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Assessment of serum lipid profiles and electrolytes among type II diabetic patients with and without hypertension attending Wolaita Sodo University comprehensive specialized Hospital, Wolaita, South Ethiopia.

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This is to certify that the thesis prepared by **Workineh H/mariam**, entitled: **Assessment of serum lipid profiles and electrolytes among type II diabetic patients with and without hypertension attending Wolaita Sodo University comprehensive specialized Hospital, South Ethiopia**; 2024 and submitted in partial fulfillment of the requirements for the degree of Master of Science in Clinical Laboratory Sciences (Clinical chemistry Specialty track) complies with the regulations of the university and meets the accepted standards concerning originality and quality.

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Abbreviations and Acronyms

ACV	Atherosclerotic cardiovascular
BMI	Body Mass Index
BP	Blood Pressure
CHD	Chronic heart disease
CI	Confidence Interval
DM	Diabetes Mellitus
FBS	Fast blood sugar
HDM	Hypertensive diabetic mellitus
HDL-c	High density Lipoprotein Cholesterol
IDF	International Diabetes Federation
IR	Insulin Resistance
LMIC	Low and Middle Income Countries
NCD	Non Communicable Disease
NDM	Normotensive diabetic mellitus
SOP	Standard Operating Procedure
SPSS	Statistical Package for Social Science
TC	Total Cholesterol
TG	Triglyceride
T2DM	Type 2 Diabetes Mellitus
WHO	World Health Organization
WSUCSH	Wolaita Sodo University comprehensive specialized Hospital

Catalog

Acknowledgment I

Abbreviations and Acronyms II

List of table V

Abstract VI

1. Introduction 1

 1.1 Background: 1

 1.2 Statement of the problem 2

 1.3 Significance of the Study 4

2. Literature review 6

 2.1 Type-2 diabetes mellitus 6

 2.2 Hypertension 6

 2.3 Type 2 DM and Hypertension 6

 2.4 previous study 6

3. Objectives 9

 3.1 General Objective 9

 3.2 Specific Objectives 9

4. Material and Method 10

 4.1 Study area 10

 4.2 Study design and period 10

 4.3 Population 10

 4.4 Sampling method 11

 4.5 Sample size calculation 11

 4.6 Eligibility criteria 11

 4.7 Study variables 12

 4.8 Data and Specimen collection 12

 4.9 Data Quality Assurance and Management 13

 4.10 Data processing and analysis 13

 4.11 Ethical considerations 14

 4.12 Operational definitions 14

 4.13 Dissemination of the finding 14

5. Results 15

5.1 Socio demographic characteristics	15
5.2 Comparison of lipid profiles and electrolytes level among hypertensive and normotensive diabetic participants.....	16
5.3 Factors associated with lipid profiles abnormality and electrolytes Imbalance among hypertensive and normotensive diabetic participants	17
6. Discussion	21
7.1 The strength of the study	23
7.2 Limitations of the study	23
8. Conclusions and Recommendations	23
8.1 Conclusions	23
8.2 Recommendations	24
9. References	25
10. Annexes	29

List of table

Table-1: Socio-demographic characteristics of hypertensive diabetic and normotensive diabetic participants at WSUCSH, Wolaita, South Ethiopia, from January 2024 to March 2024.

Table-2: Lifestyle factors, anthropometric, and clinical characteristics of study participants at WSUCSH, Wolaita, South Ethiopia, from January 2024 to March 2024.

Table-3: Comparison of lipid profiles and electrolytes in hypertensive diabetic and normotensive diabetic participants at WSUCSH, Wolaita, South Ethiopia, from January 2024 to March 2024.

Table4: Bivariate logistic regression analysis of factors associated with lipid profiles abnormality and electrolyte imbalance among hypertensive and normotensive diabetic Study participants attending WSUCSH, Wolaita, South Ethiopia, from January 2024 to March 2024.

Table5: Multivariable logistic regression analysis of factors associated with lipid profiles abnormality and electrolyte imbalance among hypertensive and normotensive diabetic Study participants attending WSUCSH, Wolaita, South Ethiopia, from January 2024 to March 2024.

Table6: Bivariate and multivariables logistic regression analysis of hypertension with lipid profiles abnormality and electrolyte imbalance among Study participants attending WSUCSH, Wolaita, South Ethiopia, from January 2024 to March 2024.

Abstract

Background: Diabetes is disease characterized by hyperglycemia with a disturbance of metabolism of carbohydrates, lipids and electrolytes. Coexistence of high blood pressure, dyslipidemia and electrolytes disturbance with diabetes has a risk for increased morbidity and mortality. Despite these alarming figures, data on the biochemical impact of coexisting diabetes and hypertension – specifically lipid profile and electrolyte variations – are limited in the Ethiopian population and study area.

Objective: To assess and compare serum lipid profiles and electrolytes level among type II diabetic patients with and without hypertension attending wolaita sodo university comprehensive specialized hospital, wolaita, South Ethiopia, from January 2024 to March 2024.

Methods: Hospital based comparative cross-sectional study was conducted on 66 hypertensive diabetic and 66 normotensive diabetic patients. Trained data collectors gathered the data using a structured questionnaire. Serum lipid profiles (HDL, LDL, TG and TC) and electrolytes (Sodium, Potassium and Chloride) were measured by Dimension EXL-200 analyzer. During analysis, Chi-square is used to compare the study groups by mean level. Binary logistic regression was used to determine associated factors with lipid profiles and electrolytes abnormality.

Results: The Mean level of TC, TG, LDL, Potassium and Chloride were significantly higher in HDM as compared with NDM. While, level of HDL-C and Sodium had a significantly lower in HDM as compared to HDM. In binary logistic regression: Hypertension, BMI, WC and DM showed strong significant association with abnormal serum level of TG, TC, LDL-C, HDL-C and Sodium in HDM than NDM.

Conclusion and Recommendation: HDM have more chances to develop high dyslipidemia and electrolytes disturbance than NDM. Hypertension, BMI, WC and DDM were factors significantly associated with abnormal lipid profiles and electrolytes level among HDM than NDM. There should be regular monitoring of lipid profile, electrolytes and hypertension for diabetic patients to prevent diabetes related complications.

Key words: Diabetes Mellitus, Hypertension, Electrolytes, Lipid profiles, WSUCSH

1. Introduction

1.1 Background:

Diabetes mellitus is a disease characterized by high levels of glucose in the blood due to imperfections of insulin production, insulin activity or both (1, 2). T2DM is usually comes due to failure of β -cells function and leads to resistance of insulin activity or insufficient production of insulin. The insulin resistance may be developed by metabolically active visceral fats that can release inflammatory substances(cytokines: TNF alpha and IL-6) that interfere insulin receptor signaling pathways. During the early stage of type 2 diabetes, b-cells release extra insulin to compensate insulin resistance and maintain sugar levels in the blood (3, 4).

Lipids are a group of naturally occurring molecules that include fats, oils, waxes, steroids, and phospholipids. They are essential to many biological functions and are a major component of cell membranes. Total Cholesterol has a function to measures the overall amount of cholesterol in the blood (includes LDL, HDL, and VLDL), LDL-C: Transports cholesterol to tissues, including artery walls, HDL-C: Removes excess cholesterol from the bloodstream and artery walls, transporting it back to the liver for elimination and TG: Store unused fats and provide energy and are the most common type of fat in the body. Pattern of lipid panels(profiles) vary depending on metabolic health, diet, genetics, and the presence of conditions like insulin resistance or obesity,(5, 6).

In DM, many factors affects levels of lipids that leads to lipid abnormality, the reason may be due to deficiency of insulin, that has many function in metabolism control (7). Insulin resistance in T2DM affects the actuvity of lipoprotein lipase (key enzyme in lipid metabolism and plays a central role in breaking down fat-carrying particles in the blood so the body can use or store the fat) and may Reduces the body's ability to process and clear triglycerides(8).

Electrolytes are minerals having an electric charge that found in the human body. Electrolytes has great function in our body, such as controlling levels of fluids, nerve conduction, acid-base balance (pH)and muscle contraction. Electrolyte disturbance may occur due to kidney disease, dehydration and vomiting that can be a contributing factors for the complications of diabetes mellitus, hypertension and other endocrine disorders (9).

Hyperglycemia can set the internal environment for osmotic diuresis while causing dilutional effect on the electrolyte concentrations. The osmotic problem of glucose leads to decreased circulating blood volume and fluid shift from the intracellular spaces resulting in cellular dehydration. The primary cause of an electrolyte imbalance in diabetes is hyperglycemia, which may occur when the body works to rid itself of the excess blood glucose by increasing urine output from the body.

