

Sacral neuromodulation implanted patients: Patient concerns during the COVID-19 pandemic and practical modifications

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Abstract

Objective: To study the effect of the COVID-19 pandemic on sacral neuromodulation (SNM) implanted patients and examine patient concerns.

Methodology: A web-based survey was sent to all SNM patients, including those with implants and who had a cancelled operation because of the pandemic. The survey consisted of 15 questions in Arabic language, which sought to evaluate outcomes, as well as patient concerns and preferences during the COVID-19 pandemic.

Results: A total of 66 patients were contacted, and of which, 62 replied. Most of the patients ($n=51$; 82.3%) had the device implanted, and 11 (17.7%) patients had a postponed operation secondary to the pandemic. There were 20 males and 42 females. The mean age was 34 years \pm SD 16.5 (9–62 years). Indications for sacral neuromodulation therapy were refractory overactive bladder OAB 35 (56.5%), retention 17 (27.4%), OAB + retention 3 (4.8%). When questioning the effect of the lockdown on patients, most reported no effect (43.5%), while 14.5% had some programming difficulties. The patients preferred telephone calls for device emergencies and clinic follow-up with 88.7% and 98.4%, respectively. Most patients had no concerns regarding their Interstim device during the pandemic and found it manageable; 8.1% had insurance concerns due to the economic changes.

Conclusion: Patients with implanted SNM for lower urinary tract symptoms were mainly concerned with device programming. Telemedicine is a great solution for continuous care in this group.

Keywords: COVID-19 lockdown, lower urinary tract symptoms, patient concerns, practical modifications, sacral neuromodulation

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Introduction

The healthcare system has faced many challenges throughout the COVID-19 pandemic. COVID-19 was first reported as pneumonia from Wuhan, China.^{1,2} By March, the World Health Organization announced that COVID-19 was a pandemic with a recommendation that all countries take immediate action.³

The pandemic led to many changes in healthcare, with treatment priority given to those with urgent medical conditions. Urology practice was affected

as emergency and oncology patients were prioritized.⁴ Patients with lower urinary tract symptoms were delayed management until the pandemic was under control. Treatment for patients with urinary incontinence, non-obstructive retention, frequency urgency, operative interventions were all postponed.

Sacral neuromodulation (SNM) therapy involves implantation of an electrode and battery. This is performed in two phases with 2 weeks between them. The first phase is

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electrode implantation under fluoroscopy. Patients need to complete a voiding diary prior to surgery and during the test period (after phase I). When patients show $\geq 50\%$ improvement, the second operation (phase II) is done for battery. This procedure needs further programming to initiate the benefits of therapy. Both procedures (phases I and II) are performed under general anesthesia in our center. However, programming sessions might require several repeated attempts until the best program for symptom control is defined. Complications of SNM include loss of efficacy, battery depletion, as well as electrode migration, breakage, and erosion. These require surgical intervention.

Sacral neuromodulation was introduced in Saudi Arabia in the last 10 years. As any new introduced therapy, close patients care, frequent programming, and good follow-up is needed. The COVID-19 pandemic caused Saudi Arabia to announce a lockdown, and elective operations were postponed to reduce the risk of patients being exposed to COVID-19. The International Neuromodulation Society has published several reports on postponed Interstim cases because of the COVID pandemic. We conducted our study to assess the impact of COVID-19 lockdown on sacral neuromodulation implant patients in our center.

Materials and methods

This study was approved by our hospitals ethics review board (Unit of Biomedical Ethics Research Committee of King Abdulaziz University, **Approval number:** Reference No 395-20), and written informed consent, was obtained electronically from patients. A web-based survey consisting of 15 questions in the Arabic language was sent to patients assessing the effect of the COVID-19 lockdown on both implanted and booked patients whose operation was postponed due to the lockdown. The survey evaluated the effect of lockdown from March 2 to May 30, 2020. The questionnaire assessed patient demographics, COVID-19 infection status, insurance service, clinic follow-up preference, potential effects on therapy, programming issues, and lockdown concerns. The questionnaire was developed using Google documents. The hospital secretary contacted both implanted and patients whose operation was cancelled. The questionnaire was sent over social media (WhatsApp) and reminder was sent to patients two weeks later. Parents of

paediatric patients provided consent on behalf of their children and also completed the survey.

