

# Anaphylactic Reaction Caused by Co-administration of Diclofenac and Ofloxacin

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## Case Report

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### ABSTRACT

Anaphylaxis is the most severe form of an allergic reaction. Drug-induced anaphylaxis can be life-threatening after drug intake by any route, including non-therapeutic exposure due to accidental contact. The most common culprit drugs are non-steroidal anti-inflammatory drugs, beta-lactam antibiotics and other antibiotics such as quinolones. A 25-year-old female patient attended the dental clinic with the complaint of toothache and was prescribed Diclofenac 50 mg and Ofloxacin 200 mg twice a day. After a day patient was brought to the Emergency and Trauma Centre of the hospital with multiple erythematous macules and papules over both forearms, multiple erythematous macules present over trunk, itching over the lesions, fever and throat pain. The patient was diagnosed as a case of Anaphylactic Reaction associated with the co-administration of Diclofenac and Ofloxacin. Drugs were discontinued on the same day, and further management was started. The causality assessment of this case was possible as per the WHO-UMC causality assessment scale.

**Keywords:** Ofloxacin, Diclofenac, Adverse Drug Reaction, Anaphylactic Reaction

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### INTRODUCTION

Anaphylaxis is the most severe form of an allergic reaction. It is rapid in onset and potentially fatal. While the prevalence of anaphylaxis is estimated to be as high as 2% and appears to be increasing, the fatality rate is extremely low (i.e., < 0.0001% prevalence in the general population, or < 0.5% case fatality rate in those hospitalized or presenting to the emergency department with anaphylaxis) and appears to be decreasing.

Drug-induced anaphylaxis can be a life-threatening condition occurring after drug intake by any route, including non-therapeutic exposure due to accidental contact.

The most common culprit drugs are non-steroidal anti-inflammatory drugs, beta-lactam antibiotics and other antibiotics such as quinolones.<sup>2</sup> Diagnosis and management are challenging since reactions are often immediate and unexpected.

In a study of 2458 anaphylaxis-related deaths in the USA between 1999 and 2010, medications were the most common cause, responsible for more than 50 % of the cases, followed by unspecified triggers, venoms and food.<sup>3</sup>

Diclofenac is a non-steroidal anti-inflammatory drug (NSAID) that treats pain and inflammatory diseases such as gout. It is taken by mouth, rectally in a suppository, used by injection, or applied to the skin.<sup>4</sup> Common side effects include abdominal pain, gastrointestinal bleeding, nausea, dizziness, headache, and

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swelling.<sup>4</sup> Serious side effects may include heart disease, stroke, kidney problems, and stomach ulceration.<sup>5</sup> Use is not recommended in the third trimester of pregnancy.<sup>4</sup> It is likely safe during breastfeeding.<sup>5</sup>

Ofloxacin is a quinolone antibiotic used for the treatment of bacterial infections like pneumonia, cellulitis, urinary tract infections, prostatitis, plague, and certain types of infectious diarrhoea.<sup>6</sup> Other uses, along with other medications, including treating multidrug-resistant tuberculosis.<sup>7</sup> Common side effects include vomiting, diarrhoea, headache, and rash.

Other serious side effect includes tendon rupture, numbness due to nerve damage, seizures, and psychosis.<sup>6</sup> Use in pregnancy is typically not recommended.<sup>8</sup>

#### Adverse effects:

Diclofenac (NSAID) and Ofloxacin (Quinolone antibiotic) are safe and well-tolerated drugs. The most frequently reported adverse effects are vomiting, diarrhoea, headache, rashes, abdominal pain, gastrointestinal bleeding, nausea, dizziness, headache, and swelling. Anaphylactic Reaction is rarely reported with co-administration of Diclofenac and Ofloxacin.

A case of Anaphylactic Reaction associated with co-administration of Diclofenac and Ofloxacin was reported to Pharmacovigilance Programme of India (PvPI), Indian Pharmacopoeia Commission (IPC), Ghaziabad by Adverse Drug Reaction Monitoring Centre (ADRM) of the hospital.

#### CASE STUDY

A 25-year-old female patient attended the dental clinic of the tertiary care centre with a complaint of toothache and was prescribed Diclofenac 50 mg and Ofloxacin 200 mg twice a day. After one day patient was brought to the Emergency and Trauma Centre of the tertiary care centre with multiple erythematous macules and papules over both forearms measuring 0.3x0.3cm to 0.5x0.5cm in size, multiple erythematous macules present over trunk measuring 0.3x0.3cm to 0.5x0.5cm in size, itching over the lesions, fever and throat pain. The oral cavity was normal. The patient was diagnosed as a case of Anaphylactic Reaction associated with the co-administration of Diclofenac and Ofloxacin. On examination, pulse rate was 147/minute, respiratory rate 18/minute, SpO<sub>2</sub> 90% at room air, temperature: normal and blood pressure 78/40 mmHg at the time of admission in Casualty. Drugs were discontinued on the same day and admitted to the medicine ward for further management.

The patient was administered Normal Saline 4 unit and Dextrose Normal Saline 4 unit intravenously over 24 hours, Inj. Efcorlin (Hydrocortisone) 100 mg TDS, Inj. Pan (Pantoprazole) 40 mg OD, Inj. Emeset (Ondansetron) 8 mg TDS and Inj. Norad (Norepinephrine) 2amp. In 50ml NS @6ml per hour for event management. She was not recovered at the time of the report.

The case was registered in Vigiflow WHO-UMC (World Health Organization-Uppsala Monitoring Centre) software under the worldwide unique number IN-IPC-300541282, AMC Report No. JNMCH/Jun-2021/01. The causality assessment of this case was possible as per the WHO-UMC causality assessment scale.

#### DISCUSSION

Anaphylaxis is a severe, systemic hypersensitivity reaction that is rapid in onset and characterized by life-threatening airway, breathing, and/or circulatory problems and that is usually associated with skin and mucosal changes.<sup>9</sup> The classic presentation includes urticaria or angioedema, hypotension, and bronchospasm.<sup>10</sup> Several cases of anaphylactic shock induced by drugs have been reported.

The patient reported multiple erythematous macules and papules, itching over the lesions and fever along with throat pain, confirming the diagnosis of anaphylaxis. Since no other drug was taken and there was no other incriminating factor, this anaphylaxis was attributed to the Co-administration of Diclofenac and Ofloxacin. The case report is the rare one with the Co-administration of Diclofenac and Ofloxacin, even though it has been used extensively in almost all age groups to manage pain with infections across the world. Vigiaccess status of this case with diclofenac is 2754 and with ofloxacin is 181, which means very less suspected adverse reaction have been reported to the WHO Programme for International Drug Monitoring (WHO PIDM) till now.<sup>11</sup>

#### CONCLUSION

It was a rare case of a life-threatening anaphylactic reaction associated with co-administration of Diclofenac and Ofloxacin. The causality assessment supported the possible diagnosis. This case report further emphasizes the need for continuous ADR monitoring and reporting for healthcare professionals and to be more vigilant on co-administration of Diclofenac and Ofloxacin to avoid such life-threatening events in future.

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