THE PREVALENCE OF MICROVASCULAR COMPLICATIONS AND ASSOCIATED FACTORS AMONG NEWLY DIAGNOSED DIABETIC PATIENT IN DAR ES SALAAM

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MMed (Internal Medicine) Dissertation
Muhimbili University of Health and Allied Sciences
October, 2016

THE PREVALENCE OF MICROVASCULAR COMPLICATIONS AND ASSOCIATED FACTORS AMONG NEWLY DIAGNOSED DIABETIC PATIENT IN DAR ES SALAAM

By

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A Dissertation Submitted in (Partial) Fulfillment of the Requirements for the Degree of Master of Medicine Internal Medicine of Muhimbili University of Health and Allied Sciences

Muhimbili University of Health and Allied Sciences
October, 2016

CERTIFICATION

The undersigned certify that he has read and hereby recommends for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled ***The prevalence of microvascular complications and associated factors among newly diagnosed diabetic patient in Dar es Salaam*** in partial fulfillment of the requirements for the degree of masters of medicine in Internal Medicine Muhimbili University of Health and Allied Sciences.

_____

Prof. Janet Lutale

(Supervisor)

_____

Date

DECLARATION AND COPYRIGHT

I, **Onesmo Julius Ulomi**, 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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ACKOWLEDGEMENT

Accomplishment of this project would have not been possible without our Mighty Jesus Christ for giving me good health, strength, and ability of learning and capability of embarking on this work.

It is not physically possible for a single individual to cover all the aspects that has made this dissertation today and I am therefore deeply grateful to all those who have participated in this protect in one way or another.

Much of any merit this dissertation may have is due to the generosity of my supervisor Prof. Janet Lutale for her guidance and patience. She has been ever supportive and I will forever treasure the knowledge and experience that I have acquire under her mentorship

To my Parents Julius Ulomi and Marry Mosha whom their innermost belief in the importance of education has made me the way I am today and am grateful for all they have done and for moral support that I needed the most.

To my beloved and supportive wife Pamela Mduma, for her sacrifice, kindness and everlasting support despite being a mother and a master student, I am grateful for understanding all the long hours of absence during working on this project.

I would also like to extend my thanks to Arusha International Conference Centre (AICC) for funding the laboratory tests and for sponsoring my Mmed studies.
I would like to thank Dr. Sibtain Moledina and Chaula Baraka for their assistance with statistical analysis.

I would like to thank my team of research assistants who assisted so tirelessly during data collection, these where Prepetua Lawi and Inoccent Martin their contribution was of great value to this project.

I would also like to thank Dr. Kaushik Ramaiya, Dr. Paschal Ruggajo for providing some of the references, Sr. Tina James and Dr. Boniface Mphumuhila of Temeke Hospital, Dr. Bushiri Rajabu at Amana Hospital, Sr. Sarah Mwakilima at MNH diabetes clinic, and all other members of staff of these sites who assisted us in one way or another.

Dr. Arkan Nasib a colleague and a brother, his kind assistance and contributions have been the key to the success of the this project

DEDICATION

To my family for the sacrifice, my wife Pamela Mduma for her kindness and everlasting support. To my daughter Ariella, her naturally positive and courageous ways of tolerating my absence has helped me to see the good side of my tiresome days.

ABSTRACT

Background:

Prevalence of diabetes Mellitus is on an increase worldwide and Tanzania is not exempted. Type 2 diabetes (T2D) is a very common disease, characterized by an asymptomatic phase between the actual onset of diabetic hyperglycaemia and clinical diagnosis.

This asymptomatic phase has been estimated to last up to 4–7 years, and it has been reported that about 30–50% cases of type 2 diabetic patients remained undiagnosed. This prodromal stage is associated with the development of microvascular complications of diabetes before clinical diagnosis of diabetes.

Scarce data on the prevalence of diabetes mellitus, and microvascular complications among known diabetic patients is available in Tanzania, however little is known about the status of nephropathy, retinopathy, neuropathy and hypertension at diagnosis of Type 2 diabetes

Objective:

To determine the prevalence of microvascular complications among newly diagnosed Type 2 diabetic patients in Dar es Salaam.

Methodology:

Cross-sectional survey conducted in three diabetic clinic, Amana, Temeke and Muhimbili Hospital from April to November 2015. A total of 195 newly diagnosed T2D patients diagnosed within 3 months.

Newly diagnosed diabetes patient were enrolled by consecutive sampling technique. Data was collected via clinical record forms and patients were screened for diabetic complications, hypertension, and dyslipidaemia and other associated risk factors. Family history was also recorded. Standard protocols were used to make the diagnosis of retinopathy, neuropathy and nephropathy.

Data was entered into a pre-designed Ms Excel spreadsheet and then imported into SPSS 15.0 for analysis Chi squared test and t test were used to test categorical and numerical variables against chronic complications of diabetes respectively. Multivariate logistic regression were performed to determine the effect of various predictors on chronic complications.

Results

Of the 195 newly diagnosed T2DM patients recruited majority 90 (46.2%) were recruited from Muhimbili National Hospital, 62 (31.8%) and 43 (22.0%) recruited from Temeke and Amana Hospital respectively

A total of 104 (53.3%) patients were found to have at least one microvascular complication, while peripheral neuropathy was observed in 72 (36.9%) participants, diabetic retinopathy in 30 (15.4%), patients microalbuminuria in 19 (9.7%) participants and diabetic nephropathy found in 28 (14.4%) patients.

Independent predictors for nephropathy were family history of diabetes (OR 2.5, CI 1.13 - 5.79), obesity (OR 0.34, CI 0.13-0.93), higher waist – hip circumference (OR 3.0, CI 1.11-8.15) and hyperlipidemia(OR 5.0, CI 1.79 14.44)

Significant predictors for neuropathy were age more than 46 years (OR 2.8, CI 1.24-6.24), family history of diabetes (OR 2.3, CI 1.13-4.48), and high blood pressure (2.27, CI 1.11-4.64).

The only significant predictor of retinopathy was raised serum creatinine 2.95(1.03-8.44) ***0.044*** Patient with diabetic retinopathy were 4 times more likely to have microalbuminuria and overall diabetic nephropathy

Conclusions

The present study was the first national hospital based urban study of microvascular complications among newly diagnosed diabetes mellitus

In our study prevalence of any microvascular complications of diabetes among newly diagnosed diabetes patients was high, stood at 53.3%, neuropathy was 36.9%, nephropathy was 14.5%, and retinopathy was 15.4%.

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LIST OF ABBRIVIATIONS

ADA	American Diabetes Association
BMC -	Bugando Medical Centre
BMI	Body Mass Index
CIND	Complications In Newly Diagnosed diabetic patients
CKD	Chronic Kidney Disease
CURES	Chennai Urban Rural Epidemiology Study
CVS	Cardiovascular system
DR	Diabetic Retinopathy
DM	Diabetes Mellitus
DNE	Diabetic Neuropathic Examination Score
DNS	Diabetes Neuropathic Score
(eGFR)	Estimated Glomerular Filtration Rate
ESRD	End Stage Renal Disease
GDP-	Growth Domestic Product
HIV -	Human Immunodeficiency Virus
IDF -	International Diabetic Association
K/DOQ1	Kidney Disease Outcomes Quality Initiative
MNH -	Muhimbili National Hospital
NPDR -	Non –Proliferative Diabetic Retinopathy
MA -	Microalbuminuria
MUHAS -	Muhimbili University of Health and Allied science
MDRD -	Modification of Diet in the Renal Disease
PDR -	Proliferative Diabetes Retinopathy

PN -	Peripheral Neuropathy
RRT	Renal Replacement Therapy
SSA	Sub Saharan Africa
T1DM -	Type one Diabetes mellitus
T2DM -	Type two Diabetes mellitus
UKDPS-	United Kingdom Prospective Diabetes Study

DEFINITION OF TERMS

Newly diagnosed diabetes patients were patients diagnosed with type 2 diabetes mellitus within three months before the study.

Microvascular complications of diabetes studied were retinopathy, neuropathy and nephropathy.

Diabetic peripheral neuropathy is a symmetrical, sensory motor polyneuropathy attributable to metabolic as a result of chronic hyperglycemia which was determined by either symptoms or signs

Diabetic retinopathy were defined as the damage to the blood vessels of the retinal as a result of chronic hyperglycemia which was determined by retinal camera as non proliferative or proliferative

Diabetic nephropathy was defined as the presence of macroalbuminuria and or declining $eGFR_{creat}$< 60 mL/min/1.73 m2

CHAPTER ONE

INTRODUCTION

In Sub-Saharan Africa, as population ages, changes in lifestyle, and urbanization have occurred, the medical community has begun to recognize the growing additional burden of non-communicable, chronic diseases such as hypertension, diabetes mellitus, congestive heart failure, and chronic kidney disease (CKD).

The prevalence of diabetes mellitus (DM) is very high worldwide. Conservative projections for 2030, estimate that there will be 18.65 million persons afflicted with diabetes mellitus in Sub-Saharan Africa alone which will be a 161% increase from the year 2000, and the trajectory of hypertension is similar with projections of a 60% increase in world-wide prevalence by the year 2025 which will mean 1.56 billion people will be affected(1)

According to International Diabetes Federation, the 2014 projections in 1000s in Tanzania showed that there are 1,795 diabetes cases (20-79 years) and 1,347.65 undiagnosed diabetes cases(20-79 years) with a national prevalence rate of 7.95%(1).

Type 2 diabetes is very common and insidious diseases proceeded by an asymptomatic phase between the beginning of diabetic hyperglycaemia and clinical diagnosis, with an estimated gap of at least 4–7 years, and 30–50% cases of type 2 diabetic patients remained undiagnosed(2). This asymptomatic phase is associated with development of chronic complications of diabetes, which remain the chief problems in diabetic care, and which cause a lack of fitness to work, disability, and premature death (3).It is not surprising to find evidence of microvascular or macro vascular diabetic complications at diagnosis among diabetic patients at diagnosis.

The period before diagnosis is imperative and significant morbidity and mortality develops during this period because people with undiagnosed diabetes are not treated for either hyperglycaemia or vascular complications of type 2 diabetes mellitus(2). Associated risk

factors for developing chronic complications may as well receive less vigorous attention and management. Determining patients with high risk accurately will have important implications and the need for screening for the presence of undiagnosed diabetes and associated risk factors

Prior to the onset of diabetes, many patients already show metabolic abnormalities, such as dyslipidaemia, which further contributing to the development of complications(4).

Other recognized risk factors associated with chronic complications of diabetes including sex, age, hypertension (presence, duration, systolic blood pressure, diastolic blood pressure), the duration of DM, Fasting blood glucose (FBG), glycated hemoglobin (HbA1c), lipid profile (triglyceride, total cholesterol, low density lipoprotein [LDL] cholesterol), blood urea nitrogen (BUN), creatinine, estimated glomerular filtration rate (eGFR), urine albumin-creatinine ratio (ACR),history of smoking (ever smoker/current smoker).(4–8)

The chronic diabetes complications can be divided into the diverse spectrum of vasculopathy associated with diabetes into two main subtypes: firstly, the diabetes-specific microvascular complications of retinopathy, nephropathy and neuropathy; and secondly, the atherothrombotic macrovascular complications of myocardial infarction, hypertension and peripheral arterial disease.

Microvascular complications from type 2 diabetes are common and include retinopathy leading to various degrees of visual impairment including blindness and has become a major cause of blindness throughout the world (9). Neuropathy, leading to pain and numbness, chronic and recurrent infected ulcers in the extremities which can lead to Amputation(10); and nephropathy characterized by proteinuria ultimately leading to end stage renal disease(11).Diabetic nephropathy constitutes the major work load of dialysis centers worldwide(12).

Access to diabetic care is limited in low and middle income countries (including Tanzania) where more than 70% of diabetic patients live(1).

About 50% of the subjects' from United Kingdom Prospective Diabetes Study (UKPDS) had substantial macro- or micro-vascular abnormalities at the time of T2DM diagnosis. It is well known that chronic complications are the major outcome of T2DM, which reduce the quality of life of patients, causing heavy burdens to the health care system, and increased diabetic mortality.

LITERATURE REVIEW

The prevalence of DM has been increasing on a worldwide scale. The International Diabetes Federation (IDF) report of 2014 indicate that about half the patients with type 2 DM are undetected, and it is estimated that 387 million people are living with diabetes and by 2035 this will rise to 592 million. (1)

Cross-sectional studies have been done in India reporting prevalence of any chronic complication among newly diagnosed diabetes patients rates ranging from 13 to 30% (3,4,13)

A recently cross-sectional study conducted in a public tertiary care hospital in Southern India, 2014 observed the prevalence of any complication of 18.04%. Prevalence of neuropathy, retinopathy, and nephropathy was found to be 8.2%, 9.5%,and 2.8%, respectively(4).

