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A Prospective Observational Study to Monitor the Adverse Drug Reactions and Their Effect on Prescription Adherence and Treatment Outcomes In Patients of Tuberculosis

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ABSTRACT

Background: Tuberculosis remains a major public health problem, and prolonged anti-tubercular therapy (ATT) is frequently associated with adverse drug reactions (ADRs), which may negatively affect treatment adherence and outcomes. Monitoring ADRs is essential for improving treatment success under the National Tuberculosis Elimination Programme.

Aim and Objectives: To monitor adverse drug reactions among tuberculosis patients receiving ATT and to evaluate their effect on prescription adherence and treatment outcomes.

Materials and Methods: This prospective observational study was conducted among 394 tuberculosis patients attending the Departments of Respiratory Medicine and General Medicine at Dr Ram Manohar Lohia Institute of Medical Sciences, Lucknow. Patients receiving ATT under NTEP were followed prospectively during intensive and continuation phases of therapy. ADRs, prescription adherence, and treatment outcomes were assessed using a structured case record form and follow-up evaluation. Statistical analysis was performed using Microsoft Excel and R software. Chi-square test was used for association analysis, and $p < 0.05$ was considered statistically significant.

Results: Among 394 patients, 119 patients developed at least one ADR, giving an overall ADR proportion of 30.2%. Hepatic toxicity was the most common ADR (37.8%), followed by gastrointestinal toxicity (27.7%), arthralgia (26.9%), and ocular toxicity (26.9%). Most ADRs were mild (52.9%) or moderate (38.7%) in severity. ADR occurrence was significantly higher among drug-resistant tuberculosis patients (62.0%) compared to drug-sensitive patients (25.6%) ($p < 0.001$). Poor prescription adherence was significantly more common among patients with ADRs (25.2%) than those without ADRs (12.4%) (OR = 2.39, $p = 0.0025$). Unfavourable treatment outcomes were also significantly higher in ADR-positive patients (34.5%) compared to ADR-negative patients (24.0%) (OR = 1.66, $p = 0.0435$). Poor adherence was significantly associated with unfavourable treatment outcomes (OR = 2.28, $p = 0.0051$).

Conclusion: Adverse drug reactions are common among tuberculosis patients receiving ATT and significantly affect prescription adherence and treatment outcomes. Early identification and appropriate management of ADRs, along with

regular adherence monitoring and patient counselling, are essential for improving treatment success under the NTEP.

Keywords*: Tuberculosis; Anti-tubercular therapy; Adverse drug reactions; Prescription adherence; Treatment outcome; Pharmacovigilance; NTEP.*

INTRODUCTION

Tuberculosis (TB) is a chronic infectious disease caused by *Mycobacterium tuberculosis* and continues to remain a major global public health problem despite the availability of effective diagnostic and therapeutic strategies (1). Tuberculosis primarily affects the lungs, although extrapulmonary involvement can occur in almost every organ system. According to the World Health Organisation Global Tuberculosis Report, TB remains one of the leading causes of mortality due to infectious diseases worldwide, especially in low- and middle-income countries (2). India contributes a substantial proportion of the global tuberculosis burden and continues to face major challenges related to diagnosis, treatment adherence, drug resistance, and treatment-related adverse effects (3).

To combat the increasing burden of tuberculosis, the Government of India implemented the National Tuberculosis Elimination Programme (NTEP), formerly known as the Revised National Tuberculosis Control Programme (RNTCP), to achieve TB elimination through early diagnosis, standardised treatment regimens, and patient-centred care (4). Standard anti-tubercular therapy (ATT) under NTEP includes multiple first-line drugs such as isoniazid, rifampicin, pyrazinamide, and ethambutol administered for prolonged durations. Although these drugs are highly effective, they are associated with various adverse drug reactions (ADRs), which may affect patient safety, treatment adherence, and therapeutic outcomes (5).

Adverse drug reactions during ATT range from mild gastrointestinal intolerance to severe hepatotoxicity, hypersensitivity reactions, neurological toxicity, haematological abnormalities, and ocular complications (6). Hepatotoxicity is among the most commonly reported ADRs associated with anti-tubercular therapy and may lead to interruption or discontinuation of treatment (7). Drug-resistant tuberculosis, including multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB), requires prolonged use of second-line anti-tubercular drugs, which are generally associated with a higher incidence of ADRs and poorer tolerability (8).

