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Management of Pelvic Floor Disorders: Biofeedback and More

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Introduction

This review will discuss selected, recently published, and clinically-relevant articles pertaining to pelvic floor disorders with an emphasis on defecatory disorders (DD) and fecal incontinence (FI). Where necessary, these articles have been placed in context by referencing earlier studies. However, space limitations preclude an exhaustive review of the prior literature.

Defecatory Disorders

Epidemiology and Clinical Features

DD refers to difficulty evacuating stool from the rectum in patients with chronic or recurring symptoms of constipation [1]. The American Gastroenterological Association Technical Review and Medical Position Statement on Constipation highlight the need for a complete anorectal examination and anorectal testing, in the appropriate patient, to differentiate DD from other causes of constipation (eg, slow transit constipation) since symptoms alone do not suffice to do so [2-3]. Identifying DD is important because many of these patients will

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Conflict of Interest

David Prichard declares that he has no conflict of interest.

Adil E. Bharucha has received consultancy fees from Medspira and Gicare Pharma. Dr. Bharucha has also received royalty payments from and has a patent with Medspira (anorectal manometry device).

Compliance with Ethics Guidelines

Human and Animal Rights and Informed Consent

This article does not contain any studies with human or animal subjects performed by any of the authors.

respond to biofeedback [4] while patients with isolated slow transit constipation (ie, without a DD) do not respond to biofeedback therapy [5].

DD are under recognized in part because of limited awareness of the entity and access to anorectal testing. Nonetheless, DD are not uncommon; the reported incidence of DD in Olmsted County was 22.6 per 100,000 person years, which is higher than the incidence of Crohn's disease but lower than the incidence of irritable bowel syndrome (IBS) [6]. DD can occur in association with other bowel conditions. In a cohort of 177 patients with inflammatory bowel disease (IBD) referred for anorectal testing, 46% of patients had a DD; the prevalence of a DD was higher in patients with Crohn's disease than ulcerative colitis [7]. In another study, 29 of 30 patients with inflammatory bowel disease and persistent lower GI symptoms without left colonic inflammation had a DD [8]. Moreover, symptoms improved in 30% of these patients following pelvic floor biofeedback therapy. In addition to constipation and symptoms of difficult defecation, patients with DD may also have upper GI symptoms (eg, rumination) [9]. Further studies are needed to determine the effects of pelvic floor retraining on upper GI symptoms in patients with DD.

Diagnosis

The lack of a criterion standard diagnostic test is major challenge to diagnosing DD. Moreover, the methods and interpretations of anorectal testing varies considerably; the current status of anorectal diagnostic testing may be summarized as follows (Table 1).

First, the agreement among anorectal tests used to diagnose DD is inconsistent. A systematic review observed that among constipated patients who were referred for anorectal testing, a higher proportion had an abnormal anorectal manometry (ARM) or an abnormal balloon expulsion test (BET) (ie, approximately 53% [median] of patients for each test) than an abnormal proctography (27% of patients) [10].

Second, the BET is a useful screening test for DD because it is simple, inexpensive, and reasonably sensitive and specific for identifying DD documented by defecography (Minguez, Herreros et al. 2004). However, that study was uncontrolled and evaluated defecography findings based on historical normal values. Recently, two controlled studies with 220 women (62 healthy and 158 constipated women) [11] and 326 patients (40 healthy subjects, 286 constipated patients) [12] •• evaluated the utility of the BET for diagnosing DD. Between 90 and 95% of healthy people expelled a rectal balloon within 1 minute; the remainder required up to 2 minutes. Based on these findings, an upper limit of normal for BET time of 2 minutes seems reasonable. The intra-individual day-to-day reproducibility for the BET time was greater than 95% [12].

Third, the results of BET and manometry are correlated but the agreement between these tests is not perfect. [11, 13-14] ••. In 1 study, impaired anal relaxation (ie, less than 20% reduction in anal pressure) was 85% sensitive and 80% specific for identifying an abnormal BET [12].

