Section: Microbiology

Original Research Article

CLINICAL EVALUATION AND LABORATORY CORRELATION OF DRUG-RESISTANT PULMONARY TUBERCULOSIS IN AJMER DISTRICT OF RAJASTHAN: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Background: Tuberculosis (TB) remains a major global health concern, further complicated by rising multidrug-resistant TB (MDR-TB). Early detection of resistance to rifampicin (RIF) and isoniazid (INH), the primary first-line anti-tubercular drugs, is critical for effective management. **Aim:** To evaluate the clinical utility of the line probe assay (LPA) in detecting drug susceptibility patterns to first-line anti-tubercular drugs among pulmonary TB patients in Rajasthan.

Materials and Methods: A prospective observational study was conducted from October 2023 to November 2024 at a tertiary care teaching hospital in Rajasthan. A total of 245 smear-positive pulmonary TB patients were enrolled. Clinical and demographic data were recorded. Sputum samples underwent microscopy, molecular testing using GenoType MTBDRplus assay for rpoB, katG, and inhA gene mutations, and culture-based drug susceptibility testing (DST). LPA results were correlated with clinical and laboratory parameters.

Results: The cohort had a mean age of 38.44 ± 15.45 years, predominantly male (74.69%) and aged 31–40 years (30.20%). Respiratory symptoms were prevalent: cough (97.96%), sputum production (98.37%), haemoptysis (40%), and fever (80%). HIV co-infection was identified in 12.24%. LPA detected rifampicin resistance in 59.18%, isoniazid resistance in 17.55%, and MDR-TB in 23.27%. Extensive drug resistance (XDR-TB) was found in 21.22%. Laboratory findings included anemia, elevated inflammatory markers, and metabolic abnormalities. LPA provided rapid results (1–3 days), enabling earlier treatment decisions compared to culture-based DST.

Conclusion: Pulmonary TB patients in this cohort presented with severe clinical manifestations and a high burden of drug resistance. LPA is a rapid, reliable diagnostic tool that enhances early detection of drug resistance, facilitating tailored treatment and improved outcomes. Integration of LPA into routine clinical practice is recommended in high-burden settings.

Keywords: Gene mutations, Line Probe Assay, MDR-TB, XDR-TB.

INTRODUCTION

Tuberculosis (TB) remains a significant global health challenge, particularly in high-burden regions such as India. The emergence of drug-resistant strains, including multidrug-resistant (MDR-TB) and extensively drug-resistant tuberculosis (XDR-TB), threatens TB control efforts by complicating treatment and increasing morbidity and mortality. Early identification of resistance to rifampicin (RIF) and isoniazid (INH), the cornerstone first-line anti-tubercular drugs, is essential for prompt initiation of effective therapy and reducing transmission.[1]

Conventional culture-based drug susceptibility testing (DST) is time-consuming, often delaying treatment decisions. Molecular diagnostics such as the line probe assay (LPA) enable rapid detection of genetic mutations in rpoB, katG, and inhA genes associated with resistance to RIF and INH, thereby facilitating timely clinical management.[2] This study aims to evaluate the clinical profile of pulmonary TB patients and correlate these findings with laboratory results, including LPA-based drug resistance patterns, in a tertiary care setting in Ajmer district of Rajasthan.

MATERIALS AND METHODS

Study Design and Setting

This prospective observational study was conducted in the Microbiology department of a tertiary care teaching hospital in Ajmer district of Rajasthan from October 2023 to November 2024.

Study Population

Smear-positive pulmonary TB patients (n=245) diagnosed clinically and microbiologically were enrolled consecutively in the current study.

Data Collection

Demographic, clinical, and socioeconomic data were recorded, including age, gender, occupation, socioeconomic status, symptoms, co-morbidities, and history of TB contact as per NTEP guidelines.

Laboratory Investigations

Sputum samples were subjected to acid-fast bacilli (AFB) microscopy with grading (1+, 2+, 3+). Samples were subjected to further to digestion, decontamination, centrifugation by NalC-NaoH method for conventional culture based drug susceptibility testing (DST) and DNA extraction for molecular testing.

