FACTORS ASSOCIATED WITH SHORT TERM OUTCOMES OF HYPOSPADIAS REPAIR AT THE UNIVERSITY TEACHING HOSPITAL, LUSAKA, ZAMBIA

BY

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DECLARATION

I, **Dr Kalota Seith,** hereby declare that this dissertation entitled "Factors associated with short term outcomes of Hypospadias repair at the University Teaching Hospital, Lusaka" represents my own work and has not been presented either wholly or in part for a diploma or degree at the University of Zambia or any other institution elsewhere.

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This dissertation of Dr Kalota Seith has been approved as fulfilling the requirements for the award of the degree of Master of Medicine in Pediatric Surgery by the University of Zambia.

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ABSTRACT

Hypospadias is a common congenital penile abnormality with an incidence of 1 in 250 per live male births. It occurs as a birth defect resulting in the urethral opening being located anywhere from the glans along the ventral aspect of the shaft of the penis up to the scrotum or perineum in extreme cases. In its moderate to severe forms surgery is always advocated because affected individuals fail to pass urine while standing, the penis is cosmetically different from others and importantly causes subfertility in adulthood. However surgery is not without complications. An audit done locally at UTH, Lusaka in the year 2017 showed high complication rates of 10 percent for distal hypospadias and 67% for proximal hypospadias. The objective of this study was to determine the short-term complications and factors that are associated with this outcome at UTH Lusaka. In this study we hypothesized that small glans size, narrow urethral plate, PDS suture for urethroplasty, age more than 18months at operation and Haemoglobin level are not associated with increased complication rate.

This was a consecutive (total enumerative) observational cohort study done at D-block and Clinic 7 at UTH Lusaka over a period of nine months. A total of 41 patients were enrolled and their demographic data, hemoglobin, maximum glans width size and urethral plate size before creating glans wing or midline plate incision were noted and measured. Logistic regression assessed urethroplasty complications (urethrocutaneous fistula, glans dehiscence, infection, penile torsion, persistent chordee) on urethral plate size, glans size, hemoglobin, suture material and catheter problems.

The average age of participants was 34months. Distal hypospadias was the most common type at 61%, while middle hypospadias was 27% and proximal hypospadias 12%.The complication rate was 34%. The most common complication seen was urethrocutaneous fistula 9(53%). The other complications seen included 2(11.8%) glanular dehiscence, 2(11.8%) infection 1(6%) persistent chordee and 1(6%) penile torsion. The risk factors for post-operative complications included, the location of the urethral opening. The more proximal the site of the hypospadias the higher the complication rate. Complications were strongly associated with hemoglobin levels of less than 11.5g/dl ($p=0.001$) and catheter blockage or dislodgment ($p=0.008$). There was no association of complications with Social economic status, Age at time of repair, glans width size or suture material. Contrary to the finding of many authors wider urethral plate in this study was associated with higher complication rate.

The conclusion was that short term complication rate at the UTH Lusaka Zambia is at 34%. The most common complication is urethrocutaneous fistula while the main factors associated with increased complications are hemoglobin less than 11.5g/dl, blocked and dislodgment urethral catheters, proximal hypospadias type. The recommendation from this study is hypospadias repair to be done with a hemoglobin of 12g/dl or more and post operatively a close catheter care is imperative.

Keywords : Hypospadias, short term outcomes, complications, complication rate, Urethrocutaneous fistula, glanular dehiscence, persistent chordee, penile torsion.

DEDICATION

To my lovely wife Mwangala and Son Hamekenu Emmanuel Seth Kalota Jr

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ABBREVIATIONS

CCG: Chromic Catgut

GMS: Glans Meatus Shaft (Score)

HOPE: Hypospadias Objective Penile Evaluation (Score)

MAGPI: Meatal Advancement Glanduloplasty Inco-operated

OPP: Operation Per Person

PDS: Polydioxanone Suture

PgA: Polyglycolic Acid

PPPS: Pediatric Penile Perception Score

PPS: Penile Perception Score

SSSR: Single Stage Success Rate

TIP: Tabularized Incised Plate

TIPU: Tabularized Incised Plate Urethroplasty

UC: Urethroplasty complications

UTH: University Teaching Hospital

UNZA: University Of Zambia

DEFINITION OF TERMS

- Short-term: two months according to Snodgrass would be able to capture 60 to 70 % of hypospadias repair complications (Snodgrass et al., 2014)

- Outcome; possible result of hypospadias repair (Lu et al., 2017)

- Factors associated with: elements contributing to (Lu et al., 2017)

- Infection: occurs within 30 days after the operation involves only skin or subcutaneous tissue of the incision and at least one of the following:

1. Purulent drainage, with or without laboratory confirmation, from the superficial incision.

2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.

3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat.

- Meatal stenosis: difficulty with passing urine with stranguria and meatal calibration of less than 6 Fr in prepubertal boys (Snodgrass et al., 2014).

- Urethrocutaneous fistulae: a connection between the urethra and the penile skin (Snodgrass et al., 2014).

- Glanular dehiscence: rupture or gapping of a wound on the glans penis along the surgical incision (Snodgrass et al., 2014).

- Wound dehiscence: rupture or gapping of a wound along the surgical incision (Snodgrass et al., 2014).

CHAPTER ONE: INTRODUCTION

1.1. Introduction

Hypospadias is a congenital anomaly that represents a spectrum of deficiency in penile development in which the urethral meatus terminates on the ventral surface of the penis proximal to the normal site, anywhere from glans to perineum (Abdelrahman et al., 2012). Implying the urethral opening may be anywhere along the ventral penile shaft, within the scrotum or on the perineum. The spectrum of hypospadias anomalies includes an abnormal urethral opening, chordee (ventral curvature of the penis), an incomplete prepuce (hooded foreskin), rotation of the penis, abnormal raphe, and fibrotic corpus spongiosum and penile fascia (Ameh et al., 2010).

The incidence of hypospadias has been estimated between 0.8 and 8.2 per 1,000 live male births. The wide variation probably represents some geographic, racial differences and the exclusion of the more minor degrees of hypospadias in some reports. However if all degrees of hypospadias are included, then the incidence is probably 1 per 250 live male births (Ashcraft et al., 2014). In a journal article titled "Worldwide prevalence of hypospadias" Springer A, pegged the prevalence of hypospadias in Africa to be 5.9 per 10,000 live male births (Springer et al., 2016).

Hypospadias has been classified by many hence numerous classifications have been proposed. These include Smith, Schaefer, Avellan, Browne, Duckett and Hadidi. The most common classification is by Duckett published in 1996. Hypospadias according to Duckett is classified by the location of the urethral meatus into Mild, moderate and severe, the mild forms include:

glandular (distal) hypospadias: (meatus on the ventral surface of the glans penis), coronal (meatus in the balanopenile furrow), or distal (in the distal third of the penile shaft). Moderate hypospadias is along the middle third of the penile shaft. Severe (posterior) hypospadias extends through the proximal third of the penile shaft to the perineum and may be described as posterior penile (at the base of the shaft), penoscrotal (at the base of the shaft in front of the scrotum), scrotal (on the scrotum or between the genital swellings), or perineum (behind the scrotum or behind the genital swellings (Coran et al., 2012).

Hypospadias affects children in many ways, firstly the affected patients penis is cosmetic difference from other children leading to the emotional impact of having a penis that looks different from other peers, secondly organic problems, such as the inability to pass urine in a standing position and more important is the subsequent sub fertility that may set in as one is in his adulthood; this is why always surgery is advocated to correct this anomaly (Abdelrahman et al., 2012).

Hypospadias surgery in history was first noted to have been performed by Alexandrian surgeons named Helidons' and Antyllus (first - second centuries). Since that time, many have contributed to development of modern hypospadias repair. More than 300 different types of repairs have been described in medical literature (Abdelrahman et al., 2012). By recognition of the nuances of the meatal variation, glans configuration and curvature characteristics. The surgeon can choose the optimal technique based on the location of the anomaly.

Hypospadias surgery is technically demanding and sometimes has complications that include post-operative bleeding, infections, devitalised skin flap, urethrocutaneous fistulae, strictures,

diverticulae, retrusive, meatus and persistent chordee. Corrective hypospadias surgery in Africa is associated with unacceptably high complication rate. Studies done in Sudan, Khartoum showed a complication rate of 38% (Abdelrahman et al., 2012), while that in Nigeria, Abuja showed a 50% complication (Aisuodionoe-Shadrach et al., 2015).

Surgical treatment outcome is influenced by many postulated factors including patient factors such as age at time of repair, type of hypospadias, glans size and urethral plate width, surgical factors such as fine appropriate suture material and instrument factors: optical magnification and delicate instruments. Most surgeons argue that these are important determinants in the outcome of hypospadias surgery. The technicality of urinary diversion using stents, Foley's catheter or suprapubic cystostomy cannot be over emphasised (Ashcraft et al., 2014). However suboptimal theatre conditions, lack of delicate instruments, special dressing and suture materials, and high infection rates in some parts of Africa especially sub-Saharan Africa make hypospadias repair even more difficult (Ameh et al., 2010).

Locally at UTH, the outcome and factors that are associated with poor outcome of surgical treatment of hypospadias have not been studied, and this was the proposed aim of this study.

1.2. Statement of the problem

In the period of January 2017 to December 2017, the Paediatric surgical unit at the University Teaching Hospital, Lusaka attended to 477 new cases of surgically correctable congenital anomalies, 105 of which were hypospadias, making 22% of the new cases seen annually. This disease has significant incidence in the pediatric age group in our setting.

Its moderate and severe forms pose a challenge urinating while standing which should be the norm and also may lead to high chances of infertility in the affected individuals in their adulthood. Therefore careful operative correction is vital to curtail these problems and aim for successful micturition and sexual life in the future (Ashcraft et al., 2014; Ameh et al., 2010).

According to the surgical department audit done at UTH for the third quarter of 2017, of all the distal hypospadias corrective surgeries carried out during this period in D block theatre 10% had complications while proximal hypospadias had a complication rate of 67%. According to a study titled 'Acute postoperative complications of hypospadias repair' published in the Indian journal of urology the acceptable complication rate for distal hypospadias repair should be less than 5% and proximal hypospadias less than 10% (Bhat and Mandal, 2008). With this, it's evident that we have high complication rates with hypospadias repair in our setting.

1.3. Study justification

The high complication rate of 10% for distal hypospadias and 67% of proximal hypospadias seen at UTH leads to an increased number of re-operations. This has the following implications:

I. Increased exposure to anaesthesia.

II. Increased theatre resource usage in the form of theatre material, time and human resource subsequently leading to increased hospital costs.

III. Besides that re-operations have been associated with poor outcomes (Snodgrass and Bush, 2014).

Therefore Information gathered from the study will be important in identifying factors associated with short term outcomes of hypospadias repair at the UTH Lusaka thereby giving an understanding on the underlying aspects to be looked at to mitigate the unwanted outcomes. In doing so this will lead to reducing the complication rate, surgical theatre resource costs and as such improving on the quality of clinical care offered to patients.

1.4. Research question

Is glans size, urethral plate size, age at operation, type of hypospadias, sutures used and the level of haemoglobin associated with outcome of hypospadias repair at UTH Lusaka?

1.5. Hypothesis

1.5.1. Null hypothesis

Small glans size, narrow urethral plate, age more than 18 months at operation, haemoglobin level and PDS suture are not associated with poor surgical outcome at UTH Lusaka.

1.6. Objectives

1.6.1. Main objective

To establish whether age at time of surgery, glans size, urethral plate width, suture material, urethral catheter blockage/dislodgement and haemoglobin level influence short term outcomes of hypospadias surgery at the UTH, Lusaka.

1.6.2. Specific Objectives

1. To identify the type of hypospadias seen at the UTH, Lusaka

2. To establish the socio-epidemiological characteristics of patients presenting with hypospadias at the UTH, Lusaka.

3. To determine the short-term outcomes of hypospadias repair at the University Teaching Hospitals Lusaka.

CHAPTER TWO: LITERATURE REVIEW

According to a prospective study on recent advances in understanding /management of hypospadias carried out at a children's Centre in Texas of United States of America, data collected after hypospadias repairs from the year 1999-2013 showed that proximal hypospadias repair has higher urethroplasty complications(UCs) than do distal repairs. TIP urethroplasty showed to have nearly two times more UCs when the meatus was midshaft or more proximal (Snodgrass and Bush, 2014).

Studies evaluating emotional, psychosexual, cognitive and surgical risks have identified that there is an optimal window for hypospadias repair at 3 to 18 months of age. However anaesthesia in children younger than 6 months is technically demanding. Therefore the favourable age for surgery is reported to be 6 to 18months (Ameh et al., 2010). This was also supported by a retrospective study done in Abuja with an average age at time of surgery of 44.9 months. It was observed that the repairs had a high complication rate of 50 percent, suggesting that hypospadias repair at older age maybe associated with high complication rate (Aisuodionoe-Shadrach et al., 2015). Similarly another study in Sudan showed a complication rate of 22 percent after the age of 3 years (Abdelrahman et al., 2012). However a study done by David Osi Fo and Andrew .O. Mene, at the paediatric surgery unit of Benin Nigeria titled hypospadias repair in a resource poor region showed that despite mean age at operation being 2.3 years +/- 2.1, after 4 years of follow up, all repairs were successful and cosmetic results were excellent in 95 percent, fair results in 3.9percent and poor only in 0.9 percent (Osifo and Mene, 2010). Implying that age at time of repair does not affect the outcome of hypospadias repair. Similarly a study by Warren Snodgrass and Nicol Bush vividly depicted that those speculations that increase in age at hypospadias repair increase urethroplasty complications

was not borne in their study. Their findings were that pre-pubertal boys with varying ages had comparable complications with teens and adult boys. Therefore they concluded that hypospadias repair can be done at any age with the same expectations of urethroplasty complication (Snodgrass and Bush, 2014).

