



RESEARCH ARTICLE

Fixed drug eruption: A case series, clinical presentation and management strategies

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Abstract

Fixed drug eruption (FDE) is a unique immunological cutaneous reaction characterized by the recurrence of sharply demarcated lesions at the same site upon re-exposure to the offending drug. This delayed Type IV hypersensitivity reaction most commonly involves antimicrobials, nonsteroidal anti-inflammatory drugs (NSAIDs) and anticonvulsants. The lesions, ranging from macules to bullae, typically heal with residual post-inflammatory hyperpigmentation. This case series presents ten detailed cases of FDE, each induced by different medications, including metronidazole, levofloxacin, cefotaxime and others. Diagnosis was primarily based on clinical history, recurrence of lesions and in some instances, histopathological findings. Management involved the discontinuation of the offending drug, along with corticosteroid and antihistamine therapy. The study underscores the importance of patient education, including the provision of drug allergy cards, to prevent recurrence. Studies suggest an association between human leukocyte antigen (HLA) class I and FDE. Patients often experience multiple recurrences over an extended period before a definitive diagnosis is made. The genitalia, perianal regions and lip mucosa are among the thin-skinned areas that are most frequently affected. Emphasis is placed on pharmacovigilance and rational prescribing practices as key strategies for minimizing the risks associated with FDE. The findings highlight the critical need for early diagnosis and intervention to mitigate complications and improve patient outcomes.

Keywords

adverse drug reactions; antimicrobials; fixed drug eruption; hypersensitivity; pharmacovigilance

Introduction

The hallmark of fixed drug eruption (FDE) is a single erythematous, macular, pruritic lesion that evolves through an acute phase, followed by desquamation and hyperpigmentation. Characteristically, identical lesions recur at the same anatomical site upon re-exposure to the offending drug. Clinically, FDE presents as sharply demarcated, round-to-oval erythematous patches that appear within hours of drug administration. These lesions heal with residual hyperpigmentation upon drug discontinuation and recur predictably when the offending drug is reintroduced (1). The incidence of FDE is estimated to range from 3.77 % to 15.34 %, with antimicrobials and non-steroidal anti-inflammatory drugs (NSAIDs) being the most frequently implicated agents.

The first documented case of FDE was reported by Bourns in 1889, describing sharply defined hyperpigmented lesions on the lips and tongue of a patient. A few years later, Brocq introduced the term *eruption érythémato-pigmentée fixe*, which eventually evolved into the modern term FDE. This historical perspective underscores the enduring clinical significance of FDE as a dermatological entity (2).

Fixed drug eruption is predominantly associated with oral medications, although less common triggers include topical or intravaginal drugs, food additives (e.g. antibiotics, flavouring agents, colouring agents, preservatives) and herbal supplements. These diverse triggers highlight the importance of a detailed drug and exposure history in diagnosing FDE (3). Awareness and timely management of FDE are crucial, as the condition can significantly impact patient quality of life and may complicate treatment regimens if not promptly diagnosed and managed.

Pathophysiology, etiology and clinical presentation

pathophysiology

The pathogenesis of FDE involves a complex interplay of immunological mechanisms. During the initial phase, memory CD8+ T-cells localized at the dermo-epidermal junction play a central role. These cells release interferon-gamma when activated by the drug antigen, causing damage to the basal layer of the epidermis. This damage is exacerbated by recruited T-cells and neutrophils, which target melanocytes and keratinocytes. The resolution phase is characterized by dermal macrophages accumulating melanin, leading to the characteristic post-inflammatory hyperpigmentation.

Interleukin-15 released by regenerating basal keratinocytes sustains the survival of resident memory CD8+ T-cells, which remain quiescent but primed for reactivation upon re-exposure to the offending drug. The recurrence of lesions at specific anatomical sites is attributed to the localized persistence of these memory T-cells, suggesting a role for cell-mediated hypersensitivity in the pathogenesis of FDE. Furthermore, interleukin-20 has been implicated in the site specificity of these lesions, while tissue damage results from intra-epidermal clusters of activated CD8+ T-cells (4).

