

**Study the factors related to compliance of tuberculosis treatment in continuation phase**

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**Abstract**

**Background:** In tuberculosis patients, compliance with treatment guidelines is essential to achieve successful outcomes. The present study was undertaken to monitor continuation phase of anti-tuberculosis treatment, its compliance and to analyze factors for non-compliance.

**Method:** A total 247 newly diagnosed sputum positive category-I tuberculosis cases registered in urban tuberculosis unit were enrolled. After applying exclusion criteria, 42 patients were excluded and remaining 205 patients were included in the study and followed for 4 months of continuation phase. Patients were grouped into compliance 162(79%) and non-compliance group 43(20%).

**Results:** Factors related to Directly Observed Treatment (DOT) provider like behavior, enquiry about drug consumption and side effect and home visit by DOT provider were protective regarding treatment compliance, OR<1. The economic factors were protective for those who were residing within 1km distance, travelling by

private vehicle, convenience of DOTS Centre timing and time required for drug collection of <15mins, (OR<1). There were 48 times more risk of patients becoming non-compliant when there is loss of daily wages (OR=48.79). Also, patients non-compliant when they had to spend >5 rupees/day to visit DOTS center. Motivational factors like family member’s observation of patient’s consumption of drugs, on table storage of drugs by patients, patient remembering drug intake on his own, belief of patients in drug treatment and patient knowing number of people on DOTS therapy, were all protective for treatment compliance, OR<1.

**Conclusion:** Non-compliance group patients had to be given extra attention for 1month beside their continuation phase period.

Therefore, impose more time, money and human resources, an extra burden on health services and health care personnel for their treatment compared to usual time taken by compliance group patients.

**Keywords:** Tuberculosis; Compliance; Non-compliance; Continuation phase; Anti-tuberculosis; Directly Observed Treatment

### **Introduction**

Tuberculosis (TB) is the leading cause of mortality as a single infectious agent globally with increasing numbers of case notification in developing countries. In India annually, about 18 lakh new cases of TB occur of which about 8 lakhs are sputum positive infectious cases [1]. TB control measures were initiated in India through National Tuberculosis Control Program (NTCP) since 1962. The objectives of program at that time were early diagnosis and treatment. Three decades later in 1992 Expert Committee set up by Government of India & Swedish International Development Agency (SIDA) revealed that only 30% of existing TB cases were being diagnosed, and of these only 30% were completing treatment [2]. Thus only 9% completed treatment of total cases of TB in the community.

To rectify these lacunae, the Government decided to give a new thrust to TB control activities by revitalizing the NTP, with assistance from international agencies, in 1993. The Revised National TB Control Programme (RNTCP) thus formulated, adopted the internationally recommended Directly Observed Treatment Short-course (DOTS) strategy, as the most systematic and cost-effective approach to revitalize the TB control programme in India [3]. It has covered whole of country in March 2006. RNTCP, achieved its goal of 70% case detection and 85% treatment success among those detected [4]. However, the program has now revised its categorization of patients from the earlier 3 categories (Cat I, Cat II, and Cat III) to 2 categories namely Cat I (Category III was merged into Category I) for new cases and Category II for Previously treated cases based on the

recommendations of NTFMc experts and endorsement by National Task Force for Medical college [4].

Compliance to therapy plays an important role in the outcome of the therapy. Non-compliance is believed to delay sputum conversion to smear negative and help the emergence of most dreaded complication, resistant mutant strains [5-7]. There are 2 phases in Anti-TB treatment, Intensive Phase and Continuation Phase [8]. Continuation phase is crucial with regard to treatment outcome. There has been study demonstrating, overall, 91% of incidences of defaulting from the treatment during continuation phase of treatment [9]. In India default rate among new sputum smear positive cases is 6% [10]. Thus, the non-compliance is very high. Research workers from different countries have found various reasons for non-compliance [5-7]. The present study was undertaken to monitor continuation phase treatment compliance among newly diagnosed sputum positive tuberculosis patients and to look into various reasons/factors for non-compliance in continuation phase in urban area.

### **Materials and Methods**

The present study was a community based longitudinal observational study undertaken in randomly selected one urban Tuberculosis Unit (TU) among a list of total 6 TU of a metropolitan city over a period of 19 months from March 2011 to September 2012.

A list of all TU in a city was obtained from City Tuberculosis Officer (CTO). Permission from Institutional Ethical Committee as well as Medical Officer of Health, & City Tuberculosis Officer (CTO), Municipal Corporation was taken before start of the study.

A total of 247 newly diagnosed sputum positive category I tuberculosis cases registered at urban TU, who were sputum positive at the start of treatment and were

negative at the end of intensive phase and who willing to participate and gave informed consent were included in the study.

