



## Neuromodulation for pelvic floor dysfunctions: exploring tibial, sacral and pudendal nerve stimulation.

W18, 15 October 2012 14:00 - 17:00

Start	End	Topic	Speakers
14:00	14:10	Introduction	<ul style="list-style-type: none"> <li>• Stefan de Wachter</li> </ul>
14:10	14:40	Tibial, pudendal and sacral nerve stimulation: does the mechanism of action differ?	<ul style="list-style-type: none"> <li>• Nico Rijkhoff</li> </ul>
14:40	15:05	Tibial, pudendal or sacral nerve stimulation: Is there one optimal stimulation method?	<ul style="list-style-type: none"> <li>• John Heesakkers</li> </ul>
15:05	15:30	Tibial, pudendal or sacral nerve stimulation: How to choose the suitable method for a specific patient?	<ul style="list-style-type: none"> <li>• Thomas Dudding</li> </ul>
15:30	16:00	Break	None
16:00	16:25	Discussion: Tibial, pudendal or sacral nerve stimulation: Is bladder and bowel management different?	All
16:25	16:50	Discussion: Tibial, pudendal or sacral nerve stimulation: sequential or parallel treatments?	All
16:50	17:00	Closing remarks - proposal treatment algorithm	<ul style="list-style-type: none"> <li>• Stefan de Wachter</li> </ul>

### **Aims of course/workshop**

Sacral nerve stimulation is a well accepted minimal invasive treatment for certain bladder and bowel dysfunctions, but tibial and pudendal nerve stimulation are currently emerging as alternatives.

The aim of the workshop is to guide decision making in patients in which neuromodulation therapy is considered, and to bridge the gap between bladder and bowel management.

The similarities and differences between the different forms of neuromodulation will be discussed focusing on mechanism of action, clinical efficacy, patient selection criteria and adverse events.

At the end of the workshop, the audience should have a clear overview of the different modalities and a possible algorithm to choose the optimal method for the individual patient.

### **Educational Objectives**

Sacral nerve stimulation is a well-accepted treatment for a defined group of patients with bladder (overactive bladder dry/wet; urinary retention) and/or bowel dysfunction (faecal incontinence; constipation). However based on the results of the test stimulation and the long term efficacy results, about 50 of the patients involved are left insufficiently treated. Pudendal nerve and tibial nerve stimulation are less known alternatives, but they may be of benefit for some of these patients.

The aim of the workshop is to present and describe the different neuromodulatory modalities available today. The content will cover the basics on the presumed mechanism of action leading to patient selection criteria. The literature data will be presented by speakers from the respective fields (engineering - urology - colorectal surgery), which will lead to an interesting discussion between similarities and differences of the different treatments, and bridge the gap between urological and colorectal management. The final purpose is to give the audience an algorithm how to choose the optimal treatment for the individual patient.

Neuromodulation for pelvic floor dysfunctions: Bowel Disorders  
ICS 2012 - Beijing, China

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## **Introduction**

Faecal incontinence is estimated to affect 2-3% of Western adult populations. In certain groups of patients, such as post-partum females the prevalence is higher still (5.5%). Faecal incontinence is not a single disease but a symptom resulting from one or more disorders that alter the complex interactions between the muscles and nerves of the anus, pelvic floor and rectum. Medical and behavioural therapies are the mainstay of treatment, but when these fail surgical procedures are considered. In recent years it has become apparent that sacral nerve stimulation is a first-line surgical option for many patients.

The effect of sacral nerve root stimulation (SNS) on gut function was first observed in the initial studies of SNS for urological disorders but formally described by Matzel et al. in 1995. The mechanism of action remains unclear but it is believed that it is the stimulation of predominantly afferent pathways that leads to treatment success. The afferent outflow of the pelvis may be asymmetric, predominantly at the level of S2 or confined to a single root. Based on this concept, the use of bilateral sacral nerve stimulation and pudendal nerve stimulation have been explored in an attempt to maximise afferent stimulation and improve clinical outcome. Stimulation of the posterior tibial nerve, which has proximal connections with the sacral plexus, has also been investigated.

