

Original Research Article

Factors associated with treatment outcome in adult tuberculosis patients under directly observed treatment short course in Ludhiana city, Punjab, India: a cohort study

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ABSTRACT

Background: Tuberculosis (TB) is a communicable disease requiring prolonged treatment and poor adherence to a prescribed treatment increases the risk of morbidity, mortality and spread of disease in the community. Objective was to study factors associated with treatment outcome in adult Tuberculosis patients on directly observed treatment short (DOTS) course in Ludhiana city, Punjab, India.

Methods: The present study was a community based prospective cohort study. It was conducted in the two tuberculosis units (TU) of Ludhiana city, Punjab, India. A total of 221 registered DOTS patients were taken as study subjects and were followed during the course of treatment to observe their treatment outcome. The information was collected on a pre-designed semi-structured questionnaire through personal interviews.

Results: Out of 221, 183 (82.8%) subjects had favourable outcome, 35 (15.8%) had unfavourable outcome and 3 (1.4%) were transferred out. The comparison between favourable and unfavourable treatment was found to be statistically significant with respect to different age groups, problems faced by subjects to reach DOTS centre, diabetes, sputum smear status, site of tuberculosis involvement and side effects of treatment.

Conclusions: Elderly and diabetic patients were found to have higher unfavourable outcome. There is need for special provisions for older age groups, illiterates and for lower socio-economic status (SES) in the form of counselling for old people and health insurance for those belonging to lower SES. Keeping in mind the default rate of the present study, initial counselling, periodic motivation of patients and prompt defaulter retrieval action would be beneficial.

Keywords: DOTS, Outcome, Treatment, Tuberculosis

INTRODUCTION

Tuberculosis (TB) is a worldwide epidemic of staggering proportions, infecting approximately one third of population. TB is a strange disease, it is infectious but chronic, not only caused by a bacillus but also by poverty, it is exogenous and yet indigenous. This disease

is so complex that it is a collection of conditions rather than a single one.¹ Recognizing that tuberculosis is one of the most neglected global health problem and that the tuberculosis epidemic is out of control in many parts of the world, the WHO declared tuberculosis to be a global health emergency in April 1993.² In India, the Revised National Tuberculosis Control Programme (RNTCP)

phase I was implemented in 1993, pilot tested, rapidly expanded from 1997 and achieved nation-wide (100%) coverage in March 2006. RNTCP phase II (2006-2011) aims to provide a road map for TB control to achieve the long-term goal, by 2015, of reducing the prevalence of tuberculosis by 50%.³ Ludhiana district TB society was established under RNTCP with an objective of controlling the disease. After raising the infrastructure, RNTCP was launched in Ludhiana in December 2002.

The therapeutic regimens given under direct observation as recommended by WHO have been shown to be highly effective for preventing and treating TB but poor adherence to anti-tuberculosis medication is a major barrier to its global control. Adherence to the long course of TB treatment is a complex, dynamic phenomenon with a wide range of factors impacting on treatment taking behaviour.⁴ Ensuring adherence to treatment for a favourable outcome has long been acknowledged as the weakest component of the TB programmes in India. Therefore, the present study was planned to ascertain the various factors associated with treatment outcome.

METHODS

A community based prospective cohort study was conducted in Ludhiana city, Punjab, India. It has two tuberculosis units (TU), TU-ESI and TU-DTC. The present study was conducted in both the Tuberculosis units (TU) of Ludhiana city. From the list of all the DOTS centres, a total of ten DOTS centers, 5 from each TU, were selected randomly (by lottery method). The period of study was from 1st April, 2010 to 31st March, 2011. All the patients above the age of 15 years, registered in the 1st quarter of the study period i.e. 1st April, 2010 to 30th June, 2010, in the selected DOTS centres formed the study subjects. Addresses of the subjects were taken from the records maintained at the DOTS centres.

