

## **A Study on Complaine Pattern of Tuberculosis Patients Under DOTS in A District of West Bengal**

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Sukamal Bisoi<sup>1</sup>, Dibakar Haldar<sup>2</sup>, Dipankar Chatterjee<sup>3</sup>, Gautam Dhar<sup>4</sup>,  
Samir Kumar Ray<sup>5</sup>, Abhik Sinha<sup>6</sup>,

<sup>1</sup>MD(Associate Professor, Dept. of Com. Med, RG Kar Medical College, Kolkata)

<sup>2</sup>MD.(Associate Professor, Dept. of Com. Med, RG Kar Medical College, Kolkata)

<sup>3</sup>MD.(Associate Professor, Dept. of Com. Med, College of Medicine, Sagar Dutta  
& Kamarhati Hospital)

<sup>4</sup>MD.(ADME, Associate Professor, Dept. of H& FW, Govt of West Bengal)

<sup>5</sup>MD(Associate Professor, Dept. of Com. Med, Murshidabad Medical

College) <sup>6</sup>MD. (Assistant Professor, Dept. of Com. Med, RG Kar Medical College,  
Kolkata)

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### Corresponding Author:

Sukamal Bisoi, MD,  
(Associate Professor, Dept. of Com. Med,  
RG Kar Medical College, Kolkata.  
Phone-9477143421,  
email-bisoisukamal@yahoo.in)

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#### Abstract

**Background:** DOTS is a comprehensive strategy for tuberculosis control based largely on Indian research and it now recognized worldwide. Still non-compliance to DOTS remains a major public health challenge. **Aims:** To know the compliance of DOTS therapy in tuberculosis patients in Howrah district of West Bengal and to find out the factors responsible for non-compliance. **Methods:** A community based cross-sectional study was undertaken to determine socio-demographic and treatment related risk factors in relation to non-compliance of patients under DOTS in Howrah district of West Bengal. Altogether 141 patients registered in 2nd quarter (1st April to 30th June 2007) in Domjure TU were interviewed by home visit after their completion of intensive phase of treatment. **Results:** 63.8% patients were compliant with treatment. Non-compliance was significantly higher among 25-54 years age group (51.4%) and in male (46%) patients. Literate patients, patients of upper and lower middle socio-economic class and those were actually supervised during swallowing of drugs were found more compliant with the treatment. **Conclusion:** Proper supervision of DOT providers with adequate counseling of patients and their close relatives might help to treatment compliance.

#### INTRODUCTION

Despite the existence of National Tuberculosis Programme since 1962, tuberculosis remains the leading infectious cause of death in India. Noncompliance

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has been one of the major obstacles to treatment management and an important challenge for tuberculosis control<sup>1</sup>.

Directly observed treatment short course (DOTS) under RNTCP is a comprehensive strategy for TB control, based largely on Indian research and it is now recognized world wide. DOTS is the only strategy which has proved to be effective in controlling TB on mass scale. DOTS ensure that patients take the medicines regularly as per directions<sup>2</sup>. The major thrust of RNTCP is achieving a cure rate of at least 85%<sup>3</sup>. Strict adherence to directly observed treatment is likely to improve patient compliance which remains a persistent and significant problem faced by health professionals. RNTCP being a switched over programme from the previous NTCP, more and more operational researches are needed to know whether it is heading towards the right direction as far as pace and quality of implementation is concerned. Keeping the abovementioned facts in view the current study was undertaken to determine socio-demographic and treatment related risk factors in relation to non-compliance of patients receiving DOTS in Howrah district of West Bengal.

### **MATERIAL & METHODS**

The present community based cross-sectional study was undertaken in Domjure tuberculosis unit of Howrah district of West Bengal for a period from July 2007 to December 2007. Service delivery for RNTCP in the district was actually started in later part of March 1999. The tuberculosis unit consisted of two blocks

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(Domjure & Bally- Jagacha) with a total of 10 treatment centres, 6 microscopy centres and 84 DOTS centres. Treatment centrewise names and personal details of patients were obtained from the Treatment Register available at TU. All the 157 patients registered for treatment in the 2nd quarter i.e. from 1st April to 30th June 2007 were taken into account for study. From the records of treatment centres it was observed out of 157 patients 3 died before interview started, 4 hospitalised after initiation of treatment, 5 migrated to other areas and 4 were not found at home even after 3 total visits. Thus altogether 141 patients were selected for the study and were interviewed by home visits with the help of a pre-designed and pre- tested schedule covering information on their socio-demographic profile, distance of DOTS centre and possible drug reactions. For patients below 10 years mothers or other responsible family members were allowed to responding the interview. To determine socio-economic class inflation rate adjusted Modified Kuppuswamy's scale was used. According to norms of RNTCP all the doses of intensive phase of treatment and in continuation phase one weekly dose must be swallowed under direct supervision of DOTS provider. In this study 'Nonsupervised' label has been attributed to those patients who had taken anti-tubercular medicines at least two doses in a week in the intensive phase of treatment without direct supervision of the DOTS provider and 'All supervised' who had taken all the doses under direct supervision. Missing  $\geq 2$  consecutive weeks of DOTS was taken as 'Noncompliance'<sup>4,5</sup>. The collected data were analyzed using standard statistical tests.

