

# Determinants of treatment interruption and outcome among smear-positive pulmonary tuberculosis patients in a tuberculosis unit of Purba Bardhaman district of West Bengal

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## ABSTRACT

**Context:** The adoption of directly observed treatment short course (DOTS) in Revised National Tuberculosis Control Programme has given impressive results with higher treatment success. But interruption of treatment has been one of the major obstacles to treatment of tuberculosis. **Aims:** The aim of the study was to evaluate the determinants of treatment interruption and outcome. It also evaluated the impact of treatment interruption on treatment outcomes. **Settings and Design:** The study was carried out in the area covered under Bhatar tuberculosis unit (TU) of Burdwan district of West Bengal. The study was a descriptive cross-sectional study. **Methods and Material:** Smear-positive pulmonary tuberculosis patients were taken as study subjects in both the components of study. Complete enumeration technique, rather than sampling, was followed in this study. Data were collected in a predesigned and pretested schedule. **Statistical Analysis Used:** Data were analyzed by percentages and proportion. Chi-square test was used to find the association between variables. **Results:** Gender, religion, and substance abuse were found to be statistically significant factors with interruption. It was also observed that treatment outcome was not statistically significant with age, gender, religion, and category of treatment. In the study, 84.6% of the study subjects with interruption less than 1 week had favorable outcome. But in study subjects with longer duration of interruption ( $\geq 2$  weeks), only 12.5% had favorable outcome. Not only interruption, duration of interruption was found to be adversely affecting the treatment outcome. **Conclusions:** Interruption had an impact on the treatment outcome in the present study. Unfavorable outcomes were significantly more frequent among patients with interruption as compared to those without any interruption.

**Keywords:** Treatment interruption, treatment outcome, tuberculosis

## Introduction

Tuberculosis remains the leading infectious cause of death in India. India had contributed to approximately 25.5% of the total global new cases detected in the year 2012.<sup>[1]</sup> About 3.6% of newly diagnosed TB cases and 20% of previously treated TB cases had MDR-TB.<sup>[2]</sup> The prevalence of TB infection is 30%.<sup>[2]</sup> Every smear-positive person, if left untreated, has the potential

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to infect 10–15 persons per year.<sup>[3]</sup> In simple terms, two persons become sputum-positive for TB and almost one person is killed every minute due to the disease (WHO 2007).<sup>[2]</sup>

Directly observed treatment short course (DOTS) is one of the key strategies in Revised National Tuberculosis Programme (RNTCP). The adoption of DOTS in RNTCP has given impressive results with higher treatment success being reported from developing and industrialized countries. But interruption of treatment is still observed in spite of all efforts.

Though limited, but evidence are available regarding the extent of interruption and its determinants. In a study done by Dave *et al.*,<sup>[4]</sup> it was observed that no significant difference was observed in proportion of treatment interrupters and non-interrupters across demographic variables except for a higher proportion of treatment interruption in patients enrolled from urban district. A study in Nigeria in 2011 revealed 19% of the patients interrupted treatment in their course of treatment. Major factors associated with interruption were living >5 km from TB treatment site, lack of knowledge of duration of treatment, and cigarette smoking. However, they did not find any association with alcohol consumption.<sup>[5]</sup>

Default, as defined in RNTCP, is an adverse outcome of treatment when the interruption extends 4 weeks. More than half the patients had missed one or more doses either in intensive phase or continuation phase defaulting from the scheduled treatment.<sup>[6]</sup> Those predicted at risk of default with DOT in a metropolitan setting are most likely to be males, alcoholics, and those missing one or more doses in IP particularly after the 12<sup>th</sup> dose.<sup>[6]</sup> In addition, retreatment patients belonging to the type treatment after default and having poor knowledge of disease are also likely to default. The higher risk of default among retreatment patients could be attributed to the majority (78%) belonging to the type treatment after default who had interrupted treatment on earlier occasions.<sup>[6]</sup> Initial counseling by treatment providers and treating physicians considering the determinants of treatment interruption and outcome plays key role in the management of this disease. Patients who have recovered from the disease may act as influencer for the newly diagnosed patients.

