Published in final edited form as:

Obstet Gynecol Clin North Am. 2016 March ; 43(1): 93–119. doi:10.1016/j.ogc.2015.10.005.

Evidence-Based Update on Treatments for Fecal Incontinence in Women

Isuzu Meyer, MD and

Division of Urogynecology and Pelvic Reconstructive Surgery, Department of Obstetrics and Gynecology, University of Alabama at Birmingham, Birmingham, AL 1700 6th Avenue South, Suite 10382, Birmingham, AL 35233

Holly E. Richter, PhD, MD

Division of Urogynecology and Pelvic Reconstructive Surgery, Department of Obstetrics and Gynecology, University of Alabama at Birmingham, Birmingham, AL 1700 6th Avenue South, Suite 10382, Birmingham, AL 35233 Phone: (205) 934-1704 Fax: (205) 975-8893

hrichter@uabmc.edu

Synopsis

Fecal incontinence is a highly prevalent and distressing condition which negatively impacts quality of life. The etiology is often multifactorial, and the evaluation and treatment of this condition can be hindered by a lack of understanding of the mechanisms and currently available treatment options. This article will review the evidence-based update for the management of fecal incontinence.

Keywords

Accidental bowel leakage; Anal incontinence; Anal sphincter; Defecatory disorders; Fecal incontinence; Treatment; Surgical treatment

Introduction

Fecal incontinence (FI), defined as the complaint of involuntary loss of liquid and/or solid stool, is a highly prevalent condition. In community dwelling women, the reported prevalence of FI varies widely from 2.2 to 24% and rises with advancing age.[1-8] Epidemiological studies suggest that up to 70% of patients with FI have not reported their symptoms to healthcare professionals.[9,10] Thus, the prevalence of FI is often

Corresponding Author Phone: (205) 934-1704 Fax: (205) 975-8893, imeyer@uabmc.edu.

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Financial disclaimer/conflict of interest:

IM: None

Consultant: Kimberly Clark; Pelvalon

Royalties: UpToDate

Conflict of interest: None

underestimated. The negative consequences of FI include not only the physical debilitation, but also the social isolation, embarrassment, loss of employment, as well as the effect on intimate relationships and self-esteem. In order to reduce the burden of FI, eliminate stigma, and to promote care-seeking, it is important to raise public awareness of the condition and various treatment options available to those who suffer in silence. Another obstacle to help-seeking is that many providers fail to screen for FI because of the complexity in evaluation as well as a lack of clinical experience and knowledge on the current management approaches.

The etiology of FI is multifactorial and caused by the disruption of the continence mechanism depended on anal sphincter function, intact rectal sensation, adequate rectal capacity, compliance, colonic transit time, stool consistency, cognitive and neurologic factors. It was reported that 80% of patients with FI had more than one continence factor compromised.[11] This article will review the evidence-based approach in the management of FI.

Management

The goal of treatment should focus on restoring continence and improving quality of life (QOL). Healthcare providers should routinely ask patients about the presence of FI directly rather than relying on voluntary reporting, and identify conditions and risk factors that may predispose to FI. In order to provide proper treatment, clinicians should determine symptom severity, characterizing stool type, the frequency, amount of leakage, and the presence of urgency. It is helpful to obtain bowel diaries as they are shown to be superior to self-reports for characterizing bowel habits, and can better predict colonic transit.[12,13] Recognizing the type of FI based on the awareness of the desire to defecate before leakage can provide clues to underlying pathology; 1) urgency incontinence, or inability to postpone defecation upon urgency, can be related to external anal sphincter (EAS) dysfunction; 2) passive incontinence, or the loss of stool without the urge to defecate, is often attributed to internal anal sphincter (IAS) dysfunction and peripheral neuropathy; 3) fecal seepage is related to incomplete evacuation and impaired rectal sensation.

Management of FI consists of conservative and surgical approaches. Conservative treatment includes life-style changes, medications, pelvic floor muscle exercises, physical therapy ± biofeedback. Unfortunately, no single option has been shown to provide consistent, long-term effectiveness with low complication rates, making FI extremely difficult to manage. However, symptoms may be alleviated by simple measures.

Dietary Considerations

Avoid offending foods

The frequency and consistency of stool can greatly affect symptom severity. Patients should be educated on factors contributing to bowel disturbances and loose stool consistency including foods containing incompletely digested sugars (fructose, lactose), sweeteners (sorbitol, xylitol, mannitol), carbonated beverages, caffeine, alcohol, cured or smoked meat (sausage, ham, turkey), spicy foods, fatty and greasy foods. Bowel and food diaries can help

identify the individual's offending food items that cause loose stools and incontinence. In the case of diarrhea, patients should be evaluated and treated for any underlying etiology. Fecal impaction should be treated and prevent further constipation to avoid overflow incontinence.

Fiber supplementation

Fiber supplementation along with dietary modification is one of the first-line treatment options for FI, which is helpful particularly in women with low-volume loose-stool associated FI. The mechanisms of dietary fiber depend on stool composition and consistency which vary among the types of fiber ingested. Fiber, when fermented but not completely degraded by colonic bacteria, has been shown to increase stool bulk. In addition, fiber with high water-holding capacity allows a gel formation which normalizes stool consistency (softens hard stool and firms loose/liquid stool). Insoluble fiber increases fecal water content and bulking, however accelerates colonic transit rate, thus having a laxative effect. Increasing rectal distension can improve sensory awareness of the need to defecate which may reduce FI episodes and promote complete evacuation of stool, leaving less in the rectum to leak.[11,14,15] Compared to constipation, data on the effects of fiber supplementation on FI are limited, and most studies are not adequately powered.

