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Tuberculosis treatment outcome and associated factors among tuberculosis patients at Wolayta Sodo Teaching and Referral Hospital, Southern Ethiopia: a retrospective study

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Significance for public health

In Ethiopia, recognition and amendment of treatment outcome is not feasible with poor surveillance system as well as limited monitoring and evaluation of the health system. Accurate recording and reporting of TB treatment outcomes and associated factors is fundamental to facilitate the End TB Strategy set target TB treatment success rate 90% by 2025. Identifying and measure this information is important for health professionals, programmers and policymakers in terms of resource planning, prioritization and distribution

Abstract

Background: Tuberculosis is a major public health problem throughout the world particularly in resource limited countries. Measuring and reporting of TB treatment outcomes and identifying associated factors are fundamental part of TB treatment. Objective: The aim of this study was to assess TB treatment outcome and associated factors among TB patients in Wolayta Sodo Teaching and Referral Hospital, Southern Ethiopia.

Design and Methods: Facility based retrospective cohort study was conducted in Wolayta Sodo Teaching and Referral Hospital. All TB patients who registered during September 2014 to August 2019 and had known treatment outcome were included in the study. The data were collected using pretested structured data extraction format that included demographic, clinical and treatment outcome variables. SPSS Version 23 for windows was used for data processing. Bivariate and multivariate analysis with 95% confidence interval (CI) was employed to infer associations between the independent and dependent variables.

Results: Of total 232 TB patient included in the study, 54.3% were male, 80.2% were urban residents, 65.9% were pulmonary TB (PTB). From the total 153 PTB cases, 31.5% were smear positive, 17.2% were HIV co-infected and all of them were on antiretroviral treatment. Most, 97.0% of the TB cases were newly diagnosed and all were treated as first line treatment category. The overall treatment success rate

was 82.5% (28% cured 54.3% completed), 11.2% loss to follow-up, 4.7% dead and 0.9% treatment failure. The treatment success rate of HIV co-infected TB patients was 77.5%. There was no significant association between TB treatment outcome and age, sex, residence, type of TB, category of patients and HIV status.

Conclusions: The treatment success rate was low (82.5%) which is below the 90% threshold defined standard with high proportion of patient's lost to follow-up (11.2%). A higher number of transfer-out cases were recorded in this study. Thus, supervision and monitoring of DOTs implementation, improved counseling service, mechanisms for lost to follow-up patients should be strengthened. Establish efficient referral and contact tracing mechanisms for transferred-out cases and document their treatment outcomes of status is also fundamental.

Key words: Tuberculosis; treatment outcome; factors; Ethiopia.

Introduction

Tuberculosis (TB) remains a major public health problem throughout the world [1]. TB is the ninth leading cause of death worldwide and the leading cause from a single infectious agent [2]. There were an estimated 1.2 million TB deaths among HIV-negative people in 2018 and an additional 251 000 deaths among HIV-positive people. In 2018 an estimated 10.0 million people fell ill with TB globally, a number that has been relatively stable in recent years. The burden of disease extremely varies among different countries, from fewer than five to more than 500 new cases per 100 000 population per year [3].

A recent systematic review and meta-analysis on TB which involves 34 studies conducted in Ethiopia revealed that the pooled estimate of successful TB treatment was 83.7%. Of successfully treated cases, 33.9% were cured and the remaining completed cases [4]. This finding is nearly similar with WHO report which showed treatment success rates of 85% for TB [3]. A 5-year retrospective study conducted at Addis Ababa on childhood TB and treatment outcome stated that 85.5% participants were successfully treated while rates of mortality and defaulting from treatment were 3.3% and 3.8%, respectively [5].

In Ethiopia, recognition and amendment of treatment outcome is not feasible with poor surveillance system as well as limited monitoring and evaluation of the health system. Accurate recording and reporting of TB treatment outcomes and associated factors is fundamental to facilitate the End TB Strategy set target TB treatment success rate 90% by 2025 [2]. Identifying and measure this information is important for health professionals, programmers and policymakers in terms of resource planning, prioritization and distribution. Therefore, the aim of this study was to assess TB treatment outcome and associated factors among TB patients in Wolayta Sodo Teaching and Referral Hospital, Southern Ethiopia.

