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Comparison of outcome of preformed silo with traditionally constructed silo among neonates with gastroschisis

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ABSTRACT

Aims: The study aimed to observe the usefulness of a preformed silo (PFS) made of Alexis wound protector/ retractor in comparison to those patients undergoing traditionally constructed silo under general anesthesia (GA).

Methods: This is a quasi-experimental study conducted in the Division of Paediatric Surgery, Bangladesh Shishu Hospital, from October 2022 to March 2024. Patients were randomly divided into group A and group B respectively. Group A, PFS using a Alexis wound retractor/protector was done without the use of GA, and the bowel was gradually allowed to reduce into the abdominal cavity. For group B, the traditional silo was constructed using a urobag under GA after doing the proper preoperative preparations. Outcome variable arrival to procedure time, bowel reduction time, initiation of first enteral feed, survival duration, and mortality were recorded and compared.

Results: A total of 60 patients with gastroschisis were enrolled in this study, of which 30 patients in each group. Both groups had a mean age of 1 day with a gestational age of 36 weeks respectively. The PFS group showed a longer survival duration of around 22 days and with the traditional silo around 12 days respectively. Initiation of enteral feed after closure was on the 5th postoperative day (POD) for the traditional silo and the 3rd POD for the PFS. Mortality of 48% in the PFS group and 52% in the traditional silo group.

Conclusion: PFS (Alexis wound retractor) can bypass the hazards of GA and can become a safer alternative to traditionally constructed silo, particularly in resource-limited settings.

Keywords: Gastroschisis, preformed silo, Alexis wound retractor, traditional silo

INTRODUCTION

Gastroschisis is one of the most common congenital abnormalities, with a growing global incidence. This anomaly of the newborn causes the intestinal loops to protrude out through an abnormal opening in the abdominal wall. This opening commonly occurs on the right of the umbilicus. The incidence is about 2 to 5 per 10.000 live births, with a male preponderance.[1] Worldwide, there is a significant variation in the outcomes for newborns with gastroschisis. Most low and middle-income countries (LMICs) report higher mortality rates between 75% and 100% compared with <4% in high-income countries (HICs).[2] This difference in mortality is mainly due to the advanced management protocol strategies of resuscitation followed by HICs. The strategies include maintenance of temperature, fluid and electrolyte balance, nutritional support, cardiopulmonary support, and ventilation support. Initial bowel coverage, and subsequently visceral reduction by primary or delayed staged closure, along with total parenteral nutrition (TPN) support which is easily available in the developed countries, unlike the low-income countries like Bangladesh.[2] Many researchers encountered promising results, with reduced mortality by implementing the use of preformed silo (PFS) in low-income countries.[3]

Gastroschisis patients require immediate and urgent care due to their prematurity and large exposed area of bowel which warrants close attention. The unprotected bowel requires preservation of heat, prevention of loss of fluid along with respiratory support. The earlier the bowel is covered and allowed to reduce, the less chance of bowel edema and fibrinous coating to accumulate over the open intestinal loops.[4] To minimize heat loss, and water loss and to prevent the intestinal injury from worsening, the first line of treatment should focus on rapid and immediate repositioning and covering of the exposed bowel in order to reduce the mortality.[5]

Treatment options for the reduction of contents of gastroschisis vary greatly. Traditionally, the most common techniques

include primary closure or delayed staged closure by traditional silos under anesthesia or delayed staged closure using a PFS at the patient's bedside without general anesthesia (GA).[6] With a reported success rate ranging from 50% to 83%, immediate primary closure can be carried out in the operating room under GA in places where facilities are available. Immediate closure has benefits such as preventing further intestinal inflammation from mechanical irritation and exposure, allowing for earlier enteral feed initiation, reducing the duration of hospital stay (LOS), and lowering the risk of wound infection. But primary closure comes with drawbacks such as the requirement for GA, an increase in ventilator days, the need for nutritional care like TPN, NICU support, and complications like abdominal compartment syndrome (ACS).[7]

