Nonpharmacologic and over-the-counter (OTC) therapies for chronic constipation include lifestyle measures, such as increased intake of fluid and fiber, OTC fiber supplements and laxatives, biofeedback, and surgery. Although lifestyle measures and OTC agents are frequently recommended in clinical practice, a closer look at the data reveals that most studies show either no effect, beneficial effects that are often cancelled out by exacerbation of constipation-related symptoms, or findings that neither support nor refute the use of these modalities. Studies examining biofeedback, which is most commonly used in patients with dyssynergic defecation, generally demonstrate benefit. This article reviews the data for each of the 4 modalities and, to illustrate their application in clinical practice, also includes a “running” case study of an actual patient who was treated with 3 of these 4 approaches to therapy.

gests that it does not play much of a role. Although 1 small study in healthy volunteers found that reducing fluid intake from 2500 mL/day to 500 mL/day reduced stool frequency by 2 bowel movements per week and stool weight by approximately 20% to 30%, another small study in volunteers found that increasing fluid by 1 to 2 L/day increased urine output but not stool output.

Similarly, studies of the effects of exercise on constipation have found little or no impact. One small study of patients with constipation who participated in an intensive exercise program (1 hour a day, 5 days a week) found no significant improvement in constipation indices. A much larger population study of more than 1000 employees of the same company found no difference in physical activity levels among those who were constipated (n = 140) and those who were not (n = 929).

**Dietary Fiber and Fiber Supplements**

In addition to dietary sources of fiber such as bran, fruits, and vegetables, there are several fiber supplements that are available in a number of formulations, such as pectin, gums, cellulose, and lignins. They work by a variety of mechanisms, including water retention, stool bulking, stimulation of fermentation, acceleration of colonic transit, and bile-acid binding. Because of the latter, these agents have also been purported to be helpful in some patients with diarrhea. Pectin and gums form viscous solutions that delay gastric emptying and nutrient absorption. Cellulose and lignins, which are insoluble, accelerate colonic transit. Commonly available fiber supplements include psyllium husk (Metamucil; Procter & Gamble Pharmaceuticals, Inc., Mason, Ohio), calcium polycarbophil, and methylcellulose.

A study evaluating the physiologic effects of fiber in 20 healthy volunteers who had radiopaque marker tests before and during consumption of a usual British diet supplemented by bran 20 g/day found that bran decreased transit time from 2.75 days to 2.0 days, suggesting an improvement in transit. Interestingly, bran accelerated transit in all 9 subjects with an initial transit time of 3 or more days and slowed transit in all 4 subjects with an initial transit time of less than 1 day. A double-blind crossover trial described in the same report found that bran significantly accelerated transit, but oat flakes had no effect.

Several other studies evaluating the physiologic effects of various fiber supplements on constipation have found that bran and ispaghula accelerate transit, but that psyllium husk had no effect on transit or other manometric parameters. Findings from 1 of these studies also suggest that bran is most beneficial in patients with colonic inertia.

Several of these studies, in addition to others, also examined the effects of various fiber supplements on constipation symptoms. Most found beneficial effects on stool frequency, weight, and consistency, but not on abdominal pain or bloating. A study by Hotz and Plein found that psyllium husk and bran decreased pain, but increased bloating in patients with constipation-predominant irritable bowel syndrome, and a study by Ashraf et al found that psyllium husk decreased pain. The only study to find a decrease in

**Case Study**

**Presentations**
- 46-year-old woman with a 4-year history of constipation
- Symptoms began gradually; she now has 1 bowel movement every 6 days with straining and hard, dry stools, but no bulging, bleeding, or pain
- Her weight is stable

**Medical History**
- Caesarean sections
- Migraine headaches
- She takes ibuprofen as needed

**Physical Examination/Evaluation Findings**
- Physical, anorectal, and pelvic examinations: normal
- Metabolic studies, including calcium and thyroid-stimulating hormone determinations: normal
- Structural tests, including colonoscopy: normal

