

## INTERVENTIONS

# Sacral Neuromodulation for Lower Urinary Tract Symptoms: Effect of Therapy on Saudi Patient Sexual Function



Mai Ahmed Banakhar,<sup>1</sup> and Ayman Youness,<sup>2</sup>

## ABSTRACT

**Background:** Sacral neuromodulation (SNM) is FDA-approved therapy for lower urinary tract and bowel dysfunction. It is newly introduced therapy in Saudi Arabia.

**Aim:** To evaluate the effect of SNM therapy in both male and female Saudi patient's sexual function.

**Methods:** A prospective cohort study was conducted for all patients who underwent SNM implantation from January 2016 till January 2020 at a single center in Jeddah, Saudi Arabia. Sexual function was assessed before and after treatment using International Index of Erectile Function (IIEF-5) for men and the Female Sexual Function Index (FSFI) for women.

**Main Outcome measures:** Sexual function score changes from the baseline was reported. Correlation analysis was studied between IIEF-5 to assess erectile dysfunction and FSFI assessing desire, arousal, orgasm, pain and sexual satisfaction and other collected data including patient's age, functional diagnosis and post void residual (PVR).

**Results:** The study included 13 total patients (8 female, 5 male) with mean age 47y (33-60). Diagnosis included non-obstructive urine retention (5), refractory overactive bladder (3), combined retention + over active bladder (OAB) (1), pelvic pain syndrome (3) and impotence in 1 patient. All male patients showed significant improvement in their IIEF-5 score from mean pre op  $7.8 \pm 5.7$  to post op score of  $19.8 \pm 2.3$  with significant p value  $p=0.003$ .

Female patients showed significant improvement in their FSFI total score from baseline of  $18.313 \pm 7.4$  to post-operative mean FSFI score  $26.7 \pm 1.8$  with p value = 0.013. Domains of FSFI which showed significant improvement were desire, arousal, orgasm and sexual satisfaction with p value = 0.002,  $p=0.01$ ,  $p=0.012$ , and  $p=0.015$ . Age, functional diagnosis and PVR did not show significant correlation with IIEF-5 and FSFI score.

**Conclusion:** Our results suggest that SNM might improve male and female sexual dysfunction regardless of patient's age and diagnosis. **Banakhar MA, Younos A. Sacral neuromodulation for lower urinary tract symptoms: effect of therapy on Saudi patient sexual function. Sex Med 2021;9:100388.**

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**KEY WORDS:** Sexual Function; Female sexual function index (FSFI); International index of Erectile function (IIEF-5); sacral neuromodulation; sacral nerve stimulation; Saudi patients with lower urinary tract symptoms

## INTRODUCTION

Lower urinary tract symptoms (LUTS) and sexual dysfunction have major effect on quality of life, with

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prevalence of the sexual dysfunction as per US National Health and Social Life Survey of about 43% in females and 31% in males.<sup>1-2</sup> In Saudi Arabia, sexual dysfunction prevalence was (83%) in males and (88.7%)<sup>3</sup> in females among diabetic patients which represent 23.7% of Saudi populations.<sup>4</sup>

Chronic medical conditions causing neurogenic bladder are associated with sexual dysfunction in men and women.<sup>5</sup> Erectile dysfunction was reported in multiple sclerosis (MS) men (50-75%).<sup>6</sup> Sexual dysfunction in MS females was higher (40-74%) than in general population.<sup>7</sup> In spina bifida females sexual dysfunction was present in 84%.<sup>8</sup>

Despite the advancement of the medical and pharmacological therapy, yet number of cases do not response to available treatment options. Recently non-pharmacological and minimally invasive procedure showed promising result in the management of LUTS and sexual dysfunction.<sup>9</sup>

Sacral neuromodulation (SNM) is FDA-approved non pharmacological therapy for certain bladder and bowel dysfunction, as refractory overactive bladder, frequency-urgency syndrome, and non-obstructive urinary retention.<sup>10-11</sup> Although, the mechanism of action still not fully understood, some studies suggest it has a positive impact on sexual function,<sup>9</sup> by stimulation of the third sacral root (S3), which eventually stimulate the pelvic organs.

