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ORIGINAL ARTICLE

Efficacy of sacral nerve stimulation for poor functional results of J-pouch ileoanal anastomosis

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Abstract
Purpose Ileoanal anastomoses (J-pouches) are an alternative to permanent ostomy. The functional outcomes associated with the use of J-pouches are usually good, but continence disorders persist in a significant number of cases and have a negative impact on quality of life. The aim of this study was to assess the efficacy of sacral nerve stimulation (SNS) for poor functional results after J-pouch ileoanal anastomosis.
Methods Patients suffering from severe fecal incontinence (FI) following coloproctectomy underwent a staged implant SNS procedure. Demographic data and functional results for FI episodes, urgencies per week, frequency of stools, ability to defer defecation, and Wexner scores were obtained at specified intervals. Patients also completed quality-of-life assessments.
Results Four female patients were included in this analysis. All 4 experienced active and passive FI at baseline and subsequently underwent test stimulation with a 75 % success rate. Three received definitive implants. These 3 patients experienced improvement in functional outcomes at 1, 3, and 6 month assessments. Improvements in quality of life were also noted.
Conclusions Our preliminary study suggests that SNS is effective for the treatment of poor functional results following J-pouch ileoanal anastomosis; however, larger studies with long-term follow-up are needed for confirmation of our findings.

Keywords Fecal incontinence · Sacral nerve stimulation · Ileal pouch–anal anastomosis

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Introduction

Ileoanal anastomoses (IAA; also referred to as 'J-pouches') are an alternative to permanent ostomy. The functional outcomes associated with the use of J-pouches are usually good, but fecal incontinence (FI) has been reported in 1–11 % of patients during the day and 2–24 % at night [1]. This can have a significantly negative impact on the quality of life of patients [2, 3].

Unfortunately, in these cases, conservative management including drugs, constipating diet, and biofeedback physiotherapy has only limited effects [4, 5]. As a result, pouch resection with definitive stoma is then the only possibility [6]. Sacral nerve stimulation (SNS) is effective in the treatment of FI. Long-term results for anal continence and quality of life associated with the use of SNS have recently been reported and show an improvement for 86 and 89 % of patients after 3 and 5 years of follow-up, respectively [7, 8].

The precise underlying mechanism of action of SNS remains unknown. Studies have suggested a variety of different factors, including improved sensory function, improved anal sphincter function, improved colon and rectal motility, and/or central nervous system effects [9–11]. Historically, the indications for use of SNS were strict and usually limited to patients with intact anal sphincters.

Nevertheless, some studies have indicated that SNS may also be effective in patients with anal sphincter defects [12]. Indications for the use of SNS excluded patients with a history of rectal surgery or inflammatory intestinal disease [13]. To date, only one case report has documented promising results of SNS after IAA [14]. Small series indicate that SNS is a safe and effective treatment in selected patients with severe, persistent FI following neoadjuvant therapy and coloanal anastomosis (CAA) performed for rectal cancer [12, 15, 16].

The aim of our study was to assess the efficacy of SNS for poor functional results after J-pouch IAA.

Materials and methods

From April 2012 to May 2013, we prospectively studied the use of SNS in patients suffering from severe FI following restorative coloproctectomy and IAA despite optimized medical management. Demographic data for each patient were analyzed, as well as reasons for IAA, duration and type (active or passive) of FI, FI status classified according to the Wexner score [17], and associated medical treatments. Exclusion criteria included perianastomotic sepsis, such as that associated with abscess or fistula, local or distant tumor recurrence, anastomotic stenosis, pouchitis, cuffitis, or an acute flare of Crohn's disease. The IAA procedure was always performed with handsewn anastomosis and complete transanal rectal mucosectomy. For all patients, the anal anastomosis took place at the top of the anal ring, at the dentate line.

For each patient, we recorded perioperative and postoperative complications, the need for device revision and maintenance of antidiarrheal treatment post-SNS. All patients signed an informed consent form.

