Original Article

Cutaneous Adverse Drug Reactions in Patients with Pulmonary Tuberculosis Receiving First-Line Anti-Tubercular Therapy: A Prospective Observational Study

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Abstract

Background: Tuberculosis (TB) continues to rank among the foremost infectious causes of death across the globe, and India is responsible for roughly one quarter of the worldwide burden. Standard first-line anti-tubercular therapy (ATT) is highly effective, yet its benefit is often undermined by adverse drug reactions (ADRs). Reactions involving the skin are among the most frequent of these, ranging from simple itching to life-threatening severe cutaneous adverse reactions (SCARs). When such reactions are overlooked or poorly managed, treatment may be interrupted, adherence may weaken and clinical outcomes may deteriorate. This study was undertaken to establish the incidence, clinical patterns, timing of onset and suspected causative drugs of cutaneous ADRs among pulmonary TB patients on first-line ATT, and to explore whether sex was associated with their occurrence. **Material and Methods:** This prospective observational study was carried out at a tertiary care hospital and enrolled 150 newly diagnosed, treatment-naïve pulmonary TB patients aged 18 to 65 years. Every participant was given the standard daily fixed-dose combination ATT prescribed under the National TB Elimination Programme (NTEP) and was reviewed each month for six months. For every Cutaneous ADR, the morphology, severity, time of onset and suspected drug were recorded, and the likelihood of a causal link was graded with the Naranjo scale. Associations between categorical variables were examined with the chi-square test or Fisher's exact test. **Results:** Cutaneous ADRs developed in 33 of the 150 patients (22.00%). Maculopapular rash was the most frequent pattern (42.42%), followed by urticaria (27.27%) and pruritus without rash (15.15%); four patients experienced a severe cutaneous reaction. The great majority of reactions (87.88%) began within the first month of treatment. Cutaneous ADRs affected 29.31% of females and 17.39% of males, a difference that did not reach statistical significance ($p = 0.086$). Isoniazid was the drug most often suspected (36.36%), followed by rifampicin (27.27%). **Conclusion:** Roughly one in five patients on first-line ATT developed a Cutaneous reaction, most often a maculopapular rash, and nearly nine in ten of these appeared during the first month. Isoniazid and rifampicin were the principal suspected agents, and the higher rate among women (29.31% versus 17.39%) was not statistically significant. Structured dermatological surveillance, concentrated in the first month of therapy, is needed so that reactions can be detected and treated promptly and adherence can be safeguarded.

Keywords: Tuberculosis, Cutaneous adverse drug reactions, Anti-tubercular therapy, Pharmacovigilance.

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Introduction

Tuberculosis remains one of the most important infectious causes of illness and death in the world. The World Health Organization (WHO) estimated that 10.7 million people developed TB and 1.23 million died of it in 2024, with India alone contributing about a quarter of all new cases at an estimated incidence of 187 per 100,000 population.[1] Between 2015 and 2024, India's incidence fell by 21%, nearly double the 12% decline seen globally; even so, the country still bears the heaviest national burden of TB, including about one third of the world's multidrug- or rifampicin-resistant disease.[1] The lungs are the organ most often involved, and pulmonary disease keeps transmission going in the community because Mycobacterium tuberculosis is spread through aerosols. Undernutrition, rapid urbanisation, overcrowding, tobacco and alcohol use, and late diagnosis all continue to drive the epidemic and to influence how well patients respond to treatment.

Successful TB control rests on long, uninterrupted treatment with several drugs given together. For drug-susceptible disease, the 2025 WHO consolidated guidelines still advise a six-month course: isoniazid, rifampicin, pyrazinamide and ethambutol for the first two months, then isoniazid and rifampicin for the remaining four.[2] In India, the National TB Elimination

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Programme (NTEP) provides this regimen as a daily, weight-band-based fixed-dose combination (FDC), administered under direct observation or supported by digital adherence tools.[3] The daily FDC approach makes dosing more accurate and administration simpler. At the same time, because four drugs begin on the same day, the agent responsible for a reaction is rarely obvious when one occurs.[4]

Adverse drug reactions are a well-known companion of first-line therapy. A retrospective cohort of 2,953 adults with drug-susceptible TB treated at public clinics in Sarawak, Malaysia, found that 23.9% experienced at least one ADR; Cutaneous reactions formed the largest category, making up 47.1% of all ADRs, ahead of hepatotoxicity (32.8%) and gastrointestinal disturbances (29.8%).[5] A recent prospective study from a district hospital in Andhra Pradesh recorded Cutaneous rashes in 15.32% of 124 patients on ATT, placing the skin among the four organ systems most often affected.[6] Reported rates of cutaneous ADRs during ATT differ considerably, from 0.6% to 7.5% in some series,[7] to about 15% in recent Indian prospective data,[6] and these differences reflect variation in case definitions, treatment regimens, study populations and the intensity of follow-up.

