Brief Report

Outcomes of Implementation of Sacral Nerve Stimulation in Incontinent Patients in Shiraz

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Abstract

Background: Fecal incontinence is a common disorder in old age; however, it may not threaten life, but it can cause morbidity and many problems. Sacral nerve stimulation (SNS) is a minimally invasive surgical procedure performed by chronic electrical stimulation of the nerves in the sacral plexus through a lead implanted at the S3 foramen. This study aimed to evaluate the outcomes of SNS in Shiraz. **Materials and Methods:** Data from patients who underwent implantation of an SNS device from 2012 to 2018 were reviewed in Shiraz. Thirty patients who had incontinence were evaluated by a committee. Pre- and postoperative assessments of the severity of incontinence were performed using Wexner Incontinence Score. Statistical analysis was performed using paired *t*-test. **Results:** Twenty-seven patients proceeded to insertion in the temporary SNS, and of these, 16 were elected to have a permanent SNS. Finally, seven patients were satisfied with their treatment. There was a significant reduction in the pre- and post-SNS Wexner Incontinence Scores from a median of 15–10, respectively ($P < 0.05$). **Conclusion:** In our study, 16 patients underwent SNS protocol, and 43.7% of them showed a good response and recovered. It is recommended as a method for the treatment of fecal incontinence. Permanent SNS is effective, showing a significant improvement in fecal incontinence scores.

Keywords: *Fecal incontinence, incontinent, sacral nerve stimulation*

Introduction

Fecal incontinence is the inability to control feces, leading to embarrassing symptoms of leakage of stool and flatus and soiling. This has substantial economic implications on individuals, family members, and the health-care system.[1] The etiology of fecal incontinence is multifactorial, and obstetric trauma is one of the most common causes. Sphincter damage after perineal surgery and degeneration of the sphincter muscles may cause incontinence. Furthermore, neurological conditions such as pudendal nerve neuropathy, diabetes mellitus, multiple sclerosis, traumatic spinal cord injuries, and congenital anorectal malformations may cause incontinence.[2] Changes in lifestyle and dietary habits such as bulking and antidiarrheal agents and biofeedback could improve the symptoms of fecal incontinence. However, these conservative treatments are effective in more than half of the patients, but surgical alternatives (sphincter repair, conventional and dynamic gluteoplasty, graciloplasty, antegrade continence enema procedures, artificial anal sphincter, and colonic conduit formation) can be considered in a number of them.[3] Failure of these treatment options often results in considering a permanent colostomy for the patients.

Sacral nerve root stimulation (SNS) was first developed in 1979 and used as a treatment for fecal incontinence in 1995 by Matzel *et al*.[4] Currently, the mechanism that underpins the efficacy of SNS for fecal incontinence is not well understood. Equally underlying physiological or biomechanical changes that could explain the alteration in the efficacy or adverse stimulation effects remain elusive. The clinical effect may be due to voluntary somatic, afferent sensory, and efferent autonomic motor stimulation achieved by sacral nerve root stimulation.[5] In addition, the pelvic part of the sympathetic chain and large myelinated alpha motor neurons that innervate the external anal sphincter and levator ani muscles is also stimulated. The resulting neuromodulation probably results in a change in the sphincter function, hindgut function, or a combination of

How to cite this article: Bananzadeh A, Hosseini SV, Izadpanah A, Izadi A, Khazraei H, Zamani M, *et al.* Outcomes of Implementation of Sacral Nerve Stimulation in Incontinent Patients in Shiraz. Adv Biomed Res 2019;8:21.

Received: October, 2018. **Accepted:** January, 2019.

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Access this article online

Website: www.advbiores.net

DOI: 10.4103/abr.abr_202_18

Quick Response Code:

these, leading to improved continence.[6] Initial promising results prompted a rapid uptake across specialized centers in Europe, and its efficacy in the short and medium terms is favorable in comparison to other surgical treatments.[7,8]

Reports on long-term follow-up of more than 5 years are starting to emerge although the number of patients has remained small.[9,10] Most studies that have reported the outcome after permanent SNS implantation have been cross sectional with a mixed group of patients and varied follow-up periods. However, this effect has not yet been evaluated in Shiraz. Here, we investigated the outcomes of SNS in patients who had undergone implantation and assessed the incontinence scores following permanent implant placement.

