Journal of Animal Environment

(E-ISSN 2717-1396, ISSN 2717-1388)

Original Research Paper

Ofloxacin-Induced Fixed Drug Eruption with Oral Mucosal Involvement in a 40-Year-Old Woman: A Case Report

Dr. Ashish Varma[1*], Dr. Anuj Varma[2], Dr. Harshad Aprajit[3], Dr. Neha Varma[4]

[1*]Department of Pediatrics, DMIHER, Sawangi Meghe, Wardha, Maharashtra, India | Email: avarma2055@gmail.com

[2]Department of Medicine, DMIHER, Sawangi Meghe, Wardha, Maharashtra, India

[3]Department of Pathology, DMIHER, Sawangi Meghe, Wardha, Maharashtra, India

[4]Department of Obstetrics and Gynaecology, DMIHER, Sawangi Meghe, Wardha, Maharashtra, India

***Corresponding Author:** Dr. Ashish Varma, M.D., Department of Pediatrics, DMIHER, Sawangi Meghe, Wardha, Maharashtra, India | Email: avarma2055@gmail.com

Abstract

Background: Fixed drug eruption (FDE) is a distinct, delayed (type IVc) hypersensitivity reaction characterised by the recurrence of one or more erythematous-to-violaceous, well-demarcated patches at the same cutaneous or mucosal site upon re-exposure to the causative agent. Fluoroquinolones, including ofloxacin, are increasingly recognised as inciting drugs, and involvement of the oral mucosa, although reported, remains uncommon and is frequently misdiagnosed as an infective stomatitis.

Case Presentation: We report a 40-year-old woman who developed burning erythema and erosions of the lower lip and buccal mucosa, together with two well-defined violaceous plaques on the index finger of the left hand and the trunk, within 10 hours of starting oral ofloxacin 200 mg twice daily for a urinary tract infection. She recalled an almost identical, undiagnosed episode eight months earlier after a febrile illness treated with an unspecified antibiotic. Ofloxacin was withdrawn, and she was treated with a short tapering course of oral corticosteroid, an antihistamine, and topical triamcinolone, with complete resolution of the oral erosions within 10 days and residual post-inflammatory hyperpigmentation at the cutaneous sites. A Naranjo Adverse Drug Reaction Probability Scale score of 8 and a WHO-Uppsala Monitoring Centre causality category of "probable" supported a diagnosis of ofloxacin-induced FDE.

Conclusion: This case highlights ofloxacin as an under-recognised cause of oral mucosal FDE and underscores the value of a careful drug and recurrence history, structured causality assessment, prompt drug withdrawal, and pharmacovigilance reporting in preventing more severe re-exposure reactions such as generalised bullous FDE.

Keywords: Fixed drug eruption; Ofloxacin; Fluoroquinolones; Oral mucosa; Adverse drug reaction; Drug hypersensitivity; Case report

1. Introduction

Fixed drug eruption (FDE) is a cutaneous adverse drug reaction in which a rash recurs at an identical anatomical site each time the culprit drug is administered, with new sites occasionally recruited on subsequent exposures. Pathogenesis is attributed to activation of CD8+ resident memory T lymphocytes lodged in previously affected epidermis, which release interferon-gamma and cytotoxic mediators upon re-encountering the drug or its metabolites, producing keratinocyte apoptosis, interface dermatitis, and post-inflammatory pigment incontinence.

Antimicrobials, non-steroidal anti-inflammatory drugs, and anticonvulsants are the classes most frequently implicated in FDE. Among antimicrobials, fluoroquinolones such as ofloxacin, ciprofloxacin, and levofloxacin are established, though less common, causative agents; cross-reactivity within the quinolone class has also been documented, which has practical implications for future antibiotic selection [1-4,8]. Mucous membrane involvement, particularly of the oral cavity, is reported in a minority of FDE cases and may occur with or without accompanying skin lesions; isolated or predominant oral involvement is easily mistaken for herpetic stomatitis, erythema multiforme, or an immunobullous disorder, which can delay recognition of the causative drug [6,7].

We describe a case of ofloxacin-induced FDE with prominent oral mucosal erosions in a middle-aged

***Corresponding Author:**
Received: 25th May, 2026; Revised: 6th June, 2026; Accepted: 8th June, 2026; Available Online: 04rd August, 2026
(DOI): 10.70102/AEJ.2026.18.2s.73

woman, and we discuss the clinical reasoning, causality assessment, and management issues relevant to this presentation, with reference to previously published cases of fluoroquinolone-associated FDE.