Molecular testing was performed using the GenoType MTBDRplus assay (Hain Lifescience) to detect mutations in rpoB (rifampicin resistance), katG, and inhA (isoniazid resistance) genes.

Hematological (hemoglobin, ESR, leukocyte count) and biochemical parameters (liver enzymes, blood sugar, albumin, renal function) were assessed.

HIV testing was performed per national guidelines.

Ethical Consideration

The study protocol was approved by the Institutional Ethics Committee of the participating hospital. Written informed consent was obtained from all participants. Confidentiality and privacy were strictly maintained throughout the study.

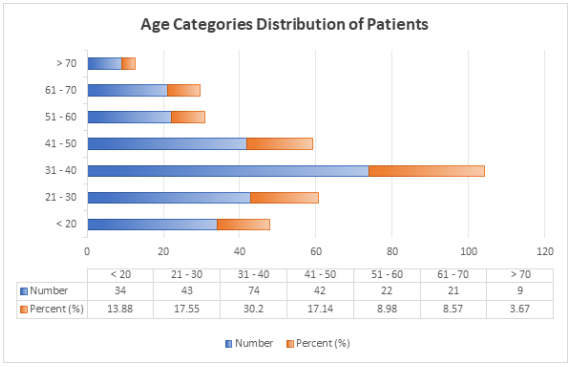
Statistical Analysis

Data were analyzed using SPSS version 25. Descriptive statistics were presented as mean ± standard deviation for continuous variables and frequencies with percentages for categorical variables. Associations between clinical features and drug resistance patterns were evaluated using chi-square tests or t-tests as appropriate. A p-value <0.05 was considered statistically significant.

RESULTS

Demographic and Socioeconomic Characteristics

The mean age was 38.44 ± 15.45 years, with the majority (30.20%) aged 31–40 years. Males constituted 74.69% of the cohort. Occupationally, tile workers (21.63%), masons (16.33%), and powder factory workers (14.29%) were predominant. Socioeconomic status was largely lower middle class (37.14%) and below poverty line (26.94%).



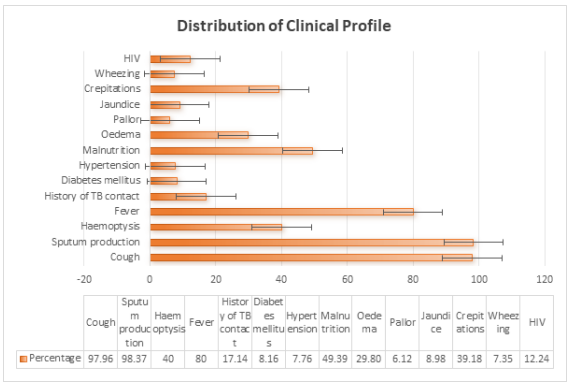
	< 20	21 - 30	31 - 40	41 - 50	51 - 60	61 - 70	> 70
Number	34	43	74	42	22	21	9
Percent (%)	13.88	17.55	30.2	17.14	8.98	8.57	3.67

Figure 1: Age and Gender Distribution of Study Population

Bar chart illustrating patient counts stratified by age groups.

Clinical Profile

Respiratory symptoms were highly prevalent: cough (97.96%), sputum production (98.37%), haemoptysis (40%), and fever (80%). History of TB contact was reported in 17.14%. Comorbidities included diabetes mellitus (8.16%) and hypertension (7.76%). Clinical examination revealed malnutrition (49.39%), oedema (29.80%), pallor (6.12%), and jaundice (8.98%). Respiratory signs included crepitations (39.18%) and wheezing (7.35%). HIV positivity was 12.24%.



