

Long-term outcomes of sacral neuromodulation for anorectal disorders: a retrospective single- center cohort study

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Research Article

Keywords: Sacral neuromodulation, anorectal disorders, fecal incontinence, low anterior resection syndrome, constipation, long-term outcomes

Posted Date: October 14th, 2026

DOI: <https://doi.org/10.21203/rs.3.rs-11210255/v1>

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Additional Declarations: No competing interests reported.

Abstract

Background

Sacral neuromodulation (SNM) is an established treatment for fecal incontinence (FI), but its long-term outcomes in other anorectal disorders remain less well defined. This study aimed to assess the long-term outcomes and morbidity of SNM in patients treated for FI, low anterior resection syndrome (LARS), or refractory constipation.

Methods

We conducted a retrospective single-center cohort study of consecutive patients who underwent SNM between December 2002 and April 2026. The primary outcome was long-term treatment success, defined as continued SNM therapy without explantation because of inadequate efficacy at last available follow-up. Secondary outcomes included postoperative complications and factors associated with treatment failure.

Results

Ninety-five patients underwent SNM testing, of whom 91 (95.8%) underwent definitive implantation. Most patients were women (85.3%), and FI was the main indication (87.1%). Median follow-up was 7.6 years. Overall, 71 patients (74.7% of the total tested cohort) achieved long-term treatment success. Among patients with FI, the median baseline Cleveland Clinic Incontinence Score was 14.5, compared with 9.6 during follow-up. Postoperative complications occurred in 18 patients (18.9%), including eight surgical-site infections and eight mechanical complications. In exploratory univariable analysis, treatment indication was associated with treatment failure ($p = 0.048$).

Conclusion

SNM was associated with sustained treatment in a substantial proportion of patients over long-term follow-up, particularly those treated for FI. The small numbers of patients treated for LARS and refractory constipation limit conclusions regarding these indications. Larger prospective studies with standardized outcome definitions and structured long-term follow-up are warranted.

INTRODUCTION

Sacral neuromodulation (SNM) is a surgical technique that has been used in urology since the late 1980s for the treatment of urinary incontinence[1, 2]. The use of this technique in fecal incontinence (FI) was described by Matzel in 1995[3]. The goal is to increase the sphincter tone to restore anal canal closing and thereby reduce symptoms of FI.

FI is a disabling condition that has a significant impact on patients. According to the Rome IV criteria, FI is defined by the involuntary loss of stool and gas occurring for at least 3 months[4]. FI affects

approximately 8% of the general population and up to 47% of individuals living in long-term care facilities[5, 6]. Several risk factors have been identified in the literature, including older age, urinary incontinence, a history of obstetric trauma, and certain neurological disorders[7, 8]. FI significantly impairs patients' quality of life, leading to anticipatory behaviors, psychological distress, and even depressive episodes[9–11].

SNM is a minimally invasive surgical technique used as a second-line treatment for fecal incontinence[12, 13]. Despite conclusive results, the mechanisms of action of SNM remain only partially understood, and numerous hypotheses have been proposed[2]. SNM is thought to modulate sacral neural pathways involved in anorectal sensory and motor functions.

Following its initial use for FI, the application of SNM was expanded to other anorectal conditions such as Low Anterior Resection Syndrome (LARS), refractory constipation, and chronic pelvic pain[14–17]. All of these conditions require long-term management. Several studies have investigated the long-term outcomes of SNM for fecal incontinence, however, only one study has evaluated long-term outcomes across the various anorectal indications[18].

Here, we present a retrospective single-center cohort study designed to assess the long-term outcomes and morbidity of SNM in patients treated for FI, low anterior resection syndrome (LARS), or refractory constipation.

METHODS

Population

This retrospective observational study was conducted in the Department of General and Digestive Surgery at H  te-pierre Hospital, Strasbourg University Hospitals, between December 2002 and April 2026. Medical data were collected after obtaining informed patient consent and approval from the local ethics committee.

This study included patients who underwent implantation of a SNM device (Medtronic® InterStim™) for the treatment of FI, LARS syndrome, or refractory constipation. Patients were identified through electronic medical records. For all patients, the indication for SNM was validated during a multidisciplinary team (MDT) meeting.

