# A cross-sectional study of extent and causes of interruption of treatment of tuberculosis in a tuberculosis unit of Purba Bardhaman district of West Bengal, India



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# ABSTRACT

Background: Tuberculosis (TB) is a communicable disease which requires prolonged treatment and having both medical and social dimensions. Adherence to treatment is very important issue in successful treatment of TB. Directly observed therapy was a key strategy in The Revised National TB Control Program. However, treatment interruption is very common. Aims and Objectives: The objective of this study is to assess the nature, extent, and reasons for interruption of treatment in Bhatar TB Unit (TU) of Purba Bardhaman district of West Bengal. Materials and Methods: The study was a descriptive and crosssectional study with two components. The study was conducted in the area covered under Bhatar TU of Burdwan district of West Bengal. Complete enumeration technique was followed in the study. In the first component of the study, 231 study subjects were found by complete enumeration, out of which 26 were discarded due to incomplete records. In the other component, 90 study subjects were interviewed at the beginning of treatment and after treatment interruption, if any. Data were analyzed using RStudio. Results: Out of the group with only record review, 205 subjects were included in the study, out of which 160 (78.05%) were male and 45 (21.95%) were female. In the other group with both record review and interview, out of 90 subjects, 64 (71.1%) were male and 26 (28.9%) were female. Out of 295 cases, 270 (91.5%) were new and 25 (8.5%) were previously treated. Out of 295 subjects, 36 (12.2%) had interrupted treatment. Seven persons out of 36 had interrupted more than once. Thirty-four persons had interrupted in intensive phase of treatment. Thirty-two persons had taken 10-20 days before interruption of treatment. The most common reason for interruption of treatment was "Not willing to take tablets." Among the other reasons were "Side effects," "Hospitalization," "Away from home," etc. Conclusion: Non-compliance to anti-tubercular drugs remains an important issue in the elimination of TB.

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Key words: Tuberculosis; Interruption; Compliance

# INTRODUCTION

Tuberculosis (TB) is a communicable disease which requires prolonged treatment. TB, have both medical and social dimensions. "It creates multiple burdens for patients, including the necessity to deal with pain, suffering,

and reduced quality of life, premature mortality, financial costs, and familial emotional trauma." Globally, in 2012, an estimated 8.6 million developed TB and 1.3 million died of it. About 1.1 million (13%) of the total TB cases were HIV-positive. "About 3.6% of newly diagnosed TB cases and 20% of previously treated TB cases had MDR-

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TB."<sup>2</sup> "TB remains the leading infectious cause of death in India. 1.9 million cases occur annually and 0.8 million have sputum positive pulmonary TB."<sup>2</sup>

Adherence to treatment is very important issue in successful treatment of TB. Directly observed therapy (DOT) was a key strategy in The Revised National TB Control Programme (RNTCP). Yet, treatment interruption is very common. Though limited, but evidence is available regarding the extent of interruption and its determinants. "In a study done by Dave et al., it was observed that the average number of doses missed during intensive phase and continuation phase was 7.5 and 11.9 respectively." Out of those, who had interrupted treatment, 29.1% of patients had interrupted treatment in intensive phase, 25.2% of patients had interrupted treatment in continuation phase and 45.7% of patients interrupted their treatment in both phases of treatment. 3 Another study conducted in Russia by Jakubowiak et al., found proportion of interruption to be 36% in intensive phase and 45% in continuation phase.<sup>4</sup>

Success of treatment in TB is largely declared based on completeness and bacteriological conversion (smear microscopy based). Treatment interruption is not considered in the definition for successful treatment (cured and treatment completed). Although it is known those missing one or more doses in Intensive Period (IP), particularly after twelfth dose is a risk factor for default.<sup>5</sup> Moreover, there remains a risk of increased relapse even after initial conversion. However, in practice, once patient is declared as cured or treatment complete (successfully treated), they are not followed up under the program unless they come to health system again with symptoms. Relapse is considered to be an important measure of efficacy of any treatment regimen. Hence, measuring treatment interruptions and correlating it with the long-term outcome of patient is useful information for finding out reasons behind relapse and other adverse outcome.<sup>6</sup> Chatterjee et al., conducted a study among TB patients registered in four different kinds of health institutions in Jamshedpur, Bihar, Purulia, West Bengal, and Roing, Arunachal Pradesh. They find that average default rate in four institutions was 27.19%. The percentage of defaulter significantly increased with age distribution and was maximum in the 45–59 years of age and declined thereafter. Proportion of defaulters decreased uniformly with increasing educational status, the difference being significant.7

