

A CROSS SECTIONAL STUDY TO ASSESS VARIOUS RISK FACTORS ASSOCIATED WITH NON-COMPLIANCE TO ANTI TUBERCULOSIS TREATMENT AMONGST PATIENTS REGISTERED UNDER NATIONAL TUBERCULOSIS ELIMINATION PROGRAMME (NTEP) IN DISTRICT BHOPAL, M.P. INDIA

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Abstract

Background: Tuberculosis (TB) is a specific infectious disease caused by mycobacterium tuberculosis affecting pulmonary and extra-pulmonary organs. Noncompliance is one of the unfavorable outcomes for patients on DOTS and represents an important challenge for the control programme. Inadequate treatment adherence is considered as a potential cause of drug resistance. This study was conducted ascertain causes of noncompliance & to study sociodemographic correlates of study participant. **Materials and Methods:** A cross sectional study was conducted. 108 Patients taking ATT fulfilling inclusion criteria were interviewed using pre design pre tested structured questionnaire. The data obtained was analysed to know causes of non-adherence. **Result:** Study was carried out between January 2021 & June 2022. In our study, 60.2% subjects were male and 39.8% were female. The main reasons for Non-adherence in personal reasons were smoking 34 (31.5 %), alcohol 33 (30.6%), 31(28.7%) cases had difficulty in procuring medication due to lockdown in COVID-19 pandemic as they were migrated/ travelling related causes, associated illness 14 (13%) followed by non-compliant attitude 8 (7.4%), in treatment related reasons, side effect related 28 (25.9 %), someone advised for treatment interruption 11(10.2%), feel better 10 (9.3%), treatment from private hospital 8 (7.4%), no improvement 6 (5.6%) and lack of home visits by health worker related reason was reported by 5 (4.6%) cases. **Conclusion:** Present study concludes that the most common cause of noncompliance amongst tuberculosis patients are smoking, alcohol, migrated/ travelling related causes and side effect of drugs, there arises immense need for continuous and effective health education to patients' and their family regarding need for high level of adherence to treatment and the complete cure of disease. Strength of study - This is a pioneering work done to analyze the factors & reasons for non-adherence in COVID-19 pandemic in State of Madhya Pradesh, Bhopal, Central India. This study will further strengthen the outcome & implementation of National Tuberculosis Elimination Programme.

INTRODUCTION

Tuberculosis (TB) is a communicable disease that is a major cause of ill health and one of the leading causes of death worldwide. Until the coronavirus

(COVID-19) pandemic, TB was the leading cause of death from a single infectious agent, ranking above HIV/AIDS.^[1] About a quarter of the global population is estimated to have been infected with TB.

India accounts for more than one-fourth (2.69 million) of global TB burden (10 Million).i.e. every year, 27 lakh new cases are notified out of a total of one crore.^[2] More than 40% of the population in India is infected with Mycobacterium Tuberculosis (prevalence of infection).

Loss to follow up (LTFU) is defined by the World Health Organization as "patients whose treatment was interrupted for two consecutive months or more." These people were previously known as Treatment after Default (TAD) patients.^[3]

The public health and clinical consequences of TB treatment loss to follow up are severe relatively to those who complete treatment. Patients who Loss to follow up may perpetuate TB transmission and have high post-treatment mortality, rates of recurrent disease and drug resistant TB.^[4]

Loss to follow-up is caused by a variety of factors, including access to health services, socioeconomic status, literacy level, and societal beliefs and practices.^[5]

Several other studies conducted earlier in different settings have also identified many factors responsible for Loss to follow up illiteracy, poverty, long duration of treatment, many medicines, access to health-related services, workplace issues, smoking and alcoholism beliefs and practices etc.^[6]

Because TB treatment is long and involves a number of medications, side effects are common, and the patient usually feels better long before treatment is finished, adherence is particularly difficult. Loss to follow up has been cited as one of the reasons for failure of achievement of the global treatment success rates throughout the world.^[7]

To combat the severe burden of the disease, it is crucial to identify and target the factors related to tuberculosis knowledge among noncompliance patients along with the efficient control measures already in existence.

