

Assessing the Frequency and Severity of Adverse Drug Reactions in Drug-Sensitive Tuberculosis Regimen: A Prospective Observational Study

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ABSTRACT

Background: Tuberculosis (TB) is a significant national health issue of India, and the multidrug regimen afflicted to treat Drug Sensitive TB (DSTB) is commonly linked with Adverse Drug Reactions (ADRs) that may jeopardize the treatment adherence and the outcome. **Objectives:** To assess the frequency and severity of ADRs associated with first-line anti-tubercular drugs (isoniazid, rifampicin, pyrazinamide and ethambutol) among patients receiving treatment for DSTB. **Materials and Methods:** A prospective, observational study was conducted over six months in the Department of Pulmonology, Durgabhai Deshmukh Hospital and Research Centre, Hyderabad. The study involved 60 microbiologically verified drug-sensitive patients of TB. Adverse drug reactions were observed and evaluated in terms of type, frequency, severity and causative drug. The analysis of data was done with the chi-square test and $p < 0.05$ as the statistically significant level. **Results:** Among 60 drug-sensitive tuberculosis patients, arthritis (26.7%), rash (23.3%), gastrointestinal upset (15%), and hepatotoxicity (15%) were the most common adverse drug reactions. Pyrazinamide was the most frequently implicated drug (43.3%), followed by rifampicin (25%), isoniazid (23.3%), and ethambutol (8.3%). Most ADRs were mild (41.7%), while pyrazinamide caused most moderate reactions and isoniazid and rifampicin accounted for the majority of severe ADRs. **Conclusion:** Patients on first-line DSTB therapy are prone to adverse drug reactions with pyrazinamide, rifampicin and isoniazid having the highest risk especially in arthritis, rash and hepatotoxicity. Structured pharmacovigilance and early clinical monitoring are essential to detect and manage ADRs promptly and to safeguard treatment adherence.

Keywords: Adverse Drug Reactions, Drug-sensitive Tuberculosis, Ethambutol, Isoniazid, Pyrazinamide, Pharmacovigilance, Rifampicin, Tuberculosis.

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INTRODUCTION

Tuberculosis (TB) is a chronic infectious disease, which is caused by organisms of the *Mycobacterium tuberculosis* Complex (MTBC). The infection may spread to extrapulmonary organs like the kidneys, spine and central nervous system although the lungs are the most common area affected. Infection with *M. tuberculosis* progresses through defined stages -exposure, latent infection and active disease -and only a minority of latently infected individuals, roughly 10%, go on to develop active TB, which is fatal in nearly half of untreated cases.

The pathogen avoids intracellular killing in alveolar macrophages, resulting in a granuloma; in immunocompetent hosts the bacilli

in the granuloma are in a dormant form, but immunosuppression due to HIV co-infection or malnutrition and other conditions may allow the caseation, cavitation and reactivation of the pathology to active disease (Houben *et al.*, 2006). Described the array of mechanisms by which pathogenic mycobacteria manipulate host immune signalling to persist within macrophages, while Jo highlighted the central role of pattern-recognition receptors such as toll-like receptors in shaping the innate immune response to *M. tuberculosis*, an interaction that also underlies opportunities for host-directed adjunct therapies (Houben *et al.*, 2006; Jo, 2008).

Globally and in India, TB continues to impose a substantial burden. In the year 2012 it was estimated by World Health Organization that there were about 8.6 million TB cases globally, of which Asia and Africa bore most of the burden and India and China bore about 38% of the total burden with only 66% of the cases being detected in the year 2012; the case detection rate was only 66 in the year 2012, leaving roughly one-third of cases undiagnosed (WHO, 2012). Sulis and colleagues noted that despite improvements in case detection and treatment success attributable to the DOTS strategy, drug-resistant TB and HIV



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co-infection continue to undermine control efforts in several regions (Sulis *et al.*, 2014). In the Indian context (Skoura *et al.*, 2015), observed that smear-positive pulmonary TB prevalence ranges from 0.6 to 7.6 per 1000 population and that multidrug resistance, while low among new cases, is markedly higher among previously treated patients (Skoura *et al.*, 2015).

