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## International Journal of Biological & Medical Research

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### Original Article

# Sputum Conversion Rate, Cure Rate and Compliance among patients with Newly Diagnosed Sputum Positive Pulmonary Tuberculosis on DOTS Therapy: A Prospective Study

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#### ARTICLE INFO

##### Keywords:

Directly observed treatment short course (DOTS),  
Revised national tuberculosis control programme (RNTCP),  
Sputum conversion rate

#### ABSTRACT

**Aim:** Sputum smear rate is an operational indicator for the Directly Observed Treatment Short-course (DOTS) strategy of Revised National Tuberculosis Control Programme (RNTCP) in India. Noncompliance to self-administered multi drug tuberculosis treatment regimens is common and is the most important cause of failure of initial therapy and relapse. Hence this study was undertaken with the objectives to assess sputum conversion rate in sputum positive pulmonary tuberculosis during DOTS, to assess the effectiveness of DOTS therapy in achieving cure rate, to assess the compliance of patients receiving DOTS therapy. **Methods:** A Prospective study of 150 new detected sputum smear positive patients were included in the study. Two sputum specimens were examined (spot and early morning) as per the RNTCP guide lines. Follow up of patients was done at day 21, day 60 and day 90 during treatment. **Results:** Sputum conversion at the end of 21 days of treatment was 70.92%, at end of 60 days it was 95.03%, by 90 days it was 99.29%. Default rate of 4.67%, death rate of 1.33% and failure rate of 0.7% was observed in the study. **Conclusion:** DOTS programme is therapeutically effective both for the individual and the community, with rapid sputum conversion rate, cure rate and better compliance.

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### 1. Introduction

Tuberculosis is a major health problem worldwide, in 2008 there were estimated 9.4 million new cases of TB globally, of which 1.98 million (1/5th) were estimated to have occurred in India.<sup>1,2</sup>

Sputum smear-positive pulmonary tuberculosis patients are the most significant source of infection for tuberculosis.<sup>3</sup> Untreated infectious tuberculosis patient is likely to infect 10 to 15 persons annually.<sup>4</sup> When sputum smear-positive patients are initiated on multidrug anti-tuberculosis treatment, there is a multifold reduction in bacillary load expelled in sputum.<sup>5</sup> Patients, who respond, are likely to become smear and culture negative during the course of treatment. Several studies have demonstrated 80 to 90% smear conversion within two to three months of treatment.<sup>6</sup>

Sputum smear examination for acid-fast bacilli during the course of treatment is an essential component of the follow-up of smear-positive tuberculosis (TB) patients. At 2 months follow-up, the sputum examination result is necessary to decide on whether to continue the intensive phase of treatment for 1 month if the result is positive, or to move to the second phase of treatment if the result is negative.<sup>7</sup> The Smear Conversion Rate (SCR) is an operational indicator for the Directly Observed Treatment Short-course (DOTS) strategy of Revised National Tuberculosis Control Programme (RNTCP) in India.<sup>8</sup>

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>9</sup> Hence this study was undertaken with the objectives to assess sputum conversion rate in sputum positive pulmonary tuberculosis during DOTS, to assess the effectiveness of DOTS therapy in achieving cure rate, to assess the compliance of patients receiving DOTS therapy.

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## 2. Materials And Methods

A prospective study was conducted on 150 newly diagnosed sputum smear positive cases enrolled under DOTS therapy (Category I) at Dr. B. R. Ambedkar Medical College Hospital. Patients with any serious complications of TB such as meningitis, disseminated tuberculosis, pericarditis, peritonitis etc. and sputum smear positive relapse, sputum smear positive failure, and sputum smear positive defaulter, HIV positive patients, diabetic patients and patients on Immuno-suppression were excluded from study. The study was conducted during October 2009 to April 2011.

Data was collected by using a preformed and structured questionnaire. Two sputum specimens were examined (spot and early morning) for acid fast bacilli to diagnose new cases as per the new RNTCP guidelines.<sup>10</sup> Sputum positive patients were administered standard regimens of anti-tuberculosis drugs as prescribed under DOTS for a period of 6 months. Two sputum smears were also collected and examined after day 21, day 60 and day 90 during the follow-up. Statistical analysis was computed by Epi-info 6 software. Chi-square test was the test of significance for qualitative data.

## 3. Results

150 newly detected sputum smear positive case were included in the study. In the study majority i.e. 97 (64.7%) were males and 53 (35.3%) were females. 53.3% of cases were in the age group of 21 to 40 years, 15.33% of patients were illiterate and majority 42% lived in slums. 39.33% of TB patients were in the 3+ sputum positivity grade (Table 1).

