Abstract

Background: Monitoring the outcome of tuberculosis (TB) treatment and investigating factors associated with unsuccessful outcome are essential, as unsuccessful treatment fuels resistance to antibiotics. This study aimed to investigate the treatment outcome and associated factors with an unsuccessful outcome at Jimma University Medical Center (JUMC), Southwest Ethiopia. Methods: A 5-year retrospective analytical study, including all types of TB cases who sought care at JUMC between September 1, 2012, and August 31, 2017, was conducted. Treatment outcomes and TB types were categorized according to the National TB Control guideline. Bivariate analysis was used to analyze the association between treatment outcome and potential variables. Results: Overall data from 1249 patients’ records were included in the study. The proportion of male patients was higher (815, 65.3%) than that of females. The mean age (± standard deviation, range) of the cases was 26 (±11.6, 1–71) years. Of the total, 292 (23.3%) were smear-positive pulmonary TB (PTB), 489 (39.2%) smear-negative PTB, and 468 (37.5%) extra-PTB (EPTB) cases. Available treatment outcomes indicate that 253 (20.2%) were cured, 850 (68.0%) completed therapy, 58 (4.8%) died, 83 (6.6%) defaulted, and 5 (0.4%) failed the therapy. About 76 (5.6%) cases were transferred out and 44 (3.2%) cases were lost to follow-up. In total, 146 (11.7%) patients had an unsuccessful outcome. Unsuccessful treatment outcome was associated with smear-negative PTB (odds ratio [OR] = 2.0, 95% confidence intervals [CI] = 1.1, 3.7), EPTB (OR = 2.1, 95% CI = 1.2, 3.4), and unknown human immunodeficiency virus (HIV) status (OR = 7.9, 95% CI = 2.5, 25.0). Conclusion: The treatment success rate of overall TB patients is lower than end TB Strategy target of ≥90% success rate. Smear-negative PTB, EPTB cases, and those with unknown HIV status tend to have unsuccessful outcome.

Keywords: Jimma University Medical Center, treatment outcomes, treatment success rate, tuberculosis, tuberculosis trends

Introduction

Tuberculosis (TB) remains the second leading cause of morbidity and mortality from an infectious disease, after human immunodeficiency virus (HIV) worldwide.[1] In 2017, there were an estimated 10.4 million incident TB cases and 1.6 million deaths, including 0.3 million individuals living with HIV/AIDS.[2] About 87% of TB incident cases were occurring in 30 high-TB burden countries. Ethiopia ranked 10th among these countries with an estimated TB incidence of 172/100,000 population.[2]

A study evaluate the treatment outcome of the patients in Pakistan revealed that the overall prevalence of 42.19% smear-positive pulmonary TB (PTB), 35% smear-negative PTB, and 22.7% extra-PTB (EPTB) with 94.9% treatment success rate (TSR).[3] Moreover, the cure rate of 61 children with non-TB mycobacterial lymphadenitis following complete lymph node excision was 54%.[4]

Unsuccessful treatment outcome in TB patient is associated with many risk factors that are likely vary depending on the local settings and contexts. A study in Bulgaria showed that sputum smear positivity and weight loss were positively associated with TB death. In Ethiopia, unknown HIV status
and smear-negative TB patients started on empiric TB treatment were also associated with unsuccessful outcome.\(^5\)\(^-\)\(^7\) Moreover, in Somalia study revealed that marital status, level of education, coinfection with HIV, treatment category, and knowledge of study patients on TB transmission were associated with unsuccessful outcome.\(^8\)

In Ethiopia, TB has long been recognized as a common public health problem since the 1950s,\(^9\) and the country have been implementing the World Health Organization (WHO) recommended directly observed treatment short-course (DOTS) strategy since 1992.\(^10\) However, still, there were an estimated 25,000 TB deaths with a rate of 24/100,000 populations.\(^2\) In addition, Ethiopia is facing a challenge of growing number of estimated 2700 multidrug-resistance TB among notified PTB cases.\(^2\)\(^,\)\(^11\) Therefore, assessment of TB treatment outcomes and evaluation of its risk factors are important for stakeholders working to monitor the performance of the National TB Control Program. However, there is no similar report among TB patients registered for DOTS in Jimma University Medical Center (JUMC). The aim of this study was to determine treatment outcome and associated factors of unsuccessful outcome among TB patients at JUMC, Southwest Ethiopia.

