

## Original Research Article

# Study of various reasons for interruption of anti-tubercular treatment in patients of tuberculosis reporting to tertiary care center of west Rajasthan

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## ABSTRACT

**Background:** Tuberculosis is a major cause of death in India. Premature cessation of treatment in tuberculosis patient is a leading cause for developing MDR (multidrug resistant tuberculosis) as well as a major threat to control programs. Despite the easy approach and free of cost, availability to antitubercular medicines the interruptions of the treatment are still on a high. So, we analyzed such various reasons leading to interrupt the antitubercular treatment.

**Methods:** Total 150 patients who interrupted the antitubercular treatment, were interviewed with a predesigned questionnaire and the result was analyzed.

**Results:** Out of total 150 patients 115 (76.7%) male and 35 (23.3%) female were interviewed, who were having history of antitubercular treatment interruption. Out of 150 patients, 79 (52.7%) patients stopped their treatment because of improvement. Total 25 (16.7%) patients had stopped their treatment because of high cost, 16 (10.7%) due to personal/family reason, 17 (11.4%) patients had stopped their treatment due to nausea/vomiting/anorexia, 5 (3.3%) due to alcoholism/drug or other addiction, 2 (1.3%) patients had stopped their treatment because they were advised to stop it by health personnel and long distance travelled to take drugs.

**Conclusions:** Improvement of symptoms was the most common reason in patients who received DOTS treatment and high cost of treatment in patients who received non DOTS treatment. Poor education and socioeconomic status of society are the other reasons for possible treatment interruptions because as soon as the patient improves, they move out to earn their wages to run the family with the unavoidable default from the treatment.

**Keywords:** DOTS, Interruption of treatment, tuberculosis

## INTRODUCTION

Tuberculosis (TB) is a chronic, debilitating and usually life-threatening illness caused by *Mycobacterium tuberculosis*. The disease primarily affects the lungs, but can also affect other organs like intestine, bone and joint, lymph node, skin, meninges and other tissues of the body.

Globally, there are more than nine million cases and 1.7 million deaths from TB in 2006 and nearly 100 million

people have died of TB in the twenty century.<sup>1</sup> In India, 1000 people die from TB every day. Tuberculosis affects young adults disproportionately and it therefore, leaves more orphans than any other infectious disease, impoverishes families, and undermines economic development.<sup>2</sup> Tuberculosis causes one-third of female infertility in India, and kills more women of reproductive age than all causes of maternal mortality combined.<sup>3,1</sup> India accounts for nearly 20% of all TB cases in the

world and cases may increase in India as the population grows and the HIV epidemic progresses.<sup>4</sup>

According to the recent estimates of the TB burden by the WHO, the incidence of smear positive TB is 75 per 100000 population and all forms of TB is 168 per 100000 population, the prevalence of all forms of TB in India is 299 per 100000 population.<sup>5</sup> India's TB problem is further compounded by an estimated 2.5 million people infected with human immunodeficiency virus (HIV), TB being the most common opportunistic infection amongst HIV infected individuals.<sup>6,7</sup>

Tuberculosis is the seventh most common cause of mortality world wide and Indian patients account for 1/5 of the global incidence of TB cases, 1.8 million new cases occur every year.<sup>8,9</sup>

Tuberculosis remain a serious public health problem in India, because India has more people with active tuberculosis than any other country in the world.

Interruption in TB treatment still remains the major barrier to its control, Inability to complete the prescribed regimen is an important cause of treatment failure, relapse, acquired drug resistance and continuous transmission of infection in the community.

Adherence to treatment reduces the spread of infection in the community and thereby decreases the burden of disease and development of new cases. Adherence to treatment requires active participation of the patients and cooperation between patient and health care provider.

Since Tuberculosis is a chronic disease and duration of treatment is long with multi drug therapy, treatment interruption is a major challenge in almost all areas of the world. Various studies have been conducted to find out the causes of discontinuation of anti tubercular treatment.

Higher treatment interruption rate is associated with various factors like early well being, illiteracy, lack of knowledge about disease, adverse effect of drugs, other associated medical illness, unstable living condition, alcohol/drug addiction, difficulty in access to the health services, loss of wages because of travel to the health center, poor communication between health staff and patient etc.

