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EVALUATION OF THE PRESCRIPTION PATTERNS OF ANTITUBERCULAR DRUGS AND ASSESSMENT OF DRUG UTILIZATION USING WHO CORE PRESCRIBING INDICATORS

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ABSTRACT

INTRODUCTION: Tuberculosis (TB) is the world's leading cause of death from a single infectious agent and among the top 10 causes of death worldwide. **AIM:** To evaluate the prescription patterns of antitubercular drugs and assess drug utilization using WHO core prescribing indicators among tuberculosis patients attending a tertiary care center. **METHODOLOGY:** This study was a hospital-based, prospective observational study aimed at evaluating the prescription patterns of antitubercular drugs. The study was conducted over a period of one year from March 2025 – February 2026 after obtaining approval from the Institutional Ethics Committee. **RESULT:** The study showed predominantly pulmonary, drug-sensitive TB among young adults, with high use of generic and NLEM-listed medicines and a substantial burden of comorbidities and concomitant medications. Adverse drug reactions occurred in 30.91% of patients, while potential drug–drug interactions were identified in 44.55% of patients. **CONCLUSION:** The prescribing pattern was largely consistent with NTEP recommendations, with increasing use of all-oral regimens for drug-resistant TB. Regular monitoring for adverse drug reactions and drug–drug interactions is essential to ensure safe, rational, and effective TB therapy.

Keywords: Tuberculosis; Prescribing Pattern; Adverse Drug Reactions

INTRODUCTION

Tuberculosis (TB) is the world's leading cause of death from a single infectious agent and among the top 10 causes of death worldwide. It was also the leading killer of people with HIV and a major cause of death related to antimicrobial resistance[1]. TB is contagious and airborne. In 2024, an estimated 10.7 million people fell ill with TB worldwide, including 5.8 million men, 3.7 million women and 1.2 million children and young adolescents. People living with HIV accounted for 5.8% of the total. The TB incidence rate also fell, by 1.7% between 2023 and 2024, and is back to the level of 2020. Globally, the net reduction in the TB incidence rate from 2015 to 2024 was 12%, far from the WHO End TB Strategy milestone of a 50% reduction by 2025. Various demographic factors, including age, gender, and socioeconomic status, influence these rates, highlighting the complexity of TB epidemiology[2]. According to the WHO Global TB Report 2022, India's TB incidence rate for 2021 was estimated at 210 cases per 100,000 population, a decline from 256 cases per 100,000 in 2015.This represents an 18% decrease, which is notably better than the global average decline of 11% during the same period.[3] The report indicates that India accounted for 26% of the global TB cases in 2020, highlighting its substantial burden in the context of worldwide TB statistics. The prevalence of TB in India is also alarming. Firstline ATDs, such as isoniazid, rifampicin, ethambutol, and pyrazinamide, form the core of standard treatment regimens. For cases involving multidrug-resistant TB (MDR-TB), second-line ATDs, including fluoroquinolones, aminoglycosides, and newer agents like bedaquiline and delamanid, are employed. Each ATD has a specific mechanism of action, targeting different aspects of Mycobacterium tuberculosis, the bacterium responsible for TB[4].Standard TB treatment regimens for drug-susceptible TB typically span six months, divided into an initial intensive phase and a continuation phase. The intensive phase involves administering isoniazid, rifampicin, pyrazinamide, and ethambutol for the first two months, followed by a continuation phase with isoniazid and rifampicin for the remaining four months. One of the most significant challenges in TB treatment is the emergence of drug resistance, particularly multi-drug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB). Patients with MDR-TB and XDR-TB require longer treatment durations, more complex and toxic drug regimens, and often face higher rates of treatment failure and mortality. [4,5] Therefore, studying prescription patterns can help identify areas where prescribing practices can be improved, thereby enhancing patient care and public health outcomes. The study has the potential to significantly improve TB treatment protocols by highlighting areas where prescribing practices can be optimized. Enhanced adherence to treatment guidelines will lead to better patient management and outcomes, reducing treatment failure rates and the incidence of drug-resistant TB[6,7]. The findings will provide valuable evidence for refining clinical practices and training healthcare providers in optimal TB treatment strategies.

