Fecal Incontinence Evaluation and Treatment

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Last Updated:

Friday, February 24, 2023

Keywords:

fecal incontinence, defecatory dysfunction

1. Introduction

The 4th International Consultation on Incontinence defined anal incontinence as **"any involuntary loss of fecal material and/or flatus"**[1] that can be sub-divided into (i) fecal incontinence (FI), any involuntary loss of fecal material or (ii) flatus incontinence, any involuntary loss of gas. Although there have been some attempts to categorize FI into groups such as major and minor incontinence and passive vs. urge related fecal incontinence, there are no universally accepted FI subdivisions. The average flow of fecal material through the colon is 1.5-2.0 liters a day, with roughly 100-150ml excreted after water reabsorption. Fecal material is transferred from colon to rectum with peristaltic contractions via the parasympathetic nervous system. The average colon transit time is 36-72 hours. **Fecal continence is dependent upon compliant storage, the ability to sense material in the rectum, and an intact sphincter mechanism that is able to relax and contract at appropriate times.**

2. Physiology of Storage and Evacuation of Stool

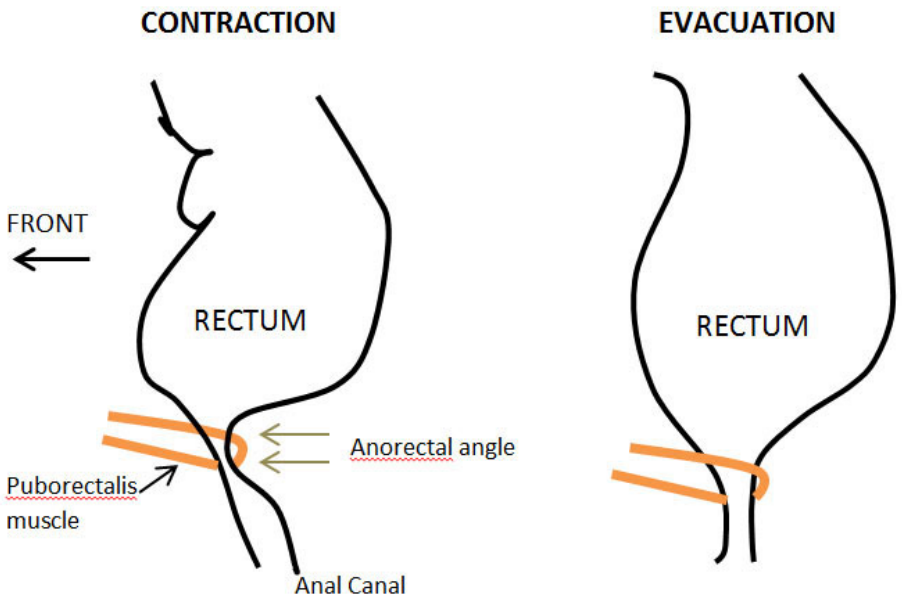

Figure 1: Anorectal Angle

2.1 Storage

When stool accumulates in the rectosigmoid, the **recto-anal inhibitory reflex (RAIR)** is triggered. Rectal distention causes a decrease in internal anal sphincter (IAS) tone, which exposes the sensory receptors of proximal anal canal to a small sample of fecal matter in order to determine if the consistency is solid, liquid, or gas. This transient decrease in IAS tone is followed by an increase in external anal sphincter tone (EAS) tone. Rectal distention results in an urge to defecate, which can be voluntarily suppressed in which case further rectal accommodation occurs.

2.2 Continence

The anal canal extends from the anorectal ring to the anal verge and is approximately 4cm long. In simplistic terms, anal canal pressure must exceed rectal pressure to maintain control and fecal continence. **The IAS (smooth muscle), the EAS (striated muscle) and the puborectalis muscles (striated muscle) act together to keep the rectum closed and make up the anal sphincter mechanism.** In addition, mucosal folds fill with blood (“anal cushions”) and may provide an extra barrier function by occluding the anal canal.

The **puborectalis muscle** is a sling like muscle that originates at the pubic rami (on either side of the pubic symphysis) and forms a U-shaped sling around the genital hiatus. Contraction results in the anorectal junction being pulled forward towards the pubic symphysis. This results in creating the **anorectal angle** (angle between lower rectum and upper anal canal) and essentially acts to “kink” the rectal lumen (**Figure 1**). The normal anorectal angle is considered to be approximately 90 degrees, and patients with FI tends to have a larger (or wider angle) which may be due to puborectalis dysfunction.[2] **The puborectalis appears to be primarily responsible for continence of solid stool** and is innervated by branches of S2-4.

