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Glycemic control and associated factors among outpatients with Type 2 Diabetes at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia.

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This is to certify that the thesis prepared by Rodas Getachew, entitled:

"**Glycemic control and associated factors among outpatients with Type 2 Diabetes at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia**" and submitted in partial fulfillment of the requirements for Master of Science Degree in Clinical Laboratory Sciences (Clinical Chemistry) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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List of abbreviations and acronyms

ADA	American Diabetic Association
BMI	Body Mass Index
CVD	Cardiovascular Disease
DCCT	Diabetes Control and Complications Trial
DM	Diabetes Mellitus
ETB	Ethiopian Birr
FBS	Fasting Blood Sugar
HbA1c	Hemoglobin A1c (Glycated hemoglobin)
IDF	International Diabetes Federation
IFCC	International Federation of Clinical Chemistry & Lab. Medicine
IQR	Interquartile Range
NGSP	National Glycohemoglobin Standardization Program
OGTT	Oral Glucose Tolerance Test
RBS	Random Blood Sugar
SPSS	Statistical Package for Social Sciences
TASH	Tikur Anbessa Specialized Hospital
T2DM	Type 2 Diabetic Mellitus
WHO	World Health Organization

Abstract

Background: The goals of glycemic management for patients with diabetes are to prevent or delay complications and optimize the quality of life. However, in clinical practice, the recommended glycemic control target is very difficult to achieve. It is important, therefore, to identify factors that influence the outcomes of glycemia to improve the quality of diabetic management.

Objectives: This study aimed to assess the level of glycemic control & identify the underlying factors associated with inadequate & poor glycemic control among type 2 diabetic outpatients at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia.

Methods: Hospital-based prospective, cross-sectional study was conducted among systematically selected 325 patients with type 2 diabetes who were attending diabetic clinics at Tikur Anbessa Specialized Hospital. Pretested, structured, interviewer-administered questionnaires were used to collect sociodemographic & diabetes-related information on participants between March and May 2021. HbA1c was used to assess glycemic control according to the HbA1c target of <7% ('good' control) as recommended by the American Diabetes Association for non-pregnant adults. The HbA1c level in the range of 7-8% was defined as an 'inadequate' control & as 'poor' at levels >8%. Data entry and analysis were performed using SPSS v26. Multivariate logistic regression analysis was used to identify determinants of glycemic control.

Result: The median level of HbA1c of the participants was 8.4% (IQR 6.8-10.1) and approximately three-quarters (73.8%) of the patients had inadequate & poor glycemic control (HbA1c ≥7%). Older age (AOR: 2.46, 95% CI: 1.28-6.01), DM duration of >10 years (AOR: 3.15, 95% CI: 2.22-6.54), insulin therapy (AOR: 3.07, 95% CI: 2.10-6.12), poor diet compliance (AOR: 1.97, 95% CI: 1.28-3.52) and failure to set targets for glycemic control (AOR: 3.42, 95% CI: 2.17-5.97) were factors associated with inadequate & poor glycemic control.

Conclusion: The study revealed that a considerable number of diabetic patients had inadequate and poor glycemic control levels. And this had been found to be associated with older age, longer duration of DM, insulin therapy, poor diet compliance, and failure to set control targets.

Keywords: glucose control, diabetes mellitus**,** HbA1c, glycosylated hemoglobin, TASH

1. INTRODUCTION

1.1. Background

Diabetes mellitus (DM) is one of the major global health challenges of the 21st century. It is a metabolic disease characterized by chronic hyperglycemia caused by multiple etiologies including defects in insulin secretion, action, or both [1]. One of the commonest non-communicable chronic-degenerative diseases and it is estimated that between 5 - 10% of the population suffer from this disease. Approximately 463 million adults (20-79 years) lived with diabetes worldwide in 2019 and about 4.2 million deaths were directly attributed to it [2, 3].

Type 2 DM is the most common form of DM, accounts for (~90% of patients) and the remaining 10% are type 1 diabetes or gestational diabetes. The prevalence of diabetes is rapidly increasing around the world, posing a severe economic burden on patients and society at large [4]. Diabetes reduces life expectancy by 5 to 10 years. Premature cardiovascular disease is the most common cause of mortality [5].

Historically, diabetes was considered a disease confined to developed countries and affluent people. However, recent reports show that the prevalence of diabetes is rising globally, particularly in developing countries [6]. The vast majority (80%) of people with diabetes live in low- and middle-income countries. According to the International Diabetes Federation (IDF), an estimated 19.4 million adults aged 20-79 years were living with diabetes in the IDF Africa Region in 2019, representing a regional prevalence of 3.9%. Africa is the region with the highest proportion of undiagnosed diabetes, with 60% of adults currently living with diabetes unaware of their condition. The report also stated that Ethiopia is one of Africa's most populous countries with the highest number of people with diabetes (~1.7 million) with a prevalence rate of 3.2% among adults [7].

Many prior studies have assessed glycemic control levels among type 2 diabetes patients in Ethiopia and reported a wide range of values. Cross-sectional studies conducted in hospitals in different parts of the country reported a poor prevalence of glycemic control ranging from 45.2 to 73.5% [8-16]. And this has been said to be associated mainly with factors such as older age, longer duration of diabetes, insulin therapy, nonadherence to medications, poor diet adherence, and physical inactivity.

1.2. Statement of the problem

Although most of the factors associated with glycemic control have been discussed in the previous studies, modifiable risk factors like setting targets for glycemic control and the overall approach and engagement of health care providers, particularly physicians, with patients which are crucial for attaining good glycemic control were not fully investigated in the previous studies.

And data on laboratory findings of patients were obtained from medical records in most of the studies conducted previously in Ethiopia. This may be subjected to documentation errors and may not provide complete and reliable information.

Furthermore, most of the studies established to evaluate the glycemic control status among patients with type 2 diabetes mellitus (T2DM) in Ethiopia were based solely on fasting blood glucose level (FBG). The use of FBG over HbA1c, which is more accurate than the measurement of FBG to evaluate glycemic control, may not correctly represent the status of glycemic control of patients. FBG levels provide a short-term picture of control, while HbA1c is the most reliable indicator of long-term glycemic control because it accurately reflects an individual's blood glucose levels over the preceding 2-3 months. The non-use of the HbA1c test in the previous studies was described as a limitation and the need for further study using the HbA1c test was implied in several studies [17-23], by the respective investigators.

Very few studies have managed to use the HbA1c test for assessing glycemic control in diabetic patients in Ethiopia and the potential limiting factors that could interfere with the HbA1c test were not taken into account in the investigations. Therefore, aiming to fill the existing gaps and provide reliable objective information on the magnitude of glycemic control, for the provision of standard care for patients, the present study sought to assess the level of glycemic control and underlying factors associated with inadequate & poor glycemic control among outpatients with T2DM using National Glycohaemoglobin Standardization Program-certified (NGSP) and Diabetes Control & Complications Trial-standardized (DCCT) HbA1c technique at a tertiary healthcare setting in Ethiopia.

1.3. Significance of the study

The findings of this study, as primary beneficiaries, will enable the study participants to know their average blood sugar level during the preceding 2-3 months and guide them to act accordingly.

In a broader and more inclusive aspect, for the provision of standard care to patients objective and reliable information is needed on the magnitude of glycemic control. And this study could be an asset in providing reliable information and could serve as a stepping stone for other related studies that may follow in the future.

Furthermore, the study could help identify factors that influence glycemic outcomes to improve the quality of diabetic management.

Finally, since Tikur Anbessa Specialized Hospital (TASH) serves as a national diabetic referral hospital, receiving patients from different parts of the country, it provides a good representation of the diabetic patient population. Therefore, the findings of the study could be inferred to the general type 2 diabetic population in Ethiopia.

2. LITERATURE REVIEW

2.1. Glycemic control

2.1.1. Glycemic control using blood glucose measurement

For decades, the diagnosis of diabetes was based on plasma glucose criteria, either the FBG or a 2-hr value in the 75-g oral glucose tolerance test (OGTT). The special requirements for the OGTT, fasting, and 2-hr postprandial plasma glucose, limit the clinical application of these methods. However, these traditional glucose measurement methods are still very important and are widely used in conjunction with other relatively newer tests such as HbA1c.

The status of glucose control and associated factors among patients with T2DM were assessed in a cross-sectional study conducted in India. The test results revealed greater than or equal to 4 years duration of diabetes, overweight/obesity, smoking, a poor diet, and nonadherence to medications as significant predictors of poor glycemic control. The authors suggested that an emphasis on promoting a healthy lifestyle that includes a healthy diet plan, smoking cessation, maintaining optimal body weight, and strictly adhering to prescribed medications would go a long way to maintaining good glycemic control [17].

Similarly, a facility-based cross-sectional study looked for factors associated with glycemic control among adult patients with T2DM in Southwest Ethiopia in 2014. A low level of education, employment, combinations of insulin and oral medications, and lower adherence to medications were likely to have poor glycemic control. The author concluded that education and awareness creation could be a cross-cutting intervention for significant factors [18].

Another cross-sectional study conducted in Ethiopia assessed the achievement of diabetes care goals. The three treatment goals namely glycemic control, lipid profile, and blood pressure control were achieved only in 3.6% of patients. The absence of standardized monitoring tools, the inconsistent patient-doctor relationship & follow-up by residents of internal medicine with little supervision were listed as factors responsible for the lower rate of achievement of the diabetes care goal [19].

2.1.2. Glycemic control using glycated hemoglobin (HbA1c) testing

Glycemic control measured by glycated hemoglobin (HbA1c) is one of the widely used clinical indicators of the quality of diabetic care. The American Diabetes Association (ADA) has

determined that HbA1c is the best measure of glycemic control, with a level lower than 7% as a goal of optimal blood glucose to prevent complications and reduce the overall cost of disease management. The HbA1c test reveals how close normal glycemic control has been maintained during the last three months. This information helps a physician assess how well a person responds to diabetes treatment and determine how long sugar levels have been high in a person newly diagnosed with diabetes.

Controlled clinical trials provide ample evidence that glycemic control is essential in reducing microvascular complications in diabetes patients. Measurement of HbA1c is the gold standard for following long-term glycemic control for the previous 3 months. Hemoglobinopathies, anemias (iron deficiency, hemolytic), and defects in the red cell membrane can affect HbA1c measurements. Other strategies, such as fructosamine measurements, which measure glycated plasma protein and correlate with glucose control in the last 2 to 3 weeks, may be necessary to assess diabetes control in these patients.

