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Treatment Outcome and Associated Factors among TB Patients in Ethiopia: Hospital-Based Retrospective Study

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Abstract ***Background*:** Tuberculosis remains a major global health problem and ranks alongside the human immunodeficiency virus (HIV) as a leading cause of mortality worldwide. For effective tuberculosis control, it is a pre-requisite to detect the cases as early as possible, and to ensure that the tuberculosis patients complete their treatment and get cured. However, in many resource-constrained settings treatment outcome for tuberculosis has not been satisfactory. ***Objective:*** The aim of the study was to assess the treatment outcome of tuberculosis and investigate the association of demographic and clinical factors with treatment success of patients enrolled in selected hospitals, Ethiopia. ***Methods:*** A fifteen-year retrospective register based historical data were collected through medical record review from 31 selected hospitals in Ethiopia. Data were analyzed using SPSS version 20 and to investigate the association of demographic and clinical factors with treatment success of patients, multiple logistic regression methods were used. A p value of less than 5% was considered as statistically significant in the final model. ***Result:*** Out of the 90,191 registered tuberculosis patients (50,167 males and 40,024 females) including all age group, 55.8% had successful treatment outcome and 44.2% had unsuccessful outcome. In the multivariate logistic model, the odds of unsuccessful treatment outcome was relatively higher among patients in the age group of ≥65 (AOR = 1.283, 95% CI: 1.186-1.387), unknown presumptive MDR TB (AOR=1.17, 95% CI:1.07-1.279) and unknown smear result (AOR=1.706, 95% CI:1.611-1.807); and was lower in age group 15-24 (AOR = 0.818, 95% CI: 0.781-0.857), among female patients (AOR = 0.89, 95% CI: 0..866-0.914) and extra pulmonary TB patients (AOR=0.889, 95% CI:0.848-0.932 as compared to their respective comparison groups. ***Conclusion:*** In this study, high proportion of unsuccessful treatment outcome was documented, therefore emphasis has to be given for patients with high risk of unsuccessful TB treatment outcome and targeted interventions should be carried out. All patients' background characteristics were significantly associated with the treatment success status. And a continuous follow-up of patients with frequent supportive supervision during the course of treatment is recommended.

Keywords: *Multivariate, logistic model, MDR TB, Adjusted Odds Ratio, TB treatment outcome*

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1. Background

According to WHO report, Ethiopia is among the 30 high burden countries for TB, TB/HIV and MDR-TB with estimated TB prevalence and incidence rates of 200 and 207 per 100,000 population in 2014 [1].Considering TB as one of the major public health challenges for the country, the FMOH has given due attention and included TB prevention and control among major priority programs [2]

Since 1997, much has been done to improve accessibility of TB diagnostic and treatment services to rural communities by equipping and staffing newly constructed primary health care units with microscopes, GeneXpert machines and trained health manpower [3,4]. Community based TB care intervention has been implemented as part of health extension program package since 2004, to decentralize TB case finding and treatment supervision to the level of health posts [5].

As it is has presented in the WHO on the Road to end TB document that, The End TB Strategy is not a "one size fits all" approach and its success depends on adaptation for diverse country settings. Thus country specific intervention is vital [6].

As a result, the country has achieved tuberculosis related MDG targets by halting and reversing the incidence rate from 369 in 1990 to 224 per 100,000 populations in 2014. It has also reduced TB prevalence and mortality rate by more than half compared to the 1990 baseline values.

Despite these achievements one-third of incident TB cases remained undetected and only a third of estimated drug-resistant TB cases are getting proper treatment every year [1]. Hence, Tuberculosis remains among the top ten causes of mortality in the country [4].

Cognizant of the facts, Ethiopia is required to exert much more effort to detect the missed one-third new TB cases and effectively treat at least 90% of notified TB cases. Treatment success rate (TSR) of TB patients was still low and a declining trend of TSR was observed [9].

Therefore, the study was conducted to assess the treatment outcome of tuberculosis and investigate the association of demographic and clinical factors with treatment success of patients enrolled in selected hospitals, Ethiopia.

1.1. Specific Objectives

1. To assess the trend of TB and treatment outcomes from the selected hospitals in the past fifteen years
2. To assess the outcomes of TB patients registered for anti-tuberculosis treatment in selected hospitals
3. To identify factors associated with treatment success for Tuberculosis patients in selected hospitals

2. Methods

The study was conducted in 31 selected hospitals from all regions and city administrative of Ethiopia. The data recorded from September-July, 2001/2 to 2015/16 were collected for the present study. The source population of the study was all patients registered for treatment of TB in the selected Hospitals. The study population was all tuberculosis patients who had treatment outcome at selected Hospitals between September-August, 2001/2-2015/16.