Data was collected and exported as Excel sheets; it was then coded for statistical analysis using IBM SPSS 26 software. *p*-values below 0.05 were considered statistically significant. Data were reported as frequencies in each question and reported as a percentage.

Results

A total of 62 out of 66 patients completed the questionnaire. Most patients, 51 (82.3%), already had the device implanted before the pandemic, while 11 (17.7%) patients had the operation postponed secondary to the COVID-19 lockdown. Most patients were from the public sector, 44 (71%); there were 12 insurance cases (19.4%) and six cash patients (9.7%). There were 20 men and 42 women. The mean age was 34 years \pm SD 16.5 (9–62 years). Indications for SNM therapy were refractory overactive bladder (OAB) 35 (56.5%), retention 17 (27.4%), OAB and retention three (4.8%), pelvic pain syndrome five (8.1%), others two (3.2% including erectile dysfunction). At the time of completing the questionnaire, only one patient was COVID-19-positive with mild symptoms.

When questioning the effect of the COVID-19 lockdown on patients, most reported no effect (43.5%) while 14.5% had some programming difficulties, and 17.7% cancelled their operation. Programming is usually done by company personnel, and most patients preferred to delay their programming sessions (32.3%); 25% agreed to programming while following COVID-19 precautions. Patients preferred telephone calls and virtual clinic for both emergency issues with the device and clinic visits for follow-up (88.7% and 98.4%, respectively). Patients preferred to delay their implantation and surgical intervention (88.7%) and preferred other less effective alternative therapies (intermittent catheterization in the retention group and using multiple anticholinergic medications in refractory OAB despite limited benefit). A total of 69.4% of cases there was a preference for general anesthesia (56.5%) over local anesthesia (43.5%) for surgical intervention. Most patients had no concerns regarding their implanted device during the pandemic; they found that it was manageable, but 8.1% had concerns regarding insurance coverage issues; 9.7% were concerned about the time delay until

Table 1. Patient demographics, diagnosis, health sector, answers to effect of lockdown, programming and clinic preference and preference of using other medications.

Diagnosis	Urine retention	Refractory OAB	OAB + retention	Pelvic pain	Others	Total
Number	17	35	3	5	2	62
Health sector						
Insurance	8	3	1	0	0	12
Cash	0	6	0	0	0	6
Public	9	20	2	5	8	44
Effect on SNM implanted patients						
Delay operation	3	5	3	0	0	11
Programming issues	4	5	0	0	0	9
No effect	1	13	0	5	8	27
Miss clinic follow-up	9	6	0	0	0	15
Prefer use other treatment						
Yes use other medication	4	23	3	5	8	43
No	0	2	0	0	0	2
No need	13	4	0	0	0	17
Programming options						
Delay programming	5	6	0	5	4	20
Yes do it with precautions	0	12	0	0	4	16
Don't know (don't need it)	12	11	3	0	0	26
Clinic follow-up visits						
Telemedicine	16	35	3	5	2	61
Physical attendance in clinic	1	0	0	0	0	1

OAB, overactive bladder; SNM, Sacral nerve stimulation.

COVID-19 issues were resolved (Tables 1 and 2; and Figures 1 and 2). There were no reported complications by any patient during the 3-month lockdown.

Discussion

This paper presents the results of a survey study examining the effect of the COVID-19 pandemic on patients who underwent SNM surgeries and programming at a single clinical center in Saudi Arabia. The survey specifically asked about care

during a 3-month lockdown window from March to May 2020.

Most SNM implanted patients reported no effect on their condition (43.5%), but programming was a major problem in 14%. Programming requires direct contact with trained personnel, which poses an infection risk, and 32.3% of patients preferred to delay their programming session or used alternative therapy to cope with their condition (43%). During the lockdown period, no patients developed any erosion,

Table 2. The questionnaire sent to patients translated into English.

