JIMMA UNIVERSITY

INSTITUTE OF HEALTH

FACULTY OF PUBLIC HEALTH

DEPARTMENT OF EPIDEMIOLOGY

TREATMENT OUTCOMES OF TUBERCULOSIS AMONG TB-HIV CO-INFECTED PATIENTS AND ASSOCIATED FACTORS IN MIZAN-TEPI UNIVERSITY TEACHING HOSPITAL MIZAN-AMAN TOWN SOUTH WESTERN ETHIOPIA. A RETROSPECTIVE COHORT STUDY

BY

MENGISTU KESERI SATSI

A THESIS SUBMITTED TO JIMMA UNIVERSITY, INSTITUTE OF HEALTH, FACULTY OF PUBLIC HEALTH, DEPARTMENT OF EPIDEMIOLOGY AS PARTIAL FULFILLMENT FOR THE REQUIREMENTS OF MASTERS OF PUBLIC HEALTH (MPH) IN GENERAL PUBLIC HEALTH.

JANUARY, 2022

JIMMA, ETHIOPIA

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ADVISORS:

KIFLE WOLDEMICHAEL (MD, MPH, PROFESSOR OF EPIDEMIOLOGY)

ZERIHUN KURA (BSC, MSC)

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ABSTRACT

Background: Tuberculosis treatment outcomes for HIV positive TB patients are worse than those for HIV-negative and TB-HIV co-infection is associated with poor TB treatment outcomes.

Objective: To assess the outcomes of TB treatment among TB-HIV co-infected patients and associated factors in Mizan-Tepi University Teaching Hospital, Mizan-Aman town, South-Western Ethiopia.

Methods: A hospital-based retrospective cohort study was conducted among 163 TB-HIV co-infected patients who registered from 2015 to 2020 in MTUTH, Mizan-Aman town. The data were collected through document review by using a structured data collection format. The data were analyzed using Statistical Package for Social Sciences (SPSS) version 20. Bivariable and Multivariable Cox proportional hazard regression analysis were used to determine the associated factors with the outcome. Adjusted hazard ratio with its corresponding 95% confidence interval was used to measure the strength of association and statistical significance respectively.

Results: Of the 163 TB-HIV co-infected 27% of the participants were cured, 34.4% had completed their treatment, 14.7% were died and 23.9% were lost to follow-up. Overall, successful outcome among TB-HIV co-infected was 61.4%. Those patients who attended primary school (aHR= 4.48, 95% CI: 1.73-11.64), who had baseline weight between 40-55kg (aHR= 2.68, 95% CI: 1.40-5.13), pretreatment BMI <18.5kg/m^2 (aHR= 3.21, 95% CI: 1.76-5.83) and history of opportunistic infections (aHR= 2.77, 95% CI: 1.29-5.91) were found statistically significantly associated with the outcomes of TB-HIV co-infected patients.

Conclusion: The overall successful TB treatment outcome among TB-HIV co-infected patients in the current study was very low. Patients who attended primary school, weight (40-55 kg), low BMI (<18.5kg/m^2) and experienced opportunistic infections were associated with outcomes of TB-HIV co-infected patients. Therefore, targeted measures should be considered to decrease poor TB treatment outcomes among exposed through careful monitoring, making the DOTs program more accessible, counseling, and linking HIV patients.

Key words: TB-HIV co-infected, TB treatment outcome, MTUTH, Ethiopia.

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ACRONYMS AND ABBREVIATIONS

AIDS: Acquired immunodeficiency syndrome

ART: Antiretroviral therapy

BMI: Body mass index

CD4: Cluster of differentiation 4

CDC: Center for disease control

CI: Confidence interval

CPT: Cotrimoxazole preventive therapy

DOT: Directly observed therapy

EPTB: Extra pulmonary tuberculosis

HIV: Human immunodeficiency virus

IPT: Isoniazid preventive therapy

MDR-TB: Multi-drug resistant tuberculosis

MTUTH: Mizan-Tepi University Teaching Hospital

TB: Tuberculosis

TB/HIV: Tuberculosis/Human immunodeficiency virus

WHO: World health organization

XDR-TB: Extensive drug resistant tuberculosis

Chapter One: Introduction

1.1. Background

Tuberculosis (TB) and Human Immunodeficiency Virus (HIV) are the most prevalent communicable diseases of major public health concern of the populations of sub-Saharan African (SSA) countries including Ethiopia (1). TB-HIV co-infected people are experiencing "double burden" that put them at high risk of mortality, rapid disease progression, and development of other opportunistic infections. Due to its immunosuppressive nature, HIV is a strong risk factor for development of TB and re-activation of latent TB (2). According to global Tuberculosis report 2020 an estimated 10.0 million (range, 8.9 – 11.0) people fell ill with TB worldwide, of which 5.6 million were men, 3.2 million were women and 1.2 million were children. People living with HIV accounted for 8.2% of the total. In 2019, 1.4 million people died from TB, including 208,000 (177,000 – 242,000) people with HIV (3). Globally the life time risk of HIV positive individuals who develop TB is 20-37 times greater than HIV negative individuals (4). About one in three deaths among HIV positive people is caused by TB. TB speeds up the viral replication and load in HIV infected people (5).

Ethiopia is one of the 14 countries with high burden of all TB, TB/HIV and Multi-drug Resistant TB (MDR-TB) in the world (2). Studies and reports showed that the prevalence of TB-HIV co-infection in the country is so high that it has ranged from 6.1 – 40.4% (6). In TB-HIV co-infected patients, HIV affects the effectiveness and success of TB treatment in many ways (2). Due to the fact that the co-infected patients are exposed to many regimens including Antiretroviral Therapy (ART), anti-TB therapy and preventive therapy of HIV related co-morbidities which in turn is associated with an increased incidence of adverse drug reaction, poor adherence and decrease drug effectiveness. In connection to this the patient may experience a high default rate leading to TB recurrence and increased risk of death (2). Therefore, well-coordinated therapeutic management is vital to ensure optimum treatment outcomes interms of response and prevention of drug resistance. Collaborative TB-HIV activities and management of co-morbidities are the key components of the "end TB strategy" (5).

To reduce the dual burden of TB-HIV among people with HIV, it is recommended to scale up the three I'-s which are intensified TB case finding followed by high quality TB treatment outcome, isoniazid preventive therapy (IPT) and infection control for TB in all congregate settings and health care facilities providing HIV care (7). According to the Ethiopia national comprehensive HIV care guideline 2018, all HIV positive patients should be evaluated for TB before ART is initiated and then at every visit. Similarly, all TB patients should be offered HIV testing services in TB clinics (7). ART should be started in all TB patients, including those with drug resistant TB, irrespective of the CD4 count. Anti-tuberculosis treatment should be initiated first, followed by ART as soon as possible with in the first 8 weeks of treatment. The HIV positive TB patients with profound immune-suppression (such as CD4 count less than 50 cells/mm3) should receive ART immediately with in the first 2 weeks of initiating TB treatment (5). Studies have shown that poor treatment outcomes among TB-HIV co-infection in a high TB burden country is associated with different socio-demographic factors, for example in Malaysia, poor outcomes were associated with age group, marital status, body weight, having a history of diabetes mellitus, opportunistic infections, ART, white blood cells (WBC) and CD4 counts(8).

The percentage of patients treated successfully is a key component for monitoring and evaluating the effectiveness of TB Directly Observed Therapy (DOT) program. This is particularly necessary for patients with TB-HIV co-morbidities where the treatment outcome could be affected by many factors. Hence, it is important to conduct a periodic evaluation of the treatment outcomes for this segment of the population to assess the level of quality of care and to imply possible directions for improvement. Finally, the WHO global strategic framework to control TB/HIV represents a coordinated response to the joint epidemics of TB and HIV. Collaboration between TB and HIV/AIDS program is crucial in supporting general health service providers. These providers need support in delivering the full range of HIV and TB prevention and care interventions to address the double burden exerted on the patients by co-infections of TB and HIV. Unfortunately, there are a few studies that have assessed TB treatment outcomes among TB-HIV co-infected people in Mizan-Tepi university teaching hospital (MTUTH) Mizan-Aman town, Bench Sheko Zone, Ethiopia.

1.2. Statement of the problem

Tuberculosis (TB) and Human Immunodeficiency Virus (HIV) constitute the main burden of infectious disease in a resource limited countries. In the individual host, the two pathogens *Mycobacterium tuberculosis* and HIV, potentiate each other, accelerating the deterioration of immunological functions and resulting in premature death if not treated (9). Globally, Tuberculosis treatment coverage was 71% in 2019 up from 69% and 59% in the year 2018 and 2015 respectively. Four World Health Organization (WHO) regions achieved levels above 75%: the Americas, Europe, South-East Asia and Western Pacific. The latest data show treatment success rates of 85% for TB, 57% for MDR TB and 76% for TB patients living with HIV(3).

According to World Health Organization (WHO) global Tuberculosis report 2020 an estimated 10.0 million (range, 8.9 – 11.0) people fell ill with TB worldwide, of which 5.6 million were men, 3.2 million were women and 1.2 million were children. People living with HIV accounted for 8.2% of the total. In 2019, 1.4 million people died from TB, including 208,000 (177,000 – 242,000) people with HIV (4). Globally the life time risk of HIV positive individuals who develop TB is 20-37 times greater than HIV negative individuals (4). About one in three deaths among HIV positive people is caused by TB (10). In Ethiopia the actual implementation of the collaborative TB/HIV activities started from May 2004. The preparations were: establishment of national TB/HIV advisory committee (THAC), TB/HIV proposal development, advocacy workshops for policy makers and program managers. The need for TB/HIV collaboration is because, most of the time, they occur commonly and impact on each other (11).

