PREDICTORS OF POOR GLYCEMIC CONTROL IN TYPE 2 DIABETIC PATIENTS ATTENDING PUBLIC HOSPITALS IN DAR ES SALAAM, TANZANIA

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By

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CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled ***Predictors of poor glycemic control in type 2 diabetic patients attending public hospitals in Dar Es salaam, Tanzania,*** in fulfillment of requirements for the degree of Master of Pharmacy (Hospital and Clinical Pharmacy) of Muhimbili University of Health and Allied Sciences.

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Prof. Appolinary Kamuhabwa

(Supervisor)

_____

Date

DECLERATION AND COPYRIGHT

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

Signature…….....**.....** **Date**……

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DEDICATION

This dissertation is dedicated to my lovely wife, Rebeka my children Brighton and Brigitte and my mother Prisca. It is also dedicated to my father, Charles Mwera, who inspired me right from childhood to study hard especially in science subjects.

ABSTRACT

Background

Diabetes is a major health problem worldwide thus becoming pandemic. Due to its chronic nature and complications accompanying the disease progression, the cost of managing diabetes is significant. Tanzania has also experienced a significant rise in the burden of diabetes and is estimated that more than 400,000 people are living with diabetes. A major concern in the management of diabetes is the occurrence of diabetic complications which occur as a result of poor glycemic control. Various factors have been found to be associated with poor glycemic control. Identification of these factors is important in order to formulate appropriate interventions that will result in improved glycemic control and prevention of chronic complications.

Objectives

The aim of this study was to determine the level of glycemic control and explore the factors associated with poor glycemic control among type 2 diabetes mellitus (T2DM) patients.

Methodology

A cross sectional study was carried out at diabetic clinics for T2DM patients at Muhimbili National Hospital (MNH), Temeke hospital, Amana hospital and mwananyamala hospital where by a systematic random sample of 469 T2DM patients were enrolled over a period of 8 weeks from 3rd March 2013 to 10th May 2013 to participate in the study. After obtaining informed consent from patients, a structured questionnaire and data collection form were used to collect information from the participants. The questionnaires sought information about socio-demographic, clinical characteristics, self-care management behaviours and medication adherence. Blood pressure, weight and height and were measured. All available last readings for fasting blood glucose (FBG) measurements and lipid were abstracted from patients' records. Poor glycemic control was defined as FBG $\geq$7.2mmol/L. Data entry, cleaning and analysis was conducted by use of Statistical package for Social Sciences (SPSS) software version 20. Data were described using mean for continuous variables and proportions for categorical variables. Significance testing of proportions was carried out by using Chi-square test, where a probability (P) of less than 0.05 was considered to be statistically significant.

Any factor with p- value of less or equal to 0.2 was considered for Binary logistic regression which was used to study the independent factors predicting "poor" glycemic control.

Results

The mean age of patients was 54.93 years. Majority (63.5%) of patients were females and only 8 patients had records of lipid profile measurements. Out of 469 patients, 69.7% had FBG ≥ 7.2 mmol/L indicating poor glycemic control. Females aged between 40-59 years were found to have a significant poor glycemic control (76.1%) as compared to their male counterparts of the same age group. Thirty eight percent of T2DM patients had poor medication adherence, which was associated with poor glycemic control. The mean disease duration since diagnosis was 7.19 years and the proportion of poor glycemic control increased with age. Significantly high proportion of poor glycemic control was observed in patients who had longer disease duration of more than 20 years since diagnosis (p=0.027). In Multivariate analysis revealed five variables associated with poor glycemic control; patients who were not insured for health care, taking more than one oral hypoglycemic agent (OHA), having normal body mass index (BMI), being obese and not adhering to diabetic medications.

Conclusion

Despite the importance of serum lipids monitoring and established association of serum lipids and diabetes and their effect on cardiovascular complications, the unexpected finding in our study was that records in lipid profile measurements were not available for almost all the patients studied in public hospitals. The findings from this study indicate that T2DM patients in Dar es Salaam have generally poor glycemic control and the independent variables associated with poor glycemic control were lack of insurance for health care, taking more than OHA, Normal BMI, obesity and low adherence to oral hypoglycemic agents. From these finding it is recommended that all diabetic patients should be screened for lipid profile since high cholesterol levels, triglycerides (TAG) and low density lipoproteins (LDL) are associated with increased risk of cardiovascular events and accumulation of cholesterol may contribute to ß-cell dysfunction. An education program should be developed to educate patients on the importance of medication adherence and weight management for better glycemic control.

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ABBREVIATION

ACEIs	-	Angiotensin converting enzyme inhibitors
ADA	-	American Diabetic Association
AHA	-	American heart association
AIDS	-	Acquired immunodeficiency syndrome
ARBs	-	Angiotensin receptor blockers
BMI	-	Body mass index
FBG	-	Fasting blood glucose
BGM	-	Blood Glucose Monitoring
CVD	-	Cardiovascular diseases
DCCT	-	Diabetes Control and Complications Trial
DSME	-	Diabetic self management education
DMOs	-	District medical officers
GDM	-	Gestational diabetes
HbA1c	-	Glycosylated haemoglobin
HDL	-	High density lipoprotein
HTN	-	Hypertension
HOPE	-	Heart outcome prevention evaluation
IGT	-	Impaired glucose tolerance
LDL	-	Low density lipoprotein
MI	-	Myocardial infarction
MNH	-	Muhimbili National Hospital
MUHAS	-	Muhimbili University of Health and Allied Sciences
NCEP	-	National cholesterol education program
NHANES	-	National health and nutrition examination surveys
OGTT	-	Oral glucose tolerance test
OHA	-	Oral hypoglycemic agents
RBG	-	Random blood glucose
SES	-	Socioeconomic status

SPSS	-	Statistical Package for Social Sciences
TAG	-	Triglycerides
TDA	-	Tanzania diabetic association
T1DM	-	Type 1 Diabetes Mellitus
T2DM	-	Type 2 Diabetes Mellitus
UKPDS	-	United Kingdom prospective diabetes study
WHO	-	World health organization

CHAPTER ONE

1.1. INTRODUCTION

1.1.1. Definition and classification

Diabetes mellitus is a metabolic disorder characterized by persistently elevated blood glucose levels and it occurs due to defects in insulin production, insulin action, or both (1). Insulin is a hormone produced by the beta cells of the pancreas and primarily performs the role of regulating the level of glucose in the blood. Diabetes is currently classified into 4 categories based on etiology. These include type 1 diabetes mellitus (T1DM), type 2 diabetes mellitus (T2DM), gestational diabetes mellitus (GDM) and other types of diabetes (2).

T1DM is form of diabetes which accounts for about 5 to 10 percent of all diagnosed cases of diabetes (3). It predominantly affects children and young adults, but can occur at any age. It occurs primarily when the pancreatic beta cells responsible for insulin production are destroyed due to a cellular–mediated autoimmune disorder, which leads to an absolute insulin deficiency (3).

T2DM mostly affects people older than 40 years of age (4) although, it has a very low prevalence in children and adolescents (i.e., about 0.3 percent). T2DM accounts for approximately 90% to 95% of all diagnosed cases of diabetes in adults (3). T2DM occurs when there is insulin resistance (i.e., a situation whereby the body produces insulin but the cells do not use it properly) followed by a gradual inability of the cells of the pancreas to adequately produce sufficient insulin to meet the demands of the body. Obesity, physical inactivity, impaired glucose metabolism, history of GDM, family history of diabetes, older age, and race/ethnicity are the factors associated with the increased risk of developing T2DM (4).

GDM is a form of glucose intolerance diagnosed in pregnant women, (especially occurs in women who are obese or have a family history of diabetes or both) and has been commonly reported among American Indians, African Americans, and Hispanic/ Latino Americans women (3). The prevalence of GDM varies across different populations, ranging from about 1 to 14 percent of pregnancies. According to a report by the American Diabetes Association

(ADA), about 4 percent of all pregnancies in the U.S. are complicated by GDM, with about 135,000 cases reported annually. In addition, about 90 percent of all pregnancies complicated by diabetes in the U.S. have been attributed to GDM (5). Although most cases of GDM resolve after pregnancy, it is still one of the predisposing factors to developing T2DM and according to the Centers for Disease Control, 5 to 10 percent of women with gestational diabetes developed T2DM immediately after pregnancy. It was also estimated that there are 40-60% chances of developing T2DM within 5-10 years after delivery in women with GDM (3).

Other types of diabetes result from specific genetic conditions (such as maturity-onset diabetes of youth (MODY)), surgery, medications, infections, pancreatic disease, and other illnesses. Such types of diabetes account for 1% to 5% of all diagnosed cases (2,3,5).

1.1.2. Epidemiology and economic burden

Diabetes mellitus is a major health problem worldwide with its prevalence increasing, thus becoming a pandemic (6). In the U.S, the estimated prevalence of diabetes (both T1DM and T2DM) in people younger than 20 years is 0.26%. This means that 1 in every 400 persons less than 20 years has diabetes. 11.3% of all people in age of 20 years or older and 26.9% of all people in age of 65 years or older (3) has diabetes. According to the World Health Organization (WHO) (7), more than 180 million people worldwide have diabetes mellitus. Moreover, a recent global estimation by the WHO indicated that there would be 366 million people with DM by the year 2030 (8). Due to the chronic nature of diabetes and complications that accompany the disease progression, the cost of managing diabetes is significant. In the U.S., about $1 out of every $5 spent on healthcare is used to treat a diabetic patient (this includes cost for treatment of diabetes and diabetes-related co morbidities). A study conducted in south Nigeria on medication adherence has shown that monthly cost of antidiabetic medications was US$22.9 (9).Tanzania has been experiencing a significant rise in the burden of diabetes. In the 1980s, the prevalence of T2DM was reported as 0.9% in the rural areas (10). In the year 2000, the prevalence of diabetes was reported to be 1.3% in rural areas and

4.0% in urban populations (11). At present, the Tanzania Diabetes Association (TDA) estimates that there are more than 400,000 people with diabetes. In Tanzania about US$4 million would have been required to take care of all patients with diabetes in 1989/90, which translates to US$138 per patient per year. This sum is equivalent to 8.1 percent of the total budgeted health expenditure for that financial year and well above the allocated per capita health expenditure in Tanzania of US$2 for the year 1989/90 (12).

1.1.3. Pathophysiology of T2DM

T2DM is characterized by insulin insensitivity as a result of peripheral insulin resistance, declining insulin production, impaired regulation of hepatic glucose production, abnormal fat metabolism and eventual pancreatic ß-cell failure. In early stages of the disorder glucose tolerance remain nearly normal despite insulin resistance because pancreatic ß-cell compensate by increasing insulin output. As insulin resistance and compensate hyperinsulinemia progress the pancreatic islets in certain individuals are unable to sustain the hyperinsulinemia state. Impaired glucose tolerance (IGT) characterized by elevation of postprandial glucose then develops (13,14). A further decline in insulin secretion and an increase hepatic glucose production leads to overt diabetes with fasting hyperglycemia, ultimately ß-cell failure may ensue (15). Initiation of the insulin response depends upon the trans-membranous transport of glucose and coupling of glucose to glucose sensor. Glucose /glucose sensor then induces an increase in glucokinase by stabilizing the protein and impairing its degradation. Glucose transport in ß-cell in people with T2DM appears to be greatly reduced, thus shifting the control point for insulin secretion from glucokinase to the glucose transport system (16,17). This defect is improved by the use sulfonylurea's (18,19). Impaired insulin secretion and insulin resistance contribute more or less jointly to development of pathophysiological conditions.

Impaired insulin secretion is a decrease in glucose responsiveness which is observed before the clinical onset of the disease. More specifically IGT is induced by decrease in glucose response early phase of insulin secretion and a decrease in addition insulin secretion after meal cause postprandial hyperglycemia.

Impaired insulin secretion is generally progressive and its progression involves glucose toxicity and lipotoxicity. When untreated glucose toxicity and lipotoxicity, these are known to cause a decrease in pancreatic ß-cell mass. The progression of the impairment of ß-cell function greatly affects a long term control of blood glucose. This leads to a decrease in glucose transport into the liver, muscle cells, and fat cells. There is also an increase in the breakdown of fat with hyperglycemia (20).

While patients during the early stages after disease onset show an increase in postprandial blood glucose as a result of increased insulin resistance and decreased early phase secretion the progression of deterioration of pancreatic ß-cell function subsequently cause permanent elevation of blood glucose (21–24).

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1.1.4. Clinical features and complications

Many patients with T2DM present with increased urination and thirst, many others have an insidious onset of hyperglycemia and are asymptomatic initially. This is particularly true in obese patients, whose diabetes may be detected only after glycosuria or hyperglycemia which is noted during routine laboratory studies. Occasionally, T2DM may present with evidence of neuropathic or cardiovascular complications because of occult disease present for some time prior to diagnosis. Chronic skin infections are common. Generalized pruritus and symptoms of vaginitis are frequently the initial complaints of women (22).

A major concern in the management of diabetes is the occurrence of complications, many of which are irreversible. Complications in diabetes occur as a result of the injurious effects of hyperglycemia (25). Long term complications of diabetes can be broadly classified into two major categories: macrovascular (e.g., peripheral arterial disease, stroke, and coronary artery disease); and microvascular (e.g., retinopathy, neuropathy, and nephropathy) (25). Other complications experienced by diabetic patients include skin complications, gastroparesis, dental infections and depression (26).

Macrovascular diseases occur due to the process of atherosclerosis. Also accompanying the atherosclerotic process is a high possibility for the occurrence of hyper- coagulation and

elevated platelet adhesion, all of which predisposes the diabetic patient towards developing a cardiovascular event. Common CVD events experienced by diabetic patients include coronary heart diseases, myocardial infarction (MI), stroke, cerebrovascular diseases, erectile dysfunction and peripheral vascular diseases (25–27).

The three microvascular complications associated with diabetes include, diabetic nephropathy, diabetic retinopathy and diabetic neuropathy (25). It has been postulated that diabetic retinopathy occurs before the development of either diabetic nephropathy or neuropathy and diabetic neuropathy occurs along with or after the development of diabetic nephropathy (27).

Diabetic nephropathy is the major cause of end stage renal disease (ESRD) and is usually characterized by the development of microalbuminuria (albumin excretion rate of 30–299 mg/ 24 hours) and if not adequately controlled, it could progress to proteinuria (> 500mg/24 hours) and overt diabetic nephropathy (25). For T2DM patients, administration of specific antihypertensive medications (i.e., angiotensin-converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs)) have been shown to reduce the risk of nephropathy and cardiovascular events (28,29). All diabetic patients should be screened yearly for microalbuminuria and serum creatinine (30).

Diabetic retinopathy is associated with abnormal increase in urinary albumin excretion (31). It is the most common microvascular complication and its risk increases with both duration and severity of diabetes (25). The rate of occurrence, from time of diagnosis, is 20 years for type 1 and 7 years for T2DM patients (32). Generally, diabetic retinopathy can be classified as either background (i.e., characterized by presence of small hemorrhages in the middle layers of the retina) or proliferative (i.e., characterized by the presence of new blood vessels on the surface of the retina with a possibility of development of vitreous hemorrhage) (33). All diabetic patients should receive yearly comprehensive eye exams (30)

Diabetic neuropathy is recognized as “the presence of symptoms and/or signs of peripheral nerve dysfunction in people with diabetes after the exclusion of other causes.” (34). It is the most frequently occurring of all complications of diabetes and could lead to clinically significant morbidities such as pain, loss of sensations, foot ulcers, gangrene and amputations

(25). The risk of developing diabetic neuropathy increases with severity and duration of the underlying hyperglycemia, hyperlipidemia, as well as hypertension (25).