Design and Methods

Study design, study site and data collection

This facility based retrospective cohort study design was conducted in Wolayta Sodo Teaching and Referral Hospital. The hospital is the first teaching and referral hospital in Wolayta Sodo Zonal Health Department which serves the community in the Zone and referrals from different health institutions. Data

were extracted from TB registry for all patients and analysis was done for outcome status was documented. The date of treatment initiation was the entry to cohort. Cohort exit was defined as treatment completion, death prior to treatment completion, treatment failure and loss to follow-up. Data on independent variables and treatment outcome were collected from TB clinic-based records. Information available from the records included: place residence, age, sex, mode of diagnosis, date of treatment onset, disease site, HIV status and HIV treatment onset, treatment regimen, history of previous TB treatment and treatment outcomes. Data were collected by experienced staffs working in TB treatment unit. Data collectors were trained and collected under the strict supervision by the principal investigators.

Study population

A total of 2155 diagnosed as having all forms of TB were registered during September, 2014 to August, 2019. Of this, only 232(11 %) with known outcome were included in the study. TB patients with incomplete data were excluded from the study.

Data collection and Diagnosis

The data were collected using pretested structured data extraction questionnaire that included demographics (age, sex), clinical history, laboratory, HIV test results, HIV treatment status, type and category of TB and treatment outcomes. Diagnosis of TB was made according to the recommendations of the Ministry of Health (MoH) of Ethiopia [6]. Treatment was based on the guidelines of the country with a full course of anti-TB therapy (DOTs). Treatment of new TB patients consists of a 2-month intensive phase with Isoniazid, Rifampicin, Pyrazinamide and Ethambutol followed by a 4-month continuation phase with Rifampicin and Isoniazid. Outcomes were categorized as successful (cured/completed) and unsuccessful (loss to follow-up, failure and died).

Operational definition

Definitions of TB treatment outcome and case based on World health organization (WHO) tuberculosis treatment guidelines fourth edition, 2019[7].

Cure: A patient whose sputum smear or culture was positive at the beginning of the treatment but who was smear-or culture-negative in the last month of treatment and on at least one previous occasion.

Treatment completed: A patient who completed treatment but who does not have a negative sputum smear or culture result in the last month of treatment and on at least one previous occasion

Treatment success: A sum of cured and completed treatment complete

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

Died: A patient who dies for any reason during the course of treatment.

Default: A patient whose treatment was interrupted for 2 consecutive months or more.

Transfer out: A patient who has been transferred to another recording and reporting unit and whose treatment outcome is unknown.

New: Patients have never had treatment for TB, or have taken anti-TB drugs for less than 1 month.

Previously treated: Patients have received 1 month or more of anti-TB drugs in the past, may have positive or negative bacteriology and may have disease at any anatomical site.

Data management and analysis

Data were entered, cleaned, and analyzed using SPSS Version 23 for windows. Appropriate descriptive statistics such as mean (with standard deviation), median (with inter quartile range [IQR]), and frequencies (with percentages) were used to describe the study population in relation to relevant variables. Bivariate and multivariate analysis with 95% confidence interval (CI) was employed to infer associations between the independent and dependent variables.

Binary and multivariable logistic regression analyses were conducted to assess the effect of the different variables on the outcome variable. All the explanatory variables with a P value ≤ 0.2 in the Bivariate analyses were included in the final multivariable logistic model in order to identify the independent predictors of TB treatment outcome. A P value < 0.05 was considered statistically significant. Crude odds ratio (COR) and Adjusted (AOR) with 95 % CI were calculated. Those associations with P -value less than 0.05 were regarded as statistically significant.

Results

Socio demographic characteristics

The TB patient registration book between September 2014 and August 2019 at Wolayita Sodo teaching and referral hospital was reviewed. A total of 232 TB patients included in the study cohort had documented treatment outcomes. More than half of these TB patients (54.3%) were male. The age of the study participants ranged from 1 to 84 years, with a median of 25 years (IQR: 16.25-32 years). About 27.2% and 27.6% of the participants was in the age range of 15 – 24 and 25-34, respectively. Of the 232 TB cases, 80.2% were urban residents (Table 1).

Clinical Characteristics of Patients

A total of 65.9% of the cases were pulmonary TB (PTB) and of these 31.5% were smear positive PTB. A total of 40 (17.2%) of the study participants were co-infected with HIV and all of them were on antiretroviral treatment. Most, 97.0% of the TB cases were newly diagnosed. All of the participants treated as first line treatment category (Table 1).

Table 1. Socio demographic and Clinical characteristics of TB patients attending WolaytaSodo Referral Hospital, Southern Ethiopia, 2019 (n=232).

