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STUDY OF DRUG RESISTANCE PROFILE IN RETREATMENT CASES OF PULMONARY TUBERCULOSIS IN A TERTIARY CARE CENTRE

Dr. Kanabur Prashanth[1*], Dr. K. Thirthashree[2], Dr. Pynuru Lalitha[3]

[1*]Assistant Professor, Department of Respiratory Medicine, BGS Medical College and Hospital (BGSMCH), Bengaluru, Karnataka, India.
[2]Assistant Professor, Department of Respiratory Medicine, Rajarajeswari Medical College and Hospital, Bengaluru, Karnataka, India.
[3]Microbiologist, Principal of Regional Health and Family welfare training centre, Kurnool, Andhra Pradesh, India.

***Corresponding Author:**Dr. Kanabur Prashanth,
*Assistant Professor, Department of Respiratory Medicine, BGS Medical College and Hospital (BGSMCH), Bengaluru, Karnataka, India.

ABSTRACT

Background

Tuberculosis (TB), caused by *Mycobacterium tuberculosis*, remains one of the world's deadliest communicable diseases, with India accounting for 2.1 million cases annually and ranking second in the global burden of multidrug-resistant (MDR) TB. Approximately 50,000 MDR-TB cases are recorded each year among retreatment pulmonary TB cases in India. This study aims to determine the proportion and pattern of drug resistance in retreatment cases of pulmonary tuberculosis.

Methodology

A prospective observational study was conducted over a period of 18 months at Rajarajeshwari Medical College and Hospital, Bengaluru, including both outpatient and inpatient cases, as well as patients suspected of drug resistance TB at the Revised national tuberculosis control programme (RNTCP) centre/ (National tuberculosis elimination programme (NTEP). All participants regardless of their sputum status ,provided two sputum samples which were analysed by cartridge based nucleic acid amplification test (CBNAAT) and line probe assays (LPA) for first- and second-line drugs and/or drug susceptibility testing at a state-accredited laboratory.

Results

Of 100 patients enrolled, 14 were found to be drug-resistance, twelve with resistance to both rifampicin and isoniazid and two with isoniazid mono-resistance. All other patients were sensitive to both first-line and second-line anti-tubercular drugs. Co-morbidities such as diabetes, HIV, malnutrition and social habits including smoking, alcohol consumption and tobacco use were associated with increased incidence of drug resistance.

Conclusion

Early diagnosis using molecular methods and prompt initiation of appropriate antitubercular therapy are crucial for reducing the morbidity and mortality associated with drug-resistant TB.

Keywords: Drug Resistance, Tuberculosis, CBNAAT, Line Probe Assay, Comorbidities.

INTRODUCTION

Tuberculosis has afflicted humanity for thousands of years. John Bunyan (1628–1688), the English Christian writer and preacher, famously described tuberculosis as "The Captain among these men of death" during a period when the incidence rate reached as high as 100 per 1,000 population per year.[1] Tuberculosis (TB) is a contagious disease caused by *Mycobacterium tuberculosis* bacilli. Global distribution, morbidity and mortality are closely associated with socio-economic conditions and lifestyle factors.

The burden of tuberculosis is universal, with approximately one-third of the world's population infected and nearly three million deaths reported annually worldwide.[2] Despite significant advancements, global TB control strategies continues to face major challenges. There remains a critical need to ensure equitable access to high-quality care, regardless of age, gender, disease type, social context and patient's affordability. Co-infection with *M. tuberculosis* and HIV (TB/HIV), along with the emergence of multidrug-resistant (MDR) and extensively drug-resistant (XDR) TB further complicates control efforts.

India has been identified by the World Health Organization (WHO) as a high-burden TB country. Tuberculosis persists as a significant public health problem, predominantly affecting individuals of lower socio-economic status. The estimated prevalence of all forms of TB in India is 5.05 per thousand population, with the prevalence of smear-positive cases at 2.27 per thousand population. The average annual incidence of smear-positive cases is 84 per 1 lakh population. TB remains a leading cause of mortality in India, resulting in more than 3 lakh deaths annually.[3]

