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ORIGINAL ARTICLE

Clinical outcome of sacral neuromodulation in incomplete spinal cord-injured patients suffering from neurogenic bowel dysfunctions

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Study design: Retrospective study.
Objectives: Efficacy and safety of sacral neuromodulation (SNM) in incomplete spinal cord-injured patients (SCIPs) affected by chronic neurogenic bowel symptoms (NBSs).
Setting: Neurourology Department. Primary to tertiary care.
Methods: Retrospective non-blinded study without controls. Thirty-nine SCIPs were submitted to temporary stimulation for NBS. Permanent implantation was carried out if both their NBSs improved and the Wexner questionnaire scores were reduced by at least 50% during the first stage compared with that at baseline. Outcome measures included episodes of fecal incontinence and number of evacuations per week, as well as the Wexner score and the Short Form 36 (SF-36) Health Survey questionnaire.
Results: Twenty-three SCIPs were submitted to definitive SNM, maintaining their clinical benefits after permanent implantation with a median follow-up of 38 months. The length of time since neurological diagnosis to SNM therapy represents the only factor related to the success of the implantation, $P<0.05$. In subjects with constipation (12), the median number of evacuations shifted from 1.65 to 4.98 per week, whereas the Wexner score changed from 19.91 to 6.82 in the final checkup with $P<0.05$. In subjects with fecal incontinence (11), the median number of episodes per week in the final follow-up was 1.32 compared with 4.55 pre-SNM. The general and mental health of both groups was measured with the SF-36 questionnaire and consistently showed statistical improvement ($P<0.05$).
Anorectal manometry showed no important variation compared with baseline. There were no major complications.
Conclusions: SNM therapy should be considered for the treatment of NBS for select patients with incomplete spinal cord injury when conservative treatments fail.
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Keywords: neurogenic bowel disorders; sacral nerve modulation; spinal cord lesion; constipation fecal incontinence

Introduction

Most adult spinal cord-injured patients (SCIPs) suffer from constipation or fecal incontinence.[1,2] One report found that 27–41% of SCIPs had gastrointestinal problems that altered their lifestyle and required treatment.[3] There is a connection between the two conditions in people with spinal cord injuries (SCIs) because any treatment with the aim of improving one condition may precipitate the other.[4] The effects of bowel dysfunctions on quality of life (QoL) are significant; people with SCI have frequent embarrassing bowel accidents that cause them to refrain from social and outdoor activities. It is also considered that specific treatments for neurological diseases may have side effects on bowel function.[5]

Treatments for constipation are primarily conservative and may include dietary and lifestyle advice, drug treatment (laxatives, suppositories and enemas), and if these prove unsuccessful, behavioral (biofeedback) therapy. For fecal incontinence, nonoperative management, such as dietary advice, anti-diarrheal medication, physical and behavioral (biofeedback) treatment, may be used. When conservative management fails, clinicians have to choose from a variety of treatment options, which include the use of bulking agents, colostomy, ileostomy, malone anterograde continence enema and sacral anterior root stimulator implantation.[6,7]

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A recent surgical approach to both fecal incontinence and constipation is sacral neuromodulation (SNM). Indications have evolved with time, and patients with fecal incontinence caused by idiopathic sphincter degeneration, iatrogenic internal sphincter damage and partial SCI reported benefiting from SNM.[8]

Nowadays, individuals are submitted to a two-stage procedure using the InterStim system (Medtronic, Inc., Minneapolis, MI, USA). In the first stage, the permanent electrode is placed in the sacral S3 root using a percutaneous technique and then connected to a temporary external stimulator, allowing patients to be assessed for a longer duration (median 1 month) and eliminating the risk of lead migration, a common consequence of the peripheral nerve evaluation test. If the main symptoms improve by at least 50%, the patient proceeds to the second stage, where a subcutaneous pocket in the buttock is created to insert the implantable pulse generator (IPG).