Commonly used fiber supplements include methylcellulose (Citrucel®, high solubility, non-fermentable), psyllium (Metamucil®, moderate solubility, fermentable) and calcium polycarbophil (Fibercon®, an insoluble hydrophilic fiber). [16,17] A recent placebo-controlled study compared the effect of dietary fiber supplements (carboxy-methylcellulose, gum arabic, and psyllium) based on the different levels of fermentability/solubility, versus placebo in subjects with loose/liquid stool associated FI. After the 32-day treatment period, psyllium significantly decreased FI episodes compared to the placebo or other fiber groups. The studies further analyzed the characteristics of feces. Of the four groups, psyllium had the highest total fiber content, suggesting that the fermented psyllium products are not completely degraded. In addition, a gel formation was found only in the feces of the psyllium group, maintaining stool consistency.[14]

Recommended daily fiber intake is 25-35 grams for adults. Fiber should be added to the diet slowly to avoid bloating. Because of the bulking nature, fiber could exacerbate symptoms in women with decreased compliance (radiation, prior surgery, proctitis).

Medications

Antidiarrheal medications have been shown to improve symptoms of diarrhea-associated FI. Loperamide (Imodium®) is a synthetic opioid which inhibits intestinal peristalsis increasing oral-cecal transit time. Loperamide can increase resting anal sphincter tone, improve rectal perception and rectal compliance.[18] Compared to placebo, loperamide was more effective for reducing urgency FI, with more people achieving full continence, improved symptoms, and fewer FI episodes.[19] Loperamide has fewer central nervous system side effects compared to diphenoxylate/atropine (Lomotil®).[20] A recent randomized double-blind placebo-controlled crossover trial examined the effectiveness of loperamide versus psyllium fiber for reducing FI episodes. In this study, participants received either daily loperamide (plus placebo psyllium powder) or psyllium powder (plus loperamide placebo) for 4 weeks

(first treatment), 2-week washout, then crossed over to the other treatment for additional 4 weeks (second treatment). A significant reduction in FI episodes per week was found in both groups compared to baseline (loperamide 7.9 to 7.1, $p<0.001$; psyllium 7.3 to 4.8, $p=0.008$). However, the number of FI episodes was similar between the loperamide first and psyllium first groups both at the end of first and second treatment. In addition, both interventions improved symptom severity and QOL. The overall rate of adverse events was similar between the groups, however constipation was seen more in the loperamide group (29% loperamide versus 10% psyllium).[21] Currently, a randomized controlled trial (RCT) using loperamide (CAPABLE: Controlling Anal incontinence by Performing Anal exercises with Biofeedback or Loperamide) is being undertaken by the Pelvic Floor Disorders Network (the National Institute of Health [NIH], NCT02008565). This trial, utilizing a factorial design compares the use of loperamide to oral placebo and the use of anal sphincter exercise training with biofeedback to usual care (basic education with pamphlet) in the treatment of women suffering from FI.[22]

Cholestyramine (2-6 grams daily) can be helpful as an adjunct therapy especially in patients with bile salt malabsorption.[16,23,24] Anticholinergic medications such as hyoscyamine 0.125 to 0.25mg, if taken 30-60 minutes before meals, are thought to be helpful in postprandial leakage. Hyoscyamine induces relaxation of intestinal smooth muscles and decreases gastric acid secretions. However, the use of hyoscyamine outside of clinical experience is supported by little evidence with lack of placebo-controlled studies.[25] Given dose-dependent adverse events related to anticholinergics (dry mouth, dizziness, and blurred vision, fatigue, constipation), this medication should be avoided in the elderly.

Amitriptyline has been shown to prolong colon transit time by decreasing rectal contractions in patients with idiopathic FI.[16,17] Clonidine, an α -2 adrenergic agonist, 0.1mg twice daily, has been also used for treatment of FI. However, a recent RCT on urgency-predominant FI reported that clonidine did not affect bowel symptoms, fecal continence, or anorectal functions, compared to placebo. Among patients with diarrhea, clonidine increased stool consistency and decreased diarrheal episodes, but not FI frequency.[26] Topical phenylephrine can increase smooth muscle tone and has been evaluated on patients with FI associated with decreased IAS tone. The results were statistically significant, however shown only weak improvements in FI symptoms. The current evidence is inconclusive to recommend this therapy.[16,19,27] Localized dermatitis or burning sensation, although short-lasting, have been observed.[19] The currently available supplements/medications and their level of evidence on treatment of FI are listed in Table 1.

Pelvic Floor Muscle Exercises and Biofeedback

Pelvic muscle exercises and biofeedback alleviate FI symptoms by improving contraction of the pelvic floor muscles, sensory-motor coordination required for continence, and enhancing the ability to perceive rectal distension.[28] Pelvic floor muscle training is recommended to nearly all patients with FI, however, no consensus exists on exercise regimen (i.e. number, intensity, duration of squeezing). The data on pre- and post-treatment comparisons of pelvic floor muscle exercises for FI are less established compared to urinary incontinence.

Biofeedback is performed using an anorectal manometry or surface electromyography (EMG). Biofeedback therapy focuses on three main targets; 1) rectal sensitivity training: gradually distending a rectal balloon with air or water to determine the sensation of rectal filling. In patients with higher threshold, the training should focus on feeling the distention at lower volume to give a signal to get to the toilet sooner or squeeze muscles to prevent leakage. Whereas if the patient has a low threshold (low capacity, hypersensitive rectum), the goal is to focus on tolerating larger volumes; 2) strength training: visual or auditory signals are used as a guidance to demonstrate the proper muscle isolation and improve squeeze pressures; 3) coordination training: focusing on coordinating rectal distention and anal sphincter contraction. The goal is to achieve a maximum sphincter squeeze in less than 1 second after a rectal balloon is inflated to prevent leakage. Currently, there is no standardization of biofeedback treatment, likely contributing to the wide range in reported success rates of exercises $\pm$ biofeedback from 38% to as high as 100 %.[11,29,30] Some studies have shown no major benefit for biofeedback, whereas more recent RCTs have favored the addition of biofeedback to pelvic floor muscle training.[29,31-33] Factors associated with worse outcomes for biofeedback include severe FI, pudendal neuropathy, underlying neurological conditions, overflow incontinence associated with behavioral/psychiatric disorders, decreased rectal capacity from resection, inflammation, or fibrosis, major structural damage to continence mechanisms. Biofeedback appears to be more beneficial in patients with urgency FI, and useful in post-sphincteroplasty or anal repair. [11,29] The American College of Gastroenterology and American Gastroenterological Association recognizes biofeedback as a safe and effective approach and recommend its use especially in patients with weak sphincters and/or impaired rectal sensation.[11,30] A recent NIH consensus statement concluded that biofeedback is effective in preventing and reversing pregnancy related FI for the first year after delivery, however, long-term data for the benefit of biofeedback on prevention are still lacking.[34] Further research should focus on standardizing optimal therapy regimens and guidelines.