#### Aims and objectives

The present study aims to assess the nature and the extent of interruption of treatment in Bhatar TB Unit (TU) of Purba Bardhaman (erstwhile Burdwan) District in West Bengal. This study also dealt with reasons of such interruption.

# **MATERIALS AND METHODS**

The study was a descriptive and cross-sectional study. The study was conducted in the area covered under Bhatar TU of Burdwan district of West Bengal. Bhatar TU was selected as it is the RHU&TC of Burdwan Medical College. Bhatar TU consists of two Block Primary Health Centres Bhatar and Monteswar having a total population of 4, 77, 656 as per census 2011.

## Sampling and sample size

Complete enumeration technique rather than sampling was followed in the study. As previously decided, all the persons fulfilling the inclusion and exclusion criteria were included in the study. Thus, sample size was calculated by complete enumeration. In the cross-sectional (retrospective) component of the study, that is, from January 2014 to March 2015, 231 study subjects were found by complete enumeration. However, 26 patients were not included for final analysis because of incomplete records. The other component extended from April 2015 to September 2015. During this period, 90 study subjects were interviewed at the beginning of treatment and after the treatment interruption, if any, apart from data collection and compilation. Study period was also from April 2015 to September 2015. Smear positive pulmonary TB patients were taken as study subjects in both the components of study.

# **Data collection**

Data were collected in a pre-designed and pre-tested schedule by review of relevant records and registers, such as 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 interruption, number of missed doses, number of doses taken before interruption, and frequency of treatment interruption were taken as variables in retrospective components. Additional variables such as educational status, socioeconomic status, substance abuse, and reasons of interruption were included in the prospective component. Modified B. G. Prasad's scale based on All India Consumer Price Index in January 2015 was considered to categorize socioeconomic status. Standard RNTCP definitions were used to define RNTCP-related variables such as type of patient and outcome of treatment.

## Statistical analysis

Data were checked for completeness and consistency; coded; and entered into MS-Excel spreadsheet. Data were analyzed using principles of descriptive statistics. Being a descriptive type of study with complete enumeration, data were analyzed by percentages and proportion in both the components of the study.

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**

This study was undertaken among smear positive pulmonary TB patients registered under RNTCP in seven quarters from January 2014 to September 2015. In first five quarters, data were collected retrospectively by review of records (Group 1). In next two quarters, data were collected by record review as well as by interview (Group 2). Hence, there were two groups –Group 1 (Group only with record review) and Group 2 (Group with record review and interview). Altogether 321 eligible subjects were studied. However, 26 patients were not included for final analysis because of incomplete records. In the Group 1, 205 subjects were included, out of which 160 (78.05%) were male and 45 (21.95%) were female. In the Group 2, out of 90 subjects, 64 (71.1%) were male and 26 (28.9%) were female. Some of the basic descriptions are in Table 1.

These patients include both new cases as well as previously treated cases, which have been depicted in Table 2.

Out of 295 subjects, 36 (12.2%) had interrupted treatment (Table 3).

Twenty-nine persons out of 36 had interrupted once and seven persons had interrupted more than once. Thirty-four persons had interrupted in intensive phase of treatment. Thirty-two persons had taken 10–20 days before interruption of treatment (Table 4).

The most common reason for interruption of treatment was "Not willing to take tablets." About 47.5% of the interrupted subjects cited this reason for their interruption of treatment. Among the other reasons, were "Side effects," "Hospitalization," "Away from home," etc (Table 5).

