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## **Electrical Stimulation for Lower Urinary Tract Dysfunction**

### **FROM THE GUEST EDITOR**

**Ubirajara Barroso Jr., M.D., Guest Editor**  
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Electrical neural stimulation (ENS) for lower urinary tract dysfunction (LUTD) has been employed for nearly 40 years. Approximately 18 papers have been published on the use of ENS for children. Although the majority of the studies on ENS report positive outcomes, the sites in which ENS was employed were uncomfortable for children. For this reason, ENS is a method that has historically been poorly accepted. During the last decade, ENS has been employed in more comfortable forms such as transcutaneous electrical neural stimulation (TENS) and posterior tibial neural stimulation (PTNS). More refractory cases can be successfully treated by implants of an ENS device.

Both standard urotherapy and anticholinergics have failed to manage more severe cases of LUTD. Moreover, constipation, which is frequently associated with LUTD, makes management of these cases more difficult. Currently, ENS has emerged as an important tool in the treatment of LUTD and constipation in children. In this issue of the Dialogues, we have the opportunity to hear from experts in the field. The goal will be to inform the readers on current ENS studies and its role in the treatment of non-neurogenic LUTD and constipation in children.

### **FROM THE EDITOR**

**Anthony A. Caldamone, M.D.**

The use of electrical stimulation for bladder and bowel dysfunction has a long and storied history. Much of the early work done in this area were small case series that were poorly controlled and had very subjective outcome measures. It was difficult, therefore, to get excited about these technologies at that time.

This issue shows how far we have come in the area of electrical nerve stimulation for bladder and bowel dysfunction. Each of the contributing authors has reported their experiences with good scientific data. The data seems to indicate that in appropriately selected cases there is a reasonable chance that nerve stimulation can help a child with an overactive bladder and bowel dysfunction as well. Reading through these contributions closely, however, you will notice that each of the contributors has a protocol that they follow in selecting their routines of evaluation and management. I think this is critical to the success that these authors have achieved with these devices.

I congratulate Dr. Barroso and his contributors for a very stimulating, no pun intended, look at the treatment of overactive bladder and bowel dysfunction in children.

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# Treatment of Overactive Bladder in Children

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Overactive bladder (OAB) is defined as involuntary bladder contractions in a healthy child. The origin is unclear but delayed maturation of the nervous system is generally accepted to be integral to this condition. For treatment there are different modalities available from urotherapy to neuromodulation and pharmacological treatment to botulinum toxin injection. These treatment modalities will be discussed shortly and a rationalized systematic approach for treatment of OAB will be suggested.

## Urotherapy

Urotherapy means nonsurgical, nonpharmacological treatment of LUTD. It can be defined as a bladder re-education or rehabilitation program aimed at correcting of filling and voiding function of the bladder-sphincter unit.<sup>1</sup> For OAB, drinking and voiding charts are helpful. The patient is motivated to drink enough and hold urine in order to increase the voided volume. Unfortunately there are no prospective controlled studies available on the use of urotherapy for the treatment of OAB, so the level of evidence is low. One prospective controlled study on holding urine shows that both with and without pharmacological treatment voided volume increases with holding exercises.<sup>2</sup>

## Neuromodulation

Transcutaneous or percutaneous neuromodulation has proven to be (level of evidence is low) a useful adjunctive treatment in children with LUTS.<sup>3-6</sup> Bower et al. illustrated that home application of TENS in children is successfully feasible in children.<sup>7</sup> The reported changes with neuromodulation include: significantly increased bladder capacity, decreased severity of urgency, improved continence, and decreased frequency of urinary tract infections. Recently a prospective randomized controlled study showed significantly better outcome compared to sham stimulation.<sup>8</sup>

## Pharmacological Treatment

### Antimuscarinic Treatment

Parasympathetic mediated, acetylcholine-induced stimulation of post-ganglionic muscarinic receptors on detrusor smooth muscle is involved in both normal and involuntary detrusor contraction. Antimuscarinic agents might block acetylcholine binding at more than one muscarinic receptor subtype. Furthermore, receptor-selective agents might block muscarinic receptors outside the bladder and cause adverse effects. Currently, oxybutinin IR and oxybutinin ER are the only antimuscarinics approved by the FDA for the treatment of OAB symptoms in children. Therefore, oxybutinin is the most widely used pharmacological therapy in children with detrusor overactivity. The recommended daily dose is 0.3 mg/kg body weight.

