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A Comparative Study Between Sputum Smear Microscopy (LED) and GeneXpert in Pulmonary Tuberculosis Patients

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Abstract

Introduction: Pulmonary TB is diagnosed by detection of MTB bacteria in a sputum. Recently, the World Health Organization endorsed the Gene-Xpert for the diagnosis of TB(1). Early diagnosis is the most effective pulmonary tuberculosis control strategy. Access to diagnostic assays in highly endemic countries for DR-TB remains a challenge. GeneXpert assay is a molecular technique detecting (MTB) and Rifampicin Resistant Tuberculosis (RR-TB) simultaneously in approximately 2 hours. .Smear negative patients are also reported to be responsible for approximately 17% of transmission and its impact on public health shouldn't be neglected.

Materials and Methods: All patients (age >14years) of either sex with clinical suspicion of pulmonary TB including symptoms of cough with or without expectoration for >2 weeks, Significant weight loss, hemoptysis & loss of appetite, any abnormality on Chest radiography as per definition of presumptive tuberculosis given by NTEP attending MGM hospital (both inpatient and outpatient) for treatment from June 2020 to April 2022. Total 200 Cases were collected from Department of Respiratory medicine.

Results: Sensitivity of Genexpert was 93.01% & sensitivity of GeneXpert in AFB smear negative cases was 75.93%, specificity was 100%, PPV 100%, NPV 51.85% & accuracy was 93.50%.

Conclusion: In this study, Sensitivity of GeneXpert is 93.6%. GeneXpert sensitivity in sputum smear negative cases is 75.93%, which is very useful to diagnose the missed cases. Rifampicin resistance in our study is found to be 27% out of which 65.21% were Secondary MDR-TB 17.14% were primary. High Rifampicin resistance in India is due to indiscriminate use of anti-TB drugs, loss of follow up of the patient leading to non-compliance of the AKT regimen. Hence, GeneXpert is an effective tool in initiation of early treatment which shows significantly higher levels of sensitivity and specificity for diagnosis of MTB.

Keywords: GeneXpert MTB/RIF assay, Multidrug resistance, Mycobacterium tuberculosis, sensitivity, specificity

Introduction

Tuberculosis (TB) has affected humans for thousands of years[1]. TB is of two types pulmonary and extra pulmonary with Pulmonary TB being the most prevalent form[2]. Early diagnosis is imperative for early patient management and successful patient outcomes. False-negative results and misdiagnosis of TB suspects is common in the developing nations, as most TB control programmes use Ziehl-Neelsen (ZN) AFB smear microscopy, which has poor sensitivity and multiple visits are required that leads to higher rate of default. Mycobacterial culture, although considered as the gold standard, but is slow and usually takes 2-6 weeks' time to yield a final result and requires proper infrastructure and technical expertise [3,4,5]. The GeneXpert utilizes DNA PCR technique for

simultaneous detection of Mycobacterium tuberculosis and Rifampicin resistance related mutations. It is the first fully

automated bench top cartridge based nucleic acid amplification (CB-NAAT) assay for TB,detection that includes all necessary steps of DNA PCR. It gives results within 2 hours. Diagnostic accuracy of GeneXpert for pulmonary TB has been reported high[9,10].

Materials And Methods

Study Design : Prospective observational study.

Study Population : All patients (age >14years) of either sex with clinical suspicion of pulmonary TB including symptoms of cough with or without expectoration for >2 weeks, Significant weight loss, haemoptysis & loss of appetite, any Abnormality on Chest radiography as per definition of presumptive tuberculosis given by NTEP attending MGM hospital (both inpatient and outpatient) for treatment from December 2018 to October 2020

Sample size : Total 200 Cases were collected from Department of Respiratory medicine.

Inclusion Criteria

1. Patients with Pulmonary Tubercuosis with age more than 14 years, of either sex (Including HIV cases).
2. Patients with clinical suspicion of pulmonary TB including symptoms of cough with or
3. Without expectorationfor >2 weeks, Significant weight loss, hemoptysis & loss of
4. appetite, Any Abnormality on Chest radiography as per definition of presumptive
5. tuberculosis given by RNTCP.
6. No H/o receiving AKT within 3 months before enrollment.

Exclusion Criteria

1. Patients with Pulmonary tuberculosis below 14 years of age.
2. Patients already on ATT.

Ethical Review : The study protocol was approved by the ethics committees of MGM medical college.

Statistical analysis : If the p-value was < 0.05, then the results were considered to be statistically significant otherwise it was considered as not statistically significant. Data were analysed using SPSS software v.23 (IBM Statistics, Chicago, USA) and Microsoft office 2007.

