# Fecal Incontinence

## Pathogenesis, Diagnosis, and Updated Treatment Strategies

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**KEYWORDS**

• Fecal incontinence • Accidental bowel leakage • Anal sphincter • Sphincter injury

**KEY POINTS**

- FI is common and often goes underreported to health care providers. Physicians should inquire about these symptoms.
- FI is commonly associated with older age; GI diseases and symptoms, such as change in bowel habits (typically loose and/or frequent stools, fecal urgency); and debility.
- First-line treatment involves a combination of dietary and lifestyle modifications. Second-line treatment involves the use of medications that help modify bowel habits, and biofeedback training. If conservative methods fail to improve FI symptoms, then other surgical options are considered, such as sacral nerve stimulation and anal sphincter augmentation.

## INTRODUCTION

Fecal incontinence (FI) is defined as the involuntary loss or passage of solid or liquid stool in patients. It is important to point out that the definition of FI does not include flatus incontinence nor fecal soilage. Fecal soilage is defined as the staining or streaking of underwear with fecal material or mucus. Additionally, anal incontinence (AI) and FI are often used interchangeably; however, AI comprises liquid and stool incontinence along with flatus incontinence in its definition.

With the publication of the Rome IV diagnostic criteria for FI in 2016, there were two key changes in the diagnosis of FI.[1] Rome IV does not distinguish structural or neurogenic causes from functional FI. With this change, the leaders from the Rome Foundation acknowledge that there are multiple, overlapping factors that lead to FI and that this prior distinction in Rome III had no impact in guiding treatment. With the Rome IV diagnostic criteria, the definition for the frequency of FI has also changed, from an

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Gastroenterol Clin N Am 51 (2022) 71–91
https://doi.org/10.1016/j.gtc.2021.10.005
0889-8553/22/Published by Elsevier Inc.

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occurrence once per month in Rome III to an occurrence of two times or greater per month in Rome IV.

Because of the disparate populations and definitions used in different studies, the prevalence of FI has varied widely, ranging from 2.0% to 20.7%.[2–6] The largest population-based survey using the National Institutes of Health Patient Reported Outcomes Measurement Information System gastrointestinal (GI) questionnaires found that one in seven people suffered from FI in their lifetime and approximately 1 in 20 had an FI episode in the last 7 days.[2] The prevalence of FI varies by age with the youngest participants having the lowest prevalence at 2.6% for those aged 20 to 29 years with increasing prevalence to 15.3% in subjects 70 years or older. The highest prevalence of FI is found in those living in nursing homes or other institutionalized settings, with a prevalence among this population between 46% and 67%.[7,8]

The true prevalence of FI is still likely underestimated because FI is significantly underreported by patients to their physicians.[9,10] Because of its embarrassing nature, patients are often reluctant to discuss their symptoms.[11–13] In a recent analysis of the Mature Women's Health Study, Brown and colleagues[9] found that two-thirds of women with FI do not seek care for their symptoms even though 40% of them had symptoms severe enough to impact their quality of life. Additionally, practitioners also bear some responsibility for the underdiagnosis of FI. Studies have demonstrated that all types of practitioners routinely fail to inquire about FI during outpatient visits.[14,15]

Quality of life is significantly negatively impacted in patients with FI. Patients report significant psychological stress with FI, causing anxiety and depression.[16,17] FI symptoms impact social activities, travel, and physical recreation.[12,18,19] For some, it leads to social isolation because of the fear and embarrassment of accidental bowel leakage.[20] To understand the burden of FI on patients, Rubin and colleagues[21] surveyed a cohort of severely ill, hospitalized subjects, of which 70% believed that bowel or bladder incontinence was as bad or worse than death. Among geriatricians, FI is a significant risk factor that increases the likelihood of referral of elderly patients to a nursing home.[22–24] Lastly, FI is associated with substantial economic costs to society.[14,25] Xu and colleagues[25] examined the direct and indirect costs of FI within the United States and found an average cost of $4110 per patient annually.

## PATHOGENESIS

Continence is a complex process that involves the interaction of a neurologically intact levator ani complex (puborectalis muscle), internal anal sphincter (IAS), external anal sphincter (EAS), and compliant rectum. FI often occurs from one or more insults to the continence process including altered bowel motility, anal sphincter muscle damage or weakening, etiologies for poor rectal compliance, which includes rectal inflammation, abnormal rectal sensation, and dysfunctional pelvic floor musculature. In 80% of patients, findings suggest more than one pathophysiologic factor that causes FI.[26] Aging impacts the mechanisms of continence in multiple ways. Both sphincters can be affected with fibrosis and thickening leading to decreased resting tone, with thinning of the EAS producing a weak squeeze pressure.[27,28] Additionally, decreased rectal sensation, rectal compliance, and rectal capacity all cause impairment of colorectal sensorimotor and rectal reservoir function.[29]

## RISK FACTORS

Multiple studies have been performed that have described risk factors for FI (**Table 1**).[8–11,13,23,30–33] Major risk factors for FI include advancing age, GI symptoms and GI diseases that cause changes in stool consistency, and nursing home

