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RESEARCH ARTICLE

Treatment Outcomes of Tuberculosis Retreatment Case and Its Determinants in West Ethiopia

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Abstract:

Background:

Tuberculosis (TB) is a major public health concern in the developing world. World Health Organization's (WHO's) list of 30 high TB burden countries accounted for 87% of the world's cases. The annual infection rate in developing countries reached 2% or more; where as in developed countries this figure is 0.5%.

Objective:

The objective of this study is to assess treatment outcomes of tuberculosis retreatment case and its determinants at Nekemte Referral Hospital (NRH), West Ethiopia.

Methods:

A retrospective cross-sectional study was conducted. All registered adult TB patients under retreatment regimen who were treated at NRH TB clinics from January 2014 to December 2017 were included in this study. A multiple logistic regression was used to assess the significance and strength of association. A P-value <0.05 was used as statistically significant.

Results:

The prevalence of retreatment case was 12.12%. Of 219 study participants 159(72.6%) were patients with relapse, 43(19.6%) were with retreatment after failure and 17(7.8%) were patients who return after loss to follow-up. On multivariable logistic analysis poor treatment outcome was more likely to occur among patients with positive Acid Fast Bacilli (AFB) result at 5th month (Adjusted odds ratio (AOR) =4.3, 95%, (1.8-10.0) p=0.001) and patients taking category 1 (2ERHZ/4RH) drugs (AOR=2.1, 95% CI= (1.1-4.5) p=0.048).

Conclusion:

This study showed that treatment outcomes of TB retreatment case were below standard set by the WHO. Factors that were significantly associated with poor treatment outcome were positive AFB resulting at 5th month and patients on category 1(2ERHZ/4RH).

Keywords: Tuberculosis, Retreatment case, Treatment outcome, Successful treatment, Treatment failure, West Ethiopia.

Article History

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1. INTRODUCTION

Tuberculosis (TB) is a major public health concern in the developing world. According to the World Health Organization (WHO) report in 2018, TB caused an estimated 1.3 million deaths (range, 1.2–1.4 million) among Human Immunodeficiency Virus (HIV)-negative people and there were an additio-

nal 300,000 deaths from TB (range, 266,000–335,000) among HIV-positive people [1]. Globally, the best estimate is that 10.0 million people (range, 9.0–11.1 million) developed TB disease in 2017: 5.8 million men, 3.2 million women and 1.0 million children. WHO's list of 30 high TB burden countries accounted for 87% of the world's cases [1].

The annual infection rate in developing countries reached 2% or more; where as in developed countries this figure is 0.5% [2]. In Africa, more than 4 million people suffer from

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active TB and 650,000 deaths occurring every year [3].

According to Ethiopian national TB guidelines: relapses, failure, return after loss to follow-up and other are the four categories to define previously treated TB patients. 'Other' includes chronic re-treatment TB patients, recurrent smear-negative pulmonary tuberculosis (PTB) and extra-pulmonary tuberculosis (EPTB) [4 - 6].

Previously conducted studies have revealed that retreatment TB cases play major role in the development of drug resistance including Multidrug resistant tuberculosis (MDR-TB) which is considered to be a global threat today [4 - 7]. The threat effect of TB retreatment at individual, community and country levels both on the economy and mortality of people in Ethiopia is a great problem today [5, 7].

Different studies had identified factors determining the retreatment TB cases such as; socio-demographic factors smear result at enrolment, year of treatment, Anti-TB regimen, patient category and HIV status [8 - 15]. Therefore, this study is designed to examine both the burden of retreatment TB cases and their treatment outcomes in Nekemte Referral Hospital (NRH) and give an appropriate recommendation based on the findings.

2. MATERIALS AND METHODS

2.1. Study Design and Population

A retrospective cross-sectional study was conducted. All registered adult TB patients under retreatment regimen who were treated at NRH TB clinics from January 2014 to December 2017 were included in this study, while patients who had discontinued treatment due to misdiagnosis were excluded.

2.2. Sample Size Determination

Since the total numbers of TB patients under the retreatment regimen were only 219, all of them were included in the study.

