# COMPARISON OF QUALITY OF LIFE AMONG PATIENTS WITH AND WITHOUT DIABETIC RETINOPATHY AT MUHIMBILI NATIONAL HOSPITAL.

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**MMed (Ophthalmology) Dissertation**

**Muhimbili University of Healthy and Allied Sciences**

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**Muhimbili University of Health and Allied Sciences**

**School of Clinical Medicine**

**Department of Ophthalmology**

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**By**

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## CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance by Muhimbili University of Health and Allied Science a dissertation entitled ***"Comparison of quality of life among patients with and without diabetic retinopathy at Muhimbili National Hospital"*,** in (partial) fulfilment of the requirement for the degree of Master of Medicine (Ophthalmology) of the Muhimbili University of Health and Allied Science.

_____

**Dr Celina Mhina**

(Supervisor)

Date_____

_____

**Prof. Milka Mafwiri**

(Co-supervisor)

Date_____

## DECLARATION AND COPYRIGHT

I, **Dr. Magreth Marwa**, declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

Signature..... Date.....

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## DEDICATION

To my lovely mother Prisca and adorable daughter Maleekah.

## ABSTRACT

**Background**: Diabetes mellitus (DM) is a chronic metabolic condition of public health importance. About 463 million individuals worldwide have DM. Diabetic retinopathy (DR) is a potentially blinding micro vascular consequence of DM causing 2.6 million visual impairment and 2.52 million blindness cases among the working age group. The presence of DM comorbidities and complications tend to have an impact on the quality of life of an affected individual. Visual impairment and blindness caused by DR may affect the individual socially, emotionally and economically. This will consequently disturb the overall life of individual patients, family and the community at large. There is scarcity of data on the quality of life among patients with diabetic retinopathy hence the need to conduct this study.

**Aim:** To assess quality of life and associated factors in patients with and without diabetic retinopathy at Muhimbili National Hospital.

**Methodology:** A cross-sectional analytical comparison study was conducted among adult patients with DM aged 18 years and above. A total of 160 patients were recruited, 86 with DR and 74 were those without DR. Participants were selected by stratified random sampling, stratum 1 with DR and stratum 2 without DR, then systematic random sampling was done in each stratum. Comprehensive ocular examination and OCT were done after a short interview. The National eye institute visual functioning questionnaire 25 (NEI-VFQ 25) tool was used for collection of data on quality of life. Data analysis was done by SPSS version 23. Chi square test was used to show the relationship between quality of life (QoL) and associated factors in which P value of $<0.05$ was considered statistically significant, and t-test was used to compare the means of two groups. Univariate and multivariate linear regression analysis was used to determine the strength of association between quality of life and the associated factors.

**Results:** Ninety-four (58.8%) patients were females and majority (60%) of participants were aged between 44-56 years with mean age of 55.2 ($\pm$8.9) years. One hundred thirteen (70.6%) had attained college or university education and Dar es Salaam accounted for 114 (71.3%) of the majority. Cataract was the most frequent ocular comorbidity occurring in 79 (65.2%) .

The overall QoL was lower in participants with DR (45.8±11.3) compared to those without DR (71.8±10.2). Participants with DR had poor vision related and general health scores compared to those without DR. After adjusting for confounders employment (b coefficient=14.3, p=0.0012) associated with higher QoL, longer duration of DM (b= -25.2, p=0.014) and DR (b= -17.2, p=0.001), higher level of HBA1c (b= -10.4, p=0.001), PDR (b= -27.1, p=0.001), presence of multiple ocular comorbidities (b= -12.5, p= 0.001), blindness category (b= -19.4, p= 0.001) and presence of DR complications (b= -34.3, p=0.001) contributed to a marked QoL score decline in multivariate analysis.

**Conclusion:** The QoL was lower in participants with DR compared to those without DR. Factors like presence of multiple ocular co-morbidities, severe visual impairment, PDR, high HBA1c levels, longer DM and DR duration, presence of DR complications were significantly associated with a low QoL score.

**Recommendations:** People with DM should have regular eye examinations to detect DR in its early stages, this can prevent vision loss and improve overall QoL**,** Maintaining optimal blood sugar levels is important to prevent or delay the onset of DR this can be achieved by including eye services and creating a **c**omprehensive multi-modal approach where patient-centred therapy and lifelong follow-up is required taking into account their wellbeing.

**Key words**: Diabetes mellitus, diabetic retinopathy, quality of life.

## Contents

CERTIFICATION ..... ii

DECLARATION AND COPYRIGHT ..... ii

ACKNOWLEDGEMENT ..... iii

DEDICATION ..... iv

ABSTRACT ..... v

Contents ..... vii

LIST OF TABLES ..... x

LIST OF ABBREVIATIONS ..... xii

DEFINITIONS ..... xiii

CHAPTER ONE ..... 1

1.0: INTRODUCTION ..... 1

1.1: BACKGROUND ..... 1

1.2: PROBLEM STATEMENT ..... 3

1.3: CONCEPTUAL FRAMEWORK ..... 4

1.4: RATIONALE ..... 5

1.5: RESEARCH QUESTIONS ..... 5

1.6: OBJECTIVES ..... 6

1.6.1: Broad objective ..... 6

1.6.2: Specific Objectives ..... 6

CHAPTER TWO ..... 7

2.0 LITERATURE REVIEW ..... 7

2.1 Quality of life of patients with diabetic retinopathy ..... 7
CHAPTER THREE ..... 11
3.0: METHODOLOGY ..... 11
3.1: Study design ..... 11
3.2: Study setting ..... 11
3.3: Study period ..... 12
3.4: Study population ..... 12
3.5: Sampling technique ..... 12
3.6: Sample size estimation ..... 13
3.7: The inclusion criteria ..... 12
3.8: Exclusion criteria ..... 13
3.9: Variables ..... 14
3.9.1: Independent variables ..... 14
3.9.2: Dependent variables ..... 14
3.10: Data collection tool ..... 15
3.11: Data collection method ..... 16
3.12: Data management and analysis ..... 18
3.13: Ethical issues ..... 18
CHAPTER FOUR ..... 20
4.0 RESULTS ..... 20
CHAPTER FIVE ..... 37
5.0 DISCUSSION ..... 37
5. 1 Limitations ..... 39

6.1 Conclusion ..... 41
6.2 Recommendation ..... 41
APPENDICES ..... 45
Appendix I: Questionnaire ..... 45
Appendix II: Kiambatanisho I: Dodoso ..... 49
Visual Functioning Questionnaire - 25 ..... 53
Appendix III: Consent Form (English Version) ..... 64
Appendix IV: Informed Consent (Swahili Version) ..... 66
Appendix V: Ethical clearance letter ..... 68
Appendix VI: Permission letter ..... 70

## LIST OF TABLES

Table 1: Social demographic characteristics of the study participants N=160.....21
Table 2: Systemic and ocular co-morbidities among participants with and without DR N=160 .....23
Table 3: Clinical characteristics of the study participants, N=160.....24
Table 4: Diabetic retinopathy grading and complications among study participants with DR, N=86.....26
Table 5: Quality of life mean scores in different subscales in participants with and without DR .....27
Table 6: Univariate and Multivariate analysis of overall quality of life with socio-demographic characteristics among participants with DR (N=86). .....28

## LIST OF FIGURES

Figure 1: Conceptual framework.....5
Figure 2: Map locating Muhimbili National Hospital (MNH), in ilala district, Dar-er- Salaam .....12
Figure 3: Flow chart for recruitment process of participants .....20

## LIST OF ABBREVIATIONS

| | |
|---|---|
| BCVA | Best Corrected Visual Acuity |
| CSME | Clinically Significant Macular Edema |
| DM | Diabetic Mellitus |
| 1DM | Type one diabetes Mellitus |
| 2DM | Type two diabetes Mellitus |
| DME | Diabetic Macular Edema |
| DR | Diabetic Retinopathy |
| ETDRS | Early Treatment of Diabetic Retinopathy Study |
| HbA1c | Haemoglobin A1c |
| IDDM | Insulin-Dependent Diabetic Mellitus |
| NIDDM | Non-Insulin Dependent Diabetic Mellitus |
| NPDR | Non-Proliferative Diabetic Retinopathy |
| OPD | Out-Patient Department |
| PDR | Proliferative Diabetic Retinopathy |
| UKPDS | UK-Prospective Diabetes Study |
| UGDP | University Group Diabetes Program |
| VEGF | Vascular Endothelial Growth Factor |
| VA | Visual acuity |
| VI | Visual Impairment |
| WESDR | Wisconsin Epidemiologic Study of Diabetic Retinopathy |
| WHO | World Health Organization |
| QoL | Quality of life |
| OCT | Optical Coherence Topography |
| MNH | Muhimbili National Hospital |
| MUHAS | Muhimbili University of Health and Allied Sciences |
| TRD | Tractional retinal detachment |
| VH | Vitreous hemorrhage |
| SD | Standard deviation |

## DEFINITIONS

**Diabetic mellitus**: Is a chronic metabolic disorder characterized by elevated levels of glucose in the blood (hyperglycemia) due to lack of or resistance to insulin. (WHO)

**Diabetic retinopathy**: Refers to micro vascular end-organ damage as a result of diabetes mellitus. It ranges from non-proliferative diabetic retinopathy (NPDR) to proliferative diabetic retinopathy (PDR) when there is neovascularization as a result of diabetes induced ischaemia.

**Diabetic maculopathy**: Refers to macular changes as part of diabetic retinopathy and is mainly characterized by macular thickening (edema) and exudations.

**Non-proliferative diabetic retinopathy**: Refers to the presence of intraretinal vascular changes prior to the development of extraretinal fibrovascular tissue.

**Proliferative Diabetic Retinopathy**; Refers to diabetic retinal changes involving new vessels formation on or within one disc diameter of the disc (NVD) and/or new vessels elsewhere (NVE) in the fundus.

**Normal systemic blood pressure**; Refers to a range of Systolic 120 – 130 mmHg and Diastolic 70 – 80 mmHg.

**Hypertension**; According to WHO refers to blood pressure reading equal to or above 140/90 mmHg.

**Hyperlipidemia**: Basing on Muhimbili National Hospital is the presence of high levels of lipid in the blood (Total cholesterol > 5.17mmol/l, LDL >3.34mmol/l).

**Hyperglycemia**; refers to high level of blood sugar (FBG ≥ 11mmol/l, HbA1c ≥ 6.5%).

**Quality of life (QoL):** Level of physical, emotional and psychological wellbeing experienced by an individual.

# CHAPTER ONE

## 1.0: INTRODUCTION

### 1.1: Background

Diabetes mellitus is a group of metabolic disorders characterized by chronic hyperglycemia due to either reduced insulin secretion, ineffective usage of insulin or a combination of both (1). Common types are classified as type 1 which is an autoimmune illness that first appears in childhood or early adulthood and Type 2 which is due to insulin resistance and a relative lack of insulin secretion, (2)(3).

The International Diabetes Federation's 8th edition of the diabetes Atlas estimates that there were 425 million people with DM globally in 2017 and that number would rise to 629 million by 2045, an increase of 48%. (1)

Diabetic eye disease results from chronic high blood glucose levels which cause damage to different ocular structures. The main ocular complications of diabetes are retinopathy, cataract, glaucoma and ocular surface disease (1). Diabetic retinopathy (DR) is the most serious ocular complication of diabetes mellitus, and it is the leading cause of blindness worldwide among people aged 20–64 years(1).

As the leading cause of blindness and visual impairement, DR not only impacts physical health but also has profound consequences on the psychological, emotional, and social well-being of patients. The growing prevalence of DM, coupled with the increasing rates of DR, underscores the importance of understanding the broader impact of this condition on quality of life (QoL) (1,3,4).

QoL is as an individual's perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns (5).

Patients' perceptions of the influence of sickness and therapy on their functioning in various parts of life make up their QoL. (4). QoL is a multidimensional concept that encompasses various aspects of an individual's life, including physical health, emotional well-being, social functioning, and overall life satisfaction. For patients with DM, QoL can be significantly affected by the direct and indirect effects of diabetes-related complications such as DR. Visual impairment due to DR can restrict daily activities, decrease independence, and lead to emotional distress, contributing to lower QoL. However, the extent to which DR specifically impacts QoL compared to other factors related to diabetes, such as glycemic control, comorbidities, and socio-demographic variables, remains an area of active research (1,5,6). Treatment, comorbidities, complications of diabetes retinopathy and its impact can all reduce the QoL, which has impact for long-term supportive care(4).

In this study QoL was assessed using the NEI-VFQ-25 tool which has been reported to be superior to most questionnaires because it considers general health, mental and social impact, difficulties with activities and response to vision problems. The tool has been validated and had been used in different studies including the study done in India which compared the QoL in patients with and without DR (5).