Diabetic retinopathy (DR)

DR is the leading cause of blindness among working aged adults around the world (14).Worldwide reported prevalence rates of DR at the time of diagnosis of type 2 diabetes vary from 5 to 35%(15–16)

Mbanya and Sobngwi (18) looked at data for the prevalence of diabetic complications in Africa and reported that retinopathy was present in 16–55% of people with diabetes. About a quarter of newly diagnosed type 2 patients presented with retinopathy, and severe retinopathy represented 15% of all cases. At diagnosis, 21-25% of type 2 patients have retinopathy in Africa

Diabetic retinopathy (DR) at diagnosis in South Indian showed the prevalence of NPDR (Non –proliferative Diabetic Retinopathy) and PDR (Proliferative Diabetes Retinopathy) to be 7.2% and 0.2% at the onset of diabetes respectively(19).In another Indian study, the Chennai Urban Rural Epidemiology Study (CURES),the overall prevalence of DR among the newly detected diabetic patients was 5.1 percent(20). Also a study of chronic complications of diabetes mellitus among newly diagnosed patients in Tehran Iran, the prevalence of retinopathy was 6% (21).

Furthermore N. Weerasuriya et al in Sri Lankan diabetic patients, reported retinopathy prevalence to be present in 15%(17)

There are no published studies in Tanzania for prevalence of DR among newly diagnosed diabetes patient but there are studies on prevalence of DR among known diabetic patients, A study conducted by Lutale et al, among outpatient diabetic patient in Dar es salaam; showed that although the proportion of patients developing any grade of DR increased with increased diabetes duration but already 21% of diabetic patients with diabetes duration less or equal to 1 year had already developed retinal changes. The prevalence of diabetic of retinopathy in that study was 27% in known T2D(22).

Nephropathy

Diabetic nephropathy is characterized by proteinuria and declining $eGFR_{creat}$< 60 mL/min/1.73 m2, and is widely known as the leading cause of end-stage renal disease (ESRD) which constitutes the major workload of dialysis centers worldwide. Indeed, the costs of dialysis and renal transplantation imposed by ESRD implicate a sizeable burden on health care resources and seriously compromise both the quality of life and life expectancy(23–27)It is well known that progression to established diabetic nephropathy occurs through several stages.

Microalbuminuria (MA) is considered to be an early stage of diabetic nephropathy (28). MA is also considered to be a predictor for cardiovascular disease both among diabetic and non diabetic subjects,(29,30) and it is well recognized that MA can be reversed and the future developments of overt diabetic nephropathy can be significantly reduced.

Defined by the National Kidney Foundation, CKD refers to documented kidney damage present for 3 months or more and graded by calculating either the creatinine clearance using the modified Cockcroft-Gault equation or the estimated glomerular filtration rate (eGFR) by use of the Modification of Diet in the Renal Disease (MDRD) equation(31). Chronic kidney disease (CKD) is the 12^{th} cause of death and the 17^{th} cause of disability. This is however an underestimate as patients with CKD are more likely to die of cardiovascular disease (CVD) than to reach end-stage renal disease (ESRD). The K/DOQI guidelines defines CKD stages as follows: stage 1, an eGFR higher than 90 ml/min/1.73 m^2; stage 2, eGFR of 60 to 89 ml/min/1.73 m^2; stage 3, an eGFR of 30 to 59 ml/ min/1.73 m^2; stage 4, an eGFR of 15 to 29 ml/min/1.73 m^2; and stage 5, an eGFR <15 ml/min/1.73 m^2.

The incidence and prevalence of CKD has increased in recent years in both developed and developing countries including in Sub-Saharan Africa (SSA)(32).

Regionally, CKD prevalence has been reported to be 12.4% in Kinshasa among adults in the general population(33).

In a study done in Dar es Salaam Tanzania, among diabetic patients attending outpatient clinic in Muhimbili hospital, Among Type 2 patients, 9.8% had microalbuminuria, and 7.2% had macroalbuminuria. Type 2 patients with abnormal albumin excretion rate had significantly longer diabetes duration 7.5 (0.2–24 yrs)(34).Another cross-sectional study conducted at the outpatient diabetes clinic of Bugando Medical Centre (BMC) in Mwanza, Tanzania Of all study participants, 309/369 (83.7%) had CKD and 91/367 (24.7%) had eGFR < 60 mL/min. A total of 295/ 369 (80.0%) had moderately to severely increased albuminuria ; 126/369 (34.1%) had overt proteinuria and 169/369 (45.8%) had microalbuminuria alone(35).

In another study of Chronic complications of diabetes mellitus in newly diagnosed patients in Tehran Iran The prevalence of nephropathy was 10%, including 13 patients (65%) with microalbuminuria, 4 patients (20%) with macroalbuminuria, and 3 patients (15%) with renal failure(21).

Peripheral Neuropathy

Peripheral neuropathy is one of the commonest complications of diabetes mellitus and it may be the first presenting symptom in T2DM. T2DM which is often preceded by a long period of unrecognized metabolic abnormality, development of the neural dysfunction is likely and can be detected at the time when the diabetes is diagnosed(36). The most common form of diabetic peripheral neuropathy (PN) is distal symmetrical sensory–motor poly neuropathy(37). Early distal sensory–motor neuropathy is usually asymptomatic and motor involvement occurs later with distal loss of strength but sensory abnormalities may be detectable by neuro-physiological testing such as nerve conduction study and electromyography. A cross-sectional survey done across 14 centers representing north, west, south and east region of India, a CIND STUDY found that about 13.15% of newly detected T2D had neuropathy(3).Although data on the prevalence of diabetes mellitus, and

chronic complications among known diabetic patients are available in Tanzania, little is known about the status of neuropathy at diagnosis of diabetes.

STATEMENT OF THE PROBLEM

As a result of the aging of the population, the prevalence of type 2 diabetes in the general population is increasing worldwide. Both types 1 and 2 diabetes mellitus have been shown to be independent co morbid conditions associated with higher mortality.

This global increase in the prevalence of DM will inevitably lead to increases in the prevalence of diabetic microvascular (predominantly retinopathy, nephropathy, and neuropathy) and macrovascular complications. These complications will be significant burdens for these individuals and on our health care systems(38)

Early detection of chronic complications is sub-optimal among the general population and even more among high risk patients including those with diabetes.

The burdens associated with these chronic complications are enormous, for instance diabetic peripheral neuropathy lead to vulnerability to physical and thermal trauma which increases the risk of foot ulceration by 7-fold and increases 15–20 times risk of amputation if coexist with peripheral vascular disease. Foot ulcers are associated with many negative sequences and high costs of treatment. The loss of mobility associated with foot ulcers affects patients' ability to perform simple, everyday tasks and to participate in leisure activities. These often lead to depression and poor quality of life(39).

RATIONALE

This study aimed at determining the prevalence of chronic complications among newly diagnosed diabetes patient in Dar es Salaam. Type 2 diabetes a very common disease is characterized by an asymptomatic phase between the actual onset of diabetic hyperglycemia and clinical diagnosis. This phase has been estimated to last at least 4–7 years, and 30–50% cases of type 2 diabetic patients remained undiagnosed. This prodromal phase is associated with the development of chronic complications of diabetes, which remain the chief problems in diabetic care, and which cause lack of fitness to work, disability, and premature death.

Appropriate and timely interventions will reduce cost, morbidity and mortality and consequently improve the overall quality of life

RESEARCH QUESTION

What is the prevalence of microvascular complications among newly diagnosed Diabetic patients attending outpatient diabetic clinic in Dar es Salaam?

What are the associated risk factors associated with microvascular complications among newly diagnosed diabetic patient attending outpatient diabetic clinic in Dar es Salaam?

OBJECTIVES

Broad Objective

Prevalence of microvascular complications and associated factors among newly diagnosed Diabetic patients in Dar es Salaam

Specific Objectives:

1. To determine the prevalence of nephropathy and associated factors among newly diagnosed diabetic patients

2. To determine the prevalence of peripheral diabetic neuropathy and associated factors among newly diagnosed diabetic patients

3. To determine the prevalence of diabetic retinopathy and associated factors among newly diagnosed diabetic patients

CHAPTER TWO

METHODOLOGY

Study Design

Descriptive cross sectional survey

Study site

The study was conducted at the MNH diabetes clinic, as well as the Amana Hospital and Temeke Hospital diabetic clinics.

MNH is a tertiary referral and teaching hospital, situated in the middle of the City of Dar es Salaam. Diabetic clinic has an average attendance of 100 patient per week conducted three times in a week with 5-6 patients newly diagnosed in a week. Amana Hospital is the Regional referral hospital, located in Ilala District; diabetes clinic is conducted twice a week with an average of 70 patients in a week, with 2-3patients newly diagnosed in a week. Temeke Hospital is a regional hospital, situated in Temeke District, with an average of 60 patients in a week, clinic conducted twice a week with 2-3 newly diagnosed diabetes patients in a week

Study populations

Adult patients aged 18 years and above, newly-diagnosed with T2DM for less than 3 months who attended outpatient diabetic clinic in Amana, Temeke and Muhimbili National Hospital were included(64).Cut-off of < 3 months duration was selected mainly because of the fact that some earlier studies had used the same criteria

Inclusion criteria:

Age 18 years and above
Newly diagnosed diabetes patient within 3 months

Sample Size Determination

The actual sample size for the study was determined using the formula for single population proportion by assuming 5% marginal error (ε), 95% confidence interval and the proportion or prevalence of chronic complications of diabetic patient among newly

diagnosed diabetic patient varies according to methodology used and definition of newly diagnosed diabetic patient, In this study the prevalence from CIND STUDY(3) with the highest prevalence of 13.15% will be used. Based on the above information the total initial sample size is calculated by using the following formula [Kish Leslie formula (1965)]:

$$N = \frac{Z^2 P(1-P)}{\varepsilon^2}$$

Whereby:

N = Sample Size

Z = Standard Normal Deviate (1.96) for 95% CI

P = Prevalence of chronic complication among newly diagnosed diabetic patients in previous study is 13.15 %

ε= Margin of Error (ε= 5%)

Minimum sample size calculated **is 175 patients**

Study Procedures

Health care workers from the three study sites i.e. Temeke, and Amana Municipal Hospital and from the Muhimbili diabetic clinics were approached and the details of the study described to them verbally and in written information. They were requested to inform the researcher and send all newly diagnosed patients to the Muhimbili National Hospital diabetic clinic for screening of the intended complications.

The patient were referred to MNH in order to have uniformity and standardized laboratory investigations, i.e Serum creatinine and fasting lipid profile, moreover MNH was the only centre with retinal photography for assessment and grading of diabetic retinopathy, patient didn't attend MNH for regular care.

The study involved all newly diagnosed diabetes patients diagnosed less than three months with age ≥ 18years who meet inclusion criteria who were informed verbally about the study and requested to give signed informed consent of their agreeing to participate into the study.

It was expected that 6-8 newly diagnosed patients per week will be diagnosed from these three clinics, who were interviewed within a week and physical examinations done and

laboratory investigations including blood and urine tests done. The recruited patients were also seen by the participating Ophalmologist for eye examination.

Clinical Data

Data was obtained by interview and through physical examination guided by a structured questionnaire, which included demographic data pertaining the current age, gender, level of education and occupation and the medical history, (Appendix I-questionnaire).

Physical examinations done included anthropometric measurements (weight, height and waist circumference). The weight was measured using a SECCA weighing scale after the subject had removed his/her, coat and jacket and left with light clothing. Weight was recorded to the nearest 0.5kg. Height was measured after the individual had removed his shoes and or cap and recorded to nearest .0.5 centimeters. Body mass Index (BMI) was then calculated for each individual by using the formula BMI= (kg)/ (height in m^2).The BMI was classified according to World Health Organization into: Underweight: BMI< 18.5; Normal weight: BMI 18.5-24.9; Overweight: BMI 25.0-29.9; Obesity: BMI>30

Waist circumferences were measured as the minimum circumference between the costal margins and the iliac crests and waist circumference above 88cm for woman and 102 for 102cm was considered as obese.

Four research assistants were trained on all study procedures and on how to collect laboratory specimens.

Assessment of Blood pressure (BP)

After a 5-minutes rest, the patient's BP was measured with a standard manual mercury sphygmomanometer while in the sitting position. The systolic blood pressure (SBP) and diastolic blood pressure (DBP) measurements were determined by the 1st and 5th Korotokoffs sounds respectively. Two such readings were taken from the top of the meniscus and expressed to the nearest 2mmHg. The mean of the two readings of blood pressure was used for the final record.

Hypertension was defined as systolic blood pressure (SBP) of more or equal to 140mmHg and/or diastolic blood pressure (DBP) of more or equal to 90mmHg or known hypertensive on treatment.

Assessment of diabetic nephropathy

The following recommendations are based on the clinical practice guidelines for diabetic kidney disease outlined by the Kidney Disease Outcomes Quality Initiative (KDOQI), which were last updated in 2012.(40) Screening for albuminuria should begin at 5 years' diabetes duration in patients with type 1 diabetes and at the time of diagnosis in patients with type 2 diabetes. The preferred screening test is a urine albumin/creatinine ratio with a first-morning void spot collection.

