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Original Research Article

THE IMPACT OF LINE PROBE ASSAY ON EARLY DIAGNOSIS, TREATMENT INITIATION AND OUTCOME FOR SUSPECTED TB PATIENTS IN A TERTIARY CARE HOSPITAL

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ABSTRACT

Background: Rapid diagnosis and timely initiation of appropriate therapy are critical for tuberculosis (TB) control, particularly in multidrug-resistant TB (MDR-TB). Conventional culture-based drug susceptibility testing (DST), although considered the gold standard, is time-consuming and delays treatment decisions. Line Probe Assay (LPA) offers rapid molecular detection of Mycobacterium tuberculosis and associated drug resistance. The objective is to evaluate the impact of LPA on early diagnosis, treatment initiation, and outcomes in suspected TB patients.

Materials and Methods: A retrospective comparative study was conducted at a tertiary care hospital. Culture-based diagnostics from May–July 2023 (n=285) were compared with LPA-based diagnostics from August–October 2023 (n=314). Data were collected from laboratory records and the Nikshay portal. Parameters analyzed included positivity rates, resistance patterns, and time from diagnosis to treatment initiation.

Results: Culture detected 20 positive cases (7%), including 5 MDR-TB, whereas LPA detected 112 positive cases (35.7%), including 10 MDR-TB and additional mono-resistant cases. The mean time to treatment modification in MDR-TB cases decreased from 60 days (culture) to 36 days (LPA). LPA enabled earlier identification of resistance, reducing duration of ineffective therapy.

Conclusion: LPA significantly reduces diagnostic delay and facilitates earlier initiation of appropriate therapy, especially in MDR-TB cases. Incorporation of LPA into routine diagnostic workflows can improve patient outcomes and reduce transmission.

Keywords: Tuberculosis, Line Probe Assay, Multidrug-resistant TB, Drug Susceptibility Testing, Rapid Diagnosis.

INTRODUCTION

Tuberculosis (TB) remains one of the leading infectious causes of morbidity and mortality worldwide, with a significant burden in developing countries such as India. According to the World Health Organization (WHO), India accounts for nearly one-third of the global TB burden, highlighting the urgent need for improved diagnostic and management strategies.[1] The emergence and increasing prevalence of multidrug-resistant tuberculosis (MDR-TB), defined as resistance to at least isoniazid and rifampicin, further complicates disease control and poses a major challenge to public health systems.[2,3]

Early and accurate diagnosis of TB and its drug resistance patterns is critical for initiating appropriate therapy, reducing transmission, and improving patient outcomes. Conventional culture and drug susceptibility testing (DST) methods remain the gold standard; however, they are time-consuming, often requiring several weeks to yield results. This delay

contributes to prolonged periods of ineffective treatment, increased morbidity, and ongoing community transmission.[3,4]

In recent years, molecular diagnostic techniques have revolutionized TB diagnostics. Among these, the Line Probe Assay (LPA) is a nucleic acid amplification-based method that enables rapid detection of Mycobacterium tuberculosis complex and associated genetic mutations conferring resistance to first-line anti-tubercular drugs such as rifampicin and isoniazid.[5-9] The WHO has endorsed LPA for rapid detection of MDR-TB, particularly in high-burden settings.[1]

Several studies have demonstrated the high sensitivity and specificity of LPA in detecting TB and drug resistance directly from clinical specimens.[5–7] Additionally, LPA significantly reduces diagnostic turnaround time compared to conventional methods, thereby facilitating earlier initiation of appropriate therapy.[2,3,6] Evidence from India and other high-burden countries indicates that implementation of LPA leads to improved case detection, reduced delays in treatment initiation, and better treatment outcomes.[3,6–8]

Despite these advantages, there remains limited data from tertiary care settings evaluating the real-world impact of LPA on diagnostic yield, treatment timelines, and patient outcomes, particularly in resource-limited environments.

Therefore, this study was undertaken to assess the impact of Line Probe Assay on early diagnosis, treatment initiation, and outcomes in suspected TB patients in a tertiary care hospital.

MATERIALS AND METHODS

The study was designed as a retrospective comparative observational study conducted in the Department of Microbiology at Government Medical College and New Civil Hospital, Surat. It included all suspected tuberculosis (TB) patients whose sputum samples were processed for either culture or Line Probe Assay (LPA) during the study periods, with the culture phase spanning May to July 2023 and the LPA phase from August to October 2023. Patients attending the TB outpatient department and meeting inclusion criteria were considered. Data were collected from laboratory records and the Nikshay portal using a pre-designed proforma. The parameters analyzed included the number of positive cases, drug resistance patterns, time from diagnosis to treatment initiation, and available patient outcomes. Statistical analysis was performed using Microsoft Excel, employing descriptive statistics such as percentages and mean values.

RESULTS

A total of 285 samples were processed by culture during May–July 2023, of which 20 (7%) were positive for TB. Among these, 5 cases were MDR-TB, 1 showed isoniazid resistance, and 14 were drug-sensitive.

During August–October 2023, 314 samples were processed by LPA, of which 112 (35.7%) were positive. Among these, 10 cases were MDR-TB, 14 were isoniazid-resistant, 1 rifampicin-resistant, and the remainder were drug-sensitive.