1.1.5. Diagnosis of T2DM

Certain criteria have been established as basis for the diagnosis of diabetes in adults. Currently, there are three possible ways through which diabetes can be diagnosed and any one of the methods chosen must be confirmed on a subsequent day using any one of the other methods, except in the event of unequivocal symptoms of hyperglycemia being present (5). The table 1 below shows the criteria that are used for diagnosis of diabetes

Table 1: Criteria for diagnosis of diabetes

Number	Glucose level
1	FPG ≥126 mg/dl (7.0mmol/l). Fasting is defined as no caloric intake for at least 8 h.
	OR
2	Symptoms of hyperglycemia and a casual plasma glucose ≥200 mg/dl (11.1mmol/l). Casual is defined as any time of day without regard to time since last meal. The classic symptoms of hyperglycemia include polyuria, polydipsia, and unexplained weight loss.
	OR
3	2-h plasma glucose ≥200 mg/dl (11.1mmol/l) during an OGTT. The test should be performed as described by the World Health Organization, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water

Source: American Diabetes Association. Diagnosis and classification of diabetes mellitus. Diabetes Care. Jan 2009; 32 Suppl 1:S62-67

1.1.6. Management and glycemic control in T2DM

Diabetes is considered to be one of the most psychologically and behaviorally demanding of the chronic diseases (4). Several large clinical trials have demonstrated that tight blood glucose control correlates with a reduction in the microvascular complications of diabetes and

the incidence of clinical complication in patient with T2DM is associated with hyperglycemia (35,36).

For optimal management of people with diabetes, it is important that the health care team devise a treatment plan tailored specifically to the needs of the individual patient. The treatment plan should include adequate glycemic control (i.e., self monitoring of blood glucose level and measurement of hemoglobin A1C) as well as adequate blood pressure and blood lipid levels monitoring (25). It also requires dietary modifications, exercise, and administration of medication on schedule (37,38). It is important that patients be allowed to play active roles in the management of their health and they should be encouraged to participate in diabetes self-management education (DSME) programs. Studies have emphasized the importance of achieving optimal glucose control through strict adherence to medications, diet, and exercise in order to minimize serious long term complications (37–40). Other important factors considered when developing a comprehensive treatment plan include patient's age, eating behaviors, work or school schedule, socio-cultural /socio-economic factors, and presence of complications of diabetes or other co-morbid conditions (25).

The American Diabetes Association (ADA) has developed a number of recommendations to guide healthcare professionals in achieving desirable glycemic control and prevention of complications of cardiovascular diseases (CVD) (25). These recommendations were similar to those presented by the American Heart Association (AHA) and the National Cholesterol Education Program (NCEP). According to ADA, treatment goals should be customized to meet individual diabetic patient's needs (i.e., based on the age and life expectancy of the patient, presence of co-morbid conditions, duration of diabetes, presence of known CVD or advanced microvascular complications, and the patient's level of hypoglycemia awareness) (25).The recommended treatment goals for T2DM are shown in table 2.

In the management of diabetes, it is important to provide adequate patient education on the disease state; associated complications; risk for developing the complications (including the signs and the symptoms); as well as the importance of achieving and maintaining adequate glycemic control, especially as it relates to the prevention and management of diabetic complications (41). Diabetes management can be broadly classified into non-pharmacological

(i.e., lifestyle changes) and pharmacological (i.e., drugs) interventions. Pharmacological intervention becomes necessary only when optimal glycemic control cannot be achieved through lifestyle changes alone. Generally, patients with an HbA1c level above 7 percent or who present with symptoms can be managed using both pharmacological and non-pharmacological interventions.

Table 2: Recommended treatment goals for management of diabetes

Parameter	Recommended level
Hemoglobin A1C (HbA1C)	<7%
Pre-prandial capillary plasma glucose	70 – 130 mg/dl (3.9 – 7.2mmol/l)
Peak postprandial capillary plasma glucose	< 180 mg/dl (<10.0mmol/l)
Blood Pressure	Diastolic < 80mmHg
	Systolic < 130mmHg
Lipids	
Low density lipoprotein(LDL)	< 100mg/dl (<2.6mmol)
Triglycerides	< 150mg/dl (<1.7mmol/l)
High density lipoprotein (HDL)	> 40mg/dl (1.0mmol/l) in men
	> 50mg/dl (1.3mmol/l) in women(25)

Source: Adapted from: American Diabetes Association. Standards of medical care in diabetes-2009. Diabetes Care. Jan 2009; 32 Suppl 1:S13-61.

Pharmacological management of diabetes involves the administration of agents such as insulin and/or OHAs (41).The choice of specific pharmalogical agents is predicated on their effectiveness in lowering glucose, extraglycemic effects that may reduce long-term complications, safety profiles, tolerability, ease of use, and expense (42).

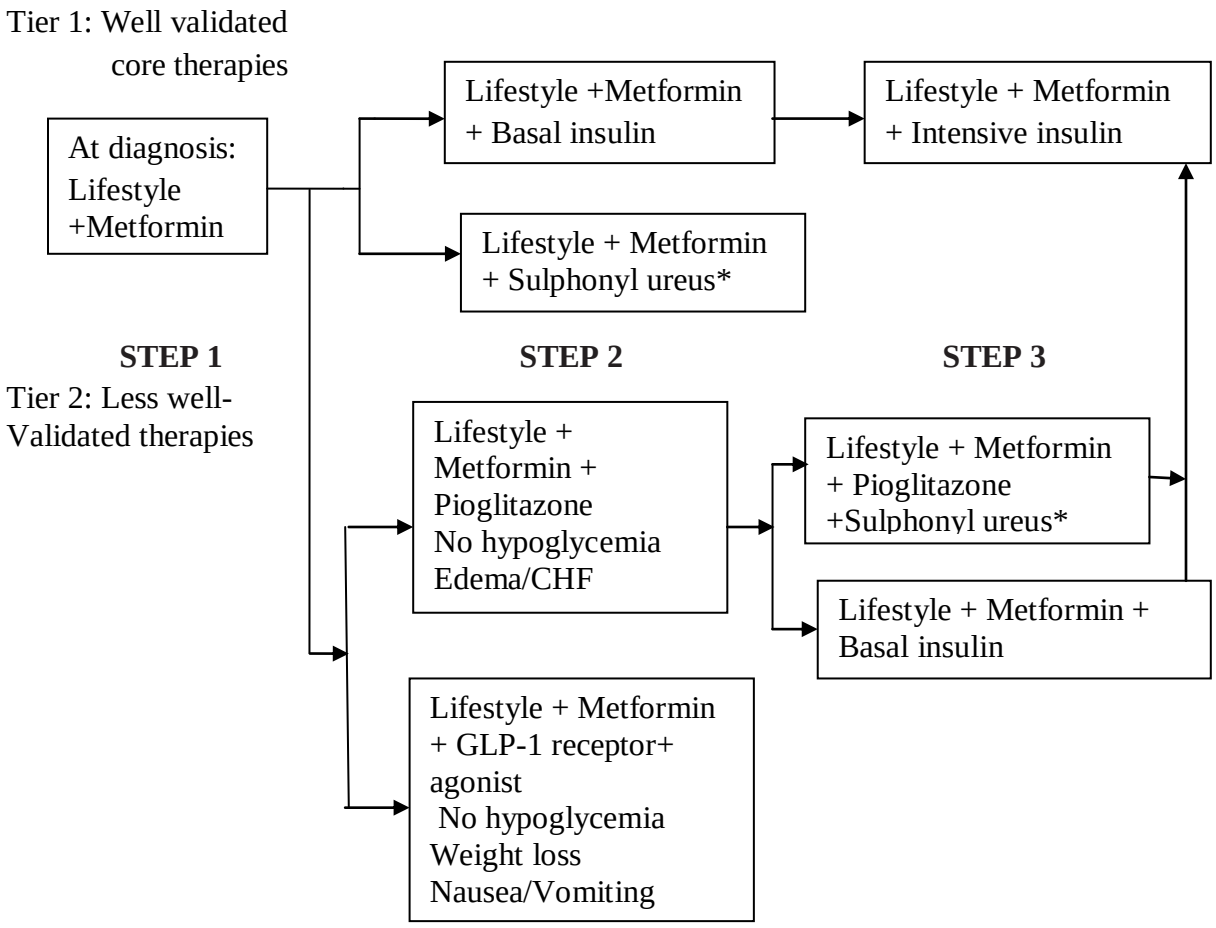
Many patients may be managed effectively with monotherapy; however, the progressive nature of the disease will require the use of combination therapy in many, if not most, patients over time, to achieve and maintain glycemia in the target range (42,43).

Metformin is recommended as the initial pharmacological therapy, in the absence of specific contraindications, for its effect on glycemia, absence of weight gain or hypoglycemia, generally low level of side effects, high level of acceptance, and relatively low cost. Metformin treatment should be titrated to its maximally effective dose over 1–2 months, as tolerated. Rapid addition of other glucose-lowering medications should be considered in the setting of persistent symptomatic hyperglycemia (42).

However, when adding second anti-hyperglycemic medications, the synergy of particular combinations and other interactions should be considered(43).

In the setting of severely uncontrolled diabetes with catabolism, defined as fasting plasma glucose levels ≥13.9mmol/l (250 mg/dl), random glucose levels consistently above 16.7mmol/l (300 mg/dl), A1C above 10%, or the presence of ketonuria, or as symptomatic diabetes with polyuria, polydipsia and weight loss, insulin therapy in combination with lifestyle intervention is the treatment of choice.(42,43)

The algorithm (Fig. 2) takes into account the characteristics of the individual interventions, their synergies, and expense. The goal is to achieve and maintain A1C levels of ≤7% and to change interventions at as rapid a pace as titration of medications allows when target glycemic goals are not being achieved. Mounting evidence suggests that aggressive lowering of glycemia, especially with insulin therapy, in newly diagnosed diabetes can result in sustained remissions without need for glucose-lowering medications, T2DM is a progressive disease (36), and patients should be informed that they are likely to require the addition of glucose-lowering medications over time



Source: adopted from American diabetes association and European association for the study of diabetes. A consensus algorithm for initiation and adjustment of therapy

Figure 1: Algorithm for the metabolic management of T2DM;

Reinforce lifestyle interventions at every visit and check A1C every 3 months until A1C is ≤7% and then at least every 6 months. The interventions should be changed if A1C is ≥7%. *Sulfonylurea's other than glibenclamide or chlorpropamide. +Insufficient clinical use to be confident regarding safety. CHF- Congestive heart failure.

1.2. LITERATURE REVIEW

1.2.1 Glycemic control and associated factors

Glycemic control is considered as the main therapeutic goal for prevention of organ damage and other complications of diabetes. Several large clinical trials (35,44) have demonstrated that tight blood glucose control correlate with reduction of microvascular complication of diabetes. Therefore achieving glycemic control is critical metabolic goal because hyperglycemia contributes to the progression of diabetes mellitus by affecting both ß-cell function and insulin sensitivity (16). Despite of the evidence from these trials establishing the benefit of intensive management of DM high proportion of patients remain poorly controlled.

The study conducted in Jordan showed that 65.1% of T2DM had poor glycemic control. Another study in Ethiopia by Wabe et al (45) showed that only 41.8% of the patient had adequate glycemic control and a study in South Nigeria (9) showed that 43.8% of the patient had adequate glycemic control. Several other studies also reported poor glycemic control among type 2 diabetic patients (46–53).

So in clinical practice optimal control is difficult to obtain on the long term basis because the reasons for poor glycemic control in T2DM patients are complex. Both patients and health care provider related factors may contribute to poor glycemic control.

In view of the benefits of strict glycaemic control, several studies have been done to explore variables that may be associated with poor control (46,54–56). Most of these studies however are from Europe and North America with minimal data available from Asia and the African continent. A variety of factors are identified in influencing glycemic control including age, sex, education, marital status, body mass index (BMI), smoking, diabetes duration and type of medication.

1.2.1.1. Socioeconomic status

Socioeconomic variables such as income, level of education and family structure have been found to be predictors of glycaemic control. In developed countries, socioeconomic status (SES) is inversely correlated with prevalence of NIDDM (57) and obesity (58). In many chronic illnesses, lower socioeconomic status is associated with poor outcomes (54). Low SES

is also characterized by decreased access to health care and perhaps by the inferior quality of health care as well. Studies have suggested that minority groups have poor glycemic control i.e., high HbA1c levels (e.g., African Americans, Hispanics, American Indians, Pacific Islanders) (59,60). However a study by Harris et al (61) did not find an association between glycemic control and insurance coverage or socioeconomic status using NHANES III data, a representative sample of the U.S. population. Similarly, the Michigan community study in U.S (62) and a study of blacks and whites in South Carolina(U.S) (63), and a study of whites and Mexican-Americans in Texas(U.S) (64) did not find an association between glycemic control and socioeconomic status. Factors predicting glycemic control in middle-aged and older adults with type 2 diabetes in U.S showed that education level and marital status were not significantly associated with glycemic control (49). Another study in UK by Chou et al showed that socioeconomic status such as education and marital status were not associated with glycemic control (59). Several other studies did not show the association between SES and glycemic control (65–67).

1.2.1.2 Age and age at onset

Age of the patient and age at onset of diabetes mellitus have been found to be significantly associated with glycaemic control. Nichols et al (68) found that age, BMI and emotional distress were significantly related to glycemic control in a health maintenance organization population in Oregon, America. They found that young age is associated with poor metabolic control. EL-Kebbi et al (69) and Rothenbacher and colleagues (70) also, reported that younger age was associated with poor glycemic control. Other studies have found that older age is associated with poor glycemic control. For instance a study in Myanmar found that age greater or equal to 60 years was associated with poor glycaemic control (71). However Shorr et al (72) and Balkkrishnan et al (73) studied the relationship between age and glycemic control and found no significant differences between age groups.

1.2.1.3. Diabetes duration

Longer duration of diabetes is known to be associated with poor glycemic control, possibly because of progressive impairment of insulin secretion with time because of ß-cell failure (35). A study in Hawaii on the factors associated with poor glycemic control found that compared with patients who had diabetes for 3 years or less, patients with diabetes for 10 or more years were more than 9 times likely to have poor control (52). Another study in Jordan on the factors associated with glycemic control showed that longer duration of diabetes was significantly associated with poor glycemic control (53). A study on factors predicting glycemic control in middle-aged and older adults with T2DM showed that participants who reported having longer duration of diabetes had higher HbA1c levels than participants who reported having fewer shorter duration of diabetes, independent of the demographic determinants (49).

