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Adherence to and outcomes of a University-Consortium gastroschisis pathway☆

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☆ **How this paper will improve care:** A clinical pathway for gastroschisis implemented at multiple institutions led to reduction in mechanical ventilation and antibiotic days. The skin-closure technique appears to facilitate pathway compliance and helps avoid intubation, an operating-room team, and general anesthesia.

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ABSTRACT

Background: Our multi-institutional university consortium implemented a gastroschisis pathway in 2015 to standardize and improve care by promoting avoidance of routine intubation and paralysis during silo placement, expeditious abdominal wall closure, discontinuation of antibiotics/narcotics within 48 h of closure, and early initiation/advancement of feeds.
Methods: Adherence to the gastroschisis pathway was prospectively monitored. Outcomes for the contemporary cohort (2015–2018) were compared with a historical cohort (2007–2012).
Results: Good adherence to the pathway was observed for 70 cases of inborn uncomplicated gastroschisis. The contemporary cohort had significantly lower median mechanical ventilator days (2 versus 5; $p < 0.01$) and antibiotic days (5.5 versus 9; $p < 0.01$) as well as earlier days to initiation of feeds (12 versus 15; $p < 0.01$). However, no differences were observed in length of stay (28 versus 29 days; $p = 0.70$). A skin closure technique was performed in 66% of the patients, of which 46% were performed at bedside without intubation, the assistance of an operating-room team, or general anesthesia.
Conclusion: In this study, adherence to a clinical pathway for gastroschisis across different facilities was feasible and led to reduction in exposure to mechanical ventilation and antibiotics. The adoption of a bedside skin closure technique appears to facilitate compliance with the pathway.
Level of evidence: Level II/III
Type of study: Prospective comparative study with historical cohort

Gastroschisis is a common congenital defect [1]. The incidence of gastroschisis has increased three-fold over the last two decades in some regions [2]. While infants born with gastroschisis usually undergo abdominal closure within several days of birth, their mean hospital stay in the intensive care unit is greater than 30 days. Prolonged hospital stays are most likely because of to slow return of bowel function requiring prolonged courses of parenteral nutrition [3–6]. As a result of this protracted inpatient hospitalization, costs of treating gastroschisis reach upwards of $180,000 [3–5].

Clinical care guidelines standardize patient care and improve the quality of care of surgical patients [7–9]. For infants with gastroschisis, single-center protocols that emphasize early primary closure have been associated with earlier initiation of nutritional support and attainment of full feeds and a reduction in ventilator days and hospital length of stay [10,11]. Despite the evidence favoring standardization of care, there remains a lack of consensus in the management of infants with gastroschisis both within and across institutions [12,13]. In an effort to improve the quality of care of infants born with gastroschisis, our multi-institutional consortium developed a clinical pathway to reduce variability in management across centers. Specific areas for improvement included operative approach, ventilation and paralysis strategies, pain management, antibiotic duration, and nutritional support. The goal of this study was to prospectively evaluate adherence to the pathway and determine whether outcomes improved following its implementation. Furthermore, we sought to evaluate whether surgical technique (skin-closure versus fascial-closure) was associated with improved adherence, patient outcomes, and a decrease in resource utilization.

Table 1
2015 Clinical pathway for gastroschisis.

Surgical Guidelines

- If silo is utilized, closure within 3 days is recommended when feasible.
- Recommend gastric and rectal decompression as strategies to facilitate reduction.

Ventilator Guidelines

- Routine intubation and paralysis are not recommended for silo placement or bedside reduction.

Antibiotic Guidelines

- Ampicillin and gentamicin are recommended as primary choice for prophylaxis.
- Discontinue antibiotics ≤48 h after abdominal closure in the absence of culture-positive sepsis or clinical instability.

Pain Management Guidelines

- Recommend use of nonnarcotic medications to control pain.
- Discontinue opioids ≤48 h after abdominal closure.

Central Venous Access Guidelines

- Peripherally-inserted (PICC) venous access is preferred over central-insertion of tunneled central venous catheters.
- Discontinue central venous catheters as soon as 100 kcal/kg/day of enteral feeds (or ad lib oral feeds) are achieved.

Feeding Guidelines

- Initiate feeds ≤48 h after gastric output becomes nonbilious.
- Use mother's own breast milk if available (do not recommend Pedialyte®).
- Advance feeding volume by ≥20 cc/kg/day as tolerated.

