

**PREVALENCE AND RISK FACTORS OF DIABETIC COMPLICATIONS AND
SCREENING PRACTICES AMONG NEWLY DIAGNOSED TYPE 2 DIABETES
PATIENTS AT KISII LEVEL 6 HOSPITAL, KISII COUNTY, KENYA.**

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of Masters in Public Health of Jaramogi Oginga Odinga University of Science and
Technology**

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DECLARATION

I declare that this thesis is my original work and that it has not been presented elsewhere for the award of a degree or diploma in any institution of higher learning.

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ABSTRACT

Diabetes Mellitus is assuming epidemic proportions with current statistics indicating that 382 million people (8.3% of the world population) have diabetes and the numbers are expected to rise to 592 million people in less than 25 years. In Africa, more than three-quarters of deaths from diabetes in 2013 occurred in people under 60 in their prime productive years. In Kenya, prevalence of diabetes stood at 3.58% in 2014. Local studies however have shown the prevalence to be at 4.2% in the general population with a prevalence rate of 2.2% in the rural areas and 12.2% in urban areas. The natural course of Type 2 Diabetes Mellitus (T2DM) diabetes as well as its risk factors is well known and understood. Ironically, the vast majority of people with the disease remain undiagnosed and for those diagnosed, more than 50% already have one type of complication or the other. The objective of this study is to determine the prevalence of diabetic complications, associated risk factors and screening practices among the newly diagnosed type II diabetes patients in Kisii County. A descriptive cross-sectional study of type II diabetes patients attending the diabetes outpatient clinic at Kisii teaching and referral hospital from December 2013 to December 2014 was adopted. Using the simple random method, a sample of 84 participants was selected. A tested researcher-administered questionnaire was used to collect data on socio-demographic and biological characteristics, diabetes complications, screening practices and physical and clinical examination findings. The data was analyzed using descriptive statistics, with the association between independent and dependent variables being tested using chi-square at a significance level of 0.05. The study found out that neuropathy (58.33%), monofilaments neuropathy (57.14%), retinopathy (47.62%) and elevated blood pressure (42.86%) were the most prevalent complications among the newly diagnosed diabetes patients. Amputation (1.19%), myocardial infarction (2.38%), CHF, TIA and Diabetic dermopathy were the least prevalent complications. Eye-related (47.62%), neurological (35.11%) and foot-related (21.03%) complications were the most prevalent with cardiovascular (10.03%) and skin-related (4.76%) complications being the least prevalent. The risk factors strongly associated with these complications are low level of education, high level of glycated hemoglobin, mode of diabetic treatment, alcohol use and female gender. Most of the diabetes patients are not used to routine check up for their illness. Health providers initiated the testing of the blood sugars for 74.12% of the newly diagnosed patients. The rest of the patients were diagnosed during routine medical check up (15.29%, n=13) and during mass screening (10.59%, n=9) in schools and other public places. In conclusion, there is a high prevalence of complications among newly diagnosed T2DM patients with more than 50% of patients having one complication or another within one year of diagnosis. Micro vascular complications were more prevalent than macro vascular complications. These complications are very serious as they can, and if poorly managed, lead to blindness, amputations, renal failure and death. Screening practices were still wanting in most patients. This study is expected to contribute to improving screening programmes and subsequently lead to more effective control of T2DM thus delaying the onset of complications.

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LIST OF ABBREVIATIONS

ADA	American Diabetes Association
BMI	Body Mass Index
CHF	Cardiac Heart Failure
CI	Confidence Interval
CINDI	Complications in Newly Diagnosed Diabetes in India
DALY	Disability adjusted life years
HbA1c	Glycated Hemoglobin
HDL	High Density Lipoproteins
IDF	International Diabetes Federation
JOOTRH	Jaramogi Oginga Odinga Teaching and Referral Hospital
KNH	Kenyatta National Hospital
KTRH	Kisii Teaching and Referral Hospital
LDL	Low Density Lipoproteins
MTRH	Moi Teaching and Referral Hospital
PPGT	Post Prandial Glucose Test
PVD	Peripheral Vascular Disease
QALE	Quality Adjusted Life Expectancy
T2DM	Type 2 Diabetes Mellitus
TIA	Transient Ischemic Attack
WHO	World Health Organization

CHAPTER ONE

INTRODUCTION

1.1. Background Information

Diabetes mellitus type 2 is the most common of the diabetes accounting to 90% of all cases of diabetes worldwide (WHO, 2011). World Health Organization (WHO) estimates that 342 million people (8.3% of the world population) are living with diabetes in the world (IDF, 2013). It causes 1.5 million deaths and contributes to 89 million DALYs and the number of those living with it expected to double in less than 25 years if necessary measures are not taken (King *et al.*, 1998; Murray *et al.*, 2012). The Western Pacific region has the highest number of people living with diabetes at 138 million while Africa has the least with 21.5 million (Federation, 2013).

In Africa, 21.5 million people live with diabetes with annual estimate of 480,900 diabetes-related deaths (Federation, 2013). The continents' most populous countries have the highest numbers of people with diabetes, including: Nigeria (3.9 million), South Africa (2.6 million), Ethiopia (1.9 million), and the United Republic of Tanzania (1.7 million). However, the countries with the highest prevalence include the island of Reunion (15.4%), followed by Seychelles (12.1%), Gabon (10.7%) and Zimbabwe (9.7%) (Federation, 2013; Hall *et al.*, 2011; Murray *et al.*, 2012).

The prevalence of diabetes in Africa may not be very accurate. It is estimated that thirteen million diabetic cases were undiagnosed in 2014. In addition, more than three-quarters of diabetes-related deaths in Africa occurred in people under 60 years compared to 65 years and above in high-income countries (Beagley *et al.*, 2014).

In Kenya, the prevalence of diabetes stood at 3.3% in 2007 (Federation, 2013). However, local studies put the prevalence at 4.2% in the general population with a prevalence rate of 2.2% in the rural areas and 12.2% in urban areas (Christensen *et al.*, 2009).

Diabetes is usually characterized by an asymptomatic phase between the actual onset of diabetic hyperglycemia and clinical diagnosis, which may last at least 4 to 7 years (Hsu *et al.*, 2013; Sereday *et al.*, 2008; Deedwania and Fonseca, 2005; ADA, 2012b). Hyperglycemia causes serious damage to the body's micro and macro-systems such as renal, neurologic systems by destroying blood vessels and nerves if uncontrolled and sustained over time. The damage usually leads to acute or chronic complications of diabetes (Deedwania and Fonseca, 2005).

According to the American Diabetes Association (2012), acute complications include diabetic coma, lactic acidosis, dehydration, severe diabetes-related infections and diabetes ketoacidosis (ADA, 2012a; ADA, 2012b). On the other hand, chronic complications can be micro vascular (Retinopathy and blindness, erectile dysfunction, diabetic foot disease, kidney disease and neuropathy) or macro vascular (stroke/cerebral vascular accidents, coronary heart disease and peripheral vascular diseases) (IDF, 2013; ADA, 2012a). These complications of diabetes are rife among patients in high, middle and low-income countries. (Moneva and Dagogo-Jack, 2002; Kaufman, 2002)

Among the chronic complications, micro vascular complications are more prevalent than macro vascular complications (Donaghue *et al.*, 2009). The prevalence rate for micro vascular complications is 33.7% to 50% compared to 27.2% to 33.4% for macro vascular complications (Sosale *et al.*, 2014; Heydari *et al.*, 2010). Cardiovascular conditions are more prevalent than cerebrovascular conditions among the macro vascular complications. Cardiovascular complications contributed 30.1% compared to 6.5% in a study in China with similar results being reported in Pakistan and Mozambique (Liu *et al.*, 2010; Ali *et al.*, 2013b). For the micro vascular complications, the prevalence of neuropathy, retinopathy and nephropathy in a decreasing order are 13.15%, 6.1% and 1.06% (Liu *et al.*, 2010; Ali *et al.*, 2013b; Sosale *et al.*, 2014).

