



## Initial Sputum Smear Grading As a Factor To Predict Treatment Outcome In New Sputum Smear Positive Pulmonary Tuberculosis

### KEYWORDS

Treatment outcomes, Sputum conversion, Bacillary load

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**ABSTRACT** **Objective:** To assess the association between the initial sputum smear grading, sputum conversion rate at two months of ATT and treatment outcomes at the end of treatment in new sputum smear positive patients.

**Methods:** a prospective study was done in 500 new smear positive TB patients coming to TB hospital Patiala. Initial sputum was graded as low (scanty and +1) and high (+2 and +3). The patients were treated as per the revised national tuberculosis programme (RNTCP) guidelines. Sputum conversion was assessed at 2 or 3 months and treatment outcome was analysed.

**Results:** Sputum conversion rates among low and high grades at the end of two and three months was statistically significant ( $p < 0.0001$  and  $< 0.004$ ). Cure rate was also found to be statistically significant  $p < 0.047$ . Default, death and failure rate was also very high in patients with high grade of sputum.

**Conclusion:** Patients with initial high bacterial load are at risk of low sputum conversion rate and low cure rate. Death, default and failure rate are linearly related to increasing initial bacterial load and increasing age whereas cure rate is inversely related. Initial sputum grading, sputum conversion rate and advancing age appear to be strong predictors of treatment outcome.

### Introduction:

Tuberculosis (TB) is a major global health problem with 9.6 million new cases and 2.2 million deaths in the year 2015. An untreated sputum positive pulmonary tuberculosis patient on an average can infect 10-15 persons annually. Sputum positivity is used as a basis for initiating anti-tubercular treatment (ATT) in pulmonary tuberculosis patients under Revised National Tuberculosis Control Programme (RNTCP). All new smear positive pulmonary tuberculosis patients, irrespective of bacillary load are given the same treatment regimen. Absence of sputum conversion at two to three months of treatment has been found to be one of the strongest predictor for poor treatment outcome in various studies-[13]. The present study was done to know the association between initial sputum grading, sputum conversion and treatment outcomes in new sputum smear positive TB patients.

### Aims and objectives:

The aim of this study was to evaluate the association between the initial sputum smear grading, sputum conversion rate at two months of ATT and treatment outcomes at the end of treatment in these patients.

### Material and methods:

This prospective study was conducted in 500 newly diagnosed smear positive pulmonary tuberculosis patients. Sputum examination and grading was done as per the RNTCP guidelines. For the purpose of this study smears with scanty and 1+ AFB were considered as low grade and smears with 2+ and 3+ AFB were considered as high grade specimens.

All new sputum smear positive patients were treated as RNTCP guidelines and were given intermittent short course category I chemotherapy under direct supervision (DOTS). Follow up sputum examination was done at 2 months and if positive at 3 months after extension of intensive phase and then at the end of treatment. Data so collected was compiled and analysed with Chi-square test & SPSS

software Version 17. A 'p' value of less than 0.05 was considered significant.

### Results:

The patients enrolled in the study were divided into two groups of low grade (scanty and +1 AFB) and high grade (+2 and +3 AFB). Majority of the patients belonged to the age group of 21-40 years. The mean age was 36.6 years, 68.6% being males and 31.4% being females. The initial sputum smear grading was low in 187 (37.4%) cases (scanty in 29 cases, 1+ in 158 cases) and high grade in 313 (62.6%) patients (2+ in 143 cases and 3+ in 170 cases). Sputum conversion rate (SCR) at 2 months was 88.77% in initial low grade as compared to 74.12% in initial high sputum grading which was statistically significant ( $p=0.0001$ ) as in table 1. At the end of treatment, cure rate was 89.84% in patients with initial low sputum grading as compared to 83.39% in initial high grade which was statistically significant ( $p=0.047$ ). Cure rate was also high in patients who had sputum conversion at 2 months ( $p < 0.001$ ). There was a high default rate in high initial sputum grading group (7.67%) and in patients who had persistent sputum positivity at 2 months of ATT (12.72%). Death rate was also high in group with initial high grading of sputum.

