EARLY DIAGNOSIS SUSPECTED PATIENTS WITH TUBERCULOSIS USING GENE EXPERT MTB/RIF ASSAY IN THQ HOSPITAL KOT RADHA KISHAN

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Abstract

Background: *Mycobacterium Tuberculosis is a globally serious problem of health. While Culture takes too much time consuming and smear of microscopy gives us false negative and false positive results. ICT kit also give false positive results. GeneXpert MTB/RIF is a dependable program that is crisp and exact to an incredible degree. This study's primary objective is to determine whether or not the GeneXpert MTB/RIF is extremely trustworthy and capable of doing accurate job.*

Objective: *To determine the early diagnosis suspected patients with tuberculosis using GeneXpert MTB/RIF assay in THQ Hospital Kot Radha Kishen.*

Methodology: *This study was conducted in THQ Hospital. There collected respectively 120 suspected pulmonary tuberculosis patients (PTB) using GeneXpert MTB/RIF machine four module at a time run four samples which give highly precise results. Out of 120 how many suspected patients were detected MTB and analysis its results separately compared with Rifampicin Resistance antibiotic.*

Results: *In results 17.5% (21/120) suspected patients were detected MTB while 3.3% (4/120) was detected Rifampicin Resistance indeterminate using GeneXpert MTB/RIF. Suspected patients of PTB were detected MTB 2.5% high, 10.8% low, 3.3% trace and 0.8% medium*

Conclusion: *The Four modules GeneXpert method has high sensing efficiency. It has excellent indicate the value of infection and detecting of RIF and MTB, instead of in culture media and sputum smear formation results are negative and sometime interprets false positive results and important reduces the rate of false interprets. The diagnosed method of MTB using culture technique take days not done in hours.*

INTRODUCTION

The gram-negative bacterium Mycobacterium tuberculosis is that causes TB. Tuberculosis had in the past been diagnosed based on the alcohol acid-fast characteristics of the bacillus. For more than a century later, Robert Koch's direct sputum smear examination is still very much in use. The smear formation of acid-fast bacilli (AFB) is the most common and inexpensive means of diagnosing respiratory infection of TB [1].

Its sensitivity is modest, though, and under a microscope, a concentration of one million colony forming U/ml is need to be considered positive. Thus, a sample with a low number of bacteria yields a negative result. However, drug sensitivity testing in culture takes a long time—at least 8 weeks and microscopy is not very sensitive [2, 3].

GeneXpert M. tuberculosis working on real time NAAT on a fully automated cartridge. To diagnose Mycobacterium infection and to identify drug resistance specific one is rifampicin in a single setting, the system is special composed for this purpose such that sample processing, double nucleic acid extraction, and DNA amplification all occur at the same time [4].

Inhalation of tuberculosis droplet nuclei, which vary in size from one to five micrometers, is the airborne method of transmission. This exposure occurs when an infected person coughs, speaks, sings, or sneezes. Warning signals and symptoms Artists, poets, and musicians are not the only ones who may experience a variety of symptoms, such as a hacking cough, blood in the mucus, difficulty breathing, lack of appetite, high body temperature, generalized weakness, and ultimately, fatal cachexia.[5]

We will call communities semi-closed that are not entirely closed and do allow some level of member mobility where new members may join while older ones leave. However, by nature, such communities serve as a space to which members regularly return day in and day out for weeks, months, or even years. These communities, for instance, include jails but may also include some urban/rural towns, schools, and others. Such communities make it possible to have numerous TB outbreaks, increased TB transmission, and rapid disease spread. The most usually route of exposure infection is by aerosols, which enables droplet nuclei carrying one to three bacilli (particle size, <5 μm) to enter alveoli basic and functional unit of lungs [6, 7].To eliminate the invading microorganisms from the host, alveolar macrophages ingest the bacteria. These cells are likely to be endowed with a variety of microbicidal processes such as phagolysosome fusion and a respiratory [8]. For the infection to be effective, the tubercle bacillus must survive its interaction with the alveolar macrophages and eventually enter the bloodstream or lymphatics [9].

It showed that the presence or lack of serum factors at the time of infection influences the emulsion pattern of macrophages infected with malignant excrescence bacilli and that these bacteria can impede phagolysosome emulsion. It has been demonstrated that M. tuberculosis may enter macrophages in this setting by use of complement receptors CR1 and CR3 [10-12].