The cutaneous reactions provoked by ATT cover a wide spectrum in both appearance and prognosis. Itching, urticaria and maculopapular exanthema are the commonest and generally resolve once the offending drug is withdrawn or with symptomatic care. In contrast, exfoliative dermatitis, drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens–Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) are SCARs that call for immediate discontinuation of every suspected drug, admission to hospital and supportive treatment. The Korean Registry of SCAR documented 53 patients with ATT-related SCARs,

of whom 77.4% had DRESS and 22.6% had SJS/TEN. Mortality reached 33.3% in SJS/TEN against 2.5% in DRESS, rifampicin was the drug most frequently implicated, and 42.9% of those who underwent drug challenge reacted to two or more drugs.[8] Recent case reports of rifampicin-induced SJS and of DRESS in a patient with tuberculous lymphadenitis confirm that such severe reactions still occur in everyday practice and that prompt recognition decides the outcome.[9,10]

Most Cutaneous reactions to ATT are non-dose-dependent (type B) reactions, arising through immune-mediated hypersensitivity or idiosyncratic mechanisms, and they typically surface during the first weeks of therapy when sensitisation and T-cell activation are at their height. In the Malaysian cohort, six of the seven ADR categories examined occurred in the intensive phase, most often around two weeks after treatment began.5 Host characteristics also shape risk. Age of 60 years or above, female sex, illicit drug use, HIV infection, diabetes and chronic liver disease were independent risk factors for ADRs in general,[5] while in a prospective Ghanaian cohort, female sex (OR 1.78), HIV positivity (OR 2.76) and alcohol use (OR 2.67) were each linked to Cutaneous reactions.[11] Nutritional status, genetic background and the use of other medicines may also contribute, and the interaction of these factors could explain why incidence differs from one population to another.

What makes Cutaneous ADRs important is their effect on treatment itself. In the Sarawak cohort, ADRs accounted for 33.0% of treatment interruptions lasting longer than two weeks and led to treatment being restarted in 34.5% of cases.5 Patients who suffer side effects, or who fear them, are less likely to adhere,[11] and prolonged or repeated gaps in therapy raise the likelihood of relapse, acquired drug resistance and treatment failure. Visible lesions, altered pigmentation and itching can also provoke stigma, anxiety and disturbed sleep, which wear down adherence further. Misattribution is a genuine danger: a drug rash may be mistaken for scabies, a fungal infection or an allergy to something unrelated, so the culprit drug is continued, or, conversely, an entire effective regimen is abandoned without need.

Systematic monitoring is therefore an essential part of TB care. Causality tools such as the Naranjo algorithm allow clinicians to grade the probability that a drug caused a reaction in a reproducible way,[12] and carefully supervised sequential reintroduction, performed in specialist settings, can pinpoint the responsible drug and permit the others to be restored in selected patients.7 Even so, ADRs to daily FDC-based ATT are common; most are mild and can be handled in the outpatient setting, but Cutaneous reactions are among the most frequent and a

number progress to severe disease.[4] A prospective study of cutaneous drug reactions at a tertiary teaching institute in northern India found antimicrobials to be the leading group of culprit drugs (64%), which underlines the need for dermatological vigilance in anyone on multidrug antimicrobial therapy.[13] In many programme settings, however, pharmacovigilance systems are overstretched, ADR reporting is incomplete, and Cutaneous reactions are often left undocumented or ascribed to other causes.

Most Indian pharmacovigilance reports on ATT pool all ADRs together and concentrate on hepatotoxicity and gastrointestinal intolerance. Few prospective studies have followed an adequately sized cohort on the current daily FDC regimen with a specific focus on Cutaneous reactions, their timing and their suspected culprit drugs. Information from patients without HIV, diabetes or other immunosuppressive conditions is particularly valuable, since it describes the baseline cutaneous risk of the standard regimen free from the confounding influence of comorbidity. A larger prospectively followed cohort also gives steadier estimates and greater power to examine host factors such as sex. We therefore studied 150 newly diagnosed pulmonary TB patients to determine the incidence, clinical pattern, time of onset and suspected causative drugs of cutaneous ADRs during first-line ATT, and to explore whether sex influences their occurrence.

