

Title	Objective	Author(s)	Institution(s)	Journal	Study design	# Patients	Summary statistics
Multicenter Randomized Controlled Trials							
<i>Randomized trial of percutaneous tibial nerve stimulation vs. sham efficacy in the treatment of overactive bladder syndrome: results from the SUMiT Trial</i>	To determine the efficacy of PTNS compared to a validated sham intervention	Peters KM, Carrico DJ, Perez-Marrero RA, Khan AU, Wooldridge LS, Davis GL, MacDiarmid, SA	Beaumont, Royal Oak, MI, Beaumont, Royal Oak, MI, Advanced Research Inst, Trinity FL, Urology Health Ctr, Fremont, NE, Mercy Health Partners, Muskegon, MI, Gregory Davis Inc, Chico, CA, Alliance Urology Specialists, Greensboro, NC	<i>J Urol</i> 2010; 183:1438 - 43	RCT 23 centers Double blind	220 >40% over age 65	Intent to treat analysis demonstrated statistically significant improvement in GRA and bladder symptoms for PTNS subjects vs. sham subjects

ABSTRACT
PURPOSE: The Study of Urgent® PC vs. Sham Effectiveness in Treatment of Overactive Bladder Symptoms (SUMiT) was a multicenter, double-blind, randomized, controlled trial comparing the efficacy of PTNS to sham through 12 weeks of therapy. The improvement in GRA, voiding diary parameters, OAB and quality of life questionnaires were evaluated.
MATERIALS AND METHODS: A total of 220 adults with OAB symptoms were randomized 1:1 to 12 weeks of treatment with weekly PTNS or sham therapy. OAB-q and quality of life questionnaires and 3-day voiding diaries were completed at baseline and at 13 weeks. Subject GRAs were completed at week 13.
RESULTS: The 13-week subject GRA for overall bladder symptoms demonstrated that PTNS subjects achieved statistically significant improvement in their bladder symptoms with 54.5% reporting moderately or markedly improved responses compared to 20.9% of sham subjects from baseline (p<0.001). All individual GRA subset symptom components demonstrated statistically significant improvement from baseline to 13 weeks for PTNS compared to sham. Voiding diary parameters after 12 weeks of therapy showed PTNS subjects had statistically significant improvements in frequency, nighttime voids, voids with moderate to severe urgency and urinary urge incontinence episodes compared to sham. No serious device-related adverse events or malfunctions were reported.
CONCLUSIONS: This pivotal multi-center, double-blind, randomized, sham-controlled trial provides Level I evidence that PTNS therapy is safe and effective in treating OAB symptoms. The compelling efficacy of PTNS demonstrated in this trial, is consistent with other recently published reports, and supports the utilization of peripheral-neuromodulation therapy for OAB.

<i>Randomized trial of percutaneous tibial nerve stimulation versus extended release tolterodine: results from the Overactive Bladder Innovative Therapy (OrBIT) Trial</i>	To compare the effectiveness of PTNS to extended release tolterodine	Peters KM, MacDiarmid SA, Wooldridge LS, Leong FC, Shobieri SA, Rovner ES, et al	Wm. Beaumont Hosp, Royal Oak, MI; Alliance Urol Specialists, Greensboro, NC; Mercy Health Ptnrs, Muskegon, MI; St. Louis Univ, St. Louis, MO; Univ. of OK, OK City, OK; MUSC, Charleston, SC	<i>J Urol</i> 2009;182:1055-1061	RCT 11 centers	100 Age 24-85 >30% over age 65 >90% female	<ul style="list-style-type: none"> PTNS demonstrated comparable effectiveness to tolterodine extended release (p=0.01) PTNS patients reported 79.5% cure or improvement vs. 54.8% for drug patients PTNS demonstrated similar clinically significant objective improvements compared to drugs for frequency, urge incontinence episodes, urge severity, nighttime voids and voided volume
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ABSTRACT
PURPOSE: The Overactive Bladder Innovative Therapy Trial (OrBIT) was a randomized, multicenter, controlled study that compared the effectiveness of percutaneous tibial nerve stimulation (PTNS) to extended release tolterodine. The reduction in overactive bladder symptoms along with global response assessments was evaluated.
MATERIALS AND METHODS: A total of 100 adults with urinary frequency were randomized 1:1 to 12 weeks of treatment with weekly PTNS or to 4 mg daily extended release tolterodine. Voiding diaries and an overactive bladder questionnaire were completed at baseline and at the end of therapy to compare 24-hour voiding frequency, urinary urge incontinence episodes, voids causing waking, volume voided, urgency episodes and quality of life indices. Global response assessments were completed by subjects and investigators after 12 weeks of therapy.
