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Original Article

Assessment of Success Rate of Directly Observed Treatment Short-Course (DOTS) in Tuberculosis Patients of South India

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ABSTRACT

Objective: To assess the success rate of DOTS for tuberculosis patients and the secondary objective was to identify the factors associated with unsuccessful treatment outcome. **Methods:** A retrospective study was conducted to review the medical records of patients (n = 1113) registered at the Directly Observed Treatment Short-Course (DOTS) clinic of Government Infectious Disease (Govt. ID) Hospital, Guntur, India. Multivariate logistic regression model was used to determine the factors associated with the treatment success rate. **Results:** The overall mean success rate of TB patients was found to be 82.8%. Treatment success rate (TSR) was steadily increased across the years from 73.9% in 2015 to 84.3% in 2016 and 88.9% in 2017 while the death rate was steadily decreased from 11.2% in 2015 to 6.25% in 2016 and 4.33% in 2017. Risk factors significantly associated with unsuccessful treatment outcome were found to be HIV positive (P<0.001), smear negative (P<0.001), all retreatment cases (P<0.001), smoking (P=0.008), and alcoholism (P=0.019). Smear positive patients had lower death rate (3.9% vs. 10.1%; $P < 0.001$) and failure rate ((2.6% vs. 8.7%; $P < 0.001$) compared to smear negative patients. Patients tested HIV positive had seen significantly unfavorable outcomes in death rate (OR= 9.17, 95% CI=5.31-15.83; $P < 0.001$) and treatment failure (OR=13.3, 95% CI= 7.31-24.17; $P < 0.001$). **Conclusion:** Implementing the DOTS strategy proved the satisfactory success rate in the South Indian hospital across three years. The unsuccessful treatment outcome was significantly associated with gender, HIV status, re-treatment, smear negative, smoking and alcoholism.

Key words: Directly observed treatment short-course, Retrospective study, Risk factors, Treatment success rate, Tuberculosis.

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INTRODUCTION

Tuberculosis (TB) has existed for millennia and remains a major global health problem. It causes ill-health in millions of people each year. In 2015, it was one of the top ten causes of death worldwide, ranking above HIV/AIDS as one of the leading causes of death from an infectious disease. Six countries accounted for 60% of the new cases: India, Indonesia, China, Nigeria, Pakistan and South Africa.[1]

In 2016, there were an estimated 1.3 million TB deaths among HIV-negative people and an additional 374 000 deaths among HIV-positive people. India accounted for 33% of global TB deaths among HIV-negative people. Globally, the TB mortality rate is falling at about 3% per year. TB incidence is falling at about 2% per year and 16% of TB cases die from the disease; by 2020, these figures need to improve to 4–5% per year and 10%, respectively to reach the first (2020) milestones of the End TB Strategy.[2]

In India, 29% of adults but 72% of HIV-positive adults live in four large states in the south where, even with the RNTCP, mortality is expected to fall by only 15% between 1990 and 2015.[3] There are more challenges for controlling TB worldwide by adopting the medication adherence. There was a high level of adherence to anti-TB treatment and also a high TB treatment success rate.[4]

Countries implementing DOT to ensure treatment adherence have shown impressive results with increasing treatment success and low default rates.[1,5,6] India has had an ongoing National TB Program (NTP) since 1962.[7] Large-scale implementation of the RNTCP began in late 1998.[8] Though the Indian government has made several announcements to eliminate TB by 2025, the WHO report showed that up to 27.9 lakh patients were estimated to be infected in the country in 2016. Out of the 27.9 lakh estimated patients, only 1,938,158 TB cases were notified in the public and private sector in India, which means over 8.5 lakh cases were missing the treatment options.

In order to overcome these lacunae, the Government decided to give a new thrust to TB control activities by revitalizing the NTP, with assistance from international agencies, in 1993. The Revised National Tuberculosis Control Programme (RNTCP) thus formulated, adopted the internationally recommended Directly Observed Treatment Short-course (DOTS) strategy, as the most systematic and cost-effective approach to revitalize the TB control programme in India.

Directly observed alternate day treatment (DOTS) for TB under RNTCP in India has shown to be effective in TB patients with or without HIV infection.[9,10] Furthermore, World Health Organization (WHO) has

recommended the use of standard short course therapy for active TB in HIV positive patients.[11]

Monitoring the treatment outcome using standardized approach is required to evaluate the effectiveness of the intervention. However, treatment outcome has not been assessed yet in South Indian population visiting Govt. ID hospital, Guntur, India Guntur, India. Therefore, this study aimed to assess treatment outcome of all type of TB patients over 3-year period retrospectively.