The range of SNM indications has been extended continuously beyond voiding disorders. These additional benefits have included a reestablishment of pelvic floor muscle awareness and normalization of bowel function. SNM in SCIPs for functional anorectal disturbances is used because other surgical procedures available have a considerably invasive component with often little guarantee of symptom resolution.[9,10] However, for this category of patients, there is sparse information with regard to the efficacy of SMN and any adverse events that concern fecal incontinence exclusively. The mean number of episodes of incontinence decreased by more than half after permanent implantation compared with baseline, and severe side effects such as infection of the IPG tined lead were not reported, even if the median follow-up after permanent implantation was 12 months.[9,10] The aim of this study was to evaluate the efficacy and complications in medium and long-term follow-up for patients with partial SCI treated with SNM for chronic NBD.

Materials and methods

This is a retrospective non-blinded study without controls in incomplete spinal cord lesion patients with NBD refractory to maximal conservative therapies who underwent implantation of the SNM system (Medtronic Inc).

Between January 2001 and January 2008, a total of 39 SCIPs (22 male, 17 female, mean age 39 ± 10 years) underwent a temporary implant using the InterStim system (Medtronic Inc).

All patients were implanted using the percutaneous second-stage procedure with tined lead placed in the foramen sacral S3 unilaterally. SCIPs were submitted to the second stage only if their neurogenic bowel symptoms (NBSs) improved by at least 50% during the first stage (which lasted a minimum of 1 month) compared with baseline. Diaries recording bowel function were used for evaluation. A decrease of at least 50% in the Wexner questionnaire scores compared with baseline (0–20 for fecal incontinence and 0–30 for constipation) during the first stage was our criteria for inclusion in the second stage.

Table 1 Patient selection criteria are reported

Patient selection criteria
Inclusion criteria
Signed informed consent
Age 18–75 years
One or more episodes of fecal incontinence per week (assessed by means of a baseline bowel habit diary)
Failed conservative therapy (antidiarrheals and biofeedback)
Competent to fill in questionnaires and attend clinics
Follow-up of longer than at least 12 months after permanent sacral neuromodulation implantation and if complete data were available
Exclusion criteria
Congenital anorectal malformation
Rectal surgery <12 months ago (<24 months for cancer)
Present external rectal prolapse or rectoanal intussusception
Chronic bowel disease (for example, inflammatory bowel disease)
Chronic diarrhoea, unmanageable by diet or drugs
Stoma *in situ*
Individuals with neurological diseases other than spinal cord injury
Bleeding complications
Pregnancy
Anatomical limitations preventing placement of electrode
Skin disease risking infection (for example, pyoderma, pilonidal sinus)
Psychiatric or physical inability to comply with study protocol
Pregnancy
Anatomical limitations preventing placement of an electrode Skin disease risking infection (for example, pyoderma, pilonidal sinus)
Subjects with a history of psychiatric conditions and those manifesting psychiatric disorders according to the Minnesota Multiphasic Personality Inventory (MMPPI2) questionnaire

To evaluate clinical improvement, patients kept a bowel habit diary for 2 weeks both before the first stage of SNM and before each follow-up. During the assessment period, all medications correlated to NBS were avoided. Primary outcome measures in subjects with fecal incontinence included episodes of fecal incontinence, solid and liquid; the number of evacuations and time per defecation were measured in patients affected by constipation.

Before the first stage, each individual underwent the following tests: anorectal manometry, anal ultrasound, defecography and total gastrointestinal transit times (GITTs), which was determined by the method described by Abrahasson.[11]

Table 1 reports the inclusion and exclusion criteria. The American Spinal Injury Association/International Medical Society of Paraplegia (ASIA/IMSOP) impairment scale was used to classify patients according to injury severity.[12] Neurological assessment was carried out by a professional neurologist to determine the stability of the case, and level and degree of injury. Individuals were divided according to their neurogenic bowel complaints: 12 suffered from chronic constipation and 11 were affected by chronic fecal incontinence. Incontinence episodes were classified as urge (inability to defer defecation) or passive (no awareness of loss of stool). All patients in the study had both urge and passive fecal incontinence.

