe gastroesophageal reflux disease (GORD) and may require surgical fixation (9). With regards to surgical procedure, there is less risk for ventral herniation, predominantly incisional-type, in patients following staged procedure in comparison to primary closure. This is likely due to the increased abdominal pressures following primary closure (12, 20, 21).

9. BOWEL ATRESIA

Intestinal atresia is one of the most common complications, with a reported incidence of 10-20% in all gastroschisis patients (16, 22, 23). Often atresia can be found on the pre-natal ultrasound scan but, in many cases, the inflammatory peel may obscure the sonographer's view and delay diagnosis (23). Several articles have implicated that the structural location of atresia may be able to guide treatment paradigms however, further research is needed to determine the significance of this finding (22, 23). Early repair of the bowel continuity is recommended in conjunction with continuous monitoring for signs and symptoms of obstruction.

10. NECROTIZING ENTEROCOLITIS

Most complications of gastroschisis are related to decreased bowel function, due to ischemia and/or necrosis. This puts children at an increased risk of developing critical conditions such as necrotizing enterocolitis (NEC). The relationship

between NEC and gastroschisis is also surprisingly high, with a documented incidence of around 20% (24). The risk factors for NEC include infection, TPN, and formula feeding in premature infants. Therefore, it is recommended that breast milk should be introduced early in aim to prevent NEC, following repair and infections should also be treated efficiently (24). Furthermore, several authors have suggested that there is an increased risk of developing NEC following staged silo procedure in cGS patients, however, this is likely to be multifactorial (9, 24, 25). One study by Youssef et al. reports that out-of-hospital birthing and line sepsis are the most significant factors for NEC risk (p=<0.01 and p=0.04 respectively) (26). In our cohort, there was an increased risk of NEC after primary closure with regard to both complicated and complex patients. However, in complex patients only, there was an increased risk of NEC in the staged silo patients. There is no significant data to date to suggest the relationship between NEC and surgical procedures (24, 25).

11. UNDESCENDED TESTES

Cryptorchidism is seen in conjunction with around 30-40% of abdominal wall defects such as gastroschisis (27-29). Many of these cases undergo spontaneous testicular migration and do not require surgical intervention therefore, several authors have recommended using solely a watch-and-wait approach (27, 29, 30). There are several proposed theories behind the spontaneous migration of the testes including increased intra-abdominal pressures and possible genetic susceptibility of gastroschisis patients (31). Our study corroborated the findings of these studies, with the majority undergoing spontaneous migration and only one patient requiring orchiopexy (25%). Future studies might determine the exact underlying etiology and genetic correlation between the two conditions.

12. CENTRAL LINE INFECTIONS

Central line infections are common in young patients with long stays in intensive care units due to insufficient aseptic techniques and monitoring. Furthermore, central line infections have been linked to conditions affecting the bowel wall and motility, such as gastroschisis, and extensive TPN use (32, 33). Gastroschisis patients seem to have a higher risk of central line infections due to a number of significant factors such as bowel stasis, higher incidence of NEC, and longer duration of TPN and hospital stay (32, 34, 35). Prematurity and low birth weights seem to be protective indicators with regard to infection risk (32). To date, there is a lack of evidence with regard to infection and the type of surgical procedure (8, 36). One study found that 80% of line infections occurred during silo placement and within 5 days of primary closure and has suggested that line infections may be correlated with increased abdominal pressures and consequent altered venous return (36). However, some studies have found that silo procedure has an increased risk of post-procedural sepsis, therefore, the development of line infection is likely to be multifactorial, regardless of procedure type (37). In our cohort, both complicated and complex patients with primary closure have an increased risk of line infections.

13. CONCLUSION

Complex gastroschisis patients have significant associated morbidity and mortality. Complications may be prevented with careful consideration of management paradigms and should be determined on a case-by-case basis. It is clear that the longer duration of silo placement and/or period of bowel instability has poorer long-term outcomes for the child. However, it is important to note that the patients requiring more time pre-operatively are likely to have more severe underlying gastrointestinal pathology.

Whilst intestinal atresia is the most common complication, there is a high incidence of cryptorchidism in complex gastroschisis patients. The majority of these patients undergo spontaneous migration of the testes for unknown reasons. Our findings should potentiate future research into the exact mechanism and etiology of migration, with regards to genetic susceptibility and external environmental factors.

In terms of both complicated and complex patients, this retrospective study demonstrated that time to silo closure is the most significant variable related to TPN and LOS in gastroschisis. It was determined by the number of surgeries and severity of the disease. For uncertain reasons, NEC and line infection were high after primary closure. Further randomized controlled trial studies might determine the underlying factor that leads to it.

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