RESULTS: The global response assessment demonstrated that subject assessment of overactive bladder symptoms compared to baseline was statistically significant in the PTNS arm with 79.5% reporting cure or improvement compared to 54.8% of subjects on tolterodine (p = 0.01). Assessments by investigators were similar but did not reach statistical significance (p = 0.05). After 12 weeks of therapy objective measures improved similarly in both groups for reductions in urinary frequency, urge urinary incontinence episodes, urge severity and nighttime voids, as well as for improvement in voided volume. There were no serious adverse events or device malfunctions.
CONCLUSIONS: This multicenter, randomized trial demonstrates that PTNS is safe with statistically significant improvements in patient assessment of overactive bladder symptoms, and with objective effectiveness comparable to that of pharmacotherapy. Percutaneous tibial nerve stimulation may be considered a clinically significant alternative therapy for overactive bladder.

Title	Objective	Author(s)	Institution(s)	Journal	Study design	# Patients	Summary statistics
Multicenter Randomized Controlled Trials							
<i>Long term durability of percutaneous tibial nerve stimulation for the treatment of overactive bladder (OrBIT Trial)</i>	To assess the sustained therapeutic efficacy of PTNS in overactive bladder subjects over 1 year	MacDiarmid SA, Peters KM, Shobeiri SA, Wooldridge LS, Rovner ES, Leong FC, Siegel SW, Tate SB, Faegins BA	Alliance Urol Spec., Greensboro, NC; Wm Beaumont Hosp, Royal Oak, MI; Univ of OK, OK City, OK; Mercy Health Partners, Muskegon, MI; Med Univ of SC, Charleston, SC; St. Louis Univ, St. Louis, MO; Metro Urology, Woodbury, MN; Univ of Louisville, Louisville, KY; Dallas Ctr for Pelvic Med, Dallas, TX	<i>J Urol</i> 2010; 183: 234-240	RCT, long-term follow-up	PTNS responders from initial OrBIT Trial: 32 at 6 months 25 at 12 months	<ul style="list-style-type: none"> For PTNS responders, subject Global Response Assessments showed sustained improvement at 6 months for 94% and at 12 months for 96% Mean improvements from baseline: <ul style="list-style-type: none"> - Frequency: -2.8 voids/day (p<0.001) - Urge incontinence: -1.6 episodes/day (p<0.001) - Nocturia: -0.8 voids/day (p<0.05) - Voided volume: +39 cc (p<0.05) OAB-q Symptom Severity was significantly improved from 12 weeks to 12 months (p<0.01) and from 6 months to 12 months (p<0.01) Treatment interval: mean = 21 days No serious adverse events occurred
<p>ABSTRACT PURPOSE: The Overactive Bladder Innovative Therapy Trial (OrBIT) during phase 1 was a randomized trial demonstrating comparable effectiveness between PTNS to extended-release tolterodine during 12 weeks of therapy. In this second phase of the OrBIT Trial we assessed the sustained therapeutic efficacy of PTNS in overactive bladder subjects during 1 year. MATERIALS AND METHODS: After 12 weeks, subjects randomized to weekly PTNS therapy with Urgent® PC were offered an additional 9 months of treatment with assessments at 6 and 12 months from baseline. Outcome measures included voiding diary data, overactive bladder questionnaires, global response assessments, and safety assessments. RESULTS: A total of 33 PTNS responders continued therapy with 32 and 25 subjects completing 6 and 12 months of therapy, respectively. Subjects received a mean of 12.1 treatments over an average of 263 days, mean of 21 days, (median 17) between treatments. Subject global response assessments showed sustained improvement from 12 weeks at 6 and 12 months, with 94% and 96% responders, respectively. At 12 months, mean improvements from baseline included frequency -2.8 voids/day (p<0.001), urge incontinence -1.6 episodes/day (p<0.001), nocturia -0.8 voids (p<0.05) and voided volume of 39 cc (p<0.05). Overactive bladder questionnaire symptom severity was significantly improved from 12 weeks to 12 months (p<0.01). No serious adverse events occurred. CONCLUSIONS: Statistically significant OAB symptom improvement achieved with 12 weekly PTNS treatments demonstrates excellent durability through 12 months. The durability of response demonstrates PTNS effectiveness as a viable, long-term therapy for overactive bladder.</p>							
Single Center Randomized Controlled Trials							
<i>Validation of a sham for percutaneous tibial nerve stimulation (PTNS)</i>	To determine the efficacy of a realistic sham against PTNS	Peters KM, Carrico D, Burks F	Wm. Beaumont Hosp, Royal Oak, MI	<i>Neurourol Urodynam</i> 2009; 28: 58-61	RCT	30 15 male, 15 female	<ul style="list-style-type: none"> Only 33% of subjects correctly identified sham treatment, well below the 50% threshold for guessing and the 75% threshold set by investigators as acceptable. The sham was proven to be an effective sham for PTNS, allowing researchers to study PTNS in sham-controlled trials.
