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The Use of Preformed Spring Loaded Silo on Delayed Primary Closure of Gastroschisis Patients at the Philippine Children's Medical Center

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Rationale: The objective of the study was to describe the outcome in a series of patients with delayed primary closure of gastroschisis using a Preformed Spring-Loaded Silo Bag (PSLS).

Methods: A prospective data collection and chart review were done all gastroschisis patients from May 2011 to April 2013. Eligible gastroschisis patients were applied with silo bag, gradual reduction of abdominal viscera and elective abdominal wall closure. The post-operative outcomes investigated were: infection rate, days to immediate fascial closure, post-operative ventilatory period, post-operative NPO period to successful enteral feeding, days in the NICU, days of hospital admission, development of post-operative complications, and mortality rate.

Results: Thirty-four gastroschisis patients were admitted from May 2011 to April 2013, of whom 25 patients qualified for the study. Majority of the patients were female, preterm, delivered vaginally, weighed <2 kg and admitted within the first 24hrs of life. 84% had prenatal ultrasound, less 50% were diagnosed correctly. 48% of mothers were less than 20 years old. Fascial closure rate was 88% (delayed abdominal closure done within 10 days). 72% were fed within 10 days after delayed abdominal wall closure. 52% were extubated within 24 hours. Average hospital stay was 35 days. Overall outcome: morbidity rate- 48%; home against medical advice (HAMA)-4%; mortality rate - 12%.

Conclusions: The use of PSLS bags for the delayed primary closure of gastroschisis appears to be a safe and beneficial.

Key words: gastroschisis, preformed spring-loaded silo bag, infant-newborn, abdominal wall, viscera

Gastroschisis is one of the most common congenital abdominal wall defects. It can be diagnosed prenatally through ultrasound. On physical examination, it can be identified with its lateral location (to the right of a normally inserted umbilicus) and the absence of covering sac.

Recent development of spring-loaded silo has changed the management of many of these patients. These silos have a ring opening appropriately larger than the gastroschisis abdominal wall defect. Thus, when the eviscerated intestine and other contents are placed in the silo, the ring can be placed below the level of the fascia. The silo can be attached to the patient in the delivery room, at the bedside, or in the operating room without the need for routine sedation or intubated general anesthesia. The viscera in the silo is gradually reduced daily into the peritoneal cavity. This reduction takes place at the bedside. When majority of the extravasated viscera has been fully reduced enough for a possible safe complete closure, the child is brought back to the operating room, the silo removed, and the fascia and skin surgically closed.

Reports in the foreign literature have claimed that delayed primary closure using preformed spring-loaded silo (PSLS) bags among gastroschisis patients has resulted in lower infection rate, decreased days to immediate fascial closure, fewer ventilatory support days, earlier start of enteral feeding[1], faster time to full enteral diet, decreased days on parenteral nutrition, shorter days of admission, and fewer complications.[2]

The authors sought to determine the outcome of using PSLS for delayed primary closure of Gastroschisis patients at the Philippine Children's Medical Center (PCMC). Specifically, they wanted to describe the clinico-demographic data of gastroschisis patients (age on admission, address,

sex, birth weight, APGAR scoring, maternal age and parity, mode of fetal delivery, its presence of prenatal diagnosis, size of abdominal wall defect, location of abdominal wall defect) surgically treated using the PSLS for delayed primary repair at PCMC. They would also determine the post-operative outcomes of these patients in terms of: infection rate, days to immediate fascial closure, post-operative ventilatory period, post-operative NPO period to successful enteral feeding, days in the NICU, days of hospital admission, development of post-operative complications, and mortality rate.

Methods

This is a prospective descriptive study of gastroschisis patients who underwent delayed primary closure using preformed spring loaded silo bag from May 2011 to April 2013. This study was approved by the Institutional Review Board-Ethics Committee of the PCMC.

The study was conducted at the PCMC Department of Pediatric Surgery. Pre and post operative care of gastroschisis patients was done at the neonatal intensive care unit. All Pediatric Surgery post-graduate fellows on-duty initially assessed and managed patients with gastroschisis. The over-all follow-up care of these patients however was undertaken by the principal investigator.