**Initial Recommendations**
- Drink 4 glasses of water a day
- Initiate a regular exercise regimen
- Schedule defecation after eating
- Eat plenty of bran cereal, bran muffins, and salads
- Take an OTC bran supplement, if needed
pain and bloating was one evaluating ispaghula.\textsuperscript{10}

In a study involving 149 patients at a tertiary care center who had undergone physiologic testing, the response to therapy with plantago seeds for 6 weeks was correlated with the functional abnormality.\textsuperscript{17} Whereas 85% of patients with normal test results responded favorably, only 37% of those with abnormal anorectal manometry and defecography and 20% of those with abnormal colonic transit had a good response. This observation suggests that fiber supplements are likely to be beneficial only in those individuals with relatively mild constipation.

**OVER-THE-COUNTER LAXATIVES AND STOOL SOFTENERS**

Various types of OTC laxatives and stool softeners are available, including surface-acting stool softeners, such as docusate; stimulant laxatives, such as bisacodyl, castor oil, and the anthraquinones senna, cascara, and frangula; osmotic agents, such as magnesium and phosphate salts and sorbitol; and lubricants, such as mineral oil. Many of the studies evaluating the efficacy of these agents are relatively small and do not provide convincing data to support or refute their use. In addition, many of these studies are poorly designed, making it difficult to glean useful information.

**META-ANALYSIS AND SYSTEMATIC REVIEW**

With the goal of including large placebo-controlled trials in a meta-analysis of studies on the efficacy of laxatives in constipation, Jones et al reviewed 250 articles in the literature.\textsuperscript{18} Of 35\textsuperscript{15} articles that met the inclusion criteria, only 11 yielded useful data from a total of 375 patients treated with laxatives and 174 patients receiving placebo. In studies lasting less than 4 weeks, laxatives increased weekly stool frequency by 1.9 (vs 1.0 for placebo) and stool weight by 476 g (vs 434 g for placebo), differences that were not statistically significant. No differences were seen in studies lasting 5 to 12 weeks. In contrast, a systematic review of trials evaluating OTC and prescription laxatives and stool softeners between 1966 and 2003 found good supporting evidence (Grade A) for the prescription agents tegaserod (Zelnorm; Novartis Pharmaceuticals, East Hanover, NJ) and polyethylene glycol (PEG) 3350 (Glycolax; Schwarz Pharma, Inc., Mequon, Wis; MiraLax; Braintree Laboratories, Inc., Braintree, Mass), moderate evidence (Grade B) for psyllium husk and lactulose, and limited evidence for milk of magnesia, senna, bisacodyl, and stool softeners.\textsuperscript{19}

**STOOL SOFTENERS**

One of the larger studies of stool softeners compared the efficacy of psyllium husk 5 g twice daily versus docusate 100 mg twice daily in 170 patients with constipation.\textsuperscript{20} All patients received therapy for 2 weeks after a 2-week baseline run-in period. As shown in Table 1, psyllium husk was significantly superior to docusate in all efficacy measures, except stool frequency per week, which was similar in both groups.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Psyllium</th>
<th>Docusate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stool water increase</td>
<td>2.33%\textsuperscript{*}</td>
<td>0.01%</td>
</tr>
<tr>
<td>Stool water weight (per bowel movement)</td>
<td>84.0 g\textsuperscript{†}</td>
<td>71.4 g</td>
</tr>
<tr>
<td>Stool weight</td>
<td>359.9 g/week\textsuperscript{‡}</td>
<td>271.9 g/week</td>
</tr>
<tr>
<td>Constipation relief score</td>
<td>475.1\textsuperscript{§}</td>
<td>403.9</td>
</tr>
<tr>
<td>Stool frequency per week</td>
<td>3.5</td>
<td>2.9</td>
</tr>
</tbody>
</table>

\textsuperscript{*} P = .007; \textsuperscript{†} P = .04; \textsuperscript{‡} P = .005; \textsuperscript{§} P = .002.