The literature strongly indicates that a history of prior tuberculosis treatment is the most powerful predictor for the development of multidrug-resistant TB.[4] In India, patients receives treatment under the Directly Observed Treatment, Short Course (DOTS) regimen under RNTCP/NTEP and private healthcare providers. Hence, effective TB management requires coordinated involvement of both sectors. Irregular, incomplete and inadequate treatment is the most common cause of acquiring drug-resistant TB. MDR-TB is characterized by resistance to the two most potent first-line anti-tubercular drugs, isoniazid (H) and rifampicin (R).[5]

Multidrug-resistant TB poses a significant burden on society, with substantial challenges in patient management. The use of highly effective regimens comprising drugs with proven antimycobacterial activity, which have not previously been administered is essential. However, this approach increases operational costs related to drug procurement, distribution, monitoring of adverse drug reactions and ensuring regular drug intake through direct supervision. Although the efficacy of antitubercular drugs is well established, implementation on a mass scale particularly under home-based treatment programs presents operational difficulties. Poor drug compliance contributes to a marked rise in drug-resistant TB cases. The primary aim of this study is to assess the drug resistance profile in retreatment cases of pulmonary tuberculosis. Specifically, the objectives are to determine the proportion of drug resistance among these retreatment cases and to elucidate the pattern of drug resistance. Our study aims to establish potential socio-economical factor, patient factor and programmatic factor associated with development of MDR in retreated pulmonary TB cases. By systematically analysing previously treated tuberculosis patients attending our hospital, this study seeks to provide valuable insights into the prevalence and types of drug resistance, thereby contributing for improved management strategies of pulmonary tuberculosis.

MATERIALS & METHODS

This prospective and observational study was conducted in the Department of Respiratory Medicine at Rajarajeswari Medical College and Hospital, Bengaluru, over an 18-month period from November 2017 to June 2019. The study included 100 adult patients, both outpatients and inpatients, who had a previous history of pulmonary tuberculosis and presented again with signs and symptoms suggestive of pulmonary tuberculosis. Patients were selected using a systematic random sampling method. The sample size was calculated based on an expected drug resistance prevalence derived from previous studies, with statistical power set at 80% and 5% level of significance, resulting in a final sample size of 100.

Inclusion criteria comprised all previously treated pulmonary tuberculosis cases, including those lost to follow-up (defaulters), relapse cases and treatment failures. Exclusion criteria were patients already on drug-resistant tuberculosis (DR-TB) treatment, extra-pulmonary TB cases, newly diagnosed drug-resistant TB and patients under 18 years of age.

All eligible patients provided informed written consent before enrolment into this study. Comprehensive data were collected on demographic characteristics, socio-economic status, clinical history, previous anti-tubercular therapy (including duration, type and regimen-government or private), family history of TB, contact history and social habits such as smoking, alcohol consumption and tobacco use. History of co-morbidities including diabetes, hypertension, HIV, hepatitis and renal disorders were documented. Each patient underwent a thorough clinical examination with recording of their vital signs, height, weight and body mass index (BMI). Both general and systemic examinations were performed and patients were followed up as outpatients or inpatients as and when required.

Investigations included a complete haemogram with peripheral smear, chest radiograph, sputum examination by fluorescent microscopy (auramine rhodamine staining), HIV and Hepatitis B serology, random blood sugar, urine analysis, liver and renal function tests, ECG and serum electrolytes. Patients were instructed to provide two sputum samples—one spot and one early morning or two spot samples collected at least one hour apart—for microscopic examination. Sputum smears were graded according to standardized criteria (negative, scanty, 1+, 2+, 3+) depending on the number of acid-fast bacilli observed under high power magnification.

Patients who were either smear-positive or had typical clinical features of tuberculosis, despite being smear-negative provided sputum samples for further analysis. These samples were transported to the state-accredited intermediate reference laboratory where they underwent CBNAAT followed by line probe assay (LPA) for first- and second-line antitubercular drugs and drug susceptibility testing (DST).

Statistical Analysis

The results were recorded and subjected to statistical analysis. Descriptive and inferential statistical analyses were performed using SPSS version 22.0 and R software version 3.2.2. Results for continuous variables are expressed as mean ± standard deviation (SD), while categorical variables are presented as frequencies and percentages. Statistical significance was assessed at the 5% level of significance. Chi-square or Fisher's Exact test was employed to evaluate the significance of study parameters on a categorical scale. Statistical significance was indicated as suggestive (+) for $0.05 < P < 0.10$, moderate (*) for $0.01 < P \leq 0.05$ and strong (**) for $P \leq 0.01$. Graphs and tables were generated using Microsoft Word and Excel.