This study compared the QoL of patients with diabetic retinopathy to that of patients without DR, considering both the direct effects of vision loss and the indirect effects stemming from the broader implications of DM management. By examining a range of factors that influence QoL, including demographic characteristics, socioeconomic status, and the presence of other diabetic complications, this study seeks to provide valuable insights into the specific impact of DR on QoL and to identify the factors that may mitigate or exacerbate this impact (4,7).

Knowing the quality of life of patients with DR could facilitate a patient-centered approach this in turn will help in clinical decision-making concerning treatment and follow up of the patient (6–9).Several studies on QoL in people with diabetes have evaluated and reported on how it affects general health and vision of an individual.

However, little is known about the quality of life (QoL) of people with diabetes, and more specifically, DR patients, in Tanzania , (21) so the aim of the study was to compare the QoL of patients with and without DR in terms of general health and vision.

### 1.2: Problem Statement

Visual impairment and blindness caused by DR may affect the individual socially, emotionally and economically, as a result, this may affect their ability to find employment, support themselves, and take care of their families, consequently disturb the overall life of individual patients, family and community at large (4, 5, 12). This is mostly due to the fact that many of the tasks that define freedom and productivity in society require strong vision, and one of the most terrible effects of progressing visual impairment is a progressive loss of independence (13–15), hence affecting the quality of life of an individual.

QoL encompasses a wide range of physical, emotional, and social well-being factors, and it is increasingly recognized as an important metric for assessing the burden of chronic diseases like DM. The onset and progression of DR can negatively influence multiple dimensions of QoL, including physical functioning, mental health, social interactions, and emotional well-being. For patients with DR, the loss of vision and its associated challenges—such as difficulty performing daily tasks, reduced mobility, and increased dependency—can lead to heightened levels of stress, anxiety, depression, and social isolation, which, in turn, contribute to further deterioration of QoL. (16,17).

Despite the growing recognition of QoL as an essential outcome in healthcare, there is limited research comparing the QoL between individuals with and without DR, especially within the context of DM management. Although it is evident that DR can affect QoL, how much more significant this impact is compared to other diabetes-related complications (such as neuropathy, nephropathy, or cardiovascular disease) is not well-established. Moreover, it remains unclear how other sociodemographic, clinical, and psychological factors may interact with DR to exacerbate or mitigate its impact on the overall QoL of patients. (5, 9, 11, 16).

Thus, the primary problem this study addressed is the lack of comprehensive, comparative data on the quality of life of patients with diabetic retinopathy versus those without, particularly in the context of managing a chronic disease like DM. Understanding how DR specifically affects QoL, independent of other complications, will help healthcare professionals better understand the unique challenges faced by these patients. Additionally, this knowledge is crucial for developing targeted interventions that aim to improve the QoL of individuals with DR, guiding more effective clinical practices and health policies.

### 1.3: Conceptual Framework

A patient with diabetic retinopathy might find it difficult to perform activities that involve vision, such as driving, reading, office work, and others, as well as to see well and may be physically disabled. Patients who suffer from significant vision impairment worry about losing their sight. Patients' social isolation is exacerbated by their lack of engagement in social events or activities, as a result they are unsatisfied with their quality of life in terms of their general health and vision.

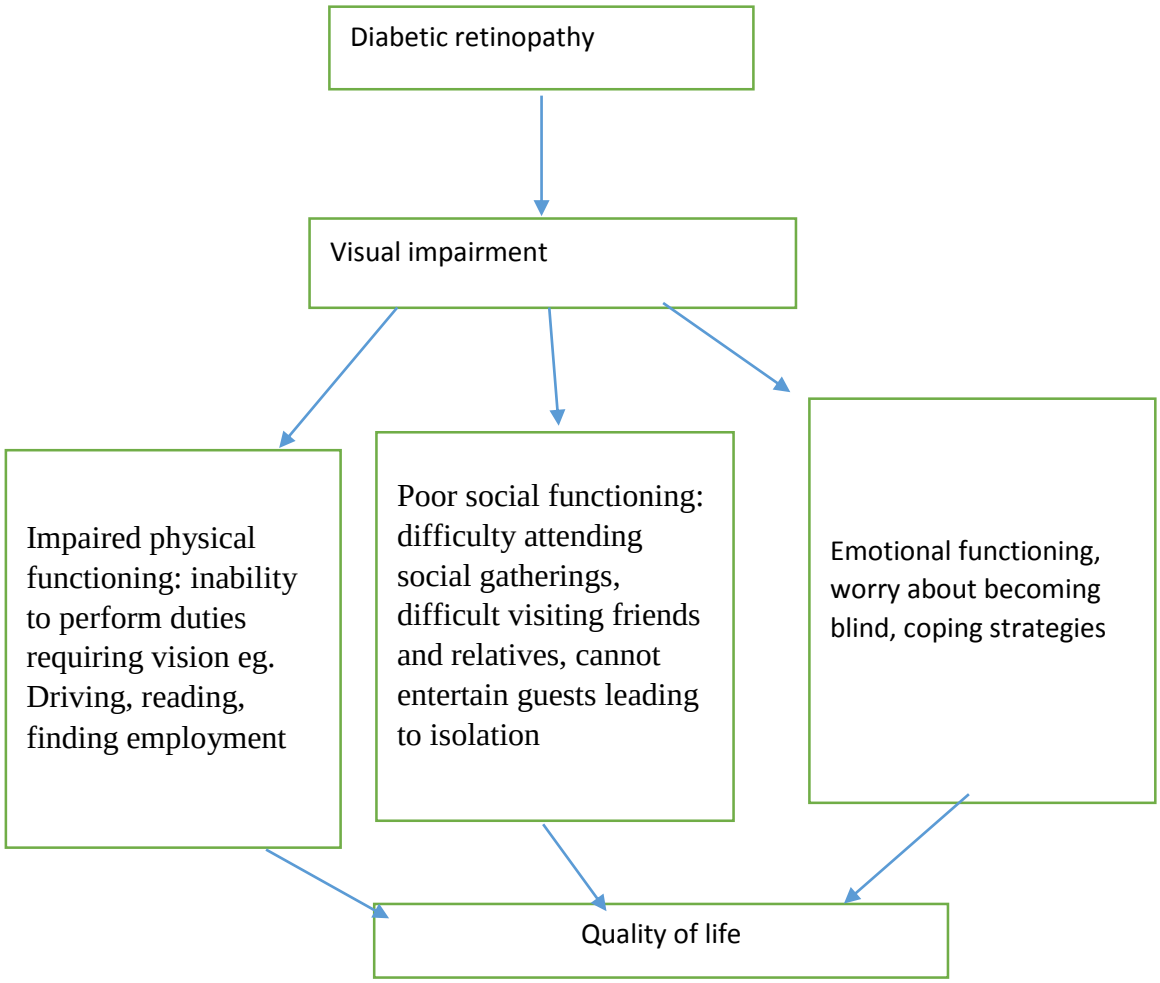



Figure 1: Conceptual framework

### 1.4: Rationale

This study will help policy makers and healthcare providers make efforts to improve access to healthcare including eye services and a comprehensive multi-modal approach where patient-centred therapy and lifelong follow-up is done while taking into account their wellbeing.

### 1.5: Research Questions

1. What is the overall QoL in patients with DR attending diabetic and retina clinic at MNH?
2. What is the vision related QoL in patients with DR attending diabetic and retina clinic at MNH?
3. What are the factors affecting QoL in patients with DR at MNH?

## 1.6: Objectives

### 1.6.1: Broad objective

To compare the QoL among patients with and without DR attending diabetic and retina clinic at MNH

### 1.6.2: Specific Objectives

1. To assess the overall QoL among in patients with and without DR attending diabetic and retina clinics at MNH
2. To assess the vision related QoL among in patients with and without DR attending diabetic and retina clinics at MNH
3. To assess factors affecting the QoL among patients with and without DR attending diabetic and retinal clinic at MNH

# CHAPTER TWO

## 2.0 LITERATURE REVIEW

### 2.1 Quality of life of patients with diabetic retinopathy

DM is a common metabolic condition that leads to a high rate of death due to its complications, as well as social, physical and economic consequences for the community. Because of the rising number of diabetic patients worldwide, particularly in developing countries, the burden of diabetes-related blindness causes significant problems to a sustainable health-care system.

In 2019, 19.4 million people in Africa were estimated to have DM. By 2045, this figure is anticipated to rise by 143% (10). The prevalence of DR is predicted to increase along with the number of DM patients, so it's critical that techniques are created to enable early detection through screening and treatment of this new epidemic. DR is very prevalent in different populations, yet the risk factors are still the same. According to a pooled analysis of 32 research conducted between 2015 and 2019 (20), the prevalence of DR was reported to be 33.98% in the United States of America (USA), 20.6% in Europe, 12.5% in South East Asia, and 33.8% in Africa. The prevalence of DR, however, was estimated to be 27.9% in Tanzania in 2015. As the medical technology improves and we shift to a more patient-centered approach it is critical to assess how much the disease has affected a patient's life.

A systematic review of QoL among patients with and without DR was done in Indonesia in 2019 by Yuhara et al. in this study it was found that diabetic individuals with DR had a lower QoL than diabetic patients without diabetic retinopathy(4).

Another study done in India by Deswal et al found that DR had a negative influence on all categories of an individual’s daily activities, with a greater negative impact on personal matters, home tasks, and being out and about, and a lower negative impact on physical appearance and diabetes management. As a result, DR had the greatest negative influence on people's physical and social activities (12).

## 2.2 DR and Vision related QoL

Diabetes mellitus and DR affect the QoL of affected individuals in various ways. A study by Aguirre et al done in Spain found that higher BCVA was linked to lower scores on the subscales of general vision, close activities, distant activities, and mental health while high scores were observed in role difficulty, reliance, driving ability, and color vision (15).

Another study by Perreira found that people with DR had lower QoL scores in terms of general vision and driving compared to those without DR (5), this findings were similar a study by Yuhara et al which showed a 9 percent decrease in vision related QoL in patients with DR compared to those without DR (4).

A study by Yuhara et al found that DR being the most common complication of DM and the leading cause of visual impairment and blindness in working age population, has a significant impact on patients QoL in terms of general health and vision which impact the physical, psychological, social and economic activities of an individual. In comparison to individuals without DR, patients with DR had poorer scores on mobility, vision, eating, and daily activities (4).

Another study by Pereira et al revealed that QoL among patients with DR was lower compared to those without DR. The most affected aspects were general health, general vision, and mental health, therefore, the existence of DR among patients with diabetes had a substantial impact on their perception of their overall health. The stress, frustration, lack of control over activities, and fear of potential disgrace linked with eyesight were also observed. In terms of ocular pain, social functioning, and color vision, higher scores were obtained (5).

In a study by Feyisa et al in Ethiopia, the health related QoL was found to be moderate, the physical functioning domain had the highest average score. The mean score in the aspects of general health, mental health, physiological pain, and energy was below average (7).

### 2.3 Factors affecting QoL in patients with and without DR

Different factors have been assessed in different studies which are thought to affect QoL in patients with and without DR in general health and vision. Some of those factors are sex, duration of diabetes, type of diabetes, severity of retinopathy, cigarette smoking and presence of comorbidities like hypertension (11,14,15).

Due to the characteristics of type 1 diabetes mellitus, some researches have demonstrated a strong correlation of this form of diabetes with a poorer QoL (4).

A study done in India by Pereira et al evaluated factors such as duration of diabetes, glucose control, severity of retinopathy, co-morbidities like neuropathy and nephropathy. The results in this study showed these factors had influence on the QoL. The study found that the QoL was significantly reduced in those with DR than without DR, where by the general heath was more affected than vision and this fact was more related to the duration of DM rather than glucose control (5).

Another study done in Iran by Soleiman J et al considered economic status, sex, smoking, literacy, severity of DR, history of eye surgery. In this study the QoL scores reduced as the income increased, and the average QoL was higher in women than in males, and it was also evident that non-smokers had a higher standard of living than smokers (14). This study found that illiterate people's QoL score was higher. Regarding DR severity, evidence from literature show that since PDR has more severe symptoms, it can have a greater impact on people's abilities and QoL than NPDR hence the negative impact on QoL. Other studies also show, those who had previous eye surgeries had a higher QoL than those who did not, which could be the result of improved eye performance following surgeries such as cataract or glaucoma (14).

The socio-demographic factors of sex, age, marital status, and educational level had a significant link with health related QoL of diabetic patients in a study by Feyisa et al done in Ethiopia.

Inability to read and write, for example, was found to be inversely related to health related QoL, meaning that people with diabetes who can't read or write have a poor understanding of the disease, complications, and therapy, as well as being unable to make better self-care decisions (7).

