College of Health Sciences

School of Medicine, Biomedical Division

Department of Medical Biochemistry and Molecular Biology

Assessment and Comparison of Serum Electrolyte Level among Pulmonary Tuberculosis Patients with and without HIV Co-infection at Ayder Comprehensive Specialized Hospital, Tigray, North Ethiopia, 2023/2024.

By:

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A Thesis Research Submitted to the Department of Medical Biochemistry and Molecular Biology, College of Health Sciences, Mekelle University in Partial Fulfilment of the Requirements for the Master of Science in Clinical Biochemistry.

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Thesis Research Submission Form

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Advisor's Approval Sheet

This is to certify that the thesis entitled "**Assessment and Comparison of Serum Electrolyte Level among Pulmonary Tuberculosis Patients with and without HIV Co-infection at Ayder Comprehensive Specialized Hospital, Tigray, North Ethiopia, 2023/2024**" is submitted in partial fulfilment of the requirements for the degree of MSc with specialization in "**Clinical Biochemistry**" to the Graduate Program of the College of Health Sciences of Mekelle University and has been carried out by **Tsegay G/her Birhane** under my supervision. Therefore, I recommend that the student has fulfilled the requirements and hence hereby can submit the thesis to the Department.

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We, the undersigned, members of the Board of Examiners of the final open defence by "**Tsegay G/her Birhane**" have read and evaluated his thesis "**Assessment and Comparison of Serum Electrolyte Level among Pulmonary Tuberculosis Patients with and without HIV Co-infection at Ayder Comprehensive Specialized Hospital, Tigray, North Ethiopia, 2023/2024**" and evaluated the candidate. This is therefore to certify that the thesis has been accepted in partial fulfilment of the requirements for the Masters Degree in **Clinical Biochemistry.**

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Declaration

I hereby declare that this MSc thesis is my original work and has not been presented for a degree in any other university and all sources of material used for this thesis have been duly acknowledged.

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Table of Contents

ACKNOWLEDGEMENT……………………………………………………………………VI

ABBREVIATIONS AND ACRONYMS…………………………………………………..…….IX

LIST OF TABLES……………………………………………………………….………...X

LIST OF FIGURES………………………………………………………………….………XI

ABSTRACT……………………………………………………………………………...XII

1. INTRODUCTION 1

1.1.Back ground of the study 1

1.2.Statement of problem 2

1.3.Significance of the study 3

2. LITERATURE REVIEW 4

2.1. Mechanisms Leading to Electrolyte Imbalances 4

2.2. Serum electrolyte disturbances 4

2.3. Impact of anti-tuberculosis and ART treatment on serum electrolytes 6

2.4. Conceptual frame work 7

3. OBJECTIVES 8

3.1. General objective 8

3.2. Specific objectives 8

4. METHODS AND MATERIALS 9

4.1. Study area 9

4.2. Study design and period 9

4.3. Population 9

4.3.1. Source population 9

4.3.2. Study population 9

4.4. Eligibility criteria 9

4.4.1. Inclusion criteria 9

4.4.2. Exclusion criteria 9

4.5. Sample size determination and sampling technique 10
4.5.1. Sample size determination 10
4.5.2. Sampling technique 11
4.6. Data collection and measurements 11
4.6.1. Data collection method 11
4.6.2. Biochemical analysis of serum electrolyte (Na^+, K^+ and Cl^-) 12
4.7. Data management and quality control 12
4.8. Data processing and analysis 12
4.9. Study variables 13
4.9.1. Dependent variables 13
4.9.2. Independent variables 13
4.10. Ethical consideration 13
4.11. Dissemination of findings 13
5. RESULTS 14
5.1. Demographic profile of study participants 14
5.2. Clinical characteristics of study participants 15
5.3. Serum Electrolyte level of study participants 16
6. DISCUSSION 19
7. STRENGTH AND LIMITATION OF THE STUDY 21
8. CONCLUSION 22
9. RECOMMENDATION 22
10. REFERENCES 23
11. ANNEXES 26

ABBREVIATIONS AND ACRONYMS

ADH -------------------------- Anti-Diuretic Hormone

ACSH ------------------------ Ayder Comprehensive Specialized Hospital

AIDS ------------------------- Acquired Immune Deficiency Syndrome

ART -------------------------- Anti-Retroviral Therapy

Cl^- --------------------------- Chloride

ETB -------------------------- Ethiopian Birr

HIV --------------------------- Human Immunodeficiency Virus

HIV-PTB --------------------- HIV Co-infected with Pulmonary Tuberculosis

IRB --------------------------- Institutional Review Board

K^+ ---------------------------- Potassium

MDR ------------------------- Multi Drug Resistant

MU --------------------------- Mekelle University

Na^+ -------------------------- Sodium

PI ----------------------------- Principal Investigator

PTB -------------------------- Pulmonary Tuberculosis

RPM ------------------------ Revolutions Per Minute

SPSS ------------------------- Statistical package for the social sciences

SST --------------------------- Standard Sampling Tubes

TB ---------------------------- Tuberculosis

WHO ------------------------ World Health Organization

LIST OF TABLES

Table 1: Sample size determination for the study assessment and comparison of serum electrolyte among PTB patients with and without HIV co-infection at ACSH, Mekelle, Northern Ethiopia from October 2023 to December 2024 (n=50)... 11

Table 2: Socio demographic characteristics of pulmonary tuberculosis patients attending Ayder Comprehensive Specialized Hospital, Mekelle, Northern Ethiopia from October 2023 to December 2024 (n=50).. 15

Table 3: Clinical characteristics of pulmonary tuberculosis patients attending Ayder Comprehensive Specialized Hospital, Mekelle, Northern Ethiopia from October 2023 to December 2024 (n=50)... 16

Table 4: Summary mean (x) ± standard deviation of serum electrolytes of pulmonary tuberculosis patients attending Ayder Comprehensive Specialized Hospital, Mekelle, Northern Ethiopia from October 2023 to December 2024 (n=50)... 16

Table 5: Serum Electrolyte of pulmonary tuberculosis patients attending Ayder Comprehensive Specialized Hospital based on PTB HIV co-infection status, Mekelle, Northern Ethiopia from October 2023 to December 2024 (n=50). 17

Table 6: Cut off values serum electrolyte for the study assessment and comparison of serum electrolyte levels among PTB patients with and without HIV co-infection at ACSH, Mekelle, Northern Ethiopia from October 2023 to December 2024 (n=50).(35). 37

LIST OF FIGURES

Figure 1: Conceptual frame work impact of tuberculosis and HIV on serum electrolytes 7
Figure 2: Gender distribution of study participants 14
Figure 3: Serum Electrolyte of study participants based on HIV-PTB co-infection status 17

ABSTRACT

Background: According to a World Health Organization report from 2021, tuberculosis is a primary cause of morbidity and one of the top causes of mortality globally. It has been discovered that electrolyte and fluid imbalances, which are common in tuberculosis and HIV/AIDS, have a significant role in morbidity and mortality.

Objective: The aim of this study was to assess and compare serum electrolyte level among pulmonary tuberculosis patients with or without HIV co-infection at Ayder Comprehensive Specialized Hospital, Tigray, North Ethiopia.

Methods: A comparative cross-sectional study utilizing a convenience sampling technique was used to sample 50 pulmonary tuberculosis patients with or without HIV co-infection at Ayder Comprehensive Specialized Hospital in the period from October 2023 to December 2024. HIV-PTB co-infected patients and PTB without HIV co-infection who fulfilled the inclusion criteria were included in the study. Socio-demographic and clinical data were collected using an interviewer administered structured questionnaire and medical record review. K-Light electrolyte analyser auto-machine analyser was used to determine the serum electrolyte status of pulmonary tuberculosis patients with or without HIV co-infection directly by taking 3 millilitres of venous blood. After checking for completeness and cleaning, the data were entered into Epi-data version 4.5 and exported into the SPSS software version 25 package for analysis, and the different variables were analysed. Linear Regression was used to assess the relationship of anti-TB and ART Rx duration with serum electrolyte level.

Result: This study found that serum sodium levels were significantly higher in pulmonary tuberculosis (PTB) patients compared to those co-infected with HIV (132.65±4.15 vs. 130.28±4.09 mEq/L; $p = 0.047$). Conversely, serum potassium levels were significantly elevated in HIV-PTB co-infected patients (5.05±0.75 vs. 3.83±0.59 mEq/L; $p = 0.000$), and serum chloride levels were higher in PTB patients without HIV co-infection (103.42±3.16 vs. 100.61±5.10 mEq/L; $p = 0.023$).

Conclusion: The study highlights the significantly higher level of serum sodium in pulmonary tuberculosis (PTB) patients without HIV co-infection compared to those co-infected with HIV. This study also showed a significantly higher level of serum potassium in HIV-PTB co-infected patients and significantly higher chloride level in PTB patients without HIV co-infection.

Key words: *Tuberculosis, HIV, Co-infection, Electrolyte*.

1. INTRODUCTION

1.1. Back ground of the study

Tuberculosis (TB) is an infectious disease of the respiratory system transmitted by airborne contact with aerosolized droplets from coughing, sneezing, or talking, especially in poorly ventilated environments. As per the World Health Organization (WHO) study from 2024, tuberculosis (TB) is a primary cause of morbidity and among the top causes of death globally (1).

