

## Original Research Article

# A STUDY ON DRUG RESISTANCE IN TUBERCULOSIS CASES AND ITS PREVALENCE AT A TERTIARY CARE CENTRE – RANGARAYA MEDICAL COLLEGE AND GOVERNMENT GENERAL HOSPITAL, KAKINADA, ANDHRA PRADESH

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**ABSTRACT**

**Background:** Tuberculosis (TB) remains a major public health concern, particularly due to the emergence of drug-resistant strains. Resistance to first-line anti-tubercular drugs such as isoniazid and rifampicin poses a significant threat to global TB control efforts. India, being one of the high-burden countries, faces a growing challenge in managing multidrug-resistant (MDR) and extensively drug-resistant (XDR) TB cases. **Aims and Objectives:** This study aims to assess the prevalence of drug-resistant TB among patients attending Rangaraya Medical College and Government General Hospital, Kakinada. Specific objectives include evaluating the proportion of multidrug-resistant, pre-XDR, and totally drug-resistant TB, and analyzing resistance patterns among newly diagnosed and recurrent TB cases.

**Materials and Methods:** A retrospective, hospital-based study was conducted over 12 months (January–December 2024) involving 923 patients with drug-resistant TB. Data were obtained from clinical records, microbiological and radiological findings, and drug susceptibility tests including CBNAAT and line probe assay (LPA). Sociodemographic factors and comorbidities such as HIV and diabetes were analyzed.

**Results:** Out of 923 TB cases, drug resistance was identified in 46 patients (4.98%), with a male predominance (71.27%). Isoniazid resistance alone was observed in 60% of drug-resistant cases, while MDR-TB accounted for 14%. Pre-XDR TB was reported in 2% of cases. HIV co-infection was associated with 4.34% of isoniazid resistance. Diabetic patients constituted 26.08% of drug-resistant cases. Notably, 85.7% of drug-resistant cases were newly diagnosed rather than recurrent.

**Conclusion:** The study highlights a significant burden of drug resistance among newly diagnosed TB cases, with a clear association with comorbid conditions such as diabetes and HIV. The findings underscore the importance of early diagnosis, targeted treatment, and rigorous public health interventions to curb the spread of drug-resistant TB in rural and semi-urban populations.

**Keywords:** Tuberculosis, Multidrug-Resistant TB, Drug Resistance, Pre-XDR TB, HIV, Diabetes Mellitus.

## INTRODUCTION

Tuberculosis (TB) is a communicable disease caused by *Mycobacterium tuberculosis*, primarily

affecting the lungs, though it can also involve other organs such as the spine, brain, and kidneys. TB spreads through airborne droplets when an infected individual coughs, sneezes, or speaks. While TB is

generally curable, delayed or incomplete treatment increases the risk of complications and mortality.

A major global concern in TB control is the rising prevalence of drug-resistant TB (DR-TB), particularly resistance to the two most potent first-line anti-TB drugs—isoniazid (H) and rifampicin (R).<sup>[1]</sup> Resistance to these drugs leads to multidrug-resistant TB (MDR-TB), while additional resistance to fluoroquinolones and second-line injectable drugs defines pre-extensively drug-resistant TB (Pre-XDR TB) and extensively drug-resistant TB (XDR-TB).<sup>[2]</sup> The emergence of these resistant strains has significantly complicated the management and control of TB.

Before the COVID-19 pandemic, TB was the leading cause of death from a single infectious agent globally, surpassing HIV/AIDS in mortality.<sup>[1]</sup> Despite ongoing efforts, drug resistance continues to be a formidable challenge in eradicating TB. Globally, the proportion of new TB cases with MDR/rifampicin-resistant TB (RR-TB) has remained at approximately 3–4%, and among previously treated cases, the rate has stayed around 18–21%.<sup>[3,4]</sup>

