



CASE REPORT

Ofloxacin/ tinidazole induced fixed drug eruption- a case report

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Introduction: An immunological cutaneous adverse drug reaction is distinguished as sharply defined lesions with red rashes and sharp borders, erythematous lesions with or without blisters developing within an hour or in a few cases within a week after drug administration is termed as fixed drug eruptions (FDE). FDE is one of the major forms of drug-induced dermatosis. Various class of drugs that are causative agents for FDE includes antibiotics, anticonvulsants, antivirals, and Non-steroidal anti-inflammatory drugs (NSAID). FDE is easily recognized and differentiated from other drug eruptions since it does not occur voluntarily or during infection.

Case report: This case report is to spotlight the case of a 52-year-old male patient who was undergoing treatment for acute gastroenteritis and suffered from FDE due to administration of IV Ofloxacin.

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Introduction

An immunological cutaneous adverse drug reaction is distinguished as sharply defined lesions with red rashes and sharp border, erythematous lesions with or without blisters developing within an hour or in few cases within a week after drug administration is termed as fixed drug eruptions (FDE). FDE is one of the major forms of drug-induced dermatosis. FDE is deemed to cause 16-21% of the ADRs. Various classes of drugs that are causative agents for FDE includes antibiotics, anticonvulsants, antivirals, and Non-steroidal anti-inflammatory drugs (NSAID) (Jhaj *et al.*, 2018; Gohel *et al.*, 2020; Kameswari *et al.*, 2014; Jain *et al.*, 2013; Baltaci *et al.*, 2012). FDE is easily recognized and differentiated from other drug eruptions since it does not occur voluntarily or during infection. Irrespective of the gender and age group of the patient, FDE can occur in both infants and elderly patients. The most prevalent age group is 20-40 years. The well-known antimicrobial Ofloxacin, which belongs to the class

of fluoroquinolones is used as a therapeutic drug in treating various diseases like urinary tract infections (UTI), acute bacterial diarrhea, enteric fever, Sexually transmitted diseases (STD's) and other bacterial infections alone or in combination with other medications (Ramani *et al.*, 2015; Ramineni *et al.*, 2015). Before prescribing antibiotics, the rationality of the treatment must be kept in mind since a lot of combinations result in frequently arising ADRs and is only because of irrational treatment. Many reports indicate fixed drug eruptions due to the irrational use of quinolones but very few have been reported with the use of ofloxacin with tinidazole (Kumar *et al.*, 2015; Bhusan *et al.*, 2015).

According to the World Health Organization (WHO) as well as Food and drug administration (FDA) ofloxacin and tinidazole is one of the examples of irrational drug combinations available in the Indian market (Gautam CS *et al.*, 2006). Here, we report a case of FDE on the



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administration of ofloxacin and tinidazole fixed-dose combination and as a single therapy alone.

Case report

A 52-year-old male patient presented to male OPD with chief complaints of vomiting, diarrhea, and fever for the

past 8 days and was diagnosed with acute gastroenteritis. The patient was admitted to the medicine male ward and treatment was initiated. He was initially prescribed the following treatment on admission as given in table 1 below.

Table 1: Drug therapy advised for Acute Gastroenteritis

DRUG	DOSE	ROUTE	FREQUENCY
TAB. OFLOX TZ (ofloxacin+tinidazole)	200mg+600mg	P/O	BD
CAP PAN DSR (Pantoprazole+domperidone)	40mg+30mg	P/O	OD
INJ.EMSET (ondansetron)	4 mg	IV	SOS
SYP. ULGEL	2 Tsp	P/O	QID
TAB.DROTIN (Drotaverine)	40 mg	P/O	SOS
Sachet Sporolac (lactic acid bacillus)	4gm	P/O	TDS

OD- once a day; **BD-** Twice a day; **SOS-** If necessary; **QID-** Four times a day; **TDS-** Thrice a day

After a few hours of administration of the first dose of the fixed drug combination of ofloxacin and tinidazole, the patient started experiencing itching and an abnormal sensation of burning and tingling in his arms and legs. When the second dose was administered patient developed lesions and rashes on his forearms and legs including burning sensation. After 24 hours the drug Oflox TZ was stopped by the physician and there was a decrease in severity of the reaction that had occurred. Later on single-drug therapy of ofloxacin 200 mg IV, OD, and tinidazole 800 mg IV, OD was initiated and instead of combination both were given separately. Other concomitant medications were still ongoing along with the therapy. After 2 hours of a single dose of drug administration patient again experienced severe itching and burning sensation on arms and legs accompanied by lesions and rashes on the same areas again (Refer Figure 1, 2, 3). The re-exposure to ofloxacin and tinidazole induced the same allergic reaction which made confirmation of FDE induced by Ofloxacin/Tinidazole. Re exposure of the drug was done by physician that time. Both the drugs were stopped immediately and Inj. Hydrocort (Hydrocortisone) 200 mg IV was administered. Apart from this patient was advised Tab. Allegra (fexofenadine) 180 mg Stat and Calamine lotion was prescribed for local application.

For further treatment patient was advised Tab. Zifi (Cefixime) 200 mg P/O; BD.

Finally, the patient started healing slowly and was discharged after 6 days of admission. The patient denied having any previous history of reaction with same drug. No information was available regarding histopathology. To determine the relationship between drug and reaction WHO-UMC causality assessment scale was used and was observed that Ofloxacin/ Tinidazole induced FDE falls under the "probable" category.



Figure 1: Ofloxacin/Tinidazole induced FDE



Figure 2: Ofloxacin/Tinidazole induced FDE



Figure 3: Ofloxacin/Tinidazole induced FDE

Discussion

Antibacterial agents and NSAID's have shown as the well-known triggering agents of FDE. The most commonly seen are fluoroquinolones and nitroimidazoles. FDE can occur irrespective of the gender and age group of the patient. (Jhaj *et al.*, 2018, Patel *et al.*, 2014) These have been reported in a very young patient of 1.5 years old as well as in 87-year-old elderly patient. (Baltaci *et al.*, 2012) The pathological process of FDE is not clearly known but it involves antibodies, antibody dependent cell mediated cytotoxicity and serum factors. (Marrapu *et al.*, 2014) Also, intraepidermal CD8+ T cells play a major role in the development of tissue damage at localized stage. (Dhar *et al.*, 1996) In this case, there was a time-related association between the administration of Ofloxacin/ Tinidazole and the onset of itching and burning sensation on arms and legs. The symptoms reduced on the dechallenge. On rechallenge, the same symptoms were observed in the patient. Hence, a diagnosis of "Ofloxacin/ Tinidazole induced Fixed Drug Eruptions" was made. There was no family history with the same drug, but the patients mother was diabetic. According to the WHO-UMC assessment Scale, the association between the drug and the adverse drug reaction was found to be Probable.

Conclusions

There is a need for creating awareness regarding irrational drug combinations among health care professionals to avoid such adverse drug reactions. ADR monitoring should be made mandatory in all hospitals. The regular antibiotic audit must be done to check the rationality of the treatment and in case of inappropriate prescribing, errors must be reported. Also, ofloxacin/ tinidazole must be included in the differential diagnosis of FDE.

Ethical declaration

Informed consent was taken from the patient before the data collection stating that no identity of the patient will be disclosed.

Conflict of interests

None declared.

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