<p>ABSTRACT AIM: Percutaneous tibial nerve stimulation (PTNS) supposedly demonstrates 50-60% improvement in OAB symptoms with no sham-controlled trials reported. This study determined the efficacy of a sham for PTNS. METHODS: Thirty healthy volunteers (15 women; 15 men) in this blinded pilot study were randomized into two equal groups: one group had PTNS on the right and sham on the left: the other group had PTNS on the left and sham on the right. A drape obscured their lower extremities. The sham utilized a placebo needle placed at the PTNS site along with a transcutaneous electrical nerve stimulator (TENS) pad on the ipsilateral foot. The unit was activated until stimulation was felt. PTNS was performed on the opposite leg, with the grounding pad mimicking the sham pad placement. PTNS stimulation was given until the subject felt stimulation in the foot. Subjects had 1 simultaneous 15 min testing of the PTNS vs. sham. Subjects then completed a questionnaire stating which leg they thought had the sham and PTNS (or "unknown"). The primary endpoint of the study was the ability to accurately identify the sham. RESULTS: In total, 10/30 (33%) of the shams were identified correctly. We would expect 50% to be identified by guessing, but only 33% were correctly identified. Females identified the sham correctly more often than males (40% vs. 27%). This procedure was validated as a feasible sham for PTNS. CONCLUSIONS: This is the first validation of a sham for PTNS that may be used in future placebo-controlled research.</p>							

Title	Objective	Author(s)	Institution(s)	Journal	Study design	# Patients	Summary statistics
Prospective Multicenter Studies							
<p><i>Percutaneous afferent neuromodulation for the refractory overactive bladder: results of a multicenter study</i></p>	<p>To determine the safety and efficacy of percutaneous peripheral afferent nerve stimulation for treatment of refractive overactive bladder and/or pelvic floor dysfunction</p>	<p>Govier FE, Litwiller S, Nitti V, Kreder KJ Jr, Rosenblatt P</p>	<p>Virginia Mason Medical Center, Seattle, WA; University of TX Southwestern Medical Center, Dallas, TX; NYU Medical Center, NY, NY; University of IA Hospitals and Clinics, Iowa City, IA; Mt. Auburn Hosp, Cambridge, MA</p>	<p><i>J Urol</i> 2001; 165: 1193-1198</p>	<p>Prospective, multicenter</p>	<p>53 23 Medicare age 65-80 yrs</p>	<ul style="list-style-type: none"> • 71% success: <ul style="list-style-type: none"> - 25% reduction mean daytime voiding frequency - 21% reduction mean nighttime voiding frequency - 35% reduction urge incontinence episodes - Statistically significant improvements in QoL indexes - 30% improvement in selective pain • No serious, unanticipated adverse events related to treatment
<p>ABSTRACT PURPOSE: More than 20 million Americans have an overactive bladder, the predominant symptoms being frequency, urgency, urge incontinence and pelvic pain. While the etiology is not completely understood, most investigators believe the causes to be many and the pelvic floor to be intimately related. Whatever the etiology, traditional therapies, including dietary manipulation, bladder drill, medications and physical therapy, are often poorly tolerated and/or ineffective. We report a prospective, multicenter clinical trial that was undertaken to determine the safety and efficacy of percutaneous peripheral afferent nerve stimulation for treatment of refractive overactive bladder and/or pelvic floor dysfunction. MATERIALS AND METHODS: A total of 53 patients with overactive bladders, in whom all traditional therapy failed, were enrolled in 1 of 5 sites within the United States. Patients received weekly percutaneous electrical stimulations via a 34 gauge needle placed near the tibial nerve 3 finger breadths above the ankle. Urodynamic studies, detailed voiding diaries, quality of life surveys, and incontinence impact questionnaires were completed before, during and after the study. RESULTS: Of the patients with a mean age of 57.4 years 89% (47 of 53) completed the 12-week study. A total of 71% of patients were classified as treatment successes by the investigators and were started on long-term treatment. On average patients noticed a 25% reduction in mean daytime and 21% reduction in mean nighttime voiding frequencies (p <0.05). Urge incontinence was reduced by an average of 35% (p <0.05). Statistically significant improvements were noted in selective pain and quality of life indexes. No significant adverse events related to treatment were noted in any patients. CONCLUSIONS: Percutaneous peripheral afferent nerve stimulation offers a safe, minimally invasive and effective treatment for managing refractive overactive bladder and/or pelvic floor dysfunction.</p>							