Assessments at baseline (T0) and follow-up visits

Before test stimulation, all patients underwent a clinical evaluation with anoscopy to assess the integrity, tone, and contractility of the external anal sphincter and the permeability of the IAA. Lower endoscopy was systematically performed to assess the presence of pouchitis. In such cases, patients were excluded from the study. Patients were asked to complete a bowel diary for 20 days evaluating the number and type of FI episodes per week, stool frequency, urgency, ability to defer defecation, and antidiarrheal treatment. FI was defined as passive for involuntary discharge of stool without awareness, whereas active FI was considered to be the discharge of fecal matter despite active attempts to retain bowel contents. Quality of life was assessed at baseline, and 3 and 6 months after SNS using two standardized assessments. The SF-36 health survey [18] was administered to assess patients' overall health across 8 domains: physical functioning (PF), role physical (RP), body pain (BP), general health (GH), vitality (VT), role emotional (RE), social functioning (SF), and mental health (MH). The French version of the Fecal Incontinence and Quality of Life Scale (FIQL) [19] was used to specifically assess FI in across four areas: lifestyle (MDV), behavior (COM), self-perception (DEP), and embarrassment (GEN).

SNS procedure

In a day surgery unit, patients were placed under general anesthesia (without curare) to avoid involuntary movement. Adequate motor response was tested in the right or left S3 or S4 foramen with a quadripolar electrode. This electrode was placed in the foramen with the best response and connected to an external test stimulator via a percutaneous extension kit. The choice of foramen for SNS was based on the best motor response of the pelvic floor contraction associated with a flexion of the ipsilateral hallux. The sensory response was assessed at the time of patient recovery after general anesthesia. At the end of the procedure, the stimulation was continuous with a pulse width of 210 microseconds, a frequency of 14 pulses per second, and an current amplitude set to match the patient's perception of perineal and anal sphincter muscle contraction. Patients were stimulated continuously over the course of the 20-day test period. Patients who achieved $\geq$50 % reduction in the number of FI episodes per week and/or $\geq$50 % reduction in the number of FI days per week were offered implantation of a permanent neurostimulation device (InterStim Therapy, Medtronic, Minneapolis, MN, USA).

At the permanent implantation, the percutaneous extension was removed in a day surgery unit under local or general anesthesia and replaced by a shorter extension connected to an internal pulse generator placed subcutaneously in a pocket in the gluteal area. The pulse generator was activated after the procedure. The stimulation amplitude was set to provide a sensation of painless stimulation around the anus. In case of no reduction in the number of FI episodes, the external test stimulator and quadripolar electrode were removed and the procedure was considered a failure.

Post-SNS assessment

Patients were evaluated 1 month after permanent implantation (T1) via clinical examination, bowel diary, and Wexner score analysis. Subsequently, the patients were evaluated 3 (T2) and 6 months (T3) after permanent implantation via clinical evaluation and analysis of quality of life.

Results

Four patients (all women), with a median age of 57 years (range 22–60 years), were included in this study. All patients had more than 2 episodes of FI per week and a Wexner incontinence score >10. All patients were treated with optimal medical therapy for more than 6 months before test stimulation. All had undergone restorative coloproctectomy with J-pouch IAA and transanal rectal mucosectomy: two for ulcerative colitis, one for familial adenomatous polyposis, and one for Crohn's disease discovered 10 years after the IAA.

Baseline assessment (T0)

All patients experienced both active and passive FI. Medians for baseline assessments were as following: duration of FI before SNS: 54 months (range 20–160 months); number of FI episodes per week: 6.5 (range 4–25 episodes); days of FI per week: 4 (range 4–7 days); number of stools per 24 h: 8 (range 5–12 stools); number of episodes of urgency per week: 10 (range 1–24 episodes); and Wexner score: 14.5 (range 13–15). Results of the SF-36 and FIQL scale prior to implantation (T0) are reported in Figs. 1 and 2.

