QUALITY OF LIFE AMONG ADULT OSTOMATES AT MUHIMBILI NATIONAL HOSPITAL

Hassan Juma Mwakimako, MD

Master of Medicine in General Surgery Dissertation

Muhimbili University of Health and Allied Science

October, 2024

Muhimbili University of Health and Allied Sciences

Department of Surgery

QUALITY OF LIFE AMONG ADULT OSTOMATES AT MUHIMBILI NATIONAL HOSPITAL

By

Hassan Juma Mwakimako

A Dissertation Submitted in (Partial) Fulfillment of the Requirements for the Degree of Master of General Surgery at

Muhimbili University of Health and Allied Sciences

October, 2024

CERTIFICATION

The undersigned certify that they have read and hereby recommend for examination of dissertation entitled **"Quality of Life among Adult Ostomates at Muhimbili National Hospital",** in fulfillment of the requirements for the degree of Master of Medicine (General Surgery) of Muhimbili University of Health and Allied Sciences.

……

PROF. LARRY AKOKO

(Supervisor)

Date: ……

……

DR. IBRAHIM MKOMA

(Co-supervisor)

Date: ……

DECLARATION AND COPYRIGHT

I, Hassan Juma Mwakimako, declare that this dissertation is my original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature: …… Date: ……

The dissertation is copyright material protected under the Berne Convention, The Copyright Act 1999, and other international and national enactments, on that behalf, on intellectual property. It may not be reproduced by any means, in full or in part, except for short extracts in fair dealing, for research or private study, critical scholarly review, or discourse with an acknowledgment, without the written permission of the directorate of postgraduate studies, on behalf of both the author and the Muhimbili University of Health and Allied Sciences.

ACKNOWLEDGMENT

I extend my sincere gratitude to the individuals whose invaluable contributions have made this research endeavor possible.

First and foremost, I express my deepest appreciation to Professor Larry Akoko, whose guidance, expertise, and unwavering support have been instrumental throughout this journey. His mentorship has been invaluable, shaping not only the direction of this research but also my growth as an aspiring scholar.

I also extend my heartfelt thanks to Dr. Nathan Brand for his insightful advice and guidance as my advisor. His expertise and encouragement have been invaluable assets, enriching the depth and quality of this work.

I am grateful to Dr. Ibrahim Mkoma for his contributions as a co-supervisor, providing valuable feedback and perspectives that have enhanced the rigor and relevance of this research.

I acknowledge with appreciation Dr. Ally Mwanga, the head of the Department of Surgery at MUHAS, for his support and encouragement throughout this research endeavor. Furthermore, I would like to thank my colleagues and fellow residents in general surgery for their camaraderie, support, and valuable discussions that have enriched my understanding and shaped the course of this study.

Lastly, I express my gratitude to all those who, directly or indirectly, contributed to this research. Your support and encouragement have been indispensable, and I am deeply thankful for your assistance along this rewarding journey.

DEDICATION

To God, the almighty ALLAH, the source of all guidance and blessings, I dedicate this work. May His infinite wisdom continue to illuminate my path and inspire my endeavors.

I also dedicate this work to my family - my beloved mother and sister, Fatma Mwalizuma and Bibi Mwakimako, whose unwavering love and guidance have been my beacon of strength. To my cherished wife, Bijuma Abdughan, whose support and encouragement have sustained me through every challenge. And to my sons, Muhammad and Juma, whose laughter and joy remind me of what truly matters. This work is dedicated to you, with heartfelt gratitude for your endless love and unwavering belief in me.

ABSTRACT

Background: Intestinal stomas are an integral component of surgery as a means of diverting the bowel, either permanently or temporarily. Despite its significance, it is associated with adverse effects on the quality of life among ostomates. This negative impact has been argued to be cultural and context-dependent. Hence, it is crucial to comprehend the impact of intestinal stomas on the quality of life of ostomates in Tanzania and to devise interventions that mitigate negative effects and promote the well-being of patients.

Aim: To study the clinical demography and its influence on stoma-specific quality of life among ostomates attending MNH.

Methods: An analytical hospital-based cross-sectional study was conducted at MNH involving adult ostomates with intestinal stomas for at least 1 month. A stoma-QoL-specific tool, validated through Swahili translation was employed. Participants were recruited from the ongoing ExLap study, theatre logs, and surgical outpatient department. The Chi-square test and logistic regression examined associations between clinical demographics and QoL scores. Additionally, Anova analysis was utilized to explore the relationships between clinical demography and various domains of stoma QoL.

Results: This study involved 126 stoma patients with a male to female ratio of 1.4:1 and the majority were <65years of age in 80.2%. Malignant conditions were diagnosed in 76.2% with elective procedures being more common at 63.5%. The median stoma duration was 6.6 months, mostly temporary colostomies in 70.6%, with 71.4% receiving stoma care counseling? The median stoma-specific quality of life score was 50 (IQR 44-59) with majority, 66%, reporting suboptimal scores. Factors found to significantly influence QoL include: Age ≥ 65 years (AOR = 3.24, p = 0.009), and having received stoma care counseling (AOR = 3.23, p = 0.022). Elderly patients had higher self-esteem (14.04 ± 3.35, p = 0.001), having good family relations (26.76 ± 5.14, p= 0.028) influenced the other quality domains. Adjusting to

stoma was significantly better among permanent ostomates (12.43 ± 3.09, p = 0.026).

Conclusion: Majority of patients with stoma at Muhimbili National Hospital experience a suboptimal quality of life. Patients with advanced age and having stoma care counselling had a higher quality of life among ostomates. Patients with temporary stomas reported difficulties in managing their ostomy devices. More efforts such as pre and post-operative comprehensive stoma therapy services should be introduced to improve quality of life among ostomates in general.

TABLE OF CONTENTS

CERTIFICATION i
DECLARATION AND COPYRIGHT ii
ACKNOWLEDGMENT iii
DEDICATION iv
ABSTRACT v
LIST OF TABLES iii
LIST OF FIGURES iv
LIST OF ABBREVIATION v
DEFINITION OF KEY TERMS vi
CHAPTER ONE 1
1.0 INTRODUCTION 1
1.1 Background of Study 1
1.2 Problem Statement 3
1.3 Conceptual framework 3
1.3.1 Explanation of the Framework 4
1.4 Rationale 4
1.5 Primary Research Question 4
1.5.1 Secondary research questions 4
1.6 Research objective 5
1.6.1 Broad objective 5
1.6.2 Specific objectives 5
CHAPTER TWO 6
2.0 LITERATURE REVIEW 6
2.1 Overview 6
2.2 Clinical demography of adult ostomates 6
2.3 Stoma-specific QOL among ostomates 7
2.4 Influence of Clinical Demographic Characteristics on QOL 8
2.5 Association between clinical demography and stoma-specific QoL domains 9

CHAPTER THREE 11
3.0 MATERIALS AND METHODOLOGY 11
3.1 Study design 11
3.2 Study setting 11
3.3 Study population 11
3.4 Sample population 11
3.5 Inclusion and exclusion criteria 11
3.5.1 Inclusion criteria 11
3.5.2 Exclusion Criteria 12
3.6 Sample Size and Selection 12
3.7 Variables 13
3.7.1 Dependent (outcome) variable 13
3.7.2 Independent (predictor) variables. 13
3.8 Recruitment 13
3.9 Methods 13
3.10 Data collection 14
3.11 Data Analysis 14
3.12 Ethical consideration 15
CHAPTER FOUR 16
4.0 ANALYSIS AND RESULTS 16
4.1 Clinical demography of stoma patients 16
4.4 Overall Stoma –specific QoL among ostomates. 17
4.5 Influence of clinical demographic characteristics on QoL among ostomates 17
4.6 Clinical demographics influence optimal stoma-QoL scores in ostomates 18
4.7 Association between clinical demography and stoma specific QoL domains scores. 20
CHAPTER FIVE 22
5.0 DISCUSSION 22
CHAPTER SIX 27
6.0 STUDY LIMITATION, CONCLUSION AND RECOMMENDATIONS 27
6.1 Limitations 27

6.2 Conclusion 27
6.3 Recommendations 28
REFERENCES 29
APPENDICES 33
Appendix 1: Consent Form (English version) 33
Appendix 2: Consent Form (Swahili version) 36
Appendix 3 Clinical Research Tools 39
Appendix 4a: Stoma -QOL (English version) 41
Appendix 4b: Stoma-QOL (Swahili version) 42
Appendix 5: Ethical Clearance 46
Appendix 5: Permission Letter 48

LIST OF TABLES

Table 1: Clinical demography of stoma Patients attended at MNH from Aug 2023 – Feb 2024 16

Table 2: Clinical demographics association with optimal and sub-optimal QoL among ostomates. 17

Table 3: Clinical demographics influence optimal stoma-QoL scores in ostomates 19

Table 4: Association between clinical demography and stoma-specific QoL domains 21

LIST OF FIGURES

Figure 1: Conceptual Framework 3

Figure 2: Illustration of Participants' stoma QoL scores 17

LIST OF ABBREVIATION

EX LAP	Exploratory laparotomy
GI	Gastrointestinal
HRQoL	Health-relativity of life
MNH	Muhimbili National Hospital
MUHAS	Muhimbili University of Health and Allied Science
QOL	Quality of life
USD	United States dollars
WHO	World Health Organization
SPSS	Statistical Package for Social Sciences

DEFINITION OF KEY TERMS

Clinical Demography: A systematic study and analysis of population characteristics and dynamics within a clinical setting or healthcare context.

Colostomy: A surgically created opening in the colon, also known as the large intestine, that is brought through the abdominal wall to create a stoma.

Ileostomy: A surgically created opening in the ileum, the last part of the small intestine that is brought through the abdominal wall to create a stoma.

Intestinal Stoma: A surgically created opening on the abdomen for the excretion of intestinal waste products.

Ostomate: Person who has undergone stoma surgery.

