

# Long-Term Sustained Therapeutic Effect of Percutaneous Tibial Nerve Stimulation in the Management of Overactive Bladder

Scott A. MacDiarmid\*, Kenneth M. Peters, Fah Che Leong, S. Abbas Shobeiri, Eric S. Rovner, Leslie S. Wooldridge, Steven W. Siegel, Susan S. Tate, Barry K. Jarnagin, Peter L. Rosenblatt, Brian A. Feagins

## Introduction and Objective

Overactive Bladder (OAB) is a chronic syndrome characterized by urinary urgency, with or without urge incontinence, usually associated with frequency and nocturia. Neuromodulation therapy targets specific nerves controlling bladder function with demonstrated efficacy in OAB management.

Percutaneous tibial nerve stimulation (PTNS) with Urgent® PC (Uroplasty, Inc., Minnetonka, MN) targets the posterior tibial nerve for OAB treatment. Clinical trials and published studies have shown PTNS to provide symptom improvement in 60-80% of the patients treated and statistically significant reductions in daytime voiding frequency, nighttime voiding frequency and leakage episodes.<sup>1-8</sup>

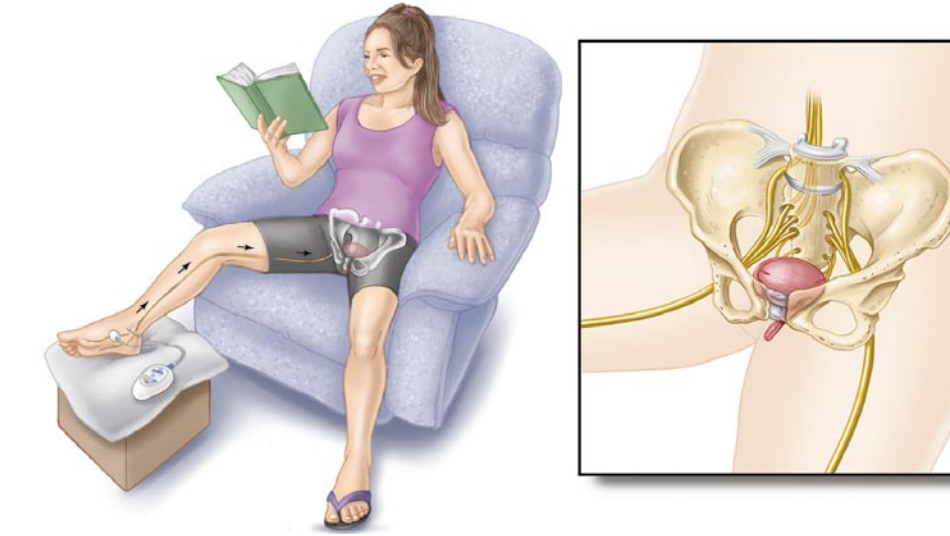


PTNS has also been shown to provide comparable outcomes to pharmacological therapy.<sup>9</sup> However, long-term follow-up data to establish the lasting benefits of PTNS was needed.

This study assesses the sustained therapeutic effect of PTNS in OAB patients over one year when a tapered therapy protocol was followed.

## Methods

The OrBIT Trial was an RCT comparing effectiveness of PTNS to extended-release tolterodine.<sup>9</sup> Patients randomized to PTNS received 12 weekly office-based treatments of 30 minutes. After the initial 12 weeks, subjects with a successful response to PTNS (N=35) continued treatment in an extension study at intervals tapered to sustain relief of OAB symptoms. Outcome measures at 6 and 12 months included voiding diaries, global response assessments and safety assessments.



## Results

- Of the 35 subjects classified as treatment success after 12 weekly PTNS treatments, 32 and 25 subjects finished 6 and 12 months of treatment, respectively; two discontinued due to lack of efficacy.
- Subjects received a mean of 11.4±5.6 additional treatments over an average of 249 days; mean of 19.6 days between treatments.
  - 12 weeks to 6 months: mean of 15.7 days between treatments
  - 6 months to 12 months: mean of 24.7 days between treatments
- One subject had 2 treatment-related adverse events of abdominal pain.
- At 6 and 12 months, physicians classified subject OAB symptoms as improved for 31/32 (97%) and 24/25 (96%), respectively.
- Similarly, 30/32 (94%) and 24/25 (96%) of subjects classified their symptoms as improved at 6 and 12 months, respectively.
- All outcome measure changes from baseline were significant (p<0.05).

