



PELVIC FLOOR DYSFUNCTION

Bowel management for the gynecologist



>> Michael R. Polin, MD
Dr. Polin is Fellow, Female Pelvic Medicine and Reconstructive Surgery, and Clinical Instructor, Obstetrics and Gynecology, Department of Obstetrics and Gynecology, at Duke University in Durham, North Carolina.



>> Cindy L. Amundsen, MD
Dr. Amundsen is Professor and Female Pelvic Medicine and Reconstructive Surgery Fellowship Director, Department of Obstetrics and Gynecology, at Duke University.

Dr. Polin reports no financial relationships relevant to this article. Dr. Amundsen reports that she receives grant or research support from the National Institutes of Health.

IN THIS ARTICLE

Evaluation algorithm for chronic constipation

Page 19

Probiotics: trend or valid treatment?

Page 25

Bowel prep for vaginal surgery

Page e1

Constipation is estimated to affect up to 27% of the general population and is more common in women, with a 2:1 female-to-male ratio.¹ Because gynecologists are frequently the main care provider for many women, understanding the diagnosis and treatment options for constipation is important. Additionally, gynecologists must manage bowel function during the perioperative period.

The diagnosis of constipation is based on the Rome III criteria.² Besides frequency of bowel movements (BMs), these criteria include evacuation symptoms and the presence of hard stools (TABLE 1). These symptoms can result from delay in colonic transit or outlet dysfunction. Constipation may be secondary to medical illness, such as central or peripheral neurologic disease, diabetes

TABLE 1 Rome III criteria for functional constipation in adults*

1. Must include ≥2 of the following signs or symptoms:

- Straining during ≥25% of defecations
- Lumpy or hard stools in ≥25% of defecations
- Sensation of incomplete evacuation for ≥25% of defecations
- Sensation of anorectal obstruction/blockage for ≥25% of defecations
- Manual maneuvers to facilitate ≥25% of defecations (ie, digital evacuation, support of the pelvic floor)
- <3 defecations per week

2. Loose stools are rarely present without the use of laxatives

3. Insufficient criteria for irritable bowel syndrome

*At least 3 months, with symptoms beginning ≥6 months before diagnosis.

TABLE 2 Common treatments for constipation

Bulk-forming laxatives absorb water, increasing fecal mass

- psyllium seed (Metamucil)
- methylcellulose (Citrucel)
- calcium polycarbophil (FiberCon)
- wheat Dextran (Benefiber)

Surfactant agents lower the surface tension of stool, allowing water to enter the stool

- docusate sodium (Colace)

Osmotic laxatives contain poorly/nonabsorbed substances, leading to intestinal water secretion

- polyethylene glycol (MiraLAX)
- magnesium citrate (Milk of Magnesia)