Tuberculosis can be diagnosed using any of the above laboratory tests with Ziehl-Nelsen staining, also commonly known as ZN staining of the counter-staining Malachite Green 15, serological testing that utilizes ICT Immune Chromatic technique kits 15. It is unreliable for the same produces false negative results or false-positive results [13]. Throughout the last ten years and some previous years Ultra GeneXpert with multi drug resistance highly precise detection of specify and sensitivity. These are termed as nucleic based acid amplification tests, NAATs for short, which amplify a specific genetic area of the Mycobacterium TB complex usually through a process called PCR [14].

In 1919, French TB researcher was collaborated in developing countries to find a Calmette-Guerin bacillus, which later they called the Bacilli Calmette Guerin (BCG) vaccine. Then further American doctors defined RIPE by Rifampin, the alternative drugs such as Isoniazid, Pyrazinamide, and Ethambutol in the treatment of TB in the twentieth-first century. HRZE is used for isoniazid (in chemically represent isonicotinic acid Hydrazide), rifampicin, pyrazinamide, and ethambutol by researchers and several practitioners outside of the US. P can be either pyrazinamide 1depending on the context [15, 16].

GeneXpert gives results around about 87% to 90% without any distortion. Some GeneXpert with four modules and six according to area where Tuberculosis suspected patients in enormous amount. While other methods for detection of Tuberculosis is not more accurate than GeneXpert. Like as Microscopy, ICT and culture tests. These methods are taken much time and give false positive results or false negative results. But GeneXpert method is reliable and high specificity with high sensitivity [17].

Early identification can facilitate effective treatment and transmission prevention. However, old technique used for diagnostic methods like sputum smear formation for microscopy and in microbiology labs

use culture media, suffer from inherent sensitivity, specificity, and limited turnaround time. There is, however, an exciting molecular diagnostics tool called GeneXpert MTB/RIF, which offers rapid identification of Mycobacterium tuberculosis or MTB. As such, with much hope for its deployment, nothing much is known yet on how to use it appropriately or how effectively GX works on patients suspected to have PTB. Respiratory infection (PTB) is the most common form of tuberculosis (TB) and remains a significant global public health concern.

MATERIAL AND METHODS
Study Design: Cross-sectional study design was employed in study.
Settings: Data collected from THQ Hospital Kot Radha Kishen.
Sampling Technique: A simple random sample approach was used in order to acquire the necessary data.

Sample Selection:
Inclusion Criteria: Patients with a suspected of pulmonary Tuberculosis (PTB) base on clinical symptoms. (Cough, weight loss, fever, etc.)
Patient above 18 years old.
Both males and female gender will be included in study.

Exclusion Criteria:
Previous diagnosis of TB or current treatment.
Below 18 years old.
Pregnancy or lactation.
Incomplete and missing medical record or sample.

Study Design and Setting
The "Tehsil Headquarters (THQ) Hospital Kot Radha Kishen" was the location where this cross-sectional research was carried out over a period of six months. Participants in the trial were individuals who were suspected of having tuberculosis (TB) and who presented with clinical signs such as a persistent cough that lasted for more than two weeks, fever, night sweats, weight loss, or hemoptysis.

Study Population and Sample Collection
Patients with a suspected case of tuberculosis were included in total. In accordance with the standards established by the World Health Organization (WHO), sputum samples were obtained from each participant in the morning. In accordance with the necessary biosafety protocols, the samples were delivered to the laboratory of the hospital after being kept in containers that were both sterile and leak-proof.

Laboratory Processing of Samples
All of the sputum samples were processed and analyzed using the GeneXpert MTB/RIF test, which was carried out in accordance with the methodology provided by the manufacturer. Simply put:The first step in the sample processing process was treating sputum samples with the Sample Reagent (SR) that was given in a ratio of 2:1, vortexing the samples, and then incubating them for fifteen minutes.

DNA Extraction and Polymerase Chain Reaction (PCR):
The mixture was placed into the GeneXpert cartridge, which was then put into the GeneXpert machine for the purpose of performing automated DNA extraction, detect Mycobacterium tuberculosis (MTB) and rifampicin (RIF) resistance, and perform real-time polymerase chain reaction (PCR).

Data Analysis
Data was analyzed using SPSS version 26. Using descriptive stats with help of Chi-square selected the Rows and Columns find the Values of MTB and RIF, and also mentioned the bar charts. Descriptive statistics were used to summarize demographic and clinical characteristics.

