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Successful Needle Stimulation of S3 Nerve is a Safe Predictor of SNS Implant Outcome

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1. Abstract

1.1. Background

The sacral nerve stimulation is widely accepted as a standard surgical procedure in the treatment of fecal incontinence. Our study is designed to simplify the process to make it less cumbersome and more cost effective.

1.2. Objective

The primary object of the study is to determine whether the simple procedure of needle stimulation of S3 nerve will predict a successful outcome with sacral nerve stimulation full system implant.

1.3. Design

The study is a retrospective analysis of a group of patients undergoing needle stimulation of S3 nerve, if successful, then proceeding directly to sacral nerve stimulation full system implant.

1.4. Settings

All patients in this study group did undergo the procedure in our outpatient ambulatory center with primarily Propofol anesthesia, with few patients undergoing the procedure with local anesthesia only.

1.4. Patients

There were 136 female and 7 male patients entered in the study over a period of five years. They were followed from six months to sixty months after the full system implant.

1.6. Outcome Measures

The restoration of continence and reduction in the incontinent episodes were measured using Wexner Incontinence Score, Fecal Incontinence Quality of Life measures (FIQoL).

1.7. Results

88% of the patients who chose to undergo sacral nerve stimulation full system implant reported excellent outcomes measured by significant clinical symptomatic improvement and quality of life measures (Wexner Incontinence Score and FIQoL). However, five patients did not have any noticeable clinical symptomatic improvement. Ten patients had improvement with just over 50% reduction in their incontinent episodes. These patients did undergo further treatment with multiple sessions of reprogramming the InterStim unit. The follow up period ranges from six months to sixty months.

1.8. Conclusion

Even though the study population is small, the correlation between S3 nerve needle stimulation and successful sacral nerve stimulation full system implant is very evident and well documented in our study.

2. Introduction

Fecal incontinence is the most emotionally devastating of all non-fatal conditions [1]. The true incidence of fecal incontinence is not clear. A comprehensive study by Nelson et al in 1995 found that fecal incontinence affects around 2.2% of the population, and 10% of those patients' exhibit severe symptoms. The recent study quoted by Giuseppe Chiariaoni revealed fecal incontinence was reported by 36.2% of patients in their group, and only 2.7% of those patients had a medical diagnosis of fecal incontinence [2]. The fecal incontinence has a significant impact on the quality of life, health expenditure, and may facilitate placement of older patients in nursing home facilities. The SNS was first introduced in Europe in 1995 and cleared by the FDA in the United States in 2012. Since then, sacral nerve stimulation has become the first line of surgical treatment for

fecal incontinence, failing conservative therapy [3]. The simple needle stimulation of the S3 nerve came into routine use after noticing a significant number of patients in our warm to hot climate failing to tolerate the lead wires being left in for any length of time following the basic InterStim stimulation. These leads were fully covered, bandaged with waterproof dressing on top, and with instructions not to disturb or remove it. These patients were unable to clean themselves for fear of potential contamination of the wires and possible infection. In addition, there is a cumbersome detailed care of the lead wires that poses a significant problem for a number of our patients. Because of the hot weather, they were unable to keep the wires for more than a day or two. Very few patients have left the dressing in place for less than one week. When the dressing is removed, the wires were already completely dislodged most of the time. This brought us to using simple needle stimulation of S3 nerve as a predictor for sacral nerve stimulation full system implant.

3. Systematic Review

Sacral nerve stimulation full system implant was found to be very effective treatment for fecal incontinence [4]. The aim of the study is to determine the feasibility of proceeding directly with the SNS full system implant following the successful needle stimulation of S3 nerve without leaving the lead wires in, but removing the needles after the procedure and, thereby, simplifying the process of basic InterStim stimulation. The study was undertaken to determine whether the simple procedure of needle stimulation of S3 nerve would predict the successful outcome of SNS full system implant done in a single stage.

4. Materials and Methods

This case study was reviewed and approved by the IRB for Tri-City Colorectal Surgery. 143 patients were chosen for the study over a period of 60 months, comprising of 136 female and 7 male patients ranging in age from 50-88. These patients were followed for 6 months to 60 months after the SNS full system implant with median follow up of 36 months. These patients were explicitly told that we are not following the traditional basic InterStim stimulation wherein the lead wires will be left in for a period of time because of the hot weather and the patients not being able to keep the wires in for any period of time. We have chosen to go for needle stimulation. If successful, we will proceed with SNS full system implant. So far, we have not had any issues with insurance companies and, in our authorization, we explicitly do say the basic InterStim stimulation was carried with needle stimulation. The leads were not left in for any period of time because of the hot weather and the historic inability of patients not being able to keep the dressing and wires in for any length of time. All patients passed the criteria for basic InterStim stimulation after undergoing anorectal manometry, endoanal ultrasound, dietary fiber therapy, occasional use of anti-diarrheal agents, and prescribed pelvic floor exercises, and had failed to show adequate improvement of the fecal incontinence. Bowel diaries, Wexner Incontinence Score, and Fecal Incontinence Quality of Life were recorded at baseline after SNS full system implant at routine prescribed follow up visits. 82% of our patients had a Wexner Incontinence Score between 15-20, as shown in Table 1. The majority of the female patients have had multiple childbirths, primarily vaginal childbirths with episiotomies. This is a list of associated medical conditions as shown in Table 2. Roughly 30% of our patients did have moderate to significant urinary incontinence. Twelve patients in our group had pelvic floor repair. Six patients have had surgical treatment for rectal prolapse. Two patients have had prior fistulotomies. The endoanal ultrasound failed to show any significant muscle defect but for local dehiscence and thinning of the sphincter bundles at the site of the fistula. One patient had spina bifida. Four patients have had prior radiation treatment primarily for prostatic and uterine carcinoma.

