# Study of Default and Its Determinants amongst TB Patients under RNTCP in Bareilly District of Uttar Pradesh

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## ABSTRACT

**Introduction:** Tuberculosis (TB) is caused by Mycobacterium tuberculosis. It primarily affects lungs and causes Pulmonary TB (PTB). Defaulter is a patient who has not taken anti-TB drugs for 2 months or more consecutively after starting treatment. Default is one of the unfavourable outcomes for patients on DOTS and represents an important challenge for the control program. It increases the risk of drug resistance, treatment failures, relapses, deaths and prolonged infectiousness, which is a hurdle to the success of TB programmes.

The present study objective is to find out prevalence and various factors that influence to default TB patients under DOTS in RNTCP in district Bareilly, Uttar Pradesh.

**Methodology:** A cross-sectional study was conducted among the TB patients registered during 1st April 2014 to 31st March 2016 under RNTCP for DOTS in Bareilly. Purposive sampling was carried out, 10 DMCs were selected in district Bareilly of which a total of 2010 TB patients were interviewed. Logistic regression (LR) was used for statistical analysis.

**Results and Conclusion:** In the present cross-sectional study, total 2010 TB patients were interviewed in which 489 (24.3%) belonged to the age group of less than 20 years and 1119 (55.7%) were male. 83.1% of the cases were taking treatment of category I. The overall prevalence of defaulters in the present study was found to be 9.35%.By applying LR the strength of association of default was seen more in 20 – 29 years of age group, sputum smear negative cases, pulmonary TB cases and patients having history of treatment of interruption and patients belonging to category II in DOTS.

## INTRODUCTION

Tuberculosis (TB) continues to intimidate the human race since time immemorial not only due to its effects as a medical malady but also by its impact as a social & economical tragedy. [1]

TB is caused by Mycobacterium tuberculosis. It primarily affects lungs and causes Pulmonary TB (PTB). [2]

The risk for developing TB is higher in persons with diabetes, other chronic debilitating disease leading to immune-compromise, poor living conditions and smokers etc.

According to Annual RNTCP report 2016 the prevalence of default in new smear positive cases is 6% and 5% in Uttar Pradesh and India. [3]

Defaulter is a patient who has not taken anti-TB drugs for 2 months or more consecutively after starting treatment. [4]

Default is one of the unfavourable outcomes for patients on DOTS and represents an important challenge for the control program. [5] It increases the risk of drug resistance, treatment failures, relapses, deaths and prolonged infectiousness, which is a hurdle to the success of TB programmes. [6-8]

Studies in India and other developing countries have focused on various causes and risk factors for default. Gender, alcoholism, treatment after default, poor knowledge of TB, irregular treatment

and socioeconomic status are some of the factors which have been found to be associated with higher default rates. [9-12]

The present study has been done to find out prevalence and various factors that influence to default TB patients under DOTS in RNTCP in district Bareilly, Uttar Pradesh.

## MATERIALS & METHODS

A cross sectional study was conducted in district Bareilly over a period of 1 year from August 2015 to July 2016 to determine the treatment seeking behaviour and default rate among TB patients registered under RNTCP by using a predesigned, pretested semi-structured questionnaire. TB patients registered under RNTCP for DOTS in Bareilly district for treatment from 1st April 2014 to 31st March 2016. There are 45 DMCs in district Bareilly. Out of these DMCs, 10 DMCs were selected randomly by using lottery method. Interview of the TB patients registered in the DMCs was taken at the health facility or by making home visits for the selected patients. A total of 2010 TB patients were interviewed during the study period.

The study protocol was approved by the Institutional Ethics Committee. Informed consent was collected from the participants and confidentiality was assured. Patients who were not willing to give consent or moved out of the geographical area were excluded from the study.

Operational definition - A TB patient who did not start treatment or whose treatment was interrupted for 2 consecutive months or more was defined as Defaulter.

The information collected was tabulated and analysed using standard statistical software (Microsoft Excel 2010 and SPSS Version 23).

**Statistical Analysis:** Logistic Regression was applied to find out the association and their strength between the variables to validate the findings of the study.