1.2.1.4. Medication adherence

Adherence to prescribed anti diabetic medications is crucial to reach metabolic control as non adherence with blood glucose lowering or lipid lowering drugs is associated with higher HbA1c and cholesterol levels respectively (74). Non-adherence is associated with an increase in A1C as well as other negative health outcomes such as increased LDL cholesterol levels, increased all-cause hospitalizations, and increased all cause mortality (74–76). Rhee et al on study of patient adherence to Anti-diabetic agents on glycemic control showed that taking diabetes medications as directed was associated with substantial improvements in HbA1c (77). Another study conducted in Malaysia showed that patients who did not adhere to their anti-diabetic medications had significantly higher HbA1c values as well as fasting blood glucose levels than those who were adherent (50). Al-Qazazi et al reported that high level of education and good medication adherence is associated with good glycemic control (78). A longitudinal study by Kuo et al and associates (79) assessed the inconsistent use of diabetes medications and its effects on diabetes complications and mortality among 908 Mexican Americans over the age of 65 years. In their study, the authors determined that 64% of the patients had high consistent use of their oral hypoglycemic medications and they had good

glycemic control. Increases in adherence will lead to improved drug regimens, reduced health care expenditures, and overall improved patient outcomes (80)

1.2.1.5. Self management behaviours

Self-management can be described as a set of skilled behaviours engaged in to manage one's own illness, 'influencing the outcomes of the treatment regimen (81). The skills needed to be known by the patients with diabetes are related to diet, exercise, self-monitoring of blood glucose, foot care, travelling and sick-day management, and taking medicine; they are the very ones responsible for carrying out day-to-day self-care activities (82). Improved self-management behaviors could help to improve glycemic control, obesity, and other diabetes-related risks to help reduce the development of diabetes-related complications (83**).** The major environmental factors that increase the risk of T2DM are over nutrition and a sedentary lifestyle, with consequent overweight and obesity. Not surprisingly, interventions that reverse or improve these factors have been demonstrated to have a beneficial effect on control of glycemia in established T2DM (84). Studies in Jordan (53) and India (85) on the effect of self management behaviors on glycemic control reported that the proportional of poor glycaemic control were 61.5% and 66.7% respectively. These studies showed that individuals with poor glycaemic control were not adhering on self management behaviours such as exercise, diet control and self monitoring of blood glucose.

Self-monitoring of blood glucose (SMBG) aims at collecting information on blood glucose levels at different time points during the day and allows for the timely identification of high levels of blood glucose. SMBG has proven effective for patients with T2DM who are using insulin (86) because the information about a patient's glucose level is useful to refine and adjust insulin dosages, resulting in an improved glycemic control. However the systemic review on self monitoring of blood glucose in patients with T2DM who are not using insulin also showed that the overall effect of SMBG was a statistically significant decrease of 0.39% in HbA1c compared with the control groups (87). Another study in Karachi Pakistan showed that self monitoring of blood glucose level is associated with clinically and statistically better glycaemic control regardless of diabetic type or therapy (88).

Exercise is widely perceived to be beneficial for glycemic control and weight loss in patients with T2DM. Regular physical activity is recommended for patients with T2DM since it may have beneficial effects on metabolic risk factors for the development of diabetic complications (89). The low-cost, non-pharmacological nature of physical activity further enhances its therapeutic appeal (90). Two randomized trials conducted in US and Finland found that lifestyle interventions including ~150 min/week of physical activity and diet-induced weight loss of 5–7% reduced the risk of progression from impaired glucose tolerance (IGT) to T2DM patients by 58% (91,92). A cluster-randomized trial that was conducted in China found that diet alone; exercise alone, and combined diet and exercise were equally effective in reducing the progression from IGT to diabetes (90). Boulé et al (89) undertook a systematic review and meta-analysis on the effects of structured exercise interventions in clinical trials of ≥8 weeks duration on HbA_{1c} (A1C) and BMI in people with T2DM. Post-intervention A1C was significantly lower in exercise than control groups (7.65 vs. 8.31%, weighted mean difference −0.66%; $P < 0.001$). In contrast, post-intervention body weight did not differ between the exercise and control groups.

1.2.1.6. Gender

Studies have shown that women have poor glycemic control when compared to men because women have more adverse effects of diabetes on the lipid profile (low HDL cholesterol and apolipoprotein A1 levels, increased levels of LDL cholesterol, small and dense LDL, apolipoprotein B, and triglycerides) and blood pressure than men (93,94). Diabetes may also alter estrogen-related diabetes protective mechanisms (95). Furthermore, low-grade inflammation may have a greater role in perturbing insulin action in women, or inflammatory factors may interact with female sex hormones, resulting in a decrease of protective effects of estrogens on body fat distribution and insulin action (96). Abnormal lipid profile is associated with Low grade inflammation of white adipose tissue (WAT) resulting from chronic activation of innate immune system leads to insulin resistance, impaired glucose tolerance and even diabetes. In individual with abnormal lipid profile is characterized with increased production and secretion of wide range of inflammatory molecules including TNF-α and interleukin-6

(IL-6) which may have local effect on WAT**.** In a study that was conducted in a Pakistani Muslim diabetic population in Manchester, UK, women were worse than men in performing regular glucose measurements, in managing persistent hyperglycemia, and had also poorer glycemic control (97). Results from a survey in Mexico have suggested that women have several social disadvantages, deterioration of healthy life, poor self-care and lack of solidarity that increases their vulnerability to reach glycemic control successfully (98). However, several studies have failed to show significant gender differences related to self-care and control of T2DM (99). The study on factors predicting glycemic control in middle-aged and older adults with type 2 diabetes also showed that sex is not significantly associated with HbA1c levels (49).

1.2.1.7. Obesity, cholesterol, triglycerides, HDL, LDL and HTN

Diabetes and a low density cholesterol level are associated with each other and with a higher coronary heart disease risk. Moreover, both are strongly associated with obesity (100). Diabetes has the effect of lowering high-density-lipoprotein (HDL) cholesterol levels, also known as "good" cholesterol, and increasing triglyceride and LDL cholesterol levels (41). Cholesterol accumulation may contribute to ß-cell dysfunction in T2DM (101). Obesity has been considered a major risk factor for the development of non–insulin dependent diabetes mellitus. Obesity and physical inactivity aggravate insulin resistance. Also, people who are insulin resistant typically have an imbalance in their blood lipids (blood fat), with an increased level of triglycerides (blood fat) and a decreased level of HDL (good) cholesterol (41). Study conducted by Harris et al (61) and Blaum and colleagues, did not find an association between obesity and glycemic control (62). Suh et al (79) also reported that obesity has no effect on glycemic control. On the other hand Koro et al (102) and Nicholas et al (68) found that higher BMI associated with better glycemic control. Ben Abdelaziz and colleagues (47) found that BMI less than $30Kg/M^2$ was significantly associated with poor glycemic control.

The study in Italy on glycemic control and cardiovascular risk factors in type diabetes reported that high cholesterol and triglycerides was associated with poor glycemic control while obesity and hypertension had no association with glycemic control (66).

1.2.1.8. Treatment type

Treatment modality has a substantial effect in predicting HbA1c levels, independent of demographic and clinical characteristics. Chiu et al showed that compared with participants who used insulin only or in combination with other regimens, participants who were treated with diet only or oral medications had lower HbA1c levels (49). A study done by Benoit et al also showed that people treated with insulin had high HbA1c when compared with oral hypoglycemic agents (48). A study conducted in south Asia by Nyunt et al has shown that the patients who were on more than OHA had poor glycemic control as compared to those on single drugs(71). Another study that was conducted in Jordan found that the patients who were on a combination of OHA and insulin had highest level of poor glycemic control when compared to patients who were on OHA or insulin treatment (53).

1.2.1.9. Presence of comorbidities

The study conducted in Ethiopia showed that hypertension, obesity, chronic renal failure, coronary heart disease, dyslipidemia and other disease such as TB, anemia, osteoarthritis, asthma and hyperthyroidism were coexisting diseases with diabetes with hypertension and obesity occurring more frequently (45). The study conducted in America (49) showed that Participants who reported having more chronic diseases had higher HbA1c levels than participants who reported having fewer chronic diseases independent of the demographic determinants. Another study that was conducted by Juarez et al did not find the association between level of comorbidities and poor glycemic control (52).

1.3. Research questions

1. What is the prevalence of poor glycemic control (FBG > 7.2 mmol/L) among T2DM patients in public hospitals in Dar es Salaam?
2. What are the effects of self-care diabetic managements (adherence to diet, medications, and exercise and blood glucose measurement) on glycemic control among T2DM patients in Public hospitals?

3. What are the effects of socio-demographic, clinical characteristics, co-morbid conditions and treatment on glycemic control among T2DM in public hospitals?

1.4. Statement of the Problem

Prospective randomized clinical trials and epidemiological studies have demonstrated that glycemic control is associated with reduced rate of retinopathy, nephropathy, neuropathy and cardiovascular diseases. Despite the evidence from large randomized controlled trials establishing the benefit of intensive diabetes management in reducing microvascular and macrovascular complications (35,44,103), high proportion of patients remains poorly controlled (104). Poor and inadequate glycemic control among patients with T2DM constitutes a major public health problem and major risk factor for the development of diabetes complications. Glycemic control remains the major therapeutic objective for prevention of target organ damage and other complications arising from diabetes (102).

Optimal glycemic control is difficult to obtain on a long-term basis because the reasons for poor glycemic control in T2DM are complex (105). Both patient- and health care provider related factors may contribute to poor glycemic control (77,105). To our knowledge no studies have been done in Tanzania to describe the risk factors associated with poor glycaemic control in T2DM patient. However studies from different parts of the world have found a variety of risk factors that predict poor glycaemic control and most of these studies were done in North America and Asia. Some of these factors have found to vary in different studies and therefore the risk factors in Tanzania could be different. These studies have also focused only on the effects of diabetes-specific self-management behaviors on glycemic control.

Tanzania is a resource limited setting where majority of people are estimated to live below poverty level; so economic access to antidiabetic medications and preventive measures may be restricted by the cost. Also additional costs for treatment of co-morbid condition such as hypertension could have an impact on disease outcome. This study focused on several factors and their association with glycemic control. Due to these variations in different studies it was

designed to assess whether similar variables reported in other countries also play a role in Tanzania.

1.5. Rationale

This study was done to identify the factors associated with poor glycemic control in T2DM patients in Dar es Salaam. Diabetes mellitus is a chronic disease which is accompanied by various chronic complications that may affect productivity and quality of life inevitably. Hyperglycemia is a strong risk factor for development of diabetic complications. Findings from this study will add on the information on management of diabetic type two by developing more effective interventions targeting factors associated with poor glycaemic control and aimed at improving glycemic control and reducing the risk of diabetic related complications.

The study will also help to strengthen the knowledge of diabetic patients regarding the disease, self management behaviours and complications and the importance of self management.

1.6. Objectives

1.6.1. Broad objective

To explore the factors associated with poor glycemic control in T2DM patients attending public hospitals in Dar es Salaam, Tanzania

1.6.2. Specific objectives

1. To determine the level of glycemic control among T2DM patients
2. To identify the socio-demographic factors and clinical characteristics associated with glycemic control among T2DM patients
3. To determine self management behaviors associated with glycemic control among T2DM patients
4. To determine treatment types and treatment complexity associated with glycemic control among T2DM patients
5. To determine the type of co-morbidities among T2DM patients as indicators of glycemic control.

CHAPTER TWO

2.0. METHODOLOGY

2.1. Study design

This study was cross sectional study through systematic sampling of diabetic patients in public hospitals in Dar es Salaam. Data were obtained using questionnaire to assess responses by the patients on self management behaviours, socio-demographic and clinical characteristics. Moreover data collection including biochemical parameters were extracted from patients medical records.

2.2. Study setting

The study was carried out at Muhimbili National hospital (MNH) and all Dar es Salaam municipal hospitals. These hospitals were Temeke hospital, Amana hospital and Mwananyamala hospital.

MNH is the referral and teaching hospital located in Dar es Salaam region. Among the services which are provided in this hospital is diabetic management under the unit of endocrinology. The diabetic clinics are conducted twice a week on Mondays and Thursdays and about 60 patients are managed per day. Monday clinics are mainly for type 1 diabetes while T2DM patients the clinics are on Thursdays.

Temeke hospital is located in Temeke district in Dar es Salaam. In this hospital the diabetes clinics are conducted every Monday, Wednesday and Friday. Each day about 35 patients are served by the clinic giving a total of 105 patients per week. Amana hospital is located in Ilala district and the diabetes clinics are conducted every Monday and Thursdays with about 20 patients per clinic. Mwananyamala hospital on the other hand is located in Kinondoni district. The clinics are conducted every Mondays, Wednesdays and Fridays with approximately 15 patients attending clinic per day.

2.3. Study population

The target population was all T2DM patients of 18 years or older attending the diabetes clinics at Muhimbili National Hospital, Temeke hospital, Amana hospital and Mwananyamala hospital.

2.4. Inclusion criteria

The participants included T2DM patients attending diabetic clinics in four hospitals in Dar es Salaam with the following criteria.

- Age ≥ 18years
- Duration of diabetes equal or greater than 1year
- Type 2 diabetic mellitus
- Consenting to participate in the study
- Patients who have been on treatment for at least 3 months

2.5. Exclusion criteria

- Very sick patients
- Newly diagnosed patients
- Pregnant women
- Patient with mental disorders

2.6. Study period

This study was carried out in a period of 8 weeks from March 2013 to May 2013.

2.7. Sample size

The sample size was calculated using the following formula for prevalence study:

$$N = \frac{1.96^2 P(1-P)}{E^2}$$

Where,

N= sample size

P=proportion of poor glycemic control from previous study

E= Marginal of error on p.

Taking Sample size was calculated based on the study by Khattab et al who found out that proportion of poor glycemic control among T2DM was 65.1% (53). The margin of error was taken at 0.05 for 95% confidence interval. The sample size thus computed was 400 participants after adjusting for a 15% attrition rate.

However 498 were enrolled in the study due to the use of systematic sampling of taking every fourth patient for a period of 8 weeks.

2.8. Sampling technique

Systematic sampling technique was used to recruit study participants. The target was to recruit 120 at MNH, 160 in Temeke, 80 in Amana and 90 in Mwananyamala hospitals depending on the average number of patients attending in each clinic. Study participants were recruited consecutively. In every clinic the first patient to be recruited into the study was selected by the nurse then every fourth patient was recruited into the study. This was done at Temeke, Mwananyamala and Amana hospitals. At MNH the patients were approached at the waiting area. The first was selected according to seat arrangement and the consecutive participants were selected after every fourth patient until the end of that day. They were explained on the purpose of the study and asked to participate in the study. Those who agreed to participate were administered with a questionnaire while waiting to see the physician. After seeing the doctor data on the measurement of fasting blood glucose, lipid profile, height, weight, blood pressure, coexisting diseases and drugs used by the patients were extracted from the patient files.

2.9. Data collection and instrument

Data were collected by using a structured questionnaire (Appendix III) and data collection form (Appendix V). The questionnaires were translated into Kiswahili and then back translated to English. The main components of the questionnaire were on socio-demographic and background information, self management behaviors and medication adherence among T2DM patients.

The data collection form covered laboratory investigations and measurements, type of medications and coexisting diseases. This information was obtained from the patient files. Data were collected at Amana hospital on Mondays and Thursdays. At Temeke hospital data were collected on Mondays, Wednesdays and Fridays. At Mwananyamala hospital data were collected on Mondays, Wednesday and Fridays while at MNH data were collected on Thursdays.

2.9.1. Socio-demographic and background information

This included age of the patient, sex, marital status, employment status, and level of education, height, weight, BMI, SBP, DBP, FBG, duration of the disease and age at diagnosis.
Age at diagnosis was found by subtracting age of the patient and disease duration.