AIM

To evaluate the prescription patterns of antitubercular drugs and assess drug utilization using WHO core prescribing indicators among tuberculosis patients attending a tertiary care center.

METHODOLOGY

This study was a hospital-based, prospective observational study aimed at evaluating the prescription patterns of antitubercular drugs. The study was conducted over a period of one year from March 2025 – February 2026 after obtaining approval from the Institutional Ethics Committee. The study was conducted at the TB care unit and the Directly Observed Treatment, Short-course (DOTS) center of PBM Hospital, Bikaner. This tertiary care hospital serves as a major referral center for tuberculosis patients in the region. Inclusion criteria involved Inpatients in general medicine wards, TB & chest ward, and ICU, Patients of either gender diagnosed with TB with confirmed laboratory findings, Patients who are willing to participate and provide informed consent.

While Outpatients, Inpatients other than those in the general medicine wards, ICU, TB & chest ward and Pregnant women and children were excluded.

RESULT

Table 1. Baseline characteristics of study subject

		No of patients	Percentage
Age in yrs	<20	4	3.64
	21-40	50	45.45
	41-60	40	36.36
	>60	16	14.55
	Total	**110**	**100.00**
Type of tuberculosis	Pulmonary TB	87	79.09
	Extrapulmonary TB	23	20.91
	Total	**110**	**100.00**
Treatment history	New case	86	78.18
	Previously treated	24	21.82
	Total	**110**	**100.00**
Resistant pattern	DS-TB	93	84.55
	MDR/RR-TB	12	10.91
	Pre-XDR TB	3	2.73
	XDR TB	2	1.81
	Total	**110**	**100.00**
Comorbidity	Hypertension	31	28.18
	Diabetes Mellitus	28	25.45
	COPD	13	11.82
	HIV infection	4	3.64

	Chronic Liver Disease	1	0.91
	No Comorbidity	49	44.55

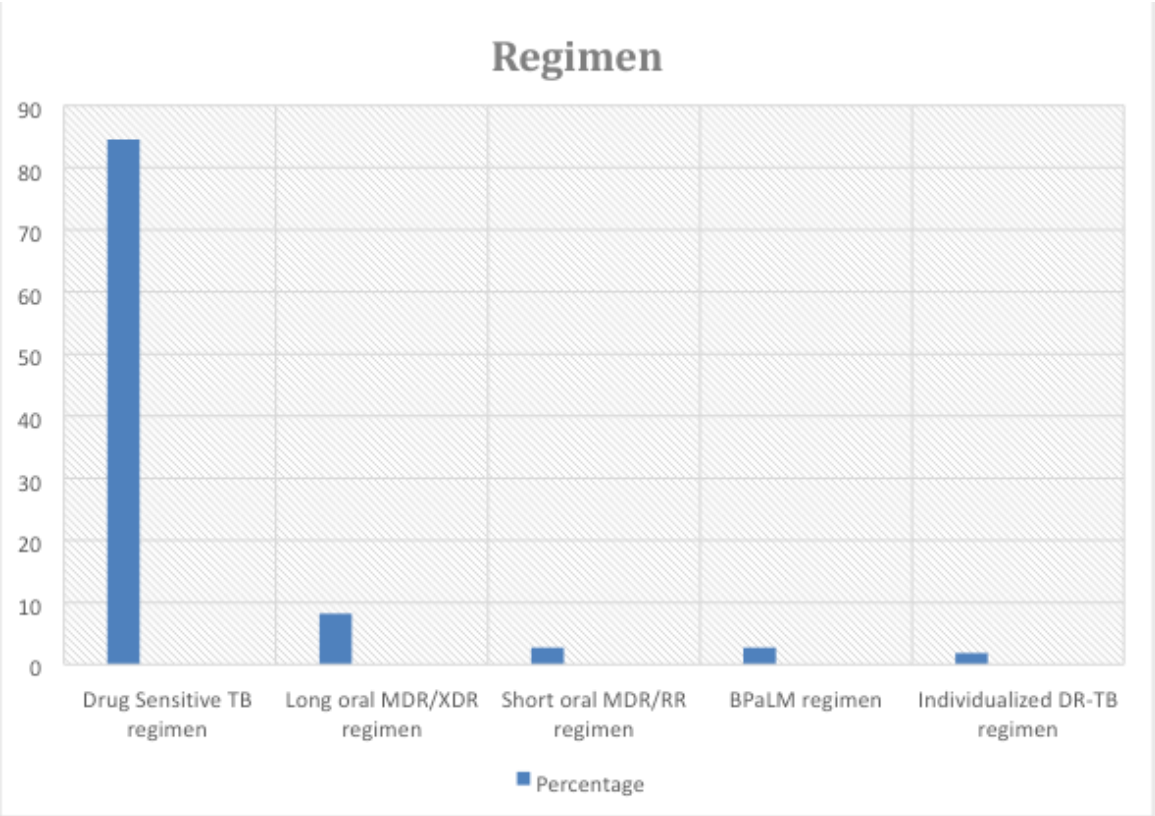
Table 1 shows that a maximum of 45.45% patients were from 21-40 yrs followed by 36.36% patients were from 41-60 yrs age, 14.55% patients were from >60 yrs and 3.64% patients were from <20 yrs. pulmonary TB was the predominant form, accounting for
79.09% of cases. The majority of patients (78.18%) were newly diagnosed cases. Drug sensitive TB constituted the majority (84.55%) and MDR/RR-TB constituted 10.91% of the study population. Pre-XDR and XDR accounted for 4.54% of cases. Hypertension was the most common comorbidity (28.18%) followed by diabetes mellitus (25.45%). Nearly 44.55% patients had no associated comorbidity.