Oxybutinin ER utilizes a novel delivery system, which results in absorption in the large intestine, thereby bypassing the first pass metabolism in the liver. This leads to a decrease in the amount of active metabolite, which is produced in the liver, resulting in a more favourable tolerability profile.<sup>9</sup>

In some countries the antimuscarinic agent with additional calcium channel-modulating properties, propiverine, is approved for use

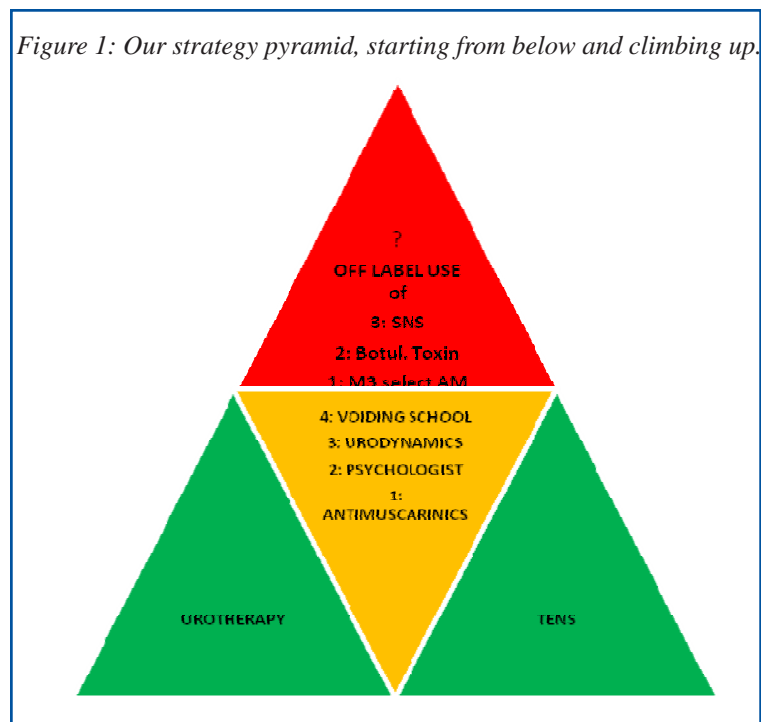
in children. The recommended daily dose is 0.8mg/kg body weight. In a multicenter placebo-controlled double-blind study, Marschall-Kehrel et al. studied the efficacy of propiverine for the treatment of OAB in children aged 5-10 years. The trial demonstrated significant superiority of propiverine over placebo and good tolerability.<sup>10</sup>

Currently newer antimuscarinics have been introduced for the treatment of detrusor overactivity in adults. None of them have been approved for use in children as yet. Other new antimuscarinics, solifenacin, darifenacin and fesoteridol are currently under investigation in pharmacokinetic and pharmacodynamic studies and will hopefully become available for use in children. Until then their use is off label.

### Botulinum Toxin

Botulinum toxin (BTX) is a potent neurotoxin that inhibits acetylcholine release at the presynaptic cholinergic junction, inducing muscle relaxation. Recently botulinum toxin has been FDA approved for therapeutic use in adult urology. In adult urology it is used to treat neurogenic detrusor overactivity, chronic urinary retention, detrusor-sphincter dyssynergia, non-neurogenic detrusor overactivity and chronic prostatic pain.<sup>11</sup> In children BTX-A toxin has been mainly used to treat urinary incontinence in children with a neurogenic bladder. Only a few studies documented the use of BTX in children. Investigators administered doses varying between 5 and 12 U/kg body weight (similar to doses used in the I.M. treatment of cerebral palsy) with a total dose of 50-360U Botox®, reflecting a higher dose/kg body weight than is used in adults.<sup>12-15</sup> Today use of BTX in children is off label.

Our treatment strategy is seen in Figure 1.



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When we see a child with OAB we will refer the patient to a dedicated urotherapist for 6 weeks of urotherapy. After 6 weeks we see the child together and decide if further therapy is needed. If more therapy is needed, we propose TENS and antimuscarinics (oxybutinin) as both are effective valuable adjuvant treatments and let the parents decide. Most parents choose TENS because of the minimal invasiveness. After 3 months of TENS we see the patient back. If results are insufficient we add oxybutinin. At this point we check for motivation and whenever we have doubts about commitment and motivation, we introduce a child psychologist in the treatment. They have to exclude underlying conditions and try to motivate the child. If the patient continues to be symptomatic after this we will do a urodynamic study. Based on the severity of the overactivity as judged from the urodynamic study, we will decide on further treatment. Intensive urotherapy is an inpatient training program, so called 'voiding school'. In cases of extreme overactivity we will prescribe off label M3 specific anticholinergics or propose botulinum toxin injection in the detrusor.

If problems still persist we will include patients in an experimental protocol of sacral nerve stimulation (SBS) which we recently started.

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## Para-Sacral Transcutaneous Electrical Stimulation (TENS) for Overactive Bladder (OAB)

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Manipulation of S3 activity (PTNS, sacral implantation, acral rhizotomy) has been employed effectively for facilitating bladder storage. However, a more invasive approach requires general anesthesia and is associated with risks such as infection, erosion, or neuronal injury.

Good results with para-sacral TENS for OAB in adults and in children were first described in 1999 by Walsh et al and Hoebeke et al., respectively.<sup>1,2</sup> The mechanics of electrical stimulation for OAB are far from being established (please, read the comments of De Gennaro and Capitanucci and Janet Chase in this issue). A supraspinal effect of electrical stimulation has been reported. Liao et al. studied six adults with idiopathic OAB who underwent sacral root stimulation.<sup>3</sup> All patients demonstrated clinical improvement after stimulation. Transcranial magnetic stimulation results showed that sustained sacral root stimulation may reorganize the human brain and its ability to excite the motor cortex and, as a result, modulate LUT function.

