



**SAINT PAUL'S HOSPITAL MILLENNIUM MEDICAL
COLLEGE**

**TREATMENT OUTCOMES AND ASSOCIATED FACTORS OF
TUBECULOSIS PATIENTS AT FELEGE MELESSE AND RAS
EMERU HEALTH CENTERS, ADDIS ABABA, ETHIOPIA
FROM 2007-2009 E.C**

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**A STUDENT RESEARCH REPORT SUBMITTED TO DEPARTMENT OF
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Table of Contents

ABSTRACT.....	2
CHAPTER ONE	3
Introduction.....	3
Background of the problem.....	3
Statement of the problem	4
Significance of the study.....	4
CHAPTER TWO	5
Literature review	5
CHAPTER THREE	10
Objectives of the study.....	10
A. General objectives.....	10
B. Specific objectives.....	10
CHAPTER FOUR.....	11
Methods and materials	11
Study design.....	11
Study area.....	11
Source population	11
Sample size determination	11
Sampling procedures.....	11
Inclusion & exclusion criteria	11
Data collection instruments.....	12
Study variable	12
Ethical clearance	13
CHAPTER FIVE: RESULTS	14
CHAPTER SIX: DISCUSSION	18
CHAPTER SEVEN: STRENGTH AND LIMITATION	20
CHAPTER EIGHT: CONCLUSION.....	20
CHAPTER NINE: RECOMMENDATION	20
REFERENCE.....	21
ANNEX	23
I. CHECK-LIST	23

ABSTRACT

Background: TB is an infectious disease caused by the bacillus *Mycobacterium tuberculosis*. It typically affects the lungs (pulmonary TB) but can also affect other sites (extra pulmonary TB). It is the ninth leading cause of death worldwide and the leading cause from a single infectious agent, ranking above HIV/AIDS. TB is the global threats that really need a special attention on the prevention and treatment. As part of the globe, Ethiopia is one of the high TB burdened country in the world. Therefore, the objective of this study will encompass in revealing the treatment outcomes and its determinant factors of TB patients in two nearby health centers.

Objective: To assess the treatment outcomes of tuberculosis and its associated factors among tuberculosis patients on anti-tuberculosis therapy in Felege Melesse and Ras Emeru Health centers, Addis Abeba in the past 3 years.

Methods and materials: The source population for this study are patients who was treated for TB at Felege Melese and Ras Emeru Health centers from 2015-2017 E.C. An institution based retrospective Cross-sectional Analytic study design and all patients' information that fulfilled the inclusion criteria was retrieved from records of patients with basic information for all registered patients. 363 subjects were selected for the study. To collect data, a check-list was used to extract data's from the medical records. After data is collected, it was entered into a computer and analyzed using SPSS version 20.0 statistical software. Multivariable logistic regression with 95% CI at $P \leq 0.05$ was used to assess the TB treatment Outcome & its associated factors. Finally; result was presented in text and graphs and communicated to all concerned bodies.

Result: From the total of 363 patients who had known treatment outcome in Felege Melesse and Ras Emeru Health centers, Tuberculosis type was categorized as smear positive PTB in 99 (27.3%), smear negative PTB in 110 (30.3%), and extra pulmonary in 154 (42.4%) cases. Record of the 363 TB patients showed that 88 (24.2%) were cured, 237 (65.3%) completed treatment, 6 (1.7%) defaulted treatment, 7 (1.9%) treatment failure and 25 (6.9%) were died. The overall treatment success rate of TB patients was 89.5%. Age ≥ 45 years (AOR=0.296, 95%CI=0.103-0.856, $p=0.025$); Smear positive PTB (AOR=2.895, 95%CI=1.174-7.137, $P=0.021$); category II treatment regimen (AOR=0.355, 95% CI= 0.142-0.892, $P=0.028$) and 2015 year of treatment (AOR=3.098, 95%CI= 1.284-7.476, $P=0.012$) were significantly associated with unsuccessful treatment outcome.

Conclusion: The mean treatment success rate of all registered pulmonary TB patients on this study was 89.5% and it was not significantly affected by gender, HIV status, TB category, body weight and treatment center. However, Age, Tuberculosis Type, treatment Regimen and year of treatment were significantly associated with treatment success.

CHAPTER ONE

Introduction

Background of the problem

TB is an infectious disease caused by the bacillus *Mycobacterium tuberculosis*. It typically affects the lungs (pulmonary TB) but can also affect other sites (extra pulmonary TB). The disease is spread when people who are sick with pulmonary TB expel bacteria into the air, for example by coughing, sneezing or talking. Overall, a relatively small proportion (5–15%) of the estimated 1.7 billion people infected with *M. tuberculosis* will develop TB disease during their lifetime. However, the probability of developing TB disease is much higher among people infected with HIV. (1)

TB is the ninth leading cause of death worldwide and the leading cause from a single infectious agent, ranking above HIV/AIDS. In 2016, there were an estimated 1.3 million TB deaths among HIV negative people (down from 1.7 million in 2000) and an additional 374 000 deaths among HIV-positive people.(2who) An estimated 10.4 million people (90% adults; 65% male; 10% people living with HIV) fell ill with TB in 2016 (i.e. were incident cases). Globally, the TB mortality rate is falling at about 3% per year. TB incidence is falling at about 2% per year; this needs to improve to 4–5% per year by 2020 to reach the first milestones of the End TB Strategy. Regionally, the fastest decline in TB incidence is in the WHO European Region (4.6% from 2015 to 2016). The decline since 2010 has exceeded 4% per year in several high TB burden countries, including Ethiopia, Kenya, Lesotho, Namibia, the Russian Federation, the United Republic of Tanzania, Zambia and Zimbabwe. Globally, the proportion of people who develop TB and die from the disease (the case fatality ratio, or CFR) was 16% in 2016. This needs to fall to 10% by 2020 to reach the first milestones of the End TB Strategy. (2)

There is considerable country variation in the CFR, from under 5% in a few countries to more than 20% in most countries in the WHO African Region. This shows considerable inequalities among countries in access to TB diagnosis and treatment that need to be addressed. Between 2000 and 2016, TB treatment averted an estimated 44 million deaths among HIV-negative people. Among HIV-positive people, TB treatment supported by ART averted an additional 9 million deaths. Drug-resistant TB is a persistent threat, with 490 000 million cases of multidrug-resistant TB (MDR-TB) emerging in 2016 and an additional 110 000 cases that were susceptible to isoniazid but resistant to rifampicin (RR-TB), the most effective first-line anti-TB drug. (2)

