Routine use of a SILASTIC spring-loaded silo for infants with gastroschisis: a multicenter randomized controlled trial

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Abstract

Background: Retrospective studies have suggested that routine use of a preformed silo for infants with gastroschisis may be associated with improved outcomes. We performed a prospective multicenter randomized controlled trial to test this hypothesis.

Methods: Eligible infants were randomized to (1) routine bedside placement of a preformed Silastic spring-loaded silo, with gradual reduction and elective abdominal wall closure, or (2) primary closure.

Results: There were 27 infants in each group. There was no significant difference between groups with respect to age, weight, sex, Apgar scores, prenatal diagnosis, or mode of delivery. The total number of days on the ventilator was lower in the spring-loaded silo group, although it did not reach statistical significance (3.2 vs 5.3, \( P = .07 \)). There was no significant difference between groups with respect to length of time on total parenteral nutrition, length of stay, or incidence of sepsis and necrotizing enterocolitis.

Conclusion: Routine use of a preformed silo was associated with similar outcomes to primary closure for infants with gastroschisis but with a strong trend toward fewer days on the ventilator. Use of a preformed silo has the advantage of permitting definitive abdominal wall closure in a more elective setting.

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Gastroschisis is a congenital abdominal wall defect initially described by Calder [1] in 1733, which is typically located to the right of the umbilicus and associated with herniation of the midgut. The incidence of gastroschisis is approximately 1 to 4 per 10,000 live births and has recently...
been increasing [2-4]. Because gastroschisis is rarely associated with other anomalies, the major morbidity is because of intestinal damage that occurs during fetal life, resulting in poor mucosal function and bowel motility in the neonatal period [5].

Since Watkins [6] first reported successful primary closure of a small gastroschisis in 1943, most pediatric surgeons have advocated immediate reduction of the bowel into the abdomen and closure of the defect as the optimal method of management [7]. However, in cases where the bowel is significantly thickened or dilated, this cannot be performed without an unacceptable increase in intraabdominal pressure (IAP), which may lead to respiratory compromise, organ failure, and significant complications. To deal with this situation, Schuster [8] in 1967 described the use of a prosthetic material sewn to the abdominal wall, with gradual reduction of the viscera into the abdomen and fascial closure at a second procedure. In 1995, Fischer and colleagues first reported the use of a SILASTIC (Down Corning, Midland, Mich) spring-loaded silo that could be placed at the bedside without sutures or general anesthesia [9]. This technique has demonstrated improved outcomes with this technique compared to immediate closure in retrospective studies [10-12]. The aim of the present study was to evaluate routine use of the spring-loaded silo when compared with attempted primary closure for the treatment of infants with gastroschisis in a prospective, randomized controlled trial.

1. Methods

Children born with gastroschisis at the Hospital for Sick Children (Toronto, Ontario, Canada), Primary Children’s Medical Center (Salt Lake City, Utah), and University of North Carolina Children’s Hospital (Chapel Hill) were eligible for the study. Inclusion criteria were diagnosis of gastroschisis, birth weight of 1500 grams or greater, and gestational age of 34 weeks or more. Infants with suspected or visible intestinal atresia were eligible for enrollment into the study. Infants were excluded from the study if the abdominal wall defect was too small to admit a spring-loaded silo, if bowel ischemia or necrosis was present, if the child had other major anomalies or medical conditions (excluding intestinal atresia) or grade IV intraventricular hemorrhage, if the surgeon was unable to obtain informed consent, or if the surgeon preferred to delay the patient into the trial. Informed consent was obtained from all parents before enrollment into the study. Research ethics board approval was obtained at each participating center.

Patients were randomized to 1 of 2 groups: (1) routine bedside placement of a preformed Silastic spring-loaded silo (Bentec Medical Inc, Woodland, Calif, or Specialty Surgical Products, Inc, Victor, Mont), with gradual reduction and elective abdominal wall closure; or (2) immediate attempt at primary closure, with placement of a silo only if primary closure was unsuccessful. A randomization plan was generated by the lead center (Toronto) through an electronic Web-based randomization program, and patients were assigned to 1 of the 2 groups using the sealed-envelope method. Patients were randomized by the responsible surgeon at the time of enrollment. Parents of patients were informed immediately of the treatment assignment. Standard operating procedures were monitored by the study coordinator at each site to ensure appropriate methods were used to implement the random allocation sequence and the study protocol.

All of the surgeons who participated in the trial were fully trained and board-certified pediatric surgeons with prior experience performing gradual reduction with SLS and abdominal wall closure, and operated on patients from both treatment groups. Silo placement and gradual reduction were performed by the staff surgeon (Toronto, Salt Lake City, Chapel Hill) or by the pediatric surgical trainee from a 2-Year Pediatric Surgery Fellowship Program (Toronto).

