Effect of sacral neuromodulation on female sexual function and quality of life: Are they correlated?

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Abstract

Introduction: Sacral neuromodulation (SNM) has become an established therapy for voiding dysfunction. Additional benefits, such as improved bowel functions and bladder pain, have been reported. Improvement in female sexual function after SNM treatment has been suggested; however, reports examining the effects of SNM on female sexual functions are scarce. We evaluate the effects of SNM on female sexual function and its impact on quality of life and analyze any correlation.

Methods: Data were collected from January 2010 to May 2012 for all female patients who underwent SNM InterStim (Medtronic, Minneapolis, MN) therapy at a single centre in Canada. They were treated for voiding dysfunction, including refractory overactive bladder, frequency-urgency syndrome and non-obstructive urinary retention. Patients were screened by percutaneous nerve evaluation (PNE) to assess their response to therapy using a 4-day voiding diary. Patients who experienced 50% or more improvement in their voiding parameters were permanently implanted. All patients completed the Female Sexual Function Index (FSFI), Short-Form Health Survey (SF-36), and incontinence questionnaires (Urinary Distress Inventory [UDI]-6) preoperatively and 4 months postoperatively.

Results: A total of 33 female patients had SNM therapy; 10 were excluded from the study because they were not sexually active. The indications were: refractory overactive bladder in 19, frequency-urgency syndrome in 2, and non-obstructive urinary retention in another 2 patients. SNM therapy significantly improved the total FSFI score (p = 0.011); the components of desire and orgasm showed significant improvement (p = 0.014 and p = 0.035, respectively). Age, body mass index, diagnosis, and urinary symptoms did not show significant correlation with FSFI score improvement. Quality of life showed significant improvement after SNM treatment in 5 categories. There was no correlation between improvement in quality of life and FSFI.

Conclusion: SNM may improve female sexual function and quality of life, yet there is no correlation between the improvement in FSFI and quality of life.

Introduction

Sacral nerve stimulation (Interstim, Medtronic, Minneapolis, MN) has become an established option in the treatment of lower urinary tract symptoms (LUTS). It is an FDA-approved therapy for refractory overactive bladder, frequency-urgency syndrome, and non-obstructive urinary retention.¹⁻⁵

Therapy includes modulation of the third sacral nerve root, using an electrode implanted in the S3 foramen, which is then connected to a pulse generator placed in a subcutaneous pocket over the buttocks. The mechanism of action is not well understood;⁶⁻⁸ however, the stimulation of the S3 nerve root modulates the function of nerves arising from the S3 root.⁹

The nerves arising from the S3 root include pelvic, pudendal nerves which innervate perineal muscle and inferior hypogastric plexus which in turn innervate pelvic organs. Stimulation of these nerves plays a major role for SNM therapy in resolving voiding dysfunction and improving bowel function.¹⁰

Promising results are being reported in conditions, such as pelvic pain syndrome and interstitial cystitis. 11-15 Few papers reported the effect of SNM therapy on female sexual function in mixed population groups with voiding dysfunction, fecal incontinence, 16 and chronic pelvic pain. 17-18 It is uncertain if the reported effect of SNM therapy in female sexual function is direct to stimulation or secondary to primary disease therapy and overall improved quality of life. Also, measurement of sexual function is notoriously difficult and relies on subjective patient-reported data on a potentially embarrassing topic.¹⁹ While other studies were limited by small sample size, none validated questionnaires, and retrospective design, which were major study limitations. In this study, we evaluate the effects of SNM on female sexual function and its impact on quality of life; we also analyze any correlation between these factors.

Methods

In this prospective, observational study, we evaluated the effect of SNM on female sexual function in voiding dysfunction patients and its impact on quality of life.

The study was approved by our local ethics approval board. The study was conducted at a single centre (Toronto Western Hospital, Toronto, Ontario, Canada) between January 2010 and May 2012. We included female patients undergoing SNM (Interstim) therapy for the following indications: overactive bladder after failed medical treatment, frequency-urgency syndrome, and chronic urinary retention. All patients were screened by percutaneous nerve evaluation (PNE) for 4 days, or a staged procedure for 2 weeks. The InterStim device was implanted in patients who had 50% or urinary symptom control and improvement on comparing voiding diary before and during the test period.

Outcome measurement

Our primary outcome was any observed changes in female sexual function associated with the application of pelvic neuromodulation. It was assessed using the validated FSFI questionnaire that assesses the 6 main domains of female sexual function (desire, arousal, orgasm, pain, vaginal lubrication, relationship satisfaction). The total FSFI score is obtained by adding all domains scores. According to Wiegel and colleagues,²⁰ a total FSFI score of ≤26 indicates female sexual dysfunction.