All data were retrieved from records of patient registration who took anti-TB treatment during the study period.

For the data collection from selected hospitals, EPHI identified and recruited health professionals working in the Outpatient Department TB clinics of the respective selected hospital as data collectors and the hospital head as supervisor/team leader besides frequent supervision made by EPHI Staff.

After data collection was completed, training has been given to the data entry team on the survey questionnaires, the nature of the data to be computerized, and the data entry template. Double data entry, cleaning and analyses were done using SPSS 20 statistical software. In order to control for possible errors during data entry, validation techniques such as supervision and running intermediate frequencies were employed.

To identify the factors for unsuccessful TB treatment outcome, study participants were categorized as having successful treatment if their record showed that they were cured or they had completed the treatment. Otherwise, they were categorized as treatment not successful (i.e. the record showed that the patient was either treatment failure, died, lost to follow-up, transferred out or not evaluated).

3. Ethical Consideration

The content of the proposal for the study on hospitals were reviewed and approved by scientific and ethical review committee of the Ethiopian Public Health Institute (EPHI) for its conformity with basic guidelines for ethical clearance of the Institute.

4. Results

4.1. Patients' Demographic Characteristics

As shown in Table 1, the high prevalence of all forms of TB cases observed among TB patients in the age group 25-34 (28.2%) followed by 15-24 (25.3%) and 35-49 (21.2%). The least prevalence seen in the age group >=65 (3.7%) followed by 50-64 (8.9%) and <=14 (12.7%).

Table 1. Socio-demographic characteristics of all Tuberculosis patients, in selected 31 hospitals Ethiopia 2001/2-2015/16

Characteristics	Frequency	Percent
Age		
≤ 14	11442	12.7
15-24	22804	25.3
25-34	25451	28.2
35-49	19139	21.2
50-64	8001	8.9
>=65	3354	3.7
Sex		
Male	50167	55.6
Female	40024	44.4
Type of TB		
Pulmonary	61400	68.1
Extra pulmonary	28405	31.5
Unknown	386	0.4
Presumptive MDR TB		
Yes	2190	2.4
No	31749	35.2
Unknown	56252	62.4
Smear result		
Positive	22272	24.7
Negative	44407	49.2
Unknown	23512	26.1
Outcome		
Cured	11981	13.3
Treatment Completed	38306	42.5
Treatment Failure	365	0.4
Died	4924	5.5
LTFU	3654	4.1
Transferred out	23659	26.2
Not evaluated	7302	8.1
Year		
2001/2	7566	8.4
2002/3	7086	7.9
2003/4	6360	7.1
2004/5	6406	7.1
2005/6	6408	7.1
2006/7	6256	6.9
2007/8	4699	5.2
2008/9	6154	6.8
2009/10	6397	7.1
2010/11	8272	9.2
2011/12	6966	7.7
2012/13	4658	5.2
2013/14	4892	5.4
2014/15	4552	5.0
2015/16	3519	3.9
Total	90191	

Moreover, greater proportion of TB cases revealed among male (55.6%) TB patients compared to females (44.4%).

Percentage distribution of TB by type shows, about 68 percent were pulmonary followed by extra pulmonary (31.5%). And only 24.7 percent of all forms of TB cases

were smear positive result.

The Figure 1 shows a trend of the proportion of all forms of TB cases. Highest proportion of TB was observed in 2010/11 (9.2%) while the lowest was observed in 2015/16 (3.9%). Generally, a decreasing trend observed from 2010/11 onwards.