Etiology

The primary causative agents of FDE are oral medications, with antimicrobials and NSAIDs being the most common culprits. Less frequently, FDE may result from:

Topical or intravaginal medications

Food additives, including antibiotics, flavouring agents, colouring agents and preservatives

Herbal supplements (5)

The spectrum of potential triggers continues to expand, necessitating a careful evaluation of patient history and exposure.

Clinical presentation

Clinically, FDE is characterized by:

Sharply demarcated erythematous patches: Round-to-oval lesions appear within hours of drug administration.



Healing with hyperpigmentation: Lesions resolve with residual pigmentation, serving as a hallmark of FDE.

Recurrent localization: Lesions consistently reappear at the same site upon re-exposure to the offending agent.

FDE lesions can be symptomatic, presenting with pruritus or discomfort. In symptomatic cases, systemic antihistamines and topical corticosteroids are effective in alleviating inflammation and discomfort (6).

Case presentations

Case study 1: Metronidazole-induced fixed drug eruption in an adult female

A 39-year-old female presented with complaints of itchy, erythematous, oval lesions over the chest, abdomen and inguinal region for three days (Fig. 1). The patient reported taking metronidazole for dysentery over the preceding four days and denied using any other medication during this period. Based on the clinical presentation, a provisional diagnosis of FDE was made, likely triggered by metronidazole.

The patient was treated with topical corticosteroids and oral antihistamines. The lesions resolved within four days of discontinuing metronidazole. A provocation test was conducted after seven days, starting with 200 mg of metronidazole, which did not elicit any reaction. However, a subsequent oral challenge with 400 mg of metronidazole caused reactivation of the lesions, presenting as redness and itching at the original sites.

Given the unavailability of patch testing at the facility and the inherent risks of oral challenge tests, causality was assessed using the Naranjo algorithm. The analysis indicated a probable causal relationship between metronidazole and the adverse drug reaction (ADR). The rapid resolution of symptoms upon discontinuation of the drug and reactivation upon rechallenge further supported this association.

The patient was counselled to avoid metronidazole in the future and was provided with detailed instructions on recognizing and managing similar reactions should they occur again.

Case study 2: Levofloxacin-induced fixed drug eruption in a diabetic patient

A 54-year-old female with a history of diabetes mellitus presented with pain and swelling in her left arm. Due to a documented allergy to ciprofloxacin in prior admissions, she was prescribed levofloxacin as an alternative. Within 12 hr of administration, the patient developed generalized cutaneous eruption involving the entire body (Fig. 2). She reported similar eruptions after ciprofloxacin exposure in the past. A dermatology consultation confirmed the diagnosis of FDE.



Fig. 1. Metronidazole-induced fixed drug eruption (FDE) lesions on the chest and abdomen.



Fig. 2. Levofloxacin-induced fixed drug eruption (FDE) presenting as generalized cutaneous eruptions.

The patient was treated with topical hydrocortisone cream and her antibiotic regimen was adjusted. The cutaneous eruption resolved over several weeks, although it left post-inflammatory hyperpigmentation. On a subsequent hospital admission, the patient developed identical skin lesions within hours of receiving levofloxacin, further confirming the diagnosis of FDE. She was counselled to avoid ciprofloxacin and levofloxacin in the future.

Case study 3: Fixed drug eruption to Forecox® in a patient with pulmonary tuberculosis

A 40-year-old man was prescribed Forecox® (a combination of rifampicin 225 mg, isoniazid 150 mg, pyrazinamide 750 mg and ethambutol 400 mg) by a private doctor for pulmonary tuberculosis. After taking the third dose, he developed multiple hyperpigmented patches on his back and lower limbs (Fig. 3). Discontinuation of the



Fig. 3. Fixed drug eruption (FDE) caused by Forecox® (Anti-TB FDC) with hyperpigmented patches on the back and lower limbs.