<p><i>Posterior tibial nerve stimulation as neuromodulative treatment of lower urinary tract dysfunction</i></p>	<p>Intermittent percutaneous posterior tibial nerve stimulation was introduced as a treatment modality filling the gap between conservative and surgical therapies in patients with certain types of lower urinary tract dysfunction</p>	<p>van Balken MR, Vandoninck V, Gisolf KWH, Vergunst H, Kiemeney LALM, Debruyne FMJ, Bemelmans BLH</p>	<p>Dept of Urology, Canisius-Wilhemina Hospital; Depts of Urology and Epidemiology, University Medical Centre, Nijmegen; Dept of Urology, University Hospital, Utrecht, The Netherlands</p>	<p><i>J Urol</i> 2001; 166: 914-918</p>	<p>Prospective, multicenter</p>	<p>37 Age 23-74</p>	<ul style="list-style-type: none"> • Prior pharmaceutical therapy unsuccessful in 91% patients • Prior surgical procedures conducted in 49% patients • 59% subjective success: patients wanted to continue therapy • For responders: <ul style="list-style-type: none"> - Frequency reduced from <ul style="list-style-type: none"> - 16 to 11 voids / day - 2.5 to 1.1 voids / night - Leakage episodes reduced from <ul style="list-style-type: none"> - 9.8 to 3.6 • QoL increased from 60.3 to 72.6
<p>ABSTRACT PURPOSE: Recently, intermittent percutaneous posterior tibial nerve stimulation was introduced as a treatment modality filling the gap between conservative and surgical therapies in patients with certain types of lower urinary tract dysfunction. MATERIALS AND METHODS: In a prospective multicenter trial posterior tibial nerve stimulation was evaluated in 37 patients who presented with symptoms of bladder overactivity, that is the urgency and frequency syndrome and/or urge incontinence, and 12 with nonobstructive urinary retention. Results were recorded in voiding diaries and on quality of life questionnaires before and after treatment. Patients were classified as responders, including those in whom therapy was successful and chose to continue treatment after the initial 12 weeks, and nonresponders, those who chose to stop treatment. RESULTS: Overall, a positive response was seen in 60% of all patients. In patients with bladder overactivity a statistically significant decrease was observed in leakage episodes, number of pads used, voiding frequency and nocturia, and an equal increase in mean and smallest volume voided. Improvements were also seen in nonobstructive urinary retention, including number of catheterizations, total and mean volume catheterized, and total and mean volume voided. Disease specific quality of life and some domains of general quality of life improved, especially of bladder overactivity. Only mild side effects were observed. CONCLUSIONS: Posterior tibial nerve stimulation is a minimally invasive and successful treatment option for patients with certain types of lower urinary tract dysfunction.</p>							

Title	Objective	Author(s)	Institution(s)	Journal	Study design	# Patients	Summary statistics
Prospective Multicenter Studies							
Percutaneous tibial nerve stimulation in the treatment of overactive bladder: urodynamic data	To evaluate urodynamic changes after PTNS for the treatment of complaints related to overactive bladder syndrome and to search for urodynamic predictive factors	Vandoninck V, van Balken MR, Finazzi Agrò E, Petta F, Micali F, Heesakkers JPFA, Debruyne FMJ, Kiemeneij LALM, Bemelmans BLH	Depts of Urology and Epidemiology, University Medical Centre, Nijmegen, The Netherlands; Dept Urology University "Tor Vergata" and IRCCS S. Lucia, Rome, Italy	<i>NeuroUrol Urodyn</i> 2003; 22: 227-232	Prospective, multicenter	90 Age 19-82	<ul style="list-style-type: none"> • 56% objective success <ul style="list-style-type: none"> - 38% dry - 56% ≥ 50% reduction in leakage episodes • 64% subjective success • Frequency volume chart data and QoL scores improved significantly • I-QoL scores improved from 49 to 67