METHODOLOGY

Ethics Approval and Consent to Participate

All participants gave written informed consent to participate. Permission to conduct the study as obtained from Government infectious Disease Hospital, Guntur, India. The study was approved by the Institutional Ethics Committee of Government infectious Disease Hospital, Guntur, India.

Study design, study settings and data collection

This was a retrospective cohort study of pulmonary tuberculosis patients registered in DOTS centre of Govt. Infectious Disease Hospital, Guntur, India from January, 2014 to December 2016 and for their treatment outcome from 2015 to 2017. All participants gave written informed consent and the study was approved by the Ethics Committee of Government Infectious Disease Hospital, Guntur, India.

The data collected from TB patients medical records included socio-demography, habits of patient, type of TB, history of TB, HIV status, treatment initiation and it's follow up, outcomes of TB. All the patient data retrieved from DOTS centre. All patients of either sex suffering from pulmonary TB were included in the study. We enrolled new and retreatment cases that were recorded during the study period. New cases involved all untreated smear positive pulmonary TB and smear negative pulmonary TB with extensive parenchymal involvement. Retreatment cases included all relapse, failure, transferred in and return after default. All other forms of TB (extra pulmonary), like military TB, TB pleurisy, hilar and/or mediastinal lymphadenopathy, spinal, intestinal and genito-urinary TB were excluded. Some patient's records were excluded due to incomplete information about treatment outcome and transferred out to other health care clinics after the declination of the prescribed treatment (Figure 1).

Data analysis

Primary outcome measure was the success rate of DOTS for tuberculosis patients and secondary outcome measures were the factors associated with unsuccessful treatment outcome. Patients were followed up to the end of treatment. According to WHO and International Union Against Tuberculosis and Lung Disease (IUATLD) guidelines, treatment outcomes were categorized as cured (finished treatment with negative smear or culture test at the end of the treatment), completed (finished treatment but does not have negative sputum smear or culture at the end of the treatment), treatment failure(sputum or culture test is positive after 5 months), default (patients who interrupted their treatment for two consecutive months or more after treatment commencement), died (patients who die of any reason during the course of treatment) and transferred out (patients who transferred to another healthcare units and whose treatment outcome is unknown). Treatment success rate is calculated as sum of cured and treatment completed.

Statistical analysis

Categorical variables were reported as frequency and percentage frequency. Data was mentioned in mean ± SD values. Chi square test was performed to determine the strength of association between that outcome and variables and crude odds ratio (COR) was determined. In addition, multivariate logistic regression analysis was applied to determine the factors affecting the treatment success rate following adjusting for all confounding variables and adjusted Odds ratio (AOR) were calculated. P-value less than 0.001 were considered as statistically significant. Data was analyzed using Epi info version.7 statistical tool and Graph Pad Prism software version 5.0.

Table 1: Patient recruitment for period of 2014-2016.

Method	Yearly Distribution			Distribution in 3yrs (%)
	2014	2015	2016	
New	194 (56)	239(67.8)	328(79)	761(68.3)
Relapse	22(6.3)	16(4.5)	32(7.7)	70(6.28)
Failure	16(4.6)	28(7.9)	15(3.6)	59(5.3)
Transferred in	26(7.5)	18(5.1)	8(1.9)	52(4.6)
Return after default	88(25.4)	51(14.4)	32(7.7)	171(15.3)
TOTAL	**346(31.1)**	**352(31.6)**	**415(37.2)**	**1113(100)**

RESULTS

Patient characteristics

A total of 1113 pulmonary tuberculosis patients had attended DOTS centre at Govt. ID hospital, Guntur, India between January 2015 and December 2017. Patients were recruited through different methods: New, Relapse, Failure, Transferred in and Return after default. The majority 761 (68.3%) of the patients were new TB cases whereas 70 (6.28%) were relapse cases; 59(5.3%) were treatment failure cases; 52 (4.6%) were transferred in cases; and 171 (15.3%) were return after default. Total retreatment cases were 352 (31.6%) cases (Table 1).