Results: Out of 200 patients, there were 127 males and 73 females in the study. 66% patients were positive for sputum afb smear microscopy and 34% were negative for sputum afb smear microscopy. Out of 200 GeneXpert MTB/Rif test samples were sent out of which 173 MTB was detected (86.5%), 27 MTB not detected (13.5%).out of 200 cases 186 cases were positive for LJ culture and 14 cases were negative. Thus 93% patients positive for LJ culture had Pulmonary Tuberculosis while 7% of the patients who were negative for LJ culture were true negative cases. Out of 200 cases 186 cases were Pulmonary tuberculosis out of which 132 (66%) cases were drug sensitive pulmonary tuberculosis & 54 (27%) were MDR-TB. Rifampicin resistance in our study is found to be 29% out of which 65.21% were Secondary MDR-TB while Primary cases were 17.14%& 14 (7%) cases were Community acquired pneumonia (CAP). Sensitivity of Sputum AFB smear microscopy was 70.97%, specificity was 100%, PPV was 100%, NPV was 20.59% & Accuracy was 73%. While sensitivity of Genexpert (overall) was 93.01% & sensitivity of GeneXpert in AFB smear negative cases was 75.93%, specificity was 100%, PPV was 100%, NPV was 51.85% & accuracy was 93.50%..

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Figure 1 : Findings Of Sputum AFB

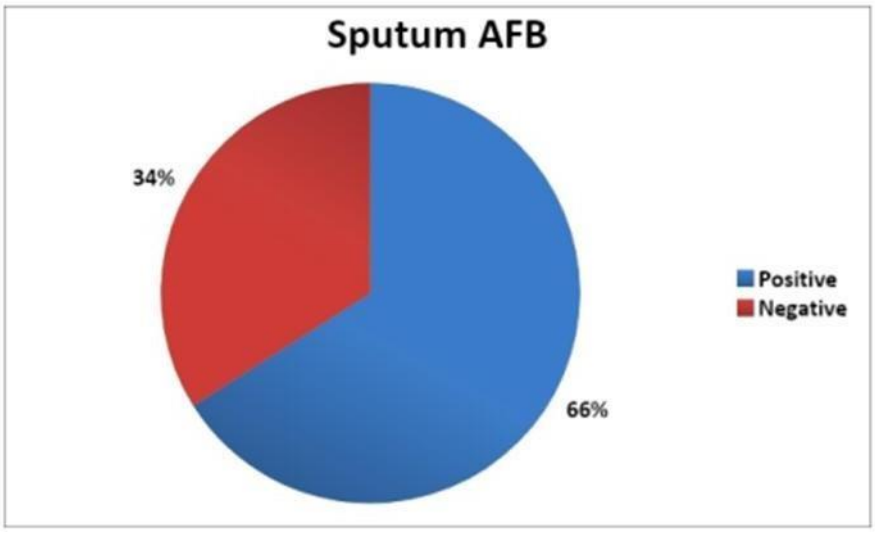

Figure 2 : Findings of GeneXpert

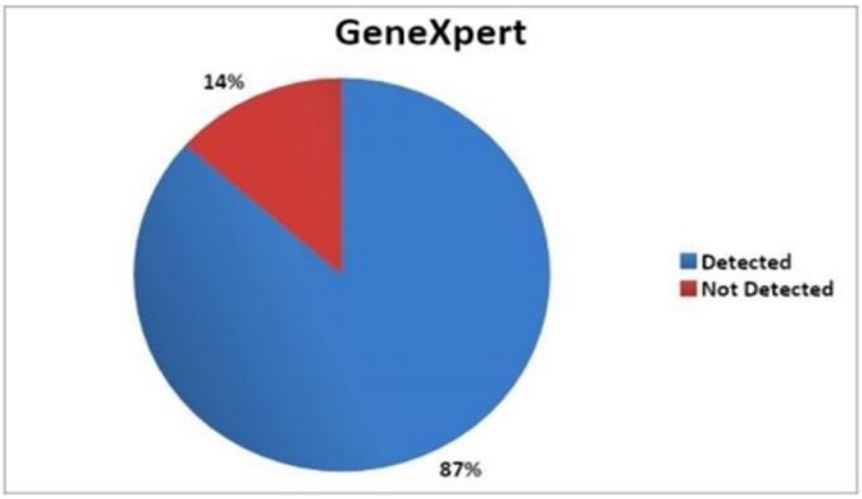

Figure 3: LJ Culture Findings

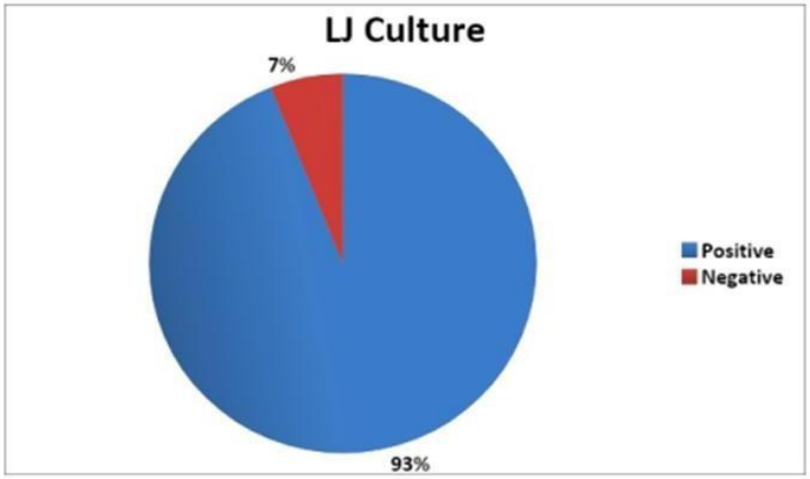

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Figure 4: Rifampicin Resistance Findings

