

Factors Affecting Treatment Outcome of Tuberculosis among Tuberculosis Patients in West Ethiopia

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Abstract

Background: Tuberculosis is a life threatening disease caused by mycobacterium tuberculosis. In developing countries the incidence of tuberculosis has been increasing steadily since the 1990s, particularly in African countries. Several European countries have lately reported a slight increase in tuberculosis, but these are mostly related to immigrants from high-incidence countries.

Objective: To assess the treatment outcomes of tuberculosis and its associated factors among tuberculosis patients on anti-tuberculosis therapy in Nekemte Referral Hospital, West Ethiopia.

Methods: A four years retrospective cross-sectional study was used and all patients' information that fulfilled the inclusion criteria was retrieved from records of patients with basic information for all registered patients. We analyzed the records of 315 tuberculosis patients who had known outcome in Nekemte Referral Hospital from September 2012-August 2016.

Results: From the total of 315 patients who had known treatment outcome 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.

Conclusion: Successful treatment outcome of TB patients was below standard. To improve treatment outcome among TB patients health education on the importance of TB treatment and the consequences of poorly treated TB have to be provided to patients during their follow up.

Keywords: Tuberculosis; Treatment outcome; Risk factors; Nekemte; Ethiopia

Introduction

Tuberculosis (TB) is a life threatening disease caused by mycobacterium tuberculosis: that are transmitted from person to person by coughing or sneezing, close contact of TB patients are most likely to become infected [1]. 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. 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) [2].

Most of the estimated number of incident cases in 2016 occurred in the WHO South-East Asia Region (45%), the WHO African Region (25%) and the WHO Western Pacific Region (17%); smaller proportions of cases occurred in the WHO Eastern Mediterranean Region (7%), the WHO European Region (3%) and the WHO Region of the Americas (3%). The top five countries, with 56% of estimated cases, were (in descending order) India, Indonesia, China, the Philippines and Pakistan [2].

In developing countries the incidence of TB has been increasing steadily since the 1990s, particularly in African countries. Several European countries have lately reported a slight increase in TB, but these are mostly related to immigrants from high-incidence countries [3].

According to the 2015 global, tuberculosis report tuberculosis (TB) is a major global health problem [4]. Over 95% of new TB cases and deaths occur in low and middle income countries [5] the highest

incidence of TB and the highest number of deaths due to TB occur in Asia and Saharan Africa [6]. The case fatality rate has exceeded 50% in some African countries where HIV infection rates are high [6-9].

The Stop TB Partnership has developed a Global Plan to End TB, 2016–2020, which focuses on the actions and funding needed to reach the 2020 milestones of the End TB Strategy. The End TB Strategy goal is to “End the global TB epidemic”. The 2035 targets are a 95% reduction in TB deaths and a 90% reduction in the TB incidence rate, compared with levels in 2015. The 2030 targets are a 90% reduction in TB deaths and an 80% reduction in the TB incidence rate, compared with levels in 2015. The most immediate milestones, set for 2020, are a 35% reduction in TB deaths and a 20% reduction in the TB incidence rate, compared with levels in 2015. The percentage of TB-affected households that experience catastrophic costs as a result of TB disease; the milestone for 2020 is zero, to be sustained thereafter [2].

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The estimated decline in the incidence rate since 2010 has exceeded 4% per year in several high TB burden countries, including Zimbabwe (11%), Lesotho (7%), the United Republic of Tanzania (6.8%), Ethiopia (6.7%), Namibia (6.2%), Kenya (5.0%) and the Russian Federation (4.2%) [10].

In 1993 the World Health Organization (WHO) announced a new strategy, called DOTS, for the worldwide control of TB. A DOT was the Directly Observed Treatment Short course strategy. All countries with a TB problem were to provide standardized short course drug treatment to, at least, all sputum smear positive TB patients [11]. In Ethiopia a standardized TB prevention and control programme, incorporating DOTS was started in 1992 [12].

The result of this study will serve as a representative quality of TB treatment provided by a health care system. It helps to improve treatment outcome and adherence of the patients and it will also help to reduce treatment failure, drug resistance, relapse and death. Therefore this study will help to assess treatment outcomes of pulmonary tuberculosis cases in Western Ethiopia.

Methods

Study setting and period

The study was conducted at Nekemte Referral Hospital, located 314 km to the west, away from capital city of Ethiopia, Addis Ababa. Nekemte Referral Hospital has different departments and wards like outpatient department (OPD), medical ward, gynecology and obstetrics ward, pediatrics ward and surgical ward. It delivers diversified health services and clinics including the emergency services, eye clinic, dental clinic, mother child health (MCH), psychiatry clinic, laboratory, radiology, pharmacy, physiotherapy, follow up of chronic diseases, TB clinic and ART clinic. The study was conducted from September 2012-August 2016 at TB clinic.

