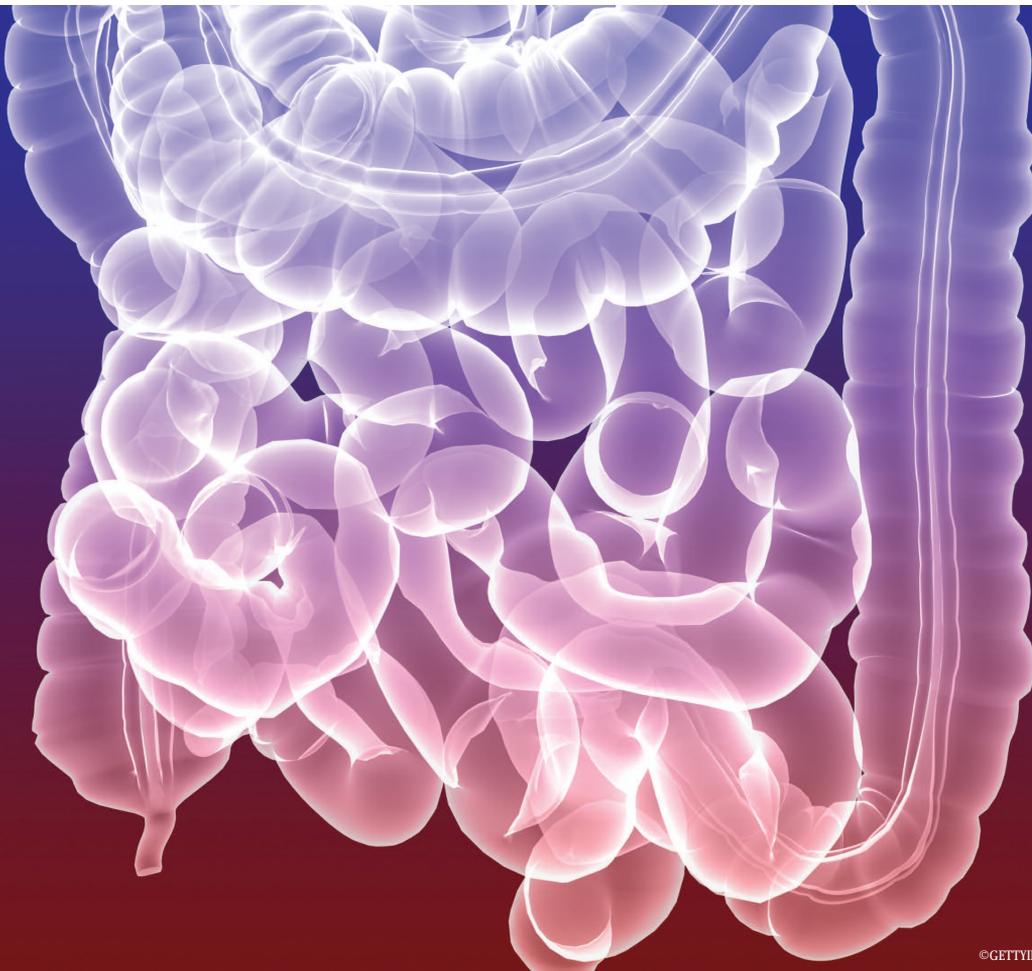


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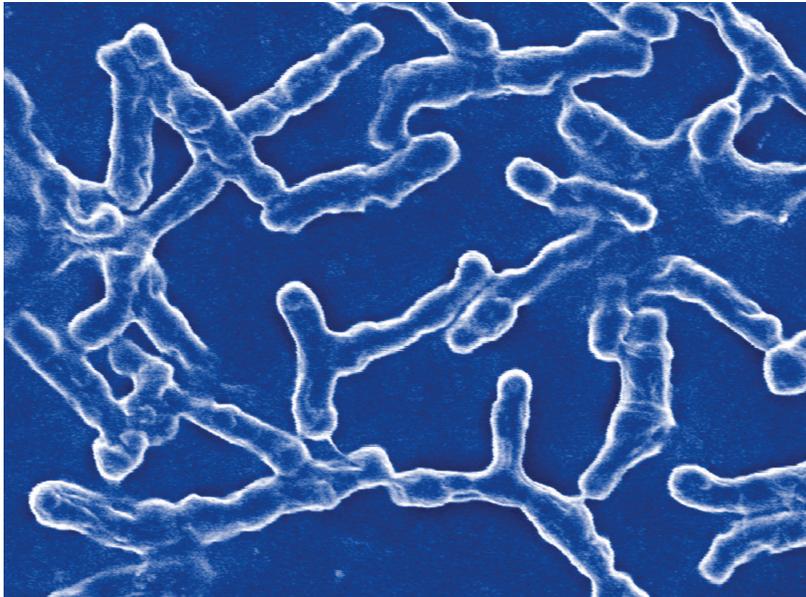
Irritable Bowel Syndrome: Overview of Diagnosis and Management of IBS Focus on Probiotics

