Open Access Surgery

Dovepress
open access to scientific and medical research

Open Access Full Text Article

CASE REPORT

Feasibility and Safety of Implanting InterStim™ Device in Conjunction with Other Neuromodulator Devices, Case Report

Maryam Aleissa[1,2], Ernesto Drelichman[1], Jasneet Singh Bhullar[1]

[1]Department of Surgery, Ascension Providence Hospital-Michigan State University College of Human Medicine, Southfield, MI, USA; [2]College of Medicine, Princess Nourah Bint Abdulrahman University, Riyadh, Saudi Arabia

Correspondence: Jasneet Singh Bhullar, Program Director of Colorectal Surgery Fellowship, Clinical Assistant Professor WSUCOM/MSUCHM, Department of Surgery, Ascension Providence Hospital-Michigan State University/College of Human Medicine, Southfield, MI, USA, Email DrjsBhullar@gmail.com

Introduction: Sacral nerve stimulation (SNS) has emerged as a viable option in patients with fecal incontinence who do not respond to conservative care. Technology has significantly progressed over the years. The current InterStim™ device is compatible with MRI, lasts for many years, and is performed using a minimally invasive technique, using mild sedation and local anesthesia. The precise mechanism of action remains unknown, and there is increasing interest in expanding the indications for the management of digestive diseases. There is now an increasing interest in brain neuromodulator devices, which may enable physicians to visit a larger number of patients simultaneously.

Case Presentation: We present a case report of a patient with fecal incontinence (FI) who failed to respond to conservative management. The patient also had an occipital device for cluster headaches. The FI symptoms improved significantly with InterStim™ and there was no interaction with another device.

Discussion: InterStim™ may be safely integrated with other neuromodulators. Additional research is required to determine the safety and benefit of InterStim™ implantation with other neuromodulators devices.

Keywords: neuromodulators, fecal incontinence, sacral nerve stimulator

Introduction

Neuromodulation devices have received approval for the therapeutic management of several conditions, including movement disorders, epilepsy, pain, depression, and urinary and fecal incontinence (FI).[1] These devices provide stimulation directed towards an offending area, region, or network inside the brain, and can be administered as a solitary intervention based on a predetermined protocol or in reaction to physiological alterations. The programming process can be adjusted and adapted based on the clinical response or physiological indicator.[1]

The use of SNS was initially documented in the 1970s for the treatment of individuals with urinary symptoms.[2] This device was subsequently approved by the Food and Drug Administration (FDA) for the treatment of urological diseases in 1997. Clinicians noticed a concurrent improvement in bowel symptoms among patients who had SNS and who presented with both urine and FI. Matzel et al (1995) documented the initial use of SNS for patients with FI only, after which the device received FDA approval in March 2011 for individuals diagnosed with FI who either did not respond to or were unsuitable for less invasive treatment options.[3] Historically, electrode insertion has required an open placement approach, which involves meticulous dissection of the foramina and fascial fixation to ensure accurate positioning of the electrode.[4] Fortunately, a minimally invasive strategy has been adopted. Surgery can be performed in either one or two stages. In the single-stage approach, before surgical intervention, a preliminary phase is performed under local anesthesia, which involves identification of the sacral nerve on both sides of the S3/S4 foraminal region, followed by insertion of a percutaneous nerve evaluation (PNE) lead and connection to an external device.[5] Patients who show a minimum of 50% improvement in their original

Received: 1 March 2024
Accepted: 19 June 2024
Published: 1 July 2024

condition, as documented in an incontinence diary, will be offered the option of undergoing a permanent implantation procedure by removing the PNE lead and placing a quadripolar lead with an implanted neurostimulator (INS). In the first stage of two-stage surgery, the PNE lead is replaced by a permanent lead inserted under fluoroscopic guidance. In patients who showed at least 50% improvement from their initial state, permanent implants were performed.[3] SNS has gained widespread acceptance among patients and surgeons owing to the utilization of minimally invasive approaches and its perceived benefits, particularly when dealing with patients who are at a higher surgical risk.[5]

In this article, we present a case report of a patients with FI who had previously undergone implantation of another neuromodulator device and discuss the safety and outcomes of this procedure.