Ethiopia accounts for 3% of the annually 3 million missed people with TB by global health system. In 2016, estimated 35% (56,164) of incident TB cases were missed. Majority of missed cases are believed to concentrate among the poor, vulnerable and underserved communities. Addressing the missed cases does not only have an epidemiological implication but also raises a human right and equity issues (12).
Based on the 2020 (WHO) global TB report Ethiopia is among the 15 high TB-HIV burden countries with 36, 434 peoples newly enrolled in HIV care of which 1914 were notified as a TB case in 2019 (3).

Despite the reported declining trends of HIV incidence rate in the country, there is a huge pool of HIV positive population that directly drives the TB epidemic in Ethiopia, whereby 8% of annually notified TB patients were found to have HIV co-infection. In Ethiopia, 82% of notified TB patients in 2016 knew their HIV status while 82% of reported HIV-positive TB patients have accessed antiretroviral therapy. However, gaps remain and many are left behind in access to care as from the estimated 14,000 people who developed TB and were co-infected with HIV, only 7,843 people were diagnosed with both, HIV infection and TB disease on same year leaving TB/HIV co-infected people at increased risk of suffering and mortality (12).

In high burden and resource limited countries like Ethiopia, integrating health services on TB and HIV has paramount importance in order to increase the effectiveness of the diagnosis and improve the management approaches (13). Considering this, the WHO introduced collaborative strategies to control HIV associated TB and Ethiopia is one of the countries exercising this program as part of health care system. The center for disease control (CDC) in Ethiopia (opened in 2001) is providing guidance and technical support towards TB-HIV co-infection and MDR-TB services. As a result, large improvements have been achieved, in HIV testing, ART provision and diagnostic potential. Studying the treatment outcomes of TB-HIV co-infection is important for programmatic changes or further improvements on the existing programs. Therefore, the objective of this study is to assess the outcomes of TB treatment and associated factors among TB-HIV co-infected patients in Mizan-Tepi University Teaching Hospital (MTUTH) Mizan-Aman town, South-Western Ethiopia.

1.3. Objectives

1.3.1. General Objective

To assess the treatment outcomes of TB among TB-HIV co-infected patients and associated factors in Mizan-Tepi University Teaching Hospital, 2015-2020.

1.3.2. Specific Objectives

1. To determine the outcomes of TB treatment among TB-HIV co-infected patients in Mizan-Tepi University Teaching Hospital, 2015-2020.

2. To identify factors associated with TB treatment outcomes among TB-HIV co-infected patients in Mizan-Tepi University Teaching Hospital, 2015-2020.

Chapter Two: Literature Review

2.1. Tuberculosis treatment outcomes among TB-HIV co-infected patients

World health organization (WHO) grouped TB treatment outcomes into favorable and unfavorable categories, documented cure or completions of anti-TB therapy were considered favorable TB treatment outcomes and death, treatment failure, default from care/LTFU, or unknown outcome were considered unfavorable TB treatment outcomes(14). TB patients will be treated and managed based on the MOH Guidelines. Treatment outcome results serve as an indirect measure of the quality of TB management and care provided by a health care system (15).

TB treatment outcomes for HIV positive TB patients are worse than those for HIV-negative and HIV co-infection was associated with poor TB treatment outcomes (default and death)(16). Improving treatment outcomes for antiretroviral therapy (ART) and anti-tubercular therapy are crucial for decreasing TB-related mortality among those with HIV/MTB co-infection (17). The World Health Organization (WHO) reported that the proportion of TB cases co-infected with HIV was highest in countries in African region in 2014. Overall, 32% of TB cases were estimated to be co-infected, which accounted for 74% of TB cases among people living with HIV worldwide (18).

Studies conducted on TB treatment outcomes of TB-HIV co-infected patients in different regions of the world shows different outcomes, for example the study conducted in India was found 74.5% successful TB treatment outcome, 5.8% had defaulted and 15.7% were deaths, treatment successes were similar among co-infected TB patients compared to those with only TB within the National TB program (19). In contrast, a study done in Nigeria demonstrated that the treatment success rate was lower in TB-HIV co-infected patients, 64.1% compared to TB-HIV negative patients with 73.6% (18). Similarly, in Ethiopia, the study conducted on treatment outcomes of TB and associated factors among TB-HIV co-infected patients at public hospitals of Harar town reported that the overall 86.8% of the TB-HIV co-infected patients had successful TB treatment outcome whereas, the remaining 13.2% patients had unsuccessful TB treatment outcome (2).

In 2018,WHO,TB report indicated TB is associated with a morbidity of 10 million, mortality of 1.5 million and about 0.5 million people fell ill with drug-resistant TB with the majority burden borne by sub-Saharan countries and Asia (20). Moreover the resurgence of TB cases due to misuse of TB drugs or lack of adherence to proper dosages during chemotherapy has led to the emergence of Multidrug resistant tuberculosis (MDR-TB) and extensively drug resistant TB (XDR TB) that are resistant to rifampicin, isoniazid drugs, and kanamycin, capreomycin or amokacin drugs commonly used in TB chemotherapy (20).

A systematic review with meta- analysis study conducted in Ethiopia indicated that the success rate for the treatment of drug-sensitive TB in adults was 80.1%, for those with associated HIV -TB, it was 71.0% , in patients with XDR-TB it was 27.1%, and for those with MDR-TB, it was 58.4% (13). Similar study in South Africa reported that outcomes of MDR-TB did not differ significantly between patients who start ART before or after initiation of MDR-TB except for mortality which was higher among patients who commenced ART before initiating MDR-TB treatment (21).

A study conducted in my study setting, Mizan-Tepi University Teaching Hospital (MTUTH), reported that the overall successful treatment outcome of HIV infected TB patients were 29%, unsuccessful treatment outcome were 71% but no treatment failure was recorded in HIV positive TB patients (16). Another study conducted in this hospital showed that there is no significant difference in treatment outcomes of TB-HIV co-infected patients, indicating that the overall treatment success rate was found to be 30.31% which was very far from the standard of WHO TB treatment outcome recommendation of 85% and unsuccessful treatment outcome 69.69% (22).

Provision of efficient, equitable, patient-centered, and evidence-based services to people living with HIV/AIDS is critical for the intervention programs to understand the nature of barriers to effective treatment and additional risks faced by PLWH with tuberculosis (TB) co-infection and also plays central role in the reduction of risk of negative outcomes such as death, loss to follow up, and inability to have viral load suppressed below 1,000 copies per ml recorded by TB/HIV co-infected patients (23).

Thus, prevention and treatment of TB among PLHIV is a priority for both HIV/AIDS and TB programs.

One of the main steps towards the control of this co-infection is diagnosing and treating TB cases early, as delay in treatment increases the risk of death, morbidity, prolonged hospitalization, and promotes transmission in the community (24).

2.2. Factors associated with TB treatment outcomes among TB-HIV co-infected patients

Evaluating the outcomes of tuberculosis treatment and understanding the specific reasons for unfavorable treatment outcome are important in evaluating the effectiveness of tuberculosis control program (25). WHO set the global target rate for a successful treatment outcome at 85% and classified treatment outcomes as cured, treatment completed, treatment failed, died, lost to follow-up, not evaluated and treatment success including sum of cured and treatment completed and those treatment outcomes are influenced by socio-demographic and socio economic factors such as nutrition, HIV, MDR TB, and strategies for TB management including DOTs (26).

Several studies have been illustrating a number of factors that predicting successful or unsuccessful TB treatment outcomes among TB-HIV co-infected patients. A study conducted in USA, demonstrated that successful outcomes were associated with having received ART, higher serum albumin levels and higher body weight, whereas unsuccessful outcomes were associated with opportunistic infections, sever malnourishment and subsequent lower body weight (27).

Similar study in Brazil showed that co-infected patients were more likely to have unfavorable outcomes, CD4 count, and delayed diagnosis of TB were related to poor outcome, because some HIV-infected individuals postpone seeking health care in order to avoid receiving an AIDS diagnosis (28). Whereas a study on factors associated with unfavorable tuberculosis treatment outcome in Zambia illustrated that TB patients that were relapse, HIV co-infected, above 59 years old and those who sought treatment from the urban clinic had increased odds of unfavorable outcomes (29). In South Africa several factors are associated with TB treatment outcomes; pregnancy, age group 26-45, smoking, diabetes mellitus, liver disease, CD4 count and renal failure are significantly associated with unsuccessful outcomes among TB-HIV co-infected patients (30).

A retrospective study was employed in University of Gondar Teaching Hospital, Ethiopia found the weight category 30-39.9kg, smear-negative PTB, EPTB, retreatment case, seropositive TB patients, and unknown serostatus TB patients were significantly associated with unsuccessful outcomes (31). Similarly, a study conducted in Woldia General Hospital shows treatment outcomes of tuberculosis were affected by age group above 45 years, and sex (females) were three times less likely to have successful outcome than males, this might be due to the fact that females have different maternal-related complications and are less immune-competent, and HIV-positive patients were nearly five times less likely to have successful treatment outcomes. This result was in line with studies reported from Northeastern Ethiopia, South-western Ethiopia (32).

On the other hand in Nigeria a number of socio-demographic characteristics were associated with TB treatment outcomes. They focused on facility based characteristics and found significantly higher treatment success rate in public than private facilities, and also primary healthcare facilities had significantly better treatment success rate than secondary and tertiary healthcare facilities. A likely reason is that TB patients at a tertiary facilities may be more severely ill than those accessing care at the secondary or primary healthcare facilities (33).