DATA ANALYSIS PROCEDURE
IBM Statistical Package for Social Science (SPSS) 26.0 window version will be used for the purpose of doing data analysis. The Chi-square test, which was used to compute and identify the numbers, gender, and percentage of patients, was suitable for descriptive statistics. obtaining the p-value, the Chi-square test was used. The variables were deemed to be non-significant when the p-value was equal to or greater than 0.1. That there is no evidence to contradict the null hypothesis.

RESULTS
Gender Distribution
Shown in this figure 48.3% were female while 51.6% were male suspected tuberculosis patients. Suspected patients of pulmonary tuberculosis of male percentage were greater than female.
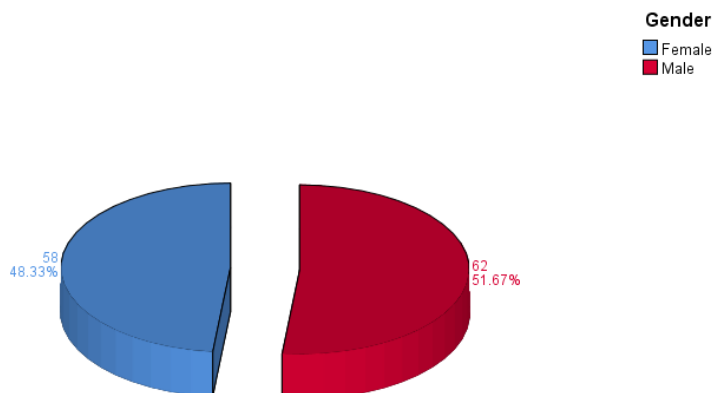

Fig. 1: Gender distribution suspected patients of pulmonary tuberculosis.

XPERT MTB ASSAY RESULTS
For the purpose of this research, a total of 120 individuals suspected of having M. tuberculosis were enrolled. These patients had pulmonary TB and did not have extra pulmonary case. The percentage of females among them was 48.3% (58/120), while the percentage of males was 51.7% (62/120). In which 0.8% (1/58) were high detected MTB, 5.0% (6/58) were low detected MTB, 0.0% (0/58) were medium detected MTB, 40.0% (48/58) were not detected MTB, 2.5% (3/58) were trace detected MTB. While Male 1.7% (2/62) were high detected MTB, 5.8% (7/62) were low detected MTB, 0.8% (1/62) were medium detected MTB, 42.5% (51/62) were not detected MTB, 0.8% (1/62) were trace detected MTB. Overall total 2.5% (3/120) were high detected MTB, 10.8% (13/120) were low detected MTB, 0.8% (1/120) were medium detected MTB, 82.5% (99/120) were not detected MTB and 3.3% (4/120) were trace detected MTB.

Table 1. Results of GeneXpert MTB (n=120)

			Detected MTB					Total
			High	Low	Medium	Not Detected	Trace	
Gender	Female	Count	1	6	0	48	3	58
		Expected Count	1.5	6.3	.5	47.9	1.9	58.0
		% within Gender	1.7%	10.3%	0.0%	82.8%	5.2%	100.0%
		% within Detected MTB	33.3%	46.2%	0.0%	48.5%	75.0%	48.3%
		% of Total	0.8%	5.0%	0.0%	40.0%	2.5%	48.3%
	Male	Count	2	7	1	51	1	62
		Expected Count	1.6	6.7	.5	51.2	2.1	62.0
		% within Gender	3.2%	11.3%	1.6%	82.3%	1.6%	100.0%
		% within Detected MTB	66.7%	53.8%	100.0%	51.5%	25.0%	51.7%
		% of Total	1.7%	5.8%	0.8%	42.5%	0.8%	51.7%

Total	Count	3	13	1	99	4	120
	Expected Count	3.0	13.0	1.0	99.0	4.0	120.0
	% within Gender	2.5%	10.8%	0.8%	82.5%	3.3%	100.0%
	% within Detected MTB	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
	% of Total	2.5%	10.8%	0.8%	82.5%	3.3%	100.0%

XPERT RIF ASSAY RESULTS

In this study, out of 120 suspected Tuberculosis patients were involved Rifampicin resistance in which 96.7% (116/120) were not detected RIF and 3.3% (4/120) were detected indeterminate RIF. In female total 2.5% (3/58) were detected indeterminate RIF, 45.8% (55/58) were not detected RIF. In male total 0.8% (1/62) were detected indeterminate RIF and 50.8% (61/62) were not detected RIF.