**Table 1**
**Risk factors for FI**

| Patient-Level Factors | Medical Comorbidities |
|---|---|
| Increasing age | Dementia |
| Latino | Diabetes mellitus |
| Obesity | HIV |
| Gender (controversial female > male) | Multiple chronic illnesses |
| Active tobacco use | Urinary incontinence |
| Non-Hispanic African American (protective) | Decreased mobility/debility |
| Asian (protective) | Neurologic diseases/prior stroke |
| Postmenopause | History of pelvic radiation |
| Nursing home resident | Multiple sclerosis |
| | History of prostate cancer |
| GI symptoms and diseases | Scleroderma |
| Diarrhea | Spinal cord injury |
| Rectal urgency | |
| Irritable bowel syndrome | Prior surgery |
| Inflammatory bowel disease | Cholecystectomy |
| Celiac disease | Hysterectomy |
| Chronic intermittent constipation | Anorectal surgery |
| Constipation/fecal impaction | Sphincterotomy |
| Rectal sensation disorders | Hemorrhoidectomy |
| Rectal hypersensitivity | Anterior resection of the rectum |
| Rectal hyposensitivity | Colectomy with/out ileoanal pouch anastomosis |
| Obstetric history | Drugs (see **Table 2**) |
| Multiparity | |
| Episiotomy | Pelvic floor disorders |
| Sphincter laceration | Rectocele |
| Operative delivery (forceps/vacuum) | Descending perineum syndrome |
| Prolonged second stage of labor | Rectal prolapse |
| Birthweight >8.8 lb | |

residency. The GI symptoms that are most strongly associated with FI are diarrhea and urgency.[2,3,30,31,34] However, any GI disease that can cause loose/watery stools or frequent bowel movements (more than 21 stools per week) can lead to FI.[2,3,15,32,34] Sometimes, FI may actually be caused by underlying constipation with or without fecal impaction, causing overflow diarrhea.[2,8] The mechanism of incontinence with diarrhea is multifactorial, but is likely caused by the increased difficulty of retaining loose/watery stool, which can overwhelm the anal sphincter as high volumes of effluent are delivered to the rectum under a short interval of time, reflex inhibition of the IAS, and/or interactions between the consistency of the stool and sphincter defects. Other major risk factors include diabetes mellitus, prior anorectal surgery, prostate cancer therapy, urinary incontinence, episiotomy, prior operative vaginal delivery or severe vaginal laceration, hysterectomy, anal intercourse, spinal injuries, and multiple chronic comorbidities.[2,3,33–40]

## DIAGNOSIS

The first step in identifying affected patients is to ask about FI. Patients prefer the term "accidental bowel leakage" over "fecal incontinence" or "bowel incontinence."[41] To start the conversation, your practice can add "accidental bowel leakage" to the GI review of systems for new or return-visit paperwork. It is important to obtain a detailed history. One must determine whether the patient has symptoms of fecal soilage or FI by the amount of leakage and characterizing stool consistency, FI frequency, and timing of episodes. Patients should be queried if the episodes are passive/insensate versus active/urge incontinence. It is these questions that can help elucidate the underlying mechanisms for their symptoms. If patients report passive incontinence, it indicates that there is more likely to be an issue with the IAS or peripheral neuropathy, whereas those with urge incontinence are more likely to have a problem with the EAS/puborectalis muscle, a noncompliant rectum, or diarrhea. In patients who report fecal soilage, there may be incomplete defecation, structural (ie, rectal prolapse), or rectal sensation issues. Current medications should be reviewed to identify any medication that can exacerbate FI (**Table 2**). It is also important to consider constipating medications as a cause for overflow diarrhea/overflow incontinence. The physical examination must include a digital rectal examination to assess for rectal prolapse, sphincter defects, rectal tone, and fecal impaction. If fecal impaction is present, then treatment should focus on the management of constipation. An algorithm for the evaluation and management of FI is described in **Fig. 1**.

### *Fecal Soilage*

An initial work-up for patients with fecal soilage should include anorectal manometry to evaluate for dyssynergic defecation. If present, the patient should be referred for

**Table 2**
**Medications that can exacerbate FI**

| | |
|---|---|
| Drugs that cause loose stools | Bariatric: orlistat<br>Cardiovascular: ACE inhibitors, ARB inhibitors, β-blockers, hydralazine, methyldopa, digoxin, procainamide, quinidine, statine, gemfibrozil, clofibrate, furosemide, acetazolamide, ethacrynic acid<br>Endocrine: metformin, GLP-1 receptor agonists, levothyroxine<br>GI: laxatives (sorbitol, lactulose), H2RAs, PPIs, magnesium-containing antacids, misoprostol, aminosalicylic acids, chenodeoxycholic acid, ursodeoxycholic acid<br>Heme/oncologic: chemotherapeutic agents, immune checkpoint inhibitors, epidermal growth factor receptor inhibitors<br>Infectious disease: broad-spectrum antibiotics<br>Neurologic: levodopa, benzodiazepines<br>Psychiatry: SSRIs, bupropion, nefazodone, trazadone, vortioxetine, lithium,<br>Rheumatologic: colchicine, NSAIDS<br>Random: magnesium supplements, bisphosphonates |
| Topical drugs applied to anus | Diltiazem gel, botulinum toxin A, glyceryl trinitrate ointment, bethanechol cream |
| Drugs that alter sphincter tone | SSRIs, β-blockers, nitrates, calcium channel antagonists, sildenafil, $\alpha_1$-adrenoreceptor blockers |

ACE, angiotensin-converting enzyme; ARB, angiotensin receptor blocker; NSAID, nonsteroidal anti-inflammatory drug; PPI, proton pump inhibitor; SSRI, selective serotonin reuptake inhibitor.