There is a gap in knowledge with regard to the appropriate age at time of operating on hypospadias from the above cited studies and as such it's prudent that a study in our setting be done that may probe to see if age at time of surgery is associated with poor outcome of hypospadias repair at UTH Lusaka.

In a study done in Palermo, Italy in 2004 on suture material: do they affect fistula and stricture rates in flap urethroplasties in hypospadias repair. The patients were stratified into two groups according to the suture material used for urethroplasty. Polyglactin (Vicryl), a polyfilament with intermediate absorption, was used in one group and polydioxanone (PDS), a monofilament with prolonged absorption, in another. No statistically significant differences were noted in fistula and/or stricture rates in the two groups. A separate study done by Snodgrass and Bush, in 2014 showed similar results that there are no differences in UCs in patients on the basis of suture types and suture methods for hypospadias repair (Snodgrass and Bush, 2014). The same conclusion was also made in a study titled 'A new suture material for Hypospadias repair' (Guarino et al., 2009). However a research carried out in Sacramento, California, USA on stricture incidence related to suture material in hypospadias repair over a seven year period from 1986 to 1992 showed contrary results. In this study they evaluated the incidence of urethral stricture and urethrocutaneous fistulae after using chromic catgut, polyglycolic acid (PgA) and polydioxanone sutures in performing urethral anastomosis during

hypospadias repair respectively. The single stage success rate (SSSR) varied according to the type of suture used for the urethral anastomosis. Of the cases that had PgA or chromic sutures, 76.1 percent were corrected in a single operation, as opposed to 50.9 percent when PDS was used. The conclusion of the study was that the stricture rate was higher and the number of operations was greater for patients who had PDS sutures. Sutures with intermediate absorption rates provide the best results in hypospadias surgery. The extreme delay in vivo absorption of PDS should preclude its use as an interrupted suture in small-calibre urethral anastomosis (DiSandro and Palmer, 1996). In another study on the effect of Human urine on tensile strength of sutures used for hypospadias surgery at Royal Free London NSH Foundation Trust Hospital, UK. Kerstein et al concluded that Vicryl is the most appropriate suture material for hypospadias repairs seeing it was able to hold the wound up until enough tissues had healed sufficiently by day 5 while still degrading within a period appropriate not to promote fistulae unlike PDS which has a greater risk of fistulae formation (Edney et al., 2004; Kerstein et al., 2013; Lopes et al., 2001).

Bush et al in a study titled Glans size is an independent risk factor for urethroplasty complications after hypospadias repair. Was able to show that under the same conditions patients with a glans size of <14 mm had a 75 percent of having urethroplasty complications compared to those who had a glans size of >14mm with a 10 percent chance of complications. Additional analysis using glans size as a continuous variable demonstrated that each 1 mm decrease in size was associated with increased risk, while conversely each 1 mm increase in size was associated with a decreasing risk (Bush et al., 2015).These were similar findings with Snodgrass w. and Bush N, in the paper 'Recent advances in understanding/ management of hypospadias' (Snodgrass and Bush, 2014). Contrary to these findings a follow ups study done in 2016 showed that there is no statistically significant association between glans width and

urethroplasty complications with an overall (odds ratio (OR) 1.12; 95 percent confidence interval (CI) 0.92-1.35; P=0.26).Therefore simply put the finding on this matter differ from opinion of some experts and other studies. The reasons for the discordance in results between these studies remain speculative however implies that further research in this matter is beneficial to the body of knowledge (Faasse et al., 2016).

Another parameter that may be key in understanding factors that affect hypospadias repair outcomes is the characteristics of the urethral plate. A prospective randomized study done in 2009 by Sarhan O, Saad M ,Helmy T and Hafe on Effect of suturing technique and urethral characteristics on complication rate following hypospadias repair concluded that urethral plate characteristics i.e. the urethral plate width significantly affects the outcome, therefore adequate urethral plate width (> 8mm) is essential for successful tubularized incised plate repair (Sarhan et al., 2009). Similar findings were made by Holland and Smith et al and Mosharafa et al in two separate studies (Holland and Smith, 2000) (Mosharafa et al., 2009). Contrary to the finding of the above three studies, a retrospective research done by Nguyen MT, Snodgrass WT and Zaontz MR in 2004. No significant difference in results was predicted by plate configuration or width. The conclusion of the study was that tubularized incised plate urethroplasty for distal repair has low complication rate regardless of urethral plate configuration or width, therefore configuration and width of urethral plate does not affect the outcome of the surgical repair (Nguyen et al., 2004). Another study that had similar findings and agreed to Nguyeni et al was done by Bush NC and Snodgrass WT. This was a prospective study that looked into whether Pre-incision urethral plate does have an impact on short term outcomes on tubularized incised plate urethroplasty. After analysis of data there was no statistically significant difference with regard to complication rate between those with urethral plate width less than 8mm and those equal to 8mm or more. The conclusion of the study was

that urethral plate width before incision did not increase urethroplasty complication. Therefore pre-incision urethral plate width is not an independent risk factor for urethral complication (Bush and Snodgrass, 2017).

It is evident that pre-incision urethral plate width cannot with confidence be associated with poor outcome since the above studies have conflicting results. Therefore this calls for further research in our setting to see how this aspect fairs at the University Teaching Hospitals, Lusaka Zambia.

A study done by David Osifo and Andrew O Mene at a paediatric unit in Benin city in Nigeria on 127 boys with hypospadias in 2003-2007 showed that 10 (7.9 percent) had fistulae, 3 (2.3 percent) had complete breakdown, 5 (4 percent) urethral stenosis, 2 (2 percent) meatal stenosis, 2 (2 percent) subcutaneous hematoma, 9 (7 percent) wound infection (Osifo and Mene, 2010). A similar study done retrospectively in Abuja, Nigeria, "hypospadias repair in Abuja, a 5 year single centre experience" by Oseremen, Terkao A, Bolarawo SE and Alexandre from 2003-2007 in which 24 boys were included. This study had an overall complication rate of 50 percent with the most common complication being urethrocutaneous fistula accounting for 9 people (37.5%) and meatal stenosis being : 3 (12.5 percent) (Aisuodionoe-Shadrach et al., 2015). A study on challenges of surgical repair of hypospadias in Ile Ife, Nigeria done by A.O Olajide, A.o Sowande, A.A Salako, F.O Olajide and O.adejuyigbe showed the commonest complication to be urethrocutaneous fistulae at 21.6 percent and residual chordee at 2 percent (Olajide et al.,2010).

Another study done by Salem H, Shelbara A and Eliasha of Cairo university Egypt showed the commonest complications to be infection and meatal stenosis both at 6 percent while urethrocutaneous fistulae only accounted for 3 percent of the complications (Salema et al., 2013), while on the other hand hypospadias study done in England showed complication to be 8.1 percent urethrocutaneous fistulae, meatal stenosis 2.3 percent and urethral strictures 1.8 percent (Wilkinson et al., 2017).

It's evident that from the above studies complication rates and the most common complications differ from place to place, even in the same country certain zones have different complication rates. The Egyptian study showed that infection was the most common complication compared to other countries that had urethrocutaneous fistulae as the most common complication. Therefore it would be prudent to see the pattern with regards to complication rates and the common complication in our setting.

CHAPTER THREE: RESEARCH METHOD

3.1. Study design

This was an observational prospective cohort study

3.2. Study site

The study was conducted in the Department of Surgery, Pediatric and Neonatal surgical (D-block) and Urology Units (clinic 7) at the University Teaching Hospitals, Lusaka.

3.3. Study duration

This study was carried over a period of nine months. Recruited patients were followed up for a period of 2 months from date of surgery. The follow up duration was based on a study by Warren Snodgrass that showed that within two months post-surgery about 60-70% of complications would be captured, therefore two months being the follow up duration (Snodgrass et al., 2014).

Study end point: End point was 2 months after the procedure was done. At this point the short-term outcome would have been expected to be established (Snodgrass et al., 2014).

Target population: All patients diagnosed with hypospadias under the age of 16 years.

3.3.1. Study population:

Patients with hypospadias satisfying the inclusion criteria.

3.4. Inclusion and exclusion criteria

3.4.1. Inclusion criteria

1. All patients scheduled for hypospadias repair.

3.4.2. Exclusion criteria

1. Patients undergoing re-operations for hypospadias repair
2. .Patients undergoing first stage hypospadias repair

3.5. Sampling

3.5.1. Sampling method:

Sampling was done by consecutive (total enumerative) sampling.

3.5.2. Sample size: 38

Considering the title of the study, research question, and the condition under discussion having finite number of surgeries of 39 and 45 done in the years 2016 and 2017 respectively.

Sample size was calculated using the Yamane formula

$$n = \frac{N \ldots.}{1+N\,(e)\,2}$$

Where:

n = Corrected sample size

N = Population size: 39+45/2= 42

e = margin of error: 5%

Assumes a 95% Confidence interval

$$n = \frac{42\ldots\ldots\ldots}{1 + (42x\ 0.052)}$$

n = 38

3.6. Procedure

Patients were recruited upon first presentation to the pediatric surgical and urology outpatient clinics. A careful history followed by clinical examination were taken. Enrollment was then

determined by the inclusion/ exclusion criteria. Information was obtained from 1) the history from parents/guardian 2) clinical records of patients and physical examination findings.

Of note, social economic status was obtained using a central statistical office of Zambia model. This employed a scoring system with a score of out of 10. It consists: source of water, nature of house floor and roof, source of power, level of education, possession of a car, TV and residence. Education and good source of water having two scores while the rest each having a score of one. A score over 6 qualified one to be of high social economic status while a score lower than 6 was considered lower social economic status.

After counseling, all parents/guardian were required to sign an informed consent form while those patients over the age of 7yrs signed an assent form for them to participate in the study. Those that consented and assented for the study were observed through surgery. Of note were the glans size, urethral plate width, type of sutures and level of haemoglobin. Outcomes were determined on the basis of presence or absence of complication such as glanular dehiscence, urethrocutaneous fistulae, meatal stenosis, and infections. All procedures, examinations and follow up that were carried out were those that are routinely carried out on all patients with hypospadias, no additional or special procedures were performed other than measuring the urethral plate and penile glanular widths.

Hypospadias repair: This procedure was performed in the operation theatre (D-block theatre). Patients were positioned in supine position, cleaned and draped. General anaesthesia was given. Fine instruments and 2.5 magnification loupes were used for all patients. Pre-operative intravenous cefotaxime was given as a prophylaxis for all patients. The whole purpose of the

surgery was to bring the urethral meatus to the tip of the penis, and achieve ventral covering of the deficient ventral urethra. During the procedure the patient was catheterized with F6 or size F8 none cuffed urinary catheter and/or suprapubic cystostomy was done. After the surgery the wound was dressed, post-operative antibiotic (oral cephalexin) and analgesia were given. Wound dressing was removed after 4 days. The urinary catheter was left in situ for an anticipated duration of 14 days. The patients were followed up for two months after surgery and assessed on the review days scheduled by the assessing doctors. While hospitalized patients were seen on daily basis and after discharge they were seen at week 2, week 4 and finally week 8.

3.7 Data collection technique

3.7.1. Data collection

Was done using a data collection sheet during history taking and each time the patient was being reviewed.

3.7.2. Data entry

The data collected was entered into an excel spread-sheet for analysis.

3.8. Data processing and analysis

The data was recorded using Microsoft excel 2010 and then exported to STATA version 13.

Statistical significance was defined by $p < 0.05$ and 95% confidence interval.

Continuous variables: were analyzed using means and standard deviations when the data was normally distributed however when the data was not, medians and interquartile ranges were employed. To test for normality Shapiro-Wilk test was used

Categorical Variables: to determine the association between categorical variables, Fisher's exact test was used probably as the number of cells were less than 5 and bearing in mind with

a sample size of 41 the data was not normally distributed. To compare continuous variables with categorical variables un-paired t-test was used when the data was normally distributed but when not Mann-Whitney test was employed.

Correlation analysis was done using Pearson's test when the data was normally distributed however when the data was not normally distributed Spearman's test was used

To rule out confounders since the dependable variables were more than 2, multi nomial logistic regression was used.

3.9 Variables

Table 3. 1.Dependent and independent variables

Independent variables	Scale of measurement
Age	Continuous
Glans size	Continuous
Urethral plate width	Continuous
hemoglobin	Continuous
Suture type	categorical
Type of repair	categorical
Type of hypospadias	categorical
Level of education	categorical
magnification	categorical
Dependent variables	**Scale of measurement**
Glanular dehiscence	Categorical
Infection	Categorical
Meatal stenosis	Categorical
Urethral strictures	Categorical

Note: the three main dependent variables that were being followed up in this study are urethrocutaneous fistulae, Glanular dehiscence and infection.

3.10. Ethical considerations

The study was conducted according to the principles of research involving human subjects as prescribed by the Declaration of Helsinki (World Medical Association in 2008).

3.10.1. Risks:

There were no peculiar risks for patients participating in this study as the study was merely an observational study of what is already patterning as standard of surgical care for hypospadias patients at UTH, Lusaka. Therefore the risks that may have occurred but never did are those that are associated with hypospadias repair surgery and the following were done to reduce and avoid these risks:

1. Pre-operative assessment to avoid anesthetic events
2. Adequate analgesics to alleviate intra-operative and post-operative pain
3. Blood transfusion unit(s) were available during the surgery to mitigate any blood loss that may have occurred

3.10.2. Benefits:

There were no direct benefits of participating in the study. No financial remuneration was provided to the patients in the study as all procedures, investigations and follow up was confined to routine procedures that are part of standard care and management as provided by the patients' physicians respectively in the urology/pediatric surgery units. Furthermore patients were assessed on schedules decided by attending doctors.

3.10.3. Voluntarism:

Participation in this study was voluntary, patients participated on their own accord, no coercion was used and if patient felt injured or inconvenienced by participating in the study, they were

advised to feel free to withdraw from the study at any time without any implications to their treatment.