Variables		Frequency	Percent
Sex	Female	106	45.7
	Male	126	54.3
Age group (years)	≤14	52	22.4
	15-24	63	27.2
	25-34	64	27.6
	35-44	29	12.5
	45-54	18	7.8
	55-64	4	1.7
	≥65	2	0.9
Residence	Urban	186	80.2
	Rural	46	19.8
Types of TB	EPTB	79	33.6
	SNPTB	78	34.5
Category of patients	SPPTB	75	31.5
	New case	225	97.0
Treatment regime	Re-treatment	7	3.0
	First line	232	100.0
	Second line	0	0.0
HIV status	Negative	192	82.8
	Positive	40	17.2
HIV treatment	Started	40	100
	Not started	0	0.0

TB, tuberculosis HIV, Human immune deficiency virus

Treatment outcome of TB patients

Of the total TB patients with known treatment outcome, the overall treatment success rate was 82.5%. Of these 65(28%) were cured and 126 (54.3%) had completed their treatment. The treatment success rate of HIV-co-infected TB patients (n=40) included in TB treatment outcome analysis was 77.5%. From a total of 39 (17.5%) unsuccessful TB treatment outcome cases, 26 (11.2%) were loss to follow-up, 11 (4.7%) dead and 2 (0.9%) had treatment failure (Fig 1). Higher treatment success rates were seen in patients who were in the age group 15-24-year, female, Extra PTB patients and HIV negative with 83.6% compared to 77.5% of the HIV positives. The Treatment cure was high among participants with age group from 45-54, HIV negative, diagnosed as smear-positive PTB and Urban residence. The treatment completion was also higher in the youngest age group (<14 and 15-24), participants diagnosed as Extra PTB and rural residence. The rate of loss to follow-up was low in patients who were male, urban residence, diagnosed with EPTB and HIV positive. Mortality was higher among patients who were male, rural residency, HIV positive and patients diagnosed as smear-negative PTB (Table 2).

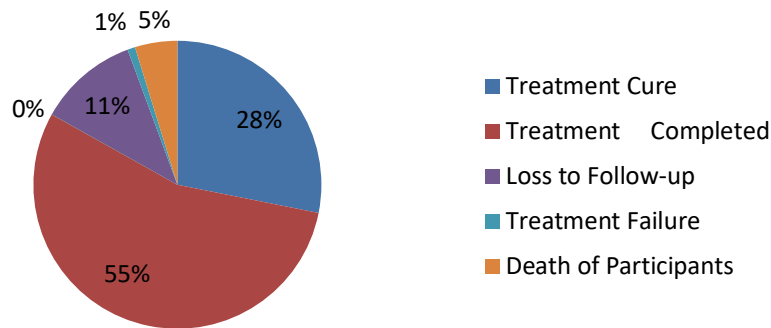


Fig1: Distribution of treatment outcome among TB patients attending Wolayta Sodo referral Hospital , Southern Ethiopia, 2019(n=232)

Table 2. Distribution of treatment outcome with socio-demographic and clinical characteristics of TB patients attending Wolayta Sodo Referral Hospital, Southern Ethiopia, 2019 (n=232)

Variables		Treatment Cure	Treatment Complete	Loss to Follow-up	Treatment Failure	Death of participants
Age	=<14	6(11.5%)	38(73.1%)	9(17.3%)	0(0.0%)	0(0.0%)
	15<=24	20(31.7%)	34(54.0%)	6(9.5%)	1(1.6%)	2(3.2%)
	25 <=34	22(34.4%)	30(47.6%)	7(10.9%)	1(1.6%)	2(3.1%)
	35<=44	9(31.0%)	12(41.4%)	3(10.3%)	0(0.0%)	4(13.8%)
	45<=54	7(38.9%)	8(44.4%)	1(5.6%)	0(0.0%)	2(11.1%)
	>55	1(16.7%)	4(66.70%)	0(0.0%)	0(0.0%)	1(16.7%)
Sex	Male	35(27.8%)	67(53.6%)	13(10.3%)	1(.8%)	7(5.6%)
	Female	30(28.3%)	59(55.7%)	13(12.3%)	1(.9%)	4(3.8%)
Type of TB	SPPTB	59(78.8%)	3(4.1%)	9(12.0%)	1(1.3%)	3(4.0%)
	SNPTB	3(3.8%)	59(75.6%)	10(12.8%)	1(1.3%)	5(6.4%)
	EPTB	3(3.8%)	64(81.0%)	7(8.9%)	0(0.0%)	3(3.8%)
Residence	Urban	55(29.6%)	98(53.0%)	20(10.8%)	2(1.1%)	8(4.3%)
	Rural	10(21.7%)	28(60.9%)	6(13.0%)	0(0.0%)	3(6.5%)
HIV Status	Positive	10(25.0%)	21(52.5%)	4(10.0%)	1(2.5%)	3(7.5%)
	Negative	55(28.6%)	105(55.0%)	22(11.5%)	1(.5%)	8(4.2%)
Total		65(28.0%)	126(54.5%)	26(11.2%)	2(.9%)	11(4.7%)

