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RESEARCH ARTICLE

The Long-Term Effectiveness of Sacral Neuromodulation in Treating Low Anterior Resection Syndrome: A Single Center Experience

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ABSTRACT

Aim: Sacral neuromodulation (SNM) has emerged as an effective treatment option for patients with fecal incontinence (FI). The efficacy of SNM in the treatment of low anterior resection syndrome (LARS) following rectal cancer surgery is encouraging. The aim of this study is to review the long-term outcomes of patients treated with SNM for LARS.

Method: A review of a prospectively maintained database of consecutive SNM procedures for LARS between June 2017 and June 2020 was conducted. Bowel habits diaries, the Cleveland Clinic Florida-Fecal Incontinence Score (CCF-FIS), the Fecal Incontinence Quality of Life (FIQoL) scale, and the LARS score were evaluated at baseline, 3 months, and 24 months after definitive SNM implantation.

Results: The study included 14 patients; 11 were males, and the mean age was 59.2 (±10.2). Thirteen patients underwent permanent implantation of the SNM device. The mean score of FI episodes was reduced from 16 to 4 ($p<0.001$), and the mean CCF-FIS dropped from 15.2 to 6.5 ($p<0.001$). All patients showed a substantial increase in their FIQoL scale ($p<0.001$). Additionally, there was a significant amelioration in the LARS score (36.7 to 17.3, $p<0.001$) and all symptoms of LARS except incontinence of liquid stool ($p=0.97$).

Conclusion: SNM improves bowel dysfunction and QoL in patients with LARS following rectal cancer surgery and maintains its effectiveness over time.

Keywords: Sacral neuromodulation, low anterior resection syndrome, rectal cancer

Introduction

During the past decades, there have been remarkable improvements in the treatment of rectal cancer with the widespread adoption of total mesorectal excision and neoadjuvant chemoradiotherapy (CRT) regimens, which have reduced the rate of local recurrence and the requirement for permanent ostomy. However, the quality of life (QoL), including functional outcomes, is still a problem.[1] Following rectal cancer surgery, many patients experience increased stool frequency, urgency, clustering, and incontinence for flatus and/or feces. The combination of these symptoms is considered low anterior resection syndrome (LARS).[2] It is reported that 25-80% of patients develop LARS after sphincter-preservation rectal surgery, which is associated with poor QoL.[3-5] Conservative treatments, which are primarily empirical and symptom-focused, such as medical treatment, dietary counseling, pelvic floor rehabilitation, and biofeedback, are still primary treatment options for LARS. However, they have not yielded the expected therapeutic success.[6,7]

Sacral neuromodulation (SNM) has emerged as an effective treatment option in patients with fecal incontinence (FI) who have failed conservative management.[8,9] There is significant data on the effects of SNM on LARS.[10] The majority of them are case reports or small case series with low numbers. In addition, three meta-analyses reported favorable outcomes on this topic. However, the data has certain drawbacks, such

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as a small patient population and heterogeneity in outcome evaluation scores, and extensive multicentric studies are yet to be published.[11-13]

This study aimed to review over the long term an institutional series of patients treated with SNM for LARS with the utilization of globally accepted evaluation scores, such as the LARS score, and to analyze the factors associated with the therapy's success.

Materials and Methods

The entire process of this study followed the ethical standards of the Declaration of Helsinki and its later amendments. The Dokuz Eylül University Non-Interventional Research Ethics Committee approved the study (approval number: 2022/28-25, date: 31.08.2022). All patients provided written informed consent for the surgery and participation in the study.

A review of a prospectively maintained database of consecutive SNM procedures for LARS at Dokuz Eylül University Hospital between June 2017 and June 2020 was conducted. The indications for SNM for LARS treatment were as follows: previous LAR for rectal cancer, ongoing FI for more than 6 months after the reversal of a diverting ileostomy, failed conservative measures with diet and lifestyle modifications, medications, and/or biofeedback therapy, and no evidence of local and/or distant recurrence of the disease. Patients with a follow-up period of less than 2 years after SNM, younger than 18 years of age, and undergoing SNM for indications other than LARS were not included. Additionally, patients who had intersphincteric LAR for rectal cancer were excluded from the study.