Materials and Methods

This study was performed in Shahid Faghihi Hospital, Shiraz, during September 2012–May 2018 and approved by Shiraz University of Medical Sciences Ethics Committee. All incontinent patients were screened by a colorectal surgeon. They were introduced to the committee members including colorectal surgeons, urologists, and nurses for selecting the candidates based on the inclusion and exclusion criteria, and finally, written consents were obtained after explaining the aims of the study.

The patients were selected for temporary external stimulator placement as peripheral nerve evaluation (PNE) before permanent surgery, and the response was evaluated by expert opinion. Some of them were the candidates for insertion of tined lead, which is a part of the permanent device. Biofeedback exercises of the anal sphincter were suggested and explained to some patients, and after 6 weeks, the same tests and evaluations were performed. Data including demographic data and improvement of incontinence after and during the PNE period were collected. Preoperative investigations included colonoscopy, electromyography (EMG) and urodynamic study, endoanal ultrasound and anorectal manometry, and Wexner Incontinence Scores. Postoperatively and after PNE, endoanal ultrasound or anorectal manometry and Wexner Incontinence Scores were obtained. Patients with >50% reduction of incontinence score in the first 2 months of follow-up were selected for permanent external stimulator placement. Those with adverse events and suboptimal therapeutic responses related to the SNS were referred to additional clinical management.

Inclusion criteria

The inclusion criteria of this study were as follows: (1) age between 20 and 60 years, (2) existence of urine or fecal incontinence, (3) intact external sphincter and levator ani muscles by anal endosonography and/or magnetic resonance imaging, (4) existence of no other ways for treatment of incontinent patients according to neurology and neurosurgery consultation, (5) existence of healthy emotional status confirmed by psychiatry consult, and (6) ability to use SNS device and report defecation habits.

Exclusion criteria

The exclusion criteria of this study were as follows: (1) complete pudendal nerve damage shown by EMG/nerve conduction study or nonrepairable destruction of the external sphincter and levator ani muscles such as complete spinal cord injury, (2) history of irritable bowel syndrome or inflammatory bowel disease, (3) pregnant patients, (4) history of a congenital anorectal disorder, (5) mental disorders confirmed by psychiatry consultation, (6) history of anterior resection or rectal prolapse, (7) active skin infection, bed sore, or existence of untreated pilonidal cyst, and (8) severe immune deficiency.

Technique

PNE is a form of neuromodulation that will demonstrate whether the patient will benefit and, therefore, be a candidate for a permanent electrode implant. Under a local or general anesthesia and prophylactic antibiotic in the prone jackknife position, the needle electrode was inserted through the skin and advanced to the S3 foramina. A Medtronic (Model No. 3023) (pulse width: 210 μs and frequency: 14 Hz) stimulator was inserted in a subcutaneous pocket created above the iliac bone. It was connected to an extracorporeal pulse generator using the attachment, and the current was switched on, giving the maximum perianal spasm and toe flexion in 15–21 days. Then, the electrodes for the permanent implant were placed in the same foramina maximum during 3 months after the test to mimic the response achieved. In this stage, the occurrence of complications of the applied procedure was evaluated by the surgeon.

After the operation, the occurrence of the following complications was assessed: local pain, bleeding, deep venous thrombosis, infection of the surgery site, hospital infection, and movement and position change of generator and lead. Patients were discharged following temporary implantation on the same day and after placement of the permanent ones.

Wexner Incontinence Score was used to quantify the severity of incontinence and assessed at 6 months and 2 years of postoperative follow-up. Before discharge, the patients were consulted by the senior author, and the stimulator programmed to the amplitude just below the threshold for individual patient sensation. These patients received continuous attention and input through regular follow-ups and were given direct contact with the surgeon.

Statistics analysis

Statistical analysis was performed using SPSS (version 16.00, Washington, USA). Data were presented as the mean ± standard deviation. Paired *t*-test was used for data comparison. $P < 0.05$ was considered statistically significant.

Results

Thirty fecal incontinence patients were identified and referred to the colorectal clinic (20 males and 10 females, mean age: 40 years [range: 22–74 years]). Eighteen male and 9 female patients underwent PNE from October 2013 to May 2018 according to the preoperative assessments. Three out of 30 patients (10%) were not suitable for consideration of a sacral nerve stimulator and underwent biofeedback therapy. Sixteen patients were satisfied during PNE and had permanent implantation and five patients had their device explanted or switched off permanently; one of them postponed an implantation because of abscess, and wound infection led to chronic discharge. Hence, the equipment was removed. Finally, 7 patients (43.7%) were satisfied with their permanent implantation [Table 1].

