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Profile Of Drug-Resistant Pulmonary Tuberculosis – Mdr And Xdr – In Patients Attending Dots Plus Site At Tertiary Care Hospital, Visakhapatnam.

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Abstract

Introduction: Tuberculosis (TB) remains a major global health issue. The rise of drug-resistant TB (DR- TB), including MDR- TB and XDR- TB, hampers control efforts despite effective treatments. These forms require longer, more toxic treatment, are associated with worse outcomes, and increase mortality. Advances in molecular diagnostics and India' s NTEP have improved DR- TB management, but factors such as prior treatment, interruptions, diabetes, HIV, malnutrition, and substance use still increase resistance. Understanding patients' clinical profiles, history, and resistance patterns is key to better outcomes and TB control. This study evaluates sociodemographics, clinical data, treatment history, and resistance patterns among DR- TB patients at the DOTS- Plus site at Andhra Medical College, Visakhapatnam. ***Objectives:*** To examine the clinical profile of drug- resistant TB for better management, analyse sociodemographic factors and treatment history among resistant cases, and identify drug resistance patterns in MDR and XDR TB patients. ***Methodology:*** This 18- month prospective observational study at the DOTS- Plus site, GHCCD, Andhra Medical College, Visakhapatnam, India, enrolled 476 patients with drug- resistant pulmonary TB via convenience sampling. Included were patients with microbiologically confirmed MDR/XDR TB by CBNAAT, LPA, or DST who consented; excluded were those with extrapulmonary TB or unwilling to participate. Collected data included sociodemographics, clinical details, habits, previous treatments, comorbidities, haematological and metabolic parameters, drug susceptibility, sputum conversion, and mortality. Ethical approval was granted by the Institutional Ethics Committee. Data were analysed using SPSS v 28. 0. Continuous data are presented as mean ± SD; categorical data as frequencies and percentages. A chi- square test was used, with p< 0. 05 indicating significance. ***Results:*** Among 476 patients with drug- resistant pulmonary tuberculosis, 338 (71. 0%) had MDR- TB, 14 (2. 2.9%) had XDR- TB, and 124 (26. 1%) had isoniazid- monoresistant TB. The mean age was 41. 0 ± 14. 8 years, and 75. 4% were male. Common risk factors included smoking (53. 8%), alcohol use (37. 4%), and diabetes mellitus (41. 0%). A history of anti- tubercular treatment was reported in 66. 6%, with recurrence as the main reason (35. 5%). Rifampicin resistance was most prevalent (51. 4%). The shorter MDR regimen was most used (47. 7%), with bedaquiline-containing regimens mainly for XDR- TB. Outcomes showed 42. 42.6% cured, 3. 6% completed treatment, 4. 6% died, and 45. 8% in treatment or awaiting outcomes. ***Conclusion:*** Drug- resistant TB mostly affects middle- aged men, linked to smoking, alcohol, diabetes, and prior treatment. Rifampicin resistance was common, with shorter MDR regimens as primary treatment. Findings emphasize early diagnosis, universal drug susceptibility testing, managing comorbidities, adherence support, and strengthening NTEP to reduce drug resistance.

Keywords: Drug-Resistant Pulmonary Tuberculosis, DOTS Plus Site, Tertiary Care Hospital.

INTRODUCTION

Tuberculosis (TB) remains one of the leading causes of morbidity and mortality worldwide, attributable to a single infectious agent. Despite the availability of effective chemotherapy, the emergence and transmission of drug-resistant tuberculosis (DR-TB) have become major challenges to global TB control (1). Drug resistance primarily results from inadequate or incomplete treatment, poor adherence, inappropriate drug regimens, and person-to-person transmission of resistant Mycobacterium tuberculosis strains (2,3). Multidrug-resistant tuberculosis (MDR-TB), defined as resistance to at least isoniazid and rifampicin, and extensively drug-resistant tuberculosis (XDR-TB), characterised by additional resistance to fluoroquinolones and at least one Group A drug (according to the current WHO definition), are associated with prolonged

treatment, increased toxicity, higher treatment costs, poorer treatment outcomes, and increased mortality (1,4). Early diagnosis using rapid molecular diagnostic techniques such as the Cartridge-Based Nucleic Acid Amplification Test (CBNAAT), Line Probe Assay (LPA), and phenotypic Drug Susceptibility Testing (DST) has significantly improved the timely detection and management of drug-resistant tuberculosis (1,5).