Fig. 4. Cefotaxime-induced fixed drug eruption (FDE) showing erythematous skin lesions with blistering on the face and cheeks.

medication for two days did not result in any improvement in the lesions. Treatment included intramuscular dexamethasone (4 mg), oral prednisolone (5 mg every 6 hr), intravenous ceftriaxone (1 g every 12 hr), framycetin cream for topical application, Mucaïne viscous gel, Betadine gargles and multivitamins.

The patient showed significant improvement within 15 days and the skin lesions healed. Follow-up to assess rechallenge with anti-tuberculosis drugs could not be conducted as the patient relocated to another state.

Case study 4: Cefotaxime-induced fixed drug eruption in a post-surgical patient

A 36-year-old female presented with dysmenorrhea and was admitted to the gynaecology ward for further evaluation. She underwent a minor surgical procedure, dilation and curettage and was administered cefotaxime 1 g intravenously as part of her postoperative antibiotic regimen.

Two days after receiving cefotaxime, the patient developed generalized erythematous skin lesions with blistering. The lesions were predominantly located on her face and cheeks and were associated with a burning sensation and pruritus. Dermatological examination revealed multiple oval-shaped erythematous and blistering lesions (Fig. 4).

Given the patient's history of drug allergies to cefixime and the clinical findings, a diagnosis of cefotaxime-induced FDE was established. The Nikolsky sign was positive, further confirming the diagnosis. Treatment included dexamethasone (10 mg/ml once daily), azithromycin (250 mg twice daily) and levocetirizine (10 mg once daily). Supportive measures, including hydration and nutritional support, were provided.

The patient responded well to the treatment, with complete resolution of the lesions after five days. Residual post-inflammatory hyperpigmentation was noted at the lesion sites. The steroid dose was tapered and the patient's condition stabilized. She was discharged with a drug allergy card documenting her allergies to cefixime and cefotaxime and was instructed to present this card during future medical consultations to prevent recurrence.

Case study 5: Ofloxacin-induced fixed drug eruption in a urinary tract infection patient

A 50-year-old woman visited the outpatient clinic with complaints of painful urination, frequent urination and high-grade fever accompanied by chills lasting three days. Laboratory analysis of blood and urine confirmed urinary tract infection (UTI) with leukocytosis and pus cells in the urine. She was prescribed ofloxacin for her condition.

Within 2 hr of taking the medication, the patient developed intense itching over her body. This was followed by black discoloration and hyperpigmented patches on her waist, abdominal region and lower limbs (Fig. 5). She recalled a similar episode 5 years prior, also attributed to ofloxacin.

Immediate medical intervention included injectable steroids, antihistamines, cephalosporin antibiotics and intravenous fluids. Ofloxacin was discontinued and the patient's symptoms improved significantly within 72 hr. Hyperpigmentation over the affected areas persisted after the lesions healed.



Fig. 5. Ofloxacin-induced fixed drug eruption (FDE) with hyperpigmented patches on the waist, abdomen and lower limbs.



Fig. 6. Furosemide-induced fixed drug eruption (FDE) characterized by hyperpigmentation on the trunk and lips with buccal mucosal erosions.

The patient was counselled extensively about her drug allergy and advised to avoid ofloxacin and similar medications in the future. Preventive strategies, including the maintenance of a drug allergy card and proper communication with healthcare providers, were emphasized. She was discharged with a follow-up plan to monitor for any delayed reactions or complications.

