QUALITY OF LIFE AND THE ASSOCIATED DETERMINANTS AMONG ADULT PATIENT WITH UROLITHIASIS ATTENDING MUHIMBILI NATIONAL HOSPITAL

Joachim Kulwa Mhaya, MD

MMed (Urology) Dissertation

Muhimbili University of Health and Allied Sciences

October, 2024

Muhimbili University of Health and Allied Sciences

Department of General Surgery

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By

Joachim Kulwa Mhaya, M.D

Dissertation Submitted In a (Partial) Fulfilment of the Requirements for the Degree of Masters of Medicine in Urology.

Muhimbili University of Health and Allied Sciences

October, 2024

CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance by the Muhimbili University of Health and Allied Sciences a dissertation titled: **"Quality of life and the associated determinants among adult patient with urolithiasis attending Muhimbili National Hospital"** in fulfillment of the requirements for Award of the Master of Medicine in Urology of Muhimbili University of Health and Allied Sciences.

_____

PROF. OBADIA NYONGOLE, MD MMed MSc (Urology)

(Supervisor)

Date:_____

_____

DR. ALBERT KATEGILE, MD MMed MSc (Urology)

(Co-Supervisor)

Date:_____

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ACKNOWLEDGMENT

I extend my deepest gratitude to the following individuals whose support and guidance were invaluable in the completion of this research dissertation: Professor Obadia Nyongole and Dr. Albert Kategile, my esteemed supervisors, whose expertise, encouragement, and unwavering dedication guided me through every stage of this research journey.

Dr. Ally Mwanga, the Head of Department of Surgery at Muhimbili University of Health and Allied Sciences (MUHAS), for providing an enriching academic environment and fostering a culture of excellence within the department.

I am grateful to the faculty and staff members of the Department of Surgery at MUHAS, both within and outside the urology specialization, for their mentorship, assistance, and contributions to my academic and professional development.

Special appreciation goes to the team at the Muhimbili National Hospital Department of Urology for their collaboration, support, and valuable insights throughout the course of this research.

To my colleagues and fellow residents in urology and general surgery, your encouragement, and shared experiences have been instrumental in navigating the challenges of residency training and research endeavors.

I am sincerely thankful to each individual mentioned above and to all whose names may not be listed here but have played a part, no matter how small, in shaping this dissertation.

DEDICATION

I’m dedicating this work with heartfelt gratitude to my beloved wife Velediana Mhuli, my parents Mr and Mrs Michael Mhaya whose unwavering support in academics has been a guiding light throughout my academic journey, their encouragement and belief fueled my determination.

ABSTRACT

Introduction: Urolithiasis, a common urinary condition, varies in prevalence globally, from 1% to 20%. Treatment options include extracorporeal shock wave lithotripsy, ureterorenal copy contact lithotripsy, percutaneous nephrolithotomy and open surgical procedure for larger stones. However, the current care approach lacks integration of patient-reported outcomes, alignment with treatment preferences, and resource optimization. Clinical aspects receive more focus in the evidence, while understanding patient quality of life (QoL), disease impact, and treatment effects remains insufficient.

Objective: This study aimed at determining the factors that influence the QoL and predictors of QoL among urolithiasis patients undergoing treatment at Muhimbili National Hospital.

Methodology: An analytical cross-sectional study involving patients with stone-related issues between October 2023 and March 2024 was carried in Muhimbili National Hospital. Patients completed stone history surveys, SF-36 questionnaire to assess Quality of life. Data were cleaned and analyzed using SPSS version 27.

Results: This study included 103 patients meeting inclusion criteria, with a mean age of 47 years (SD = 11.8). Proportion of urolithiasis was 0.67%. Gender distribution was 52.4% male and 47.9% female. The median BMI was 25.7 kg/m^2, with 54.4% falling within the normal weight range. Stone-related factors included 85.4% first-time stone formers and 14.6% recurrent formers. Stone sites varied, with 42.7% having stones ≤1cm and 42.7% presenting with hydronephrosis. Analyses revealed no significant differences in renal stone distribution by age or sex ($p > 0.05$). However, proximal ureteric stones were more prevalent among males ($p < 0.05$). SF-36 domain scores showed significant differences in role limitations due to emotions and pain between new and recurrent stone formers. Multivariate regression indicated that higher body mass index is associated with lower SF-36 PCS scores ($\beta = -1.198$, $p = 0.004$), highlighting its impact on physical HRQoL.

Conclusion: While no significant age or sex differences were found in renal stone distribution, proximal ureteric stones were more prevalent among males. Short form-36 domain scores showed significant disparities in emotional limitations and pain between new and recurrent stone formers, with higher BMI associated with lower physical health related quality of life.

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LIST OF ABRREVIATIONS AND ACRONYM

AUA	American urological association
Caox	Calcium oxalate
CT	Computed tomography
ECSWL	Extracorporeal Shock Wave Lithotripsy
HRQoL	health related quality of life
IVP	Intravenous pyelography
KUB	Kidney ureter and bladder
KSD	kidney stone disease
MCS	Mental composite score
MNH	Muhimbili National Hospital
MUHAS	Muhimbili University of Health and Allied Sciences
PCNL	Percutaneous Nephrolithotomy
PROMIS	Patient Reported Outcomes Information System
QOL	Quality of Life
SF-36	Short Form 36
WISQOL	Wisconsin Stone Quality of Life

DEFINITIONS OF KEY TERMS

Predictors are variables or factors that are used to anticipate or estimate future outcomes, trends, or events. In various fields such as statistics, data analysis, and research, predictors are utilized to make informed forecasts or predictions based on their relationship with the outcome of interest.

Quality of life (QoL) refers to an individual's overall well-being and satisfaction with various aspects of their life, including physical health, mental health, social relationships, personal fulfillment, and the environment in which they live. QoL is a multidimensional concept that encompasses an individual's subjective perception of their own life conditions and experiences.

Urolithiasis is a medical condition characterized by the formation of solid mineral deposits, known as urinary stones or calculi, within the urinary tract. These stones can develop in various parts of the urinary system, including the kidneys, bladder, ureters, or urethra.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Urolithiasis is a prevalent and frequently recurring urological condition, which can exert an adverse influence on the health-related quality of life (HRQoL) of patients, particularly among the working-age population, who are active contributors to society[1].The development or presence of calculi in the urinary system serves as a defining feature of this condition[2].Geographical differences may be seen in the frequency and distribution rates of urolithiasis, showing higher incidences in countries like Spain and Turkey[3].An upsurge in urolithiasis incidence has been duly recorded within the confines of the United States of America[4]. Urolithiasis within the tropical African context, while comparatively rarer than its Western counterparts, is steadily gaining recognition as an escalating concern. Investigative endeavors undertaken within Tanzania and the broader East African sphere delineate an escalation in documented urolithiasis instances over the preceding three decades[5,6].Nevertheless, under diagnosis persists as a significant obstacle[2].

This condition exhibits a pervasive nature, with an approximated prevalence of 13% in males and 7% in females, coupled with a progressively ascending occurrence[7]. Stone recurrence constitutes a prevalent challenge, showcasing a recurrent rate of 2-5% per annum, compounded by an escalating recurrence susceptibility following each stone episode[8]. Urolithiasis assumes a chronic trajectory for numerous individuals, aligning with the chronic ailment paradigm, which is recognized to exert a substantial influence on the well-being of those afflicted in terms of their quality of life (QoL)[9].Furthermore, it should be noted that socioeconomic status stands as a foundational risk determinant for this ailment[10].The prime age range for maximum incidence lies between 35 and 55 years. Present data indicates an elevated prevalence of kidney stones in Western nations, and women may be just as impacted as males[11].

Urinary calculi formation has been linked to a number of risk factors. Metabolic disorders as hypercalciuria, hyperoxaluria, hyperuricosuria, cystinuria, and hypocitraturia[12,13].Some studies indicates that age could be an additional contributing factor, as there's a noticeable increase in the occurrence of urolithiasis after reaching the age of 40[14].Sex stands as another significant risk determinant, with males being more prone to urolithiasis than females[3,14]. Ethnicity has also been posited as a noteworthy factor, with Caucasians exhibiting higher incidence rates compared to African-Americans and Asians[6]. Abnormalities in urinary pH and the presence of urinary tract infections are also additional variables implicated in the etiology of urolithiasis[15]. Diverse investigations probing the composition of renal stones in African population unveiled calcium oxalate as the prevailing compound spanning different age cohorts[16]. The prevalence of calcium oxalate calculi in adults has been demonstrated to hold parity between industrialized and non-industrialized nations, whereas purine and struvite stones show greater prevalence in the latter[17].

Prior studies carried out in Tanzania highlight that urolithiasis manifests a diverse array of clinical manifestations, spanning from the acute pain of ureteral colic and hematuria to systemic septic conditions, or even encompassing cases of inconspicuous or asymptomatic affliction. Furthermore, ultrasonography and plain abdominal radiographs emerge as the prevailing imaging modalities[2,5].A significant proportion of calculi were predominantly situated within the renal pelvis and ureters, with extracorporeal shock wave lithotripsy (ECSWL) emerging as the prevailing therapeutic modality[5].Percutaneous nephrolithotomy (PCNL) and supplementary interventions are typically conserved for substantial renal stones[18].

Upon the conclusion of emergency treatment which mainly aims at addressing infection, acute renal impairment, and pain relief, a definitive treatment becomes imperative. This therapeutic trajectory often assumes a convoluted, multi-staged, entailing a series of hospital visits and admissions. A considerable portion of patients contend with the burden of recurrent or multiple stones, necessitating continuous

treatments. The interplay between urolithiasis and its corresponding therapeutic measures can affect the overall QoL of patients[18–20].

