ROLE OF GENE-XPERT IN DIAGNOSIS OF SMEAR NEGATIVE PULMONARY TUBERCULOSIS

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BACKGROUND

Tuberculosis continues to be a major public health problem worldwide, with 8 million cases and 1.3 million deaths each year. Sputum smears with chest X-ray (CXR), where available are the tests routinely applied for TB diagnosis. Gene-xpert has very high sensitivity in diagnosis of smear negative pulmonary tuberculosis and it has more roles especially in low to middle income country. The aim of the study to measure the role of gene-xpert in diagnosis of smear negative pulmonary tuberculosis.

MATERIALS AND METHOD

This was hospital based cross-sectional study conducted by department of pulmonary medicine, All India Institutes of Medical Sciences, Patna. All the pulmonary tuberculosis suspects’ patients with 2 negative Ziehl-Neelsen (ZN) sputum smears were evaluated by Gene-xpert testing to diagnose pulmonary tuberculosis patients.

RESULTS

The total 106 sputum negative patients evaluated for gene-xpert. Gene-xpert was positive for Mtb in 37 (37/106, 34.9%) patients. So 2.86 patients to be tested to detect one gene-xpert positive pulmonary tuberculosis case. The prevalence of MDR in our study patients was 13.20% and in gene-xpert positive patients was 37.83 percentage (14/37). Cough and Anorexia were more significantly associated with positive result in gen-xpert. Number needed to test was lowest (1.86) for combination of symptoms such as cough fever and anorexia.

CONCLUSION

Gene-xpert assay mainly indicated for early detection of MDR-TB, particularly when applied to high-risk groups in accordance with WHO recommendation. Our study shows that it is useful test to confirm tuberculosis even in smear negative pulmonary tuberculosis.

KEYWORDS

Pulmonary Tuberculosis, Smear Negative, Gene-xpert, Multi Drug Resistance.


INTRODUCTION

Tuberculosis continues to be a major public health problem worldwide, with 8 million cases and 1.3 million deaths every year. The most widely used test for TB, sputum smear microscopy has a sensitivity of only 50% for active cases, which contributes to delayed diagnosis resulting in continued transmission. Sputum smear with chest X-ray (CXR), where available, are the tests routinely ordered for TB diagnosis. It is crucial to implement improved diagnostics in endemic settings if we want to achieve the targets of case detection, reduction in mortality, and prevalence of the disease. Gene-xpert has very high sensitivity in diagnosis of smear negative pulmonary tuberculosis and it has crucial roles especially in low to middle income countries.

AIMS AND OBJECTIVE

1. To measure the role of gene-xpert in diagnosis of sputum negative pulmonary tuberculosis.
2. To identify the relation between clinical symptoms and gene-xpert outcome.

MATERIALS AND METHOD

Type of Study
Cross-sectional hospital based study.

METHOD

The study was conducted by department of pulmonary medicine, All India Institutes of Medical Sciences, Patna. As Institute is new in phase of development, yet to have facilities for MTB culture, and diagnosis of pulmonary tuberculosis has been made with help of chest x-ray and sputum microscopy methods mainly. All the pulmonary tuberculosis suspects with 2 negative Ziehl-Neelsen (ZN) sputum smears were referred for testing at Gene-xpert Lab established by World health partner outside of institute. Patients were informed about the test and written informed consent sought to collect baseline data on demographics and symptoms at presentation.

This study was approved by the Institutional Ethical Committee, AIIMS Patna.

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All the baseline data including demography, history of Anti-tubercular treatment in past, clinical symptoms such as total duration of illness, cough more than 2 weeks, fever for more than two weeks, loss of appetite, hemoptysis in last 3 month and shortness of breath were entered.

Categorical variables were compared between patient groups testing positive and negative by Xpert using Fisher’s exact test with a P value of ≤0.05 considered as significant.

RESULTS

The study was conducted between 13th May 2015 to 31st Aug 2015. The total 132 pulmonary suspects had negative smear for AFB by ZN staining. There were 20 patients who undergo only one sputum test and therefore excluded from the study. The total 112 patients who had two sputum sample negative for Acid fast bacilli referred for gene-xpert testing, but only 106 turn-up with gene-xpert report. MTB was detected in 37 (37/106, 34.9%) patients. So 2.86 patient has to be tested to detect one gene-xpert positive pulmonary tuberculosis case. All positive patients were started with daily antitubercular treatment.

Table 1 shows baseline characteristics of study patients and most of the patients were between age 15-30 years (53/106, 50%). Female percentage was 34.9 (37/106). Gene-xpert positivity rate was highest in age group of 15-30 years (22/53, 41.50%). There were not much differences in positivity rate between male & female (34.78% vs 35.13%). Patients who received antitubercular treatment in past had less gene-xpert positivity rate in comparison to pulmonary tuberculosis suspects who never received ATT in past (32.75% vs 37.50%).

The majority of patients had high burden of MTB in gene-xpert testing (19/37, 51.35%). The prevalence of MDR in gene-xpert positive patients was 37.83% (14/37) and if we compare to total study (Sputum negative), patient positivity was 13.20% (14/106) (Table 2).

If we compare clinical symptoms, cough and Anorexia were more significantly associated with positive result in gene-xpert (Table 3). Number needed to test was lowest (1.86) for combination of symptoms such as cough fever and anorexia (Table 4).
Table 4: Number of patients detected as positive by Gene Xpert using different symptoms criteria for testing

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Total</th>
<th>Gene-Xpert Positivity</th>
<th>Number Needed to Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cough+ Fever</td>
<td>42</td>
<td>19</td>
<td>2.21</td>
</tr>
<tr>
<td>Cough+ Fever+ Anorexia</td>
<td>27</td>
<td>16</td>
<td>1.68</td>
</tr>
<tr>
<td>Cough+ Fever+ hemoptysis</td>
<td>12</td>
<td>06</td>
<td>2</td>
</tr>
</tbody>
</table>

Fig. 1: Age wise Gene-Xpert result in smear negative patients

Number on Y axis represent percentage of total study patients

Fig. 2: Gender wise and history of Anti-tubercular treatment and Gene-Xpert positivity

Number on Y-axis represent percentage of Gene-Xpert positivity.
This study did not compare with gold standard sputum culture. LIMITATION OF STUDY

We did not assess HIV status, which is required to assess such high prevalence of MDR tuberculosis in our studies.

REFERENCES


CONCLUSION

Gene-Xpert assay is mainly indicated for early detection of MDR-TB, particularly when applied to high-risk groups in accordance with WHO recommendation. Our study shows that it is useful test to confirm tuberculosis even in smear negative pulmonary tuberculosis.

LIMITATION OF STUDY

This study did not compare with gold standard sputum culture and so sensitivity and specificity cannot be calculated.