Surgical technique

After the indication has been systematically validated during a MDT meeting, sacral neuromodulation is performed in two surgical stages. The first stage is a test phase, during which a neurostimulation electrode is implanted to stimulate the S3 or S4 sacral roots. During the test phase, a neurostimulation electrode is implanted and connected to an external stimulator, while symptoms of FI, LARS, or

constipation are monitored. The test phase is considered successful when symptoms improve by more than 50%. If the trial is successful, a permanent neurostimulator is implanted. Otherwise, the electrode is removed.

Data collected

The variables analyzed included clinical characteristics (age, sex, body mass index [BMI], medical and surgical history), laboratory and diagnostic test results (electroneuromyography [ENMG], anorectal manometry), and treatment-related variables (pelvic floor physical therapy, indication, success of the trial phase, and number of SNM device replacements).

Fecal incontinence was assessed using the Cleveland Clinic Incontinence Score (CCIS), also known as the Wexner score. This score assesses the severity of incontinence on a scale from 0 to 20 across five items: incontinence of solid stool, liquid stool, and gas; the use of protective pads; and lifestyle alteration. FI is considered mild from 0 to 4, moderate from 5 to 9, moderate to severe from 10 to 16, and severe above 17[19]. Constipation was defined according to the Rome IV criteria[20].

Objectives

The primary outcome was the long-term success of sacral neuromodulation, defined as the absence of device explantation due to treatment ineffectiveness, with continued therapy and follow-up. The secondary outcomes were the complication rate, assessed according to the Clavien–Dindo classifications[21] and the identification of risk factors for treatment failure.

Statistical analysis

Statistical analyses were performed using R software (version 4.5.2), RStudio (version 2025.09), and the following packages: readxl, dplyr, tidyr, forcats, gtsummary, flextable, officer, nortest, and rstatix. A p-value < 0.05 was considered statistically significant. Categorical variables are presented as counts and percentages, whereas continuous variables are presented as either the median [interquartile range (IQR), Q1–Q3] or the mean ± standard deviation, depending on their distribution. Statistical tests were selected based on the conditions of application. Categorical variables: Chi-square test if the expected frequencies are ≥ 5 in all cells; otherwise, Fisher's exact test was used. Continuous variables: Student's t-test (equal variances, based on Levene's test, $p \geq 0.05$) or Welch's t-test (for unequal variances) when data were normally distributed in each group; otherwise, the Mann–Whitney U test was used. The percentages shown in each row (Neuromodulation Success / Failure) represent the distribution within each modality.

RESULTS

Patient characteristics

Between December 2002 and April 2026, 95 patients underwent surgery for SNM implantation (Fig. 1). The majority were women (85.3%) (Table 1). The median age was 56 years (IQR, 47.0–66.0 years). The median body mass index was 26.0 kg/m², and more than half of the patients were overweight or obese. Nearly three quarters of the women had a history of vaginal delivery, and 10 patients had a history of obstetric anal sphincter injury (OASI). Twenty-seven patients had a history of surgery for a pelvic floor disorder, and 21 had a history of proctological surgery. One in five patients had a history of depression.

FI accounted for the vast majority of SNM indications (87.1%). LARS syndrome and constipation each accounted for 6.5% of cases. Urinary incontinence was present in 32.1% of patients. The median baseline CCIS score was 14.5. Nearly one in five patients had severe incontinence, with a CCIS score > 17, while 71.7% had significant incontinence, with a CCIS score between 10 and 16.

Half of patients (56.8%) underwent perineal rehabilitation as a first-line treatment. During the preoperative evaluation, anorectal manometry was performed in 65.3% of patients, ENMG was performed in 22.1% (Table 2).