According to the World Health Organisation (WHO), an estimated 390,000 people developed multidrug- or rifampicin-resistant tuberculosis (MDR/RR-TB) globally in 2024, with approximately 150,000 deaths attributed to drug-resistant TB. Although the global burden has gradually declined in recent years, drug-resistant TB remains a substantial public health challenge, particularly in high-burden countries (1). India accounts for nearly one-fourth of the global tuberculosis burden and contributes a substantial proportion of MDR/RR-TB cases worldwide (1,6). The National Tuberculosis Elimination Programme (NTEP) has strengthened the programme's management of drug-resistant tuberculosis through universal drug susceptibility testing, expanded molecular diagnostics, and the implementation of shorter, all-oral treatment regimens (6). However, delayed diagnosis, prior anti-tubercular treatment, treatment interruption, diabetes mellitus, HIV infection, malnutrition, tobacco smoking, alcohol use, and other comorbidities continue to influence the occurrence and outcomes of drug-resistant tuberculosis (3,5,7). Several studies have demonstrated that prior anti-tubercular treatment, irregular drug intake, cavitary pulmonary disease, poor nutritional status, diabetes mellitus, and socioeconomic disadvantage are important predictors of MDR-TB, emphasising the need for comprehensive patient profiling to facilitate early diagnosis and improve treatment outcomes (7–9).

Understanding the clinical characteristics, sociodemographic profile, treatment history, comorbidities, and drug resistance patterns among patients with MDR and XDR pulmonary tuberculosis is essential for optimising patient management, reducing disease transmission, and strengthening tuberculosis control strategies. Therefore, this study was undertaken to evaluate the clinical profile, sociodemographic characteristics, treatment history, and drug resistance patterns among patients with drug-resistant pulmonary tuberculosis attending the DOTS-Plus site at the Government Hospital for Chest and Communicable Diseases, Andhra Medical College, Visakhapatnam.

METHODOLOGY

Study Design: Prospective observational study

Duration of Study: 18 months

Study Location: Government Hospital for Chest and Communicable Diseases, Andhra Medical College, Visakhapatnam, Andhra Pradesh, India.

Sampling Method: Convenient Sampling

Sample Size: 476

Target Population: Patients presenting with drug-resistant tuberculosis to the DOT PLUS site at Government Hospital for Chest and Communicable Diseases.

Inclusion Criteria:

1. MDR/XDR PTB patients in GHCCD, proven by Sputum for CBNAAT/ LPA/DST.
2. Patients who have given consent to participate in the study.

Exclusion Criteria:

1. Extra-pulmonary TB.
2. Patients who have not given consent to participate in the study.

Study Procedure: The study is conducted at the DOTSPLUS site of GHCCD Visakhapatnam. Patients are enrolled in accordance with the inclusion and exclusion criteria outlined above. Drug resistance patterns in sputum samples are determined. Patient profiles are compared across age, gender, habits, previous treatment history, associated comorbidities, blood picture, metabolic profiles, and drug susceptibility patterns. Sputum conversion during follow-up is recorded. All-cause mortality during treatment is also recorded.

Ethical Considerations: Ethical clearance was obtained from the Institutional Ethics Committee, Andhra Medical College, Visakhapatnam, Andhra Pradesh, India.

Statistical Analysis: Data were analysed using SPSS version 28.0. Categorical variables were summarised as frequencies and percentages, and continuous variables as mean ± standard deviation. Chi-square tests were used to compare variables. For all statistical analyses, $p < 0.05$ was considered statistically significant.

