ASSESSMENT OF THE PERCEIVED HEALTH RELATED QUALITY OF LIFE OF NON-INSULIN DEPENDENT TYPE 2 DIABETIC PATIENTS ATTENDING THE DIABETES CLINIC IN KENYATTA NATIONAL HOSPITAL

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DISERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTERS OF MEDICINE (INTERNAL MEDICINE) OF THE UNIVERSITY OF NAIROBI

DECLARATION

This Dissertation is my original work and has not been presented for a degree at any other university.

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DEDICATION

To the alleviation of pain and suffering, and the improvement of quality of life in patients with diabetes

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LIST OF ABBREVIATIONS

ADA- American Diabetes Association

DM- Diabetes mellitus

DCCT- Diabetes control and complication trial

GP-General Practioner

HbA1C- Glycated hemoglobin

HRQoL- Health related quality of life

KNH- Kenyatta National Hospital

NIDT2DM- Non insulin dependent type2 diabetes

QoL- Quality of life

RCT- Randomized control trial

UKMPDS- United Kingdom Prospective Diabetes Group

WHO-QoL- World Health Organization quality of life

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Abstract

BACKGROUND*:* Diabetes Mellitus is a common and demanding health related problem that has a wide effect on every day's life of the patients. It can have a profound effect on quality of life in terms of social and psychological well-being as well as physical ill-health. It is one of the most psychologically demanding of the chronic diseases; with psychosocial factors pertinent to nearly every aspect of the disease and its treatment.

OBJECTIVE*:* To Assess the perceived Health-related quality of life of diabetic patients not on insulin therapy using the WHOQoL-Bref (World Health Organization Quality of Life – Brief).

STUDY DESIGN: This was a cross-sectional study.

STUDY SITE: The study was conducted on patients attending the diabetic clinic at Kenyatta National Hospital.

RESULTS*:* Study recruited 139 patients with type2 diabetes not on insulin therapy. The study population was predominantly female (61%) , majority were 40-60yrs, having had diabetes for less than 5yrs, 75% having more than one complication. Most (75%) of the study participants were poorly controlled with HbA1C mean score of 8.04% .Majority of the study participants(84%) achieved a good score on the HRQoL scale using the WHOQoL-BREF tool. The determinants of HRQoL in our study were: age of study participants, duration of diabetes, presence of complications and income related factors. Age of the study subjects had significant association only in the social domain of HRQoL with a p-value of 0.037. Level of income had a significant association with overall HRQoL score (p-value of 0.029), psychological domain (p value of 0.023) and in the social domain (p-value of 0.029). Health care financing was significantly associated with psychological domain (p-value 0.006) and environmental domain (p-value 0f 0.04) and overall score (p-value 0.011). There was an association between employment status and HRQoL.

Having a job improved the scores in physical domain (p-value of 0.013) and social domain (p value of 0.020). Duration with diabetes had significant association with physical domain where the p value was 0.007. The HRQoL of the study subjects was associated significantly with the number of complications. Indeed the association of complications with the HRQoL involved physical domain (p-value of <0.0001) and psychological domain (p-value of 0.041) which directly impacted on the overall total score (p value of 0.041).

CONCLUSION: The results of this study show that diabetes affected HRQoL of our study participants. There is a need for interventions programs to improve glycemic control and inclusion of HRQoL assessment as part of patients on follow up. Age and duration of disease are not modifiable but complications can be reduced by better health care initiaves. Income-related factors can be modifiable through poverty alleviation and pooled health care financing.

Chapter 1: INTRODUCTION AND PROBLEM STATEMENT

1.1 DIABETES AND HRQOL

Diabetes Mellitus is a common and demanding health problem that has a wide effect on every day's life of the patients[1]. Diabetes mellitus is a chronic illness and the most common endocrine disease, although the disease is worldwide, there is significant difference in frequency among countries [2, 3]. It is a major public health problem for both developed and developing countries[4]. The increasing number of individual with type 2 diabetes indicates a global epidemic. Prevalence of the disease was estimated to be 2.8% in 2000 and is predicted to increase to 4.4% by the year 2030 worldwide.[5] In United States, more than 13.8 million individuals have diabetes and Type 2 diabetes accounts for 90% to 95% of the diagnosed cases with 800,000 new cases reported each year[6] .In Africa, the traditional rural communities still have low prevalence of 1-2% (except in specific high risk groups) while 1-13% or more adults in urban communities have diabetes. Nigeria has 7% of its population with diabetes[7, 8]. Kenya has an estimated prevalence of between 3.3% (Kenya Diabetes Study Group 2011). The prevalence of diabetes is rising in Africa and the Third world countries due to adaptation of the western lifestyle and diet[7]. Diabetes can have a profound effect on quality of life in terms of social and psychological well-being as well as physical ill-health. It is one of the most psychologically demanding chronic diseases; with psychosocial factors pertinent to nearly every aspect of the disease and its treatment[6].

In a longitudinal study the psychosocial impact of diabetes was found to be one of the five strongest predictors of mortality in diabetic patients, stronger than many clinical and physiological variables[9]. Following diagnosis many patients experience psychological problems including social

withdrawal, depression and anxiety. As the disease progresses psychosocial problems often occur secondary to the onset of complications, although several studies have reported an increased prevalence of depression and anxiety among patients irrespective of the presence of complications or loss of function[10]. Not just the disease but the treatment itself can exert a strong influence on quality of life. The control of symptoms of high blood sugar involves a prescriptive routine of diet, exercise, self-monitoring of blood and self-medication which imposes restrictions on patients' quality of life as it often does [11]. A variety of instruments has been used to measure HRQoL in type 2 diabetics including generic and diabetes-specific measures as well as assessments of functional status and psychological well-being. Generic HRQoL measures provide valuable information about the health status of patients with diabetes. It allows comparisons with other populations and chronic diseases groups. Using these measures, investigators have evaluated the association of HRQoL with multiple factors such as glycaemic control, types of treatment, numbers and types of complications and co morbid conditions, and demographic variables[13.]

1.2 THE CONCEPT OF DIABETES QOL ASSESMENT

QoL is a holistic concept which addresses many aspects of health. It has been defined by WHO as '*an individual's perception of their position in life in the context of culture and value system in which they live and relation to their goals, expectations, standards, and concerns*[12]. Assessing patients' quality of life has numerous benefits. It allows health care providers and researchers to better understand what aspects of the illness and treatment the patient views as having the greatest impact on their quality of life. It may also be found that the quality of life outcomes of a particular therapy outweighs its potential benefits. Quality of life effects of various diabetes treatments may impact health care sustaining activities of patients and the process of decision-making by health care providers. Understanding quality of life may also be useful in

communicating to patients about expectations on the impact treatment has on quality of life[15] Financial, social and psychological handicaps are integral to all chronic diseases, but diabetes differs in two important respects [13]. In the first place, although it affects virtually every aspect of everyday life to a greater or lesser degree, the patient is encouraged to lead a "normal life" without any of the concessions usually made to a person with chronic illness. Secondly, although the treatment is demanding and often complex, the patient is expected to bear much of the responsibility for making decisions which may affect his health, both in the short and long term. This burden is absent in most other chronic illnesses, even in those which are equally invisible, such as epilepsy and mental illness[14.] With chronic diseases claiming more lives than other types of diseases, effective strategies need to be developed and action plans formulated to help the affected. The present study seeks to increase our knowledge of the impact of diabetes on patients' physical, mental, and social wellbeing using the QoL concept. This concept is defined by WHO as an individual's perception of their position in life in the context of culture and value system in which they live and the relation to their goals, expectations, standards, and concerns.It is seen as a holistic concept which addresses many aspects of health. It broadly encompasses how an individual measures the goodness of multiple aspects of their life including emotional reactions to life occurrences, disposition, sense of life fulfilment and satisfaction, and satisfaction with work and personal relationships[13].There is general quality of life measures as well as disease-specific and complication-specific instruments[15]. The Patient-Reported Outcomes and Quality of Life Instrument Database is an international comprehensive data base for quality of life measures that currently includes 470 measurement instruments[16]. Quality of life measurement is subjective because of individuals' differing values and ideas regarding quality of

life. It has also been found that family, friends and health care providers are often poor judges of a patient's self-reported quality of life[15]

2 LITERATURE REVIEW

2.1 BACKGROUND

Diabetes is associated with a major burden of physical and psychological disability which are likely to substantially impair the quality of life (QoL) of the patients. Besides acute and chronic complications, quality of life in diabetic patients appears to be related to demographic, medical-historical, and Self-management factors. Self-perceived QoL is an important concept in assessing the level of metabolic control and health services given to the diabetic patients. Previous research indicated that, the level of socio-demographic status for example less formal education, lower income, marital dissatisfaction, cognitive representation of illness (e.g., understanding, consequences, cause, time-line, controllability), diabetes-specific health behaviors like diet and exercise and depression and anxiety , as well as glycemic control affect the perceived quality of life in diabetes patients [17-25].

Several studies have been undertaken to address issues of HRQoL from DCCT [16] to Bradley C and Rose M et al [27, 28] .Within these studies several health related questionnaires have been developed, to study health-related outcomes such as depression, social functioning, marital status, physical functioning and other psychological variables thought to be associated with diabetes. The questionnaires that have been used in these studies don not necessarily focus on all these aspects but may have been designed to investigate one or more of these features.

Generally the different studies on HRQoL have had variable results for example Gafvel et al found that patients with diabetes more frequently lived alone, remained childless, had more negative impact in women, participate in fewer social activities and had less satisfaction when compared to the controls [29]. Mayou et al and Hanasted reported that majority of diabetic patients experience

higher degree of well-being, satisfaction and enjoyment although a minority noted that diabetes had negatively affected various aspects of their lives [11, 30 and 31.] Mayou et al also showed no difference in HRQoL amongst patients on treatment for diabetes with diet, insulin analogues and oral hypoglycemic agents [30]. Rose et al found that those patients who believed in their self-efficacy and were optimistic about life had higher HRQoL and in turn were able to achieve their treatment goal [28]. At The Institute of Behavariol Studies in Istanbul it was showed that coping with diabetes related issues is an important factor in both type1 and 2 diabetes and that patients may benefit from programs that include coping strategies as part of their cure [32]. West and McDowell et al recommended that health care professional should be aware of factors influencing adaptations to living with diabetes since they impact on behavariol and emotional functioning [33]. DCCT study which compared intensive Glycemic control groups versus the conventional found there was no difference in QoL. This was in contrast to other studies that have shown that intensive therapy improves Glycemic control thus reducing its impact on HRQoL by slowing the onset and progression of complications [16].

ZODIAC-2 study done in the Netherlands showed that diabetes impacted on the HRQoL of diabetic subjects [34]. The determinants included sex, age, diabetes duration, complications and glycemic control. This study found that a high HbA1C level was associated with more hyperglycemic symptoms and therefore worse QoL[34]. A similar finding was reported by Goddijn et al[26]. Study in Canada by Harvey et al [35] found that diabetes had a negative impact on the HRQoL. The determinants were sex, socio-economic status, marriage, body mass index and diabetes duration. A number of studies on quality of life among people with diabetes have also been carried out in Africa. A study from Nigeria used the WHO-QoL-Bref tool found that a low 20% of the patients had good QoL scores[36].