RESULTS

Demographic and Clinical Characteristics

Figure 1 illustrates the gender distribution within the study population (N = 100), where males comprised the majority at 74% (n = 74) and females constituted 26% (n = 26). As shown in Table 1, the most prevalent age group was 41–50 years (25%), followed by 21–30 years (22%) and 31–40 years (21%). Males outnumbered females across all the age categories, although this difference was not statistically significant (P = 0.232).

With regard to the type of re-treatment, lost to follow-up (LTF) was the most common, accounting for 45% of cases, followed by relapse (RE) at 39% and treatment failure (F) at 16%. No statistically significant association was found between gender and type of retreatment cases (P = 0.657). Analysis of the treatment setting showed that an equal proportion of females (50%) received care in private and government (RNTCP) sectors. Among males, a higher proportion (58.1%) received treatment under the government programme compared to private care (41.9%), with no significant gender difference (P = 0.474).

Microbiological Results

Table 2 presents sputum microscopy and CBNAAT findings by gender. The majority of patients were sputum microscopy positive, with 46% of all cases showing a 3+ bacillary load. Specifically, 46.2% of females and 45.9% of males had a 3+ result, indicating a high burden of bacilli. Lower bacillary loads (1+ and 2+) were also observed, while negative microscopy results were more frequent among females (15.4%) than males (4.1%). Scanty (SC) results were seen exclusively in males (2.7%). There was no statistically significant difference in bacillary load distribution between genders (P = 0.389). All patients were CBNAAT positive for Mycobacterium tuberculosis (MTB), with no negative results observed and no difference by gender (P = 1.000).

Drug Resistance Patterns

Figure 2 demonstrates that 14% (n = 14) of the study population was drug-resistant, while 86% (n = 86) were drug-sensitive. Among drug-resistant cases, all 14 (14%) showed resistance to isoniazid and 12 cases (12%) were resistant to both isoniazid and rifampicin. Two cases were identified as mono-resistant to isoniazid based on first-line probe assay. No resistance was detected to second-line and other antitubercular drugs.

As detailed in Table 3, isoniazid resistance was observed in 15.3% of females and 13.5% of males-a statistically significant difference (P = 0.018). Rifampicin resistance was present in 12% of cases overall, with higher prevalence among males (14.9%) compared to females (3.8%), though this difference was not statistically significant (P = 0.177). There was no resistance to pyrazinamide, ethambutol or second-line antitubercular drugs in either gender (P = 1.000 for each).

Associations with Drug Resistance

Table 4 explores the relationship between clinical and personal variables and drug resistance. Drug resistance was more common in males (85.7%) than females (14.3%), but the difference was not statistically significant (P = 0.281). The age group 51–60 years had the highest proportion of drug resistance (35.7%) and the association between age and drug resistance was statistically significant (P = 0.043). Regarding personal habits, smoking was significantly associated with drug resistance (71.4% in the resistance group vs. 38.4% in the sensitive group, P = 0.021), while alcohol consumption and tobacco chewing were not.

Analysis of retreatment categories among drug-resistant cases revealed that lost for follow-up was the most common (50%), followed by relapse (28.6%) and treatment failure (21.4%), with no significant association (P = 0.656). There was also no significant difference in drug resistance between those treated privately and those treated under government care (P = 0.626).

Assessment of comorbidities showed that a higher proportion of drug-resistant patients had diabetes mellitus (42.8%) and malnutrition (78.6%) compared to drug-sensitive cases, although these differences were not statistically significant (P = 1.000 for both). Hypertension, Hepatitis B and HIV also showed no significant association with drug resistance.

Additional Findings

As shown in Figure 3, all drug-resistant patients (n = 14) were sputum microscopy positive, with half (50%; n = 7) displaying a 3+ bacillary load. Figure 4 presents chest X-ray findings in drug-resistant cases, where bilateral cavities were observed in 57.1%. Bilateral infiltrates and unilateral cavities were each seen in 14.3%, while unilateral and bilateral fibrosis were present in 7.1% each.