Quality of Life: Overall well-being and functional status of individuals who have undergone surgery.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background of Study

The prevalence of intestinal stoma differs among various countries and populations, with no global data currently available. Nonetheless, there exists a notable discrepancy, as Western countries exhibit higher rates compared to developing nations. This variation likely stems from variances in disease patterns, healthcare accessibility, and surgical approaches. Roughly 750,000 to 1 million individuals with ostomies are believed to live in the United States, with approximately 100,000 stoma surgeries conducted annually[1].

Data on the stoma burden in Africa is currently very limited. In our practice, commonly performed intestinal stomas encompass colostomies, ileostomies, and urostomies [2].Although Jejunostomies are occasionally created for decompression, lavage, and diversion of bowel contents, they are rare. Urostomies are typically associated with urological interventions, shifting our focus primarily to ileostomies and colostomies as integral components of gastrointestinal interventions.

Ostomates impose a substantial economic burden on the global healthcare system. According to Rethmeier LO et al., the total annual expenditure of a German ostomate was estimated at 15,754 pounds [3]. This highlights the considerable financial resources allocated to stoma care, emphasizing the need for efficient management strategies to optimize healthcare spending while ensuring quality care for ostomates.

The World Health Organization (WHO) defines QoL as an individual's perception of their position in life in the context of the culture and value systems in which they live and concerning their goals, expectations, standards, and concerns[4]. This emphasizes on the multifaceted nature of QoL, incorporating subjective evaluations of various aspects of life that are influenced by cultural, social, and personal factors.

Prioritizing quality of life (QoL) in stoma surgery ensures a patient-centered approach, integrating individual preferences, needs, and values with clinical outcomes. This focus is crucial for promoting psychological well-being and alleviating common issues such as distress, anxiety, and body image concerns experienced by stoma patients [5].

Recognizing the social and functional impact of surgery aids in addressing challenges related to social interactions, relationships, and employment, facilitating an active lifestyle. Furthermore, addressing QoL concerns enhances treatment adherence, satisfaction with care, and overall health outcomes[6]. Monitoring long-term QoL allows for ongoing support and adjustments to optimize patient outcomes postoperatively. Existing literature has demonstrated a mixed picture regarding the quality of life (QoL) among stoma patients, with a predominant proportion experiencing suboptimal QoL [7–9].

Preoperative stoma counseling is an essential component of care for potential ostomates. Many high-income countries have transitioned their practice towards establishing hospital-based preoperative counseling programs, typically led by wound, ostomy and continence nurses. These programs focus on providing comprehensive counseling and education to patients before and after stoma surgery. The involvement of specialized nurses ensures that patients receive expert guidance regarding the surgical procedure, stoma care and management, emotional support, and follow-up care [1,10]. This approach aims to enhance patient preparation, satisfaction, and overall outcomes related to stoma surgery [5]. Stoma counseling has been shown to have significant effects on QoL outcomes as early as 1-month post stoma placement as proven in various studies [5,11,12].

Currently local literature concerning the quality of life (QoL) among stoma patients is notably scarce. However, studies conducted in Uganda and Ethiopia have shed light on this matter, revealing a concerning trend: the majority of ostomates experience suboptimal QoL [8,13]. Research has consistently demonstrated that patients who receive comprehensive stoma counseling both before and after surgery tend to experience better quality of life (QoL)[14]. However, in Tanzania,

this crucial aspect of care is often lacking despite an increase in surgical practice leading to more stoma formation. The absence of such support services not only deprives patients of essential guidance but also impedes their acceptance of the stoma. By addressing this gap and ensuring the availability of comprehensive stoma counseling, healthcare providers can contribute to enhancing patient acceptance and, consequently, improving the overall quality of life for ostomates in Tanzania.

1.2 Problem Statement

The quality of life (QoL) among ostomates exhibits global variation, with high-income countries consistently demonstrating higher QoL. This discrepancy has been attributed to sociocultural, and clinical demographic differences and the implementation of the standard of care, specifically stoma counseling, which is often lacking in developing countries, including Tanzania. This situation emphasizes the necessity to examine these disparities and identify the barriers hindering the provision of stoma counseling in Tanzania. Additionally, there is a need to explore potential strategies for the effective implementation of stoma counseling to enhance the QoL of ostomates in Tanzania.

1.3 Conceptual framework

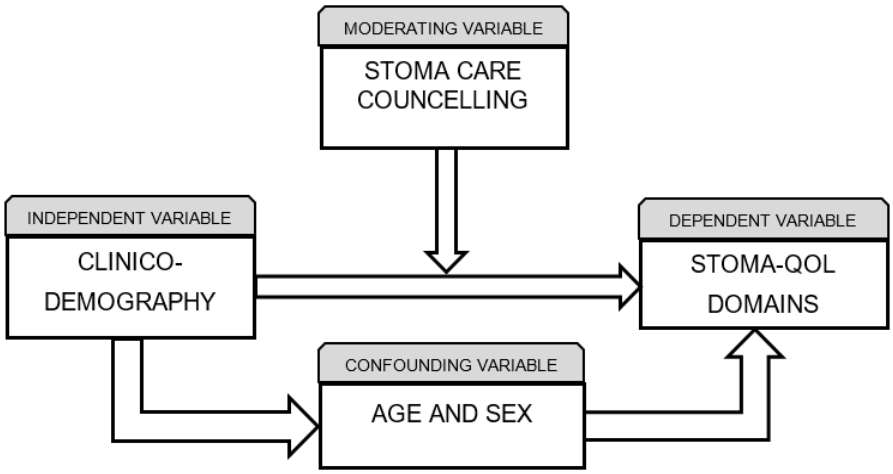


Figure 1: Conceptual Framework

1.3.1 Explanation of the Framework

The above conceptual framework consists of clinical demography as an independent variable, quality of life as the dependent variable, counseling as a moderating variable, and age and sex as confounders.

Clinical Demography has a direct influence on the quality of life, whereas proper pre and post-operative counseling moderates the clinical demography, therefore improving the quality of life.

Counseling is a supportive intervention provided to patients to address emotional, physical, and psychological challenges. Age may independently affect the quality of life, since the elderly patient may not have the same psychological and bodily image challenges as the young one. Sex as a confounder; women ostomates are more concerned with their appearance than men, and this is more likely to be a confounder in the bodily image domain of QoL.

1.4 Rationale

By conducting a comprehensive examination of the sociocultural and clinical factors contributing to the variation in QoL among ostomates, valuable insights can be gained into the specific challenges faced by ostomates in Tanzania. Identifying the barriers preventing the provision of stoma counseling in the country will shed light on the existing gaps in healthcare services and the specific needs of ostomates. Additionally, exploring potential strategies for the effective implementation of stoma counseling will contribute to the development of tailored interventions that can enhance the QoL of ostomates in Tanzania.

1.5 Primary Research Question

Do patients with intestinal stoma at MNH experience poor stoma-specific QoL?

1.5.1 Secondary research questions

1. Do ostomates at MNH experience poor stoma-specific QoL?
2. Does counseling influence the QOL of ostomates?
3. How does the clinical demography influence the quality of life ostomates?

1.6 Research objective

1.6.1 Broad objective

To study the clinical demography and its influence on stoma-specific quality of life among ostomates attending MNH.

1.6.2 Specific objectives

1. To determine the clinical demography of adult intestinal stoma patients who attended MNH in 2023.
2. To determine the overall stoma-specific QOL among ostomates at MNH.
3. To determine the influence of clinical demographic characteristics on QoL among ostomates at MNH.
4. To investigate the association between clinical demography and various domains of stoma-specific Quality of Life (QoL) among ostomates at MNH.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Overview

Quality of life is defined as a concept used to capture either individual or population well-being with or without positive or negative attributes in their lives at a specified time point [15]. The concept of QOL has become important since its first description in clinical practice. With the ever-rising new technologies in medicine and the new disease spectrum, QoL has been used as a decision-making tool for the past five decades. It has been assessed using different QOL tools in many different studies, largely in the developed world, where the results have been used in the guidance of clinical practice [9,16,17].

However, quality of life in clinical settings in Africa is still an understudied concept, especially in the surgical sciences. Tools for assessing the quality of life (QoL) are multi-sectorial and dependent on the domain of interest. Stoma-specific QoL is assessed by several special tools, one of which is the Stoma-QoL Tool. It is a 20-item questionnaire with four domains, namely body image, relation to family and friends, relation to sleep and fatigue, and ostomy bag function [18].

2.2 Clinical demography of adult ostomates

A study conducted in the U.S. found that the older age groups (71–80 and 81–95 years) had more ileostomies than the younger age groups (20–40, 51–60, and 61–70 years) did. There were the same number of colostomies and ileostomies in the 41–50 age group. When ostomy type was examined based on demographic factors, including gender, no differences were discovered[19]. Another cross-sectional study by Goodman et al. demonstrated that the majority of the patients had ileostomies compared to colostomies[16].

Pittman et al., in a descriptive cross-sectional study, discovered significant differences when several clinical indicators were studied based on the kind of ostomy. For several ostomy types, there were observable variations between

elective and emergency ostomy surgery. Colostomy was the ostomy type that was most frequently associated with urgent surgery. The type of ostomy was influenced by the surgical diagnosis[19]. The majority of studies reported inflammatory bowel disease and cancer to be the leading indications for stoma surgeries. Diverticulitis, familial adenomatous polyposis (FAP), incontinence, fistula, and Hirschsprung's disease were a few of the additional indications[2,10,17,19].

In a Ugandan study by Ssewanyana et al., male ostomates were more prevalent than females. They continued by demonstrating that sigmoid volvulus, a condition that disproportionately affects men and is widespread in central Uganda, may have contributed to the study's male preponderance. Their investigation also revealed that gangrenous bowel as a result of colonic volvulus was the most common diagnosis leading to stomas. The majority of stomas were colostomies of temporary intent and lasted for less than six months[8]. Likewise, in Ethiopia, a cross-sectional study by Zewude et al. found that the majority of study participants were residents of urban and semi-urban areas, while a few of them resided in rural areas of the country[13]. Colostomy was the most common type of stoma surgery, and the rest were ileostomies. Two-thirds of the patients had a permanent stoma. The most common reason for colostomy placement was malignancy, and the majority of patients were in their fifth decade of life[13].