An urban study among a South-African black population, it was found that patients with acceptable blood glucose control reported significantly better physical functioning, role functioning and mental health than patients with poor control had their lives impacted by diabetes [37]. Similar studies done in India and Thailand have found that diabetes does impact on various aspects of health related quality of life despite having used different HRQoL tools[38, 39] .The Indian study used SF-36 tool and found that QoL is affected by level of education, socio-economic status, gender and complications [38]. The Thailand study was a cross-sectional using WHOQoL-Bref tool reported quality of life was affected by gender, income, glycemic control and adherence to diabetic life-style and diet [39]. Using the medical outcomes questionnaire to assess the health-related quality of life (HRQoL) in insulin-treated diabetics in the Sudan, Elbagir et al reported that only 13% of their patients had good control, and this group rated their HRQoL as better than patients with poor control; however, the latter were significantly younger, with shorter diabetes duration and were free from complications. In this study it was concluded that HRQoL was generally low in this group of patients, and older age and complications were the most important predictors of quality of life[40]. There is a paucity of data in many aspects of diabetes care in the developing world. There are limited accounts of relationships between diabetes and the prevailing social economic as well as cultural conditions and their impact on patients and patients' care, this study attempts to improve on data available from the developing world in HRQoL amongst patients with Diabetes.

Diabetes and Psychological Functioning

The demands of diabetes care can have short-term and long-term impact on mood. Many patients may become chronically frustrated, discouraged, and/or enraged with a disease that often does not seem to respond to their best efforts. They may also feel hopeless or despondent about the possibility of avoiding long-term complications. It can be a difficult, emotional struggle to find a

way to include diabetes in one's life and to confront the sense of mortality that diabetes may represent. This may be especially problematic at those specific time points in the natural history such as at diagnosis, if and when insulin is first started, and when long-term complications begin to occur [41]. In addition, chronically elevated blood glucose levels may lead to persistent fatigue, which can exacerbate depressed mood. Similarly, frequent hypoglycemic episodes can be exhausting, debilitating, discouraging, and potentially quite frightening[41]. Facing a disease that is often difficult and confusing to manage, patients may feel a pervading sense of helplessness that detracts significantly from the overall sense of well-being. To assess this dimension, evaluation might focus on patients' perceived emotional distress due to diabetes-related symptoms, self-care, relevant problematic situations, and broader diabetes issues [40, 41].

Diabetes and Social Functioning

It has been suggested that the mental trauma at diagnosis is greater in diabetes than in other chronic diseases [41]. The newly diagnosed diabetic is confronted by a new vocabulary, a need to learn food values previously ignored, a new responsibility for administering his own treatment, the frightening immediate or remote responsibility of self-injection, and anxiety about the possibility of hypoglycemia and apparently terrifying medical complications [41] .The onset of diabetes at any age is an unsettling event that increases uncertainty about the future. People with diabetes, from the three-year-old girl with insulin-dependent diabetes to the 65-year-old obese male with non-insulin-dependent diabetes, usually find it upsetting to learn and to be reminded daily that they have a serious, even life-threatening condition that will not go away. Multiple stresses, which range from insulin reactions to permanent physical complications, run in three phases of health and function [42] .The stress in the first phase of diabetes is the impact of the presenting symptoms, the diagnosis, and its implications for the individual and the family. Transient reactions range from

mild to major adjustment disorders, with increased anxiety, depression, anger, withdrawal from others, diminished ability to feel intimate and playful, and impaired ability to learn and work[42] .Working people over age 45 years wonder if they will be able to keep their jobs or find new ones, as well as if they can maintain life and hospital insurance [41]. Menopausal women with diabetes wonder if they will be able to hold up their side of the marriage, take care of themselves and still be energetic, attractive, and have interests to share with their partners. Men wonder if they will become impotent[42]. People of both sexes tend to worry about becoming blind, losing one or both legs, and becoming dependent on others who may then become indifferent, contemptuous or even revolted. The mid-phase of relative well-being and full function usually lasts several years and occasionally several decades, and the third phase begins if and when the person needs to make allowances for one or more permanent physical complications. The third and last phase of living with diabetes is characterized by permanent physical complications and the need to adapt to them. When diabetes is present, the incidence of terminal kidney failure is increased by 17 times, that of amputation by 15 times while that of coronary infarct and stroke doubled. These tend to threaten self-esteem, stir up anxiety about losing hard-won skills and competence, bodily functions and parts, and produce guilt, shame, fear retaliation for shortenings, and anxiety about losing the approval, affection and respect of family, friends, and people at work[42] .With onset of serious complications of diabetes, the patient comes to draw on the reserves of family members. When a nuclear family has only two adult members, is isolated from the extended family, and both parents are working, it is less likely to be equipped to carry on with this extra burden. Such a nuclear family may be unable to sustain both its healthy and chronically sick members, for the demands are heavy, physically and emotionally[41]. A person refusing to enter into new and more onerous

living arrangements required by lower levels of function may reject his situation by suicide, divorce or abandonment

As a complication of diabetes, neuropathy can cause numbness, foot drop, diarrhea, pain, and total erectile impotence. Erectile dysfunction is an important cause of decreased quality of life in men with diabetes[43] .It has been associated with increased age, poor glycemic control, smoking, increased alcohol intake, depression, use of specific types of medications, and micro vascular diabetic complications, such as retinopathy and nephropathy as shown by McCulloch D, Shabsigh R and Lustman P.J. et al [44-46]. Impotence can cause great domestic disharmony and may be the basis of many seemingly inexplicable psychiatric and physical symptoms.

In a longitudinal study by De Berardis et al on assessment of quality of life in type2 diabetes and self-reported erectile dysfunction found that erectile dysfunction was associated with worsening quality of life[47]. Angina, myocardial infarction, and heart or kidney insufficiency are especially distressing to patients who become symptomatic and limited in function in their third and fourth decades of life. Having known an active life, they see themselves as having reached only the threshold of adult life. The beginning of either dialysis or a kidney transplant is a crisis for the patient and the family. The combination of the patient's and family members' fears and strongly held attitudes, the force of the rapidly changing medical needs of the patient, plus the medical organization's forceful way of moving to meet those needs, frustrates the patient in his desire to be his own prime mover.

The most serious consequence of peripheral neuropathy is amputation. Lower-extremity numbness makes the feet susceptible to calluses, which may break down and ultimately form ulcers. These serve as a source for bacterial invasion of the tissues, causing cellulitis and osteomyelitis[41]. This

sequence of events makes diabetes one of the leading causes of non-traumatic lower extremity amputations. A patient with amputation of a limb and those closest to him feel the amputation and deeply [41, 42]. Some relatives may have just as much difficulties accepting the patient with the amputation as does the patient, further impeding the amputee's self-acceptance. The patient's post-amputation adjustment depends on pre-surgery physical and psychological characteristics of both patient and family, and their preparation. It also has a significant impact on the family finances especially if the amputee played a major role in income generation for the family[41, 42].

Diabetes has an impact on employment. Due to effects of complications such as retinopathy, neuropathy and hypoglycemia, certain jobs may be automatically barred to them, and these include working at great heights as crane-drivers, working with potentially dangerous moving machinery, driving public service vehicles such as buses or long-distance express trains or heavy lorries, and the piloting of aircraft [41] .Most physicians will recommend that their diabetic patients do a job in which energy expenditure and meal times are predictable. This may limit their ability to generate income and may render some unemployed. Unemployment has a major impact on both morbidity and mortality; it is an indicator of living standards and poverty [48].It has been shown that unemployment rates were significantly higher for younger insulin dependent diabetic men when compared both with their controls and with published statistics [49].Among the older patients with diabetes, unemployment is high primarily due to ill health and complications. Therefore, more advice should be offered on the possibilities of retraining for different types of jobs, and patients must be encouraged to realize the importance of attending a diabetic clinic or seeing a general practitioner regularly, complying with treatment regimes, and keeping good diabetic control [49].

Diabetic drivers might be a hazard to themselves and others because of:

i. Unconsciousness or mental impairment from hypoglycemia;
ii. Complications of diabetes, in particular poor eyesight or ischemic heart disease.

In the UK, official figures suggest that hypoglycemia was responsible for 17% collapsing incidents while driving thus causing accidents [41]. Driving of a vehicle by an insulin-treated patient is potentially hazardous, and great care must be taken to ensure that the driver habitually gets a warning of the onset of hypoglycemia, does not drive at times when attacks are most likely, and always carries sugar or carbohydrates in their car in an easily accessible place

Role of Health Worker -Patient Relationship:

Diabetic patients' quality of life is also influenced by relationships between them and general practitioner or other health professionals. Those with a better relationship with their GP reported a more active coping style and a better quality of life [50] .Consideration of patients' relationship and satisfaction with the presence and role of practice nurses in general practice has also been examined. A meta-analysis of randomized controlled trials (RCTs) studies by Laurant et al and Bradley C. et al reported that patients' satisfaction with nurses led to better care and quality of life[44, 50]. This was attributed to nurses taking more time with them as compared to doctors. Active coping and Knowledge is also linked to relationships with GPs and nurses. A study by Tabriz et al[51] described that those patients with increased access to knowledge and awareness of care provision, care facilities as well as care providers coped better and had better overall satisfaction with the healthcare system.

Efforts to achieve excellent health may damage QoL. Therefore, results can be highly misleading if we interpret health status measures as if they are measures of QoL. The United Kingdom

Prospective Diabetes Study investigated the effects of intensifying blood glucose control on complications of people with type 2 diabetes with an intention to measure QoL but in late 1970s, when the study started, there were no diabetes-specific QoL measures available and they used the EuroQoL (also known as the EQ5D), which is a health status measure[52]. When the results of this study were reported later in late 1990s, the health status measure had been misinterpreted as a QoL measure[52.] The researchers incorrectly reported that intensifying treatment for people with type 2 diabetes had no impact on their QoL, when in fact, what they had found was that intensifying treatment of type 2 diabetes had no impact on the perceived health of the participants[53] .

Clinicians and nurses may feel that because of the enduring relationships they share with their patients they know them well and therefore have a good knowledge of their QoL. However; such impressions can be quite misleading. Walker and Bradley [54] showed that when the diabetes-specialist nurse rated the QoL of her teenage patients, those ratings correlated more strongly with patient's HbA1C levels than with the QoL ratings of the patients themselves which, in turn, showed a small, positive correlation with HbA1C. Thus, although the patients tended to associate better blood glucose control with worse QoL, the nurse tended to assume that better blood glucose control would be associated with better QoL.

2.2 DETERMINANTS OF DIABETES QUALITY OF LIFE

Despite the demands diabetes may make on daily life as well as the concern regarding long-term complications, these do not necessarily result in a reduced QoL as shown by Miller C.D. et al [55] .There are some medical and social factors that modify the effect of such demands on QoL.

a. Medical Factors

Developing diabetes early in life may affect personal development (i.e., the process of autonomy and independence), self-perception, and the way the sufferer is perceived by others [33]. On the other hand, an early onset may facilitate long-term adjustment to managing diabetes, as the patient has no memory of life without diabetes. An individual's satisfaction within the different life domains and level of subjective well-being has been associated with perceived difficulties in adherence to diabetic regimens, such as diet, smoking, exercise and injection treatments[56]. The greater the satisfaction with life, the easier it is to adhere to the regimen. Even if it is impossible to draw conclusions about causality, there seems to be a growing body of evidence that emotional well-being contributes to improved self-care.

