

**PREVALENCE, CHARACTERISTICS AND MORTALITY RATE IN NEONATES WITH  
GASTROSCHISIS MANAGED AT A TERTIARY HOSPITAL IN A DEVELOPING  
COUNTRY**

A research report submitted by

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## **DECLARATION**

I, Simon-Peter Terumbur Gom declare that this research report is my own work. It is being submitted in partial fulfilment for the award of MMed degree in the Department of Paediatric, University of the Witwatersrand, Johannesburg.

It has never been submitted before for any degree or examination at this or any other university.

**Candidate Signature** \_\_\_\_\_ **Date** \_\_\_\_\_

**Simon-Peter T Gom**

## **DEDICATION**

This humble work is dedicated to the almighty God who has shown me favour despite my numerous limitations

My wife Iveren E Gom, my daughters Iwanger R Gom, Kenter M Gom whom are my strength, joy and greatest motivation

My parents Mr Linus I Gom and Mrs Philomena M Gom for solidly standing by me, believing in me and always encouraging me

My father in law Mr Emmanuel T Manger who has been more than a father to me in these last years' constantly encouraging and supporting me

May God reward them abundantly.

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## **Summary**

Gastroschisis, a congenital anomaly that was once considered to be rare, has recently been reported to be occurring more frequently worldwide. It is a birth defect which represents the herniation of abdominal contents, mostly intestines via para-umbilical full-thickness abdominal wall fusion defect most often on the right side of the umbilical cord.<sup>1</sup>

Globally this defect has been reported to have good outcomes, with survival rate ranging from 73 to 95% with minimal morbidities.<sup>2,3</sup> The burden of disease of this defect is also well established in the developed world. The available data at Chris Hani Baragwanath Academic Hospital, which is one of the paediatric surgical referral centres in Gauteng, suggests a low survival rate, though this has not been formally documented, a reflection of possibly what is happening in most centres across South Africa and Africa. The prevalence of gastroschisis in neonates born at Chris Hani Baragwanath Academic Hospital (CHBAH) and outcomes of those admitted with this diagnosis is not currently known.

The objective of the study is to determine prevalence, morbidity, and mortality in neonates with gastroschisis and to determine factors associated with mortality. Data collection will include maternal and infant demographics, clinical and laboratory findings, medical and surgical management, complications and outcomes at discharge. Comparisons of the above-collected data will be made between survivors and non-survivors at hospital discharge.

The study will be a retrospective study, reviewing medical records of patients with gastroschisis born and/ or admitted at CHBAH from January 2005 to December 2015. It is hoped that findings from this study will add to knowledge about outcomes of patients with gastroschisis from a developing country and possibly assist to improve the management strategies of gastroschisis which might reduce the mortality rates.

## **1. Background**

### **1.1. Introduction**

Gastroschisis is a herniation of abdominal contents through a paramedian full-thickness abdominal fusion defect. The abdominal herniation is usually to the right of the umbilical cord. The abdominal wall defect is relatively small compared to the size of the eviscerated bowel.<sup>1-4</sup> In the wide spectrum of abdominal wall defects, gastroschisis is differentiated from omphalocele by these features; it is a para-umbilical cleft, usually to the right of the umbilicus, while omphalocele is a midline defect.<sup>1</sup> The herniated viscera in omphalocele are covered by a thin membrane consisting of amnion externally and peritoneum internally with mesenchymal connective tissue between them. While in gastroschisis the viscera are lay bare not covered by any membrane. Omphalocele has a strong genetic etiology, whilst in gastroschisis, the genetic component is still not clear. The cause of this abdominal wall defect is not known. However, some hypothesis as to the etiology of gastroschisis include the vascular disruption phenomena, vascular disruption of the omphalomesenteric artery results in the herniation of the bowel outside the abdomen.<sup>5</sup> Some animal models have suggested genetic factors, but no genetic abnormalities have been identified to be associated with gastroschisis in humans.<sup>6</sup> Some human studies have reported that cases of gastroschisis may occur within families, occurring in twins, and having a recurrence rate of 3-5% in subsequent pregnancies, suggesting genetic factors possibly playing a role in the development of gastroschisis.<sup>7</sup> Other identified risk factors include maternal use of non-steroidal anti-inflammatory drugs.<sup>8</sup>

### **1.2. Prevalence of Gastroschisis**

International Clearinghouse for Birth Defect Monitoring System has reported an increase in the prevalence of gastroschisis. Between 1974 and 1998 from 19 registries, in both live birth and stillborn babies, 3037 cases were reported, with an overall prevalence at birth increasing from 0.29/10,000 births (95% CI 0.21 to 0.40/10,000) in 1974 to 1.66/10,000 births (95% CI 1.51 to 1.85/10,000) in 1998<sup>9</sup>. A more recent report, from the International Clearinghouse for Birth Defect Surveillance and Research, documented an increase in the prevalence of gastroschisis, for example, Cuba had the highest increased prevalence of 60%, from a prevalence of 2.58 per 10,000 in 2001 to 2005 to a prevalence of 6.46 per 10,000 in 2006 to 2010. Australia showed an increase of 17%, with a prevalence of 3.98 per 10,000 in 2001 to 2005 to a prevalence of 4.83 per 10,000

in 2006 to 2010, others include Norway with a prevalence of 2.72 per 10000 to 3.32 per 10,000 and Costa-Rica with 1.46 per 10,000 to 2.32 per 10,000 all within the same period of 2001 to 2005, and 2006 to 2010 respectively. More than 32 registries were studied with most showing some increase very few with declining prevalence, such as France with 3.23 per 10,000 in 2001 to 2005 to 1.42 in 2006 to 2010, Germany with 4.34 per 10,000 to 3.69 per 10,000 and Ireland with 3.04 per 10,000 to 2.04 per 10,000 all within the period of study.<sup>9,10</sup>