TB, tuberculosis HIV, Human immune deficiency virus

Factors associated with treatment outcome of tuberculosis

Identifying the factor that contributes for the treatment outcome of tuberculosis is very important to develop and recommend prompt solutions. Accordingly, regression analysis was conducted to assess whether treatment outcomes were associated with patients' sex, age, type of TB, HIV status and residence. Then, the final model multivariate regression analysis was conducted to assess independent relationship for all variables and none of them had association with treatment outcomes of participants. Patients with age group less than 14 and 15-24 years were more likely to have poor treatment outcomes compared to TB patients with age group greater than 25 years old (AOR: 0.431; 95% CI: (0.186-1.000)) and (AOR: 0.465 95% CI: 0.205-1.054) respectively. Male patients were less likely to develop successful treatment outcome as compared to the females with (AOR: 0.778 95% CI: 0.410-1.477). Patients with smear negative (PTB-ve) were more likely to have successful treatment outcome as compared to patients with EPTB and smear positive pulmonary TB (AOR = 1.249, 95% CI; 0.530-2.946) (Table 3).

Table 3. Multivariate analysis of treatment outcome with socio-demographic and clinical characteristics of TB patients attending Wolayta Sodo Refereal Hospital, Southern Ethiopia, 2019 (n=232).

		Tuberculosis Treatment outcome		Crude OR (95% CI)	P-value	Adjusted OR (95% CI)	P-value
Characteristics		Successful treatment	Unsuccessful treatment				
Age	≤14	44(84.6%)	8(15.4%)	0.735(0.305-1.774)	0.494	0.431(0.186-1.000)	0.05
	15≤24	54(85.7%)	9(14.3%)	0.674(0.291-1.562)	0.357	0.465(0.205-1.054)	0.067
	≥25	93(80.2%)	23(19.8%)	1		1	
Sex	Male	102(81.6%)	23(18.4%)	1.181(0.593-2.350)	0.637	0.778(0.410-1.477)	0.442
	Female	89(84%)	17(16%)	1		1	
Type of TB	PPTB	60(83.7%)	12(16.7%)	1.100(0.459-2.634)	0.831	1.013(0.414-2.477)	0.978
	NPTB	64(80%)	16(20%)	1.375(0.603-3.133)	0.449	1.249(0.530-2.946)	0.611
	EXPT	66(84.6%)	12(15.4%)	1		1	
HIV Status	Positive	31(77.5%)	9(22.5%)	1.498(0.650-3.457)	0.343	0.959(0.411-2.236)	0.923
	negative	160(83.8%)	31(16.2%)	1		1	
Residence	Urban	153(82.7%)	32(17.3%)	0.993(0.424-2.330)	0.988	1.013(0.426-2.410)	0.977
	Rural	38(82.6%)	8(17.4%)	1		1	

TB, tuberculosis; HIV, Human immune deficiency virus.

Discussion

In our study, the burden of TB was higher among the age groups of 14–24 and 25–34 years with 27.2% and 27.6% respectively. This is in line with many similar studies [8-10] which confirm as TB mainly affects sexually active and reproductive age groups.

The proportion of patients category were 153 (65.9%) pulmonary TB, whom 78 (33.6%) were smear negative PTB and 79 (34.1%) extra pulmonary TB. The proportion of smear positive PTB is 31.5% which was in line of study reported from *Harar town* (32.4%) [11] and higher than the reports from deferent parts of Ethiopia, *East Wollega* 20.3 [12], *Alamata District* 23.5 % [10], *Debre Tabor* 24.5%, [9] *Debre Tabor* 26.7 [13]. According to the WHO definition smear-positive pulmonary TB cases should have at least one acid fast bacillus (AFB+) in at least one sputum sample in countries with a well functioning

EQA system[7]. Patients who came to the health facility with TB sign and symptom and had negative result for AFB microscope for any reason will be clinically diagnosed as smear negative PTB. This may contribute for the low rate of Smear positive PTB cases. On the top of this most of the health facilities in Ethiopia have been using AFB microscopy due to limited resources, which has low sensitivity (40–45%) and might contribute to lower notification rates of PTB+ (observation) [9].

