Outcomes associated with Interstim therapy for medically refractory fecal incontinence


Surgical Specialists of Spokane, 105 W 8th Avenue Suite 7010, Spokane, WA 99208, USA

**KEYWORDS:**
Fecal incontinence; Interstim therapy; Sacral nerve neuromodulation; SNS

**Abstract**

**BACKGROUND:** Fecal incontinence is a common, socially debilitating disorder. Initial management involves dietary manipulation with bulking agents or antidiarrheal medications and pelvic floor biofeedback. For patients failing these modalities, traditional surgical approaches are morbid and of variable efficacy. Sacral nerve neuromodulation (Interstim, sacral nerve stimulation) was approved in May 2011 for management of medically refractory fecal incontinence. This report summarizes our experience with this treatment modality.

**METHODS:** A prospectively maintained database from a colorectal specialty practice was reviewed from December 2011 to June 2013. Patient demographics, incontinence etiology, and medical treatment regimens were reviewed. Outcomes for Interstim placement and surgical morbidity were reviewed.

**RESULTS:** A total of 330 patients were evaluated in the clinic for fecal incontinence during the study period. A total of 33 patients (10%) were offered Interstim therapy. The mean age was 63 (39 to 91) years, and 91% (30 of 33) were female. The etiology of the incontinence was obstetric (81%), rectal prolapse (11%), neurogenic (5%), and iatrogenic (3%). The entire group failed either supplemental fiber or antidiarrheal medications and 73% (24 of 33) failed pelvic floor biofeedback. The mean number of bowel accidents/2-week bowel diary before implant was 19 (9 to 52). After phase I implant, 88% (29 of 33) experienced a successful test phase and proceeded to phase II permanent implant. The mean number of bowel accidents/2-week diary postimplant was 3 (0 to 12). A trend toward less severe episodes of incontinence postimplant was observed. There were no complications associated with either the phase I or phase II implant. There were no phase II failures although 1 patient underwent device explant 9 months after phase II implant for chronic pain.

**CONCLUSIONS:** Sacral nerve neuromodulation (Interstim, sacral nerve stimulation) is an effective and efficacious tool for management of medically refractory fecal incontinence that offers a less morbid surgical approach to this problem. Interstim should be considered the first-line surgical approach for medically refractory fecal incontinence.

Fecal incontinence is a common and socially debilitating disorder. It is estimated that 8% to 10% of the adult population experience symptoms of fecal incontinence, and this rate rises to 15% in persons of 70 years or older. Possibly because of the social stigma of the condition, only 2% to 5% of patients with fecal incontinence will eventually seek treatment. A careful history and physical examination...
are crucial to establish disease etiology and direct treatment. There are many risk factors for fecal incontinence. These include liquid stool consistency, female sex, advanced age, multiparity, neurologic injury, prior trauma, and advanced age. Lesser known risk factors include obesity, smoking, chronic obstructive pulmonary disease, hysterectomy, and bariatric surgery. Most patients with fecal incontinence can be managed with treatment to modify stool bulk or frequency with supplemental fiber and/or antidiarrheal therapy. Eliminating medications with a side effect of diarrhea is often helpful. Pelvic floor biofeedback has been shown to be helpful with short-term success rates of 70%. Long-term success rates, however, are quite variable. The patients shown to benefit most have a younger age, shorter duration, and lower severity of incontinence.

Patients with symptoms of true fecal incontinence related to an abnormal pelvic floor and refractory to medical management may benefit from surgical intervention. Historically, this has included fecal diversion, anal sphincteroplasty, or artificial bowel sphincter. Other alternatives include injectable biomaterials, radiofrequency energy delivery, and stimulated graciloplasty. Success rates for these procedures are variable, and all these interventions are associated with the potential for significant morbidity.

Sacral nerve neuromodulation (Interstim, sacral nerve stimulation [SNS]) was originally described in 1995 for management of fecal incontinence. Interstim was approved for use in the United States in May 2011 for moderate to severe (>2 accidents/wk/2-week bowel diary, failed >2 medical modalities) medically refractory fecal incontinence based on work by the SNS Study Group. This multi-institutional trial demonstrated consistent and durable efficacy and comparatively minimal morbidity. The present study summarizes our experience with this new treatment modality.

**Methods**

A prospectively maintained database of a colorectal surgical specialty practice was retrospectively reviewed from December 2011 to June 2013. All patients seeking treatment for fecal incontinence were included. Patient demographics, incontinence etiology, and medical treatment regimens were reviewed for patients undergoing Interstim therapy. Clinical outcomes for Interstim therapy and surgical morbidity were documented.

A total of 330 patients sought treatment for symptoms of fecal incontinence during the study period. Most of these patients improved with nonsurgical therapy and did not require operative therapy. All patients who were deemed to have severe incontinence refractory to medical management based on their 2-week bowel diary and treatment history were offered Interstim therapy as first-line operative intervention; 33 patients consented to proceed with Interstim therapy, and the results of these patients were analyzed.

Patients first underwent placement of the Interstim lead in the S3 neural foramina connected to an external generator (phase I). Those patients who had a successful phase I trial (>50% reduction in incontinent episodes/2 week bowel diary) underwent permanent implantation of the Interstim device (phase II). All the procedures in both phase I and phase II were performed with monitored anesthetic care.