<p>ABSTRACT AIM: The aim of this study was to evaluate urodynamic changes after PTNS for the treatment of complaints related to overactive bladder syndrome and to search for urodynamic-based predictive factors. METHODS: Ninety consecutive patients with symptoms related to overactive bladder syndrome were enrolled in this study. Patients underwent 12 PTNS sessions. For evaluating objective success, the primary outcome measure was a reduction in number of urinary leakage episodes of 50% or more per 24 hours. Patients' request for continuation of therapy was considered subjective success. This study focused on urodynamic features at baseline and on changes found after 12 PTNS treatments. RESULTS: The objective success rate was 56% (leakages/24 hours). Subjective success rate was 64%. Frequency/volume chart data and quality of life scores improved significantly ($p < 0.01$). Pre- and posturodynamic data were available from 46 participants. Detrusor instabilities (DI) could be abolished in a few cases only. Increments in cystometric bladder capacity and in volume at DI were significant ($p = 0.043$ and 0.012, respectively). Subjects without detrusor instabilities at baseline were 1.7 times more prone to respond to PTNS (odds ratio, 1.75; 95% confidence interval [CI], 0.67-4.6). The more the bladder overactivity was pronounced, the less these patients were found to respond to PTNS, the area under the receiver operating curve was 0.644 (95% CI, 0.48-0.804). CONCLUSION: PTNS could not abolish DI. PTNS increased cystometric capacity and delayed the onset of DI. Cystometry seemed useful to select good candidates: patients without DI or with late DI onset proved to be the best candidates for PTNS.</p>							
Posterior tibial nerve stimulation in the treatment of voiding dysfunction: urodynamic data	To evaluate urodynamic parameter changes following 12 weeks of PTNS therapy	Vandoninck V, van Balken MR, Finazzi-Agrò E, Heesakkers JPFA, Debruyne FMJ, Kiemeneij ALM, Bemelmans BLH	Depts of Urology and Epidemiology, University Medical Centre, Nijmegen, The Netherlands; Dept Urology University "Tor Vergata" and IRCCS S. Lucia, Rome, Italy	<i>Neuro Urolyn</i> 2004; 23: 246-251	Prospective multicenter	39 Age 28-77 12 male 27 female	<ul style="list-style-type: none"> • Bladder indices improved significantly for all patients • -200 ml in median catheterized volume • +275 ml in voided volume • Bladder contractility and bladder voiding efficacy increased significantly for all patients • QoL indices all improved
<p>ABSTRACT OBJECTIVES: To determine urodynamic changes and predictive factors in patients with voiding dysfunction who underwent 12 percutaneous tibial nerve stimulations. METHODS: Thirty nine patients with chronic voiding dysfunction were enrolled in a prospective multicenter trial in the Netherlands ($n = 19$) and in Italy ($n = 20$). A 50% reduction in total catheterised volume per 24 hr was taken as a primary objective outcome measure. Patients' request for continuation of treatment was regarded as subjective success. Objective urodynamic parameters and bladder indices were determined. Odds ratios and their 95% confidence interval were computed as a measure for predictive power in order to reveal predictive factors (Pdet at Qmax, Qmax, BVE, and BCI). RESULTS: Primary outcome measure was obtained in 41%, an additional 26% reduced their 24 hr residuals by more than 25%. Fifty-nine percent of patients chose to continue treatment. Detrusor pressure at maximal flow, cystometric residuals, and bladder indices improved significantly for all patients ($p < 0.05$). Patients with minor voiding dysfunction were more prone to notice success (Odds ratio: 0.73; 95% CI: 0.51-0.94). CONCLUSIONS: PTNS is a young treatment modality, minimally invasive, and easily accessible. It might be an attractive first line option for patients with (minor) voiding dysfunction.</p>							
Percutaneous tibial nerve stimulation in the treatment of urge incontinence	To evaluate the effect of PTNS therapy on urge incontinence	Vandoninck V, van Balken MR, Finazzi-Agrò E, Petta F, Caltagirone C, Heesakkers JPFA	Depts of Urology and Epidemiology, University Medical Centre, Nijmegen, The Netherlands; Dept Urology University "Tor Vergata" and IRCCS S. Lucia, Rome, Italy	<i>Neuro Urolyn</i> 2003; 22:17-23	Prospective, multicenter	35 Median age 57 Range 29-82 10 male 25 female	<ul style="list-style-type: none"> • 70% objective success= 50% reduction in leakage episodes • 46% completely cured • 63% patient reported success • 60% improved voiding frequency; 31% regained normal voiding pattern • 57% achieved >50% reduction in nocturia • Average I-QoL scores significantly improved
