Case Report

Fluoroquinolone-Induced Fixed Drug Eruption: A Clinically Significant Case Report

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Fixed drug eruption (FDE) is a well-recognized cutaneous adverse drug reaction (ADR) characterized by the recurrence of lesions at the same anatomical site upon re-exposure to the offending drug. Although most cases are benign, severe or generalized variants can significantly impair quality of life. We present the case of an 18-year-old male who developed multiple hyperpigmented patches and blistering after administration of ofloxacin, a commonly prescribed fluoroquinolone antibiotic. Lesions recurred after inadvertent re-challenge, confirming the diagnosis of drug-induced FDE. Causality assessment using both the WHO-UMC system and the Naranjo algorithm classified the event as "probable." The patient responded well to systemic corticosteroids, topical corticosteroids, and non-sedating antihistamines, with complete resolution over three weeks. This case emphasizes the importance of careful drug history, patient counselling, and the role of pharmacovigilance in preventing recurrent ADRs.

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Introduction

Cutaneous adverse drug reactions (CADRs) are undesirable effects of medications that manifest in the skin and its adnexa, including nails, hair, and glands. The skin is the organ most frequently involved in adverse drug reactions, accounting for approximately 45% of reported cases. The prevalence of CADRs among adult patients ranges from 1 to 3%, while overall, up to 10% of hospitalized patients experience some form of cutaneous drug reaction.[1]

Among them, fixed drug eruption (FDE) is a distinctive entity that is easily recognizable but often underreported. FDE is defined by the sudden onset of well-demarcated, erythematous or violaceous macules that recur at the same sites with each subsequent exposure to the culprit drug[2]. Healing is typically followed by residual post-inflammatory hyperpigmentation, which serves as a clinical hallmark.

The pathogenesis of FDE involves a T-cell–mediated immune mechanism, wherein drug-specific CD8+ memory T cells persist in the affected skin. Upon re-exposure, these cells are reactivated, leading to localized keratinocyte apoptosis and inflammation.[3]

Fluoroquinolones are widely prescribed antimicrobial agents due to their broad-spectrum coverage and good oral bioavailability. However, their safety profile has increasingly come under scrutiny because of reports of musculoskeletal, neurological, and dermatological toxicities. Ofloxacin, in particular, has been implicated in several reports of FDE, Stevens–Johnson syndrome, and photosensitivity reactions.[4,5]

Herein, we describe a clinically significant case of ofloxacin-induced FDE in an adolescent male, highlighting diagnostic challenges, management, and the importance of pharmacovigilance in preventing recurrence.

Case Report

Patient Information

An 18-year-old previously healthy male presented with complaints of a sudden onset of dark patches over the neck, ear, and genitalia, along with painful blisters on both hands. He reported a generalized itching and burning sensation. There was no history of fever, mucosal involvement, or systemic features.

Past History

The patient denied any prior episodes of cutaneous drug reactions. He was not on long-term medications and had no known allergies.

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Present Illness and Timeline

On day 1, the patient was prescribed a combination of ofloxacin, betamethasone, and cetirizine-phenylephrine-paracetamol for a febrile illness. Within 24 hours, erythematous lesions developed on the neck and genitalia. On day 3, he received pheniramine, dexamethasone, and ampicillin, but the lesions did not improve. On Day 5, he inadvertently re-consumed the same medication combination as on day 1, which resulted in worsening of symptoms, including the appearance of bullous lesions on the hands.

On day 6, a dermatology consultation was sought. Based on clinical suspicion of FDE, clobetasol propionate cream, prednisolone (16 mg OD), and bilastine were prescribed. The patient reported significant symptomatic improvement within 3 to 4 days.

At follow-up (Day 16), prednisolone was tapered to 8 mg daily for 10 days, and fusidic acid cream was added to prevent secondary infection. By day 26, the lesions had nearly resolved, leaving behind faint hyperpigmented patches without scarring.