Case Presentation

A 73-year-old woman with a medical history of intractable clustering headaches and trigeminal neuralgia was treated in 2016 with insertion of a Medtronic occipital nerve stimulator (ONS). The patient was referred to a colorectal surgeon with a history of FI. Colonoscopy revealed a tubular adenoma in the sigmoid colon but no other significant pathology. The surgeon recommended high-fiber diet modification and referred her for biofeedback. Although she experienced slight improvement in symptoms, she continued to experience three–four incidences per week. The patient underwent two vaginal deliveries accompanied by episiotomies: one infant weighed 10 pounds and the other 8 pounds. The patient presented with symptoms including urinary urgency and frequent urination throughout the day. She accepted an InterStim^{TM} offer and consented to undergo a two-stage procedure. Following a symptomatic improvement of more than 50% during stage one, she underwent permanent implantation in accordance with the guideline. The symptoms were assessed using a diary note, in which the patient reported a reduction of 50% in her FI incidence.

The patient had been under the care of the same colorectal surgeon for the past two years, during which time her urinary symptoms and FI have been effectively managed. Device setting adjustment usually occurred as patient symptoms changed overtime; however, no major changes need to be done during her visits. She continued to see her neurologist for the treatment of her well-controlled intractable clustering headache; however, she continued to require pain medication for trigeminal neuralgia. Informed consent was taken from the patient prior to publication, however, institutional approval was not required to publish the case details.

Discussion

SNS is currently experiencing a significant increase in utilization, with indications expanding in scope. It has been proposed as a potential intervention for the management of slow-transit constipation, pelvic floor dysfunction, and neurological disorders. However, FDA approval in the United States remains limited to FI, UI and overactive bladder.[6] In the present case, the patient had an ONS device. However, in current medical practice, more intricate devices that involve deep brain stimulation are available and may have both direct and indirect effects on the pelvic floor muscles.

Neurological disorders, such as multiple sclerosis, Parkinson's disease, spina bifida, cerebrovascular illness, and spinal cord injury, have been associated with the development of pelvic floor dysfunction. This dysfunction can manifest as symptoms including urgency, frequency, UI, FI, and urinary retention. InterStim^{TM} has demonstrated efficacy in managing these symptoms and improving the quality of life (QOL) in people lacking underlying neurologic illnesses.[7] However, whether this treatment is effective in patients with neurological conditions remains undetermined.[8,9] Several studies have shown improvements in these symptoms, as well as in patient QOL, along with SNS implantation.[8,10] These patients are often managed with a deep brain stimulator (DBS) which is the primary target of motor function in the disease. However, the effect of DBS on bladder and bowel symptoms is still equivocal.[11] Patients with Parkinson's disease showed enhanced urinary frequency, urgency, and incontinence following DBS insertion, without substantial alleviation of symptoms, such as nocturia, residual urine, and dysuria.[12] Hence, the use of SNS insertion to control defective function in these patients remains uncertain.

In a single trial, 28 patients with pre-existing neurological conditions received SNS implants to address urinary problems. A high level of satisfaction was reported in 93% of these patients, owing to a reduction in the frequency of urinary incontinence, nocturia, and bladder retention.[10] In neurogenic bowel dysfunction, SNS implants have been observed to affect individuals with incomplete spinal cord injury but not those with complete spinal cord injury. The

impact of SNS on physiological functioning of the anorectal region in patients with neurogenic bowel dysfunction remains inconclusive, and further investigation is ongoing in this field.[9,13]

Surgical planning of the device insertion site might be needed before surgery, especially when other neuromodulators are inserted into the gluteal area where the SNS device is implanted.