All treatment failure, default, relapse sputum positive cases. (Category-II), sputum smears negative patient at the beginning of intensive phase treatment, sputum smears negative extra pulmonary tuberculosis cases, those who expired during the course of treatment, HIV infected cases along with tuberculosis, those who opted for transfer out, seriously ill patients and who did not give consent to participate in the study were excluded. After applying exclusion criteria, out of 247 patients, 42 were excluded and remaining 205 patients were included in the study and followed for 4 months of continuation phase for compliance and non-compliance.

Patients were interviewed with questionnaire which was suitably designed, pre-tested and validated during the study.

The socio-demographic variables were recorded as per the questionnaire which included patient's, name, age, sex, occupation, education, address, religion, type of family. Socio-economic status were graded according to the Modified Kuppuswamy's socio-economic scale 2007. Data were also collected on general awareness, drug treatment, health care institute, economic reasons, and motivational factors.

Patients were studied for visit compliance. Each patient's treatment card, and treatment drug box was crossed checked and verified for correctness. Specific study variable studied such as diagnosis and anti-tuberculosis treatment, awareness about anti-tuberculosis treatment, health care services and institution, economic and motivation reasons were recorded as per the questionnaire.

## **Operational definitions**

### **Compliance**

Cases who missed  $\leq 3$  visit for drug collection of anti-tuberculosis treatment in continuation phase under RNTCP.

### **Non-Compliance**

Cases who missed  $< 3$  visit for drug collection of anti-tuberculosis treatment in continuation phase under RNTCP.

### **Intensive phase<sup>3</sup>**

Period in which a health worker or other trained person watches as the patients swallows the drug in his presence.

### **Continuation phase<sup>3</sup>**

Period in which patient is issued medicine for one week in a multi blister combi pack of which 1<sup>st</sup> dose is swallowed by the patients in presence of health worker or trained person.

### **Data Analysis**

Data was analysed using GraphPad Prism software (version 5.01). For qualitative data chi-square test was applied. Odds ratio (OR) with their Confidence Interval (CI) were calculated for risk factors. For quantitative data mean  $\pm$  Standard Deviation (SD) was calculated.

### **Observations and Results**

A total of 205 patients were included in the study and grouped into compliance (162; 79%) and non-compliance group (43; 21%) as defined in material and methods. The majority of the patients belonged to 21 to 30 years of age group (36.09%) with male predominance (60.97%).

The mean age of patients was  $33.44 \pm 14.36$  years. However, the various parameters such as age, sex, marital status, occupation, education, socio economic status was not significant with respect to compliance of patients as shown in table 1.

Table 1: Distribution of patients according to socio-demographic profile and Socio-economic status of the patients in compliance and non-compliance group.

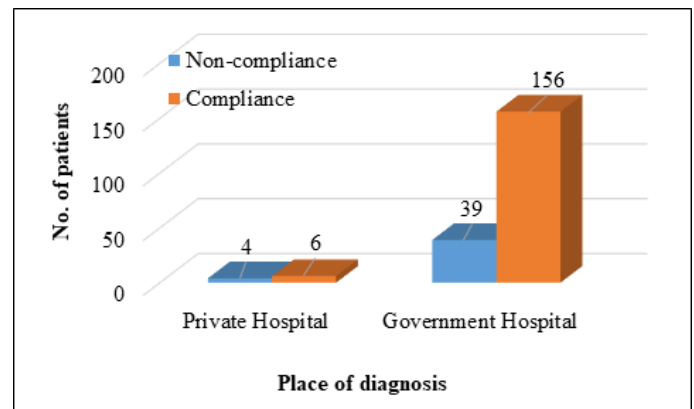
Parameters		Non-compliance (%)	Compliance (%)	P value
Age (In years)	14-20	10(23)	32(19)	0.9479
	21-30	14(32)	60(37)	
	31-40	8(19)	26(16)	
	41-50	5(12)	24(15)	
	51-60	4(9)	14(8)	
	>61	2(5)	6(4)	
Sex	Male	21(49)	104(64)	0.066
	Female	22(51)	58(36)	
Marital status	Married	34(79)	126(78)	0.855
	Unmarried	9(21)	36(22)	
Type of family	Nuclear	28(65)	129(80)	0.04
	Joint	15(35)	33(20)	
Occupation	Unemployed	2(5)	5(3)	0.1950
	Student	6(14)	20(12)	
	Housewives	18(42)	42(26)	
	Laborer	9(21)	67(42)	
	Business	7(16)	26(16)	
	Others	1(2)	2(1)	
	Education status	Illiterate	5(12)	
Primary school		7(16)	22(14)	
Middle school		13(30)	49(30)	
High school		10(24)	42(26)	
Higher secondary		4(9)	15(9)	
Graduate		4(9)	14(9)	
Socio-economic status	Upper	0(0)	0(0)	0.9379
	Upper middle	5(12)	16(10)	
	Lower middle	10(23)	37(23)	
	Upper lower	28(65)	109(67)	
	Lower	0(0)	0(0)	