A population-based study done in California, the USA using data from California Birth Defect Monitoring Programme, from 1987 to 2003, showed a significant increase in prevalence of gastroschisis, with the overall prevalence of 2.6 cases per 10,000 births, prevalence increased by 3.2 fold (95% CI 2.3 – 4.3) as against 0.6 per 10,000 (95% CI 0.5 – 0.7).<sup>11</sup> The study noted that the prevalence of gastroschisis has been associated with decreasing parental age. In an adjusted analysis, using the parental age of 25 – 29 years as the reference, mothers aged 12 – 15 years had a 4.2 times higher prevalence rate of gastroschisis, and fathers aged 16 – 19 years and 20 – 24 years had 1.6 and 1.5.<sup>12</sup> times greater prevalence rate of gastroschisis respectively. Other factors identified that have been associated with gastroschisis are nulliparity and maternal ethnicity.<sup>11</sup>

A data review from the statewide database and a national database from a neonatal health care provider, North Carolina, USA showed an increase in the prevalence of gastroschisis from 1.96 per 10,000 births in 1997 to 4.49 per 10,000 births in 2000 ( $p < 0.001$ ). The overall increase in this study was almost entirely because of an increased infant born to mothers less than 20 years old.<sup>13</sup> The National Birth Defect Prevention Network in collaboration with CDC reported that the prevalence of gastroschisis nearly doubled from 1995 to 2005. It increased from 2.3 per 10000 live births in 1995 to 4.4 per 10,000 live births in 2005.<sup>14</sup> This study also reported that gastroschisis was more common among babies born to younger women than older women and among babies born to Non-Hispanic white women than among women of other racial/ethnic groups.<sup>14</sup> Worldwide notable risk factors associated with gastroschisis include; maternal age less than 18 – 20 years, exposure to teratogens like aspirin, acetaminophen, tobacco smoking, and other recreational drugs, with low economic status.<sup>15</sup>

A survey conducted in Sub-Saharan Africa in 2012 reported that gastroschisis is encountered on a regular basis by paediatric surgeons. The middle-income countries of which South Africa is one, based on the World Bank criteria, has an average incidence of 12 cases.<sup>12</sup> annually per

institution.<sup>12</sup> In South Africa, also in line with the global trend, there has been a significant increase in the prevalence of gastroschisis. The incidence of gastroschisis at Pretoria Academic Hospital and Kalafong Hospital.<sup>3</sup> has been reported to have increased dramatically from 1981 to 2001.<sup>3</sup> The study reported 48 cases of gastroschisis at PAH and KH out of 21,495 total paediatric surgery ward admissions giving a prevalence of 2.2 / 1000 admissions. The average incidence of gastroschisis increased 35 fold in the 7 year period 1981 to 1987 to the 7 year period 1995 to 2001, while the average incidence of omphalocele compared across the same period only showed a 1.82 fold increase<sup>3</sup>. An audit at two Referral hospitals in Johannesburg, South Africa 2000 – 2005, also noted an increasing prevalence of gastroschisis in South Africa<sup>6</sup>. Apart from these two studies, there is no recent information on the prevalence of gastroschisis in South Africa.

### **1.3. Characteristics of neonates with gastroschisis**

Gastroschisis is commonly detected in the second trimester on antenatal sonography.<sup>16</sup> With the use of transvaginal sonograms, the diagnosis can be made as early as 12 weeks gestation. In early pregnancy, the bowel loops can be seen floating in the amniotic fluid. The thickness and diameter of the bowel are normal. Later in pregnancy, bowel obstruction, peritonitis, bowel perforation, and fetal growth restriction may occur. Intra-uterine growth restriction (IUGR) occurs in 38 – 77% of fetuses and is thought to be nutrients loss through exposed bowel.<sup>4,8</sup> Approximately 48 – 50% of infants with gastroschisis are small for their gestational age<sup>17</sup>. A bowel diameter greater than 17mm usually represents significant bowel dilatation, and those with a diameter greater than 11mm are usually associated with a greater number of postnatal bowel complications. Fetal abdominal circumference, which is regarded as a standard reference for assessment of fetal size, does not apply to this group of foetuses.<sup>17</sup>

Perinatal diagnosis of this condition is important for timely intervention with better outcomes; the preferred study is antenatal sonography which is a key imaging examination available, with detection rates of 70 – 99.3%. It is noninvasive and allows real-time fetal examination. Use of antenatal sonography allows for early identification of babies with gastroschisis, therefore, allowing for proper preparation around the management of these infants post-delivery. Delivery of an infant with gastroschisis must be in a tertiary care centre with neonatal intensive care and pediatric surgery capabilities.<sup>18</sup> Mode of delivery should also be planned, normal vaginal delivery does not pose an increased risk to the infant with gastroschisis.<sup>19</sup> Cesarean section should be

reserved for the usual obstetrical indications, including breech presentation. The timing of delivery should be after 36 to 37 weeks if possible. Planned preterm delivery may be required for severe growth restriction, oligohydramnios or non-reassuring fetal monitoring<sup>18, 20</sup>. These are among the benefits of antenatal diagnosis of gastroschisis.

The affected neonates are often small for gestational age,<sup>21</sup> as a result of intrauterine growth restriction (IUGR) due to nutrient loss from the eviscerated bowel.<sup>22</sup> Approximately 10% of cases are associated with malformations outside of the gastrointestinal tract and additional gastrointestinal defects may include; malrotation, intestinal atresia or stenosis, which occur in about 25 percent of cases.<sup>22</sup> Oligohydramnios is the most common amniotic fluid abnormality, but polyhydramnios may occur. Intestinal necrosis is also a common feature due to prolonged exposure to the toxic environment of the amniotic fluid; amniotic fluid becomes toxic as a result of the leaking digestive enzymes, and other components of meconium. Antenatal gastric dilatation and bowel dilatation and bowel wall thickening when present are considered to be poor prognostic factors<sup>23</sup>. Gastroschisis has been associated with spontaneous preterm delivery<sup>22</sup>. Neonates with gastroschisis might have difficulties with breathing or may need mechanical ventilation because of the inadequacy of the abdominal muscles and therefore abnormalities in diaphragmatic dynamics. Another characteristic of infants with gastroschisis is the intestinal failure, usually multifactorial, derived from motility disorders, associated intestinal anomalies and loss of intestinal length due to necrosis or surgical resection.<sup>20</sup> Burc et al noted that the prognosis of this congenital anomaly is mainly influenced by the degree of inflammation of the intestine at birth. From their work, they noted that amniotic total proteins and ferritin are elevated in fetuses presenting with gastroschisis as a consequence of an inflammatory process. Inflammation may be induced by the presence of digestive compounds in the amniotic fluid<sup>23</sup>.

