

Original Research

DETECTION OF PULMONARY TUBERCULOSIS IN SUSPECTED CASES USING THE GENEXPERT MTB/RIF ASSAY AT INTERNAL MEDICINE DEPARTMENT THONG NHAT HOSPITAL, 2024–2025

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ABSTRACT: The early diagnosis of pulmonary tuberculosis remains a critical priority in clinical practice. Although the GeneXpert MTB/RIF assay has been recommended for tuberculosis diagnosis, its implementation has not been widely adopted in many regions of Vietnam. Objectives: This study aimed to evaluate the diagnostic value of the GeneXpert MTB/RIF assay on sputum samples for detecting pulmonary tuberculosis and to compare its results with those from direct sputum smear microscopy (AFB). Methods: A cross-sectional descriptive study was conducted on 270 patients with suspected pulmonary tuberculosis who were examined and treated at the Internal Medicine Department, Thong Nhat Hospital, between January 2024 and July 2025. Results: Among the participants, 72.2% were male and 27.8% were female. The mean age was 79.5 ± 15.1 years, and the mean body mass index (BMI) was 21.1 ± 3.4 kg/m². The detection rate of tuberculosis was 14.1% using the GeneXpert MTB/RIF assay, compared to 4.8% by AFB smear microscopy. Compared to AFB smear microscopy, the GeneXpert MTB/RIF assay demonstrated a sensitivity of 84.6%, a specificity of 89.5%, a positive predictive value (PPV) of 28.9%, and a negative predictive value (NPV) of 99.1%. The rate of rifampicin resistance among detected cases was 7.9%.

Keywords: Pulmonary tuberculosis, Rifampicin resistance, GeneXpert MTB/RIF

1. INTRODUCTION

Tuberculosis has always been one of the top health concerns both in Vietnam and worldwide. According to the WHO, in 2022, the number of new tuberculosis patients detected globally was 7.5 million, causing about 1.3 million deaths. In Vietnam, this figure was 172 thousand people with approximately 11 thousand deaths due to tuberculosis, higher than the number of deaths from traffic accidents. Vietnam remains a country with a high burden of tuberculosis, ranking 11th among the 30 countries with the highest number of tuberculosis patients globally, and also ranking 11th among the 30 countries with the highest burden of multidrug-resistant tuberculosis in the world [1]. Therefore, early detection and timely treatment of tuberculosis contribute to reducing the mortality rate due to tuberculosis as well as reducing the rate of drug-resistant tuberculosis, helping patients reduce sequelae caused by the disease.

Gene Xpert MTB/RIF is a molecular biology technique integrating three technologies (gene extraction, gene amplification, and gene identification), providing rapid results within 2 hours with high accuracy. Notably, in a single report, it allows for the detection of whether the specimen contains *Mycobacterium tuberculosis*, the bacterial load, and whether the bacteria are resistant to rifampicin [2]. In 2010, WHO recommended the application of Gene Xpert MTB/RIF in tuberculosis control as an initial diagnostic test for suspected cases of multidrug-resistant tuberculosis or TB/HIV co-infection. In Vietnam, in 2020, the National Tuberculosis Program recommended expanding the Gene Xpert MTB/RIF test to all individuals showing signs of suspected tuberculosis (depending on the area) [3]. At the Internal Medicine Department - a geriatric department with elderly patients, multiple comorbidities, and prone to multidrug-resistant bacterial infections - the detection of pulmonary tuberculosis in these patients previously faced many difficulties. Therefore, we posed the research question: What is the value of the Gene Xpert MTB/RIF test in detecting pulmonary tuberculosis in suspected pulmonary tuberculosis patients at the Internal Medicine Department?

From there, we conducted this study

with the specific research objectives: the detection rate of tuberculosis in patients with suspected pulmonary tuberculosis using the Gene Xpert MTB/RIF test and the comparison of Gene Xpert MTB/RIF results with sputum AFB test results of patients examined and treated at the Internal Medicine Department, Thong Nhat Hospital, from January 2024 to July 2025.