## Voiding Parameter Improvements at 6 and 12 months of PTNS Therapy

	<b>Voids / 24 Hours</b> <i>mean ± SD</i>	<b>Nocturnal Voids</b> <i>mean ± SD</i>	<b>Urge Incontinence Episodes / 24 hours</b> <i>mean ± SD</i>	<b>Volume Voided (cc)</b> <i>mean ± SD</i>
<b>Improvements at 6 Months, N=30</b>				
<b>Change from Baseline</b>	-3.2±3.7	-1.2±1.5	-1.6±1.7	31±72
<b>Mean % change from Baseline</b>	22.7	35.1	63.6	36
<b>Improvements at 12 Months, N=25</b>				
<b>Change from Baseline</b>	-2.8±3.7	-0.8±1.5	-1.6±2.0	39±92
<b>Mean % change from Baseline</b>	19.3	12.4	77.9	54.7

Changes from baseline at 6 and 12 months significant with p<0.05 for all variables

## Conclusion

The sustained therapeutic effect of PTNS therapy demonstrates excellent durability with nearly all patients maintaining a statistically significant clinical improvement from baseline.

1. Govier, F.E., Litwiller, S.E., & Mitchell, I. (1999). Percutaneous peripheral nerve stimulation for urgency / frequency syndrome. *European Urology*, 35(52), 16.
2. van Balken, M.R., Vandoninck, V., Gisol, K.W.H., Vergunst, H., Kiemeneij, L.A.L.M., Debyrne, F.M.J., et al. (2001). Posterior tibial nerve stimulation as neuromodulatory treatment of lower urinary tract dysfunction. *J Urol*, 166, 914-918.
3. Vandoninck, V., van Balken, M.R., Finazzi-Agró, E., Petta, F., Micali, F., Heesakkers, J.P.F.A., et al. (2003). Percutaneous tibial nerve stimulation in the treatment of overactive bladder: Urodynamic data. *Neurourology Urodyn*, 22, 227-232.
4. Klingler, H.C., Pycha, A., Schmidbauer, J., & Marberger, M. (2000). Use of peripheral neuromodulation of the S3 region for treatment of detrusor overactivity: A urodynamic-based study. *Urol*, 56, 766-771.
5. Govier, F.E., Litwiller, S., Nitti, V., Kreder, K.J. Jr., & Rosenblatt, P. (2001). Percutaneous afferent neuromodulation for the refractory overactive bladder: Results of a multicenter study. *J Urol*, 165, 1193-1198.
6. Stoller M. Clinical trials of the SANSTM Afferent Nerve Stimulator to treat urinary incontinence: Results on clinical treatment of more than 90 patients. April 1999.
7. Ruiz, C.B., Outeiriño, P.X.M., Martínez, P.C., Dueñas, E.L., & López, A.L. (2004). Peripheral afferent nerve stimulation for treatment of lower urinary tract irritative symptoms. *Eur Urol*, 45, 65-69.
8. Vandoninck, V., van Balken, M.R., Finazzi-Agró, E., Petta, F., Caltagirone, C., Heesakkers, J.P.F.A., et al. (2003). Posterior tibial nerve stimulation in the treatment of urge incontinence. *Neurourology Urodyn*, 22, 17-23.
9. Peters, K.M., Leong, F.C., Shobeiri, S.A., MacDiarmid, S.A., Rovner, E.S., Wooldridge, L.S., et al. (2008). Randomized multicenter study comparing percutaneous tibial nerve stimulation with pharmaceutical therapy for the treatment of overactive bladder. Abstract, American Urologic Association, Annual Meeting, Orlando, FL.