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Drug resistance in patients with tuberculosis: a study from a tertiary care center in northern India

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Abstract

Tuberculosis (TB) continues to be a major global health challenge, with India contributing a significant share of the burden. Drug-resistant TB (DR-TB) is additionally responsible for the huge numbers. Despite the magnitude of the problem, there is a relative paucity of data with respect to the different patterns of DR-TB from Northern India. A retrospective, observational study was undertaken at the Department of Pulmonary Medicine at Chest and TB Hospital, Government Medical College, Patiala, Punjab, India, to analyze the drug resistance profile of *Mycobacterium tuberculosis* and associated risk factors, essential for aiding clinicians and evaluating evidence to strengthen programmatic strategies, with an aim to ultimately reduce the overall burden of TB. A total of 14,142 microbiologically confirmed *M. tuberculosis* cases from 2022-2024 were reviewed. Resistance patterns were characterized according to national guidelines. The prevalence of resistance patterns and associations between drug resistance and demographic variables, treatment and contact history, and comorbidities (HIV co-infection, diabetes mellitus, alcohol, and smoking) were analyzed using chi-square tests and univariate and multivariate logistic regression. In this cohort, the median age of included patients was 37 years, with the majority from 21-40 years (41.01%) and predominantly male gender (60.72%). The overall prevalence of DR-TB was 8.6%. INH monoresistance accounted for 50.53% of DR-TB, with 35.99% harboring *katG* and 14.54% *inhA* gene mutations. *katG* mutations were significantly higher in newly diagnosed patients (37.7%, p=0.006), those with a positive contact history (37.6%, p=0.027), diabetics (43.6%, p=0.038), and individuals with tobacco exposure (49.1%, p=0.034). *inhA* mutations were strongly associated with HIV co-infection (32.30%, p=0.005). Rifampicin resistance was more frequent among previously treated cases (15.3%, p<0.001), patients with no contact history (13%, p=0.003), and those with HIV co-infection (19.40%, p=0.026). Multivariate analysis demonstrated that female gender [adjusted odds ratio (AOR) 1.15, p=0.030], previous treatment history (AOR 1.78, p<0.001), and absence of contact history (AOR 1.74, p<0.001) had higher odds of having DR-TB. These findings, when interpreted in the context of existing literature, suggest that factors contributing to the development of resistance are either acquired through treatment failure or community transmission. Individual host factors, including gender and the presence of comorbidities such as HIV, diabetes, and tobacco exposure, further increase the risk. Understanding the epidemiology of drug resistance is crucial to improve patient outcomes, curb the burden of TB in our region, and eventually advance the nation's TB elimination goals.

Key words: DR-TB, pattern of drug resistance, HIV**.**

Introduction

Tuberculosis (TB), caused by *Mycobacterium tuberculosis*, is the leading infectious killer worldwide, with 10.8 million diagnosed cases and 1.25 million deaths in 2023 [1]. India, in particular, bears a disproportionate share of this burden, accounting for nearly one quarter of the global TB burden, despite housing less than 18% of the world's population [2]. The figure is more disturbing when it comes to drug-resistant TB (DR-TB) with India accounting for 27% of the people who developed MDR/RR-TB in 2023 [1]. It is of great concern as it complicates treatment and remains a formidable hurdle in achieving TB elimination goals. Development of DR-TB is a multifactorial process, influenced by socio-demographic factors, treatment and contact histories and co-morbidities [1]. Management of DR-TB requires early identification of resistance patterns and administration of appropriate treatment regimens accordingly. Furthermore, an understanding of resistance profiles and emerging trends in drug resistance allows for appropriate allocation of time and resources for the future times.

The prevalence of DR-TB and factors affecting the same vary with geography. There is a paucity of literature exploring these trends and associations in Northern India. Against this background, our study aimed to characterise the resistance profile of *Mycobacterium tuberculosis (M.tb)* and ascertain risk factors contributing to the development of drug resistance. Specifically, the objectives of our study were to assess the prevalence of DR-TB and identify the various drug resistance patterns and explore the correlations between resistance patterns and key socio-demographic factors such as age and sex, history of previous TB treatment, contact history, and comorbidities including HIV co-infection, diabetes mellitus, tobacco exposure and alcohol use.

