Neonatal surgical mortality and morbidity in CHUK, a tertiary hospital in Rwanda: An analysis of predicting factors

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May, 2021

DECLARATION

The researcher

I hereby declare that this dissertation **"Neonatal surgical mortality and morbidity in CHUK a tertiary hospital in Rwanda: Analysis of predicting factors"** is my own work and it has not been submitted by anyone to any other University for the award of a Degree.

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I hereby declare that this dissertation **"Neonatal surgical mortality and morbidity in CHUK a tertiary hospital in Rwanda: Analysis of predicting factors"** was submitted by Dr. MANIRAGUHA Victor with my approval.

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DEDICATION

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ABBREVEATIONS

ARM	: Ano-rectal Malformation
C/S	: Cesarean section
CHUK	: Centre Hospitalier Universitaire Kigali
FBC	: Full blood count
GI	: Gastro-Intestinal
HB	: Hemoglobin
HICs	: High income countries
HR	: Heart rate
IBM	: International Business Machines
JIA	: Jejuno-ileal atresia
K^+	: Potassium
LBW	: Low Birth Weight
LMICs	: Low and Middle-Income Countries
Na^+	: Sodium
NEC	: Necrotizing Enterocolitis
NSM	: Neonatal Surgical Mortality
RR	: Respiratory rate
SSA	: Sub-Saharan African
SSI	: Surgical site infection
SVD	: Spontaneous vaginal delivery
TEF	: Tracheo-esophageal Fistula
TPN	: Total Parenteral Nutrition
WBC	: White blood cell count

ABSTRACT

Background

Neonatal surgical conditions occur in 1 in 5000 live births worldwide and contribute to high morbidity and mortality among neonates. Factors contributing to neonatal mortality include prematurity, sepsis, low birth weight, and malnutrition. Neonates with surgical conditions are more prone to sepsis due to various factors including wound infection, impaired metabolism and poor feeding. The Rwandan health system allows neonates with surgical conditions to be transferred to Centre Hospitalier Universitaire Kigali (CHUK), the largest referral hospital with a specialized pediatric surgical unit for neonatal surgical management. Despite the high number of neonatal admissions at CHUK, among which neonates with surgical conditions occupy a significant proportion, little is known about determinants of surgical outcomes among newborns whose clinical conditions require surgical management. The aim of this study was to assess the predicting factors of neonatal surgical mortality and to evaluate the outcomes of neonates with surgical conditions.

Methods

A prospective cross-sectional study was conducted at the University Teaching Hospital of Kigali from October 2019 to March 2020 among neonates with surgical conditions, defined as all neonates who received surgical consultation and diagnosis confirmed by a pediatric surgeon. We excluded neonates with surgical conditions who were transferred post operatively from different hospitals to continue care at CHUK. A data collection tool was used to collect information. The outcome variables were neonatal mortality and a composite morbidity of sepsis, malnutrition, surgical site infection, and need for mechanical ventilation among neonates with gastroschisis and neonates with other surgical conditions. Data were analyzed using SPSS software version 25. Chi square and Fisher's exact tests were used to calculate the association between variables considering alpha value of 0.05 and student t-test was used to compare means. An ethical clearance was obtained from the University of Rwanda and CHUK before data collection.

Results

Eighty-two neonates were recruited in this study. 45.1% were admitted within the first 24 hours of life, 61% were males 26.9% were preterm, 51.2% had birth weight less than 2500g. Gastroschisis was the main reason of transfer among 43 (52.4%) followed by intestinal atresia that occupied 12.2%. The overall mortality rate was 57%. Mortality was more likely to occur among neonates with gastroschisis compared to neonates with non-gastroschisis surgical conditions (76.7% vs 35.9%, OR=5.893, p<0.001). Among neonates with gastroschisis, factors associated with mortality were failure of initiation of enteral feeding (100%, p=0.002) and sepsis (82.5%, p=0.001). Among neonates with surgical conditions (non-gastroschisis), factors associated with mortality were prematurity (87.5%, OR:24, p=0.001), low birth weight (72.7% vs 21.4%, p=0.003), initiation of enteral feeding at more than 48 hours (33.3% vs 25.8%, p=0.006), sepsis (64.7% vs 13.6%, OR:11.61, p<0.001), and need of mechanical ventilation (63.6% vs 25%, OR:5.25, p=0.024,). Complications such as sepsis, malnutrition, need for mechanical ventilation

were the factors associated with the development of morbidity for surgical neonates with non-gastroschisis conditions.

Conclusions

Neonatal surgical mortality is significantly high at CHUK and gastroschisis was the most common surgical condition that also accounts for the majority of deaths.

This study showed that prematurity, low birth weight, initiation of enteral feeding more than 48 hours postoperatively, sepsis and need for mechanical ventilation are significant predictors of mortality for non-gastroschisis surgical conditions. In addition, sepsis and failure to initiate enteral feeding were factors that predicted mortality in neonates with gastroschisis. In this study, sepsis was a risk factor for mortality in neonates with gastroschisis and non-gastroschisis surgical conditions. These results were very important for planning of the clinical management and preventive measures to improve the outcome.

Key words:

Surgical condition, gastroschisis, mortality, morbidity, neonatal sepsis, prematurity.

CHAPTER I: Introduction

Neonatal surgical conditions occur in 1 in 5000 live births worldwide and contribute to high morbidity and mortality among neonates (1). Compared with older children, neonates present a wide divergence in physiology, anatomy, immunity and response to stress. When neonates have a surgical illness, their metabolism becomes dysregulated and can predispose them to mortality or morbidity in hospital such as surgical site infection, sepsis, malnutrition and need of postoperative mechanical ventilation. Different studies have reported factors contributing to neonatal mortality and they included prematurity, sepsis, low birth weight, and malnutrition (2–5).

Many retrospective observational studies on neonatal surgery have reported preoperative determinants of challenges and clinical outcomes in neonates with surgical conditions (6–8). Sepsis in neonatology remains a common challenge and complicates a significant number of neonates. Neonates with surgical conditions are more prone to sepsis due to various factors including wounds (an added port of bacterial entry), impaired metabolism and poor feeding (2,9–11). This study has provided knowledge on determining factors of mortality among neonates with surgical conditions.

1.1 Background

Neonates present different pathologies depending on congenital or acquired causes and many of them require surgical management to improve the quality of life (12). The most common conditions needing surgery are congenital and they include esophageal atresia, abdominal wall defects, intestinal obstructions due to atresia or aganglionic bowels and anorectal malformations.

In Rwanda, there are 36 district hospitals, 4 provincial hospitals and 8 referral hospitals. As the system is organized, neonates who are judged to need surgical management are transferred to Centre Hospitalier Universitaire Kigali, the largest referral hospital that has a specialized surgical pediatric unit for neonatal surgical management.

Ugwu et al (2015) assessed the challenges and types of surgical problems found in the neonatal period. Most (89%) surgical conditions were congenital abnormalities (13). Neonatal surgical conditions contributed significantly to both neonatal admissions and overall neonatal mortality in developing countries. Surgical conditions in neonates presented a mortality rate of 11.8% (13). The same study on neonatal surgery in sub-Saharan Africa reported a high mortality in congenital malformations. In Nigeria, however, there was an improvement during the last decade in terms of management of neonates with surgical conditions (13,14). Morbidity and complications are often serious and life-threatening secondary to physiological disorders. Mortality from neonatal surgery was reported as 48% in Cameroon and 62.2% in Nigeria (7)(15).