<p>ABSTRACT AIMS: The objective of this study was to evaluate the effect of posterior tibial nerve stimulation (PTNS) for treatment of urge incontinence. METHODS: In a prospective multicentre study, 35 patients with complaints of urge incontinence underwent 12 weekly sessions of PTNS at one of five sites in the Netherlands and one site in Italy. Frequency/volume charts and I-QoL and SF-36 questionnaires were completed at 0 and 12 weeks. Success was analyzed by using subjective and objective criteria. Overall subjective success was defined as the willingness to continue treatment, whereas objective success was defined as a significant decrease (to <50%) in total number of leakage episodes. RESULTS: Twenty-two patients (63%) reported a subjective success. Twenty-four patients (70%) showed a 50% or greater reduction in total number of leakage episodes. Sixteen (46%) of these-patients were completely cured (i.e., no leakage episodes) after 12 sessions. Quality of Life parameters improved significantly. CONCLUSIONS: We conclude that posterior tibial nerve stimulation is an effective, minimally invasive option for treatment of patients with complaints of urge incontinence, as improvement was seen in subjective as well as objective parameters.</p>							

Title	Objective	Author(s)	Institution(s)	Journal	Study design	# Patients	Summary statistics
Prospective Multicenter Studies							
<i>Posterior tibial nerve stimulation in the treatment of idiopathic nonobstructive voiding dysfunction</i>	To evaluate the effect of PTNS on voiding dysfunction	Vandoninck V, van Balken MR, Finazzi-Agrò E, Petta F, Micali F, Heesakkers JPFA	Depts of Urology and Epidemiology, University Medical Centre, Nijmegen, The Netherlands; Dept Urology University "Tor Vergata" and IRCCS S. Lucia, Rome, Italy	<i>Urol</i> 2003; 61: 567-572	Prospective, multicenter	39 Age 28-77 12 male 27 female	<ul style="list-style-type: none"> • 50% decrease in total catheterized volume in 41% of pts • -228 ml mean total catheterized volume decrease • Nearly 60% of pts considered PTNS to be successful
<p>ABSTRACT OBJECTIVES: To evaluate the effect of stimulation of the posterior tibial nerve in the treatment of voiding dysfunction. METHODS: Thirty-nine patients with chronic voiding dysfunction necessitating clean intermittent catheterization were enrolled in a prospective multicenter trial in the Netherlands (n = 19) and Italy (n = 20). They underwent 12 weekly sessions of posterior tibial nerve stimulation. Frequency/volume charts, an incontinence Quality of Life instrument, and the MOS 36-item Short-Form Health Survey were completed at 0 and 12 weeks. Subjective success was defined by the patient's positive response resulting in a request to continue treatment. Efficacy was based on analysis of the frequency/volume charts comparing the baseline values with the data at 12 weeks. A reduction of 50% or more in total catheterized volume was considered as an objective success (primary outcome measurement). RESULTS: Of the 39 patients, 23 (59%) chose to continue treatment. The frequency/volume charts showed a 50% decrease in total catheterized volume in 16 (41%) of 39 patients. Additionally, 10 patients (26%) noted a reduction of 25% to 50% in their total catheterized volume. For all patients, the total catheterized volume decreased by a mean of -228 mL (range -49 to -528). The incontinence Quality of Life instrument and Short-Form Health Survey parameters improved significantly. CONCLUSIONS: Percutaneous stimulation of the posterior tibial nerve seems to be an effective, minimally invasive option worth trying in patients with idiopathic voiding dysfunction. Improvement was seen in objective micturition parameters, as well as in subjective Quality of Life data.</p>							
Prospective Single Center Studies							
<i>Use of peripheral neuromodulation of the S3 region for treatment of detrusor overactivity: a urodynamic-based study</i>	To determine the effect of PTNS on bladder capacity using urodynamic testing	Klingler HC, Pycha A, Schmidbauer J, Marberger M	Univ of Vienna, Austria	<i>Urol</i> 2000; 56:766-771	Prospective	15 Age 45-92 11 female 4 male	<ul style="list-style-type: none"> • With urodynamic testing: <ul style="list-style-type: none"> - Bladder instability eliminated in 76% of pts - Mean bladder capacity increased significantly - Mean volume at first unstable bladder contraction increased • Mean frequency and nocturia also decreased
