Study Design May Miss Hypnotherapy's Benefits

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EXETER, ENGLAND — The benefits of complementary therapies such as hypnotherapy are likely to be underestimated when they are evaluated using conventional clinical trial designs and outcome measures, according to Lesley M. Roberts, M.D., of the department of primary care, University of Birmingham (England).

Gut-directed hypnotherapy has proved effective in more than a dozen studies in the past 20 years. But a clinical trial in which 81 patients with irritable bowel syndrome (IBS) were randomized to hypnotherapy or usual care by a primary care physician found little difference between the approaches.

Was this a case of "right intervention, wrong outcome?" Dr. Roberts asked at a symposium on alternative and complementary therapies sponsored by the universities of Exeter and Plymouth.

"My background is in conventional medicine, so we chose conventional tools for the study—symptom scores and [an] IBS quality of life tool," she said. Such disease-specific tools are allegedly more sensitive than generic tools for evaluating conventional therapies.

Patients in the study had gastroenterologist-confirmed IBS of 6 weeks' duration or longer and had failed at least one conventional treatment. They were evaluated at baseline and at 3, 6, and 12 months.

Both groups improved over the course of the trial. Symptom scores, pain, and diarrhea were significantly superior in the hypnotherapy group at 3 months, but the difference was not maintained over time. There were no between-group differences at any time point for constipation or quality of life.

"However, when we asked patients in the hypnotherapy group about their experiences, 81% reported definite improvement, 55% reported improvement greater than they had anticipated, and 91% would recommend gut-directed hypnotherapy to their friends," Dr. Roberts said.

"So the question we had to ask was, did our study miss some important benefits? Patients were saying they felt better. The treatment was very helpful for mental well being, and it gave them control—all generic quality of life concerns. Yet we didn't pick up any quality of life benefit using the IBS-specific quality of life tool," she said.

Perhaps complementary and alternative medicine research should reconsider its emphasis on the use of conventional methodology in clinical studies and should instead use more generic outcome measures such as the subjective assessment questionnaire used in the Manchester protocol, she said. "I think the benefit of hypnotherapy is that patients are better able to cope, not that they necessarily have fewer symptoms. They feel empowered," Dr. Roberts said. ■

Agenda for Liver and Biliary Disease Research Set Until 2015

The focus of liver and biliary disease research in the United States through 2015 has been set with the release of the National Institutes of Health's Action Plan for Liver Disease Research.

The decade-long initiative is the result of coordinated effort between federal health agencies and the 18 institutes, centers, and offices in the NIH that support liver and biliary disease research. It is geared toward the rapid translation of findings from basic research to clinical practice, and vice versa.The plan includes 214 research goals, but 10 major goals cut across multiple disciplines in liver and biliary disease research:

▶ Improve the success rate of therapy for chronic hepatitis C.

▶ Develop effective antiviral therapy regimens for the long-term management of chronic hepatitis B.

▶ Develop effective therapies for the treatment of both nonalcoholic and alcoholic fatty liver disease.

▶ Detect hepatic fibrosis with sensitive, specific, and noninvasive tests.

▶ Detect hepatocellular carcinoma at earlier stages in high-risk patients with new screening tests.

▶ Develop ways to prevent gallstones.

▶ Elucidate the etiology of biliary atresia.

▶ Improve the safety, and determine the best use, of living donor liver transplantation.

▶ Develop standardized and objective diagnostic criteria of major liver diseases and their grading and staging.

▶ Reduce the overall mortality from chronic liver disease and cirrhosis.

—**Jeff Evans**

The full action plan is located at www.niddk.nih.gov/fund/divisions/ddn/ldrb/ldrb_action_plan.htm.

ALTERNATIVE MEDICINE
AN EVIDENCE-BASED APPROACH

Hypnotherapy for Irritable Bowel Syndrome

Rationale for Use

Irritable bowel syndrome (IBS) is estimated to afflict about 10%-20% of the U.S. population.

In its most severe form, IBS has an impact on quality of life that rivals that of congestive heart failure or recent stroke. Treatment consists largely of advice, reassurance, and symptomatic management with antidiarrheals, antispasmodics, and laxatives—and is notoriously ineffective.

▶ Gut-directed hypnotherapy results in significant, long-term improvements in symptoms of irritable bowel syndrome.
▶ A group of clinicians in North Carolina has developed a standardized hypnotherapy protocol that physicians can obtain at no cost.

