

ST. PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE



**ASSESSMENT OF PREVALENCE OF ADHERENCE TO
TREATMENT AND PATIENT AWARENESS ABOUT ACUTE
AND CHRONIC COMPLICATIONS OF DM AMONG DIABETIC
PATIENTS VISITING SPHMMC CHRONIC FOLLOW UP UNIT,
ADDIS ABABA, ETIOPIA**

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**A RESEARCH PAPER TO BE SUBMITTED TO DEPARTMENT OF
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ADDIS ABABA, ETHIOPIA

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ACRONYMS

DKA – Diabetic Ketoacidosis

DM – Diabetes Mellitus

FPG- Fasting Plasma Glucose

GDM – Gestational Diabetes Mellitus

HA1C- Hemoglobin A1C

HHS – Hyperglycemic Hyperosmolar State

IDDM – Insulin Dependent Diabetes Mellitus

IDF – International Diabetes Federation

MAPS- Morisky Adherence Predictor Scale

MODY - Maturity Onset Diabetes of the Young

NIDDM – Non Insulin Dependent Diabetes Mellitus

OGTT- Oral Glucose Tolerance Test

OHA –Oral Hypoglycemic Agents

RPG- Random Plasma Glucose

SMBG- Self Monitoring of Blood Glucose

SPHMMC –St. Paul Millennium Medical College

SPSS - Statistical Packages for Social Sciences

USA-United States of America

WHO – World Health Organization

ABSTRACT

INTRODUCTION: Diabetes is a general term for a group of metabolic disorder that affects the body's ability to process and use glucose for energy. According to IDF (International Diabetes Federation) Atlas, 7th edition 2015 report, there were 415 million living with diabetes as compared with estimated 382 million people were living with diabetes in 2013. Worldwide, adherence rate for medication for diabetes vary between 36 and 93%. Patient's awareness about the possible complications increases adheres to treatment and also engagement in self management behaviors.

OBJECTIVES: The objective is to assess the prevalence of adherence to treatment among diabetic patients visiting SPHMMC chronic follow up unit.

METHODS: Institution based analytical cross sectional study was conducted among 124 diabetic patients on follow up at SPHMMC. Data was collected through structured questionnaire through interview. Systematic random sampling technique will be used to select the study subjects. The collected data was entered and analyzed using SPSS version 20.

RESULTS: in this study it was found that overall treatment adherence of patients which meant those who were adherent to dietary, exercise and medication is 20(16.1%). Among the respondents 48(38.7%) patients mentioned forgetfulness as the reason for their non adherence to medication. Almost all of the respondents 123 (99.2%) know at least one complication of diabetes. Among this knowledge about eye complication took the first place with 113 (91.1%). Respondent's sex, age, education, duration of illness and presence of complication were significantly associated with the overall treatment adherence.

CONCLUSSION: in general a relatively lower adherence to treatment was observed. Some of the possible contributing factors for non adherence to medication were age, sex, education, duration of illness and presence of complication. Respondent's marital status, occupation, income, knowledge of complication, alcohol use, smoking and having glucometer at home did not show a significant association with treatment adherence.

1. INTRODUCTION

1.1 Background

Diabetes is a general term for a group of metabolic disorder that affects the body's ability to process and use glucose for energy. The most important forms of diabetes are type I, type II, gestational diabetes and DM due to other causes (e.g., genetic defects, diseases, drug or chemical-induced). Type 1 diabetes results from cell destruction usually leading to absolute insulin deficiency. Type 2 diabetes results from a progressive insulin secretory defect on the background of insulin resistance. [1]

The prevalence of diabetes has reached epidemic proportions. According to IDF (International Diabetes Federation) Atlas, 7th edition 2015 report, there were 415 million living with diabetes as compared with estimated 382 million people were living with diabetes in 2013. The number is expected to grow to 642 million by 2040 (one adult in 10 will have a diabetes). [2]

The African region is expected to experience the highest increase in coming years with estimated increase in prevalence rates of 98% for sub-Saharan Africa, and 94% for North Africa and the Middle East. Likewise in Ethiopia, diabetes has become more common and it is a fast growing disease. WHO estimated the number of cases of diabetics in Ethiopia to be about 800,000 in 2000, and projected that it would increase to about 1.8 million by the year 2030. [3]

Diabetes mellitus is associated with chronic complications like neuropathy, nephropathy retinopathy and cardiovascular disease and acute complications like DKA, HHS. Generally, 40% of patients with diabetes will develop microvascular or macrovascular complications in the course of their disease. Complications of DM have become a major public health problem in all countries. It causes significant physical and psychological morbidity, disability and premature mortality among those affected patients and imposes a heavy financial burden on health services [4]

The risk of death from cardio vascular disease is approximately three fold for patient with type-2 diabetes; and the risk of death from all cases is increased by 75% compared to patient without diabetes. [5]

Diabetes is a serious public health problem that threatens the quality of life, the success of long term maintenance therapy for diabetes depends largely on patients' adherence and self care practice. Patients should take their medication properly, adjust their diet according to what they discussed with their doctor, life style modification, monitor blood glucose level if possible and know signs of high or low blood glucose level. Patient awareness about possible complication is also the greatest weapon in the fight against diabetes mellitus. It can motivate patients to seek proper treatment and care and prepare them to keep the disease under control.[1]

1.2. Statement of the problem

DM has become one of the most important public health challenges for the 21st century. It is a common incurable chronic disease which emerged as an important clinical and public health problem throughout the world. Likewise in Ethiopia, diabetes has become more common and it is a fast growing disease. WHO estimated the number of cases of diabetics in Ethiopia to be about 800,000 in 2000, and projected that it would increase to about 1.8 million by the year 2030. It requires continual medical care and education to prevent its acute and chronic complications by comprehensive education in self-management to prevent these complications and early death from diabetes self care for diabetic. [1]

Evidence suggests that the most important predictor of reduction of morbidity and mortality due to diabetes complications is the level of glycemic control achieved. This has encouraged aggressive treatment of patients with the goal of achieving blood glucose level as close to normal as possible. Worldwide, adherence rate for medication for diabetes vary between 36 and 93%. Knowledge about DM and its complications enhances the ability of patients with DM to cope and adjust to their illness whereas poor knowledge about DM is associated with increased rate of hospitalization. [6]

Diabetes is a chronic health problem with devastating, yet preventable consequences. It is a disease for which control of the condition demands patient self-management. There are relatively high levels of non adherence in all areas of self-management behaviors. This non-adherence is perhaps due to the fact that self-management behaviors usually require changes in the patient's daily life and patient's awareness about the importance is minimal. In order to successfully make these changes, patients are encouraged by others to set goals to make the incremental changes necessary to create life-long habits that allow them to manage their diabetes. Patient's awareness about the possible complications increases adheres to treatment and also engagement in self management behaviors. [1]

Poor adherence to treatment of chronic diseases is a worldwide problem of striking magnitude. Adherence to long-term therapy for chronic illnesses in developed countries averages 50%. In developing countries, the rates are even lower given the paucity of health resources and inequities in access to health care. Poor adherence to recognized standards of diabetes care is the principal cause of development of complications of diabetes and their associated individual, societal and economic cost. [1] Assessment of the reasons for lack of adequate treatment adherence is important before embarking on specific interventions that may fail, if specific regimen barriers are not identified. Evidence-based research on anti-diabetic medication adherence in Ethiopia is scanty. Because of the above mentioned reasons it was important to conduct this research.

1.3. Significance of the study

The results of this study could help policy makers and health care providers in which areas they should work on to improve adherence and overall morbidity. It will also help patients and their families in the encouraging adherence to diabetic treatment and identify obstacles to adherence. Those with potentially lower adherence might be provided with additional support specifically tailored to individual needs, the effect of which could improve treatment outcomes.

