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Review Article

Management of Gastroschisis: Timing of Delivery, Antibiotic Usage, and Closure Considerations (A Systematic Review From the American Pediatric Surgical Association Outcomes & Evidence Based Practice Committee)

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ABSTRACT

Background: No consensus exists for the initial management of infants with gastroschisis.
Methods: The American Pediatric Surgical Association (APSA) Outcomes and Evidenced-based Practice Committee (OEBPC) developed three *a priori* questions about gastroschisis for a qualitative systematic review. We reviewed English-language publications between January 1, 1970, and December 31, 2019. This project describes the findings of a systematic review of the three questions regarding: 1) optimal delivery timing, 2) antibiotic use, and 3) closure considerations.
Results: 1339 articles were screened for eligibility; 92 manuscripts were selected and reviewed. The included studies had a Level of Evidence that ranged from 2 to 4 and recommendation Grades B-D. Twenty-eight addressed optimal timing of delivery, 5 pertained to antibiotic use, and 59 discussed closure considerations (Figure 1). Delivery after 37 weeks post-conceptual age is considered optimal. Prophylactic antibiotics covering skin flora are adequate to reduce infection risk until definitive closure. Studies support primary fascial repair, without staged silo reduction, when abdominal domain and

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hemodynamics permit. A sutureless repair is safe, effective, and does not delay feeding or extend length of stay. Sedation and intubation are not routinely required for a sutureless closure.
Conclusions: Despite the large number of studies addressing the above-mentioned facets of gastroschisis management, the data quality is poor. A wide variation in gastroschisis management was documented, indicating a need for high quality RCTs to provide an evidence-based approach when caring for these infants.
Type of Study: Qualitative systematic review of Level 1–4 studies.

1. Introduction

Neonates with gastroschisis consume a disproportionate amount of resources compared to other NICU patient groups [1]. Gastroschisis occurs in 2–6 out of 10,000 live births with increasing incidence [2–4]. The etiology of gastroschisis remains unknown, and unlike omphalocele, infants with gastroschisis have fewer associated genetic disorders or syndromes [5]. The etiology may be multifactorial involving both genetic and non-genetic risk factors such as young maternal age [2–5]. Survival rates in North America exceed 90% for both complicated and uncomplicated gastroschisis cases [2,4].

The American Pediatric Surgical Association (APSA) Outcomes and Evidence-Based Practice Committee (OEBPC) conducted a qualitative systematic literature review to address variations in practice management for infants with gastroschisis.

2. Methods

2.1. Research methodology

The membership of the APSA Outcomes and Evidence-Based Practice Committee (APSA-OEBP) participated in an iterative modified Delphi process *a priori* to vet and develop questions for a systematic review of the literature on the management of infants with gastroschisis. Through this process, three questions were selected for the systematic review and an extensive literature review of the management of infants with gastroschisis was conducted.

2.2. Research questions

1. What evidence exists that outcomes are improved if infants with gastroschisis are delivered at a designated gestational age?
2. What recommendations can be made regarding antibiotic use during the treatment of infants with gastroschisis?
3. What are the outcomes for different closure strategies, (i) timing of repair, (ii) primary fascial closure vs. delayed repair after silo, (iii) sutured vs. sutureless closure, and (iv) adjunctive techniques and monitoring?

2.3. Definitions

Gastroschisis can be categorized as simple or complicated.

- **Simple gastroschisis** involves no additional complications other than those stemming from bowel inflammation and irritation.
- **Complicated gastroschisis** is defined as a gastroschisis with atresia, intestinal volvulus, necrosis, or perforation present at delivery.

2.4. Search methods and data sources

The Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines were utilized [6]. In collaboration with a healthcare librarian, *Covidence* software [7] was utilized to perform an English language search of PubMed, MEDLINE, OVID, SCOPUS, and the Cochrane Library database for publications between January 1, 1970, and December 31, 2019. The Medical Subject Headings (MeSH) included "gastroschisis" and "abdominal muscles/abnormalities," and a complete list of search terms is included in the supplemental materials section. Non-English publications, animal studies, case reports, and abstracts without corresponding manuscripts were excluded. We assigned a level of evidence and grade of recommendation to each question based on the Oxford Centre for Evidence-Based Medicine (OCEBM) criteria [8]. This systematic review was registered with the Open Science Framework (OSF) (osf.io/qm3us) on February 15, 2021 [9].

3. Results

3.1. Question 1: what evidence exists that outcomes are improved if infants with gastroschisis are delivered at a designated gestational age?

Significant practice variation exists regarding optimal timing of delivery for gastroschisis. While some recommend allowing for a spontaneous vaginal delivery (SVD) after 38 weeks GA [10], others favor early induction of labor or a scheduled, preterm, cesarean section (CS) at GA<37 weeks to possibly reduce intestinal injury and infant mortality [11]. Critics argue that early delivery may increase prematurity-related complications, like respiratory issues, cholestasis, cognitive deficits, and higher mortality rates [12].