1.2 Problem statement

The Rwandan health system allows the district hospitals (community hospital at secondary health care level) to transfer all neonates judged to require an advanced management, such as surgical management, to a referral hospital where they can have access to a pediatric surgeon for specialized assessment and apply surgical management accordingly. The largest referral hospital in Rwanda being the University Teaching Hospital of Kigali (CHUK) admits the largest number of newborns in the country. Nearly one in every two neonates admitted at CHUK has sepsis either at admission or as developed during hospitalization (16). This number could be higher among neonates with surgical conditions. Despite the high number of neonatal admissions at CHUK, little is known about determinants of surgical outcomes among newborns. The aim of this study was to determine the factors predicting surgical neonatal mortality and to evaluate the outcomes of neonates with surgical conditions.

1.3 Hypothesis

We hypothesize that sepsis is a risk factor for mortality in patients with neonatal surgical conditions in CHUK.

1.4 Research question:

- What are the predisposing factors to neonatal surgical mortality and morbidity in CHUK?

1.5 General Objective:

- To evaluate the factors influencing the mortality of patients with neonatal surgical conditions managed at CHUK.

1.6 Specific objectives:

- To evaluate the frequency of different neonatal surgical conditions presenting to CHUK.
- To assess the mortality rate of patients with neonatal surgical conditions managed at CHUK.
- To assess the morbidities associated with surgical conditions among neonates managed at CHUK.
- To assess the factors associated with mortality in neonatal surgical patients managed at CHUK.

CHAPTER II: Literature review

Neonatal surgical mortality (NSM) is still a burden in some African countries and contributes to neonatal mortality. In high income countries (HICs), NSM is low compared to low and middle income countries (LMICs) for instance <4% of neonatal surgical mortality in the United States of America, <7% in Japan (2). African countries represent significantly high neonatal surgical mortality. For example, 52% in Uganda and 62% in Nigeria. This mortality was associated with the different types of surgical conditions and its management (2).

1. Common neonatal surgical conditions

In all countries, most common neonatal surgical conditions are congenital malformations and only few are acquired. However, the management outcomes differ as the countries differ in terms of healthcare facilities (13,17).

In several African countries, research was conducted on neonatal surgery and reported different surgical neonatal conditions such as congenital surgical pathologies and acquired surgical conditions (18). A meta-analysis also done for African neonatal surgery was focusing on challenges of management, trends in outcome and potential interventions to improve outcome. Common neonatal conditions reported were intestinal atresia in 28 (54.9%) studies, abdominal wall defects in 27 (52.9%) studies, anorectal malformations in 24 (47.1%) studies, and Hirschsprung's disease, necrotizing enterocolitis, and volvulus neonatorum each reported in 23 (45.1%) studies. Mortality rate was high (>50%) in emergency surgical neonatal pathologies involving bowel perforation or resection, congenital diaphragmatic hernia, esophageal atresia, and ruptured omphalocele or gastroschisis(12).

Abdominal wall defects

Abdominal wall defects are congenital malformations (gastroschisis, omphalocele) that are characterized by an abnormal variant opening in the abdomen through which different abdominal organs can protrude. Incidence of gastroschisis is a little bit higher than omphalocele, (2 to 6 and 0.8 to 3.9 per 10000 newborns, respectively) (18). Mortality rate from gastroschisis in developed countries is less than 10% but in low income and middle countries is greater than 90%. Poor outcome is due to lack of antenatal diagnosis, unsafe neonatal anesthesia, limited neonatal intensive care unit and lack of neonatal parenteral nutrition (19,20). The mortality rate from omphalocele depends on other associated anomalies. A study in Philadelphia showed that anterior abdominal wall defects are associated with neonatal mortality (gastroschisis 12.9% and omphalocele 20%) and morbidity (21).

Tracheoesophageal fistula

Tracheoesophageal fistula is a congenital life threatening anomaly of esophagus and trachea that occurs in 1 in 2400 to 4500 births (22). Prognosis for tracheoesophageal fistula was marked with improvement. Based on study done in Italy, a survival period improved from one year before 1996 to 25 years of survival due to advanced surgical techniques and neonatal intensive care unit.

The outcome of neonates with esophageal anomalies (EA) and tracheoesophageal fistula (TEF) depends upon associated abnormalities (23). One study reported the mortality of 12% in TEF in patients with associated cardiac disease. Among the early deaths, 61% were associated with anomalies such as cardiac and chromosomal anomalies (24).

In LMICs countries esophageal atresia mortality was reported to be in between 30-80% compared to HICs which is <10%. Delayed diagnosis, poor suctioning, sepsis, aspiration pneumonia and lack of trained personnel were highlighted to be associated with TEF mortality in LMICs. (25)

Intestinal atresia

Intestinal atresia is a congenital anomaly of intestines characterized by atretic or narrowing lesion which limits the passage of the bowel contents. There are 4 types of jejuno-ileal atresia (JIA)intestinal atresia with type IIIa as the commonest one (26). The mortality rate of jejuno-ileal atresia is less than 10% in high income countries (HICs) but 50- 60% in Africa where no nutritional support is available and presentation is late (27).

Mortality also found to be associated with location and types of atresia. Burjonruppa et al report severe atresias as one of factors predicting mortality. Ileal atresia was less severe than jejunal atresia (63.6% was type IIIb or IV) (28).

Anorectal Malformations

Anorectal malformations (ARM) are congenital spectrum of lesions which affect neonates regardless gender and involve the distal anus and rectum as well as genito-urinary system (29). ARM is the most come defect in neonates and presents with a wide spectrum defect, ranging from relatively low malformations to very complex cloacal anomalies. The management of ARM is critical because it saves the neonates' lives and determines the immediate future of the baby (30). More than 70% of anorectal malformations are associated with other anomalies. An Indian study reported the mortality 8% from ARM but 75% of them had associated anomalies whereas in Africa, mortality was up to 25% (30,31).

2. Prematurity

Prematurity (born with <37 weeks of gestation) is one factor associated with poor surgical neonatal outcome. A cohort study on critical neonates undergoing surgery under general anesthesia presented the overall mortality of 6.4% and prematurity to be among the commonest causes (32). Moreover, a study done in India on factors predicting neonatal surgical mortality reported that prematurity of <37 weeks showed to increase risk of mortality (2). In a study done in Portugal, postoperative complications were significantly associated with prematurity OR: 2.6, 50%CI, P: 0.005 (33). A study done in Chicago on the influence of prematurity on neonatal surgical morbidity and mortality showed that mortality was higher in preterm babies than in term P: 0.001 (22.2% and 2.9%, respectively)(34). Preterm neonates with surgical conditions are at higher risk of mortality more than other preterm babies with medical conditions due to different surgical conditions in association with poor immunity development and the effects of surgery and anesthesia.

3. Low birth weight

Low birth weight (<2500g) is an indicator of prenatal health care, which can have an impact on outcome in terms of mortality and morbidity.

After doing a multivariate analysis of a study done in Nepal, analysis showed increased risk of mortality in low birth weight neonates with surgical conditions OR: 8.49, 95% CI; (3.21-22.47). To have surgical conditions with low birth weight, was reported a predicting factor of neonatal surgical mortality through the literature (3). In a study done in Alexandria, Egypt, 156 neonates were recruited in a period of 1 year. Overall, 17.9% (28) of neonates had postoperative complications with a high mortality 56% seen in among low birth weight (LBW) neonates if you compare with normal infant neonates P= 0.00 and in those with other associated medical conditions P= 0.04. Among the neonatal populations with congenital malformations and other surgical conditions, low birth weight was found to be a statistically significant predictor of mortality (4). High morbidity and mortality occur among neonates with low birth weight (1).

