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Functional Outcomes and Satisfaction Rates of Sacral Nerve Stimulation in the Treatment of One and Multiples Pelvic Floor Dysfunctions

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Abstract

Objective Few studies have addressed the use of sacral nerve stimulation (SNS) in the treatment of patients with multiple pelvic floor dysfunctions (PFD). So, we evaluated the functional outcomes and level of satisfaction with SNS in selected patients with one or multiples PFD.

Methods A prospective database was used to collect information on eligible patients treated for PFD with SNS, and severity of symptoms was assessed with scores and satisfaction rates by visual analogue scale (VAS) at baseline and by the end of follow-up.

Results We recruited 70 patients, 98.6% of whom responded positively during the evaluation period (Global Response Assessment $\geq$ 50% for at least one type of PFD), resulting in the implantation of a permanent SNS device. Additionally, 49 of the patients (71%) had a single PFD (fecal incontinence [FI] = 38; constipation/obstructed defecation syndrome [C/ODS] = 11), while 20 (29%) had more than one PFD (double incontinence/n = 12; double incontinence + C/ODS/n = 8). All scores improved significantly between baseline (pre-SNS) and the end of follow-up (post-SNS), as did VAS in all groups (single and multiple PFD). The pre-SNS scores were higher in patients with a single PFD, including FI (Cleveland clinic Florida incontinence score [CCF-FI]) and C/ODS (Cleveland clinic constipation score [C-CCF] and the Renzi ODS score). The pre-SNS impact of VAS scores was similar in all groups (single and multiple PFD), but the VAS (post-SNS) was significantly lower (better response) for FI alone compared with multiple PFD.

Conclusion The SNS technique is an effective and safe option for patients with one or more PFD refractory to conservative measures. Response was positive for at least two PFD, based on reduced correspondent scores and satisfaction rate.

Keywords
- neuromodulation
- sacral nerve stimulation
- fecal pelvic floor disorders
- fecal incontinence

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Introduction

Pelvic floor disorders (PFD) include a variety of interrelated clinical entities such as urinary and/or anal incontinence, voiding and defecatory dysfunction, and pelvic organ prolapse. This condition may affect the anterior, middle, or posterior compartments, and many women experience more than one PFD, frequently associated with childbirth, obstetric factors, and age.[1–3]

These disorders are traditionally treated by urologists, gynecologists, and colorectal surgeons. Sacral nerve stimulation (SNS) is a well-established treatment option indicated for patients with chronic voiding or bowel dysfunction (including fecal incontinence, constipation, and obstructed defecation syndrome) who are unresponsive to first or second-line treatments.[4–6] It can also be used as a minimally invasive last resort before considering major surgery, as in the case of chronic persistent constipation, or subtotal colectomy or colostomy.[7–9] Few studies have addressed the use of SNS in the treatment of patients with multiple PFDs.

The present study was designed to assess the functional outcomes and satisfaction rate with SNS in consecutive patients treated for one or multiple PFDs.

Patients and Methods

A prospective database was set up to collect detailed pre-, intra-, and postoperative information for all patients treated with SNS for PFD, including fecal incontinence (FI), constipation and obstructed defecation syndrome (C/ODS), and urinary incontinence (UI). This cohort study was conducted over a 4-year period and included consecutive patients from a colorectal unit care referral pelvic floor center, from January 2015 to February 2022. The SNS treatment was prescribed only after conservative treatment failed. The latter included behavioral techniques such as biofeedback training and bladder retraining (8–30 sessions), the use of medications like loperamide and codeine phosphate for FI (coupled with diet), antimuscarinic or anticholinergic agents for urge UI, dietary changes like fiber and fluid supplementation, combinations with osmotic laxatives, and the use of type-2 chloride channel activators for C/ODS.

The exclusion criteria were rectal prolapse, stoma, cloacal defect, and anatomical deformities that might prevent the successful insertion of an electrode. The study protocol was previously approved by the hospital's research ethics committee and all participants gave their informed consent.