A total of 28 manuscripts were reviewed to address the optimal timing of delivery (Fig. 1). The 13 highest quality studies (Level 3 and above) that directly address timing of delivery as a primary or secondary aim of the study and thereby facilitated direct comparison within a figure (Fig. 2.) [3,4,10–20]. The remaining 15 were single or multi-center retrospective studies in which timing of delivery was a secondary aim, with insufficient detail for direct comparison. These were also lower grade studies (Level 4) limited by smaller cohorts and heterogeneity between comparison groups.

Even in the higher quality studies, the available evidence had limitations. Both RCTs and four of five administrative database studies included complicated gastroschisis which introduced additional heterogeneity into their outcomes [3,4,11,13–16]. Both RCTs (Logghe, 2005; Shamshiraz, 2020) ended prematurely and were underpowered after accruing only 42 and 21 patients, respectively [11,13].

Five North American, population-based retrospective cohort studies were included that analyzed state or national administrative datasets [3,4,14–16]. Two utilized the Canadian Pediatric Surgery Network (*CAPSNet*) population-based dataset to evaluate outcomes for different gestational ages and delivery methods [15,16].

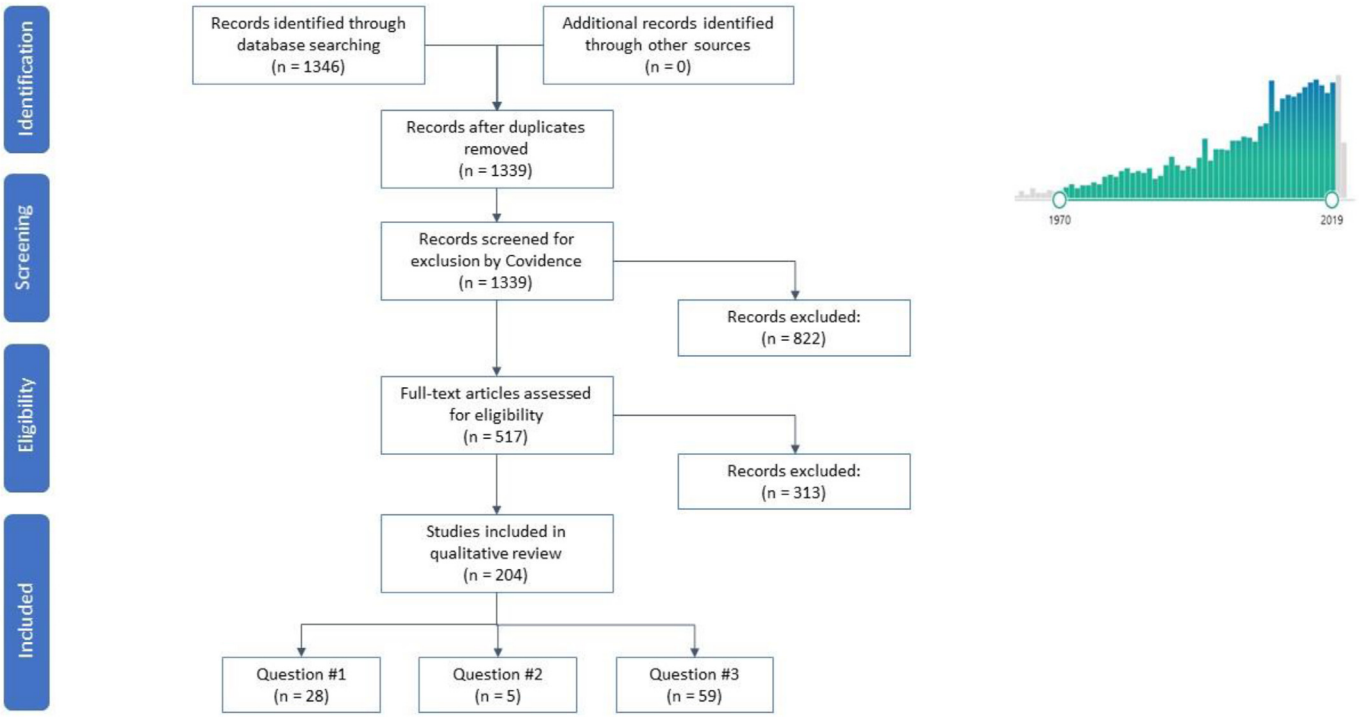


Fig. 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) methodology. 1346 records were identified through database searches and 1339 records remained after duplicates were removed. 822 articles were excluded in a step-wise, triple review approach using Covidence systematic review software, leaving 517 full-text articles for full-text review. Any additional 313 were excluded upon full-text review resulting in 204 studies for this qualitative synthesis. Some articles addressed more than one of the pre-identified questions.

Boutros et al. (2009) examined outcomes for 192 children born between 2005 and 2007 to determine the effect of gestational age (GA) and birthweight (BW) as well as the intended and actual delivery plan for the fetus [16]. When CS and SVD were compared and controlled for GA and BW, no differences in outcomes were identified. As BW and GA increased, there was an associated decrease in the length of stay (LOS), ventilator days, and days of total parenteral nutrition (TPN) administration. The authors concluded that there was no benefit to planned CS or SVD prior to 37 weeks gestation.

