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Sacral Nerve Stimulation for Refractory Bowel Dysfunction: A Prospective pilot Study with 24-Month Follow-Up

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Abstract

Background: Sacral Nerve Stimulation (SNS) has been explored as a neuromodulatory therapy for refractory bowel dysfunction; however, evidence remains heterogeneous, particularly in constipation and functional bowel disorders.

Objective: To evaluate the feasibility, safety, and exploratory clinical outcomes of SNS in patients with refractory bowel dysfunction over 24 months.

Methods: This prospective single-centre interventional study included 35 patients with refractory bowel dysfunction (chronic constipation: n=17; IBS: n=18). Primary exploratory outcomes included bowel movement duration (constipation) and Bowel Frequency (IBS). Pre- and post-intervention outcomes were compared using paired statistical analysis.

Results: SNS therapy was associated with consistent directional improvement across all patients. In constipation, mean bowel movement duration decreased substantially (mean reduction up to ~102 minutes), although statistical significance was not reached (p=0.0806). In IBS, bowel frequency decreased toward physiological ranges (p=0.0773). No major device-related adverse events were observed.

Conclusion: SNS demonstrated clinically meaningful but statistically non-significant improvements in this small prospective cohort. These findings support the feasibility and potential therapeutic role of SNS but require confirmation in larger, controlled trials with standardized outcome measures.

Introduction

Bowel dysfunction encompasses a broad spectrum of chronic gastrointestinal disorders characterized by impaired bowel motility, abnormal defecatory coordination, and dysregulated visceral sensation. Among these, chronic constipation and Irritable Bowel Syndrome (IBS) are particularly prevalent and debilitating, exerting a profound impact on patients' physical, psychological, and social well-being. Epidemiological studies suggest that chronic constipation affects up to 15% of the adult

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population, while IBS prevalence ranges between 10–20% globally, with substantial overlap between symptom domains [1,2].

Chronic constipation is a multifactorial condition involving delayed colonic transit, pelvic floor dyssynergia, impaired rectal sensation, and autonomic dysfunction. Patients frequently report excessive straining, prolonged defecation time, incomplete evacuation, and reduced bowel frequency. IBS, particularly diarrhea-predominant and mixed subtypes, is characterized by increased bowel frequency, urgency, abdominal pain, and visceral hypersensitivity, with growing evidence implicating altered gut–brain communication and dysregulated autonomic control [3-5].

Despite the availability of numerous pharmacological agents-including laxatives, prokinetics, antidiarrheals, and neuromodulators—long-term efficacy remains limited for a significant subset of patients. Behavioral therapies such as biofeedback may be beneficial but are resource-intensive and not universally effective. Surgical interventions are reserved for extreme cases and are associated with substantial morbidity and irreversible anatomical changes [6,7]. Consequently, there is increasing interest in neuromodulation-based therapies that address the underlying neural mechanisms of bowel dysfunction.

Sacral Nerve Stimulation (SNS) is an implantable neuromodulation technique that delivers electrical stimulation to the sacral nerve roots (S2–S4), which play a central role in regulating colonic motility, anorectal reflexes, pelvic floor coordination, and visceral sensory processing. SNS was initially developed for refractory urinary disorders, where its safety and efficacy are well established. Over the past two decades, its application has expanded to include fecal incontinence and, more recently, other forms of bowel dysfunction [8-10].

The therapeutic rationale for SNS lies in its ability to modulate both afferent and efferent neural pathways at the sacral spinal level, influencing enteric nervous system activity and higher autonomic centres. Experimental studies suggest that SNS enhances colonic propagating motor complexes, improves rectal compliance, normalizes anorectal reflexes, and attenuates visceral hypersensitivity [11-13]. Importantly, SNS appears to induce long-term neuroplastic changes, offering sustained symptom relief beyond the stimulation period.

However, existing clinical studies are heterogeneous, often limited by short follow-up durations, small sample sizes, or narrow outcome measures. Long-term real-world data examining functional bowel outcomes across different bowel dysfunction phenotypes remain limited.

