PATIENT REPORTED OUTCOME MEASURES FOLLOWING URETHROPLASTY IN KENYATTA NATIONAL HOSPITAL

A DISSERTATION SUBMITTED TO THE DEPARTMENT OF UROLOGY UNIVERSITY OF NAIROBI IN PARTIAL FULLFILMENT OF THE REQUIREMENTS FOR AWARD OF THE DEGREE MASTERS OF MEDICINE IN UROLOGY

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DECLARATION

I certify that this dissertation titled "Patient Reported Outcome Measures Following Urethroplasty In KNH" is my original work carried out under the guidance of my supervisors Dr. Francis Owillah and Dr. James Ikol and am completely responsible for the content of this dissertation.

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DEPARTMENTAL APPROVAL

This dissertation has been presented at the surgical department dissertation clinic on 10th October 2019 and is hereby approved for submission.

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DEDICATION

In the name of Allah the most gracious, the most merciful. This dissertation is dedicated to my parents, Hamara and Sheikh Ishaq, thank you both for the love and unconditional support to chase my dreams.

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To my wife and children, (Firdows, Mawadda and Abdulwadoud) who have provided the love, encouragement and support to see this dissertation to completion.

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LIST OF ABBREVIATIONS

UON …….University Of Nairobi

KNH ……..Kenyatta National Hospital

USD……Urethral Stricture Disease

PROM…….Patient Reported Outcome Measure

AUASI……American Urology Association Symptom Index

IPSS……International Prostate Symptom Score

LUTS……..Lower Urinary Tract Symptoms

TURP……Transurethral Resection of the Prostate

USSIM…….Urethral Stricture Symptom Impact Measure

USS-PROM……Urethral Stricture Surgery Patient Reported Outcome Measure

QOL…….....Quality of life

OPERATIONAL DEFINITIONS

Patient reported outcome measures (PROMs): set of questionnaire that the patient completes pre- and post-intervention to ascertain ifthe associated symptoms, daily function, processes, or quality of life are affected by the performance of a procedure, such as in this case, urethroplasty including DVIU and urethral dilatation.

Urethra: the channel by which urine is conveyed out of the body from the bladder.

Urethroplasty: is a repair of a defect or narrowing of the urethra with an aim of restoring adequate voiding. There are four main classes of urethroplasty performed; anastomotic urethroplasty, buccal mucosa graft urethroplasty, penile or scrotal skin graft urethroplasty, and Johansen's/staged urethroplasty in this study the term urethroplasty encompasses DVIU and urethral dilatation.

Short term: within the first six weeks post urethroplasty.

ABSTRACT

Background: patient reported outcomes in urethroplasty have become increasingly valuable in assessing success of urethroplasty and in postoperative monitoring. This study determines the status of patient reported outcomes after urethral reconstruction.

Objectives: to determine short term patient reported outcomes of urethroplasty at the Kenyatta National Hospital

Study Design: The study design applied in this study is an observational prospective study design.

Study sample:sample size will be calculated using krejcie formula with a sample size of 65 patients.

methodology: patients were sampled consecutively until the sample size was met Patient demographics, location of stricture, length of stricture and management offered were obtained. USS-PROM questionnaire was administered preoperatively and four weeks postoperatively.

Results. 64 patients completed the uss-proms questionnaire pre and post operatively with a mean age of 39.14 (SD 14.04). majority of the patients had bulbur urethral stricture (56.2%) followed by membranous. The etiology of urethral stricture in this group varied from trauma (57.8%), infections (14.1%), inflammatory (10.9%) and idiopatihic cause (0.2%). The patients were offered different forms of urethroplasty with excision primary anastomosis accounting for 56.7%, 23.3% underwent augmentation urethroplasty with buccal mucosal graft and 18.3% underwent DVIU.58 patients had post operative improvement improvement in their LUTS domain (mean difference of 0.32 to 2.87)and QOL domains (EQ-5D). 78% were either satisfied or very satisfied with the outcomes of urethroplasty. 14 patients(21.9)were not satisfied with the surgery, of this patients 7(53.8%)reported there was improvement in urinary symptoms but had developed other problems, 6 (46.2%) had no improvement in urinary symptoms.

Conclusion: uss-prom enables reliable assessment of men with urethral stricture disease, both pre and post operatively. Although majority of the patients (78%) reported improvement of their lower urinary tract symptoms and quality of life 14% were not satisfied. Dissatisfaction did not coorelate with the outcomes of surgery.

1.INTRODUCTION

Urethral stricture is characterized by the narrowing of the urethra because of the scar tissue of the tissue surrounding the urethra or the sub epithelial tissue of corpus spongiosum. This leads to obstructive and irritative voiding symptoms and can ultimately impair renal function. By agreement, the term urethral stricture is used in reference to the anterior urethra, while the terms stenosis or contracture are preferably used in reference to posterior urethral narrowing(1). The prevalence rate of this condition or disease in industrial countries is estimated to be at 0.9% (2). However, urethral stricture condition's prevalence rate in both emergent and developed countries is higher, with different patterns of presentation and causes. Dilatation of urethral strictures was described by Shusutra more than 600 years B.C(3). Urethral stricture disease continues to be a great burden on patients'wellbeing and quality of life (QOL). Indeed, the cost of treatment is also quite significant, placing a greater burden on the patients.

Treatment options for USD include endoscopic and open surgical techniques. Endoscopic management includes urethral dilatation or DVIU. Open reconstruction surgical techniques include urethroplasties which may be done in conjunction with graft of flaps. The management of USD has shifted from DVIU to now urethroplasty as a definitive procedure of choice(4).

1.1 QOL MEASUREMENT

Revicki and colleague defined quality of life as a broad range of human experience related to one's overall wellbeing. This therefore implies QOL is defined by subjective experiences perception and states (5).

There are various tools that measure quality of life in research and clinical setting. Examples of these tools are the medical outcome study short form health survey (sf-36)(6), sickness impact (sip)(7) quality wellbeing scale (QWB)(8) and WHOQOL(9)

Because of inherent biases within this tools, condition specific tools have been developed. Urethral stricture disease being a condition affecting quality of life, patients will seek medical care due to obstructive voiding symptoms such as hesitancy and straining making validated PROMS to evaluate urinary symptoms and patient satisfaction one of the most important tools in assessing success of urethroplasties.

Furthermore, PROMS are cheap, easily available and non-invasive making it one of the most important tools in assessing outcomes and recurrence in urethral stricture disease.

Traditionally success of urethroplasty was assessed by the need or absence of need of secondary procedure. Recent studies have shown that patient satisfaction and QOL changes should form the basis for assessing the levels of success of urethroplasties. Kessler and colleagues in a study conducted in 2002 assessed 267 consecutive patients who underwent urethroplasty 24 out of 30 (80%) in whom urethroplasty was considered a failure from physicians point of view were actually satisfied with the outcomes of urethroplasty(10). Thus it seems reasonable to use validated PROMS to evaluate patients' pre and post-operative symptoms and to screen for recurrence. Therefore, this study seeks to determine patient reported outcomes after urethroplasty at the Kenyatta National Hospital.

2.REVIEW OF LITERATURE

2.1 Aetiology

The aetiology of urethral strictures may be generally categorised into iatrogenic, traumatic, inflammatory and idiopathic. The most common causes of urethra strictures in developed countries are idiopathic and iatrogenic causes. While trauma is the commonest cause of strictures in developing countries. On the other hand, under iatrogenic causes, there are different medical processes, such as cystoscopy TURP, catheterization, and surgical procedures for hypospadias.

The Agency of Health Policy and Research (AHCPR) in their review of benign prostatic hypertrophy guidelines found a stricture rate of 3.1% following TURP (2).

The short sharp stricture which occurs in adolescent and young adults or youths at the intersection of the three parts of the urethra is believed to be congenital in origin. Such strictures are also attributable to incomplete rupture to the urogenital diaphragm, which is commonly referred to as Cobb’s collar or Morman's rings.

