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Original Article

The Study of Prevalence and Profile of Drug Sensitivity and Drug Resistance Among Microbiologically Confirmed Pulmonary Tuberculosis in A Tertiary Care Hospital

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ABSTRACT

Background: Tuberculosis (TB) continues to be a major public health problem in India, with rising prevalence of drug resistance, including isoniazid (INH) monoresistance, rifampicin resistance, and multidrug resistant (MDR-TB). These challenges have significant clinical and programmatic implications. Rapid molecular diagnostic tools such as CBNAAT/TRUENAT and line probe assay (LPA) allow early detection of resistance, improving patient outcomes.
Aim: To determine the prevalence and profile of drug sensitivity and drug resistance among microbiologically confirmed pulmonary tuberculosis patients in a tertiary care hospital.
Methods: A retrospective study was conducted over a period of 12 months at the pulmonary medicine department, Government General Hospital (GGH), Siddhartha medical college (SMC), Vijayawada, after obtaining approval from the institutional ethicscommittee. Medical records of all patients with microbiologically confirmed pulmonary TB diagnosed using CBNAAT, TRUENAT, Line Probe Assay [LPA], and/or culture were reviewed and analysed.
Results: A total of 300 pulmonary TB patients were included, of whom 204 (68%) were new cases and 96 (32%) were previously treated. Drug-sensitive TB was observed in 226 (75.3%) patients, while 74 (24.7%) showed resistance to one or more first-line drugs. INH mono-resistance was identified in 36 (12%) cases, rifampicin resistance in 16 (5.3%), and multidrug-resistant TB in 22 (7.3%). Drug resistance was more frequent among previously treated patients. Diabetes mellitus was present in 92 patients, of whom 30 (32.6%) had drug-resistant TB. Among 36 HIV-positive patients, 12 (33.3%) showed resistance
Conclusion: The study highlights a substantial burden of INH mono-resistance and MDR-TB, particularly among previously treated, diabetic, and HIV-positive patients. Strengthening early drug-resistance testing, comorbidity screening, and individualized treatment strategies is critical for improving TB control.

Keywords*: Pulmonary tuberculosis, drug resistance, INH mono-resistance, MDR-TB, CBNAAT, LPA.*

INTRODUCTION

Tuberculosis (TB) remains one of the most significant global public health challenges, particularly in low- and middle-income countries, despite decades of intensified control efforts. Caused by Mycobacterium tuberculosis, TB continues to rank among the leading infectious causes of morbidity and mortality worldwide. According to the World Health Organization (WHO), an estimated 10.7 million people developed TB globally in 2024, corresponding to an incidence rate of approximately 133 cases per 100,000 population. During the same year, TB was responsible for nearly 1.23

million deaths, including about 150,000 deaths among people living with HIV (PLHIV), underscoring the persistent lethality of the disease[1].
India continues to bear the highest TB burden globally, contributing approximately 25–27% of all TB cases worldwide. The estimated TB incidence in India in 2024 was over 2.8 million cases, with a mortality rate of approximately 23 deaths per 100,000 population. Despite the scale-up of diagnostic and treatment services under the National Tuberculosis Elimination Programme (NTEP), drug-resistant TB remains a major obstacle to achieving TB elimination targets. India alone accounts for nearly 32% of the global burden of multidrug-resistant or rifampicin-resistant TB (MDR/RR-TB), with an estimated 135,000 incident MDR/RR-TB cases annually[1].

Drug resistance to first-line anti-tubercular drugs poses a serious threat to effective TB control. Isoniazid mono-resistance has been identified in 7–10% of new TB cases and up to 25–30% of previously treated cases, significantly increasing the risk of treatment failure and progression to multidrug resistance if not promptly identified[2–5].

The intersection of TB with HIV infection further amplifies disease burden and mortality. TB remains the leading cause of death among people living with HIV, highlighting the importance of early diagnosis and tailored treatment strategies in this vulnerable population[1].

Diabetes mellitus (DM) has emerged as an important and growing comorbidity influencing TB epidemiology and outcomes. Epidemiological studies suggest that individuals with diabetes have a 2- to 3-fold increased risk of developing active TB compared with non-diabetic individuals[7].

In addition to increasing TB risk, diabetes adversely affects treatment outcomes. TB patients with diabetes are more likely to experience delayed sputum smear and culture conversion, higher rates of treatment failure, relapse, and mortality. Several studies have also demonstrated a higher prevalence of drug-resistant TB among diabetic patients[5,7].
Studies from tertiary care hospitals have highlighted the challenge of treatment failure and drug-resistant TB, particularly among previously treated patients. Yasin et al. reported a notable prevalence of treatment failure among pulmonary TB patients in a tertiary care teaching hospital, emphasizing the need for improved treatment monitoring[9]. Similarly, Lee and Chang documented a substantial burden of drug-resistant TB in a tertiary referral hospital, with prior treatment exposure identified as a major risk factor[10].