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#### **RESULTS**

The study revealed that out of 141 patients studied 90 (63.8%) were compliant to DOTS. In table 1, male preponderance (63%) was observed regarding gender distribution of tuberculosis patients under study. Among 89 males most (23.6%) of the patients were in the age group of 35-44 years followed by 15-24 years (22.5%). In females mostly (42.3%) were in the age group of 15-24 years. 5.7% of the total patients were found be up to 14 years(children) and 5%  $\geq 65$  years age group (old age). It was evident from Table 1 that females were significantly more compliant to DOTS than males ( $p < 0.001$ ) and compliance rate was significantly lower ( $p < 0.05$ ) among 25-54 years age groups than the age groups above or below it. Considering the occupation, 18.2% of study subjects were unskilled workers, 18.9% semiskilled (only one female) and 10.9% were skilled (all male). 12.2% were involved in other occupations like clerk/shopkeeper/farm owner etc. Among males 9.2% were unemployed and among females almost all (92%) were homemakers. Regarding caste distribution out of 141 study subjects 98 (69.6%) were general category and 43(30.4%) were reserved category (25.5% SC, 4.2% OBC and 0.7% ST). No significant difference was observed with caste differences ( $p > 0.05$ ).

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**Table 1. Distribution of compliance pattern of tuberculosis patients (N=141)**

Patient's factor	Compliant		Noncompliant		X <sup>2</sup>	d.f	p-value
	No.	%	No.	%			
<b>Age group (years)</b>					18.13	2	<0.05
<25	43	86	7	14			
25-54	36	48.6	38	51.4			
≥55	11	64.7	6	35.3			
<b>Gender</b>					10.21	1	<0.01
Male	48	53.9	41	46.1			
Female	42	80.8	10	19.2			
<b>Caste</b>					3.23	1	>0.05
General	60	61.2	38	38.8			
Reserved	30	69.8	13	30.2			
<b>Literacy status(n=138*)</b>					10.006	2	<0.01
Illiterate	15	41.7	21	58.3			
Just Literate	19	65.5	10	34.5			
Literate	23	72.6	20	27.4			
<b>Socio-economic status</b>					6.22	1	<0.05

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Upper	1	100	0	0			
Upper midle	6	75	2	25			
Lower middle	26	78.8	7	21.2			
Upper lower	55	59.1	38	40.9			
Lower	2	33.3	4	66.7			
<b>Distance of DOTS center</b>					2.2	1	>0.05
<1 km	47	70.1	20	29.9			
≥1 km.	43	58.1	31	41.9			
<b>Drug reaction</b>					1.12	1	>0.05
Present	40	69.01	18	31.0			
Absent	50	60.2	33	39.8			
<b>Addiction</b>					0.027	1	>0.05
Present	39	66.1	20	33.9			
Absent	51	62.2	31	37.8			
<b>Supervision stsus by DOTS provider</b>					9.61	1	<0.05
All supervised	51	77.33	15	22.7			
Non-supervised	39	52.0	36	48.0			

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Regarding literacy status 36 (26.1%) tuberculosis patients were illiterate, 29 (21%) just literate and 73 (52.9%) in the literate group. Three patients were below the age of 7 years and hence not considered for literacy status. It was found that literate persons were more compliant (72.6%) than illiterates (41.7%) and just literates(65.5%) and this difference was statistically significant ( $p < 0.001$ ).

66% of patients were in upper-lower socioeconomic class. The upper and lower middle socioeconomic group showed better compliance than upper-lower and lower class and this difference was found statistically significant ( $p < 0.05$ ).

74 (52.5%) out of 141 patients had to cover a distance of more than one kilometer to attend DOTS centre for ingestion of medicines. However, there was no significant difference ( $p > 0.05$ ) in compliance with distance was observed in the study.



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**Table 2. Reaction to drugs (N= 141)**

Reaction	Male (n <sub>1</sub> =89)		Female (n <sub>2</sub> =52)		Total (n=141)	
	No.	%	No.	%	No.	%
No reaction	58	65.2	25	48.1	83	58.9
Drowsiness	9	10.1	8	15.4	17	12.1
Red / Oange urine	21	23.6	13	25.0	34	24.1
Gastrointestinal upset	13	14.6	6	11.5	19	13.5
Burning sensation in hand and feet	5	5.6	4	7.7	9	6.4
Joint pain	2	2.2	3	5.8	5	3.6
Ringing in ears	2	2.2	-		2	1.4
Dizziness and loss of balance	6	6.7	8	15.4	14	9.9
No response	6	6.7	2	3.8	8	5.7

From table 2 it was revealed that after taking the drugs of intensive phase one or more drug reactions were observed among 58 (41.13%) out of 141 patients. The predominant reactions were passage of red or orange urine (24.1%), G.I. upset (13.5%), burning sensation in hands and feet (6.4%) and joint pain (3.6%). There was no significant difference of complaine pattern was observed among those who developed drug reactions and those who did not ( $p>0.05$ ).