Test stimulation

Three patients received left S3 sacral root stimulation, and one received stimulation to the left S4 sacral root. All patients required antidiarrheal treatment during the follow-up.

Assessment at day 20 after test stimulation

One patient (N4) had no improvement of FI at the 20 day assessment; however, the patient's stool frequency per day decreased from 4.7 to 4.3 and the episodes of urgency from 24 to 17.5. She was treated with adalimumab and methotrexate for existing Crohn's disease. To date, she has reported no Crohn's flare and has reported a slight improvement in the number of FI episodes per week (decreased from 25 to 21), but SNS was considered to have failed in this case, and the electrode was removed. The remaining 3 patients (N1, N2, N3) had a >50 % reduction in the number of FI episodes per week and were offered the implantation of a permanent neurostimulation device.

Assessment at 1 month after SNS (T1)

At 1 month, 3 out of 4 patients were offered a permanent neurostimulation device and were assessed at 1 month after permanent implantation. These 3 patients (N1, N2, N3) were noted to have a decrease in the median number of FI episodes per week, down from 4 (range 4–9 episodes) to 1.1 (range 0–4). Patients also experienced a decrease in the median frequency of stools, from 8 (range 7–12 stools) to 5.5 (range 4.5–6.6 stools), as well as a decrease in the median number of episodes of urgency per week. Patients experienced an increase in their ability to defer defecation from 6 min (range 1–7.5 min) to 24 min (range 17–30 min) and improved median Wexner scores. The patient who underwent total coloproctectomy with IAA for familial adenomatous polyposis (N2) reported perfect fecal continence.

Assessment at 3 (T2) and 6 (T3) months after SNS

Functional results for FI episodes, urgencies per week, frequency of stools, ability to defer defecation, and Wexner scores were improved. Functional results before and after SNS are reported in Table 1. All patients' FIQL and SF-36 scales were improved following SNS (Fig. 1) with the 6-month follow-up.

Morbidity and mortality after SNS

There was no postoperative mortality. During the test period, 2 patients experienced pain in the lower limb, and one experienced pelvic heaviness. All these symptoms disappeared after revision of the pulse generator. One

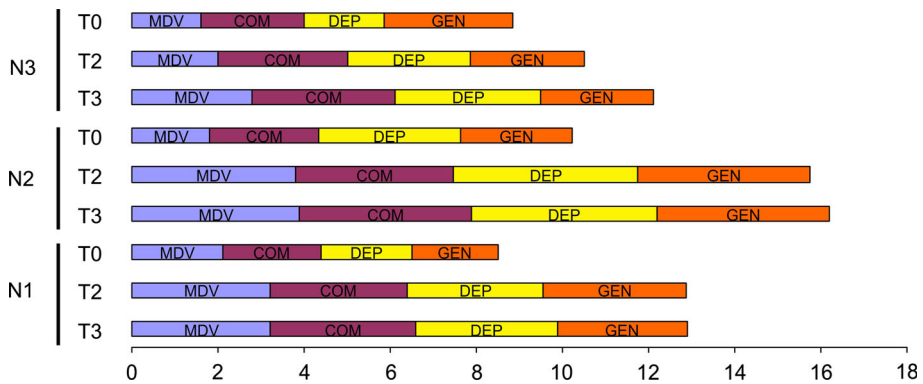

Fig. 1 Quality-of-life assessment (FIQL) before SNS (T0), and at 3 (T2) and 6 (T3) months after SNS for patients N1, N2, N3. *MDV* lifestyle, *COM* coping/behavior, *DEP* depression/self-perception, *GEN* embarrassment with others

