Original Research Article

Unmatched case control study on risk factors of defaulter among newly diagnosed TB patients on DOTS registered under RNTCP in Hooghly district, West Bengal, India

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ABSTRACT

Background: Tuberculosis is still a major public health problem in India and in addition to this, non-adherence to DOTS makes it more difficult to manage and increase risk of drug resistance. The objective was to study the factors associated with defaulter to DOTS among newly diagnosed TB patients treated under RNTCP registered in Hooghly district, West Bengal, India.

Methods: A community based unmatched case control study was conducted with the help of predesigned pretested schedule among 99 defaulters and 103 non defaulters aged 15 years and above and registered between 1st April 2013 to 31st March 2014. Data was analyzed using SPSS software (version 20). Univariate analysis was done to find out the association of outcome with different variables under study. Variable with odd ratio 3 or more included in multivariate logistic regression model.

Results: If patients were main earning member, smoker, lacking of perception regarding fatality of TB, having information source other than DOTS provider and sub center as treatment center, were found as significantly associated with defaulting in final multivariate regression model.

Conclusions: An approach, towards modification of smoking behavior, adequate health education and information dissemination and qualitative improvement of treatment center including training of health staffs are essential for treatment adherence.

Keywords: Case control, Defaulter, DOTS, West Bengal, India

INTRODUCTION

Tuberculosis (TB) remains a major public health problem in India accounting for 23.3% of global prevalence and one fourth of estimated global annual incident TB cases in 2012. Currently there are about 2.8 million cases of tuberculosis in India.¹

In India, National Tuberculosis Control Programme [NTCP] has been in existence since 1962, yet, even after 30 years, there was no appreciable change in the epidemiological situation of TB in the country. Apprehended about this situation The Revised national Tuberculosis Control Program (RNTCP) thus formulated was internationally recommended and adopted in 1993.²

The cornerstone of successful chemotherapy is adequate and regular drug intake throughout the prescribed period of treatment. One of the major reasons for this program not performing optimally is because patients fail to
adhere to the treatment rather than inadequacy of regimen. Irregular treatment leads to more failures thus enlarging the pool of infectors and increasing the risk of developing drug resistant TB and cost of treatment. As there is emergence of multidrug resistance (MDR) tuberculosis, as well as extensively drug resistance tuberculosis [XDR] and association with HIV, there is an urgent need to prevent the patients from defaulting. Defaulting from treatment continues to be one of the major obstacles in the control of TB. Since there is ongoing transmission of infection from defaulter, preventing persons from defaulting is essential for successful TB treatment.\(^3\)

Under 12\(^{th}\) five year plan this problem of defaulter was also emphasized. In the objective regarding RNTCP under 12\(^{th}\) five year plan, it was stated to reduce default rate less than 5\% for new TB cases and less than 10\% in for retreatment cases.\(^2\)

Therefore, it is necessary to understand the reasons for default after initiation of the treatment and plan strategies to reduce default and thereby increase the success of treatment outcome.

Even after implementation of DOTS strategy under RNTCP aiming at minimum defaulter rate, the default rate reported to be around 6\% in India and 8\% in Hooghly district, West Bengal, India.\(^2,4\) However, no such independent study was readily available in Hooghly district, West Bengal, Eastern Part of India in prime publication before. With this background, a case control study on RNTCP defaulters in Hooghly district, West Bengal, India was done with the objectives to identify the factors associated with defaulter to DOTS among newly diagnosed TB patients.

**METHODS**

This study was an observational unmatched case control study conducted during November 2014 to April 2015 in Hooghly district, West Bengal, India. Permission for this study was taken from institutional ethical committee of AIH&PH, Kolkata. Newly diagnosed tuberculosis (TB) patient are those who had diagnosed and registered under RNTCP and never had treatment for tuberculosis or has taken anti tubercular drugs for less than one month. A TB patient, who at any time after registration to DOTS, has not taken anti TB drugs for 2 months or more consecutively was considered as a defaulter or case and those who completed prescribed course as per RNTCP guideline and declared as cured by authority was considered as control. All the newly diagnosed sputum smear positive (NSP) TB patients aged 15 years and above and who were registered for DOTS under RNTCP in the jurisdiction of study area during 1\(^{st}\) April 2013 to 31\(^{st}\) March 2014 were taken as study population, total 3307 person of which, 3065 person were cured and 242 were defaulter. NSP TB patient who were registered during same period but died or changed address or transferred out or seriously ill were excluded from study.