Out of 1113 TB patients, 734(66%) were males while the remaining were females. The age of the patients ranged from 16 to 80 years with a mean (SD) of 47.13(14.5) years. The majority 284 (25.5%) of the patients belonged to age group 50-59 years. Rural patients made up 948(85.1%) of the cases, while 165 (14.8%) were from urban. Sixty eight percent (756) of the patients had sputum test positive and remaining had negative results. Overall, 23% (256) of the patients had a history of Human Immunodeficiency Virus (HIV) positive. There were 53.5% (596) cases had a history of smoking and 35.3% (393) had a habit of alcohol consumption. The socio demographic and clinical characteristics of tuberculosis patients included in the study are shown in Table 2.

Treatment outcomes

Out of 1113, 82.8% (922) of the patients were successfully treated (cured and treatment completed), 5.7% (64) were treatment failure, 5.9% (66) were died, 4.5% (51) were default, 0.9% (10) were transferred out. Treatment success rate was steadily increased across the years from 73.9% in 2015 to 84.3% in 2016 and 88.9% in 2017 while the death rate was steadily decreased from 11.2% in 2015 to 6.25% in 2016 and 4.33% in 2017 (Table 3).

Higher default rates were observed in elderly age group, male patients, patients living in rural areas, smear negative, HIV negative, default, patients having smoking habit and alcohol consumption. Factors associated with higher treatment failure rates included being male, elderly age group, living in rural areas, smear negative, HIV positive, treatment failure, patients with smoking habit and alcohol consumption. The death rate was found be high in elderly age group, being male, living in rural areas, smear negative, HIV positive, transferred in, patients having smoking habit and alcohol consumption.

Table 2: Socio-demographic and clinical characteristics of tuberculosis patients.

Variables	N (%)
Gender	
Male	734(66)
Female	379(34)
Age (years)	
<30	101(8.9)
30-39	234(21)
40-49	239(21.4)
50-59	284(25.5)
≥60	255(22.9)
Education	
Illiterate	162(14.5)
School	840(75.5)
Pre-university	52(4.6)
University	59(5.3)
Occupation	
Business	48(4.3)
Private	525(47.2)
Agriculture	204(18.3)
Old aged	245(22)
Govt	67(6.0)
Student	24(2.1)
Residence	
Urban	165(14.8)
Rural	948(85.1)
Marital status	
Married	935(84)
unmarried	116(10.4)
widowed	47(4.2)
divorced	15(1.3)
Smoking	
Yes	596(53.5)
No	517(46.4)
Alcohol	
Yes	393(35.3)
No	720(64.7)
HIV status	
Positive	256(23)
Negative	857(77)
Smear test	
positive	756(67.9)
negative	357(32)
History of TB treatment	
New cases	761(68.3)
retreatment	352(31.6)
Treatment outcome	
Cured	659(59.2)
Completed	263(23.6)
Died	66(5.9)
Failure	64(5.7)
Default	51(4.5)
Transfer out	10(0.9)

Table 3: Treatment outcome for 2015, 2016 and 2017.

Treatment outcome	Yearly distribution of patients			Percentage rate in 3yrs (%)
	2015	2016	2017	
Cure	174(50.3)	223(63.3)	262(63.1)	659(59.2)
Completed	82(23.7)	74(21.0)	107(25.7)	263(23.6)
Success Rate	**256(73.9)**	**297(84.3)**	**369(88.9)**	**922(82.8)**
Treatment failure	39(11.3)	5(1.4)	20(4.8)	64(5.7)
Died	26(7.5)	22(6.25)	18(4.3)	66(5.9)
Default	21(6.1)	22(6.25)	8(1.9)	51(4.5)
Transferred out	4(1.1)	6(1.7)	0	10(0.9)
Total	346(31.1)	352(31.6)	415(37.2)	1113(100)

Table 4: Treatment outcome by socio-demographic and clinical characteristics.