All neonates diagnosed with gastroschisis admitted from May 2011 to April 2013 were potential subjects. Inclusion criteria included neonates with gastroschisis with: 1) an abdominal wall defect to the right of a normally inserted umbilicus; absence of sac, 2) the presence of eviscerated abdominal organs, 3) a disproportionate volume of eviscerated bowel to abdominal wall cavity, 4) no co-morbid illness. Excluded were neonates: 1) whose eviscerated bowels were proportionate in volume to the expected abdominal cavity, 2) who presented with severe clinical sepsis or other associated anomalies (e.g. atresia, cardiac defect), 3) on continuous prolonged ventilator support prior to surgical assessment, 4) with failed attempts of primary closure at the operating room, 5) who were drop out cases (unable to complete the second stage of repair), 6) whose conditions were amenable to immediate primary repair or closure.

Only subjects with informed consent for the study were included. Confidentiality of the informants was strictly maintained.

The PSLS bag used (Figure 1) was a Ventral Wall Defect Silo Bag (Bentec Medical, Woodland, California, USA). Its open end was supported with a silicone elastomer tube containing a stainless steel coil. Sizes available according to coil diameter were 3 cm, 4 cm, 5 cm, 6 cm, 7 cm and 8 cm. Due to its prohibitive cost and limited supply, the PSLS was resterilized in gas sterilizer for re-use.

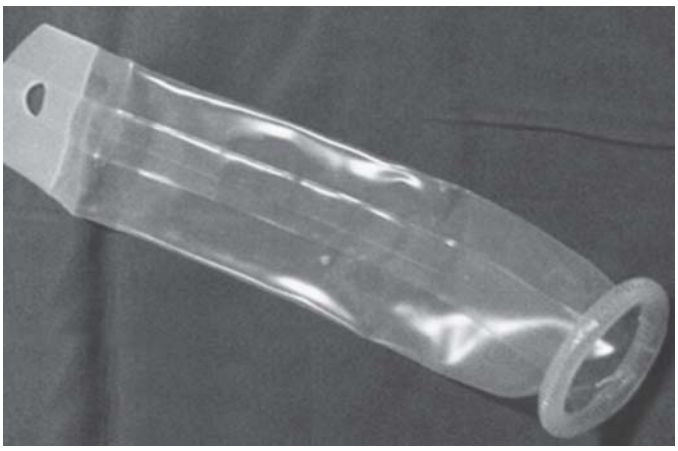

Figure 1. The preformed spring-loaded silo (PSLS) bags used in this study.

All patients with gastroschisis were stabilized and resuscitated prior to evaluation of the defect and eviscerated viscera. Evaluation of the abdominal wall defect and bowel rundown were done. Patients with eviscerated intestine underwent application of silo bag (Figure 2) after thorough lavage of the eviscerated bowels. The silo bag size would depend on the size of the defect (1 size higher than the defect). The subjects were sometimes given sedatives and/or pain medications during the manipulation of viscera and application of the silo bag. Application of silo bag was done at the

emergency room or at the NICU. After application of the silo bag, patients were observed for bowel and abdominal wall discoloration and O_2 saturation at the NICU for close monitoring. Manual reduction of the eviscerated bowel inside the silo was done on a daily basis. Delayed primary closure was considered after it was observed that the abdominal cavity could contain the residual volume of eviscerated bowel. This volume was usually reached within 5-7 days after silo bag application. The delayed primary fascial closure was performed at the operating room. The patient was returned to the NICU for post-operative critical care.

Figure 2. Photograph of the abdomen of a neonate with gastroschisis after application of a PSLS bag.

A standard case report form was used to collect information. The following subject data were collected: age, sex, birthday, birthweight, Apgar score, maternal age and parity, prenatal check-up history, and mode of delivery. The following clinical data were obtained: infection rate, days to immediate fascial closure, post-operative ventilatory period, post-operative NPO period to successful enteral feeding (OGT output: clear, less than 20 cm^3/kg/day), days in the NICU, days of hospital stay, development of post-operative complications both direct and indirect, and mortality rate.

There were 2 categories of complications, direct and indirect. Direct complications were attributable to negative effects of silo bag utilization: e.g. bowel or abdominal wall ischemia or necrosis, enterocutaneous fistula, surgical site infection, wound dehiscence, "popsicle effect" (cylindrical matting of bowels conforming to the silo bag due to a prolonged period of time of application). Indirect complications arose from associated medical problems (e.g. pneumothorax due to barotrauma; systemic infection).

Descriptive statistics were used to quantify the data collected.

Results

There were 34 gastroschisis patients admitted from May 2011 to April 2013. A total of 25 patients were included in the study. 9 patients were excluded due to the following reasons: 4 underwent primary abdominal wall closure, 2 patients had an associated small bowel atresia; 1 patient underwent transfer bag application instead of the PSLS bag due to very large, edematous bowels, and 2 patients after having undergone PSLS bag application, expired prior to the second stage procedure (drop outs).

