Treatment Outcomes of Tuberculosis Patients at Bale Robe Hospital Oromia Regional State, Ethiopia: A Five Year Retrospective Study

Erdaw Tachbele1, Biruhalem Taye2, Begna Tulu3 and Gobena Ameni3*

1Department of Nursing and Midwifery, College of Health Sciences, Addis Ababa University, Ethiopia
2Aklilu Lemma Institute of Pathobiology, Addis Ababa University, Addis Ababa, Ethiopia
3Microbiology, Immunology and Parasitology Department, Bahir Dar University, Ethiopia

Abstract

Objective: Monitoring of tuberculosis treatment outcome is scarcely done in Ethiopia. This study investigated the outcomes of tuberculosis treatment at Bale Robe Hospital in Oromia, Ethiopia.

Methods: A retrospective analysis of the profile and treatment outcome of all tuberculosis patients registered from September, 2007 to August, 2012 at tuberculosis Clinic was conducted. Patients' socio-demographic, clinical, laboratory and treatment outcomes were extracted from registration document. Bivariate and multivariate logistic regression was used to determine treatment outcomes predictor variables.

Results: We analyzed treatment outcomes of 916 tuberculosis patients, of which 544 (59.6 %) were males. Of these 180 (19.7%) were cured, 536 (58.5%) were found completed their treatment, while 82 (9%) were died, in addition, 55 (6.0%) and 54 (5.9%) were defaulters and transferred out respectively. Overall, 716 (78.2%) had a successful and 200 (21.8%) a poor treatment outcome. Being female (AOR 1.23, P=0.05), HIV positive (0.48, P<0.001) and new TB patients (AOR 2.17, P=0.002) were significantly associated with treatment outcome. Patients with HIV co-infection (AOR 4.32, P=<0.001), smear negative pulmonary tuberculosis (AOR 2.00, P=0.05) and age ≥ 65 years (AOR 5.50, P=0.03) were more likely to experience death than their counter parts.

Conclusion: The treatment success rate of 78.2% tuberculosis patients was fairly good. However, a high proportion of patients (9%) death and 22.2% of HIV prevalence among TB patients is a serious public health concern that needs to be addressed urgently in the area.

Keywords: Treatment outcomes; Tuberculosis; DOTS; Bale robe; Ethiopia

Abbreviations: AFB: Acid Fast Bacilli, AOR: Adjusted Odds Ratio, CDR: Case Detection Rate, DOTS: Directly Observed Treatment, Short Course, GTB: Global Tuberculosis Programme, HBCs: High-Burden Countries, HIV: Human Immunodeficiency Virus, MDR: Multiple Drug Resistance, NTLCP: National Tuberculosis and Leprosy Control Program, TSR: Treatment Success Rate

Introduction and Background

Despite great effort is exerted globally to combat tuberculosis (TB), still it remains the major cause of mortality worldwide and accounts for 25% of all avoidable deaths in developing countries and 2.5% of the world diseases Burdon [1].

The WHO 2013 report indicated that Ethiopia stands eighth among the world’s 22 high tuberculosis Burdon countries [2]. Tuberculosis is the leading cause of morbidity, the third cause of hospital admission and the second cause of death in Ethiopia [3].

Without treatment, TB mortality rates are high. Natural history of disease studies showed that around 70% of sputum smear positive HIV-negative pulmonary TB cases died within 10 years , and 20% of culture positive (but smear negative) cases died within 10 years [4].

Since 1990 the WHO Global Tuberculosis Programme (GTB) has promoted the revision of national tuberculosis programmes to strengthen the focus on directly observed treatment, short-course (DOTS) and close monitoring of treatment outcomes. Patients treated by DOTS at the start of therapy had a significantly higher cure rate and decreased tuberculosis- related mortality compared with patients treated by self-administered therapy [5]. The implementation of DOTS and its subsequent surveillance system of treatment outcomes revealed 82% global treatment success rate in DOTS areas in comparison to only 67% in non-DOTS areas [6].

