

**EARLY TREATMENT OUTCOMES OF URETHRAL  
STRICTURES AT MOI TEACHING AND REFERRAL  
HOSPITAL – ELDORET, KENYA**

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## DECLARATION

### Declaration by the Candidate

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**DEDICATION**

I wish to dedicate this thesis to my wife Rose and my sons John and Calvin, for always inspiring me to do my best.

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**LIST OF ABBREVIATIONS AND ACRONYMS**

<b>Cm</b>	centimeter
<b>DVIU</b>	Direct Visual Internal Urethrotomy
<b>GUS</b>	Genital Urinary System
<b>IBM</b>	International Business Machine
<b>KUB</b>	Kidney Ureter Bladder
<b>LUTS</b>	Lower Urinary Tract Symptoms
<b>MCU</b>	Micturating Cystourethrography/Urethrogram
<b>MTRH</b>	Moi Teaching and Referral Hospital
<b>N</b>	population sample
<b>PITC</b>	Provider Initiated Testing and Counseling
<b>PROM</b>	Patient Related Outcome Measure
<b>RGU</b>	Retrograde Urethrography/Urethrogram
<b>SD</b>	Standard Deviation
<b>SPSS</b>	Statistical Product and Service Solutions
<b>STI</b>	Sexually Transmitted Infection
<b>U.S.A</b>	United States of America
<b>USG</b>	Ultrasonography
<b>USS</b>	Urethral Stricture Surgery
<b>UTI</b>	Urinary Tract Infection

## DEFINITION OF KEY OPERATIONAL TERMS

**Anatomical site of stricture**-Specific location of stricture in the urethra

**Comorbidity** – Any additional disease a patient is presenting with in addition to the surgical disorder they are being managed for

**Early outcomes:** Morbidity or mortality from urethral stricture surgery occurring from post-operative day zero until discharge.

**Minor:** A study participant who is less than 18 years of age.

**Treatment outcomes** – Consequences directly related to the surgical operation-complications and patient reported satisfaction

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## ABSTRACT

**Background:** Urethral strictures are a major challenge world over with tendencies to complications and recurrence even under the best of experts. A recent study conducted at Moi Teaching and Referral Hospital (MTRH) observed that urethral strictures were the leading cause of urological problems. Although urethral strictures are common at MTRH, there is still paucity of data on anatomical characteristics, comorbidities and early outcomes of their treatment. Description of anatomical characteristics, patient comorbidities and early outcomes will inform clinical practice and improve care of patients with urethral strictures.

**Objective:** To determine modality-specific outcomes in management of urethral strictures at MTRH.

**Methods:** This was a descriptive cross sectional census study from March 2018 through June 2019. All patients who had undergone urethral stricture surgery in the duration of study were approached for recruitment. A total of 65 patients consented for the study. The setting was in the urology in-patient unit of MTRH, a tertiary 1000 bed hospital in the Western region of Kenya. An interviewer administered questionnaire was used to collect data on comorbidities, postoperative complications, and patient reported satisfaction. Information on the characteristics of strictures and the modes of treatment was obtained from patient health records. Subjects were interviewed post-surgery at any point before discharge from hospital. The primary outcomes measured were modality of treatment of strictures, their early complications and patient reported satisfaction. Descriptive statistical analysis such as frequencies and percentages were used for categorical variables. Measures of central tendency such as mean and measures of spread such as standard deviation were used for continuous variables. Data was presented in graphs and frequency tables.

**Results:** Majority of strictures 58(89.2%) were single site. The average stricture length was 2.6cm (SD  $\pm$  1.8). Bulbar urethral strictures were most common 40(52%) followed by Penile 31(40.3%). Common comorbidities were enlarged prostate (8.3%), erectile dysfunction (6.9%) and hypertension (6.9%). The main modality of urethral stricture treatment was urethroplasty in its various forms 66(84.6%). Anastomotic urethroplasty accounted for 52.6% of the procedures. Wound discomfort, scrotal pain and surgical site infection were the leading early outcomes of urethral stricture surgery. Anastomotic urethroplasty and staged urethroplasty had higher rates of complication than substitution urethroplasty. The overall rate of satisfaction at discharge from the ward was 80%.

**Conclusion:** Anastomotic urethroplasty and staged urethroplasty had higher complication rates in the early post-operative period than direct visual internal urethrotomy or substitution urethroplasty. The overall patient satisfaction was good irrespective of modality used.

**Recommendations:** Complication rates should be considered when counseling urethral stricture patients pre-operatively. Patient reported satisfaction should be routinely included as a qualitative outcome measure of success or failure of urethral stricture surgery.

## CHAPTER ONE

### 1.0 INTRODUCTION

#### 1.1 Background Information

Urethral stricture is a common urological problem involving narrowing of the calibre of the urethra caused by the presence of a scar consequent to infection or injury (Mundy & Andrich, 2010). True 'strictures' occur as a consequence of ischemic spongiosclerosis of the urethral wall (Mangera & Chapple, 2010).

This may lead to partial or complete obstruction of the urinary tract. Subsequently urinary retention may occur with resultant physiologic and anatomical derangement.

Patients present with obstructive or irritative symptoms such as urinary retention, dysuria, spraying and sexual dysfunction (Nuss, Granieri, Zhao, Thum, & Gonzalez, 2012).

Urethral strictures may impact negatively on the sexual life of male patients sometimes with occurrence of infertility due to obstructed passage of semen. Increased patient comorbidity was found to be an independent risk factor for urethral stricture complication (Chapman, Kinnaird, & Rourke, 2017).

Treatment options are selected based on the severity (length and density), location, patient comorbidities, and surgeon preference (Yafi & Hellstrom, 2015). Currently the main modalities of treatment available to urethral stricture patients include, direct visual urethrotomy and varied forms of urethroplasty (Musau & Mteta, 2009). Their respective interventional outcomes are unknown at MTRH.

Early and late effects of stricture, including complications, have not been extensively reported in the literature (Al-Qudah & Santucci, 2005). There is belief that a more complete understanding of complications following the multitude of available

procedures for stricture disease is necessary for appropriate patient counseling (Navai, Erickson, Zhao, Okotie, & Gonzalez, 2008).

## **1.2 Problem Statement**

Urethral strictures are challenging to manage regardless of treatment modality because of high complication rates (Chhetri et al., 2009). Although urethral strictures form the biggest (51%) cause of urological problems at MTRH (Musau, 2013) comorbidities and treatment outcomes are unknown or undocumented.

The impact of urethral stricture treatment has not been extensively reported in literature. Serious complications after urethroplasty are similar across globally, but minor bothersome complications appear to occur in much higher numbers than previously published. These complication rates should be considered when counseling urethroplasty patients, (Al-Qudah & Santucci, 2005).

Patients consider the outcome of urethral stricture surgery (USS) differently than do physicians (Fisch, 2013)

The contemporary evidence for the management of urethral strictures provides a practice-based algorithm which a reconstructive urologist may utilize when dealing with strictures based on location, length, anatomy and etiology (Mangera & Chapple, 2010).

With limited studies on the short term impact of treatment modalities and no existing baseline information, it is necessary to have a study that will bring out information on stricture anatomy, comorbidities and outcome of treatment. This will help bridge the knowledge gap in this set up.

### **1.3 Justification of the Study**

Despite the high prevalence of urethral strictures in MTRH, there is no study to date that reports on anatomical characteristic, patient comorbidities and treatment outcome of this condition in our set up. It is also unknown on how MTRH compares to the rest of the world. There is therefore paucity of information.

The use of a validated tool to assess patient satisfaction post USS provides a good index opportunity for quality of life assessment post USS in MTRH. This is widely practiced in most centers in the developed world. This may also be adopted as routine post USS assessment in MTRH as part of best practice for client centered feedback.

This study describes anatomical characteristics of strictures, associated comorbidities and early complications of urethral stricture surgery. Information obtained from the study can be used to draw a treatment algorithm that can be used in our set up for patient pre-operative counseling and selection of suitable and optimal treatment modality.

A changing pattern of causative factor of strictures as seen with recent studies from predominantly infectious causes to trauma presents a changing pattern of urethral strictures. This necessitates varying treatment approaches with different outcomes in the short term and long term as will be seen in the literature review.

This study aims to help inform on treatment outcomes and the needs of this urological condition within MTRH. It will also assist in developing clinical guidelines of best practises within our set up.



## **1.4 Research Question**

The following research question guided the study:

What are the treatment specific outcomes of modalities used in the management of urethral strictures in MTRH?

## **1.5 Research Objectives**

### **1.5.1 Broad Objective**

To determine the treatment specific outcomes of modalities used in management of urethral strictures MTRH

### **1.5.2 Specific Objectives**

1. To describe anatomical characteristics of urethral strictures in patients at MTRH
2. To identify comorbidities of patients presenting with urethral strictures
3. To determine specific short-term outcome of modalities of treatment used in the management of urethral strictures at MTRH

## **CHAPTER TWO**

### **2.0 LITERATURE REVIEW**

#### **2.1 Overview**

##### **2.1.1 Definition of Urethral Stricture**

A urethral stricture is an abnormal narrowing of the urethra caused by the presence of a circumferential scar, consequent to infection or injury (Singh & Scott, 1975). Patients present with obstructive or irritative symptoms such as urinary retention, dysuria, and spraying as well as sexual dysfunction. The frequency of occurrence of the symptoms seems to vary with the cause of the stricture (Nuss, Granieri, Zhao, Thum, & Gonzalez, 2012).

Urethral stricture disease is caused by any process that injures the urethral epithelium or the underlying spongiosum leading to healing by scar formation. The scar causes obliteration of the urethral lumen which leads to poor stream of urine or subsequent cessation of urine flow. The resultant scar can be of various depths, densities and lengths, replacing portions of the corpora spongiosum with loss of urothelium and subsequent circular contraction of the lumen.

##### **2.1.2 Epidemiology of Urethral Strictures**

The real incidence of male urethral stricture disease remains unknown, and worldwide differences have been observed based on geography, population, and mean country income (Lazzeri, Sansalone, Guazzoni, & Barbagli, 2016).

Urethral strictures are commonly found in males with prevalence of 229-627 per 100,000 of the proportion of population at risk according to an analytic study in the USA (Santucci RA, Joyce GF, Wise M. 2007).

Female urethral stricture disease is a rare entity (Keegan KA, Nanigian DK, Stone AR 2008). The occurrence of strictures in females was considerably lower in a study done in Nigeria showing only 2.9% occurrence (Oguike et al., 2006).

In a retrospective study at MTRH a tertiary health facility in Eldoret Kenya covering 143 patients over a five year period (2003-2007) the mean age of patients with urethral strictures was 42.7 with a standard deviation of 20.8 years (Mugalo, 2013).

### **2.1.3 Aetiology of Urethral Strictures**

In a study at MTRH 50.9% of the cases were due to urethritis, 47.3% arose out of trauma and a minority 1.8% due to rare causes (Mugalo, 2013).

A Nigerian study of 68 new stricture patients observed the recent changing pattern of urethral stricture from infection caused stricture as was in the 1960s to trauma caused stricture as from 1994-2003. In the study 55.9% of the strictures arose from trauma while 39.7% was due to post inflammatory sequelae (Oguike, Onuora, & Obarisiagbon, 2006).

In Tanzania at a tertiary mission hospital 88 inpatients consecutively sampled over a period of one year revealed that biggest cause of strictures was trauma (56.2%) followed by post urethral discharge 33.3% and balanitis xerotica obliterans at 2.9%. (Musau & Mteta, 2009)

## **2.2 Anatomical Characteristics of Urethral Strictures**

The male urethra is a tubular structure running from the tip of the penis to the neck of the bladder. It is estimated to be approximately 20cm in an adult male. It can be divided into two main segments- anterior and posterior segments. The posterior urethra comprises of prostatic urethra which is the widest part with perforations called

prostatic sinuses and membranous urethra which is the narrowest. The anterior urethra comprises of bulbar urethra and penile urethra (Snell R, *Clinical Anatomy by Systems* 1ed: Lipincott Williams & Wilkins,2006).

Urethral strictures can occur in any part of the urethra. They are thus described by the anatomical part they occur hence they can be termed as bulbar, membranous, bulbo-membranous, penile, penobulbar, meatal stenosis, bladder neck stenosis and pan urethral strictures (Oguike et al., 2006).

In a study in South Africa with a sample of 125 patients within one year, Bulbar strictures were more often associated with urethritis, penile strictures were associated with idiopathic etiology, and membranous strictures were related to external trauma (Heyns, van der Merwe, Basson, & van der Merwe, 2012).

In a study in Nigeria over a 9 year period with a sample of 68 urethral stricture patients majority of the strictures were found in the bulbar part of the urethra at 35.1% of population studied followed by membranous urethra at 19.1% bulbo-membranous and penile affected 10.3% each of the population studied while penobulbar affected 7.4% (Oguike et al., 2006).