In a tuberculosis unit of South India in 2003, Gopi *et al.*<sup>[7]</sup> observed that majority of patients were males and were aged 45 years or more. The life-style indicators for the patients were smokers and alcoholics. Overall, majority of patients were adhered. The risk factors associated with nonadherence were illiteracy, difficulty in accessing health facility, nongovernment DOT center, and DOT interfering with their daily activities. A study in northwest Ethiopia revealed that males were more likely to default than females. It showed that patient behavior and attitude about the disease are major factors affecting adherence to TB treatment. The higher social interaction outside home by males, social isolation associated with TB leading to treatment rejection, alcoholism, and other related behaviors among males might contribute to their higher default, failure, death, and transfer-out

rates.<sup>[8]</sup> The study was aimed to evaluate the determinants of treatment interruption and outcome. It also evaluated the impact of treatment interruption on treatment outcomes.

## Materials and Methods

### Study type and design

This is a descriptive study with both cross-sectional and longitudinal designs.

### Study setting

The study was conducted in the area covered under Bhatar TU of Burdwan district of West Bengal. Bhatar TU consists of two BPHCs Bhatar and Monteswar having 477,656 population as per the 2011 census. There are three designated microscopy centers – Bhatar, Aruar, and Monteswar. The entire Bhatar Block is the RHU&TC of Burdwan Medical College.

### Study period

The study was conducted during a period cover of 16 months from July 2015 to October 2016.

### Sampling and sample size

Complete enumeration technique, rather than sampling, was followed in this study. Thus, all smear-positive pulmonary TB patients registered in Bhatar TU from 1<sup>st</sup> quarter 2014 to 1<sup>st</sup> quarter 2015, that is, from January 2014 to March 2015, were included in the cross-sectional part of the study for retrospective analysis; there were 231 such subjects in this component. Similarly in longitudinal part of the study for prospective component, all eligible study subjects registered during the 2<sup>nd</sup> and 3<sup>rd</sup> quarter of 2015, that is, April 2015 to September 2015, were included; 90 such patients were registered during this period. However, 26 patients were not included for final analysis because of incomplete records. Smear-positive pulmonary tuberculosis patients registered under RNTCP at Bhatar TU of Burdwan in a specified reference period were the study subjects.

### Data collection

Data were collected in a predesigned and pretested schedule by review of relevant records and registers, like TB treatment card, TB register, and TB laboratory register in both the components as well as by interview in prospective component. Age, gender, occupation, type of patient, category of treatment, phase of interruption, duration of treatment interruption, number of missed doses, number of doses taken prior to interruption, and frequency of treatment interruption were taken as study variables in retrospective components. In the other component, 90 study subjects were interviewed at the beginning of treatment and after treatment interruption, if any. Additional variables like educational status, socio-economic status, substance abuse, and reasons of interruption were included in the prospective component. Standard RNTCP definitions were used to define RNTCP-related variables like type of patient and outcome of

treatment. However, for final analysis, cured and treatment completed were taken as “favorable outcome” and died, failure, lost to follow-up, and not evaluated were considered as “unfavorable outcome.”

## Data analysis

Data were checked for completeness and consistency, coded and entered into MS Excel sheet; then were analyzed using principles of descriptive and inferential statistics using SPSS 20 software. Then they were summarized and presented in suitable tables and diagrams and also calculating critical values. Chi-square test was used as test of significance and *P* value <.05 was considered as level of significance.

Ethical clearance was obtained from “Institutional Ethics Committee” of Burdwan Medical College and Hospital. Before conduction of interview, informed consent was obtained from all subjects.