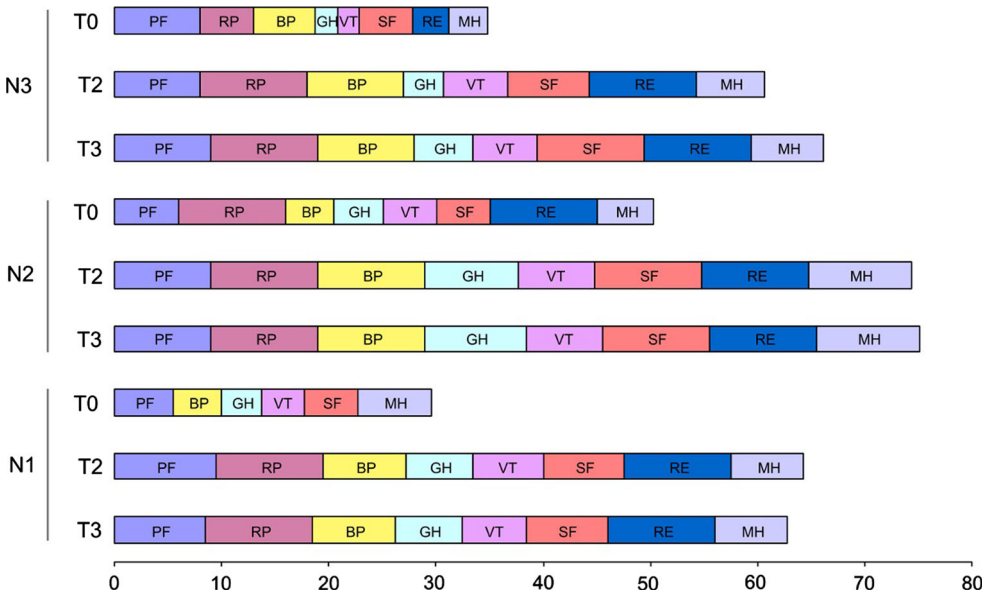

Fig. 2 Quality-of-life assessment (SF-36) before SNS (T0), and at 3 (T2) and 6 (T3) months after SNS for patients N1, N2, N3. *PF* physical functioning, *RP* role physical, *BP* body pain, *GH* general health, *VT* vitality, *RE* role emotional, *SF* social functioning, *MH* mental health

Table 1 Functional results at baseline (T0), 1 month (T1), 3 months (T2), and 6 months (T3) after SNS for the 3 patients (N1, N2, N3)

	N1				N2				N3			
	T0	T1	T2	T3	T0	T1	T2	T3	T0	T1	T2	T3
FI episode/week	9	4	3.5	1.5	4	0	0	0	4	1.1	2.3	0.5
Episodes of urgency/week	10	1.8	0	0	1	0.7	0	0	x	x	x	0
Frequency of stools/24 h	8.1	6.6	6	6	7.3	4.5	4	4	12.4	5.5	5.2	5
Ability to defer defecation (minutes)	7.5	17.5	120	120	5	30	45	60	x	x	x	x
Wexner score	15	9	8	7	14	0	0	0	15	12	14	10

X missing data (not completed by the patient)

SNS sacral nerve stimulation

patient accidentally severed the percutaneous extension 5 days before definitive implantation; however, the position of the electrode had remained unchanged, and the definitive implantation was achieved on time. Prior to definitive implantation, external test stimulators required an average of one reprogramming in 3 of the patients. No additional complications occurred during follow-up.

Maintenance of medical treatment post-SNS

Only one patient (N2) reported perfect continence 1 month after SNS and was able to completely stop antidiarrheal treatments during the 6-month follow-up. The remaining 2 required continued treatment with loperamide and codeine phosphate but not as frequently as prior to SNS.

Discussion

To the best of our knowledge, this is the first prospective study showing effectiveness of SNS for poor functional results of IAA. For 75 % of our patients, weekly FI episodes decreased by more than 50 %. Moreover, urgency, ability to defer defecation, and frequency of stools also improved. The positive effect of SNS remained at 6 months after SNS. Furthermore, the use of SNS in this study has resulted in a frequency of stools compatible with that reported in the literature for IAA (5–7 per day) [20].