In a study in Nairobi Kenya, Two hundred adult male patients with clinically suspected urethral strictures were recruited between April and November 2012. Out of the 200 patients 138 (69%) had a stricture (average size 2.9cm  $\pm$  1.6). Seventy one (35.5%) strictures were located in the posterior urethra while 36 (18%) were in the anterior and 31 (15.5%) spanned both the anterior and posterior urethra. Most (61.4%) strictures occur in single as compared to multiple (38.6%) sites (Intasab, 2012).

In a study in Nigeria, with 25 subjects a non-passable bulbo-membranous junction stricture occurring in 36% (9/25) of patients was the commonest pathology found on RGU. Multiple urethral strictures were found in 16% (4/25) of patients. A single anterior stricture was found in 8% (2/25) of patients. One of these strictures was passable while the other was not passable. A single bulbous stricture was noted in 8% (2/25) of patients. One of the bulbous strictures was passable while the other was not passable. The remaining 32% (8/25) of patients were considered to have a normal urethra as no abnormality was detected on RGU (Kiridi, Dambo, & Etukakpan, 2016).

In a prospective study in India with 75 subjects the most common stricture location observed intra-operatively was bulbar in 42 (56%) cases, followed by penile in 13 (17.33%), penobulbar in 7 (9.33%), pan urethral in 11 (14.67%) while penile and prostatic in 2(2.67%) cases (Joseph, Lamba, Joshi, Nathwani, & Pujari, 2016).

In a study done in Senegal from 2007 to 2010 with 75 subjects, urethral strictures associated with urethrocutaneous perineal fistulas accounted for 9.3%. The stricture was most frequently located in the bulbar urethra (63.3%) followed by membranous (18.7%) and penile (13.3%). Length of the stricture averaged  $2.45 \pm 1.39$  cm with a median of 2 cm. A stricture length of 1 cm was found in 17.3% of cases, between 1 and 3 cm in 64% of cases, and between 3 and 5 cm in 10.7% of cases. The stricture was longer than 5 cm in six patients (8%). The length of the stricture averaged  $1.95 \pm 0.72$  cm in the anastomotic urethroplasties and  $4.40 \pm 1.54$  cm (median of 4cm) in substitution urethroplasties. Some patients had multiple site strictures (Fall et al., 2014).

In a retrospective analysis of all strictures that had been reconstructed at a single institution in the U.S.A, the vast majority of strictures were anterior (92.2%), with most of these occurring in the bulbar urethra (46.9%), followed by penile (30.5%), penile and bulbar (9.9%), and pan urethral (4.9%) strictures (Hampson, McAninch, & Breyer, 2014).

In Nepal a study with 61 urethral stricture patients carried out from January 2004-December 2007. The common site of stricture was noted at bulbar in anterior and membranous in posterior urethra (Chhetri et al., 2009)

### **2.3 Comorbidities of Urethral Stricture Patients**

The surgical management of stricture disease can be complex and challenging due to the multiple factors that need to be considered including anatomical location, underlying pathophysiology as well as patient comorbidities (Hillary, Osman, & Chapple, 2015).

In a study in Nigeria with 42 subjects who underwent urethral stricture surgery 90% had associated comorbidities. These included recurrent UTI, bladder stone and Epididymorchitis. Comorbidities tended to increase with the delay in obtaining definitive treatment and presence of suprapubic catheter (Obi AO et al, 2017).

In a study in Turkey 224 patients with Urethral strictures were evaluated. The comorbidities noted included Diabetes Mellitus, Coronary Artery Disease, Chronic Obstructive Pulmonary Disease, Rheumatic disease, Hypertension, Erectile dysfunction and chronic constipation. In this study erectile dysfunction, hypertension and Diabetes Mellitus were the common comorbidities observed (Kizilay, Şimşir, & Özyurt, 2017).

In a study in Nigeria with 25 patients some other pathologies found in patients were: decreased bone density (2/25), sclerotic bone changes (1/25), pelvic bone fracture (1/25), elevated bladder base (1/25) bladder diverticuli (2/25) and irregular bladder outline (1/25) ( Kiridi, Dambo, &et al., 2016).

In a retrospective study in Moscow with 402 patients over a 3 year period it was established that the relationship between the diameter of the instrument, presence of chronic prostatitis in anamnesis, increased volume of the prostate, and repeated drainage of the bladder using the urethral catheter with the risk of developing scar-sclerotic changes in the urethra and/or bladder neck were statistically reliable via regression analysis (Sukhanov, Butnaru, & Vasyutin, 2018).

A 10 year study in U.S.A of 94 urethral stricture patients secondary to Lichen sclerosis identified 4 comorbidities that were prominent amongst its subjects; hypertension (51.1%) coronary artery disease (18.1%) diabetes mellitus type 2 (33.0%) and dyslipidaemia (Kirk, Yi, Hadj-moussa, & Malaeb, 2016).

## **2.4 Specific Short-term Outcome of Modalities of Treatment**

Management of urethral stricture includes urethral dilation, internal urethrotomy, urethral stent placement, and open reconstruction or urethroplasty (Anger et al., 2011).

### **2.4.1 Modalities of Treatment**

#### **Dilatation**

The use of dilatation has been systemically abandoned and is of historical relevance in the management of urethral strictures. The historical management of urethral strictures constituted regular dilations of the scar tissue but this inevitably failed for

long strictures and subjected them to secondary trauma, ischemia, scarring and further reduction of luminal calibre. (Nyongole, Akoko, Mwanga, & Mkony, 2013).

Currently the main modalities of treatment available to urethral stricture patients include, direct visual urethrotomy and various forms of urethroplasty (Musau & Mteta, 2009).

### **Direct Visual Internal Urethrotomy**

Direct vision internal urethrotomy (DVIU) is performed by making a cold-knife transurethral incision to release scar tissue, allowing the tissue to heal by secondary intention at a larger caliber and thereby increasing the size of the urethral lumen (Hampson et al., 2014).

DVIU is noted to be the preferred modality of stricture management for strictures less than 1cm (Nyongole, Akoko, Mwanga, & Mkony, 2013). The success rate of DVIU on short strictures (less than 1cm) was noted to be good as per a recent study conducted in Tanzania at approximately 69% of the sampled population (Nyongole et al., 2013).

Direct visual urethrotomy is currently the most commonly performed procedure used in managing strictures according to data compiled from medical claims records in a study in the USA over 4 years 1992, 1995, 1998, 2001 (Anger et al., 2011).

Urethrotomy has a relatively low first time success rate and an even lower success rate for subsequent urethrotomy. A study in the United States of America put the first time success rate of DVIU at 8% and success rates for subsequent DVIUs at between 0-9 % (Santucci & Eisenberg, 2010)



In addition to cold-knife internal urethrotomy, studies have evaluated the use of lasers for urethrotomy. Many types of lasers have been utilized, including carbon dioxide, argon, potassium titanyl phosphate (KTP), neodymium-doped yttrium aluminium garnet (Nd:Yag), holmium:Yag, and excimer lasers. These lasers each use different technologies and offer differing depths of tissue penetration (Hampson et al., 2014).

In a study with 51 patients with urethral strictures 22 patients were offered DVIU with a mean follow up of 51.8 months, the Internal urethrotomy success rates varied widely, ranging from 8%–80%, depending on patient selection, length of follow-up assessment, and methods of determining success and recurrence (Trial, 2017).

In India bleeding was 15.5% post urethrotomy (Jain et al., 2014).

In Turkey (Atak et al., 2011) urethrotomy had no complications post surgery.

### **Urethroplasty**

Urethroplasty is an invasive method of urethral stricture management. It involves sharp dissection and access of the urethral stricture. It can be done as a one off surgery-primary urethroplasty or it can be staged urethroplasty (Nyongole et al., 2013).

Several techniques have been used for urethroplasty, including excision and primary anastomosis, onlay grafting, and the use of flaps.

The success rate in Tanzania of urethroplasty was at 90 per cent in a recent study (Nyongole et al., 2013).

End-to-end anastomotic urethroplasty repair technique has traditionally been used for bulbar strictures that are <2cm in length. Anastomotic urethroplasty scores highly for

both objective and patient-centered subjective criteria, with most studies reporting success rates of between 90%–95% (Hampson et al., 2014)

Onlay free graft substitution or graft urethroplasties are traditionally used for strictures longer than 2cm for which an anastomotic urethroplasty is not feasible owing to anastomotic tension. Historically, preputial skin grafts were the mainstay of grafting material until oral mucosal grafts became popularized in the early 1990s (Fernández-Noyola, Ahumada-Tamayo, Martínez, & Camacho-Castro, 2013)

One-stage grafting urethroplasty utilizes the vascularity of spongiosal tissue ventrally or corpora cavernosa dorsally to support the free graft. Overall success rates for onlay grafting approach 90%, depending on the location of the onlay graft. Success rates for penile strictures range from 75–90%, depending on the length of the stricture and whether a one-stage or staged procedure is performed, whereas success rates for bulbar onlay repair are consistently around 88% (Mangera, Patterson, & Chapple, 2011).

Several types of tissue can be used as onlay grafts, including full-thickness and partial-thickness skin grafts, bladder urothelial grafts, oral mucosal (buccal or lingual) grafts, and rectal mucosal grafts. Oral grafts have become the most common graft type, owing to their short harvest time, hairlessness, low morbidity, durability, and excellent success rates (Cakiroglu, Sinanoglu, & Arda, 2017).

McAninch described a modified technique utilizing a circular fasciocutaneous flap from the distal penile skin; this technique relied on the blood supply from Buck's fascia and can be used along the entire penile and bulbar urethra. In addition, it could be used in circumcised men who did not have preputial skin for repair (Hampson et al., 2014).

It should be noted that, in general, the use of skin flaps for urethral reconstruction is more technically challenging than graft substitution urethral surgery. For men with an average stricture length of 9 cm, the initial overall success rate of fasciocutaneous flap reconstruction was 79% in one study, with recurrent stricture noted in 13% of onlay grafts and 58% of tubularized repairs (McAninch & Morey, 1998).

The overall long-term success rate, including repeat urethroplasty or urethrotomy, has been reported to be 85–95%. Most studies show that free-grafts and pedicled skin flap reconstructions have equivalent success rates in experienced hands (Hampson et al., 2014).

#### **2.4.2 Short Term Outcomes**

Tools generated by clinicians from various specialties, rather than just surgery, define recovery over three phases, their cumulative duration exceeding that of the surgically-focused enhanced recovery pathway (Bowyer, Jakobsson, Ljungqvist, & Royse, 2014).

The recovery phases described by these tools can be categorized as early, intermediate and late. The early postoperative recovery phase has been defined as the first 24 h (Bowyer et al., 2014) or the first seven days (Swan, Maislin, & Traber, 1998). The speed and extent of recovery in the early phase is influenced most by pain, nausea, peri-operative medications and delirium.

The intermediate phase of postoperative recovery has been defined as the first 28 days (Talamini, Stanfield, Chang, & Wu, 2004) or 60 days. The extent of recovery in the intermediate phase is influenced most by pain, anxiety and depression, physical impairment and cognitive dysfunction.

The late postoperative recovery phase has been defined as the first six weeks (Myles, Reeves, Anderson, & Weeks, 2000) or three months (Royse et al., 2010). Symptoms that afflict the early and intermediate phases of recovery can persist into this extended period.

Early and late effects of stricture, including complications, have not been extensively reported in the literature. Complications arising after treatment with the various modalities included long term and short term complications (Al-Qudah& Santucci, 2005).

Short term complications observed in a retrospective hospital based United States study over 4 years 2000-2004 with a sample of 60 urethral stricture patients included : Failure to void, retrograde urethrography leak, mild scrotal tenderness, foley catheter fall-out, scrotal ecchymosis, urgency, perineal hypoesthesia, post void leak, urinary tract infection, penile pain, scrotal pain, wound discomfort, stream spraying. Long term complications include; Ejaculatory dysfunction, chordee, erectile dysfunction and recurrence (Al-Qudah& Santucci, 2005).

#### **2.4.2.1 Short Term Complications**

##### **Complications of DVIU**

The main complications following urethrotomy include recurrence, perineal haematoma, urethral haemorrhage, and extravasation of irrigation fluid into perispongiosal tissues. With deep incisions at the 10 o'clock and 2 o'clock positions, there is a risk of entering the corpus cavernosa and creating fistulas between the corpus spongiosum and cavernosa, leading to erectile dysfunction (Hampson et al., 2014).

One meta-analysis of complications of cold-knife urethrotomy established an overall complication rate of 6.5%; the most common complications were erectile dysfunction (5%), urinary incontinence (4%), extravasation (3%), UTI (2%), Haematuria (2%), Epididymitis (0.5%), urinary retention (0.4%), and scrotal abscess (0.3%). Notably, erectile dysfunction is particularly common in patients with long and dense strictures requiring extensive incision. In general, complications associated with internal urethrotomy are more likely to occur in men with a positive urine culture, a history of urethral trauma, multiple stricture segments, and long (>2 cm) strictures (Hampson et al., 2014).