The development of chronic complications is attributed to the general diabetes risk factors or chronic specific risk factors. Hyperglycemia is the primary risk factor with age, smoking, hypertension, elevated triglycerides, alcohol consumption, duration of the disease and higher BMI as secondary risk factors (Deli *et al.*, 2013; Hurley *et al.*, 2013).

1.2. Statement of Problem

Diabetes is characterized by an asymptomatic phase between the actual onset of diabetic hyperglycemia and clinical diagnosis, which may last at least 4 to 7 years. This sustained high level of blood glucose causes damage to blood vessels causing micro and macro vascular complications. Diabetes contributes to 89 million DALY globally and the people living with it are expected to double in 25 years (Murray *et al.*, 2012). There are also a high number of undiagnosed diabetes cases, which poses an increased risk to developing chronic complications due to increased exposure to uncontrolled hyperglycemia. Kenya, just as the rest of the world is faced with increasing burden of diabetes. This is especially true in the rural areas like Kisii County which has in recent years seen an increase in the prevalence of diabetes and its complications with an independent diabetic clinic being operated at the Kisii Level 6 Hospital to cater to large number of patients. This is due to poor screening practices as most cases are diagnosed on admission due to complications. With half of the estimated diabetes cases said to be undiagnosed, the country stands to incur huge health expenditure due to management of chronic complications developed due to delayed diagnosis. Thus, there is need to increase available knowledge on prevalence of chronic complications of diabetes in Kenya among the newly diagnosed patients. In addition, the risk factors related to developing chronic complications will be identified and help in developing screening strategies to detect and manage all cases of diabetes early especially among the population below 60 years which contributes to 90% of diabetes deaths in Africa.

1.3. Study Objective

1.3.1. Broad Objective

The main objective for the study was to determine the prevalence and risk factors for diabetic complications among newly diagnosed Type 2 diabetic patients in Kisii Level 6 Hospital in Western Kenya.

1.3.2 Specific Objectives

The specific objectives of the study were to:

1. To determine the prevalence of chronic diabetes complications among newly diagnosed type 2 diabetes patients at Kisii Level 6 Hospital.
2. To assess the relationship between specific risk factors and complications among the newly diagnosed type 2 diabetes patients at Kisii Level 6 Hospital
3. To establish the diabetes screening practices of newly diagnosed type 2 diabetes patients at Kisii Level 6 Hospital

1.4. Research Questions

The study addressed the following questions:

1. What is the prevalence of diabetes complications among newly diagnosed type 2 diabetes patients at Kisii Level 6 Hospital?
2. What is the relationship between specific risk factors and complications among the newly diagnosed type II diabetes patients at Kisii Level 6 Hospital?
3. What are the diabetes screening practices of newly diagnosed type II diabetes patients at Kisii Level 6 Hospital?

1.5. Significance of the Study

The study contributes to the growing body of knowledge on diabetes with specific interest in prevalence, risk factors and screening practices of diabetes patients. The study also provides

evidence that is useful in developing chronic diseases and diabetic specific health promotion strategies. It also provides evidence on the need and importance of investment in diabetes identification/screening and management. This is supported by the American Diabetes Association that notes that diabetes is frequently not diagnosed until complications appear with approximately one third of all people with the disease being undiagnosed (ADA, 2012b). Hence, early identification and management of individuals with diabetes and pre-diabetes have the potential to reduce both the incidence of diabetes and its related complications (Deedwania and Fonseca, 2005).

In Kisii County, there has been an increased media attention for having a high incidence of end stage renal disease. Diabetic nephropathy, one of the micro vascular complications has been identified as the leading contributor to end-stage renal failure. This as well as other findings from the study, justifies the need for the study in the County. The findings also provide evidence necessary to help policy makers develop evidence-based policies to improve the current public health interventions on diabetes and other chronic diseases.

1.6. Scope of the Study

The study determined the prevalence of diabetes complications among newly diagnosed type 2 diabetes patients, their specific risk factors as well as established the screening practices employed at Kisii Level 6 Hospital. The study targeted newly diagnosed type II diabetes mellitus patients at Kisii Teaching and Referral Hospital within one year, retrospectively. Kisii level 6 Hospital is a referral center in Kisii County and therefore giving a representative sample whose results can be generalized to Kisii County.

1.7. Operational Definition of Terms

Type 2 Diabetes Mellitus: A metabolic, chronic disease that occurs when the pancreas does not produce enough insulin, or when the body cannot effectively use the insulin it produces (WHO, 2011).

Complications: Diabetic specific complications which can be acute or chronic. This study will take complications to mean the chronic complications that are either micro vascular (Retinopathy and blindness, Erectile Dysfunction, Diabetic Foot disease, Kidney Disease and Neuropathy) or macro vascular (Stroke/Cerebral Vascular Accidents, Coronary Heart Disease and Peripheral Vascular Diseases) (IDF, 2013).

Risk Factors: A risk factor is any attribute, characteristic or exposure of an individual that increases their likelihood of developing a disease or injury (WHO, 2011). In this study, the diabetes risk factors are the modifiable (Obesity, physical inactivity and overeating), non-modifiable risk factors (Older age, family history, racial or ethnic origin) and possibly modifiable risk factors (history of hypertension or hypertension).

Screening: The process of identifying those individuals who are at sufficiently high risk of a specific disorder to warrant further investigation or direct action. It is systematically offered to a population of people who have not sought medical attention because of symptoms of the disease for which screening is being offered and is normally initiated by medical authorities and not by a patient's request for help because of a specific complaint. The purpose of screening is to benefit the individuals being screened (ADA, 2012a).

Newly Diagnosed: The term refers to confirmation of diabetes for the first time in people who have symptoms, or who have had a positive screening test. In the study, newly diagnosed will be type II diabetes patients diagnosed one year before the commencement of this study i.e. December 2013- December 2014.

CHAPTER TWO

LITERATURE REVIEW

2.1. Burden of Diabetes in Kenya

The international diabetes federation (IDF) estimates that 3.3% of Kenyans are living with diabetes. However, local studies have a higher estimate at 4.2% in the general population with a prevalence rate of 2.2% in the rural areas and 12.2% in urban areas (Christensen *et al.*, 2009). The reported prevalence is predicted to be lower than the real prevalence due to poor reporting and undiagnosed cases. In spite of this, the burden of diabetes is lower compared to its neighbors such as Tanzania with 1.7 million people living with diabetes and 1.9 million in Ethiopia (Hall *et al.*, 2011).

Diabetes has been identified as a priority issue in management of the growing burden of non-communicable diseases in Kenya. It has been featured in both Kenyan Government's National Medium Term Plan (2014-2018), health policy (2012 - 2030) and National Health Strategic Plan (2014-2018).

2.2. Diabetes Complications

The chronic diabetic complications are classified into macro vascular and micro vascular complications. Macro vascular complications include cardiovascular and cerebrovascular diseases such as infarction, stroke, peripheral vascular disease, hypertension and transient ischemic attack. On the other hand, micro vascular complications include neuropathy, retinopathy, nephropathy, skin ulcers, diabetic foot, amputation and diabetic dermopathy.

As shown in multiple studies, micro vascular complications are more prevalent than macro vascular complications. In one such multinational study fifty four per cent of chronic complications were micro vascular while 27.2% were macro vascular (Liu *et al.*, 2010). This is similar to a study in China where 33.7% of micro vascular and 33.4% of macro vascular

complications were identified. Similar, results have been seen in Pakistan, Kenya and Nigeria (Matheka *et al.*, 2013; Oyegbade *et al.*, 2007)

Diabetic patients have been found to present in hospital with at least one chronic complication. In one study conducted in China, Liu *et al.*(2010) found half of the patients having at least one complication while in another study in Pakistan 89.8% were found.((Liu *et al.*, 2010; Ali *et al.*, 2013a). Seventy two per cent had at least one complication (micro vascular or macro vascular) and 24% had both complications in the Cost of Diabetes in Europe –Type 2 study. (Massi-Benedetti and Board, 2002). Patients presented with more than one complication when diagnosed late (Kohner *et al.*, 1998).