2. LITERATURE REVIEW

2.1. DEFINITION AND PREVALENCE

Diabetes is a serious, chronic disease that occurs either when the pancreas does not produce enough insulin (a hormone that regulates blood glucose), or when the body cannot effectively use the insulin it produces. These defect in insulin results in disturbances in carbohydrate, protein and fat metabolism. Raised blood glucose, a common effect of uncontrolled diabetes, may, over time, lead to serious damage to the heart, blood vessels, eyes, kidneys and nerves. [7]

According to IDF (International Diabetes Federation) Atlas, 6th edition 2013 report, more than 80% of people with diabetes live in Low and Middle Income Countries. An estimated 382 million people were living with diabetes in 2013. The number is expected to grow to 592 million by 2035 (one adult in 10 will have a diabetes). This equates to approximately 3 new cases every 10 seconds or almost 10 million per year and the largest age group currently affected by diabetes is between 40-59 years. The African region is expected to experience the highest increase in coming years with estimated increase in prevalence rates of 98% for sub-Saharan Africa, and 94% for North Africa and the Middle East [8]

In IDF Atlas, 7th edition 2015 report 415 million adults are estimated to currently have diabetes. In addition to these there are 318 million adults with impaired glucose tolerance, which puts them at high risk of developing the disease in the future. From these 44.3 million are in North America and Caribbean, 59.8 million are in Europe, 153.2 million are in Western pacific, 78.3 million are in Southeast Asia, 29.6 million are in South and central America, 35.4 million are in North Africa and middle east and the rest 14.2 million are in Africa. The prevalence is expected to increase to 642 million by 2040. Diabetes is accountable for 5 million deaths globally in 2015. Globally one in 11 adults has diabetes. From the total prevalence 48 % were female and 65 % were people living in urban areas. [2]

2.2. CLASSIFICATION

Criteria for the diagnosis and classification of diabetes have been revised several times over the years. The current classification system according to the World Health Organization identifies four types of diabetes namely Type 1, Type 2, GDM and others specific types. From these Type 1 and Type 2 diabetes are the two major occurring categories of diabetes. Type 2 diabetes may account from 90-95% of all diagnosed cases of diabetes.[7]

TYPE 1 DM

Type 1 Diabetes, (previously known as Insulin-Dependent Diabetes (IDDM), Type I or Juvenile-Onset Diabetes), is characterized by beta (β) cell destruction caused by an auto-immune process in people with genetic susceptibility that usually leads to absolute insulin deficiency. A combination of genetic susceptibility, immune factors (autoimmune diseases), and environmental factors (such as viruses and chemicals) are thought to provoke this auto-immune process. [9]

Patients usually have permanent insulinopenia, and they are prone to Ketoacidosis, but have no evidence of autoimmunity. Idiopathic Type 1 Diabetes Mellitus has been described mostly in African-Americans (African origin) and Asians as well as other ethnic groups. In most patients with Idiopathic Type 1 Diabetes, long-term Glycaemic control is better maintained with insulin therapy than either oral hypoglycaemic agents or diet therapy alone.[10]

TYPE 2 DM

Type 2 Diabetes Mellitus, previously referred to as Non-Insulin-Dependent Diabetes (NIDDM), Type II or Adult-Onset Diabetes, is a term used for individuals who have insulin resistance with relative (rather than absolute) insulin deficiency. There are two identifiable defects in Type 2 Diabetes Mellitus. There is predominantly insulin resistance in peripheral tissues and insulin secretory defect of the (β) beta cell.[11]

Type 2 is associated with older age, obesity, family history and lack of exercise. It is more common in women with a history of gestational diabetes, in blacks, hispanics and Native Americans. Those not obese by weight criteria may have increased percentage of body fat distributed predominantly in the abdominal region. Ketoacidosis is not frequent in Type 2 diabetes, however if it arises, it results from the stress of another illness such as infection. [11]

GDM

Gestational Diabetes Mellitus (GDM) is defined as any degree of glucose intolerance resulting in hyperglycaemia of variable severity with onset or first recognition during pregnancy. Hormones produced by the placenta to sustain the pregnancy make cells more resistant to insulin. The insulin resistance becomes worse during the second and third trimesters when more of these placenta hormones are released. The pancreas responds by producing enough extra insulin to overcome the insulin resistance but sometimes the pancreas fails to keep up to task resulting in high blood glucose. GDM accounts for nearly 90% of all pregnancies complicated by diabetes. In the majority of cases of GDM, glucose regulation will return to normal after delivery but may predispose the mother and the baby to developing Type 2 diabetes later in life. [12]

OTHER SPECIFIC TYPES

The other specific types of diabetes refer to types of Diabetes Mellitus of various known etiologies that have been grouped together to form this classification. It includes those in which the underlying defect or disease process can be identified in a relatively specific manner. They may be due to genetic defects of β -cell function (formerly called Maturity-Onset Diabetes of the Young (MODY)), defects of insulin action; diseases of the exocrine pancreas (such as pancreatitis or cystic fibrosis), endocrinopathies (for instance, acromegaly); and pancreatic dysfunction caused by drugs, chemicals or infections. Uncommon forms of immune-mediated diabetes and other genetic syndromes sometimes associated with Diabetes Mellitus also belong to this group.[7]

2.3. DIAGNOSIS

Diagnosis of diabetes is based on abnormalities of the following test; Fasting Plasma Glucose (FPG), Random plasma Glucose (RPG) with symptoms, Oral Glucose Tolerance Test (OGTT) and Glycated haemoglobin Test (HbA1c) test.

Fasting Plasma Glucose (FPG) Test

The FPG test measures venous blood glucose in a person who has fasted for at least 8 hours. FPG level of 6.1 mmol/l (110mg/dl) to 6.9mmol/l (124 mg/dl) indicates Impaired Fasting Glucose , or Prediabetes (people at risk). Prediabetes is a condition in which a person's blood sugar level is above normal range but below values diagnostic of diabetes. A FPG level of 7mmol/l (126 mg/dl) or above confirmed by repeating the test on another day, indicates diabetes.[13]

Oral Glucose Tolerance Test (OGTT)

This is done after eight to ten hours fast. Venous blood glucose levels are taken in the fasting state and at 1 and 2 hours after drinking 75 grams of glucose dissolved in water. 2-hour postprandial plasma glucose (2hrPPG) or blood glucose level which is ≥ 7.8 mmol/l to 11mmol/l indicates Impaired Glucose Tolerance (IGT) or prediabetes. 2-hour glucose level of 11.1 mmol/l (200mg/dl) or above confirmed by a second test indicates diabetes.[13]

Glycohemoglobin Test (HbA1c or A1C Test)

The A1C test is used to detect type 2 diabetes and pre-diabetes but is not recommended for diagnosis of type 1 diabetes or gestational diabetes. The test checks the amount of glucose bound to haemoglobin in the blood. HbA1c test reflects the average blood glucose over the past 2-3 months in percentages. A normal A1C level is below 5.7 %. An A1C of 5.7 to 6.4% indicates prediabetes while $A1C \geq 6.5\%$ indicates diabetes.[13]

Random Plasma Glucose (RPG) Test

RPG test is sometimes used to diagnose diabetes during screening. $RPG \geq 11.1$ mmol/l (200mg/dl) with other symptoms of diabetes is suggestive of diabetes.[13]

2.4. COMPLICATIONS

ACUTE COMPLICATION

Diabetic Ketoacidosis (DKA) and Hyperosmolar Hyperglycaemic State (HHS) are the two most serious acute metabolic complications of Diabetes Mellitus. These disorders can occur in both Type 1 and Type 2 Diabetes. The prognosis of both conditions is substantially worsened at the extremes of age and in the presence of coma and hypotension. DKA occurs when absolute or relative insulin deficiency prevents glucose uptake by the cells, leading to increasing hyperglycaemia and excessive production of ketones which lowers the blood's pH and leads to metabolic acidosis. DKA consists of biochemical triad involving hyperglycaemia (usually blood glucose higher than 11mmol/L (191 mg/dL)), Excessive ketoacids in blood and urine and metabolic acidosis(pH below 7.3) .The degree of Hyperglycaemia in DKA is quite variable and may not be a determinant of the severity of DKA.[13]