A study from Somalia have supported findings from different literature on the fact that individual factors, such as marital status, educational level and HIV status were associated with TB treatment outcomes; implying that married patients were more likely to have a successful treatment outcomes as compared to unmarried patients, similarly, patients who had attended elementary education were less likely to achieve successful outcome compared to those who attended secondary education and also, being HIV-positive lowered the chance of successful outcomes (26).

A retrospective cohort study done in Cameroon, on factors associated with death during tuberculosis treatment of patients co-infected with HIV reveals several factors associated with death in TB-HIV co-infected patients including four clinical factors:- the presence of opportunistic infections, the presence of non-AIDS related comorbidities, not receiving CPT and not receiving ART and one biological factor, having a CD4 cell count $<50/mm^3$ (34).

Understanding of the socio-demographic and clinical differences among TB-HIV and non-HIV TB patients is crucial to provide evidence based targeted interventions towards reducing both infections in high risk groups. The national tuberculosis control plan, which currently recommends all patients diagnosed with TB be tested for HIV, should be strengthened through better integration and communication between AIDS and TB programs. Findings from Lesotho suggest that favorable outcomes can be achieved in co-infected patients when MDR-TB and HIV diseases are treated concurrently and treatment is initiated promptly (35).

2.4. Significance of the study

The findings and recommendations drawn from this study are useful to the TB control program, Ministry of Health (Ethiopia), and to other TB-HIV prevention and control stakeholders in the SNNPR, South-western region including Bench Sheko Zone Health Department, MTUTH.

Information on the TB treatment outcomes and factors associated with the outcomes will be useful in designing new strategies that will ultimately further reduce TB prevalence and take targeted measures towards factors associated with poor treatment outcome.

The finding can also be used by other future researchers intending to conduct similar studies by acting as reference as well as providing evidence on the need for future research on different variables associated with different TB treatment outcomes.

Furthermore, the current study identified the contributing factors that exacerbate poor TB treatment outcomes among TB-HIV co-infected patients. On the other hand, the study also identified the gaps concerning TB control and treatment and provided evidence based information for the stakeholders whose primary intent was on TB prevention to take targeted measures.

2.5. Conceptual framework

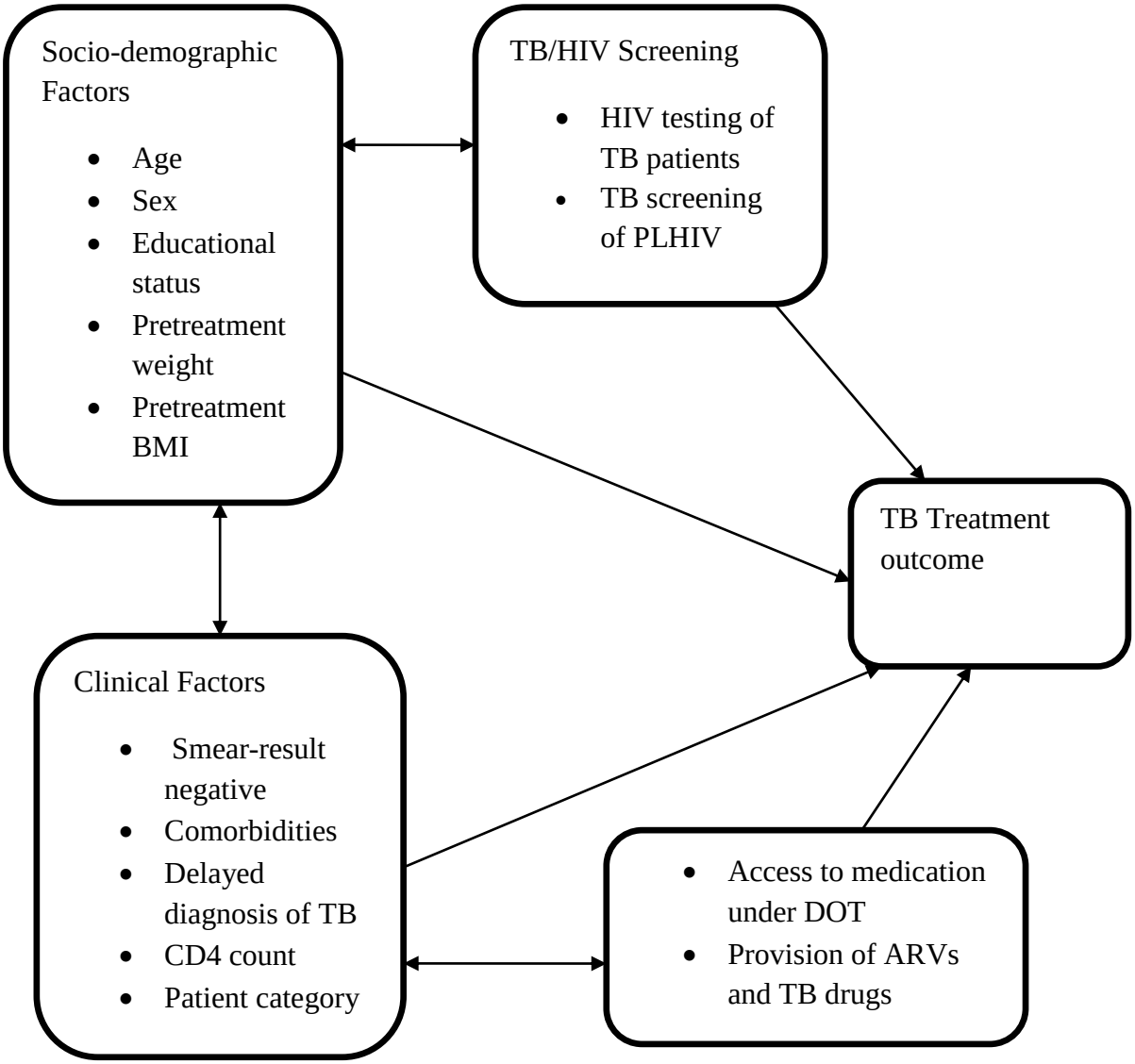

Figure 1 *Conceptual framework of TB treatment outcomes among TB-HIV co-infected patients and associated factors adopted and modified from social determinants of TB formulated by starfieldet al., 2002.*

Chapter Three: Methods and Materials

3.1. Study Setting and period

The study was conducted from May 28 to June 27, 2021, in Bench Sheko Zone, Mizan-Aman town at Mizan-Tepi University Teaching Hospital (MTUTH). The hospital is located at Bench Sheko Zone, Mizan-Aman town which is 561km away from Addis Ababa, the capital city of Ethiopia. The town has a latitude and longitude of 7^{o} 0´N and 35^{o} 35´E with an elevation of 1451 meters. Based on 2013 E.C Central Statistics Agency (CSA) population projection the zone has a population of 639,629 residents. The hospital provides services to the residents of the zone, neighboring zones (Sheka Zone and West-Omo Zone) and Gambella regional state (22). The hospital delivers services in different departments, one of which is the TB clinic. The TB clinic registers and treats patients diagnosed with TB using "Directly Observed Therapy" (DOT) strategy designed by the National Tuberculosis and Leprosy Control Program (NTLCP) of Ethiopia. The DOT strategy is implemented to enhance medication adherence and reduce subsequent drug resistance; hence, patients administer their medication under direct supervision of a health care provider. As per the state policy, the TB clinic provides the recommended medications for registered TB cases screening for HIV serostatus and referrals to ART clinic for HIV positive TB patients (22).

