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Ruptured Omphalocele and Gastroschisis: An 8year Experience WithThe Use of Female Condom (Femidom) As an Improvised Silo.

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Abstract
Background:*Omphalocele and gastroschisis are the most common anterior abdominal wall defects. In developed countries, various methods ranging from primary closure to staged closure using preformed silo have been developed in managing ruptured omphalocele and gastroschisis with excellent results. in our setting, mortality is quite high. In a bid to improve our outcome, we adopted the use of femidom in place of urobag as silo. We hereby, present our experience with the use of femidom comparing it with our former urobag silo.*
Materials and methods*: In this study, we collected data retrospectively for patients who were managed with urobag and prospectively for those managed using femidom. Patients were grouped into urobag group and femidom group for the purpose of analysis where outcomes were compared*
Results:*We had 52 patients included in this study. There were 12 patients who fell into the urobag group, 6 patients diagnosed as having gastroschisis and ruptured omphalocele each. mean birth weight was 2.26 kg. the mean waiting time for silo application was 4.7 hours. Mortality was 100%. In the femidom group the mean weight was 2.4kg and mean waiting time for silo application was 2.7 hours. Mortality was 50%.*
Conclusion*: we have found the use of femidom which is readily available, to have reduced our mortality rate from 100% to 50%. Though this rate is still not acceptable, if combined with a functional neonatal intensive care and nutritional supports we could achieve even a lower mortality rate.*
Key word: *Ruptured Omphalocele; Gastroschisis; Urobag; Femidom; Outcome.*

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I. Introduction

Anterior abdominal defects present a barrage of management decision making protocols to paediatric surgeons. omphalocele and gastroschisis are the most common anterior abdominal wall defects encountered in paediatric surgical practice.(1) omphalocele has an incidence of 4.3:10,000 live births and still births with a male to female ratio of2:1. (2) Omphalocele is associated with other anomalies like trisomies , Beckwith-Weidemann syndrome and malrotation. Omphalocele can be classified broadly into 3; omphalocele minor, giant omphalocele and ruptured omphalocele.(3)

Gastroschisis has an incidence of 4.72:10,000live births.(2) There has been reported evidence of increasing incidence of gastroschisis. This has been attributed to increased use of ecstatic drugs during pregnancy. some authors attributed this increase to decrease rate of abortion of foetuses with gastroschisis, knowing gastroschisis has a better prognosis (2) Gastroschisis can be classified into simple or complex(4)

Surgeons have used various methods to treat ruptured omphalocele and gastroschisis with different outcomes(5)(6) Some have used primary closure or delayed primary closure for omphalocele. Management of ruptured omphalocele and gastroschisis poses even greater challenge. There is no consensus in the ideal method of management of gastroschisis and ruptured omphalocele. It involves the use of ventilators, parenteral nutrition in a neonatal intensive care unit. Method of closure vary depending on the centres involved.It ranges from primary closure to use of preformed silos, to even use of. even though some studies show showed a longer ventilator requirement and nutritional support in patients who had performed silo application, when comparing primary vs staged closure.(7, 8) more studies have showed that those who had pre-formed silos required less ventilator support period than those who had primary closure.(9, 10) A multicentre randomised controlled trial however, showed no significant statistical difference between the 2 groups on requirement for nutritional

support and ventilator use even though there was a reduction of the total number of days on ventilators in those whom sprig loaded silo was used(11) In all these studies, the use of silo has been shown to be as safe and effective as for primary repair in centres with resources involved in the management of these defects. Prognosis is generally excellent ranging between 90-97% with a mortality rate of 3-10%(8) In reference to quality of life, there has been documented neurodevelopmental challenges patients with this defects face in life(3)

In low and middle income countries (LMICs) like Africa, management of these defects is faced with myriad of challenges ranging from near absence of prenatal diagnosis, home deliveries, delayed presentation to the hospital, unavailability of preformed silos and mesh. There is also limited expertise in neonatal anaesthesia, absent ventilator support and near complete absence of parenteral support in neonates(12). This has led to an unacceptable high mortality rate of between 18.6 -100%(13, 14)

An earlier retrospective study done in our centre(14), recorded a mortality rate of 100% in patients with ruptured omphalocele and gastroschisis who had silo applied using urobag/ivbags) . However, with a strong drive to change this unacceptable mortality, in 2012,we introduced the use of female condom (femidom) as an improvised silo. It is readily available in our centre, soft, elastic, atraumatic, easy to apply, does not require general anesthesia and therefore reduced need for ventilation. We analyzed our outcome using femidom compared with that of urobag and present our experience with this improvised device.

II. Materials and Methods

Study-this is both a retrospective and prospective study where data was collected retrospectively from our record department of all new born with omphalocele or gastroschisis, admitted between January 2008 and December 2011. and prospectively between January 2012 and December 2019.

Information retrieved included patient's biodata (age at presentation, sex, weight), mother's age, antenatal/perinatal history. Other information included, diagnosis, type of silo applied, interval between birth and insertion of silo, complications, time of closure of defect, type of closure, duration of hospital stay and outcome

Prior to 2012, our standard practice was the use of urobag as silo. However, after 2011 we introduced the use of female condom (femidom) as improvised silo till date. For the purpose of analysis, the patients were divided into the urobag group and femidom group.