With the rising prevalence of diabetes, HIV, and drug-resistant TB in high-burden settings, there is an urgent need for robust epidemiological data to guide integrated TB control strategies. Evaluating local patterns of drug sensitivity and resistance, along with associated comorbidities, is essential for optimizing treatment regimens and improving patient outcomes. This retrospective study was therefore undertaken to assess the prevalence of drug-sensitive and drug-resistant tuberculosis among microbiologically confirmed pulmonary TB cases in a tertiary care hospital, with particular emphasis on resistance patterns and the influence of comorbid conditions such as diabetes mellitus and HIV infection.

METHODOLOGY

This is a retrospective study conducted over a period of 12 months (January 2024 – December 2024) in the department of pulmonary medicine, Siddhartha medical college, GGH, Vijayawada after obtaining ethical clearance.Medical records of all patients diagnosed with pulmonary TB and confirmed by microbiological tests(CBNAAT/TRUENAT, Line Probe Assay [LPA], and/or culture) during the study period were reviewed.

INCLUSION CRITERIA:

- Patients who are above 18 years of age were included.
- Patients diagnosed microbiologically confirmed with pulmonary tuberculosis undergoing anti tubercular medication

EXCLUSION CRITERIA:

- Patients of age<18 yrs
- Radiological/ clinically suspected tuberculosis patients (CBNAAT/TRUENAT- negative)
- Extrapulmonary tuberculosis

CLASSIFICATION OF DRUG RESISTANCE IN PULMONARY TUBERCULOSIS:

Type of Resistance	Definition
Mono-resistance	Resistance to one first-line anti-TB drug only.
Poly-resistance	Resistance to more than one first-line drug, excluding both Rifampicin and Isoniazid.
MDR-TB	Resistant to both Rifampicin and Isoniazid.
Pre-XDR TB	MDR-TB plus resistance to either a fluoroquinolone OR a second-line injectable, but not both.
XDR-TB	MDR-TB plus resistance to any fluoroquinolone AND at least one second-line injectable.

MICROBIOLOGICAL INVESTIGATIONS:

Sputum samples from all participants were carefully collected and tested using rapid molecular methods to detect Mycobacterium tuberculosis (MTB) and associated drug resistance.

CBNAAT (Cartridge-Based Nucleic Acid Amplification Test) was carried out on the GeneXpert system following NACO/WHO guidelines. This test allows simultaneous detection of MTB and rifampicin resistance, with results available within about two hours.

TRUENAT, a chip-based real-time PCR assay, was also used for rapid point-of-care detection. DNA extraction and amplification were performed using the Truelab workstation, offering a convenient alternative in settings where rapid testing is needed.

Line Probe Assay (LPA) was conducted on smear-positive sputum samples or culture isolates. This method identifies specific gene mutations linked to rifampicin and isoniazid resistance, providing a clearer understanding of the drug resistance profile. Standard quality control procedures were applied throughout to ensure accurate and reliable results.

RESULTS

Table 1. Age-wise distribution of cases (n = 300)

Age Group (years)	Number	Percentage (%)
18–40	106	35.3%
41–60	152	50.7%
61–80	40	13.3%
81–100	2	0.7%
Total	300	100%

Most TB cases were seen in the 41-60 years of age group, followed by 18-40 years, indicating greater involvement of the working population.

Table 2. Gender-wise distribution of cases (n = 300)

Gender	Number	Percentage (%)
Male	224	74.6%
Female	76	25.4%
Total	300	100%

TB was more common among males than females, with a male-female ratio of nearly 3:1.

Table 3. Distribution of new vs. previously treated cases

Case Type	Number	Percentage (%)
New Cases	204	68.0%
Previously Treated Cases	96	32.0%
Total	300	100%

New cases formed the majority, while a notable proportion of patients had a history of previous tb treatment.

Table 4. Drug sensitivity vs. drug resistance patterns

Category	Number	Percentage (%)
Sensitive	226	75.3%
Resistant	74	24.7%
Total	300	100%

Table 5. Individual drug-resistance pattern

A. Overall resistance pattern (n = 300)

Resistance Type	Number	Percentage (%)
INH Mono-resistant	36	12.0%
Rifampicin Resistant	16	5.3%
MDR-TB	22	7.3%

The majority of cases were drug sensitive, with isoniazid mono resistance being the most frequently observed resistance pattern.