Major public health issues related to tuberculosis persist in low- and middle-income nations. The WHO reported in 2023 that 24% of tuberculosis infections occurred in Africa. Among the most prevalent public health issues in sub-Saharan African nations are TB and Human Immunodeficiency Virus (HIV) (1). According to the latest WHO data, Ethiopia has an incidence of 146 cases of all kinds of tuberculosis per 100,000 people for 2024, a 16% increase compared to previous years, placing it among the 30 nations with the greatest global TB burden (1). The Tigray region experienced a substantial increase in TB incidence due to the civil war, with projections viewing a rise to 965.5 per 100,000 people in 2022 (2).

Tuberculosis is the commonest infection among HIV patients. This co-infection constitutes a major death threat to the world. Global TB Report 2024 states that 10.8 million persons contracted TB globally in 2023, with 1.09 million TB deaths among HIV-negative individuals and an extra 161,000 among HIV-positive individuals. Of the total instances reported worldwide, thirty high-burden nations account for 87% of the cases (1). 82% of all TB-related deaths in HIV-positive and HIV-negative individuals occurred in the WHO's African and Southeast Asian areas (3). Ethiopia has a higher mortality rate among TB/HIV co-infected patients compared to other African countries, with a pooled incidence rate of 12.49 per 100 person-years (4).

Electrolyte imbalance is a too high or too low level of electrolytes after blood is drowned (5). Serum electrolyte abnormalities are common problems that occur in pulmonary TB (PTB) and HIV-PTB co-infected patients. Electrolyte disturbances are the potential cause of morbidity in HIV-PTB patients; thus, monitoring the serum electrolyte level improves an individual’s quality of life (6). Hyponatremia, and hyperkalaemia are common electrolyte imbalances in TB patients co-infected with HIV (7). Electrolyte imbalances are a significant issue for patients on ART, leading to disturbances like hyponatremia, hypokalaemia, and hypocalcaemia. These imbalances depend on the specific medications used (8).

1.2.Statement of problem

Tuberculosis (TB) is a serious public health concern that has the potential to have catastrophic health impacts since it affects the productive segment of the population, places a heavy burden on the healthcare system, and preys on the individual or household economy. According to available data, TB/HIV co-infection rate in Tigray region, Ethiopia is around 24%, which is considered comparatively higher than other regions, while the national average for Ethiopia is around 25.6%, meaning a significant proportion of HIV patients in Ethiopia are also co-infected with TB (9).

Electrolyte disturbances are one of the most challenging complications because of the paucity of presenting symptoms and potential morbidity associated with this disorder. Thus, monitoring the serum electrolyte level is very necessary for the early detection and treatment of these abnormalities, which will improve the quality of life of individuals (6).

Although derangements in the concentration of essential elements was reported in several pathological conditions, their levels in sera of TB patients' with or without HIV coinfection are not well documented in Ethiopia, especially in the study area. There is also a great variation in the studies conducted in India and Nigeria. An observational study done in India, demonstrated that serum electrolyte derangement normalizes after the initiation of therapy; however, a prospective study conducted in the same country showed that serum electrolyte derangement aggravates after the initiation of therapy (6, 10). A descriptive cross-sectional study in southern Nigeria showed that levels of sodium and chloride were significantly dropped in TB patients on drugs compared to new-case tuberculosis patients, while potassium level was meaningfully raised in TB patients on drug treatment (11).

This study was designed to determine common electrolyte abnormalities in PTB patients with and without HIV co-infection in Ethiopia, especially at ACSH. The study is also aimed at finding out whether there was any difference in the level of serum electrolytes among PTB patients and HIV-PTB co-infected patients at ACSH, Tigray, North Ethiopia.

1.3. Significance of the study

Little is known about the serum electrolyte levels in patients with pulmonary tuberculosis (PTB) without HIV co-infected and those co-infected with HIV. This study aimed to provide comprehensive information on the serum electrolyte status of PTB patients, both with and without HIV co-infection, to enhance the management of these patients at the study site. The findings informed participants and their healthcare providers about the extent of any electrolyte imbalances, enabling them to collaborate effectively in addressing these issues promptly. Additionally, the results may serve as valuable insights for program leaders and policymakers involved in developing or refining guidelines for managing TB and TB-HIV co-infection. Finally, this study will establish baseline information for future research in this area.

2. LITERATURE REVIEW

2.1. Mechanisms Leading to Electrolyte Imbalances

Electrolyte imbalances and altered mineral metabolism are major issues in people with HIV/AIDS and pulmonary tuberculosis (PTB). These disturbances can cause many health concerns, including impaired functions of the heart, neurological system, and muscular system, as well as acid-base imbalances (12).

Electrolyte imbalances in HIV/AIDS and PTB patients can result from a variety of reasons. Common symptoms of these diseases, such as vomiting, diarrhoea, and profuse perspiration, all contribute considerably to electrolyte and water loss (13). For example, in AIDS patients, hyponatremia is commonly linked to sodium loss via diarrhoea (14).

Additionally, impaired renal sodium conservation caused by HIV infection contributes to hyponatremia. The virus-induced high-grade fever can cause cell death and the release of potassium into the serum, resulting in hyperkalaemia. This condition may also be influenced by adrenal insufficiency, hyporeninemic hypoaldosteronism, and the usage of certain drugs, such as trimethoprim or pentamidine (15, 16).

Electrolyte imbalances in tuberculosis can occur via a variety of pathways, including local invasion of the adrenal glands (adrenal insufficiency), local invasion of the hypothalamus or pituitary gland, tubercular meningitis, inappropriate Anti Diuretic Hormone (ADH) secretion via pulmonary infection, and excessive electrolyte loss due to diarrhoea, vomiting, and sweating (17).

2.2. Serum electrolyte disturbances

Electrolyte imbalances are a significant concern in patients with tuberculosis (TB), affecting treatment outcomes and overall health. This review synthesizes findings from global studies, highlighting the prevalence and types of electrolyte disturbances, and examines local patterns in various countries.

Multiple studies indicate a high prevalence of electrolyte abnormalities among TB patients worldwide. A study in Japan reported that 40.7% of TB patients had serum sodium levels below 135 mEq/L, indicating a noteworthy incidence of hyponatremia (18). Meanwhile, a study in Argentina demonstrated significant variability, with hyperkalaemia reported in 5% to 53% of clients, reflecting the diverse manifestations of electrolyte disturbances across different populations (19).

In Pakistan, a cross-sectional study highlighted a markedly high prevalence of electrolyte imbalances among TB patients, emphasizing the influence of respiratory infections on electrolyte homeostasis (20). Similarly, another observational study in India revealed that 50% of newly diagnosed TB patients exhibited hyponatremia, while 45% had hypokalaemia and 35% had hypocalcaemia (21). These findings indicate a troubling trend of electrolyte disturbances in newly diagnosed cases.

A descriptive observational study in Indonesia reported that 35.1% of patients had abnormal sodium levels, 40.5% had abnormal potassium levels, and 43.2% had abnormal chloride levels (22). This consistent pattern of disturbances across different populations further highlights the widespread nature of the issue.

Research comparing serum electrolyte levels between TB patients and healthy controls has revealed significant differences. One study in India found that mean serum sodium levels were 141.5 mmol/L in healthy controls versus 121.6 mmol/L in the TB group, while mean potassium levels were lower in TB patients (3.1 mmol/L) compared to controls (4.3 mmol/L) (23). Another study in India corroborated these findings, reporting that newly diagnosed TB patients had higher chloride levels but lower sodium and potassium levels compared to normal controls (24). This indicates that TB significantly disrupts electrolyte balance.

The presence of co-infections, particularly with HIV, complicates electrolyte management in TB patients. A hospital-based study in India found that TB patients co-infected with HIV had significantly lower serum sodium levels compared to those with TB alone, while hypercalcemia was more prevalent in the co-infected group (7). This suggests that co-infections can exacerbate electrolyte disturbances and complicate patient management, calling for tailored therapeutic approaches.

A prospective study in India explored serum electrolyte abnormalities in patients with HIV and PTB, identifying hyponatremia as the most common electrolyte disturbance among HIV, PTB, and HIV-PTB co-infected individuals. The study also noted hyperkalaemia in HIV patients and hypokalaemia in those with PTB, along with variations in chloride levels, indicating that co-infections can further complicate electrolyte management (6).

2.3.Impact of anti-tuberculosis and ART treatment on serum electrolytes

A descriptive cross-sectional study in Indonesia found that 69.2% of lung tuberculosis patients experienced hypokalaemia as a direct result of anti-tuberculosis medications, often accompanied by gastrointestinal symptoms such as diarrhoea, nausea, and vomiting. This highlights the significant impact of TB treatment on serum potassium levels (25).

Conversely, an observational study in India reported that antitubercular treatment generally restores electrolyte levels to normal in patients, suggesting that while imbalances may occur during treatment, they can be effectively managed (10). Similarly, a cross-sectional observational study in Bangladesh confirmed that treatment with antitubercular drugs significantly normalized sodium, potassium, chloride, and bicarbonate levels in TB patients, emphasizing the restorative potential of appropriate therapy (26).

However, complications can arise, particularly in cases of drug-resistant TB. A study in India noted that treatment for drug-resistant tuberculosis can lead to significant electrolyte imbalances, including hypokalaemia and hypomagnesemia, which pose serious risks such as cardiac arrhythmias and renal dysfunction (27).

Moreover, the study in Nigeria adds a critical dimension by indicating that electrolyte imbalances can also arise from treatment-related complications rather than just the disease itself (11). The prospective study further complicates the narrative by highlighting the interplay of multiple infections and their effect on electrolyte homeostasis.