Currently, we are in the era of End TB strategy and Sustainable development goals (SDGs) which were endorsed by WHO for the period of 2016-2035. The basic aim is end the global TB epidemic. Targets set in the End TB Strategy include a 90% reduction in TB deaths and an 80% reduction in TB incidence by 2030, compared with 2015. (2)

Statement of the problem

Ethiopia is one of the high TB burdened countries in sub-Saharan Africa which ranks 7th among the 22 high TB burden countries in the world (2). As part of the sustainable development goal 3 and its 3rd target among the 13 targets (Ensure healthy life and promote well-being for all at all ages; By 2030, End the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water borne diseases and other communicable diseases) it's the area of concern to all countries in the world. (2) The WHO 2017 Global TB Report⁶ reiterates the progress made since 2000 and the importance of accelerating efforts to reduce incidence and mortality in the context of the Sustainable Development Goals (SDGs). (3) Despite recent progress in reducing the incidence of and mortality from TB, millions still suffer and die each year as a result of delayed diagnosis, weak health systems, and the ongoing challenges of DR-TB and TB/HIV co-infection.(3)

Without treatment, the mortality rate from TB is high. Studies of the natural history of TB disease in the absence of treatment with anti-TB drugs (conducted before drug treatments became available) found that about 70% of individuals with sputum smear-positive pulmonary TB died within 10 years of being diagnosed, as did about 20% of people with culture-positive (but smear-negative) pulmonary TB.(2) The currently recommended treatment for cases of drug-susceptible TB is a 6-month regimen of four first-line drugs: isoniazid, rifampicin, ethambutol and pyrazinamide. Treatment success rates of at least 85% for cases of drug-susceptible TB are regularly reported to WHO by its 194 Member States.(2)

According to WHO 2017 global TB report, Ethiopia is among the High burden TB, TB-HIV and MDR-TB countries that meet a minimum threshold in terms of their absolute numbers of incident cases (10 000 per year for TB, and 1000 per year for TB/HIV and MDR-TB) during the period 2016-2020. (6) For this reason, Ethiopia is using DOTs program, which was launched by WHO since 1994. The outcome of the patients on follow up is mainly depends on good drug adherence, which is basically done at health center by DOTs program. (4)

Despite relentless efforts towards combating TB and improving treatment outcomes of the disease entity, Ethiopia is still needs a Multi-centered and comprehensive approach to halt the spread of the disease, to identify the possible modifiable factors and maximize the treatment outcome. Therefore, the aim of this research is to determine the treatment outcome and its associated factors in Felege Melesse and Ras Emeru health centers in the past 3 years from 2015-2017 that makes the patients vulnerable to have poor treatment outcome.

Significance of the study

Despite many researches done on different aspects of TB, The disease entity is still a great threat in the current medical world. It has a multitude of impacts mainly in the developing countries like Ethiopia. This research will provide an understanding on the treatment outcome and possible determinant factor of TB. This know-how will be helpful in drawing conclusions on the possible area of intervention and to give recommendation to the concerned body. Moreover, the research will be conducted in two health centers where DOTs program is carried out. This will help to come up with reliable conclusion at the end.

CONCEPTUAL FRAMEWORK

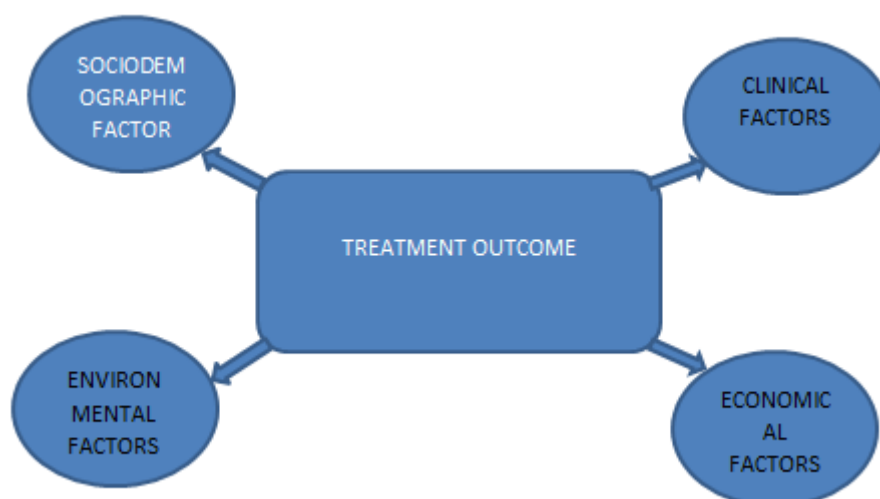


Figure 1. Conceptual framework

CHAPTER TWO

Literature review

Tuberculosis is one of the major pandemic public health problems in the history of mankind. Before the era of Antibiotics, it was the number one killer of all diseases. Even in the past 5 years, it has been the leading cause of death from a single infectious agent, ranking above HIV/AIDS. A patient who diagnosed and got treatment early has a better outcome. There are plenty of researches worldwide that showed different outcomes of TB treatment and possible associated factors.