Smoking is already observed as an associated factor for defaulter.\(^5,6\) Sample size was calculated based on assumption that smoking is an important risk factor for default, and then sample size was calculated using the Fleiss formula with continuity correction for unmatched case control study.\(^7\)

\[
p_0 = \frac{(OR)P_1}{(OR)P_1 + (1 - P_1)} = p_0 + \frac{(r + 1)}{r + 1}
\]

\[
n_{\text{cases-Fleiss}} = \frac{\left[z_{\alpha/2}\left((r + 1) \times p \times (1 - p)\right) + z_{\alpha/2}\left(r \times p \times (1 - p) + p \times (1 - p)\right)\right]^2}{r \times (p - p_0)^2}
\]

\[
n_{\text{cases-Fleiss}-cc} = \frac{n_{\text{cases-Fleiss}}}{\frac{1}{4} + \frac{1}{r} + \frac{2 \times (r + 1)}{n_{\text{cases-Fleiss}} \times r \times |p_1 - p_0|}}
\]

Where: \(\alpha: \) probability of type I error, \(\beta: \) probability of type II error, \(r: \) ratio of case and control, \(P_0: \) proportion of smoker among case, \(P_0: \) proportion of smoker among control, OR: odd ratio, \(N_{\text{fleiss}}: \) required sample size for cases using Fleiss’s formula, \(N_{\text{Fleiss-cc}}: \) required sample size for cases using Fleiss’s formula with continuity correction. By assuming an odd ratio of 2.5 and 50\% smoker in control, for equal number of sample size for case and control (1:1), a sample size of 91 for each case and control was required to demonstrate with 95\% certainty and with a power of 80\% that smoking was a statistically significant risk factor for default. Further considering 15\% as non-response total sample size became 105 for each case and control.

For selecting the cases and controls, simple random sampling method was used. Finally, 6 cases and 2 controls were not available at their addresses in spite of 3 attempts to communicate them. So at last, 99 cases and 103 controls were included in the final analysis.

A predesigned, pretested, structured schedule, (consisting of socio demographic, personal and patient related, treatment, service provider, and administration related variables) was used for data collection by interviewing sample population after their written consent at their house and equal time of 30 min was given for both cases and controls to minimize interviewer bias.

Data collected was analyzed using SPSS (version 20, IBM) to describe the data and identify any significant unadjusted odd ratio with 95\% confidence interval by Univariate analysis. Two tailed \(p\) value was reported and statistical significance was established at \(p<0.05.\) Since
availability of provider and giving blister on patient’s hand are interdependent, they were combined into new variable named as provider related issue, if any one risk factor among ‘availability of provider sometime’ or ‘blister given on patient’s hand’ is present, then it is assumed that provider related issue persists and otherwise not. Similarly distance of treatment center, availability of communication and travel cost were combined to form new variable named as travel related issue, if any one of the above factors is in favour, then it is assumed that travel related issue is not present and otherwise present, here we assumed that if one travel related factor is in favour then patient can overcome other two. At last step, multiple logistic regression procedure was used for investigating factors, only those had significant associations are presented here.

RESULTS

Mean age of the study subjects was 39.1 yr (SD 13.9), with 23.8% below 30 years age. Majority of study subjects comprised Hindu (183, 90.6%), Male (163, 80.7%) and 86 (42.6%) belonging to General caste. Total 152 (75.2%) persons were married and 21 (10.4%) were unemployed. Total 78 (38.6%) persons were residing in rented house or migratory. As per socioeconomic class (Modified Prasad scale, updated May, 2014), 138 (68.3%) persons were below class IV. Total 102 (52%) were smoker and 97 (48%) were alcoholic. Out of 84 investigating factors, only those had significant associations are presented here.