2.3. Data Collection Process and Quality Assurance

Data were collected by using data collection checklists which were designed-based on the literature review of similar studies [7 - 11]. Data were obtained from TB registers and patient treatment cards. Data collection was conducted with appropriate training of the data collectors and close supervision with continuous data monitoring to keep the quality of the data.

2.4. Data Analysis and Interpretation

After data collection, data were entered into the Statistical Package for the Social Sciences (SPSS) version 20 for analysis. Descriptive statistics were calculated for all variables. Odds ratio with 95% confidence interval, along with binary and multiple logistic regression was used to assess the significance and strength of association. A P-value <0.05 was used as statistically significant.

2.5. Definition of Terms

The cases selected for the study (retreatment after failure, retreatment after loss to follow-up, relapse) and the outcome of

these cases (cure, treatment completed, treatment failure, loss to follow-up, dead) were defined based on the standard definitions of the National TB and leprosy control program guideline of Ethiopia for the diagnosis and treatment of TB cases [5].

"Retreatment after failure" is defined as a patient who started on retreatment after the previous treatment has failed.

A patient previously treated for TB who returns to treatment having previously lost to follow-up is referred to as **"retreatment after loss to follow-up"**.

A **"relapse"** case is defined as a patient who previously was declared cured or treatment completed and is diagnosed with bacteriologically-positive (sputum smear or culture).

A patient is considered **"cured"** when sputum smear examination is bacteriologically negative in the last month of treatment and on at least one previous occasion. If a patient completed treatment without having a negative bacteriological result in the last month of treatment and on at least one previous occasion, then patient is declared as **"treatment completed"**. If a patient interrupted his treatment for 8 or more consecutive weeks after he/she had been on treatment for at least 4 weeks, the patient is considered as a **"loss to follow-up"**.

Treatment failure is defined as a patient who remains or becomes again smear-positive at the end of 5 months or later during treatment. A patient is declared **"dead"** if he/she died for any reason during the course of treatment.

Category 1: consists mainly of new, smear-positive tuberculosis cases, but includes new smear-negative cases with extensive parenchymal lesions, and new cases with severe extrapulmonary tuberculosis. The treatment regimen for this category is: 2ERHZ/4RH.

Category 2: smear-positive cases who have already received treatment for at least one month in the past and who need to receive re-treatment. The treatment regimen for this category is: 2SERHZ/1ERHZ/5ERH

2.6. Ethics Approval and Consent to Participate

Ethical clearance was obtained from the Institutional Research Ethics Review Committee of Wollega University, College of Health Sciences. This committee wrote a formal letter of permission to Nekemte Referral Hospital to seek its cooperation and access to the data. Permission was obtained from the medical director's office of the hospital. Confidentiality was ensured during the data collection, thus the name of the patient were not recorded in the data collection checklist.

3. RESULT

3.1. Socio-demographic Characteristics and Clinical Characteristics

From January 2014 to December 2017, a total of 1807 tuberculosis patients were registered at NRH, of these 219 adult patients were registered as retreatment case. Thus, in this study, the prevalence of retreatment cases was 12.12%. The

mean age of the study participants was 37.91 ± 13.2 . From all 219 patients evaluated for treatment outcomes, 76(34.7%) were cured, 70(32%) treatment completed, 47(21.5%) were failed and 5 (2.3%) died. Drug regimen used were category 1(2ERHZ/4RH) in 111(50.7%) patients and category 2 (2SERHZ/1ERHZ/5ERH) in 108(49.3%) patients (Table 1).

3.2. Treatment Outcomes

Of the 219 patients treatment outcome is known for 199 patients, thus transferred outpatients (20) were excluded from the analysis. Treatment outcomes were sorted into successful (cure and completed therapy) and unsuccessful (treatment failure, loss to follow-up and died). Of the patients with unsuccessful treatment outcomes, 40(75.5%) were from patients with relapse, 8 (15.1%) were from patients with

retreatment after failure and 5(9.4%) were from patients with retreatment after loss on follow-up. From all patients with unsuccessful treatment outcomes, a higher proportion 24(45.3%) were registered in year 2016 (Table 2).