Hanestad B.R. et al showed that duration of diabetes affected the way in which patients felt about complications, thus, the fear of developing complications increased with the duration of the disease [59]. The long duration of diabetes compounded by increasing age increases risk of more complications thus also worsening the quality of life. Research done in Nigeria, South Africa and India have shown that complications do impact negatively on HRQoL in diabetic populations[36-38]. Shillitoe R.W. et al reported[57] that complications negatively affected the perspective on diabetes, as well as social life and relationships with other people. Self-reported health has been suggested to play an important role in the adherence to diabetes management and metabolic control, and also to be important for diabetic patients' symptoms, use of health care, and their satisfaction with the doctor-patient relationship[58]. Patients with complications considered the fear of developing complications to be most worrying, while patients without complications thought that the necessity of maintaining regular habits was a greater problem. Complications like neuropathy, retinopathy

and erectile dysfunction also affect the quality of life from employment to marriage to routine daily activities.

The primary goal in diabetes management is to ensure levels of blood glucose control are close to normal as possible in order to ensure desired metabolic control and prevent complications. ZODIAC-2[34] done in the Netherlands showed that diabetes impacted on the HRQoL of diabetic subjects. They found that a high HbA1C level was associated with more hyperglycemic symptoms and therefore worse QoL. This was similar finding of Goddijn et al [26] .Hypoglycemic symptoms like tremors and sweating, often accompanied by weakness, hunger, unsteady movements and blurred vision, are relatively easy for patients to identify, except that in middle-aged women, it may occasionally be mistaken for a menopausal hot flash[42]. This can be unpleasant to the patient. With the passage of years, some people with diabetes develop neuropathy of the autonomic nervous system, which leads to rapid fall in blood glucose. In contrast to acute hypoglycemia, a gradual fall in blood glucose to low levels, especially likely to occur at night, shows up in slow, confused thinking, passivity, drowsiness, and impaired initiative, with transiently impaired memory and lessened ability to judge the passage of time. If the patient fails to make the self-diagnosis at that point, either because of preoccupation or sleep, mental incompetence becomes grossly and painfully apparent to others [43].Repeated hypoglycemic episodes have the cumulative deleterious effects of undercutting the patient's and partner's sense that the patient is dependable as demonstrated by DCCT Trial [16.]

Body mass index and waist circumference are commonly used as nutritional markers since they are clearly established as independent predictors of cardiovascular disease in type1 and 2 diabetes. This has led to recommendation to routinely monitor them in diabetic patients[61]. As a result its relationship with quality of life has been studied and found inconsistent. In a study looking at well-

being and treatment satisfaction in diabetics[62], researchers found no association between body mass index and quality of life scales. This contrasts with studies done in South Africa by Katzenellenbogen, L. et al[37] and by Baiardi F in Italy[63] where they found a positive association.

b. Social Factors

Younger patients have a more positive attitude to diabetes than those who are older[64] .This could be both the effect of youthful optimism and the fact that the disease is still at an early stage[59]. Patients in early middle-age find life with diabetes the most difficult. This period in life is often accompanied by considerable stress caused by expectations and obligations difficult to combine with managing diabetes[59].

Men have been reported to have a more positive attitude towards diabetes than women or they may have a greater need to deny problems related to their illness[59, 65]. This may present facets of a single problem. Boys are taught to be independent and adventurous from an early age, characteristics that are inappropriate in a demanding disease like diabetes. Women tend to feel more anxious about their diabetes and its complications, while men, even those with a long diabetic duration and complications, find the regulated lifestyle imposed by managing their diabetes to be the most difficult aspect of having diabetes [59, 65] .Gender roles leading to differences in the perception of health and the readiness to report symptoms may explain this.[71] Thus, it is more socially acceptable for women both to experience and to report feelings of anxiety and depression, or to have health concerns, than it is for men [59.]

Level of formal education may also play a role in determining quality of life. In a Greek study[66] they found that lower level of education was associated with poorer knowledge on diabetes and worsening hypoglycemic symptoms. This impacted on the quality of life. A similar study done in

Iran by Ghanbari A. et al found that knowledge of the disease whether by the patient or a family member led to better quality of life in the study subjects[68]. When patients have the knowledge of how to manage their disease process and the skills to change necessary behaviors, they felt empowered and implemented these changes[69, 70.]

2.3 QOL ASSESSMENT TOOLS

Health-related quality of life (HRQoL) includes a broad range of functional limitations, capabilities, and perceptions that may influence the diabetic's performance and satisfaction with life. In assessing HRQoL of the diabetic, it is important to measure not only the actual functional capability, but also the patient's perceptions of the impact of these abilities or disabilities on his or her life. Subjective as well as objective measures are required for a comprehensive evaluation of HRQoL.

Measuring QoL changes usually involves soliciting peoples' self-reported feelings, behaviors' and attitudes through interviewing or evaluating responses to questionnaires[71.] The interviewer can conduct the assessment or the individual can self-administer the questionnaire. Self-report measures of QoL consist of either a single question, a series of tests (battery) or a scale. QoL changes can also be measured in part by accessing records or observing individuals' behavior. In research studies a battery of instruments is often used to increase the strength of the research [71]. A number of different tools are available for measuring health-related quality of life, including both generic and disease-specific measures.

Generic instruments are used in general populations to assess a wide range of domains applicable to a variety of health states, conditions, and diseases[72].They are usually not specific to any particular disease state or susceptible population of patients. Among the most widely used general

health status measures are the Sickness Impact Profile, the Quality of Well-Being Scale, the McMaster Health Index Questionnaire, the General Health Rating Index [73].Disease-specific instruments focus on the domains most relevant to the disease or condition under study, and on the characteristics of patients in whom the condition is most prevalent[16, 74] .

PSYCHOMETRIC PROPERTIES OF QOL INSTRUMENTS

QoL measurement instruments have different properties and have been developed with varying amounts of rigor. Knowledge of what is called the psychometric properties of the instrument helps in decisions about whether or not to adopt a particular instrument in practice[71].

Desired Psychometric Properties

The value of a QoL measurement instrument depends upon its psychometric properties. In large part this refers to the ability of the instrument to examine in a sound way what it is intended to study. The strength of the psychometric properties of a QoL instrument depends upon the rigor of its development [71].The content of the instrument, its reliability and validity are key components of the soundness of the instrument.

The ***Validity*** of an instrument is the degree an instrument (such as a questionnaire) measures what was intended to be measured [71]. Validity refers to the application of an instrument and the confidence that can be placed on the conclusions reached. Determining the soundness of the application is a matter of degree as the test is applied to different populations. The validity of an instrument is determined in a number of ways and includes the following:

a) Content validity is whether the instrument includes all relevant aspects of the attribute being explored, which in this case is the multidimensionality of QoL. To establish what the relevant aspects are when creating an instrument, collecting information from patients, their relatives,

health professionals, and relevant literature is necessary. This enables pertinent and comprehensive content to be collected for consideration in the instrument design. Content validity is also said to exist when an instrument has good internal consistency, that is, items within the instrument that are designed to measure the same aspect of QoL actually do so [71].

b) Face validity is a form of content validity describing whether the meaning of the questions used is clear, appears appropriate and balanced and measures the variables claimed. Face validity is usually determined by asking individuals who complete the instrument during its development about their understanding of the question[71.]

c) Construct validity is the fidelity with which aspects of QoL are being measured and whether a comprehensive characterization of aspects of QoL has been applied[71]. As this is often difficult to directly observe, testing constructs is an ongoing process.

d) Predictive validity of an instrument is whether the measure can predict future differences in outcomes such as responsiveness to disease management interventions[71].

The ***Reliability*** of an instrument is the precision and accuracy with which it measures a defined issue. Reliability is said to exist when it consistently produces similar results in a specified situation [71, 74, 75].

Other Psychometric Issues

Other psychometric issues to take into account when conducting HRQoL research are effects of individual's self-report, preference, adaptation and response-shift. Self-report HRQoL instruments establish subjective appraisal of one's function or feelings or satisfaction with treatment. The wording, format or context of items in the instrument can affect different responses [75].Inadequate range of item response choice can result in the 'ceiling effect'. Patients that may have chosen a

'very good' response at base line will need a post intervention choice of 'excellent' or 'extremely satisfied' to register improvement[58].

a) Preference

Interventional health research is often conducted as randomized controlled trials with participants not able to be blinded to the treatment being studied. These patients may have a preference for one treatment or the other. This may affect adherence and resultant outcomes [76].

b) Adaptation

Whilst one may have personal preferences, emotional, cognitive and behavioral adaptation to changes in one's life occurs. It is suggested that psycho-physiological adaptation can occur in individuals with diabetes [76].This can influence any perceived changes in quality of life.

c) Response-shift

When individuals complete a HRQoL instrument at the beginning of a research project, they may over- or underestimate their feelings of well-being. The study's intervention may alert individuals to the inadequacy of their situation and thus result in poorer self-reported QoL than previously determined [76, 77]. Snoek suggests that this potentially be averted by administering a retrospective pre-test after patients have completed the post test, with instructions for reflective responses [75].

TYPES OF INSTRUMENTS

In research studies a battery of instruments is often used to increase the strength of the research [71, 74]. For example, multiple instruments can be used in large scale intervention research trials that are evaluating evidence-based interventions [76, 78, 79]. In the practice environment pragmatic consideration takes precedence and a less invasive and time consuming approach is usually taken.

For example, Bradley et al[50] created a questionnaire that is designed to measure individuals' perceptions of the impact of diabetes on the QOL Many instruments have been designed to measure QOL in general, results of which permit comparison across diseases[50] .Measurements of the effect on individual's lives with specific diseases have been furthered by design of disease specific instruments[80.] Other studies have used a generic instrument in conjunction with a disease specific instrument to provide answers to a clinical practice quality of life intervention[81, 82.] Examples include **WHO-QoL Bref** tool, **SF-36** tool, **QWB-SA** (Quality of Well-Being Questionnaire), **EuroQoL** (European Quality of Life) or **EQ-5D (Euro-QoL 5-Dimensions, DQLCTQ-R** (Diabetes Quality of Life Clinical Trials Questionnaire Revised), **ADDQoL** (Audit of Diabetes Dependent QoL) instrument etc. The WHO-QoL BREF tool was chosen because it can be used for assessment of overall satisfaction with quality of life, overall satisfaction with health, physical quality of life, psychological quality of life, social quality of life and environmental quality of life. The WHOQoL-Bref has well to excellent psychometric properties of reliability and validity. It has been validated in people with type 2 diabetes [74, 83]. Development of the WHOQoL-Bref was a multi-national project, based on a cross-culturally sensitive concept, thus it is appropriate for use across different nationalities[83] .The first part of the questionnaire has questions on how the patient self-rating of their quality of life and how satisfied they are with their health. This is a subjective assessment by the patients themselves. The next part of the tool has the questions that will be used to calculate the four domain scores which denote an individual's perception of quality of life in each particular domain .The questions are designed to cover the two week period prior to the date of the interview. The four domains measured are: physical, psychological, social and environment, through a set of 26 items that can be self-administered.

Responses to the questions use a 5-point Likert scale, inquiring 'how much', 'how satisfied' or 'how completely' the respondent felt in relation to the domain being investigated.

2.4 RATIONALE OF THE STUDY

Various studies worldwide have shown the impact of diabetes on HRQoL[34-40] .Currently the primary focus of diabetes management and method of care is focused on physical burdens of the disease with respect to the glycemic control while ignoring the personal, psychological, and social impact of the disease. There is paucity of local data on the impact diabetes has on the HRQoL. The findings of this study will enable health care professionals to obtain broader picture of the psychological impact of diabetes on patients in KNH Diabetes clinic. Knowledge will provide a deeper insight on needs to overall care of diabetic patients enabling practioners to implement other care beyond just metabolic control.

