WOULD UTILIZATION OF URETHRAL STRICTURE SCORE (U-SCORE) PREDICT THE OUTCOME OF PATIENTS UNDERGOING ANTERIOR URETHROPLASTY AT MUHIMBILI NATIONAL HOSPITAL?

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Department of Surgery

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By

Salim Ngunduly Sobbo

A Dissertation Submitted in (Partial) Fulfillment of the Requirement for the Degree of Master of Medicine (Urology) of

Muhimbili University of Health and Allied Sciences
October, 2024

CERTIFICATION

The undersigned certifies that they have read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled; **''Would utilization of Urethral stricture score (U-score) predict outcome for the patients undergoing anterior urethroplasty at Muhimbili National Hospital'',** in (partial) fulfillment of the requirements for the degree of Master of Medicine (Urology) of Muhimbili University of Health and Allied Sciences.

_____

Prof. Charles Mkony

(Supervisor)

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Date

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Dr. Fransia A. Mushi

(Co-Supervisor)

_____

Date

DECLARATION AND COPYRIGHT

I, **Salim Ngunduly Sobbo**, declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other University for similar or any other degree award.

Signature …… **Date** …….

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My family has been the greatest source of inspiration throughout this period. My story would be incomplete without appreciating your special place in me. Thank you very much.

DEDICATION

I would like to dedicate this dissertation to my esteemed family, Tamrina, my wife and our adorable Son, Sultan. Also to my parents Col. Dr. (Rtd) N. A Sobbo and Mwajuma Sobbo without forgetting my siblings Abdallah, Nicole- Clare, Myra, Ngondae, Kassoro and Hadija for their sacrifice and devotion towards my academic endeavors.

ABSTRACT

Background: Urethral stricture is a common condition, with a higher incidence in developing countries(1). A large variety of surgical procedures have been developed for the treatment of anterior urethral strictures; one tool that is used to determine the type of surgery needed for different stricture patients is called the Urethral Stricture Score (U-SCORE). The U-SCORE utilizes the stricture's length, location, number (of), and aetiology to define and quantify its attributes, enabling preoperative prediction of the required surgery's complexity and treatment outcome.

At MNH, there have been a large number of patients presenting with urethral strictures with different aetiologies, mostly due to a traumatic, iatrogenic, or infective nature. Urethroplasty is one of the most common operations performed at MNH. The paediatric surgery unit and the department of urology performed 65 anterior urethral stricture repairs (urethroplasty) from January 2022 to October 2022, with patients ranging in age from 5 to 97 years. In current MNH practice, there is no formal method of grading stricture complexity to guide the choice of surgical intervention and predict the urethroplasty outcome. This study aimed to assess the surgical complexity and outcome of anterior urethral stricture repair using the U-Score for MNH patients.

Aim: To evaluate the surgical complexity and outcome of anterior urethral stricture repair using the U-Score for patients undergoing anterior urethroplasty at Muhimbili National Hospital.

Methodology: We conducted a retrospective cross-sectional study, reviewing patient records from January 2018 to December 2022, which included patients diagnosed with anterior urethral stricture who underwent anterior urethroplasty at MNH. We extracted the length, location, number, and aetiology of the stricture from patients' records, and assessed the duration of hospital stay, surgical complexity, and postoperative complications as outcomes of interest. We calculated the U-score, performed an association between the U-score and the outcome of interest using the chi-square test, and assessed the adjusted predictor variable effect using logistic regression.

Results: We retrieved 184 patient files, of which 179 (97%) met all inclusion criteria. The median age was 51 ± 19.8 years. Patients with co-morbidities were 36 (20.2%), among which 8.4% had hypertension, 6.7% had more than one comorbidity, 3.4% were seroconverted patients (AIDS), and 1.7% had diabetes mellitus.

There were 165 patients with a low U-score, while 14 patients had a high U-score. However, 167 patients underwent low-complexity urethroplasty (EPA, BMG, and augmented anterior urethroplasty) with a mean U-score of 4.7, while 12 patients underwent high-complexity urethroplasty (double buccal mucosal graft, flap, and graft/flap combination) with a mean score of 7.1. Two patients with a high U-score underwent low-complexity urethroplasty. A higher U-score was predictive of higher surgical complexity (P value < 0.05). Also, high U-score was significantly associated with early postoperative complications, as there was a consistent increase in the risk of developing early postoperative complications with each additional U-score point.

Conclusion: We report an association between a higher U-score and anterior urethroplasty outcomes, indicating a substantial influence of the U-score on its predictive capacity for surgical complexity and postoperative complications for patients with anterior urethral stricture. Therefore, the U-score can aid in risk stratification and perioperative counselling.

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LIST OF ABRREVIATIONS

AAU	Augmented Anastomotic Urethroplasty
BMG	Buccal Mucosa Grafting
EPA	Excision and Primary Anastomosis
KCMC	Kilimanjaro Christian Medical Centre
MMed	Masters of Medicine
MNH	Muhimbili National Hospital
MUHAS	Muhimbili University of Health and Allied Sciences
PVR	Postvoid urine residual
RUG	Retrograde urethrogram
SPC	Suprapubic cystostomy
SPSS	Statistical Package for Social Sciences
TURNS	Trauma and Urethral Reconstruction Network of Surgeons
U-SCORE	Urethral Stricture Score
VCUG	Voiding Cystourethrogram

DEFINITION OF TERMS

Anterior male urethra: - consists of the meatus, fossa navicularis, penile or pendulous region, and bulbar portion of the urethra.

Posterior male urethra: - consists of the membranous urethra and prostatic urethra.

Urethral stricture: Refers to scarring and constriction of the conduit that prevents equipment from being inserted without causing damage to the mucosa that lines the conduit.