Our secondary outcomes included quality of life and urinary symptom control. Quality of life was assessed using the validated Short-Form Health Survey (SF-36), which includes 36 questions assessing 8 quality of life domains (physical functioning, physical role, body pain, general health, vitality, social functioning, emotional role, mental health). The RAND method was used for scoring the SF-36 questionnaire.

Urinary symptoms were assessed using the Urinary Distress Inventory (UDI)-6 questionnaire. This questionnaire includes 6 questions on urine frequency, leakage, lower abdomen discomfort and difficult bladder emptying. Selections include: not at all (score = 0), slightly (score = 1), moderate (score = 2), and greatly affected (score = 3). The total score is calculated by the sum of all questions scores (minimum score 0, maximum score 18).

All forms (FSFI, SF-36, and UDI-6) were completed by all patients preoperatively and an average of 4 months (range: 3-5 months) post-SNM implantation.

Surgical procedure

All patients underwent a PNE screening test under local anesthesia in an outpatient setting. At our centre, during the PNE we depend on the response location at the anal and perianal area; at follow-up, we request an x-ray to confirm the proper electrode position.

A staged procedure was undertaken if the PNE testing was difficult in terms of foramen localization, if patients could not tolerate the procedure or if there was radiological evidence of electrode migration on the post-testing plain x-ray. Patients who had a positive screening test (50% or more subjective and/or objective clinical improvement on voiding diary) underwent the SNM implantation. The procedure was done under general anesthesia with a strict sterile technique and under prophylactic antibiotic coverage. The tined lead electrode was inserted at the right or left third sacral nerve foramen, which was connected to the Interstim device. The device was inserted subcutaneously in the buttock area, right or left depending on the patient's dominant hand side. All devices were turned on and programmed on the same day of implantation and patients were taught how to use the programmer. All patients were instructed to resume their sexual activity after 4 weeks of implantation to avoid electrode migration.

Exclusion criteria

We excluded patients who were not sexually active (no sexual partner, irrespective of the comorbidity status), who did not fill out the questionnaires or who missed their outpatient follow-up appointments.

Statistical analysis

Data were collected using Microsoft Excel 2003. Statistical analysis was performed using IBM SPSS 19.0 (SAS Institute, Cary, NC). Descriptive analyses were reported as means and frequencies. Comparison between preoperative and postoperative FSFI, SF-36, and UDI-6 scores was performed using paired sample T-tests. Pearson correlation coefficient analysis was computed between FSFI scores and patient parameters (age, body mass index [BMI], diagnosis, urinary symptom). All values were considered statistically significant at $p \le 0.05$.

Results

In total 33 female patients underwent SNM implantation between January 2010 and May 2012. Ten patients were not sexually active and therefore excluded from the study. The indications were: refractory overactive bladder in 19, frequency-urgency syndrome in 2, and non-obstructive urinary retention in another 2 patients. The mean age was 51 years (range: 21-71) and the mean BMI was 28.6 ± 6.3 . Nine patients had a positive history of comorbid factors (diabetes mellitus, hysterectomy). All patients underwent the PNE test, except 1 patient who needed the staged procedure because of electrode migration (Fig. 1, Table 1).

All forms were completed by all patients preoperatively and an average of 4 months post-implantation. Comparing FSFI pre- and post-implantation scores showed that SNM treatment significantly improved the total FSFI score (p=0.011, confidence interval [CI] -5.1153 to -5.1153). Desire and orgasm were the only FSFI domains that showed significant improvement with SNM (p=0.014, p=0.035, respectively) (Table 2a, Table 2b). Person correlation coefficient analysis did not show any significant correlation between the improvement in FSFI score and age, BMI, diagnosis, and urinary symptoms (Table 3).

Quality of life showed significant improvement after SNM implantation in 5 categories: physical function (p = 0.00), energy (p = 0.00), emotional well-being (p = 0.005), social functioning (p = 0.00), and general health (p = 0.001) (Table 4).