The IAS and EAS are primarily responsible for flatal and liquid stool continence. Sufficient EAS strength is necessary to contract the sphincter voluntarily and counteract urge, otherwise urge FI can result. The IAS contributes the majority of resting anal pressure (approximately 80%) and is formed by continuation of the inner smooth muscle layer of the rectum. The IAS is innervated by autonomic nerves and not under voluntary control. The sympathetic supply to the IAS is via the hypogastric plexus and the parasympathetic supply originates from S2-4. **The IAS is responsible for sampling and sensing volume and type of material (gas, liquid, solid) in the rectum**.

The EAS surrounds the IAS and inserts anteriorly to the perineal body. The more proximal portion of the EAS does not usually form a continuous ring anteriorly[3] which may be misinterpreted as "sphincter defect" on endoanal ultrasound. The pudendal nerve provides innervation of the EAS. Puborectalis and EAS are striated muscles with baseline tone provided by type I slow twitch fibers, while type II fast twitch fibers are able to contract in response to sudden increases in intra-abdominal pressure.

2.3 Evacuation

Rectal distention during the sampling process results in an urge to defecate. If cortical control is intact, an individual can choose to suppress this urge by contracting the EAS, resulting in further rectal accommodation (affected by rectal compliance) or one can choose to defecate. Defecation occurs by first relaxing pelvic floor muscles (puborectalis and also EAS) and increasing intra-abdominal pressure. These activities result in **increasing** the anorectal angle, which "straightens" the angle between lower rectum and upper anal canal due to relaxation of puborectalis. Evacuation is accomplished with coordination of these actions along with rectosigmoid peristalsis. After completing evacuation, EAS and puborectalis contract (the "closing reflex").

3. Pathophysiology

Table 1. Medical Conditions Associated with Diarrhea
Endocrine (diabetes, thyroid disease)
Inflammatory bowel disease (Crohn's disease, ulcerative colitis)
Irritable bowel syndrome
Infectious (viral, parasitic, bacterial)
Medication related (laxatives, colchicine, magnesium-containing supplements, metformin, chemotherapy)
Surgical absence of colon
Malabsorption
Overflow from constipation
Radiation

There are many factors that can affect the complex processes of anal continence and defecation, including colonic absorption, transit time, gut motility, rectal compliance, anorectal sensation and the neuromuscular status of the sphincter mechanism.

Systemic conditions affecting gut motility or stool consistency are usually related to diarrhea due to rapid transit of large volumes of liquid stool to the rectum. Loose stools have been shown to be associated with FI in the general population.[4] Medical conditions that are associated with diarrhea are shown in **Table 1**. There are also certain pharmaceuticals such as laxatives and diuretics that have diarrhea as a side effect. Finally, fecal impaction in the rectum may impair the sensation of the IAS and therefore result in inadequate EAS contraction during the RAIR and cause subsequent stool leakage.[5] Elderly patients and nursing home residents are particularly susceptible to fecal impaction.

Neurologic factors such as spinal cord injury and peripheral neuropathy can lead to FI through a variety of mechanisms. Spinal cord lesions can cause complex defecatory dysfunction depending on the level of injury. In a simplistic model, upper motor neuron lesions can result in a “reflex bowel” in which the ability to sense rectal distention may be impaired, and therefore though the continence mechanism may be intact, the involuntary defecation reflex will result in FI. These patients can be treated with timed bowel emptying prior to the reflex emptying. A lower motor neuron lesion may result in flaccid bowel dysfunction with fecal retention and overflow incontinence. Patients with multiple sclerosis also often report FI. The exact etiology is unknown but is likely a combination of neuropathy and degree of disability. For this reason, both bladder and bowel symptoms should be queried to ensure all significant issues are addressed. Medical conditions associated with peripheral neuropathy, most commonly seen in diabetic patients, place patients at risk for FI. People with diabetes are more than twice as likely to report FI compared to non-diabetics,[6] possibly due to a combination of autonomic neuropathy and pelvic floor denervation that results in dysfunction of the IAS sensory component, decreased EAS sphincter tone, and disruption of the RAIR. **Peripheral neurologic injury from childbirth results in denervation of the anal sphincter complex and/or the pelvic floor muscles**.[7] During the second stage of labor, the pudendal nerve can get compressed or stretched at Alcock’s canal, and this has been demonstrated with increased pudendal nerve terminal motor latencies following vaginal delivery.[8] These injuries may result in late onset FI vs. the early onset FI that can be seen with laceration of the sphincter complex.

