



## Sacral Nerve Stimulation and Fecal Incontinence: Current Uses and Emerging Trends

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### Abstract

Fecal incontinence (FI) is a socially devastating condition affecting both men and women. Patients often suffer in silence, as FI is frequently unreported. It is commonly seen in patients who also experience urinary incontinence (UI). Risk factors for FI include obstetrical trauma as well as increasing age. Until recently, treatment options were limited and consisted of medical therapy or surgical options with limited efficacy or high morbidity. Initially used for UI, sacral nerve stimulation has emerged as a successful treatment modality for FI. Its mechanism of action is incompletely understood though is thought to work on afferent pathways. We survey the current use of SNS in FI as well as evolving applications for this therapy.

### Keywords

Fecal incontinence, Urinary incontinence, Sacral nerve stimulation

### Abbreviations

FI: Fecal Incontinence; UI: Urinary Incontinence; SNS: Sacral Nerve Stimulation

### Introduction

Fecal incontinence (FI) is a disabling disorder affecting up to 18% of adults [1-3]. It leads to social isolation and decreased quality of life, yet is often under reported and unrecognized [4,5]. Women are more frequently affected than men, and the prevalence increases with age. A major risk factor for FI is sphincter disruption during vaginal delivery, which is estimated to occur in up to 18% of vaginal births [6]. Patients suffering fecal incontinence often have urinary incontinence (UI), with one series demonstrating that in a survey of randomly selected adults over 50 years, 51% of men and 60% of women with fecal incontinence also reported urinary incontinence [7].

Initial treatment of FI consists of nonsurgical approaches including dietary modification, stool bulking agents, biofeedback, and ruling out other causes of FI such as diarrhoea secondary to infectious, inflammatory, or malignant etiologies [8-11]. Soluble fiber (psyllium) and medications including loperamide and lomotil are common first-line therapies, though are not without side effects which can include gas, bloating, and constipation. Colonoscopy is often performed to evaluate for infectious or inflammatory causes of diarrhoea. Transanal irrigation has been described for treatment

in fecal incontinence, though has more efficacy in patients with neurogenic bowel disorders related to spinal cord injury and multiple sclerosis [12]. Anal plugs may have a selected role attaining pseudocontinence, though are not always well tolerated [9]. Surgical options include repair of sphincter defects, injection of tissue bulking agents, and implantation of magnetic anal sphincter or artificial bowel sphincter or graciloplasty, but these have limited durability, high failure rates, and, in the case of artificial bowel sphincter, high morbidity [13-16]. For some patients, failure of traditional therapies leads to stoma placement for fecal diversion. Sacral nerve stimulation has been increasing in popularity. Unfortunately, there is limited evidence to guide treatment providers. A recent systematic review of surgical treatment for fecal incontinence found the literature to be constrained by short duration of follow up, small patient population size, and heterogeneous outcomes measured [16].

### Sacral Nerve Stimulation Results

Sacral nerve stimulation (SNS) has emerged as a safe, efficacious, and durable treatment for FI. The first reported use of SNS for FI refractory to conventional modalities was in 1995 [17]. Its use in fecal incontinence stemmed from the observation that patients with urinary incontinence undergoing SNS device placement benefited also from improved bowel function. Since then, numerous studies have demonstrated significant and sustainable improvement in incontinence. A recent Cochrane Review Meta analysis reviewed six trials examining SNS in FI [18]. One of the trials cited was by Tjandra *et al.*, and it randomized patients with severe FI to either SNS or medical management consisting of diet manipulation, stool bulking agents, and biofeedback. Patients receiving medical management had no improvement in their degree of incontinence at either 3 or 12 months, whereas the SNS patients had significantly improved incontinence scores, and their mean number of incontinence episodes dropped from 9.5 to 3.1 per week at 12 months after SNS placement. SNS patients also enjoyed significant improvements in their quality of life [19].

The durability of SNS was demonstrated in a multi-center prospective trial which followed 76 patients for five years following implantation of the device. At five years, the mean number of incontinence episodes decreased from 9.1 per week pre-implantation to 1.7 per week, and 36% of patients maintained total fecal continence at five years. Quality of life was significantly improved and this improvement was sustained at five years [20]. Other series have

examined long-term durability of SNS. One European group found that at a median follow up of seven years, 194 (71.3%) of 272 patients who had successful temporary testing and underwent permanent stimulator implantation sustained greater than 50% improvement in continence. Of the 272 patients, 136 patients (50%) sustained full continence [21]. One small series followed 23 patients for a median of 9.5 years following successful SNS placement. Of these, 12 (48%) patients maintained full continence at last follow up [22].