Data from McRorie et al.\textsuperscript{20}

**FOLLOW-UP ASSESSMENT 1**

- No increase in stool frequency or improvement in stool consistency after increased intake of bran muffins, bran cereal, salads, and bran supplements
- Straining is still present
- Bran supplements caused significant bloating

**RECOMMENDATIONS**

- Milk of magnesia; 2 tablespoons at bedtime
- If no response, add senna-based laxative as needed
- If still no response, switch to sorbitol
**Stimulant Laxatives**

Studies of stimulant laxatives have shown that they produce physiologic effects in patients with constipation and in controls. In a study of 18 patients with slow-transit constipation, bisacodyl elicited pelvic colon peristaltic waves in 11 patients. In another study, bisacodyl produced more rapid and frequent high-amplitude propagating contractions in patients with slow-transit constipation and controls, with the effect more pronounced in controls. The study also found that senna reversed constipation induced by loperamide (Imodium; McNeil Consumer Healthcare, Fort Washington, Pa).

Other studies assessing the effects of stimulant laxatives on constipation symptoms found that senna produced additive effects. In a study of 42 nursing home patients, senna plus dicytolsodium sulfosuccinate with fiber and fluid produced satisfactory defecation in 86%. In another study, psyllium husk plus senna increased stool water and produced an adequate laxative effect in 63% of patients with constipation compared to 48% for psyllium husk alone.

**Over-the-Counter Versus Prescription Laxatives**

The prescription laxatives lactulose and PEG are addressed in detail elsewhere in this monograph, but are briefly mentioned in this section because they have been compared to OTC agents or with each other in various studies.

Results from some studies comparing lactulose with various fiber supplements or bulking agents have suggested that fiber and other agents produced more satisfactory responses than lactulose. One study found that lactulose was superior to ispaghula, whereas another found no difference between lactulose and sorbitol in preference and symptomatic relief, leading the investigators to recommend sorbitol because of its lower cost. An early study (essentially placebo-controlled because it compared lactulose to glucose, which has no independent laxative effect) found that lactulose was very effective in increasing stool frequency and decreasing constipation-associated symptoms.

Results from several studies evaluating PEG have been favorable. A physiologic study showed that it increased stool frequency without any adverse effects on standard measures of colonic motor activity, whereas placebo-controlled studies demonstrated that it increased stool frequency and was very effective in relieving constipation-related symptoms. In addition, trials comparing PEG to lactulose found that PEG was more effective in increasing stool frequency and reducing pain, straining, and flatulence.

**Metabolic Complications of Laxative Therapy**

Although there has been some concern about metabolic complications of prescription laxatives, these complications are also seen with OTC agents, particularly the osmotic laxatives. For example, laxatives containing magnesium can produce neuromuscular blockade with severe weakness, cardiac dysfunction with hypotension, and paralytic ileus. Similarly, enemas containing sodium phosphate can cause hyperphosphatemic hypocalcemic coma, hypernatremia, hypokalemia, metabolic acidosis, and circulatory failure, all of which are significantly exacerbated by coexistent chronic renal insufficiency.

One area of controversy over the years is the role of anthraquinones in cathartic colon, a condition that was common 50 or 60 years ago, but is very uncommon today even though senna laxatives are still used fairly often. The subject is still controversial, as reflected by the findings of 2 of a handful of studies done in the 1990s. One study, which examined colon biopsy specimens from patients with constipation treated with anthraquinones and other laxatives, found no difference between the groups in the number of damaged neurons or type 1 vesicles. However, the other study, which used barium to assess patients taking anthraquinones 3 or more times per week and patients taking other laxatives, found that colon redundancy, dilation, and loss of haustra were more common in the former group. It was unclear whether the drugs accounted for the increased prevalence or whether patients with underlying colonic motility problems tended to use anthraquinones more often.

