Treatment outcomes of tuberculosis patients and associated factors in Bale Zone, Southeast Ethiopia: a retrospective study

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Abstract

Objective: This study assessed the outcome of tuberculosis treatment and associated factors in Bale Zone, Southeast Ethiopia in 2017.

Methods: This was 5-year retrospective study of a health registry for tuberculosis patients, which was reviewed from 1 September 2011 to 30 August 2016. Data were analyzed, and descriptive and logistic regression analyses were used to identify the factors that were associated with tuberculosis treatment outcomes.

Results: Among the 7205 tuberculosis patients, 6325 (87.8%) had a successful treatment outcome and 880 (12.2%) had an unsuccessful outcome. The age groups ≤14 years (adjusted odds ratio [AOR]=2.21), 15 to 24 years (AOR=1.61), 25 to 34 years (AOR=1.86), or 35 to 44 years (AOR=1.65); being treated at a hospital (AOR=1.63) or health center (AOR=2.52); pulmonary tuberculosis-positive (AOR=0.80); or extrapulmonary tuberculosis patients (AOR= 0.78) were the factors that were significantly associated with tuberculosis treatment outcome.

Conclusions: Public health facilities should pay special attention to the identified variables for tuberculosis prevention and control activities, especially focusing on supporting health workers who work at a health post (lowest level of Ethiopia's three-tiered healthcare system).

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Introduction

Tuberculosis (TB) is one of the deadliest communicable diseases; it causes 1.7 million deaths annually.[1] In 2016, there were an estimated 10.4 million new TB cases, which was the tenth leading cause of death globally.[2] TB is a treatable and curable disease when the patients receive proper treatment. Despite the availability of cost-effective treatment, TB continues to be a major public health problem worldwide, particularly in developing countries. Low- and middle-income countries account for over 95% of all new TB cases and deaths. One of the highest incidences and number of TB deaths in the world occurs in sub-Saharan Africa.[3–5]

The global target for TB control is to identify at least 70% of smear-positive patients and to cure at least 85% of the identified patients. If TB patients are not identified and treated in accordance with the protocol, patients with active TB will continue to spread the disease among the healthy population. The consequences of inappropriate handling of TB patients extends the period of infection and increases the rate of treatment failure and drug resistance. People of reproductive age (15–59 years) are the most susceptible to this catastrophic disease, and there is a major economic burden that is placed upon both individuals and countries. The World Health Organization (WHO) has planned to end the global TB epidemic in 2035 by reducing TB-related deaths and the TB incidence by 95% and 90%, respectively.[6–9]

In accordance with the 2018 WHO Worldwide TB report, Ethiopia is one of 30 countries with a high TB burden, with an incidence of all forms of TB of 151 per 100,000.[10,11] TB in Ethiopia is the leading cause of morbidity, and it is the third highest cause of hospital admission and the second highest cause of death in the era of human immunodeficiency virus (HIV).[12,13]

A TB control program indicator is treatment outcomes, and these outcomes include cured, completed treatment, lost to follow-up, treatment failure, death, and developed multi-drug resistant (MDR) TB. Among these treatment outcomes, the first two (cured and completed treatment) are the goals of the program, whereas the other outcomes are not the program's goals. In different studies, the risk factors for poor TB treatment outcomes were age less than 24 years, male sex, year of registration being 2018, smear-negative pulmonary TB (PTB), extrapulmonary TB (EPTB), retreatment, and HIV-positive TB patients.[14–17]

Although a standardized TB prevention and control program that integrated a directly observed treatment strategy was started Bale Zone over two decades ago, treatment outcomes and the factors that result in poor treatment outcomes have not been studied in the zone. Therefore, this study assessed the treatment outcome of TB patients and determined the correlation of factors among TB patients who underwent treatment within the 5-year study period at Bale Zone public health facilities.