In Tanzania, in the study conducted to assess stoma complications, Massenga et al. found that the vast majority of the ostomates were male. The most prevalent age ranged from 20 to 50 years. Bowel perforation was the most common cause of stoma placement. The most prevalent form of stoma was a colostomy, which was a result of anorectal carcinoma. The majority of the patients had temporary stomas.[20].

2.3 Stoma-specific QOL among ostomates

Stoma-specific quality of life refers to the assessment of the impact of having a stoma on various aspects of a person's life. It involves evaluating the physical, psychological, social, and emotional well-being of individuals living with stomas and

understanding how stoma surgery affects their daily activities, relationships, body image, and overall satisfaction.

In high-income countries, stoma patients generally experience moderate to high QoL probably, due to comprehensive pre- and post-operative care. Studies conducted using stoma-specific tools are very limited in number. According to Anaraki et al., in a study using the stoma QoL tool on Iranian ostomates, stoma patients had a high overall stoma quality of life [21]. Ketterer et al.'s research in Australia found that the overall stoma quality of life of non-metropolitan residents ranged from moderate to high[7]. According to Goodman et al., in a study conducted in the USA, 60% of patients consistently reported good stoma QoL [16]. All these studies recorded mean QoL scores of 60 and above.

Research on the quality of life (QoL) of stoma patients is severely lacking in low-income nations, notably in many African nations. The few available studies indicate that the majority of ostomates have a low or average quality of life. According to Motto et al, in a descriptive study in Cameroon, none of the ostomates had normal stoma QoL. Women were the most affected presenting with the lowest QoL [9]. More than 70% of the patients in Uganda reported sub-optimal stoma quality of life, according to Ssewanyana et al.[8]. In research conducted in Ethiopia, Zewude et al. found that more than 50% of the patients struggled with depression and changes in dietary habits [13].

2.4 Influence of Clinical Demographic Characteristics on QOL

Having an intestinal stoma is associated with poor QOL in many countries across the globe. In Europe, according to Ross et al., colon cancer patients with stomas had low QOL due to higher rates of depression, social dysfunction, difficulty engaging in sexual activity, and body image concerns [22]. In addition to the above factors, ostomates in Asia, according to a study conducted by Liao et al., have also experienced trouble finding a private space to empty their pouches and pouch leakage issues. These significantly worsened their social activities [23]. The type of stoma, whether permanent or temporary, the location of the stoma, and the surgical

diagnosis that resulted in the development of the stoma have all been found to significantly affect the quality of life of ostomates [21]. Several scholarly works published in Europe claim that a patient's age has no bearing on ostomates' quality of life[24,25].However according to Krouse and Hamashima et al, women scored significantly worse than men on measures of mental and overall health perception [24,25]. Furthermore, the level of education was found to have no discernible impact on quality of life [24]. In a Brazilian study, being married or cohabiting and religious was associated with higher scores in the physical and social domains of QoL, leading to a high overall QoL [26]. A positive influence on QoL among ostomates was also seen in nonmetropolitan Australian older patients and those who were working full or part-time [7].

The concept of QoL among adult ostomates in Africa is significantly understudied. Ostomates were found to have significant psychosocial impairments and depression, just like their counterparts in Europe and Asia [8,13]. In addition, they found it very difficult to adjust their dietary habits and clothing styles [8]. Clinical variables, such as a permanent colostomy and a cancer diagnosis, were more frequently linked to decreased overall QoL in Ethiopia, which resulted in a marked deterioration in the quality of life [13]. In Cameroon, Motto et al. reported that being female and having a permanent stoma was associated with poor QoL scores according to the body image scale. Furthermore, delays in returning to sexual activity were a common problem [9].

2.5 Association between clinical demography and stoma-specific QoL domains

Ostomates may experience variations in specific domains of their quality of life (QoL) based on differences in their clinical demography. The Stoma Specific QoL Tool evaluates four distinct domains: self-esteem and self-image, relationships with family and friends, sleep quality and fatigue levels, and the functionality of the ostomy device.

In a study conducted by Silva et al. in Portugal, it was observed that elderly ostomates exhibited statistically significant higher mean QoL scores in the domains

of self-esteem and self-image. Additionally, individuals diagnosed with malignancies and those who underwent urostomies placement demonstrated significantly higher scores in the domain of relation to family and friends. This suggests that clinical factors such as age, diagnosis, and stoma type can impact specific aspects of social and emotional well-being among ostomates [18].

Similarly, research conducted in Brazil revealed significant associations between clinical factors and various domains of QoL. Ostomates with ileostomies exhibited better scores in the physical domain, while the permanency of stoma had a notable influence on the psychological and social aspects of QoL. Moreover, non-clinical factors such as marital status and religion were found to be significantly associated with psychological, social, and spiritual domains, highlighting the intricate interplay between personal demographics and QoL outcomes [26].

In East Africa, particularly in Ethiopia and Uganda, studies utilizing QoL assessment tools such as the City of Hope QoL tool have identified significant associations between clinical variables and specific domains of QoL among ostomates. Factors such as stoma type (permanent/temporary), preoperative diagnosis, and gender were found to be linked to the psychological domain, particularly depression. Furthermore, the stoma site (colostomy/ileostomy) emerged as a significant determinant of body image concerns, emphasizing the importance of clinical considerations in addressing psychosocial aspects of QoL among ostomates in resource-limited settings [8,13].

Recognizing the diverse dimensions that influence the quality of life (QOL) of ostomates is essential for developing personalized interventions to enhance their well-being. By comprehensively understanding and addressing these domains, tailored interventions can be developed to meet the specific needs of ostomates in Tanzania, ultimately enhancing their quality of life.

CHAPTER THREE

3.0 MATERIALS AND METHODOLOGY

3.1 Study design

This was an analytical cross-sectional study on the QoL of ostomates at MNH.

3.2 Study setting

This study took place at Muhimbili National Hospital (MNH), which serves as a national referral hospital in Dar es Salaam, Tanzania. According to an ongoing EX LAP study and Data from the hospital theater database, the surgical department performs an average of 4 stomas and about 15 laparotomies per week. About 60% of all stomas performed are temporary. Hence, this hospital facilitated the recruitment of study participants.

3.3 Study population

The study involved all patients who had undergone abdominal surgery, either electively or on an emergency basis.

3.4 Sample population

Patients who had undergone abdominal surgery with intestinal stoma placement.

3.5 Inclusion and exclusion criteria

3.5.1 Inclusion criteria

i. All patients were at least 18 years of age at the time of recruitment.

ii. Individuals who underwent abdominal surgery with the creation of an intestinal stoma (colostomy or ileostomy).

iii. At least one-month post-surgical procedure.

iv. Provided verbal informed consent to participate in the study.

3.5.2 Exclusion Criteria

i. Patients with a significant stoma complication requiring another surgical procedure.

ii. Patients with stomas for palliation of incurable diseases.

3.6 Sample Size and Selection

Currently, there is no preliminary data from Tanzania on the quality of life of patients with intestinal stoma. However, in a study conducted by Latif et al, in Pakistan a total of 188 stomas were created from 2243 abdominal surgeries therefore, the proportion of stomas created was 0.08 [27]. Using these factors, a sample size calculation can be performed using the formula for sample size estimation for proportions: The sample size was calculated as follows:

N = [(Z^2 * p * (1-p)) / E^2]

Where:

n = total sample size.

Z = z-value corresponding to the desired confidence level.

p = proportion of cases based on previous research.

E = margin of error

n = [(1.96^2 * 0.08 * (1-0.08)) / 0.05^2]

n = (0.2827) / 0.0025

n = 0.1755 / 0.0025

n = 113

A minimum of 113 participants would be required to estimate the stoma quality-of-life proportion with a margin of error of 5% and a confidence level of 95%. This sample size calculation assumes a simple random sampling approach and uses the expected proportion from a similar study. Adjustments may be necessary based on

the specific context, anticipated response rates, or any additional factors that may impact the study design.

3.7 Variables

3.7.1 Dependent (outcome) variable

Stoma-Quality of life scores.

3.7.2 Independent (predictor) variables.

Age (in DOB format); sex (male or female); diagnosis category(benign vs malignant); stoma site (colostomy vs ileostomy); intent of stoma (permanent vs. temporary); procedure category (emergency vs elective); time since stoma insertion(<6 months vs ≥6 months. Stoma care counseling.

3.8 Recruitment

The Principal Investigator (PI) consecutively enrolled consenting adult patients in the study who had undergone stoma surgery at least 1 month before the interview date. All patients with stomas post-abdominal surgery who fitted the inclusion criteria were included. All patients who met the inclusion criteria underwent verbal informed consent procedures facilitated by the research coordinator. The researcher then completed a data collection tool using both the patient's medical record and their conversations. Data were uploaded into an MS Excel sheet and stored on the PI's computer until analysis time.

3.9 Methods

The study utilized a validated quality of life assessment tool, Stoma QoL questionnaires. Stoma-QoL, a specialized tool designed to assess the quality of life in patients with stomas, comprised 20 questions on a Likert scale of 1 to 4, with responses ranging from 1 "always" to 4 "not at all". This gives a minimum score of 20 and a maximum score of 80 for each respondent. The 20 questions are divided into groups producing 4 domains. They can be categorized into four domains: self-esteem and body-image including questions 4, 5, 7, 9, 11, family and friends

relations; comprising questions 12–20, sleep and fatigue; covering questions 6, 8, 10, and concerns regarding ostomy bag functioning; involving questions 1–3[18].

The participant's total responses were divided by the maximum sum (80) and then multiplied by 100 to determine a standardized QoL score on a scale of 0-100.These Scores were categorized into two groups: those exceeding 70% were classified as best or optimal, while scores below 70% were labeled as suboptimal. [8,28]. The validity and reliability of the Stoma QOL tool were assessed after translation into Swahili using a sample of 20 stoma patients who were subsequently excluded from our analysis. The average Chronbach's alpha coefficient was found to be 0.82, indicating good internal consistency. Additionally, clinical demographic data were collected, including age, gender, diagnosis, stoma duration, stoma procedure status, stoma site, stoma type, and stoma care counseling.

