



## TREATMENT OUTCOME OF PATIENTS WITH DELAYED SPUTUM CONVERSION IN CATEGORY-1 ANTI- TUBERCULOSIS TREATMENT IN CENTRAL KERALA

Ponnu Jose<sup>1\*</sup>, Nileena Koshy<sup>2</sup>, Priyanka R<sup>3</sup> and Jubina Bency AT<sup>4</sup>

<sup>1,3,4</sup>Department of Community Medicine, Jubilee Mission Medical College&Research Institute, Thrissur

<sup>2</sup>Department of Community Medicine, Government Medical College Thrissur

### ARTICLE INFO

#### Article History:

Received 15<sup>th</sup> January, 2017

Received in revised form 10<sup>th</sup> February, 2017

Accepted 22<sup>nd</sup> March, 2017

Published online 28<sup>th</sup> April, 2017

#### Key words:

Delayed Sputum Conversion, Tuberculosis

### ABSTRACT

**Introduction:** Tuberculosis (TB) is a disease that has severely affected communities and nations since time immemorial. Controlling TB in India is a tremendous challenge. Delay in sputum conversion<sup>7</sup> is defined as persistent sputum smear positivity after 2 months of intensive phase of anti tuberculosis treatment Persistent positive smears are associated with unfavourable treatment outcomes. **Objectives**1. To study the treatment outcome of patients with delayed sputum conversion in category-1 anti- tuberculosis treatment.2.To study the clinical profile of patients with delayed sputum conversion in category-1 anti-tuberculosis treatment

#### Materials and methods

**Study design-** prospective cohort study. **Study setting-** Thrissur district of central Kerala.. **Study duration-** 10 months. **Study population** The patients who had registered under Revised National Tuberculosis Control Programme (RNTCP) of Thrissur district during the first quarter of 2013 and remained sputum positive after intensive phase of anti tuberculosis treatment during the same period. **Sample size** -51.

**Results.** Among the total 51 patients, 80.39% were males and 19.61% were females. Mean age was 51yrs ±13.84.Majority had primary level of education(57.14%)and were manual labours (48.98%).Smokers and alcoholics formed 77.55% and 57.14% of the sample respectively. Diabetes Mellitus was detected in 13(27.1%) of patients. The mean duration taken to diagnose tuberculosis was 41±22 days. Treatment outcomes attained were: cured-78.43%, treatment completed-3.92%, Lost to follow up - 9.8%, failure -5.88%, MDR case-1.96%.

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## INTRODUCTION

Even though India holds 17% of worlds population, India's contribution towards global burden of tuberculosis is 26%<sup>1</sup>. Revised National Tuberculosis Control Programme of India has achieved great success in reduction of mortality morbidity and prevalence of Tuberculosis in India. In spite of these achievements, drug resistance, HIV co-infection and co-morbidities like diabetes mellitus are emerging as new threats to Tuberculosis control in India. Controlling TB in India is a tremendous challenge. Delay in sputum conversion<sup>7</sup> is defined as persistent sputum smear positivity after 2 months of intensive phase of anti tuberculosis treatment Persistent positive smears are associated with unfavourable treatment outcomes. They are likely to transmit the disease to contacts and also require extension of their initial phase for one more month. They are at increased risk of relapse and failure which puts them at risk of developing acquired drug resistance.

\*Corresponding author: Ponnu Jose

Department of Community Medicine, Jubilee Mission Medical College&Research Institute, Thrissur

A longer duration of treatment is associated with non compliance of patients with treatment, which is also another risk factor for developing drug resistant tuberculosis. WHO recommends its use as a useful indicator for monitoring the performance of TB control program.

#### Objectives

1. To study the treatment outcome of patients with delayed sputum conversion in category-1 anti-tuberculosis treatment.
2. To study the clinical profile of patients with delayed sputum conversion in category-1 anti- tuberculosis treatment.