RESULTS

DISTRIBUTION OF VARIABLES (N=476)					
VARIABLE	**CATEGORY**	**MDR**	**XDR**	**MONO RESISTANCE**	**TOTAL FREQUENCY (%)**
Age (Years)	**≤20**	25	1	10	36 (7.60%)
	21 – 40	155	9	43	207 (43.5%)
	41 – 60	136	2	62	200 (42.0%)
	≥61	22	2	9	33 (6.90%)
	MEAN ± SD: 41 ± 14.8 years				
Gender	**Male**	249	10	100	359 (75.0%)
	Female	89	4	24	117 (25.0%)
Smokers	**Male**	174	5	56	235 (49.36%)
	Female	19	0	2	21 (4.41%)
Alcoholics	**Male**	123	6	40	169 (35.50%)
	Female	8	0	1	9 (1.89%)
Smokers + Alcoholics	**Male**	116	5	40	161 (33.82%)
	Female	8	0	1	9 (1.89%)
Diabetes	**Male**	102	3	44	149 (31.30%)
	Female	38	1	7	46 (9.66%)
Hypertension	**Male**	83	2	32	117 (24.57%)
	Female	14	0	3	17 (3.57%)
Diabetes + Hypertension	**Male**	49	1	17	67 (14.07%)
	Female	13	0	2	15 (3.15%)
HIV AIDS	**Male**	27	1	5	33 (6.93%)
	Female	9	0	0	9 (1.89%)

The study included 476 patients with drug-resistant pulmonary tuberculosis, comprising 338 (71.0%) with multidrug-resistant TB (MDR-TB), 14 (2.9%) with extensively drug-resistant TB (XDR-TB), and 124 (26.1%) with monoresistant TB. The mean age was 41.0 ± 14.8 years, with most in the 21–40 (207, 43.5%) and 41–60 (200, 42.0%) age groups, and 7.6% aged ≤20 and 6.9% ≥61. Most MDR-TB cases were in the 21–40 age group (155). XDR-TB was rare. Men accounted for 75.4% (24.6), with a male-to-female ratio of about 3:1. Among males, 249 had MDR-TB, 10 XDR-TB, and 100 monoresistant; among females, 89, 4, and 24, respectively. In this cohort, smoking was reported in 256 patients (53.8%), including 235 males (49.4%) and 21 females (4.4%). Alcohol use was documented in 178 patients (37.4%), mostly males (169, 35.5%) compared with females (9, 1.9%). Concurrent smoking and alcohol use were observed in 170 patients (35.7%), mainly males (161, 33.8%). The most common comorbidity was diabetes mellitus, affecting 195 patients (41.0%), including 149 males (31.3%) and 46 females (9.7%). Hypertension was present in 134 patients (28.2%), and 82 (17.2%) had both conditions. HIV was identified in 42 patients (8.8%), mostly males (33, 6.9%) vs. females (9, 1.9%). Drug-resistant pulmonary tuberculosis mainly affected middle-aged men and was linked to modifiable risk factors such as smoking, alcohol, and diabetes.

PREVIOUSLY USED TREATMENT				
	MDR	**XDR**	**MONO RESISTANCE**	**TOTAL FREQUENCY (%)**
Category 1	137	1	39	177 (37.18%)
Category 2	79	6	22	107 (22.47%)
Category 4	17	6	8	31 (6.51%)
Shorter MDR	2	0	0	2 (0.42%)
Newly Diagnosed	103	1	55	159 (33.40%)
PREVIOUS TREATMENT FOLLOW-UP				
Recurrence	132	7	30	169 (35.50%)
Lost to Follow-up	84	4	32	120 (25.21%)
Treatment Failure	19	2	7	28 (5.88%)

Among 476 patients with drug-resistant pulmonary tuberculosis, 177 (37.2%) had previous Category I treatment, 107 (22.5%) had Category II, 31 (6.5%) had Category IV, and 2 (0.4%) had the shorter MDR regimen. 159 (33.4%) were newly diagnosed. Among MDR-TB patients, 137 (40.5%) had previous Category I, 103 (30.5%) were new, 79 (23.4%) had

Category II, 17 (5.0%) had Category IV, and 2 (0.6%) had the shorter MDR regimen. Among 14 XDR-TB patients, 6 (42.9%) had previously had Category II, 6 (42.9%) had Category IV, and 1 each had Category I and were new. None received the shorter MDR regimen. Among monoresistant cases, 55 (44.4%) were new, 39 (31.5%) were Category I, 22 (17.7%) were Category II, and 8 (6.5%) were Category IV.

