

# A STUDY OF OUTCOME OF MICROBIOLOGICALLY CONFIRMED DRUG SENSITIVE PULMONARY TUBERCULOSIS PATIENTS (NEW AND PREVIOUSLY TREATED) ON DAILY SHORT COURSE REGIMEN UNDER NTEP 2019 GUIDELINES

## Respiratory Medicine

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## ABSTRACT

The present study was conducted to evaluate the outcome of microbiologically confirmed Pulmonary Tuberculosis patients (New and Previously Treated) and to assess the success of the new introduced drug sensitive TB regimens for both new and previously treated cases. **Results:** Cured and treatment completed was reported among 60.6%, 30.5% and 39.5%, 47.4% of the subjects in new and previously treated cases respectively. Treatment failure was revealed more in previously treated cases (10.5%) as compared to new cases. One case in previously treated group was expired. **Conclusion:** The low treatment success rate among patients with in previously treated category can be further improved by studying the factors influencing the same comprehensively. Since the failure cases have been significantly higher in previously treated category, treatment schedule for such cases requires rethinking and reconsideration to have higher successful results.

## KEYWORDS

Mycobacterium tuberculosis; DSTB; New cases; Previously treated case; Cured; Treatment completed

## INTRODUCTION

The Mycobacterium tuberculosis (MTB) bacterium is the infectious agents responsible for tuberculosis (TB). The causative agent of tuberculosis, was first described by Robert Koch on March 24, 1882.<sup>[1]</sup> Worldwide, tuberculosis (TB) accounts for the vast majority of infectious mortality.<sup>[2]</sup> Around 2.7 million (27%) of the 10 million predicted global cases in 2017 occurred in India.<sup>[3]</sup>

People with active tuberculosis in their lungs can transmit the disease to others by their cough, spit, speech, or sneezing.<sup>[4]</sup> There is no transmission of tuberculosis from people who have latent TB. Immunocompromised individuals and smokers have a higher risk of active infection.

In addition to a persistent cough that may produces blood in sputum, active pulmonary tuberculosis is characterized by a high temperature, nocturnal sweats, and a loss of appetite.<sup>[5]</sup> It was also known as consumption in past because it was associated with weight loss.<sup>[6]</sup> Depending on the organ involvement, patient may experience a wide range of symptoms.<sup>[7]</sup>

Starting with a two-month course of Isoniazid (H), Rifampicin (R), Pyrazinamide (Z), and Ethambutol (E) for both new and previously treated cases, followed by Isoniazid (H), Rifampicin (R) and Ethambutol (E) for four months of daily dosing for all drug-sensitive patients (DSTB), is the recommended medication regimen as per NTEP. The purpose of this research was to examine the effectiveness of the NTEP treatment protocol for drug-sensitive tuberculosis in both newly diagnosed and previously treated individuals.

## Aim and Objectives

- To study the outcome of Microbiologically confirmed Pulmonary Tuberculosis patients (New and Previously Treated) under NTEP 2019 guidelines.
- To assess the success of the new introduced drug sensitive TB regimens for both new and previously treated cases.

## Literature Review

### Epidemiology

#### Global Tb Burden: Who 2021 Factsheet.<sup>[8]</sup>

Worldwide, tuberculosis is estimated to affect 9.9 million people in 2020 (8.9-10.9 million), with 5.5 million men, 3.3 million women, and 1.1 million children affected. People living with HIV made up 8% of that total.

Only eight countries—China, Bangladesh, India, Pakistan,

Philippines, Nigeria, South Africa and Indonesia—contributed half of the global total. Among the 1.5 million people killed by tuberculosis in 2020, 2,14,000 were HIV positive. The global tuberculosis (TB) case-per-100,000-person-year drop was 1.9% between 2015 and 2020, for a total decline of 11%.

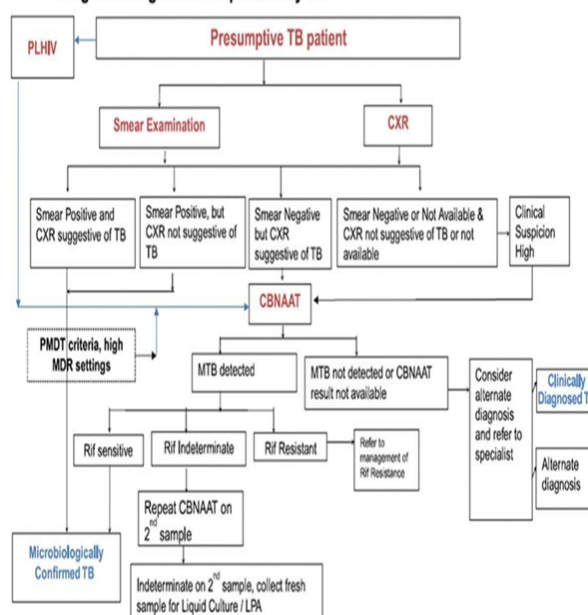
## TB Burden in India:

The Global TB Report 2021 projected that tuberculosis (TB) incidence was 188 per 1,00,000 Indians in 2020, with a range of 129 to 257 cases per 100,000 people. There was a 19% increase from 2020 to 2021 in the number of tuberculosis cases that were reported, including both new and relapsed cases, totalling 19,33,381.<sup>[9]</sup>

## Algorithm for pulmonary TB.<sup>[10]</sup>

As per NTEP guidelines, the presumptive TB patients should be diagnosed for TB and drug resistance as per the diagnostic algorithm.

