



Original Research Article

Factors Associated with Treatment Default among Tuberculosis Patients: A Case Control Study

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Received: 22/03/2015

Revised: 22/04/2015

Accepted: 24/04/2015

ABSTRACT

Introduction: Tuberculosis remains a major health problem, globally. India has more new TB cases annually than any other country. India has RNTCP programme for tuberculosis since 1993, however the treatment success rates are unacceptably low and default rates remain high.

Aims and Objectives: To study the factors associated with default among tuberculosis patients.

Materials and Methods: Case control study; conducted on 90 tuberculosis patients – 30 defaulted patients (cases) and 60 treatment completed patients (controls) registered under RNTCP during Jan 2012 to June 2013 residing in both urban and rural field practice area.. They were matched for age and sex.

Results: The mean age of the cases was 37.1 ± 14.76 years and the mean age of controls was 37.8 ± 14.59 years. Among the 25 cases, 23(92%) took medications from health worker and only 2(4%) took from auxiliary nurse midwife. On multivariate analysis lack of motivation [OR 41.168, (CI 3.810-444.850) $p=0.001$], ignorance of normal duration of treatment [OR 66.187, (CI 5.863-760.819) $p=0.001$] and transportation cost [OR 40.432, (CI 1.496-1095.1) $p=0.004$] were associated with default.

Conclusion: In the present study it was found that ventilation of house, personal habits, stigmatization, lack of motivation, ignorance of normal duration of treatment, transportation cost were the factors associated with default.

Key words: Tuberculosis, Default, DOTS, Risk factors, case-control study.

INTRODUCTION

Tuberculosis remains a major health problem, globally. It is the second leading cause of death from an infectious disease worldwide, after HIV. [1] India has more new TB cases annually than any other country. In 2011, out of the estimated global annual incidence of 9 million TB cases, 2.3 million were estimated to have occurred in India. [2]

India has RNTCP programme for tuberculosis since 1993, however the treatment success rates are unacceptably low and default rates remain high which in turn results in persistence of infectious source, increased mortality, increased relapse rates, lesser cure rates, high mortality and facilitate the development of resistant strains, which in turn hamper the control of TB in India. [3-5] Along with effective control

measures currently available, it is essential to identify and target the factors associated with treatment default among tuberculosis patients so as to tackle the heavy burden of the disease.

As per our knowledge very few community studies on factors associated with treatment default among tuberculosis patients have been conducted in India. Hence, the present study is undertaken to study the factors associated with the default and the socio demographic characteristics of patients who defaulted from RNTCP treatment.

Aims and objectives

- To study the factors associated with default.
- To study the sociodemographic characteristics of patients who defaulted from RNTCP treatment.

MATERIALS AND METHODS

Source of data: Tuberculosis patients registered under Revised National Tuberculosis control Programme during January 2012 to June 2013 residing in both urban and rural field practice area of Department Of Community Medicine of a medical college.

Study Design & Period: Case control study over a period of 2 months from April 2014 to May 2014

Study Population: 90 tuberculosis patients - 30 defaulted patients (cases) and 60 treatment completed patients (controls).

Method of collection of data: Data was collected by interviewing the study participants (cases and controls) using predesigned and pretested questionnaire by home visits. Data regarding the registered cases of tuberculosis registered during the year January 2012 to June 2013 was collected using records (Tuberculosis registers) of three urban health centers and primary health centers of field practice area of Dept. of Community Medicine of a

medical college from which the study participants (cases and controls) were selected.

As per records (TB registers) of three PHC and three UHC there were 30 defaulters during January 2012 to June 2013 and accordingly all 30 defaulters were chosen for the study and they were matched with controls for age and sex. During the home visits it was found that five defaulters had died and accordingly ten matched controls were excluded from the study. Hence, the data was collected from 25 cases and 50 controls matched for age and sex. These five defaulters who died were not replaced with any other defaulters as we had chosen the defaulters who had registered only during January 2012 to June 2013.

a) Selection of cases: Patients with smear positive pulmonary tuberculosis during Jan 2012 to June 2013 who took the treatment for minimum of one month, but interrupted the treatment for more than two months. ^[6]

b) Selection of controls: Patients who also had smear positive pulmonary tuberculosis but had started and completed the treatment during January 2012 to June 2013 and were matched for age and sex of the cases.

c) Matching: Controls were matched for age and sex. Group matching of cases and controls was done.

d) Study variables-

i) Socio demographic characteristics (age, sex, occupation, literacy, status, religion etc.)

ii) Medical and treatment data (treatment observer, HIV status, treatment regimen, sputum smear microscopy results, date of treatment started and ended.)

iii) Factors associated for default –

Reasons for interruption of DOTS treatment, Subjective factors linked to medication, Knowledge about duration of DOTS treatment,

Barriers to compliance of default with treatment

(Distance, family support, finance, duration of treatment etc).

