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Original Research Article

Effectiveness of Directly Observed Treatment, Short Course (DOTS) on Treatment of Tuberculosis Patients in Afar Region, Ethiopia

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ABSTRACT

Ethiopia is one of the 22 Tuberculosis countries and tuberculosis is the second highest cause of death in the country. The World Health Organization introduced the Directly Observed Treatment, Short course strategy in 1994 for diagnosis, treatment and monitoring to ensure effective control of tuberculosis. Regardless of many intervention primarily DOTS against tuberculosis still it is one of the health problems. The present study was done to assess Effectiveness of DOTS on treatment of tuberculosis patients.

A retrospective cross sectional study was carried out in one administrative zone of Afar region, Ethiopia in 2014. Using standardized questionnaires data from diagnosed tuberculosis patients on treatment outcome result and patient characteristics (sex, age, types of patient, patient category, HIV status) were collected. Data were analysed using SPSS version 16 and frequency, chi-square test and logistic regression were performed.

A total of 3634 tuberculosis patients were included in the analysis, 2190 male and 1444 female. Mean ages of the patients was 31. A total of 2429 (66.8%) patients completed treatment and 256 (7%) were cured while; 140 (3.9%) died, 17 (0.5%) failed, 353 (9.7%) default, while 439 (12.1%) were transferred out. Overall treatment success rate was 84.0% (3195) and increased from 74.8% in 2010 to 89.1% in 2013. Binary logistic regression analysis found that sex, types of patient, and intensive phase treatment started year (OR<1) increases treatment success whereas age and HIV status (OR>1) decreases treatment success. Treatment success rate improved per time and almost reached the WHO target of 90% that was set globally to be reached by 2015. It is recommended to know the type of the patients before attachment of patients to DOTS program, monitoring and follow up in all the health facilities, knowing the HIV status and age category for all patients before commencing treatment for tuberculosis.

Key words: DOTS, tuberculosis, effectiveness, Afar, Ethiopia.

INTRODUCTION

According to WHO Global TB report 2013, there were an estimated 9 million new TB cases in 2013 (13% co-infected with HIV) and 1.1 million deaths at global level (just under 1.0 million among HIV-negative people and 0.3 million HIV-associated TB deaths). Most of these TB cases and deaths occur among men, but the burden of disease among women is also high. Ethiopia is one of the 22 Tuberculosis (TB) High Burden Countries (HBCs) with an estimated number of 210,000 (180, 000-260,000) incident cases of TB in 2013. TB is the second highest cause of death in the country. [(1,2)]

The World Health Organization (WHO) introduced the Directly Observed

Treatment, Short course (DOTS) strategy in 1994 for diagnosis, treatment and monitoring to ensure effective control of TB. [1,3] The DOTS strategy contain five components: political commitment with increased and sustained financing, case detection through quality-assured bacteriology, standardized treatment with supervision and support, an effective drug supply and management system, and monitoring and evaluation system. This strategy aims to detect 70% of new smear-positive cases and to cure 85% of them. Ethiopia has adopted the DOTS strategy in 1997 and currently its geographic coverage reaches 90%. [4]

DOTS is often difficult to implement effectively because it requires substantial effort from both the patients and the health care providers. Different factors can affect the commitment of the patients like the substantial costs, required time, the stigma attached to TB, and others. [5,6] The recent 6 month Reportof Afar Region, Ethiopia TB control program indicators shows that case detection rate of 41.6% (WHO targets of 70% of case detection rate) and cure rate of 46% (WHO targets of 85% of cure rate). The report outlined some key challenges and constraints for TB control in the region which are the low detection of TB cases, the low cure rate for cases on treatment and the poor infection control practices both in community and health facilities. [7]

The primary outcome of DOTS is treatment success, defined by the WHO as the sum of cases cured and those who completed treatment. Treatment outcomes are classified as successful (cure/completed) or unsuccessful (default/failure/death). Although DOTS has been shown to be effective in achieving a high successful treatment rate from 86% to 96.5%, [8] factors including unknown sputum smear status, HIV co-infection, not having a treatment supporter, delay in diagnosis, and others are affecting it. [9] Implementation of the DOTS strategy in pastoralist community like the Afar region of Ethiopia is more difficult as people undergo seasonal movement in search of grass for their cattle and people live more dispersed and far from health facilities. In addition, as the region is developing region compare to other regions of the country there is low access to health education as well as low utilization of health facilities. Earlier research done in the region indicated that the quantity and the quality of staffing were not satisfactory to provide quality TB treatment services. [10] Therefore this study was done to investigate the effectiveness of DOTS for treatment of TB patients. More specifically the pattern of TB treatment success rate as well as the variation on treatment success rate among different patient characteristics like age groups, sex, type of TB, HIV status, first follow up visit, patient category and HIV status.