1. Methods

1.1. Clinical pathway (Table 1)

Our multi-institutional consortium developed a clinical pathway (i.e. clinical practice guidelines) for management of gastroschisis based on retrospective review of practices and outcomes [12]. Consortium meetings provided an opportunity for key stakeholders and site leads to develop consensus guidelines, identify potential barriers to adoption, and share implementation strategies. The goal of the pathway was to standardize care, reduce ventilator days, promote antibiotic and opioid stewardship, reduce time to full enteral feeds, and reduce length of stay. No specific closure technique was recommended as beside skin closure techniques had not yet been adopted at many consortium sites and no differences observed in outcomes between primary-closure and routine-silo strategies [12]. Site champions provided education and outreach to health care professionals involved in the primary care of these infants (neonatologists, pediatric surgeons, nurse practitioners, bedside nurses and trainees). The pathway guidelines were posted at the patient's bedside to facilitate adherence and monitor compliance. Experiences with implementation and adoption of the pathway were shared during monthly consortium conference calls and quarterly in-person meetings. Pathway implementation was phased in across all sites from 2015 to 2016. Adherence to pathway guideline recommendations was prospectively monitored at each site after the pathway was implemented.

1.2. Data collection

A multi-institutional review board reliance registry approved the study (IRB #10-04093). Data were collected at individual sites at five University of California medical campuses (Davis, Irvine, Los Angeles, San Diego, San Francisco) and entered into a central REDCap database. To evaluate operative resource utilization, data on method and location of closure and whether anesthesia and operating room teams were present for final closure were collected. Method of closure was classified as either a fascial closure (including suture approximation of the abdominal wall) or skin closure (i.e. utilizing "umbilical flap," "sutureless", "ward reduction", or "plastic" techniques).

1.3. Study design data analysis

Adherence to the pathway was determined for each of the individual guidelines by calculating the percentage of patients for whom there was compliance documented. Overall adherence was defined as the percentage of patients that were compliant with all of the following guidelines: closure within 3 days; if silo placed, no paralysis for silo placement or reduction; ampicillin and gentamicin utilized for antibiotic prophylaxis; use of nonnarcotic medications for pain control; antibiotics and narcotics discontinued within 48 h of closure; utilization of peripherally-inserted central venous access; central venous access discontinued when 100 kcal/kg/day of enteral feeds achieved; feeds initiated within 48 h of gastric output becoming nonbilious; use of mother's own breast milk; and advancing feeds by >20 cc/kg/day.

Outcomes for the contemporary cohort postimplementation of the pathway (2015–2018) were compared with outcomes from a preimplementation historical cohort (2007–2012) [12]. In order to have a valid comparison with the historical cohort, only inborn infants with uncomplicated gastroschisis were included in the analysis. Complicated gastroschisis was defined as the presence of intestinal atresia, stricture, ischemic bowel prior to closure, or severe pulmonary hypoplasia. For the contemporary cohort, adherence, outcomes, and resource utilization were compared between skin-closure and fascial-closure techniques. Wilcoxon rank-sum test and Fisher's exact test were utilized where appropriate to identify significant differences between groups ($p < 0.05$).

2. Results

2.1. Adherence to clinical pathway

All 70 uncomplicated gastroschisis patients who received antenatal care and were born at one of the consortium sites postimplementation of the pathway were included. Adherence for each recommended guideline ranged from 60% to 96%. Sixty-nine percent of patients underwent gastroschisis closure within 3 days. Of the 71% of patients who had a silo placed, paralysis was avoided in 76% of silo placements and 92% of silo reductions. Antibiotics were terminated within 48 h of closure in 80% of patients. The recommended antibiotic regimen (ampicillin and gentamicin) was utilized in 90% of patients. Opioids were discontinued (60%) or limited to as needed (16%) within 48 h of closure. Feeds were initiated within 48 h of nonbilious orogastric output in 81% of patients, and the vast majority of infants received oral feeds (91%). Goal feeds were attained in less than 10 days in 81%, and maternal breast milk was utilized for initial feedings in 96% of patients. A peripherally-inserted central venous catheter (PICC) was utilized in 93% of patients, and few patients required a tunneled central catheter (4%). The central venous catheter was removed within 48 h of achieving goal feeds in 93% of patients. Overall adherence to the pathway guidelines without making exceptions for culture-positive sepsis, clinical instability, intolerance of feeds, or other extenuating circumstances was 20% (14/70). Overall adherence increased during the study period from 14% (5 of 35 for the first half of cases for each institution) to 26% (9 of 35 for the second half of cases for each institution) ($p = 0.37$).