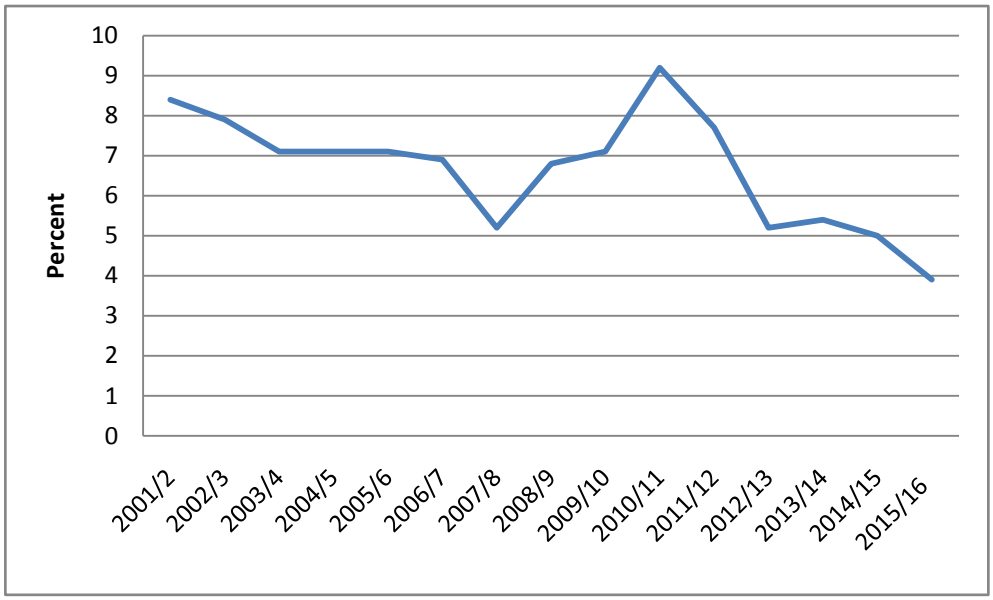

Figure 1. Trend of all forms of TB cases, in selected 31 hospitals in Ethiopia, 2001/2-2015/16

Table 2. Treatment outcomes of registered Tuberculosis patients, Ethiopia 2001/2-2015/16

Characteristics	Treatment outcome						
	Cured n(%)	Treatment Completed n(%)	Treatment Failure n(%)	Died n(%)	LTFU n(%)	Transferred out n(%)	Not evaluated n(%)
Age							
≤ 14	494(4.3)	5746(50.2)	30(0.3)	426(3.7)	431(3.8)	3309(28.9)	1006(8.8)
15-24	4118(18.1)	9836(43.1)	95(0.4)	745(3.3)	781(3.4)	5590(24.5)	1639(7.2)
25-34	3939(15.5)	10254(40.3)	106(0.4)	1524(6)	1061(4.2)	6344(24.9)	2223(8.7)
35-49	2398(12.5)	7770(40.6)	82(0.4)	1407(7.4)	842(4.4)	5100(26.6)	1540(8)
50-64	788(9.8)	3322(41.5)	35(0.4)	531(6.6)	357(4.5)	2353(29.4)	615(7.7)
>=65	244(7.3)	1378(41.1)	17(0.5)	291(8.7)	182(5.4)	963(28.7)	279(8.3)
Sex							
Male	6771(13.5)	20531(40.9)	213(0.4)	2789(5.6)	2092(4.2)	13481(26.9)	4290(8.6)
Female	5210(13)	17775(44.4)	152(0.4)	2135(5.3)	1562(3.9)	10178(25.4)	3012(7.5)
Type of TB							
Pulmonary	11592(18.9)	23403(38.1)	313(0.5)	3458(5.6)	2476(4)	14991(24.4)	5167(8.4)
Extra pulmonary	378(1.3)	14728(51.9)	48(0.2)	1446(5.1)	1161(4.1)	8546(30.1)	2098(7.4)
Unknown	11(2.8)	175(45.3)	4(1)	20(5.2)	17(4.4)	122(31.6)	37(9.6)
Presumptive MDR TB							
Yes	548(25)	725(33.1)	40(1.8)	149(6.8)	46(2.1)	601(27.4)	81(3.7)
No	4745(14.9)	13504(42.5)	66(0.2)	1731(5.5)	968(3)	8476(26.7)	2259(7.1)
Unknown	6688(11.9)	24077(42.8)	259(0.5)	3044(5.4)	2640(4.7)	14582(25.9)	4962(8.8)
Smear result							
Positive	11056(49.6)	2834(12.7)	199(0.9)	1063(4.8)	744(3.3)	4597(20.6)	1779(8)
Negative	689(1.6)	23570(53.1)	125(0.3)	2671(6)	1944(4.4)	11996(27)	3412(7.7)
Unknown	236(1)	11902(50.6)	41(0.2)	1190(5.1)	966(4.1)	7066(30.1)	2111(9)
Year							
2001/2	1210(16)	3167(41.9)	30(0.4)	530(7)	339(4.5)	1287(17)	1003(13.3)
2002/3	1169(16.5)	3025(42.7)	27(0.4)	476(6.7)	348(4.9)	1206(17)	835(11.8)
2003/4	977(15.4)	2433(38.3)	32(0.5)	489(7.7)	294(4.6)	1244(19.6)	891(14)
2004/5	793(12.4)	2917(45.5)	24(0.4)	439(6.9)	368(5.7)	1565(24.4)	300(4.7)
2005/6	691(10.8)	2801(43.7)	28(0.4)	422(6.6)	453(7.1)	1474(23)	539(8.4)
2006/7	712(11.4)	3092(49.4)	12(0.2)	334(5.3)	381(6.1)	1276(20.4)	449(7.2)
2007/8	614(13.1)	2268(48.3)	24(0.5)	298(6.3)	155(3.3)	1011(21.5)	329(7)
2008/9	788(12.8)	2682(43.6)	20(0.3)	359(5.8)	318(5.2)	1501(24.4)	486(7.9)
2009/10	714(11.2)	2723(42.6)	30(0.5)	337(5.3)	148(2.3)	1986(31)	459(7.2)
2010/11	844(10.2)	3307(40)	39(0.5)	362(4.4)	161(1.9)	2873(34.7)	686(8.3)
2011/12	832(11.9)	2593(37.2)	30(0.4)	258(3.7)	121(1.7)	2634(37.8)	498(7.1)
2012/13	697(15)	2085(44.8)	15(0.3)	186(4)	187(4)	1328(28.5)	160(3.4)
2013/14	669(13.7)	2021(41.3)	37(0.8)	147(3)	176(3.6)	1697(34.7)	145(3)
2014/15	746(16.4)	2101(46.2)	12(0.3)	151(3.3)	156(3.4)	1258(27.6)	128(2.8)
2015/16	525(14.9)	1091(31)	5(0.1)	136(3.9)	49(1.4)	1319(37.5)	394(11.2)
Total	11981(13.3)	38306(42.5)	365(0.4)	4924(5.5)	3654(4.1)	23659(26.2)	7302(8.1)