**Methods**

**Study setting**

The study was conducted at JUMC, a tertiary teaching medical center located in Jimma town, 352 km Southwest of Addis Ababa. It is the largest medical center in Oromia regional state with over 500-inpatient beds and over 15 million catchment populations. The University Medical Center served about 15,000 inpatients, 160,000 outpatient visits, and 11,000 emergency cases.\(^1\)\(^2\)\(^,\)\(^12\) All pulmonary and extrapulmonary samples collected from TB suspected patients were examined for Mycobacterium TB (MTB) at the Mycobacteriology Research Center (MRC) of Jimma University, which is established as part of an inter-university collaborative research project between the Jimma University and a consortium of Flemish Universities from Belgium.

Sputum specimen positive for acid-fast bacilli by smear microscopy and/or Gene Xpert MTB/RIF assay was known as smear-positive PTB patients. Some extra-pulmonary specimens of lymph nodes and plural tissues diagnosed by Gene Xpert MTB/RIF assay and give positive results were recorded as smear-positive EPTB. In addition, EPTB was diagnosed by the histopathological test. Smear-negative PTB patients were diagnosed on the bases of clinical sign and symptoms and chest X-ray diagnosis. All TB diagnosed patients were referred to the TB-antiretroviral therapy Clinic of JUMC for the initiation of TB treatment. Under the routine DOTS program, TB drug was provided charge free by nurses for 6 months, and the nurses were supervised the patients three times in a week during the intensive phase and once in a week during a continuation phase until they completed their treatments. The treatment outcome was monitored based on direct sputum smear microscopy results at month 5 or later during treatment for pulmonary-positive patients. Smear-negative PTB and EPTB patient’s treatment outcome were measured based on clinical evaluation in between and at the end of the treatment course.

**Study design and population**

A retrospective record review study using routine program data was conducted. All types of TB diagnosed patients consecutively registered in the TB treatment center at JUMC between September 1, 2012, and August 31, 2017, and who have full recorded information during the time of data collection were included in this study.

**Data collection procedure**

Data were obtained from the TB registers. The recorded information by clinicians or nurses on a TB register was extracted using extraction sheet by the study investigators to capture details on the study variables (demographic and treatment outcome). The patient information from TB registers was compared with laboratory registration logbooks for its completeness. Loss to follow-up patients was not included in the analysis because their treatment outcome was not known. Treatment outcomes were interpreted in accordance with National TB algorithm definitions adopted from the WHO 2007 guideline.\(^13\) Data were collected from July to August 2017.

**Study variables**

The independent variables included age, sex, types of TB diagnosed, patient’s workplaces, and HIV status. The prevalence of all forms of TB, outcomes and risk factors for unsuccessful outcomes were possible outcome variables.

**Data management and analysis**

Data were double entered into a Microsoft Excel, cleaned to check for consistency and completeness. For analysis, the data were exported to SPSS statistics version 20 software International Business Machines Corporation (IBM), Armonk, New York, USA. Descriptive statistics, including mean, ranges, and proportions, were used to summarize the data. A treatment outcome was stratified by forms of TB to calculate and compare it with each TSR. To explore the risk factors associated with unsuccessful outcomes, binary logistic regression models were fitted with having unsuccessful treatment outcomes versus those having successful treatment outcomes as the outcome variables. Crude odds ratios (COR) with 95% confidence intervals (CI) were calculated for comparison. A significance level of 0.05 was set for all statistical testing.