Urethroplasty: - is a surgical reconstruction or repair of the urethra

Bleeding defined as post-operative Anemia

Stricture recurrence as the need for a secondary procedure after initial urethroplasty

Early post-operative complications: Defined as complication that occur within 90 days after urethroplasty

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Urethral stricture is the narrowing of the penile conduit through which the urine is evacuated from the bladder to the outside hence making it difficult or painful to empty the bladder. Urethral stricture as a disease may happen in female as well as in males, but it is far commoner in men than in women for various anatomical and pathological reasons. (1)

It is a disease with a prevalence of about 200/100,000 in young men and more than 600/100,000 in older men over 65 in the USA. The annual incidence rate in the USA is thought to be 0.9%. (2) while in the United Kingdom, the frequency is much lower, with an estimate of 40 cases per 100,000 men under the age of 65 and 100 cases per 100,000 men over the age of 65. (3) Worldwide, the prevalence of male urethral strictures is estimated to be 229-627/100,000.(4)

With a proportion of 84.8%, trauma-related anterior urethral strictures have been reported in Tanzania. (5) Road traffic accidents that result in pelvic fractures, gunshot wounds, falling atop metal bars, or other heavy objects can all result in urethral strictures. According to one study, improper catheterization is the primary cause of urethral stricture in 13% of cases at Muhimbili National Hospital.(1) Also congenital anomalies and inflammation can lead to urethral strictures, infections like Balanitis Xerotica Obliterans, also known as Lichen sclerosis et atrophicus, both in India and other nations. (6)

A number of repairing techniques have been developed for treating anterior urethra strictures and different scoring systems have been developed to predict the outcome following urethroplasty. The choice of type of urethroplasty to be performed would depend on the length of the stricture, location of the stricture, number of strictures and etiology of the stricture. Hence the introduction of the U-score as a tool that comprises above mentioned parameters (length, location, number and etiology of anterior urethral stricture) would act as a predictor of surgical complexity and outcome for patients undergoing anterior urethroplasty.

U-score is a modified diagnostic tool for urethral strictures that is based on the length (1-3 points), number (1-2 points), location (1-2 points), and etiology (1-2 points), with a final score ranging from 4 to 9 points.

Location of stricture	Points
Bulbar urethra	1
Penile urethra	2
Number of strictures	
1	1
>1	2
Etiology	
Traumatic, idiopathic, iatrogenic	1
Inflammatory, Hypospadias	2
Length of stricture (cm)	
</=2	1
>2 to </= 5	2
>5	3

There are a wide range of surgical procedures available to treat and repair urethral strictures, each with a different level of complexity and success. There are several reconstructive methods that have been created to treat anterior male urethral strictures. (Anterior urethroplasty).(7)

Excision and primary anastomosis (EPA), buccal mucosal graft (BMG), and augmented anterior urethroplasty are considered to be in a group of low surgical complexity, Meanwhile double BMG, flap, or flap-graft combo are considered to be in a group of high surgical complexity.(7)

1.2 Problem Statement

Urethral stricture is among the commonest disease that may present as a primary disease (congenital stricture), secondary disease (infectious / malignant stricture) or as a complication following a procedure performed through the urethra.

With an associated prevalence of 229–627 per 100,000 males, or 0.6% of the risk population, older men are more likely to have urethral strictures than younger men.(8)

Moreover, for a developing country like Tanzania where there are limited resources, shortage of well trained nurses and medical personnel especially at peripheral and rural facilities, the knowledge on proper urethral catheterization among health personnel would reduce the incidence of iatrogenic traumatic catheterization among patients with anterior urethral stricture.

Also, in current MNH practice there is no formal method of grading stricture complexity and risk stratification to guide the choice of surgical intervention and predict the urethroplasty complexity and outcome.

Thus, because of above mentioned common cause of urethral strictures and challenges faced during predicting the outcome after urethroplasty in our settings, that the introduction of U-score would help to sensitize and update our surgeons to prevent formation of urethral strictures by avoiding injuries in the urethra during surgery and be able to predict the surgical complexity and proper counselling to the patient during anterior urethral stricture repair (Anterior urethroplasty). Hence this would reduce morbidity and unexpected outcomes following anterior urethral stricture repair at Muhimbili National Hospital.

1.3 Rationale

The result of this study provided evidence-based information on the findings of significance of using U-score in predicting the complexity and the outcome of anterior urethroplasty hence provide the best choice of urethroplasty so as to minimize complications and improve outcomes.

These results help with preoperative patient counseling and may have an impact on clinical decisions regarding the best course of action for a definitive surgical or endoscopic procedure in the operating room. Additionally, the results of this study serve as a baseline for future research on the value of employing the U-score for patients with anterior urethral strictures in the department of urology and pediatric surgery unit at MNH.