T2DM is an insidiously progressive disease. Gradually decreasing insulin secretion leads to a slow increase in hyperglycemia and an increase in HbA1c values, often vigorous clinical attempts to maintain control. Controlling blood sugar in the early years is often straightforward but becomes increasingly difficult with the progression of comorbid disease, so the appropriate need for tablets and insulin needs continued consideration. All patients with T2DM must manage their glycemic control by adhering to healthy eating, medication, and exercise in an attempt to reduce weight. This is very important. And the measurement of HbA1c can greatly help to track their progress in lifestyle and the need to adjust treatment.

Glycemic control among adult T2DM patients was assessed in a cross-sectional study conducted in Sudan. The rate of poor glycemic control was 71.9%. Unmarriedness, sugary beverages added, and high cholesterol levels were associated with poor glycemic control [20].

Another cross-sectional study assessed glycemic control and behaviors among Libyans with T2DM. Females, patients with insulin and oral hypoglycemic agents, patients with insulin and low-medication adherents were reported to be more likely to have uncontrolled and poor glycemic control, while exercise contributed to glycemic control status as a protective factor [21].

Similarly, a cross-sectional study conducted in Jimma University Specialized Hospital, Ethiopia also showed poor glycemic control though all patients were on diabetes treatment [9]. Another related study in the same hospital, Jimma University Medical Center, conducted among systematically selected adult ambulatory DM patients showed that poor glycemic control was associated with age in Type 1 diabetic patients. In Type 2 diabetics, the prevalence of poor control was significantly higher among hypertensive, female subjects with a longer duration of diabetes. The author suggested diabetes treatment at the clinic needs to be improved with more intensive management alternatives to the vulnerable groups [22].

2.2. HbA1c turbidimetric immunoinhibition method

The fully automated Beckman Coulter DxC 700 AU analyzer's HbA1c Advanced assay enables mid-to high-volume laboratories to provide physicians with state-of-the-art precision and accuracy for diagnosing diabetes mellitus, monitoring long-term glucose control in individuals with diabetes mellitus, and identifying patients who may be at risk of developing diabetes mellitus. It is National Glycohemoglobin Standardization Program-certified (NGSP) and Diabetes Control and Complications Trial-standardized (DCCT) and precise, providing clinically relevant results for diagnosing and monitoring diabetes. It is also unaffected by common hemoglobin variants, minimizing misdiagnosis or missed diagnosis for patients with these blood conditions [23].

HbA1c is measured in a latex agglutination inhibition assay. An agglutinator, consisting of a synthetic polymer containing multiple copies of the immunoreactive portion of HbA1c, causes agglutination of latex coated with HbA1c specific mouse monoclonal antibodies. In the absence of HbA1c in the sample, the antibody-coated microparticles in the HbA1c R1 and the agglutinator in the HbA1c R2 will agglutinate. Agglutination leads to an increase in the absorbance of the suspension. The presence of HbA1c in the sample results in a decrease in the rate of agglutination of HbA1c R1 and the agglutinator in the HbA1 reagent R2. The increase in absorbance is, therefore, inversely proportional to the concentration of HbA1c in the sample. The increase in absorbance is measured at 700nm.

2.3. Standardization of HbA1c method

Standardizing HbA1c results to the standardized values of the Diabetes Control and Complications Trial (DCCT) would allow individual clinical laboratories to provide diabetic patients and their healthcare providers with test results that could be directly related to both mean blood glucose

values and risks of the development and/or progression of chronic diabetes complications. Early efforts to standardize glycated hemoglobin values among clinical laboratories by using a "universal calibrator" proved feasible with some assay methods. Later studies showed, however, that such an approach, although relatively simple, did not work for many existing methods. It was found that materials prepared for use as calibrators, quality control materials, and proficiency-testing samples are often subjected to preparative processes that may cause them to yield results that differ appreciably from those of patient specimens, i.e., matrix effects. Therefore, since an important goal was to allow standardization of most existing and future assay methods, it was proposed that, for most assay methods, standardization to the DCCT reference could be performed best at the manufacturing level, where the most appropriate materials and standardization format for each method could be determined. It was also proposed that the verification of method standardization should be based on fresh sample comparisons with the DCCT reference method [24].

The International Federation of Clinical Chemistry Working Group (IFCC-WG) on HbA1c standardization has developed reference methods for HbA1c analysis. They have established a laboratory network, which includes two reference methods, mass spectroscopy, and capillary electrophoresis. Each network laboratory uses prepared mixtures of purified hemoglobin A1c and HbA0 as calibrators. The relationship between the HbA1c results of the NGSP network (%HbA1c) and the IFCC network (mmol/mol) has been evaluated and a master equation has been developed **(NGSP = [0.09148 * IFCC] + 2.152)**.

2.4. Factors affecting glycemic control

In clinical practice, the recommended glycemic control target is very difficult to achieve. It is important, therefore, to identify factors that influence the outcomes of glycemia to improve the quality of diabetic management. Various factors could influence glycemic control. Both patient and health care provider-related factors may contribute to good and poor glycemic control. To better understand these factors, they could be categorized into sociodemographic, clinical, and behavioral factors.

2.4.1. Sociodemographic factors

Sociodemographic factors: such as age, gender, marital status, educational level, occupation, monthly income, residence, and other related factors are often tested for statistical significance and

association with glycemic control. Most of the time there would be important associations, but there are also times where no associations are reported. In a population-based study, Veghari et al searched for an association between socio-demographic factors and DM patients in the north of Iran and found associations concerning gender, age, and residence. Where the prevalence of DM was higher in women, the elderly, and urban areas. The author continued to say that DM was influenced by sociodemographic factors [25]. In another study, female gender and lack of formal education were found significantly associated with increased odds of poor glycemic control [26]. On the contrary, a study investigating factors affecting glycemic control among Type II Diabetics attending Machakos Level Five Hospital in Kenya found no association between socio-demographic factors and glycemic control levels [27].

2.4.2. Clinical factors

In clinical practice, normal glycemia is difficult to obtain long-term due to the complexity of glycemic control in T2DM. It is important, therefore, to have a clear understanding of clinical factors (duration of diabetes, family history of diabetes, body mass index, type of antidiabetic medication, comorbidities, biochemical values, etc.) that are affecting glycemic control in diabetic patients. And many researchers have looked into these factors and reported important associations concerning glycemic control. A study conducted in western Ethiopia among diabetic patients found that the duration of diabetes >8years and the presence of diabetes complications were predictors of poor glycemic control [28]. Many other studies also had the same result with respect to the longer duration of diabetes [29-32]. Sisodia et al, investigated for any association between BMI and glycemic control among T2DM patients. And statistical analysis showed a strong positive correlation between BMI and poor glycemic control (HbA1c) [33]. Regarding the drug regimen, the use of oral anti-diabetic drugs in combination with insulin was reported to have a twice greater chance of poor glycemic control than the use of oral anti-diabetic drug alone [20].

2.4.3. Behavioral factors

Behavioral factors such as adherence to medications, adherence to diet, physical exercise, alcohol consumption, smoking, self-monitoring of blood glucose, keeping up with follow-up visits, setting glycemic target goals, etc. are important factors influencing the nature of glycemic control depending on the approaches taken by patients. Many studies have addressed the factors associated with diabetes. Knowledgeable patients towards diabetes or those with greater confidence in the

ability to manage self-care behaviors had been shown to have lower HbA1c values [34]. Mean HbA1c values were compared with DM patients in the absence and presence of regular physical exercise and decreased values were reported with regular physical exercise [10]. Which was due to the effect of regular physical exercise on insulin production and metabolism of the available glucose. Another study showed that diabetic patients who adhered well to diet were 2.4 times more likely to have good glycemic control compared to those who adhered poorly to diet [14].

In conclusion, diabetes is on the rise globally and this poses a significant financial burden on the individual, the healthcare system, and the country's economy. From the literature review, various socio-demographic, clinical, and behavioral factors influence glycemic control. There is conflicting information on the effect of different factors on diabetes control depending on the study method, design, population, and sample size. Therefore, it is necessary to study in TASH using the NGSP-certified HbA1c assay to clearly understand the glycemic control status of the patients and the associated factors that affect glycemic control.

2.5. Conceptual framework

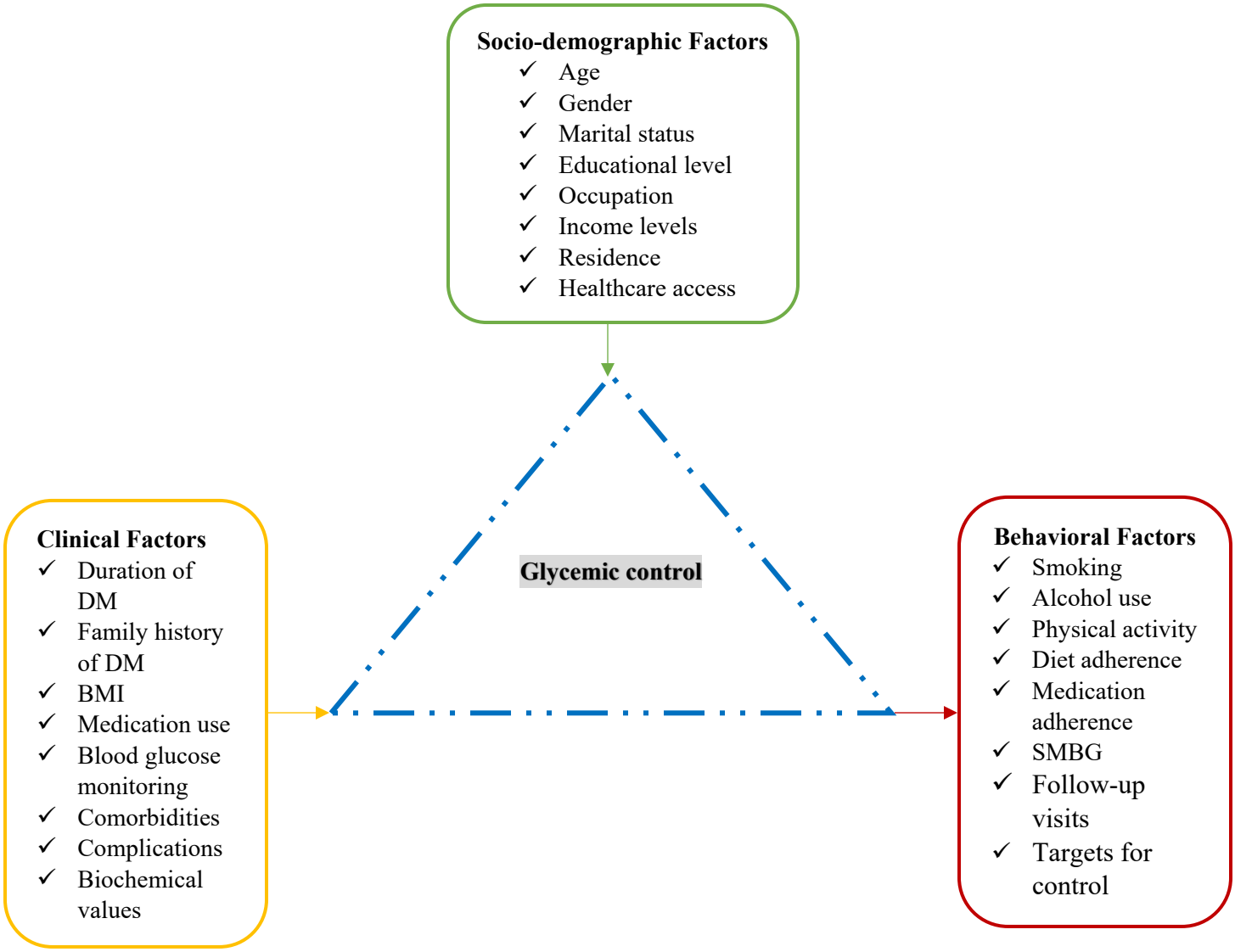

Figure 1. Conceptual framework showing factors affecting glycemic control

3. OBJECTIVES

3.1. General objective

- To assess the level of glycemic control and associated factors among type 2 diabetic outpatients attending the TASH diabetic clinic, Addis Ababa, Ethiopia; between March and May 2021.