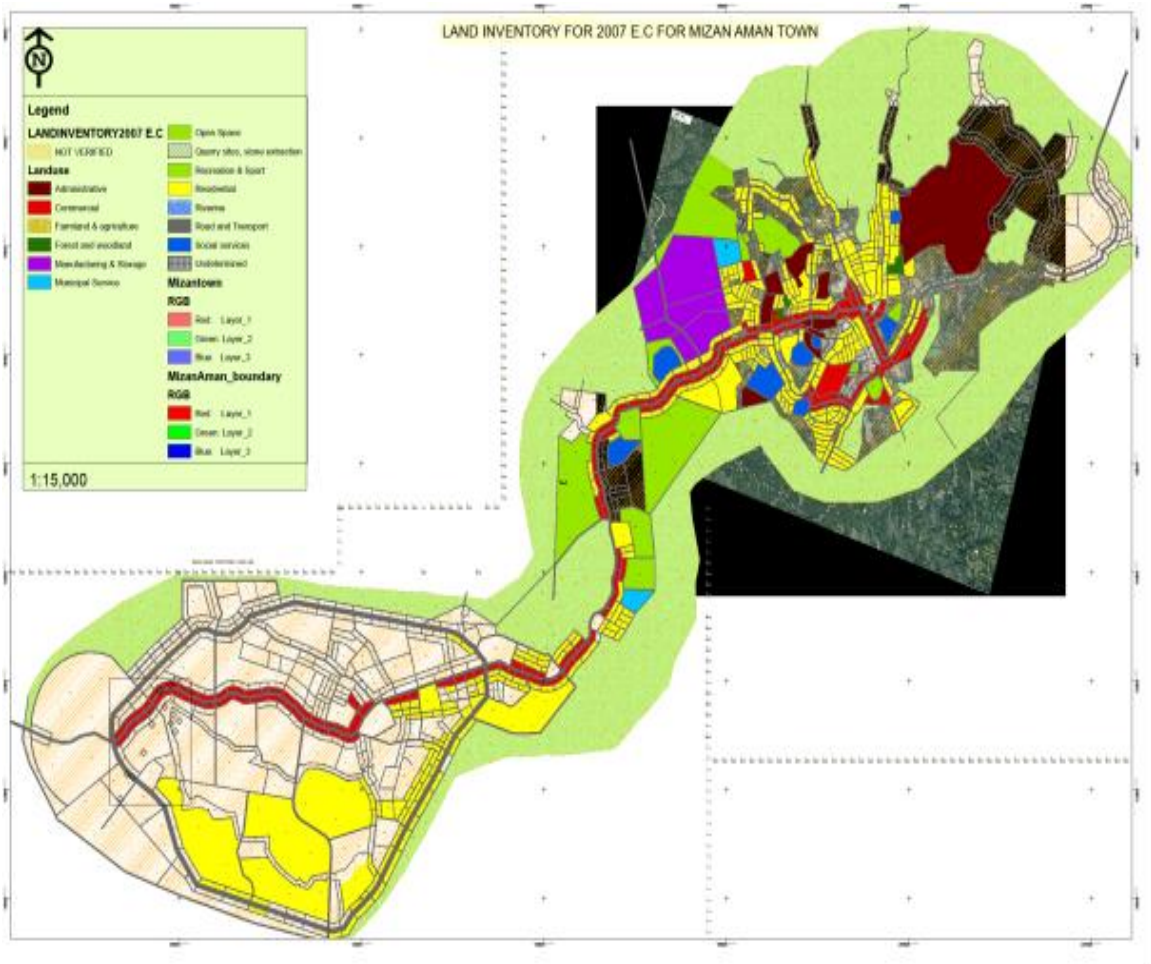

Figure 2 *Map of Mizan-Aman town, 2021. (Source: Mizan-Aman town Health Office)*

3.2. Study Design

A hospital-based retrospective cohort study was conducted by reviewing a 60- month'-s period (January 1, 2015 to December 31, 2020) medical records of TB-HIV co-infected patients.

3.3. Population

3.3.1. Source Population

All TB-HIV co-infected patients who registered and started treatment at Mizan-Tepi University Teaching Hospital.

3.3.2. Study Population

All the TB-HIV co-infected patients who meet the inclusion criteria from those registered and started treatment at Mizan-Tepi University Teaching Hospital from1st January 2015 to 31st December 2020.

3.4. Eligibility criteria

3.4.1. Inclusion criteria

- All the complete medical records of the TB-HIV co-infected patients who registered and completed TB treatment in the hospitals from1st January 2015 to 31st December 2020.
- Patients aged ≥15 years who had started and completed a course of anti-TB therapy.
- All smear positive and negative pulmonary TB and extra-pulmonary TB patients.

3.4.2. Exclusion criteria

- Patients with incomplete medical records (unknown HIV status or unknown treatment outcome)
- Transferred out patients were excluded since the treatment outcomes unknown.
- TB-HIV co- infected patients not on TB treatment.

3.5. Sample size determination

The sample size was all aged ≥15 TB-HIV co-infected patients who registered and treated at Mizan-Tepi University Teaching Hospital from January, 2015 to December, 2020.

3.6. Instrument and data collection procedure

The data were collected through reviewing all the necessary documents (TB treatment registry, monthly cohort form, yearly and follow up form) of the TB patients. A structured data collection format was used to extract data from the medical records of TB-HIV co-infected patients aged 15 years and above. The data extraction format was adopted from previous studies by considering the variables to be studied and it was translated to Amharic and back re-translated to English in order to keep internal consistency.

The data search was carried out manually and the data collection was in three parts. The first section was focused on the socio-demographic characteristics of patients. The second section was focused on the clinical characteristics and the third section were based on final TB treatment outcomes whether the patients were cured, treatment completed, lost to follow-up, treatment failure or if they were dead. Two public health officers' data collectors and one public health officer supervisor who had training on comprehensive TB-HIV care and experience in collecting data in similar situations were recruited to collect the data. The data collectors were trained about the objective of the study and the filled form was checked for completeness on a daily basis during the data collection. The whole process was supervised by the principal investigator and a *supervisor*.

3.7. Study Variables

3.7.1. Dependent variable

- TB treatment outcome

3.7.2. Independent variables

- Age
- Sex
- Educational status
- Marital status
- Pretreatment weight
- Low BMI
- Smear-result at second, fifth and seventh month.
- Opportunistic infections
- Patient category
- Delayed diagnosis of TB

3.8. Definition of terms

According to the standard definitions of the National Tuberculosis and Leprosy Control Program guideline (NTLCP) (20) and the WHO Definitions and reporting

framework for tuberculosis 2013 revision (21), the following treatment outcome definitions were used:

TB infection: - Infection with the bacilli of *Mycobacterium tuberculosis*.

Active TB disease: - Presence of signs and symptoms of TB disease in an individual who is infected with the bacilli *Mycobacterium tuberculosis*.

Case of tuberculosis: - A definite case of pulmonary TB with one or more initial sputum

Smear-positive for acid-fast bacilli or one in which a health worker has diagnosed TB and has decided to treat the patient with a full course of DOTs.

HIV infection:-Infection with the Human Immune-deficiency Virus (HIV) that is confirmed by first and second line serologic tests.

HIV/TB co-infection:-The presence of both HIV and TB infection in an individual patient.

TB treatment outcome:-The final known status of a TB patient who was started on anti-TB treatment.

Cured: A pulmonary TB patient with bacteriologic ally confirmed TB at the beginning of treatment who was smear or culture negative in the last month of treatment and on at least one previous occasion.

Treatment completed:- A TB patient who completed treatment without evidence of failure but with no record to show that sputum smear or culture results in the last month of treatment and on at least one previous occasion were negative, either because tests were not done or because results are unavailable.

Treatment failure: - A TB patient whose sputum smears or culture is positive at 5 months or later during treatment. Or Patients found to harbor a multidrug resistant (MDR) strain at any point of time during the treatment, whether they are smear-negative or-positive.

Died: - A TB patient who dies during the course of treatment.

Lost to follow-up:- A TB patient who has been on treatment for at least four weeks and whose treatment was interrupted for eight or more consecutive weeks.

Not evaluated: - A TB patient for whom no treatment outcome is assigned. This includes cases **"transferred out"** to another treatment until as well as case for which the treatment outcome is unknown to the reporting unit.

In line with **WHO criteria (21),** treatment outcome is categorized into:

Successful outcome: - if TB patients are cured (i.e., negative smear microscopy at the end of treatment and on at least one previous follow-up test) or completed treatment with resolution of symptoms.

Poor outcome: - if treatment of TB patients resulted in treatment failure (i.e., remaining smear positive after 5 months of treatment), lost to follow-up (i.e., patients who interrupted their treatment for two consecutive months or more after registration), or death.

3.9. Data analysis

The collected data was edited, cleaned, coded, and entered in Epi-data version 3.1 and analyzed by using SPSS (Statistical package for social science) version 20 for windows. Descriptive statistics, such as frequencies, percentage, mean, Interquartile range (IQR) and standard deviation were used to describe the study population in relation to socio-demographic and clinical characteristics. We used Cox proportional hazard regression analysis to identify risk factors for TB treatment outcome. We conducted bivariable and multivariable analysis. To control the effect of confounding factors, a variable that had p-value ≤ 0.25 in the bivariable regression analysis was entered into the multivariable regression model, as the independent variable and TB treatment outcome was a dependent variable. Statistical significance was obtained through adjusted hazard ratio (aHR) with its corresponding 95% confidence interval and P-value <0.05. Hosmer and Lemeshhow test was used to check the necessary assumption on the fitness of goodness of the final model and it was found fit. Finally, the results were presented by narration, graphs and tables.

3.10. Data quality assurance

To ensure quality of data, the following measures were taken: data collectors were trained for one day. In addition, principal investigator and supervisor continuously supervised the whole data collection process. Completeness of the data was checked,

coded and entered into Epi-data version 3.1. Each entry was cross checked independently to ensure the quality of data.

3.11. Ethical consideration

Ethical clearance was secured from the institutional review board (IRB) of Jimma University, and formal letter was taken to MTUTH then, the data collection was after obtaining permission from the hospital director. The aim and purpose of all components of the study was discussed and agreed on before the consent obtained from the authorities. Furthermore, before reviewing medical records of the TB-HIV co-infected patients, permission was obtained from the TB treatment unit heads. The information obtained from the study could be used only for the purpose of the study and is kept confidential. Since the collection of data is through review of medical records, there is no harm to the patients and their relatives provided confidentiality is maintained. Moreover, no personal identifier was used on the data collection form. The recorded data was not accessed by a third person except the investigator.

3.12. Dissemination plan

The major findings of the study will be primarily submitted to Jimma University and responsible bodies in the study area such as Mizan-Tepi University Teaching Hospital, Bench Sheko Zonal Health Department and administration of the study area. Finally, efforts will be made to publish the findings in a peer reviewed scientific journal.

Chapter Four: Results

4.1. Socio-demographic characteristics of TB-HIV co-infected patients.

A total of 179 TB-HIV co-infected adult patients' medical records were reviewed but 163 (91%) met the inclusion criteria. About eighty nine (54.6%) of the patients were males. Their ages ranged from 15 to 56 years with a mean of 35.4 (SD ± 8) years

with, 105 (64.4%) of the study participants were in the age group (30-44). Majority one hundred twelve (68.7%) were married status with, 74 (45.4%) of the study participants were attended primary education. Nearly one-third 53 (32.5%) among the participants were merchants and 114 (69.9%) were urban residents. The baseline weight of the participants ranged from 34 kg to 78 kg with a mean of 53.7 (SD ± 8.7) kg with, the pretreatment body mass index (BMI) of 124 (76.1%) were within 18.5-24.9kg/m^2 (**Table 1**).

