Original Article

Assessment of patient related risk factors pertaining to default and non-default among study population

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Abstract

Background: No other infectious disease, since time immemorial has inflected on mankind, the misery and suffering in all aspects of life – social, economic and health as (TB)..

Objective: To assess patient related risk factors pertaining to default and non-default among study population.

Materials & Methods: Case control study was conducted throughout the DK district involving all 5 TUsto find out the risk factors of DOTS treatment default.A total of 204 subjects were enrolled which includes 68 cases and 136 age and gender matched controls. Cases include treatment after defaults as per DOTS register from 1st January 2014 to 31st December 2014.

Results: With multivariate logistic regression analysis factors namely incorrect knowledge that incomplete treatment leads to spread of TB among family members, sharing food will lead to spread of TB and treatment duration. Also poor knowledge about symptoms of TB, feeling of taking many tablets and lack of motivation to complete treatment were found to be the independent risk factors for defaulting on treatment.

Conclusion: Incorrect knowledge that incomplete treatment leads to spread of TB among family members, sharing food will lead to spread of TB and treatment duration.

Keywords: Patient related risk factors, default, non-default, Tuberculosis

INTRODUCTION

Tuberculosis (TB) has been an affliction of mankind since before recorded history. TB inspired writers such as John Bunyan to aptly describe this deadly and mysterious disease in 1600 as “the captain of all those men of death that came against him to take him away, the consumption for it was that brought him down to the grave”. [1] In spite of the much-heralded medicinal cures developed in the 1940s and 1950s, tuberculosis still devastates populations throughout the world. Even more disturbing, Mycobacterium Tuberculosis, the agent of TB, has become increasingly resistant to antimicrobial medications, and travels with and has been especially virulent among those suffering from acquired immunodeficiency syndrome (AIDS). [2].Skeletal changes typical of tuberculosis have been seen in Egyptian mummies and in Neolithic skeletons in Europe and there is compelling evidence that the disease occurred in the indigenous populations of American continent long before the arrival of European explorers and settlers.

According to World Health Organization (WHO, 2015) Tuberculosis (TB) is a deadly infectious disease killer worldwide. TB is caused by bacteria (Mycobacterium tuberculosis) that most often affect the lungs. TB is curable and preventable and spreads from person to person through droplets in air. When people with pulmonary TB cough, sneeze or spit, they propel the TB germs into the air. A person needs to inhale only a few of these germs to become infected. About one-third of the world's population has latent TB, which means people have been infected by TB bacteria but are not (yet) ill with the disease and cannot transmit the disease. People infected with TB bacteria have a 10% lifetime risk of falling ill with TB. Globally in 2014, 9.6 million people fell ill with TB and 1.5 million died from the disease. The Millennium Development Goal target of halting and reversing the TB epidemic by 2015 has been met globally. TB incidence has fallen by an average of 1.5% per year since 2000 and is now 18% lower than the level of 2000. The TB death rate dropped 47% between 1990 and 2015. An estimated 43 million lives were saved through TB diagnosis and treatment between 2000 and 2014.Ending the TB epidemic by 2030 is among the health targets of the newly adopted Sustainable Development Goals.[3]

The RNTCP status default rate in India is 6.4% and in Karnataka default rate is 9.8%, which is more than the national average and the percentage is more compared to that recommended by RNTCP Guidelines. The rate of Treatment after Default (TAD) patients in DK district in the year 2013 was 5.8% and there is lack of data about the risk factors affecting the compliance of TB treatment DK district of Karnataka. It is a matter of concern as defaulting on TB treatment will lead to development of resistant strains of bacteria which will in turn land the patient on CAT IV treatment (MDR-TB). The treatment of MDR-TB is of longer duration and with less effective outcomes. It is necessary for us to understand the reasons for default, so that those factors can be addressed by necessary innovative approaches and prevent patients to land up with MDR-TB/ XDR-TB. Hence these factors trigger the need to undertake this study to understand the risk factors that are associated with default and to suggest appropriate health interventions to reduce default which would in turn decrease the treatment duration and decrease the burden of social, financial and psychosocial burden on the family. [1]

MATERIAL AND METHODS

The Case control study was conducted in DK District of Karnataka. The DK district has 5 TUs namely Mangalore, Moodbidri, Puttur, Belthangady and Bantwal. Mangalore TU comes under the urban area and the rest four TUs fall under the rural category. The total numbers of patients registered under DOTS in the year 2014 are 1642. The study was started after obtaining ethical approval from the institutional ethics committee and the State Tuberculosis officer (STO) and District Tuberculosis Officer (DTO).