The present study prospectively evaluates the long-term effects of SNS in patients with refractory bowel dysfunction over a 24-month period. By stratifying patients into chronic constipation and IBS groups and employing objective, clinically meaningful outcome measures, this study aims to provide robust evidence supporting the clinical utility and suitability of SNS as a neuromodulatory therapy for bowel dysfunction.

Materials and methods

Study design

This was a prospective, multi-centres pilot study conducted over a period of 24 months.

Study population

A total of 35 adult patients diagnosed with refractory bowel dysfunction were enrolled (Table 1). All patients had failed conventional medical, dietary, and behavioural therapies prior to inclusion.

Patients were categorized into:

- Group A: Chronic constipation syndrome (n=17)
- Group B: IBS (n=18)

Subgroup classification

Group A (Chronic constipation): Participants in Group A were stratified into 3 subgroups according to bowel movement timeframes. Subgroup allocation was determined by the time required to complete bowel evacuation with each subgroup reflecting a different duration of bowel movement.

- Subgroup A1 (n = 6, female-3, male-3) (Bowel Movement time 140 – 150 min/day)
- Subgroup A2 (n = 6, female-3, male-3) (Bowel movement time 75 – 85 min/day)
- Subgroup A3 (n = 5, female-2, male-3) (Bowel movement time 60 – 70 min/day)

Group B (IBS): Participants in Group B were stratified into 2 subgroups according to bowel movement frequency. Subgroup allocation was determined by the time required to complete bowel evacuation with each subgroup reflecting a different duration of bowel frequencies.

- Subgroup B1 (n = 8, female-3, male-5) (Bowel movement frequency 12-15 times/day)
- Subgroup B2 (n = 10, female-2, male-8) (Bowel movement frequency 09-10 times/day)

Table 1: Demonstrating patients´ demographic details.

Groups		Participants (Total 35)		Age	
Sub Groups		Male	Female	Male	Female
A1		3	3	P1- 17	P4- 34
				P2- 19	P5- 57
				P3- 18	P6- 35
A2		3	3	P7- 21	P10- 19
				P8- 34	P11- 57
				P9- 64	P12- 29
A3		2	3	P13- 26	P15- 30
		Total No- 17		P14- 45	P16- 60
					P17- 49
	B1	3	5	P18- 13	P21- 22
				P19- 44	P22- 64
				P20- 41	P23- 28
					P24- 39
					P25- 20
	B2	2	8	P26- 26	P28- 49
				P27- 27	P29- 53
					P30- 55
					P31- 75
					P32- 68
					P33- 59
					P34- 64
					P35- 58
		Total No-18			

Intervention

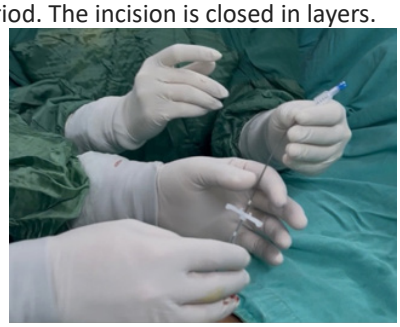
SNS was performed using a standardized two-stage approach by N.H and U.J. Patient selection and follow up were conducted by a multidisciplinary team including neuromodulation specialists and collaborating physicians.

During the first stage, a temporary quadripolar electrode was implanted under fluoroscopic guidance at the S3 sacral foramen, confirmed by appropriate motor and sensory responses. Patients demonstrating clinically meaningful improvement in voiding parameters during the trial period proceeded to permanent implantation of an implantable pulse generator.

Stage I: Test stimulation (lead placement): Under fluoroscopic guidance, a foramen needle is inserted into the S3 sacral foramen. Correct needle placement is confirmed by both fluoroscopic imaging and physiological responses to electrical stimulation. Desired motor responses include bellows contraction of the pelvic floor, plantar flexion of the great toe, and anal sphincter contraction, while sensory responses are reported in the perineal or vaginal/rectal region.

Once appropriate positioning is confirmed, a quadripolar tined lead is introduced through the needle and positioned adjacent to the sacral nerve root. The lead is tested intraoperatively to ensure optimal stimulation thresholds and appropriate responses across multiple electrode configurations.

