

HARAMAYA UNIVERSITY POSTGRADUATE

PROGRAM DIRECTORATE

**STATUS OF GLYCEMIC CONTROL AND FACTORS ASSOCIATED WITH
POOR GLYCEMIC CONTROL AMONG DIABETIC ADULT OUT-PATIENTS,
FROM DECEMBER 16, 2019 TO FEBRUARY 16, 2020 AT HIWOT FANA
SPECIALIZED UNIVERSITY HOSPITAL, HARAR, ETHIOPIA**

Internal Medicine Specialty training thesis research proposal

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Harar, Ethiopia

December, 2020

Acknowledgment

First and foremost I would like to thank Haramaya University College of health and medical sciences, Department of Internal Medicine for giving this golden opportunity to conduct this educational research as it is a great experience for me. Next, my especial thanks goes to Dr. Guta Diriba and Dr.Obsie Temesgen for their continuous support and advice. In addition, I would like to extend my grateful thanks and appreciation to all staffs of Haramaya University College of medical and health sciences, school of medicine and Hiwot Fana Specialized University Hospital for their co-operation during searching of some of the literature, documents and books I used as a guide! I would also like to thank all the writers and researchers whose work has shed some light and understanding on this particular topic.

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Lists of Acronyms

ADA	American Diabetes Association
CM	Centimeter
CSA	Central statistics Agency
CVD	Cardiovascular Diseases
DM	Diabetes Mellitus
Dr	Doctor
EC	Ethiopian Calendar
ETB	Ethiopian Birr
FBS	Fast Blood Sugar
HbA1c	Hemoglobin A1c
HFSUH	Hiwot Fana Specialized University Hospital
IDF	International Diabetes Federation
LDL	Low Density Lipoprotein
Mg/dl	Milligram per Deciliter
mm/L	Millimole Per Litre
NCDs	Non - Communicable Diseases
NNCDCP	National Non-communicable Disease Control Programme
P	P-Value
SMBG	Self-Monitoring Blood Glucose
SR	Saudi Riyal
SPSS	Statistical package forth social science
SSA	Sub-Saharan Africa
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
USD	United States Dollar
WHO	World Health Organization

Abstract

Background: Diabetes is increasing rapidly throughout the world especially in developing countries most likely because of rapid increase in urbanization, aging of the population and sedentary life style. Most diabetes patients had poor glycaemic control worldwide especially in SSA and continues to be a major challenge. Glycemic control is the most important predictor of diabetic related complications and deaths. Identifying factors associated with glycemic control help health care providers and patients to focus on areas that decrease causes of poor glycemic control, diabetic related complications and deaths. Despite this growing prevalence of diabetes and its complications, data regarding glycemic control is scarce and little is known about the factors contributing for poor glycemic control especially in Ethiopia. Such researches are of great relevance for planning healthcare programs targeting improved diabetes control. Thus assessing glycaemic control and associated factors in Eastern Ethiopia is important because there are different habits of the people, different way of life than the rest of parts of Ethiopia and undiagnosed DM is also high in this area.

Objective: To assess the status of glycemic control and factors associated with poor glycemic control among diabetic adult out-patients at Hiwot Fana Specialized University Hospital, Harar, Eastern Ethiopia, from December 16, 2019 to February 16, 2020.

Methods: Hospital- based cross sectional study will be conducted on diabetic patients who are attending in diabetic follow up clinic at HFSUH from the population of Eastern Ethiopia with sample size of 355. Data will be collected via structured questionnaire both patient interview and chart review from each patient and patient's medical records from December 16, 2019 to February 16, 2020. So the study subjects will be selected based on their card numbers (evens or odds) by systematic random sampling technique method who will have follow-up appointment on the months of December 16, 2019 to February 16, 2020 and the months are selected by using conventional method because having follow up in this period is also a chance. After completion of data collection, it will be edited and coded for processing and analysis and analyzed by using scientific calculator and SPSS statistical software. Descriptive statistics, odds ratio and multivariate analysis with 95% confidence interval will be used to show associations between target variables, frequency tables and graphs will be used to show the results.

Expected outcome: The majority of participants will have poor glycemic control and obesity, poor drug adherence, noncompliance to diet, inadequate exercise, not ever attend diabetic education and those who had no self-monitoring of their blood glucose level will be factors associated with poor glycemic control. The total estimated budget needed for the study will be 43,097 Ethiopian Birr.

CHAPTER ONE

INTRODUCTION

1.1. BACKGROUND INFORMATION

Diabetes mellitus (DM) is a metabolic disorder of multiple etiologies characterized by chronic hyperglycemia with disturbance in carbohydrate, protein and fat metabolism resulting from defect in insulin secretion, insulin action or both (Craig M, et al ,2009, Nathan DM, et al,2009, FelekeY,et al,2005, ChON et al,2013, CDC and control.National diabetes facts,et al,20051-5). Diabetes is one of the common non-communicable disease with high prevalence and risks of lifelong chronic complications (Karter A.J., MoffetH.H.,LiuJ.,Parker M.M.,Ahmed A.T.,Ferrara A.,etal,2005).

According to International Diabetes Federation (IDF) 1.9 million adults aged 20-79 year had diabetes in 2013 and another 2.9 million people had impaired glucose tolerance who are more likely to develop diabetes in Ethiopia with national prevalence of 4.36% and there were about 34,262 diabetes related deaths in the same year because of poor glyceimic control related complications (Chon, Whiting D,Guariguata L,Montoya PA,ForouhiN,Hambl et al,2013).National Survey conducted in 2015 in Ethiopia showed the prevalence of DM or raised blood sugar in the adult population is 6% and majority of them had poor glyceimic control (Yewoinhareg, Ahmed, Tedla, Helen, Abdurazak, Bereket, et al, 2016).

The most common causes of morbidity and mortality in uncontrolled diabetes are because of renal failure, coronary artery diseases and direct consequences. Glyceimic control is the main goal in all diabetic patients in preventing complications arising from diabetes. Several large prospective studies and clinical trials established the benefits of intensive diabetes management in reducing vascular complications of diabetes (Chon, Whiting D,Guariguata L,Montoya PA,ForouhiN,Hambl et al,2013).It also consumes large proportion of the annual budget for treatment of DM and its complications and reduce life expectancy and quality of life.

