Pattern of presentation of neonatal surgical disease and outcome of surgery at Kenyatta National Hospital

By

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MB ChB (UoN 2005)

A research dissertation as part fulfillment of the requirements, for the award of Master of Medicine in General Surgery degree of the University of Nairobi

20th May 2015

Declaration

I declare that this dissertation proposal is my original work and has not been presented for a degree in any other university

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DEDICATION

I dedicate this work to the memory of my father the late Walter Ajanja Obor Milai and my mother Perez Okello Ajanja

I further dedicate it to my wife Maureen Nyaitondi and children Audrey Atieno Ajanja and Adrian Obor Ajanja

Lastly I dedicate this book to all the surgical neonates who make it against numerous odds.

ACKNOWLEDGMENT

In the preparation of this study I was immensely assisted by my supervisors Dr. Kimani Wanjeri and Dr. Francis Osawa. I therefore reserve special thanks to them. I appreciate the KNH management and UON department of surgery for offering me an enabling environment in which to undertake the study. The contributions of my fellow senior house officers were greatly appreciated. The assistance given to me by the nursing staff especially in the new born unit and ward 4B did not go unnoticed. Lastly I acknowledge all family and friends who offered moral support in this endeavor.

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ABBREVIATIONS

ARM	-	Anorectal malformation
CDH	-	Congenital Diaphragmatic Hernia
EA/TOF	-	Oesophageal Atresia/Tracheoesophageal Fistula
GIT	-	Gastrointestinal tract
IHPS	-	Infantile Hypertrophic Pyloric Stenosis
KNH	-	Kenyatta National Hospital
MTRH	-	Moi Teaching and Referral Hospital
NEC	-	Necrotizing Enterocolitis
NHS	-	National Health Service
PUJO	-	Paediatric Ureteropelvic Junction Obstruction
PUV	-	Posterior urethra valves
SCT	-	SacroCoccygeal Teratoma
UK	-	United Kingdom
UON	-	University Of Nairobi
UPTH	-	University of Port Harcourt Teaching Hospital
UUTH	-	University of Uyo Teaching Hospital
DTC	-	Divided Transverse Colostomy
UWSD	-	Under Water Seal Drainage
OAUTH	-	Obefami Awolowo University Teaching Hospital

OPERATIONAL DEFINATIONS

Neonate period

The neonatal period is defined as the period between birth and the forty fourth post conception week.

Neonatal surgery

A subspecialty in paediatric surgery, that deals with the surgical care during the neonatal period.

ABSTRACT

Background; Neonatal surgery is the flagship subspecialty in paediatric surgery. Advances in neonatal resuscitation, neonatal anesthesia and neonatal transport have led to improved survival of the surgical neonate. In most centers a survival of greater than 90% is expected for the surgical neonate. Outcome of neonatal surgery is therefore a fair audit of the quality of paediatric surgical care.

Study design: Prospective observational study

Study Population: A sample size of 94 neonates admitted to the surgical units at the Kenyatta National Hospital (KNH) and all those who underwent surgery during the study period.

Objective: To determine the pattern of presentation of neonatal surgical disease and outcomes of the neonatal surgery at the KNH

Methodology: Ethical approval was obtained from the Kenyatta National Hospital (KNH/UON) Ethics and Research Review Committee. Patients who met the inclusion criteria were selected by non random progressive sampling. Informed consent was taken from parents/guardian. Data on patient biodata, gestational age, weight at birth and at admission, place of birth, application of principles of neonatal transport, prenatal diagnosis, surgical diagnosis and interventions and outcomes were collected using a pretested questionnaire. Additional data was obtained from the patient's records. The data was entered on Excel spreadsheets and analyzed using Epi Info version 3.5.1. Mean median and mode as well as ranges, ratios and proportions were employed in analysis. Categorical data was analyzed using a Chi – square test and a p – value ≤ 0.05 is regarded as significant. The result has been presented in maps, tables, bar charts, pie charts and graphs.

Results: Neonatal surgery was found to constitute 30.13% of the paediatric surgical workload. The commonest conditions are anorectal malformations (19.2%), anterior abdominal wall defects (17.2%), congenital heart defects (14.4%) and neural tube defects (9.6%). Overall mortality was 33% and the average length of stay was 10.2 days

Conclusion: ARM is the commonest condition in the neonatal surgical unit at KNH. Though comparable to what has been found in some developing countries, neonatal surgical mortality is still unacceptably high at the hospital

Recommendations: Investment in neonatal care is mandatory to achieve better outcomes. This includes prenatal diagnosis, neonatal transport and preterm care.

CHAPTER ONE

1.1 INTRODUCTION

That the child is not merely a small adult was the biggest advance of the last century in paediatric care[1]. Nowhere is this distinction more apparent than in the neonate.

Following birth, significant changes occur in the circulatory, respiratory, metabolic, and immune functions of the newborn. A surgical pathology superimposed on these essential adaptations may compromise the function of vital organs[1, 2, 3]. Prevention of problems in neonatal care is therefore the keystone in converting single organ dysfunctions to manageable challenges requiring short hospital stay and quick reunion of family with its newest member, failing which disasters occur occasioning the demise of the child[1]. The neonatal period is defined as the period between birth and the forty fourth post conception week.

Immunization, Human immunodeficiency virus control, malaria eradication, and other public health concerns take up the bulk of healthcare resources in many African countries. Subsequently diseases for which surgical intervention offers the only hope for prevention, palliation, or cure are relatively neglected by policy makers. Neonatal surgery has been a casualty of that neglect, and a lack of epidemiological studies has reinforced the perceived relative unimportance of surgical disease[1].

In most countries of the developed and developing world, surgical neonates are taken care of in highly specialized paediatric surgical centers often found in teaching and referral hospitals that serve a much larger network of peripheral hospitals[4, 5, 6, 7, 8, 9]. Failure of developing countries to invest in the care of surgical patients in general and neonatal surgery in particular has resulted in poorly organized referral of the neonate as opposed to the well-organized networks in the West as demonstrated by the NHS hospitals in the UK. Studies to bring this neglect to the attention of policy makers are, however, lacking[4, 10, 11, 12, 13].

CHAPTER TWO

2.1 LITERATURE REVIEW

In 1976, in an effort to improve the outcomes of pregnancy in the United States, hospitals caring for neonates were designated based on the complexity of care offered at each facility. Thereafter, the American Academy of Paediatrics, British Association of Perinatal Medicine (BAPM), and Canadian Paediatric Society have set the guidelines for designation of particular centers in their respective countries as shown in table 1 below:

Table 1: Levels of Neonatal Care in the USA, UK and Canada

COUNTRY	**LEVEL OF CARE**			
Canada	Level 1	Level 2	Level 3	
	Basic Neonatal Care	Special Care Newborn Nursery	Intensive Neonatal Care	
United Kingdom	Special Care (SCBU)	High Dependency Unit (NHDU)	Intensive Care (NICU)	
United States	Level 1	Level 2	Level 3	Level 4
	Well born Nursery	Special Care Nursery	Neonatal Intensive Care Unit (NICU)	Regional NICU

The specialist surgical care of children at tertiary level should be concentrated in designated units where there are the appropriate staff and facilities and a critical mass of patients sufficient to ensure an effective level of experience. It should be situated next to the NICU with ready access to appropriate obstetric services. Neonatal surgery is one of the four specialist paediatric surgical specialties and should only be undertaken by consultant

paediatric surgeons and paediatric anaesthetists [22]. A specialist paediatric surgical service should therefore include[21]: Specialist paediatric surgeons and paediatric urologists with paediatric resuscitation skills (preferably APLS or EPLS), a full range of specialist services for children(Paediatric medicine, neonatal medicine, paediatric intensive care,24-hour paediatric radiology, paediatric specialists in neurosurgery, orthopaedics, plastic surgery, nephrology, cardiology, oncology, gastroenterology and pathology, as well as child psychiatry and child psychology). Preferably, these should be on a single site. A surgical neonatal unit on the same site as the paediatric surgical unit accompanied by a robust transfer arrangements and laboratory services appropriately staffed and equipped for children. Additionally, accommodation for parents is essential and they should in general should have unrestricted access to their child and should participate in their care. Preferably, all these should all be on a single site[21]. Other crucial members of a paediatric surgical team in general and neonatal surgical care in particular are the obstetricians, anaesthetists, pharmacists, dieticians, physiotherapists, social workers, nurses, hospital administrators and other family members[1,6,7].

While a team of competent paediatric surgeons is available at KNH, most of these conditions have not been met by the paediatric surgical unit.

While regional data on epidemiological patterns of neonatal surgical diseases are inadequate, there seems to be a difference in patterns of presentation in this region and European centres, as well as better outcomes, which can be attributed to better antenatal care with prenatal diagnosis, better neonatal transport and prompt surgery backed by advanced technology [2,4,14].

