Section: Respiratory Medicine

Original Research Article

SPUTUM SMEAR MICROSCOPY VERSUS GENEXPERT MTB / RIF ASSAY IN THE DIAGNOSIS OF PULMONARY TUBERCULOSIS

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ABSTRACT

Background: Tuberculosis remains one of the major public health problems worldwide causing considerable morbidity and mortality. Early diagnosis is essential for effective control of the disease and to prevent the emergence of drug resistance. Sputum smear Microscopy is the main diagnostic tool for the diagnosis and management of pulmonary tuberculosis. WHO in the year 2011 endorsed GeneXpert MTB/Rif Assay test for the diagnosis of pulmonary tuberculosis. This test simultaneously Detects resistance to Rifampicin Myco. Tuberculosis. **Objective:** The Present study was done to compare the results of sputum. Smear microscopy and Gene Xpert MTB/Rif assay in the diagnosis of pulmonary Tuberculosis among the suspected cases of pulmonary tuberculosis. **Materials and Methods:** 53 Patients who were suspected of having, pulmonary Tuberculosis was included in the study. Two early morning sputum samples Collected from them were sent to designated microscopy centre (DMC) for Ziehl- Neelsen (ZN) staining and microscopic examination. Sputum samples were also sent for Gene Xpert MTB/Rif assay. The results were analyzed and compared. **Result:** Out of 53 suspects 30 (56.6%) were males and 23 (43.4%) were females. Among males age ranged from 15 to 75 years (Mean age 37.7 years) and among females age ranged from 13 to 55 years (Mean age 30.3 years). 10 patients out of 53 (18.9%) were sputum positive while 29 (54.7%) out of 53 were positive on Gene Xpert MTB/Rif assay. Thus Gene Xpert MTB/Rif assay detected 19 more patients of pulmonary tuberculosis in comparison to conventional microscopy. This assay also detected 8 cases of Rifampicine resistance out of which 4 were sputum negative on microscopy. **Conclusion:** The case detection rate of Gene Xpert MTB/Rif assay is better than conventional microscopy. It has added advantage of detecting Rifampicine resistance. Detection in Rifampicine resistance in sputum smear negative pulmonary tuberculosis patients has important implications in the management of drug resistance tuberculosis.

INTRODUCTION

Despite global efforts tuberculosis remains one of the major health problems worldwide. Along with HIV it is the leading cause of death globally.[1] Pulmonary tuberculosis is the most infectious form of tuberculosis. Rapid diagnosis and institution of proper anti-tuberculosis regimen is the only way to control the disease and to minimize the problem of drug resistance.

Conventional methods of diagnosis of pulmonary tuberculosis include: clinical status of the patients, chest X-ray finding, sputum smear examination for Acid Fast Bacillus (AFB) and culture of specimen for AFB, Culture remains the gold standard for the diagnosis of tuberculosis. But result of culture arrives in 4-6 weeks on solid medium culture. For practical purposes the diagnosis is based on sputum smear microscopy which requires a laboratory set-up and trained personnel. It takes 2-3 days for reports to come. It does not make difference between M. tuberculosis and atypical Mycobacteria and between dead and alive bacilli.

Various studies have recommended cartridge based nucleic acid amplification tests (CBNAAT) for the diagnosis of Myco. Tuberculosis in tuberculosis suspects. Gene Xpert MTB/Rif assay is one such test. It has high sensitivity and specificity and reports arrive within 2 hours. It simultaneously detects any existing resistance to Rifampicin which is a marker for multidrug resistant (MDR) tuberculosis.[2,3,4]

WHO also recommends it for diagnosis of tuberculosis and for quick detection of Rifampicin resistance.[5]

Aims and Study: The aim of the study was to compare the results of sputum smear microscopy and Gene Xpert/Rif assay in the diagnosis of pulmonary tuberculosis among tuberculosis suspects.

MATERIALS AND METHODS

The study was conducted at the Department of TB and Chest, Darbhanga Medical College, Laheriasarai, Darbhanga between June 2022 to January 2023. 53 suspects of pulmonary tuberculosis (PTB) based on their clinical features (productive cough for more than 2 weeks, persistence low grade fever, night sweats, weight loss) and X-ray finding suggestive of pulmonary tuberculosis were included in the study. Patients who received anti-tuberculosis treatment within a year were not included in the study. Two early morning sputum samples collected from them were sent to designated microscopy centre (DMC) for Ziehl –Neelsen staining and microscopic examination of sputum smear. Sputum samples were also sent for Gene Xpert MTB/Rif assay. The results were analyzed and compared. Statistical analysis was done by performing chisquare test.