Table 1: Distribution of cases and controls according to significant socio demographic and personal characteristics.

| Variables                | Cases (n=99) Number (%) | Controls (n=103) Number (%) | P value | COR² (95% CI) |
|--------------------------|-------------------------|-----------------------------|---------|---------------|
| 1. Age in completed years|                         |                             |         |               |
| 15-29                    | 15 (15.2)               | 33 (32.0)                   | 0.004   | 1             |
| ≥30                      | 84 (84.8)               | 70 (68.0)                   |         | 2.64 (1.3-5.3) |
| 2. Gender                |                         |                             |         |               |
| Male                     | 85 (85.9)               | 78 (75.7)                   | 0.068   | 1.946 (0.9-4.0) |
| Female                   | 14 (14.1)               | 25 (24.3)                   |         | 1             |
| 3. Caste                 |                         |                             |         |               |
| ST / SC                  | 45 (45.5)               | 25 (24.3)                   | 0.002   | 2.6 (1.4-4.7) |
| OBC/Others               | 54 (54.5)               | 78 (75.7)                   |         | 1             |
| 4. Residence             |                         |                             |         |               |
| Rural                    | 62 (62.6)               | 39 (37.9)                   | 0.000   | 2.750 (1.6-4.9) |
| Urban                    | 37 (37.4)               | 64 (62.1)                   |         | 1             |
| 5. Duration of stay (yrs)|                         |                             |         |               |
| <10                      | 37 (37.4)               | 25 (24.3)                   | 0.044   | 1             |
| ≥10                      | 62 (62.6)               | 78 (75.7)                   |         | 1.8 (1.01-3.4) |
| 6. Education             |                         |                             |         |               |
| Below Primary            | 69 (69.7)               | 48 (46.6)                   | 0.001   | 2.6 (1.5-4.7) |
| ≥ Primary                | 30 (30.3)               | 55 (53.4)                   |         | 1             |
| 7. Marital Status        |                         |                             |         |               |
| Married                  | 82 (82.8)               | 70 (68.0)                   | 0.014   | 2.3 (1.2-4.4) |
| Others                   | 17 (17.2)               | 33 (32.0)                   |         | 1             |
| 8. Main earning member   |                         |                             |         |               |
| Yes                      | 73 (60.3)               | 48 (39.7)                   | 0.000   | 3.3 (1.8-5.8) |
| No                       | 26 (32.1)               | 55 (67.9)                   |         | 1             |
| 9. Social class*         |                         |                             |         |               |
| Class IV-V               | 41 (41.4)               | 23 (22.3)                   | 0.004   | 2.5 (1.3-4.5) |
| Class I-III              | 58 (58.6)               | 80 (77.7)                   |         | 1             |
| 10. Accompanying person availability | | | | |
| Yes                      | 39 (39.4)               | 76 (73.8)                   | 0.000   | 1             |
| No                       | 69 (60.6)               | 27 (26.2)                   |         | 4.3 (2.3-7.8) |
| 12. Food availability    |                         |                             |         |               |
| Always                   | 59 (59.6)               | 88 (85.4)                   | 0.000   | 1             |
| Not always               | 40 (40.4)               | 15 (14.6)                   |         | 3.9 (2.0-7.9) |
| 13. Smoking (Ever)       |                         |                             |         |               |
| Yes                      | 65 (65.7)               | 40 (38.8)                   | 0.000   | 3.0 (1.7-5.4) |
| No                       | 34 (34.3)               | 63 (61.2)                   |         | 1             |
Table 2: Distribution of cases and controls according to their perception and knowledge regarding TB and its treatment.