Most studies showed that tight control of diabetes is very important, but majority of patients do not attain ideal blood glucose level. Reasons for poor glyceimic control is complex and multifactorial of which both patient and healthcare provider related factors may contribute to poor glyceimic control.Eventhough DM prevalence is high in Ethiopia, there is no nationwide study on status of glyceimic control so this study will show status of glyceimic control in Eastern Ethiopia.

According to American Diabetic Association (ADA, 2018), good glyceimic control is defined as Glycosylated Hemoglobin (HbA1c) value of 7 % or less or fasting blood glucose level of 80-130 mg/dl for the past three months and Poor glyceimic control is defined as HbA1c value of more than 7 % or fasting blood glucose level of < 80 mg/dl and > 130 mg/dl for non-pregnant adults for the past three months in young and uncomplicated DM or without comorbid patients. Fasting blood sugar is defined as blood glucose level measured from venous blood after 8 hours of overnight fasting or longer (IDF, et al, 2015).

Hence, assessing magnitude of glycaemic control and factors associated with poor glycaemic control are important in order to design hospital based protocol preparation and to inform clinicians for disease management in an effort to stop or decrease DM related complications, cost of treatment and death among affected individuals within the community. However, despite diabetes treatment is being practiced in HFSUH for longer periods of time, trends of the disease, status of glycaemic control and associated factors have not been assessed yet in this area. Therefore, the aim of this study will help to narrow this gap and will use as cornerstone for future plans and researches. After assessing status of glycaemic control and identifying factors associated with poor glycaemic control, possible intervention methods will be formulated and applied to improve status of glycaemic control and decrease or delay DM related complications and associated factors (IDF, et al,2015).

1.2. STATEMENT OF THE PROBLEM

Diabetes is one of the most chronic health problem globally especially in Sub-Saharan Africa (SSA) with devastating outcome, yet preventable consequences if it is controlled well. According to World Health Organization (WHO), Poor and inadequate glycaemic control constitutes a major public health problem and is a major risk factor for the development and progression of diabetes-related complications, which can greatly increase healthcare costs of the disease and reduce life expectancy and quality of life. Uncontrolled DM can result so many complications which can be classified as chronic and acute complications. Chronic complications include neuropathy, retinopathy, nephropathy, coronary artery disease, impotence, stroke, gastroparesis, incontinence, adult blindness and the leading cause of non-traumatic lower extremity amputations. And acute complications like hypoglycaemia, diabetic keto acidosis (DKA) and hyperosmolar hyperglycaemic state (HHS). Tightly controlling blood glucose level, addressing and identifying associated factors of poor glycaemic control is essential to diabetes care and management in order to delay the onset or decrease the incidence of complications. Improved glycaemic control has been proven to prevent the development and progression of diabetic complications, as well as to increase the life expectancy and quality of life of patients. Improved glycaemic control has been also shown to significantly reduce diabetes related costs. Glycemic control is mostly associated with good drug adherence, adequate physical exercise, proper diet, weight reduction, self-monitoring of blood glucose, educational level, economic status, good patient care provider communication, appropriate dose and regimen of drugs and participating patients on the management plan. While few studies on the status of poor glycaemic control and factors associated with poor glycaemic control have been carried out worldwide and in Sub-Saharan Africa especially in Ethiopia. Therefore, without understanding of factors associated with poor glycaemic control in this area, it will be difficult to address the situation (IDF, et al, 2015).

1.3. SIGNIFICANCE OF THE STUDY

Identifying the magnitude of glycaemic control and associated factors for poor glycaemic control at HFSUH adult out-patient diabetic follow-up clinic will give insights into treatment success rates. This will not only contribute to the existing body of knowledge on factors associated with poor glycaemic control in general, but will also bring new knowledge. Once the factors and the magnitude of the problems are identified, then targeted strategies to address them can be formulated and help health care providers and patients to focus on the areas that reduce causes of poor glycaemic control, diabetic related complications and deaths. The study will benefit all diabetic patients (current and future) as findings will be used to formulate strategies to improve the quality of care, minimizing identified factors of poor glycaemic control, prevent or delay diabetic related complications and minimize resources which are vested for treatment of complications. In addition, recommendations will be made to the National Non-communicable Disease Control Programme (NNCDPCP) on how to tightly control blood glucose level, status of glycaemic control, decrease associated factors and increase compliance will help to improve glycaemic control in this area. The study will also benefit the country, the region, and the hospital as well in planning and allocating both human and financial limited resources as findings may be used to formulate strategies to improve the quality of diabetes care and delay or decreased diabetes related complications. Diabetic patients especially those having follow up at HFSUH will be the most benefited from this study by improving diabetic treatment options and solving identified associated factors.

1.4 OBJECTIVE OF THE STUDY

1.4.1. GENERAL OBJECTIVE

1. To assess status of glycemic control and factors associated with poor glycemic among adult diabetic out-patients at HFSUH, Eastern Ethiopia, from December 16, 2019 to March 16, 2020.

1.4.2. SPECIFIC OBJECTIVES

- ✓ To assess the level of glycemic control among adult diabetic out-patients at HFSUH
- ✓ To determine factors related to poor glycaemic control among adult diabetic out-patients at HFSUH

CHAPTER TWO

2. LITRATURE REVIEW

2.1 Glycemic Control

2.1.2. World wide

Different studies have been conducted in the area of prevalence, and treatment outcome of diabetes, especially studies that assess the status of glycemic control and the different risk factors associated with poor glycemic control. These studies have been conducted in different countries throughout the world. There are also a few number of hospital based studies conducted in our country. Diabetes can cause multiple social, economic, political and health problems if it is uncontrolled, as a result it remains a major global health burden. Data on the status of glycemic control with diabetes in SSA and the complications of diabetes that they suffer is very scarce. Thus, around 3.8% (IDF Atlas, 2011) of all people with diabetes are currently in this region, and the number of individuals with diabetes in SSA is expected to double by 2030 and most of them had poor glycemic control. Millions of patients with poor glycemic control suffer disabling and life-threatening complications such as heart attack, stroke, kidney failure, blindness and amputation. Uncontrolled Diabetes is also implicated in and has negative consequences for certain infectious diseases like tuberculosis, pneumonia, urinary tract infections, and fungal infections, dental caries and perianal infections (IDF, et al 2009, IDF, et al, 2017, IDF, et al, 2013, IDF,et al, 2015). In the meantime, the very low expenditures per capita in poor countries demonstrate that more resources are required to provide basic diabetics control care and treatment of DM Complications because of poor glycemic control as it results in high healthcare costs, loss of labor, productivity and decreased rates of economic growth as a result of chronic absenteeism by ailing workers. The World Economic Forum has consistently identified NCDs (including uncontrolled diabetes) as a global risk for business and communities. The losses in national income from largely preventable deaths from diabetes mellitus, heart disease and stroke are enormous; For instance those losses are estimated to reach USD 558 billion in China, USD 303 billion in Russia, and USD 237 billion in India from 2005 to date hence more prevention efforts are needed to reduce this burden (IDF, 2007) (IDF, et al, 2009, IDF, et al, 2017, IDF, et al,2013, IDF et al,2015, IDF,et al,2017).

