A PROSPECTIVE STUDY TO ASSESS THE OUTCOME OF TREATMENT PROVIDED UNDER NTEP IN DISTRICT TUBERCULOSIS CENTRE IN CENTRAL INDIA

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ABSTRACT

Background: Tuberculosis (TB) patients on the National Tuberculosis Elimination Program (NTEP) treatment protocol receive daily doses without health professional-supervised drug intake as during the previous directly observed treatment short-course (DOTS) regimen**.** The aim of this study is to determine the socio-demographic and clinical characteristics, treatment outcomes, and factors associated with unsuccessful treatment outcomes of patients who received anti-tubercular drugs under NTEP.

Methods: In this prospective study, 150 TB patients taking anti-tubercular therapy were enrolled using a pre-designed structured pro forma. Socio-demographic characteristics, risk factors, the outcome of treatment, and factors that affected the compliance of patients were recorded.

Treatment outcome indicators like cured, treatment completed, treatment failed, loss to follow-up, treatment success, not evaluated, died, or transferred out should be monitored in each patient.

Results: The treatment success rate of new sputum-positive patients was 83.2% in this study. Among outcomes, 59% were cured, 27% completed treatment, 3.4% were lost to follow-up, 5.3% were not evaluated, 4% died, and 1.3% were treatment failures. Type of family, family history of TB, and presence of HIV were significantly associated with the final outcome of treatment. ($P<0.05$). The main reasons for nonadherence were not feeling well (60%), being unaware of the importance of a full-length course of treatment (80%), time strain problems/loss of wages (60%), feeling side effects of multiple drugs (40%), and some other reason (2%).

Conclusion: The present study concludes that the most common causes of noncompliance amongst tuberculosis patients are the side effects of drugs, unawareness regarding the course of treatment, and loss of wages. The immense need for continuous and effective health education improves ATT adherence and strengthens the NTEP.

Keywords: Tuberculosis, NTEP, anti-tubercular drugs, treatment outcome, non-compliance, Central India

INTRODUCTION

Tuberculosis (TB) is one of the world's main public health problems; in 2019, there were an estimated 10 million (8.9-11 million) cases [1]. India continues to be the largest contributor to worldwide tuberculosis cases, with an anticipated 2.69 million in 2019 [2]. Tuberculosis is a particular infectious illness caused by Mycobacterium tuberculosis. The disease primarily affects the lungs, resulting in pulmonary tuberculosis (PTB). Extra-pulmonary tuberculosis affects the gut, meninges, bones and joints, lymph glands, skin, and other bodily parts. The condition is typically chronic, with key symptoms including persistent cough with or without expectoration, intermittent fever, lack of appetite, weight loss, chest discomfort, and hemoptysis [3]. Until the coronavirus (COVID-19) pandemic, tuberculosis was the largest cause of death from a single infectious agent, surpassing HIV/AIDS.[4] In India, the Revised National Tuberculosis Control Programme (RNTCP) was recently renamed the National Tuberculosis Elimination Programme (NTEP), confirming the country's goal to eliminate tuberculosis by 2025, five years ahead of global targets [5]. By 2006, India's National TB Elimination Program (NTEP) had managed

tuberculosis in all of the country's districts [6]. The country has drafted and accepted a National Strategic Plan (NSP) for TB elimination 2017-2025 in accordance with the END TB strategy to achieve SDG 3.3 [7]. The NTEP has been consistently addressing challenges linked to tuberculosis control in the country through programmatic modifications based on findings from operational research. Using sputum smear microscopy and intermittent directly observed treatment short course (DOTS), the program consistently detected 70% of pulmonary tuberculosis patients and achieved an 85% treatment success rate [6]. In October 2017, the Joint Monitoring Mission suggested switching from intermittent to daily fixed-dose combination (FDC) treatment due to significant relapse rates and drug resistance [8]. To achieve the NSP goals by 2025, new interventions such as 99 DOTS (low-cost medication adherence intervention), Nikshay Poshan Yojana (financial assistance for patient nutritional support), and universal drug sensitivity testing (DST) and improved adverse event surveillance and reporting have been implemented [6]. Despite being a curable disease, tuberculosis (TB) can nevertheless be a stigmatizing sickness, owing to people's lack of understanding of its causes and spread. Every year, millions of people with tuberculosis go undiagnosed, untreated, or unreported. Unless we reach these people, we will never be able to end the global tuberculosis epidemic [9].

Aims and objectives: Assessment of Performance, Response, and Outcome of Treatment Provided under NTEP in the DOTS Centre of DTC in District Hospital, Sagar (M.P.).

MATERIAL AND METHODS

This prospective longitudinal study was conducted in the Department of Community Medicine of Bundelkhand Medical College, associated with the District Tuberculosis Centre (DTC), Sagar, Madhya Pradesh, India, from 1st January 2023 to 31st March 2023. A total of 150 patients registered in DTC during this study period were enrolled.