2.2. Comparison of outcomes (Table 2)

Comparison of outcomes between the contemporary cohort postimplementation of the gastroschisis pathway ($n = 70$) and the historical cohort ($n = 168$) is summarized in Table 2. In comparison to the historical cohort, the contemporary cohort demonstrated a reduction in median days of silo prior to closure (3 versus 5 days; $p < 0.01$), total mechanical ventilator days (2 versus 5 days; $p < 0.01$), and total antibiotics days (5.5 versus 9 days; $p < 0.01$). While the median age at initial feeds was lower following implementation of the pathway (12 vs 15 days; $p < 0.01$), there was no significant difference between the two cohorts in median age to reach full feeds, central venous catheter days, or length of stay.

Table 2
Comparison of outcomes: historical cohort (preimplementation 2007–2012) and contemporary cohort (postimplementation 2015–2018).

	Historical Cohort	Contemporary Cohort	p-value
Number of Patients	168	70	
Median Gestational Age [Range]	37 [29–40]	37 [33–40]	0.39
Median Days to Closure [Range]	1 [0–16]	1.5 [0–7]	0.52
% Silo Placed	58%	71%	0.08
Median Days of Silo [Range]	5 [0–16]	3 [0–7]	<0.01
Median Total Mechanical Ventilator Days [Range]	5 [0–44]	2 [0,34]	<0.01
Median Total Antibiotic Days [Range]	9 [2–46]	5.5 [1,60]	<0.01
Median Age at Initial Feeds [Range]	15 [1–77]	12 [5,32]	<0.01
Median Age at Full Feeds [Range]	23 [9–203]	22 [12–151]	0.05
Median Days to Full Feeds [Range]	9 [0–126]	8.5 [4–139]	0.94
Median Total Central Line Days [Range]	21 [0–91]	21 [10–103]	0.47
% Tunneled Central Catheter	16%	4%	0.01
% Peripherally Inserted Central Catheter	79%	95%	<0.01
Median Length of Stay [Range]	29 [13–203]	28 [15–157]	0.70

2.3. Comparison of skin closure and fascia closure techniques (Table 3)

In the postimplementation cohort, 46 (66%) patients underwent skin closure and 24 (34%) underwent fascial closure. A lateral extension was required in 7 of 24 (29%) of patients undergoing fascial closure and only 3 of 46 (7%) of patients undergoing skin closure. Patients undergoing skin closure technique were more likely to have their closure performed within 3 days (80% versus 46%; $p < 0.01$). Although not statistically significant when compared to patients undergoing fascial closure, patients undergoing skin closure were more likely to have opioids (65% versus 50%; $p = 0.3$) and antibiotics (85% versus 71%; $p = 0.21$) discontinued within 48 h of closure. Similarly, overall adherence was higher for patients undergoing the skin closure technique (24% versus 13%; $p = 0.35$). There were no differences in days to initial or full feeds, total central line days, or length of stay based on the method of repair.

Table 3
Comparison of fascial closure and skin closure techniques in outcomes and resource utilization.

	Fascial Closure	Skin Closure	p-value
Number of Patients	24	46	
Median Gestational Age [Range]	37 [33–40]	37 [33–40]	0.2
Median Days to Closure [Range]	4 [0–7]	0 [0–7]	<0.01
% Silo Placed	75%	70%	0.78
Median Total Mechanical Ventilator Days [Range]	3 [0–11]	1 [0–34]	<0.01
Median Total Antibiotic Days [Range]	7 [1–32]	4 [2–60]	0.12
Median Age at Initial Feeds [Range]	12 [7–32]	12 [5–29]	0.71
Median Days to Full Feeds [Range]	9 [5–55]	9 [4–139]	0.82
Median Age at Full Feeds [Range]	20 [12–76]	23 [12–151]	1.0
Median Total Central Line Days [Range]	21 [12–76]	22 [10–103]	0.96
Median Length of Stay [Range]	27 [18–99]	28 [15–157]	0.63
Operating Room Closure	88%	22%	<0.01
Inhaled Anesthetic Use	78%	22%	<0.01
Operating Room Team Utilized	92%	22%	<0.01
Intubated	96%	52%	<0.01

Table 4
2019 Updates to clinical pathway.

Surgical Guidelines
• Attempt at bedside silo-placement and closure without intubation or anesthesia is encouraged when feasible (Note: a narrow fascial defect requiring lateral extension does not prohibit this approach).
• For bedside silo placement/closure, recommend placing peripheral IV, pulse oximeter, nasal cannula (in case supplemental oxygen is required), and orogastric tube (which should be suctioned manually during reduction of bowel).
Pain Management Guidelines
• Recommend oral sucrose water for bedside silo-placement, reduction, and closure.
• If opioids are administered during bedside silo placement or skin closure, limit to a single dose when feasible to help prevent apnea and intubation.
Feeding Guidelines
• Encourage oral-care protocol with colostrum (or breast milk) at least four times daily.