In Saudi Arabia, SNM is a newly introduced therapy for lower urinary tract dysfunction symptoms.. The aim of the present study is to answer the question, “Does SNM have any effect on our patients’ sexual function?”

Our null hypothesis is that SNM therapy does not have any effect on sexual function both male and female.

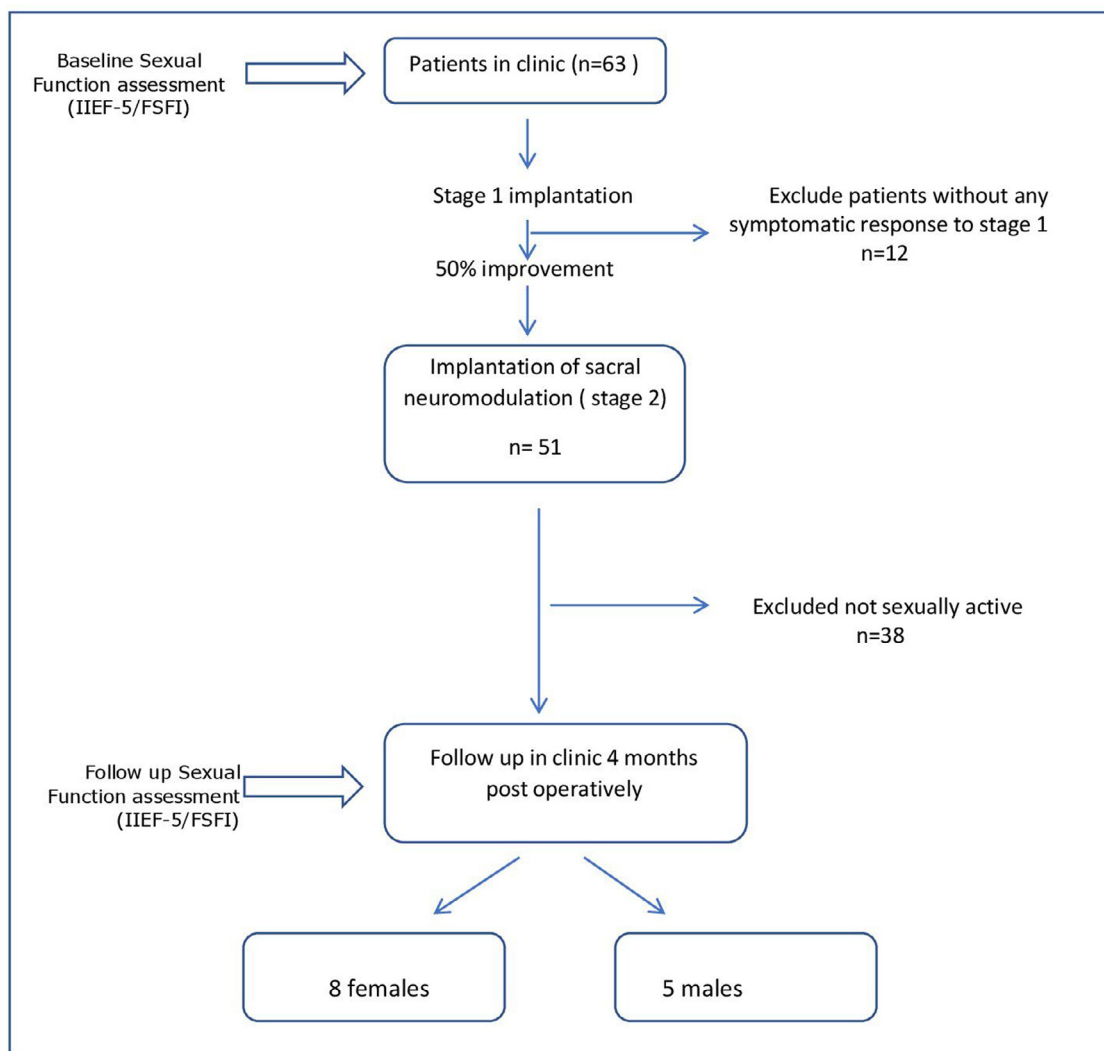
## MATERIALS AND METHODS

### Study design

We performed a prospective cohort study at tertiary hospital, Jeddah, Saudi Arabia from Jan 2016 till Jan 2020, after obtaining approval from Biomedical Ethics and research committee (Reference No 397-20). All patients gave written informed consent .

### STUDY POPULATION AND PROCEDURE

All patients underwent sacral neuromodulation therapy which is done in 2 stages using InterStim II (Medtronic, Minneapolis, MN, USA). In stage 1 procedure (trial phase at which we test the best responding nerve and do implantation of single tined, 4-electrode lead was placed into S3 foramen) after assessment of their baseline voiding diary, urodynamic assessment for their Functional diagnosis and sexual function assessment questionnaires during their clinic visit. After stage 1 procedure patients will fill a voiding diary for 2 weeks which will be compared to



**Figure 1.** Schematic representation of implanted, excluded and included in study, and time of assessment (baseline and 4 months post op).

the baseline diary before stage 1. If patient develop 50% improvement subjectively and/or objectively on voiding diary (improved voided volume/void, decreased frequency, better control of urine leak and decreased Post voiding residual PVR) they undergo implantation of the permanent Internal pulse generator InterStim II® (Medtronic, Minneapolis, MN, USA) called as stage 2 procedure. Postoperatively, patient will have their device programmed and will be taught how to use their programmer. Clinical follow up after one week to assure good wound healing and proper use of device. Further visit is 4 months latter to assure maintaining good response and assess effect of therapy on sexual function. During the second visit patients were asked to fill up sexual assessment questionnaires in waiting area and collected by nurses. We excluded patient with less than 50% improvement to stage 1 procedure and patients who are not sexually active [Figure 1](#). Patients demographics and patients PVR were collected in all patients.