Routine recording and reporting of the numbers of TB cases diagnosed and treated by National Tuberculosis Programmes (NTPs) and monitoring of treatment outcomes was one of the five components of the global TB strategy (DOTS) launched by WHO in the mid-1990s and it remains a core element of its successor, the Stop TB Strategy [2], with set targets of 84% case detection rate (CDR) and 87% treatment success rate (TSR) by 2015. Between 1995 and 2012, 56 million people...
were successfully treated for TB in countries that had adopted the DOTS/Stop TB Strategy which saved approximately 22 million lives [2]. In 2011, the global treatment success rate was 87% among all new TB cases, except the European Region where the treatment success rate ranges from 65% for new smear positive cases to 72% for new smear negative cases [2].

In Ethiopia, Directly Observed Treatment, Short Course (DOTS), was started in 1992. Since then, the DOTS programme has been successfully scaled up in the country with a 100% geographical coverage, and 95% health facility coverage [3]. The implementation of DOTS in Ethiopia has been associated with high rate of successful treatment outcome and reduced development of drug resistance [7]. According to WHO report, in 2011 Ethiopia reported treatment success rate of 90% for new smear positive, 87% for smear negative/extra pulmonary, and 78% for retreatment cases with case detection rate of 64% [2]. In reference to the updated global TB plan (2011-2015) with a set targets of 87% treatment success rate and 84 case detection rate, Ethiopia achieved the treatment success rate but needs to work hard to reach the global plan of case detection rate.

Monitoring the outcome of treatment by cohort analysis of tuberculosis patients is essential in order to evaluate the effectiveness of DOTS program and serves as a proxy of quality of TB treatment in a health care system [7, 8]. In addition to this, understanding the determinant factors of unsuccessful treatment outcomes is crucial to improve the TB control system.

To this end, very few studies have reported treatment outcomes of DOTS in different parts of Ethiopia from 2005 to 2013 [7-18]. The studies conducted so far in different parts of the country (Southern region, Addis Ababa, Gambella and Northern region) documented different rate of treatment success rates ranging from 29.5% in Gondar, North west Ethiopia [15], to 89.2% in Tigray, Northern Ethiopia [17]. According to these studies, being male, older age, place of treatment, smear negative pulmonary TB, HIV positive, smear positive pulmonary TB at 2nd month follow up and retreatment cases were found to be the determinant factors of unsuccessful treatment outcomes [7, 8, 11, 13-20].

Although Ethiopia has fully implemented DOTS program across the whole nation, information on epidemiological cohort analysis of TB treatment outcomes, especially in Oromia National Regional State is severely lacking. Therefore, this study was designed to investigate the treatment outcomes of TB patients and assess the association of demographic and clinical factors with treatment success of patients enrolled in Directly Observed Treatment Short Course (DOTS) program in Bale Robe Hospital Oromia, Ethiopia over the course of five consecutive years (From Sep 2007 to Aug 2012).

**Methods**

**Study setting**

Bale Robe is a regional hospital serving the population of Robe town and that of South West Ethiopia. Thetotal population served by the hospital is about 569,707.In the hospital a Directly Observed Therapy; Short-Course (DOTS) clinic is operating under the National Tuberculosis and Leprosy Control Program (NTLCP) of Ethiopia, under which the diagnosis of pulmonary TB is followed by examination of three sputum smears by Ziehl-Nielsen staining method for acid fast bacilli (AFB). Chest radiographs and pathological investigations are also used to support the diagnosis. Patients diagnosed with tuberculosis are referred to the DOTS clinic where they are registered and treated according to the NTLCP guideline [3, 21].

**Study design and data collection**

Institution based retrospective analysis of the profile and treatment outcome of all tuberculosis patients (cohort) registered from September, 2007 to August, 2012 at DOTS Clinic was conducted. The registration documents reviewed contain patient's age, sex, residence, weight, Acid Fast Bacilli smear result at base line, HIV status, 2nd 5th and 7th months follow up AFB smear result and weight, treatment regimen, treatment started and completed dates and treatment outcomes. The required information was extracted from TB treatment log books (registration document) using structured data reviewing formats by the investigators.

**Dependent and independent variables**

**Dependent variables**: Treatment success (cured or completed treatment) and Unsuccessful treatment (either treatment failure, defaulter, died, or transferred out).

**Independent variables** for treatment outcomes were: TB Patients’ age, sex, weight, residence HIV status, type of TB, patient category at the start of treatment and AFB smear-positive at baseline, 2 month, 5 month and 7 months.

