ADDIS ABABA UNIVERSITY

COLLAGE OF HEALTH SCIENCE

SCHOOL OF NURSING AND MIDWIFERY

POST GRADUATE PROGRAM

TREATMENT OUTCOMES ANDASSOCIATEDFACTORS AMONG PATIENTS WITH PULMONARY TB IN SELECTED HEALTH CENTERS OF ADDIS ABABA

BY: MEHIRET ZERIHUN (BSc)

A THESISTO BE SUBMITTED TO THE SCHOOL OF GRADUATE STUDIES OF ADDIS ABABA UNIVERSITY, COLLEGE OF HEALTH SCIENCES, SCHOOL OF NURSING AND MIDWIFERY IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FORTHE DEGREE OF MASTER OF SCIENCE IN ADULT HEALTH NURSING

June, 2020

ADDIS ABABA, ETHIOPIA

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BY: MEHIRET ZERIHUN (BSc)

ADVISORES: DR. HUSSEN MEKONEN (PhD)

MR. TIGISTU GEBREYOHANNIS (MScN)

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APPROVAL SHEET

ADDS ABABA UNIVERSITY

COLLEGE HEALTH SCIENCE SCHOOL OF ALLIED SCIENCES DEPARTMENT OF NURSING AND MIDWIFERY

I, the undersigned MSc student, declare that I have submitted my original work on a title Treatment outcomes and associated factors among patients with pulmonary tuberculosis among patients in selected health centers of Addis Ababa, Ethiopia for the examination.

Submitted by:

MehiretZerihun _____ _____

Name of student Signature Date

This thesis work has been submitted for examination with my approval as an advisor.

Approved by:

1. DR. HussenMekonen_____ _____
   Name of Major Advisor Signature Date

2. MR. TigistuGebreyohanniS (MScN)_____ _____
   Name of Co-Advisor Signature Date

APPROVAL BY THE BOARD OF EXAMINATION

This thesis by MehiretZerihun is accepted in itspresent form by the board of examiners as satisfyingthesis requirement for the degree of masters in Adult health nursing

INTERNAL EXAMINER:

_____	_____	_____	_____
NAME	**RANK**	**SIGNITURE**	**DATE**

External EXAMINER:

_____	_____	_____	_____
NAME	**RANK**	**SIGNITURE**	**DATE**

RESEARCH ADVISORS:

DR. HussenMekonen(PhD) _____	_____	_____	
NAME	**RANK**	**SIGNITURE**	**DATE**

MR. TigistuGebreyohanniS (MScN) _____	_____	_____	
NAME	**RANK**	**SIGNITURE**	**DATE**

DEPARTMENT HEAD

_____	_____	_____	_____
NAME	**RANK**	**SIGNITURE**	**DATE**

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STUDENT

Name: MehiretZerihun_____Signature: _____Date: _____

RESEARCH ADVISORS:

Dr. HussenMekonen(PhD) _____ _____ _____

NAME RANK SIGNITURE DATE

MR. TigistuGebreyohanniS (MScN) _____ _____ _____

NAME RANK SIGNITURE DATE

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ACRONYMS AND ABBREVIATIONS

AAU	Addis Ababa University
AOR	Adjusted odds ratio
BMI	Body mass index
CI	Confidence Interval
DM	Diabetes Mellitus
DOTs	Direct Observation therapy short course
HCs	Health centers
HIV	Human immune deficiency virus
NTLCP	National Tuberculosis and Leprosy Control Program
OR	Odd Ratio
PLHIV	People living with Human Immunodeficiency Virus
PTB	Pulmonary Tuberculosis
SPSS	Statistical Package for Social Sciences
TB	Tuberculosis
WHO	World health organization

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Abstract

Background: Despite the availability offree and effective treatment for Pulmonary tuberculosis, the success rate is not asthe expected due to different factors which imposes a major challenge particularly for developing countries.

Objectives: To determine treatment outcomes andassociatedfactors among patients with pulmonary TB in selected health centers of Addis Ababa Ethiopia in 2020.

Methodology: an institution based three years retrospective study was conducted on the documents of pulmonary tuberculosis patients who were treated fromJanuary 1st 2017-December 31st 2019 in selected health centers of Addis Ababa. A structured check list wasused to gather data from patients' medical records.Data was entered and cleaned using E pi info version 3.5.1 and exported to statistical package for social sciences (SPSS) version 24, computer software was used for analysis. Binary and multivariable logistic regression analyses were employed to assess factors that are associated with treatment outcomes.

Results: out of the total 633 patients, 361 (56.7%) were males and 275(43.23%) were females. The mean age and standard deviation of the participants was 37.49± 12.99. The overall treatment success rate was found to be 86.4%. The odds of successful treatment outcome were higher among new cases, HIV negatives, no history of smoking, and those patients who have treatment supporters.

Conclusions: the proportions of patients who are successfully treated are below the average which is set by WHO. Strategies to improve the treatment outcomes of patients with pulmonary TB should be improved especially for those patients who are at high risk of developing unsuccessful treatment outcomes.

CHAPTER I

INTRODUCTION

1.1Background

Tuberculosis has ranked in the third place among the top ten cause of death from infectious agents worldwide(1). Asian and African countries share the highest burden of tuberculosis accounting about 68% of total cases which is almost two thirds of the global total followed by the Western Pacific (18%), Eastern Mediterranean (8%), the Americas (3%) and Europe(2).Ethiopia is among the world's 22 highest TB burden countries(3). Since 1992 the country has been carrying out the directly observed treatment short course (DOTs) strategy long after 1950 at which time TB has been recognized as a common public health concern(4).

According to WHO tuberculosis treatment outcome is the end result of TB treatment(1)Treatment outcomes for tuberculosis are categorized as successful (cure and treatment completion) and unsuccessful (death, default, and failure). Treatment success is an important aspect in the TB control program(5).Treatment for tuberculosis requires the patient to take combination of different drugs for several months in order to provide them with cure which is an important and valuable aspect after TB treatment because unsuccessful treatment may pave the way for the occurrence of drug resistance(6).

Effective treatment and cure takes patients' compliance and adherence to the full course of treatment period(7). This is because the microorganism stays inactive for some time and reactivate making disease to relapse(8). So being adherent and taking these long term antimicrobials by patients are the major difficulties that impair the TB control program and may increase the amount of unsuccessful treatment outcomes(9).

Public health centers provide tuberculosis medications free of charge nevertheless patients have been seen interrupting their treatment putting their health in a very high risk (10). These defaulters in most literatures are dominated by the male population who has a history of substance and alcohol use (9).

Even though the occurrence of TB declined in the 1980's the emergence of HIV had a great contribution for the increase in the burden of the disease(11).Tuberculosis and HIV areknown to form lethal combination by co-occurring and each speeding the other's progress(12). Failure, death and relapse were mainly associated with HIV infection, Diabetes mellitus, low body mass index (13) and short duration of treatment(9)

1.2 Statement of the problem

Despite the presence of effective treatment tuberculosis has continued to be one of the top 10 causes of morbidity and mortality worldwide(14).According to the WHO 2017 data the global treatment success rate has reached 85% for new TB cases, 75% for HIV associated, 56% for MDR and 39% for extensively drug resistant TB(2). Tuberculosis treatment success rate is different from country to country as well as the factors that are associated to it(4).

Studies have shown that Eastern Mediterranean, West pacific, and South east Asian region has a greater treatment success rate(15). However, in different parts of the world such as Africa, had treatment success rate of less than 90% which interferes with the global milestone which was set by WHO for the year 2025(1).