VARIABLES	Total TB cases	Cured n (%)	Completed n (%)	Failure n (%)	Default n (%)	Died n (%)	Tranfer out n (%)
	1113	659(59.2)	263(23.6)	64(5.7)	51(4.5)	66(5.9)	10(0.9)
AGE (YEARS)							
<30	101(8.9)	57(56.4)	33(32.7)	3(2.9)	2(1.9)	1(0.9)	5(4.9)
30-39	234(21)	139(59.4)	59(25.2)	12(5.1)	5(2.1)	19(8.1)	0
40-49	239(21.4)	124(51.9)	78(32.6)	13(5.4)	12(5.02)	11(4.6)	1(0.4)
50-59	284(25.5)	202(71.1)	37(13)	17(5.9)	14(4.9)	14(4.9)	0
≥60	255(22.9)	137(53.7)	56(21.9)	19(7.4)	18(7)	21(8.2)	4(1.5)
GENDER							
Male	734(66)	417(56.8)	171(23.3)	47(6.4)	41(5.6)	51(6.9)	7(0.9)
Female	379(34)	242(63.8)	92(24.2)	17(4.5)	10(2.6)	15(3.9)	3(0.8)
RESIDENCE							
Urban	165(14.8)	98(59.3)	45(27.2)	8(4.8)	6(3.6)	6(3.6)	2(1.2)
Rural	948(85.1)	561(59.1)	218(22.9)	56(5.9)	45(4.7)	60(6.3)	8(0.8)
TYPE OF TB							
Smear positive	756(67.9)	476(62.9)	197(26.1)	27(3.6)	20(2.6)	30(3.9)	6(0.8)
Smear negative	357(32)	183(51.2)	66(18.5)	37(10.3)	31(8.7)	36(10.1)	4(1.1)
HIV STATUS							
Positive	256(23)	53(20.7)	106(41.4)	49(19.1)	1(0.4)	46(7.9)	1(0.4)
Negative	857(77)	601(70.7)	157(18.3)	15(1.7)	50(5.8)	20(2.3)	7(0.8)
TB CATEGORY							
New	761(68.3)	550(72.2)	127(16.7)	39(5.1)	3(0.4)	38(4.5)	4(0.5)
Relapse	70(6.28)	30(42.8)	15(21.4)	7(10)	9(12.8)	8(11.4)	1(1.4)
Failure	59(5.3)	25(42.3)	11(18.6)	10(16.9)	8(13.5)	5(8.4)	0
Transfer in	52(4.6)	22(42.3)	10(19.2)	5(9.6)	7(13.4)	6(11.5)	2(3.8)
Default	171(15.3)	32(18.7)	100(58.5)	3(1.7)	24(14)	9(5.2)	3(1.7)
All Retreatment	352(31.6)	109(30.9)	136(38.6)	25(7.1)	48(13.6)	28(7.9)	6(1.7)
SMOKING							
Yes	596(53.5)	344(57.7)	133(22.3)	39(6.5)	34(5.7)	42(7)	4(0.6)
No	517(46.4)	315(60.9)	130(25.1)	25(4.8)	17(3.2)	24(4.6)	6(1.2)
ALCOHOL							
Yes	393(35.3)	196(49.8)	115(29.2)	26(6.6)	24(6.1)	30(7.6)	2(0.5)
No	720(64.7)	463(64.3)	148(20.5)	38(5.2)	27(3.7)	36(5)	8(1.1)

Table 5: Factors associated with TB treatment success rate during 2015-17.

Variables	Category	Successfully treated	Unsuccessfully treated	COR (95% CI)	AOR (95% CI)
Age (years)	≤50	490(85.36)	84(14.63)	1.00	1.00
	>50	432(80.14)	107(19.85)	0.69(0.51-0.95) **	0.47(0.05-0.89)
Gender	Male	588(80.1)	146(19.9)	1.00	1.00
	Female	334(88.1)	45(11.9)	1.84(1.28-2.64) **	1.96(1.4-2.52) **
Residence	Urban	143(86.6)	22(13.3)	1.00	1.00
	Rural	779(82.1)	169(17.8)	0.71(0.43-0.99)	0.66(0.38-0.94)
Type of TB	Smear positive	673(89)	83(10.9)	1.00	1.00
	Smear negative	249(69.7)	108(30.2)	0.28(0.21-0.39) **	0.35(0.28-0.42) **
HIV status	Positive	159(62.1)	55(21.5)	1.00	1.00
	Negative	763(89)	92(10.7)	2.87(1.97-4.17) **	3.01(2.11-3.91) **
TB category	New	677(88.9)	84(11)	1.00	1.00
	All Retreatment	245(69.6)	107(30.4)	0.28(0.20-0.39)**	0.34(0.26-0.42) **
Smoking	Yes	477(80)	119(19.9)	1.00	1.00
	No	445(86)	72(13.9)	1.5(1.12-2.12) **	1.7(1.32-2.08) **
Alcohol	Yes	311(79.1)	82(20.8)	1.00	1.00
	No	611(84.8)	109(15.1)	1.47(1.07-2.03) **	1.39(0.99-1.79) **