Assessments

The severity of FI was assessed with the Cleveland Clinic Florida incontinence score (CCF-IF),[10] whereas constipation was categorized as slow colonic transit (using sitz markers), ODS with normal transit, or as a combination of both. Constipation severity was quantified with the Cleveland Clinic constipation (C-CCF)[11] score and the Renzi ODS score.[12] Diagnosis of UI was established based on complaints of involuntary urine leakage, leakage upon exertion/sneezing/coughing, and/or leakage/loss of urine associated with the urge to urinate. To do so, we administered the short form of the International Consultation on Incontinence Questionnaire (ICIQ-SF).[13]

A visual analogue scale (VAS) rated from 100 (worst) to 0 (best) was used to assess functional outcomes and patient satisfaction at baseline and by the end of follow-up.[14]

Patients with a history of vaginal delivery underwent 3D anorectal ultrasonography to evaluate the anatomical integrity of the anal sphincters, followed by dynamic ultrasonography (ecodefecography) in case of symptoms of FI and ODS.[15] The colonic transit study used radiopaque markers to detect slow transit and rule out colonic inertia, characterized by radiopaque markers in the cecum and right colon, as defined by Hinton et al.[16]

Before the investigation at the pelvic floor clinic, all patients underwent a clinical assessment, including endoscopy, in order to rule out cancer, inflammatory bowel disease, and other relevant conditions.

The SNS Technique

The SNS technique employed in this study has been described elsewhere.[17] Under sedation and local anesthesia needles were positioned into the S3 foramina bilaterally, and an external pulse generator (Screener, model 3625; Medtronic, Minneapolis, Minnesota) was used for stimulation. Following a positive response, an electrode was placed with a temporary stimulation wire. After 7 to 15 days, the patient was evaluated with a clinical interview and questionnaire. A positive response was defined as i) a subjective symptom improvement greater than or equal to 50% in the Global Response Assessment (GRA), with 0% indicating 'no response' and 100% indicating 'complete resolution of symptoms', and ii) improvement of at least one PFD. In patients with a positive response of less than 50%, the generator was reprogrammed, and the evaluation period was extended for 1 to 4 weeks. Patients with positive response received a permanent implant.

All patients were evaluated following our regular clinical practice, and visits were scheduled at 1, 3, and 6 months. The remainder of the follow-up featured visits every 6 months, depending on the loss of efficacy. The outcomes were calculated based on the last follow-up. The minimum follow-up time was 6 months.

For patients with permanent implants, the difference between baseline (pre-SNS) and end of follow-up (post-SNS) was determined with regard to functional outcomes and satisfaction based on CCF-IF, C-CCF, Renzi, ICIQ-SF, and VAS scores.

Statistical Analysis

The collected data were processed with the Statistical Package Social Sciences (SPSS, IBM Co., Armonk, NY, USA) software, version 26.0. Categorical variables were expressed as frequencies and percentages. Differences between pre- and post-SNS percentages and scores were analyzed with the Wilcoxon signed-rank or Kruskal-Wallis test. The results were expressed as mean values $\pm$ standard deviation (SD). The level of statistical significance was set at 5% ($p < 0.05$).

Table 1 Global response assessment (GRA- from 0 [no response] to 100% [complete resolution of symptoms]) showing the percentage of improvement in each score in 69 patients with permanent device. The improvement was greater in the fecal incontinence score (a > b, c, d) ($p < 0.001$)

Symptoms	Global response assessment (GRA)
	Percentage improvement
	mean ± SD (range)
Fecal incontinence	88.0 ± 10.2 (57.10 - 100)[a]
CCF score	
Constipation	74.5 ± 9.7 (56.2 - 83.3)[b]
CCF score	
Renzi score	68.3 ± 9.7 (58.3 - 78.5)[c]
ICIQ-SF	66.8 ± 18.5 (50.0 - 100)[d]

Abbreviations: CCF, Cleveland Clinic Florida; ICIQ-SF, International Consultation on Incontinence Questionnaire - Short Form; SD, standard deviation.