Many factors associated with Loss to follow up (LTFU) have been identified in quantitative studies. Therefore, the primary objective of this qualitative study to assess the factors related to tuberculosis knowledge and to identify the determinants of non-compliance in tuberculosis patients residing in district Bhopal.

MATERIALS AND METHODS

Study Population: All Tuberculosis noncompliance patients registered under NTEP during January 2021 to June 2022 residing in district Bhopal, India.

Study design and period: Cross sectional study over a period of 18 months from 1st January 2021 to 30 June 2022

Sample Size: 108 noncompliance to tuberculosis treatment patients

Method of collection of data: Sample data for this study was collected from District TB Office (DTO Bhopal) available data base. A comprehensive

sampling frame were constructed for all study patients.

During the study period, total registered patients for anti-tubercular treatment in Bhopal District Tuberculosis Center were 2988 in 2021 and 4545 in 2022. Non-compliance and loss to follow-up occurred in 117 patients out of 7533 during the study's duration. Out of 117 patients, 1 died, 1 migrated (non traceable), and 7 had incorrect addresses (not traced), resulting in the exclusion of 9 patients (who met the exclusion criteria). Total 108 patients were eligible and given written and telephonic consent for the present study. Thus finally, we got interview of 108 patients out of 117, using predesigned and pretested questionnaire by home visits, giving response rate of 92.31 %. The data obtained was tabulated and subjected to statistical analysis.

Inclusion Criteria

All non-compliant outcome patients registered in District TB Office (DTO Bhopal) under NTEP from 1st January 2021 to 30 June 2022 and given a written consent.

Exclusion Criteria

1. Patients who had not given a written consent.
2. Patients who migrated/ non traceable, absconded and died, were excluded.

Ethical Clearance

The present study was approved by Institutional Ethics Committee of L.N. Medical College & Research Centre, Bhopal. As per the order no. LNMC&RC/Dean/2021/ethical/2006 dated 18/02/2021 & after obtaining the informed consent and explaining the objectives of the study, the study subjects were interviewed.

RESULTS

In the present study, out of 108 study participants selected for the study. Mean age of study population was 38.97 ± 19.12 years which ranged from 01 to 85 years.

Maximum participants (42.6%) belonged to age group of 21-40 year, Majority of study participants were male, which is 60.2% and females were 39.8%. Majority of study participants belonged to urban area, which is 81.5% followed by rural 18.5%. Maximum numbers of participants were Hindu (66.7%) by religion, majority of participants were married (70.4%), Majority of participants had joint family (60.2%), Majority of the participants had pucca type of house (79.6%), Majority of participants (43.5%) belonged to Class IV (Upper lower class). [Table 1]

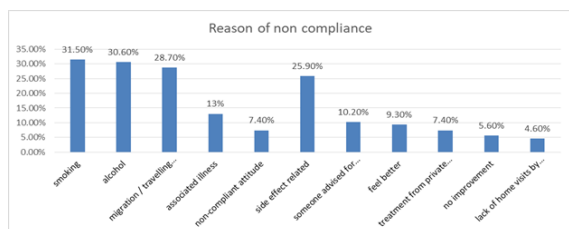


Figure 1: Reason of non-Compliance

Multiple responses were given by the study subject on asking the reasons for noncompliance. Out of 108 study subject, in personal reasons, the common reasons for non-compliance were smoking 34 (31.5 %), alcohol 33 (30.6%), migration / travelling

related causes 31(28.7%), associated illness 14 (13%) followed by non-compliant attitude 8 (7.4%), in treatment related reasons, side effect related 28 (25.9 %), someone advised for treatment interruption 11(10.2%), feel better 10 (9.3%), treatment from private hospital 8 (7.4%), no improvement 6 (5.6%) and lack of home visits by health worker related reason was reported by 5 (4.6%) cases. [Table 2]

