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RESEARCH ARTICLE

SACRAL NEUROMODULATION IN UROLOGY

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ABSTRACT

Sacral neuromodulation is a new minimal invasive therapy. It is FDA approved for refractory overactive bladder, frequency urgency syndrome and non-obstructive retention. Here we review this therapy indications, outcome, surgical procedure and complications.

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INTRODUCTION

Sacaralneuromodulation (SNM) or sacral nerve stimulation (SNS) is an increasingly used minimal invasive therapy. In involve implantation of tined lead to the third sacral root which is connected to an internal pulse generator for electricity generation. The concept of neuromodulation started at 1878 by Saxtorph intravesical electrical stimulation which was followed by different approaches (direct detrusor stimulation, pelvic nerve stimulation, pelvic floor stimulation, spinal cord stimulation and Transurethral approach). Tanagho and Schmidt stimulation of sacral root S3 generally induces detrusor and sphincter action (Nashold, 1971; Thon *et al*., 1991; Tanagho and Schmidit, 1982; Tanagho, 1988; Tanagho, 1990; Madersbacher, 1999; Vadusek *et al*., 1986). In October 1997, FDA approved Sacral neuromodulation as treatment of Urge incontinence (UI) and Urgency –frequency syndrome (U/F). At 1999 it received FDA approval as treatment of non-obstructive urinary retention (NOUR).

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Mechanism of action

It is not well understood how sacral neuromodulation works but it's mainly working to restore function by Targeting Bladder-Brain Communication. Urine storage and micturition depends on the coordination between bladder, bladder neck, urethral and urethral sphincter .Coordination of lower urinary tract muscles are under neural pathways in brain, spinal cord and peripheral nerves (Fowler *et al*., 2008). Afferent pathways convey sensory information on bladder fullness, while efferent motor pathways respond, resulting in voluntary urine control. Dysfunction of the afferent neural pathways alters the balance of inhibitory and excitatory stimuli critical to voluntary bladder control (Andersson, 2004; Chancellor, Chartier-Kastler, 2000; de Groat, 2006; Leng and Morrisroe, 2006). Low-level afferent signals are organized in the spinal cord and promote urine storage via efferent signals from the CNS. Overactive bladder may be a result of increased, abnormal afferent activity, resulting in increased efferent signaling, consequently, voluntary control of micturition is compromised. Leading Theories in Mechanism of Action in Sacral Neuromodulation are:

- The goal of Sacral Neuromodulation (SNM) is to modulate the abnormal involuntary reflexes of the lower urinary tract and restore voluntary control.

- Sacral Neuromodulation electrically stimulates somatic afferent nerves in a sacral spinal root and sends signals to the CNS that restore normal bladder function.
- Activation of somatic afferent nerves alters bladder sensory pathways and inhibits reflex bladder hyperactivity.
- Sacral Neuromodulation sends electrical stimulation to the sacral nerve via the InterStim® System, which includes an implanted neurostimulator and lead (electrode).
- The sacral nerve, in particular, influences pelvic floor behavior and is believed to modulate neural reflexes (Buback, 2001).
- Neurostimulatin provides an electrical charge to an area near the sacral nerve, resulting in altered neural activity, this stimulation likely depolarizes the nerve, causing an action potential.The signal propagates impulses along the axon as if the neuron had naturally fired an action potential (Johnson and Watson, 2008).

Urological indications of sacral neuromodulation

Sacral neuromodulation is FDA approved for Refractory overactive bladder, frequency urgency syndrome and non-obstructive urine retention. There is other off label used of this treatment which showed clinical benefit.

Refractory overactive bladder (OAB)

The International Continence Society Definition of OAB is diagnosed and defined based on symptoms as Urgency with or without urge incontinence, usually with frequency and nocturia, in absence of pathologic or metabolic factors to explain symptoms, while urgency is defined as the complaint of a sudden compelling desire to pass urine, which is difficult to defer (Abrams *et al*., 2003). Overactive bladder is a Widespread Problem that is expected to Increase. Approximately 37.4 million adults in the United States have symptoms of OAB. Epidemiologic surveys suggest that the incidence of OAB rises as the population ages increase (Stewart *et al*., 2003; United Nations, 2011; World Population Prospects, 2010; Centers for Disease Control and Prevention (CDC), 2010; National Diabetes Statistics, 2011; National Osteoporosis Foundation, 2012). The pathophysiology of OAB may depend on gender and age.Myogenic and neurogenic centric hypotheses have been proposed as causes of OAB. Functional MRI studies in OAB patients have shown diminished brain activity in certain regions responsible for voluntary voiding, suggesting the central nervous system (CNS) plays a role in OAB. These hypotheses may not be mutually exclusive, and may vary across patient and disease types (Derbyshire *et al*., 2005). Sacral neuromodulation is used as 2nd line of therapy in refractory OAB which is defined as no response to minimum of 2 types of anticholinergics. Clinical studies have shown significant improvement in urine incontinence, frequency, urgency symptoms (Derbyshire *et al*., 2005; Lombardi and Del Popolo, 2009; Vastenholt *et al*., 2003). These were FDA approved indication of Sacral neuromodulation (SNM). We will mention in next section non FDA approved (off- label) uses of SNM:

Neurogenic disorders

Partial cord injury also may benefit from Sacral neuromodulationin spinal cord injured patients detrusor hyperreflexia develops after spinal shock period resolves. Vastenholt *et al*, reported series of 37 patients with spinal cord injury who underwent implantation of sacral anterior root stimulation. He reported his 7 year follow-up of the group in which 87% continued using the implant for micturition control, 60% used it for benefits with respect to defecation. Of the 32 male patients, 65% were able to achieve a stimulator- induced erection. Everaertetal, reported the urodynamic changes in 27neuromodulation implanted patients with spastic pelvic floor syndrome, bladder neck dysfunction, sphincter hypertonia, sphincter dysfunction, atonic bladder and OAB (Lombardi and Del Popolo, 2009; Vastenholt *et al*., 2003). SNM is still effective in neurogenic bladder dysfunction group, and failures depend on the progression of the underlying neurological disease which usually are reported in the first year of follow up.

