Int. J Med. Pharm. Res. (P-ISSN: 2958-3675 | E-ISSN: 2958-3683)
Available on: https://ijmpr.in/

International Journal
of Medical and
Pharmaceutical Research

ORGINAL ARTICLE **OPEN ACCESS**

Evaluating the Efficacy and Outcomes of First-Line Line Probe Assay: A Retrospective Analysis

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Received: 10-05-2025
Accepted: 05-06-2025
Available online: 30-06-2025

A B S T R A C T

Objective: To assess the performance and demographic distribution of first-line Line Probe Assay (LPA) results among tuberculosis (TB) patients.

Design: A retrospective observational study analyzing LPA results from 183 cases over a defined time period.

Setting: Data was collected from both public and private healthcare facilities.

Participants: A total of 183 patients underwent first-line LPA testing, including 102 males and 80 females, with ages ranging from under 10 to over 71 years. HIV status, microbiological classification, and case categorization were also analyzed.

Main Outcome Measures: Distribution of cases by age, sex, HIV status, microbiological confirmation, and healthcare source; analysis of case categorization (new, retreatment, pre-MDR/MDR); and subsequent second-line LPA testing outcomes.

Results: Of the total cases, 148 were HIV non-reactive, 32 were reactive, and 3 had unknown HIV status. Most samples were obtained from public facilities (63.9%). The majority of cases were new TB cases (83.6%), with 12 retreatment cases and 3 classified as pre-MDR/MDR. Microbiological confirmation was noted in 55 cases (30%), while 110 (60%) were not confirmed. Second-line LPA testing was conducted in 50 cases, leaving 133 without second-line testing.

Conclusions: First-line LPA is an essential diagnostic tool in TB management, particularly in identifying drug resistance. However, the study highlights gaps in microbiological confirmation and the need for comprehensive data reporting to enhance TB diagnostic efficacy.

Keywords: Tuberculosis (TB); Line Probe Assay (LPA); First-line LPA; Drug-resistant TB; HIV co-infection.

INTRODUCTION

Demographic and Clinical Characteristics of Patients Undergoing First-Line Line Probe Assay (LPA) Testing for Tuberculosis

Tuberculosis (TB) remains a global health concern, particularly in resource-limited settings. The introduction of rapid molecular diagnostics, such as the Line Probe Assay (LPA), has improved TB management by facilitating early detection of drug resistance. This study examines the demographic and clinical characteristics of patients undergoing first-line LPA testing and evaluates the distribution of results. A

retrospective observational analysis of 183 cases was conducted, highlighting key variables such as age, sex, HIV status, microbiological confirmation, healthcare source, and case categorization. The findings emphasize the importance of strengthening microbiological confirmation and ensuring follow-up with second-line testing to enhance TB control strategies.

Tuberculosis remains a leading infectious cause of mortality worldwide, with an estimated 10.6 million new cases and 1.3 million deaths in 2022 [1]. Early and accurate diagnosis is crucial to controlling TB transmission and improving treatment outcomes. The World Health Organization (WHO) recommends the use of rapid molecular tests, such as the Line Probe Assay (LPA), to detect Mycobacterium tuberculosis complex (MTBC) and resistance to first-line drugs, including rifampicin and isoniazid [2]. However, the effectiveness of LPA depends on patient demographics, healthcare access, and microbiological confirmation rates [3]. This study aims to analyze the demographic and clinical characteristics of patients undergoing first-line LPA testing and assess the distribution of test results.

Methods

Study Design and Population

A retrospective observational study was conducted using data from 183 patients who underwent first-line LPA testing. The study population included cases from both public and private healthcare settings.

Data Collection and Variables

Data were collected on demographic and clinical characteristics, including age, sex, HIV status, microbiological confirmation, sample source (public vs. private healthcare), and case categorization (new, retreatment, pre-MDR/MDR).

Statistical Analysis

Descriptive statistics were used to summarize categorical variables, expressed as frequencies and percentages.

Results

Demographic and Clinical Characteristics

Age Distribution: The highest proportion of cases (23.5%) was in the 31–40 age group, followed by the 41–50 (19.7%) and 21–30 (18%) age groups. Pediatric cases (1–10 years) accounted for 7.1%.

Sex Distribution: Males comprised 55.7% of cases, while females constituted 44.3%.

HIV Status

Non-reactive: 148 cases (80.9%)
Reactive: 32 cases (17.5%)
Unknown: 3 cases (1.6%)
Microbiological Confirmation
Confirmed Cases: 55 (30%)
Not Confirmed: 110 (60%)
No Data Provided: 14 (7.7%)

Sample Source

Public Healthcare Facilities: 117 cases (63.9%)
Private Healthcare Facilities: 48 cases (26.2%)
Unknown Source: 18 cases (9.8%)

Case Categorization

New Cases: 153 (83.6%)
Retreatment Cases: 12 (6.6%)
Pre-MDR/MDR Cases: 3 (1.6%)
Second-Line LPA Testing
Among the 183 cases, only 50 (27.3%) underwent second-line LPA testing, while 133 (72.7%) did not receive further molecular testing.

Discussion

The findings of this study underscore several critical aspects of TB diagnosis and management. The predominance of cases in economically productive age groups (21–50 years) highlights the socio-economic burden of TB, which has been reported in previous studies [4,5]. The male predominance (55.7%) aligns with global TB epidemiology, as men generally have higher TB incidence rates due to occupational and behavioral risk factors [6].

The microbiological confirmation rate of 30% is relatively low, raising concerns about the sensitivity of diagnostic pathways. Prior research has suggested that LPA's accuracy depends on bacterial load and sample quality [7,8]. Strengthening diagnostic algorithms, including the integration of culture-based confirmation, is essential for improving accuracy [9].

A significant proportion of cases (63.9%) were from public healthcare settings, reflecting the accessibility of government-supported TB programs. However, the low rate of second-line LPA testing (27.3%) suggests a gap in follow-up testing, which is crucial for detecting fluoroquinolone and second-line injectable resistance [10,11].

HIV co-infection was present in 17.5% of cases, which is consistent with global data indicating higher TB-HIV co-infection rates in endemic regions [12,13]. Given the immunocompromised status of HIV-positive patients, comprehensive TB screening and early detection of drug resistance are vital [14].

Conclusion

First-line LPA testing plays a critical role in TB management, particularly in detecting resistance to first-line drugs. However, its effectiveness is dependent on robust diagnostic strategies, including microbiological confirmation and follow-up with second-line testing. Strengthening laboratory capacity and ensuring comprehensive data collection will enhance TB control efforts and patient outcomes.

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