Results with para-sacral TENS for OAB have been consistent among the studies. Hoebeke et al. tested home para-sacral TENS in 15 girls and 26 boys with refractory OAB.<sup>4</sup> The current frequency used was 2 Hz. Parents performed the stimulation for 2 hours every day, for a period of 6 months. Thirteen (32%) children did not respond to the

treatment. After 1 year, the rate of complete resolution of daytime incontinence was 51.2%. Bower et al. applied home TENS in 17 children, using 1 or 2 sessions daily for until 5 months with a frequency of 10 to 150 Hz.<sup>5</sup> Of the children with daytime urinary incontinence, 47% had the symptoms resolved. In the Malm-Buatsi et al. study, 18 children (13 girls and 5 boys; mean age 9 years) with refractory OAB underwent home para-sacral TENS treatment twice daily for 20 minutes.<sup>6</sup> The frequency of the current was not stated. Of the 18 children, 15 had pretreatment incontinence and only 3 had increased urgency/frequency. The mean follow-up after starting TENS was 13 months. Of the 15 patients with incontinence, 2 became dry (13%), 9 were significantly improved (60%), and 4 reported no improvement (27%). The use of anticholinergics concomitantly in these 3 studies confounds the interpretation of the results.

Since 2002, our department has been using a new protocol of ambulatory para-sacral TENS in children.<sup>8,9,10</sup> The theoretical advantages of this treatment in comparison with home para-sacral TENS are: 1) improvement of compliance with the treatment, 2) improvement of

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relationship between children and urotherapist (improving the results of the standard urotherapy), and 3) attainment of a higher level of tolerable current intensity than parents are able to achieve at home. In our protocol, para-sacral TENS is performed for 20 minutes, 3 times weekly, for a maximum of 20 sessions. Current frequency used is 10 Hz. We chose the frequency of 10 Hz. because according to Lindstrom et al., this frequency causes effective bladder inhibition in cats.<sup>11</sup> Moreover, this frequency has also been successfully used in adults.<sup>12</sup>

Our pilot study was published in 2006.<sup>8</sup> We prospectively studied 19 children with isolated OAB who were treated by short course, ambulatory para-sacral TENS. All 19 had symptoms of urgency. Eleven children had a history of UTI and 16 had urge incontinence. The mean (range) number of electrical stimulation sessions was 13.1 (4–20). Of the 19 children treated, 12 had a complete clinical improvement, six had a significant improvement, and one showed mild improvement. Later, we published our long-term results.<sup>9</sup> We treated 36 girls and 13 boys with a mean age of 10.2 years (range 5 to 17). Average follow up was 35.3 months (range 6 to 80). Before treatment, urgency, daytime incontinence and UTI were seen in 100%, 88% and 71% of cases, respectively. Initial success (full response) was demonstrated in 79% of patients for urgency, 76% for incontinence and 77% for all symptoms. Continued success was seen in 84% of patients for urgency, 74% for daytime incontinence and 78% for all symptoms. Considering the 30 patients with at least 2 years of follow up, treatment was successful in 73%. Recurrence of symptoms after a full response was seen in 10% of cases. Two out of 33 patients (6%) who had urinary tract infection before the procedure, still had infection after treatment.

Para-sacral TENS now is considered effective for OAB in children by studies with level one evidence. There are two randomized clinical trials published. Hagstroem et al. studied 27 children, 5 to 14 years old, with refractory OAB.<sup>11</sup> The children were randomly allocated in two groups of home para-sacral TENS or sham. The procedure was performed for 4 weeks, with 2 hour daily sessions. After 4 weeks of intervention, 8 children (61%) in the active group, showed a significant decrease in incontinence severity. Decrease in incontinence severity occurred in only 2 (17%) in the sham treated group ( $p < 0.05$ ). The active group had a significantly greater decrease in daily incontinence episodes compared to the sham treated group ( $p < 0.01$ ). In this study home para-sacral TENS did not alter maximal and average voided volumes.

We prospectively randomized 25 girls and 12 boys with an average age of 7.6 years (range from 4 to 12) into the test (ambulatory para-sacral TENS) or sham (ambulatory TENS on the scapular area) group.<sup>9</sup> Twenty sessions, 20 minutes each (10 Hz.) were performed 3 times per week in each group. After completion of the sessions, the controls who were not cured, underwent active treatment. A total of 21 patients in the test group and 16 in the sham group underwent treatment. Among the active treatment group, 61.9% of parents reported complete resolution of the symptoms. In the sham group, no parent reported cure ( $p < 0.001$ ). There was improvement in the visual analogue scale in the test group when compared with the sham group ( $p = 0.002$ ). Toronto score was reduced more significantly in the test group than in the sham group ( $p = 0.011$ ). In the test group, average and maximum voided volumes showed a statistically significant increase while the number of daily voids decreased. After sham stimulation, 13 of the 16 patients who underwent para-sacral TENS had full response.