What is your implantation status?	<ul style="list-style-type: none"> • Implanted • Booked for operation
Which sector category is your therapy?	<ul style="list-style-type: none"> • Public • Insurance • Cash
What is your gender?	<ul style="list-style-type: none"> • Male • Female
Age of patient	<ul style="list-style-type: none"> • Age in years
What was the indication for your SNM implantation?	<ul style="list-style-type: none"> • Urine retention • Refractory overactive bladder • Retention + OAB • Pelvic pain syndrome • Others
What is your COVID-19 status?	<ul style="list-style-type: none"> • Positive • Negative
What was the effect of COVID-19 pandemic on your SNM therapy?	<ul style="list-style-type: none"> • No effect • Programming issue • Delayed operation • Missed clinic follow-up
If you need programming what would you prefer?	<ul style="list-style-type: none"> • Refuse programming and rather delay it for later • Yes can do programming with precautions • I don't know I don't have any programming problem
What do you prefer for your clinical follow-up during the pandemic?	<ul style="list-style-type: none"> • Phone call • Physical clinical visit
What is your preference if you develop SNM-related emergency during the pandemic?	<ul style="list-style-type: none"> • Phone call • Emergency room visit
If you need surgical intervention for your SNM during the pandemic what is your preference?	<ul style="list-style-type: none"> • Delay it later • Yes I can undergo operation
If your SNM is not working properly do you prefer to use other less effective medial options?	<ul style="list-style-type: none"> • Yes • No • I don't know I don't need
Did you develop any complications related to your SNM?	<ul style="list-style-type: none"> • Yes • No
What type of anesthesia do you prefer if you will undergo operation during the pandemic?	<ul style="list-style-type: none"> • General anesthesia • Local anesthesia
What are your concerns of your therapy during pandemic?	<ul style="list-style-type: none"> • Insurance-related issues • Long waiting time
OAB, overactive bladder; SNM, Sacral nerve stimulation.	

infection, or electrode issues. Other concerns regarding clinical visit were managed as recommended in all health sectors, by telemedicine and virtual clinics, which was our patients' preference

(98.4%). Telemedicine or virtual clinics are good tools for healthcare follow-up without any personal contact, as reported by Miller *et al.* and Katharina *et al.*⁵⁻⁷

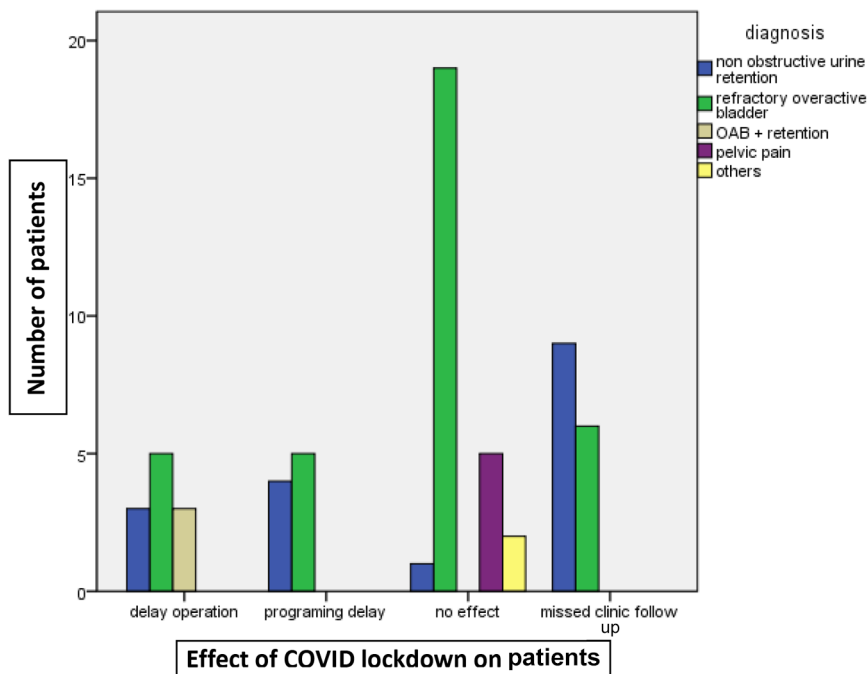


Figure 1. Bar chart showing the effect on SNM (sacral nerve Stimulation) implanted patients (delay operation, programming delay, no effect, missed clinic follow-up) categorized according to patient diagnosis.

