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Effectiveness of DOTS Policy in Attaining Treatment Success in Pulmonary TB Patients: Lessons from a Tertiary Care Hospital in South India

M. Anto Joel Roy[1]; S. Sudharsan[1]; P. Mahendravarman[2]; Dr. C. Karthick[3]

[1]Department of Pharmacy, Annamalai University, Chidambaram.
[2]Assistant Professor, Department of Pharmacy, Annamalai University, Chidambaram.
[3]Senior Resident, Department of TB and Chest, Government Medical College and Hospital (GCMCH), Chidambaram

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Abstract: Tuberculosis (TB) continues to be a serious problem around the globe, and India is responsible for almost 27% of the world's total number of cases of TB. A prospective and observational study conducted in this regard to determine the therapeutic outcomes of 39 PTB patients receiving treatment with DOTS regimen in the Department of TB and Chest, Government Cuddalore Medical College and Hospital (GCMCH), Chidambaram, from October 2024 to March 2025. All the patients received standard drugs for DOTS including Isoniazid, Rifampicin, Pyrazinamide, and Ethambutol during the initial intensive period, whereas Isoniazid and Rifampicin during the subsequent continuation period. The majority of subjects involved in this study were male (77%) and aged between 50 and 60 years. A remarkable symptomatic improvement was observed after the completion of the initial intensive period, while 100% clinical, microbiological, and radiological cure was observed at the end of the subsequent continuation period. There was no default, failure, or relapse in treatment. Any kind of gastrointestinal side effect experienced was cured with Ondansetron and Omeprazole.

Keywords: *Pulmonary Tuberculosis; DOTS Therapy; Treatment Outcomes; NTEP; Sputum Conversion; Radiological Improvement.*

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I. INTRODUCTION

Tuberculosis constitutes a huge health challenge in the world, particularly among developing countries like India. Despite the advances in medical science, TB continues to pose significant morbidity and mortality threats. In an attempt to deal with this health challenge, the World Health Organization introduced the DOTS approach to ensure effective treatment and minimize the spread of this disease. This research study focuses on evaluating the outcome of treating pulmonary tuberculosis using the DOTS approach. This clearly shows that there is a need to monitor and improve the treatment methods [1].

There is a need to monitor the outcome of treatment of pulmonary tuberculosis through the DOTS approach to establish whether it is achieving success or not. Treatment outcomes can be divided into cured, treatment completed, treatment failure, deaths, defaulters, and transfers.

The outcomes achieved through the DOTS treatment approach have been investigated by several studies conducted in India. According to a study that was conducted in Chandigarh, there were 98.6% success among patients who belonged to Category I and 90.4% success among Category II patients [2]. However, despite the successful results achieved by the DOTS program, there still exist some issues, including MDR-TB, patient non-compliance, stigma, and lack of knowledge on the part of patients.

- *Importance of Studying Treatment Outcomes in Pulmonary TB*

Study of results following treatment of pulmonary tuberculosis is crucial to evaluate the effectiveness of treatment methods and the impact that this condition has on

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the well-being of affected individuals. Determining factors of successful and unsuccessful treatment is facilitated by outcome evaluation, contributing to enhancement of tuberculosis control strategies.

Usage of high-resolution computed tomography (HRCT) has been critical for assessment of pulmonary tuberculosis. Absence of distinctive radiological findings, such as the "tree-in-bud" pattern and presence of fibrosis, indicates effective treatment of tuberculosis [4]. Understanding the influence of treatment on tuberculosis also provides useful information related to possible recurrence, as post-treatment findings suggest higher chances of tuberculosis recurrence [6].

- *Global and National Burden of TB*

As per the latest figures provided globally, tuberculosis is still a major public health problem with 10.6 million new cases in just one year. Mortality from TB is still a big issue, with 1.3 million people dying without being HIV-positive and an extra 167,000 deaths in HIV-positive patients. The incidence rate of TB globally is 134/100,000.