2.9.2. Self management behaviors

These included diet, exercise and self monitoring of blood glucose. These were collected to assess the adherence to diabetic control measures that include physical exercise, diet and blood glucose testing. This was conducted by the use of SDSCA scale (106). SDSCA scale contains 11 question items. The questions are designed to ask the patients about their diabetes self-care activities during the past 7 days. If they were sick during the past 7 days they are asked to think back to the last 7 days that they were not sick.
Following eating plans as recommended by health care provider indicated that patient was following eating plans 3 or more days in the previous 7 days. They were regarded to be on special diet if they ate recommended meals for 3 or more days in previous 7 days.
Patients were considered engaged in at least 30 min of physical activity if he had made a walk in 3 or more days in the previous 7 days. They were considered to be engaged in specific activity if they performed it in 3 or more days in previous 7 days.
Self monitoring of blood glucose was defined if the patient performed it in 5 or more days in previous seven days.

2.9.3. Medication adherence

This was determined by self reporting with the use of 8-item Morisky scale (107). The scale contains questions asking the patient to respond to yes or no to a set of 8 questions. A positive response indicate problem with adherence and with total possible score of 8. Higher scores indicate poor adherence. A positive response was awarded 1 point and negative response was awarded 0 point. Exception was in one question which asked the patients if they took their medicines that previous day in which the positive response was awarded 0 point. Patients were classified as highly adherent if the Morisky scale was 0, moderately adherent if the Morisky scale was 1 or 2 and Low adherence to medication if the scale was >2.

2.9.4. Laboratory investigations and measurements

The last readings of fasting blood glucose (FBG) measurement was taken on the day of the visit and all last reading measurements of lipid profile (HDL, LDL, triglycerides and Cholesterol) were obtained from the patient records. These were the readings from 3 months to one year of treatment. During the day of the study Blood pressure was measured by a trained nurse while the patient is on sitting position with the arm at the level of the heart and after at least five minutes of rest.

Weights were measured by using a seca scale with the patient having light clothes and no shoes. Weight was measured up to the nearest 100 grams. Heights were measured using a standard height board with the participant having no shoes. The head piece was gradually lowered until it reached the patients head and was at a 90° angle with the measuring scale. The measurements were then taken to the nearest 1 cm. Body mass index (BMI) was calculated as weight in Kg divided by height in meter squares.

BMI were categorized as shown in table below.

Table 3: Body mass index classification

Classification	Level
Normal	BMI<25 kg/m^2
Overweight	BMI 25-29.99 kg/m^2
Obese	BMI ≥ 30 kg/m^2

Hypertension was defined as a patient with systolic/diastolic pressure greater than 140/90mmHg or who are on hypertensive drugs. Glycemic status was categorized as good glycemic control if FBG≤130mg/dl (7.2mmol/L) and poor control if FBG> 130mg/dl (7.2mmol/L) Criteria for abnormal lipid profile are shown in table below.

Table 4: Criteria for abnormal lipid profile

Abnormal lipid	Type of serum lipid
Hypercholestorolemia	cholesterol ≥200mg/dl (5.2mmol/l)
Low HDL	HDL<40mg/dl for men (1.0mmol/l)
	HDL<50mg/dl for women (1.3mmol/l)
High LDL	LDL>100mg/dl (2.6mmol/l)
Hyperglyceremia	triglyceride>150mg/dl (1.7mmol/l)

Source: Adapted from: American Diabetes Association. Standards of medical care in diabetes-2009. Diabetes Care. Jan 2009; 32 Suppl 1:S13-61.

Dyslipidemea was defined as a patient with one or more of the previous abnormalities for serum lipids or the patient is receiving medication for above condition(s).

2.10. Piloting the questionnaire

This was carried out for one week prior to actual data collection to test the accuracy of the questionnaire to collect the intended data. The questionnaire was pretested in 20 patients at Temeke Hospital with T2DM of disease duration of less than 1 year. Questions which were misunderstood were corrected for data collection.

2.11. Data analysis

Data were entered, cleaned and analyzed using SPSS (Software Package for Statistical Sciences) version 20. Patient's socio-demographic characteristics and diabetes specific variables were summarized using frequency distribution tables. Data were described using mean for continuous variables (age duration of disease, systolic blood pressure and diastolic blood pressure) and proportional for categorical variables (education level, sex, dyslipidemia, FBG, cholesterol level, HDL, LDL, triglycerides, occupation and type of treatment). Associations between variables were tested by the use of chi-square. All factors with p value of 0.2 or below were considered for Multivariate logistic regression to determine independent factors predicting poor glycemic control. The dependent variable were described as dichotomous variable which categorized FBG of less than or equal to 7.2 mmol/l as good glycemic control and FBG of greater than 7.2 mmol/L as poor glycemic control. The independent variable introduced were disease duration since diagnosis, age at onset, age of the patient, BMI (overweight vs. normal weight/obesity), insurance status, Oral hypoglycemic agents (Monotherapy vs. combination therapy) and medication adherence (high adherence vs. low/medium adherence). A probability (p) value of less or equal to 0.05 was considered statistically significant.

2.12. Ethical consideration

Ethical clearance for the study was sought from Muhimbili University of Health and allied Sciences Ethical committee. Permission to conduct the study at Muhimbili National Hospital was sought from the office of the executive Director. Permission to conduct the study from Amana hospital, Temeke hospital and Mwananyamala Hospital was sought from the respective district medical officers. Respondents were explained on the aim and objectives of the study. Before providing interviews, willingness of respondents was required and written informed consent were provided after proper explanation of the purpose of the study. All data collected during the study were treated with strict confidentiality. Questionnaires were assigned study numbers and names of the patients were not used.

CHAPTER THREE

3.0. RESULTS

During the study period of eight weeks, March to May 2013, 498 T2DM patients were recruited to participate in the study. The flow diagram of the study population is shown in figure 2. Five patients did not finish the questionnaires and 13 patients who did not have FBG results were excluded from the final data analysis. Therefore a total of 469 patients provided the required information for the study.

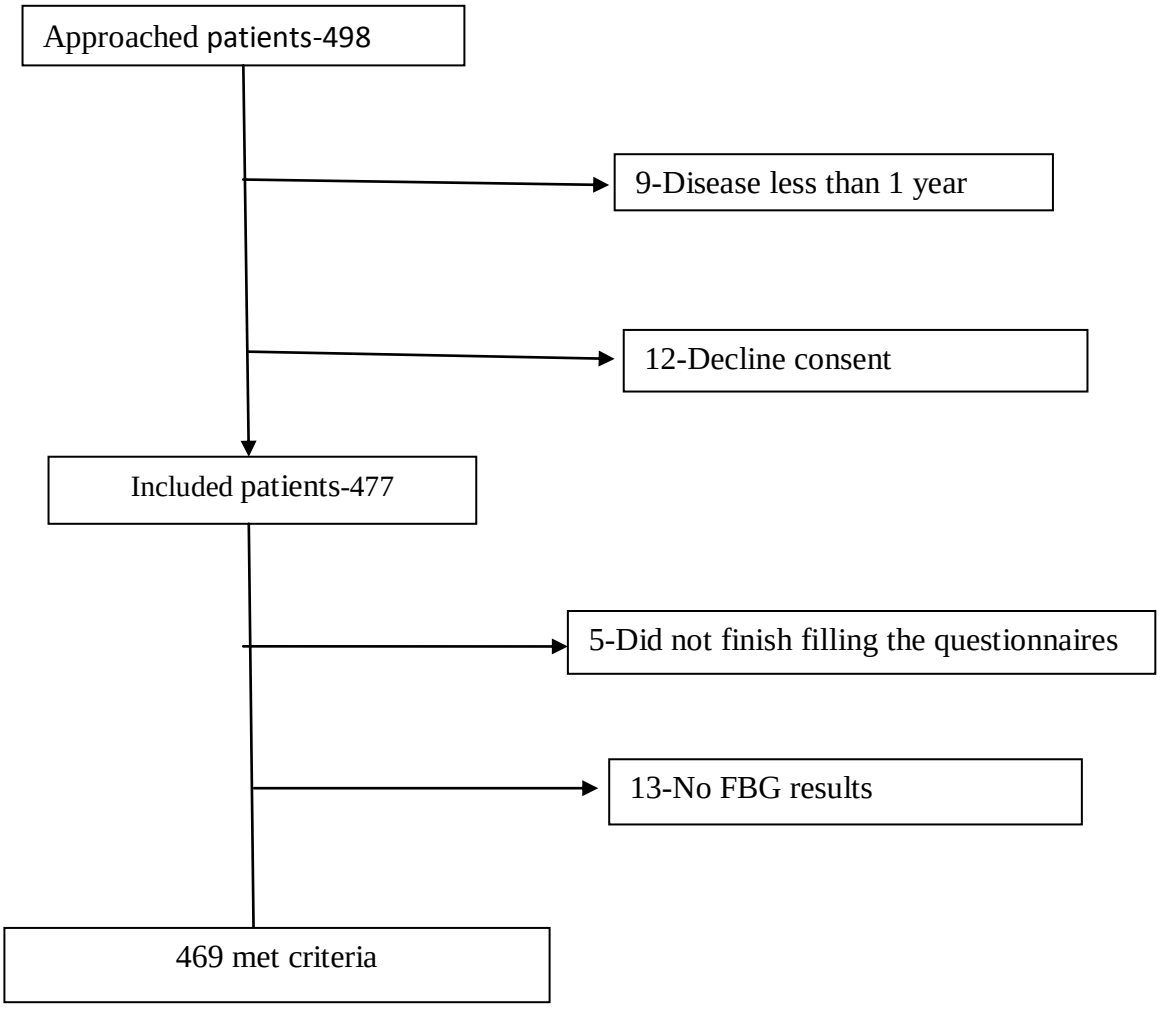


Figure 2: Flow Diagram for recruitment of Study Participants

3.1. Socio-demographic characteristics of T2DM patients

The final analysis included 469 T2DM patients. One hundred and forty three patients (30.5%) from Temeke Hospital and 17.5% of the patients from Amana (figure 3). Most (63.5%) of the patients were females. The females were younger with mean age of 53.8± 11.512 years as compared to males with mean age of 56.8 ± 12.445 years (p = 0.01). There were 50 (10.7%) patients in young age group below 40 years of age while majority 419 (89.3%) were above 40 years. The age of study participants ranged from 25 to 85 years with overall mean age (SD) of 54.94 (11.93) years. Majority (51.4%) of the participants had attained primary school education, 331(70.6%) were married, 368 (69.9%) were unemployed and only 101 (21.5%) had insurance scheme for health care. The socio-demographic factors are summarized in table 5

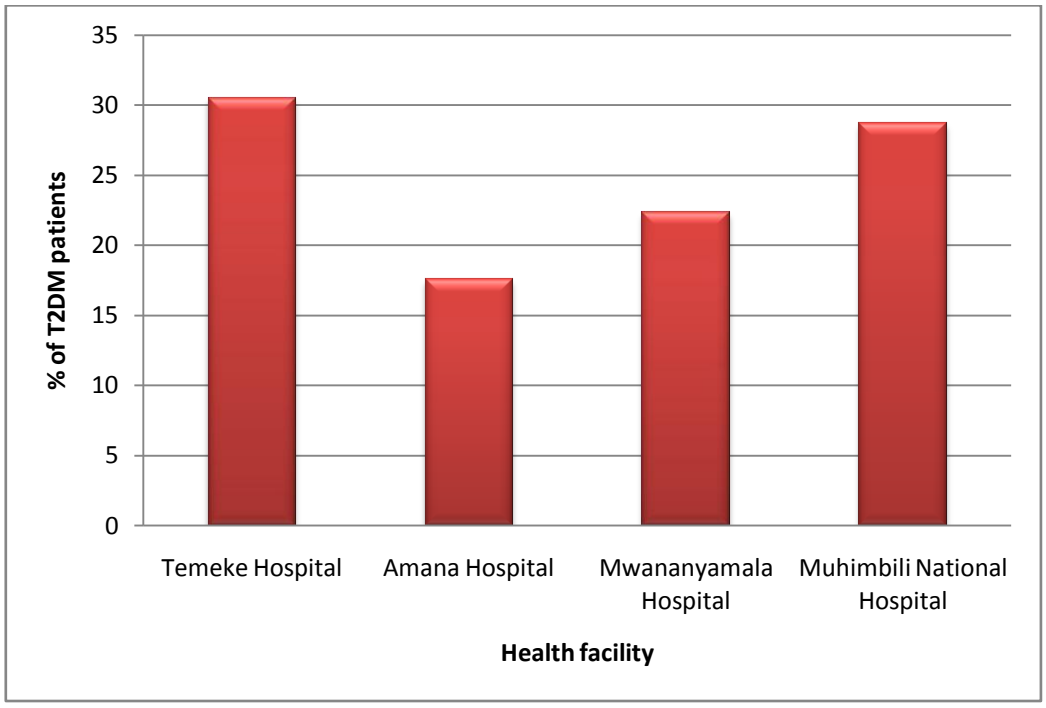


Figure 3: Distribution of patients who were recruited in different Public hospitals

Table 5: Socio-demographic characteristics of T2DM patients (N=469)

Characteristics	*Number*	*%*	*Mean(SD)*
Age(years)			
18-39	50	10.7	54.94 (11.93)
40-59	241	51.3	
≥60	178	38	
Sex			
Male	171	36.5	
Female	298	63.5	
Education level			
No formal education	139	29.6	
Primary school	241	51.4	
Secondary school	76	16.2	
Tertiary school	13	2.8	
Marital status			
Married	331	70.6	
Single	20	4.3	
Widow/widowed	91	19.4	
Divorced	27	5.8	
Employment status			
Employed	59	12.6	
Not employed	328	69.9	
Self employed	82	17.5	
Health insurance			
Insured	101	21.5	
Not insured	368	78.8	

3.2. Association of socio-demographic factors and poor glycemic control

When comparing health facilities (figure 4) it was shown that Amana hospital had a significant higher percentage of patients with poor glycemic control (80.5%) when compared with other hospitals (p= 0.015). The proportion of patients with poor glycemic control in Mwananyamala Hospital was 67.6% while the proportion of patients with poor glycemic control in MNH was 61.2%.