Study design

A retrospective cross-sectional study was conducted.

Study population

All TB Patients undergoing treatments for TB in Nekemte Referral Hospital from September 2012-August 2016.

Inclusion and exclusion criteria

Patients registered for treatment of TB at Nekemte Referral Hospital from September 2012-August 2016 were included in this study and patients with incomplete data and patients who were transferred out from this hospital to other district hospital were excluded.

Sample size determination and sampling technique

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 2012-August 2016.

Data collection process

The data was collected through medical record reviews of patients, by using a prepared check list. The data collectors were 2 BSc nurses who were briefed on how to proceed for data collection. Pre-test study was done before starting of the survey on 15 patients profile data; that was selected randomly to check the appropriateness and completeness of the check list.

Data analysis and Interpretation

Data was entered in to SPSS software version 20.0 social packages for analysis. Both bivariate and multivariate analyses were done by using binary logistic regression. Variables those having association in binary logistic regression was checked by multivariate logistic regression to identify confounders. A bivariate analysis was carried out to see the association between dependent and independent variables. All variables with p- value < 0.25 was taken to multivariable model to control for all possible confounders Odds ratio along with 95% confidence level was estimated to identify factors associated with the outcome variable using multivariable logistic regression analysis. Level of statistical significance was declared at p- value <0.05 levels.

Ethical considerations

Ethical clearance was obtained from the Ethical Review Committee of Wollega University, College of Medical and Health Sciences. The patient data was accessed up on the approval of medical director of Nekemte referral hospital. Confidentiality was ensured during the data collection, thus the name of the patient were not recorded in the data collection check list.

Definitions of terms

Definition of treatment outcome according to the national TB and leprosy control program (NTLCP) guideline adopted from WHO [12]:

- **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 in 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.

Results

Socio demographic and clinical characteristics

Total of 1807 tuberculosis patients were registered at Nekemte

Referral Hospital from September 2012-August 2016. Out of these 1454 had been transferred out to other districts, 38 were on DOTs and 315 patients had known outcome at Nekemte Referral Hospital. Of these 163(51.7%) were female and 152(48.3%) were males. Most of the patients are within the age group of 15-29(46.3%). Majority of the patients weight (kg) were 40-59 (71.1%) and 299(96.5%) were from urban (Table 1).

Clinical characteristics of TB patients

A total of 315 TB patients' data recorded from September 2012-August 2016 were analyzed. Among patients for whom disease category was documented, 68 (21.6%) were smear-positive pulmonary TB, 107(34.0%) had smear-negative pulmonary TB (PTB) and 140 (44.4%) had extra pulmonary TB (EPTB). Out of the total TB patients enrolled in this study, cured 54(17.1%), complete treatment 206(65.4%), treatment failure 24(7.6%), defaulted 11(3.5%), and 20(6.3%) were dead. Categories of patients were also documented for all types of TB patients: of these 264(83.8%) were classified as new cases, 25(7.9%) retreatment cases and 34(10.8%) transfer in. Majority of the patients 288(91.4%) were on RHZE/RH (Table 2).

Treatment outcome

From the 315 patients evaluated for treatment outcome, 260 (82.5%) had successful treatment outcome and 55(17.5%) had unsuccessful treatment outcome. Of the patients with poor treatment outcome, 24 (7.6%) had treatment failure, 11 (3.5%) had defaulted and 20 (6.3%) had died. There is no difference of treatment outcome between males and females. Patients with successful treatment outcome were younger than patients with poor treatment outcome and smear negative PTB patients had low treatment success rate when compared to smear positive PTB and extra pulmonary TB patients (Table 3).

Determinants of TB treatment outcome

The bivariable analysis showed that Age, TB type, treatment regimen and patients category were associated with low success rate. However, other factors like sex, residence, weight, HIV status, ART initiation, CPT initiation and year of treatment did not show significant association with poor treatment outcome (Table 4).

Variable with P-value <0.25 (like age, weight, TB type, treatment regimen and patients category) were entered into multivariable

analysis. Factors that were significantly associated with poor treatment outcome at $p < 0.05$ in multivariable analysis were age, TB type, and patients category. While dealing with these factors, patients who are ≥ 45 years are almost 7.1 times more likely to have poor treatment outcome than patients who are <15 years (AOR=7.1, 95% CI= 1.5-34.3, $p=0.014$). Patients who had Smear negative PTB are 3.4 times more likely to have poor treatment outcome when compared with smear positive PTB patients (AOR =3.4, 95%, CI=1.5-9.5, $P=0.023$). Patients with retreatment cases were 12 times more likely to have poor treatment outcome when compared with new cases (AOR =12.0, 95%, CI=4.2-34.4, $P<0.001$). However, other factors were not significantly associated with treatment outcome in Nekemte Referral Hospital (Table 4).