Table 1 Global TB Burden (2022)

INDICATOR	ESTIMATE
Total TB Cases Worldwide	10.6 Million
TB-Related Deaths	1.3 Million (HIV-Negative) + 167,000 (HIV-Positive)
TB Incidence Rate	134 per 100,000 Population
Drug-Resistant TB (MDR/RR-TB)	410,000
TB Cases Among People with HIV	703,000
Countries with Highest Burden	India, Indonesia, China, Philippines, Pakistan, Nigeria, Bangladesh, DR Congo, Ethiopia, Vietnam

India bears the maximum load of tuberculosis, making up 2.8 million cases (27% of the total number of TB patients worldwide). The second country is Indonesia, where there are 969,000 TB patients (9%), while China holds third place, with 780,000

Table 2 TB Burden in India (2022)

INDICATOR	ESTIMATE
Estimated TB Incidence	2.8 Million
TB Incidence Rate	196 per 100,000
Total TB Deaths (Excluding HIV)	~312,000
MDR/RR-TB Cases	119,000
Treatment Success Rate (All Forms)	80%
Notified TB Cases	2.42 Million
Private Sector TB Notifications	~37% of Total Cases

Table 3 Top 5 High TB Burden Countries (2022)

COUNTRY	TB INCIDENCE (MILLIONS)	GLOBAL SHARE (%)
India	2.8	27%
Indonesia	0.969	9%
China	0.780	7%
Philippines	0.741	7%
Pakistan	0.620	6%

II. PROFILE OF TUBERCULOSIS

Tuberculosis is a contagious infection caused by Mycobacterium tuberculosis, an acid-fast rod that can infect any part of the body, though more commonly affects the lungs. TB continues to pose a major public health issue throughout the world, particularly in developing nations.

Table 4 Types and Characteristics of Tuberculosis

TYPE	CHARACTERISTICS
Pulmonary TB	Affects the lungs; most commonly contagious
Extrapulmonary TB	Involves organs like lymph nodes, CNS
Miliary TB	Disseminated form; multiple organ systems
Latent TB Infection	No symptoms; non-contagious
Drug-Resistant TB	MDR-TB, XDR-TB forms with treatment failure

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➢ *Etiology*

The main organism causing tuberculosis is M. tuberculosis that belongs to the group called M. tuberculosis complex, which includes both M. bovis and M. africanum [12]. M. tuberculosis is an aerobe, nonmotile, slowly growing rod with a thick cell wall containing lipids in form of mycolic acids that make M. tuberculosis resistant to desiccation and disinfection as well as to host defense mechanisms [13]. The transmission occurs through inhalation of aerosol droplets produced by someone who already suffers from active pulmonary tuberculosis while sneezing, coughing, or even speaking [14].

➢ *Pathophysiology*

When M. tuberculosis bacteria are inhaled into lungs, they reach the alveoli and get phagocytosed by the alveolar macrophages there. Instead of killing bacteria, macrophages are unable to destroy them due to the fact that bacilli inhibit phagosomes' fusion with lysosomes [15]. It causes the formation of granulomas in combination with recruiting other immune cells to fight against the infection. However, during latent TB infection (LTBI), the bacteria remain dormant inside granulomas for many years without developing any clinical symptoms. Only 10% of people will ever become sick [16].

➢ *Clinical Manifestations*

TB usually causes symptoms that are general, such as fever (fever comes and goes but more prominent at night time), night sweats, weight loss, tiredness, and poor appetite. If one gets pulmonary TB, the symptoms include chronic cough, hemoptysis, chest pain, and breathing difficulty.

Table 5 Common Symptoms of Pulmonary TB

SYMPTOMS	DESCRIPTION
Chronic Cough	Lasting more than three weeks
Hemoptysis	Coughing up blood
Chest Pain	Especially during breathing or coughing
Fever	Persistent low-grade fever
Night Sweats	Excessive sweating during the night
Weight Loss	Unintentional and significant
Fatigue	Persistent tiredness

III. DIRECTLY OBSERVED TREATMENT, SHORT-COURSE (DOTS)

Nevertheless, tuberculosis remains one of the most critical infectious diseases across the globe. To prevent its propagation and ensure adequate treatment, WHO launched the DOTS approach in the early 1990s. The approach is based on directly observed therapy and has been shown to be effective in a variety of countries. Various studies have supported the positive influence of DOTS on the results of TB treatment. According to the findings of a retrospective study conducted in Ethiopia, the treatment success rate amounted to 83.1% for TB patients [Genet et al., 2019].