Researches in the World

One of the retrospective study done in Shangla, Khyber-Pakhtunkhwa, Pakistan with a title of Treatment Outcome of Tuberculosis Patients under Directly Observed Treatment Short Course and its Determinants showed that 192 (38.94%) were cured, 276 (55.98%) completed treatment, 13 (2.6%) defaulted, 9 (1.8%) died, 1 (0.2%) treatment failure, and 1 (0.2%) had transferred to other facilities. The overall mean treatment success rate was 94.93%. TB age and TB form or baseline smear were significantly associated with unsuccessful treatment

outcome. The risk of unsuccessful outcome was significantly lower among TB patients age <14 years (Adjusted odds ratio [AOR] = 0.118, 95% CI: 0.022–0.644), and PTB (smear positive: AOR = 0.125, 95% CI: 0.023–0.669; Smear negative: AOR = 0.024, 95% CI: 0.003–0.205) compared to their counterpart. (5)

Another retrospective Case-Control Study on Factors Affecting Treatment Outcomes for Pulmonary Tuberculosis in İstanbul, Turkey revealed that adverse treatment outcome were associated with >65 years of age (OR: 3.39 (1.99-5.76)) ; male gender (OR:2.11 (1.49-2.99)); born outside Turkey (OR: 5.48 (2.13-14.04)); co-morbidity (OR: 1.85 (1.29-2.65)); bilateral radiologic lesions (OR: 2.07 (1.41-3.00)); previous treatment history (OR: 3.99 (2.78-5.74)); 3rd month positive microscopy (OR: 4.96 (3.04-8.09)) and any H&R +/- others multidrug resistant (MDR) resistance (OR: 22.64 (6.92-74.08)). There was no association between the adverse treatment outcome and the application site of direct observation treatment, short course (DOTS) delivery and the supervisors. (6) An additional research done in the same place, Turkey; with the topic of Factors affecting successful treatment outcomes in pulmonary tuberculosis: a single-center experience from 2005–2011 showed that of 738 patients (258 females, 480 males) with bacteriologically confirmed PTB, 683 (92.6%) had successful treatment outcomes. Of those with a poor outcome, 29 (3.9%) had treatment default, 18 (2.4%) died, and 8 (1.1%) had treatment failure. Young age, no previous treatment, no comorbidity, no drug resistance, and high education level were factors significantly associated with successful PTB treatment outcome ($p < 0.05$ for all). (7)

There is also a research done in Anqing, China which is retrospective and with a topic of Treatment outcomes and factors affecting unsuccessful outcome among new pulmonary smear positive and negative tuberculosis patients concluded that Among 22,998 registered patients (16,939 males, 6059 females), 64.54% were smear-positive patients. The treatment success rate was 95.02% for smear-positive patients and 95.00% for smear-negative patients. Characteristics associated with an higher risk of unsuccessful treatment among smear-positive patients included aged above 35 years, treatment management model of self-medication, full-course management and supervision in intensive phase, unchecked chest X-ray, cavity in chest X-ray, and miliary shadow in chest X-ray, while normal X-ray was negative factor. Unsuccessful treatment among smear-negative patients was significantly associated with age over 45 years, treatment management model of full-course management, unchecked chest X-ray, presence of miliary shadow in chest X-ray and delay over 51 days. (8)

RESEARCH IN AFRICA

A retrospective study done in Limpopo province, South Africa from 2006-2010 with the title of Factors influencing treatment outcomes in tuberculosis patients demonstrated that Of the sampled 1200 TB cases, 72.6% were in persons aged 22 to 55 years and 86.2% were new cases. The TB mortality rate was 13.6% (much higher than the World Health Organization target of 3%), whilst the default rate was 9.8%. There was a strong association between age ($P < 0.001$), diagnostic category ($P < 0.001$), treatment regimen ($P < 0.001$), and health

facility level ($P < 0.001$) and treatment outcome. Those aged 22–55, and 56–74 years were more likely to die ($P < 0.05$). Poor treatment outcomes were also associated with initial treatment failure, receiving treatment at hospital and treatment regimen II. (9)

The research which was done in tuberculosis patients who are attending tuberculosis treatment centers in 2016-2017 Mogadishu, Somalia with the topic of factors associated with tuberculosis treatment outcomes found that of 385 TB patients. There were 315(81.8%) successful TB-TOs. Individual level factors-marital status, education level, HIV status, treatment category and knowledge on TB influenced TB-TOs (p -value < 0.05). Being married, educated, HIV-negative, new treatment case and knowledgeable on TB increased odds of successful TB-TOs ($OR > 0$, p value < 0.05) compared to other patients. TBTCs factors did not influence TB-TOs (p -value > 0.05). (10)

The other research done in Ibadan, Nigeria which was about treatment outcomes among pulmonary tuberculosis patients at treatment centers found that a total of 1,254 patients were followed up with a mean age of 35.0 ± 3.3 years. The percentages of patients with treatment outcomes assessed in the study were as follows: cure (76.6%), failure (8.1%), default (6.6%), transferred out (4.8%), and death (1.9%). The cure rate varied significantly between treatment centers from 40 to 94.4% ($P < 0.05$). The treatment centers located within the specialist health centers at Jericho and the University College Hospital had 50 and 75% cure rates, respectively. The mean age of cured patients was 31.2 ± 3.1 years, which was significantly lower than the mean age of those with poor treatment outcomes (36.7 ± 3.5 years; $P < 0.05$). Males had a higher risk of a poor treatment outcome ($RR=1.8$; 95% CI: 1.02-1.94) than females. Also, patients with a poor knowledge of tuberculosis had a higher risk of having a poor treatment outcome ($RR=1.35$; 95% CI: 1.25-1.62) compared to those with a good knowledge. (11) The other published research in Ogun state in Nigeria with a topic of Determinants of Treatment Failure among Tuberculosis Patients on Directly Observed Therapy in Rural Primary Health Care Centres stated that the overall treatment failure rate among the TB patients was 5.0% and [15.4%] of the entire negative outcome. In all, 749 [79.9%] of cases completed treatment and were cured, 135 (14.4%) defaulted, 47[5.0%] had treatment failure and 27 (2.9%) of cases were transferred out. Predictors of treatment failure were Relapse after previous treatment [$RR=2.41$, C.I=1.21-4.81] and far distance of domicile from PHC centre [$RR=6.9$, C.I=2.15-22.18]. There was no statistically significant difference in treatment failure between HIV positive and HIV negative TB patients [$RR=2.65$, C.I=0.63-11.09], cases transferred in [$RR=2.24$, C.I=0.35-14.55] and age (children $RR=1.48$, C.I=0.78-2.42)]. (12) Another a nine years (2007-2015) epidemiologic review study revealed that Zaria, North Western Nigeria the tuberculosis and the determinants of treatment outcome were The treatment success rate was 80.2% (3253 patients); 278 (6.9%) of the patients were lost to follow-up, 176 (4.3%) were transferred out, and 235 (5.8%) died. The determinants of the unsuccessful treatment outcome were being a male, aged >40 years, TB and HIV coinfection, a greater degree of sputum smear positivity before treatment, located at far distances from DOTS centers, and being on retreatment or second-line regimen. (13)

