

The American Society of Colon and Rectal Surgeons' Clinical Practice Guideline for the Treatment of Fecal Incontinence

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STATEMENT OF THE PROBLEM

Fecal incontinence is a frequent and debilitating condition that may result from a multitude of different causes. It is defined as the uncontrolled passage of feces or gas over at least 1 month's duration, in an individual of at least 4 years of age, who had previously achieved control.¹⁻⁴ In

a large survey of female patients, the term "accidental bowel leakage" was preferred.⁵ Incontinence has a negative impact on self-esteem and quality of life and may result in significant secondary morbidity, disability, and cost.⁶ Reported prevalence rates vary widely depending on the method used and the target population examined but, in general, range between 1.4% and 18%. In institutionalized patients, however, incontinence may affect up to 50%, and it is a frequent reason for transfer to nursing homes.⁷⁻¹¹ The Mature Woman's Health Study used Neilson data to survey nearly 6000 women aged ≥ 45 (86% response rate), and indicated that nearly 20% of women have fecal incontinence at least once per year, whereas 9.5% have at least 1 episode per month.⁵

Treatment is challenging and needs to be individualized.^{2,4,12} Apart from conservative and supportive measures, a number of interventions are available that vary in efficacy and morbidity. Over the past several years, new technologies have been developed, and others are emerging from clinical trials to commercialization. Their specific roles in the management of fecal incontinence have not yet been completely defined.

The scope of this updated practice parameter (last version 2007)² is to address the evaluation and management of patients with fecal incontinence based on a thorough review of the published evidence.

METHODS

An organized search of MEDLINE, PubMed, EMBASE, and the Cochrane Database of Collected Reviews was performed through March 2014. Key word combinations included "fecal incontinence" AND ["fecal OR anal OR stool"], AND ["physical therapy OR rehabilitation OR biofeedback"], AND ["sphincteroplasty" OR "implants" OR "bowel sphincter" OR "artificial sphincter" OR "radiofrequency" OR "sacral nerve stimulation" OR "injectable"]. Directed searches of the embedded references from

Dis Colon Rectum 2015; 58: 623-636
DOI: 10.1097/DCR.0000000000000397
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TABLE 1. The GRADE system-grading recommendations

	<i>Description</i>	<i>Benefit vs risk and burdens</i>	<i>Methodological quality of supporting evidence</i>	<i>Implications</i>
1A	Strong recommendation, High-quality evidence	Benefits clearly outweigh risk and burdens or vice versa	RCTs without important limitations or overwhelming evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1B	Strong recommendation, Moderate-quality evidence	Benefits clearly outweigh risk and burdens or vice versa	RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise) or exceptionally strong evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1C	Strong recommendation, Low- or very low-quality evidence	Benefits clearly outweigh risk and burdens or vice versa	Observational studies or case series	Strong recommendation but may change when higher-quality evidence becomes available
2A	Weak recommendation, High-quality evidence	Benefits closely balanced with risks and burdens	RCTs without important limitations or overwhelming evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patient's or societal values
2B	Weak recommendations, Moderate-quality evidence	Benefits closely balanced with risks and burdens	RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise) or exceptionally strong evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patient's or societal values
2C	Weak recommendation, Low- or very low-quality evidence	Uncertainty in the estimates of benefits, risks and burden; benefits, risk and burden may be closely balanced	Observational studies or case series	Very weak recommendations; other alternatives may be equally reasonable

GRADE = Grades of Recommendation, Assessment, Development, and Evaluation; RCT = randomized, controlled trial.

Adapted from Guyatt G, Guterman D, Baumann MH, et al. Grading strength of recommendations and quality of evidence in clinical guidelines: report from an American College of Chest Physicians Task Force. *Chest* 2006;129:174–181.¹³ Used with permission.

the primary articles were also performed in selected circumstances. The primary authors reviewed all English language manuscripts and studies in adults, systematic reviews, and meta-analyses. In selected instances where a full manuscript was not yet available, reports of conference proceedings were reviewed. Recommendations were formulated by the primary authors and reviewed by the entire Clinical Practice Guidelines Committee. The final grade of recommendation was performed by using the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) system¹³ (Table 1) and approved by the entire Clinical Practice Guidelines Committee.