A meta-analysis of complications associated with laser urethrotomy reported an overall complication rate of 12%, which compares unfavourably to the 6.5% incidence reported for cold-knife urethrotomy. Common complications included UTI (11%), urinary retention (9% ), Haematuria (5% ), dysuria (5% ), urinary extravasation (3% ), UTI (3% ), urinary incontinence (2%) and urinary fistula (1.5% ) (Hampson et al., 2014).

Studies in Colombia and Canada show that DVIU especially cold knife urethrotomy usually complicates with bleeding for 15% of the patients (Torres Castellanos et al., 2017).

## **Complications of Urethroplasty**

### **Anastomotic Urethroplasty**

In a study in Detroit Michigan, complication rates arising from the different approaches of urethroplasty were documented (Al-Qudah & Santucci, 2005).

Patients who underwent anterior anastomotic urethroplasty had immediate post-operative complications at the following rates Failure to void (4%), retrograde

urethrography leak (4%), mild scrotal tenderness (4%), foley catheter fall-out (4%), scrotal ecchymosis (4%), and urgency (4%). A quarter of patients had all the above complications while 72% showed no complication (Al-Qudah& Santucci, 2005).

Other complications of anterior anastomotic urethroplasty occurring in the short term were: perineal hypoesthesia (4%) post void leak (17%) UTI (4%) penile pain (4%) scrotal pain (4%) scrotal scar (4%) wound discomfort (4%) irritative LUTS (4%) stream spraying (4%) while patients presenting with all the complications were at 42% (Al-Qudah & Santucci, 2005).

Patients who underwent posterior anastomotic urethroplasty had immediate post-operative complications with the following rates: Failure to void (11%) retrograde urethrography leak (11%), scrotal swelling (11%) scrotal ecchymosis (22%) epididymitis (11%) urgency (11%) while 56% had all the above complications. Short term complications included scrotal pain (11%) post void leak(11%) while 22% had both (Al-Qudah& Santucci, 2005).

In another study in U.S.A (Granieri, Webster, & Peterson, 2015) 63% of patients (n=325) were treated using anastomotic urethroplasty. Complications were reported as follows; scrotal and/or perineal neuralgia (28%), scrotal and/or perineal hematoma (5%), catheter-related issue (4%), and excessive wound drainage (5%), wound separation (1%), wound infection (1%).

### **Substitution Urethroplasty**

Patients who underwent buccal mucosal onlay urethroplasty had short term complications at the following rates; Haematuria (5%) retrograde urethrography leak (16%) scrotal hematoma (5%) small wound dehiscence (5%) wound tightness (5%)

while 37% had all the above complications. Urosepsis was noted in 5% of the patients (Al-Qudah & Santucci, 2005).

Patients who underwent fasciocutaneous flap urethroplasty had complications with the following rates of occurrence; Epididymitis 10% foley fall out 10% penile ecchymosis (10%) penile swelling (10%) penile skin necrosis (10%) UTI (10%) retrograde urethrography leak (20%) rectal injury (10%) while 60% had all the complications excluding rectal injury (Al-Qudah & Santucci, 2005).

In Seoul Korea (Kim, Suh, Paick, & Kim, 2014) the main complications were Epididymitis 10.3% Urinary tract infection 6.9%.

Urethral stricture treatment is still a challenge to manage regardless of treatment modality used because of its high recurrence rates. Some studies indicate recurrence of urethral strictures is as high as 40% to 50 % (Chhetri et al., 2009).

### **Staged Urethroplasty**

In USA (Olsson & Krane, 1978) staged urethroplasty had similar findings. Although not enumerated, some of the complications included: increased overall hospitalization time, periods of unemployment in between procedures and sexual dysfunction following creation of iatrogenic fistula.

### **Urinary Diversion**

In USA ( French, Hudak, & Morey, 2011) 7 patients who underwent perineal urethrostomy for complex anterior urethral strictures reported no complications.

#### **2.4.2.2 Success and Patient Satisfaction in Urethral Stricture Surgery**

In the definition of a successful urethroplasty, the lack of need for a secondary procedure, is outdated and must be amended to incorporate objective and subjective outcomes. Success is assigned if a flexible cystoscope can traverse the reconstructed urethra without force (Erickson & Ghareeb, 2017).

Functional success is assigned if patient-reported outcome measures reveal improvement in voiding symptoms and urinary quality of life. Optimal follow-up strategy allows determination of anatomic and functional outcomes, protects genitourinary health, and prevents excessive invasive testing, unnecessary cost, discomfort, anxiety, and risk. Noninvasive objective uroflowmetry has high sensitivity and specificity for detecting recurrence and replaces invasive anatomic evaluation (Erickson & Ghareeb, 2017).

Subjective assessment is based on quality of life of the patient. A psychometric test such as a Likert scale is indeed useful to gauge patient satisfaction or dissatisfaction with the outcome of treatment used.

In the past, success criteria in papers on urethroplasty were heterogeneous, based on investigations of uroflowmetry, voiding cystography, cystoscopy, and the lack of further interventions from the surgeon's perspective. By 2002, however, it had been realised that patients consider the outcome of urethral stricture surgery (USS) differently than do physicians. As there was no validated questionnaire available at that time, a non-validated questionnaire/telephone interview by an independent physician was used to assess the urinary tract, voiding, sexual function, overall satisfaction, and miscellaneous impairments. It is interesting to note that 78% of the 203 patients who underwent successful urethroplasty as well as 80% of the 30 patients



for whom urethroplasty was considered a failure were found to be satisfied or very satisfied with the result (Fisch, 2013).

A 2011 study was the first to come up with a validated Urethral Stricture Surgery Patient Related Outcome Measure (USS PROM) tool (Fisch, 2013) .The tool comprised of pre-operative assessment and Post-operative assessment with Questions 1-8 targeting pre-operative status while question 9 and 10 addressed post-operative quality of life assessment (Jackson et al., 2011) –(Appendix III)

9. Are you satisfied with the outcome of your operation?

Yes, very satisfied.....

Yes, satisfied.....

No, unsatisfied.....

No, very unsatisfied.....

10. If you were unsatisfied or very unsatisfied is that because:

The urinary condition did not improve.....

The urinary condition improved but there was some other problem.....

The urinary condition did not improve and there was some other problem as well.....

A recent study in Bengali divided quality of life questions for patients with urethral stricture into seven categories (Pramanik, Pal, Bandyopadhyay, & Paul, 2017):

**Catheter related problems** (leakage, block, physical problems, change, availability, health personnel, dress change, smell of urine, water drinking),

**Disturbance of sleep** (initiation, awakening, disturbance of bed partner, sleepless night),

**Role of family members** (care giving, attitude, negligence),

**Financial condition** (jobless, help from friends, support, reversal of role, family crisis),

**Social life** (activity, enjoyment, getting hurt),

**Mental health** (loneliness, helplessness, sadness, getting hope)

**Sexual life** ( Urge, erection, coital pain, discomfort).

A study in Brazil from January 2013 to September 2014 with 35 subjects showed 84.3% of patients were satisfied or very satisfied with surgical results after urethroplasty. It concluded significant improvements in urinary symptoms and in quality of life are expected after urethroplasty and they are correlated with objective measures (Lucas et al., 2017).

In a retrospective study of 42 stricture patients from 2011 to 2018 in USA 94% of patients reported being very satisfied or satisfied with their reconstruction while 86% of patients stated they would recommend urethroplasty to others with urethral stricture disease (Broadwin & Vanni, 2018)

In Hamburg, Germany (Kessler, Fisch, Heitz, Olianias, & Schreiter, 2002) 78% of the 203 patients who underwent successful urethroplasty as well as 80% of the 30 patients for whom urethroplasty was considered a failure were found to be satisfied or very satisfied with the result.

In a prospective study in India (2017-2019) of 30 subjects with complex anterior urethral strictures, 84.6% of patients were satisfied or very satisfied with surgical results. This study demonstrated a high percent of post-operative satisfaction with a large majority of men (80.7%) reporting that they would have undergone the operation again. The study also observed a strong association of patient satisfaction with surgical success as determined by traditional measures such as improvement in uroflowmetry, International Prostate Symptom Score, and urethrogram. Men with post-operative sexual complaints, new or persistent urinary pain/dysuria, discomfort due to perineal ejaculation and pelvic pain, men reporting poor urinary stream reported dissatisfaction for their surgical procedure (Kumar, Upadhyay, Kamalkant, Kumar, & Kumar, 2019).

## **CHAPTER THREE**

### **3.0 METHODOLOGY**

#### **3.1 Study Setting**

The study was conducted in the urology unit of the adult and pediatric surgical wards at the Moi Teaching and Referral Hospital. MTRH is located in Uasin-Gishu county about 300km North West of Nairobi, Kenya. It is the largest referral hospital in the Western region and serves as a teaching hospital for the Moi University School of Medicine. On average, 8000 patients undergo surgical operations per year with a bed capacity of 1000. It has a catchment area of about 16.2 million people

MTRH is also a teaching hospital for Moi University's Schools of Medicine and Nursing that offers degrees in both undergraduate and postgraduate disciplines. It is also a center for training various diplomas for the Kenya Medical Training College and University of Baraton East Africa's School of Nursing.

#### **3.2 Study Design**

This was a prospective descriptive cross-sectional study.

#### **3.3 Study Population**

All Patients (adults and minors) presenting with clinical and radiological features of urethral strictures admitted and surgically managed in the period of study (March 2018 to June 2019)

#### **3.4 Eligibility Criteria**

##### **3.4.1 Inclusion Criteria**

All patients presenting with clinical and radiological diagnosis of stricture and surgically managed in the period of study.

This being an early post-operative period study it only covered patient follow up to point of discharge.

### **3.4.2 Exclusion Criteria**

Patients who were unfit for surgical intervention

Patients who declined to give consent to the study

Patients who had a history of recent surgeries for the urethral strictures (6 weeks-3 months)

### **3.5 Sampling Technique**

Consecutive sampling technique was used, in which all patients attending to MTRH urology/surgical wards, with urethral stricture and meeting the inclusion criteria were enrolled in the study

### **3.6 Sample Size Determination**

Every patient diagnosed to have urethral stricture(s) was approached from March 2018 to June 2019 and consent obtained. Therefore the sample size was determined by fifteen months duration of study giving a figure of 65 patients.

### **3.7 Study Methods**

Patients who underwent urethral stricture surgery were enrolled at any point before discharge in the surgical ward. Interviewer administered questionnaires were used to collect data on demographics, duration of hospital stay, causes of urethral strictures, associated comorbidities, postoperative complications, outcome of the interventions prior to discharge and patient reported satisfaction. Information on the characteristics of the strictures, laboratory results of full blood count, Urea, Electrolytes, Creatinine, HIV status and the modes of treatment were obtained from patient health records. Subject review was done to the point of discharge. The primary outcome measured

were modality of treatment of strictures and their associated complications, early success or patient satisfaction. The secondary outcome measured were the anatomical characteristics of strictures and their associated complications and patient satisfaction.

### **3.8 Data management**

#### **3.8.1 Data collection**

Data was collected using a structured data collection form (Appendix 5). The data was coded and entered into Microsoft Excel spreadsheet. .

#### **3.8.2 Data storage**

Data was stored in a computer hard drive and back up on two flash disks. Data collection forms were kept safe under lock and key for future reference.

#### **3.8.3 Statistical Data Analysis**

Data analysis was done using IBM SPSS Data Editor Version 20. Categorical variables such as stricture etiology, comorbidities, presenting complains, physical examination findings, laboratory findings stricture site, modality of treatment used, complications and patient satisfaction were summarized using frequencies and the corresponding percentages. Continuous variables such as age, duration of symptoms, duration of hospital stay, and length of strictures were summarized using mean and the corresponding standard deviation if Gaussian assumptions hold. If the Gaussian assumptions were violated, then median and inter quartile range (IQR) were used to summarize these variables.

The Independent variable of interest was surgery method used, while the outcome variables were post-operative complications and patient reported satisfaction.

Tabulation and description of the specific outcomes, relating patient characteristics, anatomical characteristics of the strictures to the outcome was done.

### **3.9 Ethical Consideration**

Approval of the study was sought from the Moi University School of Medicine/Moi Teaching and Referral Hospital Institutional Research and Ethics Committee (IREC) before conducting the study (Approval number 0002094). A written informed consent was sought from each participant or their caretaker. Data collection sheet only bore a serial number, name, initials and inpatient number. The information was treated with utmost confidentiality. Patients no longer interested in the study had the option of withdrawing at a time of their choice and still received equal standard of care as those in the study. Patients who withheld consent were treated equally as those who gave consent. There was no monetary reward or preferential treatment for participating in the study. There was no conflict of interest. Research findings were made available to any interested participants. For study participants who were below 18 years old, informed consent was sought from their parents or guardians and assent granted by the minors. The consent procedure took place in a private room in the wards and the parent or guardian was given time to consider and decide whether or not their child should participate in the study. Permission from one parent/guardian was sought but the consenting parent was given time to consult with the other parent/guardian. Verbal assent was obtained for children above seven years who were capable of understanding the information given on the purpose and nature of the study. The consent forms used in the study in both English and Kiswahili languages are attached in appendix I. Dissemination of research findings will be done through thesis defense, presentation in conferences or seminars and publication in a peer reviewed journal.