Majority of participants were smear negative new case that is 37% [Table 3], Majority of participants (64.8%) were taking treatment of intensive phase. [Table 4]

Table 1: Showing Socio-Demographic Profile

Socio-Demographic Factor	No. of patients (n=108)	(%)
Age group (years)		
0-20	16	14.81
21-40	46	42.6
41-60	27	25.0
> 60	19	17.6
Gender		
Female	43	39.8
Male	65	60.2
Socioeconomic status		
Upper	0	0
Upper Middle	2	1.9
Lower Middle	34	31.5
Upper Lower	47	43.5
Lower Class	25	23.1
Marital status		
Single	29	26.9
Married	76	70.4
Widow	3	2.8
RESIDENCE AREA		
Rural	20	18.5
Urban	88	81.5
RELIGION		
Hindu	72	66.7
Muslim	35	32.4
Christian	1	0.9
TYPE OF HOUSING		
Katcha	16	14.8
Semipucca	6	5.6
Pucca	86	79.6
FAMILY TYPE		
Joint family	65	60.2
Nuclear family	42	38.9
Third generation family	1	0.9

Table 2: Reasons for non-adherence.

Reasons of non-adherence	Percentage of patients
smoking	34 (31.5 %)
alcohol	33 (30.6%)
migration / travelling related causes	31(28.7%),
associated illness	14 (13%)
non-compliant attitude	8 (7.4%),
side effect related	28 (25.9 %)
someone advised for treatment interruption	11(10.2%),
feel better	10 (9.3%),
treatment from private hospital	8 (7.4%)
no improvement	6 (5.6%)
lack of home visits by health worker	5 (4.6%)

Table 3: Distribution of participants according to the phase of treatment

Phase of treatment	Frequency	Percentage (%)
Intensive phase	70	64.8
Continuation phase	38	35.2
Total	108	100

Table 4: Distribution of study participants according to treatment category

Treatment category	Frequency	Percentage (%)
Smear positive new case	28	25.9
Smear negative new case	40	37.0
Extra pulmonary new case	35	32.4
Retreatment	5	4.6
Total	100	100

DISCUSSION

In the present study, the data was gathered from the District Tuberculosis Centre (DTC) Bhopal, Madhya Pradesh. The period of study was about one year six months i.e. 1 January 2021 to 30 June 2022. Pilot testing of the study was done in the month of October 2020. After applying exclusion and inclusion criteria a total of 108 patients were included in the present study. These selected patients were interviewed by a pre-design pre-tested questionnaire to find out sociodemographic characteristics, knowledge, and factor related to noncompliance to anti-tubercular drugs provided under NTEP.

In the present study, majority of study participants were male, which were 60.2% and females were 39.8%. Maximum participants 46 (42.6%) under the age of 21-40 year. In a study conducted by kaur et al the age-wise distribution of TB patients was also determined to be similar finding, with the majority of patients (37.5%) belonging to the 21-40 year age group.^[8] In the same way, this study supports the gender-wise distribution of the current study, which shows that more male patients than female patients. Muture BN in Kenya have shown that the noncompliance rate was more in males when compared to females.^[9] Similar findings was observed in study done by Kulkarni PY et al where majority of non-adherent patients were males 15-49 years.^[10]

In present study majority of study participants belonged to urban area, which was 81.5% followed by rural (18.5%). Similar studies conducted by Hasker E et al about non-compliance to TB treatment were also associated to living in an urban area.^[11]

In the present study, majority of study participants were married 76 (70.4%), followed by single 29 (26.9%), and widow 3 (2.8%). Similar study conducted by Gorityala SB et al found that 85.98% of defaults were married.^[12] Similar studies conducted by Gupta et al were also reported that most of the defaults among married patients (because they were constituting the major chunk of participants).^[13]

