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Case Report

Generalized bullous fixed drug eruption mimicking Stevens-Johnson syndrome: a case report

Geeva Prabhakaran Ganesan*, Jasmine S. Sundar, S. Kalpana, S. Valarmathi, G. Srinivas

Department of Epidemiology, The Dr. Tamil Nadu MGR Medical University, Chennai, Tamil Nadu, India

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***Correspondence:**
Dr. GeevaPrabhakaran Ganesan,
E-mail: dr.geevag@gmail.com

ABSTRACT

Bullous fixed drug eruption (BFDE) is a rare but severe cutaneous adverse drug reaction that may mimic Stevens–Johnson syndrome/toxic epidermal necrolysis (SJS/TEN). A 58-year-old male with diabetes, hypertension, and coronary artery disease developed multiple erythematous and bullous lesions within 24 hours of initiating levofloxacin and ornidazole for a nail bed infection. He had a prior history of similar reaction. Clinical diagnosis of generalized BFDE was made based on history and presentation. Naranjo score indicated a possible adverse drug reaction. The suspected drugs were discontinued. The patient was managed conservatively with topical steroids, antihistamines, and supportive care. The patient improved with residual hyperpigmentation. Early recognition and differentiation from SJS/TEN are crucial to avoid unnecessary aggressive treatment and prevent recurrence.

Keywords: Bullous fixed drug eruption, Adverse drug reaction, Levofloxacin, Ornidazole, SJS-TEN mimic

INTRODUCTION

Bullous fixed drug eruption (BFDE) is a severe variant of fixed drug eruption characterized by recurrent, well-demarcated bullous lesions.[1] It often mimics Stevens–Johnson syndrome/toxic epidermal necrolysis (SJS/TEN), posing diagnostic challenges.[2] Early differentiation is essential to ensure appropriate management and prevent recurrence.[1,3]

Bullous fixed drug eruption (BFDE) is a cutaneous adverse drug reaction presented as plaques with bullae which can affect various parts of the body. The condition may be life-threatening.[1] BFDE is a severe form of fixed drug eruptions (FDE) which is usually misdiagnosed as epidermal necrolysis due to the presence of blisters and erosions.[2] Prevalence of FDEs was reported as 8.4% of total adverse drug reactions and of cutaneous reactions it is reported as 11.1%.[3]

BFDE often mimics serious conditions such as Stevens-Johnson syndrome and Toxic epidermal necrolysis (SJS-TEN), making accurate diagnosis challenging. Historically, several cases initially classified as these conditions were later identified as generalized BFDE. Although no universally accepted diagnostic criteria exist, features such as well-defined lesions, minimal mucosal involvement, and limited systemic symptoms help in differentiation. Distinguishing BFDE from SJS-TEN is crucial, as BFDE typically has a shorter drug exposure latency (within 24 hours). Despite clinical differences, the mortality of BFDE may be comparable to SJS-TEN, highlighting its severity. Diagnosis is further complicated by the lack of reliable confirmatory tests, as patch testing and other skin tests have low sensitivity, and drug provocation is contraindicated.[1]

Accurate diagnosis of BFDE is crucial, because it can closely mimic severe conditions like SJS/TEN, leading to potential mismanagement. Early recognition allows prompt identification and withdrawal of the offending

drug, preventing recurrence and reducing morbidity. Timely differentiation also helps to avoid unnecessary aggressive treatments and improves patient outcomes. This case highlights the importance of careful drug history and awareness of combination therapies as potential triggers, providing a valuable clinical learning point for early recognition and prevention of recurrence.

CASE REPORT

Patient information

A 58-year-old gentleman with a known history of diabetes mellitus, coronary artery disease (CAD), systemic hypertension and history of procedures coronary angiogram (CAG) and percutaneous transluminal coronary angioplasty (PTCA) was done one year before and was on regular medications for the same. He presented to the clinic with severe nail bed infection, pain, swelling and fever. After routine history taking and examination, he was treated with antibiotics (Levofloxacin 250 mg and Ornidazole 500 mg), antipyretics (Acetaminophen 500 mg) and proton pump inhibitors (Pantoprazole 40 mg). On the second day following treatment (that is, 24 hours after the oral intake of Levofloxacin and Ornidazole), he reported itchy tender rash on his abdomen, back, soles and oral ulcers.