Table 2. Results of GeneXpert RIF (n=120)

			Detected RIF		Total
			Indeterminate	Not Detected	
Gender	Female	Count	3	55	58
		Expected Count	1.9	56.1	58.0
		% within Gender	5.2%	94.8%	100.0%
		% within Detected RIF	75.0%	47.4%	48.3%
		% of Total	2.5%	45.8%	48.3%
	Male	Count	1	61	62
		Expected Count	2.1	59.9	62.0
		% within Gender	1.6%	98.4%	100.0%
		% within Detected RIF	25.0%	52.6%	51.7%
		% of Total	0.8%	50.8%	51.7%
Total		Count	4	116	120
		Expected Count	4.0	116.0	120.0
		% within Gender	3.3%	96.7%	100.0%
		% within Detected RIF	100.0%	100.0%	100.0%
		% of Total	3.3%	96.7%	100.0%

Graphical Description Results
GeneXpert detected MTB

The Patients were detected tuberculosis in this bar chart represents five parameters high, low, medium, not detected and trace. Shown in figure gender comparison in which 48 suspected patients were not detected MTB in female and 10 suspected patients were detected MTB, while in male 51 suspected patients were not detected MTB, 11 suspected patients were detected MTB.
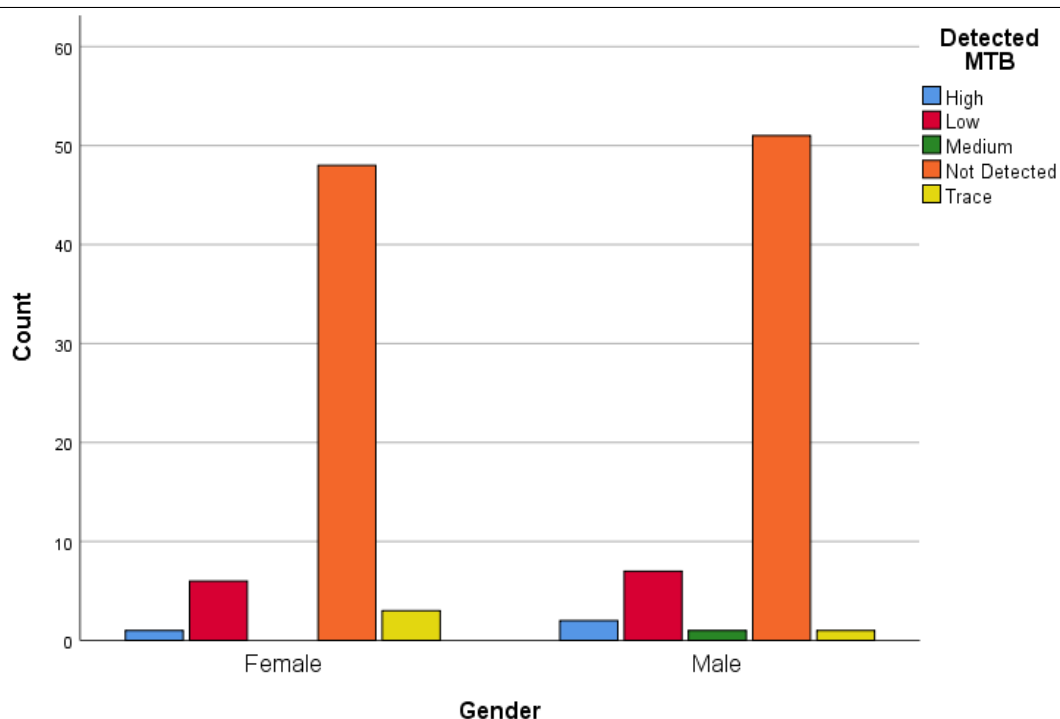
Fig. 2. MTB distribution pattern of high, low medium, trace and not detected among suspected patients of pulmonary tuberculosis.

