Case Report

Fatal Toxic Epidermal Necrolysis following consumption of unlabelled Over-the-Counter medication-A case report

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ABSTRACT

Toxic epidermal necrolysis (TEN) is a rare, severe mucocutaneous reaction, which is a type IV hypersensitivity reaction. We report a case of TEN in a 37-year-old male following consumption of an unknown over-the-counter medication obtained from a local pharmacy. Following the consumption, the patient developed tense fluid-filled lesions diagnosed as TEN. Despite intensive care support, the patient succumbed to the condition. A major challenge encountered in this case was the inability to identify the offending medication, as the drugs had been dispensed as loose, unlabeled tablets. This case highlights the serious risks associated with unidentified medication use and the need for improved medication traceability, stricter dispensing practices of labelled medication so as to prevent occurrence of severe adverse drug reactions. instead of the current one.

Key words: Adverse drug reaction, Over-the-counter medications, Pharmacovigilance

Toxic epidermal necrolysis (TEN), also known as Lyell's syndrome, is a rare, life-threatening mucocutaneous adverse drug reaction (ADR) characterized by widespread epidermal necrosis and detachment [1-3]. It is a delayed type (Type IV) hypersensitivity reaction involving both skin and mucous membranes. TEN represents the severe end of the spectrum that includes Stevens-Johnson Syndrome (SJS), with high morbidity and mortality. TEN is defined by the involvement of more than 30% of the body surface area (BSA), while SJS-TEN overlap involves 10–30% [4]. The global incidence of TEN is estimated to be approximately 1–2 cases per million population per year. However, epidemiological data from India are limited on the clinico-demographic profile of severe cutaneous adverse reactions [5,6]. The reported mortality rates can be estimated between 34 and 50%, with mortality correlating with BSA involvement [5]. The cutaneous symptoms include a painful erythematous rash, bullae, and erosions appearing on the face, trunk, and spreading to extremities. The SCORe of Toxic Epidermal Necrosis (SCORTEN) index remains a widely accepted prognostic tool to predict mortality [7]. Common causative agents include antibiotics like sulfonamides, trimethoprim-sulfamethoxazole (cotrimoxazole), fluoroquinolones, macrolides like azithromycin, clarithromycin, tetracyclines, antiepileptics such as phenytoin and carbamazepine, non-steroidal anti-inflammatory drugs, allopurinol, and nevirapine; newer biologics like immune checkpoint inhibitors like nivolumab and pembrolizumab, and herbal medications like Vajra Bhasma have also been implicated [8-10]. Early recognition and prompt withdrawal of the offending agent are critical for improving outcomes. Recent evidence suggests that there's a correlation between human leukocyte antigen (HLA) in certain drug-induced TEN. A recent analysis revealed that HLA-B 15:02 shows a significantly increased risk of Carbamazepine induced SJS/TEN [11]. Management of TEN includes primarily supportive treatment, with withdrawal of the offending agent, along with intensive care, burn care management mainly focusing on fluid and electrolyte balance, wound care and infection prevention. Corticosteroids and intravenous immunoglobulin have been used, although a universal standard therapy is yet to be established [11]. However, establishing causality becomes challenging in cases involving unidentified or unregulated medications.

We report a case of TEN following ingestion of unknown drugs obtained from a local pharmacy over the counter, highlighting the diagnostic and pharmacovigilance challenges in such settings.

