

**LIPID PROFILE AMONG HYPERTENSIVE DIABETIC PATIENTS AT
DEBRE MARKOS COMPREHENSIVE SPECIALIZED HOSPITAL,
DEBRE MARKOS, NORTHWEST, ETHIOPIA**



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ABSTRACT

Background: Diabetes is a chronic disease characterized by hyperglycemia with a disturbances in the metabolism of carbohydrates, lipids, and proteins. The coexistence of hypertension and dyslipidemia with diabetes is responsible for increased morbidity and mortality among diabetes patients. However, data on the status of lipid profile among hypertensive diabetic patient is limited in the study area and the lipid profile of the patients is not well studied in Ethiopia.

Objective: To assess lipid profile of hypertensive diabetic patients in comparison with normotensive diabetic patients at Debre Markos Comprehensive Specialized Hospital, Debre Markos, Northwest, Ethiopia from June 14 to August 26, 2020.

Methods: A hospital-based comparative cross-sectional study was conducted by involving 162 (81 hypertensive diabetic and 81 normotensive diabetic) participants using consecutive sampling technique. Five milliliters of blood was collected from an overnight fasting individual using serum separator tube. Socio-demographic data were collected using a structured questionnaire. Serum lipid profiles were measured using Biochem FC-200 analyzer. Data were coded and entered into SPSS version 25 for analysis. A comparison of lipid profiles between hypertensive diabetic and normotensive diabetic patients were done by an independent t-test.

Result: A total of 162 (50% hypertensive diabetic and 50% normotensive diabetic) study participants participated in this study. The overall prevalence of dyslipidemia among hypertensive and normotensive diabetic patients was 76(93.8%) and 54 (67.7%), respectively. Triglycerides, total cholesterol, and LDL-C were significantly higher in hypertensive diabetic patients compared to normotensive diabetic patients while, high density lipoprotein was significantly lower in hypertensive diabetic patients compared to normotensive diabetic patients.

Conclusion: Higher mean levels of TC, LDL, and TG and lower mean levels of HDL concentration was found in hypertensive diabetic patients than normotensive diabetic patients. Hypertensive diabetic had high dyslipidemia prevalence as compared to normotensive diabetic patients. There were statistically significant positive correlations between SBP and DBP with TC, TG, and LDL-C.

Recommendations: There should be frequent monitoring of lipid profile for diabetes patients. Further studies should be conducted with larger sample size using prospective study.

Keywords: Hypertensive diabetic, normotensive diabetic, Lipid profile

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ABBREVIATIONS AND ACRONYMS

BMI	Body Mass Index
BP	Blood Pressure
CVD	Cardiovascular Disease
DBP	Diastolic Blood Pressure
DDM	Duration of Diabetes Mellitus
DM	Diabetes Mellitus
DMCSH	Debre Markos Comprehensive Specialized Hospital
FBS	Fasting Blood Sugar
FFAs	Free Fatty Acids
HWC	HiP Waist Circumference
HDL-C	High-Density Lipoprotein-cholesterol
HDM	Hypertensiv Diabetes mellitus
HTN	Hypertension
IDF	International Diabetes Federation.
IR	Insulin Resistance
LDL-C	Low-Density Lipoprotein-cholesterol
NCDs	Non-Communicable Diseases
NDM	Normotensive diabetes mellitus
SBP	Systolic Blood Pressure
SOP	Standard Operating Procedure
SPSS	Statistical Package For Social Sciences
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
TC	Total Cholesterol
TG	Triglycerides
VLDL	Very Low-Density Lipoprotein
WC	Waist Circumference
WHO	World Health Organization

CHAPTER ONE: INTRODUCTION

1.1. BACKGROUND

Diabetes mellitus (DM) is one of the oldest diseases known to man. It was first reported in the Egyptian manuscript about 3000 years ago (1). DM can be categorized into two major clinical classes. About 5-10% of diabetes cases are type 1 diabetes mellitus (T1DM). It is mostly diagnosed during childhood ages and caused by β -cell damage resulting in a diminished ability of the pancreas to produce insulin. The second class is type 2 diabetes mellitus (T2DM). It constitutes over 80-90% of all DM cases and is mostly diagnosed after the age of 40. But, younger cases are being reported recently (2). DM is a chronic metabolic disorder resulting from a defect in insulin secretion, insulin action, or both. Insulin deficiency, in turn, leads to chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism (3). The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction and failure of various organs, especially the eyes, kidneys, nerves, heart and blood vessels, that makes great burden on individual with diabetes and on the health care system (4).

There is a close relationship between diabetes and hypertension (HTN) that has been recognized since the 1980s (5). Insulin resistance is considered a critical factor in the development of type 2 diabetes. Equally, insulin resistance, as well as hyperinsulinaemia and hyperglycaemia secondary to insulin resistance, are key elements in driving the expression of a phenotype which typically involves both atherogenic dyslipidaemia and hypertension (6).

DM and HTN are most common risk factors for coronary heart disease (4). About 30% of patients with T1DM have HTN, while 70% of patients with T2DM have HTN (5). Diabetic patients commonly have HTN and dyslipidemia with 2-4 folds more risk of atherosclerotic cardiovascular disease (CVD) (7). HTN in the diabetic individual markedly increases the risk and accelerates the course of cardiac disease. DM has been known to be associated with lipid disorders and cardiovascular complications. Both diabetes mellitus and hypertension alter lipid and lipoprotein metabolism and increase the risk of coronary artery disease (8).

The pancreatic beta cells compensate for insulin resistance by hypersecretion of insulin (9). A major contributor to the development of IR is an excessive amount of circulating free fatty acids (FFAs) that are released from expanded adipose tissue triglyceride (TG) stores through the

lipolysis of TG-rich lipoproteins in tissues by lipoprotein lipase (10). In the liver, FFAs result in an increased production of glucose and TGs, secretion of very-low-density lipoprotein cholesterol (VLDL-C) and low-density lipoprotein cholesterol (LDL-C), as well as a reduction in HDL-C. It also reduce insulin sensitivity in muscle by inhibiting insulin-mediated glucose uptake, and FFA flux to the liver is associated with the increased production of TG-rich VLDL-C (1).

The incidence of coronary artery diseases is 3 to 5 times higher in both male and female hypertensive diabetic patients compared to the normotensive diabetic male and female. Individuals with diabetes may have several forms of dyslipidemia leading to an additive cardiovascular risk of hyperglycemia (11). Dyslipidemia, a strong predictor of CVD, causes endothelial damage, and the loss of physiological vasomotor activity that results from endothelial damage may become manifested as increased blood pressure (12). The duration of diabetes, degree of hyperglycemia, hypertension, dyslipidemia and smoking are the strongest risk factors for chronic complications of DM that leads to biochemical abnormalities (13).

1.2. STATEMENT OF PROBLEMS

Diabetes mellitus, a major health concern throughout the world, is contributing significantly to mortality and morbidity in the 21 century (14–16). Globally, more than 463 million people, aged 20–79 years, were affected by DM and it is expected to rise up to 700 million in 2045 (17). Four million adults aged 20–79 years were died due to diabetes in low and middle-income countries (18). In sub-Saharan Africa, more than 12 million people are expected to have DM, and 330,000 of these people will die from DM related complications (19). Annual global health expenditure on diabetes is estimated to be USD 760 billion. It is projected that expenditure will reach USD 825 billion by 2030 and USD 845 billion by 2045 (17).

HTN is well known as common comorbidity in patients with diabetes with its prevalence ranging from 60% to 80% (4). HTN and DM comorbidities increase risk of microvascular complications such as nephropathy, retinopathy and neuropathy as well as macrovascular complications such as coronary artery disease, peripheral arterial disease and stroke (5). Also diabetes mellitus is associated with a considerably increased cardiovascular risk. The presence of hypertension in the diabetic individual markedly increases morbidity and mortality in hypertension abnormalities may be seen in glucose, insulin, and lipoprotein metabolism, these abnormalities have been found to be present in the first degree relatives of hypertensive patients (4). Indeed, the risk for CVD is four-fold higher in patients with both DM and HTN as compared to the normotensive diabetic (20). It is a cause of morbidity and mortality in patients with DM because of disturbance in lipoproteins (3).