3.3. Determinants of TB Retreatment Outcome

The bivariable analysis showed that sex and AFB result at 5th month and drug regimen were associated with poor treatment outcomes Table 3. Variable with P-value < 0.25 (like sex, AFB result at 2nd /3rd month, AFB result at 5th month and drug regimen) and known risk factors of TB outcomes like age and HIV status were entered into multivariable analysis. Factors that were significantly associated with poor treatment outcome at $p < 0.05$ in multivariable analysis were positive AFB

Table 1. Socio-demographic characteristics and Clinical characteristics of TB patients in Nekemte Referral Hospital, West Ethiopia, From January 2014 to December 2017 n=219.

| Variables | Category | Frequency | Percent % |
|--------------------------------|--------------------------------|-----------|-----------|
| Sex | Male | 106 | 48.4 |
| | Female | 113 | 51.6 |
| Age | 34 | 96 | 43.8 |
| | 35-54 | 100 | 45.7 |
| | 55 | 23 | 10.5 |
| Smear result at enrolment | Positive | 131 | 59.8 |
| | Negative | 77 | 35.2 |
| | Not indicated | 11 | 5.0 |
| HIV status | Positive | 72 | 32.9 |
| | Negative | 144 | 65.7 |
| | Refused | 3 | 1.4 |
| Patient category | Relapse | 159 | 72.6 |
| | Retreatment after failure | 43 | 19.6 |
| | Return after loss to follow-up | 17 | 7.8 |
| Drug regimen used | Category 1 (2ERHZ/4RH) | 111 | 50.7 |
| | Category 2 (2SERHZ/1ERHZ/5ERH) | 108 | 49.3 |
| Year of treatment | 2014 | 38 | 17.4 |
| | 2015 | 58 | 26.5 |
| | 2016 | 106 | 48.4 |
| | 2017 | 17 | 7.8 |
| AFB result at 2 and/or 3 month | Positive | 54 | 24.7 |
| | Negative | 147 | 67.1 |
| | Not done | 16 | 7.3 |
| | Not indicated | 2 | 0.9 |
| AFB result at 5th month | Positive | 49 | 22.4 |
| | Negative | 160 | 73.1 |
| | Not done | 10 | 4.6 |
| AFB result at 8th month | Positive | 19 | 8.7 |
| | Negative | 194 | 88.6 |
| | Not done | 6 | 2.7 |
| Treatment outcome | Cured | 76 | 34.7 |
| | Treatment completed | 70 | 32.0 |
| | Treatment failure | 47 | 21.5 |
| | Defaulted | 1 | 0.5 |
| | Died | 5 | 2.3 |
| | Transferred out | 20 | 9.1 |

Table 2. Treatment outcomes of TB patients by patient characteristics in Nekemte Referral Hospital, West Ethiopia, From January 2014 to December 2017 n=199.

