

Pharmacovigilance in Hospice/Palliative Care: Rapid Report of Net Clinical Effect of Metoclopramide

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Abstract

Background: Understanding the performance of prescribed medications in day-to-day practice is important to minimize harm, maximize clinical benefits, and, eventually, better target the people who are most likely to benefit, especially in hospice/palliative care where there may be limited time to optimize prescribing. Metoclopramide, a benzamide prokinetic antiemetic, is widely used for a number of indications including nausea, vomiting, hiccups, and reflux. It has recently had a new “black box” warning issued by the Food and Drug Administration in relation to tardive dyskinesia to limit use to 12 weeks.

Methods: A consecutive cohort of patients from 12 participating centers in two countries who were having metoclopramide initiated had data collected at three time points—baseline, 2 days (clinical benefit), and day 7 (clinical harm). Additionally, harms could be recorded at any time.

Results: Of the 53 people included in the cohort, 23 (43%) reported benefit at 48 hours, but only 18 (34%) of these people were still using it one week after commencing it. For the other 5, the medication was ceased due to harms. The most frequent harms were akathisia (n = 4), headache (n = 4), and abdominal pain (n = 4). Nine people (17%) had no clinical benefit and experienced harms.

Conclusion: Overall, one in three people gained net clinical benefit at one week. Limiting effects include side effects that need to be sought actively in clinical care.

Strengths

An innovative approach to use easily collected data of standard common practice in multiple sites to assess the benefit and possible harm of a pharmacological approach that has a surprisingly limited evidence base.

Weaknesses

The skill of the clinician in using metoclopramide for the appropriate indication, and consideration of presence of an underlying mechanism likely to respond to this medication, are assumptions that may vary widely in a multisite study. There is no stringent assessment of benefit other than clinical impression.

Relevance

The lack of evidence for overwhelming benefit is a reminder for discipline in careful assessment of symptom severity, potential causes and well chosen treatment approaches followed by equally careful re-assessment of benefit and/or harm in continuing, modifying or discontinuing management.