Injuries and damages to the urinary tract have been reported in approximately ten percent of patients with blunt or penetrating injuries (11). They are common in youths falling in the 15-25years age bracket. A few of these injuries occur to the urethra, among which 65% are complete tears while about 35% are partial tears (12). Anterior urethral injury may be caused by a penetrating or blunt injury. Blunt urethral trauma is caused by straddle or deceleration injury in which the relatively immobile bulbar urethra is compressed against the pubic bone. On the other hand, posterior urethral injuries are commonly attributable to pelvic fractures shear mechanisms, which occur when pelvic fracturescause a tear through the urethra at the bulbomembranous junction.

Inflammatory causes of urethral stricture include infectious and non-infectious causes or diseases. Recurrent gonococcal urethritis was historically responsible for the majority of urethral strictures. Neisseria gonorrhoea possess Pilli that enable it to attach to the urethra and cannot be cleared by urine flow because gonococci are internalised by urethral epithelial cells and then later transferred to phagocytic vacuoles where they multiply and evoke an inflammatory response. The advent of antibiotics has reduced incidents and prevalence of strictures. However, post-gonococcal stricturesare still common and are responsible for many incidences, occurrences of urethral strictures in some developing world nations.

Non-infectious inflammatory causes include lichens sclerosis previously known as balanitis xerotica obliterans also known as Lichens sclerosus. The cause is not completely elucidated but it's thought to be precipitated by infections, trauma or autoimmune processes. The spirochete borreliaburgdorferi has been implicated as a causative (13). Involvement of genitalia by lichens sclerosus causes itchiness, whitish skin, phimosis and paraphimosis while involvement of the urethra causes LUTS and stricture of meatus and entire urethra.

2.2 Management

Prior to management of urethral strictures location, length, severity and aetiology of stricture must be defined as these influences management. A number of approaches to management of urethral strictures that are minimally invasive techniques are available. They are commonly used for the management of meatal and bulbar strictures,which are less than 1 cm. For example, dilatation with balloon, serial axial dilators using the filiform and followers, cold knife incision, and incision with electro cautery or laser. Another approach to management of strictures is the Direct Vision Internal Urethrotomy (DVIU). DVIU is a form of endoscopic urethrotomy, in which the incision is made at 12 o'clock or 3 and 9 o'clock.

Urethroplasty provides a superior outcome for managing long strictures that are more than 2cm, an obliterated urethral lumen or stricture involving posterior or pendulous urethra. DVIU is a perfectly reasonable modality of management in patients that have a first time short bulbar urethra stricture. Approximately 50% of patients with the condition will be cured using this approach. However if the patient has previously undergone DVIU or dilation, but the stricture has recurred the instrumentation or use of the same intervention method will most certainly not be able to cure the patient (14, 15)

The contemporary urethral reconstruction surgery is premised on either an excision of the structure and therepair and restoration of continuity of the urethra by a spatulated, overlapping end-to-end anastomosis. However, this approach to the management and treatment of the strictures is used only when it is possible or whenthe reconstruction of the urethra by the use of graft or flaps when the former method is not appropriate or possible. Until recent years, most graft repairs in urethral stricture surgery used penile shaft skin (16). Split thickness graft "take" was good but the skin used or the penile shaft skin contract, which makes the same unsuitable for urethroplasty. On the other hand full thickness grafts do not contract; if the skin is thin and subdermal plexus is dense then the "take" is good(17). The reintroduction of buccal mucosal graft (BMG) in 1992 was a movement in the right direction because of the fact that BMG has

pan dermal plexus and other attributes including thick epithelium, thin lamina propria and minimal complications from harvesting sites thus making it ideal urethral reconstruction graft(18,19).

2.3 Definition of Successful Urethroplasty

Historically or conventionally, a successful urethroplasty was considered a situation where there was no need for secondary surgical procedure to correct any issues that could arise after urethroplasty. This approach to defining a successful urethroplasty was deemed appropriate and workable because the outcomes were observable or easy to quantitate using retrospective methodologies. However, there are many demerits of this conventional or traditional definition, such as patients not having a say in what should be considered a successful procedure or the lack of a criterial for conducting clinical assessment of the reconstructed urethra and flow of urine or voiding after the procedure. For example, there are patients who after the procedure, experience a lot of discomfort because of post-void dribbling attributable to the large calibre of the reconstructed urethra. In addition, the definition is defective because it works with the assumption that that a patient who experiences return symptoms will seek services at the same institution where he or she received initial urethroplasty. However, thinking about it, in essence, the patient may seek healthcare services elsewhere making it difficult to make follow-up as per the conventional definition (20).

Because of the aforementioned and described limitations of the traditional definition of successful urethroplasty, modern definitions of successful urethroplasty include both objective and subjective outcomes. Subjective outcomes used in follow-up of urethroplasty patients includes patient reported outcome measures (PROM). These are a set of questions in a questionnaire to which the patient provides responses to questions assessing pre and post-procedure patient experiences, including an assessment of any possible changes in symptoms, daily functions and quality of life because of the procedure (21). In line with this trend, several validated PROMs have been developed and used in surgical and non-surgical fields with an objective of recording patient perceived benefits from the implementation of an intervention, a gravitation and in line with patient-centred care.

Urethral stricture disease greatly affects the physical and emotional wellbeing of the patients who experience changes in voiding, sexual function, which lead to emotional consequences such as embarrassment, depression, and worry. Evidently, urethral stricture disease is a very complex disease or condition, with an increasing incidence and prevalence rate among the elderly, and as

observed above, majorly affects the patients' quality of life (QOL). In USD there are different types of PROMs including voiding, quality of life and sexual satisfaction PROMs. Many disease nonspecific PROMs have been used to assess the voiding challenges or issues that manifests as well as the sexual function of patients after surgery or urethroplasty procedures.

2.4 PROMs

Patient reported outcomes in urethral stricture disease provide a subjective assessment and functional outcomes of urethroplasty. Very few research studies have been conducted until presently, which have been aimed at specifically assessing patients' contentment with the outcomes, satisfaction, or dissatisfaction with the procedure. Patients' perspectives or patients' point of view, what they consider important, have unfortunately not been included in urethral reconstruction. It is only in recent times that attempts have been initiated in formulating or developing and implementing PROMS for urethral reconstruction. It has also been noted that in some cases, patients with a patent urethra, noted after the procedure, are not happy or satisfied with their surgical experience regardless of the fact that they maynot be having any challenges voiding.

2.4.1. VOIDING PROMS

Since the primary focus or objective of urethral reconstruction is to improve or mitigate voiding symptoms and QOL, urologists have increasingly become more interested and concerned withassessing and understanding patient's perception following urethroplasty. The objective of this approach is to integrate the patient satisfaction in the understanding of successful urethroplasty in the care delivery during the process. The increasing focus on patients' perspectives includes addressing aspects pertaining to the patients' experiences, quality of life, which could include assessing voiding quality, quality of sexual life, cosmetics, and pain; the overall and holistic patient experiences.

In literature reviewed, one of the first studies to validate the use of PROMs in USD was conducted by Morrey and colleagues. In the study, they used AUASI to evaluate the extent of the symptoms experienced by the patient and subsequently, determine the validity of this index as an outcome assessment tool for PROMs. In this study 9 out of 50 patients had a recurrence and none of these patients had significant improvement of their AUASI score. On the other hand, among patients without recurrence, recorded a decrease in their AUASI score from 27 to 5, which

implies that the AUASI score could be a useful and valuable screening tool or for screening purposes in such cases (22).

Similarly, Lemma et al, in their study, administered AUASI to 84 participants, or men with a rate of 70% recurrence of urethral stricture in 2 different occasions preoperatively. This group of participants was compared to 71 men who did not have any symptoms or who had not previously reported urethral strictures. There wasevidence of high reliability of AUASI with average score of 18 in urethral stricture group and 5.1 in group with no urethral stricture (23, 24).

However not all patient with recurrence of urethral stricture will be symptomatic. A study by Erickson and colleagues showed that some men with anatomical recurrence may not show any symptoms at all. In a study of 213 men, it was noted that only 13 of theparticipants with recurrence presented with symptoms, which implied that the use of PROM alone could miss recurrence in 1/3 of the urethroplasty patients (25).

In addition, limitations of the use of PROMs as the only screening tool were validated by Tam and colleagues. The findings of the study by Tam et al. which involved a comparison of the international prostate symptom score (IPSS) to cystoscopy findings, showed that the IPSS score was only fifty percent sensitive in detecting anatomical recurrence when using an IPSS score cut off of 10(26).