In the West, advances in neonatal resuscitation, neonatal transport, preoperative care and postoperative care have resulted in a survival of nearly 100% for most surgical neonates[9]. However, in developing countries where scarce resources must be utilized for the maximum benefit of numerous constituencies, imaginative alternatives to standard Western care are required[1]. Lack of total parenteral nutrition (TPN), poorly organized surgical neonatal intensive care units, unavailability or shortage of paediatric ventilators and surgical consumables, and shortage of skilled personnel contribute to the high mortality rates in African centres[9]. Improvisations such as use of urinary bags for closure of gastroschisis and ruptured omphalocele or the use of intravenous fluids and multivitamin infusions as a substitute to TPN are also associated with high rates of mortality[9]. Moreover, maternal ill health and less than desired antenatal care add to the considerable difficulties faced by the

surgical neonates in developing countries in general and Kenya in particular[1, 8]. Preterm delivery also portends a harsher prognosis for most surgical neonates and accentuates the problem for paediatric surgical units in resource inadequate centers such as the KNH[7, 8, 9, 12].

2.1.1 Burden of Neonatal Surgical Care

The lack of data on the burden of neonatal surgical diseases in Africa in general and Kenya in particular is notable[7]. At the Moi Teaching and Referral Hospital (MTRH), a study by Tenge Kuremu et al., showed that neonatal surgery constituted 10% of the paediatric surgical output[6, 8].

In a Nigerian study, it was observed that the mean number of annual neonatal admissions in the neonatal surgical unit was 137 with a range of 42–263[6]. Another Nigerian study demonstrated that 460 (6.2%) of 7,401 neonates admitted had a surgical condition.

Elsewhere, a study in a Level 3 perinatal centre serving several networks with 36000 births per year in the UK noted that an average of 140 admissions required 2137 cot-days per year. At 80% occupancy, the service required seven neonatal cots, a figure which was computed to a national requirement of one neonatal surgical cot per 5000 births[4].

2.1.2 Patterns of Presentation of Neonatal Surgical Patients

In an extensive ten year study in India 10% of neonatal surgical patients were born at the facility, and those referred from neighboring units or brought directly by parents made up the greater majority. The mean age of admission was 7.2 days with a range of 1-28 days. The male to female ratio was 1.9:1. The average birth weight of the neonates was 2100 grams with a range of 1200grams to 3700grams[15].

In the study the mean age of presentation of anorectal malformations was 6.2 days with a range of 1 to 30 days with a later presentation of female neonates due to the passage of meconium through the perineal fistula.

The average age of presentation for intestinal atresia was 3.2 days ranging from 1 to 7 days. Duodenal atresia was observed in 36.5%, jejunal atresia 32.1%, ileal atresia 29.5% and colonic atresia in 1.9% cases. Single atresias constituted 79.6% of cases, while multiple atresias constituted 20.4%. Jejunoileal obstruction was diagnosed in 61%, with 46% occurring in females and 54% in males. Prematurely born neonates constituted 37% of the sample.

Classification at surgery was as follows: Type I (23%) , type II (27%), IIIa(18%), 7% as type IIIb "apple peel" atresia (7%), and type IV "multiple atresias"(24%).

Most of the cases of Hirshsprung's disease (79%) were classical short segment, 1.8% was ultra-short segment, 16% were long segment and rests were total colonic or severe type. Male to female ratio was 3:1.

The study reported seventy-nine cases of malrotation with a mean age of presentation was 15.2 days (range 3-26 days) and a male to female ratio was 1.67:1.An associated midgut volvulus was observed in 17.7% of the patients.

There were 80 abdominal wall defects reported during the study period, of which 59 were neonates with exomphalos and 21 were neonates with gastroschisis. The average age of presentation was 3.1 days (range 1–6 day

The presentation of TEF in this study by classification was as follows: type III-B (82.6%), pure esophageal atresia (13.7%), double fistula (1.7%), H type fistula (1.5%) and fistula in the proximal esophagus (0.5%). Only 16.7% of these cases were diagnosed antenatally.

In this seminal study a total of 92 cases of congenital diaphragmatic hernia (CDH) and eventration of diaphragm were recorded. The mean age of presentation was 2.4 days (range 1–27 days). The median weight of patients was 2180 g. Male to female ratio was 1.41:1. The condition was bilateral in 1% and on right side in 8% of the neonates. Antenatal diagnosis was available for just 11.9% of the patients. In 80.4% cases it was on left side and in the rest it was right sided, with no report of Morgagni hernia

One hundred and twenty cases of posterior urethral valves (PUV) were reported in the study, the mean age of presentation was 10.4 days (range 5– 28 days) and the median weight of the neonates was 2180 grams.

There were twenty two neonates with paediatric ureteropelvic junction obstruction (PUJO), with a mean age of presentation was 16.2 days (2-28days). Male to female ratio was 2:1. 59.1% were on right side, 31.8% were on left side and 9.1% were bilateral. Antenatal diagnosis was available for 27.7% of the cases.

Of the 14 cases that were admitted with thoracic problems five were due to lobar emphysema, antenatal diagnosis was recorded in 14.2% of them. the mean age of presentation was 18.4 day with a range of 12 to 16 days. The median weight was 2310 grams.

One hundred and fifty six cases of congenital hydrocephalus were reported in this study presenting at a mean age of 22.2days (range 6 to 28days) with a mean weight of 2860grams. 252 cases of meningiomyelocele were recorded, presenting at an average age of 16.7days (range 1 to 27 days) with a median weight of 2340 grams. There were also 118 cases of posterior encephalocele presenting at a mean age of 4.6 days (range 2 t0 24 days with a median weight of 2140 grams

A similar study at the University of Port Harcourt Teaching Hospital (UPTH) found that congenital abnormalities accounted for 408 (88.7%) of all the surgical cases at the paediatric surgery unit. These included neonatal intestinal obstruction (29.4% of cases), anterior abdominal wall defects (14.2%), esophageal atresia/tracheoesophageal fistula (2.2%), bladder extrophy (2.2%), PUV (2.0%) and diaphragmatic hernia (0.5%). Neural tube defects constituted 24.8% of the congenital conditions. Fractures of long bones following birth trauma (28.8%) and perforated necrotizing enterocolitis (NEC) 14 (26.9%) were the commonest acquired conditions. Males were 57.6 %(265) of the total caseload and female neonates were 40.9 %, with 7 neonates (1.5%) being of indeterminate sex[6].

Only 20.7% of the neonates were delivered at the centre. 28.3% of all the cases seen were of low birth weight, and 8.9% were preterm. Surgery was undertaken in 36.1% of the neonates[6].

Two hundred and sixty four (57.4%) of the mothers had received antenatal care. Only 47.3% of the supervised deliveries had ultrasound examination in pregnancy. 8.8% of the congenital surgical conditions diagnosed in the antenatal period[6].

A prospective study conducted at two Nigerian referral centers had a total of 106 neonates who weighed from 1.4 to 5.9 kg (mean 2.8 ± 1.7 kg), aged between 1 and 30 days (mean 8.3 ± 2.7 days), comprising of 64 males and 42 female neonates. The male: female ratio was 1.5: 1[9].

Gastrointestinal lesions were the major indications for treatment, accounting for 73.6% of cases. These included intestinal atresia (35.9% of all gastrointestinal lesions), gastroschisis (14.1%), ruptured omphalocele (10.3%), high anorectal anomaly (10.3%), necrotizing enterocolitis (9%), malrotation (9%), gut perforation (5.1%) and Hirschsprung's disease (6.4%). Late presentation was common in all pathologies and was influenced by ignorance, superstitions, financial constraint, lack of adequate means of transportation and inadequate healthcare facilities[9].

At the University of Uyo Teaching Hospital (UUTH), Nigeria, forty-five neonates were operated upon in a three year period, with a male to female ratio of 1.7:1. 97.8% of the neonates were delivered in unorthodox health facilities and peripheral hospitals. Only one neonate was delivered at the UUTH[11]. The mean age and body weight at presentation were 47.5 ± 44.4 hours (range 1 - 216 hours) and 2.65 ± 0.61 kg (range 1.5 - 3.7 kg) respectively. The mean interval between admission and surgical intervention was 4.9 ± 6.2 days (range 0.3 - 27 days) [11]. Intestinal obstruction (midgut rotation, obstructed hernia and Hirschprung's disease) constituted 40% of the cases. Anterior abdominal wall defects (gastroschisis and omphalocele) 26.7%, imperforate anus 17.8%, TOF 8.9%, obstructive uropathy 4.4% and ruptured sacrococcygeal teratoma 2.2%.