EVALUATION AND RISK ASSESSMENT

1. **A thorough disease history should be obtained to define the etiology and specific risk factors for incontinence, characterize the duration and severity of primary symptoms, and capture secondary problems and associated pathologies. Grade of Recommendation: Strong recommendation based on low- or very low-quality evidence, 1C.**

Continence depends on the complex relationships between the anal sphincter and pelvic floor musculature, rectal reservoir function (capacity, compliance), stool consistency, and neurologic function. Conditions or defects that alter any of these factors may result in fecal incontinence. On an individual basis, however, the etiology of fecal incontinence may be multifactorial and the relative contribution of each factor may not be determined with certainty. A full discussion of contributing factors is beyond the scope of a clinical practice guideline. However, pregnancy, chronic diarrhea, diabetes mellitus, previous anorectal surgery, urinary incontinence, smoking, obesity, limited physical activity, white race, and neurologic disease have all been found to be risk factors for fecal incontinence in large population-based studies.^{7,14} Sphincter disruption from obstetric injury is clinically recognized in approximately 10% of all vaginal deliveries, but occult sphincter damage that does not cause immediate postpartum incontinence may be identified in up to 21% to 35% of vaginal deliveries.^{9,15} A higher incidence was seen in those who were multiparous or had instrument-assisted deliveries.^{1,16} Forceps delivery, occipito-posterior presentation of the child, and prolonged labor are independent risk factors.¹ An estimat-

ed one-third of these occult defects may result in symptoms of incontinence or urgency at a later date. The extent of a sphincter defect does not necessarily correlate with the degree of fecal incontinence. Furthermore, those with ultrasound evidence of a sphincter defect without clinical signs of incontinence postpartum do not appear to have deterioration of continence in the first decade.¹⁷ Evolution of other factors (eg, menopause) and a decompensation of coping mechanisms may be responsible for what may be a long delay between the time of injury and onset of symptoms.

A history of anorectal procedures (eg, hemorrhoidectomy, sphincterotomy, fistula surgery) may frequently be identified in patients with symptoms of incontinence, particularly in men.^{4,18} This finding contrasts with low percentages of incontinence reported for these procedures,¹⁹ reflecting the fact that short-term follow-up may fail to capture the delayed onset of symptoms and determine the true incidence of this long-term complication. The purpose of a detailed medical history goes beyond accounting for obstetric injury, anorectal surgery, or perineal trauma; rather, it aims to recognize contributing or exacerbating factors, such as hygiene habits, diet, medications, GI, or neurologic disorders. The information can direct and prompt a more focused examination.^{1,3,4}

2 Validated measures that assess the nature, severity and impact of incontinence on quality of life should be utilized as a part of the medical assessment for fecal incontinence. Grade of Recommendation: Strong recommendation based on moderate-quality evidence, 1B.

A number of scoring or grading instruments have been developed to describe and measure the type, frequency, and amount of incontinence and its impact on quality of life. Fecal incontinence severity has been assessed most commonly with the Fecal Incontinence Severity Index,²⁰ St. Marks Incontinence Score,²¹ and Cleveland Clinic Florida Fecal Incontinence Score (CCF),²² although other measures of fecal incontinence (FI) such as the Revised Fecal Incontinence Scale,²³ Comprehensive Fecal Incontinence Questionnaire, and International Consultation on Incontinence Questionnaire-Bowels module have been developed and validated with improved psychometric properties.^{24–26}

Many of the instruments cited above include lifestyle and quality-of-life questions as part of scoring, which can impact overall scores in patients with similar symptoms. However, there is an incontinence-specific quality-of-life measure, Fecal Incontinence Quality of Life scale²⁷ that is commonly used in conjunction with more general quality-of-life measures such as the SF-36.²⁸ All of these instruments are based on patients' subjective experience of FI, and none correlate well with objective parameters

and/or coping mechanisms. There is also no perfect correlation between any of the instruments and prediction of outcomes for various management options.

Nevertheless, the use of these instruments is recommended because a validated measure of severity is helpful in selecting patients for therapies and for measuring response to treatment over time. Patients with more severe symptoms or for whom symptoms severely affect quality of life are appropriate for more aggressive therapies up to and including colostomy. Furthermore, validated assessments facilitate comparison of study outcomes.

3. A detailed physical examination is an essential component of the evaluation of patients with fecal incontinence. Grade of Recommendation: Strong recommendation based on low- or very low-quality evidence, 1C.