Currently, Ethiopia has been challenged by the growing magnitude of non-communicable diseases (NCDs) such as DM, HTN and CVDs (14). According to the 2017 estimate by IDF, Ethiopia has 2.57 million (5.2%) adult people aged 20–79 years with diabetes, making it the largest diabetes population in sub-Saharan Africa (21,22). Of those, about 1.96 million (76%) of them do not even know that they have diabetes. Consequently, nearly 75% of the patients were admitted to hospitals due to uncontrolled diabetes (22). Worldwide, there is broad variation in serum lipid profile patterns among different population groups. Therefore, evaluation and monitoring of modifiable risk factors can be beneficial to reduce CVD morbidity and mortality of the patient. Data on the lipid profile HDM and NDM patient is limited in the study area and the lipid profile of HDM and NDM is not well studied in the study area. Additionally; the

magnitude of dyslipidemia among glycyemic stautus on diabetic patients is not known at Debre Markos. So the present study will evaluate and examine lipid profile among hypertensive diabetic patients and normotensive diabetic patients at Debre Markos Comprehensive Specialized Hospital, Debre Markos, Northwest, Ethiopia.

1.3. SIGNIFICANCE OF THE STUDY

Currently, NCDs including hypertension, diabetes, and CVDs are increasing like an epidemic in the world with the highest-burden in middle and low-income countries due to dyslipidemia and hyperglycemia. The problem is disturbing and causing major concern in resource-limited countries like Ethiopia.

The study will be helpful to evaluate serum lipid profiles in hypertensive diabetic and normotensive diabetic patients. It will be significantly important to give direction for physician for patient management. This study also will serve as a baseline for other studies and also can give valuable information for policy makers.

CHAPTER TWO: LITERATURE REVIEW

Diabetes mellitus is one of the most common non-communicable diseases, affecting the health of a significant number of the population throughout the world (19). Diabetics, development of atherosclerosis and HTN are accelerated due to insulin resistance, associated with derangement in lipoprotein components of TC values, TG, LDL-C, and HDL-C level (7).

A comparative cross-sectional study conducted in Jamaica on lipid profile of normotensive and hypertensive T2DM patients indicated that hypertensive diabetic females had significantly higher serum concentrations of TC ($286.9 \pm 63 \text{ mg/dL}$) than male ($222.74 \pm 60.71 \text{ mg/dL}$). Blood glucose was significantly associated with LDL-C and TC concentrations in diabetic subjects ($r = 0.36$, and $r = 0.33$), respectively (23).

A retrospective comparative cross-sectional study conducted in Pakistan on lipid profiles among hypertensive and normotensive diabetic patients indicated that hypertensive diabetics had significantly higher mean \pm SD of serum concentrations of TC ($194.68 \pm 31.75 \text{ mg/dL}$), TG ($196.95 \pm 78.45 \text{ mg/dL}$) than normotensive diabetic patients of TC ($179.07 \pm 38.61 \text{ mg/dL}$), TG ($165.73 \pm 48.80 \text{ mg/dL}$), and while their HDL-C of HDM ($32.75 \pm 4.47 \text{ mg/dL}$) lower than HDL-C of NDM ($39 \pm 2.94 \text{ mg/dL}$) were statistically significant (7).

A comparative cross-sectional study conducted in Iraq, there was statistically significant higher the level of TC in HDM female than NDM female patients, ($189.9 \pm 6.8 \text{ mg/dL}$ vs $163.33 \pm 23.7 \text{ mg/dL}$) respectively. There was statistically significant higher level of TC in HDM male than NDM male patients, ($250.26 \pm 31.87 \text{ mg/dL}$ vs $204.6 \pm 28.99 \text{ mg/dL}$) respectively. There was also statistically significant lower level of HDL in HDM female than NDM female patients, ($43.83 \pm 6.7 \text{ mg/dL}$ vs $47.33 \pm 7.5 \text{ mg/dL}$) respectively. A statistically significant increased in LDL-C level in HDM female patients than NDM female patients (and $111.42 \pm 23.2 \text{ mg/dL}$ vs $94 \pm 22.94 \text{ mg/dL}$) respectively. There was not statistically significant lower the level of HDL in HDM male than NDM male patients, ($47.52 \pm 7.08 \text{ mg/dL}$ vs $47 \pm 5.8 \text{ mg/dL}$) respectively. The level of TG was higher and hypertensive diabetic male than in diabetic male patients with no significant differences ($181.11 \pm 77.53 \text{ mg/dL}$ vs $123.21 \pm 45.77 \text{ mg/dL}$) respectively (4).

A comparative cross-sectional study conducted at Rajasthan, India on lipid profiles among HDM and NDM patients indicated that HDM had significantly higher mean±SD level of TG (316.45±75.3 mg/dL) than level of TG (254.42±49.4 mg/dL) NDM patients. Mean±SD level of TC (211.7±34.9 mg/dL vs 208.4±33.8 mg/dL) and HDL-C (41.95±6.5mg/dL vs 42.0±4.86 mg/dL) was not statistically significant in HDM patients compared to NDM patients respectively (24).

A comparative cross-sectional study conducted in India on lipid profiles among HDM and NDM patients indicated that NDM 75 (15%) patients had deranged total cholesterol, while in HDM 142 (28.4%) patients had deranged total cholesterol levels. The difference in both group on basis of TC was statistically highly significant with $P < 0.05$. While TG levels overall 48.4% patients had deranged TG levels. In NDM only 84 (16.8%) patients had deranged TG while in HDM 158 (31.6%) patients had deranged TG levels. The difference in both group on basis of TG was statistically highly significant with $P < 0.05$. While HDL levels in both the group 45% patients have deranged HDL levels. In NDM only 75 (15) patients had deranged HDL-C levels while in HDM 150 (30%) patients had deranged HDL levels. The difference in both groups on the basis of HDL was statistically highly significant with $P < 0.05$. Similarly, While LDL levels overall 48.4% patients had deranged LDL levels. While in HDM 158 (31.6%) patients had deranged LDL levels. The difference in both groups on the basis of LDL was statistically highly significant (25).

A comparative cross-sectional study conducted Bangladesh investigated that there was no significant differences in the mean concentrations of TC, TG, HDL-C, LDL-C, and glucose between hypertensive diabetics and normotensive diabetics patients ($P > 0.05$) (26).

A prospective observational cohort study conducted in Saudi Arabia investigated that study has demonstrated that TC, TG, and LDL-C were significantly correlated with systolic and diastolic BP, and raised among hypertensive diabetic patients as compared to non-hypertensive diabetic ($p < 0.001$ for all lipids). However, HDL-C was inversely correlated with SBP and DBP with normotensive diabetic patients (27).

A comparative cross-sectional study conducted in Nigeria, on normotensive and hypertensive T2DM patients indicated that BMI of the hypertensive diabetics were significantly greater than normotensive T2DM. All BP indices were significantly higher in hypertensive diabetic patients. All measures of dyslipidemia were higher in the hypertensive diabetics than normotensive diabetic patients, with the exception of HDL-C, which was lower in the hypertensive diabetics compared with the normotensive. The mean level of TC was higher in the hypertensive diabetics patients than normotensive diabetic patients (2). There is also a similar finding in study in Nigeria investigated that the mean values of SBP, DBP, TC, TG, LDL-C, and FBS were significantly higher in hypertensive diabetic patients. But the mean level of HDL-C was significantly lower in hypertensive diabetic patients (2).

Thus, the current study is trying to look at these contradictory concepts in this new study setting, in DMCSH, Northwest, Ethiopia.

CHAPTER THREE: OBJECTIVES

3.1. GENERAL OBJECTIVE

- ❖ To assess lipid profile of hypertensive diabetic patients in comparison with normotensive diabetic patients at Debre Markos Comprehensive Specialized Hospital, Debre Markos, Northwest, Ethiopia from June 15 to August 25, 2020.

3.2. SPECIFIC OBJECTIVES

- ✓ To compare lipid profile in hypertensive and normotensive diabetic patients.
- ✓ To compare lipid profile in hypertensive and normotensive diabetic male and female patients.
- ✓ To determine correlation of lipid profile with fasting blood sugar, anthropometric, and blood pressure.

CHAPTER FOUR: METHODS AND MATERIALS

4.1. STUDY AREA

The study was conducted in chronic illness clinic at Debre Markos Comprehensive Specialized Hospital, which is one of the oldest public hospitals in Ethiopia. It was established in 1957 E.C. The hospital is located in Debre Markos about 300 km Northwest of Addis Ababa. The hospital provides health service to more than 3.5 million people (28). It has 140 beds with 152 staff for inpatients and outpatients. The internal medicine department is one of the departments serving both regular and referral patients for chronic healthcare services. Currently 100 health centers and four district hospitals are available in the catchment area of the referral hospital. Chronic illness clinic runs twice weekly (on Monday and Tuesday) and provides integrated diabetic care for more than 5000 diabetic patients.

