Assessment of a multi strain probiotic (Symprove) in IBD

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Background: With the knowledge that the intestinal microbiome may play a significant role in the pathogenesis of Inflammatory Bowel Disease (IBD) there is renewed interest in the possible treatment with probiotics. There are numerous open labeled studies and a few randomised controlled trials that show a significant symptomatic effect of probiotics in patients with active ulcerative colitis (UC) while the effects in Crohn’s disease (CD) seem to be lacking. It is not clear however whether the probiotics reduce intestinal inflammation.

Aim: A randomized, double-blinded, placebo controlled trial was undertaken to assess if the probiotic Symprove (a multistrain water based probiotic containing L. rhamnosus, E. faecium, L. acidophilus, and L. plantarum) taken for 1 month altered the quality of life in patients with UC and CD (primary outcome) in clinical remission with only mild symptoms or reduced intestinal inflammation (secondary outcome) as assessed by a faecal calprotectin test.

Methods: Eighty patients with UC and 80 with CD were planned. The study was stopped with 63 patients with CD because of slow recruitment. Patients included were aged 18-64, who were in clinical remission (mild to moderate disease activity, insufficiently severe as to escalate treatment). Patients with acute clinical relapse of disease, serious co-existing diseases or treatment with steroids or biologicals were excluded. IBDQ quality of life and faecal calprotectin were assessed before and after being randomized (2 stage computer randomisation utilising the Mersenne Algorithm) to receive the probiotic or a matching placebo (1 ml/kg body weight daily for one month).

Results: Primary outcome: There were no significant changes in IBDQ scores in any of the groups during the study. Secondary outcome: The median faecal calprotectin levels in UC treated with probiotic fell significantly (p < 0.01) (median 600 mg/kg (range 18.0-4800 mg/kg) to 343 mg/kg (range 10-2896 mg/kg) but not (p = 0.81) in the placebo treated patients (median 275 mg/kg (range 10-2024 mg/kg) v. 153 mg/kg (range 10-5000 mg/kg) pre and post, respectively. There were no significant differences (p = 0.35) between pre and post calprotectin levels in patients with CD treated with probiotic (median 425 mg/kg (range 41-4800 mg/kg) v. 355 mg/kg (range 20-2896 mg/kg)) or placebo (194 mg/kg (range 58-1128 mg/kg) v. 339 mg/kg (range 26-4800 mg/kg), p = 0.07). The differences in calprotectin levels between the active and placebo treated CD patients was not significant (p > 0.05).

Discussion: One months course of the probiotic Symprove had no significant effect on QOL assessments in patients with relatively quiescent UC or CD. However, intestinal inflammation was significantly reduced, as assessed by faecal calprotectin, in patients with UC, but not in CD.