3.10 Data collection

The data were collected over a 4-month period by the principal investigator and the trained research assistant and recorded in an excel sheet. Cases were gathered from the ExLap study dataset, theater logbooks, and patients attending the surgical clinic. Operation notes of each patient were checked to ensure compliance with the inclusion criteria. The patient's name, hospital registration number, and contact information for the patient or next of kin were recorded in a separate excel sheet. Most patients were interviewed over the phone, but those who were seen in the clinic were interviewed in person.

3.11 Data Analysis

Data analysis was conducted using SPSS version 27. Descriptive statistics, including means, standard deviations, medians, interquartile range and frequencies summarized the clinical demography of the participants. Chi square and logistic regression analysis tests were used to check for association between clinical

demography and QoL scores. Furthermore, ANOVA was used to assess the relationship between clinical demography and various QoL domain scores.

3.12 Ethical consideration

Ethical approval was obtained from both MUHAS and the National Institute for Medical Research institutional review board (IRB) (MUHAS-REC-07-2023-1827). Verbal informed consent was obtained from all participants, ensuring their voluntary participation and the confidentiality of their personal information. Participant privacy and data protection were strictly adhered to throughout the study.

CHAPTER FOUR

4.0 ANALYSIS AND RESULTS

4.1 Clinical demography of stoma patients

Table 1 represents the clinical demography of stoma patients. A total of 126 stoma patients were recruited. Among these patients, 58.7% were male, and the majority (80.2%) were under 65 years of age. Additionally, 76.2% of the patients were diagnosed with malignant conditions, with elective procedures being more common (63.5%). The median stoma duration was 6.6 months (IQR 3.9 – 12.3), and most patients had temporary stomas (70.6%), predominantly colostomies (88.1%). Stoma care counseling was done for 71.4% of patients.

Table 1: Clinical demography of stoma Patients attended at MNH from Aug 2023 – Feb 2024, N = 126

Variable	f (%)
Age (median)	
≥ 65 years	25 (19.8)
41-64 years	63 (50.0)
≤40	38 (30.2)
Sex	
Male	74 (58.7)
Female	52 (41.3)
Diagnosis category	
Benign	30 (23.8)
Malignant	96 (76.2)
Procedure category	
Emergency	46 (36.5)
Elective	80 (63.5)
Stoma duration, months (median, IQR)	6.6(3.9 – 12.3)
Type of stoma	
Temporary	89 (70.6)
Permanent	37 (29.4)
Stoma site	
Colostomy	111 (88.1)
Ileostomy	15 (11.9)
Stoma care counselling	
Yes	90 (71.4)
No	36 (28.6)

*IQR; interquartile range, f; frequency (number of patients)

4.4 Overall Stoma –specific QoL among ostomates.

The overall median QoL score was 50 with IQR (44 to 59) on a scale of (20-80). **Figure 2** below illustrates the classification of stoma QoL scores after conversion into a linear scale of 0-100 where scores ≥70% were considered best or optimal while those below were considered suboptimal. Majority of our patients (66%) reported suboptimal stoma specific QoL scores as illustrated in the figure below

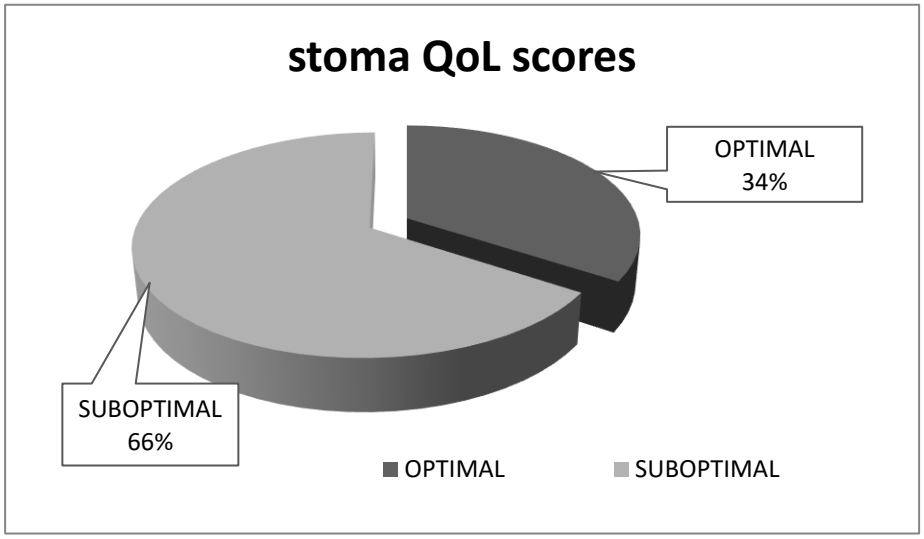


Figure 2: Illustration of Participants' stoma QoL scores

4.5 Influence of clinical demographic characteristics on QoL among ostomates

Table 2 below indicates a significant association, as determined by chi-square analysis, between age (p=0.003), stoma site (p=0.024), and stoma care counseling (p=0.023), with optimal quality of life (QoL) among individuals with stomas. A higher proportion of participants with optimal QoL (64%) were elderly compared to the younger age groups (26/27%). Additionally, the majority of participants (38%) with optimal QoL had colostomies compared to those with ileostomies (6.7%). Notably, a higher proportion (40%) of participants with optimal QoL received stoma care counseling compared to those who did not (19%).

Table 2: **Clinical demographics association with optimal and sub optimal QoL among ostomates (chi-square)**

Variable	Optimal QoL		P-value
	Yes n (%)	No n (%)	
Age			
18-40	10(26%)	28(74%)	
41-64	17(27%)	46(73%)	**0.003**
≥65	16(64%)	9(36%)	
Sex			
Male	25(34%)	49(66%)	0.923
Female	18(34%)	34(66%)	
Diagnosis category			
Benign	8(27%)	22(73%)	0.316
Malignant	35(36%)	61(64%)	
Procedure category			
Emergency	14(30%)	32(70)	0.506
Elective	29(36)	51(64)	
Stoma type			
Temporary	28(31)	61(69)	0.33
permanent	15(40)	22(60)	
Stoma site			
Colostomy	42(38)	69(62)	
Ileostomy	1(6.7)	14(93)	**0.024**
Stoma counseling			
Yes	36(40)	54(60)	**0.023**
No	7(19)	29(81)	
Stoma duration			
<6months	20(34)	39(66)	0.359
≥6months	23(34)	44(66)	

** The stoma care counselling aspect involved patient education by a nurse on how to care for their stoma including how to clean it, change pouch system and manage skin irritation and leakage issues.

4.6 Clinical demographics influence optimal stoma-QoL scores in ostomates

The analysis examines the relationship between several variables and quality of life (QoL) scores, both in a bivariate and multivariable context. **Table 3 .**

In the bivariate analysis, it was found that elderly individuals above 65years had significantly higher odds of experiencing optimal quality of life (QoL) (OR = 3.11, p = 0.004), while those in the middle-aged group exhibited significantly lower odds (OR = 0.51, p = 0.039). Furthermore, patients with a colostomy showed significantly higher odds of optimal QoL (OR = 4.55, p = 0.042), whereas participants who received counseling had significantly lower odds of optimal QoL (OR = 0.36, p = 0.032). In the subsequent multivariable analysis, the association between age and

optimal QoL remained significant for individuals aged 65 and above (AOR = 3.24, p = 0.009), However, although the association between colostomy and optimal QoL decreased after adjustment (AOR = 3.69, p = 0.055), it was no longer deemed significant. After adjustment, individuals who received stoma care counseling demonstrated higher odds of experiencing optimal QoL (AOR = 3.23, p = 0.022).

Table 3: Clinical demographics influence on optimal stoma-QoL scores among ostomates logistic regression analysis

Variable	Optimal QoL			
	Bivariate		Multivariable	
	O.R (95% C.I)	p-value	A.O.R (95% C.I)	P-value
Age				
≥ 65 years	3.11 (1.44-6.73)	0.004	3.24 (1.34-7.83)	**0.009**
41-64 years	0.51 (0.27 – 0.97)	0.039	0.62 (0.31 – 1.18)	0.170
18-40	Ref		Ref	
Sex				
Male	0.96 (0.46-2.04)	0.923	0.88 (0.38-2.28)	0.877
Female	Ref		Ref	
Diagnosis				
Malignant	0.63 (0.26-1.57)	0.326	0.69 (0.18-2.60)	0.579
Benign	Ref		Ref	
Procedure Category				
Emergency	0.77 (0.35-1.67)	0.508	1.25 (0.405-3.87)	0.697
Elective	Ref		Ref	
Ostomy site				
Colostomy	4.55 (1.06– 19.59)	0.042	3.69 (0.84-16.23)	0.055
Ileostomy	Ref		Ref	
Stoma type				
Temporary	0.67 (0.30-1.49)	0.329	0.59 (0.22-1.60)	0.303
Permanent	Ref		Ref	
Stoma Duration				
<6months	0.98 (0.47-2.05)	0.959	1.31 (0.55-3.12)	0.544
≥6months	Ref		Ref	
Counseling for stoma				
Yes	0.36 (0.14-0.92)	0.032	3.23 (1.18-8.85)	**0.022**
No	Ref		Ref	

QOL; Quality of life, **OR; Odds ratio, AOR; Adjusted odds ratios, CI; confidence interval**

4.7 Association between clinical demography and stoma specific QoL domains scores.

Table 4 illustrates the association between clinical demography and stoma-specific Quality of Life (QoL) domains scores among ostomates. Advanced age was significantly linked to certain domains of stoma-specific QoL: older ostomates exhibited fewer concerns regarding their physical appearance, as indicated by higher mean scores of 14.04 (SD ± 3.35, p = 0.001) on the self-esteem and body image domain. Additionally, elderly ostomates maintained positive relationships with family and friends despite having a stoma, reflected in a statistically significant mean score of 26.76 (SD ± 5.14, p = 0.028) on the relation to family and friends domain. Ostomates with a permanent stoma demonstrated better proficiency in managing ostomy device function, evidenced by a significant mean score of 7.51 (SD ± 2.28, p = 0.026). While no significant associations were found between other demographic variables and stoma QoL domains, although stoma site exhibited a trend towards significant association with the relation to family and friends domain.