Fourth, most studies that have evaluated the utility of anorectal manometry in DD were uncontrolled and defined dyssynergia as less than 20% relaxation of the anal sphincter

during simulated evacuation, which is based on a study that used traditional manometry in 45 healthy people [15]. With high resolution manometry, 37 % of healthy women and 54 % of women with chronic constipation who were able to evacuate a 50-ml balloon failed to relax their anal sphincter by 20 % during simulated defecation (i.e., dyssynergia) [13-14]. Indeed, a substantial proportion of asymptomatic women have a negative anorectal gradient by high resolution manometry. Hence, further studies in healthy subjects are necessary to identify normal values for anal relaxation, rectal pressure, and the rectoanal gradient during simulated evacuation and the utility of these parameters for discriminating between healthy people and patients with a DD.

In Europe, defecography is widely used to diagnose DD. In the United States of America, it has been largely replaced by the BET and ARM because of its limitations, some real and others perceived, for diagnosing DD [16]. Often, defecography is not conducted and interpreted by established criteria, which limits its diagnostic utility. Defecography also involves radiation to the pelvic organs, whereas BET and ARM do not. However, in contrast to BET and ARM, defecography characterizes structural causes of outlet dysfunction. Hence, in the United States, defecography is recommended when the results of ARM and BET are equivocal and/or do not agree with the clinical impression or when a structural cause for DD is suspected [16]. MRI is an alternative to barium defecography [17]. The advantages of MRI over barium defecography include better resolution of soft tissue surrounding the rectum and anal canal, including the bladder, uterus, and small intestine during dynamic imaging, the ability to visualize the anal sphincter and levator ani muscles with endoanal MRI, and lack of radiation exposure.

These findings suggest that the diagnosis of DD should not be based on manometry alone; indeed current guidelines require chronic constipation and the presence of 2 objective findings to confirm the diagnosis [1, 16, 18].

Management

Biofeedback Therapy for DD—When patients have failed to respond adequately to medical therapies and there is clinical evidence of DD, biofeedback is recommended [2-3, 16]. The goals of anorectal physical therapy with biofeedback techniques are to: (i) teach patients about disordered defecation, (ii) coordinate increased intra-abdominal pressure with pelvic floor muscle relaxation during evacuation, (iii) practice simulated defecation with a balloon and, where needed, (iv) to provide sensory retraining for restoring the sensation of rectal filling. In contrast to the society guidelines which have endorsed anorectal biofeedback, a meta-analysis published by the Cochrane Collaborative review concluded that “there is insufficient evidence to allow any firm conclusions regarding the efficacy and safety of biofeedback for the management of people with chronic constipation” [19]. The authors of this analysis identified significant heterogeneity among the studies, treatment methods, and outcomes. Several aspects of this meta-analysis may explain why these conclusions differed from society guidelines. First, in addition to DD, this review also included the studies that evaluated pelvic floor biofeedback therapy for rectal mucosal intussusception, rectal prolapse, rectocele and slow transit constipation. However, patients with these conditions (ie, other than DD) may not have disordered defecation and

biofeedback therapy does not benefit patients with these conditions [5]. Including patients with these disorders in the meta analysis may have diluted the potential benefit of biofeedback therapy for DD. Second, the meta analysis included many sub optimal, and non randomized, older studies. Third, the ability to blind subjects to treatment assignment in behavioral trials is limited.

Based on clinical experience, our impression is that many therapists do not incorporate the components described above when providing biofeedback therapy for DD. Moreover, a retrospective review from a tertiary referral center observed that less than 50% of patients with DD recommended for biofeedback therapy underwent therapy [20]. The barriers to biofeedback were lack of insurance coverage, distance to local treatment facilities, and acute medical issues taking precedence. Of those who underwent at least 5 biofeedback sessions, 60% reported subjective short-term improvement.

Botulinum Toxin—Uncontrolled studies published over a decade ago suggest that botulinum toxin injected in to the anal sphincter may improve symptoms, manometric (anal pressure during straining) and radiographic parameters (opening of the anorectal angle during defecation) in patients with DD [21-23]. There are no rigorously-conducted studies comparing botulinum toxin to placebo injections or to pelvic floor retraining. Botulinum toxin was not recommended in the most recent AGA guidelines regarding the management of constipation [2].