### **3.10 Study Limitations**

Unavailability of uroflowmetry services at MTRH for assessment of severity of obstruction pre-operatively and postoperatively.

Time constraints

Long term follow up may be required especially to evaluate recurrence if any. However for the purposes of the study assessment was only done to the point of discharge.

The findings may not be in keeping with other hospitals because MTRH mostly receives referrals from lower levels of care hospitals. Comparison of results in this study was mainly with tertiary centers of health from other regions.



## CHAPTER FOUR

### 4.0 RESULTS

#### 4.1 Sociodemographics

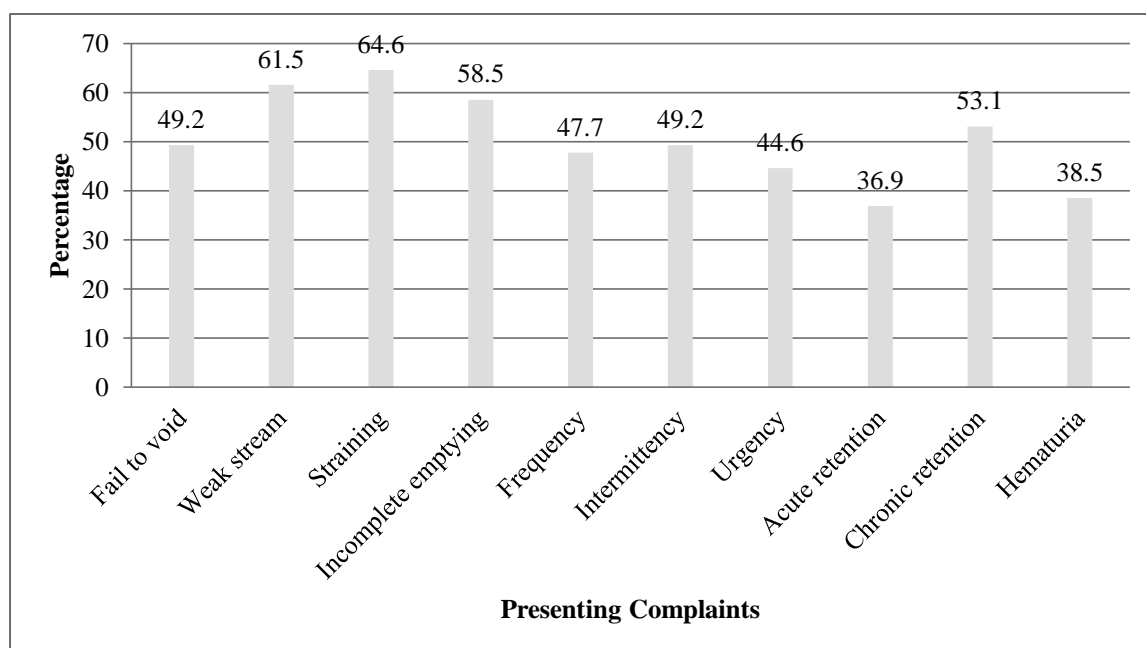
A total of 65 males participated in the study. There were 57 (87.7%) adults and 8 (12.3%) minors in the study. Table 1 shows the characteristics of the participants. The mean age of respondents was 43.1 years (SD±20.8) with an age range of 9 to 86 years. The median duration of symptoms was 4 months.

**Table 1: Patient Demographics**

Variable	Median	IQR
Age in years	41	26, 56
Time to discharge in days	6	4,10
Duration of symptoms in months	4	0.03, 24

#### Presenting Complaints

Straining, weak stream, incomplete emptying accounted for the common presenting complaints at 64.6% 61.5% and 58.5% respectively with acute retention and haematuria being the least common presentation at 36.9% and 38.5%.The graph below demonstrates frequency of occurrence of symptoms.



**Figure 1: Presenting Complaints**

### Stricture Etiology

The causes of urethral strictures were 35.4% trauma, 24.6 % STI induced urethritis, 23.1% iatrogenic and 16.9% idiopathic. Strictures due to trauma dominated between the third and fifth decades of life. Strictures due to infectious and idiopathic causes were common after the fifth decade as shown in Table 2 below:

**Table 2: Etiologies of urethral strictures in various age groups**

<b>Age in Years</b>	<b>Trauma</b>	<b>Infection</b>	<b>Iatrogenic</b>	<b>Idiopathic</b>	<b>Total</b>
<b>&lt;20</b>	8	1	2	1	<b>12</b>
<b>21-40</b>	10	3	5	0	<b>18</b>
<b>41-60</b>	5	8	3	6	<b>22</b>
<b>&gt;60</b>	0	4	5	4	<b>13</b>
<b>Total</b>	<b>23</b>	<b>16</b>	<b>15</b>	<b>11</b>	<b>65</b>
<b>Percentage</b>	<b>35.4</b>	<b>24.6</b>	<b>23.1</b>	<b>16.9</b>	<b>100</b>

Trauma as cause of urethral strictures was mainly in the younger generation while infections and idiopathic causes were in the older age groups. A total of 8 minors participated in the study. Adults and minors received same standard of care and were subjected to similar conditions. Of the minors 5 had trauma as the cause of their strictures, 2 had iatrogenic cause of stricture from poor catheterisation technique from previous unrelated surgery while 1 had a cause of stricture that was idiopathic.

Some of the iatrogenic causes included traumatic catheterizations, postoperative sequelae of prostate surgery, botched traditional circumcisions and urethral mutilation from a general surgeon in a peripheral facility.

### Systemic examination

In the systemic examination 61.5% of the respondents had suprapubic catheter placement prior to surgery while 3% had a distended bladder. Of the respondents 10.8% had periurethral abscess, 16.9% had swollen testes, 9.20% had urethrocutaneous fistula while 23.10% had urethral induration as seen in table 3 below:

**Table 3: Systemic Examination Findings**

<b>Examination</b>	<b>Percentage %</b>
<b>Abdomen</b>	
Distended bladder	4.60
Suprapubic catheter	61.50
<b>External genitalia</b>	
Periurethral abscess	10.80
Swollen testes	16.90
Urethrocutaneous fistula	9.20
Urethral Induration	23.10

### Investigations

It was noted in the patients sampled for the study that, 87.7% of the respondents had normal full blood count values while 12.3% had deranged values with low hemoglobin level, low platelet count or a high white blood cell count. Similarly 87.7% of the subjects had normal UEC values while 12.3% had deranged UEC values. Out of the 65 respondents two were immunosuppressed. This is as seen in Table 4

Of the 65 subjects in the study, 60 respondents underwent MCU and RGU diagnostic contrast studies, while 2 out of the 65 respondents underwent RGU only. The remaining 3 respondents had their diagnoses made via cystoscopy and this was mainly due to inconclusive RGU/MCU. Patients who had presented with suprapubic bulge had an abdominal pelvic ultrasound also done for diagnostic purposes.

**Table 4: Laboratory and Radiological Investigations**

<b>Investigations</b>	<b>Frequency</b>	<b>%</b>
<b>Hemogram</b>		
Normal	57	87.7
Deranged Low	4	6.2
Deranged High	4	6.2
<b>Urea Electrolyte Creatinine</b>		
Normal	57	87.7
Deranged High	8	12.3
<b>PITC</b>		
Non-Reactive	63	96.92
Reactive	2	3.08
<b>Radiologic imaging</b>		
RGU	62	95.4
MCU	60	92.3
Ultrasound	3	4.6
X-RAY KUB	0	0
RGU+MCU	60	92.3
Cystoscopy	3	4.6

#### **4.2 Anatomical Characteristics of Strictures at MTRH**

The 65 respondents in this study had a total of 77 strictures. Multiple strictures occurred at 10.7% while 89.2% of the respondents had strictures at only one site. Bulbar stricture involvement was predominant at 52% followed by penile involvement at 40.3%. Pure bulbar strictures occurred at 22.1%. Bulbo-membranous strictures accounted for 18.2% of all strictures while 11.7% were penobulbar. Overall 28.6% of the strictures were purely penile while 16.9% of the strictures were membranous. It was observed that 3.1% of the strictures had unstated lengths as seen in Table 5.

The average length of the strictures were as follows for the various anatomical sites: bulbar 2.35cm ,bulbar-membranous 2.54cm, Membranous 1.20cm Penile, 3.32cm and

Peno-Bulbar 4.31cm. The overall average length of strictures was 2.63cm (SD 1.8cm).

**Table 5: Anatomical Characteristics of Strictures at MTRH**

Site	Frequency	%	Length Mean (SD)
Bulbar	17	22.1	2.35 (1.76)
Bulbar- membranous	14	18.2	2.54 (1.13)
Membranous	13	16.9	1.2 (0.31)
Penile	22	28.6	3.32 (2.46)
Peno-Bulbar	9	11.7	4.31 (3.61)
Unstated	2	2.6	.

Out of the 7 patients with multiple site involvement, all had penile urethra involvement, 5 out of 7 had bulbar involvement while 3 had membranous involvement. Out of the 7 respondents with multiple site strictures 3 had a penile and bulbar involvement, while 2 had penile and membranous stricture. A single respondent had 3 sites involved penile, bulbar and membranous while another had a penile and peno-bulbar involvement as seen in (table 6) below:

**Table 6: Multisite strictures at MTRH**

Multisite sets	Frequency	Percentage %
Penile and bulbar	3	42.9
Penile and membranous	2	28.6
Penile, Bulbar, membranous	1	14.3
Penile and Peno-bulbar	1	14.3
TOTAL	7	100

### **Treatment by site**

#### **Bulbar Strictures**

Out of the 17 patients with pure bulbar strictures 62.5% had anastomotic urethroplasty as the modality of treatment while 12.5% had staged urethroplasty, 12.5% had urethroplasty with use of buccal mucosa grafts while 6.3% had repair using a penile

skin flap. The main modality of treatment used for bulbar urethra was urethroplasty in its various forms (87.5%) while 12.5% had DVIU as the modality of treatment.

### **Bulbar-membranous stricture**

Out of the 14 patients 71.4% had anastomotic urethroplasty as the modality of treatment while 21.3% had DVIU as the treatment modality. Urinary diversion accounted for 7.7% of treatment used for bulbar-membranous stricture.

### **Membranous Stricture**

Out of the 13 patients 69.2% had anastomotic urethroplasty as the modality of treatment, 21.1% had DVIU as the treatment modality while 7.1% of the patients had staged urethroplasty done.

### **Penile Stricture**

Out of the 22 patients with pure penile strictures 31.8% had anastomotic urethroplasty as the modality of treatment, 27.3% had staged urethroplasty, 18.2% had urethroplasty with use of buccal mucosa grafts while 9.1% had repair using a penile skin flap. The main modality of treatment used for bulbar urethra was urethroplasty in its various forms (86.4%) while 13.6% had DVIU as the modality of treatment.

### **Penobulbar Stricture**

Out of the 9 patients with peno-bulbar strictures 55.6% had anastomotic urethroplasty as the modality of treatment, 11.1% had staged urethroplasty, 11.1% had urethroplasty with use of buccal mucosa grafts while 22.2% had repair using a penile skin flap. The only modality of treatment used for peno-bulbar urethra was urethroplasty in its various forms 100%.

**Table 7: Stricture site and modality of treatment used**

Site/surgery	DVIU	STAGED REPAIR	GRAFT REPAIR	FLAP REPAIR	ANASTOMOTIC	URINE DIVERSION
Bulbar	2	2	2	1	10	0
Bulbar- membranous	3	0	0	0	10	1
Membranous	3	1	0	0	9	0
Penile	3	6	4	2	7	0
Penobulbar	0	1	1	2	5	0
Unstated						
<b>Total</b>	<b>11</b>	<b>13</b>	<b>7</b>	<b>5</b>	<b>41</b>	<b>1</b>

**Surgeries****4.3 Comorbidities of stricture patients at MTRH**

Majority of the urethral stricture patients sampled in this study had associated comorbidities. The comorbidities were grouped into 10 categories based on the systems of the body. There were a total of 72 comorbidities observed from the subjects of the study. The overall occurrence based on the system is shown in table 8 below:

**Table 8: Comorbidities of stricture patients at MTRH**

COMORBIDITY-SYSTEM	NUMBER	PERCENTAGE
GENITOURINARY	36	50.00%
MUSKULOSKELETAL	9	12.50%
C.V.S	8	11.11%
ABDOMINAL	7	9.72%
MENTAL	3	4.16%
RESPIRATORY	2	2.78%
ENDOCRINE	2	2.78%
IMMUNE	2	2.78%
DERMATOLOGICAL	2	2.78%
C.N.S	1	1.39%
TOTAL	72	100%

Tables 9(a)-9(j) below give a detailed breakdown of comorbidities captured for each system

### Genital Urinary Comorbidities

Common comorbidities noted were enlarged prostate (8.33%), pelvic fractures (8.33%) erectile dysfunction (6.94%), Hypertension (6.94%), recurred strictures (5.55%) and urethrocutaneous fistula. The 6 comorbidities above accounted for 41.7% of all the listed comorbidities.