Structural abnormalities including rectal prolapse and recto-vaginal fistula often present with FI symptoms. **Decreased rectal compliance** from radiation can affect the ability of the rectum to accommodate larger volumes of stool and lead to fecal urgency and stool leakage.

Local injury from birth trauma or surgery may result in direct rectal sphincter laceration or local nerve injury. Patients with third and fourth degree lacerations at vaginal delivery are at highest risk for developing FI.[9,10] Factors such as operative delivery, infant weight, and episiotomy increase risk of high degree lacerations and therefore anal sphincter trauma.[11] The greatest risk of EAS injury appears to occur with the first vaginal delivery[12] and sphincter laceration increases risk of

recurrent EAS injury with subsequent vaginal deliveries.[13] It is reported that 13% of women develop FI or urgency after first vaginal delivery.[14] Surgical injury is most common after fistulotomy for anal fistula and **hemorrhoidectomy** (this procedure can remove barrier function and potentially lead to inadvertent sphincter injury). The incidence of FI after **anal** sphincterotomies **for anal fissures has decreased significantly since the adoption of botulinum toxin injections as the predominant treatment of refractory anal fissures but can still occur in those receiving this intervention.**

Finally, **cognitive disorders** may impact the ability to decide about a socially acceptable time and place to eliminate, and decreased mobility may exacerbate other underlying risk factors for FI.

4. Epidemiology

Fecal incontinence is likely under-reported due to social stigmata. **Two to thirteen percent of community-dwelling adults report FI**, but the prevalence depends on the definition used and the data collection method. In a survey of community women aged 30-90 years old, FI defined as loss of liquid or solid stool at least monthly was 7.2%,[15] and prevalence increases with age (<5% for women under 50 years of age, >10% in women >60 years). Anal incontinence (defined as loss of stool and/or gas in the last 12 months) was reported by 28% of women presenting for routine gynecology care,[16] and loss of stool specifically affected approximately 20% of the women. Nursing home residents are at greatest risk of FI, with 46-54% of residents affected. **Importantly for urologists, approximately 25% of women with UI also report anal incontinence**.[17] Whether this represents a common neuromuscular cause or more widespread pelvic floor damage overall is not well understood.[18] The current understanding of the epidemiology of FI is shifting because of an increasing recognition of FI in men, better appreciation for the impact of changing obstetric practices on FI in women, and comprehension of the effect of modifiable risk factors on the development of FI over time.

In an identical twin study, menopause, obesity, (increasing) parity, and stress urinary incontinence (SUI) were found to be independent risk factors for FI after multivariate analysis.[19] **Epidemiologic studies have consistently shown increasing age and urinary incontinence to be related to FI**.[20,21] According to prospective cohort studies, **27-44% of women with anal sphincter injuries during vaginal delivery will report FI symptoms within 6-9 months**.[9,22] This is likely the reason for increased numbers of young women with FI compared to men, however the prevalence of FI in both genders increases with age. There appears to be a decline in the incidence of immediate postpartum FI from 13%-8% over the past decade. This may be due in part to decreased rates of operative delivery.[23,24]

FI is associated with reduced quality of life and can impact a patient's mental health. Further, FI is associated with increased risk of nursing home placement due to increasing caregiver burden. Despite these findings, fewer than 30% of patients suffering from FI symptoms will seek care. Even among women with both urinary and fecal incontinence presenting for urogynecologic care,[25] the rate of verbal disclosure of fecal incontinence symptoms remains low.

5. Diagnosis and Evaluation

The evaluation begins with a detailed bowel history including exacerbating factors related to diet and activity and relevant past medical and surgical history. Investigation into how much bother the patient is experiencing and quality of life impact including patient management behaviors should be undertaken as well. Many patients are more likely to report FI on self-completed questionnaire compared to voluntary reporting during the history. There are a number of patient questionnaires focusing on the severity and quality of life in patients with FI; these include the Wexner Score, the Fecal Incontinence Severity Index and Quality of Life scale.[26,27,28] The Wexner score, (also termed the Cleveland Clinic Florida Fecal Score) uses lifestyle alterations and wearing of a pad, in addition to incontinence to solids, liquid, and gas and has been predominantly utilized as an easy way to evaluate patients prior to treatment. **Table 2** outlines the components of the commonly used scale and its modification, the St. Marks (Vaizey) score for FI. Items on fecal incontinence are also included on the commonly used Pelvic Floor Disorder Inventory short form.[29]