### Diagnostic algorithm for pulmonary TB



## Drug Regimen: Ntep 2019 Guidelines

New cases: 2(HRZE) → 4(HRE)

**Previously treated cases:** 2(HRZE) → 4(RHE)

All drug-sensitive tuberculosis (DSTB) patients are treated with a combination of isoniazid (H), rifampicin (R), pyrazinamide (Z), and ethambutol (E) for two months in newly diagnosed and previously treated patients, and isoniazid (H), rifampicin (R) and ethambutol (E) for four months daily.

**The patients who were put on treatment, their outcome is evaluated as<sup>[11]</sup>**

1. **Cure** is a Pulmonary TB patient with bacteriologically confirmed TB at the beginning of treatment who was smear- or culture-negative in the last one previous occasion.

2. **Treatment completed** is a TB patient who completed treatment without evidence of failure but with no record to show that sputum smear or culture results in the last month of treatment and on at least one previous occasion were negative, either because tests were not done or because results are unavailable.

3. **Treatment success** is the sum of cured and treatment completed.

4. **Treatment failure** is a TB patient whose sputum smear or culture is positive at month 5 or later during treatment.

5. **Death** is outcome of a TB patient who dies for any reason before starting or during the course of treatment.

6. **Lost to follow-up** is a TB patient who did not start treatment or whose treatment was interrupted for 2 consecutive months or more.

7. **Not evaluated** is a TB patient for whom no treatment outcome is assigned. This includes cases "transferred out" to another treatment unit as well as cases for whom the treatment outcome is unknown to the reporting unit.

## MATERIALS AND METHODS

This was a prospective study carried out in the Department of Respiratory Medicine, K.D Medical College, Hospital And Research Center, Mathura on Pulmonary TB patients registered under DOTS as New and previously treated cases under NTEP guidelines 2019.

### Sample Selection:

#### 1. Inclusion Criteria:

Pulmonary tuberculosis patients registered as new cases and previously treated cases in department of Respiratory Medicine at K.D Medical College, Hospital and Research Center, Mathura.

#### 2. Exclusion Criteria:

- 1) Extra Pulmonary Tuberculosis
- 2) Patients below 18 years of age
- 3) Patients on treatment from private sector for Pulmonary Tuberculosis.
- 4) HIV positive patients
- 5) Pregnant and lactating women
- 6) Drug resistant TB Cases who are resistant to R, H or both in the beginning of treatment

### Following investigations was performed in this study:

- i) Hb
- ii) TLC
- iii) DLC
- vi) RBS/FBS
- v) HIV
- vi) Chest x ray:
- vii) Sputum ZN Staining:
- viii) Sputum for CBNAAT:

### Methodology:

A prospective study was carried out on Pulmonary TB patients registered under DOTS as New and previously treated cases under NTEP guidelines 2019.

The study was conducted during the period from 2022 to 2024. Detailed history including past history of Anti-Tubercular drugs were recorded after taking written and informed consent and detailed systemic examination was carried out. Sputum was send for Zn staining and CBNAAT before initiation of treatment. Periodic Zn

staining was done at 2 months and 6 months to assess the treatment response. Based on the results of ZN staining at the end of treatment, patient was assigned outcome as cure, treatment completed, treatment failure, death, lost to follow-up and Not evaluated.

## RESULTS

### 1. Gender distribution

Males were comparatively more as compared to females among both the groups.

### 2. Mean age

Mean age among the new and previously treated cases was 30.605 and 38.474 years respectively. Hence mean age was more in previously treated cases as compared to new cases with statistically significant difference as  $p < 0.05$ .

### 3. Smoking

Smoking was revealed more in previous treated cases (39.5%) as compared to new cases (21.1%), though no significant difference was found.

### 4. Symptomatology

Fever, cough, significant weight loss and hemoptysis was reported among 92.1%, 84.2%, 52.6%, 21.1% and 100%, 92.1%, 73.7%, 23.7% of the subjects in new and previously treated cases respectively. Hence significant weight loss was reported more in previously treated cases as compared to new cases with statistically significant difference as  $p < 0.05$

### 5. Blood investigations

Mean Hemoglobin and TLC among the new and previously treated cases was 10.28, 13.07 and 9.73, 13.19 respectively. Mean Hemoglobin and TLC was comparable among the study groups as  $p > 0.05$ .