Elements of a thorough clinical evaluation include external inspection, digital examination, and basic instrumentation.^{1,4,29} The perianal skin is checked for the presence of stool, skin irritation or excoriation, surgical scars, thickness of the perineal body, the presence of a patulous anus upon spreading the buttocks, or other pathologies such as an external fistula opening or rectal prolapse. Perineal sensation should also be assessed. Triggering a mucosal or full-thickness prolapse may require a Valsalva maneuver, or straining on the commode. Digital examination may provide a rough estimate of anal resting and squeeze pressures, muscle coordination including the use of accessory gluteal muscles, and sphincter integrity. Furthermore, it is important to exclude the presence of a rectal mass, stricture, or fecal impaction, which would suggest other mechanisms for incontinence. Anoscopy and proctoscopy can be useful for identifying anal canal pathology that can contribute to incontinence such as hemorrhoids, IBD, or neoplasms.

4. Anorectal physiology testing (manometry, anorectal sensation, volume tolerance, compliance) can be considered to help define the elements of dysfunction and guide management. Grade of Recommendation: Strong recommendation based on low- or very low-quality evidence, 1C.

Anorectal physiology testing consists of a number of simple, minimally invasive test elements to 1) measure the resting and squeeze pressure of the anal sphincter, 2) determine the length of the high-pressure zone and pressure profile of the anal canal, and 3) assess the anorectal sensation, rectal capacity, and rectal compliance.^{30–36} Although the ultimate goal would be to correlate objective findings with the selection of and response to various treatment options, published reports have shown a significant variability of data both in healthy control subjects, as well as in patients affected by FI, especially regarding anal

manometry.^{37,38} Although the findings do not consistently correlate with the severity of FI or prediction of outcomes, they may influence the management decisions to select the individual treatment strategy.^{32,37,39–41}

5. Endoanal ultrasound is useful to confirm sphincter defects in patients with suspected sphincter injury. Grade of Recommendation: Strong recommendation based on moderate-quality evidence, 1B.

Endoanal ultrasound is a useful and sensitive tool in the evaluation of patients with FI, especially when there is a history of vaginal delivery or anorectal surgery. Ultrasound can reliably identify internal and external sphincter defects that may be associated with sphincter dysfunction.^{42–45} The presence of a sphincter defect alone is not sufficient to predict a functional deficit, because it may be identified in continent and asymptomatic individuals.⁴⁶ However, it has been shown that qualitative assessment and scoring of the sonographic morphology of the anal sphincter muscles can correlate with symptoms and test results.⁴³

Other imaging modalities (eg, MRI) have shown substantial interobserver variability and, at this point, are likely inferior to ultrasound imaging, but they may provide additional information where endoanal ultrasound is unavailable.^{47,48}

6. Pudendal nerve terminal motor latency may be performed, but has limited impact in the diagnosis and management of patients with fecal incontinence, and is not routinely recommended. Grade of Recommendation: Strong recommendation based on moderate-quality evidence, 1B.

The value of pudendal nerve conduction studies for the management of patients with FI remains at best controversial.⁴⁹ A number of reports have correlated clinical symptoms or manometry testing with the degree of impairment.^{50–53} However, the presence or absence of pudendal neuropathy cannot be used to reliably predict outcomes after a sphincter repair,^{54–58} and are not found to correlate with outcomes of sacral neuromodulation.⁵⁹ Severe denervation and pudendal nerve damage are common in patients who remained incontinent after a sphincter repair.^{55–57,60,61}

7. Endoscopic evaluation should be performed in patients who meet the general screening guidelines or present with specific symptoms (ie, diarrhea, bleeding, obstruction) that warrant further evaluation. Grade of Recommendation: Strong recommendation based on moderate-quality evidence, 1B.

Although a colonic evaluation only rarely contributes to the diagnosis and management of incontinence, diarrhea is commonly seen in women with late-onset incontinence,

and endoscopic evaluation may be warranted to assess the etiology.⁶² Other symptoms of concern include bleeding, urgency, tenesmus, and mucus drainage that may contribute to incontinence and be indicative of colorectal cancer or more serious pathology. General screening recommendations should be followed for all other patients to exclude concomitant colorectal pathology that might require priority attention.

NONOPERATIVE MANAGEMENT

Medical Management

1. Dietary and medical management are recommended as first-line therapy for patients with fecal incontinence. Grade of Recommendation: Strong recommendation based on low- or very low-quality evidence, 1C.