A subsequent *CAPSNet* review by Nasr et al. (2013) included 630 infants born with gastroschisis between 2005 and 2010 [15]. The Score for Neonatal Acute Physiology (SNAP) was included as a variable. Independent predictors of complications included prematurity (OR 3.5, (95% CI: 2.1–7.9), p = 0.001), an adverse SNAP score (OR 1.3, (95% CI: 1.02–18.8), p = 0.02), and bowel atresia (OR 1.9, (95% CI: 1.03–19.9), p = 0.03) (Fig. 2). Once again, infants delivered at or beyond 38 weeks GA experienced decreased LOS, TPN days, and overall complications compared to those delivered prior to 38 weeks (Fig. 2).

Another study by Cain et al. (2014) analyzed 1005 infants with gastroschisis in State registry data from Florida [14]. Multiple gestations, other major birth defects, and infants with a maternal indication for preterm delivery were excluded, leaving 324 infants for analysis. When preterm infants were compared with early term (37–38 6/7 weeks gestation) infants, an inverse association between GA and the prevalence of low BW, jaundice, and infant death was identified (Fig. 2.)

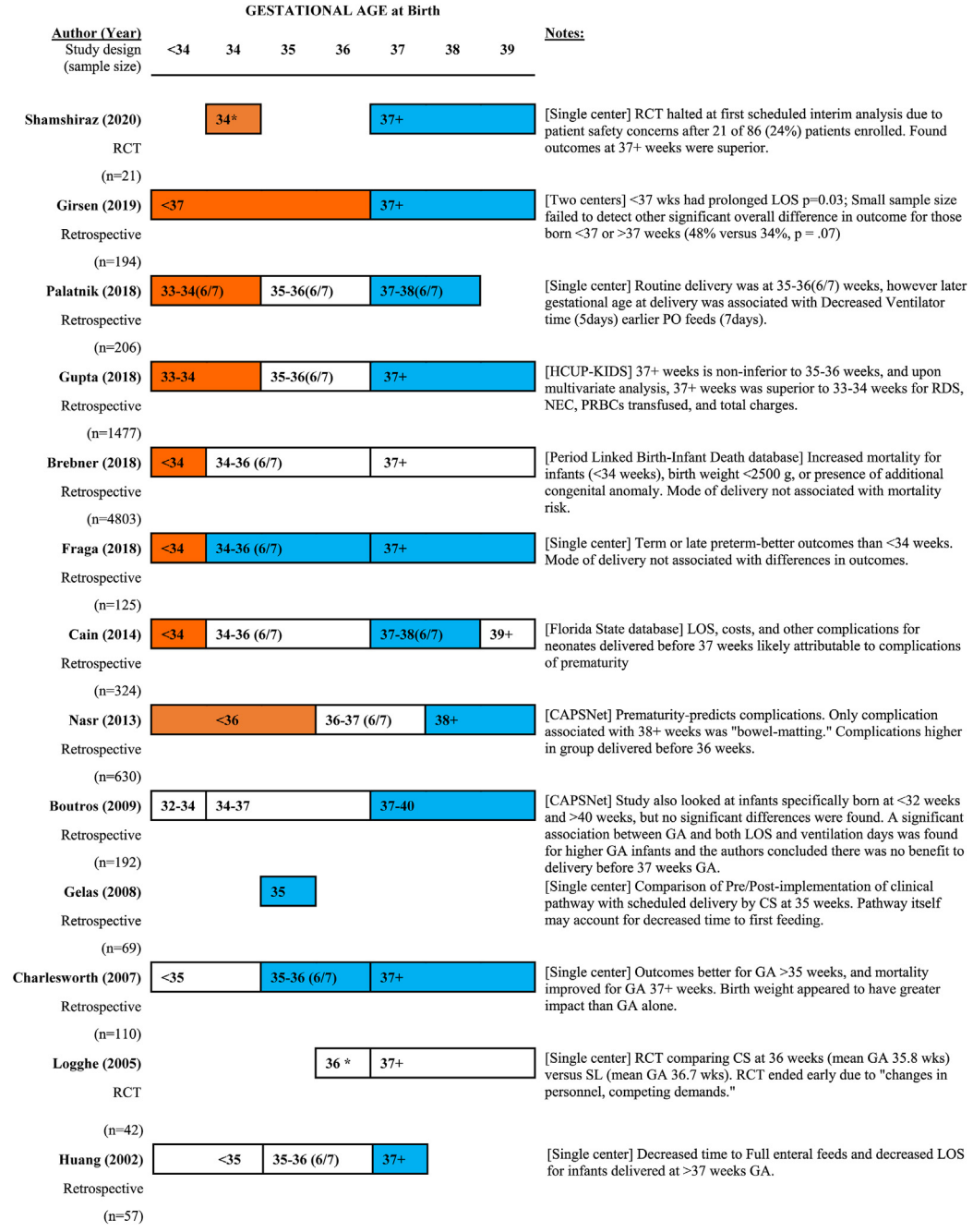
Gupta et al. (2018), examined over 4000 infants in the HCUP-KID database and found no benefit of earlier delivery at <35 weeks [3], and multivariate analysis revealed fewer complications and better outcomes with delivery at 37 weeks or later when compared to delivery <35 weeks. Complications of prematurity such as respiratory distress syndrome (RDS) and necrotizing enterocolitis (NEC) were less frequent, and blood transfusions and total hospitalization charges decreased. The authors concluded that elective, spontaneous delivery at 37 weeks or later was most beneficial (Fig. 2) [3].