Twenty (80%) of the patients admitted were aged less than 24 h. The oldest admitted neonate was 8 days old from Laguna. This patient was not immediately transferred to a specialized center due to lack of funds.

Thirteen (52%) of the patients were female and 12 (48%) were male.

Thirteen (52%) patients were referrals from different parts of Metro Manila and 12 (48%) came from the nearby provinces. Bulacan had the most number of referrals (8 patients). Some other patients came from Laguna, Batangas, Olongapo, and Catanduanes.

Patients weighing less than 2 kgs comprised more than half of the total number of patients, 14 (56%). The lightest patient weighed 1.05 kg, the heaviest weighted 2.7 kg. Both patients were successfully discharged improved.

Fourteen (56%) patients were delivered prematurely (<37 week AOG). The most pre-mature

patient admitted was 32 weeks old. This patient was discharged improved.

Twelve (48%) mothers were less than 20 years old. Eleven (44%) were aged 20-25 years. Two (8%) mothers were more than 25 years old. The youngest mother was 16 years old. This mother delivered the youngest of the patients (32 week old baby boy delivered via cesarean section for oligohydramnios). Both were discharged, improved.

Ten (40%) mothers were primigravid, while 15 (60%) were multigravid (10 mothers were gravida 2, 5 mothers were gravida 3).

Majority of the patients were delivered via normal spontaneous vaginal delivery, 23 (92%). Only 2 (8%) patients were delivered thru cesarean section due to the following indications: oligohydramnios (outborn) and repeat cesarean section (inborn).

Nine (36%) of the patients were delivered in this institution (no mortality) while 12 (48%) patients were delivered in a non-specialized general hospital: 8 in lying-in clinics, 4 in local primary hospital (1 mortality), and 4 (16) were delivered at home (2 mortalities).

Twenty-one (84%) patients had prenatal ultrasound however only 10 patients were diagnosed correctly while the 11 had normal ultrasound findings. Four (16%) mothers did not have any prenatal ultrasound. Nine out of 10 correctly diagnosed patients thru prenatal ultrasound were delivered in this institution.

Twenty-two (88%) patients underwent delayed primary full thickness (fascial) abdominal wall closure: 20 patients were discharged improved, 1 patient was brought home against medical advice and 1 patient expired at 47 days of age. Two (8%) patients had delayed primary skin closure: 1 patient expired, the other patient was discharged improved and another underwent synthetic mesh application (this patient expired at 40 days of age).

Twenty-one (84%) patients underwent delayed primary abdominal wall repair within 5 to 10 days after application of the PSLS bag. Four (16%) underwent the staged closure more than 10 days after post silo bag application. Two patients who had the longest PSLS bag application (15 days) required subsequent mesh application and skin closure respectively. Both patients subsequently expired.

Thirteen (52%) patients were extubated 24 h post closure: 6 were extubated immediately post-operatively, 7 were extubated within 24 h. Twelve (12) patients were intubated for more than 48 h after surgery. The longest time a patient was intubated was 13 days. This patient manifested respiratory distress due to right pneumothorax which required chest tube drainage.

Two (8) patients were fed less than 5 days post closure (fed at 4th post closure day). Sixteen (64%) patients were fed within 5 to 10 days. Six (24%) patients took more than 10 days to start feeding. The longest time for feed initiation was 17 days. Only 1 (4%) patient did not tolerate any form of feeding and eventually expired.

Fourteen (56%) patients had bowel movement within 24 h post closure while 11 (44%) had bowel movement after 24 h post closure. The longest was 7 days.

All of the patients had TPN with a duration of more than 10 days. The shortest was 12 days and the longest was 51 days.

All patients were admitted at NICU for more than 10 days. The shortest stay was 11 days and the longest was 49 days. The average NICU stay was 21 days.

Eleven (44%) were discharged within 3-4 weeks after admission. Fourteen (56%) had a total hospital stay of more than 1 month. The shortest hospital stay was 13 days and the longest was 92 days. The average hospital stay was 35 days.

Of the 25 patients included in the study, 12 had various complications (Figure 3): enterocutaneous fistula-2, "popsicle" phenomenon-1, SSI (surgical site infection)-4, bowel gangrene -1, pneumothorax-3, and CNS infection-1.