According to a study conducted in Spain by Roberts-Martinez et al., the QoL for people with

DR varies depending on factors like gender, type of diabetes, experiencing episodes of diabetic decompensation, duration of diabetes, the presence of comorbidities like hypertension, and BCVA. Women with DR had a lower overall QoL than men with DR, and they were more dependent, had weaker driving skills, and had worse color vision than men. However, this study did not find any conclusive links between QoL and insulin reliance or concurrent diseases, with the exception of hypertension, which was found to improve dependence. The duration of DM or DR had no bearing on the results of this investigation (15). This contradicted with the Pereira et al study in India which discovered a positive association between the severity of DR and the duration diabetes. The most affected areas were general health, general vision, and general mental health. Thus, even the mere existence of DR in diabetics significantly influenced how

they perceived their overall health (5).

# CHAPTER THREE

## 3.0: METHODOLOGY

### 3.1: Study design

This was a hospital based analytical comparison cross-sectional study.

### 3.2: Study setting

This study was conducted at MNH located in Dar Es Salaam city, Ilala region in Upanga west along United Nations road. Muhimbili is a tertiary hospital which receives patients from all over the country. It is also a teaching hospital for MUHAS.

Data was collected from diabetic and retina clinics where by the diabetic clinic is a specialized clinic under the department of internal medicine and the retina clinic is under the ophthalmology department. Both the DM and retina are specialized clinics attending patients from Dar es Salaam and other regions. At the diabetic clinic, patients have their DM progress monitored and receives medications. There is also a DR screening clinic at the DM clinic building such that the DR screening is conducted there by the optometrists trained on DR screening and grading. The DM clinic is conducted 4 days in a week, with an attendance of approximately 50-100 patients per clinic day. The retina clinic is done twice per week, Wednesdays and Thursdays with an average of 40 to 50 patients per clinic day.




**Figure 2: Map locating Muhimbili National Hospital (MNH), in ilala district, Dar-er-Salaam**

### 3.3: Study period

This study was conducted from October 2022 to December 2022

### 3.4: Study population

The study had two groups. Adult patients with DR attending the retina clinic and a comparison group which consisted of adult patients with DM but have not developed DR who were attending diabetic clinic at MNH.

### 3.5: The inclusion criteria

All adult patients that had been diagnosed with DR for at least 6 months attending diabetic and retina clinic at MNH.

Adult patients diagnosed with DM (comparison group) for at least 6 months, attending diabetic clinic at MNH.

### 3.6: Exclusion criteria

Patients suffering from any major illness, hindering patients' understanding and answering the questionnaire.

Patients with advanced ocular disease like mature cataract, advanced glaucoma and optic neuropathy.

Patients with missing data example patient failure to complete investigations.

### 3.7: Sample size estimation

The sample size was calculated from sample size for comparing two means formula using **OpenEpi** toolkit software. Mean and standard deviation taken from a previously similar study done in India by Perreira et al, which had an overall quality of life score of 73.93 ± 2.55 and 99.26± 3.57 for patients with and without DR respectively.

Sample size for comparing two means gives a minimal sample size of:

Sample size of cases =72
Sample size of controls =72

Total sample size = 144

### 3.8: Sampling technique

This study involved 2 different groups of participants with special clinic days, diabetic patients with DR attend retina clinic on Wednesday and Thursday on average of 40 to 50 patients per clinic day and those without DR were recruited from diabetic clinic on Tuesdays, Wednesdays and Thursdays.

The study employed stratified random sampling technique, where the participants were divided into two strata: stratum one being those attending retina clinic (with DR) and stratum two were those in diabetic clinic (without DR- comparison group).

From a total sample size of 144, 72 (50%) participants were selected from stratum one and the remaining 72 (50%) were from stratum two.

Systematic random sampling was used to recruit participants from each stratum. Where K value (sampling interval) was estimated by assumption of sampling frame to be the expected patient attendance during study period which was one month (N) in each clinic divide by estimated sample size(n), (K=N/n).

In stratum one k=360/72=5 and in stratum two k=600/72=8.33. Therefore every 5th patient was interviewed in stratum one, and every $8^{th}$ patient was interviewed in stratum two. On average 8 and 6 patients were interviewed per each clinic day in stratum one and two respectively, until the sample size was reached. Participants in each stratum was collected in a duration of one month, starting with retina clinic for one month and the following month participants in diabetic clinic were recruited.

### 3.9: Variables

#### 3.9.1: Independent variables

Duration of DM, type of DM, duration of DR, disease severity, visual functioning, general health, comorbidities (systemic hypertension, renal failure, heart diseases), complications of DR (vitreous haemorrhage, DME, TRD), factors affecting QoL (hyperlipidaemia, cigarette smoking, severity of disease, alcohol intake, blood glucose level ).

#### 3.9.2: Dependent variables

Outcome variable was quality of life.

#### 3.9.3: Confounders

The confounding variables that were expected to rise from demographic data were age, sex, cigarette smoking and alcohol intake.

### 3.10: Data collection tool

Data collection was done through interview, using the NEI-VFQ 25-questionnaire. This tool has been developed by RAND and sponsored by National Eye Institute hence carrying the abbreviation name NEI-VFQ-25. It is a 25-item version of the 51-item National Eye Institute Visual Function Questionnaire (NEI-VFQ). It is a validated tool that has been structured to address a wider range of visual concerns, including social and mental outcomes of visual impairment and facilitates probing into the specific aspects of vision-related quality of life and general health which can be used to assess the quality of life.

The tool has 12 subscales; these are general health, general vision, ocular pain, near vision activities, distance vision activities, social function, mental health, role limitations, dependency, driving, colour vision and peripheral vision. Academic research translations to Swahili language was done later translated back to English by another person who was blinded from the first English version to check the correctness of the translation, and it was contextualized to meet the need.

The following vision-targeted subscales are generated by the NEI-VFQ-25: global vision rating (1), difficulty with near vision activities (3), difficulty with distance vision activities (3), limitations in social functioning due to vision (2), role limitations due to vision (2), dependency on others due to vision (3), mental health symptoms due to vision (4), driving difficulties (3), limitations with peripheral (1), colour (1), and ocular pain (2). The NEI-VFQ-25 also includes a single general health rating item, which has been demonstrated in population-based research to be a reliable predictor of future health and death.

There are two steps to scoring the NEI-VFQ-25 with or without optional items: First, the survey's original numerical values were recorded in accordance with the scoring guidelines. Each item was given a score, and higher scores indicate higher functioning. The lowest and highest scores are set at 0 and 100 points, respectively, once each item is transformed into a 0 to 100 scale. For example, a score of 50 reflects 50% of the highest possible score. In this format, scores represent the attained percentage of the total possible score.

The 12 sub-scale scores are generated in step 2 by averaging the items on each sub-scale. The scale scores were not based on items with missing data (items that are left blank). A sub-scale score can be produced for sub-scales that have at least one question answered. As a result, scores represent the average of all the subscale items that the respondent chose to answer.

The vision-targeted subscale scores were averaged, with the general health rating question left out, to determine the VFQ-25's overall composite score. Each sub-scale was given the same weight by averaging the sub-scale scores rather than the individual items, while doing so gave scales with more items greater weight. Pre-testing of the tool was done in June and July to assess the practicability and the necessary adjustments were made before the time of study.

A structured questionnaire was used to collect information on social demographics and clinical information.

### 3.11: Data collection method

Data collection was done by the principal investigator and one research assistant on selected clinic days. Data collection methods included a combination of interviewer administered questionnaire; general and ocular clinical examination, and biological sample collection. The research assistant was a nurse trained to take visual acuity. Patients who attend DM clinic, and DM patients who attend retina clinic were informed about the study as they were registered in the DM and retina clinic and this was done from 7.30am to 9.30am, during this time the investigator identified eligible patients by sampling them as explained in the sampling technique. After excluding patients who were not eligible for the study, those who met the inclusion criteria and agreed to participate in the study signed an informed consent and were recruited in the study. Swahili was the official communication language between the investigator and the patients. Data collection took place in a quiet room at the clinic and estimated time to complete a questionnaire was 15-20 minutes.

After recruitment the research assistant took visual acuity of participants by using Snellen chart for both literate and illiterate patients. Visual acuity (VA) categories were recorded according to World Health Organisation (WHO) standard.

VA of 6/18 and above was considered normal vision, 6/24 to 6/60 as moderate visual impairment, below 6/60 to 3/60 was considered severe visual impairment and below 3/60 to light perception was considered as blindness. Those with suboptimal visual acuity pinhole was used and that was considered the best corrected visual acuity, and participants with spectacles VA was taken both with and without spectacles and if the participant had the best VA with spectacles that was considered the BCVA.

Demographic data of patients was obtained, then a short history was taken by the principal investigator, general questions in the questionnaire were completed by interviewing the patients.

The history focused on duration of the disease, type of DM, type of treatment of DM received, consumption of alcohol, cigarette smoking, presence of comorbidity illness like hypertension (HTN), cardiac disease, hyperlipidaemia and stroke and complications of diabetes including nephropathy and foot problems. Body weight and height were measured for calculating the body mass index (BMI) in $Kg/m^2$. A BMI of 18.5 $Kg/m^2$ or less was regarded as underweight, 18.6 to 24.9 $Kg/m^2$ as healthy weight, 25-29.9 $Kg/m^2$ as overweight and above 30 $Kg/m^2$ as obesity. Blood pressure was measured and recorded, where normal systolic ranged from 120 to 130, and diastolic from 70 to 80. Any blood pressure equal to or above 140/90 was regarded as hypertension.

Anterior segment examination was done using a slit lamp Zeiss made from Germany to assess the conjunctiva, cornea, iris, anterior chamber and lens. In this part any conjunctival redness, corneal edema, shallow anterior chamber, hyphema, pupillary abnormalities were noted. Participants were then dilated using 1% tropicamide eye drops and the fundus was examined using the same slit lamp with an aid of 78D Volk double aspheric lens/90 D Volk aspheric lens alternating with indirect ophthalmoscope with 20D Volk aspheric lens. Diabetic retinopathy was defined as the presence of micro aneurysms plus any of the following; dot-blot hemorrhages, intra-retinal micro vascular anomalies (IRMA), and new vessels on the disc or elsewhere, cotton-wool spots, exudates, and clinically significant macular oedema. Grading of diabetic retinopathy followed the Early Treatment Diabetic Retinopathy Study (ETDRS) grading scale

(mild DR, moderate DR, severe DR and Proliferative DR). Optical coherence topography was then done using Topcon 3D-SD OCT to confirm the presence of intraretinal/subretinal fluid as well as retinal thickness, this was then reviewed by the ophthalmologist for verification, and recorded in datasheets. After completion of filling the questionnaire, patients continued with their routine treatment at the clinic and were then sent to the laboratory for investigations. If the missing entries comprised more than 50% of the total entries, for example if the patient could not wait for the mydriatics to work, the patient's questionnaire was regarded as incomplete. Privacy and confidentiality of patients was maintained throughout the study.

### 3.12: Data management and analysis

After the collection of data in structured questionnaires, the data was cross checked by the principal investigator at the end of each interview and all missing or wrong entries were corrected. All information collected was confidential and locked in a secure cabinet, they were stored on secured password protected computer. Then data was entered into statistical Package for social sciences (SPSS) software version 23 for cleaning and analysis. The quality-of-life scores of patients were expressed as the means ± standard deviations. Frequency distribution of each variable was used to assess distributional characteristics of the study population. Then logistic regression analysis was done to determine the association between the dependent variable (quality of life) and each of the independent variables. Chi-square was used to show the relationship between variables and t-test was used to compare the means of two groups and it answered objective number 1 and 2. Finally, multivariate linear regression was done for answering objective number three which was to identify factors associated with quality of life among patients with DR, $p<0.05$ was considered significant.

### 3.13: Ethical issues

Ethical clearance was obtained from Institutional Review Board of MUHAS and permission to conduct the study was obtained from Executive Director of MNH. Participants were informed comprehensively about the purposes and advantages of the study and a written signed consent

was sought from patients. The patient's information remained confidential by ensuring that no direct patient identifiers (e.g. name of patients) appear on the checklist during data collection and data analysis. Those who refused to participate in this study continued with their routine management protocols at both clinics.

### 3.14: Dissemination of findings

Findings from this study was presented and discussed in the department and MUHAS scientific conference. The study report will be used to produce a dissertation for partial fulfilment of MMed degree award in ophthalmology. Manuscripts addressing the study will be written and published in peer reviewed journals, also will be available at MUHAS library, online repository and MNH.