In the context of Bikaner division, this study evaluated whether these various factors influence the compliance of the patient to the therapy or some other new factors possibly related to discontinuation of anti tubercular therapy and to identify possible solutions.

Premature cessation of treatment usually has a serious consequence not only of the patient, but also for the community as whole. Health education to the patient and to the community is needed to ensure compliance with therapy. The present study was carried out at Department

of Respiratory Medicine, S.P. Medical College, Bikaner in tuberculosis patients reported in OPD or admitted in wards.

Aims and objectives of the study was to find out and analyze the various causes of discontinuation of anti tubercular treatment (ATT) in patients of tuberculosis reporting to our institute and to analyze various strategies of antitubercular treatment DOTS as well as Non DOTS affecting the patient's compliance to therapy.

## **METHODS**

A descriptive, cross-sectional, questionnaire-based study was conducted in the Department of Respiratory Medicine, S.P. Medical College, Bikaner, from September 2011 to January 2012 in diagnosed TB patients who were reported to out and indoor patient department of our institute.

### **Methodology**

A questionnaire was designed to study the various reasons for interruption of anti-tubercular treatment (ATT) in patients with tuberculosis. Written consent was taken before interviewing them. Simple Hindi language was used in communicating with patients.

### **Study population**

Patients of tuberculosis, (pulmonary and/or extra pulmonary tuberculosis) who have taken incomplete anti tubercular treatment previously and reported to OPD or admitted in the wards of our institute. A proforma was designed for collection of data from a non compliant patient of tuberculosis using interview method. Collected data entered and analysed in Microsoft excel software using appropriate statistical tests. A p value <0.05 was considered to be significant statistically.

## **RESULTS**

Total 150 patients were interviewed, who were diagnosed as having pulmonary and/or extrapulmonary tuberculosis with history of treatment interruption. Out of these 115 (76.7%) were male and 35 (23.3%) were female. Maximum patients were in the age group 15-25 (30%). In present study 118 (78.7%) patients belonged to rural areas, 117 (78%) patients were illiterate, 68(45.3%) patients were farmers and 40 (26.66%) were laborers, 122 (81.3%) belonged to the poor socioeconomic class. 109 (72.7%) patients were smokers, 40 (26.7%) patients were alcoholic.

There were total 119 patients who had stopped their treatment once. Out of these 119 patients 77 had taken DOTS treatment while 42 had taken non-DOTS treatment. Twenty-five patients had stopped their treatment twice during the disease and out of them 16 had taken DOTS treatment while 9 had taken Non-DOTS

treatment. Surprisingly 6 patients had stopped their treatment for more than twice and out of these 6 patients 3 each had taken DOTS and Non-DOTS treatment (Table 2).

**Table 1: Demographic profile of the study population.**

	Treatment		Total
	DOTS	Non DOTS	
	No.(%)	No. (%)	No.(%)
<b>Age groups (years)</b>			
15-25	29(30.20%)	16(29.6%)	45 (30.0%)
26-35	22 (22.9%)	10 (18.5%)	32 (21.3%)
36-45	13 (13.5%)	12 (22.2%)	25 (16.7%)
46-55	9(16.7%)	17(17.7%)	26 (17.3%)
56-65	10 (10.4%)	4 (7.4%)	14 (9.3%)
>65	5 (5.2%)	3 (5.6%)	8 (5.4%)
<b>Sex</b>			
Male	76 (79.2%)	39 (72.2%)	115(76.7%)
Female	20 (20.8%)	15 (27.8%)	35 (23.3%)
<b>Religion</b>			
Hindu	84 (87.5%)	44 (81.5%)	128 (85.3%)
Muslim	9 (9.4%)	8 (14.8%)	17 (11.3%)
Sikhs	3 (3.1%)	2 (3.7%)	5 (3.3%)
<b>Residence</b>			
Rural	85 (88.5%)	33 (61.1%)	118 (78.7%)
Urban	11 (11.5%)	21 (38.9%)	32 (21.3%)
<b>Education</b>			
Illiterate	73 (76.0%)	44 (81.5%)	117 (78.0%)
Literate	15 (15.6%)	2 (3.7%)	17 ((11.3%)
Primary	4 (4.2%)	3 (5.6%)	7 (4.7%)
Middle	4 (4.2%)	1(1.9%)	5 (3.3%)
Secondary	0	4 (7.4%)	4 (2.7%)
<b>Occupation</b>			
Farmer	49 (51.0%)	19 (35.2%)	68 (45.3%)
House wives	18 (18.8%)	12 (22.2%)	30 (20.0%)
Unskilled labour	16 (16.7%)	11 (20.4%)	27 (18.0%)
Self employed/ others	6 (6.3%)	4 (7.4%)	10 (6.7%)
Skilled labour	7 (7.3%)	6 (11.1%)	13 (8.7%)
Govt employed	0	2 (3.7%)	2 (1.3%)
<b>Addiction</b>			
Smoker	68 (70.8%)	26 (48.1%)	94 (62.7%)
Alcoholic	28 (29.2%)	12(22.2%)	40 (26.7%)
Opium addiction	3(3.1%)	1(1.9%)	4 (2.7%)
Tobacco chewing	9(9.4%)	3 (5.6%)	12 (8.0%)
<b>Socioeconomic status</b>			
I	0	3 (5.6%)	3 (2.0%)
II	5(5.2%)	3 (5.6%)	8 (5.3%)
III	12 (12.5%)	5 (9.3%)	17 (11.3%)
IV	51(53.1%)	26 (48.1%)	77 (51.3%)
V	28(29.2%)	17(31.5%)	45(30.0%)