The patients diagnosed at government hospital were 195(95%). Patients first suspected at private hospital

Table 2: Association of awareness and knowledge with treatment compliance

Awareness	Non-compliance (%)		Compliance (%)	odds ratio
Sputum report at the end of 2 months	Negative	38(88)	142(88)	1.34 (CI 0.43–4.15)
	Don't know	5(12)	20(12)	
Number of visits to the DOTS Centre	Correct answer	2(5)	7(4)	1.01 (CI 0.2–5.05)
	Incorrect answer	41(95)	155(96)	

were referred to DOTS Centre for further management of tuberculosis were 10 (5%). More than 90% of patients in each group were diagnosed at government hospital. Odds ratio 2.67 shows that patients diagnosed at private hospital were 2 times likely to be non-compliant than those diagnosed at government hospital, (Figure 1). Figure 2: Association of place of patient's diagnosis and treatment compliance



The parameters like awareness of sputum report at the end of Intensive phase, number of visits to Directly Observed Treatment Short (DOTS) course Centre, public awareness about disease among family members, total duration of disease treatment and number of blister packs to be consumed in continuation phase (CP) was found to be insignificant. OR=1 (Table 2). Thus, the awareness of all the variables was not associated with the treatment compliance.

The knowledge about side effects of drugs and treatment compliance was found to be insignificant OR=1.27. Most of the patients (203;86%) assumed that interruption of treatment will not cure the disease as shown in table 2.

Person suspecting TB in Patient	On your own	3(7)	8(5)	1.44 (CI 0.37–5.69)
	Family member/ Friend/ Relative	40(93)	154(95)	
Total duration of disease treatment	Don't know	4(9)	12(8)	1.28 (CI 0.39-4.19)
	6 months	39(91)	150(92)	
Total blister packs in CP	Don't know	5(12)	17(11)	1.12 (CI 0.39-3.24)
	21-30	38(88)	145(89)	
Knowledge	Non-compliance		Compliance	odds ratio
Knowledge about side effect	Yes	3(7)	9(6)	1.27(CI 0.32-4.92)
	No	40(93)	153(94)	
Treatment interruption result	Duration will be longer	3(7)	14(7)	-
	Will spread to others	2(4)	13(8)	
	Will not cure	41(89)	162(85)	

The factors related to DOT provider like behavior, enquiry about drug consumption, side effect and home visit by DOT provider were protective regarding treatment compliance,  $OR < 1$ . The economic factors affecting patients' treatment compliance were assessed. Odds Ratio was protective for those who were residing within 1 km distance, travelling by private vehicle,

convenience of DOTS Centre timing and time required for drug collection of less than 15mins, i.e.,  $OR < 1$ . There were 48 times more risk of patients becoming non-compliant when there is loss of daily wages.  $OR = 48.79$ . patients were also non-compliant when they had to spend more than 5 rupees/day to visit the DOTS Centre (Table 3).

Table 3: Association of Health Care Unit (DOT) provider and economic factors with treatment compliance.

Parameters		Non-compliance (%)	Compliance (%)	odds ratio	
DOT providers	Satisfaction with behavior of drug dispensing by DOTS provider	Yes	29(67)	0.09 (CI 0.03-0.25)	
		No	14(33)		
	Enquiry of drug consumption and side effect by DOT provider	Yes	28(65)	161(99.4)	0.01 (CI 0.0 – 0.09)
		No	15(35)		
	DOTS provider home visit	Yes	27(63)	158(97)	0.04 (CI 0.01– 0.14)
		No	16(37)		
Economic reasons	Distance of DOTS Centre from patient's house	<1km	40(93)	0.6926 (CI 0.1757 - 2.7306)	
		>1km	03(7)		
	Mode of travel to DOTS Centre	Walking	38(88)	153(94)	0.45 (CI 0.14 - 1.41)
		Private motor vehicle	05(12)		
	Convenience of DOTS Centre timing		33(77)	161(99.4)	0.02 (CI 0.0 – 0.17)

	Loss of daily wages		10 (23)	01 (0.6)	48.79 (CI 6.04 – 394.25)
	Time spent on transportation	<15min	11(26)	32(20)	1.4 (CI 0.64 – 3.07)
		>15mins	32(74)	130(80)	
	Time required for drug collection	<15mins	33(77)	129(80)	0.84 (CI = 0.38 – 1.89)
		>15mins	10(23)	33(20)	

The patients were assessed for motivation towards treatment compliance. The various parameters like family member’s observation of patient’s consumption of drugs, on table storage of drugs by patients, patient remembering drug intake on his own, Belief of patients

in drug treatment and patient knowing number of people on DOTS therapy, were all protective for treatment compliance, OR<1 as shown in table 4.

