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TREATMENT OUTCOMES OF TUBERCULOSIS PATIENTS IN DEBRE MARKOS REFERRAL HOSPITAL, NORTH WEST ETHIOPIA (JUNE 2008-AUGUST 2013): A FIVE YEAR RETROSPECTIVE STUDY

Ahmed Esmael*¹, Girma Tsegaye², Moges Wubie¹, Habtamu Abera² and Mengistu Endris³

Department of Microbiology, Immunology & Parasitology¹, Department of Nursing², College of Health Sciences, Debre Markos University, Ethiopia

Department of Medical Microbiology, University of Gondar³, Ethiopia

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Correspondence to Author:

Ahmed Esmael

Department of Microbiology,
Immunology & Parasitology, College
of Health Sciences, Debre Markos
University, Ethiopia

E-mail: esmaelahmed8@gmail.com

ABSTRACT:

Background: Tuberculosis is the second most common cause of death due to an infectious disease after human immunodeficiency virus. According to World Health Organization 2010 report, 9.4 million incidents and 14 million prevalent cases were occurred. Ethiopia has been one of the 22 high TB burden countries with an incidence and prevalence rate of 300 and 470 cases per 100,000 populations respectively. To evaluate the effectiveness of tuberculosis control program, continuous monitoring of the outcome of tuberculosis treatment and analyze the specific reasons for unsuccessful treatment outcome are important.

Objective: To assess the treatment outcomes and possible associated factors on patients who registered on DOTS clinic of Debre Markos hospital, North West Ethiopia, from June 2008-August 2013.

Methods: A retrospective study was conducted among 717 TB patients who are registered at DOTs clinic of Debre Markos referral hospital. Socio-demographic and clinical data of the study participants were collected from the TB log from the DOTS clinic. Data were entered and analyzed using SPSS version 16 software.

Result: out of 717(371 men and 346 females) aged 18 and above, 425(59.3%) had successful and (9.4%) 67 had unsuccessful treatment outcome. In the final multivariate logistic model, the odds of unsuccessful treatment outcome was higher among patients being age older than 51 years, rural residence, pulmonary negative, positive for HIV status and being in the year 2008 as compared to their respective comparison groups.

Conclusion: Treatment outcome among TB patients in Debre Markos hospital was unsatisfactory. Those patients at high risk of an unfavourable treatment outcome should be identified early and given additional follow-up.

INTRODUCTION: Although highly effective anti-tuberculosis drugs are available, tuberculosis (TB) remains a major public health problem.

It is the second most common cause of death due to an infectious disease after human immunodeficiency virus (HIV)¹.

According to World Health Organization (WHO) 2010 report, 9.4 million incidents and 14 million prevalent cases were occurred². Africa, more specifically Sub-Saharan Africa, faces the worst TB epidemic, where TB associated morbidity and mortality occurs mainly in the economically productive age group (15-60 years)³.

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To address this situation in 1995, the World Health Organization (WHO) implemented directly Observed Treatment, Short-course (DOTS) strategy as a cornerstone of a Stop TB Strategy to achieve a case detection rate (CDR) of 84% and a treatment success rate (TSR) of 87% by 2015⁴. WHO also claimed as treatment outcome is an important indicator of TB control programs⁵. However, currently high prevalence of HIV co-infection and development of drug resistance challenges its effectiveness especially in sub-Saharan African set up^{5,6}.

Ethiopia has been one of the 22 high TB burden countries⁷ with an incidence and prevalence rate of 300 and 470 cases per 100,000 populations respectively^{8,9}. TB is one of the leading cause of morbidity and the fourth cause of hospital admission and the second cause of hospital death in Ethiopia⁹.

Ethiopia's National TB and Leprosy Control Program began to implement DOTS strategy for TB control in 1991 with a standardised recording and reporting system¹⁰. DOTS coverage is estimated at 100% geographical and 95% health facility level. The national treatment success in Ethiopia has been 83% (for all forms of TB)¹¹. Of TB cases notified to Federal Ministry of Health (FMOH), 30% were smear positive^{5,6}. In addition among re-treatment cases 64% were relapse case, treatment after failure 11%, treatment after default 13% and 56,040 had both TB and HIV co infection¹².