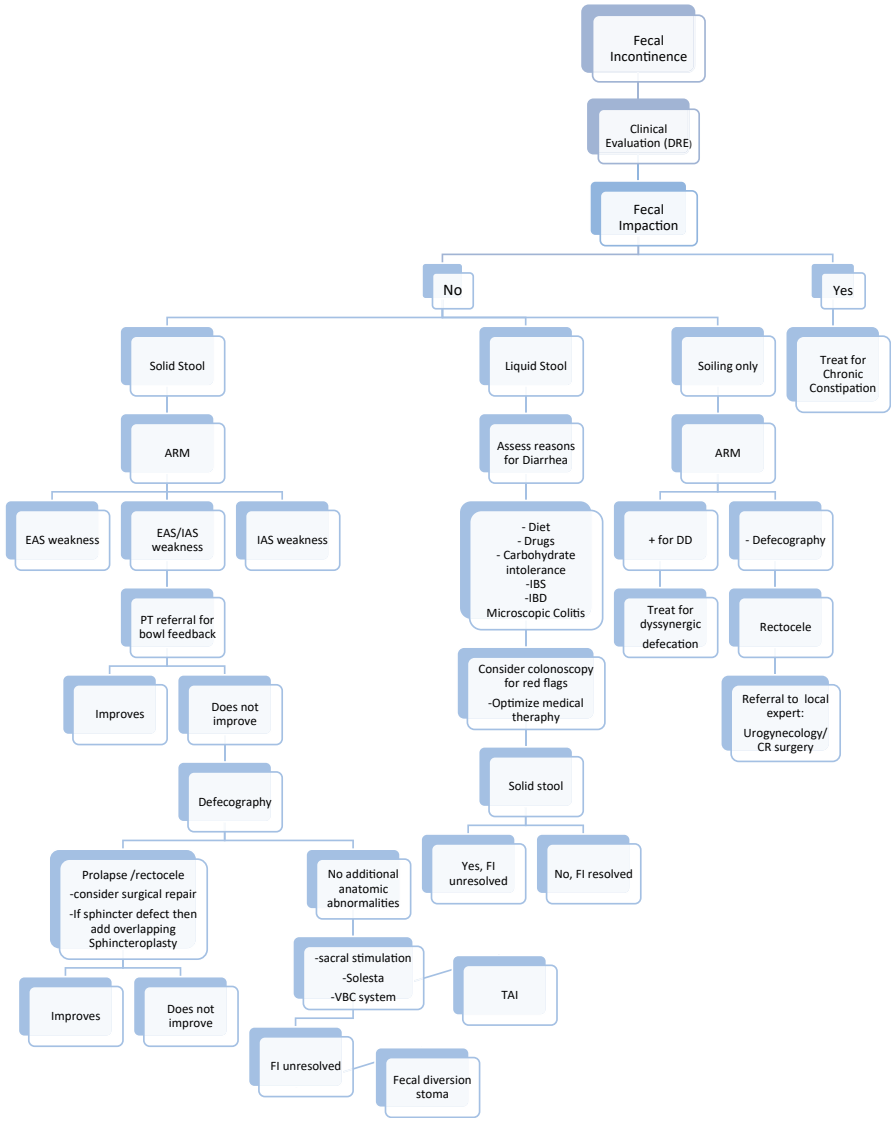


**Fig. 1.** FI treatment algorithm. ARM, anorectal manometry; CR, colorectal surgery; DD, dyssynergic defecation; DRE, digital rectal examination; IBD, inflammatory bowel disease; IBS, irritable bowel syndrome; PT, physical therapy; TAI, transanal irrigation; VBC, vaginal bowel control.

physical therapy and biofeedback training (BFT) and nonpharmacologic treatment options described next are considered (Fig. 1). Postvoid enemas are considered to remove residual stool in the rectum and anal canal.

### *Liquid Stool Incontinence*

If the patient is incontinent with liquid stool only, then evaluation for causes of diarrhea should be pursued. If there is GI bleeding or diarrhea is persistent and not meal-related or occurs during the nighttime hours, colonoscopy should be performed to rule out

organic diseases. Common causes of diarrhea include caffeine consumption, medication side effects, carbohydrate intolerance, microscopic colitis, irritable bowel syndrome, small intestinal bacterial overgrowth, bile acid malabsorption, and inflammatory bowel disease. Management generally focuses on dietary and lifestyle interventions and antidiarrheal pharmacologic options described next (see **Fig. 1**), but varies based on cause.