In 2002 Kessler et al assessed 203 patient who underwent urethroplasty. 24 out of 30 patients, or approximately 80% of the patients in whom urethroplasty was considered not considered a success from a specialist's point of view were satisfied or very satisfied with the outcome of surgical procedure. The researchers therefore concluded that what was important from a patient's was different from what was important from a surgeon's perspective. Therefore from the findings of the study, it was recommended that urethroplasty outcomes should be assessed from a subjective and objective criteria instead of using only an objective criteria (27).

The AUASI does not have content validity in USD and is thereforeis perceived as an incomplete PROM. Nus and colleagues evaluated this concern, and from their study, the ascertained and concluded that even though most common symptoms are captured in the tool, up to 21% of the patients' symptoms could not be captured in AUASI. The symptoms that were identified as not likely to be captured in AUASI were spraying of urine and dysuria (28). Such deficiencies or short-comings necessitated the development of a disease-specific PROM.

In another study, recognizing the importance of the development and use of a disease-specific PROMs, Jackson et al designed USD-specific PROM, the urethral stricture surgery PROM (USS-PROM), which includes six summative questions on lower urinary tract symptoms, and LUTS-related QOL questions and a voiding image capturing the voiding characteristics. These are followed by a five-item questionnaire made up of questions to evaluate QOL and two questions aimed at assessing the overall patient satisfaction and a visual analogue scale of health status. USS-PROM is the first validated disease-specific PROM; it has been validated at multiple institutions as established by the study by Jackson et al. (29).

Brayer and colleagues, in 2017, developed a urethral stricture specific PROM which is yet to be validated, the urethral stricture symptom impact measure (USSIM). In the process of developing these PROM, they interviewed clinicians and patients on what symptoms they considered important there was approximately 46% discordance (30). The findings of this study further illustrates that what the clinician considers as important may not necessarily be of concern to the patient and vice versa.

On the other hand, for QOL disease or condition factors,such as USD, in patient-centred focus, patient symptoms form the basis for the delivery of healthcare to patients. Patients with urethral stricture will strive to access care for the different symptoms that they experience, including obstructive voiding symptoms, characterized or taking the form of a weak stream and or hesitancy. Therefore, it is important and reasonable to integrate these aspects and use a validated PROMs to evaluate urinary symptoms that may manifest after the procedure.

Given that outcomes of urethroplasty are very subjective and beyond urethral patency as demonstrated from the studies evaluated thus far, patients may be dissatisfied with urethral reconstruction because of post-operative terminal dribbling and urine spraying following meatal reconstruction or numbness around the scrotum or even scrotalgia.

A standardised measure of subjective outcomes is essential. Bertrand and colleagues in 2016 demonstrated higher rates of the disease recurring on cystoscopy examinationof the bladder lining and urethra, and worse uroflow parameters. However on multivariate analysis, which involved PROM and objective clinical parameters and after making allowances for disease recurrence, as well as age persistence in voiding symptoms and post-procedure sexual dysfunction were the greatest independent factors of postoperative dissatisfaction. The study demonstrates that patient reported outcomes are more paramount drivers of overall patient

dissatisfaction/satisfaction and should therefore be integrated into any instrument or tool used to assess urethral reconstruction success (31).

On the other hand, Voelzke in his study concluded that USS-PROM is the only PROM that demonstrates enough psychometric values and is therefore regarded as being key towards using a condition specific PROM (32). However USS-PROM is not perfect; the questions were not generated de novo or premised on patient's word. There is also lack of uniformity among items and response choices with some choices varying from three to five responses. In addition other important factors or indicators of patients' QOL, such as sexual function and oral mucosa morbidity are not factored-in into this disease-specific PROM.

Table1: voiding PROMS

PROMS	publication	where	comments
AUA-SS	Barry et al 1992 (34)	United States of America (USA)	Not specific to USD initially developed for benign prostatic enlargement
CLSS	Homma et al 2008 (33)	Japan	Non-specific to USD addresses multiple urinary symptoms and has QOL component
Expert created	Kessler et al 2002 (27)	United States of America (USA)	Specific to USD assessing urinary and sexual symptoms also has QOL component
USS-PROM	Jackson et al 2011 (29)	United kingdom (Newcastle)	Specific USD has excellent psychometric parameters and validated
USSIM	Brayer et al 2017 (30)	United States of America (USA)	In process of validation, has significant patient input and QOL component

(AUA-SS American association of Urology Symptom score, CLSS Core Lower Urinary Tract Symptom Score,USS-PROM Urethral Stricture Surgery PROM, USSIM Urethral Stricture Symptoms and Impact Measure)

2.4.2 NON VOIDING PROMS

These PROMS mainly asses sexual function following urethropalsties and can be disease specific or disease non- specific. The first authors to assess sexual dysfunction after urethroplasty were coursey et al in 2001. They used a validated questionnaire designed by them to assess changes in erection penile length and angulation. They reported an average rate of 30% decrease in sexual satisfaction (35)

The well recognized International Index of Erectile function (IIEF) and its short form five item score (IIEF-5) have been used more commonly. These tools are validated and widely used to assess male sexual function. Anger et al in 2007 used the complete version of IIEF to assess sexual function before and after urethroplasty. He found no difference after six months of follow-up (36)

Erickson and colleagues used the short version of IIEF-5 to determine sexual function before and after different forms of urethroplasties, they noted 38% rate of sexual dysfunction post-urethroplasty (37).

Other PROMS used to assess sexual functions are Breif Male Sexual Function Inventory (BMSFI) and Mens Sexual Health Questionnaire (MSHQ). Erickson et al assessed sexual function using BMSFI and found an overall increase in ejaculatory function. In a subsequent study Erickson et al studied ejaculatory changes using seven questions of MSHQ. Overall changes in MSHQ scores was minimal (38).

Berbagli et al initially created a disease specific PROM for sexual function but non- validated. The PROM focussed on changes in ejaculatory function, changes in penile and glans sensation and overall satisfaction. The found 23% ejaculatory dysfunction (39).

The only validated disease specific sexual PROM in urethral stricture disease was reported by coursey et al this PROM focuses only on erectile function. In addition the PROM lacks reproducibility, responsiveness and construct validity (40)

2.5 Factors Associated With Poor PROMs

There is paucity of data and literature assessing factors associated with poor patient reported outcomes. Bertrand et al in 2016 assessed patient contentment after anterior urethroplasty using patient reported outcomes, and ascertained that postoperative satisfaction in men with cystocopic urethral stricture recurrence were more likely to report dissatisfaction. The study also revealed that in men with urethral or bladder pain, a postoperative decrease in sexual function and persistent LUTS were independent predictors of dissatisfaction (41).

In yet another study, Roehrborn and colleague analysed factors to which the success and failure of one stage urethroplasty for USD can be attributed and found that failure rate of urethroplasty doubled in a situation where the patient had previous manipulation for the stricture disease or if the urine was infected preoperatively despite antibiotic coverage (42).

Similarly, in their study, whose results provide an indication of the factors associated with PROMs, Marchal and colleagues analysed results and factors for success after Barbargli's dorsal urethroplasty. The results of their study indicated that variables like length of free graft, aetiology of stricture and type of graft used did not show any influence on outcome of surgery. On the other hand the location of the stricture on the bulbar urethra has shown better outcome than those operated on for structure located elsewhere. Patients reporting not having previous urethral surgery had a better chance of a successful procedure because the findings of the study indicated that 90% of patient without prior treatment had good functional outcome (43).

2.6 Study Justification/Rationale of the Study

Recent trends in medicine have shown a shift towards personalised choice of treatment and evaluation of outcomes, with a focus on the patient.

USS-PROM questionnaire has been validated (44,45,46) for patients undergoing urethral stricture surgical intervention to measure treatment success. There is scarcity of data in the use of PROMS, particularly focusing on the assessment of patient perceived symptoms and quality of life outcomes after urethral reconstruction.

Recent studies have shown the importance of patient reported outcomes. These outcomes are considered more important determinants of the overall patient satisfaction rate and should therefore forman integral part of any instrument or tool applied in assessing the success of the urethroplasty. The data collected from this study will help in counselling patients preoperatively on expected outcomes so as to reduce unnecessary anxiety by patients pot-operatively.