Standard treatment for Drug-Sensitive TB (DSTB) consists of an intensive phase followed by a continuation phase using the four first-line agents -isoniazid, rifampicin, pyrazinamide and ethambutol-administered for a minimum of six months. Although very effective, this regimen has been known to cause a significant range of Adverse Drug Reactions (ADRs). This hepatotoxicity with isoniazid has a reported average incidence of 9.2 per 1000 compliant patients and a case fatality rate of 4.7, Forget and Menzies and that cutaneous, gastrointestinal, haematological, neurological and renal adverse effects collectively lead to treatment discontinuation in up to 10% of patients (Forget and Menzies, 2006). Subsequent population-based work by Marra *et al.* (2007) which modelled drug regimens as time-dependent variables rather than treating individual drugs in isolation, identified pyrazinamide-containing regimens as consistently associated with a higher incidence of serious ADRs, including hepatitis, gastrointestinal disturbance and skin rash, independent of the phase of therapy (Marra *et al.*, 2007; Yee *et al.*, 2003). Similarly found that pyrazinamide was more often responsible for rash and hepatotoxicity than the other first-line agents, and that older age, female sex, HIV-positive status and Asian ethnicity were associated with a higher risk of serious ADRs (Yee *et al.*, 2003; Kwon *et al.*, 2020). Found that a large cohort of TB patients reported most serious adverse events were due to pyrazinamide, and predominantly hepatotoxicity and gastrointestinal intolerance, with age being a major risk factor (Kwon *et al.*, 2020).

These findings are supported by Indian data. The incidence of ADR was 7.79% in 974 patients on the Revised National Tuberculosis Control Programme regimen with gastrointestinal effects and dizziness/headache as the most common and category I patients bearing a much higher burden of reactions (Dedun, Borisagar and Solanki, 2017). In a larger Moroccan cohort (Hamdouni *et al.*, 2020), reported a 10.0% incidence of ADRs, most commonly gastrointestinal (7.4%) and cutaneous (3.7%), with an overall treatment success rate of 79.1% (Hamdouni *et al.*, 2020). More recently, Alsayed and Gunosewoyo emphasised that despite decades of use, first-line anti-TB therapy continues to be limited by toxicity, and that the development of newer, better-tolerated agents remains an unmet need in global TB control (Alsayed and Gunosewoyo, 2023).

Since there is a high morbidity due to toxicity with anti-tubercular drugs and limited prospective Indian data specifically focusing on the prevalence and severity of ADRs in DSTB, the present study was undertaken to characterise the pattern of ADRs among

patients receiving first-line therapy at a tertiary care centre in Hyderabad.

Aim

- To determine the frequency and severity of adverse drug reactions in drug-sensitive tuberculosis.

Objectives

- To determine the adverse reactions of first-line anti-tubercular drugs used in drug-sensitive tuberculosis among pulmonary and extrapulmonary tuberculosis patients.
- To assess the efficacy and safety of anti-tubercular drugs in tuberculosis disease patients”.

MATERIALS AND METHODS

Study Site And Duration

This prospective observational study was conducted in the Department of Pulmonology, Durgabhai Deshmukh Hospital and Research Centre, Vidyanagar, Hyderabad, over a period of six months.

Study Design And Sample Size

An observational, prospective study design was adopted. A total of 60 patients were enrolled based on the study criteria described below. Only an approval of the Institutional Ethics Committee was obtained before the study protocol was administered, written informed consent was obtained before enrolment.

Study Criteria

The study included all microbiologically confirmed Drug-Sensitive Tuberculosis (DSTB) patients, comprising both pulmonary and extrapulmonary tuberculosis cases, who fulfilled the eligibility criteria. Patients aged 0-14 years, those with Chronic Kidney Disease (CKD), and those with Chronic Liver Disease (CLD) were excluded, as these conditions could influence the pharmacokinetics, toxicity, and adverse drug reaction profile of anti-tubercular medications.

Tools And Primary Assessment

Data were collected using structured patient case report forms supplemented by laboratory investigation reports. Baseline work-up for all patients included complete blood picture, liver function tests, renal function tests, chest radiography and HIV screening.

Data Collection Procedure

Patients diagnosed with tuberculosis and satisfying the study criteria were enrolled after obtaining informed consent. Patient case records were used to capture demographic information,

chief complaints, previous medical and baseline investigations. All patients were being given first-line anti-tubercular medicines (isoniazid, rifampicin, pyrazinamide and ethambutol) at WHO-recommended weight-dependent doses, and were followed-up during the intensive phase of the therapy to occurrence of ADRs, which were recorded as per type, frequency (frequent, intermittent or occurring once) and severity (mild, moderate or severe), and the drug considered most likely responsible was identified through temporal association, dechallenge and clinical judgement.

Statistical Analysis

Microsoft Excel and statistical software were used to analyse data. The mean and standard deviation were used to summarise continuous data (e.g., age), whereas frequencies and percentages summarised categorical data. The association between the four first-line drugs and the pattern of ADRs was assessed using the chi-square test, with $p < 0.05$ considered statistically significant.