## **SNS for faecal incontinence**

The initial studies of sacral nerve stimulation for faecal incontinence were limited to the treatment of patients with intact anal sphincters. It was believed that this was necessary for the therapy to work. Physiological studies however have shown that there is little or no effect on anal sphincter function at sub-sensory levels of stimulation and the indications for SNS have therefore widened in recent years to include those with sphincter defects and faecal incontinence related to other aetiologies. Two multi-centre trials and 11 observational reporting on over 1000 patients that have undergone SNS suggest that the treatment is effective. Whilst there is heterogeneity in the aetiology of faecal incontinence within studies, around 80% of patients undergoing temporary SNS will have greater than 50% reduction in incontinent episodes with 85% of the patients that proceed to permanent stimulation having benefit in the short-term. This equates to roughly two-thirds of all patients on an intention to treat basis. No pre-operative predictive factors have been identified that can assess which patients are more likely to respond to therapy. However, patients with greater than 10 years follow-up have been shown to have

continued benefit from chronic SNS. There are few data to support the use of bilateral sacral nerve stimulation for faecal incontinence at present.

Eight studies have specifically looked at the effects of SNS in patients with anal sphincter disruption. A combined success rate of 73% in those undergoing permanent stimulation at mean 16 months follow-up demonstrates comparable results to those patients that undergo treatment with intact sphincters. A number of small studies have suggested that SNS may be beneficial in the treatment of patients with faecal incontinence related to incomplete spinal cord injuries and in those that have undergone pelvic irradiation, anterior resection or rectal prolapse surgery.

### **SNS for Constipation**

The effect of SNS in those patients with constipation is less clear due to lack of a coherent definition of constipation and difficulty in measuring end-points other than frequency of evacuation. A multi-centre international trial by Kamm et al. reported response to therapy in 45 of 62 patients (73%) undergoing SNS of which 81% had slow-transit constipation and 19% normal transit with evacuatory dysfunction. Cleveland clinic constipation scores, frequency of defaecation, number of successful evacuations symptoms of abdominal pain and bloating all improved with correlating improvement in the patients subjective rating of bowel function. The benefits of treatment were maintained at 24 months follow-up.

Govaert et al. report treatment success in 61 of 117 patients (52%) at 37 months follow-up. Benefit was seen in both those with slow transit constipation and evacuatory dysfunction. Carriero et al. suggest that a psychological evaluation of patients being considered for SNS is important as those with underlying psychological disorders are less likely to respond to therapy.

### **Pudendal nerve stimulation for bowel dysfunction**

The pudendal nerve is a mixed nerve that contains afferent fibres of the S2, S3 and S4 nerve roots. Stimulation of this nerve maximizes afferent root stimulation and avoids unwanted efferent stimulation of the S2 component of the sciatic nerve that can lead to pain or discomfort. The technique of pudendal nerve stimulation was first described by Spinelli et al. in 2005 to treat urological voiding disorders. Like the initial studies of sacral nerve stimulation it was observed that some patients with constipation had improved symptoms with therapy. A small pilot study by George et al. suggests that over one-half of patients who fail to respond to SNS will benefit from pudendal nerve stimulation. The same authors also describe benefit in nine of ten implanted patients with cauda equina syndrome at a mean of 12 months follow-up.