Table 1
Overall population characteristics

Variable	N (%) ¹
Sexe	
Female	81 (85.3%)
Age at implantation (years)	56 [47 ; 66]
BMI – class	
Underweight (< 18,5)	1 (1.1%)
Normal weight (18,5–25)	35 (40.2%)
Overweight (25–30)	29 (33.3%)
Obesity (> 30)	22 (25.3%)
BMI (kg/m²)	26.0 [22.6, 30.0]
Diabetes	7 (7.4%)
Insulin-dependent diabetes	2 (33.3%)
Medical history	
Obstetric history	57 (60.0%)
Vaginal delivery	45 (47,3%)
OASI	10 (10.5%)
Pelvic floor surgery	27 (28.4%)
Proctologic surgery	21 (22.1%)
Depression	18 (18.9%)
Associated urinary incontinence	26 (27.4%)
SNM indication	
Fecal incontinence	81 (87.1%)
LARS syndrom	6 (6.5%)
Constipation	6 (6.5%)
Baseline CCIS score	14.5 (3.0)
Baseline CCIS score – grade	
BMI : body mass index ; CCIS : Cleveland clinic incontinence score ; LARS : low anterior resection syndrom ; OASI : obstetric anal sphincter injury ; SNM : sacral neuromodulation	

Variable	N (%) ¹
Sexe	
Mild (0–4)	0 (0.0%)
Moderate (5–9)	2 (4.3%)
High (10–16)	33 (71.7%)
Severe (≥ 17)	11 (23.9%)
¹ n (%); Median [Q1, Q3]; Mean (SD)	
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BMI : body mass index ; CCIS : Cleveland clinic incontinence score ; LARS : low anterior resection syndrom ; OASI : obstetric anal sphincter injury ; SNM : sacral neuromodulation	

Table 2
Preoperative assessment

Variable	N (%) ¹
Pelvic floor physiotherapy	54 (56.8%)
ENMG	21 (22.1%)
Anorectal manometry	62 (65.3%)
¹ n (%); Median [Q1, Q3]; Mean (SD)	
normnormalnormalité	
ENMG : electroneuromyography	

Long-term outcomes

The neuromodulation test phase was successful in the majority of patients (95.8%) (Table 3). Seventy-one patients (74.7%) achieved successful neuromodulation outcomes during follow-up. The median CCIS score during follow-up was 9.6. However, eight patients had a CCIS score between 10 and 16. The median follow-up duration was 7.6 years, 17 patients (18.1%) were lost to follow-up. Of these patients, five died. No deaths were related to SNM. During follow-up, 35.1% of patients required at least one device replacement due to battery depletion, while 42.6% had not yet required replacement. One patient, who received the implant in 2002, underwent 5 neuromodulation device replacements.

Table 3
Sacral Neuromodulation results

Variable	N (%) ¹
Successful test phase	91 (95.8%)
SNM device replacement (number)	
0	42 (44.6%)
1	33 (35.1%)
2	12 (12.8%)
3	3 (3.2%)
4	3 (3.2%)
5	1 (1.1%)
CCIS score at follow-up	9.6 (5.0)
Mild (0–4)	3 (16.7%)
Moderate (5–9)	6 (33.3%)
High (10–16)	8 (44.4%)
Severe (≥ 17)	1 (5.6%)
Données manquantes	77
Follow-up duration (years)	7.6 [3.8, 11.2]
Overall success of SNM	
Yes	71 (74.7%)
No	24 (25.3%)
Postoperative complications	18 (18.9%)
Surgical Site Infection (SSI)	8 (47.1%)
Others	9 (52.9%)
Complications grade (Clavien-Dindo)	
II	1 (1,1%)
IIIb	17 (17.9%)
Lost to follow-up	17 (17.9%)
CCIS: Cleveland clinic incontinence score; SNM: sacral neuromodulation; SSI: surgical site infection	

Variable	N (%) ¹
¹ n (%); Median [Q1, Q3]; Mean (SD)	
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CCIS: Cleveland clinic incontinence score; SNM: sacral neuromodulation; SSI: surgical site infection	

Complications

Postoperative complications occurred in 18.9% of patients (n = 18). Of these, 94.4% (n = 17) were classified as Clavien–Dindo grade IIIb. There were 8 cases of surgical site infection (SSI) and 8 cases of electrode dislodgements, including a severed connector cable and accidental removal of the external electrode. One patient experienced pain, and another developed a skin allergy to the dressing. Seven complications occurred during the test phase.