A hundred and ten neonatal surgical cases were seen at Obafemi Awolowo University Teaching Hospital, Ile– Ife. The various indications for emergency neonatal surgery were as follows: anorectal malformations: 37% of cases, ruptured exomphalos: 11% of cases, EA/TOF: 10% of cases, Hirschsprungs disease: 9% of cases, intestinal atresia: 8% of cases, gastroschisis: 7% of cases, duodenal atresia: 4.5% of cases, malrotation: 3.6% of cases, hypertrophic pyloric stenosis: 2.7% of cases, obstructed hernia: 1.8% of cases; cloacal malformation, annular pancreas, sacrococcygeal teratoma, ectopia vesicae and meconium peritonitis accounted for 0.9% of the caseload each.

A study of 56 neonates was conducted at MTRH. The male to female ratio was 1.7:1, with a median age of presentation of 3 days and a range of 1-22 days. Referrals from other hospitals constituted 60% of the cases, with 34% being home deliveries. ARM (19 cases), gastroschisis (7 cases), intestinal atresia (8 cases) and hypertrophic pyloric stenosis (5 cases) constituted the majority of cases. Others were gut malrotation, perforation, esophageal atresia, sacrococcygeal teratoma and incarcerated hernia. The weight distribution at presentation was as follows: above 3kgs (37.5%), 2.5 – 2.9(37.5%), 2.0 – 2.4(11%) and 1.5 – 1.9(14%). Neonatal transport principles were not applied in a significant number of cases: 44% did not have nasogastric tube, 45% did not have a venous access line, 46% were severely dehydrated, 100% did not have urethral catheters, and 100% did not come in transport incubators, although warmth provision was improvised using clothing[8].

2.1.3 Outcomes of Neonatal Surgeries

Attempts have been made to identify prognostic factors of the surgical neonate[19, 20]. The following have been identified as poor prognosticators: prematurity, tachycardia, respiratory distress and sepsis. Other significant factors include weight and temperature. However, scores to assess the prognosis of a surgical neonate at the time of admission are still lacking[20].

Overall survival of anorectal malformations in the Indian study was 94%, excluding those who were discharged against medical advice. Constipation (4%), wound infection (2.2%), wound dehiscence (0.8%), anal stenosis (3%), mucosal prolapse (19.8%), recurrence of fistula (1.2%) and mortality (6%) were observed postoperatively[15].

Overall mortality for duodenal atresia was 18%, largely from the apple peel type, while the survival rate was 74.8%. The remainder went home against medical advice. The postoperative complications observed included anastomotic obstruction (12%), congestive heart failure (11%), prolonged adynamic ileus (6%), pneumonia (9%), and superficial wound infection (2%). In jejunoileal atresia adhesive bowel obstruction (early and late) occurred in 28%, anastomotic leak in 8% and superficial wound infection in 75% of the cases.

The mortality in Hirschsprung's disease was 11.4% and overall survival noted as 84.3%

In gut malrotation with or without midgut volvulus, a mortality rate of 10.3% was observed, all of which cases had delayed diagnosis of midgut volvulus. A survival rate of 86% was noted. Readmission for sub-acute intestinal obstruction occurred in about 5% of the cases and was managed conservatively.

A total of 63 cases of IHPS were admitted during the ten year study period. They had a mean duration of stay of 6.4 days (range 5–8 days). Pyloromyotomy was performed in all of them with no mortality observed. Mucosal perforation occurred in three babies and missed Ladd's band lead to reoperation in five of the patients.

Overall mortality in anterior abdominal wall defects was 38.9% and was notably higher in surgically managed patients. In gastroschisis, the overall mortality was 60%, with a survival rate of 47% and 7% of cases opting to leave against medical advice.

During the 10 years study period significant changes were charted in the management of EA/TEF, with survival improving from slightly over 50% to well over 75%. Overall survival was 57.2%; mortality was 34.3% and 8.5% of cases left against medical advice.

Cases of CDH were divided into those presenting within 7 days of delivery and those patients presenting after 7 days of delivery but before 28 days. Overall survival rate was 42.2%; mortality was 44.7% and 13.1% were discharged against medical advice. Survival was better (62.3%) in the group that presented after seven days than those who presented within a week of birth (15.3%).

Overall survival was 83.6% with no postoperative mortality. This is comparable to results in Western literature.

Management of congenital hydrocephalus was via aright sided ventriculoperitoneal shunt. Complications were reported in 42.1% of the case. these consisted of infections, upper end blockage, lower end blockage and upper end shunt migration. Rates of infection and mortality were higher than those reported in North American and European studies. The outcomes in the management of encephalocele was however similar to those in western literature

The overall mortality in neonates with surgical condition in the UPTH study was 42.6% with complications occurring in 59% of the cases. The neonatal surgical deaths constituted 11.8% of total neonatal mortality in the hospital.

The commonest postoperative complication and cause of death was infection (92%). More deaths occurred in premature neonates and those babies delivered outside the hospital, due to immaturity of physiologic functions in the former and poor neonatal transport and resuscitation in the latter. The study correlated mortality to the promptness of diagnosis, the complexity of the surgical condition, the type of surgical procedure and the presence of complications. High mortality was noted in laparotomy for intestinal resection and anastomosis (either for small intestinal obstruction or ruptured NEC), closure of ruptured omphalocele, colostomy, thoracotomy with esophageal anastomosis, and multiple abnormalities[6].

Mortality at Obefami Awolowo University, Ile – Ife, was similarly high: colostomy presented with 36.4% mortality, closure of anterior abdominal wall defect with 80.0%, intestinal anastomosis with 81.2%, anoplasty with 20.0%, esophageal anastomosis with 77.8%, duodeno-duodenostomy with 60.0%, gastrostomy with 100%, Ladd's procedure with 33.3%, repair of bladder extrophy with 100%, and no surgery with 100% mortality[12].

Osarumwese D. O et al. noted a total of 38 deaths, a prevalence rate of 35.8% among the neonates. Sex was not a significant predictor of mortality.

Disease specific mortality was as follows: intestinal atresia 21.4%, gastroschisis 81.1%, ruptured omphalocele 62.5%, high anorectal anomaly 12.5%, necrotizing enterocolitis 9%, malrotation 28.6%, gut perforation 50%, tracheoesophageal fistula 66.7%, genitourinary lesions 23.1%. There was no mortality recorded in Hirschsprung's disease. Of note is that gastrointestinal lesions accounted for 78.9%, of the surgical neonatal deaths at the two centres[9].

The associated morbidities were sepsis, wound infection, burst abdomen, respiratory failure, fluid and electrolytes derangement, hypoglycemia, anastomotic leaks and inanition. In concurrence with other studies, the majority (65.8%) of cases of mortality were referred to the unit with compromised clinical conditions, sepsis being obviously implicated in 55.3% neonates.

Anesthetic related deaths contributed to 21.1% mortality. The study established that neonates with sepsis or wound infection, late referrals, neonates with anesthetic complications and those with financial constraints died within few days on admission. Those who had nutritional problems, lack of management facilities and multiple anomalies survived much longer before death [8,9,12].

At University of Uyo Teaching Hospital, overall mortality was 62.2%, which was much higher than other studies. Disease specific mortalities varied from none in Hirschsprung's disease to 100% in gastroschisis, TOF and ruptured SCT[11]. Unlike other studies where sepsis was the predominant cause of death, peritonitis from gangrenous gut contributed to mortality in 60.7%, followed by hypovolemia in 17.9%, surgical site hemorrhage in 7.1%, hypothermia in 7.1%and anastomotic leak in 3.6%[8, 11].

Late presentation coupled with poor understanding of the milieu interior of the neonates by incompetent health care providers and poorly equipped hospitals combine to give rise to the unacceptable high morbidity and mortality in most parts of Africa. Delay in offering surgical intervention where appropriate also contributes to the high mortality and morbidity[6, 7, 8, 12].

In contrast to the Nigerian experience, sepsis was a complication in 10 cases (15%) at MTRH but was still a major cause of mortality. Wound dehiscence occurred in 3 cases (5%) and anastomotic leaks in 2 cases (25%) of ileal atresia[6, 8].