Standard urotherapy is time consuming, requires a significant time investment to be effective and does not work well as the single therapy in children with pronounced OAB. Antimuscarinics have side effects and need to be administered for several months. Moreover, antimuscarinics are associated with poor compliance. Given the simplicity of para-sacral TENS, their long-term effectiveness, and their absence of significant side effects (some children sleep during the treatment - see figure), I believe that this treatment should be considered a first line therapy for OAB in children. Moreover, para-sacral TENS



*Parasacral TENS in a 10-year old boy*

should be performed together with standard urotherapy, which can be reinforced in each session of stimulation. In our group, the isolated use of standard urotherapy is only for postponing voiding children or for those with mild symptoms of OAB. In our department, children who are complaint with 3 sessions a week of para-sacral TENS, go to PTNS. Medication is used only in cases of stimulation failure.

Para-sacral is effective for treating OAB in children. However, the optimum number of sessions, duration of each session, number of sessions per week, and the ideal current settings (pulse width, current frequency, current intensity) have to be established in future studies

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# Posterior Tibial Nerve Electrical Stimulation

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Posterior tibial nerve electrical stimulation (PTNS) was firstly tested in a clinical trial more than 25 years ago.<sup>1</sup> Nevertheless, until 2009 only uncontrolled cohort studies had been reported as second-line treatment for OAB, chronic urinary retention and interstitial cystitis. Recently, four controlled randomized trials in adult patients with OAB have provide (level 1b) evidence of efficacy of PTNS and demonstrated an excellent safety profile.<sup>2-5</sup> These landmark reports led to resurgent interest in PTNS as a potential treatment option in children with non-neurogenic refractory LUTD.

Among different neuromodulation (anogenital, intravesical and sacral) and chemo-modulation (botulin toxin) techniques, transcutaneous electrical nerve stimulation (TENS) and PTNS have the advantage in children to offer minimally invasive, non surgical and reversible second-line tools to treat LUTD. Results and peculiarities of methodology from the studies published are reported in tab.<sup>1</sup> During the last decade, TENS has been more extensively used than PTNS, to treat refractory OAB, using surfaces electrodes at suprapubic or sacral level. The first prospective, sham controlled and randomized clinical trial demonstrated that TENS is effective for treating children with OAB.<sup>6</sup> On the other hand, only three papers on PTNS (two by the same authors) have been reported in pediatric age.<sup>7-9</sup> This probably reflects the fact that needle insertion and several treatment sessions are required. However, those cohort studies, even if uncontrolled, indicated good tolerance in children even as young as 4 years old; moreover, PTNS efficacy was proven to treat not only OAB but also refractory dysfunctional voiding (DV).<sup>7,9</sup>

## Mechanism of Action

Posterior tibial nerve is a peripheral mixed sensory motor nerve, originating from the spinal roots L4-S3, which also contribute to sen-

sory and motor control of the bladder, sphincter and pelvic floor. PTNS afferent stimulation provides central inhibition of preganglionic bladder motor neurons through a direct route in the sacral cord.<sup>10</sup> This theory has been recently supported by a study on long latency somatosensory evoked potentials, which demonstrated difference between patients and sham and hypothesized a plastic reorganization of cortical network triggered by PTNS.<sup>11</sup>

## Technique

Urgent PC neuromodulation device (Uroplasty, Minnetonka, MN, USA) was approved by the FDA in 2006. PTNS treatment classically comprises 12, 30-minute weekly sessions. A 34 gauge needle is inserted 3 cm cephalad to the medial malleolus (grounding pad on the arch of the ipsilateral foot), and connected to the stimulator device; amplitude of stimulation is increased until the large toe curls or the toes fan. In children, it is advisable to start from a low level of amplitude and to increase slowly. Usually 8-10 mAmp can be achieved without pain. A 6-week protocol has been recently proven successful in women with OAB.<sup>12</sup>