Surgery for Defecatory Disorders—While sacral nerve stimulation (SNS) is primarily used to treat urinary and fecal incontinence, a review of 13, mostly uncontrolled, studies, of which 10 were in adults, suggest that it may benefit some patients with constipation [24]. Many studies included patients with slow transit constipation and a DD. In the largest (of 2) double-blind crossover studies, rectal sensation and the percentage of successful bowel movements increased during temporary SNS in 13 out of 14 women with DD documented by defecography. These changes were not evident when the stimulator was turned off. Eleven patients progressed to permanent stimulation (9/11 success at 19 months) [25]. Additional, long-term controlled trials with assessment of subjective and objective features are necessary to clarify the role of electrical stimulation in both constipation and DD.

The STARR procedure staples the redundant rectal mucosa that is associated with rectocele and intussusception; however, the link between symptoms and actual anatomic abnormalities is tenuous [26-27]. Anatomic abnormalities such as intussusception and complete rectal prolapse may result from the underlying disorder of function (impaired pelvic floor relaxation and excessive straining), which is not corrected by the procedure. Conversely, structural abnormalities may result in symptoms of obstructed defecation. A large randomized prospective multi-center trial observed that STARR was superior to pelvic floor retraining using biofeedback therapy. However, it is unclear what proportion of patients had pelvic floor dysfunction at baseline since rectal balloon expulsion was not evaluated at baseline; anal pressures were measured but not provided [28]. Moreover, there are discrepancies between improvement in symptoms and anatomy; symptoms may improve despite modest effects on anatomical disturbances [29-31] and vice versa [32]. Complications, which include pelvic sepsis, fistula, peritonitis, bowel perforation, pain and

bleeding [31, 33-34] have prompted pleas that only qualified surgeons perform STARR [33]. Finally, the long-term outcomes of patients even ideally suited for STARR are somewhat disappointing [35]. This operation has failed to gain widespread acceptance in the United States.

Fecal Incontinence

Etiology and Diagnosis

Fecal incontinence (FI) is defined by the unintentional loss of solid or liquid stool while anal incontinence (AI) includes leakage of gas and/or FI. The prevalence of FI is similar in men and women and increases with age until it plateaus at about 15% in the sixth decade of life [36-37]. Unless asked, a majority of patients will not volunteer the symptom to their physicians [38-40] (Table 2). Reinforcing previous studies [41-42] **, preliminary reports suggest that “urgency” and “frequency of bowel motions” were ranked the most important symptoms by women with FI [43]. In contrast, leakage of “gas”, ranked the lowest on this scale. Also, patients felt that a 75% reduction in episodes of FI was required for a therapy to be considered a success [44], which is higher than the 50% reduction threshold used in recent therapeutic trials.

Non-Surgical Management

The initial therapy for patients with FI include: patient education, urge suppression techniques, dietary modification, and pharmacological management of bowel disturbances. Evidence from controlled clinical trials suggests that these measures are effective in the short term, typically 4 weeks, in approximately 25% of patients [45]. However, these conservative therapies were administered by specialized therapists and not busy practicing physicians. Few studies have evaluated these approaches individually. Hence, the efficacy of these approaches administered individually are unknown. Which patient characteristics predict a favourable response to conservative therapy are also unknown. There are no data on long term efficacy.

Fiber and Pharmacological Management—In clinical practice, fiber supplementation is used for FI. In one small randomized controlled trial fiber supplementation decreased FI associated with diarrhea [46]. More recently, an abstract suggests that psyllium was as effective as loperamide in reducing weekly episodes of FI and improving quality of life [47]. Older studies suggest that among antidiarrheal drugs, loperamide was more effective than diphenoxylate and both are better than placebo for diarrhea-associated FI; however the evidence is of poor quality [48]. An uncontrolled study suggested that cholestyramine 2-6 grams daily was associated with improved fecal continence in patients with diarrhea and FI [49]. The alpha 2 adrenoreceptor agonist clonidine decreased diarrhea episodes in patients with diarrhea-associated FI but did not significantly decrease FI frequency at a dose of 0.1 mg twice daily [50-51]. Topical phenylephrine increased anal resting pressure but did not significantly improve fecal continence [52-53].