After second-stage surgery, follow-ups were scheduled at 1, 3 and 6 months, and subsequently every 6 months, during which time, stimulus parameters such as amplitude in volts, pulse width (in microseconds) and rate, mode (cycling versus

continuous) and possible battery depletion were telemetrically checked. During each follow-up visit, all subjects completed the Wexner questionnaires; the SF-36 Health Survey questionnaire was administered using the 0–100 scoring system to gain information on the impact of SNM on health-related QoL.[13] In the first and final follow-up, with the last one carried out in January 2009, all the SCIPs underwent a new anorectal manometric investigation.

Stimulation

The temporary external patient stimulator and permanent IPG were both set at a frequency between 5 and 20 Hz (mean 15 Hz), and a pulse width at 210 s. Amplitude was set at a point just above or below the threshold of patient sensation, with a median value of 1.5V (range 0.5–4.0). Stimulation was not altered at times of defecation and was set in all patients in the continuous mode.

Patients were encouraged to contact the clinic when they suspected neuromodulation-related complaints. All tests used for data analysis were carried out assuming a maximum α-error of 5% ($P<0.05$). In SCI responders, analysis of results was carried out using the Wilcoxon test to compare both the clinical parameters selected for NBS, the questionnaire scores with regard to the impact of QoL and the pre-SNM anorectal manometric findings in the first and final follow-up after permanent surgery. The χ^2-test was used to compare various parameters selected between the responding and failure groups. The study was conducted after the local ethical committee approved the study protocol. All participants provided written informed consent before enrolment and the study was conducted in accordance with the regulatory standards of Good Clinical Practice and the Declaration of Helsinki (1996).

Results

Fifty-nine percent or 23 out of 39 SCIPs (13 male, 10 female, mean age 36 ± 9 years) underwent the two-stage procedure because they reached satisfactory clinical improvement in their bowel disorders during temporary stimulation.

Analysis of the failure group

The factors taken into consideration when comparing the success and failure groups were the following: length of time from neurological diagnosis to SNM, age, gender, level and degree of lesions, Wexner scores, anorectal manometry and GITT. Only in the case of 'length of time from neurological diagnosis to SNM' was a significant statistical difference reached (using χ^2, $P<0.005$) between responders and non-responders; groups were divided according to length of time since diagnosis to actual SNM (more or <3 years).

Responding patients

Spinal cord-injured patients were divided into two groups according to their NBS: 12 suffering from constipation and 11 from fecal incontinence. Table 2 reports the main characteristics of this population.

Table 2 Main characteristics of patients submitted to permanent implantation

Number of patients	23
Mean age (years)	36 ± 9
Sex	8 female 15 male
Etiology of SCI	17 traumatic 5 myelitis 1 post-surgery
SCI level	13 lumbar 9 thoracic (T10–T12) 2 cervical
Degree of lesions	9 (C) 14 (D)
Main NBD problem	12 constipation 11 fecal incontinence

Abbreviations: NBD, neurogenic bowel dysfunction; SCI, spinal cord injury. C and D indicates the degrees of lesion according to American Spinal Injury Association/International Medical Society of Paraplegia (ASIA/IMSOP).

Constipation group

Five out of twelve subjects were female. One male underwent a hemorrhoidectomy 2 years before the first stage. Ten out of twelve patients showed slow global transit, whereas one male and one female were normal. The reference of normal parameters with regard to global intestinal transit time (GITT) was in accordance with published studies (<2.8 days in men; <4.7 days in women).[14] The mean GITT in days was 4.5 (range 2.6–6.3).