Results

During the study period, 70 patients were successfully tested, 69 (98.6%) of whom responded positively during the evaluation period, with GRA values between 50 and 100% for at least one type of PFD, resulting in the implantation of a permanent SNS device. In one patient, improvement of C/ODS symptoms (28.2%) was insufficient for a permanent implant. The mean percentage of improvement, according to GRA values, was significantly higher for the FI score in the tested phase (►**Table 1**). The complete sample included 65 women (94.2%) and 4 men (5.8%), with a mean age of 64.4 ± 15.4 years (range: 29–92). The mean follow-up was 3.0 ± 1.6 years (range: 6 months to 6 years). No cases of infection, lead/migration/erosion or device malfunction were observed during follow-up.

No sphincter defects were seen on endoanal ultrasonography in 52/75% patients. Most sphincter defects affected the external anal sphincter (11 patients from a total of 17/65%), and over half (6) displayed a combination of external and internal anal sphincter defects. There were 29 patients with a history of surgery, including sphincteroplasty, anterior rectal resection, hemorrhoidectomy, and fistulotomy (►**Table 2**).

There were 49 patients (71%) with a single type of PFD (FI = 38 and C/ODS = 11), while 20 of them (29%) had more than one: 2 dysfunctions (double incontinence n = 12); and 3 dysfunctions (double incontinence plus C/ODS n = 8). The baseline dysfunction and severity scores for each symptom are shown in ►**Table 2**. The groups did not differ significantly with regard to the distribution of patients with history of vaginal delivery/surgery or the presence of sphincter defects (►**Table 2**).

In the majority of patients, the clinical indication was due to a single PFD, with FI as the most prevalent. Pre-SNS scores were higher in patients with a single PFD, including those with FI (CCF-FI score) and C/ODS (C-CCF and Renzi scores). Moreover, the impact of VAS on the pre-SNS scores was similar in patients with single and multiple PFDs.

All scores improved significantly from baseline to post-SNS (►**Tables 3** and **4**), as did the VAS scores for single and multiple PFD. However, post-SNS VAS scores were lower (better response) in the group with FI alone (►**Table 5**).

Table 2 Variables of patients with pelvic floor dysfunctions at baseline (pre-SNS)

Variables	Patients with pelvic floor dysfunctions at baseline (pre-SNS)				
	FI	C/ODS	FI/UI	FI/IU / C/ODS	*p*-value
	38 (55%)	11 (16%)	12 (17.4%)	08 (11.6%)	
Sex					
Female/male	35 / 3	11 / 0	11 / 1	8 / 0	0.001
Age (mean ± SD)	62.5 ± 17	59.6 ± 10	75.7 ± 10	64 ± 15	0.053
Vaginal delivery (yes/no)	18 / 28	5 / 6	6 / 6	3 / 5	0.899
Sphincter defect total (yes/no)	11/27	2 /9	4 /8	0 / 8	0.292
EAS	7 / 38	2 /11	2 / 12		
EAS plus IAS	4 / 38		2 / 12		
Previous surgery (yes/no)	13 / 25	2 / 9	2 / 10	3 / 5	0.513
CCF incontinence score (mean/±)	13.4 ± 1.4	———	12.2 ± 1.8	11.9 ± 1.4	0.001
CCF constipation score (mean ± SD)	——	14.7 ± 2.0	———	11.7 ± 1.6	0.031
Renzi constipation score		14.9 ± 1.4		11.4 ± 0.5	0.003
ICIQ-SF (mean ± SD)	——	——	11.8 /± 3.8	9.5 /± 2.0	0.132
VAS (mean ± SD)	92.1 ± 10.4	92.7 ± 7.9	94.2 ± 4.6	94.2 ± 6.7	0.472

Abbreviations: CCF, Cleveland clinic Florida; C/ODS, constipation and/or obstructed defecation syndrome; EAS, external anal sphincter; FI, fecal incontinence; IAS, internal anal sphincter; ICIQ-SF, international consultation on incontinence questionnaire - short form; SD, standard deviation; SNS, sacral nerve stimulation; UI, urinary incontinence; VAS, visual analogic scale (from 0[best] to 100[worst]).