## Mechanism of Action

How SNS effects improvement in FI has yet to be fully elucidated. One study by Leroi *et al.* examined whether the effects of SNS were due to placebo. After patients were successfully implanted with an SNS device, 27 were randomized to either an “on” or “off” state of the stimulator for 1 month, and then were crossed over to the other setting. Patients were blinded to their randomized settings, and at the end of the crossover periods, they were allowed to determine which mode of stimulation they continued in for the final period. Outcomes during the crossover and final periods were measured, and the patients randomized to “on” had significantly greater improvement in incontinence episodes compared to baseline as well as “off” setting, though the patients in the “off” setting did not return to their baseline incontinence. The vast majority of patients chose to keep their devices in the “on” state. Taken together, these findings suggested against the placebo effect, and began to point to SNS exerting its effects on the storage and emptying reflexes of the pelvic bowel [23].

SNS mechanism of action was initially thought to be due to augmentation of anal sphincter function. This was in part because confirmation of correct lead placement yields an anal/perineal bellows response, which is due to levator muscle contraction and appears as a fluttering of the perianal area. Additionally, some earlier studies suggested increased anal sphincter tone. Despite mixed initial results, the majority of studies conclude that SNS does not increase the resting or squeeze tone of the anal sphincter [19,24]. Instead, current evidence points to SNS working on afferent (sensory) pathways, though whether this is via modulating somato-visceral reflexes or by moderating the perception of afferent signalling remains to be defined [25]. A recent study by Altomare *et al.* demonstrated that SNS takes advantage of neuroplasticity, restoring neural circuitry to its prior, pre-incontinence state. Its effects are in a sense memorized, at least for a short period. In this study, 19 patients with fecal and/or urinary incontinence who had successfully been treated with SNS for at least one year had their device turned off. Bowel and urinary diaries were recorded as were quality of life metrics. Devices were reactivated once patients developed symptom recurrence or became dissatisfied. At a median time of 3.4 months (range, 0.9-13.5 months) after device deactivation, 10 (53%) of patient required the stimulator to be turned back on. The remaining nine patients remained satisfied with their continence with the SNS switched off [26]. This provocative finding goes along with an observation in Leroi’s previously mentioned study, which was that patients crossed over to the “off” position had some worsening in their continence but did not return to their baseline incontinence. In that case, patients maintained many of the benefits of SNS despite the device being off for one month’s time [23].

## Candidates for SNS

Patients referred for SNS have moderate to severe FI and have failed traditional therapies. FI needs to be severe enough such that during the trial stimulation period, a greater than 50% improvement in episodes can be detected. However, the number of incontinent episodes cannot be the only prompt for SNS placement, as many patients so radically modify their life to eliminate these episodes, such as not eating for many hours prior to leaving the house, or remaining homebound. Working with patients to determine the number of episodes experienced while engaging in “normal” activities - what they would do if they did not have FI - is paramount to defining the severity of their FI.

Currently, SNS is approved for patients with sphincter deficits of

up to 60 degrees who have failed traditional management. However, there is evidence of its efficacy in patients with larger sphincter defects. One study examined outcomes in 53 patients who had successful SNS placement, and grouped them by degree of external anal sphincter defect: no defect, up to 90 degrees, 90-120 degrees. Internal anal sphincter defects were similar across the groups. In evaluating incontinence episodes per week as well as quality of life scores, the authors found no significant different in outcomes between the groups, and similar clinical benefit regardless of sphincter defect size [27]. In evaluating patients with FI, therefore, not all patients need to undergo ultrasound evaluation to define their sphincter, though in some settings this may be required prior to insurance approval of device placement.

## Emerging Indications

SNS is increasingly being used for FI associated with other etiologies such as rectal or pelvic surgery and pelvic radiation. Patients who undergo resection of part or all of their rectum, such as for a rectal cancer, are at risk for developing low anterior resection syndrome. This is a disabling set of symptoms characterized by fecal incontinence, frequency, and urgency, clustering of stools (numerous bowel movements within a few hours); and/or obstructive defecation. A handful of small case series have reported results in patients who have had rectal surgery with or without chemoradiation and underwent SNS to treat their low anterior resection syndrome. A review of seven case series found that on intention to treat analysis, 74.4% of patients with low anterior resection syndrome had at least a 50% improvement in incontinence episodes with SNS [28]. Overall, the results are promising, with many studies demonstrating clinically and statistically significant improvement in incontinence and quality of life scores, similar to those for other etiologies of FI [28,29].