**Operational terms**

Definitions for the grouping were based on the standard definitions of National TB Control Program guidelines implementing for TB control in Ethiopia\(^1\)\(^4\) adopted from the WHO 2007 guideline. The following clinical case and treatment outcome operational terms were used:

- Smear-positive PTB: A patient with two positive direct smear microscopy results or one positive direct smear microscopy result or one positive direct sputum Gene Xpert MTB/RIF result for MTB
• Smear-negative PTB: A patient with two negative sputum smear microscopy results, chest X-ray imaging showing lesions of active PTB and one of the respiratory TB symptoms: cough for >2 weeks, weight loss, fever, and hemoptysis
• EPTB: A patient with lesions of TB confirmed by histopathological examination in extra-pulmonary tissues. However, a patient with positive extra-pulmonary specimens by Gene Xpert MTB/RIF assay for MTB, but negative sputum smear result is reported as smear-positive EPTB cases.

Treatment outcomes
According to the National TB Control Program guideline in Ethiopia,[11] treatment outcomes were categorized into successful outcome (cured and completed treatment) and unsuccessful outcome (death, failure, defaulted, and transferred out) [Table 1].

RESULTS
Participant's baseline characteristics
A total of 1369 TB patients was diagnosed and registered for TB treatment in the TB treatment center at JUMC from September 1, 2012, to August 31, 2017. Of those, 1249 (91.2%) TB patients were included in the analysis, but for 120 cases treatment outcomes were not available. Flowchart showing types of TB diagnosed and HIV status of the patients at the end of the treatment in Jimma and its surroundings is described in Figure 1.

The majority 815 (65.3%) were males. The mean age (± standard deviation, range) of the patients was 26 (±11.6, 1–71) years. More than half, 674 (54.0%) of the cases were between 15 and 24 years of age. The majority, 781 (62.5%) of types of TB diagnosed were PTB and 468 (37.5%) were EPTB. In each of the years, between 3.7% and 12.5% of registered TB cases working places were in any of health facilities in Jimma and its surroundings. During the 5 years, 134 (10.7%) of registered TB patients were diagnosed HIV-positive. The number and proportion of the patient’s characteristics by years are shown in Table 2.

Trends in prevalence, types of tuberculosis diagnosed, and human immunodeficiency virus infection
The prevalence of all forms of TB among patients registered for TB treatment at JUMC was less fluctuated over the 5 years from 16% to 26.7%. The lowest prevalence of all forms of TB, 200 (16%) were documented between September 1, 2014, and August 31, 2015.

Smear-positive PTB was observed in 292 (23.3%), smear-negative PTB in 489 (39.2%), and EPTB in 468 (37.5%). Of the EPTB, 449 (95.9%) and 19 (4.1%) cases were diagnosed on the pathological basis and Gene Xpert MTB/RIF assay, respectively. The proportion of types of TB diagnosed in the course of the 5 years remained stable with small variations in percentage. The trends and distribution of TB types diagnosed in the treatment center at JUMC during the 5-year period are described in Figure 2.

HIV/TB coinfection showed decrements from 34 (16.2%) to 20 (9.2%) from September 1, 2012 to September 1, 2015,

| Table 1: Summary of the treatment outcome definitions used in this study |
|---|
| Terms | Definitions |
| Cured | PTB (+) patients who have completed full course of treatment and have two consecutive negative smear results including one after completion of therapy |
| Completed | PTB (−) patients who completed the prescribed course of treatment and have a negative sputum smear microscopy result or do not receive smear examination after completion of therapy |
| treatment | PTB (+) patients who completed the prescribed course of treatment, and do not receive smear examination after completion of therapy |
| Failed | EPTB patients who completed the prescribed course of treatment and physicians/nurses assessed the absence of the detailed clinical information about sign and symptoms |
| Died | PTB (+) patients with positive sputum smear microscopy results at month 5 or later during treatment |
| Defaulted | PTB (−) patients clinically diagnosed for TB symptoms and conversion to sputum smear positive during treatment |
| Transferred | PTB (+) patients who are clinically diagnosed with sign and symptoms, and positive histopathological test results during treatment |
| out | Died | The outcome was recorded as “death,” if the cases died from any cause during the treatment |
| Defaulted | Patients whose treatments were interrupted for two consecutive months or more after starting treatment |

TB: Tuberculosis, PTB (+): Smear-positive pulmonary TB, PTB (−): Smear-negative pulmonary TB, EPTB: Extra-pulmonary TB
respectively. However, it increased to 33 (9.9%) in the year from September 1, 2016, to August 31, 2017.