3.10.4. Written informed consent:

Written informed consent were obtained from every patient's parent/guardian participating in the study prior to their enrolment in the study and patients more than 7years of age signed an assent form.

3.10.5. Confidentiality:

The data collected was kept confidential and available only to the researcher. To further ensure this, patients were given codes and names withheld. Data collected was locked in a locker with keys kept by the researcher, once transferred to a computer; the data was kept securely under password protection accessible only by the researcher.

Permission to conduct this study was obtained from UTH Management, and the Department of Surgery. Ethical clearance and approval was sought from the local research ethical committee (ERES CONVERGE IRB).

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CHAPTER FOUR: RESULTS

4.1: Baseline demographic characteristics of the study participants

This chapter provides description of data. The first objective is to identify the types of hypospadias seen at the UTH, Lusaka. The second is to establish the socio-epidemiological characteristics of patients presenting with hypospadias at the UTH, Lusaka and how this determines outcome. The third is to determine the short-term complications of hypospadias surgery at the UTH, Lusaka. The fourth is to establish whether age at time of surgery, glans width size, urethral plate width size, haemoglobin level and suturing material influence short term outcomes of hypospadias repair at the UTH, Lusaka.

The total number of participants were 41. The median age of the participants at time of hypospadias surgery was 36 months (IQR, 22-60). The mean mother's age to the studied participants was 25 years with a standard deviation of 6.8 years. Thirty seven (90%) of the study participants were born at term, 1 (2.5%) was preterm and 3(7.5%) were post term births. Mother's education level, 3(7.3%) had primary education, 23(56.1%) had secondary and 15(36.6%) had tertiary education. Twenty (48.8%) of the studied participants had low socioeconomic status while 21(51.2%) had high socioeconomic status. Thirty five (85.4%) of mothers to the participants were not exposed to insecticides or pesticides during their pregnancy with the studied participants while 6(14.6%) were exposed to insecticides or pesticides. Eight (19.5%) had family history of hypospadias as shown (Table 4.1).

Table 4. 1.Baseline demographic characteristics of the study participants

Variable	Category	Proportion (%)
*Age (months)		36(IQR,22-60)
**Mother's age (years)		25(SD6.8)
Gestation age	Term	37(90)
	Pre-term	1(2.5)
	Post term	3(7.5)
Mother's education	Primary	3(7.3)
	Secondary	23(56.1)
	Tertiary	15(36.6)
Economic status	Low	20(48.8)
	High	21(51.2)
Maternal exposure to insecticide	Not exposed	35(85.4)
	Exposed	6(14.6)
Family History	No	33(80.5)
	Yes	8(19.5)

*median and interquartile range reported; ** mean and standard deviation reported; IQR: interquartile range; SD: standard deviation

4.2: Association between complication and baseline demographic characteristics

The median age at time of surgery for the participants who had complications was 34 months (IQR, 22-72) and those without complication was 36 months (IQR, 21- 60); p=0.79 and was not significantly different. The median age for the mothers in the group with complications was 23 years (IQR, 20-33) compared to those without complications 26 years (IQR, 20-32); p=0.93 and was not significantly different. There was no significant difference between those that had complications compared to the one who did not have complications in terms of gestational age (p=0.30), mothers level of education (p=0.10), socioeconomic status (p=0.44), maternal exposure to insecticide/pesticide during pregnancy (p=0.96) and family history (p=0.54) as shown in Table 4.2 below.

Table 4. 2.Association between complication and baseline demographic characteristic variables.

Variable	Complication	No complication	P-value
Age (months)	*34(22 - 72)	*36(21 - 60)	0.79
*Mother's age (years)	*23(20 - 33)	*26(20 - 32)	0.93
Gestation age			
Term	14	22	
Preterm	0	1	
Post term	0	3	0.30
Mother's education			
Primary	1	2	
Secondary	8	15	
Tertiary	5	10	
			0.10
Economic status			
Low	8	12	
high	6	15	0.44
Maternal exposure to insecticide			
Yes			
No	2	4	
	12	23	0.96
Family history			
Yes	2	6	
No	12	21	0.54

*median and interquartile range reported

4.3 Baseline clinical characteristics for the 41 study participants

The mean glans size for the participants was 16.3mm (SD, 3.40), the median urethral plate size was 6mm (IQR, 4 - 7), and the mean hemoglobin was 11.5g/dl (SD, 1.20). The types of hypospadias that were operated on included 25(60.9%) distal penile hypospadias, 11(26.8%) mid penile hypospadias and 5 (12.1%) proximal hypospadias (penoscrotal hypospadias). Nine (22%) had presence of chordee, no participant was found to have penile torsion, 1 (2.4%) participant had peno-scrotal transposition. Thirty six (87.8%) were done as single stage operations and 5 (12.2%) were done as two staged operations. On 39(95%) participants' urethral catheters alone were used, 2(5%) suprapubic catheters and urethral stents were used for urinary diversion. Of all the participants 15(36.6%) had problems with catheters. Of these 10 (24%) had blocked catheters and 5 (12%) pulled out their urethral catheters. Suturing material used for urethroplasties included Vicryl in 25(61%) participants and PDS in 16 (39%). Median time for discharge was 14days (IQR, 7-14) as shown in Table 4.3 below.

Table 4. 3. Baseline clinical characteristics for the 41 study participants

Variable	Category	Proportions (%)
Glans size (mm)	**16.3 (3.40)	
Urethral plate size (mm)	*6 (4-7)	
Hemoglobin (g/dl)	*11.5 (1.2)	
Type of hypospadias	Distal Penile	25 (60.9)
	Mid Penile	11 (26.8)
	Proximal	5 (12.1)
Presence of chordee	Yes	9 (22)
	No	32 (78)
Presence of Penile Torsion	No torsion	41 (100)
Scrotal transposition	Yes	1 (2.4)
	No	40 (97.6)
Type of surgery	Single	36 (87.8)
	Second stage	5 (12.2)
Type of urinary diversion used	Urethral	39 (95)
	SPC	2 (5)
Problem with catheter (urinary diversion)	Yes	15 (36.6)
	No	26 (63.4)
Urethroplasty suture used	Vicryl	25 (61)
	PDS	16 (39)
UCF resolution	No UCF:	34 (82.9)
	Resolved	2 (5)
	Not resolved	3 (12)
Day of catheter removal (problems)	14(7-14)	

* Median and interquartile range reported; mean and standard deviation reported; PDS: polydioxanone; UCF: urethrocutaneous fistula; SPC: suprapubic catheter

4.4: Types of hypospadias seen during the study

The types of hypospadias that were seen are coronal 5 (12%), subcoronal 20 (49%), mid penile 11(27%) proximal penile 1(2%) and penoscrotal 4 (10%). For purposes of meaningful data analysis these were further categorized as distal (anterior), 25(61%), middle 11(27%) and proximal hypospadias (posterior) 5(12%). Shown in figures 4.1 and 4.2

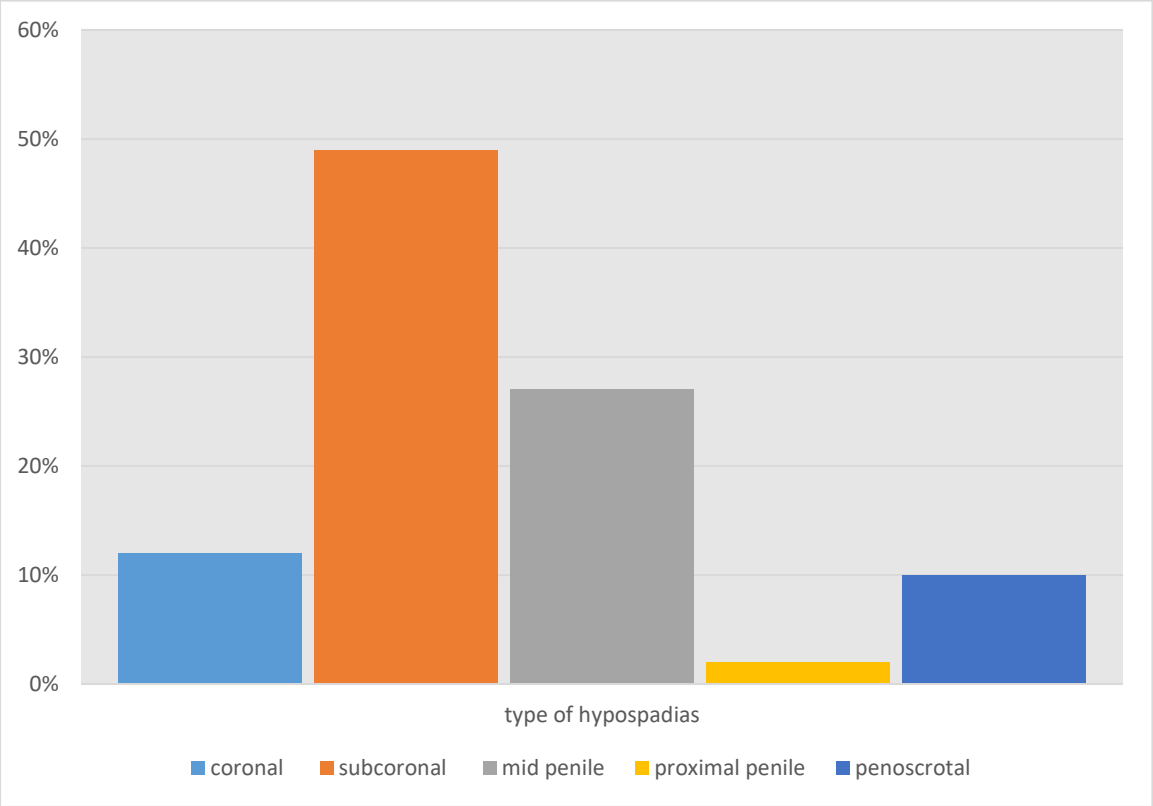

Figure 4. 1.Types of hypospadias seen during the study

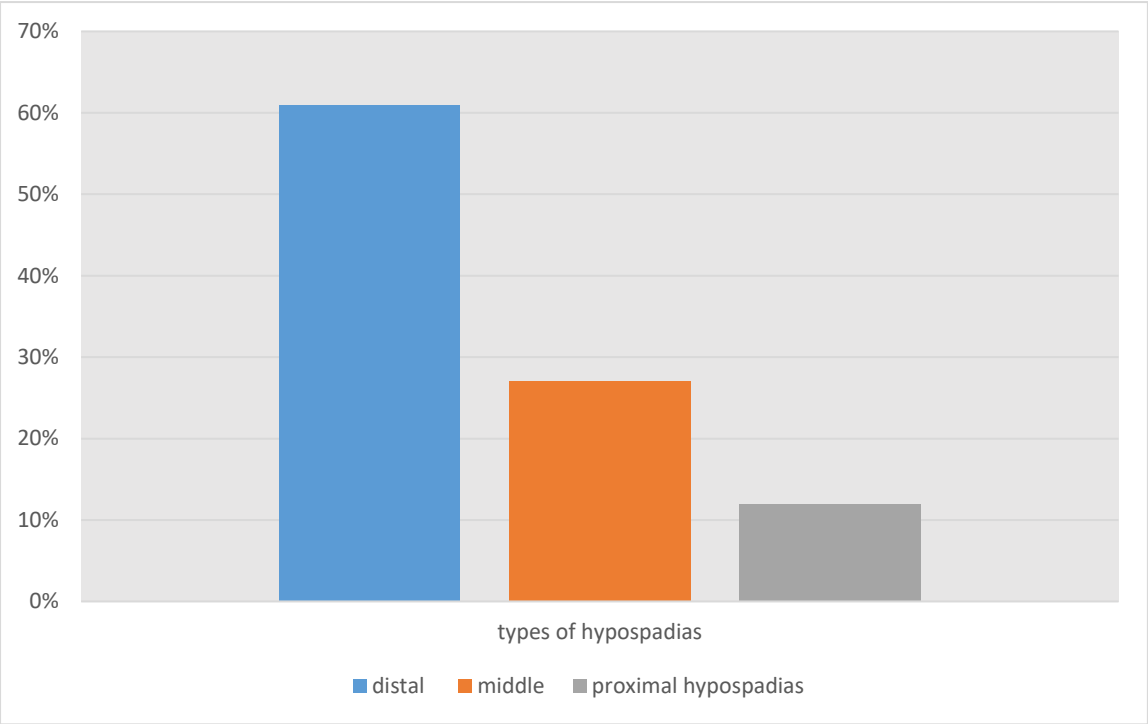

Figure 4. 2. Bar graph showing types of hypospadias seen during the study (three broad categories)

4.5 Short term hypospadias complications seen during the study

Following hypospadias repair of 41 patients, 14 (34%) developed complications as shown in fig 4.3