This Disease State Information Guide is supported by a grant from P&G

Irritable Bowel Syndrome:

Overview of Diagnosis and Management of IBS

Focus on Probiotics



Bifidobacterium infantis 35624 (Bifantis®)

IRRITABLE BOWEL SYNDROME (IBS)

Irritable bowel syndrome (IBS) is a chronic condition associated with uncomfortable or painful bowel symptoms that are not associated with organic disease or structural abnormalities. The symptoms of IBS are quite variable among individuals and occur in episodic “flares” of adverse changes in bowel habits, including diarrhea, constipation, bloating, excess gas, and urgency. The patterns of IBS symptoms are referred to as diarrhea-predominant, constipation-dominant, or alternating between diarrhea and constipation¹.

The etiology of IBS is not known. Patients may develop IBS after enteric infections or following significant life changes, such as traumatic events or serious illness, but in some patients no precipitating events can be identified. The “brain-gut” connection that regulates bowel motility, sensitivity, secretion, and absorption through

serotonin-based signaling mechanisms is an important factor, but the exact neurological mechanisms that result in IBS symptoms are not known. On the other hand, overgrowth of endogenous gut microflora or expansion of bacteria into the small bowel have been documented in many patients with IBS. These imbalances may be related to disturbances of the brain-gut connection; however, the nature of the relationship between these findings is not well understood^{2,3}. Due to these uncertainties, therapies for IBS are generally targeted at relief of symptoms rather than interference with specific disease processes^{2,3}.

DIAGNOSIS OF IBS

There are no definitive diagnostic tests or pathologies that can be used to diagnose IBS. Sets of symptom criteria have been developed to define the complex of symptoms that allow diagnosis of IBS in

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the absence of warning signs that may indicate organic disease. Rome III criteria, the most recent set of IBS criteria, were published in 2006 and are widely used in clinical trials¹.

According to Rome III criteria and in the absence of warning signs, IBS is diagnosed if the patient has experienced recurrent abdominal pain or discomfort on at least 3 days per month in the previous 3 months and at least 2 of the following signs: 1) pain or discomfort is improved with defecation; 2) onset of pain or discomfort is associated with a change in frequency of stool; 3) onset of pain or discomfort is associated with a change in the form of stool. The onset of these symptoms must have at least 6 months prior to diagnosis and the criteria must be fulfilled for at least the previous 3 months (TABLE 1)⁴. Warning signs that may indicate organic disease or structural abnormalities include rectal bleeding, anemia, weight loss, fever, family history of colon cancer, onset of symptoms after 50 years of age, and a major change in symptoms².

PREVALENCE AND IMPACT OF IBS

Survey studies that used the Rome criteria for IBS indicate a prevalence of approximately 7% in the North American population¹. These surveys also showed that women are 1.5 times more likely to develop IBS than men. However, IBS is included in the definition of Gulf War syndrome in a predominantly male population of military personnel, showing that IBS should not be considered a disorder of women alone¹. Persons under 50 years of age are more often diagnosed with IBS than older individuals and prevalence is higher in demographic groups with low income compared with groups with higher income^{1,5}.

IBS prevalence in the United States may be significantly higher than these figures indicate. A 2005 community survey documented a prevalence rate of 14%, with only 3% reporting an actual medical diagnosis of IBS⁶. As many as 70% of patients who have IBS may not seek medical care for their symptoms⁷.

Patients with IBS report significant impact of their condition on quality of life. A large comparative study using the SF-36 Health Survey showed that patients with IBS had significantly worse health-related quality of life (HRQOL) than the general population. These patients also scored significantly lower than patients with diabetes and end-stage renal disease⁸.