Table 2.WHO core prescribing indicators

WHO core prescribing indicator	Value
Total number of prescription/case sheet analyzed	110
Total number of drugs prescribed	1047
Average number of drugs per prescription	9.52
Total number of drugs prescribed by generic name	978
Percentage of drugs prescribed by generic name	93.41%
Total number of drugs prescribed from NLEM 2022	937
Percentage of drugs prescribed from NLEM 2022	89.49%
Number of encounters with injectables prescribed	22
Percentage of encounters with injectables prescribed	20.00%

Table 2 shows that a total of 1047 drugs were prescribed across 110 patients, with an average of 9.52 drugs per prescription. Generic drug prescribing accounted for 93.41% of all prescribed drugs, while 89.49% of drugs belonged to the National List of Essential Medicines (NLEM) 2022. Injectable medications were prescribed in 20.00% of patient encounters.

Figure 1,2: Antitubercular regimens and Concomitant drug categories prescribed


Regimen
90
80
70
60
50
40
30
20
10
0
Drug Sensitive TB regimen
Long oral MDR/XDR regimen
Short oral MDR/RR regimen
BPaLM regimen
Individualized DR-TB regimen
Percentage

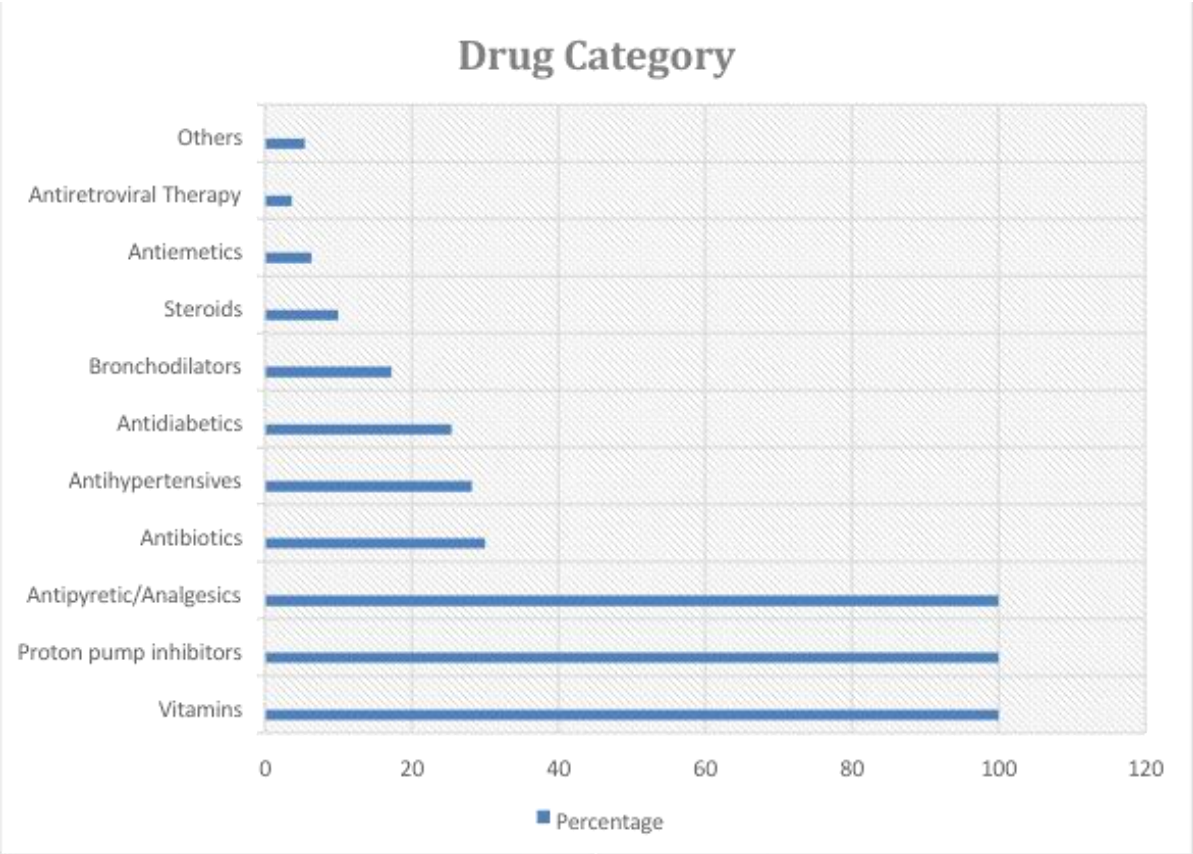

Drug Category
