Sacral Nerve Neuromodulation (InterStim®) Part I: Review of the InterStim® System

Helen Rittenmeyer

In 1988, Tanagho and Schmidt introduced sacral neuromodulation for management of the neuropathic bladder. Shafik (1999) subsequently demonstrated that electrical stimulation of the external urethral sphincter can inhibit detrusor contraction. These studies, in conjunction with the InterStim® device developed by Medtronic, Inc. (Minneapolis, MN), eventually led to the U.S. Food and Drug Administration (FDA) approval for use of the InterStim in treating refractory urge incontinence, chronic urinary retention, and urgency/frequency. The device has since been continually updated in response to technological advancement and clinical studies, resulting in improved treatment outcomes. In 2002, Medtronic released an implantable tined lead, making the procedure minimally invasive. In 2006, improved technology allowed the release of a smaller neurostimulator and improved patient programmer.

Sacral nerve neuromodulation is accepted technology for patients with refractory urge incontinence, urinary frequency syndrome, and chronic urinary retention. This treatment consists of an implantable lead and neurostimulator (battery) using light electrical pulses to stimulate the sacral nerve controlling the bladder and other muscles that control urinary function. This article reviews the indications for neuromodulation as well as patient selection and testing phases associated with this technology.

Key Words: Interstim, urgency, frequency, incontinence, retention, stage 1, stage 2, percutaneous testing.

Since sacral neuromodulation for treatment of urinary dysfunction has become widely accepted, it is important that health care providers understand the technology. Nurses and/or other health care providers in the U.S. are likely to encounter a patient with an InterStim (sacral nerve neuromodulation). When providing care, it is important that nurses understand the implanted device (neurostimulator/battery), have some understanding of how the system works, and be aware of contraindications with this therapy.

MICTURITION

The central nervous system (CNS) works to control micturition; the CNS can treat a seemingly wide range of lower urinary tract dysfunctions (Leng & Morrisroe, 2006). Urinary voiding dysfunction has been broadly classified as a problem of storage or emptying (Latini, Alipour, & Kreder, 2005). Normal storage relies on the inhibitory input to the bladder supplied by the sympathetic neurons originating in the thoracic/lumbar spinal segments and the excitatory input to the bladder outlet (Comiter, 2005).

Helen Rittenmeyer, BSN, RN, is a Nurse Manager, University of Iowa, Department of Urology, Iowa City, IA.

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Together these efferent pathways contribute to normal storage. The afferent pathways control the sensation of bladder fullness, the need to void, sensation of bladder pain, and perineal sensation. The two main afferent pathways, one from the bladder and one from the perineum, communicate the sensation of fullness of bladder volume and trigger reflex voiding in response to stimuli. The bladder is unique because it is under voluntary control and spends most of its time "off," with occasional triggers to turn it "on" and empty the urine. When these pathways are disturbed, there is a loss of checks and balances, resulting in an emergence of bladder hyperactivity and random incontinence/retention (Leng & Morrisroe, 2006). Various theories support that both the pelvic floor muscles and the external sphincter have an important role in controlling bladder functions. During bladder filling, increased muscular tone of the pelvic floor and external sphincter suppress detrusor contractility and inhibit voiding (Aboseif, Tamadoon, Chalfin, Freedman, & Kaptein, 2002). Simply stated, normal micturition is when all muscles and nerves work together to create a normal voiding pattern of 8 to 10 voids per day.

**Sacral Nerve Neuromodulation Theories**

Many theories surround the efficacy of sacral neuromodulation for urinary dysfunction. According to Griebling (2007), the sacral neuromodulation mechanism is most likely multifactorial and impacts the neural axis at several different levels. One theory suggests that the mechanism is an indirect stimulation of the pudendal nerve and direct inhibition of the preganglionic neurons, which suppress detrusor activity and thereby improve symptoms, such as urgency, frequency, or urinary incontinence. Another theory postulates that stimulation may inhibit involuntary reflex voiding by altering the transmission of sensory input from the bladder to the pontine micturition center, inhibiting ascending afferent pathways but not descending pathways. In patients who experience non-obstructive urinary retention, neuromodulation most likely causes an inhibition of the guarding reflex. This leads to a reduction in sphincteric overactivity that may reduce outlet resistance at the bladder neck and urethra (Griebling, 2007).