While many studies emphasize the normalization of electrolyte levels following antitubercular treatment, they also highlight the potential for imbalances, particularly in specific subsets of patients, such as those with drug-resistant TB or co-infections like HIV. For instance, the Indonesian study underscores a high prevalence of hypokalaemia directly linked to medication (28), while the findings from India (10) and Bangladesh (26) suggest that the right treatment can restore balance.

Electrolyte imbalances are a common complication in HIV-infected individuals, often exacerbated by HAART. These imbalances can lead to severe health issues, including irregular heartbeat, fatigue, headaches, confusion, and neurological symptoms such as numbness and tingling. A notable global concern is the association between electrolyte disturbances, particularly hypokalaemia and hyponatremia, and increased mortality rates among HIV patients. These disturbances can arise from various factors, including the direct effects of HIV, opportunistic infections, and the side effects of antiretroviral medications (29, 30).

An observational study conducted in Mexico provided further insights into the prevalence of electrolyte disturbances among HIV patients undergoing HAART. The study reported mean serum electrolyte levels as follows: sodium at 145.13 (±14.45) meq/L, chloride at 108.34 (±11.28) meq/L, phosphorus at 3.51

(±1.20) mg/dL, calcium at 9.75 (±1.24) mg/dL, magnesium at 2.13 (±0.349) mg/dL, and potassium at 4.35 (±0.58) meq/L. The study found that the most common electrolyte alterations included hypernatremia (57%), hypophosphatemia (57%), hyperchloremia (56.3%), hypercalcemia (29.1%), and hypermagnesemia (23.5%) (29).

In Nigeria, studies have shown that HAART can lead to significant electrolyte disturbances, particularly severe hypokalaemia and hypophosphatemia. These conditions are linked to the renal effects of HAART, which disrupt normal electrolyte balance. A study indicated that numerous electrolyte and acid-base abnormalities occur in HIV patients, with a higher mortality rate associated with low sodium and potassium levels. The need for close monitoring of these electrolytes in patients with baseline deficiencies has been emphasized to improve clinical outcomes (30, 31).

2.4.Conceptual frame work

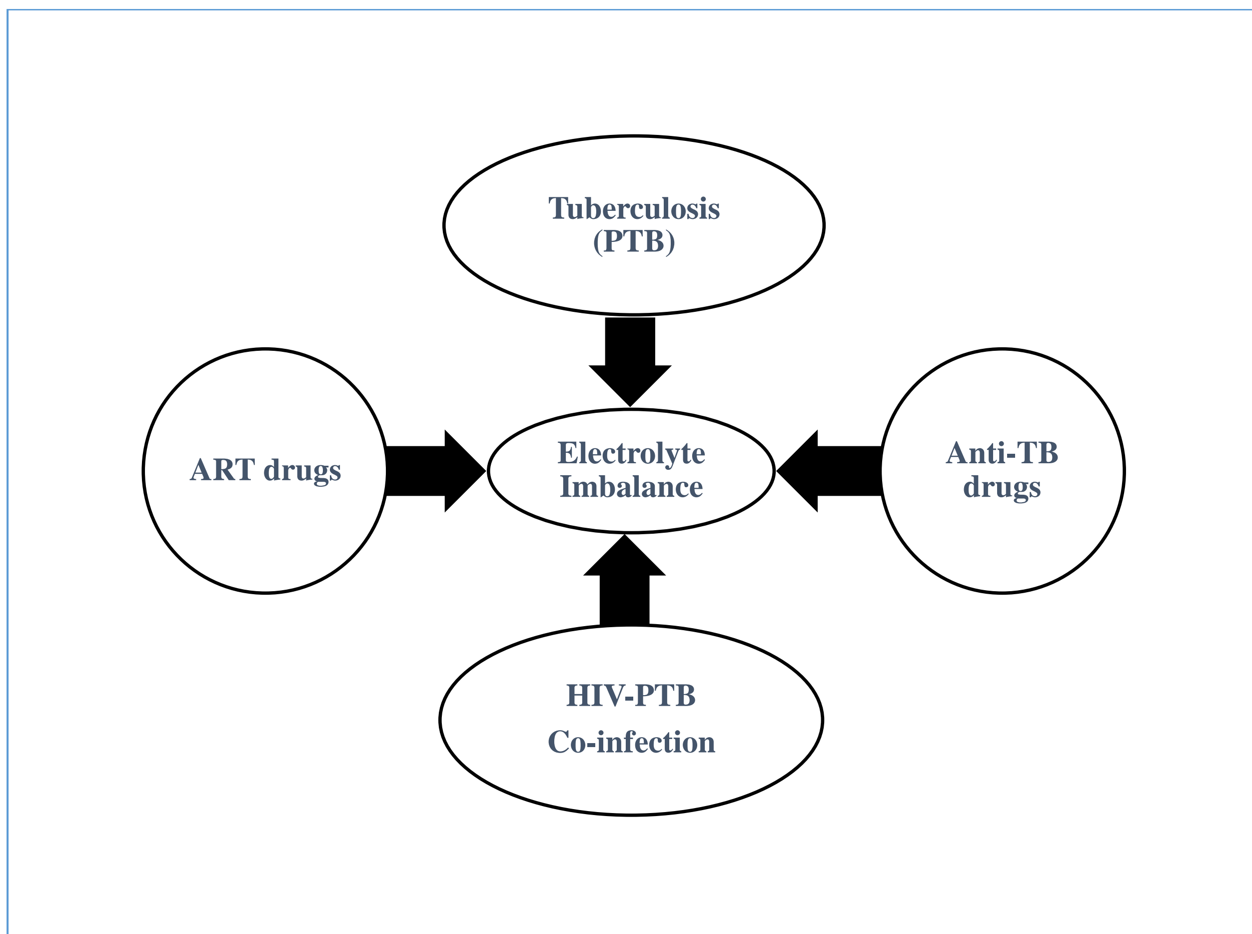

Figure 1: Conceptual frame work impact of tuberculosis and HIV on serum electrolytes (24, 32, 33)

3. OBJECTIVES

3.1. General objective

To assess and compare serum electrolyte level among pulmonary tuberculosis patients with and without HIV co-infection at Ayder comprehensive specialized hospital, Tigray, North Ethiopia, 2023–2024.

3.2. Specific objectives

- To assess the effect of PTB with HIV co-infection on serum electrolyte levels (Na^+, K^+ and Cl^-).
- To assess the effect of PTB without HIV co-infection on serum electrolyte levels (Na^+, K^+ and Cl^-).
- To compare the serum electrolyte levels (Na^+, K^+ and Cl^-) of PTB patients with HIV co-infection with PTB patients without HIV co-infection.

4. METHODS AND MATERIALS

4.1. Study area

The study was conducted at the Ayder comprehensive specialized hospital in Mekelle City, which is located in North Ethiopia. Mekelle is 780 kilometers away from Addis Ababa, and the estimated population of the town is 545,000. The city has one public referral hospital, three general hospitals and ten health centers. Ayder Comprehensive Specialized Hospital is a referral hospital serving approximately 8 million people and has played an important role in teaching students within the medical field for more than a decade (34).

4.2. Study design and period

A hospital-based comparative cross-sectional study was conducted to assess and compare the level of serum electrolyte among PTB patients with and without HIV co-infection in the period from October 1, 2023 to December 1, 2024.

4.3. Population

4.3.1. Source population

The source population for this study was all PTB patients with and without HIV co-infection at ACSH.

4.3.2. Study population

The study population was 50 PTB patients with and without HIV co-infection of all ages who visit ACSH TB clinic for treatment follow-up during the study period.

4.4. Eligibility criteria

4.4.1. Inclusion criteria

- PTB patients with and without HIV co-infection of all ages who have sputum smear positive result and willing to participate in the study.

4.4.2. Exclusion criteria

- Patients with diabetes mellitus, cardiac disease, or renal failure, cancer, thyroid disease.
- Patients on diuretic medication.
- Patients who took potassium chloride (KCl) medication.
- Patients who have dehydration.

- Patients who have trauma with massive bleeding or burn.
- Pregnant women.

4.5. Sample size determination and sampling technique

4.5.1. Sample size determination

The sample size was determined based on a sample size formula for comparing two means with the following assumptions. The value of the outcome variable was taken from the previous study done in India (6). After calculating all the values of serum electrolyte, the component with the highest value (Chloride) was taken. The reported mean ± SD values of Chloride for HIV-PTB co-infected subjects were (103.89±10.24), whereas (96.81±6.26) for PTB without HIV co-infection. By assuming significance level = 95%, 80% power of the test, type of test = two-sided, Z α\2 = the critical value at 95% confidence level of certainty (1.96). The sample size was calculated using the formula:

$$n_1 = \frac{(Z_{\alpha/2} + Z_{\beta})^2 * (\sigma_1^2 + \sigma_2^2)}{\Delta^2}$$

Where: n_1 = sample size for each group

$Z_{\alpha/2}$ = Z-score for a two-tailed test based on level

$Z_{\beta/2}$ = Z score based on β level of 80% power

σ^2 = variance of population

μ = Mean

$\Delta = \mu 1 - \mu 2$

$$n_1 = \frac{(1.96+0.84)^2 \text{ X } (10.24^2 + 6.26^2)}{(103.89 - 96.81)^2} = \underline{\mathbf{23}}$$

Therefore, the value of the sample size calculated was 23. Since an equal number of HIV-PTB co-infected patients and PTB patients without HIV co-infection was used, n x 2 = 23 x 2 =46. Taking a non-response rate of 10% =10/100 x 46 = 4. Then the total sample size was 50 (46 + 4). So, a total of 50 participants (25 PTB patients with HIV co-infection who fulfil the inclusive criteria of the cases and 25 PTB patients without HIV co-infection who fulfil the inclusive criteria of the controls) was included in this study.