Table 4: Association between clinical demography and stoma specific QoL domains

Clinical variables	Body-image		*Relation to family and friends*		*Relation to sleep and fatigue*		*Ostomy device function*	
	Mean ± SD	**P-value**	**Mean ± SD**	**P-value**	**Mean ± SD**	**P-value**	**Mean ± SD**	**P-value**
Sex								0.686
Male	11.74±3.04	0.864	24.77±5.15	0.459	7.94±2.56	0.495	6.64±2.51	
Female	11.84±3.65		24.09±4.80		7.63±2.45		6.83±2.76	
Age (years)								0.128
≥65	14.04 ± 3.35	**0.001**	26.76±5.14	**0.028**	7.52±2.31	0.454	7.64±2.68	
41-64	11.46±3.13		23.62±4.66		7.68±2.29		6.57±2.45	
18-40	10.84±2.91		24.45±5.12		8.23±2.95		6.34±2.74	
Diagnosis category								0.715
Malignant	11.43±2.88	0.504	23.30±4.98	0.135	7.63±2.83	0.647	6.87±2.91	
Benign	11.90±3.42		24.86±4.98		7.88±2.41		6.67±2.52	
Procedure category								
Emergency	11.28±3.11	0.195	24.39±4.82	0.865	7.65±2.63	0.577	6.65±2.59	0.84
Elective	12.08±3.38		24.55±5.13		7.91±2.45		6.75±2.63	
Stoma site								
Colostomy	11.86 ±3.40	0.518	24.79±5.08	0.066	7.96±2.49	0.074	6.76±2.66	0.621
Ileostomy	11.27±2.40		22.27±3.84		6.73±2.43		6.40±2.26	
Stoma type								
Temporary	11.52±3.36	0.156	24.27±4.67	0.441	7.76±2.45	0.712	6.38±2.67	**0.026**
Permanent	12.43± 3.09		25.03±5.75		7.95±2.68		7.51±2.28	
Stoma duration								
<6months	11.69±3.16	0.77	23.98±5.20	0.286	7.53±2.44	0.222	6.46±2.60	0.302
≥6months	11.86±3.43		24.94±4.82		8.07±2.55		6.94±2.61	
Stoma counselling								
Yes	12.04±3.37	0.164	24.81±4.72	0.259	7.80±2.53	0.902	6.93±2.77	0.137
No	11.14±3.06		23.69±5.64		7.86±2.50		6.17±2.08	

CHAPTER FIVE

5.0 DISCUSSION

Quality of life (QoL), as defined by WHO, encompasses individuals' perceptions of their overall health status across various domains of life [4]. It is a subjective assessment of an individual's well-being in multiple aspects of life. Quality of life is increasingly acknowledged as a critical outcome measure for survivors of major surgical and medical intervention.

In this study, we observed a median overall stoma-specific QoL score of 50 on a scale ranging from 20 to 80. These findings align with previous studies conducted in Uganda and Canada [8,29]. However, disparities were noted when comparing our results to those from developed countries, as reported by Ketterer et al. , Aluzaite et al., and Anaraki et al. , who reported higher mean and median QoL scores exceeding 60 [7,21,30]. This discrepancy may be attributed to the older age demographic of their study participants and the longer duration since stoma formation, potentially leading to adaptation to living with a stoma over time.

Remarkably, a study conducted by Zewude et al. in Ethiopia revealed that ostomates exhibited a mean QoL score exceeding 70%, despite the country's status as a developing nation. This disparity in QoL scores could potentially be linked to participants' quick adjustments to their diet and their high scores on the spiritual domain, both of which likely contributed to their overall QoL scores. This finding echoes observations made in Iran by Anaraki et al., suggesting that spiritual well-being and dietary adaptation play significant roles in influencing QoL outcomes among ostomates [13,21]. Consequently, the assessment of stoma patients' QoL is considered a subjective measure of overall surgical quality of care.

While findings from this study are consistent with previous research, it's essential to acknowledge that only approximately one-third (34%) of our respondents achieved median QoL scores categorized as 'best' or optimal, based on established criteria in surgical practice QoL patterns [8,31]. This suggests that there remains significant

room for improvement in addressing the QoL of ostomates. Consistent with existing literature, our study followed the criterion that only standardized overall QoL scores exceeding a threshold of 70% are deemed 'best' or optimal within the context of stoma-specific QoL[8,32]. However, it is noteworthy that only about a third of our study participants achieved scores exceeding this threshold. While a comprehensive exploration of the reasons behind this discrepancy was beyond the scope of our study objectives, several factors warrant speculation.

Firstly, our study population comprised patients with a relatively shorter duration since stoma insertion compared to many studies conducted in Western populations. For instance, Guren et al. reported following up patients with at least 1 year since stoma insertion using their Norwegian cancer registry [33]. The shorter duration since stoma insertion in our study might have influenced patients' adaptation and adjustment processes, thereby affecting their QoL scores.

Furthermore, our study included patients with stomas originating from various clinical diagnoses, ranging from benign to malignant causes, which could introduce heterogeneity in the patient population. This diversity in clinical diagnoses may have implications for the unique challenges and experiences faced by patients, influencing their QoL outcomes.

Despite these considerations, our study findings align with those reported in African settings, such as the study by Ssewanyana et al. in Uganda, which also reported relatively low 'Optimal' QoL scores among participants[8]. This suggests that similar challenges in achieving optimal QoL scores may be present across different African populations, emphasizing the need for tailored interventions to address the specific needs of ostomates in these contexts.

Our study also revealed a slightly higher male preponderance in the studied population, with a characteristic male-to-female ratio of 1.4:1. The majority of our participants were relatively younger adults, with approximately 80% being under 65 years old and a median age of around 50 years. Furthermore, over three-quarters of stoma patients in our study had stomas originating from malignant causes and

colostomy was the most common type reported .These findings are consistent with studies conducted in both African settings and the Western hemisphere, indicating a similar clinical demographic profile among ostomates [7,8,13,18,30,34]. For instance, a study from Uganda reported a relatively younger aged stoma population with a male predominance and a high prevalence of colostomy, mirroring our findings[8].

In contrast, different findings were reported in Pakistan by Mumtaz Ahmed and colleagues , where the majority of stomas were ileostomies due to prevalent conditions such as typhoid perforation and intestinal tuberculosis [35]. The observed younger age group among stoma patients in African settings is suggested to reflect the generally younger population compared to the developed North, while the male preponderance of ostomates may be attributed to conditions like colorectal cancer, which predominantly affect males in Africa as reported by Awedew et al., in their assessment of the burden and trend of colorectal cancer in 54 countries in Africa [36]. These discrepancies highlight the importance of considering regional and cultural factors, as well as variations in healthcare systems and patient populations, when interpreting study findings.

This investigation delved into the complex interactions between clinical demography, various QoL domains and optimal QoL among ostomates receiving care at Muhimbili National Hospital. Notably, our analysis pinpointed age as a pivotal clinical demographic factor exerting a discernible influence on the QoL among individuals living with stomas in our specific context. Specifically, elderly individuals, aged 65 and above, demonstrated higher overall quality of life scores compared to younger ostomates. This observation aligns with previous stoma studies, which consistently indicated that older ostomates tend to experience better stoma specific quality of life [7,8,13,22,33,34].

For instance, Ketterer and colleagues conducted a cross-sectional survey in non-metropolitan Western Australia, exploring the levels and factors associated with QoL among stoma patients. They observed that advanced age was linked to better QoL scores among ostomates, attributed to factors such as acceptance and tolerance of

intestinal artificial pouches. Their study, with a predominantly older population (median age = 73 years) compared to ours, reinforced the association between age and QoL scores [7].

Furthermore, Ketterer et al. identified additional factors beyond age that significantly influenced QoL scores among stoma patients, including full-time work positions and post-stoma sexual activity. These findings emphasize on the multifaceted nature of QoL determinants and the importance of considering various demographic and lifestyle factors in assessing patients' well-being.

Stoma therapy or counseling is a highly complex aspect of healthcare, typically requiring specialized enterostomal nurses who are extensively trained in this field. Presently, our facility lacks dedicated stoma therapy nurses. However, recognizing the importance of stoma care counseling, we sought to evaluate the impact of the guidance provided by our general nurses and doctors. This counseling primarily focuses on educating patients on how to care for their stomas, including techniques for cleaning, changing pouch systems, and managing issues like skin irritation and leakage.

Our study revealed that stoma care counseling significantly contributes to the optimal QoL for ostomates. This finding aligns with an interventional study conducted in Iran, which examined the effectiveness of structured training for ostomates on stoma care. Notably, the training demonstrated a significant reduction in anxiety levels among ostomates as early as one month post-stoma surgery [5]. The creation of an ostomy is a life-altering event that often induces anxiety and prompts numerous questions for ostomates, such as how to clean the stoma area safely and concerns about the security of the pouch system. Early training for ostomates has proven effective in addressing these concerns, thereby reducing anxiety levels and ultimately enhancing overall QoL.

Elderly ostomates showed less concern regarding their self-esteem and body image compared to their younger counterparts. This trend could be attributed to the likelihood that elderly individuals place less emphasis on their physical appearance,

potentially influencing the quality of life assessments within this domain. Younger ostomates are more likely to be embarrassed than the elderly. Our findings align with findings from studies conducted in the USA and Portugal [18,37].

Furthermore, this study revealed that elderly ostomates maintained positive relationships with family and friends, despite the challenges posed by living with a stoma. This underscores the importance of social support networks in mitigating the psychosocial impact of stoma surgery, particularly among older individuals who may rely more heavily on familial and social connections for emotional support and well-being. This is also reflected in the findings of Silva et al in their assessment of QoL among ostomates in Portugal[18].

Additionally, a superior proficiency in managing ostomy device function was observed among ostomates with a permanent stoma. This highlights the potential benefits of long-term adaptation and experience in coping with the practical aspects of stoma care. This mirrors findings in a study conducted in Switzerland on the effects of utilizing stoma belts where patients with permanent stomas had better coping rendering them to have better outcomes in managing stoma device functions[38].