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The present study revealed the addiction status of 141 TB patients out of which 59 had some addictions (smoking, alcohol, chewing tobacco etc.). 41(29.1%) were smoker and 12 (8.5%) were habituated to alcohol. A total number of 82(58.1%) patients had no addiction at all. Multiple addictions were present in 18 patients. However statistically no significant difference in treatment compliance was observed in this study among those who were addicted to some substances and those who were not ( $p>0.05$ ). It was observed from the present study that out of 141 patients 66 (46.8%) were actually supervised for all doses (All supervised) and 75 (53.2%) were allowed to self-intake at least two doses at their home without direct supervision by the DOTS provider. Those who had taken 'All-supervised' doses were found significantly more compliant to treatment than 'Non-supervised' in takers ( $p>0.05$ ).

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**Table 3. Reasons of non-compliance (n= 51)**

Reasons	Male (n <sub>1</sub> =41)		Femle (n <sub>2</sub> =10)		Total (n=51)	
	No.	%	No.	%	No.	%
Family problem	4	9.75	3	30	7	13.72
Long distance of DOTS centre	5	12.2	3	30	8	15.59
Lack of Time	5	12.2	3	30	8	15.59
Daily wage loss	8	19.51	0		8	15.59
Illness	6	14.63	2	20	8	15.59
Bad behaviour of the staff	2	4.47	1	10	3	5.88
Abdominal discomfort after swallowing medicine	6	14.63	1	10	7	13.72
Lack of water supply in DOTS centre	4	9.75	1	10	5	9.8
Lack of space in DOTS centre	1	4.88	0		1	1.96
Lack of awarenes	8	19.51	1	10	9	17.64
Drug reaction	10	24.4	5	50	15	29.4
Not responded	5	12.2	2	20	7	13.72

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From Table 3 it was revealed that most of the noncompliant patients were not taken treatment due to development of drug reaction (29.4%) in their intensive phase of treatment followed by long distance to travel to attend DOTS clinic(15.69%), lack of time (15.69%), daily wage loss(15.69%) and physical illness(15.69%). 9.8% stated lack of water supply in DOTS centre and 5.88% bad behavior of the staff as the reasons of noncompliance and 13.62% showed non-response regarding this matter.

### **DISCUSSION**

Failure to comply with appropriate anti TB chemotherapy is the most serious remaining barrier to the control of TB. Much has been studied about compliance till date. In those patients who defaulted from treatment were assumed to be 'defective and faulty' in behaviour and the studies were directed to detection of these faults and their causes<sup>6</sup>. Overall compliance rate of DOTS in present study (63.8%) was much less than compliance rate found in similar other studies in India and abroad<sup>5,7</sup>. The high noncompliance among the 25-54 years age group in the present study is perhaps due to their more job involvement. Kumar M et al (2002)<sup>5</sup> found that patients falling in 35-44 years were more noncompliant and patients in age group 15-24 years were least. Menzis D et al (1996)<sup>8</sup> found that older subjects were less compliant. Noncompliance to treatment is significantly higher among males (46.1%) than females (19.2%) in this study which is in contrary to study conducted

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by Moore (2001)<sup>9</sup> where noncompliance was more prevalent among female patients. However gender did not affect compliance with treatment and follow up in other studies<sup>5,8</sup>. The high noncompliance of male patients in the present study may be due to constraints of their pre-occupation for daily living. A significant difference ( $p < 0.05$ ) was found over the educational level and compliance pattern as expected that educated people could be better motivated towards adherence to DOTS. Kumar et al (2002)<sup>5</sup> also observed that non-compliance was more among illiterate patients. But educational status did not affect treatment compliance in study conducted by Liam CK et al (1999)<sup>10</sup>. Most of the patients in this study were in upper socio-economic class (66%). Though in the present study upper and lower middle socio-economic groups showed better compliance than upper and lower classes, other studies found compliance to DOTS was more among patients of lower class in comparison to upper class<sup>5,8</sup>.

Side effects with drugs were reported by 73% (fatigue was most common complaints) found in a study by P. Sukumaran<sup>11</sup>. But drug reaction (41.13%) in intensive phase and distance from the DOTS centre did not affect treatment compliance of the patients in this study. Non-compliance was found to be more among alcoholics and drug abusers in different studies<sup>4,5</sup> but in our study no difference was found.

Only 46.8% patients in the present study actually taken 'All-supervised' doses as per RNTCP norm were found more compliant to treatment than those who

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were 'Non-supervised'. This clearly indicates that patients were better motivated to comply with the treatment when they were actually supervised during swallowing of drugs as per norms of DOTS in RNTCP. This high rate of taking non-supervised dose further indicates lack of proper orientation of DOTS providers in RNTCP and inadequate supervision from T.U. level which affected the compliance of tuberculosis patients.

On the basis of above findings it may be concluded that the rate of compliance to DOTS varies with the variation of different socio-demographic characteristics like age, sex, literacy status, socio-economic status of patients, side-effects of drugs, addiction etc. Hence a well structured service, strict adherence to the norms of DOTS in RNTCP through proper supervision of DOTS provider from TU level with adequate counseling and education of patients and their close relatives might help to improve treatment compliance.

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