Patient-reported outcome measures aim for quantitative assessment of patients' HRQoL in a consistent and replicable manner. The illness and treatment effects on HRQoL stand as crucial parameters. As per AUA guidelines on urinary calculi treatment, patient preferences, primarily influenced by quality of life, should shape treatment choices [21]. Broadly applicable measures like the SF-36 and EQ-5D have been used to measure HRQoL, however these instruments frequently only evaluate a small portion of the effect and lack a thorough investigation of clinically significant areas. The effects of urinary calculi have recently been the subject of a more thorough examination (mainly employing quantitative methodologies). Notably, research on the impact of stone disease throughout the acute and chronic stages has dug into studies like Wisconsin Quality of Life (WISQOL) and questionnaires using questions from the PROMIS (Patient Reported Outcomes Information System)[19,20]. Proposals suggest that optimal treatments are those personalized to individual needs and preferences[22].

The SF-36 questionnaire is currently employed in outpatient environments and administered to older adults residing in the community. It comprises 36 questions designed to assess eight distinct health domains, encompassing physical functioning, physical role, pain, general health, vitality, social functioning, emotional role, and mental health.

1.2 Problem Statement

The prevalence of urolithiasis has been steadily increasing globally, impacting individuals of all ages and demographics. In Tanzania, the burden of urolithiasis is substantial, and Muhimbili National Hospital being a tertiary care center, witnesses a considerable influx of urolithiasis patients seeking treatment. ECSWL is the treatment of choice while the PCNL is another treatment option for larger stones. The current care approach lacks patient-reported outcomes integration, treatment preference alignment, and resource optimization. Evidence primarily targets clinical aspects. Despite literature

advocating patient QoL comprehension, including disease impact and interventions, sufficient data are lacking concerning factors influencing the QoL of patients during their treatment journey. Understanding these factors and their predictors is essential for optimizing patient care, tailoring treatment approaches, and developing support systems that address the multifaceted challenges posed by urolithiasis.

1.3 Rationale

The rationale for this study lies in the need to comprehensively understand the factors associated with QoL of individuals undergoing treatment for urolithiasis. Urolithiasis and its treatment can have a significant impact on various aspects of a patient's life, including physical, psychological, and social well-being.

By identifying factors influencing QoL in this population, the research seeks to enhance our understanding of the broader context in which urolithiasis treatment occurs, potentially leading to improved patient care and tailored interventions.

1.4 Research Questions

1.4.1 Primary research questions

What are the factors that influence the QoL among urolithiasis patients undergoing treatment at Muhimbili National Hospital (MNH)?

1.4.2 Secondary research question

1. What is the prevalence of urolithiasis among patients attending urology clinic at MNH?
2. What are the demographic characteristics of patients with urolithiasis at MNH?
3. What is the QoL based on stone history among patients undergoing treatment at MNH?
4. What are the predictors of QoL among patients with urolithiasis undergoing treatment at MNH?

1.5 Research Objectives

1.5.1 Broad objective

To determine the factors that influences the QoL among urolithiasis patients undergoing treatment at MNH.

1.5.2 Specific objectives

1. To determine the prevalence of urolithiasis among patients attending urology clinic at MNH
2. To determine the demographic characteristics of patients with urolithiasis at MNH
3. To determine the QoL based on stone history among patients undergoing treatment at MNH
4. To assess predictors of QoL among patients with urolithiasis undergoing treatment at MNH

1.6 Conceptual Framework

This conceptual framework illustrates how the demographic characteristics, stone characteristics, and predictors of QoL interact to influence the ultimate outcome of quality of life for urolithiasis patients undergoing treatment at MNH. It provides a structured framework for analyzing the relationships between these variables and their combined impact on patients' well-being[22].

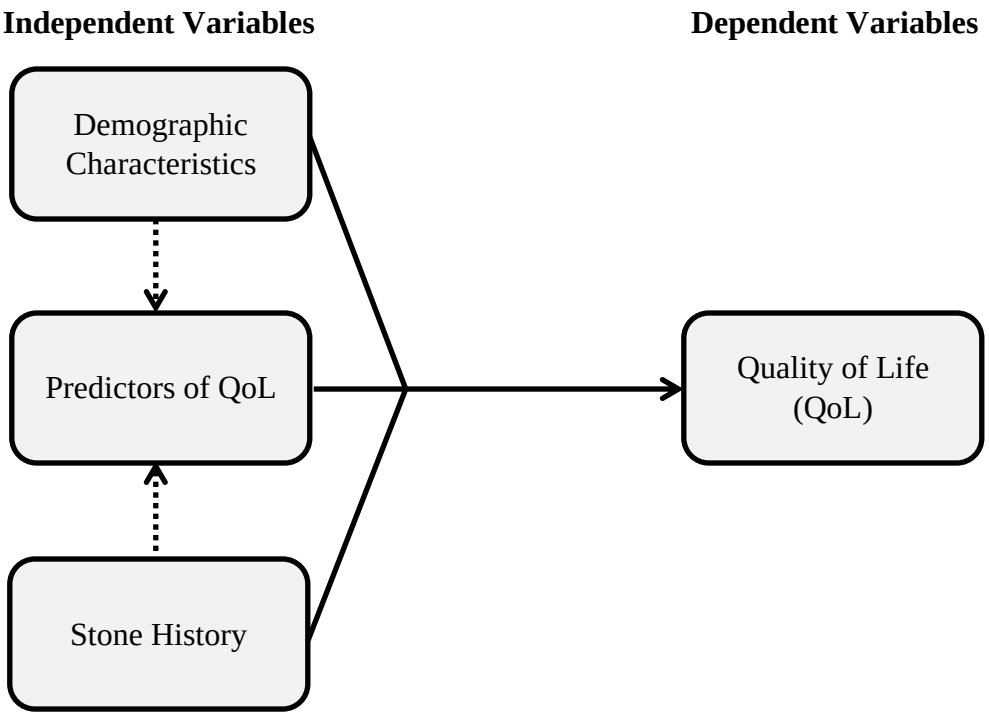


Diagram illustrating interaction between variables that influence the QoL for urolithiasis patients

I. Demographic characteristics influence the perception of QoL: Age, gender, ethnicity, socioeconomic status, educational background, and occupation are all demographic variables that can collectively influence a patient's experiences and perspectives. These demographic factors might impact how patients perceive their QoL, how they manage their condition, and how they respond to treatments

II. Stone history affect the QoL experienced by patients: stone size and location, bodily pain, anxiety, presence of hydronephrosis, and complications are all factors related to the urolithiasis condition. The size and location of stones can affect pain levels and treatment options, which can in turn influence QoL. The composition and number of stones might also correlate with treatment outcomes and symptom severity

III. Predictors of QoL such as pain intensity, treatment modality, and psychological factors impact the overall QoL. Pain intensity can directly impact how a patient rates their QoL. Treatment modality, duration, and sessions might influence the physical and emotional toll of treatment. Comorbidities and psychological factors can interact with the urolithiasis condition, affecting overall well-being. Social support can act as a buffer against stress and enhance quality of life. Post-treatment complications can have a direct negative impact on recovery and QoL.

IV. An intricate interplay of demographic characteristics, stone characteristics, and predictors collectively influences the patients' QoL during treatment.

V. QoL can be defined with parameters such as physical well-being, psychological Well-being, social well-being, and overall satisfaction.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Prevalence of Urolithiasis

Urolithiasis, a frequently encountered condition affecting the urinary system, exhibits a wide-ranging prevalence across the world, spanning from as low as 1% to as high as 20%. This condition, characterized by the formation of urinary stones within the urinary tract, is a significant health concern that varies in its occurrence across different populations and regions. These stones, composed of minerals and crystalline substances, can obstruct the normal flow of urine and lead to painful and debilitating symptoms, highlighting the importance of understanding the diverse prevalence rates associated with urolithiasis on a global scale[18,23].

According to study performed in North America by Scales and colleagues, the incidence of nephrolithiasis stood at an average of 8.8%, with a notably higher occurrence among males in contrast to females[24]. This trend was similarly observed over a four-decade span in Japan, where the estimated yearly occurrence of initial cases of upper urinary tract stones in 2005 reached 134.0 per 100,000 individuals (192.0 among men and 79.3 among women). This figure starkly contrasted with the 1965 rate of 54.2 per 100,000[25]. Notably, the annual incidence experienced an increase across all age groups, with the exception of the first three decades of life. Furthermore, the age at which the occurrence peaked saw an elevation for both men and women[25]. In Iceland, a similar escalation in prevalence was documented, with rates climbing from 7 to 24 per 100,000 for men over the age of 40 and from 7 to 21 per 100,000 for women over 50 years of age over a 24-year timeframe[26,27].

In a comprehensive study carried out by Zhang and colleagues in 2019, the prevalence of urolithiasis was found to be most pronounced in Eastern Europe, surpassing even the second-highest occurrence observed in Central Asia and the third-highest in Andean Latin America. Conversely, the regions of Eastern Sub-Saharan Africa, Central

Sub-Saharan Africa, Southern Sub-Saharan Africa, and Western Sub-Saharan Africa reported the lowest rates of urolithiasis. Interestingly, the Caribbean exhibited the highest Estimated Annual Percentage Change (EAPC) in incidence between 1990 and 2019, closely followed by South Asia. In stark contrast, East Asia recorded the lowest EAPC during the same period[23].To date, there has been no recent research conducted in Tanzania to ascertain the current prevalence of urolithiasis, leaving the national prevalence of this condition undisclosed.

2.2 Patients' Demographic Characteristics

Considerable disparities in incidence rates are observable depending on geographical location, climatic conditions, dietary habits, fluid consumption, genetic factors, gender, occupational factors, and age demographics. The management of urinary stone-related conditions incurs substantial costs due to the substantial rates of new and recurring stone formation, resulting in a significant burden of acute and chronic morbidity. Gaining insights into the epidemiological aspects of stone diseases can potentially enhance patient care and even contribute to preventive strategies.