#### **1.4 Mortality and morbidity in neonates with gastroschisis**

In recent decades, in civilized countries, there is a dramatic increase in survival of children with gastroschisis from 10% in the 1960s to above 95% currently. In the United States, an estimated 1300 to 1500 children are born with gastroschisis annually, of which an estimated 90 – 96% survives to discharge. In Europe, the mortality rate in neonates with gastroschisis is approximately 17 %.<sup>24</sup> Regretfully, success in developing countries is much lower with survival rates of around 50% reported in Nigeria and Brazil.<sup>25, 26</sup>

Among the studies reviewed, the following factors were identified as responsible for mortality in infants with gastroschisis; severe sepsis with multi-organ failure account for death in most cases followed closely by abdominal compartment syndrome, enterocolitis, and intestinal necrosis from in utero inflammation caused by intestinal waste resulting to the so-called “inflammatory peel”.<sup>23</sup> Some studies attribute the survival rate to be related to early and accurate prenatal diagnosis of this condition, risk categorization, the time taken to achieve full enteral feeding<sup>27</sup>. The presence or absence of other intestinal anomalies impact on the outcome, however, some studies argued that the percentage of congenital intestinal anomalies associated with gastroschisis is insignificant to have a major impact on survival rate.<sup>28</sup> Although, according to a retrospective charts review of over 100 infants in a 5-year period, infants with gastroschisis classified as high risk, compared with those classified as low risk, were younger and smaller (mean gestational age 34 weeks; mean birth weight 2.0 kg); had a lower rate of primary closure (65% vs. 71%.); stayed on mechanical ventilation longer (22 vs. 7 days.); and had a prolonged hospitalization (mean length of stay 85 vs. 26 days.). In addition to experiencing more complications, infants in the high-risk category had more severe complications including short bowel syndrome, pneumatosis intestinalis, pneumonia, and bowel obstruction. The survival rate of low-risk infants was 100% compared with 72% for the high-risk infants.<sup>27</sup>

A study done by Bradnock in UK 2011, compared infants with simple gastroschisis (intact, uncompromised, continuous bowel), to those with complex gastroschisis (bowel perforation, necrosis, or atresia), the study showed that it took longer to reach full enteral feeding (median difference 21 days, 95% CI 9 to 39 days) in those with complex disease; the latter group also required a longer duration of parenteral nutrition (median difference 25 days, 9 to 46 days) and a longer stay in hospital (median difference 57 days, 29 to 95 days); those with complex gastroschisis were more likely to develop intestinal failure (81% v 41 %; relative risk 95% CI 1.96, (1.56 to 2.46)) and liver disease associated with intestinal failure (23% v 40 %; 95% CI 5.13, (2.15 to 12.3)); and were more likely to require unplanned reoperation (42% v 10% ; 95% CI 4.39, (2.50 to 7.70)) compared to infants with simple gastroschisis<sup>24</sup>.

One study reported that 63.2% of patients with gastroschisis developed hospital acquired infection which significantly increased the need for mechanical ventilation, demand for parenteral nutrition and prolonged postoperative hospital stay.<sup>29</sup> Other notable complications of gastroschisis are classified as being primary and secondary in nature. Primary complications are the ones to do with

the primary defect and secondary the ones as a result of management modalities. Other intestinal malformations can be a complication, such as atresias, stenosis, intestinal necrosis or inflammation due to exposure to toxic chemicals in the amniotic fluid, and non-intestinal complications may include, respiratory inadequacy due to abnormalities in diaphragmatic dynamics. Complications associated with management include, ventilation pneumonia, hospital-acquired sepsis, liver failure due to prolonged administration of total parenteral nutrition(TPN), intestinal failure due to short bowel syndrome, abdominal adhesions, and strictures, short bowel syndrome<sup>21</sup>.

## **2. AIM AND OBJECTIVES**

### **2.1. Aim**

The aim of this study is to determine the prevalence of patients born at CHBAH, characteristics and mortality rate in neonates with gastroschisis presented at CHBAH.

#### **Objectives**

##### **2.1.1. Primary Objectives**

1. To determine the prevalence of gastroschisis in infants born at CHBAH;
2. To describe characteristics of infants presented at CHBAH with a diagnosis of gastroschisis;
3. To determine rate and causes of mortality in neonates presented at CHBAH with a diagnosis of gastroschisis;
4. To compare characteristics of survivors and non-survivors among neonates with gastroschisis;

##### **2.1.2. Secondary Objectives**

1. To determine the postnatal age at surgical repair of gastroschisis;
2. To determine the incidence of sepsis, postnatal age at initiation of enteral feeds and duration of stay in the intensive care unit and hospital;
3. To do a survival analysis of infants presented to CHBAH with a diagnosis of gastroschisis

## **3. METHODOLOGY**

### **3.1. Design:** A retrospective descriptive study

3.2. **Study setting:** This study was conducted at the department of paediatric surgery and the division of neonatology at Chris Hani Baragwanath Academic Hospital, Johannesburg, a public tertiary hospital in Johannesburg, South Africa. This hospital serves the community of Soweto, North West Province and its surrounding areas with an estimated population of 5.1 million and is a referral center for healthcare facilities in the southern part of Gauteng province and North-West province<sup>30</sup> It conducts about 20 000 births per year and caters for admissions of deliveries occurring in the Soweto clinics which are about 8000 per year

3.3. **Study Population:** Within the period of study, 97 babies diagnosed with gastroschisis were managed, 6 babies were excluded from further analysis following incomplete data.