In 2023, five countries accounted for more than half of the global burden of MDR/RR-TB: India (27%), the Russian Federation (7.4%), Indonesia (7.4%), China (7.3%), and the Philippines (7.2%).<sup>[5]</sup> India alone has made notable progress in reducing MDR/RR-TB cases by 20%, from 1.40 lakh in 2015 to 1.10 lakh in 2023. The estimated proportion of new TB cases with MDR/RR-TB in India is 2.5%, and in previously treated TB cases, it stands at 13%.<sup>[6,7]</sup>

Under the National TB Elimination Program (NTEP), drug-resistant TB is classified into five categories: isoniazid-resistant TB, rifampicin-resistant TB (RR-TB), multidrug-resistant TB (MDR-TB), pre-XDR-TB, and XDR-TB.<sup>[3]</sup>

India has scaled up diagnostic and treatment services for DR-TB over the past decade. In 2023 alone, 63,929 MDR/RR-TB cases were reported, including 11,749 pre-XDR-TB and 114 XDR-TB patients, along with 23,019 H-mono/poly drug-resistant TB patients. Treatment success for MDR-TB has significantly improved from 49% in 2017 to 75% in 2021 [8]. Similarly, treatment success for pre-XDR-TB patients increased from 36% to 68% during the same period, largely due to newer drug regimens.<sup>[9]</sup>

In line with WHO recommendations, the NTEP's National Technical Expert Group (NTEG) has proposed new strategies including the introduction of the BPaLM regimen, broader use of bedaquiline (Bdq) and delamanid (Dlm) in all age groups, and the adoption of a 9–11-month oral regimen with linezolid (Lzd) replacing ethionamide (Eto). Furthermore, CBNAAT M.tb/XDR testing has been recommended for rapid molecular detection of resistance to H, fluoroquinolones (FQ), second-line injectables (SLI), and Eto.<sup>[9]</sup>

This study was conducted at Rangaraya Medical College and Government General Hospital, Kakinada, Andhra Pradesh, to assess the pattern and prevalence of drug-resistant TB. The findings aim to inform local strategies under the NTEP and address public health challenges unique to rural and semi-urban populations characterized by agricultural occupations, low literacy rates, socio-economic barriers, and limited healthcare access

### **Objectives**

The primary objective of this study was to evaluate the patterns and prevalence of drug-resistant tuberculosis (DR-TB) among patients attending Rangaraya Medical College and Government General Hospital, Kakinada. Specifically, the study aimed to assess the incidence of multidrug-resistant TB (MDR-TB), pre-extensively drug-resistant TB (Pre-XDR-TB), and totally drug-resistant TB (TDR), and to compare resistance patterns between newly diagnosed and recurrent TB cases. Additionally, the study sought to identify associated risk factors such as HIV infection and diabetes mellitus, and to evaluate the effectiveness of existing treatment regimens. The findings are intended to support the development of more targeted therapeutic strategies and inform public health policies aimed at controlling the spread of drug-resistant TB.

## **MATERIALS AND METHODS**

### **Study Design and Duration**

This was a retrospective, hospital-based observational study conducted over a 12-month period from January 2024 to December 2024 at the Department of Pulmonary Medicine, Government General Hospital (GGH) and Rangaraya Medical College, Kakinada, Andhra Pradesh, India.

### **Study Population and Sample Size**

The study included 923 patients who were diagnosed with drug-resistant tuberculosis (DR-TB) and were registered under the DR/MDR/XDR-TB treatment regimen at the TB unit of GGH Kakinada during the study period.

### **Inclusion Criteria**

All TB patients diagnosed according to National TB Elimination Programme (NTEP) guidelines, attending the Outpatient Department (OPD) and Inpatient Wards of the Department of Pulmonary Medicine and DMC, GGH Kakinada.

Patients aged **13 years and above**.

### **Exclusion Criteria**

Children aged less than 13 years.