Another unresolved issue is whether laxative use increases the risk of colon cancer. A large population-based study from Japan found that the relative risk of colon cancer was significantly higher in constipated patients who used laxatives frequently than in those who did not (2.75 vs 1.35 for constipation alone). Conversely, a case-control series in North Carolina found that the odds ratio was higher for constipation alone than for laxative use, leading the investigators to
conclude that laxative use did not increase the risk for colon cancer. However, a meta-analysis of 14 series, which found nearly identical odds ratios for constipation alone and laxative use, questioned whether the odds ratios reflected dietary alterations and whether constipation or laxative use played a role in the development of colon cancer.

**Biofeedback**

Anorectal function is regulated by the anal sphincters and the pelvic sling muscles that normally relax during defection. When they fail to relax, as happens in adult-onset Hirschsprung’s disease, rectoceles, intussusception, and rectosphincteric dysynergia, there is outlet obstruction that interferes with the passage of stool.

Dysynergia is the prototypical constipation-related condition for which biofeedback is used, and in which it has been most extensively studied. Three types of biofeedback are commonly employed in patients with dysynergic defection: anal pressure/rectal sensation using manometry, anal pressure/rectal sensation using balloon inflation across the anus, and electromyography (EMG) using surface electrodes. As shown in the left panel of the Figure, manometric tracings of dysynergia reveal normal rectal contraction with attempted defection, but a paradoxical increase in anal pressure. The goal of biofeedback is to train the patient to relax the anal sphincter during defection so that their manometric tracings resemble those shown in the right panel of the Figure.

A critical review of 38 articles reporting use of biofeedback in constipation between 1970 and 2000 identified 10 studies with parallel design. The review

### Follow-up Assessment 2

- No improvement with laxatives, which produced cramps
- Functional testing revealed:
  - Colonic transit: 147 hours, slow in all regions
  - Anorectal manometry: paradoxical contraction on simulated defection and inability to pass balloon
  - Defecography: small rectocele, paradoxical increase in anorectal angle with defection
- Referred for biofeedback

---

**Figure. Manometric Tracings in Dyssynergia Before and After Biofeedback Training**

---
of these 10 studies found that pressure biofeedback with manometry was more successful than EMG biofeedback (78% vs 70%), that the success rates for intra-anal and perianal biofeedback were similar (69% and 72%), and that there was no clear predictor of who would respond favorably and who would not.

Favorable findings from a study assessing the physiologic effects of biofeedback on anorectal function in 25 patients with obstructive defecation are shown in Table 2, but data regarding long-term benefits are more variable. In 1 study, 12 of 24 patients with dyssynergia who responded to biofeedback initially maintained the benefits of therapy over time, but the remaining 12 patients did not. In another study, which followed 50 patients for 12 to 24 months, biofeedback was helpful in 70%, with constipation less severe in 62.5%. However, still another study found that 19 of 22 patients regressed to prebiofeedback status after 35 months.

In contrast to the critical review that found no clear predictors of response and a study finding that neither diet, pelvic exercise, manometry, EMG, nor rectal sensation predicted response, some studies have identified factors that are predictive. For example, one study found that lack of anal relaxation and inability to pass a 1-mL balloon were associated with failure, whereas another found that biofeedback was more effective in patients with normal anorectal physiology. A third study identified the number of biofeedback sessions as a predictor of outcome, with success in 18% of patients attending 2 to 4 sessions compared to 44% in those attending 5 or more sessions.

Biofeedback has also been shown to be helpful in constipation that is not caused by dyssynergia. A study of 100 patients who received biofeedback more than 1 year earlier found that although 65% had slow-transit constipation and 59% had dyssynergia, 55% of the group as a whole found biofeedback to be helpful at 1 year, with equal responses in those with slow and normal transit, with or without paradoxical contraction.