## MEASURES

Sexual function was assessed using international index erectile function (IIEF-5) for men and female sexual function index (FSFI). Only Erectile Dysfunction was assessed in men, while many different sexual dysfunctions were assessed in woman using these questionnaires, which were filled up by patients at baseline and 4 months post Interstim device implantation.

In male patients we used the Arabic validated IIEF-5<sup>12</sup> with 5 questions with optional answers scored from 1 to 5, IIEF-5 score is the sum of answers score. IIEF scores were stratified into no ED (>22), mild (17–21), moderate (8–16), and severe ED (<7).<sup>13</sup>

In female patients we used Arabic validated<sup>14</sup> FSFI which include 19 questions covering 6 domains: desire, arousal, orgasm, vaginal lubrication, satisfaction and pain with score for each answer selected. The sum of each domain score is first multiplied by domain factor ((0.6 for desire, 0.3 for arousal, and lubrication and 0.4 for orgasm, satisfaction and pain) the sum of each domain after multiplication equals total FSFI score. Female Sexual Function index FSFI score less than 26.55 cannot diagnose sexual dysfunction; it may indicate risk. Other variables include age, gender, functional diagnosis and underlying pathology. Patient age was further categorized to 2 groups above 40y or below 40y and patient post voiding residual (PVR) at 1<sup>st</sup> filled voiding diary which was categorized into 2 groups more than 100ml or less than 100ml. Any increase in sexual function scores after implantation compared to baseline score was considered as “improvement.”

Primary endpoint was changes in sexual scoring. Secondary endpoint was any association between the calculated change in score (IIEF-5, FSFI) and age, age category, diagnosis and PVR.

All data from questionnaires were collected into excel sheet and further analyzed using software SPSS for Windows, version 26. (IBM Corp., Armonk, NY, USA). Descriptive statistics were reported as frequencies for categorical variables. Comparison

between preoperative and postoperative sexual function scores was performed using the paired t test. Correlation analysis (two-sided Pearson with two degrees of freedom) was used between sexual function scores difference and other patient parameters (age, functional diagnosis, PVR). Statistical significance was considered for p-values < 0.05.

