 DOI: 10.18231/2393-9087.2016.0010

Anaphylaxis to parenteral ciprofloxacin in mother leading to foetal death

Chhaya Goyal[1], Mohammad Rafi[2,*], Ghazala Khan[3]

[1]Professor & HOD, [2]Pharmacovigilance Associate, Dept. of Pharmacology, Sri Aurobindo Institute of Medical Sciences, Indore
[3]Associate Professor, Dept. of Pharmacy, Oriental University, Indore

***Corresponding Author:**
Email: rafiguddu@rediffmail.com

Abstract

Anaphylaxis is a rare condition during ante natal care since most of the drugs except nutraceuticals are avoided in pregnancy unless essentially required to prevent developing foetus from any teratogenic effects. An anaphylactic reaction follows idiosyncrasy that may occur with any drug or food to which an individual is previously known or unknown to be allergic. Antibiotics and NSAIDs are the most common class of drugs known to cause allergic reactions. Maternal anaphylaxis has the potential to cause foetal defects (morbidity) and in rare cases foetal death (mortality), latter possibly due to hypoxia. The authors here report a similar case of maternal anaphylaxis to ciprofloxacin infusion during third trimester in which maternal outcome was positive but 8 months foetus died within an hour of reaction. Iron sucrose infusion was also administered to the mother prior to ciprofloxacin in a community clinic.

Keywords: Ciprofloxacin, Iron sucrose, Anaphylaxis, Foetal Death, Adverse Drug Reaction.

Introduction

Apart from iron, calcium and hormonal supplement, a woman may require antibiotics, non-steroidal anti-inflammatory drugs (NSAIDs), etc. in fever, diarrhea, urinary tract infections, etc. that occurs in pregnancy. These drugs are often avoided by the clinicians during first trimester that could impose risk to the foetus. With the advances in drug development and available drug data, a clinician always select the safest drug from category A or B for the patient especially in case of pregnancy. Even though some serious or fatal reactions occur in patients or their developing baby which are unpredictable allergies to drugs. Fluoroquinolones are one of the most common classes of antibiotics being prescribed irrespective of age group. Their potent and broad spectrum activity make them a viable option for the treatment of respiratory tract infections, urinary tract infections, sexually transmitted diseases and infections of skin and soft tissues.(1) The anaphylactoid reaction, which is non-immunologically mediated, has been noted with the orally administered as well as intravenously administered preparations of fluoroquinolones, frequently with ciprofloxacin.(2) Iron sucrose is a parenteral dosage form which is administered with normal saline by slow intravenous infusion to the patient for three to four hours. It is indicated in cases of severe anaemia to correct rapid stores of iron or in cases where the patient develops gastrointestinal intolerance to oral iron preparations. Thus, the use of iron sucrose has been increasing in pre and post natal care. Systemic administration of iron preparations can cause allergic or anaphylactoid reactions, which can be potentially fatal. No well controlled studies in pregnant women are available to date. The use of iron sucrose is contra-indicated in pregnancy first trimester.(3)

Case History

A 32 years old female patient with 32 weeks of pregnancy was hospitalized in emergency care of the hospital with chief complaints of severe drug reaction. Prior to hospitalization, the patient was admitted in a community nursing home with chief complaints of abdominal pain. Found anaemic she was administered inj. iron sucrose i.v. with normal saline. After some time she was administered inj.ciprofloxacin slow i.v. infusion 500mg/100ml in abdominal pain presumed to be of infectious origin. Within half an hour, patient developed anaphylaxis to the very first dose of the drug. She started vomiting and was complaining of headache. Soon she developed rigors and generalized edema with angioedema. Patient was then shifted to a tertiary care center where she was diagnosed ciprofloxacin induced anaphylaxis. Patient also informed the clinicians and gynaecologists that she had stopped perceiving fetal movements following the reaction. At midnight an urgent ultrasonography was done which confirmed intra uterine death. The mother of the fetus was medically managed in intensive care unit after which she was recovered of the reactions within few hours but foetal outcome was negative. The dead foetus was normally delivered by induced labor. Next day, the patient was discharged from the hospital. The causality of anaphylaxis to ciprofloxacin was assessed by authors as probable as per WHO-UMC causality assessment criteria.

Discussion

Most of the fluoroquinolones including ciprofloxacin belongs to pregnancy category C drugs which clearly define that animal reproductive studies shows adverse effects on foetus but there are no adequate data or well controlled studies in humans. Lack of data on fatal outcomes is attributed to

underreporting of such events. Medico-legal issues, unawareness of adverse drug reaction (ADR) reporting (why, where, to whom & how to report), perception that reporting a single case can make no difference towards patients' safety are the root causes of underreporting and missing of significant serious & fatal adverse drug reactions. To facilitate these issues, pharmacovigilance programme of India (PvPI) under MOHFW, Govt. of India in technical collaboration with WHO's Uppsala monitoring Center, Sweden was started in 2010 to monitor adverse reactions in Indian population. Under this programme ADR monitoring centers in MCI approved govt. and private medical colleges throughout the country were set up to collect the data and ADR centers are increasing in phasic manner year by year. When WHO global database was searched and analyzed by National Coordination Center for PvPI-Indian Pharmacopoeia Commission (NCC-PvPI-IPC), *this one was the only very rare case reported electronically from India* as compared to 39 from America, 1 from Africa, 78 from European nations, 1 from Asian country other than India and none from Oceania.[4] It was also stated that the pregnancy category of a drug may change depending upon the number of clinical evidence on the safety data.[4] Of course, there might be much more similar cases going unnoticed and unreported from our country.

Conclusion

Healthcare professionals i.e. HCPs (Clinicians, Pharmacists, Nurses, etc.) should report ADR of clinical significance even if they are suspected of it. This will help to bring some new medical information on drug safety in the upcoming years which will benefit our patients. There are no legal consequences on HCPs or the patients on reporting an ADR as declared by PvPI. Apart from pharmacovigilance centers throughout the country, PvPI encourages everyone to use PvPI toll free Helpline 18001803024 and / or android *ADR Reporting PvPI* app freely available on Google play store in reporting adverse reactions to drugs, herbals vaccines and recently to medical devices.

References

1. Bertino J., Fish D. The safety profile of the fluoroquinolones. Clin Ther 2000;22:798-817.
2. Kavitha Kothur, Meenu Singh, Devi Dayal. Ciprofloxacin-induced anaphylactoid reaction, Eur J Pediatr 2006;165:572-574.
3. Pharmacy Retailing (NZ) Limited. (2016) Venofer [Data sheet] available from: http://www.medsafe.govt.nz/profs/datasheet/v/venoferinf.pdf.
4. Indian Pharmacopoeia Commission. Pharmacovigilance Programme of India (PvPI) Newsletter Vol-3(6), 2013 August Issue, page 5.