Inclusion criteria:

i.   TB patients who were newly registered at the DOTS Centre of DTC in Sagar (M.P.)
ii.   Patients who gave consent were interviewed for the study.

Exclusion criteria:

i.   TB patients who were critically ill.
ii.   TB patient who doesn't want to participate in the study.

iii.   Patients who received TB therapy at private clinics/hospitals.

iv.   Patients on non-DOTS treatment regimens.

v.   Patients who were diagnosed as MDR/XDR

The Institutional Ethical Committee of Bundelkhand Medical College in Sagar (M.P.) granted the study ethical clearance. Number of registration ECR/1252/Inst/MP/2019 Socio-demographic characteristics (e.g., age, gender, family type, socioeconomic class, occupation, education, and residential status), related risk factors (a history of addiction, HIV, diabetes, or tuberculosis in the family), treatment outcomes and follow-up, and factors influencing patient compliance were all collected through in-depth interviews using a pro forma that had previously been developed and tested.

The NTEP includes guidelines for administering a multi-drug regimen in fixed-dose combinations (FDCs) based on weight band to TB patients who are under the direct supervision of a trained treatment supporter and/or digital adherence technology. Treatment results should be tracked using "cured," "completed," "failed," "lost to follow-up," "successful," "not evaluated," "dead," or "transferred out" as monitors.

Statistical analysis: The data was examined using SPSS software, version 24. While numbers and proportions (%) were used to represent categorical variables, the mean and standard deviation (SD) were used to represent continuous variables. The independent t-test and the chi-square test, sometimes referred to as Fischer's exact test, were used. A P-value was considered significant if it was less than 0.05.

RESULTS

Out of a total of 150 study patients, the majority of them (65.3%) were male, and the most common age group was 21–30 years (22%). Most of them (60%) were from urban areas; 30% were illiterate, 44.1% were laborers, and 35.3% belonged to the lower-middle class. The common risk factors of tuberculosis were overcrowding (65.3%), diabetes mellitus (54%), addiction history (46%), family history of tuberculosis (22%), and HIV (2%). [Table: 1].

Table 1: Predisposing factors and associated comorbidities among study subjects

Predisposing factors or comorbidities	Frequency	Percentage

Overcrowding	Present	98	65.3%
	Absent	52	34.7%
Addiction History	Present	69	46%
	Absent	81	54%
Diabetes mellitus	Present	81	54%
	Absent	69	46%
HIV	Present	3	2%
	Absent	147	98%
Family history of Tuberculosis	Present	33	22%
	Absent	117	78%

Among the total TB cases, 88 (59%) were cured, and 41 (27%) completed treatment. 05 (3.4%) were lost to follow-up, 08 (5.3%) were not evaluated, 06 (4%) died, and 02 (1.3%) were treatment failures [Graph: 1].

Graph 1: Treatment outcome among study participants
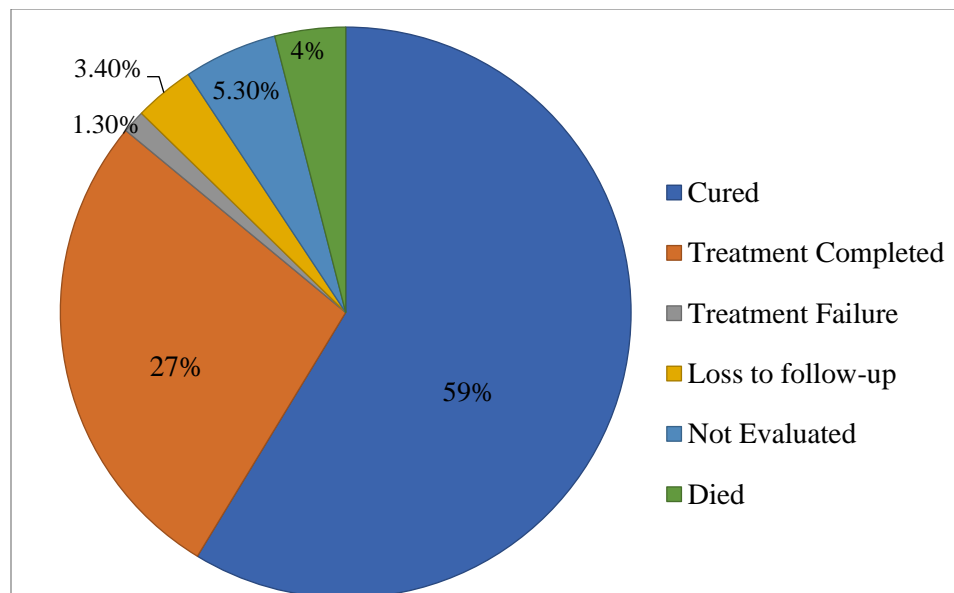
In our study, the educational status of patients, socio-economic status, presence of addiction, and presence of diabetes mellitus among tuberculosis patients was not significantly associated with the final outcome of treatment (P > 0.05), whereas type of family, presence of family history of tuberculosis, and presence of HIV were significantly associated with the final outcome of treatment. (P < 0.05) [Table: 2].

