



A CROSS-SECTIONAL DESCRIPTIVE STUDY TO ASSESS FACTORS INFLUENCING NON-COMPLIANCE TO DOTS THERAPY IN PATIENTS WITH TUBERCULOSIS IN SELECTED DOTS CENTRE OF HALDWANI, UTTARAKHAND

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ABSTRACT

Objective: To identify the persons who are Non-Compliant to DOTS therapy, to explore the factors responsible for non-compliance to DOTS therapy.

Methodology: A cross-sectional descriptive study was carried out in selected DOTS centre of Haldwani Uttarakhand. 30 tuberculosis patients who were Non-Compliant to DOTS therapy were included by purposive sampling technique. Patients were selected as per the record of DOTS centre. An unstructured interview schedule was used to assess influencing factors related to non-compliance to DOTS therapy.

Research findings: In total 73.33% (22) subjects were males and 26.67% (8) subjects were females. The non-compliance to DOTS therapy was more among 50% (15) subjects between 41-60years. Half of the study subject's head of the family were illiterate. Maximum 66.67% (20) of the subjects belong to upper lower socioeconomic strata. The major factors as reported by the subjects which surfaced and came out for non-compliance to DOTS therapy were lack of knowledge about DOTS therapy 100% (30), adverse effects of the therapy 70% (21), Lack of family support 76.67% (23), alcoholisms and drug abuse 13.33% (4), lack of money 13.33% (4), unavailability of the drugs at the centre 6.67%(2) and bad attitude of the staff members at the DOTS centre 13.33% (4).

Conclusion:

The following conclusion was drawn on the basis of the study. Non compliance was found to be mainly due to adverse effects of drugs and lack of family support, lack of awareness, no formal education, stigma related to disease, low socioeconomic status, and male are more prone to become non-compliance to DOTS therapy.

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INTRODUCTION

Tuberculosis is the ninth leading cause of death worldwide from a single infectious agent, ranking above HIV/AIDS. According to Global TB report 10.4 million people (90% adults; 65% male; 10% of people living with HIV) affected with TB and 1.67 million people died from TB in 2016. In 2016, 40% of HIV deaths were due to TB and it is leading killer among HIV-positive people. Increasing number of drug-resistant TB is a persistent threat, with 490,000 million cases of multidrug-resistant and 110,000 cases that were resistant to the most effective first-line anti-TB drug Rifampicin. More than 95% of TB deaths occur in under developed and developing countries. Seven countries account for 64% of the total, with India leading the count, followed by Indonesia, China, Philippines, Pakistan, Nigeria, and South Africa.¹

According to World Health Organization, India is in the list of top ten high TB burden countries. In 2016, 28 lakh cases of TB were reported out of which 4.5 lakh people died due to the disease. India contributes more than a million “missing” cases

every year that are not notified and most remain either undiagnosed or inadequately diagnosed and treated in the private sector. There are an estimated 79,000 multi-drug resistant TB patients among the notified cases of pulmonary TB each year and second highest number (after South Africa) of estimated HIV associated TB cases.² In 2017, in a fresh report of WHO the re-estimated the number of MDR-TB cases in India were 84,000.³ According to World Health Organization, India had the second highest total number of estimated MDR TB cases (99,000) in 2008, after China (100,000 cases).⁴

According to Uttarakhand statistic, population covered by Revised National Tuberculosis Control Program was 11,000,000. During the year 2016 a total of 15,081 patients were diagnosed and registered for treatment. 2,805 smear positive patients get cured in the year of 2016.⁵ In 2017 alone, there were 5,946 cases suspected to have MDR-TB, of which only 448 were actually diagnosed. Due to malnutrition, high tobacco consumption and poor ventilation in buildings, and

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also low socioeconomic status have resulted in 43 people being diagnosed with tuberculosis every day in the state.³ The therapeutic regimen given under direct observation as recommended by World Health Organization (WHO), have been shown to be highly effective for both preventing and treating tuberculosis, but Non-Compliance is a barrier to Global Tuberculosis control. DOTS or Directly Observed Treatment Short course is the internationally recommended therapy for TB control that has been recognized as a highly efficient and cost-effective strategy.⁶

Despite the remarkable success been made in the prevention and control of tuberculosis, still it is one of the leading causes of death in India and it is the most serious alarming public health problem in developing countries.