Table 1: Sample size determination for the study assessment and comparison of serum electrolyte among PTB patients with and without HIV co-infection at ACSH, Mekelle, Northern Ethiopia from October 2023 to December 2024 (n=50).

Previous study location	N (calculated sample size for each group)	Parameter	Sodium (Meq/L)	Potassium (Meq/L)	Chloride (Meq/L)	Reference
India	For Na^+= 30473, For K^+ = 34.4, For Cl^- = 22.5	HIV-PTB	131.53±7.89 (Not Significant)	3.82±0.64 (Not Significant)	103.89±10.24 (Significant)	(6)
		PTB	131.71±7.98 (Not Significant)	3.32±0.83 (Not Significant)	96.81±6.26 (Significant)	
India	For Na^+ = 5.3, For K^+ = 4.3, For Cl^- =3.5	HIV-PTB	137.4±2.81 (Significant)	4.10±0.49 (Significant)	103.6±2.1 (Significant)	(7)
		PTB	141.1±1.21 (Significant)	3.39±0.20 (Significant)	107.3±1.3 (Significant)	

4.5.2. Sampling technique

ACSH was selected based on the availability of PTB patients who came for treatment follow-up. Convenient consecutive participants were included until the sample size calculated is attained.

4.6. Data collection and measurements

4.6.1. Data collection method

A structured questionnaire adapted from previous studies and patient medical cards was used to collect sociodemographic and clinical data from tuberculosis patients with and without HIV co-infection. 3 millilitres of venous blood samples from PTB patients with and without HIV co-infection was drawn by a phlebotomist into standard sampling tubes (SST). Two BSc nurses as data collectors and one laboratory technologist were recruited.

4.6.2. Biochemical analysis of serum electrolyte (Na^+, K^+ and Cl^-)

Principle

Ion selective electrode (ISE) method was used as principle of electrolyte analysis to analyse Na+, K+, and Cl^-. An Ion-Selective Electrode (ISE) makes use of the unique properties of certain membrane materials to develop an electrical potential (electromotive force, EMF) for the measurements of ions in solution. The electrode has a selective membrane in contact with both the test solution and an internal filling solution. The internal filling solution contains the test ion at a fixed concentration. Because of the particular nature of the membrane, the test ions were closely associate with the membrane on each side. The membrane EMF is determined by the difference in concentration of the test ion in the test solution and the internal filling solution. The complete measurement system for a particular ion includes the ISE, a reference electrode and electronic circuits to measure and process the EMF to give the test ion concentration. The sodium and potassium electrodes are based on neutral carriers and the chloride electrode is based on an ion exchanger (35).

4.7. Data management and quality control

The questionnaire was carefully designed to ensure the quality of the data, and the entire data gathering procedure was closely monitored. To check the consistency the questionnaire was translated into the local language, Tigrigna, and retranslated back. To ensure consistency in the procedures of collecting, processing, and analysing blood specimens and data, a one-day training session was provided for supervisors, phlebotomists, and data collectors. Furthermore, in order to validate the process in compliance with the standard operating procedure and the manufacturer's instructions, the laboratory analysis was performed in an appropriately calibrated analyser with controls running alongside the subject sample. Prior to beginning the real data collection, 5% of patients at Aksum Comprehensive Specialized Hospital was participated in a pre-test.

4.8. Data processing and analysis

After checking for completeness and cleaning, the data was entered into Epi-data manager version 4.5 and exported into the SPSS software version 25 package for analysis, and the different variables was analysed. Simple descriptive statistics was used to present the socio-demographic and clinical characteristics of the study subjects. Continuous variables were presented as mean ± standard deviation and was compared using the student independent t-tests. Linear Regression was used to assess the relationship of anti-TB and ART Rx duration with serum electrolyte level. A p-value of <0.05 at 95% confidence level was considered to be statistically significant in all the analyses.

4.9. Study variables

4.9.1. Dependent variables

- Serum electrolyte levels: sodium, potassium and chloride

4.9.2. Independent variables

- Socio demographic characteristics
- PTB patients with HIV co-infection.
- PTB patients without HIV co-infection.
- Anti TB drug
- ART Drug

4.10. Ethical consideration

Before starting data collection and the preliminary study, an ethical clearance letter was obtained from the Institutional Review Board (MU-IRB 2104/2023) of the College of Health Sciences, Mekelle University (MU). Cooperation letter was written from the department of Biochemistry and Molecular Biology (Ref. No. DMB/204/2023) to TB clinic of ACSH. The objective of the study was briefly clarified and explained to each participant before enrolling any of the eligible study participants. Samples and data were collected after informed consent has been obtained from the study participants. Results that have a direct benefit to the health of the study participants was communicated to themselves and their physicians for better management. Confidentiality, anonymity, neutrality, accountability, and academic honesty was maintained throughout the study, for example, by using codes.

4.11. Dissemination of findings

The findings of this study will be submitted and presented to the Department of Medical Biochemistry and Molecular Biology, College of Health Sciences, Mekelle University. Next, I will try to present the findings at different review meetings, seminars, and workshops. The findings of the study will also be disseminated to health care professionals and other concerned bodies for better management of TB patients. Furthermore, a strong effort will be made to publish in scientific journals.

5. RESULTS

5.1. Demographic profile of study participants

A total of 50 pulmonary tuberculosis patients with or without Human Immunodeficiency Virus co-infection at the TB unit of Ayder comprehensive specialized hospital were enrolled in this study. Of these, 21(42%) were men and 29 (58%) were women. (Figure 2)

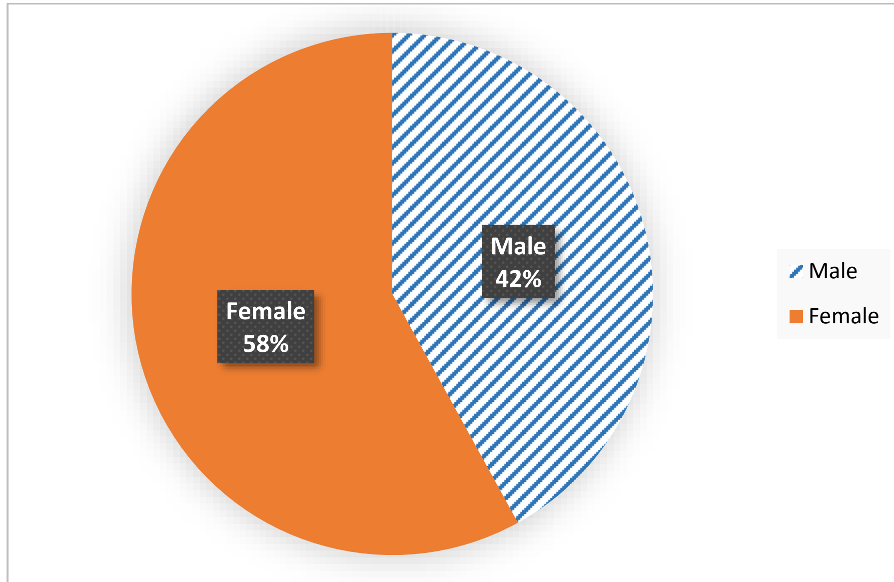

Figure 2: Gender distribution of study participants

The mean age of study participants was 34.42±11.46 years. The minimum and maximum age were 18 and 56 years, respectively. Regarding residence, 33 (66%) of the participants live in urban areas. Of the 50 participants, 10% had no formal education, 40% had primary schooling, 36% had secondary schooling and 14% had diploma and above. Of the 50 participants, 36% were unemployed, 26% were farmers, 16% were employed (government and NGO), 12% were daily laborers, and 10% were merchants. Table 3 summarizes socio demographic characteristics of participants.

Table 2: Socio demographic characteristics of pulmonary tuberculosis patients attending Ayder Comprehensive Specialized Hospital, Mekelle, Northern Ethiopia from October 2023 to December 2024 (n=50).

No	Variables	Categories	Frequency(N)	Percent (%)	Total
1	Sex	Male	21	42 %	50
		Female	29	58 %	
2	Residence	Urban	33	66 %	50
		Rural	17	34 %	
3	Ethnicity	Tigray	44	88 %	50
		Afar	3	6 %	
		Amhara	3	6 %	
4	Religion	Orthodox	46	92 %	50
		Muslim	4	8 %	
5	Marital status	Married	22	44 %	50
		Single	21	42 %	
		Divorced	5	10 %	
		Widowed	2	4 %	
6	Occupational status	Employed (government or NGO)	8	16 %	50
		Merchant	5	10 %	
		Daily labourer	6	12 %	
		Farmer	13	26 %	
		Unemployed	18	36 %	
7	Education level	Non-educated	5	10 %	50
		Primary	20	40 %	
		Secondary	18	36 %	
		Diploma and above	7	14 %	

5.2. Clinical characteristics of study participants

Twenty-five (50%) of study participants had pulmonary tuberculosis without HIV co-infection, and 25 (50%) of study participants had pulmonary tuberculosis with HIV co-infection. Concerning the type of pulmonary TB, based on the previous treatment history of participants, 45 (90%) were new cases, while 5 (10%) were relapse cases. None of them had Drug resistant TB. About anthropometric measurement, 33 (66%) participants were underweight, whereas 17 (34% of the participants) had a normal BMI (18.5-24.9). Hyponatremia was observed in 42 study participants (84% of the study group), including 22 patients with HIV-PTB co-infection and 20 with PTB alone. Hypokalaemia was observed in 11 study participants (22%), , all had PTB alone. Hyperkalaemia was present in 9 participants (18%), with 8 of these being PTB patients with HIV co-infection. Additionally, hypochloraemia was noted in 4 participants (8%) among those with pulmonary tuberculosis, all were HIV-PTB co-infected. Table 4 summarizes Clinical characteristics of participants.

