Utilising Line Probe Assay for the Diagnosis of Drug-Resistant Tuberculosis at Kota Bharu Public Health Laboratory

Siti Norsuhada Mua'ainue Deen[1], Ahmad Farid Adnan[1], Nor Haslini Hashim[1], Suhana Hashim[1], Noor Hafizan Mat Salleh[1], Syazwani Mohd Tajudin[2]*

[1]Kota Bharu Public Health Laboratory, 16010 Kota Bharu, Kelantan
[2]Department of Immunology, School of Medical Sciences, Universiti Sains Malaysia, 16150 Kubang Kerian, Kelantan

*Corresponding author: syazwaniMT@usm.my

Introduction

Drug-resistant Tuberculosis (DR-TB) has been a cause of far-reaching concern with high mortality and morbidity rates globally, making treatment more challenging. The Line Probe Assay (GenoType MTBDRplus version 2.0; Hain Lifescience, Nehren, Germany) was then developed for determining susceptibility to both Rifampicin (RIF) and Isoniazid (INH). The Line Probe Assay (LPA) can detect mutations in the rpoB gene for RIF resistance and in the katG and inhA genes for INH resistance.

Objective

To utilise the LPA for the rapid identification of *Mycobacterium tuberculosis* complex (MTBC) and its resistance to the first-line anti-TB drugs (RIF and INH) directly from the sputum specimens of suspected MDR-TB patients.

Method

A retrospective observational study was conducted at Kota Bharu Public Health Laboratory from January to December 2024. A total of 195 sputum samples were collected from healthcare facilities in Kelantan and Terengganu. DNA extraction and LPA testing were performed (Fig. 1), and the results were analysed from the data generated through SIMKA, which were used to report results to the requestors.

Result

Of the 195 samples analysed, 150 were from male and 45 from female patients, with a mean age of 46 ± 16 years. Geographically, 155 samples originated from Kelantan and 40 from Terengganu. MTBC was detected in 122/195 samples (62.5%), while 73/195 (37.5%) were negative. Among the 122 MTBC-positive cases, LPA detected drug resistance in nine cases (7.4%). Of these, seven showed mutations in the rpoB gene and two in the *katG* gene, indicating resistance to RIF and INH, respectively. The remaining 113/122 (92.6%) samples showed no resistance mutations. Indications for LPA testing included presumptive TB (n=98), follow-up cases (n=55), suspected MDR-TB (n=31), and surveillance/contact screening (n=10).

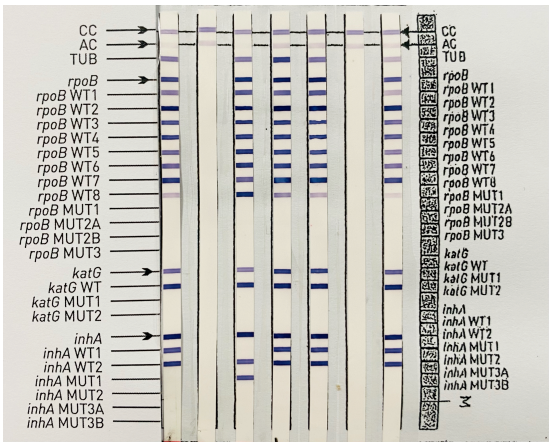

Figure 1. LPA strip

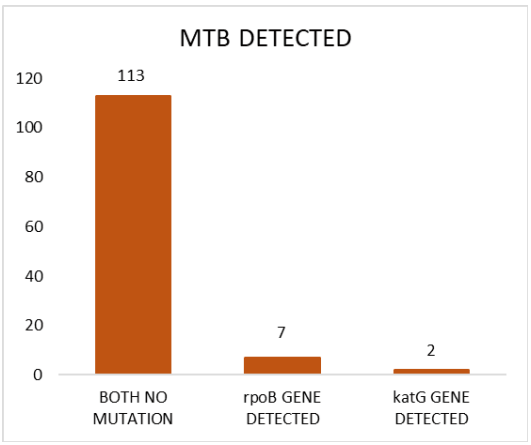

Figure 2. Result

Discussion

LPA represents a widely used assay for the diagnosis of MDR-TB. In low- and middle-incidence countries, it may also serve as a critical tool for tuberculosis elimination efforts as part of laboratory surveillance as well as the prompt diagnosis of tuberculosis, including MDR-TB in high-risk groups (1). The LPA (GenoType MTBDRplus version 2.0) tested on 644 sputum samples against phenotypic drug susceptibility testing (DST) showed 98.2% sensitivity and 97.8% specificity for RIF, and 95.4% sensitivity and 98.8% specificity for INH (2). LPA is particularly valuable as it can identify both INH and RIF resistance, making it a preferred method for diagnosing pulmonary tuberculosis in retreatment cases (3). It is also an excellent diagnostic tool, especially in high-burden regions, as it can provide interpretable results within 24-48 hours, compared to the conventional method, which takes six to eight weeks (4). LPA is valuable not only for identifying MDR-TB but also for monitoring treatment response, managing retreatment cases, conducting contact investigations, and public health surveillance. The introduction of LPA significantly improved access to DST among various patient categories, apart from suspected MDR-TB cases (5).

Conclusion

LPA, with its high sensitivity and specificity, is crucial for the rapid detection of MDR-TB, enabling timely treatment and reducing the transmission of resistant strains in high-burden settings.

Keywords: Line probe assay, DR-TB, rpoB gene, katG gene

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