Table 1. Rome III Criteria for Diagnosis of Irritable Bowel Syndrome⁴

Recurrent abdominal pain or discomfort
Occurred at least 3 days per month in the previous 3 months
Pain or discomfort is associated with 2 or more of the following:
Relieved with defecation
Onset is associated with change in frequency of stool
Onset is associated with change in form (appearance) of stool
Criteria must be fulfilled for the previous 3 months with onset at least 6 months before diagnosis
Absence of warning signs of organic disease or structural abnormalities

MANAGEMENT OF IBS SYMPTOMS

Many patients perceive that specific foods cause or increase IBS symptoms and exclude them from their diet. While this strategy is used by 60-70% of patients, it may lead to poor nutrition in some patients. These food intolerances are not related to food allergies or malabsorption⁹.

Pharmacological therapies are usually aimed at normalizing bowel habits or decreasing abdominal pain. Recommendations for

use of many pharmacological agents for IBS is based on general consensus of experts, rather than randomized clinical trials in patients with IBS. In addition, evidence for efficacy of these agents may be limited to individual symptoms, such as constipation or diarrhea, rather than for global improvement in IBS symptoms².

Prescription agents. Lubiprostone, a calcium-channel activator, increases bowel motility by increasing intestinal fluid secretion and is indicated for chronic idiopathic constipation. Adverse

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events associated with lubiprostone include nausea, diarrhea, headache, and abdominal pain or discomfort¹⁰.

Tegaserod is an agonist of 5-HT₄ receptors for serotonin, the primary neurotransmitter involved in brain-gut neurological connections. Activation of 5-HT₄ receptors stimulates peristaltic activity and internal fluid secretion and also decreases visceral sensitivity¹¹. Tegaserod is indicated for constipation-predominant IBS and chronic idiopathic constipation in women. However, tegaserod is available only on a very limited basis for women with these conditions and without cardiovascular risk factors, because of rare but severe cardiovascular ischemic adverse events. Initial diarrhea and abdominal pain may also occur¹¹.

Alosetron is an antagonist of the 5-HT₃ receptor for serotonin. Inhibition of this receptor results in less hypersensitivity and lowered motor responses in the bowel¹². Alosetron is indicated only for women with severe diarrhea-predominant IBS that has not responded to other treatments, due to the infrequent but serious potential for ischemic colitis. Constipation may also be an adverse event¹².

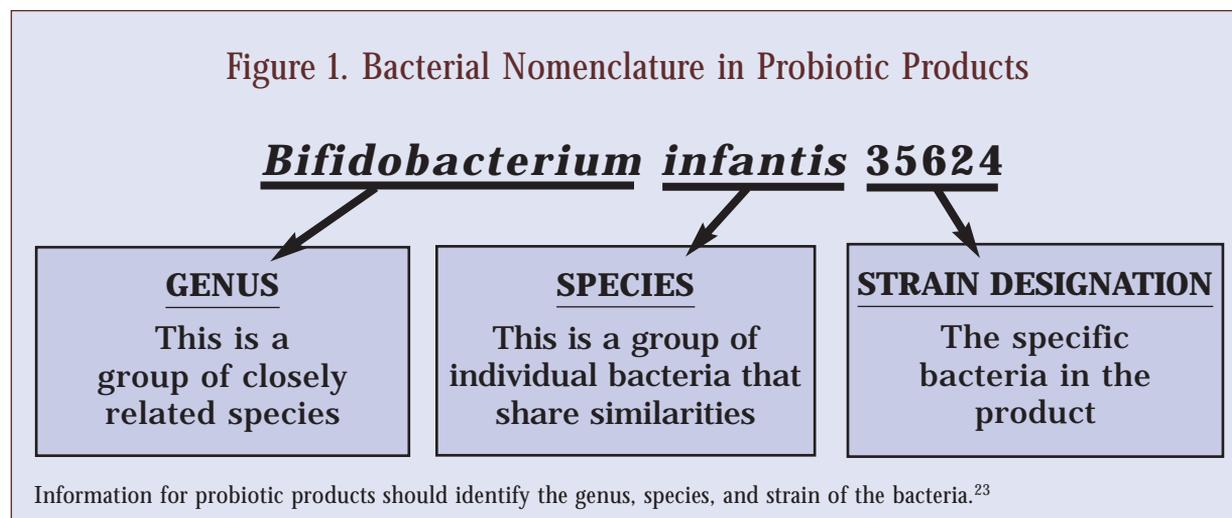
Antispasmodic agents, such as hyoscyamine or mebeverine, are sometimes prescribed for treatment of IBS-related pain. These agents may be effective for some patients, but large-scale clinical trials in IBS have not been performed². On the other hand, tricyclic antidepressants, such as

