Biofeedback Relieves Dyssynergia Long Term

One-year results look promising for patients with the most common cause of chronic constipation.

BY BRUCE JANCIN
Denver Bureau

HONOLULU — Biofeedback proved superior to standard therapy for long-term management of patients with the most common cause of chronic constipation in the first-ever randomized trial featuring a full year of follow-up.

Previous short-term randomized trials have demonstrated that biofeedback is effective in patients with dyssynergic defecation. But this form of constipation is a long-term problem—and although uncontrolled studies have suggested good long-term maintenance of efficacy with biofeedback, it was important to establish in a more rigorous randomized trial setting whether this nonpharmacologic therapy maintains its effectiveness over time.

The answer—at least through 1 year of formal follow-up—is clearly yes, Satish S.C. Rao, M.D., said at the annual meeting of the American College of Gastroenterology.

The clinical relevance of this finding lies in the fact that recent surveys indicate that up to 50% of patients with chronic constipation are dissatisfied with their current treatment.

This dissatisfaction is largely because conventional therapies focus primarily on reducing stool hardness rather than addressing the underlying physiologic dysfunction. In the setting of dyssynergic defecation, which accounts for roughly half of all cases of chronic constipation, the pathophysiology involves a lack of coordination between the pelvic floor muscles and anal sphincter, explained Dr. Rao, a gastroenterologist at the University of Iowa, Iowa City.

He reported on 52 patients, 47 of whom were women, who were randomized to a 3-month biofeedback program or standard therapy. All met strict manometric diagnostic criteria for dyssynergic defecation. Patients with the other two common types of chronic constipation—irritable bowel syndrome and slow-transit constipation—were excluded.

The biofeedback program entailed biweekly hour-long treatment sessions in which participants learned techniques aimed at increasing their pushing effort through improved anorectal coordination and sensory conditioning. They also practiced expelling a simulated stool made of silicone.

The standard-therapy control arm involved three monthly visits with a gastroenterologist, dietician, and nurse for instruction in dietary modification, exercise, toilet habits, and appropriate use of laxatives. "That's a lot more than the usual standard therapy in clinical practice," Dr. Rao noted.

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DR. RAO

Of the 52 patients, 44 completed the 3-month active treatment phase. Since no single end point adequately defines the outcome of constipation therapy, follow-up with a variety of objective and subjective measures of improvement was conducted at 3, 6, and 12 months. The 1-year intent-to-treat analysis involved 13 patients from each arm.

Only 1 of 13 patients in the biofeedback arm still met diagnostic criteria for dyssynergia at 1 year, in contrast to all 13 in the control group. Mean balloon expulsion time fell from a baseline of 143 seconds in the biofeedback group to 13 seconds at 3 months and 18 seconds at 1 year, compared with 87 seconds at 1 year in controls.

The number of complete, spontaneous bowel movements per week increased significantly in the biofeedback group, as did objective measures of anorectal and colonic function and patient satisfaction with bowel function; none of these end points improved over the course of a year in the controls.

In response to audience questions, Dr. Rao said that it has been his clinical experience outside the randomized trial setting that at least two-thirds of patients who have undergone a course of biofeedback for dyssynergic defecation maintain the benefits in multiyear follow-up, while the effects wane beyond 1 year in about one-third, who benefit from a refresher.

Dr. Rao's study, for which he received the 2005 ACG Auxiliary Award, was funded by the National Institutes of Health. ■

Lubiprostone's Novel Mechanism Effective for Chronic Constipation

BY BRUCE JANCIN
Denver Bureau

HONOLULU — Lubiprostone, an investigational drug with a novel mechanism of action, performed well for the treatment of chronic constipation in a pivotal phase III clinical trial, John F. Johanson, M.D., reported at the annual meeting of the American College of Gastroenterology.