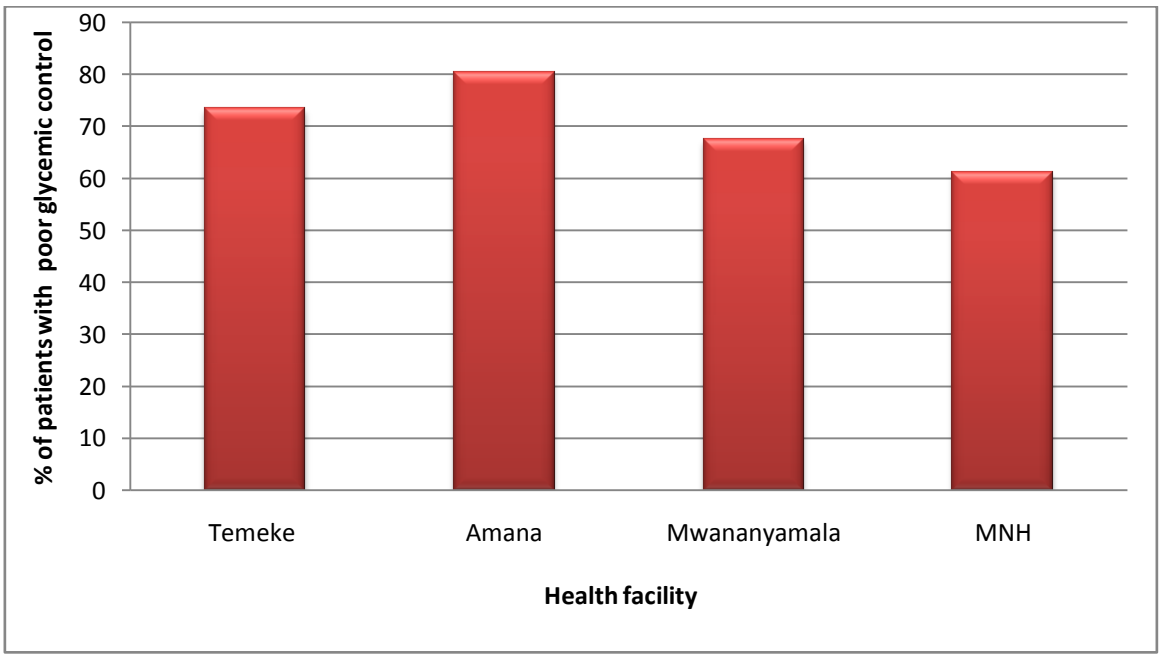


Figure 4: Proportion of patients with poor glycemic control in the respective hospitals

Table 6 shows the association between socio-demographic factors of the patients and poor glycemic control. The proportion of patients with poor glycemic control was 72.6% in the age group 40-59 years and was relatively higher than those in the other age groups but the observed difference was not statistically significant (p=0.19). Diabetes was more likely to be poorly controlled in patients who did not have health insurance (71.7%) as compared to those who were insured for health care (62.4%) and the difference was highly statistically significant (p=0.007). Marital status, employment and education level of the patients were not significantly associated with glycemic control.

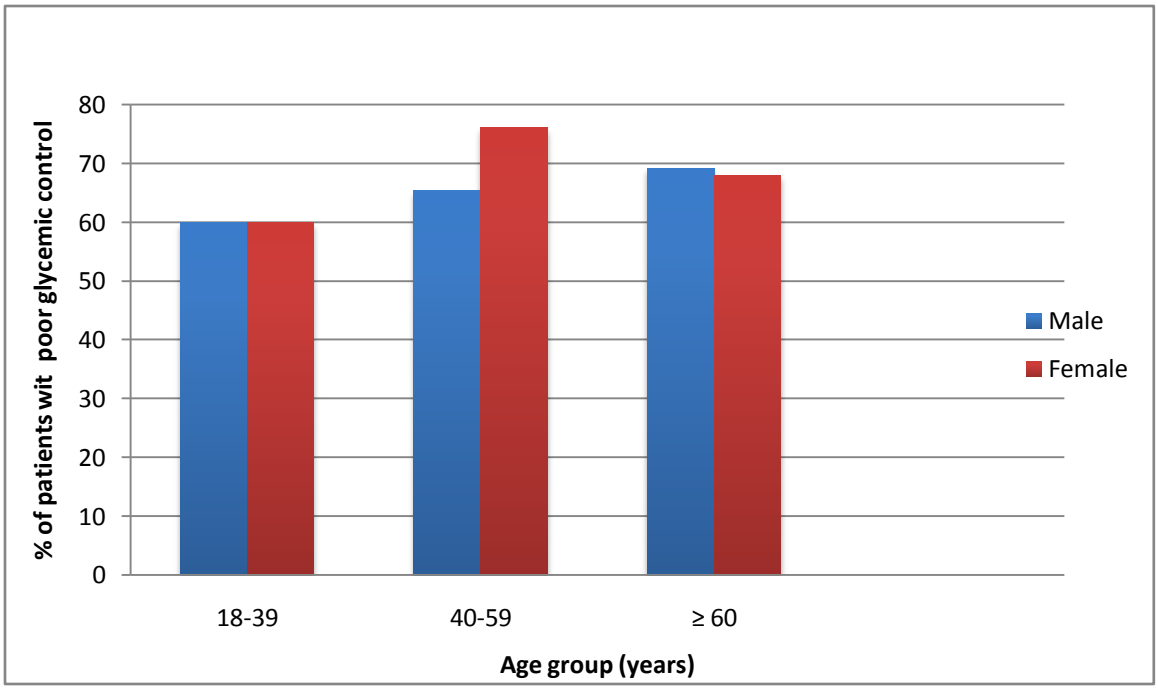
Table 6: Association of Socio-demographic characteristics and Glycemic control

Variable	Number	Poor glycemic control (%)	P- value
Age			
18-39	50	30 (60)	
40-59	241	175 (72.6)	0.19
≥60	178	122 (68.50	
Sex			0.275
Male	171	114 (66.7)	
Female	298	213 (71.5)	
Education level			
No formal education	139	96 (69.1)	
Primary school	241	173 (71.8)	0.262
Secondary school	76	54 (68.4)	
Tertiary school	13	6 (46.2)	
Marital status			
Married	331	227 (68.6)	
Single	20	16 (80.0)	0.645
Widow/widowed	91	66 (72.5)	
Divorced	27	18 (66.7)	
Employment status			
Employed	59	41 (69.5)	
Not employed	328	231 (70.4)	0.839
Self employed	82	55 (67.1)	
Health insurance			
Insured	101	63 (62.4)	0.007
Not insured	368	264(71.7)	

Sex was also not significantly associated with glycemic control. Stratification by age and sex (Figure 5) showed that females aged 40-59 years had significantly higher percentage of poor glycemic control than their male counterparts of the same age group (76.1% vs. 65.4%,

p=0.04). Also female aged 40-59 had significantly higher values of BMI (obese) than their male counterparts of the same age group (35.4% vs. 11.5%, p=0.0000)

Figure 5: Percent of T2DM patients with poor glycemic control with respect to age and sex of the patients



3.3. The clinical characteristics of T2DM patients

Three hundred and thirty (70.4%) patients had confirmed T2DM for less than 10 years. The overall mean (SD) disease duration was 7.19 ± 6.04 years with minimum of 1 year and maximum of 33 years. Most (75.3%) of the patients were diagnosed when they were above 40 years of age. Among these patients the mean fasting blood glucose was 10.3(SD=4.6) mmol/l and the proportion of patients with poor glycemic control was 69.7%. The mean blood pressure for these patients was 138.07/85.18 mmHg. Majority (40.6%) of patients had normal BMI of less than 25kg/M^2. The mean BMI of T2DM patients in this study was 27.06 ± 5.34.The clinical characteristics of the patients are summarized in table 7. Only 8 patients out

of 469 T2DM patients had records on lipid profile measurements and patient had any records of Hb1Ac measurements.

Table 7: Clinical characteristics of T2DM patients (N=469)

Variable	Number	%	Mean(SD)
Age at diagnosis (yrs)			
18-39	116	24.9	47.63 (12.46)
40-59	266	56.7	
≥60	87	18.6	
Duration of disease (years)			7.19 (6.04)
1-9	330	70.4	
10-19	110	23.5	
≥20	29	6.2	
Fasting blood glucose (mmol/L)			10.30 (4.60)
≤7.2	142	30.3	
≥7.2	327	69.7	
Blood pressure (mmHg)			
SBP≤140	230	49	138.07 (24.52)
SBP>140	239	51	
DBP≤90	274	58.4	85.18 (14.40)
DBP>90	195	41.6	
Body mass index (Kg/M^2)			
<25	189	40.6	
25-29.99	151	32.5	27.06 (5.34
≥30	125	26.9	
LDL (mmol/L)			
<2.6	4	50	ND
>2.6	4	50	
HDL (mmol/L)			
Low	4	50	ND
Normal	4	50	
Triglycerides (mmol/L			
<1.7	4	50	ND
>1.7	4	50	

ND: Due to small sample size, determination of the mean was not done for lipid profile measurements

3.4. Clinical characteristics of patients associated with glycemic control

The mean fasting blood glucose was 10.30± 4.6mmol/l. Out of 469 T2DM patients 327 (69.7%) were poorly controlled with fasting blood glucose of more than 7.2mmol/l. In this study the proportion of poor glycemic control was found to increase with disease duration and it was significantly higher in patients who presented with longer duration of diabetes of more than 20 years than those who presented with duration of less than 10 years. (p=0.027). Age at diagnosis and systolic and diastolic blood pressure were not significantly associated with glycemic control (p>0.05). Patients with normal BMI had significantly higher percentage of poor glycemic control than overweight and obese patients (76.7% vs. 69.6%and 61.6%, p=0.01). Association of clinical characteristics and poor glycemic control are summarized in table 8.

Table 8: Association of clinical characteristics of patients and Glycemic control

Variable	Number	Poor glycemic control (%)	P –value
Age at diagnosis(yrs)			
18-39	116	81 (69.8)	
40-59	266	192 (72.2)	0.204
≥60	87	54 (61.20	
Duration of disease(yrs)			
1-9	330	219 (66.4)	
10-19	110	83 (75.5)	0.027
≥20	29	25 (86.2)	
Blood pressure(mmHg)			
SBP≤140	230	163 (70.9)	0.596
SBP>140	239	164 (68.6)	
DBP≤90	274	193 (70.4)	0.689
DBP>90	195	134 (68.7)	
Body mass index(Kg/M^2)			
<25	189	145 (76.7)	
25-29.99	151	93 (61.6)	0.01
≥30	125	87 (69.6)	

3.5. Type of co-morbidities and anti-diabetic agents prescribed to T2DM patients

Table 9 summarizes the co-morbidities and anti-diabetic agents prescribed to the patients. The most frequent co-morbidity was hypertension (50.7%) followed by coronary heart disease (13.4%). Osteoarthritis was observed in 56 patients (11.9%) while 8.5% of the patients had peptic ulcers. Other diseases such as depression, HIV/AIDS, Asthma, TB, rheumatism and gout with individual frequency of less than 3% all constituted 9.4% of total co-morbidity disease.

OHA were prescribed to 391 (83.4%) of the patients while a combination of OHA and Insulin were only prescribed in only 2.1% of the patients. Insulin alone was prescribed only to 14.5% of the patients. Of the patients on OHA, 247 (63.7%) were on combination therapy while 142 (36.3%) were monotherapy. The most prescribed combination therapy contained metformin and Sulphonyl ureus (95.2%). Of the patients on monotherapy with OHA, 100 (65.2%) patients were on metformin. The most sulphonyl ureus prescribed to diabetic patients were glibenclamide and Gliclizide. Other sulphonyl ureus prescribed to T2DM patients were chlopropamide, Glimepiride and Gliazide.

Table 9: Comorbidities and pattern of antidiabetic drugs prescribing among T2DM patients

Characteristics	Number	%
Comorbidities (n=469)		
Hypertension	238	50.7
Osteoarthritis	56	11.9
Coronary heart disease	63	13.4
Chronic heart failure	17	3.6
Peptic ulcers	40	8.5
Skin infection	19	4.1
Others	44	9.4
Antidiabetics (n =469)		
OHA alone	391	83.4
Insulin alone	68	14.5
OHA and Insulin	10	2.1
OHA (n=391)		
Combination therapy	249	63.7
Monotherapy	142	36.3
OHA combination therapy (n=249)		
Metformin and Sulphonyl ureus	237	95.2
Metformin and Pioglitazone	6	2.4
Sulphonyl ureus and Pioglitazone	1	0.4
Metformin, Sulphonyl ureus and pioglitazone	5	2.0
OHA monotherapy (n=142)		
Metformin	92	64.8
Sulphonyl ureus	44	31.0
Pioglitazone	6	4.2

3.6. Poor glycemic control in terms of type of co-morbidities and anti-diabetic medications prescribed to T2DM patients

The association of glycemic control and co-morbidities and treatments to the patient is shown in table 10. The number of co-morbidities, hypertension and treatment type were not associated with poor glycemic control ($p>0.05$). However patients who were on combination therapy of OHA had very highly significant proportion of poor glycemic control (73.5%) as compared with patients on monotherapy (60.6%); $p=0.008$

Table 10: Proportions of patients with poor glycemic control in relation to co-morbidities and treatment.

Variable	Number	Poor glycemic control (%)	P-value
Number of Co-morbidities			
None	150	105 (70)	
One	176	123 (69.9)	0.988
More than 1	143	99 (69.7)	
Hypertension			
Yes	294	181 (68.9)	0.534
No	205	146 (71.8)	
Treatment type			
OHA	391	268 (68.50)	
Insulin	68	51 (75.0)	0.437
Insulin and OHA	10	8 (80.0)	
OHA			
Monotherapy	142	86 (60.6)	0.008
Combination therapy	249	183 (73.5)	

3.7. Self management behaviours in T2DM patients

One hundred and twenty patients (31.2%) did not follow health eating plans and more than half of the patients 251 (53%) reported that they were advised by health care providers to take five or more servings of vegetables and fruits while only 18.6% of the patients indicated that they were not advised. Most patients (63.3%) on average eat three servings per day. Only 90 patients (19.2%) eat five or more serving of fruits and vegetables regularly while only 80 patients (17.1%) eat fat food such as red meat fat dairy products. Three hundred and sixty one (77%) patients did not participate in physical activity and only one third (33%) of patients were on specific activity. Of 469 patients, only 115 (24.5%) tested their blood glucose at home and out of those who tested at home, only 16 (13.9%) patients monitored their blood glucose regularly. Sixty (52.2%) patients reported that they were not advised on how many times a week they were required to monitor their blood glucose at home. A summary of self management behaviours of the patients for control of diabetes is shown in table 11.

Table 11: Summary of self management behaviours (Diet, Exercise and Self monitoring of blood glucose) among T2DM patients

Variable	Number (%)	Mean (SD)
Following health eating plan		
≥3 days	265 (68.8)	4.42 (3.03)
<3 days	120 (31.2)	
Recommended servings of fruits and vegetables taken per day		
≥5 servings	251 (53.3)	
<5 servings	131 (27.9)	
Not advised	87 (18.6)	
On average servings of vegetables and fruits per day.		
≥3 serving	96 (20.8)	
<3 serving	60 (14.8)	
3 serving	297 (63.3)	
Five or more servings of fruits and vegetables.		
≥3 days	90 (19.2)	1.14 (2.3)
<3 days	379 (82.9)	

Eat high fat foods such red meat or fat dairy products?		
≥3 days	80 (17.1)	1.17 (1.56)
<3 days	389 (82.9)	
Participation in at least 30 minutes of physical activity?		
≥3 days	108 (23)	1.52 (2.69)
<3 days	361 (77)	
Participation in a specific exercise		
≥3 days	155 (33)	2.09 (2.96)
<3 days	314 (67)	
Testing of blood glucose at home.		
Do test	115 (24.5)	
Do not test	354 (75.5)	
Recommended numbers of times in testing blood glucose at home per week.		
≥5 times/week	28 (24.3)	
<5 days	27 (23.5)	
Not recommended	60 (52.2)	
Regular monitoring of blood glucose		
≥5 days	16 (13.9)	1.88 (2.26)
<5 days	99 (86.1)	

3.8 Medication adherence among T2DM patients

The assessment of patient's responses to 8-item modified Morisky adherence predictor scale showed that 17.5% of patients were highly adherent with prescribed medication, 218 (44.6%) patients had medium medication adherence while 38% of the patients were adjudged with low adherence to the prescribed anti-diabetic agents (Figure 6). The scale showed that most (57.1%) patients miss taking their medication due to different reasons. The reasons for non adherence reported were the cost of the medication which was reported in 105 (39.5%) patients, omission 48 (18%) patients, stock out of medicines in 41(16.9%) patients, travel in 41 (16.9%) patients, side effects in 25 (9.4%) patients, feeling better in 11 (4.1%) patients and use of alternative medicines in 7 (2.6%) patients. Other reasons constituted 3% of respondents

and these were being busy, many drugs, got sick, exercise and fasting. One hundred and sixty two (34.5%) of T2DM patients reported that when their disease symptoms were under control they stopped taking their medications.