A wide variation on treatment success rate has been seen in European Countries. Slovakia and Romania had the highest rate of unsuccessful treatment outcomes accounting 66.7 and 55.5 % respectively without including those that have not been evaluated(2). A study done in south Africa in 2016 the percentage of unsuccessful treatment outcome was found to be 20.4(16) and in Nigeria unsuccessful treatment rate was 19.8(17).

The occurrence of unsuccessful treatment outcome interferes with the battle that is being fought against TB and also interferes with the countries goal on the achievement of the end TB strategies that are planned to be achieved ahead(18, 19).

Even though the objectives of TB treatment are curing patients, preventing the spread of TB infectionas well as preventing multidrug resistant strain of the bacterium variety of factors including: comorbidity, life style, patient category, place of residence, multidrug resistance, presence of treatment supporter and other factors may hinder, the way to achieving the desired outcome(20, 21).The occurrence of unsuccessful treatment outcomes can be a threat to public

health programs which hinder the capacity to ensure appropriate health control strategies in a country(22). And also provides a fertile soil for the occurrence of multidrug resistant TB(23).

This and other unsuccessful treatment outcomes have an impact on the amount of budget required for the diagnosis and treatment of drug-susceptible and drug resistant TB(24). With timely diagnosis and treatment with anti-tuberculosis drugs the numbers of TB deaths can be downgraded by reducing the amount of health related risk factors(25).

Treatment outcomes for tuberculosis is not only different from one region to another but also from one institution to other(12). Even though there is annual report on all types of the tuberculosis,studiesspecific to treatment outcomes of pulmonary TB andassociatedfactors are limited. Therefore, this study is designed to determine treatment outcomes and associated factors among patients with pulmonary TB in Addis Ababa selected health centers.

1.3Significance of the study

Determining treatment outcomes and identifying those factors that are associated with unsuccessful treatment outcomes has implications in improving patients' response to treatment. It assists health care practitioners, policymakers and health care managers to identify the variations in treatment success rate and to focus on the area that fuels the occurrence of drug resistance, increased mortality and morbidity of TB patients.

The study will provide an insight that helps to improve the PTB treatment success rate by focusing on those individuals who are vulnerable to have unsuccessful treatment outcomes.

The study can also contribute as literature for those who are planning to conduct research on this topic or on a similar one.

CHAPTER II

LITERATURE REVIEW

2.1 Tuberculosis Treatment outcomes

The performance and quality of tuberculosis control program is measured by the treatment outcome of patients The possible treatment outcome of tuberculosis treatment is dichotomized as successful (cure and treatment completion) and unsuccessful (death, default and treatment failure)(12).

2.1.1 Successful treatment outcomes

Tuberculosis treatment success rate varies from region to region(12). A retrospective cohort study which was done in Johannesburg, South Africa in 2016, on primary health clinics on outcomes of drug susceptible tuberculosis showed a treatment success rate of 80% (16). Which has a wide variation from a study done in Zambia which showed treatment success rate of 57% in the year 2017 (26). This number the far from the expected which is set by WHO for the year 2020 (18).

A five years retrospective study in south west of Ethiopia in Jimma on treatment outcomes and associated factors in tuberculosis patients showed that 88% were successfully treated(4). On the other hand, a study which was done in Hossana, south nations and nationalities of Ethiopia treatment success rate was found to be 43.3%(20).

The fact that treatment outcome vary from region to region is also supported by another study which was done in the eastern part of Ethiopia in which treatment success rate was recorded to be 92.5% in the year 2017. This number makes Harar town the highest in tuberculosis treatment success rate (27).

2.1.2 Unsuccessful treatment outcomes

Different researchers have shown the prevalence of occurrence of unsuccessful treatment outcomes in their studies and implied that this may increase the complexity of TB control programs, particularly in low income countries (12)

A prospective cohort study which was done in South Korea on Predictors of unfavorable outcomes at the end of treatment among the patients who were studied with complete information available, 16% of the patients failed their treatment and 12% died(13).

Finding from a prospective cohort study conducted to assess the Predictors of Treatment Outcome for Retreatment Pulmonary Tuberculosis Cases among Tribal People of Eastern India District reported to have Unfavorable outcome of 24.8%. Of which 51.2% were defaulters, 22% were treatment failure case, and 26.8% of patients died during treatment(28). Defaulting TB treatment is a serious problem due to the possible occurrence of drug-resistance TB strains and the transmission of this strains to healthy individuals(29). And drug resistance has been shown to be the cause of treatment failure(28).

A secondary analysis of routine surveillance in Zambia Lusaka on Factors associated with unfavorable tuberculosis treatment outcomes in 2015 Showed that 8% died during treatment, 5% were lost to follow up and including those patients whose treatment outcomes that are not evaluated 29% the overall percentage of an unfavorable outcome was approximately 43%(26).

A finding from a five-year retrospective study done in Harar town in eastern Ethiopia on Tuberculosis Treatment Outcomes and Associated Factors among TB Patients Attending Public Hospitals in 2017 showed that among 376 patients who were evaluated for treatment outcome 48 of them died, 30 patients defaulted, and the rest 15 had failed their treatment(27).

A study which was done in Gondar on Treatment Outcomes of Tuberculosis and Associated Factors in 2016 showed that among the total participants who were evaluated for unsuccessful treatment outcome in the study 17.7% died, 21.3% had defaulted and 13 of them had treatment failure(15)

According to a retrospective cohort study which was done in, southern nations Nationalities and peoples region in Hosanna town on Treatment outcomes of tuberculosis patients showed that out of the PTB patients who were registered in the study period 56.7% of the patients had unsuccessful treatment outcomes with majority of them 51% were transferred out to other health facilities. There were few defaulters, treatment failures as well as deaths(20).

A 5-Year Retrospective Study on Treatment Outcomes and Associated Factors in Tuberculosis Patients at Jimma University Medical Center showed that among all TB diagnosed patients 11.7% of them had unsuccessful treatment outcome(4).

Therefore, in most of the reviewed literatures death was the most dominant unsuccessful treatment outcome followed by defaulters.

2.2 Factors associated with unsuccessful treatment outcomes

Unsuccessful treatment outcomes for tuberculosis are associated with many risk factors(30). Varieties of studies showed that knowing factors associated with undesired treatment outcomes plays a dominant role in increasing the successful treatment outcomes of tuberculosis and improve the TB control program by identifying individuals who are at high risk so that targeted interventions can be implemented to improve TB treatment(5).

2.2.1 Socio demographic factors

A retrospective cohort study on Predictors for Pulmonary Tuberculosis Treatment Outcome in Denmark indicated that the vast majority of the patients were male(31) and similarly a study in morocco on factors associated with default by tuberculosis patients showed that 81.5% of the defaulters were males, the mean age of them was 33.0 years, 26.8% were illiterate, 22.5% were unemployed.(29).

A five-year retrospective study in china on Treatment outcomes and factors affectingunsuccessful outcome among newpulmonary smear positive and negative tuberculosis patient showed that age above 45 years is associated with unsuccessful treatment outcome(30) similarly older age has been found to be associated with poor treatment outcome in a five-year retrospective study in Harar town in Ethiopia on Tuberculosis Treatment Outcomes and Associated Factors among TB Patients Attending Public Hospitals showed that age greater than 54 years was associated with unsuccessful TB treatment outcome(27).

In south-eastern NigeriaTuberculosis treatment outcome and its determinants in a tertiary care setting andA systemic review and Meta-analysis which was done in Ethiopia on Drug-susceptible tuberculosis treatment success and associated factorsshowed that older age and rural residence was associated with poor treatment outcome(5, 32).

