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Prevalence and patterns of drug-resistant tuberculosis under the national tuberculosis elimination program in Vijayapura: A retrospective observational study

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Abstract: *Objective:* To study the prevalence and patterns of drug resistance in tuberculosis patients under programmatic setting. *Method:* Patients registered under the National Tuberculosis Elimination Program (NTEP) in Vijayapura from January 2023 to January 2025 were included in the study. Further, among the bacteriologically confirmed cases, the prevalence and patterns of drug resistance were analysed. *Results:* A total of 2095 patients were included in the study. Males accounted for 59.5%, and females accounted for 44.4% of the study group. 6.7% of the cases were found to have drug-resistant tuberculosis. MDR TB (Multi-drug resistant Tuberculosis) was the commonest form of drug-resistant tuberculosis. Pre-XDR and XDR prevalence was very low in our study. *Conclusion:* Overall, drug resistance was found to be low in our study, confirming regional variation in drug resistance prevalence and patterns of drug-resistant tuberculosis.

Keywords: Drug-resistant Tuberculosis, National Tuberculosis Elimination Program, Multidrug-resistant Tuberculosis, Rifampicin Resistance, Isoniazid Resistance.

Introduction

Tuberculosis (TB), caused by *Mycobacterium tuberculosis* (Mtb), remains one of the leading causes of mortality due to infectious diseases worldwide. According to the World Health Organisation (WHO), an estimated 10.7 million people developed TB globally in 2024, resulting in approximately 1.23 million deaths [1]. Despite major advances in diagnosis and treatment, TB continues to pose a substantial public health burden, particularly in low- and middle-income countries. India alone accounts for nearly 27–32% of the global TB burden and remains one of the countries with the highest incidence of drug-resistant tuberculosis (DR-TB) [1-2].

The emergence of drug-resistant TB was recognised soon after the introduction of streptomycin monotherapy for tuberculosis treatment [3]. Since then, drug resistance has evolved into a major obstacle to global TB control. Resistance develops primarily through spontaneous genetic mutations that confer reduced susceptibility to anti-tubercular drugs, followed by selection pressure due to inadequate or incomplete therapy. Several resistance-associated mutations have been identified in *Mycobacterium tuberculosis* [4]. Mutations in the *rpoB* gene are strongly associated with rifampicin resistance, whereas mutations in the *katG* gene and the *inhA* promoter region are commonly linked to isoniazid resistance. In addition, mutations involving *gyrA*, *gyrB*, *rrs*, and *eis* genes contribute to resistance against fluoroquinolones and second-line injectable agents. Advances in molecular diagnostics, including cartridge-based nucleic acid amplification tests (CB-NAAT), Line Probe Assays (LPA), and whole genome sequencing, have enabled rapid identification of these mutations and early detection of drug-resistant TB.

Multidrug-resistant tuberculosis (MDR-TB) is defined as TB caused by strains resistant to at least rifampicin and isoniazid, or rifampicin-resistant TB (RR-TB) with or without

resistance to other first-line drugs. Pre-extensively drug-resistant TB (pre-XDR-TB) refers to MDR/RR-TB with additional resistance to any fluoroquinolone. Extensively drug-resistant TB (XDR-TB) is defined as TB caused by strains resistant to rifampicin, any fluoroquinolone, and at least one additional Group A drug such as bedaquiline or linezolid. These forms of TB are associated with prolonged treatment duration, increased adverse drug reactions, higher treatment costs, and poorer clinical outcomes.

The epidemiology of drug-resistant TB demonstrates considerable geographical variation. The highest prevalence of MDR/RR-TB has been reported in Eastern Europe and Central Asia [5-6]. Migration and cross-border transmission have also contributed significantly to the spread of drug-resistant tuberculosis in Europe [7]. In India, the burden of MDR-TB varies widely across regions and is significantly higher among previously treated patients compared to newly diagnosed cases [8-9]. Contributing factors include poor treatment adherence, delayed diagnosis, interrupted drug supply, inadequate treatment regimens, socioeconomic disparities, malnutrition, HIV co-infection, diabetes mellitus, and ongoing community transmission. Furthermore, underdiagnosis and limited access to comprehensive drug susceptibility testing remain major challenges in several resource-limited settings.

Recent advances in DR-TB management have improved treatment outcomes considerably. WHO currently recommends shorter all-oral regimens containing newer drugs such as bedaquiline, pretomanid, linezolid, and moxifloxacin (BPaLM regimen), which have significantly reduced treatment duration from 18–24 months to nearly 6 months in eligible patients. These regimens have demonstrated improved treatment success rates, better patient compliance, and reduced toxicity compared to older injectable-containing regimens.