# **DISCUSSION**

In this study, majority (28.5%) of study subjects were 20–29 years old which is economically productive group of our society. This may be due to this age group that is more vulnerable to social and occupational exposures. It is also observed that even 5.1% of the study subjects were adolescents. Chadha and Bhagi revealed in their study, 58.8% were in the age group of 21–40 years.<sup>8</sup> Median age of the subjects in the present study was

Variables	Study subjects		Total
	Group 1 (n <sub>1</sub> =205) No (%)	Group 2 (n <sub>2</sub> =90) No (%)	
10–19	5 (2.4)	10 (11.1)	15 (5.1)
20–29	68 (33.2)	16 (17.8)	84 (28.5)
≥30	132 (64.4)	64 (71.1)	196 (66.4)
Gender	,	,	, ,
Male	160 (78)	64 (71.1)	224 (76)
Female	45 (22)	26 (28.9)	71 (24)
Occupation	- (	- ( /	( /
Laborer	141 (68.8)	50 (55.6)	191 (64.7)
In business	38 (18.5)	16 (17.8)	54 (18.4)
In service	14 (6.8)	4 (4.4)	18 (6.1)
Others	12 (59)	20 (22.2)	32 (10.8)
Educational status	( /	,	,
Illiterate		28 (31.1)	28 (31.1)
Primary (Class I–IV)		10 (11.1)	10 (11.1)
High school (Class V–VIII)		44 (48.9)	44 (48.9)
Secondary (Class IX–X)		06 (6.7)	06 (6.7)
Higher secondary and above		02 (2.2)	02 (2.2)
Socio-economic status		- ( )	- ( )
Class-I , II and III (more than Rs. 1738)		9 (9.9)	9 (9.9)
Class-IV (Rs. 870–1738)		33 (36.8)	33 (36.8)
Class-V (below Rs. 870)		48 (53.3)	48 (53.3)
Substance abuse		(5515)	(*****)
No		49 (54.4)	49 (54.4)
Smokeless tobacco		07 (7.8)	07 (7.8)
Smoking		23 (25.6)	23 (25.6)
Alcohol		11 (12.2)	11 (12.2)

Table 2: Distribution of study subjects according to type of cases Variables Total (n=295) Study subjects Group 1 (n<sub>1</sub>=205) Group 2 (n,=90) No. (%) No. (%) Types of patients 186 (90.7) 84 (93.3) New 270 (91.5) 6 (6.7) 25 (8.5) Previously treated 19 (9.3)

Figures in parentheses indicate column percentages, respectively

Table 3: Distribution of study subjects according to treatment interruption

Variables	Study subjects		Total
	Group 1 (n <sub>1</sub> =205)	Group 2 (n <sub>2</sub> =90)	(n=295)
	No. (%)	No. (%)	_
Interruption status			
Interrupted	25 (12.1)	11 (12.2)	36 (12.2)
Non-interrupted	180 (87.9)	79 (87.8)	259 (87.8)

Figures in parentheses indicate column percentages respectively

Table 4: Distribution of subjects with interrupted treatment according to nature and extent of treatment interruption

Variables	Study subjects		Total
	Group 1 (n <sub>3</sub> =25)	Group 2 (n <sub>4</sub> =11)	(n <sub>5</sub> =36)
	No. (%)	No. (%)	
Frequency of interruption			
Once	20 (80)	9 (81.8)	29 (80.6)
More than one	5 (20)	2 (18.2)	7 (19.4)
Phase of interruption			
Intensive phase	23 (92)	11 (100)	34 (94.4)
Continuation phase	2 (8)	0 (0)	2 (5.6)
No of missed doses			
1	2 (8)	2 (18.2)	4 (11.1)
2–5	11 (44)	8 (72.7)	19 (52.7)
6–11	2 (8)	0 (0)	2 (5.6)
≥12	10 (40)	1 (9.1)	11 (30.6)
No of doses taken before			
interruption			
2–10	0 (0)	2 (18.2)	2 (5.6)
10–20	23 (92)	9 (81.8)	32 (88.8)
20–40	0 (0)	0 (0)	0 (0)
≥40	2 (8)	0 (0)	2 (5.6)
Duration of interruption			
<1 week	3 (12)	8 (72.7)	11 (30.6)
1–2	11 (44)	2 (18.2)	13 (36.1)
2–3	1 (4)	0 (0)	1 (2.8)
≥4	10 (40)	1 (9.1)	11 (30.6)

