

## Probiotic Receives Boon From ACG for the Treatment of Ulcerative Colitis

by David Wild

Two recent developments stand to increase recognition of the probiotic VSL#3 (Sigma-Tau Pharmaceuticals, Inc., Pomezia, Italy). The product is now included in the American College of Gastroenterology (ACG) updated practice guidelines for ulcerative colitis (UC) in adults (Kornbluth A et al. Am J Gastroenterol 2004;99:1371-1385). Additionally, results from an Italian open-label, randomized study suggest that the combination of VSL#3 and low-dose balsalazide (Colazal, Salix) is more effective than balsalazide alone or mesalamine in inducing remission in patients with mild to moderate UC (Tursi A et al. Med Sci Monit 2004;10:PI126-PI131. Epub 2004;Oct 26).

"We're just beginning to understand the complexity and mechanisms of these probiotics," commented Steven Faber, MD, a gastroenterologist at Albemarle Gastroenterology Associates, Elizabeth City, N.C., and a long-time supporter of the use of probiotics for gastrointestinal diseases. "Through the use of antibiotics, stress and poor eating habits, the gut flora is often negatively altered and beneficial bacteria are eliminated. It's important that clinicians realize that reestablishing an optimal intestinal environment is critical." (Dr. Faber is a member of the Medical Advisory Board of Gastroenterology & Endoscopy News.)

In its recent recommendations for the management of adult UC, the ACG practice guidelines encourage the use of VSL#3: "An oral probiotic formulation, VSL#3 (containing lactobacilli, bifidobacteria, and Streptococcus salivarius), was effective in the prevention of pouchitis for up to 1 year following surgery, and in the prevention of pouchitis relapse."

Furthermore, Italian researchers have found that VSL#3 is helpful in inducing remission in UC patients who are mildly to moderately ill, although it is not recommended in the ACG practice guidelines for this indication. Primary investigator Antonio Tursi, MD, of the Digestive Endoscopy Unit, Lorenzo Bonomo Hospital, Andria, Italy, and his colleagues randomly assigned their patients with UC to receive balsalazide 2.25 g daily plus VSL#3 3 g (n=28), balsalazide 4.5 g alone (n=26), or mesalamine 2.4 g daily (n=22). The investigators recorded the patients' symptoms at the study outset and at two, four and eight weeks after

the initiation of treatment. Patients recorded in a journal the number of bowel movements they had per day in addition to any rectal bleeding they observed.

Dr. Tursi and his team found that at eight weeks, 86% (24/28) of subjects receiving balsalazide with VSL#3 experienced clinical remission, compared with 81% (21/26) of patients treated with balsalazide alone and 73% (16/22) of patients treated with mesalamine ( $P < 0.02$  for balsalazide plus VSL#3 vs. mesalamine). Subjects receiving balsalazide with VSL#3 also achieved remission earlier: Patients receiving the combination treatment achieved remission at an average of four days following the start of treatment, compared with 7.5 days for the patients receiving balsalazide alone and 13 days for the patients receiving mesalamine ( $P < 0.01$ ). Furthermore, at eight weeks, the patients receiving balsalazide with VSL#3 scored significantly better on a measure of well-being and had significantly fewer daily bowel movements on average than did the patients in the other two treatment groups ( $P < 0.05$ ).

The study authors noted that prior research has found that balsalazide alone is more effective than mesalamine, but at a dosage of 6.75 g daily. Lower doses---such as the 2.25-g dose administered with VSL#3 in this study---were found in previous studies to be less effective in inducing and maintaining UC remission.

"The results of the study show that adding VSL to balsalazide is better than a double dose of the same 5-ASA [5-aminosalicylic acid]," the authors concluded. "This can potentially mean more effect with less side effects for the patient."

Based on articles by Kornbluth A et al (Am J Gastroenterol 2004;99:1371-1385) and Tursi A et al (Med Sci Monit 2004;10:PI126-PI131. Epub 2004;Oct 26).

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