4.2. STUDY DESIGN AND PERIOD

The hospital-based comparative cross-sectional study was conducted from June 15 to August 25, 2020 at DMCSH.

4.3. POPULATION

4.3.1. SOURCE POPULATION

Adult all diabetes mellitus patients who attended DMCSH chronic illness clinic for their follow up.

4.3.2. STUDY POPULATION

Adult hypertensive diabetic and normotensive diabetic patients who were attending DMCSH chronic illness clinic during the study period and who fulfill the inclusion criteria.

4.4. SAMPLE SIZE DETERMINATION

Sample size of study participants was determined in comparison between two means of equal sample size using the following assumptions; desired precision or margin of error (d)= 5%, confidence level = 95% (two-sided) ($Z_{\alpha/2}=1.96$), 80% power ($\beta=0.85$) and 1:1 ratio of HDM and DM. The mean level of TC in patients with HDM was 194.68 mg/dL and standard deviation 31.75 and the mean level of TC in patients with NDM was 179.07 mg/dL and standard deviation 38.6 used (7).

S1 = Standard deviation of HDM

S2= Standard deviation of NDM

u1= Mean concentration of HDM

μ_2 = Mean concentration of NDM

N = The minimum total sample size

$$N = (S_1^2 + S_2^2) (Z_{\alpha/2} + z_{\beta})^2 / (\mu_1 - \mu_2)^2$$

$$N = (31.75^2 + 38.6^2) (1.96 + 0.85)^2 / (194.68 - 179.07)^2$$

$$N = 19724.6355 / 243.6721$$

N = 81 HDM and 81 NDM patients. So, the minimum total sample size was 162.

4.5. SAMPLING TECHNIQUE

Consecutive sampling technique was used until the required sample sizes were attained.

4.6. ELIGIBILITY CRITERIA

4.6.1. INCLUSION

Age greater or equal to 18 years and at least one year follow up hypertensive diabetic and normotensive diabetic patients were included.

4.6.2. EXCLUSION

TB, HIV patients, pregnant women, oral contraceptive users, lactating women, and lipid-lowering drug users were excluded.

4.7. STUDY VARIABLES

4.7.1. DEPENDENT VARIABLES

Serum lipid profile (TC, TG, LDL-C, and HDL-C)

4.7.2. INDEPENDENT VARIABLES.

- ❖ Socio-demographic data (Age, Sex, Occupational status, Educational status, Residence, Marital status)
- ❖ Anthropometric data (BMI, WC and HC)
- ❖ BP (SBP and DBP)
- ❖ Clinical data (Duration of DM)
- ❖ Fasting blood glucose

4.8. OPERATIONAL DEFINITIONS

Dyslipidemia: defined as TC \geq 200 mg/dl or TG levels \geq 150 mg/dL or HDL-C $<$ 40 mg/dL, and or LDL-C \geq 100 mg/dL or both (10)

Fasting plasma glucose: Plasma glucose level when expressed in mg/dl of blood which is measured by taking a blood sample from a person who was not taking orally for at least 8-h prior to taking the blood sample (29)

Normotensive: SBP is <140 mmHg or DBP <90 mmHg (7).

Hypertensive: SBP is \geq 140 mmHg or DBP is \geq 90 mmHg (7).

Lipid Profile: A panel of blood tests for measurement of lipids in serum, such as TC, TG, and HDL-C and LDL.

Good glycemic control: Average of last three FSG measurements 80-130 mg/dL (30).

Poor glycemic control: Poor glycemic status has serum glucose \geq 130 mg/dL (30).

4.9. DATA COLLECTION AND MATERIALS

The questionnaire was first prepared in English and translated to Amharic by an expert. Then it was translated back into English to check for consistency.

- Disposable syringe with needle
- Controls (both normal and pathological)
- FC-200 clinical chemistry analyzer
- 70% alcohol
- Multi-calibrator
- Pasteur pipette
- Serum separator tube
- Stadiometer
- Centrifuge
- Cotton
- Questionnaires
- Pencil-sharpener
- Tourniquet
- Glove
- Weight scale
- Safety box
- Analogue BP apparatus
- Tape meter

4.9.1. SOCIO-DEMOGRAPHIC DATA

Socio-demographic data were collected by trained nurses using face-to-face interview using semi-structured questionnaire after obtaining informed consent from study participants.

4.9.2. BLOOD PRESSURE AND ANTHROPOMETRIC MEASUREMENT

Blood Pressure measurement: BP was measured by a physician using standard BP measurement protocol after the patient had rested for 10 minutes. The mean of two measurements was recorded for SBP. The mean of two values was recorded for DBP. Hypertension was defined as an average SBP \geq 140 mmHg and DBP \geq 90 mmHg without antihypertensive medication according to JNC VII on Prevention, Detection. Normotensive was defined as an average SBP<140 mmHg and DBP <90 mmHg (7).

Height measurement: Height was measured using stadiometer (Infiniti Med Lab Pvt. Ltd., India). Participants stood erect on the floorboard of the stadiometer with their back to the vertical backboard of the stadiometer (13).

Weight measurement: First the weight scale (Infiniti Med Lab Pvt. Ltd., India) would turn to zero then participants were asked to remove extra layers of clothing, shoes, jewelry, and any items in their pockets. Next, the participant were asked to step on the scale backward then body weight was evenly distributed between both feet, arms hang freely by the sides of the body, palms toward thighs and head was up and facing straight ahead then the weight is recorded to nearest 0.1 kg (100 gm.) (26).

Waist circumference measurement: Participants waist circumference was measured at the level of the iliac crest and the umbilicus with a tape measure to evaluate abdominal obesity (10).

Hip circumference: Hip circumference was measured over light clothing at the level of greater trochanters with the subject in standing position and both feet together (10).

4.10. DATA QUALITY CONTROL AND MANAGEMENT

4.10.1. Pre-analytical phase

After the study participants had been asked for their consent to be interviewed and about 5 ml blood was withdrawn from the study participants using serum separator tube, who had fasted overnight. In addition, the questionnaire was filled by face to face interview and some anthropometric indicators were also assessed and measured side by side as well. After collected the specimen was transported to a clinical chemistry unit of the DMCSH laboratory for analysis. The collected blood sample was left about 30 minutes at room temperature until clotted. Then the clotted blood samples was centrifuged for 5 minutes at 4000 revolutions per minute to separate serum from formed elements.

4.10.2. Analytical phase

After checking the expiry date of the reagents and control, Biochem FC-200 clinical chemistry analyzer (USA), was checked for delivering the correct result by using normal and pathological controls. Before any patients' sample was processed, dual quality controls (normal and pathological) was performed and the patient's result was taken after the controls was passed. All necessary procedures and steps were followed based on the manufacturer's instructions. Then

TG, HDL-C, TC, and glucose were measured in serum with biochem FC-200 fully automated chemistry analyzer

4.10.3. Post-analytic

The LDL-C was calculated as: $[LDL-C] = [TC] - [HDL-C] - [TG/5]$ mg/dL by the Friedewald equation (31) .Data were recorded in the document. Laboratory results were checked for completeness on a daily basis by the principal investigator. All lab results were sent to chronic illness clinic DMCSH

4.11. DATA PROCESSING AND ANALYSIS

After cleaning and coding, data were entered and analyzed with statistical package for social sciences version 25(SPSS Inc., Chicago, IL, USA). Descriptive statistics were used to analyze the data;for categorical variables, percentage and frequencies were used, whereas mean, standard deviation and range were used for continuous variables. Shapiro-wilk test were used to check normal distribution. No outlier. A comparison of lipid profiles between hypertensive diabetic and normotensive diabetic patients were done by an independent t-test. Pearson's correlation coefficient was used to assess the relationship between lipid profile and blood glucose level. Data were presented by table and text. P-value ≤ 0.05 was considered as statistically significant.

4.12. ETHICAL CONSIDERATION

Data collections were carried out after approval of the research proposal by the institutional review board (IRB) of Jimma university, institute of health with letter protocol number IRB000120/2020, and support letter from school of medical laboratory science was submitted to clinical director of DMCSH. After getting permission from all responsible body, the data collector informed the patients by reading or giving to read the information sheet which was translated to patients' language about the objectives of the study. Informed consent was obtained from the participants before running the questionnaires and blood sample collection. All study participants read and signed on the informed consent, but if the study participants are illiterate the data collector read and took the sign or thump impression when they agreed. To ensure confidentiality of data, study participants were identified using codes and unauthorized persons had no access to the collected data. Finally, the patient's laboratory results were submitted to chronic illness clinic for appropriate intervention and awareness creation on dyslipidemia to participants.

