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Relationship between Pre Treatment Bacillary Load and Smear Conversion and Treatment Outcome of Pulmonary Tuberculosis Patients in a TB Unit of Karnataka

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ABSTRACT

Background: Sputum smear microscopy is the key diagnostic tool used for case detection in RNTCP.

Objectives: Among sputum smear positive pulmonary tuberculosis patients, 1. to study the relation between pre-treatment bacillary load and sputum smear conversion & 2. to study the relation between pre-treatment bacillary load and treatment outcome.

Methodology: A prospective cohort study was conducted in Davangere TB unit, Karnataka. All sputum smear positive pulmonary tuberculosis patients registering under RNTCP in 2014 were interviewed using a structured questionnaire.

Results: About 95.5% of the study subjects in Low Positive (LP) category finally achieved smear conversion, while only 87.4% of those in High Positive (HP) category could achieve the same (p=0.01). Favorable outcomes at the end of treatment were achieved by 73.6% of subjects in LP category as compared to only 60.7% of the HP category (p=0.01).

Conclusion: A higher initial sputum smear grading of 3^+ was associated with lower conversion and cure rates.

Keywords: Pulmonary tuberculosis, Sputum smear grading, Sputum smear conversion, Treatment outcome

INTRODUCTION

Diagnosis of pulmonary tuberculosis in RNTCP can be by performing sputum smear microscopy where the smears are stained for acid fast bacilli, graded and reported. Grading of smears is also used as supervisory tool under the program. This is meant to enhance the attention of the laboratory technician while reading the smears and also facilitates supervision by Senior TB Laboratory Supervisor. Smear grading depends upon the number of acid fast bacilli seen while examining the slides.[1]

RNTCP also recommends periodic sputum smear microscopy during the course of treatment to monitor patient progress and assess overall program performance.[1] Change in the bacteriological status of sputum of patients from initial AFB positive to AFB negative after treatment is referred to as sputum smear conversion.[2] Sputum conversion rate provides an objective evidence for the patient's response to therapy and thus the treatment outcome.[2] Hence the present study was carried out to study the relation between pre treatment bacillary

load and sputum smear conversion as well as treatment outcome of sputum smear positive pulmonary tuberculosis patients.

METHODS

This prospective cohort study was conducted in Davangere TB unit of Karnataka state in India. All sputum smear positive pulmonary TB patients aged above 15 years, diagnosed in all the six Designated Microscopic Centers of RNTCP from 1st January 2014 to 31st December 2014 and registering for DOTS were included in the study. Smear negative or extra-pulmonary TB patients were excluded. Institutional Ethical Committee approval was obtained prior to the study. After obtaining informed consent, subjects were interviewed using a pre-tested and structured questionnaire to collect information regarding socio-demographic variables, HIV status and sputum smear grading.

The spot and early morning sputum samples collected were subjected to quality sputum microscopic examination by smearing, staining and examining under the microscope for presence of acid fast bacilli. The smears were graded as scanty, 1^+, 2^+ or 3^+ as per RNTCP guidelines.[1] The bacteriological smear grading of the patients at the end of the intensive phase, extended intensive phase (if indicated) and continuation phase were also assessed as mentioned above. The outcome of the patients was ascertained as per RNTCP guidelines.[1] For the purpose of analysis patients with pre-treatment sputum grading 3^+ were categorized as High Positive category (HP category). Those whose pre-treatment sputum smears were graded as 2^+, 1^+ or scanty were categorized as Low Positive category (LP category).

Statistical Analysis: Data entry and analysis was done using Microsoft EXCEL 2010. Chi square test was used for analyzing categorical variables. A p value below 0.05 was considered to be significant.

RESULTS

Totally 313 sputum smear positive pulmonary tuberculosis patients who registered under RNTCP in 2014 were included in the study. Their pre treatment smears graded as scanty, 1^+, 2^+ and 3^+ were 9 (2.9%), 102 (32.6%), 90 (28.8%) and 112 (35.8%) respectively. About 64.2% of them were in LP category, whereas 35.8% were in HP category. Among the socio demographic variables, majority of the study subjects were males (73.5%), aged below 60 years (84.3%), Hindus (80.8%) by religion and residing in urban localities (60.7%). Out of 313 pulmonary TB patients, 16 (5.1%) were found to be suffering from HIV. [Table 1]

At the end of IP, it was observed that 84.0% of the subjects in the LP category had their sputum smears converted as compared to the same in the HP category (72.7%). Whereas conversion at the end of extended IP was 95.5% for LP category as compared to only 87.4% of the HP category. A higher pretreatment sputum smear grading was significantly associated with lower rates of smear conversion at the end of intensive (p=0.02) as well as extended intensive phase (p=0.01). [Table 2]

Among the 313 study subjects, the outcome of 207 (66.1%) were declared as cured and 9 (2.9%) as treatment completed at the end of treatment. About 37 (11.8%) study subjects were declared as lost to follow up, 15 (4.8%) as treatment failure, 37 (11.8%) died, 6 (1.9%) were switched to MDR-TB regimen, while 2 (0.6%) were transferred out.

Table 1: Association of pre treatment sputum smear grading with socio demographic variables.