- **Inclusion criteria:** Only defaulters and treatment completed tuberculosis patients during the period January 2012 to June 2013.
- **Exclusion criteria:** Tuberculosis patients who have defaulted and completed treatment after June 2013.
- **Data Collection:**
- **Tools for study:** pretested and predesigned questionnaire.
- **Statistical Analysis:** Data was analyzed using percentage. Logistic regression analysis was used to find the association between default in tuberculosis patients and other factors.
- **Ethical clearance:** The present study was approved by Institutional Ethics Committee on Human Subjects Research (Ref:- IEC letter no. MDC/DOME/136 dated 24.12.2013)

RESULTS

In the present study, out of 90 study participants selected for the study, i.e. 30 cases (defaulters) and 60 controls (treatment completed), five cases had died and accordingly, ten controls were excluded from the study. Hence, the data was collected from 25 cases and 50 controls matched for age and sex.

The mean age of the cases was 37.1 ± 14.76 years and the mean age of the controls was 37.8 ± 14.59 years.

In our study, among cases, majority 19(76%) of the study participants were males and 6(24%) were females. Among the controls 38(76%) were male participants and 12 (24%) were female participants. However, this difference was not statistically significant ($p=1.000$). Out of total 16(64%) of cases were unemployed and only 9(36%) were employed. Among the control group 33(66%) of the study

participants were unemployed and 17(34%) were employed.

In the present study, 9(36%) of the cases and 15(30%) of the controls were illiterate, whereas 16(64%) of the cases and 35(70%) of the controls were literate. 8(32%) of cases had no personal habits, 3(12%) of them were smokers, 1(4%) consumed alcohol, 11(44%) smoked as well as consumed alcohol. 25(50%) of the controls had no personal habits, 3(6%) consumed only alcohol, 7(14%) of the controls smoked and consumed alcohol. The difference in personal habits among both the groups was statistically significant ($p=0.002$).

Among the cases 2(8%) belonged to class II, 1(4%) to class III, 12(48%) to class IV and 10(40%) to class V socio economic status and among the controls 1(2%) belonged to class I, 4(8%) to class II, 13(26%) to class III, 16(32%) to class IV and 16(32%) to class V socio economic status. The difference in socio economic status among both the groups was not statistically significant ($p=0.122$).

Whereas socio demographic characteristics such as, employment and educational status, socio economical status were not found to be statistically significant ($p>0.05$). (Table 1)

In our study, it was found that majority 23(92%) of the cases and 40(80%) of controls took the treatment from the health worker, 2(4%) of controls from household members, 2(8%) of cases, and 7(14%) of controls took treatment from ANM, and only 1(2%) of control took medicines from a friend.

In the present study 2(8%) of the cases and 2(4%) of the controls were co-infected with HIV. 11(44%) of the cases and 6(12%) of the controls experienced stigmatization. Majority, 20(80%) of the cases and 28(56%) of the controls experienced drug side effects. 9(36%) of

cases and 3(6%) of controls used herbal medication during therapy,9(36%) of cases and 32(64%) of controls had well ventilated house. Majority 18(72%) of the cases and 25(50%) of the controls were living in overcrowded houses.

Factors such as experiencing stigmatization, drug side effects, usage of herbal medication during therapy and ventilation of the house were found to be statistically significant ($p < 0.05$). (Table 2)

Table 1:- Socio demographic characteristics of the study participants (n=75)

Socio demographic Characteristics		Cases No. (%)	Controls No. (%)	P value
Gender	Male	19(76%)	38(76%)	1.00
	Female	6(24%)	12(24%)	
Employment status	Unemployed	16(64%)	33(66%)	0.864
	Employed	9(36%)	17(34%)	
Educational status	Illiterate	9(36%)	15(30%)	0.919
	Primary	9(36%)	15(30%)	
	High school	4(16%)	10(20%)	
	PUC/Diploma	1(4%)	5(10%)	
	Graduation	2(8%)	5(10%)	
Personal Habits	None	8(32%)	25(50%)	0.002
	Smoking	3(12%)	0(0%)	
	Alcohol	1(4%)	3(6%)	
	Others	2(8%)	14(28%)	
	Smoking+ alcohol	11(44%)	7(14%)	
	Smoking+ alcohol+ others	0(0%)	1(2%)	
Socioeconomic status	Class I	0(0%)	1(2%)	0.122
	Class II	2(8%)	4(8%)	
	Class III	1(4%)	13(26%)	
	Class IV	12(48%)	16(32%)	
	Class V	10(40%)	16(32%)	