Among patients with a history of anti-tubercular treatment, recurrence was the most common reason for retreatment, occurring in 169 (35.5%). Lost to follow-up was 120 (25.2%), and treatment failures were 28 (5.9%). In MDR-TB patients, recurrence was 132 (39.1%), followed by loss to follow-up in 84 (24.9%) and treatment failure in 19 (5.6%). Among XDR-TB, 7 (50.0%) had recurrence, 4 (28.6%) were lost to follow-up, and 2 (14.3%) failed treatment. In monoresistant TB, 32 (25.8%) were lost to follow-up, 30 (24.2%) recurred, and 7 (5.6%) failed treatment.

DRUG RESISTANCE PATTERNS	
REGIMEN	FREQUENCY (%)
Rifampicin	245 (51.40%)
Isoniazid	124 (26.05%)
Rifampicin, Isoniazid	16 (3.36%)
Rifampicin, Fluoroquinolone	57 (11.90%)
Isoniazid, Fluoroquinolone	13 (2.73%)
Rifampicin, Isoniazid, Fluoroquinolone	6 (1.26%)
Rifampicin, Fluoroquinolone, Second Line Injectables	13 (2.73%)
Others	2 (0.42%)

Rifampicin resistance was the most common, seen in 245 (51.5%) patients, followed by isoniazid resistance in 124 (26.1%). Combined resistance to rifampicin and fluoroquinolones occurred in 57 (12.0%) patients, the most common pattern beyond single-drug resistance. Resistance to both rifampicin and isoniazid was seen in 16 (3.4%), while resistance to isoniazid and a fluoroquinolone was seen in 13 (2.7%). Resistance to rifampicin, fluoroquinolones, and injectables was found in 13 (2.7%), indicating advanced TB. Triple resistance to rifampicin, isoniazid, and fluoroquinolones was seen in 6 (1.3%) patients, with 2 (0.4%) other patterns. Overall, rifampicin resistance, alone or combined, was the main pattern, emphasising its role in diagnosing and managing drug-resistant TB.

TREATMENT REGIMENS							
	Shorter MDR	**Conventional MDR**	**INH Mono**	**Mixed Pattern**	**BEDAQUILLINE**	**XDR Regimen**	**TOTAL FREQUENCY (%)**
MDR	227	46	0	9	56	0	338 (71.00%)
XDR	0	0	0	0	11	3	14 (2.94%)
MONO RESISTANCE	0	0	124	0	0	0	124 (26.05%)
TREATMENT OUTCOMES							
Not evaluated	101	12	47	7	49	2	218 (45.79%)
Loss to Follow-up	0	2	0	0	2	0	4 (0.84%)
Treatment completed	10	0	7	0	0	0	17 (3.57%)
Dead	9	7	3	1	2	0	22 (4.62%)
Cured	98	22	68	1	13	1	203 (42.64%)
Regimen Changed	9	1	1	0	1	0	12 (2.52%)

Of the 338 patients with MDR-TB, the most common regimen was the shorter MDR regimen (227, 67.2%). Bedaquiline-containing regimens were used in 56 (16.6%) patients, and 46 (13.6%) received the conventional MDR regimen. A mixed regimen was used in 9 (2.7%) patients. Among the 14 patients with XDR-TB, 11 (78.6%) received Bedaquiline-containing regimens, and 3 (21.4%) received the standard XDR regimen. All 124 patients with isoniazid-monoresistant TB received the recommended INH monoresistant regimen. Overall, the most common treatment was the shorter MDR regimen (227, 47.7%), followed by INH monoresistant (124, 26.1%), Bedaquiline-containing (67, 14.1%), conventional MDR (46, 9.7%), mixed (9, 1.9%), and XDR (3, 0.6%).

At the time of analysis, 218 (45.8%) patients had not yet been evaluated, mostly still in treatment or awaiting outcome assessment. Of those with available outcomes, 203 (42.6%) were cured, 17 (3.6%) completed treatment, 22 (4.6%) died,

12 (2.5%) changed regimen, and 4 (0.8%) were lost to follow-up. Among MDR-TB patients, 98 (29.0%) achieved cure, 10 (3.0%) finished treatment, and 9 (2.7%) died. A total of 227 (67.2%) MDR-TB patients received shorter regimens, which accounted for most successes. Among XDR-TB patients, 11 (78.6%) received Bedaquiline, with 1 (7.1%) cured, 2 (14.3%) still unevaluated, and no treatment completions or follow-up losses. Among isoniazid monoresistant patients, 68 (54.8%) were cured, 7 (5.6%) finished, 3 (2.4%) died, and 47 (37.9%) had pending outcomes. The shorter MDR regimen was mainly used for MDR-TB, with Bedaquiline key for XDR-TB. Cure was the most common positive outcome, but nearly half the population had not yet reached final assessment.