| Characteristics | | Cure (%) | Completed Therapy (%) | Treatment Failure (%) | Loss to Follow-up Treatment (%) | Died (%) | Total |
|--------------------------------|--------------------------------|----------|-----------------------|-----------------------|---------------------------------|----------|-------|
| Sex | Female | 27(28.1) | 36(37.5) | 29(30.2) | 1(1.1) | 3(3.1) | 96 |
| | Male | 49(47.6) | 34(33.0) | 18(17.5) | 0 | 2(1.9) | 103 |
| Age | 34 | 37(43.5) | 24(28.2) | 22(25.9) | 0 | 2(2.4) | 85 |
| | 35-54 | 30(32.9) | 38(41.8) | 20(22.0) | 0 | 3(3.3) | 91 |
| | 55 | 9(39.1) | 8(34.8) | 5(21.8) | 1(4.3) | 0 | 23 |
| HIV status | Positive | 27(41.5) | 20(30.8) | 14(21.6) | 1(1.5) | 3(4.6) | 65 |
| | Negative | 49(37.4) | 50(38.2) | 30(22.9) | 0 | 2(1.5) | 131 |
| | Refused | 0 | 0 | 3(100) | 0 | 0 | 3 |
| Smear result at enrolment | Positive | 47(40.2) | 39(33.3) | 25(21.4) | 1(0.8) | 5(4.3) | 117 |
| | Negative | 21(29.6) | 30(42.2) | 20(28.2) | 0 | 0 | 71 |
| | Not done | 8(72.7) | 1(9.1) | 2(18.2) | 0 | 0 | 11 |
| Patient category | Relapse | 57(38.5) | 51(34.5) | 38(25.7) | 0 | 2(1.3) | 148 |
| | Retreatment after failure | 13(36.1) | 15(41.6) | 5(13.9) | 1(2.8) | 2(5.6) | 36 |
| | Return after loss to follow-up | 6(40.0) | 4(26.7) | 4(26.7) | 0 | 1(6.6) | 15 |
| Drug regimen | Category 1 (2ERHZ/4RH) | 31(29.3) | 37(34.9) | 35(33.0) | 1(0.9) | 2(1.9) | 106 |
| | Category 2 (2SERHZ/1ERHZ/5ERH) | 45(48.4) | 33(35.5) | 12(12.9) | 0 | 3(3.2) | 93 |
| Year of treatment | 2014 | 10(31.3) | 14(43.7) | 8(25.0) | 0 | 0 | 32 |
| | 2015 | 24(43.7) | 16(29.1) | 12(21.8) | 1(1.8) | 2(3.6) | 55 |
| | 2016 | 38(39.6) | 34(35.4) | 22(22.9) | 0 | 2(2.1) | 96 |
| | 2017 | 4(25.0) | 6(37.5) | 5(31.3) | 0 | 1(6.2) | 16 |
| AFB result at 2 and/or 3 month | Positive | 16(34.0) | 15(31.9) | 16(34.0) | 0 | 0 | 47 |
| | Negative | 51(37.8) | 53(39.3) | 25(18.5) | 1(0.7) | 5(3.7) | 135 |
| | Not done | 7(46.7) | 2(13.3) | 6(40.0) | 0 | 0 | 15 |
| | Not indicated | 2(100) | 0 | 0 | 0 | 0 | 2 |
| AFB result at 5th month | Positive | 0 | 19(46.3) | 22(53.7) | 0 | 0 | 41 |
| | Negative | 62(41.1) | 58(38.4) | 25(16.6) | 1(0.6) | 5(3.3) | 151 |
| | Not done | 5(71.4) | 2(28.6) | 0 | 0 | 0 | 7 |
| AFB result at 8th month | Positive | 0 | 0 | 19(100) | 0 | 0 | 19 |
| | Negative | 74(42.1) | 68(38.6) | 28(15.9) | 1(0.6) | 5(2.8) | 176 |
| | Not done | 2(50) | 2(50) | 0 | 0 | 0 | 4 |

result at 5th month and patients on category 1(2ERHZ/4RH). While dealing with these factors, patients who had positive AFB result at 5th month were 4.3 times more likely to have poor treatment outcomes when compared with patients who had negative AFB results at 5th months (AOR =4.3, 95%,

(1.8-10.0) p=0.001). Based on a drug regimen, patients who were on category 1(2ERHZ/4RH) were 2.1 times more likely to have poor treatment outcomes than patients on category 2 (2SERHZ/1ERHZ/5ERH) (AOR=2.1, 95% CI= (1.1-4.5) p=0.048) (Table 3).

