New Hope for Persons with Fecal Incontinence

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Life just got a whole lot brighter for the 18 million adult Americans who experience fecal incontinence (FI), commonly referred to as bowel control problems. FI encompasses the inability to hold a bowel movement until reaching a toilet to defecate, as well as the accidental leakage of gas or stool, whether liquid or solid.

Prevalence of Fecal Incontinence

Recently, National Institutes of Health-funded researchers gathered data from a questionnaire submitted to more than 4,000 men and women, ages 20 and older, who participated in the Centers for Disease Control and Prevention’s 2005-2006 Annual National Health and Nutrition Examination Survey (NHANES). NHANES researchers went directly to private homes to conduct extensive interviews, and health measurements including physical examinations and laboratory tests were performed in specially designed mobile centers that traveled to locations throughout the country. The bowel health questionnaire included items about accidental bowel leakage and stool consistency. From these data, one in 12 Americans (18 million) was estimated to have FI, ranging from 3% in adults 20 to 29 years old to 15% among adults 70 and older (others estimate an FI prevalence of closer to one in 10 adult Americans). NHANES researchers found a variety of factors associated with an increased risk of FI, including advancing age, urinary incontinence, the inability to engage in physical activity, chronic illness, and diarrhea; FI prevalence did not differ significantly between genders. Until the publication of these data, efforts at both diagnosis and treatment have been minimal because prevalence was not documented and etiology was not well understood.

Women with stress urinary incontinence severe enough to warrant surgical intervention have been found to be more than twice as likely to have symptoms of FI. Half of the women presenting with FI symptoms also exhibit moderate to severe stress urinary incontinence because of the underlying pelvic floor disorder that contributes to both. Although FI may stem largely from obstetrical trauma, the problem is not limited to women — men who have undergone radiation treatment for prostate cancer may experience symptoms of FI many years later. Recent manufacturing and regulatory initiatives are promising for providers and patients seeking treatment for FI.

New Products

Injectable bulking agent approval imminent. In April, the US Food and Drug Administration (FDA) issued an Approvable Letter for Oceana Therapeutics’ (Edison, NJ) product Solesta® as a treatment for FI. The FI product is a biocompatible bulking agent, injected as a gel in the deep submucosal layer in the proximal part of the anal canal. Although the exact mechanism of action has not been identified, it is hypothesized that the product injections may narrow the anal canal and allow for better sphincter control. This approach represents a one-of-a-kind treatment option for FI and addresses the large treatment gap between conservative therapies for FI such as dietary control and more complicated, invasive treatments such as surgery. In its considerations, the FDA determined the new treatment is safe and effective and that its benefits outweigh its risks. The product offers the advantage of relatively quick outpatient administration without the need for anesthesia. The product has been developed by Oceana in collaboration with Q-Med AB of Uppsala, Sweden.

The product’s Premarket Approval Application (PMA) is approvable subject to certain requirements relative to labeling and manufacturing, inclusive of acceptable results from a postapproval study to evaluate long-term treatment data. The main body of clinical evidence for the PMA submission is a multicenter, prospective, randomized, placebo (sham) controlled study of the product’s effectiveness and safety. The study involved a 6-month double-blinded phase followed by an open-label phase in which patients originally randomized to sham treatment were offered the product. All three endpoints for efficacy (effectiveness, clinical significance, and durability) were met; in addition, the product was found easy to administer.

Given the product’s progress through the regulatory process thus far, its manufacturer has publicly expressed an anticipated approval and launch for full access by providers for patients before the end of this year.

Electronic stimulation device approved. An implanted electrical stimulation device (InterStim®, Medtronic, Minneapolis, MN) for use to help restore bowel control in people with chronic FI received full FDA approval in April. The device light stimulates the sacral nerves to affect and “regulate” pelvic muscles and the bowel. Although a less-often considered option for the severely impaired or elderly, it functions...
with the same principle as a heart pacemaker. In recently published studies\textsuperscript{11,12} of sacral nerve stimulation used to treat urge FI (results that were presented to the FDA), more than 80% of patients who had failed or were not considered candidates for more conservative therapies experienced a 50% or greater improvement in their FI episodes following the implant; full fecal continence, or control, was achieved in two fifths of patients. The most common side effects reported during clinical testing included implant site pain, a sensation of skin tingling or numbness, and infection at the site of implantation. The device already has been approved by the FDA to treat symptoms of overactive bladder and nonobstructive urinary retention. In use worldwide for a decade, the device has been bringing relief and restoring quality of life to more than 50,000 patients with intractable urge incontinence.

People are living longer with multiple chronic diseases and conditions whose etiology — or even treatment interventions — can precipitate FI. This is especially true for persons residing in skilled nursing and assisted living facilities. How many of them are patients under your care or for whom you are responsible? With these recent announcements, you have new reasons to give them and their family members additional hope for intervention beyond what you can do for them with more conservative, traditional therapies.

### References