2. MATERIALS AND RESEARCH METHODS

2.1. Study Design

Cross-sectional descriptive.

Study Time and Location: From January 2024 to July 2025 at the Internal Medicine Department, Thong Nhat Hospital.

2.2. Study Subjects

Patients examined and treated at the Internal Medicine Department, Thong Nhat Hospital, with clinical symptoms or chest X-ray images suggestive of pulmonary tuberculosis

Inclusion Criteria:

- + Agree to participate in the study.
- + All adult patients ≥ 18 years old with symptoms suggestive of pulmonary tuberculosis meeting at least one of the following two conditions:

Clinical symptoms suggestive of pulmonary tuberculosis: hemoptysis, productive cough, dry cough, cough lasting > 2 weeks, chest pain, weight loss, fever (high-grade, low-grade, afternoon fever), anorexia, fatigue, shortness of breath, weight loss.

Chest X-ray findings suggestive of TB: cavitory lesions, nodular lesions, infiltrative lesions, in one or both lungs, pleural effusion.

Exclusion Criteria:

- + Do not agree to participate in the study.
- + Patients unable to produce a sputum specimen or have no sputum.

2.3. Sample Size

Applying the formula for estimating a proportion sample size:

$$n = 1,962^2 \frac{p(1-p)}{d^2}$$

According to author Pham Thi Diem Phuc et al. (2023) [4], the positive rate of Xpert MTB/RIF test in patients indicated for Xpert MTB/RIF test was 28.8%, corresponding to $p = 0.288$; Choosing a confidence level of 95% ($Z_{1-\alpha/2} = 1.96$); Permissible error 6% ($d = 0.06$); So $n=218$.

In practice, we obtained 270 cases meeting the inclusion criteria.

2.4. Variable Definitions

Age, gender, residence, BMI, history of contact with TB patients, smoking history, comorbidities (diabetes mellitus, previous pulmonary tuberculosis, sequelae of stroke, drug-induced Cushing's syndrome).

Clinical symptoms.

Chest X-ray results.

Sputum AFB results.

Sputum Xpert MTB/RIF results.

2.5. Methods and Tools for Measurement and Data Collection

Research Method: Patients examined and treated at the Internal Medicine Department, Thong Nhat Hospital, with symptoms suggestive of pulmonary tuberculosis (clinical symptoms, imaging diagnosis) were indicated for sputum tests: 2 sputum samples for direct AFB testing at two different time points and 1 sputum sample for Gene Xpert MTB/RIF testing. The sputum AFB and Gene Xpert MTB/RIF test results were confirmed at the Microbiology Department of Thong Nhat Hospital.

Data Collection: Collecting necessary information using a data collection form. Collecting the results of Xpert MTB/RIF and AFB tests on patients' sputum samples.

2.6. Data Analysis Methods:

Calculating proportions and assessing associations using the chi-square test, 2x2 cross-tabulation. Statistical significance when $p < 0.05$.

3. RESULTS

3.1. Some General Characteristics of the Patient Group Participating in the Study

The number of male patients in the study was 195 (72.2%) and female patients was 75 (27.8%). The male-to-female ratio was 1.8/1.

The mean age of the patients participating in the study was 75.9 ± 15.1 years, the youngest was 18 years old and the oldest was 105 years old. The age group with the highest proportion was over 65 years old with 81.5% (220 cases). This was also the group with the highest rate of pulmonary tuberculosis detection with 28 cases (73.7%).

The mean BMI of the patient group participating in the study was 21.06 ± 3.4 . Patients living in urban areas accounted for the majority with 240 cases (88.9%).

