Section: Dermatology

Case Series

CUTANEOUS ADVERSE REACTIONS TO FIRST LINE ANTI TUBERCULAR THERAPY: A CASE SERIES

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ABSTRACT

Background: Cutaneous adverse drug reactions are uncommon but clinically significant complications of first-line anti-tubercular therapy (ATT). While most reactions are mild, severe manifestations such as Toxic Epidermal Necrolysis (TEN) may be life-threatening. **Objectives:** This case series highlights the diagnostic and therapeutic challenges in managing ATT-induced cutaneous adverse drug reactions. **Materials and Methods:** We report three cases of cutaneous reactions in patients receiving standard ATT under the National Tuberculosis Elimination Program. Two patients developed histologically confirmed lichenoid drug eruptions attributable to ethambutol, with resolution upon withdrawal and rechallenge. The third patient presented with features consistent with isoniazid-induced TEN, requiring intensive care and subsequent modification of the treatment regimen. **Result:** All patients achieved complete dermatologic recovery and successfully completed modified ATT courses. Our findings align with published literature identifying ethambutol and isoniazid as common triggers for cutaneous adverse drug reactions. Rechallenge played a pivotal role in identifying the culprit agents and guiding safe reintroduction of therapy. Early recognition, multidisciplinary management, and tailored treatment plans were critical for positive outcomes. **Conclusion:** This case series underscores the importance of early dermatological assessment, prompt drug withdrawal, individualized therapy, and pharmacovigilance in minimizing adverse outcomes and supporting successful TB control efforts.

INTRODUCTION

Tuberculosis (TB) remains a major global health challenge, with first-line anti-tubercular therapy (ATT) being the cornerstone of treatment.[1,2] The Fixed Dose Combination consisting of isoniazid (H), rifampicin (R), pyrazinamide (Z), and ethambutol (E) is highly effective with 100% adherence rates, according to the World Health Organization (WHO).[3] However, adverse reactions have been reported in 2–8% of patients on these drugs, with common side effects including gastrointestinal problems, hepatitis, and fever.[4,5] Rarely, cutaneous reactions have also been reported, ranging from mild pruritus to life-threatening conditions like Toxic Epidermal Necrolysis (TEN), Stevens–Johnson syndrome (SJS), and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).[2,6] Here, we report the clinical presentation, diagnosis, treatment, and prognosis of three ATT-induced cutaneous adverse drug reactions.

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MATERIALS AND METHODS

We report three cases of cutaneous reactions in patients receiving standard ATT under the National Tuberculosis Elimination Program. Two patients developed histologically confirmed lichenoid drug eruptions attributable to ethambutol, with resolution upon withdrawal and rechallenge. The third patient presented with features consistent with isoniazid-induced TEN, requiring intensive care and subsequent modification of the treatment regime

RESULTS

Case 1: Ethambutol-Induced Lichenoid Dermatitis in a Patient Treated for Pleural Tuberculosis

A 62-year-old male with no known comorbidities presented with right-sided pleural effusion and elevated adenosine deaminase (ADA) levels in the pleural fluid, suggestive of tuberculosis. He was initiated on a fixed-dose combination (4FDC) anti-tubercular therapy (ATT) under the National Tuberculosis Elimination Program (NTEP), consisting of six tablets daily. Baseline hematological and biochemical investigations were within normal limits. Approximately 10 weeks into treatment, he developed multiple erythematous papules and plaques over the limbs and trunk, associated with intense pruritus (Figure 1). Initially managed with topical emollients, liquid paraffin, and oral antihistamines, his condition progressively worsened. Topical corticosteroids were added, but the cutaneous lesions continued to spread. A dermatology consult was sought, and a skin biopsy revealed features of a lichenoid drug eruption, characterized by wedge-shaped hypergranulosis, irregular acanthosis, focal basal vacuolization, and a band-like lymphocytic infiltrate, along with parakeratosis and colloid bodies suggestive of a drug-induced lichenoid reaction likely triggered by ethambutol or isoniazid (Figure 2).

