INDONESIAN JOURNAL OF COMMUNITY HEALTH NURSING
Vol. 10, No. 1 February 2025
https://e-journal.unair.ac.id/IJCHN

TUBERCULOSIS TREATMENT OUTCOMES AND ASSOCIATED RISK FACTORS AMONG TUBERCULOSIS PATIENTS IN BULE HORA UNIVERSITY TEACHING HOSPITAL, SOUTHERN ETHIOPIA, 2021: RETROSPECTIVE CROSS SECTIONAL STUDY

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ARTICLE HISTORY

Received: 30 November 2024
Accepted: 10 January 2025

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ABSTRACT

Introduction: In Ethiopia Tuberculosis is the leading causes of morbidity. The incidence of all forms of TB in the Ethiopia was 379/100000 population which is the second on the Africa continent. There are high discrepancies in the result of treatment outcome being reported from the different region of the country with frequent poor treatment outcomes particularly from the southern Ethiopia. Thus, this study aims to assess tuberculosis treatment outcomes and associated factors among tuberculosis patients in Bule Hora University Teaching Hospital, Southern Ethiopia.

Methods: Facility based retrospective cross-sectional document review of 380 patients was conducted to assess the Tuberculosis treatment outcome and associated factors from tuberculosis patients' document registration. Data was entered into the computer using Epi-data software version 3.2 and exported to SPSS software version 25 for analysis. Bivariate and multivariate analysis with 95% confidence intervals were employed to infer associations between the independent and dependent variables.

Results: The documents of 380 tuberculosis patients were reviewed. Among this patients, 87.9% were successfully treated where as 12.1% of the patients were unsuccessfully treated. From this, 53.4% and 34.5% patients were cured and completed the treatment, respectively, where as 3.7%, 5.8%, and 2.6% patients were died, treatment failure, and defaulted, respectively during the follow-up. The age, year of treatment, the status of HIV, and patient categories were the factors that were significantly associated with TB treatment outcomes.

Conclusion: The Tuberculosis treatment outcome for the present study was 87.9%, which was lower than national target which was >96% and global target >90% which required improvement. Among 12.1% of unsuccessful TB treatment outcomes, 6.8% of them were HIV positive. The higher unsuccessful Tuberculosis treatment outcomes among HIV positive patients suggests the need to strengthen adherence education and supervision.

Keywords: *Bule Hora University Teaching Hospital, Tuberculosis, TB Treatment Outcomes, Southern Ethiopia*

Cite as:

Galgalo, Dawit. Et al. (2025). Tuberculosis Treatment Outcomes and Associated Risk Factors among Tuberculosis Patients in Bule Hora University Teaching Hospital, Southern Ethiopia, 2021: Retrospective Cross Sectional Study. *Indonesian Journal of Community Health Nurs.*, 10(1), 36-42. Doi: 10.20473/ijchn.v10i1.52090

INTRODUCTION

Globally one-third of the world population was infected with TB, every year TB affects 10million people. Every 15 seconds one person dies from TB comprising more than 2 million deaths annually (Bombarda, 2019). The Africa continent consists of 28% of the world's TB cases (Salinas, 2017). In Ethiopia TB is the leading cause of morbidity, the incidence of all forms of TB in Ethiopia was 379/100000 population, which is second from the African continent (Nemera, 2017). Tuberculosis was also the leading cause of hospital admission and the

second cause of death affecting more than 76000 people annually (Feleke, 2018).

Ethiopia is one of the 30 highest TB burden countries (HBCs) in the world. These HBCs account for approximately 87% of the total Global TB burden (Alene, 2017). Moreover, TB ranks sixth out of the top 10 causes of mortality in Ethiopia (Woldemichael, 2021). In 2015, the national case notification rate for all forms of TB was 67.3%, with a cure rate of 77.9%. One of the studies conducted in Oromia region Ethiopia revealed that the TB case notification rate was 65.4%. Unfortunately, this achievement is lower than the WHO targets for TB control of a 70% case notification rate and 85% cure rate (Megerssa, 2020).

In the Ethiopia, the prevalence, incidence, and mortality from TB are currently estimated at 200/100,000 people, 207/100,000 people, and 33/100,000 people, respectively (Tola, 2019). These indicators show that the TB burden in Ethiopia is still enormous and suggest that the National TB Control Program should be functioning very well to achieve significant reduction in morbidity and mortality resulting from TB (Gebreegziabher, 2016).