## RESULTS

Total of 51 patients had sacral neuromodulation therapy of which 38 cases were excluded (not sexually active). The study included 13 total patients (8 female, 5 male) with mean age 47y (33-60), whom were further categorized into below 40y (5) and above 40y (8). Patient diagnosis included non-obstructive urine retention (5), refractory overactive bladder (3), combined retention +OAB(1), pelvic pain syndrome (3) and impotence in 1 patient. 6 patients had no underlying pathology (idiopathic), DM in 2, spinal cord injury in 2, myelitis in three patents. Complications included two electrode migration, one battery loss, 1 electrode damage and erosion in 2 patients ([Table 1](#)). All patients showed improvement in their post SNM implantation sexual index scores ([Figure 2](#) and [3](#)).

**Table 1.** Patient characteristic according to their gender

Gender	Male	Female
Number	5	8
Mean age	53 y (40-60)	42 y (33-55)
<u>Age</u>		
≤40	1	4
>40	4	4
<u>Functional Diagnosis</u>		
NOU retention	1	4
Refractory OAB	1	2
Retention +OAB	1	0
Pelvic Pain Syndrome	1	2
Impotence	1	0
<u>Underlying pathology</u>		
Idiopathic	2	4
D.M	1	1
Spinal Cord injury	2	0
Myelitis	0	3
<u>PVR (post voiding residual)</u>		
≥ 100ml	2	4
< 100ml	3	4
<u>Sexual scoring index</u>		
Improved	5	8
No improvement	0	0
<u>Complications</u>		
Electrode migration	2	0
Battery loss	0	1
	3	4
Electrode breakage	0	1
Erosion	0	2

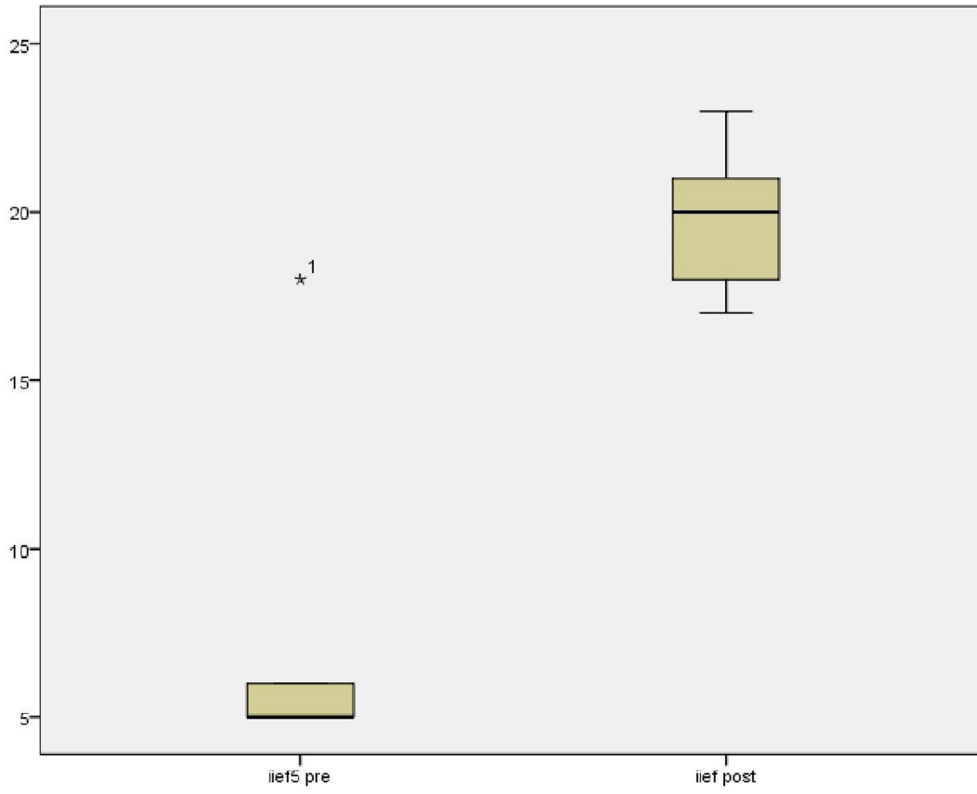


Figure 2. International Index Erectile Function (IIEF 5) score in male patients pre- and post-SNM.