Table 3 Comparison of severity of symptoms based on scores and VAS at baseline (pre-SNS) and by the end of follow-up (post-SNS) for implanted patients with one pelvic floor dysfunction (fecal incontinence or constipation or constipation combined with obstructed defecation syndrome)

	Implanted patients with one pelvic floor dysfunction		
	Pre-SNS	**Post-SNS**	
Fecal incontinence			
Fecal Incontinence Patients **(N°38/55%)**	13.4 ± 1.4	1.6 ± 1.3	0.001
VAS	92.2 ± 10.6	13.9 ± 11.8	0.001
C/ODS			
C/ODS Patients **(N°11/16%)**	14.7 ± 2.0	5.1 ± 1.3	0.002
Renzi score	14.9 ± 1.3	4.2 ± 1.9	0.002
VAS score	92.7 ± 7.8	26.0 ± 14.3	0.002

Abbreviations: C/ODS, constipation/obstructed defecation syndrome; CCF, Cleveland clinic Florida; FI, fecal incontinence; SNS, sacral nerve stimulation; VAS, visual analogic scale (from 0[best] to 100[worst]).

Table 4 Comparison of severity of symptoms based on scores at baseline (pre-SNS) and by the end of follow-up (post-SNS) for implanted patients with pelvic floor dysfunctions

Symptom scores	**Implanted patients with multiple pelvic floor dysfunctions**		
	Pre-SNS	**Post-SNS**	***p*-value**
Double incontinence patients **(N°12/17.4%)**			
CCF incontinence score (mean ± SD)	12.2 ± 1.8	2 ± 1.6	0.001
ICIQ-SF (mean ± SD)	11.8 ± 3.8	4.4 ± 3.1	0.005
VAS (mean ± SD)	94.2 ± 6.7	31.7 ± 11.1	0.001
Patients with associated FI, UI and C/ODS **(N°08/11.6%)**			
CCF incontinence score (mean ± SD)	11.9 ± 1.4	1.0 ± 1.5	0.001
CCF constipation score (mean ± SD)	11.7 ± 1.6	3.6 ± 0.91	0.007
Renzi score (mean ± SD)	11.4 ± 0.5	3.6 ± 1.2	0.007
ICIQ-SF (mean ± SD)	9.5 ± 2.0	3.1 ± 1.6	0.007
VAS (mean ± SD)	97.5 ± 4.6	26.2 ± 9.2	0.007

Abbreviations: C/ODS, constipation/obstructed defecation syndrome; CCF, Cleveland clinic Florida; FI, fecal incontinence; ICIQ-SF, international consultation on incontinence questionnaire - short form; SD, standard deviation; SNS, sacral nerve stimulation; UI, urinary incontinence; VAS, visual analogic scale (from 0[best] to 100[worst]).

Table 5 Comparison of satisfaction rate (VAS scores) at baseline (pre-SNS) and by the end of follow-up (post-SNS) as reported by implanted patients with pelvic floor dysfunctions

Satisfation rate	**Implanted patients with pelvic floor dysfunctions**				
VAS Mean SD					
	FI	**C/ODS**	**FI/UI**	**FI/IU/C/ODS**	***p*-value**
	38 (55%)	**11 (16%)**	**12 (17.4%)**	**8 (11.6%)**	
Pre-SNS VAS	92.1 ± 10.4	92.7 ± 7.8	94.2 ± 6.7	94.2 ± 6.7	0.472
Post-SNS VAS	13.9 ± 11.7	26.0 ± 14.3	31.7 ± 11.1	31.7 ± 11.7	0.001

Abbreviations: C/ODS, constipation/obstructed defecation syndrome; FI, fecal incontinence; ICIQ-SF, international consultation on incontinence questionnaire - short form; SNS, sacral nerve stimulation; UI, urinary incontinence; VAS, visual analogic scale (from 0[best] to 100[worst]).