Materials and Methods

Approval was obtained from the Institutional Ethics Committee before starting the study (vide letter No. Trg. 9(310)2024/28113 dated 13 September 2024). This was a retrospective, observational study conducted in the Department of Pulmonary Medicine at Chest and TB Hospital, Government Medical College, Patiala, Punjab. Records from the years 2022 to 2024 were reviewed. DS-TB, DR-TB, isoniazid monoresistant-TB, Multi-drug resistant (MDR) TB, Pre-extensively drug resistant (Pre-XDR) TB, extensively drug resistant (XDR) TB were defined according to the National Guidelines for Management of Drug-Resistant TB [2].

Inclusion and exclusion criteria

Inclusion criteria: Patients with microbiologically confirmed positive diagnosis of pulmonary/extrapulmonary TB, of all age groups, known resistance patterns, known treatment and contact histories and known comorbidity status from January 2022 to December 2024.

Exclusion criteria: Patients with incomplete case records or duplicate records.

Statistical analysis

Patient records meeting these criteria were subjected to statistical analysis using Microsoft Excel and IBM SPSS Statistics for Windows, Version 22.0. (Armonk, NY: IBM Corp.). Quantitative variables were summarized as mean with standard deviation or median with interquartile ranges depending on the distribution, while categorical variables were expressed as proportions. The prevalence of resistance patterns was summarized as proportions with 95% confidence intervals. Association of individual drug resistance patterns with gender, treatment and contact histories and comorbidities (HIV co-infection, diabetes, tobacco exposure and alcohol use) were assessed using the chi-square test. Univariate logistic regression analysis of overall drug resistance and demographic data, treatment and contact histories and comorbidities was performed. Multinomial logistic regression analysis was then performed on the variables that exhibited statistical significance in the univariate analysis, in order to identify the risk factors associated with DR-TB. A p-value of <0.05 was considered as statistically significant.

Results

A total of 14,142 microbiologically confirmed cases of *M. tuberculosis* were included in the study. The mean age of the patients was 39.57 +/- 17.72 years. The median age of the patients was 37 years. Maximum number of cases were seen in the age group of 21 - 40 years (n=5799, 41.01%). The majority of patients were males (n = 8587; 60.72%). Of the total cases included, 98.72% (n=13961) were that of pulmonary TB, 10.74% (n=1519) had previously been treated for TB, 86.24% (n=12197) had reported a history ≥1 TB contact, 1.85% (n=262) were HIV-TB co-infected, 13.01% (n=1840) were diabetic, 6.17 % (n=872) had tobacco exposure and 5.56% (n=786) were alcohol users (Table 1).

The overall prevalence of drug-resistant TB was 8.61% (n=1217). Drug sensitivity testing revealed that of all the DR-TB cases, 50.53% (n=615) were resistant to isoniazid alone (INH monoresistance) out of which 35.99% (n=438) demonstrated katG gene resistance and 14.54%

(n=177) cases demonstrated inhA gene resistance respectively. 8.38% (n=102) cases were resistant to rifampicin alone (RR), and 26.87% (n=327) cases were resistant to both isoniazid and rifampicin indicating multi-drug-resistant TB (MDR-TB). Prevalence of pre-extensively drug-resistant TB (pre-XDR TB) was 13.31% (n=162) and extensively drug-resistant TB (XDR-TB) was 0.9% (n=11) (Table 2).

The year-wise prevalence of DR-TB was 10.0% (2022), 8.07% (2023) and 8.48% (2024). The year-wise prevalence trends of various drug resistance patterns are demonstrated in Figure 1.

Univariate analysis was performed to ascertain association between various drug resistance patterns and demographic factors, treatment and contact histories and comorbidities (HIV co-infection, diabetes mellitus, alcohol, smoking) (Tables 3 and 4).

INH monoresistance (katG gene mutation) was significantly higher in newly diagnosed patients (37.7%, p=0.006) and those with a history of >/=1 contact (37.6%, p=0.027). It was also significantly associated with diabetes (43.6%, p=0.038) and presence of tobacco exposure (49.10%, p=0.034).

