Sputum grading as a predictor of treatment outcome of new sputum smear positive tuberculosis patients in Khammam Tuberculosis Unit

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Date of Submission: 11.06.2013
Date of Acceptance: 10.08.2013

Abstract

Introduction: The diagnosis of pulmonary tuberculosis under Revised National Tuberculosis Control Program (RNTCP) is primarily based on sputum examination, in accordance with the guidelines of World Health Organisation. All chest symptomatics are required to get two specimens of sputum examined for establishing the diagnosis at Microscopy Centre. Aim: To assess the importance of initial sputum grading as a predictor of treatment outcome of New Sputum Smear Positive Tuberculosis patients in Tuberculosis Unit (TU) Khammam. Material and methods: All the new sputum smear positive patients registered in Khammam TU during the second and third quarters of 2009 were enrolled as study subjects. A total of 413 patients were registered as per the inclusion criteria under six Designated Microscopic Centres (DMCs). The patients under each DMC area were listed. These patients were followed up till the completion of their treatment. Results: Among the enrolled patient’s (413), 1.69% (7) were found to be scanty grading, 20.34% (84) were found to be 1+ grading on sputum examination, 33.66% (139) were found to be 2+ grading on sputum examination and 44.31% (183) were found to be 3+ grading on sputum examination. The cure rate for patients with sputum 3+ grading was 80.33% and the defaulter rate was 4.92%. Cure rate for patients with sputum 1+ grading was 94.05% and the defaulter rate was 4.76%. Conclusion: The norms of RNTCP regarding sputum smear conversion rate during the intensive phase was achieved in Khammam TU.

Key words: Grading, Predictor, RNTCP, Sputum, Tuberculosis

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Introduction:

Sputum Smear Positive [SSP] pulmonary tuberculosis patients are the main source of infection for tuberculosis because when they cough or sneeze they expel droplet nuclei which carry infectious bacilli. One untreated infectious tuberculosis patient is likely to infect 10 to 15 persons annually. It is expected that 80 to 90% of patients will undergo smear conversion within two to three months of treatment. Several factors have been identified that may delay the time to smear and culture conversion. These include high initial sputum smear acid fast bacilli [AFB] grade, cavitory lesion, uncontrolled hyperglycaemia / diabetes mellitus, old age, multi-drug resistant tuberculosis, initial treatment with less than four anti-tubercular drugs.

Patients diagnosed with tuberculosis are treated under Directly Observed Treatment Short course chemotherapy (DOTS) in accordance with the Revised National Tuberculosis Control Program (RNTCP) guidelines. On April 1st 2009 the RNTCP guidelines were revised. The
number of sputum specimens collected was two, with one of them being a morning sputum specimen. Diagnosis of smear positive tuberculosis amongst tuberculosis suspects - One specimen positive out of the two is enough to declare a patient as smear positive tuberculosis and a pulmonary tuberculosis suspect is any person with cough for 2 weeks, or more. Early diagnosis of TB and initiating treatment under DOTS would not only enable the patients to get cured but also reduce the transmission of infection and disease to others. In RNTCP, the sputum smears are graded and reported based on the bacillary load. The present study was carried out on new smear positive pulmonary tuberculosis cases treated with category I regimen under RNTCP in Khammam TU, to find the association of conversion and cure related to smear grading at the start of treatment. Very few studies are done in tribal areas; hence the present study was done to know whether the norms of RNTCP are being achieved.

Material and methods:

Descriptive study involving review of existing records maintained under the RNTCP. Study was undertaken following permission from institutional ethics committee. All the new sputum smear positive patients registered in Khammam Tuberculosis Unit (TU) during the second and third quarters of 2009 were enrolled as study subjects. All eligible cases of sputum smear-positive TB registered during the study period were included in the study. A total of 413 patients were registered as per the inclusion criteria. There are six Designated Microscopic Centre (DMC) in Khammam TU. The patients under each DMC area were listed. These patients were followed up till the completion of their treatment.