3.3.1. *Inclusion criteria:* All neonates with a diagnosis of gastroschisis born and/or admitted to the department of paediatric surgery and division of neonatology from January 2009 to December 2016 at CHBAH.

**Study Procedure:** Hospital records of neonates who were born and/ or admitted at CHBAH between 1<sup>st</sup> January 2009 and 31<sup>st</sup> December 2016 with a diagnosis of gastroschisis were retrieved. These records were reviewed for the following data; maternal characteristics namely maternal age, gravidity, human immunodeficiency virus (HIV) status, place and mode of delivery. Infant characteristics included birth weight, gestational age, sex, the presence of other abnormalities, type of gastroschisis, and management of gastroschisis. Primary outcome assessed was the outcome at hospital discharge. The secondary outcomes were the duration of stay, the postnatal age at initiation of enteral feeds, need for mechanical ventilation, and presence of probable or culture-confirmed sepsis..

The neonates referred from other facilities were grouped into those referred from facilities within the province, and those from facilities outside of the province..

3.4. **Data Collection:** Data collected included the following:

**Maternal characteristics:** place of residence, age, parity, history of tobacco smoking, use of medication, human immunodeficiency virus (HIV) status, antenatal care, place and mode of delivery.

**Infant features:** birth weight, gestational age, sex, and Apgar score. The neonates referred from other facilities were grouped into those referred from facilities within the province, and those from facilities outside of the province. Neonates were also categorized according to birth weight (low birth weight, that is birth weight <2500 grams or normal birth weight,  $\geq$ 2500 grams) and according to gestational age (preterm, that is gestational age <37 weeks or term, gestational age  $\geq$ 37 weeks).

**Clinical features:** Time of diagnosis of gastroschisis in relation to birth, contents of gastroschisis, type of gastroschisis (simple or complex), and other abnormalities outside the gastrointestinal tract. Gastroschisis was grouped into complex and simple gastroschisis based on whether they had abnormalities of the gastrointestinal tract (complex) namely atresia or stenosis, necrosis, and perforation or not (simple). Secondary outcomes that were assessed were the postnatal age at initiation of enteral feeds need for mechanical ventilation and duration required on mechanical ventilation.

**Medical management:** Age at admission to surgical unit or NICU, type and volume of maintenance fluids on admission, at 72 hours post admission and 24 hours post-surgical closure, highest volume of fluids during hospital stay, insertion of central line, use of antibiotics on admission, use of motility drugs or antacids, and highest ventilator pressures and mode of ventilation required before and after surgery. Most of the parameters mentioned above, the volume of fluids, insertion of the central line, use of antibiotics on admission, use of motility drugs or antacids, and highest ventilator pressures and modes of ventilation required before and after surgery, however, were not used in the final analysis due to paucity or missing data.

**Surgical management:** Primary closure, silo bag insertion, postnatal age at the closure of the defect. Surgical management of gastroschisis was grouped as either being a primary closure or placement of a silo bag for stage reduction.

The same surgical technique fascial closing sutures were used in both those closed primarily and those for delayed closure. No standardized criteria were used to determine patients to offer primary closure and those for delayed closure, the attending Paediatric surgeon only made a clinical decision based on quality and quantity of bowel eviscerated. However, obvious abdominal visceral disproportion and bowel necrosis were major signs used to determine which modality to employ on each patient. Immediate post-operative intravesical pressures were

measured only in cases with suspected cases tight closure based on ventilator pressures and surgeon perception of the patient.

**Complications:** probable (CRP>40 mg/L or culture-confirmed sepsis, including a profile of organism(s) cultured). An episode of sepsis was defined as probable sepsis if the patient presented with clinical signs and with C - reactive protein of greater than 40 mg/L in the absence of positive blood culture. Culture confirmed sepsis was defined as the presence of clinical signs with positive blood culture results.

**Outcome:** Died or survived at hospital discharge as the primary outcome; duration of hospital stays

### **3.4.1. Definitions**

Simple Gastroschisis define as intact continuous bowel that is not compromised or breached at delivery or presentation.

Complex Gastroschisis is the presence of one of or more of intestinal atresia, bowel perforation or intestinal necrosis at delivery or presentation, or missed atresia.

Primary Closure is the once-off reduction of abdominal content after manual stretching of the abdominal wall and closure of the defect.

Silo stage reduction and closure is a serial reduction of the abdominal content base on gradual growth and expansion of the abdominal cavity using a preformed or customized silo.

### **3.4.2. Data Analysis**

Statistical analysis was performed using STATA, version 13.1(Stata Corp, USA). Summary statistics were presented as means  $\pm$  standard deviation and median with interquartile ranges for normally distributed and not normally distributed continuous variables respectively. Comparison of characteristics of survivors and non-survivors was performed using Student t-test and Mann Whitney U test for continuous variables while Chi-square (with Fisher exact test for values less than 5) for categorical variables, odds ratios with 95% confidence intervals for categorical variables. Differences were considered significant if the p-value is  $<0.05$ . The Kaplan Meier survival curves were used to compare survivor and non-survivors at time of death or discharge. Multivariate logistic regression was performed to assess for factors associated with mortality.

### **3.5 Ethical Consideration**

Approval was obtained from the Human Research Ethics Committee at the University of the Witwatersrand, certificate of clearance number; **M160710** Information identified was only used essentially for the purpose of this retrospective research and not any other use outside this work. Names were coded, and records or data were stored in a locked cabinet in order to protect the privacy of the individuals whose charts/records are being reviewed.