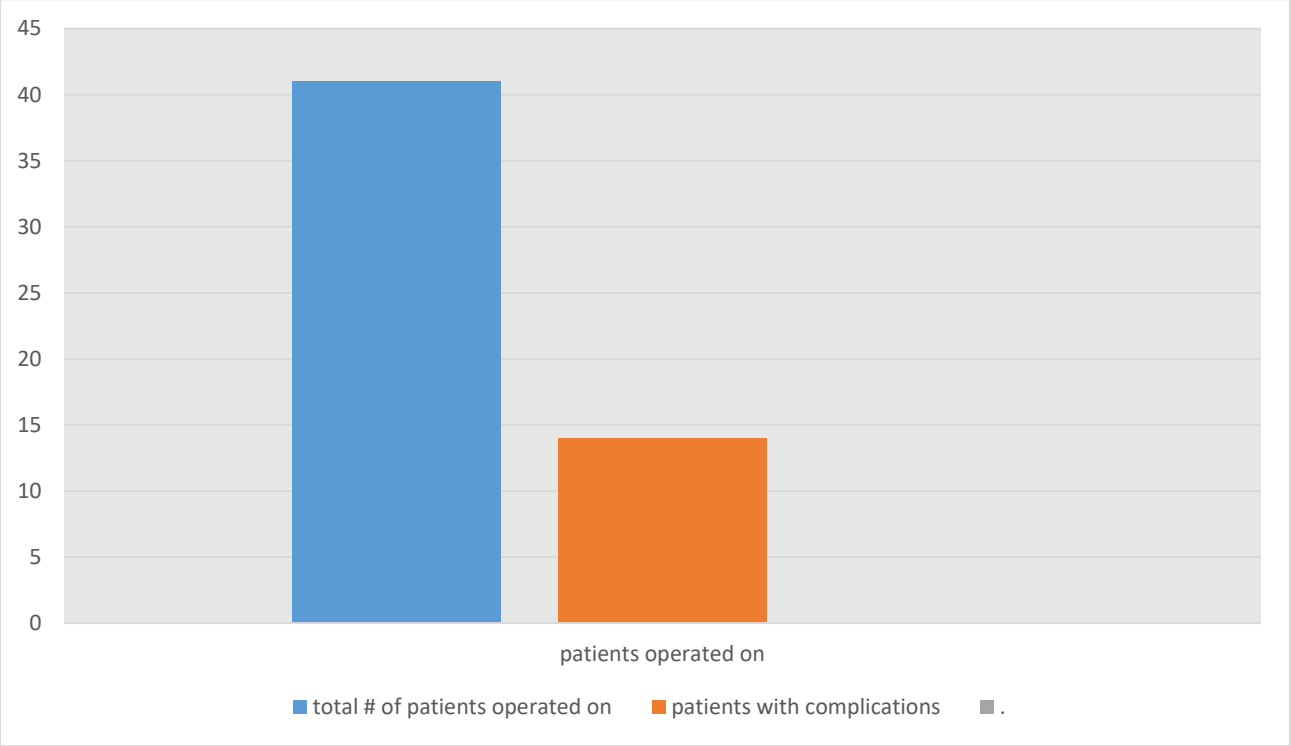

Figure 4. 3.Bar Graph showing the number of patients that developed complications

Among the 14 patients that developed complications three had more than one complication. The first one had meatal stenosis with an urethrocutaneous fistula, the second had infection with urethrocutaneous fistula and the third had infection with glanular dehiscence. Thereby leading to the following complications, 9 (53%) urethrocutaneous fistulae, 2 (11.8 %) glanular dehiscence, 2(11.8. %) meatal stenosis, 2(11.8%) infections, 1(6 %) persistent chordee and 1(6%) penile torsion. As shown in Fig 4.4 below

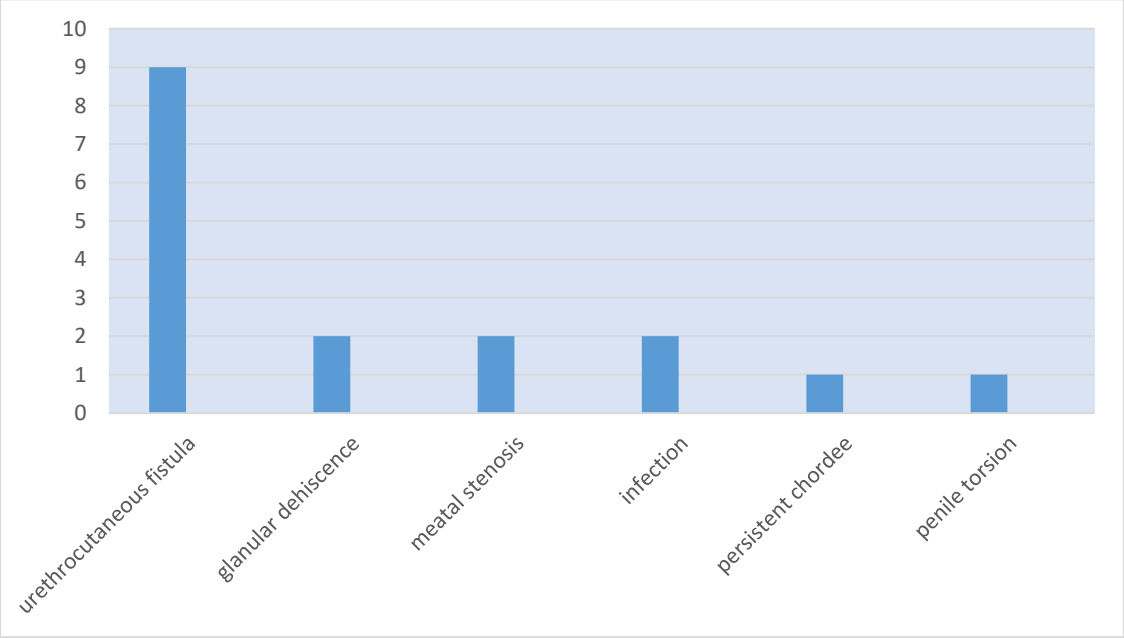

Figure 4. 4.Bar graph shows hypospadias surgery complications seen during the study

4.6. Variables under study associated with short term hypospadias outcome

4.6.0 Age at time of hypospadias repair and complications

There was no statistical difference in age at time of hypospadias repair for the studied participants that developed complications and those that didn't. Furthermore there was no statistical difference in complications between studied participants less than 18 months and those that were above 18 months at time of surgical repair as shown in figure 4.

Table 4. 4.Age at time of hypospadias repair and complications

Age at repair	Complications	No complications	Total	p-value =0.59
< 18 months	3	4	7	
>18 months	11	23	34	
Total	14	27	41	

4.6.1. Type of hypospadias and complications

Figure 4.5. Illustrates that there was a significant association between type of hypospadias and complications (p=0.003). Distal hypospadias repair had a complication rate of 20%, middle hypospadias repair had a complication rate of 36% and proximal hypospadias repair 60%.

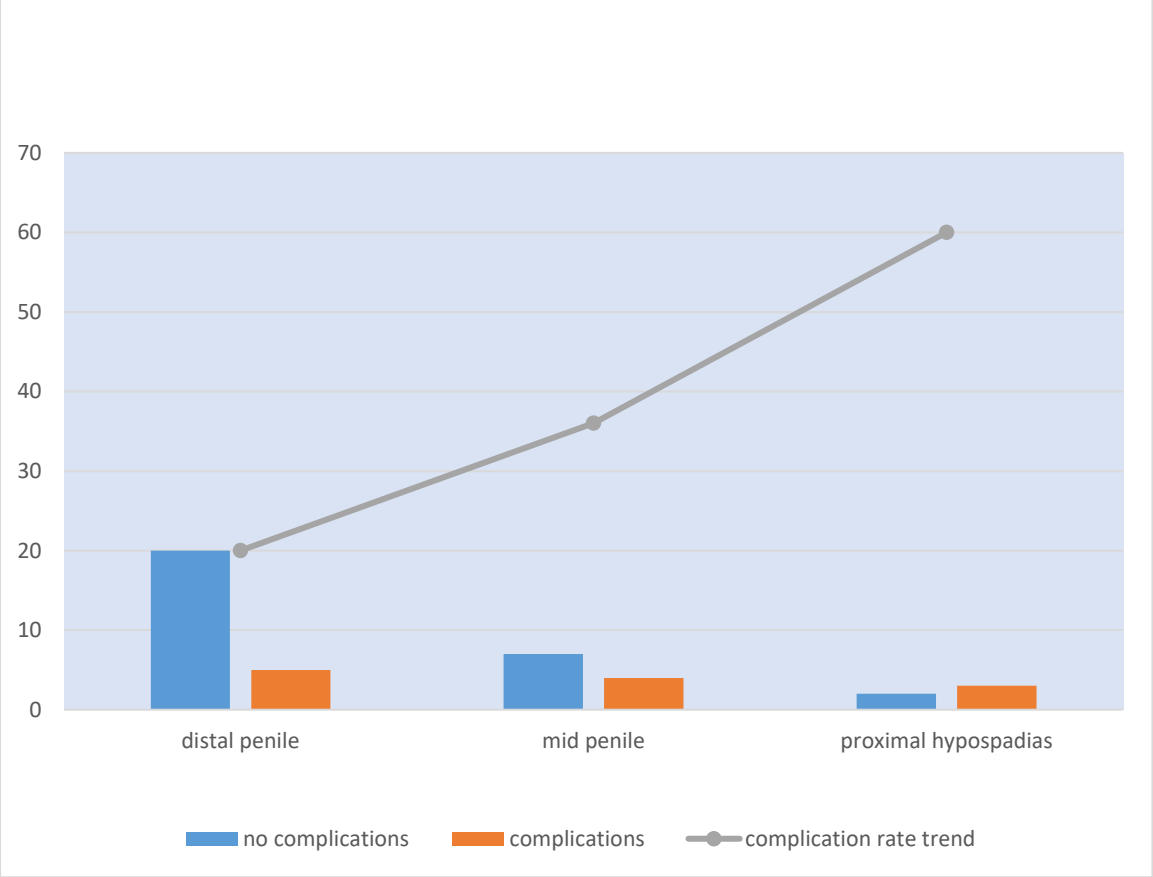

Figure 4. 5.Graph showing the types of hypospadias and associated number of complications and complication rates.

4.6.2. Hemoglobin and complications

4.6.2.1: Comparison of hemoglobin levels between patients with hypospadias repair Complications and those without complications

There was a significant difference in hemoglobin levels between patients who developed complications (who has a median hemoglobin of 11g/dl (IQR, 10.0-12.2)) compared to patients that did not develop complications (who had a median hemoglobin of 12.3 g/dl (IQR, 11.6-13.0); p=0.005.) as shown in figure 4.6.

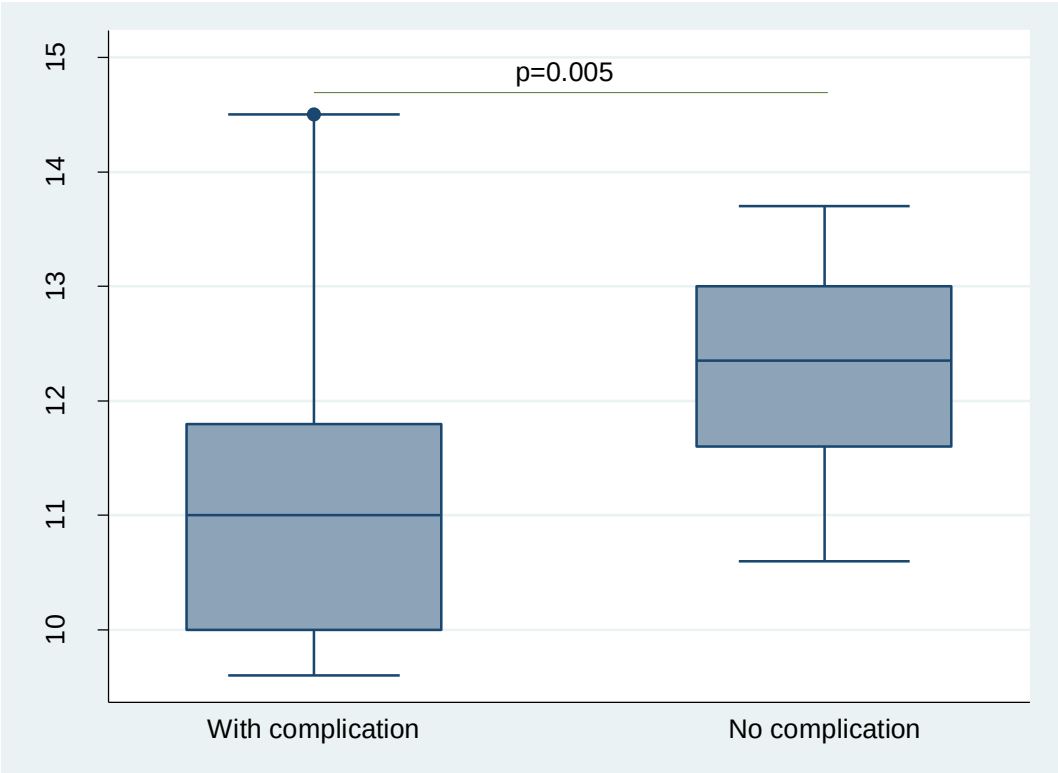

Figure 4. 6.Comparison of hemoglobin levels between patients that developed complications and those that did not develop complications.

Table 4.5. Shows that there was a significant statistical association between patients with hemoglobin less than 11.5g/dl and complications (p=0.001). Patients with hemoglobin less than 11.5g/dl had 11(61%) patients with complications compared to patients with hemoglobin of more than 11.5g/dl who had 3(13%) developing complications. There was an increased association of developing complications with hemoglobin of less than 11.5g/dl

Table 4. 5.Association of hemoglobin less than 11.5g/dl and more than 11.5g/dl with complication rate.