Statistical analysis showed no correlation between quality of life domains, age, BMI, and the difference in total FSFI score; however, urinary symptom control (UDI-6 score

Table 1. Patient demo					
Total number	33 implanted 23 included				
	10 excluded, not sexually active				
.	19 Refractory overactive bladder				
Diagnosis	2 Frequency urgency syndrome2 Non-obstructive urinary retention				
Age	Mean 51 ± 13 (range: 21–71)				
Baseline UDI-6	Mean 8.96 ± 4.416 (range: 0–18)				
BMI	Mean 28.6 ± 6.3 (range: 18.2–46.7)				
Comorbidity	14 no comorbid factors9 positive history (diabetes mellitus, hysterectomy)				
Screening test	22 Percutanoeus nerve evaluation test 1 staged				
SNM implantation	All unilateral				
Device type IPG	17 Model 3903 6 InterStim 2				
Side	12 Right S3 11 Left S3				
Postoperative UDI-6	5.13 ± 4.4				

BMI: body mass index; UDI: Urinary Distress Inventory; SNM: sacral neuromodulation; IPG: implantable pulse generator.

difference) showed significant correlation with the social functioning domain of quality of life (r = -0.419, p = 0.047) (Table 5).

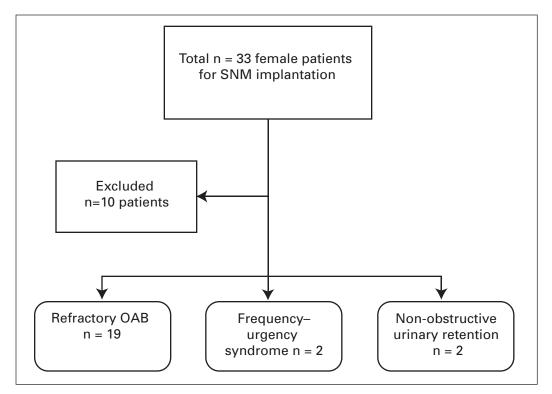


Fig. 1. Flow chart for total number of patients included and excluded in the study. SNM: sacral nerve modulation; OAB: overactive bladder.

Table 2a. Female sexual function Index scores and domains which show significant improvement post-SNM implantation Vaginal Sexual Category **Total FSFI score** Desire Arousal Orgasm Pain **lubrication** satisfaction n=23 (Mean ± SD) Baseline 15.49±9 2.03±1 2.35±1.7 2.93±2.2 2.5±1.92 2.69±1.78 2.89±2.66 Postoperative (SNM) 18.33±10.96 2.61±1 2.8±1.96 3.01±2.17 2.99±2.31 3.34±2.14 3.5±2.71 0.014 0.067 0.625 0.035 0.076 0.134

SNM: sacral neuromodulation; FSFI: Female Sexual Function Index; SD: standard deviation.

Discussion

Female sexual dysfunction is common. The US National Health and Social Life Survey reported 43% sexual dysfunction in females compared to 31% in males.²¹⁻²³

The mechanism of female sexual dysfunction has several pathways, including psychogenic, neurogenic, musculogenic and hormonal factors, which all can cause arousal, desire, orgasmic and/or pain sexual disorders. ²⁴⁻²⁶ The treatment of female sexual dysfunction is mainly focused on hormonal therapies, including estrogen and testosterone, which are not without risk. Most studies are done in postmenopausal women. ²⁷⁻³⁶ The available evidence on the effectiveness of SNM in voiding dysfunction and bowel habits raises the question of the possible effect on the genital organs that share the same S3 nerve innervations.

Table 2b. Female Sexual Function Index scores baseline and post-SNM therapy total FSFI for all study included patients

Patient	Baseline total FSFI	Post-SNM therapy total FSFI
1	27.9	29.1
2	17.1	29.5
3	14.3	15.6
4	18.5	21.6
5	14.3	27.8
6	15.3	17.6
7	17.1	29.5
8	3.6	4.4
9	16.5	21.6
10	16.5	26.4
11	28.9	29.5
12	28.9	21.6
13	29.7	29.5
14	3.2	5.0
15	18.3	20.7
16	2.0	2.0
17	2.3	1.8
18	17.2	19.0
19	3.5	3.8
20	28.8	29.5
21	22.0	29.5
22	3.8	3.6
23	4.4	3.0

SNM: sacral neuromodulation; FSFI: Female Sexual Function Index

Our prospective, observational study demonstrates a statistically significant effect of SNM on FSFI (p = 0.011, CI -5.1153 to -5.1153); this result is similar to other papers.³⁷⁻⁴¹

Although female sexual dysfunction is defined as FSFI \leq 26, our study patients had low scores with mean FSFI baseline of 15 \pm 9 and a mean post-SNM therapy FSFI of 18 \pm 10, despite their statistically significance. In the literature, the cutoff point in the FSFI score to determine clinical improvement is undetermined; the FSFI is used as an assessment tool to detect any change post-therapy.