## RESULTS

### *Prevalence of Gastroschisis*

There were 97 neonates admitted with a diagnosis of gastroschisis over the 8-year period (2009-2016), and 36 (37.1%) of them were born at CHBAH (inborn) with the remaining 61 (62.9%) being referrals (outbound). There were 167,822 live births at CHBAH over this time period resulting in a prevalence of 2.1/10 000 live births. Though there was a trend of an increase in prevalence over the study period, there was marked variation in annual prevalence over this 8-year period varying from 0.50/10 000 in 2009 to 4.90/ 10 000 live births in 2014 with a deep in 2013. (Table. 1).

**Table 1:** Prevalence of gastroschisis per 10,000 live births at CHBAH between 2009 – 2016

<b>Year</b>	<b>Number of Live Births</b>	<b>Number with Gastroschisis</b>	<b>Prevalence (per 10,000 live births)</b>
<b>2009</b>	21,969	1	0.5
<b>2010</b>	22,649	4	1.8
<b>2011</b>	22,751	5	2.2
<b>2012</b>	19,883	4	2.0
<b>2013</b>	22,288	2	0.9
<b>2014</b>	20,551	10	4.8
<b>2015</b>	18,513	8	4.3
<b>2016</b>	19,218	2	1.0
<b>Total</b>	<b>167,822</b>	<b>36</b>	<b>2.1</b>

### *Characteristics of neonates admitted with gastroschisis*

The maternal and infant characteristics of neonates admitted with gastroschisis are presented in Table 2. The median maternal age was 20 years (14-40) with almost half (45.4%) of mothers being younger than 20 years. Just over two thirds (68%) of these neonates were born to primigravida mothers. Most mothers (82%) attended antenatal clinic and one-fifth (21%) of mothers with known HIV status being positive. Mode of delivery was vaginal in 73.6% of mothers. The average gestational age of neonates at delivery was 36 weeks with just over 50% being born preterm, and average birth weight was 2270 grams with 71% being of low birth weight.

The majority (72%) of the referred patients were from within the Gauteng province, with the rest being from the North-West Province. The median postnatal age at admission amongst the referrals was 2 days (1-3), with those from outside Gauteng province being admitted later than those from within the province with a median age at admission was 1 day (1-2),  $p = 0.002$ . About 2.1% of the patients had prenatal diagnosis. Of the 2 patients with prenatal diagnosis, none died.

**Table 2:** Characteristics of neonates admitted with gastroschisis

	Number (%)
<b>Maternal Characteristics</b>	
Maternal Age Median (range)	20 (14-40) *
<20 years	44 (45.4)
20-35 years	52 (53.6)
>35 years	1 (1.0)
Gravidity (Median (Range))	1 (1 - 5) *
Primigravida	66 (68.0)
Gravida 2-4	25 (25.8)
Gravida >4	6 (6.2)
HIV Status*	
Positive	19 (21.3)
Negative	70 (78.7)
Antenatal Care*	
Yes	76 (84.4)
No	14 (15.6)
Mode of delivery*	
Vaginal	67 (73.6)
Caesarean	24 (26.4)
<b>Infant Characteristics</b>	
Gender	
Male	47 (48.5%)
Female	50 (51.5%)
Gestational Age (Mean $\pm$ SD)	36.4 $\pm$ 2.8
<34 weeks	22 (22.7)
34-36 weeks	28 (28.9)
$\geq$ 37 weeks	47 (48.4)
Birth Weight (Median (Range))	2270 (1350 - 3530) *
<1500 grams	4 (4.1)
1500-2499 grams	65 (67.0)
$\geq$ 2500 grams	28 (28.9)
<b>Place of Birth</b>	
Inborn (Chris Hani Baragwanath Academic Hospital)	36 (37.1)
Referrals	61 (62.9)
Within Gauteng Province	44 (72.1)
Outside Gauteng Province	17 (27.9)
<b>Average Age at Admission among referrals (days)</b>	
Within Gauteng Province	1(1 – 2)
Outside Gauteng Province	1(1 – 3)

SD: standard deviation \*- Missing data, 8 for HIV status, 7 for antenatal care and 6 for the mode of delivery

### ***Types and surgical management of gastroschisis***

Majority of gastroschisis was a simple type (63.7%), meaning that they did not have associated gastrointestinal abnormalities like atresias. Only one (1.1%) neonate had associated major congenital anomaly (spina bifida occulta) that was not part of the gastrointestinal tract. Among the total of 97 neonates admitted with gastroschisis, data on outcome was missing in 6 and therefore were excluded from further analysis. Among the 91 patients further analyzed 46 (50.5%) were females and 45 (49.5%) were males. One patient was not offered any surgical management as she presented with the entire bowel being necrotic, and therefore care was redirected and was given palliative care. This patient was born at home and only presented on day 3 of life to her base hospital before referral to CHBAH. Among those who were assessed to require active management (n=90), the primary closure could be achieved in only 21 patients (23.3%), with the majority of patients (n = 69; 76.7%) requiring placement of a silo bag and stage reduction with planned delayed closure. Of the 69 babies requiring silo bag and stage reduction, 21.7% died before final closure could be achieved. Among those who survived to final closure, (29.6%) were closed within the first 3 days, 61.1% within the first week and the rest (38.9%) being closed beyond a week of silo placement. The median age at final closure was 5days (1-15) and the median age at death was 10days (1-77), (Table 3)

**Table 3:** Types of gastroschisis and closure, and ages at final closure

<b>Characteristics</b>	<b>Number (%)</b>
<b>Type of gastroschisis</b>	
Simple	58 (63.7)
Complex	33 (36.3)
<b>Type of Closure</b>	
Primary Closure	21 (23.9)
Stage Reduction	69 (75.0)
No Surgical Intervention	1 (1.1)
<b>Age at final closure/death among those requiring stage reduction n=69</b>	
Median age at final closure	5 (1 – 15) *
Median age at death	10 (1-77) *
Died before closure	15 (21.7)
Survived to closure (n = 54)	
≤ 3 days	16 (29.6)
4 - 7 days	17 (31.5)
8 - 21 days	21 (38.9)

\* Median (Range)

### ***Secondary outcomes in neonates with gastroschisis***

Secondary outcomes assessed were the time it took to start oral feeds, need for mechanical ventilation and presence of sepsis (Table 4). Over half of the patients died before oral feeds were commenced (49/91, 53.8%). Among those who were finally started on feeds, the median age at starting oral feed was 15.5 (5 – 33) days. The average stay on mechanical ventilation was 13 days, with 61.8%, staying on the ventilator for more than a week. A total of 62 patients (68%) had at least one episode of sepsis during their stay in the hospital, with the majority of them having culture confirmed sepsis (74%). Common organisms isolated in neonates with culture-confirmed sepsis were Gram-negative organisms (52.4%). Though there was a high seroprevalence of HIV among the mothers, with 21% of the babies being exposed, this did not show any statistically significant influence on the outcome (Table 5).