The lead is then secured in place using its self-anchoring tines. The proximal end of the lead is tunneled subcutaneously and connected to an external pulse generator for the trial stimulation period. The incision is closed in layers.



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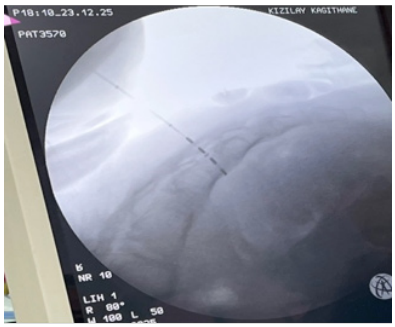

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Figure 1: (A) Illustrates the quadripolar tined lead is introduced through the needle and positioned adjacent to the sacral nerve root and **(B)** Illustrates the final lead placement under fluroscopy guidance.

Stage II: Permanent implantation: Patients demonstrating a successful response during the test phase proceed to permanent implantation. Under local or general anesthesia, the previously placed lead is connected to a permanent İmplantable Pulse Generator (IPG). A subcutaneous pocket is created, most commonly in the upper gluteal region, to accomodate the IPG. The lead extension is tunneled to the pocket and securely connected to the IPG. Device integrity and stimulation parameters are verified intraoperatively. The IPG is programmed using an external programmer, and optimal stimulation parameters are selected based on patient comfort and therapeutic response. The surgical wounds are closed in layers, and sterile dressings are applied.

Postoperative management and programming: Patients are monitored regularly, and stimulation parameters such as amplitude, pulse width, and frequency are individualized based on clinical response. Long-term follow-up includes symptom assessment, voiding diaries, and device checks. Stimulation parameters are individually optimized post-implantation: Frequency: 10–20 Hz, Pulse Width: ~210-260 microseconds, Amplitude: 1.5-8.0 mA. In some patients we used cycling programming methods too.

Outcome measures

- Group A: Time required to complete bowel movement (minutes)
- Group B: Frequency of bowel movements per day

Assessments were performed at baseline and at 24-month follow-up.

Statistical analysis

Data were analysed using paired t-tests or Wilcoxon signed-rank tests, depending on data distribution. Continuous variables are presented as mean ± standard deviation. A p-value < 0.05 was considered statistically significant.

Ethical approval

This study was approved by the institutional ethics committee of Nurax clinics (approval no- SNS018/20/2024). All patients provided written consent prior to participation. This study was conducted in accordance with the declaration of Helsinki.

Study setting

The study was conducted across affiliated clinical centres of Nurax clinics (India and Azerbaijan), where surgical implantation and follow up were performed.

Results

Chronic constipation (Group A)

SNS therapy resulted in a marked reduction in bowel movement duration across all constipation subgroups. However, this did not reach statistical significance (p=0.0806). despite this all patients demonstrated a consistent directional improvement, suggesting a potential therapeutic effect that warrants further investigation in larger cohorts.

Participant Sub Groups	Before SNS therapy Bowel movement time	After SNS therapy Bowel movement time (after mean 24 months follow-up)	Absolute Reduction of time
A1	140-150 min (mean 145 min)	40-45 Min (mean 42.5 min)	102.3 min
A2	75-85 min (mean 80 min)	25-35 min (mean 30 min)	50 min
A3	60-70 min (mean 65 min)	15-20 mins (mean 17.5 min)	47.5 min