### *Solid Stool Incontinence*

The approach for the patient with solid stool incontinence should begin with anorectal manometry to evaluate for weakness in the EAS, IAS, or both. If present, then referral to physical therapy for BFT is appropriate. If incontinence does not improve, then functional imaging with either fluoroscopic defecography or MRI defecography should be performed to evaluate for concomitant anatomic abnormalities.[35,36] If pelvic organ prolapse or rectocele is identified, then referral for surgical intervention should be considered, with or without sphincter repair as indicated. If surgical options are being considered, then an endoscopic ultrasound or transanal ultrasound is needed to assess sphincter integrity. If no anatomic abnormalities are identified, minimally invasive approaches, such as injectable bulking agents or vaginal bowel control system, is attempted. If these methods fail, surgical intervention with implantation of a sacral nerve stimulator is used. Definitive treatment with fecal diversion via colostomy or ileostomy is considered when all other treatments fail (see **Fig. 1**).

## TREATMENT OF FECAL INCONTINENCE

Treatment of FI varies from noninvasive strategies, such as dietary and lifestyle changes, physical therapy with BFT, pharmacologic agents, sphincter augmentation methods with injectable bulking agents, and bowel control systems, to minimally invasive options, such as sacral nerve stimulation (SNS), to more invasive surgical interventions of sphincteroplasty or fecal diversion surgery. These options are listed in **Fig. 1**.

### *Dietary Interventions*

Dietary interventions should focus on foods and beverages that are known to cause loose stools or urgency. Some 50% to 70% of participants report dietary triggers including caffeine, dairy, and fat-free substitutes.[42,43] Additionally, foods that are high in fermentable oligo-, di-, and mono-saccharides and polyols (FODMAP) can cause symptoms of diarrhea and urgency. Therefore, avoidance or reduction of these triggers is helpful by reducing FI symptoms.[44,45] Dietary fiber and/or stool bulking agents, such as psyllium, can improve symptoms of FI. Patients with the highest amount of fiber in their diets are least likely to experience FI.[46] In a pilot trial comparing psyllium versus gum arabic versus placebo, Bliss and colleagues[47] demonstrated a significant decrease in FI episodes after 1 month of either psyllium (49% of stools at baseline associated with FI to 17% with psyllium) or gum arabic (66% of stools at baseline associated with FI to 18% with gum arabic) as compared with placebo. In a much larger follow-up trial of 189 patients, Bliss and colleagues[48] compared psyllium versus gum arabic versus carboxymethylcellulose versus placebo on FI frequency. Psyllium was associated with a 50% decrease in FI episodes, whereas carboxymethylcellulose increased FI episodes by 32%. Minimal change was noted in the gum arabic and placebo arms. The recommended daily fiber intake for adults is 25 to 35 g. Slow introduction of fiber of no more than 5 g/wk is suggested to avoid bloating.

### *Lifestyle Modifications*

Potentially modifiable risk factors, such as obesity, inactivity, and smoking, should be addressed.[49] Weight loss has been shown to improve FI in obese women.[50,51] Behavioral techniques for FI should also be implemented. This includes bowel-retraining techniques, such as toileting scheduling, particularly after meals to counter the gastrocolic reflex, and performing a few Kegel exercises between wiping to reduce episodes of incontinence.[52] People with FI should also be taught to pause and perform Kegel exercises when they feel an episode coming on rather than rush to the bathroom. Rushing to the toilet increases abdominal wall pressure, which can overwhelm a weak sphincter complex and increase the likelihood of incontinence.

Some patients may also benefit from vaginal splinting and/or techniques, such as anal wicking or postvoid enemas, to prevent fecal soilage or mild incontinence. Vaginal splinting is used in patients with an identified rectocele and involves the insertion of their finger into the vagina with pressure applied posteriorly toward the rectum.[53] Anal wicking is the technique of placing a long piece of cotton or a cotton ball shaped into a wick between the buttocks, resting directly on the anus so that mild seepage of fecal material is contained.[53] Lastly, patients may also benefit from perianal barrier creams to prevent skin excoriation and incontinence-associated dermatitis.[54]

### *Pharmacologic Therapy*

Up to two-thirds of FI episodes are associated with diarrhea or loose stool. Medications that decrease motility should be used in patients with FI.[3] These include antidiarrheal/antimotility agents, bile acid resins, tricyclic antidepressants, and others that can enhance anal sphincter tone.

Loperamide has been evaluated as a single agent or in combination with other treatments in three randomized controlled studies. The Fecal Incontinence Prescription (Rx) Management (FIRM) randomized, crossover study of 80 adults (68% male) by Markland and colleagues,[55] compared daily loperamide versus psyllium in the treatment of FI. Both groups demonstrated improvement in number of FI episodes per week (loperamide: 7.9–4.1, $P < .001$; psyllium: 7.3–4.8, $P = .008$) and quality of life, but there was no difference between loperamide and psyllium among these end points. Loperamide was associated with higher rates of constipation (29%) and abdominal pain (17%) than psyllium, and psyllium had higher rates of diarrhea (17.1%), but no other adverse effects were noted. One participant died while taking loperamide during the second intervention, although further commentary on this was not provided. In the CAPABLE trial by Jelovsek and colleagues,[56] 300 participants were randomly assigned to four groups: (1) oral placebo plus education, (2) placebo plus anorectal manometry–assisted biofeedback, (3) loperamide plus education, or (4) loperamide plus anorectal manometry–assisted biofeedback. All four groups demonstrated some improvement in St. Mark's score, although there was no significant difference between groups at 24 weeks. Similar to Markland and colleagues, constipation was the most common adverse event reported, occurring in 2% of the groups receiving loperamide. Sjodahl and colleagues[57] randomized 64 female patients to either biofeedback (4–6 months) or medical treatment with loperamide and a stool bulking agent (2 months) and then added the other therapy to provide a course of combination therapy. When used alone, both single treatments failed to significantly decrease FI episodes. However, the number of FI episodes decreased significantly with combination treatment (median, 6 episodes/2 weeks to 2.5 episodes/2 weeks; $P < .0001$).