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CASE PRESENTATION

A 37-year-old male presented to the emergency department with painful fluid-filled lesions. The patient was referred from a secondary care hospital in view of TEN secondary to an unknown offending agent. The patient was apparently normal 15 days ago when he developed fever, for which he took over-the-counter (OTC) medication from a local pharmacy. Detailed drug history could not be elicited as the patient had consumed multiple loose, unlabeled tablets obtained directly from a local pharmacy without a prescription. According to the patient's relatives, only paracetamol and ursodeoxycholic acid could be recalled with certainty, whereas the rest remained unidentified but described as green, pink, red coloured loose tablets. The original medication strips, prescriptions and purchase records were unavailable. He consumed the tablets for 3 days, after which the patient developed reddish lesions over the body. The patient was first admitted to a secondary care hospital, where he was prescribed a course of injection Piperacillin-tazobactam 4.5 g TDS, injection pantoprazole 40 mg OD, injection Ondansetron 4 mg BD, Injection pheniramine maleate, Injection dexamethasone 4 mg BD, syrup lactulose 2 cc. The patient started deteriorating with the reddish lesions spreading all over the body associated with pain, along with the appearance of fluid-filled lesions in the mouth, which were associated with difficulty in swallowing, 5 days after getting admitted to the secondary care hospital. After which, the patient was transferred to a tertiary care hospital for further management. The SCORTEN on examination at the time of admission is shown in Table 1.

On examination, the patient had diffuse, dusky reddish hyperpigmented skin, tense bullae over the foot, erosions seen over bilateral upper limb, lower limb, genitals (glans, scrotum), trunk, face, and exudative crust present on face with erosions present on oral mucosa (lip, buccal mucosa), eyelids (Fig. 1). Pseudo-Nikolsky test was positive. Laboratory parameters of the patient were shown in Table 2.

On admission, the patient was started on Injection methylprednisolone 500 mg stat, Injection pantoprazole 40 mg, Injection hydrocortisone 100 mg stat, Injection calcium gluconate 10 mg, along with Ringer lactate, dextrose in normal saline with 10 cc KCL. The patient showed clinical deterioration on the 2nd day of admission. The SpO_2 and blood pressure were non-recordable. The patient was gasping, tachypneic, following which the patient was shifted to the intensive care unit and intubated. The patient succumbed to the complications even after persistent resuscitative efforts. The patient had no known history of drug allergy, chronic systemic illness, previous similar reactions or regular medication use. There was no significant family history of drug hypersensitivity. The sequence of events is shown in Fig. 2.

Table 1: SCORTEN score

Parameter	Criteria	Score
Age	>40 years	0
Malignancy	Present	0
Heart rate	>120 beats/min	0
Epidermal detachment (Day 1)	>10% body surface area	1
Serum urea	>10 mmol/L	1
Serum glucose	>14 mmol/L	0
Serum bicarbonate	<20 mmol/L	1

Score=3. Mortality risk-35%

Table 2: Laboratory parameters of the patient on admission

Parameter	Result
Hemoglobin	15.3 g/dL
Total leukocyte count (cells/µL)	16900
Platelet count (µL)	2.2 lakh
Blood urea nitrogen	75.3 mg/dL
Total bilirubin	13.4 mg/dL
Direct bilirubin	7.3 mg/dL
Uric acid	11.6 mg/dL



Figure 1: (a) Hemorrhagic crustation around perioral and oral mucosa; (b) generalized scalding