Morning spot urine sample of 10mlswere obtained from the patients and a dipstick urinalysis were performed noting the presence of indices of infections like leukocytes and nitrites. Those patients with urinary tract infection and albuminuria were regarded as infection related and upon completion of their treatment the ample urine was taken again for measurements. **(Appendix I)**

Patients with proteinuria detected at dipstick analysis were considered to have macroalbuminuria and test for microalbuminuria with CYBOW 12MAC strips was not be performed.

Microalbuminuria was determined in patients who tested negative for proteinuria on dipstick analysis in non-infected urine using CYBOW 12MAC strips which gave semi quantitative value of albuminuria as nil, 10mg/L, 30mg/L, 80mg/l and 150mg/L. Also urine creatinine levels were determined by CYBOW 12MAC strips also as semiquantative values and recorded as 0.9mmol/L, 4.4mmol/L, 8.8mmol/L, 17.7 mol/L and 26.5mmol/L.

A urine albumin to creatinine ratio (ACR) for each individual was then calculated from the obtained albumin and creatinine values. Urine ACR values of < 2mg/ mmol/L for men and <2.8mg/mmol/L for women were defined as normoalbuminuria, ACR values of ≥ 2.5 mg/mmol for men and ≥3.5 mg/mmol for women defined as microalbuminuria. Macroalbuminuria was defined as ACR ≥30 mg/mmol for men and women.

Venous blood samples from the antecubital fossa were obtained for serum creatinine levels, which were used to calculate the estimated glomerular filtration rate (eGFR) using the Cockcroft-Gault equation. The Cockcroft-Gault equation allows the creatinine clearance to be estimated from the serum creatinine in a patient with a stable serum creatinine:

$$\text{Cr clearance (mL/min)} = \frac{(140 - \text{Age}) \times \text{lean body weight [kg]}}{\text{Cr [mg/dL]} \times 72}$$

Whereas:

: eGFR = Estimated GFR,

Cr=Serum creatinine of the patient.

Age=Age of the patient in years

In this study, the presence of CKD was defined based on the Kidney Disease Outcomes Quality Initiative (KDOQI) of 2012 Clinical Practice Guideline for Diabetes and Chronic Kidney Disease (CKD) (41)

Diabetic nephropathy was defined as the presence of macroalbuminuria and or declining $eGFR_{creat}$< 60 mL/min/1.73 m2(67),

Assessment of Neuropathy

Peripheral neuropathy was assessed by either or the Diabetic Neuropathic Symptoms (DNS) score and Diabetic Neuropathic Examination, (DNE) score, patient tested positive to one of the test was considered to have diabetic peripheral neuropathy

The DNS score is a four-item validated symptom score, with high predictive value to screen for peripheral neuropathy (PNP) in diabetes. It includes four symptoms which are the symptoms of unsteadiness in walking, presence of neuropathic pain, paraesthesia, and numbness. The presence of a symptom was scored as 1 point and score 0 if absent. The maximum score was 4 points. A score of 1 or higher was defined as positive for PNP (42,43). **(Appendix I)**

The DNE score is a sensitive and validated hierarchical scoring system. It consists of 8 scored items. Two items concerning muscle strength, one concerning reflexes, and five concerning sensation (light touch, pinprick, light touch, vibration perception and sensitivity to joint position). Light touch perception was measured by 10g Semmes Weinstein monofilament which was applied to a non-callused site on the dorsum of the first toe just proximal to the nail bed assessed in one leg. Patients were asked to say whether they can

feel the pressure or not (yes/no).Inability to perceive the sensation was considered as abnormal sensation **(Appendix III)**

Each item was scored from 0 to 2 points (i.e. normal=0 point, moderate =1 point and severely disturbed=2 point). The maximum score being 16 points, a score of >3 points was defined as positive for PNP (44) **(Appendix III)**

Assessment of Retinopathy

The presence of retinopathy was determined by visual acuity measurement and retinal fundoscopy through Topcon plus TRC-NW8F retinal photography following mydriasis of both eyes with tropicamide and phenylephrine. These measurements were performed by an ophthalmologist.

Fundoscopic findings were classified into non proliferative diabetic retinopathy (NPDR) or proliferative diabetic retinopathy (PDR) accordingly as detailed in the attached questionnaire. **(Appendix II)**

No proliferative retinopathy (NPDR):

NPDR features included the presence of nerve-fiber layer infarcts (cotton-wool spots), intraretinal hemorrhages, hard exudates, and microvascular abnormalities (microaneurysms, occluded vessels, and dilated or tortuous vessels) in the macula and posterior retina.

Proliferative retinopathy (PDR)

PDR features were marked by the presence of new vessels arising from the disc and/or retinal vessels and presence of preretinal and/or vitreous hemorrhage, fibrosis, and traction retinal detachment.

Data Analysis plan

All questionnaires were checked daily for completeness and consistence by the principal investigator. Data were coded and entered into Microsoft excel spread and then imported in SPSS statistics 23 for analysis

Relevant frequencies and tables were drafted, means and proportions calculated

Ethical Consideration

Ethical clearance to carry out this study was obtained from the Research and Publications Committee of MUHAS.

Permission were thought from the three hospitals

Study participants were recruited after they gave a written informed consent which was administered by the principal investigator or the research assistant. **(Appendix IV&V)**

All data collected during the study were treated with utmost confidence.

Patient who decline to consent and participate in the study received the same quality of care and advice as those who gave consent to participate in the study

CHAPTER THREE

RESULTS

Of the 195 newly diagnosed type 2 diabetic patients recruited majority 90 (46.2%) of the participants were recruited from the Muhimbili National Hospital, 62 (31.8%) and 43 (22.0%) recruited from Temeke Hospital and Amana Hospital respectively. One hundred and fourteen (58.5 %) participants were female. Mean(SD) age at diagnosis was 50.5±10.6 years, with the majority of the patients (61%) having age of between 41-60 years with about (52.8%) of the participants having at least attained a primary school education and most of them (73.3%) living with partners. One thirty seven (70.8%) participants were physically active. A very small proportion (7.2%) of the patients were current smokers and the majority 166 (85.5%) had never smoked with 82 (42.1%) had a positive family history of diabetes mellitus in their first degree relatives, (Table 1).

Table 1: Socio-demographic characteristics among newly diagnosed Type 2 diabetic patients

Character	Frequency (n=195)	Percentage (%)
Recruitment hospital		
Muhimbili hospital	90	46.2
Temeke hospital	62	31.8
Amana hospital	43	22
Age group (years)		
< 45	75	38.5
46 to 55	52	26.7
≥56	68	34.9
Sex: Female	114	58.5
Marital status		
Single	21	10.8
Married	129	66.2
Divorced	11	5.6
Co-habiting	14	7.2
Widowed	20	10.3
Occupation		
Unemployed	46	23.6
Casual laborer	50	25.6
Formal employment	77	39.5
Business owner with employee	10	5.1
Retired	12	6.2
Education level		
No formal	35	17.9
Primary school	103	52.8
Secondary school	37	18.5
University/College	20	10.3
Drinking habit		
Non drinker	119	61.0
Very occasional	21	10.8
Once a week	18	9.2
Twice a week	21	10.8
Twice daily	16	8.2
Smoking habits		

Never smoked	166	85.1
Current smokers	14	7.2
Past smokers	15	7.7

On clinical and laboratory characteristics, 12 participants (6.2%) were underweight and 36 (18.5%) were obese, with 73 (37.4%) participants having a higher waist to hip ratio. Eighty six patients (44.1%) had elevated blood pressure and about two thirds (66.2%) of the study participants had high blood glucose. Twenty three (11.8%) patients had raised serum creatinine. Eighty three (42.6%) had hypercholesteremia, with 48 (24.6%) and 17 (8.7%) participants having elevated low density lipoprotein (LDL) and hyper triglycerides respectively, (Table 2).

Table 2: Clinical and laboratory characteristics of newly diagnosed type 2 diabetes patients

Variable	Frequency (N=195)	Percentage
Family history of Diabetes		
Yes	82	42.1
BMI		
Underweight	12	6.2
Normal	69	35.4
Overweight	78	40
Obese	36	18.5
Waist circumference		
Abnormal	73	37.4
Blood pressure		
Raised	86	44.1
Blood sugar		
Hyperglycemic	129	66.2
Serum Creatinine		
Raised	23	11.8
Total Cholesterol		
Raised	83	42.6
LDL-Cholesterol		
Raised	48	24.6
HDL-Cholesterol		
Raised	18	9.2
Triglycerides		
Raised	17	8.7

Prevalence of microvascular complication among newly diagnosed diabetic patients

Figure 1 below summarizes the diabetic complications which were picked in the newly diagnosed diabetic patients. A total of 104 (53.3%) patients were found to have at least one microvascular complication, whereas peripheral neuropathy was observed in 72 (36.9%) participants, diabetic retinopathy in 30 (15.4%) and diabetic nephropathy found in 28 (14.4%) patients.

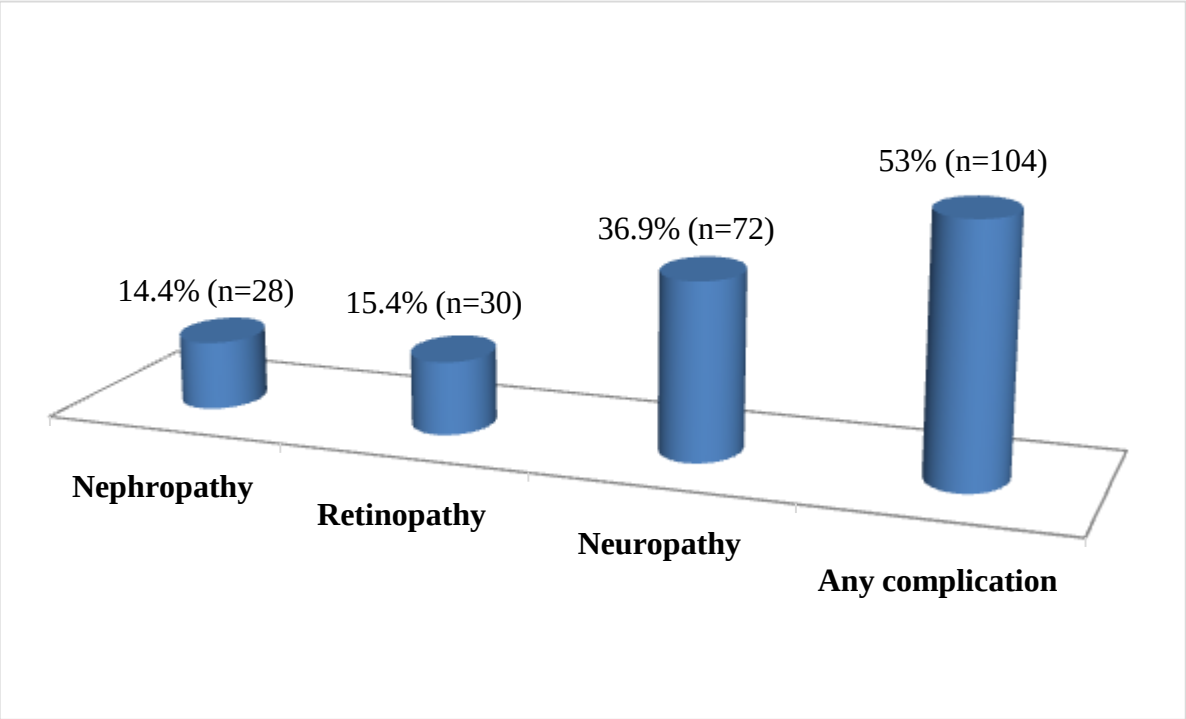


Figure 1: Distribution of the microvascular complications among 195 newly diagnosed Type 2 diabetic patients

Clustering of Microvascular complications among the 195 participants found to have diabetic complications at diagnosis

Of the 195 newly diagnosed type 2 diabetic patients, more than half 104(53.3%) were found to have at least any complication, out of whom 72 (36.9%) had only one complication, 24 (12.3%) had two complications and 8 (4.1%) had three complications. (Table 3)

Table 3: Clustering of microvascular complications among newly diagnosed Type 2 diabetes patients

Variable	Frequency (n= 195)	Percentage
No complication	91	46.7
Only one complication	72	36.9
Two complications	24	12.3
Three complications	8	4.1
At least any complication	104	53.3

Prevalence of nephropathy and associated factors

Diabetic nephropathy was determined by the presence of macroalbuminuria and or low e-$GFR_{creat}$of< 60 mL/min/1.73 m2.

The prevalence of microalbuminuria was 19 (9.7%) of the participants and 13 (6.7%) had macroalbuminuria (Figure 2) Of the total participants screened, 26 (13.3%) had $eGFR_{creat}$< 60 mL/min/1.73 m2. out of whom 25 had Stage III and 1 had stage IV diabetic nephropathy (Figure 3).