One of the key challenges in mitigating the mortality associated with TB is due to the barriers in getting access to health services, diagnosis and the adherence to treatment (Kliiman, 2009). Various factors such as economic barriers including the integration of TB services with health care system, number of visits, cost of seeking care plays a critical role in determining the access (of health services), diagnosis (of TB) and adherence of treatment regimen (Abeba, 2021). These barriers are further augmented by the complex geographical terrain and the factors embedded in social and cultural context (Marahatta, 2020).

The results from this study will be important input for policy makers, health planners and decision makers. Additionally, this study will provide appropriate information for the different health institution which exists in Guji zone particularly for Guji zone health department and Bule Hora University teaching hospital to make decision and implement appropriate intervention on prevention and management of tuberculosis. Additionally, the result of this study will be used as baseline data for other researchers who want to study TB treatment outcome and associated factors among TB patients. Finally, this study will expand literature and build existing knowledge regarding TB treatment outcome and associated factors among TB patients (Yesypenko, 2018).

Even though, there are some improvements in terms of TB treatment success and case detection rate the patient outcomes of TB treatment has been different in different parts of Ethiopia (Molie, 2019). In Ethiopia TB treatment outcome and associated factors related research work is scarce and particularly there was no such study conducted in the south parts of the Ethiopia (Belachew, 2019). Therefore, the aim of this study was to assess TB treatment outcome and factors associated among TB patients in Bule Hora University teaching hospital, southern Ethiopia.

METHODS

Study Area and Period

The study was conducted at the Bule Hora Teaching Hospital. Bule Hora Teaching Hospital has six wards (pediatric ward, Neonatal Intensive Care Unit, Obstetrics and Gynecology ward, surgical ward, Burn Unit, Medical Ward and MDR-TB Center) with approximately 118 beds. It has four OPDs (emergency, dental, ophthalmic and psychiatric OPD). The Bule Hora General Hospital also provides ART, pharmacy services, antenatal care, and delivery service to nearby communities. The study was conducted on the TB treatment outcome and associated factors among TB patients in Bule Hora University teaching hospital from Janury1-30, 2021.

Study Design

Institution based retrospective cross-sectional document review was conducted to assess the treatment outcome of TB patients and the associated factors of TB patients' documents registered from January 1, 2015, to December 31, 2019, in Bule Hora University teaching hospital .

Population

Source population: The documents of all TB patients who were registered in the hospital from the 1st of January, 2015, to December 31st, 2019.

Study population: The documents of the randomly selected TB patients who were registered in the Bule Hora Teaching hospital from the 1st of January, 2015, to December 31st, 2019.

Inclusion and Exclusion Criteria

Inclusion criteria

The documents of the registered TB patients in Bule Hora University teaching hospital were included in this study.

Exclusion Criteria

However, registries in which treatment outcomes were missing and patients were transferred to other districts were excluded from the study.

Study Variables

Dependent variables

Treatment outcomes are categorized into successful and unsuccessful treatment outcomes. Successful treatment outcomes included "cured" and "treatment completed" cases. Unsuccessful treatment outcomes included "treatment failure" cases, "defaulters," and patients who "died.

Independent variables

Socio-demographic factors: Sex, age, place of residence, place of residence, and year of treatment.
Clinical factors: Category of patient types of TB, Smear result, HIV status, ART initiated, CPT initiated, smear result after 2 months, smear result after 5 months, and smear results after 7 months, Anti-TB Drug on Intensive phase, Anti-TB Drug on continuation phase.

Sample Size Determination

For the first objective, the sample size was calculated by using a single population proportion formula based on the assumption of TB Treatment Outcomes in Metema Hospital of 65.3% (P) was used in this case.

Where;

P = TB Treatment Outcomes (65.3%).

Z = standard score corresponds to1.96.

d = margin of error 0.05 with a 95% confidence interval was used.

$$\frac{z^2(1-\alpha/2)p(1-P)}{d^2} = \frac{(1.96)^2 * 0.653 * 0.347}{(0.05)^2} = 349$$

The final sample size for this study with 10% non-response rate is a total of 384 patients' the registry reviewed.

Finally, the sample size of 384 obtained from the first specific objective was used, because it is the largest sample size estimated and would be sufficient for study.