According to International Diabetes Federation (IDF), in Africa, about 19.8 million adults were estimated to have diabetes and regional prevalence of DM is 4.9%. Of which more than 50% lives in four highly populated countries namely: Nigeria, South Africa, Ethiopia and Tanzania and most of them had poor glycemic control. Ethiopia with national prevalence of 3.36%, 23,869 diabetes related deaths and with mean 25 USD diabetes related expenditure per person is highly affected and poor glycemic control is the most common cause of hospital admissions and complications in diabetes (Bodena Bayisa, 2017).

A cross-sectional study from medical records of all patients with diabetes were reviewed from 656 (54 with T1DM and 602 with T2DM), who were attending the Endocrinology Outpatient Units from Paracatu and Joao Pinheiro Cities, Brazil from June to December 2016, showed that majority of patients had poor glycaemic control (Débora Gonçalves, da Silva, Luiz, Alberto Simeoni, Angélica Amorim,2018).

A cross sectional study was conducted to determine the predictors of poor glycemic control among 152 type two diabetes patients in Saudi Arabia, in Al-madinah, Diabetic center in 2013 showed that, the proportion of poor glycemic control was 76.4% (Andrew J.M. Boulton, David D'Alessio, Frank B,2013).

In study done in Mombi, India, in 2018, 220 Type 2 DM patients having follow up for consultation were participated for the study to assess factors associated with poor glyceemic control among patients with Type 2 diabetes mellitus, showed that majority of diabetic patients had poor glyceemic control (91.8%) while only 8.2% Type 2 diabetic patients had good glyceemic control (Ipseeta R, 2017).

Another community based cross sectional study was conducted India, in 2014, and 165 type 2 diabetic patients was randomly selected from the institute to identify and address the role of Social Determinants in glyceemic control of type 2 diabetic patients and the result of the study showed that, 67 % of patients had poor glyceemic control (Basavesh wara Medical College and Hospital, Chitra durga, April, 2014).

2.1.3. Study in Africa

A hospital-based cross sectional survey was conducted among 220 adult diabetic patients aged 18 years and above, who were attending the diabetic clinic at the Hohoe Municipal hospital, Ghana in May and June 2017, to assess Prevalence and associated factors of glyceemic control among diabetic adults and result of the study showed that, prevalence of poor glyceemic control was 86.4% whereas ideal glyceemic control was 13.6% (Fiagbe J1,2, Bosoka S1, Opong J1, Takramah W1, Axame WK1, Owusu R1,et al, 2017).

339 adult patients were participated in a cross-sectional study conducted in the university clinic at Gadarif, Eastern Sudan to assess glyceemic control among adult patients with type 2 diabetes from February to August 2017 and the result of the study showed that, the prevalence of poor glyceemic control was 71.9%(2017) (Omar, Imad R. Musa,Osman E. Osman and Ishag Adam Omar et al,2018).

A descriptive cross sectional study was done to determine factors associated with glyceemic control among 149 T2DM patients attending Mathari National and Referral Hospital Nairobi, Kenya, between 2015 and 2016 and the result of the study showed that, 81.6% had poor glyceemic control with a mean HBA1C of 9.1, 90.6% having elevated FBS (Nduati NJ, Simon K, Eva N, Lawrence M, 2016).

2.1.4. Study in Ethiopia

A hospital based cross-sectional study was conducted at out-patient diabetes clinic of Dessie Referral Hospital in Northeast Ethiopia from January to April 2017 to determine the status and factors associated with glyceemic control among 384 diabetics and the result showed that, 70.8% had poor glyceemic control (Fiseha Temesgen, Ermiyas Alemayehu, Wongelawit Kassahun, Aderaw Adamu and Angesom Gebreweld, 2018).

A hospital based cross-sectional survey was conducted among 325 adults with type 2 diabetes mellitus attending in Jimma University Teaching Hospital, South west Ethiopia from February 14 to April 9, 2014, to assess status of glyceemic control and its contributing factors among adult patients with type 2 diabetes based on fasting blood glucose level and the result showed that, majority of patients (70.9 %) had poor glyceemic control (Kassahun, Abera, Solomon, 2016).

Another hospital based cross sectional study was conducted in Jimma Zone, located in South West Ethiopia, Limmu Genet Hospital from 01 February to 01 March 2017, to assess glycemic control and associated factors among 174 type 2 diabetic patients on chronic follow-up clinic and the result showed that, 63.8% of patients had poor glycemic control (Bodena Bayisa,2017).

Hospital-based cross sectional study was conducted on 412 type 2 diabetic patients who were attending diabetic clinics at Tikur Anbessa Specialized Hospital Addis Ababa, Ethiopia from March to April, 2015 to assess status and factors associated with glycemic control among type 2 diabetic patients and the result showed that, 80% of patients had poor glycemic control (Tekalegn Y, Addissie A, Kebede T, Ayele W, 2018).

Cross-sectional study was conducted from 01 February to May 30/ 2014, in Ambo General Hospital, west showa, Ethiopia, to investigate status of glycemic control and self-care practice among 111 Ambulatory diabetes patients and the study showed that 58.5% of the respondents had type 1 diabetes and the remaining 41.5% were type 2 DM with mean FBS of three consecutive month was 183.28 mg/d and only 23.4%, 34.2% and 28.8% of the respondents were able to control their FBS below 126 mg/dL during their first, second and third visit to the hospital respectively (Bodena Bayisa,2017).