2. Case Presentation

2.1 Patient Information

A 40-year-old woman presented to the outpatient department with a two-day history of painful oral erosions and skin lesions. She had no history of smoking or alcohol use, and no relevant family history of skin or autoimmune disease. She had been in her usual state of health until three days prior, when she developed dysuria, urinary frequency, and low-grade fever, for which a local physician prescribed oral ofloxacin 200 mg twice daily along with a single dose of an antipyretic (paracetamol 500 mg).

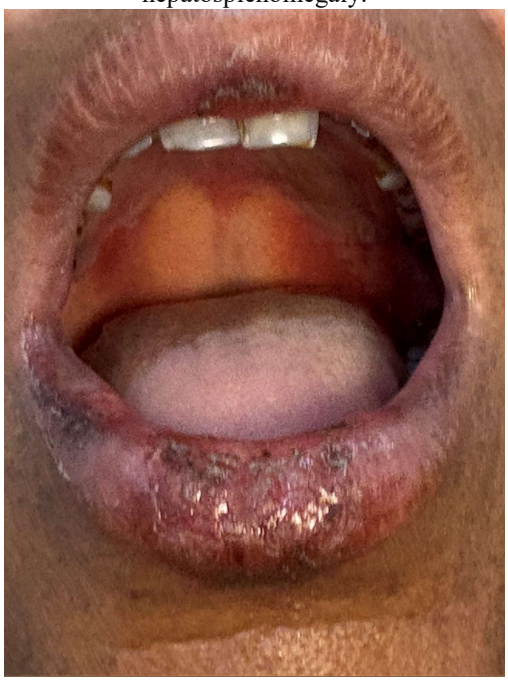
2.2 History of Presenting Illness

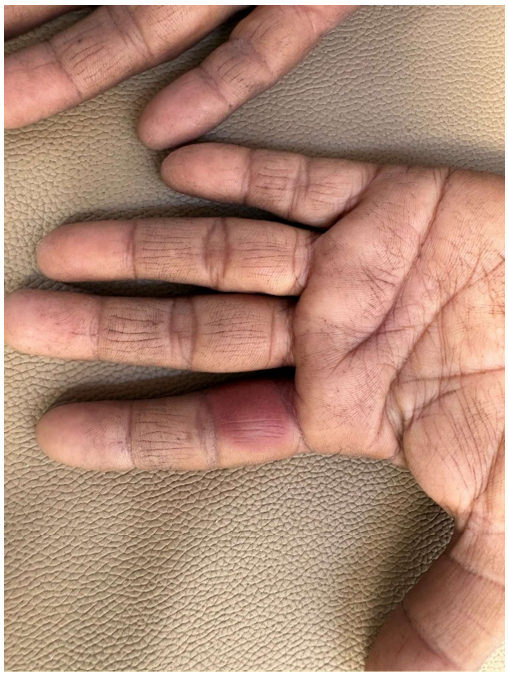
Approximately 8-10 hours after the first dose of ofloxacin, the patient noticed a burning sensation on her lower lip and inside her cheeks, followed within hours by painful erosions of the lip and buccal mucosa that made eating difficult. Over the next day, she also noticed a dusky, itchy patch on the index finger of her left hand and a similar patch on her trunk. She denied fever at this stage, ocular symptoms, genital lesions, or systemic complaints such as arthralgia or breathlessness. Paracetamol was not repeated, and no other new medication, herbal preparation, or supplement had been introduced in the preceding month.

On direct questioning, she recalled a similar but milder episode last year : a painful lip ulcer and a hyperpigmented patch on the same area of the left hand had developed a day or two after she took an unspecified "fever tablet" from a local pharmacy for a similar urinary complaint. That episode had resolved with medical consultation over about two weeks, leaving faint pigmentation that she had not previously connected to any medication and she does not have any documentation of any culprit medicine.

2.3 Clinical Findings

On examination, the patient was afebrile and haemodynamically stable. There was a single, sharply demarcated, erythematous erosion, approximately 1.5 x 1 cm, on the vermilion border and mucosal aspect of the lower lip, covered by a haemorrhagic crust. Similar shallow erosions with a surrounding violaceous halo were present on the left and right buccal mucosa. On the skin, a well-defined, round, dusky-violaceous plaque measuring 1 x 2 cm with central duskiness was noted on index finger of the left hand, and a second, smaller plaque of similar morphology was present on the trunk. There was no blistering elsewhere, no target lesions, and Nikolsky's sign was negative. Estimated body surface area involvement was well under 10%, arguing against a generalised bullous FDE or an epidermal necrolysis spectrum disorder. There was no conjunctival injection, genital involvement, lymphadenopathy, or hepatosplenomegaly.