| Variables                        | Cases (n=99) Number(%) | Controls (n=103) Number(%) | P value | COR* (95% CI) |
|----------------------------------|------------------------|-----------------------------|---------|---------------|
| 1. Belief in suffering TB        |                        |                             |         |               |
| Yes                              | 45 (45.5)              | 75 (72.8)                   | 0.000   | 1             |
| No                               | 54 (54.5)              | 28 (27.2)                   |         | 3.2 (1.8-5.8) |
| 2. Accuracy of diagnostic method |                        |                             |         |               |
| Yes                              | 61 (61.6)              | 78 (75.7)                   | 0.030   | 1             |
| No                               | 38 (38.4)              | 25 (24.3)                   |         | 1.9 (1.1-3.6) |
| 3. Faith in RNTCP                |                        |                             |         |               |
| Yes                              | 34 (34.3)              | 72 (69.9)                   | 0.000   | 1             |
| No                               | 65 (65.7)              | 31 (30.1)                   |         | 4.4 (2.5-8.0) |
| 4. Fatality of T.B.              |                        |                             |         |               |
| Yes                              | 46 (46.5)              | 86 (83.5)                   | 0.000   | 1             |
| No                               | 53 (53.5)              | 17 (16.5)                   |         | 5.8 (3-11.2)  |
| 5. Belief in other remedies      |                        |                             |         |               |
| Yes                              | 58 (58.6)              | 30 (29.1)                   | 0.000   | 3.4 (1.9-6.2) |
| No                               | 41 (41.4)              | 73 (70.9)                   |         | 1             |
| 6. Importance of treatment completion |                  |                             |         |               |
| Yes                              | 48 (48.5)              | 73 (70.9)                   | 0.001   | 1             |
| No                               | 51 (51.5)              | 30 (29.1)                   |         | 2.6 (1.5-4.6) |
| 7. Duration of treatment         |                        |                             |         |               |
| Not known/Till feel better       | 76 (76.8)              | 36 (35.0)                   | 0.000   | 6.2 (3.3-11.4) |
| 6 month                          | 23 (23.2)              | 67 (65.0)                   |         | 1             |
| 8. Presence of side effect       |                        |                             |         |               |
| Yes                              | 53 (53.5)              | 35 (34.0)                   | 0.005   | 2.2 (1.3-4.0) |
| No                               | 46 (46.5)              | 68 (66.0)                   |         | 1             |
| 9. Illness hampers income        |                        |                             |         |               |
| Yes                              | 48 (55.8)              | 39 (41.1)                   | 0.047   | 1.8 (1-3.3)   |
| No                               | 38 (44.2)              | 56 (58.9)                   |         | 1             |

*Prasad Scale based on per capita income (PCI) inflation updated to 2014; #COR: Crude Odd ratio.

Table 1 shows that the socio demographic and personal factors which were significantly associated with defaulting. Among which, non-availability of accompanying person has 4.3 times more associated with defaulter than those who had accompanying person. Among the other significant factors, those who, are the main earning member of the family (COR–3.3), have not always availability of food (COR–3.9), who are smoker (COR–3.0) having associated with defaulter three times or more.

Significant factors for defaulter related to perception and knowledge of TB and its treatment are shown in table 2. Among this factors, those who did not know the treatment duration, has highest, 6.2 times more defaulted, followed by who, did not belief TB as fatal (5.8 times), had no faith on RNTCP (4.4 times), had belief on other remedies (3.4 times) and who did not belief in suffering from TB (3.2 times) more defaulted than their counterpart.

Table 3 shows the health sector and provider related factors which were associated with defaulter. Among these significant factors, not always availability of DOTS provider lead to 11.9 times more default than where DOTS providers were always available and for those, source of information was medical officer or health staffs, had 11.5 times more defaulted than who got information from DOTS providers. Besides this, for those information about follow up sputum examination (COR –
Table 3: Distribution of cases and controls according to significant health sector and provider related factors.