While overall mortality was 24%, it was much higher among the referred neonates (44%). Disease specific mortality was as follows: ARM 32%, gastroschisis 57%, intestinal atresia 38%, malrotation 50%, GIT perforation 67%, and esophageal atresia 25% [8]

Summary

Overall survival has increased dramatically for the surgical neonates as demonstrated in the table 2 below[1, 2, 17, 18]

Table 2: Summary of Standard Outcomes of Neonatal Surgery in Europe and North America

Surgical Diagnosis	**Overall Survival (%)**
Congenital diaphragmatic hernia	50%
Esophageal atresia – tracheoesophageal fistula(stable)	>90%
Esophageal atresia – tracheoesophageal fistula(unstable)	40-60%
Intestinal obstruction Hirschsprung's disease Malrotation Duodenal atresia	>90%
Anorectal malformations	90%
Incarcerated hernia	90%
Necrotizing enterocolitis	10-50%
Gastroschisis	97%
Omphalocele	75%
Posterior urethral valves	90%
Hypertrophic pyloric stenosis	90%

As demonstrated by centers in India it is possible to emulate these excellent outcomes even in resource poor countries with low literacy levels[15, 16]

2.2 Study Justification

Neonatal surgery is the flagship specialty in paediatric surgical practice and its outcomes provide an audit to the quality of paediatric care at a facility[5]. In this regard, centers claiming to provide high quality of care are expected to have overall success rates of at least 90%. With the exception of a few conditions such as congenital diaphragmatic hernia, apple peel duodenal atresia and NEC, a favorable outcome is expected of most surgical neonates.

However, as has been demonstrated in Kenya, Africa and the developing world, most centers have not achieved the expected success rates as a result of various cultural, technical and institutional constraints. No studies are available for the KNH which is the premier referral and teaching facility in the country and in the East and Central African region. A crucial knowledge gap has thus been filled by this study.

Strategies for improving paediatric surgical care in general and neonatal surgery in particular should be evidence-based and cost-effective and should aim to benefit the largest possible number of children. By demonstrating that surgical neonates are a significant public health problem, policy change can be effected leading to a defined cost-effective package of surgical services, improved surgical care at the community level, and surgical education[10]. This study provides such evidence.

The study provides the unit with a disease based scorecard of its management of the surgical neonate. This study shows areas where expected standards have been achieved and those in which improvement is necessary. There are useful lesson that other centers will pick from the unit on optimal care in resource inadequate settings.

Being the leading hospital in the region the results of the study will serve as the benchmark for other hospitals in the region on expected outcomes. Finally with the introduction of a postgraduate paediatric surgery program at the KNH affiliated UON and an increasing number of medical schools across the country the results of the study will be of immense academic interest.

2.3 Knowledge Gap

There was no documented study on the caseload provided by the neonate at the paediatric surgical unit. It was of academic and administrative interest to compare the unit's output vis-à-vis expected standards and other centers in the developing world and beyond

2.4 Research Purpose

The purpose of this study was to determine the workload occasioned by the surgical neonates at the KNH. It further set out to establish the common patterns of presentation as well as outcomes of interventions at the unit.

2.5 Research Question

What is the burden of, pattern of presentation and outcome of neonatal surgery at the KNH?

2.6 Objectives

2.6.1 Broad Objective

To determine the pattern of neonatal surgical diseases and the outcome of their surgery at Kenyatta National Hospital

2.6.2 Specific Objectives

1. To determine the workload of neonatal surgery in the pediatric surgical unit at KNH.
2. To determine the pattern of presentations of surgical neonates at the KNH
3. To determine the outcome (mortality and morbidity) of the surgical neonates at KNH.
4. To estimate the length of hospital stay of surgical neonates at KNH.

CHAPTER THREE

3.0 Methodology

3.1 Study Setting

The setting of the study was the KNH surgical wards and newborn unit units.

3.2 Study Population

All neonates admitted to the paediatric surgery ward and managed by the paediatric surgeons for a surgical diagnosis, as well as patients under the care of the paediatric surgery service, but in another ward such as the new born unit.

3.3 Study Design

Prospective descriptive study

3.4 Sample Size

The desired sample size was determined using the following Fisher et al (1998) formula:

$$n = \frac{Z^2 pq}{d^2}$$

Where:

n = the desired sample size (when population is greater than 10,000).

Z = the standard normal deviate, set at 1.96, which corresponds to 95% confidence

level.

p = the proportion of the target population estimated to have a particular characteristic of interest estimated at 10% which is equal to 0.1

q = 1.0 – p = 0.9

d = degree of accuracy desired, here set at 0.05 corresponding to the 1.96 z-statistic used in the numerator

In substitution,

$$n = \frac{1.96^2 \times 0.1 (1 - 0.1)}{0.05^2}$$

$$= 138$$

The highest numbers of neonates in the studies reviewed was 264 which is less than 10000 and because n is less than 10,000 the second formula (Cochrane's) will be applicable in determining the sample size thus:

$$nf = \frac{n}{1 + \frac{n}{N}}$$

Where:

nf = desired sample size for a population less than 10,000

n = desired sample size for population more than 10,000 which was found to be 138

N = Population which is 264

In substitution,

$$nf = \frac{384}{1 + \frac{384}{264}}$$

$$= 91$$

The study sample will be 91.

3.5 Sampling Procedure

Non-random progressive sampling of patients who met inclusion criteria until sample size was obtained.

3.5.1 Inclusion Criteria

1.All neonates with a surgical diagnosis who needed intervention in the neonatal period.

2. Neonates in the newborn unit under the care of the paediatric surgical team

3.5.2 Exclusion Criteria

1. Neonates discharged against medical advice at the insistence of the parents/guardians
2. Neonates referred to other facilities

3.6. Ethical Considerations

The study was carried out with the approval of the Kenyatta National Hospital/University of Nairobi Ethics and Research Review Committee. Written informed consent was obtained from the guardian/parent by the principal investigator and his research assistants, and data was collected in standard forms from patient records and parent/guardian interviews. Parents and guardians were informed of the scope of the study and assurances on the confidentiality of the information collected was given with access to detailed information restricted to the principal researcher and research assistants.

3.7 Patient recruitment procedure

Patients were recruited at the various study points by trained clinicians (senior house officers). Recruitment was done using standard clinical diagnostic criteria (history taking, examination, imaging and intraoperative findings) as shown in the table 3 below

Table 3: Diagnostic criteria for making neonatal surgical diagnosis

	SURGICAL DIAGNOSIS	DIAGNOSTIC CRITERIA
1	NEC	Clinical presentation – bile aspirate, blood in stool, abdominal distension, poor feeding, apneic episodes, jaundice. Signs of peritonitis Investigations – radiographs demonstrating pneumatosis or portal vein gas
2	ARM	Physical examination demonstrating imperforate anus with or without fistula
3	PUV	Ultrasound demonstrating dilated posterior urethra
4	PUJO	Ultrasound demonstrating conspicuous kidney
5	Congenital lung malformations	Ultrasounds, radiographs and/or CT - scan
6	Congenital hydrocephalus	Clinical presentation – head circumference that is greater than normal Transcranial ultrasound or head CT – scan demonstrating enlarged ventricles
7	Malrotation	Clinical presentation – sudden onset bilious emesis Investigations – upper gastrointestinal tract contrast studies Intraoperative finding – demonstration of Ladd's band
8	Omphalocele	Physical examination demonstrating abdominal wall defect with a covering sac and herniation of intra abdominal organs
9	Gastroschisis	Physical examination demonstrating abdominal wall defect lateral to the umbilicus with exteriorization of gut without covering sac
10	Inguinal hernia	Groin lump which maybe reducible or irreducible
11	Congenital diaphragmatic hernia	Clinical presentation – respiratory distress, scaphoid abdomen Radiographs demonstrating bubble bowel pattern in the chest and lack of normal intestinal gut Intraoperative finding of a posterolateral(Bochdalek) or anteromedial(Morgagni) defects
12	EA/TOF	Clinical presentation – excessive salivation, choking during feeding, recurrent aspiration pneumonia Radiograph demonstrating coiling of nasogastric tube in the proximal pouch
13	Hypertrophic pyloric stenosis	Clinical presentation – non bilious projectile vomiting(becoming projectile), palpation of pyloric olive Barium meal demonstrating string and the double tract signs. Ultrasound
14	Hirschsprung's disease	Delayed passage of meconium, episodic abdominal distension, diarrhea and obstipation Rectal biopsy demonstrating paucity of ganglion cells
15	Duodenal atresia	Bilious vomiting shortly after birth Double bubble sign on plain abdominal radiograph

3.8 Data Collection Instrument

Data relevant to the study was collected using the questionnaire appearing in Appendix 1. The questionnaire collected patients' biodata, a brief antenatal history of the mother, and clinical findings at the time of admission, through to the time of discharge or demise.

The neonates were classified by their birth weight: normal weight: 2500g to 4500g, low birth weight: <2500 g, very low birth weight: <1500 g and extremely low birth weight: <1000 g. The length of gestation was also be used in classification as follows: preterm babies: born before 37 completed weeks of gestation, term babies: born at 37 to 42 weeks and post-term babies born after 42 weeks[2].

3.9 Data Management

The data was entered in an Excel spread sheet and analyzed using Epi Info version 3.5.1. It was protected from unauthorized access and hard copy backups were securely locked. Mean median and mode as well as ranges, ratios and proportions were employed in analysis. Categorical data was analyzed using the Chi-square test and a P-value ≤ 0.05 is regarded as significant. The result has been presented in maps, tables, bar charts, pie charts and graphs.