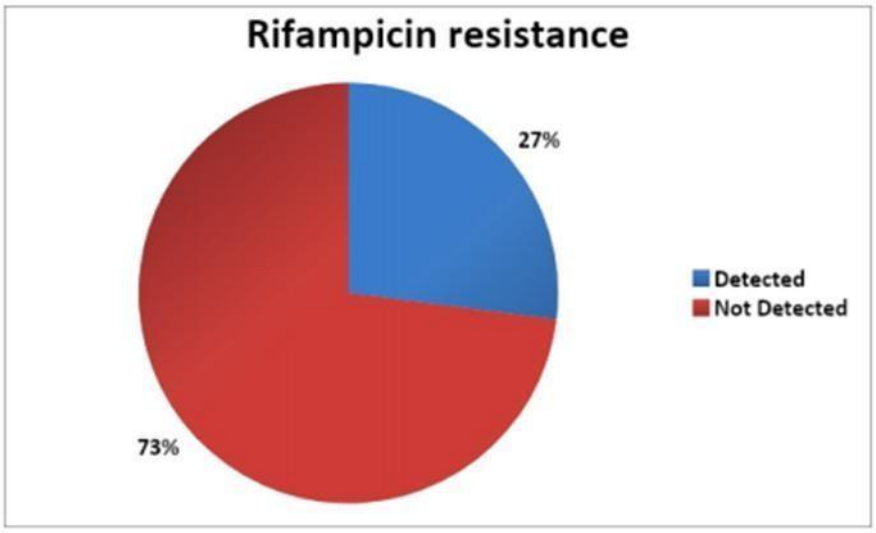

Table 1: Sensitivity analysis of Sputum AFB smear, GeneXpert and LJ Culture

	Sputum AFB smear microscopy	GeneXpert (overall)	GeneXpert in AFB smear negative cases
Sensitivity	70.97%	93.01%	75.93%
Specificity	100.00%	100.00%	100.00%
PPV	100.00%	100.00%	100.00%
NPV	20.59%	51.85%	51.85%
Accuracy	73.00%	93.50%	80.88%

	LJ Culture	Sputum AFB	GeneXpert	GeneXpert in AFB smear negative cases
TP (true positive)	186	132	173	41
FN (false negative)	0	54	13	13
FP (false positive)	0	0	0	0
TN (true negative)	14	14	14	14

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Discussion:

Early diagnosis of Tuberculosis is necessary to disrupt the disease transmission chain. Although ZN smear positive patients are considered highly infectious and being focused by most of the clinicians & national tuberculosis control programme guidelines, smear negative patients are also reported to be responsible for approximately 17% of transmission and its impact on public health could not be neglected[6,7]. We conducted a prospective study at MGM Medical College and Hospital, Navi Mumbai involving 200 patients suspected to have pulmonary Tuberculosis after approval of the ethical committee. We excluded the patients who were on AKT before entering the study. Classic laboratory techniques such as direct sputum smear microscopy sensitive. Cultures are time-consuming, they require bio safety precautions and need trained laboratory personnel. Molecular techniques have substantially changed in the field of tuberculosis diagnosis and they have been proven to yield rapid results as well as being highly sensitive. Culture continues to be the standard for the diagnosis of TB, but isolation can take up to 6 weeks due to slow growth rate of the organism [9]. Smear microscopy to detect acid-fast bacilli in clinical specimens is a rapid and inexpensive test. GeneXpert positivity for MTB in our study was 86.5% which is higher as compared to the same study with MTB positivity rate of 77.4% by GeneXpert [7].. Smear negative TB is more difficult to treat due to delay in reaching the definite diagnosis, in such cases new diagnostic approaches could be fruitful in early diagnosis and prompt treatment, hence breaking community transmission chain as is shown in present study where 75.93% ZN smear negative subjects were found to be positive for MTB by GeneXpert. Rifampicin resistance in our study is found to be 29, out of which 65.21% were Secondary MDR- TB while Primary cases were 17.14%. Prevention from this infectious disease is obligatory to increase the detection rate by using individual or combined techniques which in turn can prevent greater economic loss. Early diagnosis has great importance for the treatment of tuberculosis and the GeneXpert system is an easy and helpful tool for rapid and reliable results with high specificity and sensitivity.

Conclusion:

In our study, we found that Sensitivity of GeneXpert is 93.6% and sensitivity in sputum smear negative cases is 75.93%, which is very useful to diagnose the missed cases Rifampicin resistance in our study is found to be 29%, out of which 65.21% were Secondary MDR- TB while Primary cases were 17.14%. High Rifampicin resistance in India is due to indiscriminate use of anti-TB drugs, especially outside the NTEP[10], loss of follow up of the patient which leads to non- compliance of the AKT regien.

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