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Case Series

Diverse Cutaneous Reactions to Diclofenac Sodium: Case Series of three Patients

Sunil Mhatarba Vishwasrao[1], Sufala Sunil Vishwasrao[2], Amar Nagesh Kumar[3], Pollilan G. R.[4]

[1*]Professor and Head, Department of Pharmacology, Karpaga Vinayaga Institute of Medical Sciences and Research Centre, Madhuranthagam, Tamil Nadu

[1*]PhD Scholar, Chettinad Academy of Research & Education, Chettinad Health City, Kelambakkam, Chennai, Tamil Nadu

[2]Principal and Professor, Department of Anaesthesiology, Karpaga Vinayaga Institute of Medical Sciences and Research Centre, Madhuranthagam, Tamil Nadu. 603308

[2]PhD Scholar, Savitha Institute of Medical & Technical Sciences, Savithanagar, Thandalam, Chennai, Tamil Nadu, 602105.

[3]Associate Professor, Department of Biochemistry, Vels Medical College and Hospital, A Unit of VISTAS, Periyapalayam, Tamil Nadu, 601102

[4]Postgraduate, Department of Pharmacology, Karpaga Vinayaga Institute of Medical Sciences and Research Centre, Madhuranthagam, Tamil Nadu.603308.

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Corresponding author: Dr. Sunil Mhatarba Vishwasrao

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Abstract

Diclofenac sodium is a frequently prescribed painkiller in OPD and IPD setups of most clinicians. It is also preferred as an analgesic to deal with postoperative pain. The drug is economical and has better efficacy. Dermatological adverse reactions to diclofenac may manifest in a moderate to severe form. Early identification of ADR and prompt treatment are necessary, which helps in the patient's faster recovery. Delayed identification of ADR sometimes manifests in a severe form that can lead to fatality. Here we report three cases of diclofenac-induced ADRs with varied cutaneous manifestations.

Keywords: Diclofenac sodium, adverse drug reaction, Urticaria, Erythema, Pustulosis.

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Introduction

Diclofenac Sodium, a non-steroidal anti-inflammatory drug (NSAID), inhibits prostaglandin synthesis and is a widely prescribed analgesic agent for moderate to severe types of pain. It induces ADRs affecting various organ systems, primarily involving the gastrointestinal system in 20% of individuals [1].

Dermatological reactions to Diclofenac Sodium may be observed in oral, parenteral and topical formulations. Various dermatological reactions seen after consumption of NSAIDs include angioneurotic oedema, acute urticaria, maculopapular eruptions, erythema multiforme, and Stevens - Johnson syndrome etc. [2].

We report three cases of diclofenac-induced varied dermatological manifestations, including Acute Generalized Exanthemata's Pustulosis, Acute Urticaria and Erythema Multiforme.

Methodology and Case Details

Case 1: Acute Generalized Exanthemata's Pustulosis (AGEP)

A 62-year-old female, without any drug allergies or a relevant medical-surgical history, visited to Dermatology OPD of Karpaga Vinayaga Hospital with an itchy skin lesion over the chest wall for the past 10 Days. She had received oral diclofenac sodium from her general practitioner for myalgia. After consumption of a diclofenac sodium tablet, the patient reported having a single erythematous papule associated with itching, which progressed over 3-4 days to multiple erythematous papules and scaly lesions dominantly over the anterior chest wall region. Hence, she visited the hospital. (Figure 1: Pustules marked by arrows) She was hemodynamically stable without any organ involvement other than skin. She did not have oozing or crusting of the lesions. The patient did

not give any previous history of allergy to food or additives.

She was diagnosed as Acute Generalized Exanthematous Pustulosis (AGEP) and prescribed oral multi-vitamins, injectable anti-histaminics (Diphenhydramine 25mg IM) once a day and topical antipruritic calamine lotion for one week. Lesions started regressing after initiation of therapy (Figure 2).

Case 2. Acute Urticaria

A 28-year-old male, postgraduate medical student, visited the emergency department with complaints of itching and rash over the right arm after consumption of diclofenac sodium tablet (50mg) as self-medication for treatment of myalgia, as he travelled overnight and returned to the duty early in the morning. After 30 minutes of consumption of a diclofenac tablet, he developed itching and urticaria over the right arm, which was acutely progressing.