**Data management and statistical analysis**

Data were entered, cleared and analyzed using the statistical package SPSS for windows, version 20. For categorical data, we used proportions with 95% confidence intervals, Odds ratio and Chi-square test to compare different groups. Multivariate analysis using logistic regression model was used to analyze the association between treatment outcome and potential predictor variables. P values of less than 0.05 were considered statistically significant.

**Ethical consideration**

Institutional ethical clearance was obtained from the Institutional Review Board (IRB) of Addis Ababa University and permission was received from Bale Robe Hospital to use the data. Informed consent from study participants was not required as the survey was based on retrospective data with no patient interaction and the report is part of standard public health practice. In order to ensure confidentiality of the information, names or identification numbers of TB patients were not included in the data sheet.

**Results**

**Demographic and clinical characteristics of study participants**

A total of 916 tuberculosis patients were registered for DOTS program at Bale Robe Hospital, Oromia, between September 2007 and August 2012. Of these, 544 (59.6%) were males and 372 (40.4%) were females with the mean, standard deviation and median age of 28.84, 14.65 and 25 years, respectively. More than half (59.9%) of the study participants were concentrated between the age group of 15-34 years, which is believed to be the productive segment of the society. With regard to their residence majority 623 (68%) live in urban area where as 293 (32%) reside in rural setting. Of the total study participants, 373...
(40.7%), 305 (33.3%), and 238 (26%) were smear negative pulmonary tuberculosis, extra pulmonary tuberculosis, and smear positive pulmonary tuberculosis cases respectively. With regard to treatment categories, 808 (88.2%) of the patients were new cases, 86 (9.4%) were transferred in patients while 16 (1.6%) were relapse cases. HIV sero-status of 711 (77.6%) study participants was known, out of which 158 (22.2%) were found to be positive (Table 1).

| Characteristics        | Frequency(N) | Percentage (%) |
|------------------------|--------------|----------------|
| Sex                    |              |                |
| Male                   | 544          | 59.6           |
| Female                 | 372          | 40.4           |
| Residence              |              |                |
| Urban                  | 623          | 68             |
| Rural                  | 293          | 32             |
| Age Group              |              |                |
| ≤14                    | 101          | 11             |
| 15-24                  | 296          | 32.3           |
| 25-34                  | 253          | 27.6           |
| 35-44                  | 124          | 13.5           |
| 45-54                  | 64           | 7              |
| 55-64                  | 39           | 4.3            |
| ≥65                    | 39           | 4.3            |
| Category of Patients   |              |                |
| New Cases              | 808          | 88.2           |
| Transfer in            | 86           | 9.4            |
| Relapse                | 15           | 1.6            |
| Failure                | 5            | 0.5            |
| Default                | 1            | 0.1            |
| Transferred out        | 1            | 0.1            |
| Tuberculosis Type      |              |                |
| SPPTB                  | 238          | 26             |
| SNPTB                  | 373          | 40.7           |
| EPTB                   | 305          | 33.3           |
| HIV Status (N=711)     |              |                |
| HIV Positive           | 158          | 22.2           |

Table 1: General characteristics of study participants (n=916), Bale Robe Hospital, 2007-2012, N=916, SPPTB= Smear positive pulmonary TB, SNPTB=Smear Negative Pulmonary TB, EPTB=Extra Pulmonary TB.

Acid fast staining follow up result of registered TB patients during treatment

From the total of 238 (26%) smear positive pulmonary tuberculosis patients, 199 (83.60%) had AFB staining laboratory result at the end of the 2nd month of treatment, out of which only 3 (1.5%) were AFB positive. At the end of 5th month of treatment 193 (81%) smear positive pulmonary tuberculosis patients had AFB result, out of which 4 (2.1%) were remained positive. At the end of the 7th month a total of 173 (72.70%) had AFB laboratory result, of which all of them were AFB negative.

Treatment outcomes

We examined treatment outcomes of 916 tuberculosis patients who were registered on DOTs program at the Bale Robe hospital during the study period. Out of which 180 (19.7%) were cured, 536 (58.5%) were found completed their treatment, while 82 (9%) were died, in addition, 55 (6.0%) and 54 (5.9%) were defaulters and transferred out respectively. Overall, 716 (78.2%) had a successful and 200 (21.8%) a poor treatment outcome. Of those with a poor treatment outcome, 82 (41%) patients died, 55 (27.5%) defaulted and 54 (27%) transferred out (Table 1).