** Significant at $P< 0.001$; COR: Crude Odds Ratio; AOR: Adjusted Odds Ratio.

Elderly age group patients had higher default (7%) and failure rates (7.4%) in comparison with younger age groups. Male patients were more likely to experience death (OR =1.75, 95% CI=0.97-3.16) and default (OR=2.11, 95% CI=1.04-4.27) than females. Smear positive patients had lower death rate (3.9% vs. 10.1%; $P < 0.001$) and failure rate ((2.6% vs. 8.7%; $P < 0.001$) compared to smear negative patients. Patients tested HIV positive had seen significantly unfavorable outcomes in death rate (OR= 9.17, 95% CI=5.31-15.83; $P < 0.001$) and treatment failure (OR=13.3, 95% CI= 7.31-24.17; $P < 0.0001$). The default rate (4.5% vs. 7.9%; $P < 0.001$) is very low in new cases compared to all retreatment cases. Patents with smoking habit and alcohol consumption experienced more death (7% vs. 4.6%, 7.6% vs. 5%; $P < 0.001$) and default (5.7% vs. 3.2%, 6.1% vs. 3.7%; $P < 0.001$) as an outcome respectively (Table 4).

Multivariable logistic regression analysis showed that female patients had significantly higher treatment success rate than males (88.1% vs. 80.1%; $P < 0.001$). As the age of tuberculosis patients increased, the success rate was decreased. Elderly patients had significantly lower success rate compared to younger age groups. Furthermore, patients from rural area had lower success rate compared to patients from urban areas. However, the difference is not statistically significant (P =0.179) (Table 5).

Smear negative patients had higher risk of unsuccessful treatment outcome than smear negative patients. Poor treatment outcome was found in HIV positive patients. All retreatment cases were less likely to be treated successfully compared to new patients. Smoking habit and alcohol consumption were also considered as risk factors for unfavorable treatment outcome.

DISCUSSION

According to the WHO report 2017, data showed a global treatment success rate of 83% for TB. Targeted success rate was at least 85% among New Sputum Positive (NSP) patients. Treatment success rate among new sputum positive patients and smear negative patients were 89% and 69.7% respectively. Our study showed that treatment success rate of all tuberculosis patients was 82.8% which was close to the targeted

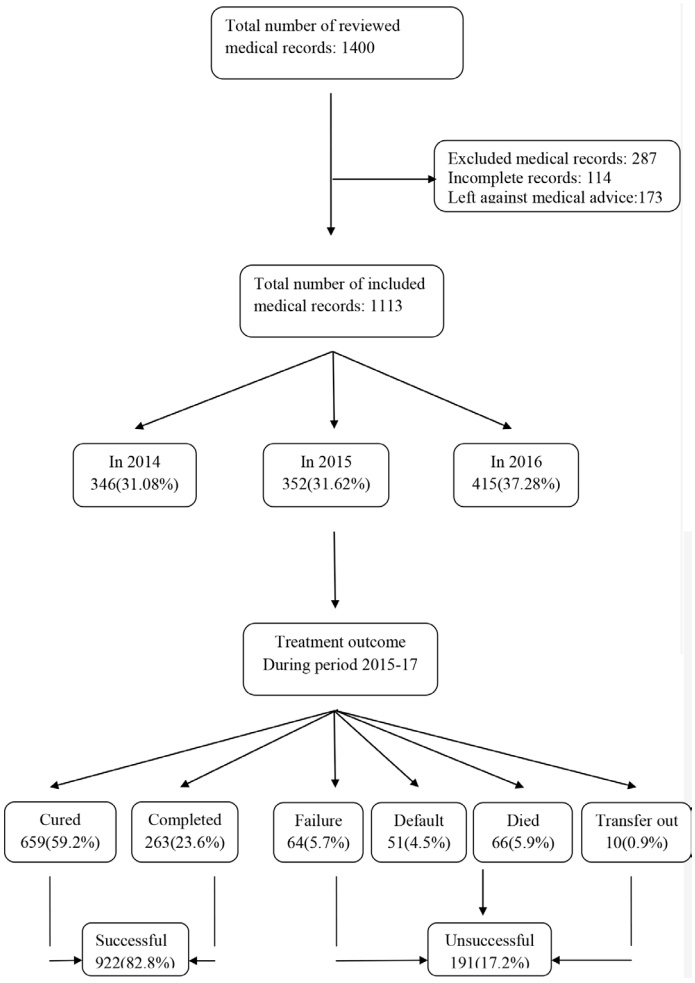

Figure 1: A schematic representation of study design and summary of results.