Laboratory Procedures: Sputum specimens submitted to the laboratory were processed for AFB microscopy. Direct smears were stained by Ziehl-Neelsen technique and graded as per RNTCP guidelines.11

Table 1: Sputum smears are examined and interpreted as indicated in the table11

<table>
<thead>
<tr>
<th>If the slide has:</th>
<th>No. of fields to be examined</th>
<th>Grading</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>No AFB in 100 oil immersion fields</td>
<td>100</td>
<td>0</td>
<td>Negative</td>
</tr>
<tr>
<td>1-9 AFB per 100 oil immersion fields</td>
<td>100</td>
<td>Scanty*</td>
<td>Positive</td>
</tr>
<tr>
<td>10-99 AFB per 100 oil immersion fields</td>
<td>100</td>
<td>1+</td>
<td>Positive</td>
</tr>
<tr>
<td>1-10 AFB per oil immersion field</td>
<td>50</td>
<td>2+</td>
<td>Positive</td>
</tr>
<tr>
<td>More than 10 AFB per oil immersion field</td>
<td>20</td>
<td>3+</td>
<td>Positive</td>
</tr>
</tbody>
</table>

Smear Conversion: It is expected that at least 80% of new smear-positive patients will convert (become sputum smear-negative) by the end of two months of treatment. At the end of three months, more than 90% of such patients could be expected to have converted.11

Data were analyzed by using the EPI-INFO Version 7 package and MS Excel 2007 for simple proportions was calculated and statistical tests of significance were applied wherever necessary

Results:

Total of 413 new sputum positive patients were registered in a six Designated Microscopic Centres (DMC). Of them 44.31% patients had 3+ sputum grading, followed by 2+, 1+ and scanty. As per the revised guidelines even a single bacilli found is taken as positive.
Table 2: Distribution of New Sputum Smear Positive Tuberculosis patients according to their grading of sputum (n=413)

<table>
<thead>
<tr>
<th>Sputum grading</th>
<th>Number of cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scanty</td>
<td>7</td>
<td>1.69%</td>
</tr>
<tr>
<td>1+</td>
<td>84</td>
<td>20.34%</td>
</tr>
<tr>
<td>2+</td>
<td>139</td>
<td>33.66%</td>
</tr>
<tr>
<td>3+</td>
<td>183</td>
<td>44.31%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>413</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

Among the patients, 1.69% was found to be scanty grading and 44.31% were found to be 3+ grading on sputum examination. Even a single bacilli present in the smear is taken as smear positive.

Table 3: Distribution of New Sputum Smear Positive Tuberculosis patients according to their grading of sputum and sputum conversion (n=413)

<table>
<thead>
<tr>
<th>Sputum grading</th>
<th>Sputum conversion</th>
<th>Number of cases converted to sputum negative</th>
<th>Number of cases enrolled</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>At the end of 2nd month</td>
<td>At the end of 3rd month</td>
<td></td>
</tr>
<tr>
<td>Scanty</td>
<td>6 (85.7%)</td>
<td>1 (14.3%)</td>
<td>7 (100%)</td>
</tr>
<tr>
<td>1+</td>
<td>75 (89.3%)</td>
<td>2 (2.4%)</td>
<td>77 (91.7%)</td>
</tr>
<tr>
<td>2+</td>
<td>128 (92.1%)</td>
<td>3 (2.2%)</td>
<td>131 (94.3%)</td>
</tr>
<tr>
<td>3+</td>
<td>151 (82.5%)</td>
<td>6 (3.3%)</td>
<td>157 (85.8%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>360 (87.2%)</strong></td>
<td><strong>12 (2.9%)</strong></td>
<td><strong>372 (90.1%)</strong></td>
</tr>
</tbody>
</table>

Chi-square = 3.386 with 3 degree of freedom;  p = 0.454

Table 4: Distribution of New Sputum Smear Positive Tuberculosis patients according to their grading of sputum and treatment outcome (n=413)