Several studies have highlighted that the occurrence of stones displays age-dependent variability, exhibiting a lower incidence during both childhood and late adulthood, while reaching its zenith during the age range spanning the fourth to sixth decades of life[4,6,14].Moreover, when considering the entirety of the data, a consistent pattern of a higher prevalence and incidence of kidney stones among males has persisted for over a century, as indicated by various research studies[28,29].Similarly, the data analysis in the research conducted by Bokhari et al. unveiled several adjusted factors associated with the development of urolithiasis. These factors included advancing age, being male, a history of smoking, the presence of comorbid conditions, a family history of urolithiasis, and not being employed in the healthcare profession[30].

In another study carried out in Kenya, Wathigo et al. observed a wide age range spanning from 3 to 87 years among the study participants, with a median age of 42 years. It's noteworthy, however, that the study included relatively few individuals below

the age of 18. The study cohort was predominantly male, with males representing more than two-thirds of the total patient population, underscoring a notable gender imbalance in the sample[6].Likewise, in a research carried out by Athumani et al. in Tanzania, the majority of the patients were 30 years of age or older, while the smallest age group receiving treatment consisted of individuals younger than 20 years of age. Additionally, the male gender was more prevalent than the female gender within the patient cohort[5].

Regarding QoL, in an American research study conducted by Bensalah et al., it was observed that factors such as age and Body Mass Index (BMI), known to exert a general influence on QoL, were also identified as variables correlated with QoL. Moreover, the number of surgical procedures a patient underwent emerged as an independent predictor of QoL. Furthermore, gender disparities were noted, with female stone formers experiencing lower QoL independently in terms of energy levels and physical functioning[22].Modersitzki et al. established that females exhibited statistically lower HRQoL scores when compared to males[31]. Furthermore, Penniston and colleagues noted that individuals with greater medical comorbidities, including obesity, advancing age, diabetes, hypertension, and musculoskeletal issues, reported poorer HRQoL in contrast to their healthier counterparts[32]. Additionally, Diniz et al. highlighted that patients from lower socioeconomic strata exhibited diminished HRQoL within the context of urolithiasis[33].

Research focused on evaluating the post-treatment QoL in individuals with urolithiasis within the African context, taking into consideration the demographic attributes of the patients, is notably limited in the existing literature. There is a paucity of comprehensive studies that delve into the impact of urolithiasis treatment on QoL while considering the specific demographic profiles of the African patient population.

2.3 QoL Based on Stone History

QoL among individuals with a history of kidney stones can be influenced by various factors. Previous studies looked at how stone events affect patients' psychological health. It was shown that those who had pressures such poor income, trouble making mortgage payments, and major emotional life events were more likely to have symptomatic stone episodes[7,33].Furthermore, in the research conducted by Miyaoka et al., it was established that experiencing recurrent stone episodes within a single year or manifesting symptoms indicative of renal colic were robustly linked to increased levels of stress[34]. This suggests that the frequency of stone-related episodes and the manifestation of painful renal colic symptoms are notable factors contributing to psychological distress in individuals with a history of kidney stones.These findings underscore the importance of addressing these specific clinical aspects when considering the overall well-being and mental health of kidney stone patients.

Certain studies have established a connection between depressive symptoms and the occurrence of stone disease. In a prospective study conducted by Angell et al., it was revealed that a noteworthy proportion of individuals with stone disease, specifically 30%, exhibited significant signs of depression[35]. This suggests a potential association between stone disease and mental health, emphasizing the need for further exploration into the psychological impact of this condition. Additionally, in a Taiwan retrospective study, researchers found a 1.75-fold increased risk of clinical depression diagnosis within a year after nephrolithiasis episodes[36]. This highlights the significant link between kidney stones and post-episode depression, emphasizing the need for further research to explore mechanisms and interventions for at-risk individuals. Similarly, Diniz et al. demonstrated that the frequency and quantity of stone episodes in individuals with urolithiasis are positively correlated with anxiety levels. As stone-related incidents become more frequent and numerous, the likelihood of experiencing anxiety-related symptoms increases[37]. This highlights the complex psychological impact of recurrent stone formation, urging further research to understand this relationship.

Additional research efforts have concentrated on assessing overall QoL in individuals with urolithiasis, utilizing the Short Form 36 (SF-36) as an evaluation tool[1,22,38]. These studies consistently reveal a reduction in QoL among stone patients. However, there is limited uniformity regarding which specific health domains are most adversely affected. Notably, Diniz et al. observed that renal colic was linked to a decline in QoL across all domains assessed by the SF-36[33]. Another study by Bensalah and colleagues identified a reduction in QoL across 5 out of the 8 domains assessed by the SF-36 questionnaire. Interestingly, individuals who had experienced a kidney stone episode within the past month reported even poorer QoL compared to those with more distant episodes[22]. Additionally, the presence of other chronic medical conditions among kidney stone patients was associated with a significant decline in QoL[22,32]. Some studies have indicated that female individuals with a history of kidney stones tend to exhibit lower QoL compared to their male counterparts[32,39]. In a longitudinal study conducted by Donnally et al. utilizing the SF-36, it was observed that QoL did not improve even after the resolution of stone-related symptoms. This raises questions about the validity of the SF-36 as a comprehensive measure for assessing QoL in the context of kidney stones, suggesting the need for alternative or supplementary evaluation tools in future research[40].

2.4 Predictors of Quality of Life

In Bensalah et al.'s study, the application of multivariate regression modeling unveiled that high BMI and advancing age emerged as the most influential factors predicting a decline in physical well-being. Surprisingly, the frequency of stone episodes did not exert any discernible influence on the SF-36 scores. However, the number of surgical interventions had a notable impact on both physical and mental components of well-being. Specifically, the frequency of ureteroscopy procedures and stent placements primarily affected mental well-being. Furthermore, the utilization of medical therapy, particularly the administration of potassium citrate, was associated with more favorable levels of quality of life[22]. Their study further showed that the number of surgical

procedures, whether total or specific, strongly predicted both mental and physical aspects of QoL.

CHAPTER THREE

3.0 RESEARCH METHODOLOGY

3.1 Study design

An analytical cross-sectional study to determine the factors that influences the QoL among urolithiasis patients undergoing treatment at Urology Department was carried out at MNH from October 2023 to March 2024.

3.2 Study area

Urology is among the departments functioning in MNH which is a tertiary referral and teaching hospital for Muhimbili University of Health and Allied Sciences (MUHAS) located in Dar es Salaam, Tanzania. It is a prominent medical institution known for providing specialized urological care to a diverse patient population. The Urology Department at MNH comprises state-of-the-art diagnostic, treatment, and research facilities dedicated to managing urological conditions. It includes 14 urology specialists, nurses and other supporting staffs. These healthcare professionals are instrumental in providing patient care and facilitating data collection. The department operates 2 adult and 1 pediatric operating theaters, radiology services, and patient wards. Approximately 150 patients with urolithiasis are being treated annually.

3.3 Study Population

The study involved suspected urolithiasis patients with first time or recurrent caliculi undergoing treatment at the Urology Department. The patient population encompasses a variety of demographics, including different age groups, genders, and socioeconomic backgrounds.

3.4 Inclusion and Exclusion Criteria

3.4.1 Inclusion Criteria

Eligible candidates comprise individuals aged 18 years or older with either current or previous history of urolithiasis.

3.4.2 Exclusion Criteria

Exclusion criteria involve patients incapable of providing verbal or written informed consent, as well as those who decline participation in the study.

3.5 Sample Size Determination

The sample size was calculated using the Cochran formula based on proportion obtained from previous similar studies in the region [6].

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

Where:

n = required sample size

Z = Z-score corresponding to the desired confidence level (for a 95% confidence level, Z-score is approximately 1.96)

P = estimated prevalence (as a decimal, so 94% becomes 0.94)

E = marginal error (as a decimal, so 5% becomes 0.05)

Substituting the values:

$$n = \frac{1.96^2 * 94 * (100-94)}{5^2}$$

n = 100

Considering a non-response in this study, the adjusted sample size was calculated using this following formula:

$$N = \frac{n}{1-r}$$

Where:

N = adjusted sample size

N = calculated sample size without considering non-response

r = expected non-response rate

Since we expect a non-response rate of 10%, then the adjusted minimum sample size will be 110 patients.

3.6 Sampling Technique

Convenient sampling was utilized to prospectively collect data from urolithiasis patients, targeting individuals who met specific inclusion criteria, such as a confirmed diagnosis of urolithiasis and a willingness to participate. Upon securing consent, participants were interviewed regarding their history of urolithiasis and were then subjected to the SF36 questionnaire, a commonly utilized instrument for evaluating health-related quality of life. This approach facilitated the effective collection of data from willing participants, offering valuable insights into how urolithiasis affects different dimensions of quality of life.

3.7 Study Variables

3.7.1 Independent Variables

1. Demographic Characteristics:
    a. Age (Continuous: years)
    b. Gender (Categorical: Male, Female)
    c. BMI (kg/m^2)
    d. Socioeconomic Status (Categorical: Low, Middle, High)
    e. Education (Categorical: None, Primary, Secondary, Tertiary)
    f. Occupation (Categorical: Employed, Unemployed, Student, Retired)
2. Stone History:
    a. Stone Location (Categorical: Renal Pelvis, Ureter, bladder)
    b. Stone Composition (Categorical: Calcium Oxalate, Uric Acid, etc.)
    c. Number of Stones (Continuous)
    d. Presence of Hydronephrosis (Binary: Yes, No)

e. Pain (Binary: Yes, No)
f. Anxiety (Binary: Yes, No)
g. Depression (Binary: Yes, No)
h. Fatigue (Binary: Yes, No)
i. Physical function (Binary: Yes, No)
j. Sleep disturbance (Binary: Yes, No)

3. Predictors of Quality of Life:
    a. Pain Intensity (Continuous: Numeric Rating Scale)
    b. Treatment Modality (Categorical: ESWL, PCNL, etc.)
    c. Treatment Duration (Continuous: measured in days/weeks)
    d. Number of Treatment Sessions (Continuous)
    e. Comorbidities (Categorical: Yes, No)
    f. Psychological Factors (Continuous: Anxiety Scale, Depression Scale)
    g. Social Support (Continuous: Scale rating)
    h. Post-Treatment Complications (Binary: Yes, No)

3.7.2 Dependent variables

4. Quality of Life (Outcome):
    a. Physical Well-being (Continuous: Scale rating)
    b. Psychological Well-being (Continuous: Scale rating)
    c. Social Well-being (Continuous: Scale rating)
    d. Overall Satisfaction (Continuous: Scale rating)

3.8 Data collection

Data were gathered from individuals who presented with symptoms indicative of urolithiasis and those whose urolithiasis diagnosis was confirmed within the clinic and urology wards of MNH during the study duration. Every eligible participant received a comprehensive explanation of the study's objectives, potential risks, benefits, and steps taken to ensure confidentiality. Those who expressed willingness to participate were provided with informed consent. A structured questionnaire was administered to systematically collect pertinent information. This questionnaire encompassed inquiries

regarding demographic details and medical history. Each patient was prospectively interviewed regarding stone history allowed to fill out theSF36 questionnaires which is the reliable instruments to evaluate QoL related to health among patients with urolithiasis, the questionnaires intended to evaluate renal stones patients' quality of life in different domains such as physical function, emotional and social wellbeing other information such as number of stone episode was prospectively collected, patients weight and height were measured using a weight and height scale and BMI was calculated by taking the ratio of weight and height squared kg/m^2.

