

Ringel Y, Palsson OS, Leyer G, Causey S, Yeskel SE, Faber SM and T Ringel-Kulka. 2008. Probiotic bacteria *Lactobacillus acidophilus* NCFM<sup>®</sup> and *Bifidobacterium lactis* Bi-07 improve symptoms of bloating patients with functional bowel disorders (FBD). *Gastroenterology* 134(4 Suppl. 1): A549.

### Abstract

FBD are the most common gastrointestinal disorders seen in primary care and GI clinics; however, the etiology still remains unknown. Evidence suggests that intestinal bacteria play a role in the pathophysiology and symptomatology of these disorders and that modulation of intestinal microflora by antibiotics or probiotics may be beneficial in the treatment of patients with these disorders.

**Purpose:** To investigate the effect of probiotic bacteria *Lactobacillus acidophilus* NCFM<sup>®</sup> (L-NCFM<sup>®</sup>) and *Bifidobacterium lactis* Bi-07 (B-LBi07) in patients with non-constipation IBS, functional diarrhea, or functional bloating.

**Methods:** Patients with FBD who met the Rome II criteria of non-constipation-IBS, or functional diarrhea, or functional bloating were enrolled in a prospective double-blind, placebo-control clinical trial. Patients were randomized into a placebo arm and an active arm of oral probiotic bacteria containing equivalent amounts of L-NCFM<sup>®</sup> and B-LBi07,  $1 \times 10^{11}$  cfu total probiotic bacteria in each dose. The placebo and probiotic products were administered bid in a capsule form over 8-weeks. Patients were evaluated for the following endpoints: global relief of GI symptoms (GSA), specific functional GI symptoms, overall symptoms severity (IBS-Severity Index), satisfaction with treatment, overall well-being, and Health Related Quality of Life (IBSQOL).

**Results:** A total of 57 (probiotic n=30; placebo n=27) patients were enrolled. Study population consisted of 72% females, 84% whites, and mean age of 37 years. Baseline demographics were similar among the two groups. Bloating and distention scores (measured on a 10 points scale) improved significantly in the probiotics group compared to the placebo group at 4 weeks ( $4.10 \pm 3$  vs.  $6.17 \pm 3$ ,  $p=0.009$  respectively) and showed a strong trend of improvement at 8 weeks ( $4.26 \pm 3$  vs.  $5.84 \pm 3$ ,  $p=0.06$  respectively). Secondary analyses using only the IBS subgroup (n= 33) showed similar results with significant improvement in bloating and distention in the probiotics group (n=17) compared to the placebo (n=15) group ( $4.24 \pm 3$  vs.  $6.73 \pm 3$ ,  $p=0.03$  respectively).

**Conclusions:** Supplement of diet with L-NCFM<sup>®</sup> and B-LBi07 BID ( $2 \times 10^{11}$  cfu total probiotic bacteria per day) significantly improved symptoms of bloating and distention in patients with FBD. This data support the role of intestinal bacteria in the pathophysiology of FBD and suggest a potential important role for these probiotic bacteria in the management of patients with these disorders.