Table 1 *Socio-demographic characteristics of TB-HIV co-infected patients at MTUTH Mizan-Aman town South-West Ethiopia, 2021 (N=163).*

Variables	Categories	TB-HIV co-infected	
		Frequency	Percent
Sex	Male	89	54.6
	Female	74	45.4
Age	15-29	30	22.1
	30-44	105	64.4
	>=45	22	13.5
Marital status	Single	16	9.8
	Married	112	68.7

	Divorced	8	4.9
	Widowed	27	16.6
Educational status	Never attended school	2	1.2
	Primary	74	45.4
	Secondary	54	33.1
	Higher education	33	20.2
Ethnicity	*Bench*	30	18.4
	Kaffa	97	59.5
	Sheko	10	6.1
	Amhara	19	11.7
	Others	7	4.3
Occupation	Farmer	34	20.9
	House wife	23	14.1
	Merchant	53	32.5
	Government employee	38	23.3
	Others	15	9.2
Residence	Urban	114	69.9
	Rural	49	30.1
Weight	<39	10	6.1
	40-55	76	46.6
	>55	77	47.2
BMI	<18.5	36	22
	18.5-24.9	124	76.1
	>=25	3	2.5
Year of TB treatment	2015	22	13.5
	2016	35	21.5
	2017	28	17.2
	2018	27	16.6
	2019	32	19.6
	2020	19	11.7

4.2. Clinical characteristics of TB-HIV co-infected patients

Majority, one hundred fifty (92%) of participants were new TB cases. Ninety five (58.3%) diagnosed with smear-negative pulmonary TB with, 148 (90.8%) of the participants have been on working functional status. One hundred thirty six (83.4%) of the study participants had experienced opportunistic infections. The opportunistic infections were commonly, pneumonia 48 (29.4%) sexually transmitted infections 33 (20.2%) and candidiasis 19 (11.7%). The Cluster of Differentiation 4 (CD4) of the TB-HIV co-infected ranged from 104 to 1014 cell/mm^3 with median (Inter Quartile Rang (IQR) of 479 (311- 693) cells/mm^3; and only 74 (45.4%) patients had CD4 count more than 500 cells/mm^3. Of the 53 (32.5%) diagnosed with smear-positive

pulmonary TB, 6 (11.3%) were tested smear positive at 2nd month. Twenty seven (50.9%), 32 (60.4%) and 36 (68%) at 2nd, 5th and 7th month respectively were not tested for their smear-result (**Table 2**).

Table 2 *Clinical characteristics of TB-HIV co-infected patients at MTUTH Mizan-Aman town South-West Ethiopia, 2021 (N=163).*

Variables	Categories	Exposed	
		Frequency	**Percent**
Patient category	New	150	92
	Retreatment	13	8
Type of TB	SPPTB	53	32.5
	SNPTB	95	58.3
	Extra pulmonary TB	15	9.2
Functional status	Working	148	90.8
	Ambulatory	12	7.4
	Bedridden	3	1.8
History of opportunistic infections	Yes	136	83.4
	No	27	16.6
Type of infections	Pneumonia	48	29.4
	Candidiasis	19	11.7
	STI	33	20.2
	Intestinal parasites	18	11

	UTI	18	11
	Other infections	4	2.4
Baseline CD4 count cells/mm^3	<200	7	4.3
	201-499	82	50.3
	>=500	74	45.4
Smear-result at 2^{nd} month	Positive	6	11.3
	Negative	20	37.7
	Not tested	27	50.9
	Negative	21	39.6
	Not tested	32	60.4
	Negative	17	32
	Not tested	36	68
Treatment outcome	Cured	44	27
	Treatment completed	56	34.4
	Died	24	14.7
	Lost to follow-up	39	23.9

4.3. Treatment outcome of TB among TB-HIV co-infected patients

Among the 163 TB-HIV co-infected, 44 (27 %) with (95% CI: 20.3-34.5) were cured and, 56 (34.4%) with (95% CI: 27.1-42.2) had completed their treatment. Death rate was seen to be highest 24 (14.7%) with (95% CI: 9.7- 21.1). A higher lost to follow-up rate were recorded 39 (23.9%) with (95% CI: 17.6-31.2). Overall, 100 (61.4%) with (95% CI: 53.4-68.9) had successful treatment outcome (defined as cured or treatment completed). Unsuccessful treatment outcome (defined as either died or lost to follow-up) were highest 63 (38.6) with (95% CI: 31.1-46.6) (**Figure 3**).

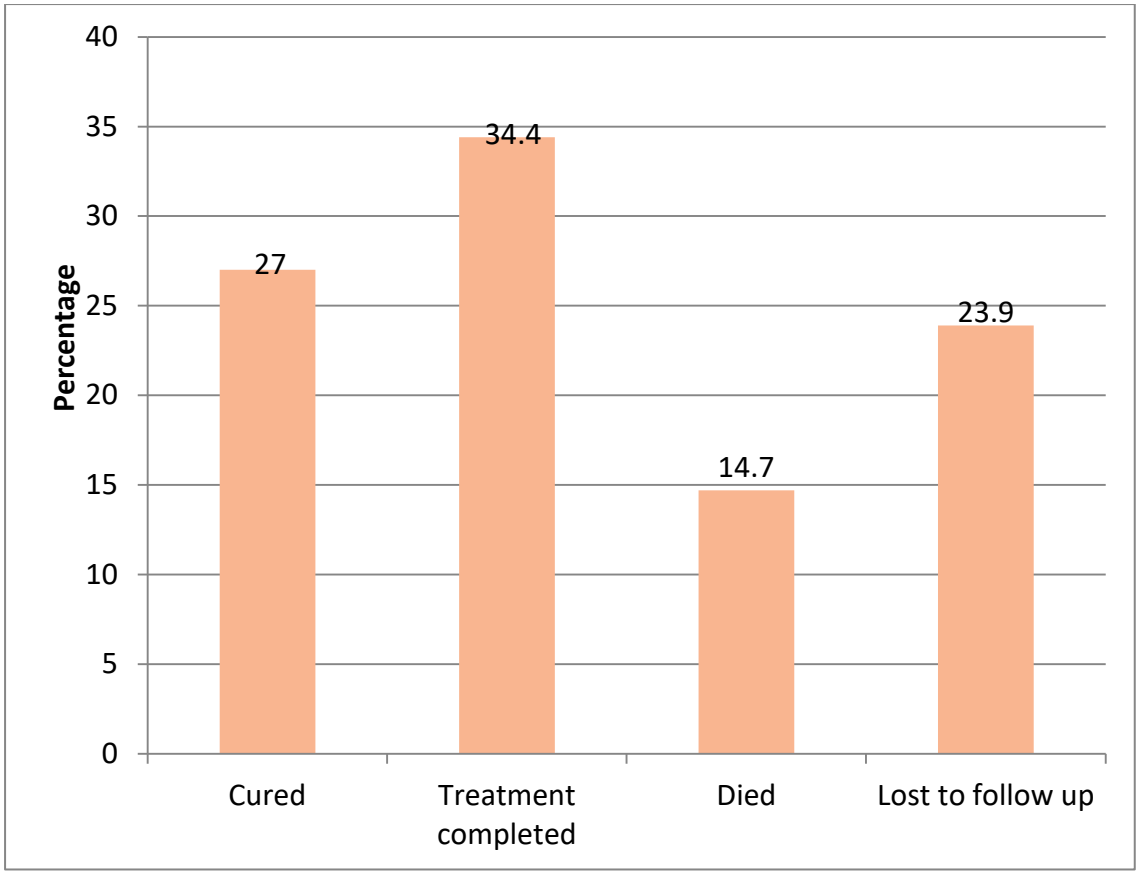

Figure 3 Treatment outcomes of TB among TB-HIV co-infected patients at MTUTH, Mizan-Aman 2021

4.4. Factors associated with TB-HIV co-infected patients.

4.4.1 Bivariable and multivariable analysis

The bivariable Cox proportional hazard regression analysis identified six candidate variables to be analyzed in multivariable model namely, educational status, type of TB, weight, history of opportunistic infections, BMI and smear-result at 2^{nd}, 5^{th} and 7^{th} month. A multivariable Cox proportional hazard regression analysis model was built for those statistically significant variables at the bivariable model. In the final model after adjusting for possible confounding factors four variables were found to be statistically significantly associated with the outcomes of TB-HIV co-infected patients. Educational status, pretreatment weight, pretreatment BMI and history of opportunistic infections remained significantly associated with the dependent variable. We found a strong independent association between outcomes of TB-HIV co-infected and greater hazard of unsuccessful outcomes among those who attended primary education (aHR = 4.48, 95% CI: 1.73-11.64), pretreatment body weight (40-55kg) (aHR= 2.68, 95% CI: 1.40-5.13), pretreatment BMI (<18.5kg/m^2) (aHR= 3.21, 95%CI: 1.76-5.85) and history of opportunistic infections (aHR= 2.77, 95% CI: 1.29-5.91). On the other hand, there is no association between outcomes of TB-HIV co-infected patients and type of TB and smear-result.at.2^{nd},.$5^{th.}$and.$7^{th.}$month.(**Table3**).