A self-directed evaluation of the patients' habits by using a diary or repeated questionnaires can often identify and eventually avoid triggering or aggravating factors in their daily routine. These habits may be difficult to detect during the short span of an interview during a physician evaluation. The patients should be educated and instructed to use diaries and systematically make subtle changes to their management that will allow for observation of the impact of these changes on their bowel function and control.⁶³ Specific attention should be directed to the effects of caffeine, sugar replacements, lactose, and other dietary components that may result in fecal urgency or diarrhea.⁶⁴ Studies have also shown that 22% to 54 % of patients can have improvement in FI with formal counseling from a specialist regarding dietary habits, fluid management, bowel routines, and changes to medications.⁶⁵ Optimization of idiopathic deviations of stool consistency may be addressed by the use of supplemental fibers to thicken stool consistency. However, in patients with impaired sphincter function, the addition of fiber can possibly result in worsening incontinence due to increased volume and liquid consistency of stools.^{66–69}

Supportive measures include skin care, protective ointments (eg, zinc oxide based), gentle soaps and wipes, as well as deodorants and pads. When all of these measures are used in complementary fashion, these efforts have proven to be effective.⁴

Suboptimal stool consistency and excessive motility play key roles in aggravating FI. Pharmacological treatments can slow colonic transit, decrease intestinal fluid secretion, increase absorption, and reduce sphincter relaxation.^{70,71} Adsorbents, such as Kaopectate act by absorbing excess fluid in the stool. Cholestyramine binds cathartic bile acids, particularly in patients with a history of cholecystectomy or ileocolonic resection. Antidiarrheal agents such as loperamide and

diphenoxylate-atropine affect intestinal motility and may increase the internal anal sphincter tone. Tricyclic antidepressants exert an inhibitory effect on motility and sphincter relaxation. Opioids result in decreased intestinal motility, decreased intestinal secretion, and increased absorption. The risk of drug dependency and constipation from the extended use of opioids and diphenoxylate may have to be weighed against the benefits on an individual basis.⁷⁰ A Cochrane review examined 16 trials that used medication to address FI by slowing motility, enhancing sphincter function, addressing constipation with laxatives, or using skin barrier cream. The review noted that most medical treatments were aimed at treating diarrhea, so no clear conclusions could be drawn regarding any of these medications.^{72,73} More recently, clonidine, which is used in diarrhea-predominant irritable bowel syndrome, was used for FI because it reduces rectal sensation and urgency. It can help patients by improving stool consistency and frequency, although the results are not conclusive.^{74,75}

2. Bowel management programs to aid in rectal evacuation are useful in select patients. Grade of Recommendation: Weak recommendation based on low- or very low-quality evidence, 2C.

Emptying the rectum by using enemas or suppositories at convenient times results in a reduction of rectal stool volume, and may help mitigate the risk of incontinence episodes. This measure may be particularly helpful in patients with underlying primary constipation with overflow incontinence, or in patients secondarily constipated because of the use of antidiarrheal medication.^{1,76,77}

Biofeedback

1. Biofeedback should be considered as an initial treatment for patients with incontinence and some preserved voluntary sphincter contraction. Grade of Recommendation: Strong recommendation based on moderate-quality evidence, 1B.

Biofeedback training or pelvic floor rehabilitation is noninvasive and hence considered a first-line treatment option for patients with FI that have not responded to simple dietary modification, medications, and other supportive measures. The goal is to improve sensation, coordination, and strength, although supportive counseling and practical advice regarding diet, bowel habits, and skin care remain important components of treatment.⁷⁸ The objective benefit reported in the literature has shown substantial variability.^{79–83} Nonrandomized prospective or retrospective case series report 64% to 89% improvement in incontinence episodes.^{79,80,84} Randomized trials have compared different approaches of biofeedback, pelvic floor exercise, advice and education, as well as tele-

phone treatment, but there are no randomized controlled trials of biofeedback to sham therapy.^{65,81,85–89} Although many of the smaller studies demonstrate advantages of using biofeedback to treat FI, the methodological weaknesses and heterogeneity of the studies make it difficult to make any definitive conclusions.^{81,90} Larger well-designed studies are needed to establish the validity of this treatment modality.

SURGICAL MANAGEMENT OPTIONS

Correction of Anatomical Pathologies

1. Obvious anatomic defects such as rectovaginal fistula, rectal or hemorrhoidal prolapse, fistula in ano, or cloaca-like deformity should be corrected as part of the treatment of fecal incontinence. Grade of Recommendation: Strong recommendation based on low- or very low-quality evidence, 1C.