He was diagnosed with drug-induced acute urticaria. (Figure 3: See arrows) He did not have any medical or surgical illness, but gave a history of maize (corn) allergy. He was hemodynamically stable and did not have a cough or breathlessness.

He received Injectable anti-histaminics (Diphenhydramine 25 mg IM), IV corticosteroids (Dexamethasone 12mg IV) and was observed in the emergency department. After 2 hours, his urticaria was resolved totally. (Figure 4) After a further 1 hour of observation, he was discharged with oral cetirizine 10mg daily once a day for 5 days and was asked to follow up after completion of Cetirizine therapy.

Case 3. Erythema Multiforme

A 40-year-old female came to the dermatology OPD with a hyperpigmented lesion over the face, predominantly over the left side of the cheek, for the past 1 week. Patient gave history of administration of injection Diclofenac Sodium (50mg) for knee pain. After one hour of drug administration, the patient complained of itching with the appearance of hyperpigmented lesions over the face (Figure 5). The patient was a known case of biopsy-proven Sweet's syndrome for the past 2 years and was on regular medication for the same. Local examination revealed a hyperpigmented target lesion over the left side of the cheek with notable erythema & edema over the face associated with tenderness. Also, it was present over the forearm extending from the dorsum of the hand to the shoulder. Similar lesions were seen over the abdomen, back (Figure 6), and thigh, extending up to the foot were seen. The patient was diagnosed with Erythema Multiforme secondary to diclofenac sodium. Patients were treated with parenteral steroids (Dexamethasone 12 mg IM), Anti-histaminics (Diphenhydramine 25 mg IM) followed by oral Prednisolone 60mg per day and Cetirizine 10 mg per day for a week. Corticosteroids gradually tapered over 15 days and discontinued.