Table 4: Association of motivation and treatment compliance of patients.

Motivation Parameters		Non-compliance (%)	Compliance (%)	odds ratio
Motivation by family member	Encourage & remind about drug intake by family member	38(88)	141(87)	1.13 (CI 0.4 – 3.2)
	Family member observe patient consume drug	32(74)	136(84)	0.56 (CI 0.25 -1.24)
Place of storage of drugs at home	On table	2(4)	18(11)	0.39 (CI 0.09 – 1.75)
	Others	41(96)	144(89)	
Person reminding drug intake to patient	On own	14(33)	63(39)	0.7586 (CI 0.3723 - 1.5458)
	Family member	29(67)	99(61)	
Patient belief in drug treatment	Yes	36(84)	161(99.4)	0.032 (CI 0.0 - 0.27)
	No	7(16)	1(0.6)	
patient knowing people on DOTS	Yes	11(25)	55(33)	0.67(CI 0.31 – 1.43)
	No	32(75)	107(67)	

**Discussion**

The present study revealed that the socio-demographic factors (viz age, sex, work, and education) were not associated with compliance. Studies on the association of demographic characteristics of patients with compliance to anti-tuberculosis medication give inconsistent results [7, 10]. The majority of patients belonged to 21 to 30 years of age group (36.09%) which is comparable with the study done by Caceres Fde M et al [11]. However, many studies have shown reproductive age group to be affected by tuberculosis [6, 12]. The probable reason for over representation of male as compared to females in

current study may be due to the fact that males have fairly large number of social contacts, whereas females stay at home. Compliance of males in the present study was 64% which was similar to study conducted by Koo HK et al [13]. The various parameters such as marital status, occupation, education, socio economic status was non-significant with respect to compliance of patients which is correlated with the Adisa R et al [14] and Ashry Gad et al [15]. An attempt was made to know the association between place of diagnosis of patients and treatment compliance which shows that patients diagnosed at private hospital were 2 times more likely to

be non-compliant than those diagnosed at government hospital (OR=2.67. Though the present study showed an association between place of diagnosis and treatment compliance.

The parameters like awareness of sputum report at the end of Intensive phase, number of visits to Directly Observed Treatment Short course Centre, number of blister packs to be consumed in continuation phase and public awareness about disease among family members was found to be insignificant, OR=1. These findings are comparable with the previous studies [16, 17]. More than 90% patients were knowing correct duration of treatment which is comparable with the study conducted by Jian Zhao H et al [16]. Awareness of correct number of blister packs in continuation phase among compliance group patients was more (89%) compared to patients in non-compliance group (88%). Patients not knowing correct number of blister packs in continuation phase were 5(12%) in non-compliance and 17(11%) in compliance group. Only 12(6%) patients gave compliant of drug side effect, of them 9(6%) patients were in compliance and 3(7%) in non-compliance. Awareness was low among patients of both the groups i.e., compliance 153 (94%) and non-compliance 40(93%) in the present study were not knowing probable side effects of the drugs. The explanation for this is that DOT provider did not give any information to patients about possible side effect of drug. This was done to avoid fear of side effects among patients and treatment discontinuation. From odds ratio 1.27. There was no strength of association between non-compliance and low awareness about side effect. Non-compliance group would have been much bigger in case they were told about possible side effects of anti-tubercular drugs. Patients who experienced side effect were 21 times likely to be non-compliant than those not having the side effect. Number of studies [18, 19] have

shown side effect of drugs as a risk factor for non-compliance. When asked about the consequence of treatment interruption, all 162 patients in compliance group thought disease will not cure while in non-compliance group 41(89%) patients believed that disease will not cure. This finding is correlated with the previous studies [7, 20].