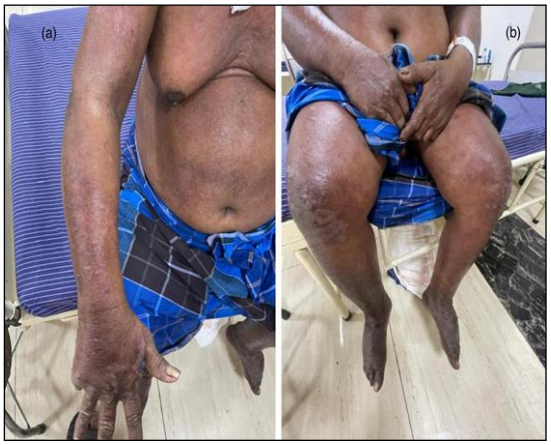

Figure 1: Hyperpigmented lichenoid plaques over the upper limbs (a), thighs, and legs (b) following initiation of anti-tubercular therapy (ATT), consistent with cutaneous adverse drug reaction.

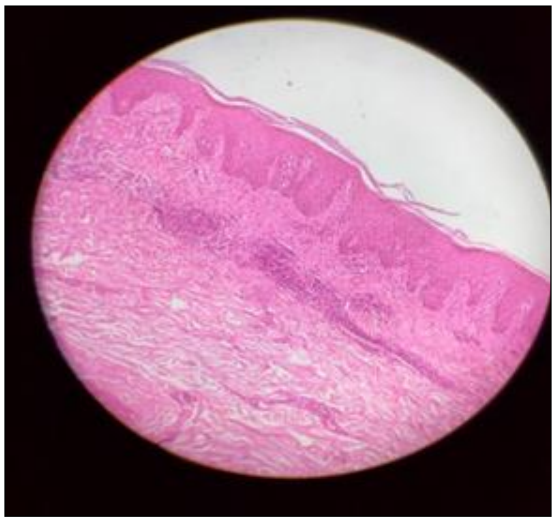

Figure 2: Biopsy showing lichenoid dermatitis.

Both isoniazid and ethambutol were temporarily withdrawn, and the patient was started on systemic corticosteroids. Clinical improvement was noted within two weeks. After complete resolution of the lesions, isoniazid was cautiously reintroduced without recurrence of the skin reaction. The patient was discharged on a modified ATT regimen consisting of rifampicin 450 mg, isoniazid 300 mg, and levofloxacin 500 mg.

However, the patient mistakenly resumed the 3FDC combination containing ethambutol, and within a week, he returned with multiple hyperpigmented plaques and excoriated erosions over the chest and extremities. Ethambutol was promptly discontinued, and systemic corticosteroids were reinstated, leading to complete resolution of skin lesions within two weeks. The patient completed his treatment on the ethambutol-free regimen, with radiological resolution of the pleural effusion and no further adverse cutaneous events.

Case 2: Ethambutol-Induced Lichenoid Dermatitis in a male with Tuberculous Ascites

A 45-year-old female, previously diagnosed with tuberculous ascites, was started on standard ATT in October 2022. However, the regimen was discontinued after two weeks due to suspected drug-induced liver injury. Following recurrence of symptoms, she was restarted on a fixed-dose combination (4FDC) regimen. Ten days after restarting ATT, the patient developed widespread pruritic, erythematous papules and plaques over the trunk and limbs (Figure 3).

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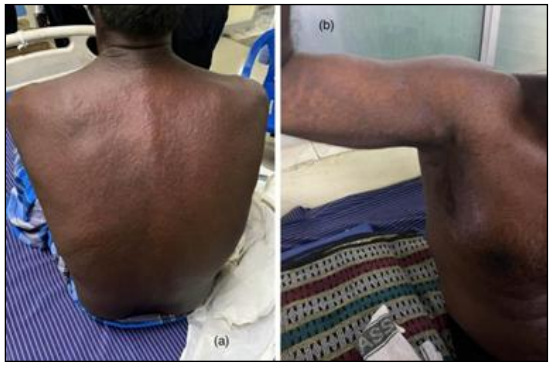

Figure 3: Diffuse erythematous maculopapular rash over the back (a) and upper limbs (b) developing after initiation of anti-tubercular therapy, indicative of a cutaneous adverse drug reaction.