Factors associated with failure

Univariate analysis of factors associated with SNM failure indicated that the indication for SNM was significantly associated with failure (p = 0.048) (Table 4). Among patients with FI, 18 (22.2%) were classified as failures, compared with 2 (33.3%) among those with LARS and 4 (66.7%) among those with constipation. Neither obstetric or surgical history nor the initial CCIS score was significantly associated with treatment failure. The occurrence of a postoperative complication was not associated with secondary SNM failure (55.6% vs. 44.4%; p = 0.067). The number of implants per patient was also associated with a trend toward a higher failure rate when there had been no or only one device replacement (p = 0.051).

Table 4
Factors Associated with Sacral Neuromodulation Failure

Variable	Total N = 95 ¹	Success N = 71 (74.5%) ¹	Failure N = 24 (24.5%) ¹	p-value
Sexe				0.746
Female	81 (100.0%)	61 (75.3%)	20 (24.7%)	
Male	14 (100.0%)	10 (71.4%)	4 (28.6%)	
BMI (kg/m²)	26.0 [22.6, 30.0]	25.9 [22.6, 30.0]	26.5 [23.6, 29.7]	0.625
Diabetes	7 (100.0%)	7 (100.0%)	0 (0.0%)	0.186
Obstetric history	57 (100.0%)	44 (77.2%)	13 (22.8%)	> 0.999
Vaginal delivery	45 (100.0%)	35 (77.8%)	10 (22.2%)	0.714
OASI	10 (100.0%)	8 (80.0%)	2 (20.0%)	> 0.999
Pelvic floor surgery	27 (100.0%)	19 (70.4%)	8 (29.6%)	0.500
Proctologic surgery	21 (100.0%)	13 (61.9%)	8 (38.1%)	0.112
Depression	18 (100.0%)	11 (61.1%)	7 (38.9%)	0.221
Indication				0.048
Fecal incontinence	81 (100.0%)	63 (77.8%)	18 (22.2%)	
LARS	6 (100.0%)	4 (66.7%)	2 (33.3%)	
Constipation	6 (100.0%)	2 (33.3%)	4 (66.7%)	
Associated urinary incontinence	26 (100.0%)	19 (73.1%)	7 (26.9%)	0.749
Baseline CCIS	14.5 (3.0)	14.9 (3.3)	13.4 (1.8)	0.183
Pelvic floor physiotherapy	54 (100.0%)	42 (77.8%)	12 (22.2%)	0.243
SNM device replacement				0.051
0	40 (100.0%)	25 (62.5%)	15 (37.5%)	
1	33 (100.0%)	28 (84.8%)	5 (15.2%)	
2	12 (100.0%)	8 (66.7%)	4 (33.3%)	
3	3 (100.0%)	3 (100.0%)	0 (0.0%)	
BMI : body mass index ; CCI : Cleveland clinic incontinence score ; LARS : low anterior resection syndrom ; OASI : obstetric anal sphincter injury ; SNM : sacral neuromodulation				

Variable	Total N = 95 ¹	Success N = 71 (74.5%) ¹	Failure N = 24 (24.5%) ¹	p-value
4	3 (100.0%)	3 (100.0%)	0 (0.0%)	
5	1 (100.0%)	1 (100.0%)	0 (0.0%)	
CCIS score at follow-up	9.6 (5.0)	9.1 (4.6)	19.0 (NA)	0.120
Follow-up duration (years)	7.6 [3.8, 11.2]	8.0 [3.8, 11.5]	6.2 [3.7, 8.9]	0.225
Post-operative complications	18 (100.0%)	10 (55.6%)	8 (44.4%)	0.067
¹ n (%); Median [Q1, Q3]; Mean (SD)				
BMI : body mass index ; CCI : Cleveland clinic incontinence score ; LARS : low anterior resection syndrom ; OASI : obstetric anal sphincter injury ; SNM : sacral neuromodulation				

DISCUSSION

Analysis of this single-center retrospective cohort demonstrates that sacral neuromodulation was a viable surgical treatment, with a long-term success rate of 74.7%. The median follow-up duration was 7.6 years, although nearly one in five patients is considered lost to follow-up by 2026. In our series, 24.5% of patients were considered to have experienced treatment failure, including primary failures during the trial phase and secondary failures observed during follow-up. In the univariate analysis, the indication for SNM was significantly associated with treatment failure ($p = 0.048$), whereas complications occurring during the trial phase were associated with a trend toward a higher failure rate ($p = 0.067$).

