ACTIVE PHARMACOVIGILANCE OF PATIROMER IN A CENTRAL HOSPITAL PHARMACEUTICAL CONSULTATION SETTING

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Background and Importance

Hyperkalaemia is an electrolyte disorder, common among patients with chronic kidney disease, diabetes mellitus, or heart failure (HF). Its occurrence is associated with an increase in mortality risk. Patiromer was recently approved by EMA for the treatment of hyperkalaemia in adult patients, and is under additional monitoring, allowing quick identification of possible new safety information.

Aim and objectives

To assess the adverse events of patiromer in HF patients with chronic hyperkalaemia in a Central Hospital.

Materials and methods

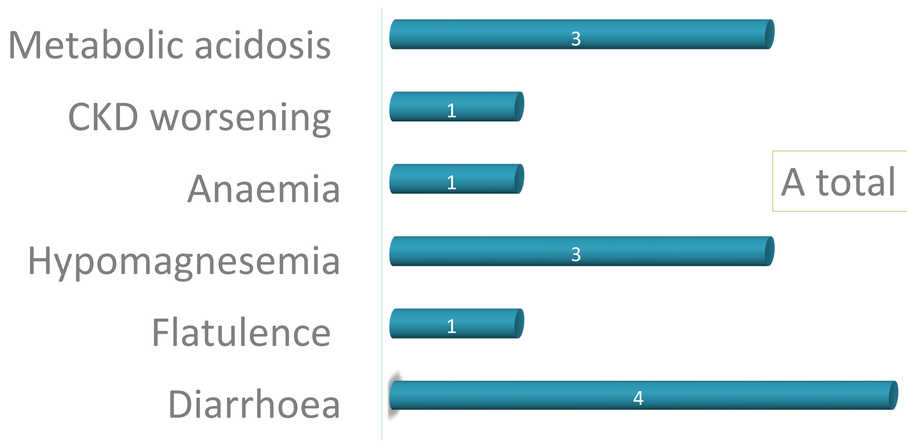
Prospective observational study that included HF patients treated with patiromer to optimize kalaemia and renin angiotensin aldosterone system inhibitor (RAASi) medication, followed in a pharmaceutical consultation between November 2020 and September 2021. A questionnaire evaluating the occurrence of adverse events was applied to all patients on days 1, 3, 7 and 30 after starting therapy and thereafter monthly, or whenever there was a clinical change considered relevant by the medical team. Out of all detected adverse events (AE), only the clinically significant ones were reported to our National Pharmacovigilance System (NPS).

Results

19 patients were included

15 males (78.9%) 4 females (21,0%)

69,1 ± 10,2 years



A total of 13 AE occurred in 11 patients

Regarding 4 of these AE, the causality has already been confirmed by the NPS, 2 metabolic acidosis were considered possible, 1 diarrhoea and 1 flatulence were considered probable.

Metabolic acidosis resulted in the hospitalization of 2 patients and a total of 7 patients discontinued patiromer after detection of AE.

Conclusion and relevance

As of June 2021, WHO has already received 10 reports of metabolic acidosis associated with patiromer, including the 2 reported in this study. Despite this AE being unexpected, these reports raise concerns and can lead to safety signal and new recommendations for patiromer's use. The preliminary results reported here prove that establishing pharmacovigilance networks is indispensable to assure safe healthcare in the real world, particularly for new drugs such as patiromer, prescribed to patients who are often comorbid.

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