<p>ABSTRACT OBJECTIVE: To determine the efficacy of peripheral neuromodulation of the S3 region in patients with urgency-frequency syndrome due to an overactive bladder. METHODS: Fifteen patients (11 women and 4 men) with urgency-frequency syndrome, as documented by a voiding chart, were diagnosed with overactive bladder. Pelvic pain was assessed by a visual analog scale (VAS). Full urodynamic workup was performed before and after 12 peripheral stimulations with a 9-V monopolar generator, the so-called Stoller Afferent Nerve Stimulator (SANS). Follow-up was for a mean (SD) of 10.9 (4 to 15) months. RESULTS: Reduction in pain was achieved in all patients, with a decrease in VAS from a mean (SD) of 7.6 (5 to 10) to 3.1 (1 to 7) (p = 0.00049). Seven patients (46.7%) had a complete response and were considered cured, 3 (20.0%) showed significant improvement, and 5 (33.3%) were classified as nonresponders. Urodynamic evidence of bladder instability, evident in all patients before treatment, was eliminated in 76.9% of patients. In all patients, mean (SD) total bladder capacity increased significantly from 197 (35 to 349) to 252 (78 to 384) ml (p = 0.00795), mean (SD) volume at first bladder sensation from 95 (16 to 174) to 133 (32 to 214) ml (p = 0.00166), and mean (SD) bladder volume at normal desire to void from 133 (27 to 217) to 188 (47 to 296) ml (p = 0.00232). In the responding group, the mean (SD) total numbers of voids was reduced from 16.1 (9 to 24) times during the day and 4.4 (2 to 6) times during the night to 8.3 (6 to 10) and 1.4 (1 to 2) times (p = 0.002539), respectively. No complications from treatment were observed. CONCLUSIONS: Peripheral neuromodulation of the S3 region can successfully treat patients with urgency-frequency syndrome due to an overactive bladder.</p>							

Title	Objective	Author(s)	Institution(s)	Journal	Study design	# Patients	Summary statistics
Prospective Single Center Studies							
<i>Percutaneous tibial nerve stimulation produces effects on brain activity: study on the modification of the long latency somatosensory evoked potentials</i>	To evaluate the long-latency somatosensory evoked potential in patients with OAB treated with PTNS	Finazzi-Agrò E, Rocchi C, Pachatz C, Petta F, Spera E, Mori F, Sciobica F, Marfia GA	"Tor Vergata" University, Rome Italy	<i>NeuroUrol Urodyn</i> 2009; 28: 320-324	Double arm, prospective PTNS 16 subjects Sham 8 subjects	24 female Mean age = 47 ± 10.5 yrs.	Cortical changes occurred after PTNS treatment but not after sham treatment with changes present up to 24 hours after PTNS treatment. This supports sustained improvement during intermittent PTNS treatments.
<p>ABSTRACT OBJECTIVE: Long-latency somatosensory evoked potentials (LL-SEP) provide information on the function of somatosensory cortical structures. Percutaneous tibial nerve stimulation (PTNS) is indicated in the treatment of lower urinary tract dysfunction. Aim of this study was to evaluate LL-SEP in patients with overactive bladder syndrome (OAB) treated by means of PTNS. METHODS: Sixteen female patients with a diagnosis of pharmacoresistant OAB underwent PTNS while eight female patients with the same diagnosis underwent sham stimulation. LL-SEP were performed at baseline and at the end of PTNS or sham stimulation. Peak latency and peak to peak amplitude of P80, P100, and P200 waves were measured. RESULTS: Mean latency of P80, P100, and P200 and mean amplitude of P200 did not show any significant change after both stimulation. Mean amplitude of P80 and P100 waves increased significantly after PTNS while it did not vary after sham stimulation. CONCLUSION: The P80 and P100 amplitude increase might reflect long-term modifications in synaptic efficiency through the somatosensory pathway. The plastic reorganization of cortical network triggered by peripheral neuromodulation can be hypothesized as a mechanism of action of PTNS. Further studies are needed to correlate LL-SEP modifications after PTNS with the success of the treatment.</p>							
Review of Literature							
<i>Percutaneous tibial nerve stimulation: a literature based assessment</i>	Review of current literature including meta-analysis of 7 studies	MacDiarmid SA, Staskin D	Alliance Urol Specialists, Greensboro, NC; Tufts University, Boston, MA	<i>Curr Bldr Dysfunction Rept</i> 2009; 4:29-33	Review of literature; PTNS effectiveness with meta-analysis	244	<ul style="list-style-type: none"> • 244 patients improved an average of 23% (p<0.001) in daily voids • 151 patients improved 41% (p<0.002) in nighttime voids • 182 patients improved 43% (p<0.001) voided volume • 167 patients improved 45% (p=.023) in incontinence episodes