Table 3: Clinical characteristics of pulmonary tuberculosis patients attending Ayder Comprehensive Specialized Hospital, Mekelle, Northern Ethiopia from October 2023 to December 2024 (n=50).

No	Variables	Categories	Frequency(N)	Percent (%)	Total (n)
1	Body Mass Index	<18.5	33	66 %	50
		18.5-24.9	17	34 %	
2	Type of Pulmonary TB based on previous treatment history	New case	45	90 %	50
		Relapse case	5	10 %	
3	Anti TB treatment status	On treatment	43	86 %	50
		Treatment not started	7	14 %	
4	PTB HIV co-infection	Yes	25	50 %	50
		No	25	50 %	
5	Serum Sodium	Hyponatremia (<135)	42	84 %	50
		Normal (135-145)	8	16 %	
		Hypernatremia (>145)	0	0 %	
6	Serum Potassium	Hypokalemia (<3.5)	11	22 %	50
		Normal (3.5–5.5)	30	60 %	
		Hyperkalemia (>5.5)	9	18 %	
7	Serum Chloride	Hypochloremia (<96)	4	8 %	50
		Normal (96–108)	42	84 %	
		Hyperchloremia (>108)	4	8 %	

5.3. Serum Electrolyte level of study participants

The level of serum sodium in PTB patients was significantly higher when compared with HIV-PTB co-infected patients (132.65±4.15 vs. 130.28±4.09 meq/l) (p value = 0.047). Serum potassium levels were significantly higher in HIV-PTB co-infected patients when compared with PTB patients (5.05±0.75 vs. 3.83±0.59 meq/l) (p value 0.000). Serum chloride level was also significantly higher in PTB patients compared with HIV-PTB co-infected patients (103.42±3.16 vs. 100.61±5.10 meq/l) (p value = 0.023).

Table 4: Summary mean (x) ± standard deviation of serum electrolytes of pulmonary tuberculosis patients attending Ayder Comprehensive Specialized Hospital, Mekelle, Northern Ethiopia from October 2023 to December 2024 (n=50).

Parameter	N	Sodium (meq/l)	Potassium (meq/l)	Chloride (meq/l)
HIV-PTB	25	130.28±4.09	5.05±0.75	100.61±5.10
PTB	25	132.65±4.15	3.83±0.59	103.42±3.16
p value		0.047*	0.000*	0.023*

Table 5: Serum Electrolyte of pulmonary tuberculosis patients attending Ayder Comprehensive Specialized Hospital based on PTB HIV co-infection status, Mekelle, Northern Ethiopia from October 2023 to December 2024 (n=50).

Serum electrolyte	Categories	Infection status		Total Study participants (n)
		HIV-PTB	PTB	
Serum sodium (Na^+) level	Hyponatremia	22 (88%)	20 (80 %)	42 (84%)
	Normal	3 (12 %)	5 (20 %)	8 (16%)
	Hypernatremia	0 (0%)	0 (0%)	0 (0%)
Serum Potassium (K^+) level	Hypokalemia	0 (0%)	11 (44 %)	11 (22%)
	Normal	17 (68%)	13 (52%)	30 (60%)
	Hyperkalemia	8 (32%)	1 (4%)	9 (18%)
Serum chloride (Cl^-) level	Hypochloremia	4 (16%)	0 (0%)	4 (8%)
	Normal	19 (76%)	23 (92%)	42 (84%)
	Hyperchloremia	2 (8%)	2(8%)	4 (8%)

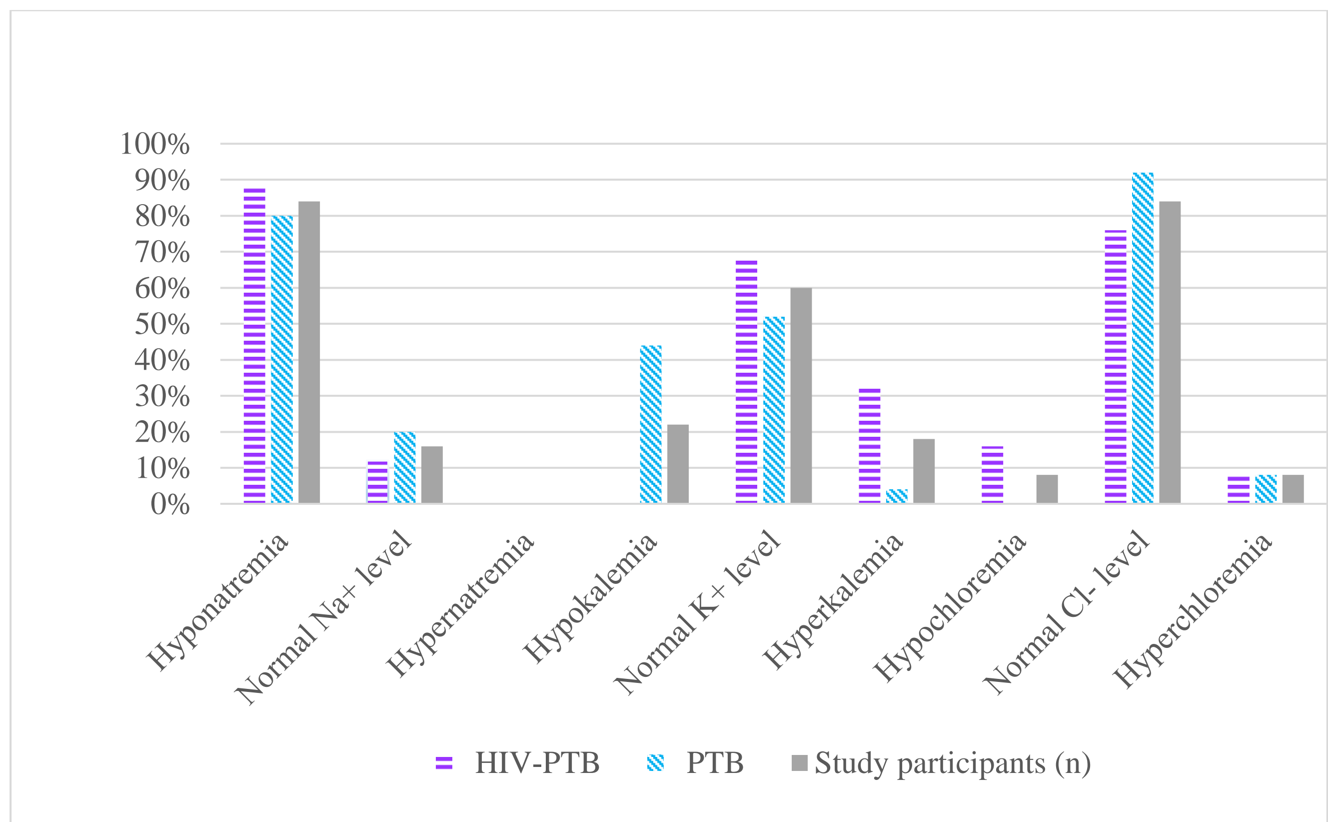

Figure 3: Serum Electrolyte of study participants based on HIV-PTB co-infection status

Relationship of Anti-TB Treatment duration with serum electrolyte

A unit increase in Duration on anti TB treatment in days resulted a significant increase in Serum Sodium by 0.022 units (p value = 0.023), r=0.32, serum Potassium by 0.005 units (p value 0.026), r=0.32 and serum Chloride by 0.034 units (p value = 0.001), r=0.46.

Relationship of ART duration with serum electrolyte

A unit increase in ART treatment duration in days resulted in a non-significant increase in serum sodium of 0.001 units (p value = 0.127), r = 0.31; serum chloride by 0.00 units (p value = 0.676), r = 0.09; and a non-significant decrease in serum potassium by -6.481×10^{-5} units (p value = 0.514), r = -0.14.

6. DISCUSSION

Serum electrolyte disturbances

Ethiopia's persistent struggle with tuberculosis (TB) and its co-occurrence with HIV underscores a serious public health challenge. The country remains among the top 30 nations with the highest burden of TB and TB/HIV co-infection. Notably, 8% of reported TB cases in Ethiopia are co-infected with HIV, illustrating a critical intersection of two epidemics that significantly contribute to morbidity and mortality rates (9, 33). The findings from this study highlight the substantial prevalence of electrolyte imbalances, particularly in patients co-infected with HIV and TB, which can exacerbate the clinical management of these individuals and increase the risk of adverse outcomes.

In this study, 84% of participants exhibited hyponatremia, with notable differences between the HIV-PTB co-infected group and those with PTB alone (88% vs. 80%). Hyponatremia is a well-documented complication in HIV-infected individuals, often exacerbated by associated conditions such as diarrhoea, renal impairment, and malnutrition. The higher incidence found in the co-infected group aligns with previous research indicating that electrolyte disturbances are prevalent among patients with HIV and significantly impact their overall health status (6).

Similarly, the study found hyperkalaemia in 32% of the HIV-PTB co-infected group, which is significantly higher than in the PTB-only group (4%). The mechanisms behind hyperkalaemia in this context may include renal dysfunction and tissue breakdown, common in severe infections and malnutrition (15, 16). Hypochloraemia was also prevalent in the HIV-PTB co-infected group (16% in HIV-PTB vs. 0% in PTB), suggesting a specific electrolyte disturbance that warrants further investigation.