2.3. Micro vascular Complications

Micro vascular complications such as neuropathy, retinopathy and nephropathy were found to be 13.15%, 6.1% and 1.06% respectively. Females had a higher prevalence (13.3, 6.4 and 1.17) of these complications compared to males (13, 5.8 and 0.96) (Sosale *et al.*, 2014).

Diabetic Neuropathy

Diabetic peripheral neuropathy is a common complication estimated to affect 30 to 50% of diabetic patients (Deli *et al.*, 2013). The prevalence of neuropathy vary across countries with 68.5% in Pakistan, 27.3% in Cameroon, 27.6% in South Africa, 13.2% in India, 17.8% in China and 44% in Nigeria (Osuji *et al.*, 2012; Tumbo and Kadima, 2013; Ali *et al.*, 2013a). Among newly diagnosed diabetic patients, the prevalence of diabetic neuropathy is 17.8%, 13.2% and 68.5% in China, India and Pakistan respectively.

Retinopathy

In a cross sectional study in China among the newly diagnosed diabetic patient, Liu and colleagues found a 4.8% prevalence of retinopathy (Liu *et al.*, 2010). This was almost similar to the findings by Heydari *et al.*(2010) in Pakistan who found the prevalence to be 6% of the respondents (Heydari *et al.*, 2010). However, Tumbo *et.al* (2013) and Thomas RL *et.al* (2013)

found the prevalence at 19.5% and 55.4% in hospital based studies (Tumbo JM and Kadima FN, 2013). Retinopathy is thus the most common micro vascular complication of diabetes in newly diagnosed patients.

Nephropathy

Diabetic nephropathy is one of the leading causes of chronic kidney disease and end-stage renal disease (Viswanathan *et al.*, 2012). Nephropathy was present in 20.2% of newly diagnosed diabetic patients (Sereday *et al.*, 2008). The prevalence was 1.06% in India, 1.11% in South Africa and 10.7% in China. In Pakistan, the prevalence was 56.2%, which is higher compared to other countries (Sereday *et al.*, 2008; Sosale *et al.*, 2014; Ali *et al.*, 2013a).

Diabetic Foot /Ulcers

Diabetic foot is the main chronic complication of diabetes affecting the foot. It is 20% prevalent in a South African Study (Kadima FN and Tumbo JM, 2013). However, it is 0.8% in China and 13% in Cameroon (Liu *et al.*, 2010; Chantal Nanfack *et al.*, 2012; Ndip EA, 2006).

2.4. Macro vascular Complications

Cardiovascular and cerebrovascular diseases are the main macro vascular complications. Cardiovascular diseases include hypertension, infarction, peripheral vascular disease and congestive heart failure. Cerebrovascular complications include stroke and transient ischemic attack (ADA, 2012a).

Cardiovascular conditions are more prevalent than cerebrovascular conditions. Cardiovascular complications contributed 30.1% compared to 6.5% in a study in China with similar results being reported in Pakistan and Mozambique (Hsu *et al.*, 2013; Liu *et al.*, 2010).

The prevalence of the cardiovascular conditions among newly diagnosed diabetic patients is also high. The prevalence of ischemic heart disease and hypertension were 6% and 23.3% respectively in chronic complications in India (CINDI) study in India. In Netherlands, the

prevalence of myocardial infarction, ischemic heart disease and peripheral vascular disease were 13.3%, 39.5% and 10.6% respectively (Spijkerman *et al.*, 2003b; Spijkerman *et al.*, 2004). Ischemic heart disease prevalence was high in Netherlands compared to India. In both studies, women had a high prevalence in comparison to men (8, 26.5, 31 and 27.6 versus 4, 25.5, 23 and 19) (Sosale *et al.*, 2014)

2.5. Risk Factors of Developing Complications

The risk factors of diabetes are classified as modifiable, non-modifiable and possibly modifiable risk factors (Kauffman, 2002). Modifiable risk factors include obesity, physical inactivity, and overeating. Non-modifiable risk factors include older age, racial or ethnic origin, family history and genetic predisposition while possibly modifiable risk factors include history of dyslipidemia and hypertension (Kauffman, 2012 & WHO, 2011).

Hyperglycemia is the primary risk factor with age, smoking, hypertension, elevated triglycerides, alcohol consumption, duration of the disease and higher BMI as secondary risk factors (Deli *et al.*, 2013).

Age and history of hypertension are some of the risk factors identified as contributing to development of chronic complications of diabetes (Heydari *et al.*, 2010; Liu *et al.*, 2010). Litwak *et al* (2013) identified duration of diabetes, low-density lipoprotein (LDL-C) and systolic blood pressure as the main risk factors while HDL-C was a protective factor (Litwak, 2013). Gender is another risk factor identified with more females than males having chronic complications. Thirty five per cent and 38.8% of females had at least one macro vascular and micro vascular complication respectively compare to 31.1% and 28.9% of males (Hsu *et al.*, 2013; Liu *et al.*, 2010).

Late diagnosis has been shown to increase complications by 14 events per 10,000 patients and reduce quality-adjusted life expectancy (QALE) by 2 years for every 1-year delay in diagnosis. Development of macro vascular complications – stroke and myocardial infarction

increased compared to micro vascular complication due to delayed diagnosis (Laiteerapong *et al.*, 2012).

Hyperglycemia is the primary risk factor with age, smoking, hypertension, elevated triglycerides, alcohol consumption, duration of the disease and higher BMI as secondary risk factors (Deli *et al.*, 2013).

2.6. Screening Practices

The World Health Organization refers to screening as “the process of identifying those individuals who are at sufficiently high risk of a specific disorder to warrant further investigation or direct action” (WHO, 2011). Screening for diabetes is an established practice in most countries. Studies have shown that screening is effective and thus justified for patients above the age of 40 years (Leiter *et al.*, 2001). International Society of Pediatrics and Adolescents Diabetes guideline (2009) also outlines the need to identify the targeted group carefully to achieve the maximum benefit (Kadima FN and JM, 2013). Screening helps to identify undiagnosed cases and complications early thereby reducing the burden of disability due to chronic complications.

Diabetes patients should undergo regular check-ups to screen for micro albumin, glycated hemoglobin, lipoproteins, blood pressure, distal symmetric polyneuropathy, and eye exam (Leiter *et al.*, 2001). The screening can either be population based or opportunistic. Opportunistic screening is conducted to all patients attending the clinic, while the population based screening targets the whole population or high risk groups within the population.

Screening has shown to be a cost-effective way of preventing chronic complication of diabetes (Oyegbade *et al.*, 2007; Tumbo and Kadima, 2013). Glycated hemoglobin (HbA1c) is the main indicator that is used in most studies on screening. Echouffo-Tcheugui *et al* (2012) found that 30% of non-fatal myocardial infarction and 12% of cardiovascular deaths were averted due to screening of the diabetes patients for complications (Echouffo-Tcheugui

et al., 2012). Massi-Benedetti (2002) also found screening to be cost effective since for every dollar spent on screening, 84 to 323 dollars are saved (Massi-Benedetti and Board, 2002).

Most diabetes patients do not undergo routine check-up in Kenya. Only 20.2% of diabetes patients had done the glycated hemoglobin (HbA1c) test at least once in Kenya with 79.8% never having done the test. This was despite 67.7% of them having heard about the test (Matheka *et al.*, 2013).