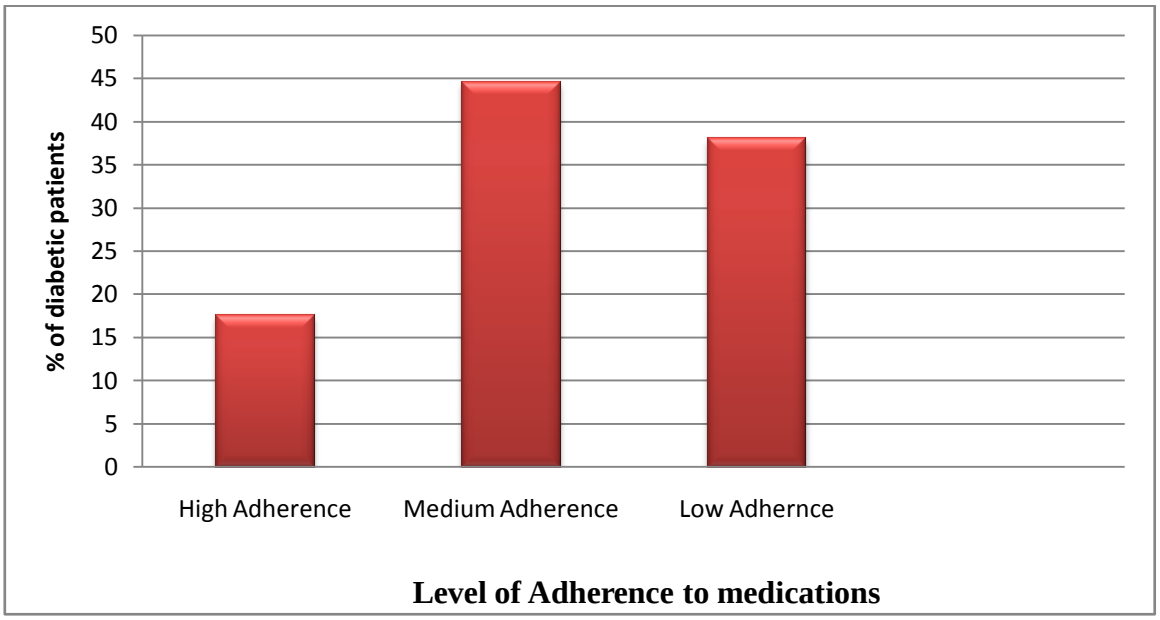


Figure 6: Medication adherence among T2DM patients.

3.9. Proportion of poor glycemic control according to diabetes self management behaviours

Table 12 shows the proportion of patients with poor glycemic control according to diabetes self management behaviours. There were no statistical difference between following health eating plan, physical activity and SMBG and glycemic control ($p > 0.05$), However relatively high proportion poor glycemic control was observed in patients who did not follow health plans, exercise regularly and those who regularly monitor their blood glucose. The number of servings per day was also not associated with poor glycemic control.

The proportion poor glycemic control was significantly higher in patients who presented with low medication adherence (80.9%) than patients who had moderate medication adherence (61.7%) and high medication adherence (60.5%), $p=0.000$

Table 12: Association of self management behavior and glycemic control among type 2 diabetic patients (N=469)

Variable	Total N	Poor glycemic control	P- value
General diet (n=385)*			
≥3 days	265	182 (68.7)	0.795
<3 days	120	84 (70.0)	
Average serving per day			
Less than 3	60		
3 Servings	297		
More than 3	96		
Five or more servings of fruits and vegetables			
≥3 days	90	62 (68.9)	0.848
<3 days	379	265 (69.9)	
High fat foods such red meat or fat dairy products			
≥3 days	80	65 (68.8)	0.835
<3 days	389	272 (69.9)	
Physical activity			
≥3 days	108	79 (73.1)	0.377
<3 days	361	248 (68.7)	
Specific exercise session (such as walking, swimming, and biking)			
≥3 days	155	105 (67.7)	0.525
<3 days	314	248 (70.7)	
SMBG			
≥5 days	16	13 (81.2)	0.425
<5 days	99	71 (71.9)	
Medication adherence			
Low adherence	178	144 (80.9)	
Moderate adherence	209	129 (61.7)	0.000
Good adherence	82	54 (65.9)	

*84 Patient did not respond on general diet

3.10. Binary logistic regression of factors associated with poor glycemic control.

All factors with p-value of ≤ 0.2 on univariate analysis were considered for multivariate analysis so as to control for confounding factors. Table 13 shows the factors associated with poor glycemic control on binary logistic regression analysis; Normal BMI, Obesity, low medication adherence, combination therapy and lack of insurance for health care were found to be predictors of poor glycemic control. Other factors such as disease duration and age and age at diagnosis did not show statistical significance for association with glycemic control.

In this study it was observed that poor glycemic control is more likely to occur 2.234 times in patients with normal BMI (OR (95% CI) = 2.234 (1.278, 3.904) as compared to patients who were overweight. In addition, it was found that obese patients were 2.347 times more likely to have poor glycemic control (OR (95%CI)) = 2.347(1.274-4.324), p=0.006) than the overweight T2DM patients.

It was observed that patients who were using combination therapy of OHA were more than 2.528 times likely to be poorly controlled (OR (95%CI)) =2.528 (1.475-4.331) as compared to patients who were on monotherapy. Also poor glycemic control is likely to occur 2.084 times more in patients with poor medication adherence as compared to patients who were highly adherent to medications (OR (95% CI) = 2.084 (1.069, 4.060). patients who did not have insurance for health care were more than 1.861 times likely to have poor glycemic control as compared to patients who were insured for health care (OR (95%CI) = 1.861 (1.044, 3.318)).

It was also observed that poor glycemic control is more likely to occur 4.177 times in patients attending at Amana hospital (OR (95%CI) = 4.177 (1.878-9.291) as compared to patient who attended at MNH. Patients attended at Temeke hospital were more than 2.76 to be poorly controlled (OR (95%CI) =2.76 (1.461-5.216) as compared to patients who attended at MNH.

Table 13: Binary Logistic regression analysis of factors associated with poor glycemic control among T2DM patients.

Variable	aOR	95%CI	P- value
Age group (years)			
Less than 40	1		
40-59	2.501	0.785-7.967	0.121
≥ 60	2.453	0.616-9.771	0.203
Insurance status			
Insured	1		
Not insured	1.861	1.044-3.318	0.035
Age at diagnosis			
Less than 40	2.312	0.692-7.725	0.173
40-59	1.624	0.753-3.502	0.216
≥ 60	1		
Disease duration			
1-9	1		
10-19	1.623	0.871-3.027	0.128
≥ 20	3.262	0.775-13.723	0.107
BMI			
Normal	2.234	1.278-3.904	0.005
Overweight	1		
Obese	2.347	1.274-4.324	0.006
Medication Adherence			
Low Adherence	2.084	1.069-4.060	0.031
Medium Adherence	0.827	0.448-1.527	0.543
High Adherence	1		
OHA complexity			
Combination therapy	2.528	1.475-4.331	0.001
Mono therapy	1		
Facility name			
Amana Hospital	4.177	1.878-9.291	0.000
Temeke Hospital	2.76	1.461-5.216	0.002
Mwananyamala Hospital	0.196	0.8-2.958	0.196
Muhimbili National hospital			

aOR =adjusted odds ratio, CI-confidence interval

CHAPTER FOUR

DISCUSSION

Glycemic control is considered as the main therapeutic goal for prevention of organ damage and other complication of diabetes.(53). Achieving glycemic control is a critical metabolic goal because hyperglycemia contributes to the progression of diabetes by adversely affecting both ß-cell function and insulin sensitivity (18). ADA recommends that FBG in diabetes patient should be below 7.2mmol/L as these values are associated with lower risk of microvascular complication (30).

This study shows that, the proportion of patients with T2DM who did not attain target level of fasting blood glucose of less or equal to 7.2mmol/L in public hospitals in Dar es Salaam were 69.7%. This value is high than those reported in other studies conducted in Africa. For instance the study in Ethiopia indicated that 58% of studied population had inadequate glycemic control (45). Another study conducted in Nigeria showed that only 43.8% of T2DM patients had good glycemic control (9). Different estimates of proportion of T2DM patients with poor glycemic control have been reported in other settings. For example the study in Jordan showed that 65.1% of studied population had poor glycemic control (Hb1Ac >7%) (53). In UK 69% T2DM patients did not attain targeted glycemic control (99). In Saudi Arabia only 27% of the patients reached target level of glycemic control (108). Furthermore another study in Malaysia indicated that 76.4% of T2DM patients had poor glycemic control. Several other studies have also indicated poor glycemic control with T2DM patients (46,51,67,105,109,110). Although this may indicate that diabetic patients in Tanzania have poor glycemic control, the reason for such high prevalence of poor glycemic control may perhaps reflect inadequate services provided, such as insufficient effort on patient's education and motivation from health care providers and lack of facilities for Hb1Ac measurements and unavailability of certain types of certain types of medication in primary health care settings. Another possible explanation may be lack of understanding on the importance of glycemic control and self management practices among T2DM patients, physicians or both.

Hb1Ac test was not used to monitor or assess glycemic control in any of the patient. Only FBG was used to monitor and assess glycemic control. Hb1Ac was not routinely used as recommended for patients probably on account of the high cost of the test in the hospital. However it might have been used as a better objective indicator of glycemic control. FBG and/or RBG are commonly used for assessment of patient's glycemic response. Hb1Ac is an established gold standard in assessing glycemic control. ADA recommends that in patient with controlled glycemic control at least 2 Hb1Ac tests should be conducted per year and those with poor glycemic control Hb1Ac test should be done after every 3 months (30). However our study produced high proportion of poor glycemic control comparable to those produced by Hb1Ac measurements.

In this study it was observed that Amana hospital had statistically significant high percentage of patients with poor glycemic control when compared to Muhimbili National hospital (MNH). Information obtained from Amana hospital indicates that Ilala districts has established several diabetic clinics in the area and therefore Amana hospital most likely receive patients who are already poorly controlled and with complications. This probably can explain why Amana hospital has high proportion of patients with poor glycemic control. Another reason for observed difference could be because Muhimbili National Hospital (MNH) is a specialized hospital in terms of human resources and facilities than Amana hospital as such, patients attending diabetic clinic at MNH are exposed to better health care including counseling services. Moreover pattern of disease burden, disease complexity, comorbidities, disease outcomes, experiences of health care providers and resource utilization are different between primary health care and tertiary health care settings.

In this study, the mean age of the T2DM patients was 54.94±11.93 years with majority of them in age group of 40-59 years. This age group had higher proportion of patients with poor glycemic control when compared with the age group of less than 40 years and those of 60 years or above with proportion of poor glycemic control. However the observed difference between age groups was not statistically significant. ($p > 0.05$). This findings are consistent with several studies(72,73) which failed to show the association between age and glycemic

control. However a study conducted in Myanmar by Nyunt et al (71) reported that age greater or equal to 60 years was associated with poor glycemic control. Other studies (68–70) showed that young age is associated with poor glycemic control. The observed variation of association between age and poor glycemic control could be explained by the difference in population characteristics and distribution of age in different studies.

In many chronic illnesses low socio-economic status (SES) is associated with poor adverse disease outcomes (54). Low SES is also characterized by decreased access to health care and perhaps by the inferior quality of care as well. Studies have suggested that the minority groups in the USA have poor glycemic control (59,60). Relatively low percentages of diabetic patients in this study had completed secondary and tertiary studies. However education of patients was not associated with glycemic control. Other socio-economic factors such as marital status and employment status were also not associated with poor glycemic control. These findings are consistent with the study by Harris et al who did not find an association between glycemic control and SES (51). In addition, Chiu et al (49) assessed the factors predicting glycemic control in middle aged and adult with T2DM patients in US and concluded that education level and marital status were not associated with glycemic control. Several other studies (62–64) have not shown any association between SES and glycemic control.

Although we did not find the direct association between FBG and factors such as education, employment and other socio-demographic characteristics such variable are likely to affect patient access to quality health care and could therefore have an indirect impact on glycemic control. For instance educated individuals may have better understanding and access to the type of integrated and comprehensive medical care than those who are less educated and most likely with lesser income to afford medication and the recommended diet for glycemic control.

On the other hand patients with no health insurance were significantly more likely to have poor glycemic control as compared to patients with health insurance. In this study only 21.5% of the patients did have insurance for health care. In multivariate analysis, non insured patients were likely to be more than 1.861 times to have poor glycemic control when compared with

patients with health insurance. Lack of insurance which covers the cost of prescribed medications may contribute to increased risk of inconsistent use of medication. Therefore having access to health insurance may lead to better glycemic control. Lack of health insurance has been linked to low utilization of diabetic preventive services. However the study conducted by Harris et al (51) did not show association between insurance status and glycemic control. The observed differences could be probably explained by difference in population characteristics, resource utilizations, human resources and facilities.

Majority of patients (63.5%) in this study were females probably justifying that obesity and insulin resistance which are risk factors for T2DM are found to be more in women than men. Women in this study were likely to have poor glycemic control as compared to males. Studies have shown that women have more adverse effects on lipid profile than men (93,94). Estrogen related protective mechanism may also be affected by diabetes (95). The decrease in protective effect of estrogen on the body fat distribution and insulin action may also be caused by low grade inflammation which may have greater role in disturbing insulin action in women or inflammatory factor may interact with female sex hormones (96). However the current study did not show significant difference between males and females in terms of their glycemic control. This finding is consistent with several studies(49,54,99) which also failed to show significant association between sex and glycemic control, an indication that other factors and individual characteristics have much influence on glycemic control than the sex of an individual.

However, when patients were stratified by age group and sex we found that females aged 40-59 years had significantly higher percentages of poor glycemic control than their male counterparts of the same age group. This difference can be explained probably by the fact that in premenopausal women diabetes causes impairment of endothelial function beyond that caused by obesity alone (95). Also women aged 40-59 years in this study were found to have significantly higher prevalence of obesity than men of the same age group. This could probably explain why women in the age group of 40-59 years had poor glycemic control as compared to men in same age group.

The current study showed that longer duration of diabetes was significantly associated with poor glycemic control. The proportion of patients with poor glycemic control was found to increase with increase in disease duration. The proportion of poor glycemic control was significantly higher in patient who had diabetes for long duration than those with short duration. This finding is consistent with several studies (49,52,53) which showed that the proportion of poor glycemic control was significantly higher in patients who presented with longer duration of more than 10 years. For instance Juarez et el showed that patients who had diabetes for more than 10 years were more than 9 times likely to have poor glycemic control than those who had diabetes for 3 years. Longer duration of diabetes is known to be associated with poor glycemic control possibly because of progressive impairment of insulin secretion with time because of ß- cell failure and increase in insulin resistance and eventually decrease in insulin secretion (35). Also the increased amount of carbohydrates attached to HB1Ac as disease progress could explain why patients who have had diabetes for long time are most likely to have poor glycemic control. However on multiple regressions analysis the duration of diabetes was not associated with poor glycemic control.