Novel applications trialled include use in imperforate anus, Crohn’s disease, and irritable bowel syndrome (IBS). Patients with congenital imperforate anus undergo a surgery within the first few months of life whereby the anal opening is created in the middle of the sphincter muscle complex and a bowel-anal anastomosis is created. As they mature, many patients develop fecal incontinence due to inadequately developed sphincter muscles. A small case series reported on two patients with FI due to congenital imperforate anus; one achieved significant improvement in his symptoms whereas the other patient had no improvement and did not advance beyond the trial phase [30]. Complicating the performance of SNS in these two patients was that both had sacral agenesis, a common finding in imperforate anus, which limited the side on which the stimulating lead could be placed. Another case series demonstrated trends towards quality of life improvements in children undergoing SNS placement for FI [31]. Use of SNS in Crohn’s disease was presented in a case series of five patients with FI, sphincter disruption, and anoperineal lesions (abscess, fistula) due to Crohn’s disease. Patients underwent SNS placement and at a median follow up of 14 months, all five patients demonstrated at least a 50% improvement in their incontinence [32]. The role of SNS in IBS was investigated in a small pilot study in which six patients underwent temporary sacral nerve stimulation. All six had diarrhoea-predominant IBS. Scores of IBS severity and quality of life prior to and during the three week test period were evaluated, and statistically significant improvements were seen in all areas [33]. The same authors subsequently performed a randomized, controlled, blinded crossover study of SNS in patients with either diarrhoea-predominant or mixed IBD. Patients underwent a temporary testing period whereby the stimulation was deemed successful if they had a reduction of at least 30% in their IBS symptom scores. Twenty patients had successful permanent implantation and completed the two-month crossover study, during which patients were randomized to either stimulator on or off for a one month period and then were switched to the other setting. The investigators again found significant improvements in IBS severity and IBS-specific quality of life scores during the stimulation period as compared to the off period [34].

Needing further investigation is the role of SNS in patients with constipation. A small number of studies have examined SNS

effects on colonic motility, rectal compliance, and rectal sensitivity, disorders of which can lead to constipation. Overall, the results are mixed. There is some evidence of improved transit time in patients with slow transit constipation as well as improved rectal sensitivity to distention, whereas rectal compliance so far does not seem to be altered by SNS [35]. Unfortunately, the underlying etiology of constipation varies significantly from an abdominal process (e.g. slow colonic transit) to a pelvic process (rectal hyporeactivity, paradoxical contraction, anal sphincter spasm, enterocele, etc.) and evaluating results of SNS in constipation is hampered by a failure to accurately define and distinguish the particular type of constipation suffered by studied patients. One recent study evaluating SNS in idiopathic slow transit constipation had more stringent eligibility criteria to exclude patients with pelvic functional and anatomic causes of constipation. The authors performed a blinded crossover trial where patients, after having been implanted with the permanent stimulator, were randomized to either sub-sensory stimulation (stimulation just below what patients could perceive) versus sham, and then to supra-sensory stimulation (at a level the patient could perceive) versus sham. Each testing period was three weeks interrupted by washout periods of two weeks. Only 16 of 55 patients undergoing permanent placement had demonstrated a response during the temporary lead placement, which was defined as having a bowel movement plus the sense of complete evacuation on more than two days per week for at least two weeks. The authors found that the temporary testing period had a sensitivity of 50%, as eight of the patients who initially responded did not have response during the permanent period. They did not identify any difference between sub-sensory stimulation and sham periods or between supra-sensory and sham, and concluded that SNS did not improve the frequency of bowel movements [36]. It is not clear, though, whether the time periods used in this study were long enough to detect differences. Additionally, it is difficult to conclude on the efficacy of permanent SNS placement when many of the group did not have response to temporary placement. Further delineation of which constipated patients benefit from SNS is needed.

As noted previously, there is significant overlap of urinary and fecal incontinence amongst patients. Given the success of SNS in each condition individually, its use in double incontinence has been appealing. The only series to examine results of SNS in patients prospectively identified as having both FI and urinary incontinence was by El-Gazzaz *et al.* In this series, 24 patients underwent permanent SNS placement after demonstrating at least 50% reduction in urinary symptoms during the trial period. Of these, 22 patients were followed for median of 28 months (range, 3-49). Seven patients (31.8%) sustained improvements in both urinary and fecal incontinence. Eleven patients (50%) had improvements in urinary symptoms, of which four patients (18.2%) had improvement in urinary symptoms alone. Ten patients (45.5%) had improvement in FI, of whom three patients (13.6%) had improvement in FI alone [37]. A series by Faucheron *et al.* examined outcomes in 57 patients undergoing SNS placement that were identified with either fecal or urinary incontinence and found on patient evaluation to have incontinence in the other system. Median follow up was 62.8 months (range, 15-116). At the end of the follow up period, 42 (73.7%) of patients reported satisfaction with results of SNS for both FI and UI. Of these patients, the median FI score improved by over 50%, and there was significant improvement in urge incontinence symptom profile [38]. Other series reporting on SNS for fecal incontinence with urinary incontinence as a secondary criterion have demonstrated a range of improvement in combined incontinence from 20-100% [39].

## Conclusion

SNS continues to be a safe, well-tolerated, and durable treatment whose use has expanded from urinary incontinence to idiopathic and fecal incontinence. Its indications continue to evolve in patients with fecal incontinence from a variety of etiologies including low rectal and pelvic surgery and radiation, congenital abnormalities, as well as for those suffering combined incontinence. Continued studies into its mechanism of action will help guide successful implementation for future patients.

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