2.4 Diagnostic Assessment

Complete blood count, liver and renal function tests, and random blood glucose were within normal limits, and there was no peripheral eosinophilia. A 4 mm punch biopsy was taken from the edge of the hand

lesion for histopathology to exclude erythema multiforme and an immunobullous process given the mucosal involvement. Histopathology showed a vacuolar interface dermatitis with scattered necrotic keratinocytes, mild superficial perivascular lymphocytic infiltration with occasional eosinophils, and pigment incontinence in the papillary dermis - findings consistent with FDE and without the full-thickness epidermal necrosis or acantholysis expected in toxic epidermal necrolysis or pemphigus, respectively.

Causality was assessed using two complementary structured tools. The Naranjo Adverse Drug Reaction Probability Scale yielded a score of 8, corresponding to a "probable" adverse drug reaction, based on the plausible temporal relationship, the recurrence of lesions at the same sites on a prior undocumented exposure, the absence of an alternative aetiology, and improvement on withdrawal of the drug. Applying the WHO-Uppsala Monitoring Centre (WHO-UMC) causality categories similarly placed the reaction in the "probable" category, as a formal rechallenge was not performed for safety and ethical reasons. Given the strong clinical and historical evidence, a diagnostic drug provocation test was not considered necessary or justifiable in this patient.

2.5 Therapeutic Intervention

Ofloxacin was discontinued immediately upon presentation. The patient was started on oral prednisolone 30 mg daily, tapered over ten days, along with oral levocetirizine 5 mg once daily for pruritus. Triamcinolone acetonide 0.1% was applied to the oral erosions three times daily, and a bland petrolatum-based lip emollient was advised. Her urinary tract infection was managed with an alternative, structurally unrelated antibiotic (nitrofurantoin) selected specifically to avoid any quinolone-class agent.

2.6 Follow-Up and Outcomes

The oral erosions re-epithelialised substantially within five days and had fully healed by day nine, without scarring. The cutaneous plaques faded over the same period, leaving residual post-inflammatory hyperpigmentation at both sites, which was still visible but fading at the four-week follow-up visit. No new lesions developed. The patient was counselled in detail about the diagnosis, the likely cross-reactivity of ofloxacin with other fluoroquinolones (ciprofloxacin, levofloxacin, norfloxacin), and the importance of informing all future prescribers. She was issued a written drug alert card documenting the suspected reaction. She was advised to remember the culprit drug whenever she will visit any doctor for future visit.

3. Discussion

Fixed drug eruption accounts for a meaningful proportion of cutaneous adverse drug reactions, and mucosal involvement, though under-recognised, is not rare: published series have reported oral mucosal involvement in roughly one-third of established FDE cases, with a minority of patients showing exclusively mucosal disease without any skin lesions [6]. Oral lesions are most often bullous or erosive, typically affecting the lips, tongue, and hard palate, and can mimic herpes simplex stomatitis, erythema multiforme, aphthous ulceration, or Behçet's disease, which contributes to diagnostic delay when the cutaneous component is subtle or absent [7].

Ofloxacin and other fluoroquinolones are well-documented, if relatively infrequent, causes of FDE. Several case reports have described ofloxacin-induced FDE presenting with genitourinary infection as the indication, as in the present case, with lesions typically appearing within hours to a day of drug intake and resolving with hyperpigmentation after withdrawal [1,2,3]. Cross-reactivity among fluoroquinolones sharing the quinolone nucleus, and hypersensitivity reactions to this drug class more broadly, have also been described, which is clinically relevant when selecting a replacement antimicrobial, as illustrated by the switch to a structurally unrelated agent in our patient [4,8].

