

Once-Daily Probiotic Treatment Maintains Remission in Pouchitis

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Medscape Medical News 2004. © 2004 Medscape

Jan. 7, 2004 — Once-daily high-dose probiotic therapy (VSL#3) sustains antibiotic-introduced remission in ulcerative colitis patients with pouchitis, according to a randomized, double-blind study published in the January issue of *Gut*.

"In parallel with clinical, endoscopic, and histological remission, a high level of QOL [quality of life] was maintained with this therapy," Toshiki Mimura, MD, and colleagues from St. Mark's Hospital in London, U.K., report.

Investigators drew 36 patients with recurrent (occurrence at least twice in the previous year) or refractory (requiring continuous use of antibiotics) pouchitis from St. Mark's Hospital and a center in Bologna, Italy.

All patients had a Pouchitis Disease Activity Index (PDAI) score of 7 or higher, with zero being no inflammation and 18 being the worst. Researchers induced remission in all patients with a four-week course of the antibiotics metronidazole (400 mg or 500 mg twice daily) and ciprofloxacin (500 mg twice daily).

Twenty patients were randomized to receive placebo, while 16 patients received 6g VSL#3 (3-g sachets containing 300 billion bacteria/g, made up of four strains of lactobacilli, three strains of bifidobacteria, and one strain of *Streptococcus salivarius* subsp *thermophilus*) once daily for one year or until relapse.

The researchers conducted physical examination prior to randomization and every two months for 12 months, or until relapse, which was defined as an increase in clinical PDAI score of 2 or higher together with an increase in the endoscopic PDAI score of 3 or higher compared with baseline. Researchers performed endoscopic and histological evaluations before randomization, at two months, and at 12 months.

The primary end point was a cumulative maintained remission rate at 12 months. Health-related QOL, a secondary outcome, was assessed at study entry, every two months, and at the time of relapse using the inflammatory bowel disease questionnaire (IBDQ).

Researchers evaluated the other secondary outcome, patient satisfaction with the treatment at study entry, every two months and at the time of relapse. Subjects chose their answer from the following options: (1) very dissatisfied, unhappy most of the time; (2) generally dissatisfied, unhappy; (3) neither dissatisfied nor satisfied; (4) generally satisfied, pleased; (5) very satisfied, happy most of the time.

Researchers confirmed the presence of viable probiotic bacteria in the stool of patients in the active group via stool analysis of a subgroup of 12 patients receiving active treatment or placebo at the beginning of treatment and after 60 days.

The median compliance rate was 96% in the VSL#3 group and 97% in the placebo group.

Seventeen patients (85%) in the VSL#3 group maintained remission at one year, while in the placebo group; one patient (6%) maintained remission ($P < .0001$). Two patients in the VSL#3 group relapsed at month two and month eight while one patient dropped out due to acute gastroenteritis-like symptoms.

The IBDQ score remained high in the VSL#3 group ($P = .30$) but deteriorated in the placebo group ($P = .0005$) over the year.

In terms of patient satisfaction, the investigators did not find a significant difference at entry between the two groups (median, 4 vs. 4 points; $P = .26$) but they differed significantly at the time of relapse or 12 months (4 points in the VSL#3 group vs. 2 points in the placebo group; $P < .0001$).

"This study has demonstrated that in patients with recurrent or refractory pouchitis who have achieved remission with intense antibiotic treatment, the probiotic therapy VSL#3 is highly effective in maintaining remission," write Dr. Mimura and colleagues.

This study was partially supported by VSL Pharmaceuticals, Inc.

Gut. 2004;53:108-114

Reviewed by Gary D. Vogin, MD