Methods

Study setting

This institutional-based retrospective cohort study design was conducted in the Bale Zone public health facilities that treated TB patients by the health records for patients who were registered from 1 September 2011 to 30 August 2016. Bale Zone is located in Oromia Regional State, and it is 430 km southeast of Addis Ababa, Ethiopia. The data were collected from four hospitals, 70 health centers, and 31 health posts (health posts are the lowest level of Ethiopia's three-tiered healthcare system). Hospitals and health centers had both diagnosis and treatment services for TB

patients, while health posts only had treatment services for TB patients. After a TB diagnosis, the patients were referred to the TB clinic for registration and TB treatment services, which were free of charge. All patients who underwent anti-TB treatment during the 5 years of the review period and who had a treatment outcome were included in this study. TB patients followed the standard treatment course for a minimum duration of 6 months. Patients who did not have a record of their treatment outcome or who were transferred to another institution were excluded.

Data collection tools and methods

Data were obtained from the logbook of TB patients using structured tools that were adapted from different studies and the Ethiopian TB and leprosy treatment guidelines.[15,18–20] Data were collected by trained health professionals who were under the supervision of trained supervisors. The investigators controlled all the data collection process activities.

The patient health record review checklist includes variables such as socio-demographic characteristics (age, sex, weight, residence, place where the patient underwent the treatment, year of treatment); comorbidity (TB/HIV co-infections); type of TB for which the patient was treated (smear-negative PTB, smear-positive PTB, and EPTB); and patient category (new patient, retreatment patient, and transfer-in).

Definitions of clinical cases and treatment outcomes. In accordance with the standard definitions of the National Tuberculosis and Leprosy Control Program guideline (NTLCP), we used clinical case and treatment outcome definitions from the WHO, which are described below.[20]

Pulmonary TB, smear-positive: A patient with at least two sputum specimens that were positive for acid-fast bacilli (AFB) by microscopy, or a patient with only one sputum specimen that was positive for AFB by microscopy and chest radiographic abnormalities that were consistent with active PTB.

Pulmonary TB, smear-negative: A patient with symptoms that were suggestive of TB with at least two sputum specimens that were negative for AFB by microscopy and with chest radiographic abnormalities that were consistent with active PTB (including interstitial or military abnormal images); or a patient with two sets of at least two sputum specimens that were taken at least 2 weeks apart and that were negative for AFB by microscopy, radiographic abnormalities that were consistent with PTB, and a lack of clinical response to 1 week of broad-spectrum antibiotic therapy.

Extrapulmonary tuberculosis

EPTB included TB in organs and places in the body other than the lungs, such as lymph nodes, abdomen, genitourinary tract, skin, joints, bones, and meninges. A diagnosis of EPTB was based on fine-needle aspiration cytology, biochemical analyses of cerebrospinal/pleural/ascitic fluid, the patient's pathological examination results, or strong clinical evidence that was consistent with active EPTB followed by the physician's decision to treat the patient with a full course of anti-TB chemotherapy. In all patients with EPTB, sputum examinations and chest radiographs were used to investigate the involvement of the lung parenchyma. The participating hospitals lacked the facilities that are required for culture and drug susceptibility testing.

Treatment outcome: The treatment outcome was divided into seven categories in accordance with the NTLCP guidelines. These categories were as follows:

Cure: a patient who finished their treatment with negative bacteriology results at the end of treatment;

Completed treatment: a patient who finished treatment, but without a bacteriology result at the end of treatment;

Failure: a patient who remained smear-positive after 5 months of treatment, despite taking their medication correctly;

Lost to follow-up: a patient who interrupted their treatment for 2 or more consecutive months after registration;

Died: a patient who died from any cause during the course of treatment;

Transferred out: a patient whose treatment results are unknown due to transfer to another health facility; and

Successfully treated: a patient who was cured or completed their TB treatment.