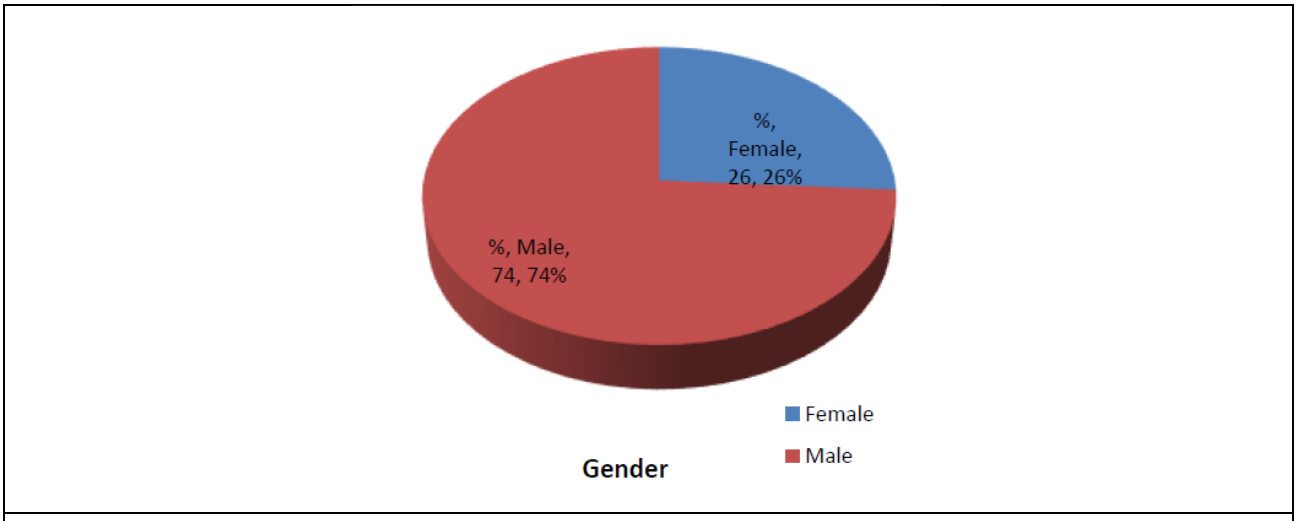

Figure 1: Pie chart showing the Gender Distribution of the study

Category	Female n (%)	Male n (%)	Total n (%)	P value
Age in years				
<20	1 (3.8%)	2 (2.7%)	3 (3%)	
21–30	10 (38.5%)	12 (16.2%)	22 (22%)	
31–40	3 (11.5%)	18 (24.3%)	21 (21%)	P = 0.232
41–50	6 (23.1%)	19 (25.7%)	25 (25%)	
51–60	2 (7.7%)	15 (20.3%)	17 (17%)	
61–70	3 (11.5%)	6 (8.1%)	9 (9%)	
>70	1 (3.8%)	2 (2.7%)	3 (3%)	
Type of re-treatment case				
LTF	14 (53.8%)	31 (41.9%)	45 (45%)	P = 0.657
RE	8 (30.8%)	31 (41.9%)	39 (39%)	
F	4 (15.4%)	12 (16.2%)	16 (16%)	
Type of treatment (Private/Govt)				
PR (Private)	13 (50%)	31 (41.9%)	44 (44%)	P = 0.474
RNTCP (Govt)	13 (50%)	43 (58.1%)	56 (56%)	

Table 1. Patient Characteristics

Category	Female n (%)	Male n (%)	Total n (%)	P value
Microscopy (bacillary load)				
Negative	4 (15.4%)	3 (4.1%)	7 (7%)	
1+	4 (15.4%)	16 (21.6%)	20 (20%)	P = 0.389
2+	6 (23.1%)	19 (25.7%)	25 (25%)	
3+	12 (46.2%)	34 (45.9%)	46 (46%)	
SC	0 (0%)	2 (2.7%)	2 (2%)	
CBNAAT / MTB Detected				
Positive	26 (100%)	74 (100%)	100 (100%)	P = 1.000
Negative	0 (0%)	0 (0%)	0 (0%)	