amitriptyline and desipramine, are often prescribed at low doses for IBS symptoms. These agents prolong exposure to neurotransmitters, such as serotonin and norepinephrine, by blocking uptake by neurons^{13,14}. At low doses, these agents may benefit patients with IBS by decreasing hyperalgesia, improving sleep, and normalizing bowel transit times¹⁵. Improvement of coexisting depression or anxiety may also occur when used at the higher doses recommended for these disorders². In addition, the selective serotonin-reuptake inhibitors (SSRIs) paroxetine, citalopram, and fluoxetine have been studied in patients with IBS in several clinical trials. These agents may have a direct effect on IBS symptoms of pain and bloating as well as psychological effects on depression and anxiety¹⁶.

Finally, the nonabsorbable antibiotic rifaximin, which has been shown to inhibit bacterial overgrowth in the bowel¹⁷, improved global IBS symptoms and the individual symptom of bloating, in a small randomized clinical trial. However, it is not approved for this indication. The benefit of improved symptoms lasted for up to 10 weeks after discontinuation of treatment. Individual scores for pain, diarrhea, and constipation did not change¹⁸.

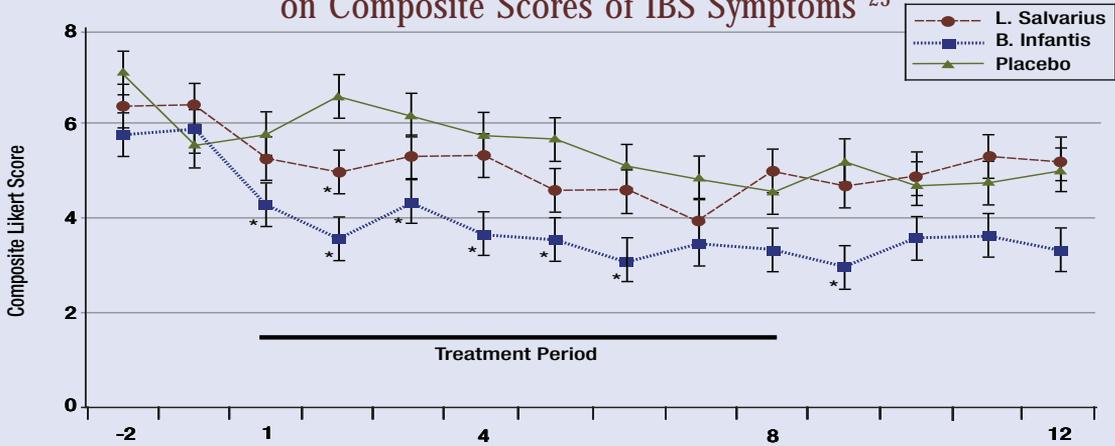
Non-prescription agents. Constipation may be treated with traditional laxatives, such as polyethylene glycol 3350 or lactulose. Diarrhea, bloating,

Figure 1. Bacterial Nomenclature in Probiotic Products



IRRITABLE BOWEL SYNDROME

Figure 2. Effect of *Bifidobacterium infantis* 35624 on Composite Scores of IBS Symptoms²³