Of the 195 patients studied, the overall diabetic nephropathy prevalence was 28 (14.4%) of whom 2 (7.1%) patients had proteinuria only, 15(53.6) patients have low eGFR only and 11 (39.3) has both proteinuria and low eGFR (Figure 4)

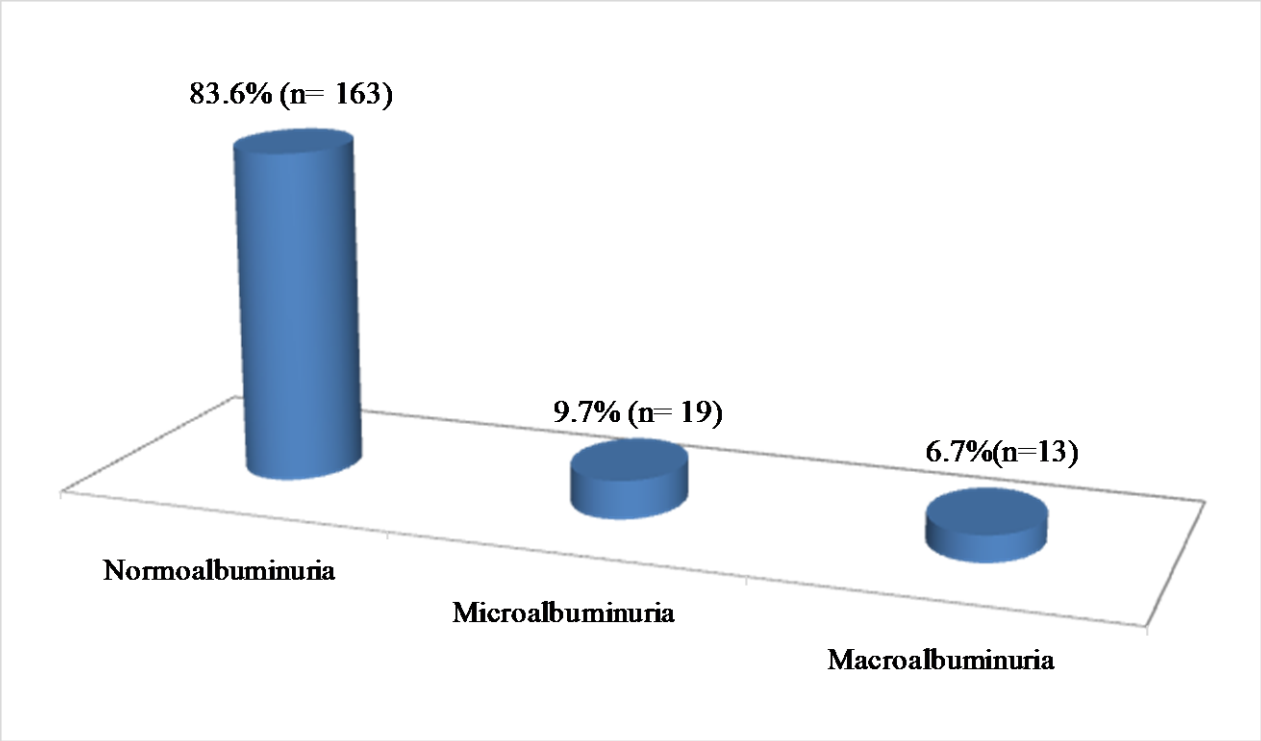


Figure 2: Albuminuria findings among the 195 newly diagnosed Type 2 diabetic patients

The proportion of patients with nephropathy was higher among widows (40%) compared to

those who were married (14.7%), or cohabiting (7.1%) (p=0.002). (Table 4) Also a higher waist circumference was more prevalence in patient with compared to those without nephropathy (23.9 % versus 9.1%) (P-value 0.009) (Table 5) Elevated total cholesterol was significantly more common in those with nephropathy compared those without nephropathy

(33.7% versus 12.5%) (p- 0.001) as shown in Table 5

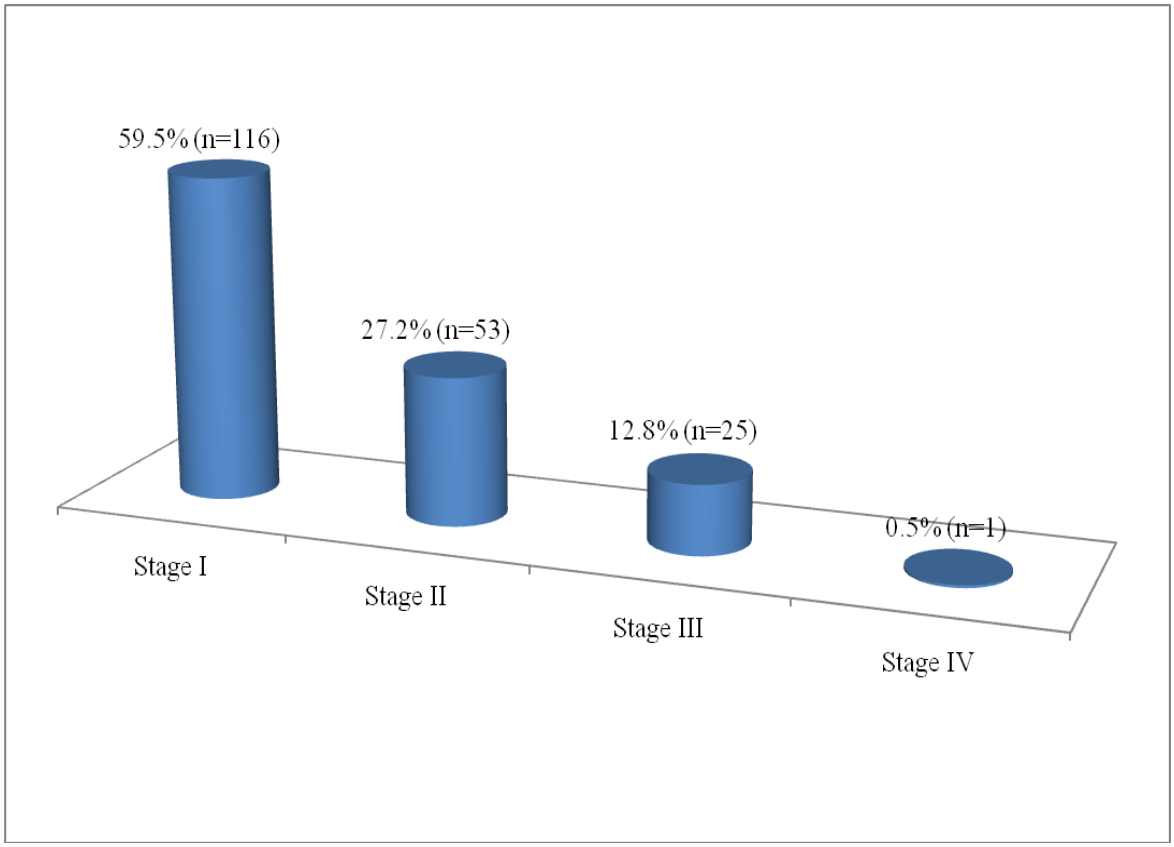


Figure 3: Diabetic nephropathy stages by low e-GFR in the 195 newly diagnosed Type 2 diabetes patients

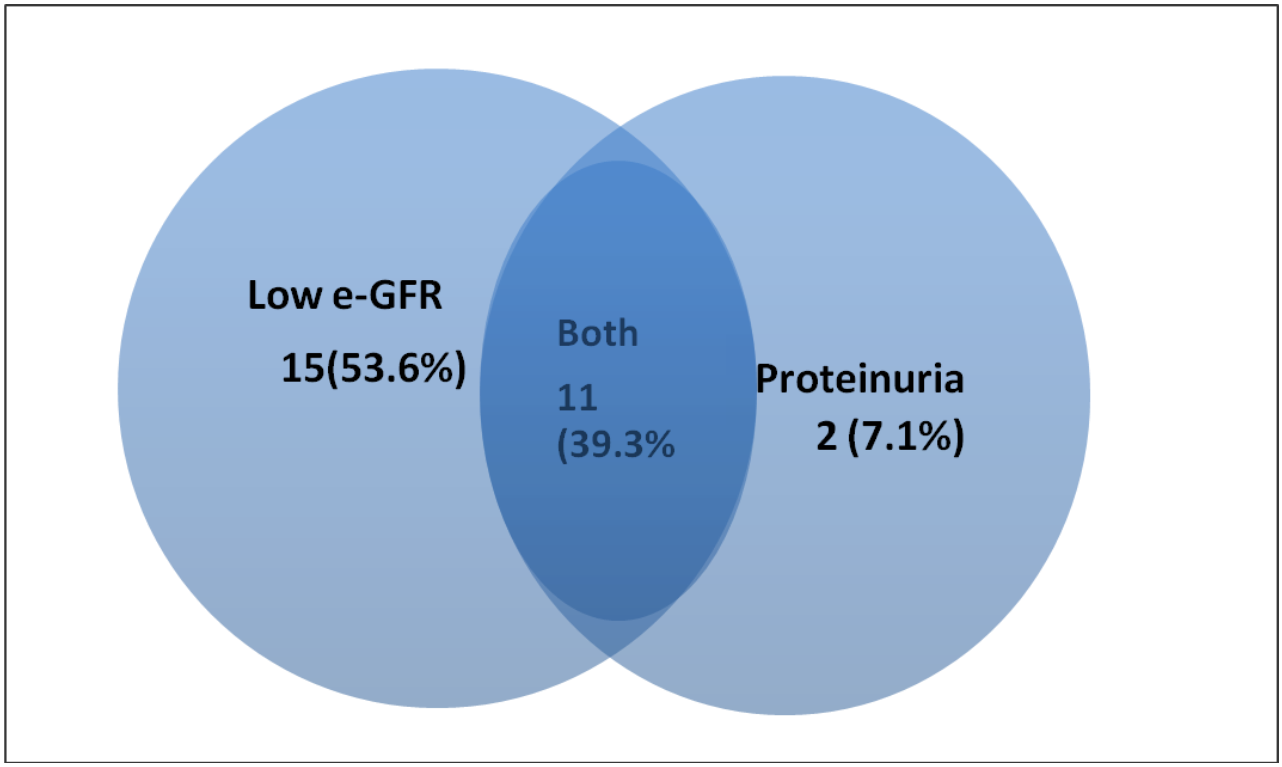


Figure 4: Prevalence of Diabetic Nephropathy among newly diagnosed Type 2 diabetic patients assessed by a low e-GFR and Proteinuria (N-28)

Prevalence of peripheral neuropathy and associated factors

Overall prevalence of peripheral neuropathy was 72(36.9%) among 195 newly diagnosed type two diabetic patients. Peripheral neuropathy picked by neuropathy symptoms (DNS) was 63/72 (87.5%) and that picked by neuropathic signs (DNE) was 59/72 (81.9%), with 50/72 (69.4%) of the neuropathy being picked by both methods, (Figure 5)

The proportion of patients with neuropathy increased with increasing age, with the lowest proportion being among those aged below 45 years (20.0%) compared to (47.5%) among those aged above 45 years ($p<0.001$).(Table 4)

The proportion of patients with neuropathy was higher among those who were widowed (70.0%) compared with those who are divorced (63.7%) followed by those who were single (23.6%), married (23.8%), or cohabiting (57.1%) ($p=0.006$). (Table 4)

The proportion of patient with neuropathy was higher in patients who had no formal education (67.5%) compared with those with university education (35.0%) followed by primary education (33.0%) and secondary education (21.6%) (p=0.001) (Table 4)

Family history of diabetes in the 1st degree relative was observed to be more associated with neuropathy (40.2%) compared with those with no family history (26.5) (P= value 0.044) (Table 4)

Peripheral neuropathy was more common among participants with elevated high blood pressure (54.7%) compared to non-hypertensive (22.9%) (p=<0.001). (Table 5)

Level of education, alcohol and smoking habit were not observed to be statically associated with any of the complications