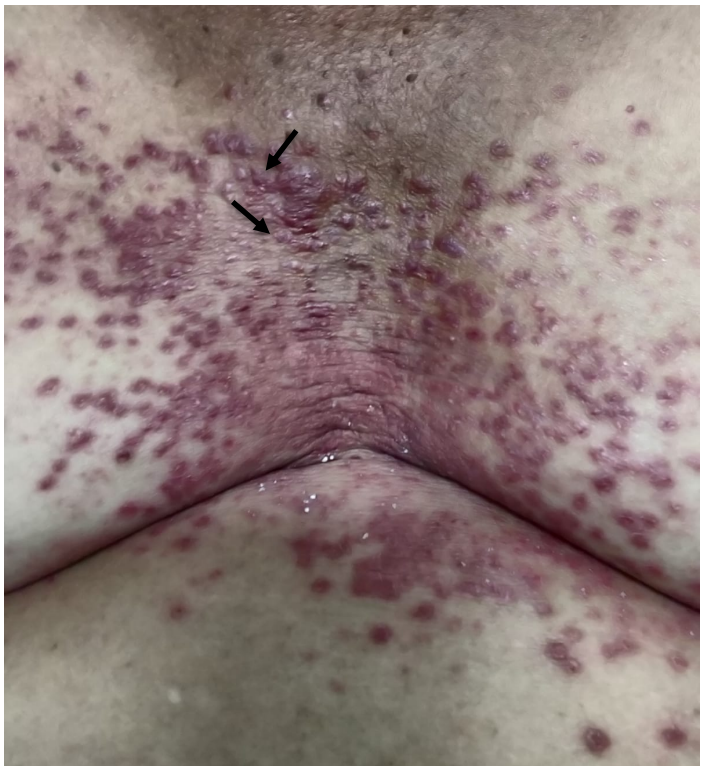

Figure 1: Erythematous lesions with pustules marked by arrow

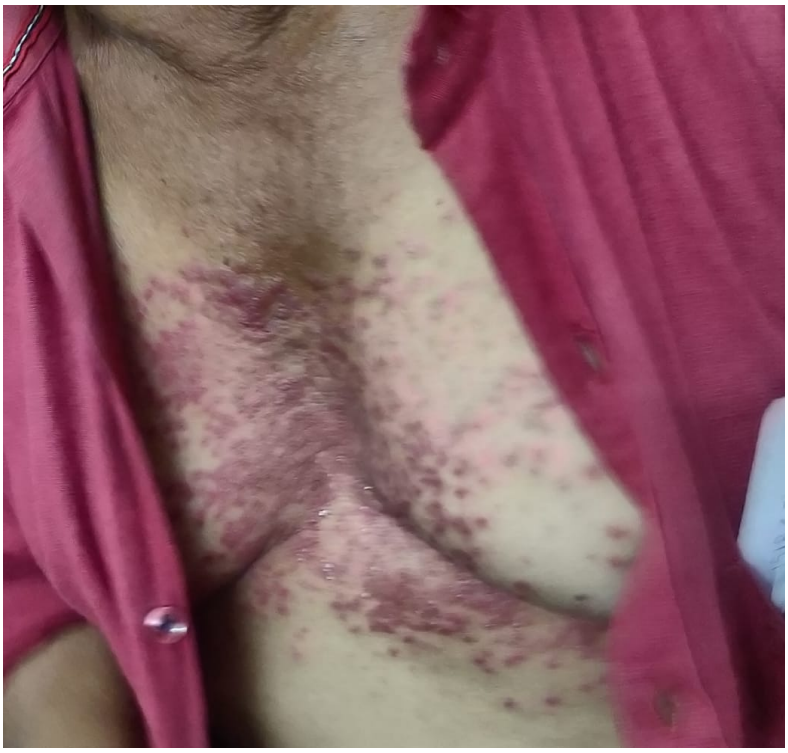

Figure 2: Post-treatment lesions recovering with disappearance of pustules

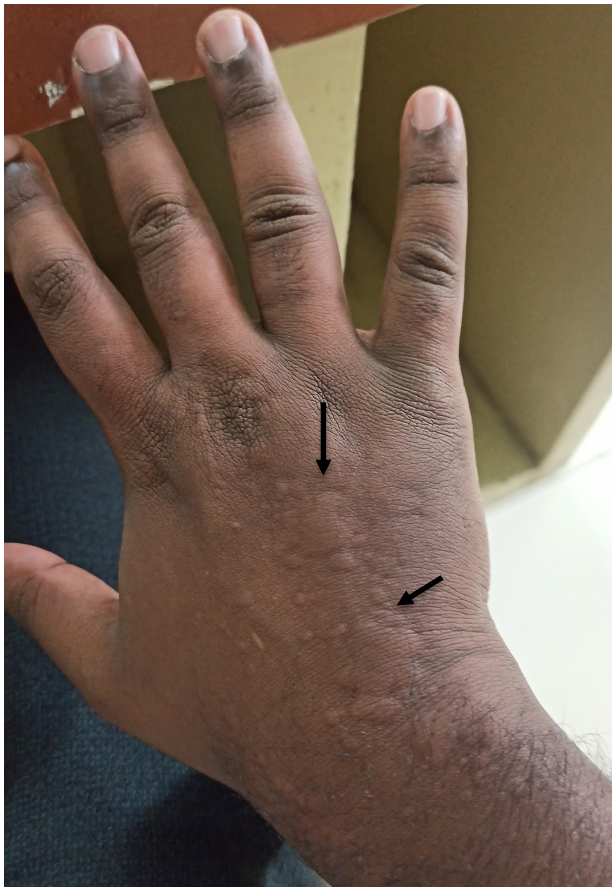

Figure 3: Urticaria marked by arrow

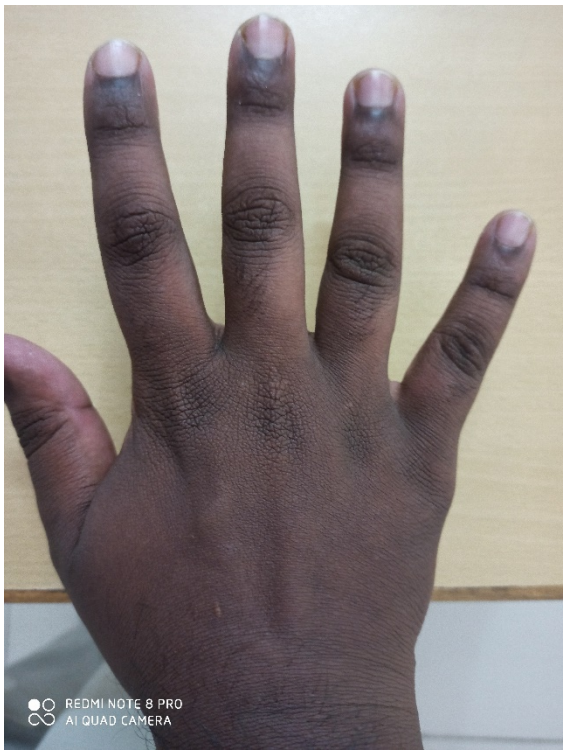

Figure 4: Complete resolution of lesions

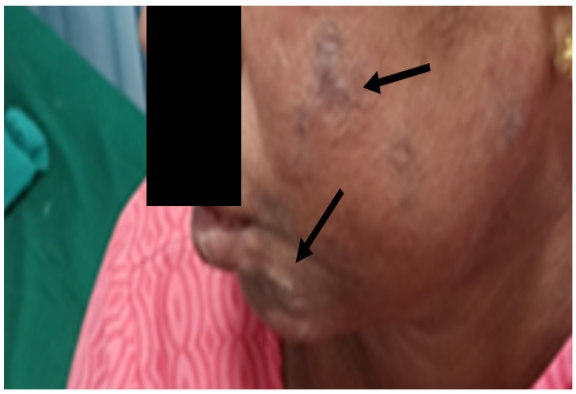

Figure 5: Macular lesions on the face

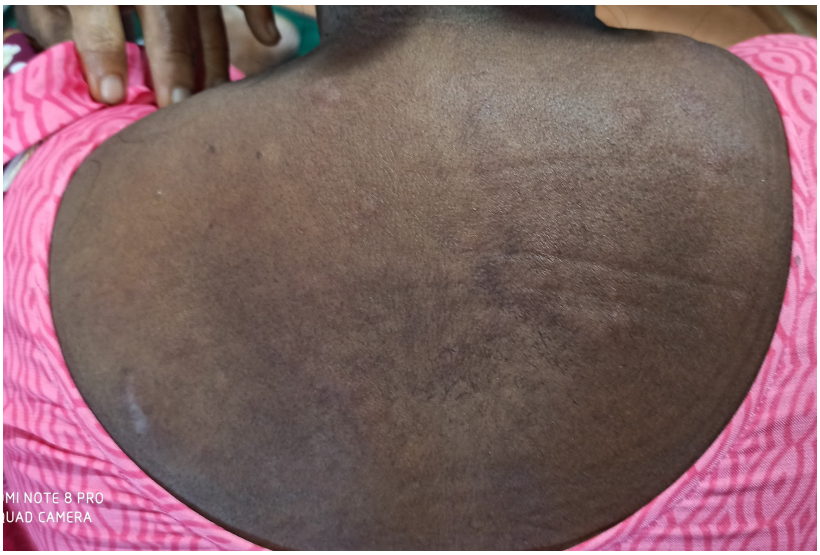

Figure 6: Macular Symmetrical lesions on the back

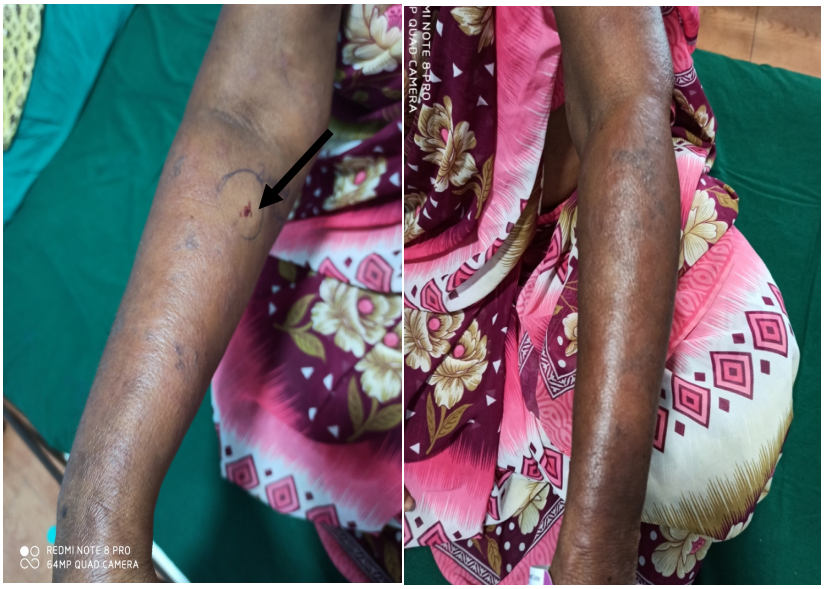

Figure 7: Bilateral macular lesions on the arm with ulceration seen on the right arm

Discussion

Case 1

Acute generalized exanthematous pustulosis (AGEP) is a rare, severe cutaneous adverse drug reaction seen in 90 % of ADRs [3]. It is characterised by an acute pustular rash affecting elderly individuals with female preponderance [4] and usually resolves in a couple of weeks after discontinuation of the culprit drug. Cases of AGEP may remain unreported due to the spontaneous resolution of the symptoms. This case was diagnosed by clinical history, examination and AGEP score validated using Euro SCAR criteria. [5] In our case, the calculated score was 8. [Morphological variables: Pustules-Typical (+2), Erythema-Typical (+2), Distribution-Typical (+2), Post pustular desquamation-Yes (+2) and Polymorphonuclear neutrophils >7,000/mm3-Yes (+1)].

Causality assessment using the Naranjo scale was probable. (Score 7)