Understanding regional patterns of drug resistance is therefore essential for strengthening tuberculosis control strategies. Identifying the local prevalence of pre-XDR and XDR-TB can provide valuable epidemiological insights and support the development of targeted interventions, improved diagnostic approaches, and region-specific treatment policies. Several systematic reviews have highlighted substantial regional variation in the prevalence and patterns of drug-resistant tuberculosis across India [8, 10]. Understanding regional patterns of drug resistance is therefore essential for strengthening tuberculosis control strategies Such data are crucial for optimizing tuberculosis control programs and advancing national goals toward TB elimination.

Material and Methods

This retrospective observational study was conducted after obtaining approval from the Institutional Ethics Committee. The study analysed data of tuberculosis (TB) patients registered under the National Tuberculosis Elimination Program (NTEP) in Vijayapura city, Karnataka, between January 2023 and January 2025.

Data were collected from NTEP records maintained at designated microscopy centres and tuberculosis units in Vijayapura city. Demographic details, clinical characteristics, site of disease, microbiological investigations, and drug-resistance profiles were extracted from the records using a structured data collection format.

Both pulmonary tuberculosis (PTB) and extrapulmonary tuberculosis (EPTB) cases were included in the study. Patients of all age groups and both sexes diagnosed with tuberculosis during the study period were considered eligible. Cases with incomplete records, missing microbiological data, or unavailable drug-susceptibility testing results were excluded from the analysis.

Drug-resistant tuberculosis (DR-TB) cases were classified according to the updated World Health Organization (WHO) definitions. Resistance patterns evaluated included rifampicin-resistant tuberculosis (RR-TB), multidrug-resistant tuberculosis (MDR-TB), pre-extensively drug-resistant tuberculosis (pre-XDR-TB), and extensively drug-resistant tuberculosis (XDR-TB), wherever applicable.

Microbiological diagnosis and detection of drug resistance were performed using molecular diagnostic techniques available under the NTEP. Truenat and CBNAAT (Cartridge-Based Nucleic Acid Amplification Test) were used for the rapid detection of *Mycobacterium tuberculosis* and rifampicin resistance. Line Probe Assay (LPA) was utilised for first-line and second-line drug susceptibility testing to identify resistance to isoniazid, rifampicin, fluoroquinolones, and second-line injectable drugs. Cases identified as drug-resistant were further evaluated for resistance to Group A drugs as per current WHO recommendations.

The primary objective of the study was to determine the prevalence and patterns of drug resistance among tuberculosis patients registered under the NTEP in Vijayapura city. Secondary objectives included assessing the distribution of drug-resistant TB among pulmonary and extrapulmonary cases and describing demographic and clinical characteristics associated with drug resistance. Data were entered into Microsoft Excel and analysed using appropriate statistical methods. Descriptive statistics such as frequencies, percentages, means, and standard deviations were used to summarize the data. The prevalence of various patterns of drug resistance was expressed as proportions of the total TB cases studied.

Results

A total of 2095 patients with tuberculosis (TB) were included in the study. Most patients belonged to the economically productive age group of 20–60 years, accounting for 65.3% of the study population. The highest proportion of patients was observed in the 30–39 years age group (18.9%), followed by 20–29 years (18.3%) and 40–49 years (16.4%). Males constituted the majority of the study population (59.5%), while females accounted for 40.4% and transgender individuals for 0.1% (Table 1).

Pulmonary TB was more common than extrapulmonary TB, accounting for 57.3% of cases, whereas extrapulmonary TB constituted 42.7%. Bacteriologically confirmed TB cases accounted for 32.7% of the total study population. Initial valid molecular WHO-recommended rapid diagnostic tests (mWRD) were available for 33.6% of patients (Table 2).

Table-1: Demographic characteristics of study participants (N = 2095)

Variable	Number of patients (n)	Percentage (%)
<10	156	7.4
10–19	208	9.9
20–29	383	18.3
30–39	397	18.9
40–49	344	16.4
50–59	267	12.7
≥60	340	16.2
Female	846	40.4
Male	1247	59.5
Transgender	2	0.1

Table-2: Clinical and diagnostic characteristics of tuberculosis patients (N = 2095)

Variable	Number of patients (n)	Percentage (%)
Bacteriologically confirmed - Yes	685	32.7
Bacteriologically confirmed - No	1410	67.3
Initial mWRD offered - Yes	703	33.6
Initial mWRD offered - No	1392	66.4
Pulmonary TB	1200	57.3
Extrapulmonary TB	895	42.7

Among the study population, 10.9% were people living with HIV, while 89.1% were HIV non-reactive. Regarding diabetic status, 5.9% of patients were diabetic, 89.6% were non-diabetic, and diabetic status was unknown in 4.5% of cases (Table 3).