**Results**

**Patient demographics**

The mean age of the group undergoing Interstim therapy was 63 (39 to 91) years, and 91% (30 of 33) were female. The etiology of the incontinence was obstetric (81%), rectal prolapse (11%), neurogenic (5%), and iatrogenic (3%). All patients failed either supplemental fiber or antidiarrheal medications and 73% (24 of 33) failed pelvic floor biofeedback. A 2-week bowel diary was reported before surgical intervention and after phase I implantation. Success of the phase I trial was defined as a more than 50% reduction in episodes of incontinence as established by the SNS Study Group.

**Treatment outcomes**

The patient group had a mean number of bowel accidents per 2-week bowel diary before implant of 19 (9 to 52). After phase I implant, 88% (29 of 33) experienced a successful test phase. The mean number of bowel accidents per 2-week diary decreased to 3 (0 to 12) after phase II implant. There was also a trend toward less severe episodes of incontinence. All procedures were performed under monitored anesthesia care and on an outpatient basis. There were no surgical complications associated with either the phase I or phase II implant. In short follow-up, there were no phase II failures although 1 patient underwent device explant 9 months after phase II implant for chronic pain at the generator site.

**Comments**

Symptoms of fecal incontinence are a common and under-reported source of social morbidity. A careful history and physical examination, supplemented by pelvic floor functional testing, will allow classification by disease etiology and severity, which dictates appropriate therapy. Patients with true fecal incontinence related to an abnormal pelvic floor most commonly suffer from remote obstetric or iatrogenic neuromuscular injuries. Most of these patients can be managed nonoperatively with simple manipulation of bowel consistency and frequency and supplemented with pelvic floor biofeedback. Surgical intervention is typically reserved for those who fail medical therapy.

Patients in our clinic are all advised to undergo these nonoperative therapies as first-line treatment, and most are offered biofeedback in addition to stool manipulation.
Based on our database, only 10% of patients evaluated for fecal incontinence and treated with appropriate medical therapy believed their symptoms were severe enough to proceed with surgical therapy. For those patients who failed to improve with nonoperative therapy and are sufficiently symptomatic, operative intervention is offered. We have used a 2-week bowel diary as the primary measure of the severity of fecal incontinence both before intervention and to quantify the success of interventions.

Traditional operative interventions consist of either sphincter augmentation (sphincteroplasty, artificial sphincter, biomaterial injection, and stimulated graciloplasty) or fecal diversion. All these interventions are associated with the risk of major morbidity and inconsistent efficacy. Interstim offers a modality that seems to best balance the operative risk vs clinical efficacy.

In the present study, almost 90% of patients achieved clinical success defined by a greater than 50% reduction in fecal incontinence. The average number of bowel accidents decreased from 19 per 2-week diary to 3 per 2-week diary. Many achieved complete continence and for those with ongoing fecal incontinence, the frequency and severity were substantially less. This result was achieved with no major or minor morbidity and being performed with monitored sedation rather than general anesthesia, and all procedures were done on an outpatient basis. The procedure was extremely well tolerated by all patients.

The present study is certainly limited by its retrospective nature and short follow-up; however, prior studies have shown durable maintenance of continence over longer follow-up periods. Based on these results, Interstim should be considered an excellent first-line surgical treatment for medically refractory fecal incontinence.

References


Discussion

Frederic J. Cole, Jr, M.D.: The first use of SNS was for urinary urge incontinence and nonobstructive urinary retention in the early 1980s. It has been used to treat fecal incontinence since 1995 and became available for this purpose in the United States in 2011. Dr McNevin et al have presented their experience using SNS in the treatment of fecal incontinence. They retrospectively reviewed 330 patients in their prospectively maintained database of patients who were evaluated for true fecal incontinence in their colorectal practice. Of these, 33 patients were offered treatment with sacral nerve stimulation using the InterStim device (Medtronic) as a first-line surgical therapy. All patients had true incontinence and had failed medical therapy with dietary manipulation to bulk the stool with fiber, antidiarrheal agents, and elimination of diarrhea-inducing mediations as defined by their 2-week stool diary. Seventy-three percent of the patients had failed pelvic floor biofeedback therapy as well. They used a 2-phase treatment process with initial temporary electrode placement with an external pulse generator, followed by permanent implantation of a pulse generator if the patient experienced a positive result from the phase I trial. Their results of an 88% positive response to phase I trial, no failures of permanent implantation, and 1 patient requiring explantation of the device because of pain at the implant site are in line with the previously published results including the 2009 Cochrane analysis by Mowatt et al.1–4 The authors conclude that SNS is an effective and efficacious tool for the management of medically refractory fecal incontinence that offers a less morbid surgical approach and should be considered the first-line surgical approach for medically refractory fecal incontinence.

I have several questions for the authors:
1. Can you flesh out your protocol for medical management a bit for us? How long are patients treated medically before being deemed to have failed medical management? What are the specifics of your medical interventions?

2. Is the 2-week stool diary your only assessment tool for fecal incontinence? Do you make use of other tools such as the Wexner continence grading system, the Fecal Incontinence Quality of Life, or SF 36 in assessing your patients?

3. Others have reported problems with pain associated with the implants when the generator is placed anteriorly. Where did your group implant the InterStim device?

4. In performing their Cochrane analysis, Mowatt et al\(^1\) were only able to find 3 small crossover studies that met their inclusion criteria. They conclude their report with a call for high-quality, randomized, crossover trials to better define the role of this modality in the treatment of this very difficult problem. Have you considered using this descriptive analysis as a springboard for a more rigorous trial of SNS in the treatment of fecal incontinence?

References