Generally being elderly, residence from rural area and being male has a higher risk of unsuccessful treatment outcomes as compared to their counter parts.

2.2.2Clinical characteristics

2.2.2.1 Comorbidity

Several medical conditions are risk factors for TB and poor treatment outcomes. According to WHO people living with HIV are15-22 times more likely to develop TB and it is the major HIV related death(2). TB can worsen the glycemic control in people with diabetes and also associated with poor treatment outcomes which jeopardize the global fight against TB(33).Thelikely hood of treatment mortality is higher among TB patients with co morbidity(23)

In Denmark a retrospective cohort study on Predictors for Pulmonary Tuberculosis Treatment Outcome showed that anemia at time of treatment initiation and history of mental disorder were associated with unsuccessful treatment outcome(31).

A prospective cohort study in South Korea on Predictors of pulmonary tuberculosis treatment outcomes showed that diabetes, low BMI, MDR-TB are associated with poor treatment outcomes majorly diabetes mellitus and MDR-TB were risk factors for poor treatment outcomes and relapse (13) the finding of this study is similar to the study which was done in Uzbekistan(33).

A systematic review and meta-analysis on Tuberculosis treatment outcomes in Ethiopia from 2003 to 2016, and impact of HIV co infection and prior drug exposure showed that on unsuccessfully treated cases nearly 50% of cases died, 45.1% defaulted and the remaining 7.5% failed their treatment. In other words HIV positives have 1.98 times more likely to have unsuccessful treatment out comes as compared to HIV negatives(3).

Studies showed that Tuberculosis causes one in four deaths among people living with human immunodeficiency virus (PLHIV)(34)and it is considered as an important risk factor associated with increased progression of latent TB infection in to active TB disease as well as poor treatment outcomes(26, 35).

In different literatures anemia at the start of treatment(31), HIV coinfections(3, 26, 35), DM (33) were associated with higher rates of unsuccessful treatment outcomes.

2.2.2.2 Patient category

A Prospective Cohort study which was done in east India to determine the Predictors of Treatment Outcome for Retreatment in patients with Pulmonary Tuberculosis showed that Unfavorable outcome was common among Category II patients as compared with new cases (28). Similarly a secondary analysis of routine surveillance data in Lusaka, Zambia on Factors associated with unfavorable tuberculosis treatment outcomes showed that relapse cases are associated with unsuccessful treatment outcomes(26).

A retrospective cohort study in Morocco on Risk factors for tuberculosis treatment failure, default, or relapse and outcomes of retreatment showed that among the total category II retreatment patients 31% of them had unsuccessful treatment outcomes of which the majority 25% of them were defaulters followed by treatment failure and death(9).

A systemic review and Meta-analysis which was done in Ethiopia on Drug-susceptible tuberculosis treatment success and associated factors showed that retreatment cases were associated with poor treatment outcome(32). Similarly on other systematic review and meta-analysis to explore the association of poor treatment outcome with previous history of TB treatment showed that Poor treatment outcome was 2.17 times more likely to occur in retreated cases compared to newly diagnosed TB cases(3).

Unmatched case control study which was done in Togo on factors associated on pulmonary tuberculosis treatment failure in, 2015-2016 indicated that treatment failure is 13 times more likely to occur on patients who had previous history of anti-TB treatment as compared to those who had no history of anti-TB treatment(11).

Most reviewed literatures showed that treatment outcomes of category II patients are suboptimal as compared with category I patients.

2.2.2.3 Smear microscopy result

Similar results were found on a five year retrospective studies which were conducted in Uzbekistan and Ethiopia that those patients with smear positive pulmonary TB had the highest rate of unsuccessful treatment outcomes as compared to smear negative pulmonary TB(20, 36).

On the contrary a retrospective cross sectional study in Gondar onTreatment Outcomes of Tuberculosis and Associated Factorsshowed that smear negative TB patients had the highest rate of unsuccessful treatment outcomes(15).

2.2.3 Risky behavior

2.2.3.1 Smoking and alcohol use

There is no doubt on treatment results of those patients who has history of tobacco smoking could be unsuccessful. Smoking can increase the risk of TB by 2-3 folds as well as the unsuccessful treatment outcome(37). Smoking and alcohol use is also associated with poor TB treatment adherence(23).

A study which was done in Denmark on predictors of pulmonary tuberculosis treatment outcome showed that tobacco users had the highest rate of unsuccessful treatment outcomes followed by alcohol abusers(31) which is similar to the study which was done in morocco in which tobacco and alcohol were associated with a higher risk of default(29).

A retrospective cohort study in 2017 in Brazil on the Impact of smoking on sputum culture conversion and pulmonary tuberculosis treatment outcomes showed that smokingwas associated with a delay in sputum culture conversion at the end of the second month of TB treatment as well as with poor treatment outcomes(37)

In Malaysia on Treatment outcome of new smear positive pulmonary tuberculosis patients showed that being alcoholic is associated with mortality(38).

2.2.4 Presence of treatment supporter

Absence of social support can potentially lead to non-compliance andpoor treatment outcome.A study which was done in Ghana on treatment outcomes of tuberculosis showed that those patients who have treatment supporters are 9.69 times more likely to have successful treatment outcomes (12).

2.3 Conceptual frame work

This conceptual frame work is adapted from a study done in university of Ghana, Legon on tuberculosis treatment outcome and associated factors at the TettehQuarshie memorial hospital (39). It includes SociodemographicFactors, presence of risk behaviors, clinical factors like smear microscopy result, patient treatment category, patient HIV/AIDS status and presence of other co morbidities, presence of treatment supporter. In this study HIV /AIDS is separated from other co morbidities because of its great effect on TB patients.