### **Posterior tibial nerve stimulation for faecal incontinence**

Posterior tibial nerve stimulation (PTNS) can be applied either via a percutaneous or transcutaneous route. 11 studies to date have reported on the benefits of the therapy (total 216 patients; 127 patients percutaneous, 89 transcutaneous). Quantitative comparisons between studies are difficult due to the diversity of treatment protocols used, variation in recorded outcome measures and differences between the populations studied. Ten out of eleven studies assessed outcome using the Cleveland clinic continence score. Two studies that assessed the outcome of PTNS in patients with IBD and incomplete spinal cord injury reported no success from therapy. In the other eight studies, successful outcome (reduction of incontinent episodes by >50%) was reported in 63% to 80% of patients undergoing percutaneous PTNS and 9%, 16% and 80% of those undergoing transcutaneous PTNS. Only short-term outcomes have been reported with no study providing greater than 12 months follow-up. In our unit we have completed a randomized, blinded, controlled trial comparing the percutaneous and transcutaneous technique with sham transcutaneous stimulation. Of 30 patients treated, successful outcome, defined by >50% reduction in incontinent episodes was observed in 9 of 11 patients undergoing percutaneous PTNS, 5 of 11 patients undergoing transcutaneous PTNS and one of 8 patients in the sham group. Further evaluation of this treatment and comparison with sacral nerve stimulation is now awaited.

### **Suggest Reading**

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- Spinelli, M., S. Malaguti, et al. (2005): A new minimally invasive procedure for pudendal nerve stimulation to treat neurogenic bladder: description of the method and preliminary data. *Neurourol Urodyn* 24(4): 305-9.
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## **Sacral, Pudendal or Tibial Nerve Stimulation: Is there one optimal stimulation method?**

ICS 2012 Beijing China

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### ***Introduction***

The definition of Overactive Bladder syndrome (OAB) is urgency, with or without incontinence with or without nocturia and often accompanied by frequency. The International Continence Society defines OAB as a symptomatic syndrome suggestive of lower urinary tract dysfunction. It is estimated that 12-14% of all adults suffer from OAB and as the population of aging adults continues to grow this number is likely to increase. Neuromodulation represents an important and ever expanding treatment option for patients suffering from OAB.

Neuromodulation is the electrical or chemical modulation of a nerve to influence the physiologic behavior of an organ. Tanagho et al. in 1989 pioneered the initial investigations into electrical stimulation for neuromodulation. Since this early work neuromodulation has become an important tool in the treatment of bladder dysfunction. Neuromodulation offers a minimally invasive, non-ablative and reversible method to treat voiding dysfunction.

### ***Sacral Nerve Stimulation***

Sacral nerve stimulation (SNS) has been approved by the FDA for over 10 years to treat urinary urgency, frequency, urge incontinence and non-obstructive urinary retention. Also the long term success rates are good (van Kerrebroeck 2007) The success of neuromodulation in treating voiding symptoms can be assessed by either a peripheral nerve evaluation (PNE) or staged implantation. The long-term success of SNM has been well-established in the literature.

Various attempts have been tried to optimize the effect of SNS. This has been done by trying to find predictive factors that influence the effect of SNS. The results of all these studies are contradictory. Benson et al (2000) focused on optimizing the anal sphincter EMG response during test stimulation of the sacral roots. They concluded that an optimal motor response, measured by EMG, gives a better outcome than a suboptimal motor response. Koldewijn et al (1994) looked at urodynamic parameters and concluded that detrusor overactivity was predictive for SNS success. Groenendijk et al (2007) found that urethral instability was predictive for a good response of SNS. Weil et al (1998) observed that psychiatric disorders were predictive for a inferior outcome. However this could not be copied by Marcelissen (2011) et al from the same department, although they concluded that patients with a psychological background do experience more adverse events after implantation. So on the one extreme some implanters look at the pure motor responses to predict good outcome whereas on the opposite side psychological factors play a role in the response to an implant.

We know that tined lead testing gives a better result than PNE testing. Also bilateral stimulation seems to be better than unilateral stimulation as was shown by Kaufmann et al in pigs (2009). Others come to the same conclusion although the cost-benefit ratio of bilateral stimulation is questioned since not a lot of patients seem to have additional benefit.