Prescription adherence is one of the most important determinants of successful tuberculosis treatment. Inadequate adherence may result in treatment failure, relapse, emergence of drug resistance, prolonged infectivity, and increased mortality (9). Several factors influence adherence during ATT, including socioeconomic status, pill burden, duration of therapy, comorbidities, and particularly the occurrence of adverse drug reactions. Patients experiencing ADRs often intentionally interrupt or discontinue therapy because of discomfort and fear of toxicity (10). Therefore, monitoring and early management of ADRs play a critical role in ensuring successful treatment completion.

Pharmacovigilance during anti-tubercular therapy has gained increasing importance under programmatic management strategies recommended by WHO and NTEP (11). Early identification, reporting, and management of ADRs can reduce treatment interruption and improve adherence and therapeutic outcomes. However, there remains limited prospective Indian data evaluating the relationship between ADRs, prescription adherence, and treatment outcomes among tuberculosis patients receiving ATT under routine clinical conditions.

Hence, the present prospective observational study was undertaken to monitor adverse drug reactions among tuberculosis patients receiving anti-tubercular therapy under the National Tuberculosis Elimination Programme and to evaluate the effect of ADRs on prescription adherence and treatment outcomes.

MATERIALS AND METHODS

Study Design and Setting

This prospective observational study was conducted among patients diagnosed with tuberculosis attending the Outpatient Department (OPD) and Inpatient Department (IPD) of the Department of Respiratory Medicine and the Department of General Medicine at Dr. Ram Manohar Lohia Institute of Medical Sciences. The Departments of Respiratory Medicine and General Medicine were responsible for patient diagnosis, clinical management, and initiation of anti-tubercular therapy under the National Tuberculosis Elimination Programme (NTEP). The Department of Pharmacology coordinated patient follow-up, monitoring of adverse drug reactions (ADRs), assessment of prescription adherence, and evaluation of treatment outcomes.

Study Duration

The study was conducted over a period of 18 months. Recruitment of participants, baseline clinical assessment, follow-up during the intensive and continuation phases of anti-tubercular therapy, data collection, and monitoring were carried

out during the first 12 months. The subsequent 6 months were utilized for data compilation, statistical analysis, interpretation of findings, thesis writing, and preparation of the final manuscript.

Ethical Approval

Prior approval for the study was obtained from the Institutional Ethics Committee of Dr. Ram Manohar Lohia Institute of Medical Sciences. Written informed consent was obtained from all participants before enrollment into the study. Participation was voluntary, and participants were informed regarding their right to withdraw from the study at any stage without affecting their standard treatment and medical care. Confidentiality of patient identity and clinical information was maintained throughout the study. The study was conducted in accordance with the ethical principles laid down in the Declaration of Helsinki.

Study Population

The study population consisted of patients diagnosed with pulmonary or extrapulmonary tuberculosis and registered under the Tuberculosis Unit functioning under the National Tuberculosis Elimination Programme (NTEP). Eligible participants fulfilling the inclusion criteria and willing to participate were consecutively enrolled in the study.

Sample Size

The sample size was calculated based on the prevalence of adverse drug reactions reported in a previous study by Mate et al., in which the proportion of ADRs among tuberculosis patients was found to be 36.13%. The sample size was estimated using the following formula:

$$n = \frac{Z^2 pq}{d^2}$$

Where:

- n= required sample size
- Z= standard normal variate at 95% confidence interval (1.96)
- p= prevalence of ADRs (36.13%)
- $q = 1 - p$
- d= allowable error (5%)

The calculated sample size was 355. After adding 10% to compensate for possible loss to follow-up and incomplete data, the final sample size was increased to 394 participants.

Inclusion Criteria

1. Patients diagnosed with tuberculosis and undergoing treatment under the National Tuberculosis Elimination Programme attending the OPD/IPD of the Departments of Respiratory Medicine and General Medicine at Dr. Ram Manohar Lohia Institute of Medical Sciences.
2. Patients aged more than 18 years.

Exclusion Criteria

1. Critically ill patients.
2. Patients with human immunodeficiency virus (HIV) infection.
3. Patients with abnormal baseline liver function tests (LFT) or kidney function tests (KFT).
4. Patients developing adverse drug reactions attributable to medications prescribed for other comorbid illnesses.