3.2. Specific objectives

- To determine the magnitude of good, inadequate and poor glycemic control levels among patients with T2DM at TASH, Addis Ababa, Ethiopia; between March and May 2021.

- To identify the underlying factors associated with inadequate and poor glycemic control among patients with T2DM at TASH, Addis Ababa, Ethiopia; between March and May 2021.

4. MATERIALS AND METHODS

4.1. Study area

The study was carried out in the outpatient medical diabetes clinic of the Tikur Anbessa Specialized Hospital, which is one of the busiest and largest public referral hospitals in the country located in Addis Ababa. The hospital has a bed capacity of 800 and offers diagnosis and treatment for over 500,000 patients a year. The endocrinology unit at the hospital has two clinics visit schedules and provides comprehensive diabetes care to around 800 to 1000 diabetic outpatients a month [32].

Study design and period

A hospital-based prospective cross-sectional study was used. And the study was conducted for 3 months between March and May 2021.

4.2. Population

4.2.1. Source population

All T2DM diabetic patients who attended the medical outpatient diabetic clinic of TASH were considered the source population.

4.2.2. Study population

Patients with T2DM who attended the outpatient medical clinic during the study period and who met the inclusion criteria were taken as the study population.

4.3. Inclusion and exclusion criteria

4.3.1. Inclusion criteria

- Ambulatory patients diagnosed with T2DM
- Duration of follow-up of at least 1 year
- Willingness to participate in the study

4.3.2. Exclusion criteria

- Anemia of any cause, patients receiving erythropoietin or blood transfusion & subjects with conditions that affect erythrocyte production.
- Pregnant women
- Other Types of DM

4.4. Study variables

4.4.1. Dependent variable

- Glycemic control (measured by HbA1c)

4.4.2. Independent variables

- Sociodemographic factors: age, gender, marital status, educational level, occupation, monthly income, residence, healthcare access.
- Clinical factors: duration of DM, family history of DM, body mass index (BMI), mode of therapy, presence of comorbidity, biochemical values.

- Behavioral factors: medication adherence, diet adherence, physical exercise, smoking, self-monitoring of blood glucose (SMBG), keeping up with follow-up visits, setting targets for glycemic control.

4.5. Sample size determination and sampling method

4.5.1. Sample size determination

The sample size was determined using single population proportion formula considering a 59.4% proportion (p) of poor glycemic control as reported from an earlier study assessed with HbA1c [9], with a confidence interval (CI) of 95% and 5% marginal error (d).

$$n = \frac{(Z\propto_{/2})^2 \times pq}{d^2}$$

Where:

- n = sample size
- Z (a/2) = Z score at a 95% confidence interval = 1.96
- p = 0.594 (proportion of patients with poor glycemic control)
- q = 1 - p
- d = 0.05 (5% error margin)

Therefore, n becomes:

$$n = \frac{(1.96)^2 \times 0.594 * 0.406}{(0.05)^2} = 371$$

The estimated average number of patients with T2DM expected to visit the diabetic clinic during the study period was N = 2136. Since the source population (N) had less than 10,000 respondents, the sample size was adjusted with a correction formula (nf):

$$nf = \frac{n}{1 + \frac{n}{N}} = \frac{371}{1 + \frac{371}{2136}} = 323$$

Assuming 10% non-response rate: **(0.1) * (323) = 32.3**

323 + 32 = **355**

4.5.2. Sampling method

A systematic random sampling technique was used to select study participants at each k-th interval. The actual sampling fraction (k^{th}) was determined by dividing the total number of source population attending the clinic during the study period (2136) by the corrected sample size (355) k = 6.01. Therefore, every sixth patient was approached and invited to participate in the study until the required sample size was reached.

4.6. Measurement and data collection

4.6.1. Data collection procedure

Data were collected after the completion of the physician's office visit session. After obtaining informed consent from each study participant, information about sociodemographic, behavioral, and clinical characteristics was recorded through face-to-face interviews using structured and pretested questionnaires. The questionnaire was developed based on various similar previous studies and was further modified to include important variables from this study. It was initially prepared in English, translated into Amharic, the local language, and retranslated into English again to ensure consistency. The patient's medical records were also reviewed the same day after the interview, to look for potential limiting factors that could interfere with the HbA1c test. Data were collected in collaboration with outpatient department nurses & laboratory personnel under close supervision by the principal investigator. The World Health Organization (WHO) safety guidelines and protocols for COVID-19 were strictly followed at all times.

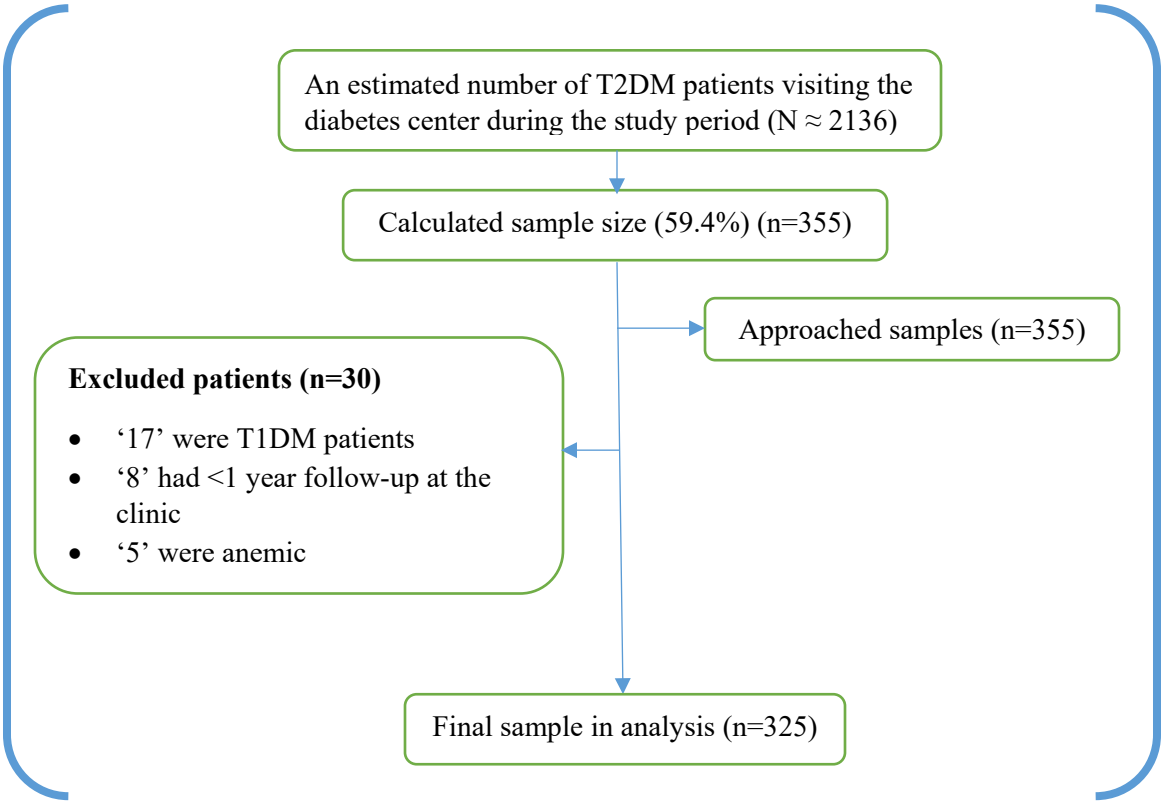

Figure 2. Schematic presentation of the sampling procedure

4.6.2. Laboratory examinations

Laboratory investigations were carried out for biochemical parameters: level of glycated hemoglobin (HbA1c), fasting blood sugar (FBS), renal function test (RFT) & lipid profile. All laboratory analyses were performed using the fully automated **Beckman Coulter DxC 700 AU** clinical chemistry analyzer.

4.6.2.1. HbA1c analysis

3 ml of freshly drawn venous blood in an EDTA tube was used for the determination of HbA1c. HbA1c was evaluated using a turbidimetric immunoinhibition method. The HbA1c assay involves the use of four reagents: total hemoglobin R1, HbA1c R1, HbA1c R2, and hemolysis reagent. The HbA1c (HbA1c) reagent, when used in conjunction with Beckman Coulter Systems, HbA1c calibrators, and hemolyzing reagent, is intended for quantitative determination of hemoglobin A1c concentration in human whole blood. It has a broad analytical range of 20 to 140 mmol/mol HbA1c (IFCC); 4 to 15% HbA1c (NGSP). It is National Glycohemoglobin Standardization Program-certified (NGSP) and Diabetes Control and Complications Trial-standardized (DCCT) and

unaffected by common hemoglobin variants (HbC, HbS, HbE, and HbD traits) and elevated fetal hemoglobin (HbF) minimizing inaccurate results for patients with these blood conditions [35]. All human samples were considered potentially biohazardous. Therefore, universal precautions were taken in specimen handling (gloves, lab garments, face masks, etc.).