The differential diagnosis in a patient with painful oral erosions and a compatible drug history includes erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis, herpetic gingivostomatitis, and immunobullous diseases such as pemphigus vulgaris and mucous membrane pemphigoid. Features favouring FDE over these alternatives include a clear history of recurrence at the same site with previous drug exposure, limited body surface area involvement, absence of a prodromal viral illness, and characteristic histopathology showing interface changes with pigment incontinence rather than full-thickness epidermal necrosis or acantholysis. In the present case, the patient's recollection of an almost identical episode eight months earlier, although not medically evaluated at the time, was a key clue and illustrates how a directed history of recurrent, site-specific lesions can substantially narrow the differential before any investigation is performed.

Structured causality assessment tools such as the Naranjo scale and the WHO-UMC system provide a reproducible framework for documenting the probability of drug causation, particularly when a formal rechallenge is not ethically justifiable, as was the case here [5]. Their routine use, alongside skin biopsy where the presentation is atypical or mucosa-predominant, supports a confident clinical diagnosis while avoiding unnecessary re-exposure to the suspected drug.

From a pharmacovigilance perspective, this case adds to a growing body of literature calling for greater awareness of ofloxacin, and fluoroquinolones in

general, as causes of FDE, and for routine antibiotic stewardship and adverse-drug-reaction reporting whenever cutaneous or mucosal reactions follow antimicrobial therapy [1,9]. Clear documentation and patient-held drug alert information are simple, low-cost measures that can prevent progression to more severe variants such as generalised bullous FDE on inadvertent re-exposure.

Limitations: This is a single case report, and, as is appropriate given the risk of triggering a more severe reaction, no formal oral drug provocation test or patch test was performed to confirm causation; the diagnosis instead relies on a compatible history, recurrence pattern, structured causality scoring, and supportive histopathology.

4. Conclusion

Ofloxacin should be considered in the differential diagnosis of oral mucosal fixed drug eruption, particularly when erosive lip or buccal lesions follow initiation of a fluoroquinolone for a genitourinary or other infection. A careful history focused on prior, possibly undiagnosed, episodes at the same site is central to timely recognition. Prompt withdrawal of the offending drug, supportive topical and systemic therapy, structured causality assessment, and clear counselling on cross-reactivity within the fluoroquinolone class are key to good outcomes and to preventing recurrence or escalation to generalised bullous FDE.

5. Declarations

Ethics approval and consent to participate: Not applicable (single de-identified case report; no interventional research was undertaken).

Consent for publication: Written informed consent was obtained from the patient for publication of this case report. [Insert consent statement/reference number as per journal and institutional policy; attach signed consent form if required by the submitting journal.]

Availability of data and materials: Not applicable; no datasets were generated or analysed beyond what is presented in this report.

Competing interests: The authors declare that they have no competing interests.

Funding: This case report received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Authors' contributions: [Author 1] managed the patient and drafted the manuscript. [Author 2] contributed to literature review, critical revision, and supervision. All authors read and approved the final manuscript.

Acknowledgements: None.

References

1. Varma AR, Varma AR, Arora SP, Naqvi WM. Case report: Ofloxacin-induced fixed drug eruption [version 1]. F1000Research. 2024;13:181.
2. Kamal AFF, Vardhamane SH, Saba A. A case report of ofloxacin induced fixed drug eruptions and hypersensitivity reaction. Int J Basic Clin Pharmacol. 2017;6(7):1825-7.
3. Manuel GG, Thapa P, Sajan T. Ofloxacin induced fixed drug eruption: a case report. Open J Clin Med Case Rep. 2020.
4. Dhar S, Sharma VK. Fixed drug eruption due to ciprofloxacin. Br J Dermatol. 1996;134(1):156-8.
5. Naranjo CA, Busto U, Sellers EM, Sandor P, Ruiz I, Roberts EA, et al. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther. 1981;30(2):239-45.
6. Anderson HJ, Lee JB. A review of fixed drug eruption with a special focus on generalized bullous fixed drug eruption. Medicina (Kaunas). 2021;57(9):925.
7. Özkaya E. Oral mucosal fixed drug eruption: characteristics and differential diagnosis. J Am Acad Dermatol. 2013;69(2):e51-8.
8. Scherer K, Bircher AJ. Hypersensitivity reactions to fluoroquinolones. Curr Allergy Asthma Rep. 2005;5(1):15-21.
9. Jhaj R, Chaudhary D, Asati D, Sadasivam B. Fixed-drug eruptions: what can we learn from a case series? Indian J Dermatol. 2018;63(4):332-7.
10. WHO Uppsala Monitoring Centre. The use of the WHO-UMC system for standardised case causality assessment. Uppsala: Uppsala Monitoring Centre; 2018.