Discussion

In this cross-sectional study, the successful treatment outcomes of all TB types were 82.5% which is lower than the NTLCP and WHO target of 85%. The finding of this study is consistent with the study conducted in Addis Ababa [13] which reported 82.7% of success rate. Our study showed that 17.1% and 65.4% of the TB patients attending DOTs were cured and completed treatment, respectively. These account an overall treatment success rate of 82.5%. Different from this study other studies conducted in Northern Ethiopia had shown better treatment success rate 87.8% and 89.2% in Dabat [14] and Tigray [15] respectively. According to the report, the two main factors that contributed for the high success rate in the northern: health posts nearer to patients' residence and the use of volunteer community health workers (CHWs) or health extension workers (HEWs) in tracing patients who default from treatment to follow-up the patients are not yet done in Oromia region, Nekemte town. In addition, poor health system organization and deficient follow-up procedures could have contributed for poor treatment outcome. The patients' attitude and behavior towards the disease are also major factors influencing treatment adherence.

The finding of the present study showed that treatment success rate is better than other studies done in University of Gondar Teaching Hospital (60.1%), Debremarkos (59.3%), Gambella (55.7%), Hadiya zones (38%-73%), and Northwest Ethiopia at Felege Hiwot Referral Hospital (26%) [16-20]. The success rate in this study is also higher than studies done in Nigeria [21] and Malawi [22] which have reported success rate as 76.6% and 72% respectively. The comparably more successful treatment outcome recorded in this study shows the performance of institutional DOTs in TB control program in Nekemte Referral Hospital and improved awareness and adherence of TB patients to treatment that may signify the importance of the DOTs strategy.

In this study the unsuccessful treatment outcome of TB accounts for 17.5%, which was comparable with study conducted in southern Ethiopia [23] that reported 16.7% unsuccessful treatment outcome. However the unsuccessful treatment outcome of this study is higher than studies from Southern Ethiopia at Dilla University Referral Hospital [24] and Tigray [15] which reported 14.8% and 10.8% of unsuccessful treatment outcome respectively. This could be due to difference in sample size and study settings. The treatment failure rate in this study comprised major portion of the unsuccessful outcome in TB treatment.

This study showed that smear negative PTB had significantly ($p=0.023$) lower treatment success rate compared to the smear positive PTB and EPTB patients. Similarly studies from Tigray [15], Gondar [16] and southern region [23] showed that patients with smear negative PTB have poor treatment outcome. This could be due to high rate of

Variables	Category	Frequency	Percentage %
Sex	Female	163	51.7
	Male	152	48.3
Age	<15	24	7.6
	15-29	146	46.3
	30-44	93	29.5
	≥ 45	52	16.5
Weight (kg)	<20	12	3.8
	20-29	7	2.2
	30-39	20	6.3
	40-49	127	40.3
	50-59	97	30.8
	60-69	40	12.7
	≥ 70	12	3.8
Residence	Urban	299	94.9
	Rural	16	5.1

Table 1: Socio demographic characteristics of TB patients in Nekemte Referral Hospital, West Ethiopia, September 2012-August 2016.

Variables	Category	Frequency	Percentage %
Tuberculosis type	Smear positive pulmonary TB	68	21.6
	Smear negative pulmonary TB	107	34.0
	Extra pulmonary TB	140	44.4
Treatment regimen	RHZE/RH	288	91.4
	RHZES/RHE	27	8.6
HIV status	Positive	86	27.3
	Negative	220	69.8
	not tested	9	2.9
ART initiation for HIV positive patients	Yes	78	90.7
	No	8	9.3
CPT information for HIV positive patients	Yes	80	93.0
	No	6	7.0
Patient category	New cases	256	81.3
	Retreatment cases	25	7.9
	Transfer in	34	10.8
Smear result at 2nd month for PTB +ve patients	Positive	0	0.0
	Negative	60	19.0
	Not tested	255	81.0
smear result at 5th month for PTB +ve patients	Positive	0	0.0
	Negative	58	18.4
	not tested	257	81.6
smear result at 7th month for PTB +ve patients	Positive	0	0.0
	Negative	53	16.8
	not tested	262	83.2
Year of treatment	September 2012-August 2013	106	33.7
	September 2013-August 2014	84	26.7
	September 2014-August 2015	90	28.6
	September 2015-August 2016	35	11.1
Treatment outcome	Cure	54	17.1
	Completed therapy	206	65.4
	Failure	24	7.6
	Default treatment	11	3.5
	Dead	20	6.3

Table 2: Clinical characteristics of TB patients in Nekemte Referral Hospital, West Ethiopia, September 2012-August 2016.