The number of patients who had ever or were still smoking was 108 cases (40%). Common comorbidities: previous pulmonary tuberculosis in 17/270 patients (6.3%), type 2 diabetes in 89/270 patients (33%), drug-induced Cushing's syndrome in 28/270 patients (10.4%), sequelae of stroke in 36/270 patients (13.3%).

Table 1. Some Common Clinical Symptoms

Symptoms	Number of Cases	Percentage (%)
Cough	251	93
Fever	175	64,8
Fatigue, poor appetite	230	85,2
Chest pain	54	20
Shortness of breath	190	70,4
Weight loss	101	37,4
Lesions on Chest X-ray	250	92,6

Cough was the most common symptom at 93%, followed by fatigue and poor appetite at 85.2%. Almost all cases in the study had lesions on chest X-ray with a rate of 92.6%.

3.2. Sputum AFB Test

Table 2. Detection Rate of Pulmonary Tuberculosis in Suspected Pulmonary Tuberculosis Patients by Direct Ziehl-Neelsen Staining AFB Test

Result	Frequency	Percentage (%)
Positive	13	4,8
Negative	257	95,2

3.3. Sputum Xpert MTB/RIF Test

Table 3. Detection Rate of Pulmonary Tuberculosis in Suspected Pulmonary Tuberculosis Patients by Gene Xpert MTB/RIF Test

Result	Frequency	Percentage (%)
Positive	38	14,1
Negative	232	85,9

Table 4. Gene Xpert MTB/RIF Results Compared to Sputum AFB

Gene Xpert MTB/RIF	AFB (+) n, %	AFB (-) n, %	n, %
Gene Xpert MTB/RIF (+)	11	27	38
Gene Xpert MTB/RIF (-)	2	230	232
Total	13	257	270

Gene Xpert MTB/RIF positive for TB bacteria accounted for 14.1% (38/270); AFB (+) sputum accounted for 4.8% (13/270).

The sensitivity of Gene Xpert MTB/RIF compared to sputum AFB was Se 84.6% (11/13), specificity Sp 89.5% (230/257), positive predictive value PPV 28.9% (11/38), negative predictive value NPV 99.1% (230/232).

Table 5. Rifampicin Resistance Results in Gene Xpert MTB/RIF

Gene xpert MTB/RIF (+)	Frequency (n)	Percentage %
Rifampicin Resistant	3	7,9

Rifampicin Not Resistant	32	84,2
Resistance Not Determined	3	7,9
Total	39	100

Among the 38 cases of pulmonary tuberculosis detected by the Gene Xpert MTB/RIF test, there were 3 cases recorded as rifampicin resistant (7.9%), and the majority were non-rifampicin resistant cases (84.2%).

4. DISCUSSION

Within the scope of the study, we recorded 270 cases of suspected pulmonary tuberculosis meeting the inclusion criteria. The male/female ratio of the patient group was 1.8/1. According to the National Tuberculosis Program 2023, the male/female ratio among new and relapse patients is 2.53/1. This result is also equivalent to some studies [4,6]. The mean age recorded in the study was 75.9 ± 15.1 years, the most common age group was over 65 years old, and this was also the age group with the highest detection of pulmonary tuberculosis. This differs from some studies. According to Rahadiyanto [6], the mean age commonly affected by pulmonary tuberculosis was 46.71 ± 14.57. In the study by Pham Thi Diem Phuc [4], the mean age of the study subjects was 57.0 ± 16.1. The highest incidence of tuberculosis was in the 25-64 age group (74.2%). This difference is due to our sample population being patients treated at the Internal Medicine Department, Thong Nhat Hospital. This is the general internal medicine department of a geriatric hospital, so it typically has a majority of elderly patients.

Pulmonary tuberculosis is a disease with diverse clinical manifestations, with many symptoms easily confused or overlapping with other respiratory and cardiovascular diseases. In our study, the most common symptoms were cough and fatigue/poor appetite, with rates of 93% and 85.2%, respectively. This result is also consistent with other studies. In the study by Nguyen Kim Cuong [8], cough at any time accounted for 92.7%, fever was also a common symptom at 88.6%, and fatigue accounted for 89.4%. According to

Le Hoan [5], common clinical symptoms for pulmonary tuberculosis patients include: productive cough (81.7%), chest pain (21.5%), shortness of breath (20.5%), fatigue (11.9%), fever (11%).