INH monoresistance (inhA gene mutation) was significantly higher in those with HIV co-infection (32.30%, p=0.005). RR was significantly higher in previously treated patients (15.3%, p<0.001) and those with no contact history (13%, p=0.003). It was also significantly associated with HIV co-infection (19.40%, p=0.026).

Multivariate analysis was also performed to ascertain the association and strength of risk factors for overall drug resistance (Table 5).

After controlling for other variables, female gender (AOR=1.15, p=0.030), previous treatment history (AOR=1.78, p<0.001) and no contact history (AOR=1.74, p<0.001) had higher odds of having DR-TB (Table 6).

Discussion

In our study, we observed a predominance of males, particularly in the 21 - 40 years age group, which constitutes the economically productive section of society [3]. The burden of TB in this group may be attributed to greater social mobility, higher number of contacts and increased exposure to dust and smoke. In addition, higher rates of smoking, alcohol and substance abuse also contribute to TB in men [4-6]. While overall TB prevalence was higher in men, drug resistance was higher in women, with multivariate analysis revealing a modest yet statistically significant increase in odds of drug resistance among women. This disparity may reflect the impact of power and gender differentials which limit women's autonomy in decision making,

restrict financial independence and mobility, and compel prioritization of household responsibilities over personal health. These factors, coupled with social stigma, delayed symptom recognition, inadequate nutrition, and inconsistent treatment access, likely contribute to treatment failure and the emergence of drug-resistant strains [6]. Overall, our findings highlight distinct gender-specific trends in epidemiology i.e. men in their most productive years carry the greatest burden of the disease, mainly due to occupational and lifestyle exposures, whereas women show a higher proportion of drug resistance, likely due to socio-cultural and structural barriers to timely care.

1.85% of patients were HIV-reactive which is in alignment with the national estimate of 2% HIV co-infection among TB patients in India [1,7]. 13.01% of the included patients were diabetics. Previous studies that screened for diabetes among TB patients in India have reported a wide range of prevalence data, ranging from 1.9% to as high as 35% [8]. 6.17% of patients had a history of tobacco exposure which is lower in contrast to existing studies in the Indian context [9], possibly due to a hesitancy in self-reporting of smoking habits as well as a lack of understanding on the means of exposure to tobacco.

The association between TB and HIV is well established, with HIV increases the susceptibility to TB, risk of progression of infection to disease, likelihood of reactivation and re-infection and the risk of development of DR-TB [5,10]. In our study, HIV was a significant risk factor for INH monoresistance (inhA gene mutation) and RR-TB. This association may be attributed to immunosuppression in HIV reactive patients, resulting in higher bacillary loads, increased likelihood of incomplete or prolonged treatment courses, and treatment interruptions due to drug interactions or adverse effects, all of which facilitate the selection of resistant strains. Supporting this, Salindri, Argita D et al. reported 1.85 times higher odds of INH monoresistance in HIV-TB co-infected individuals [11]. Similarly, RR has been repeatedly demonstrated, in existing literature, to be higher among HIV-TB co-infected patients [12,13].

Diabetes mellitus is increasingly recognised as a comorbid risk factor in TB, associated with higher rates of treatment failure and increased risk of development of DR-TB [8,14]. Our study found a statistically significant association between DM and INH monoresistance (katG gene mutation) which has similarly been demonstrated in cohorts in other parts of India and globally as well [15,16].

Tobacco exposure has been shown to have a negative impact on pulmonary immunity and response to treatment, thus contributing to treatment failure and evolution of drug resistance [17,18]. A study conducted in South India, demonstrated a significant association between

smoking history and INH monoresistance (katG gene mutation), in line with the results of our study [19]. While alcohol use was also significantly associated with INH monoresistance in the same cohort, our study revealed no such association. In the context of DR-TB, HIV, diabetes and tobacco exposure need to be detected early and managed promptly in order to ensure successful treatment outcomes for patients.