Baseline Assessment

Patients were evaluated at baseline using bowel habits diaries, the Cleveland Clinic Florida-Fecal Incontinence Score (CCF-FIS),[14] the Fecal Incontinence Quality of Life (FIQoL) scale,[15] and the LARS score.[2] A regularly recorded bowel habits diary for a minimum of 1 month was used for baseline FI frequency and severity. FI was described as the involuntary loss of solid or liquid stool for at least 1 month in a patient who had normal control previously.[16] In addition, all patients were evaluated with anal manometry, flexible sigmoidoscopy, and, if necessary, a transanal ultrasound.

Sacral neuromodulation procedure: The SNM procedure was performed as a two-stage process: (1) the tined lead testing phase and (2) the permanent implantation phase, as previously described by Matzel et al.[17,18]. Both stages were performed in the operating room under intravenous sedation with local anesthesia by two specialist colorectal surgeons (TB, AEC). Preoperative antibiotic prophylaxis was administered routinely.

Tined Lead Testing Phase

The patients were placed in the prone position with the head, chest, and hips well supported in an effort to minimize lumbar lordosis. The feet and toes were lifted off the table to allow validation of the toe and foot response upon stimulation. The patient's buttocks were taped away so the cheeks were exposed to observe the anus during electrostimulation.

After the sacral skin was sterilized with an antiseptic solution, the procedure was initiated with an X-ray AP view of the sacrum, assuming the patient was in the optimal position. The sacral foramina's medial edges were the X-ray landmarks. A vertical line on each side of the sacral foramen and a line connecting the lower edges of the sacroiliac joint were used as markings. All were marked on the skin, producing an "H" figure. The intersection points of this "H" defined the upper medial portion of the S3 foramen, which is the optimal entry point for the tined lead. The S3 foramen was located using these radiological landmarks, and a needle was then inserted through this foramen. After identifying the S3 nerve root and eliciting the appropriate response (the flexion of the big toe and bellowing of the anal opening), the curved tined lead with four electrodes (Medtronic, Minneapolis, MN, USA) was positioned at the S3 foramen. The electrode was then tunneled to a subcutaneous pocket in the buttock, followed by the percutaneous extension wire to be used for external stimulation during the test period.

During a test period of at least 2 weeks, a bowel habits diary and the CCF-FIS were used to evaluate the efficacy of the treatment. The test period was considered successful if there was a >50% improvement in the continence score or a >50% decrease in the number of FI episodes. If the test period was successful, a permanent device was implanted.

Permanent Implantation of the Sacral Neuromodulation Device

Following a successful test period, the external pulse generator was removed, and the intern pulse generator (IPG) (or permanent pulse generator) was connected and placed in the subcutaneous pocket previously created.

Follow-Up

One week after the definitive SNM implantation, a first consultation was planned to examine the surgical wound and evaluate the efficacy of the therapy. Program settings were modified as necessary. Two weeks after implantation, a similar clinical appointment was arranged. Follow-ups were conducted in the first year at the 3rd, 6th, and 12th months, and annually thereafter. The bowel habits diary, the CCF-FIS, the FIQoL scale, and the LARS score were used to monitor the treatment's efficacy. Treatment success was defined as at least a 50% decrease in FI episodes, at least a 50% improvement in the FI scores compared to the baseline,

and a reduction to minor or no LARS [the LARS score was categorized as no LARS (0-20), minor LARS (21-29), and major LARS (30-42)].[2]

Statistical Analysis

Statistical analysis was performed by a biostatistician (HE) using SPSS version 25.0 software (SPSS Inc., Chicago, IL, USA). Data were described using mean, standard deviation, median, and minimum-maximum. The association between the categorical variables and the success of the SNM treatment was determined with Fisher's exact test. The association between the continuous variables and the success of the SNM treatment was tested by the Mann-Whitney U test. Associations were performed using the Friedman test for analytic comparisons (pre-SNM; post-SNM 3rd-month, post-SNM 24th-month scores, such as Fl episodes, the CCF-FI, the FIQOL scale, and the LARS score). P-values <0.050 were defined as statistically significant.

Results

Study Population

Fourteen patients were included in the study; 11 (78.6%) were male, and the mean age was 59.2 (±10.2). Twelve patients (85.7%) had at least one comorbid condition. Thirteen (92.9%) patients received neoadjuvant CRT. A coloanal anastomosis was performed in eight (57.8%) patients. The median distance from the anal verge to the anastomosis was 2.3 cm (ranging from 0 to 6 cm). A diverting loop ileostomy was conducted in all patients. The median interval to the diverting ileostomy closure was 10 months (range: 5-21). The median interval after a diverting ileostomy closure to the SNM test period was 23 months (range: 6-95). The median follow-up time was 35 months (range: 2458). Table 1 provides a detailed summary of all patient characteristics.