Clinical Findings

- Hyperpigmented, well-demarcated patches on the neck, ear, and genitalia
- Blistering on the dorsum of the hands
- No mucosal involvement, lymphadenopathy, or systemic signs

Diagnostic Assessment

Provisional diagnosis

Fixed drug eruption secondary to ofloxacin

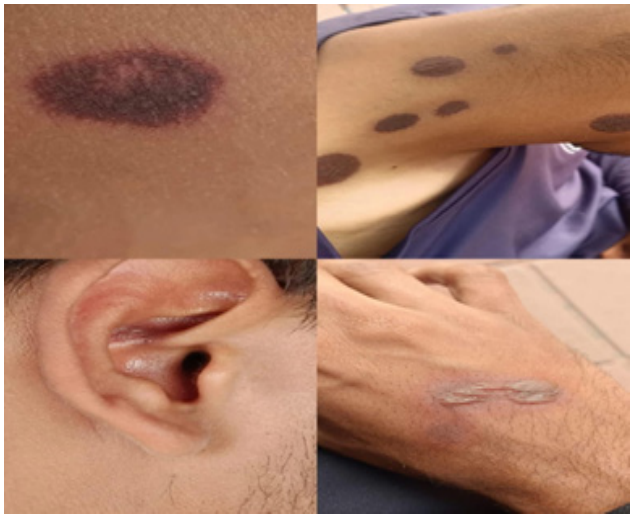

Figure 1: Hyperpigmented patches on neck, hands, ear suggestive of FDE (Lesions appeared on day 1 soon after the first dose and worsened on day 5 on repetition of dosage)

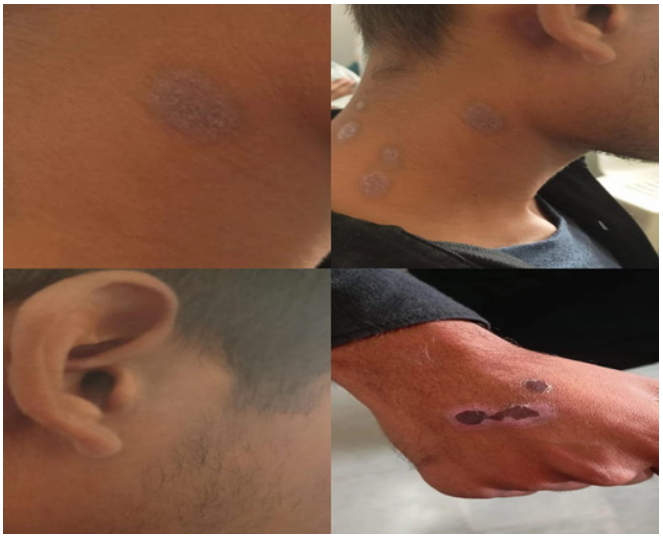

Figure 2: Resolution of lesions post-treatment (Day 26)

Differential diagnoses considered

Stevens–Johnson syndrome, erythema multiforme, drug-induced exanthema (ruled out based on lesion morphology, absence of mucosal involvement, and temporal relation with ofloxacin intake)

Causality Assessment

- WHO-UMC: Probable
- Naranjo Algorithm: Probable (score 6)

Ethical consideration

Re-challenge was not performed due to the risk of aggravation.

Therapeutic Intervention

Topical therapy

Clobetasol cream twice daily; fusidic acid cream for infection prophylaxis

Systemic therapy

Prednisolone (16 mg/day × 10 days, tapered to 8 mg/day), bilastine once daily × 10 days

Monitoring

Daily symptom diary and dermatology follow-ups on day 10 and 20

Follow-up and Outcomes

The patient demonstrated marked improvement after 10 days of therapy, with near-complete resolution at three weeks. He was counseled regarding strict avoidance of ofloxacin and related fluoroquinolones, provided with a drug alert card, and educated about recognizing early signs of recurrence.