Infants in the first group had a spring-loaded silo placed in the delivery room or the neonatal intensive care unit. Intubation was not routinely used, and sedation was only used if it was felt to be necessary by the surgeon. Reduction of the eviscerated bowel was accomplished by the daily application of gentle pressure, followed by the placement of a clip or umbilical tape across the silo to maintain the reduction. When the bowel was completely reduced, a clinical decision was made by the responsible surgeon for either silo removal and abdominal wall closure in the operating room under general anesthesia or abdominal wall closure at the bedside using the umbilical flap technique [13].

Infants in the second group underwent an attempt at primary closure. These infants underwent complete bowel reduction and abdominal wall closure, either in the operating room under general anesthesia or at the bedside using the technique described by Bianchi [14]. If the operating surgeon believed that primary closure would result in excessive IAP, a clinical decision was made to delay abdominal wall closure, and a spring-loaded silo was applied for gradual reduction and subsequent closure.

Maternal history, patient demographics, characteristics of the gastroschisis, intraoperative details, and postoperative data were collected on each patient. Maternal data included age, prenatal diagnosis, previous medical history and history of drug use (prescription or illicit drugs, tobacco, or alcohol), mode of delivery, and obstetric complications. Patient demographics included age, gestational age, weight, birth weight, and Apgar scores. Characteristics of the gastroschisis were recorded including the degree of eviscerated contents, size of the defect, presentation of the defect, degree of bowel injury as defined by the operating surgeon (1 = no apparent injury; 2 = mild injury; 3 = moderate injury; 4 = severe injury; 5 = extremely severe injury), and presence of atresia.
Intraoperative data collected included the precise timing of the abdominal wall closure, location of the surgical procedure, IAP as reflected by intragastric pressure, other procedures at the time of closure and complications. For infants enrolled in the spring-loaded silo group, details of the silo application and reductions, bowel assessment, and ventilation status were collected until the time of abdominal wall closure. For all patients, data collected daily during the first 14 days after the abdominal wall closure included ventilation status, use of total parenteral nutrition (TPN), details of feeding and complications.

Based on pilot data obtained during our retrospective study [10], a 2-sample t test power analysis was performed on the primary outcome (days on ventilator). To achieve 80% power with an $\alpha$ of .05, a total sample size of 88 patients (44 in each group) would be required. An interim analysis of the data after the first 44 patients was conducted with consideration for stopping criteria of statistically significant differences between the 2 treatment groups or the occurrence of unanticipated serious adverse events leading to significant risk to patients. All data were entered into a secured electronic database that was provided to each of the participating centers.

The primary outcome for this study was length of time on the ventilator. Secondary outcomes were length of time on TPN, length of hospital stay (LOS), IAP at the time of definitive abdominal closure, and incidence of sepsis and necrotizing enterocolitis (NEC). Two-sample t tests were performed for continuous data including the length of time infants received mechanical ventilation, length of time on TPN, LOS, and IAP. $\chi^2$ Analysis was performed for proportional data, such as incidence of NEC, episodes of culture-positive sepsis, and other complications, with a $P$ value of .05 considered significant.

### 2. Results

A total of 195 infants with gastroschisis were admitted to the participating centers between June 2001 and December 2006 (Fig. 1). After screening for eligibility and obtaining consent for enrollment, 55 patients were randomized (Toronto, 20; Chapel Hill, 6; Utah, 30), with 28 infants in the spring-loaded silo group and 27 infants in the primary closure group. One patient in the spring-loaded silo group was excluded from the study because of repeated dislodgment of the silo, requiring use of a sewn prosthetic device and inability to perform secondary closure. There were 14 surgeons who participated in the trial. Abdominal wall closure was performed by the staff surgeon and the number of cases completed by each participating surgeon were as follows: 14 for surgeon 1; 1 for surgeon 2; 1 for surgeon 3; 1 for surgeon 4; 1 for surgeon 5; 3 for surgeon 6; 1 for surgeon 7; 2 for surgeon 8; 3 for surgeon 9; 12 for surgeon 10; 4 for surgeon 11; 7 for surgeon 12; 2 for surgeon 13; 2 for surgeon 14. A total of 54 patients were included in the analysis, 27 infants in each group. The study was terminated in December 2006 despite not achieving the initial target of 88 patients, as it was felt that at the existing rate of patient accrual, it would take an extensive amount of time to enter a sufficient number of patients in the study; and during this period, other changes in perioperative management of surgical neonates may invalidate the study comparisons.