Monitoring and evaluation of treatment outcomes of TB patients is an integral part of DOTS program⁴. However researchers in Ethiopia showed treatment success rate varied in different region. For instance treatment success in Tigray was 89.2%¹³, in Gondar 29.5%¹⁴, in Addis Ababa ranges from 68.3% to 80.4%^{15,16}.

Moreover, independent risk factors which influence the TB treatment outcomes (positively or negatively) also depicted by many scholars and the specific reason were different with regards to specific set up. For instance; being female, age group 15-24 years, smear positive pulmonary tuberculosis, being urban resident, treatment center and year of enrollment were significantly associated with higher treatment success rate^{14,15}.

The odd of unsuccessful treatment outcome was higher among patients older than 40 years of age, family size greater than 5 persons, unemployed and among retreatment cases¹³.

A study conducted in Addis Ababa depicted that patients' attitude and behaviour towards the disease are major factors influencing treatment adherence¹⁸. In Southern region of Ethiopia showed the main determinants for defaulting appear to be factors related to physical access to a treatment centre¹⁹. Despite the availability of DOTS service in Debre Markos hospital for a period of time, the treatment outcome and possibly associated factors has not been assessed before. Therefore, the aim of this study was to assess the treatment outcomes and possible associated factors on patients who registered on DOTS clinic of Debre Markos hospital, North West Ethiopia (June 2008- August 2013).

METHODS: The study was conducted at Debre Markos Referral Hospital in Debre Markos, which is 300 km away from Addis Ababa. The hospital provides health service to more than 3.5 million populations in its catchments. In this hospital, DOTS clinic is operating under the National Tuberculosis and Leprosy Program (NTLCP) of Ethiopia, under which patients are diagnosed with tuberculosis by examination of morning-spot-morning sputum smears by Zeihel-Nielsen staining, for the presence of Acid fast bacilli (AFB), chest radiographs, and for EPTB, pathological investigations were used. Patients are referred to the DOTS clinic where they are registered and treated according to the National Tuberculosis and Leprosy Control Program (NTLCP)⁸.

We analyzed a five year retrospective records of 717 tuberculosis patients registered at Debre Markos referral Hospital's DOTS clinic from June 2008 to August 2013. Demographic data such as patient's age, sex, address, as well as the study subject's clinical data HIV serostatus, and tuberculosis type were included in the registration form. Data were entered, cleaned and analyzed using SPSS (Statistical Package for Social Science) version 16 by a trained data encoder. Multivariate analysis using logistic regression model was computed. P values < 0.05 were statistically significance.

OPERATIONAL DEFINITION: According to the standard definitions of the National Tuberculosis and Leprosy Control Program guideline (NLCP) adopted from WHO⁸, the following clinical case definitions were used: TB treatment outcome categories were defined according to WHO and the International Union against Tuberculosis and Lung Disease guideline²¹.

WHO defines treatment success as the sum of patients who are cured and those who have completed treatment. In line with WHO criteria, treatment outcomes were categorized into:

Successful outcome: if PTB patients were cured (i.e., negative smear microscopy at the end of treatment and on at least one previous follow-up test) or completed treatment with resolution of symptoms.

Unsuccessful outcome: if treatment of PTB patients resulted in treatment failure (i.e., remaining smear-positive after 5 months of treatment), default (i.e., patients who interrupted their treatment for two consecutive months or more after registration), or death. However, patients who transferred out to other districts were excluded from the treatment outcome evaluation as information on their treatment outcome was unavailable.

Ethical considerations: Ethical clearance was obtained from Research and Publication Directorate Office of Debre Markos University. Permission letter was taken from hospital administrative bodies. Anonymity of the respondents name was kept.

RESULT:

Socio-demographic characteristics of study participants: A total of 717 TB patients were enrolled in this study. Of whom, 371 (51.7%) were males with mean age of 30.6 years (SD \pm 14.3). The mean initial weight during intensive anti-tuberculosis treatment was phase 45.2 KGs (SD \pm 22.7).