**Table 1:**

	Low grade	High grade	p value
Total no of patients	187(37.4%)	313(62.6%)	
SCR at 2 months of ATT	166(88.77%)	232(74.12%)	0.0001
SCR at 3 months of ATT	179(95.72%)	274(87.54%)	0.004
Cure rate at end of treatment	168(89.84%)	261(83.39%)	0.047
Default rate at end of treatment	11(5.88%)	24(7.67%)	0.47
Death rate	3(1.60%)	15(4.79%)	0.08
Failure rate	5(2.68%)	13(4.15%)	0.46

Also noted is a point that, out of the 16 patients who were sputum positive at end of extended IP, 13 were from initial high sputum grade.

7 patients were declared cured at end of treatment, 3 patients defaulted whereas 3 patients were declared failures out of which 2 were proved MDR TB (LPA showed rifampicin resistance). Overall cure rate was 56.25% in patients who were sputum positive at 3<sup>rd</sup> month of ATT.

The present data was also analysed to find out any correlation of SCR and outcome with age. Out of 442 patients aged 60 years or less, SCR was 80.77% as compared to 70.68% in patients aged more than 60 years ( $p=0.073$ ). Cure rate and death rate was also high in patients aged more than 60 years which was statistically significant.

**Table 2:**

	≤60 years	>60 years	p value
Total patients	442(88.4%)	58(11.6%)	
SCR at 2 months of ATT	357(80.77%)	41(70.68%)	0.073
Cure rate at end of treatment	385(87.1%)	44(75.86%)	0.021
Default rate	31(7.02%)	4(6.89%)	1
Death rate	10(2.26%)	8(13.80%)	0.0003
Failure rate	16(3.62%)	2(3.45%)	1

### Discussion:

As per the RNTCP guidelines all new smear positive cases are given category 1 irrespective of the initial bacillary load in same duration and number of medicine. This study shows the effect of the initial bacillary load on sputum conversion and treatment outcomes in newly diagnosed sputum smear positive pulmonary TB patients. Sputum conversion rates and cure rates decreased as the initial grading was high.

Difference in the sputum conversion at the end of two months was statistically significant in both the groups. The previous studies by Gopi et al[4] and Kauban [2] also demonstrated a statistically significant correlation between initial sputum grading and conversion.

The difference in the cure rate was between the two groups was also statistically significant ( $p=0.047$ ). Cure rate was also high in patients who had sputum conversion at 2 months ( $p<0.001$ ). There was a statistically significant correlation between initial sputum grading and cure rate in studies by Gopi et al[4], Nwokeukwu et al[5] and Sherwal et al[6].

Default and death rate was also high in patients with higher sputum grading. Previous studies have also shown a higher cure rate in patients with high initial grading and low sputum conversion at two months[5,7]. Failure rate was high in initial high grade group and in those with low SCR at 2 months of ATT though it was statistically not significant.

We also analysed the correlation of SCR and outcome with age. SCR, cure rate and death rate were also high in patients aged more than 60 years which was statistically significant. In a previous study there was a low conversion rate in patients aged over 60 years[8]. There was no statistically significant correlation between gender and SCR or outcome.

The limitations of this study were lack of knowledge of initial drug resistance.

### Conclusion:

In view of the above findings, its summarised that patients with initial high bacterial load are at risk of low sputum conversion rate and low cure rate. Death and default rate are linearly related to increasing initial bacterial load and increasing age whereas cure rate is inversely related. Failure rate is significantly increased by low conversion rate at 2 months of ATT.

appear to be strong predictors of treatment outcome. In patients with initial high bacterial load (2+ and 3+), advanced age (>60 years), a modification of current RNTCP regimen (which as of now, has a unified chemotherapy regimen irrespective of initial bacteriological load) is called for. Prolonging the treatment can help in the improvement of conversion and outcomes in this patients with high bacillary load. Reassuring the DOTS regimen and increased motivation can decrease the default in all the patients especially ones with high load.

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Initial sputum grading, sputum conversion rate and advancing age