METHODOLOGY

A (mixed approach) cross sectional descriptive design was adopted for this study in DOTS centre, Haldwani District Nainital State Uttarakhand India. Based on the records obtained from the DOTS centre the 30 non-compliant patients were selected by purposive sampling technique. All Non-Compliant patients available during data collection and willing to participate in the study were included and all Non-Compliant patients who confined to bed and could not take part were excluded.

Table No 1 Frequency and percentage distribution of demographic data of patients

n=30

S I. No	Demographic data	Frequency	Percentage (%)
Age			
1.	• < 20	03	10.00
	• 21-40	08	26.67
	• 41-60	15	50.00
	• > 60	04	13.33
Gender			
2.	• Male	22	73.33
	• Female	08	26.67
Education of head of family			
3.	• Post-graduate and professional degree	01	03.33
	• Higher secondary certificate	02	06.67
	• High school certificate	05	16.67
	• Middle school certificate	06	20.00
	• Literate, less than middle school certificate	01	03.33
	• Illiterate	15	50.00
Occupation of head of family			
4.	• Professional	01	03.33
	• Clerical/shop owner	02	06.67
	• Skilled worker	03	10.00
	• Semiskilled worker	05	16.67
	• Un-skilled worker	12	40.00
	• Unemployed	07	23.33
Monthly income of family in rupees			
5.	• 20715-41429	03	10.00
	• 15536-20714	03	10.00
	• 10357-15535	04	13.33
	• 6214-10356	11	36.67
	• 2092-6213	09	30.00
Socioeconomic class			
6.	• Upper	01	03.33
	• Upper middle	02	06.67
	• Lower middle	06	20.00
	• Upper lower	20	66.67
	• Lower	01	03.33
Marital status			
7.	• Unmarried/Single	06	20.00
	• Married	23	76.67
	• Divorced/Separated	01	03.33
Type of family			
8.	• Nuclear family	10	33.33
	• Joint family	20	66.67

Interviews were conducted at their home after taking written permission. Data was collected with the structured questionnaires (Demographic data) and Unstructured Interview Schedule to assess the factors influencing Non-Compliance to DOTS therapy. Descriptive statistics (frequency and percentage distribution) was used to analyses demographic characteristics of the study subjects and the responses obtained from the patients were analyzed using content analysis.

RESULT

50% (15) of the study subjects were in the age group of 41-60 years, majority 73.33% (22) of subjects were males, 50% (15) of head of the family were illiterate, 40% (12) of the head of family occupation were categorized as unskilled workers, majority 36.67% (11) of the subjects family income were within 6214-10356, 66.67% (20) of the subjects belonged to upper lower socio status group, 76.67% (23) of the subjects were married and majority 66.67% (20) of the subjects lived in joint families.

The Non-Compliance to therapy in multifactorial.

Table No 2 Frequency and Percentage distribution of Personal factors.

n=30

Sl. No.	Subjects responses on various aspects of TB	Frequency (n)	Percentage (%)	
Knowledge about TB				
1.	• TB is a communicable disease	29	96.67	
	• TB spreads from smoking, drinking alcohol, sharing food with infected person.	26	86.67	
	• Don't know how it spreads.	05	16.67	
	• TB is due to sin	09	30.00	
	• TB can be prevented by precaution and treated by medicines.	29	96.67	
	• Family history of TB	08	26.67	
	Knowledge about DOTS therapy			
	2.	• No awareness about the medicines.	30	100
		• DOTS therapy mandatory for the TB treatment	26	86.67
		• It can be treated with Ayurvedic medicines.	04	13.33
The reasons of stopping treatment				
3.	• Various side effects experienced by the subjects e.g. weakness, loss of appetite, vomiting, dizziness, burning sensation in the stomach, joint pain and Jaundice.	30	100	
	• Chest pain and breathlessness after stopping the treatment.	29	96.67	
	• Abdominal pain after stopping the treatment.	01	03.33	
	Family support			
4.	• Family members did not like share the utensils to be used for eating the food.	23	76.67	
	• Family members did not say anything on stopping the treatment.	22	73.33	
Stigma related to disease				
5.	• Subjects felt very bad when they came to know that they have TB	28	93.33	
	• Subjects were sad and depressed and always used to think what will happen now.	06	20.00	
	• Neighbours did not know that they have TB	16	53.33	
	• Everyone knows about my disease	14	46.67	
Duration of therapy				
6.	• Subjects withdrawn the treatment within 1 month	05	16.67	
	• Subjects withdrawn the treatment within 1-3 months.	18	60.00	
	• Subjects withdrawn the treatment within 3-6 months.	07	23.33	