Table 1: Comparison of Positivity Rates

Diagnostic Method	Total Samples	Positive Cases	Positivity Rate (%)
Culture	285	20	7%
LPA	314	112	35.70%

Table 2: Drug Resistance Pattern

Resistance Type	Culture (n=20)	LPA (n=112)
MDR-TB	5	10
Isoniazid-resistant	1	14
Rifampicin-resistant	0	1
Drug-sensitive	14	87

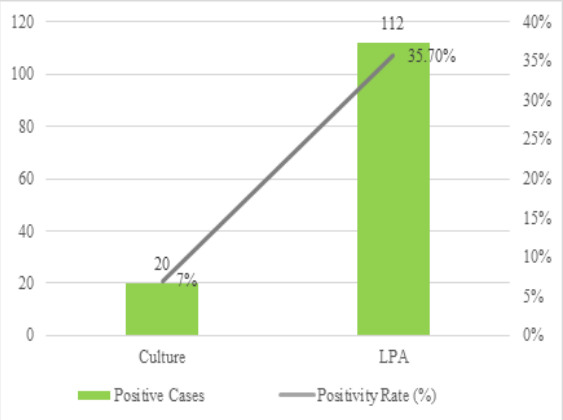

Figure 1: Comparison of Positivity Rates

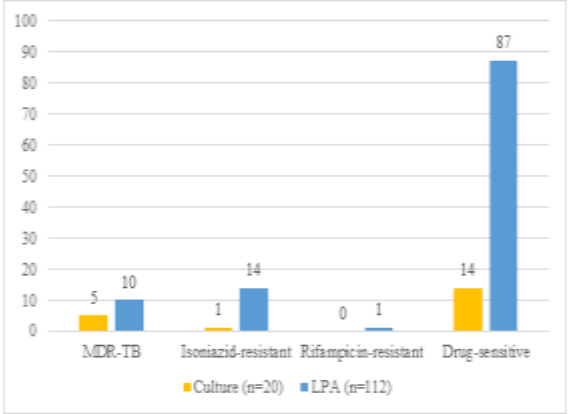

Figure 2: Drug Resistance Pattern

LPA demonstrated a significantly higher detection rate compared to culture. Additionally, approximately 80% of drug-resistant TB cases had a previous history of TB.

The mean time from diagnosis to treatment modification for MDR-TB cases was reduced from 60 days in the culture group to 36 days in the LPA group.

Early detection of resistance through LPA enabled timely initiation of appropriate MDR regimens, reducing the duration patients remained on ineffective therapy.

DISCUSSION

The present study highlights the significant role of Line Probe Assay (LPA) in improving the diagnosis and management of tuberculosis, particularly multidrug-resistant TB (MDR-TB), in a tertiary care setting. The findings demonstrate a markedly higher positivity rate with LPA compared to conventional culture methods, along with a substantial reduction in time to treatment initiation.

The higher detection rate observed with LPA in this study is consistent with previous research demonstrating its superior sensitivity, especially in detecting Mycobacterium tuberculosis directly from clinical specimens.[5–7] Raizada et al. reported that LPA has high diagnostic accuracy when used directly on sputum samples, significantly enhancing early detection of MDR-TB.[6] Similarly, Nathavitharana et al. in a systematic review confirmed that LPA provides reliable and rapid detection of both TB and drug resistance, supporting its utility in high-burden settings.[5]

A key finding of this study is the reduction in time from diagnosis to treatment initiation, particularly for MDR-TB patients. This is in line with studies by Singla et al. and Eliseev et al., which demonstrated that implementation of LPA significantly decreases diagnostic delays and accelerates initiation of appropriate therapy.[2,3] In the present study, the mean time to treatment modification decreased from 60 days with culture to 36 days with LPA, reflecting improved clinical efficiency and patient management.

Early detection of drug resistance is crucial for optimizing treatment regimens and preventing the progression and transmission of resistant strains. LPA enables rapid identification of resistance mutations, thereby reducing the duration of ineffective therapy and limiting disease spread.[4,6,12] Studies from India and other regions have shown that early initiation of appropriate MDR-TB treatment improves treatment success rates and reduces mortality.[2,8]

Furthermore, the study observed that a significant proportion of drug-resistant TB cases had a prior history of TB, which aligns with existing literature indicating that previously treated patients are at higher risk of developing drug resistance.[2,8] This underscores the importance of strict treatment adherence, effective follow-up, and early resistance testing in such populations.

Comparative studies have also evaluated LPA alongside other molecular diagnostics such as Xpert MTB/RIF, demonstrating that while both methods offer rapid results, LPA provides additional information on resistance patterns, making it particularly valuable in guiding individualized treatment regimens.[14,15] Recent analytical studies further support the role of LPA in detecting second-line drug resistance, expanding its utility in comprehensive MDR-TB management.[11,13]

Despite its advantages, LPA is not without limitations. It requires well-equipped laboratory infrastructure and trained personnel, and its performance may be reduced in smear-negative samples unless culture amplification is performed.[7] Nevertheless, its benefits in reducing diagnostic delay and improving patient outcomes outweigh these limitations in most tertiary care settings.

Overall, the findings of this study reinforce the growing body of evidence supporting the integration of LPA into routine TB diagnostic algorithms. By enabling rapid and accurate detection of drug resistance, LPA plays a critical role in strengthening TB control programs and improving patient care outcomes.

Limitations

- Retrospective study design
- Limited duration of study
- Lack of long-term outcome data for all patients
- Possible selection bias

CONCLUSION

The introduction of Line Probe Assay significantly improves early diagnosis and reduces the time to treatment initiation in tuberculosis patients, particularly those with multidrug-resistant TB (MDR-TB). It enhances the detection of drug resistance and facilitates timely initiation of appropriate therapy, thereby improving patient outcomes and helping to reduce transmission. In view of these benefits, routine incorporation of LPA into TB diagnostic algorithms in tertiary care settings is strongly recommended. Additionally, there is a need to strengthen laboratory infrastructure to support rapid molecular diagnostics and to conduct prospective studies for evaluating long-term patient outcomes.

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