



Original Research Paper

Oral Fixed Drug Eruption Induced by Ofloxacin: A Case Report

Dr. Anuj Varma¹, Dr. Harshad Aprajit², Dr. Neha Varma³, Dr. Ashish Varma^{4*}

¹Department of Medicine, DMIHER, Sawangi Meghe, Wardha, Maharashtra, India

²Department of Pathology, DMIHER, Sawangi Meghe, Wardha, Maharashtra, India

³Department of Obstetrics and Gynaecology, DMIHER, Sawangi Meghe, Wardha, Maharashtra, India

^{4*}Department of Pediatrics, DMIHER, Sawangi Meghe, Wardha, Maharashtra, India | Email: avarma2055@gmail.com

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

Abstract

Fixed drug eruption (FDE) is a distinct cutaneous and mucosal adverse drug reaction that characteristically recurs at the same anatomical site on re-exposure to the causative agent. Isolated mucosal involvement without any skin lesions is uncommon, and often being misdiagnosed as herpetic stomatitis, aphthous ulceration, erythema multiforme or an autoimmune vesiculobullous disorder. We report a case of a 50-year-old woman who developed a solitary, well-demarcated erosive plaque of the oral mucosa, with a central white slough and surrounding erythema, following intake of oral ofloxacin. The lesion was confined entirely to the oral cavity with no cutaneous, ocular, genital or other mucosal involvement. A temporal association between drug intake and lesion onset, together with the characteristic clinical morphology, supported a diagnosis of ofloxacin-induced oral FDE. The offending drug was withdrawn, and the patient was managed conservatively/with topical–systemic corticosteroids, with satisfactory resolution. This report highlights the need for a high index of suspicion for FDE when evaluating oral ulcerative lesions, particularly in patients with a recent history of fluoroquinolone use, and underscores the importance of a detailed drug history in the diagnostic workup of oral mucosal ulceration.

Keywords: Fixed drug eruption; ofloxacin; fluoroquinolone; oral mucosa; adverse drug reaction; oral ulceration.

Introduction

Fixed drug eruption (FDE) is a well-recognised, T-cell-mediated cutaneous adverse drug reaction that recurs at an identical anatomical site each time the causative drug is administered, a feature attributed to the persistence of intraepidermal CD8⁺ effector-memory T cells within the resting lesion.

FDE accounts for a substantial proportion of cutaneous drug reactions seen in Indian dermatology practice, and antimicrobials — including fluoroquinolones — are among the most frequently implicated agents. Oral mucosal involvement in FDE, whether isolated or accompanying skin lesions, is reported in only a small minority of cases, with the tongue and hard palate being the most commonly affected intraoral sites; a solitary oral lesion without any cutaneous eruption is distinctly uncommon and can pose a diagnostic challenge, as it mimics several other erosive and ulcerative oral mucosal disorders.

Ofloxacin, a second-generation fluoroquinolone widely prescribed for urinary, gastrointestinal and respiratory infections in India, has been implicated in cutaneous and mucosal FDE in several case reports, with presentations ranging from a solitary genital or oral patch to generalised bullous eruptions. We describe a case of ofloxacin-induced FDE presenting as a erosive oral lesion, with the aim of increasing clinical awareness of this presentation among physicians, dentists and pharmacologists.

Case Report

Patient information: A 50-year-old woman presented with a painful lesion involving the oral mucosa of 2 days duration. She gave a history of having taken oral ofloxacin 200mg for febrile illness, prescribed 2 days prior to presentation, with onset of oral symptoms approximately 10-12 hours after intake of the drug. She was also taking paracetamol with this but she had never experienced similar episode with paracetamol in past. So we can suspect ofloxacin as a culprit causative drug for this FDE.

***Corresponding Author:**

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She had no similar episode in the past. There was no history of genital or ocular involvement, and no history of similar lesions on the skin. She was not taking other medicine and had no known drug allergies previously documented in her records.

Clinical findings: General and systemic examination was unremarkable, with no lymphadenopathy and no cutaneous, ocular, genital or anal lesions. Intraoral examination revealed a solitary, well-demarcated erosive plaque involving the labial and adjoining buccal/gingival mucosa, with a central greyish-white pseudomembranous slough and a surrounding erythematous halo; sloughing of the overlying epithelium had resulted in a shallow, tender ulceration (Figures 1 and 2). The lesion margin was regular, and no target-like or annular skin lesions, bullae, or Nikolsky sign were noted elsewhere. She also had small denudation ulcer with discharge on upper lip.