## RESULT

In our study the prevalence of defaulters in the study subjects came out to be 9.35%.

Table – 1 shows the socio-demographic characteristics of 2010 subjects who participated in the study in which the age distribution revealed that maximum subjects (24.3%) were in the age group of < 20 years followed by 18.5% belonging to 20 – 29 years, 17.9% belonging to 40 – 49 years, 16.5% belonging to 30 – 39 years, 12.6% belonging to > 60 years and 10.2% belonging to 50 – 59 years age group. Male cases contributed 55.7% of the study population while 33.6% were females. More than two third of the study population that is 67.6% were married. Educational profile showed that 18.2% were illiterate.

More than four fifth (83.1%) showed pulmonary site of involvement while rest (15.5%) had extra pulmonary site of involvement. Majority of the cases that is 69.5% was sputum smear positive while 15% was sputum smear negative and in 15.5% cases sputum examination was not done as they were extra pulmonary cases. More than two third (83.1%) of the cases was taking treatment in category I while the rest (16.9%) was undergoing treatment of category II.

Majority of the patients (72%) did not break their continuity for the treatment while approximately one fourth of the cases (28%) showed interruption in their treatment.

By applying logistic regression, we saw that in the age group 20-29 years of study participants have 95% more chance of defaulting from treatment. Study participants of age group 30 -39 years have a chance of 78% for defaulting from the treatment. Study participants belonging to the age group of 40 – 49 years have a 26% chance of defaulting from treatment. 90% chance of defaulting is there in age group of 50 – 59 years whereas in more than 60 years of age group there is 7% less chances of defaulting from treatment as compare to study participants in age group less than 20

years. Age group less than 20 years of the study participants were taken as reference category. In the gender, Females were taken as reference category. In the study it was found that in Males there is 31% risk of more defaulting as compared to females.

Out of 2010 patients taken in the study, 1670 patients were in category I of RNTCP in which 179 patients have defaulted and 340 patients in category II in which 53 defaulted. On applying logistic regression by keeping category I patients as reference it was seen that category II patients had twice the risk of defaulting as compared to category I.

In sputum smear status, by keeping the extra pulmonary cases as reference in which sputum examination was not done, it was seen that in smear positive cases it was than three times the risk of default and in sputum negative cases it was almost five times the risk of default.

According to site of involvement in TB, extra pulmonary TB patients were kept as reference. In the study it showed that patients having pulmonary involvement had almost four times the risk of defaulting from the treatment.

Logistic regression was applied on the history of treatment interruption, by keeping patients who didn't have any treatment interruption history in reference category it was observed that people who had a positive history for treatment interruption had seven times more risk of becoming a defaulter.

In table – 3, reasons for default were asked by the TB patients who became defaulters. Reasons given by them were classified into personal and treatment related reasons for default.

In personal reasons, maximum defaulters (77.1%) revealed that they left treatment because their work is getting affected, while 61.7% had non-compliant attitude, 34% left treatment because of advice by family members and friends that there is no benefit in taking treatment for such a long time, 32.4% gave reasons of financial constraints, 18.9% needed permission from any family members to go to DOTS centre, 15.43% smoked during their treatment, 4.3% were travelling during the treatment period and 3.72% were consuming alcohol during the treatment.

In treatment related reasons, 124 (66%) defaulters had lack of faith in treatment, 62.2% were tired of coming to DOTS centre for taking drug alternate day, 33% of defaulters didn't knew the duration of treatment. side effects were reported by 112 (59.57%) patients in which most common side effect was seen is gastritis (54.8%) followed by joint pain and red colour urine in 32.4% and 19.7% respectively. Symptomatic relief was seen in 67 (35.6%) cases, in which most of the patient (50.75%) reported relief from symptoms after taking treatment for 2 – 3 months, followed by treatment of 1 – 2 month in 20 (29.85%) defaulters, 9 (13.43%) in less than 1 month of treatment and only 4 (5.97%) had symptomatic relief after taking treatment for more than 3 months.