The result in Table 2 indicates that as age of tuberculosis patients increased death rate of patients was increased from 4 (4%) to 19 (6.4%), 21 (8.3%) to 14 (11.3%), 10 (15.5%) to 7 (11.3%) and 7 (11.3) in the age group of 0-14 years, 15-24 years, 25-34 years, 35-44 years, 45–54 years, 55-64 years and 65 years, respectively. Whereas the age of tuberculosis patients increased, treatment success rate of patients decreased from 91 (90.1%) to 229 (77.4%) to 99 (79.8%), 50 (78.1%), to 25 (64.1%), and 26 (66.7%), respectively.
Table 2: Treatment outcomes by sex, residence, age group, patient category, TB type, HIV status, and year of treatment Bale Hospital, Oromia Regional State, Ethiopia: A Five Year Retrospective Study. J Nurs Care 6: 386. doi:10.4172/2167-1168.1000386

| Male         | 413 (75.9) | 38 (7)  | 39 (7.2) | 45 (8.3) | 9 (1.7) | 544 (100) |
|--------------|------------|---------|----------|----------|---------|-----------|
| Female       | 303 (81.5) | 16 (4.3) | 16 (4.3) | 37 (9.9) | 0 (0)   | 372 (100) |
| Residence    |            |         |          |          |         |           |
| Urban        | 485 (79.5) | 35 (5.6) | 35 (5.6) | 52 (8.3) | 6 (1.0) | 623 (100) |
| Rural        | 221 (75.4) | 19 (6.5) | 20 (6.8) | 30 (10.2)| 3 (1.0) | 293 (100) |
| Age Groups(years) |          |         |          |          |         |           |
| ≤14          | 91 (90.1)  | 2 (2.0)  | 4 (4.0)  | 4 (4.0)  | 0 (0)   | 101 (100) |
| 15-24        | 229 (77.4) | 22 (7.4) | 22 (7.4) | 19 (6.4) | 4 (1.4) | 296 (100) |
| 25-34        | 196 (77.5) | 17 (6.7) | 16 (6.3) | 21 (8.3) | 3 (1.2) | 253 (100) |
| 35-44        | 99 (79.8)  | 6 (4.8)  | 5 (4.0)  | 14 (11.3)| 0 (0)   | 124 (100) |
| 45-54        | 50 (78.1)  | 3 (4.7)  | 1 (1.6)  | 10 (15.5)| 0 (0)   | 64 (100)  |
| 55-64        | 25 (64.1)  | 2 (5.1)  | 4 (1.6)  | 7 (17.9) | 1 (2.6) | 39 (100)  |
| ≥65          | 26 (66.7)  | 2 (5.1)  | 4 (10.3) | 7 (17.9) | 1 (2.6) | 39 (100)  |
| Patient Category |        |         |          |          |         |           |
| New          | 645 (79.8)| 44 (5.4) | 39 (4.8) | 73 (9)   | 7 (0.9) | 808 (100) |
| Relapse      | 10 (67.7)  | 3 (20)   | 0 (0)    | 2 (13.3) | 0 (0)   | 15 (100)  |
| Failure      | 3 (60)     | 1 (20)   | 0 (0)    | 1 (20)   | 0 (0)   | 5 (100)   |
| Defaulter    | 1 (100)    | 0 (0)    | 0 (0)    | 0 (0)    | 0 (0)   | 1 (100)   |
| Transferred in| 56 (65.1)  | 6 (7)    | 16 (18.6)| 6 (7)    | 2 (2.3) | 86 (100)  |
| Transferred out | 1 (100)   | 0 (0)    | 0 (0)    | 0 (0)    | 0 (0)   | 1 (100)   |
| Tuberculosis Type |      |         |          |          |         |           |
| SPPTB        | 190 (79.8)| 16 (6.7) | 11 (4.6) | 16 (6.7) | 5 (2.1) | 238 (100) |
| SNPTB        | 284 (76.1)| 19 (5.1) | 19 (5.1) | 49 (13.1)| 2 (0.5) | 373 (100) |
| EPTB         | 242 (79.3)| 19 (6.2) | 25 (8.2) | 17 (5.6) | 2 (0.7) | 305 (100) |
| HIV Status( N=711) |     |         |          |          |         |           |
| HIV positive | 106 (67.1)| 10 (6.3) | 10 (6.3) | 31 (19.6)| 1 (0.6) | 158 (100) |
| HIV Negative | 447 (80.8)| 30 (5.4) | 38 (6.9) | 33 (6.0) | 5 (0.9) | 553 (100) |
| Year of Treatment |     |         |          |          |         |           |
| 2008         | 152 (78.4)| 15 (7.7) | 6 (3.1)  | 18 (9.3) | 3 (15)  | 194 (100) |
| 2009         | 156 (81.7)| 5 (2.6)  | 18 (6.4) | 12 (6.3) | 0 (0.0) | 191 (100) |
| 2010         | 158 (79.4)| 7 (3.5)  | 14 (7.0) | 17 (8.5) | 3 (1.5) | 199 (100) |
| 2011         | 144 (75.8)| 12 (6.3) | 16 (8.4) | 15 (7.9) | 3 (1.6) | 190 (100) |
| 2012         | 106 (78.2)| 15 (10.6)| 1 (0.7)  | 20 (14.1)| 0 (0.0) | 142 (100) |