4.2. Treatment Outcome

Of 90,191 TB patients who were registered at selected hospitals during the study period, 1,198 (13.3%) were cured, 38,306(42.5%) completed their treatment, 365 (0.4%) were with treatment failure, 4,924 (5.5%) died, 3654 (4.1%) lost to follow up, 23,659 (26.2%) were transferred out to other health facility and 7,302(8.1%) were not evaluated. The cure rate of TB patients varied from 4.3% in age group <=14 to 18.1% in age group 15-24 (Table 2).

4.3. Type of TB

Except TB patients in age group <= 14 (55.1%), in all other age groups about 70% of TB patients were infected with pulmonary TB. The proportion of pulmonary TB is relatively high among males (69.2%) compared to females (66.7%) TB patients.

Generally, in all TB patients background characteristics pulmonary TB was more prevalent compared to extra pulmonary TB. Although, Pulmonary TB is higher than extra pulmonary TB, higher proportion of were observed in the lower age group (≤14) compared with the other age groups.

4.4. Factors Associated with Treatment Outcomes

As shown in Table 4 below, status of treatment successful outcome was significantly associated with patients' age group, sex, type of TB, presumptive MDR TB, smear result and year of registration (P-value < 0.05) with successful and unsuccessful treatment outcome proportion of 55.8% and 44.2%, respectively.

The unsuccessful treatment outcome was 1.283, 1.167, 1.116 times more likely among TB patients in age group ≥ 65, 50-64 and 35-49, respectively compared to patients in age group <=14.

With unknown presumptive MDR TB the unsuccessful treatment outcome was 1.17 times more likely compared to TB patients with presumptive MDR TB. The odd of unsuccessful treatment outcome was 1.347 times more likely among TB patients with negative smear result compared to TB patients with positive smear result.

Among Female patients unsuccessful treatment outcome was 11 percent less likely compared to male patients. The unsuccessful treatment outcome was about 11 percent less likely among extra pulmonary TB patients compared to pulmonary.

Table 3. Characterristics of registered TB patients in 31 selected hospitals, Ethiopia 2001/2-2015/16