RESULTS

A total of 60 patients with drug-sensitive tuberculosis were enrolled and monitored over the study period. The demographic, clinical, radiological and adverse-reaction findings are summarised in Tables 1-12.

This study consisted of 60 patients in total, of whom males (58.3%) showed a higher frequency of adverse reactions to the drug-sensitive tuberculosis regimen than females (41.7%); the mean age of participants was 46.22 ± 16.38 years (range 18-75 years).

“Night sweats (20%) and fever (18.3%) were the most frequently reported presenting complaints, followed by cough and weight loss (16.7% each), shortness of breath (15%) and chest pain (13.3%), reflecting a predominance of systemic and respiratory symptoms among the study population.

Diabetes (25%) and anemia (21.7%) were the most common pre-existing comorbidities, followed by hypertension (16.7%)

and asthma (10%); 26.7% of patients had no significant past medical history.

Radiological work-up showed a diverse pattern of findings; fibrosis and normal appearances were each seen in 28.3% of chest radiographs, while cavitary lesions, consolidation, nodules and pleural effusion were noted on CT in a substantial proportion of patients, indicating a heterogeneous spectrum of pulmonary involvement.

Arthritis (26.7%) and rash (23.3%) were the most frequently observed adverse reactions, followed by gastrointestinal upset and hepatotoxicity (15% each); anorexia and urticaria were the least prevalent reactions (1.7% each).

The largest percentage of ADRs (43.3%) involved pyrazinamide, with rifampicin (25%) and isoniazid (23.3%) rated as second and third most frequently implicated drugs, respectively, and ethambutol had the lowest frequency of reactions (8.3%).

ADRs occurred intermittently in 35% of patients, frequently in 33.3%, and as a single episode in 31.7%, indicating a fairly balanced distribution across the three frequency categories.

Mild reactions predominated (41.7%), although a substantial proportion of ADRs were severe (33.3%) and potentially required urgent clinical intervention, with the remainder classified as moderate (25%).

Pyrazinamide was closely related with arthritis (81.3% of the arthritis cases) and rash (50%); rifampicin was primarily associated with anorexia (100%), and peripheral neuropathy (75%); isoniazid was most often responsible for gastrointestinal upset (77.8%); and ethambutol was the sole drug associated with visual disturbances (100%) (χ^2 test, $p < 0.001$).

Pyrazinamide accounted for the highest proportion of both frequent (50%) and intermittent (42.9%) reactions, while isoniazid and rifampicin showed broadly comparable rates across all frequency categories; the difference among drugs did not reach statistical significance ($p = 0.967$).

Pyrazinamide caused the most frequent mild (44%) and moderate (60%) reactions, and isoniazid and rifampicin had equal percentages of causing severe reactions (35 and 35, respectively). Interestingly, there were all lower and no moderate or severe reactions to ethambutol, its effects being confined to the mild category. The difference in severity distribution among the four drugs approached but did not reach statistical significance ($p = 0.067$).

Table 1a: Distribution of patients based on gender.

Gender	Frequency	Percentage (%)
Female	25	41.7
Male	35	58.3
Total	60	100

Table 1b: Distribution of patients based on age.

Minimum	Maximum	Mean	Std. Deviation
18	75	46.22	16.380

Table 2: Distribution of patients based on chief complaints.

Chief complaint	Frequency	Percentage (%)
Chest pain	8	13.3
Cough	10	16.7
Fever	11	18.3
Night sweats	12	20.0
Shortness of breath	9	15.0
Weight loss	10	16.7
Total	60	100

Table 3: Distribution of patients based on past medical history.

Past medical history	Frequency	Percentage (%)
Anemia	13	21.7
Asthma	6	10.0
Diabetes	15	25.0
Hypertension	10	16.7
None	16	26.7
Total	60	100

Table 4: Distribution of patients based on computed tomography findings.