Increased urination causes electrolyte and water loss, which may alter the body's electrolyte balance. Hyperglycemia is mainly restricted to the extracellular space so water moves from intracellular to the extracellular compartment initially, diluting the plasma sodium(10).

Hypertension can be defined as the SBP(during heart beats) equal to or above 140 mm Hg and DBP(during the heart is relax) equal to or above 90 mm Hg (11). High blood pressure is a pressure in the blood vessels which makes the heart harder to pump the blood. High BP is abnormalities in the sodium metabolism in all physiologic levels, including the whole-body, renal, and also the cellular (12).

The mechanisms behind hypertension in Diabetes may be due to insulin resistance (that leads to increased sympathetic nervous system activity, which raises the heart rate and vascular tone (blood vessels stay more constricted), sodium retention by the kidneys → increases blood volume → higher BP) and endothelial dysfunction (lipids profile and electrolytes imbalance due to high blood glucose damages the endothelium (inner lining of blood vessels and persistent vasoconstriction leads to elevated blood pressure. Taking high salt cause retention of fluid then blood volume will be increased and leads to in a high blood pressure condition(13). The current study aimed to assess and compare the serum lipid profiles and electrolytes level among type 2 diabetic patients with and without hypertension attending WSUCSH, Ethiopia.

1.2 Statement of the problem

The studies showed that diabetes is a disease that has major concern in regionally and globally, and it is a cause for deaths in many countries (14). The long-term impact of This disease can include a retinopathy, nephropathy, peripheral neuropathy. WHO reports that, high blood glucose was the third highest factor for premature deaths, next to Hypertension and tobacco.

Other studies confirmed that incidence of DM in worldwide in 2019 was 463 million that is anticipated to reach 642 million by 2040, becoming the biggest global health problem (15). Of the cases of all diabetes, 90% were T2DM in the world (15). Lipids disturbance and electrolyte imbalance become a major risk for cardiovascular disease (CVD) risk in T2DM (16 17).

The study showed that, the prevalence of lipid profile disturbance is increasing fast (80% to 90%) in the world including developing countries like Ethiopia. In Ethiopia, the burden of these diseases is also growing rapidly. According to the Ethiopian Ministry of Health and the IDF, the national diabetes prevalence was estimated at 6.5% in 2021, while hypertension affects approximately 24% of the adult population. Despite these alarming figures, data on the biochemical impact of coexisting diabetes and hypertension—specifically lipid profile and electrolyte variations—are limited in the Ethiopian population.(18).

Diabetic patients frequently develop different types of subclinical electrolyte disorders. It usually related to hyperglycemia-induced osmotic fluid shifts or a total body deficit caused by osmotic diuresis and, if not corrected, it leads to hyperketonaemia (19). The most frequently seen electrolyte abnormality in DM in clinical practice is hyponatremia, which is associated with increased morbidity and mortality. Hyperglycaemic status also induces hypovolemic-hyponatraemia due to osmotic diuresis.

Dyslipidemia is frequent in diabetic patients caused by due to an altered distribution because of hyperglycemia-induced abnormal metabolism(20). Dyslipidemia confers an excess atherosclerotic cardiovascular risk in type 2 diabetes mellitus (DM) patients, and also this requires urgent and prompt identification and management to reduce morbidity and mortality that come from its complication(21).

High blood pressure commonly coexist with diabetic patients (22). High blood pressure and diabetes comorbidity is a risk for complication including nephropathy, retinopathy and stroke (23). Problem of CVD is 4 times greater in the comorbid state than diabetes alone (24). Studies showed that 30–60% of people with diabetes also have hypertension. The coexistence of both conditions not only compounds the risk of cardiovascular events but also exacerbates disturbances in lipid metabolism and electrolyte balance, which are key indicators of metabolic

and renal health. Elevated cholesterol, triglycerides, sodium, potassium, and other electrolyte imbalances are frequently observed and are associated with poor disease outcome (25).

The study showed that hypertension is greatly associated with high risk of coronary heart disease when coexist with diabetes (26). Despite these alarming figures, data on the biochemical impact of coexisting diabetes and hypertension—specifically lipid profile and electrolyte variations—are limited in the Ethiopian population. There is inconsistent (poor) studies and findings on similar cases in the study area populations, that is why it has been choosed. Understanding these variations is crucial, as they have direct implications on disease progression, risk stratification, and the design of appropriate management protocols and may provide direction into the mechanism(s). So that by minimizing these existing gaps, the upcoming risks, morbidity and mortality can be controlled and reduced.

Therefore, the current study aimed to assess and compare serum lipid profiles and electrolytes levels among type II diabetic patients with and without hypertension attending WSUCSH, Ethiopia.

1.3 Significance of the Study

The coexistence of diabetes mellitus and hypertension is a common and serious public health concern that significantly increases the risk of cardiovascular, renal, and metabolic complications. Both conditions independently affect lipid metabolism and electrolyte balance, and their combination may result in more profound biochemical disturbances. However, in many resource-limited settings, including Ethiopia, there is a lack of detailed data assessing how lipid profiles and electrolyte levels differ between diabetic patients with and without hypertension.

This study is significant for several reasons:

1. **Improved Clinical Management:** By identifying specific patterns of lipid and electrolyte abnormalities in diabetic patients with and without hypertension, the study will help clinicians tailor treatment plans more precisely, leading to better disease control and reduced complications.
2. **Early Detection and Prevention:** Understanding these biochemical changes can support earlier detection of cardiovascular and renal risks, especially in hypertensive diabetic patients, allowing for timely intervention and preventive strategies.
3. **Public Health Planning:** The findings will provide evidence-based data for health policymakers in Ethiopia to design targeted screening, education, and management programs for patients with diabetes and/or hypertension.

4. Bridging the Knowledge Gap: There is limited research in Ethiopia that compares lipid and electrolyte levels among diabetic patients based on hypertensive status. This study will contribute to filling that gap in the local and regional literature.

5. Academic Contribution: The study will serve as a valuable resource for future researchers and healthcare professionals interested in the biochemical and clinical implications of comorbid diabetes and hypertension. Therefore, by showing existing gaps, this study used as an updated data and deliver information to clinicians about electrolyte and lipid profile disturbances in patients with type II diabetes with and without hypertension. The study also used as reference material to conduct more studies on similar cases..

Accordingly, the study aimed to assess and compare serum electrolytes (sodium, potassium, and chloride) and lipid profiles (TC, LDL, HDL, TG) levels among type II diabetic patients with and without hypertension as their variation.

2. Literature review

2.1 Type-2 diabetes mellitus

It's resistance of insulin is due to an impaired signaling of insulin by the phosphoinositol-3 kinase (P13K) with signaling of protein kinase (MAPK), major reason of the impairment for insulin-stimulated metabolism of glucose (27). WHO has estimated that, there were 422 million adult diabetic patients in the world in 2014.

Almost half of all deaths due to high blood glucose occur before the age of 70 years. WHO projects that diabetes will be the 7th leading cause of death in 2030. More than 425 million people have diabetes in the world and approximately 38.7 million people in the Middle East and North Africa Region; by 2045 this will rise to 82 million. There were 7.5 million cases of diabetes in Pakistan in 2017 (28). Over weight by itself can cause an insulin resistance (29).

2.2 Hypertension

Approximately 970 million people around the world have high blood pressure. By 2025 predicted that, there will 1.56 billion patients with hypertension (30). According to WHO in 2014, its prevalence in Indonesia in male and female is 24% and 22.6%, respectively (31). A study in 2015 indicated the prevalence of SBP from 1990 to 2015 is increased from 17.3% to 20.5% (32).

2.3 Type 2 DM and Hypertension

The prevalence of high blood pressure in diabetics is two times than non-diabetics (33). Nearly, 60% of diabetic patients have a high blood pressure (34). Institutional-based study demonstrated that prevalence of high blood pressure in diabetic patients was 62.7% (35).

Coexistence of Hypertension and diabetes as the main factor for both micro and macro-vascular diseases in diabetic patients (36). It can be a cause for limb amputation, kidney disease and for other diseases that have a significant impact for life (37).

2.4 previous study

2.4.1 Dyslipidemia and electrolyte disturbance in Type-2 DM patients with and without Hypertension

According to the National Cholesterol Education guidelines, “hypertriglyceridemia is when TG is > 150 mg/dl, hypercholesterolemia when TC >200 mg/dl, high LDL-C when the value is >100

mg/dl, and low HDL-C when the value is <40 mg/dl". Hence, lipid and electrolytes disturbance is refers to presence of one or more lipids and electrolytes parameter measurements abnormality(For instance, $\text{Na} \geq 144$ mmol/L, $\text{K} \geq 5$ mmol/L and $\text{Cl} \geq 106$ mmol/L) respectively (38).