### **Data Collection**

Data were collected retrospectively from hospital medical records and TB registers. The information included:

- Sociodemographic details
- Clinical presentation and radiological findings
- Past TB treatment history
- Comorbid conditions (e.g., HIV, diabetes mellitus)

Laboratory investigations, including drug resistance profiles

Substance use history (tobacco, alcohol, or drug abuse)

#### Diagnostic Procedure

Patients presenting with symptoms of pulmonary tuberculosis underwent chest X-ray and CBNAAT (Cartridge-Based Nucleic Acid Amplification Test). If Mycobacterium tuberculosis (MTB) was detected via CBNAAT, the samples were sent for Line Probe Assay (LPA) to the reference laboratory in Visakhapatnam to determine specific drug resistance patterns. Patients whose sputum samples showed resistance to one or more anti-tubercular drugs were included in the study.

#### Ethical Considerations

This study was approved by the Institutional Ethics Committee of Rangaraya Medical College and Government General Hospital, Kakinada, Andhra Pradesh (Ref No: IEC/RMC/2025/1376, dated 18/03/2025). Informed consent was obtained from all participants before enrollment into the study.

## RESULTS

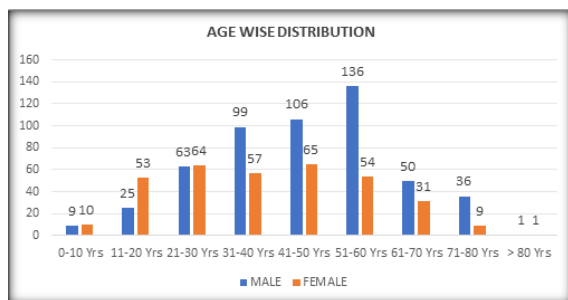


Figure 1: Prevalence of Tuberculosis - Age and Gender

Table 1: Prevalence of Tuberculosis - Age and Gender

	AGE	0-10 yrs	Nov-20 yrs	21-30 yrs	31-40 yrs	41-50 yrs	51-60 yrs	61-70 yrs	71- 80 yrs	>80 yrs
			yrs	yrs	yrs	yrs	yrs	yrs	yrs	
GENDER	MALE	9 (0.97%)	25 (2.70%)	63 (6.82%)	99 (10.72%)	106 (11.48%)	136 (14.73%)	50 (5.41%)	36 (3.90%)	1 (0.10%)
	FEMALE	10 (1.08%)	53 (5.7%)	64 (6.93%)	57 (6.17%)	65 (7.04%)	54 (5.85%)	31 (3.35%)	9 (0.97%)	1 (0.10%)
TOTAL	923	19 (2.05%)	78 (8.45%)	127 (13.75%)	156 (16.90%)	225 (24.37%)	190 (20.58%)	81 (8.77%)	45 (4.87%)	2 (0.21%)

Table 2: Gender-wise Distribution of Drug-Sensitive and Drug-Resistant Tuberculosis Cases

GENDER	TOTAL NUMBER OF CASES: 923 (100 %)	
	SENSITIVE	DRUG RESISTANT
MALE	545 (59.04 %)	34 (3.68 %)
FEMALE	332 (35.96 %)	12 (1.30 %)
TOTAL	877 (95.01%)	46 (4.98 %)

The drug resistance was reported in 34 men where it was only about 12 cases were noted in women .it was reflecting that there was male preponderance in men where women were not, this was may be due to

## GENDER WISE DISTRIBUTION OF DRUG RESISTANCE IN TUBERCULOSIS

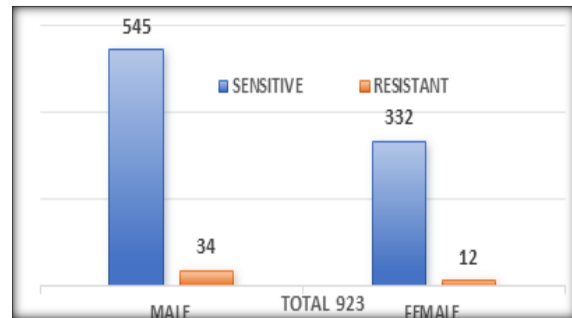


Figure 2

The drug resistance noted for individual drugs were about 60 % for inh alone and rifampicin was about 8% and multi drug resistance was about14% and fluoroquinolones were about 2%. women have reported about 26% of drug resistance where men were about 71.27% of the drug resistance in ATT.