<p>ABSTRACT An estimated 34 million adults in the United States have an overactive bladder, which has a significant impact on health and quality of life and significant overall financial impact on the health care delivery system. Current treatment alternatives include behavioral modifications, pelvic floor therapy, medications, sacral nerve stimulation, intravesical injection, and surgery. A recent addition to the urologist's armamentarium of care is percutaneous tibial nerve stimulation. This article reviews a variety of sources that present current thinking about PTNS, its clinical use, and its place in the continuum of care.</p>							
<i>Percutaneous neuromodulation</i>	To review current evidence for PTNS use in pelvic floor dysfunction	Cooperberg MR, Stoller ML	Dept of Urol, UCSF, San Francisco, CA	<i>Urol Clin N Am</i> 2005; 32: 71-78	Review of current literature	430 adult pts in 8 studies; 72 pediatric patients in 3 studies	Reviews literature from 1998 through 2004 that shows improvement in night-time voids, incontinence episodes, frequency, catheterization volume and QoL indices following PTNS therapy
<p>ABSTRACT Neuromodulation for pelvic floor dysfunction has evolved from central sacral stimulation, a relatively invasive, experimental procedure, to percutaneous peripheral neurostimulation, which is both minimally invasive and well-tolerated by patients. Multiple series have now reported consistent positive results for varied manifestations of pelvic floor dysfunction. Future applications will involve an implantable peripheral neurostimulator coupling with the posterior tibial nerve, empowering patients to adjust the frequency or amplitude of stimulation. It is anticipated that broader availability of this modality will offer hope to the frequently underdiagnosed and underreported population of patients with pelvic floor dysfunction.</p>							

Title	Objective	Author(s)	Institution(s)	Journal	Study design	# Patients	Summary statistics
Retrospective Chart Reviews							
<i>Percutaneous tibial nerve stimulation for the treatment of urinary frequency, urinary urgency and urge incontinence: results from a community-based clinic</i>	Report results of 53 PTNS patients	Wooldridge LS	Mercy Health Partners, Muskegon, MI	<i>UNJ</i> 2009; 23:177-185	Retrospective chart review	53	<ul style="list-style-type: none"> Statistically significant mean decreases in: <ul style="list-style-type: none"> Day voids (p<0.0001) Night voids (p<0.001) Urge incontinence episodes (p<0.0001) No significant side effects
ABSTRACT Overactive bladder affects 16% of the adult population. This retrospective analysis evaluated the application of PTNS, a minimally invasive neuromodulation therapy, in a population of patients who failed to achieve adequate control of symptoms of urinary urgency, urinary frequency, and urinary incontinence with conservative treatments. A course of 12 PTNS sessions was prescribed and administered in the context of an independent community-based, nurse practitioner-led continence practice. The results of this analysis indicated that patients treated with PTNS therapy experienced statistically significant decreases in both day and night voids, and in episodes of urge incontinence. This study confirmed the results of previous studies indicating that PTNS therapy is a safe and effective treatment that can be successfully incorporated in a community-based setting.							
<i>Percutaneous tibial nerve stimulation for treatment of overactive bladder and urinary retention in an elderly population</i>	Report PTNS results from a community based urology practice	Zinkgraf K, O'Leary Quinn A, Ketterhagen D, Kreuziger B, Stevenson K	Waukesha Hospital, Waukesha WI	<i>UNJ</i> 2009; 29:30-34	Retrospective chart review	30 Age 27-93 Mean age 75	PTNS effective for frequency and urgency, in an elderly population refractory to conservative therapy and drugs
ABSTRACT PTNS is a treatment option for patients who present with urinary urgency, frequency, and urge incontinence. When behavior modification and/or pharmacotherapy did not adequately relieve symptoms, this treatment was found to decrease incidence of overactive bladder in the authors' patient population.							



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About PTNS Treatment

The Urgent PC Neuromodulation System, from Uroplasty, Inc., provides Percutaneous Tibial Nerve Stimulation (PTNS) for the treatment of urinary urgency, urinary frequency and urge incontinence. The Urgent PC is also indicated for the treatment of faecal incontinence. The device technology and treatment protocol are founded on the SANS device (Stoller's Afferent Nerve Stimulator).

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