2.7 Broad Objective

To determine patient-reported outcomes measure score for Various Urethroplasties Conducted at the Kenyatta National Hospital?

2.8 Specific objectives

To assess the pre- and post-operative patient reported outcomes following urethroplasties in Kenyatta national hospital.

To compare mean patient reported symptom scores for different urethroplasty techniques in Kenyatta national hospital.

3.METHODOLOGY

3.1 Location of the Study

The study was conducted at the Kenyatta National Hospital (KNH)'s urology ward as well as the clinic. KNH is a 2000 bed capacity public tertiary, referral hospital located in the Upper Hill part of Nairobi. It's also a teaching hospital for the University of Nairobi's School of Medicine. It's one of the largest hospital in Central and East Africa. It serves a large catchment of approximately 3 million citizens. This makes it appropriate for the purpose of fulfilling the required sample size for this study.

Urology ward is located in 5^{th} floor at KNH in ward 5B it has a capacity of about 24 beds housing patient scheduled for both elective and emergency urological procedures. The ward also a doctors office where patients can have a quiet private talk with the health workers. This was the venue where the researcher informed the participant about the study and consent was taken.

3.2 Study Design

The study design that was used for this study is a hospital-based observational prospective study.

3.3 Sample Selection and Sample Size Determination

Kenyatta National Hospital records, point to an annual turnover of 80 Adults patients undergoing surgical intervention for urethral stricture. This study intends to utilize this indicative patient turnover as its population. The sample size is calculated using Krejcie formula[1] given its robustness in correcting for finite populations as follows;

$$S = \frac{Z^2 (1-\infty/2) \times NP (1-P)}{d^2 (N-1) + Z^2 (1-\infty/2) P (1-P)}$$

Where;

S = sample size to be determined

[1]

$Z^2(1-\infty/2)$ =is the standard error of the mean corresponding to a 95% confidence interval and the corresponding value from a t-table is 1.96.

N = *E*stimated population size (80)

P =is the expected prevalence of the event to occur. Value of P was 0.5

. *d* = is the target margin of error which will be 5 % (0.05) to increase precision.

Therefore, the sample size becomes:

$$s = \frac{1.96^{2\,x}\ 80 \times 0.5\ (1 - 0.5)}{0.05^2 \times 79 + 1.96^2 \times 0.5 \times 0.5}$$

Hence the desired sample size will be = 65 patients

3.3.1 Inclusion criteria

Adult patients from urology clinics in KNH and in the wards with urethral stricture confirmed by urethrogram and have indications for urethral reconstruction were selected and qualified for inclusion. Pateints selected for the study were adult patients undergoing surgical intervention for urethral stricture.

3.3.2 Exclusion criteria

Patients undergoing repeat/revision urethroplasty and patients undergoing staged urethroplasty or minors were not included in the study. Minors, being underage or having not achieved the majority age to make decisions that qualify them to provide reasonable and informed consent or legally agree to be included in the study, were excluded from the study. Females and patients with malignant urethral strictures were also excluded.

3.4 recruitment procedure

Patients with urethral stricture disease who were scheduled for urethroplasty and meeting the inclusion criteria were recruited from the ward before surgery. The researcher then explained the study to the participants and informed consent obtained this was done from the doctors room in the urology ward which offers a quiet and private environment. All discussions were done in a language that the participant best understands. These was followed by filling the preoperative PROMS then postoperative PROMS after removal of urethral catheter.

3.5 Study Procedure.

Consecutive non-random sampling was done to recruit patients pre-operatively. Preoperative assessment included taking patients' history, including demographic characteristics, stricture aetiology location, and extent of stricture. Participants were made aware of the purpose and nature, as well as the scope of the study. The researcher then discussed the consent with the study participants scheduled to undergo urethroplasty in KNH at the urology clinic or urology ward. The consent was then taken in a language which the participant best understands and in the event of a language barrier; a translator was used to translate the conversation between the researcher and the study participant. The researcher also ensured study participants understand the topic and intention of the study before the study participant agree or disagree to enrol into the study. Subsequently, the prospective participants, upon provision of a written consent was recruited into the study. Recruited participants then filled researcher administered questionnaire preoperatively and post operatively after removal of urethral catheter or at four weeks.

3.5.1 Data Collection

Data was collected preoperatively and four weeks postoperatively. Preoperative data collection will include patient demographics, stricture site, stricture aetiology, stricture length, LUTS questions, quality of life questions and sexual function. While postoperative questions included: management offered, LUTS questions, quality of life questions, satisfactions with operation. The frequency, proportions and mean scores of Proms was determined. The Student t test was used to compare the means and Chi Square was used to determine if there is association of the variables. A p-value <0.05 at 95 confidence interval will demonstrate statistical significance.

The data collection tool (USS-PROM) comprises of LUTS first six questions Q1-6 to generate a total score between 0 (asymptomatic) and 24 (most symptomatic) followed by LUTS specific QOL question and peeling voiding picture. The EQ-5D questions assess overall health related quality of life; each question in EQ-5D question is scored between 1 and 5 with total score of 25. These scores will then be used to calculate mean score for various urethroplasties pre- and post-operatively.

3.5.2 Quality Control

The principal investigator will recruit the patients himself, obtain informed written consent from the patients and in case of a language barrier, a translator will be invited to assist in the filling of

the questionnaire after the patient consents. The principal investigator will collect, countercheck and record the data himself.

3.5.3 Data Management

Data collected will have patient three initials and serial number so as to minimize participant identifiers. The collected data will be entered in Microsoft excel, the folder and computer will be password protected. Standards to protect personal data will be followed.

4.RESULTS

Data entry and analysis was done using SPSS version 23, Chicago Illinois. Pre and post-ostoperative changes in voiding symptoms and quality of life scores following urethropasty were recorded and the mean difference scores obtained. The mean age for the patients in the study was 39.14 (SD 14.04). A total of 30 (47.9%) of the pre-operative patients had either a urethral or suprapubic catheter. The site of the urethral stricture was assessed and presented in table 1. A majority of the patients, 36 (56.2%) had bulbar urethral strictures, followed by membranous urethral strictures, 11 (17.2%), penile 10 (15.6%), prostatic 6 (9.4%) and one bladder neck stricture (1.6%).

Table 1: The anatomical site for the stricture among patients with urethral strictures at the Kenyatta National Hospital (n=65)

Site of stricture	**Frequency**	**Percentage**
Bladder neck	1	1.6
Bulbar	36	56.2
Membranous	11	17.2
Penile	11	15.6
Prostatic	6	9.4

The etiology of the urethral strictures was assessed and presented as shown in table 2. Most of the strictures were as a result of trauma, 37 (57.8%). This was followed by infections 9 (14.1%), inflammatory causes 7 (10.9%), idiopathic 4 (6.2%) while other causes accounted for 8 (10.9%).

Table 2: Etiology of urethral strictures among patients at the Kenyatta National Hospital

Etiology	**Frequency**	**Percentage**
Trauma	37	57.8
Infections	9	14.1
Inflammatory	7	10.9
Idiopathic	4	6.2
Others	8	10.9

The patients underwent management of urethral stricture disease using different modalities as shown in table 3. A majority of the patients underwent Excision and Primary Anastomosis, 34 (56.7%), 14 (23.3%) had augmentation urethroplasty, 11 (18.3%) underwent DVIU while 1 (1.7%) underwent dilation.

Table 3: Management for the patients with urethral strictures at the Kenyatta National Hospital (n=65)

Management	Frequency	Percentage
Augmentation urethroplasty	14	23.3
Dilation	1	1.7
DVIU	11	18.3
EPA	39	56.7

The urethral strictures were assessed across the three domains of the USS-PROM. Table 4 shows the Male Lower Urinary Tract Symptoms (LUTS) domain, the pictorial domain and the EQ-5D scores comparing both the pre and post-operative outcomes.

Table 4: Lower Urinary Tract Symptoms (LUTS) domain, the pictorial domain and the EQ-5D scores comparing both the pre and post-operative outcomes.