During interview when the subjects were asked about the course of the disease such as ‘What is TB’ and ‘How it spreads’ 96.67% (29) subjects responded that TB is a communicable disease. 30% (9) respondents believed that TB occurs due to sin. One of the respondents said that “TB occurs when we commit more sins”. One of the major reasons reported for discontinuing of the treatment was varying degree of adverse effects such as weakness, nausea, vomiting, loss of appetite, burning sensation of the stomach and joint pain also experienced by 100% (30) of the study subjects. Out of 30 subjects one respondent said that “I stopped the treatment because medicines were very strong”. 76.67% (23) subjects reported that their family members did not like sharing anything such as food and eating utensils. One of the respondents reported that “They used to serve meal separately while eating and kept me aside for few months” while another subject’s said that “ In my family there is only my husband he totally excluded me and even did not like sitting with me”. More than half 53.33% (16) of the study subjects did not want to admit that they were suffering from TB and also did not want to disclose it to their neighbors, friends or anyone. One of the respondents said “Even my son and daughter in-law don’t know about my disease if I tell them, then they won’t allow me to sit with them also”. Another subject’s mentioned “My neighbors don’t know about my disease otherwise they won’t come to my house”. 60% (18) of the study subjects discontinued the treatment within 1-3 months.

Table No. 4 Frequency and percentage distribution of the Social factors

n=30			
Sl. No.	Subjects Responses on various aspects of TB	Frequency (n)	Percentage (%)
1.	Distance and conveyance		
	• Subjects used to go to the DOTS centre by vehicle	26	86.67
	• Subjects used to go to the DOTS centre by walk only.	04	13.33
2.	Negative conditioning (Rumors related disease and DOTS therapy)		
	• Lack of money	04	13.33
	• Negative information about DOTS therapy	03	10.00

When the subjects were asked about how did you reached to the DOTS centre most of the subjects 86.67% (26) reported that DOTS centre was far from their home and they used to go to the DOTS centre by their own or public transport vehicle. . 10% (3) of the study subjects reported that they heard that TB medicines are not effective and can’t cure the disease as one of the subjects said “She used to say that TB medicine can’t cure the disease and you will die so stop taking medicine, my illness has not been cured even after taking these medicines” and another respondent said that “TB can’t be cured people die due to this disease”.

16.67% (5) subjects reported that they had to buy some medicines from outside also. One respondent reported that “We buy medicines from outside because medicine given by the DOTS centre did not suit me”. 6.67% (2) also reported about non-availability of the medicines at the DOTS centre. They said that medicine were not available at the time of their visit. Another subjects said that “When we reached there they said medicines are not available it happened 4-5 times”. 13.33% (4) of the study subjects reported that behavior of the

staff was very bad and they never listened to their problems. One subjects reported that the “Staff behavior was not fine they never motivate a person. Whenever I used to tell my problems to them they never gave an ear to it”. Another subject reported that “When I used to reach to the DOTS centre they said that doctor is not available and whenever I reported them that I am having so much cough please either give me or write one cough syrup they neither gave nor prescribed”. A quarter of the study subjects 26.67% (8) responded that it used to take 1hr at the DOTS centre while 6.67% (2) subjects responded that it used to take approx 4-5 hrs as one subject statement was “I stopped going to DOTS centre because of time as I am a driver so I can’t go there according to their time” and another subject said that “It took so much time we are labor class and our whole day get wasted due to these medicines”. 16.67% (5) of the study subjects reported that they did not get any information regarding treatment from the health care staff.

Table No.5 Frequency and percentage distribution of the DOTS centre related factors

n=30			
Sl. No.	Subjects Responses on various aspects of TB	Frequency (n)	Percentage (%)
1.	Non availability of the drugs		
	• Buy medicines from outside	05	16.67
2.	• Medicine were ended at the DOTS centre	02	06.67
	Attitude of health care provider		
	• Bad behavior of health care staff	04	13.33
3.	Long waiting time		
	• It took 1 hr	08	26.67
	• It took 4-5 hrs	02	06.67
4.	Inadequate guidance/ Information provide in the health centre		
	• They did not give any information	05	16.67

DISCUSSION

The findings of the study divided under demographic and factors related to Non-Compliance to DOTS therapy.