Lubiprostone is a functional fatty acid that selectively activates the GI type-2 chloride channels. Lubiprostone enhances intestinal fluid secretion without altering serum electrolyte levels, explained Dr. Johanson, a gastroenterologist in private practice in Rockford, Ill.

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DR. JOHANSON

He reported on 237 patients with a history of chronic idiopathic constipation of at least 6 months duration who participated in a double-blind multicenter trial in which they were randomized to 4 weeks of lubiprostone at 24 mcg b.i.d. or placebo taken with food and water. Overall, 90% of the patients were women, and two-thirds were below age 50 years.

Lubiprostone acted fast: 61% of treated patients experienced a spontaneous bowel movement within 24 hours after their first dose, compared with 31% of controls. Within 48 hours, 79% of patients on lubiprostone and 66% on placebo had experienced a spontaneous bowel movement without rescue medication. After 1 week, 72% of patients in the lubiprostone group were categorized as full responders, meaning they had four or more spontaneous bowel movements per week, compared with 49% in the placebo group, a difference that held up through the remainder of the trial.

Mild nausea was the most frequent adverse event associated with lubiprostone; it was reported by 21% of patients, compared with 4% on placebo. Adverse events led 15 patients in the lubiprostone arm and 1 on placebo to drop out of the study. Six patients discontinued lubiprostone because of nausea, four due to dyspnea, and three because of abdominal pain.

Dr. Johanson also presented the results of a 24-week multicenter open-label study involving 306 lubiprostone-treated patients. Only 54% completed the full 24 weeks. By then, 20% had quit due to adverse events, of which nausea, followed by headache, was the most common, and 16% had dropped out due to lack of efficacy.

Patient self-assessed constipation severity on a 0-4 scale averaged 3.05—categorized as severe—at baseline and improved steadily by a mean of 1.19 points at week 4 and by 1.83 points at week 18. Significant improvements in self-rated abdominal bloating and discomfort were also noted.

Dr. Johanson, who serves as a consultant to Sucampo Pharmaceuticals, told FAMILY PRACTICE NEWS that the company expects to receive a decision from the Food and Drug Administration this winter on its application to market lubiprostone.

In animal studies, lubiprostone has been shown to stimulate the recovery of ischemic colonic and ileal mucosa.

Phase III clinical trials of lubiprostone for the treatment of patients with irritable bowel syndrome are ongoing. ■

Anal Incontinence Prevalence Rates Found Higher for Genders Than Once Believed

BY KATE JOHNSON
Montreal Bureau

MONTREAL — Anal incontinence is four times more prevalent than previously thought, and it affects older men and women almost equally, according to what British researchers describe as the first systematic review of the prevalence of this disorder.

"Age, not gender, is the most important factor, and obstetric trauma does not have a major effect," Philip Toozs-Hobson, M.D., reported at the annual meeting of the International Continence Society.

The review of 29 studies with a total of 69,152 participants found an overall rate of anal incontinence of 3.5% in men and 4.5% in women across all age groups.

Such findings suggest "that the 1% rate presumed by government agencies is an underestimate," said Dr. Toozs-Hobson, a consultant gynecologist at Birmingham (England) Women's Hospital.

Moreover, the effects of obstetric trauma could not be seen in these data, he said.

"It has long been thought that the incidence of anal incontinence is higher in women because trauma occurs to the anal sphincter during childbirth," he said.

"However, this study does not provide evidence that women under 60 years have significantly higher rates of incontinence, when compared with men of similar age."

When data were broken down according to age, the prevalences for men and women under age 60 years were 0.8% and 1.6%, respectively.

While the rates were much higher in people over age 60 years—they remained similar across the genders, at 5.1% for men and 6.2% for women, he said.

"Many experts believe that the effects of obstetric trauma may only appear in older age, but we did not find significant interaction between age and gender," he said.

Since anal incontinence is increasingly becoming recognized as a significant cause of physical and psychological morbidity, these data have implications for community health care providers, Dr. Toozs-Hobson noted at the meeting. ■