Altogether three visits were done for each subject (including two home visits and one visit at the DOTS centre). Two home visits were conducted with the help of DOTS provider, TBHV (tuberculosis health visitor) or STS (senior treatment supervisor). The first home visit was done to gather information regarding epidemiological characteristics, socioeconomic status, health status and to assess environmental conditions. Total subjects enrolled for the study were 224 out of which 221 could be interviewed during the first visit. There were 3 subjects who could not be interviewed during the first visit as either the house was found locked or subject was not available. Three more attempts were made to contact these subjects and as they were still not available so they were excluded from the study. After the completion of intensive phase (IP) of treatment, a second visit was done at DOTS centre and study subjects were interviewed to know compliance, status of sputum examination, side effects and improvement in symptoms etc. Finally, a third visit at the end of the treatment was

done at home to know the change in weight, status of sputum examination and to ascertain the treatment outcome.

The treatment outcome was broadly categorized into favourable and unfavourable outcomes. 'cured and treatment completed' were regarded as favourable outcome whereas 'died, default and failure' were regarded as unfavourable outcome. The subjects who had treatment outcome as Transferred out were not included in the analysis as it was not feasible to know the final treatment outcome of these subjects. The information was collected on a pre-designed semi-structured questionnaire by the investigator through personal interviews.

The data collected in respect of various variables was statistically analyzed using microsoft excel 2007 and Epi Info version 3.3.2. The Chi-square test was applied to see the association between the attributes. A $P < 0.05$ was considered as statistically significant.

RESULTS

Study cohort

In the present study, out of 221 subjects, 142 (64.3%) were males and 79 (35.7%) females. The proportion of subjects aged 15-44 years were 168 (76.0%). Mean age in males was 35.16 ± 14.77 as compared to 31.27 ± 15.04 in females. 124 (56.1%) were natives of Punjab, while 97 (43.9%) were migrants. Around one third i.e. 33 (34.0%) of the migratory subjects were staying in Ludhiana for more than 15 years. Majority 162 (73.3%) of the subjects were Hindus. It was observed that 51 (23.1%) of the subjects were illiterate, while 33 (14.9%) were educated above matric. Out of 221 subjects, 93 (42.1%) were unemployed. Socio-economic status was calculated according to modified Udai Pareek scale. Maximum 118 (53.4%) subjects belonged to lower middle class.

Table 1: Treatment outcome of subjects as per RNTCP guidelines.

Treatment outcome	Number (N=221)	Percentage
Cured (among NSP cases)	68	80.0
Treatment completed	93	42.1
Treatment Success rate	183	82.8
Died	06	2.7
Failure	03	1.4
Defaulted	26	11.8
Transferred out	03	1.4

According to site of involvement, 166 (75.1%) subjects were classified as suffering from pulmonary tuberculosis and 55 (24.9%) subjects were extra-pulmonary subjects. According to initial sputum status, 118 (53.4) subjects were sputum positive and 103 (46.6%) were sputum negative. Out of 221 subjects 140 (63.4%) belonged to

category-I, 48 (21.7%) subjects belonged to category-II, while 33 (14.9%) belonged to category-III treatment. Majority of the subjects 171 (77.4%) were new, 23

(10.4%), 14 (6.3%) and 1 (0.5%) subjects were relapse, treatment after default and failure respectively, 3 (1.4%) were transfer in, while 9 (4.1%) were others.

Table 2: Favourable and unfavourable treatment outcome (N=221).

Favourable outcome		Unfavourable outcome			Transferred out
Cured	Treatment completed	Default	Failure	Died	
90 (76.3)*	93 (42.1)	26 (11.8)	03 (1.4)	06 (2.7)	03 (1.4)

*Cure rate among all sputum positive subjects.

Table 3: Distribution of subjects showing socio-demographic factors related to outcome.