The relationship between health workers and patients was assessed. All the respondents in this study ranked the health worker attitudes from “not satisfied” to “Highly satisfied”. Despite this, more than 29 (67%) patients who ranked the behavior as satisfied were non-compliant. Number of patients dissatisfied with the behavior of DOTS provider was 14(33%) in non-compliance and 7(4%) in compliance group. However, dissatisfaction of patients about DOTS provider behavior was associated with non-compliance. Similar findings are reported in study done by Jagga Rajamma K et al [21]. About enquiry by DOT provider, almost all patients in compliance group confirmed enquiry of drug consumption and side effects on each visit by DOTS provider. However, in non-compliance group 28(65%) confirmed and 15(35%) denied, enquiry by DOTS provider. The majority of patients in compliance group (97%) confirmed DOTS provider home visit whenever they missed visit to DOTS Centre for drug collection on schedule day. In non-compliance group, 27(63%) patients confirmed DOTS provide visit. The study findings show an association of treatment compliance and DOTS provider home visit.

Distance and cost of travelling to the clinic were not significant factors affecting treatment compliance and it was interesting to note a significant proportion (93%) of patients who did not comply with treatment were staying within 1 kilometers of the DOTS Centre and did not have to pay any money to travel there. This could mean that

while distance and medicine availability may not be deterring factors for patients to come to pick up their medicines on time, other healthcare system factors such as health worker attitudes, clinic timing and waiting time at the clinic were influencing compliance to treatment. Majority of patients (93%) came to DOTS Centre for drug collection walking while rest 7% patients preferred motor vehicle for drug collection. There was association between mode of travel to DOTS Centre and treatment compliance. DOTS Centre timing was found to be associated with treatment compliance, though, DOTS Centre timing was convenient for 161(99.4%) patients in compliance group whereas for 33(77%) patients in non-compliance group, DOTS timing was not convenient. These findings are correlated with the earlier studies [6, 7].

Only one (0.6%) patient in the compliance group and 10(23%) patients in non-compliance group had to lose their wages for drug collection. There was no relation between loss of wages and treatment compliance. Patients in compliance group who had to spend <15mins on the day for drug collection were 20%. On the other hand, 11(26) patients in non-compliance group spent <15mins. Compliance group patients who had to spend >15mins on transportation to DOTS Centre were 130(80%) while the non-compliance group patients spending more than >15mins were 32(74%). In compliance group, 129(80%) patients replied that they got the drugs within <15mins as they reached the DOTS Centre, in case of non-compliance group it was 33(77%) patients. Around 20% patients in compliance and 23% in non-compliance group had to wait for >15mins for drug collection. Waiting at the DOTS Centre for drug collection was not found to be associated with treatment compliance.

Despite encouragement and reminding from family member 38(88%) patients were in non-compliance group whereas in compliance group, 141(87%) patients were encouraged and reminded by family member about drug intake which is comparable with the study done by Seetha MA et al [22]. We found no relation between repeated encouragement and motivation throughout duration of treatment by family member and treatment compliance of patients. 136(84%) patients in compliance group and 32(74%) patients in non-compliance group were observed by family member while consuming the drugs. Observation by family member was not associated with any difference in treatment compliance. This finding is similar to the other studies [11, 21]. Majority of patients (90%) used other place for storing their drugs whereas 10% stored their drugs on table. There was no relation between place of storing the drug and treatment compliance. 38% of patients took drugs on their own. Patients who were reminded by family member were in compliance group were 61%. However, non-compliance group had 33% patients without being reminded by family member. More than 90% patients were believed in DOTS treatment which is comparable with the previous studies [7, 23, 24]. Most of the patients did not knew any people who were on DOTS therapy (67%) whereas patients who knew people on DOTS therapy were 33%. There was no association of patient knowing people on DOTS therapy and treatment compliance.

#### **Limitations**

1. Study population was restricted to just one tuberculosis unit.
2. Study was limited to urban area only
3. An in-depth qualitative study is required to further study factors for non-compliance



## **Conclusion**

It is concluded from the results that 43 patients were in non-compliance group. These patients had to be given extra attention for 1 month beside their continuation phase period. Therefore, impose more time, money and human resources, an extra burden on health services and health care personnel for their treatment compared to usual time taken by compliance group patient. Thus, it is recommended following activities to increase compliance in patients.

1. There is need to emphasis more on educating the patients about the expected side effects of drugs at the beginning of treatment as it was noticed that awareness of drug side effects was low among patients in both the groups. Further it was also seen that patients having drug side effects were more likely to be non-compliant. Hence it is recommended to make patients aware about probable drug side effect at the beginning of drug treatment course and report them.
2. Factors related to DOT provider like patients' satisfaction with DOT provider's behavior, enquiry about health of patients and home visit by DOT provider was found to be protective for treatment compliance in the present study. It is recommended to enhance DOT provider interpersonal communication skill by training and retraining under RNTCP so as to improve and understand patient problems and maintain treatment compliance.

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