	Cough	Sputum production	Haemoptysis	Fever	History of TB contact	Diabetes mellitus	Hypertension	Malnutrition	Oedema	Pallor	Jaundice	Crepitations	Wheezing	HIV
Percentage	97.96	98.37	40	80	17.14	8.16	7.76	49.39	29.80	6.12	8.98	39.18	7.35	12.24

Figure 2: Prevalence of Key Clinical Symptoms

Stacked bar chart depicting proportions of cough, sputum production, haemoptysis, fever, history of TB contact, HIV, other signs andco-morbidities.

Laboratory Findings

All patients were sputum smear-positive with bacillary loads graded as 1+ (30.20%), 2+ (27.76%), and 3+ (42.04%). Mean hemoglobin was 11.61 g/dL, with elevated ESR (42.88 mm/hr) and leukocytosis

(37.60 × 10^3/µL). Metabolic abnormalities included raised random blood sugar (149.16 mg/dL), elevated liver enzymes (SGOT 106.06 IU/L, SGPT 106.90 IU/L), hypoalbuminemia (2.99 g/dL), and mildly elevated blood urea (4.07 mmol/L).

Drug Resistance Patterns

LPA detected rifampicin resistance in 59.18%, isoniazid resistance in 17.55%, and combined resistance (MDR-TB) in 23.27%. XDR-TB was identified in 21.22%. Only 11.02% were sensitive to both RIF and INH.

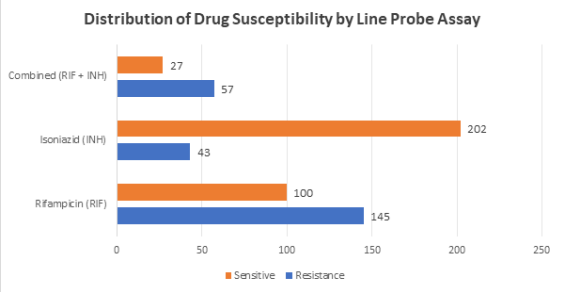


Figure 3: Drug Resistance Patterns Detected by LPA

Clustered bar chart showing proportions of Rifampicin resistance, Isoniazid resistance, combined MDR-TB.

DISCUSSION

This study highlights the significant clinical and laboratory burden of pulmonary TB in study setting, complicated by a high prevalence of drug resistance. The predominance of young, working-age males from lower socioeconomic strata engaged in high-risk occupations aligns with known epidemiological patterns in TB-endemic areas. The advanced clinical presentation, characterized by severe respiratory symptoms, malnutrition, and co-morbidities such as diabetes and hypertension, indicates delayed diagnosis and challenges in disease management.[3]

The high rates of rifampicin resistance (59.18%) and MDR-TB (23.27%) detected by LPA underscore the critical role of rapid molecular diagnostics in resource-limited settings. Compared to conventional DST, the LPA's rapid turnaround (1–3 days) facilitates earlier initiation of tailored therapy, which is essential to reduce transmission and improve treatment outcomes.[4,5] The detection of XDR-TB in over one-fifth of patients is particularly concerning and calls for enhanced surveillance and individualized treatment approaches.[6,7]

Laboratory findings correlate with clinical severity; patients with higher bacillary loads and elevated inflammatory markers are more likely to harbor resistant strains, complicating prognosis.[8] Anemia and metabolic derangements reflect systemic involvement and underline the need for comprehensive clinical management.[9] HIV co-infection further complicates treatment and necessitates integrated care strategies.[10]

Incorporating LPA into routine clinical workflows supports timely decision-making and helps mitigate the spread of resistant TB strains. Focused public health interventions targeting vulnerable populations, early diagnosis, and appropriate treatment regimens are imperative for effective TB control in this region of Rajasthan.[11,12]

CONCLUSION

Pulmonary TB patients in this cohort present with severe symptoms and a substantial incidence of treatment resistance. The LPA is a rapid and reliable diagnostic adjunct that facilitates early detection of resistance to rifampicin and isoniazid, enabling clinicians to tailor treatment effectively. Integration of LPA into standard clinical practice is recommended to optimize patient outcomes, reduce transmission, and strengthen TB control efforts in high-prevalence regions.

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