Pelvic Floor Exercises—These exercises are recommended for patients with FI. The methods for teaching these exercises are variable and the efficacy of pelvic floor exercises

alone have not been evaluated in a RCT. However, pre-post comparisons suggest that pelvic floor exercises may be effective for patients with FI [54]. There are no RCTs comparing exercise training by digital rectal examination to verbal instructions only.

Biofeedback Therapy for FI—Biofeedback therapy utilizes electronic or mechanical devices to provide augmented awareness of physiological responses to patients and their therapists to facilitate neuromuscular retraining. The objectives are to improve the strength and isolation of pelvic floor muscle contraction, ability to sense and contract pelvic floor muscles in response to weak distensions of the rectum, and/or ability to tolerate larger rectal distensions without experiencing uncontrollable urge sensations. Objective benefits of biofeedback therapy include increased rectal sensation in patients with reduced rectal sensation and shorter latency between rectal distension and contraction of the external anal sphincter. Only relatively minor effects on anal resting and squeeze pressure have been observed [55]. Of 3 RCTs of biofeedback therapy, two large studies [56-57] showed no benefit for biofeedback compared to pelvic floor exercises taught by digital rectal exam. A third study observed that among patients who failed conservative management biofeedback training by an experienced biofeedback therapist was superior to pelvic floor exercises alone; 76% of biofeedback patients and 41% of pelvic floor exercise patients reported adequate relief at 3 and 12 months [58]. Biofeedback is recommended for the treatment of FI [16, 59]. Further research is needed to standardize the treatment protocols and the training of biofeedback therapists.

Peri-anal Injectable Bulking Agents—One perianal bulking agent (dextranomer in stabilized hyaluronic acid [NASHA Dx]) is approved by the FDA for managing FI based on a multicenter, placebo-controlled randomized trial of 206 patients with FI in which a 50% reduction in incontinence episodes was reported more frequently for NASHA Dx (52% of patients) than placebo (31%) at 12 months [60]. Over 80% of patients in this trial required 2 injections of NASHA Dx. Only 6% became completely continent which is lower than the proportion (40%) that were completely continent at 12 months after SNS. In contrast to SNS, NASHA Dx did not improve QOL relative to placebo at 12 months. At 3 years, the responder rate in patients who received NASHA Dx was sustained at 52% and QOL had improved compared to baseline [61]. However, this paper did not report corresponding figures for the placebo group. Finally, in a randomized controlled trial, differences between NASHA Dx and pelvic floor retraining were not statistically significant [62]. Based on the evidence, the American College of Gastroenterology guidelines concluded that “minimally invasive procedures such as injectable anal bulking agents may have a role in patients with FI who do not respond to conservative therapy (weak recommendation, moderate-quality of evidence)” [16].

Sacral Nerve Stimulation

In a multi-center North American trial, a permanent sacral nerve stimulator was implanted in 120 patients with FI who benefited from temporary stimulation; 1, 3, and 5 year follow-up data have been reported [63-65]. Of 120 patients, 76 (63%) patients were included in a 5 year report and 72 had provided bowel diaries [65] ••. The remaining 44 patients had exited the study for various reasons. Of 72 patients, 64 (89%) had a 50% reduction in the number

of incontinent episodes per week and 36% had complete continence; QOL had significantly improved compared to baseline. These figures are very similar to the three year follow up data. Although only 63% of the original cohort is available for analysis, these findings suggest that SNS is beneficial for a select group of FI patients who have failed medical therapy. However, patients with chronic diarrhea, large sphincter defects, chronic inflammatory bowel disease, visible sequelae of pelvic radiation, active anal inflammation, neurologic diseases such as clinically significant peripheral neuropathy or complete spinal-cord injury, and anatomic limitations preventing the successful placement of an electrode were excluded from the study. After 5 years, 36% of the followed cohort (ie, 76 patients) had required device revision, replacement, or explant. This study was uncontrolled. The mechanisms by which SNS improves fecal incontinence are unknown because effects on anorectal functions are relatively minor [66]. SNS but not sham stimulation increased the frequency of retrograde propagated sequences throughout the colon. Similar to anti-diarrheal agents, these effects may delay colonic transit [66].