It is estimated that 1% of the population has bile acid diarrhea, thus putting individuals at risk for FI.[58] Remes-Troche and coworkers[59] compared the use of BFT with cholestyramine matched to a group who underwent BFT only. Subjects in the combination therapy group showed decreased stool frequency ($P < .01$), improved stool consistency ($P = .001$), and a reduced number of incontinent episodes ($P < .04$). In contrast, in the BFT group, stool frequency ($P = .8$) and stool consistency (0.23) did not improve compared with baseline.

In another small, open trial of 20 mg of amitriptyline in 18 patients compared with 24 control subjects, 89% in the amitriptyline group reported reduction of FI episodes.[60] Amitriptyline also led to significant improvement in median incontinence score ($P < .001$) and anal pressure ($P < .001$) compared with baseline. However, general use is limited in the elderly population because of anticholinergic, orthostatic hypotension and sedating side effects.

In a Cochrane Review, Omar and Alexander[61] identified 16 trials evaluating the efficacy of various medications for the treatment of FI in heterogenous subjects including the elderly, postsurgical, and diarrhea cohorts. This review included seven antidiarrheal medication trials (loperamide, codeine, diphenoxylate plus atropine), six trials for medications that enhance anal sphincter tone (phenylephrine gel or sodium valproate), one trial of zinc aluminum ointment, and two trials of laxatives in patients with FI caused by constipation and overflow diarrhea. No studies that compared a medication with another treatment modality were included. Although the data are limited, these studies showed improvement in FI but most reported side effects (only zinc-aluminum ointment had no reported adverse effects). There were insufficient data to recommend any one type of medication over another.

### *Biofeedback Therapy*

Pelvic floor muscle training alone has been shown to be effective for the treatment of urinary incontinence, but outcomes for FI seem to be improved with the addition of BFT in uncontrolled studies.[62,63] BFT is a form of physical therapy that uses electronic instruments to monitor unconscious, physiologic activities and then use a visual or auditory signal to "feedback" the information to the patient. Although BFT techniques vary, the methods, which may be used independently or in combination, include: strength training to improve the striated muscles of the pelvic floor, rectal sensory training to enhance the ability to perceive and respond to rectal distentions, and then integrating the coordination of strength and sensory training for the anal sphincters.[64] In addition to pelvic floor exercises (PFE), BFT modalities include surface and/or intra-anal electromyography, manometric pressures, electrical stimulation, rectal distention balloons, and transanal ultrasound.[65] The success of BFT is variable with reports of 50% continence rates and up to 75% decrease in FI episodes in uncontrolled studies.[64] The first landmark trial by Norton and colleagues[66] randomized 171 patients with FI to one of four treatment groups: (1) standard care including advice from experienced specialist nurses for 3 to 6 months, (2) standard care plus anal sphincter exercises taught verbally and by digital examinations, (3) the above plus computer-assisted biofeedback involving coordination techniques with visual feedback of sphincter contractions, and (4) all of the above plus the daily use of a home biofeedback device. BFT was not superior to standard care with advice (53% improved in BFT group vs 54% in standard care + advice). These findings suggest that BFT does not offer any added benefit over standard care alone. However, this study did not evaluate the efficacy of BFT in patients who did not respond to conservative measures. To address this limitation, Heymen and colleagues[67] randomized 108 patients (after excluding 60 subjects who were adequately treated with

medication, education, and behavioral strategies) to either PFE alone or manometric biofeedback plus PFE. Manometric biofeedback was more effective than PFE taught by verbal instructions with an intention-to-treat analysis demonstrating 77% achieving adequate relief. Additionally, instrumented biofeedback and PFE were more effective than conservative management alone. In reviewing the aforementioned CAPABLE trial, which had two arms that offered BFT singly and in combination with loperamide, the change in the FI severity relative to baseline was not significantly different among these groups versus the placebo plus education group. In the most recent Cochrane Review, Norton and Cody[63] did not find any evidence that specific types of biofeedback or exercise were more beneficial than the other, but found that BFT or electrical stimulation was more efficacious than PFE alone in patients that have failed to respond to other conservative measures. In aggregate, the data suggest that a structured course of education and medical management should initially be offered to patients with FI and if this fails, BFT should be considered.