Patient who were 40-59 years at diagnosis were more presented in a group of poor glycemic control whereas patients who were old (≥ 60 years) were more presented in a group of good glycemic control. However our study failed to show the association between age at diagnosis and poor glycemic control. This finding is in agreement with other studies (72,73) which showed that age at diagnosis was not associated with glycemic control.

In our study we found that body mass index (BMI) is associated with poor glycemic control. A higher proportion of patients with poor glycemic control were observed in patient with normal BMI followed by obese patients and overweight patients. In multivariate analysis this association between BMI and poor glycemic control remained statistically significant. The analysis revealed that patients with normal BMI were more likely to have poor glycemic control 2.122 times when compared to overweight patients. This can probably be explained by the fact that patients with poor control have lost weight due disease process, while improved

glycemic control is associated with weight gain. This explanation is consistent with the UKPDS findings indicating that intensive glycemic control caused 2 to 5kg weight gain (35).

Obese patients were more likely to have poor glycemic control when compared with overweight patients. This may be due to aggravation of insulin resistance due to increased fat mass and visceral adiposity which affect insulin sensitivity and cause insulin resistance (41). This findings is different from that observed by Harris et al (51) and Blaum et al (62) who did not find any association between BMI and glycemic control. Ben et al (47) on the other hand reported that, patients with BMI of less than 30kg/M^2 were significantly associated with poor glycemic control. However finding of the latter study is not in agreement with finding of our study in which the patients with BMI of 25-29.99kg/M^2 had better glycemic control when compared to other groups. Other studies (68,102) showed that higher BMI was associated with better glycemic control. The observed differences in different studies could be due to different population characteristics and the level glycemic control. For example study by Ben et al (47), good glycemic control was defined by Hb1Ac of less or equal to 7.2% while that of Blaum et al (62) poor glycemic control was defined by Hb1Ac above 11.6%

Diabetes has the effect of lowering HDL and increasing TAG and LDL and cholesterol. Cholesterol accumulation on the other hand may contribute to ß-cell dysfunction in T2DM. Poor glycemic control and increased serum lipids are risk factors for microvascular and macrovascular complication in T2DM. It is possible that both glycemic control and lipid concentration are markers for quality of diabetes care either at individual level or at the level of health care system. However in this study, Cholesterol, TAG, HDL and LDL were only performed in eight patients. Out of these 8 patients, 4 patients had high level of LDL and out of these, three had poor glycemic control. This call for regular screening of lipid profile so as to prevent cardiovascular complication associated with increased level of TAG, LDL, cholesterol and decreased level of HDL.

The present study showed that the mean blood pressure was 138.07/85.18 mmHg among the patients recruited for the study. This shows that blood pressure was higher than that recommended by ADA in T2DM patients which should be below or equal to 130/80mmHg

(30). Blood pressure is elevated in many people with T2DM. Increased blood pressure levels are associated with a spectrum of later health problem in people with diabetes notably cardiovascular diseases (especially stroke), eye damage and kidney damage. However, systolic and diastolic blood pressures were not significantly associated with poor glycemic control in this study. A study by Bruno et al (66) also showed that blood pressure was not associated with glycemic control

Hypertension and coronary heart diseases were the most frequent co-morbidities among T2DM patients in this study. These findings are consistent with the established theory of metabolic syndrome, which is strongly associated with cardiovascular disease in T2DM. This is also in line with the findings in the study conducted in Ethiopia (45) which showed that hypertension and coronary heart diseases were the most frequent coexisting diseases.

In the present study no significant difference was found between hypertension and number of comorbidities with poor glycemic control. A study by Juarez et al (52) also did not find any association between level of comorbidities and poor glycemic control in T2DM patients. The latter study did not also find the association between the history of hypertension and glycemic control in T2DM patients. The lack of association between hypertension and glycemic control could be explained by the adverse effect of weight gain with improved glycemic control observed in overweight patients, which may worsen other physiological parameters such as Hypertension and hypercholesterolemia.

In this study majority of T2DM patients were on oral hypoglycemic agents (OHA) while only 2.1% of the patients were using a combination of OHA and insulin. High proportion of patients with poor glycemic control was observed in a group of those who were using a combination of OHA and insulin. Studies have shown that patients with poor glycemic controls and with longer duration of disease are more likely to be prescribed with high dose of OHA medications or insulin or a combination of OHA and insulin. Patients with poor glycemic control require more aggressive treatment with insulin or a combination of OHA and insulin. For example a study by Chiu et al (49) showed that the patients who were using OHA alone had good glycemic control when compared with patients who were treated with insulin

only or insulin in combination with OHA. Another study by Benoit et al (48) showed that patients who were treated with insulin had poor glycemic control when compared with oral hypoglycemic agents. However, this study did not show an association between the type of treatment and poor glycemic control among T2DM patients. Lack of association between treatment type and glycemic control in our study could be due to the fact that only 14.5% of patients were using insulin. Since studies have shown that better glycemic control is achieved through the use of insulin in combination of OHA and given high prevalence of patients with poor glycemic control, it is most likely that under use of insulin in this study may have contributed to poor glycemic control among patients. This low use of insulin could be partly because patients and physicians have often colluded in implicit and unspoken contract to continue OHA for as long as possible. Physicians prevaricate with a view that they are giving improvement of diet or another effort of weight-loss one last chance. Also the phobia of using needles when taking insulin makes some physician reluctant to change their medication regimen to insulin therapy.

Patients who were prescribed with combination therapy of OHA had poor glycemic control when compared to patients on monotherapy. This significant association between combination therapy and poor glycemic was maintained in the multiple regression analysis. It was found that patients on combination therapy were more than 2.528 times to have poor glycemic control when compared with patients on monotherapy. These findings are in agreement with the study conducted in Myanmar (71) which also found that patients who were on more than one medication had poor glycemic control. This may be due to the fact that these patients have already advanced form of diabetes. Since patients with poor glycemic control were more likely to be prescribed with combination of OHA, this may indicate that physician are attempting multiple therapies to provide better disease control. This is consistent with recommended intensive control of blood glucose which requires multiple therapies (111). This finding is in agreement with the study that was conducted in south Nigeria (9) which showed that 70.3% of T2DM patients were on combination therapy and it was reflected on the necessity of intensive control of blood glucose level.

These findings may also indicate that deterioration of diabetes over time and the need for additional medication over time increases. Therefore combination therapy of OHA associated with higher level of fasting blood glucose most likely represent a marker of severity of diabetes rather than the effect of medications. In UKPDS, fasting plasma glucose deteriorated with time due to progressive deterioration of ß- cell or an increase in insulin resistance over many years (111). A parallel deterioration was observed in sulphonyl ureus and metformin suggesting that neither of these agents accelerated or slowed the rate of decline of ß-cell function. The natural history of T2DM is the progression of islet ß-cell failure. Insulin remains the only glucose lowering therapy which can maintain blood glucose control despite such progression (111).

Exercise is a cornerstone of diabetes management along with dietary and pharmacological interventions (89,112). Exercise is widely perceived to be beneficial for glycemic control and weight loss in patients with T2DM. Current guidelines recommend that patients with type 2 diabetes should perform at least 150 minutes per week of moderate-intense aerobic exercise while resistance exercise should be performed in at least 3 times per week (113,114).

In our study, regardless of the importance of physical activity in the control of diabetes, only a small percentage of patients with T2DM were on regular physical activity and specific exercise. However, this study showed that patients who were following regular physical exercise were not statistically different from patients who did not perform regular physical activity in terms of glycemic control. The lack of association in our study between physical exercises and glycemic control was inconsistent with the findings in other studies (53,85) which reported that regular physical activity is associated with good glycemic control. This could probably be explained by the small number of patients who performed regular physical activity in this study. Physical activity improves glycemic control, reduce blood pressure, and positively affect other coronary heart disease risk factors for individuals living with T2DM. Apart from that, diabetes can influence the participation of patients in physical activity because of disease complications.

SMBG is essential component of diabetes self care in obtaining good glycemic control (87). SMBG allow patients to evaluate their individual response to therapy and assess whether targets are being achieved. It is also useful in medication adjustments. T2DM patients who use SMBG are able to know their own status as well as allowing them to be independent in self care. SMBG is a tool that provides easier communication to patients with their physicians. The present study showed that only 24.5% of patients tested their blood glucose at home. Most patients reported that they have been explained by health care providers the importance of monitoring their blood glucose at home in the management of glycemic control. However, most patients failed to perform their blood glucose at home because of the cost of glucometer machines. In those who tested their blood glucose at home only 13.9% of patients were able to regulate their blood glucose regularly. The main reason for non adherence to self SMBG was the cost of test strips and patients measured their blood glucose only when they felt worse.

SMBG has proven effective for patient with T2DM who are using insulin (86) because the information about patient's glucose level is used to refine and adjust insulin dosages resulting in an improved glycemic control. On the other hand the systemic review conducted in US on SMBG in T2DM patients who are not using insulin showed that the overall effect of SMBG was statistically significant decrease of 0.39% in HbA1c control compared with control group (87). In our study regular monitoring of blood glucose was not associated with the level of glycemic control. These findings are different from those reported by Khattab et al (53) which showed that low adherence to SMBG was associated with poor glycemic control. Another study in Pakistan showed that SMBG level was associated with clinically and statistically better glycemic control regardless of diabetic type or therapy (88). Lack of association with SMBG as compared to previous studies could be due to a small number of individuals in a group of patients who monitor their blood glucose regularly.

In this study, most patients reported that they followed health eating plan. Most of the patients on average eat 3 or less servings of vegetables and fruits which is contrary with the recommended serving of 5 or more servings of fruits and vegetables. Most patients reported

that they were advised to take 5 or more servings of fruits and vegetables per day but because of inadequate financial resources they could not afford to have five servings per day.

Diabetic patients who had good adherence of eating 5 or more servings of fruits and vegetables were likely to be those who were employed or who had attained high level of education. Only few T2DM patients reported that they have taken regularly red meat and fat dairy products indicating that patients have the knowledge on the effect of fat consumption on disease outcomes. The present study showed that following health eating plan, regular eating of five or more servings of fruits per day and eating low of fat food were not associated with glycemic control. The lack of relationship between adherence to diet and glycemic control in our study is inconsistent with a number of studies (53,85) which showed that poor adherence to diet was associated with poor glycemic control. The lack of association between diet and glycemic control in our study could be due to difference in socio-cultural factors which may have influence on food consumption patterns.

Studies have shown that Adherence to anti-diabetic agents is crucial to reach metabolic control as non adherence is associated with an increase with higher Hb1Ac as well as other negative outcomes such as increased LDL levels, increased all cause hospitalizations and increased all cause mortality (74–76). Regardless of comparisons, the fasting blood glucose of T2DM patients in this study is clearly poor. One possible reason is that patients are not complying with prescribed treatment. The current study has shown that 38% of the patients had low adherence to prescribed anti-diabetic medications and only 17.4% of patients had high adherence to prescribed medications. Patients with poor adherence to prescribed anti-diabetic medications had significantly high prevalence of poor glycemic control when compared with those with high and medium medication adherence. Patients with low adherence in this study were more than 2.084 times likely to have poor glycemic control when compared with patients with high medication adherence. These findings are consistent with several studies (9,45,50,77,78,115) which reported that poor adherence to antidiabetic medications was associated with poor glycemic control . For instance a study conducted in Ethiopia (45) indicated 58.2% of the prevalence of non adherence to medication while patients with poor

medication adherence had high level of FBG. In the present study medication adherence was not associated with complexity of treatment regimen, type of treatment, duration of diseases and insurance status of the patient. Our findings are in agreement with a systematic review of compliance on diabetic treatment which concluded that many T2DM patients complied poorly with treatment but this was not related with complexity of treatment regimen and severity of disease (116). As a result of poor adherence, patients do not receive optimal benefit from their drug therapy. Suboptimal treatment can lead to increased use of health care services (acute care and hospitalizations), reduction in patient's quality of life, and increased health care costs (drug costs and medical costs) (76).

The hindrance factor for poor medication adherence reported in this study was the cost of prescribed medications. The high cost of medications was reported by majority of the patients as the most important reason preventing optimal adherence. This observation is supported by previous studies where financial constraints were identified as the major hindrance to medication adherence among T2DM populations (9,45,73,80). For example the study conducted in South Nigeria showed that the monthly cost of anti-diabetic medications was US $22.9 and most patients could not afford to have constant supply of medications. The effect of non adherence to medication due to cost may also be contributed by the fact most of the patients in our study had no insurance for health care.

Other reasons for non adherence to anti-diabetic medication to this study were forgetfulness, travel, use of alternative medicines and a sense of feeling well due to decreased diabetic symptoms. These reasons have also been mentioned in other studies (9,45,54), an indication that more health education is needed to enhance medication adherence and better glycemic control among T2DM patients.

CHAPTER FIVE

CONCLUSION

Diabetes is a major health care burden for individual and for a society as whole. Optimal glycemic control reduces disease related complications, thereby improving patient outcomes and eventually decreasing health care cost. Overall, the findings from the current study indicated that glycemic control of T2DM patients in public hospitals in Dar es Salaam was generally poor.

In spite of the importance of exercise in the control of diabetes only a small proportion of patients with T2DM were adhering to physical activity. Although diet and exercise are important parts of diabetes treatment, they eventually fail to control blood glucose in most patients. Ultimately the majority of patients will require multiple regimen treatments. This study have shown that majority of the patients with T2DM are managed with OHA combination therapy because of their poor glycemic control.

Lack of adherence to prescribed therapy is a problem in all therapeutic areas particularly in chronic condition like diabetes because the therapeutic regimens are often complex and therapy must be a lifelong. In the current study poor medication adherence was associated with poor glycemic control. The external challenge for medication adherence was the cost of anti-diabetic medications for most of the patients. Cost related adherence problem are common among T2DM patients with co-morbid conditions. Patients who did not have health insurance were found to have poor glycemic control. Therefore lack of insurance for health care may have an impact on access to medical care in T2DM patients.

Despite the importance of serum lipids monitoring and established association of serum lipids and diabetes and their effect on cardiovascular complications, the unexpected finding in our study was that records of lipid profile measurements were not available for almost all patients in public hospitals.

Hb1Ac is established gold standard in assessing glycemic control. Hb1Ac test was not used to monitor or assess glycemic control in any of the patients. Only FBG was used to monitor and

assess glycemic control. However it might have been used as a better objective indicator of glycemic control. FBG and/or RBG were the common measurements used for assessment of patient's glycemic response.

Patients who were obese and those with normal BMI were found to have significantly high proportion of poor glycemic control.

In summary, the finding from this study indicate that T2DM patients in Dar es salaam have generally poor glycemic control and the independent variables associated with poor glycemic control were lack of insurance for health care, taking more than one OHA, Normal BMI, obesity and low adherence to anti-diabetic medications.

RECOMMENDATIONS

In order to improve metabolic control it is recommended that all diabetic patients should be screened for lipid profile as high cholesterol level, TAG and LDL are associated with increased risk of cardiovascular events and accumulation of cholesterol may contribute to ß-cell dysfunction. An education program that emphasize on the importance of medication adherence, physical exercise and weight management would be of benefit in improving glycemic control.