An examination revealed multiple erythematous and bullous ranging in size from 1 x 1 cm to the largest of around 10 x 7 cm on entire back, abdomen, face, thigh and legs. The bullae contained clear serous fluid. Skin erosions were also noted over the genital and perineal regions with multiple ulcers in the oral cavity (Figure 1(a-f)). On a detailed reassessment, the patient reported a history of a similar occurrence 6 months ago when he received an antibiotic course during a treatment in a local clinic for a respiratory infection, which was not mentioned during the first consultation. Further details including the exact diagnosis and treatment received were unavailable. On examination, Nikolsky sign was negative. The lesions, as per the patient history healed in 2-3 weeks without any consequences (Table 1).

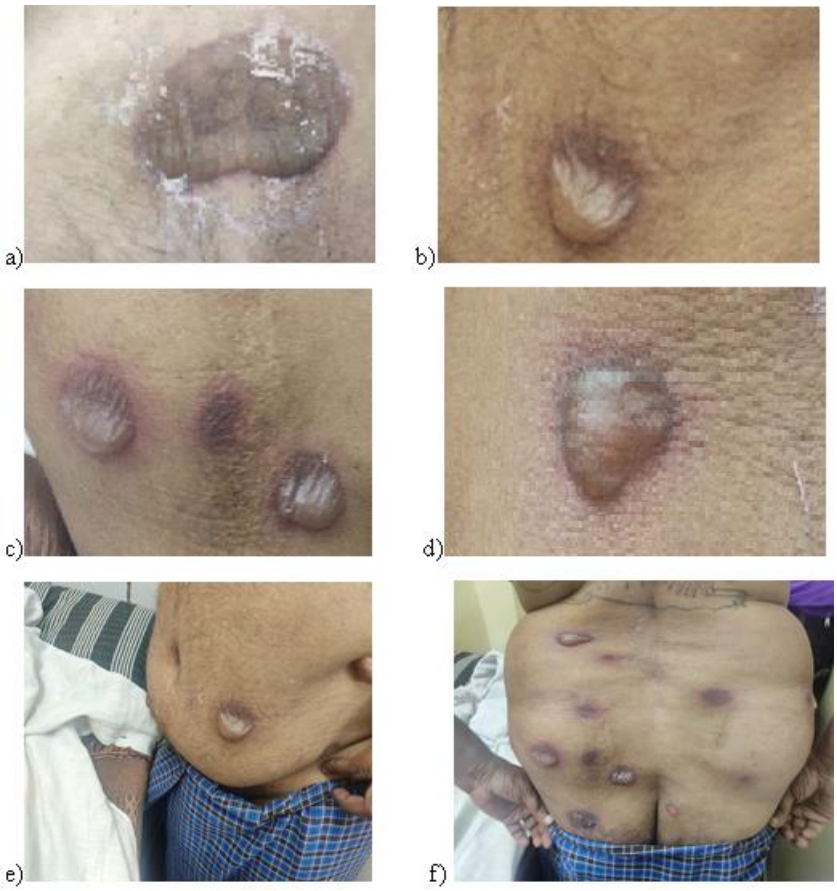

Figure 1 (a-f): BFDEs in the patient.

Diagnosis

The diagnosis of bullous fixed drug eruption was made on clinical grounds along with the fact that he had past history of a similar but milder reaction to the drug 6 months back which he had taken for respiratory infection. Naranjo adverse drug reaction probability scale score was +3, which indicates possible adverse drug reaction. However, oral provocation test and patch testing with Levofloxacin and Ornidazole could not be done as the patient did not consent for the same and was referred to a higher center.