## PTNS In Childhood LUTD

In the first study by Hoebeke for treating refractory (more than 2 years of standard therapy) OAB, urgency improved in 10/28 and disappeared in 7/28 children; voiding frequency normalized in 16/19; daytime incontinence was cured in 4/23 and improved in 12/23; abnormal uroflowmetry curve became bell-shaped in 9/21 children ( $p < 0.004$ ) and mean bladder capacity increased from 185.16 to 279.19 ml ( $p < 0.001$ ). Only 1 out of the 32 children discontinued because of fear of the needle.<sup>8</sup> Tolerability was defined by means of psychodiagnostic validated tests in the first 10 children enrolled for PTNS.<sup>7</sup> An anxiety-depression test (CHEOPS), a Visual Analogue Scale (VAS), and the Italian Pain Questionnaire (QUID) were administered at 1°, 15° and 30° minutes of the 1st, 6th and 12th sessions. Although an anxious-depression trait was found in 6 children and 7 parents, good acceptance was expressed. Generally low levels of pain were recorded, decreasing between minutes 1 and 30 and between first and last session sessions, this allowing to speculate that pain scores were more related to fear of needle than to true pain. Recently, we analysed long-term results of our longitudinal cohort of children, obtaining a level 3 evidence evaluating of PTNS efficacy and durability of results. Improvement was significantly greater ( $p < 0.002$ ) in non-neurogenic (78%) than in neurogenic (14%) patients.<sup>9</sup> Among non-neurogenic LUTD, at 2-year follow-up 5/12 (41%) children with OAB and 10/14 (71%) with DV were completely cured (Table 1). By repeating a second PTNS cycle and by maintaining chronic monthly stimulation, 9 additional children (5 with OAB and 4 with DV) resolved LUTS which relapsed 1 year following the first PTNS cycle. Overall, at long-term follow-up 10/12 children with OAB and 14/14 patients with DV were asymptomatic; 'chronic' PTNS was required in 50% and 29% of children, respectively with OAB or DV, to maintain results.<sup>9</sup>

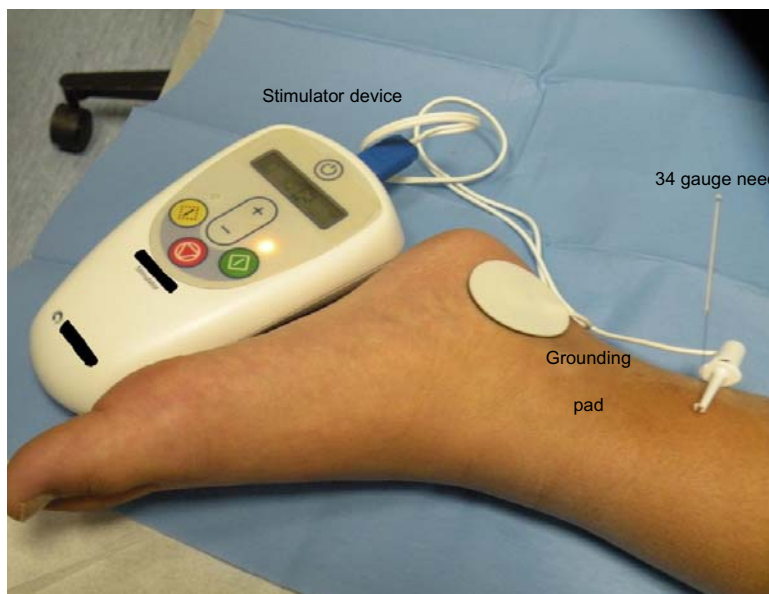


Figure: Percutaneous posterior tibial nerve stimulation in a 6 year old girl. The 34 gauge needle is inserted 3 cm into the skin (3 fingerbreadths cephalic to the medial malleolus) and connected to the stimulator device.

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## PTNS In Bowel Dysfunction

Although never investigated in children as yet, studies have been published on PTNS to treat fecal incontinence (FI) in adult patients, with up to 78% success rate,<sup>13</sup> compiling a prospective study evaluating clinical and QOL outcome.<sup>14</sup> Since constipation and fecal incontinence are relevant co-morbid factors in children with LUTD, it should be of interest to obtain information about PTNS effects on bowel dysfunction in the paediatric age group.

## Conclusions

PTNS is a slightly more invasive method of neurostimulation than TENS. Nevertheless, the good long-term results and the demonstration of relevant improvement and cure rates in children with DV indicate that this technique should be part of the paediatric urological armamentarium for specialized second-line urotherapy. TENS have been more extensively proven effective in refractory OAB and only PTNS has been applied in DV. While awaiting further randomized controlled trials, it might be reasonable to offer both TENS and PTNS options to the children and their caregivers, taking into account personal facilities and needs.

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**Table: Results and different methods of TENS and PTNS in children with non-neurogenic LUTD**

Year/Author	LUTD	N°. pts.	Stimulation	Frequency/ Intensity	Treatment Period	Follow-up	LUTS improvement rate (%)
- 2001, Bower WF J.Urol., 166(6):2420	OAB	14	2h/daily	10 Hz -°	1 mos	1 mos	73
- 2001, Hoebcke P J.Urol., 166(6):2416	OAB	41	2h/daily	2Hz -°	6 mos	1 yr	51
- 2006, Barroso U BJU Int., 98(1):166	OAB	19	20 min./sess. 3 sess./week	10 Hz 6-42 mA°	1-6 week	1 yr	63
- 2007, Malm-Buatsi E Urol., 70(5):980	OAB	18	20min./sess. twice daily	- 0-60 mA°	8 ± 7 mos	1 yr	73
- 2010, Lordelo P <sup>6</sup>	OAB	21	20 min./sess. 3 sess./week	10Hz -°	7 weeks	7 weeks	61.9
- 2002, Hoebcke P <sup>8</sup>	OAB	31	30 min./sess. 1 sess./week	20 Hz 1-10 mA°	12 week	3 mos	Urge: 60 Inc: 17 Freq.: 84
- 2004, De Gennaro M <sup>7</sup>	OAB DV	10 7	30 min./sess. 1 sess./week	20 Hz 1-10 mA°	12 week	3 mos	OAB: 80 DV: 71
- 2009, Capitanucci ML <sup>9</sup>	OAB DV	14 14	30 min./sess. 1 sess./week	20 Hz 1-10 mA°	12 week + maintenance (1 sess./mos)	2 yr	OAB: 83 DV: 100