Socio demographic variables	LP category (%)	HP category (%)	Total (%)	p value	OR (95% CI)
Age group					
below 60 years	166 (82.6)	98 (87.5)	264 (84.3)	0.25	0.678 (0.347 – 1.322)
above 60 years	35 (17.4)	14 (12.5)	49 (15.7)		
Gender					
Male	149 (74.1)	81 (72.3)	230 (73.5)	0.72	0.912 (0.542 – 1.535)
Female	52 (25.9)	31 (27.7)	83 (26.5)		
Religion					
Hindu	163 (81.1)	90 (80.4)	253 (80.8)	0.87	1.049 (0.584 – 1.882)
Muslim	38 (18.9)	22 (19.6)	60 (19.2)		
Domicile					
Rural	75 (37.3)	48 (42.9)	123 (39.3)	0.33	0.794 (0.496 – 1.271)
Urban	126 (62.7)	64 (57.1)	190 (60.7)		
Hiv					
Positive	11 (5.5)	5 (4.5)	16 (5.1)	0.69	0.807 (0.273 – 2.358)
Negative	190 (94.5)	107 (95.5)	297 (94.9)		
Total	201 (100)	112 (100)	313 (100)		

Table 2: Association of pre treatment sputum smear grading with conversion as well as treatment outcome

Conversion & Outcome	LP category (%)	HP category (%)	Total (%)	p value	OR (95% CI)
Conversion at end of IP					
Yes	152 (84.0)	72 (72.7)	224 (80.0)	0.02	1.96 (1.08 – 3.56)
No	29 (16.0)	27 (27.3)	56 (20.0)		
Conversion at end of extended IP					
Yes	171 (95.5)	83 (87.4)	254 (92.7)	0.01	3.09 (1.21 – 7.85)
No	8 (4.5)	12 (12.6)	20 (7.3)		
Outcome					
Favorable	148 (73.6)	68 (60.7)	216 (69.0)	0.01	1.8 (1.10 – 2.95)
Unfavorable	53 (26.4)	44 (39.3)	97 (31.0)		

Table 3: Association of sputum smear conversion with treatment outcome

Conversion	Favorable outcome (%)	Unfavorable outcome (%)	Total (%)	p value	OR (95% CI)
Conversion at end of IP					
Yes	184 (85.2)	40 (62.5)	224 (80.0)	0	3.45 (1.83 – 6.47)
No	32 (14.8)	24 (37.5)	56 (20.0)		
Conversion at end of extended IP					
Yes	210 (97.7)	44 (74.6)	254 (92.7)	0	14.31 (4.94 – 41.4)
No	5 (2.3)	15 (25.4)	20 (7.3)		

The study subjects with pre treatment sputum smear grading of 3^+ (39.3%) were found to be significantly associated (p=0.01) with unfavorable outcomes when compared to study subjects with lower smear grading such as 2^+, 1^+ or scanty (26.4%) with a crude OR (95% CI) of 1.80 (1.10 – 2.95). **[Table 2]**

An attempt was also made to check the influence of smear conversion on treatment outcome. It was observed that smear conversion at the end of IP (p=0.000) as well as extended IP (p=0.000) was highly significantly associated with treatment outcome of pulmonary TB patients. Unfavorable outcomes were found to be more in those study subjects who failed to achieve smear conversion. **[Table 3]**

DISCUSSION

Pre-treatment sputum smear grading is a direct measure of bacillary load of the pulmonary TB patients. Available studies have highlighted the importance of initial sputum smear grading and its impact on smear conversion and treatment outcome.[3,4]

Gopi PG et al observed in their study that among those patients with positive smear at 2 months, 41.1% of the patients had a high (3^+) smear grading compared to 18.7% of patients with a lower (scanty or 1^+ or 2^+) smear grading. Significantly more patients (13.2%) remained smear positive at 3 months among those with a higher smear grading than that among patients with a lower smear grading (5.3%) (p<0.001). A significant decrease in conversion (p<0.001) as well as cure rate (p=0.01) was observed with increase in initial smear grading.[5]

Nwokeukwu H et al noted that conversion rate (p=0.03) and success rate (p=0.003) reduced significantly with increasing initial smear grading. Higher initial smear grading was significantly associated with poor outcomes such as default (p=0.009) and death (p=0.005) at the end of the treatment.[6]

Patel et al documented in their study that as the pretreatment sputum smear grade increased from scanty to 3^+, the proportion found smear-positive during follow-up increased by 2–3 times (p< 0.05).[7]

Dudala SR et al in Khammam TB unit observed that cure rate for patients with 3^+ smear grading was 80.33% while for patients with 1^+ grading was 94.05%. As the bacillary load increased, cure rate decreased (p=0.023).[8]

Similar findings were observed by Abhijit Mukherjee et al too.[9] But Behnaz et al observed that initial smear grading did not influence outcome, despite influencing smear conversion.[10] This may be due to cultural differences.

Operational advantages of smear examination over culture include: quick results, correlation with infectiousness & aid in identification of patients at high risk of death from tuberculosis if untreated.[2]

Studies also reveal that higher initial bacillary load and consistent smear positive status at the end of IP are significant risk factors for developing MDR TB.[11,12] In the era of drug resistant tuberculosis, the importance of higher initial smear grading should not be overlooked. These patients also continue to

spread the infection for longer time and hence should be motivated to take appropriate cough etiquette measures.

CONCLUSION

The present study revealed that patients in the HP category were at higher risk of achieving non conversion and unfavorable outcomes when compared to patients in the LP category. This reiterates the importance of adequate cough hygiene as well as prioritizing these patients for drug resistance screening.

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