In that same year, a study by Brebner et al. (2018) reviewed over 4800 infants from a 5-year period (2009–2013) using the Period Linked Birth-Infant Death Database (Fig. 2) [4]. It found a higher risk of mortality for infants born before 34 weeks (OR 5.09; 95% CI: 2.61–9.92), as well as low BW infants, and those with another congenital anomaly, OR 13.91 (95% CI: 8.55–22.62).

Three of the remaining studies in Fig. 2 also support the idea that delivery at 37 weeks or later is associated with better outcomes in all measures. However, other studies had different findings. Charlesworth et al. (2007) reviewed 110 infants at a single center and found lower mortality for infants born at 37 weeks or later, but also noted reduced overall complications for those born at >35 weeks GA [20]. Two additional single center studies suggest that earlier delivery could be beneficial. Fraga et al. (2018) found improved outcomes for all infants born at >34 weeks GA [18], and Gelas et al. (2008) reported reduced complications following scheduled C-section at 35 weeks [19].

The other 15 articles, not shown in Fig. 2, were smaller, single, or multi-center retrospective studies of lower quality. While these studies did not primarily focus on delivery timing, they did examine aspects of outcomes related to gestational age (GA) and delivery method. These studies had limitations, including smaller sample sizes and did not supply enough specifics for direct comparison in Fig. 2.

In summary, the 28 reviewed articles offer limited but consistent insights. Delivery before 34 weeks of gestation consistently leads to poorer outcomes due to prematurity-related complications, sepsis, and low birth weight. On the other hand, delivering at 37 weeks or later is associated with improved outcomes (Fig. 2). The primary advantage of later GA delivery is the avoidance of prematurity-



RCT - Randomized controlled trial; LOS - Length of stay; GA - Gestational Age; ; BWt - Birth Weight; HCUP-KIDS Healthcare Cost and Utilization Project-Kids' Inpatient Database; CS - Cesarean section; SL - Spontaneous labor

* Elective induction of labor

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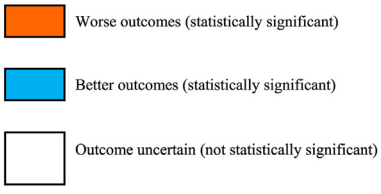

Fig. 2. Impact of gestational age at delivery on overall outcomes.

related complications, leading to reduced use of mechanical ventilation, decreased reliance on parenteral nutrition, quicker transition to enteral feeding, lower infection rates, and shorter hospital stays. Based on this systematic review, it is advisable to avoid elective early delivery, as outcomes tend to improve at 37 weeks or later.

3.2. Question 1 – section summary and recommendations

What evidence exists that outcomes are improved if infants are delivered at a designated GA?

A planned delivery before 37 weeks GA is not beneficial and may be harmful in that early delivery promotes the complications of prematurity. Delivery of infants with gastroschisis after 37 weeks post conception is preferable.

Grade C recommendation supported by Level 2, 3, and 4 evidence.

3.3. Question 2: what recommendations can be made regarding antibiotic use during the treatment of infants with gastroschisis?

Four published studies with recommendations for antibiotic use in the treatment of gastroschisis were identified (Fig. 1) [21–24]. Two studies reported antibiotic use in infants with gastroschisis, both after birth and prior to closure, as well as later in the NICU course (Table 1.) [21,22].

Baird et al. conducted a review of the CAPSNet database, analyzing outcomes from 395 patients across 16 Canadian centers [21]. The average gestational age in this cohort was 36.2 weeks (range: 25–41), with an average BW of 2556 ± 595 g. Almost all infants initially received antibiotics (98%) for an average of 6.1 days (range: 1–36 days), which was more than twice the time taken for abdominal wall closure (averaging 2.1 days after birth). The most commonly prescribed antibiotic regimen was ampicillin combined with gentamicin (n = 251, 65.0%). Wound infection occurred in 12.6% of cases, while catheter-related infection (CRI) affected 4.9% of patients. Coagulase-negative staphylococcus was the primary isolate (58.8%) for both types of infection. The most frequently identified organisms in bacteremia were Staph. epidermidis, *E. coli*, Enterococcus, *S. aureus*, and Candida.