Sacral Neuromodulation

The SNM testing period included 14 patients with LARS. However, one patient showed no improvement in symptoms and did not progress to the phase of permanent implantation. As a result, 13 (92.8%) patients underwent permanent SNM implantation. The median duration of the test phase was 14 days (range: 9-59). One patient's test period was extended to 59 days unintentionally due to the coronavirus disease-2019 pandemic.

During the postoperative period, one patient underwent explantation of the tined lead and IPG due to an infection at the surgical site, followed by successful reimplantation 3 months later. During the follow-up period, the authors explanted the SNM device from two patients: one who developed lumbar stenosis 50 months after implantation and needed an magnetic resonance imaging (MRI) for diagnosis, and another who developed local recurrence 32 months after implantation and underwent abdominoperineal resection. Finally, one patient required SNM replacement 62 months after implantation due to a depleted battery. Figure 1 shows the follow-up charts of the patients' SNM test and permanent implantation phases.

Sacral Neuromodulation Outcome

During the follow-up period at baseline, 3 months, and 24 months after permanent implantation, the mean number of FI episodes were 16, 4, and 4; respectively (p<0.001), the mean CCF-FIS was 15.2, 6.6, and 6.5; respectively (p<0.001), the mean FIQoL score was 45.4, 86, and 86; respectively (p<0.001), and the mean LARS score was 36.7, 16.2, and 17.3; respectively (p<0.001). There was a significant decrease in FI episodes, the CCF-FIS, and the LARS score, and a significant improvement in the FIQoL score (Figure 2).

Before SNM, all patients had major LARS (scores ranging from, 31-41). At the follow-up, 24 months after implantation, four of the 13 patients had minor LARS (scores ranging from, 25-27), and nine of the 13 patients had no LARS (scores ranging from, 5-19). An analysis of the LARS score components revealed a consistent pattern of score reduction, except for liquid stool incontinence. For LARS question 1 (LARS 1: incontinence for flatus), the mean score decreased significantly from 4.73 to 0.36 (p<0.001); for LARS question 3 (LARS 3: frequency of bowel movements), the mean score decreased significantly from 4 to 2.9 (p=0.001); for LARS question 4 (LARS 4: clustering of stools), the mean score decreased significantly from 9.9 to 5.1 (p=0.001); and for LARS

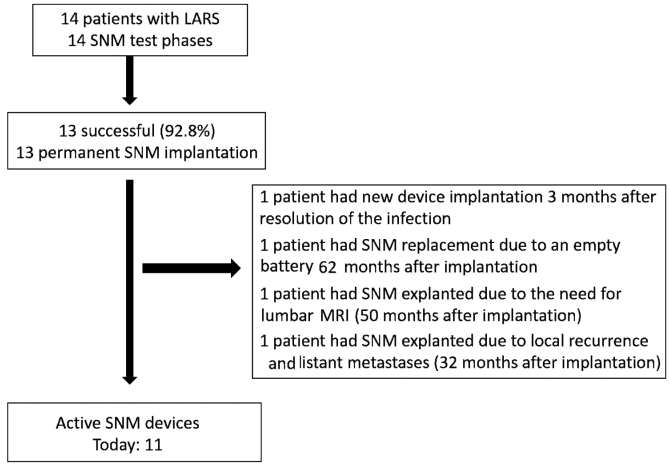


Figure 1. Flowchart of the sacral neuromodulation process and follow-up

LARS: Low anterior resection syndrome score, SNM: Sacral neuromodulation, MRI: Magnetic resonance imaging