Sputum conversion rate among 141 subjects (excluding Default and Dead) at the end of 21 days of treatment was 70.92%, at the end of 60 days 95.03% and at end of the 90 days 99.29% (Table 2)

In the study 140 (93.33%) patients were cured by the end of 90 days of DOTS therapy (Male-92.78%, Female-94.33%). Default rate was 4.67%. Failure rate was 0.66% and Death Rate was 1.33% (Table 3). 7 (4.67%) patients defaulted during the intensive phase of treatment. Default Rate among male was 5.15% and among female 3.77. There was no statistical significance between males and females.

## 3. Results

Table 1: Profile of TB patients

Profile of TB Patients	n=150 (Mean ± SD) n=30	n=150	Percentage
Sex	Male	97	64.7 %
Age	Female	53	35.3 %
	< 20 years	17	11.33 %
	21 to 40 years	80	53.33 %
	>40 years	53	35.33 %
Education	Illiterate	23	15.33 %
	Primary School	73	48.66 %
	Secondary and Above	54	36.00%
Locality	Urban	61	40.66 %
	Urban Slums	63	42.00 %
	Rural	26	17.33 %
Initial Sputum grading	1+(10-99 AFB per 100 oil immersion fields)	47	31.33%
	2+ (1-10 AFB per oil immersion fields)	44	29.33%
	3+ (More than 10 AFB per oil immersion fields)	59	39.33%

Table 2: Sputum Conversion Rate at 21st day, 60th day and 90th day

Sputum	Day-21 (n=141)	Day-60 (n=141)	Day-90 (n= 141)
Negative	100 (70.92%)	134 (95.03%)	140 (99.29%)
Positive	41 (29.78%)	7 (4.96%)	1 (0.7%)

Table 3: Outcome of DOTS therapy at 90th day

Outcome	Cured	Default	Failure	Death
Males	90(92.78%)	5(5.15%)	0	1(1.03%)
Females	50(94.33%)	2 (3.77%)	1(1.89%)	1(1.89%)
Total	140(93.33%)	7(4.67%)	1(0.66%)	2(1.33%)

X<sup>2</sup> = 2.121, Degrees of Freedom= 3, p value = 0.5478

## 4. Discussion:

In a Prospective study of 150 new sputum smear positive pulmonary tuberculosis cases it was observed that 97 case were males (64.7%) and 53 were females (35.3%). Majority were in the age group of 21 to 40 years i.e. 53.3%. Similar observations were made by SL Chadha et al were (67.6%) males and (32.4%) females. Majority of cases were between the age group of 21-40 years i.e. (58.8%).<sup>11</sup> It re-emphasizes the fact that tuberculosis affects economically productive age-group.



In the study it was observed that sputum conversion rate among 142 subjects at the end of 21 days of treatment was 70.92%, at the end of 60 days 95.03% and at end of the 90 days 99.29%. A study by RKS Chaudhari et al observed a sputum conversion of (64.4%) at the end of 2 months and 81.3% at the end of 90 days.<sup>12</sup> SL Chadha et al and sanjay Rajpal et al observed 92.6% and 91.2%. Sputum conversion rate after 90 days.<sup>11,13</sup> Ruohonen et al reported 82.8% conversion rate at the end of the 2nd month and 91.1% at the end of the 3rd month.<sup>14</sup> The study conducted by Frieden showed that sputum conversion rates at the end of 2 months were 62.2% and 81.3% at the end of 3 months.<sup>15</sup> This study observed better conversion rate compared to other studies, this can be due to better compliance and regular treatment.

It was observed that there were 7 defaulters (4.67%) during the intensive phase of treatment in the study. Majority of the defaulters had 3+ sputum positivity grading (57.14%). Alcohol addiction, drug toxicity was the most common reason for default. Study by Sanjay Rajpal et al observed a higher default rate of 7.2% and 11% of default cases with 3+ grading.<sup>13</sup> The default rate in studies by SL Chadha et al and RKS Chaudhari et al was (7.7%) and (5.0%).<sup>11,12</sup> Study by N. Pandit et al observed 93% compliance rate to DOTS. Noncompliance among 63.2% patients was due to toxicity of drugs, 15.8% feeling better during treatment and 10.5% due to lack of knowledge about various aspects of TB and its treatment.<sup>16</sup> Similarly Adverse effects, dissatisfaction to drugs, sense of wellbeing, work load were the reasons for noncompliance in the studies by Maseer Khan et al and Bam Tsa et al.<sup>17,18</sup>

In the study the observed death rate was (1.33%). Similar observations were made by SL Chadha et al death rate of (1.2%) and failure rate of 1.6%.<sup>11</sup> The study by RKS Chaudhari et al death rate was (3.3%) and failure rate was 3.3%.<sup>12</sup> In the study by Sanjay Rajpal et al the treatment failure/death rate was (8.8%).<sup>13</sup>

## 5. Conclusion:

The study concludes that the DOTS programme is therapeutically effective both for the individual and the community, with rapid sputum conversion rate, better compliance and cure rate.

## Acknowledgments:

- a. Dr. Mohan, Medical Officer of RNTCP Cell.
- b. All the patients for their cooperation during the study

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