4.6.2.2. Other biochemical parameter analysis

5 ml of venous blood samples from study subjects were also drawn in a serum separation tube (SST), in which serum was used to measure the RFT, FBS and lipid profile of study subjects. The FBS was measured based on Hexokinase-UV/NAD-NADH method at 340/380 nm. The urea test was based on the Urease/L-glutamate dehydrogenase (GLDH) Enzymatic method at an absorbance of 340 nm. Creatinine was obtained based on the Kinetic Modified Jaffe procedure at 520/800 nm. Total cholesterol analyzed based on Cholesterol Esterase/Peroxidase, Bichromatic principle at 540/600 nm. Triglyceride using Enzymatic GPO-Trinder procedure at 660/800 nm. HDL-C measured by Accelerator Selective Detergent, Bichromatic at 600/700 nm. And LDL-C was measured based on Cholesterol Esterase/Peroxidase, Bichromatic method at 540/660 nm.

4.7. Data quality assurance

The quality of the data was ensured by properly designing the tool and the questionnaire was pretested on 5% of the sample randomly selected patients with T2DM at St. Paul's Hospital Millennium Medical College before the actual data collection, and some minor modifications were made accordingly. The principal investigators throughout the data collection process were under close contact and supervision. The completeness and consistency of the collected data were checked daily. Strict procedures were also implemented in the laboratory analysis of the analytes. A daily quality control test was performed for each analyte prior to sample analysis. Controls were also performed with each new lot of reagent and after specific maintenance or troubleshooting steps. A fasting state blood sample was used for all analytes measurements. Samples were drawn into prelabeled barcoded SST and EDTA tubes and were checked for quality & quantity. Blood samples collected in test tubes were processed with as little delay as possible and brought to the laboratory for estimation of biochemical parameters on the same day. The results obtained were properly coded and documented.

4.8. Data analysis and interpretation

Data entry and analysis were performed using SPSS version 26. Descriptive statistics, including frequency, percentages, and median, were used to summarize baseline sociodemographic data from patients and evaluate the distribution of responses. Logistic regression analysis was conducted to look for any association between predictors and outcome variables. Factors with a P-value < 0.25 in the bivariate analysis were exported to the multivariate logistic regression analysis. Multivariate analysis using logistic regression was performed to control the effect of potential confounder variables and to identify independent predictors of inadequate & poor glycemic control. Consequently, statistically significant associations were determined based on the adjusted odds ratio (AOR) with its 95% CI and the P-value <0.05.

Glycemic control was defined according to the HbA1c target of < 7% ('good' control) as recommended by the American Diabetes Association for non-pregnant adults. The HbA1c level in the range of 7-8% was defined as 'inadequate' control and 'poor' at levels greater than 8% [36].

4.9. Operational definitions

Good glycemic control: a glycemic control is considered good when a patient has HbA1c <7% for non-pregnant adult diabetic patients, and less than 8% for patients with comorbid and/or vascular complications and/or older than 60 years and/or a history of severe hypoglycemia [36].

Poor glycemic control: a glycemic control is considered poor when a patient has HbA1c >7% for adult diabetic patients and greater than 8% for comorbid and/or vascular complications and/or older than 60 years and/or a history of severe hypoglycemia [36].

Adherence to medication: if the study participant took all his/her anti-diabetic medications in the last seven days [36].

Adherence to diet: If the study participant had followed the recommended diet for more than 3 days in the last seven days [36].

Adherence to exercise: If the study participant had followed the recommended level of exercise for more than 3 days in the last 7 days [36].

4.10. Ethical considerations

Ethical clearance was obtained from the Research and Ethics Review Committee (DRERC) of the Department of Medical Laboratory Sciences of the College of Health Sciences of Addis Ababa University (DRERC/590/21/MLS). A permission letter was also granted from the TASH endocrinology unit. Furthermore, prior to data collection, each patient was taken through the consent process by being informed about the purpose of the study, the selection procedures, the need to draw a small blood sample & access to their medical records, and the assurance of confidentiality by not using names to improve anonymity. Subsequently, the patient's willingness to take part in the study was affirmed by obtaining written consent.

4.11. Dissemination of result

The results of this study could serve as reference material for researchers, experts, or policy makers for intervention. To reach these bodies the finalized paper will be disseminated through publication in peer-reviewed local and international journals.

5. RESULTS

5.1. Sociodemographic characteristics of the participants

A total of 325 patients with T2DM were involved in the study. Among them, women comprised the majority of respondents 186 (57.2%). The median age of the participants was 54 years (IQR 45-62). 217 (66.8%) of the participants were married. 120 (36.9%) had completed their secondary education & 106 (32.6%) were either in college or had already earned their degrees. 158 (48.6%) were government or private employees. More than half of the respondents (53.8%) were urban dwellers. 111 (34.2%) were making less than 1500 ETB a month. And a considerable number of study participants (60.6%) had access to hospital services free of charge (Table 1).

Table 1. Sociodemographic characteristics of the study participants (outpatients with T2DM, n = 325) at TASH, Addis Ababa, Ethiopia, 2021.

Variables	Category	Frequency (%)
Age, median (IQR)		54 years (45-62)
Age group (yr)	18 - 44	74 (22.8)
	45 - 54	92 (28.3)
	55 - 64	101 (31.1)
	≥ 65	58 (17.8)
Gender	Male	139 (42.8)
	Female	186 (57.2)
Marital status	Single	52 (16)
	Married	217 (66.8)
	Divorced	18 (5.5)
	Widow/er	38 (11.7)
Educational level	No formal education	37 (11.4)
	Primary ed. (grade 1 - 8)	62 (19.1)
	Secondary ed. (grade 9 - 12)	120 (36.9)
	College and above	106 (32.6)
Occupation	Unemployed	13 (4)
	Gov't/Private Employee	158 (48.6)
	Self-employed	95 (29.2)
	Homemaker	24 (7.4)
	Retired/Pension	35 (10.8)
Monthly income (ETB)	< 1500	111 (34.2)
	1500 - 5000	130 (40)

	> 5000	84 (25.8)
Residence	Urban	175 (53.8)
	Rural	150 (46.2)
Healthcare access	Free	197 (60.6)
	Paid	128 (39.4)

IQR, interquartile range; **ETB**, Ethiopian birr.

5.2. Clinical characteristics and disease management practices

The median duration of diabetes since diagnosis was 9 years (IQR 4-15). One hundred and fifty-three (47.1%) of the respondents implied that they have been living with diabetes for more than a decade. A family history of diabetes mellitus, in at least one parent or sibling, was recorded in 19.7% of the participants. Most of the respondents, 74.2% had a body mass index value between (18.5-24.9kg/m2), normal weight, while 19.1% appeared to be overweight (25-29.9kg/m2). Twelve (3.7%) were obese (≥30 kg/m2) and the remaining 3.1% fell within the underweight range (<18.5kg/m2). Comorbidities were present in almost 40% of the study participants. The most prevalent comorbidity was hypertension, which represented almost 20% of all comorbidities, followed by dyslipidemia (7.7%) and ischemic heart disease (3.1%). One hundred and fourteen (35.1%) respondents have already developed one or more diabetic complications. Diabetic neuropathy was the most (14.2%) commonly shared diabetes complication among the study participants. And 29 (9%) of the respondents were affected by multiple complications related to diabetes.

Only twelve (3.7%) of the participants were in a non-pharmacological mode of therapy. Most of the study participants (44.6%) used insulin, 93 (28.6%) were on oral hypoglycemic agents, and the rest 75 (23.1%) used combinations of insulin and oral hypoglycemic agents.

Over 50% of the participants had routine follow-up visits more than three times a year. About 70% adhered fully to their prescribed medications during the previous week before the study. A little more than half of the respondents 168 (51.7%) were following the recommended healthy eating plan adequately. And 138 (42.5%) participated in at least 30 minutes of physical activity for more than 3 days a week. 41.8% of the respondents have the means to self-monitor their blood glucose levels, own a glucometer, or access nearby clinics or pharmacies. As few as eight (2.5%) participants were active smokers. And around 40% of the respondents indicated that they have set a glycemic target goal for management, which they strive to achieve (Table 2).

Table 2. Clinical characteristics and disease management practices of study participants at TASH, Addis Ababa, Ethiopia, 2021.

Variables	Category	Frequency (%)
DM duration, median (IQR)		9 years (4-15)
Duration of DM	2 - 5 years	50 (15.4)
	6 - 10 years	122 (37.5)
	≥ 11 years	153 (47.1)
Family history of DM	Yes	64 (19.7)
	No	261 (80.3)
BMI (kg/m^2)	Underweight (<18.5)	10 (3.1)
	Normal weight (18.5-24.9)	241 (74.2)
	Overweight (25-29.9)	62 (19.1)
	Obese (≥30)	12 (3.7)
Mode of therapy	Oral hypoglycemic agents	93 (28.6)
	Insulin	145 (44.6)
	Combination of both	75 (23.1)
	Diet modification/Exercise alone	12 (3.7)
No. of follow-up visits	≤ 3 times/year	156 (48)
	> 3 times/year	169 (52)
Medication adherence (n = 313)	7 days/week (adequate)	228 (70.2)
	< 7 days/week (inadequate)	85 (26.2)
Diet adherence	>3 days/week (adequate)	168 (51.7)
	0 - 3 days/week (inadequate)	157 (48.3)
Physical exercise	> 3 days/week (Adequate)	138 (42.5)
	0 - 3 days/week (Inadequate)	187 (57.5)
Access to SMBG	Yes	136 (41.8)
	No	189 (58.2)
Glycemic targets goal (HbA1c/FBS/RBS)	Yes	129 (39.7)
	No	196 (60.3)
Smoking status	Current smoker	8 (2.5)
	Ex-smoker (>1 year)	16 (4.9)
	Nonsmoker	301 (92.6)
Co-morbidity	Present	129 (39.7)
	Absent	196 (60.3)
Type of co-morbidity(ies)	Hypertension	63 (19.4)
	Dyslipidemia	25 (7.7)
	Ischemic heart disease (IHD)	10 (3.1)
	Hypertension + IHD	7 (2.2)
	Others*	24 (7.4)
Complication	Present	114 (35.1)

	Absent	211 (64.9)
Type of complication(s)	Neuropathy	46 (14.2)
	Retinopathy	23 (7.1)
	Retinopathy + Neuropathy	21 (6.5)
	Retinopathy + Neuropathy + Nephropathy	8 (2.5)
	Cardiac complications	16 (4.9)

Others* - Asthma, Thyroid disorders & Obesity.

BMI, body mass index; **SMBG**, self-monitoring of blood glucose; **HbA1c**, hemoglobin A1c; **FBS**, fasting blood sugar; **RBS**; random blood sugar.