Maternal characteristics were not statistically different between the 2 groups (Table 1). Maternal age ranged from 16 to 33 years in the spring-loaded silo group and 15 to 30 in the primary closure group, with a mean age of 21.7 years in both groups. In the spring-loaded silo group, 19% of mothers reported drug use during pregnancy compared to 30% of mothers in the primary closure group. There was a prenatal diagnosis of gastroschisis in almost all cases in both groups. Of the 54 infants enrolled in the study, 51 (94%) were delivered vaginally, and there was no difference in mode of delivery between the 2 groups.

Patient characteristics at enrollment are shown in Table 2. There was no difference between groups with respect to gestational age, sex, weight, or Apgar scores. Characteristics of the gastroschisis defect are shown in Table 3. There was

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**Table 1** Maternal characteristics

<table>
<thead>
<tr>
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<th>SLS</th>
<th>PC</th>
<th>$P$</th>
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<tbody>
<tr>
<td>Age (y)</td>
<td>21.78 ± 4.2</td>
<td>21.70 ± 4.3</td>
<td>.95</td>
</tr>
<tr>
<td>Prenatally diagnosed (n = 54)</td>
<td>25 (93%)</td>
<td>26 (96%)</td>
<td>.63</td>
</tr>
<tr>
<td>Drug use (n = 54)</td>
<td>5 (19%)</td>
<td>8 (30%)</td>
<td>.34</td>
</tr>
<tr>
<td>Cesarean delivery (n = 54)</td>
<td>2 (7%)</td>
<td>1 (4%)</td>
<td>.55</td>
</tr>
</tbody>
</table>

Data are means ± SD. All $P$ values are not significant. SLS indicates spring-loaded silo intervention; PC, primary closure treatment.
no statistical difference between the 2 groups with respect to mean size of the defect, degree of injury, or presence of intestinal atresia.

Intention-to-treat analysis was performed on patients included in the study. Of the 27 patients that were included in the primary closure group, 20 were successfully closed immediately as described by the standard primary closure approach. For 7 of the primary closure patients, this was not possible because of high intraabdominal pressure at the time of attempted closure. These patients received a silo for gradual reduction and later abdominal wall closure. Mean age at definitive abdominal wall closure was 138 hours (5.8 days) among patients randomized to the spring-loaded silo group and 63 hours (2.6 days) for those randomized to the primary closure group ($P = .014$). Of the 54 patients included in the study, 51 (94%) had definitive abdominal wall closure in the operating room under general anesthesia, whereas the other 3 underwent bedside closure. These 3 patients were allocated to the spring-loaded silo treatment and were closed using the umbilical flap technique after 1 or 2 days of gradual reduction using a silo. None of our study patients died after abdominal wall closure.

Outcomes are presented in Table 4. Total number of days on the ventilator for the spring-loaded silo group was 3.17 ± 2.9 days compared with 5.29 ± 5.2 days for the primary closure patients ($P = .014$). Of the 54 patients included in the study, 51 (94%) had definitive abdominal wall closure in the operating room under general anesthesia, whereas the other 3 underwent bedside closure. These 3 patients were allocated to the spring-loaded silo treatment and were closed using the umbilical flap technique after 1 or 2 days of gradual reduction using a silo. None of our study patients died after abdominal wall closure.

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Patient characteristics</th>
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<tbody>
<tr>
<td></td>
<td>SLS</td>
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<tr>
<td>Gestational age (wk)</td>
<td>36.4 ± 1.2</td>
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<tr>
<td>Birth weight (g)</td>
<td>2446 ± 567</td>
</tr>
<tr>
<td>Sex (male/female)</td>
<td>9:18</td>
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<tr>
<td>Apgar score (1 min)</td>
<td>6.67 ± 2.5</td>
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<tr>
<td>Apgar score (5 min)</td>
<td>8.26 ± 1.4</td>
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</table>

Data are means ± SD. All $P$ values are not significant.

Outcomes comparing use of preformed spring-loaded silo vs primary closure

<table>
<thead>
<tr>
<th>Table 4</th>
<th>Outcomes comparing use of preformed spring-loaded silo vs primary closure</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>SLS</td>
</tr>
<tr>
<td>Days on ventilator</td>
<td>3.17 ± 2.9</td>
</tr>
<tr>
<td>Days on TPN</td>
<td>38.8 ± 33</td>
</tr>
<tr>
<td>Day in hospital</td>
<td>49.1 ± 34</td>
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<tr>
<td>IAP (mm Hg)</td>
<td>9.9 ± 3.9</td>
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<tr>
<td>Positive blood culture (%)</td>
<td>25.9</td>
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<tr>
<td>Incidence of NEC (%)</td>
<td>11.1</td>
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</table>

Data are means ± SD. All $P$ values are not significant.