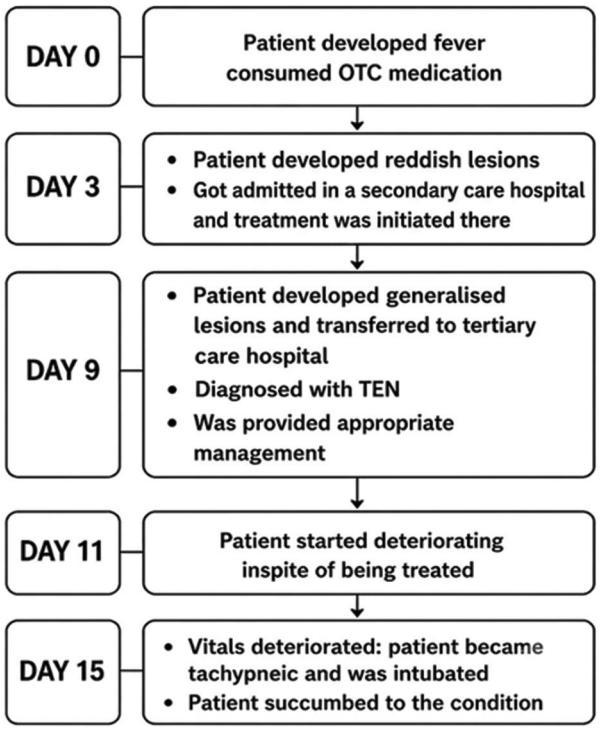


Figure 2: Sequence of events

DISCUSSION

TEN is a severe form of Type IV hypersensitivity reaction, characterized by extensive keratinocyte apoptosis mediated through granulysin, perforin, granzyme B, and Fas ligand interactions. Genetic susceptibility, particularly HLA alleles, has been implicated in drug-induced TEN [5]. Along with that, respiratory tract involvement is recognised as an extracutaneous manifestation of TEN and has been associated with poor clinical outcomes. The underlying mechanism involves epithelial injury leading to inflammation, epithelial sloughing and impaired gas exchange [12,13]. In the above scenario, pulmonary involvement may have contributed to the patient's clinical deterioration and fatal outcome.

A case report by Pereira da Silva et al. published (2025), a fatal case of TEN which developed after self-medicating with paracetamol and ibuprofen in a 71-year-old male patient. The authors emphasise the potential role of ibuprofen, used as a common OTC non-steroidal anti-inflammatory drug, as a common trigger in frail elderly individuals [14]. Another systematic review by Wang *et al*. of 1,059 published SJS/TEN case reports from 1980 to 2020 reported a mortality rate of 24.4% among patients with TEN, highlighting the severity of the condition and its fatal nature. However, the predominant triggers described were antibiotics, antiepileptic drugs, along with allopurinol being the most common offending agents [2]. Yet another report by Channabasappa *et al*. reported a case of TEN induced by acetaminophen in a patient following the use of this commonly prescribed OTC analgesic and antipyretic. The authors highlighted that although acetaminophen is generally considered a safe medication, it can rarely precipitate life-threatening severe cutaneous adverse reactions such as TEN [9]. In contrast to the majority of reported cases where the offending agent was identified, causality assessment in the present case was hindered due to consumption of loose, unlabeled medications obtained from a local pharmacy.

The present case highlights the challenges faced with ADRs following consumption of unidentified OTC. OTC means drugs that are available and can be obtained without a prescription. Globally, most countries have well-defined regulatory frameworks governing OTC approval and sale to ensure safety [4,15]. OTCs are regulated by the Food and Drug Administration in the United States, and in other European countries, they have established pathways to ensure safety, efficacy, appropriate labeling, and adherence to good manufacturing practices before the drug can be marketed without a prescription [16].

However, the scenario in India remains undefined. The Central Drugs Standard Control Organisation (CDSCO) is the central authority for regulation of drugs in India. The term OTC remains formally unrecognized in Indian legislation, and there is no separate legal category for non-prescription medicines [17]. In recent times, the CDSCO aims to formally classify OTC drugs to improve and enhance patient safety [18]. Despite the efforts, the implementation remains a challenge due to irrational drug use and handling of the medication in India. The widespread availability of OTC increases the risk of severe drug reactions, including life-threatening conditions like TEN. The socioeconomic factor plays a major role in the widespread use of OTC medication and the use of loose medications, particularly in resource-limited settings where financial constraints and low health literacy lead to self-medication [19].

The inability to identify the offending agent in the above scenario posed a significant limitation. As the patient consumed loose, unlabeled medications obtained from a local pharmacy, accurate determination of the causative drug was not possible. The absence of drug identity, batch details, and prescription records hindered pharmacovigilance reporting. Such scenarios establish the need for stricter regulation of medical dispensing practices and increased awareness regarding risk associated with unidentified OTC and loose medications. Although fatal TEN following self-medication has previously been reported, the present case differs in that the offending drug could not be identified because the patient consumed loose, unlabeled medications obtained over the counter.

CONCLUSION

The above case report highlights potentially fatal consequences of severe cutaneous ADRs following consumption of unidentified OTC medication. The inability to find the offending agent posed a barrier in formal causality assessment using established pharmacovigilance tools. This highlights the need for stricter regulation of medication dispensing practices, along with improved public awareness regarding risks of self-medication.

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