4. Nutrition

Neonatal feeding is very crucial for metabolism support and growth. Breastfeeding in the first 6 months is very important for all neonates. Neonates with surgical conditions also need to be fed as soon as possible like other neonates or can receive nutrition support in cases where it is needed.

Intestinal permeability increased 2 to 4 times as early in the postoperative period and normalized within 5 days. Malnutrition was associated with increased intestinal permeability and decrease in villous height (35). Enteral and parenteral nutrition together with better knowledge of neonatal metabolic requirements showed to increase survival rate and improve the quality of life of neonates (36). Access to total parenteral nutrition depends on capacity in LMICs, especially since there is no enough expertise of total parenteral nutrition (TPN) delivery in low-income countries and use of intravenous fluids with dextrose is mostly available. TPN is available for most patients in need in HICs (37).

5. Surgical Site Infections (SSI)

Surgical site infections (SSI) are defined as infections that occur on the body where the incision was made (38). Neonates with surgical conditions are prone to get SSI, a local infection that can lead to systemic infection and end up by death if not managed properly. A study done by Vincenzo et al, SSI was categorized as superficial and involved the skin only or more seriously affecting the surrounding tissues or involving organs and material implant (38). SSI was the most common hospital acquired complication among others and was found to be a significant cause of morbidity and mortality in neonates and infants (39,40). Prematurity and gastrointestinal (GI) surgery showed to be the commonest factors associated with an increased risk of SSI (38,41,42).

A study done in Canada for neonatal surgical site infections revealed premature neonates were vulnerable to SSI (84%) due to their low neonatal immunity. Gastroschisis patients were also vulnerable to SSI after closure (15%) (43). No related mortality rate was presented due to having SSI.

6. Sepsis

Sepsis is a life threatening organ dysfunction caused by a dysregulated host response to infection and is shown to be associated with mortality (44). A meta-analysis study done in 2017 on predictors of mortality in neonates and infants hospitalized with sepsis or serious infections in developing countries showed sepsis to be associated with mortality (4). Analysis revealed sepsis and serious infections to be the most common factors associated with mortality (90%), but can be preventable by respecting all neonatal sepsis measures from World Health Organization guideline (45–47). A systematic review in sub-Saharan African countries evaluated mortality among the group of neonates with sepsis or severe infections and mortality was found to be in between 14.6-36% in hospitalized neonates (4).

In a surgical neonatal sepsis study done in two hospitals in Bangladesh reported that neonatal sepsis is still a major concern in LMICs depending on different factors such as home delivery, delay in presentation, poor hygiene, etc. (48,49). Invasive procedures expose the neonates with surgical conditions to nosocomial infections and sepsis. Despite a management plan to treat sepsis and to decrease the mortality rate, sepsis remained a significant cause of death among the neonates with surgical conditions. Most cases of sepsis occur when the surgeries are performed on an emergency basis (5,50–52). Whereas in a study done in 2009, aiming to find out the current prevalence, patterns and factors associated with neonatal surgical mortality in Africa, showed that sepsis and late referrals contributed to early mortality (53).

Manchanda at el (2012) conducted a multivariate analysis and found that sepsis was among the factors leading to poor neonatal prognosis (6). Management of sepsis is very crucial and needs to be well applied and monitored.

Currently, there is no study in Rwanda assessing outcomes and factors associated with mortality in neonatal surgical patients.

CHAPTER III: Methods

3.1 Study design

This was a prospective cross-sectional study among patients who were managed by the pediatric surgery service for different neonatal surgical pathologies from October 2019 to March 2020.

3.2 Study setting

The study was conducted at CHUK, which receives patients from different public hospitals and private clinics for further management of neonatal surgical conditions. This is the only hospital in Rwanda which has a functional pediatric surgery service. CHUK has one pediatric surgery ward with 15 beds, two pediatric surgeons, a pediatric surgery fellow and one pediatric anesthesiologist.

3.3 Inclusion criteria

- All patients of less than 28 days of life with surgical conditions managed at CHUK. We define neonatal surgical conditions as any pathology requiring a surgical consult and admission for management by the pediatric surgery team.

3.4 Exclusion criteria

- Any neonatal surgical patient whose attendant refused to consent for being involved in this study.
- Any neonatal patient managed by CHUK pediatric surgery but transferred to another hospital as inpatient for further management.
- A neonate who was transferred post-operatively from another hospital to continue further management in Pediatric surgery at CHUK.

3.5 Enrollment and Data analysis

3.5.1 Procedure

Neonates with surgical conditions were identified from the pediatric emergency department and neonatology unit after a surgical consultation of a pediatric surgeon. All neonates with surgical conditions were enrolled in this study. All neonates with surgical conditions from the emergency department were admitted in pediatric surgical wards and neonatology for neonates born at CHUK and followed through their hospital course. Data were collected during the hospital stay from admission until either discharge or 30 days post-operative. Data were recorded from the patient file and confirmed with patients' parents. The number of all neonates in the pediatrics department was obtained from the register records.

3.5.2 Data collection and Variables

During data collection, we used a hard copy form and data entered into Microsoft excel. Variables were categorized as; socio-demographic data (age, gender, referring province, insurance), laboratory data full blood count (FBC), electrolytes, blood cultures) and clinical data (mode of delivery, gestational age, birth weight, vital signs, diagnosis, procedure, intraoperative events,

duration of surgery, post-operative disposition, post-operative complications, length of hospital stay, and status at hospital discharge).

Definitions and Variables

All variables found on questionnaire during the data collections were defined according to the study design as follow:

- Surgical neonate defined as all neonates under 28 days of life with a congenital or acquired surgical condition
- Age at admission was defined as days of life at hospital admission.
- Birth weight was categorized in low birth weight (<2500g) and normal birth weight (>2500g) according to the World Health Organization (WHO) guideline on neonatal protocol (54).
- Prematurity was defined as a neonate who was born under 37 gestation weeks based on WHO (55).

Diagnosis

- Surgical condition is defined as conditions which are found in pediatric surgery diagnoses.

Surgery

- Surgery was defined as a procedure under general or local anesthesia.
- Duration of surgery is the time elapsed between induction and recovery as indicated on the anesthesia records form.
- Intraoperative adverse events were considered as arrhythmia, need of vasopressor, transfusion or cardiac arrest during surgery.

Complications

- Surgical site infection was based on a clinical diagnosis made by the pediatric surgeon based on wound break down or discharging pus for superficial and deep infections. (56).
- Malnutrition was defined based on clinical assessment by pediatrician or pediatric surgeon, on bases of total intakes, edema and weight loss trends among others (57).
- Sepsis was defined based on clinical diagnosis made by the pediatrician or pediatric surgeon. Sepsis was characterized by weakness, fever, inability to tolerate feeds with or without positive septic workup such as white blood cells (WBC), blood culture, urinalysis in neonates with surgical conditions (58).
- Postoperative mechanical ventilation was considered as a need for postoperative re-intubation or continuous intubation post-surgery.

Nutrition

- Total parenteral nutrition (TPN) was reported as a binary variable. Any surgical neonate who was given TPN was recorded positively.
- For patients with gastroschisis, early initiation of enteral feeding was defined as starting feeding within < 7 days from birth; intermediate initiation of enteral feeding was defined as starting feeding in 7-14 days of life; late enteral feeding initiation was defined as start feeding in >14 days of life. This included feeding orally or through a nasogastric tube.
- For patients with non-gastroschisis conditions, early enteral feeding was defined as initiation of feed < 48 hours post-operatively. This included feeding orally or through a nasogastric tube. For those who did not undergo operation, initial enteral feeding was not recorded because some died immediately before surgery others were treated with non-operative management while breastfeeding. In this study, the primary outcome was mortality and second outcome was morbidity.