3. Discussion

The optimal approach to abdominal closure for infants with gastroschisis has remained controversial over many years. The significant risk for morbidity and mortality associated with gastroschisis has prompted critical evaluation of current methods of treatment. Although most early reports documented better outcomes in children who underwent primary closure, these studies suffered from treatment...
bias because the children with severe intestinal damage were generally the ones that could not be closed primarily [7,15,16]. Several investigators in the 1980s and 1990s studied the phenomenon of ischemic bowel after primary closure for gastroschisis and suggested that elevated intraabdominal pressure was responsible [9,17-19]. Lacey et al [20] reported that intraoperative bladder pressure monitoring permitted appropriate silo placement and reduced postoperative bowel necrosis and renal failure. In 1996, Dimitriou et al [21] found that primary closure was associated with a temporary but significant deterioration in pulmonary function because of decreased respiratory compliance.

The advantages of using a preformed spring-loaded silo include ease of silo placement, optional use of general anesthesia or sedation, ability to visualize the bowel, and ability to reduce the bowel at an appropriate rate for each individual patient. Theoretically, routine gradual reduction using a spring-loaded silo should avoid sudden increases in IAP and therefore should minimize the incidence of pressure-related respiratory complications and intraabdominal organ hypoperfusion. These theoretical advantages have been demonstrated in a number of retrospective case series and comparative studies. In 2000, we compared 43 children undergoing routine spring-loaded silo insertion with a prior cohort of children undergoing attempted primary closure and found a shorter length of postoperative ventilation, lower postoperative airway pressure, shorter time to feeds and LOS, and a lower incidence of NEC and septic episodes [10]. Schlatter et al [12] found that routine use of the spring-loaded silo prevented the early dependence on ventilation seen with primary closure. They reported no erythema or vascular compromise in the spring-loaded silo patients. Intraabdominal pressure monitoring in Schlatter’s study was inconsistently measured in both groups, and conclusions about less abdominal wall tension in the spring-loaded silo were subjective. We had similar problems with surgeon compliance using either bladder or intragastric pressure to estimate IAP. Owen et al [11] compared routine staged reduction and closure at the bedside with no general anesthesia to immediate fascial closure under general anesthesia. They reported a significantly reduced number of days on mechanical ventilation for infants in the preformed silo group.

All of the previously mentioned studies suffered from their retrospective nature and the use of historical controls. Our goal was to compare routine use of the spring-loaded silo with the traditional primary closure approach in a prospective randomized manner. We found that the only differences between the groups were a shorter time of mechanical ventilation and lower IAP at the time of definitive closure. Although neither of these differences was statistically significant, the study was clearly underpowered according to our initial calculations, and we believe that both of these differences would likely have reached statistical significance if we had been able to achieve the desired numbers. Our inability to achieve our desired number of patients is a testament to the difficulties of performing randomized trials in neonatal surgical emergencies, particularly difficulty obtaining consent and difficulty achieving equipoise among pediatric surgeons [22].

As with many surgical procedures, continuous improvements in technique occur and novel approaches emerge over time. Bedside closure of gastroschisis without intubation or general anesthesia was described by Bianchi and Dickson [23] in 1998. They suggested that this technique was associated with improved cardiovascular, respiratory, and renal stability, without increased incidence of infection. In a later prospective study, they reported on 35 patients with gastroschisis, 25 of whom were successfully reduced and closed using this protocol. Jona [24] subsequently adapted this approach for the abdominal wall closure after use of the spring-loaded silo, also with excellent results. Because these innovations were introduced during the course of our study, we permitted surgeons to use bedside closure in both groups in our study, a change that was approved by the research ethics board. In specific circumstances, changes in technique have been previously allowed in other surgical randomized trials [25,26].

This trial was associated with a number of limitations. Most importantly, we experienced difficulty with patient enrollment because of parent refusal or absence for consent and individual surgeon preference not to randomize patients. Ultimately, this limited the number of patients enrolled and prevented adequate statistical power to be achieved. Lack of surgeon compliance also limited our ability to measure IAP adequately. The multicenter nature of the study likely resulted in differences in surgical technique and neonatal management of these children. To minimize this problem, randomization was done within each institution, so that the number of patients in each group was evenly distributed within each institution.

Despite its limitations, our study documents that infants with gastroschisis can be successfully managed with gradual reduction using the preformed spring-loaded silo followed by later closure and that this approach is at least as safe as an immediate attempt at primary closure. In addition, the routine use of a preformed spring-loaded silo permits definitive abdominal wall closure in a more elective setting.

References