# CHAPTER FOUR

## 4.0 RESULTS

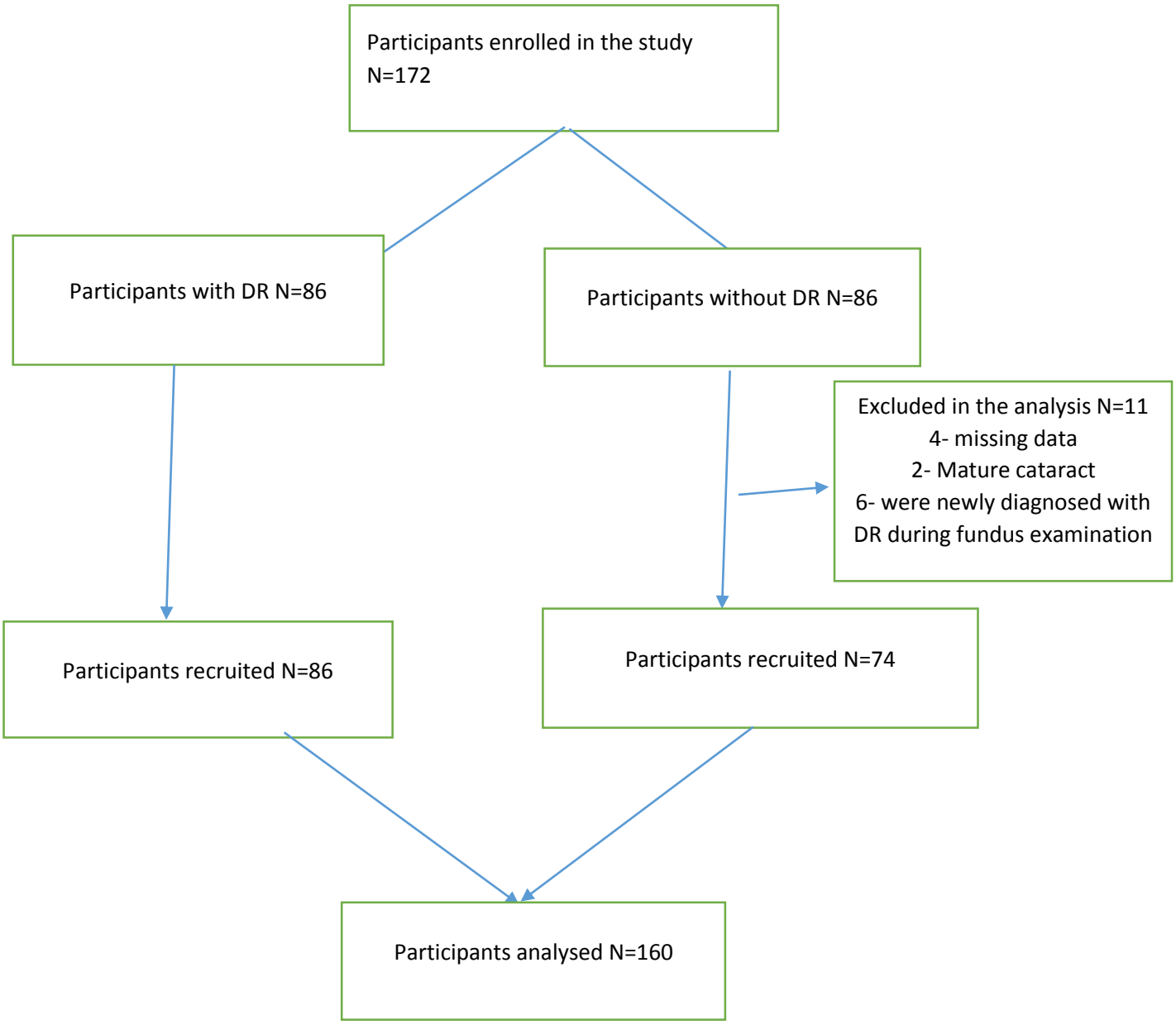



**Figure 3: Flow chart for recruitment process of participants**

There were 160 participants in the study. The male to female ratio in patients with DR and those without DR were 1:1.6 and 1:1 respectively. Most participants were aged between 44-56 years in both groups with a mean of 54.6(± 1.9) years and 56.1(± 2.1) years in participants with DR and without DR respectively. Majority of the participants had college/university education (table 1).

**Table 1: Social demographic characteristics of the study participants N=160.**

| **Variable** | **With DR** | **Without DR** | **p-value** |
|---|---|---|---|
| | **N (%)** | **N (%)** | |
| **Sex** | | | |
| Male | 33 (38.4) | 33 (44.6) | 0.425 |
| Female | 53 (61.6) | 41 (43.6) | |
| | | | |
| **Age (*age group)*** | | | |
| *31-43* | 7 (8.1) | 8 (10.8) | 0.462 |
| *44-56* | 50 (58.1) | 46 (62.2) | |
| *57-69* | 24 (27.9) | 17 (23.0) | |
| *Above 69* | 5 (5.8) | 3 (4.1) | |
| **Mean** | 54.6(± 1.9) years | 56.1(± 2.1) years | |
| **Education level** | | | |
| No formal education | 11 (12.8) | 1 (1.4) | **0.001** |
| Primary | 16 (18.6) | 4 (5.4) | |
| Secondary | 8 (9.3) | 7 (9.5) | |
| College/University | 51 (59.3) | 62 (83.7) | |
| | | | |
| **Residence** | | | |
| Dar es salaam | 65 (75.6) | 49 (66.2) | 0.192 |
| Outside Dar es salaam | 21 (24.4) | 25 (33.8) | |

| | | | |
|---|---|---|---|
| **Marital Status** | | | |
| Single | 11 (12.8) | 19 (25.7) | **0.031** |
| Married | 54 (62.8) | 46 (62.2) | |
| Divorced | 8 (9.3) | 6 (8.1) | |
| Widow/Widower | 10 (11.6) | 1 (1.4) | |
| Cohabiting | 3 (3.5) | 2 (2.7) | |
| | | | |
| **Occupation** | | | |
| Peasant | 37 (43.0) | 3 (4.1) | **0.001** |
| Dependent | 16 (18.6) | 16 (21.6) | |
| Employed | 26 (30.2) | 41 (55.4) | |
| Retired | 1 (1.2) | 1 (1.4) | |
| Petty cash trade/Small business | 6 (7.0) | 13 (17.5) | |
| | | | |
| **Monthly Income** | | | |
| Less than 319000 | 43 (50.0) | 34 (45.9) | 0.814 |
| 319000 – 1310000 | 42 (48.8) | 39 (52.7) | |
| Above 1310000 | 1 (1.2) | 1 (1.4) | |

**Table 2: Systemic and ocular co-morbidities among participants with and without DR N=160**

| | With DR | Without DR |
|---|---|---|
| **Systemic co-morbidities** | **N (%)** | **N (%)** |
| No | 23 (26.7) | 47 (63.5) |
| Hypertension only | 30 (34.9) | 23 (31.1) |
| Hypertension, Kidney disease and diabetic foot ulcers | 1 (1.2) | - |
| Hypertension and stroke | 4 (4.6) | 2 (2.6) |
| Hypertension, stroke and heart disease | 4 (4.6) | - |
| Hypertension and diabetic foot ulcers | 15 (17.4) | 1 (1.4) |
| Hypertension and Heart disease | 5 (5.8) | 1 (1.4) |
| Hypertension, Heart disease and others | 1 (1.2) | - |
| Kidney disease only | 1 (1.2) | - |
| Kidney disease and diabetic foot ulcers | 1 (1.2) | - |
| Diabetic foot ulcers only | 1 (1.2) | - |
| Total | 86 (100) | 74 (100) |
| | | |
| **Ocular co-morbidities** | | |
| No | 23 (26.7) | 51 (68.9) |
| Immature cataract only | 47 (54.7) | 14 (18.9) |
| Immature cataract and glaucoma | 4 (4.7) | - |
| Immature cataract and optic neuropathy | 5 (5.8) | - |
| Glaucoma only | 7 (8.1) | 5(6.8) |
| Optic neuropathy only | - | 4 (5.4) |
| Total | 86 (100) | 74 (100) |

Hypertension and immature cataract were the commonest systemic and ocular co-morbidities among participants with DR respectively while majority of participants without DR had no comorbidities (Table 2).

**Table 3: Clinical characteristics of the study participants, N=160**

| **Variable** | **With DR N (%)** | **Without DR N (%)** | **p-value** |
|---|---|---|---|
| **BCVA** | | | |
| Normal vision | 20 (23.3) | 73 (98.6) | 0.0001 |
| Moderate visual impairment | 43 (50.0) | 1 (1.4) | |
| Severe visual impairment | 9 (10.5) | 0 (0) | |
| Blindness | 14 (16.2) | 0 (0) | |
| | | | |
| **Cigarette smoking** | | | |
| Yes | 42 (48.8) | 20 (27.0) | 0.025 |
| No | 44 (51.2) | 54 (73.0) | |
| | | | |
| **Alcohol consumption** | | | |
| Yes | 58 (67.4) | 47 (63.5) | 0.314 |
| No | 28 (32.6) | 27 (36.5) | |
| | | | |
| **DM treatment** | | | |
| None | 0 (0.0) | 5 (14.0) | 0.167 |
| Oral medications | 70 (81.4) | 44 (51.2) | |
| Injectable | 16 (18.6) | 25 (33.8) | |
| | | | |
| **Type of DM** | | | |
| T1DM | 16 (18.6) | 34 (46.0) | 0.076 |
| T2DM | 70 (81.6) | 40 (54.0) | |
| | | | |
| **BMI** | | | |
| Underweight (<18.6) | 5 (5.8) | 7 (9.5) | 0.521 |
| Normal (18.6-24.9) | 79 (71.8) | 66 (89.2) | |
| High (25-29.9) | 2 (1.2) | 0 (0) | |
| Obesity (>30) | 1(1.2) | 1 (1.4) | |
| | | | |
| **DM Duration** | | | |

| | | | |
|---|---|---|---|
| < 1 year | 6 (7.0) | 5 ( 6.8) | 0.149 |
| 1-10 years | 46 (53.5) | 65 ( 87.8) | |
| 11-20 years | 27 (31.4) | 3 ( 4.1) | |
| > 20 years | 7 (8.1) | 1 ( 1.3) | |
| | | | |
| **DR Duration** | | | |
| < 1year | 29 ( 33.7) | 0 (0) | 0.098 |
| 1-10 years | 50 ( 58.1) | 0 (0) | |
| 11-20 Ears | 6 ( 7.0) | 0 (0) | |
| >20 years | 1 ( 1.2) | 0 (0) | |
| | | | |
| **Medical expenses** | | | |
| Insurance | 43 (50.0) | 43 (50.0) | 0.729 |
| Waiver | 21 (24.4) | 7 (8.1) | |
| Self | 22 (25.6) | 24 (27.9) | |
| | | | |
| **HbA1c** | | | |
| < 6% | 11 (12.8) | 38 (51.3) | 0.067 |
| 6-8% | 38(44.2) | 33(44.6) | |
| >8% | 37 (43.0) | 3 (4.1) | |
| | | | |
| **Total Cholesterol** | | | |
| Normal (0-5.17mmol/l) | 53 (61.6) | 68 (91.9) | 0.476 |
| Raised (>5.17mmol/l) | 33 (38.4) | 6 (8.1) | |
| | | | |
| **LDL** | | | |
| Normal (0-3.34mmol/l) | 39 (45.3) | 62 (83.8) | 0.381 |
| Raised (>3.34mmol/l) | 47 (54.7) | 12 (16.2) | |
| | | | |
| **BUN** | | | |
| <1.8 mmol/l | 5 (5.8) | 5 (6.8) | 0.762 |
| 1.8-7.1 mmol/l | 78 (90.7) | 66 (89.2) | |
| >7.1 mmol/l | 3 (3.5) | 3 (4.1) | |

A higher proportion of participants with DR had visual impairment while majority of those without DR had normal vision. This difference was statistically significant (p-value<0.0001). Most of participants with DR had HbA1c ranging between 6-8% while those without DR HbA1c was <6%, however, the difference was not statistically significant-(Table 3).

**Table 4: Diabetic retinopathy grading and complications among study participants with DR, N=86**

| **Variable** | | **N** | **(%)** |
|---|---|---|---|
| **DR grade Right Eye** | Mild NPDR | 2 | 2.3 |
| | Moderate NPDR | 28 | 32.6 |
| | Severe NPDR | 36 | 41.9 |
| | PDR | 20 | 23.2 |
| | | | |
| **DR grade Left Eye** | Mild NPDR | 4 | 4.7 |
| | Moderate NPDR | 34 | 39.5 |
| | Severe NPDR | 28 | 32.6 |
| | PDR | 20 | 23.3 |
| | | | |
| **Complications of DR** | None | 41 | 47.7 |
| | DME only | 35 | 40.7 |
| | DME and TRD | 2 | 2.3 |
| | VH only | 4 | 4.7 |
| | VH and TRD | 2 | 2.3 |
| | TRD only | 2 | 2.3 |

The commonest DR grading was NPDR in BE, and majority of participants had DR complications with DME being the commonest (Table 4).