Construct	LUTS domain	Pre-operative mean	Post-operative mean	Mean difference	95 % C I	P value
6 Q LUTs	Q1	3.90	1.03	2.87	2.48-3.26	<0.001
	Q2	3.46	0.33	3.13	2.81-3.45	<0.001
	Q3	3.35	0.97	2.38	2.10-2.67	<0.001
	Q4	2.05	0.56	1.49	1.17-1.83	<0.001
	Q5	2.54	1.00	1.54	1.27-1.81	<0.001
	Q6	0.65	0.33	0.32	0.01-0.64	<0.001
Peeling	Q8	3.70	1.60	2.1	1.80-2.42	<0.001
EQ-5D	Q9	1.20	1.08	0.12	0.01-0.26	0.071
	Q10	1.16	1.05	0.11	0.01-0.21	0.041
	Q11	1.31	1.08	0.23	0.09-0.38	0.002
	Q12	1.97	1.25	0.72	0.53-0.91	<0.001
	Q13	2.23	1.53	0.70	0.45-0.96	<0.001

In response to the question on how much the urinary symptoms interfered with life, most of the patients, 18 (48.1%) in the pre-operative period reported a lot of interference compared to zero

(0) who had no interference in the post-operative period. Thirteen (35.1%) of the patients in the pre-operative period somewhat experienced interference in their life while only 3 (4.8%) had interference in the post-operative period. These findings were statistically significant ($p<0.001$).

Table 5: Extend of interference of the urinary symptoms with life in the pre-operative and post-operative period

Variable	Pre-operative Period	Post-operative Period	P value
	Frequency (%)	Frequency (%)	
Not at all	01 (2.7)	15 (23.8)	
A little	05 (13.5)	45 (71.4)	<0.001
Somewhat	13 (35.1)	03 (4.8)	
A lot	18 (48.6)	0 (0)	

In the above the table only patients who did not have catheter (urethral or suprapubic) were assessed.

Furthermore, when analysed for satisfaction with the operation among patients who underwent urethroplasty at the Kenyatta National Hospital a majority of the patients, 28 (43.8%) were very satisfied with the outcome; 22 (33.4%) were satisfied while 14 (21.9%) were not satisfied as presented in table 5. .

Table 6: Level of satisfaction among patients who underwent surgery for urethral strictures at the Kenyatta National Hospital (n=65)

Variable	Frequency	Percentage
No unsatisfied	13	21.9
Yes, satisfied	24	33.4
Yes, very satisfied	28	43.8

Among the patients who were not satisfied, the reasons for lack of satisfaction were assessed and presented in table 7. Seven (53.8%) developed other related symptoms while 6 (46.2%) reported no improvement after the surgery.

Table 7: Reasons for lack of satisfaction among patients following urethroplasty (n=13)

Variable	Frequency	Percentage
No improvement post operatively	6	46.2
There was improvement though developed another problem	7	53.8

Figure 1 shows the mean difference in the LUTS scores, with pre-operative patients scoring of 2.66 and post-operative score of 0.77.

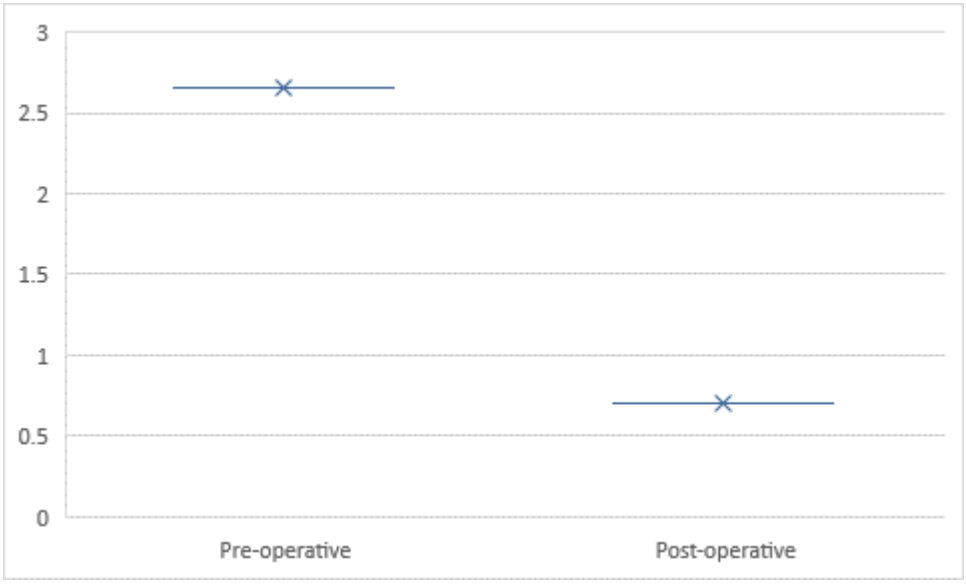

Figure 1: Pre versus Post-operative lower urinary tract symptoms scores (mean and 95% confidence intervals)

Figure 2 shows the mean difference in the strength of urination with pre-operative patients scoring of 3.35 and post-operative score of 0.97.

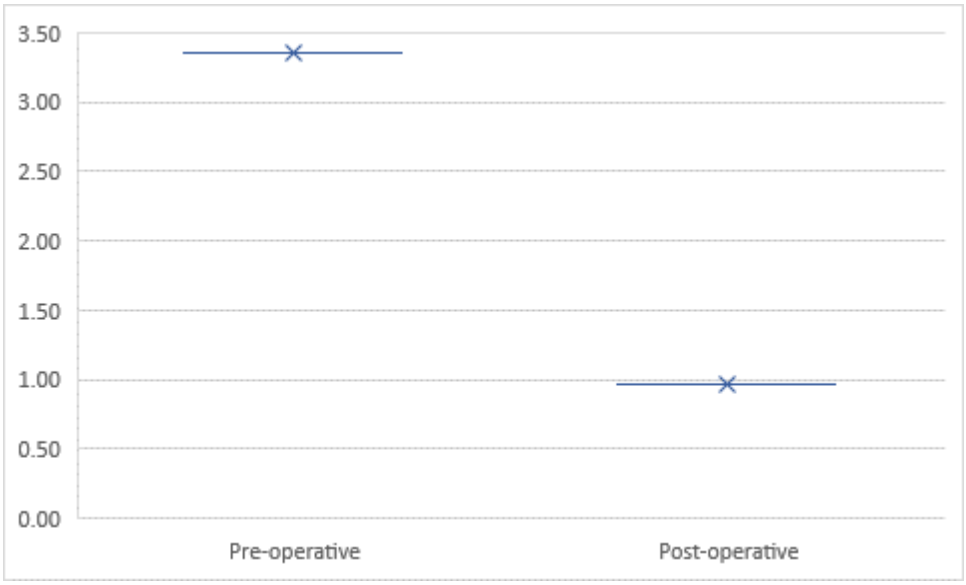

Figure 2: Pre and post-operative mean picture scores for the strength of urination (mean and 95% Confidence interval)

Figure 3 shows the mean difference in the EQ-5D visual analogue scores, with pre-operative patients scoring of 1.57 and post-operative score of 1.2.

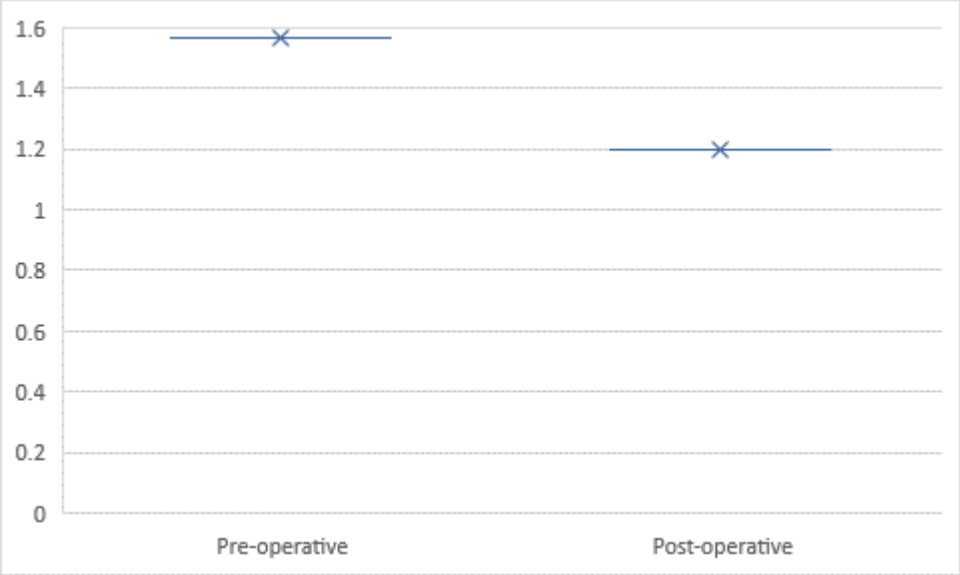

Figure 3: Pre versus Post-operative mean EQ-5D visual analogue scores (mean and 95% confidence interval)

A one-way ANOVA was conducted to determine if the quality of life measures was different across the different treatment modalities for urethroplasty. Participants were classified into four groups based on the surgeries done: Augmentation urethroplasty (n = 14), urethral dilation (n = 1), DVIU (n =11) and EPA (n = 34). There were no outliers, as assessed by boxplot. Data is presented as mean ± standard deviation. The EQ-5D score was not statistically significantly different between different groups, as show in the table below ($p>0.05$).