Case study 6: Furosemide-induced fixed drug eruption in a patient with oedema

A 40-year-old female presented with lower limb swelling, facial puffiness and decreased urine output was admitted to the medical ward for evaluation and treatment. As part of her management, she was prescribed furosemide (40 mg twice daily) along with other supportive medications to address her symptoms. On the second day of admission, the patient developed hyperpigmented patches on her trunk and lips, accompanied by buccal mucosal erosions, causing significant discomfort (Fig. 6). Based on the timing and clinical presentation, furosemide was identified as the likely causative agent for FDE and the medication was promptly discontinued. The patient was treated with dexamethasone (8 mg twice daily) and other supportive measures, leading to a gradual resolution of the lesions within 7 days.

A causality assessment using the Naranjo and WHO-UMC scales confirmed a "probable" relationship between furosemide and the adverse reaction. Before discharge, the patient was counselled on avoiding furosemide in the future and provided with a drug allergy card to alert healthcare providers about her sensitivity to the drug.

This case highlights the importance of early recognition and intervention in drug-induced FDE to prevent complications and ensure patient safety.

Case study 7: Ciprofloxacin-induced fixed drug eruption in a male patient

A 32-year-old male presented with itching in the lips, palms and lower limbs shortly after starting ciprofloxacin (500 mg twice daily) prescribed for conjunctivitis. On the second day of therapy, he noticed the development of fluid-filled lesions on his palms and lips. These lesions were accompanied by discomfort and worsening pruritus (Fig. 7).

The patient reported a history of similar complaints a month earlier following ciprofloxacin use, which resolved after stopping the medication. He denied taking any other medications during this period. Based on the clinical presentation and past history, a diagnosis of ciprofloxacin-induced FDE was made.

Treatment included an injection of pheniramine maleate (Avil), hydrocortisone hemisuccinate (Effcoril) and a short course of oral prednisolone (20 mg daily for 5 days). Supportive measures such as hydration and avoidance of sun exposure were also recommended. The lesions resolved within 5 days, leaving residual hyperpigmentation characteristic of FDE.

The patient was counselled about the potential recurrence of FDE with ciprofloxacin or related drugs and was advised to avoid this class of antibiotics in the future. Strategies for documenting drug allergies, including maintaining a drug allergy card, were discussed with the patient for prevention of recurrence.

Case study 8: Mefenamic acid-induced fixed drug eruption in a child

A 10-year-old male child, with no significant medical or allergy history, presented to the dermatology department with multiple hyperpigmented lesions distributed on the upper extremities, chin and hands (Fig. 8). The lesions developed a week after starting a combination of mefenamic acid and paracetamol for fever and body pain. The child did not report any associated symptoms such as fever, itching or burning sensation at the site of the lesions.

Upon examination, the lesions were well-demarcated, darkly pigmented macules consistent with FDE. There were no signs of systemic involvement. The child had no history of taking other medications or any recent illnesses apart from the fever for which the drugs were prescribed.

Treatment was initiated with topical corticosteroid therapy to address inflammation and reduce lesion pigmentation. The symptoms resolved gradually, leaving residual hyperpigmentation, which is typical of FDE. A dermatologist confirmed the diagnosis and

