New Treatments for Fecal Incontinence: Update for the Gastroenterologist

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Fecal incontinence is one of the most emotionally devastating of all nonfatal conditions. Many patients do not respond satisfactorily to conservative measures, and there is a need for new and effective strategies when medical therapy fails. The development of sacral nerve stimulation and other forms of neuromodulation and the injection of biologically compatible substances into the anal sphincter complex have brought renewed enthusiasm for using these novel treatments in this underserved population. Because injectable bulking agents such as dextranomer in stabilized hyaluronic acid can be administered in an outpatient setting, this procedure is being marketed to both gastroenterologists and surgeons. This article reviews both sacral nerve stimulation and dextranomer bulking agents and compares their strengths and potential limitations in patients with fecal incontinence.

Keywords: Sacral Nerve Stimulation; Injectable Anal Bulking Agents; Neuromodulation.

Fecal incontinence is one of the most devastating of all nonfatal conditions, resulting in considerable embarrassment and anxiety to those who suffer from it. It affects 2% to 17% of people living in the community[1] and almost half of all nursing home residents.[2] Many individuals with fecal incontinence are so ashamed that they frequently do not volunteer this complaint to their physicians and must be asked directly.[3]

The prevalence of fecal incontinence is comparable in both men and women; it is increased in older age groups, those with poor health status or physical limitations,[1] and individuals residing in nursing homes.[2] Other recognized associations include complications associated with childbirth, certain surgical procedures, the coexistence of diarrhea or irritable bowel syndrome, and specific diseases (Table 1).

The causes of fecal incontinence include a number of broad categories that occur alone or in combination.[4] Many of these are suggested by a careful history and directed physical examination including perianal inspection, digital rectal examination, and a focused neurologic examination of the perineum and lower extremities. Such an examination is heavily dependent on the experience and skills of the examining physician. Unfortunately, it is not taught well at any level of medical training, including gastroenterology fellowship programs.[5] In selected patients, especially when there is diagnostic uncertainty, tests to assess anorectal structure and function may be performed to assess pathogenetic mechanisms.

The major clinical point to emphasize is that fecal incontinence is a disorder that occurs via a number of different mechanisms, not all of which can be characterized by examination and testing. The corollary is that no single treatment approach is appropriate for all patients, and it is incumbent on those who propose a new treatment to identify those patients most likely to benefit on the basis of carefully performed clinical studies.

Fecal incontinence can be subtyped clinically into passive incontinence, which occurs without warning, and urge incontinence, which occurs despite active efforts to retain stool. Contributing factors include structural or functional weakness of the anal sphincters and/or puborectalis muscle, impaired rectal sensation, and reduced colonic and rectal storage capacity. Finally, the consistency and delivery of stool to the anorectum are important; for example, diarrhea and or rapid stool propulsion may uncover subclinical weakness of continence mechanisms.[6] For the clinician, introduction of measures to treat the diarrhea and slow the delivery of stool to the rectum are important components of the conservative management of incontinence. However, many patients do not respond satisfactorily to conservative measures[7] and there is a need for new and effective strategies when medical therapy fails. The need is particularly urgent because traditional surgical approaches are of uncertain efficacy for functional fecal incontinence, even in patients who have documented anal sphincter defects.[8] For example, in short-term studies, up to 85% of patients with incontinence and sphincter defects are improved after overlapping anal sphincteroplasty. However, long-term results have been disappointing, with failure rates of greater than 50% after 40 to 60 months,[9] and even greater deterioration thereafter[10,11]; this is especially true in older patients.

Abbreviations used in this paper: **CCFIS, Cleveland Clinic Fecal Incontinence Severity; FDA, Food and Drug Administration; FIQOL, fecal incontinence–specific quality-of-life; SNS, sacral nerve stimulation.**

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Table 1. Disorders Associated With Fecal Incontinence (Partial List)

Pudendal neuropathies
Idiopathic[a]
Diabetes mellitus[a]
Radiation injury[a]
Central nervous system disorders
Stroke[a,b]
Dementia[a,b]
Multiple sclerosis[a]
Spinal cord tumor/injury[a,b]
Anal sphincter weakness
Internal anal sphincter (eg, scleroderma, sphincterotomy, idiopathic)
External anal sphincter
Obstetric[a]
Surgical[a]
Decreased rectal storage capacity
Radiation[a]
Surgery
Active inflammation[a]
Other
External rectal prolapse[a,b]
Diarrhea[a,b]
Fecal impaction[a,b]

[a]Probably not a candidate for injectable bulk therapy.
[b]Probably not a candidate for sacral neuromodulation.