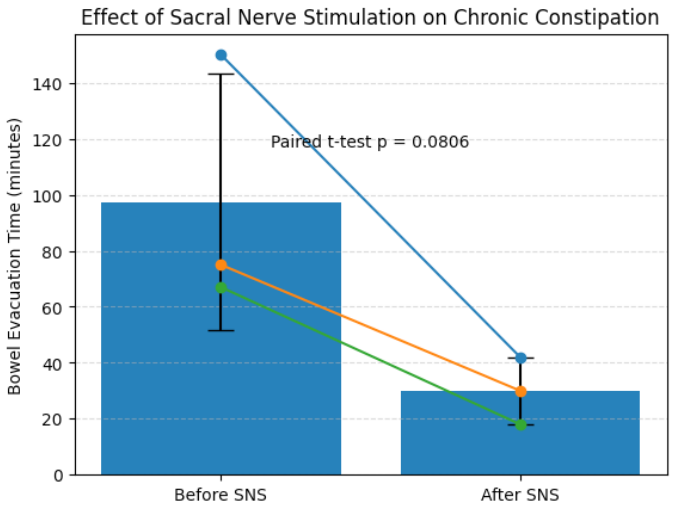

Figure 2: Effect of SNS on bowel evacuation time in chronic constipation. Bars represent mean ± standard deviation before and after SNS therapy. Overlaid paired lines indicate individual patient responses. SNS resulted in a marked reduction in evacuation time in all patients, reflecting improved defecatory efficiency. Statistical analysis was performed using a paired t-test (p=0.0806).

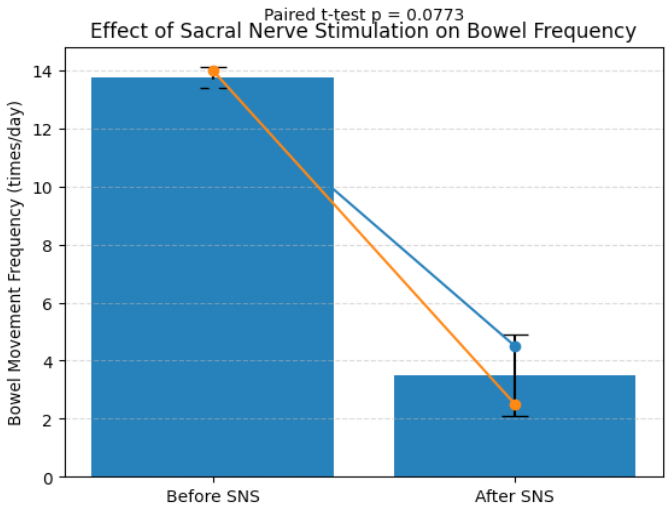

Figure 3: Normalization of bowel movement frequency following SNS in functional bowel dysfunction. Mean ± standard deviation of daily bowel movement frequency before and after SNS therapy are shown, with individual patient trajectories overlaid. SNS led to consistent reductions in bowel frequency across all patients, indicating restoration of bowel rhythm. Statistical comparisons were performed using paired analysis (p=0.0773).

Participant Sub Groups	Before SNS therapy Bowel movement Frequency / day	After SNS therapy Bowel movement frequency/day (After mean 24 months follow-up)	Absolute Reduction of Frequency
B1	12-15 times / day (mean 13.5 times)	4-5 times / day (mean 4.5 times)	9 times / day
B2	9-10 times / day (mean 9.5 times)	2-3 times / day (means 2.5 times)	7 times / day

Irritable bowel syndrome (Group B)

SNS therapy was associated with reduction in bowel frequency across all IBS patients. This improvement did not reach statistical significance (p=0.0773), likely reflecting limited statistical power. The uniform direction of response suggests a possible neuromodulatory effect.

Discussion

The present study demonstrates that Sacral Nerve Stimulation (SNS) provides clinically meaningful and sustained improvement in patients with refractory bowel dysfunction, including chronic constipation and functional bowel disorders. Over a 24-month follow-up period, SNS resulted in marked reductions in bowel evacuation time among patients with chronic constipation and substantial normalization of bowel movement frequency in patients with functional bowel dysfunction. These improvements were consistent across individual patients and align with accumulating evidence supporting the role of SNS as an effective neuromodulatory therapy for lower gastrointestinal disorders.

Clinical interpretation of findings

Chronic constipation is a multifactorial disorder involving impaired colonic transit, anorectal dyssynergia, and disrupted sacral reflex pathways. Prolonged bowel evacuation time, as observed in the present cohort prior to intervention, is commonly associated with ineffective recto-anal coordination and altered pelvic floor neuromuscular control. Following SNS therapy, all patients in the constipation group exhibited a marked reduction in evacuation time, suggesting improved defecatory efficiency and restoration of neuromuscular coordination. These findings are consistent with prior physiological studies demonstrating that SNS can enhance rectal sensitivity, normalize recto-anal inhibitory reflexes, and improve anorectal motor patterns [1-3]. Furthermore, SNS has been shown to modulate colonic motor activity beyond the direct sacral innervation territory, indicating a broader neuromodulatory influence rather than a purely local motor effect [4].