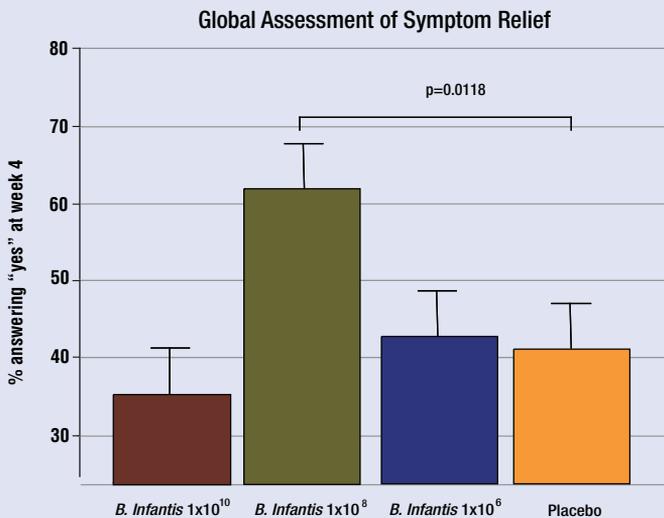
Source: O'Mahony et al. *Gastroenterology* 2005;128:541-551.

and cramping are potential adverse events of these agents². Traditional antidiarrheal agents, such as loperamide, are generally effective for patients with diarrhea-predominant IBS. Regular use of low

doses of loperamide, in particular, have been recommended to relieve uncontrollable diarrhea and decrease patients' anxiety about urgency. Constipation is a potential adverse event².

Figure 3. Comparison of effects of placebo and *Bifidobacterium infantis* 35624 on Subjects' Global Assessment (SGA) of IBS symptoms. Positive response rates recorded at wk 4 at the end of therapy - "yes" or "no" response:

"Please consider how you felt in the past week in regard to your IBS, in particular your general well-being, and symptoms of abdominal discomfort or pain, bloating or distension and altered bowel habit. Compared to the way you felt before beginning the medication, have you had adequate relief of your IBS symptoms?"



Whorwell et al. *Am J Gastroenterol* 2006;101:1581-1590.

FOCUS ON PROBIOTICS FOR MANAGEMENT OF IBS SYMPTOMS

Probiotics are live microorganisms that confer health benefits when administered in adequate amounts. Because of the association between IBS and imbalances or overgrowth of gut microflora, probiotics in oral supplements and such foods as yogurt have been widely publicized for helping patients achieve relief from symptoms. To promote adequate clinical investigation of these effects, guidelines for the evaluation of the health benefits of oral probiotics have been set forth by the World Health Organization (WHO), the International Scientific Association for Probiotics and Prebiotics (ISAPP), and the World Gastroenterology Organisation (WGO) (FIGURE 1)^{19,20,21}.

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Table 2. Probiotic strains tested in randomized, controlled clinical trials in patients with IBS^{21,22,25}

Strain	Trade name	Manufacturer	Met 1° endpoint in clinical trials
<i>Bifidobacterium infantis</i> 35624	Align	Procter & Gamble	Yes
<i>Bifidobacterium animalis</i> DN 173 010	Activia	Danone/Dannon	No
<i>Lactobacillus rhamnosus</i> ATCC 53013 (LGG)	Vifit	Vatio	No
<i>Lactobacillus reuteri</i> ATCC 55730	Reuteri	BioGaia Biologics	No
<i>Lactobacillus plantarum</i> 299V	GoodBelly	NextFoods	No
Mixture of 1 strain <i>Streptococcus thermophilus</i> , 4 <i>Lactobacillus</i> spp., 3 <i>Bifidobacterium</i> spp. strains	VSL#3 (medical food)	Sigma-Tau	No

A key aspect of these guidelines is the importance of *strain-specificity* in clinical evaluations of probiotics. Hundreds of probiotic products have been promoted for relief of gastrointestinal symptoms and may contain one or more different microorganisms and strains. However, the guidelines agree that consistent identification of microorganisms down to the strain level is needed to verify that clinical studies were conducted with exactly the same strain as those in commercial products. Specification of well-characterized strains also assures that the identity, quality, and safety of the administered microorganism used for clinical trials and commercial products can be verified consistently¹⁹.

A second important factor in the correspondence between clinical studies and commercial products is the level of *colony-forming units (CFUs)* of the microorganism in each case. The level of viable organisms that was tested and found effective in clinical studies should be the same as that in the commercial product for the specified shelf life².

It is clear from these guidelines that all probiotic products are not alike in their characteristics, quality, and effects on gastrointestinal symptoms. The probiotics found in commercial products and foods may be different organisms at different levels. Because of these differences, the effects of probiotics are often not adequately confirmed in clinical studies to support claims of health benefits²⁰. Thus, it is particularly important to recom-

mend probiotics from a reputable manufacturer that has thoroughly tested and verified the safety and potency of specific products in clinical trials. Patient information that accompanies probiotic products should provide clear information that will ensure proper storage and use of probiotics so that organisms remain at levels of viability and potency that were effective in clinical trials.