**Table 5: Quality of life mean scores in different subscales in participants with and without DR**

| Subscales | With DR Mean (±SD) | Without DR Mean (±SD) | Mean difference | P-Value |
|---|---|---|---|---|
| **Overall QoL Score** | 45.7(±11.8) | 71.6(±9.9) | -25.9 | 0.001 |
| **Vision composite score** | 45.8(±11.3) | 71.8(±10.2) | -26.0 | 0.002 |
| **General Vision** | 35.1(±19.9) | 78.7(±16.7) | -43.6 | 0.001 |
| **Ocular pain** | 98.5(±2.3) | 91.1(±9.6) | 7.4 | 0.001 |
| **Near activities** | 39.2(±19.5) | 71.6(±18.8) | -32.3 | 0.014 |
| **Distance activities** | 45.0(±18.8) | 79.1(±16.4) | -34.0 | 0.001 |
| **Social functioning** | 47.9(±16.2) | 72.4(±10.9) | -24.5 | 0.001 |
| **Mental health** | 40.8(±15.4) | 66.9(±9.3) | -26.0 | 0.001 |
| **Role difficulties** | 42.2(±17.6) | 74.2(±11.4) | -31.9 | 0.001 |
| **Dependency** | 86.5(±11.3) | 84.1(±13.6) | -37.6 | 0.973 |
| **Colour vision** | 49.1(±9.0) | 87.1(±17.2) | -38.0 | 0.001 |
| **Peripheral vision** | 57.1(±12.5) | 84.5(±17.9) | -27.4 | 0.001 |
| **General Health** | 40.7(±16.1) | 69.1(±9.8) | -28.5 | 0.001 |

The overall score, vision composite score and general health score were lower in participants with DR, and the difference was statistically significant ($p<0.001$) (Table 5).

**Table 6: Univariate and Multivariate analysis of overall quality of life with socio-demographic characteristics among participants with DR (N=86).**

| **Social demographic characteristics** | **Univariate** | | **Multivariate** | |
|---|---|---|---|---|
| | **B coefficient** | **P value** | **B coefficient** | **P value** |
| **Age Groups** | | | | |
| 31-43 | Ref | | | |
| 44-56 | 1.1 | 0.804 | | |
| 57-69 | -3.5 | 0.461 | | |
| >69 | -3.7 | 0.708 | | |
| **Sex** | | | | |
| Male | Ref | | | |
| Female | 1.3 | 0.645 | | |
| **Residence** | | | | |
| Dar es Salaam | Ref | | | |
| Outside Dar es Salaam | -1.3 | 0.578 | | |
| **Marital Status** | | | | |
| Single | Ref | | | |
| Married | -4.12 | 0.238 | | |
| Divorced | -1.03 | 0.952 | | |
| Widow/Widowed | -3.8 | 0.320 | | |
| Cohabiting | 0.94 | 0.907 | | |
| **Occupation** | | | | |
| Peasant | Ref | | Ref | |
| Employed | 14.2 | 0.001 | 7.1 | **0.012** |
| Dependent | 12.5 | 0.001 | 8.2 | **0.015** |

| | | | | |
|---|---|---|---|---|
| Petty Cash | 5.7 | 0.067 | 3.4 | 0.167 |
| Retired | 8.7 | 0.001 | 5.2 | **0.046** |
| **Education** | | | | |
| No formal education | Ref | | | |
| Primary | 1.1 | 0.654 | | |
| Secondary | 1.9 | 0.578 | | |
| College/University | 3.1 | 0.895 | | |
| **Monthly Income** | | | | |
| > 1,310,000 | Ref | | Ref | |
| 0 | -19.3 | **0.001** | -9.3 | **0.032** |
| <319,000 | -11.2 | **0.001** | -6.2 | **0.039** |
| 319,000-1,310,000 | -3.67 | 0.001 | -2.1 | 0.879 |
| **Medical Expenses** | | | | |
| Insurance | Ref | | | |
| Waiver | -3.1 | 0.125 | | |
| Self | -1.5 | 0.352 | | |
| Others | -1.0 | 0.209 | | |
| **Alcohol** | | | | |
| Yes | Ref | | | |
| No | -1.3 | 0.765 | | |
| **Tobacco** | | | | |
| Yes | Ref | | | |
| No | 5.6 | **0.047** | 1.2 | 0.567 |

Participants aged 44-56: QoL score 1.1 units higher than 31-43 group (p = 0.804), not statistically significant. 57-69: QoL score 3.5 units lower than 31-43 group (p = 0.461), not

statistically significant. Over 69: QoL score 3.7 units lower than 31-43 group (p = 0.708), not statistically significant. Conclusion: Age does not significantly affect QoL compared to the reference group.

Employed: QoL score 14.2 units higher than peasants (p = 0.001), statistically significant. Dependent: QoL score 12.5 units higher than peasants (p = 0.001), statistically significant. Petty Cash: QoL score 5.7 units higher than peasants (p = 0.067), not statistically significant. Retired: QoL score 8.7 units higher than peasants (p = 0.001), statistically significant. Conclusion: Employment status, especially being employed or dependent, is strongly linked to higher QoL.

0 income: QoL score 19.3 units lower than high earners (p = 0.001), statistically significant. <319,000: QoL score 11.2 units lower than high earners (p = 0.001), statistically significant. 319,000–1,310,000: QoL score 3.67 units lower than high earners (p = 0.001), statistically significant. Conclusion: Lower income is strongly associated with lower QoL, with no income having the most significant impact.

In multivariate analysis; Employed participants have a significantly higher QoL score (7.1 units) than those in the "Peasant" reference category (p = 0.0012). Dependent individuals also have a higher QoL score (8.2 units), and the result is statistically significant (p = 0.015). Petty Cash holders show a positive but statistically insignificant trend (p = 0.167). Retired participants show a 5.2-unit higher QoL score, which is statistically significant (p = 0.046). Conclusion: Employment, being dependent, and retirement are associated with higher QoL, while petty cash status does not show a significant effect.

Income Levels: Zero income is associated with a significantly lower QoL score (9.3 units) compared to the highest income group (p = 0.032). Income below 319,000 is also linked to lower QoL score (6.2 units, p = 0.039). Income between 319,000 and 1,310,000 shows no significant impact (p = 0.879). Conclusion: Low income is associated with significantly lower QoL, with the greatest impact seen at the lower income levels.

**Table 7: Univariate and Multivariate analysis of overall quality of life with clinical characteristics among participants with DR (N=86).**

| **Clinical characteristics** | **Univariate** | | **Multivariate** | |
|---|---|---|---|---|
| | **B coefficient** | **P value** | **B coefficient** | **P value** |
| **DM Duration** | | | | |
| < 1 year | Ref | | | |
| 1-10 years | -4.3 | **0.001** | -2.4 | 0.213 |
| 11-20 years | -17.3 | **0.001** | -12.4 | **0.023** |
| > 20 years | -25.2 | **0.001** | -19.4 | **0.014** |
| **DR Duration** | | | | |
| < 1 year | Ref | | | |
| 1-10 years | -5.8 | 0.067 | -2.3 | 0.254 |
| 11-20 years | -10.5 | **0.001** | -6.7 | **0.021** |
| > 20 years | -17.2 | **0.001** | -11.4 | **0.001** |
| **Medical Conditions** | | | | |
| No | Ref | | | |
| Hypertension | -2.3 | 0.092 | -0.12 | 0.146 |
| Kidney disease | -8.3 | **0.017** | -1.4 | 0.567 |
| Stroke | -11.4 | **0.008** | -3.3 | 0.127 |
| Diabetic foot ulcer | -13.7 | **0.039** | -4.5 | 0.089 |
| Heart Disease | -8.9 | **0.028** | -3.6 | 0.156 |
| Others | -1.3 | 0.234 | -0.3 | 0.879 |
| **Ocular Conditions** | | | | |
| No | Ref | | Ref | |
| Cataract | -12.5 | **0.001** | -9.5 | **0.001** |

| | | | | |
|---|---|---|---|---|
| Glaucoma | -8.8 | **0.001** | -4.8 | **0.012** |
| Optic Neuropathy | -5.3 | 0.145 | -2.3 | 0.676 |
| **Type of DM** | | | | |
| T1DM | Ref | | | |
| T2DM | -1.9 | 0.652 | | |
| **DM Treatment** | | | | |
| No | Ref | | | |
| Oral Medication | -11.0 | **0.001** | -7.3 | **0.042** |
| Injectable | -6.9 | 0.012 | -4.2 | **0.047** |
| **BMI** | | | | |
| underweight (<18.6) | Ref | | | |
| normal (18.6-24.9) | -1.3 | 0.651 | | |
| high (25-29.9) | -3.2 | 0.781 | | |
| obesity (>30) | -3.1 | 0.462 | | |
| **BCVA** | | | | |
| normal >6/18 | Ref | | Ref | |
| impairment <6/18-6/60 | -8.3 | **0.001** | -6.3 | **0.001** |
| severe impairment <6/60-3/60 | -12.7 | **0.001** | -10.4 | **0.001** |
| blindness <3/60-PL | -19.4 | **0.001** | -16.4 | **0.001** |
| **Grading of DR** | | | | |
| Mild NPDR | Ref | | Ref | |
| Moderate NPDR | -5.4 | **0.001** | -3.4 | **0.001** |
| Severe NPDR | -19.6 | **0.001** | -17.6 | **0.001** |
| PDR | -27.1 | **0.001** | -23.7 | **0.001** |
| **Complications of DR** | | | | |

| | | | | |
|---|---|---|---|---|
| No | Ref | | | |
| DME | -24.9 | **0.001** | -19.3 | **0.001** |
| VH | -26.4 | **0.001** | -22.9 | **0.001** |
| TRD | -17.2 | **0.001** | -11.5 | **0.001** |
| Multiple complications | -34.3 | **0.001** | -23.7 | **0.001** |
| **HBA1c** | | | | |
| < 6% | Ref | | Ref | |
| 6-8% | -1.2 | 0.678 | -0.2 | 0.678 |
| > 8% | -10.4 | **0.001** | -8.6 | **0.001** |
| **Total Cholesterol** | | | | |
| Normal(0-5.17mmol/l) | Ref | | | |
| Raised (> 5.17mmol/l) | -2.3 | 0.879 | | |
| **LDL** | | | | |
| Normal(0-3.34mmol/l) | Ref | | | |
| Raised (> 3.34mmol/l) | -1.2 | 0.234 | | |
| **BUN** | | | | |
| <1.8 mmol/l | Ref | | | |
| 1.8-7.1 mmol/l | -4.2 | 0.354 | | |
| >7.1 mmol/l | -5.1 | 0.234 | | |
| **Creatinine** | | | | |
| <53 mmol/l women/<61.9mmol/l men | Ref | | | |
| 53-97.2 mmol/l/ 61.9-114.9mmol/l men | -2.7 | 0.456 | | |
| >97.2mmol/l women/ > 114.9mmolmen | -2.9 | 0.325 | | |

Diabetes (DM) Duration: 1–10 years: QoL score 4.3 units lower than <1 year (p = 0.001), statistically significant. 11–20 years: QoL score 17.3 units lower (p = 0.001), statistically significant. >20 years: QoL score 25.2 units lower (p = 0.001), statistically significant. Conclusion: Longer duration of diabetes is associated with progressively lower QoL.

Diabetic Retinopathy (DR) Duration: 1–10 years: QoL score 5.8 units lower than <1 year (p = 0.067), not statistically significant. 11–20 years: QoL score 10.5 units lower (p = 0.001), statistically significant. >20 years: QoL score 17.2 units lower (p = 0.001), statistically significant. Conclusion: Longer duration of DR is associated with significantly lower QoL.

Medical Conditions: Hypertension: QoL score 2.3 units lower (p = 0.092), not statistically significant. Kidney disease: QoL score 8.3 units lower (p = 0.017), statistically significant. Stroke: QoL score 11.4 units lower (p = 0.008), statistically significant. Diabetic foot ulcer: QoL score 13.7 units lower (p = 0.039), statistically significant. Heart disease: QoL score 8.9 units lower (p = 0.028), statistically significant. Other medical conditions: QoL score 1.3 units lower (p = 0.234), not statistically significant. Conclusion: Kidney disease, stroke, foot ulcers, and heart disease are associated with significantly lower QoL.

Ocular Conditions: Cataracts: QoL score 12.5 units lower (p = 0.001), statistically significant. Glaucoma: QoL score 8.8 units lower (p = 0.001), statistically significant. Optic neuropathy: QoL score 5.3 units lower (p = 0.145), not statistically significant. Conclusion: Cataracts and glaucoma significantly lower QoL, but optic neuropathy does not.

Diabetic Retinopathy Severity: Moderate NPDR: QoL score 5.4 units lower than mild NPDR (p = 0.001), statistically significant. Severe NPDR: QoL score 19.6 units lower (p = 0.001), statistically significant. PDR: QoL score 27.1 units lower (p = 0.001), statistically significant. Conclusion: Severe DR, especially PDR, has the most significant negative impact on QoL.