## MATERIALS AND METHODS

The study was a prospective cohort study, done in the district of Thrissur of central Kerala. It was done for a period of 10 months. The category-1 tuberculosis patients registered under Revised National Tuberculosis Control Programme (RNTCP) of Thrissur district during the first quarter of 2013 were

selected. There were 276 patients registered under RNTCP during this period. These patients were distributed among six tuberculosis units (TU) of Thrissur district. Among these patients those who remained sputum positive after intensive phase of anti tuberculosis treatment were taken as study subjects. There were 51 patients with delayed sputum conversion. They were followed up till the completion of treatment to know their outcome. Data were collected through patient interviews using a pretested semi structured questionnaire. Final outcome was confirmed by checking patient information registers kept by their respective Senior TB Treatment Supervisor. Data was coded and entered in Microsoft excel and analysed using Epi info. The quantitative data were descriptively summarized and expressed in mean with standard deviation and the qualitative variables in percentages. Strength of association was calculated using Relative Risk with 95% confidence level.

**Definition<sup>2</sup>**

**Successful Outcome**

A patient whose final outcome was either cured or completed treatment had a “successful outcome” while any other outcome was classified as “unsuccessful”.

**Cured**

Initially sputum smear positive patient who has completed treatment and had negative sputum smears on two occasions, one of which is at the end of the treatment is declared as cured

**Treatment completed**

Initially sputum smear positive patient who has completed treatment with negative smears at end of the intensive phase / two months in the continuation phase, but none at the end of treatment, the outcome is declared as treatment completed.

**Failure**

Any TB patient who is smear positive at five months or more after starting the treatment is considered as ‘Failure’.

**Lost to follow up**

A patient whose treatment was interrupted for 2 consecutive months or more.

**Switched over to MDR-TB Treatment**

A patient who has been diagnosed as having MDR-TB by an RNTCP accredited laboratory, prior to being declared as “Failure”, and is placed on the RNTCP MDR-TB treatment regimen.

**Ethical consideration**

This study was approved by the institutional review board at Medical College and the District Tuberculosis Centre, Thrissur. Written informed consent was obtained from all study participants

**RESULTS**

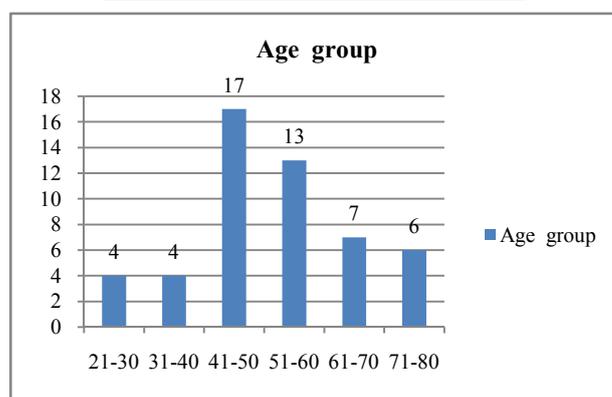
**Clinico social profile**

Among the total 51 patients, 80.39% were males and 19.61% were females. Mean age was 51yrs ±13.84. Majority had primary level of education (57.14%) and were manual labours (48.98%). Smokers and alcoholics formed 77.55% (Figure-1) and 57.14% of the sample respectively. No addiction was

found among females. The mean duration taken to diagnose tuberculosis was 41±22 days. Majority had cough and weight loss as initial symptom. Diabetes mellitus was diagnosed in 27.1% of patients.

**Table 1** Time taken to diagnose tuberculosis

Time taken to diagnose	Frequency	Percentage
2wks	1	2.04%
4wks	14	28.57%
6wks	10	20.41%
8wks	11	22.45%
>8wks	13	26.53%