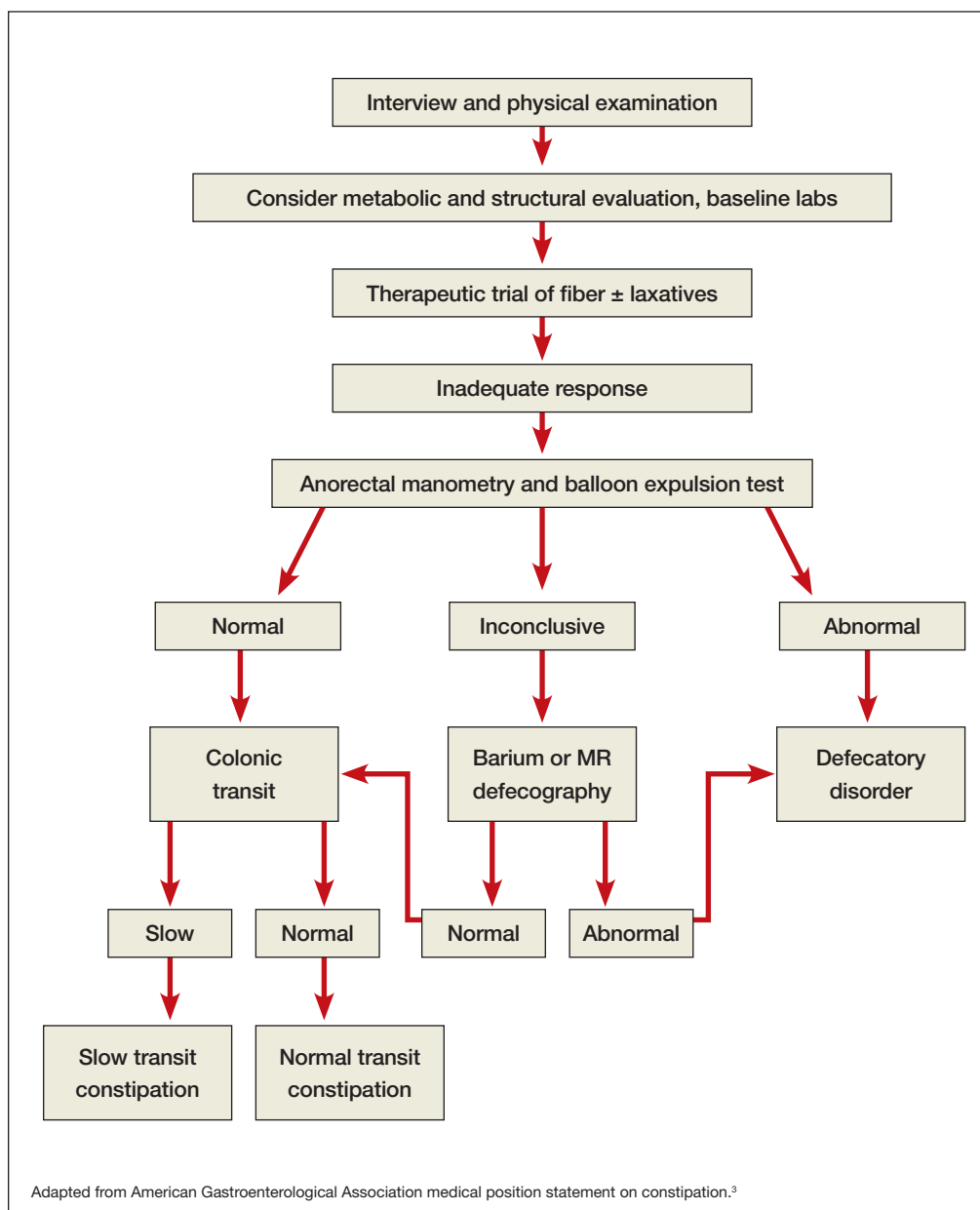
Stimulant laxatives increase colonic transit and alter electrolyte transport across the colonic mucosa

- bisacodyl (Dulcolax)
- senna (Senokot)

mellitus, hypothyroidism, or medications. Evaluation begins with a careful history and vaginal and perianal/anal examination.³ Initially, a trial of fiber supplementation with or without over-the-counter (OTC) laxatives may be tried (TABLE 2). If patients have an inadequate response to this therapy, further evaluation may be pursued (ALGORITHM).

In this article, we review the results of randomized trials comparing the efficacy of OTC medical treatments for constipation, including daily, low-dose polyethylene glycol (PEG) and probiotics. Additionally, we review key trials evaluating perioperative bowel management prior to laparoscopic gynecologic and vaginal surgery.

Evaluation algorithm for chronic constipation



If patients have an inadequate response to fiber supplementation with or without over-the-counter laxatives, further evaluation may be pursued

CONTINUED ON PAGE 24



Long-term PEG usage safe and effective?

Corazziari E, Badiali D, Bazzocchi G, et al. Long-term efficacy, safety, and tolerability of low daily doses of isosmotic polyethylene glycol electrolyte balanced solution (PMF-100) in the treatment of functional chronic constipation. Gut. 2000;46(4):522-526.