A hospital-based cross-sectional study was conducted to assess the level of glycemic control and associated factors among 391 diabetic patients aged ≥ 18 years who visited the Diabetes Clinic in January and February 2013 for medical evaluation and medication at University of Gondar Referral Hospital were participated in the study and the result showed that, 64.7% had poor glycemic control (Solomon Mekonnen Abebe, Yemane Berhane,, Alemayehu Worku, Shitaye Alemu, Nebiyu Mesfin, 2015).

2.2. Associated Factors

2.2.1. World Wide

A cross-sectional study from medical records of all patients with diabetes were reviewed from 656 (54 with T1DM and 602 with T2DM), who were attending the Endocrinology Outpatient Units from Paracatu and Joao Pinheiro Cities, Brazil from June to December 2016, showed that factors associated with poor glycemic control were among T2DM patients, a lower education level, prolonged time since diabetes diagnosis, insulin treatment and less frequent follow-up with dietitians and endocrinologists and being females whereas most patients with T1DM were of normal weight, had less than 5 or from 10 to 20 years since the diagnosis of the disease and self-monitored blood glucose levels frequently (Débora Gonçalves, da Silva, Luiz, Alberto Simeoni, Angélica Amorim, 2018).

A cross sectional study was conducted to determine the predictors of poor glycemic control among 152 type two diabetes patients in Saudi Arabia, in Al-madinah, Diabetic center in 2013 showed that poor glycemic control was highest among males, aged 60 years and above, no formal education, not working, and those with monthly income between SR 1000 to 3000 and had significant association between family history of diabetes mellitus but there was no significant association between gender, age group, level of education, working status and monthly income (Andrew J.M. Boulton, David D'Alessio, Frank B, 2013).

In study done in Mombi, India, in 2018, 220 Type 2 DM patients having follow up for consultation were participated for the study to assess factors associated with poor glycemic control were among patients with Type 2 diabetes mellitus, showed that statistically significant association with BMI, central obesity, dyslipidemia and diabetes self-care practices (glucose management, dietary control) (Ipseeta R, 2017).

Another community based cross sectional study was conducted India, in 2014, and 165 type 2 diabetic patients was randomly selected from the institute to identify and address the role of Social Determinants in glyceimic control of type 2 diabetic patients and the result of the study showed that, literacy, duration of diabetes, married females, worries and lack of awareness were statistically highly significant association with poor glyceimic control but factors like occupation, BMI and income didn't show any statistically significant association with poor glyceimic control (Basaveshwara Medical College and Hospital, Chitradurga, April, 2014).

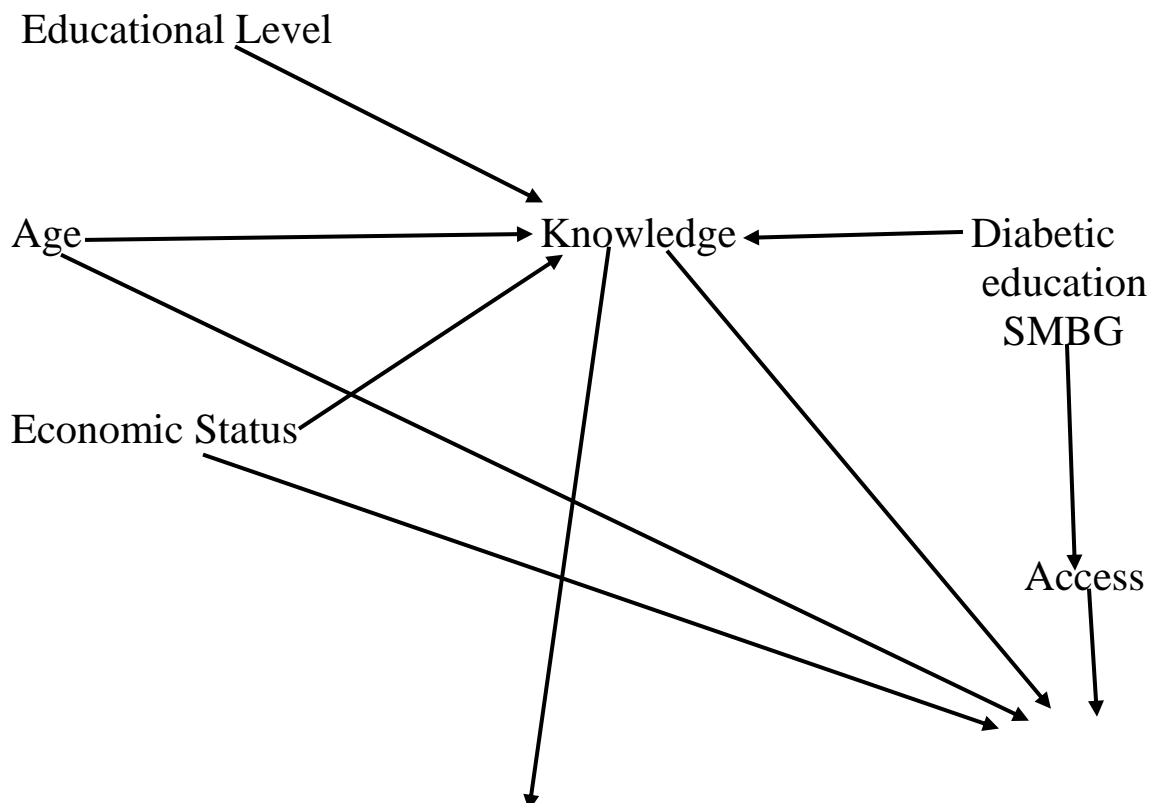
2.2.2. Study in Africa

A hospital-based cross sectional survey was conducted among 220 adult diabetic patients aged 18 years and above, who were attending the diabetic clinic at the Hohoe Municipal hospital, Ghana in May and June 2017, to assess Prevalence and associated factors of glyceimic control among diabetic adults and result of the study showed that, poor glyceimic control was significantly associated with age, occupation, and hypertension and defaulter rate. Those with high socioeconomic status were 5.55 times more likely to have good glyceimic control as compared to those with low socioeconomic status and civil servants were 84% times less likely to have good glyceimic control as compared to those who were unemployed (Fagbe J1,2, Bosoka S1, Opong J1, Takramah W1, Axame WK1, Owusu R1, et al, 2017).