The prevalence of hyponatremia in this study was higher than studies conducted in various regions, including India, Japan and Iran where similar trends have been observed (95% CI: 71.4 - 94.0). A study from India showed that the prevalence of hyponatremia was significantly higher in the HIV-PTB group compared to the PTB group (52% vs. 32% ($p < 0.01$) (36) and another study from the same country reported a 59.3% prevalence of hyponatremia among TB patients (37). A study in Japan also showed that the incidence of hyponatremia in TB patients was 40.7% (18), and a study done in Iran reported that the prevalence of hyponatremia was 51% (38). This highlights the global nature of this issue. These results underscore the importance of vigilant monitoring of electrolyte levels in co-infected patients to prevent complications that could arise from these imbalances.

This study found significantly lower mean serum sodium levels in HIV-PTB co-infected patients (130.28 ± 4.09 mEq/L) compared to TB-only patients (132.65 ± 4.15 mEq/L), consistent with findings from India and Ethiopia (p value = 0.047). Studies from India showed significantly lower mean sodium levels in HIV-PTB

co-infected patients compared to TB-only patients, with values of 137.4 ± 2.81 vs. 141.1 ± 1.21 mEq/L (6) and 132.1 ± 5.3 vs. 137.6 ± 4.1 mmol/L (39).

The mean serum potassium level was significantly higher in the HIV-PTB group (5.05 ± 0.75 mEq/L) compared to the PTB-only group (3.83 ± 0.59 mEq/L). This aligns with studies in India, with one hospital study reporting mean values of 4.10 ± 0.49 mEq/L for HIV-TB patients compared to 3.39 ± 0.20 mEq/L for TB-only patients (7), Similarly, another cross-sectional study also reported significantly higher potassium levels in HIV-PTB co-infected patients (4.2 ± 0.7 vs. 3.8 ± 0.5 mmol/L (6).

The mean serum chloride level was significantly lower in HIV-PTB patients (100.61 ± 5.10 mEq/L) compared to PTB-only patients (103.42 ± 3.16 mEq/L) (p value = 0.023). In line with our report, a hospital-based study in India also found lower serum chloride levels in those co-infected with HIV (103.6 ± 2.1 vs. 107.3 ± 1.3 mEq/L) compared to patients with PTB alone (7).

Relationship of Anti-TB Treatment and ART duration with serum electrolyte

This study revealed that a unit increase in Duration on anti TB treatment in days resulted in a significant increase in Serum Sodium by 0.022 units (p value = 0.023), r=0.32, serum Potassium by 0.005 units (p value 0.026), r=0.32 and serum Chloride by 0.034 units (p value = 0.001), r=0.46. The analysis showed that prolonged anti-TB treatment correlates with increases in serum sodium, potassium, and chloride levels, emphasizing the importance of effective anti-TB therapy in managing electrolyte imbalances. This observation aligns with previous studies in India that have shown treatment with antitubercular medications can significantly normalize electrolyte levels, indicating a potential area for intervention to improve clinical outcomes (10).

This study found that a unit increase in ART treatment duration in days resulted in a non-significant increase in serum sodium of 0.001 units (p value = 0.127), r = 0.31; serum chloride by 0.00 units (p value = 0.676), r = 0.09; and a non-significant decrease in serum potassium by -6.481×10^{-5} units (p value = 0.514), r = -0.14. Our findings of minimal changes in sodium and chloride levels diverge from the more pronounced disturbances observed in Nigeria, where decreased levels were noted (40). In contrast, the Mexican study showed a predominance of hypernatremia and other electrolyte abnormalities, indicating that the effects of HAART may vary significantly based on regional factors (41).

7. STRENGTH AND LIMITATION OF THE STUDY

This study focuses on comprehensive assessment of electrolyte disturbances among patients attending the TB unit, providing valuable insights into a region heavily affected by both TB and HIV. This localized research fills a critical gap in understanding the dynamics of co-infection in a high-burden setting. This study employs a cross-sectional design, which limits the ability to establish causal relationships among PTB, HIV-PTB and electrolyte disturbances. Longitudinal studies would provide better insights into the temporal dynamics of these conditions. Additionally, this study may not have accounted for all potential confounding factors that could influence electrolyte levels, such as dietary intake. A more detailed assessment of these factors could provide a clearer picture of the underlying causes of electrolyte disturbances.

8. CONCLUSION

The findings of our study demonstrate that the significantly higher level of serum sodium in pulmonary tuberculosis (PTB) patients compared to those co-infected with HIV. This study also showed a significantly higher level of serum potassium in HIV-PTB co-infected patients and significantly higher chloride level in PTB patients.

Anti-Tuberculosis therapy is positively correlated with enhanced electrolyte levels and may aid in normalizing these imbalances, thus presenting a potential intervention to improve clinical outcomes.

9. RECOMMENDATION

Electrolyte disturbances in PTB and HIV-PTB patients necessitate regular monitoring and management to prevent complications. Healthcare professionals should routinely assess serum electrolyte levels, while policymakers and clinicians should develop specific treatment protocols for restoring these imbalances. Additionally, further research with larger, longitudinal studies is needed to account for confounding factors such as dietary intake.

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11. ANNEXES

Annex-I

1.1. Information sheet (English Version)

My name is **Mr. Tsegay G/her**, who is a postgraduate student at Mekelle University, College of Health Sciences, Department of Medical Biochemistry and Molecular Biology, was study his research entitled "Assessment and comparison of serum electrolyte level among PTB patients with and without HIV co-infection at Ayder comprehensive specialized hospital." The following information is to inform you about the study and get your permission to participate in it. You are kindly invited to participate in this study.

Research Title: Assessment and comparison of serum electrolyte level among PTB patients with and without HIV co-infection at Ayder comprehensive specialized hospital, Tigray, North Ethiopia.

Sponsoring organization: Department of Biomedical, College of Health Sciences, Aksum University.

Advisors: Aman Mehari (MSc., Asst. Prof. of Medical Biochemistry), G/kidan G/her ((MSc., Asst. Prof. of Medical Biochemistry) and Hagos Amare (Phd, MSc., Asst. Prof. of Medical Biochemistry).

Aim of the study: The main aim of this study is to assess and compare serum electrolyte levels among PTB patients with and without HIV co-infection.

Procedure: The procedure of sample collection is easy and uncomplicated; the sample was collected under strict aseptic precautions. 5-7 ml of venous blood was collected by trained phlebotomists from an antecubital vein of the selected subjects and stored in appropriate test tubes.

Risk and discomfort: The phlebotomist was collect the specimen; therefore, there was no harm associated with sample collection without a little pain in the injected areas of your hand.

Role of study subjects: selected study participants are expected to provide the minimum needed specimen for the study and to give accurate information to fill out the questionnaire properly.

Expected benefits and incentives: You was not be provided with any direct incentives for your participation in the research. But the cost of a general medical examination was covered by the project. In addition, based on the results obtained from the research, you was treated accordingly, or the results may serve as baseline data.

Confidentiality: All your personal information collected for the purpose of the present study was kept confidential.

Rights of Participants: You have the right to withdraw from the study, withhold information, refuse provision of specimens and reject to cooperate in the study.

Whom to contact

I would like to inform you that this study has been evaluated and approved by the Institutional Review Board (IRB) of Ayder Comprehensive Specialized Hospital, College of Health Sciences, Mekelle University (MU). If you have any questions about the rights of the study participant, the address is:

- Department of Medical Biochemistry and Molecular Biology, School of Medicine, Biomedical Division, College of Health Science, Mekelle University:

  Tel.251344416692

  P.O. Box 1187. Mekelle, Tigray, Ethiopia

- Principal investigator of the study

  Tsegay G/her

  Telephone: 09-14-81-79-96

  Gmail: tsegayew12@gmail.com

Annex 1.2. Informed consent (English version)

I have clearly been informed about the research project, which aims to assess and compare serum electrolyte levels among PTB patients with and without HIV co-infection. The objectives of the research project have clearly been explained to me, and I have been told that the results obtained from me was help me as well as the community in better managing the disease. I had also been informed about the confidentiality of this research project. Moreover, I have also been well informed of my right to keep hold of information, decline to cooperate, and withdraw from the study. Therefore, with a full understanding of the importance of the study, I agreed voluntarily to provide the requested samples, and my benefit was only from the free laboratory investigation result(s).