### *Anal Augmentation*

#### *Perianal injection of bulking agents*

The use of an injectate to augment the native anal sphincter is considered in patients with mild to moderate FI and those who have failed conservative medical therapies. At present, the most common injectable medication is dextranomer microspheres stabilized with hyaluronic acid (NASHA/Dx, Solesta, Palette Life Sciences, Santa Barbara, CA), although other injectable materials have been used (eg, autologous fat, carbon-coated beads, collagen, glutaraldehyde and silicone). A multicenter, randomized, sham-controlled study found that approximately half of the subjects receiving NASHA/Dx had a greater than 50% reduction in the number of FI events compared with 30% of patients with the sham injections (odds ratio, 2.36; 95% confidence interval [CI], 1.24–4.27; $P = .0089$).[68] An earlier, open-label trial demonstrated similar effectiveness results that lasted at least 12 months after treatment.[69] A later, randomized, controlled, evaluator-blinded trial comparing NASHA/Dx with BFT of 126 patients with AI demonstrated similar improvements in St. Mark's score between both arms (NASHA/Dx baseline 12.9 [95% CI, 11.8–14.0] to 8.3 [95% CI, 6.7–9.8]; BFT baseline 12.6 [95% CI, 11.4–13.8] to 7.2 [95% CI, 7.2–8.8]).[70] Adverse events that have been reported include pain (14%) and bleeding (7%) with serious rare complications of rectal or prostate abscess.

### *Radiofrequency Energy*

The use of radiofrequency energy to the IAS to stimulate increased collagen deposition in the IAS and improve continence and sphincter tone has been approved by the Food and Drug Administration (FDA) since 2002.[71] A recent review found 11 studies with a total of 220 patients. The authors concluded that radiofrequency energy may be useful for the carefully selected patient (those with adequate muscle mass and collagen in the sphincter at baseline) to reduce the number of incontinence episodes and improve quality of life.[72] However, the results from the available studies have been variable, including two small recent studies.[73,74] Lam and colleagues[73] performed a small prospective cohort trial that failed to show any significant clinical response or durability up to 3 years following the procedure and also failed to show any improvement in anorectal pressures or rectal compliance, as measured by rectal endoscopic ultrasound and anorectal manometry. Visscher and colleagues[74] performed a randomized, sham-controlled trial of 40 subjects using a change in Vaizey incontinence score as the primary outcome. Both arms showed a small improvement in the Vaizey incontinence score, although with a negligible

clinical impact. Because of these disappointing results, this therapy is not widely available in clinical practice.

## Neuromodulation

### Sacral nerve stimulation

In patients with moderate to severe FI who have failed to respond to more conservative measures, SNS is considered. SNS (Interstim, Medtronic, Minneapolis, MN) has been used for the last 20 years and is thought to improve FI by chronically stimulating the sacral nerves, and therefore the corresponding muscles, by applying a low-voltage electrical current via an implanted electrode through the corresponding sacral foramen.[75] Patton and colleagues[76] found that SNS induces colonic retrograde propagated contractions thus delaying colonic transit and delivery of stool to rectum. SNS placement is performed in a two-stage process with permanent device implantation if there is a reduction in FI in the trial period.

A recent Cochrane Review found that SNS is effective in improving FI.[75] In multiple small crossover studies, with the SNS device turned on, FI episodes were reduced 59% to 88% compared with conventional medical therapy.[77–79] FI symptom improvement seems to be durable, with Hull and colleagues[80] reporting 89% of patients reporting continued significant reduction in weekly episodes of FI at 5 years postimplantation compared with baseline (mean, 9.1 episodes of FI per week at baseline compared with 1.7 per week at 5 years), and about a third of patients continent. Multiple studies have shown impressive results with SNS even in patients with known sphincter defects, noting that the degree of defect did not impact results.[81–84]

## Percutaneous Tibial Nerve Stimulation

The tibial nerve shares nerve fibers with the sacral nerve and stimulation of the tibial nerve is comparable with SNS in the treatment of urinary incontinence.[85–87] Uncontrolled trials and one small randomized controlled trial demonstrated 44% to 82% efficacy using the criteria of success of greater than 50% reduction in FI episodes.[88] Thin and colleagues[89] showed that percutaneous tibial nerve stimulation and SNS had comparable results in the treatment of FI, at least in the short term. However, when percutaneous tibial nerve stimulation was compared with a sham electrical stimulation procedure in two large randomized controlled trials, no difference was seen in FI clinical outcomes between the two groups.[90,91] Therefore, enthusiasm for this noninvasive treatment as a primary treatment of FI alone has dampened, but it provides a viable treatment option in patients with concurrent urge incontinence.

## Insertion Devices

### Anal inserts

Anal inserts that temporarily occlude the anal canal and prevent stool leakage are an option in patients with FI. Approved in the United States, Renew inserts (Renew Medical, Foster City, CA) are a single-use, disposable silicone device that is expelled at defecation. In a multicenter, open-label study of 73 patients, 78% had a 50% or greater reduction of FI and were very or extremely satisfied, with a median reduction of 0.9 episode/day to 0.2 episode/day.[92] However, there was a 35% drop out rate because of complaints of constant rectal pressure, because the device sits below the dentate line. In a small study of patients with familial adenomatous polyposis who had undergone restorative proctocolectomy with ileal pouch–anal anastomosis, the device was effective in 6/15 (40%) and acceptable to 8/15 (53%) of patients.[93]

This device could be considered for patients with low-grade FI and soilage but at present is no longer commercially available in the United States because of FDA import restrictions.