Demographic characteristics

The present study revealed that the majority of subjects 50% (15) were in the age group of 41-60 years. The present study findings are consistent with a similar study done by Mittal C. and Gupta SC. (2011) in Agra city and it was found that default rate was more in the age group of more than 45 years (22.8%)⁷.

The findings of present study revealed that out of 30 subjects 73.33% (22) subjects were males and 26.67% (8) were females. The present study findings had its support from the study done by Blesson Mathew, Dona Kurian, Jibin Mathew, TR. Ashok kumar and T. Sivakumar (2015), on reason for medication non-adherence in tuberculosis patient in Tamilnadu which inferred that males 81.82% (45) were more prone to defaulter than female.⁸

In the present study the majority 50% (15) of subject’s head of the family were illiterate and 20% (6) were middle school certificate. The present study findings also consonance with other study done by Neeraj R, Kushwah S.S, Singh S.P. and Dubey D. (2015), on an assessment of treatment compliance among patients on DOTS in M.P and it was seen that 57% (37)

Non-Compliant rate was more in illiterate people as compared to educated people.⁹

According to the occupation the present study showed that 40% (12) head of the subjects were in unskilled category worker such as labour, vegetable seller, fruit seller. The present study findings are consistent with a similar study done Ramchandra T, Kumar N, Pragathi and Lakkoju N. (2017) in Telangana, and revealed that most of the defaulters 35.9% were unskilled workers (daily labour).¹⁰

The findings of the present study revealed that out of 30 subjects 36.67 % (11) of the study subjects' monthly family income was between Rs.6214-10356. The present study findings are consistent with a similar study done by Kaur T. and Sethi D. (2016), to assess factors associated with adherence to DOTS Therapy among patients in Punjab and data showed that 24% (7) of the subjects monthly income was Rs. 5000-10,000/-¹¹

The present study showed that the majority 66.67% (20) of subjects belong to upper lower socioeconomic status group so it is evident that on the basis of above data the Non-Compliance rate was high in lower socio status group. The findings of the present study strengthened by another study done by Aurora H., and Kapoor S. (2016), conducted a study on determinants of lost to follow up during treatment among tuberculosis patients in Delhi and found that 53.9% subjects' belong to low socioeconomic status and it showed that it was one of the disabling factors which contribute to Non-Compliance to DOTS therapy.¹²

As regards to marital status 76.67% (23) of the study subjects were married in the present study. The present study findings consistent with the another study done by Harshul G, Patel G, Shah E, Shah H, Dholakia H and Patel Harsh (2017), in Ahmadabad on assess the non-adherence to anti Tuberculosis treatment factors among Patients with Pulmonary Tuberculosis also showed that the prevalence of non-adherence was more in married people.¹³

In the present study majority 66.67 % (20) of the subjects lived in joint families. The present study findings also consonance with other study done by Ansari S, Abdulmohsen H, Alam S, Sharma M. and Khalid. (2016), on contribution of non-pharmacological factors in Non-Compliance of dots amongst tuberculosis patients in Delhi and found that 42% of the study subjects lived with joint family.¹⁴

Factors related to Non-Compliance to DOTS therapy

According to the present study findings 96.67% (29) of the study subjects had knowledge about TB and knew how it spreads and can be prevented. Findings of the study are consistent with the finding of the study done by Sakalle S, Bhagwan Waske, Sanjay Dixit, Dhruvendra Pandey, Suraj Sirohi, Satish Saroshe *et al.* (2014), on patients compliance of tuberculosis enrolled under Revised National Tuberculosis control programme in Indore and showed that 62% (31) of the subjects were aware about Tuberculosis and how it can be prevented.¹⁵

On the contrary another study done by AK Nepal, K. Shiyalap K, S Sermsri, B Keiwkarnka (2012), conducted to assess the patients' compliance to the treatment and its associated factors in Palpa District Nepal and it showed that half of the study

subjects were Non-Compliant due to lack of knowledge regarding TB and DOTS therapy¹⁶.

The present study findings revealed that none of the 30 subjects (100 %) of the subjects were aware about DOTS therapy. The study findings had supported by the study done by Kaur Baljit, Samuel P, Ramesh K Garcha and K. Manpreet on assess the knowledge regarding DOTS therapy among Tuberculosis clients at TB sanatorium in Amritsar in a view to develop and distribute an Information Booklet in Amritsar (2014), and concluded that 66% subjects had inadequate knowledge about DOTS therapy¹⁷.