Table 2: Sputum Microscopy and CBNAAT Results by Gender

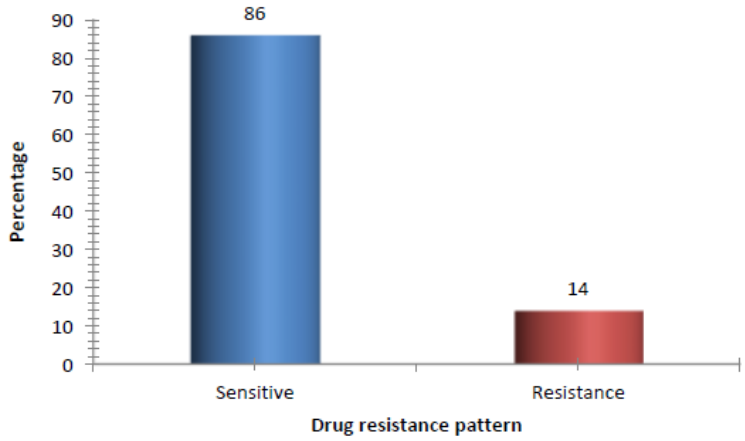

Figure 2: Bar Diagram depicting Drug Resistance Pattern

Drug Resistance Pattern	Female n (%)	Male n (%)	Total n (%)	P value
Isoniazid				
- Resistance	4 (15.3%)	10 (13.51%)	14 (14.0%)	P = 0.018
- Sensitive	22 (84.61%)	64 (86.48%)	86 (86.0%)	
Rifampicin				
- Resistance	3 (3.8%)	9 (14.9%)	12 (12.0%)	P = 0.177
- Sensitive	23 (96.2%)	65 (85.1%)	88 (88.0%)	
Pyrazinamide				
- Resistance	0 (0%)	0 (0%)	0 (0%)	**P = 1.000**
- Sensitive	26 (100%)	74 (100%)	100 (100%)	
Ethambutol				
- Resistance	0 (0%)	0 (0%)	0 (0%)	**P = 1.000**
- Sensitive	26 (100%)	74 (100%)	100 (100%)	
2nd line ATT				
- Resistance	0 (0%)	0 (0%)	0 (0%)	**P = 1.000**
- Sensitive	26 (100%)	74 (100%)	100 (100%)	

Table 3: Drug Resistance Profile by Gender

Variable	Sensitive n (%)	Resistance n (%)	Total n (%)	P value
Gender				
Female	24 (27.9%)	4 (14.3%)	26 (26%)	P = 0.281
Male	62 (72.1%)	10 (85.7%)	74 (74%)	
Age group				
- <20	2 (2.3%)	0 (0%)	2 (2%)	
- 21–30	21 (24.4%)	2 (14.3%)	23 (23%)	
- 31–40	19 (22.1%)	2 (14.3%)	21 (21%)	P = 0.043
- 41–50	22 (25.6%)	3 (21.4%)	25 (25%)	
- 51–60	12 (14%)	5 (35.7%)	17 (17%)	
- 61–70	9 (10.5%)	0 (0%)	9 (9%)	
- >70	1 (1.2%)	2 (14.3%)	3 (3%)	
Personal History				
- Smoking	33 (38.4%)	10 (71.4%)	43 (43%)	P = 0.021*
- Drinking	41 (47.7%)	8 (57.1%)	49 (49%)	P = 0.511
- Tobacco	38 (44.2%)	6 (42.9%)	44 (44%)	P = 0.926
Type of Re-treatment Case				P=0.656

- LTF/D	38 (44.2%)	7 (50.0%)	45 (45%)	
- RE	35 (40.7%)	4 (28.6%)	39 (39%)	
- F	13 (15.1%)	3 (21.4%)	16 (16%)	
Type of Treatment				
- PR (Private)	37 (43.0%)	7 (50.0%)	44 (44%)	P = 0.626
- RNTCP (Govt)	49 (57.0%)	7 (50.0%)	56 (56%)	
Co-Morbidities				
- Diabetes mellitus	14 (16.27%)	6 (42.8%)	20 (20%)	P = 1.000
- Malnutrition	51 (59.3%)	11 (78.57%)	62 (62%)	P = 1.000
- Hypertension	13 (15.11%)	5 (35.71%)	18 (18%)	P = 1.000
- Hepatitis B	7 (8.1%)	0 (0%)	7 (7%)	P = 0.589
- HIV	12 (13.95%)	2 (15.0%)	14 (14%)	P = 0.936