Most of the patients considered for temporary placement of SNS had previously undergone perianal surgery, ranging from anal sphincter repair, hemorrhoidectomy, and anal pull through. There are some etiologies for these patients, as shown in Table 1.

The overall Wexner Incontinence Score improved significantly from the baseline; a median of 15 (range: 6–20) reduced to 10 (range: 0–20) after 6 months ($P < 0.05$). The device required reprogramming in 50% of cases; however, this was usually performed at an outpatient appointment. Manometry parameters were reported as: range of squeezing pressure: 84–97, range of resting pressure: 12–46 and mean pressure were in the range of 24–50 mmgH.

Pre assessments showed that colonoscopy due to altered bowel habit was done, and all of segments were normal without proctitis. EMG examination of all the tested quadrants of the anal sphincter was normal. There was no definite electrical evidence of a neuropathy and myopathy in the anal sphincter and no definite evidence of active neurogenic proven in the anal sphincter (in mild partial sphincter injury, EMG may be normal). In two patients with chronic partial

Table 1: Demographic characteristics of the patients underwent peripheral nerve evaluation

No	Age	Sex	Etiology for SNS	SNS (yes, no just PNE) status	Wexner Incontinence Score after 2 years of surgery
1	43	Female	Complete fecal incontinence	No SNS	
2	37	Female	Complete fecal incontinence	Yes SNS	0
3	34	Male	Complete fecal incontinence	Yes SNS but remove due to abscess after 6 months	
4	22	Male	Hirschsprung's disease	Yes SNS but remove due to unknown chronic diarrhea	
5	76	Female	Complete fecal incontinence	No SNS	
6	43	Male	Cord injury		
7	40	Female	No defined	Yes SNS	0
8	25	Male	Spinal cord injury (lumbar fracture)	No SNS	
9	25	Female	Neurogenic bladder (hypo-contractive and low compromise)	Yes SNS	1
10	22	Female	fecal incontinency, urinary retention and CSNS dysfunction	Yes SNS but one lid should be implant after off	
11	28	Male	Detrusor-external sphincter dyssynergia	Yes SNS but off	
12	51	Male	Spinal cord injury (lumbar fracture)	3 years ago that was failed and was removed due to infection, SNS	
13	74	Male	Spinal cord injury (lumbar fracture)	No SNS	
14	40	Male	Cauda equina syndrome	No SNS	
15	40	Male	Diabetes mellitus Sphincteroplasty	No SNS	
16	41	Male	No defined	Ok	2
17	39	Male	No defined	Ok Gas passing daily	4
18	42	Male	No defined	Ok	1
19	38	Female	No defined	Yes SNS	1
20	40	Female	No defined	Yes SNS	3 (new case)
21	40	Female	No defined	No SNS	
22	36	Male	No defined	No SNS	
23	44	Male	No defined	No	
24	39	Male	No defined	Yes SNS	2 (new case)
25	41	Male	No defined	Yes SNS	1 (new case)
26	40	Male	No defined	No	
27	40	Male	No defined	Yes SNS, remove to car accident	

SNS: Sacral nerve stimulation, PNE: Peripheral nerve evaluation, CSNS: C-sacral nerve stimulation

neurogenic process involving the anal sphincter, nerve injury was not complete. The urodynamic study revealed mild-to-normal sensation, capacity, and compliance. In one patient, a significantly decreased sensation, high capacity, flaccid motor, and sensory nerve were seen. In the rectal examination, weak sphincter squeezing and resting pressure were seen, and sacral dermatome and sensory sensation of the perineum were absent. In endorectal sono, no significant perianal disease, internal sphincters, and fragmented deep part of the external sphincter were found. In defecography, the angle at rest was 80°; there was no incontinency pattern in the rectoanal angle. Small bowel contrast study revealed that the small bowels were normal in direction and diameters down to the beginning of the ileum, where the diameter of the ileal loops was reduced; although the ileal loops were narrowed, mucosal pattern was preserved. The transit time was in the normal range.

Morbidity

For some patients there was problem with device for example, two months later fecal incontinency occurred or 1 month later urinary retention and C-sacral nerve stimulation (CSNS) dysfunction were seen and SNS program revision was done for them, it was found that there were angulations in the wire of CSNS and there was no CSNS in its site where the wire angulations were resolved. One patient was a case of neurogenic bladder (hypocontractive and low compromise). In the micturition test, neurogenic detrusor hypocontractibility had been diagnosed 1½ years ago. There was no morbidity from the procedure itself; however, there were some technical failures reported with two patients having wire failure due to wire dislodgement and one patient suffering from battery failure.

