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Case Report

Ofloxacin-induced maculopapular rash in the infant

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ABSTRACT

Adverse drug reactions (ADRs) are a major cause of morbidity and mortality in countries having limited healthcare resources. The ofloxacin is an antimicrobial used for treating several bacterial infections. The ofloxacin, belonging to quinolone group of drugs, is bactericidal and acts by inhibition of bacterial DNA gyrase. Among the adverse drug reaction of ofloxacin, skin rashes are rare. An ofloxacin-induced maculopapular rash is the unique rare condition in the infant. The present case report was assessing the causality in ofloxacin induced maculopapular rash in the infant. Naranjo Adverse Drug Reaction Probability Scale and World Health Organization and Uppsala Monitoring Centre (WHO-UMC) system for standardized case causality assessment were used for assessing the causality. According to the Naranjo and WHO-UMC, ofloxacin scaled as the probable/likely cause of this ADR in infant. So, authors can conclude that the ofloxacin should be used cautiously in the pediatric age group.

Keywords: Adverse drug reaction, Exanthema, Infant ofloxacin, Maculopapular, Rash

INTRODUCTION

Adverse drug reactions (ADRs) are a major cause of morbidity and mortality in countries having limited healthcare resources.[1]

Of all the Adverse Drug Reactions, antimicrobials contribute 28% which is highest compared to the other drugs.[2] Incidence of Cutaneous eruption varies from 1-8% for several classes of antibiotics.[3] Rate of allergic cutaneous reactions to floroquinolones is 1.6%.[3]

The ofloxacin, belonging to quinolone group of drugs, is bactericidal and acts by inhibition of bacterial DNA gyrase.[4] The ofloxacin is an antimicrobial used for treating several bacterial infections. Ofloxacin is found to be highly effective orally in reducing the cost and risk to the patients suffering from pneumonia.[5] Ofloxacin is very useful in the treatment of acute bacterial diarrhea in developing countries.[6] Ofloxacin was found to be useful in the open fractures and post traumatic osteomyelitis.[7] Ofloxacin can be considered safe for the urinary tract infections.[8] It is favourable in the cure of chronic

obstructive pulmonary disease (COPD) exacerbation requiring mechanical ventilation.[9] Short courses of ofloxacin are cheap, nontoxic, and effective for the treatment of uncomplicated multidrug-resistant typhoid fever.[10]

It is also effective in skin, soft tissue and central nervous system infections. It can be used in surgical prophylaxis. It is efficacious in immunocompromised patients. It can be used in otorhynological infections.[11]

Among the adverse drug reaction of ofloxacin, skin rashes are rare.[12] The first skin rash reported in 1986 in phase II clinical trial in Europe and Japan.[13] An ofloxacin-induced maculopapular rash is a rare condition in pediatric population less than 1 year. No case reported until now in infant age group. Therefore, it was important to assess the causality in ofloxacin induced maculopapular rash in the infant in our case report.

CASE REPORT

Informed consent from the parents obtained for examination and taking the photographs of the rash of the child.

Table 1: Naranjo adverse drug reaction probability scale assessment.[14]

Answer	Present study score
There are previous conclusive reports on this reaction as stated in the discussion section of this article.	+1
The administration of ofloxacin strongly associated with appearance of the rash.	+2
Rash disappeared after withdrawal of ofloxacin.	+1
Re-challenge with ofloxacin not done because of the ethical issue.	0
The consulting dermatologist ruled out the viral exanthema.	+2
Re-challenge with placebo not done too.	0
Laboratory test for detection of drug in toxic concentration in blood or body fluids was not done.	0
Relationship of the severity of reaction with dose of drug was not evaluated.	0
This was the first time the patient was administered the ofloxacin as there was no previous episode of gastroenteritis.	0
The Pediatrician's prescription containing ofloxacin and paracetamol can be considered for objective evidence.	+1
Total	+7
Total score (- 4 to +13)	Interpretation of Naranjo ADR probability scale
>9	Definite
5 to 8	Probable
1 to 4	Possible
≤0	Doubtful

Table 2: World Health Organization and Uppsala monitoring centre (WHO-UMC) system for standardized case causality assessment.[15]

Causality term	Assessment criteria	
Probable/ likely	1	There is temporal relationship with Adverse Drug Reaction to ofloxacin intake
	2	The consulting dermatologist ruled out the viral exenthem. The rash did not reappear even after paracetamol continued for the fever
	3	Rash disappeared after withdrawal of ofloxacin
	4	Re-challenge neither with ofloxacin nor with Placebo needed

A 5 and half-month-old child presented in the pediatric department with the acute maculopapular rash. The rash was erythematous in nature, insidious in onset and gradually progressive. Starting on the face, rash progressed to all over the body (generalized). Rash was red in color on the face and on the extremities. Rash was smooth in texture. Itchy in nature. There was no cough. There was no conjunctivitis. There were no respiratory symptoms including runny nose. There were no swollen joints or joint pain. There were no any swollen lymph nodes. More rash on face and back than on extremities. No previous history of any other rash on the body. The child

was given syrup paracetamol 4ml tds p.o. and syrup ofloxacin 4ml tds p.o. for acute gastrointestinal infection with fever. Apart from these, no other drug was prescribed. After the appearance of the rash, ofloxacin was withdrawn but paracetamol continued for the fever. The rash disappeared after withdrawal of ofloxacin.

DISCUSSION

After the history, Naranjo Adverse Drug Reaction Probability Scale (Table 1) and World Health Organization and Uppsala Monitoring Centre (WHO-UMC) system for standardized case causality assessment (Table 2) were used for assessing the causality.[14,15] According to the Naranjo and WHO-UMC, ofloxacin scaled as the probable/likely cause of this ADR.

In a retrospective analysis, Steven-Johnson syndrome and toxic epidermal necrosis induced by ofloxacin had higher morbidity and mortality compared to anticonvulsant drugs.[16] Having Immediate hypersensitivity reaction with ofloxacin, and cross sensitivity with other fluoroquinolones, no two drugs from the same group recommended for use.[17-19]

Present case is the unique one as no rash has been reported in the infant age group due to ofloxacin. The rash similar to our case, described in the 5-year-old female child weighing 16kg.[20]Another case in 14kg, the 4-year-old male child reported.[20] Moreover, the 6-year-old male child with rash notified.[20] A 48-year-old mother and 21-year-old son identified developing the perioral rash.[21] Hypersensitive vasculitis stated in the 67-year-old lady in the past.[22] In these cases, ofloxacin causality assessment confirmed as probable/likely. These cases show that there are earlier conclusive reports of similar reaction which is important to scale our ADR on the Naranjo Scale.

CONCLUSION

In conclusion, the ofloxacin should be used cautiously in the pediatric age group.

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