BCVA: Visual impairment: QoL score 8.3 units lower (p = 0.001), statistically significant. Severe impairment: QoL score 12.7 units lower (p = 0.001), statistically significant. Blindness: QoL score 19.4 units lower (p = 0.001), statistically significant. Conclusion: Reduced visual acuity, especially blindness, significantly lowers QoL.

Diabetic Macular Edema (DME) and Other Complications: DME: QoL score 24.9 units lower (p = 0.001), statistically significant. VH (Vitreal Hemorrhage): QoL score 26.4 units lower (p = 0.001), statistically significant. TRD (Tractional Retinal Detachment): QoL score 17.2 units lower (p = 0.001), statistically significant. Multiple complications: QoL score 34.3 units lower (p = 0.001), statistically significant. Conclusion: Complications related to DR (DME, VH, TRD, and multiple complications) significantly lower QoL, with multiple complications having the most severe impact.

HbA1c Levels: 6–8%: QoL score 1.2 units lower (p = 0.678), not statistically significant. >8%: QoL score 10.4 units lower (p = 0.001), statistically significant. Conclusion: Poor glycemic control (HbA1c > 8%) is significantly associated with lower QoL score, while moderate levels do not have a significant impact.

Tobacco Use: Non-smokers: QoL score 5.6 units higher (p = 0.047), statistically significant. Thus, not using tobacco is significantly associated with a higher QoL score. (Table 7).

After adjusting for confounders; Duration of DM: 1-10 years: No significant impact on QoL (p = 0.213). 11-20 years: 12.4 units lower QoL score, statistically significant (p = 0.023). >20 years of DM: 19.4 units lower QoL score, statistically significant (p = 0.014). Conclusion: Longer duration of DM is associated with progressively lower QoL score.

DR Duration: 1-10 years: No significant impact (p = 0.254). 11-20 years: 6.7 units lower QoL score (p = 0.021). >20 years: 11.4 units lower QoL score (p = 0.001). Conclusion: Longer DR duration is linked to significantly lower QoL score, with the lowest QoL score in those with DR for more than 20 years.

Medical Conditions: Conditions such as hypertension, kidney disease, stroke, heart disease, diabetic foot ulcers, and other medical conditions did not show statistically significant associations with QoL score (all p-values > 0.05). Conclusion: These conditions do not have a meaningful impact on QoL score compared to participants without medical conditions.

Ocular Conditions: Cataracts (p = 0.001), glaucoma (p = 0.012), and moderate NPDR (p = 0.001) all significantly lower QoL score. Severe NPDR (p = 0.001) and PDR (p = 0.001) show a progressively greater negative impact on QoL score. Visual impairment: Statistically significant reductions in QoL score score with moderate, severe, and blindness (p = 0.001). Conclusion: Ocular conditions, particularly severe forms of DR and visual impairment, are strongly associated with lower QoL score.

Complications: DME, VH, TRD, and multiple complications all show significant negative impacts on QoL score (p-values < 0.05), with the lowest QoL in participants with multiple complications. Conclusion: DR complications are associated with progressively lower QoL score, especially in participants with multiple complications.

HbA1c: HbA1c >8% is significantly associated with a lower QoL (8.6 units lower, p = 0.001). HbA1c between 6% and 8% does not significantly affect QoL (p = 0.678). Conclusion: Poor glycemic control (HbA1c >8%) significantly decreases QoL.

Tobacco Use: Non-tobacco users have a slightly higher QoL, but the result is not statistically significant (p = 0.567). Conclusion: Tobacco use does not appear to have a significant impact on QoL. (Table 7).

Overall Conclusion: Employment, higher income, shorter durations of DM and DR, and better glycemic control are all associated with significantly better QoL. Ocular conditions, particularly severe DR, visual impairments, and diabetic eye complications, contribute to a marked decline in QoL. While certain medical conditions and tobacco use show some trends, these factors were not found to have a significant impact on QoL in this study.

# CHAPTER FIVE

## 5.0 DISCUSSION

The quality of life of patients is one of the important elements to be considered in the management of DM. DR is a common complication of DM that may lead to vision loss hence affecting the quality of life of affected individual. In the current study, the NEI-VFQ-25 was used to assess the quality of life related to health and vision. In this study the overall QoL mean score was lower in participants with DR (45.7± 11.8) compared to those without DR (71.6±9.9). This discrepancy can be due to visual impairment as a result of DR, this highlights the need for addressing the importance of controlling the modifiable risk factors for development of DR (like glycaemic control, cigarette smoking and alcohol intake).

The overall QoL in participants with DR in our study was lower compared to Bicer et al in Turkey and Pereira et al. in India (with DR 59.72 ±18.2, without DR 70.33± 18.2 and with DR 73.93±25.55, without DR 99.26±1.01 respectively) (5, 19). The lower overall QoL in our study can be explained by the fact that majority of our participants had severe NPDR and PDR grades which may significantly affect the vision related activities and consequently affecting the QoL of an individual.

Participants in our study had lower vision composite scores (45.8±11.3), almost similar findings were obtained by Bicer et al in Turkey and Lucia et al in Spain, however Pereira et al in India found higher scores (63.69±19.3). Participants with DR had lower scores in all subscales with the exception of ocular pain and dependency when compared to those without DR, similar findings were obtained by Pereira et al in India and Lucia et al in Spain (5, 20). The significant higher scores of ocular pain in participants with DR may be due to the fact that participants with DR have regular visits to the eye clinic where most conditions which causes ocular pain like dry eyes and allergic conjunctivitis are being taken care of.

In this study, participants with DR were found to have decreased general health score than those without DR. Pereira's et al in India reported similar findings (5).

Poor vision may impact individual ability to complete activities of daily living, and social, emotional and economic wellbeing which may consequently affect the individual's general health. We recommend further studies to investigate how poor vision related quality of life affect the general health.

Participants who are employed had better QoL score compared to other categories, contrary to the study done by Kamran et al in Iran (14). Being employed provides structure, financial security, social links, a sense of purpose, and personal development. However, it is important to prioritize job satisfaction, work-life balance, and a supportive work environment in order to ensure that employment has a good impact on overall well-being and quality of life.

In this study poor glycemic control, was significantly associated with decreased quality of life score, similarly to the Yuhara et al study in Indonesia (4), but this findings were different from the study done by Shah et al in India and Aguirre et al in Spain. This indicates that poor glycemic control increases the chance of developing and progression of DR and other DM complications like nephropathy, and diabetic foot ulcer, by aiming for better glycemic control, people may be able to lessen complications, ease physical symptoms, improve their overall quality of life, and boost their psychological wellbeing.

Participants who had poor vision (blindness category in WHO classification) had lower QoL score; this finding was similar to the study done in Kenya by Emade et al. This shows that prevention of poor vision due to DR by regular DR screening and early intervention when changes of DR are detected could significantly improve an individual's quality of life. This also highlights the importance of visual health in relation to the patient's wellbeing.

Our study found that presence of ocular comorbidity mainly cataract and glaucoma and systemic comorbidities had significant association with decreased quality of life score, this finding was similar to the study done by Yuhara et al (4). Presence of comorbidities increases disease burden which further deteriorates the QoL, hence measures for early detection and intervention of comorbidities like visually significant cataract could improve QoL.

Although participants with various medical conditions had lower QoL scores compared to those with no medical conditions, the lack of statistical significance may suggest that these association may not be strong enough to warrant definitive conclusions hence it maight be valuable to explore these associations further with larger sample size or additional variables to clarify the potential impacts.

Our study also found that longer duration of DM were related to lower quality of life score similarly to the study done by Shah et al in India and Aguirre et al in Spain(5, 15). People who have diabetes frequently need to make considerable lifestyle changes, including dietary restrictions, consistent exercise, and medication adherence. The necessity of these adjustments over time may have an impact on relationships, social interactions, and general lifestyle, thus lowering quality of life. The work of healthcare providers is vital in reducing the negative effects of diabetes on quality of life. They can offer information and support, including psychological support, to help people manage their diabetes more effectively, avoid complications, and deal with the difficulties brought on by the condition. To maximize quality of life, regular monitoring, prompt interventions, and individualized treatment programs are necessary (23).

This study also found that longer duration of DR was significantly associated with decreased QoL score. Study by Perreira et al in India and Aguirre et al in Spain (5, 15) obtained similar results. The gradual nature of diabetic retinopathy and the potential danger of vision loss can result in emotional discomfort, anxiety, despair, and social isolation. People who are visually impaired may experience fear, frustration, and a sense of helplessness. The impact of these psychological factors may also lower one's standard of living. The necessity of ongoing medical treatments and adherence to treatment regimens may severely burden people's daily lives, which can reduce their overall quality of life.

In the current study proliferative diabetic retinopathy was associated with notable decrease in QoL score, similar to the study by Vijayan et al in India, Shah et al in India, Emade et al in Kenya , Ashish et al in India (2,5, 21, 22). People who have DR may endure worsening visual impairments as the disease progresses.

They may also encounter other difficulties that may have a severe influence on their quality of life, such as poor job performance and limited career options. Healthcare professionals can assist people in maintaining a higher quality of life score and enhancing their general well-being by addressing the visual impairments, psychological effect, social obstacles, and treatment burden associated with advanced diabetic retinopathy.

In our study, the presence of any complication from diabetic retinopathy was associated with a significantly lower quality of life score, with multiple complications having the most substantial negative impact. Similar findings were obtained from the study done by Brown et al and Martinez et al in Spain (13, 15). This highlights the severity and detrimental effects of complications arising from diabetic retinopathy on quality of life, emphasizing the need for early detection and management of diabetic retinopathy may help mitigate the long-term complications.

# CHAPTER SIX

## 6.0 CONCLUSION AND RECOMMENDATION

### 6.1 Conclusion

The overall QoL score among participants with DR at MNH is low. Vision related quality of life score among participants with DR was also low. Longer duration DM and DR, presence of ocular comorbidity, high levels of HBA1c, poor vision, presence of ocular and systemic comorbidities, and presence of DR complications and advanced grade of DR were associated with poor overall QoL.

### 6.2 Recommendation

People with DM should have regular eye examinations to detect DR in its early stages, this can prevent vision loss and improve overall QoL.

Maintaining optimal blood sugar levels is important to prevent or delay the onset of DR. Appropriate management of comorbid eye condition is important to prevent further deterioration of vision and QoL.

Educating and providing support to patients with DR can help them cope with visual impairment and help them make necessary modifications to their daily routine to improve their QoL.

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# APPENDICES

## QUALITY OF LIFE IN PATIENTS WITH AND WITHOUT DIABETIC RETINOPATHY AT MUHIMBILI NATIONAL HOSPITAL (MNH)

### Appendix I: Questionnaire

**BIODATA**

**Code number…….**

**Patient**

1. **Age …….**
2. **Sex**
    1. Male
    2. Female
3. **Residence……..**
4. **Marital status**

1. Married
2. Single parent
3. Divorced
4. Widowed

5. **Occupation**

    1. Peasant/Farmer
    2. Petty business
    3. Employed
    4. Business

6. **Education level**

1. No formal education
2. Primary
3. Secondary
4. Tertiary (College/University)

**CLINICAL HISTORY**

| SN | QUESTION | CATEGORIES | RESPONSE |
|---|---|---|---|
| 7 | For how long have you been diagnosed to have DM(YRS) | 1-Below 10yrs<br>2-Above 10yrs | |
| 8 | Do/did you drink alcohol? (consistently for at list 2yrs prior or after DM illness) | 1-Yes<br>2-No | |
| 9 | Do/did you smoke(consistently for at list 2yrs prior or after DM illness) | 1-Yes<br>2-No | |
| 10 | Are you hypertensive? | 1-Yes<br>2-No | |
| 11 | If no from 14 above | Measure BP | |
| 12 | Are you in the treatment of DM? | 1-Yes<br>2-No | |
| 13 | If yes in question 15 what type of treatment you use?<br>Injection(insulin) or Drugs(OHGD) | 1-Injection<br>2-OHGD<br>3-Mixed<br>4-Diety | |
| 14 | What type of diabetes mellitus does the patient suffer from? | 1.IDDM<br>2.NIDDM | |