Our study revealed two concurrent patterns in the epidemiology of DR-TB (a) the emergence of resistance in patients with prior treatment due to treatment failure, poor adherence, and inadequate regimen supervision and (b) direct community spread of resistant strains [20]. The first pattern is supported by our finding that previously treated patients had 1.78 times higher odds of DR-TB compared to newly diagnosed cases, in line with global evidence identifying it as a major driver of acquired resistance [1,3,6]. This reflects opportunities for improvement at multiple levels i.e patient (ensuring adherence and minimizing treatment interruptions), clinician (early detection of resistance and timely regimen adjustment), and programmatic (enhancing the effectiveness of ongoing programs and strengthening quality control measures). The second pattern is reflected in the finding that cases with absence of known TB contacts had 1.74 times higher odds of DR-TB, suggesting that transmission is simultaneously occurring through undiagnosed community interactions as opposed to confined household spread, in accordance with transmission-based models, validated in existing literature [4,5].

In our cohort, INH monoresistance predominated (50.5%), with katG mutations accounting for the majority of cases (71.2%). Uniquely, INH monoresistance (katG) was strongly linked to newly diagnosed patients and those with known contacts, suggesting active community transmission of resistant strains in Northern India [21]. This finding, which is in contrast to the first National Drug Resistance Survey (2014-2016) [22], reinforces the need for more vigilant and systematic INH susceptibility testing to correctly detect the pattern of drug resistance, following treatment guidelines and building community-based surveillance models to accurately assess the burden of INH monoresistance in the community [5], Though less likely in the Indian context because of a limited use, isoniazid preventive therapy has been hypothesized to contribute to emergence of isoniazid mono-resistance by exerting selective pressure despite its impact on reduction of drug-sensitive disease and needs to be strongly considered while using it for TB preventive therapy at the community level [21,22], In contrast, rifampicin resistance was primarily associated with previous TB treatment and absence of known contacts, in accordance with existing literature [4]. This strongly implies that rifampicin resistance is either acquired during treatment, likely driven by poor adherence, possibly due

to drug intolerance (e.g. hepatotoxicity, GI side effects) and inadequate management of adverse events or from the community transmission of RR-TB strain, giving us a blue print for our TB elimination efforts [5].

In our study, MDR-TB (26.9%) emerged as the second most predominant resistance pattern, followed by pre-XDR (13%), while XDR (0.9%) remained the least common. Goyal V. et al, in their systematic review and meta-analysis conducted across western India, have demonstrated prevalence rates of MDR, Pre-XDR, and XDR-TB as 39.9%, 7.9% and 1.9% respectively [23]. These differences likely reflect regional variations and heterogeneity in patient selection. Another possible reason could be the updated NTEP resistance pattern classification which now considers RR cases independently, unlike previous studies that commonly grouped RR/MDR-TB together. Alternately, the lower prevalence of MDR-TB in our study, may reflect the success of programmatic interventions in the region, particularly improved case detection and adherence to standardised treatment regimens [5].

Our study featured a large sample size of recent data with an updated and accurate characterization of drug resistance patterns in the region. However, our study was limited by its retrospective observational design. We were unable to take into account the BMI and nutritional status of our patients, which are important considerations in the natural history and treatment of TB. Lastly, the regionality of our study may slightly limit its ability to extrapolate our findings to the national level, but can prove extremely useful in the North Indian context.

DR-TB remains a pressing challenge in the national efforts to eliminate TB. Our study delineates the epidemiology of DR-TB in Northern India, highlighting the influence of comorbidities, gender-specific trends, and the dual contribution of prior treatment and community transmission in the development of DR-TB. Analysis of regional drug resistance profiles and the factors driving the development of DR-TB allows for rational allocation of time and resources at the programmatic level, aids clinicians in tailoring diagnosis and treatment regimens, and eventually improves patient outcomes.

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Table 1. Demographic characteristics.

Characteristic	Category	N=14142	%
Age	<20	2206	15.6
	21-40	5799	41.01
	41-60	4117	29.11
	61-80	1911	13.51
	>80	109	0.77
Gender	Males	8587	60.72
	Females	5551	39.25
	Transgender	4	0.03
Type of TB	Pulmonary TB	13961	98.72
	Extra-pulmonary TB	181	1.28
Treatment History	New diagnosis	12623	89.26
	Previously treated	1519	10.74
Contact History	No known contact history	1945	13.75
	>/= 1 contact	12197	86.25
HIV Co-infection	Non-reactive	13880	98.15
	Reactive	262	1.85
Diabetes Status	Non-diabetic	12302	86.99
	Diabetic	1840	13.01
Tobacco Exposure	No	13270	93.83
	Yes	872	6.17
Alcohol Use	No	13356	94.44
	Yes	787	5.56

TB, tuberculosis.