Yes_______

No________

Annex 1.3. Questionnaire (English version)

I. Demographic and Socioeconomic Profile

	Name of Hospital/Health Facility	________
	Participant code:	________
100	Sex	1.Male 2. Female
101	Age in years	
102	Residence	1. Urban 2. Rural
103	Ethnicity	1.Tigray 2. Afar 3. Oromo 4. Amhara 5. Other (specify)
104	Religion	1. Orthodox 2. Muslim 3. Protestant 4. Other (specify)
105	Marital status	1. Married 2. Single 3. Divorced 4. Widowed
106	Occupational Status	1. Employed (Government, NGO) 2. Merchant /Self-employed 3. Daily Laborers 4. Farmer 5. Unemployed (student, housemaid)
107	Educational status	1. Cannot read and write 2. Primary school (1-8) 3. Secondary school (9-12) 4. College and above
108	Body Mass Index (BMI)	_________kg/m^2

109	Do you have Chronic illness (diabetes mellitus, cardiac disease, cancer, thyroid disease, or renal failure)?	1. Yes 2. No
110	Is the patient on diuretic medication? (Observe from patient medical record)	1. Yes 2. No
111	Did the patient took potassium chloride (KCl) medication? (Observe from patient medical record)	1. Yes 2. No
112	Does the patient have dehydration? (Ask if he/she has thirsty, sunken of eye ball, or dry mouth and tongue)	1. Yes 2. No
113	Do you have trauma with massive bleeding or burn?	1. Yes 2. No
114	Are you pregnant?	1. Yes 2. No

If the answers for question number 109 -114 is no proceed to question number 115.		
115	Type of PTB based on previous treatment history	1. New case 2. Relapse case 3. MDR TB
116	Anti-TB treatment status	1. On treatment 2. Treatment not started
117	For how long did the patient took anti-TB?	________(months)
118	PTB co-infected with HIV	1. Yes 2. No
119	HIV/AIDS Stage of patient	1. Stage I 2. Stage II 3. Stage III 4. Stage IV
120	ART treatment status	1. On treatment 2. Treatment not started
121	For how long did the patient took ART medication?	________(months)
122	If on ART treatment in which regimen of ART drugs? Specify	

II. Record from health institution patient history and laboratory results

III. Biochemical Parameters

	Parameter	**Results**
123	Serum sodium (Na^+)	________ (mmol/L)
124	Serum Potassium(K^+)	________ (mmol/L)
125	Serum chloride (Cl^-)	________ (mmol/L)

ልጋብ 1.1. ናይ ተሳተፍቲ ዓርሰ ፍቃድ መተኣማመኒ ሓበሬታ መዉሃቢ ቅጥዒ (ስርሒት ትግርኛ)

ሽመይ ፀጋይ ገ/ሄር ይበሃል::ኣብ መቐለ ዩኒቨርሲቲ ጥዕና ሳይንስ ኮሌጅ ናይ ሕክምና ባዮኬሚስትሪን ሞለኩላር ባዮሎጂን ት/ቲ ክፍሊ ናይ ድሕረ ምረቃ ተምሃራይ ናይ መመረቂ ፅሑፍ 'ኣብ ኮምፕሬሄንሲቭ ስፔሻላይዝድ ሆስፒታል ዓይደር ምስ ኤች ኣይ ቪ ዝተደረበን ዘይተደረበን ሕማም ዓባይ ሰዓል ዘለዎም ተሓከምቲ ኣብ ደሞም ዉሽጢ ዘለዉ መዓድናት ምድህሳስን ምንፅፃርን" ብዝብል ርእሲ እናሰርሑ እንትኮኑ ኣብዚ ፅንዓት ድማ ንሶም/ንሰን ንክሳተፉ ስለዝተመረፁ ፍቃዶም እናሓተትኩ ካብዚ ቀፂሉ ዝርከብ መረዳእታ ምስተነበበሎም ኣብቲ ፅንዓት ፍቃደኛ ኮይኖም ንክሳተፉ ብትሕትና ይሓቶም/ን፡፡

ርእሲ እቲ ፅንዓት: ኣብ ኮምፕሬሄንሲቭ ስፔሻላይዝድ ሆስፒታል ዓይደር ምስ ኤች ኣይ ቪ ዝተደረበን ዘይተደረበን ሕማም ዓባይ ሰዓል ዘለዎም ተሓከምቲ ኣብ ደሞም ዉሽጢ ዘለዉ መዓድናት ምድህሳስን ምንፅፃርን

ስፖንሰር: ባዮሜዲካል ዲፓርትመንት ኮሌጅ ጥዕና ሳይንስ ፣ ኣክሱም ዩኒቨርሲቲ

መማከርቲ: ኣማን መሓሪ (ሓጋዚ ፕሮፌሰር) ፣ ገ/ኪዳን ገ/ሄር (ሓጋዚ ፕሮፌሰር) ፣ ሓጎስ ኣማረ (ሓጋዚ ፕሮፌሰር)

ናይዚ ፅንዓት ዓላማ፡ ምስ ኤች ኣይ ቪ ዝተደረበን ዘይተደረበን ሕማም ዓባይ ሰዓል ዘለዎም ተሓከምቲ ኣብ ደሞም ዉሽጢ ዘለዉ መዓድናት ምድህሳስን ምንፅፃርን ዝብል እዩ::

እቲ ፅንዓት ዘስዕቦ ሳዕቤን: እቲ ዝእከብ ናሙና ብበዓል ሞያታት ስለ ዝኮነ ምስዚ ተተሓሒዙ ዝመፅእ ምንም ዓይነት ሳዕቤን የለን፡፡ ኮይኑ ግና ናሙና ኣብ ዝዉሰደሉ ከባቢ ዝተወሰነ ናይ ሕማም ስምዒት ክህሉ ይክእል እዩ፡፡

ካብ ተሳተፍቲ ትፅቢት ዝግበር፡ ኣብቲ ፅንዓት ዝተመረፀ ነቲ ፅንዓት ዘድሊ ናይ ደም ናሙና ብፍቃድ ምሃብን ንዝተዳለወ መሕትት ትክክለኛ ሓበሬታ ክህቡ ይግባእ፡፡

ጥቕማጥቕምን መበራታትዕን: ኣብዚ ፅንዓት ንክሳተፉ ምንም ቀጥታዊ ዝወሃብም ነገር የለን። ነቲ ዝስራሕ ምርመራ ግን ወፃኢኡ በቲ ፕሮጀክት ይሽፈን::

ምስጢር ምሕላው: ነዚ ፅነዓት ኢሎም ዝሃብዎ ሓበሬታ ምስጢሩ ዝተሓለወ እዩ፡፡

ናይ ተሳተፍቲ መሰል: ኣብቲ ፅንዓት ተሳትፎ ኣብ ዓርሰ ፍቃድ ዝተመስረተ እዩ፡፡ ኣብዚ ፅንዓት ሓበሬታ ዘይምሃብ፣ ዘይምትሕብባር፣ ናሙና ዘይምሃብ ወይድማ ዘይምስታፍ መሰሎም ሕሉው እዩ፡፡ ተወሳኺ መብራህርሂ እንተደልዮም፡ እዚ ፅንዓት ኣብ ዓይደር ኮምፕሬሄንሲቭ ስፔሻላይዝድ ሆስፒታል፣ ጥዕና ሳይንስ ኮሌጅ፣ መቐለ ዩኒቨርስቲ ፅንዓትን ምርምርን ክፍሊ ዝተፈቀደ ምኳኑ ክገልፀሎም እፈቱ።

- ኣብቲ ፅንዓት ንዝተሳተፉ ተሳተፍቲ ተተሓሓዝቲ ጉዳያትን ሕቶ እንተሃልይዎም እዚ ዝስዕብ አድራሻ ይጠቀሙ፡ ክ/ት/ቲ ሕክምና ባዮኬሚስትሪን ሞለኩላር ባዮሎጂን ፣ ህክምና ትምህርት ቤት ፣መቐለ ዩኒቨርስቲ

ፖ.ሳ.ቁ፡ 1187 መቐለ ፣ ትግራይ፣ ኢትዮጵያ

ስልኪ፡ 251-0344416692

- ኣብቲ ፅንዓት ዝልዓል ሕቶ እንተሃልይዎም ዋና ተመራማሪ በዚ ዝስዕብ አድራሻ ምርካብ ይክእሉ፡

ፀጋይ ገ/ሂር

ስልኪ ቁፅሪ: 09-14-81-79-96

ኢሜይል:tsegayew12@gmail.com

ልጋብ 1.2. <u>ናይ ተሳተፍቲ ስምምዕነት መረጋገፂ ቅጥዒ (ስርሒት ትግርኛ)</u>

ኣነ ኣብዚ ፅንዓት ንክሳተፍ ናይ ስምምነት ቃለይ ዝሀብ ብሓፈሻ ናይቲ ፅንዓት ዓላማን ጥቅምን ብምርዳእ ብፍፁም ፍቃደኝነት እዩ፡፡ ኣብቲ መሕትት ናተይ መረዳእታ ብምስጢር ከም ዝተሓዝን ተነጊሩኒ:: ብተወሳኺ ኣብቲ ፅንዓት ዉሽጢ ንዘይምስታፍ እንተደልየ መሰለይ ሕሉዉ እዩ:: ኣብ ዝኮነ ሰዓት ካብቲ ፅንዓት ብዓርሰ ዉሳነይ ምዉፃእ መሰለይ ከምዝኮነን ካብቲ ፅንዓት ብምዉፅኣይ ምንም ዓይነት ፀገም ከምዘይበፅሓንን ብዝግባእ ተገሊፁለይ ፡፡ ስለዝኮነ ኩነታቱ ብዝግባእ ብምፅናዕ ብዓርሰ ፍቃደይ ኣብዚ ፅንዓት ንክሳተፍ ፍቃደይ ሂበ ኣለኹ፡፡ብተወሳኺ ዝህቦ ናይ ደም ናሙና ንምርመራ ኣብ ውሽጢ ደም ዝርከቡ መዓድናት ጥራሕ ከምዝዉዕል ተነጊሩኒ ተስማዕሚዐ ኣለኹ፡፡ ግልፂ ዘይኮነለይ ነገር ናይ ምሕታት ዕድል ተዋሂቡኒ ብዝርደኦኒ ቋንቋ መልሲ ረኺበ፡፡ ካብዚ ብተወሳኺ ኩሉ ናይ ላብራቶሪ ምርመራ ዉፅኢት ኣብ ጊዜኡ ንሓኪመይ ከምዝወሃብን ከምኡዉን ዉፅኢተይ ምፍለጥ እንተደልየ ክፈልጥ ከምዝክእል ተነጊሩኒ፡፡ ብሓፈሻ ኣነ ኣብ ላዕሊ ኣብቲ መተኣማመኒ ቅጥዒ ዝተጠቀሱ ኩሎም ብዝርደኦኒ ቋንቋ ተነቢቡለይ፡፡