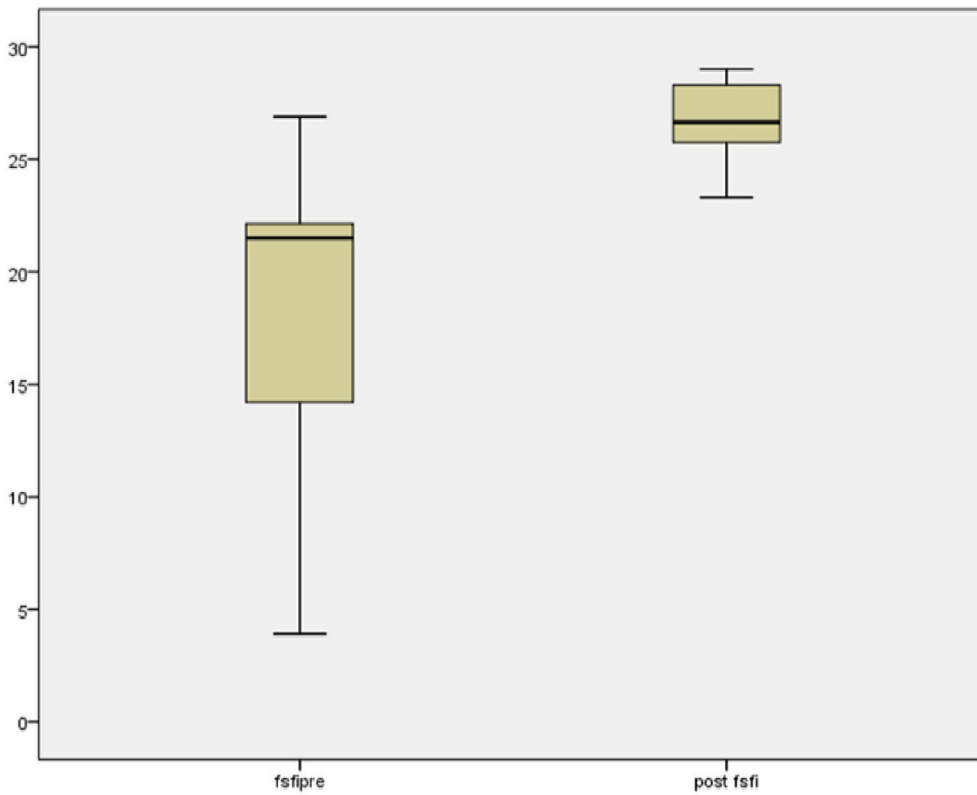


Figure 3. female sexual function index (FSFI) score in female patients pre and post SNM.

**Table 2.** Mean international index erectile function (IIEF-5) score followed by score details for all study included male patients (baseline and post SNM implantation)

Category n = 5	Baseline IIEF-5	Post SNM IIEF-5
Mean for all patients ±SD	7.80 ± 5.71	19.80 ± 2.38 (P = 0.003)
Patient 1	18	23
Patient 2	5	20
Patient 3	5	21
Patient 4	5	17
Patient 5	6	18

**Table 3.** Pearson correlation between change in IIEF-5 and age categories (<40>), functional diagnosis and PVR.

Category	Pearson correlation coefficient	P value
Age category	0.354	0.559
Diagnosis	0.404	0.500
PVR	0.743	0.150

PVR = post voiding residual.