Morbidity was defined as postoperative complications such as sepsis, malnutrition, surgical site infection and need for mechanical ventilation.

3.5.3 Data analysis

Collected data regarding neonatal surgical mortality and morbidity in CHUK was analyzed using IBM SPSS software version 25. Patients' characteristics were analyzed and presented as frequency and percentages. For continuous variables, the means and standard deviations (SD) were presented.

Due the high number of neonates with gastroschisis and its unique management, which cannot be applied to other conditions, analysis of patients was divided based on diagnosis of gastroschisis versus non-gastroschisis conditions.

Chi square and Fisher's exact tests were used to calculate the association between variables and student t-test was used for means comparison in scale variables. An association between variables was considered significant if the p-value was less than 0.05. Odds Ratios (OR) were calculated and 95% Confidence Interval (95% CI) were presented. A bivariate analysis was used to evaluate factors associated with mortality and morbidity in the group with gastroschisis and in the group with non-gastroschisis surgical conditions separately.

Sample size

Equation 1. Yamane Sample size formula

$$* n = \frac{N}{1+N(e)^2} = 80$$

*n= sample size

N= Population size: 100(5.4%) (January 2018- December 2018)
e= level of precision or sampling of Error which is ± 5%

3.5.4 Ethical considerations and data management

Ethical approval was obtained from the institutional review board of the University of Rwanda and CHUK ethics committee prior to study initiation. Informed consent was obtained from parents and after data collection, the collected data were de-identified. The data were encrypted and protected by a password held by only the research team.

CHAPTER IV: Results

During our study period, 486 neonates were admitted at CHUK with 276 (56.8%) admitted immediately after birth in the neonatology unit and 210 (43.2%) admitted through pediatric emergency from outside CHUK. Among these admissions, 82 (16.9%) were admitted due to a surgical condition and they were included in this study. Among the 82 neonates included in this study, 78 (95.1%) were admitted through the emergency department from other health institutions while only 4 (4.9%) were born in CHUK. Neonates with gastroschisis occupied 52.4% of all neonatal surgical conditions.

4.1 Patient characteristics

Table 1 shows the demographic characteristics of the enrolled neonates with surgical conditions. Among the provinces of origin in the country, eastern province represented 28% of all admitted neonates with surgical conditions. The mean birth weight was 2536.5±570.1g (min:1500g-max:4200g) and more than half (51.2%) had low birth weight. The mean age of life at presentation was 3.9±5.8 days with a male preponderance (male to female ratio of 3:2). The majority of neonates were born at term (73.2%) and by spontaneous vaginal delivery (78%). The majority of patients (91.5%) had community health insurance. Only 2 neonates did not have health insurance.

Table 1. Patients' socio-demographics

	N	%
Province		
Kigali	17	20.7
Northern	10	12.2
Southern	13	15.9
Eastern	23	28.0
Western	19	23.2
Age at admission		
≤24 hours	37	45.1
>24-48 hours	23	28
>48 hours	22	26.8
Mean ± SD (days)		3.9 ±5.8 (1-28)
Gender		
Male	50	61
Female	32	39
Mode of delivery		
Spontaneous Vaginal Delivery(SVD)	64	78
CS	18	22
Gestational age at delivery		
29-32	3	3.7
33-36	19	23.2
≥37W	60	73.2
Birth weight		
<2500g	42	51.2
≥2500g	40	48.8
Mean ± SD (days)		2536.5 ± 570.1
Insurance		
None	2	2.4
Category 1	13	15.9
Category 2	31	37.8
Category 3	31	37.8
Category 4	0	0
Private	5	6.1

Table 2 shows that the most common surgical condition was gastroschisis (52.4%) followed by intestinal atresia (12.2%), anorectal malformations (9.8%) and omphalocele (6.1%).

Table 2. Diagnosis

Diagnosis	**N**	**%**
Gastroschisis	43	52.4
Intestinal atresia	10	12.2
ARM/Imperforated anus	8	9.8
Omphalocele	5	6.1
Meconium plug	4	4.9
Inguinal hernia	2	2.4
Dry gangrene	1	1.2
Necrotizing Entecolitis	1	1.2
EA-TEF	1	1.2
Annular pancreas	1	1.2
Pyomyositis	1	1.2
Ranula oral cyst	1	1.2
Ischemic upper limb	1	1.2
Burn	1	1.2
Femur fracture	1	1.2
Hirschsprung disease	1	1.2
Total	82	100

4.2 Clinical characteristics of patients with gastroschisis

The clinical characteristics of neonates with gastroschisis are presented in Table 3. Among neonates with gastroschisis, 72% had low birth weight, 32% were premature, 32% were transferred from eastern province. All neonates who had gastroschisis underwent surgically sterile procedures like putting silo-bag and daily manual bowel reduction at bedside. No neonate with gastroschisis underwent surgery in the operating room under anesthesia. Nearly half (48.8%) of them never initiated enteral feeding while only 3 (7%) could receive total parenteral nutrition. As complications, 20.9% developed malnutrition, 93% had sepsis, and 34.9% needed ventilation.

Table 3. Clinical characteristics among neonates with gastroschisis

Variable	N	%
Province		
Kigali	7	16.3
Northern	2	4.7
Southern	9	20.9
Eastern	14	32.6
Western	11	25.6
Insurance		
None	2	4.7
Category 1	7	16.3
Category 2	19	44.2
category 3	13	30.2
Category 4	0	0
Private	2	4.7
Gestational Age		
29-32W	2	4.7
33-36W	12	27.9
>36W	29	67.4
Mode of Delivery		
SVD	34	79.1
CS	9	20.9
Birth weight		
<2500g	31	72.1
>=2500g	12	27.9
Initial enteral feeding from birth		
≤7 days	13	30.2
8-14 days	8	18.6
>14 days	1	2.3
No feeding	21	48.8
Disposition		
Ward	39	90.7
PICU	1	2.3
Neonatal Unit	3	7
TPN given		
Yes	3	7
No	40	93
Complications		
Malnutrition	9	20.9
Sepsis	40	93
Ventilation (Any)	15	34.9

4.3 Clinical characteristics of patients with non-gastroschisis conditions

The clinical characteristics of neonates with non-gastroschisis surgical conditions are presented in Table 4. Among neonates with non-gastroschisis surgical conditions, more than 76% were born by spontaneous vaginal delivery and 71.8% of all admitted surgical neonates born with normal birth weight. Kigali city was the most province of origin. During surgical management, 26 (66.7%) neonates were operated on for a mean operative time of 116.7 ± 69.7 minutes. Intraoperative complications included the need for vasopressors and cardiac arrest in one neonate. More than two thirds (71.8%) were admitted to the pediatric ward. More than 79% initiated enteral feeding within the first 48 hours postoperatively.

The most common complication among neonates with the non-gastroschisis surgical condition group was sepsis presenting among 53.3%, followed by need for mechanical ventilation (38.5%), 28.2% had low birth weight, 20.5% were premature babies, surgical site infection (23.1%) and malnutrition (11.5%).