Table 2. Jorge-Wexner Scale* and St. Mark's Score for Fecal Incontinence**

Incontinence Type	Never	Rarely (Less than once per month)	Sometimes (Between once per week and once per month)	Often (between once per day and once per week)	Always (at least once per day)
Solid Stool	0	1	2	3	4
Liquid Stool	0	1	2	3	4
Gas	0	1	2	3	4
Wears Pads	0	1	2	3	4
Lifestyle Alterations	0	1	2	3	4
				No	Yes
Need to wear pad or plug				0	2
Taking constipating medications				0	2
Lack of ability to postpone defecation for 15 minutes				0	4

**Wexner Scale denoted in gray. Zero is a score for perfect continence and 20 for complete incontinence*

***St. Mark's Score was based on the Jorge-Wexner scale but added two further items for assessment: the use of constipating medication and the presence of fecal urgency. The relative weighting of pad (or anal plug) use was decreased in this score.*

A physical exam that focuses on the vaginal and anorectal exam is necessary to evaluate for **structural abnormalities** such as prolapse, fistulas, hemorrhoids and also to assess the neuromuscular integrity of the pelvic floor. **Pelvic floor muscle strength** can be appreciated with vaginal palpation and voluntary squeeze to assess the puborectalis muscle. Visual inspection can also reveal loss of the perineal body, which may appear as very thin distal rectal/vaginal septum. A **rectal exam** is used to assess anal sphincter resting tone and squeeze tone as well as the puborectalis posteriorly. In addition, the puborectalis and EAS should relax when patient bears down. Some patients will display paradoxical contraction while bearing down which may be associated with difficult defecation and incomplete emptying.

Reflex testing, such as the anal wink or bulbocavernosus reflex, can confirm an intact motor component of S2-S4 pudendal nerve innervation of the EAS. Be aware, however, that the reflex may be undetectable on clinical exam in up to 20% of “normal” asymptomatic women.[30]

Further investigation can include **endoscopy** (if symptoms suggest that malignancy or inflammatory bowel disease should be ruled out), endoanal US, and anorectal physiology studies. Colonoscopy is indicated if there is a sudden change in bowel habits, including obstructed defecation, stool appearance and consistency; bleeding; weight loss; abdominal or pelvic mass; or strong family history of colon cancer.

High Resolution Anorectal Manometry can measure function of the anal sphincter in terms of strength and sensation. Catheters with a pressure sensor (air-filled microballoon, microtip, fluid filled) are placed into the anus and rectum to measure resting pressures and squeeze pressures as well as a “cough reflex.” Rectal sensitivity is measured with a rectal balloon that is slowly filled with air or fluid to detect patient’s first sensation and maximum capacity and can be helpful to detect hypersensitive rectum or neuropathy.

To test the recto-anal inhibitory reflex, a balloon is used for rectal distention and anal catheter to simultaneously measure pressure. In an intact RAIR, one should see reflex pressure rise with rectal distention due to EAS contraction, followed by a fall in anal pressure during accommodation.

Additional testing can include defecography, which provides real-time dynamic imaging of the defecatory process that is performed using barium contrast (radiograph) or MRI. Barium defecography can identify anatomic features, which only become evident during the defecation process, such as rectal prolapse, rectocele with fecal trapping, and intussusception. MRI defecography allows visualization of all pelvic floor compartments and structures such as cystocele and vaginal prolapse. **Endoanal US** is used to assess for continuity of IAS and EAS, but a degree of anterior EAS deficiency is physiologic in some patients and may be difficult to distinguish from a true sphincteric defect resulting from local trauma.[31] Electromyography (EMG) and pudendal nerve terminal motor latency (PNTML) are also used in this evaluation, and may include cough reflex testing which can be integrated into the anorectal manometry study.[31]

6. Treatment

6.1 Behavioral Treatment

First line treatment of FI typically includes education and behavioral modification in terms of diet and bowel habits. As looser stool is more likely to leak, efforts toward making the stool firmer can sometimes improve FI symptoms. One small randomized study favored **fiber supplements** over placebo with regard to improving loose stool and decreasing the number of FI episodes to half that of the control group. [32] Some foods are thought to contribute to IBS symptoms and certain food allergies can cause changes in stool as well.