**Table 1: Distribution of TB cases as per socio-demographic and clinical characteristics**

| Characteristics | Frequency (N=2010) | % |
|---|---|---|
| Age | | |
| <20 Years | 489 | 24.3 |
| 20 - 29 Years | 371 | 18.5 |
| 30 -39 Years | 332 | 16.5 |
| 40 - 49 Years | 359 | 17.9 |
| 50 - 59 Years | 206 | 10.2 |
| > 60 Years | 253 | 12.6 |
| Gender : Male | 1119 | 55.7 |
| Married | 1358 | 67.6 |
| Education: Illiterate | 365 | 18.2 |
| Occupation | | |
| Professional | 50 | 2.5 |
| Skilled Worker | 21 | 1.0 |
| Unskilled Worker | 769 | 38.3 |
| Housewife | 514 | 25.6 |
| Student | 487 | 24.2 |
| Unemployed | 169 | 8.4 |
| Type of TB | | |
| Pulmonary TB | 1699 | 84.5 |
| Extra Pulmonary TB | 311 | 15.5 |
| Smear Status | | |
| Smear Positive | 1398 | 69.5 |
| Smear Negative | 301 | 15 |
| Not Applicable (Extra Pulmonary TB cases) | 311 | 15.5 |
| Category of Treatment | | |
| Category I | 1670 | 83.1 |
| Category II | 340 | 16.9 |
| History of treatment interruption | | |
| Yes | 562 | 28 |
| No | 1448 | 72 |

**Table 2: Risk of defaulting from treatment by applying logistic regression**

| Characteristics | Defaulter | Non Defaulter | Odds Ratio | p-value |
|---|---|---|---|---|
| Age | | | | |
| <20 Years | 33 | 456 | Reference | - |
| 20 - 29 Years | 46 | 325 | 1.956 | .005 |
| 30 -39 Years | 38 | 294 | 1.786 | .020 |
| 40 - 49 Years | 30 | 329 | 1.260 | .378 |
| 50 - 59 Years | 25 | 181 | 1.909 | .021 |
| > 60 Years | 16 | 237 | .933 | .825 |
| Gender | | | | |
| Male | 116 | 1003 | 1.316 | .081 |
| Female | 72 | 819 | Reference | - |
| Category of Treatment | | | | |
| Category I | 135 | 1535 | Reference | - |
| Category II | 53 | 287 | 2.086 | < .001 |
| Smear Status | | | | |
| Smear Positive | 137 | 1261 | 3.645 | < .001 |
| Smear Negative | 42 | 259 | 5.441 | < .001 |
| Extra-pulmonary TB | 9 | 302 | Reference | - |
| Site of Involvement | | | | |
| Pulmonary TB | 179 | 1520 | 3.951 | < .001 |
| Extra Pulmonary TB | 9 | 302 | Reference | - |
| History of treatment interruption | | | | |
| Yes | 131 | 431 | 7.417 | .001 |
| No | 57 | 1391 | Reference | - |

**Table 3: Reasons for default**

| Reasons* | Frequency (n = 188) | Percentage (%) |
|---|---|---|
| Personal Reasons | | |
| Work is getting affected | 145 | 77.1 |
| Non-compliant attitude | 116 | 61.7 |
| Advice by someone | 64 | 34.0 |
| Financial constraints | 61 | 32.4 |
| Permission to go to DOTS centre | 34 | 18.9 |
| Smoked during the treatment | 29 | 15.43 |
| Migration/Travelling | 8 | 4.3 |
| Consumed alcohol during the treatment | 7 | 3.72 |
| Treatment related | | |
| Lack of faith in treatment | 124 | 66 |
| Tired of alternate day treatment | 117 | 62.2 |
| Didn't know the duration of treatment | 62 | 33 |
| Took medicines empty stomach | 13 | 6.9 |
| Side effects | 112 | 59.57 |
| Gastritis | 103 | 54.8 |
| Joint pain | 61 | 32.4 |
| Red colour urine | 37 | 19.7 |
| Symptomatic relief after taking ATT for | 67 | 35.6 |
| < 1 month | 9 | 13.43 |
| 1 -2 month | 20 | 29.85 |
| 2 - 3 month | 34 | 50.75 |
| >3 month | 4 | 5.97 |

* Multiple responses

## DISCUSSION

The present study entitled "Study of default and it's determinants amongst TB patients under RNTCP in Bareilly district of UP" was planned to find out the prevalence of defaulters, understand the factors for default among TB patients undergoing DOTS in district Bareilly.