A study done in Bangladesh showed, there was no a significant difference in all lipid profiles and level of glucose among HDM and NDM (39).

A study conducted in Pakistan indicated that HDM were in a significant higher mean level of TC (195.58 ± 31.81 mg/dL) and TG (197.75 ± 79.36 mg/dL) than normotensives level of TC (178.07 ± 29.61 mg/dL) and TG (164.83 ± 47.91 mg/dL). But in HDM, mean level of HDL-C (31.75 ± 5.38 mg/dL) significantly lowered than in NDM (38 ± 2.83 mg/dL)(42).

A comparative cross-sectional study conducted in Iraq, there was statistically significant higher level of TC in HDM female than NDM female patients, (189.9 ± 6.8 mg/dL vs 163.33 ± 23.7 mg/dL) respectively. There was statistically significant higher level of TC in HDM male than NDM male patients, (250.26 ± 31.87 mg/dL vs 204.6 ± 28.99 mg/dL) respectively. There was also statistically significant lower level of HDL-C in HDM female than NDM female patients, (43.83 ± 6.7 mg/dL vs 47.33 ± 7.5 mg/dL) respectively. A statistically significant higher LDL-C level was seen in HDM female patients than NDM female patients (111.42 ± 23.2 mg/dL vs 94 ± 22.94 mg/dL) respectively. There was not statistically significant lower the level of HDL-C in HDM male than NDM male patients, (47.52 ± 7.08 mg/dL vs 47 ± 5.8 mg/dL) respectively. The level of TG was higher in hypertensive diabetic female than in normotensive diabetic female patients with no significant differences (146.21 ± 77.53 mg/dL vs 123.11 ± 45.77 mg/dL) respectively. But significant higher TG level was seen in hypertensive diabetic male than in normotensive diabetic male patients (181.11 ± 77.53 mg/dL vs 123.21 ± 45.77 mg/dL) respectively (44).

A study conducted in Saudi Arabia showed that LDL, TC and TG had significant association with SBP and DBP, and higher in hypertensive diabetics than normotensives. However, HDL-C was raised among normotensive diabetic patients as compared to hypertensive diabetic patients (45).

The study done on assessment of Electrolyte Profile in Diabetic, Hypertensive and Comorbid State in Niger Delta University, Bayelsa State, Nigeria showed that the concentration of sodium

in comorbid patient (123.12 ± 5.46) was significantly ($P < 0.05$) lower when compared with diabetes patients (133.16 ± 4.43) and hypertensive (133.16 ± 4.43). Chloride and Potassium were not reveal significant difference. And concluded as, there is an overall prevalence of electrolytes disorder in comorbid condition of diabetes and hypertension (47).

A cross-sectional study conducted in Blantyre, Malawi showed that Dyslipidemia had prevalence of 58% in diabetics, 55% in hypertensive and 71% in comorbid state. In this study, high prevalence of dyslipidemia was observed in all groups. Being overweigh and over 30 years of age were a significant factor for dyslipidemia in diabetics. In comorbid state participants, poor hypertension controll was a great factor for high dyslipidemia(51).

3. Objectives

3.1 General Objective

- ✓ To assess level of serum lipid profile and electrolytes among type II diabetic patients with and without hypertension attending wolaita sodo university comprehensive specialized hospital, wolaita, South Ethiopia, from January 2024 to March 2024.

3.2 Specific Objectives

- ✓ To compare level of serum lipid profiles and electrolytes among hypertensive diabetic and normotensive diabetic patients.
- ✓ To determine factors associated with lipid profiles and electrolytes of hypertensive and normotensive diabetic patients

Hypothesis

NH: There is no difference in mean values of serum electrolytes and lipid profiles among hypertensive and normotensive diabetic patients.

AH: There is difference in mean values of serum electrolytes and lipid profiles among hypertensive and normotensive diabetic patients.

4. Material and Method

4.1 Study area

The study was conducted at WSUCSH which is located at south Ethiopia, wolaita sodo town, 329 KM from Addis Ababa, which is the capital city of Ethiopia. The town is with an elevation of between 1600 and 2100 meters (5,200 and 6900 ft) above sea level and with a mean annual rainfall of 1,014 millimeters. As 2007 census, total population in wolaita sodo city was 76,050 and estimate in 2021 had population of 194,977.

The hospital in the diabetic clinic ward gives a service of risk assessment, diagnosis and comprehensive treatment under supervision of endocrinologists and physicians. In the diabetes and hypertension clinic ward the hospital service includes,

- ✓ Pre-diabetes and hypertension screening test and prevention
- ✓ Blood sugar and hypertension control within normal range to prevent complication
- ✓ Treatment of diabetes and hypertension complication
- ✓ Patients follow up

4.2 Study design and period

A hospital based comparative cross-sectional study was performed on hypertensive and normotensive diabetic patients from January 2024 to March 2024 in wolaita sodo university comprehensive specialized hospital, South Ethiopia.

4.3 Population

4.3.1 Source population

All T2DM patients with and without hypertension attending wolaita sodo university comprehensive specialized hospital.

4.3.2 Study population

All T2DM patients with and without hypertension attending WSUCSH and who was volunteered and fulfilled the inclusion criteria.

4.4 Sampling method

A convenient sampling technique was performed during the study period in the hospital.

4.5 Sample size calculation

When the variable is quantitative data like blood pressure, weight, height, etc., then the following formula can be used for calculation of sample size for comparison between two groups.

Margin of error (d) = 5%, CI = 95% ($Z_{\alpha/2}=1.96$), 80% P ($z_{\beta}=0.84$), 1:1 ratio of HDM (Hypertensive diabetics) to NDM (Normotensive diabetics). Mean of TG for HDM was 222.65 mg/dL with SD of 54.10 and mean of TG in NDM was 191.38 mg/dL with SD of 67.20 (55).

S_1 = SD of HDM S_2 = SD of NDM

μ_1 = Mean value in HDM μ_2 = Mean value in NDM

N = Minimum total sample size

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

$$N = (54.10^2 + 67.20^2) (1.96 + 0.84)^2 / (222.65 - 191.38)^2$$

$$N = 58350.376 / 977.8129$$

$$N_1 = N_2 = \text{HDM} = \text{NDM} = 60$$

In this case, we had 60 T2DM patients without hypertension and 60 T2DM patients with hypertension.

- ✓ But with 10% contingency, the study was compared 66 type 2 diabetic patients without hypertension and 66 type 2 diabetic patients with hypertension.
- ✓ So that, a total sample of 132 with 10% contingency was included.

4.6 Eligibility criteria

4.6.1 Inclusion criteria

This study included that;

- ✓ Patients with confirmed T2DM with and without hypertension.
- ✓ Patients with confirmed T2DM with and without hypertension who had at least 1 year consecutive follow up period (As WHO, for research including T2DM, a follow up period of at least 1 year is generally considered appropriate for inclusion criteria allowing for meaningful data collection).
- ✓ Voluntary individuals.

4.6.2 Exclusion criteria

- ✓ Study participants who had renal disease, thyroid dysfunction, chronic kidney disease (CKD), chronic liver disease, cancer, cardiac heart failure, pregnant women, those who are critically ill, had incomplete medical records and with hearing difficulty were not included.

4.7 Study variables

4.7.1 Dependent Variable

- Lipid profiles level
- Electrolytes level

4.7.2 Independent variable

- ✓ Hypertension
- ✓ BMI (Body mass index)
- ✓ DDM (Duration of diabetes mellitus)
- ✓ Age
- ✓ Sex
- ✓ Marital status
- ✓ Residence
- ✓ Educational level
- ✓ Smoking status and Alcohol use

4.8 Data and Specimen collection

4.8.1 Data collection and procedure

Two collectors and one supervisor trained Nurses working at DM Clinic OPD ward controlled the data collection process within three month period. Interviewer administered structured questionnaire data collection tool was used. The questionnaire prepared in English and the

concept of the questionnaire was translated into Amharic languages. All necessary information was included consisting of socio-demographic, medical history and laboratory investigation data.