Most of the study participants were urban resident 457 (63.7%), new cases 705 (98.3%) and had pulmonary negative TB 433 (60.4%) (**Table 1**).

TABLE 1: CHARACTERISTICS OF THE STUDY PARTICIPANTS REGISTERED AT DOTS CLINIC AT DEBRE MARKOS REFERRAL HOSPITAL FROM JUNE 2013 TO AUGUST 2013 (n=717)

Characteristics	Frequency	Percent
Sex		
Male	371	51.7
Female	346	48.3
Age		
<18	124	17.3
18-30	287	40
31-40	161	22.5
41-50	80	11.2
>=51	65	9.1
Residence		
Urban	457	63.7
Rural	259	36.3
Category during initial phase		
New	705	98.3
Relapse	11	1.5
Default	1	0.1
Types of TB		
Pulmonary positive	103	14.4
Pulmonary negative	433	60.4
Extra-pulmonary	181	25.2
Over all	717	100

Treatment outcomes of study participants: Among the study participants enrolled 349 (48.7%) had completed their treatment, 225(31.4%) were transfer out, 76 (10.6%) cured, 63(8.8%) died and 4(0.6%) failure cases.

Of the study participants assessed 425 (59.3%) had successful and 67 (9.4%) unsuccessful outcomes. Types of TB, death rate, failure rate and transfer out rate steadily decreased across the respective years (**Table 2**).

Factors associated with TB treatment outcomes: Poor treatment success rate were significantly associated with being age group \geq 51, rural residence, pulmonary negative, positive for HIV status and being in the year 2008 (**Table 3**).

TABLE 2: TREATMENT OUTCOMES OF THE STUDY PARTICIPANTS REGISTERED AT DOTS CLINIC AT DEBRE MARKOS REFERRAL HOSPITAL FROM JUNE 2013 TO AUGUST 2013.

Variables	Treatment outcome				
	Cured	Died	Failure	Completed	Transfer out
Age group					
<18	7	5	0	63	49
18-30	44	18	2	150	73
31-40	19	19	0	70	53
41-50	3	9	0	39	29
>=51	3	12	2	27	21
Sex					
Male	44	31	2	176	118
Female	32	32	2	173	107
Residence					
Rural	56	34	4	271	92
Urban	20	29	0	78	133
Tuberculosis type					
Pulmonary positive	75	5	3	1	119
Pulmonary negative	0	44	1	211	177
Extrapulmonary	1	14	0	137	29
HIV status					
Negative	50	26	3	191	126
Positive	26	37	1	158	99
TB- HIV co-infection					
Yes	26	37	1	158	99
No	50	26	3	191	126

(Total= 717)

TABLE 3: FACTORS ASSOCIATED WITH TREATMENT OUTCOME AMONG TUBERCULOSIS PATIENTS AT DEBRE MARKOS REFERRAL HOSPITAL TB AND LEPROSY CLINIC FROM JUNE 2008 TO AUGUST 2013.

Characteristics	Treatment success		COR (95% CI)	P-value	AOR (95%CI)	P-value	
	Yes (N)	No (N)					
Age group	<18	71	53	0.724(.396-1.322)		0.448(.215-.933)	
	18-30	196	91	0.450(.261-.777)*	0.293	0.372(.190-.728)**	0.032
	31-40	89	72	0.784(.441-1.39)	0.004	0.551(.266-1.142)	0.004
	41-50	42	38	0.877(.456-1.689)	0.410	0.548(.247-1.215)	0.109
	>=51	32	33	1	0.695	1	0.139
Sex	Male	224	147	0.966(.716-1.30)		0.842(.586-1.20)	
	Female	206	140	1	0.819	1	0.351
Residence	Rural	98	162	1		1	
	Urban	332	125	0.228(.165-.315)*	0.00	0.321(.221-.464)**	0.00
Tuberculosis type	Pul. positive	76	27	1.14(.653-1.99)	0.644	0.897(.465-1.728)	0.745
	Pu. negative	216	217	3.22(2.18-4.76)*	0.00	1.96(1.22-3.15)**	0.005
	Extrapul.	138	43	1		1	
HIV status	Negative	185	136	1		1	
	Positive	245	151	1.84(.025-.284)*	0.001	1.65(.047-.578)**	0.005
Year	2008	142	222	7.68(3.88-15.2)*		4.383(2.12-9.05)**	
	2009	98	33	1.65(.77-3.53)	0.00	1.377(.619-3.06)	0.00
	2010	73	11	0.74(.299- 1.83)	0.194	0.867(.338-2.223)	0.433
	2011	62	8	0.633(.237-1.69)	0.515	0.548(.196-1.53)	0.766
	2012/13	54	11	1	0.362	1	0.251