### ***Pudendal Nerve Stimulation & Neuromodulation***

The pudendal nerve is a peripheral nerve that is mainly composed of afferent sensory fibers from sacral nerve roots S1, S2 and S3. The bulk of afferent sensory fibers are contributed by S2 (60.5%) and S3 (35.5%) according to afferent activity mapping procedures. Consequently the pudendal nerve is a major contributor to bladder afferent regulation and bladder function.

#### *Pudendal nerve anatomy*

The pudendal nerve originates primarily from the second, third and fourth sacral nerve roots, and sometimes gains contributions from the adjacent roots of S1 and S5. The sacral nerve roots are composed of autonomic and somatic nerve fibres. The autonomic branches traverse more

ventrally and form the pelvic plexus for parasympathetic innervation of among other things the detrusor muscle. Nerve branches of the somatic component combine to one major trunk of the pudendal nerve. The nerve lies medial and caudal to the sciatic nerve trunk and enters the gluteal region via the greater sciatic foramen. At the level of the ischial spine, the pudendal nerve passes between the sacrospinous ligament anteriorly and the sacrotuberous ligament posteriorly. More caudal, the pudendal nerve enters laterally the ischiorectal fossa at the medial side in a fascial sheath (pudendal canal, Alcock's canal) close to the obturator internus muscle.

#### *Pudendal nerve branches*

The pudendal nerve has three major branches: the inferior rectal nerve, the dorsal genital nerve and the perineal nerve, with a high variation rate in branching patterns. Adjacent to the ischial spine and the sacrotuberous ligament the pudendal nerve consists of one, two and three trunks in 56-75%, 14-35% and 6-12% of respectively. In 21% the inferior rectal nerve originates independently from the S4 root and never branches from the main pudendal nerve. The remainder of the pudendal nerve divides near the entrance of Alcock's canal or within Alcock's canal into the perineal nerve and the dorsal genital nerve. Comparable to the rectal nerve the dorsal genital nerve originates independently from the S2 root in 25%.

#### *Pudendal nerve and OAB*

The main driver of OAB is urgency, a sensory effect. It seems to make sense therefore to change the behaviour of the bladder in OAB by working on the afferent nerves. Because the pudendal nerve carries such a large percentage of afferent fibers this makes neuromodulation of the pudendal nerve an attractive option for refractory OAB.

Direct pudendal nerve stimulation stimulates more pudendal nerve afferents than SNS most likely does. This implies that theoretically it is a better target than SNS for neuromodulation and the more selective stimulation can be done without stimulation of buttocks or leg muscles. One study compared pudendal nerve stimulation with standard sacral nerve stimulation in a prospective, single blinded, randomized trial. Patients had both sacral and pudendal quadripolar tined leads placed in the first stage of their operation. Patients were then blinded to whether



they were receiving pudendal or sacral stimulation and asked to rate their symptoms and chose a preferred site for stimulation. When patients received pudendal stimulation they had a 63% improvement in symptoms versus a 46% improvement in symptoms with conventional sacral neuromodulation. When patients were asked which lead they would prefer to receive stimulation from 79.2% of patients chose the pudendal lead and 20% chose the sacral lead. Spinelli et al also evaluated 15 treatment refractory patients with neurogenic bladder after CPNS with a tined lead placed under neurophysiologic guidance. Statistically significant reductions in incontinent episodes ( $p < 0.02$ ) and improvements in maximum cystometric capacity and pressure on urodynamics studies were seen. Constipation and fecal incontinence also improved. Currently at our institution the most common indication for pudendal neuromodulation is for patients that have had failure of sacral neuromodulation. A recent review of our data found 41 of 44 (93.2%) who had previously failed sacral neuromodulation had a positive response to pudendal stimulation and had a permanent implant placed. The placement of the lead is done via a posterior approach and does require electrophysiologic monitoring of the pudendal nerve action potentials intraoperatively to confirm pudendal stimulation.