Others
Antiretroviral Therapy
Antiemetics
Steroids
Bronchodilators
Antidiabetics
Antihypertensives
Antibiotics
Antipyretic/Analgesics
Proton pump inhibitors
Vitamins
0
20
40
60
80
100
120
Percentage

Figure 1 shows that the Drug sensitive TB regimen was the most commonly prescribed antitubercular treatment (84.55%), followed by the Long oral MDR regimen (8.18%). Short oral MDR regimen and BPaLM regimens were each prescribed in 2.73% of patients, while Individualized DR-TB regimen accounted for 1.81%. Figure 2 shows that vitamins, PPIs and antipyretic / analgesics were prescribed to all inpatients. Antibiotics, antihypertensives and antidiabetics were the most frequently prescribed additional therapeutic categories.

Table 3. Adverse drug reactions and Drug-Drug interactions (DDI)

ADR	**No of patients**	**Percentage**
Present	34	30.91
Absent	76	69.09
Total	**110**	**100.00**
DDI	**No of patients**	**Percentage**
Present	49	44.55
Absent	61	55.45
Total	**110**	**100.00**

The table shows that ADRs were observed in 30.91% patients. potential drug-drug interactions were identified in 44.55% of patients, whereas 55.45% of patients did not have any clinically significant interaction.