Hyperosmolar Hyperglycaemic State (HHS) is another complication of steadily increasing hyperglycaemia and polyuria. It is more of a state of altered consciousness when coma is not present. In HHS, there is more severe hyperglycaemia and hyperosmolality than DKA. The hyperosmolality dehydrates the brain markedly and causes major changes in mental function. Ketosis may or may not be present to some degree in HHS. HHS is less common than DKA but the rate of mortality is much higher. [13]

CHRONIC COMPLICATION

Some chronic complications of diabetes include macrovascular and microvascular diseases with progressive development of conditions. Macrovascular disease is a very serious complication of diabetes and is the most common cause of premature death. Coronary heart disease, cerebrovascular disease, Peripheral Vascular disease are the three main macrovascular diseases associated with diabetes [13]

Other chronic complications resulting from diabetes are: retinopathy (that results from damage to network of capillaries that supply blood to the retina) which leads to blindness, nephropathy that leads to renal failure, peripheral neuropathy with risk of foot ulcers, amputation, charcot joints

and autonomic neuropathy causing gastrointestinal, genitourinary, and cardiovascular symptoms and sexual dysfunction.[13]

Complications of diabetes include the progressive damage, dysfunction and failure of various organs including the kidneys, nerves, heart, eyes and blood vessels. Diabetes can also affect the limbs, particularly the feet. Cardiovascular disease, retinopathy, nephropathy, peripheral vascular disease and peripheral neuropathy are co-morbidities of diabetes. Infections, such as influenza or pneumoia are also a serious concern for patients with diabetes, as they are more likely to die as a result of infection than individuals who do not have diabetes.[13]

2.5. MANAGMENT

Type 1 and 2 diabetes are chronic conditions that cannot be cured but managed. The ultimate goal of diabetes management is to keep blood glucose levels within the normal range without causing hypoglycaemia. Diabetes management also involves measures to control blood pressure and cholesterol levels. Management of diabetes includes diet, exercise, and use of appropriate medications (insulin in the case of type 1 diabetes, oral medications, as well as possibly insulin, in type 2 diabetes).[14]

Patient adherence to treatment recommendations has been shown to be related to many factors: disease related factors, patient socioeconomic status and other patient demographic variables, such as race, gender, health insurance status and social support. Lower adherence rates in these populations can be a result of attitudes concerning health and illness, medication practices, beliefs in Western or non-Western treatments and other cultural and religious beliefs. Reasons for non-adherence can vary greatly. For some, nonadherence to medical treatment is sometimes seen as a rational choice patients make in an attempt to maintain personal identity, achieve health goals, and preserve health-related quality of life. Research on adherence has typically focused on the barriers patients face in taking their medications. Common barriers to adherence are under the patient's control, such as forgetting to take the medication, distraction by other priorities, making the decision to purposefully omit doses, not seeking information to make the best decision, and emotional factors that permit taking medication (i.e., depression), so that attention to them is a necessary and important step in improving adherence.[15]

2.6. RELATED RESEARCHES ON ADHERENCE TO TREATMENT AND AWARENESS ABOUT COMPLICATIONS OF DM

In a related research done at Jimma hospital among 118 patients, about awareness of diabetic patients about their illness and associated complications 72.04% of respondents had knowledge on acute complications of DM. Among the respondents 67.8% had knowledge on chronic complications. The literacy status is statically associated with the knowledge about acute, as well as chronic complications. Of 85 (72.03%) patients who had knowledge about acute complications, 50 (58.82%) patients experienced hypoglycemia. Of which 32 (37.65%) patients experienced Diabetic Ketoacidosis and 3 (3.53%) patients experienced both Diabetic Ketoacidosis and hypoglycemia. Interviews revealed that among 80 patients who had knowledge about a chronic complications, majority 68 (25.37%) had retinopathy, 54 (20.15%) had hypertension, 46 (17.24%) had neuropathy, 36(13.43%) had a diabetic foot ulcer, 34 (12.7%) had heart attack and 30 (11.20%) had nephropathy. Retinopathy and hypertension were the most common chronic complications among patients who had complications.[5]

In another study at Jimma hospital on medication adherence in 347 diabetes mellitus patients, on the basis of self report for their anti diabetic drug adherence 72 (20.8 %) of the patients claimed that they had excellent tendency to take medication with the agreed recommendation from health care provider, 98 (28.2%) very good, 117 (33.7%) good, and 60 (17.3%) said they had poor adherence. In self report for the pattern of drug use, 178 (51.3%) of patients said that they had never missed (neither daily dose nor time of taking) dose, 127 (36.6%) missed either daily dose or time of taking some times and 42 (12.1%) missed either daily dose or time of taking. Among those who had missed their medication the most common reasons for missing medications were forgetfulness 107 (50.2%), being busy 34 (16%), others including side effects of drugs, disappearance of the symptoms and perceived inefficacy of the prescribed antidiabetic drugs and others 72 (33.8%). The factors identified by patients as underpinning non- adherence were lack of finance 152 (37.1%), side effect of the drugs 119 (29.2%), multiple drug therapy 75 (18.3%), perceived inefficacy of prescribed anti diabetic drugs leading to concomitant self medication with traditional medicine 40 (9.8%) and easily inaccessibility of drugs 23 (5.6%).[6]

A systematic review on adherence with medications for diabetes at New Haven, USA and found adherence to oral hypoglycemic agents ranged from 36-93%.[19] In other cross sectional study on medication adherence among ambulatory type 2 diabetes patients at a tertiary healthcare setting in Southwestern Nigeri, it was found that approximately 60% of patients were adherent to the prescribed medications. [20] Different rates of adherence were reported by studies conducted in Nigeria 72.5% [22], Malaysia 47% [23], India 16.6% [24], Southern California, USA 40% [25] and Brazil 78.3% [26].

A study on non-adherence to treatment among diabetic patients in Zimbabwe reasons for not adhering to medication indicated that forgetfulness, taking too much drugs per day, travelling away from home (for example, attending funerals, work trips, meetings and financial constraints were significantly associated with non adherence to treatment recommendations.[16]

In one cross sectional study conducted in Pakistan on glycemic control, diabetic complications and patient awareness, a total of 200 patients with type 2 diabetes mellitus were evaluated. On interviewing about disease awareness and education, only 39% of patients had recalled an educational consultation with a doctor or health care worker about diabetic complications, their prevention or about lifestyle changes. [17]

Across- sectional survey conducted at a foundation clinic, Shifa College of Medicine, Islamabad the majority of patients (67.5%) had type II diabetes. 27.5% did not have knowledge about their illness. Hypertension was present in 37.5% of the study participants and about 52.5 had family history of diabetes. Sedentary lifestyle was noted in 52.5% of diabetes patients. The awareness of the participants was low (15%). In that study 57.5% of participants were not aware about any kidney problems but 52.5% reported ophthalmologic and eye related issues. [18]

In a study conducted at Black Lion hospital on treatment adherence and glycemic control among type 2 diabetic patients it was found that over all treatment adherence was 9 % and adherence to antidiabetic medication was 66.8%. Up on evaluation of the reasons for antidiabetic medication

non-adherence, it was identified that 100 (93.5%) patients mentioned forgetfulness as the reason for their nonadherence. For each of 29 (27.1%) and 26 (24.3%) patients, experiencing side effects and feeling well without treatment were the reasons for antidiabetic medication nonadherence. Others included busyness, fasting, sleeping and lack of access to medications [21]

3. OBJECTIVES

General objective:-

- To assess the prevalence of adherence to treatment among diabetic patients visiting SPHMMC chronic follow up unit.

Specific objectives:-

- To assess the proportion of patients adherent to pharmacologic treatment of DM
- To assess the proportion of patients adherent to non pharmacologic treatment of DM
- To assess the reasons contributing to non-adherence to pharmacologic treatment among DM patients
- To assess patient awareness about acute and chronic complications of DM

4. METHODS AND MATERIALS

4.1. STUDY AREA

St. Paul's Hospital was built in 1969 (was named St Paul General Specialized Hospital until 2008) by Emperor Haile Selassie in collaboration with the German Evangelical Church, as a source of medical care for underserved populations. It currently has 392 beds, with an annual average of 200,000 patients and a catchment population of more than 5 million. Approximately 75% of the patients receive medical service free of charge. There are over 1300 clinical and non-clinical staffs in over 13 departments, most recently launching its new hemodialysis unit and kidney transplant center. The hospital currently started to build a new cancer and cardiac center. The Medical School opened in 2007, the new Millennium era of the Ethiopian calendar. It is intended to alleviate the severe shortage of medical doctors in the country. The chronic follow up unit is open in week days and it has been a great means to help the society. Diabetic patients are seen on Wednesday and Thursday both in the morning and in the afternoon. It's estimated that on average there will be 100-150 diabetic patients seen per day in these days.