Patients who experience FI in conjunction with, or as a result of anatomic defects (eg, rectovaginal fistula, rectal or hemorrhoidal prolapse, fistula in ano, cloaca-like deformity) should have those defects corrected first, because this step may frequently improve or eliminate the incontinence.^{4,13}

Sphincter Repair

1. Sphincter repair (sphincteroplasty) may be offered to symptomatic patients with a defined defect of the external anal sphincter. Grade of Recommendation: Strong recommendation based on moderate-quality evidence, 1B.

Disruption of the normally circumferential anatomy of the anal sphincter muscle may diminish the effect of its contraction, because the shortening of the muscle will not translate into an adequate narrowing of the anal canal. Ideally, restoring sphincter integrity would result in a dynamically adaptable outlet resistance. However, continence is a complex interplay between muscle strength, rectal sensation, rectal compliance, and nerve function. A sphincteroplasty may therefore be less dynamic than desired, but nonetheless, achieves a rigid increase in outlet resistance and at least partially improves the incontinence symptoms.

Sphincteroplasty for defects caused by obstetric injury have been associated with good-to-excellent short-term results in up to 85% of patients.⁹¹ Studies have not used uniform criteria to define success, making comparisons between different series difficult. It is clear, however, that the benefits deteriorate with long-term follow-up. After 5 years, as few as 10% to 14% of patients had sustained improvement in most studies.^{4,41,91–94} In view of these results, an increasing number of authors have questioned the value of sphincteroplasty, especially in women who develop

incontinence decades after any obstetric trauma, and have moved onto other treatment modalities such as sacral neuromodulation.^{95–99} No comparison between these 2 modalities has been reported to date.

Multiple reports have attempted to identify factors predictive of unfavorable sphincteroplasty outcomes with variable and contradictory results. Across the spectrum of studies, no single preoperative variable (demographics, anorectal physiology testing) could be reliably correlated with outcome. Unilateral or bilateral pudendal neuropathy was associated with poor outcome in some but not all studies.^{54–57}

There has been speculation as to the value of adjuvant measures (eg, biofeedback therapy),¹⁰⁰ or combination of sphincteroplasty with sacral neuromodulation, in achieving a better and sustained function and quality of life over time.¹⁰¹ However, further studies are required to assess this and determine what impact it may have upon treatment outcomes.

2. Repeat anal sphincter reconstruction after a failed overlapping sphincteroplasty should generally be avoided unless other treatment modalities are not possible or have failed. Grade of Recommendation: Strong recommendation based on low- or very low-quality evidence, 1C.

Functional failure of overlapping sphincteroplasty is common, particularly with an increasing time interval from surgery. In the absence of a rational identification of factors responsible for failure, like recurrent sphincter injury from additional vaginal delivery, repeat repairs are unlikely to be more successful. Some authors have reported that up to 50% patients achieve a “good” result if an external sphincter defect can be demonstrated by endorectal ultrasound and repaired.¹⁰² These are small series with significant potential for selection bias, because only the patients for whom the surgeons expected a good improvement were offered repeat sphincter repair. Additionally, no comparisons with alternative modalities are available. It may therefore be more prudent to offer alternative and more promising treatment modalities, which can be used in the setting of existing sphincter defects, such as sacral nerve stimulation.

3. Plication of the external anal sphincter (Park postanal repair) is not recommended. Grade of Recommendation: Strong recommendation based on moderate-quality evidence, 1B.

Given the number of alternative successful options, plication of a lax external sphincter muscle (postanal repair) is not recommended, because it has not shown any or only questionable benefit.^{103–106}

Injection of Bulking Agents

1. Injection of biocompatible bulking agents into the anal canal may help to decrease episodes of passive fecal incontinence. Grade of Recommendation: Weak recommendation based on moderate-quality evidence, 2B.