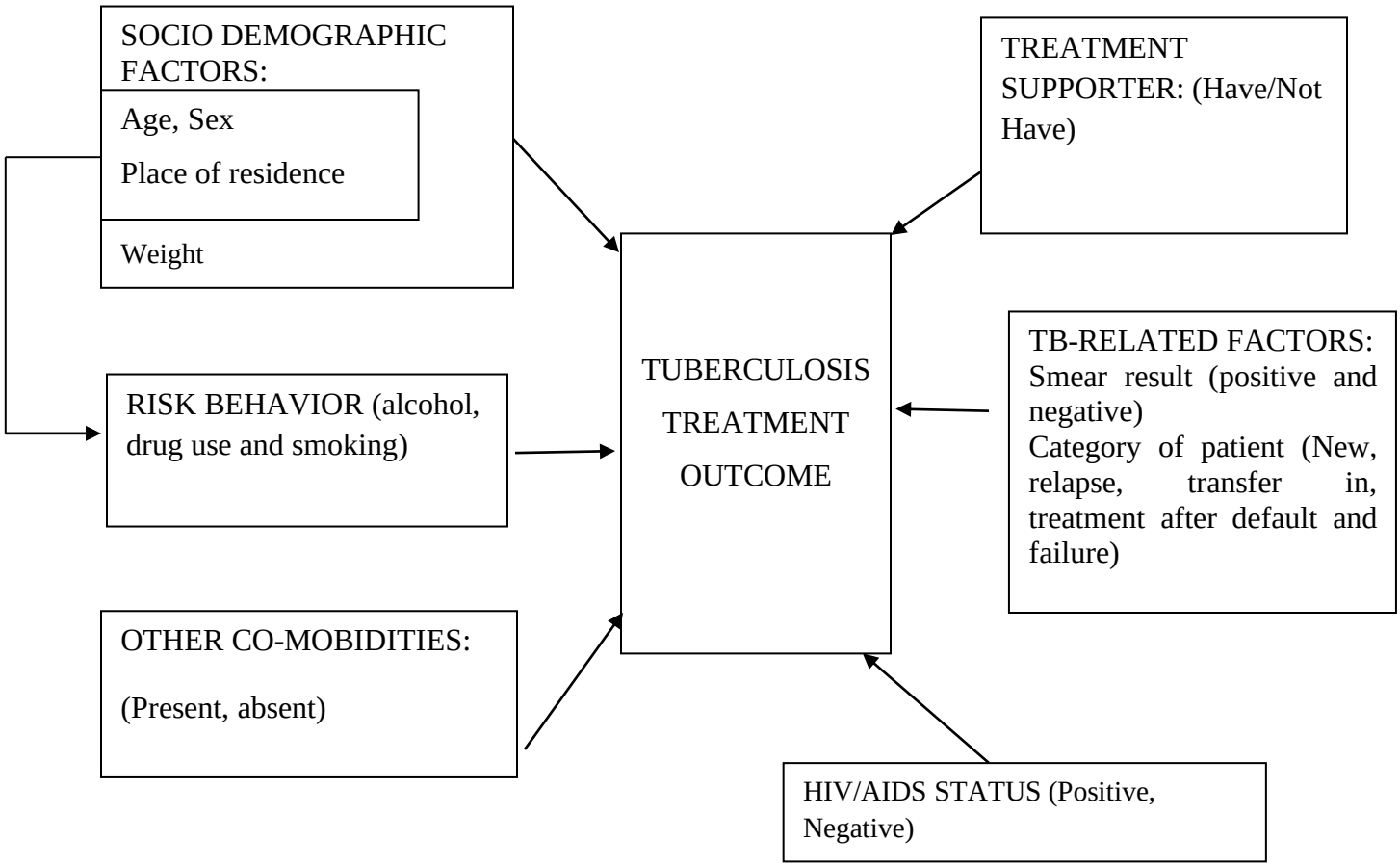

Figure 1 Conceptual frame work of factors associated with unsuccessful treatment out comes among patients with pulmonary TB

CHAPTER III

OBJECTIVES OF THE STUDY

3.1 General objective

To identifytreatment outcomes and associatedfactors among patients with pulmonary Tuberculosis in selected health centers of Addis AbabaEthiopia, 2020

3.2 Specific objectives

1. To determine treatment outcomes among patients with pulmonary tuberculosis in selected health centers of Addis Ababa Ethiopia,2020
2. To determine associated factors related to treatment outcomes among patients in selected health centers of Addis Ababa Ethiopia, 2020.

CHAPTER IV

METHODS AND MATERIALS

4.1 Study area

The study was conducted in selected health centers of Addis Ababa, Ethiopia. Addis Ababa is the capital city of Ethiopia, Headquarter of the African Union as well as the United Nations Economic Commission for Africa. The city was founded by emperor Menelik II in 1886. It has a subtropical highland climate with an average elevation of 2355m above sea level. The city has a total area of 527 $Km^{2.}$ and subdivided into ten sub cities. According the 2007 census report the population is estimated to be 3.2 million(40). Addis Ababa city administration health bureau provides both curative and preventive health care services in the city(41).

4.2Study design

Institution based retrospective document review has been conducted among pulmonary TB patients who have completed their standard treatment regimen in Addis Ababa, Ethiopia.

4.3 Study period

The study period was from January 1st 2017- December 31st 2019

4.4 Source population

The documents of all PTB patients who were treated with standard anti TB drug regimen at Addis Ababa health centers.

4.5 Study population

Study populations are the documents of pulmonary tuberculosis patients who had been treated with standard anti TB drug regimen from January 1st2017-December 31st 2019 and had treatment outcome at the selected health centers.

4.6 Eligibility Criteria

4.6.1 Inclusion Criteria

The documents of all pulmonary tuberculosis patients aged 18 and above registered as new, retreatment and transfer in patients

4.6.2 Exclusion Criteria

Documents of patients with incomplete data registry, those patients who were transferred to other districts

4.7 Sample size determination and sampling technique

4.7.1 Sample size determination

The sample size was calculated using single population proportion formula

$$n = \frac{(Z\alpha/2)2\ P(1-P)}{d2} \times DEFF$$

Where: n= required sample size

z= critical value at 95% CI (1.96)

p= prevalence rate of pulmonary TB treatment completion in Addis Ababa=0.5

DEFF-design effect = 1.5

0.5 Margin of error (d) to be 5% (d = 0.05)

3.8416x 0.5x0.5/0.0025=384

384, then by adding 10% non response rate and multiplying it by design effect the final sample size becomes 633

n=633

4.7.2 Sampling technique

Multi stage sampling has been used to select the health centers. Simple random sampling was used to include Health centers in the ten sub-cities of Addis Ababa as well as to select the patient's cards. The documents of all pulmonary TB patients who fulfill the inclusion criteria have been used. Data collectors have been trained on the use of the instrument before the actual data collection period. The principal investigator has been supervising the process.

4.7.3Sampling procedure

From all the 10 sub cities of Addis Ababa city administration four sub cities were selected by lottery method. These sub cities wereLideta, Nifas silk, Gulele and Yeka. Since the four selected clusters contain more population units than needed, the health centers were proportionally allocated for each sub cities based on the number of health centers each sub city has, then the documents of the pulmonary TB patients who fulfill the inclusion criteria within the selected health centers were utilized by lottery method.