In infants with delayed fascial closure (defined as >24 h after delivery), the risk of wound infection significantly increased (21% vs. 8%, p = 0.001). However, the rate of wound infection did not affect the rate of catheter-related infections. Catheter-related infections significantly extended the length of hospital stay (p < 0.0001). This retrospective database analysis could not establish whether infection caused or resulted from a prolonged NICU course. Most infections were linked to skin flora. The prevalence of Staphylococcal isolates in this study supports using a beta-lactamase-resistant penicillin derivative like Cloxacillin, combined with an aminoglycoside for empiric therapy, reserving vancomycin for confirmed cases of CRI [21].

Schlueter et al. conducted a single institution retrospective review of 129 infants with simple gastroschisis [22]. All received antibiotics, and 97% received ampicillin and gentamicin for an average of 9.8 days. Infants treated with a silo received antibiotics for 13 days compared to 7 days for those who underwent a primary closure. In 46%, a silo was used to accomplish reduction and closure at an average of 7.4 days. Eleven (18.6%) of these experienced a surgical wound infection. There were 8 CRIs in the entire cohort (6.2%). Fewer wound infections were observed in the sutureless closure group compared to sutured closures (0/21 vs. 31/108, P = 0.01) [22].

3.4. Question 2 – section summary and recommendations

What recommendations can be made regarding antibiotic use during the treatment of infants with gastroschisis?

1. There is minimal guidance regarding prophylactic treatment with antibiotics until closure of the defect. In the absence of strong evidence, narrow spectrum antibiotics to cover skin flora until the defect is closed, and perhaps for an additional 24 h after closure, is likely adequate in a clinically well infant.

Grade C recommendation supported by Level 3 and 4 evidence.

Table 1
Studies that examine the use of antibiotics during the initial treatment of gastroschisis infants.

Publication	Complicated Gastroschisis	Type	Results	Conclusion
Baird et al. Ped Surg International 2012 N = 395	44/395 (11.1%)	Retrospective CAPS-net data	12.6% wound infection 14.9% catheter related infection Delayed closure (>24 h) associated with higher wound infection (21.2% vs 8.2%)	Infections are common in gastroschisis. Initiate antibiotic coverage at birth and continue treatment until the abdominal defect is closed. The frequency of Staphylococcal isolates identified in this study supports the use of a beta-lactamase resistant penicillin derivative combined with an aminoglycoside as empiric therapy, with vancomycin reserved for documented episodes of CRI.
Schlueter et al. J Pediatr Surg 2015 N = 155	0 All simple gastroschisis	Retrospective review	24% infection rate within 60 days Prematurity, low birthweight, use of silo, sutured repair associated with infection	Infections are common. Avoid silo and preferentially close early when feasible. Sutureless repair resulted in significantly fewer infections.
Khalil et al. Pediatr Surg Int 2008 N = 72	No comment	5-year Retrospective review	Abnormal gut flora associated with wound infection (p = 0.035), but treatment did not impact infection rate.	Endogenous bacteria form the bulk of the organisms causing infection. Early enteral feeding approached significance and reduced infection rates. (P = 0.056)
Ram et al. Euro J of Ped Surg 2013 N = 43	No comment	Prospective	C reactive protein is elevated when silo reduction is performed and may not reflect infection.	C reactive protein is not a reliable marker for infection

3.5. Question 3: what are the outcomes for different closure strategies, (i) repair timing, (ii) primary fascial closure vs. delayed repair after silo, (iii) sutured vs. sutureless closure, and (iv) adjunctive techniques and monitoring?

Fifty-nine articles were reviewed to discuss these four subtopics (Fig. 1).

3.5.1. Repair timing

Ten retrospective cohort studies were identified that examined the timing of repair and gastroschisis outcomes [25–34]. The definition of timing of repair, as the exposure of interest, varied. Some examined the time from birth to first operative intervention (primary closure or silo placement) [25–27], while others only reported the time to definitive fascial closure [28]. Furthermore, some treated time exposure as a dichotomous categorical variable (e.g. repair before or after 4 h from birth) [29–33], and others examined it as a continuous variable for linear regression models [28]. Six studies offered no adjustment for confounding factors or disease severity [25,26,28,29,34,35]. Four specifically excluded complex gastroschisis from the analysis [26,28,34,35].

Three studies found no statistically significant association between earlier repair and postoperative outcomes including LOS [25,29,30]. Two unadjusted studies found that earlier repair was associated with more rapid attainment of full enteral feeds and decreased LOS and proposed that infants undergoing early repair had subjectively less bowel inflammation [30,31]. Some studies likely suffered from significant selection bias as silo placement and definitive closure were determined by clinician-specific practice [26,28,31].

Five studies employed multivariate adjustment models to control for confounding factors. All four found a small independent association between early repair and improved outcomes such as earlier feeding, decreased LOS, and decreased duration of mechanical ventilation [27,32–35]. In each study, however, the outcomes were influenced by other fixed factors such as complicated gastroschisis with intestinal injury, infection, gestational age, and prematurity.

