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Research interests

- Functional gastrointestinal disorders
- Irritable bowel syndrome
- Hypnosis

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Benefits associated with supplementation with an encapsulated probiotic preparation in subjects with irritable bowel syndrome

Background: We have previously demonstrated benefits in irritable bowel syndrome (IBS) with a milk-based probiotic preparation of a novel probiotic strain, *Bifidobacterium infantis* 35624.

Aim: To evaluate benefits in IBS with an encapsulated preparation of the same probiotic strain.

Methods: After a 2 week run-in phase, 291 female subjects with Rome II-positive IBS were randomized to placebo (n=73), or one of three doses of *B. infantis* 35624: 10⁶ (n=74), 10⁷ (n=74), or 10⁸ (n=70) CFU/capsule, given once daily for 4 weeks. IBS symptoms were monitored daily, by telephone, using an interactive voice response system (IVRS) and scored according to a 6-point Likert scale; stool frequency and form (using the Bristol Stool Scale) were also monitored daily. The primary efficacy variable was the abdominal pain score; secondary efficacy variables included other IBS symptoms, a composite symptom score, subject's global assessment (SGA) of IBS symptom relief and quality of life. In all IBS symptom efficacy analyses, "centers" and "subjects within centers" were treated as random factors. All results were adjusted by baseline so dosage comparisons (placebo vs. 10⁶ vs. 10⁷ vs. 10⁸) were based on Least-square Means.

Results: For the primary efficacy variable, abdominal pain/discomfort (-0.58 ± 0.10 vs. -0.41 ± 0.10 vs. -0.89 ± 0.10 vs. -0.46 ± 0.10) as well as for all secondary variables of composite score (-1.16 ± 0.26 vs. -1.11 ± 0.26 vs. -2.13 ± 0.26 vs. -1.07 ± 0.26), bloating/distension (-0.41 ± 0.10 vs. -0.37 ± 0.10 vs. -0.71 ± 0.10 vs. -0.39 ± 0.10), incomplete evacuation (-0.22 ± 0.10 vs. -0.26 ± 0.10 vs. -0.52 ± 0.10 vs. -0.21 ± 0.10), passage of gas (-0.26 ± 0.09 vs. -0.21 ± 0.09 vs. -0.51 ± 0.09 vs. -0.27 ± 0.09) and SGA for symptom relief (-0.20 ± 0.26 vs. -0.20 ± 0.25 vs. 0.74 ± 0.27 vs. -0.74 ± 0.28), bifidobacterium in a dose of 10⁸ was significantly superior (P-value < 0.05) to placebo and all other bifidobacterium doses. The efficacy variable SGA for symptom relief was analyzed using a logistic model so its associated results are given on the logit scale. The corresponding success rates are 45% vs. 45% vs. 68% vs. 32%. No significant adverse events were recorded.

Conclusion: *B. infantis* 35624, in a dose of 10⁸ bacteria/day is effective in relieving all of the cardinal symptoms of irritable bowel syndrome. This study confirms benefits observed in previous studies, at a lower daily dose of probiotic in a capsule form, while demonstrating the complexity of achieving stable probiotic formulations.