339 adult patients were participated in a cross-sectional study conducted in the university clinic at Gadarif, Eastern Sudan to assess glyceimic control among adult patients with type 2 diabetes from February to August 2017 and the result of the study showed that, being single, adding sugar to drinks and high cholesterol level were associated with poor glyceimic control whereas duration of diabetes, medications used, and triglycerides were not associated with poor glyceimic control (Omar, Imad R. Musa, Osman E. Osman and Ishag Adam Omar et al, 2018).

A descriptive cross sectional study was done to determine factors associated with glyceimic control among 149 T2DM patients attending Mathari National and Referral Hospital Nairobi, Kenya, between 2015 and 2016 and the result of the study showed that, 37.6% with elevated Total Cholesterol and 60.4% having high LDL levels. 24% had moderately increased urine for albumin creatinine ratio while 11.4% had severely increased urine for albumin creatinine ratio. Gender, FBS and using drugs for other co-morbidities were associated with poor glyceimic control (Nduati NJ, Simon K, Eva N, Lawrence M, 2016).

2.2.3. Study in Ethiopia



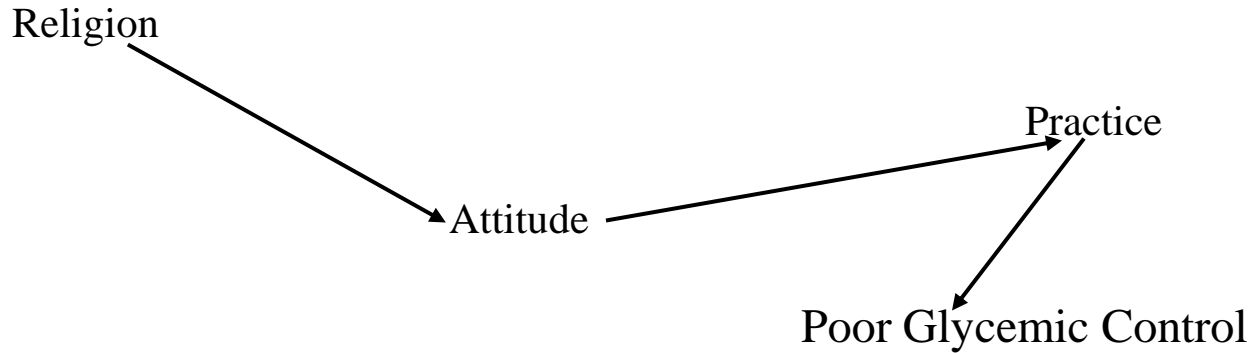


Figure1: conceptual framework showing factors affecting glycemic control

CHAPTER THREE

3. METHODS AND MATERIALS OF THE STUDY

3.1. Study Area and Period

The study will be conducted in Harar, one of the most popular historical cities in the Eastern part of Ethiopia, surrounded by the State of Oromia. The total numbers of kebeles of the city are 19, while the rural part of the State has 17 farmers associations. The State's size is estimated at 340 km². The Harari National Regional State (HNRS) is populated by 183,344 people (CSA 2007). The percentage share of males and females is about 50% each. The urban residents of the State were 99,321 while its rural inhabitants were 84,023. And the population of East Harargae is estimated about 3,000,000 according to East Harargae Health Breau.

Harar, the capital city of the HNRS is located 526 KM from the capital Addis Ababa. According to the current regional health bureau, there are two government Hospitals, Army Hospital, Federal Police Hospital, two private Hospitals, one non-government (Fistula) hospital, eight Health Centers, twenty nine private clinics, twenty six health posts and one regional laboratory serving the people of the state and Eastern Ethiopia.

Hiwot Fana Hospital is one of the two government Hospitals; its administration was totally taken by Haramaya University since 2003 E.C, hence got the name Hiwot Fana Specialized University Hospital. It serves as the Referral Hospital of the State and East Harage, thus expected to serve about 5.2 million catchment are population of the people of Eastern Ethiopia according to HFSUH. It has four main departments; Internal Medicine, Gynecology and Obstetrics, Surgery, and Pediatric with 33, 42, 50 and 60 beds respectively. The medical ward has female and male wing and intensive care unit. .

Data will be collected from December 16, 2019 to February16, 2020 and the study will be conducted from December 16, 2019 to March 16, 2020.

3.2. STUDY DESIGN

Hospital- based cross sectional study will be conducted on diabetic patients who are attending in diabetic follow up clinic.

3.3. Source population

All diabetic out patients visiting diabetic clinic at HFSUH

3.4. Study population

All randomly selected diabetic out patients visiting diabetic clinic at HFSUH

3.5. Study Subject

All diabetic patients having follow-up at adult outpatient diabetes clinic at HFSUH from December 16, 2019 to February16, 2020.

3.6. Inclusion and Exclusion Criteria

3.6.1. Inclusion Criteria

1. All diabetic patients having follow-up at HFSUH aged ≥ 18 years old in December 16, 2019 to February16, 2020 for control of blood sugar and medication.

3.6.2. Exclusion Criteria

1. Those who are critically ill and unable to participate in the interview
2. Those who are recently diagnosed and less than 3 months since diagnosis
3. Those who had no 3 consecutive follow-ups
4. Those who are currently pregnant

3.7. Sample Size

The sample size will be determined by using the following formulae

$$n = \frac{Z^2 P(1-P)}{W^2} \quad \text{and}$$

Where n= minimum sample size required

P= Proportion of population (prevalence rate), taken from a similar study done in Dessie Referral Hospital in Northeast Ethiopia, from January to April 2017, which was 70% (0.7) (Fiseha, et al,2018).

W=Margin of error expressed in proportion (0.05)

N_f =final sample

$$n = \frac{(1.96)^2 \times 0.7 \times (1-0.7)}{(0.05)^2} \quad n = 323$$

Adding 10% non-response rate to the above figure

$$N_f = \frac{323 \times 10}{100} = 32.3 \sim 32 \quad 323 + 32 = \mathbf{355}$$

3.8. Sampling Procedure and Sampling Technique

The diabetic adult outpatient follow-up clinic works three times per week throughout the year (12 months) and the months are selected by conventional method. There are a total of 879 diabetic patients having follow up at HFSUH and in every month about 450 patients visit the adult diabetic outpatient clinic. The two months follow-up schedule is chosen for data collection to avoid repetition of cases as patients revisit the clinic every 1-3 months. So the study subjects will be selected based on their card numbers (evens or odds) by systematic random sampling technique method who will have follow-up appointment on the months of December 16, 2019 to February 16, 2020 and the months are selected by using conventional method because having follow up in this period is also a chance.