3.5.2. Primary fascial closure vs. delayed repair after silo

Twenty-eight articles compared outcomes for patients managed with an attempt at initial primary repair versus those with a staged approach (silo). These included a small randomized controlled trial, which found no significant difference in LOS, time to full feeds, or number of ventilator days between the two approaches [36]. The remaining 27 articles were retrospective cohort studies. Twenty of these employed no adjustment for confounding factors and suffered from selection bias. Of these unadjusted studies, the most uniform finding was that primary repair was generally associated with a shorter LOS and faster feeding advancement than staged repair [18,25,37–46].

In contrast, several unadjusted cohort studies report conflicting results. Three report no association between repair strategy and feeding or LOS [30,47,48]. One study reports opposite findings in that primary repair was associated with a longer LOS and prolonged feeding advancement [49], however this study compared a historical cohort where all infants underwent an attempt at primary closure to a more recent group where the clinician initially placed a spring loaded silo (SLS) on all infants. Within this study nearly one-third of the primary repair patients in the historical cohort failed their initial closure attempt and thus required staged repair [49].

When repair strategy and ventilator days were examined, four studies reported more ventilator days with primary repair [40,49–51], and four studies reported more ventilator days with staged repair [25,39,41,43] (Table 2.). However, none provided details of critical care management or indications for mechanical ventilation that might contribute to these findings, except for two studies [43,51]. One had a defined protocol to avoid intubation in silo patients [51], and one had a clinical care protocol for gastroschisis infants [43] (Table 2). Notably, three studies found an association between primary repair and necrotizing enterocolitis. Two controlled for GA [49,52] and one did not [41].

Eight retrospective cohort studies attempted to adjust for other patient-level factors using logistic regression or proportional hazard models. As with the previous studies, the most frequently assessed outcomes were LOS and time to full feeds. While three of these adjusted studies found no association with these metrics [53–55], the majority, and those of generally higher quality adjustment, found primary repair to be associated with a shorter LOS and quicker feeding advancement [1,10,56–58].

The variety of techniques to address the gastroschisis defect reflect surgeon-specific practice and the clinical scenario. Later studies that evaluate the preformed silo appear to include some healthy infants that would have done well with primary closure. The greatest limitation to these retrospective studies is the inability to adjust for clinical indicators that may drive the decision for primary repair versus planned staged repair, such as bowel status or degree of viscero-abdominal disproportion.

3.5.3. Sutured vs. sutureless closure

Sutureless or “plastic” repair was introduced in 2004 as an approach allowing bedside closure with potentially lower intra-abdominal pressures and has been widely adopted in recent years [59]. We identified 21 studies that evaluated closure techniques. There were 14 that reviewed sutureless closure and 7 evaluating adjunctive techniques.

One of the fourteen was a RCT of 39 infants that excluded complicated gastroschisis. When sutureless closure was compared to a standard sutured repair performed in the operating room, the study reported a significantly longer LOS and time to full feeds [60].

The thirteen remaining studies were all retrospective cohort studies, and only three adjusted for confounders in the analyses [61–63]. In contrast to the above RCT that reported significantly longer LOS and time to full feeds after sutureless repair, nine of these retrospective studies found no difference in outcomes between sutureless and sutured repair [61–68]. One retrospective study reported conflicting findings and documented an association between sutureless closure and a shorter LOS [69].

Ventilator days and anesthesia events were the most uniformly examined outcomes. While one study found no difference in these outcomes between the two techniques [61], eight reported that sutureless closure was associated with significantly fewer ventilator days, and general anesthesia was frequently not indicated and not required [62–64,66–68,70,71]. One study specifically compared sutureless closure performed with or without routine intubation. A comparison of the two approaches revealed no difference in outcomes. Even in the small subset of patients who failed a non-intubation approach and ultimately required mechanical ventilation to achieve a sutureless closure, no increased morbidity was observed [72].

The results were mixed among the studies that reported postoperative surgical site infections. Two reported no difference [66,67] and two documented a trend toward fewer infectious events with sutureless closure [22,68].

Regarding post-repair hernias, persistent umbilical defects are more common with sutureless repair and are present in 60–90% of patients, although the majority close similar to native umbilical hernias. Only 5–10% of these patients ultimately require operative herniorrhaphy at a 4-year follow-up [59,61,64].

Table 2
A comparison of gastroschisis closure strategies, ventilator days and other outcomes.

