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A COMPARATIVE STUDY OF CARTRIDGE-BASED NUCLEIC ACID AMPLIFICATION TEST (CBNAAT) AND REAL-TIME POLYMERASE CHAIN REACTION (RT-PCR) FOR DETECTION OF RIFAMPICIN RESISTANCE IN MYCOBACTERIUM TUBERCULOSIS

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ABSTRACT

Background: Tuberculosis (TB) remains a major global health threat(1) with drug-resistant strains posing significant diagnostic and therapeutic challenges . Rapid detection of rifampicin resistance is critical for early initiation of appropriate therapy. **Objective:** To evaluate the diagnostic performance of RT-PCR in detecting rifampicin resistance in sputum samples of pulmonary TB patients, using CBNAAT as the gold standard. **Methods:** An observational comparative study was conducted over two years at a tertiary care center in Kolhapur, India. Forty-five sputum smear-positive pulmonary TB patients were enrolled. All samples underwent CBNAAT and RT-PCR testing. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of RT-PCR were calculated against CBNAAT. **Results:** Among 45 patients, CBNAAT detected rifampicin resistance in 25 (55.6%) and sensitivity in 20 (44.4%). RT-PCR correctly identified 18 rifampicin-resistant cases and all 20 rifampicin-sensitive cases. Sensitivity and specificity of RT-PCR were 72.0% and 100.0%, respectively. PPV was 100.0% and NPV was 74.1%. **Conclusion:** RT-PCR demonstrated excellent specificity and PPV but lower sensitivity compared to CBNAAT. While RT-PCR may serve as a supplementary diagnostic tool, CBNAAT remains superior for rapid and reliable detection of rifampicin resistance (2)(3)(4).

KEYWORDS

Tuberculosis, Rifampicin Resistance, CBNAAT, RT-PCR, Drug-resistant TB

INTRODUCTION

Tuberculosis (TB), caused by Mycobacterium tuberculosis, continues to be a leading cause of morbidity and mortality worldwide, with India carrying one of the highest burdens(1). The emergence of multidrug-resistant TB (MDR-TB), particularly resistance to rifampicin, complicates disease control efforts. Early detection of drug resistance is essential for timely treatment initiation and prevention of transmission (5). Conventional culture-based methods remain the gold standard but require weeks for results. Molecular assays, including CBNAAT (GeneXpert MTB/RIF) and RT-PCR, have been developed to provide faster detection(2)(3). CBNAAT offers automated, near-point-of-care testing with high sensitivity and specificity(4). RT-PCR, though widely available in molecular laboratories, has variable diagnostic performance(6)(7). This study aimed to compare the diagnostic accuracy of RT-PCR with CBNAAT for detection of rifampicin resistance in sputum samples of pulmonary TB patients.

MATERIALS AND METHODS

Study Design and Setting: Observational comparative study at Dr. D. Y. Patil Medical College, Kolhapur, over two years.

Sample Size: 45 consecutive sputum smear-positive pulmonary TB patients aged ≥18 years.

Inclusion Criteria: AFB-positive sputum smear, clinical and/or radiological evidence of pulmonary TB (8).

Exclusion Criteria: AFB-negative sputum samples, refusal to consent.

Ethical Approval: Obtained from the Institutional Ethics Committee. Written informed consent was taken.

Sample Collection and Processing: Early morning sputum samples were collected aseptically.

CBNAAT: Performed using GeneXpert MTB/RIF cartridges (2)(3); results interpreted as MTB detected ± rifampicin resistance.

RT-PCR: DNA extracted and amplified targeting rpoB gene mutations(9)(10). Internal controls, positive and negative controls were included in each run.

Statistical Analysis: Diagnostic accuracy parameters of RT-PCR were calculated against CBNAAT (gold standard) using SPSS v20.

RESULTS

Demographics: Of 45 patients, 16 (35.6%) were aged 31-40 years; mean age 39.4 years. Gender distribution was nearly equal (51.1% female, 48.9% male).

CBNAAT Findings: MTB was detected in all samples; 25 (55.6%) were rifampicin resistant and 20 (44.4%) rifampicin sensitive.

Table No. 1 -Diagnostic Performance of RT-PCR:

RIF Resistance	Sample
True positive	18
True negative	20
False positive	0
False negative	7

Table No. 2 -Characteristics –

Characteristics	Value	CI 95%(approximate)
Sensitivity	72.00%	50.6%- 87.9%
Specificity	100.00%	83.2%-100.0%
PPV (Positive Predictive Value)	100.00%	81.5%-100.0%
NPV (Negative Predictive Value)	74.10%	55.3%-86.8%

DISCUSSION

This study highlights the diagnostic strengths and limitations of RT-PCR compared with CBNAAT for detection of rifampicin resistance. While RT-PCR achieved perfect specificity and PPV, its sensitivity was suboptimal, missing nearly one-third of resistant cases. Previous studies similarly reported higher diagnostic accuracy with CBNAAT, particularly in high-burden settings (2)(3)(4). Our rifampicin resistance prevalence (44.4%) was notably higher than in some earlier Indian studies(8), possibly reflecting local epidemiology or small sample size. The findings underscore that CBNAAT remains the preferred first-line molecular assay for rapid detection of rifampicin resistance (1). RT-PCR may still be valuable in research or as a confirmatory test in well-equipped laboratories, but its limited sensitivity restricts stand-alone use in clinical practice(6)(7)(5).

CONCLUSION

RT-PCR demonstrates excellent specificity and predictive values but lower sensitivity compared with CBNAAT for rifampicin resistance detection. CBNAAT should continue as the frontline diagnostic tool in high TB-burden settings (1)(4). Strengthening access to CBNAAT in resource-limited areas remains crucial for TB control.

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