Figure 3: Types of ADR

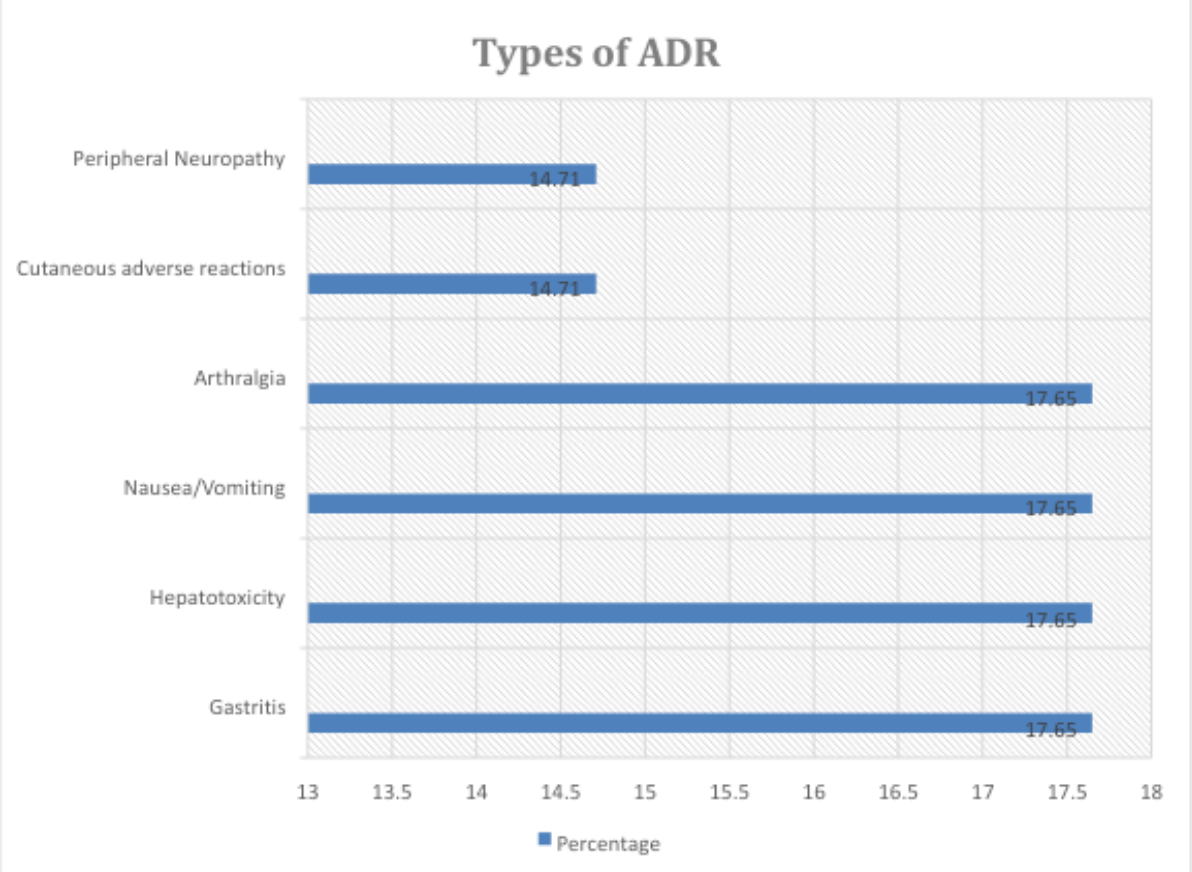


Figure 3 shows that gastritis, hepatotoxicity, nausea/vomiting and arthralgia were the most commonly observed adverse drug reactions, each accounting for 17.65%. Cutaneous adverse reactions and peripheral neuropathy constituted 14.71% each.

Table 4:Severity category of potential drug-drug interactions (Medscape classification)

Severity category	Number of interactions	Percentage
Significant – Monitor closely	72	80.90
Serious – Use alternative	14	15.73
Minor	3	3.37
Contraindicated	0	0.00
Total	**89**	**100.00**

Table 4 shows that a total of 89 potential drug-drug interaction pairs were identified among 49 patients with DDIs. The majority of interactions (80.90%) belonged to the "Significant – Monitor closely" category, while 15.73% were classified as "Serious – Use alternative". No contraindicated drug combinations were encountered.