2.7. Conceptual Framework

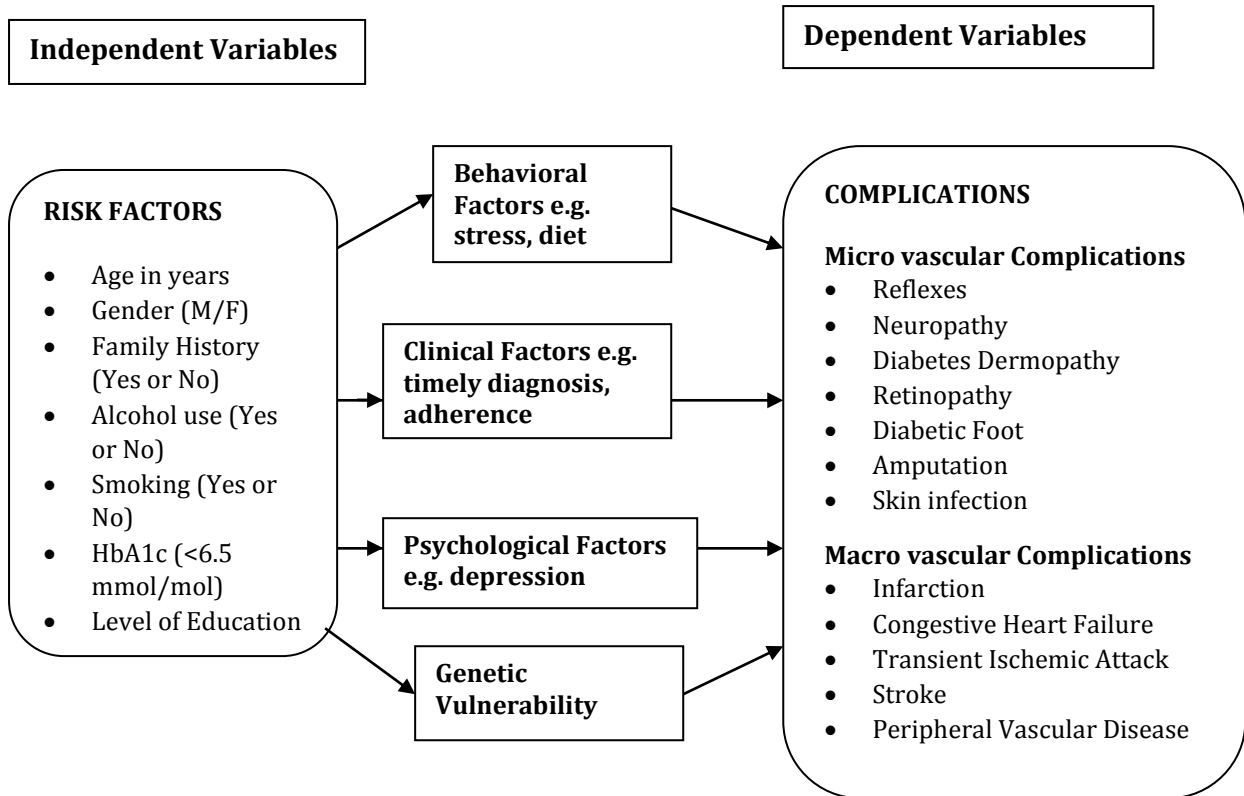


Figure 1 Conceptual Framework of Diabetic Complications and Related Risk Factors

(American Diabetes Association, 2000)

This study hypothesizes that diabetes complications are influenced by specific risk factors in individual respondents. Risk factors include socio-demographic and biological characteristics (Independent variables) and complications include micro vascular and macro vascular complications (Dependent/Outcome variables). It is assumed that respondents with specific risk factors are more likely to get specific complications. It is further assumed that with timely screening the risk factors can be controlled and therefore prevent development of complications.

CHAPTER THREE

METHODOLOGY

3.1. Study Site

The study was conducted at Kisii Level 6 Hospital (KL6H). KL6H is the main referral health facility for Kisii County. It has a catchment population of over a million people, mainly from the Abagusii ethnic community. It offers a variety of services ranging from the basic primary health services to complex referral services for kidney, cardiac and other services.

Kisii County is in the Western region of Kenya. It is one of the most populated counties in Kenya with a population of 900,000 people mainly living in the rural area.

3.2. Study Design

The study adopted a cross-sectional hospital based survey. The cross sectional study design entailed collection of information on the individual study parameters at a single point in time between August and December 2014. It provides a basis of describing the status of phenomena at a fixed point in time and does not allow for inference of changes and trends of the same over time.

3.3. Study Population

These were newly diagnosed type 2 diabetes patients, above 18 years of age attending the diabetes outpatient clinic at Kisii Level 6 hospital who gave informed written consent to participate in the study

3.4. Sampling Techniques and Sample Size

3.4.1 Sampling Techniques

Simple random sampling was used to select the required sample size of 100 patients among 137 patients. A list of outpatient numbers for all the newly diagnosed patients was extracted from the files and random numbers assigned to the patients. The numbers were written in small pieces of paper and folded. They were then put together and two of the research assistants randomly picked a paper from the pool. The patients selected were then contacted

and recruited into the study. However, 16 patients didn't meet the inclusion criteria as they did not give an informed written consent thus only 84 patients were included in the study.

3.4.2 Sample Size

The sample size was calculated using Fischer's formula (Mugenda and Mugenda, 1999); $n = [Z^2 (PQ)]/d^2$

Where:

N is the desired sample size

Z is the standard normal deviate (score), set at 1.96; which corresponds to 95% level of significance.

P is the proportion of the target population estimated to have a particular characteristic. In this case, 7 % was used. This was arrived at by calculating the percentage of the newly diagnosed Type 2 diabetes patients out of the total number (both new and old) patients seen at the Diabetes Out-patient Clinic between March 2013 and March 2014.

Total number of patients seen = 1958

Number of newly diagnosed = 137

Therefore P = $137 / 1958 \times 100 = 7\%$

Q is 1-p

D is the degree of accuracy desired, set as 0.05.

Substituting the figures in the formula,

$N = [(1.96)^2 \times (0.07 \times 0.93)] / 0.05^2$

N = 100

3.5. Inclusion Criteria

The respondents included:

- Were type 2 diabetes patients diagnosed within one year prior to the commencement of the study (December 2013 – December 2014)

- Were attending the diabetes outpatient clinic at Kisii Level 5 hospital
- Gave informed written consent to participate in the study

3.6. Exclusion Criteria

The study excluded respondents who:

- Were diagnosed more than a year prior to the study
- Were not attending the diabetes outpatient clinic at Kisii Level 6 hospital
- Did not give informed written consent to participate in the study

3.7. Data Collection Tools and Techniques

Data was collected using a researcher-administered questionnaire. The questionnaire had four parts: demographic variables, physical examination, clinical tests and the screening practices section. The physical examinations were conducted and documented by trained and qualified research assistants (2 clinical officers and 2 nurses). It included Body Mass Index (BMI), blood pressure both in supine and sitting positions and neurological examination. The patients were referred to an ophthalmologist for fundoscopy, history of cerebrovascular accident (CVA), its signs and symptoms were also documented and HbA1C test done for all the patients. Sensory deficits were evaluated by means of a tuning fork and fixed monofilament test to exclude diabetic foot. Patients were also examined for diabetic dermopathy and skin infections.

A pilot study was conducted at Awendo District hospital that is located within the same geographical location and share similarities with the Kisii Teaching and Referral Hospital. The data collection tools were modified to ensure reliability of the data.

All the questionnaires were scrutinized for errors, omissions, and inconsistencies and data entered into STATA 13 for statistical analysis.

3.8. Data Analysis

Descriptive statistics including mean, frequencies and simple percentages were computed for continuous and categorical variables. Chi-square test was used in analysis of categorical variables to test for associations between independent and dependent variables of the subjects. Level of significance set at $p < 0.05$. Data is presented in graphs, tables and pie charts.

