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Case Report

Ofloxacin/Ornidazole Induced Toxic Epidermal Necrolysis: Case Report

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ABSTRACT

Toxic Epidermal Necrolysis (TEN) is a rare, life-threatening mucocutaneous disorder, most often triggered by medications and less frequently by infections. It is clinically characterized by widespread erythema, epidermal necrosis, and extensive bullous detachment of the skin and mucous membranes, which may progress to exfoliation, sepsis, and even death. Drugs commonly associated with TEN include sulfonamides, non-steroidal anti-inflammatory agents, imidazole antifungals, cephalosporin's, anticonvulsants, and allopurinol. We report the case of a patient admitted to a tertiary care center with painful, fluid-filled skin lesions involving the trunk and extremities. Medical history revealed intake of Ofloxacin with Ornidazole for chest pain and breast swelling. Based on clinical features, history, and causality assessment, Ofloxacin/Ornidazole was identified as the most likely culprit. The drug was discontinued and symptomatic management initiated.

Keywords: Adverse Drug Reaction, Ofloxacin, Severe Cutaneous Adverse Reaction (SCAR), Skin Lesions, Toxic Epidermal Necrolysis.

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INTRODUCTION

Toxic Epidermal Necrolysis (TEN) Stevens-Johnson Syndrome (SJS) is uncommon, severe drug-induced hypersensitivity reactions that are typified by extensive keratinocyte apoptosis and epidermal necrosis. They carry a high risk of death and long-term complications. Early detection and prevention through cautious drug use are crucial for treatment (Borchers *et al*., 2008).

The fixed-dose combination of Ofloxacin (fluoroquinolone) and Ornidazole (nitroimidazole) is used to treat mixed bacterial and protozoal infections. Ofloxacin provides broad-spectrum bactericidal activity against gram-positive and gram-negative organisms. Ornidazole is effective against anaerobic bacteria and protozoa. Together, they offer comprehensive coverage for gastrointestinal, gynecological, and other mixed infections (Tripathi, 2019). Ofloxacin approved in 1990 is a member of the second-generation fluoroquinolone having little therapeutic advantage over current treatments (especially to ciprofloxacin) for having a longer half-life, better oral bioavailability, and a wider range of uses for some Sexually Transmitted Diseases (STDs). They exhibit bactericidal effect by concentrating intracellularly, resulting in rapid cell death (Roujeau *et al*., 1995; Ramani *et al*., 2015; Manchukonda and Ramakrishna, 2016). Although fluoroquinolone are effective broad-spectrum bactericidal agents, they have occasionally been associated with Severe Cutaneous Adverse Reactions (SCAR), SJS and TEN (Graham and Tripp, 2025). TEN, also referred to as Lyell's syndrome, is characterized by widespread erythema, epidermal necrosis, and detachment of the epidermis from mucous membranes, often accompanied by systemic complications (Yoon *et al*., 2010).

CASE REPORT

A 28-year-old female presented to medicine department with a two-day history of generalized itching that rapidly progressed to dark, fluid-filled bullous lesions associated with pain and burning sensations. The lesions were distributed over the trunk, back, and bilateral extremities (Figure 1). The patient also reported vomiting, fever with chills, reduced urine output, loss of appetite, and disturbed sleep.

She had consumed a fixed-dose combination of Ofloxacin (200 mg) and Ornidazole (500 mg) for chest pain and right breast

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swelling. Notably, she recalled experiencing a similar reaction two years prior, though details were unclear. On examination, widespread bullae, erosions, and hyperpigmented purpuric patches were noted, with tenderness over the trunk and extremities. The patient was admitted to the dermatology intensive care unit, and the suspected drug combination was discontinued. Supportive therapy included intravenous fluids (dextrose normal saline and ringer lactate), topical liquid paraffin, gentian violet lotion, betadine gargles, and triamcinolone oral paste. Additional treatment included antiemetic (ondansetron), proton pump inhibitors (pantoprazole), paracetamol for fever, protein supplementation, cyclosporine, azithromycin, antihistamines, broad-spectrum antibiotics (amoxicillin-clavulanate, meropenem), corticosteroids (dexamethasone, hydrocortisone), diuretics, and electrolyte correction therapies.