Surgical Management

Significant innovative changes in the surgical treatment of FI have recently emerged. However, existing studies vary in the primary outcome measured (QOL, dichotomous continent/incontinent, number of leakage episodes) making the interpretation and comparison of the results more challenging. In general, surgery should be offered to patients who have failed a credible attempt of conservative therapies.

Traditional Approaches

Sphincteroplasty

The most common cause of FI is external anal sphincter disruption often noted in the anterior segment.[35] Delayed repair of anal sphincter disruption remote from delivery is reviewed in this section. For most women, sphincter injuries are caused by obstetric trauma. The etiologies for chronic sphincter disruptions can be due to either unrecognized injuries at the time of childbirth, from a perineal repair breakdown, or persistent injuries after the primary repair. Among women who had a sphincter laceration repaired at the time of

delivery, 35% continued to have IAS gaps, of those women, the majority had concomitant EAS disruptions noted on endoanal ultrasound at 6-12 months postpartum.[36]

The traditional sphincteroplasty is performed via a curvilinear incision made in the perineum on the outer edge of the EAS in the plane between the rectum and vagina.[37,38] To avoid pudendal nerve injury posteriorly, care should be taken not to extend the dissection laterally beyond 180° circumference of the anus. The sphincter muscles are typically divided through scar anteriorly if present, then plicated in an overlapping fashion to narrow the canal. When disrupted, both internal and external sphincters are mobilized en block to create the overlapping repair. Separate dissection of the internal and external sphincters does not appear to provide better functions postoperatively.[39,40] Levator muscle plication has been shown to improve functional outcomes, however, may cause significant dyspareunia in women.[41-43]

Sphincter plication has been shown effective at least in the short-term.[35,44] Initially, 70-80% of patients reported symptom improvement. However, long-term success rates deteriorate over time ranging from 20 – 67% by 5 years, and even lower (0 – 40%) at 10 years.[35,45-47] Bravo Gutierrez et al demonstrated a 6% complete continence rate at 10 years in their long-term study with 130 patients. In the same population, the incontinence rate increased from 36% at 3 years to 57% at 10 years.[48] The existing data on the long-term efficacy of sphincteroplasty as noted in a recent systematic review are shown in Figure 1. The most common complication is wound infection, ranging from 2 to 35%. Deep infection resulted in poor long-term outcomes.[44,45,49] Other factors of long-term failure include advanced age at the time of repair, duration of FI symptoms, and pudendal neuropathy, although controversial.[44,49] Preoperative anorectal manometry and endoanal ultrasonography have a limited role in predicting surgical success.[11] Nonetheless, diagnosis of a sphincter defect on imaging studies, most commonly with endoanal ultrasound, is warranted prior to sphincteroplasty.[49]

Special Population: Obstetric Anal Sphincter Injuries (OASIS)

Pregnancy and childbirth are unique risk factors for FI in women. Two mechanisms of sphincter injury are either traction pudendal neuropathy or anatomical disruption of the anal sphincter complex. OASIS from laceration or episiotomy at the time of vaginal delivery are strongly associated with FI, both immediate and delayed. In primiparous women, nearly 35% had sphincter defects noted on endoanal ultrasound at 6-8 weeks following vaginal delivery.[50] However, many women with OASIS do not develop FI symptoms until 2-3 decades after the initial insult.[51] The evidence for the optimal management in preventing OASIS is limited. The role of primary cesarean delivery to prevent OASIS is controversial. Both long-term follow-up data (5-12 years) as well as large population meta-analyses (12,000 – 31,500 women) showed no difference between spontaneous vaginal delivery versus cesarean section in preventing FI, whereas operative vaginal delivery and medial episiotomy are well-documented risk factors for OASIS.[52-56] The issue is often complicated in women with prior OASIS to determine the mode of delivery in the subsequent delivery. The risk of repeat OASIS with vaginal delivery has been reported 4-8%.[57,58] Currently, the American College of Obstetricians and Gynecologists does not

suggest primary elective cesarean delivery for prevention of FI (Grade 2C) because planned cesarean delivery conferred no protection against FI.[59] In women with a history of FI or OASIS, data on the optimal mode of delivery for subsequent pregnancies are limited. Many experts advise that a woman with persistent FI and a poorly functioning anal sphincter be offered a planned cesarean for subsequent deliveries only after discussing the risks and benefits of both options and understanding the lack of data on this matter.[60,61]

In regard to third and fourth degree obstetric laceration repairs at the time of delivery, the existing data comparing overlapping versus end-to-end repair are conflicting. For the immediate repair with no scar present, most studies showed that the two approaches do not differ in surgical outcomes.[46,47] More recently, the randomized trial by Farrell et al. reported that end-to-end repairs of complete third and fourth degree obstetric lacerations are associated with significantly lower rates of anal incontinence at 12 months. However, no differences were observed over 3 years.[62]

Neosphincter Construction

In patients with severe refractory FI due to structural damage such as complete perineal disruption from massive trauma or infection, neosphincter construction has been attempted either from autologous gracilis muscle or an artificial bowel sphincter.