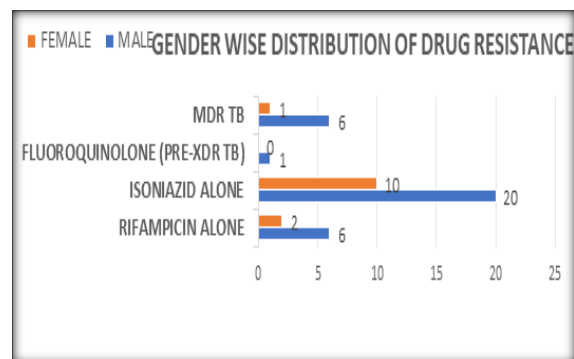


Figure 3: Gender Wise Distribution of Drug Resistance

Table 3: Individual drug resistance detected on gender basis

ANTI TUBERCULAR DRUG REISTANCE	RIFAMPICIN ALONE	ISONIAZID	FLUOROQUINOLONE	MDR TB
		ALONE	(PRE-XDR TB)	
GENDER	DETECTED	DETECTED	DETECTED	DETECTED

MALE	6 (13.04%)	20 (43.47%)	1 (2%)	6 (13.04 %)
FEMALE	2 (4%)	10 (20 %)	0	1 (2 %)
TOTAL (46)	8 (16%)	30 (60%)	1 (2 %)	7 (14 %)

**Table 4: Distribution of drug resistance in HIV reactive and non reactive individuals in male and female gender**

GENDER	HIV REACTIVE		HIV NON-REACTIVE	
	SENSITIVE	RESISTANT	SENSITIVE	RESISTANT
MALE	70 (7.75%)	2 (0.22%)	471 (52.15%)	22 (2.32%)
FEMALE	45 (4.98%)	0	285 (31.56%)	9 (0.99%)
TOTAL	115 (12.73%)	2 (0.22%)	756 (83.72%)	31 (3.32%)

Note: In 13 cases HIV status data was not available

**Table 5: Distribution of individual drug resistance in HIV reactive and non-reactive individuals in male and female gender**

GENDER	HIV REACTIVE					HIV NON-REACTIVE				
	RIF RESISTANCE ALONE	INH RESISTANCE ALONE	FLUROQUINALONE RESISTANCE ALONE	RE X DR TB	M DR TB	RIF RESISTANCE ALONE	INH RESISTANCE ALONE	FLUROQUINALONE RESISTANCE ALONE	P RE XDR TB	M DR TB
MALE	0	2 (4.34%)	0		0	0	15 (32.6%)	0	1 (2.17%)	6 (13%)
FEMALE	0	0	0		0	0	8 (17.3%)	0	0	1 (2.17%)
TOTAL (46)	0	2(4.34%)	0		0	0	23(50%)	0	1 (2.17%)	7 (15.21%)

Note: In 13 cases of HIV Status, Data was not available

Drug resistant tb with HIV showing its resistant pattern was 4.34% (2 cases in male + 0 cases in female) with INH resistance and no rifampicin resistance was noted

Drug resistant tb without HIV showing its resistant pattern was 50% (23cases 15 male +8female) with INH resistance and no rifampicin resistance was noted

Drug resistant TB with HIV with PRE XDR pattern with 2.17 % (1 MALE+0 FEMALE).