Surgery

Subtotal colectomy with ileorectal anastomosis is considered the therapy of last resort for refractory slow-transit constipation. Several reports have been published on the procedure and its variations. Responses were similar in the 8 reports published since 2000, with approximately 60% to 90% of patients having good results. However, there was significant postoperative morbidity in many of the reported series, including pain, incontinence, diarrhea, ileus, and small bowel obstructions. In 1 of the studies, which involved colectomy and the placement of ileostomy, stomal retractions developed in 25% of the patients, hernia in 8%, sepsis in 3%, and persistence of difficult evacuation in 4%.

Colectomy has also been examined in mixed patterns of constipation. In a series of 16 patients with slow-transit constipation plus dyssynergia, colectomy resolved symptoms in 7. However, 2 patients had severe incomplete evacuation that was unresponsive to

### Table 2. Physiologic Effects of Biofeedback

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage anal relaxation</td>
<td>Increased</td>
</tr>
<tr>
<td>Intrarectal pressure</td>
<td>Increased</td>
</tr>
<tr>
<td>Defecation index</td>
<td>Increased</td>
</tr>
<tr>
<td>Balloon expulsion time</td>
<td>Decreased</td>
</tr>
<tr>
<td>Straining effort</td>
<td>Decreased</td>
</tr>
<tr>
<td>Rectal sensation</td>
<td>Improved</td>
</tr>
<tr>
<td>Satisfaction with bowel movement</td>
<td>Improved in 60%</td>
</tr>
<tr>
<td>Laxative use</td>
<td>Decreased</td>
</tr>
<tr>
<td>Digital disimpaction</td>
<td>Markedly decreased (94%)</td>
</tr>
</tbody>
</table>

Data from Rao et al.
additional sessions of biofeedback, 3 had diarrhea, and only 9 were satisfied with the surgery.

Other conditions associated with constipation that may be treated surgically are rectocele and rectal intussusception. Studies involving surgical closure of the rectocele have generally shown response rates of 70% to 80%. However, as demonstrated in 3 of these studies, patients with slow-transit constipation, dyssynergia, or reduced rectal sensation do not respond as well to rectocele repair.

Data on retropexy with or without resection for rectal intussusception are limited, but available studies show a high degree of patient satisfaction, good to excellent response rates at 1 year, with a low incidence of complications, and a reduction in constipation and transit time.

Other therapies for constipation include anal dilation, botulinum toxin, and electrogalvanic stimulation to relieve outlet obstruction, and various surgical approaches to specific conditions underlying constipation. These include endorectal pull-through, the Duhamel procedure, ileocolic anastomosis, and myomectomy for Hirschsprung’s disease; reduction rectoplasty for megarectum; division of the puborectalis for dyssynergia; and antegrade enema, colonic pacing, and sacral nerve stimulation for slow-transit constipation.

**CONCLUSIONS**

Nonpharmacologic and OTC therapies for chronic constipation include alterations in fluid and fiber intake, OTC fiber supplements and laxatives, biofeedback, and surgery.

Data on lifestyle measures have shown that increased fluid intake and exercise have little or no effect on constipation. Studies examining the effect of OTC fiber supplements have found beneficial effects on colonic transit for some agents in some patients, but they have also found no effect on or exacerbation of symptoms, such as abdominal pain or bloating.

A similar situation exists with OTC laxatives, in which many studies evaluating efficacy are relatively small and do not provide convincing data to support or refute their use. Biofeedback data are more consistent in demonstrating benefit, with some studies identifying subsets of patients who are more likely and less likely to respond. Surgery, which is considered the option of last resort, provides reasonably good results, but it is also associated with considerable postoperative morbidity.

**DISCUSSION**

**Dr Lee:** How many biofeedback sessions over what period of time are typical for patients with constipation? How well do patients comply?

**Dr Hasler:** That varies from center to center. At our center, we typically schedule patients for 3 consecutive sessions, separated by 3 to 4 weeks in most cases. Then we re-evaluate to see if they’ve had any sort of response in terms of symptoms. Our institution switched from manometry-based biofeedback to EMG, thus we also like to see EMG evidence of success. If there’s a response, we will use biofeedback again as needed, but if there’s absolutely no response, we usually discontinue it.