B. New vs. previously treated breakdown

Resistance Type	New Cases (n = 204)	%	Previously Treated (n = 96)	%
INH Mono-resistant	16	7.8%	20	20.8%
Rifampicin Resistant	6	2.9%	10	10.4%
MDR-TB	8	3.9%	18	18.7%

Drug resistance was observed more often in previously treated patients than in new cases, though resistance was also present among new cases.

Table 6. Comorbidity profile – sensitive and resistant cases

Comorbidity	Total cases, n (%)	Drug-resistant cases, n (%)	Drug-sensitive cases, n (%)
Diabetes mellitus	92 (30.7)	15 (32.6)	77 (67.4)
HIV positive	36 (12.0)	6 (33.3)	30 (66.7)

DISCUSSION

The present study demonstrated that drug-sensitive tuberculosis constituted the majority of cases, with 238 out of 300 patients (79.3%) showing sensitivity to first-line anti-tubercular drugs. This proportion is comparable to findings reported in several Indian studies, where drug-sensitive TB ranged from 70% to 85% among newly diagnosed patients. Thomas et al. reported drug sensitivity in approximately 76% of pulmonary TB cases from Tamil Nadu, while Gupta et al. observed sensitivity rates of nearly 72% in a North Indian cohort[3,5]. The World Health Organization (WHO) Global Tuberculosis Report 2024 also indicates that the majority of newly diagnosed TB cases globally remain drug-sensitive, emphasizing the continued effectiveness of first-line regimens when resistance is promptly excluded[1].

Age- and sex-wise analysis revealed that most drug-sensitive cases were concentrated in the 41–60-year age group, with a marked male predominance (74.6%). Similar demographic trends have been described in national and international reports, attributing higher sensitivity rates in males to earlier diagnosis and better treatment access, despite higher exposure risks[1,3].

INH Monoresistance

INH monoresistance was observed in 36 patients (12.0%), with a significantly higher prevalence among previously treated cases (20.8%) compared to new cases (7.8%). This finding supports earlier observations that prior incomplete or irregular therapy contributes to the emergence of INH resistance[2,4]. Similar resistance proportions among retreatment cases have been reported in studies from Mumbai and North India[2],4]. The WHO 2024 report also notes that INH resistance is substantially more common in previously treated patients, often exceeding 25%, which aligns closely with the present findings[1].

Rifampicin Resistance

Rifampicin resistance was detected in 5.3% of patients, with higher prevalence among previously treated cases (10.4%) than new cases (2.9%). This pattern is consistent with WHO data showing a strong association between rifampicin resistance and prior TB treatment exposure[1]. Comparable findings have been reported in studies from Tamil Nadu and North India, where rifampicin resistance among retreatment cases ranged from *9–12%*[3,5]. The routine use of CBNAAT in this study enabled rapid detection of rifampicin resistance, supporting its role as a frontline diagnostic tool[8].

Multidrug-Resistant Tuberculosis

MDR-TB was identified in 7.3% of cases, with markedly higher prevalence among previously treated patients (18.7%) compared to new cases (3.9%). This distribution closely mirrors WHO 2024 estimates, which report MDR/RR-TB rates of 3–4% among new cases and 18–21% among retreatment cases[1]. Similar trends have been documented in Indian hospital-based studies, reinforcing the role of previous treatment as a major determinant of MDR-TB development[5,7].

Comorbidities

Comorbidities significantly influenced both drug sensitivity and resistance patterns. Among patients without comorbidities, drug sensitivity was observed in nearly 85% of cases, whereas sensitivity dropped to 67.4% among patients with diabetes mellitus. Kumar et al. reported similar findings, with drug sensitivity rates of approximately 65–70% among diabetic TB patients compared to over 80% in non-diabetic individuals[7]. Diabetes-related immune dysfunction, higher bacillary load, and delayed sputum conversion are considered key contributors to reduced drug sensitivity.

HIV co-infection also adversely affected treatment susceptibility. In the present study, drug sensitivity among HIV-positive patients was approximately 66.7%, compared to over 80% in HIV-negative patients. WHO data suggest that TB-HIV co-infected individuals have higher rates of unfavorable outcomes and lower treatment success, largely due to immunosuppression and drug–drug interactions[1]. Similar observations were reported by Yasin et al. and Lee and Chang

in tertiary care hospital settings, where coexisting conditions were associated with increased resistance and treatment failure[9,10].

Diagnostic modalities

Diagnostic modalities played a critical role in identifying both sensitive and resistant cases. CBNAAT facilitated early exclusion of rifampicin resistance, allowing prompt initiation of standard first-line therapy in drug-sensitive cases. Sharma et al. reported that CBNAAT correctly identifies rifampicin-sensitive TB in over 95% of cases, supporting its reliability for early decision-making[8]. Line Probe Assay (LPA), used in selected patients, further confirmed drug sensitivity and resistance patterns, with Jain et al. demonstrating agreement rates of 92–96% with culture-based methods[6].