2.5 BROAD OBJECTIVE OF THE STUDY:

To determine the perceived quality of life of diabetic patients attending the out-patient Diabetes clinic at KNH.

2.6 SPECIFIC OBJECTIVES

I. To determine the perceived health related quality of life of patients with type2 diabetes not on insulin therapy attending the Diabetic Clinic in KNH, Nairobi

II. To determine the association of diabetes HRQoL of the study patients with duration of diabetes, complications profile(complications documented on the file only) , glycaemic control, level of education, body mass index and social economic status

CHAPTER 3: METHODOLGY

3.1 STUDY DESIGN- This was a cross sectional study carried out at the Diabetes Clinic, KNH

3.2 SAMPLE SIZE

The minimum sample population is 129 and was derived using the formula below:

$n = [(z^2 * p * q) + ME^2] / [ME^2 * (z^2 * p * q)]$

Where;

z is the critical z score at 95% confidence level = 1.96

p is the estimated proportion with good QoL among diabetics(reference from a similar study done in Nigeria where 21% had good quality of life [36])

q = 1-p the proportion without good QoL among diabetics

ME is the margin of error set at 5%

3.3 SAMPLE POPULATION

The sample population was obtained from the Diabetic clinic at the KNH which runs from Monday to Friday. The main clinic is on Friday with on average 70 patients per session whilst the mini clinic which runs from Monday to Thursday with average 30 patients per day.

Inclusion criteria:

I. Known type 2 diabetic for not less than 1year on oral hypoglycemic agents.

II. Ages between 18yrs and 70yrs

III. Stable disease-no hospitalization in past 3months

IV. Informed consent

Exclusion criteria

I. History of cognitive impairment

II. History of substance abuse e.g. alcohol, drugs etc

III. History of concomitant disease that affects the nervous system or independently affects the quality of life.

IV. Gestational diabetes

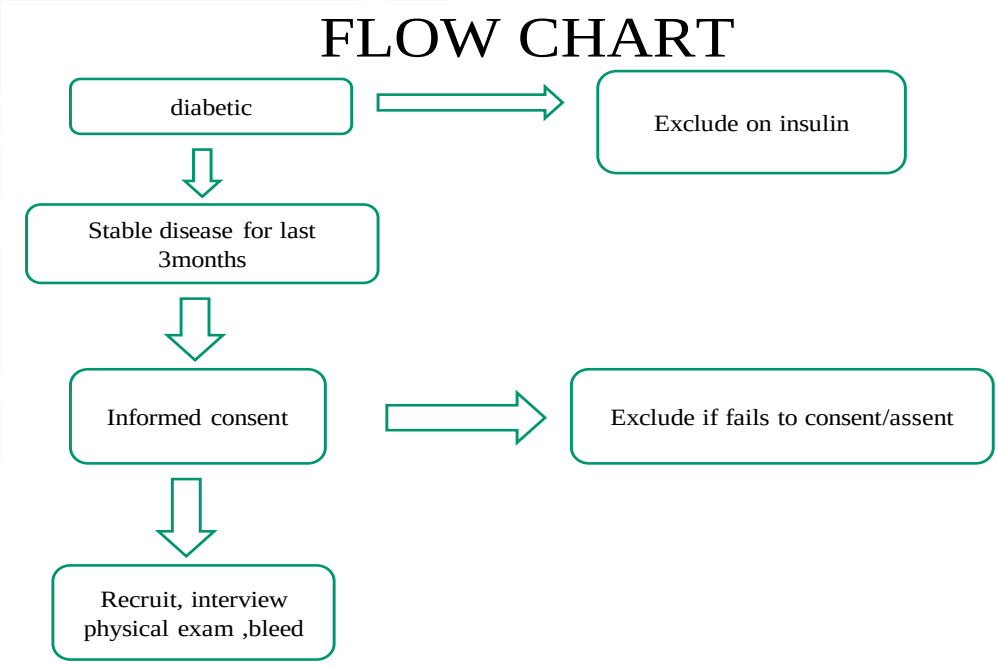
3.4 THE STUDY INSTRUMENT CONSISTS OF THE FOLLOWING:

A) Questionnaire on social demographic and clinical history (appendix 3)

B) WHOQoL-Bref questionnaire (appendix 3)

3.5 METHOD AND PROCEDURES

Figure 1: flow chart



The principal investigator and the two research assistants perused through the files to determine patients fit for the study inclusive criteria so as to recruit them. Those fulfilling the inclusive criteria were explained to the study terms and procedures and an informed consent obtained. The questionnaire was then administered to the study subjects by the principal investigator and the trained research assistants. Upon completion each questionnaire form was assigned a number code so as to maintain anonymity and for data collection purposes. The WHO-QoL questionnaire tool has 4 domains. The four domain scores denote an individual's perception of quality of life in each particular domain. The four domains measured are: physical, psychological, social and environment, through a set of 26 items that can be self-administered. Responses to the questions used a 5-point Likert scale, inquiring 'how much', 'how satisfied' or 'how completely' the respondent felt in relation to the domain being investigated. .

After completion of the questionnaire blood pressure was then taken using a sphygmomanometer and the values recorded as per WHO protocol and 2mls of blood aseptically was drawn from the antecubital fossa for HbA1C measurement and taken to Lancet Laboratory for analysis. Any other relevant medical information was obtained from the files. Relevant information included duration of diabetes, complications and co morbidities. Heart failure and ischemic heart disease were grouped as cardiac, gastroparesis included altered bowel habits. Complications such as retinopathy and neuropathy were collected directly from the file; erectile dysfunction was documented either from the file or assessment by self-report by the patient.

Anthropometry**:** Weight (kg) and height (m) was taken for each patient. The Two measurements of weight were taken and average of the two done to the nearest 0.1kg was used. Two measurements of height were taken and the average to the nearest 0.5m was used. Afterwards a BMI was calculated as kg/m^2.

3.6 DATA ANALYSIS

The data were verified, cleaned and entered into a Microsoft database access and analysis done using SPSS version 17.0. Continuous variables such as age were summarized as mean and standard deviation while categorical variables such as gender, occupation and level of education were presented as proportions. Presentation of data was done using frequency tables, graphs and pie charts. Associations were done using Chi square test and ANOVA. All statistical tests were interpreted at ≤ 0.05 level of significance.

HRQoL scores was calculated using the WHO-QoL BREF tool. The mean score of items within each domain is used to calculate the domain score in the WHO-QoL tool. Mean scores are then multiplied by 4 in order to make domain scores comparable with the scores used in the WHOQoL-100. (Higher scores denote higher quality of life).Where more than 20% of data is missing from an assessment, the assessment was discarded. Where an item is missing, the mean of other items in the domain is substituted. Where more than two items were missing from the domain, the domain score was not be calculated (with the exception of domain 3, where the domain should only be calculated if less than one (<1) item was missing).

Definition of study variables

Nutritional assessment was assessed as follows (BMI scores as per kg/M^2):

Less than 19= underweight

20-24= normal

25-30= pre obese

Greater than 30= obese

Blood pressure assessment was assessed as follows (mm/hg):

Less than 90/60= low

100/70 to 130/90= normal

Greater than 130/90= high

Glycemic control was assessed as follows:

HbA1C was less than 7%= good

HbA1C was greater than 7%=poor

Overall QOL score was categorized as:

0-40=poor

41-60=fair

Greater than 61=good

3.7 QUALITY CONTROL

I. The WHO-QOL tool is a validated tool for the use in assessing HRQoL of type2 diabetics

II. Use of trained research assistants in the administration of the WHO-QOL tool and sample collection to minimize errors

III. The recommended procedure for specimen collection, proper labeling, preparation and storage was followed strictly at all times to minimize pre-analytical sources of error.

IV. Samples for HbA1C were handled and analyzed by Lancet Laboratories that have both internal and external checks for quality assurance.

3.8 ETHICS

I. Approval was obtained from the Department of Clinical Medicine and Therapeutics of the University of Nairobi and Kenyatta National Hospital Research and Ethics committee before data collection.

II. Confidentiality was maintained at all times

III. Informed consent or assent was obtained from all study participants

IV. Patients were free to withdraw from the study at any point and were not be discriminated against on withdrawal

V. HbA1C results were communicated to the patient and primary physician for clinical decision making

VI. Full cost was met by the investigator.

CHAPTER 4: RESULTS

4.1: SAMPLE POPULATION CHARACTERICS

139 consenting subjects with type 2 diabetes on oral hypoglycemic agents were recruited. Most of the study participants were aged 40-60 years, with a mean age of 56.37 years. Majority were females 61.3 %(n=84). More than half (57.6%) were married with the remainder classified as single (widowed/ divorced/ separated/ single). Majority (90%) had received a minimum of primary school education. Most (60 %) had some employment whether part or full time with 58.4% having a combined income of more than 50,000 a year with 87% personally responsible for their house meaning either owned the house or paid rent

The important socio-demographic characteristics of the recruited patients are shown in Table 1 and figure2.

Figure 2: Age distribution of study participants

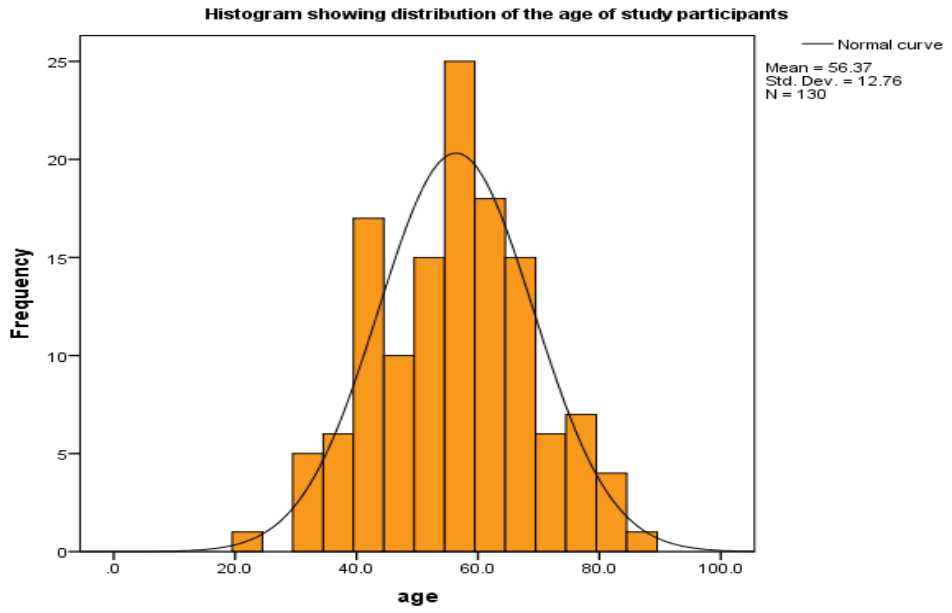


TABLE 1: Socio-demographic characteristics of the study population

Characteristic	Category	%
Gender	Male	38.7%
	Female	61.3%
Level of education	None	8.7%
	Primary	44.9%
	High School	34.1%
	College	12.3%
Marital status	Single	42.4%
	Married	57.6%
Housing	not personally responsible	12.9%
	personally responsible	87.1%
Employment	Unemployed	39.9%
	Employed	60.1%
Total combined family income for the past 12 months	Less than ksh5,000	15.1%
	Ksh5,000 - Ksh19,999	9.4%
	Ksh20,000 - Ksh49,999	17.0%
	Ksh50,000 - Ksh99,999	15.1%
	Ksh100,000 - Ksh149,999	12.3%
	More than Ksh150,000	31.1%

4.12: DIABETES RELATED CHARACTERISTICS OF THE STUDY POPULATION

More than half (52.5%) of the study population had been diagnosed with diabetes for less than 5years yet a majority (57.6%) of the participants had more than three complications as shown in figure 5 with neuropathy leading at 41% . Majority (75%) of the patients had poor glycaemic control as illustrated by HbA1C mean score of 8.04 %. of the participants in table 2.