Table 8: ANOVA test to determine the difference in means for the different types of urtheroplasty among patients with urethral strictures at the Kenyatta National Hospital

		Sum of Squares	df	Mean Square	F	Sig.
Mobility	Between Groups	.383	3	.128	.697	.558
	Within Groups	9.893	54	.183		
	Total	10.276	57			
Self-care	Between Groups	.135	3	.045	.325	.807
	Within Groups	7.469	54	.138		
	Total	7.603	57			
Usual activities	Between Groups	.437	3	.146	.679	.569
	Within Groups	11.580	54	.214		
	Total	12.017	57			
Pain/ Discomfort	Between Groups	1.090	3	.363	.821	.488
	Within Groups	23.893	54	.442		
	Total	24.983	57			
Anxiety/Depression	Between Groups	4.113	3	1.371	2.352	.082
	Within Groups	31.473	54	.583		
	Total	35.586	57			

CHAPTER FIVE: DISCUSSION

Interventions targeting urethral strictures aim to improve symptoms and reduce risk of recurrence. Their success should be measured in transparent and transferable terms that testify to the benefit conferred to an individual patient and allow comparisons of clinical and cost effectiveness between surgeons, competing surgical procedures, and health care providers [2]. The basic tool used in the follow-up is the measurement of Qmax [8]. However, the limit value of Qmax has not been set, hence necessitatin the use of other tools such as the USS-PROM [3]. In our study, a total of 65 patients with urethral strictures with a mean age of 39.14 (SD 14.04) were reviewed.

Most of the strictures were as a result of trauma, 37 (57.8%), by infections 9 (14.1%), inflammatory causes 7 (10.9%), idiopathic 4 (6.2%) while other causes accounted for 7 (10.9%). Our findings are comparable to study done by Morey et al, where of the 12 bulbar strictures, 9 (75%), external urethral trauma (n=16%), or iatrogenic (n=1, 9%). Etiology of penile strictures was lichen sclerosus (n=2), hypospadias failure (n=1), and iatrogenic (n=1). Similary, in a study by Mugalo et al. 51% were due to urethritis, 47% were due to trauma and 1.8% due to rare causes like uethral diverticulum and uethral carcinoma.

A majority of the patients, 36 (56.2%) had bulbar strictures, followed by membranous strictures, 11 (17.2%), penile 10 (15.6%), prostatic 6 (9.4%) and one bladder neck strictures (1.6%). This findings are comparable to the findings in a study by McAninch in 2004 where bulbar strictures were 53%, penile wee 36% while membranous were 11% (22).

While several advances have been made towards the management of patients with urethral strictures, our study findings indicate that a majority of the patients, 34 (56.7%) underwent

Excision and Primary Anastomosis, 14 (23.3%) underwent augmentation urethroplasty, 11 (18.3%) underwent DVIU while 1 (1.7%) underwent dilation. These findings contrast with those of a study done by Jenkinson et al, where 45% of the surgeries were end to end, 20% were oral mucosal graft, 17% were penile skin, Johansen had 15% while Mesh graft was 3%.

The LUTS score improved significantly from a mean of 3.31 before the surgery to 0.97 postoperatively (chi square = 6.84, p = 0.02). Additionally, the means for all the individual measures of LUTs were significantly different ($p<0.001$) between them. Except for one domain in the EQ-5D assessment, all the other parameters also had a statistically different mean between the pre and post-operative period. Similar findings were noted in a study done by Jackson in 2011(29) where the LUTS score improved significantly from a median of 21 before surgery to 7 postoperatively ($\chi 2$ ANOVA = 8.95, p = 0.03) using a Polish tool, similar to what was used in this study.

Total LUTS scores decreased from a median (mean) of 12 (11.8) preoperatively to 1 (3.0) postoperatively ($p < 0.0001$; 95% CI, 6.8–11.5). Peeling's stream picture scores followed a similar pattern: median (mean) scores fell from 4 (3.7) preoperatively to 2 (1.8) postoperatively ($p < 0.0001$, 95% CI, 1.3–2.1). These figures corroborate with one scale point improvement in the Likert type condition-specific QoL question in 37 of 49 men (76%) (cite).

In the same study, EQ-5D visual analogue scores improved from a preoperative mean of 80 (71) to 90 (81) postoperatively (p = 0.0006; 95% CI of the mean of difference, 4–14; Table 3 and Fig. 5). EQ-5D time trade-off (TTO) scores were calculated from UK-weighted value sets corresponding to one of 243 possible five-digit health states generated by EQ-5D.

Following urethroplasty, TTO scores improved from a mean of 0.77 preoperatively to 0.87 postoperatively (p = 0.003; 95% CI of the mean of the difference, 0.04–0.18).

Lastly, our study findings demonstrate no difference in the patients' perception following the different types of surgery for uretral strictures.

Study Limitations

Our more restricted approach, comprising semistructured interviews with patients and clinicians together with quantification of changes following urethroplasty. A potential drawback in this approach is neglecting other causes of voiding symptoms, such as benign prostatic enlargement (BPE), when they coexist with a urethral stricture.

We conducted our study on a relatively heterogeneous group of patients with stricture located in the bulbar, penile or membranous urethra, subjected to various urethroplasty techniques. However, it is not dedicated to patients with urethral strictures and does not allow for a full evaluation of the urethroplasty result. As demonstrated by Nuss, up to 21% of patients show symptoms that are not detected by IPSS before the urethroplasty [11].

One of the essential weaknesses of the questionnaire is the lack of questions addressing the aesthetic changes of the genitals and the impact on sexual life and relationships as mentioned by Verla et al. [10]. It should be pointed out that urethral stricture is the leading cause of difficulty in voiding in younger and middle-aged men. For this group, sexual dysfunction is a concern of particular importance. The USS-PROM also does not evaluate ejaculation disorders that affect up to 85% of patients with urethral strictures and may persist after the procedure, despite a successful reconstruction of the urethra [15].

Conclusion

The USS-PROM tool is versatility with the possibility of its application in different patient populations, regardless of cultural differences. The questionnaire enables reliable assessment of men with urethral stricture, both before and after surgery, and may be a valuable tool for researchers and clinicians. In addition, our study findings failed to demonstrate any differences in the patients' quality of life after the different surgical interventions for urethroplasty.

Recommendations

Wide-scale deployment of this PROM within and without KNH will allow stratification of outcomes according to a spectrum of factors including but not limited to patient age, comorbidity, and body mass index; stricture length and location; and surgical competence. The performance of this PROM in the context of various interventions such as urethrotomy and other types of urethroplasty deserves further assessment for symptomatic and clinical outcomes in men undergoing urethroplasty.