Our male patients showed 4 had IIEF-5 score less than 7 and 1 had score of 18. Our study showed significant improvement in their IIEF-5 score from mean pre op  $7.8 \pm 5.7$  to post op score of  $19.8 \pm 2.3$  with significant p value ( $P = 0.003$ ) (Table 2). There was no significant correlation between the change in IIEF-5 scores and patients age, functional diagnosis nor PVR categories (Table 3).

Female patients showed significant improvement in their FSFI total score from baseline of  $18.313 \pm 7.4$  to post-operative mean FSFI score  $26.7 \pm 1.8$  with p value = 0.013. Domains of FSFI which showed significant improvement were Desire, Arousal, orgasm and sexual satisfaction with p value = 0.002,  $P = 0.01$ ,  $P = 0.012$ , and  $P = 0.015$  (Table 4a and 4b). Correlation analysis showed no relation between change in FSFI score and Age, diagnosis and PVR categories (Table 5).

When FSFI domains were correlated with age, functional diagnosis and PVR, significance was noted between age and both vaginal lubrication  $P = 0.023$ , pain  $P = 0.012$  and between PVR and pain p value 0.023 (Table 6).

## DISCUSSION

SNM proved its effectiveness in bladder and bowel dysfunction by stimulating the S3 nerve root, which is the same pathway that innervate the genital organs which raises a question for its

**Table 4b.** Female sexual function index score (baseline and post SNM implantation) for all study included female patients.

Patient	Baseline total FSFI	Post SNM implantation total FSFI
Patient 1	10.7	26.2
Patient 2	21.1	26
Patient 3	22.1	28.1
Patient 4	26.9	29
Patient 5	22.2	28.5
Patient 6	21.9	25.5
Patient 7	3.9	27.1
Patient 8	17.7	23.3

**Table 5.** Pearson correlation between change in Female sexual function index and age categories (<40>), functional diagnosis and PVR.

Category n=8	Pearson correlation coefficient	P value
Age	0.36	0.381
Functional diagnosis	0.346	0.402
PVR	0.579	0.132

PVR = post voiding residual.

effectiveness in sexual activities. However, its mechanism of action on sexual function remains poorly understood. Genital organs are innervated by autonomic and somatic nerves. the urinary bladder innervated by sympathetic nerves through the hypogastric nerve which lead to inhibition of the bladder wall contraction, and contraction of smooth muscle at the bladder base and urethra.<sup>15</sup> Sympathetic stimulation in male causes detumescence but also play a role in semen ejection to the posterior urethra,<sup>16</sup> in female it causes pelvic contractions with orgasm.<sup>17</sup> Voiding phase mediated by Parasympathetic innervation which cause bladder wall contraction. By stimulating of parasympathetic nerve, smooth muscle relaxation, vasodilation and high blood inflow occurred which lead to penile erection in male, vulvar and clitoral swelling in female.<sup>17,18</sup> Pudendal nerve provide somatic innervation which is responsible for transmission of sensation and pelvic wall contraction,<sup>17</sup> in men is also responsible for sperm ejaculation.<sup>16</sup>

Monitoring of the brain activity during SNM showed changes in activities in more sophisticated network of cortical centers rather than pons or periaqueductal grey matter which is well-known bladder control center.<sup>19,20</sup>

**Table 4a.** Female sexual function index score total and domains (baseline and post SNM implantation).

Category n=8	Total FSFI score	Desire	Arousal	Vaginal lubrication	Orgasm	Sexual satisfaction	Pain
Baseline	18.31 ± 7.4	2.4 ± 1.15	2.13 ± 0.9	3.8 ± 1.5	2.8 ± 1.3	3.2 ± 1.3	3.9 ± 2.1
Post SNM implantation	26.7 ± 1.8	3.6 ± 0.8	3.6 ± 0.6	4.5 ± 0.6	4.5 ± 0.6	4.7 ± 0.14	5.6 ± 0.4
P value	0.013	0.002	0.001	0.255	0.012	0.015	0.053

**Table 6.** Pearson correlation coefficient between FSFI domains and Age, age categories, functional diagnosis and PVR categories.