Materials and Methods

This prospective observational study was conducted in the Department of Pharmacology of a tertiary care hospital over a period of two years. The study protocol received approval from

the Institutional Ethics Committee, and written informed consent was taken from each participant before enrolment. The purpose of the study was to evaluate the cutaneous adverse effects associated with first-line anti-tubercular drugs in patients diagnosed with pulmonary tuberculosis.

A total of 150 newly diagnosed pulmonary TB patients aged 18 to 65 years, who had been started on first-line ATT according to NTEP guidelines,3 were enrolled consecutively. Patients qualified for inclusion if their diagnosis of pulmonary TB had been confirmed, either microbiologically or clinically, if they had never received anti-tubercular treatment and were about to begin first-line drugs, and if they were willing to take part and provide informed consent. Exclusion criteria were extrapulmonary TB, any dermatological condition known to be present before ATT was started, HIV infection, diabetes mellitus, autoimmune disease or use of immunosuppressive therapy, previous treatment with ATT, and pregnancy or lactation.

All participants received a daily, weight-band-based fixed-dose combination of isoniazid, rifampicin, pyrazinamide and ethambutol during the two-month intensive phase, followed by isoniazid and rifampicin during the four-month continuation phase, in accordance with NTEP and WHO recommendations.2,3 Doses were allotted by body weight as laid down in the standard treatment guidelines.

Demographic details, medical history, comorbidities and baseline biochemical investigations were noted at enrolment. Patients were evaluated at baseline and thereafter every month for six months and they were instructed to report at any time if a skin symptom appeared. At each visit, and whenever symptoms arose between visits, patients were examined clinically for cutaneous ADRs. Every Cutaneous reaction was recorded with regard to its type (for example maculopapular rash, urticaria, pruritus without rash, exfoliative dermatitis or SJS), its severity, the interval between the start of therapy and onset, and the drug or drugs suspected. Dermatology consultation was sought when needed, and causality was assessed with the Naranjo Adverse Drug Reaction Probability Scale.12 In severe reactions, the suspected drugs were stopped and treatment was modified accordingly.

Data were entered into Microsoft Excel and analysed with SPSS version 26.0. Means, standard deviations and percentages were used to describe the data. Associations between categorical variables were tested with the chi-square test or Fisher's exact test, and a p-value below 0.05 was taken to indicate statistical significance.

Results

All 150 enrolled pulmonary TB patients were followed and analysed. By age, 44 patients (29.33%) were between 18 and 30 years, 60 (40.00%) between 31 and 45 years, 35 (23.33%) between 46 and 60 years and 11 (7.33%) were older than 60 years; the 31–45 year group was therefore the largest. Men numbered 92 (61.33%) and women 58 (38.67%).

Among the 150 patients receiving first-line ATT, 33 (22.00%) developed a cutaneous ADR, while the remaining 117 (78.00%) had no Cutaneous side effects. This is equivalent to roughly one in every 4.5 patients encountering a dermatological complication during treatment.

Of the 33 patients with Cutaneous ADRs, maculopapular rash was the commonest presentation, affecting 14 (42.42%). Urticaria followed in 9 (27.27%), pruritus without rash in 5 (15.15%), exfoliative dermatitis in 3 (9.09%) and Stevens–Johnson syndrome in 1 (3.03%); one further patient (3.03%) had a reaction classed as other (Table 1). Four patients, three with exfoliative dermatitis and one with SJS, had severe reactions and all four required hospital admission. In terms of management, 22 of the affected patients were treated symptomatically with ATT continued under supervision, 9 needed a temporary interruption of therapy followed by sequential reintroduction of drugs, and 2 required permanent withdrawal of one or more drugs.

Table 1: Types of Cutaneous adverse drug reactions observed (n = 33)

Type of Cutaneous ADR	Frequency (n)	Percentage (%)
Maculopapular rash	14	42.42
Urticaria	9	27.27
Itching/pruritus	5	15.15
Exfoliative dermatitis	3	9.09
Stevens–Johnson syndrome	1	3.03
Other	1	3.03

Cutaneous ADRs occurred in 17 of 58 females (29.31%) and in 16 of 92 males (17.39%); correspondingly, 41 females and 76 males remained free of cutaneous reactions. The chi-square test yielded $\chi^2 = 2.95$ with $p = 0.086$, so the association between sex and the occurrence of Cutaneous ADRs was not statistically significant.

The interval between starting ATT and the appearance of the cutaneous reaction is shown in Table 2. Eleven patients (33.33%) reacted within the first week, 10 (30.30%) between one and two weeks, 8 (24.24%) between two and four weeks, and 4 (12.12%) after four weeks. Taken cumulatively, 87.88% of all Cutaneous ADRs arose within the first month of therapy.