Investigations revealed elevated ESR (39 mm/hr), neutrophilia, thrombocytopenia, anemia (Hb 7.7 g/dL), and hypoalbuminemia. LFTs showed mild derangements, while renal profile indicated hyponatremia (128mEq/L) and hypochloremia. Arterial blood gas analysis demonstrated metabolic acidosis. Blood smear revealed microcytic hypochromic anemia. Cutaneous examination confirmed 50-60% body surface area involvement, with a SCORETEN of 3. Nikolsky's sign was positive. Culture reports identified *Staphylococcus aureus* and *Pseudomonas aeruginosa* sensitive to multiple antimicrobials.

DISCUSSION

In the present case, Ofloxacin in combination with Ornidazole was strongly suspected as the causative drug, given the temporal relationship with symptom onset and a similar previous episode. Several published case reports provide clear evidence that individuals develop TEN following oral use of ofloxacin, which strongly implicates ofloxacin as the cause (Ramani *et al*., 2015). On the other hand, direct evidence of ornidazole causing TEN is limited, but it is consistently associated with severe skin reactions, especially when used in combination with ofloxacin at fixed doses (Gupta, 2014).

The adverse reaction was evaluated using Naranjo's causality scale, which produced a score of 7, consistent with a probable association (Table 1). The Hartwig's severity assessment scale classified the event as moderately severe, since it prolonged hospitalization and required intensive management. TEN was first described in 1956 by Lyell, who recognized its similarity to burns and proposed that SJS and TEN represented different severities of the same disease spectrum (Choudhury and Chakravarty, 2016). The extent of epidermal detachment differentiates SJS (<10%), TEN (>30%), and overlap syndrome (10-30%).

The pathogenesis of TEN is complex, involving immune-mediated keratinocyte apoptosis. Cytotoxic CD8+ T cells and Natural Killer (NK) cells play a central role through the release of cytotoxic proteins such as perforin, granzyme, Tumor Necrosis Factor (TNF)-α, and TNF-Related Apoptosis-Inducing Ligand (TRAIL). Multiple mechanisms have been proposed, including delayed type IV hypersensitivity, direct cytotoxic reactions, and abnormal keratinocyte drug metabolism that presents drug metabolites to cytotoxic lymphocytes via HLA molecules (Mahipathy *et al*., 2019; Estrella-Alonso *et al*., 2017).

The history and clinical findings are suggestive of TEN secondary to Ofloxacin/ Ornidazole intake in the present case. The histopathological assessment of TEN shows keratinocyte apoptosis leading to necrosis, which is the cause of the disorder's widespread epidermal detachment. Although, precise mechanism causing TEN is still unknown, but recent data related to clinical, histopathological and immunological research attributes TEN to an immune mediated process as a severe drug induced hypersensitivity reaction and cytotoxic T cell play a major role in the early phases of the disease development (Mahipathy *et al*., 2019; Melde, 2001). Fluoroquinolones, due to their broad-spectrum antibacterial activity and minimal side effect profile, are being used increasingly. However, their association to cutaneous reactions is not very often, but is being observed more due to their frequent use as evident through published literature which reports ciprofloxacin contributing to a higher incidence of cutaneous reaction than Ofloxacin (Roujeau *et al*., 1995; Mahipathy *et al*., 2019).

Comparative literature insight into Fluoroquinolone-induced TEN

The present case is comparable to previously reported instances of Ofloxacin- and Ofloxacin/Ornidazole-induced Toxic Epidermal Necrolysis (TEN). (Ramani *et al*., 2015) documented cutaneous reactions in children after taking Ofloxacin, indicating its potential for severe dermatological toxicity. Manchukonda and Ramakrishna (2016) reported a fixed drug eruption caused by Ofloxacin/Ornidazole, showing that this combination can lead to hypersensitivity reactions even at therapeutic doses. Gupta (2014) reported a case of Ofloxacin-induced TEN with extensive epidermal necrolysis, emphasizing the risk of severe cutaneous adverse reactions. (Yoon *et al*., 2010) described a case of Ofloxacin-induced TEN with mucosal involvement, similar to the systemic manifestations observed in the present case.

