### **Original Article**

# A STUDY ON PATIENT COMPLIANCE OF TUBERCULOSIS ENROLLED UNDER REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

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### INTRODUCTION

Tuberculosis (TB) is a global health concern; nearly one third of the global population is infected with Mycobacterium tuberculosis and at risk of developing the disease.<sup>[1]</sup> More than 90% of global TB cases and deaths occur in the developing world, where 75% of cases are in the most economically productive age group. <sup>[2]</sup> India ranks first among the world's highburden tuberculosis (TB) countries.<sup>[3]</sup>

World Health Organization (WHO) recommends the Directly Observed Treatment Short-course (DOTS) strategy for control of TB. The strategy has been

## ABSTRACT

**Background:** Tuberculosis (TB) is a global health concern, India ranks first among the world's high-burden tuberculosis (TB) countries. Non-compliance to self administered multi drug tuberculosis treatment regimens is common and is the most important cause of failure of initial therapy and relapse.

**Objective:** To assess various aspects of patient compliance to DOTS for the treatment of tuberculosis, to assess the role of socio-demographic factors, life style related factors, side effects of anti tubercular drugs in patient compliance.

**Material & Method:** A cross sectional Study with informed written consent was conducted in 50 Sputum positive tuberculosis patients enrolled under RNTCP in Manoramaraje TB hospital (Attached to medical college & hospital) and Prakash chandsethi Hospital (UHTC) Indore. Patients were selected using convenient sampling method. All sputum positive Failure, relapse and defaulters were included in study. A predesigned, semi structured questionnaire was used as tool to interview the patients. The data was analyzed using Microsoft office excel sheet.

**Results:** In total 50 patients, 42% females and 58% males were included in our study. 22% and 12% of patients had history of Infection at family and workplace respectively. 44 % of total patients did not complete the category I treatment. 28% of the patients were not compliant to current treatment of Category II. Most common reason behind non compliance was obtaining relief from symptom of tuberculosis.

**Conclusion:** The disease mainly affects the low socioeconomic strata where maintenance of high level of compliance is difficult. The main reasons of low patient compliance are lack of awareness about the disease, more concern about earning the wages, low motivation during drug therapy and early appearance of side effects.

**Key words:** Tuberculosis, Noncompliance, Directly observed treatment short course, Defaulter, Adherence

adopted by more than 180 countries and is considered as the most appropriate and cost-effective approach for TB control.<sup>[4]</sup> The WHO target for global TB control was to detect at least 70% of the estimated smearpositive TB cases and to achieve a treatment success rate of 85% in 2005. <sup>[5]</sup>

Adherence is defined by WHO as "the extent to which a person's behavior- taking medication, following a diet, and or executing lifestyle changes, corresponds with agreed recommendations from a health care provider".<sup>[6]</sup> Compliance to therapy plays an important role in the outcome of the therapy. Compliance is defined as the extent to which the patient's behavior coincides with medical advice. Noncompliance to self administered multi drug tuberculosis treatment regimens is common and is the most important cause of failure of initial therapy and relapse. Non-compliance may also result in acquired drug resistance, requiring more prolonged and expensive therapy that is less likely to be successful than treatment of drug susceptible tuberculosis. <sup>[7]</sup>

Patient compliance is a key factor in treatment success. In many countries, a significant proportion of patients stop treatment before completion, for various reasons. Promoting compliance through a patient-centred approach is much more effective than spending resources on defaulter tracing.<sup>[8]</sup>

Studies have shown thatsatisfied patients are more likely to utilize health services <sup>[9]</sup>, comply with medical treatment <sup>[10]</sup>, and continue with the health care providers <sup>[11]</sup>. Asking patients what they think about the care and treatment they have received is an important step towards improving the quality of care, and to ensuring that local health services are meeting patients' needs <sup>[12]</sup>. In the southern region of Ethiopia (Southern Nations Nationalities and Peoples' Regional State), Even though, Directly Observed Treatment Shortcourse( DOTS) was introduced in 1996, evidence shows that one in five patients still continue to default from treatment <sup>[13]</sup>.

Compliance with TB treatment is a complex issue, influenced not only by social, cultural and economic factors but also by knowledge and attitude of patients towards TB. Studies of patients' adherence to TB treatment in Ethiopia have identified socio-economic and structural barriers to adherence, including lack of money to pay for transportation, high distance from clinics, the difficulties associated with daily treatment and rigid routines at health facilities. Inadequate knowledge about the illness was also found to adversely impact adherence. The studies also showed that family support, involvement in TB clubs, and adequate knowledge about the disease were facilitators of TB treatment adherence. <sup>[14-22]</sup>

In the study of Finlay et al. <sup>(23)</sup> it was reported that cases had not received enough education about TB at the beginning of their treatment and they were not told why treatment would take six or more months. Similar result was obtained in study of Sardar et al<sup>(24)</sup> which revealed that lack of proper counselling, knowledge about the correct method of TB transmission, patients visiting quacks and the urge to leave treatment once they started feeling better.