Table 1:

	Severity of Fecal Incontinence	
Wexner Incontinence Score		Number of Patients
20		6
15-19		117
12-15		20

Table 2:

	Associated Medical Conditions	
Medical Conditions		Number of Patients
Urinary incontinence		43
Pelvic floor repair		12
Rectal prolapse treated with surgery		6
Fistulotomies (endoanal ultrasound did not show muscle defect)		2
Radiation treatment		4 (1 prostate and 3 uterine cancer)
Spina bifida		1

5. Procedure

143 patents underwent needle stimulation of S3 nerve bilaterally to observe Bellowing and plantar flexion of the great toe. Needles were removed at the end of the procedure without leaving the lead wires. Failure to observe strong Bellowing and plantar flexion with low amplitude below 1 mV is considered a failure. There was a significant difference in the required amplitude to achieve strong Bellowing and plantar flexion of the great toe between the right and left side in only 6 patients. The rest of the patients had the same or very small variations in the amplitude setting that was required to produce similar responses on both sides. The procedure was always performed in an outpatient setting in our ambulatory center, and rarely in an office setting (two patients). 139 patients underwent the procedure using IV sedation with Propofol given by the anesthesiologist or nurse anesthetist. Four patients underwent local anesthesia using Xylocaine and Bupivacaine. The use of local anesthesia for the basic InterStim stimulation has been discontinued at this time due to patients not wanting to undergo the procedure with local anesthesia only. All patients were placed in the prone position with pillows under the pelvis and lower abdomen to flatten the sacrum. All patients were given preoperative antibiotics, primarily Ancef, with the dose varying according to the patient's weight. The patient's back, buttock and upper thighs were prepped with ChloraPrep solution. The patients were draped as per operating room protocol. After identifying the area of the S3 foramen, roughly 8 fingerbreadths above the tip of the coccyx, the area was widely infiltrated with local anesthesia. Needle stimulation was performed bilaterally starting at a very low amplitude as explained above. Bellowing and plantar flexion of the great toe with stimulation of low amplitude below 1 mV is considered a successful outcome. Failure to observe strong Bellowing and plantar flexion below 1 mV was considered a failure. If the patient did not have strong Bellowing and plantar flexion, and the response was weak below 1 mV, the needle position was adjusted to see whether a good response can be achieved at very low amplitude. Failure to observe strong Bellowing and plantar flexion below 1 mV after testing at different needle positions was still considered a failure. Starting August 2020, we started using MRI safe units. Starting in October 2022, we started using batteries that last between 12-15 years. Prior to August 2020, in the initial stages of this study, patients were given MRI incompatible units and battery lasting an average of four years.

6. Results

Stimulation was successful in 131 patients. Eight of these patients chose not to proceed with full system implant. The remaining 123 patients underwent full system implant. 108 patients, roughly 88%, had a positive outcome measured by significant clinical symptomatic improvement and quality of life measures (Wexner Incontinence Score and FIQoL), showing reduction of at least 50% of incontinent episodes. The results are shown in Table 3.

The 10 patients who had a score of 9-12 expressed that they have had at least 50% reduction in the fecal incontinent episodes. Five patients, however, did not have sufficient clinical symptomatic improvement and were not satisfied with the outcome. 30 of the patients, roughly 24%, undergoing SNS full system implant did have full restoration of continence. 78 patients had significant reduction of the fecal incontinent episodes for which they are very grateful for having undergone the procedure. Ten of the 123 patients had at least 50% reduction in the fecal incontinent episodes and were moderately satisfied. Five patients, however, did not have sufficient clinical symptomatic improvement, and were not satisfied with their outcome. The 15 patients who had the incontinence score above 9 on the Wexner scale did undergo further treatment with multiple sessions of reprogramming the InterStim unit to see if there could be further improvement. So far, 6 of these patients have had their unit explanted. Two patients from this group, even though not having had the expected outcome, decided not to have the unit explanted and had inactive units left in. The remaining 6 patients from this group have indicated that they have achieved an overall reduction of 50% of the fecal incontinence episodes.

Table 3:

	Outcome Following SNS Full System Implant	
Wexner Incontinence Score		Number of Patients
0		30
1-5		63
6-8		15
9-12		10
14-16		5

6. Complications

There were no complications that were reported following simple needle stimulation of S3 nerve (basic InterStim stimulation). Complications from SNS full system implants were as shown in Table 4. There were no immediate infections reported in this group of patients undergoing full system sacral nerve stimulation SNS implant. There were three delayed infections occurring from eight weeks to twenty four weeks (two to six months). The cause of this infection was not clear. These patients were treated with antibiotics and, without improvement, did undergo explantation of the units. These patients were closely monitored with the help of infectious disease consultant on long term antibiotic therapy. Culture of the pocket site yielded E coli in one patient. The other two patients had very light growth of Staph and Strep.

