Effects of Sacral Neuromodulation on Urinary and Fecal Incontinence

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ABSTRACT: **Background:** Fecal incontinence is defined as involuntary passage of stool through the anus. It may vary from soiling to complete evacuation. This involuntary loss of feces, flatus or urge incontinence adversely affects quality of life. Urinary urge incontinence is characterized by symptoms of frequency, urgency and urge incontinence (either alone or in combination). Urgency frequency syndrome is defined as symptoms of frequency and urgency without incontinence episodes.

Objectives: To evaluate the efficacy of sacral neuromodulation on these pathologies.

Methods: Following a detailed investigation, 51 patients with either urinary or fecal incontinence, or both, who did not respond to medical and behavioral treatment were offered the temporary implant. Of the 51 patients 40 showed improvement and advanced for a permanent device.

Results: After a mean follow-up of 5 years (range 1–8), there was a significant reduction in the number of incontinence episodes ($P < 0.0001$), and the number of pads used also declined significantly ($P < 0.0001$). A marked improvement in quality of life was reported by 71.4% of the women and 58.3% of the men.

Conclusions: Sacral neuromodulation as shown in this study appears to be a promising treatment for urinary and fecal incontinence and can dramatically improve patients' quality of life.

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KEY WORDS: sacral neuromodulation (SNM), fecal incontinence, urinary incontinence, quality of life, electrode

"Of all the developments in colorectal surgery in this decade, this is one of the most exciting," said Joe J. Tjandra, MD, from the Epworth Hospital Colorectal Center in Melbourne, Australia, "It dramatically improves patients' lives" [1]. "The advantage of sacral neuromodulation (SNM) is that it affects muscle as well as sensation and reflexes, which are all important in continence" [1].

***The first two authors contributed equally to the study**

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Drs. Shmidt and Tanagho from California were the first to introduce sacral electrical stimulation for urinary dysfunction in 1982 [2,3]. More than 100,000 implants for urinary and fecal incontinence have since been performed worldwide. Today, SNM therapy for pelvic pain, urinary and bowel control is a therapeutic approach for patients with overactive bladder, urinary retention, fecal incontinence, constipation, and double incontinence. This therapy uses sacral neuromodulation to modulate the neural reflexes that influence the bladder, urethral and anal sphincters and pelvic floor [1]. We present our experience in treating patients with pelvic or perineal pain, overactive bladder, or fecal incontinence and double incontinence, by implanting a sacral stimulator in S3 or 4.

PATIENTS AND METHODS

From January 2005 until December 2012 we implanted the sacral stimulator in 66 patients with intractable perineal, perianal and pelvic pain. In this retrospective case series study, we included only 51 patients who in addition to pain had fecal or urinary incontinence. Fifteen patients were excluded: 5 with constipation, 8 with urinary retention and 2 with pelvic pain only.

The efficacy of sacral neuromodulation in the 51 patients with either urinary or fecal incontinence was evaluated without considering the effect on perineal, perianal or pelvic pain.

All patients underwent a full diagnostic workup for fecal incontinence: a detailed questionnaire, physical evaluation, anorectal manometry, transanal ultrasonography, defecography, and pudendal nerve latency in some. For urinary dysfunction, patients filled in a bladder diary for 24 hours. In addition, urinalysis, urine cultures (to rule out significant hematuria and infection), physical examination, and urodynamic evaluation were performed. The patients' quality of life was evaluated according to the parameters listed in the Cleveland Clinic Florida (Wexner) fecal incontinence score and pelvic floor impact questionnaire (PFIQ-7). The main results of both questionnaires are presented.

PATIENT SELECTION

Patients with pelvic pain and/or fecal and/or urinary incontinence who underwent full investigation and did not improve with medical, behavioral and biofeedback therapy were offered the stimulation trial. The inclusion criteria comprised fecal incontinence (> 1/week), soiling, overactive bladder, urge/frequency, or urge incontinence. Exclusion criteria were congenital anorectal malformations, presence of full-thickness rectal prolapse, chronic diarrhea (unmanageable by diet or drugs), stoma in situ, bleeding complications, pregnancy, anatomical limitations preventing placement, or skin/tissue disease that would significantly increase the risk of infection. Also excluded were patients with constipation, patients with urinary retention and patients with pelvic pain only.