3.9. Ethical Considerations

Approval for the study was obtained from the Jaramogi Oginga Odinga Teaching and Referral Hospital-Ethics and Review Committee (JOTRH-ERC) through the dean school of health sciences. Consent and authorization was also obtained from the Department of Research, Kisii Teaching and Referral Hospital. An informed written consent was further obtained from the study respondents before interviewing them. The respondents were free to withdraw from the study at any point. Completed questionnaires were kept in a locked cabinet accessed by the investigator only.

CHAPTER FOUR

RESULTS

4.1. Socio-demographic and Biological Characteristics of the Respondents

Eighty-four respondents were interviewed. Fifty seven per cent (57.1%: n=48) of them were female with 43% (42.9%: n=36) being male. Table 1 illustrates the socio-demographic characteristics of the respondents. Most of the respondents (77.4%, n=65) were married and only 7% were single. Sixty two per cent of respondents had tertiary or secondary level of education. Only 2.4% of the respondents smoked while 27% used alcohol. Male respondents smoked and used alcohol more than female respondents (5.7% and 41.7% respectively compared to 2.4% and 27.1% for females). Table 2 illustrates the biological characteristics of the respondents. As seen in Figure 1 seventy two per cent of the respondents used oral medication for management of their diabetes while only 4.7% used both oral medication and insulin. Only thirty eight per cent of the respondents had abnormal HbA1c level.

4.2. Prevalence of Diabetes Complications

Eighty two per cent (82.6%; n=69) of the respondents had at least one diabetic complication on diagnosis. Micro vascular complications were more prevalent with neuropathy, monofilament neuropathy and retinopathy leading. Table 3 shows the prevalence of diabetic complications among the respondents. Neuropathy (58.3%), monofilaments neuropathy (57.2%), retinopathy (47.6%) and elevated blood pressure (42.9%) were the most prevalent complications among the newly diagnosed diabetes patients. Amputation (1.19%), myocardial infarction (2.4%), cardiac heart failure (3.6%), TIA (3.6%) and Diabetic dermopathy (3.6%) were the least prevalent complications. Eye-related (47.6%), neurological (35.1%) and foot-related (21.0%) complications were the most prevalent with cardiovascular (10.0%) and skin-related (4.8%) complications being the least prevalent. Only seventeen per cent (17.4%; n=15) of the respondents had no diabetic complication on diagnosis.

Table 1 Socio-demographic Characteristic of the Respondents

Characteristics	Male		Female		Total
	Frequency n=36	Percentage (%)	Frequency n=48	Percentage (%)	Percentage (n=84; %)
Age					
18 – 24 years	1	2.8	0	0.0	1.2
25 – 34 years	3	8.3	5	10.4	9.4
35 – 44 years	11	30.6	16	33.3	31.8
45 years and above	21	58.3	27	56.3	57.7
Marital Status					
Single	4	11.1	2	4.2	7.1
Married	29	80.6	36	75.0	77.6
Divorced	1	2.8	2	4.2	3.5
Widowed	2	5.6	8	16.6	11.8
Level of Education					
None	0	0.0	3	6.3	3.5
Primary	13	36.1	16	33.3	34.1
Secondary	7	19.4	15	31.2	25.9
Tertiary	16	44.4	14	29.2	36.5
Smoking					
Yes	2	5.7	0	0	2.4
No	34	94.3	48	100	97.6
Alcohol					
Yes	15	41.7	7	14.6	27.1
No	21	58.3	41	85.4	72.9

Table 2 Biological Characteristics of the Respondents

Characteristics	Male		Female		Total
	Frequency n=36	Percentage (%)	Frequency n=48	Percentage (%)	Percentage (n=84; %)
Treatment of Diabetes					
Oral	23	63.9	37	77.1	71.8
Insulin	11	30.6	9	18.7	23.5
Both	2	5.5	2	4.2	4.7
Family History					
Yes	5	86.1	13	27.1	15.3
No	31	13.9	35	72.9	84.7
HbA1c Levels					
Normal	18	50.0	33	68.7	61.2
Abnormal	18	50.0	15	31.3	38.1

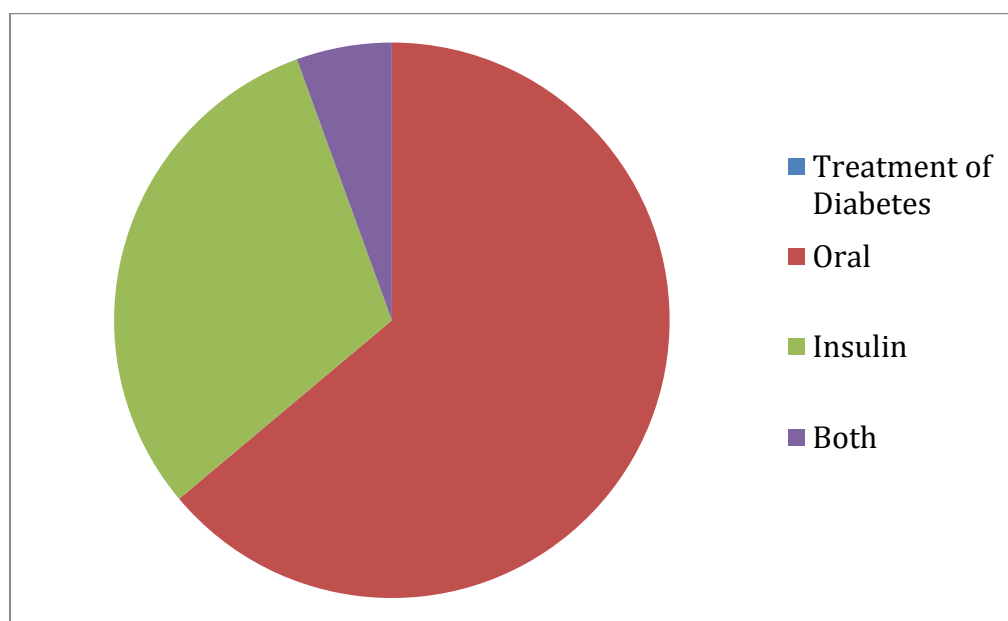


Figure 2 Treatment of Diabetes among the Respondents

Table 3 Prevalence of Diabetes Complications

Complications	Frequency (n=84)	Percentage (%)
Macro vascular:		
Cardiovascular System		
Infarction	2	2.38
Cardiac Heart Failure (CHF)	3	3.57
Transient Ischemic Attack (TIA)	3	3.57
Angina	5	5.95
Peripheral Vascular Disease	5	5.95
Stroke	5	5.95
Elevated Blood Pressure (BP)	36	42.86
Micro vascular:		
Neurological		
Reflexes	10	12.05
Neuropathy	49	58.33
Foot		
Amputation	1	1.19
Diabetic Foot	4	4.76
Monofilaments Neuropathy	48	57.14
Skin		
Diabetes Dermopathy	3	3.57
Skin Infection	5	5.95
Eyes / Vision		
Retinopathy Fundoscopy	40	47.62