Characteristics		Cure	Completed therapy	Failure	Default treatment	Died	Total
Sex	Female	25	110	13	5	10	163
	Male	29	96	11	6	10	152
Age	<15	1	21	1	0	1	24
	15-29	34	97	3	7	5	146
	30-44	16	63	2	4	8	93
	≥ 45	3	25	18	0	6	52
Residence	Urban	53	192	23	11	20	299
	Rural	1	14	1	0	0	16
Tuberculosis type	Smear positive PTB	51	10	3	3	1	68
	Smear negative PTB	1	77	12	7	10	107
	Extrapulmonary TB	2	119	9	1	9	140
Patient category	New cases	44	178	12	7	15	256
	Retreatment cases	5	6	8	4	2	25
	Transfer in	5	22	4	0	3	34
Year of treatment	Sept 2012-Aug 2013	21	67	5	5	8	106
	Sept 2013-Aug 2014	15	55	7	2	5	84
	Sept 2014-Aug 2015	13	60	8	3	6	90
	Sept 2015-Aug 2016	5	24	4	1	1	35

Table 3: Treatment outcomes of TB patients by patient characteristics in Nekemte Referral Hospital, West Ethiopia, September 2012-August 2016.

Variables	Categories	Treatment outcome of TB		COR (95% CI) P value	AOR (95% CI) P value
		Successful	Unsuccessful		
Age	< 15	22	2	1	1
	15-29	131	15	1.3(0.3-5.9) P=0.769	0.9(0.2-4.3) P=0.872
	30-44	79	14	1.9(0.4-9.2) P=0.400	1.4(0.3-6.7) P=0.705
	≥ 45	28	24	9.4(2.0-44.3)P=0.004	7.1(1.5-34.3)P=0.014
Weight	<20	11	1	1	---
	20-29	7	0	0.0(0.0) P=0.999	---
	30-39	13	7	5.9(0.6-55.9)P=0.120	---
	40-49	101	26	2.8(0.4-22.9)P=0.329	---
	50-59	85	12	1.6(0.2-13.1)P=0.686	---
	60-69	33	7	2.3(0.3-21.1)P=0.451	---
	≥ 70	10	2	2.2(0.2-28.1)P=0.544	---
Tuberculosis type	Smear positive PTB	61	7	1	1
	Smear negative PTB	78	29	3.2(1.3-7.9) P=0.010	3.4(1.2-9.5) P=0.023
	Extrapulmonary TB	121	19	1.4(0.5-3.4) P=0.504	2.0(0.7-6.1) P=0.202
Treatment regimen	RHZE/RH	242	46	1	---
	RHZES/RHE	18	9	2.6(1.1-6.2) P=0.028	---
Patient category	New cases	222	34	1	1
	Retreatment cases	11	14	8.3(3.5-19.8) P<0.001	12.0(4.2-34.4)P<0.001
	Transfer in	27	7	1.7(0.7-4.2) P=0.255	1.7(0.6-4.5) P=0.316

Table 4: Logistic regression analyses of factors associated with treatment outcome in TB patients at Nekemte Referral Hospital, West Ethiopia, September 2012-August 2016.

HIV co-infection in this group of patients, which may decrease the treatment success and increase mortality.

This study also showed that the patients with age of ≥ 45 years had significantly ($p=0.014$) low TB treatment outcome. This finding is similar to other studies done in Tigray [15] and southern region [23]. 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 [25,26].

Retreatment cases also showed that significant association ($P<0.001$) with poor treatment outcome. The poor treatment outcome of TB patients obtained in this study was similar with a study done in Tigray [15], Gondar [16] and southern region [23]. High proportion of poor outcome in retreatment cases in this study might occur due to sub-optimal therapy and drug resistance.

This study did not show differences in treatment outcome for gender and residence, however a study done in southern region [23] 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 contribute to poor treatment outcomes and a study done in Dilla university referral hospital [24] 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.

Limitations 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.

Conclusion

Successful treatment outcome of TB patients in Nekemte Referral Hospital during our study was 82.5%. The unsuccessful treatment outcome was significantly associated with age, type of TB and patients

category thus, patients with older age, smear negative pulmonary TB and patients with retreatment cases requires attention to improve treatment outcome. 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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Competing Interests

No competing interests between authors.

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