**Table 4:** Age at start of feeds, days on mechanical ventilation and proportion complicated by sepsis and causes of death

Characteristics	Number (%)
<b>Feeding (n = 91)</b>	
Number never started on feeds	49 (53.8)
Number started on feeds	42 (46.2)
Median postnatal age initiation of feeds	15.5 (5 – 33) *
<8 days	4 (9.5)
8 - 14 days	14 (33.3)
15 - 28 days	23 (54.8)
29 - 42 days	1 (2.4)
<b>Days on Mechanical Ventilation (n=86*)</b>	
Median number of days on mechanical ventilation	13 (1 – 76) *
<1 week	34 (38.2)
1-2 weeks	23 (25.8)
3-4 weeks	13 (14.6)
>4 weeks	19 (21.4)
<b>Proportion with sepsis</b>	
No sepsis	29 (31.5)
Sepsis	62 (68.5)
Probable sepsis	17 (27.4)
Confirmed sepsis	45 (72.6)
Organisms isolated among those with confirmed sepsis (61 episodes)	
Gram negative bacteria	32 (52.4)
Gram positive bacteria	13 (21.3)
Fungal	16 (26.2)
<b>Mortality</b>	
Deaths	52 (57.1)
Median postnatal age at time of death	10 (1 – 77) *
Causes of deaths	
Sepsis	32 (61.6)
Bowel necrosis	15 (28.9)
Respiratory failure	2 (3.8)
Compartment syndrome	2 (3.8)
Grade 4 IVH/seizures	1 (1.9)
Other Associated anomalies ( <i>spina bifida occulta</i> )	1 (1.1)

IVH – Intraventricular Haemorrhage \* -Median (Range)

### ***Mortality rate***

The mortality rate at hospital discharge amongst neonates with gastroschisis was 57%. The median age at death was 10 days (range 1-77 days) (Table 4). The common causes of death were sepsis (61%) and bowel necrosis (28%). Among the patients that died, 62% of them died within the first three weeks of admission. Factors associated with mortality were low birth weight (OR: 9.20, 95% CI 1.92-44.2; p = 0.014), female (OR: 2.36, 95% CI 1.01-5.53; p = 0.048), stage

reduction with delayed closure (OR:3.68, 95% CI 1.34-10.1;  $p = 0.012$ ) and those with complex gastroschisis (OR:16.3 95% CI 4.46-60.0;  $p < 0.001$ ) (Table 5).

**Table5:** Comparison between survivors and non-survivors in neonates with gastroschisis

Characteristics	Survivors (39)	Non-Survivors (52)	Univariate		Multivariate	
	n (%)	n (%)	OR (95% CI)	P-value	OR (95% CI)	P-value
<b>Gender<sup>^</sup></b>			2.36(1.01-5.53)	0.048	1.52(0.51-4.57)	0.453
Male	24(61.5)	21(40.4)				
Female	15(38.5)	31(59.6)				
<b>Surgical Management*<sup>^</sup></b>			3.68(1.34-10.10)	0.012	2.29(0.66-7.92)	0.191
Primary Closure	14(35.9)	7(13.5)				
Stage Reduction	25(64.1)	44(84.6)				
<b>Type of Gastroschisis<sup>^</sup></b>			16.3(4.46-60.00)	<0.001	33.9(5.85-196.0)	<0.001
Complex	3(7.7)	30(57.7)				
Simple	36(92.3)	22(42.3)				
<b>Gestational Age<sup>#</sup></b>			1.76(0.76-4.08)	0.184	N/A	N/A
≥37 weeks	17(43.6)	30(57.7)				
<37 weeks	22(56.4)	22(42.3)				
<b>Birth weight<sup>#</sup></b>			3.25(1.27-8.28)	0.014	9.20(1.92-44.2)	0.006
≥2500g	17(43.6)	10(19.2)				
<2500g	22(56.4)	42(80.8)				
<b>Presence of Sepsis<sup>^</sup></b>			1.35(0.55-3.32)	0.517	N/A	N/A
No	11(28.2)	18(34.6)				
Yes	28(71.8)	34(65.4)				
<b>HIV Exposed<sup>^</sup></b>			0.51(0.22-1.21)	0.380	N/A	N/A
Yes	7(17.9)	12(23.1)				
No	31(79.5)	39(75.0)				
Unknown	1(2.6)	1(1.9)				
<b>Place of Birth<sup>^</sup></b>			0.96(0.55-1.68)	0.889	1.13(0.61-2.08)	0.699
CHBAH	17(43.6)	22(42.3)				
Outside	22(56.4)	30(57.7)				

\*one patient died before surgical decision was made # t-test; <sup>^</sup>Chi Square and Fisher Exact; OR -Odd ratio; CI – Confidence Interval