1.4 Conceptual Framework

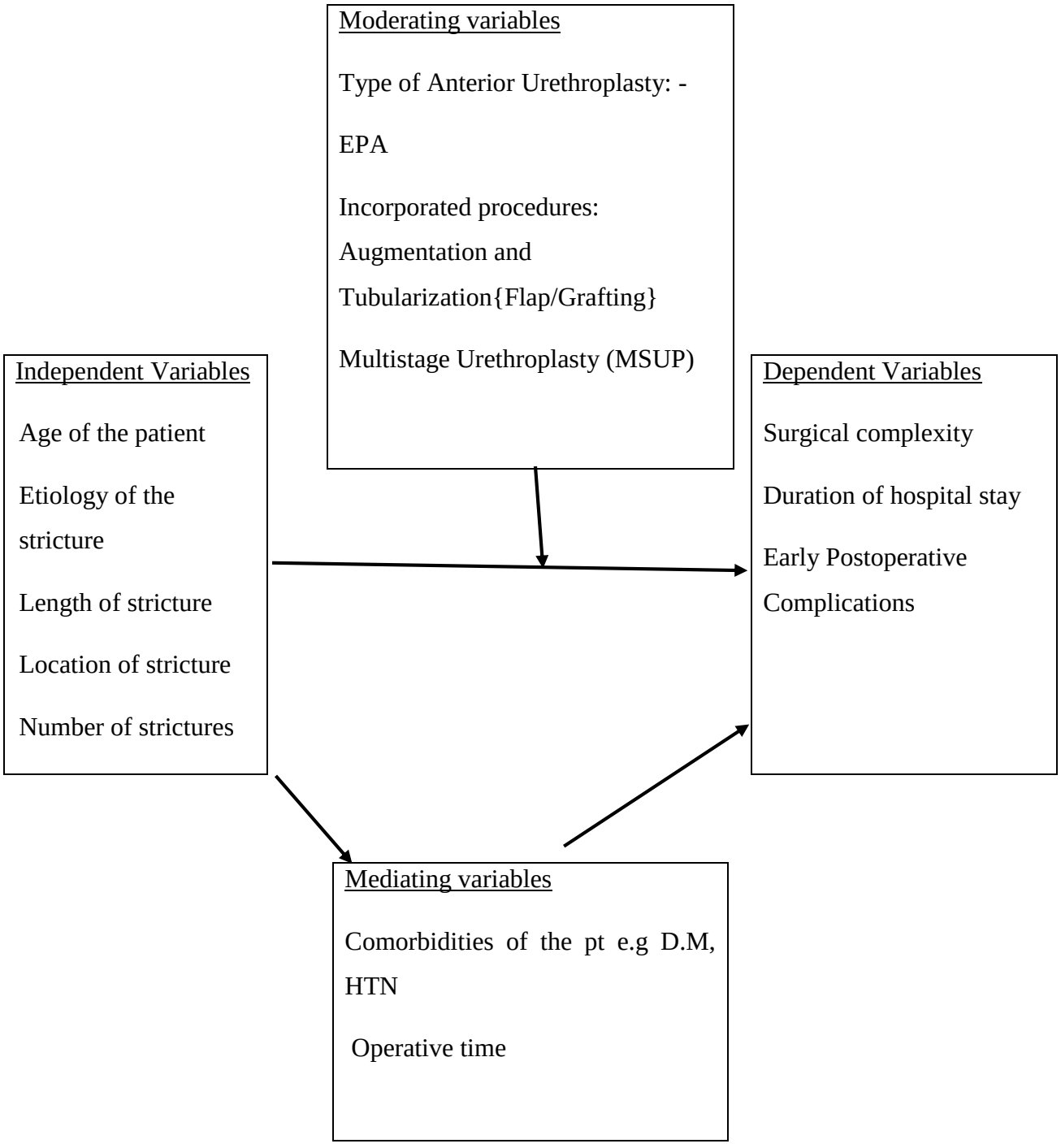


Figure 1: Conceptual frame work

This is a cross sectional study which involved 179 patients of anterior urethral stricture who underwent anterior urethroplasty at Muhimbili National Hospital.

Sociodemographic characteristics of the study participants together with other independent variables like etiology of stricture, length, location and number of strictures as shown in Figure 1 above, have direct influence on the outcome of interest as stipulated in the figure, but also things like operative time and patients' comorbidities might influence the outcome of interest. Furthermore, the type of urethroplasty used affects how strongly the dependent and independent variables are related.

In this study, the length of the stricture will be recorded from a perioperative sono-urethrogram and compared to the measurement made by the surgeon in the operating room. Moreover, the pre-operative retrograde urethrogram will identify the number and location of strictures. In the meantime, the patient's file history will be used to evaluate whether the stricture's etiology was traumatic, iatrogenic, idiopathic, or inflammatory.(9)

Urethral stricture complications post urethroplasty have been categorized into 2 groups as early complications as complications which occur with 90 days after urethroplasty for example Surgical site infections ,post operative anemia, stricture recurrence and late complications as complications developed after 90 days from surgery.(10)

1.5 Research Questions

1.5.1 General research question

What is the significance of the U Score in predicting the surgery complexity, length of hospital stay, and post operative complications for patients with anterior urethral stricture undergoing urethral stricture repair at MNH?

1.5.2 Specific research question

1. What are the repair procedures done at MNH for patients with anterior urethral stricture attending Muhimbili National Hospital?
2. What are the outcomes of repair procedures for patients with anterior urethral stricture attending Muhimbili National Hospital?
3. What is the association between U-score and surgery complexity, length of hospital stay and post operative complications for patients with anterior urethral stricture attending urethral stricture repair at MNH.

1.6 Objectives

1.6.1 Broad objective

To determine the significance of the U Score in predicting the surgical complexity, length of hospital stay and post operative complications for patients with anterior urethral stricture at MNH?

1.6.2 Specific Objectives

1. To determine the anterior urethral stricture repair procedures done at MNH for patients with anterior urethral stricture attending Muhimbili National Hospital.
2. To determine the outcomes of anterior urethral stricture repair procedures for patients with anterior urethral stricture attending Muhimbili National Hospital
3. To determine the association between U-score and surgery complexity, length of hospital stay and post operative complications for patients with anterior urethral stricture attending urethral stricture repair at MNH

CHAPTER TWO

2.0 LITERATURE REVIEW

Socio-demographic and clinical characteristics of urethra stricture patients

The proper diagnosis and effective management of urethral stricture disease require an in-depth understanding of the anterior urethra's anatomy. The term "stricture" refers to a fixed anatomic narrowing of the urethra such that the lumen cannot accommodate instrumentation without causing disruption of the urethral mucosal lining. Spongiofibrosis or scarring of the corpus spongiosum are conditions that can affect the anterior urethra.

The following categories can be used to classify the primary causes of urethral strictures: -

1. Inflammatory and infective: urethritis, sexually transmitted infections e.g gonorrhea
2. Traumatic

   (a) Internal (iatrogenic): Instrumentation during urological procedures e.g urethral catheterization, cystoscopy, transurethral resection.

   (b) External: Penile fracture, pelvic fracture, gunshot and stab wounds, perineal or straddle injury
3. Idiopathic and Congenital

A study conducted in South Africa to evaluate the sociodemographic, clinical, and etiological aspects of urethral stricture disease revealed that urethritis has significantly decreased and idiopathic etiology has increased, whereas internal (iatrogenic) trauma has remained the most frequent cause, with a slight increase in external trauma. Urinary tract inflammation (urethritis) was substantially more prevalent in third-world countries than in first-world ones, and it has continued to be so during the previous ten years despite a little decline. The prevalence of external trauma increased during the previous ten years and was roughly twice as common in third-world countries as it was in first-world ones. The prevalence of idiopathic etiology grew in first-world nations over the previous ten years and has stayed twice as common there as in third-world nations.

In the present study, as compared to the earlier study, this study indicated a decrease in urethritis and external trauma and an increase in iatrogenic trauma. Better public awareness and preventative programs, as well as efficient antibiotic treatment of sexually transmitted

infections, are likely responsible for the decreasing occurrence of urethritis. The increased prevalence of external trauma may be connected to increased levels of violence and road traffic density, while the increased frequency of iatrogenic trauma is related to greater usage of catheterization and transurethral urological procedures.(11)

In Tanzania, studies have shown an increasing prevalence of urethral stricture as a result of substantial numbers of youth getting involved in motor cycle taxi business with frequent involvement in motor crush injuries. (1)

Most of pediatric urethral strictures are caused by iatrogenic injury, which includes urethral instrumentation (such as during valve ablation as a treatment for the posterior urethral valve, or PUV), and perioperative urethral catheterization in the pediatric population. Congenital and infectious strictures are uncommon but still possible in children. (12)

According to a study from an institute for urethral and genital reconstructive surgery in Italy, urethral stricture disease affects people of all ages, but the frequency of stricture disease formation tends to increase until around age 45 and then decreases. Strictures develop more frequently in people between the ages of 20 and 70 and are less common in people older than this.(13)