5.3. Glycemic control & biochemical parameters

The median level of HbA1c of the study participants was found to be 8.4% (IQR 6.8-10.1). Good glycemic control was achieved only in eighty-five (26.2%) of the total respondents, as per the American Diabetes Association criteria of less than 7%. About 17% had inadequate control (7-8%) (Figure 3). And more than half of the participants (56.9%) had poor glycemic control (>8%). Fasting blood sugar level was greater than or equal to 130 mg/dL in 58.2% of the respondents, while approximately 80% of the respondents had a total cholesterol value below 200 mg/dL (Table 3).

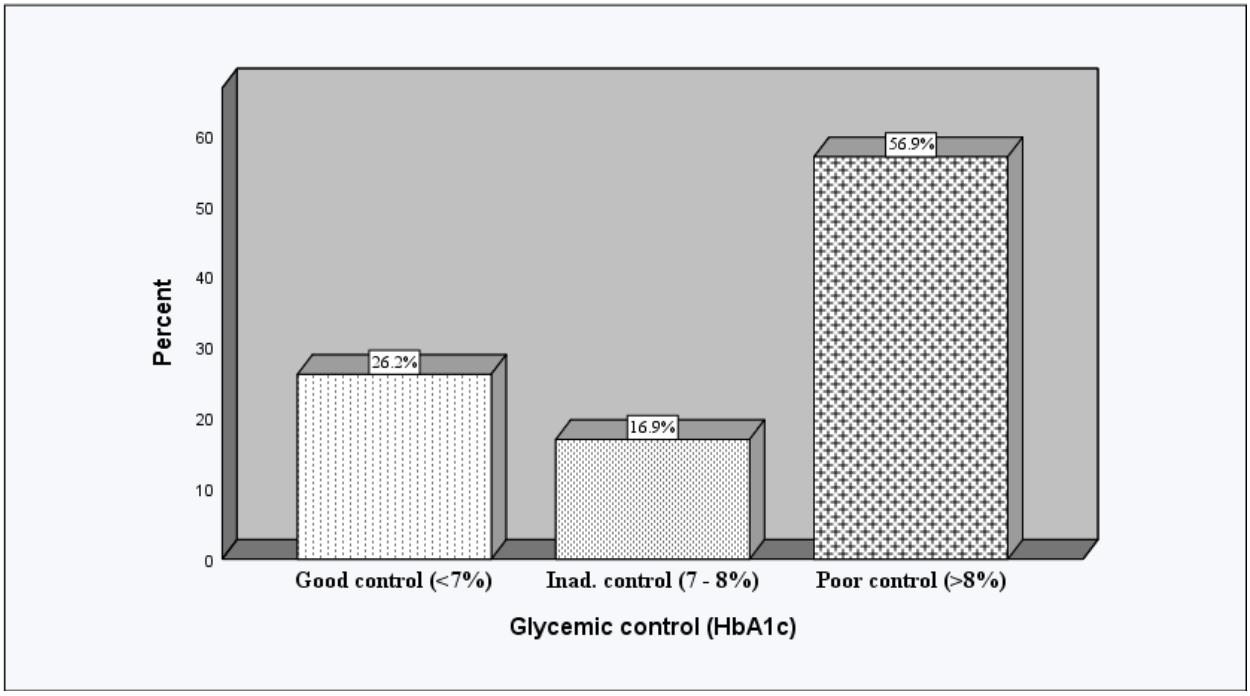

Figure 3. Level of glycemic control among patients with T2DM at TASH, Addis Ababa, Ethiopia, 2021.

Table 3. Glycemic control & biochemical parameters of study participants in TASH, Addis Ababa, Ethiopia, 2021.

Parameters	Category	Frequency (%)
HbA1c level, median (IQR)		8.4% (6.8-10.1)
Glycemic control (HbA1c)	Good control (<7%)	85 (26.2)
	Inadequate control (7 - 8%)	55 (16.9)
	Poor control (>8%)	185 (56.9)
FBS (mg/dL)	<130	136 (41.8)
	≥130	189 (58.2)
Total cholesterol (mg/dL)	<200	259 (79.7)
	≥200	66 (20.3)
Triglyceride (mg/dL)	<150	210 (64.6)
	≥150	115 (35.4)
HDL-C (mg/dL)	M: ≥40, F: ≤50	171 (52.6)
	M: <40, F: <50	154 (47.4)
LDL-C (mg/dL)	<130	211 (64.9)
	≥130	114 (35.1)
Urea (mg/dL)	10 - 50	308 (94.8)
	>50	17 (5.2)
Creatinine (mg/dL)	0.5 - 1.2	297 (91.4)
	>1.2	28 (8.6)

HDL-C, high-density lipoprotein cholesterol; **LDL-C**, low-density lipoprotein cholesterol.

5.4. Factors associated with glycemic control

In the bivariate logistic regression: age, gender, duration since diagnosis of diabetes, body mass index, mode of therapy, diet adherence, physical exercise, glycemic target goal, and comorbidity were associated with glycemic control and exported into the multivariable logistic regression model.

The results of the stepwise logistic regression analysis to identify factors associated with inadequate & poor glycemic control showed that older age, duration of DM of more than 10 years, insulin therapy, adherence to diet less than 3 days a week, and failure to set glycemic target goals were factors associated with inadequate & poor glycemic control (AOR: 2.46, 95% CI: 1.28-6.01, P = 0.03), (AOR: 3.15, 95% CI: 2.22-6.54, P = 0.016), (AOR: 3.07, 95% CI: 2.10-6.12, P = 0.022), (AOR: 1.97, 95% CI: 1.28-3.52, P = 0.002) and (AOR: 3.42, 95% CI: 2.17-5.97, P = 0.00), respectively.

The study showed that older age individuals with diabetes, specifically in the age category of (55-64) years, tend to have inadequate & poor control over their blood sugar levels compared to their younger counterparts. Patients with diabetes mellitus for more than ten years were found to be 3.15 times more likely to have inadequate & poor glycemic control than those with shorter durations. And the odds of having inadequate & poor glycemic control were found 3.07 times higher among patients with insulin therapy than those on different treatment regimens. In addition, there was also a noticeable difference in adherence to a diet. Study participants who adhered to the diet of fewer than 3 days a week were approximately twice as likely to have inadequate & poor blood glucose control compared to those who adhered to the recommended healthy eating plan adequately. Finally, patients without established glycemic target goals were found to be 3.42 times more likely to have inadequate & poor glycemic control than those who established one (Table 4).

Table 4. Bivariate and multivariate logistic regression analyses of factors associated with glycemic control among outpatients with T2DM at TASH, Addis Ababa, Ethiopia, 2021.

Variable	Category	Glycemic control (HbA1c)		Bivariate Analysis		Multivariate Analysis	
		Good (<7%) n = 85	Inad/Poor (≥7%) n = 240	COR (95% CI)	P-value	AOR (95% CI)	P-value
Age group (yr)	18 - 44	26	48	1	-	1	-
	45 - 54	26	66	0.74 (0.39-1.18)	0.042*	1.63 (0.66-4.18)	0.11
	55 - 64	16	85	1.90 (1.10-3.20)	0.002*	2.46 (1.28-6.01)	**0.03***
	≥ 65	17	41	1.72 (1.02-3.06)	0.008*	1.97 (1.30-5.97)	**0.04***
DM duration	≤ 10 years	72	100	1	-	1	-
	> 10 years	33	120	1.62 (1.13-3.43)	0.000*	3.15 (2.22-6.54)	**0.016***
Mode of therapy	OHA	46	47	1	-	1	-
	Insulin	41	104	2.50 (1.30-4.50)	0.000*	3.07 (2.10-6.12)	**0.022***
	OHA & Insulin	25	50	1.12 (0.24-3.72)	0.029*	2.36 (0.82-5.97	0.073
	Diet modification/Exercise alone	11	1	0.52 (0.38-2.88)	0.054	0.91 (0.52-3.53)	0.160
Diet adherence	>3 days/week	80	88	1	-	1	-
	0 - 3 days/week	45	112	2.32 (1.35-3.99)	0.000*	1.97 (1.28-3.52)	**0.002***
Glycemic target goal (HbA1c/FBS/RBS)	Yes	82	47	1	-	1	-
	No	49	147	2.61 (1.90-4.82)	0.000*	3.42 (2.17-5.97)	**0.000***

*p < 0.05 is statistically significant. **COR**, crude odds ratio; **AOR**, adjusted odds ratio; **CI**, confidence interval; **OHA**, oral hypoglycemic agent.

6. DISCUSSION

The goals of glycemic management for patients with diabetes are to prevent or delay complications and optimize the quality of life. Therefore, the measurement of HbA1c is considered an important diagnostic tool in monitoring diet control and therapeutic regimes during the treatment of diabetes. To the best of my knowledge, hardly any study based its assessment on HbA1c readings in Ethiopia. Therefore, this study aimed to evaluate the glycemic control status of patients with T2DM using the NGSP certified and DCCT standardized HbA1c assay method and to point out possible determinants of inadequate & poor glycemic control in a tertiary healthcare setting in Ethiopia. The study finding showed that almost three-quarters (73.8%) of the study participants had inadequate and poor glycemic control (HbA1c ≥7%). The prevalence of inadequate & poor glycemic control status was comparable to previous studies conducted in Saudi Arabia (74.9%) [34], Ghana (70%) [37], Uganda (73.52%) [38] and Northeast Ethiopia (70.8%) [16]. On the other hand, the magnitude of inadequate and poor glycemic control status in the current study was greater than previously reported in the USA (69%) [39], India (37.5%) [17], Tanzania (49.8%) [40], Northwest Ethiopia (60.5%) [41], Addis Ababa, Ethiopia (68.3%) [12] and Eastern Ethiopia (45.2%) [8]. However, the finding in the present study appeared to be lower than some studies reported in Nigeria (83.3%) [42], Kenya (81.6%) [43], and Addis Ababa, Ethiopia (80%) [44]. Although the abovementioned studies had the same study designs and comparable sample sizes, there were variations in the reported numbers. The discrepancy between the present and previous studies may have arisen mainly from differences in the types and methods of glucose measurement. Some researchers based their studies on FBS measurements and others on HbA1c. The other is the use of different assay methods, especially in the case of HbA1c determination, where the use of assays outside those certified by NGSP and standardized to DCCT gives falsely high or low readings in patients with hemoglobin variants and therefore compromises comparability between HbA1c laboratories [23]. Other factors related to the clinical and sociodemographic characteristics of the study participants may also have contributed to the observed variations.