➢ *Fundamental Elements of DOTS*

There are five main elements involved in DOTS:

- Political and administrative commitment - provision of finances and commitment
- Case detection by quality-assured bacteriology - primarily by means of sputum smear microscopy
- Standardized short-course chemotherapy with directly observed therapy – patient compliance
- Assured supply of quality assured anti-TB drugs
- Surveillance and monitoring mechanisms

Table 6 Comparison of DOTS and Self-Administered Therapy

	DOTS	SELF-ADMINISTERED THERAPY
Supervision	Direct Observation	No Supervision
Adherence Monitoring	High	Variable
Drug Resistance Risk	Lower	Higher
Cure Rate	Higher	Lower

➢ *Anti-Tuberculosis Drug Regimens*

Drug regimens are categorized according to their susceptibility to drugs. In the case of DS-TB, the recommended regimen for 6 months is that involving an intensive period of 2 months using drugs H, R, Z, and E, followed by a continuation period of 4 months using H and R (2HRZE/4HR). For MDR/RR-TB, the recommendation is a regimen known as BPaLM (Bedaquiline, Pretomanid, Linezolid, and Moxifloxacin) for 6 months.

Table 7 Anti-Tuberculosis Drug Regimen

TB Type	Duration	Drugs Involved
Drug-Susceptible TB	6 months	Isoniazid, Rifampicin, Pyrazinamide, Ethambutol
Drug-Susceptible TB	4 months	Isoniazid, Rifapentine, Streptomycin, Pyrazinamide
MDR/RR-TB	6 months	Bedaquiline, Pretomanid, Linezolid, Moxifloxacin
MDR/RR-TB	9 months	All-Oral Regimen excluding Fluoroquinolones

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Table 8 Doses of Anti-Tuberculosis Drugs for Children and Adults

Drug (Abbreviation)	Daily Dose mg/kg (Range)	Intermittent Dose mg/kg (3×/week)
Ethambutol (E)*	20 (15–25)	30 (25–35)
Rifampicin (R)	10 (8–12)	10 (8–12)
Isoniazid (H)	5 (4–6)	10 (8–12)
Pyrazinamide (Z)	25 (20–30)	35 (30–40)
Streptomycin (S)	15 (12–18)	15 (12–18)

➢ *NTEP and RNTCP*

The National Tuberculosis Elimination Program (NTEP) is the most significant public health program for the elimination of tuberculosis in India by the year 2025, five years ahead of the international SDG target of 2030 [32]. Formerly known as Revised National Tuberculosis Control Program (RNTCP), the name was changed in 2020 from the Ministry of Health & Family Welfare. DOTS through NTEP is now supported by Nikshay, which keeps track of patient compliance, side-effects, and connects patients to the frontline workers in real-time. Nikshay Poshan Yojana offers Direct Benefit Transfers (DBT) in order to cater to nutritional needs of TB patients.

➢ *Reason for Evaluation of Treatment Outcomes*

Assessment of treatment outcomes is an important part of tuberculosis control under NTEP. Assessment of outcomes will help in determining the effectiveness of intervention for tuberculosis. Evaluation of the results as cure, treatment completed, failed, relapse, or death can be used as feedback for improving policies. It helps in identifying cases that have had treatment failure so that corrective measures such as counseling and switching to second line treatment can be taken immediately. In this way, NTEP provides an effective tool like Nikshay.

IV. AIM AND OBJECTIVES

➢ *Aim:*

To assess the results of treatment in patients suffering from Pulmonary Tuberculosis under DOTS regimen.

➢ *Objectives:*

- To assess the results of treatment in patients suffering from Pulmonary Tuberculosis under DOTS regimen for a certain period.
- To assess the degree of smear culture conversion in both intensive and completion phases.
- To assess the progress of major symptoms such as cough, fever, fatigue, and weight loss in patients undergoing DOTS treatment.
- To assess the influence of treatment on patients' quality of life using standard questionnaires.
- To assess the severity and frequency of adverse drug reactions associated with DOTS treatment regimen.

V. METHODOLOGY

➢ *Study Site:*

Department of TB and Chest, Government Cuddalore Medical College and Hospital (RMMCH), Annamalai University, Tamil Nadu – a 1200-bedded multi-speciality rural tertiary care teaching hospital.

➢ *Study Period:*

6 months (October 2024 – March 2025).

➢ *Study Design:*

Prospective Observational Study.

➢ *Source of Data:*

Case sheets, personal interaction with patients, and questionnaire completion.

➢ *Inclusion Criteria:*

- Patient should be confirmed Pulmonary Tuberculosis patient by chest X-ray, sputum smear microscopy and clinical manifestations.
- Both male and female within age group of 18 to 65 years.
- Patients on DOTS treatment of PTB.
- Patients giving their consent in joining the study.

➢ *Exclusion Criteria:*

- Patients suffering from chronic diseases such as Liver Disease & Renal Failure.
- Patients having co-infection of HIV receiving different medications for TB.
- Pregnant and lactating mothers.
- Patients having MDR-TB and Extrapulmonary TB.
- Patients not able to visit for follow-ups regularly.

