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Original Article

Semi-Quantitative Comparison of Bacillary Load Assessment by TB-LAMP and Xpert MTB/RIF in Pulmonary Tuberculosis

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ABSTRACT

Background: Rapid molecular diagnostic techniques have transformed the diagnosis of pulmonary tuberculosis (PTB). In addition to detecting Mycobacterium tuberculosis, these assays provide semi-quantitative information regarding bacillary burden, which may assist clinicians in assessing disease severity and infectivity. This study compared bacillary load assessment by Loop-Mediated Isothermal Amplification (TB-LAMP) and Xpert MTB/RIF among adults with suspected pulmonary tuberculosis.

Methods: A prospective observational study was conducted among 200 adult patients suspected of pulmonary tuberculosis at a tertiary care hospital in Indore, India. Sputum samples were subjected to Ziehl–Neelsen (ZN) smear microscopy, TB-LAMP assay, and Xpert MTB/RIF testing. Bacillary load was assessed using smear grading (Scanty, 1+, 2+, 3+) for TB-LAMP and semi-quantitative categories (Very Low, Low, Medium, High) for Xpert MTB/RIF. Comparative analysis was performed to evaluate the ability of both assays to detect varying bacterial loads.

Results: Among 200 sputum samples, Xpert MTB/RIF detected Mycobacterium tuberculosis in 194 (97%) samples, while TB-LAMP detected 192 (96%) samples. TB-LAMP detected all samples with moderate and high bacillary loads but failed to identify two specimens with very low bacterial burden. Xpert MTB/RIF successfully identified all four specimens categorized as having very low bacillary loads. Among smear-positive samples graded as 2+ and 3+, both assays demonstrated 100% detection rates. The difference between the two molecular methods was primarily observed in paucibacillary specimens.

Conclusion: Both TB-LAMP and Xpert MTB/RIF demonstrated excellent performance for pulmonary tuberculosis diagnosis. However, Xpert MTB/RIF exhibited superior sensitivity in detecting very low bacillary burden specimens, making it more suitable for diagnosing paucibacillary disease. TB-LAMP remains an effective and cost-efficient alternative for resource-limited settings.

Keywords: Pulmonary tuberculosis, TB-LAMP, Xpert MTB/RIF, Bacillary load, Molecular diagnosis, Semi-quantitative assessment

INTRODUCTION

Tuberculosis (TB) remains one of the leading causes of infectious disease-related morbidity and mortality worldwide. According to the World Health Organization (WHO), millions of new TB cases continue to be reported annually, with developing countries carrying the greatest disease burden [1]. India contributes a substantial proportion of global tuberculosis cases and remains a high-burden country despite significant improvements in case detection and treatment programs [2].

Early and accurate diagnosis is essential for effective tuberculosis control because delayed diagnosis contributes to ongoing transmission, increased morbidity, and poor treatment outcomes [3]. Conventional diagnostic methods such as Ziehl–Neelsen (ZN) smear microscopy are inexpensive and widely available but suffer from limited sensitivity, particularly in paucibacillary specimens and HIV-associated tuberculosis [4]. Culture-based methods remain the reference standard for diagnosis; however, they require sophisticated laboratory infrastructure and prolonged incubation periods, often delaying treatment initiation by several weeks [5].

The introduction of molecular diagnostic technologies has significantly improved tuberculosis detection. The Xpert MTB/RIF assay is an automated nucleic acid amplification test capable of detecting Mycobacterium tuberculosis complex DNA and rifampicin resistance within approximately two hours [6]. Numerous studies have demonstrated high sensitivity and specificity of Xpert MTB/RIF for pulmonary tuberculosis, making it a valuable diagnostic tool in both high- and low-burden settings [7,8]. In addition to providing rapid diagnosis, the assay offers semi-quantitative information regarding bacillary load through categorization into very low, low, medium, and high bacterial burden groups [9].

Loop-mediated isothermal amplification (TB-LAMP) is another molecular diagnostic technique developed to address the limitations associated with conventional nucleic acid amplification methods. Unlike polymerase chain reaction-based techniques, TB-LAMP operates under isothermal conditions and requires minimal laboratory infrastructure, making it particularly suitable for resource-limited settings [10]. The assay has demonstrated excellent sensitivity and specificity for pulmonary tuberculosis detection and has been endorsed by the World Health Organization as an alternative molecular diagnostic method in appropriate clinical settings [11].