CT findings	Frequency	Percentage (%)
Cavitary lesions	11	18.3
Consolidation	13	21.7
Nodules	10	16.7
Normal	13	21.7
Pleural effusion	13	21.7
Total	60	100

DISCUSSION

The present prospective observational study evaluated Adverse Drug Reactions (ADRs) among 60 patients receiving first-line Anti-Tubercular Therapy (ATT) for drug-sensitive tuberculosis. The study population showed a male predominance (58.3%) with a mean age of 46.22 ± 16.38 years, a demographic pattern consistent with previous pharmacovigilance studies reporting a higher burden of tuberculosis and treatment-related ADRs among middle-aged men. The most common presenting symptoms, including fever, cough, night sweats, and weight loss, reflected the classical clinical manifestations of active tuberculosis. Comorbidities such as diabetes mellitus, anaemia, and hypertension were also observed, highlighting their potential influence on disease progression, treatment response, and susceptibility to ADRs. Diabetes, in particular, has been recognised as an important risk factor for tuberculosis and is associated with poorer treatment outcomes, emphasising the need for careful monitoring during therapy. The ADR profile identified in the present study was characterised mainly by

Table 5: Distribution of patients based on chest X-ray findings.

Chest X-ray findings	Frequency	Percentage (%)
Cavitation	7	11.7
Consolidation	13	21.7
Fibrosis	17	28.3
Infiltrates	6	10.0
Normal	17	28.3
Total	60	100

Table 6: Distribution of patients based on type of adverse drug reaction observed.

ADR observed	Frequency	Percentage (%)
Anorexia	1	1.7
Arthritis	16	26.7
Gastrointestinal upset	9	15.0
Hepatotoxicity	9	15.0
Nausea	4	6.7
Peripheral neuropathy	4	6.7
Rash	14	23.3
Urticaria	1	1.7
Visual disturbances	2	3.3
Total	60	100

Table 7: Distribution of patients based on drug responsible for adverse reactions.

Responsible drug	Frequency	Percentage (%)
Isoniazid	14	23.3
Rifampicin	15	25.0
Pyrazinamide	26	43.3
Ethambutol	5	8.3
Total	60	100

arthritis, rash, gastrointestinal disturbances, and hepatotoxicity, findings that are generally consistent with previous reports. Forget and Menzies (2006) identified gastrointestinal intolerance, cutaneous reactions, and hepatotoxicity as the most frequent ADRs associated with first-line ATT, with isoniazid-induced hepatotoxicity representing one of the most clinically significant complications. Similarly, Dedun, Borisagar, and Solanki (2017) reported gastrointestinal complaints together with neurological symptoms such as dizziness and headache, while Hamdouni *et al.* (2020) also observed gastrointestinal and cutaneous reactions as the predominant ADRs in a Moroccan cohort. In contrast, arthritis was the most common ADR in the present study, likely reflecting the prominent role of pyrazinamide. Pyrazinamide is metabolised to pyrazinoic acid, which reduces renal uric acid excretion and may result in hyperuricaemia, arthralgia, and inflammatory arthritis. This mechanism supports the significant association observed between pyrazinamide and articular toxicity.

Pyrazinamide accounted for the highest proportion of ADRs (43.3%), followed by rifampicin, isoniazid, and ethambutol. This finding agrees with previous studies by (Yee *et al.*, 2003; Kwon *et al.*, 2020; Marra *et al.*, 2007). Which identified pyrazinamide as a major contributor to treatment-related toxicity, particularly hepatotoxicity, rash, and gastrointestinal intolerance. Although pyrazinamide was responsible for most ADRs in the present study, these reactions were predominantly mild to moderate, whereas isoniazid and rifampicin were more frequently associated with severe ADRs. Although this difference was not statistically significant, it highlights the importance of continuous pharmacovigilance throughout treatment rather than restricting monitoring to the intensive phase alone. Drug-specific toxicity patterns observed in the study corresponded with the established

safety profiles of first-line ATT. Gastrointestinal symptoms were more frequently associated with isoniazid, pyrazinamide showed a strong association with arthritis and rash, and visual disturbances occurred exclusively among patients receiving ethambutol, consistent with its known risk of optic neuritis. The statistically significant association between the offending drug and the type of ADR ($p < 0.001$) reinforces the need for targeted monitoring strategies. Patients receiving pyrazinamide should be assessed for joint symptoms and hyperuricaemia when clinically indicated, those receiving ethambutol require baseline and periodic assessment of visual acuity and colour vision, while patients receiving isoniazid should be monitored for hepatotoxicity and neurological complications, particularly in the presence of additional risk factors. Although over 40% of ADRs were mild

Table 8: Distribution of patients based on frequency of adverse drug reaction.

Frequency of ADR	Frequency	Percentage (%)
Frequent	20	33.3
Intermittent	21	35.0
Once	19	31.7
Total	60	100

Table 9: Distribution of patients based on severity of adverse drug reaction.

Severity of ADR	Frequency	Percentage (%)
Mild	25	41.7
Moderate	15	25.0
Severe	20	33.3
Total	60	100

Table 10: Comparison of adverse reactions among the four first-line drugs.