All implanted patients experienced improvement in quality of life as measured by SF-36 and FIQL. Such improvement in quality of life following SNS has been previously reported for FI [21] but never in the case of IAA.

Since its introduction in 1978, the IAA procedure has repeatedly undergone improvements in technique. Despite these improvements and continued developments in surgical technique and perioperative care, the functional outcome has not significantly changed. In a recently published meta-analysis, mean 24-hour defecation frequency was 5.9 with a mean nighttime frequency of 1.5. The incidence of mild and severe FI during the day was 14.3 and 6.1 %, respectively [20].

Two studies have previously shown an improvement in compliance with the neorectum in terms of sensitivity, urgency, and maximum tolerable volume following SNS in 10 patients with FI after resection for cancer [15, 22]. Causes and effects of bowel dysfunction following low anterior rectal resection have been well described in a recent review [23]. Functional symptoms collectively falling under the heading of low anterior resection syndrome are due to diverse mechanisms including damage of the anal sphincter, level of the anastomosis, neorectal compliance, disturbance of the rectoanal inhibitory reflex, anastomotic ischemia, and stretching of the neorectal mesentery. However, the most obvious mechanism potentially responsible for cases of low anterior resection syndrome which present with FI is a mechanical tear of the sphincter muscle [23]. It is likely that SNS improves external and internal sphincter function [9–11, 24], which contributes to its favorable results in patients with these indications. SNS has been associated with a low morbidity which was also found in the present study. Moreover, a recent consensus statement from 26 Italian colorectal surgeons with a large experience in SNS reported a 96 % agreement about dysfunction after rectal surgery as an indication for SNS [25]. Our study confirms the feasibility of SNS for patients with J-pouch–anal anastomosis, as the J-pouch was never injured by the transsacral electrode in any of our patients.

The importance of the anal transition zone in maintenance of continence, preservation of the anorectal sampling reflex, and controlling the urge to defecate is well described [26]. In our series, all patients underwent handsewn IAA with complete transanal rectal mucosectomy, and the effectiveness of SNS in these cases was not compromised by the absence of the anal transition zone. The role of preservation of the anal transition zone and avoidance of rectal mucosectomy in FI and sampling reflex function remains to be a topic of debate. Some of the earlier series suggested that mucosectomy was associated with at least a temporary increase in nocturnal incontinence and urgency [27, 28]. A recent meta-analysis, however, found no differences in functional outcome between studies on performing handsewn (with complete mucosectomy) or stapled (with preservation of the anal transition zone) anastomoses [20]. Our experience with SNS in patients with stapled anastomosis is limited to one patient who underwent total proctectomy and CAA for cancer (data not shown). In this case, SNS was also found to be effective in controlling FI and urgency at 6-month follow-up.

Based on our encouraging results, we advocate that the previously narrow criteria for SNS treatment should be expanded to include the indications of dysfunctional IAA. When faced with poor functional outcome following IAA (with or without mucosectomy), the first step is to rule out pouchitis, anastomotic stenosis, and pelvic sepsis. In absence of such complications, a trial of SNS seems to be justified.

Limitations

Our study is limited by a small sample size and short follow-up period. Several recent studies demonstrate that SNS provides a significant sustained long-term improvement in FI symptoms [7, 8], while others have reported a loss of long-term efficacy in 15–30 % of cases [24, 26]. In addition, the absence of physiological examination (e.g., anorectal manometry, electromyography, or endoanal ultrasound) prevented us from determining the mechanisms of action of SNS in these indications.

Conclusions

Based on our findings, SNS seems to be effective for the treatment of poor functional results after IAA. Additional studies on larger numbers of patients, and including long-term follow-up, are necessary to confirm these preliminary results. Functional exploration could lead to a better understanding of the mechanism of action of SNS for these indications.

Conflict of interest None.

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