Assessment of bowel diaries showed a significant improvement in bowel movements and a reduction in defecation time. During follow-up visits, all patients' symptoms improved by at least 50%, as determined by both the Wexner scores and the clinical parameters recorded in the diaries. The median improvement in Wexner scores was 66.6% (range 55.3–77.3%), whereas at the final visit, it was 65.4% (range 55.3–77.3%). Table 3 shows the mean variation in the clinical parameters selected in the first and final follow-up after surgery compared with baseline.

Fecal incontinence group

All subjects but one had a normal GITT in accordance with the aforementioned criteria. The mean GITT in days was 3.15 (range 1.6–5.1).

Three out of eleven patients, two of whom were female, were fully continent up to the most recent follow-up. During follow-up visits, all patients' symptoms improved by at least 50%, as determined by both the Wexner scores and the clinical parameters recorded in the diaries. The median improvement in Wexner scores was 65.6% (range 54.5–81.2%) in the first visit after surgery, whereas at the final visit it was 62.4% (range 50–76.9%). Table 4 shows the mean variation in the clinical parameters selected in the first and final follow-up after surgery compared with baseline.

Table 3 Constipation category

Key bowel parameters	*Baseline*	*First visit after permanent SNM*	*Final visit after SNM*	P-*value Wilcoxon test*
Wexner score	19.91 (range 17–23)	6.55 (range 4–9)	6.82 (range 5–9)	$^{**}P<0.018$
Number of evacuation per week	1.65 (range 1.5–2)	5.40 (range 4.5–7)	4.98 (range 4.5–7)	$^{**}P<0.018$
Time per defecation (in min)	45.85 (range 20–80)	10.41 (range 5–15)	11.67 (range 5–15)	$^{**}P<0.020$

Abbreviation: SNM, sacral neuromodulation.
P when comparing outcomes at all checkups with baseline. Wexner scores and diary entries are reported at baseline, first and final visit after SNM. Mean time from neurological diagnosis to SNM therapy was 41 months (range 18–96). Mean follow-up period from permanent implant to final visit was 44.3 months (range 18–96).
**Significant statistical evidence was detected both in the first and final visit post-SNM.

Table 4 Fecal incontinence

Key bowel parameters	*Baseline*	*First visit after permanent SNM*	*Final visit after permanent SNM*	P-*value Wilcoxon test*
Mean Wexner score	13.09 (range 11–18)	4.45 (range 3–8)	4.91 (range 3–9)	$^{**}P<0.018$
Mean number of fecal incontinence/week	4.55 (range 3–8.5)	1.16 (range 0–3)	1.32 (range 0–2.5)	$^{**}P<0.018$
Mean pads used/die	2.36 (range 1–4)	0.91 (range 0–2)	0.95 (range 0–2)	$^{**}P<0.020$

Abbreviation: SNM, sacral neuromodulation.
P when comparing outcomes at all checkups with baseline. Wexner scores and diary entries are reported at baseline, first and final visit after SNM. Mean time from neurological diagnosis to SNM therapy was 33 months (range 15–57). Mean follow-up period from permanent implant to final visit was 46 months (range 23–8).
**A statistical significant improvement was documented both in the first and final visit post-SNM surgery.

Table 5 Median score of SF-36 at baseline, first and final checkups after second stage

SF-36	*Fecal incontinence group*				*Constipation group*			
	Baseline	*First visit after SNM*	*Final visit after SNM*	P-*value*	*Baseline*	*First visit after SNM*	*Final visit after SNM*	P-*value*
PF	52.3	55.2	55.6	NS	53.7	54.4	54.9	NS
RF	51.6	52.7.7	53.6	NS	52.6	53.4	53.1	NS
BP	55.9	57.3	58.2	NS	53.6	54.8	54.4	NS
GH	50.1	69.8	66.4	<0.05	54.4	64.4	62.1	<0.05
VT	51.1	52.7	53.6	NS	53	54.4	54.1	NS
SF	49.1	66.6	64.7	<0.05	58.2	59.5	58.7	NS
RE	47.4	67.8	66.2	<0.05	54	55.8	55.4	NS
MH	51.3	66.4	65.1	<0.05	52.5	67.4	65.8	<0.05

Abbreviations: BP, bodily pain; GH, general health; MH, mental health; NS, not significant; PF, physical functioning; RE, role emotional; RF, role physical; SF, social functioning; SF-36, Short Form 36; VT, vitality.
Statistical analysis was carried out using χ^2-test.