Long-term assessment of SNM is important, and the number of patients lost to follow-up may pose a challenge when evaluating this functional disorder. Despite the long follow-up period, this series includes a number of patients who were lost to follow-up. These patients had predominantly received their implants before 2015, more than 10 years prior to the end of the study period. Of the patients who were lost to follow-up, five had died. Matzel et al. demonstrated, in a small series, the sustained efficacy of SNM for the long-term treatment of FI[22]. In the series reported by Altomare et al., the long-term success rate of SNM for the management of FI, based on the per-protocol analysis, was 71.3% after at least 5 years of follow-up[23]. However, some series have reported a 5-year success rate up to 89%, defined as a sustained $\geq 50\%$ improvement in FI symptoms compared with baseline[24].

Since then, the indications for SNM have evolved, and FI is no longer its sole indication. The French cohort reported by Duchalais et al. evaluated SNM across its various anorectal indications[18]. The authors demonstrated that the long-term outcomes of SNM for FI remained stable over time. However, the results for the other indications were less conclusive. In our series, the findings regarding LARS syndrome are limited by the small sample size. The literature supports the role of SNM in this indication.

As suggested by some authors, the role of SNM in the treatment of transit constipation remains to be established[25, 26].

In the Dutch series by Govaert et al.[27], the presence of an external anal sphincter defect was also identified as a risk factor for SNM failure. In our series, we were unable to demonstrate an association between medical history, particularly obstetric history, and treatment failure. This may be related to a lack of statistical power. In the literature, few predictors of success have been identified beyond technical factors, such as electrode type[28, 29].

The complication rate was 18.9%, the majority of these complications required surgery (Clavien-Dindo IIIb). Half of these complications (8 patients ; 8.4%) involved a mechanical etiology, resulting either from electrode displacement during follow-up (n = 6), confirmed by X-ray, or from accidental severing or detachment of the external connector during the testing phase (n = 2). In addition, 8 patients (8.4%) experienced a surgical site infection (SSI) requiring device removal. Among these patients, 6 were able to undergo reimplantation after resolution of the septic episode. Half of these complications occurred during the trial phase. The SSI rate was comparable to that reported in the literature[30, 31]. The majority of complications were classified as Clavien–Dindo grade IIIb because they required removal of the SNM device. In the long-term results reported by Matzel[22], 25% of patients required device removal because of pain or neurological disease.

The strengths of this study include the systematic validation of SNM indications by a multidisciplinary team (MDT), as well as long-term clinical follow-up conducted by the same practitioners using consistent clinical practices. Despite the long-term follow-up, this single-center cohort study is limited by its retrospective design and the resulting lack of statistical power. Furthermore, the lack of standardization in the definition of neuromodulation failure makes comparisons with other series difficult. Typically, failure of sacral neuromodulation during the trial phase is defined as a < 50% improvement in symptoms over a trial period of 14–21 days. During follow-up, however, the definition of secondary failure is more variable. We defined secondary failure as either removal of the neuromodulation device because of inadequate functional outcomes or failure to replace the device after battery depletion. In Jarrett’s literature review[32], the reported rate of secondary failure following sacral neuromodulation ranged from 4.4% to 21%. Assessing the effectiveness of SNM in anorectal conditions was also a significant limitation, as patients may have difficulty describing their symptoms, and symptom perception may vary between individuals. Moreover, long-term follow-up may introduce temporal bias due to changes in clinical practices and/or devices over time. Some cases of secondary failure may be related to a placebo effect during the test phase, which may have led to SNM implantation[24, 29].

CONCLUSION

In this single-center retrospective cohort, sacral neuromodulation was associated with sustained treatment in a substantial proportion of patients during long-term follow-up, with the greatest body of

evidence supporting its use for fecal incontinence. The overall morbidity rate was 18.9%, and most complications required surgical management. The small number of patients treated for LARS and refractory constipation limits the interpretation of outcomes for these indications. Prospective multicenter studies using standardized definitions of treatment success and failure, validated functional and quality-of-life outcomes, and structured long-term follow-up are needed to better define the role of SNM across anorectal disorders.