Injectable compounds may play a role for patients with mild incontinence. The ideal injectable agent would be a biocompatible compound that is small enough to inject, yet large enough to minimize migration. Since the first report of polytetrafluoroethylene paste injection in 11 patients in 1993,¹⁰⁷ a total of 24 studies have been published, describing a variety of implant materials (autologous fat, synthetic bovine dermal collagen, Teflon, silicone (PTQ), carbon beads, and stabilized hyaluronic acid), injection sites (intersphincteric space vs submucosal), and techniques (ultrasound vs blind). Results of these studies have been inconsistent and difficult to interpret owing to the multiple compounds and injection techniques that have been used. A Cochrane review published in 2010 extensively reviewed the evidence of injectable therapy for FI.¹⁰⁸ Although some studies showed modest short-term improvements, no study evaluated the long-term benefits of these therapies. Some materials appeared to work better than others, in one study, silicone (PTQ) performed better than carbon-coated beads.¹⁰⁹ Ultrasound-guided injections appeared to have short-term benefits compared with blind injection.¹¹⁰ However, only 1 placebo-controlled trial was included. This trial demonstrated subjective symptomatic improvement in only 23% of patients with PTQ injection compared with 27% who received a placebo saline injection.¹¹¹ The Cochrane review concluded that little evidence was present to support the use of perianal bulking injection for FI.¹⁰⁸

In 2011, the US Food and Drug Administration (FDA) approved a nonanimal stabilized hyaluronic acid dextranomer gel for submucosal injection. The clinical evidence for this treatment is limited, because no comparisons with other treatments are available. The largest series was a prospective randomized, double-blinded, and sham-controlled multicenter trial in Europe and the United States.¹¹² Response was defined as a reduction in the number of weekly incontinence episodes by 50% or more. Dextranomer-injected patients had a 52% reduction compared with a 31% reduction in the sham treatment group with a low incidence of complications. The sham response was similar to the 27% of patients improving after sham injection in another trial,¹¹¹ and the improvement in sham patients persisted at 6-month follow-up. Despite a reduction in episodes, incontinence scores were not significantly different between the treatment and sham groups. Additionally, nearly all of the patients in the treatment group received 2 injections. A single-institution study indicated that patients receiving 2 injections were more likely to achieve 50% improvement than patients receiving a single injection (66% response rate vs 53%). Only patients achieving 75% improvement in episodes experienced a quality-of-life benefit on SF-36 score.¹¹³ The Cochrane review was repeated in 2013 to include the available evidence for dextranomer gel injection.¹¹⁴ Although modest improvements

in short-term outcomes were seen, long-term follow-up with regard to safety and efficacy awaits further experience. The nonanimal stabilized hyaluronic acid/dextranomer (NASHA Dx) study group recently released the 36-month data, reporting a decrease in symptoms in 52% of patients at 6 months and at 36 months, as well. Mean CCF-incontinence score was similarly lower (14 vs 11, $p < 0.001$) at 36-month follow-up compared with baseline.¹¹⁴ Injectable compounds are contraindicated in patients with active IBD, rectocele, previous anorectal radiation, full-thickness rectal prolapse, and anorectal malformations.¹¹²

Radiofrequency Energy Delivery

1. Application of temperature-controlled radiofrequency energy to the sphincter complex may be used to treat fecal incontinence. Grade of Recommendation: Weak recommendation based on moderate-quality evidence, 2B.

The application of radiofrequency energy for FI was adapted from the treatment for gastroesophageal reflux disease and FDA approved for use in FI in 2002. This procedure uses thermo-controlled delivery of radiofrequency energy to the anal canal. A recent animal model study indicated significant sphincter muscle remodeling marked by increased smooth muscle/connective tissue ratio and increased collagen I compared with collagen III content in the treatment group as well as a decrease in the number of interstitial cells of Cajal following treatment.¹¹⁵ The procedure is conducted in an endoscopy unit or operating room with the patient under conscious sedation. The reported evidence is relatively sparse and has relevant limitations. To date, the outcomes of 220 patients have been reported across 10 studies.^{116–122} Most studies have been small single-center series with short-term follow-up. At 12 months, 55% to 80% of patients were deemed as responders based on showing some improvement in CCF scores, although most series did not demonstrate a 50% improvement in CCF scores.¹²² Long-term follow-up is very limited at present, but any clinical benefit achieved in the short term appears to be sustained in the long term.¹²² Importantly, patients with IBD, diarrhea, chronic constipation, and history of pelvic radiation were excluded from these studies. Another absolute contraindication is previous injection of foreign material such as dextranomer gel. Complications were rare and included pain, ulcerations, and bleeding. Because of the limitations in the available data, alternative treatments should be pursued before considering radiofrequency energy delivery.