Graciloplasty

A sling like structure is constructed using the patient's own gracilis muscle with one end attached to the pubis, encircling the anus, and the other end reattached to the opposite ischial tuberosity. A pulse generator (available in Europe but not in the US) can be implanted to transform a fast twitch skeletal muscle (fatigue-prone) into a slow twitch muscle (fatigue-resistant) providing a sustained sphincter like response.[11,63] Clinical success rates of 38-90% have been reported. However, gracilis muscle transfer has drawbacks; deterioration in effectiveness over time, a long learning curve for surgeons, and high morbidity. The complications include infection (28%), problems related to the device (15%), and leg pain (13%).[64] The revision rate due to major complications was up to 50%. [11] The muscle does not function as a dynamic sphincter, thus evacuating feces can be challenging. Up to 90% of patients reported constipation or difficulty evacuation.[65] An overall mortality of 2% (0-13%) was reported.[64]

Artificial Bowel Sphincter (ABS)

The currently available ABS consists of an inflatable cuff implanted around the anal canal with a pressure-regulating balloon placed in the prevesical space and a pump in the labia connecting the cuff and balloon. Patients can inflate the cuff to prevent stool passage and deflate to allow defecation. Existing data on the success rates and safety vary considerably. The largest study with 52 patients with a mean follow-up of 64 months reported the median Wexner score decreased significantly after ABS implantation even though full continence was rarely achieved.[66] However, defecatory difficulties or constipation is not uncommon, the reported rates ranging from 6 – 83%.[66,67] The overall revision rate was 13-50%, however, cumulative risk of revision increases over time from 7% at 1 year, 40-60% at 5 years, and eventually reaching a plateau around 90% after 5-10 years.[66-68] In addition,

the explantation rates also increase overtime, 20% at 1 – 3 years to 40% at 5 years.[66] The most common reason for surgical revision was device malfunction such as micro-perforation and leak from the cuff as repeated inflation and deflation often causes cuff fatigue. Device erosion and infection are the most common reasons for device explantation.[68] Given the high morbidity, revision and explantation rates, the use of ABS is currently limited, mostly for the treatment of end-stage severe FI.

Neuromodulation

Sacral Neurostimulation (SNS)

SNS was first introduced in Europe in 1995 as a minimally invasive treatment for FI.[69] The InterStim® (Medtronic, Inc., Minneapolis, MN) was approved by the US Food and Drug Administration (FDA) for treatment of chronic refractory FI in April 2011. The electrode is inserted typically in the S3 foramen to provide low-amplitude electrical current via a battery operated stimulator. Proposed mechanisms of action include that SNS acts through a somatovisceral reflex pathway to reduce colonic activity, a direct effect on the anal sphincter complex to increase sphincter tone, reduce spontaneous sphincter relaxation, and change rectal sensitivity or compliance through afferent nerve modulation.[70-73] However, improvements in FI symptoms without changing sphincter pressures have also been reported.[70,74,75] Although data are limited, SNS has been shown effective in patients even with disrupted anal sphincters, including previously failed sphincteroplasty. The extent of sphincter gap differs in existing data; up to 180° sphincter separation has been studied. Treatment outcomes appear to be independent of size, although the results are less predictable, and effect sizes are smaller in these studies.[69,76-78] A few studies evaluated the efficacy of SNS in patients with neurogenic bowel (FI due to nerve injury or neurologic conditions), and SNS appears to be effective even in patients with neurologic disorders. However, long-term data are lacking.[79,80]

SNS is a two-step procedure; 1) the testing phase with a temporary external neurostimulator and 2) placement of a battery-operated implantable pulse generator (IPG). For the testing phase, the “staged trial” technique with a permanent lead placement is preferred to the percutaneous nerve evaluation (PNE) using a temporary monopolar lead. Some use the PNE approach as this can be done in the office with local anesthesia, however, is more prone to incorrect lead placement and lead migration (especially in obese or active patients) resulting in high false negative rates. In addition, the PNE testing phase is typically 4-7 days, whereas the use of a permanent lead in a staged procedure allows a longer testing period, usually 2 – 4 weeks for the evaluation of FI treatment. Studies have shown high progression rates to IPG implantation with the staged procedure using a permanent lead.[81] Batteries must be replaced approximately 7 years after implantation.

In the pivotal US multicenter trial including 133 patients undergoing InterStim® procedure in 2010, 90% had a successful test stimulation and proceeded to the permanent implantation. At 12 months, 83% of the patients achieved therapeutic success, and 41% had complete continence. Incontinence episodes decreased from 9.4 episodes per week at baseline to 1.9 at 12 months, and 2.9 at 24 months.[82] This trial was extended, and the long-term results of SNS were published in 2013. Of the initial subjects, 63% (n = 76/120) were available for 5

year follow-up. FI episodes per week were 1.7 at 5 years, with 89% of the subjects having 50% symptomatic improvement, 36% having complete continence.[83] Most studies define success as a 50% reduction in FI episodes per week. When reviewing short- (< 12 months), medium- (12 – 36 months), and long-term (> 36 months) success for SNS, the median rates (range) were 63% (33 – 66), 58% (52 – 81), 54% (50 – 58) per intention to treat analysis, compared to the median per-protocol rates of 79% (69 – 83), 80% (65 – 88) and 84% (75 – 100), respectively. Sustained clinical benefit of up to 14 years has been demonstrated in greater than 80% of subjects.[84] Existing data on the efficacy of medium- to long-term follow-up studies are listed in Table 2.

Most adverse events (67%) occurred within the first year of implantation, and the majority required none to minimal interventions such as medications. Common device-related adverse events are implant site pain (28%), paresthesia (15%), and changes in the sensation of stimulation (12%). [85] However, a recent meta-analysis reported a lower rate of implant site pain of 6%.[86] Pain is usually managed conservatively by reprogramming of the device, medication, or no treatment. In some cases, revision or explantation of the neurostimulator and/or the lead may be required.[85-88] With advancements in the lead design and techniques, explantation of the device is rarely necessary (on average 3-4%). [86,89] The infection rate is typically around 3%, however, up to 11% has been reported. [82,85,90] Because of the minimally invasive surgical technique, high success rates, minimal morbidity with no mortality, the current data suggest that SNS is an effective approach for treatment of FI.[69,90-92] Future studies should also explore the efficacy of SNS on patients not limited to intact sphincters as well as patients with neurogenic disorders for broader applicability.[93]

One of the concerns with the InterStim® system is the use of magnetic resonance imaging (MRI). The InterStim® system has shown to be MRI conditional based on non-clinical testing. Not all InterStim® devices are MRI safe: all models of 3058 neurostimulators (InterStimII®) are MRI eligible, whereas some of the 3023 (InterStim®) models are not. The non-MRI eligible series numbers can be found in the Medtronic MRI Safety Guidelines (Medtronic, Inc., Minneapolis, MN). Patients with MRI eligible neurostimulators can undergo a certain head MRI scan (1.5-Tesla horizontal closed bore with radiofrequency transmit head coil only). The neurostimulator needs to be turned off prior to examination. Patients during test stimulation or having any neurostimulation system components not fully implanted should not undergo MRI. It is important to discuss the risks of undergoing MRI with patients prior to implantation.