**INDICATIONS FOR TREATMENT**

Urinary dysfunction continues to impact the quality of life for millions of Americans. Many recent studies have demonstrated long-term efficacy, outlined complications, and examined the quality of life before and after sacral nerve neuromodulation. Pelvic floor dysfunction affects a large number of individuals who will consult their physician for a variety of reasons, including irritative voiding symptoms (frequency, urgency and urge incontinence, difficulty in voiding with sense of incomplete emptying, and/or a large post-void residual and retention) (Aboseif et al., 2002; Latini et al., 2005; Leng & Morrisroe, 2006).

The InterStim device was introduced in 1997 (see Figure 1). This therapy is currently an effective treatment modality in refractory pelvic floor dysfunction (Aboseif et al., 2002; Leng & Morrisroe, 2006), a set of complex problems that have not been managed well with conventional treatment modalities. Along with FDA approval, physicians will use these universal definitions to base the decision to test and/or implant the InterStim device.

- **Ure incontinence** is defined as an involuntary loss of urine associated with a strong sense of urinary urgency (Fanti, Newman, & Colling, 1996).
- **Urgency-frequency** is characterized by the uncontrollable urge to urinate, resulting in frequent, small volume voids. Patients complain that they do not feel like they empty their bladder after voiding, which may or may not cause pain and discomfort (Blaivas, 2007).
- **Urinary retention** is defined as the inability to empty the bladder. As part of urinary retention, there is non-obstructive overflow incontinence associated with overdistension of the bladder. Complete retention is the inability to initiate urination, while partial retention is characterized by residual volume of >50cc. This group of patients will present with frequent or constant dribbling, or signs of urge/stress incontinence. A likely cause of urinary retention is an abnormal urethral input, an overactive guarding reflex that inhibits detrusor activation and is also known as Fowler's syndrome. This is a loss of the normal feedback

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**Figure 1.** Interstim® Introduced in 1997

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loops that leads to incomplete emptying or urinary retention (Comiter, 2005).

Patients presenting with one of these conditions are considered candidates for InterStim therapy.

**Patient Selection**

Prior to introducing this therapy, patients under consideration for InterStim should have been treated and failed other conservative therapy. These therapies include behavioral modification, pelvic floor training, biofeedback, medications (Ditropan®, Detrol®, VESIcare®, Oxitrol™ patch), and clean intermittent catheterization for urinary retention (Bosch, 2006; Latini et al., 2005). However, the literature shows the problem with conservative treatment is that many patients discontinue their therapies, especially drug therapy, because of the intolerable side effects, contraindications to treatment, and/or high cost and time constraints. These patients will return to the clinic looking for other options, making InterStim therapy a viable option widely accepted as a treatment of choice.

An extensive work up is necessary prior to selecting a patient for testing or implantation of the InterStim. This evaluation begins with a careful history, physical examination, cystoscopy, and urodynamic assessment as essential components for appropriate patient selection.

All tests and conservative therapies (anticholinergics, tricyclics, and striated/smooth muscle relaxants) that have been tried and failed need to be documented prior to the beginning InterStim testing (Siegel, 2005). Once the patient makes the decision to try InterStim therapy, it is recommended that he or she completes a set of voiding diaries that are used to predict the efficacy of neuromodulation. Diaries are kept for three full days (day and night) prior to the testing period. A second set of diaries will be completed during the test phase. After the testing is completed, the second set of diaries is reviewed. If the patient has urge incontinence, the practitioner will compare the baseline diaries to the post-testing diaries for the severity of urge-incontinence episodes and the number of pads used in a 24-hour period. When the patient presents with urgency-frequency syndrome, the diaries focus on the number of voids, the voided volumes, and the degree of urgency. When the patient experiences inefficient voiding or urinary retention, the variables assessed will be the amount voided versus catheterized volumes in 24 hours as well as the patient’s sense of emptiness (Siegel, 2005).

This is the opportune time to discuss expectations of treatment with the patient so both the practitioner and the patient understand the goals of therapy. It is essential that patients understand that at the end of the test period, when comparing the two sets of voiding diaries, they must show 50% or greater improvement in their symptoms. It is not unusual to see the patient so hopeful that the therapy will work that they believe they are better, when in fact, their diaries do not indicate their symptoms have improved by 50% or more. Conversely, many times patients may not feel they have improved when their diaries show a significant or greater than 50% improvement, especially in those patients who void 20 to 25 times per day. With patients experiencing urgency-frequency, it is expected that their frequency is decreased by half and will see rare episodes of urgency; with the patient who is incontinent, decreasing the number of pads used per day is expected. With patients who have retention and are currently doing intermittent catheterization, the goal is that they are now voiding on their own and/or have decreased the number of catheterizations per day.
flexion of the great toe; both are consistent with stimulation at the S3 foramen (see Figure 3). Once the lead is inserted, it is connected to an external stimulator box, and a dressing needs to be applied to secure the wire for three days. Discharge instructions include limited bending at the waist, no excessive exercising, and keeping the dressing clean and dry. The patient is instructed to immediately start a second set of diaries for three days and return to the clinic after three days to have the wire removed, to review diaries, and to make future decisions about the feasibility of the treatment. If the test is successful, the patient will return later to have surgery, at which time a tined lead and neurostimulator (battery) will be implanted. If the test is unsuccessful, the wire will be removed, and the physician will discuss alternative therapies with the patient.