Sacral Neuromodulation

1. Sacral neuromodulation may be considered as a first-line surgical option for incontinent patients with and without sphincter defects. Grade of Recommendation: Strong recommendation based on moderate-quality evidence, 1B.

Sacral neuromodulation (SNM) is thought to modulate rectal sensation by activating or deactivating chemical mediating receptors, stimulating the afferent pathway, and changing brain activity relevant to the continence mechanism.^{51,123,124} SNM has been consistently shown to result in a reduction in frequency of FI episodes.^{125–129} Pooled analysis of all studies to date indicates that 79% (69%–83%) of patients experience $\geq 50\%$ improvements in weekly FI episodes in the short term (0–12 months) and 84% of patients experience $\geq 50\%$ improvement at long-term (> 36 month) follow-up when a per-protocol analysis is followed (only patients who received a full system implant are analyzed).¹²⁹ Because this procedure involves 2 stages, some studies report results on an intention-to-treat basis, whereby patients in whom the stage 1 test stimulation fails are considered as failures. When the pooled analysis was reported on an intention-to-treat basis, 63% of patients experienced $\geq 50\%$ improvements in weekly FI episodes in the short term (0–12 months).¹²⁹ Approximately 35% of patients achieve 100% continence at long-term follow-up. A prospective nonrandomized multicenter study conducted in 14 centers across the United States, Canada, and Australia showed greater than 50% improvement in 89% of patients and complete continence in 36% at 5 years of follow-up.¹³⁰ There was a fairly good safety profile with an infection rate of 10.8%, but no permanent morbidity. At 5 years, 24.4% of patients required at least 1 revision or replacement, highlighting the need for long-term patient follow-up.

The presence of a sphincter injury does not appear to impact the outcome of SNM. The largest study to examine this included 91 patients with no sphincter defect and 54 patients with ultrasound-defined complete external defect (mean defect size = 105 degrees). In this study, patients with a complete external sphincter defect improved from a baseline median CCF score of 15 at baseline to 2.5 at 12 months. By comparison, patients without a sphincter defect had a baseline median CCF score of 14 and a 12-month score of 3 ($p =$ not significant).¹³¹ A systemic review of 10 studies ($n = 119$) showed an average decrease of CCF incontinence scores from 16.5 to 3.8 in the setting of a sphincter injury.⁹⁸ Success has been reported in patients with defects of up to 120 degrees.¹²⁸ A prospective randomized trial comparing sacral nerve stimulation with a medically managed control group showed 100% continence in 41.5% and 75% to 99% improvement based on the CCF score in 24.4% of sacral nerve stimulation patients (even in the presence of sphincter defects).¹²⁸ Brouwer et al⁵⁹ demonstrated that the presence of a sphincter defect, pudendal neuropathy, or a history of a previous sphincter repair did not decrease the efficacy of SNM. Despite excellent evidence demonstrating long-term success, there is only one study comparing it to another surgical modality. A total of 15 patients implanted with an SNM device

were compared with 15 historical controls implanted with an artificial bowel sphincter. Although postoperative CCF incontinence scores were slightly better in the artificial bowel sphincter (ABS) group, postoperative quality of life did not differ, and postoperative constipation scores were slightly worse in the ABS group.¹³²

Sphincter Replacement Strategies

- 1. Implantation of an artificial bowel sphincter remains an effective tool for select patients with severe fecal incontinence. Grade of Recommendation: Strong recommendation based on low- or very low-quality evidence, 1C.**

The ABS provides a dynamic and patient-controlled replacement of a failed sphincter. The majority of reported series are retrospective analyses, and only a limited number of prospective studies have been published.^{134–138} With very few exceptions, the studies documented the high degree of improvement of the FI if the device could be implanted and retained without complications.^{133–136,138} However, all studies showed a high rate of complications, which included infections (acute and chronic), device erosions, anorectal ulcerations, device malfunction secondary to leaking of fluid from the device, device migration, pain, and constipation.^{139,140} A recent systematic review found that 59% of devices were still functional at 5-year follow-up.¹⁴¹ Complications typically occur early in the postoperative period (acute infections, technical problems), or in the later course (erosion, late infections, device malfunction, functional problems such as outlet obstruction, which has an 8% incidence in pooled analysis).^{139–141} Patient selection is crucial for successful outcomes. Because of the high success rates and safety profiles of other treatments such as sacral neuromodulation, ABS is generally reserved for patients in whom all other treatments have failed, or those with extensive sphincter destruction (>180 degrees), congenital malformations, neurogenic incontinence from spinal cord injury, or postsurgical significant bowel dysfunction with intact anal canal anatomy.