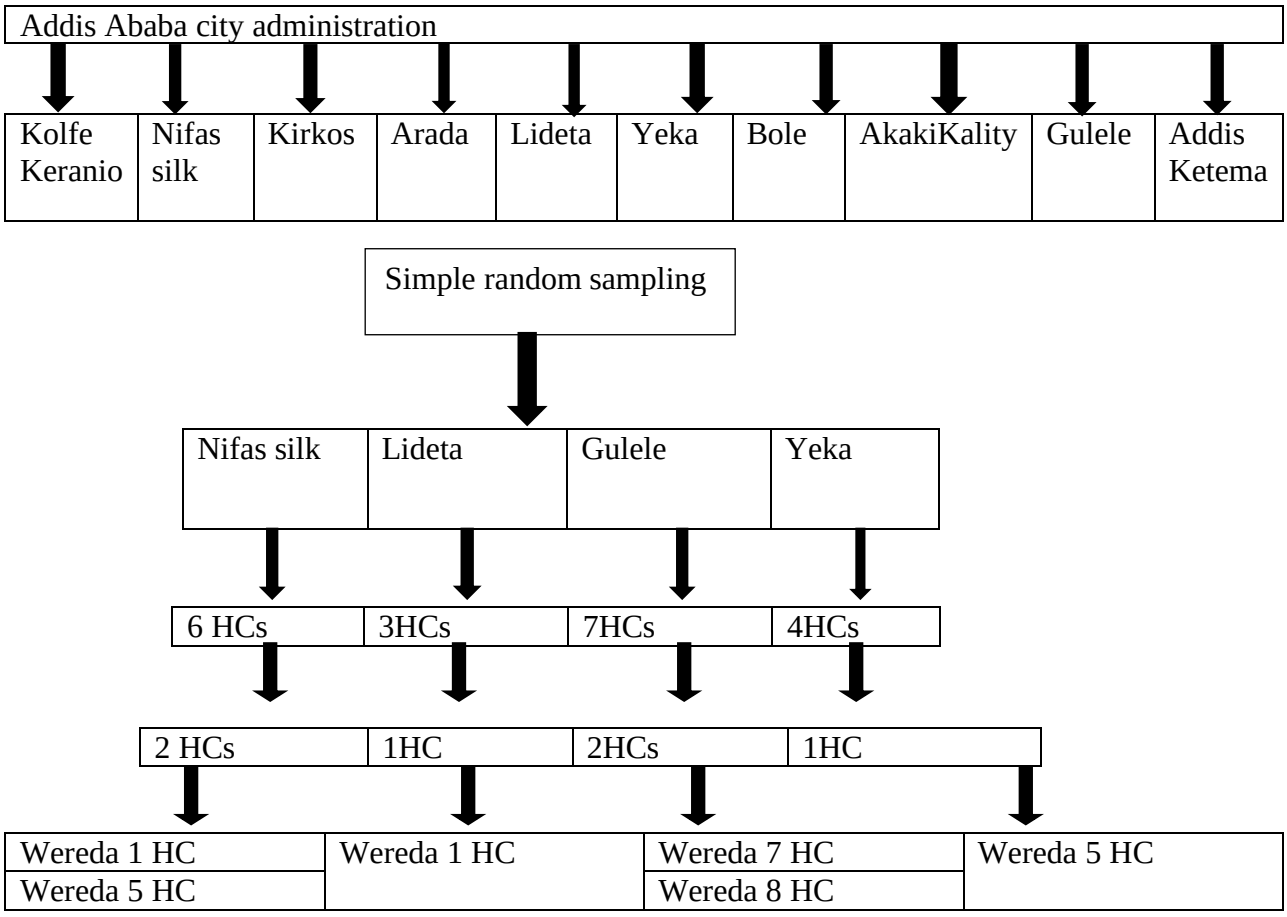

Figure 2 Multistage sampling of the sub cities from which health centers are to be selected

4.8Operational definitions

Socio demographic factors include factors that include the age, sex and place of residence of the patient

Age: How old (in years) a participant was at the time of anti-TB treatment initiation.

Sex: Refers to the biological sex (male and female)

Place of residence: the place where the participant lives during treatment was classified as Addis Ababa and other cities and towns.

Weight:the weight in Kg of a patient at the time of drug initiationand classified based on adult drug dosage administration

History of smoking; includes those patients who has previous history of smoking or those patients who are current smokers.

Treatment supporter is a contact person who is listed on the TB registration formandsupervises a TB client to take his or her drug.

TB related factors are those factors that include the patient category and smear microscopy result

Patient category: treatment category at the initiation of treatmentwhich includes new cases, relapse, treatment after default, treatment after failureandtransferred in**.**

According to the standard definitions of the National Tuberculosis and Leprosy Control Program (NTLCP) guideline adopted from WHO, the following clinical case and treatment outcome definitions have been used

Treatment outcome is the result of a patient's health condition after finishing a course of treatment. These may be cure, death, default, failure and transferred out.

Treatment success: a treatment that ends up either in cure or treatment completion.

Unsuccessful TB treatment outcome; when the treatment of a patient ends up in treatment failure, death or default.

New TB case; refers to a patient who has never been treated for TB or has taken the anti TB treatment for less than one month

Cured; A pulmonary TB patient who no longer has the clinical symptom of TB and who is bacteriologically conformed sputum smear or culture negative.

Treatment completed: a patient who has ingested the total number of dozes prescribed with in specified period of time.

Died; A patient who died during the course of TB treatment.

Defaulter: a pulmonary TB patient who has interrupted treatment for two or more months after being treated for at least one month.

Treatment failure; A TB patient whose sputum smear or culture is found to be positive at month 5 or later during treatment

Transfer out: A patient who has started treatment at a given center then transferred to other center to continue treatment.

Category I: new cases

Category II: relapse, treatment failure and return after default

4.9 Variables

4.9.1 Dependent Variable

Treatment outcome

(Successful and unsuccessful)

4.9.2 Independent Variables

Socio demographic factors (Age, sex, place of residence)

Weight

TB related factors (smear microscopy result, treatment category)

Risk behavior (smoking)

HIV/AIDS status

Presence of other co morbidities

Presence of treatment supporter

4.10 Data collection tool and procedure

4.10.1 Data collection instrument

A pre tested check list that was used in local research has been utilized(43) to extract data from the TB notification, investigation, treatment and registration book which is recommended by the WHO and individual patient chart was also used. The instrument contain basic information like the sociodemographic characteristics (patient's age, sex, residence), clinical characteristics like comorbidities, TB related characters and treatment outcome which was defined according to the standard definitions of the National Tuberculosis and Leprosy Control Program (NTLCP) from the WHOwas used.

4.10.2 Data quality Assurance

The principal investigator has given orientation and training for data collectors who are selected based on their experience in TB clinic. During the same time any doubts and queries have been clarified. The principal investigator was checking the completeness of the collected data to ensure that all the needed information had been properly collected and recorded.

4.10.3 Data processing and analysis

The completed checklists were cross-checked by the principal investigator for completeness. Every item that has been completely filledwascoded.Thecoded data were, entered and cleaned usingEpi data version 3.5.1 then exported to SPSS version 24 statistical packages for social sciences for statistical analysis. Descriptive statistics was used to describe the frequencies and percentages of sex, age, weight, co morbidity,patientcategory(new, treatment failure, relapse, transferred in, other and return after default), treatment supporter, and sputum smear result of the patient (smear positive pulmonary TB, smear negative pulmonary TB). Logistic regression including Bivariate and Multivariate analysis was used to examine association between dependent and independent variables. Those variables with p-value <0.2 in bivariate analysis were included in multivariable logistic model and level of significance was determined at p-value <0.05 and 95%confidence interval.

4.10.4 Ethical consideration

Ethical approval was obtained from Research Ethics Committee of Addis Ababa University Collage of Health Science School of Nursing and Midwifery. Permission was obtained from the

health center's Chief Executive Office to carry out the study, datahas been collected by staff members who are working in the unit and the names of the participants was neither made available to anyone nor was written on the check list.

4.10.5 Dissemination of the result

The results of this investigation will be presented to Addis Ababa University, College of Health Science School of Nursing and Midwifery as partial fulfillment of Master's degree in Adult Health Nursing. The finding will also be given to the selected health centers of Addis Ababa where the research was conducted. Hard and soft copies will be made available in the library of AAU, for graduate students as well as for other researchers and readers who choose to use it as a reference.

CHAPTER V

Results

5.1 Sociodemographic and Clinical Characteristics of patients

Out of total 633 patients who had been treated from January 2017to December 2019 at the selected health centers, (56.7%) were males and 275(43.3%) were females. out of the total participants the minimum age was 18 and maximum was 86, the mean age and standard deviation of the participants was 37.5± 13.023.Out of the total 551(87.1%) of the participants reside in Addis Ababa. Majority of the patients 451(71.2%)were in weight category 55-70.9 kg.

Results

Table 1 shows socio demographic and clinical characteristics of 636 pulmonary TB patients that were registered between 1st January 2017 and 31st December 2019.