° sensory threshold

# Sacral Neuromodulation as Contemporary Therapy for Refractory Pediatric Voiding Dysfunction

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Sacral nerve stimulation (SNS) is postulated to improve OAB by correcting deficient spinal inhibitory signals, hence suppressing detrusor contractions and allowing pelvic floor relaxation. While the exact mechanism is unknown, it is thought that leads placed at S3 nerve roots take effect via afferent bladder innervation.<sup>1,2</sup> This is done through direct stimulation of afferent anorectal branches (pelvic nerves), afferent sensory fibers (pudendal nerve), and lower extremity muscle afferents. In addition, neurologic alteration is shown in sensorimotor learning areas of the brain during acute therapy with SNS. Bladder awareness, urge, and timing of micturition are modified with chronic sacral neuromodulation.<sup>3</sup>

SNS was trialed in the first patient by Brindley in 1972<sup>4</sup> with use in children since 2001, beginning as transcutaneous electrical nerve stimulation (TENS).<sup>6,7</sup> TENS provided early data on treatment of neurogenic and non-neurogenic dysfunctional elimination disorders. Favorable results were seen using TENS for the treatment of non-neurogenic urgency/urge incontinence,<sup>6,7,8</sup> but results were less promising among children with spina bifida where only a trend toward improvement in bladder capacity and defecation was noted.<sup>9</sup> Success rates of 51% at one year, prospective randomized controlled data and "child friendly" technique continue to make this a viable treatment option. Different settings and stimulation schedules remain a problem when comparing various study outcomes.<sup>10</sup> Posterior tibial nerve stimulation (PTNS) has also been described for both neuropathic and non-neuropathic voiding dysfunction.<sup>11,12,13</sup> Lumbar to sacral nerve rerouting is perhaps the newest investigational treatment for neurogenic voiding dysfunction. Reports of significant improvement in spontaneous voiding are described in early data by Xiao et al, although conflicting data exist with respect to continence.<sup>14,15</sup> SNS has recently shown success in a randomized, controlled trial of children with neurogenic bladder, resulting in improved bladder capacity and continence (but not urodynamic parameters).<sup>16</sup> For the remainder of this review, we will focus predominantly on SNS for voiding dysfunction in neurologically intact children.

Inherent to the success of pediatric sacral neuromodulation is ap-

propriate patient selection. After failure of behavioral modification, timed voiding, maximal anti-cholinergic/pharmacologic therapy, treatment of constipation, and biofeedback, consideration can be given toward sacral neuromodulation. Botulinum toxin (Botox®) injection into the detrusor is often offered as an alternative or may have already been tried; however, Botox® failure is not required prior to offering SNS. Preoperatively, a detailed history, physical exam, urinalysis and culture, abdominal radiograph, retroperitoneal ultrasound and urodynamic evaluation with post-void residual were routinely recommended.<sup>17</sup> Formal urodynamic studies, voiding cystourethrogram and lumbosacral MRI (due to contraindication after implanted pulse generator (IPG) placement are now routinely obtained by our group. Typically, a two stage technique under general anesthesia is employed, using the Interstim® II device (Medtronic, Minneapolis, MN) with quadripolar tined lead placement via percutaneous transforaminal access to the third sacral spinal nerve (S3). Radiation can be minimized with a methylene blue tattoo for localization of the lead connector, allowing for placement of the IPG without fluoroscopy.<sup>18</sup> Motor responses to S3 stimulation include bellows movement of the pelvic floor, and plantar flexion of the great toe (as opposed to S2 mediated pinching of the anal sphincter and plantar flexion with lateral foot rotation, or S4 bellows without lower extremity movement).<sup>19</sup> Following implantation, patient history and voiding diaries are performed to evaluate urinary frequency, urgency, incontinence, nocturnal enuresis and constipation. Clinical success has been characterized as greater than or equal to 50% improvement in symptoms.<sup>17</sup> Functional bladder capacity and urodynamic studies are variably performed by other investigators,<sup>16</sup> however, no standardized screening or follow up has been defined. This is problematic for data comparison. Concerns over lead migration with vertical growth, battery longevity, and traumatic fracture in a pediatric population as yet have no solution. However, device miniaturization and lead redesign have been suggested<sup>16</sup> and explantation is possible with sustained treatment effect (minimum 12 months) and stable symptoms after device deactivation for 6 months.<sup>17</sup>