Case control study, where cases are Treatment after Defaults (TAD) and controls are newly registered cases who have completed treatment as per TB register. Study period was two years from August 2013 to November 2015.

Study participants include all TB patients registered under five TU units from January 1st 2014 to December 31st 2014. Cases were defined as TB patients who received anti-tuberculosis treatment for one month or more from any source and returns to treatment after having defaulted, i.e., not taken anti-TB drugs consecutively for two months or more, and is found to be sputum smear positive and registered under DOTS during 1st Jan 2014 to 31st Dec 2014 as Treatment after Default (TAD).

Controls are defined as new TB cases registered under DOTS during the same period, who had not defaulted and completed TB regimen as per RNTCP guidelines.Controls were matched to cases by age and gender at a ratio of cases to controls is 1:2.

Inclusion criteria:

Subjects aged 18 years and above and who consent to participate in the study and registered under DOTS.

Exclusion criteria:

a) The TB patients who are transferred out and could not be contacted even with two visits.
b) Non-availability of health records of patients.

Sample size and sampling method[4]

Sample size was estimated by using Fleiss Statistical Methods for rates and proportions, formulae 3.18 & 3.19 Epi Info™ 7.1.5 software based on expected defaulters among controls as 20%, minimum anticipated odds ratio of 2.5, 80% power, two sided confidence interval of 95% and odds ratio of controls to cases as 2:1 was found to be 67 cases and 134 controlsand after including 1 10% non response rate the sample went up to 74 cases and 148 controls. The total number of cases registered, as TAD in the year 2014 were 72. Out of the 72 cases, 4 cases could not be approached as they were not available even after 2 visits. Hence the final sample consisted of 68 cases and 136 age and gender match controls were enrolled by purposive sampling.

A pre-designed, pre-tested semi structured questionnaire was formulated based on review of literature of similar studies. The questionnaire was further reviewed by the subject experts from Community Medicine department for content validity. Sources of data included TB registers and Interview.

Statistical Analysis

Data was analyzed with SPSS version16. Chi- square (X^2) test was applied to study the association of various study variables with cases and controls. Those factors found significant on univariate analysis ($p<0.05$) were subjected to logistic regression analysis to look for odds of defaulting with respect to the risk factor.

RESULTS

In the study population majority were males (91.2%) and females were 8.8%. The mean age of the study population was 42.9±13 years. Majority of the study participants belonged to Hindu religion (76%), married (61.3%), literate (52.5%), belonging to Joint family (56.4%), employed (83.3%), belonged to a family of ≤ 5 members (57.8%), resided in the same residence for > 24 months (82.8%) and the study subjects were equally distributed across rural and urban regions (50%).Majority of the study participants belonged to upper lower class (36.8%) and upper middle class (37.3%) class of socio economic status.

Table1 (a): Multivariate logistic regression between patient related risk factors with DOTS defaulters (n=204) [R^2=90.2%]

Sl/No	Patient related risk factors	Case (n=68) n(%)	Controls (n=136) n(%)	Adjusted odds ratio	95% CI	P value
1	**Continuation of treatment after symptom relief**					
	Agree (r)	29(42.6)	125(91.9)			
	Disagree	39(57.4)	11(8.1)	2.735	0.165-45.30	0.482
2	**TB can be cured if treatment is fully completed**					
	Agree (r)	21(30.9)	126(92.6)		0.410-42.98	
	Disagree	47(69.1)	10(7.4)	4.197		0.227
3	**Incomplete treatment leads to TB spread among family**					
	Agree (r)	15(22.1)	124(91.20			
	Disagree	53(77.9)	12(8.8)	86.918	7.243-1041.57	**<0.001***
4	**Coughing in open leads to spread of TB**					
	Yes(r)	10(14.7)	127(93.4)			
	No	58(85.3)	9(6.6)	8.684	0.853-88.93	0.068
5	**Sharing food will lead to TB**					
	Disagree (r)	32(47.1)	100(73.5)			
	Agree	36(52.9)	36(26.5)	11.185	1.320-94.77	**0.02***
6	**Overcrowding spreads TB**					
	Yes(r)	19(27.9)	134(98.5)			
	No	49(72.1)	2(1.5)	4.670	0.310-70.379	0.265

*(*p<0.05 statistically significant, (r) is reference)*

Table1 (b): Multivariate logistic regression between patient related risk factors with DOTS defaulters (n=204) [R^2=90.2%]