Study	Exclude complicated gastroschisis	Controlled for GA	Comparison groups	Conclusion ventilator days	Conclusion other outcomes
Four studies compare primary fascial closure and spring loaded silo (SLS)					
All report TOTAL ventilator days and more ventilator days with **Primary Repair**					
Akinnola et al. 2014 Eur J of Ped Surg N = 163	yes	No comment	Older cohort of primary closure or surgical construction of silo vs. newer cohort use of SLS	SLS approach-Fewer ventilator days. PC- 5 days (range, 1–22 days) versus SLS 3.5 (range, 0–20 days) days P = 0.01	No difference in time to full feeds, LOS, mortality or morbidity.
Gurien et al. 2017 J Pediatr Surg N = 627	yes	Controlled for GA	Primary repair (0–1 day) vs. staged repair SLS (4–14 days)	Primary repair: longer ventilator days- 5.4 (5.6) vs SLS 3.5 (4.9) days- P = 0.001	No significant differences for mortality, readmissions, postoperative LOS, sepsis or other outcomes.
Minkes et all 2000 J Pediatr Surg N = 43 Likely capture healthy infants	No comment	Controlled for GA	Historical primary repair vs. newer SLS placement.	SLS approach-Fewer ventilator days (4 v. 6 days, P = 00.03) and had lower intraoperative P (28 v 21 cm H20, P = 0.02	SLS time to tolerate full feedings was 21 days and 27 days for EC (P = 0.07). SLS group had fewer complications, lower median hospital charges ($71,498 v $85,147; P = 00.05).
Owen 2006 J Pediatr Surg N = 65 Defined clinical protocol	Yes	Matched for GA & birth weight	SLS vs operative fascial closure (23% failed primary closure)	OFC- 4 days (1–16) vs. SLS -0 days (0–19) P = 0.0001	No differences in time to feed or LOS. 73% of all neonates managed with SLS required no GA
Four studies compare primary repair vs. staged repair					
Three report TOTAL ventilator days and more ventilator days with **Staged repair**					
One (Pearl et al.**) reports post intervention vent days and more vent days with SLS**					
Alali et al. 2011 Eur J of Pediatr Surg N = 87	no	No comment	Primary fascial repair (PR) vs. staged repair (SR)	PR -one week or less on MV (66% in PR vs. 11% in SR, P < 0.01	Repair immediately after delivery is beneficial in terms of achieving primary closure of the defect, leading to shorter times on assisted ventilation and parenteral nutrition, and shorter hospital stays.
Dingemann et al. Euro J of Pediatr Surg 2017 N = 39	no	No comment	Primary vs. secondary closure	Primary closure in 72% of infants - shorter duration of ventilation P = 0.003	No mortality, and the type of surgical approach had no significant impact on the incidence of complications. Primary closure being associated -shorter duration of hospitalization (p < 0.001).
Kidd et al. Annals of Surg 2003 N = 118	yes	No comment	Primary closure vs. staged surg closure 1993–1997 32 vs 6 Primary vs SLS 1997–2003 27 vs. 53	Primary closure vs staged closures- 2.5 (3.6) vs 8.6 (4.8) days P = 0.008	Staged closure, introduction of SLS-resulted in a longer initial hospital stay and **more days of mechanical ventilation** but fewer cases of NEC, intestinal stricture, and reoperation. Less abdominal compartment syndrome
Pearl et al. Pediatr Surg International 2018 (data from 1998 to 2017) N = 150 Defined clinical pathway- irrigate bowel w mucolytic agent and aim for early closure	Yes- They were reported and analyzed separately	no significant difference	Primary closure vs. SLS	109 (77%) with a primary repair vs 33 (23%) with a SLS Days to extubation: 2 vs 9 days P < 0.05	A significant negative relationship identified between time to closure in hours and all outcome variables including length of stay, days on ventilator, days to initiate feeds, and days to full feeds. Recommends early evaluation and attempt to close.

3.5.4. *Adjunctive techniques*

Seven studies were examined to evaluate adjunctive techniques that facilitate safe fascial closure. Although several strategies exist in the literature, the evidence is weak. Two studies evaluated an intraoperative bladder pressure of >20 mm Hg to indicate likely failure of primary closure. Although this technique may change management in up to 70% of patients, both studies were case series without statistical analyses. Firm conclusions regarding the utility and clinical applicability of this approach cannot be drawn [73,74]. One reported no cases of oliguria or renal failure [73]. The second reported a similar oliguria/anuria rate of 33% for both primary and staged closure when intraoperative bladder pressure monitoring guided closure [74].

Similarly, two small case series evaluated the utility of intra-operative vascular duplex and gastric tonometry in guiding closure decisions, but no comparisons of outcomes are available [75,76].

One unadjusted retrospective cohort study that examined end-tidal CO2>50 mmHg as a cutoff for primary fascial closure found that

more patients achieved primary closure after implementation of this monitoring technique, with no change in clinical outcomes [77]. Another retrospective study looked at the association between fascial extending incisions and the length of TPN use and found that these were positively correlated but not independent of the factors driving the need for the fascial incision (e.g. complicated gastroschisis) [78].

The most useful study in this subset of articles was a 2012 retrospective cohort study that concluded the use of pre-closure paralysis was associated with prolonged time to closure and prolonged ventilator days. The associations persisted in the multivariate analysis [79].

3.6. Question 3 – section summary and recommendations

What are the outcomes for different closure strategies, (i) timing of repair, (ii) primary fascial closure vs. delayed repair after silo, (iii) sutured vs. sutureless closure, and (iv) adjunctive techniques and monitoring?

3.6.1. Timing of repair

Infant hemodynamic stability and viscero-abdominal disproportion are the primary considerations. Careful clinical evaluation, followed by closure within a few hours after birth, captures many infants that tolerate closure. This approach is acceptable and may be associated with a decreased time to feeding and LOS when achieved without physiologic disruption

- Grade C recommendation based on Level 3 evidence.