Categories	Corr (p value)	Desire	Arousal	Vaginal lubrication	Orgasm	Sexual satisfaction	Pain
Age		0.224 (0.594)	0.197 (0.64)	0.779 (0.023)	0.431 (0.286)	0.643 (0.086)	0.835 (0.012)
Age category		-0.186 (0.66)	-0.071 (0.868)	0.341 (0.408)	0.465 (0.245)	0.431 (0.286)	0.508 (0.199)
Functional diagnosis		0.088 (0.837)	0.150 (0.729)	0.221 (0.599)	0.376 (0.599)	0.481 (0.227)	0.498 (0.215)
PVR		0.322 (0.432)	0.244 (0.560)	0.542 (0.165)	0.345 (0.402)	0.668 (0.07)	0.779 (0.023)

corr = correlation coefficient.

Female Sexual dysfunction risk is defined as FSFI  $\leq$  26.55 in female and total IIEF-5 less than 22 in male. In the literature, the cutoff point in the FSFI and IIEF-5 score to determine clinical improvement is undetermined, for that we consider any increase in scores after implantation compared to baseline score as improvement. Neurogenic bladder has effect on sexual activity on both males and female patients.<sup>21,22</sup>

Our prospective cohort study demonstrates statistically significant improvement in IIEF-5 p-value  $P = 0.003$  in male patients. Lombardi et al.<sup>23</sup> showed that 45% of men with incomplete spinal cord injury who were submitted to SNM reached and maintained a normal IIEF-5 score for > 3 years. Also, Oliveira et al.<sup>19</sup> showed improvement on IIEF-5 that corresponded to a change in erectile dysfunction from moderate to mild but was statistically not significant.

Female Sexual Function index (FSFI) score less than 26.55 cannot diagnose sexual dysfunction; it may indicate risk, in our study we are assessing the effect on patients sexual function if it would be improved by sacral nerve stimulation (SNM). The total score and effect on sub scales of FSFI is reported. Female patients demonstrated significant improvement in their FSFI total score with p value = 0.013. Domains of FSFI which showed significant improvement were Desire, Arousal, orgasm and sexual satisfaction. Similarly, Zabihi et al.<sup>24</sup> reported a 53% improvement in all FSFI domain scores except for desire and pain. also, Oliveira et al.<sup>25</sup> showed some improvement in all domains, but only lubrication showed statistically significant improvement. Banakhar et al.<sup>9</sup> reported significant improvement in total FSFI and desire and orgasm domains.

Correlation between sexual function and other factor (age, functional diagnosis and PVR) were considered in our study, it was shown to have a strong correlation between sexual scores improvement and PVR but no significant correlation between them. Age and functional diagnosis showed weak correlation (Table 3 and 5). Regarding age and PVR our results were similar to Oliveira et al.<sup>25</sup> but defer in FSFI and functional diagnosis which showed significant correlation in their results.

Interestingly, we found significant correlation between age and FSFI domains vaginal lubrication and pain, and also between PVR and pain.

### Study Limitations

Our study included small sample size but this is not unexpected for a study of this nature, however it has the advantage of

prospective cohort study design, and the impact of SNM therapy on patient sexual function. Another limitation to our study is that we assessed neither relationship status nor vascular issues in these patients.

Also sacral neuromodulation therapy is implanted after more than 50% response to stage 1 SNM and patients with < 50 response were excluded in our study so this is not a treatment likely to benefit all similar patients.

### CONCLUSION

Our results suggest that sacral neuromodulation might improve male and female sexual dysfunction regardless of patient's age, functional diagnosis and PVR.

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*Conflict of Interest:* The authors report no conflicts of interest.

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### STATEMENT OF AUTHORSHIP

Mai Banakhar: design, writing, ethical approval request, statistical analysis, review, writing methodology and results; Ayman Younos: data collection, writing introduction and discussion.

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