Several strains of probiotic organisms have been tested in randomized, controlled clinical trials in patients with IBS with inconsistent results in these studies. (TABLE 2)²². This is not a comprehensive list of products but includes several that may be available in United States pharmacies, health-food stores, or online. *Bifidobacterium infantis* 35624 is the only probiotic product to have met primary efficacy endpoints in randomized, controlled clinical trials.

The probiotic supplement *Bifidobacterium infantis* 35624 has recently been tested in 2 randomized, placebo-controlled clinical trials in male and female patients with IBS. In one study of 77 patients, symptoms of pain, bloating, and bowel movement difficulty were improved in patients who received *Bifidobacterium infantis* 35624 compared with those who received a lactobacillus supplement and compared with placebo treatment (FIGURE 2)²³. In the second study of 362 female patients, global IBS symptoms, as well as the individual symptoms of abdominal pain, bowel dysfunction, incomplete evacuation, strain-

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ing, and gas were significantly improved compared with placebo (FIGURE 3)²⁴. It should be noted that *Bifidobacterium infantis* 35624 was effective in all subtypes of IBS and in male and female patients.

CONCLUSION

IBS is a chronic condition that causes significant decreases in quality of life with episodes of painful or uncomfortable bowel symptoms that may be severe. Since the causes of IBS are not well understood, treatments are targeted at indi-

vidual symptomology. Interference with serotonin-based signaling mechanisms that control the brain-gut connection and regulation of imbalances in gut microflora are the two main pharmacologic strategies for treatment of IBS symptoms. Probiotic therapy may provide relief through the latter strategy; however, use of probiotic products that have been identified to the species level and tested in randomized clinical trials is recommended by international guidelines. This discrimination allows confidence in health claims supported by clinical trials of probiotic products. ♦

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PATIENT INFORMATION AID

Irritable bowel syndrome (IBS) is a chronic condition characterized by abdominal pain or discomfort with recurrent episodes of such symptoms as diarrhea, bloating, constipation, gas and bloating, and urgency. The patterns of IBS symptoms and their severity vary widely among patients. Symptoms are usually classified as diarrhea-predominant, constipation-predominant, or alternating.

CAUSES OF IBS

IBS is not the result of organic disease and no physical or structural abnormalities are associated with IBS. Patients may develop IBS symptoms after a gastrointestinal infection, other major illness, traumatic events, or stressful life situation. The neurological connections between the brain and the gut are known to be an important factor in regulation of bowel motility, absorption, and sensitivity. In addition, imbalances in the normal gut bacteria have been found in many patients and may be responsible for IBS symptoms.

DIAGNOSIS OF IBS

There is no test or specific pathology to identify IBS. The patient with IBS should meet Rome criteria for the past 3 months, have had symptoms for at least 6 months, and not have warning signs that may indicate organic disease. Warning signs

that may indicate diseases other than IBS include rectal bleeding, anemia, weight loss, fever, family history of colon cancer, onset of symptoms after 50 years of age, and a major change in symptoms.

MANAGEMENT OF IBS SYMPTOMS

Treatment options for IBS are targeted at normalizing bowel habits and reducing abdominal discomfort. Most patients find that certain foods may trigger episodes of IBS and learn to avoid them to reduce symptoms. Traditional over-the-counter medications for diarrhea or constipation are sometimes recommended for individual symptoms, but may have no effect on abdominal pain or bloating. Several prescription medications that affect the “brain-gut” connection have been developed for IBS, depending on the type of symptoms the patient is experiencing. These include alosetron (for diarrhea-predominant IBS) and tegaserod or lubiprostone (for constipation-predominant IBS).

Should I tell my healthcare provider about IBS symptoms?

The majority of individuals with IBS do not consult a healthcare provider about their symptoms, even when the symptoms have a major effect on their lives. However, many IBS symptoms can be reduced or even eliminated by strategies and medications that are now available. When you first visit your healthcare provider about IBS symptoms, be ready to tell him or her the following information:

Kinds of symptoms and how long they have been occurring.