4.13. DATA DISSEMINATION AND UTILIZATION OF RESULTS

The finding of the study will be disseminated to the School of Medical Laboratory Sciences, and Jimma university health science library to serve as baseline data for further research activities. The finding of this study will be sent for publication in peer-reviewed journals to make it accessible for the scientific world. It will also be presented on different scientific forums.

CHAPTER FIVE: RESULTS

5.1. SOCIO-DEMOGRAPHIC CHARACTERISTICS OF PARTICIPANTS

A total of 162 (81 HDM and 81 NDM) study participants were participated in the study. From HDM patients 43(53.1%) were females and 44(54.3%) of NDM patients were males. The mean age of HDM patients was 53.94 ± 10.87 and NDM patients was 43.83 ± 10.04 years. One hundred twenty eight (79%) of the study participants were married. Majority, 125(77.2%) of the study participants were urban residents (Table 1).

Table 1: Socio-demographic characteristics and behavioral related factor of the study participants at DMCSH, Debre Markos, Northwest, Ethiopia, 2020.

Socio-demographic variables(n=162)		HDM(n=81)	NDM(n=81)
Age		53.94±10.87	43.83±10.04
Sex	Male	38(46.9)	44(54.3)
	Female	43(53.1)	37(45.7)
Educational status	Can not read and write	26(32.1)	17(21.0)
	Can read and write	20(24.7)	24(29.6)
	Primary school	9(11.1)	3(3.7)
	High school	18(22.2)	22(27.2)
	College and above	8(9.9)	15(18.5)
Marital status	Single	1(1.2)	9(11.1)
	Married	65(80.2)	63(77.8)
	Divorced	2(2.5)	5(6.2)
	Widowed	13(16.0)	4(4.9)
Residence	Urban	61(75.3)	64(79.0)
	Rural	20(24.7)	17(21.0)
Occupational status	Government employed	15(18.5)	19(23.5)
	House wife	17(21.0)	13(16.0)
	Merchant	18(22.2)	24(29.6)
	Private worker	12(14.8)	11(13.6)
	Farmer	19(23.5)	14(17.3)

5.2. COMPARISON OF LIPID PROFILE AMONG HYPERTENSIVE DIABETIC AND NORMOTENSIVE DIABETIC PATIENTS.

The overall prevalence of dyslipidemia among hypertensive and normotensive diabetic patients was 76(93.8%) and 54 (67.7%), respectively. Hypertensive diabetic participants had 71 (87.7%) of elevated LDL-C, 69(85.2%) of elevated TC , and 68(84%) of elevated TG (Figure 1).

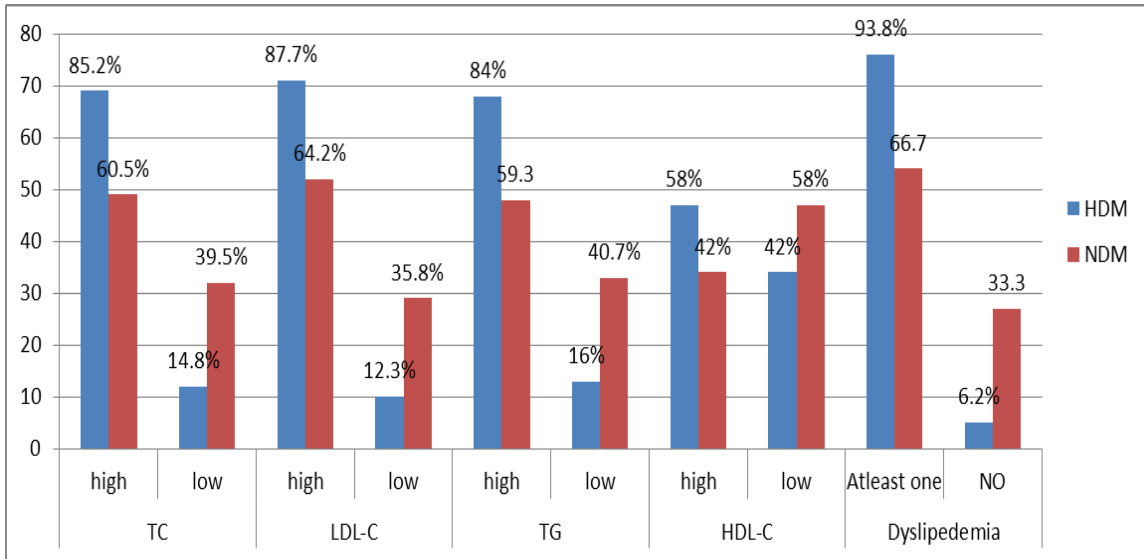


Figure 1: Prevalence of dyslipidemia among hypertensive diabetic and normotensive diabetic patients

The result showed that the mean \pm SD of duration of diabetes mellitus (5.99 \pm 2.44 year vs 4.25 \pm 2.70 year), WC (94.68 \pm 6.58cm vs 84.43 \pm 6.05cm), SBP(144.81 \pm 10.97mmHg vs 115.68 \pm 10.60mmHg), and DBP (92.35 \pm 7.79mmHg vs 75.19 \pm 5.03mmHg) were significantly higher in HDM as compared to NDM patients ($P < 0.05$), respectively. However, the mean concentration of fasting blood glucose was not significantly higher in HDM compared to NDM patients.

All lipid profile (TG, TC, LDL-C) were significantly higher in HDM patients compared to NDM patients except HDL-C which was significantly lower in NDM patients compared to normotensive diabetic patients. TC mean level value in HDM patients was significantly higher than NDM patients ($P > 0.05$) (Table 2).

Table 2: Comparison of lipid profile, anthropometric and clinical characteristics of hypertensive diabetic and normotensive diabetic participants from June at DMCSH, Debre Markos, Northwest, Ethiopia, 2020.

Variables	HDM (Mean±SD)	NDM (Mean±SD)	P – value
BMI (Kg/M ²)	24.04±2.66	23.38±2.68	0.114
WC (cm)	94.68±6.58	84.43±6.05	0.001**
HC (cm)	97.04±8.66	95.42±8.03	0.22
DDM (year)	5.99±2.44	4.25±2.70	0.001**
SBP (mmHg)	144.81±10.97	115.68±10.60	0.001**
DBP (mmHg)	92.35±7.79	75.19±5.03	0.001**
FBS (mg/dL)	144.72±40.23	137.33±41.64	0.253
TG (mg/dL)	222.65±54.10	191.38±67.20	0.001**
TC (mg/dL)	277.35±58.60	233.56±57.45	0.000**
HDL-C (mg/dL)	36.43±6.64	46.30±13.21	0.000**
LDL-C (mg/dL)	196.38±57.20	149.0±58.72	0.000**

BMI: Body mass index, WC: Waist circumference, HC: Hip circumference, DuDM: Duration of diabetes, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, FBS: Fasting blood sugar
 * Statistically significant at ≤ 0.05 ** statistically significant at ≤ 0.001 . TG: Triglyceride; TC: Total cholesterol; HDL-C: High density lipoprotein cholesterol; LDL-C: Low density lipoprotein cholesterol.

The mean level of TC and LDL-C concentration was statistically significant higher in HDM males than NDM males ($p < 0.05$). The mean level of HDL-C concentration was higher in normotensive diabetic males (48.48 ± 14.83) than in HDM males (38.13 ± 6.87) ($p < 0.002$) (Table 3).

Table 3: comparison of lipid profile in hypertensive diabetic male and normotensive diabetic male at DMCSH, Debre Markos, Northwest, Ethiopia, 2020 .

Variables	HDM male (Mean±SD)	NDM male (Mean±SD)	P value
TG (mg/dL)	222.95±53.94	196.57±73.83	0.066
TC (mg/dL)	277.00±55.74	236.55±57.74	0.002*
HDL-C (mg/dL)	38.13±6.87	48.48±14.83	0.001**
LDL-C (mg/dL)	194.28±53.36	148.75±60.15	0.001**

The mean level of TC , LDL-C and TG concentration was significantly higher in HDM females than NDM females (p<0.05). The mean level of HDL-C concentration was significantly decreased in HDM females than NDM females (p=0.0001) (Table 4).

Table 4: Comparison of lipid profile in hypertensive diabetic females and normotensive diabetic females DMCSH, Debre Markos, Northwest, Ethiopia,2020.