Data Collection Procedure

Patients attending the OPD and IPD of the Departments of Respiratory Medicine and General Medicine who were diagnosed with tuberculosis and fulfilled the study eligibility criteria were screened consecutively and enrolled after obtaining written informed consent. Baseline demographic and clinical information including age, sex, type of tuberculosis, associated risk factors, comorbidities, treatment regimen, and relevant laboratory investigations were recorded at initiation of anti-tubercular therapy.

All enrolled participants received standard NTEP-based anti-tubercular treatment and were followed prospectively during both the intensive and continuation phases of therapy. During scheduled follow-up visits, participants were assessed for the occurrence of adverse drug reactions, prescription adherence, and clinical response to treatment. Patients were instructed to report any discomfort, interruption of therapy, or suspected adverse drug reaction during the treatment period. Treatment outcomes were documented at the completion of therapy according to NTEP and World Health Organization (WHO) treatment outcome definitions.

Outcome Measures
The primary outcome measure was the proportion of patients developing adverse drug reactions during anti-tubercular therapy.

Secondary outcome measures included:
- Assessment of prescription adherence during treatment.
- Evaluation of treatment outcomes at the end of therapy.

Treatment outcomes were categorised as:
- Cured
- Treatment completed
- Treatment failure
- Lost to follow-up
- Death

These categories were defined according to NTEP and WHO guidelines.

Tools for Data Collection
Data were collected using a structured Case Record Form (CRF), which included demographic details, clinical history, risk factors, comorbidities, adverse drug reactions, treatment adherence, and outcome parameters. A predesigned, investigator-developed structured questionnaire was used to assess prescription adherence during routine follow-up visits.

Timeline of the Study
The study was conducted over a total duration of 18 months. Recruitment of tuberculosis patients, baseline evaluation, follow-up, and data collection were conducted during the first 12 months of the study. The subsequent 6 months (12–18 months) were utilised for data compilation, statistical analysis, interpretation of results, and preparation of the thesis manuscript.

Statistical Analysis
Data entry and preliminary data cleaning were performed using Microsoft Excel. Statistical analysis was carried out using R statistical software. Continuous variables were expressed as mean ± standard deviation, while categorical variables were represented as frequencies and percentages. The Shapiro–Wilk test was used to assess the normality of data distribution. Chi-square test was applied to determine associations between categorical variables. A p-value of less than 0.05 was considered statistically significant.

Ethical Considerations
The study was conducted in accordance with ethical principles for biomedical research involving human participants. Institutional Ethics Committee approval was obtained before commencement of the study. Written informed consent was obtained from all participants before enrollment, and confidentiality of patient-related information was strictly maintained throughout the study period.

RESULT AND OBSERVATIONS

Table 1: Baseline Demographic Characteristics of Study Participants (n = 394)

Variable	Category	Number of Patients (n)	Percentage (%) / Value
Age (years)	Mean ± SD	—	45.2 ± 14.7
Age Group (years)	18–30	72	18.3%
	31–45	121	30.7%
	46–60	128	32.5%
	>60	73	18.5%
Gender	Male	281	71.3%
	Female	113	28.7%

The mean age of the study population was 45.2 ± 14.7 years, with the majority of participants belonging to the 46–60 years age group. Male participants constituted the predominant proportion of the study cohort.

Table 2 Anthropometric Profile of Study Participants (n = 394)

Variable	Category / Summary	Number of Patients (n)	Percentage (%) / Value
Height (cm)	Mean ± SD	—	162.2 ± 8.9
Weight (kg)	Mean ± SD	—	48.8 ± 9.8
BMI (kg/m²)	Mean ± SD	—	18.7 ± 3.2

BMI Category	Underweight (<18.5)	195	49.5%
	Normal (18.5–24.9)	185	47.0%
	Overweight (25–29.9)	14	3.6%

Table 3: Baseline TB Disease Profile, Treatment Regimen, and Risk Factors of Study Participants (n = 394)