Table 4. Clinical characteristics among neonates with non-gastroschisis surgical conditions

Variable	N	%
Province		
Kigali	10	25.6
Northern	8	20.5
Southern	4	10.3
Eastern	9	23.1
Western	8	20.5
Insurance		
None	0	0
Category 1	6	15.4
Category 2	12	30.8
category 3	18	46.2
Category 4	0	0
Private	3	7.7
Gestational Age		
29-32	1	2.6
33-36	7	17.9
>36W	31	79.5
Mode of Delivery		
SVD	30	76.9
CS	9	23.1
Birth weight		
<2500g	11	28.2
>=2500g	28	71.8
Operated		
Yes	26	66.7
No	13	33.3
Intra-operative events (N=26)		
Vasopressors	1	3.8
Arrhythmia	0	0
Cardiac arrest	1	3.8
Transfusion	0	0
Duration of surgery (N= 26)		
<60min	3	11.5
60-119mins	11	42.3
>120mins	12	46.2
Mean ± SD	116.7 ±69.7	
Initial Enteral Feed (N=39)		
<48hours	31	79.5
>48hours	3	7.7
No feeding	5	12.8
Disposition		
Ward	28	71.8
PICU	10	25.6
Neonatal Unit	1	2.6
TPN Given		
Yes	3	7.7
No	36	92.3
Complications		
SSI	6	23.1
Malnutrition	3	11.5
Sepsis	16	53.3
Need for ventilation	10	38.5

4.4 Mortality among neonates with surgical conditions

Figure 1 represents the mortality and survival rates among all neonates recruited in this study. More than half (57%) died from neonatal surgical conditions or their complications while only 43% survived. The mortality rate was 76,7% and 35.9% among neonates with gastroschisis and neonates with non-gastroschisis conditions respectively.

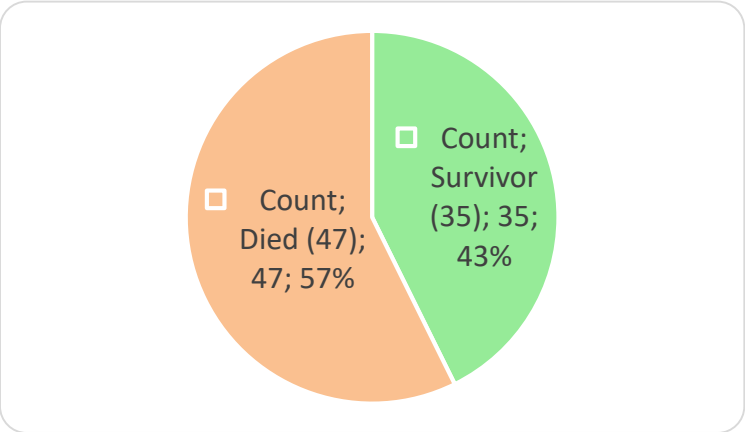

Figure 1. Mortality rate among neonates with surgical conditions

4.5 Factors associated with mortality

4.5.1 Analysis of Gastroschisis condition

Table 5 represents factors associated with mortality among neonates with gastroschisis. Factors associated with mortality among neonates with gastroschisis were lack of initiation of enteral feeding (100% vs 54.5%, $p<0.001$) and the presence of sepsis (82.5%, $p=0.001$). Furthermore, factors such as province of origin, gender, age at admission and malnutrition were not statistically significantly associated with mortality.

Table 5. Determinants of survival among neonates with gastroschisis

		Status at discharge N (%)				
		Survivor	Died	p-value	OR	95% CI
Province	Kigali	3 (42.9)	4 (57.1)	0.466	-	
	Northern	1 (50.0)	1 (50.0)			
	Southern	2 (22.2)	7 (77.8)			
	Eastern	3 (21.4)	11 (78.6)			
	Western	1 (9.1)	10 (90.9)			
Gender	Male	6 (26.1)	17 (73.9)	0.637	1.412	[O.335-5.944]
	Female	4 (20)	16 (80)			
Gestational Age	Term	9 (31)	20 (69)	0.112	5.143	[0.579-45.693]
	Pre-Term	1 (7.1)	13 (92.9)			
Age at admission	<24 hours	9 (26.5)	25 (73.5)	0.332	2.88	[0.315-26.360]
	24-48 hours	1 (11.1)	8 (88.9)			
	>48 hours	0 (0)	0 (0)			
Birth weight	<2500	7 (22.6)	24 (77.4)	0.866	0.875	[0.185-4.141]
	=>2500	3 (25)	9 (75)			
Disposition	Ward	9 (23.1)	30 (76.9)	0.789		
	PICU	0 (0)	1 (100)			
	Neonatal Unit	1 (33.3)	2 (66.7)			
Initial enteral feeding	Yes	10 (45.5)	12 (54.5)	**0.000**	-	
	No	0 (0)	21 (100)			
Early enteral feeding (22)	≤ 7days	7 (53.8)	6 (46.2)	0.342	0.429	[0.073-2.500]
	> 7 days	3 (33.3)	6 (66.7)			
TPN given	Yes	0 (0)	3 (100)	0.323	-	
	No	10 (25)	30 (75)			
Malnutrition	Yes	0 (0)	9 (100)	0.063	-	
	No	10 (29.4)	24 (70.6)			
Sepsis	Yes	7 (17.5)	33 (82.5)	**0.001**	-	
	No	3 (100)	0 (0)			

The impact of gastroschisis on mortality among neonates with surgical conditions is represented in Table 6 and shows that, the likelihood of dying in hospital is five times higher in neonates with gastroschisis compared to neonates with other surgical conditions (76.7% vs 35.9%, p<0.001, OR=5.893 (2.248-15.446)).

Table 6. Gastroschisis impact on mortality

Surgical condition (N=82)	**Survivor**		**Died**		**p-value**	**OR**	**95% CI**
	N	**%**	**N**	**%**			
Gastroschisis	10	23.3	33	76.7	<0.001	5.893	(2.248-15.446)
Non-gastroschisis	25	64.1	14	35.9			

4.5.2 Analysis of non-gastroschisis neonatal surgical conditions

As shown in Table 7, the factors associated with mortality among neonates with non-gastroschisis surgical conditions were prematurity (87.5% vs 22.6%, OR:24.0, 95%CI: 2.509-229.561, p=0.001),

low birth weight (72.7% vs 21.4%, p=0.003), initiation of enteral feeding at more than 48 hours (33.3% vs 25.8%, p=0.006), sepsis (64.7% vs 13.6%, OR:11.611, 95%CI:2.410-55.939, p=0.001) and the need for ventilation (63.6% vs 25.0%, OR:5.250, 95%CI: 1.175-23.457, p=0.024).

Factors such as being operated on, SSI and malnutrition did not have a significant association with mortality.