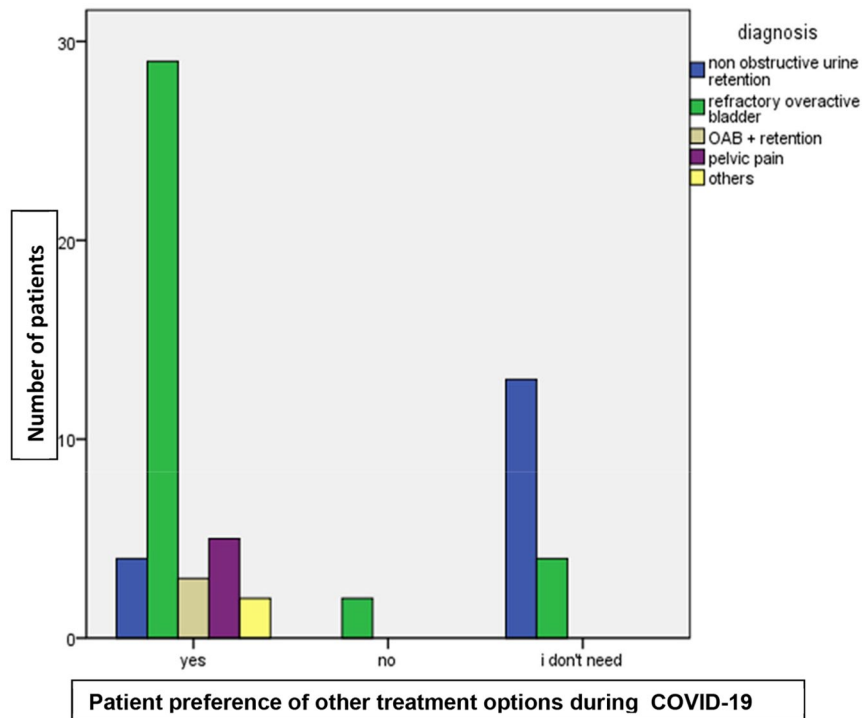


Figure 2. Bar chart shows the patient preference of other treatment during COVID-19 lockdown (yes: prefer to use other treatment; no: don't need) categorized according to diagnosis.

Sacral neuromodulation is an FDA approved therapy for refractory overactive bladder,⁸ frequency urgency syndrome and non obstructive urinary retention.⁸⁻¹⁰ It showed to be effective in other off label uses as chronic Pelvic pain,¹¹ in neurogenic bladder.¹² Anne *et al.* and Mahran *et al.* reported its use in pediatric patients and in pregnancy^{13,14} Pediatric sacral neuromodulation is not FDA approved but showed favourable results in multiple studies.¹⁴ In our study we included pediatric cases who were implanted for refractory overactive bladder and urinary retention, neurogenic bladder secondary to spina bifida.

Bekkers and Koopman¹⁵ and Evenett *et al.*¹⁶ predict the COVID-19 pandemic will have major effects on the world economy, which might affect patient decisions. As sacral neuromodulation can be an expensive option, our patients had concerns about private insurance coverage in the future.

Study limitations include the single center and small sample size, included in the study. It would be preferable to increase the sample size and perform a multicenter study, worldwide. The questionnaire is also not validated, and the authors want to consider this in the future. The age range of our patients is 9–62 years as the use of this therapy in children is relatively, which limits the generalizability of the results.

Conclusion

We found that patients with implanted SNM for lower urinary tract symptoms were facing major issues with device programming during the COVID-19 lockdown.

Consent

All patients gave written consent, parents of paediatric patients gave consent on behalf of children.

All consents were obtained electronically.

Author contributions

Mai Banakhar: data collection, design, writing; ethical approval request: statistical analysis; review.

Conflict of interest statement

The author(s) declared that there is no conflict of interest.

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