DOTS; Directly observed treatment short course

**Table 2: Number of treatment interruption in relation to treatment (DOTS and Non DOTS strategy).**

No. of treatment interruption	Treatment				Total	
	DOTS		Non DOTS		No.	%
	No.	%	No.	%		
Once	77	80.2	42	77.8	119	79.3
Twice	16	16.7	9	16.7	25	16.7
More than twice	3	3.1	3	5.6	6	4.0
Total	96	100	54	100	150	100

Out of total 150 patients who had stopped their treatment, 9 (6%) patients had stopped the treatment after 15 days only out of them 3 had taken DOTS treatment and 6 had taken Non-DOTS treatment. 10 patients had stopped their treatment after 1 month period, while 43 had stopped after 2 months and 46 (30.7%) had stopped after 3 months duration. 24(16%) patients had stopped their treatment after 4 months duration while 18 had stopped their treatment after >4 months duration. On comparison of these data the difference was statistically significant (p<0.05). Maximum treatment interruption were in 2<sup>nd</sup> and 3<sup>rd</sup> month (Table 3).

**Table 3: Duration of starting and interrupting ATT in relation to treatment (DOTS and Non DOTS strategy).**

Duration of treatment before interruption (months)	Treatment				Total	
	DOTS		Non DOTS		No.	%
	No.	%	No.	%		
0.5	3	3.1	6	11.1	9	6.0
1	8	8.3	2	3.7	10	6.7
2	34	35.4	9	16.7	43	28.7
3	28	29.2	18	33.3	46	30.7
4	12	12.5	12	22.2	24	16.0
>4	11	11.5	7	13.0	18	12.0
Total	96	100	54	100	150	100

Out of total 150 patients 79 (52.7%) patients stopped their treatment because of improvement and out of these 78 patients 62 had taken DOTS treatment while only 17 had taken Non-DOTS treatment. Total 17 (11.4%) patients had stopped their treatment due to nausea/vomiting/anorexia out of them 13 had taken DOTS treatment and only 4 patients had taken Non-DOTS treatment. 5(3.3%) patients had stopped the treatment due to alcoholism/drug or other addiction, 2 patients each had stopped their treatment because advised to stop by health personal and long distance travelled to take drugs while 25 patients had stopped their treatment because of high cost. One patient had stopped their treatment because no improvement or deterioration while 3 patients had stopped their treatment due to misbelieve to take ATT as hazardous. 16 patients had stopped their treatment due to personal/family reason. Maximum persons interrupt the treatment due to improvement of

symptoms. Cost of the therapy also play a major role in interruption of the therapy (16.7%) in the patients taking

non DOTS therapy (Table 4).