The safety and efficacy of SNS in pregnancy, the unborn fetus, and delivery has not been established. Existing data on SNS in pregnancy are derived from a retrospective study or case series with a small number of women with urinary complaints.[94,95] Due to lack of evidence, those who are considering or during pregnancy should turn off their neurostimulator.

Percutaneous Tibial Nerve Stimulation (PTNS)

PTNS for FI has been approved in Europe, but is under investigation in the US. The PTNS treatment uses a 34-gauge needle as an electrode to stimulate the posterior tibial nerve near

the medial malleolus to achieve effects via L4 – S3 nerve roots. PTNS is a minimally invasive outpatient therapy with almost no associated morbidity. The reported estimated cost is less than 1/10th compared to that of SNS.[96-99] However, PTNS requires repetitive treatments to maintain effectiveness. Weekly returns to the clinic for 12 consecutive weeks followed by maintenance visits may not be suitable for some patients. Thus, the success of PTNS depends highly on patients' motivation.

Until recently, the existing data on PTNS were derived from case series demonstrating that 52-83% achieved a 50% reduction in frequency of FI.[96,100,101] However, the duration and frequency of the therapy varies among the studies, making direct comparisons difficult. The largest prospective study including 115 patients with a median follow-up of 26 months (range, 12 – 42) reported 52% of patients achieving a 50% reduction in FI episodes as well as improving QOL.[100,102] The first multi-center RCT (the CONTROL of Faecal Incontinence using Distal NeuromoulaTion [CONFIDeNT]) in the United Kingdom was recently published. This trial included 227 patients to evaluate the efficacy and cost-effectiveness of PTNS (n=115) comparing to sham electrical stimulation (n=112). Interestingly, the study reported no difference between the PTNS and sham groups in the efficacy at 12 weeks; 38% in PTNS versus 31% in sham have achieved a 50% reduction in the number of FI episodes per week with the adjusted ratio of 1.28 (95%CI 0.72-2.28; p=0.40).[103]

Data comparing PTNS and SNS are limited. Al Asari et al. reported no significant differences in the mean Wexner and FI Quality of Life (FIQoL) scores between PTNS and SNS groups up to 12 months on treatment of refractory FI.[98] A RCT comparing PTNS and SNS in the treatment for FI is currently being undertaken in Switzerland (NCT01069016).[100,104]

Another form of PTNS is the transcutaneous approach using cutaneous pads instead of a needle.[105] This less invasive device may allow patients to self-administer the treatment at home and potentially become a cost effective option. However, existing data on the efficacy of the transcutaneous approach are extremely limited. As more data become available, the ideal treatment protocol (interval, duration, stimulation approach) as well as the role of PTNS for treatment of FI should be validated.

Perianal Injectables

Perianal injection of a bulking agent to increase the resting anal sphincter tone was first described in 1993.[106] Before the injectable therapy was available, the treatment for passive incontinence and IAS dysfunction was limited. Bulking materials into the submucosa or intersphincteric space increase the tissue volume in the high-pressure zone, especially in the proximal sphincter canal, creating a tighter seal at rest. Injectables could also target defective areas of the IAS, if present, to create canal symmetry.[107,108] Bulking agents introduced to date include autologous fat, Teflon, bovine glutaraldehyde cross-linked collagen (Contigen), carbon-coated zirconium beads (Durasphere), polydimethylsiloxane elastomer, dextranomer in non-animal stabilized hyaluronic acid, hydrogel cross-linked with poly-acrylamide (Bioplastique), porcine dermal collagen (Permacol), synthetic calcium hydroxylapatite ceramic microspheres, polyacrylonitrile in cylinder form. In 2011, non-

animal stabilized hyaluronic acid/dextranomer (NASHA Dx) was approved by the FDA for the treatment of FI refractory to conservative therapy (Figure 2). In the lithotomy, left-lateral, or prone position, 1 mL is injected into the deep submucosa through an anoscope at 4 sites (typically, 3, 6, 9, and 12 o'clock), slightly above the dentate line targeting the proximal part of high pressure zone. When the response is not satisfactory, a repeat injection can be administered after 4 weeks. Given the minimally invasive technique, this therapy can be an office procedure with significantly low morbidity.

A double-blinded RCT for the short-term efficacy of NASHA Dx versus sham injections for FI demonstrated that 52% in the NASHA Dx group and 31% in the sham group achieved a 50% reduction in FI episodes. At 12 months, the treatment response increased to 69% in the NASHA Dx group. Interestingly, no difference was observed between the two groups at 3 months, suggesting the placebo effects cannot be negated.[106,108] The study was extended to 36 months evaluating the long-term efficacy. Of the 136 patients randomized to the NASHA Dx group in the initial study, 82% (112/136) were available for the long-term assessment. The study showed that the success rate (a 50% reduction in FI episodes) was sustained at 52.2% at 36 months follow-up. Complete continence was seen in 13.2% at 36 months, increased from 6% at 6 months. Interestingly, the majority of the patients (82% in the original study, 87% in the long-term follow-up study) received a second injection after 4 weeks from their initial treatment. No patients received further injections.[109] Common treatment related adverse events were transient and minor bleeding, pain, discomfort, mostly self-resolved. Of the 136 patients, only 2 had serious adverse events (abscesses) within 6 months, which were treated with antibiotics or surgical intervention. Adverse events unique to long-term follow-up (6-36 months) are injection site nodules seen in 2%.[106,108]

Although complete continence may not be achieved, perianal bulking therapy may be an effective and safe option to alleviate symptoms especially in patients with mild to moderate passive FI. However, the evidence on NASHA Dx is currently limited to short-term efficacy. The injection techniques (submucosal versus intersphincteric space, trans-anal ultrasound guidance, injection volume) and the optimal injectable substances are yet to be determined.