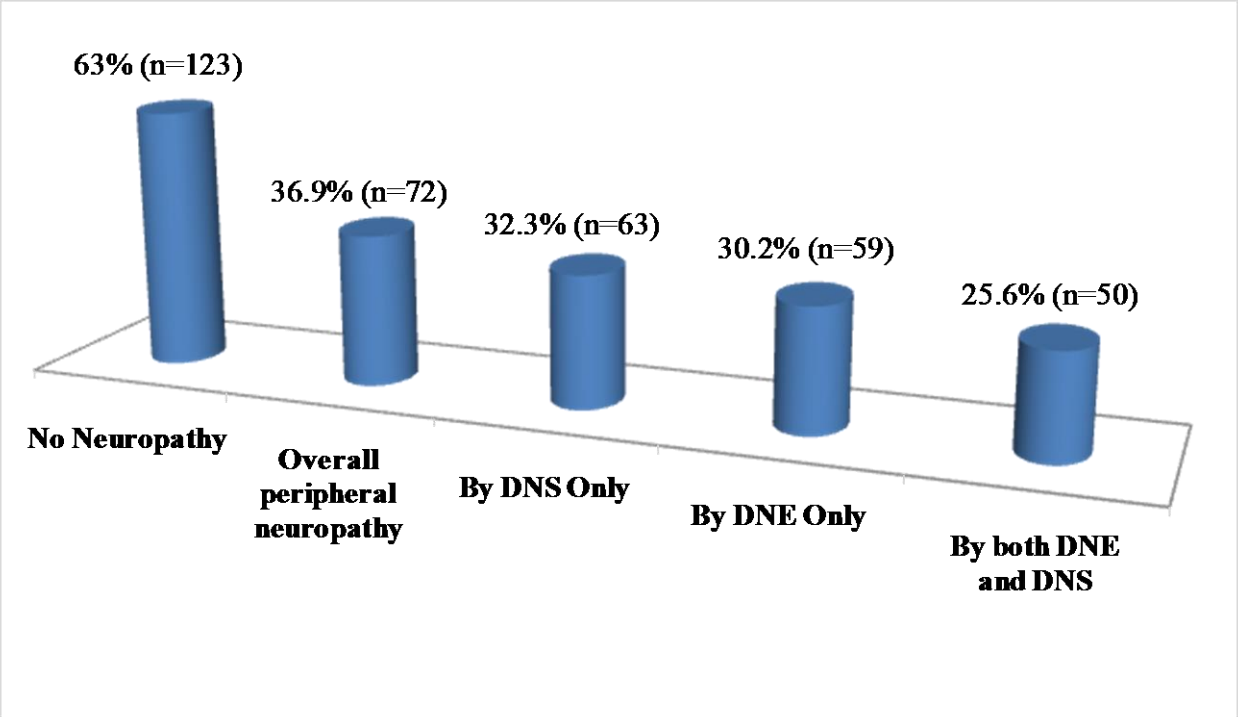


Figure 5: Peripheral neuropathy findings among the 195 newly diagnosed Type 2 diabetes patients

Prevalence of diabetic retinopathy

The overall prevalence of retinopathy was 30/195 (15.4%) of which 25/30 (83.3%) participants had non proliferative retinopathy and 5 (16.7%) participants had proliferative retinopathy. (Figure 6)

Elevated serum Creatinine was significantly more common in those with retinopathy compared those without retinopathy (34.8% versus 12.5%) (p- 0.012) (Table 5)

Microalbuminuria was significantly more common in those with retinopathy compared those without retinopathy 42.1% versus 12.5%) (p- 0.003) and nephropathy was more common in patient with retinopathy than those without retinopathy 33.3% vs 10.5% (p- 0.001) (Table 5)

Retinopathy was observed more in patients with elevated blood pressure (20.9%) compared with those with normal blood pressure (11%) although the difference was not statistically significant with (P = 0.057) (Table 5)

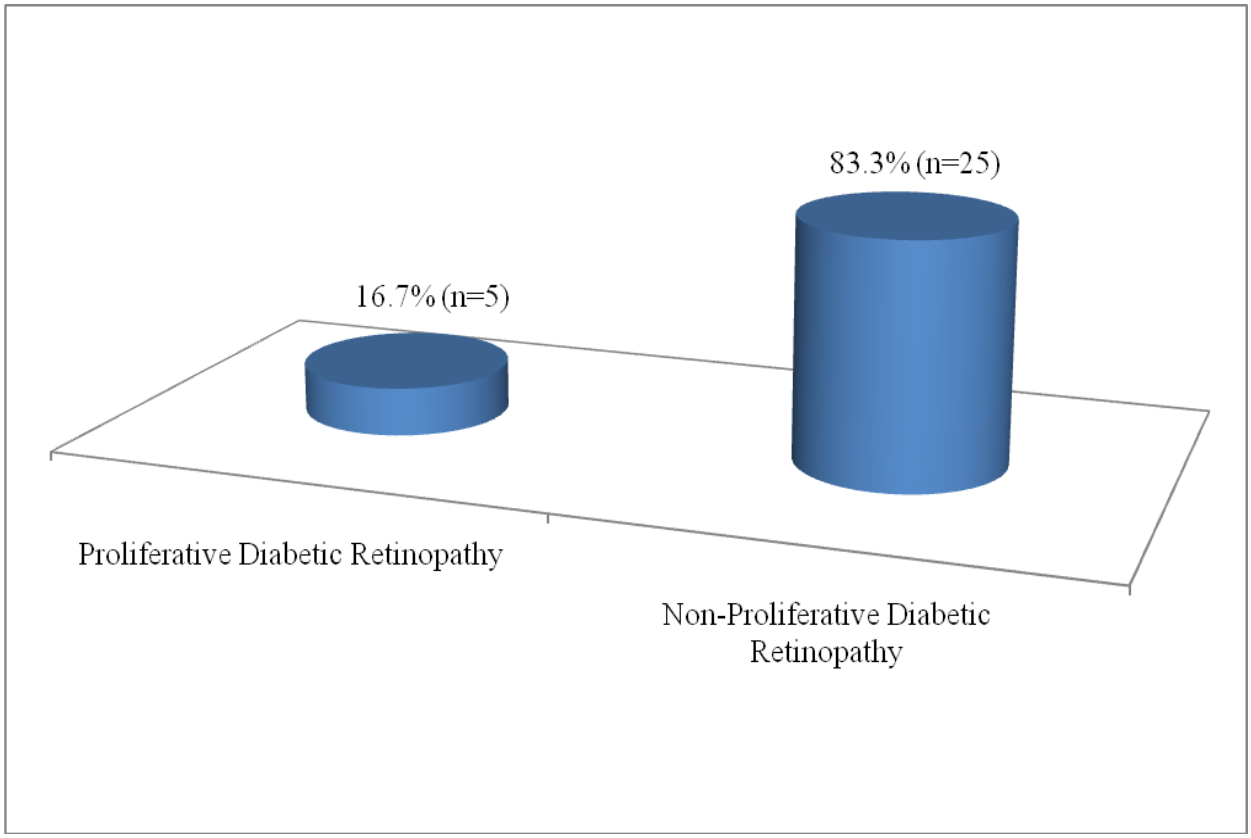


Figure 6: Distribution of diabetic retinopathy among newly diagnosed diabetic patients (N=30)

Table 4: **Association between microvascular complications and socio-demographic among newly diagnosed diabetic patients**

CHARACTERISTICS	**TOTAL**	**Any complications (n, %)**	**p value**	**Nephropathy (n, %)**	**p value**	**Retinopathy (n, %)**	**p Value**	**Neuropathy (n, %)**	**p value**
	195	**N=104 (53.3)**		**N=28 (14.4)**		**N=30 (15.4)**		**N=72 (36.9)**	
Recruitment hospital									
Muhimbili hospital	90	46 (51.1)	0.384	13(14.4)	0.456	9(10.0)	0.065	33(36.7)	0.912
Temeke Hospital	62	31(50.0)		7(11.3)		10(16.0)		22(35.5)	
Amana Hospital	43	27(62.8)		8(18.6)		11(25.6)		17(39.5)	
Age group (years)									
Less than 45	75	29 (38.7)		4 (9.8)		10 (13.3)		15 (20.0)	
46 to 55	52	28 (53.8)	**0.001**	16 (13.1)	0.151	8 (15.4)	0.775	18 (34.6)	**0.001**
56 and above	68	47 (69.1)		8 (25.0)		12 (17.6)		39 (57.3)	
Female gender	114	64 (56.1)	0.351	19 (16.7)	0.276	13 (11.4)	0.068	45 (39.5)	0.452
Marital status									
Single	21	8 (38.1)		0 (0.0)		2 (9.5)		6 (28.6)	
Married	129	62 (48.1)		19 (14.7)		19 (14.7)		37 (28.7)	
Divorced	11	8 (72.7)	**0.013**	0 (0.0)	**0.001**	1 (9.1)	0.601	7 (63.6)	**0.001**
Co-habiting	14	10 (71.4)		1 (7.1)		3 (21.4)		8 (57.1)	
Widowed	20	16 (80)		8 (40.0)		5 (25)		14 (70.0)	
Occupation									
Unemployed	46	27 (58.7)		10 (21.7)		4 (8.7)		21 (45.7)	

Casual laborers	50	30 (60)		4 (8.0)		9 (18)	19 (36.0)	
Formal employment	77	37 (48.1)	0.549	7 (14.3)	0.488	14 (18.2)	0.570	25 (33.8)	0.622
Business owner	10	4 (40)		5 (17.9)		2 (20)	2(20.0)	
Retired	12	5 (60)		1 (10.0)		1 (8.3)	5 (41.7)	
Education level								
No formal	35	28 (80)	**0.001**	3 (8.6)		6 (17.1)	23 (65.7)	***0.001***
Primary school	103	54 (52.4)		17(16.5)	0.621	18 (17.5)	0.586	34 (33.0)	
Secondary school	37	13 (35.1)		4 (11.1)		3 (8.1)	8(21.6)	
University/College	20	9 (45)		0 (0.0)		3 (15)	7 (35.0)	
Fhx of diabetes	82	45 (54.9)	0.713	13 (11.5)	0.216	10 (12.2)	0.293	35 (42.7)	***0.044***

Table 5: Association between microvascular complications, Clinical and laboratory characteristics of newly diabetic patients

CHARACTERISTI	TOTA 195	Any 104 (53.3)	p-	Nephropa 28 (14.4)	p-	Retinopa 30 (15.4)	p-value	Neuropathy 72 (36.9)	p-value
Waist									
Abnormal	73	41 (56.2)	0.540	16 (23.9)	***0.009***	13 (17.8)	0.468	26 (35.6)	0.878
Blood pressure									
Hypertension	86	59 (68.6)	**<0.001**	13 (15.1)	0.839	18 (20.9)	0.057	47 (54.7)	**<0.001**
Blood glucose level									
Hyperglycemic	129	75 (58.1)	0.060	31 (24)	0.237	22 (17.1)	0.366	47 (36.4)	0.085
Serum Creatinine									
Raised	23	22(95)	**<0.001**	20(87.0)	**<0.001**	8(34.8)	***0.012***	10(43.5)	0.153
Lipid-Total									
Raised	83	50 (60.2)	0.096	20 (24.1)	**0.001**	14 (16.9)	0.621	32 (38.6)	0.764
LDL-Cholesterol									
Raised	48	30 (62.5)	0.143	10 (20.8)	0.158	8 (16.7)	0.777	21 (43.8)	0.302
HDL-Cholesterol									
Raised	18	13 (72.2)	0.092	6 (38.9)	0.058	5 (27.8)	0.126	8(44.4)	0.609
Triglycerides									
Raised	17	10 (58.8)	0.635	4 (23.5)	0.259	5 (29.4)	0.093	5 (29.4)	0.605
Microalbuminuria		N/A		N/A				N/A	
Absent	176					22(12.5)	***0.003***		
Present	19					8(42.1)			
Nephropathy		N/A		N/A				N/A	
Absent	153					16 (10.5)	**<0.001**		
Present	42					14 (33.3)			

Mean values of associated factors for microvascular complications among newly diagnosed diabetes patients

The mean±(SD) of the associated factors among newly diagnosed Type 2 diabetes patient which were statistically significantly higher were age for any complications (53.58±11.15 versus 47.49±9.13) ***<0.001***, nephropathy (54.60±12.32 versus 49.32 ± 9.76) ***0.004*** and neuropathy (55.03±10.60 versus 48.47±9.93) ***<0.001.*** Also the level of serum Creatinine was significantly higher for any complications (96.30±29.50 versus 76.72±14.02) ***<0.001***, neuropathy (116.4±31.31 versus 77.9 ±14.23) ***<0.001*** and retinopathy (96.84±33.2193 versus 84.34±22.63) ***0.011.***Higher lipid total cholesterol was significant higher in patients with any complication (5.44±1.59 versus 4.96±1.10) 0.016 and nephropathy (2.83±1.19 versus 5.03±1.30) ***0.001***. LDL cholesterol was significantly elevated in patients with any complications (2.61±1.10 versus 2.33±.86) ***0.049*** and nephropathy (5.03±1.30 versus 2.83±1.19***) 0.009*** as compared to those patients without these microvascular complications as shown in Table 6 below.