(*COR, Statistically significant but lost in AOR) and (**AOR= statistically significant), p<0.05.

DISCUSSION: The main objective of the study was to assess treatment outcome and possible associated factors among TB patients at Debre Markos referral hospital.

The World Health Organization (WHO) implemented DOTS strategy as a cornerstone of a Stop TB Strategy to achieve a treatment success rate (TSR) of 87% by 2015⁴.

WHO also claimed as treatment outcome as an important indicator of tuberculosis control programs^{4, 5}

In the present study, the treatment success rate was 59.3%. However, this treatment success rate was lower than success rate reported by WHO 87%⁴, Federal Ministry of health 87.4%²⁰, and in different regions of Ethiopia such as a study conducted in Tigray 89.2%¹³, in Southern region 74.8%²⁹, in Addis Ababa 68.3% and 80.4%^{15,16}. The low treatment success rate observed in this study might be due to high transferred out rate 31.4% and death rate 8.8%. On the other hand one study showed that poor knowledge of tuberculosis among patients contributes for variations in health center treatment outcomes²².

The failure rate in the present study was 0.6% and it is steadily decreased across the study period. This finding was in line with Federal Ministry of health 2011 report of failure rate 0.6%²⁰. Probably this might be due to the current collaborative activities on DOTs to curbe the incidence and the development of drug resistance strains of TB.

The total death rate found in the present study was 8.8% higher than a study conducted in Addis Ababa 3.7%¹⁵, in Nigeria 1.9%²², and in Kenya 1.5%²⁵. However, our finding was lower than a study conducted in Gondar 10.1%¹⁴. Although, it is not significant this study also demonstrated that death rate of tuberculosis patients was decreased across the study periods. This might be due to increasing efforts to encourage tuberculosis patients for HIV screening and initiating anti-retroviral therapy for TB/HIV co - infected patients at this hospital.

Previous studies indicated that HIV status is associated with poor treatment outcomes^{31, 32}. Our study also showed that HIV positive patient 1.65 times more likely to had poor treatment out comes. Similarly smear-negative PTB patients had the lowest rate of successful treatment outcome. These patients have a higher frequency of HIV co-infection³³⁻³⁴.our result also depicted similar finding. According to many reports, urban residents^{35, 36} had higher probabilities of successful treatment outcome. This finding was in agreement with present study.

In the present study, we depicted that the probability of poor outcomes of TB treatment in patients age (18-30) was 0.372 less likely than patients age greater than or equal than 51. This finding was in agreement with the findings of previous studies in which older age increases the risk for unfavourable treatment outcome^{23, 35, 37}.

In the present study, poor treatment outcomes of TB were significantly associated being with in year 2008 than 2013. This finding was in agreement with a study conducted by Baye et al. in Gondar¹⁴. Probably this might be an indication of infancy of DOTS implementation and efficiency at the specified period.

Unlike the results of other studies, factors such as sex of patients did not show any statistically significant association with unsuccessful treatment outcome. Probably the reason might be risk factors for unsuccessful outcome were associated with patient behaviour and attitudes¹⁸.

CONCLUSION AND RECOMMENDATION:

Treatment outcome among TB patients in Debre Markos hospital was unsatisfactory. In the final multivariate logistic model, the odds of unsuccessful treatment outcome was higher among patients being age older than 51 years, rural residence, pulmonary negative, positive for HIV status and being in the year 2008 as compared to their respective comparison groups. Those patients at high risk of an unfavourable treatment outcome should be identified early and given additional follow-up.

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