Older age, duration of DM of more than 10 years, being on insulin therapy, adherence to diet fewer than 3 days a week, and failure to set glycemic target goals were significantly associated with inadequate & poor glycemic control. The study showed that older age individuals with diabetes, specifically 55 years of age and above, tend to have inadequate & poor control over their blood glucose levels compared to their younger counterparts. This finding is consistent with results from

previous studies [11, 42]. This could be explained in part because of the less stringent glycemic goal approach toward older adult patients considering factors such as limited life expectancy, extensive comorbid conditions, and advanced microvascular or macrovascular complications, where risks and burdens outweigh the potential benefits of intensive control. Contrary to these findings, they associated older age with good glycemic control in a study conducted in Palestine [45]. Elsous et al. associated older age with literacy, knowledgeability & experience and concluded that older individuals were more likely to have well-controlled glycemic levels, which was not the case in the present study. Some other studies also had similar results [37, 41].

Patients with longer durations of DM (>10 years) were found to be 3.15 times more likely to have inadequate & poor glycemic control than those with shorter durations. And this finding is commonly shared among many related studies [16, 39, 46, 47]. Due to the chronic and progressive nature of diabetes, patients with longer durations of the disease may eventually find it difficult to maintain good glycemic control. Impaired insulin secretion due to beta-cell dysfunction could explain this [48]. According to similar studies [38, 45, 49], the odds of having inadequate & poor glycemic control were 3.07 times higher among patients receiving insulin therapy than among those receiving different treatment regimens. Many patients with T2DM eventually need insulin therapy once disease progression overcomes the effect of hypoglycemic agents [50]. This could be the reason for the increased prevalence of inadequate & poor glycemic control status among insulin users.

Non-compliance with dietary recommendations was also associated with inadequate & poor glycemic control. Study participants with a diet adherence of fewer than 3 days a week were approximately two times more likely to have inadequate & poor blood glucose control compared to those who adhered adequately to the recommended healthy eating plan, which was also highlighted in some other studies [15, 50]. Finally, patients who failed to set HbA1c target goals for glycemic management were 3.42 times more likely to have inadequate & poor glycemic control than those who had established a plan. This could be due to a lack of awareness of target blood glucose levels for managing diabetes among diabetes patients, which had also been reflected in recently conducted studies [44, 51]. Furthermore, only 41.8% of the respondents were found to have the means to self-monitor their blood glucose levels, where some own a glucometer and others access nearby clinics or pharmacies. The numbers may be higher than reported in previous studies [50, 52, 53] but this could be because most of the participants in the present study resided in urban

areas. Given the high prevalence of diabetes in the country, access to and distribution of SMBG devices is still far from sufficient.

7. STRENGTH AND LIMITATION

7.1. Strength

This study is the first to use the NGSP-certified/DCCT-standardized HbA1c method to assess the level of glycemic control among diabetic patients in TASH. The fact that the study was conducted at the national diabetes referral hospital level and the use of systematic random sampling techniques allows generalization of the findings to patients with T2DM in Ethiopia. In addition, first-hand information was obtained via face-to-face interviews and laboratory tests performed on the same day. The study also investigated most of the possible modifiable and nonmodifiable factors affecting glycemic control, further strengthening the findings.

7.2. Limitation

As this was a cross-sectional study, a better relationship between glycemic control and different potential factors that progressively affected it could not be well established.

8. CONCLUSION AND RECOMMENDATION

8.1. Conclusion

The results of this study showed that approximately three quarters (73.8%) of the study participants had inadequate & poor glycemic control, which is far below the recommended standards. And this had been found to be associated with older age, longer duration of DM, insulin therapy, poor diet compliance, and failure to set control targets.

8.2. Recommendation

Greater efforts must be made to address the factors associated with inadequate & poor glycemic control and optimize quality of life. Appropriate attention should be paid to patients with older age, longer duration of DM, insulin therapy, poor diet compliance and who have not established goals for glycemic control. Addressing these issues could prove vital to achieving good glycemic control.

Various awareness initiatives should be held on diabetes care and ways of self-management of the disease.

Meanwhile, patients need the help of healthcare providers, especially physicians, in setting a glycemic target for managing diabetes. Goals should be individualized considering the duration of DM, life expectancy, comorbidities, advanced microvascular or macrovascular complications, hypoglycemia unawareness, and individual patient preference as recommended by the American Diabetic Association. More stringent targets (HbAlc <6.5%) are suggested for patients with DM of short duration, long life expectancy, and no significant cardiovascular disease (CVD) if they can be achieved safely without inducing significant hypoglycemia. Less stringent goals (HbA1c up to 8%) are recommended for patients with limited life expectancy, significant comorbidities, advanced microvascular or macrovascular complications, and those with frequent or severe episodes of hypoglycemia. The target goals should also be reevaluated over time to balance risks and benefits as patient factors change. In general, physician office visits should be participatory, patients should participate in a shared decision-making process with clinicians in matters related to their health and care to better implement diabetes care goals.

Furthermore, to provide standard care to patients, objective and reliable information is needed on the magnitude of glycemic control. In this regard, clinically effective and reliable results should be obtained using HbA1c methods that are certified by the NGSP and standardized to the DCCT.

Finally, a concerted effort is needed to increase access and availability of tools for self-monitoring of blood glucose levels.

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10. ANNEXES

Participant information sheet

Title of the Research Project: Glycemic control and associated factors among outpatients with Type 2 Diabetes at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia.

Principal Investigator: Rodas Getachew (BSc, MSc candidate)

Name of the organization: Department of Medical Laboratory Sciences, College of Health Sciences, Addis Ababa University.

Introduction

You are invited to participate as a study subject in research conducted by an MSc candidate, from Addis Ababa University. Your participation is voluntary. The research teams will include one principal investigator, two advisors; from Addis Ababa University medical laboratory department. Please take as much time as you need to read or listen to the information sheet.

Purpose of the Research Project

The health laboratory plays an indispensable role in the health care system. It supports diagnosis (to rule in or rule out a diagnosis), monitoring of response to treatment, epidemiological surveillance, prevention, and research (to understand the pathophysiology of a particular disease process). There is a lack of information on glycemic control of type 2 diabetic patients obtained from HbA1c measurement. Therefore, the purpose of this proposed study is to assess the level of glycemic control using HbA1c measurement among type 2 diabetic outpatients at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia. You have been chosen for this study. Therefore, we invite you to participate in this study and contribute to the assessment of the glycemic control status of patients with T2DM outpatients. Therefore, the result of this study is expected to improve the glycemic control status of T2DM in Ethiopia.

Procedures and the expected participation

If you are willing to participate, you must understand the purpose of the study and give your consent. Not only this, but also a specimen collected from you will be used for the research purpose, and the results of your sample will be exposed to some concerned professional staff as needed. The required clinical sample will be collected by laboratory OPD staff members. Then, you are requested to give your consent to the sample collector. After consent, a blood sample will

be taken from the veins of your arm. Additionally, there will be a face-to-face interview for additional questions.

Potential risks and Discomforts

There may be minimal risk and discomfort when taking venous blood. However, we will try to minimize discomfort as much as possible, as the blood samples will be taken by experienced laboratory professionals.

Confidentiality

We respect your privacy and confidentiality. Any information that identifies you will not be shared with anyone else outside the study team. The information we will collect from you as part of the study will be kept in a locked file cabinet, or be protected by a password on the computer only accessible to personnel involved in the study. There is no sensitive issue that you will be asked about related to your social desirability, but any information obtained in connection with this study and that can be identified with you will remain confidential.

Potential Benefits to Subjects and/or to the society

You will not receive any payment for your participation in this research study as compensation. However, based on the diagnosis result you will be treated in view of that.

Participation and withdrawal from the Study

Participation is voluntary and you have the right not to participate in this study. You may withdraw at any time and place without consequences of any kind. You may also reject to give any sample. You can ask any questions regarding this study and you have a right to get a laboratory diagnosis result free.

Contact information

If you have any questions about this study you can contact the principal investigator for further information.

Name: Rodas Getachew

Phone: +251 921 622607

Email: rodasgetachew22@gmail.com

የተሳታፊዎች ፈቃድና መተማመኛ ቅፅ

በአዲስ አበባ ዩኒቨርስቲ ጤና ሳይንስ ኮሌጅ የሕክምና ላቦራቶሪ ሳይንስ ት/ክፍል በማስተርስ ዲግሪ ተማሪ የመመረቂያ ጥናት ላይ እዲሳተፉ ተጋብዘዋል። እባክዎ በዚህ ጥናት ለመሳተፍ ከመስማማትዎ በፊት ከዚህ ቀጥሎ የሚገኘዉን ምንባብ በጥሞና ያንብቡና ግልጽ ያልሆነልዎትን ማንኛዉም ሃሳብ ይጠይቁ።

መግቢያ

የጥናቱ ርዕስ “Glycemic control and associated factors among outpatients with Type 2 Diabetes at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia”

የእርስዎ በዚህ ጥናት ላይ የሚኖርዎት ተሳትፎ ሙሉ በሙሉ በበጎ ፈቃደኝነት ላይ የተመሰረተ ነዉ። በዚህ ጥናት ዉስጥ ላለመሳተፍ ወይም ለመሳተፍ ከወሰኑ በኃላ ለማቋረጥ የሚወስኑ ቢሆንም እንኩዋ በዚህ ሆስፒታል የሚሰጠዉ ማንኛዉም አገልግሎት አይቋረጥም። በጥናቱ ለመሳተፍ የሚስማሙ ከሆነ የስምምነት ቅጹ ላይ በጹሁፍ ወይም በጣት ፊርማ ማስቀመጥ ይጠበቅዎታል።

የጥናቱ ተሳታፊ ለመሆን የሚጠበቅበዎት ምንድን ነው?

በዚህ ጥናት ለመሳተፍ የሚስማሙ ከሆነ ናሙናዎ ለጥናቱ እንዲሚዉል መስማማት ይጠበቅብዎታል። ከተወሰደዉ ናሙና ላይ የሚገኙ መረጃዎች ከዚህ ሆስፒታል ዉጭ ለሚገኙና ለስራዉ አግባብነት ላላቸዉ ሰዎች ቢነገር የማይቃወሙ መሆኑን መስማማት ይጠበቅብዎታል። ይሁን እንጅ ይህ አይነቱ መረጃ የርስዎን ማንነት የሚገልፁ መረጃዎችን ማለትም ስም፣ አድራሻና የስልክ ቁጥር የመሳሰሉትን መረጃዎቸን አይጨምርም። ይልቁንም ለዚህ አገልግሎት ብቻ የሚዉል እርስዎን ለማወቅ የሚያስችል መለያ ቁጥር ጥቅም ላይ እንዲዉል ይደረጋል። በተጨማሪም ስለርስዎ አጠቃላይ የጤና ሁኔታ ለሚቀርቡ አንዳንድ ተጨማሪ ጥያቄዎች መልስ መስጠት ይኖርብዎታል።

በዚህ ጥናት መሳተፍ የሚያስከትላቸዉ ቸግሮች ምንድን ናቸዉ?