Overall, the high proportion of drug-sensitive TB observed in this study underscores the importance of early diagnosis and routine drug susceptibility testing to preserve the effectiveness of first-line anti-tubercular therapy. At the same time, the reduced sensitivity observed among patients with diabetes and HIV highlights the need for integrated management of comorbidities to improve treatment outcomes and prevent the emergence of drug resistance.

CONCLUSION

The present study highlights a significant burden of drug-resistant tuberculosis in a tertiary care hospital setting, with resistance occurring more commonly among previously treated patients. INH monoresistance, rifampicin resistance, and MDR-TB showed clear associations with prior treatment exposure, consistent with WHO 2024 data and findings from major Indian studies. Comorbidities, particularly diabetes mellitus and HIV infection, contributed substantially to the risk of drug resistance, emphasizing the need for integrated TB–DM and TB–HIV management strategies. Rapid molecular diagnostics such as CBNAAT and Line Probe Assay proved essential in early detection of resistance and timely initiation of appropriate therapy. Strengthening adherence monitoring, routine baseline drug-susceptibility testing, and improved surveillance are critical to controlling the spread of drug-resistant TB in India.

LIMITATIONS:

1. Single-center hospital-based study: The findings may not fully represent the broader community or regional drug-resistance trends.
2. Limited sample size: Although adequate for preliminary analysis, larger multicenter studies would provide more robust epidemiological insights.
3. Incomplete assessment of all risk factors: Factors such as socioeconomic status, nutrition, smoking, and alcohol use were not evaluated, which may influence resistance patterns.
4. Diagnostic heterogeneity: Not all patients underwent Line Probe Assay or culture-based DST due to logistic constraints; reliance on CBNAAT alone may underestimate certain resistance mutations.
5. Follow-up data not included: Treatment outcomes, adherence patterns, and conversion rates were not analyzed, limiting interpretation of long-term clinical impact

DECLARATION:

Conflicts of interest: the authors declare no conflicts of interest.
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REFERENCES

1. World Health Organization. (2024). Global tuberculosis report 2024. World Health Organization.
2. Dalal, A., Pawaskar, A., Das, M., Desai, R., & Prabhudesai, P. (2016). Clinical significance of isoniazid mono-resistance in Mumbai: A retrospective cohort study. The International Journal of Tuberculosis and Lung Disease, 20(4), 472–477. https://doi.org/10.5588/ijtld.15.0604
3. Thomas, B. E., Manogaran, C., & Mahadevan, S. (2019). Patterns of drug resistance in pulmonary tuberculosis: A study from Tamil Nadu. Lung India, 36(5), 402–407. https://doi.org/10.4103/lungindia.lungindia_38_19
4. Prasad, R., Singh, A., Balasubramanian, V., & Gupta, N. (2020). Prevalence of INH and rifampicin resistance among newly diagnosed and previously treated tuberculosis patients in Uttar Pradesh. Journal of Clinical and Diagnostic Research, 14(8), OC10–OC15.
5. Gupta, A., Singh, M., & Sharma, P. (2021). Drug-resistance patterns and associated factors among pulmonary tuberculosis patients in North India: A hospital-based study. Indian Journal of Tuberculosis, 68(3), 356–362. https://doi.org/10.1016/j.ijtb.2020.10.007
6. Jain, P., Garg, K., & Sharma, N. (2022). Agreement between CBNAAT, liquid culture, and line probe assay for detection of Mycobacterium tuberculosis and rifampicin resistance. Indian Journal of Medical Microbiology. Advance online publication.
7. Kumar, A. M. V., Venkatesh, S., & Thomas, A. (2017). Impact of diabetes mellitus on drug-resistant tuberculosis among patients in South India. Tropical Medicine & International Health, 22(9), 1143–1150. https://doi.org/10.1111/tmi.12908

8. Sharma, S. K., Kohli, M., Yadav, R. N., Chaubey, J., Bhasin, D., & Sharma, R. (2020). Evaluation of CBNAAT in diagnosis of drug-resistant tuberculosis in India. PLoS ONE, 15(4), e0231931. https://doi.org/10.1371/journal.pone.0231931
9. Yasin, M., Ahmad, Z., & Suleman, A. (2016). Prevalence of treatment failure among pulmonary tuberculosis patients in a tertiary care teaching hospital. Journal of Bacteriology & Mycology: Open Access, 3(4), 273–276.
10. Lee, J. H., & Chang, J. H. (2001). Drug-resistant tuberculosis in a tertiary referral teaching hospital of Korea. Korean Journal of Internal Medicine, 16(3), 173–179. https://doi.org/10.3904/kjim.2001.16.3.173