Hemoglobin(g/dl)	With complication	Without complication	Total	Complication rate (%)	p=0.001
< 11.5	**11**	**7**	**18**	**61**	
>11.5	**3**	**20**	**23**	**13**	
Total	**14**	**27**	**41**		

Figure 4.7. Shown below: Hypospadias patients who had hemoglobin less than11.5g/dl had a complication rate of 61% while those with hemoglobin more than 11.5g/dl had 13%**.**

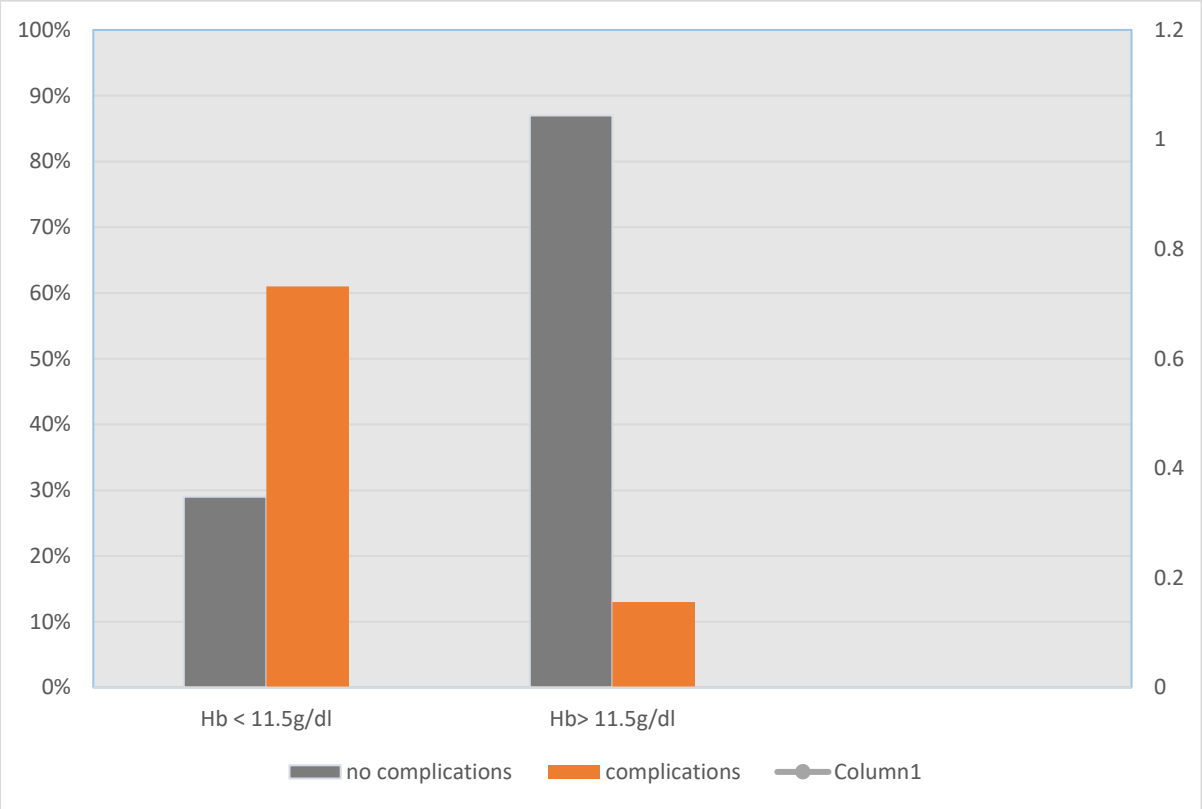

Figure 4. 7.Graph showing hemoglobin less than 11.5g/dl, and hemoglobin more than 11.5g/dl with their respective complication rate

4.6.3. Problems with catheter (urinary diversion) and complications

Problems with catheter (urinary diversion) was defined as patients whose urethral catheters either got blocked or was pulled out by the study participants.

Table 4.6. Shows that there was a statistical significant association between studied participants that had problems with catheters and complications, (p=0.008). There was an increased number of complications with people that had problems with catheters than those that did not.

Table 4. 6: **complications and problems with catheter (urinary diversion)**

	Complications	**No complications**	**Total**	**Odds ratio=6.3**
Problem with catheter	**9**	**6**	**15**	
No problem with catheter	**5**	**21**	**26**	
Total	**14**	**27**	**41**	

Figure 4.8. Shows that after adjusting for other variables the probability of developing complications when the patient had a catheter problem were much higher than one who did not. In this analysis the odds of developing complications when one had a catheter problem were 6 times compared to 2 when one didn't have catheter problems.

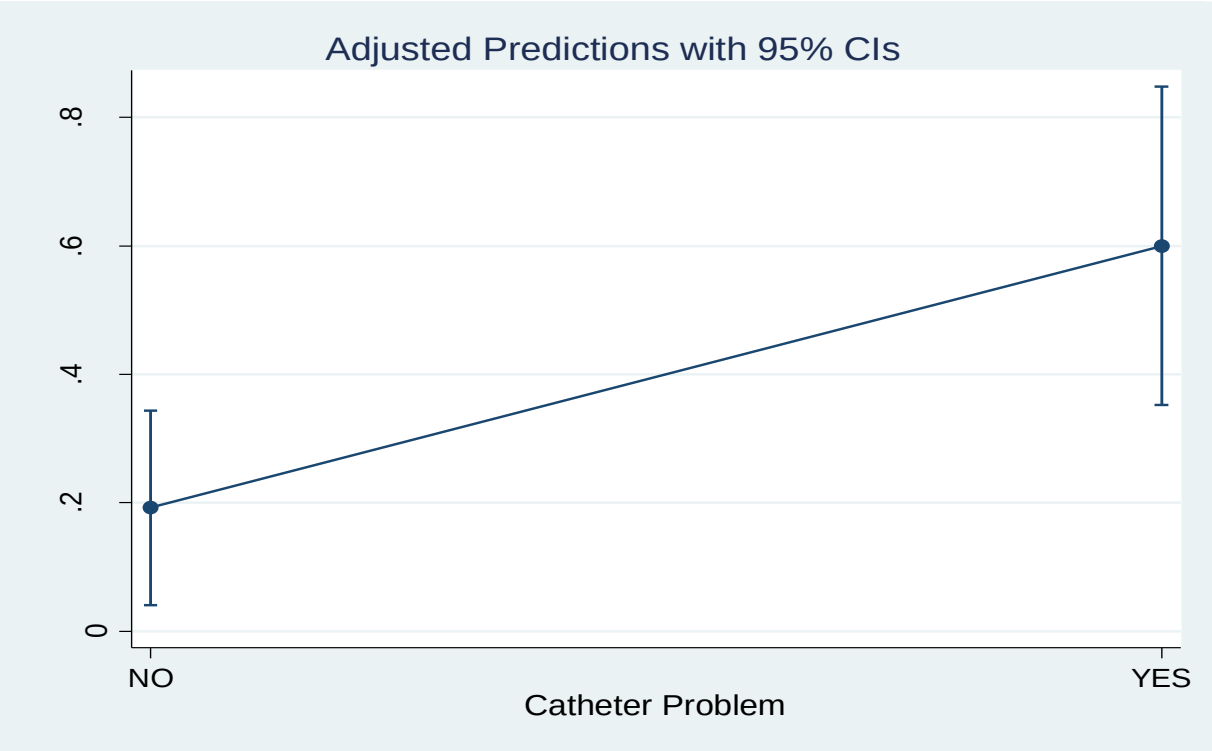

Figure 4. 8. The probability of developing complications when catheter problems are present

4.6.4. Urethral plate width size and complications

4.6.4.1 Comparison of urethral plate width size between patients with hypospadias complications and those without complications

There was statistical difference in urethral plate width in patients with complication and those who didn't (p=0.01). Patients with complications had a median urethral plate width of 7mm (IQR, 5-11); those without had a median of urethral plate of 5mm (IQR, 4-7). Shown in figure 4.9.

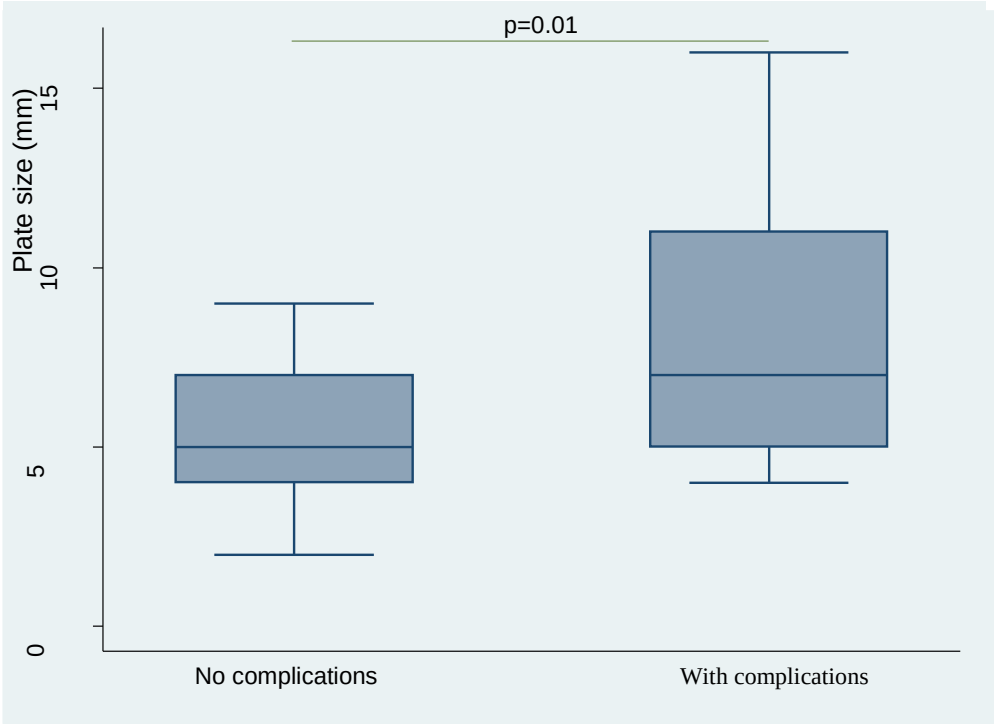

Figure 4. 9: Comparison of urethral plate size between patients that had complications and those without complications

4.6.4.2: Comparison of complications between patients with urethral plate width size <8mm and >8 mm

The patients with urethral plate width < 8mm were 31. Seven (23%) developed complications. On the other hand those with urethral plate width > 8mm were 10 and 7 (70 %) of these developed complications .Therefore the complication rate for patients with the urethral plate width size of less than 8mm was 23% while that for those with urethral plate size greater than 8mm was 70% as shown in the bar graph below in Table 4.7 and Figure 4.10.

Table 4. 7. Complications when urethral plate width is greater or less than 8mm

	Outcome of Hypospadias Repair		
Urethral plate width size	**Complications**	**No complications**	**Total**
<8mm	7	24	31
>8mm	7	3	10
Total	14	27	41

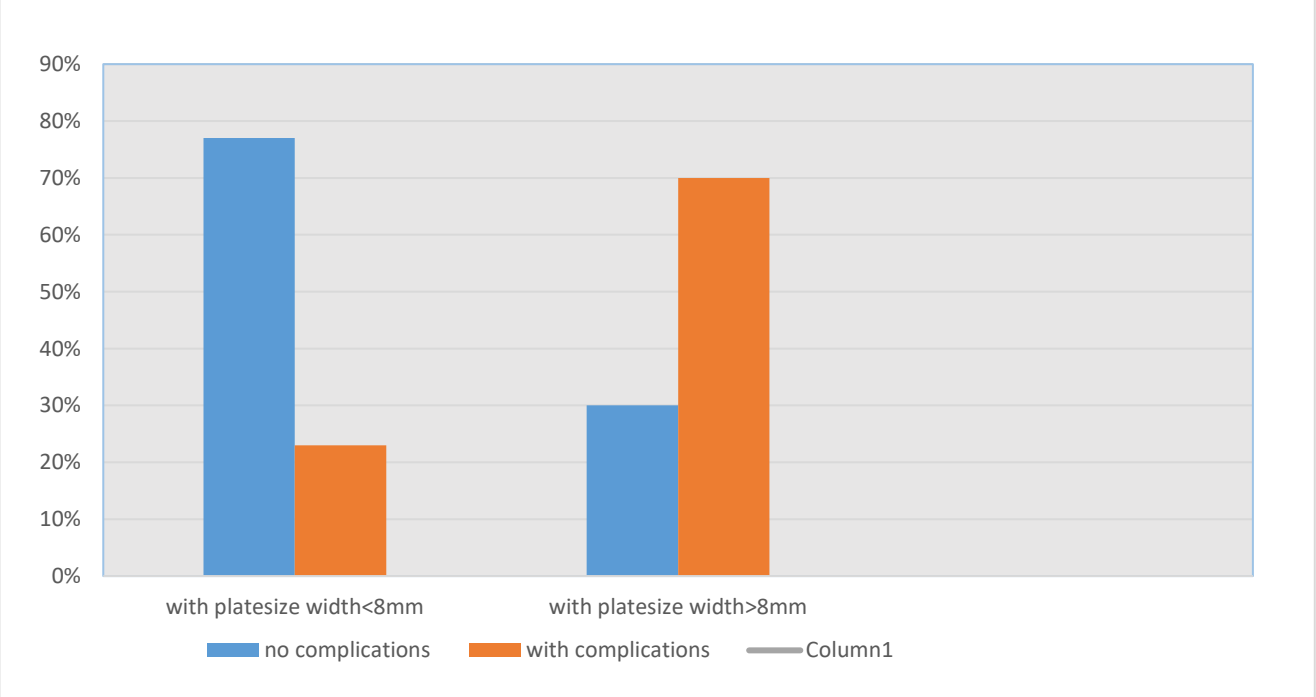

Figure 4. 10: Comparison of complications in patients with plate size <8mm and >8mm

Figure 4.11. Shows that after adjusting for other variables the adjusted predictions of the social economic status with 95% confidence interval, the probability of developing a complication with a urethral plate width of more than 8mm were higher than when the urethral plate width was less than 8mm.