**Table 4: Reasons for interruption of ATT in relation to treatment (DOTS and Non DOTS strategy).**

Reason for interruption of ATT	Treatment				Total		$\chi^2$	P
	DOTS		Non DOTS		No.	%		
	No.	%	No.	%				
Improvement	62	64.6	17	31.5	79	52.7	14.232	<0.001
High Cost	0	-	25	46.3	25	16.7	53.333	<0.001
Nausea/Vomiting/Anorexia	13	13.5	4	7.4	17	11.4	0.941	>0.05
No Improvement or Detoriation	0	-	1	1.9	1	0.7	1.790	>0.05
Alcoholism/Drug or Other Addiction	3	3.1	2	3.7	5	3.3	0.036	>0.05
Advised to Stop by Health Personnel	2	2.1	0	-	2	1.3	1.140	>0.05
Long distance travelled to take drugs	2	2.1	0	-	2	1.3	1.140	>0.05
Mis-belief to take ATT as Hazardous	2	2.1	1	1.9	3	2.0	0.009	>0.05
Personal/Family reason	12	12.5	4	7.4	16	10.7	0.941	>0.05
Total	96	100	54	100	150	100		

## DISCUSSION

Worldwide, tuberculosis is the second most common cause of death in adults attributable to a single infectious agent. Tuberculosis remains the leading cause of death due to infection in India, which bears nearly 30% of the global tuberculosis burden.<sup>11</sup>

National tuberculosis programme launched in 1962, suffered from several serious drawbacks including managerial weakness, inadequate funding, over reliance on chest radiographs, non-standardized treatment regimens, high treatment defaults and poor recording and reporting system. The Government of India launched the Revised National TB Control Programme (RNTCP) in 1992 based on DOTS strategy with the objective of detecting at least 70% of new sputum positive TB patients and curing at least 85% of such patients.

This study was an interview based analysis of the reasons for ATT interruption in 150 patients of pulmonary tuberculosis interviewed during September 2011 to February 2012. Out of 150 patients, 115(76.7%) were males and 35(23.3%) were females. Male gender is a risk factor for treatment interruption as male are main earning member of the family and they ignore the treatment over the family responsibilities. This is supported by various studies by Sweta et al.<sup>12-18</sup>

In present study maximum number of interruptions were in age group 15-25 years (30%), combinedly maximum interruption (78%) were in productive age group i.e. 15-45 years. Same has been observed by studies conducted by Sweta et al, Castelnuno et al and Shargic et al.<sup>12,19,20</sup> Sophia et al found majority of the defaulters were in age group of 35-54 years.<sup>21</sup> Kumar et al, reported that non compliance was maximum in age group of 35-44 years

(25.4%).<sup>22</sup> Reason for this may be that in majority of these cases the patients were economically active in the family and hence could not spare time to visit DOTS clinic on a regular basis. Since 74% patients included in study belonged to rural area and most of them were farmers and labourers (71%).

Out of the total cases 81.3% patients were from poor socioeconomic class (Prasad scale IV and V).<sup>10</sup> Kumar et al, reported that patients of upper class had higher non compliance (16%) as compared to lower class (7.4%).<sup>22</sup> It could be because the patients of upper class are economically well so they shift to private practitioners. Secondly, they may prefer private practitioners for privacy. Jindal observed that more than 50% patients of all TB and over 70% of those with extensive disease belonged to low income groups amongst both urban and rural population.<sup>23</sup>

In our study, majority of patients (78%) were illiterate. Probably the illiterate patients did not understand the ill consequences of irregular treatment. Kumar et al also reported non compliance more among illiterate patients (13.9%).<sup>22</sup> This is very obvious from above findings that illiteracy, poor economic status and ignorance are main factors for the interruption of the treatment as the person belonging to these groups delay the treatment initiation and stop the treatment as soon as they get better and start earning for the family. Castelnuno et al, observed that poor knowledge about treatment, disease transmission and prevention affect treatment adherence.<sup>19</sup>

Present study shows that 62.7% patients were smokers. Kumar et al reported that non compliance was more among smokers (11.5%) in comparison to the non smokers (6.1%).<sup>22</sup> Smoking is shown to inhibit both immunological and non immunological beneficial lung



defences and increases the mortality from TB as well as in patients infected with HIV.<sup>23</sup> In our study 26.7% patients were alcoholic. Forty alcoholic patients who interrupted ATT, maximum interruption were in <4 months due to improvement of symptoms. Kumar et al observed more non compliance among alcoholics (23.9%) than non alcoholic.<sup>22</sup> William et al, also attributed non compliance to alcoholism and homelessness.<sup>24</sup> Similar observations have been made by Sophia et al and Santha et al supporting our study.<sup>18,21</sup>

In our study 79% patients interrupted anti-tubercular treatment once, 16.7% patients interrupted ATT treatment twice and 4% patients interrupted thrice.