GeneXpert detected Rifampicin Resistance
Shown in this figure Rifampicin Resistance detected indeterminate were overall 4 suspected patients of tuberculosis. While (116/120) were not detected RIF.
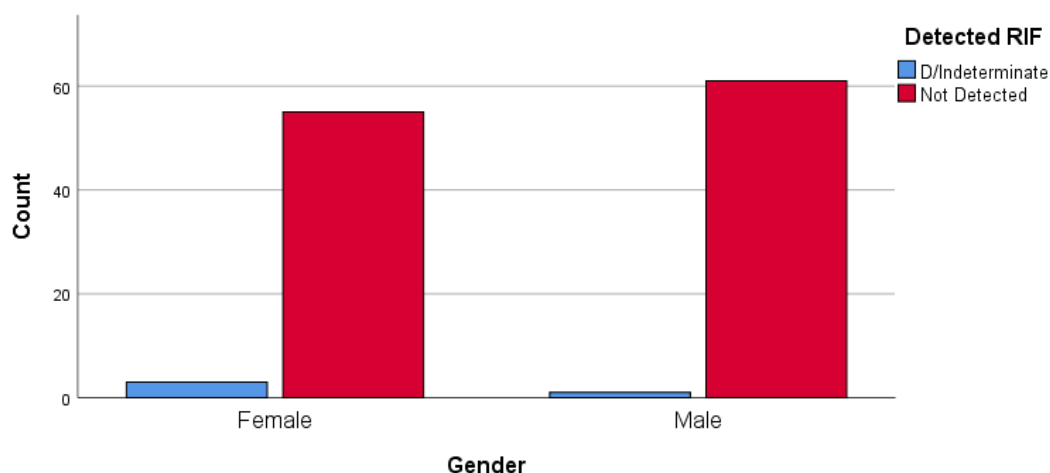

Fig. 3: Rifampicin Resistance distribution pattern detected and not detected among suspected patients of pulmonary tuberculosis.

DISCUSSION

Through the use of the GeneXpert MTB/RIF test, the purpose of this research was to facilitate the early detection of patients who were suspected of having tuberculosis at THQ Hospital Kot Radha Kishen. There was a 17.5% total prevalence of tuberculosis MTB suspected patients, which corresponds to the general prevalence. When compared to the findings of a research that was carried out at the Xpert MTB/RIF Assay in AJK, Pakistan, the results of this investigation produced a lower percentage (26%). In KPK, Pakistan, the findings of the Xpert MTB/RIF test were 38.45. percent. Jigjiga town is home to the Karamara hospital, which serves as the seat of the Somali region (25.5%) China accounts for 36.6% of the total, while India accounts for 18.98% 41% North Ethiopia's University of Gondar Hospital, which accounts for 24.6% of the total[18]. Higher than Care Children's Hospital (4.5%) and (6.17%) in the Amahara Region Ethopia [19, 20]. While Resistance Rifampicin (RIF) overall prevalence in suspected tuberculosis patients were 3.3%. The interpretations of this study was lower when separately compared with University of Gondar Hospital (15.8%) [18]. The Botswana National Tuberculosis Reference Laboratory (14.1%) [21]. Asian countries in which Bangladesh and Nepal have been found to have RIF resistance high rates of 50% and 86.5%, respectively [22, 23]. 71 patients were detected resistant to rifampicin in Gondar Hospital [18]. Rifampicin Resistant were diagnosed 54.4% in Eastern Uttar Pradesh and (7.11%) in Chennai India [24, 25]. Comparisons of these studies of variation may be related to sample size, technique of sample, study period time, sample collection process and preventions of TB Control. However, in this study sample collection technique was used.

In this study, 17.5% patients were detected of M. Tuberculosis (MTB) in which male 8.9% while female was detected MTB 8.3%. However, indeterminate detected resistance of rifampicin 3.3%. Other studies in which AJK, Pakistan also reported that the prevalence overall 26% (734/2,790) were confirmed to have MTB, 45.5% were detected M. tuberculosis in suspected patients in KPK, Pakistan where the average MTB detection rate for the three methods used in various nations was 18.5%, 22.3%, and 11.6% (28, 38, 50). In a research conducted at Karamara Hospital in Jigjiga, the capital of Somalia, 19.4% of tuberculosis patients tested positive using the Xpert MTB/RIF assay (44 out of 244). Additionally, 9.0% of specimens tested showed rifampicin resistance (4 out of 38). There were 13.6% occurrences of 51 indeterminate RIF outcomes. Using the GeneXpert MTB/RIF test 42, 18.9% (45/238) of probable M. tuberculosis patients in China were found, with 7 instances demonstrating rifampicin resistance. Among 1,820 individuals suspected of having TB, this research was conducted at Gondar Hospital, northwest Ethiopia. Out of 448 confirmed instances of Mycobacterium TB, 71 individuals suspected of having TB were found to be resistant to rifampicin [18]. In Care Children's Hospital Lahore total samples of MTB/RIF were 1320, Out of (110/1320) suspected patients were detected MTB while five patients were detected rifampicin resistance indeterminate and sample of sputum mix with buffer was taking around about 10 minutes then using a cartridge was installed in the GeneXpert MTB/RIF four modules while when compared method in this study was also similar according to this while some studies were used specimens of extra pulmonary and pulmonary tuberculosis but in this study specific specimen was used in pulmonary tuberculosis. According to this study, significantly the detection rate of MTB was higher in male than females and also in AJK, Pakistan detection rate of MTB was male higher than female in this study age group (15-29) high frequency suspected patients were detected [19, 26]. Suspected patients of pulmonary tuberculosis were higher in males due to higher exposure of social and crowded environment for work activities and other activities such as smoking alcoholism.