3.8.1 Research Assistants Recruitment and Training

To optimize the data collection process, the research engaged three research assistants who possessed a strong medical background, particularly in urology. These individuals also demonstrated proficiency in both spoken and written English and Swahili languages, excellent communication skills, and adept research capabilities. A two-day training session was organized to provide these research assistants with a comprehensive orientation to the project. During this training, they gained insights into the study's objectives, rationale, and expected outcomes, along with a clear understanding of its significance within the urolithiasis context and its implications for patient care. The training emphasized ethical principles, patient confidentiality, and the procedures for obtaining informed consent. Research assistants were rigorously trained to uphold the highest ethical standards in all patient interactions. Additionally, they received intensive instruction on the utilization of data collection instruments to ensure data is collected accurately and effectively. This comprehensive training ensured that the research assistants were well-prepared to carry out their roles effectively and ethically in the research project.

3.8.2 Validity and Reliability of the Study tool

To ensure the reliability of measuring QoL among patients who have undergone treatment for urolithiasis, Cronbach's alpha test was employed. An alpha score of 0.86 demonstrated strong internal consistency within the scale. To enhance the validity of the study tool, items with lower consistency were eliminated. Before the actual study

commenced, a practicality pretest was conducted among treated patients in MNH's urology department. Research assistants received comprehensive instructions pertaining to the study context. Strict adherence to eligibility criteria was maintained to minimize potential biases. Prior to the initiation of the investigation, a thorough verification of tools and equipment were undertaken to ensure they are error-free.

3.9 Data Management and Analysis

3.9.1 Data Management

To maintain the confidentiality of the data, unique IDs were assigned to specific patients. To maximize the efficiency of data analysis, variables were methodically and correctly encoded. To find and fix any discrepancies, missing data, abnormalities, or inconsistencies in the dataset, careful data cleaning was done. Prior to a thorough data cleaning process, a special spreadsheet was created to serve as the hub for the collated data. Following this, the data were analyzed using SPSS version 27.

3.9.2 Analysis of Data

The total number of patients diagnosed with urolithiasis during the study period was calculated. Then the prevalence of urolithiasis was determined by dividing the number of patients with urolithiasis by the total number of patients attending the clinic during the same period. Demographic characteristics were summarized and analyzed using descriptive statistics (mean, standard deviation and frequency distributions).

QoL scores and subscale scores were analyzed using t-test. QoL scores were compared with established norms or reference populations. Patterns in QoL were identified based on stone history (e.g., recurrent stones vs. first-time stone formers, anxiety, depression, bodily pain, and physical function).Multivariable logistic regression analysis was performed to assess potential predictors of QoL among patients with urolithiasis. Variables such as age, gender, stone history, comorbidities, treatment methods, and other relevant factors were included. The strength and significance of associations between predictor variables and QoL outcomes were examined.

3.10 Ethical consideration and approval

Prior to commencing this study, ethical clearance was sought from the Institutional Review Board (IRB) of MUHAS to ensure the research complies with established ethical standards and principles. Additionally, necessary permissions were obtained from the relevant authorities at MNH to facilitate the data collection process. To safeguard data privacy, no patient identifiers, such as names, were recorded in the data collection tool. The collected data was handled with the utmost confidentiality, and the principal investigator prioritized the well-being of the participants, ensuring that they are not exposed to any harm during the study. Conflicts of interest were avoided, and the researcher strictly adhered to professional standards and ethical codes throughout the study's duration, maintaining the highest levels of integrity, honesty, and transparency. Participants received comprehensive verbal information about the study, and they were given an invitation to voluntarily participate. It was explicitly communicated that declining participation would have no adverse consequences on their part. Only participants, who provide written consent (annexed), indicating their willingness to take part in the study, were included. Finally, all collected information and research findings were securely stored in a protected and secure location during the data collection process to maintain the confidentiality and integrity of the data throughout the study. These measures collectively ensured that the research is conducted ethically, with utmost consideration for participants' rights and data protection.

CHAPTER FOUR

4.0 ANALYSIS AND RESULTS

4.1 Proportion of urolithiasis

During the study period, a total of 15,445 patients attended the urology clinic. Among them, 103 patients met the inclusion criteria for the study. This represents the subset of patients included in the study sample. Therefore, the proportion of urolithiasis among patients attending the urology clinic during the study period is approximately 0.67%.

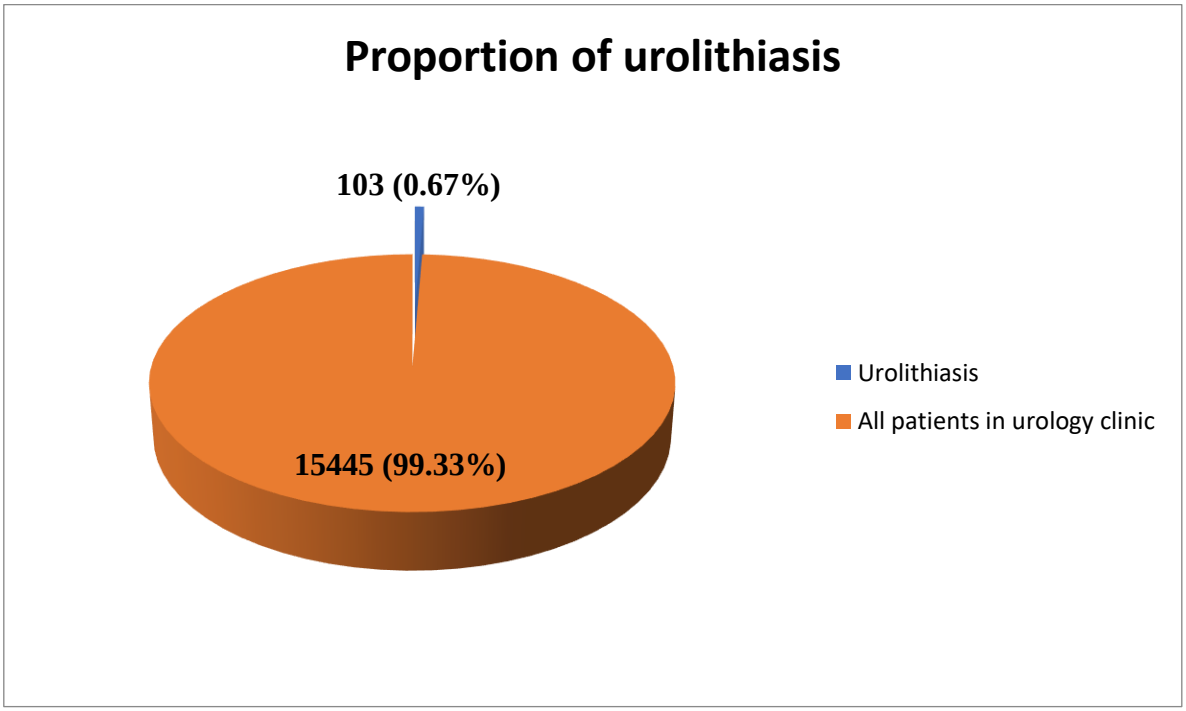


Figure 1: A pie chat illustrating proportion of urolithiasis

4.2 Demographic characteristics of patients with urolithiasis

A total of 103 patients who met inclusion criteria were included in this study. The patients had a mean age of 47 years with a standard deviation of 11.8 years. Gender distribution showed that 54 (52.4%) were male and 49(47.9%) were female. The median BMI was 25.7 kg/m2, with the majority falling within the normal weight range of 18.5-24.9 (54.4%). In terms of stone-related factors, 88(85.4%) patients were first-time

stone formers, while 15(14.6%) were recurrent stone formers. Stone sites included renal (unilateral and bilateral), ureteric (proximal, mid, distal, and bilateral), and bladder stones. Among the patients, 42.7% had stones ≤1cm, while 57.3% had stones >1cm.Furthermore, 42.7% of patients presented with hydronephrosis, while 57.3% did not have it. These demographic and clinical characteristics provide valuable insights into the patient population under study, facilitating a better understanding of urolithiasis management.