3.6.2. Primary fascial closure vs. delayed repair after silo

Primary repair without staged silo reduction should be attempted when physiologic status and abdominal domain permit, as this is associated with earlier initiation of feeds and decreased length of hospital stay

- Grade C recommendation based on **Level 2 evidence.**

3.6.3. Sutured vs. sutureless closure

Sutureless repair is safe, effective, and often associated with similar postoperative feeding and LOS metrics compared to sutured repair. If employed with a standard protocol to minimize sedation and intubation, the sutureless repair is associated with a decreased use of mechanical ventilation and anesthesia compared to sutured repair

- Grade B recommendation based on **Level 2 evidence.**

3.6.4. Adjunctive techniques and monitoring

Physiologic monitoring modalities that indicate elevated intra-abdominal pressure may inform decisions for surgeons competent with the techniques

- Grade D recommendation based on level 4 evidence.

Pre-closure paralysis should be avoided in infants with gastroschisis.

- Grade C recommendation based on level 4 evidence

4. Conclusions

This summarizes a review of a heterogenous body of literature on gastroschisis. The quality of the evidence available consisted of studies with a Level of Evidence ranging from 2 to 4 and Recommendation Grade between B and D. Several good quality retrospective studies exist; however, no well-designed RCT's have been performed. This speaks to the need for prospective, multicenter studies to better understand this rare condition.

Delivery before 37 weeks is not beneficial, and may be harmful, in that the complications of prematurity outweigh any identifiable benefit. Elective delivery at a minimum of 37 weeks PCA should be considered. This approach balances the risk of early delivery with infectious complications that increase as gestational age progresses past 38 weeks. Earlier delivery could reduce prenatal mortality, and the frequency or type of prenatal monitoring may also affect it, though these aspects are beyond the scope of this review.

Prophylactic narrow spectrum antibiotics to cover skin flora are adequate treatment to avoid infectious complications until the gastroschisis defect is closed. There is no guidance to suggest antibiotic duration, beyond an additional 24 h after closure is warranted. Comparative studies eliminating antibiotics do not exist. In some centers, this practice may reflect the common neonatology practice of administering antibiotics until sepsis is ruled out.

With respect to the timing of defect closure, when infant hemodynamics and viscero-abdominal disproportion permit, early fascial closure is feasible. A careful clinical evaluation of these parameters should guide timing and closure techniques. An association between early closure and earlier initiation of feeds was reported, but this may reflect the overall satisfactory infant status and may simply capture stable infants.

When choosing the approach to defect closure, a sutureless repair has advantages. Compared to sutured repair, this approach confers similar time to postoperative feeding and LOS, but has a decreased risk of post-closure wound infection. Standardized protocols may decrease the need for sedation, anesthesia and intubation, and therefore reduce need for mechanical ventilation. Routine, pre-closure paralysis should be avoided as it prolongs time on the ventilator. Physiologic monitoring modalities such as intravesical pressure, vascular duplex, end-tidal CO2 and gastric tonometry may guide abdominal wall closure and the use of sedation and paralysis; however, the data supporting this are weak. The effect of a management decision on postoperative outcomes (eg. mortality, LOS, ventilator parameters, nutritional metrics) is confounded by a myriad of other disease and treatment-related factors that can be difficult to define at a granular level and require comparative studies.

5. Limitations

This systematic review is limited by predominantly single-center studies with small sample sizes. Larger administrative dataset reviews were heterogeneous in their aims, hindering direct study-to-study comparisons. Some conclusions are based on our interpretation of evidence, preventing a comprehensive evidence-based review.

The timing of delivery section faces limitations due to significant heterogeneity in study design. Insights from the 28 reviewed articles suggest that early delivery before 34 weeks results in poorer outcomes due to prematurity-related complications, sepsis, and low birth weight. The optimal age for delivery is less certain, but improved outcomes are observed at 37 weeks or later. However, findings are compromised by outcome and delivery decision heterogeneity. Both RCTs attempting to address this question were

terminated early, limiting meaningful conclusions from these abbreviated efforts.

The limited number of articles on antibiotic use in gastroschisis hinders meaningful conclusions in this manuscript section. There is a notable need for more rigorous research on this topic to better guide clinicians in making decisions about antibiotic use and duration.

The concluding section on closure strategies and timing of repair encountered comparable issues with study heterogeneity. Variations included authors evaluating time to closure as a dichotomous categorical variable (e.g., repair before or after 4 h from birth) or as a continuous variable for linear regression models. Numerous studies lacked adjustments for confounding factors or disease severity. Additionally, while four articles explicitly excluded complex gastroschisis from their analysis, it wasn't always clear whether other studies distinguished between complex and simple gastroschisis patients.

Overall, the literature lacks sufficient Level I randomized or high-level comparative data, making it challenging to formulate practice recommendations for gastroschisis management. There is a notable demand for additional high-quality studies to inform more evidence-based decisions in the future.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jpedsurg.2024.03.044.

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