	Favourable outcome	Unfavourable outcome	Tests of significance
Age			
15-24 (n=75)	69 (92.0)	06 (8.0)	$\chi^2=10.930$, d.f.=4 p=0.027
25-34 (n=57)	44 (77.2)	13 (22.8)	
35-44 (n=36)	33 (91.7)	03 (8.3)	
45-54 (n=22)	16 (72.7)	05 (22.7)	
>55 (n=31)	21 (67.7)	08 (25.8)	
Gender			
Male (n=142)	118 (83.1)	22 (15.5)	$\chi^2=0.034$, d.f.=1 p=0.854
Female (n=79)	65 (82.3)	13 (16.4)	
Ethnicity			
Native (n=124)	104 (83.9)	18 (14.5)	$\chi^2=0.348$, d.f.=1 p=0.555
Migrant (n=97)	79 (81.4)	17 (17.5)	
Caste			
SC (n=92)	77 (83.7)	15 (16.3)	$\chi^2=0.007$, d.f.=1 p=0.932
Non-SC (n=129)	106 (82.2)	20 (15.5)	
Education			
Illiterate (n=51)	39 (76.5)	11 (21.5)	$\chi^2=8.187$, d.f.=4 p=0.085
Primary (n=26)	18 (69.2)	08 (30.8)	
Middle (n=74)	65 (87.8)	07 (9.5)	
Matric (n=37)	32 (86.5)	05 (13.5)	
Above matric (n=33)	29 (87.9)	04 (12.1)	
Occupation			
Employed (n=128)	108 (84.4)	19 (14.8)	$\chi^2=0.270$, d.f.=1 p=0.603
Unemployed (n=93)	75 (80.6)	16 (17.2)	
Marital status			
Married (n=130)	105 (80.8)	23 (17.7)	$\chi^2=1.799$, d.f.=1, p=0.180
Unmarried (n=81)	72 (88.9)	08 (11.1)	
SES			
Low (n=13)	09 (69.2)	04 (30.8)	$\chi^2=4.136$, d.f.=2, p=0.126
Low middle (n=118)	94 (79.7)	21 (17.8)	
High middle (n=86)	77 (89.5)	09 (10.5)	
High (n=4)	03 (75.0)	01 (25.0)	

*3 subjects were transferred out which were not counted in either of the outcome.

Table 4: Association of other characteristics with treatment outcome.

	Favourable outcome (n=183)	Unfavourable outcome (n=35)	Tests of significance
Distance (km)			
<1.5 (n=110)	96 (87.3)	13 (11.8)	$\chi^2=2.757$, d.f.=1 p=0.097
≥1.5 (n=111)	87 (78.4)	22 (19.8)	
Problem faced to reach DOTS centre			
Yes (n=54)	36 (66.7)	17 (31.5)	$\chi^2=13.335$, d.f.=1 p=0.000
No (n=167)	147 (88.0)	18 (10.8)	
Smoking			
Present (n=52)	40 (77.0)	10 (19.2)	$\chi^2=0.749$, d.f.=1 p=0.387
Absent (n=169)	143 (84.6)	25 (14.8)	
Alcohol			
Present (n=66)	55 (83.3)	11 (16.7)	$\chi^2=0.026$, d.f.=1 p=0.871
Absent (n=155)	128 (82.6)	24 (15.5)	
Drug addiction			
Present (n=36)	28 (77.8)	07 (19.5)	$\chi^2=0.481$, d.f.=1 p= 0.488
Absent (n=185)	155 (83.8)	28 (15.1)	
Diabetic status			
Diabetic (n=19)	13 (68.4)	06 (31.6)	$\chi^2=3.722$, d.f.=1 p=0.054
Non-diabetic (n=202)	170 (84.2)	29 (14.4)	
Weight gain (kg)			
≤ 2 (n=63)	61 (96.8)	02 (3.2)	$\chi^2=1.464$, d.f.=1 p=0.226
>2 (n=123)	122 (99.2)	01 (0.8)	
Side-effects*			
Yes (n=81)	69 (85.2)	11 (13.6)	$\chi^2=7.309$, d.f.=1 p=0.007
No (n=119)	114 (95.8)	04 (3.4)	
Sputum status			
Smear positive (n=118)	92 (80.0)	24 (20.3)	$\chi^2=3.951$, d.f.=1 p=0.047
Smear negative (n=103)	91 (88.3)	11 (10.7)	
Site of involvement			
Pulmonary (n=166)	131 (78.9)	33 (19.8)	$\chi^2=6.953$, d.f.=1 p=0.008
Extrapulmonary (n=55)	52 (94.5)	02 (3.6)	
Type of patient			
New (n=173)	150 (86.7)	22 (12.7)	$\chi^2=6.445$, d.f.=1 p=0.011
Retreatment (n=48)	33 (68.8)	13 (27.0)	
Category			
I (n=140)	118 (84.3)	21 (15.0)	$\chi^2=6.445$, d.f.=1 p=0.011
II (n=48)	33 (68.8)	13 (27.1)	
III (n=33)	32 (97.0)	01 (3.0)	

*200 subjects could be followed for second home visit.