There were total 2010 TB cases interviewed in the present study. Nearly one fourth of the TB cases i.e. 489 (24.3%) were from the age group less than 20 years of age. The findings of this study are similar to the findings of Sumer C et al (2012) [13] where most of the TB patients were in the age group of 16-24 years (26.95%). Whereas study done by Roy N et al (2011) [14] the 27.84% of study population was in age group of 25-35 years.

In the present study out of 2010 TB patients, 1119 (55.7%) of the study participants were male and 1358 (67.6%) were married. The above finding is similar to Verma AK et al (2007) [15] where out of 130 participants 55.8% were male. And in the study conducted by Gupta S et al (2007) [16] 145 (72.14%) of the participants were married.

In the present study it was noticed that 365 (18.2%) cases were illiterate, 769 (38.3%) were unskilled worker and 514 (25.6%) were housewives. The findings of this study are similar to the findings of Sarpal SSS et al (2011) [17] where 73 (13.4%) patients were illiterates and 109 (20%) were housewives. On the contrary, Varshney AM et al (2010) [18] study shows that 55% were unskilled workers and 69% having monthly income less than Rs 2500.

In the present study overall prevalence of default in the study subjects was found to be 9.35%. Default rate in Category I and II cases were found to be

8.08% and 15.59% respectively, while default rate in Pulmonary TB cases and Extra-pulmonary TB cases came out to be 10.54% and 2.89% respectively. Default rate in sputum smear positive cases was 9.80 but in sputum smear negative cases it was 13.95%. Almost similar type of prevalence is reported in the Annual RNTCP report (2016) in which prevalence of default in new smear positive cases is 6% and 5% in Uttar Pradesh and India. Default rate in new smear negative is 7% and 6% in Uttar Pradesh and India while in new extra pulmonary cases default rate is 3% both in Uttar Pradesh and India. In retreatment cases i.e. Category II cases default rate in relapse was 12% and 10% in Uttar Pradesh and India, in failure cases it was 14% and 13% in Uttar Pradesh and India while in treatment after default it was 14% and 16% in Uttar Pradesh and India respectively. [3]

Reasons for default in the current study were similar to other studies conducted by Gopi PG et al (2005), [19] Gorityala SB et al, [20] Gupta S et al (2007), [16] Jaggarajamma K et al (2006) [21] and Jha UM et al (2006) [22] study.

## CONCLUSION

In spite of patients being treated under RNTCP there have been cases of default. Default is one of the unfavourable outcomes of ATT. It is one of the most important contributory factors for drug resistance, treatment failures, relapses, deaths and prolonged infectiousness.

In the present study the default rate came out to be 9.35% among TB patients registered under RNTCP in district Bareilly, Uttar Pradesh. Default rate in Category I and II cases were found to be 8.08% and 15.59% respectively. Default rate in sputum smear positive cases was 9.80 but in sputum smear negative cases it was 13.95%.

Logistic Regression revealed that chances of defaulting from treatment was more in PTB (four times as compared to EPTB), and cases having history of treatment interruption (7.4 times as compared to those giving no history of treatment interruption).

Multiple responses were given by the defaulters on asking for the reasons for default. Out of 188 defaulters, in personal reasons, the common reasons for defaulting were that their work was getting affected by 145 (77.1%) followed by non-compliant attitude in 116 (61.7%).

In treatment related reasons, 124 (66%) had lack of faith in treatment, 117 (62.2%) were tired of alternate day treatment of DOTS, side effects were the reasons for defaulting was given by 112 (59.57%) and defaulting because of symptomatic relief was reported by 67 (35.6%) cases.

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