CONTRAINDICATIONS

These included an inadequate clinical response to the therapeutic trial or limited cognitive function that could interfere with the operation of the neurostimulatory device. Patients who anticipate the need for future magnetic resonance imaging (MRI) are also not ideal candidates

METHODS

The device that we used was the Eon mini 3788™ (St. Jude Medical, MN, USA). An electrode was inserted in the S3 foramen and connected to an external stimulator for 2 weeks. Patients used the temporary electrode implant for 2–3 weeks prior to the permanent insertion. Incontinence episodes were evaluated according to the bladder diary data. Permanent insertion of a sacral stimulator was indicated if the patient reported at least 50% improvement in the rate of incontinence episodes. Both procedures were performed under local anesthesia in a day clinic. Patients were invited for follow-up every 6 months.

A staged implant procedure was performed as follows: A needle guide is inserted under local anesthesia in the S2, S3 or S4 sacral foramen and an adequate motor/sensory response is tested. The placement of the electrode is confirmed by patients' sensation in the anal and perineal region and anal sphincter contraction and by X-ray of the pelvis following the insertion of the electrode [Figure 1A]. A quadripolar electrode is placed in the foramen with the best response and connected, via a percutaneous extension kit, to an external test stimulator.

A temporary test stimulation is conducted for 10 to 14 days and patients are asked to complete a daily bowel or urinary diary. Those achieving 50% reduction in the number of incontinence episodes per week and/or 50% reduction in the number of incontinence days per week are offered the implantation of a permanent neurostimulation device.

At the permanent implantation, the percutaneous extension is removed and replaced by a shorter extension connected to an internal pulse generator placed subcutaneously in a pocket in the gluteal area [Figure1B].

RESULTS

During the years 2005–2012, we conducted a sacral neuromodulation trial for fecal and urinary incontinence in 51 patients. Eleven patients failed to improve, and 40 patients advanced for permanent implant (78.4%). The age range of the 28 women and 12 men was 38 to 82 years.

The indications for SNM were urinary incontinence in 9 women and 1 man, fecal incontinence in 11 women and 7 men, and combined incontinence in 8 women and 4 men [Table 1]. The etiology of incontinence was spinal cord injury

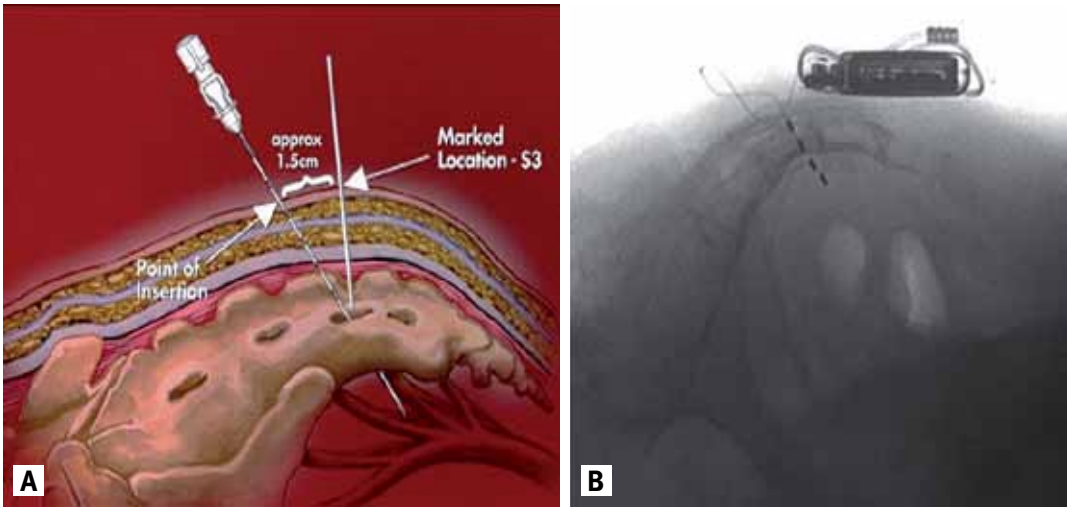


Figure 1.
[A] Needle insertion in S3.

[B] Subcutaneous pocket formation for a permanent stimulator

in 2 women and 3 men, and anorectal surgery (hemorroidectomy, fistulectomy, anterior resection) in 13 women and 9 men. The other 13 women had no clear etiology except for vaginal deliveries and aging. One had ulcerative colitis [Table 1].

Some complications were noted. The electrode was displaced in six women and one man and necessitated repositioning under computed tomography (CT). Three patients (one woman and two men) had wound infection and the device was removed and reinserted after resolution of the infection. Three other patients complained of pain at the implant site which subsided with time [Table 1].