Radiofrequency Ablation Therapy

Radiofrequency ablation (RF) therapy (Secca®) was approved by the FDA in 2002 for treatment of refractory FI. This therapy device consists of an anoscope with 4 nickel-titanium curved needle electrodes to apply a temperature-controlled RF energy (65°C to 85°C) to the submucosa of the IAS (Figure 3). In theory, heat applied to the submucosa induces collagen denaturation and tissue fibrosis, thus the affected anal canal becomes constricted with increased resistance to stool passage.[110,111] A similar technique has been used for gastro-esophageal reflux disease and benign prostatic hypertrophy.[110] The long-term (5 years) study of the Secca® system reported that the mean Wexner incontinence score improved from 14 to 8 ($p < 0.0003$), and 84% of the subjects achieved 50% symptomatic improvements. However, the study was limited by a small sample size with only 19 patients.[112] Current data on the efficacy and safety of the Secca® system are limited by the short-term follow-ups and small sample sizes as existing studies included

neither greater than 50 patients (n = 8-50) nor follow-up longer than 5 years (6-60 months). [111-113] Therefore, there is insufficient evidence for the use of RF ablation.

Fecal Diversion

A colostomy or ileostomy is considered a definitive therapy yet the last option when other treatments have failed or are unsuitable. Many people are afraid that having an ostomy can negatively impact their QOL than living with FI. Early discussion regarding treatment options including diversion is helpful to cope with possible lifestyle changes in patients with severe FI, if appropriate. People with an ostomy can be very active in their social and professional lives. Most activities including sports can be performed with minimal modifications. Ostomy should not affect sexual function. A study reported that both general and disease specific QOL were better in patients with colostomy; the colostomy group had higher scores on social function on the SF-36 as well as the coping, embarrassment, lifestyle, and depression scales on the FIQoL compared to patients with FI.[114] Another study demonstrated that most patients with previous FI felt positively about having a stoma with the median score of 8 for the ability to live with a stoma and 9 for satisfaction with the stoma (both a scale of 0-10). The majority (83%) reported the stoma restricted their life “a little” or “not at all” with significant improvement from their previous incontinence.[115] Fecal diversion via laparoscopy is a safe and effective option with decreased morbidity such as reduced postoperative pain, ileus, and the length of hospital stay.[11,116,117] Although considered as a last resort, diverting ostomy can ameliorate symptoms and improve QOL in women with severe refractory FI.

Recently Available Treatment Options: Devices

Anal plugs

Anal plugs are designed to temporarily occlude the anal canal to prevent stool leakage. Existing studies suggest that anal plugs may be difficult to tolerate as demonstrated by a considerably high dropout rate (35%). If tolerated, the device may be helpful to alleviate symptoms particularly in patients with impaired anal-rectal sensation and those who are institutionalized or immobilized.[118] The REST study is the most recent multi-center, prospective, single-arm non-randomized trial to assess the efficacy, tolerability, and safety of a new single-use disposable device (the Renew Insert) including 91 patients with moderate-to-severe FI.[119] The device is a silicone anal insert, designed for self-insertion with an applicator, to seal the rectum to help prevent leakage and is naturally expelled with a bowel movement (Figure 4). Of the 91 subjects (intention to treat [ITT] cohort), 73 (80%) completed all 12 weeks of treatment (“completers”), whereas 85 (93%) completed at least one week of treatment (modified ITT [mITT] cohort). The study showed a significant reduction in FI frequency, 0.9 FI episodes per day at baseline to 0.2 episodes at 12 weeks ($p<0.001$) in the mITT cohort. A 50% reduction in FI frequency was seen in 62% and 78% of the ITT and mITT cohorts, respectively. The study also demonstrated a significant reduction in the Wexner scores (16.2 baseline versus 10.9 with treatment, $p<0.001$). Adverse events were seen in 51%, however almost all (98%) events were mild such as anorectal urgency (26%), irritation (13%), gastrointestinal discomfort (4%), gas (3%), or hemorrhoids

(6%). Subjectively, 78% of the completers were either very or extremely satisfied with the device.[119]

Vaginal Bowel Control System

A vaginal bowel control system (Eclipse™ System) has been designed to provide a low-risk, effective, and easily reversible treatment for women with FI. The device consists of a silicone-coated base with an inflatable balloon and a hand-held pressure-regulated pump. The system is inserted into the vagina, similar to a pessary, with the balloon directed posteriorly. When the balloon is inflated, the vaginal wall occupies rectal space, preventing unwanted stool passage. Deflating the balloon allows stool passage, thus patients are able to control their own bowel movements (Figure 5). Typically, the vaginal insertion produces little or no sensation. The LIFE study was a trial for women with FI to evaluate the effectiveness and safety of the Eclipse™ device. Of 110 subjects, 61 were successfully fitted with the device and subsequently proceeded with a 4 week treatment period. The study reported 79% (intention-to-treat) and 86% (per protocol) reported a 50% reduction in FI episodes. Subjectively, 86% reported their bowel symptoms “very much better” or “much better,” and a significant improvement in QOL was demonstrated using the FIQoL and Modified Manchester subscales. Adverse events were observed in 47 of 110 participants (all mild to moderate), and many device-related events were noted during the fitting period, including 15% pelvic discomfort, 10% urinary leakage or urgency, 9% vaginal findings (erythema, abrasions, irritation), 8% pelvic pain, 7% vaginal spotting. During the treatment period, the rate of adverse events were much lower with 10% pelvic discomfort, 3% UI or urgency, 5% vaginal findings, 3% pelvic pain.[120] Currently, the device is being investigated on the durability of the safety and effectiveness for extended follow-up periods (3 and 12 months of use) by a multi-center, prospective, open-label clinical trial (the LIBERATE study, NCT02428595).