The present study data shows that almost 100% subjects experienced various side effects which they experienced during treatment and similar findings have been found in many studies. Another study findings supported the present study done by Srivastava K., Gupta Abhishek, Saxena Ruchi, Sharma P R., and Midha Tanu, (2017) on Non-Compliance to DOTS therapy in Kanpur also supported these findings and found that 24% TB patients Non-Compliance reason was adverse effects of DOTS therapy¹⁸.

In the present study shows that 76.67% (23) of the subjects reported that lack of good family support which is necessary for adherence to treatment regime and early recovery. The findings are consistent with the study done by Yellappa V. Lefevre P, Battaglioli T, Narayanan D, Stuyft V.P. *et al.* (2016), in Karnataka on coping with tuberculosis and directly observed treatment which revealed that subjects missed the treatment due to lack of family/social support⁴¹.

The present study showed that more than half of the study subjects 53.33% (16) did not share their disease status with their relatives or neighbours for the fear of getting excluded or getting bad comments. Findings of the study are consistent with study done by Dhingra V. K and Khan Shadab (2010), in Delhi on sociological study on stigma and which revealed that 60% of the patients were hiding their disease from everyone²³.

In the present study findings revealed that 60% (18) of the subjects discontinued the medicine within 1-3 months. The present study findings also consonance with other study done by Uzma, S. Saeed M, Bashir A. (2015) in Pakistan which revealed the factors affecting compliance of patients with DOTS, and revealed that 62.5% (20) of the subjects withdrew the treatment within in one month³⁴.

The present study data shows that the 86.67% (26) of the subjects used to reach to the DOTS centre by their own vehicle and Public transport. Another study finding consistent with present study findings done by Suparna Bagchi, Guirish Ambe, Nalini Sathiakumar (2010), in Mumbai and data revealed that the patients were not adhered due to long distance to DOTS centre⁴⁶.

The present findings showed that 10% (3) of the subjects heard about rumors regarding DOTS therapy that TB medicines can't cure the disease. According to the another study report done by Sinha Teeku and Tiwari S. (2010), in the district Raipur (Chhattisgarh) and findings inferred that 2.26% subjects discontinued the treatment due to lack of faith in treatment and rumors against therapy.¹⁹

The present study data shows that 16.67% (5) of the subjects had to buy some medicines from outside also. 6.67% (2)

subjects reported that medicines were ended at the DOTS centre. The present study also consonance with the other study done by Ranjan A. Singha, Pakharea A, Arun M, Hemant Kokanea, Ashish Shewadeb D, Chauhan A. *et al.* (2017), which revealed that the main barriers to continuation of treatment was stock-out of drugs at the DOTS centre.²⁰

In the present study 13.33% (4) of the study subjects reported that behavior of DOTS staff was very bad and respondents did not satisfied with the staff behavior. The similar study done by Yellappa V, Lefevre P, Battaglioli T and Narayanan D, Stuyft V.P. (2016), in Karnataka South India and it showed that one of the major reasons of Non-Compliance was unfavorable attitude of the RNTCP staff.²¹

The present study revealed that 16.67% (5) of the study subjects complaint about DOTS centre's staff that they did not give any information about related to treatment. The present study further supported by a qualitative study by Sahile Z, Yared A. and Kaba M. (2018), in Ethiopia and concluded that the subjects reported about negative behavior of the DOTS staff.²²

CONCLUSION

The following conclusion was drawn on the basis of the study. In total 73.33% (22) subjects were males and 26.67% (8) subjects were females. The Non-Compliance to DOTS therapy was more among 50% (15) subjects between 41-60years. Half of the study subject's head of the family were illiterate. Maximum 66.67% (20) of the subjects belong to upper lower socioeconomic strata. The major factors as reported by the subjects which surfaced and came out for Non-Compliance to DOTS therapy were lack of knowledge about DOTS therapy 100% (30), adverse effects of the therapy 70% (21), Lack of family support 76.67% (23), alcoholisms and drug abuse 13.33% (4), lack of money 10% (3), unavailability of the drugs at the centre 6.67%(2) and bad attitude of the staff members at the DOTS centre 13.33 % (4).

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