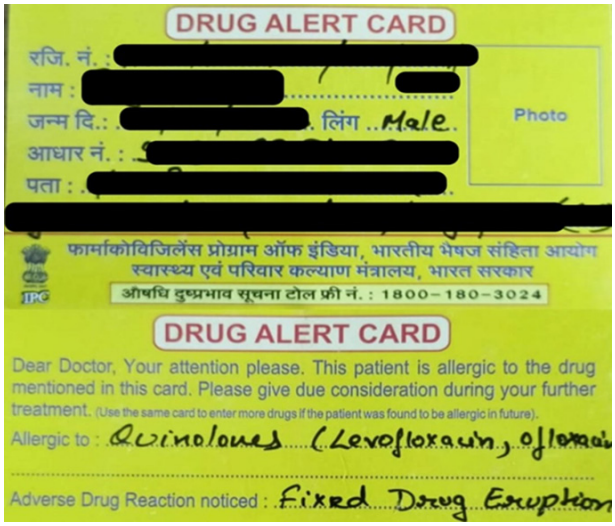

Figure 3: Drug alert card warning against fluoroquinolone use

Discussion

FDE is a common but often overlooked ADR. The incidence is estimated at 2 to 10% of all cutaneous ADRs.[2] While sulfonamides, NSAIDs, and tetracyclines are classical culprits, reports implicating fluoroquinolones, including ofloxacin, are steadily increasing.[4,6]

Pathogenesis

The hallmark of FDE is localized, drug-specific CD8+ memory T-cell activation. These T cells persist in the basal layer of epidermis at previously affected sites and are reactivated upon re-exposure, releasing IFN-γ, TNF-α, and granzyme B, leading to keratinocyte apoptosis and blister formation[3].

Clinical spectrum

Lesions typically appear within hours of drug intake, presenting as round or oval erythematous patches, often with burning or pruritus. On healing, residual pigmentation is common. Severe variants include bullous FDE and generalized FDE, which can mimic Stevens–Johnson syndrome.

Diagnosis

Diagnosis relies heavily on clinical history, temporal relationship, and lesion recurrence upon re-exposure. Patch testing and oral provocation may be performed in selected cases, but were avoided in our patient due to the risk of severe reaction. Causality assessment tools, such as WHO-UMC and the Naranjo scale, help standardize reporting.[7]

Although multiple drugs were prescribed initially, ofloxacin was considered the most likely causative agent. Paracetamol was excluded as the patient had previously tolerated it without adverse reactions and it was not consumed independently during re-exposure. Betamethasone, being a corticosteroid, is rarely implicated in fixed drug eruption and is more commonly therapeutic, while cetirizine and phenylephrine have minimal association with this reaction. The recurrence and worsening of lesions at identical sites following inadvertent re-exposure to the ofloxacin-containing regimen strongly support ofloxacin as the offending drug, further corroborated by a "probable" causality rating on both WHO–UMC and Naranjo scales.

Previously reported cases of ofloxacin-induced fixed drug eruption describe rapid-onset, well-demarcated lesions with frequent genital or acral involvement and residual hyperpigmentation, findings that closely parallel our case.[4] Similar to earlier reports, re-exposure resulted in lesion exacerbation, supporting an immunologically mediated mechanism. However, the multifocal distribution and bullous involvement observed in our patient suggest a relatively extensive presentation compared to most reported cases. Notably, cross-reactivity among fluoroquinolones has been documented due to shared core chemical structures, implying that patients with ofloxacin-induced FDE remain at risk of reactions to other agents within the class and should therefore avoid all fluoroquinolones in the future.

Management

First-line management involves immediate withdrawal of the offending drug. Topical corticosteroids provide symptomatic relief for localized disease, whereas systemic corticosteroids are reserved for extensive or bullous forms. Antihistamines relieve associated pruritus. Antibiotics like fusidic acid are useful when secondary infection is suspected. Importantly, counseling the patient and providing a drug alert card prevent inadvertent re-exposure, which otherwise risks more severe outcomes.[6]

Pharmacovigilance

Fluoroquinolones carry FDA black box warnings for serious adverse effects, including tendinopathy and neuropathy, but cutaneous reactions such as FDE are under-recognized.[5] Reporting such cases is crucial to enrich pharmacovigilance databases and guide safer prescribing practices.

Clinical Implications

This case highlights the importance of:

- Taking a detailed drug history in all suspected ADRs

- Educating patients about ADR recognition and reporting
- Avoiding unnecessary polypharmacy
- Issuing written drug avoidance documentation (e.g., Drug Alert Card)

Conclusion

Ofloxacin-induced fixed drug eruption, though rare, is a clinically important dermatological ADR. Prompt identification, appropriate management, and patient counseling are vital to ensure complete recovery and prevent recurrence. This case underscores the necessity of pharmacovigilance and rational antibiotic prescribing.

Informed Consent

Written informed consent was obtained from the patient for publication of this case report and associated clinical images.

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