**EXAMINATION FINDINGS**

| SN | QUESTIONS | CATEGORIES | RESPONSE |
|---|---|---|---|
| 15 | Is there a high BMI? (≥ 25)<br>The BMI normal-(18.6-24.9)<br>The BMI for Obesy (≥30) | 1-Under weight(<18.6)<br>2- (18.6-24.9) Normal<br><br>3-(25-29.9) High<br><br>4-(≥30) | |
| 16 | Visual acuity | 1-Normal >6/18<br>2-Impared <6/18 -6/60<br>3-Severe imparement <6/60-3/60<br>4-Blindness <3/60-PL | RE---<br>LE---- |
| 17 | Retinal findings for DR | 1-Yes<br>2-No | |
| 18 | If yes in 21 above are there any DR changes in any of the eyes? | 1.Mild NPDR<br>2.Moderate NPDR<br>3.Severe NPDR<br>4.Very severe NPDR<br>5.PDR without High-risk changes<br>6.PDR with High-risk changes. | RE----<br><br>LE---- |
| 19 | Are there any Diabetic Maculopathy changes in any eye? | 1-Yes<br><br>2-No | RE-----<br><br>LE------ |
| 20 | If 'yes' in Q23, what is the stage of Maculopathy? | 1.Clinically Significant macula edema<br>2.Non-clinically significant macula edema | RE------<br><br>LE------- |
| 21 | Are there feature of dvanced diabetic end stage disease | 1-Yes<br><br>2-No | RE……<br><br>LE…….. |

**LABORATORY FINDINGS**

| SN | | CODING | RESPONSE |
|---|---|---|---|
| 22 | HbA1c (%) | (1) <6%<br>(2) 6-8%<br>(3) >8% | |
| 23 | Total Cholesterol | (1) 0-5.17mmol/l(Normal)<br>(2) >5.17mmol/l(Raised) | |
| 24 | LDL | (1)0-3.34mmol/l(Normal)<br>(2)>3.34mmol/l(Raised) | |

**QUALITY OF LIFE IN PATIENTS WITH AND WITHOUT DIABETIC RETINOPATHY AT MUHIMBILI NATIONAL HOSPITAL (MNH)**

**(UBORA WA MAISHA KWA WAGONJWA WA KISUKARI WENYE SHIDA NA WASIO NA SHIDA KATIKA PAZIA LA KUONEA WANAOPATA HUDUMA KATIKA HOSPITALI YA TAIFA MUHIMBILI)**

**Appendix II: Kiambatanisho I: Dodoso**

**SEHEMU A;**

**TAARIFA BINAFSI**

**Namba ya dodoso…….**

**Mgonjwa**

1. **Umri …….**
2. **Jinsia**
    1. Kiume (Me)
    2. Kike (Ke)
3. **Makazi……..**
4. **Hali ya ndoa**
    1. nimeolewa/nimeoa
    2. sijaoa/sijaolewa
    3. nimetalikiana
    4. mjane/mgane
5. **Kazi**
    1. Mkulima
    2. Mfanya biashara
    3. Mwajiriwa

**6. Kiwango cha elimu**

5. Sijasoma
6. Shule ya msingi
7. Shule ya secondary
8. Elimu ya chuo

**SEHEMU B**

| **No** | **Swali** | **Migawanyo ya kung'amua** | **Matokeo** |
|---|---|---|---|
| 7 | Kwa muda gani umekuwa na kisukari(miaka) | 1-Chini ya miaka 10<br>2-Zaidi ya miaka 10 | |
| 8 | Uliwahi/Unakunywa pombe(kwa muda wa miaka 2 kabla ya kisukari) | 1-Ndiyo<br>2-Hapana | |
| 9 | Uliwahi/Unavuta sigara(mfululizo kiasi cha muda wa miaka 2 kabla au baada ya kisukari) | 1-Ndiyo<br>2-Hapana | |
| 10 | Je Ni mgonjwa wa shinikizo la damu ? | 1-Ndiyo<br>2-Hapana | |
| 11 | Je Unatumia matibabu ya kisukari ? | 1-Ndiyo<br>2-Hapana | |
| 12 | Kama ni ndiyo kwenye swali numba 15.<br>Ni matibabu gani unatumia,kuchoma sindano au kunywa dawa? | 1-Sindano<br>2- Kunywa dawa | |
| 13 | Ni aina gani ya kisukari ambayo mgonjwa anayo ? | 1-Tegemezi kwa sindano<br>2-Isiyotegemezi kwa sindano | |

**SEHEMU YA C**

**MATOKEO YA UCHUNGUZI (EXAMINATION)**

| Namba | Kipimo | Migawanyo ya kung'amua | Matokeo |
|---|---|---|---|
| 14 | Kuna uzito wa juu au wa chini ? | 1-Ndiyo<br>2-Hapana | |
| 15 | Kuna shinikizo la damu ? | 1-Hapana<br>2-Ndiyo | |
| 16 | Kiwango cha uono | Kulia……<br>Kushoto……. | |
| 17 | Kuna dalili za uhalibifu wa pazia la kuone kutokana kisukari | 1-Ndiyo<br>2-Hapana | |
| 18 | Kamajibu ni'ndio' kwenye SW20, ni kwa kiasi gani? | 1-Kidogo<br>2-Wastani<br>3-Sana<br>4-Sana Kuzidi<br>5-Madhara endelevu bila halihatarishi.<br>6-Madhara endelevu na hali hatarishi | |
| 19 | Kuna dalili za kisukari zinazohusisha macula ya jicho lolote? | 1-Ndiyo<br>2-Hapana | |
| 20 | Kama ni ndiyo swali numba 21 ni za kiwango gani. | 1-Kiasi cha maana<br>2-kiasi kisicho cha maana | |

**SEHEMU D**

| Namba | Kipimo | Migawanyo ya kung'amua | Matokeo |
|---|---|---|---|
| 21 | HbA1c | (1) <6% | |
| | | (2) 6-8% | |
| | | (3)>8% | |
| 22 | Total Cholesterol | (1) 0-5.17mmol/l(Normal)<br>(2) >5.17mmol/l(Raised) | |
| 23 | LDL | (1)0-3.34mmol/l(Normal)<br>(2)>3.34mmol/l(Raised) | |

**QUALITY OF LIFE IN PATIENTS WITH AND WITHOUT DIABETIC RETINOPATHY AT MUHIMBILI NATIONAL HOSPITAL (MNH)**

**(UBORA WA MAISHA KWA WAGONJWA WA KISUKARI WENYE SHIDA NA WASIO NA SHIDA KATIKA PAZIA LA KUONEA WANAOPATA HUDUMA KATIKA HOSPITALI YA TAIFA MUHIMBILI)**

**Visual Functioning Questionnaire - 25**

PART 1 - GENERAL HEALTH AND VISION

**1.** In general, would you say your overall health is*: *(Circle One)*

Excellent ..... 1

Very Good..... 2

Good..... 3

Fair..... 4

Poor..... 5

2. At the present time, would you say your eyesight using both eyes (with glasses or contact lenses, if you wear them) is excellent, good, fair, poor, or very poor or are you completely blind? *(Circle One)*

Excellent ..... 1

Good..... 2

Fair..... 3

Poor..... 4

Very Poor..... 5

Completely Blind..... 6

**3.** How much of the time do you worry about your eyesight? *(Circle One)*

None of the time..... 1

A little of the time..... 2

Some of the time..... 3

Most of the time..... 4

All of the time? ..... 5

4. How much pain or discomfort have you had in and around your eyes (for example, burning, itching, or aching)? Would you say it is: *(Circle One)*

None ..... 1

Mild..... 2

Moderate ..... 3

Severe, or..... 4

Very severe... 5

**PART 2 - DIFFICULTY WITH ACTIVITIES**

The next questions are about how much difficulty, if any, you have doing certain activities wearing your glasses or contact lenses if you use them for that activity. (Circle One)

| | **No difficulty at all** | **A little difficulty** | **Moderate difficulty** | **Extreme difficulty** | **Stopped doing this because of your eyesight** | **Stopped doing this for other reasons or not interested in doing this** |
|---|---|---|---|---|---|---|
| 5. How much difficulty do you have reading ordinary print in newspapers? Would you say you have: | 1 | 2 | 3 | 4 | 5 | 6 |
| 6. How much difficulty do you have doing work or hobbies that require you to see well up close, such as cooking, sewing, fixing things | 1 | 2 | 3 | 4 | 5 | 6 |

| | | | | | | |
|---|---|---|---|---|---|---|
| around the house, or using hand tools? Would you say: | | | | | | |
| 7. Because of your eyesight, how much difficulty do you have finding something on a crowded shelf? | 1 | 2 | 3 | 4 | 5 | 6 |
| 8. How much difficulty do you have reading street signs or the names of stores? | 1 | 2 | 3 | 4 | 5 | 6 |
| 9. Because of your eyesight, how much difficulty do you have going down steps, stairs, or curbs in dim light or at night? | 1 | 2 | 3 | 4 | 5 | 6 |
| 10. Because of your eyesight, how much difficulty do you have noticing objects off to the side while you are walking along? | 1 | 2 | 3 | 4 | 5 | 6 |
| 11. Because of your eyesight, how much difficulty do you have seeing how people react to things you say? | 1 | 2 | 3 | 4 | 5 | 6 |
| 12. Because of your eyesight, how much | 1 | 2 | 3 | 4 | 5 | 6 |

| | | | | | | |
|---|---|---|---|---|---|---|
| difficulty do you have picking out and matching your own clothes? | | | | | | |
| 13. Because of your eyesight, how much difficulty do you have visiting with people in their homes, at parties, or in restaurants? | 1 | 2 | 3 | 4 | 5 | 6 |
| 14. Because of your eyesight, how much difficulty do you have going out to see movies, plays, or sports events? | 1 | 2 | 3 | 4 | 5 | 6 |

15. Now, I'd like to ask about driving a car. Are you currently driving, at least once in a while?

*(Circle One)*

Yes..... 1 *Skip to Qn 15c*

No..... 2

15a. IF NO, ASK: Have you never driven a car or have you given up driving? *(Circle One)*

Never drove ..... 1 *Skip to Part 3, Q 17*

Gave up..... 2

15b. IF GAVE UP DRIVING: Was that mainly because of your eyesight, mainly for some other reason, or because of both your eyesight and other reasons?

*(Circle One)*

Mainly eyesight..... 1 *Skip to Part 3, Q 17*

Mainly other reasons..... 2 *Skip to Part 3, Q 17*

Both eyesight and other reasons ... 3 *Skip to Part 3, Q 17*

15c. IF CURRENTLY DRIVING: How much difficulty do you have driving during the daytime in familiar places? Would you say you have?

*(Circle One)*

No difficulty at all..... 1

A little difficulty..... 2

Moderate difficulty ..... 3

Extreme difficulty..... 4

16. How much difficulty do you have driving at night? Would you say you have: *(Circle One)*

No difficulty at all..... 1

A little difficulty..... 2

Moderate difficulty..... 3

Extreme difficulty..... 4

Have you stopped doing this because of your eyesight..... 5

Have you stopped doing this for other reasons or are you not interested in doing this .....6

16a. How much difficulty do you have driving in difficult conditions, such as in bad weather, during rush hour, on the freeway, or in city traffic? Would you say you have: *(Circle One)*

No difficulty at all..... 1

A little difficulty..... 2

Moderate difficulty..... 3

Extreme difficulty..... 4

Have you stopped doing this because of your eyesight.....5

Have you stopped doing this for other reasons or are you not interested in doing this .....6

**PART 3: RESPONSES TO VISION PROBLEMS**

The next questions are about how things you do may be affected by your vision. For each one, I'd like you to tell me if this is true for you all, most, some, a little, or none of the time.

*(Circle One on Each Line)*

| READ CATEGORIES: | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|---|---|---|---|---|---|
| 17. Do you accomplish less than you would like because of your vision? | 1 | 2 | 3 | 4 | 5 |
| 18. Are you limited in how long you can work or do other activities because of your vision? | 1 | 2 | 3 | 4 | 5 |
| 19. How much does pain or discomfort in or around your eyes, for example, burning, itching, or aching, keep you from doing what you'd like to be doing? Would you say: | 1 | 2 | 3 | 4 | 5 |

For each of the following statements, please tell me if it is definitely true, mostly true, mostly false, or definitely false for you or you are not sure.

*(Circle One on Each Line)*

| READ CATEGORIES: | Definitely true | Mostly true | Not sure | Mostly false | Definitely false |
|---|---|---|---|---|---|
| 20.I stay home most of the time because of my eyesight | 1 | 2 | 3 | 4 | 5 |
| 21. I feel frustrated a lot of the time because of my eyesight | 1 | 2 | 3 | 4 | 5 |
| 22. I have much less control over what I do, because of my eyesight | 1 | 2 | 3 | 4 | 5 |
| 23. Because of my eyesight, I have to rely too much on what other people tell me | 1 | 2 | 3 | 4 | 5 |
| 24. I need a lot of help from others because of my eyesight | 1 | 2 | 3 | 4 | 5 |
| 25. I worry about doing things that will embarrass myself or others, because of my eyesight | 1 | 2 | 3 | 4 | 5 |

**ADDITIONAL QUESTIONS**

SUBSCALE: GENERAL HEALTH

A1. How would you rate your overall health, on a scale where zero is as bad as death and 10 is best possible health?