**Bladder related (5)**-bladder stone 1/bladder tumor 1/ Bladder Diverticuli 1/Cystitis 2

**Testicular related (4)**-Hydrocele 1/Epididymorchitis 1/Epididymal cyst 1/monorchism 1.

**Sexual dysfunction (6)**-Erectile Dysfunction 5/Retrograde ejaculation1.

**Ureter related (2)**-Hydronephrosis 2 .

**Kidney related (2)**-Chronic Kidney Disease 2 .

**Perineum (1)**-Fournier's Gangrene 1 .

**Prostate Related (6)** - BPH 6 .

**Recurred Stricture (4)** 4 .

**Urethral tract related (6)**-Urethrocutaneous fistula 4/Urethritis 2.

**Table 9(a): Genital Urinary Comorbidities**

<b>G.U.S COMORBIDITY</b>	<b>NUMBER</b>	<b>PERCENTAGE</b>
Bladder related	5	13.88%
Testicle related	4	11.11%
Sexual dysfunction	6	16.66%
Ureter related	2	5.55%
Kidney related	2	5.55%
Perineum	1	2.77%
Prostate Related	6	16.66%
Urethral tract related	6	16.66%
Recurred Stricture	4	11.11%
<b>TOTAL</b>	<b>36</b>	



**Table 9(b): Abdominal Comorbidities**

<b>ABDOMINAL</b>	<b>NUMBER</b>	<b>PERCENTAGE</b>
Right Inguinal Hernia	1	14.28%
Esophageal carcinoma	1	14.28%
Liver cirrhosis	1	14.28%
Splenic rupture	1	14.28%
Rectal perforation	1	14.28%
Hemo-peritoneum	1	14.28%
Penetrating Abdominal Injury	1	14.28%
<b>TOTAL</b>	<b>7</b>	<b>100%</b>

**Table 9(c): Respiratory Comorbidities**

<b>RESPIRATORY</b>	<b>NUMBER</b>	<b>PERCENTAGE</b>
Tuberculosis	1	50%
Asthma	1	50%
<b>TOTAL</b>	<b>2</b>	<b>100%</b>

**Table 9(d): Endocrine Comorbidities**

<b>ENDOCRINE</b>	<b>NUMBER</b>	<b>PERCENTAGE</b>
Diabetes Mellitus	2	100%
<b>TOTAL</b>	<b>2</b>	<b>100%</b>

**Table 9(e): Immune Comorbidities**

<b>IMMUNE SYSYTEM</b>	<b>NUMBER</b>	<b>PERCENTAGE</b>
HIV	2	100%
<b>TOTAL</b>	<b>2</b>	<b>100%</b>

**Table 9(f): Central Nervous system Comorbidities**

<b>C.N.S</b>	<b>NUMBER</b>	<b>PERCENTAGE</b>
Spinal Cord Injury	1	100%
<b>TOTAL</b>	<b>1</b>	<b>100%</b>

**Table 9(g): Psychological Comorbidities**

<b>PSYCHIATRIC</b>	<b>NUMBER</b>	<b>PERCENTAGE</b>
Depression	2	66.67%
Alcoholism	1	33.33%
<b>TOTAL</b>	<b>3</b>	<b>100%</b>

**Table 9(h): Cardiovascular System Comorbidities**

<b>C.V.S</b>	<b>NUMBER</b>	<b>PERCENTAGE</b>
Hypertension 5	5	55.55%
Thrombocytopenia 1	1	11.11%
Anaemia 3	3	33.33%
<b>TOTAL</b>	<b>9</b>	<b>100%</b>

**Table 9(i): musculoskeletal comorbidities**

<b>M.S.S</b>	<b>NUMBER</b>	<b>PERCENTAGE</b>
Pelvic fractures	6	66.67%
Osteoarthritis	1	11.11%
Proximal femoral fractures	2	22.22%
<b>TOTAL</b>	<b>9</b>	<b>100%</b>

**Table 9(j): Dermatologic Comorbidities-**

<b>DERMATOLOGIC</b>	<b>NUMBER</b>	<b>PERCENTAGE</b>
Herpes Zoster	1	50%
Squamous cell carcinoma	1	50%
<b>TOTAL</b>	<b>2</b>	<b>100%</b>

#### 4.4 Urethral Stricture Treatment Outcomes at MTRH

Post-Operatively, the leading overall complications were wound discomfort 80%, scrotal pain 52.3%, bleeding per urethral/wound site 50.8% and penile pain 47.7%.

This is as illustrated in the **table 10** below:

**Table 10: Overall Complications Post Urethral Stricture Surgery**

COMPLICATION	FREQUENCY OUT OF 65	PERCENTAGE
Wound discomfort	52	80%
Scrotal Pain	34	52.3%
Bleeding	33	50.8%
Penile pain	31	47.7%
Perineal Edema	30	46.2%
Scrotal swelling	24	36.9%
Surgical Wound Infection	11	16.9%
Urine Extravasation	9	13.8%
Urinary Tract Infection	7	10.8%
Iatrogenic Fistula	6	9.2%
Surgical wound dehiscence	6	9.2%
Perineal Hypoesthesia	4	6.2%
Catheter fall out	1	1.5%
TOTAL	65	100%

Out of the 65 patients who had USS 52(80%) were satisfied with their outcomes of surgery while 13(20%) were unsatisfied with the outcomes of their surgery. The main reason given for lack of satisfaction with the surgery was non improvement of the urinary condition or unresolved comorbidities.

A total of 287 complications were reported for the surgeries done. The absolute numbers for the complications for the respective surgical technique used and the anatomical site is as seen in the Table 11 below:

**Table 11: Complications per anatomical location and surgical technique used**

	DVIU	STAGED	GRAFT	FLA	ANASTOMOSIS	DIVERSION	TOTAL
				P			
Bulbar	2	15	8	6	49	0	80
Bulbar- membra nous	3	0	0	0	48	2	53
Membr anous	3	7	0	0	32	0	42
Penile	6	29	10	2	26	0	73
Peno- Bulbar	0	3	5	9	22	0	39
TOTAL	14	54	23	17	177	2	287

Bulbar urethral surgery had the highest complication rate of 4.7 complications per site, with membranous site noted to have the least complications rating. DVIU modality had the least rate of complication per surgery as compared to anastomotic urethroplasty and staged urethroplasty which had the highest rates of complication rating noted in the immediate post-operative period. This is seen in the Tables 12 and 13 below:

**Table 12: Rate of complications per stricture site**

<b>SITE</b>	<b>COMPLICATIONS</b>	<b>NUMBER OF STRICTURES</b>	<b>COMPLICATION RATE FOR SITE</b>
Bulbar	80	17	4.71
Bulbar- membranous	53	14	3.79
Membranous	42	13	3.23
Penile	73	22	3.31
Peno-Bulbar	39	9	4.33

**Table 13: Rate of Complication per method of surgery used**

<b>SURGERY METHOD</b>	<b>COMPLICATIONS</b>	<b>NUMBER OF SURGERIES</b>	<b>% OF SURGERIES</b>	<b>COMPLICATION RATE FOR SURGERY METHOD USED</b>
DVIU	14	11	14.3%	1.27
STAGED	54	13	16.9%	4.15
GRAFT	23	7	9.1%	3.28
FLAP	17	5	6.4%	3.4
ANASTOMOTIC	177	41	53.2%	4.32
URINE DIVERSION	2	1	1.3%	2

**DVIU**

The main complications noted were bleeding and penile pain 28.6% each.

**STAGED URETHROPLASTY**

The main complications noted were wound discomfort-16.7% Bleeding-14.8% and penile pain 9.25%

**ONLAY GRAFT MODALITY**

The main complications noted were penile pain and wound discomfort each at 21.7%

**FLAP SUBSTITUTION MODALITY**

The main complications were penile pain and wound discomfort at 17.6% each

## ANASTOMOTIC URETHROPLASTY

The 5 main complications were wound discomfort 22.03%, scrotal pain 18.1% perineal edema 13%, scrotal swelling 12.4%, bleeding 10.7% and penile pain 10.2%

**Table 14a: Post-operative complication and treatment:**

### Bulbar site (80)

<b>Treatment</b>	<b>Post operative complication</b>	<b>Freq</b>
<b>DVIU cold knife(2)</b>	Bleeding	1
	Penile pain	1
<b>Staged Urethroplasty (15)</b>	Bleeding	2
	UTI	1
	Wound Infection	1
	Urocutaneous fistula	2
	Wound dehiscence	1
	Fail void	1
	Scrotal pain	2
	Wound discomfort	2
	Scrotal swelling	1
	Perineal edema	2
<b>Urethroplasty-Onlay grafting(8)</b>	Penile pain	2
	Scrotal pain	1
	Wound discomfort	2
	Scrotal swelling	2
	Perineal edema	1
<b>Urethroplasty-use of flaps(6)</b>	Bleeding	1
	Penile pain	1
	Scrotal pain	1
	Wound discomfort	1
	Scrotal swelling	1
	Perineal edema	1
<b>Urethroplasty-Anastomotic(49)</b>	Bleeding	6
	UTI	3
	Wound Infection	3
	Wound dehiscence	1
	Penile pain	4
	Scrotal pain	8
	Wound discomfort	10
	Scrotal swelling	8
	Perineal edema	6

**Table 14b: Post-operative complication and treatment:  
Bulbar membranous site (53)**

<b>Treatment</b>	<b>Post-operative complication</b>	<b>Freq</b>
<b>DVIU cold knife(3)</b>	None	3
<b>Urethroplasty- Anastomotic(48)</b>	Bleeding	3
	UTI	1
	Wound Infection	3
	Urocutaneous fistula	2
	Wound dehiscence	1
	Fail void	1
	Extravasation	2
	Penile pain	3
	Wound discomfort	8
	Scrotal pain	10
	Scrotal swelling	6
	Perineal edema	7
	Perineal hypoesthesia	1
<b>Urinary diversion-(2)</b>	Urocutaneous fistula	1
	Wound discomfort	1

**Table 14c: Post-operative complication and treatment:  
Membranous site (42)**

<b>Treatment</b>	<b>Postoperative complication</b>	<b>Freq</b>
<b>DVIU cold knife(3)</b>	Bleeding	2
	Pain	1
<b>Staged Urethroplasty (7)</b>	Bleeding	1
	UTI	1
	Wound Infection	1
	Wound dehiscence	1
	Extravasation	1
	Penile pain	1
	Wound discomfort	1
<b>Urethroplasty- Anastomotic(32)</b>	Bleeding	4
	Extravasation	2
	Penile pain	1
	Scrotal pain	7
	Wound discomfort	9
	Scrotal swell	3
	Perineal Edema	4
	Perineal hypoesthesia	2

**Table 14d: Post-operative complication and treatment:  
Penile site (73)**

<b>Treatment</b>	<b>Post operative complication</b>	<b>Freq</b>
<b>DVIU cold knife(6)</b>	Bleeding	2
	Penile pain	3
	Wound discomfort	1
<b>Staged Urethroplasty (29)</b>	Bleeding	4
	UTI	2
	Wound Infection	2
	Urocutaneous fistula	2
	Wound dehiscence	2
	Failure to void	1
	Extravasation	3
	Penile pain	3
	Scrotal pain	2
	Wound discomfort	5
	Scrotal swelling	1
	Perineal Edema	2
	<b>Urethroplasty-Onlay grafting(10)</b>	Penile pain
Scrotal pain		2
Wound discomfort		2
Scrotal swelling		2
Perineal Edema		2
<b>Urethroplasty-use of flaps(2)</b>	Penile pain	1
	Wound discomfort	1
<b>Urethroplasty- Anastomotic(26)</b>	Bleeding	4
	Extravasation	1
	Penile pain	5
	Scrotal pain	3
	Wound discomfort	7
	Scrotal swelling	3
	Perineal Edema	2
	Perineal hypoesthesia	1



**Table 14e: Post-operative complication and treatment:  
Peno Bulbar site (38)**

<b>Treatment</b>	<b>Postoperative complication</b>	<b>Freq</b>
<b>Staged Urethroplasty (3)</b>	Bleeding	1
	Penile pain	1
	Wound discomfort	1
<b>Urethroplasty-Onlay grafting(5)</b>	Bleeding	1
	Wound Infection	1
	Penile pain	1
	Scrotal pain	1
	Wound discomfort	1
	Perineal Edema	1
<b>Urethroplasty-use of flaps(9)</b>	Bleeding	1
	Wound Infection	1
	Wound dehiscence	1
	Extravasation	1
	Penile pain	1
	Scrotal pain	1
	Wound discomfort	1
	Scrotal swell	1
	Perineal Edema	1
<b>Urethroplasty-Anastomotic(22)</b>	Bleeding	2
	Penile pain	5
	Scrotal pain	4
	Wound discomfort	5
	Scrotal swelling	2
	Perineal edema	4