We found a significant improvement in desire and orgasm domains of the FSFI. The orgasm improvement could be due to the vibration sensation and electrical current at the pelvic area, while the desire improvement may be due to the SNM effect and the restoring activity associated with brainstem autoregulation and attenuation of cingulate activity. 42 Quality of life improvements in the emotional role, general health and social function may also affect the desire in patients after SNM therapy. Conversely, in 7 patients Pauls and colleagues³⁷ found that all patients had significant improvement in total FSFI and all domains except arousal. Ingber and colleagues, however, failed to report any significant improvement after 6 months of SNM even after a subgroup analysis.43 Zahibi and colleagues used a different technique for SNM insertion and reported significant improvement in all domains and total FSFI score.³⁸ In contrast, Lombardi and colleagues saw significant improvements in satisfaction and total FSFI scores.39

Our study showed improvement in 5 quality of life categories; this makes us question the indirect effect of SNM on sexual function. Correlation analysis showed no relation between FSFI score difference and all quality of life catego-

Table 3. Pearson correlation between the difference in total FSFI score and age, diagnosis, BMI and UDI-6 difference

Category	Pearson correlation coefficient	<i>p</i> value
Diagnosis	-0.288	0.339
Age	0.028	0.899
BMI	0.065	0.769
Urinary symptom improvement (UDI-6)	-0.028	0.898

BMI: body mass index; UDI: Urinary Distress Inventory; FSFI: Female Sexual Function Index.

Category n=23	Physical functioning (Mean ± SD)	Physical role (Mean ± SD)	Mental health (Mean ± SD)	Vitality (Mean ± SD)	Emotional role (Mean ± SD)	Social functioning (Mean ± SD)	Body pain (Mean ± SD)	General health (Mean ± SD)
Baseline	46.5 ± 13.9	40.2 ± 48	50.72 ± 47	26.52 ± 21	44.7 ± 29	44.7 ± 29	56.2 ± 29.2	35.7 ± 19
Postoperative (SNM)	66.3 ± 21	42.4 ± 23	46.4 ± 43	42.4 ± 25	59.1 ± 28.4	70.1 ± 28	50.3 ± 25.6	53.4 ± 23.05
<i>p</i> value	0.00	0.845	0.710	0.00	0.005	0.00	0.985	0.001

ries. It can be explained that urinary control contributes to improvements in quality of life that in turn results in better sexual performance; however, our study did not demonstrate any statistical significance due to our small sample size. Also, there was no correlation between the FSFI scores and age, BMI, primary diagnosis and urinary symptom on UDI-6. Interestingly, urinary symptom scores (UDI-6) demonstrated a significant correlation with the social functioning category; this is expected in these patients who face embarrassment and who tend to avoid social gathering due to their urinary symptoms. This result is similar to Pauls' reported lack of correlation between FSF improvement and urinary symptoms control.³⁷ While Bradley and colleagues reported a trend between FSFI and changes in urinary symptoms, there was no significant association with their small study population (n = 10).⁴⁰ In contrast, Signorello and colleagues reported a significant correlation between clinical improvement and improvement in sexual function, but their study is also limited by its small sample size.⁴¹

Our prospective study is limited by the sample small size, but in comparison to all the reported series, it included more patients (n=23). Our study has the advantage of analyzing the confounding effect of other factors (quality of life, urinary symptoms, patient demographics), which were lacking in the previously reported studies.

Conclusion

SNM may improve FSFI in patients with voiding dysfunction. SNM may play a role in managing female sexual dysfunction in the future. We recommend the development of randomized controlled trials for the use of SNM in pure female sexual dysfunction using the staged procedure after excluding anatomical and psychogenic causes.

Competing interests: Dr. Banakhar, Dr. Gazwani, Dr. El Kelini, Dr. Al-Shaiji and Dr. Hassouna declare no competing financial or personal interests.

This paper has been peer-reviewed.

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Table 5. Pearson correlation p value between quality of life domains and the difference in total FSFI score, age, BMI, and UDI-6 difference

Category n=23	Physical functioning	Physical role	Mental health	Vitality	Emotional role	Social functioning	Body pain	General health
Total FSFI score difference	0.54	0.245	0.455	0.72	0.938	0.811	0.100	0.598
Age	0.59	0.39	0.25	0.25	0.41	0.212	0.646	0.91
UDI-6 score difference	0.215	0.13	0.40	0.7	0.252	0.047	0.37	0.36
BMI	0.88	0.27	0.16	8.0	0.712	0.623	0.93	0.071

BMI: body mass index; UDI: Urinary Distress Inventory; FSFI: Female Sexual Function Index.

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