Table 2: Distribution of study participants according to predisposing factors & their final outcome of treatment

| Predisposing factors		Outcome of treatment					
		Cured	Treatment Completed	Treatment Failure	Loss to follow up	Not Evaluated	Died
Education	Illiterate	24 (27.3%)	14 (34.1%)	0 (0%)	1 (20%)	3 (37.5%)	3 (50%)
	Primary school	13 (14.8%)	6 (14.6%)	1 (50%)	3 (60%)	1 (12.5%)	1 (16.7%)
	Secondary school	45 (51.1%)	17 (41.5%)	1 (50%)	0 (0%)	3 (37.5%)	2 (33.3%)
	Graduate	6 (6.8%)	4 (9.8%)	0 (0%)	1 (20%)	1 (12.5%)	0 (0%)
Socio-Economic Status	Lower	53 (60.2%)	27 (65.8%)	0 (0%)	4 (80%)	6 (75%)	6 (100%)
	Middle	19 (21.6%)	7 (17.1%)	1 (50%)	0 (0%)	1 (12.5%)	0 (0%)
	Upper	16 (18.2%)	7 (17.1%)	1 (50%)	1 (20%)	1 (12.5%)	0 (0%)
Type of Family	Nuclear	22 (25%)	7 (17.1%)	2 (100%)	0 (0%)	1 (12.5%)	0 (0%)
	Joint	66 (75%)	34 (82.9%)	0 (0%)	5(100%)	7 (87.5%)	6 (100%)
Family H/O TB	Present	20 (22.7%)	5 (12.2%)	0 (0%)	1 (20%)	2 (25%)	5 (83.3%)
	Absent	68 (77.3%)	36 (87.8%)	2 (100%)	4 (80%)	6 (75%)	1 (16.7%)
Addiction history	Present	43 (48.9%)	15 (36.6%)	1 (50%)	2 (40%)	3 (37.5%)	5 (83.3%)
	Absent	45 (51.1%)	26 (63.4%)	1 (50%)	3 (60%)	5 (62.5%)	1 (16.7%)
Diabetes	Present	43 (28.7%)	23 (15.3%)	1 (0.66%)	3 (2%)	6 (4%)	5 (3.33%)
	Absent	45 (30%)	18 (12%)	1 (0.66%)	2 (1.33%)	2 (1.33%)	1 (0.66%)
HIV	Positive	0 (0%)	1 (0.66%)	1 (0.66%)	0 (0%)	0 (0%)	1 (0.66%)
	Negative	88 (58.7%)	40 (26.7%)	1 (0.66%)	5 (3.33%)	8 (5.33%)	5 (3.33%)

Sixty percent of newly diagnosed sputum smear-positive patients were cured, twenty-three percent finished treatment, one-sixth failed treatment, four percent were lost to follow-up, six percent were not examined, and four percent passed away while undergoing treatment. Therefore, 83.2% of newly diagnosed sputum-positive patients had a successful course of therapy. The treatment success rate for new smear-negative patients was 100% since all of them finished their course of treatment. The treatment success rate for retreatment cases was determined to be 100%, with 80% of the patients curing and 20% finishing treatment. The final treatment success rate of pulmonary TB cases was 111 (84.08%). Among extra-pulmonary patients, 50% were cured, and 50% completed their treatment. Thus, the treatment success rate of extra-pulmonary TB cases was 100% [Table: 3].

Table 3: Treatment outcome in study participants according to clinical type

Type of study participants		Cured	Treatment Completed	Treatment failure	Loss to follow up	Not evaluated	Died
Pulmonary	New Smear positive (125)	75 (60%)	29 (23.2%)	2 (1.6%)	5 (4%)	8 (6.4%)	6 (4.8%)
	New Smear negative (2)	0 (0%)	2 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	Retreatment (5)	4 (80%)	1 (20%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Extra-Pulmonary (18)		9 (50%)	9 (50%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Various regions for noncompliance to tubercular treatment were not feeling well (60%), unaware of the importance of a full, long course of treatment (80%), had time strain problems/loss of wages (60%), felt side effects of multiple drugs (40%), and had some other reason (20%). [Graph: 2].