MATERIALS AND METHODS

Study design and setting

A retrospective cross sectional study was carried out to assess treatment outcome of TB patients registered from July 2010 to June 2013 in zone one of Afar region, Ethiopia. The Afar Regional State is one of the nine National Regional States of Ethiopia and located in the northeastern part of the country. Since Zone one is highly populated (39.1% of the total population) and has 2 hospitals, 8 health centers which all have TB clinics and the capital city of the region found within it [11] the study was done within this zone.

Data collection

A standardize structured questionnaire to collect patient information including patients' socio-demographic variables like age, sex as well as information on HIV status, types of patient, patient category, first follow up visit and treatment outcome for the TB patients was developed. All TB patients who had started anti-TB treatment from July 2010 to June 2013 in the six health facilities of zone one was included in the study. The rest 4 health facilities were not included in the study because of resource limitation. Those for whom the register did not have all the

require data as per the prepared questionnaire were not included in the analysis. Registered TB patients who transferred out within 28 days after starting treatment were not included in the study. All data were collected by nurse trained data collectors. Supervisor monitored data collection for completion of the questionnaires daily in the time data collection.

Data analysis

Data were coded and entered into SPSS version 16 for analysis. Frequency for independent variables and Chi-square test for proportions was made. Binary logistic regression was used to analyze the association between treatment outcome of TB and the independent variables.

Ethical clearance

Ethical approval was obtained from the Health Science Research Ethical Committee of Samara University in Afar region. A permission letter from the Afar regional health bureau was given to all DOTS centers or health facilities to facilitate obtaining facility permission for the data collection.

RESULTS

Patient characteristics

A total of 4290 TB patient-records from July 2010 to June 2013 were reviewed. Among these 3634 (84.7%) of records had complete data for the variables of interest.

Table 1: TB Patients' characteristics by health facilities from2010-2013 (n = 3634)

Variables	HF╥-1 (587, 16.2%)	HF-2 (505, 13.9%)	HF-3 (1035, 28.5%)	HF-4 (879, 24.2%)	HF-5 (296, 8.1%)	HF-6 (332, 9.1%)	Total (N, %)
Sex							
Male	361 (61.5%)	310 (61.4%)	586 (56.6%)	551 (62.7%)	178 (60.1%)	204 (61.4%)	2190 (60.3%)
Female	226 (38.5%)	195 (38.6%)	449 (43.4%)	328 (37.3%)	118 (39.9%)	128 (38.6%)	1444 (39.7%)
Age							
0-14	64 (10.9%)	53 (10.5%	138 (13.3%)	120 (13.7%)	23 (7.8%)	33 (9.9%)	431 (11.9%)
15-29	242 (41.2%)	205 (40.6%)	359 (34.7%)	268 (30.5%)	110 (37.2%)	129 (38.9%)	1313 (36.1%)
30-44	194 (33.0%)	160 (31.7%)	316 (30.5%)	315 (35.8%)	110 (37.2%)	89 (26.8%)	1184 (32.6%)
45-59	63 (10.7%)	57 (11.3%)	136 (13.1%)	89 (10.1%)	26 (8.8%)	59 (17.8%)	430 (11.8%)
≥60	24 (4.1%)	30 (5.9%)	86 (8.3%)	87 (9.9%)	27 (9.1%)	22 (6.6%)	276 (7.2%)
First follow up AFB result							
Negative	258 (44.0%)	237 (46.9%)	863 (83.4%)	612 (69.6%)	218 (73.6%)	249 (75.0%)	2437 (67.1%)
Positive	136 (23.2%)	134 (26.5%)	161 (15.6%)	179 (20.4%)	59 (19.9%)	63 (19.0%)	732 (20.1%)
Not done	193 (32.9%)	134 (26.5%)	11 (1.1%)	88 (10.0%)	19 (6.4%)	20 (6.0%)	465 (12.8%)
Types of patients							
SSP^{Ω} PTB	136 (23.2%)	134 (26.5%)	161 (15.6%)	179 (20.4%)	59 (19.9%)	63 (19.0%)	732 (20.1%)
SSN$^{£}$ PTB	270 (46.0%)	225 (44.6%)	759 (73.3%)	459 (52.2%)	157 (53.0%)	227 (68.4%)	2097 (57.7%)
EPTB	181 (30.8%)	146 (28.9%)	115 (11.1%)	241 (27.4%)	80 (27.0%)	42 (12.7%)	805 (22.2%)
Patient category							
New case	548 (93.4%)	438 (86.7%)	973 (94.0%)	831 (94.5%)	272 (91.9%)	313 (94.3%)	3375 (92.9%)
Relapse	7 (1.2%)	40 (7.9%)	24 (2.3%)	0 (0%)	1 (0.3%)	11 (3.3%)	83 (2.3%)
Treatment failure	2 (0.3%)	13 (2.6%)	14 (1.4%)	2 (0.2%)	22 (7.4%)	3 (0.9%)	56 (1.5%)
Treatment after default	17 (2.9%)	4 (0.8%)	3 (0.3%)	0 (0%)	0 (0%)	0 (0%)	24 (0.7%)
Transfer in	13 (2.2%)	9 (1.8%)	13 (1.3%)	40 (4.6%)	1 (0.3%)	2 (0.6%)	78 (2.1%)
Others☛	0 (0%)	1 (0.2%)	8 (0.8%)	6 (0.7%)	0 (0%)	3 (0.9%)	18 (0.5%)
HIV status							
Reactive	97 (16.5%)	75 (14.9%)	161 (15.6%)	98 (11.1%)	34 (11.5%)	45 (13.6%)	510 (14.0%)
Non-reactive	399 (68.0%)	411 (81.4%)	855 (82.6%)	781 (88.9%)	262 (88.5%)	283 (85.2%)	1991(82.3%)
Test not done	91 (15.5%)	19 (3.8%)	19 (1.8%)	0 (0%)	0(0%)	4 (1.2%)	133(3.7%)