The purpose of the study to know the various aspect of patient compliance for treatment of tuberculosis (DOTS), to assess the role of socio-demographic factors, life style related factors, role of side effects of anti tubercular drugs in patient compliance of tuberculosis.

### MATERIALS AND METHODS

A cross-sectional study was conducted in urban area of Indore district. Study sites included Manoramaraje TB hospital (Attached to Medical College & Hospital), Prakash chandsethi Hospital Indore (Urban Health Training Centre). Study population included all category II Sputum Smear Positive tuberculosis patients enrolled under (Revised National Tuberculosis control Programme) RNTCP. Written informed consent was obtained prior to interview. Patients were selected using convenient sampling. Sample size was 50 patients (enrolled under RNTCP) who were interviewed for study. Study Duration was 5 months duration. Inclusion Criteria included all the category II T.B patients: a) Sputum positive failure, b) Sputum positive relapse, c) Sputum positive treatment after defaulters, who gave informed consent. Patients missing drugs for more than 2 consecutive weeks were taken as non compliant. Exclusion Criteria included all the patients come under category I and Category DOTS-plus and all those who did not give informed consent. A semi structured questionnaire was used for IPI (Interpersonal interview). The data was analyzed using appropriate statistical software (MS excel).

### **OBSERVATIONS& RESULTS**

Out of 50 patients 29 were male and 21 were female. Out of all patients included 44% were Defaulter, 38% Failure and 18% Relapse cases.40% were of 13 – 29 years, 32% of 30 – 49 years and 24% of more than 50 years age group, 32% were illiterate, 48% educated up to primary and 12% up to high school.48% of patients had monthly income less than Rs 1500 and 41% between Rs 1500 – 5000. 82% were married, 16% unmarried, 2% widow, 22% of Patients had family history and 12% of patients had workplace history of Tuberculosis. 32% patients had history of Alcohol consumption and 38% had history of Smoking (Table 1).

During their previous treatment 12 % patients started drugs after six months of diagnosis, 44% did not complete their category I treatment, 62% did not take drug regularly,

4 % missed their treatment due to lack of medicine, 92% patients experienced side effects during their therapy, 36 % patients left the treatment on obtaining relief from the symptoms of TB.48% patients experienced economical problem and 12% patients experienced social problem during their therapy (Table 2).

Table 3 indicates that 36 (72%) patients showed compliance to the treatment.A total of 14 (28%) patients did not consume the drugs for more than 2 consecutive weeks were considered as non compliant. The reasons for non compliance were classified underthree heads as suggested by Bansal AK et al. <sup>(25)</sup>. On further analysis, it was observed that many of the patients showed multiple reasons of noncompliance. There were total 14 non compliant patients of which 35.71% failed to comply because offear of adverse reaction,50% patientsstopped due to feeling better,35.71% were non-compliant because of lack of motivation and 57.14% because of different obstacles. (Table 4)

Table: 1 Distribution of Knowledge, history, lifestyle related factors among patients

| Parameters                   | Present (%) | Absent (%) |
|------------------------------|-------------|------------|
| Awareness about tuberculosis | 31 (62)     | 19 (38)    |
| Family History               | 11 (22)     | 39 (78)    |
| Workplace History            | 6 (12)      | 44 (88)    |
| Alcohol habit                | 16 (32)     | 34 (68)    |
| Smoking Habit                | 19 (38)     | 32 (62)    |

 
 Table 2: Distribution of parameters present during their previous treatment

| Parameters                           | Present(%) | Absent(%) |
|--------------------------------------|------------|-----------|
| Completed their previous treatment   | 22 (44)    | 26 (56)   |
| Whether they took regular treatment  | 19 (38)    | 32 (62)   |
| Default due to lack of medicine      | 2 (4)      | 48 (96)   |
| Having Side effects during Treatment | 46 (92)    | 4 (8)     |
| Discontinue treatment on obtaining   | 18 (36)    | 32 (64)   |
| relief from symptoms                 |            |           |
| Economical Problem experienced       | 24 (48)    | 26 (52)   |
| during treatment                     |            |           |
| Social Problem experienced during    | 6 (12)     | 44 (88)   |
| treatment                            |            |           |

