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FIDAXOMICIN RELATED METABOLIC ACIDOSIS: A CASE REPORT

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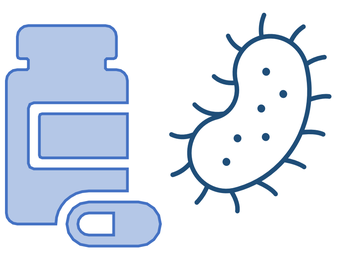
Section 5: Patient Safety and Quality Assurance

ATC code: A07 - Antidiarrheals, intestinal antiinflammatory/antiinfective agents

BACKGROUND AND IMPORTANCE

Fidaxomicin is a macrolide antibiotic used to treat intestinal *Clostridium difficile* (CD) infection in case of absence to metronidazole or vancomycin treatments. On the other hand, **pharmacovigilance** collects information, analyzes and notifies cases of suspected Adverse Drug Reactions (ADRs) in order to prevent them in the future.



AIM AND OBJECTIVES

To describe a case of **metabolic acidosis** in a patient treated with **fidaxomicin** and establish it is possible association.

MATERIALS AND METHODS

We describe the case of an 82-year-old male, diagnosed with **multiple myeloma** and treated with two full cycles of bortezomib-dexamethasone. He was referred to the Emergency department after presenting **melenic diarrhea for one week**. As a result, he was hospitalized and diagnosed with upper gastrointestinal bleeding, acute prerenal renal failure, mild thrombopenia, hypokalemia and hyponatremia. After fluid and electrolyte stabilization, it was decided to start with **fidaxomicin 200 mg/12h** due to fever, confusional syndrome, persistence of diarrhea and positive CD toxin test. The following constants were measured to confirm metabolic acidosis: gas level of bicarbonate (HCO_3^-), partial pressure of carbon dioxide (pCO_2), hydrogen ion potential (pH) and anion GAP. The degree of drug/adverse reaction causality was evaluated using the Naranjo algorithm.

RESULTS

Two blood gas tests on consecutive days, confirmed very low **HCO_3^-** (9 mmol/L) and **pCO_2** (16 mmHg) with normal **pH** (7,4), after which the patient was diagnosed with compensated **metabolic acidosis with normal GAP anion**. Finally, it was decided to suspend fidaxomicin and in the following days, the patient experienced a progressive clinical improvement. **Naranjo's algorithm established the causality relationship as 'probable'** (score of 6). The regional pharmacovigilance centre (RPC) was notified.

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CONCLUSION AND RELEVANCE

The European Medicines Agency technical sheet of fidaxomicin does not describe metabolic acidosis as an ADR. However, **UpToDate® Clinical Library reports <2% of cases of metabolic acidosis** in adults treated with fidaxomicin. The RPC reported this case as the only fidaxomicin ADR notified in our country.

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REFERENCES AND/OR ACKNOWLEDGEMENTS

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