How often they occur

How IBS symptoms affect your family life, work situation, and social life.

Whether you can identify foods or situations that make IBS symptoms worse

Whether you do anything to help your IBS symptoms (food avoidance, supplements, etc.)

Prescription and over-the-counter medications you take now

PATIENT INFORMATION AID

Low doses of antidepressants are sometimes effective for abdominal pain in patients with IBS, because of the neurological connections between the brain and the gut. These agents are generally given at lower doses than would be effective for mood disorders. Symptoms of bloating and gas have been shown to be affected by agents that change the balance of bacteria in the gut, such as antibiotics. Probiotic foods and supplements have received considerable promotion for improvement of intestinal health. The quality of these claims for probiotic

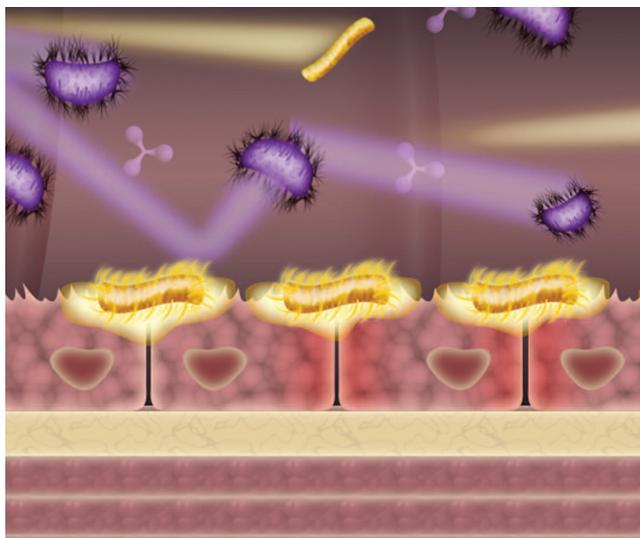


Illustration of polysaccharide coated *Bifidobacterium infantis* 35624 attached to epithelial cells to create a natural defense.

products is difficult to ascertain unless the microorganisms have been standardized, identified to the strain level, and tested in randomized clinical trials. Recommendations for probiotics for patients with IBS should be supported by data from studies specifically in this population. The probiotic supplement *Bifidobacterium infantis* 35624 has been found effective in ran-

domized, placebo-controlled clinical trials for global IBS symptoms, as well as the individual symptom of bloating in men and women with all subtypes of IBS. ♦

RESOURCES

IRRITABLE BOWEL SYNDROME (IBS) AND PROBIOTICS

International Foundation for
Functional Gastrointestinal Disorders
PO Box 170864
Milwaukee, WI 53217-8076
Phone: (414) 964-1799
Toll-free: (888) 964-2001
Fax: (414) 964-7176
E-mail: iffgd@iffgd.org
<http://www.iffgd.org/>
IBS web sites: <http://www.aboutibs.org/> and
<http://www.iamibs.org/>

The American College of Gastroenterology
P.O. Box 342260
Bethesda, MD 20827-2260
Phone (301) 263-9000
<http://www.acg.gi.org/>

World Digestive Health Day 2009—
Irritable Bowel Syndrome
The World Gastroenterology Organisation focuses the
attention of the world gastroenterology community (medical
professionals, other healthcare workers, and the general
public) on IBS on **May 29, 2009**.
<http://www.worldgastroenterology.org/wdhd-2009.html>

American Gastroenterological Association
4930 Del Ray Avenue
Bethesda, MD 20814
Phone: (301) 654-2055
Fax: (301) 654-5920
E-mail: member@gastro.org
<http://www.gastro.org/wmspage.cfm?parm1=2>

International Scientific Association
for Probiotics and Prebiotics
502 Mace Blvd. Suite 12
Davis, California
95618 USA
Phone (530) 753-0681
<http://isapp.net/>

National Center for Complementary
and Alternative Medicine
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892 USA
E-mail: info@nccam.nih.gov
<http://nccam.nih.gov/>

COUNSELING CORNER

The following series of questions and answers serves as a patient education aid to assist health care professionals in counseling patients with irritable bowel syndrome (IBS).

Q: My physician told me I have IBS. How is IBS diagnosed?