Sl/No	Variable	Case (n=68) n (%)	Controls (n=136) n (%)	Adjusted odds ratio	95% CI	P value
7	**Symptoms of TB**					
	Poor/average(r)	12(17.6)	74(54.4)			
	Good	56(82.4)	62(45.6)	121.059	3.956-3704.207	**0.006***
8	**Treatment duration**					
	Correct(r)	31(46.6)	116(85.3)			
	Incorrect	37(54.4)	62(14.7)	66.907	4.858-921.57	**0.002***
9	**Discrimination by family/friends/relatives**					
	absent(r)	43(63.2)	130(95.6)			
	Present	25(36.8)	6(4.4)	2.076	0.115-37.415	0.620
10	**Lack of motivation to complete treatment**					
	Absent(r)	18(26.5)	127(93.4)			
	Present	50(73.5)	9(6.6)	276.643	14.289-5355.96	**<0.001***
11	**Fear of side effects**					
	Absent(r)	34(50)	112(82.4)			
	Present	34(50)	24(17.6)	0.655	0.073-5.88	0.705
12	**Number of tablets to be taken**					
	Little (r)	4(5.9)	54(39.7)			
	Many	64(94.1)	82(60.3)	11.722	0.962-142.8	**0.05***

*(*p<0.05 statistically significant, (r) is reference)*

On applying multivariate logistic regression, the patient related factors namely incomplete treatment leads to TB spread among family, Sharing food will lead to TB, knowledge about symptoms of TB, treatment duration, lack of motivation to complete treatment and number of tablets to be taken were found to be the independent risk factors for defaulting on DOTS.

Table 2: Multivariate logistic between habits of patients with DOTS defaulters (n=204) [R^2=31.3%]

Sl/No	Habits	Case (n=68) n(%)	Controls (n=136) n(%)	Adjusted odds ratio	95% CI	P value
1	**Smoking**					
	Never use(r)	24(35.3)	101(74.3)			
	Current use	44(64.7)	35(25.7)	4.254	2.126-8.511	**<0.001***
2	**Tobacco (smokeless)**					
	Never use(r)	45(66.2)	117(86.0)			
	Current use	23(33.8)	18(13.2)	4.544	1.996-10.345	**<0.001***
3	**Alcohol**					
	Never use(r)	23(33.8)	91(66.9)			
	Current use	45(66.2)	45(33.1)	3.264	1.620-6.576	**<0.001***

*(*p<0.05 statistically significant, (r) is reference)*

On applying multivariate logistic regression, the habits of study subjects namely smoking, use of smokeless tobacco and alcohol consumption were found to be the independent risk factors for defaulting on DOTS.

Table 3: Multivariate logistic between provider related risk factors with DOTS defaulters (n=204) [R^2=46.1%]

Sl/No	Provider related risk factors	Case (n=68) n (%)	Controls (n=136) n(%)	Adjusted odds ratio	95% CI	P value
1	**Attitude/Behavior of treatment provider**					
	satisfactory	37(54.4)	120(82.8)	4.463	2.076-9.593	<0.001*
	unsatisfactory(r)	31(45.6)	10(17.2)			
2	**Collection medication by family**					
	Allowed	37(54.4)	44(32.4)	2.106	1.073-4.141	**0.03***
	Not allowed(r)	31(45.6)	92(67.6)			
3	**Distance from treatment centre**					
	<5 kms(r)	52(76.5)	125(91.9)			
	>5kms	16(23.5)	11(8.1)	3.376	1.318-8.651	**0.011***
4	**Disease explained by provider**					
	Yes (r)	41(60.3)	113(83.1)			
	No	27(39.7)	23(16.9)	2.991	1.411-6.343	**0.004***
5	**Swallow medicines in front of provider**					
	Yes (r)	57(83.8)	130(95.6)			
	No	11(16.2)	6(4.4)	2.340	0.647-8.463	0.195

*(*p<0.05 statistically significant, (r) is reference*)

On applying multivariate logistic regression, the provider related factors namely attitude and behavior of provider, collection of medicines by family members, distance from treatment centre and explanation of disease by provider were found to be the independent risk factors for defaulting on DOTS.

DISCUSSION

In the present study, majority of the cases (57.4%) were of the opinion that it was not necessary to continue treatment after relief from symptoms as compared to controls (8.1%) which was statistically significant (p <0.05).The odds of defaulting was 15.3 times more among subjects with the opinion that it was not necessary to continue treatment after relief of symptoms in comparison with those who agree with p value < 0.05 and CI 6.99-33.39 as shown in table no 12(a). In a study by Slama K et al[5] according to 108 defaulters the main reason for defaulting was the feeling of being cured.