(Circle One)

0 1 2 3 4 5 6 7 8 9 10

Worst Best

SUBSCALE: GENERAL VISION

A2. How would you rate your eyesight now (with glasses or contact lens on, if you wear them), on a scale of from 0 to 10, where zero means the worst possible eyesight, as bad or worse than being blind, and 10 means the best possible eyesight?

(Circle One)

0 1 2 3 4 5 6 7 8 9 10

Worst Best

SUBSCALE: NEAR VISION

| | **No difficulty at all** | **A little difficulty** | **Moderate difficulty** | **Extreme difficulty** | **Stopped doing this because of your eyesight** | **Stopped doing this for other reasons or not interested in doing this** |
|---|---|---|---|---|---|---|
| A3. Wearing glasses, how much difficulty do you have reading the small print in a telephone book, on a medicine bottle, or on legal forms? Would you say**:** (Circle One) | 1 | 2 | 3 | 4 | 5 | 6 |
| A4. Because of your eyesight, how much difficulty do you have figuring out whether bills you receive are accurate? (Circle One) | 1 | 2 | 3 | 4 | 5 | 6 |
| A5. Because of your eyesight, how much difficulty do you have doing things like shaving, styling your hair, or putting on makeup? (Circle One) | 1 | 2 | 3 | 4 | 5 | 6 |

## SUBSCALE: DISTANCE VISION

| | No difficulty at all | A little difficulty | Moderate difficulty | Extreme difficulty | Stopped doing this because of your eyesight | Stopped doing this for other reasons or not interested in doing this |
|---|---|---|---|---|---|---|
| A6. Because of your eyesight, how much difficulty do you have recognizing people you know from across a room? (Circle One) | 1 | 2 | 3 | 4 | 5 | 6 |
| A7. Because of your eyesight, how much difficulty do you have taking part in active sports or other outdoor activities that you enjoy (like golf, bowling, jogging, or walking)? (Circle One) | 1 | 2 | 3 | 4 | 5 | 6 |
| A8. Because of your eyesight, how much difficulty do you have seeing and enjoying programs on TV? (Circle One) | 1 | 2 | 3 | 4 | 5 | 6 |

**SUBSCALE: SOCIAL FUNCTION**

| | **No difficulty at all** | **A little difficulty** | **Moderate difficulty** | **Extreme difficulty** | **Stopped doing this because of your eyesight** | **Stopped doing this for other reasons or not interested in doing this** |
|---|---|---|---|---|---|---|
| A9. Because of your eyesight, how much difficulty do you have entertaining friends and family in your home? (Circle One) | 1 | 2 | 3 | 4 | 5 | 6 |

**SUBSCALE: ROLE LIMITATIONS**

A11. The next questions are about things you may do because of your vision. For each item, I'd like you to tell me if this is true for you all, most, some, a little, or none of the time. (Circle One)

| | **All the time** | **Most of the time** | **Some of the time** | **A little of the time** | **None of the time** |
|---|---|---|---|---|---|
| a. Do you have more help from others because of your vision? | 1 | 2 | 3 | 4 | 5 |
| b. Are you limited in the kinds of things you can do because of your vision? | 1 | 2 | 3 | 4 | 5 |

**SUBSCALES: WELL-BEING/DISTRESS (#A12) and DEPENDENCY (#A13)**

The next questions are about how you deal with your vision. For each statement, please tell me if it is definitely true, mostly true, mostly false, or definitely false for you or you don't know. (Circle One)

| | **Definitely true** | **Mostly true** | **Not sure** | **Mostly false** | **Definitely false** |
|---|---|---|---|---|---|
| A12. I am often irritable because of my eyesight. | 1 | 2 | 3 | 4 | 5 |
| A13. I don't go out of my home alone, because of my eyesight. | 1 | 2 | 3 | 4 | 5 |

**Appendix III: Consent Form (English Version)**

**MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES**

**DIRECTORATE OF RESEARCH AND PUBLICATIONS, MUHAS.**

Reg No. …….. Date……

**Consent to participate in a research study**

Greetings. I am Dr. Magreth Marwa, a postgraduate student, doing a master's of medicine in ophthalmology at the Muhimbili University of Health and Allied Sciences. I am researching intending to determine the quality of life among adult patients with and without diabetic retinopathy attending diabetic and retina clinics at Muhimbili national hospital.

**Purpose of the study**

To compare the quality of life among adult patients with diabetes mellitus with and without diabetic retinopathy attending diabetic clinic at Muhimbili national hospital.

**Participants of the study**

All adult patients with diabetes mellitus with and without retinopathy attending Muhimbili national hospital in diabetic and retina clinic will participate in this study. The participants will undergo ocular examinations and noninvasive ocular investigations.

**Confidentiality**

All the participants who will join the study their names will not be required but will be identified by the use of numbers. The information obtained during data collection will be kept under a strict locked environment where it is only the researcher will have access and will be destroyed after the dissertation has been submitted and accepted for the award of a postgraduate degree.

**Risk**

No harm is expected to occur because of joining the study.

**Benefits**

Results of this study will provide insight on the quality of life and related factors in patients with and without diabetic retinopathy and hence provide the basis on how to design protocols focused on the well-being of the patient, in addition to considering the clinical characteristics.

**Right to withdrawal**

Joining in this study is completely your choice. You can withdraw at any particular moment even after signing the consent form. Withdrawal will not involve penalty or any benefits to which you are entitled.

**Whom to Contact**

In case of any concern or question about the study you can contact the researchers, Dr.Magreth Marwa (mob. 0693 276119), and Dr.Celina Mhina(mob.0746 535289) and professor Milka Mafwiri (mob. 0765 323280) at Muhimbili University, P.O. BOX 65001, Dar es Salaam. You can also contact the Director for, research and Publications Dr Bruno Sunguya P.O.BOX 65001, Dar es Salaam, for any matters concerning this study.

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

Signature of participant……..

Signature of researcher/research assistant……

**Appendix IV: Informed Consent (Swahili Version)**

**CHUO KIKUU CHA AFYA NA SAYANSI SHIRIKISHI MUHIMBILI**

**KURUGENZI YA TAFITI NA UCHAPISHAJI**

IDHINI YA KUSHIRIKI KWENYE UTAFITI

Namba ya usajili…… Tarehe……

Habari,

mimi ni Dr. Magreth Marwa, mwanafunzi wa shahada ya pili ya udaktari, idara ya macho, chuo kikuu cha afya Muhimbili.Nafanya utafiti kuangalia ubora wa maisha kwa wagonjwa wa kisukari wenye shida na wasio na shida katika pazia la kuonea wanaopata huduma katika hospitali ya taifa muhimbili

Usiri

Washiriki wote wa utafiti huu hawatatambuliwa kwa majina yao ila kwa namba. Habari zote za washiriki zitahifadhiwa/zitafungiwa mahali salama ambapo mtafiti mkuu tu ndiye atakayekuwa na funguo na makabrasha yote yatateketezwa mara baada ya utafiti kuisha na mtafiti kutunukiwa shahada ya pili ya udaktari.

**Lengo la utafiti**

Kuangalia ubora wa maisha kwa wagonjwa wa kisukari kwa watu wazima ( wenye rika kubwa) wenye shida na wasio na shida katika pazia la kuonea wanaopata huduma katika hospitali ya taifa muhimbili.

**Washiriki wa utafiti**

Washiriki kwenye utafiti huu ni wagonjwa wa kisukari ambao ni watu wazima waliogundulika kuathirika na wasioathirika kwenye pazia la kuonea kutokana na kisukari , wanaodhuria kliniki ya kisukari na retina katika hospital ya taifa Muhimbili.Washiriki watafanyiwa uchunguzi wa macho wa kawaida na kwa kutumia vifaa ambavyo havihatarishi hali ya macho.

**Madhara**

Hakuna madhara yanayotarajiwa kwa washiriki wa utafiti.

**Faida**

Matokeo ya utafiti huu zitasaidia kutengeneza miongozo mizuri ya kiafya katika kutengeneza mifumo itakayosaidia wagonjwa wa sukari ambao wamepata na wasiopata matatizo kwenye retina.

**Haki ya kujitoa**

Ushiriki katika utafiti ni wa hiyari,na mshiriki yoyote ana haki ya kuamua kujitoa katika utafiti wakati wowote kujitoa hakutaathiri kiwango cha huduma kwa mgonjwa.

Mawasiliano

Ikiwa kuna swali lolote kuhusu utafiti huu, tafadhali wasiliana na Dr Magreth Marwa (mob. 0693 276119), Dr.Celina Mhina(mob.0746 535289) na professor Milka Mafwiri (mob. 0765 323280), S.L.P 65001, Dar es salaam. Hata hivyo, ikiwa kuna suala lolote linalohusu mwenendo wa kimaadili ya utafiti wa kimatibabu, wasiliana na mwenyekiti wa kamati ya tafiti na machapisho wa chuo kikuu cha afya na sayansi shirikishi Muhimbili Dk. Bruno Sunguya , S.L.P 65001, Dar es salaam.

Sahihi ya mshiriki…….

Sahihi ya mtafiti/mtafiti msaidizi……..

## Appendix V: Ethical clearance letter

**UNITED REPUBLIC OF TANZANIA**
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
**OFFICE OF THE DIRECTOR - RESEARCH AND PUBLICATIONS**

Ref. No.DA.282/298/01.C/1358 Date: 08/09/2022

**MUHAS-REC-09-2022-1358**

Magreth Marwa,
MMed in Ophthalmology,
School of Medicine
**MUHAS**

**RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: COMPARISON OF QUALITY OF LIFE AMONG PATIENTS WITH AND WITHOUT DIABETIC RETINOPATHY AT MUHIMBILI NATIONAL HOSPITAL (MNH)**

Reference is made to the above heading.

I am pleased to inform you that the Chairman 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: 08/09/2022
EXPIRATION DATE OF APPROVAL: 07/09/2023

**STUDY DESCRIPTION:**
**Purpose:**
The aim of this case control study is to assess quality of life in patients with and without diabetic retinopathy at Muhimbili National Hospital.

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-%2014264.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/.

Prof. Bruno Sunguya
**Chairman, MUHAS Research and Ethics Committee**

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

Cc: Director of Postgraduate Studies

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line: +255-22-2150302/6; Ext. 1038; Direct Line:+255-22-2152489;Telefax:+255-22-2152489;E-mail:drp@muhas.ac.tz;Web:https://www.muhas.ac.tz

## Appendix VI: Permission letter

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

**MUHIMBILI NATIONAL HOSPITAL**

*In reply please quote;*

**Ref. No.: MNH/TRCU/Perm/2022/048** **Date: 12th October, 2022**

Head of Department
Internal Medicine
**Muhimbili National Hospital**

**RE: PERMISSION TO COLLECT DATA AT MNH.**

| | |
|---|---|
| **Name of student** | **Magreth Marwa** |
| **Title** | **"Comparison of Quality of Life among Patients with and without Diabetic Retinopathy at Muhimbili National Hospital."** |
| **Institution** | **Muhimbili University of Health and Allied Sciences** |
| Supervisors | Dr. Celina Mhina |
| Co-Supervisor | Prof. Milka Mafwiri |
| **Period** | 12th October, 2022, to 12th November, 2022 |

Approval has been granted to the above mentioned student to collect data at MNH.

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

Sincerely,

**Reid B. Mchome**
**Coordinator - TRCU**
**For: Head of Teaching, Research and Consultancy Unit**

c.c DMS
c.c **Magreth Marwa**

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

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

**MUHIMBILI NATIONAL HOSPITAL**

*In reply please quote;*

**Ref. No.: MNH/TRCU/Perm/2022/048** **Date: 12th October, 2022**

Head of Department
Internal Medicine — noted for cooperation, Adv - Endo will cooperate
**Muhimbili National Hospital** As INV

**RE: PERMISSION TO COLLECT DATA AT MNH.**

| | |
|---|---|
| **Name of student** | **Magreth Marwa** |
| **Title** | **"Comparison of Quality of Life among Patients with and without Diabetic Retinopathy at Muhimbili National Hospital."** |
| **Institution** | **Muhimbili University of Health and Allied Sciences** |
| Supervisors | Dr. Celina Mhina |
| Co-Supervisor | Prof. Milka Mafwiri |
| **Period** | 12th October, 2022, to 12th November, 2022 |

Approval has been granted to the above mentioned student to collect data at MNH.

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

HEAD, TEACHING, RESEARCH & CONSULTANCY UNIT P.O Box 65000 DAR ES SALAAM

Sincerely,

**Reid B. Mchome**
**Coordinator - TRCU**
**For: Head of Teaching, Research and Consultancy Unit**

c.c DMS
c.c **Magreth Marwa**

Upanga West, Kalenga Street, Plot No. 10480/3, P.O. BOX 65000, Dar es Salaam, Tanzania.
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