Note: Elevated Blood Pressure - >130/90 mmHg

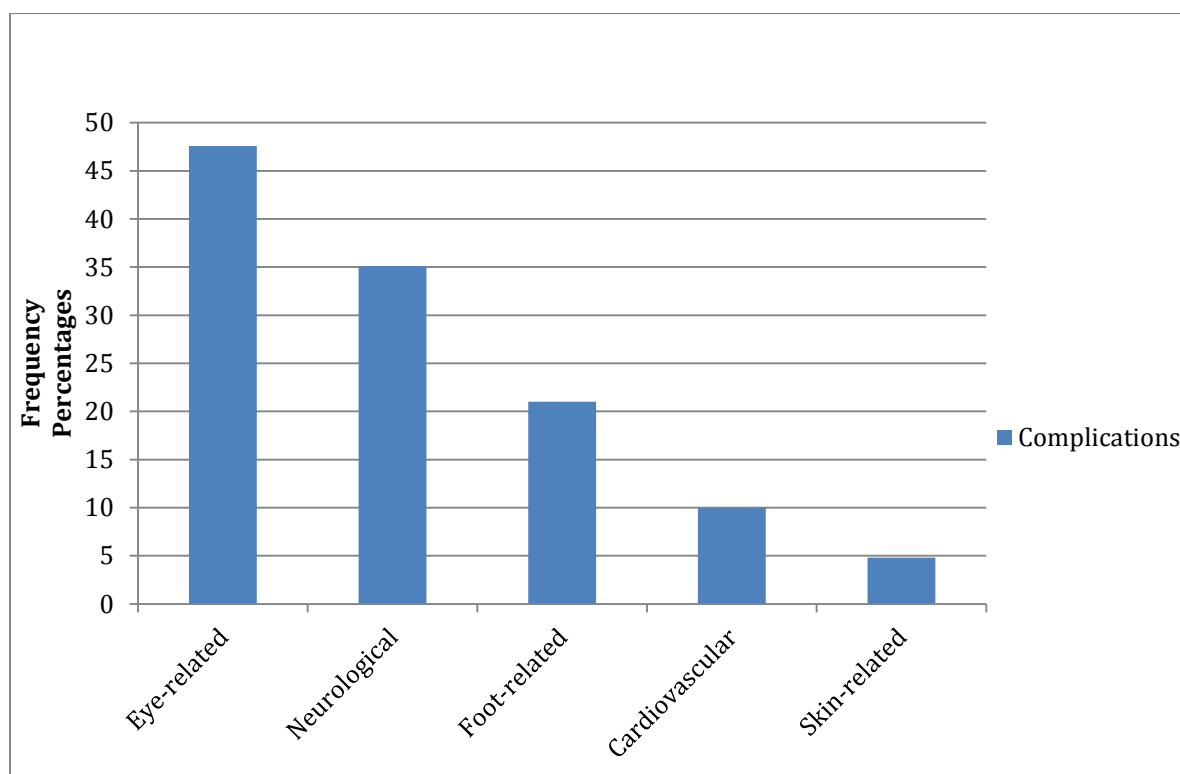


Figure 3 Prevalence of Diabetes Complications among the Respondents

4.3. Risk Factors among the Newly Diagnosed Type 2 Diabetes Patients

Table 4 illustrates the association between risk factors and complications in the respondents.

The level of education ($p=0.014$) and mode of treatment ($p=0.048$) were significantly associated with cardiac heart failure and transient ischemic attack respectively. Diabetes dermopathy was significantly associated with the mode of treatment ($p=0.048$) with skin infection being strongly associated with mode of treatment ($p=0.001$).

The level of HbA1c in the body had a significant relationship with both reflexes ($p=0.006$) and neuropathy ($p=0.001$). Neuropathy is also significantly associated with level of education ($p=0.015$). Stroke was significantly associated with the level of education ($p=0.015$) while retinopathy was related to alcohol use ($p=0.025$) and level of HbA1c ($p=0.003$). Monofilaments neuropathy was significantly associated with gender ($p=0.042$) as was elevated blood pressure ($p=0.048$), Monofilament neuropathy was also significantly associated with level of education ($p=0.046$) and level of HbA1c ($p=0.001$).

However, no risk factors were significantly associated with amputation, infarction, diabetic foot and angina

Table 4 Risk Factors among Newly Diagnosed Type 2 Diabetes Patients

Risk Factors	Complications	P-value(<0.05)
Level of education -None* -Primary* -Secondary -Tertiary	Cardiac Heart Failure(CHF)	0.014
	Neuropathy	0.015
	Stroke	0.015
	Monofilaments Neuropathy	0.046
Mode of treatment -Oral* -Insulin -Both	Skin Infections	0.001
	Diabetic Dermopathy	0.048
	Cardiac Heart Failure(CHF)	0.048
Level of HbA1c ->6.5 mmol/mol* -<6.5 mmol/mol	Monofilament Neuropathy	0.001
	Neuropathy	0.001
	Retinopathy	0.003
	Reflexes	0.006
Gender -Female* -Male	Monofilaments Neuropathy	0.042
	Elevated Blood Pressure(BP)	0.048
Alcohol Use	Retinopathy	0.025

*NB: The variables marked with * were the main risk factors of developing diabetic complications.*

4.4. Screening Practices of Diabetes Patients

Most of the diabetes patients were not used to routine check up for their illness. Health providers initiated the testing of the blood sugars for 74.1% of the newly diagnosed patients. The rest of the patients were diagnosed during routine medical check up (15.3%, n=13) and during mass screening (10.6%, n=9) in schools and other public places.

A majority of the newly diagnosed patients (56%, n=47) have had their HbA1c checked only once within 12 months with 41.7% (n=35) having never checked their HbA1c levels. Only 2.4% (n=2) of the patients checked their HbA1c every 3 or 6 months.

Similar to the HbA1c testing, most of the patients do not frequently check their low-density lipoproteins (LDL) and high-density lipoproteins (HDL) level. 34.1% (n=29) check theirs yearly while 42.4% (n=36) have never checked their LDL and HDL level with 23.5% (n=20) checking a long time ago.

Ninety one per cent (90.6%, n=77; 1.2%; n=1; 8.24%, n=6) of the patients had never undergone dental checkup with only 1.2% having undergone the check-up yearly and 8.24% going a long time ago. Only 11.76% (n=10) have undergone the recommended yearly eye check up with 57.6 % (n=49) and 30.6% (n=26) having undergone the checkup longtime ago and never respectively.