4.8.2 Specimen collection and processing

About 5 ml of overnight fasting (8-12 hours) venous blood was collected from study participant in the morning. The sample was transferred into serum separator jell coated tube. The sample was for 30m to clot. Then centrifuged for 5m at 3000 rpm to get serum. Then it is transferred to a 1.5-mL nung tubes and stored at the optimal temperature until analysis started. Then lipid profiles and electrolytes was tested using Siemens Dimension EXL-200 analyzer. But, sample was kept at -20 0C for analysis greater than Seven days in refrigerator.

4.9 Data Quality Assurance and Management

4.9.1 Pre-analytical

All data collected by the trained health professionals. Laboratory procedures concerning sample collection, transportation and processing were handled by laboratory technologists based on the standard operational procedures (SOPs).

4.9.2 Analytical

The accuracy and functioning of laboratory instruments, reagents and technical performance were checked by professional laboratory technologists using Standard quality control (normal and pathological) protocols before running patients sample. Then participants sample was analyzed by Siemens Dimension EXL-200 chemistry analyzer.

4.9.3 Post-analytical

The results were checked daily by principal investigator based on SOP.

4.10 Data processing and analysis

The data were checked, cleaned and entered in to Epi-data software version 3.1, and then it was exported to SPSS version 23.0 software for analysis. Descriptive statistics were used to analyze the data for categorical variables between groups and expressed by percent and frequency. Then mean and SD for comparison by using independent t-test. During the analysis time, the binary logistic regression analysis used for determine the associated factors of abnormal lipid profiles and electrolytes.

4.11 Ethical considerations

Before starting the study, approval and supportive letters had been written from AAU to WSUCSH then, the principal investigator obtained supportive and permission letter from the hospital clinical directorate director. All data were collected from the study participants after they are volunteered. For reasons of privacy, confidentiality and anonymity were taken in the study by using codes). The participants were informed for that there is no any harm for their participation.

4.12 Operational definitions

Fasting blood sugar: Blood glucose measured from venous blood after at least 8 h of overnight.

Abnormal lipid profile: It is an elevated or altered concentration of any one of the four lipids parameters within the blood, TC \geq 200 mg/dl, LDL \geq 130 mg/dl, TG \geq 150 mg/dl as elevated and HDL $<$ 40 mg/dl as low, irrespective of gender (WHO).

Lipitension: Derangement of lipoprotein components due to hypertension.

Abnormal electrolytes result: An altered concentration of electrolytes occurs when the body has too much or not enough minerals in the blood and by the decrease of the circulating blood volume. Normal Range: Sodium: 136 to 144 mmol/L, Potassium: 3.7 to 5.1 mmol/L, Chloride: 97 to 106 mmol/L (WHO).

Waist circumference: Male $>$ cut off value is 102 cm and Female $>$ cut off value is 88 cm.

Hypertension: Can be defined as a systolic blood pressure is equal to or above 140 mm Hg and diastolic blood pressure is equal to or above 90 mm Hg.

Hypertensive diabetic: A person who has both diabetes and high blood pressure (hypertension), meaning they are simultaneously dealing with elevated blood sugar levels and elevated blood pressure (WHO).

Normotensive diabetic: A person who has diabetes but has normal blood pressure, meaning their blood pressure is within a healthy range (WHO).

4.13 Dissemination of the finding

After the completion of research the findings presented and submitted to AAU department of Medical Laboratory for master of science in clinical chemistry. It is also planned to communicate WSUCSH, WSU collage of health science and other concerned bodies for documentation. Therefore, it may act as a valuable resource and updated data for researchers and policy makers for further study and designing intervention.

5. Results

5.1 Socio demographic characteristics

A 132 (66 HDM, 66 NDM) participants were involved. 35/66 (53%) were females in HDM and 37/66 (56%) were males in NDM. The mean ages of HDM and NDM patients were 49.50 ± 4.612 and 42.64 ± 5.471 respectively. 83/132 (62.9%) of the study participants were married. Majority, 96/132 (72.7%) residents were from urban as shown in **Table 1**.

Table1: Socio demographic characteristics of hypertensive and normotensive diabetic participants attending WSUCSH, Wolaita, South Ethiopia, from January 2024 to March 2024.

Socio-demographic variables		HDM(n=66)	NDM(n=66)
Age	(Mean±SD)	49.50±4.612	42.64±5.471
	<40 years	13(19.7%)	24(36.4%)
	≥40 years	53(80.3%)	42(63.6%)
Sex	Male	31(47%)	37(56%)
	Female	35(53%)	29(44%)
Educational status	No formal education	25(37.9%)	9(13.6%)
	Primary school	21(31.8%)	9(13.6%)
	Secondary school	11(16.7%)	25(37.9%)
	College and above	9(13.6%)	23(34.9%)
Marital status	Single	1(1.5%)	24(36.4%)
	Married	45(68.2%)	38(57.6%)
	Divorced	20(30.3%)	4(6%)
Residence	Urban	41(62.1%)	55(83.3%)
	Rural	25(37.9%)	11(16.7%)
Occupational status	Government employed	10 (15.1%)	29(44%)
	Merchant	26(39.4%)	17(25.8%)
	Farmer	12(18.2%)	1(1.5%)
	Daily laborer	0(0%)	6(9%)
	House wife	18(27.3%)	13(19.7%)

The result showed that 19/66(28.8%) and 33/66(50%) HDM patients consumed alcohol and overweighted respectively. Dietary salt intake had a significant difference between HDM and NDM. And that 13/66(19.7%) and 28/66(42.4%) of NDM study participants was consumed alcohol and overweighted respectively.

The mean of DDM (5.26 ± 1.5 vs 4.38 ± 1.38) and WC ($90.45\pm 4.13\text{cm}$ vs $85.61\pm 10.78\text{cm}$), were elevated in HDM than NDM) significantly, respectively as shown in **Table-2**.

Table-2: Life style, anthropometric and clinical characteristics among hypertensive and normotensive diabetic participants attending WSUCSH, Wolaita, South Ethiopia, from January 2024 to March 2024.

Variables	Study Participants (n= 132)		P-value
	HDM(n=66)	NDM(n=66)	
Smoking status			
Yes	11(16.6%)	6(9%)	0.2
No	55(83.3%)	60(91%)	
Alcohol consumption			
Yes	19(28.8%)	13(19.7%)	0.19
No	47(71.2%)	53(80.3%)	
Dietary salt consumption			
Yes	15(22.7%)	54(81.8%)	0.001**
No	51(77.3%)	12(18.2%)	
BMI status (Mean±SD)	27.43±3.52	26.46±4.55	0.175
Normal weight	27(41%)	35(53%)	0.17
Over weight	33(50%)	28(42.4%)	
Obese	6(9%)	3(4.6%)	
DDM (Mean±SD)	5.86±1.51	4.25±1.38	0.001**
<5 (year)	22(33.4%)	41(62.2%)	0.001**
≥5 (year)	44(66.6%)	25(37.8%)	
WC (cm) (Mean±SD)	90.45±4.13	85.61±10.78	0.001**
FBS (mg/dL) (Mean±SD)	140.76±10.22	138.11±5.13	0.062

BMI: Body mass index, WC: Waist circumference, DDM: Duration of diabetes, FBS: Fast blood sugar, * significant at ≤ 0.05 and ** significant at ≤ 0.001 .

5.2 Comparison of lipid profiles and electrolytes level among hypertensive and normotensive diabetic participants.

TG, TC and LDL-C were elevated significantly in HDM than NDM, except HDL-C that was higher in NDM than HDM significantly.

The mean of Potassium (4.46 ± 0.55 mmol/L vs 4.02 ± 0.94 mmol/L) and Chloride (107.38 ± 5.98 mmol/L vs 104.32 ± 7.42 mmol/L) were elevated significantly in HDM than NDM patients respectively. However, the mean of Sodium (134.62 ± 6.65 mmol/L vs 130.86 ± 5.46 mmol/L) was higher in NDM than HDM significantly, respectively as shown in **Table 3**.

Table-3: Mean Comparison of lipid profiles and electrolytes Parameters between hypertensive and normotensive diabetic participants attending WSUCSH, Wolaita, South Ethiopia, from January 2024 to March 2024.

Variables	HDM (Mean±SD)	NDM (Mean±SD)	P value
TG (mg/dL)	200.74±19.39	181.92±21.02	0.001**
TC (mg/dL)	254.27±18.69	225.12±28.11	0.000**
HDL-C (mg/dL)	37.95±3.16	45.39±3.44	0.000**
LDL-C (mg/dL)	162.82±14.64	137.24±21.88	0.000**
Sodium (mmol/L)	130.86±5.46	134.62±6.65	0.001**
Potassium (mmol/L)	4.46±0.55	4.02±0.94	0.001**
Chloride (mmol/L)	106.38±5.98	104.32±7.42	0.010*

TG:

Triglyceride; TC: Total cholesterol; HDL-C: High density lipoprotein cholesterol; LDL-C: Low density lipoprotein cholesterol.