In this multicenter, randomized, double-blind, placebo-controlled, parallel trial, investigators evaluated the safety, efficacy, and tolerability of a daily low-dose PEG-based osmotic diuretic.

Details of the study

Seventy-eight patients (80% of them female) aged 18 to 75 years with chronic constipation, defined by Rome III diagnostic criteria, underwent a 4-week “run-in” period, with a standardized daily diet of fiber 15 g, water 1500 mL, and twice-daily PMF-100 (PEG/osmotic solution). Patients were randomized if they responded to the regimen, with response defined as having at least two BMs per week and no defecatory disturbance or at least three BMs per week with or without defecatory disturbance. Eight patients were not randomized, one due to nonresponsiveness. Study patients completed 20 weeks of either twice-daily PMF-100 or placebo. Patients, at their own discretion, decreased the frequency of the study drug based on the frequency of their BMs. Use of another laxative was not allowed unless a BM had not occurred over a 5-day period.

The combined primary outcome was at least three BMs per week, no defecatory disturbances, and no additional laxative use. Secondary outcomes (frequency of BMs and defecatory disturbances) were assessed using a bowel diary.

No differences were noted in baseline

measurements between the two groups. Of the PMF-100 group, 70% completed the study, compared with 30% of the placebo group ($P<.01$). Nonresponse to treatment was the reason for dropout in 7% and 46% of patients, respectively ($P<.005$). Other causes of withdrawal did not differ between the groups.

At the end of the 20 weeks, 77% of patients in the PMF-100 group reported remission, compared with 20% in the placebo group ($P<.001$). During the study, the PMF-100 group reported more BMs per week (7.4 vs 4.3; $P<.001$). Furthermore, the treatment group was less likely to report straining at defecation, hard/pellet stools, and need for use of additional laxatives. Adverse events (nausea, anal pain/itching, hematochezia, epigastric pain, and fecal incontinence) were similar between groups. There were no differences in laboratory values.

Study strengths

This was a well-designed trial showing the safety, efficacy, and tolerability of a daily low-dose PEG-based osmotic diuretic. The population was mainly women with functional chronic constipation, similar to a gynecologic population. The results of this trial are consistent with what has been shown for other trials evaluating various PEG preparations.^{4,5}

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Women who fail initial fiber therapy may respond to daily low-dose PEG on a continuous basis. Resolution of constipation and defecatory symptoms is likely and should be seen within 1 month. Therapy can be continued safely for at least 6 months.



Low-dose polyethylene glycol/osmotic solution resulted in constipation remission in 77% of patients



New and trendy OTC treatment option

Del Piano M, Carmagnola S, Anderloni A, et al. The use of probiotics in healthy volunteers with evacuation disorders and hard stools: a double-blind, randomized, placebo-controlled study. J Clin Gastroenterol. 2010;44(suppl 1):S30-S34.

Factors such as age, unhealthy diet, and use of prescription drugs alter the intestinal bacterial flora. As patients strive for a more holistic approach to their health, interest is growing in the benefit of probiotics for treating chronic constipation. To explore the value of such probiotics, Del Piano and colleagues conducted a three-armed, randomized, double-blind placebo-controlled trial of two different probiotic preparations and a placebo among patients aged 24 to 71 years with evacuation disorders and constipation.

Details of the study

One probiotic preparation (A) was composed of *Lactobacillus plantarum* and *Bifidobacterium breve* at a concentration of 2.5×10^9 cfu per day; the other (B) was composed of *Bifidobacterium animalis* subspecies *lactis* at a concentration of 5×10^9 cfu per day. Patients took their preparation for 30 days and recorded data on weekly defecations (primary outcome), along with feces consistency, ease of expulsion, sensation emptying, anal itching/burning/pain with defecation, and abdominal bloating (secondary outcomes).