Key: ╥HF= Health facilities, Logia health center (HF1), Samara health center (HF2), Dubti referral hospital (HF3), Assayta district hospital (HF4), Milie health center (HF5), Chifra health center (HF6), Ω---SSP=sputum smear positive, £---SSN=sputum smear negative, ☛=other, i.e., previously successfully treated or defaulted patients having smear negative TB, extrapulmonary TB (EPTB), or previously treated patients with unknown treatment outcome).

The 656 records with incomplete data were excluded from the analysis. Of 3634 patients included in the analysis, 2190 were male and 1444 female (see-table 01). The mean ages of the patients were 31. About two third of patients was in the age range of 15-44 years.

At the first follow up visit, AFB sputum examination was done for 3169 patients (87.2%), of which 732 (20.1%) had

a positive smear results. In health facility three (HF3), first visit sputum examination was done for 99% of patients of whom (99%) 3375 (92.9%) were new cases.

Health facility two (HF2) reported a much higher proportion of relapse cases (7.9%) than all other facilities where the relapse rate was below 3.3%. HIV test results were available for 2501. About 3375 (92.9%) were new cases, and the remaining were relapse, transfer in, treatment failure, treatment after default, and others in decreasing order. There were relatively high relapse cases in health facility two (HF2) whereas very low in HF4 and HF5. HIV test was done for 2501 (96.3%), of which 510 (14.0%) were HIV positive (see table 01).

Treatment outcome and treatment success rate

Of the 3634 patients 2429 (66.8%) completed treatment and 256 (7%) were cured, 140 (3.9%) died, 17 (0.5%) failed treatment, 353 (9.7%) defaulted, and 439 (12.1%) were transferred out. Figure 1 provides an overview of treatment outcome in the six facilities. Treatment completion rate was highest in HF-3, 73.2% and HF-4, 76.0%. in HF-2 more than a quarter of patients were transferred out, 28.1%. Over-all treatment success was 84.0% (3195/3634 patients). Treatment success rate varied between health facilities ranging from 88.8% in HF-5 to 71.5% in HF-2.

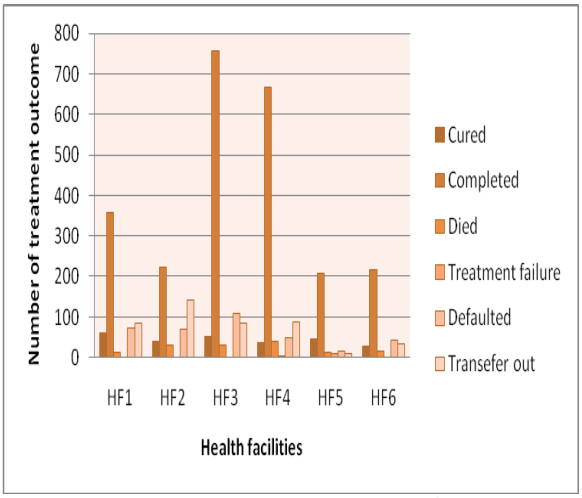

Fig 1: Bar graph showing treatment outcome of TB patients in six health facilities (n = 3634)