Investigational Treatment Options

Autologous Myoblast Injection

Autologous myoblast injection is an investigational procedure. As the anal sphincter muscles degenerate over time upon injury leading to sphincter dysfunction, injection of autologous cells can potentially replace or repair the damaged tissue and enhance their function. The exact mechanisms, histomorphologic and functional changes of disrupted sphincter muscles in response to myoblasts, are being studied using animal models. [121-123] In humans, similar regenerative therapy with autologous cells injected into the urethral sphincter in patients with stress urinary incontinence appears to be beneficial in small investigational studies.[124,125] The pilot study has been conducted to evaluate the clinical efficacy of the autologous myoblast cell injection (cultured and harvested from the pectoralis muscle) in women with symptomatic FI due to disrupted EAS from obstetric trauma. This study demonstrated an increase in squeeze pressures at 1 and 6 months post-injection, however returned to baseline by 12 months. In addition, significant improvements were noted in both overall symptoms and QOL as measured by the Wexner score and FIQoL scale at 12 months post injection.[126] A RCT of intrasphincteric injections with autologous myoblasts versus saline solution is being undertaken (NCT01523522). Autologous cells

have definite advantages over embryonic stem cells as the former avoids adverse events related to foreign materials and bypass ethical concerns.

Magnetic anal sphincter (MAS)

Anal sphincter augmentation using a magnetic ring has been introduced to treat FI. The FENIX™ Continence Restoration System consists of a flexible band of interlinked titanium beads, each with a magnetic core, to form a ring. The magnetic attractions among the beads reinforce the closing pressure of the anal sphincter to prevent leakage of stool. Straining to defecate will separate the beads to allow voluntary passage of stool. (Figure 6) This device is surgically implanted around the anal canal.[127,128] A similar device has been used to treat gastro-esophageal reflux disease. Short- to mid-term efficacy of MAS appears to be promising.[127,129,130] One study with a median follow-up of 18 (6 – 45) months reported a success rate of 70% (defined as improvement of the postoperative CCF-IS score by > 50%). In the same study, the QOL scores (measured by the FIQoL) also improved postoperatively.[127] Another prospective study reported improved QOL and decreased incontinence severity (measured by the FIQoL and CCF-FIS scores, respectively) and demonstrated 76% of the subjects having 50% reduction in FI episodes per week.[131] However, current data are derived from observational studies with a small sample size (7 to 23 subjects).[127,129-131] In addition, the definition of success varies among the studies, making direct comparisons difficult. A randomized trial with a larger sample size is needed to further evaluate the long-term efficacy and safety of MAS.

Sling for FI

The Trans-Obturator Post-Anal Sling (TOPAS) system is a self-fixating polypropylene mesh placed under the anorectum to provide anatomical support. The mesh is placed lateral to the puborectalis muscle and inferior to the anorectum, and brought through the ischiorectal fossa using two needle passers via the trans-obturator approach, thus reinforcing the normal anorectal angle. A prospective multi-center open-label study including 29 women reported a significant decrease in the mean number of FI episodes per 14 days (from 6.9 to 3.5 episodes) at 24 months. In addition, 56% of the subjects reported treatment success, defined as a 50% reduction in number of FI episodes per 14 days compared to baseline. Device related adverse events were observed in 12 patients with total 19 events during the study period. The most common events were de novo urinary incontinence or bladder spasm (n=6), worsening FI (n=2), and constipation (n=2), and one patient had disk herniation related to the positioning during the procedure. No device erosions or extrusions were noted in the 24 month follow-up period.[132]

There is an on-going prospective multi-center, single-arm open label study (15 colorectal surgery and urogynecology centers in the US). The “TRANSFORM” (NCT01090739) study is evaluating the safety and effectiveness of the TOPAS system for the treatment of FI in women who failed conservative therapy. The study included 152 women with FI who were implanted with the TOPAS system. Treatment success was defined as a 50% reduction in number of FI episodes. Outcomes were assessed at baseline, 3, 6, and 12 months post-operatively. Preliminary results showed that 69% of women had a 50% reduction in FI episodes. The median frequency was 9 episodes and 5 incontinence days per week at

baseline down to 2.5 episodes and 2 incontinence days per week at 12 months. Treatment-related adverse events were seen in 71 patients with a total of 113 events, 97% were managed without therapy or through non-surgical treatment. The most common complications (> 5%) were pain, primarily in the buttock, pelvic or groin, and incision site infection. No mesh erosions, extrusions, organ perforations, bowel obstructions, or device revisions were reported.[133] The final report has yet to be published.

Summary/Discussion

FI is a physically and psychosocially debilitating disorder which negatively impacts QOL. Despite a reasonably high prevalence rate, many women are reluctant to report symptoms and seek care, and thus feel succumbed to the condition. In addition, healthcare providers often fail to screen for FI, not only due to the complexity in evaluation, but also because of the limited awareness of the prevalence, lack of clinical experience and knowledge on currently available therapies.

Treatment of FI can be challenging as the etiology is often multifactorial. Prevention and early intervention should focus on eliminating potential modifiable risk factors such as loose stool, diarrhea, routine practice of episiotomy and operative vaginal delivery especially forceps assisted, and identifying women suffering from FI at earlier stages to avoid worsening symptoms. Management consists of conservative and surgical approaches, and more invasive therapies are reserved for patients with refractory conditions. Traditionally, treatment options were limited once patients failed conservative therapies. Surgery for FI was considered invasive with high complication rates, and the success rates deteriorated over time. However, recent research has provided additional data on the existing treatments as well as the development of less invasive options and new investigational treatments. Of the currently available options, only 3 therapy modalities have been evaluated by RCTs with sufficient size to provide level I evidence, which include biofeedback, NASHA Dx perianal injection, and PTNS. Although SNS is supported by strong level II evidence, the current RCT data on SNS are derived from patients with intact EAS and FI without neurologic disorders, thus generalizability is limited. Based on the US Preventative Services Task Force scoring system, most treatments were assigned grade B recommendations. Biofeedback is the only modality with a grade A recommendation.[93] Further RCTs evaluating long-term efficacy and safety of each modality as well as well-designed comparative studies of available options, and the effectiveness of combination therapies are still needed to solidify a management algorithm for FI. In addition, future research should focus on the cost effectiveness of current therapies as direct and indirect costs associated with FI are substantial. The optimal treatment regimen is often a combination of various conservative and surgical approaches. As more data emerge, healthcare providers should become familiar with the available options and critically evaluate both immediate and long-term outcomes on the efficacy and safety, and individualize FI management using evidence-based practice.