On examination, there was diffuse involvement of the limbs and torso with excoriated, violaceous papules. She also reported itching and discomfort, which did not respond to topical emollients or antihistamines. Visual examination of the lesions raised suspicion for a lichenoid drug eruption. A skin biopsy was performed, which confirmed the diagnosis with characteristic histological findings: hypergranulosis, irregular acanthosis, basal cell vacuolization, and a lichenoid lymphocytic infiltrate. Ethambutol and isoniazid were withheld, and the patient was started on systemic corticosteroids. The skin lesions improved significantly within two weeks. Isoniazid was reintroduced without complications. However, ethambutol rechallenge led to recurrence of similar skin lesions, confirming its causative role. Ethambutol was permanently discontinued, and the patient was continued on a modified regimen comprising rifampicin, isoniazid, and levofloxacin. She completed the full course of therapy with no further dermatological complaints.

Case 3: Toxic Epidermal Necrolysis Secondary to Anti-Tubercular Therapy

A 36-year-old female with newly diagnosed pulmonary tuberculosis was initiated on standard first-line anti-tubercular therapy (HRZE) at a district hospital. Within a few weeks of starting treatment, she began experiencing drowsiness, vertigo, and confusion. Her initial vitals revealed hypotension (BP: 62/58 mmHg), tachycardia (PR: 115/min), and oxygen saturation of 98% on room air. She was admitted and received intravenous fluids, antiemetics, and antibiotics, and was referred to a tertiary care center for further management. Upon admission to the ICU, the patient was alert and oriented but reported painful lesions over her entire body for the past month and progressive difficulty swallowing over the preceding two weeks. On examination, widespread hyperpigmented macules and patches with crusting were noted over the trunk and extremities. Mucosal involvement included ulcerations over the oral and genital mucosa. Re-epithelializing lesions measuring 2 × 4 cm were noted over the neck (Figure 4). Oral examination showed a white-coated tongue, and she was unable to tolerate oral intake.

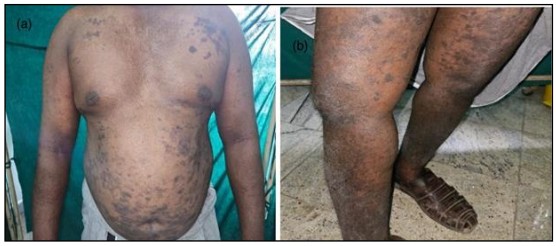

Figure 4: Lichenoid hyperpigmented papules and nodules over the trunk (a) and lower limbs (b) following initiation of anti-tubercular therapy (ATT).

Routine laboratory investigations revealed elevated blood urea (60 mg/dL), mild hyponatremia (Na: 127 mEq/L), and normal creatinine and coagulation profiles. 2D echocardiography showed moderate pericardial effusion with preserved ejection fraction (LVEF 60%). Based on the clinical presentation, a diagnosis of TEN, secondary to anti-tubercular therapy, was made. All anti-tubercular medications were discontinued immediately. The patient was managed in the ICU with intravenous meropenem (1 g TDS), clindamycin (60 mg TDS), dexamethasone, hepatoprotective agents, antifungals, and supportive care, including fluid and electrolyte management. Over the subsequent weeks, her mucocutaneous lesions gradually re-epithelialized. She was transitioned to an ethambutol- and rifampicin-sparing ATT regimen upon stabilization.

DISCUSSION

Ethambutol-induced lichenoid dermatitis and isoniazid-induced TEN represent the clinical spectrum of cutaneous adverse reactions to ATT.[7] While lichenoid eruptions tend to be chronic yet manageable, TEN constitutes a life-threatening emergency requiring immediate and aggressive intervention.[8] Goel et al. investigated multiple risk factors and classified the severity of reactions using the Modified Hartwig and Siegel scale, guiding the decision for drug rechallenge based on severity: mild (level 2), moderate (levels 3 and 4), and severe (levels 5–7) reactions.[9] Effective management involves prompt withdrawal of the suspected drug, symptomatic treatment with antihistamines and corticosteroids, and, in severe cases, systemic immunosuppressive therapy.[10] Accurate identification of the causative agent through a carefully monitored rechallenge is essential to allow continuation of therapy without further complications.[11,12] This case series emphasizes the critical role of early recognition, appropriate regimen modification, and patient education in minimizing morbidity and preventing treatment disruption. In drug-induced reactions, drug metabolites may act as haptens, initiating immune-mediated responses.[13]