ATT was interrupted before 3 month by 108(72%) patients. Maximum interruption were in 2<sup>nd</sup> month (28.7%) and 3<sup>rd</sup> month (30.7%). Patients who had taken DOTS therapy interrupted treatment in 2<sup>nd</sup> month (35.4%) and patients who had consumed non DOTS therapy stopped treatment in 3<sup>rd</sup> month (33.3%). These observations also favoured by Sweta et al (2 and 3 month), Castelnuro et al, Yeung et al and Oliviera et al (2 month) on the contrary Tekle et al (81%) and Chee et al (70%) concluded that most interruption were in continuation phase.<sup>12,19,25-28</sup>

While analyzing reasons for interruption of ATT for the first time 52% patients stopped ATT due to improvement of symptoms, also favoured by studies done by Sweta et al (30.05%), Castelnuro et al (29.8%), Tissera et al.<sup>12,19,29</sup> Improvement of symptoms (63.5%) is most common reason for ATT interruption in patients on DOTS therapy. Besides health education, the retrieval mechanism of the patients to be improved by strengthening health care facilities and monitoring of health care services. Next most common reason for treatment interruption was high cost of treatment 25 (16.7%) exclusively reported by patients on non-DOTS (purchasing medicine from market). The third most common reason was ATT induced side effect i.e. anorexia/nausea/vomiting (10.7%) which were more in patients on DOTS therapy (12.5%) as also studied by Sweta et al (12.84%), Jaggarajamma et al (42%).<sup>12,30</sup> Other common reason for treatment interruption was personal/family reason 10.7%, which includes migration of patients from one place to another, non compliant attitude of the patient and family problems. Other causes of treatment interruption includes alcoholism (3.3%) which was also observed in a study by Jakubowiak et al as 2<sup>nd</sup> most common cause of treatment interruption (30%).<sup>31</sup> Two percent patients stopped ATT as they believed ATT to be hazardous which signifies the need of knowledge about drugs and their regular intake for cure of diseases. Also 2(1.3%) patients stopped ATT on advised by private practitioner physician, same was observed by Sweta et al (7%).<sup>12</sup>

In present study 1.3% patients stopped ATT because of long distance to travel to take drugs, also concluded by

Chatterjee et al.<sup>32</sup> Pathak reported because of loss of daily wages during receiving medicine may leads to patient to stop ATT.<sup>33</sup> Mishra et al, observed that cost of travel to treatment centre causes treatment interruption.<sup>34</sup> Hill et al, observed that significant time loss of daily wages or cost travelled to receive drugs is a risk factor for treatment default<sup>35</sup>. Maximum number of interruption of ATT were found between 2-3 month because of clinical improvement of symptoms.

So, it is very important to provide repeated health education to patients emphasizing the need to continue ATT despite improvement in symptoms. Patients and their relatives should be informed and educated about the chronicity of disease, its transmission in the community, longer duration of treatment and need of treatment even after clinical improvement.

## CONCLUSION

Treatment interruptions were maximum in 3<sup>rd</sup> month of ATT. Improvement of symptoms was most common reason in patients who received DOTS treatment and high cost of treatment in patients who received non DOTS treatment. Poor education and socioeconomic status of society are the other reasons for possible treatment interruptions because as soon as patient improves they move out to earn their wages to run the family with unavoidable default from the treatment. Apart from this the timings of the health centre that provide the treatment facility to the patients are not in accordance with the work timings of these patients resulting in interruption of treatment. To reduce treatment interruption, patients and their relatives must be counselled and educated about the adverse effect of drugs used and how they can be minimized. They should immediately contact the DOTS provider and medical officer inspite of stopping the treatment. Minor side effects due to drugs also play a role in interruption of ATT added by poor communication and less attention given by physician as well as DOT provider to resolve these problems. Last but not the least that at the start and throughout the treatment patients should be educated about the disease and treatment and motivated to complete the treatment for the favourable outcome. For that doctor-patient interaction should be on regular basis.

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