3.9. Data Collection Methods

Data collection team will be comprised of two interns, two nurses and the investigator as an advisor who will also serve as supervisor and will be responsible in coordinating the overall process. Structured questionnaires will be prepared in English initially and will be translated to local language Amharic by a person who has good ability of both languages and will be back translated into English to be filled by the interns and nurses after written consent will be taken from all the subjects and will be interviewed by using pre-designed, pre-structured questionnaire and some of the required information will be obtained from the medical record charts which had basic information like patients' age, sex, type of diabetes, type of medication they are taking, level of FBS and duration of diabetes. Weight in kilogram and height in meter are measured at the time of interviewing and body mass index (BMI) is calculated in kilogram per meter square (kg/m^2). Pretesting of questionnaires will be done on similar but different population prior to the actual survey. Questions will be revised based on the feedback from the pretest. In the meantime, logistic arrangement and coordination of the data collection will be made by visiting the adult outpatient diabetes clinic. Data collectors will be trained. With the help of staffs working in the clinic, selected patients will be identified and informed about the purpose of the study and written consent will be ensured. The volunteering selected patients will then be briefed on the purpose of the study. The supervisor in the meantime should have to insure the data quality with close supervision of the data collection process.

4.0. Variables

Dependent Variable:

The dependent variables to be tested in this study is level of poor glycemetic control.

Independent Variables:

Age, sex, educational level, religion, and experience, type of diabetes, duration of diabetes, economical status are the main independent variables believed to affect the dependent variables.

4.0.1. Operational Definition

Glycemic control: For the purpose of this research, participants are classified in to two categories:

1. Good glycemic control: three months average fasting blood sugar of 80-130mg/dl which is taken from the chart recorded by physician or laboratory report.
2. Poor glycemic control: three months average fasting blood sugar of <80 and >130mg/dl which is taken from the chart recorded by physician or laboratory report.

Fasting blood sugar: Blood glucose measured from venous blood after 8 hours of overnight fasting or longer.

Adherence to medication: if the study participant took his/her anti diabetic medication as ordered by physician (dose, frequency, type of medication).

Adherence to diet: if the study participant had followed recommended diet for 3 or more days in the last 7 days or avoiding simple sugar totally.

Adherence to exercise: if the study participant had did exercise for 30 minutes for 3 or more days in the last 7 days or walk at least 3 days per week until they fell tired as an exercise or for work place.

Regular follow-up: a diabetic patient registered at diabetic follow-up clinic who attend their follow up program as scheduled by the hospital or physician.

Symptoms of hypoglycemia: diaphoresis, hunger, confusion, seizure, palpitations, irritability, headache...and symptoms of hyperglycemia are polyuria, polydipsia, weight loss, fatigue, weakness, blurring of vision, frequent superficial skin infections...information taken from the chart recorded by physician or laboratory report or by asking patients of symptoms with in the past 3 months.

Body mass index in kg/m²: Weight in kilogram, height in meter and Waist circumference in cm are measured at the time of interviewing and body mass index (BMI) is calculated in kilogram per meter square (kg/m²) and Normal if <25 and overweight & obese if ≥25 and Waist circumference in cm (normal for men <102 and female <88).

4.0.2. Data Quality Control

The data quality control will be ensured by better understanding of the questionnaires for the data collators during training and daily supervision. At least 10% filled questionnaires will be checked by the advisor every day and feedback will be given for data collectors accordingly for future correction.

4.0.3. Data Analysis

After completion of data collection, it will be edited and coded for processing and analysis and analyzed by using scientific calculator and SPSS statistical software version 20. Descriptive statistics, odds ratio and multivariate analysis with 95% confidence interval will be used to show associations between target variables, frequency tables and graphs will be used to show the results.

4.0.4. Ethical Consideration

Ethical clearance will be secured from the Ethical committee of Haramaya University College of health and medical sciences, Department of Community Health. Official permissions will be asked from HFSUH administration and outpatient director. Respondents will be informed well about the study, written voluntary and signed consent will be obtained by signing on the prepared consent sheet from each participant patient and will be included those who are willing to participate in this study. Information will be held confidential.

4.0.5. Expected Outcome

In this study majority of participants will have poor glycemic control and obesity, poor drug adherence, noncompliance to diet, inadequate exercise, not ever attend diabetic education, longer duration diabetes, not having follow up regularly and those who no self-monitoring of their blood glucose level will be factors associated with poor glycemic control.

4.0.6. Information Dissemination

The research result will be distributed for the regional health bureau, the hospital, physicians, policy makers and other stake holders in the form of guideline or reference after publication in order to use it for proper management and reducing associated factors contributing to poor glycemic control.

4.0.6. Limitation of the study

The limitation of the study will be the use of FBS over HbA1c since a standardized method for measuring HbA1c was not available, thus possibly leading to underestimation of the prevalence of poor glycemic control which also will affect the result of study. Even though, it will lead to underestimation of the prevalence of poor glycemic control, FBS will also use to conduct this research in this hospital since there is no HbA1c service, because the research will give highlight on the status of glycemic control and associated factors in Eastern parts of Ethiopia since there is no previous study.