Variable	Category	Number of Patients (n)	Percentage (%)
TB Site	Pulmonary TB	328	83.2%
	Extra-pulmonary TB	66	16.8%
Type of TB (Programmatic Categories)	Drug-sensitive (DS)	344	87.3%
	MDR-TB	28	7.1%
	RR-TB	17	4.3%
	XDR-TB	5	1.3%
Resistance Status	Drug-sensitive	344	87.3%
	Drug-resistant (MDR/RR/XDR)	50	12.7%
Standardized Regimen	DS regimen (2HRZE/4HRE)	344	87.3%
	MDR (All-oral longer regimen)	28	7.1%
	RR-TB regimen	17	4.3%
	XDR regimen	5	1.3%
Diabetes Mellitus (DM)	No	338	85.8%
	Yes	56	14.2%
Alcohol Use	No	268	68.0%
	Yes	126	32.0%
Smoking	No	260	66.0%
	Yes	134	34.0%
Combined Risk-factor Patterns	None recorded	182	46.2%
	Smoking only	57	14.5%
	Alcohol only	51	12.9%
	Alcohol + Smoking	48	12.2%
	DM + Smoking	16	4.1%
	DM + Alcohol	14	3.6%
	DM + Alcohol + Smoking	13	3.3%
	DM only	13	3.3%

Table 4: Overall Proportion and Pattern of Adverse Drug Reactions among TB Patients on ATT under NTEP (n = 394)

Parameter / ADR Pattern	Number of Patients (n)	Percentage (%)
Total number of patients	394	100%
Patients with ADRs	119	30.2%
Patients without ADRs	275	69.8%
95% Confidence Interval for ADR proportion	—	25.9–34.9%
Types of ADRs among patients with ADRs (n = 119)		
Hepatic toxicity	45	37.8%
Gastrointestinal toxicity	33	27.7%
Arthralgia	32	26.9%
Ocular toxicity	32	26.9%
Cutaneous reactions	28	23.5%
Hematological reactions	28	23.5%
Neurological reactions	27	22.7%
Others	28	23.5%

Table 5: Distribution of Adverse Drug Reactions According to Gender, Age Group, and BMI Category

Variable	Category	Total Patients (N)	ADR Present (n)	ADR (%)	p-value
Gender	Male	281	91	32.4%	0.137
	Female	113	28	24.8%	
Age Group (years)	18–30	72	24	33.3%	0.688

	31–45	121	37	30.6%	
	46–60	128	40	31.3%	
	>60	73	18	24.7%	
BMI Category (kg/m²)	Underweight (<18.5)	195	59	30.3%	0.562
	Normal (18.5–24.9)	185	54	29.2%	
	Overweight (25–29.9)	14	6	42.9%	

Table 6 : Distribution of Adverse Drug Reactions According to Clinical Characteristics and Risk Factors

Variable	Category	Total Patients (N)	ADR Present (n)	ADR (%)	p-value
TB Site	Pulmonary TB	328	100	30.5%	0.784
	Extra-pulmonary TB	66	19	28.8%	
Drug Resistance Status	Drug-sensitive TB	344	88	25.6%	<0.001
	Drug-resistant TB	50	31	62.0%	
Diabetes Mellitus Status	No diabetes	338	102	30.2%	0.978
	Diabetes present	56	17	30.4%	
Alcohol Use	No	268	86	32.1%	0.234
	Yes	126	33	26.2%	
Smoking Status	Non-smoker	260	76	29.2%	0.558
	Smoker	134	43	32.1%	

Table 7 : Severity Distribution of Adverse Drug Reactions According to Modified Hartwig and Siegel Severity Scale (n = 119)

Severity Category	Number of Patients (n)	Percentage (%)
Mild	63	52.9%
Moderate	46	38.7%
Severe	10	8.4%

Table 8 : Association of ADR Occurrence and Severity with Prescription Adherence among TB Patients on ATT

Variable	Category	Good Adherence n (%)	Poor Adherence n (%)	Total	Statistical Significance
ADR Status	ADR (–)	241 (87.6%)	34 (12.4%)	275	$\chi^2 = 9.153$, p = 0.0025
	ADR (+)	89 (74.8%)	30 (25.2%)	119	OR = 2.39 (95% CI: 1.38–4.13)
ADR Severity	Mild	47 (74.6%)	16 (25.4%)	63	$\chi^2 = 0.164$, p = 0.921
	Moderate	35 (76.1%)	11 (23.9%)	46	
	Severe	7 (70.0%)	3 (30.0%)	10	
	Total	89 (74.8%)	30 (25.2%)	119	

Table 9: Association between ADR Occurrence and Subtype of Poor Adherence (n = 64)