DISCUSSION

In the present study, the majority of patients belonged to the 21-40 years age group (45.45%), followed by 41-60 years (36.36%). This indicates that tuberculosis predominantly affects the economically productive age group, resulting in significant social and economic consequences. Similar observations were reported by Biradar et al. (2016), where the majority of patients belonged to the 26-35 years age group. Pulmonary TB constituted 79.09% of cases, whereas extrapulmonary TB accounted for 20.91%. Similar findings were reported by Krishnakanth et al. [8](96.7% pulmonary TB). The predominance of pulmonary TB may be attributed to its airborne transmission and greater diagnostic detection through sputum examination and radiological investigations.

Regarding treatment history, 78.18% patients were newly diagnosed cases while 21.82% were previously treated cases. Similar findings were observed by Manikanta et al.[9] (2025), where 91% patients were newly diagnosed. The higher proportion of new cases reflects ongoing transmission within the community and highlights the need for strengthened preventive measures and early diagnosis.

Drug-sensitive TB (DS-TB) constituted 84.55% of cases in the present study. MDR/RR-TB, Pre-XDR TB, and XDR TB accounted for 10.91%, 2.73% and 1.81% respectively. Similar observations were reported by Virak et al.[10], where rifampicin-sensitive TB constituted the majority of cases. The predominance of DS-TB indicates effective implementation of NTEP strategies; however, the presence of MDR/RR-TB, Pre-XDR TB, and XDR TB cases remain a significant public health concern due to their prolonged treatment duration, higher costs, and increased risk of adverse drug reactions.

Tobacco use (42.73%) was the most common risk factor identified in the present study, followed by smoking (40.91%) and alcohol consumption (20.91%).

Hypertension (28.18%) and diabetes mellitus (25.45%) were the most common comorbidities observed. Pandurangan et al. also reported hypertension and diabetes mellitus as major comorbid conditions among tuberculosis patients. Diabetes mellitus is a well-established risk factor for TB because of impaired cellular immunity and delayed sputum conversion. The coexistence of these chronic diseases increases treatment complexity and necessitates careful monitoring.

Evaluation of prescribing practices revealed that 1047 drugs were prescribed across 110 patients, with an average of 9.52 drugs per patient. This relatively higher number reflects the combination therapy of TB, multiple comorbidities, supportive medications, nutritional supplements and drugs prescribed for management of adverse effects.

Generic prescribing accounted for 93.41% of all prescribed drugs, which is comparable to the findings of Virak et al. (90.9%). This high percentage reflects good adherence to NTEP recommendations and promotes cost-effective therapy.

A total of 89.49% of prescribed drugs belonged to the National List of Essential Medicines (NLEM) 2022. Similar observations were reported by Virak et al.[10] (77.1%) . High utilization of essential medicines indicates rational prescribing practices and compliance with national treatment guidelines. Injectable drugs were prescribed in only 20% of encounters, which reflects the current shift towards all-oral regimens for drug resistant TB and reduced dependence on injectable agents.

The present study primarily aimed to evaluate the prescribing pattern of antitubercular drugs among patients receiving treatment under NTEP. Analysis of treatment regimens revealed that DS-TB regimen constituted 84.55%, making it the most commonly prescribed regimen. Long oral MDR/XDR regimen, short oral MDR/RR regimen, BPaLM regimen and individualized DR-TB regimens
accounted for 8.18%, 2.73%, 2.73% and 1.81% of prescriptions respectively. The predominance of the DS-TB regimen observed in the present study is expected because drug sensitive TB continues to represent the majority of tuberculosis cases in India. Similar findings were reported by Virak et al. [10](2024) and Krishnakanth et al[8]. (2020), who observed that standard first-line antitubercular regimens constituted the majority of prescriptions. The widespread use of standard DS-TB regimens indicates adherence to NTEP recommendations and reflects appropriate utilization of first line antitubercular drugs.

The standard DS-TB regimen consisting of isoniazid, rifampicin, pyrazinamide and ethambutol remains the cornerstone of tuberculosis treatment because of its proven efficacy, shorter treatment duration, lower cost and favourable treatment outcomes. The high utilization of this regimen in the present study demonstrates rational prescribing practices and conformity with national treatment guidelines.