A total of 300 patients were enrolled in the study; 50% were female. No difference was noted in baseline symptoms among the three groups. No change from baseline was noted in BMs per week within the placebo group during the 30 days (5.6 vs 5.8, respectively).

However, both probiotic preparations resulted in increased bowel frequency by day 30 (5.3 vs 7.3 BMs per week for probiotic A [$P < .001$] and 5.8 vs 6.9 BMs per week for probiotic B [$P < .001$]).

When comparing each probiotic with the placebo at days 15 and 30, a statistically significant increase in bowel frequency was found with each probiotic preparation. Furthermore, all secondary outcomes improved during the 30 days with the probiotic preparations but not the placebo. There was a statistically significant improvement in these variables when either probiotic was compared with placebo. No adverse events were reported.

Strengths and limitations

This randomized, double-blind, placebo-controlled trial showed improvement in bowel frequency, based on a bowel diary, with two different probiotic preparations when compared with placebo. The study population did not have to meet Rome III criteria for constipation, and baseline frequency of BMs was high. Patients did report subjective improvement in their defecatory symptoms with both probiotic preparations, but use of validated questionnaires would have strengthened this finding.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Patients with mild constipation and defecatory complaints may benefit from the addition of a probiotic preparation. However, more thorough studies need to be performed to characterize the true extent of probiotics' benefits.



Two different probiotic preparations significantly increased bowel movement frequency within 30 days compared with placebo



Bowel prep before laparoscopic gynecologic surgery

Siedhoff MT, Clark LH, Hobbs KA, Findley AD, Moulder JK, Garrett JM. Mechanic bowel preparation before laparoscopic hysterectomy: a randomized controlled trial. Obstet Gynecol. 2014;123(3):562-567.

Over the past decade, extrapolation of data from colorectal surgery literature, showing no benefit from preoperative mechanical bowel preparation,⁶ has led to less frequent use of mechanical bowel preparations for open benign gynecologic surgery. Nevertheless, there has been slower adoption of this practice with laparoscopic and vaginal surgery. In a recent study, Siedhoff and colleagues explored surgeons' assessments of surgical field exposure in patients who did and did not complete preoperative mechanical bowel preparation.

Details of the study

This was a single-masked, randomized, controlled trial involving women undergoing laparoscopic hysterectomy for benign indications. Patients were randomly assigned to either a sodium phosphate enema the night before surgery and, if their stool was not clear, another enema on the morning of surgery versus no preparation. All patients had clear liquids the day prior to surgery, then fasted beginning at midnight. The surgeon was blinded to the randomization.

The primary outcome was a questionnaire completed by the surgeon that assessed surgical field exposure. Secondarily, patients completed a questionnaire addressing symptoms (cramps, hunger, bloating, embarrassment, insomnia, weakness, dizziness, thirst, nausea, and incontinence).

Baseline characteristics of the 160 randomized patients did not differ between

the two groups. Analysis was on an intent-to-treat basis, but only two patients did not complete the bowel preparation. Overall, the study population had a mean age of 41 and body mass index of 33.5 kg/m². No differences were noted in surgical characteristics between the two groups, including complication rate. The mean surgery time was 139 minutes with a mean estimated blood loss of 61 mL and a mean uterine weight of 385 g.

The surgeon's assessment of the surgical field did not differ between the two groups. This finding also held true when subgroup analysis was performed for obesity, endometriosis, irritable bowel syndrome or inflammatory bowel disease, and chronic constipation. Interestingly, the odds of the surgeon guessing whether a patient had had a preparation were 50:50. The only difference in patient symptoms was an increase in insomnia in the no-preparation group.

Minor drawback

This well-performed trial demonstrated no significant value for mechanical bowel preparation before benign laparoscopic hysterectomy in a young population. How these results might extrapolate to an older population who may have a higher rate of prior pelvic surgery or diverticular disease is uncertain.

