



Complementary and Alternative Treatments for Functional Gastrointestinal Disorders

By: Kirsten Tillisch, M.D. and Steven Tan, M.D., MTOM, LAC, Center for Neurovisceral Sciences and Women's Health, David Geffen School of Medicine at UCLA

Abdominal pain or discomfort, bloating, distension, and altered bowel habits can all be symptoms of disorders such as irritable bowel syndrome (IBS) and functional dyspepsia (FD). IBS consists of abdominal pain or discomfort in association with changes in bowel habits (diarrhea, constipation, or both in alternation). Functional dyspepsia is pain or discomfort in the upper abdomen, often associated with nausea or bloating, which is not related to ulcers or any visible problem within the stomach or intestines. While symptoms of these disorders may be mild, in some cases they can become severe and can impair quality of life significantly. Functional disorders of the gastrointestinal tract, like FD and IBS, are the most common problems seen by gastroenterologists and make up a large proportion of visits to primary care doctors as well.[1] Nevertheless, only a small proportion of people with these disorders actually seek medical care. Despite the high prevalence of these disorders standard medical treatment options are at times limited. If conventional medical therapies prove unsuccessful or have unwanted side effects, many people choose to pursue complementary or alternative therapies (CAM). Complementary therapies are done *in addition to* traditional medical treatments, and alternative therapies are done *instead of* medical treatments. Many CAM modalities exist and they can be roughly grouped into several categories including herbal/dietary, somatic therapies (such as acupuncture or massage), mind-body therapies (such as hypnosis or meditation), and movement or breathing exercises (such as yoga or tai chi). In this review we will discuss each of these categories, focusing on those that have been studied most rigorously.

CAM use in the United States

The use of complementary and alternative medicine (CAM) in the United States has been growing over the past decade. In 1997, it was shown that 42% of Americans used some type of CAM for a medical disorder or for overall health benefits.[2] The number of visits to CAM practitioners in 1997 exceeded those to primary care medical doctors and patients viewed their CAM practitioners with equal confidence to that of Western medical doctors.[2,3] Between the years 1990 and 1997, the costs of CAM professional services had increased from \$15 billion to \$21 billion per year.[2] Since that time CAM usage appears to have had continued growth.

Why has CAM become so popular? In gastrointestinal functional disorders, patients are often dissatisfied with the conventional options available and with the approach of their physicians. Often patients express the desire to be treated as a

whole person, rather than just in terms of their symptoms or disorder, as is often the approach with Western medicine's subspecialty emphasis. Many CAM modalities incorporate a holistic approach and may allow patients to feel they are more actively participating in their own healthcare. Additionally, it is often perceived that "natural" therapies will be more safe and effective than "synthetic" medications. This is not supported by evidence, unfortunately, and recent difficulties seen with such herbal therapies as Ephedra and Aristolochia show that this may not always be the case.[4-7] As the awareness of both functional gastrointestinal disorders and CAM increases, better study of the variety of potential treatment options must increase as well.

On February 6, 2004, the Food and Drug Administration (FDA) issued a final rule prohibiting the sale of dietary supplements containing ephedrine alkaloids (*Ephedra*) because such supplements present an unreasonable risk of illness or injury. Under the Dietary Supplement Health and Education Act (DSHEA) of 1994, FDA may remove a dietary supplement from the market if it presents a significant or unreasonable risk of illness or injury when used according to its labeling or under ordinary conditions of use. Based on new information, the Food and Drug Administration on April 11, 2001 began advising consumers to immediately discontinue use of any botanical products containing aristolochic acid. These products may have been sold as "traditional medicines" or as ingredients in dietary supplements. Aristolochic acid is found primarily in the plant *Aristolochia*, but may also be present in other botanicals. Consumption of products containing aristolochic acid has been associated with permanent kidney damage, sometimes resulting in kidney failure that has required kidney dialysis or kidney transplantation. In addition, some patients have developed certain types of cancers, most often occurring in the urinary tract.

Herbal therapy

Herbal therapies have been used for a variety of disorders since ancient times. A recent study of patients using CAM modalities for gastrointestinal disorders showed that 48% of them used an herbal therapy.[8] Traditional Chinese Medicine (TCM) has long used combination herbal therapy, where TCM herbal formulas are developed based on a patient's pattern of symptoms, rather than for a specific disease process. Because of this, there is more than one formula for a disorder such as IBS. Additionally, the formulas are altered over time as the pattern of symptoms changes. Herbs used in TCM formulas for IBS include many common foods such as rhubarb, barley, tangerine

peel, cardamom, and licorice, and most formulas will include 5 or more herbs. While these therapies have been used in China for thousands of years, there has not been much research in the Western literature to assess their efficacy. One well-designed trial does exist and gives us hope that these treatments will be helpful for IBS patients. In this study, 116 patients were randomized into three groups: placebo (an inert formula looking and smelling just like the herbal treatment), a formula individually formulated for the patient by a trained TCM practitioner, or a standard formula using herbs that may help IBS symptoms in general.[9] The patients were treated for 16 weeks and their symptoms were then reassessed. Those receiving either of the herbal treatments had a greater improvement than those taking the placebo. At a follow up visit 14 weeks after the therapy had ended, those that had been given the individualized treatment had continued improvement. [Editor's Note: In this study there were 20 different herbal preparations included – therefore the “truly efficacious” agent or agents could not be identified.]