Drug-resistant TB constituted 15.45% of the study population. Among these patients, long oral MDR/XDR regimens were prescribed more frequently than short oral MDR/RR regimens. The increasing utilization of all-oral drug resistance regimens observed in the present study reflects the transition from injectable-containing regimens to safer and more effective oral treatment options recommended by WHO and NTEP. These regimens improve treatment adherence, reduce hospitalization requirements and minimize injectable-related adverse effects such as ototoxicity and nephrotoxicity.

Proton pump inhibitors were commonly prescribed for prevention and management of gastrointestinal adverse effects associated with antitubercular therapy. Gastritis, dyspepsia and epigastric discomfort are frequent complaints among patients receiving ATT, and therefore prophylactic use of acid-suppressive therapy was common.

Antipyretic and analgesic medications were prescribed for symptomatic management of fever, myalgia, arthralgia, headache, etc. Such supportive treatment improves patient comfort and may contribute to better treatment adherence.

Antihypertensive drugs and antidiabetic medications constitute an important component of concomitant therapy because hypertension and diabetes mellitus were among the most common comorbidities observed in the study population. Appropriate management of these chronic diseases is essential as uncontrolled diabetes has been associated with delayed sputum conversion, increased treatment failure and poor clinical outcomes.

Bronchodilators and corticosteroids were prescribed in patients with associated respiratory conditions such as COPD, bronchial asthma, pleural disease and severe inflammatory manifestations. These medications contributed to symptomatic improvement and better respiratory function.

Similar findings were reported by Shah et al.[11], where vitamins, minerals, proton pump inhibitors and supportive medications constituted major concomitant prescriptions. Adverse drug reactions were

observed in 30.91% of patients. Gastritis, hepatotoxicity, nausea/vomiting and arthralgia were the most frequently reported
ADRS (17.65% each), followed by cutaneous reactions and peripheral neuropathy (14.71% each).
Potential drug-drug interactions were identified in 44.55% of patients and a total of 89 interaction pairs detected. It was done using the Medscape drug interaction checker. Among this, 80.9% belonged to the "Significant – Monitor closely" category and 15.73% were classified as "Serious – Use alternative". No contraindicated combinations were observed.
Similar findings were reported by Biradar et al[12]., who identified a substantial number of potential drug interactions among TB patients. Rifampicin, being a potent inducer of hepatic microsomal enzymes, is responsible for many clinically relevant interactions involving antidiabetic agents, antihypertensives, Antiretroviral drugs and other concomitant medications.

CONCLUSION

Tuberculosis predominantly affected young and middle-aged adults, males, rural residents and individuals belonging to lower socioeconomic groups. Pulmonary tuberculosis was the most common clinical presentation, and the majority of patients were newly diagnosed cases. Drug-sensitive tuberculosis constituted the majority of cases, with standard drug-sensitive TB regimens being the most frequently prescribed
antitubercular treatment. High rates of generic prescribing (93.41%) and NLEM prescribing (89.49%) indicate good adherence to rational prescribing practices and NTEP recommendations. Long Oral MDR/XDR regimens, Short Oral MDR/RR regimens and BPaLM regimens were utilized appropriately in drug-resistant tuberculosis patients, reflecting the adoption of current national treatment strategies.
Vitamins, proton pump inhibitors and analgesics were the most commonly prescribed concomitant medications, while antibiotics, antihypertensives and antidiabetic drugs were frequently prescribed according to clinical requirements and associated comorbidities.
Adverse drug reactions were observed in 30.91% of patients, with gastritis, hepatotoxicity, nausea/vomiting and arthralgia being the most commonly reported adverse effects.
Potential drug-drug interactions were identified in a substantial proportion of patients, emphasizing the importance of regular medication review and pharmacovigilance.
Overall, the prescribing pattern of antitubercular drugs at the study centre was found to be rational and largely consistent with current NTEP guidelines and WHO core prescribing indicators.

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