The development of sacral nerve stimulation (SNS) and other forms of neuromodulation[12] and the injection of biologically compatible substances into the anal sphincter complex[13] have brought renewed interest and enthusiasm for treating this underserved population. Both approaches were extrapolated from their successful use in patients with urinary incontinence to the treatment of fecal incontinence. Because injectable bulking agents such as dextranomer in stabilized hyaluronic acid[14] can be administered in an outpatient office setting and requires no sophisticated skills on the part of the practitioner, this procedure is being marketed aggressively to both gastroenterologists and colorectal surgeons. Therefore, it is important that gastroenterologists become familiar with these techniques and the potential limitations of their use in patients with fecal incontinence.

Injections of Dextranomer in Stabilized Hyaluronic Acid for the Treatment of Fecal Incontinence

The concept of injecting a biomaterial to augment anal canal pressures to treat fecal incontinence was first proposed about 2 decades ago; since then, many different substances have been injected with varying results and often using suboptimal investigative designs.[13] There has been renewed interest in injectable bulking agents since the publication of a randomized, sham-controlled study that reported the outcomes of injection of dextranomer in stabilized hyaluronic acid (NASHA Dx; Q-Med AB, Uppsala, Sweden) into the submucosa of the anal canal in 136 patients with fecal incontinence and sham injections in a control group of 70 patients.[14] NASHA Dx has long been used as a bulking agent in urologic procedures with few side effects,[15] and there seemed to be biologic plausibility for its use in selected patients with fecal incontinence. Although the optimal group of patients intuitively would seem to be those with passive incontinence and low anal canal pressures, the pivotal study, which was performed with input from the Food and Drug Administration (FDA), studied mainly nonobese female patients who were not characterized as having either urge or passive incontinence.[14] The inclusion of patients with urge incontinence seems somewhat counterintuitive because such patients often have weakness of the external anal sphincter as well as decreased rectal capacity and rectal hypersensitivity,[16] none of which would be expected to be altered by an injectable bulking agent. The validated Cleveland Clinic Fecal Incontinence Severity (CCFIS) scale[17] and a fecal incontinence–specific quality-of-life (FIQOL) scale[18] were administered before and after treatment. However, no studies of anorectal sensory or motor functions were performed at any time. This omission deprived the investigators of an opportunity to determine if outcomes correlated with objective improvement in anal canal pressures or other anorectal parameters.

As appears to be the traditional standard for efficacy in studies of fecal incontinence, the primary end point chosen was a 50% or greater decrease in the number of incontinence episodes and a corresponding increase in days free of episodes of incontinence, as assessed over a 2-week period at various predetermined time intervals after treatment. A second injection was permitted in patients who had no improvement within 1 month and, indeed, 80% of patients in the active treatment group required a second injection. Based on these criteria, 53% of patients receiving NASHA Dx vs 32% receiving injection of a sham were classified as responders at 6 months. Curiously, no significant differences in responses were noted at 3 months. Of greater concern, no significant improvements between active and sham patients were noted in 3 of the 4 parts of the FIQOL scale (lifestyle, depression and self-perception, and embarrassment scales) and only a small improvement was noted in the coping and behavior scale. Six percent of treated patients were fully continent at 6 months, although this was not reported in the original report (to my knowledge, no data have been reported for sham-treated patients). Subsequent reports indicated that 11% of the NASHA Dx–treated patients were fully continent at 12 months, a somewhat puzzling finding in that efficacy of most surgical treatments for incontinence tends to diminish with time and it is unclear as to why a bulking agent would continue to improve continence barriers over time. By using 6-month data, one would have to treat 17 patients (with up to 2 injections) to produce 1 fully continent individual (or 9 patients if we use the 1-year results). NASHA Dx was approved by the FDA in 2012 as both safe and effective for the treatment of fecal incontinence and now is being marketed as an office-based treatment to be administered by