### *Vaginal Bowel Control System*

The vaginal bowel control system (Eclipse System, Pelvalon Inc, Sunnyvale CA) is a vaginally placed device that was approved by the FDA in 2015 for women with FI. The device is fitted like a vaginal pessary with a posteriorly directed inflatable balloon. With balloon inflation, it occludes the rectal vault and prevents incontinence. At time for defecation, the patient then temporarily deflates the system. The major advantage of this device is that it is easily reversible and controlled by the patient. Richter and colleagues[94] were able to successfully fit 61 of 110 participants with 86% of women enrolled in the trial achieving treatment success and 41% reporting continence. A follow-up open-label study followed 73 participants who were successfully fitted with the system for 12 months.[95] The authors found that close to half reported lasting continence and 80% of the remaining participants had more than a 75% reduction in incontinence episodes. The most common adverse event was vaginal wall injury, with most adverse events (90/134%; 67%) occurring during the fitting period. Per Eclipse System instructions, practitioners are to evaluate for vaginal atrophy and "continue any existing prescription of vaginal estrogen cream, and consider the prescription of vaginal estrogen cream for patients with mild or moderate atrophy."[96]

### *Transanal Irrigation*

Transanal irrigation is where large-volume water is introduced into the distal colon through the anus, facilitating emptying of the rectosigmoid and the left colon. There are various systems in use for this, including Biotrol (Biotrol International, Earth City, MO), Peristeen (Coloplast Inc, Humlebaek, Denmark), and Navina (Wellspect HealthCare, Mölndal, Sweden). With the performance of regular irrigations, control of bowel function is accomplished.[97] Studies available to assess the efficacy of transanal irrigation in FI are heterogenous with most enrolling patients with constipation, and only a single study enrolling individuals with isolated FI.[98] Efficacy rates vary, from complete continence in 9% to 38%, to 75% reporting improvement. Discontinuation rates have been reported as high as 57% because of a lack of efficacy, pain, and the lengthy nature of the irrigation procedure.

### *Surgical Options*

More invasive surgical options are considered when conservative therapies have failed. Besides SNS, other options include sphincteroplasty, muscle transposition, antegrade continence enema (ACE), and fecal diversion. The transobturator posterior anal sling and artificial bowel sphincter are no longer available in the United States.

#### *Sphincteroplasty*

Repair of the anal sphincter with an anterior overlapping technique has long been used to treat FI caused by EAS injury when conservative therapies have failed. Most women with FI caused by anal sphincter injury have a history of vaginal delivery, and the most common risk factors include multiple vaginal deliveries, need for vaginal instrumentation during labor, third- or fourth-degree tear, pudendal nerve injury, and failed prior sphincteroplasty.[99,100] In the short-term, the median rate of either good or excellent fecal continence with sphincteroplasty is 70%, ranging from 30% to 83%.[101,102] However, numerous recent long-term studies have failed to confirm the durability of sphincteroplasty.[101,103–107] Long-term continence decreases from 0% to 60% in

most studies. Although many studies have suggested that advanced age at the time of the surgery was a risk factor for long-term failure, a recent systematic review did not find any consistent risk factors predictive of failure.[107] Additionally, a large retrospective review of 321 women did not show any significant difference in long-term severity of FI, quality of life, or postoperative satisfaction between younger and older women.[108] Based on these findings, sphincteroplasty is no longer considered a primary treatment option for patients with FI.

#### *Muscle transposition*

Transposition of the gracilis muscle is another surgical technique that was used more commonly in the past for medically refractory FI, but it is rarely used now because of the high rate of adverse events associated with this procedure and availability of less invasive but equally effective treatment options.[102]

#### *Antegrade continence enema*

ACE for the treatment of FI has long been used in the pediatric population with good success.[109] However, this technique is rarely used in the adult population. The surgery involves the creation of a stoma from the appendix, terminal ileum, cecum, or another proximal access point, with water or enema solution instillation via this access point, which allows fecal material to be flushed from the colon in an antegrade manner. A recent systematic review found that most adults (47%–100%) were still performing ACE at 6 to 55 months follow-up, and at least a third of patients achieved full continence.[110] In the most recent observational study of 30 Dutch patients with FI or constipation, using the Malone continence scale (success rate is calculated by combining the full and partial success rates, using the number of subjects [n = 30] in the intention-to-treat group as denominator), ACE resulted in a disappointing overall success rate of 37%.[111]

#### *Fecal Diversion*

Use of colostomy or ileostomy for fecal diversion is considered when all other modalities of treatment have failed.[112,113] This is considered a last option for patients with FI, but for some can dramatically improve quality of life.[114] Physicians may consider this in patients with severe perianal trauma, severe neurogenic incontinence, severe radiation-induced incontinence, or complete pelvic floor denervation. Norton and colleagues[115] found that 83% of patients who had undergone colostomy placement for their FI had minimal to no restrictions in their life with their ostomy, and that 84% would choose to have the stoma placement again.

### *Potential Future Treatments*

#### *Translumbosacral neuromodulation therapy*

Using the translumbosacral anorectal magnetic stimulation test, there is evidence for neurogenic disturbances with prolongation of the latency and amplitude of motor-evoked potentials in 88% of subjects with FI.[116] With these findings, Rao and colleagues[117] studied the efficacy of repetitive magnetic stimulation or translumbosacral neuromodulation therapy delivered at 1, 5, or 15 Hz at two lumbar and two sacral sites over 6 weeks in 33 patients with FI who had failed conservative measures. In all arms, FI improved using the end point of greater than or equal to a 50% reduction in the number of FI episodes. After 6 weeks of treatment, 1 Hz (10 of 11 patients; 91%) was more effective than 5 Hz (4 of 11 responders; 36%) and 15 Hz (6 of 11 responders; 54%), with a pooled responder rate of 61% (20 of 33 responders). Future, sham-controlled studies of translumbosacral neuromodulation therapy in men and women with FI are necessary to evaluate this promising modality.