(Melde, 2001) identified Ofloxacin as a likely cause of TEN, highlighting the potential for life-threatening dermatological reactions despite its broad-spectrum efficacy. (Mahipathy *et al*., 2019) reported a case of Lyell's syndrome (TEN) with systemic complications, mirroring the multi-organ involvement seen in our patient. (Estrella-Alonso *et al*., 2017) emphasized TEN as a critical illness, emphasizing the importance of early withdrawal of the offending drug and intensive supportive care.

These reports collectively suggest that Ofloxacin, whether used alone or in combination with Ornidazole, is consistently associated with TEN, albeit rarely. The similarities among cases, such as

Table 1: Causality Assessment of suspected ADR using Naranjo Scale.

Question		Yes	No	Don't Know/ NA	Score*
1	Are there previous conclusive reports on this reaction?	+1	0	0	1
2	Did the adverse event appear after the suspected drug was administered?	+2	-1	0	2
3	Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0	1
4	Did the adverse event reappear when the drug was re-administered?	+2	1	0	0
5	Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	2	0	2
6	Did the reaction reappear when a placebo was given?	-1	1	0	0
7	Was the drug detected in blood (or other fluids) in concentrations known to be toxic?	+1	0	0	0
8	Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	0
9	Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0	0
10	Was the adverse event confirmed by any objective evidence?	+1	0	0	1
Total Score					7

*Score: Definite: ≥ 9, Probable: 5-8, Possible: 1-8, Doubtful: 0 Report: The suspected ADR found to be Probable on Naranjo scale assessment.