## Results

For retrospective analysis, during the reference period of five quarters, a total of 231 patients were registered among which data for 26 subjects could not be retrieved because of illegible and incomplete records; so 205 subjects were finally analyzed. For

prospective part, all 90 patients registered during the reference period of two quarters were included. Thus in the present study, a final sample of 205 + 90 = 295 smear-positive pulmonary TB cases were studied.

In this section, the findings of these 295 study subjects are presented in the following sections.

Various sociodemographic and clinicotherapeutic variables related to treatment interruption are presented in [Table 1].

## Discussion

This study was undertaken among smear-positive pulmonary tuberculosis patients registered under RNTCP in seven quarters from January 2014 to September 2015. In the first five quarters, data were collected retrospectively by review of records. In the next two quarters, data were collected prospectively by record review as well as by interview. Altogether 295 eligible subjects were studied, for treatment interruption and its impact on treatment outcome.

### Factors associated with interruption [Table 1]

The present study showed age in years was not statistically significant with interruption of treatment. In the age group

**Table 1: Determinants and their impact on treatment interruption**

Variables	Interruption status			Chi-square value	df	P
	Yes (%)	No (%)	Total			
Age (in years)						
10-19	1 (6.7)	14 (93.3)	15 (100)	4.381	3	0.223
20-39	21 (16.8)	104 (83.2)	125 (100)			
40-59	10 (9.3)	97 (90.7)	107 (100)			
≥60	4 (8.3)	44 (91.7)	48 (100)			
Gender				4.929	1	0.026
Male	14 (19.7)	57 (80.3)	71 (100)			
Female	22 (9.8)	202 (90.2)	224 (100)			
Religion				5.347	1	0.021
Hindu	34 (14.4)	202 (85.6)	236 (100)			
Muslim	2 (3.4)	57 (96.6)	59 (100)			
Occupation				6.19	3	0.102
Laborer	20 (10.5)	171 (89.5)	191 (100)			
Business	5 (9.3)	49 (90.7)	54 (100)			
Service	3 (16.7)	15 (83.3)	18 (100)			
Others	8 (25)	24 (75)	32 (100)			
Substance abuse (n=90)				14.977	1	0.00
No	0 (0)	49 (100)	49 (100)			
Yes	11 (26.8)	30 (73.2)	41 (100)			
Educational status (n=90)				3.336	2	0.189
Illiterate	6 (21.4)	22 (78.6)	28 (100)			
Class I-X	5 (8.3)	55 (91.7)	60 (100)			
XI and above	0 (0)	2 (100)	2 (100)			
Category of treatment				0.857	1	0.355
Cat I	31 (11.5)	239 (88.5)	270 (100)			
Cat II	5 (20)	20 (80)	25 (100)			
Type of patient				0.857	1	0.355
New	31 (11.5)	239 (88.5)	270 (100)			
Previously treated	5 (20)	20 (80)	25 (100)			

Figures in parentheses indicate row percentages, respectively

of 20–39 years, the proportion of interruption was as high as 16.8%. Even 6.7% of the adolescents and 8.3% of elderly people interrupted treatment. Kumar *et al.*<sup>[9]</sup> found that noncompliance was maximum in age group of 35–44 years and was minimum in age group 15–24 years. Pandit *et al.*<sup>[10]</sup> and Sukumaran *et al.*<sup>[11]</sup> observed in their study that majority of the patient (85%) were in the age group of 15–55 years. These findings underline necessity to design age-specific measures to deal with interruption.

This present study revealed that interruption was significantly higher among females (19.7%) than male (9.8%) patients. The association of gender with treatment interruption was statistically significant. Kumar *et al.*<sup>[9]</sup> revealed in their study that noncompliance was equally prevalent amongst male and female, wherein it was 10.4% and 11%, respectively. A study conducted in Meru, Kenya, found that more males interrupted treatment and cited forgetfulness as the commonest reason for treatment interruption.<sup>[12]</sup> The higher social interaction outside home by males, social isolation associated with TB, alcoholism, and other related behaviors among males might contribute to their higher default rates. But this study revealed not only males, females were vulnerable for treatment interruption and even more than males.