There was a retrospective hospital based study carried out on records of 1025 TB cases, treated from 2009-2012 cohorts with a topic of tuberculosis Treatment Outcomes and Determinants among Patients Treated in Hospitals in Imo State, Nigeria and they found that Most of the cases reviewed had pulmonary tuberculosis. 96.7% and majority (86.3%) of them had sputum smear positive results at diagnosis. Majority, 79.7% of the patients were new cases and the treatment outcome showed a total success rate of 81.4%, (cured, 46.3% and completed treatment, 35.1%), default, (9.8%), died (6.5%) and failed treatment (1.5%). Factors found to significantly affect treatment outcome in this study were; age, gender, educational status, religion, living with someone, treatment regimen, HIV status of patients and type of patient at presentation/diagnostic criteria, $p < 0.05$. (14)

Another 5 year retrospective study in tuberculosis patients at National Hospital Abuja Nigeria showed that of 389 cases assessed. The HIV sero-prevalence rate in the study was 42.7%. Fifty-three percent of the study population was within the age category 30–49 years. There was strong evidence of an association between TB/HIV co-infection rate among the various age categories ($p = 0.01$). HIV positive cases had a lower treatment success rate, 48.8% vs. 78.5% ($p < 0.001$), a higher rate of treatment failure, 10.8% vs. 4% ($p = 0.01$), and a higher rate of default, 38.6% vs. 17% ($p < 0.001$). (15)

Tuberculosis treatment outcome and its determinants in a tertiary care setting in south-eastern Nigeria revealed that A total of 671 patients (55% male, 45% female) with a mean age of 36.4 years were registered for treatment; 147 (22%) were smear-positive, 270 (40%) smear-negative and 254 (38%) had extra-pulmonary tuberculosis. Also, 189 (28.2%) of them were HIV positive and; 341 (51%) lived in a rural area. Overall, 387 patients (57.7%) had a successful treatment outcome and 284 (42.3%) had an unsuccessful treatment outcome. Of the patients with unsuccessful treatment outcome, 192 (67.6%) had defaulted, 55 (19.4%) had died, 3 (1%) had treatment failure and 34 (12%) were transferred-out. Nil significant change in trend of treatment success over the study period [$P = 0.75$ for trend]. In multivariable analysis, unsuccessful treatment was associated with older age (aOR = 2.3), rural residence (aOR = 2.1), smear negative PTB (aOR=1.6), being on retreatment (aOR 3.8), and HIVseropositivity (aOR=1.7). (16)

An observational research on the Profile and determinants of unsuccessful tuberculosis outcome in rural Nigeria found that 1180 rural TB patients started treatment, of whom 494 (41.9%) were female. The treatment success rate was 893 (75.7%), while the rates of death, loss-to follow-up, and treatment failure were 129 (10.9%), 100 (8.5%), and 18 (1.5%) respectively. In the final multivariable logistic regression model, the odds of unsuccessful treatment outcome were higher among patients who received care at the urban public facility (aOR = 2.9, 95%CI: 1.9-4.4), smear-negative (1.3, 1.0-1.8) and extra pulmonary (2.7, 1.3-5.6) TB patients, human immunodeficiency virus (HIV) co-infected (2.1, 1.5-3.0), and patient who received the longer (8-mo) anti-TB regimen (1.3, 1.1-1.8). (17)

RESERCH IN ETHIOPIA

A register based historical cohort study was done in Addis Abeba with topic of Treatment outcome of tuberculosis patients under directly observed treatment found that of 6450

registered tuberculosis patients; 18.1% were reported as being cured, 64.6% were documented as treatment completed, 3.7% died during follow-up, 5.1% were reported as defaulters, 0.4% were documented as treatment failure and 8.2% were transferred out to another health institution. Treatment center and year of enrollment were significantly associated with treatment success. (18)

The research published with the topic of treatment outcomes and associated factors among tuberculosis patients in Southwest Ethiopia found that Treatment outcome among tuberculosis patients was satisfactory in the study area. Male gender, age greater than 35 years, smear negative and extra-pulmonary tuberculosis, retreatment with anti-tuberculosis medications, rural residence, being at prison, TB-HIV co-infection without co-trimoxazole preventive therapy and antiretroviral therapy were known to be independent predictors of poor treatment outcomes. (19)

There is also a 5 years retrospective study on treatment outcomes of tuberculosis patients in debre markos referral hospital, North West Ethiopia (June 2008-august 2013) showed that out of 717(371 men and 346 females) aged 18 and above, 425(59.3%) had successful and (9.4%) 67 had unsuccessful treatment outcome. In the final multivariate logistic model, the odds of unsuccessful treatment outcome was higher among patients being age older than 51 years, rural residence, pulmonary negative, positive for HIV status and being in the year 2008 as compared to their respective comparison groups. (20)

Research on treatment outcome of tuberculosis patients at Gondar University Teaching Hospital, Northwest Ethiopia. A five - year retrospective study found that From the total of 4000 patients, tuberculosis type was categorized as extra pulmonary in 1133 (28.3%), smear negative pulmonary tuberculosis in 2196 (54.9%) and smear positive pulmonary tuberculosis in 671 (16.8%) cases. Of all patients, treatment outcome was classified as successfully treated in 1181(29.5%), defaulted in 730 (18.3%), died in 403 (10.1%), treatment failed in six (0.2%) and transferred out in 1680 (42.0%) patients. Males had the trend to be more likely to experience death or default than females, and the elderly were more likely to die than younger.