Table 1. Demographic and clinical characteristics of the patients

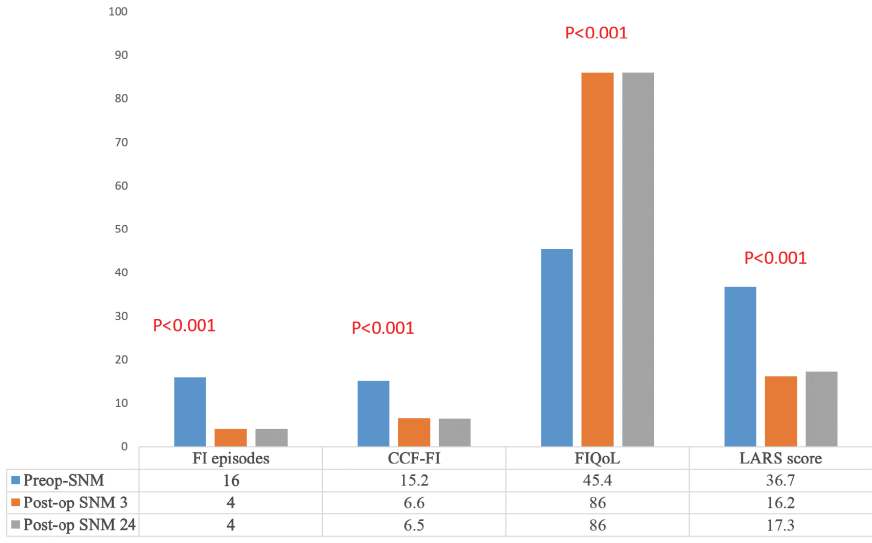
	(n=14)	Percentage (%)
Sex		
Male	11	78.6
Female	3	21.4
Age: mean (SD) (years)	59.2±10.2	
BMI: mean (SD)	24.8±3.5	
ASA		
I	7	50
II	7	50
Comorbidity	12	85.7
Diabetes	4	28.5
Arterial hypertension	6	42.8
Coronary heart disease	1	7.1
Others	1	7.1
Smoking	4	28.5
Clinical staging		
cT		
T2	1	7.1
T3	12	85.7
T4	1	7.1
cN		
N0	-	-
N+	14	100
Neoadjuvant chemoradiotherapy (+)	13	92.9
Surgical approach		
Open surgery	13	92.9
Laparoscopic surgery	1	7.1
Type of surgery		
PME	3	21.4
TME	11	78.6
Type of anastomosis		
Colorectal	6	42.9
Coloanal	8	57.1
Anastomotic technique		
End-to-end, stapled	14	100
Median anastomotic distance from the anal verge (range), cm	2.3 (0-6)	
Anastomotic leakage	1	7.1
Pathological staging		
pT		
T0	1	7.1
T1	1	7.1
T2	5	35.2
T3	7	50
pN		
N0	7	50
N+	7	50
Adjuvant chemoradiotherapy	12	85.7
Median interval until diverting ileostomy closure (range), months	10 (5-21)	
The median interval from a diverting ileostomy closure to the SNM test period (range), months	23 (6-95)	
Median duration test period (range), days	14 (9-59)	
Median follow-up duration (range), months	35 (24-58)	
Permanent SNM implantation rate	13	92.8

SD: Standard deviation, BMI: Body mass index, ASA: American Society of Anesthesiologists classification, PME: Partial mesorectal excision, TME: Total mesorectal excision, SNM: Sacral neuromodulation

question 5 (LARS 5: urgency), the mean score decreased significantly from 13.7 to 7 (p=0.002). Only LARS question 2 (LARS 2: incontinence for liquid stool) had no significant improvements; the mean score decreased from 3 to 2.18 (p=0.97) (Figure 3).

Success of Sacral Neuromodulation Therapy

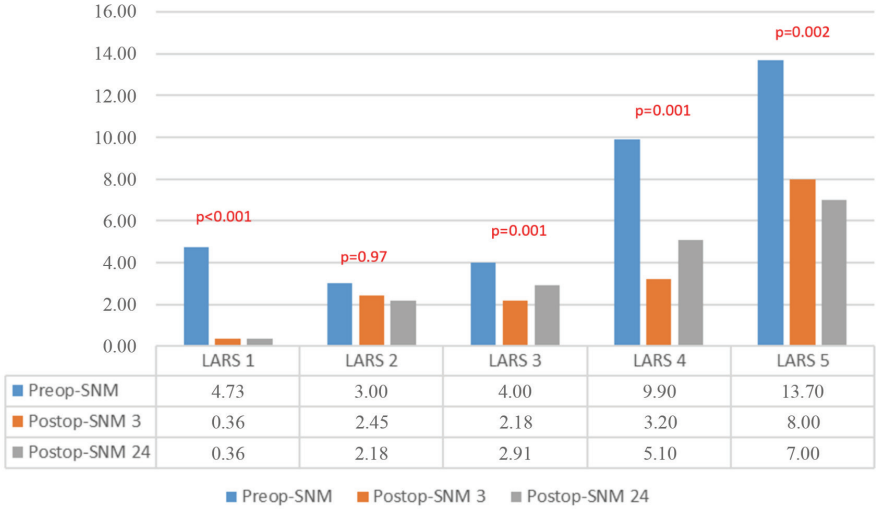
Of the 14 patients with LARS in the testing phase, 13 (92.8%) had a positive testing phase outcome. Age (p=0.210), gender (p=0.38), the American Society of Anesthesiology (ASA) score (p=0.051), body mass index (p=0.186), smoking (p=0.837), neoadjuvant CRT (p=0.588), the type of anastomosis (coloanal vs. colorectal) (p=0.707), the interval between the rectal cancer surgery and the diverting ileostomy closure (p=0.242), and the interval between the diverting ileostomy closure and the SNM test phase (p=0.139) were all thought to affect the success rate of therapy but were found to have no statistically significant impact.