5.3 Factors associated with lipid profiles abnormality and electrolytes Imbalance among hypertensive and normotensive diabetic participants

After performing bivariable logistic regression analysis, BMI and WC had a significant association with level of LDL-C, HDL-C, TC, TG and Sodium. DDM had a significant association with the serum TC, LDL-C, TG and Sodium levels as in **Table-4**.

Table4: Bivariate logistic regression analysis of associated factors with lipid profiles and electrolytes abnormality in hypertensive and normotensive diabetic participants attending WSUCSH, Wolaita, South Ethiopia, from January 2024 to March 2024.

Variable	Study group	TC		HDL-C		LDL-C		TG		Sodium		Potassium		Chloride			
		COR	P	COR	P	COR	P	COR	P	COR	P	COR	P	COR	P		
Age	<40	13	24	1*		1*		1*		1*		1*		1*		1*	
	≥40	53	42	1.821	0.179	1.628	0.367	2.111	0.061	1.526	0.464	2.133	0.066	1.532	0.388	1.762	0.214
Sex	M	31	37	1*		1*		1*		1*		1*		1*		1*	
	F	35	29	1.495	0.439	1.687	0.381	2.111	0.131	1.786	0.287	2.233	0.111	1.859	0.217	0.886	0.706

BMI	<25 kg/m ²	27	35	1*		1*		1*		1*		1*		1*		1*	
	≥25 kg/m ²	39	31	1.876	0.001	1.321	0.044	4.221	0.000	1.513	0.012	2.261	0.000	1.132	0.097	1.111	0.100
WC	Male >cut off value	12	10	1*		1*		1*		1*		1*		1*		1*	
	Female >cut off value	21	14	1.714	0.002	1.390	0.047	1.978	0.001	1.750	0.002	1.887	0.001	1.117	0.083	1.123	0.076
DDM	<5yr	22	41	1*		1*		1*		1*		1*		1*		1*	
	≥5yr	44	25	1.681	0.019	1.374	0.138	2.831	0.001	1.761	0.018	1.603	0.043	1.103	0.113	0.813	0.142

Abbreviations: TG: Triglyceride; TC: Total cholesterol; HDL-C: High density lipoprotein cholesterol; LDL-C: Low density lipoprotein cholesterol; BMI: Body mass index; WC: Waist circumference; DDM: Duration of diabetes; COR: crude odds ratio; P: p - value; 1*: reference category.

In multivariable logistic regression analysis (For a significant association with P – value ≤ 0.025 in Table-4), Study groups with BMI ≥ 25 kg/m² had a higher chance of having abnormal TC in Hypertensive diabetic patients than normotensives (AOR= 1.371, 95% CI: 1.004-1.871, P =0.047).

Study groups with WC >cut off value had a higher chance of having abnormal LDL-C in female Hypertensive diabetic patients than female normotensive diabetic patients (AOR=1.528, 95% CI: 1.011-2.221, P =0.014).

Study groups with DDM ≥ 5 yr had a higher chance of having abnormal TG in HDM than NDM (AOR = 2.772, 95% CI : 1.231- 6.266, P = 0.012) as shown in **Table 5**.

Table5: Multivariable logistic regression analysis of associated factors with lipid profiles and electrolytes abnormality in hypertensive and normotensive diabetic participants attending WSUCSH, Wolaita, South Ethiopia, from January 2024 to March 2024.

Variable		Study group		TC		HDL-C		LDL-C		TG		Sodium	
		HDM	NDM 1*	AOR(95% CI)	P	AOR(95% CI)	P	AOR(95 % CI)	P	AOR(95 % CI)	P	AOR(9 5% CI)	P
BMI	<25k g/m2	27	35	1*		1*		1*		1*		1*	
	≥25k g/m2	39	31	1.371 (1.004- 1.871)	0.047	0.975 (0.763- 1.245)	0.840	3.817 (1.238- 8.245)	0.021	1.449 (0.915- 1.914)	0.045	1.969 (1.212- 3.211)	0.006
WC	Male >cut off value	12	10	1*		1*		1*		1*		1*	
	Fema le >c ut off value	21	14	1.478 (1.983- 2.185)	0.018	1.203 (1.024- 1.414)	0.054	1.528 (1.011- 2.221)	0.014	1.531 (1.021- 2.257)	0.014	1.549 (1.139- 2.572)	0.012
DDM	<5yr	22	41	1*		1*		1*		1*		1*	
	≥5yr	44	25	2.111 (1.104- 4.025)	0.021			2.332 (1.062- 5.621)	0.018	2.772 (1.231- 6.266)	0.012	1.772 (0.921- 3.566)	0.052

Abbreviations: AOR: adjusted odds ratio; CI: confidence interval 1*: reference category

After performing bivariable logistic regression analysis, hypertension had a significant association with the serum HDL-C, LDL-C and Sodium levels.

In multivariable logistic regression analysis (For a significant association with P – value ≤ 0.025 in Table-6), Study participants with hypertension had a higher chance of having abnormal HDL-C than normotensive study participants (AOR=8.094, 95% CI: 3.338-17.621, P =0.000 as shown in Table-6.

Table6: Bivariate and multivariable logistic regression analysis of hypertension with lipid profiles abnormality and electrolyte imbalance among Study participants attending WSUCSH, Wolaita, South Ethiopia, from January 2024 to March 2024.

Variable		TC	HDL-C	LDL-C	TG	Sodium	Potassium	Chloride	HDL-C	LDL-C	Sodium
		(COR/P)	(COR/P)	(COR/P)	(COR/P)	(COR/P)	(COR/P)	(COR/P)	(AOR/P)	(AOR/P)	(AOR/P)
Hypertension	Yes	1.98 7 / 0.084	9.80 0 / 0.000	10.6 25 / 0.000	1.61 5 / 0.234	5.27 1 / 0.003	0.366 / 0.152	2.00 1 / 0.096	8.094 (3.338–17.621) / 0.000	11.776 (3.172–22.784) / 0.000	4.325 (1.003–13.588) / 0.002
	No	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*

Abbreviations: HP: Hypertension; TG: Triglyceride; TC: Total cholesterol; HDL-C: High density lipoprotein cholesterol; LDL-C: Low density lipoprotein cholesterol; COR: crude odds ratio; AOR: adjusted odds ratio; CI: confidence interval, P: p - value; 1*: reference category

6. Discussion

The present study assessed and compared level of lipid profiles and electrolytes among hypertensive and normotensive diabetics at WSUCSH. In this study, the mean level of TG, TC, LDL, Potassium and Chloride were elevated significantly in HDM than NDM patients, but HDL-C and Sodium were higher in NDM than HDM patients significantly.

In this study, the significant increased level of LDL-C, TG, and TC and lowered level of HDL-C in the hypertensive diabetic participants, as compared with normotensive diabetic participants is inline with findings in studies conducted in Saudi Arabia, Turkey, Pakistan and Iraq (42, 43, 44, 45). This may be a result of by that, the comorbidity state, which is major reason for morbidity and mortality because it increases disturbance of lipoproteins (46). But the result is in contrast to study conducted in Bangladesh and Iraq (47, 48). For this result variation, possible reason might be sample size and life style difference.

The significantly increased Potassium and Chloride, and lowered level of Sodium in hypertensive diabetics, as compared with normotensive diabetics was inline to results in studies conducted in India (49). The possible reason for these electrolytes result variation among study groups might be due to the comorbid state of the two diseases that leads to the abnormalities of electrolytes imbalance, which is a factor for complications (50). But this result in contrast to findings in study conducted in Nigeria which found insignificant increase of Potassium in hypertensive diabetic study participants and insignificant increase of Chloride in normotensive diabetic study participants (51). Ethnicity, sample size and age difference, BMI status and life style can be possible reason for this result variation. There is no a significant difference of FBS concentration level among HDM and NDM patients.

Logistic regression analysis revealed a significant association between BMI and WC with TC, LDL-C, TG and Sodium levels of study participants. In this study, hypertensive diabetic study participants having BMI >25kg/m² had 1.371, 3.817 and 1.969-fold higher risk of developing Hypercholesterolemia, Elevated LDL-C and Hyponatremia as compared to normotensive diabetic participants (COR =1.876; AOR (95% CI) = 1.371 (1.004-1.871); (COR =4.221; AOR (95% CI) = 3.817 (1.238-8.245); (COR = 2.261; AOR (95% CI) = 1.969 (1.212-3.211), respectively. This was comparable with the study done in Yemen (53). This might be due to

presence of coexistence of hypertension with diabetes that can increase risk of associated factors (BMI) on lipid profiles and electrolytes abnormality.