	2017	2018	2019	Total
Age in Years				
18-24	41(17.2)	25(12.3)	22(11.45)	88 (13.9%)
25-34	81(34.03)	51(25.1)	64(33.3)	196 (30.9%)
35-44	60(25.2)	65(32.0)	52(27.0)	177(27.9%)
45-54	32(13.4)	39(19.2)	35(18.2)	106(16.7%)
≥55	21(8.8)	19(9.35)	15(7.8)	55(8.7%)
Sex				
Male	141(59.2)	112(55.1)	106(55.2)	359(56.7%)
Female	97(40.7)	91(44.8)	86(44.8)	274 (43.3%)
Residence				
Addis Ababa	193(81.1)	186(91.6)	172(89.6)	551(87.1%)
Other cities	45(18.9)	17(8.4)	20(10.4)	82 (12.9%)
Weight (Kg)				
30-39.9	5(2.9)			5(.8%)
40-54.9	64(26.8)	39(19.2)	39(20.3)	142(22.4%)
55-70.9	155(65.1)	155(76.4)	141(73.4)	451(71.2%)

≥71	14(5.9)	9(4.4)	12(6.3)	35(5.5%)
Category of the patient				
New	175(73.5)	156(76.8)	148(77.1)	479(75.7%)
Relapse	20(8.4)	9(4.4)	9(4.6)	38(6.0%)
Treatment after failure	11(4.6)	6(3.0)	6(3.1)	23(3.6%)
Treatment after default	13(5.4)	13(6.4)	7(3.6)	33(5.2%)
Transferred in	19 (7.9)	19(9.3)	22(11.5)	60(9.4%)
Other Co morbidities (e.g. DM)				
Yes	61(25.6)	29(14.3)	32(16.7)	122(19.3%)
No	177(74.4)	174(85.7)	160(83.3)	511(80.7%)
HIV/AIDS status				
Positive	66(27.7)	24(11.7)	16(8.3)	106(16.7%)
Negative	173(72.4)	180(88.20	177(91.7)	530(83.3%)
Smear microscopy result				
Smear positive	103 (43.3)	74(36.5)	74(38.5)	251(39.7%)
Smear negative	135 (56.7)	129(63.5)	118(61.5)	382(60.3%)
History of smoking				
Yes	65(27.3)	59(29.1)	48(25.0)	172(27.2%)
No	173(72.7)	144(70.9)	144(75.0)	461(72.8%)
Treatment Supporter				
Yes	182(76.5)	191(94.1)	173(90.1)	546(86.3%)
No	56(23.5)	12(5.9)	19(9.9)	87(13.7%)

With respect to HIV status one hundred six (16.7%) of patients were found to be HIV positive. patients were grouped under treatment categories of which the majority (479) 75.7% of the patients are new cases. The smear microscopy of three hundred eighty two (60.3%) patients is negative while the rest were smear positive. patients have been assessed for smoking and 27.2% of the participants were found to have history of smoking .Five hundred forty six (86.3%) of the participants had treatment supporter.

5.2 Treatment outcomes of patients and its trend over time

In the present study, the proportion of patients with successful treatment outcomes was found to be86.4% in which 38.4% of them were cured while 61.6% completed their treatment. On the other hand among the13.6% of patients with unsuccessful treatment outcomes 21.2% of them died during treatment while 24.7% of them failed their treatment and54.1% were treatment defaulters. In this study the percentage of treatment success rate has increased during the study period. The treatment success rate has been found to be lower in the year 2017 (79.4%) and higher in the year 2019(92.2%). The overall mortality rate has decreased from 20.4% to 2.04% during the study period

Table 2.**Tuberculosis Treatment Outcome in selected health centers of Addis Ababa (2017-2019)**

Characters		Treatment outcomes					
		Successful		Unsuccessful			
		Cured N(%)	Treatment completed N(%)	Died N(%)	Failed N(%)	Defaulted N(%)	Total N(%)
Age category	**18-24**	32(5.1)	42(6.6)	2(0.3)	4(0.6)	8(1.3)	88(13.9)
	25-34	73(11.5)	103(16.3)	4(0.6)	4(0.6)	12(1.9)	196(31.3)
	35-44	62(9.8)	90(14.2)	1(0.2)	9(1.4)	15(2.4)	177(28.1)
	45-54	30(4.7)	63(9.9)	2(0.3)	3(0.5)	7(1.1)	105(16.6)
	≥55	9(1.4)	33(5.2)	9(1.4)	0	4(0.6)	55(8.7)
Sex	**Male**	105(16.6)	200(31.6)	13(2.1)	7(1.1)	34(5.4)	359(56.7)
	Female	105(16.6)	137(21.6)	5(0.8)	14(2.2)	12(1.9)	274(43.3)
Residence	**Addis Ababa**	193(30.5)	288(45.5)	13(2.1)	17(2.7)	39(6.2)	550(86.9)
	Other cities	17(2.7)	49(7.7)	5(0.8)	4(0.6)	7(1.1)	82(12.9)
Weight category	**30-39.9**	0	3(0.5)	1(0.2)	0	1(0.2)	5(0.8)
	40-54.9	62(9.8)	60(9.5)	1(0.2)	8(1.3)	11(1.7)	142(22.4)
	55-70.9	143(22.6)	254(40.1)	14(2.2)	12(1.9)	27(4.3)	450(71.1)
	≥71	5(0.8)	20(3.2)	2(0.3)	1(0.2)	7(1.1)	35(5.5)
Patient category	**New**	182(28.8)	254(40.1)	9(1.4)	8(1.26)	26(4.1)	479(75.7)
	Relapse	6(0.9)	22(3.5)	3(0.5)	2(0.3)	5(0.8)	38(6.0)

	Treatment after failure	0	9(1.4)	3(0.5)	2(0.3)	9(1.4)	23(3.6)
	Treatment after default	4(0.6)	15(2.3)	2(0.3)	9(1.4)	2(0.3)	32(5.05)
	Transferred in	18(2.8)	37(5.8)	1(0.2)	0	4(0.6)	60(9.5)
Other Co morbidities (e.g. DM)	**Yes**	27(4.3)	61(9.6)	7(1.1)	11(1.7)	15(2.4)	121(19.1)
	No	183(29.0)	276(43.6)	11(1.7)	10(1.6)	31(4.9)	514(80.7)
HIV/AIDS status	**Positive**	20(3.1)	50(7.9)	10(1.6)	9(1.4)	16(2.5)	105(16.6)
	Negative	190(30.0)	287(45.3)	8(1.3)	12(1.9)	30(4.7)	530(83.7)
Smear microscopy result	**Smear positive**	111(17.5)	98(15.5)	6(0.9)	12(1.9)	24(3.7)	251(39.6)
	Smear negative	100(15.8)	239(37.8)	12(1.9)	9(1.4)	22(3.5)	382(60.3)
History of smoking	**Yes**	46(7.2)	87(13.7)	8(1.3)	2(0.3)	29(4.6)	172(27.2)
	No	164(26)	250(39.5)	10(1.6)	19(3.0)	17(2.6)	460(72.7)
Treatment supporter	**Yes**	197(31.1)	307(48.5)	14(2.2)	8(1.3)	19(3.0)	545(86.1)
	No	13(2.1)	30(4.7)	4(0.6)	13(2.0)	27(4.3)	87(13.7)
Year of treatment	**2017**	60(9.5)	129(20.4)	10(1.6)	11(1.7)	28(4.4)	238(38.0)
	2018	81(12.8)	100(16.0)	7(1.1)	3(0.5)	11(1.7)	203(32.0)
	2019	69(11)	108(17.1)	1(0.2)	7(1.1)	7(1.1)	192(30.3)

5.3 Factors associated with treatment outcome of tuberculosis

Out of the total patients who had unsuccessful treatment outcome 41% of them were HIV positive which are dominated by defaulters followed by death. When it comes to patients who have other co morbidities e.g. DM 38% of them had unsuccessful treatment outcomes which were also dominated by defaulters and failures.

Regarding smokers 27.2% of the total patients had history of smoking and among these patients 46% had unsuccessful treatment outcomes in which 74% were defaulters which were dominated by male patients. Among the total patients who had no treatment supporter 52% of them had unsuccessful treatment outcomes in which 61% of them defaulted their treatment.