Table 3 indicated that as age of tuberculosis patients increased, prevalence of smear negative pulmonary tuberculosis cases showed increasing pattern from 35.6% in the age group of 0-14 years to 71.8% in the age group of 66-99 years, whereas prevalence of Extra-
pulmonary tuberculosis (EPTB) showed decreasing pattern from 57.4% in the age group of 0-14 years to 17.9% in the age group of 65-99 years ($x^2=71.36$, p. value=0.00). In multi variate analysis, younger ages ($\leq$ 14 years) were more likely to develop EPTB than their older counterparts (AOR=8.81, CI=3.03-25.65) result not shown.

As shown in Table 4, female tuberculosis patients had significantly higher treatment success rate (81.5% versus 75.9%) than male (AOR=1.23, CI=1.10-1.75). In addition, patients in the age group of 0-14 years (AOR=4.99, CI=1.75-14.27), 25-34 years (AOR=2.52, CI=1.10-8.91) and 35-44 years (AOR=3.50, CI=1.37-8.91) had significantly higher treatment success rate compared to the other age groups. With regard to patient category at the start of treatment, new TB patients had significantly higher treatment success rate (AOR=2.17, CI=1.32-3.57) than retreated cases including relapse, failures, defaulters, transferred in cases. Whereas, HIV positive tuberculosis patients had significantly lower treatment success rate (AOR=0.43, CI=0.28-0.65) than HIV negative ones (Table 4).

| Characteristics | Frequency | Treatment success | COR | 95% CI | P-Value | A OR * | 95% CI | P-value |
|-----------------|-----------|-------------------|-----|--------|---------|--------|--------|---------|
|                 | Yes N (%) | No N (%)          |     |        |         |        |        |         |
| **Sex**         |           |                   |     |        |         |        |        |         |
| Male            | 544 (59.6)| 413 (75.9)        | 151 | 1.10-1.75 | 0.008  | 1.23  | 1.10-1.75 | 0.008   |
| Female          | 372 (40.4)| 303 (81.5)        | 69  | 1.04-1.93 | 0.05   | 1.23  | 1.10-1.75 | 0.05    |

Table 3: Association of TB type with sex, Age category and TB patient categories, Bale Robe Hospital, Oromia, September, 2007-August, 2012, N=916.SPPTB=Smear Positive Pulmonary TB, SNPTB=Smear Negative Pulmonary TB, EPTB=Extra Pulmonary TB, N=Number.
Table 4: Crude and Adjusted odds ratios for various factors that might affect treatment outcomes among tuberculosis patients, Bale Robe Hospital, September 2007-August 2012, N=916, TB=Tuberculosis, OR=Odds Ratio, CI=Confidence Interval, N=Number, *=All the variables in the table are included in the model.