Table 4: Associations with Drug Resistance Pattern

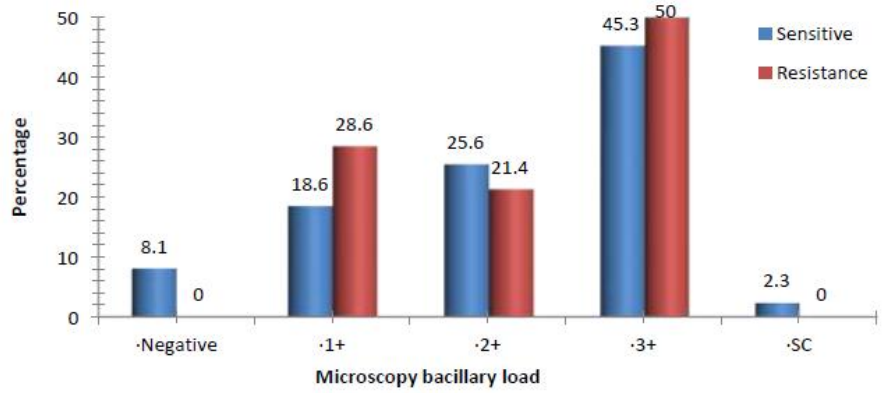

Figure 3: Bar Diagram depicting the Bacillary Load in the Drug Resistant and Sensitive cases

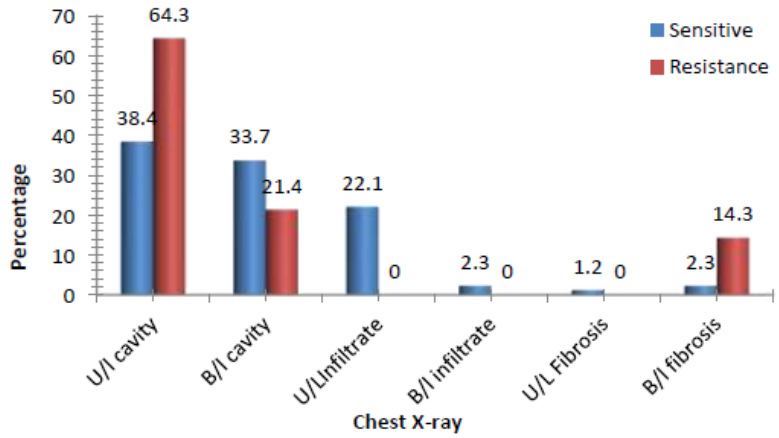

Figure 4: Bar Diagram depicting Chest X-ray Features in Retreatment cases

DISCUSSION

Multidrug-resistant tuberculosis (MDR-TB), characterized by resistance to at least isoniazid and rifampicin, remains a significant global public health challenge, particularly in countries like India with a high TB burden and variable access to timely diagnosis and quality treatment.[6,7] MDR-TB leads to reduced response to conventional treatment, increased mortality and prolonged infectiousness, thereby exacerbating transmission within communities.

Demographic Profile and International Comparison

In the present study, MDR-TB among previously treated (retreatment) cases was observed at a prevalence of 12%. This figure aligns closely with recent Indian reports from national surveys and the National Institute for Research in Tuberculosis (NIRT), which cite MDR-TB rates in retreatment cases ranging from 11% to 12%. However, international and regional studies show considerable variability; for instance, MDR-TB prevalence in retreatment cases has been reported as high as 41% in Punjab, Pakistan and up to 54% in Bangladesh, while some Indian cohorts have reported rates ranging from 15% to over 30%.[8-13] These disparities likely reflect differences in TB program robustness, diagnostic access, treatment adherence and local epidemiology.