Inclusion criteria included all who presented with ruptured omphalocele or gastroschisis within the study period managed using improvised silo.

Exclusion criteria included those who had ruptured omphalocele and gastroschisis but had primary closure without the use of silo or those with incomplete records. All those with associated anomalies were also excluded.

Description of patients' management:

Patients in both groups

All Patients were resuscitated on presentation, using intravenous fluid, placing the eviscerate bowel loops in an opened urine bag which was then tied round the patient's trunk. with nasogastric tube and urethral catheter in place. Intravenous ceftriaxone (50mg/kg/day in 2 divided doses) and metronidazole (7.5mg/kg/dose 8hrly) were started.

Urobag group:

The patients were then taken to the theatre and intubated under general anaesthesia. The eviscerated bowel loop were cleaned with warm saline and were placed into empty sterile intravenous fluid/uro bag which was then sutured round the margin of the defect to serve as silo. Dressing was then applied round the margin of the applied silo to further help in creating an airtight peritoneal cavity and the patients were then extubated and nursed supine in incubators in the SCBU.

Femidom group. (all procedures done under aseptic technique by the bedside in the SCBU)

For each patient, a femidom was used. This is a 17cm long polyurethane bag with a neck diameter of 7.5cm and comes with a semi-rigid ring of 4.5cm diameter (fig1). It was soaked in cetrimide for 10 minutes to dissolve the lubricant and rinsed with normal saline. The free (semi- rigid) ring was sutured to the neck of the femidom to anchor at 12, 3,6 and 9 o'clock positions using size 3/0 vicryl or silk sutures and then ready for use. The patients were draped, having iv 10mg/kg 8hrly of paracetamol. pulse oximetre was used to monitor each patient's vitals. Lidocaine (3mg/kg) was infiltrated round the margin of the defect. The eviscerated bowel loops were rinsed with warm saline and inserted into the prepared femidom (silo). With artery forceps holding up the margin of the defect at 2,5 7 and 11 o'clock positions, the anchored ring at the neck of the femidom was then manoeuvred circumferentially and slotted into the peritoneal cavity. On slotting of the whole ring into the peritoneal cavity, the attached ring would then spring out and abbot on the anterior abdominal wall from within, thereby creating a sealed peritoneal cavity. The patients were then nursed in the incubators in semi-prone position.

All groups had daily/serial reduction/ligation of the silo until complete or near complete reduction of the bowel was achieved before fascial or skin closures were attempted.

Statistics
Data was recorded on excel spread sheet and thereby exported to epi info version 7.3.2.1
Limitations
We have no neonatal intensive care unit to manage those patients that needed ventilator support
We had no access to parenteral nutrition.

III. Results

Within the sturdy period we had managed 133 patients aged 1-288 hours. Birth weight ranged from 1.9 kg to 4.2 kg with a median weight of 2.6 kg. There were 59 males and 74 females (M:F ratio 1:1.25).

Of the 133 patients, 52 met the inclusion criteria for this sturdy. There were male 24 (46.1%) female 28(53.9%) with a ratio of 1:1.17

Urobag group: 12 patients were managed, with 5 (41.7%)males and 7(58.3%)females and age range 1 to 36 hours (median- 24 hours). Diagnosis of gastroschisis and ruptured omphalocele was made in 6 each. In those with gastroschisis mean weight was 1.9kg and gestational age was 34 weeks. While those with ruptured omphalocele had a mean weight of 2.65kg and mean gestational age of 38 weeks.

Mean waiting time for surgery was 4.7 hours. Mean operating time was 1hour 30 minutes (including time taken to intubate). Only one patient had skin closure after 15 days and died 3 days later. Complete Reduction and closure was not achieved in the remaining 11(91.7%) patients. None (100%) was dim fit to commence enteral feeding. All developed sepsis while on silo. Duration of hospital stay ranged from 1 to 21 days with a mean of 4.9 (median-3) days. We lost all the patients (100% mortality) (table 1)

Femidom Group- Ruptured omphalocele were 34 and gastroschisis 6. Mean age at presentation was 25 hours while the mean birth weight was 2.4kg. Mean waiting time for procedure was 2.7 hours while the mean procedure time was 38 minutes. Mean time to closure was 4.1 (median 5.5) days. Median time for Commencement of enteral feeding was 5 days post closure. There were 18(80%) patients who had fascial closure, while in 2(20%), only skin closure was achieved. Silo complications included rupture in 4(10%), extrusion in 3(7.5) and upper GI bleeding was noticed in I (2.5%) patient. post closure complications were seen as skin/flap necrosis(1,5%), wound infections (4,20%) and in 1(5%) patients. Duration of hospital stay ranged from 1to 60 days with mean duration of 16.3(median- 16.0) days. We recorded mortality in 20(50%) babies. All mortalities were before closure. (table 2)