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Women undergoing laparoscopic hysterectomy for a benign indication may forego a mechanical bowel preparation as such preparation did not improve the surgical field.



Bowel preparation did not lead to significant between-group differences in this young study population (mean age, 41 years)



Bowel prep before vaginal surgery

Ballard AC, Parker-Autry CY, Markland AD, Varner RE, Huisingsh C, Richter HE. Bowel preparation before vaginal prolapse surgery: a randomized controlled trial. Obstet Gynecol. 2014;123(2 pt 1):232-238.

In this single-masked, randomized controlled trial in women undergoing reconstructive vaginal prolapse surgery, Ballard and colleagues randomly assigned patients to either a clear liquid diet with two saline enemas the day before surgery or a regular diet the day before surgery.

Details of the study


All 150 patients were instructed to fast beginning at midnight the night before surgery, and the surgeon was blinded to randomization. The study's primary outcome was the surgeon's perception of the operative field assessed by a questionnaire. The secondary outcome was the patient's satisfaction with their preoperative regimen as reported on validated questionnaires.

An intent-to-treat analysis was performed (mean age, 60 years); 84% of patients assigned to bowel preparation completed more than 50% of the enemas. Baseline characteristics and surgical procedures were similar between groups. Approximately 33% of patients underwent hysterectomy concomitantly with the prolapse repair. Operative time, estimated blood loss, and bowel injury were similar between the two groups.

No difference between groups was noted in the surgeons' assessment of the surgical field—which was rated as excellent or good in 85% of patients who underwent the

bowel preparation compared with 90% in the no-preparation group ($P = .3$). Additionally, no difference was noted in the presence of rectal stool or gas by inspection and palpation. Patient satisfaction was significantly lower among those who underwent bowel preparation compared with patients who did not. Patients undergoing bowel preparation were more likely to have abdominal fullness or bloating ($P = .004$), abdominal cramps or pain ($P < .001$), anal irritation ($P < .001$), and hunger pains ($P < .001$).

Prep group saw no benefit and decreased satisfaction

This well-performed clinical trial showed that the use of mechanical bowel preparation did not significantly improve surgeons' intraoperative acceptability of the operative field during vaginal prolapse surgery. However, approximately 25% of patients underwent sacrospinous suspensions; therefore, intraperitoneal access was not necessary in these patients. The study results demonstrated decreased patient satisfaction and more distressing bowel symptoms in patients who underwent a mechanical bowel preparation with an enema. 



Bowel preparation led to decreased patient satisfaction and increased likelihood of abdominal bloating, cramps, or pain; anal irritation; and hunger pains

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Use of a mechanical bowel preparation is not necessary to improve the surgical field in vaginal prolapse surgery. Not having patients undergo a bowel preparation will improve patients' assessment of their preparation for surgery.

References

- Higgins PD, Johanson JF. Epidemiology of constipation in North America: a systematic review. *Am J Gastroenterol.* 2004;99(4):750-759.
- Longstreth GE, Thompson WG, Chey WD, Houghton LA, Mearin F, Spiller RC. Functional bowel disorders. *Gastroenterology.* 2006;130(5):1480-1491.
- Bharucha AE, Dom SD, Lembo A, Pressman A. American Gastroenterological Association medical position statement on constipation. *Gastroenterology.* 2013;144(1):211-217.
- American College of Gastroenterology Chronic Constipation Task Force. An evidence-based approach to the management of chronic constipation in North America. *Am J Gastroenterol.* 2005;100(suppl 1):S1-S22.
- Ramkumar D, Rao SS. Efficacy and safety of traditional medical therapies for chronic constipation: systematic review. *Am J Gastroenterol.* 2005;100(4):936-971.
- Guenaga KF, Matos D, Wille-Jørgensen P. Mechanical bowel preparation for elective colorectal surgery. *Cochrane Database Syst Rev.* 2011;(9):CD001544.