INTRODUCTION
Norfloxacin is an antibiotic which is commonly prescribed for the treatment of urinary tract and genital infections. Besides, it is also routinely used for the treatment of infectious diarrhea with other anti-diarrheal drugs. There are different adverse effects associated with norfloxacin but among those allergic reactions sometimes becomes troublesome. This case report presents a less common allergic reaction cheilitis occurring secondary to norfloxacin intake. No records of this unfamiliar and rare adverse drug reaction of this drug were found in the popular databases like Pubmed and Elsevier.

Case Report
A 23-year-old boy presented with mild weakness, abdominal pain and five loose stools for last 2 days and no appetite. On physical examination, it was revealed that he had a body temperature of 98°F and no sign of dehydration was there. He admitted to doctor of having spicy junk foods at a roadside stall, after which he had these symptoms. He was provisionally diagnosed with acute infectious diarrhea and doctor prescribed him norfloxacin tab (400mg) QD for 2 days and loperamide 2mg capsules BID for 3 days. On the next day, the patient came to the doctor and presented with the problem of moderate pain, itching, redness, edema in both the lips after 2 hours of norfloxacin and loperamide drug intake. There were cracks on the lips and bleeding from those cracks and due to this, he was not able to speak properly. On examination, the doctor suspected that he had drug-related cheilitis and supposed to be caused by the norfloxacin. He was advised to continue the loperamide with the drug metronidazole this time and to stop the norfloxacin immediately. He was also prescribed with the drug Famotidine for the treatment of allergy as it was the severe hypersensitivity reaction. On the next visit, after 5 days, the patient was found to be recovering from Cheilitis and had no episodes of diarrhea. On following up, it was found on the thirteenth day that the inflammation, itching got resolved but some cracks in the lower and upper lip were still there and healing. The patient was not ready to be photographed. The case was diagnosed as a case of Cheilitis probably due to norfloxacin after the causality assessment using the WHO-UMC Causality Assessment Scale.

DISCUSSION
Cheilitis is the inflammation of the lips. The symptoms of cheilitis include lip dryness, cracking, peeling, redness and itching. Common causes include irritated skin, frequent sun exposure, infection, allergies, and auto immune response. Norfloxacin which comes under the category of fluoroquinolone antibiotics causes immediate and delayed hypersensitivity reactions and may affect the internal organs and circulating blood cells. The underlying pathogenesis is remained partly understood. Recent studies have shown the presence of quinolone specific IgE in vitro in more than 50% of individuals with immediate-type reactions. Primarily, it is used for treating urinary and genital tract infections but it is also good for the treatment of bacterial diarrheas. The pharmacokinetic hallmark of norfloxacin 400mg oral dose shows a peak serum concentration of 1.3-1.58µg/ml, an elimination half-life of 3-7 hours and have effective penetration into prostatic and kidney tissue.

The adverse effects of norfloxacin are generally well tolerated and discontinuation of therapy is not required. The allergic reactions due to this medicine generally involve itching, skin rash or hives, vomiting, light-headedness, shortness of breath and fast heart rate. This case involved the hypersensitivity reaction affecting the lips. Although, some of the fluoroquinolones have shown the moderate hypersensitivity reactions involving the face, tongue, and lips. This case indicated towards severe hypersensitivity reaction due to norfloxacin that caused cheilitis.
As many case reports are concerned with suspected adverse drug reactions, so the pharmacovigilance can be difficult. Moreover, the adverse drug reactions are seldom specific or related to the drug in the absence of diagnostic tests and a rechallenge. Although there are great numbers of algorithms that have been developed to assess the causality between an event and the drug but the most widely accepted algorithms are WHO-UMC scale and Naranjo scale7. In our case, WHO-UMC scale has been used with assessment criteria which are given in Table 1. On applying this scale, the level of causal relationship was found to be “Probable” as ReChallenge could not be done as it is unethical.8

Different reports of allergic reactions due to norfloxacin have been reported but this type of case report involving severe cheilitis is very rarely reported. Therefore, this case has been presented for its rarity and to make the people attentive and careful about this type of allergic reaction by commonly prescribed medication.

ACKNOWLEDGEMENT

Authors are highly grateful to their parents and friends who have been always with us and without them, the case report could not have been possible.

ABBREVIATIONS

WHO-UMC: World Health Organisation-Uppsala Monitoring Centre; mg: Milligram; µg: Microgram; BID: bis die (Two times a day); QD: quaque die (once daily); Tab: Tablet

<table>
<thead>
<tr>
<th>Causality Terms</th>
<th>Assessment Criteria</th>
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<tbody>
<tr>
<td>Certain</td>
<td>Event or laboratory test abnormality, with plausible time relationship to drug intake Can’t be explained by disease or other drugs Response to withdrawal plausible (pharmacologically, pathologically) Event definitive pharmacologically or phenomenologically (an objective and specific medical condition or a recognized pharmacological phenomenon Re-challenge satisfactory, if necessary</td>
</tr>
<tr>
<td>Probable/ Likely</td>
<td>Event or laboratory test abnormality, with reasonable time relationship to drug intake Unlikely to be attributed to a disease or other drugs De-challenge positive Re-challenge not required</td>
</tr>
<tr>
<td>Possible</td>
<td>Event or laboratory test abnormality with reasonable time relationship to drug intake Can also be explained by disease or other drugs De-challenge information may be lacking or it is unclear</td>
</tr>
<tr>
<td>Unlikely</td>
<td>Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable but not impossible Disease or drugs confer plausible explanation</td>
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REFERENCES


Cite this article as:


Source of support: Nil, Conflict of interest: None Declared

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Table 1: WHO-UMC causality assessment scale showing relatedness criteria