The study revealed, female hypertensive diabetic individuals with WC >cut off value had 1.478, 1.528, 1.531 and 1.549-fold higher risk of developing Hypercholesterolemia, Elevated LDL-C, Hypertriglyceridemia and Hyponatremia as compared to female normotensive diabetic individuals (COR =1.714; AOR (95% CI) = 1.478 (1.983-2.185); (COR =1.978; AOR (95% CI) = 1.528 (1.011-2.212); (COR =1.750; AOR (95% CI) = 1.531 (1.021-2.257); (COR =1.887; AOR (95% CI) = 1.549 (1.139-2.572), respectively. And that, hypertensive diabetic individuals with DDM \geq 5yr had 2.111, 2.332 and 2.772-fold higher risk of developing Hypercholesterolemia, Elevated LDL-C and Hypertriglyceridemia as compared to normotensive diabetic individuals (COR =1.681; AOR (95% CI) = 2.111 (1.104-4.025); (COR =2.831; AOR (95% CI) = 2.332 (1.062-5.621); (COR =1.761; AOR (95% CI) = 2.772 (1.231-6.266) respectively. This finding was comparable with the study conducted in Rwanda (54). Due to hypertension with diabetes the effect of associated factors (WC) for the abnormality of lipid profiles and electrolytes levels will be higher.

In this study, hypertension had a significant association with the serum LDL-C, HDL-C and Sodium levels of study participants. This study revealed that, study participants having hypertension had 8.094, 11.776 and 4.325 times higher risk of developing Lowered HDL-C, Elevated LDL-C and Hyponatremia than normotensive study participants, (COR =9.800; AOR (95% CI) = 8.094 (3.338-17.621); (COR =10.625; AOR (95% CI) = 11.776 (3.172-22.784); (COR =5.271; AOR (95% CI) = 4.325 (1.005-13.588), respectively. The finding was inline with study conducted in Saudi Arabia (42). The similarity of the finding might be due to hypertension that highly related with derangement of lipoprotein components by rising levels of bad lipids and decreasing good lipids among diabetic patients and results in a atherosclerotic cardiovascular diseases. Coexistence of diabetes mellitus and hypertension is main reason for development and progression of micro and macro-vascular complications.

The study showed that, development of dyslipidemia and hypertension in diabetics were accelerated due to the insulin resistance, and this hypertension was related to high derangement in lipoprotein components (lipitension)and results in high complications (36). Higher electrolyte abnormalities are evident in coexist state of diabetes and hypertension. Patients with this

conditions have more chance to develop high electrolytes imbalance due to complications they develop (50).

7. Strength and Limitations of the study

7.1 The strength of the study

- * In this study, there were high response or participation rate that minimizes non-response bias.
- * The use of standardized procedures for sample collection and analysis ensures consistency and comparability across study groups.
- * As our knowledge, this study is the first of its kind conducted in this particular study area, addressing a significant gap in local data regarding the biochemical profiles of diabetics with and without hypertension.

7.2 Limitations of the study

- Dietary habits were not assessed in depth.
- Sample size was small.
- Treatment for diabetes were not assessed

8. Conclusions and Recommendations

8.1 Conclusions

- ❖ There were a significant differences in the lipid profiles and electrolytes levels between HDM and NDM patients.
- ❖ Hypertensive diabetic participants had higher dyslipidemia and electrolytes imbalance than normotensive diabetics.
- ❖ Associated factors (BMI, WC and DDM) had a significant effect for the abnormality of lipid profiles and electrolytes value in HDM than NDM patients. It might be due to presence of coexistence of hypertension with diabetes.

8.2 Recommendations

- ✓ First of all, during managing diabetes, it is necessary to screen and manage the patients for electrolytes imbalance, hypertension and dyslipidemia in order to make good management at early stages that used to prevent diabetes related complication.
- ✓ During follow up, regular monitoring of lipid profiles and electrolytes should be performed for the hypertensive patients to in order to prevent other complications.
- ✓ Further similar research should be done by using larger sample size.

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10. Annexes

Annex 1 (A): Information sheet (English Version)

Title of the Research Project: Assessment of serum electrolytes and lipid profiles among type II diabetic patients with and without hypertension attending at wolaita sodo comprehensive specialized hospital, SNNPR, Ethiopia

Principal Investigator: Workineh H/mariam (BSc, MSc candidate)

Name of the Organization: Addis Ababa University College of Health Science, Department of Medical Laboratory Science

Introduction

You are kindly invited to participate as a study subject in a research conducted by Addis Ababa University College of Health Science, Department of Medical Laboratory Masters student thesis. Your participation is voluntary. The research teams will include one principal investigator, two advisors from Addis Ababa University. Please take as much time as you need to read or listen to the information sheet.

Purpose of the Research Project

We are asking you to take part in this study because we will try to assess levels of serum electrolytes and lipid profiles among type II diabetic patients with and without hypertension and recommending tangible solutions to minimize and control the complication and progress of diabetes and hypertension.

Procedures and the expected participation

If you are willing to participate, you need to 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 it is needed. The required clinical sample will be collected by residents of the clinical chemistry department. Then, you are requested to give your consent to the sample collector.

After consent, a sample will be taken from venous puncture. Moreover, there will be a face-to-face interview for additional questions.

Potential risks and Discomforts

During the collection of specimens from you, appropriate precaution will be taken and all samples will be collected by trained health professionals. If anything

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 related with your social desirability but any information that is obtained in connection with this study and that can be identified with you will remain confidential. happened, appropriate medical care will be provided to you.

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. Hence, you are indirectly benefiting other patients and the society in this respect.

Participation and Withdrawal from the Study

The 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 to 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 following principal investigators and advisors for further information.

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Annex 1(B): Information sheet (Amharic version)

የተሳታፊዎች ፈቃድና መተማመኛ ቅፅ

በአዲስ አበባ ዩኒቨርሲቲ ጤና ሳይንስ ኮሌጅ የሕክምና ለቦራቶሪ ሳይንስ ት/ክፍል በማስተርስ ድግሪ ተማሪ የመመረቂያ ጥናት ላይ እዲሳተፊ ተጋብዘዋል። እባክዎ በዚህ ጥናት ለመሳተፍ ከመስማማትዎ በፊት ከዚህ ቀጥሎ የሚገኘውን ምንባብ በጥሞና ያንብቡና ግልጽ ያልሆነልዎትን ማንኛውም ሃሳብ ይጠይቁ።

መግቢያ

የጥናቱ ርዕስ “To assess serum electrolytes and lipid profiles among type II diabetic patients with and without hypertension attending wolaita sodo comprehensive specialized hospital, SNNPR, Ethiopia”

የእርስዎ በዚህ ጥናት ላይ የሚኖርዎት ተሳትፎ ሙሉ በሙሉ በበጎ ፈቃደኝነት ላይ የተመሰረተ ነው። በዚህ ጥናት ውስጥ ላለመሳተፍ ወይም ለመሳተፍ ከወሰኑ በኋላ ለማቋረጥ የሚወስኑ ቢሆንም እንኩዋ በዚህ ሆስፒታል የሚሰጠው ማንኛውም አገልግሎት አይቋረጥም። በጥናቱ ለመሳተፍ የሚስማሙ ከሆነ የስምምነት ቅጹ ላይ በጸሁፍ ወይም በጥንቅቅ ፊርማ ማስቀመጥ ይጠበቅዎታል።

የጥናቱ ተሳታፊ ለመሆን የሚጠበቅበዎት ምንድን ነው?

በዚህ ጥናት ለመሳተፍ የሚስማሙ ከሆነ ናሙናዎ ለጥናቱ እንዲሟወል መስማማት ይጠበቅብዎታል። ከተወሰደው ናሙና ላይ የሚገኙ መረጃዎች ከዚህ ሆስፒታል ውጭ ለሚገኙና ለስራው አግባብነት ላላቸው ሰዎች ቢነገር የማይቃወሙ መሆኑን መስማማት ይጠበቅብዎታል። ይሁን እንጅ ይህ አይነቱ መረጃ የርስዎን ማንነት የሚገልጡ መረጃዎችን ማለትም ስም፣ አድራሻና የስልክ ቁጥር የመሳሰሉትን መረጃዎችን አይጨምርም። ይልቁንም ለዚህ አገልግሎት ብቻ የሚወልድ እርስዎን ለማወቅ የሚያስችል መለያ ቁጥር ጥቅም ላይ እንዲወልድ ይደረጋል። በተጨማሪም ስለርስዎ አጠቃላይ የጤና ሁኔታ ለሚቀርቡ አንዳንድ ተጨማሪ ጥያቄዎች መልስ መስጠት ይኖርብዎትዎታል።

በዚህ ጥናት መሳተፍ የሚያስከትላቸው ችግሮች ምንድን ናቸው?