4.2. STUDY DESIGN AND PERIOD

Institution based analytical cross sectional study was conducted from May 1 – May 31 2017 in SPHMMC Addis Ababa.

4.3. SOURCE POPULATION

All diabetic patients who have been treated and registered at the diabetic follow up clinic of SPHMMC in the study period.

4.4. STUDY POPULATION

All diabetes patients attending diabetic follow up clinic during the study period sampled from the source population

4.5. SAMPLE SIZE

The Sample size was determined using single population proportion formula taking $p = 9\%$ (adopted from similar research) with 95% confidence level, 5% margin of error.

$$n = \frac{Z^2 p (1-p)}{d^2}$$

$$d^2$$

$Z=1.96$ corresponding to 95% confidence interval

n =sample size

$p=9\%$ (prevalence of treatment adherence taken from a similar research done in Black Lion Hospital)

d = degree of precision within (+ or -) 5% of the true value

The sample size will be 126 patients. The expected number of source population in the study period (N), based on the average number of patients coming to the clinic during the diabetic days in the time period was 1000. The corrected sample size, using the following correction formula will be 112 patients.

$$n_f = \frac{n_o}{1 + \frac{n_o}{N}}$$

For non respondents with a contingency of ten percent, the total sample number was 124 patients.

4.6. SAMPLING PROCEDURE

Systematic random sampling method was used to recruit samples for the study. The actual sampling fraction k was calculated to be 8 by taking the total number of patients to be seen in the study period as 1000. Then every 8th patient was interviewed. The first patient was randomly chosen.

4.7. INCLUSION CRITERIA

Patients who were: diagnosed with type-1 or type-2 DM, ≥ 18 years old, on pharmacological management and followed up for at least three times have participated in the study.

4.8. EXCLUSION CRITERIA:

Diabetic patients who were: seriously ill

4.9. VARIABLES

Dependent variable

- ✓ treatment adherence

Independent variables

- ✓ Demographic variables - age, sex, educational status, family monthly income, marital status, occupation
- ✓ Patient characteristics - presence of co-morbidities and complications, type and number of prescribed antidiabetic drugs, duration of diabetes, knowledge about DM complications

4.10. DATA COLLECTION PROCEDURES

Data collection tool: The data was collected using structured questionnaire. The questionnaire was prepared in English and Amharic. The questionnaire was developed according to the objectives of the study (it was adopted from similar research).

Methods of data collection: data was collected by the investigator using structured questionnaire through interview.

4.11. OPERATIONAL DEFINITION

Adherence- the extent to which diabetic patient's behavior – taking medication, following a diet or executing lifestyle changes, corresponds with agreed recommendations from a health care provider.

Adherent to antidiabetic medications: A patient who scored ≤ 1 for the MAPS was said to be adherent to antidiabetic medications

Non-adherent to antidiabetic medications: A patient who scored > 1 for the MAPS was said to be non-adherent to antidiabetic medications

Adherent for dietary recommendations: A patient who cut off both sweet carbohydrate and fatty meals was regarded as adherent for dietary recommendations

Non-adherent for dietary recommendations: A patient who failed to cut off both sweet carbohydrate and fatty meals was regarded as non-adherent for dietary recommendations

Adherent for exercise recommendations: A patient exercised ≥ 3 days and for ≥ 150 minutes (with no more than 2 consecutive days gap in between without exercise) a week was regarded as adherent to exercise recommendations

Non-adherent for exercise recommendations: A patient who failed to exercise for ≥ 3 days and for ≥ 150 minutes (with no more than 2 consecutive days gap in between without exercise) a week was regarded as non-adherent to exercise recommendations

Treatment adherence: A patient was said to be adherent to treatment if he/she adhered to all three treatment approaches (antidiabetic medications, exercise and dietary recommendations).

Treatment non-adherence: A patient was said to be non-adherent to treatment if he/she failed to adhere to all three treatment approaches (antidiabetic medications, exercise and dietary recommendations).

Adequate knowledge about DM complications: The knowledge regarding the complications of diabetes was considered adequate when a patient could mention $\geq 3/5$ complications as mentioned in the data collection instrument.

Some knowledge about DM complications: The knowledge regarding the complications of diabetes was considered some when a patient could mention 1-2/5 complications as mentioned in the data collection instrument.

No knowledge about DM complications: The knowledge regarding the complications of diabetes was considered no when a patient could not mention at least one of the five major DM complications mentioned in the data collection instrument.

4.12. Data quality control

Care was taken on questionnaire design. The questionnaire, which was originally developed in English, was translated to Amharic language, and back translated to English so as to

ensure its consistency and it was pretested after which relevant changes and modifications was made with the input from the pretesting. Investigators were properly trained on the whole data collection process. Each day the principal investigator saw whether the investigators have done their job correctly or not.

PRETEST: A trial test of the questionnaire was conducted among 13 diabetic patients on follow up at Ras Desta Damtew memorial hospital taking 10 % of the total sample size. These patients were not included in the actual sample size. The pre-test was used to revise questionnaire clarity, order of question, time required to complete the questionnaire and consistency of the data.

4.13. DATA MANAGEMENT AND ANALYSIS PROCEDURE

Data collected was checked visually for completeness, coded and entered into SPSS version 20. The data collected was analyzed by SPSS 20 using frequency tables cross tabs and chi-square methods.

4.14. ETHICAL CONSIDERATION

Before the data collection permission was obtained from SPHMMC public health department. During data collection, all methodological and ethical considerations were taken care of. Informed consent was obtained from the participants. The participants were encouraged to ask questions. All information obtained in the course of this study would be treated with confidentiality and would not be used outside the scope of the study.

4.15. DISSEMINATION OF RESULT

After the research paper gets approved by the advisor, the findings of the study would be submitted to SPHMMC public health department. The findings of this study would be presented in different conferences and seminars whenever possible.

5. RESULTS

5.1. SOCIO-DEMOGRAPHIC CHARACTERISTICS

Among the respondents, males comprise 63(50.8%). Based on age distribution majority of the respondents were in the age group 51-60 years accounting for 41.9% (52). The minimum age of respondents was 30 and the maximum was 88 with a mean age of 55.09 (SD= 9.812). About 81 (65.3%) of the respondents were married and 44 (35.5%) of respondents attained secondary education. Being a house wife and a government employee took highest percentage 28 (22.8%) each. Economically majority of respondents 49(39.5%) get a high monthly income. (see table 1 below)

Table1:- Socio-demographic characteristic of patients with diabetes attending the chronic follow up unit in SPHMMC, Addis Ababa

Variable	Frequency	Percentage
Sex		
male	63	50.8%
female	61	49.2%
Age (years)		
≤40	10	8.1%
41-50	35	28.2%
51-60	52	41.9%
61-70	19	15.3%
>70	8	6.5%
Marital status		
Single	12	9.7%
Married	81	65.3%

Divorced	11	8.9%
Widowed	20	16.1%
Occupation		
Farmer	5	4%
Gov't employee	28	22.6%
Merchant	25	20.2%
Daily laborer	9	7.3%
House wife	28	22.6%
Retired	27	21.8%
Others	2	1.6%
Educational status		
Can't read and write	25	20.2%
Primary	40	32.3%
Secondary	44	35.5%
Higher education	15	12%
Monthly income (ETB)		
Very low (≤ 445)	-	-
Low (446-1200)	16	12.9%
Average (1201-2500)	40	32.3%
Above average(2501-3500)	19	15.3%
High (≥ 3501)	49	39.5%

5.2. DISEASE RELATED CHARACTERISTICS

Duration of DM

Of all the respondents the average duration since being diagnosed was 7.82 (SD= 5.479) years ranging from under 5 years 41(33.1%), from 5 to 10 years 49(39.5%) and over 10 years 34(27.4%).