Table 2. Prevalence of various resistance patterns.

Resistance Pattern	N	% (out of total TB cases)	% (out of DRTB cases)
		N=14142	N=1217
INH monoresistance (katG gene mutation)	438	3.1	35.99
INH monoresistance (inhA gene mutation)	177	1.25	14.54
RR	102	0.72	8.38
MDR	327	2.31	26.87
Pre-XDR	162	1.15	13.31
XDR	11	0.08	0.9

INH, isoniazid; RR, rifampicin resistant; MDR, multi-drug resistant; pre-XDR, pre-extensively drug resistant; XDR, extensively drug resistant.

Table 3. Drug resistance patterns and their association with treatment history and contact history.

	Treatment History					Contact History				
	New TB Patients		Previously Treated		p	No Contact History		History of >/=1 contact		p
Resistance Patterns	**N**	**% (95% CI)**	**N**	**% (95% CI)**		**N**	**% (95% CI)**	**N**	**% (95% CI)**	
INH monoresistance (*katG* mutation)	382	37.70 (34.68-40.74)	56	27.60 (21.56-34.28)	0.006*	76	30.00 (24.46-36.10)	362	37.60 (34.48-40.69)	0.027*
INH monoresistance (*inhA* mutation)	156	15.40 (13.22-17.75)	21	10.30 (6.52-15.38)	0.063	29	11.50 (7.81-16.05)	148	15.40 (13.13-17.79)	0.118
RR	71	7.00 (5.51-8.75)	31	15.30 (10.62-20.97)	<.001*	33	13.00 (9.15-17.83)	69	7.20 (5.61-8.97)	0.003*
MDR	262	25.80 (23.17-28.65)	65	32.00 (25.66-38.91)	0.07	76	30.00 (24.46-36.10)	251	26.00 (23.29-28.93)	0.201
Pre-XDR	133	13.10 (11.10-15.35)	29	14.30 (9.78-19.87)	0.654	38	15.00 (10.85-20.03)	124	12.90 (10.81-15.14)	0.369
XDR	10	1.00 (0.47-1.81)	1	0.50 (0.01-2.71)	0.702	1	0.40 (0.01-2.18)	10	1.00 (0.50-1.90)	0.476

INH, isoniazid; RR, rifampicin resistant: MDR, multi-drug resistant; pre-XDR, pre-extensively drug resistant; XDR, extensively drug resistant.

Table 4. Drug resistance patterns and their associations with HIV co-infection and diabetes status.

	HIV Status					Diabetes Status				
	Non-Reactive		Reactive		p	Non-Diabetic		Diabetic		p
Resistance patterns	**N**	**% (95% CI)**	**N**	**% (95% CI)**		**N**	**% (95% CI)**	**N**	**% (95% CI)**	
INH monoresistance (*katG* mutation)	431	36.30 (33.60-39.15)	7	22.60 (0.096-41.10)	0.115	373	34.90 (32.06-37.87)	65	43.60 (35.53-51.98)	0.038*
INH monoresistance (*inhA* mutation)	167	14.10 (12.15-16.19)	10	32.30 (16.68-51.37)	0.005*	161	15.10 (12.98-17.36)	16	10.70 (6.26-16.85)	0.16
RR	96	8.10 (6.61-9.80)	6	19.40 (7.45-37.47)	0.026*	92	8.60 (7.00-10.46)	10	6.70 (3.27-12.00)	0.528
MDR	320	27.00 (24.47-29.60)	7	22.60 (9.59-41.10)	0.585	290	27.20 (24.51-29.93)	37	24.80 (18.13-32.57)	0.549
Pre-XDR	161	13.60 (11.68-15.66)	1	3.20 (0.08-16.70)	0.11	142	13.30 (11.32-15.48)	20	13.40 (8.40-19.97)	0.966
XDR	11	0.90 (0.46-1.65)	0	No observation	1	10	0.90 (0.45-1.72)	1	0.70 (0.02-3.68)	1

INH, isoniazid; RR, rifampicin resistant: MDR, multi-drug resistant; pre-XDR, pre-extensively drug resistant; XDR, extensively drug resistant.