The dorsal genital nerve can also be used for stimulation. At the moment attempts are made to use conditional stimulation of the dorsal genital nerve in neurogenic patients. The aim is to stimulate the nerve at the moment that it is necessary and not continuously. A proper stimulus or trigger to start the stimulation is looked for.

### **Percutaneous Tibial Nerve Stimulation**

The percutaneous tibial nerve (PTNS) is a peripheral mixed sensory-motor nerve that originates from spinal roots L4 through S3, which also contribute directly to sensory and motor control of the urinary bladder and pelvic floor. Multiple studies have demonstrated that PTNS shows some efficacy in treating symptoms of OAB and altering urodynamic findings in patients with OAB. Stimulation of the nerve inhibits bladder activity by depolarizing somatic sacral and lumbar afferent fibers. Afferent stimulation provides central inhibition of the preganglionic bladder motor neurons through a direct route in the sacral cord. PTNS is typically performed with

patients in the sitting position with the knees abducted and the soles of the feet together. A 34 gauge needle is inserted 3 cm into the skin at a level 3 fingerbreadths cephalad to the medial malleolus. A grounding electrode is placed on the arch of the ipsilateral foot. The amplitude of the stimulation is increased until the large toe curls or the toes fan. Each session lasts for approximately 30 minutes. The tibial nerve is easily accessible without requiring an operating room or an anesthetic. As with all novel techniques, the data was initially anecdotal and is now becoming more robust. A recent trial involving 100 subjects comparing PTNS to Tolterodine-LA demonstrated equivalent objective efficacy between treatment groups. The Global Response Assessment demonstrated the PTNS subjects' assessment of OAB symptoms was statistically significant for improvement or cure in 79.5% compared to 54.8% in the tolterodine subjects ( $p=0.01$ ). A follow-up trial demonstrated that 96% maintained a clinical response at 12 months with an average of one treatment every 21 days. Until recently, level-one evidence comparing PTNS to a sham has been lacking. This is important due to the large placebo effect encountered with interventions for voiding dysfunction.

A randomized blinded control study offered data validating a sham for PTNS so that future investigations into this technique might be compared to a true placebo. This validated sham was used in the Sumit Trial. In collaboration with 20 clinical centers, the first sham-controlled trial on PTNS for the treatment of OAB was completed. 220 subjects were randomized and the 13-week global response assessment (GRA) showed PTNS subjects had statistically significant improvement in overall bladder symptoms with 54.5% reporting moderately or markedly improved compared to 20.9% of sham subjects ( $p < 0.001$ ). PTNS subjects had statistically significant improvements in frequency, nighttime voids, voids with moderate to severe urgency and urinary urge incontinence episodes compared to sham.

If PTNS is successful a tapering protocol is needed. This means that after having had the initial 12 weekly treatments the ideal stimulation frequency has to be sought. This appears to be once in 2-3 weeks. If all patients have to be seen and treated in the clinic this has much practical consequences. Also it makes the patient dependant from the caregiver. A stimulation method that could be done by the patients themselves could be the solution. Transcutaneous

stimulation is difficult because the skin acts as a major resistance layer. This implies that much energy is needed to pass the skin and this makes stimulation painful. An implant as described by van der Pal et al could therefore be the solution.

**Suggested Reading**

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Neuromodulation for pelvic floor dysfunctions: exploring tibial, sacral and pudendal nerve stimulation  
ICS 2012 - Beijing, China

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### **Basics and mechanisms**

Electrical stimulation can be used to obtain symptom relief in patients with urinary bladder dysfunction and also in patients with fecal incontinence. Sacral nerve stimulation has been used most frequent but positive results have also been shown with pudendal nerve and posterior tibial nerve stimulation.

This talk will cover the basic aspects and differences of stimulation at the various locations. It will address the neurophysiological evidence supporting the clinical benefits and will covers the working mechanisms.



## Notes

Record your notes from the workshop here