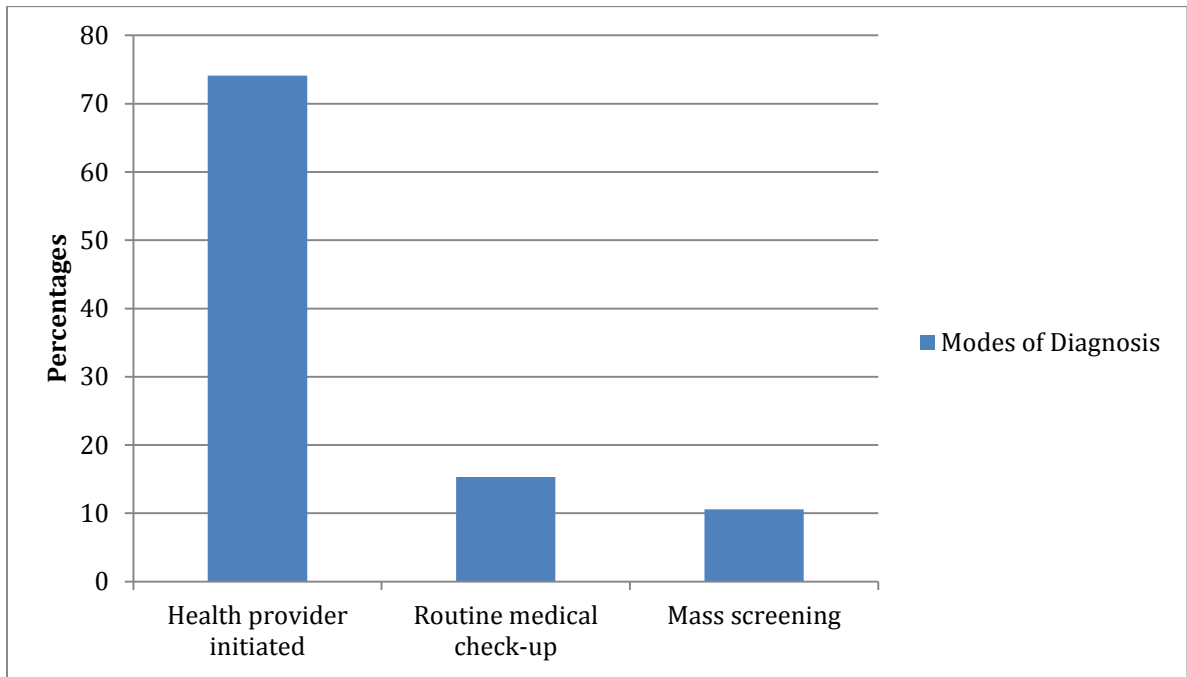


Figure 4 Modes of Diagnosis among the Respondents

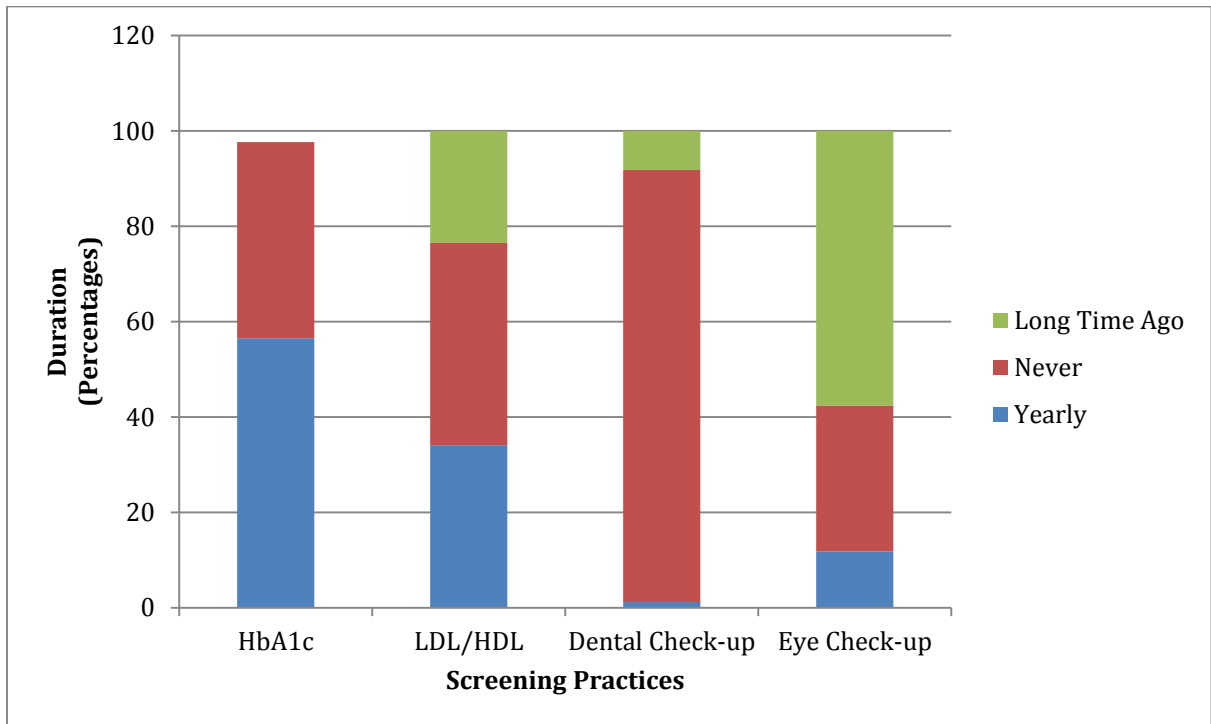


Figure 5 Screening Practices among the Respondents

CHAPTER FIVE

DISCUSSION

This study examined most of the macro vascular and micro vascular complications of diabetes among newly diagnosed diabetic patients. The study confirmed the finding of similar studies where newly diagnosed patients presented with one or more complications (Liu *et al.*, 2010). This is an indication of late diagnosis of diabetes in Kenya especially in the rural areas. The findings also indicate that neuropathy (58.3%), monofilaments neuropathy (57.2%), retinopathy (47.6%) and elevated blood pressure (42.9%) were the most prevalent complications among the newly diagnosed diabetes patients as is the case in previous studies (Spijkerman *et al.*, 2003a; Liu *et al.*, 2010; Spijkerman *et al.*, 2004; Marshall and Flyvbjerg, 2006; Tumbo and Kadima, 2013). This reflects the general pattern of diabetic complications among newly diagnosed diabetic patients where micro vascular complications are more prevalent than the macro vascular complications. It also indicates hypertension as the most prevalent macro vascular complication, contrary to finding of other studies where angina was the most prevalent cardiovascular complication (Liu *et al.*, 2010). However, as found in other studies, neuropathy and retinopathy are the most prevalent micro vascular complications (Marshall and Flyvbjerg, 2006; Tumbo and Kadima, 2013).

The least prevalent complications were amputation (1.2%), myocardial infarction (2.4%), cardiac heart failure (3.6%), Transient Ischemic Attack (3.6%) and diabetic dermopathy (3.6%). This differed with studies in India and China, which reported a high prevalence of myocardial infarction and ischemic disease (Sosale *et al.*, 2014; Osuji *et al.*, 2012; Viswanathan *et al.*, 2012). This may be due to the small sample size used in this study, however, in Pakistan a similar lower prevalence of myocardial infarction was noted (Ali *et al.*, 2013a). Complications of the foot and skin were generally low compared to most studies (Kengne *et al.*, 2005; Ndip EA, 2006). Amputation was the least due to it being a common

complication of late stage of diabetes thus could not be very evident in most newly diagnosed diabetic patients.

The study found that the high levels of glycated hemoglobin (hyperglycemia), low level of education, mode of treatment (orals), alcohol use and female gender were the main risk factors of developing diabetic complications. These are among the most common risk factors identified by other studies (Ndip EA, 2006; Sosale *et al.*, 2014; Teimouri *et al.*, 2014; Donaghue *et al.*, 2009; Kim *et al.*, 2011; Viswanathan *et al.*, 2012). However, studies have also identified high blood pressure as a risk factor whereas we treated it only as a complication (Sosale *et al.*, 2014; Osuji *et al.*, 2012). Most of the risk factors were related directly to late diagnosis. Studies have found low level of education and female gender as factors for poor health seeking behavior (Teimouri *et al.*, 2014; Rathmann *et al.*, 2013). In this study, both low level of education and female gender have been shown to be risk factors for developing complications in newly diagnosed diabetes patients. This can be attributed to either delay in diagnosis or to poor compliance to the prescribed treatment. With this knowledge, screening strategies could be developed with a special focus on these groups of patients.

Health providers initiated diabetic screening in most of diabetic patients in the study. Still, only 56% had undergone the glycated hemoglobin (HbA1c) test within a year of diagnosis, however that is higher than the 20.2% screening rate in Kenya (Matheka *et al.*, 2013). This could be attributed to high cost of the test or lack or low level of education or awareness which is already identified as a risk factor (Leiter *et al.*, 2001). Similarly, most patients were not being screened using other tests for example lipid profiles, which could help diagnose complications. Only, 34.1% and 42.4% check their Low-density lipoproteins (LDL) and high-density lipoproteins (HDL) yearly respectively. Moreover, most newly diagnosed diabetic patients do not undergo routine medical, eye and dental check-up. Failure to undergo regular

check-up may lead the patients to present with preventable complications. This could explain the high rate of neuropathy and retinopathy among the respondents. Screening has been established to be cost effective for high-risk groups and could help identify and manage diabetes and its complications early.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1. Conclusion

The study found that the prevalence of at least one diabetic complication among newly diagnosed diabetes patients vary from 1.2 to 58.3%. Neuropathy, monofilaments neuropathy, retinopathy and elevated blood pressure were the most prevalent complications while amputation, myocardial infarction, cardiac heart failure, transient ischemic attack and diabetic dermopathy were the least prevalent respectively among the newly diagnosed diabetes patients. Eye-related (47.6%), neurological (35.1%) and foot-related (21.0%) complications were the most prevalent with cardiovascular (10.0%) and skin-related (4.8%) complications being the least prevalent

On the other hand, the level of education, female gender, alcohol consumption, mode of diabetic treatment, high level of glycated hemoglobin were the risk factors for most of the diabetic complications. Level of education was a key risk factor in three complications – stroke, neuropathy and monofilaments neuropathy while high glycated hemoglobin was a risk factor for reflexes, neuropathy, retinopathy and monofilament neuropathy.