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APPENDICES

APPENDIX ONE: DEMOGRAPHICS INFORMATION COLLECTION INSTRUMENT

Patient demographics:

Age:

Currently on urethral or suprapubic catheter

☐Yes

☐No

Site of stricture:

☐Meatus

☐Penile

☐Bulbar

☐Membranous

☐Prostatic

☐Bladder neck

Aetiology of stricture:

☐Trauma

☐Infections

☐Inflammatory

☐Idiopathic

☐Others

Management offered:

☐Dilatation

☐DVIU

☐EPA

☐Augmentation urethroplasty

APPENDIX TWO:URETHRAL STRICTURE SURGERY PATIENT REPORTED OUTCOME MEASURE QUESTIONNAIRE

1 Is there a delay before you start to urinate?

☐Never

☐Occasionally

☐Sometimes

☐Most of the time

☐All of the time

2 Would you say that the strength of your urinary stream is…

☐Normal

☐Occasionally reduced

☐Sometimes reduced

☐Reduced most of the time

☐Reduced all of the time

3 Do you have to strain to continue urinating?

☐Never

☐Occasionally

☐Sometimes

☐Most of the time

☐All of the time

4 Do you stop and start more than once while you urinate?

☐Never

☐Occasionally

☐Sometimes

☐Most of the time

☐All of the time

5 How often do you feel your bladder has not emptied properly after you have urinated?

☐Never

☐Occasionally

☐Sometimes

☐Most of the time

☐All of the time

6 How often have you had a slight wetting of your pants a few minutes after you had

☐finished urinating and had dressed yourself?

☐Never

☐Occasionally

☐Sometimes

☐Most of the time

☐All of the time

7 Overall, how much do your urinary symptoms interfere with your life?

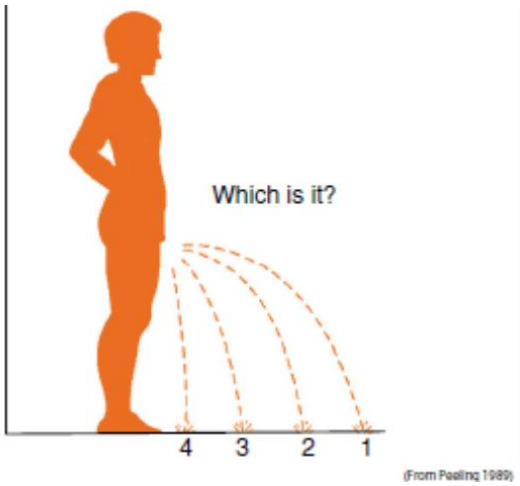
☐Not at all

☐A little

☐Somewhat

☐A lot

8 Please ring the number that corresponds with the strength of your urinary stream over the past month.



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

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

☐I have no problems in walking about

☐I have some problems in walking about

☐I am confined to bed

Self-Care

☐I have no problems with self-care

☐I have some problems washing or dressing myself

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

☐I have no problems with performing my usual activities

☐I have some problems with performing my usual activities

☐I am unable to perform my usual activities

Pain/Discomfort

☐I have no pain or discomfort

☐I have moderate pain or discomfort

☐I have extreme pain or discomfort

Anxiety/Depression

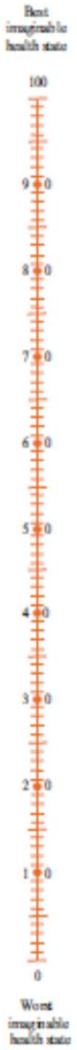
☐I am not anxious or depressed

☐I am moderately anxious or depressed

☐I am extremely anxious or depressed

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0. We would like you to indicate on this scale how good or bad your own

health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.



APPENDIX III - CONSENT FORM

ENGLISH VERSION

This is a form designed to seek the informed consent of individuals recruited to participate in the study. Individuals aged 18 years and above will expressly provide their consent to participate in the study. The parents/guardian/next of kin of individuals or children who have not attained the majority or legal age, will provide consent for the minors to be included in the study.

Title of the Study

The title of the study is:

'Patient-Reported Outcomes following urethroplasty in Kenyatta National Hospital'

Principal Investigator

Dr. Issack Abdullahi Sheikh

Institution: School of Medicine, Department of Urology, University of Nairobi

Supervisors

1. Dr. Francis Owilla
2. Dr. Ikol A. James

Invitation to Participate in the Study

My name is Dr. Issack Abdullahi Sheikh, a Postgraduate student at the School of Medicine, University of Nairobi. I am conducting a research study titled '*patient reported outcome measures following urethroplasty.*' I am inviting you to participate in this research study. However, before you decide to participate, it is important that you understand why the research is being conducted and what it entails. Kindly read the following information carefully and ask the researcher any questions or clarifications where you need more information. Participation is purely voluntary, and you are allowed to consent either immediately after getting this information or after a period of consultation.

Please read the information provided carefully and feel free to ask questions or seek clarification from the researcher or any other doctor of your choice if you need

additional information about this study. Upon providing your consent, you will be recruited into the study. If you consent to participate in the study, you will be recruited into the study consecutively. Within the course of the study, personal information, information about your condition, and other relevant information will be sort and collected for research purposes only. The information will be handled with utmost confidentiality. The information will only be accessed by the researcher and any other person authorized to do so by the KNH/UON ethics and research committee. All personal identifiable information (PIN) will be coded to protect your identity. All notes, interview transcriptions, and any other information will be kept in a locked file cabinet, and any electronically collected PIN will be stored in a password protected personal computer and external storage devices.

Study Procedure

Upon recruitment, participation in the study will be through clinical interviews, a review and recording of imaging and operative findings, as well as other information that will be important in the completion of this study. As mentioned earlier, participation is voluntary and you may choose to withdraw from the study at any stage, and such a decision and action will not affect how you access treatment and other healthcare services in this hospital or institution.

Benefit(s)

There will be no direct benefit to you for your participation in this study. However, as a participant in this study, you will make immense contributions towards the development of the knowledge and understanding of the condition that will benefit healthcare practitioners locally, regionally, and globally, particularly in understanding the condition. Such an understanding will foster the achievement of evidence-based care patient' management objectives. There will be no remuneration or financial benefits to you for participating in this study.

Risk(s)

There are no additional risks to you as a result of your involvement or participation in this study. All the general protocols of anaesthesia and other applicable surgical principles, professional ethics and conduct will be observed and adhered to at all times during the study to minimize and if possible to eliminate any risks that may result from your involvement in this study.

This study proposal has been reviewed and approved by the KNH/UON ERC which is a body that ensures the protection of persons like yourself that take part in research studies.

This approval has been granted after the submission of the study proposal to the committee by the Chairman of the Department of Surgery, School of Medicine of the University of Nairobi with the approval of my University and Kenyatta National Hospital supervisors.

In the very event that you require any additional information or for any other purpose regarding this study, relevant contact details are listed below:

1. Dr Issack Abdullahi Sheikh
   Department of Urology
   School of Medicine
   University of Nairobi
   Tel no: 0726914444
2. Dr Francis Owilla
   Department of Surgery
   School of Medicine
   University of Nairobi
   P.O. Box 19676
   KNH, Nairobi
   Tel no: 0714788856
3. The Secretary
   KNH/UON Ethics and Research Committee (ERC)
   Tel no: +2542726300-19 Ext.44102
   P O BOX 20723-00202, Nairobi, Kenya
   Email: uonknh_erc@uonbi.ac.ke
4. Dr. Ikol A, James
   KNH Research and Programs Department
   Kenyatta National Hospital
   Tel: 0722750042

CONSENT CERTIFICATE

I……., out of my own free will, give consent of myself /my proxy…… to take part in this research study carried out by Dr. Issack Abdullahi Sheikh, the nature of which has explained to me. I also understand and acknowledge that my participation in the study is purely voluntary. I understand that I am free to withdraw this study consent, and subsequently, from the study, at any time. I also understand that withdrawing my consent, and subsequently, from the study, will not affect the quality of care given to myself/my proxy at the Kenyatta National Hospital.

Signature of participant/Guardian/Next of kin……

Date……

Left thumbprint if participant illiterate (witness to countersign)

I certify that the above consent has been freely given in my presence

Witness Name…….

Witness Signature……..

Date…….

Left thumbprint if the witness is illiterate)

STATEMENT BY THE RESEARCHER

I, Dr. Issack Abdullahi Sheikh, confirm that the information relating to this study as contained in the information sheet has been accurately read to the participant. I confirm that I have ensured that the participant understand the content. The participant understands that:

1. Declining to provide his or her consent or otherwise participate in this study will not affect the quality of care offered at this institution
2. All information provided by the participant will be treated with strict confidentiality.
3. The findings, and subsequently, the conclusions and inferences drawn thereof, may be used to influence local, regional and global clinical practice of patients undergoing the procedure, urethral stricture.