Table 3 Bivariable and multivariable analysis of factors associated with TB-HIV co-infected patients at MTUTH, Mizan-Aman town, Southwest Ethiopia 2021 (N =163)

Variables	Categories	N (%)	P-value	HR (95% CI)	Adjusted HR (95% CI)
Educational status	Never attended school	2 (1.2)	0.21	1.70 (0.89-3.26)	2.27 (0.24-4.53)
	Primary	74 (45.4)	0.002	2.90 (1.14-7.41)	4.48 (1.73-11.64)
	Secondary	54 (33.1)	0.51	0.85 (0.48-1.51)	0.92 (0.63-3.88)
	Higher education	33 (20.2)		1	1
Weight (kg)	<39	10 (6.1)	0.23	3.44 (0.15-12.33)	3.85 (0.18-14.66)
	40-55	76 (46.6)	0.04	1.86 (1.02-3.39)	2.68 (1.40-5.13)
	>55	77 (47.2)		1	1
BMI (kg/m^2)	<18.5	39 (23.9)	0.001	2.50 (1.45-4.31)	3.21 (1.76-5.85)
	18.5-24.9	124 (76.1)	0.94	0.64 (0.36-1.13)	0.50 (0.29-1.10)
	>=25	3 (2.5)		1	1
Type of TB	SPPTB	53 (32.5)	0.22	0.39 (0.20-1.78)	0.32 (0.17-1.75)
	SNPTB	95 (58.3)	0.63	1.50 (0.71-3.48)	1.63 (0.94-2.81)
	EPTB	15 (9.2)		1	1
History of opportunistic infections	Yes	136 (83.4)	0.005	2.73 (1.34-5.82)	2.77 (1.29-5.91)
	No	27 (16.6)		1	1

Smear-result at 2nd month	Not tested	27 (50.9)	0.24	1.91 (0.84-4.36)	1.95 (0.47-3.28)
	Negative	20 (37.7)	0.18	1.77 (0.97-3.15)	1.81 (0.63-3.39)
	Positive	6 (11.3)		1	1
Smear-result at 5th month	Negative	21 (39.6)	0.36	0.35 (0.12-1.37)	0.32 (0.10-1.26)
	Not tested	32 (60.4)		1	1
Smear-result at 7th month	Negative	17 (32)	0.58	0.44 (0.14-1.45)	0.39 (0.83-15.72)
	Not tested	36 (68)		1	1

Chapter Five: Discussion and Recommendations

5.1. Discussion

In the current study successful outcome among TB-HIV co-infected patients was (61.4%). A successful outcome constitutes (cured and treatment completed). Cured (27%) and treatment completed (34.4%). The overall successful outcome among TB-HIV co-infected patients was very much low (61.4%). This finding is consistent to the results reported from international epidemiology data base (64%) and western Ethiopia (60%) (14, 36). The findings of this study is also lower than several studies conducted in Cameroon (78.6%), Harar eastern Ethiopia (86.8%), Ethiopia analytic study (88.2%), Ghana (77%), India (72%) and Gondar University referral hospital (77.3%) (1, 2, 37, 38, 39, 40) .

Of course, the current finding showed substantial improvement compared to the two studies conducted in Mizan-Tepi university teaching hospital (30.3%) and Malaysia (27.9%) (22, 41). The possible reason for the lower treatment success rate observed in the current study among TB-HIV co-infected patients might be related to high death rate of (14.7%) and lost to follow-up (23.9%) to the initiation of ART for all co-infected patients. The reasons for many countries that are failing to achieve adequate treatment outcomes are default, transfer, re-infection and in some cases high death rates (36). The variation between our finding and results of others might be due to the presence of TB and HIV drug to drug interaction, patient's awareness about importance of adhering to TB treatment and availability of facilities used to screen or diagnose TB in HIV/AIDS patients.

Unsuccessful outcome in the current study among TB-HIV co-infected patients was very high (38.6%). Unsuccessful treatment outcome includes death (14.7%) and lost to follow-up (23.9%). In the current study, the death rate among the TB/HIV co-infected patients (14.7%) is in agreement with several studies conducted in western Ethiopia with death rate of (17.4%), India ranging from (11-19%), Botswana (13.6%) and Myanmar (18%) (36, 39, 42, 43, 44, 45).

But the current death rate was lower than the rate demonstrated from different studies which report death rate ranging from 21.5% to 29.4%:- Ghana (21.5%), Malaysia (23.3%) and Cameroon (29.4%) (8, 34, 38) . However, the WHO reported that TB associated death rate among TB-HIV co-infected patients was 11% (2). Nonetheless, smaller death rates as compared to the current study were reported from Zambia (9%) and Nigeria (9.7%) (18, 29). The possible explanation for the high death rate recorded could be due to rapid disease progression, immunodeficiency, late diagnosis and other opportunistic infections (2).

Lost to follow-up from TB treatment program is a major public health problem that can be associated with adverse drug reactions, social stigma and lack of awareness about the disease (2). The proportion of lost to follow-up in the current study was (23.9%). This finding is higher than reports from Nigeria (18.5%), India (1%), Ethiopia (10%), Cameroon (4.2-9.5%) and Zambia (5%) (18, 29, 34, 36, 37, 42). But lower than another study reported from Nigeria (38.6%) (46). The possible reason related to high lost to follow-up rate might be due to weak smear result follow-up and lack of or poor defaulter tracing mechanism in the second, fifth and seventh months. Another reason could be ignorance about the need for treatment compliance coupled with inadequate knowledge about TB, traveling outside treatment areas, consequently missing clinic appointment and alcohol abuse.

In the current study factors associated with the outcomes of TB-HIV co-infected patients were identified as education, pretreatment weight, pretreatment BMI and history of opportunistic infections. Patients who attended primary education had increased hazard with outcomes of TB-HIV co-infected patients in the current study. This finding was in line with similar studies reported from Somalia and South Africa (26, 47). This corresponds to TB-HIV co-infected patients with lower educational status in our study had lower outcome. Educational level is perceived to reduce ignorance and increase knowledge on drug management and consequences (26).

Our finding also revealed an increased hazard between baseline body weights (40-55kg) measured at the commencement of TB treatment and the outcomes of TB-HIV co-infected patients. This finding was supported by studies published from Harar Public Hospitals, University of Gondar and Tanzania (40, 48, 49).

In keeping with previous studies, baseline weight and HIV infection were found to be independently associated with the outcomes of TB-HIV co-infected patients (50). Studies showed that risk of death from TB increases in individuals with weight loss. Weight loss is much pronounced in patients with dual infection (TB and HIV) compared to HIV negative TB patients. This might be explained partly by the loss of appetite and loss of energy by the disease itself and being inactive that may lead to the progression of severity of disease and even to death (40).

Furthermore, low BMI (<18.5kg/m^2) was strongly associated with the outcomes of TB-HIV co-infected patients. These finding was in agreement with the reports from Lesotho and South Africa (35, 51). Because low BMI is a sign of sever TB or HIV disease, the strong association between low BMI and greater odds of negative outcome is not surprising and underscores the importance of early initiation of appropriate therapy.

Likewise, the current study found a greater hazard among TB-HIV co-infected patients who had history of opportunistic infections. This finding was consistent with the study conducted in Eastern Ethiopia and Malaysia demonstrated that experiencing opportunistic infections were independently associated with TB-HIV co-infected patients, where it contributes to unfavorable outcomes (2, 8).

On the other hand, type of TB and smear-result at 2^{nd}, 5^{th} and 7^{th} month were not associated with the outcomes of TB-HIV co-infected patients. These findings are in contrast to results of other studies from Eastern-Ethiopia which showed that TB-HIV co-infected patients diagnosed with smear-positive PTB were associated with the outcomes of TB-HIV co-infected patients (2). A similar study conducted in Uzbekistan shows that extra pulmonary TB is more common in the HIV-associated population, it becomes increasingly prevalent with progressive immunodeficiency, and it contributes a strong association among TB-HIV co-infected patients (53). Another study conducted in North-West Ethiopia and South-Western Ethiopia showed that smear-result at 2^{nd}, 5^{th} and 7^{th} month were associated with outcomes of TB-HIV co-infected patients (36, 52). This could be observed by effect of smear examination follow-up on treatment success, where the high sputum conversion rate for HIV positive patients during second and fifth month sputum follow-up is an indication that the smear examination during DOTS has the capacity for achieving good results.

Thus, further prospective and qualitative studies will be important to assess the reason why type of TB and smear-result at 2^{nd}, 5^{th} and 7^{th} month had been seen to have no effect on TB-HIV co-infected patients in our study.

5.2. Limitation of the study

The current study was faced with incompleteness of patient's files. Some important variables which might have impact on treatment outcome of TB patients, like socioeconomic characteristics (income, family size, living condition, social support, distance to the health facility), treatment and disease related variables (adherence level, viral load) and behavioral factors like (knowledge and attitude about the disease, substance use, such as alcohol abuse, cigarette smoking) were not recorded. Moreover, some patients were transferred to other health facilities where it was difficult to track what happened thereafter. Exclusion of medical records of patients who were transferred out and/or found to be incomplete may have also slightly affected our results.

5.3. Conclusion

The overall TB treatment success rate among the TB-HIV co-infected patients in the current study during the study period at Mizan-Tepi University Teaching Hospital was very low (61.4%) and with high proportion of unsuccessful treatment outcome of (38.6%). Those who attended primary education, pretreatment weight (40-55 kg), low BMI (<18.5kg/m^2) and history of opportunistic infections were statistically significantly associated with outcomes of TB-HIV co-infected patients.

5.4. Recommendations

To Mizan-Tepi University Teaching Hospital

1. Based on the findings of this study, we recommend that frequent supportive supervision and health education programs for patients with a high risk of unsuccessful treatment outcome should be carried out.
2. Targeted measures should be considered to decrease poor TB treatment outcomes among high-risk patients through careful monitoring, making the DOTs program more accessible, counseling, and linking HIV patients.
3. To reduce defaulters especially among HIV positive TB patients, it is paramount that proper TB health education, with emphasis on the duration, side effects and the risk associated with disrupting TB treatment, be given at the first visit of every patient to the DOTS clinic and reinforced at subsequent visits.