Differential diagnosis

Generalized FDE and Stevens-Johnson syndrome/ toxic epidermal necrolysis (SJS-TEN) was the two major differential diagnosis.

Family history

No history of FDE among first-degree relations.

Treatment

Levofloxacin and Ornidazole were stopped immediately with strict advice of not to take further given. Local measures to prevent infection and emollients over the raw areas were instituted. Clobetasol propionate 0.05% topical ointment for twice a day and fexofenadine hydrochloride tablet 180 mg one a day at night was prescribed and the patient was referred to a higher center.

Consultation with a Dermatologist was obtained after admission in a Government Hospital a decision to defer oral steroids was made due to underlying diabetes mellitus and coronary artery disease, as their use can lead to significant hyperglycemia, increased risk of infections, fluid retention, and potential worsening of cardiovascular status. Considering the risk–benefit balance, conservative management was preferred to prevent exacerbation of comorbid conditions while still ensuring adequate control of the cutaneous reaction. A diabetologist consultation was done and insulin was started and a Cardiologist consultation was done for routine cardiac medications.

Follow-up

The patient was discharged a week later with hyper-pigmented lesions and appropriate treatment (Figure 2). Levofloxacin and Ornidazole was deemed as the most likely drug agent caused adverse effect based on his history and its profile. He was explained the need to avoid the drug and educated about the importance of highlighting his allergic drug history in all future contacts with the medical care system.

Figure 2: Healed eruptions post-treatment.

Outcomes

Total 144 participants were included in the study. 75 were females (52%) and rest were males (48%).

DISCUSSION

Bullous fixed drug eruption (BFDE) and Stevens–Johnson syndrome/toxic epidermal necrolysis (SJS–TEN) are both drug-induced cutaneous adverse reactions, but they differ significantly in pathogenesis, severity, and clinical presentation. SJS–TEN is an immune-complex–mediated hypersensitivity reaction associated with widespread keratinocyte apoptosis, whereas BFDE is a delayed type IVc hypersensitivity reaction mediated by CD8+ T cells. Clinically, SJS–TEN is a severe, potentially life-threatening condition with extensive skin involvement, systemic symptoms such as fever and malaise, and prominent mucosal erosions affecting the oral, ocular, and genital regions. In contrast, BFDE is usually less severe, with well-defined erythematous or bullous lesions that are often localized and recur at the same anatomical sites upon re-exposure to the offending drug.

Another key distinction lies in the onset, distribution, and progression of lesions. SJS–TEN typically develops 1 to 4 weeks after drug exposure and presents with rapidly spreading, poorly demarcated lesions that may involve significant epidermal detachment. BFDE, on the other hand, appears within hours of re-exposure to the causative drug and is characterized by sharply demarcated lesions that may heal with residual hyperpigmentation. Mucosal involvement is minimal or absent in BFDE but is a hallmark feature of SJS–TEN. Management also differs substantially; SJS–TEN requires intensive supportive care and may involve systemic therapies, whereas BFDE is generally managed with withdrawal of the offending drug, topical corticosteroids, and symptomatic treatment.[4]

FDE are a part of a spectrum of hypersensitivity skin reactions following the ingestion of certain drugs (most commonly antibiotics, antimalarials, non-steroidal anti-inflammatory drugs (NSAID), paracetamol and barbiturates). Characteristics of BFDE include dusky red or violaceous plaques occurring over a fixed area of the body within hours of exposure to medications and lesions typically reoccurring over the same region on re-exposure to the same medications.[5]

FDEs usually appear as solitary, erythematous, bright red or dusky macules that may evolve into an edematous plaque or bullous-type lesions.[6] Residual hyperpigmentation is common. Rechallenge or patch testing at the previously affected site (were positive in about 43% of cases) may be performed to determine the exact causative drug when the causative drug is uncertain.[5] Histopathology, especially detailed histopathological examination from early-stage lesions or perilesional skin, may be helpful. FDEs are identified by vacuolar interface dermatitis with epidermal necrosis and a superficial and deep perivascular infiltrate of lymphocytes, eosinophils and neutrophils, even after these differentiating features, precise delineation remains a challenge and often relies on the experience of the clinician and dermatopathologist.[7]

Table 1: Timeline of events of the patient.