This study showed 14.4% of Hindu patients interrupted treatment, while the proportion was only 3.4% among Muslim patients. This association between religion and treatment interruption was also statistically significant in this study. On the other hand, Kumar *et al.*<sup>[9]</sup> found noncompliance was higher (14.4%) among Muslims. This result suggested that might be the so-called religious beliefs/constraints were overcome in this area of present study. Policy makers may involve religious leaders in counseling and motivation of the patients for successful treatment completion.

The present study showed that 26.8% of the study subjects with substance abuse interrupted their treatment. On the contrary, none of the patients without substance abuse interrupted in their course of treatment. So, the association was statistically significant. Kumar *et al.*<sup>[9]</sup> revealed in their study that

noncompliance was more prevalent among smokers (11.5%). Gopi *et al.*<sup>[7]</sup> observed that defaulter rate was higher among smokers. Kumar *et al.*<sup>[9]</sup> and Jaggarajamma *et al.*<sup>[13]</sup> revealed in their study that noncompliance was more prevalent among alcoholics, 23.9% and 21%, respectively. So, substance abuse is a major hindrance to treatment interruption.

This study showed 21.4% of the study subjects who were illiterate interrupted treatment, though it is not statistically significant. Patients who are educated also interrupted during their course of treatment. Gopi *et al.*<sup>[7]</sup> found 39% illiterate, Chadha *et al.*<sup>[14]</sup> revealed in their study 39% were illiterate and just 3% college educated. Other factors identified in a study conducted in South Sudan were long distance to the health facility, stigma from the society, high cost of transportation, traditional beliefs as well as rural residency.<sup>[15]</sup> The role of family physician is most important as he can suggest the most appropriate intervention considering the sociodemographic characteristics of the family.

### Outcome of treatment and its determinants [Table 2]

In this study, cured and treatment completed were taken as “favorable outcome” and died, failure, lost to follow-up, and not evaluated were considered as “unfavorable outcome.” The proportion of favorable and unfavorable outcome in this study was 94.9% and 5.1%, respectively. The major objective of RNTCP was to achieve overall 85% cure rate of smear-positive pulmonary tuberculosis patients. In this reference period of study, though overall, favorable outcome was over 90%. It is one of success stories of the program.

On the contrary, Vasankari *et al.*<sup>[16]</sup> found in Finland that favorable outcome was achieved in 70.1% cases, consisting of those cured (31.65%) and treatment completed (38.5%). There was no treatment failure, 5.1% were defaulted, and death was outcome in 17.2% cases. A study in Thailand showed that favorable outcome was achieved in 70% cases, consisting of about 30% cured and 40% treatment completed. No patients were treatment failure.

**Table 2: Determinants and their impact on treatment outcome**

Variables	Treatment outcomes			Chi-square value	df	P
	Favorable	Unfavorable	Total			
Age of the study subjects (in years)						
10-19	100 (100)	0 (0)	15 (100)	2.448	3	0.485
20-39	116 (92.8)	9 (7.2)	125 (100)			
40-59	103 (96.3)	4 (3.7)	107 (100)			
≥60	46 (95.8)	2 (4.2)	48 (100)			
Gender of the study subjects				0.304	1	0.581
Female	66 (93)	5 (7)	71 (100)			
Male	214 (95.5)	10 (4.5)	224 (100)			
Religion of the study subjects				0.988	1	0.320
Hindu	222 (94.1)	14 (5.9)	236 (100)			
Muslim	58 (98.3)	1 (1.7)	59 (100)			
Category of treatment				0.047 (Continuity correction)	1	0.826
Cat I	257 (95.2)	13 (4.8)	270 (100)			
Cat II	23 (92)	2 (8)	25 (100)			

Figures in parentheses indicate row percentages, respectively. None of the sociodemographic variables are found to be significant with treatment outcome