success rate. Similar satisfactory results were observed in other studies in India.[12,13] This might be due to improved adherence of TB patients to treatment. But still there were unsatisfactory treatment success rates. This might be due to failure in identifying the TB treatment failure in early stages. World Health Organization (WHO) recommends diagnosis of TB treatment failure by sputum smear microscopy at 5 months or later during treatment.[14]

Our study showed that treatment success rate increased significantly from 73.9 to 88.9% during the study period 2015-2017. The death rate declined from 11.2 to 4.3% over time. Several other studies demonstrated upward trend in Treatment Success Rate (TSR) and decline in death rate.[15]

Our study also revealed default, death, treatment failure rate and transfer out of 4.5%, 5.9%, 5.7% and 0.9% respectively. These constituted an overall unsuccessful treatment outcome rate of 17.2% which is lower than other studies (32.2% and 26% respectively).[16,17]

In this study, a total of 1113 TB patients were included. Most of the patients were male similar to other previous studies.[18,19] This could possibly be due to underutilization of the DOTS service by females or high proportion of males being exposed to the infection in the area.

Unfavorable outcomes such as death, default and treatment failure were more seen in elderly patients. Younger patients were treated successfully than remaining age groups which was observed in previous studies.[20]

Our results were consistent with a previous study in which patients from urban areas (81.1%) attending to DOTS had higher success rate compared to patients from rural areas (66.7%).[21] Poor environmental conditions in the rural areas make patients more vulnerable to tuberculosis and other diseases of poverty and as these populations often are not able to access timely diagnosis or complete the full duration of anti TB treatment, and hence were at risk of unfavorable treatment outcomes including deaths, defaults, failures and drug resistance. Moreover they stop using anti TB medication abruptly once the symptoms were relieved usually after 2 months of initiation of treatment.

Patient was considered smear positive when at least two sputum tests were positive for Acid Fast Bacilli (AFB) by microscopy. If the patient had suggestive symptoms of TB, with at least two specimens which were negative for AFB by microscopy, he was considered smear negative. Success rate was found significantly higher in smear positive patients (89%) compared to smear negative patients (69.7%). Our study also revealed that higher death rate and treatment failure occurred with smear negative patients. This is agreed by other studies.[22,23]

The TSR was worse in tuberculosis patients with HIV than without HIV. The study also found that patients with HIV had about 2.5 times higher odds of death and eleven fold higher odds of treatment failure compared to HIV negative TB patients. Studies conducted in Uzbekistan and Ethiopia showed the unfavorable treatment outcomes in TB with HIV patients.[24,25]

The TSR among re-treatment cases was much lower than new smear positive patients. This was supported by previous studies where re-treatment cases were significantly associated with unsuccessful treatment outcome. WHO Guidelines for the programmatic management of drug-resistant tuberculosis.[26,27] Moreover, the current study revealed that there was a higher default and death rate among re-treatment compared to the new cases.

Both smoking and alcoholism were considered as important risk factors for unsuccessful treatment outcomes like treatment failure, death rate and default rate. Our result is supported by earlier studies.[28,29]

CONCLUSION

It is possible to achieve the recommended WHO target which is 85% for newly diagnosed smear positive patients. There is significant increase of TSR over the study period. Implementing the DOTS strategy proved the satisfactory success rate in the hospital across three years. The unsuccessful treatment outcome was significantly associated with gender, HIV status, re-treatment, smear negative, smoking and alcoholism. Regular follow up and creating awareness among patients with poor socioeconomic background is important. In addition, more care should be taken for smear negative and HIV positive patients by regular sputum follow up tests.

Limitations

Although study focused on various socio-cultural factors which affect the outcome of treatment, details of income of patients could not be retrieved from the register. We could not assess the degree of drug resistance due to unavailability of drug susceptibility tests. Some patients were transferred out each year due to unavailability of DOTS near to their residence.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

AOR: Adjusted odds ratio; **COR:** Crude odds ratio; **DOTS:** Directly Observed Treatment Short-Course; **Govt. ID:** Government Infectious Disease; **RNTCP:** Revised National Tuberculosis Control Program; **TSR:** Treatment Success Rate; **WHO:** World Health Organization.

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