Table-3: HIV and diabetes status among tuberculosis patients (N = 2095)

Variable	Number of patients (n)	Percentage (%)
Reactive HIV	229	10.9
Non-reactive HIV	1866	89.1
Diabetic	123	5.9
Non-diabetic	1878	89.6
Unknown diabetic status	94	4.5

Valid drug resistance testing results were available for 626 patients. Rifampicin resistance was detected in 47 patients, representing 2.2% of the total TB cases and 7.5% of tested patients. Isoniazid resistance was identified in 46 patients (2.2% of total TB cases; 7.3% of tested patients). Multidrug-resistant TB (MDR-TB), defined as resistance to both rifampicin and isoniazid, was observed in 24 patients (1.1% of total TB cases; 3.8% of tested patients). Isoniazid mono-resistance was detected in 22 patients (1.1% of total TB cases; 3.5% of tested patients).

Fluoroquinolone resistance was detected in 13 patients (0.6% of total TB cases; 2.1% of tested patients). Pre-extensively drug-resistant TB (Pre-XDR-TB), defined as RR/MDR-TB with additional fluoroquinolone resistance, was identified in 10 patients (0.5% of total TB cases; 1.6% of tested patients). One patient had rifampicin-resistant TB with fluoroquinolone resistance and additional resistance to linezolid or bedaquiline. No confirmed extensively drug-resistant TB (XDR-TB) cases were identified in the study (Table 4).

Table-4: Patterns of drug resistance among tuberculosis patients

Drug resistance pattern	n	% among total TB cases	% among tested patients
Rifampicin resistance detected	47	2.2	7.5
Isoniazid resistance detected	46	2.2	7.3
MDR-TB	24	1.1	3.8
Isoniazid mono-resistance	22	1.1	3.5
Fluoroquinolone resistance detected	13	0.6	2.1
Pre-XDR-TB	10	0.5	1.6
RR-TB with additional Linezolid/ Bedaquiline resistance	1	0.05	0.2
Confirmed XDR-TB	0	0.0	0.0

Discussion

The present retrospective observational study was conducted to evaluate the prevalence and patterns of drug-resistant tuberculosis (DR-TB) among patients registered under the National Tuberculosis Elimination Program (NTEP) in Vijayapura city between 2023 and 2025. A total of 2,095 tuberculosis patients were included in the analysis. The majority of patients belonged to the economically productive age group of 20–60 years, and males constituted 59.5% of the study population. Pulmonary tuberculosis was more common than extrapulmonary tuberculosis, accounting for 57.3% of cases.

In the present study, bacteriological confirmation was available in 32.7% of patients, while valid drug-resistance testing (DRT) results were available for only 626 patients (29.9%). The relatively low proportion of patients undergoing valid DRT reflects limited utilization of molecular diagnostic facilities and may have contributed to underestimation of the true burden of drug-resistant tuberculosis in the study population. Universal drug-susceptibility testing remains a major challenge in programmatic settings, particularly among clinically diagnosed and extra pulmonary TB cases.

Among the total study population, rifampicin resistance was detected in 47 patients (2.2%), while isoniazid resistance was detected in 46 patients (2.2%). When calculated among patients with valid DRT results, rifampicin resistance and isoniazid resistance accounted for 7.5% and 7.3%, respectively. Multidrug-resistant tuberculosis (MDR-TB), defined as resistance to both rifampicin and isoniazid, was identified in 24 patients, representing 1.1% of the total cases and 3.8% of tested patients. These findings indicate that RR/MDR-TB constituted the most common form of drug resistance observed in the study.

Global surveillance studies have demonstrated persistently high rates of drug-resistant tuberculosis in Eastern Europe and Central Asia, highlighting important regional differences in resistance trends [6, 11]. The prevalence of rifampicin resistance observed in our study was comparatively lower than

that reported in several other Indian studies a study conducted by Sayantani Endow et al. reported rifampicin resistance in 3.34% of tuberculosis cases [12], which was slightly higher but comparable to the findings of the present study. Similarly, according to the National Anti-Tuberculosis Drug Resistance Survey 2018 [13], the prevalence of MDR-TB among new and previously treated cases was 2.84% and 11.60%, respectively. The World Health Organization Global Tuberculosis Report 2025 reported MDR/RR-TB prevalence rates of 3.3% among newly diagnosed cases and 16% among previously treated cases. In contrast, our study demonstrated relatively lower rates of MDR/RR-TB overall.

Interestingly, rifampicin resistance and MDR-TB were observed more frequently among newly diagnosed and treatment-naïve cases than among retreatment cases. This finding differs from national and global trends, where higher rates of drug resistance are usually reported among previously treated patients. The higher burden of resistance among newly diagnosed patients in the present study may indicate ongoing primary transmission of drug-resistant strains within the community. In addition, incomplete treatment histories, delayed diagnosis, and low testing coverage among retreatment patients may also have influenced these findings.