I further confirm that the participant has been allowed to consult and seek clarification of all aspects of this study and that he/she has freely and willingly given consent to participate in the study. The participant has also been provided with a copy of the informed consent form.

Name of researcher ……

Signature…….

Date…….

KISWAHILI VERSION

Jina langu ni Dkt. Issack Abdullahi Sheikh, mwanafunzi wa Uzamili katika Shule ya Tiba, Chuo Kikuu cha Nairobi. Ninafanya utafiti uliopewa jina la '*Patient-Reported Outcomes following urethroplasty in Kenyatta National Hospital*.' Ninakualika kushiriki katika utafiti huu. Walakini, kabla ya kuamua kushiriki, ni muhimu kuelewa ni kwa nini utafiti unafanywa na nini unajumuisha. Soma kwa uangalifu habari ifuatayo na uulize mtafiti maswali yoyote au ufafanuzi mahali unahitaji habari zaidi. Ushiriki ni hiari, na unaruhusiwa ukubali mara moja baada ya kupata habari hii au baada ya kipindi cha mashauriano.

Tafadhali soma habari iliyotolewa kwa uangalifu na jisikie huru kuuliza maswali au utafute ufafanuzi kutoka kwa mtafiti au daktari mwingine wowote wa chaguo lako ikiwa unahitaji ufafanuzi au ikiwa unahitaji maelezo ya ziada juu ya utafiti huu. Baada ya kutoa idhini yako, utaandikishwa kwenye utafiti. Ikiwa utakubali kushiriki katika utafiti, utaandikishwa katika masomo mfululizo. Katika kipindi cha masomo, habari ya kibinafsi, habari kuhusu hali yako, na habari nyingine muhimu zitatungwa na kukusanywa kwa sababu za utafiti tu. Habari hiyo itashughulikiwa na usiri mkubwa. Habari hiyo itapatikana tu na mtafiti na mtu mwingine yeyote aliyeidhinishwa kufanya hivyo na kamati ya maadili ya KNH / UON na utafiti.

Maelezo yote ya kibinafsi yanayotambulika (PIN) yatatambuliwa ili kulinda utambulisho wako. Vidokezo vyote, maandishi ya mahojiano, na habari nyingine yoyote itahifadhiwa kwenye chumba kidogo cha kuhifahdi faili kilichofungwa, na PIN yoyote iliyokusanywa kwa njia ya elektroniki itahifadhiwa kwenye nywila iliyohifadhiwa ya kompyuta ya kibinafsi na vifaa vya nje vya kuhifadhi.

Utaratibu wa Utafiti

Baada ya kuajiri, ushiriki katika utafiti utakuwa kupitia mahojiano ya kliniki, hakiki na rekodi ya matokeo ya utaftaji na kazi, na pia habari nyingine ambayo itakuwa muhimu katika kukamilisha utafiti huu. Kama ilivyotajwa hapo awali, ushiriki ni wa hiari na unaweza kuchagua kujiondoa kwenye masomo katika hatua yoyote, na uamuzi na hatua kama hiyo haitaathiri jinsi unavyopata matibabu na huduma zingine za afya katika hospitali hii au taasisi hii.

Faida

Hautakuwa na faida yoyote moja kwa moja kwako kwa ushiriki wako katika utafiti huu. Walakini, kama mshiriki wa utafiti huu, utatoa michango mikubwa kuelekea ukuzaji wa maarifa na uelewa wa hali ambayo itanufaisha watendaji wa huduma za afya ndani, mkoa, na kimataifa, haswa katika kuelewa hali hiyo. Uelewa kama huu utakuza kufanikiwa kwa madhumuni ya usimamizi wa mgonjwa wa huduma ya wagonjwa. Hakutakuwa na malipo yoyote au faida za kifedha kwako kwa kushiriki katika utafiti huu.

Hatari

Hakuna hatari za ziada kwako kwa sababu ya kuhusika kwako au ushiriki katika utafiti huu. Itifaki zote za jumla za anesthesia na kanuni zingine zinazotumika za upasuaji, maadili ya kitaaluma na mwenendo zitazingatiwa na kuzingatiwa wakati wote wakati wa masomo ili kupunguza na ikiwezekana kuondoa hatari zozote zitakazotokana na kuhusika kwako katika utafiti huu.

Pendekezo hili la uchunguzi limepitiwa na kupitishwa na KNH / UON ERC ambayo ni mwili ambao unahakikisha ulinzi wa watu kama wewe ambao hushiriki katika masomo ya utafiti. Idhini hii imepewa baada ya kuwasilisha ombi la uchunguzi kwa kamati na Mwenyekiti wa Idara ya upasuaji, Shule ya Tiba ya Chuo Kikuu cha Nairobi kwa idhini ya wasimamizi wangu wa Chuo Kikuu cha Kitaifa na Wakenya.Katika tukio ambalo unahitaji habari yoyote ya ziada au

kwa sababu nyingine yoyote kuhusu utafiti huu, maelezo muhimu ya mawasiliano yameorodheshwa hapa chini:

1. Dr IssackAbdullahi Sheikh

   Department of Urology

   School of Medicine

   University of Nairobi

   Tel no: 0726914444

2. Dr Francis Owilla

   Department of Surgery

   School of Medicine

   University of Nairobi

   P.O. Box 19676

   KNH, Nairobi

   Tel no:071478856

3. The Secretary

   KNH/UON Ethics and Research Committee (ERC)

   Tel no: +2542726300-19 Ext.44102

   P O BOX 20723-00202, Nairobi, Kenya

   Email: uonknh_erc@uonbi.ac.ke

4. Dr.Ikol A, James

   KNH Research and Programs Department

   Kenyatta National Hospital

   Tel: 0722750042

Sehemu ya Pili; Cheti cha Idhini

Mimi, …… .., kwa hiari yangu mwenyewe, nape ridhaa yangu / proksi yangu …… …… kuchukua sehemu ya utafiti huu uliofanywa na Dk. Issack Abdullahi Sheikh, hali ambayo imenielezea. Ninaelewa na ninakubali kuwa ushiriki wangu katika utafiti ni wa hiari. Ninaelewa kuwa niko huru kuondoa idhini hii ya kusoma, na baadaye, kutoka kwa masomo, wakati wowote. Ninaelewa pia kuwa kuondoa idhini yangu, na baadaye, kutoka kwa utafiti huo, haitaathiri ubora wa huduma niliyopewa mwenyewe / wakala wangu katika Hospitali ya Kitaifa ya Kenyatta.

Jina la mgonjwa/Msimamiziwamgonjwa……

Sahihi……

Tarehe……

Alama yakidole gumba cha kushoto(mgonjwa asiyejua kuandika)

Nimeshuhudiayakwambaidhiniyamhusikaimetolewakwahiariyakemwenyewe

Jina la shahidi……..

Sahihiyashahidi……

Tarehe……

Alama ya kidole gumba cha kushoto(shahid iasiyeju akuandika)

Sehemu ya Tatu: Idhibati ya Mtafiti Mkuu

Mimi, Dk Issack Abdullahi Sheikh, ninathibitisha kwamba habari inayohusiana na utafiti huu kama ilivyo kwenye karatasi ya habari imesomwa kwa usahihi kwa mshiriki. Ninathibitisha kuwa nimehakikisha kuwa mshiriki anaelewa yaliyomo. Mshiriki anaelewa kuwa:

1. Kuamua kutoa idhini yake au vinginevyo kushiriki katika utafiti huu hakuathiri ubora wa utunzaji unaotolewa katika taasisi hii
2. Habari zote zinazotolewa na mshiriki zitatibiwa kwa usiri kali.
3. Matokeo, na mwishowe, hitimisho na uvumbuzi unaoletwa, zinaweza kutumiwa kushawishi mazoezi ya kliniki ya kitaifa na ya kimataifa ya wagonjwa wanaochukua utaratibu, urethral.

Ninathibitisha zaidi kwamba mshiriki ameruhusiwa kushauriana na kutafuta ufafanuzi wa nyanja zote za utafiti huu na kwamba ameruhusu kwa hiari na kwa hiari kushiriki kushiriki katika utafiti. Mshiriki pia amepewa nakala ya fomu ya idhini iliyoelimishwa.

Jina la mtafiti ……

Sahihi…….

Tarehe…….