3.10 Study Limitations

1. For a number of surgical diagnoses, the overall mortality, complications and quality of life after surgical interventions cannot be accurately captured in the neonatal period
2. Neonates managed in the private wing of KNH were not eligible for recruitment to the study.

CHAPTER FOUR

4.1 RESULTS

A total of 94 neonates were consecutively sampled for the study. During the study period a total of 312 paediatric surgical patients were managed in the hospital's surgical wards

The burden of neonatal surgical disease during the period of the study was 30.13%. The overall male female ratio of the study participants was 1.2:1. Three of the patients had ambiguous genitalia.

The median age of presentation at the hospital was 3 days, while the modal age of presentation was 1 day. An average age of presentation was calculated at 7.3 days of age

Preterm neonates constituted 23.4% of the patients while term neonates were 76.6% of the patients. No postdate patients were recorded during the study period (Figure 1)

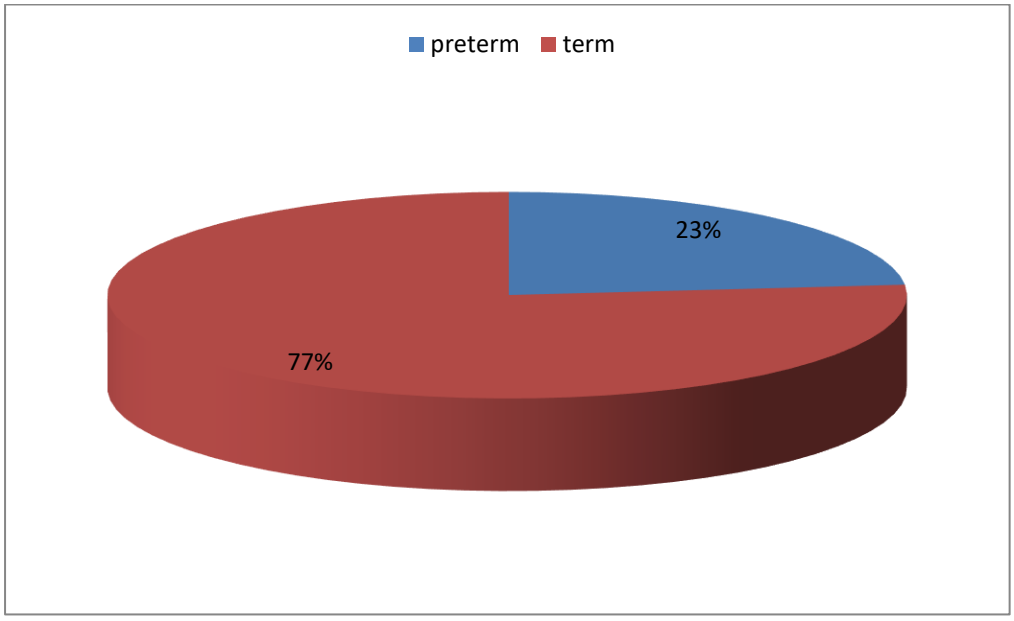

Figure 1: Gestational age of neonates at delivery

Neonates with normal birth weights constituted 80.85%, while those with low birth weight were15.96% of the patients. Very low birth weight neonates were 2.13% and extremely low birth weight neonates were 1.06%. The average weight of the term neonate was 2.9kgs while that of the preterm neonate was 1.84kgs (Figure 20)

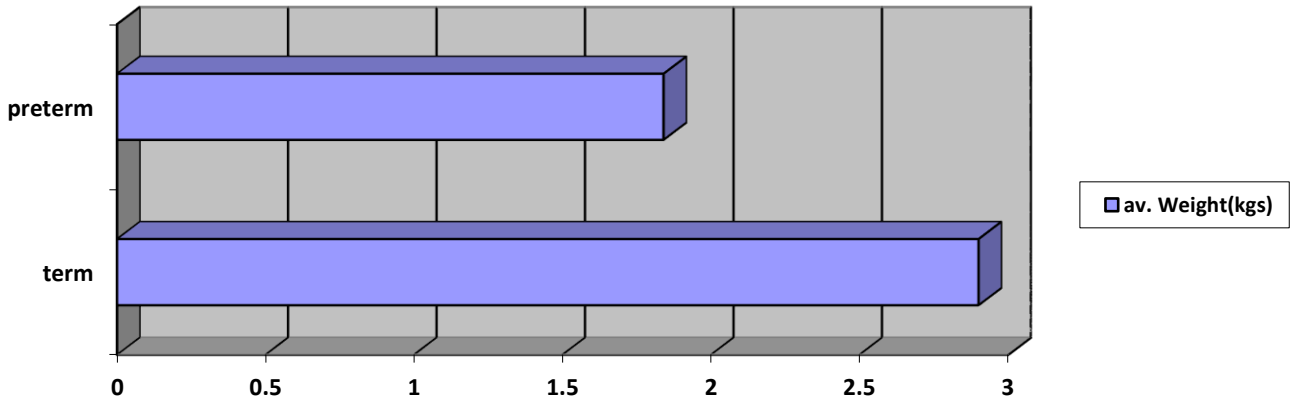

Figure 2: Average neonatal weight at birth (kgs)

The average length of stay in the unit was 10.2 days (10.5 days for term babies and 9.1 days for preterms)

Patients born at the hospital constituted 18.08.% of the patients, while referrals were 81.92% of the patients. A majority of the referrals were from Nairobi and the surrounding counties (more than 90% were from within a 200km radius from Nairobi), though patients came from as far as Bura in North Eastern Kenya and the Democratic Republic of Congo(Figure 3)

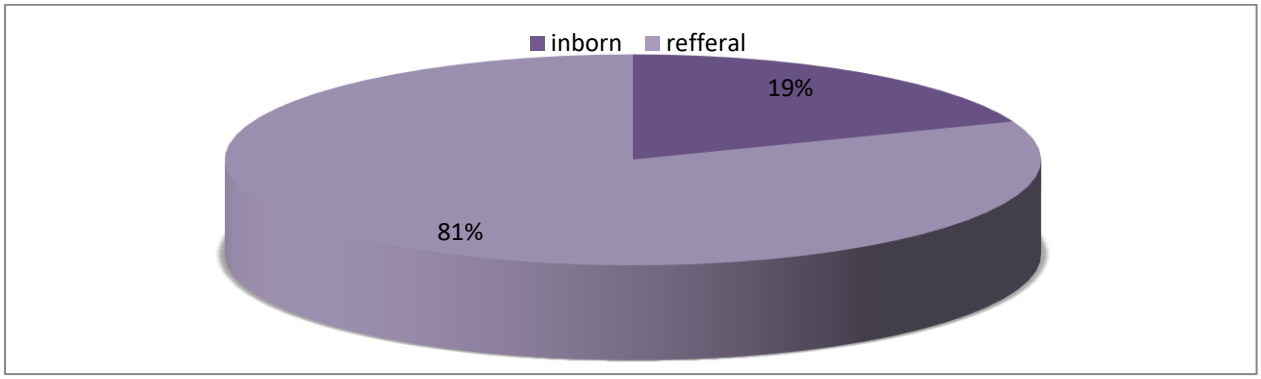

Figure 3: Place of delivery of neonates

Only three of the patients were home deliveries

A majority of the patients were brought to hospital by ambulances from the referring facilities (55.3%)

Principles of neonatal transport were partially adhered to, as follows:

Nasogastric tube 53.95%

Venous access 76.68%

Urethral catheter – only one patient

Warmth/transport incubator 100%

Patients with anterior abdominal wall defects came with exposed gut wrapped in wet sterile gauze

The hydration status of most neonates was as follows:

Well hydrated 60.64%

Mild dehydration 17.02%

Severe dehydration 19.15%

ANC attendance was excellent at 90.4% but there was no incidence of prenatal diagnosis

Patients with a single pathology made up 87% of the patients while multiple pathologies aand syndromic neonates were 13%

The pattern of presentation of the surgical neonates during the study period was as follows(Table 4 and figure 4):