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Isoniazid, in particular, is metabolized in the liver to reactive intermediates that may trigger idiosyncratic reactions in genetically predisposed individuals. In our case series, three distinct presentations of cutaneous adverse drug reactions to first-line anti-tubercular therapy were documented. Two patients developed lichenoid drug eruptions, both temporally associated with ethambutol exposure and confirmed by histopathology. Withdrawal of ethambutol and administration of systemic corticosteroids led to resolution in both cases, while re-challenge confirmed ethambutol as the offending agent. The third case was a severe manifestation of TEN occurring within weeks of ATT initiation, involving extensive mucocutaneous detachment and systemic symptoms. Prompt discontinuation of all ATT agents and intensive supportive care resulted in gradual recovery. All three cases underscore the importance of early recognition, prompt withdrawal of the suspected drug, and individualized regimen modifications to safely complete anti-tubercular treatment. The cutaneous adverse drug reactions (CADRs) described in our series reflect patterns increasingly recognized in the literature, particularly those involving lichenoid drug eruptions. Several reports documented cases where patients developed pruritic, violaceous plaques following ethambutol exposure, with histological findings confirming lichenoid tissue reactions.[14,15,16] In all instances, cessation of ethambutol led to significant clinical improvement, thereby strengthening the causal link. Similarly, our patients developed widespread papulonodular eruptions within two weeks of ATT initiation, resistant to conservative management, but responsive to corticosteroids and drug withdrawal. The recurrence of lesions on ethambutol reintroduction, but not with isoniazid or rifampicin, confirmed its role. These reports, alongside our findings, point toward ethambutol as a notable cause of lichenoid CADRs, highlighting the necessity of dermatologic surveillance during treatment. Early identification not only facilitates targeted drug discontinuation but also helps retain other effective agents through differential re-challenge protocols. Broader epidemiological support for these observations was available in previous reports.[2,7] In a retrospective review of 40 patients, it has been noted that 45% of CADRs were due to ethambutol, making it the most frequently implicated drug.[2] Similarly, another prospective study of 56 patients identified lichenoid eruptions in 10.7% of cases, with ethambutol again emerging as a leading cause.[7] These studies also emphasized that maculopapular and lichenoid rashes constituted over 60% of all cutaneous reactions, often requiring drug modification. Our case series mirrors these findings, as two patients presented with histologically confirmed lichenoid dermatitis, both linked to ethambutol and resolved following withdrawal. The consistency of these observations across multiple studies suggests that ethambutol may carry a higher risk of lichenoid eruptions than currently appreciated. This underscores the need to include lichenoid patterns among routine dermatologic differential diagnoses when evaluating cutaneous symptoms in patients receiving ATT. In addition to diagnosis, the therapeutic approach employed in these studies aligns with our management strategy. Researchers have implemented a conservative stepwise reintroduction of individual ATT drugs, retaining only those tolerated without recurrence of skin lesions.[14,16] Katran et al.[15] further demonstrated the utility of patch testing and desensitization when re-challenge was ambiguous or contraindicated. Our cases similarly benefited from controlled re-challenge protocols, which helped safely reinstitute isoniazid while avoiding ethambutol. The success of these approaches supports a structured protocol for evaluating CADRs: initial withdrawal of all agents, symptom control using corticosteroids and antihistamines, followed by sequential reintroduction based on clinical and histopathological correlation. Incorporating this framework into clinical practice may reduce morbidity associated with ATT interruption and allow completion of therapy with minimal compromise. It also reinforces the importance of interdisciplinary collaboration between dermatology, infectious disease, and pharmacology teams in managing ATT-induced CADRs. The third case in our series, characterized by toxic epidermal necrolysis (TEN), aligns with multiple reports of severe mucocutaneous adverse reactions linked to first-line anti-tubercular drugs. A 75-year-old male who developed TEN three weeks into standard ATT, with mucosal erosions and widespread skin detachment requiring immediate ICU care and drug withdrawal was reported by Datta et al.[17] Das et al.[18] in another study reported a patient with over 60% body surface involvement and multi-mucosal ulceration, confirmed by a positive Nikolsky sign and histopathology. These presentations parallel our case, where the patient exhibited painful erosions, mucosal ulceration, and systemic symptoms necessitating critical care support. Importantly, in all cases, ATT cessation and supportive management were critical for survival and resolution. Valuable epidemiological insight into ATT-induced severe cutaneous adverse reactions (SCARs) through a registry-based analysis was provided by Jin et al.[6] They found that among 53 patients with SCARs, 12 had SJS/TEN, and isoniazid was implicated in over two-thirds of these cases. The study further highlighted that patients with TEN were significantly older, had a higher rate of ICU admissions (41.7%), and a markedly increased mortality rate (33.3%) compared to those with DRESS. This association emphasizes the importance of age as a risk factor and supports our clinical observation, wherein timely ICU admission, corticosteroid therapy, and ATT withdrawal contributed to a favorable outcome. Such findings argue for heightened vigilance in elderly patients receiving ATT. In our case, once the patient