QoL

A statistical improvement in two subscales of the SF-36 QoL questionnaire on mental health and general health was observed in both groups at all post-surgery follow-ups. In addition, the fecal incontinence group maintained a statistically significant enhancement in all post-SMN follow-ups according to the Wilcoxon test ($P<0.05$) with regards to two domains (role emotional and social functioning) of the SF-36 questionnaire. Table 5 reports the median scores of the SF-36 subscales at baseline for both groups in the first and final visits after SNM, and which domains show a statistical improvement.

Anorectal manometric findings

Table 6 reports the median anorectal manometric findings pre-SNM in the first and final follow-up. Statistical significance was not attained on any anorectal manometry parameters after SNM compared with that at baseline. In the fecal incontinence group, the major variation after SNM was detected in the reduction of the rectal volume sensation at threshold, whereas in patients suffering from constipation, the main change was a median decrease in the urge rectal volume sensation.

Complications

A total of 1038 months of SNM yielded 12 adverse events in five patients, seven of these affecting the fecal incontinence group. Four battery changes were required for four patients, two in each group.

The mean life span of the replaced IPGs in these patients was 70.8 months (range 46–81).

All complications prompted unscheduled visits; four cases were related to pain at the generator site, three to spasticity pain in the lower limbs and one to excessive tingling in the vaginal region. All were resolved through telemetrically modifying the previous stimulation parameters.

Table 6 Anorectal manometry findings

	Maximum RP (cm H_2O)	*Maximum SP (cm H_2O)*	*Rectal volume sensation (ml)*		
			Threshold	*Urge*	*Maximum tolerated*
Constipation					
Pre-SNM	31.58 ± 5.61 (range 25–42)	57.41 ± 6.72 (range 45–70)	68.58 ± 13.99 (range 40–90)	111.66 ± 16.56 (range 90–140)	158.30 ± 14.35 (range 135–190)
First visit after SNM	32.25 ± 5.59 (range 27–45)	58.25 ± 7.32 (range 45–70)	67.33 ± 13.33 (range 40–90)	105 ± 18.73 (range 80–130)	156.91 ± 13.50 (range 135–180)
Final visit	31.33 ± 4.87 (range 27–40)	57.16 ± 7.45 (range 45–70)	67.66 ± 13.31 (range 40–90)	104.58 ± 19.70 (range 70–130)	157.08 ± 14.37 (range 135–180)
P-value	>0.05	>0.05	>0.05	<0.062	>0.05
Fecal incontinence					
Pre-SNM	29.63 ± 9.27 (range 15–47)	60.27 ± 7.19 (range 48–73)	49.27 ± 14.45 (range 25–70)	117.72 ± 25.03 (range 90–160)	149.09 ± 32.69 (range 120–210)
First visit after SNM	31.09 ± 7.63 (range 18–47)	61.45 ± 6.53 (range 51–74)	47.90 ± 13.93 (range 25–68)	118.63 ± 27.21 (range 85–170)	148.63 ± 34.93 (range 115–215)
Final visit after SNM	30.18 ± 8.37 (range 17–46)	61.09 ± 6.60 (range 51–73)	48 ± 14.43 (range 25–70)	118.18 ± 27.04 (range 90–170)	147.45 ± 32.97 (range 110–205)
P-value	>0.05	>0.05	<0.062	>0.05	>0.05

Abbreviations: RP, resting pressure; SNM, sacral neuromodulation; SP, squeeze pressure.
P when comparing outcomes at all checkups with baseline. Anorectal manometry data at baseline, first and final follow-up are shown for both groups.