Variables	HDM female	NDM female	P value
TG (mg/dL)	222.4±54.82	184.89±58.71	0.004*
TC (mg/dL)	277.65±62.08	230±57.69	0.001**
HDL-C (mg/dL)	34.93±6.14	43.73±10.61	0.000**
LDL-C (mg/dL)	198.24±60.95	149.29±57.8	0.000**

5.3. CORRELATIONS BETWEEN LIPID PROFILES WITH FBS, DDM AND ANTHROPOMETRIC MEASUREMENTS OF STUDY PARTICIPANTS

In our study, positive correlations were found between SBP and DBP with TC, TG, and LDL-C while HDL-C showed statistically significant negative correlation with SBP and DBP. DDM also significantly correlated with LDL-C and TC (Table 5).

Table 5: Correlation between lipid parameters versus BMI, BP and FBS among study participants at DMCSH, Debre Markos, Northwest, Ethiopia, 2020.

	TC	HDL-C	TG	LDL-C
	r (p)	r (p)	r (p)	r (p)
DDM	0.2 (0.007*)	0.1 (0.22)	0.04 (0.6)	0.22 (0.005*)
BMI	0.15 (0.06)	-0.04 (0.63)	0.05 (0.5)	0.14 (0.07)
WC	0.21 (0.005*)	-0.28 (0.000**)	0.14 (0.07)	0.24 (0.002)
HC	0.02 (0.8)	-0.08 (0.31)	0.005 (0.95)	.004 (0.96)
SBP	0.35 (0.001**)	-0.38 (0.000**)	0.26 (0.001**)	0.37 (0.001**)
DBP	0.37 (0.001**)	-0.41 (0.001**)	0.27 (0.001**)	0.39 (0.001)
FBS	0.2(0.02*)	-0 .011 (0.89)	0.18 (0.025*)	0.15 (0.05*)

r: Pearson's correlation coefficient; p: p-value.

* Statistically significant at ≤ 0.05 ** statistically significant at ≤ 0.001 .

CHAPTER SIX: DISCUSSION

This thesis compared lipid profiles between hypertensive diabetic and normotensive diabetic patients at Debre Markos Comprehensive Specialized Hospital. In the present study, we found that mean level of TC, TG, and LDL-C were significantly higher in hypertensive diabetic patients compared to normotensive diabetic patients while HDL-C was significantly lower in hypertensive diabetic patients than normotensive diabetic patients. This finding was consistent with study conducted in Iraq (4,8).

In our study the prevalence of dyslipidemia among hypertensive and normotensive diabetic patients was 76(93.8%) and 54 (67.9%), respectively. Hypertensive diabetic participants had 71 (87.7%) of elevated LDL-C, 69(85.2%) of elevated TC , and 68(84%) of elevated TG. This finding was similar with study India (32). Our finding was also similar study conducted in India (33). This finding was also similar with study conducted in Pakistan (34)

In our study the mean level TC,TG and LDL-C concentration of hypertensive diabetic patients was significantly higher than normotensive diabetic patients ($p<001$ for all). While mean level of HDL-C was significantly lower in hypertensive diabetic patients than normotensive diabetic patients($p<001$). This study in line with study was conducted in Nigeria (2). This study was also similar with study conducted in Turkey (35). This study was comparable with study done in Pakistan (7). This finding was also similar with study conducted in India (24). This finding was similar with study conducted in Iraq (4). But our result was in contrast to study done in Bangladesh (26). Our result was also in contrast to study done in Iraq (8). Our finding was in contrast to study conducted in Jamaican (23). This finding was also in contrast to study conducted in Pakistan (34). The possible reason of variation of the result might be due to geographical area, source population, sample size,age,obesity,reference range,sex, life style and Lab method.

Mean level of TC, LDL-C and TG of hypertensive diabetic female patients were significantly higher than normotensive diabetic male patients ($p=001$ for all). While there was reduced mean level of HDL-C concentration in hypertensive diabetic female patients than normotensive diabetic female patients ($p<001$). Mean level of TC, LDL-C and TG of hypertensive diabetic male patients were statistically significant higher than normotensive diabetic male patients ($p<001$). While there were reduced mean level of HDL-C in hypertensive diabetic male patients

than normotensive diabetic male patients ($p < 0.001$). This finding is also in line with study done in Pakistan (7). This finding is also similar with study done at puducherry, India (24). This study in line with study was conducted in Nigeria (2). This study was also similar with study conducted in Turkey (35). This study was comparable with study done in Pakistan (7). This finding was similar with study conducted in Iraq (4). But our result was in contrast to study done in Bangladesh (26). Our result was also in contrast to study done in Iraq (8). Our finding was in contrast to study conducted in Jamaican (23). This finding was also in contrast to study conducted in Pakistan (34). The possible reason of variation of the result might be due to geographical area, source population, sample size, age, obesity, reference range, sex, life style and Lab method. In our study the mean level of TC and LDL-C concentration was significantly higher in hypertensive diabetic males than normotensive diabetic males. The mean level of HDL-C concentration was higher in normotensive diabetic males than hypertensive diabetic males. The mean level of TC, LDL-C and TG concentration was significantly higher in hypertensive diabetic females than normotensive diabetic females. The mean level of HDL-C concentration was significantly decreased in hypertensive diabetic females than normotensive diabetic females. This finding was in line with study done in Iraq (4). This finding was also similar with study conducted at Abeokuta, Nigeria (12).

Our study showed that the mean levels of SBP and DBP were significantly higher in HDM than NDM patients. Mean level of FBS concentration was not significantly higher in HDM compared to NDM patients ($P > 0.05$). This study was comparable with study done in Pakistan (7). Our result was similar with study conducted in Turkey (35). Our finding was similar with study conducted in Jamaican (23). The reason for similarity of the result might be due to study design, age similarity, similarity in reference range.

In this study, we also tried to correlate lipid profiles with various clinical and anthropometric variables. There were statistically significant positive correlations between SBP and DBP with TC, TG, and LDL-C while HDL-C was statistically significant negative correlations with SBP and DBP. The present study had been comparable with study done in Saudi Arabia (27). The reason for similarity of the result might be due to study design, age similarity, similarity in reference range.

In our study duration of DM also significantly correlated with LDL-C and TC. Blood glucose was not significant correlation with LDL-C and TC concentrations in diabetic participants. This study inconsistent with study conducted in Jamaican (23). The possible reason of variation of the result might be due to geographical area,source population, sample size,age,obesity,reference range,sex, life style and Laboraory diagnosis method.

CHAPTER SEVEN : CONCLUSIONS AND RECOMMENDATIONS

7.1. CONCLUSIONS

- ❖ There was statistically significant difference in lipid profile level hypertensive diabetic patients and normotensive diabetic patients.
- ❖ Hypertensive diabetic had high dyslipidemia prevalence as compared to normotensive diabetic patients.
- ❖ The mean level of TC , LDL-C and TG was significantly higher in hypertensive diabetic females and males.
- ❖ There were statistically significant positive correlations between SBP and DBP with TC, TG, and LDL-C
- ❖ HDL-C was statistically significant negative correlations with SBP and DBP
- ❖ Duration of DM significantly correlated with LDL-C and TC

7.2. RECOMMENDATIONS

Based on the above research finding the following recommendations are forwarded

- ❖ There should be frequent monitoring of lipid profile among HDM and NDM patients
- ❖ Clinical care of the diabetic patients for better control of blood glucose
- ❖ Further studies should be conducted with larger sample size using prospective study
- ❖ Health information should be given HDM and NDM patients

LIMITATION OF THE STUDY

- Sample size was small.
- More over, we could not compare the effects of lipid profile variation due to diet, physical activity, medication.
- Being a cross-sectional study by design it cannot associate causal relationships between the factors under study.

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ANNEXES

ANNEX I: INFORMATION SHEET (ENGLISH VERSION)

RESEARCH PROJECT: LIPID PROFILE IN HYPERTENSIVE DIABETIC PATIENTS AT DEBRE MARKOS COMPREHENSIVE SPECIALIZED HOSPITAL, DEBRE MARKOS, NORTHWEST, ETHIOPIA

Sponsoring organization: School of Medical Laboratory Sciences, Faculty of Health Sciences, Institute of Health and Jimma University.

Name of Principal Investigator: Yayeh Melaku

Advisors

Mr. Shiferaw Bekele

Mr. Waqtole Cheneke

Introduction: Dear participants you are kindly requested to take part in this research project as a study participant voluntarily. Read the information provided in this sheet carefully and then respond freely and voluntarily to what the investigator interviews you.