The overall proportion of successful treatment outcome among the TB patients included in this study was 191 (82.5%) with 65(28%) were cured and 126 (54.5%) had completed. The finding of our study shows nearly similar treatment outcome compared to a finding of systematic review and meta analysis conducted in Ethiopia which describes that the overall TB treatment success rate was 86% with subgroup analysis of Addis Ababa (93%), Oromia (84%), Amhara (86%), SNNPR (83%), Tigray (85%) and Afar (86%)[14]. Again the finding of the present study was comparable with a systematic review reporting the pooled estimate TB treatment outcome of 83.7%, and sub-group analysis findings of Afar 88.9%, Oromia 88.5% and Gambella 86.1% [15]. This is by considering the fact that the systematic review and meta-analysis were reporting aggregate findings of articles conducted in different time period in which the findings of studies conducted previously may affect the overall pooled results. The proportion of patients with successful treatment outcomes was found to be nearly similar with global and Ethiopian treatment success rate of 83% and 84% respectively [7].

However the finding of the present study showed low over all treatment outcome compared to many reports from different parts of Ethiopia, *Harar Town* 92.5% [11] *Alamata* 90.1 % [10]*Ethiopia* 90.9 % [16] *Debre Tabor* 90.1% [9]*East Wollega* 91.9% [12]*Southwest Ethiopia* 89.7% [17]*Southern Ethiopia* 89.9%) [8]. This low treatment success rate compared to the recent studies might be due to poor implementation of DOTs strategy, counseling service and poor health care utilization behavior of the community which was indicated by high loss to follow up (11.2%) compared to reports from *Harar Town* 2.4%) [11], *Hosanna* 1.4% [18]*Eastern Ethiopia* 1.8% [19], *East Wollega* 2.9% [12] (2.5%) [20]. Excluding all transfer out patients in the study may also another reason to have large proportion of unsuccessful treatment outcome since most transfer out patients expected to have better progress than patients need to follow in the hospital in the intensive treatment phase. The findings of the current study had slightly higher treatment success rate compared to reports from *Eastern Ethiopia* 78.3% [19] *Northern Ethiopia* 79.5% [20] and *Jinka* 74% [21], *Busan, South Korea* 83.9% [22]. The logistic regression analysis of our study shows TB treatment outcome was not significantly associated with patients' age, sex, type of TB and residence of participants (see Table 3). Where us studies conducted in different parts of Ethiopia were report an association between TB treatment outcome with age [11,13,14,22,23], sex [11-13,22], type of TB [18,23], HIV status [11,12,14,18] and residence [12-14,18,24] of the participants. The difference may be due to the size of the study participants and the statistical pooling effect of the reference groups.

The prevalence of HIV among the patients in this study was 40 (17%), which is comparable with the reports from Hosanna 16.3% [18] and Oromia region 18.6% [25]. However the finding of the present study shows low HIV positive prevalence in contrast to the findings from Amhara region 24.2% [26], Harar Town 22.8% [11], and Debre Tabor 24.2% [9]. The finding also shows higher rate of HIV positive status compared to the range of findings from 6.8% to 13.5% [10,12,13]. This variability may be due to differences in the health care service in different parts of the country, the health care utilization behavior

of the community and access to the health care facility. Again it may be because of the difference of HIV prevalence in regions.

Although our study has a significant input for researchers and policy makers, it was not possible to determine all factors which could affect treatment outcomes since the results were based on secondary data which routinely collected from health facilities. It was not able to assess factors of TB treatment outcome that are related to the patients, the health care providers and the health service. Moreover, since the study was conducted in a single hospital it was difficult to generalize the findings to all TB patients.

Conclusions and Recommendation

The treatment success rate of tuberculosis patients treated at Wolayta Sodo Teaching and Referral Hospital was disproportionally low (82.5%) below the 85% threshold defined standards. A high proportion of patient's lost to follow-up (11.2%) which is a serious public health concern that needs to be addressed urgently.

A higher number of transfer-out cases were recorded in this study. Thus, the studied health facility should network with other health service centers to document the treatment outcomes of patients. Thus, enhanced supervision and monitoring of DOTs strategy implementation, improved counseling service, community identification of lost to follow-up patients and establish efficient referral and contact tracing mechanisms for transferred-out cases.

Ethical Clearance

Ethical permission was obtained from Wolayta Sodo Teaching and Referral Hospital ethical committee, Southern Ethiopia. This study has no contact with patients. Thus, the patients' information obtained was made anonymous. After clearing the data, numbers have been removed and participants were de-identified prior to analysis.

Consent for publication

No applicable

Availability of data and material

All relevant data are included in this published article

Competing interests

The authors declare that they have no competing interests

Authors' contributions

MT conceived and designed the study. MT and LD and SW performed the study. MT and TH analyzed and interpret the data. MT, SB and AM have developed the manuscript. All authors read and approved the final manuscript.

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