Our study cohort demonstrated a male predominance (64.3%) and a concentration of cases within the 22–60 year age group, findings consistent with most Indian and South Asian studies. This age bracket represents the economically productive and socially active segment of the population, who are thus at higher risk for TB exposure and transmission. Males are also more likely to seek care early, while females may delay treatment due to social stigma and healthcare barriers. Notably, some studies have reported higher MDR-TB rates among older or female populations, often attributed to delayed diagnosis and presentation.[14-18]

Lost to Follow-up (Defaulters) and Treatment Outcomes

A particularly striking finding in this study was the high proportion of lost to follow-up (defaulters), accounting for 50% of retreatment cases-substantially higher than rates reported in many Indian cohorts. For example, studies by Surendra K. Sharma et al. (AIIMS, Delhi) and Mahendra Kumar et al. (Udaipur) observed defaulter rates between 24% and 30%. High default rates reflect persistent challenges in treatment adherence, likely driven by factors such as prolonged therapy, side effects, socio-economic difficulties, lack of patient education and weak follow-up mechanisms. These findings highlight the urgent need for enhanced patient counselling, community-based support and robust tracking systems to minimize default rates and prevent the emergence and transmission of MDR-TB.[14,19–22]

Regimen Types: Public vs. Private Sector

In this study, no significant difference in drug resistance prevalence was observed between patients treated in the government sector and those treated privately. This mirrors findings from other research in India, where the risk of developing drug resistance has been shown to be more closely linked to patient-related factors such as treatment interruption and non-compliance rather than the sector of care. This underscores the importance of harmonizing treatment protocols and ensuring quality care across both public and private providers, as well as the necessity for collaborative case management.[23–25]

Comorbidities and Risk Factor Profile

Analysis of comorbidities revealed high rates of malnutrition (78.5%), diabetes mellitus (42.9%) and HIV (14.5%) among drug-resistant TB cases. These rates are generally higher than those reported in comparable national and international studies, such as those from Egypt and Kolkata, where malnutrition rates were around 58–60% and diabetes and HIV rates were also lower. The strong association between malnutrition and MDR-TB highlights the bidirectional relationship between TB and nutritional status: undernutrition increases susceptibility to infection and impairs recovery, while active TB exacerbates nutritional deficits. Likewise, diabetes is increasingly recognized as a key risk factor for MDR-TB, potentially due to immune system impairment and poor glycemic control, which hinder effective response to infection and treatment. HIV co-infection further compounds disease risk and complicates management.[26–29]

Social Habits: Smoking, Alcohol, and Tobacco

Social habits were strongly associated with drug resistance in our cohort. Among MDR-TB cases, 71.4% were tobacco smokers, 57.1% consumed alcohol and 42.9% were tobacco chewers. These rates are equal to or higher than those seen in other Indian and international studies. Smoking is a well-

established independent risk factor for TB, associated with an approximately two-fold increased risk of infection and poor treatment outcomes. Continued tobacco use during TB therapy has also been linked to higher rates of recurrence and drug resistance. Alcohol use impairs immunity and increases the risk of non-adherence, further compounding the likelihood of treatment failure and the development of MDR-TB. These findings reinforce the urgent need for integrated cessation programs targeting tobacco and alcohol use as part of comprehensive TB management.[30–32]

Radiological Features

Radiological assessment revealed that the majority of drug-resistant cases exhibited cavitary lung lesions, consistent with findings from several published studies. Cavitary disease is associated with higher bacillary loads and an increased risk of developing and transmitting drug-resistant organisms. This underlines the importance of early identification and aggressive management of patients with cavitary lesions, particularly among those with additional risk factors.[11,28,33]

Summary and Public Health Implications

Overall, the findings of this study reinforce the ongoing challenges posed by MDR-TB in retreatment cases within high-burden settings. Male predominance, concentration in economically productive age groups, high rates of lost to follow up, substantial comorbidity burden (notably malnutrition and diabetes), prevalent risky social habits and radiological evidence of advanced disease all point to the complexity of MDR-TB management. To address these challenges, there is a pressing need for strengthened patient education, rigorous follow-up, targeted interventions for high-risk groups (including lost to follow up and those with substance abuse), integration of nutritional and diabetes management into TB care and sustained efforts to harmonize and enforce quality care standards across both public and private sectors.

CONCLUSION

Drug resistance in tuberculosis is a persistent and evolving threat, highlighting the need for regular surveillance and research into MDR-TB prevalence and risk factors. Comprehensive data on epidemiological factors, co-morbidities and their interactions are essential to inform national treatment policies. Successful prevention and control of drug-resistant TB depend on early diagnosis, timely initiation of effective treatment, strict adherence monitoring, nutritional support, and integrated management of comorbidities such as malnutrition, diabetes and HIV. Additionally, psycho-social support, public awareness and strengthened infection control are crucial for curbing the spread of drug resistance.

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