Additionally, it was shown that strictures most occurred in different age groups, with the penile urethra being the most prevalent location for strictures in children aged 0 to 10, and the bulbar urethra for those aged 11 to 40. The strictures were universally localized in the penile and bulbar urethra in those who were >41 years old. Patients older than 51 years had a higher frequency of pan urethral strictures.(13)

Different anterior urethral stricture repair procedures

Numerous surgical procedures are available to treat urethral strictures because, like other surgical diseases, urethral stricture may necessitate surgical repair depending on the length, etiology, number, and location of the strictures (14). The complexity and results of these methods differ. Pre- and intra-operative assessments, as well as joint decision-making between the patient and doctor, are used to determine the best course of action. Unfortunately, there are few established methods for determining stricture complexity. In order to compare surgical techniques and surgical outcomes between centers, a standardized scoring system for the severity of stricture disease (U-score) was created. It has since been

demonstrated to be helpful for patient perioperative counseling regarding surgical complexity and stricture recurrence.

The association between U-score and surgical complexity, length of hospital stay and post operative complications

Through a study conducted at King Abdulaziz university in Saudi Arabia in collaboration with university of San Francisco in the United States, where by 389 patients with anterior urethroplasty, 341 had a mean U- score of 4.7 and underwent low complexity urethroplasty while 48 patients with a mean U- score of 6.9 underwent high complexity urethroplasty.(8)

In another study conducted at Burnes-Jewish Hospital from 2009 to 2012 whereby of 102 patients who underwent anterior urethroplasty, 63 patients had mean score of 5.2 and underwent low complexity surgeries while 39 patients who had mean score of 7.3 underwent high complexity surgeries.(7)

Apart from that, in a study performed by Lucas et al, on developing a urethral stricture score as a method for describing anterior urethral stricture which included retention of urine as one among its component score showed that 95 patients underwent anterior urethroplasty, of whom 29 with a mean score of 5.7 underwent EPA, 29 patients with mean score of 8.8 underwent BMG, 14 patients with the mean of 9.23 underwent AAU, 8 patients with a mean of 11.01 underwent flap and 15 patients with a mean of 14.9 underwent combination flaps/grafts. Increasing Urethral stricture score was significantly associated with surgical complexity.(4)

Hence a higher U-score was found to be predictive of higher surgical complexity.

Anterior urethroplasty being the gold standard surgical treatment for anterior urethral stricture, it has several possible complications for example urine incontinence, weak stream, surgical site infection, hemorrhage, hematoma, recurrence of stricture e.t.c.

U-score was found to be a useful quantitative scoring system for male anterior stricture to predict the outcomes of anterior urethroplasty. This was found in a study conducted at Toho University Faculty of Medicine in Japan from 2011 to 2016 where 29 patients with anterior urethral stricture who underwent anterior urethroplasty depending on the complexity of procedure and the score, were followed in a retrospective study. Nine patients had a U-score

of 4, seven had a U-score of 5, four had a U-score of 7, and two had a U-score of 8, but none had a U-score of 9. The groups with higher U-scores experienced a stepwise decline in the recurrence-free survival rate. Furthermore, it was demonstrated that patients with higher U-scores required longer recovery times than those with shorter recovery times. This demonstrates that in patients undergoing an anterior urethroplasty, the U-score can be utilized to predict the period of recurrence as well as perioperative outcomes.(15)

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study design

This was a hospital based retrospective cross-sectional study that involved 179 patients who had been diagnosed with anterior urethral stricture by urethrogram and underwent anterior urethroplasty at MNH over a 5 years period (2018-2022).

3.2 Study area description

This study was carried out at the MNH's urology department at Upanga and Mloganzila. MNH serves as both a teaching hospital for MUHAS students and a Tertiary Hospital for the nation. It is situated in Dar es Salaam's Ilala District, in the Upanga West Ward. Patients from all around the nation, including Zanzibar, are treated at the facility. With 1,500 beds and a weekly inpatient capacity of 1,000–1,200, this facility serves as the nation's premier referral center. Case notes from urology patients who underwent anterior urethroplasty at MNH and Mloganzila were included in the study.

3.3 Study population

This study included all patients operated for anterior urethral stricture with fully documented urethrogram results and interpretation during a study period of 5 years between 2018 and 2022 inclusively.

3.4 Sample size calculation

This was established using a cohort research method that involved selecting a random sample of people from the target group and estimated the prevalence of one or more parameters. Consequently, a sizeable sample was needed to adequately estimate the prevalence in the population.

The sample size was estimated using the Leslie kish formula (1965)

$$n = \frac{Z^2P(100-P)}{D^2}.$$

Where Z Standard deviation of the normal distribution =1.96 (confidence level at 95%)
P= prevalence 87.6%, (Obtained from a study done by Alwaal et al, 2015 investigated the Urethral Stricture Score and Association with Anterior Urethroplasty Complexity and Outcome 87.6% has low complexity urethroplasty with low U score) D= a tolerable error of 5%. The sample size was n= 167, however adjusting for non-response assuming a 90% response rate, the adjusted sample size was 184.

3.5 Inclusion and exclusion criteria

3.5.1 Inclusion Criteria

- Patients underwent Anterior urethroplasty at MNH
- Patients with Urethrogram documentation
- Patient with complete O.P findings and recommendations

3.5.2 Exclusion Criteria

Any patients file with incomplete data regarding the type of surgery, duration of hospital stay, post operative information: presence or absence of complications and stricture characteristics.

3.6 Variables

3.6.1 Independent Variable

Number of strictures
Age of the patient
Etiology of the stricture
Length of stricture
Location of stricture

3.6.2 Dependent Variable

Surgical complexity
Duration of hospital stay
Early Complications

3.7 Sampling technique

A convenience sampling technique was used to recruit the participants that fit the inclusion criteria during the desired study duration. We excluded from the study about 5 patients who underwent urethra-cutaneous fistula repair, meatoplasty and DViU following anterior urethral stricture.

3.8 Data collection and investigation tools

Research assistants filled out an organized English checklist to collect data. Data were collected from patient files or notes, hospital databases that contained medical records, and missing data in hospital databases were traced to the proper sources. If any of these sources were not available, the case notes were eliminated from the study.

The clinical data of the research patients' case, including their age, the cause of their strictures, where they are located, how long they are, and how many there are, were entered into a data collection tool.

Pretesting the data collection checklist was done using a few randomly selected records from the medical record department.