Table 1 Patients demographic characteristic

Patients' characteristics	frequency	percent
Age, mean ± SD (years)	47±11.8	
Sex		
Male	54	52.4
Female	49	47.9
BMI (kg/m^2)		
Median (range)	25.7 (20.1-38.9)	
< 18.5	0	0.0
18.5-24.9	56	54.4
25.0-29.9	35	33.9
≥ 30	12	11.7
Stone episode		
First time stone former	88	85.4
Recurrent stone former	15	14.6
Stone site		
Renal		
Unilateral	48	46.6
Bilateral	11	10.7
Ureteric		
Proximal	22	21.4
Mid	4	3.9
Distal	11	10.7
Bilateral	1	1.0
Bladder	6	5.8
Size		
≤1cm	44	42.7
>1cm	59	57.3
Hydronephrosis		
Yes	43	42.7
No	59	57.3

The table 2 provides a summary of stone locations categorized by age and sex, with corresponding p-values indicating statistical significance. No significant differences were observed in renal stone distribution by age or sex ($p > 0.05$). Regarding bilateral renal stones, there was no significant difference by age, but a significant difference was noted between male and female patients ($p < 0.05$). Proximal ureteric stones showed no significant differences by age but were significantly more prevalent among males ($p < 0.05$). Mid ureteric stones exhibited no significant differences by age or sex. For distal ureteric stones, no significant difference was found by age, but a significant difference was observed between male and female patients ($p < 0.05$). Urinary bladder stones showed no significant differences by age or sex.

Table 2: SF36 Mean stratification

SF-36 domains	Mean (±SD)	
Physical functioning[a]	44.2	(22.6)
Role limitations due to physical problems[a]	20.4	(40.5)
Bodily pain[a]	22.2	(23.7)
General health[a]	42.2	(46.4)
Vitality[b]	46.6	(50.1)
Social functioning[b]	42.9	(14.1)
Role limitations due to emotional problems[b]	48.9	(16.5)
Mental health[b]	50.5	(19.5)
Component scores		
Physical component summary score (PCS)[a]	32.3	(14.0)
Mental component summary score (MCS)[b]	47.2	(13.5)

The provided data offers insights into various domains of health-related quality of life assessed through the SF-36 questionnaire. Mean scores (± SD) indicate respondents' perceptions across physical and mental dimensions. Physical functioning scores reflect moderate perceived physical abilities, while role limitations due to physical and emotional problems suggest varying degrees of impairment in daily activities and responsibilities. Bodily pain scores indicate mild pain experiences, and general health perceptions appear moderately positive. Vitality scores indicate moderate energy levels, while social functioning scores suggest satisfactory engagement in social activities despite health challenges. Mental health scores depict relatively positive psychological well-being. The physical component summary score (PCS) suggests moderate overall physical health, while the mental component summary score (MCS) indicates moderately positive mental health. These findings collectively provide a comprehensive understanding of respondents' health status, highlighting areas of strength and areas for potential improvement in both physical and mental dimensions of health-related quality of life.

4.3 QoL based on stone history among patients

The table 3 compares SF-36 domain scores between new stone formers and recurrent stone formers, providing mean values (± SD), t-values, and p-values. While physical function, limitations to physical activities, vitality, emotional well-being, social functioning, and general health scores did not significantly differ between the two groups ($p > 0.05$ for all comparisons), significant differences were observed in limitations to emotions and pain scores. New stone formers reported significantly higher limitations to emotions compared to recurrent stone formers ($p < 0.001$ for both groups), while recurrent stone formers reported significantly higher pain scores ($p = 0.585$ and $p = 0.534$, respectively). These findings suggest that while certain aspects of health-related quality of life may differ between new and recurrent stone formers, overall similarities exist in most domains.

Table 3: SF-36 QoL based on stone episode among patients with urolithiasis (t-test)

SF-36 Domain	New stone former			Recurrent stone former		
	Mean ± SD	t-value	p-value	Mean ± SD	t-value	p-value
Physical function	22.7 ± 25.2	-0.894	0.374	47.7 ± 10.7	-1.169	0.247
Limit to physical	18.0 ± 39.4	-0.799	0.427	27.3 ± 45.6	-0.757	0.454
Limit to emotion	28.3 ± 21.8	1.354	**<0.001**	7.3 ± 13.2	1.349	**<0.001**
Vitality	40.6 ± 16.0	-1.342	0.184	43.2 ± 17.6	-1.389	0.172
Emotional well being	58.0 ± 41.0	-0.548	0.585	49.8 ± 50.3	-0.626	0.534
Social function	43.3 ± 12.6	0.840	0.404	39.1 ± 11.5	0.973	0.334
Pain	45.8 ± 16.9	-4.191	0.585	43.6 ± 11.8	-5.000	0.534
General health	53.1 ± 21.6	0.602	0.549	48.9 ± 14.4	0.581	0.565

Key; SD, Standard Deviation; SF-36, Short form 36; QoL, Quality of Life

Significant differences were found in pain scores, with patients with renal stones reporting significantly higher levels of pain compared to those with ureteric stones ($p = 0.008$ and $p = 0.014$, respectively). Additionally, significant differences were observed in emotional well-being scores, with patients with renal stones reporting lower scores than those with ureteric stones ($p = 0.584$ and $p = 0.591$, respectively). Other SF-36 domain scores, including physical function, limitations to physical activities, vitality, social functioning, and general health, did not show significant differences between patients with renal stones and those with ureteric stones ($p > 0.05$ for all comparisons). These findings suggest that while patients with renal stones may experience higher levels of pain and lower emotional well-being compared to those with ureteric stones, overall health-related quality of life in other domains appears comparable between the two groups. (See table 4)

Table 4: SF-36 QoL based on Stone site among patients with urolithiasis

SF-36 Domain	Renal stone			Ureteric stone		
	Mean ± SD	t-value	p-value	Mean ± SD	t-value	p-value
Physical function	45.5 ± 20.9	1.407	0.163	36.7 ± 29.6	1.101	0.287
Limit to physical	19.3 ± 39.7	-0.648	0.518	26.7 ± 45.7	-0.585	0.566
Limit to emotion	22.3 ± 23.7	0.550	0.885	21.3 ± 24.5	0.546	0.889
Vitality	41.7 ± 16.9	-0.863	0.485	45.0 ± 19.4	-0.919	0.548
Emotional well being	47.7 ± 50.2	-2.684	0.584	40.0 ± 50.7	-2.691	0.591
Social function	43.4 ± 14.3	-1.334	0.390	40.0 ± 13.1	-1.196	0.269
Pain	50.7 ± 16.0	2.684	**0.008**	38.7 ± 15.9	2.691	**0.014**
General health	50.0 ± 18.9	0.704	0.185	56.7 ± 22.1	0.613	0.248

Key; SD, Standard Deviation; SF-36, Short form 36; QoL, Quality of Life

Table generated using independent t-test

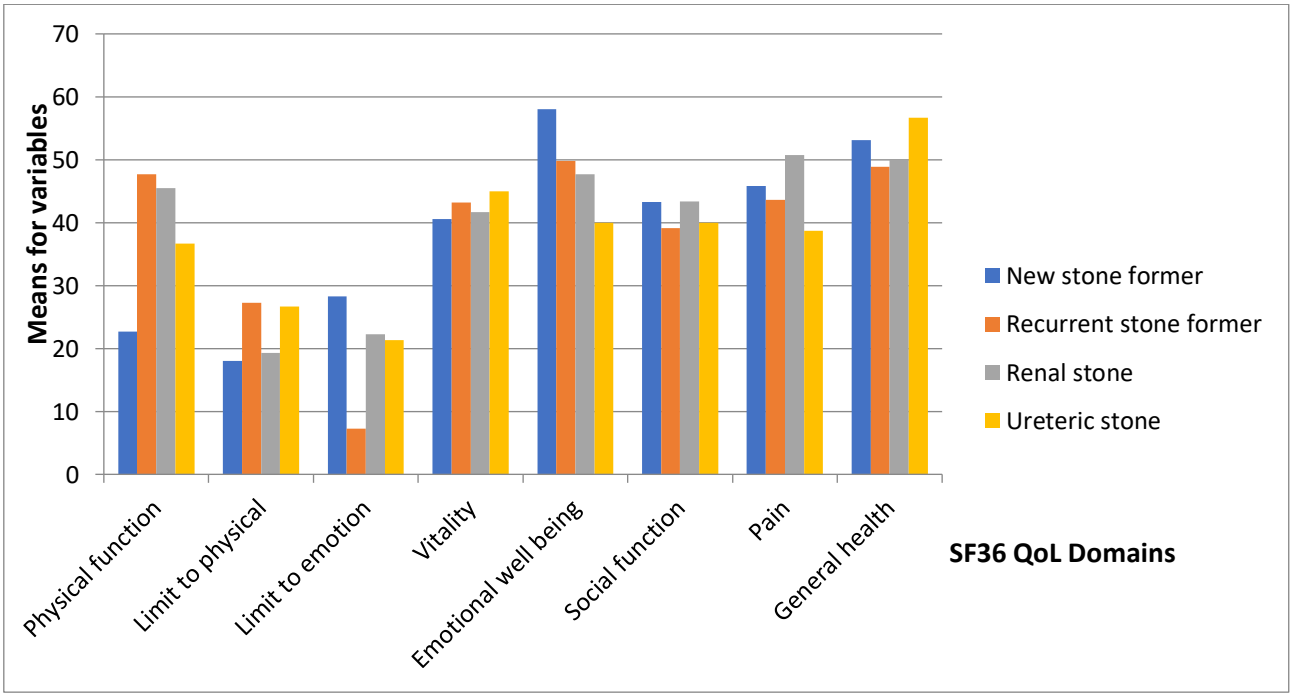


Figure 2: A grouped bar chat illustrating difference in means among new, recurrent stone formers, renal and ureteric stones.

4.4 Quality of life predictors among patients with urolithiasis

In Table 5, a multivariate linear regression model was utilized to analyze predictors of Health-Related Quality of Life (HRQoL) using the SF-36 PCS and MCS as outcome variables. For the SF-36 PCS, the model summary indicated an overall significant association ($p < 0.001$), with a constant β value of 54.976. Among the predictors, only Body Mass Index (BMI) showed a significant negative association ($\beta = -1.198$, $p = 0.004$), suggesting that higher BMI is associated with lower SF-36 PCS scores. Other predictors such as Age, Gender, and Stone Episode did not show significant associations. For the SF-36 MCS, the model summary also indicated a significant association ($p < 0.001$), with a constant β value of 53.464. However, none of the predictors (Age, Level of education, surgical intervention) showed significant associations with SF-36 MCS scores. Overall, these findings suggest that BMI has a significant impact on the physical component of HRQoL, but none of the included variables significantly affect the mental component.