Treatment outcome

Treatment outcomes of tuberculosis patients in the two DOTS centres are shown in Table 1. Treatment success rate was 82.8% (183 out of 221), cure rate was 80.0% (68 out of 85 new smear positive subjects), default rate was 11.8% (26 out of 221), death rate was 2.7% (6 out of 221), failure rate and transferred out rate was 1.4% (3 out of 221).

It is evident from Table 2 that 183 (82.8%) of the subjects had favourable outcome and 35 (15.8%) had unfavourable outcome and 3 (1.4%) subjects were transferred out, which were not counted in either. Cure rate was 90 (76.3%) among all sputum positive subjects and 68 (80.0%) among new sputum positive (NSP) subjects.

Table 3 shows that unfavourable outcome was maximum in age group >55 years (67.7%) and minimum in 15-24 years age group (8.0%). The proportion of cases with favourable outcome differed significantly between different age groups. The difference between favourable and unfavourable outcome with respect to gender and caste was found to be statistically non-significant. A slightly higher unfavourable outcome was observed in migrants (17.5%) as compared to natives (14.5%), but it was statistically non-significant. Unfavourable outcome was maximum in subjects educated till primary (30.8%) followed by illiterates (21.5%). Favourable outcome was maximum (87.9%) in subjects who were educated above matric, however, the relation was non-significant. Unfavourable outcome was more (17.2%) in unemployed subjects as compared to 14.8% in employed. In married subjects, unfavourable outcome was more (17.7%) as compared to unmarried and others (11.1%). Unfavourable outcome was maximum in subjects from low SES (30.8%), followed by high SES (25.0%). No significant relation was observed between favourable and unfavourable outcome with respect to SES.

Table 4 shows unfavourable outcome was observed in almost one fifth of the subjects staying at a distance of more than 1.5 km. A statistically significant ($p=0.000$) relation was observed between treatment outcome and problems faced to reach DOTS centre. No Statistical significant relationship was observed between treatment outcome and smoking, alcohol and drug addiction individually.

A statistically significant relationship was observed between unfavourable treatment outcome and diabetic status ($p=0.054$). Among those with diabetes only 13 (68.4%) had favourable outcome as compared to 170 (84.2%) among non-diabetics.

Weight gain was recorded for subjects after initiation and at the completion of treatment. Weight gain could be recorded for 186 subjects as 35 subjects had unfavourable outcome and the weight at the end of treatment could not

be recorded in these subjects. The relation between treatment outcome and weight gain during treatment was statistically non-significant ($p=0.226$). The mean weight gain among subjects was 3.74 ± 2.9 kg (range -10 to 17 kg).

During 2nd home visit 200 subjects could be followed, unfavourable outcome was found in 11 (13.6%) of the subjects who had experienced one or the other side effect, as compared to 04 (3.4%) in subjects who had not experienced any side-effects. A statistically significant relationship was observed between treatment outcome and side-effects of treatment ($p=0.007$).

The comparison of treatment outcome shows a significant difference with respect to sputum smear status ($p=0.047$), site of TB involvement ($p=0.008$), category of treatment ($p=0.011$) and type of patient ($p=0.011$).