Table 6: Demographic and laboratory predictors of chronic complications among newly diagnosed diabetes patient

Associated factors		Any complication (n, %) (n, %)	p-value	Nephropathy (n, %)	p-value	Retinopathy (n, %)	p-value	Neuropathy (n, %)	p-value
Total		104 (53.3)		42 (21.5)		30 (15.4)		72 (36.9)	
Age	With	53.58±11.1	***<0.001***	54.60±12.32	***0.004***	52.37±12.06	0.282	55.03±10.60	***<0.001***
	Without	47.49±9.13		49.32 ± 9.76		50.11±10.26		48.47±9.93	
BMI	With	26.45±5.12	0.149	26.567±5.33	0.348	25.95±4.82	0.982	26.57±5.139	0.225
	Without	25.44±4.58		25.7±4.74		25.92±4.89		25.65±4.73	
S.creati	With	96.30±29.5	***<0.001***	116.4±31.31	***<0.001***	96.84±33.2193	***0.011***	89.14±23.30	0.288
	Without	76.72±14.0 2		77.9 ±14.23		84.34±22.63		85.01±25.50	
T.Chole	With	5.44±1.59	***0.016***	5.90±1.55	***0.001***	5.34±1.68	0.604	5.28±1.6	0.622
	Without	4.96±1.10		5.03±1.30		5.19±1.34		5.17±1.32	
LDL	With	2.61±1.10	***0.049***	2.83±1.19	***0.009***	2.42±1.04	0.753	2.49±1.02	0.864
	Without	2.33±.86		2.38±0.92		2.48±0.99		2.46±0.99	
HDL	With	1.53±.72	0.673	1.67±0.83	0.593	1.62±0.95	0.274	1.50±0.58	0.983
	Without	1.49±.53		1.46±0 .57		1.48±0.56		1.50±0.66	
Triglyce	With	2.10±8.23	0.294	1.41±0.71	0.753	1.32±0.71	0.735	1.25±0.60	0.502
	Without	1.19±.51		1.75±6.79		1.74±6.54		1.88±7.31	

Associated factors for microvascular complications among newly diagnosed diabetic patients by logic regression analysis

On univariate analysis; factors which were significantly associated with presence for nephropathy were age > 45 (OR 2.36, CI 1.085- 5.151) p value*0.030* being widowed (OR 24.44, CI 2.727- 29.09) p value***0.004,*** hyperlipidemia (OR 3.56, CI 1.732 – 7.333), ***0.001(***Table 7)

On multivariate analysis for nephropathy and associated factors family history of diabetes; obesity, higher waist – hip circumference and hyperlipidemia were shown to be independent predictors of nephropathy in the newly diagnosed diabetic patients (Table 8)

Associated factors which were statistically significant on univariate analysis for neuropathy were Age > 45 (OR 3.41, CI 1.693- 6.856), ***0.001*** being divorced (OR 5.60, CI 1.146- 27.37), ***0.033*** widowed (OR 4.80, CI 1.251- 18.42), ***0.022***, having no formal education (OR 0.49, CI 0.228-1.090), ***0.019*** family history of diabetes (OR 1.86, CI 1.015 – 3.421), ***0.045*** and high blood pressure (OR 2.94, CI 1.580 – 5.468), ***0.001***. (Table 7)

On multivariate analysis age, no formal education, family history of diabetes, and high blood pressure were shown to be independent predictors of neuropathy. (Table 8)

Other associated factors which were analyzed on univariate logistic regression but were not statistically significant included level of education, occupation, gender, smoking history, BMI, blood pressure (Table 7)

While for diabetic retinopathy only elevated blood pressure blood pressure (OR 2.14, CI 0.968 – 4.731), and underweight (OR 4.43, CI 1.057- 18.55) were identified to be the statistically significant on univariate analysis,

None of the associated factors were significant in multivariate analysis (Table 8)

Logistic regression were also performed between microalbinuria and Nephropathy and retinopathy

Microalbuminuria was significant associated with retinopathy (OR 4.10, CI 1.4-11.84) ***0.009*** shown to be independent predictors of nephropathy (Table 9)

On multivariate analysis retinopathy (OR 4.49, CI 1.916- 10.56) shown to be independent predictors of nephropathy (Table 9)

Table 7: Univariate analysis on any complication, neuropathy, retinopathy and nephropathy among newly diagnosed diabetic patients

characteristics	Any complication Odds (95% CI)	P value	Nephropathy Odds (95% CI)	P value	Retinopathy Odds (95% CI)	P Value	Neuropathy Odds (95% CI)	P value
Age group (years)								
46 and above	2.64 (1.46-4.79)	***0.001***	2.36 (1.09-5.15)	***0.030***	1.30 (0.57-2.95)	0.531	3.41 (1.693- 6.856)	***0.001***
Gender								
Female	1.31 (0.74-2.32)	0.352	1.56 (0.76-3.19)	0.225	0.49 (0.21-1.07)	0.071	1.36 (0.735- 2.527)	0.325
Marital status								
Married	1.50 (0.58-3.87)	0.398	4.81 (0.62-37.54)	0.134	1.64 (0.35-7.63)	0.527	1.19 (0.406-3.497)	0.750
Divorced	4.33 (0.88-21.3)	0.071	2 (0.11-35.41)	0.636	0.95 (0.01-11.8)	0.968	5.60 (1.1146-27.37)	0.033
Co-habiting	4.06 (0.95-17.4)	0.059	8 (0.79-81.33)	0.079	2.59 (0.37-17.9)	0.335	1.28 (0.276-5.934))	0.752
Widowed	6.50 (1.59-26.5)	***0.009***	24.44 (2.73-219.1)	***0.004***	3.17 (0.54-18.7)	0.203	4.80 (1.251-18.42)	***0.022***
Occupation								
Casual laborer	1.06 (0.47-2.39)	0.897	0.71 (0.27-1.84)	0.479	2.31 (8.08)	0.192	0.80 (0.349-1.842)	0.602
Formal employment	0.73 (0.33-1.65)	0.453	0.73 (0.28-1.89)	0.513	2.69 (0.78-9.29)	0.117	0.56 (0.236-1.338)	0.193
Business owner with employee	0.53 (0.20-1.37)	0.188	0.94 (0.32-2.78)	0.917	1.75 (0.40-7.64)	0.457	0.62 (0.226-1.711)	0.358
Retired	0.47 (0.12-1.89)	0.287	0.32 (0.04-2.75)	0.296	2.63 (0.41-16.8)	0.309	0.39 (0.074-2.043)	0.264
Education level								
Primary school	0.28 (0.11-0.69)	***0.006***	1.28 (0.49-3.29)	0.605	1.02 (0.37-2.83)	0.964	0.49(0.228-1.090)	***0.019***

Secondary school	0.14 (0.05-0.39)	<***0.001***	0.63 (0.18-2.19)	0.463	0.43 (0.01-1.86)	0.256	0.29(0.105-0.815)	0.081
University/College	0.21 (0.06-0.69)	***0.010***	1.33 (0.36-4.93)	0.666	0.85 (0.19-3.86)	0.836	0.35(0.105-1.181)	0.092
Drinking habit								
On special occasions only	0.40 (0.15-1.07)	0.067	0.52 (0.14-1.88)	0.317	0.30 (0.04-2.84)	0.255	0.34(0.095-1.231)	0.1000
Once a week	1.61 (0.57-4.57)	0.374	1.19 (0.39-3.63)	0.755	1.20 (0.31-4.59)	0.790	1.64(0.600-4.485)	0.334
Twice a week	0.88 (0.35-2.24)	0.794	0.33 (0.07-1.49)	0.148	1.88 (0.61-5.79)	0.275	1.03(0.383-2.746)	0.960
Twice daily	0.80 (0.28-2.28)	0.681	0.72 (0.19-2.69)	0.621	2.00 (0.58-6.93)	0.274	1.23(0.417-3.632)	0.707
Family history of diabetes	1.11 (0.63-1.97)	0.713	1.71 (0.86-3.39)	0.128	0.65 (0.29-1.47)	0.295	1.86(1.015-3.421)	***0.045***
BMI								
Underweight	1.28 (0.37-4.44)	0.694	0.61 (0.12-3.07)	0.551	4.43 (1.06-18.6)	***0.042***	1.14 (0.310-4.215)	0.841
Overweight	0.92 (0.48-1.75)	0.792	0.50 (0.22-1.16)	0.108	1.61 (0.59-4.35)	0.348	1.21 (0.605-2.420)	0.590
Obese	1.44 (0.64-3.27)	0.383	0.65 (0.27-1.58)	0.346	2.14 (0.69-6.66)	0.190	1.01 (0.419-2.413)	0.990
Waist circumference								
Abnormal	1.20 (0.67-2.15)	0.540	1.94 (0.97-3.88)	0.060	1.34 (0.61-2.95)	0.469	0.943(0.506-1.756)	0.853
Blood pressure								
Hyper-tensive	3.11 (1.72-5.63)	<***0.001***	1.06 (0.53-2.11)	0.867	2.14 (0.97-4.73)	0.060	2.94()1.580-5.468	***0.001***
Blood sugar								

Hyperglycemic	1.77 (0.97-3.23)	0.061	1.58 (0.74-3.39)	0.239	1.49 (0.63-3.56)	0.368	1.79(0.919-3.491)	0.087
Lipid-Total Cholesterol								
Raised	1.63 (0.92-2.89)	0.097	3.56 (1.73-7.33)	***0.001***	1.22 (0.56-2.66)	0.622	1.12 (0.611-2.052)	0.714
LDL-Cholesterol								
Raised	1.64 (0.84-3.21)	0.144	1.75 (0.83-3.69)	0.142	1.14 (0.47-2.75)	0.777	1.36 (0.688-2.689)	0.377
HDL-Cholesterol								
Raised	2.46 (0.84-7.18)	0.100	2.58 (0.93-7.14)	0.068	2.34 (0.77-7.13)	0.135	1.38 (0.506-3.735)	0.532
Triglycerides								
Raised	1.28 (0.47-3.50)	0.635	1.59 (0.53-4.79)	0.412	2.55 (0.83-7.86)	0.103	0.621 (0.194-1.986)	0.422

Table 8: Multivariate analysis on any complication, neuropathy, retinopathy and nephropathy among newly diabetic patients

Characteristics	Any complications Odds (95% CI)	P value	Nephropathy Odds (95% CI)	P value	Retinopathy Odds (95% CI)	P Value	Neuropathy Odds (95% CI)	P value
Age group (years)	1.62 (0.81-3.25)	0.175	2.11 (0.83-5.32)	0.115	1.11 (0.42-2.95)	0.830	2.44 (1.08-5.49)	***0.032***
Female gender	1.04 (0.45-2.42)	0.930	0.97 (0.34-2.78)	0.956	0.54 (0.19-1.56)	0.256	1.17 (0.47-2.88)	0.739
Widowed	1.44 (0.50-4.19)	0.502	5.86 (0.66-51.94)	0.113	2.01 (0.38-10.8)	0.415	0.87 (0.26-2.86)	0.815
Non formal-education	0.21(0.07-0.58)	***0.003***	0.86 (0.26-2.84)	0.805	0.75 (0.23-2.51)	0.644	0.49 (0.19-1.27)	***0.013***
Drink twice daily	0.89 (0.45-1.78)	0.749	0.56 (0.23-1.37)	0.204	0.98 (0.39-2.42)	0.956	1.14 (0.55-2.39)	0.724
Smoking habits current smoker	1.01 (0.37-1.78)	0.985	0.81 (0.19-3.23)	0.756	1.34 (0.40-4.47)	0.638	0.76 (0.24-2.42)	0.645
Family history of Diabetes	1.36 (0.71-2.76)	0.352	2.56 (1.13-5.79)	***0.025***	0.62 (0.26-1.51)	0.294	2.25 (1.13-4.48)	***0.049***
BMI -obese	0.95 (0.45-2.62)	0.900	0.34 (0.13-0.93)	***0.035***	1.97 (0.68-5.72)	0.213	1.19 (0.53-2.70)	0.667
Higher waist circumference	1.36 (0.63-2.03)	0.436	3.01 (1.11-8.15)	***0.033***	1.24 (0.45-3.41)	0.679	0.89 (0.38-2.07)	0.791
High Blood pressure	2.32 (1.18-2.97)	***0.014***	0.45 (0.18-1.12)	0.087	2.08 (0.84-5.16)	0.116	2.27 (1.11-4.64)	***0.001***
Hyperglycemia	1.88 (0.97-4.55)	0.064	1.68 (0.71-3.99)	0.237	1.29 (0.51-3.30)	0.592	1.84 (0.89-3.82)	0.101
Serum Creatinine	52.8(4.6-599.8)	***0.001***	40.8 (7.7-215.3)	**<0.001**	2.95(1.03-8.44)	***0.044***	0.23(0.01-92.56)	0.629
Lipid-Total Cholesterol	1.21 (0.5-3.68)	0.678	5.01 (1.79-14.44)	***0.008***	0.86 (0.26-2.92)	0.811	0.65 (0.25-1.73)	0.390
LDL-Cholesterol	1.19 (0.45-2.93)	0.721	0.59 (0.21-1.65)	0.312	0.81 (0.23-2.84)	0.738	1.72 (0.60-4.93)	0.309
HDL-Cholesterol	1.85 (0.52-3.17)	0.344	2.35 (0.70-7.90)	0.619	1.68 (0.44-6.41)	0.452	1.19 (0.35-4.10)	0.776
Triglycerides	0.81 (0.24-6.61)	0.716	0.89 (0.23-3.44)	0.874	1.88 (0.51-6.96)	0.345	0.59 (0.15-2.36)	0.459

Table 9: Association between microalbuminuria, nephropathy and retinopathy among the newly diagnosed diabetic patients

Variable	Odds ratio	95% Confidence Interval		p-value
		Lower limit	Upper limit	
Nephropathy	4.49	1.916	10.56	***0.001***
Microalbuminuria	4.10	1.421	11.842	***0.009***

CHAPTER FOUR

DISCUSSION

Prevalence of chronic complications

In this study, prevalence of at least one microvascular complications in the recruited 195 newly diagnosed type 2 diabetes patients in Dar es Salaam was 53.3%. These findings indicate a huge burden of microvascular complications in these newly diagnosed patients with diabetes mellitus. A study by Harris et al. showed that the onset of newly diagnosed T2DM probably occurs even earlier than 4–7 yr before clinical diagnosis (2) Based on this study results this proportion is higher when compared with similar cross-sectional studies that have been done in India which reported low prevalence rates of at least any microvascular complications, ranging from 13 to 32% (3,4)

This variability in the prevalence may be due to difference in age at T2DM diagnosis, sample size, existing diagnostic facilities, and/or variable diagnostic criteria followed by the studies.