Case 2

Although the estimated prevalence of acute urticaria and angioneurotic oedema is 0.1-0.3% [6-7], hypersensitivity reactions in atopic individuals are higher during early childhood [8-9]. Acute urticaria presents as the rapid development of pruritic rash and erythematous wheals. The lesions may be localized or generalized, displaying a wide range of clinical features from mild urticaria to angioedema. The neglected cases may lead to higher morbidity and mortality, underscoring the critical need for timely intervention. In our case, the reaction was acute in onset, and there was a prompt and effective response to the treatment. Subsequently rash disappeared after administration of intravenous corticosteroids and antihistaminic agents. The delayed intervention could have posed a potential life-threatening anaphylaxis. Causality assessment using the Naranjo scale was probable. (Score 8)

Case 3

Erythema multiforme (EM) is an immune-mediated cutaneous ADR that varies widely in severity. It is classified into EM Major, the more severe variant involving mucous membranes and EM Minor, a less severe form of self-limiting ADR [10]. EM has been reported with NSAIDs such as piroxicam [11], indomethacin, ibuprofen, sulindac [12]. Reports are showing various cutaneous reactions to diclofenac, such as biopsy-proven epidermal dysmaturation [13], fixed drug eruption14 and diclofenac-induced fatal erythema multiforme. [15].

The name multiforme originates as there is multiple variations in the skin lesions from macules, papules, vesicles to ulcers [16]. In our case, lesions were more of a macular type with ulceration at occasional places (Figure 5). The lesions were symmetrical, mainly seen on the face, back and arms (Figure 7).

The diagnosis of EM minor was made from clinical findings and using diagnostic criteria for EM [10]: Acute self-limiting course, within 1-4 weeks duration, discrete, round, symmetrical lesions without involvement of mucous membranes. The patient responded promptly to anti-histaminics and corticosteroids.

Causality assessment using the Naranjo scale was probable. (Score 7)

Conclusion

Diclofenac is a commonly used drug by clinicians and is also preferred for postoperative analgesia in

some instances. Dermatological reactions to diclofenac are frequently encountered, however, they may go unnoticed, especially in children, leading to serious complications requiring hospitalization and contributing to an increasing economic burden to the family. AGEP is the most common dermatological reaction.

Clinicians should be well versed in classical clinical presentation and treatment protocol. Untreated urticaria, even in its mild form, may worsen and lead to complications. EM, though rare, can manifest in a severe form. Even though EM is self-limiting, you need constant vigilance. The healthcare providers should be aware of potentially life-threatening ADRs.

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