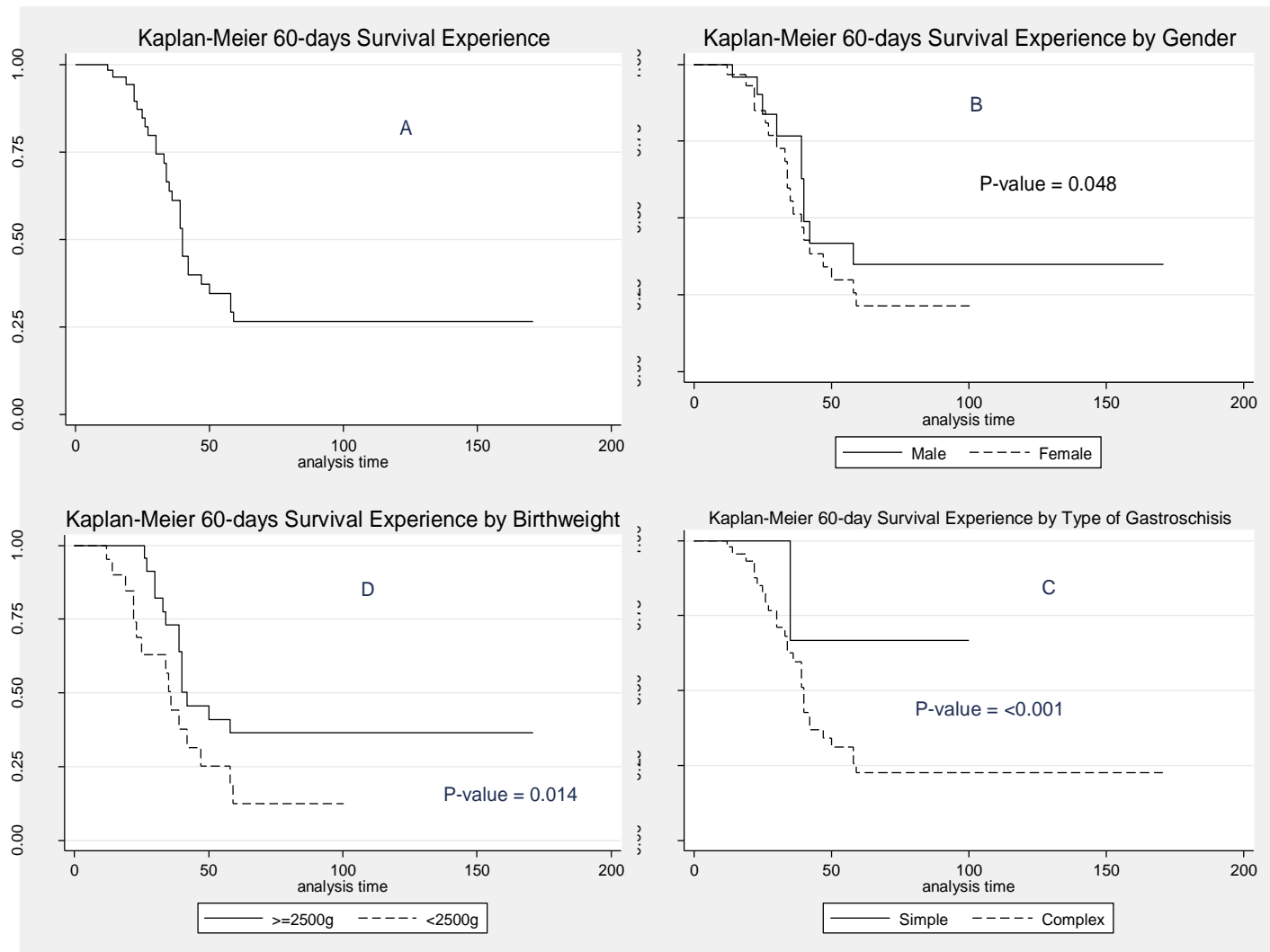


Figure 1: Overall 60-day Kaplan Meier survival experience of babies managed for gastroschisis at CHBAH between 2009 – 2016. B: Kaplan-Meier 60-day survival experience of patients by gender, C: Kaplan-Meier 60-day survival experience of patients by type of gastroschisis, D: Kaplan-Meier 60-day survival experience by birthweight.

## Discussion

Our local inborn prevalence of gastroschisis was found to be 2.1 per 10,000 live births, and there was a trend of an increase in prevalence in line with other previous reports.<sup>3, 25</sup> However, there was marked variation in annual prevalence over the 8-years study period. About two-thirds of the patients with a diagnosis of gastroschisis in this hospital were referrals. This reflects limited availability of centers that offer paediatric surgical services in the country and inability for in-utero diagnosis of gastroschisis as obstetric ultrasound is not routinely offered to all pregnant mothers in the country.<sup>26</sup> Based on the Guidelines for Maternity Care in South Africa, antenatal sonography is reserved for only high-risk pregnancies. This is due to the lack of trained manpower. Therefore, despite the high percentage of attendance at antenatal care observed in this study, only two patients (2.1%) had a prenatal diagnosis of gastroschisis and those two patients had planned delivery with a good outcome.

More than 40% of neonates with gastroschisis were born to mothers who were teenagers and more than 60% were primigravida. These findings are similar to those reported in other studies that there is an association between young maternal age, low parity, and prevalence of gastroschisis.<sup>1, 2, 27, 28</sup> Two-thirds of babies with gastroschisis were of low birth weight and about half of them were delivered premature, a similar finding to previous studies reporting characteristics of neonates with gastroschisis.<sup>29</sup> The low birthweight is thought to be due to loss of nutrients through the wall of the eviscerated bowel.<sup>4, 6, 8, 9</sup> A high index of suspicion for gastroschisis should be entertained among pregnant women with a combination of these factors. Thus, antenatal ultrasonography may be necessary for such patients.