Data processing and statistical analysis

Data were checked for completeness, cleaned, and entered into a database using Epi-data version 3.1 (JM Lauritsen, http://www.epidata.dk), then transferred to the Statistical Package for Social Science (SPSS) version 21 (IBM Corp., Armonk, NY, USA) for analysis. Both descriptive (mean, percentages, and frequencies) and inferential analyses were conducted. The dependent variable is dichotomous, and it included successfully treated (cured or completed treatment) and not successfully treated (default [lost to follow-up], treatment failure, death, and developed MDR) outcomes. Bivariate logistic regression analysis was used to identify factors that were associated with the dependent variable. The possible effects of confounders were controlled through multivariate logistic regression analysis to identify independent predictors of the study variable. Association between the explanatory and dependent variables was assessed at a p-value of 0.05. The variables that showed a p-value <0.05 were considered to be statistically significant for all the independent variables in the final model.

Ethical considerations. Ethics approval was provided by the Madda Walabu University on 16 November 2017. A supportive letter was obtained from the University Research Directorate to Zonal Health Department. A supportive letter was then obtained from the health facilities administration at the Zonal Health Department. The patient data were accessed after approval by the health facilities administration and before data collection. Confidentiality was ensured during data collection; the name or identification number and the address of the patient were not recorded in the data collection checklist.

Results

Socio-demographic and clinical characteristics of the tuberculosis patients

In this study, 7205 health records from TB patients who were registered from 1 September 2011 to 30 August 2016 for TB treatment services were reviewed. The median age of study participants was 26.00 years with an interquartile range of 20 to 38 years. Among the participants, 4093 (56.8%) were men. For the treatment adherence support centers, 4726 (65.6%) of the patients underwent their treatment at health centers. Nearly three-fourths of the patients (5304; 73.6%) who were in the initial referral linkage had sought health care on their own. The patients' clinical records showed that 2873 (39.9%), 2409 (33.4%), and 1923 (26.7%) of the patients were PTB-negative or PTB-positive, or had EPTB, respectively. Among all of the TB patients, HIV test results were positive for 745 (10.3%) patients. Among the HIV-positive patients, 661 (88.7%) had started antiretroviral therapy (ART; Table 1).

Treatment outcomes and their trends

Among 7205 TB patients, 6325 (87.7%) had a successful treatment outcome, which

Table 1. Socio-demographic characteristics of tuberculosis patients in Bale Zone health facilities, Southeast Ethiopia, September 2011 to August 2016.

Variables	Frequency (n=7205)	Percentage (%)
Sex		
Male	4093	56.8
Female	3112	43.2
Age (years)		
≤14	972	13.5
15–24	2113	29.3
25–34	1850	25.7
35–44	981	13.6
45–54	608	8.4
55–64	366	5.1
≥65	315	4.4
Source of initial referral		
Health extension workers	288	4.0
Self	5304	73.6
Other health facility	941	13.1
Unknown	672	9.3
Treatment adherence support center		
Hospital	2331	32.4
Health center	4726	65.6
Health post	148	2.1
TB category		
New	6631	92.0
Retreatment	170	2.4
Default	111	1.5
Transfer-in	285	4.0
Failure	8	0.1
TB–HIV co-infection		
Yes	745	10.3
No	6460	89.7
HIV-positive TB patients who were taking ART		
Yes	661	88.7
No	84	11.3

TB, tuberculosis; HIV, human immunodeficiency virus; ART, antiretroviral treatment.

means that 4525 (62.8%) and 1800 (25.0%) of these patients had a treatment outcome that was treatment completed and cured, respectively. Overall, 2409 of the TB patients were smear-positive, and the cure rate was 74.7% (1800 patients); 880 (12.2) patients had an unsuccessful treatment outcome, which comprises 236 (3.3%) patients who were lost to follow-up, 99 (1.4%) patients who had treatment failure, 525 (7.3%) patients who died, and 20 (0.3%) patients who developed MDR TB (Table 2). Among TB patients who developed MDR,[20] 17 (85%) of these patients were from the new TB category. The death rate steadily decreased over the study period, from 212 (9.6%) in 2012 to 2013 to 81 (5.9%) in 2015 to 2016, and the number of patients who were lost to follow-up decreased from 59 (4.7%) in 2012 to 36 (2.7% 186) in 2016. The results showed a decreasing trend in TB patient deaths and

Table 2. Tuberculosis patient treatment outcomes in Bale Zone health facilities, Southeast Ethiopia, September 2011 to August 2016.