Graph 2: Causes of Non- compliance among study participants
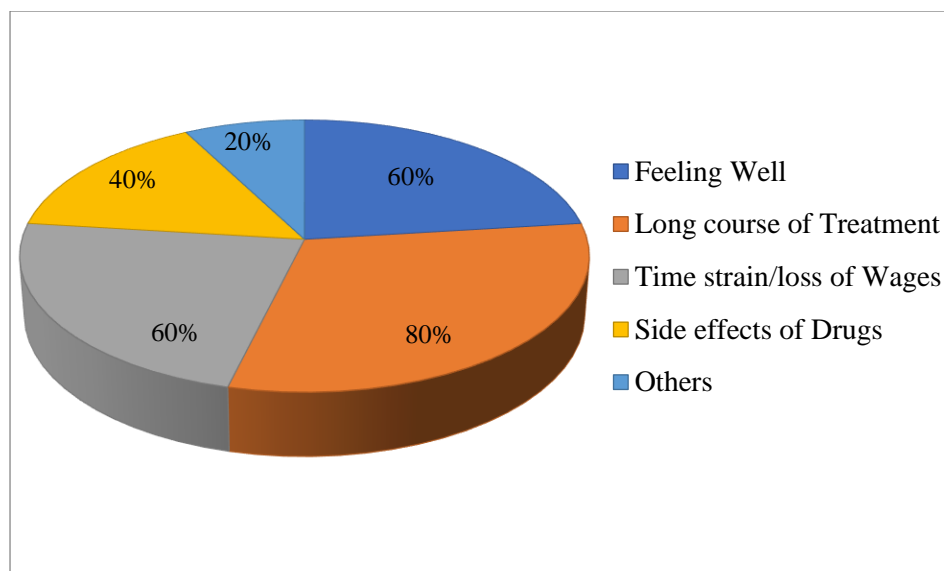
DISCUSSION

In 2014, India's NTEP began employing daily medication dosing for all drug-susceptible TB patients instead of the prior thrice-weekly dosing regimen. This shift raised concerns about the additional burden of patients visiting clinics daily instead of three times a week. The NTEP has therefore changed from DOTS to either self-administered therapy [SAT] or monitoring with DOTS. Since the treatment pattern has changed from DOTS to a daily dosing schedule, it is critical for a healthcare professional to be able to confirm that a patient is taking their medications as prescribed [10].

In our study, the majority of the patients were in the 21-30 years age group, predominantly males, similar findings were observed by P. Uday kumar et al. [11] and Kaur M. et al. [12]. The age and gender difference of the patients was in accordance with the epidemiology of TB.

We have found that the overcrowding, diabetes mellitus, addiction history, family history of tuberculosis, and HIV were the common predisposing factors of tuberculosis, in agreement with Jethani S. et al. [13] and Sadiq S. et al. [14].

The treatment success rate (cure rate plus treatment completion rate) of new sputum smear-positive TB patients was 83.2% in current research, concordant with the NTEP guidelines-2024 [15], which reported that in a well-performing area, the treatment success rate was 80-85%.

According to the TB India report 2023 [16], the treatment outcome report of TB patients notified in 2021 in Madhya Pradesh, in which 84.7% had been successfully treated.

In the present study, the overall compliance rate was 96.66%. Our results are comparable with Srivastava et al. [17] and Upadhyay et al. [18], who also found compliance rates of 86.33% and 86.33%, respectively. This may be due to differences in working conditions.

In our study, the educational status of patients, socio-economic status, presence of addiction, and presence of diabetes mellitus among tuberculosis patients were the common reasons for noncompliance but were not associated significantly (P > 0.05). Our findings correlate with Sharma D, et al. [19].

We have observed that type of family, presence of family history of tuberculosis, and presence of HIV were significantly associated with the final outcome of TB treatment, consistent with Azeez A, et al. [20] and Prajapati AC, et al. [21]. It is a known fact that overall unsuccessful outcomes in TB–HIV co-infection are high.

The main reasons for noncompliance to tubercular treatment were not feeling well, being unaware of the importance of a full-length course of treatment, time strain problems/loss of wages, and feeling side effects of ATT drugs. Similar results were reported by other studies: Subbaraman et al. [22] and Thamineni R, et al. [23]. The main reasons for non-adherence to ATT stated by patients were ATT side effects, loss/missing daily wages, forgetting to take medications, being too busy with other tasks, and being out of town or home.

CONCLUSION

Despite the greater treatment success rate, we concluded that the lack of conversion to follow-up and treatment failure serves as a warning on how to prevent even one case of MDR/XDR TB. Since the most common causes for non-adherence were ATT side effects, loss of missed daily wages, forgetting to take drugs, and ignorance of the risks of TB, it remains challenging for patients and service providers to appropriately follow up after the whole course of DOTS treatment.

CONFLICTS OF INTEREST

None

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