THE EFFECT OF ADJUVANT SYNBIOTIC COMBINATION ON INDUCTION OF REMISSION IN PATIENTS WITH MILD-MODERATE ULCERATIVE COLITIS

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AIMS / BACKGROUND

Ulcerative colitis is a chronic inflammatory disorder of the colon that, along with Crohn's disease, comprises the group of disorders known as inflammatory bowel disease (IBD). Although the pathophysiology of IBD remains incompletely understood, it is currently thought to involve a complex interplay between genetic predisposition of the host and aberrant intestinal microbial homeostasis resulting in inflammation (Nature 2010; 464:577). Current therapies for ulcerative colitis, include topical anti-inflammatory agents such as mesalamine, the systemic “immunomodulators,” such as azathioprine and 6-mercaptopurine, and the “biologic therapy” infliximab. All of these therapies are known not only for their potential efficacy, but for a wide range of side effects as well.

As our understanding of IBD has progressed, there has been a growing interest in modifying not only the inflammatory response, but the gut microbiota as well. It has long been posited that modifications of the composition and structure of bacterial populations in the gut may play a significant role in human disease and enteric infection (Clin Microbiol Rev 1990;3:335–344). As such, there have been many attempts to identify the potential beneficial effects of probiotics supplementation for various indications. Probiotic supplements have potential benefit in pouchitis, irritable bowel syndrome, traveler’s diarrhea, acute gastroenteritis, antibiotic-associated diarrhea, Clostridium difficile-associated diarrhea, and radiation-induced diarrhea. There have been several studies assessing the efficacy of various probiotics in the treatment of ulcerative colitis. Several early studies assessed the efficacy of Escherichia coli Nissle 1917 for maintenance of remission compared with mesalamine via double-blinded, randomized, controlled trials and found them to have equivalent efficacy (Aliment Pharmacol Ther 1997;11:853–858; Lancet 1999;354:635–639). There have also been several randomized, controlled trials of Bifidobacteria, with mixed results (Aliment Pharmacol Ther 2004;20:1133–1141; Gut 2005;54:242–249). Lactobacillus GG has also been assessed in comparison to mesalamine in prevention of relapse, without significant difference between groups (Aliment Pharmacol Ther 2006;23:1567–1574). VSL#3, a combination of 4 strains of Lactobacilli, 3 strains of Bifidobacteria, and 1 strain of Streptococcus thermophilus, has also been evaluated in several small studies, demonstrating the ability to induce remission (Am J Gastroenterol 2005;100:1539–1546) in a noncontrolled study, and superiority when used in combination with balsalazide compared with balsalazide or mesalamine alone (Med Sci Moni 2004;10:PI126–131). Aims of our study were to assess the efficacy of Probiotic Gold NBL® (Lactobacillus acidophilus, Lactobacillus rhamnosus, Bifidobacterium bifidum, Enterococcus faecium, Bifidobacterium longum, fructooligosaccharide, lactulose) on clinical response in patients with active UC.

METHODS

This was an open-label cross-sectional study. Twenty-two patients (mean age 42±13 (17–67), M/F: 13/9) were enrolled. These patients had clinical and endoscopy score 4 and above levels. All patients received mesalazine 4 grams/day plus Probiotic Gold NBL® one sachet per day. Laboratory and clinical data were collected from each visit. After 8 weeks of treatment, patients were re-assessed for clinical and disease activity. We have compared these data with a historical cohort of 16 UC patients.

RESULTS

Among 22 patients, 2 patients did not have endoscopy control, and the remaining 20 patients were reassessed after 8 weeks.

Two patients had flare-up under probiotic plus mesalazin treatment in the first week and these patients were switched to steroid treatment.

Intention-to-treat analysis (ITT) showed that,

Complete remission was achieved in 81.1% (18/22) vs 62.5% (10/16) (p<0.01) in study and control groups, respectively.

Partial remission was achieved in 9% (2/22) vs 3.12% (5/16) (p<0.01) and Non-response was seen in 9% (2/22) vs 6.25% (1/16) (NS) in study and control groups, respectively.

The mean decrease in the clinical activity score was 5.89±1.22 vs 4.35±1.56 (p=0.044), respectively.

CONCLUSION

Our study demonstrated that Probiotic Gold NBL® is effective in achieving clinical responses and remissions in patients with mild-to moderately active UC, further supporting the potential role in UC therapy.