**Table 6: Gender wise distribution of TB positive cases in diabetic and non-diabetic individuals**

	DIABETIC	NON-DIABETIC	UNKNOWN STATUS
MALE	76 (8.23%)	487 (52.76%)	17 (1.84%)
FEMALE	39 (4.22%)	300 (32.50%)	5 (0.54%)
TOTAL	114 (12.35%)	787 (85.26%)	22 (2.38%)

**Table 7: Distribution of drug resistance in diabetic cases and non-diabetic cases with male and female gender wise**

	DIABETIC	NON-DIABETIC	NOT KNOWN	TOTAL
MALE	9 (19.56%)	13 (28.26%)	8 (17.39%)	30 (65.21%)
FEMALE	3 (6.52%)	12 (26.08%)	1 (2.17%)	16 (34.78%)
TOTAL	12 (26.08%)	25 (54.34%)	9(19.56%)	46 (100%)

The people whom were suffering with drug resistant tb with diabetes mellitus in this study was reported as 9 cases (19.56%) male and female were about 3 cases (6.52%) in this study. males were more associated with diabetes than females and this was

due the high prevalence of MDR-TB in men the non-diabetics were about 25 cases (54.34%) there were some limitations in this study due to under reporting of cases, 9 cases (MDR-TB) which comprises about 19.56%.

**Table 8: Distribution of individual drug resistance in diabetic and non-diabetic individuals in male and female gender**

GENDER	DIABETIC						NON-DIABETIC			
	INDIVIDUAL DRUG RESISTANCE	RIF RESISTANCE ALONE	INH RESISTANCE ALONE	FLURO QUINALONE RESISTANCE ALONE	REXDR TB	M DR TB	RIF RESISTANCE ALONE	INH RESISTANCE ALONE	FLURO QUINALONE RESISTANCE ALONE	REXDR TB
MALE	0	6 (21.42%)	0	0	1 (3.57%)	0	9 (32.14%)	0	1 (3.57%)	6 (21.42%)
FEMALE	0	3 (10.71%)	0	0	0	0	5 (17.85%)	0	0	1 (3.57%)
TOTAL (46)	0	9 (32.14%)	0	0	1 (3.57%)	0	14 (50%)	0	1 (3.57%)	7 (25%)

**Table 9: Distribution of drug resistance in new and recurrent cases of tuberculosis**

	NEW CASE	RECURRENT CASES	TOTAL
MALE	18 (64.28%)	2 (7.14%)	20 (71.42%)
FEMALE	6 (21.42%)	2 (7.14%)	8 (28.57%)
TOTAL	24 (85.71%)	4 (14.28%)	28 (100%)

Note: 17 patients were Enrolled in NTEP under MDR regimen without no proper documentation

The drug resistant tb cases were seems to be more closely related to the new cases rather than recurrent cases. In this study the results obtained was tabulated as above. Drug resistance was noted in the 18 male tb patients which were newly diagnosed tb cases and only 2 male patients found as drug resistant tb cases in the recurrence and 6 female drug-resistant tb

patients were identified in newly diagnosed tb conditions where only 2 female patients found having drug resistant tb in recurrent cases both male and female gender were showing the drug resistance in newly diagnosed tb cases rather than the recurrent cases.

**Table 10: Distribution of drug resistance in hiv affected and non-infected individuals in new and recurrent cases on gender basis**

	NEW CASE		RECURRENT CASES		TOTAL
	HIV INFECTED	HIV NON-INFECTED	HIV INFECTED	HIV NON-INFECTED	
MALE	3 (7.89 %)	19 (50%)	0	6 (15.78 %)	28 (73.68%)
FEMALE	0	7 (18.42%)	0	3 (7.89 %)	10 (26.31 %)
TOTAL	3 (7.89 %)	26 (68.42%)	0	9 (23.68%)	38 (100%)

Note :- Among 46 DR cases - 8 cases 4 were reported as HIV status unknown and 4 were not differentiated to be new or recurrent cases

The drug resistance reported in new tb cases with hiv were 3 in number (NEW) and and non hiv infected tuberculosis cases with drug resistance were 16 (new) among males, where recurrent tuberculosis cases with drug resistance associated with hiv were 0 case and non hiv with drug-resistance was reported as 6 cases among males  
The total number of male cases in DR tb were 28 (new tb hiv3+recurrent tb hiv0+new dr tb non hiv19 +dr tb with hiv 6=28). The total number female DR tb were 10 cases  
Newly diagnosed drtb with hiv female were 0 and recurrent drtb with hiv also no cases but new drtb without hiv were female were 7 cases and dr tb recurrent without hiv were 3 cases.