To Ministry of Health

4. The TB registers should be improved to capture other socio-demographic, clinical and behavioral characteristics of the patients. This will provide detailed information for further analysis on factors associated with the patients that may affect their treatment outcomes.
5. We would like to strongly recommend that national TB programmes and health personnel to urgently maintain continuity of essential services for people affected with TB-HIV during the COVID-19 pandemic.

To the scientific community

6. The scientific community should focus on the investigation of a combined drug (TB and ARV) to reduce drug to drug interactions and where it favors for poor TB treatment outcome.

To Bench Sheko Zone Health department

7. Strengthening TB/HIV joint interventions like providing information and education on TB and HIV to increase community awareness of both infections and their inter-relationship.
8. Intensify tuberculosis case finding in areas of high HIV prevalence, where there is effective local TB programmes achieving good rates of successful treatment.

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Annex -1-Data extraction format

Treatment outcomes of TB among TB-HIV co-infected patients and associated factors in MTUTH, Mizan-Aman town, South-West Ethiopia, data collection form 2021**.**

Part I, **Socio-demographic characteristics**

No	**Questions**	**Categories**	**Skip**
101	Sex of patient	1. Male 2. Female	
102	Patient's age	_____(in years)	
103	Marital status	1. Single 3. Divorced 2. Married 4. Widowed 5. Separated	
104	Educational level	1. Never attended school 2. Primary 3. Secondary 4. Higher education	
105	Ethnicity of patient	1. Bench 2. Kaffa 3. Sheko 4. Amhara 5.Other, specify_____	
106	Patient's occupation	1. Farmer 2. House wife 3. Merchant 4. Government employee 5. Other, specify_____	

107	Place of residence	1. Urban 2. Rural	
108	Pretreatment weight (Kg)	_____	
109	Pretreatment BMI (kg/m^2)	_____	
110	Year TB treatment initiated	_____	
Part II: Clinical characteristics			
201	What is category of the patient	1. New 2. Retreatment 3. Others, specify_____	
202	What is the type of Tuberculosis	1. Smear positive 2. Smear negative 3. Extra pulmonary	
203	Functional status of patient	1. Working 2. Ambulatory 3. Bedridden	
204	HIV status	1. positive 2. Negative 3. Unknown	
205	Does the patient have history of opportunistic infections?	1.Yes 2. No	If No skip to Q#207
207	What is Smear result at 2^{nd} month for PTB +ve patients?	1. Positive 2. Negative 3. Not tested	
208	What is Smear result at 5^{th} month for PTB +ve patients?	1. Positive 2. Negative 3. Not tested	

209	What is Smear result at 7th month for PTB +ve patients?	1. Positive 2. Negative 3. Not tested	
	Part: XLI Treatment outcomes		
301	What is the treatment outcome of the patient?	1.Cured 2.Treatment completed 3.Died 4.Treatment failure 5.Lost to follow-up	

<u>የመረጃ ማስባሰቢያ ቅጽ</u>

በሚዛን-ቴፒ ዩኒቨርሲቲ ማስተማሪያ ሆስፒታል የቲቢና ኤች .አይ.ቪ. ህመ.ማን የቲቢ ህክምና ውጤትና ተያያዥ ችግሮች መረጃ ማሰባሰቢያ ቅጽ፡፡

ክፍል አንድ ፡- የህመምተኛው ማህበራዊና አካባቢያዊ ሁኔታዎች፤

ተ.ቁ	ጥያቄዎች	የመልሶች ምደባ	ወደ ቀጣይ ዝለል
101	ፆታ	1. ወንድ 2. ሴት	
102	ዕድሜ	----------(ዓመት)	
103	የጋብቻ ሁኔታ	1. ያላገባ 3. የተፋታ 2. ያገባ 4. ባል/ሚስት የሞተችበት/የሞተባት	
104	የትምህርት ደረጃ	1. ምንም ያልተማረ 2. ማንበብና መፃፍ የሚችል/የምትችል 3. 1ኛ ደረጃ ያጠናቀቀ/ች 4. 2ኛ ደረጃ ያጠናቀቀች 5. ዲፕሎማና ከዛ በላይ	
105	የታካሚው/ዋ ብሔረሰብ	1. ቤንች 2. ካፋ 3. ሸኮ 4. አማራ 5. ሌላ ካለ ይገለጽ----------	
106	የታካሚው/ዋ ስራ/መተዳደሪያ	1. አርሶ አደር 2. የቤት እመቤት 3. ነጋዴ 4. የመንግስት ሠራተኛ 5. የግል/ግብረ-ሰናይ ድርጅት 6. የቀን ሠራተኛ 7. ሌላ ካለ ይገለጽ----------	
107	መኖሪያ አካባቢ/ቦታ	1. ከተማ 2. ገጠር	
108	ህክምና ከመጀመሩ/ሯ በፊት የክብደት መጠን (በኪ.ግ)	----------	
109	ህክምና ከመጀመሩ/ሯ በፊት የሰውነት ክብደትና ቁመት መጠን (በኪ.ግ/ሜ^2).	----------	
110	የቲቢ ህክምና የጀመሩበት ዓ.ም	----------	

ክፍል ሁለት፡- ክሊኒካል/የህክምና ምርመራ ሁኔታዎች			
201	የህመምተኛው ዓይነት	1. አዲስ ታካሚ 2. በድጋሚ እየታከመ ያለ 3. ሌላ ከሆነ----------	
202	የቲቢ በሽታ ዓይነት	1. የሳንባ ቲቢ የተረጋገጠ/Positive 2. የሳንባ ቲቢ የሚያጠራጥር/Negative 3. ከሳንባ ውጪ የሆነ ቲቢ	
203	የህመምተኛው ስራ/እንቅስቃሴ ሁኔታ	1. ስራ እየሰራ ያለ 2. በተሸከርካሪ እየመጣ የሚታከም 3. የአልጋ ቁራኛ	
204	የኤች.አይ.ቪ ሁኔታ	1. ኤች.አይ.ቪ ያለበት 2. ኤች.አይ.ቪ የሌለበት 3. የኤች.አይ.ቪ ሁኔታው የማይታወቅ	
205	ህመምተኛው ተጓዳኝ ህመሞች አሉበት?	1. አዎን 2. አይደለም	መልሱ አይደለም ከሆነ ወደ ጥያቄ ቁጥር 207 ሂድ
206	ለጥያቄ ቁጥር 208 መልሱ አዎን ከሆነ የተጓዳኝ ህመሙ ዓይነት ምንድነው?	1. የሳንባ ምች 2. ካንዲዲያሲስ 3. የአባላዘር በሽታዎች 4. የአንጀት ጥገኛ ትላትል 5. የሽንት ቧንቧ ኢንፌክሽን 6. ሌላ ካለ----------	
207	የህመምተኛው/ዋ /ሳንባ ቲቢ ያለበት/ባት የምርመራ ውጤት ከ2ወር ህክምና ክትትል በኋላ ምን ይመስላል?	1. በሽታው ያለበት/ባት 2. በሽታው የሌለበት/ባት 3. አልተመረመረም/ችም	
208	የህመምተኛው/ዋ /ሳንባ ቲቢ ያለበት/ባት የምርመራ ውጤት ከ5ወር ህክምና ክትትል በኋላ ምን ይመስላል?	1. በሽታው ያለበት/ባት 2. በሽታው የሌለበት/ባት 3. አልተመረመረም/ችም	
209	የህመምተኛው/ዋ /ሳንባ ቲቢ ያለበት/ባት የምርመራ ውጤት ከ7ወር ህክምናክትትል በኋላ ምን ይመስላል?	1. በሽታው ያለበት/ባት 2. በሽታው የሌለበት/ባት 3. አልተመረመረም/ችም	

ክፍል ሶስት፡- የቲቢ ህክምና ውጤት ህክምናውን ከጨረሱ በኋላ			
301	**የህመምተኛው ህክምና ውጤት ምነ ይመስላል?**	1. **ከቲቢ በሽታ የዳነ** 2. **የቲቢ ህክምና የጨረሰ** 3. **የሞተ** 4. **ህክምናው ያልተሳካ** 5. **ህክምናውን ያቋረጠ** 6. **ወደ ሌላ ተቋም በዝውውር የሄደ**	

Annex-2- Participant Information sheet and consent form

Jimma University, Institute of Health, Faculty of public health, Department of Epidemiology

Project title: Treatment outcomes of TB among TB-HIV co-infected patients and associated factors in Mizan-Tepi University Teaching Hospital, Mizan-Aman town, Bench-Sheko Zone, Southwest, Ethiopia, 2021.

Name of the organization: Jimma University, Name of the sponsor: Jimma University

Instruction: please read a copy of the full informed consent to the participants.

Introduction:

Information sheet and consent form prepared for treatment outcomes of TB among TB-HIV co-infected patients in MTUTH prior to the collection of data in this research project. The research group includes principal investigator, two data collectors, and one supervisor.

Purpose of the research:

The aim of this study is to assess treatment outcomes of TB among TB-HIV co-infected patients and associated factors and the information of this study will be useful for effective treatment outcome interventions. The study will be carried out for one month.

Benefits, Risk and Discomfort:

There is no discomfort that might be observed during data collection, because the data is going to be extracted from TB registration and follow up forms so that there is no direct contact with the patients. The data will help us to find more about treatment outcomes of TB and factors affecting effective treatment among co-infected patients and this will help us to improve treatment outcomes in the facility and other institutions. There is no risk or direct benefit to the patients in this research.

Incentive:

We will not pay for patients for taking part in this study.

Confidentiality:

The information that we collected in this study will be kept confidential by using codes instead of any personal identifiers and is meant only for the purpose of the study.