3.9 Data management and analysis

Lastly, data were entered and analyzed using the SPSS 25th version. Data cleaning was done before the analysis. Descriptive analysis for numeric variables was done using Mean and standard deviation for those with normal distribution, for skewed continuous variables median and interquartile range were used. For categorical variables, the frequency was used for descriptive analysis. The incidence proportion was determined by taking the number of those who developed complications after urethroplasty to the total number of the patients' files included in the study. Association between the U Score and the development of complications after urethroplasty, length of hospital stay and surgical complexity were done using the *chi-square* test and logistic regression to assess the adjusted predictor variables effect. The P value <0.05 was considered to be statistically significance.

To classify surgical complexity, criteria defined by Eswara et al, were used, which classified surgical complexity into low complexity (anastomotic, buccal mucosal graft, augmented anterior urethroplasty), and high complexity (double buccal mucosal graft, flap, and graft/flap combo)

3.10 Data analysis

Finally, data were entered and analyzed using the SPSS 25th version. Data cleaning was done before the analysis. Descriptive analysis for numeric variables was done using Mean and standard deviation for those with normal distribution, for skewed continuous variables median and interquartile range were used. For categorical variables, the frequency was used for descriptive analysis including low and high surgical complexity. Association between the U score and the complexity and post operative complication of the urethroplasty was done using the *chi-square* test and logistic regression were used to assess the adjusted predictor variables effect including operative time and the comorbidities and multivariate analysis for the predictors with P value of <0.05 was done to assess the effect of the confounders. Eventually, data were presented in tables.

3.11 Ethical clearance

The Research and Ethics Committee of the MUHAS IRB was asked for clearance and a waiver of informed consent after the proposal was reviewed for any ethical issues pertaining to the study as there was no direct communication with the patients, data were extracted from the records.

The MNH authority was consulted for approval before reviewing patient medical data. In this study, no names were recorded. During and after the study, patient confidentiality was taken into account. Data that were used in the study were not manipulated in any way. To prevent plagiarism, correct citation had been taken into account when producing this study research.

3.12 Limitations

i. Inaccurate or absent data in hospital databases or files.
ii. Being retrospective, the study is vulnerable to inaccurate recording, misplaced records, and a lack of follow-up.

3.13 Mitigation

Any inaccurate data discovered in a patient's case notes were investigated to determine where it came from. Any instances where there was a lack of follow-up were recorded as missing clinical data and omitted from the study. Records from the theater and radiology department where the urethrogram was performed were used to corroborate it.

3.13 Report Dissemination

The final report will be submitted to MUHAS and MNH research Unit. The findings will be presented for defense and manuscripts for publication will be submitted to our local and international peer-reviewed journals as a fulfillment for an MMed. degree.

CHAPTER FOUR

4.0 RESULTS

4.1 Patient Clinical-Demographic Characteristics

Through the Data recording systems at Muhimbili national hospital, a search for patients who underwent anterior urethroplasty in treating anterior urethral stricture was conducted. The search yielded 268 patient records. Further sorting was done by looking at those patients with complete records with interpretation of urethrogram and 184 records were found. 5 patients underwent Meatoplasty and Direct Vision internal Urethrotomy (DViU). Hence among 184 patients' files records, only 179 files (97.3%) were recruited in the study.

Median age is 51 ± 19.8 SD age range between 11- 92 years. Patients with co-morbidities were 36 (20.2%), among which 8.4% had hypertension, 6.7% had more than one comorbidity, 3.4% were seroconverted patients (AIDS) and 1.7% of patients had diabetes mellitus. [Table 1]

Table 1: Patient clinical-demographic characteristics

Patient Characteristic	Frequency	Percent (%)
Median age 51 ± 19.8 S.D (11 – 92 years)		
Co-morbidity (n=36)		
Hypertension	15	8.4
Diabetes mellitus	3	1.7
HIV	6	3.4
Multiple	12	6.7
None	143	79.9

Key: *SD- standard deviation*

4.2 Stricture characteristics

The commonest site for the strictures of the anterior urethra was found to be in the bulbar urethra 145 (81%) predominantly distal bulbar while 34 (15%) strictures were in the penile urethra. The median length of stricture was 1.9 cm ranging from 0.1 to 5 cm. Moreover, the study revealed that most of the strictures (84.4%) were due to trauma while inflammatory strictures were 15.6%. Ninety-five percent of the strictures were single stricture while multiple strictures constituted 5%. [Table 2]

Table 2: Stricture characteristics

Stricture Characteristic	Frequency	Percent (%)
Median Stricture Length 1.92 ± 0.9 (0 – 5)		
Location of Stricture		
Bulbar urethra	145	81.0
Distal bulbar	56	38.6
Mid bulbar	51	35.2
Proximal bulbar	38	26.2
Penile urethra	34	18.99
Proximal penile	16	47.1
Mid penile	18	52.9
Number of stricture		
Single stricture		
Multiple stricture	170	95
	9	5
Aetiology of stricture		
Traumatic	149	83
Inflammatory	28	15.6
Idiopathic	2	0.01

Key: *SD- standard deviation*

4.3 Perioperative characteristics

All patients underwent baseline preparation at least 2 days prior to surgery and their urethrograms were reviewed by the specialists during panel discussion at least 5 days before surgery. Patients had their surgeries done on elective basis: - 167 (93.3%) had low complexity surgeries while 12 patients (6.7%) had high complexity surgeries according to U-score categorization whereby excision and primary anastomosis (EPA), buccal mucosal graft (BMG), and augmented anterior urethroplasty are considered to be in a group of low surgical complexity, -and double BMG, flap, or flap-graft combo are considered to be in a group of high surgical complexity [Table 3].

Table 3: Perioperative characteristics

Variable	Frequency	Percent (%)
Surgical complexity		
Low complexity	167	93.3
High complexity	12	6.7
Type of Urethroplasty		
EPA	92	51.4
BMG (single stage)	35	19.6
Staged BMG	43	24.0
Double BMG	9	5.0
Graft and flap combination	0	0.0
Median time for the Surgery (hours) 2.5 ± 0.6 S. D (1.5-5)		
Median Length of hospital stay (days) 5 ± 2.5 S. D (4-20)		
Post-operative complication		
Yes	27	15.1
No	152	84.9

Key: *SD- standard deviation*

4.4 Post-operative complications

Patients who developed postoperative complications were 27 (15.1%). Among them 11.1% had anemia due to post-operative bleeding and 33.3% had recurrent stricture. Other complications were SSI, 11.1%. The remaining 44.4% were presenting as other complications. [Table 4]

Table 4: Post operation Complications.