Table 2:- Duration of DM since being diagnosed among patients attending the chronic follow up unit in SPHMMC, Addis Ababa

Variable	Frequency	Percentage
Duration of DM		
<5 years	41	33.1 %
5-10 years	49	39.5 %
>10 years	34	27.4 %

Knowledge about diabetic complications

Almost all of the respondents 123 (99.2%) know at least one complication of diabetes. Among this knowledge about eye complication took the first place with 113 (91.1%). From the total respondents 97 (78.2%) had adequate knowledge of complications, 26 (21%) had some knowledge of complications and 1 (0.8%) had no knowledge of complications.

Table 3:- Knowledge about diabetic complications among patients attending the chronic follow up unit in SPHMMC, Addis Ababa

Variable	Frequency	Percentage
At least knows one Diabetic Complication		
Yes	123	99.2%
No	1	0.8%

Knowledge on Specific Diabetic Complications		
Neuropathy	81	65.3%
Kidney complication	90	72.6%
Heart complication	14	11.3%
Eye complication	113	91.1%
Foot ulcer	112	90.3%
Others	1	0.8%
Category of Knowledge about Diabetic Complications		
No knowledge	1	0.8 %
Some knowledge	26	21 %
Adequate knowledge	98	78.2%

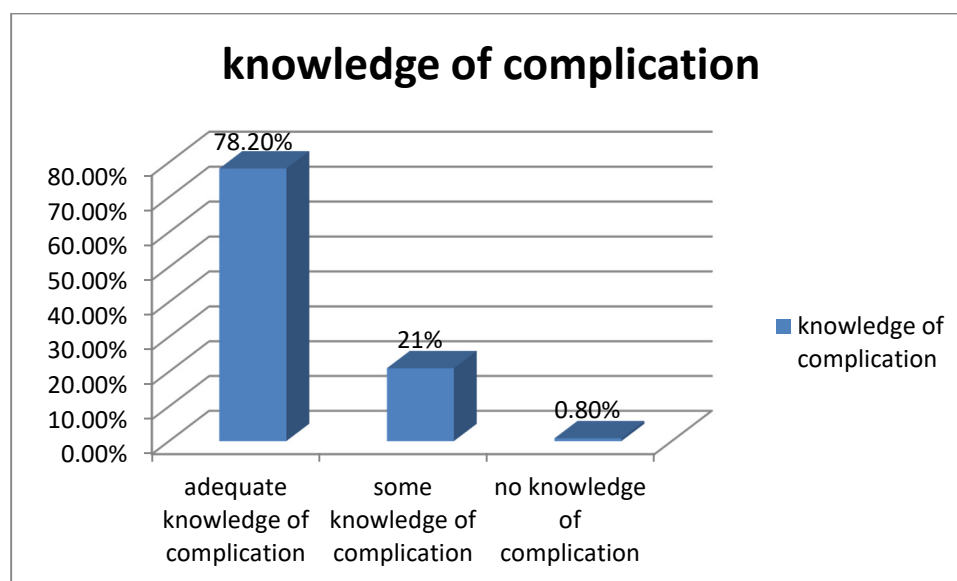


Figure1:- knowledge of complication

Presence of complications of DM

From all the respondents 75 (60.5%) were found to have at least one of diabetic complication, among which neuropathy took the highest percentage with 50 respondents (40.3%)

Table 4:- Presence of diabetic complications among diabetic patients attending the chronic follow up unit in SPHMMC, Addis Ababa

Variable	Frequency	Percentage
Diabetic complication		
Absent	49	39.5%
Present	75	60.5 %
Specific diabetic complication		
Neuropathy	50	40.3 %
Kidney complication	18	14.5 %
Heart complication	2	1.6 %
Eye complication	38	30.6 %
Foot ulcer	16	12.9 %
Other complication	1	0.8 %

5.3. NON PHARMACOLOGICAL APPROACH OF DIABETIC CARE

The non-pharmacological treatment modalities practiced by patients included: diet restriction (110, 88.7%), exercise (26, 21%), self-monitoring of blood glucose (SMBG) (40, 32.3%), never drink alcohol regularly (84, 67.7%) and never smoke (106, 88.5%).

From the total respondents 121 (97.6%) of them had dietary plans prepared with their physicians, 120 (96.8%) were told to cut off sweet carbohydrate and 110 (88.7%) were told to cut off fatty meals.

Table 5:- Non-pharmacological approaches of diabetic care among diabetic patients attending the chronic follow up unit in SPHMMC, Addis Ababa

Variable	Frequency	Percentage
DIET		
Cutoff sweet carbohydrate meals	120	96.8%
Cutoff fatty meals	110	88.7%
Overall dietary adherence Yes	118	88.7%
No	14	11.3%
EXERCISE		
Presence of exercise plan Yes	102	82.3%
No	22	17.7%
Exercise according to plan Yes	46	37.1%
No	56	45.2%
Days per week doing exercise <3	7	5.6%
>=3	39	31.5%
Duration of exercise minute per week < 150	20	16.1%
>= 150	26	21%
Overall exercise adherence No	20	16.1%
Yes	26	21%
ALCOHOL		
Ever drink alcohol regularly No	84	67.7
Yes	40	32.3%
Drinking regularly now No	116	93.5%
Yes	8	6.5%

How much per day	≤ 2 for male & ≤ 1 for female	4	3.2%
	≥ 2 for male & > 1 for female	4	3.2%
CIGARETTE			
Ever smoked	No	106	85.5%
	Yes	18	14.5%
Smoking now	No	113	91.1%
	Yes	11	8.9%
Amount of cigarette per day	$<$ half a pack	10	9.1%
	$>$ half a pack	1	0.8%
SMBG			
Presence of glucometer	No	79	63.7%
	Yes	45	36.3%
No of blood glucose measurement per week	< 7	5	4%
	≥ 7	40	32.3%

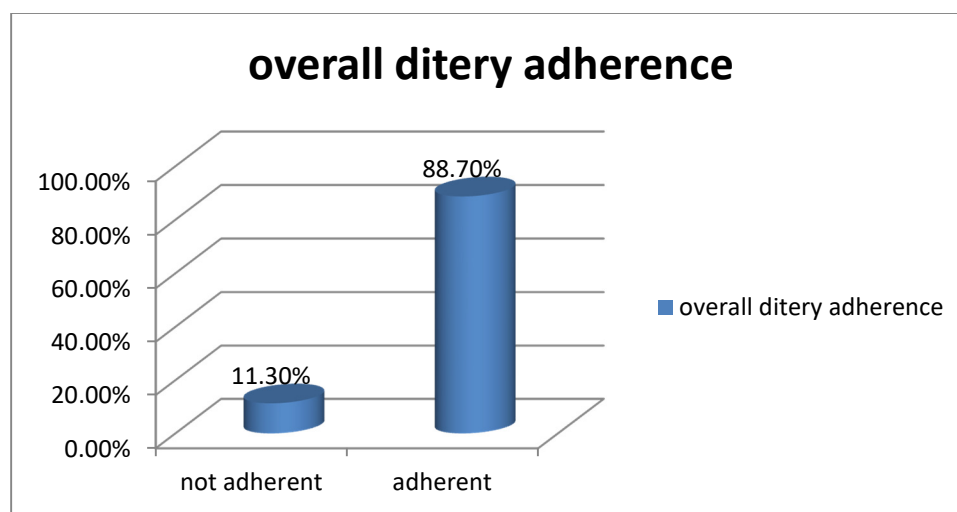


Figure 2:-overall dietary adherence

5.4. RATE OF ANTIDIABETIC MEDICATION ADHERENCE

Assessment of patients' responses to the 4-item Morisky adherence predictor scale showed that 67 (54%) patients were adherent to the prescribed regimen of their antidiabetic medications.