Table 2: Time of onset of Cutaneous ADRs after initiation of ATT (n = 33)

Onset after start of therapy	Frequency (n)	Percentage (%)
Within 1 week	11	33.33
1–2 weeks	10	30.30
2–4 weeks	8	24.24
After 4 weeks	4	12.12

Suspected causative drugs: Based on clinical assessment and Naranjo scoring, isoniazid was the drug most often implicated, responsible for reactions in 12 patients (36.36%). Rifampicin was suspected in 9 (27.27%), pyrazinamide in 6 (18.18%) and ethambutol in 2 (6.06%), while in 4 patients (12.12%) the reaction was attributed to a combination of more than one drug (Table 3). Causality was graded as probable in most cases. Suspected drug was assured based on dechallenge test.

Table 3: Suspected drugs causing Cutaneous ADRs by clinical judgement and Naranjo scale (n = 33)

Suspected drug	Number of cases (n)	Percentage (%)
Isoniazid	12	36.36
Rifampicin	9	27.27
Pyrazinamide	6	18.18
Ethambutol	2	6.06
More than one	4	12.12

Discussion

Cutaneous reactions are among the most common and most consequential adverse effects of first-line ATT. India carries a quarter of the global TB burden and treats most of its patients with daily FDC regimens, so the influence of these reactions on programme outcomes is likely to be greatest here.[1,3] In this prospective study of 150 newly diagnosed pulmonary TB patients without HIV, diabetes or other immunosuppressive conditions, 22.00% developed a cutaneous ADR, maculopapular rash was the leading morphology, 87.88% of reactions occurred within the first month, and isoniazid was the drug most frequently suspected. The sections below set these findings beside the most recent literature and consider what they mean for clinical practice.

The 31–45 year age group formed the largest share of our cohort, and 61.33% of participants were male. Such a predominance of working-age adults agrees with recent Indian data, in which most patients on ATT were between 28 and 48 years of age and slightly more than half were male.[6] The pattern mirrors the concentration of TB among economically active adults, who face the greatest occupational exposure, crowding and delay in seeking care, and it implies that a drug reaction that interrupts treatment carries a disproportionate economic and social cost. Age of 60 years or more has been identified as an independent risk factor for ADRs,[5] but the small number of older adults in our sample (11 patients) restricted our ability to examine this relationship. The urban–rural distribution in our study (53.33% urban) probably reflects the catchment area and referral pattern of our tertiary centre rather than any true difference in risk.

Cutaneous ADRs developed in 22.00% of our patients, a rate higher than the 15.32% reported in a recent prospective Indian series6 and above the 0.6–7.5% range quoted in earlier reports.[7] In the large Malaysian cohort, Cutaneous reactions accounted for 47.1% of all ADRs, and 23.9% of patients developed an ADR of some kind.[5] Several methodological considerations make direct comparison of these figures difficult. First, studies differ in whether they count only dermatologist-confirmed reactions or any patient-reported skin symptom, including isolated itching. Second, our prospective design, with scheduled monthly review and the option of unscheduled visits, is more sensitive than retrospective record review, which mainly captures reactions severe enough to have been documented. Third, many series include previously treated patients, patients with HIV or diabetes, and those on second-line regimens, all of which increase the likelihood of reactions; our exclusion of these groups should, if anything, have lowered the observed rate. Finally, the daily weight-band FDC used under NTEP exposes patients to all four drugs continuously from the first day, and its reaction profile may differ from that of the thrice-weekly regimens used in older studies.[4]

As regards morphology, maculopapular rash (42.42%) was the most frequent reaction in our series, followed by urticaria (27.27%) and pruritus without rash (15.15%). Together, maculopapular rash and urticaria made up about 70% of reactions, which fits the pattern generally expected and that seen in earlier series. The four severe reactions (three exfoliative dermatitis and one SJS) are clinically important despite their small number. In the Korean SCAR registry, DRESS accounted for most ATT-related SCARs, but SJS/TEN carried a far higher mortality (33.3% versus 2.5%),8 and recent reports describe rifampicin-induced SJS and DRESS during the treatment of tuberculous disease.[9,10] These data justify a low threshold for admitting patients who present with fever, facial oedema, mucosal involvement, skin tenderness, blistering, or abnormal liver function and eosinophil counts, and for stopping all suspected drugs without delay. That the severe reactions in our study were identified early probably reflects the scheduled review and prompt dermatology referral built into the protocol.