With respect to resource utilization, patients undergoing skin closure were less likely to be intubated and more likely to undergo bedside closure without general anesthesia and without an operating room team. A total of 21 patients (30% of the total cohort and 46% of those who underwent the skin closure technique) were performed at the bedside without intubation, the assistance of an operating room team, or general anesthesia.

3. Discussion

This study demonstrates the successful implementation of a standardized clinical pathway for infants with gastroschisis in a multicenter university consortium. Despite less invasive support, more expeditious closure, and earlier initiation of feeds, there was no difference in length of hospital stay. These findings suggest that intestinal dysmotility intrinsic to gastroschisis remains a rate limiting factor for hospital discharge. Nonetheless, our pathway has demonstrated reductions in the utilization of resources including ventilators, antibiotics, opioids, and anesthesia.

Adherence to the pathway and reductions in the resource utilization were likely improved by the adoption of the bedside skin closure technique, which was rarely utilized in the historical cohort. Although this study was not designed to compare skin closure and fascial closure methods, skin closure was associated with a lower likelihood of intubation and fewer mechanical ventilator days. We also observed that opioids and antibiotics are more likely to be discontinued within 48 h with the skin closure technique. Fascial closure is often performed by developing skin flaps, which can cause skin erythema that can be difficult to distinguish from cellulitis and thus make antibiotic cessation more challenging for providers. Similarly, avoiding fascial closure may reduce postoperative pain and make opioid cessation more facile for providers. Finally, bedside skin closure was associated with less resource utilization. In fact, 30% of the patients in our contemporary cohort of uncomplicated gastroschisis were able to undergo bedside skin closure without intubation, anesthesia, or the assistance of an operating room team.

In response to the results of this study, our consortium has updated our initial pathway with additional recommendations (Table 4). We now recommend bedside skin closure when feasible as the preferred surgical closure technique. Additionally, in order to avoid opioid-associated apnea, we promote the administration of oral sucrose to help pacify patients during bedside skin closure. This recommendation was in response to the anectodal observation early in our experience that some patients were intubated owing to apnea after multiple doses of opioids. Furthermore, if opioids are administered, we recommend limiting their use to a single dose infused over several minutes to help prevent respiratory depression. In order to reassure providers about patient safety, we recommend the neonatal team place a peripheral intravenous line, pulse oximeter, nasal cannula (in case supplemental oxygen is required), and an orogastric tube (which should be suctioned manually during bowel reduction) prior to any procedures. In order to assist with intestinal motility, we recommend an oral care protocol.

Efforts to reduce resource utilization have many potential collateral benefits. Ventilator stewardship reduces the risk of barotrauma and ventilator-associated pneumonia. Antibiotic stewardship reduces the risk of antibiotic toxicity, drug resistance, and intestinal dysbiosis. Opioid stewardship reduces the risk of respiratory depression and opioid dependence, which may have long-term neurological sequelae. Anesthetic stewardship has the potential to reduce the adverse effects of anesthesia on the developing brain. In contrast, more invasive approaches involving paralysis, mechanical ventilation, trips to the operating room, and general anesthesia are more likely to be stressful to the patient and family and increase health care costs.

There were several limitations to our study. While adherence to individual guidelines was relatively high, overall adherence to all guidelines proved difficult to achieve. Our goal was not to achieve 100% overall compliance, but to encourage neonatal and surgical providers to adopt best practices when feasible. While we suspect that compliance was mainly impacted by patient circumstances (e.g. apnea, concerns for sepsis, clinical instability, intolerance of feeds) and surgeon inexperience with skin closure technique, we cannot definitively conclude this based on this study with the limited sample size. The favorable results observed for the skin closure technique may have been influenced by selection bias as patients undergoing this technique were potentially less complex than those undergoing fascial closure. For example, the percentage of patients requiring lateral extension was higher for those patients undergoing fascial closure. However, we suspect that the surgical technique selected was most influenced by surgeon preference, as the skin closure technique was not widely performed prior to implementation of the pathway. The hiring of surgeons comfortable with the skin closure technique and the early recognition of favorable results are likely contributors to the increased adoption of the skin closure technique.

In conclusion, we report the successful implementation of a standardized clinical pathway for gastroschisis which resulted in improvements on a number of important clinical measures. The consortium was essential in the development of consensus recommendations and helpful in sharing implementation strategies, which facilitated adoption at individual sites. Ongoing monitoring and evaluation of the pathway by our multidisciplinary consortium have led to further modifications with the goal of continuing quality improvement.

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