Cisapride was effective in the short term for constipation in children


QUESTION: In children with constipation, what is the effectiveness of cisapride (a prokinetic agent)?

Design
12 week randomised (allocation concealed†), blinded (clinicians, patients, outcome assessors, and statisticians)‡, * placebo controlled trial.

Setting
Gastroenterology clinic of a hospital in Mexico City, Mexico.

Patients
40 children who were 2–16 years of age, had a history of chronic constipation, and had < 3 bowel movements per week during a 2 week observation period before enrolment. Exclusion criteria were Hirschsprung disease, other congenital abnormalities of the gastrointestinal tract, or pelvic floor dyssynergia. Data were available for 36 patients (90%) (mean age 6 y, 67% boys).

Intervention
Patients were disimpacted and allocated to cisapride (n = 17) or placebo (n = 19) for 12 weeks. The medications were given as an oral suspension, 0.2 mg/kg of body weight per dose, 3 times daily; the dose was increased to 0.3 mg/kg if no response was seen at 8 weeks. Patients were asked to sit on the toilet for 5 minutes/day. Patients were to take Senokot if no bowel movement occurred after 48 hours of treatment; a daily enema was added to the treatment regimen if Senokot was unsuccessful.

Main outcome measure
Clinical response (>3 spontaneous bowel movements (SBMs)/wk with no fecal soiling and no use of other laxatives for >2 wks).

Main results
At 12 weeks, more patients who received cisapride met clinical response criteria than patients who received placebo (p < 0.03) (table). Patients who received cisapride had an increase from baseline in number of SBMs/week (from 0.9 to 4.1, p < 0.05), fewer fecal soiling episodes/day (from 1.8 to 0.08, p < 0.05), and fewer doses of laxatives/week (from 10.3 to 0.8, p < 0.05). Placebo group patients had a decrease in fecal soiling episodes/day (from 1.5 to 0.4, p < 0.05) and doses of laxatives (from 11.5 to 2.1, p < 0.05) but no increase in the number of SBMs/week. Mean time to response was 9.1 weeks in the cisapride group compared with 11 weeks in the placebo group (p < 0.04).

Conclusion
In children with constipation, cisapride increased the number of spontaneous bowel movements and reduced fecal soiling and the use of laxatives.

*See glossary.
†Information provided by author.
‡Clinical response = >3 spontaneous bowel movements/wk, no fecal soiling, and no use of other laxatives for >2 weeks. Abbreviations defined in glossary; RBI, NNT, and CI calculated from data in article.

Cisapride v placebo for children with constipation at 12 weeks

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Cisapride</th>
<th>Placebo</th>
<th>RBI (95% CI)</th>
<th>NNT (CI)</th>
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</thead>
<tbody>
<tr>
<td>Clinical response</td>
<td>76%</td>
<td>42%</td>
<td>82% (4 to 244)</td>
<td>3 (2 to 60)</td>
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\[NNT = \frac{1}{\text{absolute risk reduction}}\]

REFERENCE