Table 5: Multivariate linear regression model for predictor HRQoL

Outcome variables	Predictors	B	SE	R^2	*p*-value
SF-36 PCS	Model Summary		13.621	0.083	<0.001
	Constant	54.976	10.736		
	Age	0.028	0.118	0.001	0.811
	Gender	2.502	2.751	0.011	0.365
	Body mass index	-1.198	0.406	0.001	0.004
	Stone episode	2.624	3.907	0.003	0.503
SF-36 MCS	Model Summary		13.630	0.015	<0.001
	Constant	53.464	7.428		
	Age	-0.058	0.119	0.002	0.625
	Level of education	-1.486	1.705	0.009	0.386
	Surgical intervention	-0.332	0.522	0.004	0.526

Key: β, Unstandardized beta coefficient; MCS, Mental componentsummary score; PCS, Physical component summary score; R^2, Coefficient of determination; SE, Standard error

CHAPTER FIVE

5.0 DISCUSSION

The proportion of urolithiasis among patients attending the urology clinic during the study period is notably lower at approximately 0.67% compared to the nephrolithiasis in North America, which stands at an average of 8.8%[24]. Moreover, while the study in North America highlighted a higher occurrence among males, which is somehow similar to this study, the trends observed over time in Japan and Iceland show escalating rates of kidney stones, indicating geographical and temporal variations[25–27]. Specifically, in Japan, the yearly occurrence of upper urolithiasis increased significantly over four decades, contrasting with historical rates. Similarly, in Iceland, prevalence rates rose over a 24-year timeframe, particularly among specific age and gender groups [26,27].

This study finding depicts a patient population with a mean age of 47 years and a near-even gender distribution. Most patients had a normal BMI, with the majority being first-time stone formers. Contrasting this with the study conducted in Kenya[6], which had a wider age range but a median age similar to ours, it's evident that gender distribution was skewed, with males comprising the majority of the cohort. Similarly, in the Tanzanian study, patients were predominantly older, with males outnumbering females[2,5]. In contrast, Patel et al.'s study highlighted a higher proportion of recurrent stone formers, a larger representation of females, and a slightly older mean age[7]. These comparisons demonstrate variations in patient demographics, stone-forming history, and associated factors across different regions and populations.

The findings from our study provide a comprehensive overview of respondents' health status, shedding light on both physical and mental dimensions of health-related quality of life (HRQoL). Mean scores indicate moderate perceived physical abilities, varying degrees of impairment in daily activities and responsibilities due to physical and emotional problems, mild pain experiences, moderately positive general health perceptions, moderate energy levels, satisfactory engagement in social activities

despite health challenges, and relatively positive psychological well-being. While some differences were observed between new and recurrent stone formers, overall similarities exist in most domains of HRQoL.

Patients with renal stones reported significantly higher levels of pain and lower emotional well-being compared to those with ureteric stones. However, other domains such as physical function, limitations to physical activities, vitality, social functioning, and general health did not show significant differences between the two groups.Our findings also highlight the impact of certain variables on HRQoL. BMI emerged as a significant predictor of the physical component of HRQoL, with higher BMI associated with lower SF-36 PCS scores. However, none of the included variables significantly affected the mental component of HRQoL. These results align with findings from other studies, including those by Bensalah et al[22], Modersitzki et al[31]., Penniston et al[32]., and Diniz et al[33]., which emphasize the multifactorial nature of HRQoL in individuals with a history of kidney stones.

Factors such as age, BMI, surgical interventions, and the presence of comorbidities can significantly influence HRQoL, highlighting the importance of comprehensive assessment and tailored interventions to improve the well-being of kidney stone patients. These insights underscore the need for a holistic approach to patient care, encompassing not only the management of stone-related symptoms but also the optimization of HRQoL across physical and mental dimensions.

CHAPTER SIX

6.0 CONCLUSION, LIMITATIONS AND MITIGATIONS, RECOMMENDATIONS

6.1 Conclusion

The study provides crucial insights into the prevalence, demographic and clinical presentations, as well as the quality of life of patients with urolithiasis. With a prevalence of approximately 0.67%, the study population exhibited a mean age of 47 years, with a balanced gender distribution and predominantly normal BMI. Stone-related factors varied, reflecting a mix of first-time and recurrent stone formers with differing stone sizes and presentation of hydronephrosis. Health-related quality of life assessment highlighted moderate physical functioning, mild pain experiences, and relatively positive psychological well-being among patients. Significant differences were observed between new and recurrent stone formers in limitations to emotions and pain scores, with renal stone patients reporting higher pain levels and lower emotional well-being. Furthermore, multivariate regression analysis identified BMI as a significant predictor of physical HRQoL.

6.2 Limitations and Mitigations

However, it's important to acknowledge several limitations of the study. Firstly, being conducted at a single center, the generalizability of the findings may be limited, as the patient population and healthcare practices may not be representative of other settings. Additionally, the relatively small sample size might restrict the statistical power of the analysis and the ability to detect smaller, yet clinically relevant, differences. The use of convenient sampling is subject to selection bias. Furthermore, inherent biases in data collection, such as reliance on self-reported information and potential recall bias, could impact the accuracy and reliability of the results. Moreover, the study's cross-sectional design limits the ability to establish causality or determine temporal relationships between variables.

6.3 Recommendations

Future research with larger, more diverse samples, utilizing random sampling methods, longitudinal designs, and incorporating multi-center collaborations, would help address these limitations and provide a more comprehensive understanding of urolithiasis and its impact on patients' lives.

Investigating the effectiveness of interventions aimed at improving HRQoL in patients with urolithiasis, such as dietary modifications, lifestyle interventions, or psychological support programs, could provide valuable insights into strategies for optimizing patient outcomes. Clinicians should consider the multifaceted nature of urolithiasis and its impact on patients' physical and mental well-being when designing individualized treatment plans. Addressing pain management, emotional well-being, and overall quality of life should be integral components of urolithiasis management strategies.

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APPENDICES

Appendix I: Informed Consent

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

ID. NO ☐

CONSENT FORM FOR PARTICIPATING IN A RESEARCH STUDY

Hello, greetings! My name is **Joachim Mhaya from** Muhimbili University of Health and Allied Sciences (MUHAS). I am researching ***"quality of life and the associated determinants among patients with urolithiasis attending Muhimbili national hospital"***.

The aim of the Study : To assess the quality of life and the associated determinants among patients with urinary tract stones (urolithiasis) attending Muhimbili National Hospital.

Procedure: An interviewer will contact you to make some sort of arrangement for a convenient time of your choice for the interview. We hope that you will be willing to share your information with the research team. If you have questions about this research, including questions about how to schedule for the interview or about your participation, please do not hesitate to ask or contact the research team at any time.

Confidentiality: All information and issues relating to your participation in the study will be treated confidential, no unauthorized person will have access to your information. Furthermore, to protect the confidentiality, your names will not be used in the written copy of the discussion.

Right to refuse or withdraw : It is your choice to participate in this study. Also, you don't have to talk about anything you don't want to and you may end the interview at any time. However, I encourage you to participate because your report is very important in this study.

Benefits: There are no direct benefits to you from being in the study, however, your participation in this study will provide useful information for improving healthcare and treatment for patients with urinary tract stone

Risks : There will be no harm to you as a result of participation in this study.

Whom to Contact: In case of any inquiry please contact the principal investigator, Dr Joachim Mhaya, from MUHAS, P. O. BOX 65001, Dar es Salaam, and mobile number **0762769231.**If you ever have questions about this study you may call, the Chairperson of the Research and Publications Committee, MUHAS. P.O. Box 65001, Dar es Salaam-Tanzania **255 0222151596**.

I_____ have read the contents of this form and understand. My questions have been answered. I agree to participate in this study.

Signature of participant_____ Date _____.

Signature of researcher/research assistant_____.

Appendix III: Informed Consent – Swahili Version

CHUO KIKUU CHA AFYA NA SAYANSI SHIRIKISHI MUHIMBILI

FOMU YA IDHINI YA KUSHIRIKI KATIKA UTAFITI WA UTAFITI

Habari ! Jina langu ni Dkt Joachim Mhaya kutoka Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili (MUHAS). Ninatafiti "***ubora wa maisha na visababishi vinavyohusishwa kati ya wagonjwa wenye mawe katika mfumo wa mkojo wanaohudhuria hospitali ya taifa ya Muhimbili***".

Lengo la utafiti

Kutathmini ubora wa maisha na vibainishi vinavyohusishwa miongoni mwa wagonjwa wenye mawe ya njia ya mkojo (urolithiasis) wanaohudhuria Hospitali ya Taifa Muhimbili

Utaratibu

Mhojiwa atawasiliana nawe ili kufanya aina fulani ya mpangilio kwa wakati unaofaa wa chaguo lako kwa mahojiano. Tunatumahi kuwa utakuwa tayari kushiriki habari yako na timu ya utafiti. Kama una maswali kuhusu utafiti huu, ikiwa ni pamoja na maswali kuhusu jinsi ya ratiba ya mahojiano au kuhusu ushiriki wako, tafadhali usisite kuuliza au kuwasiliana na timu ya utafiti wakati wowote.

Usiri

Taarifa zote na masuala yanayohusiana na ushiriki wako katika utafiti yatachukuliwa kwa siri, hakuna mtu asiyeidhinishwa atakuwa na upatikanaji wa habari

yako. Zaidi ya hayo, kulinda usiri, majina yako hayatatumika katika nakala iliyoandikwa ya majadiliano.