In terms of compliance, our rates have been pretty good, approximately 70% or better, because our patients tend to be at the end of their rope. Most have failed all laxative therapy, and they’re ready to try anything.

**Dr Rao:** That’s similar to what we do, although we tailor the number of sessions to the needs of the patient. There is no fixed number, but 6 is fairly typical.

The number of sessions for a given patient depends on many factors, including the patient, the level of understanding of the instruments and the equipment, the willingness to work on some of the initial issues, and the ability to learn and master a new technique. It’s a question of trial and error. It takes a lot of learning. Some patients are quick learners, some are slow learners, and some are not well motivated. Our program includes a 1-hour education and training session, and then we schedule biweekly sessions thereafter. We rarely go beyond 6 sessions. If they haven’t responded by then, I usually make a determination that it’s not working and I discontinue biofeedback.

If they do respond, I offer 3 more sessions over the next year—at 6 weeks, 3 months, and 6 months—as reinforcement. That’s an important component, even though we have not assessed it in a prospective or controlled fashion. It’s important in ensuring the long-term beneficial effects of biofeedback.

**Dr Lembo:** What if the manometry pattern normalizes after the first or second session? Do you stop them or do you still have them come back?

**Dr Rao:** If the manometry pattern normalizes, it often goes hand-in-hand with the ability to expel the balloon easily, within a few seconds perhaps, and with symptomatic improvement. However, that rarely hap-
pens after only 2 sessions. Even if it does, there may be some persistent straining or hard stools.

In addition, there are some people who continue to do digital disimpaction, despite normalization of the manometry pattern. We try to address all of their symptoms and try to get them back to more normal physiologic behavior. We address why they have to use digital maneuvers and how they can overcome it.

**Dr Lembo:** Ones of the issues that comes up is the lack of sensitivity of any one test, or even all the tests, used in diagnosis. Even patients with normal test findings seem to get better with biofeedback. Do you really need to do any tests? If you have a high degree of clinical suspicion, based on symptoms or the physical examination, why can't you just send the patient for biofeedback without a lot of testing that doesn't have very good sensitivity or specificity?

**Dr Rao:** St Mark's group is moving towards that kind of strategy, and Michael Kamm thinks that may be a way to go. He sends all patients in his practice, whether they have fecal incontinence or constipation, for biofeedback first. If they fail, he does the evaluation and testing. That approach is acceptable at St Mark's, but it won't serve well at my institution.

I believe in testing first because it gives me a much better understanding of what the problem is before I embark on treatment. Some patients probably don't need any biofeedback training, which is labor intensive and requires a lot of motivation. If a patient's ability to relax the pelvic floor is normal, or if an incontinent patient has a normal manometric profile, you can't make them better physiologically. They are already normal.

You can send patients for anorectal manometry to identify abnormalities and then go ahead with biofeedback; that's a reasonable argument. However, if they don't have abnormalities, you then have to have a consult and find out what's going on. I still think biofeedback should be preceded by testing to identify pelvic floor dysfunction. If it's present, then proceed with appropriate management or behavioral therapy.

Another important point about biofeedback is that it is a holistic approach. It comprises several interventions in addition to the physiologic conditioning. You're probably changing their laxatives, you're changing their lifestyle, and you're teaching them timed toileting and maybe even coping strategies. Patients find all of these to be helpful. That is why we performed controlled studies to see if these factors were responsible for improvement rather than the physiologic conditioning. Our studies clearly showed that physiologic conditioning truly makes a difference.**

**Dr Bharucha:** There was a paper by Chiarioni et al in Gastroenterology earlier this year showing that an abnormal balloon expulsion test predicts a positive response to biofeedback therapy in constipated patients.**

**Dr Lembo:** That's something you can do in your office.

**REFERENCES**