There are advantages and disadvantages to the percutaneous test. It is a mildly invasive outpatient procedure that can be completed in about 30 minutes, and the patient is awake and leaves the clinic after a minimal recovery period. However, the lead is placed and then removed in three to four days. If successful and the decision is made to go to a full implant, there is no guarantee the lead will be placed in the same area of the S3 foramen, and there may be a slight variation in the sensation the patient feels with a permanent implant.

**STAGED TESTING AND IMPLANTATION**

In 2002, a new method for testing evolved, where the chronic lead that has four points of stimulation is inserted, and the lead is kept in place, moving directly into the second stage or the implantation of the neurostimulator (battery). This staged procedure gained attention and is the current procedure of choice (Brazzelli, Murray, & Fraser, 2006) (see Figure 4). This method of using the chronic tined lead for testing is FDA-approved. It is far superior and recommended by most institutions when used following a failed or inconclusive percutaneous test.

The tined lead is a suture-less anchoring system that allows for a smaller surgical incision. Because of the small incision, the surgical procedure is performed by physician preference either under a combination of intravenous (IV) sedation and local or general anesthesia. If the test is performed using short-acting medications,
the patient is awake and can provide verbal responses describing how he or she feels and where the stimulation is located during the procedure (Leng & Morrisroe, 2006) (see Figure 4). Using this type of testing allows the patient to participate and enhances the chance of a good response and successful test.

The first part of the staged approach is the test; the lead can stay in place up to two to three weeks, shorter for urgency and urge incontinence and longer for urinary retention. In an operating room, the tined lead is placed in a sterile fashion into the S3 foramen under fluoroscopy. It is tested by either verbal response from the patient or motor responses, such as tightening of the levators or a bellows response in the anal area as well as plantar flexion of the great toe. Once the lead is in a good position, the practitioner will make a small pocket in the left or right upper hip. Wires are tunneled under the skin with one wire left outside the skin to attach to the external stimulator box. Dressings are applied over the incisions, and the patient is taken to the recovery area, where instructions are given before discharge. The patient is not discharged unless he or she has a clear understanding of how to use the patient programmer.

COMPLICATIONS, TROUBLESHOOTING, AND CONTRAINDICATIONS

There are several complications associated with the implantable system. Some common reasons for re-operation include a need to relocate the neurostimulator because of pain at the site, or revision of the lead for suspected or detected lead migration and infection. If the infection is superficial, the usual management is antibiotics; however, if there is a deep infection that is not resolved with oral or IV antibiotics, then explantation of the neurostimulator is required (Brazzelli et al., 2006). Some troubleshooting is necessary to determine if a revision is needed. It is necessary to review the pulse rate, width, frequency, impedance, patient use, and neurostimulator life to ensure all are within normal parameters. X-rays may be taken to compare lead location to determine if there is migration of the lead. An algorithm to troubleshoot the malfunctioning InterStim can be used; it is an organized systematic approach to the malfunctioning device that allows a higher salvage rate (Gaynor-Krupnick, Dwyer, Rittenmeyer, & Kreder, 2006).

Contraindications for the patient with an implanted device include shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy. The diathermy’s energy can be transferred through the implant and could be harmful. MRIs are not recommended.

CONCLUSIONS

Studies have shown that InterStim therapy (sacral nerve neuromodulation) is an effective treatment modality for patients
with refractory pelvic floor dysfunction, chronic urinary retention, and urgency-frequency syndrome. The procedure can be performed as a safe, minimally invasive test in the office or as a staged, same-day procedure in an ambulatory care unit. Therapy is successful if the patient’s symptoms are improved by 50% or greater and they are satisfied with the outcome of the therapy. Physician preference will determine future follow up, which should include yearly checks to determine efficacy of the therapy and a review of the electrical system.

References