**Table 15: Summary of Percentage of Non-Satisfied Clients Based On Treatment Modality Used**

<b>MODALITY</b>	<b>NUMBER DONE</b>	<b>UNSATISFIED</b>	<b>PERCENTAGE UNSATISFIED</b>
DVIU	11	1	9.1%
STAGED	13	8	61.5%
GRAFT	7	0	0%
FLAP	5	0	0%
ANASTOMOTIC	41	3	7.3%
DIVERSION	1	1	100%

**Table 16: Summary of Percentage of Non-Satisfied Clients per Anatomical Site of Stricture**

<b>SITE</b>	<b>NUMBER OF STRICTURES</b>	<b>UNSATISFIED</b>	<b>PERCENTAGE UNSATISFIED</b>
BULBAR	17	2	11.8%
BULBAR-MEMBRANOUS	14	3	21.4%
MEMBRANOUS	13	2	15.4%
PENILE	22	6	27.3%
PENOBULBAR	9	0	0%

**Table 17: Reason for Non Satisfaction**

<b>Site</b>	<b>Treatment</b>	<b>QOL</b>	<b>Freq</b>	<b>Reason</b>	<b>Problem</b>
<b>Bulbar</b>	<b>Staged Urethroplasty</b>	Unsatisfied	1	No improvement plus other problems	ESRD
		Very Unsatisfied	1	No improvement plus other problems	Squamous carcinoma
<b>Bulbar membranous</b>	<b>DVIU Urethroplasty-Anastomotic</b>	Unsatisfied	1	Improved but other problems	Bladder Ca
		Unsatisfied	1	No improvement	Wound dehiscence and failure to void
		Unsatisfied	1	No improvement plus other problems	Erectile dysfunction
<b>Membranous</b>	<b>Staged Urethroplasty Urethroplasty-Anastomotic</b>	Unsatisfied	1	No improvement	Still passing urine via fistula
		Unsatisfied	1	Improved but other problems	Suprapubic catheter
<b>Penile</b>	<b>Staged Urethroplasty</b>	Unsatisfied	1	Improved but other problems	Inability to have sex post op
			1	No improvement	Still passing urine via fistula
			1	No improvement plus other problems	ESRD,Recurrence
		Very Unsatisfied	1	No improvement plus other problems	Squamous carcinoma
	<b>Urethroplasty-Anastomotic</b>	Unsatisfied	1	No improvement plus other problems	Recurrence and Now urinating via perineum

Dissatisfied clients who underwent anastomosing urethroplasty cited wound dehiscence, prior recurrence of the stricture and presence of the suprapubic catheter in the immediate post-operative period as some of the reasons of not being satisfied with their procedures.

One patient who had DVIU as the modality of treatment cited bladder carcinoma non resectable as the cause of not being satisfied with the surgery outcome.

## **CHAPTER FIVE: DISCUSSION**

This study sought to identify anatomical characteristics of urethral strictures at MTRH, establish comorbidities of patients presenting with urethral strictures and evaluate specific short-term outcome of modalities of treatment used in the management of urethral strictures at MTRH.

This study revealed the mean duration of hospital stay of patients who undergo stricture surgery is 8.2days at MTRH. This duration favors observation of early outcomes as done in this study. It also concurs with the definition of early post-operative period (Swan et al., 1998).

### **5.1 Characterization of anatomical site of urethral strictures at MTRH**

Description of anatomical characteristics has been widely studied across many centres. However lack of standardised anatomic grouping of strictures in the various studies sometimes limits direct comparisons of results. The recent International Consultation on Urological Disease (ICUD) panel on urethral strictures (2010) aimed to bring more consistency to the literature in terms of terminology, definitions and specific management recommendations (Hillary et al., 2015).

At MTRH 10.8% of the study population had strictures at multiple sites while majority (89.2%) of the respondents had strictures at only one site. This concurs with a study in Senegal that had 97.3% of single site strictures and 2.7% of multiple site strictures. The similarity may arise due to a comparable sample of 65 patients in this study and 75 in the Senegal study. The study setting of tertiary hospitals was similar in the two studies. In a study in Nairobi (Intasab, 2012) single site stricture dominance (61.4%) and multiple site strictures of 38.6% was observed. The occurrence of multiple site of stricture was much higher in Nairobi because of a larger sample size

of 139 patients. The setting of the study in Nairobi involved a tertiary hospital and a nearby private facility thus the catchment population was significantly larger. Nonetheless the trend indicates that single site strictures are dominant.

At MTRH the mean length of stricture was 2.6cm (SD±1.8cm). This concurs with a study in Senegal (Fall et al., 2014) that reported mean stricture length of 2.5cm (SD±1.4cm). The findings were also in concurrence with a study in Nairobi (Intasab, 2012) that reported mean stricture length of 2.9cm (SD±1.6cm). The catchment population in the three studies has similar economic characteristics. This in turn has an effect in trends of etiology which are similar in countries where the studies took place.

In India (Joseph et al., 2016) the mean length of stricture was 3.6cm (SD± 3.0). The findings contrast those from this study. Most strictures in India were common following urethral instrumentation and catheterization (iatrogenic causes). A rapidly evolving health care system and industrialization in India has increased access to healthcare and resultant iatrogenic injuries.

At MTRH majority (52%) of strictures had bulbar involvement. The predominance of bulbar stricture involvement concurs with literature from other studies. A study in Nigeria (Oguike et al., 2006) had a majority (45.4%) of bulbar stricture. The concurrence in the two studies begins with similar sample sizes: 65 in MTRH, 68 in Nigeria. The trends in etiology in both studies demonstrate a shift from urethritis to a predominance of trauma. The studies have their setting in tertiary hospitals in developing countries; the characteristics of the catchment populations are thus similar.

A study in India (Joseph et al., 2016) had a much higher rate (74.7%) of bulbar stricture involvement. The etiology of bulbar stricture was predominantly iatrogenic

and idiopathic unlike at MTRH where accidental trauma was predominant. The setting in India is that of a country with an emerging economy and a rapidly evolving health sector. This has seen increased urethral instrumentation and catheterization. The study in India cited increased instrumentation and catheterizations as key in increasing rates of bulbar stricture occurrence in addition to trauma.

In Senegal (Fall et al., 2014) bulbar stricture was predominant (63.3%) with urethritis being the common stricture etiology (Oguike et al 2006). Senegal is comparatively a less developed country with challenges in universal health access. This could explain the predominance of urethritis. This could explain the higher frequency of occurrence of bulbar strictures.

Penile urethra was the second most common stricture site (40.3%) at MTRH. This concurs with a study in India (Joseph et al., 2016) that had penile stricture occur at 36.7%. A comparable sample size of 75 in India with 65 at MTRH may explain the similar findings.

Membranous strictures occurrence in Nigeria 19.1% (Oguike et al., 2006) and Senegal 18.7% (Fall et al., 2014) had similar rates to MTRH 16.9%. A sample size of 68 in Nigeria, 75 in Senegal and 65 in this study are comparable. The study setting of tertiary hospitals in under-developed countries brings similarity in the catchment population.

There was no prostatic urethral stricture in this study. The prostatic urethra is the widest part of the male urethra. This explains the rarity of prostatic strictures consistent with other studies.

## **5.2 Description of Comorbidities in Urethral Stricture Patients at MTRH**

The surgical management of stricture disease can be complex and challenging due to the multiple factors that need to be considered including anatomical location, underlying pathophysiology as well as patient comorbidities (Hillary et al., 2015). Increased patient comorbidity was found to be an independent risk factors for urethral stricture complication (Chapman et al., 2017).

At MTRH it was observed that comorbidities had an impact on patient perception of success or failure of surgical intervention offered. Patients who had comorbidities that were not reversible in nature were often unsatisfied even if the surgical intervention offered resolved their urinary condition. Subjects with irreversible comorbidities /potentially incurable comorbidities included end stage renal disease, malignancy, and erectile dysfunction. Squamous cell carcinoma, bladder malignancy, esophageal carcinoma were the malignancies observed at MTRH.

A study in Turkey (Kizilay et al., 2017) concurred with findings on some comorbidities of urethral stricture disease. Hypertension (29%) erectile dysfunction (28.6%) and Diabetes Mellitus (16.5%) were the leading comorbidities observed. At MTRH erectile dysfunction (6.94%) and Hypertension (6.94%), were the third most common comorbidities after prostate enlargement (8.33%) and pelvic fractures (8.33%). The mean age of urethral stricture patients in Turkey was 68 years while at MTRH 43 years. The difference in age would explain the differences in rates of occurrence. It is expected that hypertension and erectile dysfunction would be more prevalent in the elderly. This also explains why Turkey had higher rates of chronic constipation (26.7%) and coronary artery disease (11.6%).

In Nigeria (Obi AO, 2017) a study noted an increased incidence of comorbidities such as recurrent urinary tract infections, catheter retention, catheter dislodgement,

epididymorchitis, and vesical stone. All patients had suprapubic urinary diversion on presentation. Supra-pubic catheterization urinary diversion is well known to be associated with risks of infection, stone formation, and other complications. These comorbidities tended to increase with the delay in obtaining definitive treatment. At MTRH comorbidities associated with the genital urinary system accounted for 50% of all comorbidities. These comorbidities included cystitis, epididymorchitis and bladder stones. Majority (61.5%) of the respondents at MTRH had suprapubic catheterization prior to surgery. This supports the observation from Nigeria that suprapubic catheterization is associated with more comorbidities for urethral stricture patients.

A study in U.S.A (Kirk et al., 2016) identified 4 comorbidities that were prominent amongst its subjects. Hypertension (51.1%) coronary artery disease (18.1%) Diabetes mellitus type 2 (33.0%) and dyslipidaemia. The mean age was 51.5years (SD±15.2). There was a 61.7% current history of smoking and 57.4% current history of alcohol use in the subjects of the study. Even though hypertension is common at MTRH the rates are much lower than what is seen in U.S.A. The lifestyle trend of widespread tobacco and alcohol use in U.S.A predisposes this population to lifestyle diseases. A higher mean age of population sampled in the U.S.A study favours a higher prevalence of chronic diseases. The rate of occurrence of diabetes mellitus, hypertension was much lower at MTRH because patients sampled were much younger than in the U.S.A.

In a study in Nigeria (Kiridi, Dambo, & et al., 2016) with 25 patients some comorbidities found were: decreased bone density (8%), sclerotic bone changes (4%), pelvic bone fracture (4%), elevated bladder base (4%) bladder diverticuli (8%) and irregular bladder outline (4%). The findings contrast those in MTRH. In Nigeria the study focussed on radiological cystourethrogram findings without clinical

consideration. This explains why the comorbidities have bony associations. In addition the sample size difference between MTRH (65) and Nigeria (25) may also explain the difference in comorbidity rates.

### **5.3 Determination of specific short-term outcome of modalities of treatment used in the management of urethral strictures**

Early and late effects of urethroplasty, including complications, have not been extensively reported in the literature (Al-Qudah & Santucci, 2005). At MTRH all possible adverse outcomes were included as complications. There was no categorization as to what would be perceived as major or minor complications. This included patient reported complaints post operatively and what was observed clinically. In this study patient follow up was to the point of discharge.

Most studies on urethral stricture outcome focused on recurrence and other long term complications such as chordee, erectile dysfunction and incontinence Al-Qudah & Santucci, 2005;(Navai et al., 2008). In MTRH this is a pioneer study on complications and may be useful in creating a validated tool for early post-operative assessment of urethral stricture surgery. The findings may also be used for preoperative counseling of patients on what to expect following surgery.

This study encouraged voicing of all patient concerns or complaints post-surgery. Thus the complications were notably many. A study in the U.S.A observed when patients complains are included as part of complications the rate of complications apparently increase (Al-Qudah & Santucci, 2005).



### **Direct Visual Internal Urethrotomy**

At MTRH 14.3% of all strictures were treated by DVIU. This method had the lowest complication rate of approximately 1 complication per surgery. The main complications were bleeding (28.6%) and penile pain (28.6%) and concur with what was observed in India (Jain et al., 2014) where bleeding was 15.5% post urethrotomy. Review of literature (Santucci & Eisenberg, 2010) shows bleeding as the predominant complication associated with cold knife DVIU. The rate of bleeding observed in India was lower because of a larger sample size of 90. In addition over 50% of patients in India received holmium laser urethrotomy which has a lower rate of bleeding compared to the cold knife urethrotomy offered at MTRH.

### **Anastomotic Urethroplasty**

At MTRH, 53.2% of strictures were treated by anastomotic urethroplasty. With the average length of stricture being 2.6cm in this study it would be expected as the preferred modality of treatment. However it also had the biggest burden of complications with 177 complications of the 287 overall complications. This modality had an average of ~4 complications per every surgery and by far the highest observed among the various modalities. The main complications were wound discomfort (22%), scrotal pain (18.1%) and scrotal swelling (12.4%).

At MTRH the occurrence of wound discomfort (22%), scrotal pain (18.1%) perineal edema (13%), scrotal swelling (12.4%), bleeding (10.7%), penile pain (10.2%), UTI (2.25%) and perineal hypoesthesia (2.25%) was at higher rates than in U.S.A (Al-Qudah & Santucci, 2005) who had wound discomfort (3.2%) scrotal pain (6%) scrotal swelling (3.2%) UTI (3.2%), perineal hypoesthesia (3.2%) and penile pain (3.2%) . This can be due to retrospective nature of the study in U.S.A. There is possibility

some complications were not recorded by attending clinicians. The study in U.S.A did not use a tool to collect complications from patients. At MTRH the prospective study had an USS PROM tool that was used consistently for all patients.