Variable	Frequency	Percentage (%)
Treatment outcomes		
Successful	6325	87.8
Unsuccessful	880	12.2
Successful treatment outcome		
Completed	4525	62.8
Cured	1800	25.0
Unsuccessful treatment outcome		
Lost to follow-up	236	3.3
Failure	99	1.4
Death	525	7.3
Developed multi-drug resistant tuberculosis	20	0.3
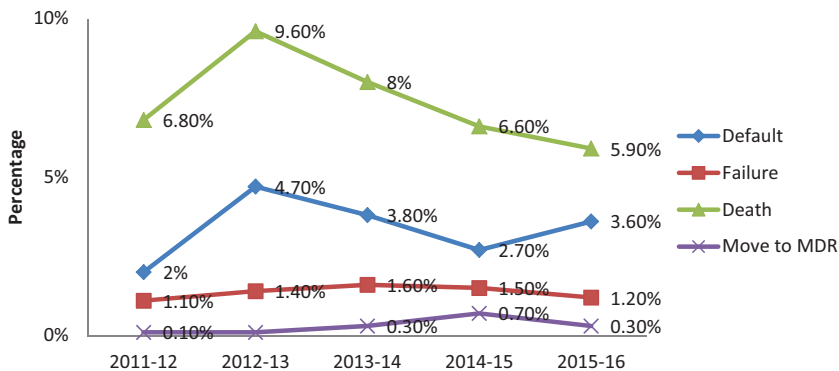
Figure 1. Trends for unsuccessful treatment outcomes in Bale Zone health facilities, Southeast Ethiopia, September 2011 to August 2016.
MDR, multi-drug resistant; Failure, treatment failure; Default, lost to follow-up.

in TB patients who were lost to follow-up (Figure 1). Smear-negative PTB decreased from 748 (26.0%) patients in 2012 to 487 (17.0%) patients in 2016, but the smear-positive PTB detection rate increased from 28.5% to 38.5% in 2012 and 2016, respectively (Figure 2). Among the 2406 smear-positive PTB patients, 2193 (91.1%) of the patients were smear-negative after 2 months.

Factors associated with tuberculosis treatment outcome

The association of explanatory variables such as residence, sex, TB type, TB category, TB/HIV co-infection, initial referral, treatment adherence support center, year of treatment, and patient age category were assessed with the TB treatment outcome using a bivariate analysis. Thus, residence, TB type, treatment adherence support center, year of treatment, and age group were associated with the treatment outcomes in the bivariate analyses.

In the final model using multivariate logistic regression, age, TB type, treatment adherence support center, and year of treatment for patients became independent predictor variables for the TB treatment
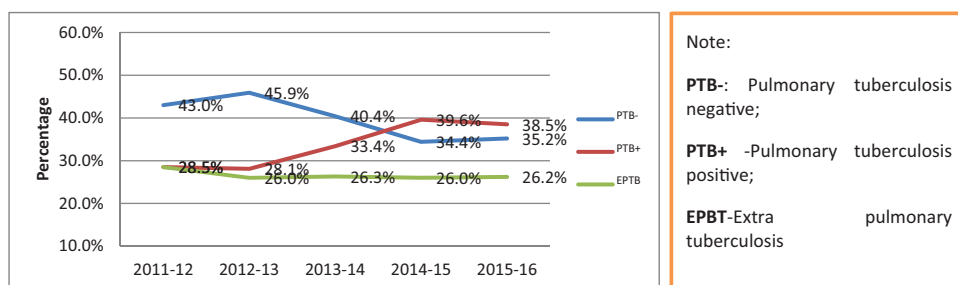
Figure 2. Trends for different types of tuberculosis in Bale Zone public health facilities, Southeast Ethiopia, September 2011 to August 2016.

outcome. TB patients who had continued their treatment at a hospital or health center showed a three-fold better treatment outcome and more than a two-fold improvement compared with patients who continued their treatment at a health post (adjusted odds ratio [AOR]: 2.96 [1.41–6.20] and 2.57 [1.44–4.57]), respectively. TB patients whose age was ≤14 years, 15 to 24 years, 25 to 34 years, and 35 to 44 years were more likely to show a successful treatment outcome, with the an AOR of 2.21 (1.53, 3.19), 1.61 (1.16, 2.22), 1.86 (1.34, 2.59), and 1.65 (1.16, 2.35), respectively (Table 3).