Nevertheless, primary closure is not always possible, in the case of patients who have excessively thickened, distended bowel (matting), small abdominal domain, or complex gastroschisis (atresia, necrosis, perforation) which may require delayed staged closure, which can be further achieved by either by a traditional or PFS. A traditional silo is mostly constructed using a Saline bag or a Urobag sutured around the defect, requiring preoperative preparation and GA. The delayed staged closure lowers the risk of ACS, and decreased ventilator days. Both primary closure and traditional silo require GA, neonates account for about 55% of anesthetic-related cardiac arrests, with 82% occurring during induction. Respiratory risks of anesthesia include laryngospasm, airway obstruction, and difficult intubation. Recent studies have also revealed the toxic effects of general anesthetics on pediatric patients. Neonates are also more prone to developing malignant hyperthermia.[8]

A PFS, consists of a transparent silastic bag with a spring-loaded ring, which has been introduced and extensively used over the past 20 years, to avoid GA. Others have used bedside reduction without anesthesia (Bianchi Procedure)[9], Alexis wound protector/ retractor as PFS used for staged reduction at the cot side, in places where spring loaded PFS is not available or is expensive.[10] Advantages of PFSs include, their low technological needs, ability to be administered at the bedside by any health care professional, and avoidance of newborn anesthesia and surgery. PFS negates the need for critical care due to less chance of developing ACS.[11]

PFS has also been shown to be successful in decreasing mortality in low-resource environments where there are insufficient frameworks, inconsistent availability of pediatric surgeons, and inadequate staffing and training for newborn anesthesia and surgery.[2] Bangladesh, being a developing country, suffers from, a lack of resources, social prejudice, and insuffiecient information. Along with inexperienced health workers and medical personnel, who play a vital role in the management of patients with gastroschisis.[12] The PFS may help bypass the modulates that are scarce in developing countries like Bangladesh.[13] The use of Alexis wound protector/retractor as PFS in places where PFS was not easily available has helped to reduce mortality in countries with limited logistics.[14]

This study aims to observe the usefulness of a PFS made of Alexis wound protector/retractor and to compare its outcome with those of babies undergoing traditionally constructed silo under GA.

METHODS

The study was carried out with the permission of the Ethical Committee Bangladesh Shishu Hospital and Institute (Date: 25.10.2022, Decision No: 2023702). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

This was a quasi-experimental study. This study approach was selected as random assignment of neonates to either treatment modality was not feasible due to ethical concerns and clinical protocols. The study was conducted in Bangladesh Shishu Hospital and Institute (BSHI), Dhaka, Bangladesh, from October 2022 to March 2024.

Neonates with gastroschisis admitted to Bangladesh Shishu Hospital and Institute (BSHI) were included in this study. Complicated gastroschisis (with atresia, perforation, volvulus) and patients with any major congenital anomalies like (diabetes mellitus, and congenital cyanotic heart disease) were excluded from this study.

Convenient purposive sampling was done. Total of 60 patients were included in this study and divided into two groups, group A (PFS) and group B (Traditionally constructed) silo with 30 patients in each group. Out of the study population, the individual sample units were selected according to clinical judgment until the desired sample size was attained. The sample size was determined based on a power analysis conducted during the study design phase. Using G*power software, we estimated that a sample size of 60 would provide adequate statistical power (0.80) to detect a medium effect size (Cohen's d=0.5) with a significance level (α) of 0.05 for an independent t-test comparing the two groups. Practical considerations, such as the availability of participants and resource constraints were also taken into account.

The demographic data was extracted using pre-designed questionnaire. The outcome parameters included the arrival to procedure time, bowel reduction time, initiation of enteral feed after closure, survival duration, and mortality. Patients in each group were not under any regular prenatal follow up detection of defect was at birth for both groups. No post-discharge follow-up was included in this study.

Study Procedure

All gastroschisis patients were managed under the close guidance of pediatric surgeons.