Table 3. Logistic regression analysis of factors associated with treatment outcome in TB patients at Nekemte Referral Hospital, West Ethiopia, From January 2014 to December 2017 n=199.

| Variables | Categories | Treatment Outcome of TB | | COR (95% CI) P value | AOR (95% CI) P value |
|---------------------------|------------|-------------------------|--------------|----------------------|----------------------|
| | | Successful | Unsuccessful | | |
| Sex | Male | 63 | 33 | 2.2(1.1-4.1)p=0.018 | 2.1(1.0-4.4)p=0.052 |
| | Female | 83 | 20 | 1 | 1 |
| Age | 34 | 61 | 24 | 1.1(0.4-3.1)p=0.838 | 1.6(0.4-6.5)p=0.471 |
| | 35-54 | 68 | 23 | 1.0(0.3-2.7)p=0.936 | 1.5(0.4-6.0)p=0.555 |
| | 55 | 17 | 6 | 1 | 1 |
| Smear result at enrolment | Positive | 86 | 31 | 0.9(0.5-1.8)=0.802 | --- |
| | Negative | 51 | 20 | 1 | --- |

(Table 3) contd....

| Variables | Categories | Treatment Outcome of TB | | COR (95% CI) P value | AOR (95% CI) P value |
|--------------------------------------|--------------------------------|-------------------------|--------------|----------------------|-----------------------|
| | | Successful | Unsuccessful | | |
| HIV status | Positive | 47 | 18 | 1.2(0.6-2.3)p=0.622 | 1.3(0.6-2.8)p=0.481 |
| | Negative | 99 | 32 | 1 | 1 |
| Drug regimen | Category 1(2ERHZ/4RH) | 68 | 38 | 2.9(1.5-5.7) p=0.002 | 2.1(1.1-4.5)p=0.048 |
| | Category 2(2SERHZ/1ERHZ/5ERH) | 78 | 15 | 1 | 1 |
| Year of treatment | 2014 | 24 | 8 | 0.6(0.2- 2.0)p=0.372 | --- |
| | 2015 | 40 | 15 | 0.6(0.2- 2.0)p=0.432 | --- |
| | 2016 | 72 | 24 | 0.6(0.2-1.7)p=0.300 | --- |
| | 2017 | 10 | 6 | 1 | --- |
| Patient category | Relapse | 108 | 40 | 1 | --- |
| | Retreatment after failure | 28 | 8 | 0.8(0.3-1.8)p=0.557 | --- |
| | Return after loss to follow-up | 10 | 5 | 1.4(0.4-4.2)p=0.604 | --- |
| AFB result at 2nd/3rd month | Positive | 31 | 16 | 1.7(0.8- 3.6)p=0.137 | 1.2(0.5-2.6)p=0.730 |
| | Negative | 104 | 31 | 1 | 1 |
| AFB result at 5th month | Positive | 19 | 22 | 4.5(2.2- 9.3)p<0.001 | 4.3(1.8-10.0) p=0.001 |
| | Negative | 120 | 31 | 1 | 1 |
| AFB result at 8th month ⁸ | Positive | 0 | 19 | --- | --- |
| | Negative | 142 | 34 | --- | --- |

AOR: Adjusted Odds Ratio

COR: Crude Odds Ratio

4. DISCUSSION

This study aimed to assess the TB retreatment case and their outcomes in NRH. From a total of 219 patients, this study evaluated 199 patients with known treatment outcomes after excluding transferred out patients which are 20 in number and found that only 73.4% of patients had achieved successful treatment outcome. According to WHO target, treatment success rate for high burden TB countries like Ethiopia should be 90% and above. Therefore, this study indicates poor results compared to WHO target [1].

HIV status of the patients was also assessed with 32.9% positive status which is the same with the study done in AHMC [15] which are relatively same with the prevalence of HIV in the community and higher than the study done in Ethiopian Somali region [14]. The might be due to pastoral life style of the patients in these study areas. Studies were done in Uganda [16] and Benin [17] revealed that unknown HIV status was significantly associated with poor treatment success compared to known HIV status, however, in both studies, no statistical difference was seen between HIV- positive and HIV- negative patients on treatment outcome. In the present study, no patients with known treatment outcome were registered as unknown HIV status, but similar to the above studies there was no significant difference in treatment and success was found between HIV-positive and HIV-negative patients.

In this study, sex has not shown a statistical difference in treatment outcome. However, studies from Bangalore city of India [18] and Italy [19] had reported that male patients were more likely to have poor treatment outcomes than female patients. Similar to the present study no significant associations were observed between unsuccessful outcome and gender in other studies from the Ethiopian Somali region [14], AHMC [15] and India [20]. This might be due to epidemiological factors and integrated research is required to outline the relative roles played by epidemiology in this area.