### 6. Radiological extent of lesions

Only 1.3% of the subjects were having no lesions. Minimal, moderate and advance lesion was revealed only in 1.3%, 40.8%, 40.8% and 17.1% of the subjects respectively. Minimal, moderate and advance lesion was found to be comparable in new and previously treated cases as  $p > 0.05$ .

### 8. Outcome

Cured and treatment completed was reported among 60.6%, 30.5% and 39.5%, 47.4% of the subjects in new and previously treated cases respectively. Treatment failure was revealed more in previously treated cases (10.5%) as compared to new cases. One case in previously treated group was expired. Hence treatment outcome was better in new cases as compared to previously treated cases with statistically significant difference as  $p < 0.05$ .

## DISCUSSION

Cure rate, or the percentage of patients whose tuberculosis infection has been successfully eradicated confirmed by microbiological testing, is a measure of the efficacy of anti-tuberculosis treatment. As an additional measure of success, treatment must be continued until the stated end point. In order to reduce tuberculosis (TB) prevalence, the World Health Organization (WHO) states that a success rate of 85% is required. Accordingly, no more than 15% should be the combined rates of mortality, failure, and default.<sup>[12]</sup>

For newly treated instances, 60.6% of patients reported being cured, while for previously treated cases, the corresponding percentages was 39.5%. Treatment completed was assigned in 30.5 in new and 47.7 in previously treated cases respectively. There was a higher rate of treatment failure in cases that had already been treated (10.5%) compared to fresh cases. The previously treatment group had one case that had already expired. There was a statistically significant difference ( $p < 0.05$ ) between the treatment outcomes of new cases and previously treated cases, suggesting that the former had superior results.

In our study, 2.6% default rate among new cases is in line with other studies reported rates of 6–8%.<sup>[13]</sup> In order to improve the success of the tuberculosis control plan, it is necessary to completely eradicate this by inspiring the patient and also by effectively implementing DOTS.

The overall success rate was 88% in research conducted by Rani P et al.<sup>[14]</sup> Class I patients had a 92% success rate and category II patients an

84% success rate, both of which were more than the national average. Category I patients had better outcomes than category II patients.

## CONCLUSION

Further improvement of the poor treatment success rate among patients in the previously treated category can be achieved by detailed analysis of the factors influencing the same. Research on the most effective ways to address social determinants such as poverty, HIV/AIDS, and other similar issues should continue. In order to scale the programme even further and make it more effective, it is possible to assess the different adherence measures that have been put in place. Rethinking and reconsidering the treatment schedule for previously treated cases is necessary to increase the success rate, since there has been a considerable increase in failure cases in this category.

## REFERENCES

1. History: World TB Day. Centers for Disease Control and Prevention (CDC). 12 December 2016. Available from: <https://www.cdc.gov/tb/worldtbdays/history.htm>.
2. Alemu Abajobir A, Hassen Abate K, Abbafati C, Abbas KM, Abd-Allah F, Suliankatchi Abdulkader R, et al. Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990–2016: A systematic analysis for the Global Burden of Disease Study 2016. *Lancet* 2017;390:1211–59.
3. World Health Organization. Global Tuberculosis Report. 2018. Available from: <https://www.who.in>.
4. Basic TB Facts. Centers for Disease Control and Prevention (CDC) 2012. Available from: <https://www.cdc.gov/tb/about/index.html>.
5. World Health Organization, Stop TB Initiative (World Health Organization). Treatment of tuberculosis: guidelines. World Health Organization; 2010.
6. The Chambers Dictionary. New Delhi: Allied Chambers India Ltd. 1998. p. 352.
7. Bennett JE, Dolin R, Blaser MJ. Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases E-Book: 2-Volume Set. 9<sup>th</sup> ed. Philadelphia : Elsevier; 2010: p3022–34.
8. Factsheet Global TB report. World Health Organization. 2021. Available from: <https://www.who.in>.
9. TB annual report India. 2022 Available from: <https://tbcindia.gov.in>.
10. TOG chapter 3. Central Tuberculosis division Government of India. Ministry of Health & Welfare. Technical and Operational Guidelines for TB Control in India: 2016, Available from: <https://www.tbcindia.gov.in>.
11. TRAINING MODULES (1-4) FOR PROGRAMME MANAGERS AND MEDICAL OFFICERS; New Delhi, India: Central TB Division, MoHFW, Government of India; July 2020., Available from: [www.tbcindia.gov.in](http://www.tbcindia.gov.in)
12. WHO Fact Sheet TB 2021. Available from: <https://www.who.in>.
13. Joseph N, Nagaraj K, Bhat J, Babu RY, Kotian SM, Ranganatha YP, et al. Treatment outcomes among new smear positive and retreatment cases of tuberculosis in Mangalore, South India—a descriptive study. *Australas Med J*. 2011;4(4):162–7.
14. Rani P, Bansal SK, Ahir GC, Gupta S. Evaluation of Treatment Outcome of Pulmonary Tuberculosis Patients on Category I And Category II DOTS. *J Adv Med Dent Sci Res*. 2017;5(2):74.