Table 6:- Responses to the 4-item Morisky Instrument among diabetic patients attending the chronic follow up unit in SPHMMC, Addis Ababa

QUESTION	FREQUENCY	
	Yes	No
Do you ever forget to take your antidiabetic medication (s)?	50(40.3%)	74(59.3%)
Do you sometimes, not being careful in taking your medication (s)?	28(22.6%)	96(77.4%)
When you feel better, do you sometimes stop taking your antidiabetic medication (s)?	17(13.7%)	107(86.3%)
Sometimes if you feel worse when you take your antidiabetic medication (s), do you stop taking them?	5(4%)	119(96%)
Overall medication adherence	67(54%)	57(46%)

Reason for medication non adherence

During evaluation of the reasons for anti-diabetic medication non-adherence, it was found that 48(38.7%) patients mentioned forgetfulness as the reason for their non adherence. For each of 11(8.9%) and 11(8.9%) patients, complex regimen and feeling well without treatment were the reasons for anti-diabetic medication non adherence, respectively.

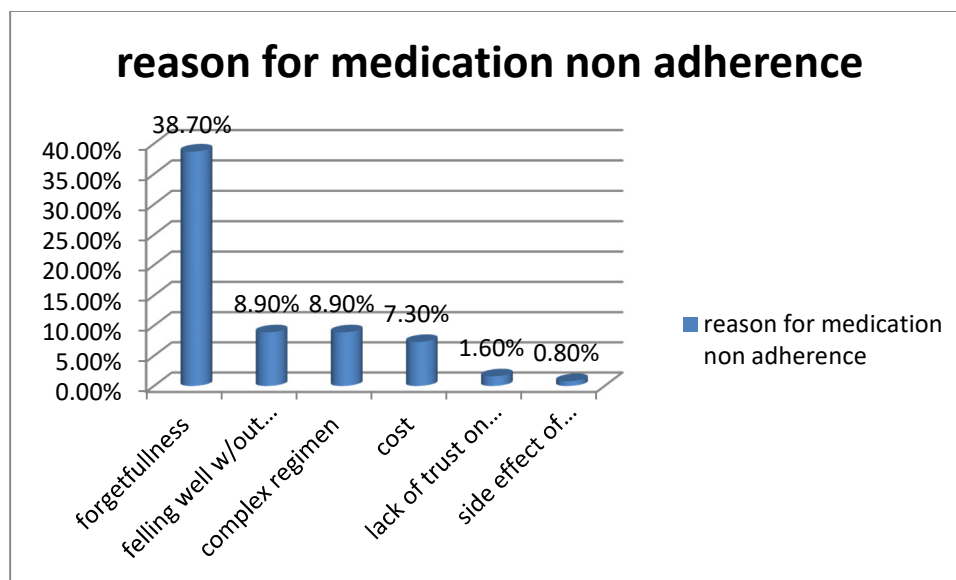


Figure 3:-reason for medication non adherence

Adherence to treatment

Finally while evaluating the overall treatment adherence of patients which meant those who were adherent to dietary, exercise and medication, it was found that 20(16.1%) were adherent to treatment.

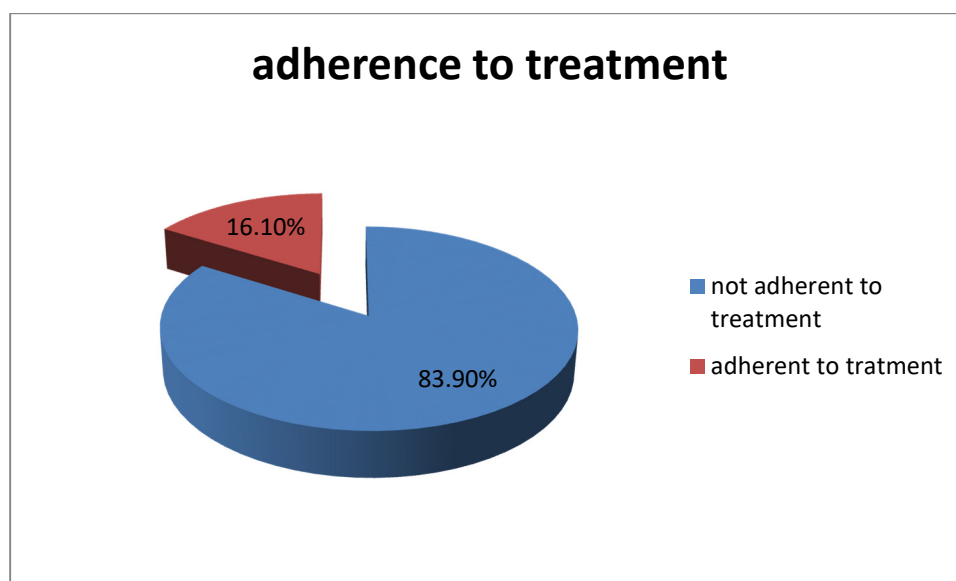


Figure 4:-overall adherence to treatment

5.5. REASONS CONTRIBUTING TO NON-ADHERENCE TO TREATMENT

The study demonstrated that the overall treatment adherence was 16.1%. Respondent's sex, age, education, duration of illness and presence of complication were significantly associated with the overall treatment adherence.

Among the respondents those with high level education are more likely to be adherent to treatment. Another interesting finding is that the presence of knowledge about complication has no statistical significant on the adherence to treatment. But those respondents who have at least one complication of DM were found to be adherent more to treatment than those with no complication.

Respondent's marital status, occupation, income, knowledge of complication, alcohol use, smoking and having glucometer at home did not show a significant association with treatment adherence.

Table 7:-reasons contributing to non adherence to treatment

Chi square test of	Asymp. Sig. (2-sided)	Comment
Treatment adherence * sex	0.018	Significant
Treatment adherence * age	0.003	Significant
Treatment adherence * education	0.01	Significant
Treatment adherence * duration of illness	0.001	Significant
Treatment adherence * presence of complication	0.01	Significant
Treatment adherence * marital status	0.146	Not significant

Treatment adherence * occupation	0.158	Not significant
Treatment adherence * income	0.068	Not significant
Treatment adherence* knowledge of complication	0.371	Not significant
Treatment adherence * drinking alcohol regularly	0.773	Not significant
Treatment adherence * smoking	0.846	Not significant
Treatment adherence * having a glucometer	0.057	Not significant

6. DISSCUSSION

The goals of diabetes treatment are to keep blood glucose levels as near normal as possible while avoiding acute and chronic complications and diabetes requires continual intensive treatment in order to reduce the risk and progression of chronic micro- and macro-vascular complications. The prevention and control of both types of complications are significantly influenced by adherence to treatment. The multiple lifestyle modifications that are of importance in the management of diabetes require a high degree of adherence from the patients as well.

In this research adherence to anti-diabetic medication was found to be 54% among the total population. In a similar research done in Jimma hospital on medication adherence in 347 diabetes mellitus patients anti diabetic drug adherence was 20.8 % [6]. A systematic review on adherence with medications for diabetes at New Haven, USA and found adherence to oral hypoglycemic agents ranged from 36-93% [19]. In another study in Southwestern Nigeri, it was found that approximately 60% of patients were adherent to the prescribed medications [20]. In a study conducted at Black Lion hospital on treatment adherence and glycemic control among type 2 diabetic patients it was found that adherence to antidiabetic medication was 66.8% [21]. The medication adherence in other similar researches was found to be in Nigeria 72.5% [22], Malaysia 47% [23], India 16.6% [24], Southern California, USA 40% [25] and Brazil 78.3% [26].

Adherence to therapies is a primary determinant of treatment success. Failure to adherence is a serious problem, which not only affects the patient but also the health care system. Medication non adherence in patients leads to substantial worsening of disease, death and increased health care costs. Among patients not adherent to medication the main reason for non adherence was found to be forgetfulness in 38.7% of cases. This result is similar to the study done in Jimma where the main reason for non adherence is forgetfulness in 50.2% cases [6]. Similarly in a research done in Black lion hospital forgetfulness is the main reason for medication non adherence (93.5%) [21].