Most of the newly diagnosed patients had good screening practices. However, only half of them had done the glycated hemoglobin test with even fewer checking their low-density lipoproteins (LDL) and high-density lipoproteins (HDL) level respectively or undergoing routine eye or dental check-up. In addition, the health care providers initiated most of the screening.

6.2. Recommendations

Based on the findings of the study, the following are recommended:

1. Need for more funding to enable more studies on non-communicable diseases especially diabetes to be carried out in Kenya e.g. cohort or case-control studies with larger sample sizes.
2. There is a need to develop policy that will increase screening of diabetes in high-risk groups particularly at community level so as to identify the patients early before onset of complications.
3. Diabetes awareness should also be enhanced to encourage more people to know their diabetic status and the associated complications plus treatment options so as to address it early if they have it or live healthy if they do not have it.
4. In addition, other strategies such as group counseling of diabetic patients should be explored to increase their knowledge on complications of diabetes and associated risk factors as well as provide social support to manage diabetes effectively.
5. Lastly, health care workers should continue providing diabetes information and screening high-risk groups patients.

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APPENDIXES

Appendix 1: Respondents' Information Leaflet

Hello. My name is.....

I am conducting a research on the role of peer support in management of diabetes. I would very much appreciate your participation in this research.

The interview will take between 20 minutes to complete. Whatever information you provide will be kept confidential and will not be shared with anyone other than members of our research team.

Your participation in this research is voluntary, and if I come to any question you are not comfortable in answering, please let me know and I will move on to the next question; or you can stop the interview at any time. However, I hope that you will participate in this research since your views are important.

At this time, do you want to ask me anything about the research?

Signature of interviewer:**Date:**.....

Appendix 2: The Questionnaire

Serial Number:

Received Consent:

“Prevalence of Diabetes Complications among Newly Diagnosed Type 2 Diabetes Patients at Kisii Teaching and Referral Hospital.”

Section 1: Demographic Data

1. What is your age (in years)?
 - a) 18 – 24 years
 - b) 25 – 34 years
 - c) 35 – 44 years
 - d) 45 and above
2. What is your gender?
 - a) Male
 - b) Female
3. What is your current marital status?
 - a) Single/ Engaged
 - b) Married
 - c) Divorced/Separated
 - d) Widowed
4. What is the highest level of education attained?
 - a) None
 - b) Primary
 - c) Secondary
 - d) Tertiary
5. What treatment are you using currently?
 - a) Oral anti-diabetic agents
 - b) Insulin
 - c) Both
6. Do you smoke?
 - a) Yes
 - b) No
7. If yes, for how many years? Number of Years:.....
8. Have you ever taken alcohol?
 - a) Yes
 - b) No
9. If yes, for how many years? Number of Years:.....
10. Does anyone in your family have diabetes?
 - a) Yes
 - b) No

Section 2: Physical Examination

	System/Organ	Standard Normal Ranges	Normal Result (√)	Abnormal Result (√)
11	Cardiovascular System			
	Blood Pressure	<130/90 mmHg		
	Angina			
	Chronic Heart Failure			

	Infarction			
	Peripheral Vascular Disease			
	Stroke			
	Transient Ischemic Attack			
12	Neurological			
	Neuropathy	Tuning Fork / Monofilament		
	Reflexes			
13	Skin			
	Diabetic Dermopathy			
	Skin Infection			
14	Foot			
	Neuropathy (Monofilament)			
	Amputation			
	Diabetic Foot			
	Retinopathy			
	Fundoscopy			

Section 3: Clinical Tests

	Clinical Test	Normal Ranges	Normal Result (√)	Abnormal Result (√)
15	HbA1c Test			

Section 4: Screening Practices

16. How were you diagnosed with diabetes?
- During medical routine check-up?
 - Provider Initiated?
 - Mass screening
 - Information on Diabetes from the media (Radio, Television)
17. How often do you have your HbA1c checked? Every:
- 3 Months
 - 6 Months
 - 1 year
 - Never
18. How often do you have Low Density Lipoprotein and High Density Lipoproteins checked?
- Yearly
 - Years
 - Never
19. How often do you have your eyes checked?
- Yearly?
 - Other?
 - Never?
20. How often do you have a dental checkup? Every:
- 6 Months
 - 1 Year
 - Never

Appendix 3: Ethical Approval



MINISTRY OF HEALTH

Telegrams: "MEDICAL", Kisumu
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KISUMU

P/1/VOL.XIV /234

29th Jan, 2016

Ref:

Date

PI..... Dr. Maureen Muyodi Musundi

JOOTRH.

Dear Maureen Musundi,

**RE: FORMAL APPROVAL TO CONDUCT A STUDY ENTITLED: "DIABETIC
COMPLICATIONS AND RISK FACTORS IN RECENTLY DIAGNOSED TYPE 2
DIABETICS IN KISII COUNTY"**

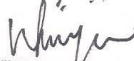
The JOOTRH ERC (ACCREDITATION NO. 01713) has reviewed your article on above subject and granted permission for the study to be conducted Kisii County. You are therefore, permitted to commence your study immediately.

Also note that you will be required to notify the committee of any amendment(s), serious or unexpected outcomes related to the conduct of the study or termination for any reason.

Finally, note that you will also be required to share the findings of the study with us in both hard and soft copies upon completion.

The JOOTRH ERC takes this opportunity to thank you for choosing the institution for review of your protocol and wishes you the best in your endeavours.


Yours sincerely,


MAKUNDA W. NANCY,
For: SECRETARY - ERC,
JOOTRH - KISUMU.



Appendix 4: Data Collection Approval

MINISTRY OF HEALTH



Telegramme "medical" Kisii
Telephone: (058) 31310 Kisii
Email: kisiihospital@gmail.com
Web: www.kisiihospital.org.ke

DEPARTMENT OF RESEARCH
THE KISII TEACHING & REFERRAL HOSPITAL
P.O. BOX 92
KISII

REF. NO. _____ DATE: 11th November, 2014

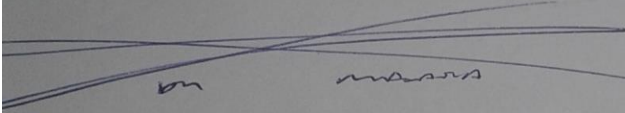
MAUREEN MUYODI

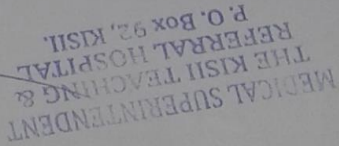
RE: DATA COLLECTION

This is to inform you that the department of research at Kisii Teaching and Referral Hospital has reviewed your proposal titled "prevalence of diabetes complications among newly diagnosed type 2 diabetes patients at Kisii Level 6 Hospital."

The following are our comments.

- 1) You have been authorized to proceed with data collection.
- 2) Ensure your research is for academic purpose only.
- 3) Ensure a copy of the final report is submitted to this office for retention and use.


DR. E. B. MASANTA
DEPARTMENT OF RESEARCH
KISII TEACHING & REFERRAL HOSPITAL


MEDICAL SUPERINTENDENT
THE KISII TEACHING &
REFERRAL HOSPITAL
P. O. Box 92, KISII.