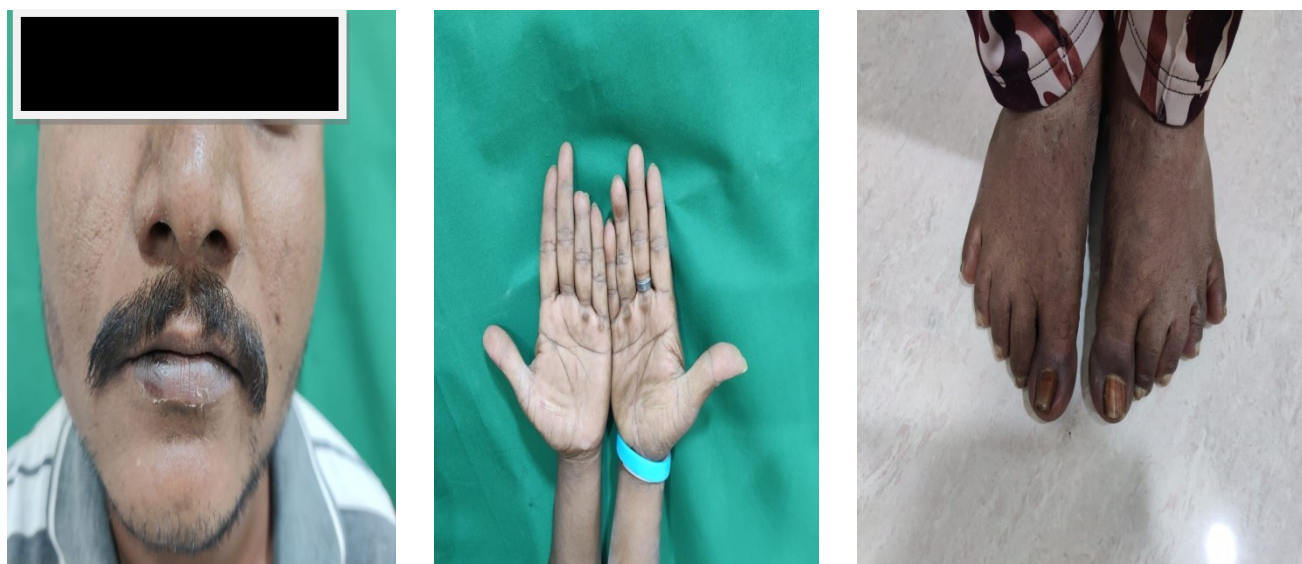


Fig. 7. Ciprofloxacin-induced fixed drug eruption (FDE) showing fluid-filled lesions on the palms and lips.



Fig. 8. Mefenamic acid-induced fixed drug eruption (FDE) with hyperpigmented lesions on the upper extremities, chin and hands.

mefenamic acid was withdrawn. The causality assessment using the Naranjo probability scale yielded a score of five, categorizing the causality as "probable."

The patient and his caregivers were counselled extensively on the nature of the condition and the importance of avoiding mefenamic acid in the future. They were advised to inform any prescribing healthcare professional about this adverse drug reaction during future medical consultations. A drug allergy card was issued for reference.

Case study 9: Co-trimoxazole-induced fixed drug eruption in a urinary tract infection Patient

A 55-year-old male presented with a 2 days' history of round, pruritic, erythematous patches over the right forearm and back. He was undergoing treatment for UTI with co-trimoxazole, prescribed by a local practitioner. The lesions appeared during the second day of cotrimoxazole therapy and were associated with mild itching but no systemic symptoms such as fever or malaise (Fig. 9).

On clinical examination, the lesions were well-defined, erythematous and hyperpigmented patches localized to the right forearm and back. The patient denied taking any other medications or experiencing similar reactions in the past. A provisional diagnosis of FDE due to cotrimoxazole was made.

The patient was admitted to the dermatology department and co-trimoxazole was discontinued immediately. Treatment included intravenous dexamethasone (8 mg twice daily), topical antibiotics for lesion care, oral analgesics for symptom relief and antihistamines to manage itching. Supportive care with adequate hydration and observation for any new lesions was provided.

Over the course of seven days, the lesions healed without complications or the development of new ones. The patient was discharged on a tapering dose of steroids to prevent rebound symptoms. Post-inflammatory hyperpigmentation persisted, which is characteristic of FDE.

The patient was educated about ADR and counselled to avoid co-trimoxazole in the future. Strategies to prevent recurrence, such as maintaining a drug allergy record and informing healthcare providers about the reaction, were emphasized.

Case study10: Doxycycline-induced fixed drug eruption in a dental infection patient

A 35-year-old female visited the dermatology outpatient department with complaints of itching and hyperpigmentation over her cheeks for the past 3 days. She reported taking doxycycline (100 mg twice daily) for a dental infection prescribed by her dentist. The patient denied using any other concurrent medications.