Characteristics	Type of TB		
	Pulmonary	Extra Pulmonary	Unknown
Age			
≤ 14	6310(55.1)	5069(44.3)	63(0.6)
15-24	15581(68.3)	7141(31.3)	82(0.4)
25-34	17961(70.6)	7404(29.1)	86(0.3)
35-49	13569(70.9)	5468(28.6)	102(0.5)
50-64	5631(70.4)	2332(29.1)	38(0.5)
>=65	2348(70)	991(29.5)	15(0.4)
Sex			
Male	34696(69.2)	15262(30.4)	209(0.4)
Female	26704(66.7)	13143(32.8)	177(0.4)
Presumptive MDR TB			
Yes	1823(83.2)	357(16.3)	10(0.5)
No	20258(63.8)	11422(36)	69(0.2)
Unknown	39319(69.9)	16626(29.6)	307(0.5)
Smear result			
Positive	21882(98.2)	367(1.6)	23(0.1)
Negative	37921(85.4)	6316(14.2)	170(0.4)
Unknown	1597(6.8)	21722(92.4)	193(0.8)
Outcome			
Cured	11592(96.8)	378(3.2)	11(0.1)
Treatment completed	23403(61.1)	14728(38.4)	175(0.5)
Treatment failure	313(85.8)	48(13.2)	4(1.1)
Died	3458(70.2)	1446(29.4)	20(0.4)
LTFU	2476(67.8)	1161(31.8)	17(0.5)
Transferred out	14991(63.4)	8546(36.1)	122(0.5)
Not evaluated	5167(70.8)	2098(28.7)	37(0.5)
Year			
2001/2	5438(71.9)	2052(27.1)	76(1)
2002/3	4778(67.4)	2292(32.3)	16(0.2)
2003/4	4272(67.2)	2051(32.2)	37(0.6)
2004/5	4283(66.9)	2120(33.1)	3(0)
2005/6	4307(67.2)	2076(32.4)	25(0.4)
2006/7	4517(72.2)	1719(27.5)	20.(0.3)
2007/8	3315(70.5)	1369(29.1)	15(0.3)
2008/9	4235(68.8)	1881(30.6)	38(0.6)
2009/10	4336(67.8)	2015(31.5)	46(0.7)
2010/11	5074(61.3)	3164(38.2)	34(0.4)
2011/12	4493(64.5)	2461(35.3)	12(0.2)
2012/13	3330(71.5)	1318(28.3)	10(0.2)
2013/14	3413(69.8)	1466(30)	13(0.3)
2014/15	3166(69.6)	1361(29.9)	25(0.5)
2015/16	2443(69.4)	1060(30.1)	16(0.5)

Table 4. Treatment outcomes by TB patients background characteristics, Ethiopia 2001/2-2015/16

Characteristics	Treatment outcome		Adjusted Odds Ratio	
	Unsuccessful n (%)	Successful n (%)	AOR(95% C.I)	P-value
Age				
≤ 14	5202(45.5)	6240(54.5)	1	
15-24	8850(38.8)	13954(61.2)	0.818(0.781,0.857)	<0.001
25-34	11258(44.2)	14193(55.8)	1.027(0.982,1.075)	0.242
35-49	8971(46.9)	10168(53.1)	1.116(1.064,1.170)	<0.001
50-64	3891(48.6)	4110(51.4)	1.167(1.101,1.237)	<0.001
>=65	1732(51.6)	1622(48.4)	1.283(1.186,1.387)	<0.001
Sex				
Male	22865(45.6)	27302(54.4)	1	1
Female	17039(42.6)	22985(57.4)	0.89(0.866,0.914)	<0.001
Type of TB				
Pulmonary	26405(43)	34995(57)	1	1
Extra pulmonary	13299(46.8)	15106(53.2)	0.889(0.848,0.932)	<0.001
Unknown	200(51.8)	186(48.2)	1.129(0.921,1.383)	0.243
Presumptive MDR TB				
Yes	917(41.9)	1273(58.1)	1	1
No	13500(42.5)	18249(57.5)	1.004(0.918,1.098)	0.939
Unknown	25487(45.3)	30765(54.7)	1.170(1.07,1.279)	0.001
Smear result				
Positive	8382(37.6)	13890(62.4)	1	1
Negative	20148(45.4)	24259(54.6)	1.347(1.301,1.394)	<0.001
Unknown	11374(48.4)	12138(51.6)	1.706(1.611,1.807)	<0.001
Year				
2001/2	3189(42.1)	4377(57.9)	1	1
2002/3	2892(40.8)	4194(59.2)	0.923(0.864,0.986)	0.018
2003/4	2950(46.4)	3410(53.6)	1.171(1.094,1.253)	<0.001
2004/5	2696(42.1)	3710(57.9)	0.996(0.93,1.066)	0.901
2005/6	2916(45.5)	3492(54.5)	1.143(1.069,1.223)	<0.001
2006/7	2452(39.2)	3804(60.8)	0.867(0.810,0.929)	<0.001
2007/8	1817(38.7)	2882(61.3)	0.867(0.805,0.935)	<0.001
2008/9	2684(43.6)	3470(56.4)	1.05(0.980,1.124)	0.165
2009/10	2960(46.3)	3437(53.7)	1.189(1.111,1.273)	<0.001
2010/11	4121(49.8)	4151(50.2)	1.364(1.28,1.453)	<0.001
2011/12	3541(50.8)	3425(49.2)	1.425(1.333,1.523)	<0.001
2012/13	1876(40.3)	2782(59.7)	0.935(0.867,1.008)	0.079
2013/14	2202(45)	2690(55)	1.146(1.065,1.234)	<0.001
2014/15	1705(37.5)	2847(62.5)	0.852(0.789,0.920)	<0.001
2015/16	1903(54.1)	1616(45.9)	1.724(1.588,1.872)	<0.001
Total	39904(44.2)	50287(55.8)		