Five percent cases were defaulted or transferred out. Treatment was stopped prematurely by the physician in 8% cases. Death was the outcome in 17% cases.<sup>[17]</sup>

Sociodemographic and clinicotherapeutic variables like age, gender, religion, category of treatment, etc., were not found to be significantly associated with treatment outcome. Focused counseling by the treating physician considering the determinants of outcome may increase the share of successful outcome in this program. A study in Pondicherry by Veerakumar *et al.*<sup>[18]</sup> found that age, literacy, male gender, alcoholism, smoking, and category of pulmonary tuberculosis patients' treatment were the factors affecting pulmonary tuberculosis (PTB) treatment outcome. A study in northwest Ethiopia revealed the odds of successful treatment outcome were higher among patients above 45 years of age and lower among females, rural residents, and negative smear result at the second month of treatment as compared to their counterparts.<sup>[8]</sup>

### Effect of interruption and treatment outcome [Table 3]

The present study showed out of total 36 patients with interruption, 11 (30.6%) had unfavorable outcome, i.e., died, relapse, failure, and transfer out. On the contrary, only 1.5% of patients without interruption had unfavorable outcome. This association between interruption and treatment outcome was found to be statistically significant in the study. It clearly suggests that treatment interruption has an impact on treatment outcome. However, Dave *et al.* found no significant difference in proportion of treatment interrupters and non-interrupters across demographic variables except for a higher proportion of treatment interruption in patients enrolled from urban district. They found, out of 657 subjects, 71 (10.85%) had relapse of TB. Another 39 (5.9%) patients died due to TB.<sup>[4]</sup>

It was also observed that duration of treatment interruption was also statistically significant with treatment interruption. A percentage of 84.6 of the study subjects with interruption less than 1 week had favorable outcome. But in patients with longer duration of interruption ( $\geq 2$  weeks), only 12.5% had favorable outcome.

Thus not only interruption, duration of interruption was found to adversely affect the treatment outcome. Longer the duration of

interruption, more likely to have unfavorable treatment outcome. Accordingly program implementers need to plan and direct all necessary measures right from the beginning of treatment to address the issues.

## Conclusion

Gender, religion, and substance abuse were found in this study to have impact on treatment interruption. Specific strategy targeting risk factors may be employed by dedicated trained staff to avoid interruption. Sociodemographic and clinicotherapeutic variables were not found to be significantly associated with treatment outcome. Unfavorable outcomes were significantly more frequent among patients with interruption. Not only interruption, duration of interruption was found to adversely affect the treatment outcome. Merely diagnosing tuberculosis is not a guarantee for cure, active involvement of treating physician in management process and targeted intervention to neutralize determinants of interruption will result in favorable outcome in the program.

### Limitations

If all patients registered in the reference period irrespective of sputum smear status were included in the study, the pattern of interruption would have been more evident. In the longitudinal component of the study, all patients were interviewed at the beginning and again after each treatment interruption, if any. This may have acted as intervention not to interrupt treatment after counseling. The study would have been much better if more TUs were included in the study in different setting like rural and urban.

### Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

**Table 3: Impact of treatment interruption on treatment outcome**

Variables	Treatment outcomes			Chi-square value	df	P
	Favorable	Unfavorable	Total			
Treatment interruption						
Interrupted	25 (69.4)	11 (30.6)	36 (100)	55.119	1	0.000
Uninterrupted	255 (98.5)	4 (1.5)	259 (100)			
Duration of interruption						
<1 week	11 (84.6)	2 (15.4)	13 (100)	15.345	2	0.000
1-2 weeks	13 (86.7)	2 (13.3)	15 (100)			
$\geq 2$ weeks	1 (12.5)	7 (87.5)	8 (100)			

Figures in parentheses indicate row percentages, respectively. Not only interruption, duration of interruption was found to be adversely affecting the treatment outcome

## Conflicts of interest

There are no conflicts of interest.

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