Initial management: Bowel protection with a translucent bag, for temperature regulation and homeostasis, and for prevention of evaporative losses. The presence of hypoxia, hypothermia, and dehydration was recorded. The presence of hypoxia was measured by using a pulse oximeter, temperature was measured using an electronic thermometer. The presence of dehydration was noted by the presence of depressed fontanelle, sunken eyes, skin pinch, and urine output.

An initial examination of the intestines was done to exclude obvious findings of atresia, necrosis, perforation, or volvulus. Bowel condition, presence of edema, matting, perforation, or necrosis recorded. A nasogastric tube was placed for gut decompression and a urinary catheter was introduced to

empty the urinary bladder. Intravenous access was acquired for fluid resuscitation. Patient weight recorded. Patients who met the inclusion criteria were randomly divided into group A and group B respectively.

For group A: PFS (Alexis wound retractor/protector) made of a colorless transparent polyurethane film wrap, having two rings at both ends was used. The bottom ring is blue and is flexible, the upper ring is white and folds on itself. After the initial management, the intestinal loops were placed inside via the bottom ring into the silo, the bottom end of the PFS was then carefully introduced into the abdominal cavity, in the operative room without the use of GA and mechanical ventilation (**Figure 1**). The upper ring was then twisted and the opening was tied with a gauge or suture material, then the ring was folded on itself to keep slight pressure on the abdominal wall (**Figure 2**). Analgesic was given per-rectally. The silo is checked daily, and the reduction time is recorded (**Figure 3**). After Application of PFS (Alexis wound retractor).

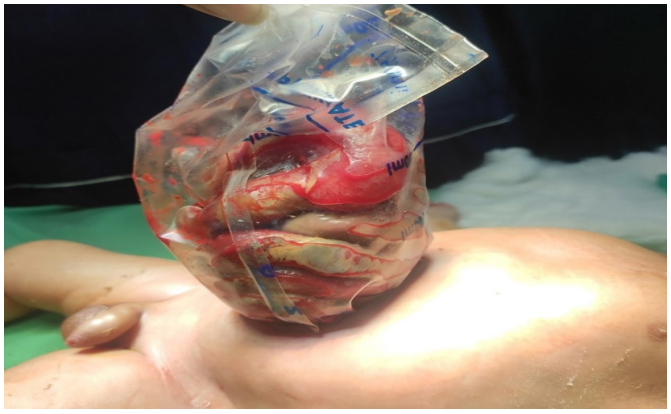

Figure 1. After application of traditional silo

Figure 2. Application of preformed silo (Alexis wound retractor), after insertion of the bottom ring within abdominal cavity, the upper ring twisted and tied with suture material to allow pressure to be exerted on the abdominal wall

Figure 3. Serial reduction with preformed silo

For group B: Preoperative anesthetic investigations done. Traditional silo constructed under GA. After induction of the anesthesia, a sterile Urobag was taken and cut to an appropriate size according to the gastroschisis defect, the Urobag was then sutured around the defect. The silo was checked daily and the reduction time was recorded.

After the procedure: The daily decrease of the bowel content within the silo inspected, the days required for reduction recorded.

After Complete Reduction

Group A: Closure was done in the operation theatre without GA.

Group B: Closure was done in the operation room under GA.

After closure, the postoperative day (POD) of initiation of the first enteral feed was recorded.

A complete blood count with peripheral blood, C-reactive protein, and blood culture was sent when sepsis was suspected.

Statistical Analysis

Data were coded, entered, and analyzed in a computer. The statistical analysis was conducted using SPSS (Statistical Package for Social Science) version 26 statistical software. The findings of the study were presented by frequency, and percentage in tables. Mean and standard deviation for continuous variables and frequency distribution for categorical variables were used to describe the characteristics of the total samples. Associations of continuous data were assessed using student t-tests. Fisher's exact test was used for mortality. The value of $p<0.05$ was considered significant.

Operational Definitions

1. Arrival time: Time taken in hours for the patient to reach the hospital after birth.

2. Reduction time: Time taken in days for the eviscerated bowel to return to the abdomen and be ready for closure.

3. Survival duration: Time in days from procedure to discharge or death.

RESULTS

In both groups A and B, most patients presented at the age of 1 day, with no significant difference (**Table 1**). Both groups A and B had similar gestational age of 36 weeks, with a p-value of 0.819 which was not significant (**Table 1**). In both group A and B.