DISCUSSION

The present study evaluated the sociodemographic profile, prior treatment history, drug resistance patterns, treatment regimens, and treatment outcomes among 476 patients with drug-resistant pulmonary tuberculosis attending a tertiary care DOTS-Plus centre in Visakhapatnam. Multidrug-resistant tuberculosis (MDR-TB) accounted for the majority of cases (71.0%), followed by isoniazid monoresistant tuberculosis (26.1%) and extensively drug-resistant tuberculosis (XDR-TB) (2.9%).

The mean age of the study population was 41.0 ± 14.8 years, with nearly 86% of patients in the economically productive age group of 21–60 years. Similar findings have been reported in the WHO Global Tuberculosis Report 2025 and in Indian studies by Prasad et al. and Singh et al., which demonstrated that drug-resistant tuberculosis predominantly affects young and middle-aged adults, resulting in significant socioeconomic consequences (1a,10, 7a). Early exposure, occupational mobility, and greater community transmission may explain this age distribution. A marked male predominance (75.4%) was observed in the present study, consistent with national and international reports (1a,11). Male predominance has been attributed to greater exposure to environmental and occupational risk factors, higher rates of smoking and alcohol consumption, and differences in healthcare-seeking behaviour (12). Smoking (53.8%) and alcohol use (37.4%) were highly prevalent among the study participants. These behavioural risk factors have consistently been associated with delayed sputum conversion, treatment failure, recurrence, and increased mortality among patients with drug-resistant tuberculosis (13,14). Similarly, diabetes mellitus was the most common comorbidity (41.0%), highlighting the growing dual burden of tuberculosis and diabetes in India. Previous studies have shown that diabetes impairs host immunity, increases the risk of active tuberculosis, and adversely affects treatment outcomes (15,16). HIV infection was identified in 8.8% of patients, comparable with reports from other Indian studies evaluating drug-resistant tuberculosis (17).

Among treatment histories, Category I was the most common prior regimen (37.2%), while one-third of patients were newly diagnosed. Among previously treated patients, recurrence (35.5%) and loss to follow-up (25.2%) were common. These findings support earlier observations that inadequate treatment adherence, interrupted therapy, and prior anti-tubercular treatment are major contributors to drug resistance (5a,18). The substantial proportion of newly diagnosed patients also suggests ongoing primary transmission of resistant Mycobacterium tuberculosis strains within the community. Rifampicin resistance alone was the predominant drug resistance pattern (51.4%), followed by isoniazid monoresistance (26.1%) and combined rifampicin-fluoroquinolone resistance (11.9%). These findings are consistent with current WHO recommendations, which identify rifampicin resistance as a reliable surrogate marker for multidrug-resistant tuberculosis and justify the widespread use of rapid molecular diagnostic techniques such as CBNAAT and Line Probe Assay for early detection (1,4a). The shorter MDR regimen was the most frequently prescribed treatment for MDR-TB patients, whereas most XDR-TB patients received Bedaquiline-containing regimens, reflecting current National Tuberculosis Elimination Programme (NTEP) recommendations favouring all-oral treatment regimens (19). Among patients with evaluable outcomes, cure was the most frequent favourable outcome. However, a large proportion of patients had not yet completed treatment at the time of analysis, which explains the high proportion of "not evaluated" outcomes. Continued follow-up is therefore essential for accurately assessing long-term treatment success.

CONCLUSION

The present study demonstrates that drug-resistant pulmonary tuberculosis predominantly affects middle-aged men and is commonly associated with smoking, alcohol use, diabetes mellitus, and prior anti-tubercular treatment. Rifampicin resistance was the most common resistance pattern, and the shorter MDR regimen was the primary treatment strategy. These findings emphasise the need for early diagnosis, universal drug susceptibility testing, effective management of comorbidities, adherence support, and strengthened NTEP strategies to reduce the burden of drug-resistant tuberculosis.

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