The proportion of default rate was increased across the years from 97(9.2%) to 228(42.9%). Being female, age group 15-24 years, smear positive pulmonary tuberculosis and being urban resident were associated with higher treatment success rate. (21)

A five year (June 2009 to August 2014) retrospective study on Treatment outcomes of tuberculosis patients in Nigist Eleni Mohammed general hospital, hosanna, southern nations, nationalities and peoples region, Ethiopia found that Out of 768 TB patients who were registered at the hospital during the study period, 249 (32.4%) completed the treatment, 84 (10.9%) cured, 11 (1.4%) defaulted, 397 (51.7%) were transferred out to other health facility, 23 (2.9%) died and 4 (0.5%) failed the treatment regimen. In this study, the overall treatment success of TB was 333 (43.3%) as compared to their counterparts, 435 (56.7%). Patients who presented pulmonary TB + ve were more likely to develop risk of poor treatment outcomes as compared to the patients with extra pulmonary TB and pulmonary TB-ve (AOR = 1.915,95% CI;1.213,3.028). The proportion of TB HIV co-infection was16.4%, and HIV + ve TB

patients were more likely to develop risk of poor treatment outcomes as compared to their counterparts (AOR = 0.796, 95% CI;0.512,1.236). (22)

A four years retrospective cross-sectional study was used among TB patients in west Ethiopia on factors affecting treatment outcomes. On this research it was found that From the total of 315 patients who had known treatment out come in Nekemte Referral Hospital, tuberculosis type was categorized as smear positive pulmonary TB in 68(21.5%), smear negative pulmonary TB in 107(34.0%), and extra pulmonary in 140(44.4%) cases. Records of the 315 TB patients showed that 54(17.01%) were cured, 206(65.4%) completed treatment, 24(3.5%) had treatment failure, 11(3.5%) defaulted, 20(6.3%) were died. The overall treatment success rate of the TB patients was 82.5%. Age $\geq$ 45 years (AOR=7.1, 95% CI=1.5-34.3, p=0.014), smear negative PTB (AOR=3.4, 95%, CI=1.5-9.5, P=0.023) and retreatment cases (AOR=12.0, 95%, CI=4.2-34.4, P<0.001) were significantly associated with unsuccessful treatment outcome. (23)

A Case-Control Study on Predictors of Poor Tuberculosis Treatment Outcome at Arba Minch General Hospital, Southern Ethiopia revealed that Male sex (Adjusted Odds Ratio (AOR)=1.6; 95%CI:1.1-2.3), age >35 years (AOR=2.4; 95%CI:1.6-3.4), rural residence (AOR=1.5; 95%CI:1.0-2.2), retreatment category (AOR=3.3; 95%CI:1.3-8.4), smear negative Pulmonary TB (AOR=2.4; 95%CI:1.4-4.1), Extra-pulmonary TB (AOR=2.5; 95%CI:1.3-4.6), HIV positives (AOR=2.4; 95%CI:1.6-3.5) and TB treated (unknown HIV status) in the year before 2011 (AOR=2.5; 95%CI:1.3-5.1) were found predictors of poor TB treatment outcome. (24)

CHAPTER THREE

Objectives of the study

A. General objectives

To assess the treatment outcomes and associated factors of Tuberculosis patients at Felege Melesse and Ras Emeru health centers, from 2015-2017.

B. Specific objectives

- To determine the treatment outcomes of TB patients
- To identify the possible associated factors & to describe the relationship with the treatment outcomes

CHAPTER FOUR

Methods and materials

Study design

A three years retrospective cross-sectional Analytic study was used to carry out this research.

Study area

The study was conducted in two nearby health centers; Felege Melese and Ras Emeru Health center. The health centers are found in Arada kifle ketem. They provide different health related services and one of them is regarding TB treatment and follow-up. They used the Direct Observed Treatment short course therapy (DOTs) principle to properly and strictly address the drug adherence and pick up the complications early. Beside the TB treatment, they also provide ART and follow up. The study was conducted from September 2015-August 2017 at TB clinic.

Source population

All TB Patients undergoing treatment for TB in Felege Melese and Ras Emeru health centers.

Study units and period

All TB Patients undergoing treatment for TB in Felege Melese and Ras Emeru health centers from September 2015-August 2017.

Sample size determination

All patients' information that fulfilled the inclusion criteria was retrieved from records of patients with basic information for all registered patients who took anti-tuberculosis treatment during the period of September 2015-August 2017.

Sampling procedures

Source of data: TB registry

Sampling: Health centers were selected by simple random technique from 32 health centers found in Arada Kifle Ketema and the study participants was patients who got treatment in the study period at the specified health centers who fulfill the inclusion and exclusion criteria.

Inclusion & exclusion criteria

Patients registered for treatment of TB at Felege Meles and Ras Emeru health centers from September 2015-August 2017 were included in this study and patients with incomplete data and patients who were transferred out from the health centers to other health centers were excluded.

Data collection instruments

Data was collected by the investigator using a structured sheet specially designed for this study. Patients diagnosed for TB were transferred to DOTS clinic and started treatment according to the national guideline. Patient data on age, sex, residence, type of TB, smear results at base line and 2nd, 5th, and 7th months, HIV status, year of treatment, patient category during the start of treatment, and the outcomes of treatment were extracted from Felege Melesse and Ras Emeru Health Center, DOTS clinic. Pre-test study was done before starting of the survey on 15 patients profile data at Selam Health Center; that was selected randomly to check the appropriateness and completeness of the check list.

Study variable

Dependent

Treatment outcome

Independent

Socio demographic factors (age, sex, residency, weight), year of treatment, HIV status, TB type, Patient category, treatment regimen, AFB result at the beginning of treatment, at 2nd, 5th and 6th months.

DATA MANAGEMENT AND ANALYSIS

The completed check list was checked for completeness and consistency by the principal investigator. Code was given to the completed check lists. The coded check lists were categorized by health institution (health service delivery points). The principal investigator would enter the data using SPSS 20 statistical packages. Data cleanup was performed to check for, accuracy, consistencies, & values. Any error would then be identified and corrected. Central tendency & dispersion were used, analyzed and described in the form of frequency tables. Internal comparison was made.

Definitions of terms

Definition of treatment outcome according to the national TB and leprosy control program (NTLCP) guideline adopted from WHO [25]:

- **Cured:** - Finished treatment with negative bacteriology result at the end of treatment.
- **Completed treatment:** - Finished treatment, but without bacteriology result at the end of treatment.
- **Failure:** - remaining smear positive at five months despite correct intake of medication.
- **Defaulted treatment:** - Patients who interrupted their treatment for two consecutive months or more after registration.
- **Died:** - Patients who died from any cause during the course of treatment.
- **Transferred out:** - Patients whose treatment results are unknown due to transfer to another health facility.
- **New case (N):** A patient who never had treatment for TB or has been on previous anti-TB treatment for less than four weeks.
- **Retreatment case(R) :-** A patient declared cured or whose treatment was completed of any form of TB in the past but who reports back to the health service and is now found to be AFB smear positive or culture positive.
- **Transfer in (T):** A patient started treatment in one health institution and moved to another health institution to continue treatment.
- **Successful treatment outcome:** - if TB patient were cured or completed treatment with resolution of symptoms.
- **Unsuccessful treatment outcome:** - if treatment of TB patients resulted in treatment failure, default or death.