Table 1. Indications for sacral stimulation, etiology and complications

	Women (n=28)	Men (n=12)
Indications for placement		
Perineal pain and urinary incontinence	9 (32.1%)	1 (9.1%)
Perineal pain and fecal incontinence	11 (39.3%)	7 (63.6%)
Perineal pain and combined incontinence	8 (28.6%)	4 (36.4%)
Etiology		
Spinal cord injury	2 (7.1%)	3 (25%)
Anorectal surgery	13 (46.4%)	9 (75%)
Other	13 (46.4%)	0
Complications		
Displacement of electrode, requires repositioning under CT	6 (21.4%)	1 (8.3%)
Wound infection	1 (3.6%)	2 (16.6%)
Pain at implant site	1 (3.6%)	2 (16.6%)

SHORT AND LONG-TERM FOLLOW-UP

To date 60% of patients still use the implant (57.1% women and 66.7%). The reasons for disuse in the remaining 40% were: four women died (all used the stimulator for 1–6 years), two deteriorated with age and failed to operate the device (they used it for 5 and 7 years respectively), three women could not cope with it, and three women were lost to follow-up. Two men deteriorated with age (one used the device for 6 years), and another two could not cope with it.

The incontinence episodes (urinary and fecal) declined significantly in both women and men, from a mean of 3.2 ± 1.0 to 0.7 ± 1.1 ($P < 0.0001$), and 3.0 ± 1.5 to 0.6 ± 1.3 ($P < 0.0001$) respectively [Figure 2]. The use of pads also declined in women and men, but significantly in women only. In women the decline in pad use was from 2.4 ± 1.1 to 0.7 ± 0.9 ($P < 0.0001$) and in men from 1.1 ± 1.5 to 0.4 ± 0.7 ($P = 0.17$) [Figure 3]. Improvement in quality of life was reported in 67%; 71.4% of women and 58.3% of men were very pleased with the procedure and reported marked improvement in their quality of life since the implantation.

DISCUSSION

Fecal incontinence is a debilitating, humiliating and life-altering affliction. It affects approximately 2% of the population [4]. The prevalence increases with age, and above age 50 years the rates increase to 11% in men and 26% in women [5,6]. The standard management for symptomatic fecal incontinence is non-operative, such as use of bulking agents, pelvic floor exercises, dietary changes, or operative treatment such as repair of a localized sphincter defect [7,8]. However, the long-term results of sphincter repair are unpredictable and often poor [8]. Sphincter replacement with artificial bowel sphincter [9] or graciloplasty [10] is used as salvage therapy for end-stage fecal incontinence, but both options are associated with substantial morbidity. Overactive bladder also seriously affects quality of life and can be caused by any of the following: decreased inhibitory control in the central nervous system, disruption of sacral and suprasacral sensory processing, increased afferent activity, or increased sensitivity to efferent stimulation within the detrusor or the urothelium of the bladder, and sometimes a combination of these factors [11].

Over 9 million women in the United States suffer from pelvic pain. Many of these patients were found to have bladder symptoms as a component of their pain syndrome. Urgency, urinary frequency, and voiding dysfunction occur in at least 80% of patients with various chronic pelvic pain syndromes. Given our understanding of visceral pain disorders and the importance of central sensitization, many of these patients also have high-tone pelvic floor dysfunction. Other pain disorders associated with this hypertonic pelvic floor dysfunction

Figure 2. Incontinence episodes following stimulation

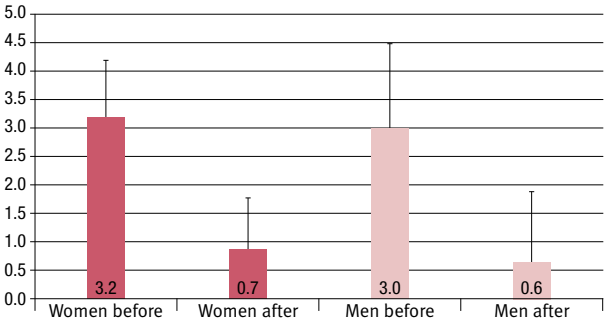
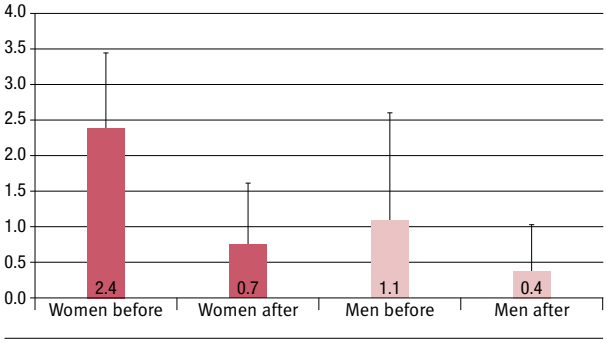


Figure 3. Pad usage following stimulation



include vulvodynia, urethral syndrome, proctalgia fugax, and various defecatory pain and dysfunction disorders [12].