Out of the total patients with unsuccessful treatment outcomes about 52% of the patients had no treatment supporters or contact persons of which 61.3% of them defaulted their treatment.
The association of treatment outcome with socio demographic characteristics (age, sex and residence), treatment category of the patient, smear microscopy result, weight, HIV status, other co morbidities, smoking and presence of treatment supporter were assessed in bivariate analysis. those variables with P value <0.2were taken to multi variable logistic regression model in which being in age category 25-34, living in other cities other than Addis Ababa, being in weight category 40-54.9, 55-70.9, being treatment after default, treatment after failure presence of other co morbidities e.g. DM, being HIV positive, having history of smoking, and not having a treatment supporter were found to be significantly associated with treatment outcome.

In the multivariate analysis being treatment after default, treatment after failure, being HIV positive, having history of smoking, and not having a treatment supporter were found to be independently and significantly associated with treatment outcome.The chance of having successful treatment outcome is 9.880(AOR= 9.880, 95% CI 3.105-31.439) and 8.865 (AOR=8.865, 95% CI 3.141-25.021) times higher among new cases as compared to treatment after defaults and treatment after failure patients respectively. The chance of having successful treatment outcome is 0.169(AOR=0.169 95% CI 0.075-0.380) times less likely among patients who are HIV positiveas compared HIV negatives. Similarly those patients who have history of smoking are 0.273(AOR=0.273 95% CI 0.140-0.533) times least likely to have successful

treatment outcomes as compared to those who have no history of smoking. On the other hand the odds of having successful treatment outcome is 20.172(AOR=20.076 95% CI 9.852 -40.913) times higher among patients who have treatment supporter as compared to those who has no treatment supporter.

Table 3Bi variate analysis of treatment outcome with socio-demographic and clinical characteristics of TB patients in selected health centers of Addis Ababa

Characters		Successful	unsuccessful	OR(crude)	95%CI Lower	Upper
Age category	**18-24**	74(11.6)	14(2.15)	1		
	25-34	176(28)	20(3.1)	.601*	.288	1.253
	35-44	152(24)	25(4)	.869	.427	1.770
	45-54	93(14.6)	12(1.9)	.739	.327	1.668
	≥55	42(6.6)	13(2.0)	1.636	.703	3.807
Sex	**Male**	305(48.3)	54(8.4)	1		
	Female	242(38.2)	31(4.9)	.747	.467	1.193
Residence	**Addis Ababa**	481(76.1)	69(10.8)	1		
	Other cities	66(10.4)	16(2.5)	1.666*	.913	3.038
Weight category	**30-39.9**	3(0.5)	2(0.4)	1		
	40-54.9	122(19.1)	20(3.2)	.246*	.039	1.565
	55-70.9	397(62.9)	53(8.3)	.204*	.033	1.249
	≥71	25.0(3.9)	10(1.6)	.600	.087	4.149
Patient category	**New**	436(69)	43(6.75)	1		
	Relapse	28(4.5)	10(1.6)	3.621*	1.648	7.956
	Treatment after failure	9(1.4)	14(2.2)	15.773*	6.451	38.565
	Treatment after default	19(2.9)	13(2.0)	7.471*	3.501	15.945
	Transferred in	55(8.6)	5(0.8)	.922	.350	2.426
Other Co	**Yes**	88(14.2)	33(5.1)	1		

morbidities (e.g. DM)	**No**	459(73)	52(8.0)	.293*	.180	.478	
HIV/AIDS status	**Positive**	70(11)	35(5.5)	1			
	Negative	477(75.4)	50(7.9)	.204*	.124	.335	
Smear microscopy result	**Smear positive**	208(32.9)	42(6.5)	1			
	Smear negative	339(53.5)	43(6.8)	.614*	.389	.969	
History of smoking	**Yes**	133(21)	39(6.2)	1			
	No	414(65.4)	46(7.1)	.387*	.243	.618	
Treatment supporter	**Yes**	504(80.1)	41(6.4)	1			
	No	43(6.7)	44(6.8)	12.279*	7.263	20.759	

Key: *there is association if p-value <0.2 COR (Crude Odds Ratio)
1(reference category)

Table 4 Multivariate analysis of treatment outcome with socio-demographic and clinical characteristics of TB patients in selected health centers of Addis Ababa

Characters		Treatment outcomes				
		Successful	unsuccessful	AOR (Adjusted)	95%CI	
					Lower	Upper
Age category	**18-24**	74(11.6)	14(2.15)	1		
	25-34	178(28)	20(3.1)	.378	.121	1.182
	35-44	153(24)	25(4)	.573	.169	1.949
	45-54	93(14.6)	12(1.9)	.483	.120	1.943
	≥55	42(6.6)	13(2.0)	2.470	.629	9.694
Residence	**Addis Ababa**	484(76.1)	69(10.8)	1		
	Other cities	66(10.4)	16(2.5)	1.981	.876	4.481
Weight category	**30-39.9**	3(0.5)	2(0.4)	1		
	40-54.9	122(19.1)	20(3.2)	.679	.052	8.896
	55-70.9	400(62.9)	53(8.3)	.556	.038	8.167
	≥71	25.0(3.9)	10(1.6)	1.695	.088	32.686
Patient category	**New**	438(69)	43(6.75)	1		
	Relapse	29.0(4.5)	10(1.6)	1.820	.649	5.103
	Treatment after failure	9(1.4)	14(2.2)	9.880**	3.105	31.439
	Treatment after default	19(2.9)	13(2.0)	8.865**	3.141	25.021
	Transferred in	55(8.6)	5(0.8)	.904	.276	2.959
Other Comorbidities (e.g. DM)	**Yes**	88(14.2)	33(5.1)	1		
	No	462(73)	52(8.0)	.273	.140	.533
HIV/AIDS status	**Positive**	70(11)	35(5.5)	1		
	Negative	480(75.4)	50(7.9)	.169**	.075	.380

Smear microscopy result	**Smear positive**	208(32.9)	42(6.5)	1		
	Smear negative	339(53.5)	43(6.8)	.579	.313	1.070
History of smoking	**Yes**	134(21)	39(6.2)	1		
	No	416(65.4)	46(7.1)	.273**	.140	.533
Treatment supporter	**Yes**	507(80.1)	41(6.4)	1		
	No	43(6.7)	44(6.8)	20.076**	9.852	40.913

Key: ** Statistically significant if
P-value < 0.05, AOR (Adjusted odds ratio), 1(reference category)

CHAPTER VI

Discussion

The current study found that, the prevalence ofsuccessful treatment outcomes among patients with pulmonary tuberculosis to be 86.5%. The finding is lower than the target set by WHO for the year 2020(18).The success rate is even lower than the studies which are conducted in Harar (92.5%) (27), Mekelle(44), 89.5% Jimma (88.2%)(4)but higher than the studies in Gondar(60.1%)(15), Hosanna (43.3%)(20), Gambella (70.8%)(22), Sodo town (81.5%)(45). The variation in treatment success rate could be variation in DOTs service, participant variation in health seeking behavior, differences in duration of study period.

The treatment success rate has been found to be lower in the year 2017 (79.5%) and higher in the year 2019(92.2%). These could be due to improved implementation of DOTS strategy and improved patient awareness regarding tuberculosis as well as its treatment adherence. In this study similar to other studies unsuccessful treatment outcomes is higher among category II patients as compared to category I patients(3, 36). Patients who were previousdefaulters are more likely to fail their treatment and the odds of successful treatment outcomes is 9.880(AOR= 9.880, 95% CI 3.105-31.439) and 8.865 (AOR=8.865, 95% CI 3.141-25.021) times higher among new patients as compared to those who are treatment after default and treatment after failure which is consistent with the findings from Morocco, Zambia, India and here in Ethiopia (9, 26, 28, 32). This could be due to bacterial resistance to the anti-TB drugs.