Aim of the research project: To compare serum lipid profile hypertensive diabetic patients and normotensive diabetic patients at Debre Markos Comprehensive Specialized Hospital, Debre Markos, Northwest, Ethiopia.

Procedure: If you agree to take part in the study, the investigator or a health worker will give you verbal and/or written information about the study and you will be given the consent form to sign, the physician or health professional will ask you some questions about your and perform a complete medical examination and assess whether you qualify to participate in the study. If you are fit for the study about 5 ml of blood samples will also be collected for only the laboratory analysis of the lipid profile.

Discomforts and risks and benefits: The some of discomfort you may encounter in giving the sample is no more than when one does in his/her routine examination. But, there could be cases in which minor pain and change in color of your skin following the blood drawing occur transiently. The blood will be withdrawn by licensed health care professionals in the hospital and appropriate care will also be taken. You will not be provided with any direct incentives for your participation in the research. In addition, based on the results obtained from the research you will have cared accordingly or the results may serve you as baseline data. In addition, the result of the

study will be beneficial for the better prevention and care of hypertensive diabetic patients complication. Hence, you are indirectly benefiting other patients and society in this aspect.

Confidentiality: All pieces of information about the patients will be kept confidential. Logbooks used in the laboratory will have no names but codes. The information sheet that links the coded number to a patient name will be locked inside a box and it will not be revealed to anyone except your physician and the principal investigator. You have the full right to withdraw from participating in this study at any time before and after consent even without explaining the reason. Your decision will not affect your right to get health service you are supposed to get otherwise.

Right to refuse or withdraw: You have the full right to withdraw from participating in the study at any time before and after consent without explaining the reason and not respond to some or all the questions. Your decision will not affect your right to get health service you are supposed to get otherwise

Contact information: If you have any questions or concerns, you can contact Yayeh Melaku Belay at any time using the listed address. **Mob:** 09-10-48-99-50

email: yayehmelaku@gmail.com.

Thank you

ANNEX II- INFORMATION CONSENT FORM

I confirm that, as I give consent to participate in the study, it is with a clear understanding of the objectives and conditions of the study and with recognition of my right to withdraw from the study if I change my idea.

I have been given the necessary information about the research. I have also been assured that I can withdraw my consent at any time without penalty or loss of benefits. The proposal is explained to me in the appropriate language I understand. I_____ do hereby give consent to Dr. /Mr. /Mrs. /Miss _____to include me in the proposed research.

Participant code _____

Participant (signature) _____date_____

Name of the data collector_____

Data collector (signature) _____date_____

ANNEX III: QUESTIONNAIRE

Data collection questionnaire designed to take information socio-demographic characteristics and clinical data among hypertensive diabetic patients who attend at Debre Markos Comprehensive Specialized Hospital, Debre Markos, Northwest, Ethiopia.

Code: _____

Sr. No.	Questions	Possible Responses
Part I Socio-Demographic Characteristics		
1.	Age (in years)	_____
2.	Sex	1. Male 2. Female
3.	Educational status	1. Can not read and write 2. Can read and write 3. Elementary 4. High school 5. College and above
4.	Marital status	1. Single 2. Married 3. Divorced 4. Widowed
5.	Residency	1. Urban 2. Rural
6.	Occupational status	1. Civil servant 2. Housewife 3. Merchant 4. Private worker 5. Farmer 6. Other specify-----
Part II Clinical data		
7.	Duration of DM (years)	
8.	Do you have HTN?	1. Yes 2. No
Part III Anthropometric Measurement		

9.	Height(m)	
10.	Body weight (Kg)	
11.	Waist circumference (cm)	
12.	Hip circumference (cm)	
Part IV Blood Pressure Measurement		
13.	Systolic pressure (mmHg)	
14.	Diastolic pressure (mmHg)	

Part V: Laboratory result report form

Code	Sex	Age (years)	HDL (mg/dl.)	LDL (mg/dl)	T chol (mg/dl)	TG (mg/dl)	GLU (mg/dl)	

Name of laboratory investigator ----- Signature-----date-----

ለጥናቱ ተሳታፊዎች የሚሰጥ መረጃ (AMHARIC VERSION INFORMATION SHEET)

የጥናቱ ርዕስ: በደብረ ሚቆስ ኮምፕሌንስቭ ስካላይዝድ ሆስፒታል የደም ግፊት ደም ሰኳር ሕመምን ከደም ሰኳር ሕመም ጋር የደም ስብ "profile" ንጽጽር ላይ ማጥናት ደብረ ሚቆስ፣ ኢትዮጵያ፡፡

ተመራማሪ: ያየህ መላኩ

አማካሪ: 1. ሸፈራው በቀለ

2. ዋቅቶላ ጩቀ

የተቋሙ ስም: - በደብረ ሚቆስ ኮምፕሌንስቭ ስካላይዝድ ሆስፒታል ፣ ሜዲካል ላቦራቶሪ ትምህርት ክፍል ወጪዎን የሚሸፍነው ተቋም: - ጅም ዩኒቨርሲቲ

መግቢያ: - ይህ የማህበራዊ ቅፅ አሁን እርስዎ እንዲሰጡ የምንጠይቀዎትን ምርመራ ጥናት የሚያብራራ ነው፡፡ በዚህ ጥናት ለመሳተፍ ከመወሰንዎ በፊት ይህንን ቅፅ መረጃ ሰብሳቢዎቹ በሚሰጡበት ጊዜ በጥሞና በማድመጥ ጥያቄ ካለዎት በመጠየቅ ትክክለኛውን መልስ ይመልሱ፡፡ በዚህ ጥናት መሳተፍ ከጀመሩ በኋላ በማንኛውም ጊዜ ጥያቄ ካለዎት መጠየቅ ይችላሉ፡፡

የጥናቱ ዓላማ የደም ስብ "profile" በደብረ ሚቆስ ኮምፕሌንስቭ ስካላይዝድ ሆስፒታል የደም ግፊት ደም ሰኳር ሕመምን ከ ሰኳር ሕመም ጋር ንጽጽር ላይ ማጥናት፣ በደብረ ሚቆስ፣ ሰሜን ምዕራብ ኢትዮጵያ፡፡ የጥናቱ ሂደት: ይህን ጥናት ለማካሄድ የደም ናሙና በመወሰድ የላቦራቶሪ ምርመራ ማድረግ ነው፡፡

ከጥናቱ ጋር የተያያዘ ጉዳት/አለመሆኑት: እርስዎ በዚህ ጥናት ወስጥ በመሳተፍ ለከፋጉዳት የሚደረግ ሁኔታ አይኖርም፡፡ ደም በመወሰድበት ወቅት አነስተኛ ሕመም ሊሰማዎት ይችላል፡፡ እንዲሁም የመቅላት ሁኔታ ደም ከተወሰደበት በኋላ ላይ ሊታይ ይችላል፡፡ ነገርግን ይህ ሁኔታ የከፋጉዳት የሚያስከትል አይደለም፡፡

በጥናቱ የመሳተፍ ጥቅም: እርስዎ በዚህ ጥናት ላይ በመሳተፍ ነፃ የደም ስብልኬት (lipid profile) እና ነፃ የደም ሰኳር ምርመራ ያገኛሉ፡፡

የጥናቱ ተሳታፊ ድርሻ: በዚህ ጥናት ለመሳተፍ ፍቃደኛ ከሆኑ ከጠፍቶ ሁኔታ ጋር የተያያዘ ሌሎች የግል መረጃዎችን እንዲሰጡ ይጠየቃሉ፡፡ በመቀጠልም የሰውነት ክብደቱን እና የደም ግፊቱን እንዲለከና 5 ሜሊ መጠን ያለው የደም ናሙና ለተጠቀሰው ዓላማ እንድንወስድ ይጠየቃሉ፡፡

የጥናቱ ተሳታፊ መብት: በጥናቱ ላይ ለመሳተፍ ባይስማሙ ምንም አይነት ቅጣት የሚያስከትል ሲሆን ማንኛውም እርስዎ ሊያገኙ የሚገባውን ህክምናና ተያያዥ መብት የሚያሳጣ መሆኑን እናረጋግጣለን፡፡

የጥናቱ መረጃዎች ምሽግ ማሳሰቢያ: እርስዎን በተመለከተ የምንናገረውን መረጃ በጥናቱ ወቅትም ሆነ ከዚያ በኋላ ባሉት ጊዜያት እንዲሁም ከጥናቱ የተገኘው መረጃ ማሽግ ማሳሰቢያ ሲሆን መረጃዎቹም የሚዘጋጁበት በስም ሳይሆን በልዩ ኮድ ነው፡፡ ይኸው መረጃ በጥንቃቄ የሚዘጋጅ የተፈቀደለት ተመራማሪ እና ለህክምና ባለሙያዎች ብቻ ይህም እጅግ አስፈላጊ በሆነ ጊዜ ብቻ ካልሆነ በስተቀር ሌላ ለማንም ሰው

አይሰጥም፡፡ ማንኛውም ክርስቶስ ጋር የተያያዘ ወጠኩ በልዩ ኮድ ብቻ የሚገዛ ሰነድ ወጠቱም ለሳይንሳዊ ዓላማ ብቻ ስም በማይገልፅ ሁኔታ እንዲታተም ይደረጋል

ስለጥናቱ ሚጃ ማገኘት በፈልጉ፡ ጥናቱን በተመለከተ ግልጽ ያልሆነ ማንኛውንም ጥያቄ ካለዎት ነፃ ሆነው ከዚህ በታች ባለው አድራሻ ማጠቃለያ ይችላሉ፡

ያየህ መላኩ በላይ

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Email: yayehmelaku@gmail.com

በጣም እናመሰግናለን!!