In another study in U.S.A (Granieri, Webster, & Peterson, 2015) 63% of patients (n=325) were treated using anastomotic urethroplasty. Complications were reported as follows; scrotal and/or perineal neuralgia (28%), scrotal and/or perineal hematoma (5%), catheter-related issue (4%), and excessive wound drainage (5%), wound separation (1%), wound infection (1%). Although the rates of complications concur with findings at MTRH, the spectrum of complications in U.S.A was narrower. This may be due to the retrospective nature of the study. In addition no data collection tool was used to record complications immediately they occurred. The investigators relied on patients' oral report almost 3 months post-surgery. This brings in a recall bias that confounds on their results.

In yet another study in U.S.A (Navai et al., 2008) the only reported complications were wound sepsis (5%) bleeding (2.5%) and positioning related complications (2.5%). The variety of complications was much narrower than at MTRH. This may be because the main outcome under study in U.S.A was recurrence, a long term complication. The early complications were only added to evaluate association with stricture recurrence.

### **Substitution Graft Modality**

At MTRH buccal mucosal graft was the common graft material used and 9.1% of strictures were treated by this modality. The complication rate was ~3 complications per surgery. The main complications noted were penile pain 21.7% and wound discomfort 21.7%. Scrotal pain, scrotal swelling, perineal edema occurred at 17.4%

respectively. Bleeding and wound infection at 4.3% each. This contrasted to U.S.A (Al-Qudah&Santucci, 2005) who had scrotal hematoma-5% haematuria-5% and wound infection 5%. The complication rates seem to be higher at MTRH because of a lower number of patients who underwent the procedure; (7) strictures in MTRH as compared to (19) from USA.

In a study in India (Joseph et al., 2016) the main complications were Penile edema-10.5% peri-catheter pus discharge-13.2% urinary tract infection-15.8% wound infection-10.5%. These complications were of infectious nature. The contrast in findings from India and MTRH can be explained by investigator bias. Almost 50% of all strictures in India were managed by substitution graft urethroplasty despite the mean length being 2.82 (SD  $\pm$  2.34) cm. Infection is a common post-operative complication following graft technique. There was no explanation offered as to why the method was used more frequently than other methods. This may explain the high rates of infection post operatively. The study method from India did not indicate whether there was use of antibiotics following graft substitution urethroplasty. The relatively high use of buccal mucosa substitution urethroplasty contrasted with other studies of similar nature that had predominance of anastomotic urethroplasty (Al-Qudah & Santucci, 2005; Granieri et al., 2015)

### **Substitution Flap Modality**

At MTRH, 6.4% of strictures were treated with this modality. The rate of complications was ~3 complications per surgery. In this study penile pain 17.6% and wound discomfort at 17.6%. Bleeding, scrotal pain, scrotal swelling, perineal edema occurred at 11.8% each. This contrasted with findings from USA (Al-Qudah&Santucci, 2005) Epididymitis 10% penile swelling-10% UTI-10% rectal

injury-10% penile pain-10%.The contrast in rates can be explained by the number of patients who underwent Substitution flap treatment in USA (10) versus (5) at MTRH. The study in U.S.A was retrospective and no data collection tool was used to record complication in a consistent manner unlike at MTRH.

In Seoul Korea (Kim, Suh, Paick, & Kim, 2014) the main complications were Epididymitis 10.3% Urinary tract infection 6.9%. The findings contrast those at MTRH. This is possibly due to the retrospective nature of study in Korea. In addition there was no tool that was used to collect data on complications from study subjects. It is therefore possible that some complications were missed or not recorded in Korea.

### **Staged Urethroplasty**

At MTRH 16.9% of the strictures were treated using this modality. The complication rate was 4 per surgery.The main complications noted were wound discomfort-16.7% Bleeding-14.8% and penile pain-9.25% for the first stage. The creation of iatrogenic fistulas was particularly concerning to sexually active patients who had this modality of treatment. The patients often had to leave employment during the duration of treatment .In USA (Olsson & Krane, 1978) staged urethroplasty had similar findings. Although not enumerated, some of the complications included: increased overall hospitalization time, periods of unemployment in between procedures and sexual dysfunction following creation of iatrogenic fistula. The complications of staged urethroplasty will vary with the procedure done at a particular stage. There is a big paucity of data on outcomes of staged urethroplasty from current literature. This compromises comparability of our findings with other studies.

## **Urinary Diversion**

A single patient received perineal urethrostomy. This followed a long and complex traumatic stricture in a patient with end stage renal disease on dialysis. Post diversion wound discomfort, perineal pain and wound sepsis was observed. In USA ( French, Hudak, & Morey, 2011) 7 patients who underwent perineal urethrostomy for complex anterior urethral strictures reported no complications. The contrast with MTRH can be explained by the fact that the single patient at MTRH had lower immunity due to end stage renal disease. In addition the patient had undergone a non-successful urethroplasty at another facility. This could have led to more fibrosis with increased discomfort or pain post procedure.

## **Patient Satisfaction**

In the past, success criteria in papers on urethroplasty were heterogeneous, based on investigations of uroflowmetry, voiding cystography, cystoscopy, and the lack of further interventions from the surgeon's perspective. By 2002, however, it had been realised that patients consider the outcome of urethral stricture surgery (USS) more differently than do physicians(Fisch, 2013).

A 2011 study in the United Kingdom (Jackson et al., 2013) was the first to come up with a validated Urethral Stricture Surgery Patient Related Outcome Measure (USS PROM) tool. The tool comprised of pre-operative assessment and Post-operative assessment of quality of life.

At MTRH the validated USS PROM tool was used to assess patient satisfaction. Out of 65 subjects, 52 were satisfied with the outcome of the surgery while 13 were not

satisfied. Despite the occurrence of many complications the overall rate of satisfaction (80%) was good.

In Hamburg, Germany (Kessler, Fisch, Heitz, Olianias, & Schreiter, 2002) 78% of the 203 patients who underwent successful urethroplasty as well as 80% of the 30 patients for whom urethroplasty was considered a failure were found to be satisfied or very satisfied with the result. These results concur with findings at MTRH. The main reason for non-satisfaction in the two groups was impairment of sexual life of any degree.

A study in Brazil (Lucas et al., 2017) showed 84.3% of patients were satisfied or very satisfied with surgical results after urethroplasty and concluded significant improvements in urinary symptoms and in quality of life are expected after urethroplasty and they are correlated with objective measures. This concurs with findings at MTRH.

In a study in USA (Broadwin & Vanni, 2018), 94% of patients reported being very satisfied or satisfied with their reconstruction. Additionally 86% of patients stated they would recommend urethroplasty to others with urethral stricture disease. The satisfaction rate may have been higher than MTRH because it was a retrospective study. Patient sexual function and satisfaction were evaluated by the International Index of Erectile Function (IIEF) and a patient perception questionnaire. These tools were different from those used at MTRH.

In a study in India (Kumar et al., 2019), 84.6% of patients were satisfied or very satisfied with surgical results. This study demonstrated a high percent of post-operative satisfaction with a majority of men (80.7%) reporting that they would have undergone the operation again. Men with post-operative sexual complaints, new or

persistent urinary pain/dysuria, discomfort due to perineal ejaculation and pelvic pain, men reporting poor urinary stream reported dissatisfaction for their surgical procedure. This concurs with findings at MTRH. At MTRH post-operative sexual complaints, comorbidities were however the predominating reasons for non-satisfaction.

Urinary diversion caused dissatisfaction in the lone subject in the study, mainly due to lack of possible surgical alternatives to remedy the condition, recurrence post previous surgical attempts and erectile dysfunction.

Staged urethroplasty had the highest number of unsatisfied clients. This was mostly due to comorbidities that were relatively non reversible such as End stage renal disease, Squamous cell carcinoma of the penis and perineal skin, stricture recurrence, passing urine via an iatrogenic fistula, inability to engage in coitus post operatively, and need for additional surgery. This concurs with a study in India (Kumar et al., 2019) that observed men with post-operative sexual complaints, new or persistent urinary pain/dysuria, discomfort due to perineal ejaculation and pelvic pain, men reporting poor urinary stream reported dissatisfaction for their urethral stricture surgical procedure.

Dissatisfied clients who underwent anastomosing urethroplasty cited wound dehiscence, recurrence of the stricture and presence of the suprapubic catheter in the immediate post-operative period as some of the reasons for not being satisfied with the procedure.

One patient who had DVIU as the modality of treatment cited bladder carcinoma non resectable as the cause of not being satisfied with the surgery outcome.

## CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

### 6.1 Conclusion

The etiology pattern of urethral stricture at MTRH has changed. The main cause of urethral stricture at MTRH was trauma.

Single site strictures were more common than multiple site strictures at MTRH. The predominant anatomical site of urethral stricture involvement at MTRH is the bulbar urethra followed by penile urethra involvement.

Common comorbidities seen in urethral stricture patients at MTRH were enlarged prostate (8.33%), pelvic fractures (8.33%) erectile dysfunction (6.94%), hypertension (6.94%), and urethrocutaneous fistula (5.55%).

At MTRH the common immediate post-operative outcomes of urethral stricture surgery included: wound discomfort, scrotal pain, bleeding per urethral/wound site, penile pain, perineal edema, scrotal swelling, and surgical site infection. The overall rate of satisfaction was 80% for patients who underwent urethral stricture surgery.



## **6.2 Recommendations**

Emphasis should be placed on identifying and managing comorbidities peri-operatively in urethral stricture patients to improve patient outcome or manage patient expectations.

Patient reported satisfaction is a useful indicator of surgery success and should be routinely included in post-operative assessment of urethral stricture patients.

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## APPENDICES

### Appendix I: Consent Forms

#### PART A INTRODUCTION

##### English Version

My name is Dr. Ashiundu Edwin Miima a medical doctor registered by the Kenya Medical Practitioners' and Dentists Board (A8834)

I am currently pursuing Masters of Medicine degree in the Department of General Surgery at Moi University.

I am doing my research study on physical characteristics of strictures, associated comorbidities, complications of urethral stricture surgery and patient reported satisfaction following urethral stricture surgery. I request to use your data and findings for the purposes of improving the management of urethral strictures.

Data that will be collected include: demographic data, anatomical characteristics of the strictures, comorbidities of urethral stricture disease and outcome of treatment. You will receive the standard care in line with the hospital protocols and your choice to withhold consent or to withdraw from the study will not affect your treatment. The information that you give for the purposes of this study will be treated with utmost confidentiality.

There are no direct benefits such as payment or incentives for participating in this study and neither are there any risks to the participants.

If you have any questions about your rights as a research subject, you can contact;

The Chairman,

Institutional Research and Ethics Committee,

Moi University/Moi Teaching and Referral Hospital

P.O. Box 3-30100

Eldoret.

Telephone number: 053-2033471/2/3 Extension 3008.

**PART B: CONSENT BY RESEARCH PARTICIPANT**

I, the undersigned, do voluntarily accept to participate in this research study. The nature and the purpose of the study have been fully explained to me by the principal investigator, Dr. Ashiundu Edwin Miima .

I understand that I may choose to withdraw at any time should I change my mind and that any information that I will give will be treated with utmost confidentiality and will only be used for the purposes of this study.

Name-----

Signature ----- Date-----

I confirm that I have given the information regarding this research to the above participant and they are free to contact me should they have any questions or concerns.

Dr. Ashiundu Edwin Miima (0726256430)

Signature-----Date-----

**PART C: CONSENT BY PARENT/GUARDIAN ON BEHALF OF MINOR**

I, the undersigned as the parent/legal guardian, do voluntarily accept to let my son/daughter participate in this research study. The nature and the purpose of the study have been fully explained to me by the principal investigator, Dr. Ashiundu Edwin Miima

I understand that I may choose to withdraw at any time should I change my mind and that any information that I will give will be treated with utmost confidentiality and will only be used for the purposes of this study.

Name-----

Signature ----- Date-----

I confirm that I have given the information regarding this research to the above participant and they are free to contact me should they have any questions or concerns.

Dr. Ashiundu Edwin Miima (0722 536937)

Signature-----Date-----

**PART D: ASSENT BY A CHILD OVER 7 YEARS**

I accept to voluntarily accept to participate in this research study. The nature and the purpose of the study have been fully explained to me by the principal investigator, Dr. Ashiundu Edwin Miima

I understand that I may choose to withdraw at any time should I change my mind and that any information that I will give will be treated with utmost confidentiality and will only be used for the purposes of this study.

I confirm that I have given the information regarding this research to the above participant and they are free to contact me should they have any questions or concerns.