COMMUNICATION OF THE RESULT

Since the report from this study is expected to be useful for all concerned bodies who want to develop policies, and implementation of the possible intervention to minimize the risk factors predispose the patient to acquire the disease and also to enhance the treatment outcome. The result will also be disseminated to any organization or institution or individuals who have direct or indirect input to the project. All attempts will be made to present the results of the study on local and/or international Journals.

Ethical clearance

Letter of ethical clearance was obtained from SPHMMC. Letter for cooperation from each level is expected; the confidentiality of the patients' information was maintained.

CHAPTER FIVE: RESULTS

SOCIODEMOGRAPHIC CHARACTERSTICS

Total of 380 tuberculosis patients were registered at Felege Meles and Eras Emeru health centers from September 2015-August 2017. Out of these 15 had been transferred out to other districts and 2 had incomplete data, the rest of the patients were on DOTs and with known outcome at the two health centers. Of these 181(49.9%) were female and 182(50.1%) were males. The minimum age was 2 years and the maximum was 86 years, mean age 31.19 and Most of the patients are within the age group of 15-29(169, 46.6 %). Majority of the patients weight (kg) were 40-59 (257, 70.8%) and 380 (100%) were from urban. From the total 198 (54.5%) of patients were treated in Felege Melesse Health center (Table 1).

Table 1: Sociodemographic characterstics of TB patients in Felege Melesse and Ras Emeru Health centers, Addis Abeba, Ethiopia, September 2015-August 2017.

Variables	Category	Treatment center		
		FMHC N, (%)	REHC N, (%)	Total N, %
Sex	Male	99 (50)	82(49.7)	181(49.9)
	Female	99 (50)	83(50.3)	182(50.1)
	Total	198 (54.5)	165(45.5)	363(100)
Age (yrs)	1-14	12 (6.1)	10(6.1)	22(6.1)
	15-29	95 (48)	74(44.8)	169(46.6)
	30-44	61(30.8)	50(30.3)	111(30.6)
	>=45	30(15.2)	31(18.8)	61(16.5)
Weight (kg)	1-19	10 (5.1)	4(2.4)	14(3.9)
	20-39	14(7.1)	14(8.5)	28(7.7)
	40-59	139(70.2)	118(71.5)	257(70.8)
	>=60	35(17.7)	29(17.6)	64(17.6)
Residence	Urban	363(100)		
	Rural	0(0)		
Treatment center	FMHC	198(54.5)		
	REHC	165(45.5)		
Year of treatment	2007	71(35.9)	20(12.1)	91(25.1)
	2008	75(37.9)	60(36.4)	135(37.2)
	2009	52(26.3)	85(51.5)	137(37.7)

CLINICAL CHARACTERSTICS

A total of 363 TB patients' data recorded from September 2015-August 2017 were analyzed. Among patients for whom disease category was documented, 99 (27.3%) were smear-positive pulmonary TB, 110(30.3%) had smear-negative pulmonary TB (PTB) and 154 (42.4%) had extra pulmonary TB (EPTB). Out of the total TB patients enrolled in this study, cured 88(23.3%), complete treatment 237(62.7%), treatment failure 7(1.9%), defaulted 6(1.6%), and 25(6.6%) were dead. Categories of patients were also documented for all types of TB patients: of these 318(84.1%) were classified as new cases, 44(11.6%) retreatment cases and 15(4%) transfer in. Majority of the patients 339(89.7%) were on RHZE/RH (Table 2)

Table 2: Clinical characterstics of TB patients in Felege Melesse and Ras Emeru Health centers, Addis Abeba, Ethiopia, September 2015-August 2017.

Variables	Category	Treatment center		
		FMHC n, %	REHC n, %	Total n, %
Tuberculosis type	Smear positive pulmonary TB	48(24.2)	51(30.9)	99(27.3)
	Smear negative pulmonary TB	60(30.3)	50(30.3)	110(30.3)
	Extra Pulmonary TB	90(45.5)	64(38.8)	154(42.4)
Treatment Regimen	RHZE/RH	176(88.9)	150(90.9)	326(89.8)
	RHZES/RHE	22(11.1)	15(9.1)	37(10.2)
HIV Status	Positive	41(20.7)	37(22.4)	78(21.5)
	Negative	157(79.3)	128(77.6)	285(78.5)
ART initiation for HIV positive patients	Yes	18(9.1)	26(15.8)	44(12.1)
	No	23(11.6)	11(6.7)	34(9.4)
CPT information for HIV positive patients	Yes	33(16.7)	35(21.2)	68(18.7)
	No	8(4.0)	2(1.2)	10(2.8)
Patient category	New cases	163(82.3)	143(86.7)	306(84.3)
	Retreatment cases	28(14.1)	14(8.5)	42(11.6)
	Transfer in	7(3.5)	8(4.8)	15(4.1)
Smear result at 2 nd months for PTB +ve patients.	Positive	1(0.5)	3(1.8)	4(1.1)
	Negative	43(21.7)	45(27.3)	88(24.2)
	Not tested	2(1.0)	1(0.6)	3(0.8)
Smear result at 5 th months for PTB +ve patients	Positive	0(0.00)	2(1.2)	2(0.6)
	Negative	43(21.7)	42(25.5)	85(23.4)
	Not tested	2(1.0)	4(2.4)	6(1.7)
Smear result at 6 th months for PTB +ve patients	Positive	0(0.00)	1(0.6)	1(0.3)
	Negative	42(21.2)	43(26.1)	85(23.4)
	Not tested	3(1.5)	3(1.8)	6(1.7)
Treatment outcome	Cured	44(22.2)	44(26.7)	88(24.2)
	Completed	136(68.7)	101(61.2)	237(65.3)
	Defaulter	2(1.0)	4(2.4)	6(1.7)
	Treatment Failure	4(2.0)	3(1.8)	7(1.9)
	Died	12(6.1)	13(7.9)	25(6.9)
	Transferred out	11(2.9)	4(1.1)	13(3.51)

Treatment outcome

From the 363 patients evaluated for treatment outcome, 325 (89.5%) had successful treatment outcome and 38(10.5%) had unsuccessful treatment outcome. Of the patients with poor treatment outcome, 7 (18.4%) had treatment failure, 6 (15.8%) had defaulted and 25 (6.9%) had died. There is no significant difference of treatment outcome between males and females. Patients with successful treatment outcome were younger than patients with poor treatment outcome and smear positivity or negativity didn't show any difference in the poor treatment outcome. But, extra pulmonary TB had a better outcome in comparison with smear negative PTB and smear negative PTB. (Table 3)

Table 3: Treatment outcomes of TB patients by patient characteristics in Felege Melese and Ras Emeru health centers Addis Abeba, Ethiopia, September 2015-August 2017.