Bowel motility is at its maximum in the morning, therefore committing to a **daily, regular toileting schedule** can aid in achieving complete evacuation on a consistent basis. This can be especially helpful for patients with constipation and "overflow" FI.[33]

Exercises and biofeedback can include strengthening of the pelvic floor and EAS as well as sensitivity training in which the IAS is "re-trained" to correctly sense rectal volume by using a rectal balloon at gradually lower volumes for more warning time.[34] For patients with fecal urgency, the converse may be used with gradually larger rectal volumes instead to increase tolerability. Compared to a regimen of pelvic floor muscle exercises alone, 6 biweekly biofeedback sessions resulted in greater reduction in FI symptom scores, and biofeedback patients were more likely to achieve complete continence (44% vs 21%, p=0.008). In a related study comparing the addition of supervised pelvic floor muscle training (PFMT) to behavioral and medicine treatment alone, 38% in the PFMT group reported they were "very much better" or "much better" compared to 18% in the control group. [35] A recent retrospective review showed that a "low-intensity" biofeedback regimen of 3 sessions approximately 1 month apart is also effective, particularly in those patients able to demonstrate good exercise technique. [36] Recently, as a result of the COVID-19 pandemic, home-based treatments have been getting more attention. One small study suggested that home-based protocols of biofeedback treatment targeting FI patients are non-inferior, safe and effective when compared to office-based therapies. [37]

Neuromuscular coordination utilizes rectal distention with a balloon and simultaneous pressure recording with catheters in the anal canal. Patients with FI can be taught to perform an EAS squeeze during the RAIR (remember there is a transient drop in anal canal pressure during this reflex) to prevent leakage.

The American Society of Colon and Rectal Surgeons' practice guideline recommends that pelvic floor muscle rehabilitation with biofeedback should be considered for initial treatment for patients with FI who have some degree of voluntary sphincter contraction. [38]

A novel vaginal bowel-control system (Eclipse System, Pelvalon, Sunnyvale, CA) was approved by the US Food and Drug Administration in February 2015. The system utilizes an inflatable vaginal insert with a pump that provides temporary occlusion of the distal rectum and can be deflated for defecation. In a prospective cohort study, 55% of eligible subjects were successfully fit with the device. At 1 month, 80% of subjects reported at least 50% improvement in FI episodes, 70% had ≥75% reduction, and 41% had complete continence. In addition to significant improvement in quality

of life measures, 90% subjects were satisfied with the device. Approximately 80% of subjects continued use for a total of 3 months, with 86% demonstrating ongoing treatment success. Twenty-three percent of subjects reported an adverse event, most commonly pelvic discomfort in 10% of participants. [39] A multicenter, prospective, open-label clinical study is currently underway to investigate safety and efficacy at one year. Insurance coverage for the Eclipse device is currently challenging for many patients. There is also decreased availability of the device to many surgeons and patients. [40]

Another device available for FI patients is the Renew Medical Insert (Renew Medical Inc, Foster City, CA). Lukacz et al reported the results of a 19-month study of adult patients with at least weekly incontinence of solid or liquid stool with Jorge-Wexner Score/Cleveland Clinic Florida Fecal Incontinence Scores (CCF-FIS) of 12 or greater (see **Table 2**). The trial involved continuous anal insert device (Renew) over a 12-week period with the primary outcome being a ≥ 50% reduction in the number of bowel accidents. There were 73 completers and 18 noncompleters in the study (intention-to-treat: 91 patients). Sixty-two percent of the intention-to-treat subjects had a ≥ 50% reduction in the number of bowel accidents with the device. Mean FI severity scores improved from 16.2 ± 2.1 at baseline to 10.9 ± 4.4 after use ($p < 0.001$). The majority of 73 completers were very or extremely satisfied with the device with no serious adverse events related to device use.[41] Unfortunately, there can be considerable difficulty with insurance coverage and is limited in availability in the United States.