## DISCUSSION

Tuberculosis (TB) continues to be a major public health concern in India, with its impact extending beyond the lungs to other organs including the spine, brain, and kidneys. The emergence and increasing prevalence of drug-resistant TB (DR-TB) have significantly complicated its management. According to the National TB Elimination Programme (NTEP), DR-TB is categorized into five types: isoniazid-resistant TB, rifampicin-resistant TB (RR-TB), multidrug-resistant TB (MDR-TB), pre-extensively drug-resistant TB (Pre-XDR-TB), and extensively drug-resistant TB (XDR-TB). Recent national and international treatment guidelines have shifted toward shorter, all-oral regimens for managing MDR/RR-TB, improving treatment compliance and patient outcomes. Our study supports this initiative by providing regional



data from Andhra Pradesh, where the burden of TB remains substantial. Nationally, the estimated prevalence of DR-TB is around 0.1% of all TB cases, with Andhra Pradesh reporting 3% in newly diagnosed cases and 12–17% in recurrent cases. Our findings of 2.6% resistance in new TB cases and 16.6% in recurrent cases align with this trend and are comparable with other regional studies from India, such as those conducted in Gujarat, Karnataka, and Hyderabad.<sup>[10-14]</sup>

The link between HIV infection and TB, particularly DR-TB, is a critical area of concern. National data indicate that 5.5% to 20% of DR-TB cases are found in HIV-positive individuals. In our study, 10% of DR-TB cases were associated with HIV, with a higher incidence among male patients. Similar trends have been observed in studies from tertiary care centers across India, reflecting the interplay between immune suppression and TB progression.<sup>[11,13]</sup>

Diabetes mellitus is another comorbidity that significantly contributes to the development and poor prognosis of DR-TB. It creates an immunocompromised state that increases susceptibility to TB infection and reduces treatment efficacy. National reports suggest that 14–40% of TB patients are diabetic. Our findings of 33% DR-TB cases with concurrent diabetes—24.75% among males and 8.25% among females—are consistent with those reported in similar retrospective studies from central and southern India.<sup>[10,12,14]</sup> Lifestyle factors such as obesity, older age, poor glycemic control, smoking, alcohol consumption, and low socioeconomic status were common among the affected male population.

Interestingly, our study showed that 2.6% of drug-resistant cases were newly diagnosed, while 16.6% were recurrent. This suggests not only the emergence of resistance due to inadequate or incomplete prior treatment but also possible primary transmission of resistant strains within the community. Several Indian studies have reported similar patterns, attributing them to widespread use of first-line drugs without proper sensitivity testing and poor adherence to DOTS protocols.<sup>[10,12,13]</sup>

The higher burden of DR-TB in our study population may be partly due to the region's demographic and occupational structure. The area includes large rural and tribal populations engaged in agriculture and cattle rearing, who often face challenges such as low literacy rates, social stigma, lack of awareness, poor access to health services, and difficult transportation to healthcare facilities. These barriers delay diagnosis and treatment, further propagating disease transmission and drug resistance.

## CONCLUSION

This study from Rangaraya Medical College and Government General Hospital, Kakinada, provides critical insights into the burden and patterns of drug-resistant tuberculosis (DR-TB) in the region. By identifying key associations with HIV, diabetes, and treatment recurrence, it serves as a valuable resource for addressing DR-TB at the grassroots level. The findings highlight gender-based differences and sociodemographic factors influencing resistance. This dataset can act as a high-resolution blueprint for local TB control strategies, aiding early identification, targeted interventions, and better preparedness. Integrating these insights into the National TB Elimination Programme will enhance efforts to combat TB and reduce drug resistance across diverse population subgroups.

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