**Treatment outcomes**

Among all TB diagnosed patients, 253 (20.2%) were cured, 850 (68.0%) treatment completed, 58 (4.8%) died, 5 (0.5%) failed treatment, and 83 (6.6%) defaulted. The rate of defaulters reported in smear-negative PTB and EPTB during the 5 years accounted for 43 (8.8%) and 38 (8.1%), respectively. Deaths were documented in all of the three forms of TB, and the proportion was low in smear-positive PTB patients 4 (1.6%). During the 5-year period, 76/1369 (5.6%) TB cases were transferred out to other health facilities, but their treatment outcome was not known.

The overall TSR observed was 88.3%. The trend of TB treatment outcome among types of TB diagnosed cases registered at JUMC is presented in Table 3.

**Factors associated with treatment outcome**

In all, 1103 patients (88.3%) had a successful treatment outcome, 146 patients (11.7%) had unsuccessful treatment outcome. In all types of TB diagnosed patients, there was no difference in gender with respect to treatment outcomes of male and female (65.3% vs. 34.7%, \(P = 0.612\)).

There is no significant difference between TB patients without HIV infection (976/1103 [88.5%]) who had successful treatment outcome and TB patients coinfected with HIV 116/1103 (10.5%, \(P = 0.818\)). TB patients not tested for HIV 11/1103 (1.0%) had also shown successful treatment outcome. However, those patients not tested for HIV 5/16 (31.3%) were almost eight times more likely to have an unsuccessful treatment outcome than HIV-coinfected TB patients (COR 7.9; CI 95%: 2.5–25.0, \(P \leq 0.001\)).
Smear-negative PTB cases were two times more likely to have an unsuccessful treatment outcome compared with smear-positive PTB patients (COR: 2.0; CI 95%: 1.15–3.70, \( P = 0.016 \)). Factors associated with unsuccessful treatment outcomes were shown in Table 4.

**Discussion**

This study found that almost a similar trend in the prevalence of smear-positive PTB cases during the 5-years in this setting. The annual distribution of smear-positive PTB registered patients in this study is in agreement with the already known findings from Southern Ethiopia.\(^{14,15}\) However, lower than in Nigeria (85.8%).\(^{16}\) This low number of pulmonary smear-positive TB cases in this study might be due to the low sensitivity of smear microscopy and chest X-ray findings for the diagnosis of TB in this setting.

In this study, most of TB diagnosed patients were smear-negative PTB. The trends in the prevalence were almost remained stable throughout the past 5 years with some rare fluctuating patterns from year to year. More than one-third of the patients in this study were diagnosed with smear-negative PTB patients, and the highest percentage was registered in 2017. Similar findings were determined for the high prevalence of smear-negative PTB from South Africa, which is 46%.\(^{17}\) This similarity may be due to the fact that most of the presumptive PTB cases were diagnosed on the basis of clinical and radiological indicators. Furthermore, some suspected TB cases might be first diagnosed and transferred in from private health facilities;