Discussion

This retrospective cohort study showed that the successful treatment outcome was 87.7%, which is lower than the NTLCP and WHO target of 90%.[21] It was also lower than that in the studies that were conducted in some parts of Ethiopia including 92.5% in Harar Town, Eastern Ethiopia[17] and 89.0% in the Tigray region of Ethiopia.[22] However, there was higher success compared with studies that were conducted in Gonder (60.1%),[14] the Southern region of Ethiopia (74.8%),[23] and the Northwest region of Ethiopia (82.6%).[18] This difference might be because of the area that the study covered, treatment period, and patients' residence area.

The unsuccessful treatment outcome of this study was 12.3%, which was better than that in other studies that were conducted in the Southern part of Ethiopia (Dilla, 14.8%),[18] Northern Ethiopia (Tigray, 10.8%),[21] and Addis Ababa (17.3%).[24] The differences might be the sample size, study period, or study setting.

This study also verified that the TB patient death rate decreased from 9.6% to 5.9% over time (September 2012–August 2016). This might be due to increasing efforts to recruit TB patients for HIV screening and initiating ART for TB/HIV co-infected patients. In this study, among the total number of patients for whom their information was complete and analyzed, the proportion of men with TB was higher than that of women. This result is consistent with previously published studies.[19] In some instances, women have more difficulty accessing a diagnostic facility, but the broader pattern also reflects real epidemiological differences between the sexes. This could be due to the underutilization of Directly Observed Treatment Short course (DOTS) by women because they do not attend healthcare visits.[8] Smear-negative PTB steadily decreased from 748 (26.0%) patients in 2012 to 487 (17.0%) patients in 2016, but the smear-positive PTB detection rate increased from 28.5% to 38.5% in 2012 and 2016, respectively, in this study. However, a study from

Table 3. Multivariable logistic regression model that predicts the treatment outcome in Bale Zone health facilities, Southeast Ethiopia, September 2011 to August 2016.

Explanatory variables	Treatment outcome		COR (95% CI)	AOR (95% CI)
	Not successful, n (%)	Successful, n (%)		
Residence				
Urban	258 (14.2)	1557 (85.8)	0.79 (0.67, 0.92)	0.94 (0.79, 1.12)
Rural	622 (11.5)	4768 (88.5)	1.00	1.00
TB type				
PTB−	315 (11.0)	2558 (89.0)	1.00	1.00
PTB+	320 (13.3)	2089 (86.7)	0.80 (0.68, 0.95)	**0.80 (0.67, 0.95)**
EPTB	245 (12.7)	1678 (87.3)	0.84 (0.71, 1.01)	**0.78 (0.65, 0.94)**
Treatment adherence support centers				
Hospital	362 (15.5)	1969 (84.5)	1.68 (1.14, 2.50)	**1.63 (1.09, 2.45)**
Health center	483 (10.2)	4243 (89.8)	2.72 (1.84, 4.02)	**2.52 (1.69, 3.76)**
Health post	35 (23.6)	113 (76.4)	1.00	**1.00**
Age (years)				
≤14	93 (9.6)	879 (90.4)	2.00 (1.39, 2.87)	**2.21 (1.53, 3.19)**
15–24	261 (12.4)	1852 (87.6)	1.50 (1.09, 2.06)	**1.61 (1.16, 2.22)**
25–34	197 (10.6)	1653 (89.4)	1.78 (1.28, 2.46)	**1.86 (1.34, 2.59)**
35–44	116 (11.8)	865 (88.2)	1.58 (1.11, 2.24)	**1.65 (1.16, 2.35)**
45–54	100 (16.4)	508 (83.6)	1.08 (0.75, 1.54)	1.00 (0.76, 1.58)
55–64	58 (15.8)	308 (84.2)	1.12 (0.75, 1.68)	1.15 (0.76, 1.72)
≥65	55 (17.5)	260 (82.5)	1.00	1.00
Year				
2011–2012	174 (10.0)	1566 (90.0)	1.11 (0.88, 1.40)	1.16 (0.91, 1.46)
2012–2013	199 (15.7)	1068 (84.3)	0.66 (0.52, 0.83)	0.73 **(0.58, 0.92)**
2013–2014	200 (13.7)	1259 (86.3)	0.78 (0.62, 0.97)	0.85 (0.67, 1.06)
2014–2015	155 (11.4)	1201 (88.6)	0.95 (0.76, 1.21)	0.10 (0.77, 1.27)
2015–2016	152 (11.0)	1231 (89.0)	1.00	1.00