Sampling Technique

Totally 380 TB patients documents reviewed from January 1st, 2015, to December 31st, 2019, in Bule Hora University teaching hospital. The registries which met the inclusion criteria were selected through a systematic sampling technique. This sampling interval (K) was obtained by dividing the total TB patients by its sample size (k =1869/940=1.99 ~2. The 1st sample was taken by lottery method from 1; then the data were collected from the registration log book.

Operational Definition

Successful outcome: if the TB patient will be cured (negative smear microscopy at the end of the treatment and on at least one previous follow-up test) or completed treatment with resolution of symptoms.

Unsuccessful outcome: if the treatment resulted in treatment failure (remaining smear positive after 5 months of treatment), patients are defaulted (patients who interrupted their treatment for two consecutive months or more after registration), or patients died. According to the standard definitions of the National Tuberculosis and Leprosy Control Program guidelines of Ethiopia, the following definitions were used for treatment outcomes (Van, 2020).

Cured: if the patient had finished treatment with negative bacteriological results at the end of the treatment.

Treatment completed: if the patient had finished treatment, but without bacteriological results at the end of the treatment.

Treatment failure: a patient who, while on treatment, remained smeary positive or became again smear positive at the end of five months or later after commencing treatment or a patient who was PTB negative at the beginning and turned out smear positive at the end of the intensive phase.

Defaulter: a patient who had been on treatment for at least 4 weeks and whose treatment was interrupted for 8 or more consecutive weeks.

Died: if the patient died from any cause during the treatment.

New case: a patient who had never had treatment for TB or had been on anti-TB treatment for less than four weeks.

Three types of TB were considered in this study. These are smear positive pulmonary TB (PTB+), smear negative pulmonary TB (PTB-), and extrapulmonary TB (EPTB).

Smear positive pulmonary TB (PTB+): a patient who had at least 2 initial smear examinations positive for AFB by direct microscopy or one initial smear examination positive and culture positive or one initial smear positive and radiographic abnormalities consistent with TB.

Smear negative pulmonary TB (PTB-): a patient who had three initial smear examinations negative for AFB and no response to the course of broad-spectrum chemotherapy and again 3 smear examinations negative by direct microscopy and radiographic abnormalities consistent with PTB and three initial smear examinations negative by direct microscopy but positive by culture and decision by a clinician to treat with anti-TB

extra pulmonary TB (EPTB): a patient who had TB in organs other than the lungs proven by one culture-positive specimen from extra pulmonary sites or histopathological evidence from a biopsy or TB based on strong clinical evidence for active EPTB and the decision by a physician to treat with anti-TB.

Data collection tools and technique and data quality assurance

The standard TB registry, laboratory findings, and monthly cohort follow-up form were reviewed to generate the required data. The standardized checklist was used including all important socio-demographic data, clinical characteristics (sputum smear, type of TB, patient type, HIV status, drug regimen, and treatment outcomes), laboratory findings, and follow-up data.To improve the quality of the data, the questionnaire was pretested a week before the actual data collection time on a 5% sampled unit in a Qarca hospital and modification was done accordingly. The supervisor and data collectors were trained for two days before data collection. The proper supervision of data consistency and completeness was undertaken throughout the data collection and analysis.

Data processing and analysis

Data was entered into the computer using Epi-data software version 3.2 and exported to SPSS software version 25 for analysis. Appropriate descriptive statistics such as mean (with standard deviation), median (with interquartile range [IQR]), and frequency (with percentages) were used to describe the study population in relation to relevant variables. Bivariate and multivariate analyses with 95% confidence intervals were employed to infer associations between the independent and dependent variables. Binary logistic regression was used to calculate the crude odds ratio (COR) with a 95% confidence interval. Each variable was entered into a logistic regression model to determine the presence of a statistically significant association with the outcome variable. Multicollinearity among selected independent variables was checked through variance inflation factor (VIF). The assumption on the fitness of goodness of the final model was checked by Hosmer and Lemeshow test.

Ethical consideration

This study was conducted in accordance with the research ethics of the University of Bule Hora. Ethical clearance was obtained from the institutional ethical review board of the University of Bule Hora. As this is a retrospective study, the consent of patients was not obtained. However, patient information has been handled anonymously with assuring confidentiality.