CHAPTER SIX

6.0 STUDY LIMITATION, CONCLUSION AND RECOMMENDATIONS

6.1 Limitations

This study was conducted at a single referral center, which may lead to referral bias and limit our findings' generalizability to a broader population.

Additionally, our study design was cross-sectional, which made it challenging to establish temporal relationships between exposure and outcome variables simultaneously.

6.2 Conclusion

This study highlighted several important insights into the factors affecting the quality of life (QoL) among ostomates. Firstly, age emerged as a significant determinant of QoL, indicating that younger individuals may face unique challenges related to living with an ostomy. The elderly showed less concern on their self-esteem/body image domains and their relations to family and friends were less affected compared to younger ostomates.

Secondly, among those who reported optimal QoL, stoma care counseling emerged as an independent determinant of QoL. Those who underwent stoma care counseling experienced a good quality of life.

Two-thirds of participants reported sub-optimal stoma QoL scores with a median score of 50. This highlights the importance of addressing the specific needs of ostomates through tailored interventions and support services. By providing targeted education, comprehensive counseling, and access to resources, healthcare providers can strive to enhance the overall well-being and satisfaction of ostomates, thereby improving their quality of life and the quality of care they receive.

6.3 Recommendations

1. Future research should expand its scope beyond national referral centers to encompass a diverse array of healthcare settings. This broader approach would alleviate selection biases and afford a more holistic perspective on the experiences of ostomates across various levels of care.

2. Longitudinal study designs should be used due to their capacity to assist in establishing temporal relationships between exposures and outcomes, providing valuable insights into the progression of factors over time and their effects on the quality of life among ostomates.

REFERENCES

1. Burgess-Stocks J, Gleba J, Lawrence K, Mueller S. Ostomy and Continent Diversion Patient Bill of Rights: Research Validation of Standards of Care. J Wound, Ostomy Cont Nurs. 2022;49(3):251–60.
2. Ahmad QA, Kamran Saeed M, Muneera MJ, Sarfraz Ahmed M, Khalid K. Indications and complications of intestinal stomas - a tertiary care hospital experience. Biomedica. 2010;26(January):144–7.
3. Rethmeier L, Boisen E, Cabral C. Burden of Illness in Ostomates: A German-Based Claims Database Analysis. Value Heal. 2018;21:S83.
4. The World Health Organization quality of life assessment (WHOQOL): Position paper from the World Health Organization. Soc Sci Med [Internet]. 1995;41(10):1403–9. Available from: https://www.sciencedirect.com/science/article/pii/027795369500112K
5. Khalilzadeh Ganjalikhani M, Tirgari B, Roudi Rashtabadi O, Shahesmaeili A. Studying the effect of structured ostomy care training on quality of life and anxiety of patients with permanent ostomy. Int Wound J. 2019;16(6):1383–90.
6. Jin Y, Tian X, Li Y, Jiménez-Herrera M, Wang H. Effects of continuous care on health outcomes in patients with stoma: A systematic review and meta-analysis. Asia-Pacific J Oncol Nurs. 2022;9(1):21–31.
7. Ketterer SN, Leach MJ, Fraser C. Factors Associated with Quality of Life among People Living with a Stoma in Nonmetropolitan Areas. Nurs Res. 2021;70(4):281–8.
8. Ssewanyana Y, Ssekitooleko B, Suuna B, Bua E, Wadeya J, Makumbi TK, et al. Quality of life of adult individuals with intestinal stomas in uganda: A cross sectional study. Afr Health Sci. 2021;21(1):427–36.
9. Bwelle Motto G, Bang GA, Ngoumfe JCC, Ekani Boukar YM, Sendjong RLK de, Ngo Nonga B, et al. Outcomes and Quality of Life of Patients with a Digestive Stoma in Sub-Saharan Africa: Case of the Yaounde Central Hospital, Cameroon. Surg Sci. 2021;12(11):381–9.
10. Altuntas YE, Kement M, Gezen C, Eker HH, Aydin H, Sahin F, et al. The role

of group education on quality of life in patients with a stoma. Eur J Cancer Care (Engl). 2012;21(6):776–81.

11. Sier MF, Oostenbroek RJ, Dijkgraaf MGW, Veldink GJ, Bemelman WA, Pronk A, et al. Home visits as part of a new care pathway (iAID) to improve quality of care and quality of life in ostomy patients: a cluster-randomized stepped-wedge trial. Color Dis. 2017;19(8):739–49.
12. Su X, Zhong MH, Ye XM, Zhen L, Yin XX, Qin F, et al. Effects of Evidence-Based Continuing Care Bundle on Health Outcomes in Rectal Cancer Patients With Temporary Stomas: A Multicenter Randomized Controlled Trial. Cancer Nurs. 2021;44(3):223–34.
13. Zewude WC, Derese T, Suga Y, Teklewold B. Quality of Life in Patients Living with Stoma. Ethiop J Health Sci. 2021;31(5):993–1000.
14. Karadağ A, Menteş BB, Üner A, Irkörücü O, Ayaz S, Özkan S. Impact of stomatherapy on quality of life in patients with permanent colostomies or ileostomies. Int J Colorectal Dis. 2003;18(3):234–8.
15. Pennacchini M, Bertolaso M, Elvira MM, De Marinis MG. A brief history of the quality of life: Its use in medicine and in philosophy. Clin Ter. 2012;162(SUPPL.3).
16. Goodman W, Downing A, Allsop M, Munro J, Taylor C, Hubbard G, et al. Quality of life profiles and their association with clinical and demographic characteristics and physical activity in people with a stoma: a latent profile analysis. Qual Life Res [Internet]. 2022;31(8):2435–44. Available from: https://doi.org/10.1007/s11136-022-03102-5
17. Davidson F. Quality of life, wellbeing and care needs of Irish ostomates. Br J Nurs. 2016;25(17):S4–12.
18. Silva JO, Gomes P, Gonçalves D, Viana C, Nogueira F, Goulart A, et al. Quality of Life (QoL) Among Ostomized Patients – a cross-sectional study using Stoma-care QoL questionnaire about the influence of some clinical and demographic data on patients' QoL. J Coloproctology. 2019;39(1):48–55.
19. Pittman J. Characteristics of the patient with an ostomy. J Wound, Ostomy Cont Nurs. 2011;38(3):271–9.

20. Massenga A, Chibwae A, Nuri AA, Bugimbi M, Munisi YK, Mfinanga R, et al. Indications for and complications of intestinal stomas in the children and adults at a tertiary care hospital in a resource-limited setting: A Tanzanian experience. BMC Gastroenterol. 2019;19(1):1–10.
21. Anaraki F, Vafaie M, Behboo R, Maghsoodi N, Esmaeilpour S, Safaee A. Quality of life outcomes in patients living with stoma. Indian J Palliat Care. 2012 Sep;18(3):176–80.
22. Ross L, Abild-Nielsen AG, Thomsen BL, Karlsen R V, Boesen EH, Johansen C. Quality of life of Danish colorectal cancer patients with and without a stoma. Support Care Cancer [Internet]. 2007;15(5):505–13. Available from: https://doi.org/10.1007/s00520-006-0177-8
23. Liao C, Qin Y. Factors associated with stoma quality of life among stoma patients. Int J Nurs Sci [Internet]. 2014;1(2):196–201. Available from: http://dx.doi.org/10.1016/j.ijnss.2014.05.007
24. Krouse RS, Herrinton LJ, Grant M, Wendel CS, Green SB, Mohler MJ, et al. Health-related quality of life among long-term rectal cancer survivors with an ostomy: Manifestations by sex. J Clin Oncol. 2009;27(28):1664–4670.
25. Hamashima C. Long-term quality of life of postoperative rectal cancer patients. J Gastroenterol Hepatol. 2002;17(5):571–6.
26. Diniz IV, Costa IKF, Nascimento JA, da Silva IP, de Mendonça AEO, Soares MJGO. Factors associated to quality of life in people with intestinal stomas. Rev da Esc Enferm. 2021;55:1–8.
27. Latif A, Shabbir F, Hameed K. Prevalence of intestinal stoma formation in the management of abdominal surgery in emergency Department of Allama Iqbal memorial teaching hospital. Pakistan J Med Heal Sci. 2016;10(2):498–502.
28. Jayarajah U, Samarasekera DN. A cross-sectional study of quality of life in a cohort of enteral ostomy patients presenting to a tertiary care hospital in a developing country in South Asia. BMC Res Notes. 2017;10(1):1–8.
29. Lai E, Peterson AC, Liu G, Karimuddin A, Crump RT, Sutherland JM. Psychometric validation of the Stoma-QOL questionnaire in a Canadian cross-sectional sample of colostomy and ileostomy patients. Scand J

Gastroenterol [Internet]. 2018;53(6):721–6. Available from: https://doi.org/10.1080/00365521.2018.1457713

30. Aluzaite K, Nuttall JW, O'Connor M, Harvie R, Schultz M. Quality of life in postostomy surgery patients: A cross-sectional survey. JGH Open. 2020;4(5):987–94.
31. Sinha A, Goyal H, Singh S, Rana SPS. Quality of life of ostomates with the selected factors in a selected hospital of Delhi with a view to develop guidelines for the health professionals. Indian J Palliat Care. 2009;15(2):111–4.
32. Saini P, Gaba R, Faridi MS, Agarwal N, Kaur N, Gupta A. Quality of Life of Patients After Temporary Ileostomy for Ileal Perforation- A Questionnaire Based Study. Indian J Surg. 2014;76(1):38–43.
33. Guren MG, Eriksen MT, Wiig JN, Carlsen E, Nesbakken A, Sigurdsson HK, et al. Quality of life and functional outcome following anterior or abdominoperineal resection for rectal cancer. Eur J Surg Oncol. 2005;31(7):735–42.
34. Mohebi S, Parham M, Sharifirad G, Gharlipour Z. Social Support and Self - Care Behavior Study. 2018;(January):1–6.
35. Ahmad Khan M, Jamal S, Rashid R, Ahmad N. Quality of Life Assessment in Patients with Stoma in Muslim Population. Inst Med Sci. 2011;7(4):222.
36. Awedew AF, Asefa Z, Belay WB. Burden and trend of colorectal cancer in 54 countries of Africa 2010–2019: a systematic examination for Global Burden of Disease. BMC Gastroenterol [Internet]. 2022;22(1):1–12. Available from: https://doi.org/10.1186/s12876-022-02275-0
37. Mitchell KA, Rawl SM, Schmidt CM, Grant M, Ko CY, Baldwin CM, et al. Embarrassment in Veterans Living With an Intestinal Stoma. 2007;34(October):524–32.
38. Karhu EK, Hernandez AE, Restrepo AM, Hui VW. Ostomy Belt Use Improves Quality of Life in Patients with a Stoma. Surgeries (Switzerland). 2024;5(1):92–102.