In our study majority of noncompliance patients belonging to joint family (60.2%) followed by nuclear family (38.9%) and third generation family 1 (0.9%). Similarly a study conducted by Bagchi et al showed that the drug defaulters in Pulmonary Tuberculosis belonging to joint family (70.6%).^[14] Similarly overcrowded living conditions were revealed as important default predictors as

evidenced in studies conducted in Uzbekistan by Jakubowiak et al.^[15]

In present study majority of non-compliant patients (43.5%) belonged to Class IV (Upper lower class) followed by Class III (31.5%), Class V (23.1%), Class II (1.9%). No participants belonged from Class I as per socioeconomic classification. A similar conclusion that poverty and TB are closely related was made in research by Siroka et al.^[16]

In present study alcohol addiction present in 17.6 % study population and smoking and tobacco addiction is 25.9 % and 10.2 % respectively.

Present study observed that alcohol related causes of treatment interruption is 30.6 % in study population. In multiple regression analysis, alcohol is significant risk factors for treatment interruption: associated with age, marital status and type of housing [p = 0.004, 0.002, and 0.04].

Majority of the patients were defaulted during Intensive Phase (64.8%) compared with Continuation Phase (35.2%) in our study. Similar study done by Veeramani G et al⁸⁶ and observed that 70% of the patients were defaulted during Intensive Phase compared with Continuation Phase 30%.^[17]

In present study majority of participants were smear negative new case, that is 37%, followed by extra pulmonary new case (32.4%), smear positive new case (25.9%) and least number of participants were from retreatment category (4.6%). A similar study done by Harries AD et al in Malawi and observed that smear-negative patients were also more likely to have unsuccessful treatment outcomes, with higher rates of treatment default compared to their smear-positive counterparts.^[18]

In present study there are 24.1% participants having associated illness as Diabetes mellitus, Hypertension, Bronchial Asthma and Carcinoma etc. There are 13% participants reported as associated illness mainly causing treatment interruption in present study. Similarly, a study conducted by Srinath M. P observed that HIV infections were the most important comorbidities followed by bronchial asthma in treatment interruption.^[19] Similarly a study conducted by Vasantha et al found the same observation in a study conducted among the urban population.^[20] Similarly, a study conducted by Kartalogu, et al observed that, diabetes etc. were the major comorbidities in their study for treatment interruption.^[21]

In present study 25.9% participants reported that side effect of anti-tubercular drugs were main cause of interruption of treatment. Side effects to anti-TB

drugs were reported for non-compliance in other studies like Chang KC.^[22]

CONCLUSION

This study revealed non-compliance to TB treatment amongst patients registered under NTEP in district Bhopal. Multiple responses were given by the study subjects on asking the reasons for non-compliance.

Majority of participants (42.6%) belonged to under the age of 21-40 years, Majority of study participants were male, which is 60.2% and females were 39.8%. Majority of study participants belonged to urban area, which is 81.5% followed by rural (18.5%). Maximum numbers of participants were Hindu (66.7%) by religion, majority of participants were married (70.4%), Majority of participants had joint family (60.2%), Majority of the participants had pucca type of house (79.6%), Majority of participants (43.5%) belonged to Class IV (Upper lower class), Majority of participants were smear negative new case that is 37%, Majority of participants (64.8%) were taking treatment of intensive phase.

Out of 108 study subject, in personal reasons, the common reasons for non-compliance were smoking 34 (31.5 %), alcohol 33 (30.6%), migration / travelling related causes 31(28.7%), associated illness 14 (13%) followed by non-compliant attitude 8 (7.4%), in treatment related reasons, side effect related 28 (25.9 %), someone advised for treatment interruption 11(10.2%), feel better 10 (9.3%), treatment from private hospital 8 (7.4%), no improvement 6 (5.6%) and lack of home visits by health worker related reason was reported by 5 (4.6%) cases.

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