There is no doubt that TB/HIV co infection is the major reason for the occurrence of unsuccessful treatment outcomes. In this retrospective study, the proportion of TB/HIV co infection is 16.6% which is much greater than the national prevalence of TB/HIV which is 6.1% (WHO). The reason for this is due to variation in sample size. Among TB/HIV co-infected patients, 41% of them had unsuccessful treatment outcomes. The chance of having successful treatment outcome is 0.169(AOR=0.168 95% CI 0.075-0.380) times less likely among patients who are HIV positive as compared HIV negatives. The finding of this study is similar to the five year retrospective findings of thestudy which was done in university of Gondar teaching hospital

(15), and south eastern Nigeria(5)as well as a systemic review and meta analysis which was done in Ethiopia(3).

The overall treatment success rate for TB/HIV positive patients was 66% which is lower than a retrospective study which was done in Haramaya university Eastern Ethiopia and other similar studies(15, 27, 32, 35). The reason for poor treatment outcomes among TB/HIV co-infected patients is due to increased occurrence of opportunistic infections as the stage of the disease becomes advanced and occurrence of immune reconstitution inflammatory syndrome (15), poor adherence due to high pill burden(27), increase in drug-drug interaction, drug adverse effect due to intake of anti TB and ART drugs concurrently (3)

The overall mortality rate has decreased from 20.4% to 2.04% during the study period which is consistent with the study which was done in Denmark(31). The increase in public health awareness and increased quality of TB control program may contribute to this finding.

Due to immune pathological relation of smoking with TB, studies have shown that smoking was associated with higher prevalence of PTB (37)as well as poor treatment outcomes(23).Out of thetotal participants 27.2% of them had history of smoking and among these patients 46% had unsuccessful treatment outcomes in which 74% were defaulters which were dominated by male patients. Patients who have history of smoking are 0.273(AOR=0.273 95% CI 0.140-0.533) times less likely to have successful treatment outcomes as compared to non-smokers this finding is consistent with a study which was done in Malaysia (47). These could be due to smoking related damage to the alveolar macrophages(46) and inhibition of the action of anti TB drugs (23).This increased rate of unsuccessful treatment outcomes among male population may be due to their connection and engagement in risky behaviors such as substance abuse and alcohol use(21). The major problem in effective TB control program is the number of defaulters which may have a large impact in transmitting the disease to their families and developing drug resistance(47), in this study among those with unsuccessful treatment outcomes the overall rate of total defaulters were 54%which was decreasing within the study period and it could be due to increased awareness of the participants through health education about the importance of adherence.

The study also showed that the odds of having successful treatment outcome is 20.172(AOR=20.076 95% CI 9.852 -40.913) times higher among patients who have treatment supporter as compared to those who has no treatment supporter. This finding is supported by a study which was done in Ghana the reason could be that treatment supportersare essential in order to increase patient's compliance with treatment and help patients to adhere to the full course of the treatment(12).

Strength and limitations of the study

The study tried to include all data from large number of TB patients with in the study period by taking representative health centers from the randomly selected sub cities of Addis Ababa. It also included not only the TB registry book but also each patient card in order to include additional variables which were relevant to the study. However, since the source of data was secondary the quality of the data was always in question. Due to incompleteness of other common risk factors that may lead to unsuccessful treatment outcome like chest X-ray findings, some symptoms specific to PTB, occupation, distance from home to the treatment center, marital status, and educational status were not included in the study since it requires patient contact and tracing. Those patients' cards with incomplete values were excluded from the study which may increase or decrease the rate of treatment outcomes. Lastly death in NTLCP was defined as a patient who died during the course of treatment but the cause of death could be non TB related.

Conclusion and recommendation

The study showed that the overall treatment success rate was 86.5% which is lower than the global target set by WHO which should be greater than 90%. This retrospective study showed that being HIV positive, being defaulter, taking treatment after failure, having history of smoking and not having a treatment supporter is associated with unsuccessful treatment outcomes. Careful attention and special consideration should be given for those patients who are at high risk of developing unsuccessful treatment outcomes,this could be done by increasing patients' health education, establishing smoking cessation activates, encouraging and motivating the patient throughout the course of treatment and afterwards, during follow up, beginning home visits with this individuals, Furthermore there should be a system for tracing defaulters and knowing and recording fate of transferred out cases.

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ANNEXES

Annex I: Training manual

Tile: Treatment outcomes and associated factors among pattients with pulmonary tuberculosis in selected health centers of Addis Ababa, Ethiopia 2020.

Introductions: the training manual mainly aids data collectors to internalize the purpose of the study, to be familiar with the contents, the words and sentences that are used in the check list. It also gives them information regarding the method of data collection in order to ensure the quality of the data and maintaining confidentiality of the information collected.

Objectives of the research**:**To determine factors that are associated with unsuccessful treatmnet outcomes among patients with pulmonary TB in selected health centers of Addis Ababa, Ethiopia 2020.

Purpose of the training:

5 To make data collectors familiar with the words and sentences that are used in the check lis**t.**

6 To enable data collectors in resolving problems that occurs during data collection.

Methods of training: Discussion of data collection tool

Responsibility of research team members:

Principal investigator: control the overall activities of the study

- monitor for the correctness of data collection at data collection places
- Monitor for consistency and completeness of data at data collection places
- Monitor for availability of necessary supplies for the Data collection
- Ensure data quality at place of data collection

Data collectors:

- Handle necessary supplies to perform the study
- Perform the Data collection
- Communicate with principal investigator for solving problems which are beyond their capacity.

Training program for data collectors total time taken for training will be only one day

Table 5 Training program for data collectors

Time (local tome)	**Activities**
2:30-4:00AM	Well coming , introducing self, introduction about the proposal, objectives, training over view
4:00-4:15AM	Tea break
4:15-6:00AM	Over view of survey methodology ,key aspects of survey methodology ,role and responsibilities of personnel's
6:00-7:00 AM	Lunch
7:00-8:30AM	Data collection procedure ,preparation for data collection, procedure of data collection, solving problems faced during data collection, what to do at the end of data collection
8:30AM-9:00AM	Replay for the questions to be raised

Annex II Check list

Table 6 Data extraction template for Treatment outcomes and associated factors among pattients with pulmonary tuberculosis in selected health centers of Addis Ababa, Ethiopia 2020

Data extraction form
INSTRUCTIONS:
1. Tick the box as appropriate
2. Write in the spaces provided
Date of Review……
Treatment Cards IdentificationNumber……

Variable	**Value**	**Mark**
Demographic characteristics associated with treatment outcome		
Address	Addis Ababa	
	Other cities	
Sex	Male	
	Female	
Age		
Predictor variables associated with treatment outcome		
Patient category	New	
	Relapse	
	Treatment after Failure	

		Treatment after Default	
		Transferred in	
Type of TB		Smear positive PTB	
		Smear negative PTB	
Comorbidity	HIV status	Positive	
		Negative	
		Unknown	
		Refused test	
	DM	Yes	
		No	
	HTN	Yes	
		No	
	Other specify		
Treatment Supporter		yes	
		No	
Treatment out come			
Cured			
Complete			
Died			
Failure			
Defaulter			
Year of treatment			
DOTS/treatment center			