Treatment of diabetes is not only medications it also includes non pharmacologic approaches. These include dietary modification, exercise, SMBG, avoiding smoking and alcohol, and other life style modifications. In this research it was found that diet restriction (110, 88.7%), exercise adherence (26, 21%), self-monitoring of blood glucose (SMBG) (40, 32.3%), never drink alcohol regularly (84, 67.7%) and never smoke (106, 88.5%). In a similar research done in Black Lion hospital among 322 respondents the results are similar it was found that diet restriction (207, 64.3%), exercise adherence (69, 21.4%), SMBG(11, 7.4%), never drink alcohol regularly (235, 71.0%) and never smoke (285, 88.5%). [21]

This study also illustrated that almost all of the respondents 123 (99.2%) know at least one complication of diabetes and among this knowledge about eye complication took the first place with 113 (91.1%). In a similar research done at Black lion (83.5%) patients knew at least one diabetic complication and among this, knowledge about eye complications took the first among the complications, for which 95.9% of patients knew about.

Additionally in this research it was found that from the total respondents 97 (78.2%) had adequate knowledge of complications, 26 (21%) had some knowledge of complications and 1 (0.8%) had no knowledge of complications. In the research done at Black lion 18.0% and 65.5% of the respondents had some and adequate knowledge, respectively, about diabetic complications. This relative increment in knowledge is probably due to increased effort in physicians in teaching patients and the mass media increases the society's awareness. [21]

Among the respondents 40.3% have kidney complication of diabetes being the commonest complication found in this research. The results found in a similar research done in Black lion shows eye complication to be the commonest 70.8%. [21]

In this research it was found that the overall treatment adherence (adherent to all dietary, medication and exercise) is 16.1%. This is slightly higher than the result of a research done Black Lion hospital 9%. Based on chi square test results respondent's sex, age, education, duration of illness and presence of complication were significantly associated with the overall treatment adherence. Respondents who have complication were found to be adherent more than those without complication. In a related research done in Black Lion age, occupation, income, having glucometer and number of prescribed drugs were found to have statistically significant association with adherence to treatment. [21]

7. CONCLUSION AND RECOMMENDATION

7.1. CONCLUSION

In general this study indicated that the treatment adherence of diabetes patients in SPHMMC follow up clinic is 16.1%. Forgetfulness was the most important reason preventing optimal adherence to prescribed medications. Almost all of the respondents 123 (99.2%) know at least one complication of diabetes. Among this knowledge about eye complication took the first place with 113 (91.1%).

Overall a relatively lower adherence to treatment was observed. Respondent's sex, age, education, duration of illness and presence of complication were significantly associated with the overall treatment adherence. Respondent's marital status, occupation, income, knowledge of complication, alcohol use, smoking and having glucometer at home did not show a significant association with treatment adherence.

7.2. RECOMMENDATIONS

Recommendation to physicians:- it is very important that patients who came for follow up get all the possible information about their illness. Especially in diabetes patients the management needs collaboration of the patient and the physician. For this reason I recommend physicians working in follow up clinic give detail information about diabetes management plan, its importance and the significance of adherence in long term disease progress.

Recommendation to patients:- diabetic patients who are on follow up must ask what is not clear for them during follow up visits. They also have to discuss their problems for adherence and plan a solution for it with their physician. They should also try not to miss their appointed visits.

Recommendation to policy makers:-they should increase means to educate patients on adherence and complication by different ways like mass media. Additionally if possible glucometer should be available at affordable price so that patients can monitor their glucose level which has a huge implication on development of complication.

8. STRENGTH AND LIMITATION OF THE STUDY

The strength of this research are it used systematic random sampling method to prevent bias. It also uses primary data which is more reliable.

The limitations of this research include it is a cross sectional study so it will not allow to see a follow up, which would have provided a better design for identifying the problem of non adherence. Since I used chi square to see association it's difficult to assess the strength of association between the dependent variable and contributing factors. It needs further analytical study.

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10. APPENDICES

Appendix 1

Information and Consent form

Dear respondents

My name is TSEDALE AYALEW. I am an investigator on behalf of a Degree Intern student in ST. PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE studying DOCTOR OF MEDICINE, who wants to conduct this survey. The purpose of this study is to generate information on adherence to treatment and patient's awareness about acute and chronic complications of Diabetic Mellitus. Hence, in order to effectively attain this goal, I kindly need your help. Here is a questionnaire for you to complete. There is no need to put your name on the questionnaire; no individual response will be reported. It is your full right to refuse to answer any or all of the questions you do not wish to answer. Please take a few minutes to answer the questions. If there is anything that requires clarification please don't hesitate to ask the facilitator for clarification. Do you wish to participate in the study?

- ☐ Yes, I want to participate in the study (please go to the next page)
- ☐ No, I don't want to participate. (Stop)

THANK YOU VERY MUCH!!

Questionnaire ID No-----

Instruction -The following are questions and statements for you. Please indicate your response by circling the number of your choice

Part I: Socio-demographic Characteristics

1. Sex

- a. Male
- b. Female

2. Age _____ Years

3. Marital Status

Single ☐

Married ☐

Divorced ☐

Widowed ☐

4. Occupation

Farmer ☐

Gov't Employee ☐

Merchant/Trade ☐

Daily Laborer ☐

House wife ☐

Retired ☐

Others Specify _____

5. Educational Status

- a. cannot read and write
- b. Primary (1-8)
- c. Secondary (9-12)
- d. Higher Education

6. Monthly Family Income (in ETB) _____

Part II: Disease related Characteristics

7. Duration of diabetes _____ Years

8. Presence of knowledge about diabetes complications

- a. Yes
- b. No

9. If yes to q. no 8, which of the following diabetes complication you know (can tick more than once))

- a. Neuropathy
- b. Kidney complications
- c. Heart complications
- d. Eye complications
- e. Diabetic Foot Ulcer
- f. Others Specify _____

10. If yes to q. no 8, do you have any one of the complications?
- a. Yes
 - b. No
11. If yes to q. no 10, which diabetic complication are present (can tick more than once)
- a. Neuropathy
 - b. Kidney complications
 - c. Heart complications
 - d. Eye complications
 - e. Diabetic Foot Ulcer
 - f. Others, if any_____

Part III: Non-pharmacological Approaches of Diabetes Care

12. Diet

12.1. Do you have dietary plan you set with your doctor?

- a. Yes
- b. No

12.2. If yes to q. no 12.1, do you adhere to your plan?

- a. Yes
- b. No

12.3. What type of dietary plan you have?

12.3.1. Cut off sweet carbohydrate meals

- a. Yes
- b. No

12.3.2. Cut of fatty meals (butter, cheese, fried foods, fatty cuts of red meat, egg yolks, poultry skin...)

- a. Yes
- b. No

12.3.3. Other plan, if any _____

13. Exercise

13.1. Do you have exercise plan you set with your doctor?

- a. Yes
- b. No

13.2. If yes to q. no 13.1, do you adhere to your plan?

- a. Yes
- b. No

13.3. How many days per week you do moderate intensity exercise?_____ day(s)

13.4. How many minutes per week you do moderate intensity exercise?_____ minutes

13.5. Other forms of exercise, if any_____

14. Alcohol

14.1. Do you ever drink alcohol regularly?

- a. Yes
- b. No

14.2. If yes to q. no 14.1, do you currently drink alcohol on a regular basis?

- a. Yes
- b. No

14.3. If yes to q. no 14.2, how much do you drink per day_____

- a. No more than 2 (for men) and 1 (for women) drinks
- b. Greater than 2 (for men) and 1 (for women) drinks

{NB: A drink serving is 12 ounces (340.8 ml) of beer, 5 ounces (142 ml) of wine, or 1.5 (42.6 ml) ounces of hard liquor such as scotch, gin, tequila, or vodka. 1 ounce is equal to 28.4 ml}