APPENDICES

Appendix 1: Consent Form (English version)

PART I: INFORMATION

Dear Participant,

My name is Hassan Juma Mwakimako , and I work as a researcher at Muhimbili University of Health and Allied Sciences (MUHAS) on a project called, “Quality of life among Adults ostomates at Muhimbili National Hospital Dar es Salam, Tanzania.’’

Participation:

You were subjected to abdominal surgery, which is why you are being invited to take part in this study. For the study, we have already gathered some data regarding your procedure. We had to collect this data as soon as feasible following your surgery in order to ensure the accuracy of the information about your procedure. We were unable to obtain your permission for this collection due to your medical condition. If you agree to take part in this study, we will keep the data we have already obtained on you. Your medical records will also be examined in order to learn more details about your surgery. Information on your surgery's specifics and any extra medical conditions you might be dealing with will be gathered.

We will subject you to a single questionnaire if you only underwent laparotomy without stoma formation. If you have a stoma placed, we will subject you to two questionnaires. The time taken to answer these questionnaires is a maximum of 10 minutes.

Confidentiality: Your data will be used by researchers to carry out this investigation. When the research utilizing your data is finished, we might share it with other researchers so they can use it in future research. We won't divulge your identity or any other details that could identify you to the researchers. We will make every effort to keep the data we obtain from you secure. We'll keep your personal

information confidential. The completed surveys will be kept secure and separate from information that identifies you. Direct access to completed surveys will only be available to a few select researchers. Names and other details that might identify you won't be used if this study is published or discussed at scientific events. Your research data may be reviewed by Muhimbili University of Health and Allied Sciences authorized representatives to supervise or oversee the conduct of this study.

Right to withdrawal: This is a research study, and participation is voluntary. Yes, you do not have to complete a survey. If you choose not to be in this study you will not lose any of your regular benefits, and you can still receive medical care from Muhimbili University Hospital.

Benefits: There is no benefit to you. The survey results will be used for research.

Injury/Harm: We don't anticipate that taking part in this study will endanger you in any way.

Who to contact: For any inquiry regarding this study please do not hesitate to contact Dr. Hassan Juma Mwakimako, resident doctor in the general surgery Department at MUHAS +255766604213, or Research Supervisor Professor Larry Akoko,+255756448468; P.O Box 65001, Dar Es Salaam.

For any questions pertaining to rights as a research participant, contact Dr. Nahya Salim the Director of Research and Publications at MUHAS; P.O. Box 65001, Dar es Salaam, Tel: +255 713250074.

PART II: CERTIFICATE OF CONSENT

Please consider your decision after reading the following sentences: Please tick on one option within the brackets below.

Are you willing to take part in the survey??

a) YES [ ]
b) NO [ ]

Do you give someone authorization to reach you in the future to inquire about your health Status?

a) YES [ ]
b) NO [ ]

Do you consent to someone contacting your next-of-kin and/or emergency contact if you cannot be reached?

a) YES [ ]
b) NO [ ]

You have been given copies of this consent form to keep.

I, _____, have read the contents in this form. My questions have been answered. I agree to participate in this study.

If you wish to be in this study, please sign below.

_____

Participant Name

Date Participant's Signature for Consent

Date Person providing consent on behalf of patient (if patient unable)

Date Person Obtaining Consent

Appendix 2: Consent Form (Swahili version)

SEHEMU YA I: TAARIFA

Jina langu ni Hassan Juma Mwakimako , na ni mtafiti kutoka Chuo Kikuu cha Afya na Sayansi Shirikishi (MUHAS), kwenye mradi wa “Kuchunguza matokeo ya ubora wa maisha miongoni mwa wagonjwa baada ya kuekewa njia mbadala ya haja kubwa” katika hospitali kuu ya Muhimbili nchini Tanzania.

Ushiriki: Unaombwa kushiriki katika utafiti huu kwa sababu umefanyiwa upasuaji wa tumbo.Fahamu yakwamba ni wewe pekee ndio utakaye shiriki katika utafiti huu wala si mtu yeyote mwingine atakaye kuwasilisha.Tayari tulishachukua taarifa zako za upasuaji punde tu ulipomaliziwa upasuaji wako hapo awali .Vile vile tumechukua taarifa za magonjwa yako yoyote mengine yasiyo husiana na upasuaji wako.Iwapo ulifanyiwa upasuaji wa tumbo bila ya kuekewa njia mbadala ya haja kubwa, utajaza dodoso moja linalouliza maswali kuhusu afya yako kwa ujumla. kwa yule aliyefanyiwa upasuaji na keukewa njia mbadala ya haja kubwa, atajaza madodoso mawili,la afya jumla na la afya kulingana na njia ile mbadala ya haja kubwa.

Usiri: Wajumbe wa timu yetu ya utafiti wataweza kuona na kutumia taarifa zako kwa ajili ya kufanya utafiti huu. Baada ya utafiti kukamilisha matumizi ya taarifa zako, tunaweza kushirikisha watafiti wengine na hivyo kuzitumia taarifa zako katika tafiti zingine hapo baadae. Hatutatumia jina lako au taarifa zako zingine binafsi. Hatutakuomba ridhaa nyingine ya ziada katika kutumia taarifa zako zisizo na utambulisho**.** Endapo utafiti huu utachapishwa/kusambazwa au kutolewa/kuzungumza katika mikutano ya kisayansi, majina na taarifa zozote zinazo kukutambulisha wewe hazitatumika. Wawakilishi wenyeidhini kutoka katika shirika la Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili wanaweza kupitia taarifa zako za utafiti kwamadhumuni ya kuangalia au kusimamia mwenendo wa utekelezwaji wa utafiti huu.

Haki ya kujitoa: Ushiriki kwenye utafiti huu ni wa hiari na washiriki wanaweza kujitoa kwenye utafiti huu wakati wowote baada ya kukubali

Faida: Hakuna faida ya moja kwa moja kwako. Matokeo yatatumika kwa utafiti. Tunatumaini kwamba taarifa zitakazo kusanywa katika utafiti huu zitasaidia kutaarifu mikakati ya kuboresha huduma za upasuaji wa tumbo kwa wagonjwa kwa walioekewa njia mbadala ya haja kuu hapo baadae.

madhara: hatutarajii wewe kudhurika kwa kushiriki kwako kwenye utafiti huu

kwa mawasiliano: Endapo utakua na swali lolote linalohusu utafiti huu, wasiliana na wafuatao: Dkt. Hassan Juma Mwakimako(Mtafiti mkuu), mwanafunzi wa Shahada ya Uzamili Idara ya upasuaji , Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili, S.L.P.65001, Dares Salaam. Simu +255 766604213 ama msimamizi wangu wa utafiti Professor Larry Akoko . simu +255 756 448 468

Kwa maswali kuhusu haki zako kama mshiriki, unaweza kuwasiliana na Dkt. Nahya Salim, Mwenyekiti wa Kitengo cha Utafiti, Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili, P.O.Box 65001, Dar es Salaam. Simu: +255 713250074.

IDHINI

Mimi, _____, nimesoma yaliyomo kwenye fomu/hati hii.

Maswali yangu yamejibiwa. Naridhia kushiriki kwenye utafiti huu.

Tafadhali soma sentensi zifuatazo na ufikirie kuhusu chaguo lako. Baada ya kusoma sentensi, Tafadhali weka alama na herufi za kwanza za majina yako kwenye sanduku linalohusika. Chochote utakachoamua kuchagua hakita athiri huduma yako.

Je unakubali kushiriki katika utafiti huu?

a) NDIYO [ ]
b) HAPANA [ ]

Je unatoka ruhusa ya mtu kuwasiliana na wewe hapo baadae, kuuliza maswali kuhusu hali yako ya kiafya na matibabu unayopata?

a) NDIYO [ ]
b) HAPANA[ ]

Je unatoa ruhusa ya mtu kuwasiliana na ndugu na/au mtu aliye andikwa kwa dharura

kama hatutaweza kukupata?

a) NDIYO [ ]
b) HAPANA [ ]

Umepewa nakala za fomu hii ya idhini ili uhifadhi
Umepatiwa nakala ya fomu hii uwe nayo

_____

_____
Jina la Mshiriki

Tarehe Sahihi ya Mshiriki Kuridhia

Tarehe Sahihi ya Shahidi (kama mshiriki hawezi kusoma)

Tarehe Sahihi ya Msahili/Mtafiti Msaidizi

Appendix 3 Clinical Research Tools

Section A: Demographic characteristics of study participants:

1. Hospital Registration no.: ……..
2. Date of birth: DD/MM/YYYY
3. Sex: Male [ ] Female [ ]
4. Marital status
   i. single [ ]
   ii. Married [ ]
   iii. Cohabiting [ ]
   iv. Widow [ ]
   v. Divorced [ ]
5. Permanent living address: Dar es salaam [ ] Outside Dar es salaam [ ]
6. Patient's mobile no.: +255…….
7. Collateral mobile no.: +255…….
8. Religious affiliation: ……
   i. Christian [ ]
   ii. Muslim [ ]
   iii. Other [ ] Specify: …….
   iv. Non-religious [ ]

Section B: Comorbidities:

9. Smoking status:
   i. Never [ ]
   ii. Quit smoker [no of cigarettes /day…... yrs.: ….]
   iii. Active/current [av. Sticks/day…... yrs. of smoking……]
10. Current comorbidities: ……
11. Do you use any medication(s) at present?
    i. Yes [ ]
    ii. No. [ ]
12. If yes, please list the medication(s): ……...