| Characteristics | Death Status | Crude OR | 95% CI | P-Value | Adjusted OR * | 95% CI | P-Value |
|-----------------|--------------|----------|--------|---------|--------------|--------|---------|
| HIV Status      | Alive N (%)  | Died N (%)|        |         |              |        |         |
| HIV Positive    | 127 (80.4)   | 31 (19.6) | 3.85   | 2.27-6.52 | 0            | 4.32   | 2.45-7.64 | <0.001 |
| HIV Negative    | 520 (94.4)   | 33 (6.0)  | 1      | ----     | ----         | ----   | ----     |
| TB Types        |              |          |        |         |              |        |         |
| SPPTB           | 222 (93.3)   | 16 (6.7)  | 1.22   | 0.60-2.47 | 0.58         | 1.17   | 0.52-2.57 | 0.72   |
| SNPTB           | 324 (86.9)   | 49 (13.1) | 2.56   | 1.44-4.55 | 0            | 2      | 1.05-3.84 | 0.05   |
| EPTB            | 288 (94.4)   | 17 (5.6)  | 1      | ----     | ----         | ----   | ----     |
| Age Group (years) |            |          |        |         |              |        |         |
| ≤ 14            | 97 (96)      | 4 (4.0)  | 1      | ----     | ----         | ----   | ----     |
| 15-24           | 277 (93.6)   | 19 (6.4)  | 1.66   | 0.55-5.01 | 0.36         | 2.04   | 0.56-7.39 | 0.28   |
| 25-34           | 232 (91.7)   | 21 (8.3)  | 2.2    | 0.73-6.56 | 0.59         | 1.5    | 0.41-5.54 | 0.55   |
| ≥ 35            | 110 (88.2)   | 14 (11.3) | 3.09   | 0.98-9.70 | 0.05         | 1.31   | 0.32-5.35 | 0.71   |

Of the total 916 registered patients in the cohort, 834 (91%) survived, while 82 (9%) were died in the entire follow-up period. In this study, the proportion of death from pulmonary negatives, pulmonary positives and extra pulmonary TB patients were 13.1%, 6.7 and 5.6%, respectively.

Participants’ HIV sero-status, tuberculosis type, and age, were significantly associated with patients’ death (p<0.05). In multivariate logistic regression older ones (age ≥ 65) were more likely to die than the younger groups (AOR=5.50, CI=1.21-25.01). HIV positive tuberculosis patients were four times more likely to die than HIV negative TB patients (AOR=4.32, CI=2.45-7.64). In addition, smear negative pulmonary tuberculosis patients were two times more likely to die than smear positive and extra pulmonary tuberculosis patients (AOR=2.56, CI=1.44-4.55, AOR=2.00, CI=1.05-3.84) Table 5.
In the current study, from the total of 200 (21.8%) TB patients with a poor treatment outcome, the largest proportion (41%) was caused by death followed by defaulters (27.5%) and transferred out (27%). The overall death rates of TB patients in this study was found to be 82% (9%), which is greater than 33.3% in Northwest Ethiopia [25], 37% in a study done in Addis Ababa [12], 3.6% in Gambella [20] and 2.6% in Southern Ethiopia [8] but slightly lower than a study conducted in Gondar University Hospital [15] with death rate of 10.1%.

It is evident that, as the age of the study subjects advanced, the death rate of patients was steadily increased from 4% in the age group of ≤ 14 years to 17.9% in the age group of ≥ 55 years (Table 2). This is in agreement with the finding of a study done in Gonder and Addis Ababa [13,15]. Older age ≥ 65 years has been found to be an independent factor to determine death, due to increasing co-morbidities as well as the general immunological deterioration with age [15].

In agreement with previous studies done in different part of the world, in the present study, older ages, smear negative [12,15] and HIV positive [7,10] pulmonary TB patients were more likely to die than their counter parts.

Conclusion

Being female, younger age and HIV negative were predictor variables for treatment success of TB patients. Although the treatment success rate is fairly good, a high proportion of patients death (9%) and 22.2% of HIV prevalence among TB patients is a serious public health concern that needs to be addressed urgently in the area.

Authors Contribution

BT: Conceived, designed the project and collected the data, and reviewed the manuscript.

ET: Developed the proposal, analyzed, interpreted the data and prepared the manuscript for publication.

Begna T: Designed the project, collected the data and reviewed the manuscript. All of these authors provided critical comments for revision and approved the final version of the manuscript.

GA: Developed the proposal, analyzed, interpreted the data and prepared the manuscript for publication.

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