There were no septic complications. The patients tolerated the explantation very well. All these patients have had re-implantation on the opposite side after a period of four to six months with successful outcomes. Three patients had sudden loss of efficacy with increased fecal incontinence. These patients belong to the group of patients who were implanted with units with short battery life. X-rays failed to reveal anything significant. The impedances were very high on electronic evaluation of these units. The pocket site was explored with visualization of significant twisting of the wires to the extent that, in one patient, it had pulled out of the head of the neurostimulator. All these three patients had re-implantation at the same time with an excellent outcome. Three patients have had their battery dislodged with loss of function due to direct impact either from a fall, blunt trauma to the back or auto accident. These patients were explored and the units explanted. Two of these three patients have had their units re-implanted at the same time. One decided to not have it re-implanted. These events occurred 24 months after the sacral nerve system implant in these three patients. In two patients who were very thin, with one losing a significant amount of weight due a problem related to her teeth and removal of dentures with inability to eat, the unit did erode through the skin. In both the patients, the unit had been explanted. One patient is planning to undergo re-implantation. We will need a long lead wire and probably bringing it across to the front of the abdomen. That would be possible and has been reported. So far, eleven patients have had their units explanted for an explantation rate of just under 10%.

Table 4:

Complications	Number of Patients	Time of Occurrence	Outcome and Remedial Measures
Delayed Infection	3	2-6 months	Re-implantation and successful outcome so far
Sudden loss of efficacy with increased fecal incontinence (lead wire malfunction)	3	18-24 months	Re-implantation and successful outcome so far
Blunt trauma with loss of efficacy and increased fecal incontinence due to fall or blunt trama to the back or auto accident	2	24-48 months	Remedial measures with re-implantation and of efficacy and increased successful outcome. One patient decided not fecal incontinence due to fall to have it re-implanted
Erosion of the battery (occurring in very thin patients)	2	8-12 months	Explantation of the unit

7. Discussion

The use of simple needle stimulation of S3 nerve completely eliminates the need for difficult, detailed care of the lead wires. This can be very trying and testing, especially during the eight months of warm to hot weather in our area. We have eliminated the traditional basic InterStim stimulation testing wherein the lead wires were left in and replacing it with SNS full system implant following successful simple needle testing. The 15 patients who did not have a good score on the Wexner scale following the full system implant (9-16) were followed very closely and were put through multiple session of reprogramming. This was done to see if there could be further improvement. Six of these patients have had their units explanted. Nine of them still have their units. Some of them are inactive as indicated in the Results section. Six of the patients in this group indicated they have at least 50% reduction in their fecal incontinent episodes. The programming of the algorithm for sacral nerve modulation can result in improvement clinically that can be observed in a patient even though they had initial unsatisfactory results as borne by the studies that were done and published [5,6,7]. These patients did undergo further treatment with reprogramming in our office with the help of the technicians on site in adjusting and modulating the InterStim unit regarding the amplitude, pulse width, frequency cycling and electro-configuration. The satisfaction to proceed by the patient sometimes did not correlate well with the bowel diary or the Wexner Incontinence Score, the Fecal Incontinence Quality of Life measures. This is a very small fraction of the patients. The patients who were not satisfied, even though the Wexner Incontinence Score and the FIQoL measures have significantly improved, were very dependent on adjusting or modulating their unit. They required constant assistance. This has been noted and published [8,9].

8. Limitation of The Study

This study is a single center study. The study population was small and retrospective. It is not a prospective, blinded study or controlled study. The results from our study compares well with published successful outcome of full system sacral nerve stimulation implant following a traditional basic InterStim stimulation testing, leaving the lead wires in for a period of time [10-15].

9. Conclusion

The successful outcome of full system SNS implant following positive simple needle stimulation of S3 nerve is comparable to the patient's outcome undergoing basic needle stimulation wherein the lead wires were left in for two weeks and, if successful, then undergoing SNS full system implant [10-16]. The advantages are that the basic InterStim stimulation can be done with IV sedation in the ambulatory center or office setting. This would not require care for the leads or leaving the patient's wires bandaged for a week or two. Converting the method of perform-

ing SNS full system implant to simple needle stimulation and, if successful, to full system SNS implant procedure will eliminate the need to leave the lead wires in for two weeks and will cut down the cost of these procedures. The combined cost of these procedures will be much higher than the simple single needle stimulation of S3 nerve and going directly with the full system SNS implant if successful. This procedure will totally eliminate the need for cumbersome wound care which is always necessary for the traditional basic InterStim stimulation setting and possible infection.

10. Summary

Even though the study population of the group is small, high correlation between just the needle stimulation of S3 nerve and successful full system SNS implant outcome is very evident and well demonstrated. Further controlled large population, multi-center study would be necessary to accept this modality as standard.

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