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Original Article

Gene Xpert Based Two-Year Analysis of Mycobacterium Tuberculosis from North Maharashtra Region

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ABSTRACT

GeneXpert is a rapid molecular test used to diagnose tuberculosis (TB) and simultaneously detect rifampicin resistance. The rise of Human Immunodeficiency Virus (HIV) has made the way for the re-emergence of Mycobacterium Tuberculosis (MTB) infection, referring to its close link as the "Cursed Duet". Drug-resistant tuberculosis (DR TB) develops due to incomplete or improper treatment, and today, early diagnosis with simultaneous better understanding of multidrug-resistant (MDR) and extensive drug-resistant (XDR) tuberculosis is needed for the institution of proper treatment and prevention of spread of MDR TB in the community.

The main aim and objectives of the study are:

1. To detect Mycobacterium tuberculosis infection in presumptive TB cases using Gene Xpert.
2. To determine the prevalence of Rifampicin-resistant cases in these patients.

A retrospective, record-based study was conducted. The smear microscopy and GeneXpert data were collected from the District Tuberculosis Centre from January 2023 to December 2024 and analysed.

Out of 3180 presumptive TB samples in our study, 3012 (94.72%) were pulmonary samples, and 168 (5.28%) were extrapulmonary samples. The overall positivity rate of TB for presumptive TB cases was 86.8%, with 4.86% showing rifampicin resistance. Among the 915 presumptive DRTB cases, MTB positivity was in 288 cases (31.47%), with 4 cases (1.38%) showing rifampicin resistance.

The GeneXpert MTB/Rif assay is a rapid and highly sensitive test for the early diagnosis of pulmonary and extrapulmonary TB, thereby interrupting the transmission chain, and also for detecting rifampin resistance, thereby preventing treatment failure due to late and improper diagnosis and treatment.

Keywords*: Presumptive TB, GeneXpert, HIV, MDR TB, Presumptive DRTB.*

INTRODUCTION

The disease tuberculosis (TB), which is caused by the bacterium Mycobacterium tuberculosis, is one of the life-threatening infectious diseases and a leading cause of mortality throughout the world. [1] Despite a lot of efforts made globally, TB remains a significant threat to public health, particularly in developing and underdeveloped countries.

The reports of the World Health Organisation (WHO) summarised that approximately 10.8 million people were infected with TB in 2023, which included 55% men, 33% women and 12% children and young adolescents. A total of 1.25 million deaths resulted from TB that year, which included 161,000 individuals living with HIV. [2]

The rise of HIV has resulted in a way for increase in Mycobacterium tuberculosis infection, referring to its close link as the "Cursed Duet". [3] Although antiretroviral therapy reportedly decreases the risk of TB infection in HIV patients, TB remains 5 times more common in HIV/AIDS positive people. [4]

India has the second-highest burden of MDR TB after China. [5] Drug resistant tuberculosis has developed due to incomplete or improper treatment, and at present, early diagnosis of TB with better understanding of MDR and XDR tuberculosis is needed. [6] The WHO initiated GeneXpert MTB/Rif assay is a cartridge based, semi-quantitative, nested real-time PCR in-vitro diagnostic test, that has changed the structure of TB control by simultaneous diagnosis of TB and rifampicin resistance detection. [7] However, the sites of TB infection and the different diagnostic specimens tested impact the accuracy of the GeneXpert assay results. Therefore, the selection of appropriate specimens is pivotal when using GeneXpert to identify suspected TB cases. [1] Without early detection and initiation of proper treatment, TB remains an important public health threat, which increases the mortality rate, particularly in low-resource settings.

Aims and objectives of the study: The present study was conducted to fulfil the following objectives:
1. To detect Mycobacterium tuberculosis infection in presumptive TB cases using Gene Xpert.
2. To determine the prevalence of Rifampicin-resistant cases in these patients.

MATERIALS AND METHODS

Study design: Retrospective study.

Study period: From January 2023 to December 2024.

A record-based study was done for a period of 2 years, that is, from January 2023 to December 2024. The GeneXpert data was collected from the District Tuberculosis Centre and was then analysed.

Collection of specimens: Two sputum samples were collected from each of the registered RNTCP patients and were subjected to GeneXpert MTB/RIF Assay. The specimens were stored and transported at 2°C to 8°C, then examined for obvious food particles or other solid particulates like tobacco, and if found, those samples were rejected and were requested for repeat samples. The remaining samples were then processed in the laboratory.

HIV screening as per the NACO guidelines of the TB patients registered at the DOTS centre is routinely advised after proper pretest counselling and informed consent.

The GeneXpert results of all the processed samples were collected and the findings were analysed.

Inclusion criteria: All the smear-negative presumptive TB cases and presumptive DR TB cases, either from previously treated cases or new suspects, and MDR suspects were enrolled.

Exclusion criteria: All positive cases diagnosed with smear microscopy were excluded.

Statistical Analysis: The obtained data was entered in Microsoft Office Excel 2007 and analysed. Frequencies and percentages were calculated.