95%CI, 95% confidence interval; TB, tuberculosis; COR, crude odds ratio; AOR, adjusted odds ratio; PTB, pulmonary tuberculosis; EPTB, extrapulmonary tuberculosis.

Ethiopia indicated that the number of PTB-positive or -negative patients was decreasing over the periods that were reviewed.[25] Among all types of registered TB patients, smear-positive PTB was 33.4%. This was higher than that in studies that were conducted in North Ethiopia Gondar (19.1%)[18] and the Awi Zone (18.7%),[25] which might be due to differences in the infrastructure and the study period in these studies.

In this study, there was no statistically significant association between treatment outcome and TB patient residence or TB type. However, among registered TB patients in Southern Ethiopia (Dilla), a TB patient's residence and TB type showed an association with TB treatment outcome, where a poor treatment outcome was observed among both smear-positive and -negative PTB patients. There were no treatment outcome differences by sex in this study, which is similar to the results of studies that were conducted in Southern Ethiopia (Dilla) and Addis Ababa.[18,24] TB/HIV co-infection did not show an effect on the treatment outcome, which was similar to the results of a study from

Northwest Ethiopia.[18,26] TB patients who were ≤14 years of age, 15 to 24 years, 25 to 34 years, and 35 to 44 years showed more successful TB treatment outcomes. This result is supported by previously published studies.[19,24,27] However, older people have an increased susceptibility to infectious diseases, particularly diseases of the respiratory tract.[28] Another variable that was a determining factor for the success of TB treatment in this study was the place where the patients underwent their treatment. This means that patients who underwent TB treatment at a hospital or at a health center were more likely to show treatment success compared with patients who underwent treatment at a health post. This might be due to differences in the infrastructure, service access, and knowledge among health care providers. However, this was a secondary analysis. The limitations of this type of data are well known, especially in low-income countries where data documentation is poor. In addition, important patient information that could affect TB treatment outcome, including co-morbidity with other chronic illnesses, distance from the treatment center, patient occupation, and patient educational level were not obtained; thus, they were not included in the analysis.

Conclusions and recommendation

The proportion of patients with successful treatment outcomes was lower than the WHO target that was set to end TB strategies, which was 90%. Over 50% of patients were in the reproductive age range of 15 to 44 years. Among the patients who developed MDR, a high proportion were from the new TB category. Thus, public health facilities and the health department of communicable disease control in Bale Zone may need to develop strategies to address new TB cases, while adhering to treatment and supporting health workers who work at health posts. Further, it is recommended that these factors are studied using a strong study design and primary data.

Author contributions

BW, JD, and ND conceived and designed the study. BW, ND, JD, and TT performed the analysis and interpreted the data. JD and TT assisted the analysis. BW and ND prepared the manuscript. ND and TT critically reviewed the manuscript. All authors read and approved the final manuscript.

Availability of data and materials

The datasets that were used in this study for analysis and other information are available from the author upon reasonable request.

Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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