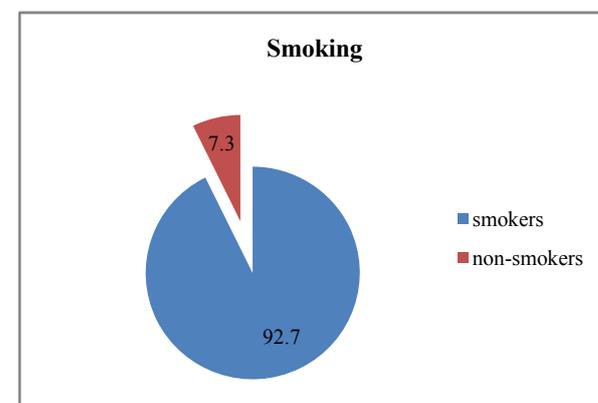


**Figure 1** Distribution of patients according to age group

Patients with high sputum load (2+ and 3+) were 79.1%. After intensive phase their sputum load was scanty-19(38.8%) and 1+ in 30(61.2%) patients. Treatment outcomes attained were: cured- 78.43%, treatment completed-3.92%, Lost to follow up- 9.8%, failure -5.88%, MDR case- 1.96% (table-3) the treatment success rate was 82.35%. The risk for outcomes other than ‘cured’ were female gender, (RR=1.76(0.372-8.39), age more than 40yrs (RR=2.12(0.232-19.36), Diabetes Mellitus (RR=2.28(.53-9.76), high initial sputum load (RR=3.5(.64-18.05).

**Table 2** Sputum load before treatment and after intensive phase of treatment

Initial sputum	Sputum after intensive phase	
	Frequency	Percentage(%)
Scanty	2	4.1
1+	9	18.4
2+	11	22.4
3+	29	56.9
Total	51	100



**Figure 2** Smoking habits of study participants

**Table 3** Treatment outcome of patients with delayed sputum conversion

Treatment Outcome	Frequency	Percentage(%)
Cured	40	78.43
Default	5	9.80
Failure	3	5.88
Completed	2	3.92
MDR	1	1.96
Total	51	100

## DISCUSSION

This study is one among few studies in India that evaluated the profile and outcomes of TB patients who failed to convert after intensive phase of treatment. In India, tuberculosis affects the adults in their most productive age group i.e.15-54yrs. In India 80% of sputum positive cases belong to this group<sup>3</sup>, which is similar to the proportion found in the current study (74.5%). Majority of patients (79.3%) showed initial high sputum load (2+ or 3+). The initial high sputum load is found to be a consistent finding among patients showing delayed sputum conversion globally.<sup>4,5,6,7</sup>

Delay in diagnosing tuberculosis leads to high sputum load which in turn affect the prognosis and treatment outcome<sup>8,9</sup>. The mean duration taken to diagnose tuberculosis was 35±22 days while the recommendation for suspecting TB is two weeks. Successful outcome among the patients were 41±22 days which is near to the outcome of patients without delayed conversion. The successful outcome percentage in the above study is more when compared to other studies in Boffesson, Cameroon<sup>10</sup> (76.6%), Nigeria (78.1%) but less, in the studies done in Republic of Vanuatu by Fanai S *et al.*<sup>11</sup> (90%) and Sri Lanka<sup>12</sup> (92%). Default though less 5(9.80%) need to be addressed as it denotes the need for increasing awareness regarding importance of regular drug intake. The suspected risk for outcomes other than 'cured' were female gender, (RR=1.76, 95%CI=, age more than 40yrs (RR=2.12), Diabetes Mellitus (RR=3.4), high initial sputum load (RR=2.1).but none showed significant relation in any statistical tests.

The treatment outcome showed good result which in turn shows the well implemented and well monitored services from the health care providers in the district

## CONCLUSION

The study was done in Kerala, a state in India with the best health care policies and services. Revised National Tuberculosis Control Programme (RNTCP) has achieved great success in reduction of morbidity and mortality of Tuberculosis in Kerala. In the current study the treatment success rate was 82.35% which was similar to the outcome observed among patients with normal sputum conversion after intensive phase of treatment. 'Default' was 9.8%, failure - 5.88%, MDR case- 1.96%. The suspected risk factors for outcomes other than 'cured' were female gender, age more than 40yrs, Diabetes Mellitus, high initial sputum load, but none showed significant relation in any statistical tests.

## Recommendation

Health education should be strengthened to the patients regarding importance of treatment, its course and duration

with special mention about the need for smoking cessations. Physicians, both from private and government sectors must be recommended to strictly follow treatment algorithm for diagnosis. Disease can be suspected if presenting with typical symptoms even before 2 weeks. Co morbidities with tuberculosis especially diabetes mellitus should be monitored strictly. More detailed studies with large cohorts are required in this area to throw light into the hidden areas of delayed sputum conversion in some patients.

## Limitation

Sample size was less. Dietary assessment of patients not done.

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