Table 7. Determinants of survival among neonates with non-gastroschisis surgical conditions

		Survivor N (%)	Died N (%)	p-value	OR	95% CI
Province	Kigali	9 (90)	1 (10.0)	0.310	-	-
	Northern	5 (62.5)	3 (37.5)			
	Southern	2 (50)	2 (50.0)			
	Eastern	4 (44.4)	5 (55.6)			
	Western	5 (62.5)	3 (37.5)			
Gender	Male	18 (66.7)	9 (33.3)	0.617	1.429	0.353-5.788
	Female	7 (58.3)	5 (41.7)			
Gestational Age	Term	24 (77.4)	7 (22.6)	**0.001**	24.000	2.509-229.561
	Pre-Term	1 (12.5)	7 (87.5)			
Age at admission	<24 hours	1 (33.3)	2 (66.7)	0.326	-	-
	24-48 hours	8 (57.1)	6 (42.9)			
	>48 hours	16 (72.7)	6 (27.3)			
Birth weight	<2500g	3 (27.3)	8 (72.7)	**0.003**	0.102	0.021-0.509
	≥2500g	22 (78.6)	6 (21.4)			
Disposition	Ward	19 (67.9)	9 (32.1)	0.362	-	-
	PICU	6 (60)	4 (40.0)			
	Neonatal Unit	0 (0)	1 (100)			
Operated	Yes	19 (73.1)	7 (26.9)	0.098	0.316	0.078-1.271
	No	6 (46.2)	7 (53.8)			
Enteral Feeding	<48 hours	23 (74.2)	8 (25.8)	**0.006**	-	-
	≥48 hours	2 (66.7)	1 (33.3)			
	No feeding	0 (0)	5 (100)			
TPN given	Yes	1 (33.3)	2 (66.7)	0.248	4.000	0.329-48.656
	No	24 (66.7)	12 (33.3)			
SSI	Yes	5 (83.3)	1 (16.7)	0.518	0.467	0.044-4.895
	No	14 (70)	6 (30.0)			
Malnutrition	Yes	1 (20.0)	4 (80.0)	**0.028**	9.600	0.951-96.922
	No	24 (70.6)	10 (29.4)			
Sepsis	Yes	6 (35.3)	11 (64.7)	**0.001**	11.611	2.410-55.939
	No	19 (86.4)	3 (13.6)			
Ventilation	Yes	4 (36.4)	7 (63.6)	**0.024**	5.250	1.175-23.457
	No	21 (75.0)	7 (25.0)			

CHAPTER V: Discussion

The aim of this study was to assess the predicting factors of neonatal surgical mortality and to evaluate the outcomes of neonates with surgical conditions at CHUK. In general, prematurity, low birth weight, failure of enteral feeding initiation, malnutrition, sepsis and need of mechanical ventilation were the factors associated with mortality in neonates with surgical conditions. The results of this study show that proportion of neonates with surgical conditions were significant with 16.9% of all causes of neonatal admission compared to Nigeria (6.2%) (14). The increased rate of neonatal surgical conditions in this study also could be explained by our study site being the only hospital in the country that has a surgical neonatal unit which naturally increases the numerator of neonates with surgical conditions without an equivalent increase in the number of all neonatal admissions.

The most common conditions found in our study were related to the abdominal wall defects which normally are scanned during prenatal period. In our setting, prenatal scanning took place at hospitals for the wellbeing of fetus and mother. Prenatal care in Rwanda is delivered at health facilities (health centers and secondary and tertiary hospitals) and 98% of women try to attend more than one prenatal visit but only 68.9% of neonates are delivered at health facilities (59). A number of pregnant women are still giving birth at home (29%). This is different from United states where >95% of pregnant women attend prenatal visits and deliver at health facilities (60). A very low percentage (4) of pregnant women meet a doctor in prenatal care at the level of hospitals (59). There is no formal anomaly scan performed by a competent clinician in the 2^{nd} /3^{rd} trimester and this explains the fact that the overwhelming majority of congenital deformities such as omphalocele and gastroschisis are discovered at birth.

Mortality occurred among 57% of neonates with surgical conditions, at CHUK during our study period. This is comparable to the results of the study from the Children's Hospital at Westmead that also showed 54.8% of mortality among neonates with surgical conditions but higher than the results from a facility based study in Nigeria showing that among all admitted neonatal surgical conditions 42.6% had neonatal death (13,61). However, this study retrieved data for eight years while our study has collected data for only 6 months.

Gastroschisis has a poor outcome in affected neonates mainly because of its pathophysiology and clinical characteristic of leaving the bowels exposed to air with eventual insensible loss of fluid and electrolytes which further worsens the neonatal clinical status (62).The management of gastroschisis typically involves a good neonatal resuscitation, availability of nutrition support, pediatricians, neonatal and critical care nurses, pediatric surgeons and pediatric anesthesiologists within an appropriate environment to deliver neonatal critical care. In addition to this, the primary closure under general anesthesia or bedside preformed silo-bag placement with serial manual reduction and delayed closure showed to offer good prognosis in HICs (62). In our study, the majority of neonates with gastroschisis were given intravenous fluids, bedside silo bag placement, serial bowels reduction with delayed closure and admitted in general wards with major limitation to access of TPN. Despite all efforts to manage gastroschisis cases, gastroschisis presented a high

mortality rate (three quarters of all NSM) in our hospital which is different from developed countries but which can also be seen in the high mortality rate in Ghana (63). Moreover, with no strong evidence, mortality rate among neonates with gastroschisis in our study can also be related to the lack of parenteral nutrition which is among the essential components of medical care for neonates with gastroschisis.

The role of early initiation of enteral feeding in gastroschisis as documented by Thompson et.al and Aljahdali et.al describes that initiation of early feeding is associated with fewer mortality, shorter hospital stay and better weight gain among neonates with gastroschisis (64,65). This was also demonstrated in our results showing a significant negative association between the timing of enteral feeding initiation and neonatal mortality. Delay to initiate enteral feeding depended on severity of condition by poor bowel development with high bowel intolerance. Neonatal death was lower among neonates for whom enteral feeding was initiated in less than 7 days of life. It is likely that early feeding stimulates the gastric mucosa adaptation allowing the ability of full enteral feeding earlier (64).

Sepsis was associated with high mortality among neonates with gastroschisis and sepsis was also a finding in a tertiary teaching hospital in Nigeria (13). Despite the effort to treat neonatal sepsis, the previous studies showed some resistance to antibiotics like ampicillin or gentamycin in management of neonatal sepsis at CHUK (66,67).

Among neonates with non-gastroschisis surgical conditions, factors associated with mortality were prematurity, low birth weight, malnutrition, need for mechanical ventilation and sepsis. Prematurity was significantly associated with surgical neonatal mortality in non-gastroschisis surgical conditions. Similarly, prematurity was strongly associated with neonatal mortality in India as well as in Mexico (68). Immunity and metabolism of preterm neonates are less strong than the ones of term neonates and this made them to be vulnerable to mortality (34).

However, among neonates with non-gastroschisis surgical conditions, there was a significant positive association between birth weight and neonatal survival. This is in agreement with the study conducted in Ghana describing the negative effect of low birth weight in neonates with surgical conditions (63).

During bivariate analysis, malnutrition was a predicting factor of neonatal surgical mortality among neonates with non-gastroschisis conditions. Corresponding result also reported malnutrition to be among the factor predisposing to neonatal surgical mortality (35). Malnutrition is associated with increased intestinal permeability and decrease in villous height in postoperative period. All of these lead to poor gastrointestinal tract intolerance and functions which cause malnutrition and this can be reversed by enteral feeding or parenteral nutrition support. In the period of our study, TPN was not well available due to the cost and availability of resources. Different studies reported TPN to decrease neonatal malnutrition as nutrition support and increase survival rate (36,69).

Sepsis and need for mechanical ventilation were the significant factors associated with mortality in non-gastroschisis conditions. This is similar to the findings from other resource limited settings highlighting sepsis and need for mechanical ventilation as significant predictors of neonatal death (2). The lack of adequate ventilation specifically for neonatal ventilation in resource limited settings may also impact neonatal survival and hence lead to higher mortality rates (63). In the bivariate analysis, the presence of sepsis hindered the neonatal outcome significantly regardless of the type of diagnosis and this is in line with the findings from Nigeria and in Alexandria (1,13).