Declarations

No grant support

Ethical requirements: Informed consent was obtained from all individual participants included in the study

None of the authors declare any conflict of interest

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

FUNDING

No funding was received for this study.

Author Contribution

D.L. and B.R. conceived the presented idea and designed the study. D.L., B.R., and F.S. validated the analytical methods and supervised the data collection. D.L. wrote the manuscript, with critical feedback and support from B.R. and F.S. All authors discussed the results and approved the final version of the manuscript.

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Figures

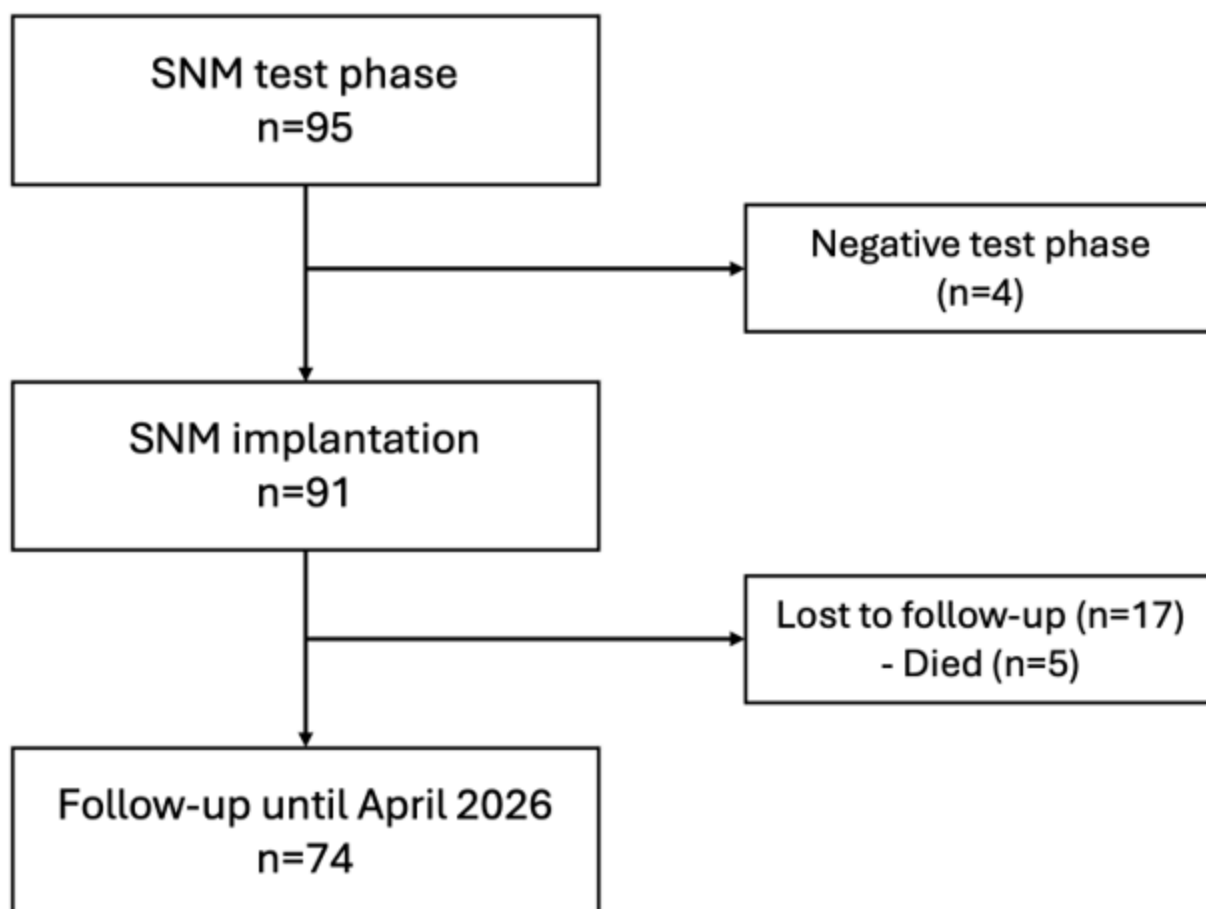


Figure 1

Sacral neuromodulation (SNM) flow-chart