Patients who had positive AFB result in 5th month were 4.3 times more likely to have poor treatment outcomes when compared with patients who had negative AFB results at 5th months (AOR =4.3, 95%, (1.8-10.0) p=0.001). This is due to the fact that if the patient is found smear positive at the end of the 5th month of treatment, in two different specimens, the patient is declared as treatment failure.

Based on drug regimens, patients who are on category 1(2ERHZ/4RH) are more likely to have poor treatment outcomes when compared with patients on category 2(2SERHZ/1ERHZ/5ERH). This is the same with the study done in Ethiopian Somali and AMHC [14, 15]. According to Ethiopian national TB guidelines, a retreatment regimen (2SRHZE/1RHZE/5RHE) should have been used for all retreatment cases. But more than half of patients were inappropriately treated with category I regimen (2RHZE/4RH), similarly, the study was done in Uganda [21] and Malawi [22] reported that only 32% and 38% of the patients were on category II regimen respectively. The overall treatment success rate was low among retreatment TB patients receiving category I regimen suggesting that; there was a practice of inappropriate use of regimen. The reason for the inappropriateness might be due to the lack of knowledge of the health care professionals about the recommendations of the guideline and lack of adherence to the guideline.

CONCLUSION

This study showed that TB retreatment case outcomes were below standard set by the World Health Organization (WHO). The main finding of the study is that half of the patients were given the wrong treatment (Category 1 - standard short course therapy) when all should have had Category 2 treatment (basically the awful WHO Category 2 regimen which involves breaking the cardinal rule of TB management which is never to add a single drug to a failing regimen - apparently this is still standard practice in Ethiopia though it has undoubtedly

contributed to the development of drug resistance worldwide. Factors that were significantly associated with poor treatment outcome of retreatment patients were positive smear result of AFB result at 5th month and drug regimen of category 1(2ERHZ/4RH). We recommend implementation of DOTS plus strategy both at initiation and continuation phases of treatment. To evaluate response of TB retreatment cases monitoring should be done more frequently than the recommended interval to take early action.

LIMITATIONS

Limitation of this study was that the study design we used was a retrospective study which may be subjected to biases. Variables like educational level, adherence, patient-health worker communication and provider and health system related factors because of the retrospective nature of our study were not addressed. Another limitation was that the sample size we used was small.

LIST OF ABBREVIATIONS

| | |
|---------------|--|
| AHMC | = Adama Hospital Medical College |
| DOTS | = Directly Observed Treatment Short Course |
| DST | = Drug Sensitivity Testing |
| EPTB | = Extra-Pulmonary Tuberculosis |
| FMOH | = Federal Ministry of Health |
| MDR TB | = Multidrug resistant Tuberculosis |
| MTB | = Mycobacterium Tuberculosis |
| NRH | = Nekemte Referral Hospital |
| TB/HIV | = Tuberculosis and HIV Co-Infection |
| TSR | = Treatment Success Rate |
| WHO | = World Health Organization |

AUTHORS' CONTRIBUTIONS

MGD and MTS:-contributed to the conception of the research idea, study design, set the objective, participated in data collection and analysis, and participated in editing the manuscript. BME, GBW, GF and BGL:-contributed to the study design, set the objective, participated in data analysis, and participated in editing the manuscript. All of the authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The ethical approval was obtained from Institutional Research Ethics Review Committee of Wollega University Oromia, Ethiopia with approval number of WU:142,365/ST1-59.

HUMAN AND ANIMAL RIGHTS

Not applicable.

CONSENT FOR PUBLICATION

This committee wrote a formal letter of permission to Nekemte Referral Hospital to seek its cooperation and access to the data. Permission was obtained from the medical

director's office of the hospital. Confidentiality was ensured during the data collection, thus the name of the patient were not recorded in the data collection checklist.

AVAILABILITY OF DATA AND MATERIALS

Data and materials are available with the authors and will be available upon request.

FUNDING

None.

CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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