| Variables                                           | Cases (n=99) | Controls (n=103) | P value | COR (95% CI) |
|-----------------------------------------------------|--------------|------------------|---------|--------------|
| 1. Information source                               |              |                  |         |              |
| MO/Health staff                                     | 76 (76.8%)   | 23 (22.3%)       | 0.000   | 11.5 (5.9-22.1) |
| DOTS provider                                       | 23 (23.2%)   | 80 (77.7%)       |         | 1            |
| 2. Information content                              |              |                  |         |              |
| a. Follow up sputum examination                     |              |                  |         |              |
| Yes                                                 | 59 (59.6%)   | 89 (86.4%)       | 0.000   | 1            |
| No                                                  | 40 (40.4%)   | 14 (13.6%)       |         | 4.3 (2.1-8.6) |
| b. Importance of treatment completion               |              |                  |         |              |
| Yes                                                 | 60 (60.6%)   | 86 (83.5%)       | 0.000   | 1            |
| No                                                  | 39 (39.4%)   | 17 (16.5%)       |         | 3.3 (1.7-6.4) |
| 3. Availability of DOTS provider                    |              |                  |         |              |
| Always                                              | 57 (57.6%)   | 97 (94.2%)       | 0.000   | 1            |
| Not always                                          | 42 (42.4%)   | 6 (5.8%)         |         | 11.9 (4.8-29.8) |
| 4. Provider related issue*                          |              |                  |         |              |
| Absent                                              | 54 (71.6%)   | 92 (74.4%)       | 0.000   | 1            |
| Present                                             | 45 (27.4%)   | 11 (28.6%)       |         | 6.9 (3.3-14.6) |
| 5. Blister given to patients’ hands in intensive phase |            |                  | 0.018   | 3.1 (1.2-8.3) |
| Yes                                                 | 16 (16.2%)   | 6 (5.8%)         |         |              |
| No                                                  | 83 (83.8%)   | 97 (94.2%)       |         |              |
| 6. Behavior of DOTS provider                        |              |                  |         |              |
| Good & very good                                    | 38 (38.4%)   | 60 (41.7%)       | 0.005   | 1            |
| Satisfactory to very bad                            | 61 (61.6%)   | 43 (58.3%)       |         | 2.2 (1.3-3.9) |
| # COR: Crude Odd ratio; *= newly formed variable.   |              |                  |         |              |

Table 4: Distribution of cases and controls according to some organizational and operational factors.

| Variables                                           | Cases (n=99) | Controls (n=103) | P value | COR (95% CI) |
|-----------------------------------------------------|--------------|------------------|---------|--------------|
| 1. Type of Treatment Centre                         |              |                  |         |              |
| Hospital /PHI                                       | 33(33.3)     | 74(71.8)         | 0.000   | 1            |
| SC                                                  | 66(66.7)     | 29(28.2)         |         | 5.1(2.8-9.3) |
| 2. Distance of t/t center from home                 |              |                  |         |              |
| ≤ 2 Km                                              | 36(36.4)     | 63(61.2)         | 0.000   | 1            |
| > 2 Km                                              | 63(63.6)     | 40(38.8)         |         | 2.8(1.6-4.9) |
| 3. Availability of communication (to reach treatment centre) |          |                  |         |              |
| Yes                                                 | 50(50.5)     | 78(75.7)         | 0.000   | 1            |
| No                                                  | 49(49.5)     | 25(24.3)         |         | 3.1(1.7-5.6) |
| 4. Cost of travel (INR)                             |              |                  |         |              |
| > 10                                                | 61(61.6)     | 32(31.1)         | 0.000   | 3.5(2-6.4)   |
| ≤ 10                                                | 38(38.4)     | 71(68.9)         |         | 1            |
| 5. Travel related issue*                             |              |                  |         |              |
| Absent                                              | 40(40.4)     | 70(68)           | 0.000   | 1            |
| Present                                             | 59(59.6)     | 33(32)           |         | 3.2(1.8-5.6) |
| 6. Waiting time in treatment centre                 |              |                  | 0.017   |              |
| < 1 hr                                               | 41(41.4)     | 60(58.3)         |         | 1            |
| ≥ 1 hr                                               | 58(58.6)     | 43(41.7)         |         | 2(1.1-3.5)   |
| 7. DOTS centre timing                               |              |                  |         |              |
| Convenient                                          | 39(39.4)     | 79(76.7)         | 0.000   | 1            |
| Inconvenient                                        | 60(60.6)     | 24(23.3)         |         | 5.1(2.8-9.3) |
Significant operational and organizational factors which were associated with defaulter is shown at table 4. Among these significant factors, a satisfactory to very bad opinion about overall RNTCP administration lead to the highest, 6.7 times more default, followed by type of treatment center and their timing, cost of travel, availability of provider and giving blister given on patient’s hand are interdependent, they were combined into new variable named as provider related issue, whose odd ratio is also 3.4 (3.3–3.5) times; 95% Cl 1.035–3.457, for those who missed at least one dose; *=newly formed variable.