Discussion

SNS is now established as a safe procedure that offers a unique opportunity to select appropriate patients through a temporary trial before permanent implant placement. Our results were in line with the patients' expression of satisfaction which was subjectively assessed. There are many reports in patients with neurological deficit for whom this method was used and controversy was seen in the reports, but some beneficial effects on the bowel, bladder, and sexual function have been shown.[7,11] This report is the preliminary description of a Phase I clinical trial in evaluating the safety and efficacy of SNS implementation in patients with incontinence in Shiraz.

Ripetti *et al*.[12] revealed an increase in maximal squeeze pressure in manometries after SNS. Furthermore, Fariello[13] showed, in a review article, the positive effects of SNS on the bowel, bladder, and erectile function. SNS stimulates the pelvic and pudendal nerves and perineum muscles, which play an important role in the bowel and bladder function. Stimulation was done on the afferent sensory pathway,[14,15] which may modulate the patients' perception of stool coming down into the rectum and/or anus and improve their ability to defer defecation.[16]

Here, we reported three patients with spinal cord injury, who had undergone implantation of permanent stimulation to exert sacral nerve neuromodulation. Outcomes of Wexner Incontinence Score showed higher satisfaction of defecation. There is no evidence as yet to suggest why some patients do not gain sufficient benefit to warrant permanent implantation. In our series, 7 out of 16 patients (43.7%) had marked improvement in incontinence scores with temporary wire placement, leading to permanent implant placement.

Jarrett *et al*., in a systematic review of published literature, found that 56% of 266 patients proceeded to the permanent implant.[6] Uludag and Baeten, Jarrett *et al*., Rosen *et al*., and Leroi *et al*. had permanent implantation rates of 77%, 78%, 80%, and 55%, respectively.[6,17-19] This shows that our rate was within the previously reported range (74%) and variation in the selection of patients caused these differences. Quality of life was not assessed as a part of routine follow-ups. Improvement of the quality of life of incontinent patients with this SNS procedure has been shown in some recently studies.[20,21] Improved continence scores have been reported by different scales of measurement (Wexner Incontinence Score and Cleveland Clinic Incontinence Scores)[22] with variable number and length of time of the follow-up in patients, and these can make valid comparison of the studies difficult. Our study showed a significant reduction in Wexner Incontinence Score from median 15–10 ($P < 0.05$). This is comparable with other studies that showed a similar reduction in scores from a range of 12–18 to 1–10.[22]

One possible explanation is that a period of up to 6 months may be required for the patient to adjust and establish cortical alteration by chronic stimulation despite the observation that sensation of stimulation around the anus is immediately achieved after switching on the device. It is also interesting to note that the overall improvement in the incontinence episodes was not a predictor of the long-term favorable outcome. In two patients, there was an initial surgery 1 month before SNS. Two years ago, SNS with the test (PNE) and tined lead was done for the patient (change PNE to tired lead because of difficult foremen insertion finding and abdominal anatomy). After that during 1 month, the insertion of the permanent stimulator was done. One patient had a history of SNS for 3 years that had failed and had been removed 4 months before the second admission for SNS. This suggests that the mechanism of SNS may not be an actual augmentation of the sphincter function or any other mechanical prevention of leakage, but it is indeed modulation of urgency perception to allow the patients' sufficient time to reach the toilet.

This study showed that the favorable outcome of SNS for fecal incontinence was achieved by just over 40%

of patients who had been considered for this treatment. The results suggested that more detailed assessment of the symptom components, particularly during PNE and the first 6 months after implantation, may give us a better view on the prognosis of the therapy. These data may be used in the future decision-making, particularly in terms of patient selection during PNE and potentially earlier surgical intervention when the treatment efficacy is lost; this helps to identify those who may benefit more from this treatment and increase the chance of successful outcomes in the long term.

Limitations

The follow-up was performed on the basis of incontinence scores. Although this is a useful tool, there are symptoms that are not well captured with the score such as the degree of urgency and use of incontinence pads. The small sample size is an inherent problem with our study. Although the success rates are good, longer-term efficacy needs to be further evaluated.

Conclusion

Twenty-seven patients from 2012 to 2018 underwent PNE; finally, 16 patients had SNS implantation and 7 of them were satisfied after 2 years at least. This study has shown that the use of SNS for fecal incontinence results in significant improvement in incontinence.

Acknowledgment

The authors would like to thank Professor Pakravan for his technical advice and colorectal clinic technicians for their assistance.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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