Section C: Initial Clinical assessment:

13. Pre-operative clinical/surgical diagnosis-(es): ……

14. Procedure status**:**

    i. Emergency [ ]

    ii. Elective [ ]

Section D: Operative information:

15. Operation date: DD/MM/YYYY

16. Procedure name: ……

17. Ostomy done? Yes [ ] No [ ], if yes Ostomy name: …….

18. Ostomy type

    i. Temporary [ ]

    ii. Permanent [ ]

19. Did you get stoma care Counseling?

    Yes [ ] No [ ]

Appendix 4a: Stoma -QOL (English version)

Stoma-QOL
A Quality of Life Questionnaire
For People with Ostomy

Date:____/____ 20___

*Please check the response that best describes how you are feeling **at the moment***

	Always	Sometimes	Rarely	Not-at-all
1. I become anxious when the pouch is full	□1	□2	□3	□4
2. I worry that the pouch will loosen	□1	□2	□3	□4
3. I feel the need to know where the nearest toilet is	□1	□2	□3	□4
4. I worry that the pouch may smell	□1	□2	□3	□4
5. I worry about noises from the stoma	□1	□2	□3	□4
6. I need to rest during the day	□1	□2	□3	□4
7. My stoma pouch limits the choice of clothes that I can wear	□1	□2	□3	□4
8. I feel tired during the day	□1	□2	□3	□4
9. My stoma makes me feel sexually unattractive	□1	□2	□3	□4
10. I sleep badly during the night	□1	□2	□3	□4
11. I worry that the pouch rustles	□1	□2	□3	□4
12. I feel embarrassed about my body because of my stoma	□1	□2	□3	□4
13. It would be difficult for me to stay away from home overnight	□1	□2	□3	□4
14. It is difficult to hide the fact that I wear a pouch	□1	□2	□3	□4
15. I worry that my condition is a burden to people close to me	□1	□2	□3	□4
16. I avoid close physical contact with my friends	□1	□2	□3	□4
17. My stoma makes it difficult for me to be with other people	□1	□2	□3	□4
18. I am afraid of meeting new people	□1	□2	□3	□4
19. I feel lonely even when I am with other people	□1	□2	□3	□4
20. I worry that my family feels awkward around me	□1	□2	□3	□4

Please answer all questions. Thank you for filling out the questionnaire.

Appendix 4b: Stoma-QOL (Swahili version)

Date:_____/_____ 20____

*Please check the response that best describes how you are feeling **at the moment***

	Kila mara	Mara nyingine	Nadra	Hapana kabisa
1.Ninakuwa na wasiwasi wakati pochi limejaa	1	2	3	4
2. Nina wasiwasi kuwa pochi litalegea	1	2	3	4
3. Ninahisi haja ya kujua choo kilicho karibu ni wapi	1	2	3	4
4. Nina wasi wasi kuwa pochi linaweza kunuka	1	2	3	4
5. Nina wasi wasi juu ya sauti zinazotoka kwenye njia niliyotengezwa ya choo	1	2	3	4

6 Nahitaji kupumzika wakati wa mchana	1	2	3	4
7. Pochi langu limenifanya kuwa na mipaka katika uvaaji nguo wangu	1	2	3	4
8. Nahisi uchovu wakati wa mchana	1	2	3	4
9. Njia mbadala ya haja inanifanya nahisi sivutii katika tendo la ngono	1	2	3	4
10. Ninalala vibaya wakati wa usiku	1	2	3	4
11. Nina wasiwasi kwamba pochi linatoa sauti	1	2	3	4
12 Ninahisi aibu juu ya mwili wangu kwa sababu	1	2	3	4

ya hii njia mbadala ya haja				
13. Inakuwa vigumu kwangu kukaa mbali na nyumbani usiku kucha	1	2	3	4
14. Ni ngumu kuficha ukweli kwamba ninavaa pochi	1	2	3	4
15 Nina wasiwasi kuwa hali yangu ni mzigo kwa watu wangu wa karibu	1	2	3	4
16. mimi huepuka kuwa karibu na marafiki zangu	1	2	3	4
17. Hii njia mbadala ya haja hufanya iwe vigumu	1	2	3	4

kwangu kuwa na watu wengine				
18. Naogopa kukutana na watu wapya	1	2	3	4
19.Ninajihisi mpweke hata ninapokuwa na watu wengine	1	2	3	4
20.Nina wasi wasi kwamba familia yangu inajiskia vibaya kuwa karibu nami	1	2	3	4

Tafadhali jaza maswali yote. Asante sana kwa kujaza maswali haya.

Appendix 5: Ethical Clearance

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/1827 Date: 28/07/2023

MUHAS-REC-07-2023-1827
HASSAN JUMA MWAKIMAKO
SCHOOL OF MEDICINE
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: QUALITY OF LIFE AMONG ADULTS WITH INTESTINAL STOMA AT MUHIMBILI NATIONAL HOSPITAL: A CASE-CONTROL 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: 28/07/2023
EXPIRATION DATE OF APPROVAL: 28/07/2024

STUDY DESCRIPTION:
Purpose:
The purpose of this cross-sectional study is to study and compare the overall quality of life of ostomate individuals and non-ostomate laparotomy patients 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-%2014844.pdf and in the MUHAS archives.

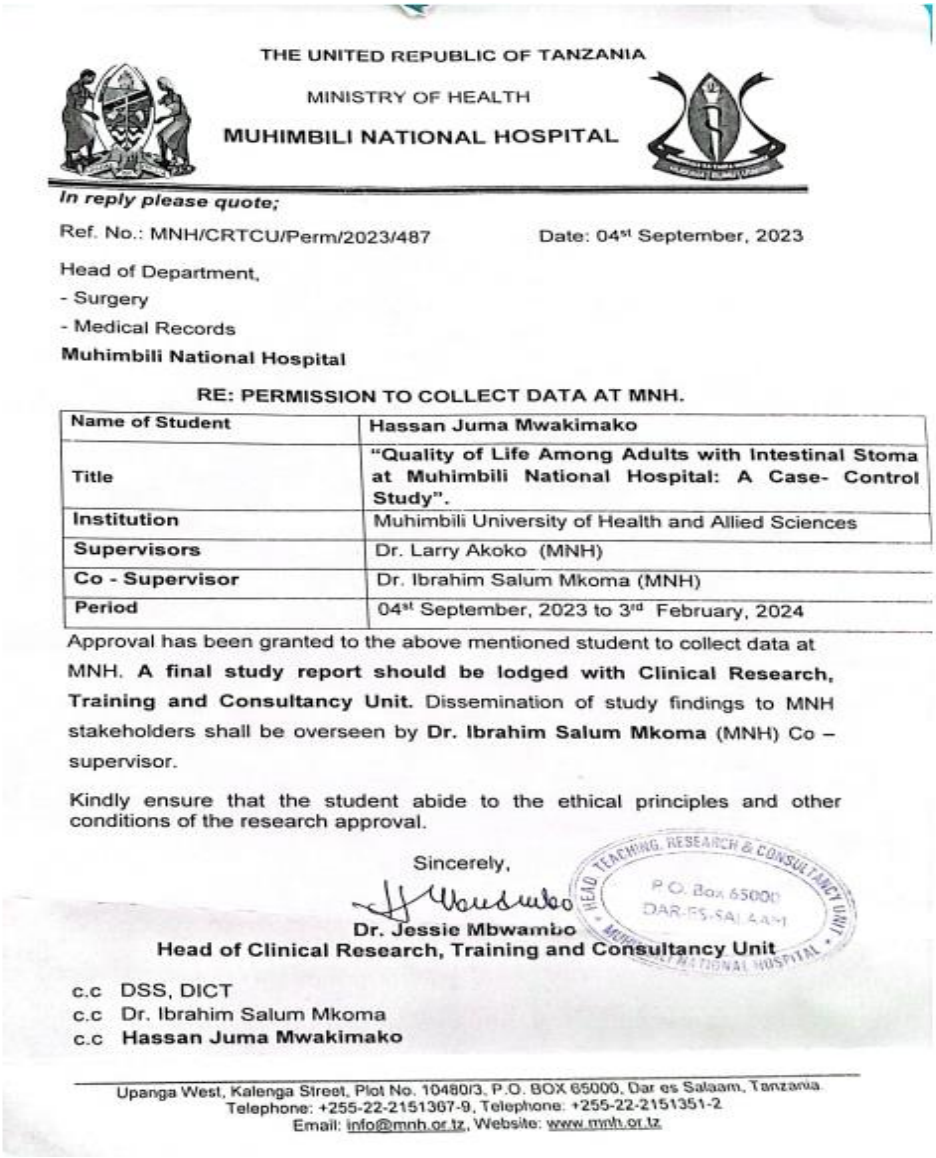
The PI is required to:

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 Mabsoud,
Chairperson, MUHAS Research and Ethics Committee



Appendix 5: Permission Letter



THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

MUHIMBILI NATIONAL HOSPITAL

In reply please quote;

Ref. No.: MNH/CRTCU/Perm/2023/487 Date: 04st September, 2023

Head of Department,
- Surgery
- Medical Records

Muhimbili National Hospital

RE: PERMISSION TO COLLECT DATA AT MNH.

Name of Student	**Hassan Juma Mwakimako**
Title	**"Quality of Life Among Adults with Intestinal Stoma at Muhimbili National Hospital: A Case- Control Study".**
Institution	Muhimbili University of Health and Allied Sciences
Supervisors	Dr. Larry Akoko (MNH)
Co - Supervisor	Dr. Ibrahim Salum Mkoma (MNH)
Period	04st September, 2023 to 3rd February, 2024

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. Ibrahim Salum Mkoma** (MNH) Co – supervisor.

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

Sincerely,

Dr. Jessie Mbwambo
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 DSS, DICT
c.c Dr. Ibrahim Salum Mkoma
c.c **Hassan Juma Mwakimako**

Upanga West, Kalenga Street, Plot No. 1048013, 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