Right to refuse or withdrawal:

Patients have full right not to allow for the information that will be collected from their medical records and refusing to participate will not affect anything you want.

Who to contact:

If you have any questions you may ask now or later. If you wish to ask questions later, you may contact: Mengistu Keseri, Phone: +251917150810, E-mail: menegistukesri@gmail.com

Consent form

Hello! My name _____and I am collecting data for the research being conducted by Mr. Mengistu Keseri, Masters Student from Jimma University. He is doing research on treatment outcomes of TB among TB-HIV co-infected patients and associated factors as the partial fulfillment for master's degree in General public health. You are selected to be one of the participants from the study. I would like to assure you that all your information during data collection will be strictly confidential and that information collected from your medical record will be used only in scientific reports without any mentioning of personal information including your name. There is no harm or incentive for collecting your medical information. Information gathered from the study will be used to improve programs that promote TB treatment outcomes.

Do you have any question? Can I proceed with the questions?

1. Yes_____ (thank you and continue) 2. No ____ (Thank you and stop)

<u>አባሪ ፤ የተሳትፎ መረጃ ወረቀት እና ስምምነት ቅጽ</u>

ጅማ ዩኒቨርስቲ፣የጤና ሳይንስ ተቋም፣የህብረተሰብ ጤና ፋኩልቲ፣የኢፒደሚዮሎጂ ት/ትክፍል

የፕሮጀክትርዕስ- በሚዛን-ቴፒ ዩኒቨርሲቲ ማስተማሪያ ሆስፒታል የቲቢና ኤች .አይ.ቪ ህመ-ማን የቲቢ ህክምና ውጤትና ተያያዥ ችግሮች ሚዛን-አማን ከተማ በደቡብ ምዕራብ ኢትዮጵያ 2021እ.ኤ.አ

የድርጅቱ ስም- ጅማዩኒቨርስቲ የስፖንሰር ሰጪው ስም - ጅማ ዩኒቨርሲቲ

መመሪያ: እባክዎን ሙሉ የመረጃ ስምምነት ቅጽን ያንብቡ ለተሳታፊው

መግቢያ

በዚህ የምርምር ፕሮጀክት ውስጥ ተሳታፊ ከመሆናቸው በፊት በሚዛን-ቴፒ ዩኒቨርሲቲ ማስተማሪያ ሆስፒታል በቲቢና ኤች .አይ.ቪ ህመ-ማን የቲቢ ህክምና ውጤትና ተያያዥ ችግሮች ዙሪያ የመረጃ ልውውጥ እና የስምምነት ቅጽ ተዘጋጅቷል። የጥናቱ ቡድን፤ የጥናቱ ባለቤት፣አራት የመረጃ አሰባሳቢዎች እና አንድ ተቆጣጣሪን ያጠቃልላል።

የጥናቱዓላማ

የዚህ ጥናት ዓላማ-በሚዛን-ቴፒ ዩኒቨርሲቲ ማስተማሪያ ሆስፒታል የቲቢና ኤች .አይ.ቪ ህመ-ማን የቲቢ ህክምና ውጤትና ተያያዥ ችግሮች ዙሪያ መረጃዎችን ለማሰባሰብ ሚዛን-አማን በደቡብ ምዕራብ ኢትዮጵያ 2021። የዚህ ጥናት መረጃ ውጤታማ የቲቢ ህክምናን ለማሻሻል ጠቃሚ ነው።ጥናቱ ለአንድ ወር ይካሄዳል።

ጥቅማጥሞች እና ስጋት

በዚህ ምርምር ውስጥ መካተት ምንም አይነት ጉዳት ወይም ምቾት አይነሳም ምክንያቱም የህመምተኛው መረጃ ከመዛግብት ስለሚሰበሰብና ቀጥተኛ የሆነ ግንኙነት ስለሌለው። የእርስዎ ተሳትፎ የቲቢና ኤች .አይ.ቪ ህመ-ማን የቲቢ ህክምና ውጤትና ተያያዥ ችግሮች ስለሚመለከቱ ጉዳዮች የበለጠ እንድናውቅ ይረዳናል እናም ይህ በሆስፒታሉ እና በሌሎች የጤና ተቋማት ያሉትን ጉድለቶችን ለይተን እንድናሻሽል ይረዳናል። በዚህ ምርምር ውስጥ መሳተፍ አደጋ ወይም ቀጥተኛ ጥቅም የለም።

ማበረታቻ

በዚህ ጥናት ውስጥ በመሳተፍዎ አንከፍልዎትም።

ምስጢራዊነት

በዚህ ጥናት ውስጥ የሰበሰብነው መረጃ ከማንኛውም የግል መለያዎች በሚስጥር ይጠበቃል እናም ለጥናቱ ዓላማ ብቻ ነው የሚውለው።

የመቃወም ወይም የመተው መብት

ህመምተኛው ከመዛግብት ስለሚሰበሰቡ መረጃዎች እምቢታም የመቃወም ሙሉ መብት እና በማንኛውም ጊዜ የግሉ መረጃ እንዳይሰበሰብ የመከልከል መብት አለው፣እና ለመሳተፍ እምቢ በማለቶ የሚፈልጉትን ነገር አይጎዳውም።

ማንን መገናኘት እንዳለብዎት

መጠየቅ የሚፈልጉት ነገር ካለ አሁን ወይም በኋላ መጠየቅ ይችላሉ። ጥያቄዎችን በኋላ መጠየቅ ከፈለጉ,መልሰው ሊጠይቁ ይችላሉ፤ስልክ: +251917150810, ኢሜል: menegistukesri@gmail.com

<u>ስምምነት</u>

ጤና ይስጥልኝ: ስሜ _____እባላለሁ; እና የጅማ ዩኒቨርስቲ የማስተርስ ተማሪ አቶ መንግስቱ ከሰሪ ለሚያካሄደው ጥናት መረጃ እሰበስባለሁ። ተማሪው በዚሁ በሚዛን-ቴፒ ዩኒቨርሲቲ ማስተማሪያ ሆሰፒታል የቲቢ ህክምና ውጤት በቲቢ እና ኤች.አይ.ቪ ህሙማን ላይና ተጓዳኝ ችግሮች ላይ ምርምር እያደረገ ነው። እርስዎ ከጥናቱ ተሳታፊዎች እንዲሆኑ ተመርጠዋል። የርስዎ ህክምና መረጃ ከህክምና መዛግብት የሚሰበሰበው በሙሉ በሚስጢር የተጠበቀ እንደሚሆንና ስምዎንም ጨምሮ የግል መረጃዎን ሳይጠቅሱ በሳይንሳዊ ሪፖርቶች ውስጥ ብቻ የሚያገለግሉ መሆናቸውን ማረጋገጥ እፈልጋለሁ። ለተሳትፎዎ ምንም ዓይነት ጉዳት ወይም ማበረታቻ የለም። ከጥናቱ የተሰበሰበው መረጃ የቲቢ ህክምና ውጤቶችንና ተጓዳኝ ጉዳዮችን እንዲሁም ፕሮግራሞችን ለማሻሻል ጥቅም ላይ ይውላል። ስለዚህ ጥናት ማንኛውንም ጥያቄ ካልዎት እኔን ወይም ዋና ተመራማሪውን መጠየቅ ይችላሉ።

ጥያቄ አለዎት? በጥያቄዎቹን መቀጠል እችላለሁን?

1.አዎ_____(እናመሰግናለን እንቀጥል) 2. አይ_____ (እናመሰግናለን እናቁም)

Annex-3-Revised World Health Organization (WHO) Clinical Staging of HIV/AIDS for adults and adolescents.

Clinical stage 1

- Asymptomatic
- Persistent generalized lymphadenopahty

Clinical stage 2

- Moderate and unexplained weight loss (< 10% of presumed or measured body weight)
- Recurrent respiratory tract infections (such as sinusitis, bronchitis, otitis media, pharyngitis)
- Herpes zoster
- Recurrent oral ulcerations
- Papular pruritic eruptions
- Angular cheilitis
- Seborrhoeic dermatitis
- Onychomycosis (fungal nail infections)

Clinical stage 3

- Unexplained chronic diarrhea for longer than one month
- Unexplained persistent fever (intermittent or constant for longer than one month)
- Severe weight loss (>10% of presumed or measured body weight)
- Oral candidiasis
- Oral hairy leukoplakia
- Pulmonary tuberculosis (TB) diagnosed in last two years
- Severe presumed bacterial infections (e.g. pneumonia, empyema, meningitis, bacteraemia, pyomyositis, bone or joint infection)
- Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis
- Unexplained anemia

Clinical stage 4

- HIV wasting syndrome
- Pneumocystis pneumonia
- Recurrent severe or radiological bacterial pneumonia
- Chronic herpes simplex infection (orolabial, genital or anorectal of more than one month's duration)
- Esophageal candidiasis
- Extra pulmonary tuberculosis
- Kaposi's sarcoma
- Central nervous system toxoplasmosis
- HIV encephalopathy

DECLARATION

I hereby declare the thesis entitled treatment outcomes of TB among TB-HIV co-infected patients and associated factors in Mizan -Tepi University Teaching Hospital has been carried out by me under the supervision of prof. Kifle W/Michael and Mr. Zerihun Kura, Department of Epidemiology, and this thesis is my original work and all sources of material used for this thesis have been duly acknowledged.

Investigator: Mengistu Keseri Satsi Signature: _____ Date: _____

This thesis has been submitted for examination with my approval as university supervisor

Prof. Kifle W/Michael Signature: _____ Date: _____

Advisor

Mr. Zerihun Kura Signature: _____ Date: _____

Co-advisor