Creation of a Stoma

- 1. Creation of a colostomy is an excellent surgical option for patients who have failed or do not wish to pursue other therapies for fecal incontinence. Grade of Recommendation, 1C.**

Creation of a well-formed ostomy at an appropriate site is very successful in controlling the FI with the primary disadvantage being the psychosocial price of becoming an ostomate. When alternative therapies are not appropriate or have failed, a stoma will usually allow the patient to resume normal activities and improve quality of life.^{137,142} In a survey, 83% of patients with FI who had a permanent colostomy created reported a significant improvement in

lifestyle, and 84% of the patients would choose to have the stoma created again.¹⁴³

NON-FDA APPROVED TREATMENTS

Some treatments are currently not approved for use in the United States by the FDA, but they are used enough worldwide that a discussion of their supporting evidence is warranted.

Percutaneous Tibial Nerve Stimulation

- 1. Percutaneous tibial nerve stimulation may be considered because it provides short-term improvement in episodes of fecal incontinence. Grade of Recommendation: Weak recommendation based on low- or very low-quality evidence, 2C.**

Percutaneous tibial nerve stimulation is a nonsurgical treatment that consists of the application of electrical stimulation to the posterior tibial nerve in multiple successive treatments. The best treatment schedule has not been defined. A limited number of case series have demonstrated a median decrease of 4 points from pretreatment CCF scores and a median change of 4 episodes per week in short-term follow up.¹²⁹ The overall results are equivocal, with only 1 study showing a statistically significant improvement in CCF score at 6 months.¹²⁹ This treatment is currently not FDA approved for use in the United States, although a multicenter trial has recently been completed and results are pending. Further recommendations await long-term results to determine its ultimate role in managing FI.

Magnetic Sphincter

- 1. Current data are insufficient to support the use of the magnetic sphincter for fecal incontinence. Grade of Recommendation: Weak recommendation based on low- or very low-quality evidence, 2C.**

A newer alternative anal occlusion device is the magnetic ring, which consists of a string of titanium beads with a magnetic core that is implanted to encircle the anus. The pressure generated during defecation breaks the magnetic attraction, allowing the beads to separate and the anal canal to open. With the use of an anterior or anterolateral incision, a tunnel is created to encircle the external sphincter. A sizer is then used to select the proper number of beads. The literature on this topic is limited; preliminary evaluations from pilot studies suggest a fairly good efficacy despite lower closing pressure but a simpler implantation technique.^{144–146} Failure rates were not included in these studies and some patients were shared among studies, making it difficult to determine the efficacy and safety of this device. Absolute contraindications include

active infection, severe tissue rigidity, the presence of cancer, anoreceptive intercourse, or lack of sufficient tissue around the anus or the rectovaginal septum. This device is still not commercially available in the United States, but an application for FDA approval under humanitarian use has been filed and will need to be studied further before it is accepted as a standard approach for FI. Overall recommendations await long-term results to determine its ultimate role in managing FI.

OTHER TREATMENTS

Several other treatments have been described, including injection of alternative bulking agents that are not available in the United States,^{107–111,114,147–164} pudendal nerve stimulation,^{165,166} pudendal nerve decompression,¹⁶⁷ perineal puborectalis sling,¹⁶⁸ dynamic graciloplasty^{169–179} (which is not available in the United States), and gluteus muscle wrap.¹⁸⁰ These techniques are not in mainstream use, and a discussion is beyond the scope of this practice parameter. Antegrade colonic enemas via cecostomy or appendicostomy have also been described,^{181–185} but the literature currently only describes their use in the pediatric setting. These techniques and supporting data are summarized in a 2014 review article commissioned by The American Society of Colon and Rectal Surgeons.¹⁸⁶

Appendix A

Contributing Members of the ASCRS Clinical Practice Guideline Committee

Janice Rafferty, Chair; Scott R. Steele, Co-chair; W. Donald Buie, Advisor; Patricia L. Roberts, Council Representative; Joseph Carmichael; George Chang; William J. Harb; Samantha Hendren; Jennifer Irani; James McCormick; Ian Paquette; Madhulika Varma; Martin Weiser; Kirsten Wilkins.

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