It is also recommended that Hb1Ac should be used as a measure of glycemic control as it reflects an average glycemia for up to three months.

There is also a need for regular appraisal of drug prescribing and better monitoring of patient adherence to the prescribed medications and other diabetic related management practices. Training in learning processes and factors governing behavior change are essential for those all involved in delivery of patient care

To prevent debilitating complications of diabetes, to improve quality of life and to reduce the rising cost associated with the disease the use of viable cost reduction strategies such as pooled procurement, encouraging prescribing of low price but good quality generic antidiabetic agents and strengthening of provision of subsidizing by government may increase

access to the needed antidiabetic agents to ensure improved adherence and sustainable glycemic control.

The use of a life style regimen should be emphasized in the entire span of diabetes. There is also a need to have registered dietitians who will educate diabetic patients on diet modifications.

Study limitations

The study was a cross-sectional where causal relationship between independent variables and dependent variables cannot be established. A longitudinal study is needed to assess the relationship of variables over time.

Indirect method which relies on self report (morisky green questionnaires) was used to measure medication adherence. This might be expected to produce inflated adherence. However the proportion of patients reporting good adherence was actually lower than that found in other studies on adherence. At the same time information on medication adherence, SMBG, physical exercise and diet were obtained by self report and may be limited by recall bias.

In addition, we did not make comparison of FBG measurements at patients' first visit, at 3 months, 6 months and 12 months follow-up due to lack of information in the patient's medical records at the clinics.

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APPENDICES

Appendix I: Consent (English version)

TITLE OF THE STUDY: PREDICTORS OF POOR GLYCEMIC CONTROL IN TYPE 2 DIABETCS PATIENTS ATTENDING PUBLIC HOSPITALS IN DAR ES SALAAM, TANZANIA

My name is Emmanuel Charles Mwera, a 2nd year resident doing master of pharmacy in hospital and clinical pharmacy at Muhimbili University of Health and Allied Sciences (MUHAS).

I am conducting a study with the above title as part of my study program.

Aims of the study:

This study aims to explore the factors that are associated with poor control of blood sugar among type 2 diabetes mellitus patients. In addition we will determine the knowledge on diabetes and diabetes self management behaviours among the patients

Participation in this study:

You can participate in this study if you are 18 years old or more and you have been on management for at least 3 months.

The study mainly involves responding to a questionnaire which has general questions about your demographic characteristics, your socioeconomic status and a section on questions related to medication adherence, self management behaviours and diabetes knowledge.

In addition, Blood pressure, weight and height will be measured by the nurse as part of routine care at the clinic before seeing the physician and these data will be used in the study.

If you choose not to participate in this study, you will continue to receive the normal care at the diabetic clinic.

Risks:

We do not anticipate any risks involved in participating in the study

Benefits:

By participating in this study, you will know your glucose control as measured by

Fasting blood glucose and the level will be interpreted for you and hence you will be able to take measures to improve the control or maintain it if it is within normal levels.

Confidentiality:

All information collected during this study will be kept strictly confidential and will not be revealed to anybody outside the research team.

Cost:

You will not be required to make any payments to participate in this study and no payment will be made to you.

For further information, questions or queries, you can contact:

1. The Principal Investigator,

   Mr Emmanuel Charles Mwera
   School of pharmacy
   MUHAS
   P. O. Box 65001,
   Dar es Salaam.
   Cell no: +255 713 525 117
   Email: mweraema@yahoo.ca

2. The supervisor,

   Prof. Appolinary Kamuhabwa
   School of pharmacy,
   MUHAS.
   P. O. Box 65001
   Dar es Salaam

I, _____, have read/been told of the contents of this form and have understood its meaning. I agree for to participate in this study.

Signature of participant _____

Signature of Researcher _____ Date _____

Appendix II: Consent form (Kiswahili version)
Id No _____

FOMU YA RIDHAA YA KUSHIRIKI KATIKA UTAFITI

Jina langu ni Mr. Emmanuel Charles Mwera mwanafunzi wa mwaka wa pili katika fani ya Hospital and clinical Pharmacy katika chuo kikuu cha afya na sayansi shirikishi Muhimbili (MUHAS). Ninafanya utafiti kuangalia mambo yanayohusiana na kiwango cha sukari kwa watu aina mbili ya wa ugonjwa wa kisukari katika hospitali ya Taifa, Muhimbili, Dar es Salaam.

Madhumuni ya utafiti:

Utafiti huu unalenga kujua sababu zinazohusiana na kuzidi kwa kiasi cha sukari kwa wagonjwa wa ugonjwa wa kisukari (type 2). Pia, utafiti huu utaangalia kuhusu uelewa wako kuhusu ugonjwa wa kisukari na jinsi ya kujihudumia mwenyewe.

Ushiriki katika utafiti:

Unaweza kushiriki katika utafiti huu kama una umri wa miaka 18 au zaidi na umekuwa akipata matibabu kwa angalau miezi mitatu.

Utafiti huo hasa unahusu kujibu maswali kuhusu wewe mwenyewe, na sehemu ya maswali kuhusiana na ugonjwa wa kisukari. Pia muuguzi atakupima presha yako, uzito na urefu na vipimo hivi vitatumika kwenye utafiti . Kama ukiamua kutoshiriki katika utafiti huu, utaendelea kupata huduma kama kawaida kwenye kliniki ya wagonjwa wa kisukari na hutaathirika kwa njia yoyote.

Hatari:

Hatutarajii kwamba utakuwa na hatari zinazohusika kwa kushiriki katika utafiti huu.

Faida za utafiti:

Kwa kushiriki katika utafiti huu, utajua kiwango cha sukari kwa kutumia kipimo cha FBG na hii itakusaidia kuchukua hatua za kuboresha kiwango cha sukari au kuidumisha kama ipo katika ngazi ya kawaida.

Usiri:

Taarifa zote zitakazokusanywa katika utafiti huu zitakuwa siri, hivyo ushiriki wako hautajulikana na mtu yoyote. Taarifa hizi zitajulikana kwenye timu ya watafiti tu.

Malipo:

Kwa kushiriki kwenye utafiti huu, hautalipwa wala hautalipa chochote.

Ukiwa na swali au tatizo lolote, unaweza kuwasiliana na wafuatao:

1. Mtafiti mkuu,
   Mr Emmanuel Charles Mwera
   School of pharmacy,
   MUHAS
   P. O. Box 65001,
   Dar es Salaam.
   Cell no: +255 713 525 117
   Email: mweraema@yahoo.ca

2. Msimamizi wa utafiti
   Prof. Appolinary Kamuhabwa
   School of pharmacy,
   MUHAS.
   P. O. Box 65001
   Dar es Salaam

Mimi, _____, nimesoma/nimesomewa maelezo yote yaliyomo kwenye fomu hii na nimeelewa. Nakubali kushiriki katika utafiti huu.

Sahihi ya mshiriki _____

Sahihi ya Mtafiti _____

Tarehe _____

Appendix III: Questionnaire (English version)
A: demographic and background information

1. Patient file number_____
2. Age (Years) _____
3. Sex F/M ☐
4. Date of diagnosis _____
5. Disease duration _____
6. Level of education
   i) No formal education
   ii) Primary school
   iii) Secondary school
   iv) Tertiary school
   v) others
7. Marital status
   i) Married
   ii) Single
   iii) Widow
   iv) Widowed
8. Occupation
   i) Employed
   ii) Not employed
9. Insurance status
   i) Insured
   ii) Not insured

B: Self management behaviours

The questions below are designed to ask you about your diabetes self-care activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

1. How many of the last SEVEN DAYS have you followed a healthful eating plan? _____

2. On average, how many serving of vegetables and fruits do you take per day as advised by your health care provider? _____

3. How many servings of fruits and vegetables did your health care provider advice you to take per day?_____

4. On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables? _____
5. On how many of the last SEVEN DAYS did you eat high fat foods such as red meat or full-fat dairy products? _____
6. On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking). _____
7. On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work? _____
8. On how many of the last SEVEN DAYS did you test your blood sugar? _____
9. How many numbers of times have been recommended by your health care provider for you to test your blood sugar? _____
10. At what time do you test your blood sugar? _____

11. On how many of the last SEVEN DAYS did you test your blood sugar in accordance to the number of times recommended by your health care provider? _____

C: medication adherence

1. Do you sometimes forget to take your medicine?
   i) Yes _____
   ii) No _____
2. People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past 2 weeks, were there any days when you did not take your medicine?
   i) Yes _____
   ii) No _____
3. If the answer is yes to Q2, what were the reasons for missing taking the medicines
   i) Travelling
   ii) Medication side effects
   iii) Feeling unwell
   iv) Other reasons please specify _____,_____
4. Have you ever cut back or stopped taking your medicine without telling your doctor because you felt worse when you took it?
   i) Yes _____
   ii) No_____
5. When you travel or leave home, do you sometimes forget to bring along your medicine?
   i) Yes _____
   ii) No _____
6. Did you take all your medicines yesterday as advised by your health care provider?
   i) Yes _____
   ii) No _____
7. When you feel like your symptoms are under control, do you sometimes stop taking your medicine?
   i) Yes_____
   ii) No_____

8. Taking medicines every day may be inconvenient for some people. Have you ever felt hassled about sticking to your treatment plan?
   i) Yes _____
   ii) No_____
9. How often do you have difficulty remembering to take all your medicines?
   A. Never
   B. Sometimes
   C. Usually
   D. All the time

Appendix IV: Questionnaire (Kiswahili version)

1. Namba ya faili la mgonjwa _____
2. Umri wa mgonjwa(miaka)_____
3. Jinsi MME/KE_____
4. Tarehe uliyogundulika kuwa una ugonjwa wa kisukari_____
5. Muda wa ugonjwa tangu kugundulika_____
6. Kiwango cha elimu
    a. Hujaenda shule
    b. Elimu ya msingi
    c. Elimu ya sekondari
    d. Elimu ya mafunzo ya juu
    e. Kiwango kingine
7. Hali ya ndoa
    a. Umeoa/olewa
    b. Mseja
    c. Mjane
    d. Mgane
8. Hali ya kazi
    a. Umeajiriwa
    b. Haujaajiriwa
9. Kipato chako kwa mwezi_____
10. Hali ya Bima
    i) Natumia bima
    ii) Situmii bima

B: Self management behaviours

Maswali yafuatayo yamebuniwa kukuuliza kuhusu kujihudumia mwenyewe kwa kipindi cha muda wa siku saba zilizopita. Kama ulikuwa mgonjwa kwa muda wa siku saba zilizopita fikiria siku saba ambazo ulikuwa hauumwi.

1. Mara ngapi kwa siku saba zilizopita umefuata utaratibu mzuri wa ulaji wa vyakula?_____
2. Kwa wastani unakula milo mingapi ya mboga na matunda kwa siku kama ulivyoshauriwa na mtalaamu wako wa afya? _____
3. Ni milo mingapi ya mboga na matunda umeshauriwa kula kwa siku na mtalaamu wa afya?_____
4. Ni mara ngapi kwa siku saba zilizopita umekula milo mitano au zaidi ya mboga na matunda? _____
5. Ni mara ngapi kwa siku saba zilizopita umekula chakula cha mafuta mengi kama vile nyama nyekundu au jamii ya vyakula vya mafuta vitokanavyo na maziwa?_____
6. Ni mara ngapi kwa siku saba zilizopita umejihusisha na mazoezi ya viungo angalau kwa dakika thelathini(jumla ya dakika mfululizo bila kupumzika ikihusisha na kutembea)? _____
7. Ni mara ngapi kwa siku saba zilizopita umejihusisha na mazoezi maalumu(kama vile kuogelea,kutembea, kuendesha baiskeli) zaidi ya yale unayofanya ukiwa nyumbani au kama sehemu ya kazi yako?_____
8. Ni mara ngapi kwa siku saba zilizopita umepima kiwango chako cha sukari katika damu? _____
9. Ni mara ngapi kwa wiki wataalamu wa afya wamekushauri upime kiwango chako cha sukari kwenye damu?_____
10. Ni muda gani unachukua kipimo chako cha sukari kwenye damu? _____
11. Ni marangapi kwa siku saba zilizopita umepima kiasi chako cha sukari kwenye damu kama ulivyo shauriwa na mtaalamu wako wa afya?

C: Uaminifu katika kutumia dawa.

1. Wakati mwingine unasahau kutumia dawa?
    i) Ndio
    ii) Hapana
2. Wakati mwingine watu wanaacha kutumia dawa zao kwa sababu nyingine zaidi ya kusahau. Fikiria kwa wiki mbili zilizopita, kulikua na siku zozote ambazo haukutumia dawa?
    i) Ndio
    ii) Hapana
3. Kama jibu lako kwa swali la 2 ni ndio ni sababu gani zilisababisha kuacha kutumia dawa zako.
    i) Kusafiri
    ii) Madhara yatokanayo na dawa
    iii) Kujisikia vibaya
    iv) Sababu zinginezo. Taja _____,_____
4. Ulishawahi kupunguza au kuacha kutumia dawa bila kumwambia dactari kwasababu ulijisikia vibaya baada ya kutumia?
    i) Ndio
    ii) Hapana
5. Wakati unapo safari au kutoka nyumbani, kunawakai unasahau kubeba dawa zako?
    i) Ndio
    ii) Hapana
6. Je, umetumia dawa zako jana kama ulivyo shauriwa na mtaalamu wako wa afya?
    i) Ndio
    ii) Hapana
7. Wakati unapo hisi kua huna dalili za ugonjwa, je unaacha kutumia dawa?
    i) Ndio
    ii) Hapana

8. Kutumia dawa kila siku kwa watu wengine huleta usumbufu. Je kuna wakati unashindwa kufata mpangilio wa matibabu yako?
    i) Ndio
    ii) Hapana
9. Ni mara ngapi unapata shida kukumbuka kutumia dawa zako zote?
    i) Sijawahi kusahau
    ii) Mara chache
    iii) Mara nyingi
    iv) Wakati wote

Appendix V: Data collection form

1. Patient file number_____
2. Coexisting diseases
    i) _____
    ii) _____
    iii) _____
    iv) _____
    v) _____
    vi) _____
3. Name of medication used by the patient
    i) _____
    ii) _____
    iii) _____
    iv) _____
    v) _____
    vi) _____
    vii) _____
4. Type of anti-diabetic medication(choose one)
    i) Oral anti-diabetic agent(s) alone
    ii) Insulin alone
    iii) Oral anti-diabetic agent and insulin
5. Height (M)_____
6. Weight (Kg) over a period a time
    i) _____
    ii) _____
    iii) _____
    iv) _____

7. Body mass index (Kg/M^2) over period of time
    i) _____
    ii) _____
    iii) _____
    iv) _____
8. Cholesterol level (mg/dl)
    i) _____
    ii) _____
    iii) _____
    iv) _____

9. HDL (mg/dl)
    i) _____
    ii) _____
    iii) _____
    iv) _____

10. LDL (mg/dl)
    i) _____
    ii) _____
    iii) _____
    iv) _____
11. Triglycerides (mg/dl)
    i) _____
    ii) _____
    iii) _____
    iv) _____

12. RBG (mg/dl)

i) _____

ii) _____

iii) _____

iv) _____

13. BP (mmHg)

i) _____

ii) _____

iii) _____

iv) _____

14. The recorded levels of fasting blood glucose over a period of time.

i) _____

ii) _____

iii) _____

iv) _____

v) _____