Isoniazid mono-resistance was identified in 22 patients, accounting for 1.1% of the total cases and 3.5% of tested patients. Although the overall prevalence was low, isoniazid mono-resistance was relatively more common among retreatment cases. Nandini Singh et al. reported a prevalence of isoniazid mono-resistance of 3.71% in North India [14], which was slightly higher than that observed in the present study. The same study demonstrated substantially higher rates of isoniazid mono-resistance among previously treated TB patients, suggesting prior anti-tubercular therapy as an important risk factor for the development of resistance.

Fluoroquinolone resistance was detected in 13 patients (0.6% of total cases and 2.1% among tested patients). The prevalence of fluoroquinolone resistance observed in our study was lower compared to other published reports. Rohini Sharma et al. reported fluoroquinolone mono-resistance in 3.2% of drug-sensitive TB cases [15]. The lower prevalence observed in the present study may reflect regional differences in fluoroquinolone exposure, lower second-line drug selection pressure, or limited second-line drug susceptibility testing.

Pre-extensively drug-resistant tuberculosis (pre-XDR-TB), defined according to updated WHO criteria as RR/MDR-TB with additional fluoroquinolone resistance, was identified in 10 patients, accounting for 0.5% of total cases and 1.6% of tested patients. No confirmed XDR-TB cases fulfilling complete WHO criteria were identified in the study. However, isolated resistance involving Group A drugs such as Linezolid and Bedaquiline was observed in a very small number of patients. The low prevalence of pre-XDR-TB and absence of confirmed XDR-TB in our study may partly be due to incomplete second-line drug susceptibility testing and limited availability of comprehensive molecular testing facilities.

A retrospective study conducted by Gajjala Suvarna et al. among MDR-TB patients reported pre-XDR-TB and XDR-TB prevalence rates of 9.6% and 2.1%, respectively [16], which were considerably higher than those observed in our study. Differences in study population, referral patterns, testing strategies, and inclusion of high-risk MDR-TB cohorts may explain these variations.

In the present study, all forms of drug resistance were more commonly observed among males. Drug resistance was relatively less common among Pediatric patients and elderly individuals above 60 years of age. The higher prevalence among males may be related to increased exposure to risk factors such as smoking, alcohol consumption, occupational exposure, delayed healthcare-seeking behavior, and poor treatment adherence.

The present study has certain limitations. Being a retrospective study based on routinely collected NTEP data, the possibility of incomplete documentation and missing records cannot be excluded. Additionally,

only 29.9% of patients had valid drug-resistance testing results, which may have led to underestimation of the true burden of drug resistance in the community. The high proportion of clinically diagnosed cases and relatively low utilization of WHO-recommended molecular rapid diagnostic tests (mWRDs) further limited comprehensive resistance profiling.

Despite these limitations, the study provides important programmatic data regarding the prevalence and patterns of drug-resistant tuberculosis in Vijayapura city. The findings highlight the need for universal access to molecular diagnostics, expansion of drug-susceptibility testing services, early identification of resistant cases, and continuous surveillance of resistance trends under the NTEP. Strengthening diagnostic coverage and long-term monitoring of drug resistance patterns are essential for effective tuberculosis control and prevention of transmission of resistant strains.

Conclusion

The present study provides important insights into the prevalence and patterns of drug-resistant tuberculosis among patients registered under the National Tuberculosis Elimination Program (NTEP) in Vijayapura city between 2023 and 2025. Although the overall prevalence of drug-resistant tuberculosis was relatively low, rifampicin-resistant tuberculosis and multidrug-resistant tuberculosis constituted the most common forms of resistance identified in the study. Isoniazid mono-resistance and fluoroquinolone resistance were also observed, while the prevalence of pre-XDR-TB was low and no confirmed XDR-TB cases were detected.

The majority of drug-resistant cases occurred among individuals in the economically productive age group and were more common among males. Notably, a higher proportion of RR/MDR-TB was observed among newly diagnosed patients, suggesting possible ongoing community transmission of resistant strains.

The study also highlights important programmatic challenges, including low rates of bacteriological confirmation and limited utilization of molecular WHO-recommended rapid diagnostic tests and drug-susceptibility testing. These limitations may contribute to under-detection of drug-resistant tuberculosis and hinder accurate estimation of the true burden of resistance.

Strengthening universal drug-susceptibility testing, improving access to rapid molecular diagnostics, and ensuring early detection and appropriate management of drug-resistant tuberculosis are essential for effective tuberculosis control under the NTEP. Continuous surveillance and long-term monitoring of resistance trends are necessary to guide public health strategies and prevent further transmission of resistant tuberculosis strain.

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