Posterior Tibial Nerve Stimulation (PTNS)

A review published in 2012 identified 8 studies with percutaneous PTNS, 4 with transcutaneous PTNS and 1 comparing both methods of PTNS with a sham transcutaneous group [67]. A 50% or greater reduction in frequency of FI was observed in between 63% to 82% of 273 patients. The review concluded that “many of the published studies are of poor quality” and that “comparison between studies is difficult owing to differences in the outcome measures used, technique of PTNS and the timing and duration of treatment”. A multicenter double-blind RCT in 144 FI patients observed that transcutaneous stimulation was not significantly better than sham stimulation [68]. In another study, percutaneous stimulation was significantly better than transcutaneous or sham stimulation [69]. A preliminary report suggests that clinical outcomes for both SNS and PTNS were comparable on intention to treat basis among 40 patients who were randomized to SNS or PTNS [70]. An interim analysis suggests that PTNS was superior to sham stimulation at 12 weeks in patients with systemic sclerosis and FI [71]; compared to their “placebo” group, patients with PTNS demonstrated improvement. However, the placebo response rate in this interim analysis was negligible.

Surgical Procedures for the Management of FI

When sphincter injuries are recognized immediately after childbirth, they are repaired immediately. However, the enthusiasm for repairing defects that are recognized years after vaginal delivery has declined since it is recognized that the improvement in fecal continence is not sustained over time [16]. Dynamic graciloplasty entails continuous electrical stimulation of surgically transposed gracilis muscle around the anal canal; the device required for electrical stimulation is not approved in the United States. This procedure and the artificial anal sphincter are beset by significant morbidity (e.g., infections and device problems) for which re-operation may be required. Hence, these procedures are seldom used in the United States.

Transanal radiofrequency therapy (SECCA), which is delivered by a probe in the anal canal, creates submucosal injury designed to cause scarring and increased resistance to stool

passage. The recently published ACG guidelines made no recommendation and concluded there was insufficient evidence regarding the use of SECCA, artificial anal sphincter, and dynamic graciloplasty for FI [16]. These guidelines also recommend that colostomy should be a last resort procedure in a patient with severe or intractable FI.

Conclusions

DD and FI are common but under-recognized conditions. DD can be diagnosed by a careful clinical assessments and anorectal testing and should be managed by pelvic floor retraining. Our understanding of the strengths and limitations of anorectal tests for DD is evolving. Regrettably, pelvic floor retraining for DD is not widely available. Surgery is rarely indicated for DD. Patient education, dietary modification, and bowel medications are effective in approximately 25% of patients with FI. The next step is pelvic floor retraining and SNS if necessary thereafter. Further studies are necessary to determine the role of perianal injectable bulking agents and PTNS for FI.

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and Hepatology. 2014 Epub ahead of print Access to anorectal testing (ARM, electromyography and defecography) is limited in community practice. This research demonstrates the high level of agreement between BET and ARM (78%) and/or electromyography (83%). The BET is a simple, cheap and valid test which can be used to screen for DD among constipated responding incompletely to conservative therapy in the community.

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Opinion Statement

Defecatory disorders (DD) and fecal incontinence (FI) are common conditions. DD are primarily attributable to impaired rectoanal function during defecation or structural defects. FI is caused by one or more disturbances of anorectal continence mechanisms. Altered stool consistency may be the primary cause or unmask anorectal deficits in both conditions. Diagnosis and management requires a systematic approach beginning with a thorough clinical assessment.