Over-all outcome: morbidity rate was 48% and mortality rate was 12%. Of the 3 mortalities, 2 were delivered at home and 1 was delivered at a local hospital. There were no mortalities in the patients delivered in this institution. Twenty-one (84%) subjects were discharged, improved. One (4%) patient went home against medical advice.

Discussion

Gastroschisis is a common surgical problem with an incidence of 1:6,000-10,000 live births compared to omphalocele of 1:4,000.3 In PCMC, there were 34 cases of gastroschisis admitted from May 2011 to April 2013, with only 3 omphalocele cases.

The immediate care focuses on protecting the eviscerated bowel, preventing hypothermia, and providing appropriate fluid resuscitation.[4] Two features of gastroschisis make the initial care somewhat different from that of omphalocele. The patient is frequently premature, and closer attention must be done for heat preservation, respiratory support, and the large surface area of exposed intestine. The latter is also responsible for increased fluid needs and heat loss.[5]

The primary goal of surgical treatment is complete closure of all the layers of the abdominal wall (i.e. muscles, fascia, and skin). This can be achieved through either definitive closure or staged repair. If the extraperitoneal viscera can be placed in the peritoneal cavity without difficulty and without undue intraabdominal pressure, then a one- stage repair is preferable.[4] In more than one-half of the cases, a primary closure cannot be performed and alternatives must be selected. Options include skin coverage without closing the fascia, the use of a synthetic or biologic patch to close the defect if reduction is complete but closure of the fascia is unsafe, or the use of an abdominal wall silo.

Over the years, the outcomes of gastroschisis patients have greatly improved due to improvement in specialized neonatal intensive care, availability of parenteral nutrition, and improved surgical technique of staged eviscerated bowel reduction for delayed primary closure. The survival rate now of these infants has exceeded 90%.[5] The staged reduction has evolved through the years. In 1967, Schuster developed a mesh silo to hold herniated viscera temporarily until primary closure.[3] The spring loaded silo in 1995 which had the advantage of avoiding the need for fascial sutures. These silo bags were first introduced in 1995.[7] Majority of the developed countries use this commercially available silo bag. Some countries, particularly developing countries, still use improvised devices such as: ~~these are~~ blood transfusion bags, sterile surgical gloves, and Bogota bags. In the Philippines, very few institutions used this commercial PSLS bag for their gastroschisis patients due to its cost and unavailability. Majority of the tertiary centers still use the blood transfusion bags.

The clinical profile of gastroschisis patients admitted in PCMC is comparable to that seen in foreign literature. More than half of these patients were premature and had a low birthweight. These two factors increase the risk for the over-all negative outcome.[8]

Of the patients who underwent fascial closure, only 1 expired. The 2 other mortalities underwent skin closure only and mesh application.

Initial post-operative enteral feedings were also started within 5-10 days and reached full feeds within 4 to 5 days from its initiation. Comparatively, in the study by Robert Minkes, et al.[1] full feeding was reached at day 21 on the average. Days under ventilator support were dramatically shorter on these gastroschisis patients. Majority were extubated within 24 hours. Patients undergoing immediate primary closure were discharged earlier compared to patients who underwent delayed primary closure. Majority of these patients were not discharged immediately due to financial concerns. The PCMC gastroschisis patients who underwent delayed primary staged closure had an average length of 35 hospital days (international studies: 26 days).[1]

The common complications of abdominal wall closure are wound dehiscence, enterocutaneous fistula formation and abdominal compartment syndrome. There were several complications noted in the study: surgical site infection, bowel gangrene, entrocutaneous fistula. A number of patients developed pneumothorax after abdominal wall defect repair - 12%. In this study, an 8 percent complication rate secondary to pneumothorax was noted. A review of gastroschisis patients admitted at the PCMC from 2009 to 2013 showed a steady decline in mortality rate. In 2009 - 27.2%; 2010 - 20%; 2011 - 17.39%, 2012- 8.3% and as of April 2013 - 0% mortality rate.

Shorter hospital stay, shorter days for ventilator support, and early start of enteral feeding are among the few advantages observed for patients who underwent delayed primary staged repair procedure with the use of PSLS bags.

Conclusions

The use of PSLS bags for the delayed primary closure of gastroschisis appears to be a safe and beneficial.

The authors recommend studies comparing: 1) the use of PSLS bag and the traditional use of transfer (blood) bag, 2) locally made and commercially produced spring loaded silo bags, 3) the use of preformed spring loaded silo bag vs primary closure for gastroschisis patients.

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