ናሙና በሚሰበሰብበት ወቅት ምንም አይነት የከፋ ችግር አያጋጥምዎትም። ሆኖም ግን ናሙናዉን ለመሰብሰብ ልምድ ያለዉ ባለሙያ ስለሚመደብና አስፈላጊዉ የጥንቃቄ እርምጃ ስለሚወሰድ የህመም ስሜት አይኖርም።

የህክምና መረጃ በሚስጥር ተጠብቆ መቆየት የሚችለዉ እንዴት ነዉ?

ስለራስዎ የሰጡት ማንኛዉም መረጃና ከተወሰደዉ ናሙና ላይ የተገኘዉ የላቦራቶሪ ዉጤት የሚዉለዉ ለጥናቱ አላማ ብቻ ነዉ። ይህን ማህደር ሊያገኙ የሚችሉት የተወሰኑ የጥናቱ ተባባሪ ሰዎች ብቻ ናቸው። ከዚያም በላይ ስለ እርስዎ ያለውን ማንኛውንም መረጃ የተለየ የይለፍ ቃል ባለው የኮምፒውተር የመረጃ ማህደር ውስጥ እንዲቀመጥ ይደረጋል።

በዚህ ጥናት መሳተፍ የሚያስገኛቸው ጥቅሞች ምንድን ናቸው?

ይህ ጥናት የማስተርስ ዲግሪ መመረቂያ እንደመሆኑ መጠን በዚህ ጥናት በመካፈልዎ በገንዘብ የሚያገኙት ጥቅም ባይኖርም ከጥናቱ በሚገኘው ውጤት ግን ተጠቃሚ ነዎት። የእርስዎ ተሳትፎ የእርስዎንና የወገንዎን የደም ውስጥ የስካር መጠን የመቆጣጠር ብቃትን ለማወቅና ለመከታተል ከፍተኛ ጥቅም ይኖረዋል።

በዚህ ጥናት ተሳታፊ የመሆንዎ መብቶች ምንድን ናቸው?

በዚህ ጥናት መሳተፍ ሙሉ በሙሉ በእርስዎ ፈቃደኝነት የተመሰረተ በመሆኑ በማንኛውም ሰዓትና ቦታ የማቋረጥ ሙሉ መብት የተጠበቀ ከመሆኑም በላይ እራስዎን ከጥናቱ በማግለልዎ ምክንያት የሚቀርብዎት ምንም አይነት የሆስፒታል አገልግሎት አይኖርም። ከዚህም በተጨማሪ ጥናቱን በተመለከተ ማንኛውንም አይነት ጥያቄ የመጠየቅና ገለጻ የማግኘት መብት አልዎት። የላብራቶሪ ምርመራ ውጤቱንም በነጻ ማግኘት ይችላሉ። ነገር ግን እርስዎ በሚሰጡን መረጃ የቸግሩን ስፋት ለመከላከል እና ለመቆጣጠር ጠቃሚ ስለሆነ ለሚቀርብልዎት ጥያቄ ቀጥተኛ መልስ ይሰጡን ዘንድ በታላቅ አክብሮት እንጠይቃለን።

ጥያቄ ካለኝ ወይም ችግር ቢያጋጥመኝ ምን ማድረግ ይገባል?

ይህንን ጥናት በተመለከተ ወይም ከዚህ ጥናት ጋር በተዛመደ መልኩ ስለሚያጋጥሙ ድንገተኛ አደጋዎች ወይም ጥያቄ ካለዎት በሚመለከተው አድራሻ ይጠቀሙ።

ስም: ሮዳስ ጌታቸው

ሞባይል፡ +251 921 622607

ኢሜል፡ rodasgetachew22@gmail.com

Informed consent form

Card No (I care) _____

I have read this consent form or had the information read to me. I had the opportunity to discuss this research study with the study investigator. I've had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I can choose to withdraw anytime. I agree to participate in this research study. I understand that all efforts will be made to keep the information regarding my identity confidential. By signing this consent form, I have not given up any of the legal rights I have as a participant in a research study.

I am willing to give my consent for providing the requested information and specimens as the clinician finds best for me.

Signature: _____ Date_____

የተሳታፊዎች ስምምነት ማረጋገጫ

የካርድ ቁጥር (I care) _____

ከላይ በካርድ ቁጥር የተወከልኩት ተሳታፊ “Glycemic control and associated factors among outpatients with Type 2 Diabetes at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia” ጥናት ላይ በቂ ገለጻ ተደርጎልኛል። ለጥናቱም የደም ናሙና እንደሚያስፈልግ ተገልጾልኛል።የጥናቱንም አላማዎችም ተረድቻለሁ።

በቃለ መጠይቁ ላይ የገለጽኳቸው መረጃዎች በሙሉ በሚስጥር የተጠበቁ እንደሚሆኑ ተነግሮኛል በጥናቱ ላይ ያለመሳተፍና ማንኛውንም መረጃ ያለመስጠት እንዲሁም በማንኛውም ጊዜ ከጥናቱ ራሴን የማግለል መብቴ የተጠበቀ እንደሆነ ተገልጾልኛል።

ስለዚህ ለዚህ ጥናት መረጃና የስምምነት ቃሌን የሰጠሁት በአጠቃላይ ሁኔታውን በመረዳትና በፍጹም ፍቃደኝነት ነው። በተጨማሪም ጥያቄ ለመጠየቅ ተፈቅዶልኝ ለማወቅ የፈለኩትን ያህል ማብራሪያ አግኝቻለሁ። የዚህ ጥናት ተሳታፊ በመሆኔ የማገኘው ጥቅም የሁሉንም ምርመራ ውጤት በነጻ ማግኘት እንደሆነ ተረድቻለሁ።

በአጠቃላይ እኔ ከላይ በመተማመኛ ቅፅ የተጠቀሱትን ሁሉ በሚገባና በተረጋጋ መንፈስ አንብቤዋለሁኝ። ስለዚህ በዚህ ጥናት ለመሳተፍ ፈቃደኛ መሆኔን በፊርማዬ አረጋግጣለሁ።

ፊርማ---------- ቀን -----/-----/----------

(የስምምነት ቅጹን ማንበብ ለማይችሉ ተሳታፊዎች)

የአማካሪ ጤና ባለሙያ ስም ----------

ፊርማ ---------- ቀን ----------

Structured questionnaires

Part I: Eligibility (Screening Questionnaire)

1. Do you suffer from any form of anemia?
    a. Yes ☐
    b. No ☐
2. Have you recently undergone a blood transfusion?
    a. Yes ☐
    b. No ☐
3. Are you alcoholic or do you regularly consume alcoholic drinks?
    a. Yes ☐
    b. No ☐
4. Are you pregnant? (For females only)
    a. Yes ☐
    b. No ☐
5. Has the consent been clearly explained and obtained?
    a. Yes ☐
    b. No ☐

NB: Stop the interview if the answer to questions 1, 2, 3, 4 is **"Yes"** or to 5 is **"No"**. And continue with the next participant, please.

Part II: Questionnaires on sociodemographic and healthcare access of the study participants

No.	Variables	Category
1.	Age _____ Years	18 - 44 ☐ 45 - 54 ☐ 55 - 64 ☐ ≥ 65 ☐
2.	Sex	Male ☐ Female ☐
3.	Marital status	Single ☐ Married ☐ Divorced/separated ☐ Widow/er ☐
4.	Educational level	No formal education ☐ Primary ed. (grade 1 - 8) ☐ Secondary ed. (grade 9 - 12) ☐ College & above ☐
5.	Residence	Urban ☐ Rural ☐
6.	Occupation	Unemployed ☐ Gov't/Private Employee ☐ Self-employed ☐ Housewife ☐ Retired/Pension ☐
7.	Monthly Income (ETB) _____	< 1500 ☐ 1500 - 5000 ☐ > 5000 ☐
8.	Healthcare access	Free ☐ Paid ☐

Part III: Questionnaires on the clinical characteristics of the study participants

No.	Variables	Category
1.	DM duration _____Years	2 - 5 years ☐ 6 - 10 years ☐ ≥ 11 years ☐
2.	Family History of DM	Yes ☐ No ☐
3.	BMI (kg/m^2) (Write your answers)	Weight (kg) _____ Height (m) _____
4.	Mode of therapy	Oral hypoglycemic agents ☐ Insulin ☐ Combination of both ☐ Diet modification/Exercise alone ☐
5.	How many times a year do you show up to your follow-up clinic visit appointments? _____ times/yr.	≤ 3 times/year ☐ > 3 times/year ☐
6.	Do you take your prescribed medications at the right time & dosage without ever forgetting?	Yes, 7 days/week (Adequate) ☐ No, < 7 days/ week (Inadequate) ☐
7.	Do you strictly adhere to your recommended diet program? (Avoiding fatty foods & consuming more vegetables & fruits).	Yes, > 3 days/week (adequate) ☐ No, 0 - 3 days/week (in adequate) ☐
8.	How many times a week do you participate in physical activities?	> 3 days/week (Adequate) ☐ 0 - 3 days/week (Inadequate) ☐
9.	Do you've access to a device to self-monitor your blood glucose level (SMBG)?	1. Yes (own glucometer) ☐ Yes (access nearby clinic/pharmacy ☐ 2. No ☐
10.	Have you set glycemic target goals for management? (HbA1c/FBS/RBS)	Yes ☐ No ☐

11.	Smoking status	Current smoker ☐ Ex-smoker (>1 year) ☐ Non-smoker ☐
12.	Presence of co-morbidity?	Yes ☐ No ☐
13.	Type of co-morbidity(ies) (Can tick more than once)	Hypertension ☐ Dyslipidemia ☐ Obesity ☐ Ischemic Heart Disease ☐ Peripheral Vascular disease ☐ Others, Specify _____
14.	Presence of complication?	Yes ☐ No ☐
15.	Type of complication(s) (Can tick more than once)	Retinopathy ☐ Neuropathy ☐ Nephropathy ☐ Coronary Heart disease ☐ Diabetic Foot Ulcer ☐ Others, Specify _____

ክፍል 1: ቅድመ መጠይቅ (የጥናት ብቁነት ማረጋገጫ)