RESULTS

During the period from January 2023 to December 2024, of the total a total of 3,180 presumptive TB and presumptive DR TB samples were sent for GeneXpert testing. All of these samples were referred from the public sector, and none were referred from the private sector. Among the 3,180 samples, 3012 (94.72%) were classified as pulmonary samples, and 168 (5.28%) were categorized as extrapulmonary samples. (Table 1 and figure 1).

Table 1: Table representing the various categories of suspected TB cases that were subjected to GeneXpert and their frequency.

Category	Frequency	Percentage
Pulmonary	3012	94.72%
Extrapulmonary	168	5.28%
Total	3180	100%

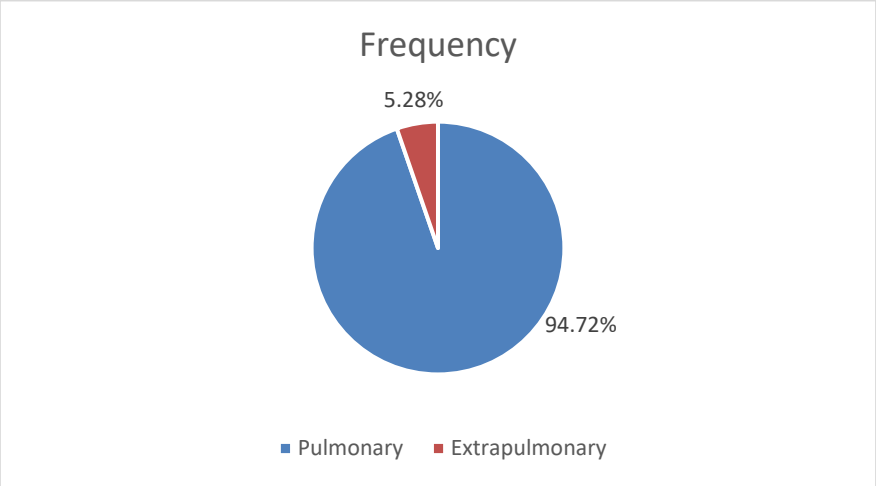

Figure 1: Chart representing the frequency of pulmonary and extrapulmonary TB samples.

Of the total presumptive TB cases, the MTB detection rates were as follows: 52 cases (10.92%) in people living with HIV (PLHIV) with 1 case(1.92%) having rifampicin resistance, 22 (6.89%) in pediatric cases with no rifampicin resistant case, 117 (28.19%) in smear-negative with X-ray suggestive of TB cases with no rifampicin resistant case, 26 cases (14.85%) in extrapulmonary TB, and 204 cases(25.95%) among those offered upfront molecular tests with 6 cases (2.94%) showing rifampicin resistance as presented in Table 2. No samples were received from other vulnerable groups (according to Active Case Finding guidelines), and no cases were identified among contacts of TB and drug-resistant TB patients. Thus, the overall positivity rate of TB in presumptive TB were 421 cases (86.8%), with 7 (4.86%) cases showing rifampicin resistance, as shown in Table 2.

Table 2: Stratification of patients and prevalence of TB and rifampicin-resistant tuberculosis among various categories of presumptive TB cases.

Stratification of patients		Total	MTB not detected (MTB-)	MTB Detected (MTB+)	Rif Resistance not detected (Rif-)	Rif Resistance detected (Rif+)	Percentage of TB positivity	Percentage of R^rTB
Presumptive TB	PLHIV out of presumptive TB	476	424	52	51	1	10.92	1.92
	Paediatric out of presumptive TB	319	297	22	22	0	6.89	0
	Smear Negative X-ray suggestive of TB	415	298	117	117	0	28.19	0
	Other Vulnerable group (as per ACF guidelines)	0	0	0	0	0	0	0
	Contacts of TB & DRTB patients	0	0	0	0	0	0	0
	EPTB	175	149	26	26	0	14.85	0
	Upfront Molecular test offered	786	582	204	198	6	25.95	2.94
	Total	2171	1750	421	414	7	86.8	4.86

Among the 915 presumptive drug-resistant tuberculosis cases, MTB was detected in 288 (31.47%) for newly notified TB patients (who underwent universal drug susceptibility testing) with 4 cases (1.38%) having rifampicin-resistant tuberculosis, no MTB samples for previously treated TB patients (also tested) and for non-responders (including patients

with drug-sensitive TB and high-risk TB). Thus, the MTB positivity rate among those with presumptive drug-resistant TB was 31.47% with 1.38% showing rifampicin resistance (1.38%) (Table 3).

Table 3: Stratification of patients and prevalence of TB and rifampicin-resistant tuberculosis among various categories of DRTB cases.