Complication (48)	Frequency	Percent (%)
Post-operative complications (n=27)		
Surgical site infection	3	11.1%
Bleeding (Anemia)	3	11.1%
Recurrent stricture	9	33.3%
Others	12	44.4%

4.5 U-score characteristics

Most patients were found to have Low U-score 4 (42.5%) and 5 (33.5%). This was obtained via distribution of patients across different U-score categories then by using surgical complexity stratification, 165 patients underwent low complexity urethroplasty with a mean U-score 4.7 while 14 patients underwent high surgical complexity urethroplasty with mean u-score of 7.1 [table 5]

Table 5: U-score characteristics

U-score Characteristic	Frequency	Percent (%)
U-score grouped (n=179)		
Low score ≤ 6	165	92.2
High score ≥ 7	14	7.8
U-score		
4	76	42.2
5	60	33.5
6	29	16.2
7	7	6.1
8	8	1.7

4.6 Factors associated with surgical complexity

Patients who had single urethral stricture, bulbar located, stricture length less than 2 cm and traumatic by etiology with low U-score, had low surgical complexity intraoperatively compared to the patients who had multiple strictures, penile located, stricture length more than 2 cm and inflammatory by etiology with high U-score, p value <0.05.

Table 6: Binary and multivariate analysis on the Factors associated with Surgical complexity

Variable	cOR	CI	P-value	aOR	95% CI	P- value
Stricture Location						
Penile	1	1	1	1	1	1
Bulbar	0.34	0.01-0.16	<0.05	0.05	0.01-0.1	0.01
Number of Stricture						
Single	1	1	1	1	1	1
Multiple	115	19-702	0.05	4	0.12-136.96	0.442
Aetiology						
Traumatic	Ref			1	1	1
Inflammatory	6.6	1.95-22.3	<0.05	7.6	1.91-30.1	0.004
Length of stricture						
>2cm	Ref			1	1	1
≤ 2 cm	0.4	0.29-0.44	<0.05	0.2	0.03-0.61	0.02
U-score						
High	Ref			1	1	1
Low	0.012	0.003-0.047	<0.05	0.25	0.08-0.83.	<0.05

In the above presented table showing a binary and multivariate logistic regression we had to break down each parameter of U-score and measure its association and its predictive capacity in determining the surgical complexity so as to see the contribution of each U-score parameter in predicting surgical complexity and eventually the U-score as whole in association with surgical complexity.

4.7 Factors associated with post-operative complications

Patients who had single urethral stricture, bulbar located, stricture length less than 2 cm and traumatic by etiology with low U-score, had low risk of developing post operative complications compared to the patients who had multiple strictures, penile located, stricture length more than 2 cm and inflammatory by etiology with high U-score, p value <0.05.

Table 7: Binary and multivariate analysis on the Factors associated with postoperative complications

Variable	cOR	CI	P-value	aOR	95% CI	P- value
Stricture Location						
Bulbar	Ref					
Penile	3.856	1.589-9.358	0.04	2.12	0.69-6.41	0.18
Number of Stricture						
Multiple	Ref					
Single	0.329	0.077-1.404	0.138	0.39	0.03-3.89	0.423
Etiology						
Traumatic	Ref					
Inflammatory	1.078	0.342-3.397	0.898	2.7	0.53-14.2	0.229
Length of stricture						
>2cm	Ref					
≤ 2 cm	0.3	0.14-0.78	<0.05	0.53	0.2-1.39	0.193
Uscore						
High	Ref					
Low	0.194	0.061-0.616	<0.05	0.17	0.02-1.72	0.14

In the above presented table showing a binary and multivariate logistic regression we had to break down each parameter of U-score and measure its association and its predictive capacity in determining the postoperative complications so as to see the contribution of each U-score parameter in predicting postoperative complications and eventually the U-score as whole in association with postoperative complications.

4.8 Association of U-score and Length of Hospital stay

Patients who had low U score were having shorter duration of hospital stay hence proving that there is a statistical significance association between U-score and the duration of hospital stay, p value <0.05.

Table 8: Association of U-score and Length of Hospital stay

Variable	OR	CI	P-value
U score category			
High U score	Ref		
Low U score	0.4	0.36-0.51	<0.05

CHAPTER FIVE

5.0 DISCUSSION

The purpose of this study was to obtain a better understanding of the utilization of U-score in predicting the surgical complexity and post operative complications of anterior urethral stricture repair for patients undergoing anterior urethroplasty as a surgical treatment of anterior urethral stricture. The results revealed that several factors play a significant role in determining the occurrence of postoperative complications including bleeding and Surgical site infection.

The study was done at MNH reviewing the patient records between January 2018 and December 2022. A total of 184 patient records with anterior urethral stricture were retrieved: among those records, 179 (97.3%) met inclusion criteria and were recruited in the study. The median age for patients to present with anterior urethral stricture was at the age of 51 years with age range between 11 and 92 years. These findings were consistent with the findings in the study conducted by C.F. Heyns et al at Stellenbosch University in Cape Town, South Africa and Palminteri et al, and in the study conducted by O. V. Nyongole et al in Dar-es-salaam Tanzania, which showed that the median age for patient to present with anterior urethral stricture was 49.9 , 50 and 51 years on each study with age ranging between 10 and 93 years.(1) (11)(13)

Moreover, in the same study done by C.F. Heyns et al majority of the anterior urethral strictures were located in bulbar (68%) showing similarity with our study which revealed 81% of all anterior urethral strictures were located in the bulbar urethra.(11)

According to a study by K. Theisen et al., patients with penile urethral strictures had a 13.4-fold increased risk of re-admission and post-urethroplasty problems when compared to those with bulbar urethral strictures. These results are consistent with those of our study, which showed that patients with penile urethral strictures experienced more post-operative complications than patients with bulbar strictures who underwent anterior urethroplasty.(16)

Our study confirms the findings of Eswara et al and Mitsui et al in demonstrating the U-score association with surgical complexity. In both mentioned studies, it was observed that patients who presented with low U-score were subjected to low complexity surgical

procedures and vice versa as similar observation noted in our study that revealed that the odds of having complex surgery were 0.012 times lower in patients with lower scores than those with higher scores.(7)(15)

Our study correlates with the findings of Alwaal et al in demonstrating the U-score association with post operative complications as it was shown that there was consistent increase of post operative complication with each point increase of U-score, this was confirmed in our study which showed that patients who had higher U-score had high probability of developing post operative complications as low U- score was a protective factor of developing post operative complication with an odds ratio of 0.194.(17)

The findings of this study have brought to light the substantial influence of the U-score in predicting the duration of hospital stay after urethroplasty as it has been revealed in the study conducted by Mitsui et al in demonstrating the U-score association with duration of hospital stay where by patients who had higher score were having longer hospital stay after surgery, these findings confirms with our study findings whereby it has been shown that having low U-score was a protective factor for the duration of hospital stay with an odds ratio of 0.4.(15).