እዚ ብምግንዛብ ኣብዚ መፅናዕቲ ንዓይ ዝምልከት መረዳእታን ናይ ደም ናሙና ንምሃብ ተስማዕሚዐ ኣለኹ፡፡

እወ________

ኣይፋል_____

ልጋብ 1.3. መሕትት (ስርሒት ትግርኛ)

3. ማሕበራዉን ስነ-ህዝባውን ሕቶታት

	ሽም ጥዕና ትካል	_________
	ናይ ተሳታፊ ኮድ	_________
100	ፆታ	1.ተባ 2. ኣን
101	ዕድመ ብዓመት	_________
102	መንበሪ ቦታ	1. ከተማ 2. ገጠር
103	ብሄር	1.ትግራይ 2. ዓፋር 3. ኦሮሞ 4. ኣማራ 5. ካሊእ(ጥቀስ/ሲ)
104	ሃይማኖት	1. ኦርቶዶክስ 2. ሙስሊም 3. ፕሮቲስታንት 4. ካሊእ (ጥቀስ/ሲ)
105	ኩነታት ሓዳር	1. ዝተመርዐወ/ት 2. ዘይተመርዐወ/ት 3. ዝተፋተሐ/ት 4. ሓዳር ዘይብሉ/ላ
106	ስራሕ	1. ተቖፃሪ (ኣብ መንግስቲ ወይ መንግስታዊ ዘይኮነ) 2. ነጋዳይ 3. ሓረስታይ 4. መዓልታዊ ሰራሕተኛ 5. ስራሕ ዘይብሉ/ላ
107	ትምህርቲ ደረጃ	1. ምንባብን ምፅሓፍን ዘይክእል 2. 1ይ ብርኪ (1-8) 3. 2ይ ብርኪ (9-12) 4. ኮለጅን ካብኡ ንላዕልን
108	BMI	_________ኪ.ግ/ሜ^2

109	ሕዱር ሕማም ኣለካ/ኪ ድዩ? (ሕማም ሽኮርያ፣ ሕማም ልቢ፣ ካንሰር፣ ሕፈስ ወይ ኮላሊት)	1. እወ 2. ኣይፋል
110	ተሓካሚ/ት ናይ ኮላሊት መድሓኒት ይወስድ ድዩ (ትወስድ ድያ)? (ናይ ተሓካሚ ካርዲ ሕክምና ብምርኣይ)	1. እወ 2. ኣይፋል
111	ተሓካሚ/ት ፖታስየም ክሎራይድ መድሓኒት ይወስድ ድዩ (ትወስድ ድያ)? (ናይ ተሓካሚ ካርዲ ሕክምና ብምርኣይ)	1. እወ 2. ኣይፋል

112	ተሓካሚ/ት ፃምእ ሰውነት ኣለዎ/ዋ ድዩ/ያ? (ፃምእ፣ ኣዕንቲ ንውሽጢ ምእታው ወይ ምድራች ኣፍን መልሓስን እንተሃልዩ ብምሕታት)	1. እወ 2. ኣይፋል
113	ተሓካሚ/ት ምፍሳስ ብዙሕ ደም (ጉድኣት) ወይ ሓደጋ ቃፀሎ ኣለዎ/ዋ ድዩ/ያ?	1. እወ 2. ኣይፋል
114	ጥንስቲ ዲኪ?	1. እወ 2. ኣይፋል
ካብ 109 ክሳብ 114 ንዘው ሕቶታት መልሲ ኣይፋል እንተደኣ ኮይኑ ናብ ሕቶ ቁፅሪ 115 ይቀፅሉ		
115	ዓይነት ሕማም ቲቢ ብመሰረት ሕሉፍ ሕክምና	1. ሓዱሽ 2. መድሓኒት ዝተላመደ
116	ኩነታት ምጅማር ፀረ-ቲቢ መድሓኒት	1. መድሓኒት ዝጀመረ 2. መድሓኒት ዘይጀመረ
117	ተሓካሚ/ት ንክንደይ ኣዋርሐ ፀረ-ቲቢ መድሓኒት ወሲዱ/ዳ?	_________(ኣዋርሕ)
118	ምስ ሕማም ኤች ኣይ ቪ ዝተደረበ ቲቢ ድዩ?	1. እወ 2. ኣይፋል
119	ብርኪ ሕክምና ሕማም ኤች ኣይቪ	1. ብርኪ ሓደ 2. ብርኪ ክልተ 3. ብርኪ ሰለስተ 4. ብርኪ ኣርባዕተ
120	ኩነታት ምጅማር ፀረ-ኤች ኣይቪ ሕክምና	1. መድሓኒት ዝጀመረ 2. መድሓኒት ዘይጀመረ
121	ተሓካሚ/ት ንክንደይ ኣዋርሐ ፀረ-ኤች ኣይቪ መድሓኒት ወሲዱ/ዳ?	_________(ኣዋርሕ)
122	ፀረ-ኤች ኣይቪ መድሓኒት ዝጀመረ እንተይኑ ዝወስዶ ዓይነት መድሓኒት ጥቀስ/ሲ	

2. <u>መረዳእታ ካብ ናይ ተሓካሚ ታሪክን ምርመራ ውፅኢትን</u>

3. <u>ባዮ ኬሚካል መለክዕታት (ኣብ ደም ዝርከቡ መዓድናት)</u>

	መለክዒ	ውፅኢት
123	Serum sodium (Na^+)	_________ (mmol/L)
124	Serum Potassium (K^+)	_________ (mmol/L)
125	Serum chloride (Cl^-)	_________ (mmol/L)

Annex II. Specimen, reagents, procedures and results of serum electrolyte (Na+, K+ and Cl^-)

Specimen

Serum was collected using standard sampling tubes (SST). Samples was separated from the clot or cells promptly after collection.

Materials and reagents

Instrument/materials

- **K-Light electrolyte analyser**: a clinical chemistry analyser intended for the in vitro quantitative determination of biochemical analytes in body fluids.
- **Centrifuge**: to separate the whole blood in to serum/serum and cells.
- **Test tubes**: for sample collection.
- **Micropipette**: for sample transferring.
- **Micropipette tips**: for sample transferring by attaching with micropipette.
- **Cuvettes**: a sample container which is loaded to K-Light electrolyte for analysis.
- **Racks**: to hold the Cuvettes.

Reagents

- **Sodium Electrode**: used to measure the potential of the sodium ion.
- **Potassium Electrode**: used to measure the potential of the potassium ion.
- **Chloride Electrode**: used to measure the potential of the chloride ion.
- **Reference Electrode**: has constant potential.
- **ISE Diluent Gen.2**: 1:31 dilution of sample
- **ISE Internal Standard Gen.2**: is measured during calibration as well as before and after each routine sample. These measurements are used to correct for system-related drifts (junction potential differences, differences in electrode conditions, and the like).
- **ISE Reference Electrolyte**: Reference electrode measurements.
- **ISE Cleaning Solution**- Washing the ISE flow path.

Procedures

The machine is fully automated and every step is processed by the machine but there are also steps before giving the sample to the analyser.

1. Reagents, controls and calibrators was added to the reagent rack system

2. Before we run the sample, we were run the calibration and control according the manufacturer's recommendation. Accordingly, controls were run every 24 hours and calibrations was run if the reagent is new batch and if there is fluctuation of control results.

3. After the blood sample was collected, we wait the sample to clot for 30 minutes if we use the serum. If we need a serum, no clotting is needed and we were immediately centrifuge it.

4. After clotting, the sample was centrifuged at 3000-3500 r/min for 5 minutes to get enough serum.

5. Serum/serum sample was added to the standard cuvette.

6. Test order (electrolyte analysis (Na+, K+, Cl-) was created in the machine for each patient according to the K-Light electrolyte user manual.

7. Sample was put in sample rack system.

8. Finally the machine was started to run the sample.

9. The machine was processing all the reaction procedures and finally the result was displayed.

Result and interpretation

The K-Light electrolyte System calculates the electrolyte concentration of each sample. Sodium and chloride was reported to the nearest whole number in mmol/L. Potassium was reported to the nearest tenth in mmol/L (35).

Table 6: Cut off values serum electrolyte for the study assessment and comparison of serum electrolyte levels among PTB patients with and without HIV co-infection at ACSH, Mekelle, Northern Ethiopia from October 2023 to December 2024 (n=50).(35).

Serum electrolyte parameter	Categories	Cut of values
Serum sodium (Na^+) (mmol/L)	Hypernatremia	>145
	Normal	135-145
	Hyponatremia	<135
Serum Potassium(K^+) (mmol/L)	Hyperkalaemia	>5.5
	Normal	3.5–5.5
	Hypokalaemia	<3.5
Serum chloride (Cl^-) (mmol/L)	Hyperchloremia	>108
	Normal	96–108
	Hypochloraemia	<96

Annex III. Assurance of Principal Investigator

I, the undersigned, agree to accept all responsibilities for the scientific and ethical conduct of the research project and for the provision of required progress reports as per the terms and conditions of the requirements of the department. I was providing a timely progress report to my advisors and seek the necessary advice and approval from my Main advisor in the course of the research.

Name of Master's Student: Tsegay G/her

Signature: __________ Date: __________

Approval of the Main advisor

Name of the Main advisor: Mr. Aman Mehari

Signature: _________ Date: __________