CHAPTER FOUR

4.1. Work Plan

The anticipated activities/tasks, duration/time require to accomplish each task, and personnel required (PDs) for performing the research dissemination and utilizations of results are presented

in Table 1 below. The work plan comprises of four phases, each with distinctive tasks and duration of accomplishment as follows:

- Phase I: Research Proposal (RP) Preparation phase having different steps;
- Phase II: Research Proposal approval phase;
- Phase III: Data collection and analysis;
- Phase IV: Research report preparation, submission and dissemination of research

Table 1: Research Work Plan Table

No.	Tasks to be performed	Duration/ Dates	Persons Assigned to activities	No of Persons	Required person Days	Total Person Days(PDs)
1 Research Proposal Preparation(RPP) (Phase I)						
1.1	Preliminary information gathering & advisory for RP	Oct1-5/2019	Investigator	1	3	3
			Research advisor	1	1	1
1.2	RP Draft submission for comments	Oct6-30/2019	Investigator	1	2	2
			Research advisor	1	2	2
1.3	Inclusion of comments in RP	Nov1-10/2019	Investigator	1	2	2
			Research advisor	1	1	1
1.4	Complete Rsubmission	Nov11-20/2019	Investigator	1	3	3
2.RPP Approval/Phase II						
2.1	Funding	Nov20-30,2019	Investigator	1	3	3
			Research advisor	1	3	3
2.2	Ethical Approval from local authorities	Dec1-10/2019				
2.3	Visiting clinic for communication & arrangement	Dec11/2019	Investigator & data collector team	5	2	10
			Research advisor	1	2	2
3.Data collection and Analysis (Phase II)						
3.1	Training & Orientation on data collection	Dec12/2019	Data collector team	5	5	25
			Research advisor	1	2	2
3.2	Logistic Arrangement for data collection	Dec13-15/2019	Investigator	1	2	2
			Research advisor	1	2	2
3.3	Data Collection	Dec16-Feb 16/2020	Data Collector team	5	60	300
			Research advisor	1	60	60
3.4	Data entry & editing	Feb17-20/2020	Investigator	1	15	15
			Research advisor	1	15	15
3.5	Data & checking analysis	Feb21-25/2020	Investigator	1	15	15
			Researcadvisor	1	15	15
4.Report Preparation & submission (phase IV)						
4.1	Preliminary report Preparation&submission	Feb26-30/2020	Investigator	1	5	5
			Research advisor	1	2	2
4.2	Final Report completion	Mar1-5 /2020	Investigator	1	5	5
			Research advisor	1	2	2

4.3	Defense	Mar6-8 /2020	Investigator	1	1	1
			Research advisor	1	1	1
4.4	FinalReportSubmission	Mar9-12 /2020	Investigator	1	4	4
			Research advisor	1	4	4
4.5	FinalReportPublishing & Dissemination	Mar13-16 / 2020	Investigator	1	15	15
			Research advisor	1	15	15

4.1. Budget

To accomplish the envisaged research as planned, the necessary human power, materials, supplies, equipment & necessary logistics with respective budget are key requirement to be fulfilled. In line with the above work plan, detailed budget break down for all tasks are prepared accordingly and total budget is estimated 25,000 ETB which is funded by Haramaya University College of health and medical sciences, see details in Table 2 below.

Table 2: Research Budget Estimate in Ethiopian Birr

No	Major activities to be performed	Persons Assigned to tasks	No of Persons	Days Required	Cost Per Unit PDs(Birr)	Total cost for Total PDs (Birr)
1	Preparation of RP (Phase I)	Investigator	1	20	50	1,000
		Research advisor	1	10	50	500
		Sub Total	2	30		1,500
2	RP Approval (Phase II)	Investigator	1	5	50	250
		Research advisor	1	5	50	250
		Sub Total	2	10		500
3	Data collection & Analysis (Phase III)	Investigator	1	60	100	6,000
		Research advisor	1	60	100	6,000
		Sub Total	2	60		12,000
4	Report Preparation & submission (Phase IV)	Investigator	1	30	100	3,000

		Research advisor	1	30	100	3,000	
Sub Total			2	60		6,000	
Total Personnel cost						20,000	
No	Transport Cost						
	Vehicles for Activities	Types of vehicles	Unit	Quantity /No	No of days	Cos / day	No .Veh X days x Cost/day
1	Vehicles for data collectors	4 wheel car with driver , fuel &all cost	No	1	2	50	100
2	Vehicle for advisor	DX with all costs	“	1	2	50	100
	TransportCost /Subtotal			2			200

Table 2: Research Budget Estimate in Ethiopian Birr Continued

No	Equipment & Supplies	Descriptions	Unit	Quantity	Costs per item	Total Costs
1	Questionnaire	For duplication	No	400	0.5	200
2	Clip board	For Training	“	4	5	20
3	Flip chart paper	For Training & data collectors	“	5	5	25
4	Pen	“ ” “ “	“	5	5	25
5	Pencil	“ ” “ “	“	10	2	20
6	Eraser	“ ” “ “	“	10	2	20
7	Sharpener	“ ” “ “	“	5	5	25
8	Mobile Card	“ ” “ “	Lum sum	1	50	50
9	Marker	“ ” “ “	“	5	5	25
10	Printing paper	“ ” “ “	Pack	10	40	400
11	Photo copying	“ ” “ “	Lum sum	250	1	250
12	Printing	“ ” “ “	Lum sum	100	1	100
13	Binding	“ “ “		10	20	200
Equipment and Supplies Total						1,360
3	Training					
	Training items	Descriptions	Unit	Participants	Cost per item	Total costs

	Hall rent	For WS & data collection	1	12	200	200
	Tea/Coffee/Cookies	“ ” “	15	12	10	150
	Mineral Water	“ ” “	15	12	6	90
For Training Total						440
4	Subtotal Cost					22,000
	Supervision fee					3,000
	Grand Total Research Cost					25,000

The source of budget, Haramaya University college of Health and Medical Sciences.

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Annex1: 5.1. PARTICIPANT INFORMATION SHEET AND INFORMED VOLUNTARY CONSENT FORM FOR PARTICIPANTS (AGE ≥18 YEARS)

My name is _____ I am working as a data collector for the the stud being conducted in HFSUH diabetic outpatient clinic by Dr. Mamaru Tadesse who is studying for his Internal medicine Specialty Certificate program at Haramaya University, College of Health and Medical Sciences. I kindly request you to lend me your attention to explain you about the study and being selected as the participant.

1. The study title:

Status of glycemic control and factors associated with poor glycemic control among diabetic adult out-patients at Hiwot Fana Specialized University Hospital, Harar, Eastern Ethiopia.

2. Purpose/aim of study:

The finding of this study can be a paramount importance for all diabetic patients (current and future) as findings will be used to formulate strategies to improve the quality of care, minimizing identified factors of poor glycaemic control, prevent or delay diabetic related complications and minimize resources which are vested for treatment of complications. In addition, recommendations will be made to the National Non-communicable Disease Control Programme (NNCDPC) on how to tightly control blood glucose level, status of glycaemic control, decrease associated factors and increase compliance will help to improve glycaemic control in this area. The study will also benefit the country, the region, and the hospital as well in planning and allocating both human and financial limited resources as findings may be used to formulate strategies to improve the quality of diabetes care and delay or decreased diabetes related complications. Moreover, the aim of this study is to write a thesis as a partial requirement for the fulfilment of Internal medicine Specialty Certificate program for the principal investigator.

