PWE-064

EFFICACY OF PRUCALOPRIDE IN THE TREATMENT OF CHRONIC IDIOPATHIC CONSTIPATION: SYSTEMATIC REVIEW AND META-ANALYSIS

doi:10.1136/gut.2011.239301.327

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Introduction Chronic Idiopathic Constipation (CIC) is a functional disorder of the gastrointestinal tract. Patients often self-medicate with laxatives, but there are high levels of dissatisfaction with their efficacy. Prucalopride is a selective 5-hydroxytryptamine receptor agonist licensed for the treatment of CIC. As yet, there has been no quantitative summary of its efficacy in the condition. We conducted a systematic review and meta-analysis to examine this issue.

Methods Randomised control trials (RCTs) comparing prucalopride with placebo in the treatment of adults with CIC were identified from a literature search of MEDLINE, EMBASE and conference proceedings (up to September 2010). Trials had to use at least 1 week of therapy. CIC was defined using a physician's opinion, clinical symptoms, or the Rome criteria. Studies had to report dichotomous data assessing response or non-response to therapy. Data were extracted independently by two investigators, as intention-to-treat analyses, with drop-outs assumed to be treatment failures. Adverse events data were extracted, where reported. Data were pooled using a random effects model, and the efficacy of prucalopride in CIC was reported as a relative risk (RR) of failure to respond to therapy with 95% CI.

Results The search strategy identified 241 citations, of which 16 articles were retrieved for further evaluation. Seven RCTs, containing 2639 patients, satisfied inclusion criteria and yielded extractable data. Duration of therapy ranged from 4 to 12 weeks. Agreement between investigators for assessment of eligibility was good ($\kappa = 0.75$). Overall, 1288 (71.7%) of 1796 patients randomised to receive prucalopride failed to respond to therapy compared with 731 (86.7%) of 843 placebo patients (RR of failure to respond with prucalopride = 0.82; 95% CI 0.76 to 0.88). The number needed to treat with prucalopride was 6. Analyses according to dose of prucalopride used demonstrated similar efficacy for 2 mg (RR = 0.85; 95% CI.80 to 0.90) and 4 mg (RR = 0.83; 95% CI 0.77 to 0.90) once daily. Six trials reported total numbers of adverse events, which were commoner with prucalopride (RR = 1.14; 95% CI 1.05 to 1.24). Individual adverse events including headache (RR 1.70; 95% CI 1.25 to 2.31), nausea (RR = 1.98; 95% CI 1.39 to 2.82) and diarrhoea (RR = 2.72; 95% CI 1.80 to 4.13) were all commoner with prucalopride. There was no significant increase in serious adverse event rates detected with prucalopride (RR = 0.88; 95% CI 0.58 to 1.34).

Conclusion Prucalopride is superior to placebo for the treatment of CIC. The drug appeared safe, but adverse events were significantly commoner, particularly headache, nausea and diarrhoea, and patients should be warned of these potential side effects of treatment.

Competing interests None.

Keywords Constipation, Meta-analysis, Prucalopride.

Gut: first published as 10.1136/gut.2011.239301.327 on 13 March 2011. Downloaded from http://gut.bmj.com/ on April 18, 2024 by guest. Protected by copyright.