### Table 3: Tuberculosis treatment outcomes and treatment success rate at the end of tuberculosis treatment at Jimma University Medical Center, Southwest Ethiopia (n=1249)

| Types of TB diagnosed | Treatment outcomes | Total | TSR of TB patients at JUMC |
|-----------------------|--------------------|-------|-----------------------------|
|                       | Cured              | Completed | Died | Failure | Defaulter | Successful | Unsuccessful |
| PTB (+), n (%)        | 253 (86.6)         | 31 (10.6) | 4 (1.6) | 2 (0.6) | 2 (0.6) | 292 | 284 (97.2) | 8 (2.8) |
| PTB (−), n (%)        | 0 (0.0)            | 409 (83.6) | 35 (7.1) | 2 (0.5) | 43 (8.8) | 489 | 409 (83.6) | 80 (16.4) |
| EPTB, n (%)           | 0 (0.0)            | 410 (87.6) | 19 (4.0) | 1 (0.3) | 38 (8.1) | 468 | 410 (87.6) | 58 (12.4) |
| Total, n (%)          | 253 (20.2)         | 859 (68.0) | 58 (4.8) | 5 (0.4) | 83 (6.6) | 1249 | 1103 (88.3) | 146 (11.7) |

TB: Tuberculosis, PTB (+): Smear-positive pulmonary TB, PTB (−): Smear-negative pulmonary TB, EPTB: Extra-pulmonary TB, TSR: Treatment success rate, JUMC: Jimma University Medical Center

### Table 4: Associated factors with unsuccessful treatment outcome in tuberculosis patients at Jimma University Medical Center, Southwest Ethiopia, stratified by treatment outcomes (n=1249)

| Variables                        | Successful outcome (n=1103), n (%) | Unsuccessful outcome (n=146), n (%) | Total (1249), n (%) | COR (95% CI) | \( P \) |
|----------------------------------|-----------------------------------|-----------------------------------|-------------------|--------------|--------|
| Gender                           | Male                              | 718 (65.1)                        | 97 (66.4)         | 815 (65.3) | 0.9 (0.6-1.3) | 0.612 |
|                                  | Female                            | 385 (34.9)                        | 49 (33.6)         | 434 (34.7) | R       |        |
| Age (years)                      | 0-14                              | 65 (5.9)                          | 13 (8.9)          | 78 (6.2)  | 0.7 (0.2-3.0) | 0.668 |
|                                  | 15-24                             | 606 (54.9)                        | 68 (46.6)         | 674 (54.0) | 0.4 (0.1-1.5) | 0.189 |
|                                  | 25-34                             | 263 (23.8)                        | 29 (19.9)         | 292 (23.4) | 0.5 (0.2-1.8) | 0.310 |
|                                  | 35-44                             | 71 (6.4)                          | 16 (11.0)         | 87 (7.0)  | 0.5 (0.2-2.3) | 0.477 |
|                                  | 45-54                             | 43 (6.4)                          | 5 (3.4)           | 48 (3.8)  | 0.5 (0.13-2.7) | 0.492 |
|                                  | ≥65                               | 43 (3.9)                          | 9 (6.2)           | 52 (4.2)  | 0.4 (0.08-2.0) | 0.285 |
| Patients workplaces              | Out of health facilities          | 992 (89.9)                        | 135 (92.5)        | 1127 (90.2) | 0.7 (0.4-1.3) | 0.293 |
|                                  | In any health facilities          | 111 (10.1)                        | 11 (7.5)          | 122 (9.8) | R       |        |
| Types of TB diagnosed            | PTB (+)                           | 284 (25.7)                        | 8 (5.5)           | 292 (23.3) | R       | -      |
|                                  | PTB (−)                           | 409 (37.0)                        | 80 (54.8)         | 489 (39.2) | 2.0 (1.13-3.7) | 0.016 |
|                                  | EPTB cases                        | 410 (37.1)                        | 58 (39.7)         | 468 (37.5) | 2.1 (1.2-3.4) | 0.013 |
| HIV status                       | Reactive                          | 116 (10.5)                        | 18 (12.3)         | 134 (10.7) | R       | -      |
|                                  | Nonreactive                       | 976 (88.5)                        | 123 (84.2)        | 1099 (88.0) | 0.9 (0.5-1.7) | 0.818 |
|                                  | Unknown                           | 11 (1.0)                          | 5 (3.4)           | 16 (1.3)  | 7.9 (2.5-25) <0.001 | -  |

Successful: Cured and completed, Unsuccessful: Defaulted and died, N: Total number of cases, COR: Crude odds ratio, CI: Confidence interval, R: Reference category, TB: Tuberculosis, PTB (+): Smear-positive pulmonary TB, PTB (−): Smear-negative pulmonary TB, EPTB: Extra-pulmonary TB, HIV: Human immunodeficiency virus
Therefore, the clinicians might abuse the low sensitivity of smear microscopy and might rush to diagnose presumptive TB cases as possible smear-negative PTB patients.\(^1\) This makes clear why the smear-negative PTB cases had unsuccessful treatment outcomes in this study.