Characteristics		Treatment outcomes					
		Cure	Completed	Failure	Default	Died	Total
Sex	Female	31	131	3	5	15	182
	Male	57	106	3	5	10	181
Age	1-14	3	16	0	1	2	22
	15-29	51	110	3	2	3	169
	30-44	24	69	3	3	12	111
	>=45	10	42	1	0	8	61
Tuberculosis type	Smear Positive PTB	84	1	3	2	9	99
	Smear negative PTB	2	94	3	2	9	110
	EPTB	2	142	1	2	7	154
Patient category	New cases	71	210	0	4	21	306
	Retreatment cases	10	20	7	2	3	42
	Transfer in	7	7	0	0	1	15
Year of treatment	2015	19	56	4	2	10	91
	2016	30	93	3	1	8	135
	2017	39	88	0	3	7	137
	Total	88	237	7	6	25	363
Treatment center	FMHC	44	136	4	2	12	198
	REHC	44	101	3	4	13	165

Associated Factors of TB treatment outcome

The Bivariable analysis showed that Age, year of treatment, Tuberculosis type and treatment regimen was associated with low success rate. However, other factors like treatment centers,

sex, residence, weight, HIV status, ART initiation, CPT initiation, patient category and smear result for PTB patients at 2nd, 5th and 6th months did not show significant association with poor treatment outcome (Table 4).

Variable with P-value <0.05 (like age, year of treatment, Tuberculosis type and treatment regimen) were entered into multivariable analysis. Factors that were significantly associated with poor treatment outcome at p<0.05 in multivariable analysis were also the same (age, year of treatment, TB type, and treatment regimen. While dealing with these factors, patients who are 15-29 years are almost 0.296 times less likely to have poor treatment outcome than patients who are >45 years (AOR=0.296, 95% CI= 0.103-0.856, p=0.025). Patients who had Smear positive PTB are 2.895 times more likely to have poor treatment outcome when compared with Extra PTB patients (AOR =2.895, 95%, CI=1.174-7.137, P=0.021). Patients who treated with RHZE/RH drug regimen are 0.355 times less likely to have poor treatment than with RHZES/RHE drug regimen (AOR= 0.355, 95%, CI=0.142-0.892, P=0.028) and patients who are on treatment in the year 2015 has 3.098 times more likely to have poor treatment outcome when it's compared to those who are treated on the year 2017 (AOR=3.098, 95%, CI=1.284-7.476, P=0.012). However, other factors were not significantly associated with treatment outcome in Felege Melese and Ras Emeru health centers. (Table 4).

Table 4: Determinants of TB treatment outcome in Felege Melese and Ras Emeru health centers Addis Abeba, Ethiopia, September 2015-August 2017.

Variables	Categories	Treatment outcome of TB		COR, (95% CI) , P value	AOR, (95% CI), P value
		Successful	Unsuccessful		
Sex	Male	163	18	0.894(0.456-1.753), P=0.745	
	Female	162	20	1	
Age	1-14	19	3	0.912(0.233-3.73), P=0.898	1.694(0.381-7.54), P=0.489
	15-29	161	8	0.287(0.105-0.782), p=0.015	0.296(0.103-0.856), P=0.025
	30-44	93	18	1.118(0.469-2.667), P=0.801	1.161(0.463-2.913), P=0.75
	>=45	52	9	1	1
Weight	1-19	12	2	1.357(0.25-7.357), P=0.723	
	20-39	24	4	1.357(0.363-5.069). P=0.65	
	40-59	232	25	0.877(0.361-2.13), P=0.773	
	>=60	57	7	1	

HIV status	Pos	63	15	2.712(1.338-5.496), P=0.006	
	Neg	262	23	1	
TB type	Smear pos PTB	85	14	2.372(1.009-5.575), P=0.048	2.895(1.174-7.137), P=0.021
	Smear negative PTB	96	14	2.1(0.896-4.921), P=0.088	1.843(0.754-4.505), P=0.18
	EPTB	144	10	1	1
Treatment Regimen	RHZE/RH	297	29	0.304(0.131-0.705), P=0.006	0.355(0.142-0.892), P=0.028
	RHZES/RHE	28	9	1	1
Patient category	New cases	281	25	1.246(0.157-9.867), P=0.835	
	Retreatment cases	30	12	5.6(0.661-47.424), P=0.114	
	Transfer in	14	1	1	
Treatment center	FMHC	180	18	0.725(0.37-1.421), p=0.349	
	REHC	145	20	1	
Year of treatment	2015	75	16	2.709(1.17-6.276), P=0.02	3.098(1.284-7.476), P=0.012
	2016	123	12	1.239(0.516-2.972), P=0.631	1.14(0.455-2.855), P=0.78
	2017	127	10	1	1

CHAPTER SIX: DISCUSSION

In this health institution based cross-sectional study information was extracted from documents of 363 registered TB patients; 50.1% of the patients were Female. In contrary to this study, researches done in Debre Markos (48.2%) ,Turkey (34.95%), china (26.34%) and Nigeria (41.9) showed lesser females affection by TB. On this study Most of the patients affected by the disease are in their reproductive age group (169, 46.6%). This may indicate negative impact on the socio-economic condition of the society. In this study EPTB patients constituted the prevailing form of TB.