The longer operative time during anterior urethroplasty and the use of flaps, grafts, or both were found to be associated with a longer length of hospital stay in the study by Lacy et al. This is consistent with our findings, which interpreted those factors as parameters in the U-score and demonstrated that higher U-score and high urethroplasty complexity were associated with longer hospital stay.(18)

This study provides valuable insights into the U-score as a predictor of surgical outcomes and complexity to patients with anterior urethral stricture undergoing anterior urethroplasty. The findings suggest that patients with low U-score have lower risk of developing surgical complexity and postoperative complications and are likely to have shorter hospital stay compared to those patients with higher U-scores.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATION

6.1 Conclusion

The findings of this study have brought to light the substantial influence of the use of the Urethral stricture score (U-score) to its predictive capacity for surgical complexity and postoperative complications for patients with anterior urethral stricture. On top of that, U-Score may be expected to help in perioperative patient counselling and might influence the decision to undergo a more successful definitive procedure such as perineal urethrostomy rather than more complex, less successful anterior urethroplasty. It has also enhanced our understanding of the burden of postoperative complications and the common complications that we usually encounter post-surgery.

6.2 Recommendations

- Based on the study findings and discussion, I would recommend the utilization of Urethral stricture score (U-Score) for MNH patients who present with anterior urethral stricture who are expecting to undergo anterior urethroplasty at MNH. This will help in perioperative patients counselling and predict surgical complexity and post operative complications.

- Enhance Preoperative and Postoperative Care Protocols:

    - The focus should be emphasized on improving preoperative and postoperative care protocols to enhance and optimize patient well-being in attempt to minimize complications following anterior urethroplasty. This includes adherence to infection prevention control and adhering to the meticulous principles of surgery, like proper use of instrumentation, tissue handling and avoiding overzealous use of electrocautery.

- Proper perioperative patients counselling:
    - It is very crucial to counsel patients for the procedure they undergo and anticipate the challenges during surgery and complications expected afterwards.

6.3 Study limitations and implications

- The retrospective nature of this study is a limitation, hence to adopt prospective study designs to minimize biases inherent in retrospective data collection and ensure precise documentation, reducing coding errors.
- A fraction of urethral stricture patients in Tanzania are managed at our facility, this study only included patients who were treated at our facility, which may not accurately represent the entire community in this country.
- Increasing sample size is crucial for generalizability and statistical power.

These data have some potential intervention implications. For example, we are now aware of the common complications that our patients encounter post anterior urethroplasty. This gives us an insight on what to anticipate and plan a proper urethroplasty technique based on U-score criteria in preventing and reducing post-operative complications. Also, we believe that the development of a standardized scoring system for stricture disease severity like the U-score would be useful for patient perioperative counselling regarding surgical complexity and stricture recurrence and would allow for stricture related research to be reported in a common language among centres when comparing surgical techniques and outcomes.

We can suggest several avenues of research that may be helpful regarding our subject, and suggest a prospective study as we can have good quality data.

REFERENCES

1. East I, Afr C, Online J. ISSN 2073-9990 East Cent. Afr. J. surg. (Online). 2013;18(April):84–9.

2. Iii TGS. Current management of urethral stricture disease. 2016;27–33.

3. Baradaran N, Fergus KB, Moses RA, Patel DP, Gaither TW, Voelzke BB, et al. Clinical significance of cystoscopic urethral stricture recurrence after anterior urethroplasty : a multi - institution analysis from Trauma and Urologic Reconstructive Network of Surgeons (TURNS). World J Urol [Internet]. 2019;(0123456789). Available from: https://doi.org/10.1007/s00345-019-02653-6

4. Wessells H, Angermeier KW, Elliott S, Gonzalez CM, Kirkby E, Kodama R, et al. SC. J Urol [Internet]. 2016; Available from: http:// dx.doi.org/10.1016/ j.juro.2016.07.087

5. Article O. Early Outcome of the Types of Urethroplasty in a Tertiary Centre in Northern Tanzania. 2013;10(1):33–6.

6. Mchembe MD, Kategile A, Mteta KA. No Title. 2011;16:130–4.

7. Eswara JR, Han J, Raup VT, Dielubanza E, Gonzalez CM, Vetter JM, et al. Urethral Stricture Complexity. Urology [Internet]. 2015;85(2):474–7. Available from: http://dx.doi.org/10.1016/j.urology.2014.10.011

8. Alwaal A, Blaschko SD, Mcaninch JW, Breyer BN. Epidemiology of urethral strictures. 2014;2000(2):209–13.

9. Alwaal A, Sanford TH, Harris CR, Osterberg EC, Mcaninch JW, Breyer BN. Urethral Stricture Score is Associated with Anterior Urethroplasty Complexity and Outcome. J Urol [Internet]. 2016;195(6):1817–21. Available from: http://dx.doi.org/10.1016/ j.juro.2015.12.100

10. Kunz I, Wirtz L-M, Roggenbuck U, Krege S, Kroepfl D. Early Postoperative Complications of One-Stage Substitution Urethroplasty with Oral Mucosa Graft: A Monocentric Retrospective Study. Urol Int [Internet]. 2023 Dec 22;108(1):20–7. Available from: https://doi.org/10.1159/000534028

11. Heyns CF, Merwe J Van Der, Basson J, Merwe A Van Der. Etiology of male urethral strictures-Evaluation of temporal changes at a single center , and review of the literature. J Adv Res [Internet]. 2012;18(1):4–9. Available from: http://dx.doi.org/10.1016/j.afju.2012.04.009

12. Rourke KF, Cammon KAMC, Sumfest JM, Jordan GH. Open Reconstruction Of Pediatric And Adolescent Urethral Strictures : Long-Term Followup. 2003;169(May):1818–21.

13. Palminteri E, Berdondini E, Verze P, Nunzio C De, Vitarelli A, Carmignani L. Contemporary Urethral Stricture Characteristics in the Developed World. Urology [Internet]. 2013;81(1):191–7.