Haki ya kukataa au kujiondoa

Ni uamuzi wako kushiriki katika utafiti huu. Pia, sio lazima uzungumze juu ya chochote ambacho hutaki na unaweza kumaliza mahojiano wakati wowote. Hata hivyo, ninakuhimiza kushiriki kwa sababu ripoti yako ni muhimu sana katika utafiti huu

Faida

Hakuna faida za moja kwa moja kwako kutokana na kuwa katika utafiti, hata hivyo, ushiriki wako katika utafiti huu utatoa habari muhimu kwa kuboresha huduma za afya na matibabu kwa wagonjwa walio na jiwe la njia ya mkojo

Athari

Hakutakuwa na madhara kwako kama matokeo ya kushiriki katika utafiti huu

Nani wa kuwasiliana nae : Kama kuna uchunguzi wowote tafadhali wasiliana na mchunguzi mkuu, Dk Joachim Mhaya, kutoka MUHAS, P. O. BOX 65001, Dar es Salaam, na namba ya simu 0762769231.Kama umewahi kuwa na maswali kuhusu utafiti huu unaweza kumpigia simu, Mwenyekiti wa Kamati ya Utafiti na Machapisho, MUHAS. P.O. Box 65001, Dar es Salaam-Tanzania 255 0222151596.

Mimi……. Maswali yangu yamejibiwa.Ninakubali kushiriki katika utafiti huu.

Saini ya mshiriki_____ tarehe_____

Saini ya mtafiti / mtafiti msaidizi_____.

Appendix IV: Data Collection Tool

DEMOGRAPHIC DATA

1. ID #: ……..
2. Name: ……....
3. Age…….
4. Gender: M / F
5. Address…….
6. Occupation……
7. Education level…….
8. Any chronic illness yes/no (mention) …….
9. Stone episode (first time/recurrent……...
10. Stone site…….....
11. Type of intervention ……
12. Body weight (kg)……..
13. Height (meter)…… BMI…….

Appendix v: SF-36 Questionnaire

Please answer the 36 questions of the Health Survey completely, honestly, and without interruptions.

GENERAL HEALTH:

1. In general, would you say your health is?
    - Excellent
    - Very Good
    - Good
    - Fair
    - Poor
2. Compared to one year ago, how would you rate your health in general now?
    - Much better now than one year ago
    - Somewhat better now than one year ago
    - About the same
    - Somewhat worse now than one year ago
    - Much worse than one year ago

LIMITATIONS OF ACTIVITIES:

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.
    - Yes, limited a lot
    - Yes, Limited a Little
    - No, Not Limited at all
4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf
    - Yes, limited a Lot

- Yes, Limited a Little
- No, Not Limited at all

5. Lifting or carrying groceries
   - Yes, limited a Lot
   - Yes, Limited a Little
   - No, Not Limited at all
6. Climbing several flights of stairs
   - Yes, limited a Lot
   - Yes, Limited a Little
   - No, Not Limited at all
7. Climbing one flight of stairs
   - Yes, limited a Lot
   - Yes, Limited a Little
   - No, Not Limited at all
8. Bending, kneeling, or stooping
   - Yes, limited a Lot
   - Yes, Limited a Little
   - No, Not Limited at all
9. Walking more than a mile
   - Yes, limited a Lot
   - Yes, Limited a Little
   - No, Not Limited at all
10. Walking several blocks
    - Yes, limited a Lot
    - Yes, Limited a Little
    - No, Not Limited at all
11. Walking one block
    - Yes, limited a Lot
    - Yes, Limited a Little

- No, Not Limited at all

12. Bathing or dressing yourself
    - Yes, limited a Lot
    - Yes, Limited a Little
    - No, Not Limited at al

PHYSICAL HEALTH PROBLEMS:

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

13. Cut down the amount of time you spent on work or other activities
    - Yes
    - No
14. Accomplished less than you would like
    - Yes
    - No
15. Were limited in the kind of work or other activities
    - Yes
    - No
16. Had difficulty performing the work or other activities (for example, it took extra effort)
    - Yes
    - No

EMOTIONAL HEALTH PROBLEMS:

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

17. Cut down the amount of time you spent on work or other activities
    - Yes
    - No
18. Accomplished less than you would like
    - Yes
    - No
19. Didn't do work or other activities as carefully as usual
    - Yes
    - No

SOCIAL ACTIVITIES:

20. Emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?
    - Not at all
    - Slightly
    - Moderately
    - Severe
    - Very Severe

PAIN:

21. How much bodily pain have you had during the past 4 weeks?
    - None
    - Very Mild
    - Mild
    - Moderate
    - Severe
    - Very Severe
22. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?
    - Not at all
    - A little bit
    - Moderately
    - Quite a bit
    - Extremely

ENERGY AND EMOTIONS:

These questions are about how you feel and how things have been with you during the last 4 weeks. For each question, please give the answer that comes closest to the way you have been feeling.

23. Did you feel full of pep?
    - All of the time
    - Most of the time
    - A good Bit of the Time
    - Some of the time
    - A little bit of the time
    - None of the Time
24. Have you been a very nervous person?
    - All of the time
    - Most of the time

- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

25. Have you felt so down in the dumps that nothing could cheer you up?
    - All of the time
    - Most of the time
    - A good Bit of the Time
    - Some of the time
    - A little bit of the time
    - None of the Time
26. Have you felt calm and peaceful?
    - All of the time
    - Most of the time
    - A good Bit of the Time
    - Some of the time
    - A little bit of the time
    - None of the Time
27. Did you have a lot of energy?
    - All of the time
    - Most of the time
    - A good Bit of the Time
    - Some of the time
    - A little bit of the time
    - None of the Time
28. Have you felt downhearted and blue?
    - All of the time
    - Most of the time
    - A good Bit of the Time
    - Some of the time
    - A little bit of the time
    - None of the Time
29. Did you feel worn out?
    - All of the time
    - Most of the time
    - A good Bit of the Time
    - Some of the time
    - A little bit of the time
    - None of the Time

30. Have you been a happy person?
    - All of the time
    - Most of the time
    - A good Bit of the Time
    - Some of the time
    - A little bit of the time
    - None of the Time
31. Did you feel tired?
    - All of the time
    - Most of the time
    - A good Bit of the Time
    - Some of the time
    - A little bit of the time
    - None of the Time

SOCIAL ACTIVITIES:

32. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?
    - All of the time
    - Most of the time
    - Some of the time
    - A little bit of the time
    - None of the Time

GENERAL HEALTH:

How true or false is each of the following statements for you?

33. I seem to get sick a little easier than other people
    - Definitely true
    - Mostly true
    - Don't know
    - Mostly false
    - Definitely false
34. I am as healthy as anybody I know
    - Definitely true
    - Mostly true
    - Don't know
    - Mostly false
    - Definitely false

35. I expect my health to get worse
    - Definitely true
    - Mostly true
    - Don't know
    - Mostly false
    - Definitely false
36. My health is excellent
    - Definitely true
    - Mostly true
    - Don't know
    - Mostly false
    - Definitely false

Appendix VI: Short Form 36 Swahili Version

DATA YA IDADI YA WATU

Jina:..... Umri..... Anwani..... Tarehe:.....Jinsia: Me / Ke Kazi..... Kiwango cha elimu..... Ugonjwa wowote sugu ndio / hapana (Taja) ..... Kipindi cha jiwe (mara ya kwanza / mara kwa mara..... mahali lilipo jiwe..... Aina ya tiba uliyokwisha patiwa..... ..... Uzito wa mwili..... kimo……BMI.....

MASWALI YA SF-36

Tafadhali jibu maswali 36 ya Utafiti wa Afya kabisa, kwa uaminifu, na bila usumbufu.

AFYA YA JUMLA:

1.Kwa ujumla, je, unaweza kusema kuwa afya yako ni?

- Nzuri zaidi
- Nzuri sana
- Nzuri
- wastani
- Mbaya

2. Ikilinganishwa na mwaka mmoja uliopita, unawezaje kupima afya yako kwa sasa?

- nzuri sana ukilinganisha na mwaka mmoja uliopita
- nzuri kiasi ukulinganisha na mwaka mmoja uliopita
- hakuna badiliko lolote
- mbaya kiasi ukilinganisha na mwaka mmoja uliopita
- mbaya sana ukilinganisha na mwaka mmoja uliopita

UPUNGUFU WA SHUGHULI:

3.Zifuatazo ni shughuli ambazo unaweza kufanya wakati wowote. Je, afya yako kwa sasa inakuzuia kufanya shughuli hizi? Kama ni hivyo, ni kwa kiasi gani?

a) Shughuli za nguvu, kama vile kukimbia, kuinua vitu vizito, kushiriki katika michezo .

- Ndio! siwezi kabisa
- Ndio , naweza kwa kiasi kidogo

- Hapana, naweza kufanya bila kizuizi chochote

b) Shughuli za wastani, kama vile kuchota maji, kufagia, kubeba mtoto ?

- Ndio! siwezi kabisa
- Ndio , naweza kwa kiasi kidogo
- Hapana, naweza kufanya bila kizuizi chochote

c) Kuinua au kubeba mfuko au kikapu chenye mahindi, au viazi kiasi cha debe moja?

- Ndio! siwezi kabisa
- Ndio , naweza kwa kiasi kidogo
- Hapana, naweza kufanya bila kizuizi chochote

d) Kupanda ngazi kadhaa?

- Ndio! siwezi kabisa
- Ndio , naweza kwa kiasi kidogo
- Hapana, naweza kufanya bila kizuizi chochote

e) Kupanda ngazi moja?

- Ndio! siwezi kabisa
- Ndio , naweza kwa kiasi kidogo
- Hapana, naweza kufanya bila kizuizi chochote

f) Kuinama, kupiga magoti, au kusimama?

- Ndio! siwezi kabisa
- Ndio , naweza kwa kiasi kidogo
- Hapana, naweza kufanya bila kizuizi chochote

g) Kutembea mwendo mrefu ambao ni zaidi ya nusu saa bila kupumzika?