It should be noted that while ≥50% reduction in the number of FI episodes is generally used to define "success" in FI trials, a recent patient preference study showed that a ≥75% reduction appears to be more clinically relevant to patients in terms of defining a successful treatment.[42]

6.2 Medication

Loperamide (Imodium®) is an opioid agonist that acts primarily at **peripheral opioid receptors**. The mechanism of action appears to be reducing gut motility and increasing water absorption, resulting in firmer stool consistency.[43] The usual starting dose is 2-4 mg daily, and can be titrated up to 16mg daily generally being administered 30 minutes prior to meals and at bedtime. Side effects include abdominal cramps and nausea. **Diphenoxylate-atropine sulfate** (Lomotil®) is another opiate agonist commonly used for diarrhea. The starting dose is 1-2 tablets (2.5-5 mg) every 6 hours, and effects can be maintained by 5mg a day if treatment is successful. Although codeine has also been used for FI as well to promote constipation, its role is limited by the significant side effect profile and central nervous system effects. Of note, a recent randomized controlled trial comparing loperamide to psyllium found no difference in reduction of weekly FI episodes (approximately 50% reduction), however patients taking loperamide were more likely to report constipation and headache. [44]

Other medications aim to increase outlet resistance by enhancing anal sphincter activity or through bulking agents. Phenylephrine has been studied as a pharmacologic treatment to enhance anal sphincter tone, however patient trials are small and convincing clinical efficacy is lacking.

The results of an NIH-sponsored multicenter study investigated the efficacy and safety of these first-line treatments. In the recently published CAPABLe from the PFDN, women with FI were randomized to treatment groups that included education plus placebo, six visits of biofeedback plus placebo, or either of these treatments plus loperamide. The primary outcome was the change in St Mark's [45] fecal incontinence severity scale at 24 weeks. Though there was no difference in the primary outcome between groups, all of the active treatments achieved the minimally important change of -5 pts on the St. Mark's score, whereas the placebo did not. In addition, there were significantly more women in the biofeedback group who achieved at least 50% reduction in daily leakage episodes compared to education alone. In addition, loperamide is typically recommended for diarrhea related FI, and the majority of the women in this study had normal stool consistency. It should be noted that the education pamphlet does mention dietary changes to treat FI including fiber and water intake. Although treatment outcomes were fairly equivalent amongst groups, it is reassuring that all of these first line treatments can be effective treatment for FI. [46]

6.3 Sacral Neuromodulation

Sacral neuromodulation **(SNM)** was first investigated in the mid-1990s, initially for bladder indications, and was FDA approved for FI in 2011. This therapy has the advantages of reduced morbidity along with a testing phase to determine effectiveness before the implant is performed. Safety and efficacy was confirmed in a prospective multicenter study of 120 patients with FI defined as defined as greater than 2 incontinent episodes on average per week. [47] At 12 months, 83% of subjects achieved therapeutic success (defined as ≥50% reduction in the number of incontinent episodes per week compared with baseline) and 70% subjects achieved >75% improvement including 41% of subjects who were 100% continent. Incontinent episodes decreased from a mean of 9.4 per week at baseline to 1.9 at 12 months. These results have been maintained out to 36 months. [48] The exact mechanism of sacral neuromodulation is not well understood, but there appears to be effects at the interneuron level in the spinal cord that results in modulation of efferent outflow. Decreased rectal contractions and increased anal pressure have been measured during sacral neuromodulation and may contribute to improved continence in patients with FI.[45,49] SNM enhances retrograde colonic motility (rectosigmoid brake) in FI patients. This helps improve stool retention and continence. The presence of a sphincter defect or prior sphincter repair does not appear to affect treatment efficacy in prospective cohort studies.[50,51] Long term follow up of 325 patients showed that 60% patients maintained efficacy for a median of 7 years, though the device was removed in 23% patients for loss of efficacy, and 14% patients required battery repositioning due to discomfort. [52]

The American Society of Colon and Rectal Surgeons' practice guideline recommends that SNM be considered as a first-line surgical option for patients with FI with and without sphincter defects, though the overall clinical picture should be considered when deciding between SNM or sphincteroplasty. Even with improved and extended uses of SNS for treatment of FI, it has been found to lack efficacy in certain scenarios. Recent data suggests that SNS is ineffective in patients

with rectal intussusception. [53] Defecography is the imaging test of choice to identify patients with deep rectal intussusception and this should be considered in patients with symptoms of partial defecation or in whom intussusception is suspected by a history of partial defecation and intermittently adequate control of defecation, particularly in the setting of a physical examination consistent with good rectal sensation. Most patients that benefit from SNS will have impaired rectal sensation. SNS has in fact been shown to decrease the rectal pressure threshold for sensation, or "first sensation", allowing for earlier sensation of stool within the rectal vault. This advanced notice has been hypothesized to improve continence not by augmenting control, but by allowing for an earlier notification of the urge to defecate, allowing the individual to transit to the toilet prior to having an involuntary movement. There is also evidence to suggest that while SNS may increase rectal compliance and resting tone, it does not augment voluntary squeeze. [54,55]

Evaluating SNS candidates with defecography prior to lead placement may help to identify patients who will fail to show optimal benefit from the therapy if they are being considered for SNS to treat FI alone without urinary incontinence present.