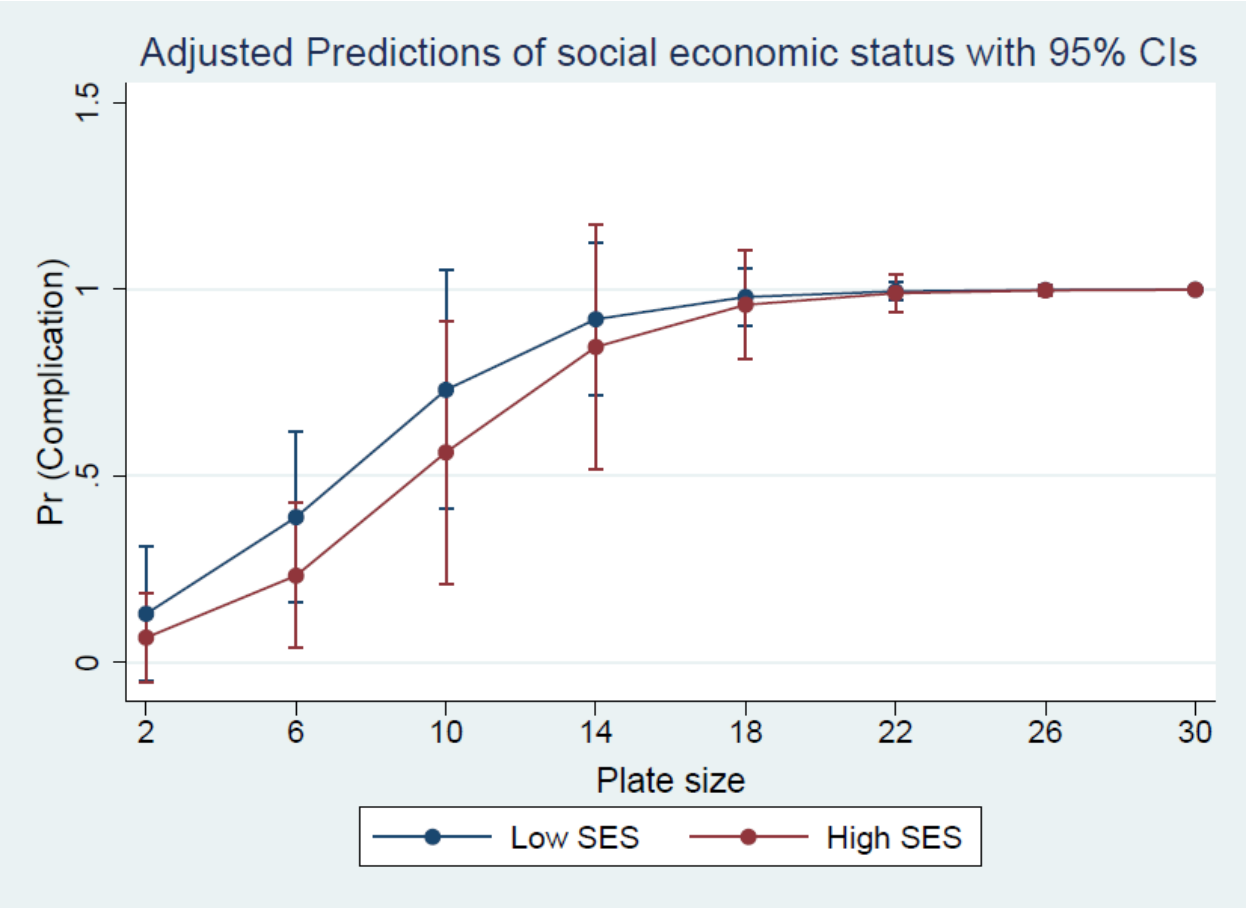

Figure 4. 11. Showing the probability of developing complications with increasing urethral plate size

4.6.5. Glans width size and hypospadias repair complication

There was no statistical difference in glans width size between the groups with complications (who had a median glans width of 16 mm (IQR, 14 - 18)) and those without complications (who had a median glans width of 17mm(IQR, 13 – 19)); (p=0.43) as shown below in Figure 4.12

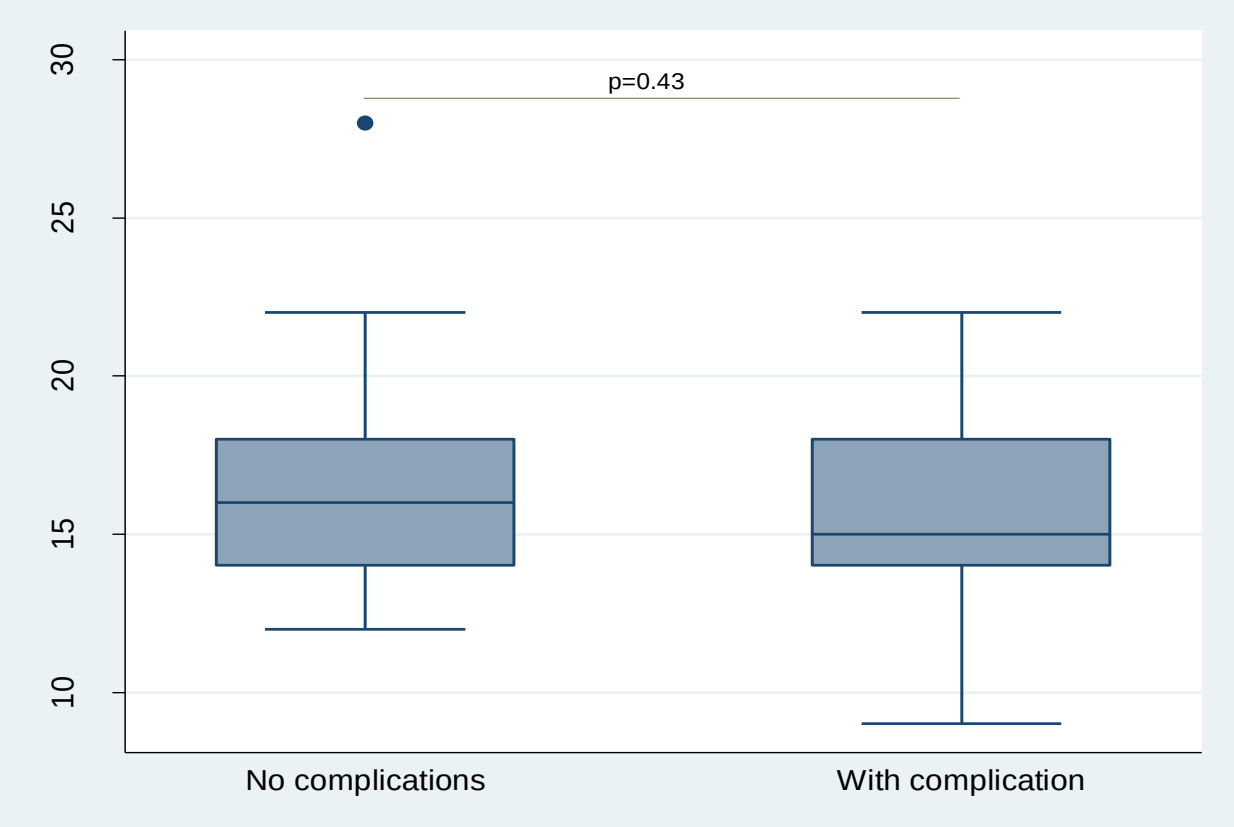

Figure 4. 12: comparison of glans size between patients with complications and those with no complication

4.6.5.1: Comparison of complications between patients with glans width size <14mm and those with glans size >14mm

There was no statistical (p=0.80) difference in complications between patients with glans width size greater than 14mm or less than 14mm.

Table 4. 8.Association of glans size less or greater than 14mm with complications

Glans width size (mm)	Outcome of Hypospadias Repair		Total	P=0.80
	Complications	No complications		
<14	2	4	6	
>14	12	23	35	
Total	14	27	41	

Figure 4.13. Shows that after adjusting for other variables, the predictive margins of social economic status showed that the probability of developing complications reduce with increasing glans size

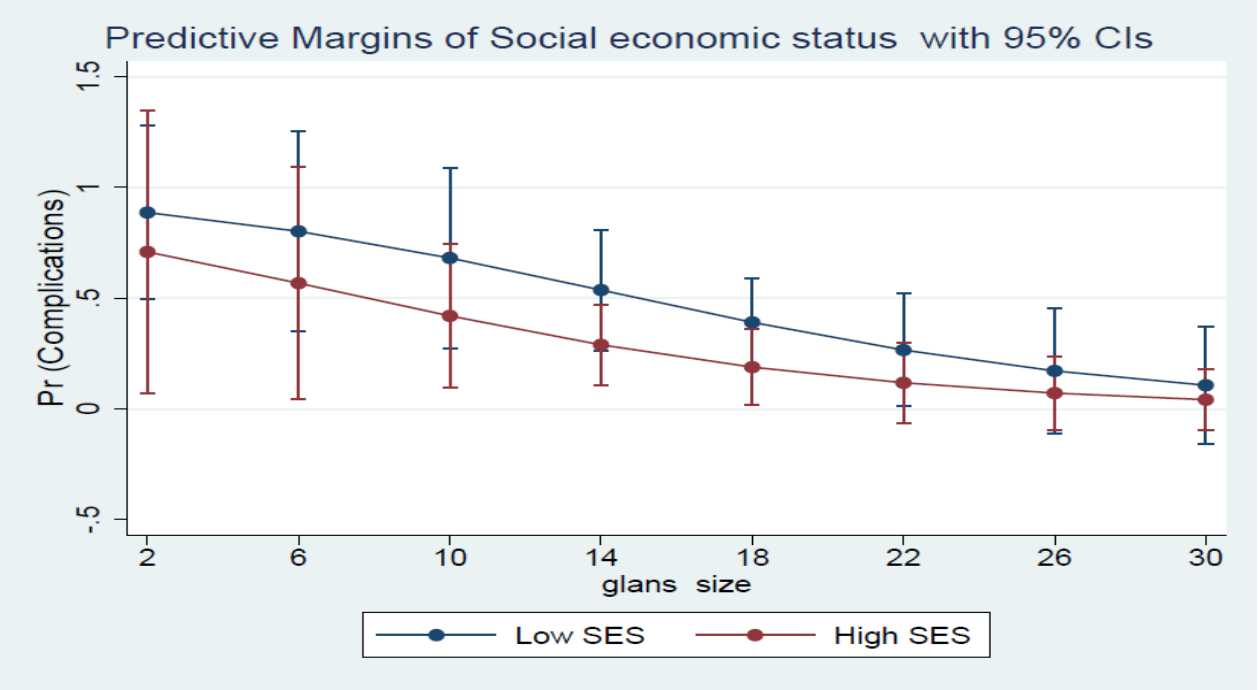

Figure 4. 13. Shows the probability of developing complications with increasing glans size width

4.7. Association between complications and clinical characteristics.

There was significant association between complications and type of hypospadias (p=0.003), problem with catheter (p=0.008) and UCF resolution (p<0.001). There was no association between complications and presence of chordee (p=0.13), presence of penile (p=0.16), type of urinary diversion used (0.35) and Urethroplasty suture used (0.75) as shown in Table 4.9 below.

Table 4. 9.Association between complications and clinical characteristics

Variable	Complications	No complications	P-values
Type of hypospadias			
Distal Penile			
Mid Penile	5	20	
Proximal	4	7	
	5	0	0.003
Presence of chordee			
Yes			
No	4	5	
	23	9	0.13
Presence of Penile Torsion	--	41	
Scrotal transposition			
Yes			
No	1	0	
	13	27	0.16
Type of catheter used			
Urethral	12	27	
SPC	0	2	0.35
Problem with catheter			
Yes	9	6	
No	5	21	0.008
Urethroplasty suture used			
Vicryl	9	16	
PDS	5	11	0.754
UCF resolution			
No UCF	0	30	
Yes	2		
No	9		<0.01

UCF: urethrocutaneous fistula, PDS: Polydioxanone Suture, SPC: Suprapubic Catheter

4.8. Correlation matrix among independent variables

There was significant and positive correlation between type of catheter and urethral plate size (r=0.48; p<0.001) and between hemoglobin and problem with catheter (r=0.60, p<0.001) as shown in Table 4.8 below.

Table 4. 10: **Correlation matrix among independent variable**

	Glans size	**U. Plate size**	**Hb**	**Type of catheter**	**Problem with catheter**	**Suture type**	**Type of hypospadias**
Glans size	1.00						
U. Plate size	0.05 0.77	1.00					
Hb	0.23 0.77	0.17 0.28	1.00				
Type of catheter	-0.12 0.45	0.48* <0.001	0.28 0.08	1.00			
Problem with catheter	0.30 0.06	0.16 0.30	0.60* <0.001	0.30 0.06	1.00		
Suture type	0.20 0.21	0.04 0.79	- 0.06 0.73	0.05 0.75	0.22 0.16	1.00	
Type of hypospadias	0.21 0.19	-0.03 0.86	-0.13 0.40	-0.03 0.87	-0.06 0.73	0.08 0.60	1.00

Hb: hemoglobin; U plate size: urethral plate size.

4.9: Multivariable logistic regression analysis

When univariate regression model was constructed, for every 1 unit increase in hemoglobin level was significantly associated with about 33% reduction in complications. After adjusting for baseline demographic characteristics in multivariable regression, the reduction in complications was 26%, p =0.03. Increase in glans width size and urethral plate width size were protective against complications but were not significant., Having problems with catheter was associated with 2.91 odds of developing complications in the univariate analysis which reduced to 1.54 odds in the multiple regression but was not significant. Having any type of hypospadias (proximal or mid penile) was associated with increased complications comparing to distal type but was not significant (Table 4.9.1).

Table 4. 11. **Multiple regression analysis of the association between the complications and the clinical predictor variables**

	Univariate			**Multiple**		
Variables	**OR**	**95% CI**	**p-Value**	**aOR**	**95% CI**	**p-Value**
Plate size	0.94	0.72-1.22	0.64	1.00	0.62-1.62	0.10
Glans size	0.90	0.72-1.12	0.33	0.79	0.60-1.03	0.08
Problems with catheter	2.91	0.75-11.4	0.12	1.54	0.2210.8	0.67
Hemoglobin	*0.67	0.20-0.73	0.01	0.74	0.55-0.79	0.03
Type of hypospadias						
Distal	Ref.					
Mid penile	1.47	0.33-6.63	0.62	1.79	0.28-11.49	0.49
proximal	1.71	0.23-12.55	0.60	1.22	0.00-15.2	0.54
Type of catheter	***	***	***			
Urethral						
SPC						

***: type of catheter omitted because of collinearity; aOR: adjusted odds ratio; OR: odds ratio CI: confidence interval

CHAPTER SIX: DISCUSSION

5.1. Types of hypospadias at the university teaching hospital

Individual types of hypospadias that were seen during the study included twelve percent (12%) coronal, forty nine percent (49%) sub coronal, twenty seven percent (27%) mid penile, two percent (2%) proximal penile and ten percent (10%) penoscrotal hypospadias.