	FI episodes	CCF-FI	FIQoL	LARS score
Preop-SNM	16	15.2	45.4	36.7
Post-op SNM 3	4	6.6	86	16.2
Post-op SNM 24	4	6.5	86	17.3

Figure 2. Fecal incontinence episodes, the CCF-FIS, the FIQoL scale, and LARS score before sacral neuromodulation (SNM) implantation and 3 and 24 months after SNM implantation

SNM: Sacral neuromodulation, FI: Fecal incontinence, CCF-FIS: Cleveland Clinic Florida-Fecal Incontinence Score, FIQoL: Fecal Incontinence Quality of Life, LARS: Low anterior resection syndrome score, p: Friedman test*



	LARS 1	LARS 2	LARS 3	LARS 4	LARS 5
Preop-SNM	4.73	3.00	4.00	9.90	13.70
Postop-SNM 3	0.36	2.45	2.18	3.20	8.00
Postop-SNM 24	0.36	2.18	2.91	5.10	7.00

Figure 3. LARS score components before SNM implantation and 3 and 24 months after SNM implantation

LARS 1: LARS question 1, reduced incontinence for flatus, LARS 2: LARS question 2, improvement of incontinence for liquid stool, LARS 3: LARS question 3, reduced clustering of stools, LARS 4: LARS question 4, reduced frequency of bowel movements, LARS 5: LARS question 5, reduced urgency, SNM: Sacral neuromodulation, p: Friedman test*

Discussion

This study showed that the long-term evaluation of the efficacy of SNM based on FI episodes, the CCF-FIS, the FIQoL scale, and the LARS score revealed that its effectiveness persisted significantly. During the median 35-month follow-up period, no SNM therapy was discontinued due to loss or lack of efficacy. Also, the study cohort was homogeneous in that it consisted of patients who underwent LAR for rectal cancer with the same surgical team and technique, 13 of the 14 patients received neoadjuvant CRT, and all patients had major LARS. Following the test phase, permanent SNM implantation was performed successfully in 13 out of the 14 patients with LARS (92.8%). There was no morbidity or mortality except for wound infection in one patient. The authors' results demonstrated that SNM is a safe and effective treatment for patients with LARS.

The patient selection criteria for SNM therapy and the factors associated with the treatment success are not well defined. Rubio-Perez et al.[19] found that patients who had had previous radiotherapy and fewer anastomoses could have a worse response to SNM therapy. In another study of patients with LARS secondary to rectal cancer surgery, of whom 14 out of 15 underwent neoadjuvant CRT, only 50% of patients received an SNM implant after testing. The authors discussed the effects of radiation and fibrosis in reducing efficacy.[10] In this study, neither previous chemoradiation nor fewer anastomoses (coloanal vs. colorectal) were found to have an impact on success. This may be due to the small number of participants in the study. Age, gender, the ASA score, reported smoking habits, the interval from rectal surgery to a diverting ileostomy closure, or the interval from a diverting ileostomy closure to implantation were not found to be effective in terms of success, in line with the existing literature.[10,19]