Figure 3: Duration on diabetes in the study patients

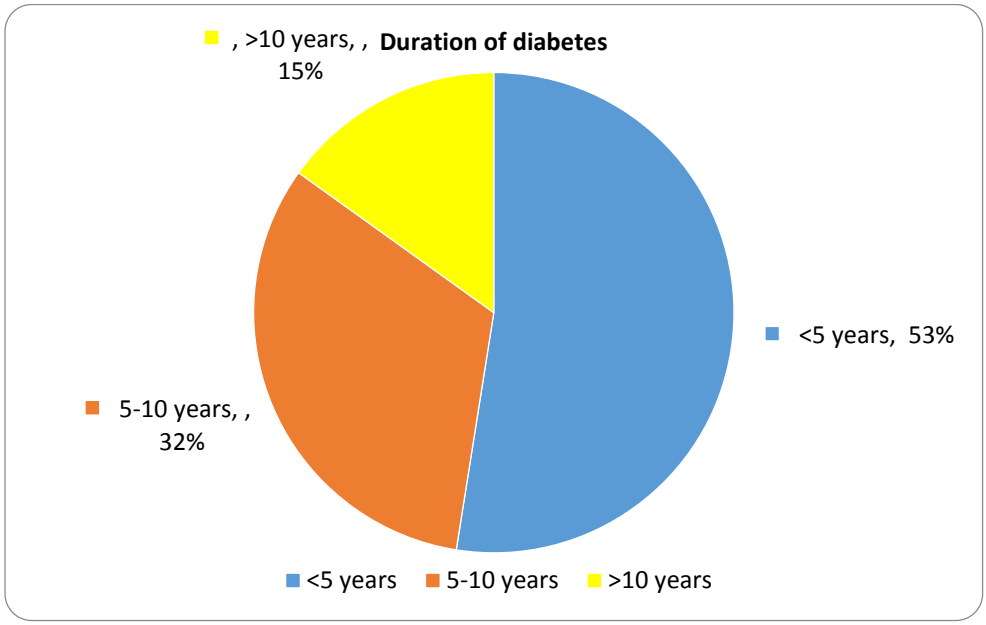


Figure 4: Types of complication of the study patients

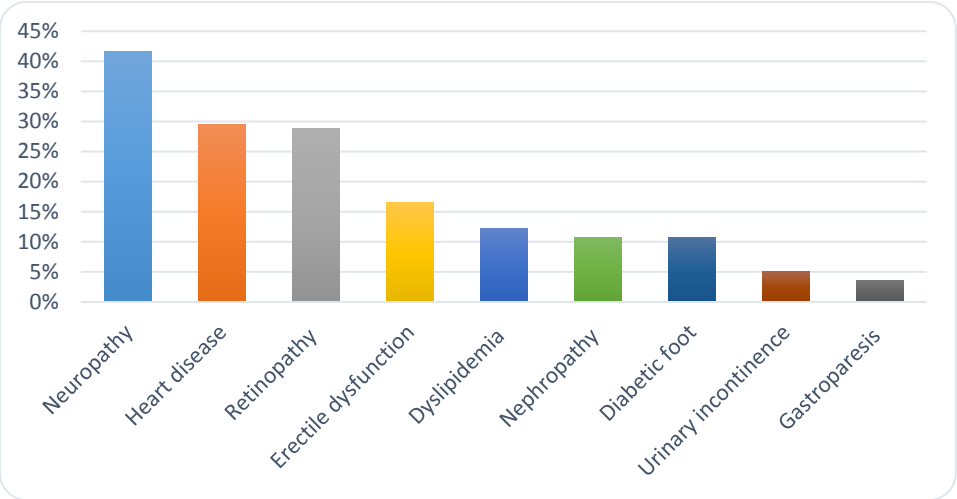


Figure 5: Number of complications of the study patients

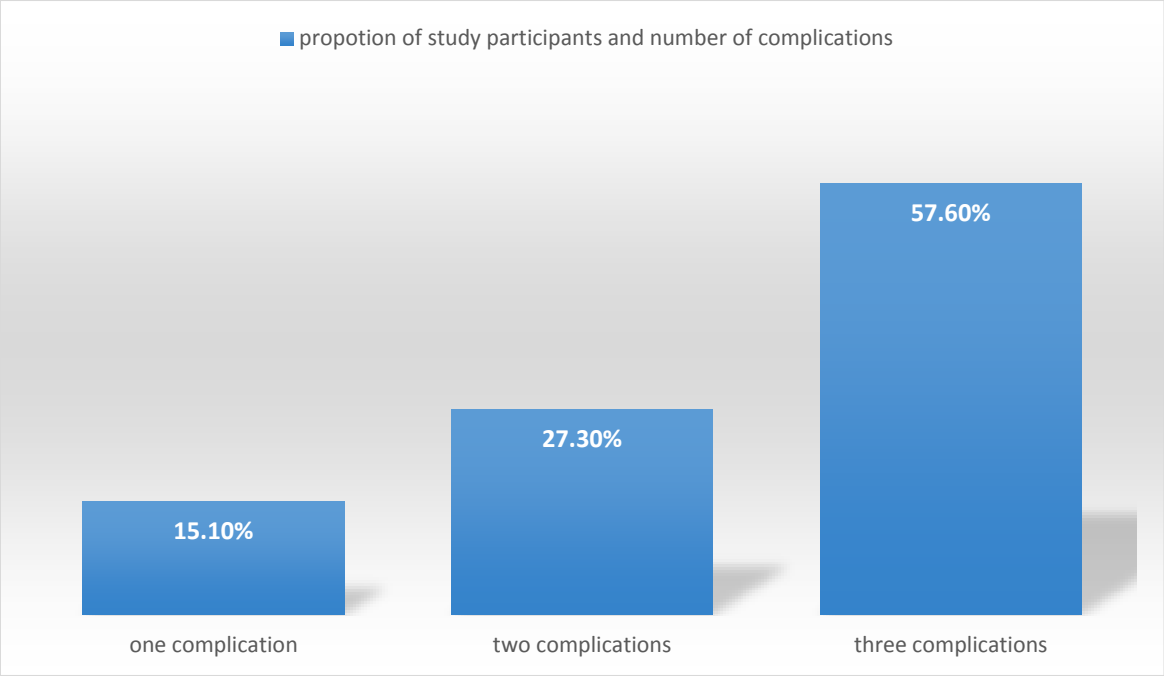


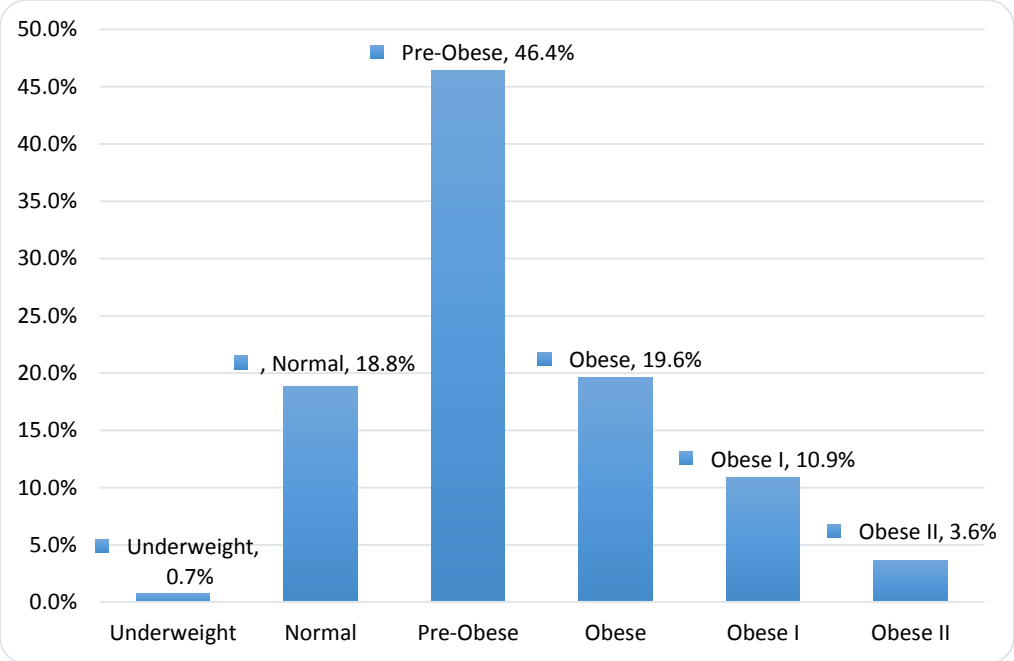
Table 2: category of HbA1C of the study subjects

HbA1C (%)	N	%
Good (<6.9)	32	24.4%
Fair (7-9)	33	25.2%
Poor (>10)	66	50.4%

4.13: ANTHROPOMETRIC MEASURES OF THE STUDY POPULATION

Majority of the study participants (80%) were rated as overweight and obese according to WHO measures with a mean BMI of 29.18

Figure 6: BMI of study subjects



4.2: Perceived HRQoL and Health satisfaction of the study participants

The table below shows the HRQoL and Health satisfaction of the study subjects. Only 40% of the patients rated their HRQoL as good, 35% of the total sample population were satisfied with their health despite majority (84%) of the patients scoring highly on the WHO-QoL tool. This is shown in tables 3 and 4

Table 3: Health Satisfaction and Self-rating of HRQoL of the study subjects

Self-Rating of quality of life	%	Self-reported Health satisfaction	%
Very poor	6.5%	Very dissatisfied	7.9%
Poor	15.8%	Dissatisfied	30.2%
Neither poor nor good	37.4%	Neither dissatisfied nor satisfied	25.9%
Good	33.8%	Satisfied	34.5%
Very good	6.5%	Very satisfied	1.4%

Table 4: Overall HRQoL scores of the study subject

HRQoL scores	**Categories of HRQoL scores**	**N**	**%**
Total Scores Maximum 100	<=40(poor)	1	0.7%
	41-60(fair)	21	15.2%
	>60(good)	116	84.1%

HRQoL Domain scores

Each domain was assigned an individual score. Majority of the patients had good scores in each domain with social domain having the highest at 73.8% of the available 100% and environmental domain scoring the lowest mean of 68.3%.