Table 1. Comparison of demographic variables between group A and group B

Variables	Group A n=30 f (%)	Group B n=30 f (%)	p-value
Age (days) Mean±SD (range)	1.5±0.51 (1-2)	1.4±0.57 (1-3)	0.600
Gestational age (weeks) mean±SD (range)	36.4±0.86 (33-37)	36.2±0.82 (34-38)	0.819
Weight at birth (kg) mean±SD (range)	2.16±0.37 (1.5-3.0)	2.22±0.44 (1.5-3.2)	0.126
Hospital arrival time (hours) mean±SD (range)	8.70±1.60 (6-12)	8.97±1.90 (5-12)	0.344

SD: Standart deviation

The weights for both group A and group B were also similar about 2 kg, with no significant difference (**Table 1**). In both groups, the maximum arrival time was 12 hours, with a p-value of 0.344 showing no significant difference (**Table 1**).

For group A arrival to procedure time was a maximum of 3 hrs and for group B, the maximum time taken from arrival to procedure was 11 hours. The results were statistically significant (p-value: 0.0001) (**Table 2**). In group A most patients required a mean of 5 days for complete reduction and in group B most patients required a mean of 8 days for complete reduction. The difference between the groups was not statistically significant (**Table 2**).

Table 2. Comparison of variables between group A and group B

	Group A (preformed silo) (n)	Group B (traditional silo) (n)	p-value
Arrival to procedure (hours)	2.33±0.48 (30)	9.43±1.07 (30)	0.0001
Bowel reduction time (days)	5.33±0.48 (30)	7.80±0.55 (30)	0.796
Start of enteral feed after closure, POD (days)	2.73±0.45 (26)	5.14±0.36 (21)	0.034
Survival duration (days)	22.97±3.56 (30)	12.47±3.50 (30)	0.479
Mortality	48% (26)	52% (28)	0.268
Cost of procedure	4000 BDT	12000 BDT	

POD: Postoperative day

The enteral feed initiation was possible on the 3rd post-operative day for group A. Whereas for group B enteral feed initiation was possible on the 5th the post-operative day. The number of patients varied in each group as some patients expired before enteral feed could be started. The results were significant with a p-value of 0.034 (**Table 2**).

Survival duration for group A was around 22 days, and in group B survival duration was around 12 days. This difference between the two groups was not significant with a p- p-value of 0.479 (**Table 2**). Mortality was 48% in group A and 52% in group B respectively (**Table 2**). The main cause mortality was sepsis which was determined by blood culture. In both groups, onset of sepsis was detected on 3rd to 5th day after procedure, the cause of sepsis was determined to be nosocomial infection in few of the cases but most cases the cause remained undetermined, detailed determinant of sepsis was not included in this study.

DISCUSSION

This study was carried out in order to compare whether the PFS (Alexis wound retractor) can be used as an alternative to Traditionally constructed silo.

In this study, the arrival to procedure time in the PFS group, which was placed without GA, was significantly lower ranging from 2-3 hours compared to traditionally constructed silo which was done under GA and yielded a range of 8-11 hours, the time taken from arrival to the procedure was statistically significant in this study. Previous research showed PFS allowed for faster application, bypassing GA, operation, and avoiding hand sewing of silo, unlike traditional silo construction which is in agreement with this study.[3,15,16] The requirement for GA, and endotracheal tube insertion leads to an increased risk of neurotoxicity, the PFS can help bypass these added risks.[13,17]

The present study result reflects that the bowel reduction time was shorter in the PFS group, compared to the bowel reduction time in the traditionally constructed silo group, even though the results were statistically not significant, these findings are in parallel with the research which demonstrated shorter bowel reduction time was achievable with the use of PFS which leads to the early establishment of enteral feed.[18] The PFS allowed equal dissemination of pressure along the abdominal wall due to the presence of the uniform circular ring unlike the traditionally constructed silo where hand sewing is required, this differences in pressure distribution may have contributed to the difference in results.[18]