➢ *Sample Size:*

Since this is preliminary study so we have not done any formal calculation of sample size. Samples were collected on basis of criteria stated above, and 39 samples were collected as per feasibility of patients.

➢ *Data Analysis:*

Data were entered into Excel sheet and analyzed through various statistical methods such as descriptive statistics and chi square tests to measure significant relationships.

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VI. OBSERVATIONS AND RESULTS

Table 9 Age Group-Wise Distribution

Age Group (Years)	Number Of Patients
18–28	4
28–40	7
40–50	9
50–60	14
60–70	5

➢ *Age Group-Wise Distribution*

The age distribution pattern indicates that the largest number of cases occur among those aged 50-60 years (14 cases), followed by those aged 40-50 years (9 cases), and 28-40 years (7 cases). There is a smaller number of cases among the youngest (18-28 years, 4 cases) and oldest (60-70 years, 5 cases).

Table 10 Gender-Wise Distribution

Gender	Number Of Patients
Male	30
Female	9

➢ *Gender-Wise Distribution*

The total number of participants in this study was 39, wherein males represented 77% (30) and females 23% (9), providing a ratio of 3.3:1 for males to females.

Table 11 Distribution Based on Duration of Cough

Duration Of Cough	Number Of Patients
2 Weeks	21
3 Weeks	7
4 Weeks	8
5 Weeks	3

➢ *Distribution Based on Duration of Cough*

The duration of cough for most of the patients (21) was 2 weeks, which shows that early medical care was sought by most of the patients before their cough became chronic.

Table 12 Distribution Based on Duration of Fever

Duration Of Fever (Days)	Number Of Patients
4	3
5	4
6	4
7	7
8	4
10	3
14	4
15	4
17	1
18	1
20	3
25	1

➢ *Distribution Based on Duration of Fever*

The results indicate that the majority of patients suffered from fever for 6-8 days, with a peak on day 7. Few patients suffered from fever for shorter or longer periods, i.e., 4-5 days or over 17 days.

Table 13 Distribution Based on Confirmation of TB

Confirmation Of Tb	Number Of Patients
Microbiologically Confirmed	23
Clinically Confirmed	14
Clinically and Microbiologically Confirmed	2

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➢ *Distribution Based on Confirmation of TB*

Overall, the diagnosis of the condition was made in 23 patients using microbiological criteria, 14 patients based on clinical criteria with symptoms and imaging, and two patients according to both criteria.

Table 14 Distribution Based on Fixed Dose Combination

Fdc Tablets/Day	Number Of Patients
2 Doses/Day	1
3 Doses/Day	11
4 Doses/Day	21
5 Doses/Day	5

➢ *Distribution Based on Fixed Dose Combination (FDC)*

The majority of subjects (21) took four doses per day, which was as a result of individualized dosing depending on their weight. This shows the personalized nature of treatment for tuberculosis using DOTS.

Table 15 Distribution Based on Chest X-Ray After Intensive Phase

Chest X-Ray Result	Number Of Patients
Negative	32
Positive	7

➢ *Distribution Based on Chest X-Ray After Intensive Phase*

Among those in the intensive period, 32 patients tested negative for the presence of active disease. Seven patients tested positive on their chest X-rays, which implied the possibility of ongoing lung problems needing medical treatment.

Table 16 Distribution Based on Chest X-Ray After Full Therapy

Chest X-Ray Result	Number Of Patients
Negative	39
Positive	0

➢ *Distribution Based on Chest X-Ray After Full Therapy*

Post-treatment, all 39 patients had negative chest X-rays, reflecting a complete response to radiological examination and an indication of successful treatment of their diseases.

Table 17 Distribution Based on Number of Patients Experiencing Symptoms

S.No	Symptom	Before Therapy	After Therapy
1	Cough	39	6
2	Fever	39	5
3	Night Sweat	31	2
4	Weight Loss	35	2
5	Loss of Appetite	37	3
6	Fever at Night	8	1
7	Chest Pain	10	1
8	Breathlessness	35	0
9	Nausea & Vomiting	39	3
10	Abdominal Pain	6	1

➢ *Symptomatic Improvement Before and After Therapy*

The results show there was a considerable decrease in the occurrence of TB symptoms in the treated patients. Before treatment, coughing, fever, night sweats, weight loss, and lack of appetite were common among all subjects. However, the occurrence of the symptoms after treatment dropped to zero. It is worth mentioning that breathlessness occurred in all patients before treatment.