The first to perform an electric implant for urinary incontinence were Tanagho and Schmidt from the University of California in 1982 [2,3], who initiated a clinical program and a multicenter trial that was conducted by Urosystems, Inc. Today, SNM is an established treatment option for patients with various chronic bladder disorders [9] such as urge incontinence or urgency-frequency that have failed to respond to more traditional therapies [11]. The U.S. Food and Drug Administration (FDA) approved SNM for intractable urge incontinence in 1997 and in 1999 added urgency-frequency syndromes and non-obstructive urinary retention [11]. In 1994, anal electric stimulation was described for the treatment of fecal incontinence, and in 2010 the FDA approved the use of SNM for fecal incontinence as well. To date, more than 100,000 implants have been performed worldwide.

The mechanism of action of SNM is not well understood and requires further investigation; it seems to involve modulation of spinal cord reflexes and brain networks by peripheral afferents rather than direct stimulation of the motor response. The intriguing question is how SNM is efficacious for both urinary retention and urgency-frequency syndrome, as well as fecal incontinence and constipation. The explanation seems to lie in the different underlying pathophysiology of these disorders [13].

The observation that early SNM in patients with complete spinal cord injury during spinal shock could prevent the development of detrusor overactivity and urinary incontinence may indicate modulation at the level of the spinal cord itself. Acute spinal cord injury leads to detrusor contractility and complete urinary retention, which is followed by slow development of detrusor overactivity incontinence caused by C-fiber-mediated spinal reflex pathways, probably related to the interrupted regulatory mechanism between the lower urinary tract and midbrain for urine storage and voiding. Early SNM may preserve nerve plasticity, such that C-fibers remain silent, detrusor overactivity is avoided, and sympathetic preganglionic neuron activity in the thoracolumbar cord is suppressed, supporting detrusor contractility [13].

Mellgren et al. [14] reported on the long-term efficacy and safety of sacral nerve stimulation for fecal incontinence in 2011. They showed a 90% success rate in 133 patients who underwent test stimulation, and 120 (110 females) with a mean age of 60.5 years and a mean duration of fecal incontinence of 7 years received a permanent implant. Mean length of follow-up was 3.1 (range 0.2–6.1) years, with 83 patients completing all or part of the 3 year follow-up assessment. At 3 year follow-up, 86% of the patients ($P < 0.0001$) reported 50% reduction in the number of incontinence episodes compared with baseline, and the number of episodes per week decreased from a mean of 9.4 at baseline to 1.7. Perfect continence was achieved in 40% of subjects. Michelsen and co-authors [15] reported similar results 6 years post-implantation, and Hetzer [16] emphasized the significant improvement in quality of life following the sacral modulator implant.

The displacement rate of the electrode is low. Faucheron et al. [17] reported a displacement rate of 2.2% in his series (2/87). In our study we found a relatively high rate of electrode dislodgement (17.5%) probably because we did not use the tined-lead electrode in the first few cases. The location of the electrode was confirmed by X-ray after the procedure, and a clinically suspected displacement was also demonstrated by X-ray. The repositioning under CT was easy and safe and indicates the exact location of the electrode with no need for another trial.

With regard to urinary incontinence and overactive bladder, in the study by Marcelissen et al. [18] the long-term results of 64 patients from a single center after 53 months (range 35–77) showed 64% success with 50% improvement. Maeda and team [19] report 42.6% favorable outcome of sacral nerve stimulation for fecal incontinence after 60 months. In our series, with a mean follow-up of 5 years (range 1–8), of 40 patients who advanced for a permanent implant 67.5% reported marked improvement in life quality, with significant reduction in incontinence episodes and use of pads ($P < 0.001$)

In conclusion, we believe that sacral neuromodulation is a promising procedure for the treatment of fecal and urinary incontinence; it is also used for perineal pain, constipation and urinary retention. With time, a much larger group of pathologies will probably benefit from this procedure.

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