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When the Remedy Becomes the Rash: A Case of Fixed Drug Eruption Due to Paracetamol Use in a Leukemia Patient

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Case Report

ABSTRACT

Background: *AFixed Drug Eruption (FDE) is a localized cutaneous adverse drug reaction marked by the recurrence of lesions at the same site upon re-exposure to a particular drug. While NSAIDs and antibiotics are commonly implicated, paracetamol is also known, though less frequently, to induce FDE.*

Case report: *A 38-year-old male with chronic myeloid leukemia (CML), well-controlled on dasatinib for the past two years, presented with recurrent fixed drug eruptions after taking paracetamol (650 mg) for fever and cold. The episode was complicated by cellulitis with blister formation on the right arm—a new development for the patient. The FDE lesions appeared at previously affected sites, suggesting reactivation due to paracetamol exposure*

Conclusion: *This case underscores the need to recognize paracetamol as a potential cause of FDE. It highlights the importance of thorough drug histories, patient education, and safe analgesic alternatives in recurrent FDE, especially in immunocompromised individuals.*

Keywords: *Fixed drug eruption; paracetamol; adverse drug reaction; drug-induced skin reaction; pharmacovigilance; causality assessment*

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INTRODUCTION

Fixed Drug Eruption (FDE) is an immunologically mediated cutaneous adverse drug reaction characterized by the recurrence of sharply demarcated lesions at the same anatomical sites upon re-exposure to the causative agent.[1] Although NSAIDs and antimicrobials are the most frequently implicated drugs, paracetamol—one of the most widely used antipyretics and analgesics—has also been reported to induce FDE, albeit less commonly.[2] Recognition of this association is vital, given the over-the-counter availability and frequent self-medication with paracetamol. This case is notable not only for its recurrence of FDE with paracetamol in a patient with chronic myeloid leukemia (CML) but also for the concurrent development of cellulitis, adding a layer of clinical complexity.

Leukemia (CML) for the past two years was under regular treatment with the tablet dasatinib (50 mg daily) and had shown stable disease control. He presented to the dermatology outpatient department with complaints of itchy, violaceous patches on the left upper back, left lower back and right upper chest accompanied by blistering and erythema on the right arm. These lesions had appeared shortly after he had taken paracetamol 650 mg tablets—procured over the counter—for fever and cold during a seasonal weather transition.

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Notably, the patient had experienced similar skin eruptions in the exact locations in the past after taking paracetamol, strongly suggesting a recurrence of fixed drug eruption. This episode was different, however, due to the concurrent development of painful blisters and erythema over his right arm, which was diagnosed clinically as cellulitis—an event occurring for the first time in this patient.

His other medications included the tablet Pancos-DSR (pantoprazole with domperidone), syrup Cosgel Plus (simethicone-based antacid), and occasional Nucort-M4 (methylprednisolone). No new medications were introduced, and all others had been well tolerated previously. Laboratory results showed leukocytosis and neutrophilia, consistent with the cellulitic process. There was no mucosal involvement or systemic hypersensitivity.

Paracetamol was promptly discontinued. The patient was treated with topical mometasone and oral antihistamines for the FDE lesions, appropriate antibiotics for cellulitis, and tramadol for pain. The lesions began resolving within 10 to 14 days, leaving residual post-inflammatory hyperpigmentation. The patient was counseled on avoiding paracetamol in the future and advised to report any future symptoms immediately.

Table 1: Diagnostic and Management Approach to Fixed Drug Eruption (FDE)

Step	Details
Clinical recognition	Well-demarcated erythematous or violaceous plaques, often recurring at the same sites on re-exposure; common locations: Trunk, extremities, lips, genitalia.
History taking	Identify recent drugs taken (prescribed and OTC), timing of lesion onset
Causality assessment	Use tools like the Naranjo Scale, WHO-UMC, Hartwig and Schumock Scale
Differential diagnosis	Rule out Steven Johnson Syndrome/Toxic Epidermal Necrolysis, Erythema multiforme, cellulitis, and contact dermatitis.
Management	Withdraw suspected drug; apply topical corticosteroids and antihistamines
Prevention	Document drug allergy; educate patient; avoid re-prescription; consider alternate drugs

CAUSALITY ASSESSMENT

Causality assessment was carried out using standard methods:

- **WHO-UMC Criteria**: The reaction was assessed as probable due to the recurrence of symptoms after re-exposure and resolution upon withdrawal of paracetamol.