Other individual herbs are used for specific gastrointestinal symptoms. Peppermint oil has been studied for use in both IBS and FD in capsule form. It is thought to act by decreasing muscle spasm in the gastrointestinal tract. Several small trials have shown that it is better than placebo in improving abdominal discomfort, bloating, or overall symptoms.[10-12] Unfortunately, heartburn is a common side effect of peppermint oil treatment. Extensive reviews of the available trials using peppermint oil have determined that the data are insufficient to make clear recommendations for its use at this time.[13,14]

Artichoke leaf extract (ALE) has been tested in Europe as a treatment for both dyspepsia and IBS. It has been shown to improve bile flow, but its mechanism in decreasing the symptoms of IBS or FD is unclear. One large trial has shown improved dyspepsia symptoms and quality of life scores compared to placebo after 6 weeks of ALE therapy.[15] However, much more research is needed on this compound before it can be recommended for use outside of clinical studies.

Ginger is another common food product often used for gastrointestinal symptoms. Studies in IBS or dyspepsia have not been performed, but TCM practitioners, as well as many home remedies, often employ ginger. Ginger extract is thought to be anti-inflammatory, to strengthen the gastric lining, and to stimulate motility of the intestines. It has been shown to decrease nausea in several trials.[16]

Constipation is often treated with herbal therapies that stimulate secretion of fluids into the bowel and muscular contraction of the intestines. The most common include senna, cascara, aloe, and rhubarb root. These are most likely to be helpful in constipation associated with IBS, but rhubarb is included as an aid for both diarrhea and constipation in some texts.[16] Whether the motility effects of these herbs improve dyspepsia symptoms is untested.

Unfortunately, although they are readily available without a prescription, clear safety and drug interaction information is unavailable on most herbal therapies.

Acupuncture

Acupuncture has its roots in ancient Chinese medicine but has become popular worldwide for many ailments. The basic theory underlying acupuncture is that there are channels of energy (Qi), called meridians, that run through the body. On the meridians are 360 acupuncture points. In a state of good health, energy flows freely on these channels. In disease, the energy flow is

disrupted, leading to symptoms. Acupuncture to specific points is thought to release the energy and redirect its flow. In some cases electrical stimuli are given to the acupuncture needles to increase the effect (electro-acupuncture). Two very small trials examining acupuncture for the treatment of IBS have been performed with contradictory results.[17,18] Despite this lack of data, many patients pursue acupuncture for abdominal pain, bloating, and nausea. Acupuncture is generally safe if performed by a licensed acupuncturist and may be a good adjunct in patients who are sensitive, intolerant, or refractory to oral interventions. For severe cases, many acupuncturists will use acupuncture in conjunction with herbal therapy.

Diet

Most patients with IBS or dyspepsia can identify one or more foods that will induce their symptoms. The difficulty is that these trigger foods vary widely and no specific foods have universal effects in all patients. Raw fruits and vegetables may be irritating to patients with a tendency towards diarrhea, while a high fiber diet can help in those with constipation. A careful food diary can often identify intolerance to specific foods. Stringent diets, called exclusion diets, have been tested in patients with IBS with widely varying results. These diets consist of decreasing the diet to a very small number of specific foods and then gradually adding foods back one by one. Good responses to elimination diets vary from only 6% to 58% of cases depending on the study, so they are not widely recommended.[13] These diets are also difficult to adhere to and should be undertaken with the assistance of a dietician to maintain proper nutrition.

Alteration of the intestinal flora

Probiotics are substances or organisms that contribute to the balance of bacteria in the intestines. Probiotics are readily available in health food stores, and usually contain beneficial bacteria such as *lactobacillus* or *bifidobacterium*. The intestinal flora (the organisms that colonize the intestines) is thought to help in regulating the gastrointestinal tract's motility, immune system, and secretion of fluids so researchers have looked at probiotics to see if they can alleviate the symptoms of IBS or dyspepsia. The studies so far have not shown any benefit of probiotics in dyspepsia, but some have shown improvement of IBS.[19,20] One study showed decreased abdominal pain and flatulence as well as improved satisfaction with bowel movements, while another did not.[21] At this time we can't be sure if probiotics will be a useful therapy of IBS. Further trials are currently being conducted.

Hypnotherapy

Hypnotherapy has been shown to be effective for IBS in several clinical trials.[22-24] Hypnosis usually requires weekly individual sessions over several months, but has been tried in groups and by self-instruction as well. Hypnosis involves progressive relaxation, then suggestions of soothing imagery and sensations focused on the individual's symptoms. Improvements in overall well being, quality of life, abdominal pain, constipation, and bloating have been noted.[13] One of the difficulties with hypnosis is that it is very dependent on the therapist, and it may be difficult to find a therapist both trained in hypnosis and knowledgeable about functional gastrointestinal disorders. Additionally, like many alternative therapies, it can be costly and often is not covered by insurance plans.