Among the significant factors associated with defaulter, only those factors having odd ratio ≥3 were considered in multivariate logistic regression by enter method. At this step, since availability of provider and giving blister given on patient’s hand are interdependent, they were combined into new variable named as provider related issue, whose odd ratio is also 6.9 (3.3–14.6) [by univariate analysis, Table 3]. Similarly distance of treatment center, availability of communication and travel cost were combined to form new variable named as travel related issue, whose odd ratio is also 3.1 (1.8–5.6) [by univariate analysis, Table 4]. Out of 17 variables (Table 5) patient who were main earning member, ever smoker, did not think TB as fatal disease, source of information (MO/ health staff), type of treatment center (sub center/ SC) were found significantly associated with defaulter.

**DISCUSSION**

This study revealed various socio demographic and personal factors, factors regarding patient perception and knowledge about TB and its management, health sector and provider related factors and organizational and operational factors which were associated with defaulter individually by univariate analysis. Those are already mentioned earlier.

Defaulting from DOTS has historically been considered as one of the most challenging problem of RNTCP contributing to disease burden, drug resistant etc. This study was aimed towards identification of those factors which was associated with defaulting from DOTS. Multiple logistic regression reveals patient who were received information from MO or health staff (12.2 times; 95% Cl: 4.193–35.308), for those sub center was the treatment center (3.7 times; 95% Cl: 1.376–9.974) more likely to default than their respective counterpart.

**Table 5: Multivariate analysis (logistic regression) of the factors associated with defaulter.**

| Variables                                             | Sig.  | AOR    | 95% C.I. for AOR# |
|-------------------------------------------------------|-------|--------|-------------------|
| 8. Opinion about overall RNTCP administration          |       |        |                   |
| Good and very good                                    | 0.000 | 1      |                   |
| Satisfactory to very bad                              | 0.001 | 1      |                   |
| 9. Method of retrieval action#                        |       |        |                   |
| Home visit                                            | 0.444 | 3.537  | 1.035 12.091      |
| Other                                                 | 0.044 | 3.537  | 1.035 12.091      |
| # AOR: Adjusted Odd ratio.                            |       |        |                   |

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Present study observed earning status (main earning member p=0.000) as a significant factor associated with defaulter. Shargie and Lindtjørn et al had also found that earning member have to go for earning with shortage of time compromises treatment.\textsuperscript{9} In our study, we found smoking (p=0.000) is associated with higher defaulter. Bagchi, Lamsel et al found similar result. This study had also observed, those who did not think TB as fatal disease were more likely to default.\textsuperscript{3,6} Pandit and Chudhury had also found in their study that lack of knowledge about TB is a contributing factor to defaulter.\textsuperscript{10} One interesting finding is that if MO or health staff were the source of information, then patient was 11.5 times (95\% CI: 5.9–22.1) more likely to be defaulted than those who got information from DOTS provider. It may be due to the fact that MO or health staff having huge workloads other than DOTS, may find it difficult to give adequate time and information to TB patient.

Our study did have certain limitations. Since this is a case control study, only odds ratio could be measured. Measurement of relative risk or attributable risk is not possible. Some other possible important factors may not have been included in this study and had relied on memory and past records. Lastly study results cannot be generalized, it will be applicable in Hooghly district or similar type of population only. There is a future scope to perform this type of study in large scale.

All other factors, excepting few factors like age, caste, residence, marital status etc are modifiable. Focus should be given towards these modifiable factors. It is recommended that health care staff in TB programs should direct health education to quit smoking and alcohol intake, also counsel about fatality about T.B, regularly monitor the DOTS provider in order to reduce treatment defaulting. Counseling by DOTS provider is more effective than by other health staffs. So other health staffs needed to be trained for proper counseling. Poor physician–patient communication should be addressed. Sub center should be more strengthened and make more feasible time schedule for patients. Proper counseling and motivation of patients regarding various aspects of the disease is a must to ensure compliance, increase awareness about T.B compliance The message that needs to be conveyed to everyone is that DOTS is the best available strategy for curing TB patients and that all the elements of DOTS must be adopted in letter and in spirit. Only then India will be able to look forward to the day when it will be no suffering from tuberculosis.

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