Treatment completion varied over time and increased from 349 (61.9%) in 2010 of 6 month data, outcome result for treatment completed was 349 (61.9 %) in 2010 of 6 month data, 689 (65.2%) in 2011 of 1 year data, 839 (67.7%) in 2012 of 1 year data and 552 (71.3%) in 2013 of 6 month data (note: it is a 3 year data of Ethiopian calendar). Over the same period the proportion that died, failed treatment and defaulted decreased. Similarly treatment success rate increased overtime from 74.8% in 2010 to 89.1% in 2013 (see Fig 02).

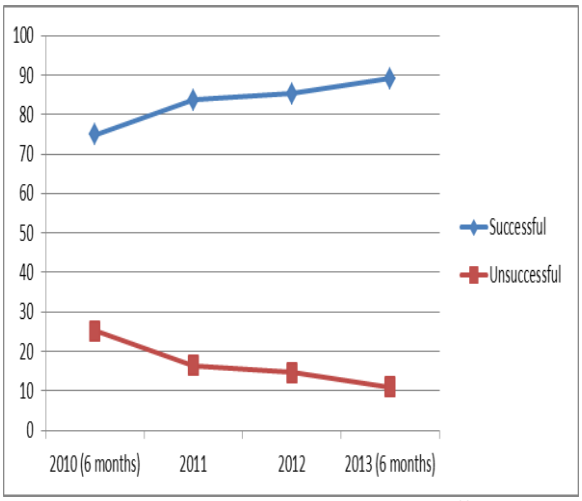

Fig 2: Line graph showing treatment success in different years

Factors associated with TB treatment success

Female patients had higher treatment success than males (87% versus 82.0%), P-value=0.000. Treatment success differed by age with the 0-14 years having the highest, 86.4%. Patients treated for sputum smear positive TB and extrapulmonary tuberculosis had a higher treatment success rate than those treated for smear negative TB (86.1/86.2% versus 86.2%repectively, P-value=0.018, table 02.

Patients with a known HIV result (whether positive or negative) had a better treatment outcome than those with no test result (84.7%/84.5% versus 69.5%, P-value=0.000). In three health facilities (HF3, HF4 and HF5) treatment success was better than in the other health facilities (P-value=0.000).

Table 2: Uni-variant and multi-variant analysis of different variables with treatment success

Variables	Chi-square test			Binary logistic regression analysis	
	Successful	Unsuccessful	P-value	OR (CI)	P-value
Sex					
Male	1565(82.0%)	344 (18.0%)	0.000	1.00 (-)	-
Female	1119(87.0%)	167 (13.0%)		0.677 (0.544, 0.843)	0.000
Age					
0-14	324 (86.4%)	51 (13.6%)		1.00 (-)	0.007
15-29	964 (83.8)	186(16.2%)		1.620 (1.011, 2.595)	0.045
30-44	892 (85.4%)	153 (14.6%)	0.015	1.546 (1.050, 2.278)	0.027
45-59	321 (82.9%)	66 (17.1%)		2.077 (1.400, 3.082)	0.000
≥60	183 (76.9%)	55 (23.1%)		1.611 (1.029, 2.522)	0.037
Types of patients					
Sputum smear positive PTB	550 (86.2%)	88 (13.8%)		1.00 (-)	0.001
Sputum smear negative PTB	1520 (82.4%)	324 (17.6%)	0.018	0.978 (0.694, 1.376)	0.897
Extra PTB	614 (86.1%)	99 (13.9%)		0.645 (0.491, 0.849)	0.002
HIV status					
Reactive	382 (84.7%)	69 (15.3%)		1.00 (-)	0.004
Non-reactive	2229 (84.5%)	410 (15.5%)	0.000	2.154 (1.345, 3.451)	0.001
Test not done	73 (69.5%)	32 (30.5%)		2.428 (1.415, 4.167)	0.001
IP treatment started year					
2010 (6 month data)	377 (74.8%)	127 (25.2%)		1.00 (-)	0.001
2011	766 (83.6%)	150 (16.4%)	0.000	0.467 (0.324, 0.674)	0.000
2012	912 (85.3%)	157 (14.7%)		0.655 (0.464, 0.925)	0.016
2013 (6 month data)	629 (89.1%)	77 (10.9%)		0.599 (0.429, 0.837)	0.003

Binary logistic regression analyses showed female were 0.7 times more likely to have a successful treatment outcome than male. Those of 15-29 years were 1.6 times likely to have an unsuccessful treatment outcome than those 0-14 years old. Patients treated for EPTB were 0.6 times more likely to response to TB treatment than those treated for sputum smear negative PTB. However, there was no statistically difference between patients treated for smear positive and negative PTB. Patients who attend the four-week attendance three or more than three times during the follow up were more likely successful in treatment of TB than who attend less.