The detection rate of pulmonary tuberculosis by the Gene Xpert MTB/RIF test in our study was 14.1%, and the rate of positive direct AFB smear was 4.8%. This rate shows a fairly significant difference compared to recent studies. Specifically, in the study by Le Hoan [5], the rate of positive sputum Gene Xpert MTB/RIF was 7.6%, and positive direct sputum AFB test accounted for 3%. According to Pham Thi Diem Phuc [4], the detection rate of new pulmonary tuberculosis in suspected pulmonary tuberculosis subjects by Xpert MTB/RIF test was 28.8%. The study by Gupta [10] showed that the detection rate of tuberculosis by Gene Xpert MTB/RIF was 21.6% and that of direct sputum AFB smear was 18.2%. The study by Rahadiyanto [6] showed a rather high result: both Gene Xpert MTB/RIF and sputum AFB had a positive rate for tuberculosis of 57.3%. This difference can be explained by many factors, including differences in sample selection criteria, sample collection location, and the epidemiological situation of the localities where the studies were conducted.

Our study recorded the sensitivity of Gene Xpert MTB/RIF compared to sputum AFB as Se 84.6%, specificity Sp 89.5%, positive predictive value PPV 28.9%, negative predictive value NPV 99.1%. This result is also quite similar to recent studies showing that the sensitivity and specificity of Gene Xpert MTB/RIF are quite high. According to Phan Thanh Binh [9], the sensitivity of the sputum Gene Xpert MTB/RIF test in diagnosing new AFB(-) pulmonary tuberculosis was 72.28%, new AFB(+) pulmonary tuberculosis was 93.65%, and for all new pulmonary tuberculosis was 80.49%. In a study in India by author Gupta with 319 suspected TB patients, it was recorded: the sensitivity of the Gene Xpert MTB/RIF technique was 100%, specificity was 98.81%.

The study recorded 27 cases with positive gene xpert MTB/RIF while direct AFB smear of sputum gave negative results for *Mycobacterium tuberculosis*. This shows the value of Gene xpert MTB/RIF in the early detection of pulmonary

tuberculosis, at a stage when the bacterial concentration is still low and cannot be detected directly by staining microscopy.

The rate of rifampicin-resistant tuberculosis was 3 cases (7.9% of pulmonary tuberculosis patients). This result is not different from previously recorded studies [4,5]. All three of these cases had no history of pulmonary tuberculosis or previous tuberculosis treatment. This means that the condition of rifampicin-resistant *Mycobacterium tuberculosis* does not depend on whether the patient has been infected with this bacterium before.

From this, it shows that sputum Gene Xpert MTB/RIF has high value in the detection and diagnosis of pulmonary tuberculosis due to its relatively high sensitivity and specificity. In addition, Gene Xpert MTB/RIF also reports whether the tuberculosis bacteria are resistant to rifampicin, which contributes greatly to the success of treatment. However, the current reality in Vietnam is that sputum Gene Xpert MTB/RIF is mainly performed and applied at central health levels - where there are modern equipment and machinery - and is not yet common at grassroots health levels, where medical care conditions are still limited.

5. CONCLUSION

The detection rate of pulmonary tuberculosis by Gene Xpert MTB/RIF was 14.1%. Compared to sputum AFB, Gene Xpert MTB/RIF has relatively high sensitivity and specificity, at 84.6% and 89.5%, respectively. Therefore, Gene Xpert MTB/RIF plays an important role in the diagnosis of pulmonary tuberculosis, especially early pulmonary tuberculosis and in elderly patients with multiple comorbidities.

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