Sacral nerve neuromodulation in patients with underlying neurologic disease

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OBJECTIVE: Sacral nerve neuromodulation (SNS) is an effective treatment for lower urinary tract dysfunction. Many underlying neurologic processes affect lower urinary tract function. We present results of SNS in patients with underlying neurologic dysfunction.

STUDY DESIGN: This is a retrospective case series of 33 patients with neurologic disease and lower urinary tract dysfunction who underwent an InterStim stimulation procedure. Results were evaluated by pre- and postoperative voiding diaries. Success was defined as greater than 50% improvement.

RESULTS: Twenty-eight of 33 patients (85%) underwent implantation: 13 of 16 (81%) multiple sclerosis, 4 of 6 (67%) Parkinson disease, and 11 of 11 (100%) other neurologic disorders. Incontinence episodes per 24 hours decreased 68%, number of voids per 24 hours decreased 43%, nocturia decreased 70%, and there was a 58% reduction in intermittent self-catheterization per 24 hours. Ninety-three percent reported overall satisfaction.

CONCLUSION: Sacral nerve neuromodulation is an effective treatment for lower urinary tract dysfunction in patients with underlying neurologic disease.

Key words: detrusor overactivity, detrusor sphincter dyssynergia, lower urinary tract dysfunction, sacral nerve neuromodulation, urge incontinence

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In 1997, the US Food and Drug Administration approved Medtronic Interstim therapy for the treatment of nonobstructive urinary retention and symptoms of overactive bladder, including urgency, frequency, and urge incontinence. A multicenter, international, prospective study of 581 patients found that Interstim therapy resulted in a greater than 50% reduction in voiding frequency, incontinence episodes, and retention in patients with intractable symptoms of urge incontinence, urgency, frequency, and retention.[1] This original study excluded patients with underlying neurologic disorders. However, more recently, with the subsequent evolution of the technology of sacral nerve neuromodulation, this modality has been included as a treatment option for patients with refractory lower urinary tract dysfunction as result of an underlying neurologic disorder. Bosch and Groen[2] reported a reduction in incontinence episodes from 4 to 0.3 per day after sacral nerve stimulation in 6 patients with multiple sclerosis who suffered from refractory urge incontinence. In a small case series of 9 women with neurogenic urge incontinence as a result of multiple sclerosis, traumatic spinal cord injury, and myelitis, patients experienced a significant reduction in incontinence episodes and number of voids per day after sacral nerve stimulation.[3]

Neurologic conditions, such as multiple sclerosis, Parkinson disease, spina bifida, cerebrovascular disease, and spinal cord injury, can result in pelvic floor dysfunction, including urgency, frequency, urinary and anal incontinence, and urinary retention.[4-6] Although the neurologic processes may be different, they can all affect the complex micturition reflex pathway, resulting in lower urinary tract dysfunction. We present a case series of 33 patients with underlying neurogenic lower urinary tract dysfunction, specifically detrusor overactivity, urge incontinence, urgency, frequency, nocturia, and urinary retention, who have failed conservative therapy. Neurologic conditions include multiple sclerosis, Parkinson disease, spina bifida, cerebrovascular disease, and spinal cord disease.

Materials and Methods

Charts of patients who had undergone InterStim therapy at the University of California, Irvine, Medical Center between the years 1999 and 2006 were identified after approval from the institutional review board. Thirty-three patients with underlying neurologic disease who had undergone a trial of sacral nerve stimulation for refractory urgency, frequency, urge incontinence, and urinary retention were reviewed. A complete urogynecologic evaluation was performed at baseline, including a history and physical examination, urinalysis, 4-day voiding diary, multichannel urodynamics, and electrodiagnostic evaluation of the pelvic floor when appropriate. Multichannel urodynamics was per-

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formed using a Medtronic Logic G/2 system (Minneapolis, MN). Electrodiagnostic evaluation of the pelvic floor was done using the Medtronic Keypoint portable system. These studies included motor nerve conduction studies of the pudendal and perineal nerves and sacral reflexes including the clitoral-anal, urethral-anal, and bladder-anal reflexes.[7]

Patients who experienced greater than 50% improvement in symptoms of frequency, nocturia, incontinence episodes per 24 hours, and number of pads per 24 hours on a 4-day postoperative voiding diary were offered placement of the InterStim implantable pulse generator (IPG). For patients with urinary retention, a greater than 50% decrease in the number of catheterizations and a greater than 50% increase of voided volumes were used as criteria for implant.