From the distribution of various types of hypospadias, sub coronal hypospadias was the most common type of hypospadias seen at U.T.H, Lusaka and it accounted for forty nine percent (49%) of hypospadias. However, for the purposes of meaningful data analysis, this was further categorized into three (3), being: distal penile, middle and proximal hypospadias. This is the favored classification of most authors and is based on the locations of the hypospadiac meatus after repair of the chordee (orthoplasty).

Using this classification, sixty-one percent (61%) of the hypospadias seen were distal, twenty seven percent (27%) were middle and twelve percent (12%) were proximal hypospadias.

Campbell et al, 2007, USA and Coran and Adzick, 2012, USA discussed the occurrences of distal hypospadias to be fifty to seventy percent (50% to 70%) of the entire spectrum of hypospadias, while middle hypospadias is thirty percent (30%) and proximal hypospadias is twenty percent (20%). Aschcraft at el 2014 described distal hypospadias to be the most common type at fifty two percent (52%) followed by proximal hypospadias at 31.7% and middle hypospadias at 16.3%. Abdelrahman et al 2011, also found distal hypospadias to be the

most common type with forty eight percent (48%).(Campbell et al., 2007; Coran and Adzick, 2012)

Our findings were comparable with other studies because we found that distal hypospadias was the most common type. However, the proximal type of hypospadias seen in the study accounted for only ten percent (10%) of the hypospadias and was lower than what was reported by others as shown above. This therefore suggests that U.T.H sees fewer numbers of proximal hypospadias compared to other centers.

5.2 Social- demographic data

The total number of patients enrolled in the study was 41 males. At the time of operation, the ages ranged from twenty two (22) months to sixty (60) months with the medium age of 36 months. This finding was similar with a study conducted by Abdelrahman et al (2012) done in Sudan where about more than fifty percent (50%) of patients were operated on at a mean age of thirty six (36) months. However, this is different from a study conducted by (Aisuodionoe-Shadrach et al., 2015) in Nigeria where the mean age of the patients at operation was 44.9 months.

The studied participants' mothers' ages ranged from fifteen (15) years old to forty two (42) years old with a mean age of twenty five (25) years (S.D. 6.8 years).

Ninety percent (90%) of the studied participants were born at term, twenty five (25%) [1], were born prematurely and seven point five percent (7.5%) [3], were post term births.

The mothers' education levels varied, a percentage of fifty six point one percent (56.1%) [23], had secondary education. Seven point three percent (7.3%) [3], had primary education while thirty six percent (36%) [15], had tertiary education.

There was no association between prevalence of hypospadias and low social economic status. Forty eight point eight percent (48.8%) [20], of the studied participants had low social economic status while fifty one point two percent (51.2%) were from the high social economic status.

The study by Aisodione Shadreck et al, on the contrary showed that fifty-four percent (54%) were of low social economic status. Olajide et al of Nigeria in his study of the Ile-ife found that ninety percent (90%) of the hypospadias were from a low social economic status. The difference may be that these studies were done in lower social economic status regions of Nigeria therefore most patients being tagged as coming from low social economic status.(Olajide et al., 2009)

A study conducted in Finland on geographic differences in prevalence of hypospadias showed no association of hypospadias with social class.(Aho et al., 2003)

A percentage of nineteen point five (19.5%) [8], had a family history of hypospadias from this study. Ashcraft et al also found a nineteen percent (19%) family history in an index child with a second degree relative. Margot et al found a family history of twenty three percent (23%). While a study done in Sudan found a twelve percent (12%) family history of hypospadias.

Jason Lee et al writes that fourteen percent (14%) male siblings of affected boys have hypospadias. (Abdelrahman et al., 2011)

The findings in this study had a slightly higher percentage of family history than most of the above quoted studies, however, they compare relatively well with them.

5.3 Hypospadias complications seen in the study

The overall complication rate of hypospadias seen during the study was thirty four percent (34%).The most common complication seen was urethrocutaneous fistula accounting for (53%) [5], of complications, followed by glanular dehiscence at eleven point eight percent (11.8%) [2], meatal stenosis at (11.8%) [2], infection at 11.8% [2], persistent chordee and penile torsion accounting for 6% [1].

(Aisuodionoe-Shadrach et al., 2015) had an overall complication of fifty percent (50%) with the commonest complication being urethrocutaneous fistula accounting for thirty seven point 5 percent (37.5%). Salem et al 2013 Egypt in his study showed that the most common complication was infection.A study by Wilkinson et al conducted in England showed that the urethrocutaneous fistula complication rate was at eight point one percent (8.1%), meatal stenosis at two point 3 percent (2.3%) and urethral stricture at one point eight percent (1.8%).(Canning, 2018; Wilkinson et al., 2017)

This spread difference shows that various centers have different aspects of hypospadias surgery requiring different attention.

5.4 Factors associated with outcomes of hypospadias at the university teaching hospital

5.4.1 Age at time of Hypospadias Repair and Complication

The study showed that there was no difference in the complication rate with regards to the age at the date of operation. This finding was similar to that of Snodgrass and Bush, 2014. In their study findings, they emphasized that speculations made by other surgeons which state that increased age at time of repair increases urethroplasty complications was not borne in their study and surgical experience. Therefore, pre-puberty boys of varying ages have the same expectations of urethroplasty complications as those at any age. This conclusion was also found by Osifo and Mene, Hayashi and Kojima. (Hayashi and Kojima, 2008; Osifo and Mene, 2010; Snodgrass and Bush, 2014)

However, contrary findings by Aisodione-Shadreck et al, 2012 in Abuja showed that age at the time of surgery had a high complication rate of 50%, suggesting that hypospadias repair at an older age is associated with complications. Abdelrahman et al, 2012 had similar findings.

It has become acceptable that early hypospadias repair is desirable as it is evidence that healing may be better with reduced inflammatory factors and less scaring on the patient. Technical advances over the past few decades have made it possible to repair hypospadias in the first six (6) months, Manley and Epstein reported reduced patient anxiety when repair was carried out before eighteen (18) months. At this age, anesthesia associated risks are no greater than in the adults. The findings of this study suggests that most of our patients present late. Having no increased risks of complications whether surgery is done at an earlier age or at a later age, makes this information useful in planning for surgery at U.T.H.

5.4.2 Types of hypospadias and complications

The study showed that there was a significant association between types of hypospadias and complications. Proximal hypospadias had the highest complication rate of sixty percent (60%). Middle hypospadias had a complication rate of thirty six percent (36%) and distal hypospadias had the least complication rate of twenty percent (20%). Similarly, Snodgrass and Bush, 2014, Abdelrahman et al and other literature consistently agree that the highest complications lay among proximal hypospadias repair.

The acceptable complication rate according to Bhat et al should be less than five percent (5%) for distal hypospadias and less than twenty percent (20%) for proximal hypospadias. The reasons for a high complication rate in our study maybe partly associated with the high rates of problems with catheters and low hemoglobin as has been highlighted in this study.

5.4.3 Hemoglobin and Complications

The study showed a significant difference in hemoglobin levels between patients that developed complications and those that didn't develop complications. The median hemoglobin of the patients that developed complications was 11 g/dl (IQR 10.0-12.2) and those that didn't develop complications was 12.3 g/dl (IQR 11.6-13.0).

There was an association between developing complications with hypospadias repair and having hemoglobin less than 11.5 g/dl (p-value 0.001).

A thorough literature review was done and no study was found specifically associating reduced hemoglobin of this level to complications regarding hypospadias surgery. However, following the basic principles of surgery, hemoglobin is the main carrier of oxygen to tissues. Therefore

if hemoglobin is reduced it impinges on the quality of healing by slowing down the healing process.(Raftery, 2008).

Fowler et al 2015 meta-analysis of patients undergoing major urological surgery study showed that pre-operative reduced hemoglobin was associated with poor surgical outcome. A similar finding was seen with Cui et al, in a study on Pre-operative Assessment of patient undergoing major urological surgery. In this study, recommendations were made that treatment with hematinic for about six (6) weeks should be given to patients with low hemoglobin levels going for major urological surgery. The aim is to achieve hemoglobin of more than 13 g/dl pre-operatively in both sexes.(Cui et al., 2017; Fowler et al., 2015)

The findings of this study agrees with those of Folwer et al and Cui et al partly because Cui et al was studying urological conditions as is the case with this study.

5.4.4 Catheter (Urinary Diversion) Problems and Complications

Problems with the catheter or urinary diversion was defined as patients that had blocked catheters or catheters that were pulled out or dislodged by the study participants.

Two methods of urinary diversions were used, ninety five percent (95%) [39], of patients used intra-urethral urinary diversion and the remaining five percent (5%) [2], used supra-pubic catheters. With regards to patients on whom supra-pubic catheters were used, these initially developed urethrocutaneous fistula. However prior to the completion of the study, the fistulas totally resolved. Therefore the patients with intra-urethral catheters inadvertently developed more complications.

Important to this study is that there was both a statistical and clinical significant association between problems with catheter and increased complication (p=0.0005). The study showed that the probability of developing complications were six (6), more if one had a problem with their catheter.

Aschraft et al stated that in theory, urinary diversion should decrease complications and problems with stents becoming plugged or dislodged. Further, Hardwicke J et al besides having similar findings with Aschraft et al, elucidated that silicone catheters had an increased association with catheter problems (blockage, infection, bladder spasms) and complications. Demirbilek et al had similar findings as Hardwick J et al. He further found that suprapubic catheter was associated with lesser numbers of complications compared to intra-urethral catheters.(Demirbilek and Atayurt, 1997; Hardwicke et al., 2010)

However, Ascraft et al, McCormack et al and de Badiola et al observed that problems with the stent becoming blocked or dislodged are uncommon and urinary diversion should decrease complications.(Ashcraft et al., 2014; de Badiola et al., 1991; McCormack et al., 1993)

These splitting views from the above cited literature may be because Hardwicke J et al showed increased complications because he used silicone cuffed catheters in his study while Merormack et al and De Debadiola et al used non cuffed silicone stents for urethral stents.

However, in this study, catheters used though non-cuffed were non-silicone catheters and as such this may explain the high complication rate and difference in results. Evidence has shown that non-cuffed silicone catheters have less chances of blockage as compared to latex catheter. This may explain the difference in the study findings.

5.4.5 Urethral Plate Size and Complication

The study showed that patients with more complications had a wider urethral plate size and a median width of 7mm (IQR 5-11) as compared to those without complications who had narrower urethral plate size with a median width of 5mm (IQR 4-7mm). Furthermore, stratifying patients on basis of width showed that patients with urethral width size smaller than 8 mm had fewer complications than those with urethral plate width size greater than 8 mm. Therefore the odds of developing complications increases with increasing urethral plate size. This was profoundly statistically significant.

Nguyeni et al 2004 showed in his study that there is no statistical difference in outcome with the different plate sizes. Similar findings were published by Bush and Snodgrass 2017. However, Sarham et al 2009 showed contrary findings and suggested that a urethral plate which is bigger than 8 mm is associated with successful hypospadias repair. This was the same finding with Holland and Smith, 2000 and Mosharafa et al 2009.(Holland and Smith, 2000; Mosharafa et al., 2009; Nguyen et al., 2004; Sarhan et al., 2009)

The difference in the quoted studies may be partly because the group that showed no difference in outcome only included the distal type of hypospadias repair which in itself has a good outcome, for instance Nguyeni et al only included distal type of hypospadias and this may be the reason his study could not show any difference. Sarhan et al included in his study the three

(3) types of hypospadias and probably was able to show that urethral plate size was associated with complications.

Our findings differ from the above-cited studies, as this could have been a surgeon dependent factor. In our setting, surgeons are more meticulous with hypospadias repair once they notice the plate size width is narrow. This may explain the good outcome seen in patients with narrower urethral plate. Besides this, the patients with wider urethral plates are the older children who are more combative when it comes to managing their catheters and wounds.

5.4.5 Glans Size and Complications

The study did not find any association between glans size and complication. Patients with glans size bigger than 14 mm had comparable complications with those with glans size of less than 14 mm. Faasse et al 2016 showed similar findings, that there is no statistical association between glans size and urethroplasty complications. Contrary to this, Bush et al was able to show that under same conditions patients with a glans size smaller than 14 mm had seventy five percent (75%) chance of urethroplasty complications. Similar findings were arrived at by Snodgrass and Bush, 2014.

The difference in the cited literature could be that Faasse et al used testosterone cream pre-operatively while Bush et al and Snodgrass 2014 did not use testosterone cream.(Faasse et al., 2016; Snodgrass and Bush, 2014; Yerkes and Faasse, 2016)

However, the discordance in results between the studies and this study remains speculative and may imply that either more research on this matter is required or that this study may not have been powered enough to bring out statistical significance with regards to glans size.

5.4.7 Types of Urethroplasty Sutures and Complications

There was no statistical and clinical difference between vicryl and PDS sutures with regard to complications. Snodgrass and Bush 2014 and Guarnio et al 2009 showed similar findings which were that no statistical differences were noted in fistula and or stricture rates when either vicryl or PDS was used. Disandro and Palmer, 1996, showed that complication rate was higher for study subjects who had PDS than those with vicryl. Edney et al, 2004, Kerstein et al 2013, Copes et al, 2001 had similar findings.(DiSandro and Palmer, 1996; Guarino et al., 2009)

Partially, the difference in the findings is that some researchers studied the effect of sutures on non-human subjects, for instance, Edney et al compares the sutures in porcine model while Kerstein et al studied the effect of human urine on tensile strength that was done in the laboratory. This would have different variables at play unlike if it were done in vivo. In this regard, this would explain the contrasting findings of some of the above-cited studies from this study and that of Snodgrass and Bush, 2014. (Edney et al., 2004; Kerstein et al., 2013; Snodgrass and Bush, 2014)

5.4.8 Social Economic Status and Complication

From our study, social economic status had no association with complications of hypospadias repair.This was similar to the finding by Abdelraham et al and Aho et al. However Olajide A et al and Ahmed et al showed increased complications of hypospadias among patients from the low social economic status.