In 20 prospectively followed patients described by Roth et al<sup>17</sup>,

*(continued on next page)*



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90% went on to second stage IPG placement. Resolution or greater than 50% improvement occurred in 88% of children with urinary incontinence, 63% with nocturnal enuresis, 89% with daytime frequency, and 59% with constipation. By comparison, TENS results in 51% one-year durable response rates for non-neurogenic OAB, and SNS with 81% showing improved incontinence for neurogenic bladder.<sup>7,16</sup> Complications commonly cited with SNS are device or wound infection, electrode migration, loss of effect and lead fracture. Revision rates range between 7-18% due to lead migration, faulty connection, and wound infection.<sup>16,20</sup> In our own observations, revisions have also been necessary due to uncomfortable buzzing or painful sensations and battery replacement (Reinberg YE, personal communication) given 4.4 year average battery life (Interstim®II product specifications, Medtronic, 2010).

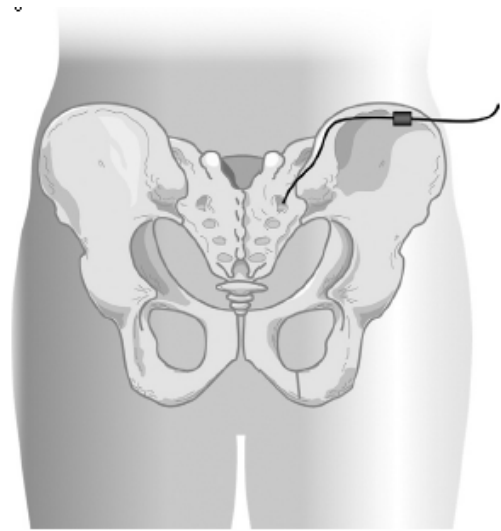
Overall, SNS is a promising technique for refractory pediatric voiding dysfunction. It is essential to develop standardized pre-operative evaluation and post-operative follow up protocols for uniform comparison of data.

**The authors have no disclosures or conflicts of interest.**

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a.



b.



Figure. These pictures demonstrate a modified technique described by McGee et al (2009). An “incisionless” first stage procedure is performed by accessing the S3 foramina percutaneously then tunneling the lead using a commercially available 14Fr ureteral access sheath to the ipsilateral axillary line. A methylene blue tattoo is used to mark the external lead connector (a). In picture (b), the methylene blue tattoo localizes the future placement site for the implantable pulse generator (IPG).

Reprinted from *Urology*, Vol 73, Issue 3, McGee S, Routh JC, Granberg CF, et al., *Sacral Neuromodulation in Children With Dysfunctional Elimination Syndrome: Description of Incisionless First Stage and Second Stage Without Fluoroscopy*, Pages 641-644, Copyright (2009), with permission from Elsevier.

# Electrical Stimulation and Childhood Constipation

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The limitations of laxative-based treatments and surgical options for the treatment of childhood constipation highlight the importance of developing an alternative method for treating constipation. Electrical stimulation is a commonly used and well-accepted therapeutic modality in the treatment of bladder dysfunction and urinary incontinence in both children and adults. Likewise the concept of the application of electrical stimulation to alter gastrointestinal tract motility is not new. As far back as 1913, studies have reported the effect of electrical stimulation of somatic afferents from skin and muscle on gastrointestinal tract motility in dogs, cats and rats.<sup>1</sup> More recently studies been carried out on healthy adult human volunteers and people with specific dysfunctions of the gastrointestinal tract.

Four forms of electrical stimulation have been used to treat human gastrointestinal disorders: transcutaneous electrical nerve stimulation (TENS), interferential current (IFC), electroacupuncture (EA) and sacral nerve stimulation (SNS).

With TENS the electric stimulus is delivered at variable current strengths, pulse rates and pulse widths and usually using pre-gelled self-adhesive electrodes. The waveform is biphasic in order to avoid the electrolytic and iontophoretic effects of a unidirectional current. In adults, TENS has been shown to alter the gastric antral motility index<sup>6</sup>, lower oesophageal sphincter pressure in achalsia<sup>2</sup> and has been reported as improving post-lung transplant gastroparesis.<sup>3</sup> TENS has also been used to treat diarrhoea predominant irritable bowel syndrome, with patients reporting a decrease in stool frequency and a decrease in abdominal pain.<sup>4</sup> In children simultaneous improvements in bowel function have been noted when TENS is used to treat urinary symptoms but this has not been systematically studied.<sup>5</sup>

IFC is a form of electrical stimulation that involves the transcutaneous application, via electrodes, of two crossed, slightly out of phase, medium-frequency currents. This produces an amplitude-modulated current effect within the tissues. The frequency, amplitude and pulse width of the output waveforms can be regulated, and usually currents range from 3,900 to 4,100Hz, and typically a quadripolar model is adopted where four electrodes are placed over the target area.