$p < 0.05$ -significant $p > 0.05$ -non significant

Table 2:-Select Factors for default among tuberculosis patients

Select Factors		Cases No.(%)	Controls No. (%)	P value
Treatment observer	Health worker	23(92%)	40(80%)	0.625
	Household member	0(0%)	2(4%)	
	ANM	2(8%)	7(14%)	
	Friend	0(0%)	1(2%)	
Co-infected with HIV	Yes	2(8%)	2(4%)	0.856
	No	23(92%)	48(96%)	
Experienced stigmatization	Yes	11(44%)	6(12%)	0.002
	No	14(56%)	44(88%)	
Experienced side-effects	Yes	20(80%)	28(56%)	0.041
	No	5(20%)	22(44%)	
Used herbal medication during therapy	Yes	9(36%)	3(6%)	0.003
	No	16(64%)	47(94%)	
House well ventilated	Yes	9(36%)	32(64%)	0.022
	No	16(64%)	18(36%)	
Over-crowding	Yes	18(72%)	25(50%)	0.069
	No	7(28%)	25(50%)	

$p < 0.05$ - significant $p > 0.05$ - non significant

Univariate analysis showed that the risk factors such as ventilation of the house [OR 0.316(95% CI 0.116-0.866) $p = 0.024$], personal habits [OR 0.471(95% CI 0.172-1.288) $p = 0.003$], stigmatization[OR

5.762(95% CI 1.802-18.424) $p = 0.003$], use of herbal medications [OR 8.812(95% CI 2.121-36.622) $p = 0.003$], unpleasant taste of medicines [OR 11.294(95% CI 1.401-91.017) $p = 0.023$], difficulty in taking the

medications on empty stomach [OR 7.944(95% CI 2.493-25.316) p<0.001], side effect of drugs [OR 4.125(95% CI 1.235-13.782) p=0.021], lack of motivation[OR 29.333(95% CI 7.298-117.904) p<0.001], ignorance of normal duration of the treatment [OR 96(95% CI 11.558-797.396) p<0.001], financial problems[OR 3.143(95% CI 1.017-9.709) p=0.047], transportation cost [OR 6(95% CI 1.767-20.369) p=0.004], long travelling time [OR

3.5(95% CI 1.164-10.524) p=0.026], fear of seeking the health team after first interrupting the treatment[OR 13.037(95% CI 4.002-42.465) p<0.001], lack of repeated smears [OR 3.849(95% CI 1.450-10.20) p=0.007] and poor knowledge of tuberculosis treatment [OR 3.692(95% CI 1.197-11.386) p=0.023] were associated with default in tuberculosis patients.(Table 3)

Table 3: Univariate analysis of factors associated with default among tuberculosis patients

Risk factors	Unadjusted odds ratio	95% Confidence limits	P value
Ventilation of the house	0.316	0.116-0.866	0.024
Personal Habits	0.471	0.172-1.288	0.003
Experienced Stigmatization	5.762	1.802-18.424	0.003
Usage of Herbal medications	8.812	2.121-36.622	0.003
Unpleasant taste of medicines	11.294	1.401-91.017	0.023
Difficulty in taking medicine on empty stomach	7.944	2.493-25.316	<0.001
Claimed to have side effects of drugs	4.125	1.235-13.782	0.021
Lack of motivation	29.333	7.298-117.904	<0.001
Ignorance of normal duration of treatment	96	11.558-797.396	<0.001
Financial problem	3.143	1.017-9.709	0.047
Transport cost	6	1.767-20.369	0.004
Long travelling time	3.5	1.164-10.524	0.026
Fear of seeking the health team after first interrupting the treatment	13.037	4.002-42.465	<0.001
Lack of repeated smears	3.849	1.450-10.20	0.007
Poor knowledge of TB treatment	3.692	1.197-11.386	0.023

p<0.05- significant

p>0.05- nonsignificant

Table 4: Multivariate logistic regression analysis of factors independently associated with default

Risk factors	Adjusted Odds ratio	95% Confidence intervals	P value
Lack of motivation	29.333	7.298-117.904	<0.001
Ignorance of normal duration of treatment	96	11.538-797.396	<0.001
Transportation cost	6	1.767-20.369	0.004

p<0.05-significant

p>0.05- non significant

Multivariate logistic regression analysis (with Adjusted odds ratio) showed that risk factors such as lack of motivation [OR 29.333(95% CI 7.298-117.904) p<0.001],

ignorance of normal duration of treatment [OR 96(95% CI 11.538-797.396) p<0.001], transportation cost [OR 6(95% CI 1.767-