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stabilized, an individualized, ethambutol- and rifampicin-sparing regimen was introduced, mirroring previous approaches reported.[19,20] Collado-Chagoya et al.[19] described a high-risk paediatric- patient with a family history of drug hypersensitivity who developed an SJS/TEN overlap after rifampicin and isoniazid, managed through slow desensitization protocols and close immunological monitoring. Similarly, In another case, use of moxifloxacin and bedaquiline as part of a second-line ATT regimen following generalized bullous eruptions has been reported.[20] These reports, along with our own case, highlight the importance of flexible, individualized regimens when re-challenge is unsafe or contraindicated. They also underline the evolving role of second-line agents and desensitization protocols in maintaining tuberculosis treatment continuity amidst severe adverse reactions.

Additionally, the clinical utility of sequential re-challenge in determining the specific offending agent in cases of cutaneous adverse drug reactions (CADRs) to anti-tubercular therapy has been highlighted.[21] In their case series involving three patients with generalized pruritic rashes, stepwise reintroduction of ATT components revealed rifampicin and pyrazinamide as causative agents in two cases. These findings underscore the role of rechallenge not only in confirming drug causality but also in guiding safe reintroduction of alternative regimens, thereby avoiding unnecessary exclusion of effective first-line agents. Our series similarly employed controlled re-challenge, which pinpointed ethambutol as the offending agent in two patients, allowing for retention of other essential drugs like isoniazid and rifampicin. Re-challenge is especially valuable in resource-limited settings, where second-line drugs may not be readily accessible, and preserving core components of the regimen is crucial for achieving therapeutic success and minimizing resistance development.

Furthermore, the demographic profile of our patients is consistent with findings reported by Kheradmand et al.[5] who documented a significantly higher incidence of adverse drug reactions in patients aged over 59 years compared to younger cohorts. Their retrospective cohort of 3903 TB patients found that the odds of experiencing an ADR were 2.63 times higher in the elderly, with a confidence interval of 1.54–4.49. This correlation reinforces the need for age-stratified vigilance in ATT prescribing and monitoring. Two of the three patients in our series were over 60 years of age, both of whom experienced significant cutaneous drug reactions necessitating regimen modification. Age-related pharmacokinetic changes, polypharmacy, and altered immune responses may contribute to increased susceptibility in older patients. These observations support the inclusion of routine risk stratification, including age and comorbid conditions, when initiating ATT, particularly under programmatic settings such as the National Tuberculosis Elimination Program, where standardized regimens may overlook individual vulnerabilities.

CONCLUSION

Cutaneous adverse drug reactions to first-line anti-tubercular therapy represent a diagnostically challenging and clinically significant spectrum of presentations, ranging from self-limiting lichenoid eruptions to life-threatening toxic epidermal necrolysis. Ethambutol and isoniazid were the most frequently implicated agents in our series. Accurate identification of the offending drug through clinical judgment, histopathological evaluation, and controlled re-challenge is essential to ensure patient safety without compromising tuberculosis treatment. This case series underscores the importance of early dermatological assessment, prompt drug withdrawal, individualized therapy, and pharmacovigilance in minimizing adverse outcomes and supporting successful TB control efforts.

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