A pilot study (n=8) investigating the effect of IFC was undertaken in a group of children who had chronic constipation and soiling for a minimum of four years with exhaustive medical and behavioural treatment to no effect.<sup>6</sup> The study found that following a treatment period of one month there was a decrease in the reported incidence of soiling and an increase in the incidence of spontaneous defecation. A subgroup of the children who had previously had appendicostomies formed in order to be able to perform bowel washouts (n=3), reported a decreased need for bowel washouts following treatment with IFC, and 2 children were able to stop using their appendicostomy altogether. Although the children in this series of case studies had diagnostic nuclear transit studies prior to the intervention, this objective measure was not

repeated after the intervention and results were based on self-reported bowel diaries.

In a follow-up randomized sham-controlled trial in which IFC was again applied 3 times per week for 4 weeks, thirty-one pre-treatment, 22 post-real IFC, and 8 post-sham IFC studies were identified in 26 children (mean age, 12.7 years; 16 male).<sup>7</sup> Colonic transit was significantly faster in children given real treatment when compared to their pre-treatment transit studies at 24 (P d" .0001), 30 (P = .0039), and 48 (P = .0001) hours. Those children who received sham IFC had no significant change in colonic transit. Further study has confirmed these results plus a significant decrease in soiling, abdominal pain and increased physical quality of life but no significant change in the defecation rate. There were no adverse affects and treatment was comfortable.<sup>8</sup> When a home-based IFC machine became available those children whose defecation frequency had not improved did so with daily treatment.<sup>9</sup> A pilot study using IFC, but with different electrode placement has also shown promising results in children with severe constipation.<sup>10</sup>

EA involves attaching the inserted needle to an electric pulse generator. It has been shown that conducting polymer pads are as effective as needles, so cutaneous stimulation (without skin penetration) using TENS over acupuncture points is possible. The application of EA and cutaneous electrical stimulation has been demonstrated to cause a significant increase in the percentage of normal frequency gastric electrical activity with concomitant decreases in the percentages of periods of tachygastric and bradygastric rhythms,<sup>11</sup> but studies on constipation are not available.

SNS occurs within the sacral canal and is utilised in the management of urinary and faecal incontinence and chronic pelvic pain. Following acute peripheral nerve evaluation to locate the optimal sacral spinal nerve, patients progress to sub-chronic peripheral nerve evaluation for a minimum of 7 days to assess the relative efficacy of sacral nerve stimulation. If a clear benefit is perceived then a permanent implantable device

is surgically inserted.

Studies have reported that SNS is beneficial for constipation in adults.<sup>12</sup> Humphreys et al reported on twenty-three patients (6-15 years old) who had both bladder and bowel dysfunction treated with SNS, and followed for a mean of 13.3 months after surgery.<sup>13</sup> Constipation improved in 12 of 15 patients (80%) and was unchanged in 3 (20%) postoperatively, however 'improvement' was not defined, neither how it was judged. Thirteen patients still reported symptoms of constipation at the end of the trial period and four of the ten children who had faecal incontinence at the outset continued to do so.

Roth et al also treated twenty children with bladder and bowel dysfunction with SNS. Improvement was defined as an increase in the number of bowel actions per week and a decrease in the weekly num-

(continued on next page)

*Electrical stimulation is a commonly used and well-accepted therapeutic modality in the treatment of bladder dysfunction and urinary incontinence in both children and adults. Likewise the concept of the application of electrical stimulation to alter gastrointestinal tract motility is not new.*

ber of episodes of painful defecation.<sup>14</sup> Of the 17 children (85%) with constipation at the onset of the study, 7 (41%) had resolution of constipation and 5 (29%) exhibited improvement. Fecal incontinence was not reported. Lead revision, infection, skin sensitivity and device failure are the documented complications.

Alterations in bowel function have been reported in children with myelomeningocele using transrectal<sup>15</sup>, intra-vesical<sup>16</sup>, transcutaneous electrical stimulation<sup>17</sup> and interferential current.<sup>18</sup> This area is also under-researched, if there is even partial innervation there is the potential for therapeutic effects of electrical current.

Neuromodulation is the term used to cover an induced change in “neural traffic” over time and provides a reasonable explanation for changes in bowel motility and possible trophic effects. Neuromodulation of the bladder with electrical current is proposed to act centrally by rebalancing excitatory and inhibitory information and returning the neural drive towards a more normal status. It is likely that changes are mediated by supraspinal as well as spinal pathways, as evidenced by work showing EEG activity in the post-central gyrus during S3 stimulation.<sup>19</sup> In the studies of IFC bowel actions were rarely stimulated by treatment immediately. Rather, a more gradual improvement occurred over successive days and weeks reinforcing the concept of central changes, and improvements were sustained for at least 2 months after ceasing treatment. This is also contrary to what would be expected were the effects due purely to a placebo response.

Electrical stimulation to influence bowel motility is a promising new treatment that requires further research to establish optimal electrical parameters, including electrode position, parameters of current, frequency and duration of treatment, and also to elucidate the mode of action.

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