ናሙና በሚሰበሰብበት ወቅት ምንም አይነት የከፋ ችግር አያጋጥምዎትም። ሆኖም ግን ናሙናውን ለመሰብሰብ ልምድ ያለው ባለሙያ ስለሚመደብና አስፈላጊው የጥንቃቄ እርምጃ ስለሚወሰድ የህመም ስሜት አይኖርም።

የህክምና መረጃ በሚስጥር ተጠብቆ መቆየት የሚችለው እንዴት ነው?

ስለራስዎ የሰጡት ማንኛውም መረጃና ከተወሰደው ናሙና ላይ የተገኘው የላቦራቶሪ ውጤት የሚወለደው ለጥናቱ አላማ ብቻ ነው። 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 ድግሪ መመረቂያ እንደመሆኑ መጠን በዚህ ጥናት በመካፈልዎ በገንዘብ የሚያገኙት ጥቅም ባይኖርም ከጥናቱ በሚገኘው ውጤት ግን ተጠቃሚ ነዎት። የእርሶዎ ተሳትፎ የእርስዎንና

የወገንዎችን የደም ስኳር የደም ግፊት እና የኮሌስትሮል መጠን ለማወቅና ለማከታተል 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 አለብዎት።የላብራቶሪ ምርመራ ውጤቱንም በነጻ ማግኘት ይችላሉ። ነገር ግን እርስዎ በሚሰጡን መረጃ የችግሩን 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፡

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Annex 2 (A): Informed consent form (English version)

Unique code: _____ Date: _____

I had been informed that the objective of this study is Assessment of serum electrolytes and lipid profiles among type II diabetic patients with and without hypertension attending at wolaita sodo comprehensive specialized hospital, SNNPR, Ethiopia. The results of this study have an

importance to treat me and other patients, and to be used as an input for the future development of strategies or guidelines for diagnosing of diabetes mellitus and comorbid condition in Ethiopia. I had been also informed about the confidentiality of this study. The principal investigator requested me to participate in the study that would require my willingness to provide the required data that include blood sample, and filling questionnaire. Therefore, with full understanding of the importance of the study, I agreed voluntarily to provide the requested samples and my benefit will be only from the free laboratory investigation result/s.

I _____ hereby give my consent for providing the requested information and specimens as the doctors find best for me.

Signature: _____ Date _____

Annex 2 (B): Informed consent form (Amharic version)

የተሳታፊዎች ስምምነት ማረጋገጫ

የሚስጥር ቁጥር -----

እኔ ስሜ ከላይ የተጠቀሰው ተሳታፊ “Assessment of serum lipid profiles and electrolytes among type II diabetic patients with and without hypertension attending wolaita sodo comprehensive specialized hospital, SNNPR, Ethiopia.” ጥናት ላይ በቂ ገለጻ ተደርጎልኛል። ለጥናቱም የደም ናሙና እንደሚያስፈልግ ተገልጿል። 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 ተገልጿል።

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 በፈርማዬ አረጋግጣለሁ።

ፈርማ----- ቀን -----/---/-----

(የስምምነት ቅጹን ማንበብ ለማይችሉ ተሳታፊዎች)

የአማካሪ ነርስ ስም ----- ፊርማ ----- ቀን-----

Annex 3 (A): Structured Questionnaire for the Study participants (English Version)

Participant's identification code: _____ Date _____

SECTION-1: Socio-demographic factor

No	Questions	Responses
1	Age	Years
2	Sex	1.Male 2.Female
3	Marital Status	1. Single 2. Married 3. Co-habiting 4. Separated
4	Religion	1. Orthodox 2. Protestant 3. Muslim 4. other, specify _____
5	Education Level	1. No formal education 2. Primary 3. Secondary 5. College or University
6	Residence	1.Urban 2.Rural
7	Occupation	1. Gov.t Employee 2.Merchant 3. Farmer 4. Daily laborer 5.Other

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SECTION-2: Behavioral, Life style Factors, Diabetes and Hypertension Knowledge Questionnaire

No	Questions	Responses

		Yes	No	I don't Know
1	Diabetes is caused by failure of the kidneys to keep sugar out of the urine			
2	Diabetes and Hypertension can be cured.			
3	Do have frequent medical checkup			
4	Do you drink alcohol?			
5	Have you ever been smoke tobacco product?			
6	Do you do any vigorous-intensity sports, fitness activities that cause large increases in breathing or heart rate like running or football, local dancing for at least 30 minutes continuously?			
7	Take diabetes and Hypertension medication as prescribed			
8	Follow specialist's dietary recommendations			
9	A fasting blood sugar level of 210 and a BP of 140/90 is too high			
10	check blood sugar and BP levels frequently enough			
11	Diabetes and Hypertension can damage my kidneys			
12	Diabetes often causes poor circulation			
13	Duration of diabetes and Hypertension in years			
14	Comorbidities	1. Hypertension 2. Kidney disease 3. Diabetes 4. Other 5. No associated disease		

15	Concomitant drugs	1.Antihypertensive 2.Antidiabetic or metformin 3.lipid lowering 4.Weight reducing 5.Others
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SECTION-3: Anthropometric and Biochemical profile

Participant's identification code: _____

Date _____

Anthropometric measurement (filled by nurse)				
No	Parameters		Result	Laboratory personnel comment
1	Height		Cm	
2	Weight		Kg	
3	Waist circumference		Cm	
4	BMI		Kg/m ²	
5	BP		mmHg	
WSUCSH Laboratory Request Form for Participants (filled by Lab technologist)				
1	FBS		mg/dL	
2	Lipid profile	T. Cholesterol	mg/dL	
3		HDL	mg/dL	
4		LDL	mg/dL	
5		Triglyceride	mg/dL	

6	Sodium	(mmol/L)	
7	Potassium	(mmol/L)	
8	Chloride	(mmol/L)	

Reported by: Name of lab technologist _____ Date of report _____ Signature _____

Annex 3 (B): Structured Questionnaire for Diabetic and Hypertension Study participants (Amharic Version)

የተሳታፊው ሚስጥራዊ ቁጥር:- ----- ቀን-----

ለክቡራን ተሳታፊዎች ከዚህ በታች የተዘረዘሩት ጥያቄዎች ከእናንተ የሚፈለጉ ናቸው። ጥያቄው በአዲስ አበባ ዩኒቨርሲቲ ጤና ሳይንስ ኮሌጅ በህክምና ላቦራቶሪ ድጋፍ ተቀባይነት ለድህረ ምረቃ ጥናት የሚያስፈልጉ ናቸው። የዚህ ጥናት አላማው በደረጃ ሁለት ስኩር እና የደም ግፊት ታማሚዎች ላይ የደም ስኩር ፤ኤልክትሮላይት እና ኮላስትሮል መጠን ማጥናት ነው። የእናንተ መልስ መስጠት ለዚህ ጥናት አላማ ዕውን መሆን አስፈላጊ ነው።

ለትብብርዎ እናመሰግናለን!!!

ክፍል አንድ: የተሳታፊዎች አጠቃላይ መረጃ

ከዚህ በታች እርስዎን በትክክል የሚገልጽዎትን ክብ ያድርጉ

ተ.ቁ	ጥያቄ	መልስ
1	ዕድሜ	_____ ዓመት
2	ፆታ	ሀ. ወንድ ለ. ሴት
3	የትዳር ሁኔታ	ሀ. ያገባ/ች ለ. ያላገባ/ች ሐ. የተፋታ/ች መ. የሞተበት(ባት)
4	ሐይማኖት	ሀ. ኦርቶዶክስ ለ. ፕሮተስታንት ሐ. ሙስሊም መ. ላሎች.....

5	የትምህርት ደረጃ	ሀ. የቀለም ት/ት ያልተማሩ ለ. አንደኛ ደረጃ ሐ. ሁለተኛ ደረጃ መ. ዲፕሎም ና ከዛ በላይ
6	የመኖሪያ አድራሻ	1.ገጠር 2.ከተማ
7	የተሰማሩበት የስራ መስክ	1.የመንግስት ሰራተኛ 2.ነጋዴ 3.ግብርና 4.የቀን ሰራተኛ 5.ሌላ.....