Prevalence of retinopathy, neuropathy, microalbuminuria and nephropathy were observed in 15.4%, 36.9%, 9.7% and 14.5% respectively.

The prevalence of retinopathy among these newly diagnosed patients in Dar es Salaam is slightly lower to most studies done in other part of Africa. Mbanya and Sobngwi (18) for instance, looked at the prevalence of diabetic complications in Africa and reported retinopathy prevalence at diagnosis of 21-25% among type 2 diabetes patients. Similar diabetes prevalence rates among new diabetic patients have also reported elsewhere, (17,45).Lower prevalence at diagnosis have however also been documented from studies done by Sosale et al from Southern India (3,46,47), by de Fine Olivarius from Denmark and Tapp RJ et al from Australia with the prevalence of 5%, 6.2% and 6% respectively. Higher retinopathy prevalence were reported in the large study conducted in UK, United Kingdom Prospective Diabetes Study (UKPDS) which found DR prevalence of 35% among newly diagnosed diabetes patents (48)

The prevalence of DR in this study was within the limits of the international range, although it is difficult to ascertain the reasons for such difference in prevalence rates among various studies in various populations but race, age at diagnosis, method of detecting DR, health care facilities, and other risk factors could have contributed to the variations in the reported DR prevalence among different communities

Peripheral neuropathy in the current report was observed in more than one third (36.9%) of the patients, a prevalence that is almost similar with studies done in other part of the world like Northern India, Saudi Arabia and in Taiwanese patients with reported prevalence of 29%, 38%,33.9% respectively (36,49,50). Higher peripheral neuropathy prevalence of 52% was observed in Tehran Iran . However Sosale et al (3), Karmakar *et al* (51), observed a lower prevalence of diabetic peripheral neuropathy in 13.% and 9% patients respectively at diagnosis in their studies.

This difference in prevalence between our study and other study as explained by various authors(22). This could have been contributed, probably our patients attend the diabetes Clinic much later because of less awareness of the disease, while genetic predisposing to develop complications cannot be ignored, exposure to a longer duration of asymptomatic high blood glucose due to poor access to adequate health care facilities and personnel due to lower socioeconomic status and lack of awareness of the disease and its detrimental consequences may also be a contributory factor.
Hence both genetic factors and low awareness of the disease and its complications may contribute to this high prevalence of chronic complications among newly diagnosed diabetic patients in Dar es Salaam.

Microalbiminuria (MA) is the first clinically detectable stage of involvement of the kidney, Several epidemiological studies reported prevalence rates of Microalbiminuria ranging between 8–32% among T2DM (34,35,52–55) the prevalence of Microalbiminuria in the present study is 9.7%, which is within the international range and is almost similar with studies done by W. Gatling et al (52) and S. M. marshall et al (53)in the white UK population revealed a prevalence of microalbuminuria of 7% and 9% respectively . This finding was clearly lower than the equivalent rates reported in the other studies (54,55) and the differences could be attributed to the method of assessment or study design.

It is established that once Microalbiminuria is present, it is most likely to progress to proteinuria, over the next 5–10 years, in 20– 50% of subjects. With the presence of MA, it is as well recognized to cause decline in renal function varies but the average loss in glomerular filtration remains around 10–12 ml/min/year and is accelerated by hypertension (56), though it is potentially reversible. Microalbiminuria is also strongly associated with traditional cardiovascular risk factors and cardiovascular complications and events(55). MA is also associated with other diabetes complications such as retinopathy and neuropathy. The association is held even after adjustment for other cardiovascular risk factors such as age, hypertension, smoking, dyslipidemia, abdominal obesity and hyperglycemia

The prevalence of Diabetic nephropathy in earlier studies has shown that nephropathy is present in about 15-18% of patients with newly diagnosed type 2 diabetes(57).This present study showed that almost quarter 14.4% of the participants developed nephropathy; this finding is nearly similar to studies done in most parts of world. ; Harrzallah F et al in Tunis (58). Observed nephropathy in 13%,and Navneet Agarwal et al found the prevalence of 17.34% in Mumbai, but higher prevalence was reported by Weerasuriya (17) observed diabetic nephropathy prevalence of 29% in newly diagnosed Sri Lanakan diabetic patients. However there are also studies reporting low prevalence like studies done by Sosale from southern India, the UKPDS and Iraj Heydari et al in Tehran Iran which reported prevalence of 1%, 7% and 10% respectively.

Even higher diabetic nephropathy prevalence have been also reported in other countries like reports from India and western studies is due to delay for medical seeking behavior, delayed screening/ earlier detection of diabetes or a change in risk factors in unclear. Furthermore, the observed differences may be due to the difference in the study designs, methodologies and possibly ethnic differences among various populations.

Associated risk factors in newly diagnosed diabetes patients with microvascular complications

In the present study majority of the patients (61%) were from the younger age group of 41-60 years and 22.6% from the age group of 35- 40 years. This young age of diabetes presentation has also been seen in other prevalence studies from most developing

countries, where the age range at presentation is 45 -64 years, whereas a higher age at diagnosis of diabetes from developed countries group > 65 years. Younger age of onset implies that these patients develop diabetes in the most productive years of their life and they have greater chance of developing complications. Both environmental and genetic factor might explain the younger onset of age with high prevalence of diabetes.

The present study found that advanced age more than 46yrsof age was associated with a 2.8 fold likelihood of developing of peripheral neuropathy compared with lower age, this finding was statically significant in both univariate and multivariate analysis, In many other previous studies, advanced age has been reported a significant risk factor for diabetic neuropathy in Type 2 diabetes (10,48,49)

A number of biological alteration associated with aging process are recognized to facilitate the effect of age on diabetic neuropathy. These include increase in the production of advanced glycosylation end-products, defects in the polyol pathway, and impaired resistance to oxidative stress (59) important factors in development of diabetic neuropathy. Increasing age seems to be a strong risk factor for diabetic neuropathy, independent of the duration of diabetes mellitus and glycaemic control (59).

No formal educational level of patients with diabetes complications in our study was associated with likelihood of developing any complication and peripheral diabetes neuropathy, this it may contribute and play as the determinant for individuals who require a careful elaborated plan on the reeducation of eating habits, physical activity and pharmacological treatment.
Randomized study performed in a German Center of Diabetes identified that among socioeconomic aspects, a low level of education can interfere with the learning effect of diabetes-related care(60). The low level of education can make it difficult for individuals to understand essential care for the control of the disease and prevention of complications(61)

Prevalence of high blood pressure found in this study (44.1%) were similar that of UKPDS in African Caribbean population subset but was lower in comparison to other ethnic group. In our study high blood pressure was 2.3 fold higher chance of developing any complications and 2.2 fold likelihood of developing peripheral neuropathy this findings was consistence with other studies done by Al-Mahroos et al (3,10).

The underlying mechanism by which hypertension may lead to microvascular complications is obscure. However, an alternative explanation might relate to a direct blood pressure load or hemodynamic stress effect(62).

Family history of diabetes in the 1st degree relative independently of other risk factors considered, the odds of having diabetes nephropathy and neuropathy were, respectively, 2.5 and 2.2 times higher. Previous studies have indicated almost the same relationship, versus people without a family history of diabetes, those who have a family history of diabetes are two to six times as likely to have type 2 diabetes in the US (63)More specifically, a recent study based on NHANES and other studies data found that family history of diabetes was significantly and independently associated with diabetes in U.S. adults (based on self-reports)(64)

In this study nephropathy was significantly related to obesity, those who were obese as picked by higher waist circumference were 3fold chances of developing nephropathy compared with those with normal circumference. This findings was as well observed in a study done by Martina Tomic et al (65) . Obesity accompanying type 2 diabetes is known to be closely linked with insulin resistance and elevated sympathetic nervous activity. These findings suggest that elevated sympathetic nerve activity associated with insulin resistance may contribute to the onset and maintenance of cardiovascular and renal complications in diabetes, and hypertension in obesity(66)

In this study age was not a significant factor associated with DR, this finding is similar to those cited by other studies which have shown that older age at diagnosis of DM is a risk factor for the presence of DR (67) which could account for the differences in the prevalence of DR in the previously cited studies(68,69)

The other risk factors of hypertension, hyperlipedemia, BMI and smoking were also not associated with DR, although hypertension is a recognized risk factor in type 2 DM patients with DR [(69,70). Van Leiden et al.(70) reported positive association with BMI while Nguyen et al.(71) and Owens et al. (72) reported negative association. Surprisingly the UKPD study(69) showed that the severity of DR was more in leaner than obese women

Our multivariate logistic regression analyses indicated that patients with DR were 4 times more likely to have microalbuminuria and overall diabetic nephropathy compared with those without diabetic retinopathy, this finding was similar with a cross sectional study conducted by El-Asrar et al (73) which showed that patient with retinopathy were DR were 4.37 times to develop nephropathy. Several other studies have shown that the presence of DR itself may divulge patients at risk of DN (13,74). Villar et al (15) also demonstrated that DR was one of the most important risk factors for the development of incipient nephropathy in normoalbuminuric, normotensive patients irrespective of the type of diabetes.

This finding may be helpful in adopting clinical significance of retinopathy as a strong predictor of nephropathy.

Implication of the study finding

The findings of this study need to be viewed of the practicalities of the current Tanzanian situation. The prevalence of microvascular complications at diagnosis among newly diagnosed diabetes patients is alarming. The morbidity, mortality and reduction in quality of life conferred by these complications are also likely to be high. While such data on long term morbidity and mortality are missing in Tanzania, literature from other parts of the world suggests that these sequelae confer a significant impact on everyday functioning, quality of life and increased mortality.(75,76)

Type diabetes mellitus is a common disease that is associated with high mortality and morbidity from macrovascular and microvascular disease. It is largely the complications associated with diabetes which make it such a major public health problem.(75,76)

In a study done by A. Ruigómez et al,(77) who were looking the diabetes, related complication at the time of diagnosis of T2DM as an important prognostic factor, they found that 360 (33%) patients already presented with one or more of T2DM complication at the time of first diagnosis, and 437 (41%) developed a new complication related to T2DM during an average follow-up time of three years and eight months, while among those with history, the risk of developing a new T2DM complication was twice as greater.

On mortality; Patients who developed a new T2DM complication had a twofold increased risk of dying during the follow-up period compared to those with no complication, while

the mortality rate among patients with history of a complication was two times greater compared to diabetic patients with no history

As recommended by different authors(78,79)The findings of this study warrant an active search among newly diabetes patients for microvascular complications, primary health care practitioners can screen for diabetes complications and associated risk factors to all diabetes patients irrespective of their diabetes duration. The tools to detect such complications are fairly simple, rapid and not overly costly and there should not be a reason to miss this population who may require assistance beyond standard treatment.

Study limitations

Our study has several limitations. First, this study is a clinic based study. This could have introduced some degree of referral bias and the result cannot be generalized in the population

Second, some factors, including dyslipidemia and hypertension, are not only associated risk factors for microvascular complications but also consequences of renal damage. As a result, causality between these factors is impossible to conclude

Third, although we excluded the patients who were younger than 30 years when diagnosed with DM and were receiving insulin therapy in the current study, it is possible that the sample does not uniformly consist of type 2 DM patients.

Despite these limitations, our study strongly suggests that the burden of diabetes microvascular complications will grow in the coming decades, both in population size and costs, and will have significant impacts on the lives of Tanzanians, the Government and the financial stability of health insurance Funds.

CHAPTER FIVE

Conclusions

The present study was the first national hospital based urban study of microvascular complications among newly diagnosed diabetes mellitus. The study showed prevalence and associated risk factors similar to those shown in other studies. It is of concern that considerable proportion of patients had clinically significant morbidity at diagnosis and for years before diagnosis of diabetes and its complications. In our study prevalence of any microvascular complications of diabetes among newly diagnosed diabetes patients was high stood at 53.3%, neuropathy was 36.9%, nephropathy was 14.5%, and retinopathy was 15.4%.

Recommendations

Due to the high rate of microvascular complications among newly diagnosed diabetes patients found in this study (53.3%) it is recommended that, one of the major strategy will be identifying diabetes mellitus early, preferably at the community level, and those diagnosed with diabetes handled early to prevent them from getting the complications.