Dr. Ashiundu Edwin Miima (0726 256430)

Signature-----Date-----



**CONSENT FORM: KISWAHILI VERSION****SEHEMU A: UTANGULIZI**

Majina yangu ni Ashiundu Edwin Miima. Mimi ni daktari aliyehitimu na kusajiliwa na bodi ya madaktari wa Kenya nambari A8834. Kwa wakati huu ninasomea shahada ya juu ya upasuaji katika chuo kikuu cha Moi.

Ninafanya utafiti unaohusu magonjwa yanayosababishwa na kupunguka kwa uwazi wa njia ya kukojoa kati ya wagonjwa waliofanyiwa upasuaji katika hospitali ya Rufaa ya Moi. Kiini cha utafiti huu ni kuchunguza aina tofauti ya upungufu wa uwazi wa njia ya kukojoa, magonjwa husika na matokeo baada ya upasuaji. Maelezo haya yanaweza kutumiwa kuimarisha matibabu na kuangazia jinsi ya kuzuia magonjwa haya kwa kupitia mikakati itakayotekelezwa kwa kaunti na nchi kwa jumla.

Ujumbe utakao jumuishwa ni kama: maelezo kuhusu waathiriwa, aina tofauti ya upungufu wa uwazi wa njia ya kukojoa, magonjwa husika na matokeo baada ya upasuaji Utapata matibabu ya ugonjwa wako kama inavyohitajika katika hospitali ya MTRH na ukiamua kutojijumuisha au kujiondoa katika utafiti huu matibabu yako hayataathirika. Maelezo utakayotoa yatahifadhiwa vyema.

Hakuna manufaa ya kibinafsi kama malipo kwa kujumuishwa katika utafiti huu wala hakuna madhara kwa wale watakaohusishwa. Iwapo utakuwa na maswali kuhusu utafiti huu, unaweza kuwasiliana na ,

Mwenyekiti

Institutional Research and Ethics Committee,

Moi University/Moi Teaching and Referral Hospital

P.O. Box 3-30100

Eldoret.

Telephone number: 053-2033471/2/3 Extension 3008.

**SEHEMU B: KIBALI CHA UTAFITI NA MHUSIKA**

Mimi niliyetia sahihi hapo chini, nimekubali kwa hiari yangu kujumuishwa katika utafiti huu. Nimeelezwa kuhusu huu utafiti na mtafiti, Dr. Ashiundu Edwin Miima.

Ninaelewa kuwa ninaweza kujiondoa kutoka utafiti huu wakati wowote nikibadili nia yangu na kuwa ujumbe nitakaotoa utahifadhiwa vyema na kutumiwa katika utafiti huu peke yake.

Jina-----

Sahihi ----- Tarehe-----

Ninahakikisha kuwa nimetoa maelezo yanayohitajika kwa mhusika huyu na anaweza kuwasiliana nami kwa nambari ya simu iwapo ana swali au tashwishi.

Dr. Ashiundu Edwin Miima (0726256430)

Sahihi-----Tarehe-----

**SEHEMU C: KIBALI CHA UTAFITI NA MZAZI/MLEZI KWA NIABA YA MWANAWAWE**

Mimi niliyetia sahihi hapo chini kama mzazi/mlezi, nimekubali kwa hiari yangu mwanangu ajumuishwe katika utafiti huu. Nimeelezwa kuhusu huu utafiti na mtafiti, Dr. Ashiundu Edwin Miima

Ninaelewa kuwa ninaweza kumuondoa mwanangu kutoka utafiti huu wakati wowote nikibadili nia yangu na kuwa ujumbe nitakaotoa utahifadhiwa vyema na kutumiwa katika utafiti huu peke yake.

Jina-----

Sahihi ----- Tarehe-----

Ninahakikisha kuwa nimetoa maelezo yanayohitajika kwa mhusika huyu na anaweza kuwasiliana nami kwa nambari ya simu iwapo ana swali au tashwishi.

Dr. Ashiundu Edwin Miima(0726256430)

Sahihi-----Tarehe-----

**SEHEMU D: KIBALI CHA UTAFITI KWA WATOTO**

Mimi nimekubali kwa hiari yangu nijumuishwe katika utafiti huu. Nimeelezwa kuhusu huu utafiti na mtafiti, Dr. Ashiundu Edwin Miima

Ninaelewa kuwa nina weza kuondoka kutoka utafiti huu wakati wowote nikibadili nia yangu na kuwa ujumbe nitakaotoa utahifadhiwa vyema na kutumiwa katika utafiti huu peke yake.

Ninahakikisha kuwa nimetoa maelezo yanayohitajika kwa mhusika huyu na anaweza kuwasiliana nami kwa nambari ya simu iwapo ana swali au tashwishi.

Dr. Ashiundu Edwin Miima (0726256430)

Sahihi-----Tarehe-----

**Appendix II: Questionnaire****PROFORMA QUESTIONNAIRE  
BIODATA**

Name:.....

Age:..... Sex:..... Registration No:.....  
Date of Discharge:.....

Address:.....Phone Number:.....

**Presenting Complaints:**Failure to void                      Yes  No Weak Stream:                      Yes  No Straining:                      Yes  No Incomplete Emptying:            Yes  No Frequency:                      Yes  No Intermittency:                    Yes  No Urgency:                      Yes  No Acute Retention                    Yes  No Chronic Retention                Yes  No Haematuria                      Yes  No 

Duration of symptoms:.....

Comorbid condition.....

**History of presenting illness**

- a) History of Trauma to Perineum: Yes  No
- b) History of STI? : Yes  No
- c) History of penile or perineal skin lesions? : Yes  No
- d) Any comorbid conditions? : Yes  No
- e) History of pelvic / lower limb fracture Yes  No
- f) Iatrogenic cause Yes  No

**Systemic examination****Per abdomen**

- a) Suprapubic bulge Yes  No
- b) Suprapubic catheter Yes  No

**External genitalia**

- a) Periurethral abscess Yes  No
- b) Swollen testes Yes  No
- c) Urethrocutaneous fistula Yes  No
- d) Urethral Induration Yes  No
- e) None Yes  No

**Laboratory investigations-**

- a) FULL  
HAEMOGRAM.....
- b) UREA ELECTROLYTES CREATININE.....
- c) PITC.....

**Radiological imaging**

- a) RGU-
- b) MCU-
- c) USG -
- d) X RAY KUB-
- e) Site, length, number, associated anomalies.....  
 .....  
 .....

	SITE	LENGTH	NUM BER	ASSOCIATED ANOMALIES
<b>PENILE</b>				
<b>PENO-BULBAR</b>				
<b>BULBAR</b>				
<b>BULBAR-</b>				
<b>MEMBRANOUS</b>				
<b>MENBRANOUS</b>				
<b>PAN-URETHRAL</b>				
<b>UNSTATED</b>				

**Treatment-Operative Procedure**

- a) DVIU COLD KNIFE
- b) URETHROPLATY-ANASTOMOSING
- c) URETHROPLAST- ONLAY GRAFTING   
 .....
- d) URETHROPLASTY-USE OF FLAPS   
 .....
- e) Staged repair  
 .....

**Postoperative complication-table**

a) Bleeding	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
b) Urinary tract infection	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
c) Wound infection	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
d) Urocutaneous fistula	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
e) Wound dehiscence	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
f) Failure to void	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
g) Foley Catheter fall off	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
h) Spraying	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
i) Extravasation of urine	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
j) Penile Pain	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
k) Scrotal pain	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
l) Hematoma	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
m) Wound discomfort	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
n) Scrotal swelling	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
o) Perinealedema	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
p) Perineal hypoesthesia	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
q) None	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>

### Appendix III: Quality of Life Questions

Adopted from **Urethral Stricture Surgery Patient Related Outcome Measure(USS PROM) tool ( Jackson et al., 2011)**

9. Are you satisfied with the outcome of your operation?

Yes, very satisfied.....

Yes, satisfied.....

No, unsatisfied.....

No, very unsatisfied.....

10. If you were unsatisfied or very unsatisfied is that because:

The urinary condition did not improve.....

The urinary condition improved but there was some other problem.....

The urinary condition did not improve and there was some other problem as well.....



## Appendix IV: Hospital MTRH



An ISO 9001:2015 Certified Hospital



# MOI TEACHING AND REFERRAL HOSPITAL

Telephone: (+254)053-2033471/2/3/4  
 Mobile: 722-201277/0722-209795/0734-600461/0734-683361  
 Fax: 053-2061749  
 Email: [ceo@mtrh.go.ke](mailto:ceo@mtrh.go.ke)/[directorsoffice@mtrh@gmail.com](mailto:directorsoffice@mtrh@gmail.com)

Nandi Road  
 P.O. Box 3 – 30100  
 ELDORET, KENYA

**Ref:** ELD/MTRH/R&P/10/2/V.2/2010

10<sup>th</sup> April, 2018

Dr. Ashiundu Edwin Miima,  
 Moi University,  
 School of Medicine,  
 P.O. Box 4606-30100,  
**ELDORET-KENYA.**

### APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:-

**"Urethral Stricture Treatment Outcome in Eldoret Kenya".**

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

**DR. WILSON K. ARUASA, MBS**  
**CHIEF EXECUTIVE OFFICER**  
**MOI TEACHING AND REFERRAL HOSPITAL**

cc - DCEO, (CS)  
 - Director of Nursing Services (DNS)  
 - HOD, HRISM

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*All correspondence should be addressed to the Chief Executive Officer  
 Visit our Website: [www.mtrh.go.ke](http://www.mtrh.go.ke)*

**A WORLD CLASS TEACHING AND REFERRAL HOSPITAL**

## APPENDIX V : IREC APPROVAL AMMENDMENT



MOTEACHING AND REFERRAL HOSPITAL  
P.O. BOX 3  
ELDORET  
Tel: 33471/2/3

## INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

Reference IREC/2017/232

**Approval Number: 0002094**

Dr. Ashiundu Edwin Miima,  
Moi University,  
School of Medicine,  
P.O. Box 4606-30100,  
**ELDORET-KENYA.**

Dear Dr. Ashiundu,

**RE: APPROVAL OF AMENDMENT**

The Institutional Research and Ethics Committee has reviewed the amendment made to your proposal titled:-

***"Urethral Stricture Treatment Outcome in Eldoret Kenya".***

We note that you are seeking to make an amendment as follows:-

- To add short questions in the questionnaires.

The amendment has been approved on 6<sup>th</sup> December, 2018 according to SOP's of IREC. You are therefore permitted to continue with your research.

You are required to submit progress(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change(s) or amendment(s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

**PROF. E. WERE**  
**CHAIRMAN**  
**INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE**

cc: CEO - MTRH      Dean - SPH      Dean - SOM  
Principal - CHS      Dean - SOD      Dean - SON



MOI UNIVERSITY  
COLLEGE OF HEALTH SCIENCES  
P.O. BOX 4606  
ELDORET  
Tel: 33471/2/3  
6<sup>th</sup> December, 2018



## APPENDIX VI :IREC APPROVAL AMMENDMENT



MOI TEACHING AND REFERRAL HOSPITAL  
P.O. BOX 3  
ELDORET  
Tel: 33471/2/3

Reference: IREC/2017/232  
**Approval Number: 0002094**

Dr. Ashiundu Edwin Miima  
Moi University,  
School of Medicine,  
P.O. Box 4606-30100,  
**ELDORET-KENYA.**



MOI UNIVERSITY  
COLLEGE OF HEALTH SCIENCES  
P.O. BOX 4606  
ELDORET  
Tel: 33471/2/3  
29<sup>th</sup> March, 2019



Dear Dr. Ashiundu,

### **RE: CONTINUING APPROVAL**

The Institutional Research and Ethics Committee has reviewed your request for continuing approval to your study titled:-

***"Urethral Stricture Treatment Outcome in Eldoret Kenya".***

Your proposal has been granted a Continuing Approval with effect from 29<sup>th</sup> March, 2019. You are therefore permitted to continue with your study.

Note that this approval is for 1 year; it will thus expire on 28<sup>th</sup> March, 2020. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

**DR. S. NYABERA**  
**CHAIRMAN**  
**INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE**

cc: CEO - MTRH  
Principal - CHS  
Dean - SOM  
Dean - SPH  
Dean - SOD

**Appendix VII: Budget**

<b>ITEM</b>	<b>AMOUNT (Kshs)</b>
<b>Stationery</b>	5,000
<b>Transport</b>	40,000
<b>Internet bundles</b>	10,000
<b>Airtime</b>	5,000
<b>Ethical approval</b>	3,000
<b>Data analysis</b>	30,000
<b>Typing, printing and binding</b>	30,000
<b>Miscellaneous</b>	15,000
<b>Total</b>	<b>138,000</b>

**Appendix VIII: Time frame**

<b>ACTIVITY</b>	<b>COMMENCEMENT</b>	<b>COMPLETION</b>
<b>Proposal development</b>	October 2016	March 2017
<b>Proposal writing</b>	March 2017	May 2017
<b>Proposal submission</b>	June 2017	February 2018
<b>Data collection</b>	March 2018	June 2019
<b>Data analysis</b>	July 2019	September 2019
<b>Thesis writing</b>	October 2019	November 2019
<b>Thesis submission and defense</b>	May 2020	October 2020