During the analysis looking at predictors of mortality in our patient population, sepsis was significantly associated with neonatal death, mainly in the gastroschisis group but also in the non-gastroschisis group. Sepsis is also a significant predictive factor of morbidity in the non-gastroschisis conditions group. The higher likelihood of having neonatal sepsis among neonates with gastroschisis could be explained by the clinical aspect of gastroschisis that exposes bowel surfaces to the external environment leading to an inflammatory process making the neonates more susceptible to microbial invasion. Additionally, the poorly developed gastrointestinal tract (mucosal integrity) of preterm neonates leads to feeding intolerance and development of malnutrition and susceptibility to infection, a composite of which are also associated with neonatal mortality as demonstrated in this study (70,71). Many attempts in looking for intravenous line access are the potential sources in developing sepsis. Surgical neonatal sepsis is still a burden in our hospital and represents a high number of neonatal mortality rates as presented in our study.

Limitations of the study

The main limitation of our study is the relatively small sample size and being a facility-based study, which limits its generalizability to represent the country and also lowers the statistical power. Also, our study was not powered enough to exclude confounders such as malrotation, atresia, necrosis and perforation from causes of mortality among neonates with gastroschisis and yet, these conditions are documented to complicate 25% of gastroschisis (62).

CHAPITER VI: Conclusion and recommendations

Neonatal surgical mortality is significantly high at CHUK and most of admitted neonates with surgical conditions (95%) were born outside of CHUK. Gastroschisis was the most common surgical condition that also accounts for the majority of deaths.

This study showed that prematurity, low birth weight, initiation of enteral feeding more than 48 hours postoperatively, sepsis and need for mechanical ventilation are significant predictors of mortality for non-gastroschisis surgical conditions. In addition, sepsis and failure to initiate enteral feeding were factors that predicted mortality in neonates with gastroschisis. In this study, sepsis was a risk factor for mortality in neonates with gastroschisis and non-gastroschisis surgical conditions and this has confirmed our research hypothesis.

Recommendations

We suggest utilizing all measures to decrease the surgical neonatal sepsis rate at CHUK. Infection prevention and control during surgical neonatal care, good resuscitation and use of appropriate antibiotics in need are among meticulous care in reduction of sepsis. Improvement in medical and surgical care management of premature neonates is important as the survival rate was high among term neonates.

We recommend making TPN available for nutritional support to prove if parenteral nutrition can contribute to the decrease of surgical neonatal mortality and other complications

We recommend encouraging pregnant mothers to attend prenatal visits regularly and get scanned to rule out the congenital anomalies for the well-being of fetus. This will improve in having high number of premature and low birth weight neonates.

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APPENDIX

APPENDIX 1: QUESTIONNAIRE FOR ASSESSING NEONATAL MORTALITY AND MORBIDITY AT UNIVERSITY TEACHING HOSPITAL OF KIGALI (CHUK)

□ Demographic data

□ Age in days on admission: …….. ID:

□ Sex: ……..

□ District: ……

□ Province: ……

□ Referring District Hospital ……..

Insurance category:

□ Clinical characteristics

□ Birth History:

- Mode of Delivery: ……..
- Preterm: Yes No If yes, what the term age? 1) 26w-28w
  2) 29w-32w
  3) 33w- 36w
- Term
- Birth Weight (Kg) …..

□ Vital signs on admission:

- Blood Pressure (mmHg): …….....
- Pulse Rate (bpm) …….…,
- Respiratory Rate (cycles/min): …….…
- SPO2: ……..…,
- Temperature (Celsius):…..

□ Primary Diagnosis: ……...

□Secondary Dx: ……..

□ Tertiary Dx: ……..

Laboratory data on admission:

□ WBc: ……, Hemoglobin:…..…… Platelets: ……Neutrophils: ……...,

□ Electrolytes: sodium: ……. ……..Potassium: ……..Chloride: ……..

Laboratory extreme data In hospital:

Low: Wbc:…….. Hb:…… K+: ……. Na+: …….

High: Wbc:…….. Hb:……. K+: ……. Na+: …….

Blood Culture done: Yes No

If Yes, was it?

- Negative
- Positive if positive, germs……..

Surgery: Yes No

In Theatre (Operative data):

 Procedure: ……..

 Intra op events:

- Vasopressors
- Heart arrhythmias/
- Arrest
- Transfusion

Duration of Surgery: ……..

 Disposition:

- PICU
- NICU
- WARD

 Inpatient follow up:

- TPN: Yes No
- When Enteral feeding……...Days
- SSI: Yes No
- Malnutrition: Yes No
- Sepsis: Yes No
- Post op Ventilation: Yes No

 Primary outcome: In hospital death: Yes No

 Secondary outcome:

- Length of hospital stay……..

Discharged: Yes No

APPENDIX 2: INFORMED CONSENT

Research title:" **Neonatal surgical Mortality and morbidity in CHUK, a tertiary hospital in Rwanda: An analysis of predicting factors**

INVESTIGATOR: Dr. MANIRAGUHA Victor

Tel: 0788531311, email: vmvicky01@gmail.com

INFORMATION SHEET & CONSENT

Please read carefully before deciding on participation

Purpose of the study: To determine the factors predicting neonatal surgical mortality and morbidity in CHUK as tertiary Hospital in Rwanda.

What you will do in the study: To accept, being followed during the hospital stay.

Time required being included in the study: You will be included in the study from the time of admission in at Pediatric emergency department until the day 30 post operation it will not interfere with your own program or usual life.

Risks related to the study: There are no anticipated risks for anyone who will be included in the study

Benefits from the study: there is no financial benefit to participate in this study, but later it may help patients with this condition to be managed earlier.

Confidentiality: All information will be kept confidential there will be no access for anyone else than the researcher or the patient.

Right to withdraw from the study: Any participant is free to withdraw from the study at any time without consequences either for him or his life.

Results from the study may be published in scientific conferences or medical journals for better understanding and management of this condition by many health care workers.

If you have concern about the study, contact

Dr. MANIRAGUHA Victor, University of Rwanda, Resident in Surgery; Tel: + (250)788531311
E-mail: vmvicky01@gmail.com

If you have questions about your rights in the study, contact:

Professor Kato J. Njunwa, Chairperson, Institutional Review Board, Tel: +250788490522

Dr Brenda Asiimwe-Kateera, Secretary, Institutional review Board

College of Medicine and Health Sciences, University of Rwanda/
P.O.Box 3286 Kigali/Rwanda Email: researchcenter@ur.ac.rw; website : http//chms.ur/ac/rw

Agreement:

I,…… agree to participate in the research study described above

Signature: **Date**

AMASEZERANO YO KWEMERA KUJYA MUBUSHAKASHATSI

UMUTWE W' UBUSHAKASHATSI: Neonatal surgical Mortality and morbidity in CHUK, a tertiary hospital in Rwanda: An analysis of predicting factors

IMPAMVU ZITERA GUPFA CYANGWA GUTINDA MUBITARO KUBANA BATARENGEJE IMINSI 28Y'AMAVUKO BAFITE INDWARA ZIBAGWA MUBITARO BYA CHUK.

UKORA UBUSHAKASHATSI: **Dr. MANIRAGUHA Victor**

Tel 0788531311, e-mail: vmvicky01@gmail.com

IBISOBANURO NO KWEMERA KUJYA MU BUSHAKASHATSI

Soma neza mbere yo kwemera kujya mu bushakashatsi

Icyigamijwe mu bushakashatsi: kureba inzitizi mu mivurire y'indwara zibagwa z'abana batarengeje iminsi 28 y' amavuko no gusesengura ikibitera nyuma yo kubagwa.