Consent Form (Amharic Version)

ከላይ የተጻፈውን የሚጃ ቅፅ አንብቤ የጥናቱ ዓላማና ጥቅም በግልጽ ተረድቻለሁ በማንኛውም ጊዜ ከጥናቱ ያለምንም ችግርና መንገላታት መውጣት እንደምንችል ተገልጾልኛል፡፡ ከዚህም በተጨማሪም የጥናቱን ዓላማ በሚገባኝ ቋንቋ ተረድቻለሁ፡፡ በዚህ መሠረት ያለጥናት በድኑ አባላት ተፅዕኖ በሙሉ ፈቃደኝነት በዚህ ጥናት ወስጥ በመሳተፍ የሚጠበቅብኝን አስተዋፅዖ ለማጠናከር በፊርማዬ አረጋግጣለሁ፡፡

የተሳታፊው የሚጠየቀው ቁጥር -----

የተሳታፊው ፊርማ -----ቀን -----

የሚጃ ሰብሳቢው ስም -----ቀን -----

የሚጃ ሰብሳቢው ስም ፊርማ -----

ቃለ-መጠይቅ

ይህ ቃለ መጠይቅ የተዘጋጀው ለ ግፊት ሰኳር ህመምን እና ለሰኳር ህመምን በደብረ ማርቆስ ስፔሻላይዝድ ሆስፒታል በሚከታተሉ ህመምን የሚበራዊእናሰነ -ህዝብባህሪያት፣ ክለኒካል ዳታ መረጃ ለማወቅ ነው።

መለያ ቁጥር _____

ተ. ቁ	መጠይቅ	ምላሾች
ክፍል1: የሚበራዊእናሰነ -ህዝብባህሪያት		
1.	ዕድሜ(በዓመት)	_____
2.	ፆታ	1. ወንድ 2. ሴት
3.	የትምህርት ደረጃ	1. ማንበብና መጻፍ የሚችል/ችል 2. ማንበብና መጻፍ የሚችል/ችል 3. አንደኛ ደረጃ

		4. ሀላተኛ ደረጃ 5. ኮሌጅ እና ከዚያ በላይ
4.	የጋብቻሁኔታ	1. ያላገባ/ች 2. ያገባ/ች 3. የተፋታ/ች 4. በጥቅም የተለየ /ች
5.	የማምረት አካባቢ	1. ከተማ 2. ገበያ
6.	የሚሰጥበት የሥራ አይነት	1. የመንግስት ሥራተኛ 2. የቤት እመቤት 3. ነጋዴ 4. የግል ሥራተኛ 5. ገበሬ 6. ሌላ ከሆነ ይጥቀሱ
ክፍል 2: ከሊኒካል ዳታ		
7.	ስኳር በደም ከተገኘበት ሰዓት ጊዜ ሆኖ	
8.	የደም ግፊት አለበዎት	1. አወ 2. የለም
ክፍል 3 : የሰውነት ልኬት		
9.	ቁመት (ሜ)	
10.	ክብደት (ኪ.ግ)	
11.	የወገብ ዙሪያ (በሴ.ሜ)	
12.	የዳሌ ዙሪያ (በሴ.ሜ)	
ክፍል 4 : የደም ግፊት ልኬት		
13.	ሰለቶሊክ የደም ግፊት (mmHg)	
14.	ዳያስቶሊክ የደም ግፊት (mmHg)	

ክፍል 5: ላቦራቶሪ ምርመራ ወጠት

መለያ	ጾታ	እድሜ	HDL (mg/dl.)	LDL (mg/dl)	TC (mg/dl)	TG (mg/dl)	GLU (mg/dl)

ላቦራቶሪውን የሰራውስም-----ፊርማ-----ቀን-----

ANNEX IV: SOP LIPID PROFILE AND GLUCOSE IN BIOCHEM FC-200 CLINICAL CHEMISTRY ANALYZER

Laboratory procedures for blood specimen collection and processing.

- 1). A sterile, dry 5ml plastic syringe was selected and attached to an appropriate needle.
- 2). A tourniquet was tied on the upper arm of the patient and was asked to make a fist.
- 3). Cotton wool soaked in 70% alcohol was used to clean the skin for vein puncture.
- 4). Vein puncture was used with the bevel of the needle appropriately angled at 30^o.
- 5). About 5mls of blood was collected from volunteer patients.
- 6). The needle was removed carefully and the puncture site pressed with a piece of cotton wool to stop bleeding.
- 7). The needle from the syringe was carefully disposed off properly in safety box.
- 8). The site of vein puncture was inspected for bleeding. A piece of cotton wool was placed on the site.
- 9). The blood was transferred gently to the test tube and labeled with participant identification number.

10).The sample was allowed to stand to clot for 30 minute and centrifuge at 400 rpm for 5 minutes.

11). Serum sample was ready for analysis of lipid /glucose level (36,37) .

Fasting blood glucose (FBG) determination Principle

Blood glucose determination was done by GOD method. Glucose is oxidized by the enzyme glucose oxidase (GOD) to give D- gluconic acid and hydrogen peroxide. Hydrogen peroxide in presence of the enzyme peroxidase (POD) oxidizes phenol which combines with 4-aminoantipyrine to produce a red colored quinoneimine dye. The intensity of the color developed is proportional to glucose concentration in the sample at 500nm wave length .

Reference range of FBG: Normal: 70 - 100 mg/dL, IFG: 100-125mg/dL, High FBG \geq 126mg/dL.

Colorimetric determination of total cholesterol

Total cholesterol was measured enzymatically in serum in a series of coupled reactions that hydrolyze cholesteryl esters and oxidize the 3-OH group of cholesterol. Cholesterol esters are hydrolyzed to free cholesterol by cholesterol ester hydrolase. The free cholesterol produced is oxidized by cholesterol oxidase to cholest-4-en-3-on with the simultaneous production of hydrogen peroxide, which oxidatively couples with 4-aminoantipyrine and phenol in the presence of peroxidase to yield quinoneimine dye with maximum absorption between 500-550 nm.

Reactions

The test came in the form of a commercial kit in which serum sample was incubated with enzymes and reagents from the kit and the change in absorption at 500nm was measured spectrophotometrically. This change in absorption is proportional to the concentration of total cholesterol in the serum sample and calculated by comparison with absorption changes that occur with standard solutions containing known cholesterol Concentrations.

Procedure

Ten microliter (10 μ L) serum sample was added into the sample cups and put on the sample disk which rotated to bring the desire sample cup in to position next to the sample probe for specimen sampling. About 1000 μ L reaction reagent (4-Aminophenazone, phenol, peroxidase, cholesterol esterase, and cholesterol oxidase) was pipetted into reagent bottles leveled for TC and put on reagent disk and then on the screen menu of the machine TC was entered as a parameter to be tested. The sample probe pipetted sample from the sample disk and transfers to the reaction disk

which contains cuvettes. On the other side of the machine, the reagent probe pipetted reagents from the reagent disk and transfers it into reaction disk which was a large rotatable disk holding reusable cuvettes with a stirring paddle to stir or mix thoroughly the sample and the reagents. The cuvettes was immersed into reaction water bath and incubated at 37⁰C for 5 minutes. Next the reaction disk was rotated the cells to all reaction stations including the photometer light path. Finally, the light passed through the cuvettes and absorbance of the sample was measured at 500nm.