20.369) $p=0.004$] were independently associated with default.(Table 4)

DISCUSSION

Defaulting from treatment is recognized as one of the main problems in tuberculosis control, which provides favorable conditions for the maintenance of disease transmission, high mortality and development of resistant strains. [7, 8]

The present study was an effort to identify the factors associated with treatment default among tuberculosis patients in the urban and rural field practice area of Department of Community Medicine in a medical college. Socio demographic characteristics of the study participants (Table 1)

In our study, majority that is 76% of cases and controls were males and 24% of cases and controls were females. Similarly in various studies conducted in various parts of India, Kenya and South Africa have shown that the defaulter rate was more in males when compared to females. [9-14]

In the present study majority, 64% of the cases were unemployed indicating resources for transport and other opportunity cost could have been a challenge for treatment completion. Similarly more defaulters were unemployed in studies conducted in Bangalore and Kenya. [9,10] Whereas studies conducted in South India and South Africa have shown that there were more defaulters who were employed when compared to unemployed. [11, 15]

In the current study, 9(36%) of the cases and 15(30%) of the controls were illiterate, which is similar to study conducted in different parts of India. [13,16,17] Whereas in studies conducted in Tiruvallur and South Africa, 19% and 13% of the cases were illiterate respectively. [11,15] Lower the educational status of a person as seen in our study could be the reason for lack of awareness about the mode of spread and

prevention of tuberculosis among the defaulters.

In our study 92% of the cases had one or the other personal habits, whereas only 50% of the controls had personal habits. Whereas studies conducted in various parts of India, Brazilian Amazon, South Africa, Kenya on defaulters have shown that 30% of the defaulters had personal habits. [4, 9, 10, 11, 16]

Select Factors for default (Table 2)

In our study, it was found that majority 23(92%) of the cases and 40(80%) of controls took the treatment from health workers and 2(8%) of cases and 2(4%) of controls from household members. Similarly another study has shown that majority took the treatment from public health facility. [12] Whereas study conducted in Ahmedabad showed that only 14% took treatment from TB health visitor and in Kenya 72% took treatment from household members. [9, 13]

In the present study, 2(8%) of the cases and 2(4%) of the controls were co-infected with HIV. Majority, 20(80%) of the cases and 28(56%) of the controls experienced drug side effects and 11(44%) of the cases and 6(12%) of the controls experienced stigmatization which was similar to other studies. [4,9] Whereas some studies conducted in different regions of India have not reported any side effects of the drugs. [12,13]

Univariate and Multivariate logistic regression analysis of factors associated with default among tuberculosis patients (Table 3 and 4)

In the present study on Univariate analysis, it was seen that risk factors such as ventilation of the house, stigmatization, use of herbal medication, unpleasant taste of medicines, difficulty in taking the medications on empty stomach, side effects of the drugs, lack of motivation, ignorance of normal duration of the treatment, financial problems, transportation cost, long travelling time, fear of seeking the health

team after first interrupting the treatment, lack of repeated smears and poor knowledge of tuberculosis treatment were associated with treatment default.

Multivariate regression analysis also showed that factors such as lack of motivation, ignorance of normal duration of treatment, transportation cost were independently associated with default. Similar associations of risk factors with treatment default were also seen in various studies conducted in Bangalore, Kenya, South Africa and Brazilian Amazon. [4, 9-11]

CONCLUSIONS

In the present study it was found that ventilation of house, personal habits, stigmatization, lack of motivation, ignorance of normal duration of treatment, transportation cost were the factors associated with default. There is no difference among cases and controls in factors pertaining to knowledge of tuberculosis and adherence to treatment. These factors should be considered in addressing care and policy actions to control tuberculosis. Information about the disease and treatment are part of routine health services, but must be appropriate to the level of education of population, in order to prevent default and promote adherence to treatment so as to encounter the spread of multidrug resistance to anti TB drugs. As per our knowledge very few community studies on factors associated with treatment default among tuberculosis patients have been conducted in India, hence, there is a need for further research in this area.

ACKNOWLEDGEMENT

The author would like to thank the Director General, ICMR for financial assistance for this study. My sincere gratitude to my guide for guiding me throughout the study. I am also thankful to the Principal JNMC, Belgaum, Staff of Department of Community

Medicine, Staff of UHC and PHC for their co-operation throughout the study.

Conflict of interest: None declared

Source of funding: ICMR

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How to cite this article: Soumya, Baliga SS, Mallapur MD. Factors associated with treatment default among tuberculosis patients: A case control study. Int J Health Sci Res. 2015; 5(5):22-29.