DIETARY SUPPLEMENTS

As defined by Congress in the Dietary Supplement Health and Education Act (DSHEA) (www.fda.gov/opacom/laws/dshea.html#sec3), which became law in 1994, a dietary supplement is a product (other than tobacco) that

- is intended to supplement the diet;
- contains one or more dietary ingredients (including vitamins; minerals; herbs or other botanicals; amino acids; and other substances) or their constituents;
- is intended to be taken by mouth as a pill, capsule, tablet, or liquid; and
- is labeled on the front panel as being a dietary supplement.

Although dietary supplements are regulated by the U.S. Food and Drug Administration (FDA) as foods, they are regulated differently from other foods and from drugs. Whether a product is classified as a dietary supplement, conventional food, or drug is based on its intended use. Most often, classification as a dietary supplement is determined by the information that the manufacturer provides on the product label or in accompanying literature, although many food and dietary supplement product labels do not include this information.

In addition to regulating label claims, FDA regulates dietary supplements in other ways. Supplement ingredients sold in the United States before October 15, 1994, are not required to be reviewed by FDA for their safety before they are marketed because they are presumed to be safe based on their history of use by humans. For a new dietary ingredient – one not sold as a dietary supplement before 1994 – the manufacturer must notify FDA of its intent to market a dietary supplement containing the new dietary ingredient and provide information on how it determined that reasonable evidence exists for safe human use of the product. FDA can either refuse to allow new ingredients into or remove existing ingredients from the marketplace for safety reasons.

Manufacturers do not have to provide FDA with evidence that dietary supplements are effective or safe; however, they are not permitted to market unsafe or ineffective products. Once a dietary supplement is marketed, FDA has to prove that the product is not safe in order to restrict its use or remove it from the market. In contrast, before being allowed to market a drug product, manufacturers must obtain FDA approval by providing convincing evidence that it is both safe and effective.

By law (DSHEA), the manufacturer is responsible for ensuring that its dietary supplement products are safe before they are marketed. Unlike drug products that must be proven safe and effective for their intended use before marketing, there are no provisions in the law for FDA to “approve” dietary supplements for safety or effectiveness before they reach the consumer. Also unlike drug products, manufacturers and distributors of dietary supplements are not currently required by law to record, investigate or forward to FDA any reports they receive of injuries or illnesses that may be related to the use of their products. Under DSHEA, once the product is marketed, FDA has the responsibility for showing that a dietary supplement is “unsafe,” before it can take action to restrict the product’s use or removal from the marketplace.

GENERAL SAFETY ADVISORY FOR CONSUMERS (THIS INFORMATION DOES NOT REPLACE MEDICAL ADVICE)

- Before taking an herb or a botanical, consult a doctor or other health care provider – especially if you have a disease or medical condition, take any medications, are pregnant or nursing, or are planning to have an operation.
- Before treating a child with an herb or a botanical, consult with a doctor or other health care provider.
- Like drugs, herbal or botanical preparations have chemical and biological activity. They may have side effects. They may interact with certain medications. These interactions can cause problems and can even be dangerous.
- If you have any unexpected reactions to an herbal or a botanical preparation, inform your doctor or other health care provider.

For more information on dietary supplements, contact: Office of Dietary Supplements, National Institutes of Health, Web site: ods.od.nih.gov or, Center for Food Safety and Nutrition U.S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835, Web site: vm.cfsan.fda.gov

Sources: NIH Office of Dietary Supplements (dietary-supplements.info.nih.gov/) and FDA, Dietary Supplements www.cfsan.fda.gov/~dms/supplmnt.html

Movement therapy and meditation

No studies on FD or IBS are available for specific movement therapies such as yoga or tai chi. It has been shown, however, that relaxation response meditation aids symptoms of abdominal pain, bloating, flatulence, and diarrhea, based on a small study.[25] These types of therapies are particularly attractive, as they have no potential concerning side effects and may be helpful for symptoms outside the gastrointestinal tract as well as promoting general stress reduction.

Conclusions

Complementary and alternative approaches to functional gastrointestinal disorders provide an exciting opportunity for both patients and doctors faced with the difficulty of managing these chronic disorders. Currently, many questions about the

efficacy and safety of CAM therapies still exist. More research into alternative therapies for functional gastrointestinal disorders is needed before definite recommendations can be made. As popularity of CAM increases among the public, acceptance by Western medical professionals and scientists has grown. Increasingly, CAM modalities are being studied in the United States. The National Institutes of Health has increased the funding of such research from \$2 million per year in 1992 to over \$100 million in 2003. Over the next decade we can expect to see much more information about the safety and efficacy of CAM treatments, which is currently lacking. It is important that CAM practitioners, primary care doctors, and gastroenterologists work together with their patients to find the appropriate treatment or combination of treatments from the vast array of conventional and alternative options available.

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