Discussion

Studies have shown that SNS is an attractive alternative for patients with fecal and urinary incontinence refractory to conservative management. SNS may improve not only symptoms but also patients' quality of life and satisfaction scores.[7–9,17–20] Additionally, patients with chronic constipation could undergo SNS testing (a minimally invasive procedure) before being referred for more aggressive and sometimes irreversible surgical procedures.[7–9,21,22]

Nearly all our patients (n = 69; 98.6%) responded favorably to SNS, with GRA scores $\geq$ 50%, and definitive implants to treat one or multiple PFD. However, patients with FI alone displayed significantly greater improvement. Associated PFDs were observed in 20% of our sample. The severity of each related symptom was scored pre- and post-SNS to determine the efficacy of the treatment, and satisfaction was rated through VAS. All post-SNS scores were significantly better at the end of follow-up, even in patients with more than one PFD, and VAS scores decreased in all groups, most significantly in patients with FI alone when compared to patients with multiple conditions. It is reasonable to assume that improvement of symptoms is easier to identify for patients with a single PFD. Moreover, in the literature, SNS is associated with better outcomes in FI than in C/ODS.

Other studies have used the VAS to evaluate FI patients treated with SNS.[9,23] In this study, the scale was found to be a simple and useful tool.

Our sample of patients with C/ODS only was small, but the results indicate a significant improvement in scores and satisfaction (VAS), especially since patients with colonic inertia were excluded from the study. It was similar to that of a previous study,[10] which included patients with a radiopaque marker in the left colon, sigmoid and rectum, and/or dyssynergia.

The observed SNS success rates for constipated patients diverges from the literature,[7–9,21–26] possibly due to differences in patient profile and selection criteria.

When treating FI and constipation patients with SNS, Hidaka et al.[9] found higher levels of satisfaction (VAS), as well as constipation and FI scores improved equally at 5-years of follow-up. However, the VAS scores of SNS-C and SNS-FI patients differed significantly in the follow-up period (6–36 months). The constipation group included many younger patients, making it is more difficult to identify the optimal stimulation setting and to recognize placebo effects.

Our study did not evaluate the number of additional visits. Most visits were scheduled to evaluate the patient or rescheduled in case of loss of efficacy. Double incontinence was observed in 17% of our sample, which is slightly lower than the 20 to 30% reported in the literature.[27,28] The assessment of improvement of urinary symptoms was effective as long as VAS was also applied to measure the level of satisfaction.

Little has been published on double incontinence so far, and results have been inconsistent. However, our study revealed a significant improvement of both symptoms and patient satisfaction in this group.

Despite variations in group size, no difference was observed in the distribution of patients with regard to parity, sphincter defect, or previous surgery. Thus, none of these factors is likely to have interfered with the results. A previous study correlated multiple factors with post-therapy results, satisfaction, and failure to respond, but no factor was significant in the analysis.[29]

No complications occurred in this study and no explanation was required. One C/ODS patient experienced insufficient improvement to qualify for an implant. The therapy is considered safe, with a reported explantation rate of 8 to 15%.[9,30]

Our study was limited by the heterogeneity of its sample. Additionally, 20% of the patients had associated PFDs, distributed across the groups. However, patients with associated PFDs also experienced significant improvement in the two or three-score system adopted, as well as in their VAS scores. Finally, it may be argued that the VAS scores could have been complemented with a quality of life questionnaire.

Conclusion

The SNS technique is effective and safe for heterogeneous patients with one or multiples PFDs which are refractory to conservative measures and pharmacological treatments. Response was positive for at least two PFDs, based on reduction of severe symptoms and correspondent scores, as well as satisfaction rate.

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Conflict of Interests
The authors have no conflict of interests to declare.

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