14. Erickson BA, Flynn KJ, Hahn AE, Cotter K, Alsikafi NF, Breyer BN, et al. Development and Validation of a Male Anterior Urethral Stricture Classification System. Urology [Internet]. 2020;

15. D YMM, Ph D, D HKM, Ph D, D SHM, D HIM, et al. Urological Note U-score system for predicting time to recurrence after urethral reconstruction in patients with anterior urethral stricture. 2018;1–2.

16. Theisen K, Fuller TW, Bansal U, Reese J, Lamm V, Chen M, et al. Safety and Surgical Outcomes of Same-day Anterior Urethroplasty. Urology [Internet]. 2017;102:229–33. Available from: http://dx.doi.org/10.1016/j.urology.2016.12.003

17. Alwaal A, Sanford TH, Harris CR, Osterberg EC, Mcaninch JW, Breyer BN. Urethral Stricture Score (U-score) is Associated with Anterior Urethroplasty Complexity and Outcome. J Urol [Internet]. 2016;

18. Lacy JM, Madden-Fuentes RJ, Dugan A, Peterson AC, Gupta S. Short-term Complication Rates Following Anterior Urethroplasty: An Analysis of National Surgical Quality Improvement Program Data. Urology [Internet]. 2018;111:197–202. Available from: http://dx.doi.org/10.1016/j.urology.2017.08.006

APPENDICES

Annex 1: Data Collection Checklist

CHECKLIST FOR THE U-SCORE TOOL

PARAMETER	VALUE	SCORE	TYPE OF URETHROPLASTY
Length of stricture	<2cm …….1 point 2-5cm ……..2 points >5 cm ……..3 points		
Location	Bulbar …..1 point Penile ….2 points		
Number of stricture(s)	1 ...1 point >1 …2 points		
Etiology	Traumatic, idiopathic,-iatrogenic ...1 point Inflammatory,-hypospadias..2 points		
Total U-score			

2. Comorbidities of the patient e.g D.M , HTN ……
3. Operative time (in hours) ……..
4. Type of the urethroplasty:……
5. Days in the hospital post operatively
6. Development of complication
7. Surgical complexity,
    a. Low complexity (anastomotic, buccal mucosal graft, augmented anterior urethroplasty).
    b. High complexity (double buccal mucosal graft, flap, and graft/flap combo)

Appendix II: Approval for ethical clearence

UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR – RESEARCH, PUBLICATIONS AND INNOVATION

Ref. No.DA.282/298/01.C/1915 Date: 07/10/2023

MUHAS-REC-19-2023-1915
SALIM N. SOBBO
SCHOOL OF MEDICINE
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: WOULD UTILIZATION OF URETHRAL STRICTURE SCORE (U-SCORE) PREDICT THE OUTCOME OF PATIENTS UNDERGOING ANTERIOR URETHROPLASTY AT MUHIMBILI NATIONAL HOSPITAL.A RETROSPECTIVE CROSS SECTION STUDY

Reference is made to the above heading,

I am pleased to inform you that the Chairperson has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 18/09/2023
EXPIRATION DATE OF APPROVAL: 18/09/2024

STUDY DESCRIPTION:
Purpose:

This will be retrospective study that aims to the significance of U score in predicting the surgical complex and outcome following urethroplasty at MNH.

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided:
https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%2014942.pdf and in the MUHAS archives.

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country,
8. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
9. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
10. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.

Dr. Nahya Salim Masoud,

Chairperson, MUHAS Research and Ethics Committee

Muhimbili University of Health and Allied Sciences
DIRECTOR
Research, Publications & Innovations
Box 65001

Appendix III: Introduction letter

UNITED REPUBLIC OF TANZANIA
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR – POSTGRADUATE STUDIES

In reply quote;
Ref. No. HD/MUH/T.278/2021 12th October, 2023

The Executive Director,
Muhimbili National Hospital,
P.O. Box 65000,
DAR ES SALAAM

Re: INTRODUCTION LETTER

We would like to inform you that the bearer of this letter is Salim N. Sobbo with Reg. No. HD/MUH/T.278/2021 is a student at Muhimbili University of Health and Allied Sciences (MUHAS) "pursuing MMed. Urology.

As part of his studies, he will be doing an elective research titled: "**Would utilization of urethral Stricture Score (U-Score) Predict the Outcome of Patients Undergoing Anterior Urethroplasty at Muhimbili National Hospital a Retrospective Cross Section Study."** he is being supervised by Dr. Fransia Mushi from MNH and Prof. Charles Mkony from MUHAS.

The research has been approved by the Chairman of University Senate.

Kindly provide him the necessary assistance to facilitate the conduct of his research.

We thank you for your cooperation.

Victoria Mwanilwa
For: DIRECTOR, POSTGRADUATE STUDIES

c.c Salim N. Sobbo

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line: +255-22-2150302/6; Ext. 1015; Direct Line:+255-22-2151378;Telefax:+255-22-2150465;E-mail:dpgs@muhas.ac.tz;Web:https://www.muhas.ac.tz

Appendix IV: Permission letter to conduct data at MNH

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

MUHIMBILI NATIONAL HOSPITAL

In reply please quote;

Ref. No.: MNH/CRTCU/Perm/2023/526 Date: 16th October, 2023

Head Department,

- Urology

- Surgery

Muhimbili National Hospital

RE: PERMISSION TO COLLECT DATA AT MNH.

Name of Student	**Salim N. Sobbo**
Title	**"Would Utilization of Urethral Stricture Score (U-Score) Predict the Outcome of Patients Undergoing Anterior Urethroplasty at MNH a retrospective Cross Section Study"**
Institution	Muhimbili University of Health and Allied Sciences
Supervisor	Prof. Charles Mkony (MUHAS)
Co - Supervisor	Dr. Fransia Mushi (MNH)
Period	16th October, 2023 to 30th December, 2023

Approval has been granted to the above mentioned student to collect data at MNH. **A final study report should be lodged with Clinical Research, Training and Consultancy Unit.** Dissemination of study findings to MNH stakeholders shall be overseen by Dr. Fransia Mushi (MNH) Co – supervisor.

Kindly ensure that the student abide to the ethical principles and other conditions of the research approval.

Yours Sincerely,

P.O. Box 65000 DAR-ES-SALAAM

Dr. Jessie Mbwambo

Head of Clinical Research, Training and Consultancy Unit

c.c DSS

c.c Dr. Fransia Mushi

c.c **Salim N. Sobbo**

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