Prior research has examined the safety of co-implantation of InterStim™ alongside cardiac devices, revealing no interactions between these two devices.[14] In this article, we present a patient treated with neuromodulators who successfully underwent SNS without any device interactions. The indications of InterStim™ is expanding to include patients with pelvic floor dysfunction due to different pathophysiology. This is a case report, and further studies are required to validate the feasibility and safety of this intervention.

Consent for Publication

Written consent was obtained from the patient before publication.

Disclosure

Dr JS Bhullar is part of the training facility at Medtronic. The authors report no other conflicts of interest in this work.

References

1. Krauss JK, Lipsman N, Aziz T, et al. Technology of deep brain stimulation: current status and future directions. *Nat Rev Neurol*. 2021;17(2):75–87. doi:10.1038/s41582-020-00426-z
2. Brindley GS, Polkey CE, Rushton DN. Sacral anterior root stimulators for bladder control in paraplegia. *Paraplegia*. 1982;20(6):365–381. doi:10.1038/sc.1982.65
3. Katuwal B, Bhullar J. Current Position of Sacral Neuromodulation in Treatment of Fecal Incontinence. *Clin Colon Rectal Surg*. 2021;34(1):22–27. doi:10.1055/s-0040-1714247
4. Hetzer FH. Fifteen years of sacral nerve stimulation: from an open procedure to a minimally invasive technique. *Colorectal Dis*. 2011;13(Suppl 2):1–4. doi:10.1111/j.1463-1318.2010.02517.x
5. De Wachter S, Knowles CH, Elterman DS, et al. New Technologies and Applications in Sacral Neuromodulation: an Update. *Adv Ther*. 2020;37(2):637–643. doi:10.1007/s12325-019-01205-z
6. Thomas GP, Dudding TC, Rahbour G, Nicholls RJ, Vaizey CJ. Sacral nerve stimulation for constipation. *Br J Surg*. 2013;100(2):174–181. doi:10.1002/bjs.8944
7. Hetzer FH, Hahnloser D, Clavien P-A, Demartines N. Quality of Life and Morbidity After Permanent Sacral Nerve Stimulation for Fecal Incontinence. *Arch Surg*. 2007;142(1):8–13. doi:10.1001/archsurg.142.1.8
8. Lombardi G, Del Popolo G. Clinical outcome of sacral neuromodulation in incomplete spinal cord injured patients suffering from neurogenic lower urinary tract symptoms. *Spinal Cord*. 2009;47(6):486–491. doi:10.1038/sc.2008.172
9. Lombardi G, Nelli F, Mencarini M, Del Popolo G. Clinical concomitant benefits on pelvic floor dysfunctions after sacral neuromodulation in patients with incomplete spinal cord injury. *Spinal Cord*. 2011;49(5):629–636. doi:10.1038/sc.2010.176
10. Wallace PA, Lane FL, Noblett KL. Sacral nerve neuromodulation in patients with underlying neurologic disease. *Am J Obstet Gynecol*. 2007;197(1):96.
11. Witte LP, Odekerken VJJ, Boel JA, Schuurman PR, Gerbrandy-Schreuders LC, de Bie RMA. Does deep brain stimulation improve lower urinary tract symptoms in Parkinson's disease? *Neurourol Urodyn*. 2018;37(1):354–359. doi:10.1002/nau.23301
12. Zong H, Meng F, Zhang Y, Wei G, Zhao H. Clinical study of the effects of deep brain stimulation on urinary dysfunctions in patients with Parkinson's disease. *Clin Interv Aging*. 2019;14:1159–1166. doi:10.2147/CIA.S204368
13. Worsøe J, Rasmussen M, Christensen P, Krogh K. Neurostimulation for neurogenic bowel dysfunction. *Gastroenterol Res Pract*. 2013;2013:563294. doi:10.1155/2013/563294
14. Ooi YC, Falowski S, Wang D, Jallo J, Ho RT, Sharan A. Simultaneous use of neurostimulators in patients with a preexisting cardiovascular implantable electronic device. *Neuromodulation*. 2011;14(1):20–25. doi:10.1111/j.1525-1403.2010.00314.x