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APPENDICES

Appendix I: Questionnaire

Study No_____

THE PREVALENCE OF CHRONIC COMPLICATIONS AMONG NEWLY DIAGNOSED DIABETIC PATIENT DAR ES SALAAM

BACKGROUND INFORMATION AND SOCIODEMOGRAPHIC

CHARACTERISTICS OF STUDY PARTICIPANTS

1. Serial number: _____
2. Name: _____Hosp No:_____-
3. Telephone contact _____
4. Date of birth (dd/mm/yy): _____5. AGE

1. 18-29
2. 30-40
3. 40-50
4. 50-65
5. > 65

5. Gender: 1. M 2. F
6. Marital status

1. Single 2. Married 3. Divorce
4. Co-habiting 5. Widowed

SOCIO-ECONOMICAL STATUS

7. Occupation

1. Unemployed 2. Casual laborer
3. Formal employment (unskilled work)
4. Formal employment (skilled job)
5. Business owner with employees

8. Highest level of education attained

1. None 2. Primary 3. Secondary 4. College / University

9. Drinking habit

1. Non drinker

2. Drink on special occasions only
3. Drink once a week
4. Drink twice a week
5. Drink daily

10. On average how much do you drink per week……

11. What type of alcohol drink

12. Smoking habits

1. Never smoked
2. Current smoker
3. Stopped smoking

(When stopped…….. how long did you smoke…….)

13. If current smoker:

1. Smokes 1-9cigarettes per day
2. Smokes 10-19
3. Smokes > 20 cigarettes per day

CLINICAL CHARACTERISTICS

14. Family history of diabetes in first degree relatives

1.Yes 2. No

15. History of other Co-morbidity,

1. Hypertension Y /N
2. Heart failure Y/ N
3. Cardiovascular event Y /N
4. Arrhythmias Y/ N
5. HIV infection Y/ N

DNS questionnaire

Question	**Score**	
	0	**1**
1. Are you suffering of unsteadiness in walking (*Need for visual control, increase in the dark, walk like a drunken man, lack of contact with the floor*)		
2. Do you have burning, aching pain or tenderness at your legs or feet (*Occurring at rest or at night, not related to exercise, exclude intermittenent claudication.*)		
3. Do you have prickling sensation at your legs and feet? (Occurring at rest or at night, *distal> proximal, stocking glove distribution)*		
4. Do you have places of numbness on your legs or feet? *Distal> proximal, stocking glove distribution*		
Total score		
Aggregate score		

TICK APPROPRIATELY

The questions will be answered either YES (positive: 1point) if a symptom has occurred during the last 2weeks or No (negative: no point) if it did not. Maximum score is 4 and minimum 0

PHYSICAL FINDING

16. Height……cm
17. Weight……kg
18. BMI……Kg/m^2
19. Waist Circumference …….. cm

1. Underweight
2. Normal
3. Overweight
4. Obese

20. Blood Pressure SBP1…….. DBP1……., SBP2…….. DBP2……..

1. Normotensive
2. Hypertensive
3. Hypotensive

Appendix II: Diabetic Neuropathy Examination (DNE) Score

Patient Name:……..Hosp: no:……Study No:_____

DIABETIC NEUROPATHY EXAMINATION (DNE) SCORE

Muscle strength	**SCORING**		
	0	**1**	**2**
1. Quadriceps femoris: extension of the knee			
2. Tibialis anterior: dorsiflexion of the foot			
Reflex			
3. Triceps surae			
Sensation: index finger			
4. Sensitivity to pinpricks			
Sensation: big toe			
5. Sensitivity to pinpricks			
6. Sensitivity to touch			
7. Vibration perception			
8. Sensitivity to joint position			
Total scores			
Aggregate score			

Only the right leg and foot are tested. TICK APPROPRIATELY

Maximum score: 16 points

<u>Scoring from 0 to 2</u>:

Score 0 = Normal

Score 1 = Mild/moderate deficit

• Muscle strength: Medical Research Council scale 3–4

• Reflex: decreased but present

• Sensation: decreased but present

Score 2 = severely disturbed/absent

• Muscle strength: Medical Research Council scale 0–2

• Reflex: absent

• Sensation: absent

Interpretation: 0-2 No peripheral neuropathy

>3 Positive for peripheral neuropathy

DNE Score=

1. No peripheral neuropathy
2. Peripheral neuropathy present ☐

Examining Doctor: …… **Date:** …….

Appendix III: Diabetic Eye Examination

Patient Name:……..Hosp: no:……Study No:_____

DIABETIC EYE EXAMINATION

General examination	Rt Eye	Lt Eye
1. Visual acuity		
2. Eye pressure		
3. Cataracts		
Signs of Retinopathy		
Back ground retinopathy **Vascular damage**	Rt Eye	Lt Eye
4. Micro aneurysms		
5. Hemorrhage		
6. Dot and Blot		
7. Flame shaped		
8. pre retinal		
Vascular leakage		
9. Hard exudates		
10. Retinal (Macular) edema		
Ischemic and Hypoxia		
11. cotton wool spots		
12. Narrowed arteries		

13. Venous Changes		
14. Intra-retinal micro vascular abnormalities		
Proliferative Signs		
15. Retinal neovascularization		
16. Fibrous Scar		
17. Vitreous hemorrhage		
Conclusion of eye examination findings		

Summary of examination:

_____

Lab investigations

21. Blood Sugar on the day of investigation

FBG…….mmol/L or RBG……..mmol/L

1 Euglycemic

2 Hyperglycemic

3. Hypoglycemic

22. Serum Creatinine level…….umol/L

23. Lipid –Total cholesterol …….. (mmol/l)

1. Normal
2. Raised

24. LDL – CHOL …….. (Mmol/l)

1. Normal
2. Raised

25. HDL- Chol …….. (mmol/l)

1. Normal
2. Raised

26. Tryglcerides ……(Mmol/l)

1. Normal
2. Raised

Urine examination

1. Dipstix: Proteinuri 0= neg, 1=+1, 2=+2 …… ☐
2. MICRAL: Albuminuria ☐
3. MICRAL: Creatinine ☐
4. ACR ……. ☐

27. Estimated Glomerular Filtration Rate (eGFR) ----------

1. < 5 mL/min/1.73 m^2
2. 5-10<mL/min/1.73 m^2 ☐

3. 10-15< mL/min/1.73 m^2

4. ≥ 15 mL/min/1.73 m^2

28. CKD grading in diabetes …….

Appendix IV: Informed Consent – English Version

Study No_____

INFORMED CONSENT

CONSENT FORM TO PARTICIPATE IN THE STUDY.

TITLE; THE STUDYOF CHRONIC COMPLICATIONS AMONG NEWLY DIAGNOSED DIABETIC PATIENT ATTENDING DIABETIC CLINIC IN DAR ES SALAAM

Greetings! My name is Dr. Onesmo J Ulomi, a medical doctor in the department of Internal Medicine. I would like to conduct a study mentioned above for my thesis.

Purpose of the study: The aim of the study is to determine the magnitude of chronic complications among newly diagnosed diabetic patient attending diabetic clinic in DSM. This will help in raising local awareness of preventing chronic comlications among patient with diabetes and to address the burden and its outcome of these complications

How to participate: Patients who meet the inclusion criteria will be recruited into the study. They will be interviewed using a questionnaire, which will include their social demographic characteristics, medical history, and clinical examination and undergo some measurements and Laboratory investigations including, BP, Height and weight, lipid profile, urine and renal function test

Risks We don't expect any harm will happen to you as a result of joining this study.
There may be a mild pain and a risk of bruise during venopuncture.

Confidentiality: The questionnaire will have a code number and no name shall be used any patient's results will not be revealed to anybody except attending doctors and patient him/herself. This means that the information you provide will receive the utmost confidentiality

Right to withdraw and alternatives

Taking part in this study is completely your choice. If you choose not to participate or if you decide to stop participant you will continue receiving all the services, which you would normally get from this hospital.

Cost: No payment is requested from you as a fee to participate in the study.

Person to contact in questions or problems:

Dr. Onesmo J Ulomi Tel: 0784416656 at the department of internal Medicine , MUHAS

Prof J. LutaleTel: 0754 292485 study supervisor Department of Internal Medicine, MUHAS.**Or**

Prof. Mainen J Moshi,

Director of reserch andpublication

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Chair person of Research Ethical Committee at the office of the director of postgraduate studies at MUHAS

Do you have any questions?

I…… have read/been told of the contents of this form and understood its meaning and my questions has been answered. I agree to participate in this study.

Signature…….. (Participant) Date……

Signature…….. (Researcher) Date……

Appendix V: Informed Consent – Swahili Version

FOMU YA IDHINI

FOMU YA IDHINI KUSHIRIKI KATIKA UTAFITI

MADA:, TAFITI YA MATATIZO SUGU MIONGONI MWA WAGONJWA WAPYA WALIOGUNDULIKA NA UGONJWA WA KISUKARI WANO HUDHURIA KLINIK JIJINI DAR ES SALAAM

Salaam; Jina langu ni Dr. Onesmo J Ulomi, Mganga katika idara ya Tiba ya Ndani. Napenda kufanya utafiti zilizotajwa hapo juu kwa Thesis yangu

Lengo la utafiti

Lengo la utafiti ni kufahamu ukubwa wa matatizo sugu miongoni mwa wagonjwa wapya waliogundulika na ugonjwa wa kisukari wanaohudhuria clinic za kisukari katika mji wa DSM

Hii itasaidia katika kuongeza uelewa wa ndani juu ya kuzuia matatizo sugu miongoni mwa wagonjwa wa ugonjwa wa kisukari na kutangaza ukubwa wa tatizo hili na matokeo yake.

Jinsi ya kushiriki

Wagonjwa ambao wana vigezo kuingizwa wataajisajiliwa katika utafiti. Watahojiwa kwa kutumia dodoso, ambayo itahusisha maswali, pamoja na sifa ya kijamii idadi ya watu, historia ya matibabu yao na uchunguzi wa kiafya kwa kufanyiwa baadhi ya vipimo vya maabara , uchunguzi mwingine ukiwa ni pamoja na kupima shinikizo la damu, Urefu na uzito, mafuta ya mwili, mkojo na figo.

Madhara

Hatutarajii madhara yoyote kutokea kwako kama matokeo ya kujiunga na utafiti huu.
Unaweza kupata maumivu kidogo wakati wa kutolewa damu kwa ajili ya vipimo.

Usiri

Dodoso itakuwa na kanuni namba na hakuna jina litakalotumika na matokeo ya mgonjwa yoyote hayatowekwa wazi kwa mtu yeyote Yule isipokuwa kwa mgonjwa mwenyewe na madaktari na wauguzi wanaokuhudumia.

Hii ina maana kwamba taarifa zako ulizozitoa zitahifaziwa na kutunzwa kwa usiri mkubwa

Haki ya kujitoa kwenye utafiti na njia mbadala

Kushiriki katika utafiti huu ni kabisa uchaguzi wako. Kama utachagua kutoshirika au kuamua kuacha kushiriki, utaendelea kupokea huduma zote, ambazo kwa kawaida upatawa katika hospitali hii.

Gharama

Hakuna malipo au gharama yeyote utakayo tozwa kwa kushiriki katika utafiti huu.

Watu wa kuwasiliana nao kama una maswali au matatizo

Dk Onesmo J Ulomi simu namba 0784 416 656 Mtafiti wa Mradi

Prof J. Lutale (Tel 0754 292485) Idara ya Tiba ya Ndani, MUHAS.

Iwapo utakuwa na swali lolote kuhusu haki zako kama mshiriki katika utafiti huu wasiliana na

Prof. Mainen J moshi,

Mkurugenzi wa utafiti

Chuo kikuu cha Tiba na Sayansi ya Afya Muhimbili

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Barua pepe: drp@muhas.ac.tz

Je, una maswali yoyote?

Mimi ..... nimesoma / nimeambiwa yaliyomo ndani yah ii fomu na kuelewa maana yake na maswali yangu yamejibiwa vizuri na nimeridhika. Mimi nakubali kushiriki katika utafiti huu.

Sahihi……..... .. (Mshiriki) Tarehe .....

Sahihi .... (Mtafiti) Tarehe .....

Appendix VI: Ethical Clearance

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

Directorate of Postgraduate Studies

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Ref. No. MU/PGS/SAEC/Vol.XIV/

9th June, 2015

Dr. Onesmo J.Ulomi
MMed. Internal Medicine
MUHAS.

RE: APPROVAL OF ETHICAL CLEARANCE FOR A STUDY TITLED: "PREVALENCE OF CHRONIC COMPLICATIONS AMONG NEWLY DIAGNOSED DIABETES PATIENTS IN DAR ES SALAAM"

Reference is made to the above heading.

I am pleased to inform you that, the Chairman has, on behalf of the Senate, approved ethical clearance for the above-mentioned study. Hence you may proceed with the planned study.

The ethical clearance is valid for one year only, from 5th June, 2015 to 4th June, 2016. In case you do not complete data analysis and dissertation report writing by 4th June, 2016, you will have to apply for renewal of ethical clearance \prior to the expiry date.

Prof. O. Ngassapa
DIRECTOR, POSTGRADUATE STUDIES

cc: Director of Research and Publication
cc: Dean, School of Medicine