This was not the finding in this study. It is likely that this topic of assessing complications of hypospadias among social economic categories requires further study.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

At the U.T.H, Lusaka, the most common type of hypospadias seen is distal hypospadias. While proximal hypospadias has the highest complication rate. The type of hypospadias, problems with catheter (urinary diversion) and low hemoglobin are the main factors associated with short term complications of hypospadias repair.

Therefore, mitigating these issues may improve the outcome of successful hypospadias repair at U.T.H, Lusaka.

6.2. Study limitations

The limitations encountered during this study as follows:

1. The sample size was not powered enough to bring out statistical significance of certain variables.
2. The study design adopted limited the bringing out of clinical correlation of certain variables with the statistical arms.
3. The small number of patients that used supra-pubic catheters for urinary diversion made it difficult to ascertain if it was a better method than the urethral catheter.

6.3. Recommendations

1. Close catheter care.
2. Use of silicone catheters as opposed to non-silicone catheters to improve problems with catheters or use supra-pubic catheters as they may have lesser chances of blocking and dislodgment.
3. Seeing from this study that there was a significant number of patients that had problems with urethral catheters, a follow up study to compare suprapubic catheters with urethral

catheters and ascertain whether Suprapubic catheter would be associated with less complications.

4. Hypospadias repair to be done when hemoglobin levels are 12 g/dl. And above
5. Assess for malnutrition and levels of albumin before surgery so as to know the cause of low hemoglobin in the hypospadias patients.

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APPENDICES

Appendix I: Participants information sheet for the study on 'factors associated with short term outcomes of hypospadias repair at the university teaching hospital in Lusaka Zambia'

My name is Dr Seith Kalota, a medical doctor pursuing a master degree in Paediatric Surgery in the department of Surgery at the University Teaching Hospital. As part of my academic qualification I am conducting a study to establish factors associated with short term outcomes of hypospadias repair at the University Teaching Hospital in Lusaka Zambia.

During this study, your participation will require questions asked to you surrounding the condition of your child, should you find the questions personal or otherwise you are not obliged to answer but feel free to skip the questions. A full examination as well as a thorough examination of the private parts will be done taking measurements of the width of the head of the penis (glans penis) and the width of the whitish strip in front of the place where urine comes out from (urethral plate) before your child undergoes surgery. Follow up assessments after surgery will be taken and recorded for a period of two months.

The identity and all information collected during this study will be kept confidential under lock and key, to which only the researcher will have access to. The study will not affect your child's treatment in any way nor will it have any added benefit outside the standard management of your condition.

The participation of your child will be voluntary and a written consent will be obtained from you indicating that you understand the procedure and are willing to go through with it. If at any time during the study you feel that your child is injured, inconvenienced or for whatever reason you feel the need to withdraw from the study, you shall be permitted and treatment will not be withheld or without any form of penalty.

Any queries or clarifications can be directed to me, Dr Seith Kalota, Department of Surgery, Independence Avenue, Private bag RW1X, University Teaching Hospital, Lusaka, Zambia. Phone Number +260977580549, Email :sondoyi@gmail.com Or you may contact the ERES CONVERGE INSTITUTIONAL REVIEW BOARD, 33 Joseph Mwilwa Road, Roads Park, Lusaka, Zambia. Phone Number: +260955155633/+260966765503, Email: eresconverge@yahoo.co.uk

Appendix II: Consent form for the study on 'factors associated with short term outcomes of hypospadias repair at the university teaching hospital in Lusaka Zambia'

I_____ have read the above information, or it had been read to me. I have had the opportunity to ask questions concerning the study and these have been answered to my satisfaction. I consent voluntarily that my child participates in this study.

Name of participant_____

Signature of Participant's Parent/guardian: _____

Date: _____

NOTE:

1. You are free to skip questions that may deem personal or otherwise.

2. If at any time during the study you feel that your child is injured, inconvenienced or for whatever reason you feel the need to withdraw from the study, you shall be permitted and treatment will not be withheld and will not incur any form of penalty**.**

INFORMATION SHEET AND CONSENT FORM TRANSLATED IN NYANJA LANGUAGE

Zochitika I: Achikhulupiriro cha achikhulupiriro a kuphunzira pa zinthu zonse zokhudza ndi zothandiza zothandiza za hypospadias zokhudzitsa ku University kuphunzitsa ntchito ku Lusaka Zambia

Dzina langa ndi Dr Seith Kalota, dokotala yemwe akutsata digiri yapamwamba pa zachipatala kuchipatala cha opaleshoni ku chipatala cha yunivesite ya kuphunzitsa. Monga gawo la chiopsezo changa, ndikupanga phunziro kuti ndikhazikitse zomwe zikugwirizana ndi zotsatira zochepa za hypospadias kukonza ku chipatala cha yunivesite ku Lusaka Zambia.

Phunziro lino, kutenga nawo mbali kudzafuna mbiri yakale yozungulira mkhalidwe wa mwana wanu, ngati mutapeza mafunso aumwini kapena ngati simukuyenera kuyankha koma mumamasuka mafunso ndi kufufuza kwathunthu komanso kufufuza bwinobwino Mankhwala amtunduwu amatenga kuchuluka kwake kwa mutu wa penis (glans penis) komanso kufalikira kwa mdima wonyezimira kutsogolo kwa malo omwe mkodzo umatuluka kuchokera ku (urethral plate) mwana wanu asanachite opaleshoni. Tsatirani zothandizira pambuyo pa opaleshoniyo mutengedwe ndikulemba kwa miyezi iwiri.

Zomwe zimadziwika ndizomwe zimasonkhanitsidwa pa phunziroli zidzasungidwa mwachinsinsi pamatsekedwe ndi makiyi, komwe kokha wofufuza adzapeza. Phunziroli silidzakhudza chithandizo cha mwana wanu mwanjira ina iliyonse ndipo sichidzakhalanso ndi phindu linalake pokhapokha mutayang'anira bwino matenda anu.

Mwana wanu adzadzipereka mwaufulu ndipo chidziwitso cholembedwa chidzapezedwa kuchokera kwa inu chomwe chikusonyeza kuti mumamvetsetsa momwe mukufunira komanso mukufunitsitsa kutero. Ngati panthawi iliyonse yophunzira mumamva kuti mwana wanu wavulazidwa, osasokonezeka kapena chifukwa chake mumamva kuti mukufunikira kuchoka pa phunziroli, muloledwa ndipo mankhwala sadzatsutsidwa kapena opanda chilango chilichonse.

Mafunso alionse kapena mafotokozedwe angawathandize kwa ine, Dr Seith Kalota, 0977580549, ofesi ya opaleshoni, P / bag RW1X, UTH, Lusaka. Kapena mungathe kulankhulana ndi ERES CONVERGE IRB, 33 Joseph Mwilwa Road, Roads Park, Lusaka. Nambala ya foni 0955155633.

Zochita 2: Fomu yophunzitsira yophunzira pa zikhalidwe zokhudzana ndi zikhalidwe zothandiza za hypospadias zokhudzitsa pa ntchito ya university yophunzitsa ku lusaka ku zambia

I ..... awerenga nkhaniyi, kapena iwerengedwa kwa ine. Ndakhala ndi mwayi wopempha mafunso okhudza phunziroli ndipo awa ayankhidwa kuti ndikhutire. Ndimavomereza mwa kufuna kwathu kuti mwana wanga alowe nawo mu phunziro ili.

Dzina la wophunzira: .....

Chizindikiro cha kholo kapena wochirikiza: .....

Tsiku: .....

ZINDIKIRANI:

1. Muli mfulu kudumpha mafunso omwe angaganizire nokha kapena ayi.

2. Ngati panthawi yophunzira mukuganiza kuti mwana wanu wavulala, osasokonezeka kapena chifukwa chake mumamva kuti mukufunika kuchoka pa phunziroli, muloledwa kuti mankhwala asamalidwe bwino sadzatsutsidwa ndi antchito sangakhale ndi chilango chilichonse.

STATEMENT BY RESEARCHER

I have accurately read out the information sheet to the participant's guardian and to the best of my ability made sure that the he/she has understood that the following will be done: full examination of the child, measuring of the width of the glans penis and urethral plate before surgery as well as follow up assessments for six weeks after surgery.

I confirm that the participant's guardian was given an opportunity to ask questions about the study and all the questions asked have been answered correctly and to the best of my ability. I confirm that the participant's parent/guardian has not been coerced into giving consent and that it has been given freely and voluntarily.

Name of researcher _____

Signature of researcher _____Date _____

Appendix III: Child assent form

I am Dr Kalota Seith from the University Teaching Hospital. I am doing a study to find out what factors affect outcome of hypospadias repair at UTH, Lusaka.

Before your surgery I will measure the head of your penis and the width of the white strip in front of the point where you pass urine from. You will not feel any pain during this process as you will be put to sleep in theatre. You will need to come back for a check-up for two month after surgery at your surgeon's scheduled dates.

If you do not want to take part in this study, you do not have to, and if you feel as though you would like to stop at any point during the study, you are free to do so.

You should discuss with your parent/guardian before you agree to take part. Your parents will be spoken to and will be asked for permission for you to participate, but if you do not want to, you do not have to.

If you have any questions, feel free to ask them, now or later, and I will do my best to answer them. If you think of a question later, you or your parents can contact me at 0977580549, or find me at the University Teaching Hospital in the department of surgery.

Sign this form only if you:

- Have understood what will happen to you during the study
- Have had all your questions answered
- Have talked to your parents/ guardian about the study
- Agree to take part in this study

I _____ (Participants name) in the presence of my parents/guardian and with their consent, do agree voluntarily to participate in this study.

Signature/thumb print: _____

Date _____

Investigators name: _____

Signature/thumb print: _____

Date: _____

Appendix IV: Witness form

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

Name of witness: _____ thumb print of participant

Signature/ thumb print of participant _____

Date _____

Appendix V: Data collection sheet

Patient code: _____

Operation date: _____

Number	Question	Coding Category
PART A: SOCIO-DEMOGRAPHIC INFORMATION		
A1	**Age:**	
A2	**Residence:**	
A3	**Parent's educational level**	
		Nil: 1
	Mother:	**Primary: 2**
	Father:	**Secondary: 3**
		Tertiary: 4
PART B:	**BIRTH HISTORY**	
B1	**Gestational Age at Delivery:**	**Term:1**
		Preterm: 2
		Post-Term: 3
B2	**Mother's age at delivery:**	
B3	**Maternal exposure to**	**Yes:1**
	Insecticide or pesticide:	**No: 2**
PART C:	**FAMILY HISTORY**	
C1	**Family Hx of Hypospadias:**	**Yes: 1**

Number	Question	Coding Category
		No: 2
PART D:	**CLINICAL FEATURES OF HYPOSPADIAS**	
D1	**Type of hypospadias:**	**Glandular: 1, Coronal: 2**
		Sub-coronal: 3, mid-penile: 4
		Proximal Penile:5 ,Scrotal: 6
		Perineal: 7
D2	**Presence of chordee:**	**Yes: 1**
		No: 2
D3	**Chordee:**	**< 30°: 1**
		>30°: 2
D4	**Glans size:_____**	
D5	**Characteristics of the urethral plate on the glans:** **Urethral plate size: _____**	**Cleft: 1**
		Incomplete Cleft: 2
		Flat: 3
D6	**Penile torsion:**	**Present: 1**
		Absent: 2
D7	**Scrotal transposition:**	**Present: 1**
		Absent: 2
D8	**Co-morbidities:**	**Inguinal Hernia: 1**

Number	Question	Coding Category
		Cryptorchidism: 2
		ARM: 3
		Others(specify) : 4
D9	**Pre-operative HB:_____**	
D10	**Pre-operative antibiotics**	**Yes: 1**
		No: 2
PART E:	**SURGICAL PARAMETERS**	
E1	**Type of surgery**	**TIPU single stage: 1**
		TIPU two stage: 2
		MAGPI: 3
		Meatal based flap: 4
		Matieu duplay: 5
		Onlay flap: 6
		Others: 7
E2	**Urethral catheter size:_____**	
E3	**Topical antibiotics:**	**Yes :1**
		No: 2
E4	**Dressing:**	**Korban: 1**
		Vaseline gauze: 2
		Gauze dressing: 3
		Others: 4
PART F:	**SUTURE TYPES USED**	

Number		Question		Coding Category	
	urethroplasty	dartos	glans	skin	Coding category
Suture types					Vicryl 7/0: 1
					Vicryl 6/0: 2
					Vicryl 5/0: 3
					PDS 7/0: 4
					PDS 6/0: 5
					PDS 5/0: 6
					Monocryl 7/0: 7
					Monocryl 6/0: 8
					Monocryl 5/0 : 9
					Others: 10

PART G:			**POST OPERATIVE ASSESSMENT**						
Day	**Status of urinary catheter**	**swelling**	**Wound appearance/ infection**	**Urine extravasations**	**Glanular dehiscence**	**UCF**	**Meatal stenosis**	**Retrusive meatus**	**Persistent chordee**
1									
2									
3									
4									
5									
6									
7									
8									

PART G: POST OPERATIVE ASSESSMENT									
Day	**Status of urinary catheter**	**swelling**	**Wound appearance/ infection**	**Urine extravasations**	**Glanular dehiscence**	**UCF**	**Meatal stenosis**	**Retrusive meatus**	**Persistent chordee**
9									
10									
11									
12									
13									
14									
42									
60									