ADR Status	Intentional Poor Adherence n (%)	Unintentional Poor Adherence n (%)	Total	Statistical Significance
ADR (+)	20 (66.7%)	10 (33.3%)	30	$\chi^2 = 12.46$, p = 0.0004
ADR (–)	9 (26.5%)	25 (73.5%)	34	
Total	29 (45.3%)	35 (54.7%)	64	

Table 10: Association between ADR Status and Treatment Outcomes among TB Patients on ATT (n = 394)

Variable	Category	ADR (–) n (%) (n = 275)	ADR (+) n (%) (n = 119)	Total (n)	Statistical Significance
Binary Treatment Outcome	Treatment success	209 (76.0%)	78 (65.5%)	287	$\chi^2 = 4.075$, p = 0.0435
	Unfavourable outcome	66 (24.0%)	41 (34.5%)	107	OR = 1.66 (95% CI: 1.04–2.66)
Detailed Treatment Outcome Categories	Cure	150 (54.5%)	56 (47.1%)	206	p = 0.343
	Treatment	59 (21.5%)	22 (18.5%)	81	

	completed				
	Lost to follow-up (LTFU)	27 (9.8%)	17 (14.3%)	44	
	Failure	17 (6.2%)	10 (8.4%)	27	
	Death	9 (3.3%)	8 (6.7%)	17	
	Switch of regimen	13 (4.7%)	6 (5.0%)	19	

Table 11: Association of ADR Severity and Prescription Adherence with Treatment Outcome

Variable	Category	Treatment Success n (%)	Unfavourable Outcome n (%)	Total	Statistical Significance
ADR Severity among ADR-positive Patients (n = 119)	Mild	45 (71.4%)	18 (28.6%)	63	$\chi^2 = 1.31$, $p = 0.518$
	Moderate	29 (63.0%)	17 (37.0%)	46	
	Severe	6 (60.0%)	4 (40.0%)	10	
	Total	80 (67.2%)	39 (32.8%)	119	
Prescription Adherence (n = 394)	Good adherence	250 (75.8%)	80 (24.2%)	330	$\chi^2 = 7.842$, $p = 0.0051$
	Poor adherence	37 (57.8%)	27 (42.2%)	64	OR = 2.28 (95% CI: 1.31–3.98)

DISCUSSION

The present prospective observational study was conducted to evaluate adverse drug reactions associated with anti-tubercular therapy and their impact on prescription adherence and treatment outcomes among tuberculosis patients receiving treatment under the National Tuberculosis Elimination Programme. Tuberculosis remains a significant public health concern in developing countries, where prolonged multidrug therapy, malnutrition, and comorbid conditions contribute substantially to morbidity and treatment-related complications (1,2).

In the present study, the mean age of participants was 45.2 ± 14.7 years, with the majority belonging to the 46–60 years age group. Similar findings have been reported in previous studies, where tuberculosis was found to be more common among middle-aged adults, representing the economically productive population group (12). Male predominance was observed in the present cohort, with males constituting 71.3% of participants. This finding is consistent with previous epidemiological studies demonstrating higher tuberculosis prevalence among males, possibly due to occupational exposure, smoking, alcohol consumption, and healthcare-seeking behaviour differences (13).

A significant proportion of patients in the present study were underweight, reflecting the close association between tuberculosis and undernutrition. Malnutrition impairs host immunity and increases susceptibility to active tuberculosis, while TB itself contributes to weight loss and nutritional deficiency (14). The coexistence of undernutrition and tuberculosis may also increase vulnerability to adverse drug reactions and poor treatment outcomes.

Pulmonary tuberculosis constituted the majority of cases in the study, which is comparable with national and international epidemiological trends (2,3). Drug-sensitive tuberculosis represented the predominant category, while drug-resistant tuberculosis accounted for a smaller but clinically important proportion of patients. Drug-resistant TB remains a major challenge because of prolonged therapy duration, increased toxicity, and reduced treatment success rates (8).

The overall proportion of ADRs observed in the present study was 30.2%, which is comparable to findings reported in previous Indian and international studies evaluating ADRs during anti-tubercular therapy (15,16). Differences in ADR frequency among studies may be due to variations in patient characteristics, treatment regimens, nutritional status, and methods of ADR monitoring. Hepatic toxicity was the most common ADR observed in the present study, followed by gastrointestinal adverse effects, arthralgia, and ocular toxicity. Similar findings have been documented in earlier studies where hepatotoxicity was identified as the most frequent and clinically significant adverse effect associated with ATT (7,17).