Diagnostic assessment: A clinical diagnosis of drug-induced oral mucosal lesion was considered, and fixed drug eruption was suspected on the basis of the temporal relationship with ofloxacin intake and the characteristic solitary, well-demarcated erosive morphology. Differential diagnoses considered included herpetic stomatitis, major aphthous ulceration, erythema multiforme, and an erosive autoimmune vesiculobullous disorder (pemphigus vulgaris/mucous membrane pemphigoid), which were rendered less likely by the absence of a prodrome, the well-defined single lesion, negative Nikolsky sign, and lack of multiple target lesions or widespread mucocutaneous involvement.

Routine haematological investigations were within normal limit.

Therapeutic intervention: Ofloxacin was discontinued immediately, and the patient was treated with iv fluids, oral steroids like prednisolone, levocetirizine, and sucralfate oxytocain syrup for oral ulcer along with oral hygiene measures and a bland, non-irritating diet.

Follow-up and outcome: The lesion showed progressive healing over 8 days, resolving with mild post-inflammatory pigmentation. The patient was counselled regarding avoidance of ofloxacin and other fluoroquinolones in future, and advised to inform treating physicians of this reaction.

Discussion

Fixed drug eruption is a T-cell-mediated hypersensitivity reaction in which intraepidermal/intraepithelial CD8⁺ effector-memory T cells persist at the site of a resolved lesion and are rapidly reactivated on re-exposure to the causative drug, producing localised keratinocyte apoptosis, erythema, and, in more severe forms, bullae and epithelial sloughing. This same immunological mechanism, when it occurs within the oral epithelium, accounts for the erosive, well-demarcated appearance seen in mucosal FDE.

Oral involvement in FDE is uncommon, and a solitary intraoral lesion without any associated skin, ocular, genital or anal lesion — as in the present case — is even rarer; a large retrospective series of oral mucosal FDE described the tongue and hard palate as the most frequently affected sites, with a bullous or erosive morphology predominating and a substantial proportion of patients initially misdiagnosed as having herpetic stomatitis or Behçet's disease. This diagnostic confusion underlines the importance of a systematic drug history in every patient presenting with an acute erosive or ulcerative oral lesion.

Fluoroquinolones, including ofloxacin, are established causes of FDE, and reported presentations range from a solitary oral or genital patch to severe generalised bullous variants; involvement confined to mucosal surfaces (oral, conjunctival, nasal, and anal) without any skin lesions has also been documented in association with ofloxacin, illustrating the variable anatomical extent of this reaction. Cases in children and adults have similarly described multiple morphological presentations after ofloxacin exposure, and combination products such as ofloxacin–ornidazole, which are widely used for presumptive gastrointestinal and genitourinary infections in India, have also been implicated.

The differential diagnosis of a solitary erosive oral lesion is broad and includes herpetic gingivostomatitis, major aphthous ulceration, oral erythema multiforme, and the erosive autoimmune vesiculobullous disorders (pemphigus vulgaris and mucous membrane pemphigoid). Oral erythema

multiforme typically presents with more widespread haemorrhagic crusting of the lips and multiple oral erosions, often preceded by a prodrome, whereas FDE tends to produce fewer, sharply demarcated lesions and characteristically recurs at the same site on re-exposure to the causative drug. A negative Nikolsky sign and the absence of target lesions or a preceding prodromal illness, as in the present case, further argued against an autoimmune bullous disorder and erythema multiforme respectively, favouring a diagnosis of FDE. Where feasible, oral rechallenge or patch testing at the site of the healed lesion, and the Naranjo Adverse Drug Reaction Probability Scale, can help substantiate drug causality, although rechallenge is rarely performed in routine clinical practice because of the risk of provoking a more severe reaction.

Management of oral FDE centres on prompt identification and withdrawal of the causative drug, supportive oral care, and topical or short-course systemic corticosteroids for symptomatic relief; most lesions heal within one to two weeks of drug discontinuation, generally without scarring, although residual post-inflammatory pigmentation may occur at cutaneous sites. Patients should be clearly counselled to avoid the causative drug and other agents of the same class in future, given the risk of cross-reactivity among fluoroquinolones, and the reaction should be documented in the patient's records to prevent inadvertent re-exposure.

Conclusion

Solitary oral fixed drug eruption is an uncommon but clinically important presentation of ofloxacin hypersensitivity that can be mistaken for infective, autoimmune, or other inflammatory oral mucosal diseases. A careful drug history, awareness of the characteristic solitary, well-demarcated erosive morphology, and prompt withdrawal of the offending fluoroquinolone are key to accurate diagnosis and favourable outcome. Clinicians managing acute oral ulcerative lesions should routinely consider FDE in the differential diagnosis, particularly in patients with recent antimicrobial exposure.

Consent

Written informed consent was obtained from the patient for publication of this case report and accompanying clinical images. A copy of the consent is available for review by the Editor-in-Chief of this journal on request. [To be confirmed/attached by the author prior to submission.]

Conflict of Interest

The author declares no conflict of interest.

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