Table 5: HRQoL domain scores of the study subjects

	N	Mean	Median	% score	Minimum score	Maximum score	Standard Deviation
DOM1: Physical Health	139	14.01	14.86	70.1%	7.00	20.00	3.23
DOM2: Psychological	139	14.58	14.67	72.9%	6.40	20.00	2.76
DOM3: Social relationships	139	14.75	14.67	73.8%	8.00	20.00	3.09
DOM4: Environmental	139	13.66	13.50	68.3%	6.50	20.00	2.83
Total Domain Scores	139	56.94	57.90	72.4%	30.76	78.86	9.54

4.3 DIABETES HRQoL AND ITS DETERMINANTS

HRQoL and Age

Age of the study subjects had significant association only in the social domain of HRQoL with a *p-value of 0.037* as shown in table 6

Table 6: Association between HRQoL and Age of the study subjects

HRQoL domain	Age	N	Mean	Minimum score	Maximum score	ANOVA P value
Physical	<40 years	21	14.9206	8.57	20.00	0.470
	40-60 years	70	14.1537	7.43	19.43	
	>60 years	48	13.7083	8.00	18.86	
Psychological	<40 years	21	14.8333	10.00	18.67	0.937
	40-60 years	70	14.6895	7.33	20.00	
	>60 years	48	14.5556	9.33	20.00	
Social	**<40 years**	**21**	**16.7273**	**12.00**	**20.00**	**0.037***
	40-60 years	**70**	**14.9429**	**8.00**	**20.00**	
	>60 years	**48**	**14.1806**	**8.00**	**20.00**	
Environmental	<40 years	21	13.9250	7.50	17.50	0.136
	40-60 years	70	13.2386	7.50	20.00	
	>60 years	48	14.2813	6.50	20.00	
Total Scores	<40 years	21	59.7900	46.45	74.83	0.609
	40-60 years	70	57.0247	30.76	76.02	
	>60 years	48	56.7257	36.33	78.86	

HRQoL and Level of income

Level of income had a significant association with overall HRQoL score *(p-value of 0.029),* psychological domain *(p value of 0.023)* and in the social domain *(p-value of 0.029).*

Table7: HRQoL and Level of income of study subjects

HRQoL domain	Income over 12 months	N	Mean	Minimum score	Maximum score	ANOVA P value
Physical	Less than ksh5,000	21	12.9107	7.43	16.00	0.507
	Ksh5,000 - Ksh19,999	13	14.0000	8.57	20.00	
	Ksh20,000 - Ksh49,999	23	13.6190	8.00	18.86	
	Ksh50,000 - Ksh99,999	21	14.2917	8.00	18.86	
	Ksh100,000 - Ksh149,999	18	14.5495	10.29	18.86	
	More than Ksh150,000	43	14.6782	8.57	19.43	
psychological	**Less than ksh5,000**	**21**	**12.6083**	**7.33**	**16.00**	**0.023***
	Ksh5,000 - Ksh19,999	**13**	**13.6667**	**8.00**	**17.33**	
	Ksh20,000 - Ksh49,999	**23**	**14.7407**	**9.33**	**18.67**	
	Ksh50,000 - Ksh99,999	**21**	**14.8583**	**8.00**	**20.00**	
	Ksh100,000 - Ksh149,999	**16**	**14.6667**	**10.67**	**20.00**	
	More than Ksh150,000	**43**	**15.4424**	**11.20**	**20.00**	
Social	**Less than ksh5,000**	**21**	**12.5417**	**8.00**	**20.00**	**0.029***
	Ksh5,000 - Ksh19,999	**13**	**14.5333**	**10.67**	**20.00**	
	Ksh20,000 - Ksh49,999	**23**	**14.4444**	**8.00**	**20.00**	
	Ksh50,000 - Ksh99,999	**21**	**14.7083**	**9.33**	**20.00**	
	Ksh100,000 - Ksh149,999	**16**	**15.4872**	**10.67**	**20.00**	
	More than Ksh150,000	**43**	**15.7083**	**12.00**	**20.00**	
Environmental	Less than ksh5,000	21	12.3438	6.50	18.50	0.153
	Ksh5,000 - Ksh19,999	13	13.0000	11.00	17.50	
	Ksh20,000 - Ksh49,999	23	13.5278	11.00	18.50	
	Ksh50,000 - Ksh99,999	21	13.1250	7.00	16.50	
	Ksh100,000 - Ksh149,999	16	14.2308	7.50	20.00	
	More than Ksh150,000	43	14.4182	10.50	18.00	
Total. Scores	**Less than ksh5,000**	**21**	**50.4045**	**30.76**	**68.50**	**0.029***
	Ksh5,000 - Ksh19,999	**13**	**55.2000**	**39.57**	**74.83**	
	Ksh20,000 - Ksh49,999	**23**	**56.3320**	**40.90**	**76.02**	
	Ksh50,000 - Ksh99,999	**21**	**56.9833**	**32.83**	**75.36**	
	Ksh100,000 - Ksh149,999	**16**	**58.9341**	**45.45**	**78.86**	
	More than Ksh150,000	**43**	**60.0622**	**47.31**	**72.00**	

HRQoL and health care funding

Health care financing was significantly associated with psychological domain *(p-value 0.006)* and environmental domain *(p-value 0f 0.04)* and overall score *(p-value 0.011)* as shown below in table 8

Table 8: Mode of health care funding and HRQoL of the study subjects

HRQoL domain	Health care funding	N	Mean	Minimum score	Maximum score	ANOVA p- value
Physical	Govt funding	7	14.2857	7.43	20.00	0.082
	Private insurance	7	14.7755	10.29	17.71	
	Self-pay	109	14.2272	8.00	19.43	
	Family support	16	12.0744	7.00	19.33	
Psychological	**Govt funding**	**7**	**14.0000**	**7.33**	**20.00**	**0.006***
	Private insurance	**7**	**16.6667**	**14.00**	**18.67**	
	Self-pay	**109**	**14.7584**	**8.00**	**20.00**	
	Family support	**16**	**12.7167**	**6.40**	**17.33**	
Social	Govt funding	7	14.6667	8.00	20.00	0.138
	Private insurance	7	16.5714	14.67	20.00	
	Self-pay	109	14.8318	8.00	20.00	
	Family support	16	13.4167	8.00	18.67	
environmental	**Govt funding**	**7**	**13.2388**	**8.00**	**17.50**	**0.040***
	Private insurance	**7**	**16.5000**	**15.50**	**20.00**	
	Self-pay	**109**	**13.6073**	**7.00**	**20.00**	
	Family support	**16**	**12.9750**	**6.50**	**17.50**	
Total. Scores	**Govt funding**	**7**	**54.7024**	**30.76**	**75.36**	**0.011***
	Private insurance	**7**	**64.5136**	**59.79**	**73.71**	
	Self-pay	**109**	**57.4247**	**32.83**	**78.86**	
	Family support	**16**	**51.1827**	**33.00**	**69.10**	

HRQoL and Employment status

There was an association between employment status and HRQoL. Having a job improved the scores in physical domain *(p-value of 0.013)* and social domain *(p value of 0.020)*

Table 9: Employment status and HRQoL of the study subjects

HRQoL domain	Employment status	N	Mean	Minimum score	Maximum score	ANOVA P value
Physical	**Unemployed**	**54**	**13.2069**	**7.43**	**18.86**	**0.013***
	Employed	**85**	**14.5869**	**7.00**	**20.00**	
Psychological	Unemployed	54	14.3273	7.33	20.00	0.366
	Employed	85	14.7647	6.40	20.00	
Social	**Unemployed**	**54**	**14.0364**	**8.00**	**20.00**	**0.020***
	Employed	**85**	**15.2764**	**8.00**	**20.00**	
Environmental	Unemployed	54	13.6922	6.50	20.00	0.941
	Employed	85	13.6554	7.00	20.00	
Total. Scores	Unemployed	54	55.2628	30.76	77.05	0.078
	Employed	85	58.1926	32.83	78.86	

HRQoL and Duration of diabetes

Duration with diabetes had significant association with physical domain where the *p value was 0.007* as shown below in table 10.

Table 10: Duration of diabetes and HRQoL of the study subjects

HRQoL domains	Age	N	Mean	Minimum score	Maximum score	ANOVA P value
Physical	**<5 years**	**73**	**14.6849**	**7.43**	**20.00**	**0.007***
	5-10 years	**45**	**13.7291**	**8.00**	**19.33**	
	>10 years	**21**	**12.2653**	**7.00**	**18.29**	
	Total	**139**	**14.0099**	**7.00**	**20.00**	
Psychological	<5 years	73	14.9023	7.33	20.00	0.218
	5-10 years	45	14.4563	9.33	20.00	
	>10 years	21	13.7333	6.40	19.33	
	Total	139	14.5813	6.40	20.00	
Social	<5 years	73	14.5926	8.00	20.00	0.763
	5-10 years	45	14.8148	10.00	20.00	
	>10 years	21	15.1429	9.33	20.00	
	Total	139	14.7488	8.00	20.00	
Environmental	<5 years	73	13.6274	6.50	20.00	0.281
	5-10 years	45	14.0778	7.00	20.00	
	>10 years	21	12.8891	7.50	20.00	
	Total	139	13.6617	6.50	20.00	
Total. Scores	<5 years	73	57.7066	30.76	78.86	0.300
	5-10 years	45	57.0780	36.90	76.02	
	>10 years	21	54.0306	32.83	77.05	
	Total	139	56.9422	30.76	78.86	

HRQoL and Complication loading

The HRQoL of the study subjects was associated significantly with the number of complications. Indeed the association of complications with the HRQoL involved physical domain *(p-value of <0.0001)* and psychological domain *(p-value of 0.041)* which directly impacted on the overall total score *(p value of 0.041)* as shown below in table 11.

Table 11 HRQoL and Complication loading of the study subjects

HRQoL domains	Number of complications	N	Mean	Minimum score	Maximum score	ANOVA P value
Physical	**One**	**21**	**16.5986**	**11.43**	**20.00**	**<0.0001***
	Two	**38**	**14.2707**	**8.00**	**19.43**	
	three and above	**80**	**13.2065**	**7.00**	**19.33**	
psychological	**One**	**21**	**15.8413**	**10.40**	**20.00**	**0.041***
	Two	**38**	**14.7579**	**9.33**	**19.20**	
	three and above	**80**	**14.1667**	**6.40**	**20.00**	
Social	One	21	14.5333	8.00	20.00	0.876
	Two	38	14.9474	8.00	20.00	
	three and above	80	14.7083	8.00	20.00	
	Total	139	14.7488	8.00	20.00	
Environmental	One	21	13.9810	6.50	18.50	0.103
	Two	38	14.3816	8.50	20.00	
	three and above	80	13.2359	7.00	20.00	
Total. Scores	**One**	**21**	**60.7524**	**36.33**	**77.13**	**0.041***
	Two	**38**	**58.3575**	**42.57**	**73.71**	
	three and above	**80**	**55.3174**	**30.76**	**78.86**	

HRQoL and Gender

Gender had no influence on HRQoL of the study subjects as shown in table 12.

Table12: Association between Gender and HRQoL of the study subjects

HRQoL domain	Gender	N	Mean	Minimum	Maximum	Chi-square
						P value
Physical Health	Male	54	14.5930	8.00	19.43	0.094
	Female	85	13.6355	7.00	20.00	
Psychological	Male	54	14.6189	8.00	20.00	0.825
	Female	85	14.5111	6.40	20.00	
Social relationships	Male	54	14.5513	8.00	20.00	0.579
	Female	85	14.8571	8.00	20.00	
Environmental	Male	54	13.3509	7.00	19.50	0.308
	Female	85	13.8616	6.50	20.00	
Total. Scores	Male	54	56.9623	32.83	72.00	0.955
	Female	85	56.8653	30.76	78.86	

HRQoL and Marital status

Marital status of the study subjects did not have significant influence on HRQoL in all domains including the overall HRQoL as shown in table 13.

