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Nimesulide MD induced rashes all over the body: A case report

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Abstract

A 13-year-old female patient came to the hospital with rashes all over the body. After being administered Nimesulide MD for fever, the patient is having an unexpected symptoms of rashes, and itching was observed. Following assessment, the patient was given IV Dexa and IV Avil. On assessing causality of the adverse drug reaction (ADR), different ADR assessment scales such as the WHO-UMC (Uppsala Monitoring Center) scale, Naranjo scale, and Hart wig's severity assessment scale were used, and the ADR was found by these scales to be 'possible', 'probable', and 'moderate', respectively. It was found that the ADR is not fatal but causes patient anxiety and reduced quality of life. This case report is meant to make physicians and clinicians aware and vigilant about the ADR caused by Nimesulide, facilitating its early detection and management.

Keywords

rashes; itching; adverse drug reaction; nimesulide; causality assessment.

Abbreviations

ADR: Adverse Drug Reaction; WHO-UMC: World Health Organization- Uppsala Monitoring Centre; CBC: Complete Blood Cell.

Background

Nimesulide is a non-steroidal anti-inflammatory drug (NSAID) with preferential inhibitory activity on the cyclooxygenase 2 (COX-2) enzyme. The drug was initially launched in the European nation in 1985 and was afterward marketed in additional than fifty countries, as well as the Republic of Korea. Its potent analgesic, medicament, and antipyretic properties, with a comparatively low risk for canal facet effects, as incontestable by varied clinical trials. Moreover, nimesulide, when administered orally, is rapidly and extensively absorbed, thus allowing effective pain control. However, nimesulide-induced hepatotoxicity was

first reported in 1997, and severe, and even fatal, cases of liver injury have been reported in patients who received nimesulide treatment. Consequently, the employment of nimesulide was restricted or withdrawn from the market in 2002 in the Kingdom of Spain and the Republic of Finland, followed by many different countries [1].

Nimesulide could be an anti-inflammatory drug (NSAID) with relative specificity for cyclooxygenase that's not offered within us however is employed wide in alternative countries within the treatment of acute pain. Nimesulide has been joined to an occasional rate of transient humor protein elevations throughout medical care, however conjointly to several instances of clinically apparent acute liver injury which will be severe and can result in acute liver failure, need for emergency liver transplantation, and death [4].

When a new drug is licensed, its adverse effects are incompletely known, because only a limited number of locality volunteers and highly selected patients have taken it. Thus, efficient post-marketing drug surveillance is needed, but unfortunately such surveillance does not exist or is inadequate in India. Nimesulide (4-nitro*2 phenoxy methane sulfonamide), which is a nonsteroidal anti-inflammatory drug, has been available in the Indian Market since 1997 for its antipyretic and anti-inflammatory activity. None of the reports in medical literature indicate its superior effectivity as antipyretic as compared to paracetamol and anti-inflammatory compared with alternative medication of this category like diclofenac and NSAID. Varied studies have established the critical adverse events with nimesulide like hepatotoxicity, excretory organ toxicity, severe skin reactions as well as fastened eruptions, canal toxicity, a synergy of seizures. potentiation of colitis passive cigarette smoking [2].

Case Presentation

A 13-year-old female patient went to the hospital with rashes and itching all over the body due to being administered Nimesulide for fever in the night without a prescription. In the hospital, the patient assessment was done, and also taken a medical history, medicinal history, and social history, and laboratory investigational studies of the child were as follows. Her vital sign was found to be 120/80 mmHg clotting. Complete blood count revealed Hb-10.2 g/dl, TLC-5300 l, RBC count-5.2 mn/mm, platelets-261, Bleeding time& clotting time (BTCT), sodium- 136 mg/dl, and potassium- 4.4 mg/dl were normal. After that intravenous line was established for administering drugs and she was prescribed: Inj. Dexa 1.5 ml OD, Inj. Avil 2 ml OD/dl & bilirubin direct-5.2 mg/dl. SGOT, SGPT and Alkaline phosphate were 587 IU, 1245 IU and 2932 IU, respectively. Liver function test after 9 day from withdrawal of Nimesulide showed Bilirubin total-1.34 mg/dl & bilirubin direct-0.81 mg/dl. SGOT, SGPT and Alkaline phosphate were 98.48IU, 189.6IU and 1603IU, respectively. These parameters of Liver function showed significant improvement after withdrawing Nimesulide. Complete blood count revealed Hb-11.2 g/dl, TLC-9300 l, 3 PCV-34%, RBC count-4.2mn/mm MCH-26.67 pg, MCV-380.95 fl, MCHC-32.94 %, platelets-261 10/l, Bleeding time & clotting time (BTCT) were normal (Bleeding time-3'36"minute, clotting time-6'13"minute), while Prothrombin time Index: PTI control-12 sec, PTI test-13 sec, PTI-92% was also within the normal limits.