The present study found a statistical significance between cases (69.1%) and controls (7.4%) with respect to whether TB can be cured if full treatment is taken (p <0.05) and the odds of defaulting was 28.2% (CI 12.4-64.3) among cases who do not believe that TB can be cured even with completion of full treatment (p <0.05). A study by EL-Din et al[6] found that subjects who disagreed with the statement that full treatment will cure TB completely were having 11.5 (2.99-44.1) times odds of defaulting. These findings were consistent with our study findings.

Our study majority i.e. 77.9 % cases were of opinion that incomplete treatment will not lead to spread of TB among family members as compared to controls 8.8% and this difference was observed to be statistically significant(p<0.05).

This wrong perception about TB will spread to family members even with complete treatment had 36.5 (CI 16.0-83.3) times odds of defaulting on treatment also this was found to be an independent risk factor for default.

Our study found majority of the cases (52.9%) were of the opinion that sharing food will lead to spread of TB as compared to controls (26.5%) which was statistically significant ($p < 0.05$) and the odds of defaulting was 3.12 times more in subjects who agreed to, sharing food will lead to spread of TB compared to those who disagreed ($P < 0.05$). A case control study conducted in Sikkim by Dolma KG et al[7] stated that wrong perceptions, like tuberculosis is spread by sharing food with infected patients needs to be addressed to remove the stigma and misconception attached to the disease.

In the present study there was a statistical significance between cases (72.1%) and controls (1.5%) with respect to the knowledge about overcrowding and those who have incorrect knowledge about role of overcrowding in spread of TB has 26 times odds of defaulting on treatment in comparison with those having correct knowledge (<0.05). A similar case control study conducted in Sikkim by Dolma.KG et al[7] stated overcrowding to be associated significantly with default.

Our study found a statistical significance between cases (54.4%) and controls (14.7%) with respect to duration of treatment ($p < 0.05$). Also it was observed that subjects who had incorrect knowledge about duration of treatment had 66.9 times odds of defaulting compared to those who have correct knowledge($p<0.05$). A study by Tekle.P et al[8] found 14% of defaulters to lack knowledge about duration of treatment.

In present study, majority of cases (83.6%) had poor knowledge about TB before contacting the disease compared to controls (52.9%) which was statistically significant ($p < 0.05$) and the odds of defaulting was 4.60 times more in subjects who did not have knowledge about TB before contacting the disease compared to those who had knowledge ($p < 0.05$). A similar case control studies [10,] also found association of knowledge about TB with default. Subject with inadequate knowledge on TB had 2.6 time (CI 95%= 1.48-4.4) odds of defaulting compared to adequate knowledge as reported by Muture et al.[10]

Many social factors like poverty, illiteracy, ignorance and overcrowding are interrelated and contribute to the prevalence of the disease and treatment outcome.[11] Our study also found these patient related social factors as risk factors for defaulting on DOTS.

In the present study, discrimination by family members/relatives showed statistical significance with respect to cases (36.85) and controls (4.4%), ($p < 0.05$) and subjects who reported that they were discriminated by family/relatives/friend, in comparison to those who were not had 12.59 times odds of defaulting on treatment ($p < 0.05$). Study by Tekle P et al[8] found family support to be associated significantly with default.

In the present study, majority of cases (73.5%) compared to controls (6.6%) lacked motivation to complete treatment, which was found statistically significant ($p < 0.05$) and subjects who lacked motivation to complete treatment, compared to those who did not lack motivation had 39.2 times odds of defaulting on treatment ($p < 0.05$).Study by Chennaveerappa et al[12] stated lack of motivation by study participants as a reason for defaulting on treatment. Lack of motivation was found to be the independent risk factor for defaulting on treatment in our study.

In the present study, There was a statistical significance between cases (94.1%) and controls (60.3%) with respect to number to tablets ($p < 0.05$) and also subjects who felt the tablets were many, in comparison to those who felt they were little, had 10.5 times odds of defaulting on treatment ($p < 0.05$).Study by Jaggaramma K et al[13] reported that more quantity of tablets found to be associated with default and was consistent with our study findings.

CONCLUSION

Incorrect knowledge that incomplete treatment leads to spread of TB among family members, sharing food will lead to spread of TB and treatment duration. Also poor knowledge about symptoms of TB, feeling of taking many tablets and lack of motivation to complete treatment were found to be the patient related independent risk factors for defaulting on treatment.Smoking, use of smokeless tobacco and alcohol consumption were found to be the independent risk factors for defaulting on DOTS.

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