3. Procedure and duration:

I will be interviewing you using a questionnaire to provide me with a pertinent data that is helpful for the study. There are 26 questions to answer and 3 check list questions from your chart where I will fill the questionnaire by interviewing you and referring your chart. The interview will take about 10 minutes, so I kindly request you to spare me this time for the interview.

4. Risks and benefits

Being participating in this study will have minimal risk, but only taking few minutes from your time. There would not be any direct payment for participating in this study. But the findings from this research may reveal important information for the local health planners.

5. Confidentiality

The information you will provide us will be confidential. There will be no information that will identify you in particular. The findings of the study will be general for the study community and will not reflect anything particular of individual persons or housing. The questionnaire will be coded to exclude showing names. No reference will be made in oral or written reports that could link participants to the research.

6. Rights

Participation for this study is fully voluntary. You have the right to declare to participate or not in this study. If you decide to participate, you have the right to withdraw from the study at any time and this will not label you for any loss of benefits which you otherwise are entitled. You do not have to answer any question that you do not want to answer.

7. Contact address

If there are any questions or enquires any time about the study or the procedures, please contact: +251- 911855750 at mobile phone, email drmamaru@gmail.com; as well as contact Institutional Health Research Ethics Review Committee (IHRERC) at office phone 025-4662011 or P.O.Box 235, Harar,Ethiopia

8. Declaration of informed voluntary consentI have read /was read to me the participant information sheet. I have clearly understand the purpose of the research, the procedures, the risks and benefits, issues of confidentiality, the

rights participating and the and the contact address for any queries. I have been given the opportunity to ask questions for things that may have been unclear. I was informed that I have the right to withdraw from the study at any time or not to answer any question that I do not want. Therefore, I declare my voluntary consent to participate in this study with my initials (signature).

Name and signature of participant: _____ Date _____

Name and signature of Data Collector: _____ Date _____

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Being participating in this study will have minimal risk, but only taking few minutes from patient time. There would not be any direct payment for participating in this study. But the findings from this research may reveal important information for the hospital and regional bureau.

5. Confidentiality

There will be no information that will identify the participants in particular. The findings of the study will be general for the study community and will not reflect anything particular of individual persons. The questionnaire will be coded to exclude showing names. No reference will made in oral or written reports that could link participants to the research.

6. Rights

Participation for this study is fully voluntary. The participant have the right to declare to participate or not in this study .If they decide to participate, they have the right to withdraw from the study at any time and this will not label them for any loss of benefits which they otherwise are entitled. They do not have to answer any question that you do not want to answer.

7. Contact address

If there are any questions or enquires any time about the study or the procedures, please contact: +251- 911855750 at mobile phone, email drmamaru@gmail.com; as well as contact Institutional Health Research Ethics Review Committee (IHRERC) at office phone 025-4662011 or P.O.Box 235, Harar,Ethiopia

8. Declaration of informed voluntary consent

I have read the participant information sheet. I have clearly understand the purpose of the research, the procedures, the risks and benefits, issues of confidentiality, the rights participating and the and the contact address for any queries. I have been given the opportunity to ask questions for things that may have been unclear. I was informed that the participants have the right to withdraw from the study at any time or not to answer any question that they do not want. I am also informed that the Hospital has the right to stop this study from being conducted if any misdeeds and unethical procedures are observed during data collection process in the Hospital's premises. Therefore, I declare my voluntary consent to behalf of HFSUH management to allow this study to be conducted in this Hospital with my initials (signature).

Name and signature of Head of the Hospital: _____ Date _____

Name and signature of Data Collector: _____ Date _____

7. Curriculum Vitae

Name: Dr. Mamaru Tadesse

Sex: Male

Marital status: married

Nationality: Ethiopian

Date of birth: 1986 G.C

Contact Address

- Physical address: Harar
- Phone Number:0911855750
- Email: drmamaru@gmail.com

Educational background

- August 2001: Certificate of high school completion
- August 2003: Ethiopian higher education entrance qualification certificate
- September2006:BSC degree in dentistry from **ADDIS ABABA UNIVERSITY**
- 2015: Degree of Doctor of Medicine from **ADDIS ABABA UNIVERSITY TIKUR ANBESA SPECIALIZED HOSPITAL**

Training taken, Honors and Awards

- Certificate of basic ART training
- ART TOT training
- HTN & DM TOT training

Experience

- 3 year experience working as a BSC DENTIST at Hiwot FANA hospital and Zemen Dental clinic
- 5 year experience working as a BSC dentist at Yeabsira dental clinic: Addis Ababa
- One year experience working as a General practitioner and lecturer at HFSUH,Harar
- Currently final year Internal Medicine Resident

Languages spoken and Ability

1. English: excellent
2. Amharic: excellent
3. Oromifa:Fair

Reference

- 1, Professor Adem Ali, cardiothoracic surgeon
- 2, professor Yewoinhareg, endocrinologist
- 3, Professor Amha Mekasha, pediatric cardiologist
4. Dr.Wondwosen Fantaye Assistant Professor of Dentistry
5. Dr.obsie Temesgen, assistant professor of internal medicine, MD, internist
6. Dr.Guta Driba,assistant professor of internal medicine,MD,internist,MPH

ASSURANCE OF PRINCIPAL INVESTIGATORS

We the undersigned agree to accept all responsibilities for the scientific and ethical conduct of the research project. I will provide timely progress report to my advisor and seek the necessary advice and approval from my primary advisors in the course of the research. I will communicate timely to my advisors all stakeholders involved in the study including any source of funding for this research.

Name of the students: _____

Signature: _____

Date: _____

Approval of the Advisor

Name of the advisor:_____

Signature: _____

Date: _____

Approval sheet

**HARAMAYA UNIVERSITY
POST GRADUATE PROGRAM DIRECTORATE**

Submitted by:

Name of Student

Signature

Date

Approved by:

1. _____

Name of Major Advisor

Signature

Date

2. _____

Name of Co-Advisors

Signature

Date