In this current study, the initiation of enteral feed after closure was earlier in the PFS group with the highest frequency occurring on the 3rd POD compared to the traditionally constructed silo group where the highest frequency occurred on the 5th POD, these results were statistically significant and are in alignment with conclusions made in studies by.[13,19] Who reported earlier first feed was achievable with the use of PFS. Application of PFS followed by delayed closure in infants with gastroschisis was associated with rapid return of bowel function was also reported in a study by.[20] Early initiation of enteral feed can lead to better outcomes as reported in previous studies.[21] As no GA or surgical trauma was inflicted for the PFS, no delay in reversal of bowel movement was encountered, which may have contributed to the similarities in results.

In this study, the survival duration for the patients with gastroschisis treated with the PFS was higher compared to the patients treated with traditionally constructed silo but these results were not statistically significant. There were no similar studies comparing survival duration between preformed and traditional silos. However, some studies have concluded that the survival duration was not dependent on the type of intervention, in the case of gastroschisis management.[22]

This study reports showed that the mortality was similar in both groups, with 48% mortality in the PFS group and 52% mortality in the traditionally constructed silo respectively. The main cause of death was found to be sepsis in both groups. This can be explained by the deficiency in the neonatal friendly environment, non-availability of NICU, improper immediate primary resuscitation, and absence of TPN. The type of intervention did not play a role in the mortality of patients in both groups, these findings were in conjunction with other study findings.[23] Unhygienic health delivery systems including maternal and neonatal health, poor transportation facilities without stabilization, delay in presentation, and late referrals make the situation worse and result in poor outcomes. Nosocomial infection, antimicrobial resistance, sharing wards, and equipments have all been identified as the source of sepsis for neonates leading to a high mortality in developing countries.[24] According to reports it is suggested that gastroschisis can become an important indicator in reflecting the ability of an institute to provide proper and adequate healthcare.[25]

In the present study, both groups presented with a gestational age of 36 weeks mostly preterm, with a high frequency of birth

weight of 2 kg, with a male predominance of 68% similar to other studies.[26,27]

These previous authors have concluded that gastroschisis with a lower birth weight can lead to poor outcomes due to their increased susceptibility to infection and need for nutritional support.

Most of the patients in this study, similar to previous research, had a delay in hospital arrival with a maximum of 12 hours in each group but this was not statistically significant in this study.[28] Even though it was not statistically significant this delay in hospital arrival with inadequate resuscitation may eventually contribute to unfavourable outcomes. Late presentation to the tertiary centers without adequate resuscitation is a major problem in the management of gastroschisis in low-resource framework was reported.[29]

The cost of PFS in comparison to traditionally constructed was quite low as reflected in the present study. Thus with the limited logistics, the PFS can be used in place of the traditional use of primary closure or traditional silo, avoiding the need for neonatal anesthesia and surgery, thus helping to improve the mortality in developing countries like Bangladesh.[14]

Limitations

- Birth to arrival time was not under the control of the researcher.
- The neonatal friendly environment could not be ensured in all cases.
- Long term follow-up and post-discharge data was not included in this study.

Recommendation

- Alexis wound retractor can be used as an alternative for traditionally constructed silos.
- Further comparative study between both these procedures with optimal perioperative conditions should be carried out.

CONCLUSION

As an alternative to traditionally constructed silos, PFSs can avoid the risks associated with GA and can be a more affordable and safer option, particularly in resource constraints environment. However, to greatly increase these patients' chances of survival, enhanced perioperative neonatal care is needed.

ETHICAL DECLARATIONS

Ethics Committee Approval

The study was carried out with the permission of Ethical Committee Bangladesh Shishu Hospital and Institute (Date: 25.10.2022, Decision No: BSHI/2022/2645).

Informed Consent

Written informed consent was obtained from the parents of all patients.

Referee Evaluation Process

Externally peer-reviewed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

The authors declared that this study has received no financial support.

Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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