- Ndio! siwezi kabisa
- Ndio , naweza kwa kiasi kidogo
- Hapana, naweza kufanya bila kizuizi chochote

h) Kutembea mwendo mfupi ambao ni chini ya nusu saa bila kupumzika?

- Ndio! siwezi kabisa
- Ndio , naweza kwa kiasi kidogo
- Hapana, naweza kufanya bila kizuizi chochote

i)Kutembea kutoka goli hadi goli la kiwanja cha mpira wa miguu bila kupumzika?

- Ndio! siwezi kabisa
- Ndio , naweza kwa kiasi kidogo
- Hapana, naweza kufanya bila kizuizi chochote

j) Kuoga au kuvaa nguo bila kusaidiwa?

- Ndio! siwezi kabisa
- Ndio , naweza kwa kiasi kidogo
- Hapana, naweza kufanya bila kizuizi chochote

MATATIZO YA AFYA YA KIMWILI:

B4 Katika wiki 4 zilizopita, umekuwa na matatizo yoyote katika kazi au shughuli zako za kila siku kutokana na afya yako ya mwili?

a) kupunguza muda unao tumia kwenye kazi au shughuli zako

o Ndiyo

o Hapana

b) kufanya kazi kwa kiwango cha chini kuliko matarajio yako?

o Ndiyo

o Hapana

c) huwezi kufanya baadhi ya shughuli zako?

o Ndiyo

o Hapana

d) huwezi kabisa kufanya kazi au shughuli yeyote bila msaada?

o Ndiyo

o Hapana

MATATIZO YA AFYA YA KIHISIA:

B5 Katika wiki 4 zilizopita, umekuwa na matatizo yoyote kati ya haya yafuatayo katika kazi yako au shughuli zako za kila siku kama matokeo ya matatizo yoyote ya kihisia (kama vile kuhisi huzuni au wasiwasi)?

a)Kupunguza muda uliotumia kwenye kazi au shughuli zingine?

o Ndiyo

o Hapana

b)Kufanya kazi chini ya kiwango kuliko ulivyo kusudia?

o Ndiyo

o Hapana

c) nishindwe kufanya baadhi ya kazi au shughuli zangu kama zamani?

o Ndiyo

o Hapana

SHUGHULI ZA KIJAMII:

B6 Katika kipindi cha mwezi mmoja uliopita matatizo ya kiafya au mawazo yameathiri shughuli zako za kifamilia,kijamii shughuli na marafiki au vikundi unavyo shirikiana navyo?

- hapana
- ndio! kiasi kidogo
- kwa wastani
- ndio kwa kiasi kikubwa
- ndio kwa kiasi kikubwa sana

MAUMIVU:

B7 Ni kiasi gani cha maumivu ya mwili ambacho umekuwa nacho katika wiki 4 zilizopita?

- hapana hakuna maumivu
- maumivu kiasi kidogo
- maumivu makali kidogo
- maumivu makali
- maumivu makali sana

B8 Katika kipindi cha wiki 4 zilizopita, maumivu yali kuzuia kwa kiasi gani kufanaya kazi zako kama kawaida (ikiwa ni pamoja na kazi zote za nyumbani na nje ya nyumbani kwako)?

- hapana kwa namna yeyote

- kwa kiasi kidogo sana
- Kwa wastani
- Kwa kiasi kikubwa
- Kwa kiasi kikubwa sana

NGUVU NA HISIA:

B9 Maswali yafuatayo ni kuhusu jinsi ulivyohisi hali yako katika wiki 4 zilizopita. Kwa kila swali, tafadhali toa jibu linalo akisi hali yako kwa wakati huo .

a) Je, ulihisi kuwa imara na mwenye nguvu?

- Ndio wakati wote
- Ndio mara nyingi
- Ndio kwa wastani
- Ndio mara chache
- Mara chache sana
- Hapana

b) Je, ulikuwa mtu mwenye wasiwasi sana?

- Ndio wakati wote
- Ndio mara nyingi
- Ndio kwa wastani
- Ndio mara chache
- Mara chache sana
- Hapana

c) Je, ulijisikia mnyonge na kwamba hakuna kitu kinachoweza kukufurahisha?

- Ndio wakati wote
- Ndio mara nyingi
- Ndio kwa wastani
- Ndio mara chache
- Mara chache sana
- Hapana

d) Je, ulijisikia kuwa mtulivu na mwenye amani?

- Ndio wakati wote
- Ndio mara nyingi
- Ndio kwa wastani
- Ndio mara chache
- Mara chache sana
- Hapana

e) Je, ulikuwa na nguvu nyingi?

- Ndio wakati wote
- Ndio mara nyingi
- Ndio kwa wastani
- Ndio mara chache
- Mara chache sana
- Hapana

f) Je, ulihisi kuwa mnyonge?

- Ndio wakati wote
- Ndio mara nyingi
- Ndio kwa wastani
- Ndio mara chache
- Mara chache sana
- Hapana

g) Je, ulihisi kuwa na uchovu?

- Ndio wakati wote
- Ndio mara nyingi
- Ndio kwa wastani
- Ndio mara chache
- Mara chache sana
- Hapana

h) Umekuwa mtu mwenye furaha?

- Ndio wakati wote
- Ndio mara nyingi
- Ndio kwa wastani
- Ndio mara chache
- Mara chache sana
- Hapana

i) je ulijiskia kuchoshwa na hali yako?

- Ndio wakati wote
- Ndio mara nyingi
- Ndio kwa wastani
- Ndio mara chache
- Mara chache sana
- Hapana

SHUGHULI ZA KIJAMII:

B10 Katika kipindi cha wiki 4 zilizopita, ni kiasi kwa kiasi gani matatizo ya afya yako au mawazo yameingilia shughuli zako za kijamii (kama vile kutembelea na marafiki, jamaa, nk)?

- Wakati wote
- Mara nyingi
- wastani
- mara chache
- Hapana

AFYA KWA U JUMLA:

B11 Ni kauli zipi kati ya zifuatazo ni za kweli kuhusu afya yako?

a) Nahisi kuwa ugonjwa wangu ni nafuu zaidi kuliko watu wengine

- ni kweli kwa kiasi kikubwa
- ni kweli kwa kiasi kidogo
- sifahamu

- si kweli
- si kweli kwa kiasi kikubwa

b) Nina afya njema kama watu wengine?

- ni kweli kwa kiasi kikubwa
- ni kweli kwa kiasi kidogo
- sifahamu
- si kweli
- si kweli kwa kiasi kikubwa

c) Natarajia afya yangu itakuwa mbaya zaidi?

- o ni kweli kwa kiasi kikubwa
- ni kweli kwa kiasi kidogo
- sifahamu
- si kweli
- si kweli kwa kiasi kikubwa

d) Afya yangu ni nzuri?

- ni kweli kwa kiasi kikubwa
- ni kweli kwa kiasi kidogo
- sifahamu
- si kweli
- si kweli kwa kiasi kikubwa

Appendix VII: Ethical Clearances

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/1950 Date: 23/10/2023

MUHAS-REC-10-2023-1950
DR. JOACHIM KLWA MHAYA
COLLEGE OF MEDICINE
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: QUALITY OF LIFE AND THE ASSOCIATED DETERMINANTS AMONG PATIENT WITH UROLITHIASIS ATTENDING MUHIMBILI NATIONAL HOSPITAL

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: 23/10/2023
EXPIRATION DATE OF APPROVAL: 23/10/2024

STUDY DESCRIPTION:
Purpose:

The purpose of this observational cross- sectional study is to determine the quality of life and the associated determinants among patient with urolithiasis attending Muhimbili national

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-%2014801.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. Kasusu Nyamuryekung'e

Ag. Chairperson, MUHAS Research and Ethics Committee

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

Appendix VIII: 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.284/2021

02nd November, 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 Joachim Kulwa Mhaya with Reg. No. HD/MUH/T.284/2021 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: "**OF LIFE AND THE ASSOCIATED DETERMINANTS AMONG PATIENT WITH UROLITHIASIS ATTENDING MUHIMBILI NATIONAL HOSPITAL."** he is being supervised by Prof. Obadia Nyongole from MUHAS and Dr. Albert Kategile from MNH.

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.

Ms. Victoria Mwanilwa
For: DIRECTOR, POSTGRADUATE STUDIES

c.c Joachim Kulwa Mhaya

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 IX: Permission Letter

THE UNITED REPUBLIC OF TANZANI

MINISTRY OF HEALTH

MUHIMBILI NATIONAL HOSPITAL

In reply please quote;

Ref. No.: MNH/CRTCU/Perm/2023/560 Date: 14th November, 2023

Head of Department

Urology

Muhimbili National Hospital

RE: PERMISSION TO COLLECT DATA AT MNH

Name of Student	**Joachim Kulwa Mhaya**
Title	**"Quality of Life and the Associated Determinants Among Patients with Urolithiasis Attending Muhimbili National Hospital".**
Institution	Muhimbili University of Health and Allied Sciences
Supervisor	Prof. Obadia Nyongole (MUHAS)
Co-supervisor	Dr. Albert Kategile (MNH)
Period	14th November, 2023 to 14th May, 2024

Approval has been granted to the above principal investigators to collect data at MNH. Dissemination of study findings at MNH shall be overseen by Dr. Albert Kategile (MNH) supervisor.

Kindly ensure the named principal investigator abide to the ethical principles and other conditions of the research approval.

Sincerely,

Dr. Deus Buma

For: Head of Clinical Research, Training and Consultancy Unit

HEAD, TEACHING, RESEARCH & CONSULTANCY UNIT * P.O. Box 65000 DAR-ES-SALAAM * MUHIMBILI NATIONAL HOSPITAL

c.c DICT

c.c Dr. Albert Kategile

c.c **Joachim Kulwa Mhaya**

Upanga West, Kalenga Street, Plot No. 10480/3, P.O. BOX 65000, Dar es Salaam, Tanzania.
Telephone: +255-22-2151367-9, Telephone: +255-22-2151351-2
Email: info@mnh.or.tz, Website: www.mnh.or.tz