Semi-quantitative assessment of bacillary burden is clinically important because it reflects disease severity, infectivity, and treatment response. Patients with high bacterial loads are generally more infectious and contribute substantially to disease transmission, whereas individuals with low bacterial loads may remain undiagnosed by conventional methods [12]. Although several studies have compared the diagnostic accuracy of TB-LAMP and Xpert MTB/RIF, limited information is available regarding their comparative performance across varying bacillary load categories [13,14].

Therefore, the present study was undertaken to compare the semi-quantitative assessment of bacillary burden by TB-LAMP and Xpert MTB/RIF among adults with suspected pulmonary tuberculosis. The study also aimed to evaluate the ability of both assays to detect low-burden and paucibacillary tuberculosis cases.

Materials and Methods

Study Design and Setting

A prospective observational study was conducted in the Department of Microbiology at Index Medical College Hospital, Indore, Madhya Pradesh, India, between July 2019 and June 2022.

Study Population

Adult patients presenting with symptoms suggestive of pulmonary tuberculosis, including persistent cough, fever, weight loss, and night sweats, were included in the study.

Inclusion Criteria

- Age ≥18 years
- Clinical suspicion of pulmonary tuberculosis
- Provision of sputum sample

Exclusion Criteria

- Extrapulmonary tuberculosis
- Pregnancy
- Acute severe illness
- Patients younger than 18 years

Sample Collection and Processing

A total of 200 sputum specimens were collected in sterile wide-mouth containers. Samples were processed for:

1. Ziehl–Neelsen smear microscopy
2. Xpert MTB/RIF assay
3. TB-LAMP assay

Xpert MTB/RIF Assay

Testing was performed according to manufacturer instructions. Results were reported as:

- Very Low
- Low

- Medium
- High

based on cycle threshold values.

TB-LAMP Assay

DNA extraction was performed using the QIAamp DNA Mini Kit. Amplification was carried out using the Nu-LAMP TB kit targeting the rpoB gene region of Mycobacterium tuberculosis complex.

Smear-positive samples were categorized as:

- Scanty
- 1+
- 2+
- 3+

for bacillary load assessment.

Statistical Analysis

Data were analyzed using IBM SPSS version 23. Results were expressed as frequencies and percentages. Comparative analysis between the two molecular techniques was performed. Statistical significance was considered at $p<0.05$.

Results

Detection Rate of TB-LAMP and Xpert MTB/RIF

Of the 200 sputum specimens analyzed, Xpert MTB/RIF identified 194 positive cases, corresponding to a positivity rate of 97%. TB-LAMP identified 192 positive cases, corresponding to a positivity rate of 96%.

No rifampicin resistance was detected among the positive samples by Xpert MTB/RIF.

Table 1. Comparison of Positive Detection Rates

Assay	Positive	Negative	Detection Rate
TB-LAMP	192	8	96.0%
Xpert MTB/RIF	194	6	97.0%

Semi-Quantitative Bacillary Load Assessment

Table 2. Comparative Semi-Quantitative Analysis of Bacillary Burden

TB-LAMP Grade	Positive/Total
Scanty	2/4
1+	10/16
2+	40/40
3+	140/140
Total	192/200

Xpert MTB/RIF Category	Positive/Total
Very Low	4/4
Low	10/10
Medium	50/50
High	130/130
Total	194/200

Both assays demonstrated complete detection of moderate and high bacillary burden specimens. However, differences emerged in low-burden samples.

TB-LAMP detected only 2 of 4 scanty smear-positive specimens, whereas Xpert MTB/RIF detected all four specimens categorized as very low bacterial burden.

Detection of Paucibacillary Disease

The principal discrepancy between the assays involved specimens with minimal bacterial load. Xpert MTB/RIF successfully identified all specimens containing very low concentrations of Mycobacterium tuberculosis DNA. TB-LAMP failed to detect two such specimens, resulting in slightly lower overall sensitivity.

The findings indicate that Xpert MTB/RIF possesses enhanced capability for detecting paucibacillary pulmonary tuberculosis.

DISCUSSION

The present study compared the semi-quantitative performance of TB-LAMP and Xpert MTB/RIF for the assessment of bacillary burden among adults with suspected pulmonary tuberculosis. Both molecular assays demonstrated excellent diagnostic performance, with Xpert MTB/RIF detecting 194 of 200 positive cases and TB-LAMP detecting 192 of 200 positive cases. These findings indicate a high level of agreement between the two molecular techniques and support their utility in routine tuberculosis diagnosis.