15. Cigarette Smoking

15.1. Do you ever smoke cigarettes?

- a. Yes
- b. No

15.2. Are you currently a smoker?

- a. Yes
- b. No

15.3. If yes to q. no 15.2, how much cigarettes you smoke per day? _____Packs

- a. < half
- b. half
- c. >half

16. Self monitoring of blood glucose (SMBG)

16.1. Do you have a glucometer?

- a. Yes
- b. No

16.2. If yes to q. no 16.1, how frequently do you perform SMBG per week? _____times

- a. < 7
- b. ≥ 7

Part IV: Medication adherence (4-item Morisky Adherence Predictor Scale, MAPS)

(Patients are expected to remember for the past 1 month only)

17. Do you ever forget to take your antidiabetic medication (s)?
- a. Yes
 - b. No
18. Do you sometimes, not being careful in taking your antidiabetic medication (s)?
- a. Yes
 - b. No
19. When you feel better, do you sometimes stop taking your medication (s)?
- a. Yes
 - b. No
20. Sometimes if you feel worse when you take your medication (s), do you stop taking them?
- a. Yes
 - b. No

Part V: Reasons for medication non-adherence (can tick more than once. If no single yes response for part 5 questions, go to part 6)

21. Which one of the following was the reason for your medication non adherence
- a. Cost of medication too expensive
 - b. Forgetfulness
 - c. Feeling well without medications
 - d. Complex regimen
 - e. Physicians mode of approach
 - f. Lack of trust on the efficacy of medications
 - For metformin ☐ For Glibenclamide ☐
 - For insulin ☐ For others, if any_____
 - g. Experiencing side effects
 - For metformin ☐ For Glibenclamide ☐
 - For insulin ☐ For others, if any_____

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1. □□

a. □□□

b. □□

2. □□□ _____ □□□ (□□□□ □□□)

3. □□□□ □□□

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□□ □□□□ _____

5. □□□□□□ □□□

a. □□□□□□/□□/

b. □□□□ □□□ (1-8)

c. □□□□ □□□ (9-12)

d. □□□□□□ □□/□□□□/□□□□□□□

6. □□□□□ □□□□ □□ (□□□□) _____ (□□□□ □□□)

□□□ **2**□ □□□ □□ □□□□□□□

7. □□□□ □□□□□ □□□ □□ □□□ □□ □□□□□? _____ (□□□□ □□□)

8. □□□□ □□□ □□□□□□□□□□□ □□□ □□□□ □□□□□?

a. □□

b. □□□□□□

9. □□□□ □.8 □□□□ □□ □□□ □□□□ □□□ □□□□□□□□□□ □□□ □□□□
□□□□□□ □□□ □□□□□ □□□□□? (□1 □□□ □□□□ □□□□)

a. □□□□□□/□□□□□□

b. □□□□□□ □□□

c. □□□ □□□ □□ □□□□□□ □□□□

d. □□□□ □□□

e. □□□□ □□□□

f. □□ □□ □□□□ _____

10. □□□□ □□□ □□□□□□□□ □□□ □□□ □□?

- a. □□
- b. □□□

11. □□□□ □.10 □□□□ □□ □□□ □□□□ □□□ □□□□□□□□ □□□ □□□ □□□□
□□□□□□ □□□ □□□□ □□? (□1 □□□ □□□□ □□□□)

- a. □□□□□/□□□□□□
- b. □□□□□ □□□
- c. □□□ □□□ □□ □□□□□ □□□□
- d. □□□□ □□□
- e. □□□□ □□□□
- f. □□ □□ □□□□ _____

□□□ 3□ □□□□□□ □□ □□ □□□□ (Non-Pharmacologic Treatment)

12. □□□

12.1. □□□□□ □□ □□□□ □□□□□ □□□□□ □□□□□ □□□□?

- a. □□
- b. □□□□

12.2. □□□□ □□ □□□□ □□□□□□ □□□□□ □□□□ □□□□□?

- a. □□
- b. □□□□□□

12.3. □□ □□□□ □□□□□ □□□□□?

12.3.1. □□□ □□□□□□□

- a. □□□□□□
- b. □□□□□□

12.3.2. □□□ □□ □□□□□□(□□□ □□ □□□□ □□□ □□□ □□□□ □□□□□ □□□□□
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- a. □□□□□□
- b. □□□□□□

12.3.3. □□ □□□□ □□□□□ □□□□□ □□□ □□□□ _____

13. □□□□ □□□ □□□□□□ (□□ □□□□□ □□□ □□□□□ □□□□□□□□ □□□
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13.1. □□□□□ □□ □□□□ □□□□□ □□□□ □□□ □□□□□ □□□□□ □□□□?

- a. □□
- b. □□□□

13.2. □□□□ □□ □□□□ □□□□□□□ □□□□ □□□□ □□□ □□□□□□ □□□□?

- a. □□
- b. □□□□□

13.3. □□□□□ □□□ □□ □□□□□ □□□ □□□ □□□□ □□□ □□□□□□ □□□□?
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13.4. □□□□□ □□□ □□□ □□□ □□□□□ □□□ □□□ □□□□ □□□ □□□□□□
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13.5. □□ □□□□ □□□□ □□□ □□□□□□ □□ □□□□ _____

14. □□□□□ □□□

14.1. □□□□□ □□□ □□□□□□□ □□□□ □□□□?

- a. □□
- b. □□□□□

14.2. □□□□ □□ □□□□ □□□□ □□□□□□□ □□□□□ □□□ □□□□?

- a. □□
- b. □□□□□

14.3. □□.□. 14.2. □□□□ □□ □□□□ □□□ □□ □□□ □□□□? _____ (□□□ □□□)

- a. □□□ 2 (□□□□□) □□□ □□□ 1 (□□□□) □□□
- b. □ 2 (□□□□□) □□□ □ 1 (□□□□) □□□ □□□

(□□□ □□□ □□□ 340.8 □.□□□ □□□ 142 □.□□□ □□□□ 42.6 □.□□□ □□□□
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15. □□□

15.1. □□□ □□□□ □□□□?

- a. □□
- b. □□□□□

15.2. □□□□ □□ □□□□ □□□□ □□□ □□□□?

- a. □□
- b. □□□□□

15.3. □□.□. 15.2 □□□□ □□ □□□ □□□ □□ □□□ □□□ □□□□? _____ (□□□
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- a. < □□□ □□□
- b. □□□ □□□
- c. > □□□ □□□

16. □□□□ □□□ □□□□ □□□ □□□□□ □□□□□□

16.1. □□□ □□□□ □□□□ □□□□?

- a. □□□
- b. □□□□

16.2. □□□□ □□ □□□□ □□□□□ □□ □□□ □□ □□□ □□□□□ □□□□□ □□□□□?

_____□□ (□□□□□ □□□)

- a. < 7 □□
- b. >= 7 □□

□□□ **4:** □□□□ □□□□□□ □□ □□ □□□□□ □□□□□□□□ (4-item Modified Morisky Adherence Predictor Scale, MMAPS) (□□□□□□ □□□□□□

□□□□□□□□ □□□□ **4** □□□□□ □□ □□)

17. □□□□ □□□□□□□□ □□□□□ □□□□ □□□□?

- a. □□
- b. □□□□□

18. □□□□□ □□ □□□□ □□□□□□□□ □□□□□ □□□□ □□□□ □□□□ □□□□?

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- b. □□□□□

19. □□□ □□□□ □□□ □□□□□ □□ □□□□□□□ □□□□ □□□□?

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- b. □□□□□

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- b. □□□□□

□□□ **5:** □□□□ □□□□□□ □□ □□ □□□□□□ □□□□□□□□ □□□□□ □□□□ □□□□ □□□□□□□□

(□□□□ **4** □□□□□ □□□□□ ‘ □□ ’ □□□ □□□ □□□ □□ □□□□□ **2** □□□□□ □□□□ □□□□ □□□□□ □□□□□)

21 □□□□ □□□□□□□ □□ □□ □□□□□□ □□□ □□□□□ □□□□□□ □□□□□□□

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- a. □□□□□ □□□□□ □□□ □□□□□ □□□
- b. □□□□□ □□□□□ □□□□
- c. □□ □□□□□□ □□□□□□ □□□ □□□□
- d. □□□□□□ □□ □□□□□ □□□□□□ □□□□□□ □□□

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g. □□□□□ □□□□□□ □□□ (Side Effect)

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