Figure 1: Cellulitis over right arm with blisters

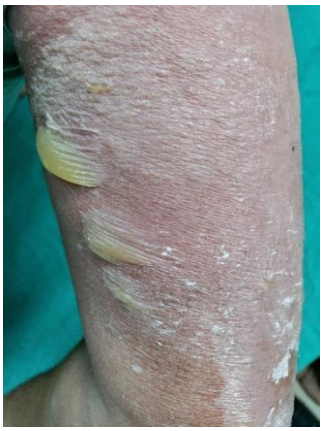


Figure 2: FDE over left upper back

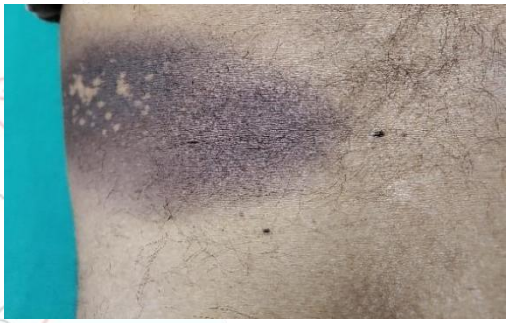


Figure 3: FDE over left lower back

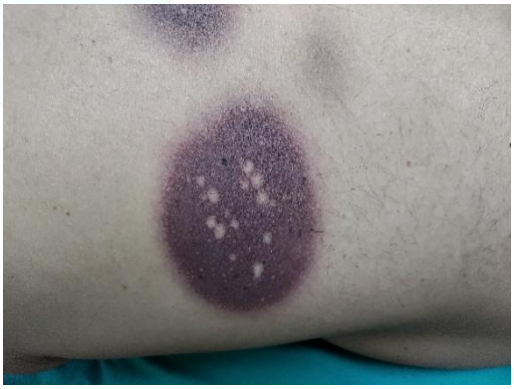
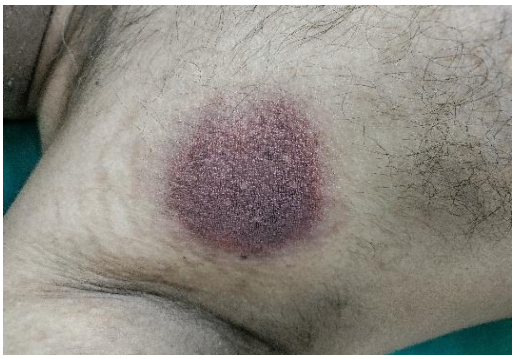


Figure 4: FDE over right upper chest



- **Naranjo Algorithm**: A score of 7, indicating a probable adverse drug reaction.
- **Hartwig and Siegel Scale**: Level 3 – Moderate severity, requiring drug withdrawal and specific treatment but not hospitalization.
- **Schumock and Thornton Preventability Scale**: The reaction was definitely preventable, given the known history of paracetamol-induced FDE and the availability of alternative medications.[3]

DISCUSSION

FDE is a type IV hypersensitivity reaction where memory CD8+ T cells remain resident in previously affected epidermal sites and are reactivated upon re-exposure to the offending agent.[4] Although paracetamol is generally considered safe and widely used, it is an under-recognized cause of FDE. The skin lesions typically appear within 30 minutes to 8 hours of drug ingestion and are often misattributed if patients fail to disclose over-the-counter medication use.[5]

This case illustrates the recurrence of paracetamol-induced FDE in a patient with stable CML, which makes the reaction clinically significant due to the patient's immunocompromised status. The addition of a new event—cellulitis—requires differentiation from severe cutaneous adverse reactions like Steven Johnson Syndrome and Toxic Epidermal Necrolysis, but the fixed nature of the lesions and their typical locations pointed towards FDE.

Preventing such reactions involves comprehensive approaches. Most importantly, documenting previous drug reactions clearly in medical records and educating the patient on avoiding over-the-counter use of the offending drug are critical steps. Patients should be issued drug-allergy cards or mobile alerts to avoid inadvertent re-exposure. Although pharmacogenetic testing is not currently standard for paracetamol-induced FDE, advances in immunogenomics may enable preemptive screening for drug hypersensitivity syndromes in the future, especially in high-risk or immunocompromised populations.

Table 2: Common drug classes causing Fixed drug eruption (FDE) and Site predilection

Drug class	Common Offending Drugs	Typical Site of FDE
Paracetamol	Paracetamol	Trunk
NSAIDs	Ibuprofen, Diclofenac	Lips, Extremities
Antibiotics	Cotrimoxazole, Tetracycline	Genitals, Trunk
Anticonvulsants	Phenytoin, Carbamazepine	Oral mucosa, Trunk
Antifungals	Fluconazole	Extremities

Alternatives such as **topical analgesics**, **cold compresses**, or **tramadol** (when necessary) can be safely used for pain relief in such patients, provided they are monitored. Clinicians should also utilize electronic prescribing systems with decision-support tools to flag known hypersensitivities.

CONCLUSION

This case demonstrates that even commonly used and seemingly benign medications like paracetamol can cause recurrent fixed drug eruptions, particularly in patients with underlying comorbidities such as CML. The co-occurrence of cellulitis introduced a diagnostic challenge but did not obscure the hallmark features of FDE. Prevention of recurrence depends on effective patient education, accurate medical record-keeping, and vigilance during prescribing. The growing role of pharmacogenetics may further enhance preventive strategies in the future.

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