Table 3: Distribution of patients according to compliance

|                | Number | Percentage |
|----------------|--------|------------|
| Compliance     | 36     | 72         |
| Non compliance | 14     | 28         |
| Total          | 50     | 100        |

Table: 4 Reason for noncompliance to current treatment

| Parameters                        | Frequency (%) |
|-----------------------------------|---------------|
| Lack of Information               |               |
| Fear of adverse reaction          | 5 (35.71)     |
| Felt better and stopped treatment | 7 (50)        |
| Lack of Motivation                |               |
| Difficult to take so many pills   | 4 (28.57)     |
| no faith in treatment             | 1 (7.14)      |
| Obstacles                         |               |
| Moved away from treatment center  | 2 (14.28)     |
| Timing not convenient             | 3 (21.42)     |
| Nobody to accompany to the center | 3 (21.42)     |
| DOTS center far away              | 2 (14.28)     |

### DISCUSSION

In this study most of the patients belong to age group 13 – 49 years (72%), education less than primary(less than 5<sup>th</sup> standard) (80%) andmonthly income less than Rs 5000 (89%), thus according to modified kuppuswamy scale maximum patents belong to lower (V) and upper lower (IV)socio-economical class.

In our study 38% of the participants had poor knowledge of Tuberculosis, mainly contributed by females. In the study of Pandit et al, 10.5 % of the participant had poor knowledge about disease.  $^{(26)}$ 

The study reveals that most of patientsbelong to low socioeconomic status and had economical problem during their treatment due to loss of daily wages and travel expenses. 12% patients especially the females experience social problems during the treatment, the reason being the far distance of the centre, none availability of any one to accompany her, and social stigma associated with tuberculosis prevalent in the society.

Table 3 indicates that 36 (72%) in comparison to 14 (28%) patients complied as per DOTS, similar to the finding of Sinha T et al.  $^{(27)}$  (65.93%),Mehrotra et al  $^{(28)}$ (67.0%), Santha T et al  $^{(29)}$ (72%) and Bhat S et al $^{(30)}$  (76.89%).

Various reasons observed in the present study for noncompliance are more or less similar to the findings of different studies conducted by different authors in different parts of the country. 28% of the total patients were not compliant to current treatment of Category II. Similar results were also found in the previous study of Sinha T et al. <sup>(27)</sup> (33.38%),Mehrotra et al <sup>(28)</sup> (33.0%), Santha T et al <sup>(29)</sup> (28%) and Bhat S et al <sup>(30)</sup> (23%).

In the present study50% of the 14 noncompliant patients left treatment on obtaining relief from symptom of tuberculosis, which is the most common cause of non-compliance in the present study, the findings of which were similar to study of Sinha et. al.(27)(34.48%), chain k et al <sup>(31)</sup> (27%) and Juvekar SK et al <sup>(32)</sup> (27%). Non compliance due to fear of adverse reactions, the 2<sup>nd</sup> most common reason, was found in 35.71%, similar to the studies of Bhat S et al<sup>(30)</sup> (13.20%) and Juvekar SK et al (31)(10.0%). 3rd most common cause of non compliance was found tobe difficulty to take so many pills (28.57%). Non compliance due to moved away from the treatment centre was found in 14.28% patients which was similar to the findings of the study of Rani SM et al<sup>(33)</sup> (22.0%). Other reasons for noncompliance were timing not convenient (21.42%), No one to accompany to the centre (21.42%), DOTScentre is far away (14.28%) similar to the findings of other studies.(27-30)

This study was carried out with 50 patients who was not representative of all sputum smear positive T.B patients in Indore District, needs more sample size to be incorporated which unfortunately was not included due to time constraint. Since the method of obtaining information was IPI (interpersonalinterview) method, we had to rely solely on the history as given by the patient. There may also be chances of recall bias. The recommendations based on the present study areto achieve the target of RNTCP, proper counseling and motivation of patients regarding various aspects of the disease is a must to ensure compliance, increase awareness about T.B in the public through talks, seminars, lectures, camps, advertisements, documentaries, posters. Quitting Alcohol and smoking is difficult & could not be improved by educational intervention alone. Effective Behaviour Change communication (BCC) and stringent regulation of legal provisions is required to attain this goal.

### CONCLUSION

The main reasons of low patient compliance are lack of awareness about the disease, more concern about earning the wages, non convenient timings, low motivation during drug therapy and early appearance of side effects and non accompaniment to the centre especially for the females. The disease mainly affects the low socioeconomic strata where maintenance of high level of compliance is difficult. Adherence to the long course of TB treatment is a complex, dynamic phenomenon with a wide range of factors having deep impact on treatment-taking behaviour.

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