The timing of reactions was striking: 87.88% occurred within the first month and 33.33% within the first week. This agrees with the Malaysian cohort, in which most ADRs appeared in the intensive phase at about two weeks after initiation,[5] and with the delayed-type hypersensitivity mechanisms believed to underlie most cutaneous reactions to ATT, which usually declare themselves one to three weeks after exposure. The practical lesson is that surveillance for cutaneous reactions should be concentrated early in treatment. Treatment supporters and health workers should explain the warning signs to patients at initiation, an early contact within the first two weeks (by telephone or through digital adherence platforms where available) should be encouraged, and patients should be told to report any rash, blistering, mouth sores or fever immediately instead of waiting for the monthly appointment.

Cutaneous ADRs affected 29.31% of females and 17.39% of males, a difference that was not statistically significant ($p = 0.086$). Female sex has nonetheless emerged repeatedly as a risk

factor for ADRs during ATT: it independently predicted Cutaneous reactions in the Ghanaian cohort (OR 1.78, 95% CI 1.05–3.02),[11] and it was among the risk factors for ADRs overall in the Malaysian study.[5] Suggested explanations include sex-related differences in immune responsiveness, hormonal effects on drug metabolism and hypersensitivity, and the possibility that fixed weight-band dosing exposes lighter patients to relatively higher doses per kilogram, although this last point remains a hypothesis. With 150 patients, the study may still lack the power to detect a moderate difference, and the trend should be examined in larger multicentre cohorts.

In our series, isoniazid was the most commonly suspected drug (36.36%), followed by rifampicin (27.27%) and pyrazinamide (18.18%), and 12.12% of reactions were attributed to more than one drug. The ranking of culprit drugs varies across studies: in a recent prospective Indian series, pyrazinamide and isoniazid were the drugs most often suspected across all ADR types,[6] whereas rifampicin was the agent most frequently implicated in ATT-related SCARs in Korea.[8] These differences probably arise from the mix of ADR types included, the regimens used and, importantly, the inherent difficulty of assigning causality when four drugs are started together in one FDC.[4] Naranjo scoring lends reproducibility to this judgement,[12] but it cannot replace a structured reintroduction protocol. Where reactions are not severe, supervised sequential reintroduction under specialist guidance can identify the culprit and allow the remaining effective drugs to be restored,[7] and hypersensitivity involving more than one drug is not unusual, as shown by the Korean series in which 42.9% of challenged patients reacted to two or more drugs.[8] Reintroduction is generally avoided after SJS/TEN and, in all other situations, should be attempted only with careful monitoring.

The clinical and programmatic implications of these findings are considerable. Adverse reactions accounted for about one third of treatment interruptions longer than two weeks in a large cohort,[5] and patients who experience side effects are less likely to complete treatment.[11] Each avoidable interruption carries a risk of relapse and drug resistance in a country that already bears a third of the world's MDR/RR-TB.1 Early recognition and appropriate management of Cutaneous ADRs therefore protect not only the individual patient but also the goals of the programme. We would recommend routine documentation of skin symptoms at every contact, training of treatment supporters to recognise warning signs, a clear referral pathway to dermatology, standardised causality assessment, and consistent reporting of ADRs to the national pharmacovigilance system so that rarer severe reactions are not lost. Counselling is equally important, because visible lesions and itching can cause distress and stigma that make patients reluctant to continue treatment.

This study has several strengths: its prospective design, consecutive enrolment, uniform treatment with the current NTEP daily FDC regimen, scheduled monthly follow-up, dermatological evaluation where required, and formal causality assessment. Its limitations must also be acknowledged. It was conducted at a single tertiary centre, which may limit generalisability. Patients with HIV, diabetes, autoimmune disease and previous ATT were excluded, so the findings cannot be extended to these higher-risk groups. Because FDC tablets were used, causality at the level of the individual drug could not always be established, and systematic rechallenge was not performed. Cutaneous reactions that settled between visits may have been under-reported, and the study did not include genetic or HLA testing, nor an analysis of nutritional status and alcohol use as independent risk factors. The number of events was too small to permit multivariable analysis of risk factors. Larger multicentre studies that include patients with comorbidities are needed to confirm and build upon these observations.

Conclusion

In this prospective study of 150 pulmonary TB patients receiving first-line ATT, cutaneous adverse drug reactions occurred in 22.00%, with maculopapular rash the most common manifestation. Most reactions began within the first month of treatment, and isoniazid and rifampicin were the principal drugs implicated. Although females had a higher rate of reactions, the difference was not statistically significant. Vigilant dermatological monitoring concentrated early in therapy, prompt recognition of severe reactions, structured causality assessment and robust pharmacovigilance are essential for timely management and for preserving adherence and treatment success.

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Conflicts of interest

There are no conflicts of interest.

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