Use of Sacral Neuromodulation in the Management of Voiding Dysfunction

Developed by the
SUNA Sacral Nerve Stimulation Special Interest Group
Revised Oct 2010
More than 85,000 patients have received InterStim Therapy.
Program Goal

To discuss the prevalence & treatment of urinary control problems and the use of sacral neuromodulation as a treatment option for patients with urinary urgency-frequency, urinary urge incontinence and/or urinary retention who fail or cannot tolerate conservative treatments.
Learning Objectives:

After completing this program you will be able to:

- Discuss the prevalence of urinary urgency-frequency, urinary urge incontinence and/or urinary retention.
- Define sacral nerve stimulation (SNS)
- Discuss the treatment algorithm used to treat urinary urgency-frequency, urge incontinence and retention.
- Discuss the theory of mechanism of action of sacral nerve stimulation.
- Explain the basic steps for the test stimulation and implant procedures used for InterStim Therapy
- Identify the implantable and external equipment used for sacral nerve stimulation.
- State the FDA approved indications for SNS.
- Identify patients appropriate for SNS when provided a case scenarios.
Voiding Dysfunction: A Hidden Problem

- Patients are embarrassed to talk to healthcare providers about voiding problems
- Many providers typically do not ask patients about voiding problems
- Quality of life issues can include:
  - Anxiety, depression, infections, nocturia, odors, embarrassment, diet restrictions, discomfort / pain, limitations of social activities and employment opportunities, and cost of protective garments
Normal Micturition

Requires coordinated activity between the nerves and the muscles that control voiding.
Filling Phase

**Automatic Actions:**
- Brain signals detrusor muscle to relax to allow urine to fill bladder
- Once bladder fills to capacity, bladder nerves signal fullness back to brain

**Conscious Actions:**
- As bladder fills, you become aware of fullness
- The response is to void or wait for an opportunity to void.
Emptying Phase

- **Automatic Actions:**
  - Voiding reflex occurs
  - Nerves in spinal cord signal detrusor muscles to contract and internal sphincter to relax to allow urine to flow from bladder into urethra

- **Conscious Action:**
  - Once urine enters urethra, you consciously relax the external sphincter to allow urine to pass through the urethra
Abnormal Micturition

Voiding dysfunction occurs when a patient’s normal micturition reflexes are altered because of a neurological disease, infection, inflammation, or anatomical abnormalities in voluntary voiding reflexes.
Urinary Urgency-frequency and Urinary Urge Incontinence

US prevalence = 33.3 million\(^1\)

- 7.3 million
  - Women: 2.9 million
  - Men: 1.1 million
- 2.0 million
  - Women: 2.0 million
  - Men: 0.8 million
- Total: 1.8 million
  - Women: 1.3 million
  - Men: 0.5 million

16.5% of US population\(^1\)

- 30% actively seeking care (excluding men w/BPH ~8.0 million)\(^2\)
- Patients who cannot tolerate pharmacotherapy (~55%) 4.0 million\(^3\)
- Patients with continued symptoms actively seeking further treatment (~70%)\(^4\)
  - 2.8 million

Potential patient candidates for SNS\(^*\) (~65%)\(^*\)

Net Prevalence @ 1.8 million

* Assuming clinical exclusion of 20% & economic exclusion of 15%

Overview

Sacral Nerve Stimulation (SNS)
**Definition:**
An implantable system that stimulates the sacral nerves modulating the neural reflexes that influence the bladder, sphincter, and pelvic floor.

**Indications:**
SNS is used to treat urinary retention and the symptoms of overactive bladder (OAB), including urinary urge incontinence and significant symptoms of urgency-frequency in patients who have failed or could not tolerate more conservative therapies.
SNS - Therapy

SNS utilizes mild electrical pulses to simulate the nerves associated with voiding function. Neurostimulation may significantly improve normal voiding function.
SNS Theory of Mechanism

- **Urge incontinence:**
  Modulation enables more normal detrusor muscle behavior

- **Urgency-frequency:**
  Modulation helps reduce detrusor and pelvic floor muscle spasticity
Pharmacotherapy vs. SNS Therapy

Pharmacotherapy: Mechanism of Action
- Targets efferent effects
- Poor patient compliance related to the side effects (i.e. dry mouth)

SNS Therapy: Mechanism of Action
- Targets afferent effects & modulation of the pelvic floor
- General lack of side effects known associated with drug therapy

InterStim Therapy
- Should be considered after more conservative treatment options have failed and before surgical options are considered
Clinical Results: 5-Year Efficacy

Purpose
This post-approval, non-randomized, multicenter study provided data on the long-term effects of sacral nerve stimulation for the treatment of urinary urge incontinence, urinary urgency-frequency, and urinary retention in patients who had failed or could not tolerate more conservative treatments. The study took place at 17 centers in the United States, Canada, and Europe.