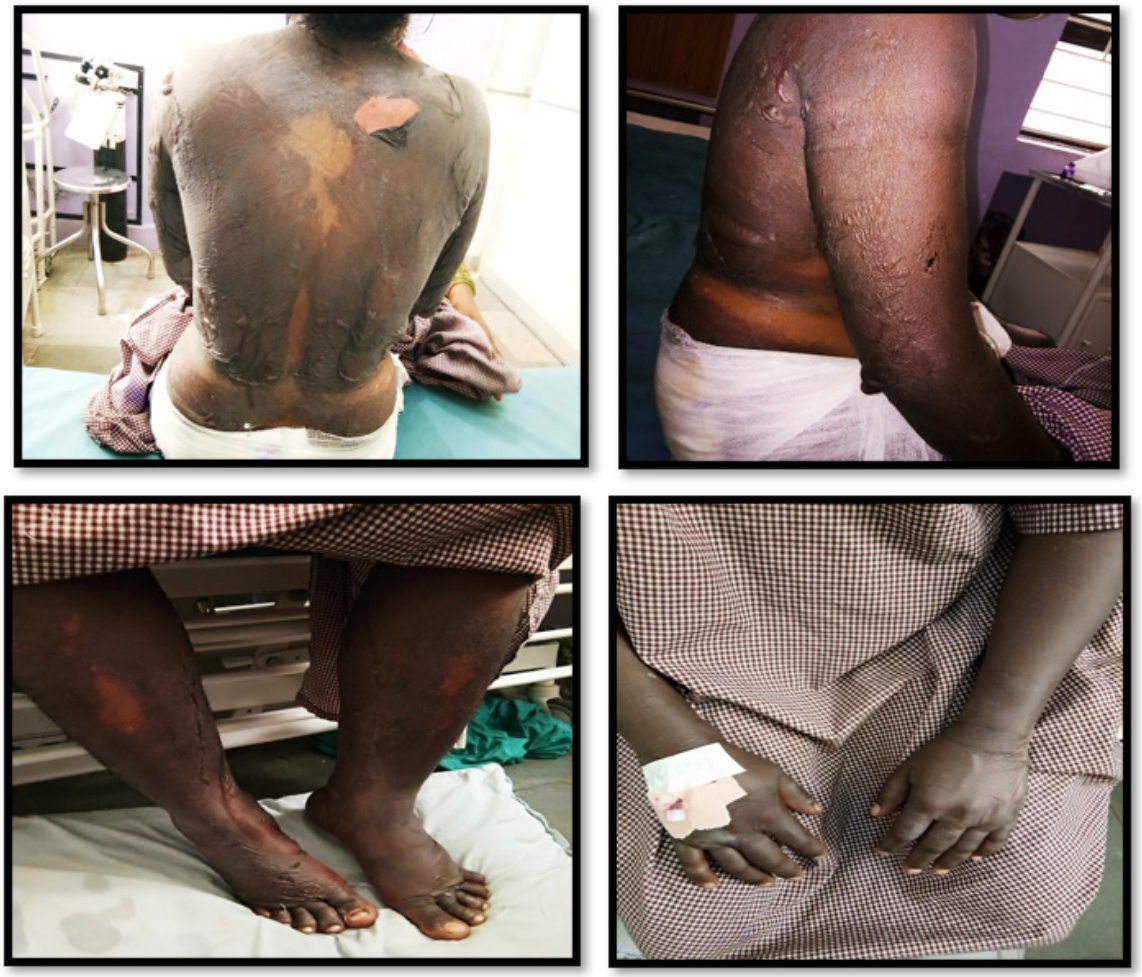

Figure 1: Multiple hyper pigmented purpuric patches present over trunk and bilateral upper and lower extremities.

rapid onset of bullous eruptions, mucosal involvement, systemic complications, and prolonged hospitalization, underscore the need for cautious prescribing, early identification, and immediate discontinuation of the causative agent.

Pharmacist Role in Drug Safety

Clinical pharmacists are essential in early detection and reporting of adverse drug reactions, such as severe cutaneous reactions like TEN. Screening and monitoring of high-risk drug prescriptions, recognize signs/symptoms of drug hypersensitivity requiring immediate medical attention and educate patients on untoward serious effects of drugs are some of the core responsibilities of the pharmacist action. Inclusion of pharmacists in multidisciplinary teams enhances patient safety and bolsters surveillance and prevention of drug-induced toxicities.

CONCLUSION

This case highlights a rare but serious adverse drug reaction associated with Ofloxacin/Ornidazole, manifesting as TEN. Causality assessment confirmed a probable relationship, while severity assessment placed the event in the moderately severe category. Clinicians should exercise caution when prescribing Ofloxacin or related fluoroquinolone, particularly in patients with a prior history of drug-induced cutaneous reactions. Patient education and close monitoring are essential to prevent recurrence and reduce morbidity.

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ABBREVIATIONS

CD: Cluster of Differentiation; **DNA:** Deoxyribonucleic Acid; **ESR:** Erythrocyte Sedimentation Rate; **Hb:** Hemoglobin; **HLA:** Human Leukocyte Antigens; **LFTs:** Liver function tests; **ROS:** Reactive Oxygen Species; **SCORETEN:** Severity-of-Illness Score for Toxic Epidermal Necrolysis; **SCAR:** Severe Cutaneous Adverse Reaction; **SJS:** Stevens-Johnson syndrome; **STDs:** Sexually transmitted diseases; **TEN:** Toxic Epidermal Necrolysis; **TNF:** Tumor Necrosis Factor; **TRAIL:** TNF-related apoptosis-inducing ligand.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

FUNDING

The study neither applied for nor received funding from any source.

SUMMARY

Toxic Epidermal Necrolysis (TEN) is a rare and severe drug-induced hypersensitivity reaction that causes widespread epidermal necrosis and systemic complications. A 28-year-old female who developed rapidly progressing bullous lesions covering more than 50% of her body surface area, mucosal involvement, fever, and metabolic disturbances after taking a fixed-dose combination of Ofloxacin and Ornidazole. Treatment involved immediate discontinuation of the offending drugs, supportive care, corticosteroids, antibiotics, and correction of fluid/electrolyte imbalances. The causality assessment reveals fluoroquinolone-induced TEN and underscores the importance of careful prescribing, early recognition, and prompt withdrawal of drugs to prevent life-threatening complications.

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