### *Magnetic anal sphincter*

The magnetic anal sphincter (MAS; Fenix, Torax Medical, Inc, St. Paul, MN) is a newer therapeutic option that was approved by the FDA as a humanitarian use device. The device is composed of a band of small, interlinked titanium beads with magnetic cores. This MAS is surgically implanted around the EAS. It functions to reinforce and improve competence of the sphincter. The magnets separate with Valsalva maneuver, thus allowing for defecation.

In a feasibility study, Lehur and colleagues[118] implanted MAS in 14 women, all of whom had previously failed other treatments. Only 5 of 14 were followed for at least 6 months, but among this group, there was a 91% mean reduction in average weekly FI episodes and a significant improvement in quality of life. Two of the 14 patients had the device explanted because of infection, and one had spontaneous passage of the device. Other observed adverse events included bleeding, pain, and obstructed defecation. This pilot group plus additional participants (35 total) were implanted with MAS between 2008 and 2011 and followed for a median period of 5.0 years (range, 0–5.6 years).[119] There was a 31% drop out rate because of device removal. In patients who retained their MAS device, 79%, 91%, and 73% reported treatment success at 1, 3, and 5 years. There were 30 adverse events reported in 20 patients, most commonly defecatory dysfunction (20%), pain (14%), erosion (11%), and infection (11%).

In a separate single-center study, Pakravan and Helmes[120] reported the results of 18 patients implanted with MAS for FI, followed up to 2 years (mean follow-up, 607 days). Because of an intraoperative rectal perforation in one subject, the procedure was aborted. Of the 17 remaining subjects, 76% of patients demonstrated at least a 50% reduction in number of weekly FI events. None of their patients required surgical removal of MAS, but 29% had pain and/or swelling.

### *Stem cell therapy*

Both animal and human studies in which local injections of mesenchymal (bone marrow– or adipose-derived) or muscle-derived (muscle-derived stem cells or myoblasts derived from them) stem cells have been reported. These studies have demonstrated some encouraging functional results by stimulating the repair of acute and subacute anal sphincter injuries.[121] Stem cells combined with normal cells on bioengineered scaffolds have achieved the successful creation and implantation of intrinsically innervated anal sphincter constructs.[122] The clinical evidence, based on adipose-derived stem cells and myoblasts, is extremely limited yet has yielded some promising results, and seems to be safe.[123–125] Although there may be promise for this method in the future, much more research into the utility of autologous or stem cell transplant must be undertaken before it is ready for use in clinical practice.

## SUMMARY

FI is a common and debilitating condition that often goes underreported to health care providers. As a provider, it is important to ask patients about FI symptoms and to identify risk factors. Although there are many possible risk factors associated with FI, the most significant seem to be advancing age, diarrhea or loose stool, GI diseases stool, fecal urgency, and generalized debility.

A therapeutic algorithm is presented in **Fig. 1**. Evaluation and management are tailored to specific symptoms and characteristics of the incontinence. Work-up often begins with a detailed digital rectal examination and in many cases, anorectal manometry. Depending on the patient's symptoms, other procedures (eg, colonoscopy, dynamic pelvic floor imaging) may also be needed. Once the burden of illness and cause of FI has been characterized, conservative treatments should be pursued.

Typically, initial therapies involve a combination of lifestyle and dietary modifications, pharmacologic agents, and BFT. If these treatments fail to improve FI symptoms, then other interventions are considered. Generally, less invasive options should be tried first, such as SNS, before other surgical options are explored.

## CLINICS CARE POINTS

- Patients with gI symptoms and diseases associated with diarrhea at a marked increased risk for FI.
- Patients will not freely volunteer that they have FI-you must ask.
- Reverse the reversible (loose stool/diarrhea).Look for dietary causes-osmotics in their diets, caffeine, and lack of fiber.
- Start low and slow with psyllium and increase it gradually weekly.Toileting schedule after each meal can reduce episodes of FI.
- Rushing to the toilet will increase the likelihood of FI by increasing the intra-abdominal pressure and overwhelming the sphincter complex.
- Utilizing a physical therapist trained in pelvic floor is essential for effective biofeedback training.
- Sacral stimulation demonstrates the highest efficacy of continence.

## DISCLOSURE

S. Menees discloses the following: Consultant for Takeda. W.D. Chey discloses the following: Consultant for AbbVie, Alfasigma, Allakos, Alnylam, Arena, Biomerica, Ferring, Gemelli, Ironwood, Nestle, Phathom, Progenity, Redhill, Ritter, Salix/Valeant, QOL Medical, Takeda, Urovant, and Vibrant; grants from Commonwealth Diagnostics International, Biomerica, Salix, QOL Medical, and Vibrant; and Stock Options from GI on Demand, Modify Health, and Ritter.

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