6.4 Posterior Tibial Nerve Stimulation

Posterior tibial nerve stimulation is a form of peripheral neuromodulation and is FDA approved for urgency, frequency, and urgency incontinence. This technique is not FDA approved for FI, though prospective cohort studies have demonstrated symptom improvement. In 115 patients with refractory FI, the average number of weekly FI episodes decreased from 5 to 1 after 12 PTNS sessions with sustained improvement out to a minimum of 12 months (range 12-42 mos) utilizing a maintenance regimen. 52% of patients reported >50% reduction in FI episodes, however 14% of the original cohort progressed to SNM for inadequate symptom control. [56] Interestingly, in a sham controlled randomized trial, there was a greater decrease in weekly FI episodes per week in the PTNS arm, however there was no difference in subjects achieving ≥50% improvement between groups (38% PTNS vs 31% sham) at 12 weeks.[57] The most common side effect is mild pain at the needle site (3% subjects), and no serious adverse events were reported.

6.5 Injectable agents

Finally, an **injectable bulking agent**, **non-animal stabilized hyaluronic acid/dextranomer (NASHA Dx, Solesta®)** is FDA approved for FI. In this procedure, 1 mL of this agent is injected through an anoscope into each quadrant of the submucosa, roughly 5 mm above the dentate line. A randomized, sham controlled study of 206 patients showed that 52% subjects vs. 31% control had a 50% or more reduction in the number of incontinence episodes at 6 months and 13% achieved complete continence in the treatment group. [58] Per protocol, 82% of patients in the treatment arm received a second injection a month after initial treatment, and these effects were sustained out to 36 months.[59] There were 2 serious adverse events in the treatment group, one prostatic abscess and one perianal abscess. Patients with mild-moderate FI, shorter duration of symptoms, and patients with "obstetric causes" of FI were more likely to respond to bulking treatment.[60] This procedure can

be effective in patients with postoperative anal defects. Solesta® is contraindicated in patients with inflammatory bowel disease and history of radiation to the pelvic area, as well as those with significant structural abnormalities such as rectal prolapse or significant rectocele. Clinical trials are underway comparing biofeedback treatment to injectable agents in the treatment of FI.[61] Modest long-term effectiveness, lack of insurance coverage and cost of treatment have resulted in a low utilization of bulking agent injections as a treatment for FI. Additional injectables can include polyacrylate and autologous fat. Polyacrylate injectables have been compared to biofeedback in small trials, and demonstrate a 3.4 points (95% CI, 1.2-5.5) mean decline in Wexner score compared to head-to-head with biofeedback, although quality of life outcomes have not differed between the injectable and biofeedback groups. [62] Autologous fat injections have also been implemented in experimental fashion, though durability, comparative effectiveness and cost effectiveness are not yet shown in the literature. [62,63]

6.6 Stem Cell Therapy

Sphincteric injections of autologous myoblasts is currently under investigation as a treatment for FI. A recently published randomized placebo-controlled study showed similar improvement in the two arms at 6 months, though at 12 months there was greater improvement in the incontinence score in the treatment group only, while the placebo group returned to baseline. Overall response rate at 12 months was 58% vs 8% ($p< 0.03$).[64]

6.7 Surgery

If conservative treatment fails, surgical treatment can be considered. In a patient with anterior disruption of the anal sphincter demonstrated on US, an **overlapping sphincteroplasty** can be performed. Dissection is carried out to mobilize the 2 ends of the EAS, which are then re-approximated in the midline in an overlapping or end-to-end fashion. Unfortunately, **continence rates in studies with long term follow-up tend to be low** (9-37%) despite shorter-term 3-5 year success rates reaching ~80%.[65,66,67,68] Improvement and patient satisfaction can be as high as 70%. [66,68]

Although a posterior anal sling was FDA approved for treatment of women with FI, the company is now closed, therefore it is unclear when this procedure will be available for use. Briefly, a transobturator approach is used to place a polypropylene mesh sling under the mid anal canal. In a prospective multi-center study of 152 patients, ≥50% reduction in number of FI episodes was achieved by 69% of subjects at 12 months. Side effects included buttock/pelvic/groin pain and infection. [69]

Further surgical treatments include post-anal repairs in which the puborectalis muscle is exposed and plicated in an attempt to recreate the anorectal angle and passive muscle transposition using graciloplasty and gluteus maximus transposition. These procedures are infrequently performed and are associated with high morbidity and moderate benefit. “Dynamic” graciloplasty has also been described, utilizing electrical stimulation with an implanted pacemaker and electrical lead. Success

rates are higher compared to the passive transposition (60%), however complications and morbidity are again high, limiting the application of these procedures. Fecal diversion is a final option for those patients with refractory FI.