A history of drinking and a family history of tuberculosis are two additional risk factors for pulmonary tuberculosis infection. The major reason why smokers are more likely to get Mycobacterium TB is that both smoking and drunkenness weaken the immune system. Immune system abnormalities and dysfunction have been directly linked to the development of active TB from latent forms. 29 52. Although medication resistance and MTB detection were recorded independently in 53 cases, this investigation did not include patients who had both tuberculosis and HIV coinfections and did not compare their results. With a detection period that is

up to two hours shorter than previous approaches, the Xpert MTB/RIF test is a valuable diagnostic tool for the early diagnosis of pulmonary and extrapulmonary tuberculosis. As a result, limiting the disease's spread and enhancing treatment results in the future depend on early diagnosis of TB in suspected individuals [27, 28].

CONCLUSION

Mycobacterium Tuberculosis in suspected patients were detected frequently found low in amount. Rifampicin Resistance was found low in previous studies. GeneXpert highly sensitive and specific for MTB/RIF that's why prefer to this technique instead of smear formation or culture media. During smear formation spread of airborne fumes and odors can cause exposure of environment and also infect the person. Staining give false negative results that cause delayed treatment leads to serious health problem. The sputum sample was deals in separately lab and experience person who followed the Standard operating procedure (SOPs). Besides, Ultra GeneXpert and Multi Drug resistance is required.

RECOMMENDATION

To further enhance the early diagnosis of tuberculosis (TB) using the GeneXpert MTB/RIF assay at THQ Hospital Kot Radha Kishen, future research should focus on several key areas. First, expanding diagnostic capabilities by integrating GeneXpert with other emerging technologies—such as computer-aided detection (CAD) for chest radiography or novel biomarker-based assays—could improve accuracy and efficiency. Additionally, operational research should assess cost-effectiveness, barriers to implementation, and optimal testing algorithms to maximize resource utilization in this setting. Special attention should be given to high-risk populations, including pediatric TB cases, HIV-coinfected patients, and extrapulmonary TB, where diagnostic challenges remain significant. Quality improvement initiatives, such as enhanced training for laboratory staff and robust quality assurance protocols, will ensure consistent test reliability. Further studies should also explore drug resistance patterns, treatment outcomes, and the impact of rapid diagnosis on patient adherence and stigma reduction. Comparative studies between GeneXpert and alternative molecular tests (e.g., TB-LAMP) could help refine diagnostic strategies.

Telemedicine and digital health applications, including AI assisted interpretation and mobile health follow-ups, may further optimize TB diagnosis in resource-limited settings. Finally, policy-oriented research should generate evidence for sustainable funding, national TB program integration, and advocacy for expanded access to rapid diagnostics. By addressing these areas, future research can strengthen TB detection, improve patient outcomes, and contribute to global TB elimination efforts.

LIMITATION

In this study limited sources were four module GeneXpert MTB/RIF and also limited short time period. If does six or eight module or long time period then may be increase sample size. Then further GeneXpert MTB/RIF could not did compare with culture media due to not available microbiology lab in THQ Hospital. Further, we could not to perform multi drug resistance with GeneXpert.

Originality and submission Status of Manuscript:
The work done and material used in this manuscript has not been previously published and is not being concurrently submitted elsewhere.

Ethical Approval:
Approved From BOS.

Declaration of Conflicting Interest:
The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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