RESULTS

1. **Age distribution of patients:** Among males (n=30) age ranged from 15 to 75 years (Mean age 37.7 years) and among females (n=23) age ranged from 13 to 55 years (Mean age 30.3 years).
2. **Sex distribution of patients:** Out of 53 suspects 30 (56.6%) were males and 23 (43.4%) were females.
3. **Results of sputum smear examination:** Out of 53 suspects 10 were positive for AFB. Among 10 positives, 5 patients were new (no history of antituberculous treatment) while 05 had history of previous anti-tuberculous treatment.
4. **Result of Gene Xpert MTB/Rif assay:** Myco. Tuberculosis (MTB) positive 29 suspects (13 new patients and 16 with history of anti-tuberculous treatment) out of 53 was positive for MTB.

Rifampicine resistance: 08 patients were resistant for rifampicine. Among resistance cases 4 were sputum positive and rest 04 were sputum smear negative for AFB. One patient each from both groups (smear positive and smear negative) with rifampicine resistance had no history of previous anti-tuberculous treatment.

Comparison of the results of sputum smear exam and Gene Xpert MTB/Rif assay: Sputum smear examination detected pulmonary tuberculosis in 10 patients out of 53 (18.9%) while Gene X pert MTB/Rif assay detected tuberculosis in 54.7% (29 out of 53 suspects). This result is significant (p value <0.001).

Table 1: Sex distribution of patients

Sex	Number (n) %
Male	30 (56.6%)
Female	23(43.4%)
Total	53(100%)

DISCUSSION

Table 2: Overall results of sputum smear microscopy and Gene Xpert MTB/ Rif assay (Number of PTB suspects, n=53)

Results	Total no. of samples	Samples with Rifampicine resistance
Smear +ve/Xpert +ve	**10**	**04**
Smear +ve/Xpert -ve	**0**	**x**
Smear -ve/Xpert +ve	**19**	**04**
Smear -ve/Xpert -ve	**24**	**x**
Total Samples	**53**	**08**

Table 3: Case detection rate {Total no. of samples n=53)

Total no. of PTB suspect	Smear positive samples	Xpert positive samples	Absolute difference %
N=53	10(18.9%)	29(54.7%)	35.8% (p<0.001)

The result of our study is similar to the findings of various previous studies.[6,7,8,9,10] Praveen JV et al in study on 205 suspects of tuberculosis found sputum positive for MTB in 52.68% samples as compare to 70.24% positivity on Gene Xpert Positive /Rif Assay. The Xpert assay also detected 4 cases of Rifampicin resistance.[6] In another study by Amin Bushra on 314 samples of sputum from tuberculosis suspects the positivity for AFB were 15.9% and 35.3% on smear examination and Gene Xpert MTB/Rif assay respectively. Additionally the Xpert assay detected 14 cases of Rifampicine resistance.[7] Milton Chemhuru et al in a study at two different hospitals in Zimbabwe found sputum positivity for AFB in 13.4% and 13.2% samples of tuberculosis suspects respectively.[8] Nagbonziza JCE in his study on sputum samples from 648 tuberculosis suspects found positivity for AFB in 7.8% while corresponding positivity on Gene Xpert MTB/Rif assay was 12.6%.[9] Alvarez-Uria G et al in their study on 106 suspects of tuberculosis found sputum smear positivity for AFB in 63.9% samples. The figure for Xpert MTB assay was 74.7% in the corresponding samples.[10] In all the above studies the

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higher detection of cases by Gene Xpert MTB/ Rif assay was statistically significant.

CONCLUSION

In comparision to sputum smear microscopy for AFB Gene Xpert MTB/Rif assay is more sensitive and gives quick results in the diagnosis of tuberculosis among pulmonary tuberculosis suspects. It gives additional information of any Rifampicine resistance present. Detection of Rifampicine resistance in sputum smear negative samples is important for the management of drug resistant tuberculosis.

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