Table 4: Pattern of presentation of surgical neonates at the KNH

	DIAGNOSIS	NUMBER	PERCENTAGE
1	Anorectal malformation	20	19.2
2	Congenital heart defects(venticuloseptal defect, atrioseptal defect, dextrocardia, patent ductus arteriosus and transposition of great vessels)	15	14.4
3	Gastroschisis	12	11.5
4	Neurosurgical(spinabifida, hydrocephalus and encephalocele)	10	9.6
5	Hirschsprung's disease	8	7.7
6	Omphalocele	6	5.8
7	Intestinal Artesia	5	4.8
8	0rthopedic	4	3.8
9	Necrotizing enterocolitis(NEC)	4	3.8
10	Congenital lung anomalies	3	2.9
11	Abscess	3	2.9
12	Pyloric stenosis	3	2.9
13	Posterior urethral valves	3	2.9
14	Sacrococcygeal teratoma	2	1.9
15	EA/TOF	1	0.96
16	Inguinal hernia	1	0.96
17	Cystic hygroma	1	0.96
18	Cryptochidism	1	0.96
19	Hypospadia	1	0.96
20	Intrauterine intussusception	1	0.96

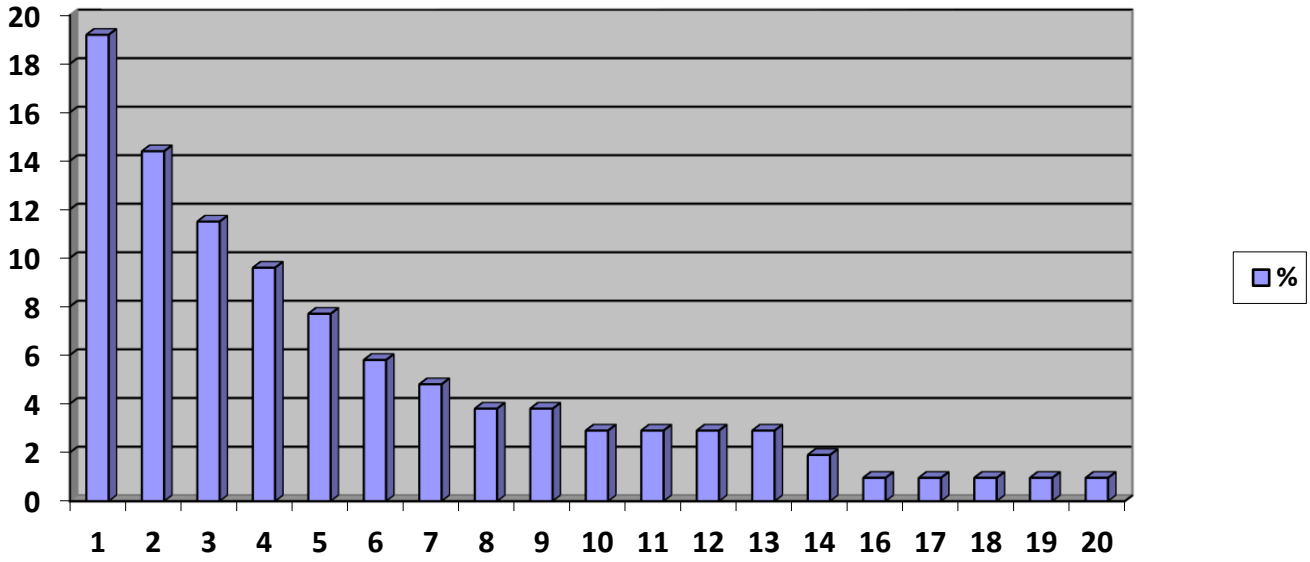

Figure 4: Pattern of presentation of surgical neonates at the KNH

Appropriate investigations to establish diagnosis and plan the management were carried out on all of the patients

The outcomes of the procedures were observed to vary by the specific diagnosis as shown in the table 5 and figure 5 below.

Table 5 : Mortality and complications of surgery on neonates at the KNH

	OUTCOME OF SURGERY ON NEONATES					
SURGERY	**UNEVENTFUL**		**COMPLICATIONS**		**DEATH**	
	F(no.)	**%**	F(no.)	**%**	F(no.)	**%**
Divided sigmoid colostomy	12	**60**	5	**25**	3	**15**
Incision and drainage	3	**100**	0	**0**	0	**0**
Herniotomy	1	**50**	0	**0**	1	**50**
Excision of extra digits	1	**100**	0	**0**	0	**0**
Catheterization/vesicostomy	2	**100**	0	**0**	0	**0**
Resections/anastomosis	3	**60**	1	**20**	1	**20**
Closure of spina bifida	2	**100**	0	**0**	0	**0**
VPS	3	**100**	0	**0**	1(planned)	**-**
Rectal biopsy/serial biopsy/ DTC	1	**16.7**	4	**66.6**	1	**16.7**
UWSD	2	**100**	0	**0**	0	**0**
Pyloromytomy	1	**33**	2	**77**	0	**0**
Bogota bag placement	0		2	**16.6**	10	**83.4**
Septoplasty	0	**0**	0	**0**	1(planned)	**-**
Conservative/medical management	25	**56.9**	6	**13.6**	13	**29.5**

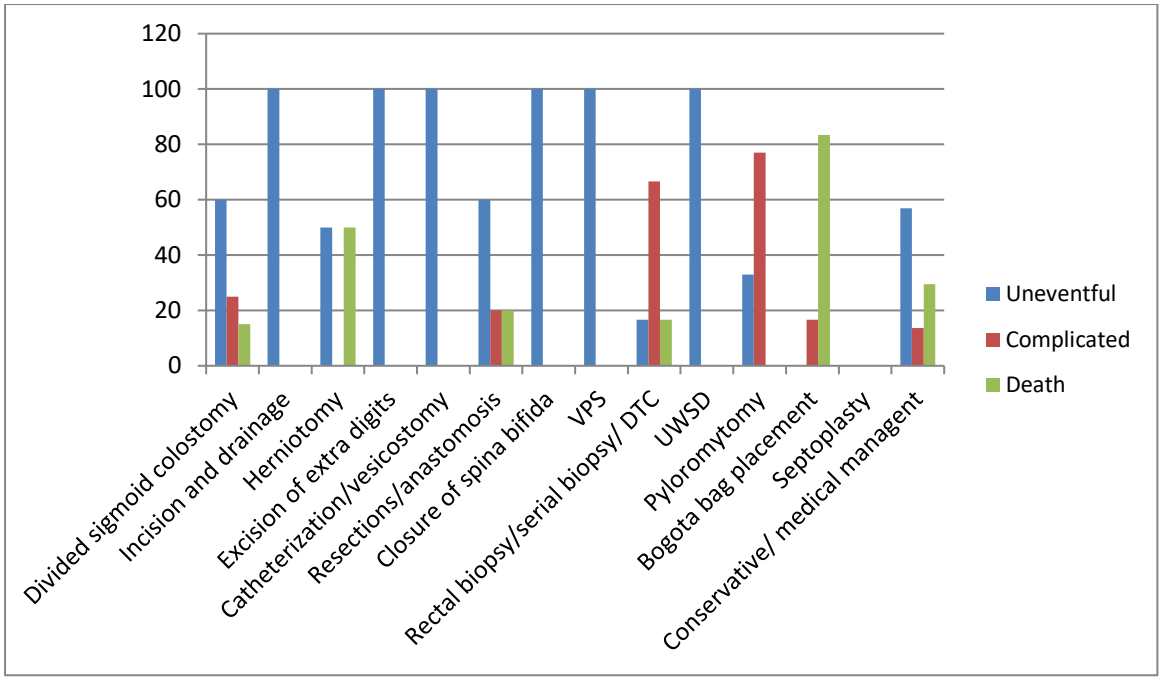

Figure 5: Mortality and complications of surgery on neonates at the KNH

Preterm mortality was recorded at 59% while mortality among term babies was 25%

Mortality as noted to be higher among referrals at 40.4% than among inborn patients (16.7%)

Mortality was slightly higher in syndromic neonates and those with multiple pathologies (38%) compared to those neonates who had a single pathology (30%)

There was no delay in surgery as the interval between surgery and diagnosis was 1.97 days on average. There was no marked difference in the interval to surgery between patients who had an uneventful postoperative recovery (1.7 days) and patients who succumbed (1.6 days). Patients who had complications but survived seemed to have a slightly longer wait for surgery than the other two cohorts (2.9 days). The delay in undertaking surgery seem to be related to the hydration status at the time of admission since a majority of this patients were dehydrated unlike the patients who did not have any complications, as demonstrated in table 6 below

Table 6: Hydration status of surviving neonates at the time of admission

Surviving neonates	**Well hydrated at admission (%)**	**Dehydrated at admission (%)**
No complications	79.5	20.5
Complications	38	62

The commonest complication was infections which accounted for 74%. Respiratory distress syndrome accounted for 16%, all of whom were preterms. Other complications included malnutrition, contrast pneumonitis, anastomotic leak and anesthetic complications. These accounted for 10% of the complications

CHAPTER FIVE

5.1 DISCUSSION

Neonatal surgical mortality has been steadily falling around the world in the last five decades. This has been attributed to better diagnosis and treatment of the surgical neonate. Improvements in preoperative stabilization, maintenance of good neonatal transport principles and good postoperative care have been instrumental in ensuring survival of the surgical neonate[6].