The mortality rate was more than 57.1%, This is in contrast to that reported in developed countries where mortality rates are reported to be less than 10%.<sup>12 13, 21</sup> Studies from developing countries namely Nigeria and Brazil have reported similar mortality rates to the one reported in this study.<sup>14, 15</sup> These two countries have many similarities in terms of economic and social development and therefore availability of healthcare resources with South Africa. The differences in mortality rates between developed and developing countries could be because of limited surgical services and intensive care beds in developing countries resulting in delays in the repair of gastroschisis. In developed countries, many pregnant mothers have access to antenatal ultrasound screening for fetal congenital abnormalities, and therefore there is early detection of

birth defects. Thus, healthcare providers have ample time to plan in advance and ensure that such affected babies are born in centers with surgical services. This will improve outcome as complications associated with transportation post-delivery would have been avoided with the in-utero transfer. The delays in getting these neonates to a center with surgical services in developing countries increase the period of gut exposure to an external non-sterile environment with associated oedema of the bowel. Furthermore, delay in accessing surgical care also reduces the chance of primary exposure. Delays in the closure of gastroschisis are known results in the delay in starting enteral feeding, requiring prolonged periods of total parenteral nutrition and use of central venous access. Use of central lines and prolonged use of parenteral nutrition has been shown to be associated with an increased risk of infection.<sup>23</sup> The use of central lines and total parenteral nutrition in the background of overcrowded and understaffed neonatal intensive care units in developing countries increases the risk of sepsis in these neonates, thus, the high sepsis rate and its associated mortality in this study. The main cause of mortality in this study was nosocomial infections. The other contributor to mortality was extensive bowel necrosis, suggesting inadequate care of bowel post-delivery. The foregoing may suggest that further training of peripheral healthcare providers in our environment on the management of neonates with gastroschisis before closure and post-surgery is essential.

Factors associated with higher mortality were being female, having complex gastroschisis, type of surgical closure, and being low birth weight. The high mortality rate in female neonates with gastroschisis has not been reported in the literature before. This was an incidental finding which not much explanation could be offered. However, the incidence of gastroschisis was not statistically different in both gender as 46 (50.5%) female and 45 (49.5%) males were managed within the study period. In addition, gender lost its statistical significance as a risk factor after with multivariate analysis. Thus, the higher mortality rate among female as observed in this study needs further evaluation. The complex gastroschisis, low birth weight has also been reported to be associated with mortality,<sup>9, 29-31</sup> but the finding that the type of surgical intervention was associated with mortality in this study is in contrast with most studies. Most studies reviewed show no significant difference in outcome parameters between the primary closure group and the stage reduction group. The indication to choose primary closure or stage reduction depends largely on the surgeon; this then becomes subjective and is preferred when the size of the defect is small.<sup>12, 21, 29</sup>

A limitation of this study is that we may not be able to determine the overall prevalence of gastroschisis in the region since the prevalence from our study was obtained from only one centre. Secondly, six neonates did not have complete information on outcomes, therefore, the mortality rate may be an underestimate with the worse scenario being a mortality rate of 59.8% (58/97) or overestimate with the best scenario being a mortality rate of 53.6% (52/97). The strength of the study is that the data is for a long period and therefore one could look at the trend and secondly that all infants with the outcome data could be characterized in terms of maternal characteristics, anthropometric measurements, and secondary outcomes. In conclusion, though there has been an overall increase in trends in the prevalence of gastroschisis in our hospital there has been a wide variability over the years. Most neonates with gastroschisis are born to mothers who are pregnant for the first time and are born preterm and of low birth weight. A significant number of neonates are referrals highlighting a need for an antenatal obstetric ultrasound to screen for congenital abnormalities so that these neonates can be delivered in a hospital with surgical services and intensive care beds. Neonates with gastroschisis have a high mortality rate with the major cause of deaths being healthcare-associated sepsis, therefore, more attention must be paid to issues around infection control and consideration of routine intraabdominal pressure monitoring post closure.

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**APPENDIX**

**DATA COLLECTION FORM**

Study Number.....

Initials.....

**MATERNAL DETAILS**

Residence.....

Maternal Age at Delivery..... Gravida: .....; Parity: .....

RVD Status: Positive  Negative  Not recorded

If positive, is the mom on ARV's? YES  NO

If yes, when did mom start ARV's? Before Pregnancy / During Pregnancy / Not recorded

Booked: Yes  No  Mode of Delivery: VD  C/S

Place of Delivery: Bara  Other Hospitals

If other hospitals, state name.....

Age at referral.....

Had Antenatal Sonar: YES  NO

If yes, Gastroschisis diagnosed? YES  NO

**INFANT DETAILS**

Age..... Gestational Age at Birth.....B/WT.....

AGA  SGA  LGA

Sex: M  F

APGARS at 1min  5min  Birth HIV PCR (if applicable).....

Gastroschisis, Simple  Complex

**Criteria for complex Gastroschisis:** Necrotic intestines, perforated bowel, Intestinal stenosis or Atresia, or/and other intestinal anomalies.

**SURGICAL MANAGEMENT**

Is primary Closure done? YES NO If yes, Bedside or Theatre

If no, Silo bag placed, Bedside  or Theater

Age at final closure.....

**MEDICAL MANAGEMENT**

Max Fluid before surgery on Day 1..... Day 2..... Day 3.....

Max Fluids after surgery on Day 1..... Day 2..... Day 3.....

Antibiotics used empirically? YES  NO,  If yes, for how long:.....

Paralysis used? YES  NO  If yes, drug name: .....

Mechanical Ventilation YES  NO  If yes, Date start..... Date end.....

Before Surgery/ After Surgery/ Both

Max PIP before surgery ..... Max PIP after surgery.....

HFOV: Yes  No,  if yes: Before / After surgery /Both

Age when TPN started.....

Age when oral feeds started: .....

Age when attained full oral feed (≥120ml/kg/day).....

Antacids used while on feeds: YES/ NO

Motility drugs used while on feeds: YES/ NO, if yes what: .....

**COMPLICATIONS**

Was there Sepsis? YES  NO

If yes, Probable (CRP >40)  or culture-proven

If confirmed, what were the organisms?

.....  
.....

Organism(s) antibiotics sensitivity.....

Did sepsis diagnose when? Before final closure/ After final closure/both

At the diagnosis of sepsis, the patient had the central line: Yes/ No

At diagnosis patient on TPN: Yes/ No

Other complications.....

.....

**OUTCOME:** Died  Survived

Date of outcome.....

If dead, state the cause of

death:.....

.....