Table 5. Drug resistance patterns and their associations with tobacco exposure and alcohol use.

	Tobacco Exposure					Alcohol Use				
	No Exposure		Exposure Present		p	No		Yes		p
Resistance patterns	**N**	**% (95% CI)**	**N**	**% (95% CI)**		**N**	**% (95% CI)**	**N**	**% (95% CI)**	
INH monoresistance (*katG* mutation)	410	35.30 (32.59-38.17)	28	49.10 (35.63-62.71)	0.034*	416	35.70 (32.98-38.57)	22	41.50 (28.14-55.87)	0.392
INH monoresistance (*inhA* mutation)	168	14.50 (12.51-16.64)	9	15.80 (7.48-27.87)	0.785	171	14.70 (12.71-16.86)	6	11.30 (4.27-23.03)	0.496
RR	96	8.30 (6.75-10.01)	6	10.50 (3.96-21.52)	0.549	97	8.30 (6.81-10.07)	5	9.40 (3.13-20.66)	0.777
MDR	317	27.30 (24.78-29.99)	10	17.50 (8.75-29.91)	0.104	313	26.90 (24.36-29.54)	14	26.40 (15.26-40.33)	0.939
Pre-XDR	158	13.60 (11.70-15.73)	4	7.00 (1.94-17.00)	0.227	156	13.40 (11.50-15.49)	6	11.30 (4.27-23.03)	0.663
XDR	11	0.90 (0.47-1.69)	0	No observation	1	11	0.90 (0.47-1.68)	0	No observation	1

INH, isoniazid; RR, rifampicin resistant: MDR, multi-drug resistant; pre-XDR, pre-extensively drug resistant; XDR, extensively drug resistant.

Table 6. Strength of association of various risk factors and overall drug resistance.

Characteristics	Category	DSTB % (95%CI)	DRTB % (95%CI)	p	OR (95% CI)	AOR (95% CI)	p
Gender	Males	91.74 (91.14-92.32)	8.26 (7.68-8.86)	0.003*	1	1	-
	Females	90.88 (90.10-91.63)	9.12 (8.37-9.90)		1.11 (0.999-1.26) *	1.15 (1.01-1.30)	0.03*
	Transgender	25 (0.63-80.59)	75 (19.41-99.37)		11.11 (1.566-79.00)	13.1 (1.84-93.18)	0.01
Treatment History	New diagnosis	91.97 (91.48-92.44)	8.03 (7.56-8.52)	<0.001*	1	1	
	Previously treated	86.64 (84.82-88.31)	13.36 (11.69-15.18)		1.77 (1.50 - 2.07) *	1.78 (1.52-2.08)	<0.001*
Contact History	>/= 1 contact	92.10 (91.60-92.57)	7.90 (7.43-8.40)	<0.001*	1	1	
	No known contact history	86.99 (85.42-88.46)	13.01 (11.54-14.58)		1.74 (1.50-2.02) *	1.74 (1.50-2.02)	<0.001*
HIV Co-infection	Non-reactive	91.46 (90.98-91.92)	8.54 (8.08-9.02)	0.06	1	-	-
	Reactive	88.17 (83.63-91.82)	11.83 (8.18-16.37)		1.44 (0.98-2.10)	-	-
Diabetes Status	Non-diabetic	91.32 (90.81-91.81)	8.68 (8.19-9.19)	0.405	1	-	-
	Diabetic	91.90 (90.56-93.11)	8.10 (6.89-9.44)		0.93 (0.78-1.11)	-	-
Tobacco Exposure	No	91.26 (90.77-91.73)	8.74 (8.27-9.23)	0.025*	1	1	
	Yes	93.46 (91.61-95.01)	6.54 (4.99-8.39)		0.73 (0.55-0.96) *	0.76 (0.57-1.01)	0.051
Alcohol Use	No	91.28 (90.79-91.75)	8.72 (8.24-9.21)	0.055	1	-	-
	Yes	93.26 (91.27-94.91)	6.74 (5.09-8.73)		0.757 (0.57-1.01)	-	-