At the KNH the burden of neonatal surgical disease is 30.13% which is higher than similar studies in India and MTRH which were 10%[8, 15] The male female ratio is 1.2: 1 which is similar to other studies (p = 0.8782)[6] . This was statistically insignificant. Inborn patients were 18.08% significantly higher than in the Indian study (10%) but similar to the Nigerian one at 20.7%[6, 15]

The mean age of presentation is 7.3 days which is similar to other studies in India (7.2 day) and Nigeria (8.3days) [6, 15]. The median age of presentation was 3 days which is similar to the study done at MTRH[8.] Term patient were 76.6% of the patients which is lower than was found in the Nigerian study (91.1%). The weight distribution of surgical neonates differed significantly from those found at MTRH[8] (Table 7)

Table 7: Comparison of birth weights of neonate between Kenyatta National Hospital (KNH) and Moi Teaching and Referral Hospital (MTRH)

BIRTH WEIGHT	KNH (%)	MTRH (%)
Normal	80.85	75
Low birth weight	15.96	11
Very low birth weight	2.13	14
Extremely low birth weight	1.06	0

Length of stay was 10.2 days on average. This has not been recorded in other studies

Principles of neonatal transport was partially adhered to in a majority of patients as compared to MTRH (Nasogastric tube insertion (53.95% vs. 56%), venous access(76.68% vs. 55%)and keeping the neonate warm using a transport incubator or mothers wrapping the neonate in warm linen (100% in both). Urethral catheterization was not routine in both studies[8]. An

additional measure such as covering exposed gut in anterior abdominal wall defects was routine. Severe dehydration was noted in 19.15% which is lower than the 46% observed in MTRH[8]

The pattern of presentation differs significantly from other studies[6, 8, 12](table 8,9 and 10)

Table 8: Comparison of patterns between KNH and UUTH

Diagnosis	**Intestinal obstruction (%)**	**Anterior abdominal defects (%)**	**ARM (%)**	**TOF(%)**	**Obstructive uropathy (%)**	**SCT (%)**
KNH	13.46	17.3	19.2	0.96	2.9	1.9
UUTH	40	26.7	17.8	8.9	4.4	2.2

Table 9: Comparison of patterns between KNH and Obefami Awolowo University Teaching Hospital (OAUTH)

Diagnosis	**ARM (%)**	**Omphalocele (%)**	**EA/TOF (%)**	**Hirschsprung's disease (%)**	**Intestinal atresia (%)**	**Gastroschisis (%)**	**IHPS (%)**	**hernia** (%)	**SCT**
KNH	19.2	5.8	0.96	7.7	4.8	11.5	2.9	0.96	1.9
OAUTH	37.9	11	10	9	12.5	7	2.7	1.8	0.9

Table 10: Comparison of patterns between KNH and MTRH

Diagnosis	**ARM (%)**	**Gastroschisis (%)**	**Intestinal atresia (%)**	**IPHS (%)**	**Gastro-intestinal tract perforation (%)**	**EA/TOF (%)**	**Hirschsprungs disease** (%)	**SCT (%)**	**Hernia (%)**
KNH	19.2	11.5	4.8	2.9	0.96	0.96	7.7	1.9	0.96
MTRH	33.9	12.5	14.3	8.9	7.1	5.4	7.1	1.9	7.1

Mortality in the hospital during the study period was 33% which was similar to other studies in the developing world[6, 8, 15]. Notably the mortality was higher than those reported at MTRH[8].

The disease specific mortality rates was different from other studies (table 11)[6, 9, 15]

Table 11: Comparison of disease specific mortality at KNH, MTRH, two Nigerian referral centers and an Indian hospital

DIAGNOSIS	KNH (%)	MTRH (%)	NIGERIA REFFERAL CENTERS (%)	INDIA (%)
ARM	**15**	32	12.5	6
SCT	**0**	0	-	-
Hernia	**50**	0	-	-
Intestinal atresia	**20**	38	21.4	18
Spina bifida	**0**	-	-	3.9
Congenital hydrocephalus	**0**	-		21.9
Hirschsprung's	**16.7**	25	0	-
IPHS	**0**	0	-	0
Gastroschisis	**83.4**	57	-	60

Morality of inborn patients was lower than those of referrals which is similar o those found in other studies, but mortality rates were lower than in comparable African studies ($p = 0.0001$)[8]. This was statistically significant

Mortality among preterms was higher than in term infants as in other studies, but the rates were better than most African centers ($p = 0.001$)[8]. This was statistically significant

There is a relationship between a delay in surgical intervention and the development of postoperative complications. This delay can be explained by the hydration status at the time of admission with well hydrated patients having less complications and thus shorter hospital

stay than dehydrated patients who had higher complication rates. Therefore the application of principles of neonatal transport should be emphasised.

The commonest complication was due to infections (74%) which were similar to other studies[9, 2].

Among preterms respiratory distress syndrome was particularly prevalent contributing to an overall 16% of the complications. This has not been documented in other studies in African centers but is postulated by Manchand V. as one of the poor prognosticators along with prematurity, tachycardia and sepsis[19]

CHAPTER SIX

6.1 CONCLUSION

Neonatal surgical patients constitute 30.I3% of paediatric surgical patients. Anorectal malformations, congenital heart defects, anterior abdominal wall defects and neural tube defects constitute the bulk of surgical neonates. Mortality at the hospital is high at 33%. The patients stay in the hospital for an average of 10.2 days with no significant difference between preterm and term neonates. Significant delay before surgical intervention due to dehydration and the subsequent fluid resuscitation is associated with higher postoperative complication rates

6.2 RECOMMEDATIONS

Neonatal surgeries constitute a sizable bulk of surgical work at the hospital. Investment in the care of neonates with a view to achieving better survival should be undertaken. Training in neonatal transport, improvement in prenatal diagnosis and better care of preterm neonates with respiratory distress syndrome is necessary. The deplorable state of patients with gastroschisis require particular attention since mortality nearly 100 % (even the two patients who made it out of the neonatal period seem unlikely to celebrate their first birthday)

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APPENDICES

APPENDIX I: STUDY TIME FRAME

Proposal writing and submission for ethical approval.	November 2014
Data collection and Analysis	April/May 2015
Dissertation writing	May 2015
Presentation and submission of dissertation	May 2015

APPENDIX II: BUDGET

Item	**Amount (Kshs)**
Stationary	15,000
Statistician	20,000
Research fee	2,000
Research assistants	20,000
Printing and binding	20,000
Total	78,000

APPENDIX III: CONSENT FORMS

"Pattern of Presentation of neonatal surgical disease and Outcome of Surgery at Kenyatta National Hospital"

Consent Form

This Informed Consent form is for the parent/guardian of neonates under management of the paediatric surgical team.

The title of the study is "Pattern of Presentation of neonatal surgical disease and Outcome of Surgery at Kenyatta National Hospital"

Principal investigator: Dr. Ajanja Samson Otieno

Institution: Department of Surgery, School of Medicine, University of Nairobi.

This informed consent has three parts:

- Information sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)
- Statement by the researcher

You will be given a copy of the full Informed Consent Form.

PART I: Information sheet

Introduction

My name is Dr. Ajanja Samson Otieno, a post graduate student at the University of Nairobi's School of Medicine. I am carrying out a study to determine the burden, pattern of presentation and outcomes of neonatal surgery at the KNH paediatric surgical unit

Study Purpose

The purpose of this study is to determine the number of children below 28 days who are attended to at the paediatric surgical unit of Kenyatta National Hospital. It further seeks to

establish the common conditions in these children as well as the outcomes of interventions at the unit.

Confidentiality

The information obtained will be treated with confidentiality and only be available to the principal investigator and the study team. Your name will not be used. Any information about you will have a number on it instead of your name. We will not be sharing the identity of those participating in this research.

Sharing the Results

The knowledge that we get from this study will be shared with the policy makers in the Ministry of Health and Doctors through publications and conferences. Confidential information will not be shared.

Risks and Discomfort

The study will not involve any procedures on the children, and will be undertaken through review of the information in their files as well as a brief interview with the mother. No risks or discomfort will be incurred by electing to participate in the study.

Cost and Compensation

There will be no extra cost incurred for participating in this study nor is there compensation offered.

Ethical Concerns

This proposal has been reviewed by the UoN School of Medicine Department of Surgery and approved by the KNH/UoN Ethics and Research Review Committee. This Committee makes sure that research participants are protected from harm in the course of research

PART II: Certificate of Consent

I have read the above information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Signature of Participant _____

Date _____

If non-literate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Thumb print of participants.