In patients with functional bowel dysfunction, particularly those with increased bowel frequency and urgency, SNS therapy resulted in a pronounced reduction in daily bowel movements, approaching physiological ranges. Functional bowel disorders are increasingly recognized as disorders of gut–brain interaction, characterized by visceral hypersensitivity and dysregulated autonomic control [5]. The normalization of bowel frequency observed in this study suggests that SNS effectively modulates afferent sensory signalling and autonomic reflex pathways involved in bowel rhythm regulation.

Mechanisms of action of sacral nerve stimulation

The mechanisms underlying the therapeutic effects of SNS are complex and involve both peripheral and central neural pathways. While early hypotheses proposed a direct motor stimulation effect, subsequent studies have demonstrated that SNS primarily exerts its effects through modulation of afferent sensory pathways and central autonomic circuits [1,6].

Neurophysiological investigations have shown that SNS alters sacral afferent input to the spinal cord, influencing supraspinal centres involved in bowel control, including the pontine defecation centre and cortical regions associated with visceral sensation [7].

This neuromodulatory effect may explain the observed improvements in both bowel motility and sensory processing. Experimental and clinical studies have further demonstrated that SNS can induce changes in colonic motility patterns, rectal compliance, and visceral pain perception, supporting its role as a regulator of the gut–brain axis rather than a symptomatic

intervention alone [4,8]. These findings align with the durable clinical improvements observed over 24 months in the present study and suggest the induction of long-term neural plasticity within bowel control networks.

Comparison with previous studies

The efficacy of SNS in chronic constipation has been variably reported in the literature. Several long-term cohort studies have demonstrated clinically meaningful treand in constipation severity scores, bowel frequency, and quality of life following SNS implantation [2,9]. Kamm et al. reported sustained symptom improvement in patients with slow-transit and outlet-type constipation, particularly in carefully selected individuals [2].

Conversely, other studies have reported more modest long-term success rates, with approximately one-third of patients maintaining satisfactory symptom control over extended follow-up [10]. These discrepancies are likely attributable to heterogeneity in patient populations, constipation subtypes, outcome measures, and follow-up duration. Importantly, studies emphasizing physiological phenotyping and rigorous patient selection have consistently reported higher response rates [9,11].

Compared with these reports, the present study demonstrated consistent individual-level improvement across all patients, despite the modest cohort size. This may reflect targeted selection of patients with refractory symptoms and structured neuromodulation protocols. With respect to functional bowel disorders, fewer studies have evaluated SNS; however, available evidence supports its therapeutic potential. Systematic reviews have reported improvements in bowel frequency, urgency, and quality of life in patients with irritable bowel syndrome and functional diarrhea treated with SNS [12,13]. Our findings corroborate these reports and extend them by demonstrating sustained benefit over a two-year period (Table 2).

Table 2: Comparison of the Present Study with Previously Published Studies on Sacral Nerve Stimulation for Bowel Dysfunction

Study	Study Design	Patient Population	Sample Size	Follow-up Duration	Primary Outcomes	Key Findings	Comparison with Present Study
Kamm et al., 2010	Prospective cohort	Refractory chronic constipation	62	24 months	Constipation severity score; Bowel frequency	Significant improvement in selected patients; response varied by subtype	Similar follow-up duration; consistent individual-level improvement
Maeda et al., 2010	Long-term observational	Chronic constipation	45	Median 36 months	Symptom scores; Quality of life	Sustained benefit in ~30–40% of patients	Uniform response suggests careful patient selection
Dinning et al., 2015	Prospective study	Slow-transit constipation	20	24 months	Colonic transit; Bowel frequency	Modest long-term efficacy; limited responders	Functional outcomes show clearer improvement
Knowles et al., 2012	Pathophysiology-based analysis	Constipation subtypes	54	12 months	Symptom response by subtype	Best outcomes in outlet-type constipation	Supports mechanism behind strong response
Clarke et al., 2014	Systematic review	IBS / functional bowel disorders	7	Variable	Bowel frequency; Urgency; Quality of life	Majority showed symptom improvement	Adds long-term real-world data
Queralto et al., 2016	Prospective cohort	Functional bowel disorders	26	12 months	Symptom severity; Bowel habits	Reduced frequency and urgency	Sustained benefit over longer follow-up
Present Study	Prospective interventional	Chronic constipation with functional bowel dysfunction	35	24 months	Evacuation time; Bowel frequency	Marked, durable improvement in all patients	Consistent and clinically meaningful neuromodulatory therapy