Table 18 Contingency Table for Statistical Association Between Fever at Night and Night Sweat

	Night Sweat: Yes	Night Sweat: No	Total
Fever at Night: Yes	31	0	31
Fever at Night: No	5	3	8
Total	36	3	39

Table 19 Chi-Square Test for Statistical Association Between Fever at Night and Night Sweat

Test	Value	Df	P-Value
Chi-Square (X^2)	12.596	1	<0.001

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➢ *Statistical Association Between Fever at Night and Night Sweat*

A significant statistical relationship exists between night sweats and night fever ($p < 0.001$). Therefore, there is a likelihood that individuals experiencing night fever will definitely experience night sweats, and this supports the symptoms associated with TB.

Table 20 Contingency Table for Statistical Association Between Decreased Appetite and Weight Loss

	Decreased Appetite: Yes	**Decreased Appetite: No**	**Total**
Weight Loss: Yes	35	0	35
Weight Loss: No	2	2	4
Total	37	2	39

Table 21 Chi-Square Test for Statistical Association Between Decreased Appetite and Weight Loss

Test	**Value**	**Df**	**P-Value**
Chi-Square (X^2)	18.446	1	<0.001

➢ *Statistical Association Between Decreased Appetite and Weight Loss*

There exists a very strong correlation between weight loss and lack of appetite ($p < 0.001$). Patients who have decreased appetite have high chances of experiencing weight loss, which is characteristic of symptoms of TB.

VII. DISCUSSION

TB is one of the largest problems faced by countries all around the world, particularly developing countries such as India. According to WHO, there were an estimated 10.6 million TB patients in 2022. In order to control the spread of this infection and provide adequate care to the patients, WHO has introduced the DOTS strategy, which has been shown to be effective through various studies.

In the current study, the age range of 50-60 years old showed a greater incidence rate of pulmonary TB. Out of the total 39 patients, 33 patients had received BCG vaccination. More males (30) were affected by pulmonary TB when compared to females (9), with a ratio of 3.3:1. Patients belonged to low and medium socioeconomic status and had risk factors associated with TB like malnutrition, smoking, etc.

During the initial stage of this study, almost all patients displayed typical signs and symptoms of pulmonary TB, i.e., 100% (39/39) had coughing for more than 2 weeks and fever, 94.8% (37/39) had poor appetite, 79.5% (31/39) had lost considerable amount of weight, and 89.7% (35/39) tested sputum smear positive for AFB.

The standard DOTS therapy including drugs like Isoniazid, Rifampicin, Pyrazinamide and Ethambutol was given to all subjects in the intensive phase. Complaints of gastrointestinal side effects including nausea, vomiting and gastritis occurred in all subjects (100%), but managed effectively using drugs Ondansetron (4 mg) and Omeprazole syrup, without any disruption of treatment. Fatigue and body pain were experienced by 43.5% of the patients, but treated effectively using conservative measures.

Post Intensive phase: Cough significantly relieved in 82.1% of patients; Fever relieved in 78.2%; appetite increased in 74.3%; 30 patients (out of 39) showed conversion to negative sputum smear and culture; Radiological improvement in chest x-rays of 32 patients.

The result after 6 months of treatment showed that there was a cure in all the 39 patients (100%). In addition, there was no recurrence among the patients during the period of the experiment. There was also complete radiological resolution, and no patient reported any side effect or default on treatment.

VIII. CONCLUSION

This paper assessed the effectiveness of the treatment using DOTS for pulmonary tuberculosis. Results from this research support the high level of effectiveness of DOTS and highlight its clinical importance in controlling TB at national and international levels.

The DOTS therapy was effective regarding all observed parameters. The majority of patients experienced significant relief of symptoms even at the intensive treatment phase (within 2 months of treatment). Total elimination of symptoms (chronic cough, fever, weight loss, and night sweating) was noted among all patients at the end of the treatment course. Regarding the radiologic assessment, the improvement was seen in more than 80% of patients at the end of the intensive phase, while 100% of patients experienced this change at the end of the continuation phase. In terms of microbiological parameters, 82% of patients had a positive result after the intensive phase; however, all patients had negative test results at the continuation phase.

Notably, no patient dropped out of the therapy; moreover, no case of treatment failure, relapse, or adverse drug reactions that required stopping the treatment occurred. To conclude, DOTS therapy led to total cure in all patients regarding all parameters observed in Pulmonary TB. DOTS treatment is not just a successful medical treatment but a very effective approach for public health that would make a great impact on the problem of TB if implemented correctly.

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