Signature of Participant _____

Date _____

Contact Persons

If you wish to ask any questions later, you may contact:

Principal researcher:

Dr. Ajanja S. O,

Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 19676 KNH, Nairobi 00202

Mobile Number: 0723948769.

University of Nairobi Supervisors:

- Dr Francis Osawa,

Lecturer, Department of Surgery,

University of Nairobi,

School of Medicine

P.O. Box 19676 KNH, Nairobi 00202

- Dr. Kimani Wanjeri

Lecturer, Department of Surgery,

University of Nairobi,

School of Medicine

P.O. Box 19676 KNH, Nairobi 00202

If you have any ethical concerns, you may contact:

Secretary, KNH/UoN-ERC

P.O. Box 20723 KNH, Nairobi 00202

Tel +254-020-2726300-9 Ext 44355

Email: KNHplan@Ken.Healthnet.org

PART III: Statement by the researcher

I have accurately read out the information sheet to the participant, and to the best of my ability made sure that the participant understands that the following will be done:

- All information given will be treated with confidentiality.
- The results of this study might be published to facilitate planning for and management of surgical neonates.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Name of researcher taking consent _____

Signature of researcher taking consent _____

Date _____

(Day/Month/Year)

Fomu ya Ruhusa

Fomu hii ya kibali inafaa kujazwa na mzazi ama anayeishi na mtoto anayepokea matibabu kutoka kitengo cha upasuaji wa watoto katika hospitali kuu ya Kenyatta (KNH).

Swala kuu la utafiti ni "KUCHUNGUZA IDADI YA WATOTO WANAOHUDUMIWA NA KITENGO CHA UPASUAJI WA WATOTO KNH, PAMOJA NA MAGONJWA WANAYOTIBIWA, NA MATOKEO YA MATIBABU HAYO".

Mtafiti mkuu: Dkt. Ajanja Samson Otieno

Taasisi: Idara ya Upasuaji, Chuo cha Udaktari, Chuo Kikuu cha Nairobi.

Fomu hii ya kibali ina sehemu tatu:

- Muhtasari wa utafiti (kukujuza kuhusu utafiti huu)
- Cheti cha ruhusa (ambapo utatia sahihi ukikubali kuhusika katika utafiti huu)
- Taarifa kutoka kwa mtafiti

Utapokea nakala yako kamilifu ya fomu hii ya ruhusa.

SEHEMU I: Muhtasari wa Utafiti

Mwanzo

Jina langu ni Dkt. Ajanja Samson Otieno, mwanafunzi wa upasuaji katika Chuo cha Udaktari cha Chuo Kikuu cha Nairobi. Ninafanya utafiti kuchunguza idadi ya watoto wanaohudumiwa katika kitengo cha upasuaji cha watoto katika hospitali ya KNH, pamoja na magonjwa wanayotibiwa, na matokeo ya matibabu hayo.

Lengo la Utafiti

Lengo la utafiti huu ni kudadisi idadi ya watoto chini ya siku 28 wanaohudumiwa katika kitengo cha upasuaji wa watoto cha KNH. Aidha, unalenga kutambua magonjwa watoto hawa wanayougua, na matokeo ya matibabu wanayopokea katika kitengo hiki.

Usiri

Habari zitakazotokana na utafifi huu zitawekwa siri, na zitajulikana tu na mtafiti pamoja na wasaidizi wake. Jina lako ama la mtoto halitatumiwa kutoa taarifa zozote. Habari zozote

kukuhusu ama kumhusu mtoto zitatambulika kwa kodi ya nambari badala ya jina. Watakaohusika katika utafiti huu hawatatambulishwa kwa mtu yeyote.

Kutolewa kwa Taarifa za Matokeo

Matokeo ya utafiti huu yatatangazwa kwa Wizara ya Afya na madaktari kupitia chapa na kongamano za kisayansi. Habari za siri hazitatangazwa.

Madhara

Utafiti huu utatekelezwa kupitia upekuzi wa faili ya mtoto pamoja na mahojiano na mzazi wa mtoto. Kuchagua kuhusika katika utafiti huu hakutamdhuru mtoto kwa njia yeyote.

Gharama na Malipo

Hakuna gharama yoyote ya kuhusika katika utafiti huu. Vilevile, hakuna malipo yeyote.

Idhini ya Utafiti

Utafiti huu umeidhinishwa na idara ya upasuaji katika Chuo Kikuu cha Nairobi, pamoja na kamati ya maswala ya utafiti KNH/UON. Idara na kamati hii zinahakikisha kuwa utafiti hauna madhara yoyote kwa wahusika.

SEHEMU II: Cheti cha Ruhusa

Nimesome ama nikasomewa maelezo ya awali, nikapata nafasi ya kuuliza maswali yoyote, na nikajibiwa kwa ukamilifu. Nakubali sasa, kwa hiari yangu mwenyewe, kuhusika, na kumhusisha mtoto wangu, katika utafiti huu.

Sahihi ya mhusika _____

Tarehe _____

Ikiwa Mhusika hana sahihi:

Kidole Gumba cha Mhusika _____

Tarehe _____

Mawasiliano

Ikiwa ungependa kuuliza maswali yeyote baadaye, tafadhali wasiliana na:

Mtafiti mkuu:

Dr. Ajanja S. O

Department of Surgery, School of Medicine, University of Nairobi,

P. O. Box 19676 KNH, Nairobi 00202

Mobile Number: 0723948769.

Wasimamizi wa Mtafiti kutoka Chuo Kikuu cha Nairobi:

- Dr. Francis Osawa

  Lecturer, Department of Surgery,

  School of Medicine,

  University of Nairobi

  P. O. Box 19676 KNH, Nairobi 00202

- Dr. Kimani Wanjeri

Lecturer, Department of Surgery,

School of Medicine,

University of Nairobi

P. O. Box 19676 KNH, Nairobi 00202

Ikiwa una maswala yeyote kuhusu uadilifu wa utafiti, wasiliana na:

Secretary, KNH/UON ERC

P. O. Box 20723 KNH, Nairobi 00202

Tel: +254-020-2726300-9 Ext 44355

Email: KNHplan@ken.healthnet.org

SEHEMU III: Taarifa Kutoka Kwa Mtafiti

Nimemsomea mhusika muhtasari wa utafiti na nikajizatiti kuhakikisha kuwa anaelewa ya kwamba yafuatayo yatatendeka:

- Ujumbe wowote utakaopatikana utatendewa usiri.
- Matokeo ya utafiti huu yanaweza yakachapishwa ili kusaidia katika matibabu ya watoto walio na haja ya upasuaji kwa matibabu.

Mhusika amepata nafasi ya kuuliza maswali kuhusu utafiti, na maswali yake yote yamejibiwa kwa ukamilifu jinsi niwezavyo. Mhusika hajalazimishwa kutoa ruhusa kuhusika katika utafiti huu, na ametoa ruhusa kwa hiari yake mwenyewe.

Mhusika amepokea chapa ya fomu hii.

Jina la mtafiti _____

Sahihi ya mtafiti _____

Tarehe _____

(Siku/Mwezi/Mwaka)

APPENDIX IV: QUESTIONNAIRE

Study number: _____

Patient number: _____

Residence: _____

Age: _____

Sex: _____

Gestational age at delivery: _____

Weight at birth/presentation: _____

Weight at admission: _____

Place of delivery:

KNH ☐

County Hospital ☐

Health Centre/ Dispensary ☐

Home/TBA ☐

Mode of Transfer _____

Application of principles of neonatal transport	YES ☐	NO ☐
Nasogastric tube	YES ☐	NO ☐
Venous access line	YES ☐	NO ☐
Urethral catheter	YES ☐	NO ☐
Warmth provision/Transport incubator	YES ☐	NO ☐

Others (specify) _____

Hydration status **at admission**

Well hydrated	YES ☐	NO ☐
Mild dehydration	YES ☐	NO ☐
Severe dehydration	YES ☐	NO ☐

ANC attendance YES ☐ NO ☐

ANC diagnosis YES ☐ NO ☐

Surgical diagnosis _____

Type of surgical intervention _____

Interval between admission and intervention _____

Investigations done

Full haemogram YES ☐ NO ☐

U/E/C YES ☐ NO ☐

Coagulation profile YES NO

LFTs YES NO

Others (specify) _____

Imaging (specify) _____

Outcome

Death ☐

Discharge ☐

Complication YES (specify) NO

_____

Length of stay: _____

APPENDIX V: WEEKLY RECORD OF ADMISSIONS TO THE PAEDIATRIC SURGICAL WARD

Week (a)	Total number of admissions (b)	Number of neonates admitted (c)	Number of surgical neonates in NBU/other wards (d)	Number of patients managed in other wards by paediatric surgeons (e)
TOTAL				

BURDEN OF NEONATAL SURGERY =c/ (b +d +e) x 100