DISCUSSION

In this study, 380 smear positive TB patients profile extracted from TB registration documented from July 2010 to June 2013 in the pastoralist Afar region of Ethiopia was analyzed.The results indicated that DOTS was effective in the treatment of tuberculosis in the study area with a treatment success rate of 84% near 85% target and within reach of the 90% global target and agree with the study done by Shallo D, *et al* (83.6%), Hailu, *et al* (85.5%). [12,13]

The treatment outcome, cure (7%) agree with study done by Wegderese S, *et al*, 8.8%, [14] and by Bong Ngeasham Collins in default (9.5%), died (5.7%), and treatment failure (1.1%). [14] But there is inconsistency in completed (16.98%) and transferred out (72.74%) with Wegderese S, *et al*, study. [14] The difference may because of access of TB clinics which reduces transferred out and suitable for adherence or to complete.

The variation in cured and completed as treatment outcome and specific the higher rates for these in health facility 3 and 4 compared to the others could be due to difference in quality of service in hospital and health center. Similarly the variation seen in treatment success rate among the health facilities may be because of difference in types of staff profile, management, and quality of service.

The overall treatment success rate in zone 1 of Afar as observed in the study was 84% comparable to studies done in other regions on Ethiopia for example in Arsi zone in southern Ethiopia (83.6%), (87.8%), and southern part (95.61%). [13-15] However in other area of Ethiopia different findings have been observed for example in Western Ethiopia where a treatment success rate of 60.7% was observed. [16] The difference could be due to antiretroviral therapy status, year of treatment, and sputum examination

follow up status which are better done in the present study.

Pattern of treatment outcome and treatment success rate were found increased time to time. For example treatment completed increased from 2010, 61.9% to 2013, (71.3%) and treatment success rate from 2010, 74.8% to 2013, 89.1%. This may be because of improvement in the intervention time to time as the issue is given well attention by concerned body including the government.

Most of the patients were male in contrast to a study done in Gondar by Tessema B. [(17)] Females were more effective to tuberculosis treatment than male (p-value=0.000). This could be due to difference in DOTS service utilization, unequal access to the service, or difference in immune status. In the present study female patients had more successful treatment outcome compare to male (82.0% versus 87.0% with P-value=0.000). Patients with old age were associated with unsuccessful for the tuberculosis treatment when compare to young ages group as like for example age group in 45-49 (17.1% unsuccessful) have 2.077 times (CI: 1.400, 3.082) more likely to be unsuccessful in tuberculosis treatment when compare to age group in 30-44 (14.6% unsuccessful). This finding agrees with study by Tessema B. [(17)] Patients with age range of 45-59 year old were more likely to unsuccessful treatment outcome (P-value=0.000). It is also consistant with the report by Gebretsadik B [(18)] and others. [(17,19)] Patients whose HIV status did not know were more associated with unsuccessful treatment (30.5%) [OR=2.428, CI: 1.415, 4.167] when compare to patients whose HIV status was known (15.5% unsuccessful for non-reactive) which agrees with the finding reported by Shallo D, *et al*, Hannock T, *et al.* [(13,20)]

CONCLUSION

The study evaluated the effectiveness of the DOTS in the study area and association of some variables with it. Treatment success rate almost reached to the WHO targets although yet need to work a lot for fulfillment of the global targets, 90% in 2015. Both the treatment outcomes and treatment success rate were improved time to time. Furthermore important variables like sex, types of patients and intensive phase treatment start year were identified as statistically significant association with treatment success. And variables like age and HIV status were found associated with unsuccessful treatment of tuberculosis.

In order to improve and sustain the treatment of TB patients in the health facilities, It is recommended to know the type of the patients before attachment of patients to DOTS program, improved DOT, monitoring and follow up in all the health facilities, knowing the HIV status and age category is strongly recommended for all patients before commencing treatment for tuberculosis, follow up sputum examination test to do at the end of treatment or at 5th month and maintaining and improving the present intervention

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Author contribution

TZ and CG were having an equal role in all the research process, including in study design, data collection and analysis, decision to publish, or preparation of the manuscript, whereas ET and KK participated in data collection, decision to publish, or preparation of the manuscript.

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