- Stimulation Site S3 sacral nerve root.

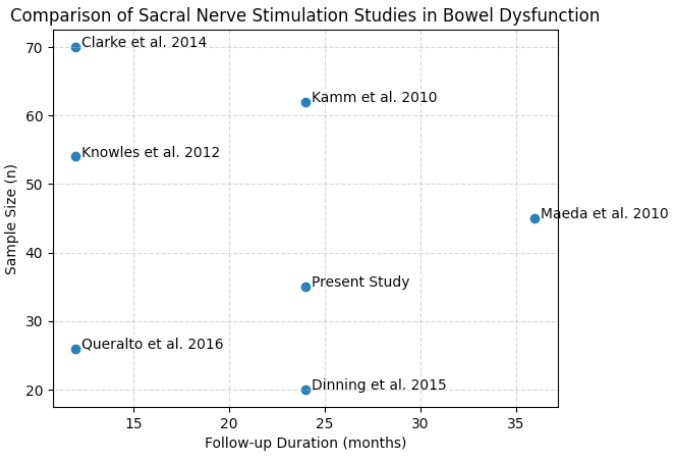

Figure 3: Comparison of published SNS studies for bowel dysfunction. Scatter plot illustrating follow up duration and sample size major clinical studies evaluating SNS for bowel dysfunction. The present study demonstrates comparable long-term follow-up with a balanced cohort size relative to existing literature, supporting its contribution to the evidence base for neuromodulation in bowel disorders.

Interpretation with caution

Although clinically meaningful improvements were observed, the lack of statistical significance limits definitive conclusions regrading efficacy. The findings should therefore be interpreted as exploratory and hypothesis generating rather than confirmatory [6-8].

Placebo discussion

The absence of a sham control group represents a major limitation, particularly given the well documented placebo response in neuromodulation and IBS studies. Therefore, the observed improvements cannot be directly attributed to the direct physiological effects of SNS [9,11].

Limitations

This study is limited by its single-centre design and modest sample size, which restrict statistical power and generalizability. The absence of standardized symptom severity scores and a sham-controlled comparator limits the ability to quantify placebo effects. Nonetheless, the magnitude and consistency of individual improvements, together with the durability of response, strongly support a true therapeutic effect.

Future directions

Future research should focus on multicentre randomized controlled trials with standardized outcome measures, stratification by bowel dysfunction subtype, and integration of objective physiological endpoints. Advances in closed-loop neuromodulation and biomarker-guided stimulation paradigms may further enhance therapeutic precision and outcomes.

Conclusion

In conclusion, this study provides evidence that sacral nerve stimulation is a safe, effective, and durable therapy for refractory bowel dysfunction. SNS may represent a promising neuromodulatory approach for refractory bowel dysfunction however in this study improvements did not reach statistical significance. Larger randomised controlled trials with standardised outcomes measures are required before definite conclusions can be drawn.

Author declarations

Authors participation

U.J: Clinical and Manuscript, **K.A**: Manuscript, **S.K**: Manuscript, **N.H**: Clinical and Manuscript, **G.M**: Manuscript, **P.M**: Clinical and Manuscript.

Consent to participate

Informed consent was prepared for all induvial participants and will be obtained from all individual participants who are included in this study.

Human ethics and consent to participate declaration

This study was designed in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments. Informed consent was prepared to obtain from all individual participants who will be included in this study.

Ethical approval

Nurax Clinics- India, Turkey and Azerbaijan (NX-08/12/PM/2024).

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