Upon further questioning, she disclosed a history of similar symptoms following doxycycline use in the past. A review of the patient's medical records confirmed prior occurrences of FDE following doxycycline administration. Dermatological examination revealed a well-defined, hyperpigmented patch localized to the cheek region (Fig. 10).

Based on her clinical presentation and detailed history, a diagnosis of doxycycline-induced FDE was established. The drug was immediately discontinued and the patient was prescribed oral cetirizine (10 mg daily) to manage itching and topical betamethasone cream for lesion resolution. The lesions improved gradually over 2 weeks, with complete resolution of active symptoms but with residual post-inflammatory hyperpigmentation.

The patient was counselled on the importance of avoiding doxycycline in the future and informed of the potential severity of recurrent reactions. A drug allergy card was issued, listing doxycycline as an allergen, with instructions to present it during future medical consultations. She was also educated about the nature of FDE and advised to remain vigilant for similar reactions to related medications.

Diagnosis

4.1. Clinical history and examination: Essential for identifying the offending drug, especially in recurrent cases, by correlating oral intake within the last 24 hr with symptom onset.

Histopathology: Skin biopsy is a valuable tool:

Early lesions: Interface dermatitis, apoptotic keratinocytes and dermal oedema.

Late lesions: Presence of melanophages in the upper dermis, indicative of post-inflammatory hyperpigmentation.

Oral challenge test: Used selectively to confirm the diagnosis; should be avoided in severe cases like generalized bullous FDE.

Patch testing: Conducted directly at the lesion site, yielding positive results in half of the cases, but less effective on normal skin (6).



Fig. 9. Co-trimoxazole-induced fixed drug eruption (FDE) presenting as erythematous patches on the forearm and back.



Fig. 10. Doxycycline-induced fixed drug eruption (FDE) showing hyperpigmented patches on the cheeks.

Discussion

Fixed drug eruption is a distinct type of cutaneous adverse reaction to medications that is characterized by the recurrent appearance of sharply demarcated lesions at specific locations upon re-exposure to the offending drug. Typically, FDE manifests as oval or circinate macules; however, less common presentations include plaques, bullae, or erosions (7). Lesions may be solitary or multiple, emerging within hours to days following drug ingestion. After the acute phase, hyperpigmentation is a hallmark feature, often persisting long after resolution of the inflammatory process. Recurrent episodes of FDE localize to the same region, giving rise to the term "fixed." Commonly affected areas include the genitalia, lips and hands, though lesions can occur elsewhere. Lesions typically heal with scaling and pigmentation within days to weeks after discontinuation of the offending agent. Re-exposure to the causative drug often triggers a faster and more extensive recurrence, sometimes involving additional sites (8).

The pathogenesis of FDE involves a complex interplay of immune mechanisms, primarily classified as a Type IV hypersensitivity reaction. Latent cytotoxic CD8⁺ T-cells residing in the lesional epidermis are key players in FDE. Upon drug re-exposure, these T cells become activated, releasing cytotoxic granules that mediate localized tissue damage (9). The offending drug acts as a hapten, binding preferentially to basal keratinocytes and inducing an inflammatory cascade. Tumour necrosis factor-alpha (TNF- α) and intercellular adhesion molecule-1 (ICAM-1) play critical roles in facilitating T-cell migration to the site of insult. Associations with human leukocyte antigen (HLA) class I antigens suggest a possible genetic predisposition to FDE, with peak incidence observed in individuals aged 21–30 years (10).