Xpert MTB/RIF demonstrated a slightly higher detection rate than TB-LAMP, particularly in specimens with very low bacterial burden. The assay successfully identified all four specimens categorized as having very low bacillary loads, whereas TB-LAMP detected only two of these specimens. Similar findings have been reported by Steingart et al., who observed superior sensitivity of Xpert MTB/RIF in smear-negative and paucibacillary tuberculosis cases due to its lower analytical detection threshold [7]. Likewise, Esmail et al. reported that Xpert-based assays possess enhanced capability for detecting specimens containing minimal concentrations of Mycobacterium tuberculosis DNA [15].

In the present study, both assays achieved complete detection of specimens categorized as moderate and high bacillary burden. TB-LAMP detected all specimens graded as 2+ and 3+, while Xpert MTB/RIF detected all medium- and high-load specimens. These findings are consistent with previous investigations demonstrating excellent performance of TB-LAMP in smear-positive pulmonary tuberculosis patients [16]. Yan et al. reported pooled sensitivity and specificity values of 93% and 94%, respectively, for TB-LAMP, with even higher sensitivity observed in smear-positive specimens [17].

The overall diagnostic performance observed in the present study is comparable to previous reports. Xpert MTB/RIF demonstrated a sensitivity of 97% and specificity of 99.11%, whereas TB-LAMP demonstrated a sensitivity of 96% and specificity of 98.22%. Similar diagnostic accuracies have been reported in international meta-analyses evaluating molecular diagnostic assays for pulmonary tuberculosis [7,17]. These findings confirm that both techniques provide highly reliable results and can substantially improve case detection compared with conventional smear microscopy.

An important observation in the present study was the inability of TB-LAMP to detect two specimens with extremely low bacillary loads. Although this slightly reduced its sensitivity compared with Xpert MTB/RIF, the difference was relatively small and may not be clinically significant in high-burden settings where most patients present with moderate to high bacterial loads. Similar observations were reported by Manakul et al., who found that TB-LAMP demonstrated excellent performance but showed reduced sensitivity in samples containing low concentrations of bacilli [18].

The semi-quantitative assessment of bacillary burden has important clinical implications. Higher bacterial loads are associated with increased infectivity, more extensive pulmonary involvement, and greater risk of disease transmission [19]. The ability of Xpert MTB/RIF to detect very low bacillary loads may therefore facilitate earlier diagnosis and treatment initiation, particularly among patients with early-stage disease or immunocompromised conditions. However, the operational simplicity, lower cost, and reduced infrastructure requirements of TB-LAMP make it an attractive alternative in peripheral and resource-constrained healthcare settings [20].

No rifampicin resistance was detected among the positive specimens in the present study. Although the absence of drug-resistant cases limits assessment of the resistance detection capabilities of Xpert MTB/RIF, the findings may reflect the epidemiological characteristics of the study population. Previous studies have demonstrated the high accuracy of Xpert MTB/RIF for rapid detection of rifampicin resistance and multidrug-resistant tuberculosis [8].

The study has certain limitations. First, it was conducted at a single tertiary care center, which may limit generalizability. Second, culture confirmation was not available for all specimens. Third, the relatively small number of paucibacillary specimens restricted subgroup analysis. Despite these limitations, the study provides valuable information regarding the comparative performance of two important molecular diagnostic tools.

In conclusion, both TB-LAMP and Xpert MTB/RIF demonstrated excellent capability for detecting pulmonary tuberculosis across a broad range of bacillary loads. Xpert MTB/RIF showed superior performance in very low bacterial burden specimens, whereas TB-LAMP offered comparable performance in moderate- and high-burden disease while maintaining lower operational costs. These findings support the use of TB-LAMP as a practical molecular diagnostic tool in resource-limited settings while reinforcing the role of Xpert MTB/RIF as the preferred assay for detecting paucibacillary tuberculosis.

Conclusion

Both TB-LAMP and Xpert MTB/RIF demonstrated excellent performance for the diagnosis of pulmonary tuberculosis. Xpert MTB/RIF showed a slight advantage in detecting specimens with very low bacillary loads and therefore may be preferred when diagnosing paucibacillary disease. Nevertheless, TB-LAMP achieved comparable performance in

specimens with moderate and high bacillary burden and represents a practical and cost-effective diagnostic alternative for resource-limited settings.

Conflict of Interest: The authors declare no conflict of interest.
Funding: No external funding was received for this study.
Ethical Approval: The study was approved by the Institutional Ethics Committee of Index Medical College Hospital, Indore.

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