RESULTS

Socio-Demographic Characteristics of the Participants

In this study, the total 380 TB patient registration logbook of five years was reviewed with a 99% response rate. The reviewed document indicated that from the total 380 TB patients received anti-TB drugs, 52.90% were male whereas 47.10% of the patient were female. The majority (51.10%) of the patient was found between the age group of 20-40 years with a standard deviation of 17.78(Table 1)

Table 1: Socio demographic status of TB treatment outcome and associated factors in Bule Hora University teaching hospital, Ethiopia 2021

Variables	Categories	Frequency	Percent%
Respondent Sex	Male	201	52.90
	Female	179	47.10
Respondent Residence	Urban	243	63.90
	Rural	137	36.1
Age Of Patient	<20	150	39.50
	20-40	177	46.60
	>40	53	13.90
Year Of Treatment	2016	1	0.30
	2017	122	32.10
	2018	138	36.30
	2019	119	31.30
HIV Status	Positive	26	6.80
	Negative	354	93.20
Patient Category	New Case	356	93.70
	Re Treatment	24	6.30
Types Of TB	Pulmonary TB	347	91.30%
	Extra PTB	33	8.70%
Smear Result	Smear Positive	232	61.10%
	Smear Negative	148	38.90%

Tuberculosis Treatment Outcome

In the review of the document of 380 TB patients, 87.9% were successfully treated whereas 12.1% of the patients were unsuccessfully treated. From this, 53.4% and 34.5% of patients were cured and completed the treatment, respectively, whereas 3.7%, 5.8%, and 2.6% of patients died, treatment failure, and defaulted respectively during the follow-up.

Factors Associated With Tuberculosis Treatment Outcomes

The binary logistic regression was carried out to determine the factors associated with TB treatment outcome. The variables which had significance at the level of p<0.25 in the simple binary logistic regression were entered into the multiple binary logistic regression model. Finally, the variables which were still significant at the level of p<0.05 in the final model were taken as factors that were significantly associated with the outcome variables.

The four variables which were significant in the first model were still significant in the final model. Thus, the age of the patient, year of treatment, the status of HIV, and patient categories were the factors that were significantly associated with TB treatment outcome in the final model.

The patients between the age group of 20-40 were 83% less likely to have a successful TB treatment outcome than the patients with an age group of fewer than 20 years [AOR;0.17, 95%CI(0.04,0.76)].

The tuberculosis patients who were screed positive for HIV/AIDS were 86% less likely to had a successful TB treatment outcome than HIV/AID negative patients [AOR; 0.24, 95%CI (0.08, 0.70)]

The patients who were registered for tuberculosis treatment in 2010 had four times successful TB treatment outcomes than the patients who were registered in 2012 [AOR; 4.19, 95%CI (1.30, 9.57) (Table 2)

Table 2: the factors that are significantly associated with TB treatment outcome using bivariate and multivariate logistic regression

		TB treatment outcome		COR (95% CI)	AOR (95% CI)
Variables		Successful	Unsuccessful		
		N (%)	N (%)		
Age of patient	<20	147(43.60)	3(7.00)	I	I
	20-40	156(46.30)	21(48.80	0.76(0.38,1.54)	0.17(0.04,0.76)
	>40	34(10.10)	19(44.20)	0.03(0.01,0.13)	0.02(0.05,0.11)
HIV status	negative	321(95.30)	33(76.70)	I	I
	positive	16(4.70)	10(23.30)	0.16(0.06,0.39)	0.24(0.08,0.70)
patient category	new case	323(95.80)	33(76.70)	0.14(0.05,0.34)	0.31(0.10,0.92)
	re treatment	14(4.20)	10(23.30)	I	I
year of treatment	2010	117(34.70)	5(11.60)	3.37(1.19,9.60)	4.19(1.30,9.57)
	2011	116(34.40)	22(51.20)	0.76(0.38,1.54)	0.59(0.26,1.35)
	2012	104(30.90)	15(34.90)	I	I

Abbreviations: AOR, adjusted odd ratio; CI, confidence interval; COR, crude odd ratio; HIV, human immunodeficiency virus

