

Fixed Drug Eruption Induced By Diclofenac Sodium –A Case Report

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Abstract: Fixed drug eruption is a cutaneous reaction which occurs by repetitive exposure to the offending drugs like antimicrobials, anticonvulsants and NSAIDs. Here we are presenting a case of 65 year old male of fixed drug eruptions due to administration of injections diclofenac sodium. Diclofenac is a commonly used anti inflammatory drug for relieving pain.

Keywords: Diclofenac, Fixed drug eruption, Naranjo scale.

I. Introduction

Fixed Drug Eruption is mainly characterized by skin lesions that recur at the same anatomic site upon repeated exposure to an offending agent^[1]. Fixed Drug Eruption is the most common Cutaneous drug reaction attributed to a drug in Indian patients^[2]. The drugs most commonly attributed in FDE are antimicrobials like Quinolones, Sulfonamides, Trimethoprim, Tetracyclines, Dapsone etc. Non-Steroidal Anti Inflammatory drugs like Ibuprofen, Diclofenac, Naproxen etc and anticonvulsants like Phenytoin, Phenobarbitone etc.

II. Case Report

A 65 years old male presented to skin OPD with history of a lesion over penis with itching and burning. A complete drug history was taken which revealed that he had taken injection Diclofenac Sodium for arthritis. After 24-hours he developed itching, followed by pigmented lesion. On dermatological examination, there is ulcerative, crusty, pigmented lesion over dorsal aspect of penis (Fig 1). There was no involvement of upper extremities, trunk and face as well. All routine investigations were in normal limits. The assessment of the reaction was carried out by Naranjo ADR probability Scale [Table.1]. A diagnosis of Fixed drug eruption to

Table 1: The Naranjo adverse drug reaction probability scale; Questionnaire	Yes	No	Do not know	Score
1. Are there previous conclusive reports on this reaction?	+1	0	0	+1
2. Did the adverse event occur after the suspected drug was administered?	+2	-1	0	+2
3. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0	+1
4. Did the adverse reaction reappear when the drug was readministered?	+1	0	0	+2
5. Are there alternative causes (other than the drug) that could have on their own caused the reaction?	+2	-1	0	0
6. Did the reaction reappear when a placebo was given?	-1	+2	0	0
7. Was the blood detected in the blood (or other fluids) in concentrations known to be toxic?	-1	+1	0	+1
8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	0
9. Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0	+1
10. Was the adverse event confirmed by any objective evidence?	+1	0	0	0
	+1	0	0	
			Total	+7

Diclofenac was made and the patient was told not to take the drug. The treatment was started with Injection Decadran 2CC OD for 5days and Tablet Prednisolone 20 mg OD for next 10 days, then the dose was tapered. The patient was recovered after 5days.

Scoring
> 9 = definite ADR · 5-8 = probable ADR · 1-4 = possible ADR · 0 = doubtful ADR

III. Discussion

Fixed drug Eruptions are one of the commonest adverse drug reactions encountered by the dermatologists in day to day practice. Fixed Drug Eruption is a distinctive drug induced dermatoses with a characteristic recurrence at the same site of the skin or mucous membrane after repeated administration of the causative drug^[1]. It was described by Bourns in 1889; later it was termed as “fixed eruption” by Brocq^[3]. The list of causative agents is long, including non-narcotic analgesics, antibacterial agents, anti fungal agents, antipsychotics and other miscellaneous drugs and ultraviolet radiation, emotional and psychiatric factors like heat, menstrual abnormalities, pregnancy, fatigue and cold^[4].

Fixed drug eruption presents mainly as sharply marginated, round, oval itchy plaques of erythema and edema becoming dusky violaceous or brown and sometimes vesicular or bullous^[1]. Most of the reactions occur within 30min to one day of drug exposure^[1,5]. The lesions may be solitary or multiple. The most common sites are the genitalia in males and the extremities in females^[5]. Fixed Drug Eruption is believed to be an Lymphocytic mediated reaction, where the offending drug induce local reactivation of memory - T-cell lymphocytes^[6,7] localized in epidermal & dermal tissues and these cells have the capacity to produce large amount of IFN gamma^[8], which is likely to play a significant role in the development of Fixed Drug Eruption.

Diclofenac Sodium (Non Steroidal Anti Inflammatory Drug)) is widely used to treat pain and inflammation. The most common adverse drug reactions reported are GIT side effects in 20% of patients^[9] and increased levels of hepatic transaminase in plasma. Other side effects of Diclofenac are CNS effects like headache, dizziness, rashes, allergic reactions, fluid retention and edema.. A case of anaphylactic reaction to diclofenac sodium, 15min after intramuscular injection of diclofenac for the treatment of low back pain has been reported^[10]. A case of a patient who developed diclofenac induced hepatitis concomitant with GI bleeding^[11] was also reported. Two cases of Nicolau’s syndrome following diclofenac administration^[12] were reported. Another case was reported previously which developed as dark erythematous lesion associated with burning and itching after taking Tab. Diclofenac . The lesions were found on both the lower limbs^[13].

In the present case report the patient had developed lesion over penis 24hrs after taking Intramuscular Injection of Diclofenac Sodium 75mg for arthritis(Fig 1). The Naranjo adverse drug reaction(ADR)probability Scale^[14] was used to assess the reaction. The probability of ADR Induced by diclofenac was confirmed by Naranjo ADR Scale .Based on the Naranjo ADR probability scale, in this case the following criteria are considered. There are previous reports on this adverse reaction(score+1). The patient was apparently normal before the intake of drug and the reaction developed after administration of diclofenac(score+2), After discontinuation of diclofenac, patient’s condition was improved(score+1), Causes other than the drug causing the reaction has been ruled out(score+2), similar reaction due to such type of drug in the past has occurred(score+1). Total score is +7, the patient was categorized as “probable ADR” due to diclofenac administration.

In our case, this drug was widely used for the treatment of pain. FDE is one of the rare side effect of this group. It may be misdiagnosed and treated by the medical practioners ,because they are unaware of this uncommon side effect.

Fig 1: Diclofenac induced fixed drug eruption over penis



IV. Conclusion

Here by we report this case, to create awareness about this rare side effect of diclofenac and caution should be taken while administering NSAIDs, especially diclofenac to prevent this type of reaction.

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