Table 13: HRQoL and Marital status of the study subjects

HRQoL domain	Marital status	N	Mean	Minimum	Maximum	Chi-square P value
Physical	Single	59	14.2768	7.00	19.43	0.405
	Married	80	13.8131	7.43	20.00	
Psychological	Single	59	14.3028	6.40	20.00	0.309
	married	80	14.7867	7.33	20.00	
Social	Single	59	14.2825	8.00	20.00	0.126
	married	80	15.0970	8.00	20.00	
Environmental	Single	59	13.7317	6.50	20.00	0.803
	married	80	13.6100	7.00	19.50	
Total. Scores	Single	59	56.5939	33.00	78.86	0.712
	Married	80	57.2024	30.76	76.02	

HRQoL and Level of education

The level of education of the study patients had no influence on the HRQoL as seen below in table 14.

Table 14: HRQoL and Level of education of the study subjects

HRQoL domain	Education level	N	Mean score	Maximum score	Chi-square P value
Physical	None	12	12.5754	17.71	0.358
	Primary	63	14.1382	20.00	
	High School	47	14.3384	19.43	
	College	17	13.5630	18.86	
Psychological	None	12	14.2556	19.33	0.826
	Primary	63	14.6946	20.00	
	High School	47	14.6837	20.00	
	College	17	14.0706	20.00	
Social	None	12	14.8333	20.00	0.390
	Primary	63	14.2514	20.00	
	High School	47	15.0922	20.00	
	College	17	15.4510	20.00	
environmental	None	12	13.9250	20.00	0.701
	Primary	63	13.3968	18.50	
	High School	47	14.0015	20.00	
	College	17	13.4235	20.00	
Total. Scores	None	12	55.5893	77.05	0.753
	Primary	63	56.3461	77.13	
	High School	47	58.1158	76.02	
	College	17	56.5081	78.86	

HRQoL and BMI

BMI had no influence on the HRQoL of the study subjects as seen in table 15.

Table 15: HRQoL and BMI of the study subjects

HRQoL	BMI (category)	N	Mean score	Maximum score	ANOVA P value
Physical	Underweight/Normal	28	14.3122	18.86	0.573
	Obese	111	13.9185	20.00	
Psychological	Underweight/Normal	28	15.1457	20.00	0.235
	Obese	111	14.4372	20.00	
Social	Underweight/Normal	28	14.6173	20.00	0.806
	Obese	111	14.7818	20.00	
Environmental	Underweight/Normal	28	13.7815	20.00	0.810
	Obese	111	13.6340	20.00	
Total. Scores	Underweight/Normal	28	57.8566	78.86	0.574
	Obese	111	56.6945	77.13	

HRQoL and HbA1C

Glycaemic control of the study patients had influence on the HRQoL as shown in table 16.

Table 16: HRQoL and HbA1C of the study subjects

HRQoL domain	Glycaemic control	N	Mean	Minimum score	Maximum score	Chi-square P value
Physical	Good	34	14.2827	7.43	19.33	0.772
	Fair	36	13.7128	7.00	19.43	
	Poor	69	14.0289	8.00	20.00	
psychological	Good	34	14.6708	7.33	19.33	0.800
	Fair	36	14.7879	6.40	20.00	
	Poor	69	14.4162	8.00	20.00	
Social	Good	34	14.6875	8.00	20.00	0.304
	Fair	36	15.4141	8.00	20.00	
	Poor	69	14.3939	8.00	20.00	
Environmental	Good	34	14.2210	8.00	20.00	0.136
	Fair	36	14.0939	8.50	20.00	
	Poor	69	13.1894	6.50	20.00	
Total Scores	Good	34	57.8621	30.76	77.05	0.515
	Fair	36	58.0088	33.00	78.86	
	Poor	69	56.0284	32.83	76.02	

Discussion

This study sought to determine the overall HRQoL of ambulatory patients with type 2 diabetes on oral hypoglycemic agents using the WHO-QoL Bref tool. We recruited 139 study participants. Majority were female (61.3%) with a mean age of 56.37%. This is consistent with other studies from Nigeria, India and Thailand [36, 38 and 39.] This is not surprising as females having a better health seeking behavior than males. The main age group of the study population was between 40 and 60 years. The is in keeping with what is known that developing countries are affected at a relatively younger age (35 -55 years) as compared to the developed world of (55-75 years) [85] These ages are important because that is an age-group bracket of active economic activity for both self-care and family. Majority (60%) of the study participants had a source of employment (Table1). The population had poor metabolic control as evidenced by majority (75%) having more than 3 complications with neuropathy leading at 41% (figure 4, 5). The glycemic control was poor with 3 in 4 participants having an HbA1C greater than 7%.

We found 40% of the subjects rated their health as good and small proportion (35%) were satisfied with their health status. This is not surprising as diabetes is a chronic disease and can be a difficult condition to live with for many patients. The demand of self-care can be burdensome, frustrating and overwhelming both in terms of commitment to self-care and resource consumption .This is in keeping with studies done in Nigeria and Kuwait [36, 84]. Diabetes affected overall HRQoL and its domains (Table 5) especially social and physical domains. Majority (84%) of our study subjects however did however score above fair on the overall QoL scale. The discrepancy between self-rating and actual overall score could be attributed to the fact that our tool was investigator-administered to the study subjects. This could have led to biased responses as some of the questions

involved personal information from the study participants. This results are comparable with study done by B Isa et al in Nigeria [36.] They had a sample size of 251 and found that majority (86%) scored fair and above on the WHO-QOL Bref scale and also poorly in terms of self-rated HRQoL. Similar results were found in Kuwait [84.] Though comparisons would be difficult due to different socio-economic status between the two study populations in Kuwait and ours. This contrasts with study done in South Africa by Katzenellenbogen et al done on a similar socio-economic status study population .They found that majority of the study subjects diabetic patients achieved worse HRQoL scores. This can be attributed to using a different tool (ADDQoL) than in our study and also had a smaller sample size of 69 patients [37].

The main findings in this study were that the HRQoL was significantly associated with age, level of income and health care financing, employment status, duration of diabetes and its complications. It was surprising that just above half of the study patients (52.5%) had diabetes for less than 5yrs yet at least 3 out of 4 study subjects had 3 or more complications. Are we diagnosing our diabetics late? Why is the metabolic control poor? Age of the participants emerged as a significant association with HRQoL, on the social domain and not in the three other domains (table 6). A plausible interpretation is that interactions of aging-related disabilities with complications of diabetes seem to have influence on the social domain of the study patients. Aging overlaps with duration of diabetes in patients, and this is compounded by complication loading. It is therefore not surprising that duration of diabetes, number of complications per person were significantly associated with HRQoL of our study participants .This is similar to other studies done in Nigeria, South Africa, Thailand and by the Zodiac group[34, 36, 37and 39]. Diabetes as a chronic disease is demanding in both self-care commitment and resource consumption (medication, monitoring and attending hospital). It is therefore imperative that ability to meet these requirements may affect

one's own HRQoL. Majority of our study population are in the bracket of active economic activity for both self-care and family. We know that diabetes on its own can affect income generation directly and indirectly through complications e.g. neuropathy, retinopathy thus HRQoL studies are important in the context of one's personal well-being and the ability to work and earn a living. This study found that employment status, ability to purchase own health care and high annual income levels were significantly associated with physical, psychological and social domains of HRQoL . Other studies in Nigeria, South Africa, India and Thailand have made similar observations though the context of health care provision of patients, organizations of diabetes care and financing may vary in environments within which these studies were conducted [36-39].

Duration of diabetes, age and complication loading affected the physical, social and psychological domains which compares to most of the studies done on HRQoL Nigeria , Kuwait , Sweden , CODE-study and South Africa [36, 37, 62, 84and 86]. This affected their social lives, income generating activities and increase amount spent on diabetes health care and was reflected by poor scores of HRQoL in physical and social domains. Jacobson et al[31] studied both type 1 and 2 diabetes and found that quality of life decreased in relation to the number of complications of their study patients [31]. Rubin et al noted that the presence of co-morbid conditions and unfavorable socio-economic characteristics can further interact with the severity of diabetes and its complications to strongly influence different domains of HRQoL[25]. This has been partially demonstrated in this study. Complications such as neuropathy (41%) and retinopathy (29%) affected physical and psychological domains. Others like erectile dysfunction adversely affected the psychological domain. New onset erectile dysfunction has been shown to be a marker of more underlying complications like macro-vascular and neuropathy. It has been shown to worsen HRQoL of diabetic patients[47].

Glycemic control in this group was poor where the mean score was 8.04%. Only 1 in 4 of the study subjects attained the target HbA1C level of <7% .This is comparable to studies done in this clinic on glycemic control by Otieno C et al[88.] The poor metabolic control may be explained by multiple probable reasons that include scores irregularity of testing due to various reasons including inadequate financing for diabetic healthcare, inadequate knowledge by patients on diabetes self-care, medication as shown Otieno C et al[88]. We also noted lack of relevance on importance of regular testing of HbA1C (actually majority (90%) had no idea what HbA1C was) amongst the study participants. The level of glycemic control by HbA1c did not influence the HRQoL and its domains in this study. ZODIAC-2 and QUED study also using HbA1C made a similar finding in their studies of HRQoL of patients with type 2 diabetes [34,47]. This contrasts with a study done in South Africa[37] where they showed that glycemic control does impact on the HRQoL though they used a different tool to measure the HRQoL and had a smaller sample size. Similar results were seen in a study done in Thailand where they used WHO-QoL BREF tool but used random blood sugar for glycemic control instead of HbA1C as in our study [39]. These two studies found that poor glycemic control led to more hyperglycemic symptoms which impacted on the HRQoL thus underscoring the importance of symptoms in determination of one's HRQoL .The serial blood sugars may have been a better tool to assess because of the symptoms of both hyperglycemia (polyuria, poor vision etc.) and hypoglycemia (loss of consciousness etc.) would have had a larger impact on the HRQoL especially over a two week duration rather than HbA1C which is more of a historical assessment as shown by the QUED and ZODIAC-2 study groups [34,]

Marital status, gender and level of education of our study participants were not significantly associated with their HRQoL. Marital status of study participants did not affect HRQoL. This is surprising because one would expect better psychosocial support in the married ones as seen in

studies from India and Sweden[38, 62] HRQoL. They found that married male participants had better HRQoL of life. This was attributed to male dominated study group and better social support from their families especially their wives. In our study female gender bias may have skewed the results and good support from family and extended family may have contributed but it's still difficult to conclude. Level of education had no impact on HRQoL which is surprising because diabetes treatment is demanding and often complex, the patient is expected to bear much of the responsibility for making decisions which effect his/her health, both in the short- and long-term. Plausible explanation is that majority had received (90%) minimum primary education. This contrasts with other study done in India though it used a different tool and had a larger sample size of 269 patients and study patients had different levels of education[38.]

CONCLUSIONS AND RECOMMENDATIONS

There is reduced quality of life in our patients with diabetes. This is compounded by a small percentage of the study subjects (35-40%) satisfied with their health. There was poor metabolic control as evidenced by large number having multiple complications and poor HbA1C despite having had diabetes for a short duration of time. The determinants of HRQoL in the study patients in our study were: age of study participants, duration of diabetes, presence of complications and income related factors- employment status, amount of income, mode of health care financing. Factors that were not associated with HRQoL in our diabetic population were: gender, marital status, level of education, BMI and HbA1C. This study was able to show that being an older age, having had diabetes for a longer duration with multiple complications and inability to afford health care are likely to have poor HRQoL scores.