1. የደም ማነስ በሽታ አለብዎት?
   ሀ) አዎ አለብኝ ☐
   ለ) አይ የለብኝም ☐
2. ለህክምና የሚሆን ተጨማሪ ደም ወስደው ያውቃሉ በቅርቡ?
   ሀ) አዎ ወስጃለው ☐
   ለ) አይ አሎሰድኩም ☐
3. የአልኮል መጠጦችን አዘውትረው ይጠቀማሉ?
   ሀ) አዎ እጠቀማለው ☐
   ለ) አይ አልጠቀምም ☐
4. ነፍሰ ጡር ነዎት (ለሴትዎች ብቻ)
   ሀ) አዎ ነኝ ☐
   ለ) አይ አይደለሁም ☐
5. የጥናቱ አላማና ከእርሶ የሚጠበቅቦትን ተረድተው በጥናቱ ለመሳተፍ ፍቃደኝነትዎን አረጋግጠዋል?
   ሀ) አዎ አረጋግጫለው ☐
   ለ) አይ አላረጋገጥኩም ☐

ማሳሰብያ: የጥያቄ ቁጥር 1, 2, 3, 4 ምላሽ **"አዎ"** ከሆነ ወይም የጥያቄ ቁጥር 5 ምላሽ **"አይ"** ከሆነ መጠይቁን አቋርጠው ወደ ሚቀጥለው ተሳታፊ ያምሩ።

ክፍል 2፡ አጠቃላይ መግለጫዎች

ተ.ቁ	ጥያቄ	መልስ
1.	ዕድሜ _____ ዓመት (በቁጥር ይፃፍ)	18 - 44 ዓመት ☐ 45 - 54 ዓመት ☐ 55 - 64 ዓመት ☐ ≥ 65 ዓመት ☐
2.	ፆታ	ወንድ ☐ ሴት ☐
3.	የጋብቻ ሁኔታ	ያላገባ/ች ☐ ያገባ/ች ☐ የፈታ/ች ☐ የሞተበት/ባት ☐
4.	የትምህርት ደረጃ	መሠረታዊ ት/ት ያልተማረ/ች ☐ 1ኛ ደረጃ ያጠናቀቀ/ች (1 - 8) ☐ 2ኛ ደረጃ ያጠናቀቀ/ች (9 - 12) ☐ ኮሌጅ/ዩኒቨርስቲ ያጠናቀቀ/ች ☐
5.	የመኖርያ ስፍራ	ከተማ ☐ ከከተማ ወጣ ያለ/ ገጠራማ ክፍል ☐
6.	የስራ ሁኔታ	ስራ የሌለው/ላት ☐ የመንግስት ሰራተኛ ☐ የግል ሰራተኛ ☐ የቤት እመቤት ☐ ጡረተኛ ☐ ሌላ ካለ ይገለጹ_____
7.	ወርሃዊ ገቢ _____ (በኢትዮጵያ ብር)	< 1500 ☐ 1500 - 5000 ☐ > 5000 ☐
8.	የጤና አገልግሎት ሁኔታ	በነፃ ☐ በክፍያ ☐

ክፍል 3: *ህመም ነክ መግለጫዎች*

ተ.ቁ	ጥያቄ	መልስ
1.	የስኳር በሽታ ታማሚ ከሆኑ ምን ያህል ጊዜ ሆነዎት? _____ዓመት (በቁጥር ይፃፍ)	ከ 2 - 5 ዓመት ☐ ከ 6 - 10 ዓመት ☐ 11 ዓመትና ከዚያ በላይ ☐
2.	በቤተሰብዎ ውስጥ ከእርሶ ልላ የስካር ታማሚ አለ? (እናት/አባት...)	አዎ ☐ የለም ☐
3.	መልሶትን ይፃፉ	የሰውነት ክብደት መጠንዎ (ኪ.ግ) ---------- ቁመት (ሜ) ----------
4.	የሚወስዱት የመድሃኒት (ህክምና) አይነት	የሚዋጥ ክኒን ☐ በመርፌ የሚወሰድ ኢንሱሊን ☐ የሁለቱም ድብልቅ ☐ የአመጋገብ ስርዐት ለውጥ/ ስፖርታዊ እንቅስቃስ ማድረግ ብቻ ☐
5.	በዓመት ምን ያህል ጊዜ የህክምና ክትትል ያደርጋሉ? _____	3 ጊዜ ና ከዚያ በታች ☐ ከ 3 ጊዜ በላይ ☐
6.	የታዘዘሎትን መድሃኒት ሳይረሱ በአግባቡና በሰዐቱ የመውሰድ ልምዶ እንዴት ነው?	ጥሩ ነው (በሳምንት 7 ጊዜ) ☐ ጥሩ አይደለም (በሳምንት ከ 7 ጊዜ ያነሰ) ☐
7.	ጤናማና የተስተካከለ አትክልትና ፍራፍሬን ያማከለ የአመጋገብ ስርዐት ምን ያህል ይተገብራሉ?	በሳምንት ከ 3 ቀን በላይ ☐ በሳምንት ከ 0 - 3 ቀን ☐
8.	የአካል ብቃት እንቅስቃሴ በሳምንት ምን ያህል ጊዜ ያደርጋሉ? _____ ።	ከ 3 ቀን በላይ ☐ ከ 0 - 3 ቀን ☐
9.	ተንቀሳቃሽና በቀላሉ የደም ስኳር መጠንን ባሉበት መለካት የሚያስችል መሳርያ (Glucometer) ተጠቃሚ ነዎት?	1. አዎ፣ የራሴ አለኝ ☐ አዎ፣ በአቅራቢያ ካለ ክሊኒክ/ፋርማሲ እጠቀማለሁ ☐ 2. የለኝም ☐
10.	የደም ውስጥ ስኳር መጠንዎን ለመቆጣጠር ያስችሎ ዘንድ ያስቀመጡት የስኳር መጠን ዕቅድ (በቁጥር) አለ? "Glycemic targets goals (HbA1c/FBS/RBS)"	አዎ አለ ☐ የለም ☐
11.	ሲጋራ ያጨሳሉ?	አዎ አጨሳለሁ ☐ በፊት አጨስ ነበር አሁን አቁምያለሁ ☐ አላጨስም ☐

12.	ከስኳር ህመም ሌላ ተጓዳኝ የጤና እክል አለብዎት?	አዎ ☐ የለብኝም ☐
13.	የጥያቄ **"12"** መልስዎት አዎ ከሆነ ምን አይነት የጤና እክል እንዳለብዎት ይግለጹ?	የደም ግፊት ☐ ከልክ ያለፈ ውፍረት ☐ ከፍ ያለ የደም ውስጥ ስብ መጠን (Cholesterol) ☐ የልብ ችግር ☐ ኤች አይ ቪ ኤድስ ☐ ሌላ ካለ ይገለጹ _____
14.	የስኳር በሽታ ታማሚ በመሆኖ ያስከተለብዎት ሌላ የጤና ችግር አለ?	አዎ ☐ የለም ☐
15.	የጥያቄ **"14"** መልስዎት አዎ ከሆነ ምን አይነት የጤና ችግር እንዳስከተለብዎት ይግለጹ?	የኣይን ችግር ☐ የኩላሊት ችግር ☐ ልብና ከልብ ጋር የተያያዙ ችግሮች ☐ የነርቭ ችግር (መጠዝጠዝ/መደንዘዝ) ☐ የእግር ቁስለት ☐ ሌላ ካለ ይገለጹ _____

HbA1c test procedure

Type of Specimen

Freshly drawn blood treated with EDTA is the preferred specimen.

Specimen Storage and Stability

1. Samples (non-pretreated) are stable up to 8 hours when stored at 25°C, 7 days when stored at 2-8°C, and up to 3 months when frozen at -20°C.
   Whole blood samples are stable for 18 months at -70°C. Frozen samples should be thawed only once.
2. Each laboratory should evaluate sample handling procedures to avoid variable results.

Sample Preparation

First, the Hemolyzing Reagent is brought to room temperature prior to use. In a pre-treatment step, whole blood is mixed with the Hemolyzing Reagent in a 1:100 dilution (10 µL of sample or control plus 1000 µL of Hemolyzing Reagent) and mix thoroughly, avoid foaming and the resultant hemolysate is assayed after hemolysis is complete (allow at least 1 minute for Hemolysis). Tetradecyltrimethylammonium bromide (TTAB) in the hemolyzing reagent eliminates interference from leukocytes. The concentrations of both HbA1c and Total Hemoglobin are determined. The HbA1c/Total Hemoglobin ratio is expressed either as mmol/mol (IFCC) or % HbA1c (DCCT/NGSP). Total Hemoglobin reagent is used to measure total hemoglobin concentration by a colorimetric method. HbA1c reagent is used to measure hemoglobin A1c concentration by a turbidimetric immunoinhibition method. In the reaction, hemoglobin A1c antibodies combine with HbA1c from the sample to form soluble antigen-antibody complexes. Polyhaptens from the reagent then bind with the excess antibodies and the resulting agglutinated complex is measured turbidimetrically. Change in absorbance is measured at 340/700 nm. [44]

Outlined Procedures

1. Bring the Hemolyzing Reagent to room temperature before use.
2. Pipette 1000 µL of Hemolyzing Reagent into a test tube. Do not pipette directly from the reagent bottle (use a disposable tube). Ensure the entire volume is dispensed from the tip.
3. Thoroughly mix the whole blood sample to ensure a uniform distribution of erythrocytes.
4. Add exactly 10 µL of whole blood sample to the test tube.

5. Rinse the pipette tip in Hemolyzing Reagent by aspirating and dispensing several times. Ensure that the entire volume is dispensed from the tip.
6. Vortex the hemolysate for 5 seconds at medium speed, avoiding the formation of foam.
7. Assay the hemolysate after hemolysis, which is indicated by a color change from red to brown-green (approximately 1-2 minutes).

Note: All hemolyzed samples should be thoroughly mixed immediately prior to assay. The hemolysate is stable for 4 hours when stored at 15-25°C, up to 24 hours when stored at 2-8°C, if stored in a sealed container.

Reference Intervals

Adults: 4.0 - 6.0% (NGSP) or 20 - 42 mmol/mol (IFCC unit)

To convert results from IFCC (mmol/mol) to NGSP (%) units.

Master Equation: NGSP = (0.0915 x IFCC (mmol/mol)) + 2.15

DECLARATION

I, the undersigned, declare that this M.Sc. thesis is my original work, has not been presented for a degree in this or any other university, and that all sources of materials used for the thesis have been duly acknowledged.

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Signature: _____

Date of submission: _____

This thesis has been submitted with our approval as university-based advisors.

Advisor: **Samuel Kinde (MSc, PhD Fellow)**

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Date: _____

Place: Addis Ababa, Ethiopia.

Advisor: **Gobena Dedefo (MSc, PhD Fellow)**

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.