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Symptomatic efficacy of beidellitic montmorillonite in irritable bowel syndrome: a randomized, controlled trial.

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Abstract

BACKGROUND: Beidellitic montmorillonite is a purified clay containing a double aluminium and magnesium silicate.

AIM: To assess the efficacy and the safety of beidellitic montmorillonite (3 g, t.d. for 8 weeks) in patients with irritable bowel syndrome (IBS).

METHODS: A multicentre, double-blind, placebo-controlled, randomized study with parallel groups, was performed in IBS patients selected according to ROME I criteria. Patients were included after a 1-week washout period to confirm that abdominal pain and/or discomfort was rated at least 2 on a 0-4 graded Likert scale. Patients were then randomized and stratified according to their predominant bowel habit profile into three groups. The use of rescue medication was allowed: polyethylene glycol 4000 (10-20 g/day) as a laxative agent in case of stool absence for three consecutive days, phloroglucinol (80 to a maximum of 320 mg/day) as a spasmolytic agent for no more than 8 days. The main end-point was the improvement of abdominal pain and/or discomfort by at least 1 point on the Likert scale.

RESULTS: A total of 524 patients constituted the overall intent-to-treat population (ITT), 263 were assessed in the beidellitic montmorillonite group, i.e. 93 diarrhoea-predominant IBS (D-IBS), 83 constipation-predominant IBS (C-IBS), 87 alternating constipation/diarrhoea-IBS (A-IBS); 261 in the placebo group, i.e. 81 D-IBS, 92 C-IBS and 88 A-IBS. Initial analysis in the ITT population demonstrated a higher rate of success with beidellitic montmorillonite (51.7%) when compared with the placebo group (45.2%); however, the difference was not statistically significant. Improvement was significant in C-IBS both in ITT (beidellitic montmorillonite group = 49.4%, placebo group = 31.5%, $P < 0.016$) and per protocol populations (59.4% vs. 37.8%) ($P < 0.01$). The time to improvement of abdominal pain and/or discomfort (log Rank test) was also significantly in favour of beidellitic montmorillonite, ($P < 0.04$). The average number of stools per day was not different from baseline, either in all patients or in C-IBS patients. Spasmolytic and

laxative agent intakes were not different between the two groups. Subjective evaluation by patients of treatment efficacy and visual analogue scale test of treatment efficacy by investigators were significantly better in the beidellitic montmorillonite group ($P < 0.05$). Tolerance of beidellitic montmorillonite was considered optimal without any significant adverse event.

CONCLUSIONS: Although pain or discomfort was not significantly improved in the entire IBS population treated with beidellitic montmorillonite in comparison with placebo, this study demonstrates that beidellitic montmorillonite is efficient for C-IBS patients ($P < 0.016$). This effect of beidellitic montmorillonite on pain cannot be explained by changes in bowel habits. The efficacy of this well-tolerated therapy warrants further confirmatory therapeutic trials in C-IBS patients.

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