Figures in parentheses indicate column percentages, respectively

40 years.<sup>8</sup> However, Vasankari et al., observed in Finland, the median age is 67.2 years which was much higher than our study.<sup>9</sup>

In this study, 76% of the study subjects were male and rest were females. Pandit and Choudhary, <sup>10</sup> Jaggarajamma et al., <sup>11</sup> in their study reported 63% and 69%, of the patients

Table 5: Reasons for interruption of treatment among the interrupted

Reasons of interruption*	Study subjects		Total
	Group 1 (n <sub>3</sub> =25)	Group 2 (n <sub>4</sub> =11)	(n <sub>5</sub> =36)
	No. (%)	No. (%)	No (%)
Side effects	4 (16)	1 (9.1)	5 (12.5)
Hospitalization	3 (12)	1 (9.1)	4 (10)
Away from home	3 (12)	8 (72.7)	11 (27.5)
Not willing to take tablets	16 (64)	3 (27.3)	19 (47.5)
Others	1 (4)	0 (0)	1 (2.5)

\*Multiple responses; Figures in parentheses indicate percentages among the groups

as males, respectively, who are usually earning member of family in our society.

By occupation, 64.7% of the study subjects in the present study were laborers. The disease is more prevalent among those engaged in business (18.4) than those in service (6.1). Pandit and Choudhary<sup>10</sup> found nearly 50% of patients were laborers, few from either business or Government service. Those findings were more or less similar to the present study. The findings of the study once again highlight that substantial proportion of sputum smear positive pulmonary TB cases were laborers. The housing condition, overcrowding, and work place environment may be responsible for this.

In this study, 31.1% of the subjects were illiterate and around half of the subjects (48.9%) were high school educated. Only 2.2% were educated up to higher secondary and above. On the contrary, Pandit and Choudhary<sup>10</sup> found 50% were educated up to primary and 23% were illiterate. Gopi et al., <sup>12</sup> found 39% illiterate, Chadha and Bhagi<sup>8</sup> revealed in their study 39% were illiterate and just 3% college educated. It is evident that around one third of sputum positive pulmonary TB patients were illiterate in most of the studies.

The present study showed that majority of study subjects belonged to lower economic status of Class-IV (36.8%) and Class-V (53.3%) as per B G Prasad classification. Only 9.9% of the study subjects belonged to upper socioeconomic status. Pandit and Choudhary<sup>10</sup> found nearly 81% of patients were from lower socioeconomic class of IV and

V, as per B G Prasad classification. Sukumaran et al., <sup>13</sup> and Chadha and Bhagi<sup>8</sup> observed in their studies all patients (100%) and 82% were from the lower socioeconomic stratum, respectively. Hence, low socioeconomic status was identified as one of the consistent characteristics of TB in all the studies in the present one.

The study depict 52.2% study subjects did not have any substance abuse. Smoking (25.6%) is the most common form of substance abuse. On the other hand, alcoholism was observed in 12.2% cases. Gopi et al., 12 observed 41% smokers and 31% alcoholics.

DOT is most important strategy in RNTCP and being implemented throughout the country. Dedicated staff is also available for treatment supervision at level of TU. Still interruption to an extent may occur but, specific measures are suggested in program guidelines for retrieval action. In spite of this, overall 12.2% of total study subjects interrupted treatment during their course of treatment. However, Dave et al., observed 49.6% of patients interrupted treatment during course of therapy in their study. Kandel et al., <sup>14</sup> found 47.5% treatment interruption in their study. These findings were much higher than the present study.

Further analysis revealed, 94.4% of patients interrupted their treatment in the intensive phase and even 5.6% of the study subjects interrupted treatment in the continuation phase. The majority study subjects (88.8%) interrupted treatment after initial 10–20 doses. The study showed that 36.1% study subjects interrupted treatment only for 1–2 weeks. These results suggested that the patient was not enough motivated about the adherence of treatment.