The high frequency of hepatotoxicity may be attributed to the combined hepatotoxic potential of isoniazid, rifampicin, and pyrazinamide. Gastrointestinal symptoms such as nausea, vomiting, abdominal discomfort, and anorexia were also commonly reported and may significantly compromise patient compliance with prolonged treatment (6). Arthralgia observed in the study is likely attributable to pyrazinamide-induced hyperuricemia, while ocular toxicity may be related to ethambutol administration.

Most ADRs in the present study were mild to moderate in severity according to the Modified Hartwig and Siegel Severity Scale, whereas severe ADRs constituted only a small proportion of cases. Similar severity patterns have been

reported in previous pharmacovigilance studies on ATT (18). This finding suggests that the majority of ADRs can be effectively managed through early recognition, counselling, symptomatic treatment, and close monitoring without permanent discontinuation of therapy.

No statistically significant association was observed between ADR occurrence and age, gender, BMI, diabetes mellitus, smoking, alcohol use, or site of tuberculosis. However, ADR occurrence was significantly higher among patients with drug-resistant tuberculosis. This finding is expected because drug-resistant TB treatment regimens involve prolonged administration of second-line drugs with greater toxicity profiles and higher pill burden (8).

An important finding of the present study was the significant association between ADR occurrence and poor prescription adherence. Patients who developed ADRs had significantly higher odds of poor adherence compared to those without ADRs. Similar observations have been reported in previous studies where ADRs were identified as one of the strongest predictors of treatment interruption and non-compliance (10,19). Intentional non-adherence was substantially more common among ADR-positive patients, indicating that treatment-related discomfort directly influences patient behaviour and continuation of therapy.

The present study also demonstrated a significant association between ADR occurrence and unfavourable treatment outcomes. Patients experiencing ADRs had higher proportions of treatment failure, death, loss to follow-up, and regimen switching compared to ADR-negative patients. Although the detailed treatment outcome distribution did not achieve statistical significance, binary outcome analysis revealed a meaningful association between ADRs and unfavourable outcomes. These findings indicate that ADRs may negatively affect treatment success through interruption of therapy, poor adherence, and treatment modifications.

Furthermore, poor adherence itself was significantly associated with unfavourable treatment outcomes. Patients with poor adherence had more than two-fold higher odds of unfavourable outcomes compared to adherent patients. Inadequate adherence during anti-tubercular therapy is a well-recognised contributor to treatment failure, relapse, and emergence of drug-resistant tuberculosis (9,20).

Although increasing ADR severity showed a trend toward progressively higher unfavourable outcomes, the association did not reach statistical significance. This may be due to the relatively small number of severe ADR cases included in the study. Nevertheless, severe ADRs may still have important clinical implications because they frequently necessitate hospitalisation, treatment interruption, or modification of anti-tubercular regimens.

The present study has several strengths, including its prospective design, systematic follow-up, and simultaneous evaluation of ADRs, adherence, and treatment outcomes under real-world programmatic conditions. However, certain limitations should be acknowledged. Being a single-centre study, the generalizability of findings may be limited. Some mild ADRs may have remained underreported, and adherence assessment partly relied on self-reporting, which may introduce reporting bias.

Overall, the findings of the present study highlight the importance of active pharmacovigilance and regular patient monitoring during anti-tubercular therapy. Early identification and prompt management of ADRs may improve treatment adherence and optimise therapeutic outcomes. Strengthening patient counselling, nutritional support, and individualised management strategies may further reduce treatment interruptions and contribute to successful tuberculosis control under the National Tuberculosis Elimination Programme.

CONCLUSION

Adverse drug reactions were observed in 30.2% of tuberculosis patients receiving anti-tubercular therapy under the National Tuberculosis Elimination Programme. Hepatic toxicity was the most common ADR, and most reactions were mild to moderate in severity. Drug-resistant tuberculosis patients showed significantly higher ADR occurrence.

ADRs were significantly associated with poor prescription adherence and unfavourable treatment outcomes. Poor adherence itself was also strongly associated with reduced treatment success. These findings highlight the importance of early detection and management of ADRs, regular patient counselling, and adherence monitoring to improve treatment outcomes in tuberculosis patients receiving ATT under NTEP.

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