Discussion

Evidence from our study shows that permanent SNM in partial SCIPs who followed treatment for a median of at least 3 years substantially improved both continence in individuals with severe fecal incontinence and defecation in subjects suffering from constipation who are resistant to maximal medical treatments. All 23 SCIPs have a satisfactory bowel routine at present; they continue to follow a careful diet, and pharmacological treatments such as laxatives are used only occasionally and with a lower dosage compared with that at baseline. Major complications such as infection of the implant or lead dislodgement were not detected. Three out of 23 SCIPs underwent magnetic resonance imaging during a routine checkup after SNM and did not have any complications of the sacral electrode or implanted pulse generator.

The loss of voluntary control of bowel function has been described as the second most distressing aspect of life after SCI.[15] Consequently, both groups' higher scores in the SF-36 mental health and general health domains are explained by their significant bowel function improvement. Fecal incontinence is much more stressful than constipation, generating more negative repercussions on a psychological level (low self-esteem and altered body image), limiting social and recreational activity and interfering with sexual function as well. In our sample, the median role emotional and social functioning domain scores at baseline were lower in the fecal incontinence group.

Our percentage of successful temporary stimulation (59%) is lower compared with that of other authors, who reported their SNM findings mainly on patients with bowel disorders of idiopathic origin. Our findings are encouraging, however, considering that all these patients maintained satisfactory clinical benefits in a median follow-up of >3 years.

In our study, the only factor related to the success of implantation is the length of time from neurological diagnosis to SNM therapy, and this predictive factor should be confirmed to increase the percentage of responders during test stimulation.[16] Long-term clinical benefits and an increase in the number of responders would lead to a cost reduction in SNM therapy; indeed, in the long term, costs are likely to be comparable with those of conservative, sanitary and stoma therapies, even if comparative health costing in this area is difficult to determine because of the many factors that need to be taken into account.[17] A recent outcome and cost analysis of SNM for fecal incontinence has shown that it is highly effective. A cost-effective system might be to select motivated subjects who are willing to undergo an intensive period of care during the first stage and at the same time evaluate possible associations with previous treatments to attain better and more satisfactory clinical results.

Fortunately, the recent introduction of a percutaneous technique for implanting the permanent electrode, which is minimally invasive, offers the advantage of allowing to test for its efficacy (at least 1 month) and may favor an early approach to SNM in partial SCIPs suffering from NBS.

However, at this time, a successful first-stage trial stimulation based on improved clinical findings compared with

baseline remains the best indicator for definitive surgery, knowing that some patients require more time (2–3 months) to develop a significant clinical response; in fact, it is not easy to find individual appropriate combination stimulus parameters on pulse width, frequency and amplitude.

On the contrary, in our study, anorectal measurements not only did not predict which patients gained sufficient benefit to warrant permanent implantation but significant variation of anorectal manometry findings was not detected after permanent SNM. Literature reported discordance and varying results with regard to anorectal findings after permanent SNM in patients suffering from bowel dysfunctions.[18,19]

At this time, the possible effects of SNM on colonrectal transport are still unclear.[18] Still to be resolved is the contribution and importance of the complex multisynaptic mechanisms of the multiple nerves within the sacral plexus, as well as the enteric nerves, the spinal cord, the brainstem and the cerebral cortex and their changes during SNM. The multiple and complex mechanism of actions of SNM on all pelvic organ functions is highlighted by a recent study on patients with partial SCI; most of these patients suffered from concomitant bowel, bladder and sexual dysfunctions due to the same neurological etiology, and showed a remarkable clinical improvement in neurogenic lower urinary tract symptoms and sexual function in the medium and long term.[20]

Larger, high-quality randomized crossover trials are needed to allow the effects of SNM on these conditions to be assessed with more certainty. Studies comparing SNM directly with other surgical treatments are needed to establish the surgery's efficacy, so that SNM may become the surgical treatment of choice for patients with partial SCI and NBS who do not respond to conservative treatments.

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