However, in other studies by Dave et al.,3 and Jakubowiak et al.,4 much lower proportion in intensive phase and higher proportion in continuation phase were noted. Dave et al., showed out of those who had interrupted treatment, 95 (29.1%) patients had interrupted treatment in intensive phase, 82 (25.2%) patients had interrupted treatment in continuation phase, and 149 (45.7%) patients interrupted their treatment in both phases of treatment. In the same study, they also found that the average number of doses missed during intensive phase and continuation phase was 7.5 and 11.9, respectively. Average duration of any interruption during treatment was 6.5 days. In this study, also majority (66.7%) of the treatment interruption was <2 weeks. This result showed that measures were taken to retrieve the patients, so the duration of treatment interruption was short. Another study conducted in Russia by Jakubowiak et al., 4 found proportion of interruption to be 36% in intensive phase and 45% in continuation phase. The present study showed that 19.4% of the study subjects had multiple episodes of interruption during their course of treatment indicating lack of monitoring and supervision by health personnel. Each patient should be counseled at the beginning as well as after each episode of interruption to bring back to treatment. A study conducted by Gupta and Behera found multiple treatment interruptions were common. Same study also revealed maximum interruptions by 3<sup>rd</sup> month of anti-tubercular treatment.<sup>6</sup> A study by Chandrasekaran found among the defaulters, half defaulted during the first 2 months and another one-third during the extension period of treatment in the intensive phase.<sup>15</sup>

The present study showed that away from home (27.5%) and not willing to take medicine (47.5%) were two most important cited reasons for interruption. Both the issues should have been taken care of by supervisors, especially after the introduction of ASHA workers, as they are from the same locality. About 10% of the study subjects interrupted because of hospitalization due to other reasons. Special attention should be taken by care givers to address this issue. It also emphasizes to develop an online portal to include details of treatment and whereabouts of all registered patients. About 12.5% of the study subjects interrupted because of drug side effects.

On the contrary, a study conducted by Gupta and Behera et al.,<sup>6</sup> found that early improvement and high cost of treatment were found to be the two most common reasons, leading to treatment interruption. They further explained that as interruption frequently occurs at the 3<sup>rd</sup> month of treatment, which coincides with clinical improvement.

Sinha and Tiwari<sup>16</sup> conducted study in District Raipur (Chhattisgarh) in 2006, revealed main reasons for non-compliance were having felt better, due to fear of adverse reactions. The third most common cause of non-compliance was found to be being moved away from the treatment center. Other reasons for non-compliance were difficult to find time from work to visit the center, difficulty to take so many pills, and non-availability of medicine.

Mittal and Gupta<sup>17</sup> found that non-compliance was found to be mainly due to side effects of medicines, lack of awareness, and symptomatic relief/no relief for long time. They further found initial counseling by the health personnel explaining the treatment plan before initiating the treatment, periodic motivation of the patients, and prompt action to tackle any problem will surely enhance compliance. Similarly, necessity of counseling is highlighted by this study.

## Limitations of the study

If all patients irrespective of smear status were included in the study, the pattern of interruption in whole TU would have been more evident. In the prospective component, all patients were interviewed at the beginning and again after each treatment interruption. This may acted as intervention not to interrupt treatment after counselling. The study would have been much better if more than 1 TU were included in different settings like rural, urban.

## CONCLUSION

The disease more commonly affecting males than females and the most commonly affected age group being the productive period of 20–29 years. Social and occupational exposures may be responsible for this finding. In spite of directly observed treatment, interruption is quite prevalent among one tenth of total study subjects. Even multiple episodes of interruption (19.4%) were found. Counseling by trained staff before starting treatment should be incorporated in program. Majority of the patients (52.7%) missed 2–5 doses and 11.1% of the study subjects missed only one dose. Reasons for interruptions among the subjects in the area reported to be multiple-being away from home (27.5%), unwillingness to take medicine (47.5%) were most common.

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## **Authors' Contributions:**

CN- Concept and interpretation of study, data analysis, prepare first draft copy of article; KM- Reviewed the literature, manuscripts preparation; DB- Preparation and review of manuscripts; KM- Statistical analysis, coordination, reviewed manuscripts.

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