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ተ.ቁ	ጥያቄ	መልስ		
		አወ	አይ	አላውቅም
1	የስካር ህመም የሚከሰተው ኩላሊት በሰውነታችን ውስጥ ያለውን የስካር መቆጣጠር ባለመቻሉ ነው			
2	ከስኩር ህመምና የደም ግፊት በሽታ መዳን ይቻላል			
3	የህክምና ክትትልወን በየጊዜው ያደርጋሉ			
4	>MçM SÖØ ÃÖkTK<			
5	¼fUvJ -Ö?„<” ÃÖkTK<			
6	ስፖርታዊ እንቅስቃሴ በሳምንት ውስጥ በየቀኑ ለ30 ደቅቃ ያህል ያለመቆረጥ ያደርጋሉ			
7	መድሀኒትወን በሀኪምወ ትዕዛዝ ነው ሚወስዱት			

8	በስፔሻሊስት ሀኪምወ የተነገረውን አመጋገብ ስርአት ይከተላሉ			
9	ምግብ ሳይበላ በፊት ያለው የስካር መጠን ከ 210 ከበለጠ በጣም ከፍተኛ ነዉ ሚባለዉ			
10	የስኩረውን መጠን በየጊዜዉ ይከታተላሉ			
11	የስካር ህመምና የደም ግፊት በሽታ ኩላሊትን ይጎዳል			
12	የስካር ህመም የደም ዝዉዉርን ያዛባል			
13	የስካር ህመምና የደም ግፊት በሽታ ምን ያክል ጊዜ ቆየብዉት			
14	ተጉዋዳኝ ህመም ካለብዉት የትኛው	1.የደምግፊት 3.የኩላሊት 4.ሌላ	2.የስካር 5.የለብኝም	
15	ለሌላ ህመም ሚወስዱት መድሀኒት ካለ	1.ለደም ግፊት 2.ቅባት መቀነሻ 4.ሌላ	2.ለስካር 3.ክብደት ለመቀነስ	

Annex 4: Laboratory SOPs

Venous blood collection procedure

1. Introduce yourself and identify the patient
2. Explain the procedure to the patient

3. Wash hands and wear gloves
4. Prepare materials (syringes, needles, test tubes etc.)
5. Prepare the patient and apply tourniquet
6. Disinfect the draw site
7. Collect 5ml of blood with either vacutainer tubes or syringe and needle
8. Exit the pain, apply pressure and check the patient.
9. Discard the needle in safety box
10. Label the specimen in each tube
11. Allow the specimen for 30minutes (to facilitate clotting) and centrifuge with medium speed for 5minutes
12. Separate serum from the blood by Pasteur pipette
13. Perform lab. Test according to the manufacturer's manual and store the remaining serum at - 20 °C (56, 57).

Annex-4.1. Principles of Laboratory analysis and procedures

Measurement of serum total cholesterol (TC)

Procedure: Samples, standard and reagent blank were pre-incubated for 5 minutes at 37 ° C. Samples (10 µL) or standard (10 µL) and reagent blank (1000 µL) were pipetted into cuvette and mixed thoroughly by inversion. The cuvettes were inserted into the cell holder and stopwatch was started to count. The absorbance of sample, standard and the reagent blank was measured at 400 nm within 60 minutes. Finally the absorbance of the sample (ΔA sample) and the standard (ΔA standard) against the reagent blank was calculated.

2. Measurement of serum Triglyceride (TG)

Reagents: The reagents are standard and ready for use on automated analyzer. Enzymatic assay and measurement was done at 540 nm wavelengths, 1cm optical path, and 37 °C temperature against reagent blank.

Reagent(R): phosphate buffer (PH 7.5)-100mmol/l, LPL-1500 U/L, GK-800 U/L, G-3-P oxidase - 4000 U/L, Peroxidase -440 U/L, Phenol – 7.5 mmol/L, 4-aminoantipyrine – 0.7 mmol/L, ATP – 0.3mmol/L.

Procedure: Samples, standard and blank were pre-incubated for 5 minutes at 37 °C. Reagent blank (1000 µL) and samples (10 µL) or standard (10 µL) was put into cuvette and mixed gently by inversion. The cuvettes were inserted into the cell holder and stopwatch started to count. The absorbance of sample, standard and blank was measured at 540 nm. Finally, the absorbance of the sample (ΔA sample) and the standard (ΔA standard) against the reagent blank will be calculated.

3. Measurements of serum high density lipoprotein cholesterol (HDL-C)

Reagent: Reagents are standard and ready for use on automated analyzer. Enzymatic assay was done at 593 nm wavelength, 1 cm optical path, 37 °C temperature and measurement was done against reagent blank. PIPES-200mmol/L(PH-7.0),Sodium cholate-1mmol/L, Cholesterol ester >250U/L, Cholesterol oxidase>250U/L,Phenol-4 mmol/L->1KU/L, 4-aminoantipyrine-0.33 mmol/L,Phenol-4 mmol/L,Non-ionic surface-2 g/l,Biocides.

Procedure: Reagent blank, samples and calibrator were pre-incubated for 5 minutes at 37 °C. Reagent blank (10 µL distilled water and 750 µL enzymes) and samples (10 µL samples and 750 µL enzymes) or calibrator (10 µL calibrator and 750 µL enzymes) was pipetted into cuvette and mixed gently by inversion. The cuvettes were inserted into the cell holder and stopwatch were started to count. The absorbance of sample, standard and the reagent blank were measured at 593 nm after 5 minutes. Finally the absorbance of the samples (ΔA sample) and the calibrator (ΔA standard) against the reagent blank was calculated.

4. Measurement of serum low density lipoprotein (LDL)

Most of the circulating cholesterol is found in three major lipoprotein fractions: very low density lipoproteins (VLDL), LDL and HDL. $[\text{Total chol}] = [\text{VLDL-chol}] + [\text{LDL-chol}] + [\text{HDL-chol}]$

LDL-cholesterol is calculated from measured values of total cholesterol, triglycerides and HDLcholesterol according to the relationship: $[\text{LDL-chol}] = [\text{total chol}] - [\text{HDL-chol}] - [\text{TG}]/5$ where $[\text{TG}]/5$ is an estimate of VLDL-cholesterol and all values are expressed in mg/dL.

5. Measurement of fasting blood glucose

Fasting glucose is measured by GOD-PAP enzymatic method with deproteinization on a fully automated clinical chemistry analyzer. Glucose present in the serum is oxidized by the enzyme glucose oxidase (GOD) to gluconic acid with the liberation of hydrogen peroxide, which is converted to water and oxygen by the enzyme peroxidase (POD). 4-aminoantipyrine [4-AA], an oxygen acceptor, takes up the oxygen and together with phenol forms a red colored chromogen proportional to the concentration of glucose in the sample can be measured at 500nm(480 – 520 nm)

Measurement of Electrolytes

Electrolytes are measured by a process known as potentiometry. This method measures the voltage that develops between the inner and outer surfaces of an ion selective electrode. The electrode (membrane) is made of a material that is selectively permeable to the ion being measured. For example, sodium electrodes are made from a special glass formula that selectively binds sodium ions. The inside of the electrode is filled with a fluid containing sodium ions, and the outside of the glass membrane is immersed in the sample. A potential difference develops across the glass membrane that is dependent upon the difference in sodium concentration (activity) on the inside and outside of the glass membrane. This potential is measured by comparing it to the potential of a reference electrode. Since the potential of the reference electrode is held constant, the difference in voltage between the two electrodes is attributed to the concentration of sodium in the sample.

Ion selective membranes can be made from materials other than glass. For example, the antibiotic valinomycin is used to make potassium-measuring electrodes. Ion selective electrodes can be used to measure whole blood, serum, or plasma since they respond to the electrolyte activity in the water phase of the sample only. One important aspect of electrolyte measurement is an artifact (erroneous result) called pseudo-hyponatremia that may occur when sodium is measured using a diluted blood sample. This happens when the plasma contains excessively high lipids or protein. These solids displace plasma water from the specimen, resulting in a low measurement of sodium that does not occur with an undiluted sample.

11. 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.

M.Sc. candidate:

Workineh H/mariam (BSc)

Signature:

Date of submission:

This thesis has been submitted with our approval as advisors.

Advisors:

Abebe Edao (MSc, Ass. Professor)

Signature:

Date:

Place:

Addis Ababa, Ethiopia.

Mekdes Alem (MSc)

Signature:

Date:

Place:

Addis Ababa, Ethiopia