Timeline	Events
Day-1	Visited the healthcare facility for severe nail bed infection, pain, swelling and fever. After routine history taking and examination, he was treated with antibiotics (Levofloxacin 250 mg and Ornidazole 500 mg), antipyretics (Acetaminophen 500 mg) and proton pump inhibitors (Pantoprazole 40 mg)
Day-2	24 hours after the oral intake of Levofloxacin and Ornidazole, patient visited the clinic and reported itchy tender rash on his abdomen, back, soles and oral ulcers.
Day-2	Patient was admitted in a government hospital. Local measures to prevent infection and emollients over the raw areas were instituted. Consultation with a Dermatologist-decision to defer oral steroids was made. A diabetologist consultation was done and insulin was started and a Cardiologist consultation was done for routine cardiac medications.
Day-9	The patient was discharged a week later with hyper-pigmented lesions and appropriate treatment.

Table 2: Comparison of the features of various BFDE case reports.

Author name & Country	Patient age (yrs)/ gender	Drug	Mucosal involve-ment	Sites	Timing after drug intake	Outcome
Singh et al, India[8]	40/ M	Chlordiazepoxide	No	Both upper limbs, anterior trunk, posterior trunk and back of the neck	Within 24 hours	Dark grey hyperpigmented lesions. In one week, skin lesions resolved completely, leaving residual hyperpigmentation.
Paulmann et al, Germany[9]	42/ M	Metamizole	Yes	Throughout the body	Within 24 hours	Residual post-inflammatory hyperpigmentation
Wang et al, China[10]	45/ M	Paracetamol and dipyrone	No	Lips, armpits, extremities, genitals and anus	Within hours of intake	Recurrence with other drug (dipyrone) and refused treatment
Choi et al, South Korea[11]	83/ M	COVID-19 vaccine (Pfizer)	No	Throughout the body	4 hours	After treatment, no additional lesions
Present case report	58/ M	Levofloxacin + Ornidazole	Yes	Entire back, abdomen, face, thigh, legs, genital and perineal regions with multiple ulcers in the oral cavity	Within 24 hours	Hyper-pigmented lesions

Various cases were diagnosed and reported for FDEs for drugs like Chlordiazepoxide in a 40-year-old male with eruptions in both upper limbs, anterior trunk, posterior trunk and back of the neck, drug Metamizole in a 42-year-old male, with eruptions throughout the body, and drug Paracetamol and dipyrone in a 45-year-old male, with eruptions in Lips, armpits, extremities, genitals and anus (Table 2).[8-10]

The management of widespread FDEs, besides immediate withdrawal of the offending agent, involves antiseptic solutions and emollients to promote the healing of local ulcers and supportive measures for pain and infection prevention. Oral antiseptic rinses for mucosal erosions and local ointments for perianal lesions are usually used. The role of steroids is unproven but are resorted to in severe cases.[5]

There are some limitations in this case report. The present case report is a single case. We could not take biopsy, patch test or any other investigations from our end as the patient was not willing and was referred to a higher center. The

lack of previous medical records of the patient during the initial consultation. However, we obtained a detailed history of previous drug allergies and with the clinical symptoms, diagnosed the patient with BFDE.

CONCLUSION

The case report highlights the importance of distinguishing bullous fixed drug eruption from Stevens–Johnson syndrome/toxic epidermal necrolysis to ensure appropriate management and avoid unnecessary aggressive treatment and the importance of detailed history taking. Early identification of the offending drug and prompt withdrawal remain crucial in preventing recurrence and reducing morbidity. The present case study provides the importance of history taking, especially previous history of drug allergies. Generalized bullous fixed drug eruption is a rare variant of fixed drug eruptions and may be confused with Steven Johnson syndrome/toxic epidermal necrolysis. Differentiating between the two entities is important as it may have important prognostic and management implications.

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