primary studies - published RCT

Effects of cisapride in patients with cystic fibrosis and distal intestinal obstruction syndrome.

Code: PM2231217 **Year:** 1990 **Date:** 1990 **Author:** Koletzko S

Study design (if review, criteria of inclusion for studies)

double-blind, placebo-controlled, crossover trial

Participants

17 patients (12.9 to 34.9 years; 12 boys) with cystic fibrosis and chronic recurrent distal intestinal obstruction syndrome (DIOS).

Interventions

After a baseline period, patients received, in random order, cisapride (7.5 to 10 mg) and placebo three times daily by mouth, each for 6 months.

Outcome measures

Gastrointestinal symptoms (flatulence, abdominal pain, fullness, abdominal distension, nausea, anorexia, heartburn, diarrhea, vomiting and regurgitation) were scored three times monthly and physical examinations assessed. At baseline and at each 6-month period, assessment included food intake for 7 days, 3-day stool collection, pulmonary function tests, and abdominal radiographs.

Main results

During cisapride therapy compared with placebo, there were significant reductions in flatulence (p less than 0.005), fullness, and nausea (p less than 0.05). Patients with the worst symptom scores benefited most from cisapride. With cisapride, 12 patients felt better and three worse (p less than 0.05); physicians judged 11 patients improved and two worse (p less than 0.05). No side effects were noted. There were no significant differences between cisapride and placebo periods in nutritional status, x-ray scores, pulmonary function, food intake (fat, protein, calories), stool size and consistency, and fecal losses of fat, bile acids, chymotrypsin, and calories. For acute episodes of DIOS, intestinal lavage was needed 6 times in 4 patients during treatment with cisapride, and 11 times in 6 patients receiving placebo. In comparison with unselected patients with cystic fibrosis and pancreatic insufficiency who were receiving enzyme supplements and who had no distal intestinal obstruction, fecal fat losses (percentage of intake) were almost twice as high in the study group with DIOS (31.2 +/- 20.6% vs 16.2 +/- 17.6%; p less than 0.01).

Authors' conclusions

in the dosage used, long-term treatment with cisapride appears to improve chronic abdominal symptoms in patients with cystic fibrosis and DIOS, but fails to abolish the need for intestinal lavage. Cisapride treatment had no effect on digestion and nutritional status of cystic fibrosis patients with pancreatic insufficiency.

http://dx.doi.org/10.1016/S0022-3476(05)83350-5

See also

J Pediatr. 1990 Nov;117(5):815-22.

Keywords

Adolescent; Adult; Cisapride; Gastrointestinal Agents; Gastrointestinal Diseases; Intestinal Obstruction; pharmacological_intervention; Piperidines;