The successful treatment outcomes of all types were 89.5% which is a bit lower than the current WHO target of 90%. This study showed that 88 (24.2%) and 237 (65.3%) of the TB

patients attending DOTs were cured and completed treatment, respectively. This account for an overall treatment success rate of 89.5%. Regarding the success rate finding of this research it has a closer result with the one done in Turkey which reported 92.6% success rate. Apart from this research other studies done in Pakistan and China revealed a much better treatment success rate of 94.93% and 95% respectively. However the other researches done in Nekemete, Hosaena, Gonder, Debre Markos, A.A, Nigeria and Mogadisho came up with lower treatment success rate of 82.5%, 43.3%, 54.9%, 59.3%, 82.7%, (80.2%, 81.4%, 57.7%, 75.7%) and 81.1% respectively. The comparably more successful treatment outcome recorded in this study shows the performance of institutional DOTs in TB control program in Felege Melesse and Ras Emeru health centers and improved awareness and adherence of TB patients to treatment that may signify the importance of the DOTs strategy and also the use of health extension workers (HEWs) in tracing patients who default from treatment to follow-up the patients.

In this study the unsuccessful treatment outcome of TB patients accounts for 10.5% which is higher than in Pakistan and Turkey that reported 5.07% and 7.4% respectively. The other research done in Addis Abeba reported not significant difference in unsuccessful treatment outcome which is 15.3%. However, regarding poor treatment outcome, this study has a lower unsuccessful rate than the researches done in Nigeria, Gonder, Debre Markos, and Hosaena with (42.3%, 24.3%), 44.1%, 40.7% & 46.7% rates respectively. This could be due to difference in sample size and study settings. Death rate in this study comprised major portion of the unsuccessful outcome in TB treatment followed by Treatment Failure rate.

This study showed that Smear positive had significantly ($P=0.021$) lower treatment success rate compared to Extra pulmonary & Smear negative Pulmonary TB. This result is consistent with the research done in Nigeria which reported a greater smear positivity before the initiation of treatment is associated with poor treatment outcome. But other researches which were done in Pakistan, China, Nigeria, South West Ethiopia, Debre Markos, Gonder, West Ethiopia & Arba Minch showed that being Smear Positive Pulmonary TB patient was an indicator of good treatment outcome.

This study also showed that the patients with age of > 45 years had significantly ($p=0.025$) low TB treatment outcome. This finding is similar to other studies done in Nekemete Referral hospital; West Ethiopia, China and Nigeria. This might be associated with increased co-infections with other diseases as well as the general physiological deterioration with age that might contribute to poorer treatment outcome.

This study also showed that patients who was on Category II drug regimen therapy had significantly ($P=0.028$) poor treatment outcome. The result is consistent with the findings in South Africa and Nigeria. This might be due to the category II drug regimen is used mainly for retreatment cases.

Year of treatment, mainly those who were treated on 2015, was also significantly ($P=0.012$) associated with poor treatment outcomes. The finding of this study is also similar with the health center based research done in Addis Abeba. The possible explanation for this finding

could be improved health seeking behavior of the patients, better awareness among health care providers and government emphasis towards TB prevention and treatment.

Unlike other studies, this study did not show differences in treatment outcome for gender, residence and place of treatment, although studies done in South West Ethiopia, Gondar and Arba Minch showed that being male is associated with poor treatment outcome, this might be due to males are highly exposed to cigarette smoking alcohol consumption, which might in turn contribute to poor treatment outcomes and studies done in South West Ethiopia, Debre Markos and Arba Minch showed that being from rural area was associated with poor treatment outcome this might be due to low DOTS performance, inadequate health seeking behavior and lower patient awareness about TB treatment. The reason for the differences could be due to difference in sample size and study settings.

CHAPTER SEVEN: STRENGTH AND LIMITATION

This study like other study is based on secondary data analysis. Thus, it has strength and limitations which should be considered to interpret the findings. The main strength of the study is that it was conducted at health centers that represent different level of potential health service coverage in Addis Ababa. Hence, the finding can clearly reflect the treatment outcome of TB patients under DOTS program at the primary health care level in Addis Ababa. The major limitation of this study was that being retrospective made us not to study important variables including education level, distance from the treatment center, patient-health worker communication, delay in health care seeking and provider and health system related factors which could affect TB treatment outcome. Tuberculosis patients transferred to other health facilities were also not included.

CHAPTER EIGHT: CONCLUSION

The mean treatment success rate of all registered pulmonary TB patients was 89.5% and it was not significantly affected by gender, HIV status, TB category, body weight and treatment center. However, Age, Tuberculosis Type, treatment Regimen and year of treatment were significantly associated with treatment success.

CHAPTER NINE: RECOMMENDATION

Thus as a recommendation, patients with older age, smear positive PTB and treatment Drug regimen other than Category I requires attention to improve treatment outcome. Moreover, to improve treatment outcome of TB, emphasis has to be given by the health care professionals, regional health bureau and ministry of health in providing health education on the importance of TB treatment and the consequences of poorly treated TB.

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25. National TB and leprosy control program (NTLCP) guideline

ANNEX

I. CHECK-LIST

CL code.....

Rx center.....

S/n	Lists of factors	
	Segment 1: Socio Demographic Factors	
101	Age.....	
102	Sex 1. Male 2. Female	
103	Residency 1. Urban 2. Rural	
104	Weight.....	
	Segment 2 : clinical characteristics of Patients	
201	Year of treatment.....	
202	HIV status 1. Positive 2. Negative 3. Not tested	
203	ART initiation for HIV positive patients 1. Yes 2. No	
204	CPT initiation for HIV positive patients 1. Yes 2. No	
205	Tuberculosis type 1. Smear positive PTB 2. Smear negative PTB 3. EPTB	
206	Rx regimen.....	
207	Patient category 1. New case 2. Retreatment case 3. Transfer in	
208	Smear result for PTB positive patients	
	20801	• At 2 months 1. Positive 2. Negative 3. Not tested
	20802	• At 5 months 1. Positive 2. Negative 3. Not tested
	20803	• At 7 months 1. Positive 2. Negative 3. Not tested
	Segment 3 : Treatment outcomes	
301	○ Cured	
	○ Completed	
	○ Transferred out	
	○ Defaulted treatment	
	○ Treatment failure	
	○ Death	


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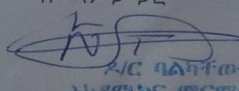

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In reply please refer to our ref. No.

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