Acknowledgments

HER: Grant Support: Partially supported by the National Institutes of Diabetes and Digestive and Kidney Diseases, 2K24-DK068389

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Key Points

- Fecal incontinence, defined as the complaint of involuntary loss of liquid and/or solid stool, is caused by disruption of the multicomponent continence mechanism.
- Fecal incontinence is a physically and psychosocially debilitating condition. Many women are reluctant to report their symptoms and seek care.
- Management options for fecal incontinence consist of conservative and/or surgical approaches, and more invasive therapies should be reserved for patients with a refractory condition.
- Traditionally, options were limited once patients had failed conservative therapies. Surgical management of fecal incontinence was considered invasive and provided only short-term success with high complication rates.
- Recent research has demonstrated not only the long-term safety and efficacy data on existing modalities, but also the development of less invasive options and investigational devices.

Figure 1. Long-term Efficacy outcomes of sphincteroplasty

From Glasgow SC and Lowry AC, Long-term Outcomes of Anal Sphincter Repair for Fecal Incontinence: A Systematic Review, *Diseases of the Colon & Rectum*, Vol 55, 482-490, Copyright: Wolters Kluwer Health, Inc. (2012); with permission.

Figure 2. Dextranomer-microspheres in sodium hyaluronate gel injection (Solesta™)
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Pharmaceuticals, Inc.

Figure 3. Radiofrequency Ablation Therapy (Secca®)
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Figure 4. Anal Plug (RENEW Inserts)

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Figure 5. Vaginal Bowel Control system (Eclipse™ System)

5A and 5B: From Richter HE, Matthews CA, Takase-Sanchez MM, et al. A vaginal bowel-control system for the treatment of fecal incontinence, *Obstetrics and Gynecology*, Vol 125 (3) 540-7, Copyright: Wolters Kluwer Health, Inc. (2015); with permission. **5C:** Reprinted with permission from Pelvalon, Inc.

Figure 6. Magnetic Anal Sphincter (FENIX™ Continence Restoration System)

A: Magnetic attraction augmenting the anal sphincter

B. MAS expands to allow passage of stool

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Table 1

Current evidence on medical treatment of FI

Medication	Suggested dose	Level of Evidence [†]	Recommendation Grade ^{††}
Fiber supplementation	2-6 grams [*]	II	B
Loperamide	2-4 mg per dose up to 16mg/day	II	B
Diphenoxylate (with atropine)	2.5-5mg (0.025mg) per dose up to 20mg per day	II	B
Cholestyramine	2-6 grams per day	III	C
Hyoscyamine	0.125-0.25mg before meal	III	C
Amitriptyline	20mg nightly	II	B
Clonidine	0.1mg twice daily	II	C
Phenylephrine topical	2.5-cm application at 10%-30% gel shown to have a therapeutic effect at 1 hour	II	C

From Tan EK, Vaizey C, Cornish J, Darzi A, Tekkis PP: Surgical strategies for faecal incontinence-- a decision analysis between dynamic graciloplasty, artificial bowel sphincter and end stoma. *Colorectal Dis* 2008, 10:577-586; with permission.

^{*} suggested total daily intake for adults is 25-35grams

[†] I: 1 properly randomized controlled trial available; II: evidence based on well-designed cohort or retrospective case-controlled studies; III: the evidence based on expert opinion or descriptive studies, case reports

^{††} A: strongly recommended; B: recommended; C: evidence is not sufficient to recommend for or against the therapy

Table 2

Sacral Neuromodulation efficacy in medium- to long-term follow-up studies

Author	Year	Median Follow-up	Number of Subjects	FI episodes per week		50% reduction in FI episodes (%)		Complete continence (%)	
				Baseline	Post-therapy	Per Protocol	ITT *	Per Protocol	ITT *
Matzel et al	2004	24	30	16	2	88	81	35	32
Gourcerol et al	2007	12	29	5	1	69	33	21	10
Tan et al	2007	12	53	10	3	-	-	-	-
Holzer et al	2007	35	29	2	1	-	-	-	-
Melenhorst et al	2007	36	33	10	2	79	59	-	-
Melenhorst et al	2007	48	15	10	2	-	-	-	-
Melenhorst et al	2007	60	10	10	2	-	-	-	-
Tjandra et al	2008	12	53	10	3	71	63	47	42
Munoz-Duyos et al	2008	36	29	1	0	86	58	48	33
El-Gazzaz et al	2009	28	24	5	2	-	-	-	-
Govaert et al	2009	35	169	-	-	77	53	-	-
Dudding et al	2009	51	18	6	0	94	-	39	-
Altomare et al	2009	74	52	4	1	-	-	18	10
Matzel et al	2009	118	9	9	0	78	58	44	33
Wexner et al	2010	12	106	9	1	83	66	-	-
Koch et al	2010	24	35	11	2	-	-	21	11
Michelsen et al	2010	24	126	8	1	-	-	-	-
Oom et al	2010	32	37	9	0	81	65	5	4
Ratto et al	2010	33	10	26	1	-	-	-	-
Lombardi et al	2010	46	11	5	1	100	-	27	-
Boyle et al	2011	17	37	7	1	73	54	46	40
Hollingshead et al	2011	33	86	9	1	83	-	-	-
Mellgren et al	2011	36	77	9	2	86	59	40	26
Uludag et al	2011	85	50	8	0	84	-	-	-
Santoro et al	2012	18	16	14	0	-	-	68	68
Duelund-Jakobsen et al	2012	46	147	6	1	75	-	36	-
Devroede et al	2012	48	77	9	2	87	50	34	20
George et al	2012	114	23	9	2	-	-	52	48
Hull et al	2013	60	72	9	2	89	-	36	-

*
ITT: intention to treat