DISCUSSION

This was a preliminary study conducted on the TB treatment outcome and associated factors in the Bule Hora Teaching hospital on tuberculosis patients who were enrolled and had taken Ant- TB drugs from 2017 to 2019. In the study, the prevalence of successful TB treatment outcomes was 87%. This finding was controversial than the national estimates of the Ethiopian Ministry of Health which indicates a 96% of TB treatment success rate (Megerssa, 2020). The result of this study is lower than the study conducted in Harar Hospital which showed that The overall rate of treatment success among the patients was 92.5% and higher than the study conducted at Woldia General Hospital [80.7%], Metema Hospital[65.3%], Gimbi Town health facility [74%], Afar Region [81.8%]and Pakistan [66%]. The difference may be due to the period and place the studies were conducted as well as the setting in which the studies had been performed (Jemal, 2015). However, the result of current studies was similar to the study conducted in the Tigray region [87%] Bale zone [87.8%] had a successful treatment outcomes (Study, 2020). The results of this study found that 3.7%, 5.8%, and 2.6% of patients died, treatment failure, and defaulted respectively during the follow-up. This finding was nearly the same as the study conducted in Metema Hospital that indicated the overall death, defaulter, and failure rates among the study participants were (3.0%), (3.3%) and (0.7%) respectively (Jemal, 2015). However, this finding is different from the study conducted in Pakistan that showed that 51.2% were defaulters, 22% were failure

cases, and 26.8% of patients died during treatment (Akhtar, 2011).

In this study, the majority of cases were new cases [93.7%] and pulmonary TB [91.3%], whereas re-treatment and extra-pulmonary TB were 6.3% and 8.7% respectively. The tuberculosis patients who were screed positive for HIV/AIDS were 86% less likely to have a successful TB treatment outcome than HIV/AID negative patients. This is the same to the study conducted in Woldie General Hospital that demonstrated Human Immunodeficiency Virus negative tuberculosis patients were 3.9 times more likely to have a successful treatment outcome than HIV positive tuberculosis patients and the study conducted to the Matema Hospital that showed co-infection with HIV were independent predictors for poor treatment outcomes (Jemal, 2015). This finding was similar to the study conducted in Gimbi and Afar region that demonstrated co-infection with HIV were independent predictors for poor treatment outcomes (Nemera, 2017). The patients between the age group of 20-40 were 83% less likely to have a successful TB treatment outcome than the patients with an age group of fewer than 20 years [AOR;0.17, 95%CI(0.04,0.76)]. This finding is similar to a study conducted in the Bale Zone (Woldemichael, 2021).

CONCLUSION

In the review of the document of 380 TB patients, 87.9% were successfully treated whereas 12.1% of the patients were unsuccessfully treated. From this, 53.4% and 34.5% of patients were cured and completed the treatment, respectively, whereas 3.7%, 5.8%, and 2.6% of patients died, treatment failure, and defaulted respectively during the follow-up. The patients between the age group of 20-40 were 83% less likely to have a successful TB treatment outcome than the patients with an age group of fewer than 20 years. The tuberculosis patients who were screed positive for HIV/AIDS had poor TB treatment outcomes. The patients who were registered for tuberculosis treatment in 2017 had four times successful TB treatment outcome than the patients who were registered in 2019. The proportion of patients with successful treatment outcomes was lower than the WHO target that was set to end TB strategy, which was 90%. This finding was controversial than the national estimates of the Ethiopian ministry of health which indicates 96% of TB treatment success rate. Thus, public health facilities and the health department of Communicable Disease Control in the West Guji Zone may need to develop strategies to address new TB cases, while adhering to treatment and supporting health workers who work at health posts. Furthermore, it is recommended that these factors are studied using a strong study design and primary data.

LIMITATION OF THE STUDY

The study was a cross-sectional in its design which makes it impossible to determine the causal relationship between TB treatment outcomes and associated factors. The document review measurements that were used might also have inherent biases and the potential for incompleteness of certain data. Despite these limitations, the result of this study is important to give important clue for researches in similar population.

ACKNOWLEDGEMENTS

We would like to express our gratitude to Mr. Boko Loka and Dr. Safayi Elema for their ongoing contributions to the creation of this research thesis. Our sincere gratitude and appreciation are also extended to the study participants, the hospitals engaged in the study, as well as my family and friends, all of whom contributed valuable information and resources to the thesis preparation process.

ETHICAL APPROVAL AND CONSENT TO PARTICIPATE

This study was conducted in accordance with the research ethics of the University of Bule Hora. Ethical clearance was obtained from the institutional ethical review board of the University of Bule Hora. As this is a retrospective study, the consent of patients was not obtained. However, patient information has been handled anonymously with assuring confidentiality.

DECLARATION OF CONFLICTING INTERESTS

Regarding the research, writing, and/or publication of this paper, the authors reported that they had no potential conflicts of interest.

FUNDING

For their research, writing, and/or publication of this work, the authors got no financial assistance.

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