Stratification of patients		Total	MTB not detected (MTB-)	MTB Detected (MTB+)	Rif Resistance not detected (Rif-)	Rif Resistance detected (Rif+)	Percentage of TB positivity	Percentage of R^rTB
Presumptive DRTB (Pulmonary)	Notified TB patients (New)-UDST	915	627	288	284	4	31.47	1.38
	Notified TB patients (Previously treated)-UDST	0	0	0	0	0	0	0
	Non-responders (DSTB & H^rTB)	0	0	0	0	0	0	0
	Total	915	627	288	284	4	31.47	1.38

DISCUSSION

Our study found that the co-infection rate of HIV and Tuberculosis was 10.92%. These figures are higher than those reported by Warkari, et al (7.28%) [8] and Sawant SS, et al (9%) [9], and Pradhabane G, et al (7.54%) [1]. The rate of rifampicin resistance among these cases in our study was 1.92%, which was lower than that reported by Pradhabane G, et al (5.59%) [1]. Our study is consistent with these studies, which has suggested the benefit of Xpert in HIV positive smear-negative patients.

In terms of paediatric tuberculosis prevalence, our study showed a positivity rate of 6.89%, which was higher than that reported by Pradhabane G et al(2.22 %) [1]. According to Warkari PD et al [8] nearly 5.74% of TB cases in India occur among children, which is also lower than our findings.

Our study found a prevalence of 28.19% among smear-negative, X-ray-suggestive tuberculosis cases enrolled in this research. The prevalence is higher than the 20.53% reported by Pradhabane G et al [1] in India and that reported by Khadke et al (23.61%) [10].

In our study, the prevalence of tuberculosis among extrapulmonary patients was 14.85% which was higher than that reported by Pradhabane G et al (9.78 %) [1], while it is lower than that reported by Singhal et al (29.7%) [11].

Those patients subjected to upfront molecular testing showed a heightened risk, with a positive percentage of 25.95%, with 2.94% diagnosed with rifampicin-resistant tuberculosis, which is higher than that reported by Pradhabane G, et al (14.88% and 1%).

We didn't receive any cases of tuberculosis and rifampicin-resistant tuberculosis among contacts of TB and DRTB patients.

CONCLUSION

MTB is extremely difficult to contain and manage, and usually requires a multidisciplinary, coordinated set of activities. Identification of acid-fast bacillus (AFB) in smear microscopy is a rapid and inexpensive option, and culture, though time-consuming and requiring appropriate infrastructure and technical expertise, is fundamental for diagnosing tuberculosis.

This study emphasises the importance of WHO-endorsed GeneXpert MTB/RIF, and its contribution in the present day towards the diagnosis of tuberculosis, especially smear-negative, suspected TB cases, extrapulmonary TB and rifampicin-resistant tuberculosis, which overall significantly impact TB control programs. Patients who are HIV positive are more likely to show smear-negative TB, which delays the diagnosis of TB in such patients, and as such, GeneXpert serves as a useful tool and thereby helps in the management of these patients, thus reducing the morbidity and mortality. Further, the implementation of the test in every developing and underdeveloped country having a major disease burden is a wise investment in restricting the global burden, as targeted by the WHO.

Abbreviations: TB: Tuberculosis.
R^rTB: Rifampicin-resistant Tuberculosis.
MDR-TB: Multidrug-resistant tuberculosis.
MTB: Mycobacterium tuberculosis.
RNTCP: Revised National Tuberculosis Programme.
DOTS: Directly Observed Therapy, Short-Course.
AKT: Anti Koch's treatment.
XDR-TB: Extensively drug-resistant tuberculosis.
WHO: World Health Organisation.
HIV: Human Immunodeficiency Virus.
AIDS: Acquired Immunodeficiency Syndrome.
PLHA: People living with HIV/AIDS.
SNPT: Smear-negative pulmonary TB.

Definitions of Presumptive TB:

1. **Presumptive Pulmonary TB** refers to a person with any of the signs and symptoms suggestive of TB, including cough > 2 weeks, fever > 2 weeks, significant weight loss, hemoptysis, or any abnormality in chest radiograph.
   Note: *In addition, contacts of microbiologically confirmed TB patients, PLHIV, diabetics, malnourished, cancer patients, patients on immunosuppressants or steroids, should be regularly screened for signs and symptoms of TB.*

2. **Presumptive Extrapulmonary TB** refers to the presence of organ-specific signs and symptoms like swelling of lymph node, pain and swelling in joints, neck stiffness, disorientation, and/ or constitutional symptoms like significant weight loss, persistent fever ≥ 2 weeks, and night sweats.

3. **Presumptive pediatric TB** refers to children with persistent fever and/ or cough for more than 2 weeks, loss of weight*/ no weight gain and/ or history of contact with infectious TB cases**. (*Note: * History of unexplained weight loss or no weight gain in past 3 months; loss of weight is defined as loss of more than 5% body weight as compared to the highest weight recorded in the past 3 months. ** In a symptomatic child, contact with a person with any form of active TB within the last 2 years may be significant*.

4. **Presumptive DRTB** refers to those TB patients who have failed treatment with first-line drugs, pediatric T B non-responders, TB patients who are contacts of DRTB (or RIF resistance), TB patients who are found positive on any follow-up sputum smear examination during treatment with first-line drugs, previously treated TB cases, and TB patients with HIV coinfection.

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