Patients with sputum smear-negative results and unknown HIV status had worse treatment outcome compared with those who were sputum smear-negative and HIV-positive results, with treatment defaulter and death being the two main adverse events. In addition, this study clearly confirmed that the decrement in TB-HIV coinfection proportions in between September 1, 2012, and August 31, 2016. However, HIV prevalence was turned to rise to 9.9% in 2017. The overall HIV prevalence determined in this study was 10.7% for the last 5 years, which was lower than the findings of 16.9% in Nigeria.\(^16\) In this study, TB diagnosed patients with unknown HIV test result were almost eight times more likely to have an unsuccessful treatment outcome than HIV-positive TB patients. These findings are in line with other studies done elsewhere.\(^18\) Reasons for unsuccessful treatment outcomes probably associated with any presence of comorbidities (diabetes mellitus and other chronic disorders) that impair cell-mediated immunity, not only targeting the CD\(_4\) T lymphocytes as in the case with HIV infection but also by interfering with the function and activation of other immune cells.\(^19\)

The unsuccessful treatment outcome was significantly higher among smear-negative PTB patients and two times more likely than smear-positive PTB patients with the incidence of default (8.8%) was significantly higher compared with other study (0.8%) in other parts of Ethiopia,\(^20\) and in Pakistan, which was (2.6%).\(^21\) Therefore, specific measures are needed to improve compliance among TB patients in the study area, focusing on addressing the challenges in defaulters and promoting adherence.

In this study, there were lower TSR for TB cases in comparison with the End TB Strategy targeted by the WHO until 2025.\(^21\) On the other hand, high TSR was observed in this study than those of the findings from Gambella hospital (63.4%) and Gondar town (70.5%), both studies were reported from Ethiopia.\(^15,22\) This difference may be due to the fact that MRC in this setting has a greater involvement in accordance with functionality to provide training and access.

There were low transferred out proportions in this study. This finding was low in comparison with other findings, 17.12% and 13.8% in studies conducted in Gambella and Gondar University hospitals, respectively.\(^23,24\) This is probably due to the expansion of DOTS facilities in the region have contributed to this low number of transferred out cases in this study.

TB infection control has been a growing concern among health-care workers in developed countries,\(^20,25\) but it is a neglected problem among individuals working in health facilities in southwest part of Ethiopia. This study revealed that in each of the 5 years, between 3.7% and 12.5% of TB patients registered for DOTS at JUMC were working in any health facilities. The primary reason for this occupational TB infection may be due to low awareness and poor commitment to follow the effective implementation of infection control practices in their workplace setting.

The strengths of this study were the inclusion of data from large number of TB patients registered for routine conditions in JUMC from Jimma town and its surroundings for the last 5 years, which makes the results representative of the situation in the Southwest of Ethiopia. However, the study was not without pitfalls. The data were secondary and were sometimes missing from the register books as well as dataset; sputum status was based on smear-microscopy examination and Gene Xpert MTB/RIF rather than culture test.

**Conclusion**

The TSR of TB patients was lower than that of ≥90% End TB Strategy success rate targeted until 2025. The unsuccessful treatment outcome was documented more in smear-negative PTB patients, with death and defaulter being a major problem. It is evident that HIV infection turned to rising among TB patients in the area. Thus, early HIV and TB screening and antiretroviral treatment initiation should be strengthened.

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**Conflicts of interest**

There are no conflicts of interest.

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