ADR observed	Isoniazid n (%)	Rifampicin n (%)	Pyrazinamide n (%)	Ethambutol n (%)	Total
Anorexia	0 (0)	1 (100)	0 (0)	0 (0)	1
Arthritis	0 (0)	2 (12.5)	13 (81.3)	1 (6.3)	16
GI upset	7 (77.8)	1 (11.1)	1 (11.1)	0 (0)	9
Hepatotoxicity	3 (33.3)	2 (22.2)	3 (33.3)	1 (11.1)	9
Nausea	1 (25.0)	2 (50.0)	1 (25.0)	0 (0)	4
Peripheral neuropathy	0 (0)	3 (75.0)	0 (0)	1 (25.0)	4
Rash	3 (21.4)	4 (28.6)	7 (50.0)	0 (0)	14
Urticaria	0 (0)	0 (0)	1 (100)	0 (0)	1
Visual disturbances	0 (0)	0 (0)	0 (0)	2 (100)	2

Table 11: Frequency of adverse reactions among the four first-line drugs.

Frequency of ADR	Isoniazid n (%)	Rifampicin n (%)	Pyrazinamide n (%)	Ethambutol n (%)	Total	p value
Frequent	4 (20.0)	4 (20.0)	10 (50.0)	2 (10.0)	20	0.967
Intermittent	5 (23.8)	6 (28.6)	9 (42.9)	1 (4.8)	21	
Once	5 (26.3)	5 (26.3)	7 (36.8)	2 (10.5)	19	

Table 12: Severity of adverse reactions among the four first-line drugs.

Severity of ADR	Isoniazid n (%)	Rifampicin n (%)	Pyrazinamide n (%)	Ethambutol n (%)	Total	p value
Mild	4 (16.0)	5 (20.0)	11 (44.0)	5 (20.0)	25	0.067
Moderate	3 (20.0)	3 (20.0)	9 (60.0)	0 (0)	15	
Severe	7 (35.0)	7 (35.0)	6 (30.0)	0 (0)	20	

and manageable with symptomatic treatment, nearly one-third were severe, indicating that clinically significant toxicity remains an important challenge during tuberculosis treatment. Early recognition and prompt management of ADRs are essential to minimise treatment interruption, improve adherence, and reduce preventable morbidity. These findings support previous reports by Chadha (2005), who demonstrated favourable treatment outcomes under DOTS despite treatment-related toxicity, and by Alsayed and Gunosewoyo (2023), who emphasised the continuing need for safer and better-tolerated anti-tubercular therapies. The present study has certain limitations, including its relatively small sample size, single-centre design, and reliance on clinical judgement for ADR attribution rather than validated causality assessment tools such as the WHO-UMC or Naranjo scales. HIV status was also not analysed as a potential modifier of ADR risk. Future multicentre studies involving larger populations, longer follow-up, validated causality assessment methods, and subgroup analyses according to age, sex, comorbidities, HIV status, and concomitant medications are required to better identify risk factors and strengthen pharmacovigilance strategies. Overall, the findings demonstrate that ADRs remain an important concern during first-line ATT, with pyrazinamide emerging as the most frequently implicated drug. Strengthening active pharmacovigilance, early recognition of adverse reactions, and appropriate patient monitoring may improve treatment safety, adherence, and overall therapeutic outcomes in patients with drug-sensitive tuberculosis.

CONCLUSION

Adverse drug reactions are common among patients receiving first-line therapy for drug-sensitive tuberculosis, with arthritis, rash, gastrointestinal upset and hepatotoxicity being the most frequently observed. The most frequent drug associated with ADRs in general and mild-to-moderate reactions in particular was pyrazinamide, whereas the isoniazid and rifampicin disproportionately affected severe reactions, and ethambutol was the safest of the four drugs, causing only mild reactions (primarily, visual disturbance). These findings highlight the need for vigilant, drug-directed clinical and laboratory monitoring throughout the course of anti-tubercular therapy to enable early detection, timely intervention and preservation of treatment adherence, thereby supporting the broader goal of successful tuberculosis control.

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ABBREVIATIONS

TB: Tuberculosis; **SOB:** Shortness of Breath; **ICF:** Informed Consent Form; **BP:** Blood Pressure; **RR:** Respiratory Rate; **OD:** Once a Day; **H:** Isoniazid; **Z:** Pyrazinamide; **E:** Ethambutol; **R:** Rifampicin; **OP:** Outpatient; **IP:** Inpatient; **ADR:** Adverse Drug Reaction.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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