Icyo usabwa muri ubu bushakashatsi: kwemera ko dukomeza kugukurikirana igihe ukiri mubitaro

Igihe usabwa kumara mu bushakashatsi: kuva ugiye mubitaro kugeza urangije kuvurwa waba warabazwe ukageza ku munsi wa 30 nyuma yo kubagwa ukiri muri ubu bushakashatsi. Ibi ntacyo bizabangamira muri gahunda zawe ndetse n'ubuzima bwa buri munsi.

Ingaruka mbi zijyanye no kujya muri ubu bushakashatsi: nta ngaruka mbi cyangwa izindi nkurikizi zitezwe ku muntu uri muri ubu bushakashatsi.

Inyungu yo kujya mu bushakashatsi: nta gihembo giteganyijwe k'uwinjiye muri ubu bushakashatsi.

Gusa nyuma yaho bishobora kuzafasha abana abarwaye izondwara zibagwa kujya zimenyekana n' inzitizi zitera kutagira umusaruro mwiza zigakosorwa aho bishoboka.

Kugirirwa ibanga: amakuru azatangwa azakomeza kugirwa ibanga hagati y' umushakashatsi n'uywayatanze, nta wundi muntu uzaba ashobora kuyageraho uretse abo bombi gusa.

Uburenganzira bwo kwivana mu bushakashatsi: buri wese winjiye muri ubu bushakashatsi ashobora kwivanamo igihe abishakiye nta zindi nkurikizi.

Ibizava mu bushakashatsi bisangizwa abandi mu nama cyangwa mu binyamakuru by abaganga mu kurushaho kumenya ubu burwayi no kubuvura hakiri kare.

Ukeneye ibindi bisobanuro wabaza:

Dr MANIRAGUHA Victor, University of Rwanda, Umuganga wihugura mu Kubaga; tel: +(250)788531311 E-mail: vmvicky01@gmail.com

Mugihe uburenganzira bwawe buhutajwe wabaza:

Professor Kato J. Njunwa, Chair person, Institutional Review Board, tel: +250788490522

Dr Brenda Asiimwe-Kateera, Secretary, Institutional review Board

College of Medicine and Health Sciences, University of Rwanda/ Kaminuza y' u Rwanda, Ishuli ry'ubuvuzi n' ibijyanye ubuzima.
P.O.Box 3286 Kigali/Rwanda
Email: researchcenter@ur.ac.rw; website : http//chms.ur/ac/rw/

Kwemera

Jyewe,…….. nemeye kujya mu bushakashatsi nasobanuriwe haruguru. Ndemeza kandi ko nasobanuriwe neza icyo bugamije ndetse n'akamaro kabwo.

Umukono **italiki**

APPENDIX 3: ETHICAL APPROVAL

UNIVERSITY of RWANDA

COLLEGE OF MEDICINE & HEALTH SCIENCES

SCHOOL OF MEDICINE & PHARMACY

OFFICE OF THE ACADEMIC HEAD
DEPARTMENT OF SURGERY

Kigali, July 31, 2019

TO CMHS IRB COMMITTEE

I am writing in support to Dr. MANIRAGUHA Victor application for CMHS IRB approval to conduct a research study entitled: **"Neonatal surgical morbidity and Mortality in CHUK as tertiary hospital in Rwanda: An analysis of predicting factors"**

Dr. MANIRAGUHA Victor is a 3rd year resident general surgery MMED program in the department of surgery. His research study will evaluate the factors affecting the Neonatal surgical morbidity and Mortality, assessing the preoperative and postoperative factors predicting to poor outcomes of neonatal surgical patients in CHUK and it will evaluate the short term surgical outcomes for operated patients. Strategies will be proposed to improve the quality in neonatal surgical management.

He has presented his research proposal to the department of surgery and has obtained the department clearance to carry on this study.

If any addition information is needed, please contact us on 0788732667 or on email: fostino21@yahoo.com

With regards,

Dr. NTIRENGANYA Faustin, MD, Mmed/ General & Plastic Surgeon
Academic Head of Department
Department of Surgery/ CHUK

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 12th/September /2019

Dr MANIRAGUHA Victor
School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 450/CMHS IRB/2019

Your Project Title ***"Neonatal Surgical Morbidity and Mortality in CHUK as Tertiary Hospital in Rwanda: An Analysis of Predicting Factors"*** has been evaluated by CMHS Institutional Review Board.

		Involved in the decision		
		Yes	No (Reason)	
Name of Members	**Institute**		**Absent**	**Withdrawn from the proceeding**
Prof Kato J. Njunwa	UR-CMHS	X		
Prof Jean Bosco Gahutu	UR-CMHS	X		
Dr Brenda Asiimwe-Kateera	UR-CMHS	X		
Prof Ntaganira Joseph	UR-CMHS	X		
Dr Tumusiime K. David	UR-CMHS	X		
Dr Kayonga N. Egide	UR-CMHS	X		
Mr Kanyoni Maurice	UR-CMHS		X	
Prof Munyanshongore Cyprien	UR-CMHS	X		
Mrs Ruzindana Landrine	Kicukiro district		X	
Dr Gishoma Darius	UR-CMHS	X		
Dr Donatilla Mukamana	UR-CMHS	X		
Prof Kyamanywa Patrick	UR-CMHS		X	
Prof Condo Umutesi Jeannine	UR-CMHS		X	
Dr Nyirazinyoye Laetitia	UR-CMHS	X		
Dr Nkeramihigo Emmanuel	UR-CMHS		X	
Sr Maliboli Marie Josee	CHUK	X		
Dr Mudenge Charles	Centre Psycho-Social	X		

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 11th September, **Approval has been granted to your study.**

Please note that approval of the protocol and consent form is valid for **12 months**.

Email: researchcenter@ur.ac.rw P.O Box 3286 Kigali, Rwanda www.ur.ac.rw

You are responsible for fulfilling the following requirements:

1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the enrolment of participants.
3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval
5. Failure to submit a continuing review application will result in termination of the study
6. Notify the IRB committee once the study is finished

Sincerely,

Date of Approval: The 12th September 2019

Expiration date: The 12th September 2020

Professor GAHUTU Jean Bosco
Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Cc:

- Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate Studies, UR

CENTRE HOSPITALIER UNIVERSITAIRE
UNIVERSITY TEACHING HOSPITAL

Quality Health Care
Training & Research

Ethics Committee / Comité d'éthique

August 20th, 2019

Ref.: EC/CHUK/ 164 /2019

Review Approval Notice

Dear Maniraguha Victor

Your research project: ***"Neonatal Surgical morbidity and mortality in CHUK as tertiary hospital in Rwanda: an analysis of predicting factors"***

During the meeting of the Ethics Committee of University Teaching Hospital of Kigali (CHUK) that was held on 20th August 2019 to evaluate your protocol of the above mentioned research project, we are pleased to inform you that the Ethics Committee/CHUK has approved your renewal.

You are required to present the results of your study to CHUK Ethics Committee before publication.

PS: Please note that the present approval is valid for 12 months.

Yours sincerely,

ETHICS COMMITTEE CHUK

Dr. RUSINGIZA KAMANZI Emmanuel

The Chairperson, Ethics Committee,

University Teaching Hospital of Kigali

<<University teaching hospital of Kigali Ethics committee operates according to standard operating procedures (Sops) which are updated on an annual basis and in compliance with GCP and Ethics guidelines and regulations>>

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