Investigations

The patient was diagnosed with rashes and itching induced by Nimesulide MD, no other abnormality and deformity were found on physical examination. During the examination, the patient was conscious and

responsive. Sensory organs were intact. Her complete blood count, blood sugar, and blood pressure were found to be normal. Serum electrolytes were within the limits.

Causality assessment of the adverse drug reaction (ADR) was conducted using different scales such as the WHO-UMC (Upsala Monitoring Center) scale, Naranjo scale, and Hartwig's scale severity assessment, and the ADR was found by these scales to be 'possible', 'probable', and 'moderate', respectively nimesulide was found to be the first participant drug for this ADR.

Treatment

On assessing the ADR, the patient was immediately given IV Dexa 1.5 ml and IV Avil 2 ml to calm down and cause rashes and itching, hence reversing the action of the Nimesulide MD. The ADR-causing drug was omitted from the further treatment chart resulting in complete eradication of rashes and itching. Antihistamine's category which is the recommended treatment for rashes and itching was not given as the symptoms resolved on withdrawal of Nimesulide. No other was required for the management of the ADR.

Outcome and Follow-Up

The rashes and itching symptoms subsided with the use of a single dose of inj. Dexa and inj. Avil. On follow-up, it was observed that no similar rashes and itching symptoms after the use of the Dexa and Avil.

Discussion

Nimesulide is a nonsteroidal anti-inflammatory drug (NSAID) with anti-inflammatory, antipyretic, and analgesic properties. It inhibits autocoid synthetase/cyclooxygenase, which limits autocoid production. Its enzyme inhibiting efficiency is intermediate, however is comparatively selective for the cyclooxygenase-2 (COX-2) therefore the potential for stomachal injury and intolerance is a smaller amount. It is also a free radical that limits prostaglandin production. Its enzyme inhibiting efficiency is intermediate, however is comparatively selective for the cyclo-oxygenase-2 (COX-2) therefore the potential for stomachal injury and intolerance is a smaller amount. It is also a free radical scavenger and helps protect against the tissue damage thato ccurs during inflammation.

Absorption: Well, absorbed from canal following oral admin. Peak plasma levels: 1-3 hr. With bid admin of one hundred mg, steady-state is achieved within 24-36 hr.

Distribution: 99% bound to plasma protein.

Metabolism: Hepatic biotransformation; principal metabolites 4-hydroxy-nimesulide.

Excretion: Elimination half-life: 2-5 hr. Metabolites in urine: 80%, feces: 20% of the administered dose.9% bound to plasma protein.

Overdose: Epigastric pain, nausea, vomiting, drowsiness, lethargy, GI Hemorrhage, seizures, hypertension, apnea, coma, anaphylactic reactions, and renal failure. Treatment is supportive.

Contraindicated: Hypersensitivity; GI bleeding, active peptic ulcer disease; severe renal and heart failure; hepatic impairment or known liver disease; coagulation disorders; pregnancy; children <12yr.

Special precaution: History of GI tract disease, infections, edema, hypertension, elderly, lactation.

Adverse drug reactions: Epigastric discomfort, heartburn or abdominal cramps, nausea, vomiting and diarrhea; skin rash, pruritus, edema, headache, dizziness, drowsiness; hypersensitivity reactions (e.g., bronchospasm, rhinitis, angioedema urticaria); GI Hemorrhage/perforation; bullous/erosive stomatitis, purpura, thrombocytopenia, toxic epidermal necrosis, hematuria, oliguria, and renal failure; increases in liver enzymes.

Potentially Fatal: Fatal hepatitis, Stevens-Johnson syndrome

Learning Points

- Rashes and Itching is a dermatological disorder that manifests as raised erythematous lesions, an outbreak of swollen, pale red bumps or plaque (wheals) on the skin that appears suddenly either as a result of the body's reaction to certain allergens or for unknown reasons.
- The Nimesulide MD tends to cause Epigastric discomfort, heartburn or abdominal cramps, nausea, vomiting and diarrhea; skin rash, pruritus, edema, headache, dizziness, drowsiness; hypersensitivity reactions (e.g., bronchospasm, rhinitis, angioedema urticaria); GI hemorrhage/perforation; bullous/erosive stomatitis, purpura, thrombocytopenia, toxic epidermal necrosis, hematuria, oliguria, and renal failure; increases in liver enzymes.
- Causality assessment of the ADR was conducted using different scales such as the WHO-UMC (Upsala Monitoring Center) scale, Naranjo scale, and Hartwig's severity assessment scale, and the ADR was found by these scales to be 'possible', 'probable', and 'moderate', respectively.
- The Nimesulide MD was found to be the first participant drug for this ADR.

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