Symptoms do not reliably differentiate a DD from other causes of constipation such as slow or normal transit constipation. Therefore, all constipated patients who do not adequately respond to medical therapy should be considered for anorectal testing to identify a DD. Preferably, two tests indicating impaired defecation are required to diagnose a DD. Patients with DD or if testing is not available and the clinical suspicion is high should be referred for biofeedback-based pelvic floor physical therapy.

Patients with FI should be managed by lifestyle modifications, pharmacotherapy for bowel disturbances, and management of local anorectal problems (eg, hemorrhoids). When these measures are not beneficial, anorectal testing and pelvic floor retraining with biofeedback therapy should be considered. Sacral nerve stimulation or perianal bulking could be considered in patients who have persistent symptoms despite *optimal* management of bowel disturbances and pelvic floor retraining.

Table 1**Key Questions in the Assessment and Management of Defecatory Disorders**

Issue	Evidence
Are symptoms useful for discriminating DD from other causes of constipation?	Symptoms evaluated by a questionnaire are not useful in discriminating DD from other causes of constipation.
Which is the most useful test for diagnosing DD?	Rectal balloon expulsion test. Because of the discordance among the findings of anorectal tests, at least two objective criteria are recommended to confirm a diagnosis of DD.
What is the upper limit of normal for balloon expulsion time in the seated position?	Two minutes. Many centers use 1 minute, which is also acceptable; the additional yield of waiting for 2 minutes is modest. This test is highly reproducible.
What is the utility of anorectal manometry to diagnose DD?	Historically, dyssynergia provided the basis for diagnosing DD and biofeedback therapy. However, dyssynergia is often observed in healthy people. Hence, the diagnostic value of i) a negative rectoanal gradient and ii) the failure to reduce anal pressure by >20% during simulated evacuation are both under scrutiny.
When is appropriate to utilize defecography in evaluating constipated patients?	When (i) ARM and BET fail to establish a diagnosis of DD in patients who have clinical features of DD, (ii) ARM and BET are not available, and (iii) a structural disorder is suspected.
What evidence exists regarding the conservative management of DD?	Comprehensive lifestyle (fiber supplementation) and pharmacological management should be offered, but evidence is limited. Biofeedback-based therapy is necessary for DD but is not widely available. Further studies regarding standardization of biofeedback techniques and efficacy in primary and secondary care are required.
What interventional approaches are recommended for DD?	Pelvic floor injection of botulinum toxin is not recommended for DD. Preliminary studies suggest that sacral nerve stimulation may be beneficial; more evidence is required. Based on the data, the STARR procedure cannot be recommended for DD.

Abbreviations: DD – defecatory disorders

Table 2**Key Questions in the Assessment and Management of Fecal Incontinence**

Issue	Synopsis
Should every patient be questioned regarding FI?	Yes. FI affects up to 15% of the population. Patients are unlikely to voluntarily report FI. Hence, patients prone to FI (eg, patients with diarrhea) should be asked about the symptom.
Do all patients need tests?	No. After excluding inflammatory or neoplastic causes (where appropriate) conservative management should be offered initially as detailed in the text.
What physical therapy options are available?	Pelvic floor exercises may be recommended initially. Biofeedback therapy is recommended where conservative management does not successfully reduce symptoms.
Does sacral nerve stimulation benefit patients with FI?	Yes. In selected patients who have failed medical therapy SNS is beneficial. However, up to one third of patients will undergo device revision, replacement or explant within 5 years.
Is there an alternative to sacral nerve stimulation?	Injectable peri-anal bulking agents may have a role in patients with FI who do not respond to conservative therapy. Further research is needed to identify patients most likely to benefit from this therapy. Percutaneous posterior tibial nerve stimulation is less invasive than SNS and on an intention to treat analysis demonstrates similar clinical results. Further studies are required before this intervention can be recommended.
Is there a role for surgery in the management of patients with FI?	Primary (immediately post-partum) repair of sphincteric deficits is widely adopted. Delayed repair of sphincter defects has fallen out of favor. Dynamic graciloplasty and the artificial anal sphincter are not recommended due to the high morbidity associated with these procedures.

Abbreviations: FI – fecal incontinence