Adverse cutaneous reactions to drugs, including FDE, are a frequent occurrence, affecting 2–3 % of hospitalized patients. Drugs commonly implicated in FDE include antimicrobials, NSAIDs and anticonvulsants. Fluoroquinolones (FQs), such as levofloxacin, are widely used antimicrobials that are known to cause FDE. Levofloxacin, a second-generation fluoroquinolone and the active isomer of ofloxacin, exhibits potent bactericidal activity and is often used empirically for a variety of infections (11). Cefotaxime, a third-generation cephalosporin, inhibits bacterial cell wall synthesis and is another antibiotic frequently associated with FDE. Similarly, fixed-dose combinations (FDCs) such as multidrug antituberculosis regimens pose a unique challenge as they can cause diverse cutaneous adverse reactions, including FDE. Identifying the

causative agent in FDC-induced FDE can be difficult, delaying therapeutic adjustments (Table 1) (12).

If offending drugs are not discontinued, recurrent episodes of FDE can become more severe and widespread, leaving residual post-inflammatory hyperpigmentation. This highlights the importance of early diagnosis, which relies on correlating fixed lesion locations with the history of drug intake (Table 2). Drug safety is variable among individuals; a medication that is safe for one person may trigger severe reactions in another (13). Therefore, ADRs must be carefully monitored and reported through pharmacovigilance systems. Awareness about ADRs, rational drug use and the role of clinical pharmacists as drug safety experts are crucial in minimizing FDE and other drug-induced conditions (14).

While the gold standard for FDE diagnosis is systemic re-challenge, it is often considered unethical due to the risk of severe reactions, including anaphylaxis. Safer alternatives include patch testing, which allows simultaneous testing of multiple drugs and the evaluation of cross-reactivity. Doxycycline, for instance, a tetracycline-class antibiotic, inhibits bacterial protein synthesis by binding to the 30S ribosomal subunit and has been reported in FDE cases. Patch testing is a safe diagnostic approach that provides valuable insights while minimizing risks (15).

Fixed drug eruption remains a significant clinical concern, requiring careful diagnosis and management to prevent recurrence and associated complications. Periodic safety monitoring, awareness programs and the active role of clinical pharmacists can enhance patient safety and improve outcomes in cases of drug-induced adverse reactions.

Conclusion

Fixed drug eruptions are a common type of cutaneous adverse drug reaction, frequently associated with antimicrobials and anti-inflammatory agents. Patients with a history of fixed drug eruptions are at an increased risk of developing extensive and multiple lesions upon re-exposure to the offending drug or related compounds. However, fixed drug eruptions is largely preventable through early identification, prompt withdrawal of the causative medication and careful avoidance of implicated drugs. Clinicians play a pivotal role in counselling patients about the nature of fixed drug eruptions and the importance of reporting drug allergies. Providing patients with a drug allergy card and instructing them to present it during future medical consultations ensures better management and prevention of recurrence.

Table 1. Clinical characteristics and management of fixed drug eruption associated with different drug classes

Drug	Drug class	Recurrence frequency	Latency period	Severity of FDE	Lesions / itching	Treatment used
Metronidazole	Nitroimidazole antimicrobial	Common on re-exposure	Few hours to 2 days	Mild to moderate	Erythematous plaques with itching/burning	Drug withdrawal, topical corticosteroids, antihistamines
Levofloxacin	Fluoroquinolone antibiotic	Common due to class cross-reactivity	30 min to 24 hr	Moderate; may become bullous	Hyperpigmented plaques with pruritus	Discontinuation, corticosteroids, antihistamines
Forecox® (Anti-TB FDC)	Fixed-dose anti-tubercular combination (Rifampicin, Isoniazid, Pyrazinamide, Ethambutol)	Possible with repeated intake	Hours to days	Moderate to severe	Multiple pigmented lesions with itching/burning	Drug cessation, topical/systemic corticosteroids
Cefotaxime	Third-generation cephalosporin	Less common but reported	Few hours	Severe in generalized bullous FDE	Bullous eruptions with intense itching	Drug withdrawal, systemic corticosteroids, supportive care
Ofloxacin	Fluoroquinolone antibiotic	High recurrence tendency	30 min to 1 day	Mild to moderate	Solitary or multiple plaques with pruritus	Antihistamines, topical steroids
Furosemide	Loop diuretic	Rare recurrence	Hours to days	Moderate to severe in extensive cases	Extensive erythematous lesions with itching	Drug discontinuation, corticosteroids
Ciprofloxacin	Fluoroquinolone antibiotic	Common on re-administration	Few hours	Mild to moderate	Hyperpigmented plaques with burning/itching	Topical corticosteroids, antihistamines
Mefenamic Acid	NSAID	Frequent recurrence and possible cross-reactivity	30 min to several hours	Moderate	Well-defined plaques with itching	Drug avoidance, antihistamines, corticosteroids
Co-Trimoxazole	Sulfonamide antibiotic combination	High recurrence frequency	1–2 days	Moderate to severe	Pigmented lesions with pruritus	Drug withdrawal, desensitization in selected cases, corticosteroids
Doxycycline	Tetracycline antibiotic	Possible due to tetracycline cross-reactivity	Hours to 2 days	Mild to moderate	Localized erythematous plaques with itching	Topical corticosteroids, antihistamines