Results
The study demonstrated that InterStim Therapy can be a long-term solution for patients with overactive bladder or non-obstructive urinary retention. Based on the subset of study subjects for whom both baseline and five-year data were available (i.e., the evaluable sample), improvement ranged from 39% to 78%, depending on the outcome assessed. If all implanted study subjects are considered (i.e., the intent-to-treat sample) and missing five-year data are imputed using baseline values (or, in the absence of baseline values, from the mean baseline of all subjects with baseline values), the results range from 28% to 58%, depending on the outcome assessed.

See InterStim Therapy Clinical Summary for complete details.
5-Year Clinical Efficacy
Urge Incontinence – 60 month post-implant

Intent to Treat Patients – defined as all implanted study subjects, including those who dropped out and were imputed as no change from baseline.

Evaluable Patients – defined as the subset of subjects for whom both baseline and 5-year data were available.

- ≥ 50% Reduction in Leaks/Day
- ≥ 50% Reduction in Heavy Leaks/Day

1 Excludes patients who reported no heavy leaks at baseline and at 60 months post-implant
5-Year Clinical Efficacy
Urge Frequency - 60 month post-implant results

- Intent to Treat
  - ≥ 50% Reduction in Voids/Day
  - ≥ 50% Increase in Volume Voided/Void
  - ≥ Improved Degree of Urgency Prior to Void

Patients %

- 28% (n = 25)
- 40% (n = 25)
- 40% (n = 25)
- 39% (n = 18)
- 56% (n = 18)
- 56% (n = 18)
5-Year Clinical Efficacy
Urinary Retention - 60 month post-implant results

Intent to Treat

Evaluable Patient

Patients %

≥ 50% Reduction in Catheterizations/Day

≥ 50% Reduction in Volume/Catheterizations
Patient Selection/ Cases

Factors influencing Patient Selection
Treatment Algorithm
For Urinary Urgency-frequency
and/or Urinary Urge Incontinence

Initial Screening
Voiding Diary
Urodynamic Workup
Behavioral Techniques Interventional Techniques Medications
Continue as Appropriate
SNS Test Stimulation
Retention Treatment Algorithm

- Initial Screening
  - Voiding Diary
  - Urodynamic Workup
    - Rule Out Obstruction
      - Medications and/or Catheterization
        + Continue as Appropriate
        - SNS Test Stimulation
Other Issues Influencing Patient Selection

- Mental status
- Psychiatric status
- Patient expectations
- Multiple Sclerosis
- Back or neurological problems
- Support system
- Discussion of alternative treatment
- Issues that contribute to SNS failure
Overview

1\textsuperscript{st} Phase testing/PNE
2\textsuperscript{nd} stage Implant
when to program
Test & Implant Procedures

- **1st Phase: Test stimulation**
  - Test can be done with a temporary or chronic lead

2nd stage Implant

Temporary Lead

Chronic Lead
Test stimulation:

- Is done to determine how the patient will respond to the implanted device

- Is an outpatient procedure performed in the office or OR depending upon the lead used (temporary in office/chronic in OR)

- Lead is placed under the skin through the S-3 foramen in close proximity to the S-3 nerve

- Lead is connected to an external device worn on belt for a period of 3-7 days

- The decision for implantation of the permanent device is made based on response to the test stimulation
Voiding Diary Documentation

3 days of diaries before test and during test

Urge Incontinence
- Number of leaking episodes per day
- Severity of leaking episodes per day
- Number of pads/diapers per day

Urgency-frequency
- Number of voids per day
- Volume of voids per day
- Degree of urgency

Retention
- Catheterized volume vs voided volume
- Number of catheterizations per day vs number of voids per day
2nd Phase: Chronic Implant

- If tested with temporary lead: Implantation of neurostimulator (INS) and lead and/or extension (if necessary)*
- If tested with chronic lead: Implantation of neurostimulator (INS)

* Components requiring implantation depend on the selected InterStim neurostimulator used for the implant.
2nd Stage

Implant Procedure 2nd Stage:

- Outpatient procedure done in operating room using general or local anesthesia
- Stimulator is implanted and connected to a lead that will stimulate the sacral nerve
- Stimulator is usually placed in upper buttock
- The entire implantable System resides under the skin
- Entire procedure takes 20-30 minutes
System Implantation: Connect implanted Lead to INS

- Create a subcutaneous pocket
- Tunnel the implanted lead to the pocket site
- The implanted lead, extension (if required), and INS are connected and placed in the pocket.
- Verify system integrity (no short or open circuit), then close the pocket.
Benefits of SNS
Potential Adverse Events

- Test stimulation period allows informed choice for patient and doctor
- Effective treatment in properly screened patients
- Safe
- Reversible
- Does not preclude use of alternative treatments

- Potential risks, pain at neurostimulator site, infection transient electric shock
When Do You Program?

- After initial implantable neurostimulator (INS) implantation:
  - Day of surgery—1 week (physician preference)

- Patient’s system requires “reprogramming”:
  - Symptoms reappear
  - Discomfort
  - Loss of stimulation
Case Studies
Retention with frequency-urgency
History

- 65 y/o wf with retention, frequency, urgency and voiding dysfunction. Strains to void in addition to doing CIC and spontaneous voiding
- Leaking in between CIC
- Small cystocele noted
Voiding Diary

- Pt voids 2-4 oz q 2-3 hrs
- Pt caths 3 x day (ave. = 200-300cc)
- Leaking in between cathing
- Wears 3-4 pads per day
Cystoscopy

- Normal urethra, bladder and ureters
- Normal pelvic exam and female genitalia
- No edema, lesions or palpable abnormalities
- Anterior and apical compartments are well supported
Strains to Void
Video Urodymanics
Urodynamic Results

- Normal storage parameters consisting of normal sensation/compliance and capacity
- No Detrusor overactivity
- No SUI
- Abnormal voiding (strains to void)
- No evidence for outlet obstruction
Recommendations and Results

- SNS Test
- Voids 4-5 times a day and emptying (cathing less than 50cc)
- No leaking in between cathing
- Pt implanted 3 wks later
Post InterStim Implant

- Doing extremely well and emptying with no need to perform CIC
- PVR post implant in office 13cc
- Continues spontaneous voiding
- Reports occasional twitching of her toe
- F/U 1 yr or PRN-per clinic protocol
Patient Care Management

- Mention SNS to patients and family early in treatment to give them an opportunity to adjust to the idea of an implanted device give them encouragement that there are alternative treatments if conventional therapy fails.

- Perform thorough patient workup and correct any mixed incontinence issues or obstructive uropathy to give a SNS trial the best chance to succeed.
To achieve optimal results for SNS patients may need:

- to continue on or go on pharmacologic therapy
- Continue dietary modifications
- Continue or initiate pelvic floor rehabilitation
Patient/ Family Considerations

- Provide realistic expectations of sacral nerve simulation so that everyone clearly understands that it is to help, not necessarily cure, their urinary problem.

- Assist patients to recognize their role in achieving optimal urinary functioning and maintaining integrity of SNS.
Management of Care

- Life choices that may affect system integrity and longevity
- Impact on other chronic health problems or urinary status
- Patients need to be counseled regarding the inability of having MRI once the SNS is placed
- Patient responsibility to continue concomitant therapy, if recommended, and to use SNS as prescribed
Management of Care

- Recognize there is a learning curve for surgeons to become proficient with lead placement.
- Evaluate the patient as a whole at follow-up visits instead of automatically reprogramming SNS when the patient has complaints.
- Utilize a consistent approach to patient management and programming issues to facilitate patient compliance and improve outcomes.
- Be persistent.
Summary

- SNS is an effective treatment option for patients with non-obstructive urinary retention, urge incontinence or urgency/frequency, with or without IC.
- Consider SNS early in the treatment algorithm.
- Reinforce realistic expectations.
- Concomitant therapy may be needed with SNS to obtain optimal results.
Educational Material Available

Patient Education Resources include:

- Imagine Hope (brochure/DVD)
- InterStim® Therapy Using Your iCon Programmer (DVD)

Clinician Resources include:

- Decision Trees for Troubleshooting
- Programming Basics Tutorial (online/DVD)
- Patient Management Questionnaire
- Patient Identification Tip Sheet
- Patient Programming Work Sheet
- Programming Pointers Guide
- Reimbursement Information
- Webb site for patients www.everyday-freedom.com
- Webb site for clinician www.medtronic.com
Revision for SUNA Oct 2010

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