Interstitial cystitis (IC) and pelvic pain

IC per se is not an FDA approved indication for Sacral neuromodulation. A lot of studies showed patient symptoms relieve with SNM improved patient quality of life & narcotic requirements in refractory IC. Peters reported total of 18 out of 21 interstitial cystitis patients who used chronic narcotics before Interstim. The mean narcotic use dropped, from 81.6 mg/day Morphine Dose Equivalent (before implantation) that decreased afterward to 52.0mg/day (36%, P=0.015), 4 of 18 patients ceased using all narcotics after permanent Interstim implantation. Ghazwani *et al* reported long term follow up of 21 female patients with painful bladder syndrome in which 52% showed response to PNE and proceeded for permanent IPG implantation. They had a significant improvement in bladder pain and voiding parameters at 1- year follow-up which was maintained at 5 years, with improvement in urgency, average voided volume, pelvic and perineal pain.Gajewski and Al-Zahrani recommended SNM in these patients before any major invasive surgical interventions if the conservative measures have failed (Lukban *et al*., 2002).

Chronic genitourinary pain

Sacral neuromodulation control a variety of forms of genitourinary pain as chronic nonbacterial prostatitis and chronic epididymo-orchalgia. Feler *et al* reported a 75% improvement in a 44y male diagnosed with chronic epididymitis and chronic non bacterial prostatitis. Vulvodynia consists of chronic vulvar discomfort including itching, burning and dyspareunia. Feler *et al* reported a 71y female who suffered of Vulvodynia for 9 years in which sacral neuromodulation provided excellent pain relief.

Sexual function

Few reported cases claiming improved sexual function in both genders. Lombardi *et al* reported sacral neuromodulation for lower urinary tract function in male patients which showed impact on their erectile function. Total of 22 patients had their IEF-5 score shifted from 14.6 to 22.2. In females, papers reported improvement in sexual function index of arousal and lubrication in voiding dysfunction female group. Pauls *et al* reported total female sexual function index improvement (p=0.002), and significant improvement domains of desire (p=0.004) and lubrication (p=0.005) in voiding dysfunction group. Female sexual function overall indices improved in voiding dysfunction female group P=0.028 (CI-23.14- -1.62),

the parameters of satisfaction=0.037 (CI -4.9- -0.0177) & lubrication P=0.018 (CI -6.082 - -0.687) showed significant improvement in comparison to the other parameters (Lombardi *et al*., 2008).

Children

Children are faced with various degrees of lower urinary tract dysfunction that often deteriorate upper tract function. Usual treatment modality of intermittent catheterization & anticholinergics are not uniformly successful and major reconstructive procedures are needed. Humphreys *et al* reported SNM in 16 children with refractory voiding dysfunction with mean age of 11 years. His study group showed 75% improved or resolved urinary incontinence, 83% improved their nocturnal enuresis, urinary retention improved in 73% of patients (Tanagho, 1992).

Contraindications

Anatomical bony abnormalities of the sacrum are one of the contraindications for SNM. Other contraindications are: patients with mental incapacity or psychiatric illnesses, unsuccessful Trial (test stimulation), coagulation disorders and local acute sacrum infection. SNM appears to be safe in the presence of a cardiac pacemaker without cardioversion/ defibrillation technology. Some conditions are considered challenging as MRI & pregnancy, but general rule is to turn off device during all pregnancy period, and avoid MRI (Martin *et al*., 2004; Torsten Sommer *et al*., 2000; Wang *et al*., 1999; Wiseman *et al*., 2002; Wallace *et al*., 2007).

Surgical technique

After clinical evaluation &urodynamics assessment patients are requested to fill up voiding diary for minimum of 3 days (baseline), which will be followed by test stimulation trial. There are two different types of test stimulation: percutaneous nerve evaluation (PNE) and staged test trial. Percutaneous nerve evaluation (PNE) is done as an outpatient procedure under local anesthesia. It involves placement of a thin insulated wire into the third sacral foramen. Usually fluoroscopy is needed to localize the foramen during the PNE insertion. While staged test trial is done under General anesthesia in Operating room using tined lead for longer duration of 2 weeks in contrast to 3-5 days in PNE test. During test trial, patients will fill up a second voiding diary for proper response assessment. If patients had ≥ 50% symptom relive on voiding diary then patient is considered as candidate for sacral neuromodulation therapy and Interstim implantation which is implanted in a subcutaneous pocket in gluteal area after being connected to the tined lead.

Complications

As any surgical procedure, complications are risk post operatively. The commonest complication of SNM is IPG site pain (15%), followed by electrode migration (8.5%), infection (6%) and transient shock (5%).

Conclusion

SNM therapy using Interstim devise is FDA approved for refractory OAB, non-obstructive retention and frequency urgency syndrome. Off label uses are reported and showed effectiveness of SNM as a therapy. All patients should undergo test stimulation trial before permanent implantation.

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