Table 2. Summary of ten cases of drug-induced fixed drug eruption (FDE)

Case	Offending drug	Age & sex	Rechallenge	Causality assessment using WHO-UMC scale	Outcome
1	Metronidazole	39/F	+Ve	Certain	Resolved
2	Levofloxacin	54/F			Healed with Residual Marks
3	Forecox® (Anti-TB FDC)	40/M			Recovered
4	Cefotaxime	36/F			Recovered
5	Ofloxacin	50/F			Recovered with Hyperpigmentation
6	Furosemide	40/F	-	Probable	Recovered
7	Ciprofloxacin	32/M			Healed with Residual Marks
8	Mefenamic Acid	10/M			Recovered with Hyperpigmentation
9	Co-Trimoxazole	55/M			Recovered
10	Doxycycline	35/F			Healed with Residual Marks

FDC: Fixed-dose combination, TB: Tuberculosis, +Ve: Positive

Furthermore, the active reporting of adverse drug reactions is crucial for improving pharmacovigilance systems, enriching drug safety databases and ultimately enhancing patient outcomes. Awareness and knowledge of drugs commonly implicated in fixed drug eruptions should be integral to prescribing practices to minimize the risk of adverse drug reactions and ensure patient safety.

Future research on fixed drug eruption should focus on improving understanding of its pathogenesis, diagnosis and management. Large multicentre studies involving diverse populations are needed to provide better epidemiological data and identify common causative drugs, recurrence patterns and demographic risk factors. Further investigation into the immunological and genetic mechanisms of fixed drug eruptions is also important.

Another important area for future study is the establishment of standardized diagnostic protocols. Since fixed drug eruptions can mimic other dermatological conditions, future research should evaluate the combined role of clinical examination, patch testing, oral provocation tests, dermoscopy and histopathology in improving diagnostic accuracy. Newer technologies such as artificial intelligence-based image analysis and molecular biomarkers may also aid in early and non-invasive diagnosis.

Comparative studies assessing different treatment approaches are required to determine the most effective management strategies and reduce complications such as post-inflammatory hyperpigmentation. Strengthening pharmacovigilance systems and patient education programs may further help in early recognition, prevention and safer drug use among affected individuals.

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Authors' contributions

UPK contributed to the concept and design of the study and prepared the manuscript. KNV was involved in data collection and study design. BK contributed to data collection and compilation of the data. KSK. carried out the final revision of the manuscript. ES was responsible for the submission of the revised manuscript.

Compliance with ethical standards

Conflict of interest: Authors do not have any conflict of interests to declare.

Consent from the patient: Consent from the patients and permission for image publication were obtained for the study.

Ethical approval: The research/study approved by the Institutional Review Board at Santhiram Medical College and General Hospital, number IEC/SRMC/2025/202, dated July 06, 2025

Ethical issues: None

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