Recommendations

I. Inclusion of QOL as part of management of patients with diabetes who attend the Diabetes clinic in Kenyatta National Hospital.

II. Study on HRQoL in diabetic population attending the KNH, Diabetic clinic.

III. Intervention programs to improve glycemic and metabolic control in our diabetic patients.

IV. Multi-Disciplinary approach in the management of our diabetic population. This is to include diabetic educators, social workers, and psychologists. This will ensure that not only emphasis will be on diabetes control but also on the impact it has on the HRQoL.

Limitations

I. It's a cross-sectional study performed at a single center therefore not representative of the general diabetic population in Kenya

II. Response bias – it was administered by the investigators and some of the questions were too personal. This may have led to a response bias amongst the study participants.

III. Lack of an insulin dependent arm of study participants as a comparison group.

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APPENDIX 1: PATIENT INFORMATION FORM

My name is Dr. Eugene Genga. I am a post – graduate student of Internal Medicine at the University of Nairobi. The purpose of this statement is to inform you about a research study that I am carrying out. I am carrying out a research study on the quality of life of diabetic patients attending Kenyatta National Hospital. The aim of the study is to find out how patients who have diabetes are coping from their own perspective. Recommendations can then be made to the health care providers on interventions that can improve the quality of life of our patients.

Participation in this study is voluntary. Should you accept to participate, then the following is a summary of what the study involves:

1. Obtaining socio-demographic information such as age, gender from the patient.

   NOTE: Your name and hospital identification number shall not be included in this information for your privacy.

2. A physical examination – similar to the examination that your primary doctor usually performs. It includes listening to your chest and palpating your abdomen. It will be performed by a qualified medical practitioner.

3. Administration of a questionnaire to assess aspects of quality of life.

4. This will require about half an hour of your time.

Please note that your identity shall not be recorded nor revealed to any other person(s).

All information will be treated as confidential.

Your primary health physician shall be informed of any findings relevant to your medical care

A consent form shall be supplied for you to sign if you agree to participate.

If you do not agree to participate, there will be NO consequences. You medical care will continue as usual. Even if you agree to participate, you are free to withdraw from the study at any time with NO consequences at all.

Thank you for taking time to read this information.

If you have any questions, please do not hesitate to ask.

Clarifications may also be addressed to any of the following:

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P.O.Box 30197

Nairobi.

Telephone: 0723596189

Prof. C.F. Otieno

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Nairobi.

APPENDIX 2: CONSENT FORM

Introduction

This research study is being conducted by Dr Eugene Genga at the Kenyatta National hospital to determine how living with diabetes has influenced your quality of life.

Procedures

You will be asked to complete a questionnaire or online questionnaire. The questionnaire Consists of 33 questions and will take approximately 20 minutes. Questions will include Details about your social affiliations, demographics and your own personal views and Feelings about living with diabetes.

Risks/Discomforts

There are minimal risks for participation in this study. However, you may feel emotional Discomfort when answering questions about personal beliefs

Benefits

There are no direct benefits to subjects. However, it is hoped that your participation will Help researchers learn more about how social influences affect attitudes toward living with diabetes. The results of the study will be communicated back to the participants or the primary physician including my HbA1c results.

Confidentiality

All information provided will remain confidential and will only be reported as group data With no identifying information. All data, including questionnaires will be kept in a

Secure location and only those directly involved with the research will have access to

Them. After the research is completed, the questionnaires will be destroyed.

Compensation

Participants will not receive any monetary compensation for participating in the study.

Participation

Participation in this research study is voluntary. You have the right to withdraw at

Anytime or refuse to participate entirely without any fear of victimization.

Questions about the Research

If you have questions regarding this study, you may contact Dr Eugene Genga at gengaeuegne@yahoo.com or call 0723596189.

I……hereby consent to take part in this research study on the quality of life of patients with diabetes.

The nature of this study has been explained to me by Dr. Eugene K.G /his assistant. I have been assured that participation in this study is voluntary and will not negatively affect my medical care, and that any information obtained will be treated as confidential.

Signed/thumbprint……..

On this day and date……..

Witness…….

Date……

Investigator's Statement

I, the investigator, have provided an explanation on the purpose and implications of the above research study to the participant.

Signed…….

On this day and date……

APPENDIX 3: STUDY PROFORMA

How long have you had diabetes :(tick where applicable)

Less than 5years	5-10 years	More than 10 years

1. What is your gender? Male ☐ Female ☐

2. What is your date of birth? ___/____/_____
Day Month Year

3. What is the highest level of education you received?
None at all ☐
Primary School ☐
High School ☐
College ☐

4. What is your marital status?

Single	☐	Separated	☐
Married	☐	Divorced	☐
Living as Married	☐	Widowed	☐

5. Please describe the home where you live.
(Check "Yes" or "No" for each question. Check "Yes" to all that apply.)
Yes No
a. It is owned or being bought by you (or someone in the household). ……
b. It is rented for money by you (or someone in the household). ……..
c. It is occupied without payment or money or rent. …….
d. I live with friends. ……
e. I live with family. …….
f. I have no permanent residence. ……..
g. I live in a correctional facility (jail, prison). …….

4. How do you pay for your health care?
(Check "Yes" or "No" for each question. Check "Yes" to all that apply.)
Yes No
a. Government funding (Medicaid.....
b. Private insurance ……..
c. Self-pay, out of pocket ……..
d.Family support (son/daughter/other).....

5. Do you work for pay outside the home? …… Yes No

6. Check the box that best corresponds to your current work situation.
(Check "Yes" or "No" for each question.)
Yes No
a. Working full time ……
b. Working part time ……..
c. Not working and not looking for work …….
d. Unemployed and looking for work ……..
e. Disabled or retired and not looking for work …….
f. Currently in school …….

7. What is your total combined family income for the past 12 months, before taxes, from all sources, wages, public assistance/benefits, help from relatives, alimony, and so on? If you don't know your exact income, please estimate.
(Check one box)
a. Less than ksh5,000 ……..
b. Ksh5,000 - Ksh19,999……..
c. Ksh20,000 - Ksh49,999…….
d. Ksh50,000 - Ksh99,999…….
e. Ksh100,000 - Ksh149,999……
f. More than Ksh150,000 ……..
g. Don't know ……..
h. Chose not to answer ……

Please read each question, assess your feelings, and circle the number on the
Scale that gives the best answer for you for each question.

8. How would you rate your quality of life?

(Please circle the number)				
Very poor	**Poor**	**Neither poor nor good**	**good**	**Very good**
1	**2**	**3**	**4**	**5**

9. How satisfied are you with your health?

(Please circle the number)				
Very dissatisfied	**Dissatisfied**	**Neither dissatisfied nor satisfied**	**satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

The following questions ask about **how much** you have experienced certain things in the last two weeks.

10. To what extent do you feel that physical pain prevents you from doing what you need to do?

(Please circle the number)				
Not at all	**A little**	**A moderate amount**	**Very much**	**An extreme amount**
1	**2**	**3**	**4**	**5**

11. How much do you need any medical treatment to function in your daily life?

(Please circle the number)				
Not at all	**A little**	**A moderate amount**	**Very much**	**An extreme amount**
1	**2**	**3**	**4**	**5**

12. How much do you enjoy life?

(Please circle the number)				
Not at all	**A little**	**A moderate amount**	**Very much**	**An extreme amount**
1	**2**	**3**	**4**	**5**

13.To what extent do you feel your life to be meaningful?

(Please circle the number)				
Not at all	**A little**	**A moderate amount**	**Very much**	**An extreme amount**
1	**2**	**3**	**4**	**5**

14. How well are you able to concentrate?

(Please circle the number)				
Not at all	**A little**	**A moderate amount**	**Very much**	**An extreme amount**
1	**2**	**3**	**4**	**5**

15. How safe do you feel in your daily life?

(Please circle the number)				
Not at all	**A little**	**A moderate amount**	**Very much**	**An extreme amount**
1	**2**	**3**	**4**	**5**

16. How healthy is your physical environment?

(Please circle the number)				
Not at all	**A little**	**A moderate amount**	**Very much**	**An extreme amount**
1	**2**	**3**	**4**	**5**

The following questions ask about **how completely** you experience or were Able to do certain things in the last two weeks.

17. Do you have enough energy for everyday life?

(Please circle the number)				
Not at all	**A little**	**moderately**	**mostly**	**Completely**
1	**2**	**3**	**4**	**5**

18. Are you able to accept your bodily appearance?

(Please circle the number)				
Not at all	**A little**	**moderately**	**mostly**	**Completely**
1	**2**	**3**	**4**	**5**

19. Have you enough money to meet your needs

(Please circle the number)				
Not at all	**A little**	**moderately**	**mostly**	**Completely**
1	**2**	**3**	**4**	**5**

20. How available to you is the information that you need in your day-to-day life?

(Please circle the number)				
Not at all	**A little**	**moderately**	**mostly**	**Completely**
1	**2**	**3**	**4**	**5**

21. To what extent do you have the opportunity for leisure activities?

(Please circle the number)				
Not at all	**A little**	**moderately**	**mostly**	**Completely**
1	**2**	**3**	**4**	**5**

22. How well are you able to get around?

(Please circle the number)				
Very poor	**Poor**	**Neither poor nor well**	**well**	**Very well**
1	**2**	**3**	**4**	**5**

23. How satisfied are you with your sleep?

(Please circle the number)				
Very dissatisfied	**Dissatisfied**	**Neither dissatisfied nor satisfied**	**satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

24. How satisfied are you with your ability to perform your daily living Activities?

(Please circle the number)				
Very dissatisfied	**Dissatisfied**	**Neither dissatisfied nor satisfied**	**satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

25. How satisfied are you with your capacity for work?

(Please circle the number)				
Very dissatisfied	**Dissatisfied**	**Neither dissatisfied nor satisfied**	**satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

26. How satisfied are you with your abilities?

(Please circle the number)				
Very dissatisfied	**Dissatisfied**	**Neither dissatisfied nor satisfied**	**satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

27. How satisfied are you with your personal relationships?

(Please circle the number)				
Very dissatisfied	**Dissatisfied**	**Neither dissatisfied nor satisfied**	**satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

28. How satisfied are you with your sex life?

(Please circle the number)				
Very dissatisfied	**Dissatisfied**	**Neither dissatisfied nor satisfied**	**satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

29. How satisfied are you with the support you get from your friends?

(Please circle the number)				
Very dissatisfied	**Dissatisfied**	**Neither dissatisfied nor satisfied**	**satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

30. How satisfied are you with the conditions of your living place?

(Please circle the number)				
Very dissatisfied	**Dissatisfied**	**Neither dissatisfied nor satisfied**	**satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

31. How satisfied are you with your access to health services?

(Please circle the number)				
Very dissatisfied	**Dissatisfied**	**Neither dissatisfied nor satisfied**	**satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

32. How satisfied are you with your mode of transportation

(Please circle the number)				
Very dissatisfied	**Dissatisfied**	**Neither dissatisfied nor satisfied**	**satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

The follow question refers to **how often** you have felt or experienced certain things in the last two weeks.

33. How often do you have negative feelings, such as blue mood, despair, anxiety, depression?

(Please circle the number)				
Never	**Seldom**	**Quite often**	**Very often**	**Often always**
1	**2**	**3**	**4**	**5**

Did someone help you to fill out this form? *(Please circle Yes or No)*

Yes No

How long did it take to fill out this form? _____

THANK YOU FOR YOUR TIME