DISCUSSION

In the present study, the treatment success rate was 82.8% which is lesser than RNTCP norm i.e. 85% and default rate is 11.8% which is much higher than what is expected under RNTCP i.e. <5%. In the present study, the treatment outcome was categorized as favourable and unfavourable outcome, as was done in studies done by Sophia et al, Vasankari et al and Mukherjee et al.⁵⁻⁷

Table 3 shows that favourable outcome was more in younger age group and with increasing age it becomes poor. The findings of the study are concurrent with the findings of Gaur et al and Joseph et al.^{8,9}

In the present study it was observed that patient with higher education had favourable outcome which is similar to the findings of Moharanna et al in Orissa, India.¹⁰ Unfavourable outcome was almost same in native and migrants. Jaggarajamma et al also stated that migration was not a significant reason for non-compliance.¹¹ Similar results were found in a study in Mangalore by Joseph et al.⁹

Among socio-demographic variables treatment outcome (favourable and unfavourable) was found to significantly associated with age ($p=0.027$). The association of gender, ethnicity, caste, education, occupation, marital status and SES was found to be non-significant. A study by Kumar M et al reported that amongst all factors, association between non-compliance and age was statistically highly significant ($P=0.001$).¹² The findings were also similar to a study conducted by Pandit and Choudhary in Gujarat, India.¹³

Distance to health centre plays a key role in case-finding process and treatment outcome. In an ambulatory treatment service, needing repeated visits for drug collection, distance certainly assumes a great significance. In the present study, mean distance of DOTS centre was 1.5 km which is comparable to the findings of Sophia et al where the average distance

travelled by patients to collect drugs was 2 km.¹⁴ Unfavourable outcome was observed in almost one fifth of the subjects staying at a distance of more than 1.5 km. Unfavourable outcome was observed in almost one third (31.5%) subjects who had faced problems to reach the DOTS centre. The relationship between treatment outcome and problems faced by the subjects to reach DOTS centre was observed to be statistically significant ($p=0.000$). In a prospective study by Sophia et al in Kolar district of Karnataka, India it was observed that distance travelled was one of the reasons for the patients to discontinue the treatment and become defaulters.¹⁵ Ahmed et al in their study on 'Utilization of RNTCP services by gender, age and distance of DOTS centre' in Bellary, India found that treatment outcome was poorer among those residing at more than 20 kms.¹⁶

Diabetes has been associated with increased risk of treatment failure, relapse and mortality in TB patients. In the present study, unfavourable outcome was observed to be present in almost one third 6 (31.6%) diabetics as compared to 29 (14.4%) non-diabetics. Statistically significant relationship was observed between diabetes and unfavourable treatment outcome. Dooley et al in Maryland, USA and reported that diabetes was a relatively common morbidity and had a negative impact on treatment outcome.¹⁷ Gupta et al in Manipal, India also reported that Diabetes mellitus was the most (30.9%) prevalent condition and significantly more common than other risk factors.¹⁸

Weight gain is a prognostic indicator in RNTCP programme. Patients gaining body weight show improvement towards the end of treatment. In the present study favourable outcome was observed in 122 (99.2%) subjects who had gained >2 kg of weight during treatment. However, relationship was statistically not significant ($p=0.226$). Khan et al reported that weight gain of 5% or less was associated with increased risk of relapse.¹⁹ Vasantha et al also concluded that weight gain at the end of the treatment was associated with cure of patients.²⁰

ATT induced side effects lead to unfavourable outcome in 11(13.6%) of the patients in the present study. In a study from Tiruvallur district, India Jaggarajamma et al found drug related problems to be a cause of interruption of patients.¹¹

In the present study favourable and unfavourable treatment outcome were found to be significantly associated with sputum status ($p=0.047$), site of involvement ($p=0.008$) and category of treatment (0.011). The main risk factors for default in the present study were sputum smear status and inconveniency to reach DOTS centre which are in accordance with the findings of a study conducted by Jaggarajamma et al in Tiruvallur district in South India.¹¹ Risk factors for default were category of treatment ($P<0.001$), smear status ($P<0.001$),

type of disease ($P<0.001$) and inconvenience for DOTS ($P<0.001$).

CONCLUSION

The findings of the present study suggest that treatment success rate was low and default rate was high as per RNTCP norms. To improve treatment success rate and decrease default rate, retrieval of defaulters and periodic monitoring should be practised. Counselling and motivation should be done regularly, so that default rate can be decreased for better treatment success rate.

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