Although the precise cause of IBS is uncertain, research has shown that a fundamental physiologic component is dysregulation of the bidirectional communication between the enteric nervous system and the brain. This brain-gut axis involves the activity of numerous neurotransmitters and related receptors, including serotonin and the 5-HT_3 and 5-HT_4 receptors (Med. Sci. Monit. 2004;10:RA125-31).

Moreover, many patients with the disorder also experience anxiety and other psychological symptoms along with their diarrhea, constipation, and pain, and their digestive symptoms sometimes correlate with mental and emotional states. Because of this link with psychological symptoms, researchers for the past 20 years have been investigating ways of harnessing the brain-gut axis to alleviate the condition. One of the most successful approaches has been hypnosis.

The U.K. Experience

For more than 20 years, patients with IBS referred to University Hospitals of South Manchester, England, have been treated with hypnotherapy in a program devised by gastroenterologist Peter J. Whorwell, M.D. His protocol, known as gut-directed hypnotherapy, involves hypnotic deep progressive relaxation and suggestion directed toward control of gut function. Patients are encouraged to use imagery to gain control over their gut activity. For example, a patient with diarrhea might visualize the digestive tract as a rushing river that can be slowed to a calm stream. Pain can be alleviated by applying warmth generated when the patient places a hand on his or her belly.

The Manchester protocol includes 12 sessions over a 3-month period. Patients also are given audiotapes to use at home on a daily basis.

The first small study evaluating the technique randomized 30 patients with severe, refractory IBS to hypnotherapy or psychotherapy. Both groups showed improvements in abdominal pain and distension and well-being. However, the psychotherapy group had no improvement in bowel habits, while the hypnotherapy group experienced "dramatic improvements" in all outcome measures, and no relapses were seen during 3 months of follow-up (Lancet 1984;2:1232-4). In a subsequent report, clinical improvement was maintained in all of the hypnotherapy patients for 2 years (Gut 1987;28:423-5).

The Manchester center later became the first hypnotherapy unit in the British National Health Service dedicated to IBS treatment. Investigators there have continued to follow their patients, and now have reported on long-term outcomes. Among the first 204 patients who completed a course of gut-directed hypnotherapy and responded to a subjective assessment questionnaire, 106 (52%) reported that their symptoms were "very much better" in the immediate posttreatment period, while 39 (19%) were "moderately better" and 32 (16%) were "slightly better" (Gut 2003;52:1623-9).

And the benefits persisted. Among responders who replied to the questionnaire, 81.3% reported that the initial symptomatic improvements were maintained—or even increased further—for periods up to 5 years. Extracolonic symptoms such as anxiety and depression also continued to improve.

The hypnotherapy must be gut specific, according to Dr. Whorwell. "Over the years we have found that the therapy has to be focused on the gut rather than just directed in a more general way. Thus, just telling patients they are going to relax and feel better does not seem to work," he said in an interview.

The U.S. Experience

A group of therapists at the University of North Carolina at Chapel Hill has instituted a similar program with equivalent success. They also have investigated the mechanisms by which hypnosis might affect IBS symptoms. In a series of tests, they found that hypnotherapy did not alter rectal pain thresholds or smooth muscle tone, autonomic nervous system activity, or frontalis muscle EMG activity (Dig. Dis. Sci. 2002;47:2605-14). Rather, they suggested that the effects of hypnosis are mediated through reduction in somatization, "primarily by altering the patient's focus of attention and/or by changing his or her beliefs about the meaning of sensations arising from the gastrointestinal tract."

The North Carolina clinicians also have spearheaded efforts to make hypnotherapy more widely available to patients in the United States, noting that psychological treatments are currently offered to fewer than 10% of patients with functional GI disorders seen in primary care or gastroenterology clinics. They have established a Web site with links listing hypnotherapists and other resources for patients. Clinicians can request by e-mail their protocol package, free of charge, containing verbatim scripts and other materials, at www.ibshypnosis.com.

Unanswered Questions

Aside from uncertainty about the mechanisms of effect of gut-directed hypnotherapy, questions also remain concerning whether hypnotherapy is superior to other forms of psychological therapy. Benefits have been reported with cognitive-behavioral, interpersonal, and psychodynamic therapies, but no side-by-side comparisons have been done, according to Olafur S. Palsson, Psy.D., of the North Carolina group (Gastroenterology 2002;123:2132-5). Furthermore, data are lacking on using hypnotherapy as adjunctive therapy with medications such as antidepressants and the 5-HT modulators.

—**Nancy Walsh**