7. Cost

A single-institution survey of patients suffering from FI found that on average patients will spent $4110 on total costs for managing their FI. The authors also calculated that there was an additional productivity loss of approximately $1549. Symptom severity is also associated with greater cost and greater productivity loss. This only represents a portion of total costs for FI, which include outpatient visits, conservative therapies such as PT, cost of pads, and lost productivity. [70]

8. Clinical Care Pathway

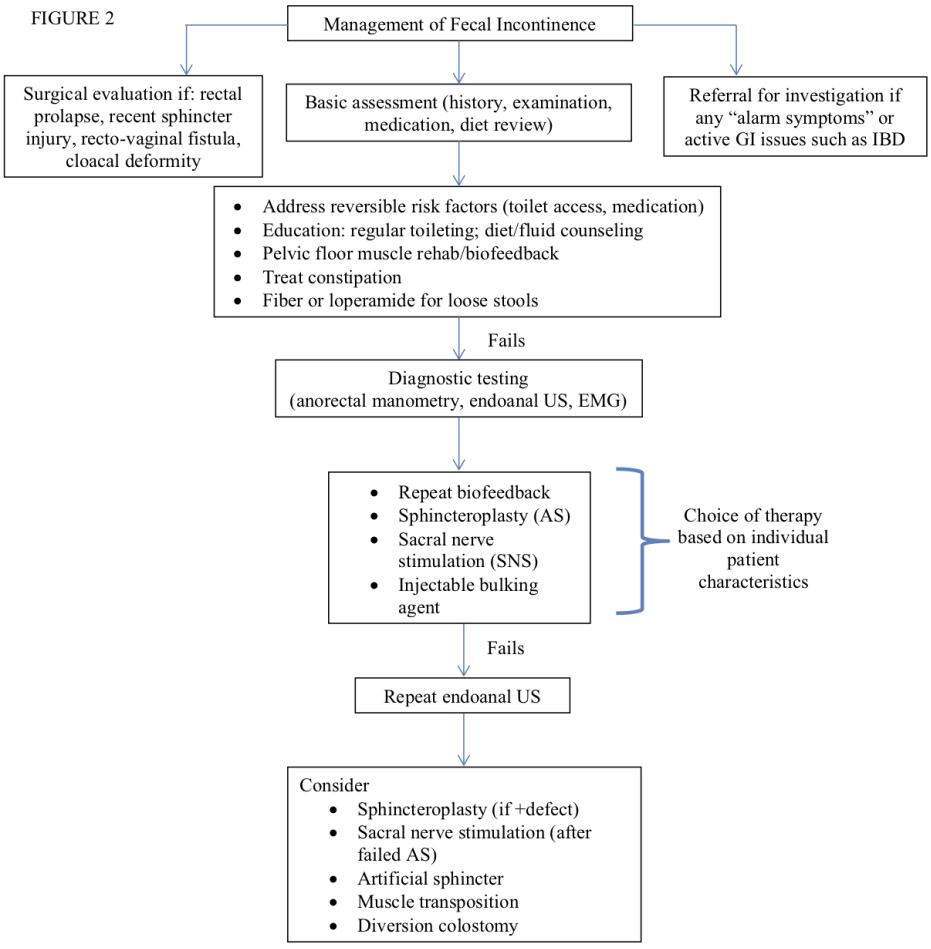

Figure 2: Clinical Care Pathway[1]

9. AUA Update Series

Constipation and Fecal Incontinence—What the Urologist Should Know. Popiel P, Chai T and Rickey L, Vol. 38, Lesson 3, 2019

Videos

A New Technique for Removal of Chronically Implanted Neuromodulator Leads

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AnjaUssing?‡IngeDahn§UllaDue?¶MichaelSørensen§JannePetersen‡#ThomasBandholm
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