Fig.1 showing a femidom

Figure 2A new born with femidom applied

Table 1. Outcome of management of Gastroschisis and Ruptured Omphalocele using Urobag/Ivbags Between 2008 and December 2011 in Jos University Teaching Hospital

WEIGHT (KG)	MEAN AGE (HR)	TYPE OF DEFECT		MEAN TIME TO APPLICATION OF SILO (HR)	MEAN /MEDIAN DURATION OF HOSPITAL STAY(DAYS)	OUTCOME	
		GASTROSCHISIS	RUPTURED OMPHALOCELE			HOME	MORTALITY
1.5-1.9	22.2(24.0)	4	1	4.0	6.4(3.0)	0	5(
2.0-2.4	16.3(24.0)	2	1	4.7	5.0(4.0)	0	3
2.5-2.9	8.7(9.0)	0	3	5	3.0(3.0)	0	3
3.0-3.5	36.0(36.0)	0	1	5	3.0(3.0)	0	1
TOTAL	18.5 (24.0)	6(50)	6(50)	4.7	4.9(3.0)	0	12(100%)

Table 2. Outcome of management of Gastroschisis and Ruptured Omphalocele using femidom Between 2012 and December 2019 in Jos University Teaching Hospital

WEIGHT (KG)	MEAN AGE (HR)	TYPE OF DEFECT		MEAN TIME TO APPLICATION OF SILO (HR)	MEAN /MEDIAN DURATION OF HOSPITAL STAY(DAYS)	OUTCOME	
		GASTROSCHISIS freq./%	RUPTURED OMPHALOCELE freq./%			HOME	MORTALITY
1.5-1.99	17.1(6.0)	2	5	3.3	7.0(4.0)	1	6
2.0-2.49	38.8(9.0)	3	10	2.5	11.1(4.0)	3	10
2.5-2.99	22.3(13.0)	1	12	2.8	21.5(22.0)	10	3
3.0-3.49	12.7(4.0)	0	3	3.3	20.7(23.0)	2	1
3.5-3.99	11.5(9.5)	0	4	2.0	29.3(20.5)	4	0
TOTAL	25.0(9.0)	6	34	2.7	16.3(16.0)	20(50%)	20(50%)

IV. Discussion

Our study showed that the femidom group had an overall better outcome than the urogroup. The mortality rate in using femidom as improvised silo was lower than lower than the mortality using urobag as improvised silo.

The median time to closure using femidom in our study is similar to that reported by comparable to studies done by Aaron R. Jensen et al(15) in their study using preformed silo where their mean time to closure was 5.7days. This finding shows that femidom as an improvised silo has good similarity in output with preformed silo. In a study in north-eastern Nigeria however, the median time to closure was 8 (10 ±6.5) days(16). This is longer compared to our findings. The difference could be because they included those who were managed with urobag as improvised silo.

Study by Yeming Wu et al(17)in which they had a mean time to fascial closure of 3.7 days. this has been found to have a direct bearing on duration of hospital stay.(18)

The median time to commencement of enteral feeding was comparable to a study by

Complications encountered with femidom included rupture and extrusion which necessitated the reapplication (in the case of rupture occasionally doubling it) and thereby increasing the risk of sepsis. Yeming Wu et al also found displacement rate of 13,3% of patients who had performed silo.(17)This complication was not recorded in our urobag group as the silos were sutured to the anterior abdominal wall .Gupta, R and Singh, A ,also did not find any complication of such in their use of urobag as silo in the management of 3 patients with gastroschisis (19)

In our study, we found the mortality rate reduced by half using femidom as improvised silo, while there was no survival using the urobag. This agrees with the study reported in North-Eastern Nigeria where the survival rate was 22% (16)

. This is slightly lower than in our study, the reason could be the use of mixed methods where some patients in the North -Eastern study were managed with urobag and others with femidom. The relatively lower mortality in our study was likely as a result of the none use general anaesthesia as against other methods of silo application where general anaesthesia was required. This is corroborated by a study in china where preformed silos were applied without anaesthesia with a survival rate of 94.1% as against their previous method of application under anaesthesia which had a survival rate of 60.9%(20) Even though the study from china showed a higher survival rate than ours it may have been due to early presentation and availability of NICU and parenteral nutrition in their study.

The dismal outcome in our use of urobag was similar to the findings by Hassan et al where only 1 patient out of 40(mortality of 97,5%). patients with gastroschisis survived. This they attributed to ultimately to sepsis.(21)

Challenges with the use of femidom as improvised silo: We had some difficulties resizing the femidom, which comes prefixed size for adult female cervix. The larger the size, the higher the tendency to splinting of the diaphragm in preterm low birth weight babies. There was disparity between the diameter of the femidom ring and the neck of the femidom. Extra force is required in anchoring the ring (firm) to the neck (soft) and occasionally in the process, the needle pierced through the sheet making it susceptible to leaks and eventual tear.

V. Conclusion

we have found the use of femidom which is readily available, to have reduced our mortality rate from 100% to 50%. Though this rate is still not acceptable, if combined with a functional neonatal intensive care and nutritional supports we could achieve even a lower mortality rate.

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