Reference rang of TC: Desirable: TC< 200mg/dl, Borderline High: 200-240mg/dl, High: > 240mg/dl.

Serum triglyceride assay method

The method was based on the enzymatic hydrolysis of triglycerides to glycerol and free fatty acids (FFA) by lipoprotein lipase (LPL). Glycerol is converted to glycerol-3-phosphate (G3P) and adenosine-5-phosphate by glycerol kinase and Adenosine tri phosphate. G-3-P is oxidized by glycerol phosphate oxidase to form dihydroxy acetone phosphate and hydrogen peroxide (H₂O₂). In the presence of peroxidase and H₂O₂, 4-aminoantipyrine couples with phenol to form a coloured product (a quinoid dye) that can be measured spectrophotometrically at a wave length of 500nm.

Reactions Principle:

The triglyceride test came in the form of a commercial kit containing the reagents, reactants and enzymes needed. Serum samples was incubated with the kit reagents and enzymes for 5 minutes at 37⁰C and absorbance measured at 500 nm against the reagent blank and against known concentrations of standard triglyceride concentrations. The change in absorbance is proportional to the concentration of triglyceride in the serum sample.

Procedure

Ten micro liter (10μL) serum samples was added into the sample cups and put on the sample disk which rotates to bring the desire sample cup into position next to the sample probe for specimen sampling. About 1000μL buffer and 1000μL substrate was pipetted into reagent bottles labeled for TG and put on the reagent disk. Then on the screen menu of the machine TG was entered as a parameter to be tested. The sample probe pipetted sample from the sample disk and transfers to the reaction disk which contained cuvettes. On the other side of the machine, the reagent probe pipetted reagents from the reagent disk and transfered it into rotatable reaction disk

holding reusable cuvettes with a stirring paddle to stir or mix thoroughly the sample and the reagents. The cuvettes was immersed in to reaction water bath and incubated at 37⁰C for 5 minutes. Next the reaction disk was rotated the cells to all reaction stations including the photometer light path. Finally, the light was passed through the cuvettes and absorbance of the sample was measured at 500nm.

Reference range of TG: Desirable: < 150 mg/dl, Borderline High: 150-199 mg/dl, High: > 200 mg/dl.

LDL-cholesterol determination

Most of the circulating cholesterol is found in three major lipoprotein fractions: very low density lipoproteins (VLDL), LDL and HDL.

LDL-cholesterol was calculated from measured values of total cholesterol, triglycerides and HDL cholesterol according to the Friedewald equation:

$$[\text{LDL C}] = [\text{TC}] - [\text{HDL}] - [\text{TG}]/5$$

Where [TG]/5 is an estimate of VLDL-C and all values are expressed in mg/dL. The equation is derived from another equation, [TC] = [VLDL-C] + [LDL-C] + [HDL-C], but TG are easier to estimate than VLDL and [TG/5] is a good estimate of VLDL, although the Friedewald equation is not valid for calculating LDL if the serum TG is above 400 mg/dL.

Reference range of LDL: Optimum: < 100 mg/dl, Near or above optimum: 100-129 mg/dl, Borderline High: 130-159 mg/dl, High: > 159 mg/dl.

Serum HDL determination methods

The very low and the low density lipoproteins from serum were precipitated by phosphotungstate in the presence of magnesium chloride. After removal by centrifugation the clear supernatant was used for the determination of HDL-cholesterol.

Principles of the Method

The basic principle of the method was as follows. The apoB containing lipoproteins in the specimen reacted with antibodies to apoB that rendered them nonreactive with the enzymatic cholesterol reagent under conditions of the assay. The enzymes used also pegylated, and this allowed them to react only with HDL and not with antibody-bound LDL, VLDL or chylomicrons. The apoB containing lipoproteins were thus effectively excluded from the assay and only HDL was detected under the assay conditions.

The HDL-Cholesterol test was a two reagent homogenous system for the selective measurement of serum or plasma HDL-Cholesterol in the presence of other lipoprotein particles. The assay was comprised of two distinct phases. In phase one it is likely that in the presence of slightly alkaline buffer and magnesium sulfate and dextran sulfate selectively form water-soluble complexes with LDL, VLDL, and chylomicrons, which were resistant to PEG-modified enzymes.

In phase two the cholesterol concentration of HDL cholesterol was determined enzymatically by cholesterol esterase and cholesterol oxidase coupled with PEG to the amino groups (approx. 40%). Cholesterol esters were broken down quantitatively into free cholesterol and fatty acids by cholesterol esterase. In the presence of oxygen, cholesterol is oxidized by cholesterol oxidase yields cholestenone and hydrogen peroxide. In the presence of peroxidase, the hydrogen peroxide generated reacts with 4-aminoantipyrine and HSDA to form a purple-blue dye. The color intensity of this dye is proportional to the cholesterol concentration and was measured spectrophotometrically.

Procedure

Ten micro liter (10 μ L) serum samples was added into the sample cups and put on the sample disk which rotates to bring the desire sample cup into position next to the sample probe for specimen sampling. About 1000 μ L buffer and 1000 μ L substrate was pipetted into reagent bottles labeled for HDL-C and put on the reagent disk. Then on the screen menu of the machine HDL-C was entered as a parameter to be tested. The sample probe pipetted sample from the sample disk and transfered to the reaction disk which contained cuvettes. On the other side of the machine, the reagent probe pipetted reagents from the reagent disk and transfered it into rotatable reaction disk holding reusable cuvettes with a stirring paddle to stir or mix thoroughly the sample and the reagents. The cuvettes was immersed in to reaction water bath and incubated at 37⁰C for 5 minutes. Next the reaction disk was rotated the cells to all reaction stations including the photometer light path. Finally, the light passed through the cuvettes and absorbance of the sample was measured at 500nm.

Reference range of HDL: Low: \leq 40 mg/dL and High: \geq 60 mg/dL.



Ref.No: IPB00020/2020
Date: 17/2012

Institute of Health
Jimma University
Tel : +251 917762109
E-mail: konetsanet@gmail.com

To: Yayeh Melaku

Subject: Ethical Approval of Research Protocol

The IRB of Institute of Health has reviewed your research project titled,

"Lipid profile in hypertensive and normotensive diabetic adult patients at Debre marikos specialized hospital in North west, Ethiopia."

Thus, this is to notify that this research protocol has presented to the IRB meets the ethical and scientific standards outlined in national and international guidelines. Hence, we are pleased to inform you that your research protocol is ethically cleared.

We strongly recommend that any significant deviation from the methodological details indicated in the approved protocol must be communicated to the IRB before it has been implemented.

With Regards!

Dr Netsanet Workneh

IRB Chairperson



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Jimma University
የሕክምና ላቦራቶሪ ሳይንስ ትምህርት ቤት
School of Medical Laboratory Sciences



Ref No ME/L/123/2012
Date 07/07/2012

ሰደብረግርቆስ ሰፔሻላይዜድ ሆስፒታል
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ጉዳዩ: ትብብር እንዲደረግላቸዉ ስለመጠየቅ

ከላይ በርሱ ለመግለፅ እንደተሞከረዉ በጅማ ዩኒቨርሲቲ የደህረ ምረቃ ት/ቤት በሚድካል ክሊኒካል ኮሚሽን ትምርት ዓይነት ሁለተኛ ዲግሪያቸዉን እየሰሩ ያሉት ተማሪ ያየህ መላክ "Lipid profile in Hypertensive and normotensive diabetic adult patients at Debremerkos specialized hospital North west, Ethiopia በሚል ርዕስ ላይ ጥናት ስለሚያደርጉ ለዚህ ጥናት የሚያስፈልጉ ትብብር እንድታደረጉላቸው በትህትና እንጠቃለን።

Handwritten signatures and notes:
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ከሰጠታ ጋር
Signature

Annex V Declaration Sheet

I, the undersigned, MSc clinical chemistry student declare that this proposal is my original work in partial fulfillment of the requirement for the degree of master science in clinical chemistry. Where other work has been used, it has been carefully acknowledged and referenced in accordance with the requirements.

Name of the principal investigator

1. Mr. Yayeh Melaku Sign..... Date of submission

Approved by my assessor, advisors and school head;

1. Mr.Sintayehu Asaye (MSc) Sign..... Date of submission

2.Mr.Shiferaw Bekele (MSc, Assi .professor CLS) Sign..... Date of submission

3. Mr.Waqtola Cheneke (MSc, Asso .professor CLS) Sign Date of submission

4. Mr.Kedir Abdela (MSc) Sign Date of submission