A: IBS is diagnosed by a set of symptoms and how long they have occurred, not by a specific test. A healthcare provider takes a careful history of all your abdominal symptoms and how long they have been occurring. The healthcare provider may also inquire about other symptoms, such as anemia or weight loss, to be sure that another disease is not present. If these symptoms are present, or if you have a family history of other digestive diseases or cancer, more tests may be indicated.

Q: What can I do to improve my IBS symptoms?

A: Many patients find that certain foods trigger their symptoms or make them worse. If you keep track of which foods do this, avoidance may help reduce the severity or the frequency of IBS episodes. Your physician should be aware of your diet changes in order to tell if you need to try other kinds of therapy.

Probiotics may be another option to try to reduce your IBS symptoms. These work by adding beneficial bacteria to your system. Many probiotic products make claims for improving intestinal health, but only a few have actually been tested in patients with IBS. It is important to choose one that has been standardized and thoroughly tested by

a reputable manufacturer. For patients with IBS, claims should be backed up by randomized, controlled clinical trials that were conducted in individuals with IBS.

Q: What kinds of therapy are available for IBS symptoms?

A: Depending on the kind of IBS symptoms you have, your healthcare provider may determine that several different therapies may help. Some medications focus on the connections between the gut and the brain that control how material moves through your digestive system and how sensitive your system is. Like all medications, there may be side effects (some serious) and contraindications to use of these therapies in your particular case. Other kinds of medications influence the kinds of bacteria that are naturally present in the small intestine. Gut bacteria have been shown to be unbalanced or in the wrong part of the gut in some patients with IBS, so these medications are used to try to restore the proper numbers and types of bacteria in the small intestine. Probiotics are not drugs, but supplementation of live bacteria that may help the balance in the gut.

Q: I have seen advertising for probiotic foods and supplements that are supposed to improve digestive health. What are probiotics?

COUNSELING CORNER

A: Probiotic foods (such as yogurt) and supplements contain live bacteria that may benefit digestion by changing the pattern of bacteria in the gut. Many probiotics have been claimed to help with such IBS symptoms as bloating, diarrhea, and constipation. However, it may be difficult to tell how many beneficial bacteria and what types are present in foods and supplements. This makes it particularly important to buy supplements made by a reputable manufacturer who has thoroughly tested the exact type of bacteria that is used in the supplement in clinical trials.

Q: If I take a probiotic supplement, what should I look for?

A: You should ask your healthcare provider to be sure that there is no reason why you should not take a probiotic supplement. Most people who do not have other serious diseases can take a probiotic safely. The information for a probiotic supplement should clearly state the exact type and strain of bacteria in the supplement and how many bacteria are in each serving. It should tell you how much to take and how often to take it. It should also tell you how to store the probiotic so that the bacteria stay alive until the end of the "best by" period. The information should also tell you what to expect when you begin taking the probiotic and what to do if you miss taking it. You may want to keep track of how your symptoms change during the first 3 to 4 weeks of using the probiotic. This is helpful information for your healthcare provider as well.

Q: How should I decide which probiotic to take?

A: The probiotic should be standardized and identified down to the strain level of the microorganism by a reputable manufacturer. Testing in clinical trials should have been done in patients with IBS, so that the specific symptoms you have were caused by the same problems. Convenient methods for storing the probiotic, so that the microorganisms stay at peak effectiveness throughout the "best by" period, may affect your choice as well. Finally, the ease of taking the probiotic in a capsule or in extra food may influence your choice.

Q. Can I take other probiotic foods or supplements at the same time?

A. Yes, in general. However, you may not be able to tell which supplement is working as you wished or which causes more symptoms. In the same way as you might test foods to see if they affect your IBS symptoms, probiotics can be added one at a time so that you understand their effects.

Q. Can I take other medications at the same time as probiotic foods or supplements?

A. Yes, in general there are no interactions between probiotics and other medications. However, if you have serious digestive disease or other serious disease, check with your healthcare provider before starting probiotics.

Q. How long should it take for the effects of probiotics to start?

A. You may notice some changes in your digestive system in the first few days, but a good trial of a probiotic is 3 to 4 weeks. Some gas and bloating may occur at first. These effects should pass off and result in improved symptoms by the end of a 4-week trial period. ♦

This Disease State Information Guide is supported by a grant from P&G