<table>
<thead>
<tr>
<th>Initial Sputum Grading</th>
<th>Cured</th>
<th>Others*</th>
<th>Total cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scanty</td>
<td>6 (85.7%)</td>
<td>1 (14.3%)</td>
<td>7 (100%)</td>
</tr>
<tr>
<td>1+</td>
<td>79 (94%)</td>
<td>5 (6%)</td>
<td>84 (100%)</td>
</tr>
<tr>
<td>2+</td>
<td>123 (88.5%)</td>
<td>16 (11.5%)</td>
<td>139 (100%)</td>
</tr>
<tr>
<td>3+</td>
<td>147 (80.3%)</td>
<td>36 (19.7%)</td>
<td>183 (100%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>355 (95.4%)</strong></td>
<td><strong>58 (4.6%)</strong></td>
<td><strong>372 (100%)</strong></td>
</tr>
</tbody>
</table>

* Note others include treatment failure, default, treatment completed, death
Chi-square = 10.097 with 3 degree of freedom;  p= 0.023

The cure rate for 3+, 2+, 1+ and scanty initial sputum grading is 80.3%, 88.5%, 94% and 85.7% respectively. There is a significant association between initial sputum grading and their treatment outcome. As the bacillary load increases cure rate decreases.

Discussion:

Sputum positive patients are capable of transmitting infection. In RNTCP all new smear positive pulmonary tuberculosis patients, irrespective of bacillary load, should be given the same treatment regimen with same number of drugs and dosages. 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.4-8

In the present study, 90.07% of enrolled patients were sputum negative at the end of 3rd month of treatment. As per RNTCP norm the sputum conversion rate should be >90% and in the present study it is 90.07%. So RNTCP norm of sputum conversion rate has been achieved by Khammam TU of total enrolled cases (2nd...
quarter and 3rd quarter 2009). Our findings are similar with other studies, Kumaresan JA et al found that sputum smear conversion was 85% at the end of 2 month, Singla R et al also reported that sputum was negative in 81.1% of patients at the end of the 2nd month and 91.6% at the end of the 3rd month. In a study done by Banu Rekha VV et al 60.43% of the cases was sputum negative by the end of Intensive phase. A study done by Moharana PR et al stated that the sputum conversion rate among NSP was 82.6% at the end of Intensive phase. Kaur G et al in their study stated that sputum conversion rate among NSP cases at three months was 93.8%.

Among the enrolled patients, 44.31% were found to be 3+ sputum grading on examination and 1.69% were found to be scanty grading. In this study, the cure rate for patients with 3+ sputum grading was 80.33% versus 90.43% for the rest of the patients (combined graded sputum scanty, 1+ and 2+). In a study done by Bawri S et al 42% were found to be 3+ sputum grading and 11% were found to be scanty grading. In a study done by Banu Rekha VV et al there was an equal number of patients being registered with 1+ and 2+ sputum grading (43.5%). Rajpal Sanjay et al in their study stated that 47.9% were registered with 3+ sputum grading, 5.2% were found to be scanty grading, and new sputum smear positive patients showed 85% cure rate for 3+ sputum grading and 97.7% for the rest of the patients (combined graded sputum scanty, 1+ and 2+). The study by Singla R et al showed a cure rate of 76.6% for 3+ sputum grading and 85.1% for scanty, 1+, 2+ sputum grading. The failure rates were 7.7% for 3+ sputum grading and 4.5% for scanty, 1+, 2+ sputum grading. A study done by Gopi PG et al stated that cure rate of 3+ sputum grading was 71.7%, 2+ sputum grading it was 78.1%, 1+ sputum grading it was 76.8% and for scanty sputum grading it was 88.4%.

**Conclusion:** The norms of RNTCP regarding sputum smear conversion rate during the intensive phase was achieved in Khammam TU.

**Limitation of Study:** Status of smear was relied completely on lab technician. We did not cross check the quality of reporting of sputum smear slides.

**Recommendations:**

1. Service providers should be able to initiate treatment on the same day of consultation.
2. Laboratory operations and procedures should be realigned with sputum collection and reporting of results on the same day, within the constraints of existing human resources and laboratory workload.
3. The contact time between infectious patients and vulnerable groups attending the same facility should be minimized, especially in settings with a high HIV prevalence or a high burden of drug-resistant TB. Separation and rapid triage of coughing patients is especially important to reduce the risk for TB transmission in health-care settings.
4. Monitoring of patient drop-out between laboratory and patient registers and of trends in case detection and treatment outcomes is essential.

**Conflict of Interest:** nil

**Source of funding:** nil

**References:**