InterStim lead wire placement technique

Patients were consented for the procedure and placed in the prone position. Bony landmarks over the sacrococcygeal region were used to identify the level of the S3 foramen. Local anesthesia was used to infiltrate the subcutaneous tissue over the sacrum. An insulated 22-gauge spinal needle was used to cannulate the S3 foramen on the right and/or left side. Proper placement was determined with fluoroscopy and electromyography (EMG) as well as subjective (sensory) and objective (motor) response to electrical stimulation. The electrodiagnostic responses were monitored using a ring electrode on a 14-French foley catheter and sponge electrode placed in the rectum.[8] Electrical stimulation was administered via a Medtronic Keypoint EMG system. During stimulation, the female patient perceives a tapping, pulling, or vibration in the vagina, perineum, or rectum. In male patients, the sensation is localized to the scrotum, penis, or rectum. The clinical motor response is the "bellows" seen as a visible pulling in of the rectum or plantar flexion of the great toe.

Once the correct response was obtained, a quadripolar lead wire was placed into the S3 foramen through an introducer. Fluoroscopy was again used to confirm position. The latencies and amplitudes of compound muscle action potentials along the S3 nerve from each electrode were recorded at subclinical levels of sensation and at maximal stimulation. Finally, the introducer was withdrawn and lead wire tynes deployed under fluoroscopy. The lead wire was tunneled to the ipsilateral side to a pocket, which was created in the posterior hip. The lead wire was then connected to a temporary external wire that was tunneled to the contralateral side for the trial period.

InterStim test trial

All 33 patients underwent lead wire placement and a test trial for a period of 1 to 3 weeks. Patients underwent programming of the external test unit according to their subjective and objective response to lead wire stimulation. The stimulation was set on continuous mode, and patients were instructed on how to adjust the amplitude of the generator with the goal of maintaining a light tapping or vibratory sensation in the vagina, perineum, or rectum. Patients were given 4-day voiding diaries to complete. Patients with a greater than 50% reduction in leakage episodes or pad use were eligible for placement of the IPG.

InterStim implantable pulse generator placement

Patients were placed in the prone position. Local analgesia was used to infiltrate the fat pad in the posterior gluteal region below the posterior iliac crest. A 4 cm incision was made, and a 4 × 3 cm subcutaneous pocket was made for the IPG unit. The quadripolar lead wire was disconnected from the temporary external system and brought through this incision. The IPG unit was then secured to the lead wire. The patients underwent further programming telemetrically with the initial stimulation parameters, including mode (continuous or cyclic), pulse width, frequency, and amplitude. Follow-up visits were completed at 2 and 4 weeks, 6 months, and 12 months. Additional adjustments on the IPG stimulation were performed as needed.

Demographic information including age, gender, underlying neurologic conditions, and lower urinary tract symptoms were summarized using descriptive statistics.

Statistical analysis was performed using the paired *t* test and Wilcoxon ranked sum test as appropriate. Ninety-five percent confidence intervals are reported. A *P* value of less than .05 was considered statistically significant. NCSS (Kaysville, UT) 2004 statistical software was used for analysis.

Results

Thirty-three patients (31 females and 2 males) underwent sacral nerve test stimulation. The median number of previous treatments, including behavioral therapy and anticholinergic therapy, was 2 (range, 1-4). Mean follow-up was 12.4 months (range, 4-32 months). Table 1 shows the distribution of neurologic diseases in our study group and their baseline characteristics. Twenty-eight of 33 patients (85%) had a successful test stimulation trial and underwent placement of the InterStim implantable pulse generator after showing a greater than 50% reduction in leakage episodes, nocturia, or pad usage. The implanted group was comprised of 13 of 16 patients with multiple sclerosis (81%), 4 of 6 patients with Parkinson disease (67%), 2 of 2 patients with cerebrovascular accident (100%), 2 of 2 patients with spina bifida (100%), 1 of 1 patient with cerebral palsy (100%), 6 of 6 patients with other neurological disorders (100%) including disk disease, neurofibromatosis, encephalitis, and polyneuropathy. Of the patients who failed the test stimulation procedure (less than 50% improvement), 3 of 5 (60%) had multiple sclerosis and 2 of 5 (40%) had Parkinson disease. Three of 28 patients (11%) had their pulse generators removed at 5 months, 9 months, and 36 months. Reasons for removal included, neuropathic pain, hypersensitivity to stimulation, and failure of the device after passing through a metal detector. This patient is planning on undergoing reimplantation with the new, smaller IPG.