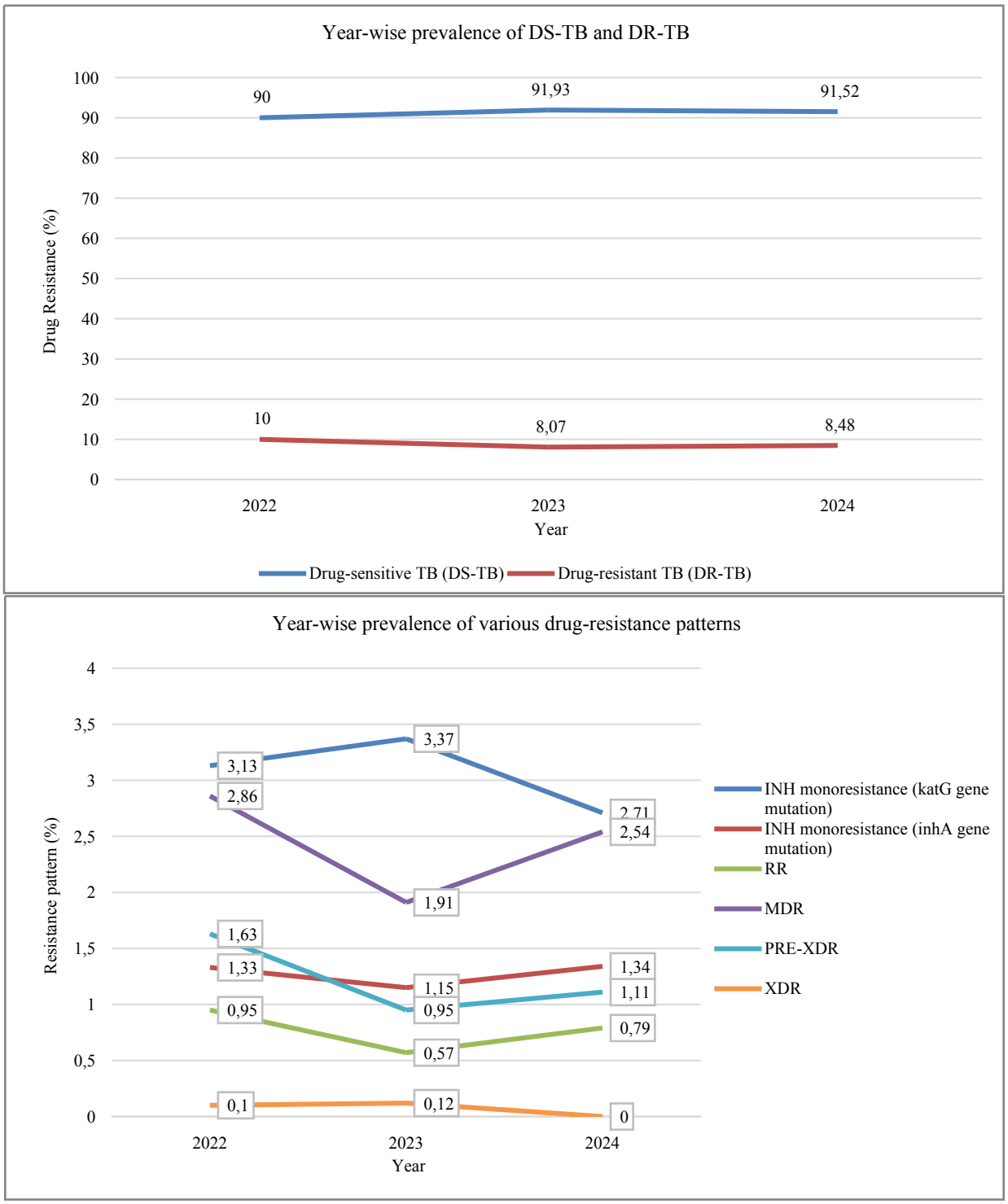

Figure 1. Year-wise prevalence of DR-TB and various drug-resistance patterns.