The variability in the definition of treatment outcomes, the use of different scoring systems, and the small number of patients are all drawbacks of the studies evaluating SNM therapy for LARS. Various reviews and meta-analyses have pooled published evidence.[11-13,20-22] These studies showed that the SNM implantation technique is not standardized and that there are variations in patient preoperative assessment, intraoperative and postoperative monitoring, as well as QoL evaluation instruments. In the review by Huang and Koh[12], which evaluated 10 studies and included 75 patients with an SNM implant, the CCF-FIS was used to define the response in all studies, whereas the LARS score was used in only three studies.[23-25] A few prospective studies evaluated the efficacy of SNM for LARS, but only one used the LARS score to assess the therapy.[10,23,26] In a prospective study involving 11 patients, D'Hondt et al.[23] demonstrated that all patients exhibited a significant decrease in their CCF-FIS (p=0.0033) and LARS score (p=0.0033) and suggested that the LARS score could be used to evaluate the efficacy of SNM therapy in patients with LARS. In this study, each question of the LARS score was addressed individually, and the authors found that the SNM therapy significantly improved all LARS symptoms.[23] This center published a five-year retrospective study of patients with isolated FI or LARS in 2020. Of the 62 implants, 16 were in patients with LARS. They evaluated the SNM effectiveness with the CCF-FIS and the LARS score and reported that both were associated with treatment success in a similar trend during long-term follow-up. In addition, the authors analyzed the different components of the LARS questionnaire. They confirmed that SNM is effective for all components of LARS.[20]

In this study, the authors evaluated the effectiveness of SNM in patients with LARS using FI episodes, the CCF-FIS, the LARS score, and the FIQoL scale. The authors demonstrated that the SNM treatment significantly improved FI episodes, the CCF-FIS, and the LARS score in the early period compared to baseline and maintained this during long-term follow-up. Similarly, the authors demonstrated that early positive effects on the FIQoL scale persisted over time and reached a plateau. In addition, the impact of SNM on each symptom of the LARS score was analyzed. In contrast to the literature, the authors observed a significant improvement in all LARS symptoms, with the exception of liquid stool incontinence. The authors believe this derives from the score distribution of the second question of the LARS score (LARS 2: accidental leakage of liquid). In this question, patients are presented with three options and three scores. The score distribution for this question is "0" if there is no accidental stool leakage, "3" if there is less than one per week, and "3" if there is at least one stool leakage per week. Giving the same score to two different symptom grades does not provide an appropriate assessment opportunity, even if SNM causes a significant improvement in the symptoms of these patients. The authors know that the LARS score was initially intended as a screening tool for LARS and not as a treatment efficacy evaluation tool. Nevertheless, without a superior alternative, the authors believe that the LARS score could help assess the severity of the symptoms and the response to treatment. However, the LARS score question 2 (LARS 2) may be inadequate for evaluating the outcomes and may show that they are less successful than they are. The authors suggest that SNM efficiency should be considered along with the CCF-FIS and the LARS score in patients with LARS.

The permanent SNM device had to be removed in four patients in the authors' series. In one patient, the device was removed after 32 months due to cancer recurrence. The patient underwent abdominoperineal resection and explantation of the SNM device. In patients with an increased risk for local recurrence and the possible need for abdominoperineal excision, SNM treatment may be postponed after the second-year postoperative follow-up if there is no evidence of local recurrence. On the other hand, it may be done as early as possible to improve the patient's QoL during their expected relatively shorter survival time. Balancing the cost of the treatment and the potential increase in QoL may be difficult. In another patient, the authors removed the SNM device because the patient needed lumbar MRI. Widespread use of MRI-compatible devices may be a solution. The authors explanted the SNM device in another patient due to a surgical site infection. The authors removed both the tined lead and IPG and

successfully reimplanted a new SNM device after the resolution of the infection. Finally, the authors replaced one IPG due to an expired battery life after 62 months of operation.

Study Limitations

The authors' study has several limitations, notably its retrospective design and single institutional structure. The study's small sample size may have also diminished the statistical significance of some variables. Moreover, the study lacks a control group for comparison, which may eliminate possible confounding factors. In addition, the cost-effectiveness of the treatment was not considered in the study.

Conclusion

This study's results demonstrate that SNM improves bowel dysfunction and QoL in patients with LARS following rectal cancer surgery and maintains its effectiveness over time. However, further studies are needed to assess the role of SNM in improving LARS symptoms.

Ethics

Ethics Committee Approval: The entire process of this study followed the ethical standards of the Declaration of Helsinki and its later amendments. The Dokuz Eylül University Non-Interventional Research Ethics Committee approved the study (approval number: 2022/28-25, date: 31.08.2022).

Informed Consent: All patients provided written informed consent for the surgery and participation in the study.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: T.B., A.E.C., Concept: T.B., A.E.C., B.M., S.S., Design: T.B., A.E.C., B.M., S.S., Data Collection or Processing: T.B., A.E.C., B.M., Analysis or Interpretation: T.B., A.E.C., H.E., Literature Search: T.B., A.E.C., B.M., S.S., Writing: T.B., A.E.C., B.M., S.S.

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