5. Discussion

As a major indicator for the evaluation of the performance of a national TB program, assessment of anti-tuberculosis treatment outcome and identifying factors associated with unsuccessful treatment outcome is crucial. In this hospital based historical cohort study, information was extracted from 90191 registered TB patients; 44.4% of the patients were females. Similarly, previous study at University of Gondar Teaching Hospital documented the same proportion of female patients registered for TB treatment [7]. In this study the successful outcome proportion is found to be 55.8% while it is 60.1% in the previous study at Gondar Teaching Hospital, and this difference could be due to the inclusion of transfer-out TB patient as unsuccessful treatment outcome in this study.

The 0.4% treatment failure and 5.5% death rate documented in our findings are lower than Gondar teaching hospital, where 0.8% failed treatment and 17.7% had died.

Low rate of unsuccessful TB treatment was observed in the patient record review done in Metema hospital (34.7%) [9]. Similarly, a study done in Gambella hospital revealed 29.3%, this could be due to the fact that the study doesn't include transfer out cases [10]. Very low proportion of unfavorable outcome was observed in the other study done in Addis Ababa Health facilities which revealed closer proposition of failure to success to the WHO standard (17.8%) [11] and 12.9% had unsuccessful treatment outcome [12]. Furthermore, in western oromia the overall mean treatment rate of fail to success TB patients was 14.8% and 26% had bad outcome [13] and in another study failure of TB treatment fount to be 29% and 26%, respectively [14,15]. Generally the lower and higher difference in failure to success on TB treatment from this current study was observed due to possibly methodological and geographical factors. A bit comparable result has been observed on the unfavorable outcome (39.9%) on the study done in Gonder referral hospital [16].

In multivariable logistic regression the unsuccessful treatment outcomes of our finding were significantly higher in age groups ≥ 65, 50-64 and 35-49 ; and among smear negative TB patients compared to patients in age group <=14 and TB patients with positive smear result, respectively. The unsuccessful TB treatment outcome was significantly lower among female and extra pulmonary TB patients compared to male and pulmonary TB patients, respectively.

Since this study is based on secondary data analysis, it has limitations as well as strengths which need to be noted while interpreting the findings. The main strengths of the study is covering 31 hospitals from all regions of the country by assessing the available fifteen years records.

The main limitation of this study like in other low income countries is the poor quality of reports [8].

In this study age, sex, type of TB were identified as factors associated with the result of treatment outcome, similarly being male, and co-infection were significantly associated with unsuccessful treatment of TB [9], this is because HIV co-infection is predominated among males whereas, co-infection with HIV and being male were associated with unsuccessful treatment outcome. On the other hand Tuberculosis type, age greater than 45, Baseline CD4 count less than 20cell/ul were factors associated with unsuccessful treatment outcome [14]. Being residing in outside the town, having less than the mean baseline weight (<43.7 kg) at initiation of TB treatment, being in the bedridden condition and experiencing anti-TB treatment side effect were the factors that resulted the patient in treatment failure [16]. HIV co-infected patients were associated with unsuccessful treatment outcomes [15]. Smear positive pulmonary TB and TB/HIV co-infections were significantly associated with unsuccessful treatment outcome [17].

6. Conclusion

The overall TB treatment success rate for all registered patients was 55.8% with high proportion of unsuccessful treatment outcome of 44.2%. In addition to this, the following risk factors were identified as potential predictors for unsuccessful treatment outcome: patients' age, sex, type of TB, status of presumptive MDR TB and smear result. According to the findings of this study, emphasis should be given for patients with high risk of unsuccessful treatment outcome and targeted interventions need to be carried out.

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Conflict of Interests

No conflict of interests between authors

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